

# XENOTRANSPLANTATION: ETHICAL ISSUES

Bioethics & Animals (Spring 2013)

Laura Guidry-Grimes

# Beginning Considerations

- Severe organ shortage
  - Half of those **on the waitlist** will die waiting for organs...
  - Many more will die who need organs but do not meet the criteria for being put on the waitlist.
- Xenotransplants of whole organs or xenografts of tissues could potentially help this shortage.
  - FDA definition: “any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a nonhuman animal source or (b) human body fluids, cells, tissues or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs.”
- FDA 2003 Guidelines on patient selection:
  - “Because of the potentially serious public health risks of possible zoonotic infections, you should limit Xtx to patients with serious or life-threatening diseases for whom adequately safe and effective alternative therapies are not available except when very high assurance of safety can be demonstrated.”



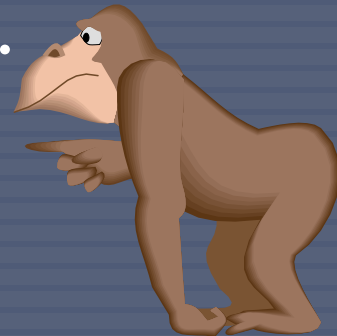
Robert Veatch

# Natural Law

- **Violates God's plan or offends against humanity**
  - Especially problematic for whole vital organs?
- **“practical psychological problems of xenografts: how people will be viewed by others and themselves” (261)**
  - Insuperable issue?
- **Sanctity and importance of human life**
  - Argument in favor of pursuing all viable options, inc. Xtx

# Animal Rights/Welfare

- Regan: organ giver as “other victim”
- Abuse, exploitation of non-human animals
  - **Should there be a moratorium on using non-human primates for organs?**
- “Grocery store” organ market worry
  - Would encourage breeding many animals (esp. pigs and primates) for organ and tissue purposes...
  - **But is this a morally repulsive idea?**

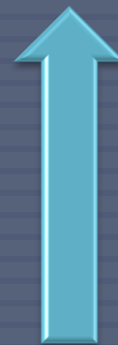


# Animal Rights/Welfare

- “if there is ever a case for using an animal for the benefit of humans, it would be when the sacrifice of one animal will offer the possibility of saving an identifiable human life” (262)

▣ **Do you agree with this general ranking for how we are permitted to use non-human animals?**

1. Xenotransplant/-graft
2. Medical research
3. Food
4. Sport



Most ethically permissible  
(perhaps obligatory)

Least ethically permissible  
(perhaps prohibited)

# Nontherapeutic Intervention Problem

- Important distinction:
  - ▣ **Therapeutic:** evidence to believe that the procedure will provide medical benefit
  - ▣ **Nontherapeutic:** inadequate evidence to believe the procedure will provide medical benefit, but might nonetheless provide generalizable knowledge
- “novel procedures, especially nontherapeutic ones, should first be tested on consenting adults when possible” and without consent “only when the risks are very minor” (263)
  - ▣ **Worries:** a) not always clear whether Xtx is therapeutic or not; b) inadequate guidance for consent and proxy consent

# Resource Allocation

- Xtx “constitute exotic technological innovation with low probability of short-term payoffs” (264)
- **Problem of justice:** How should we distribute scarce resources? How should different claims to those resources be weighed and incorporated?
- **A utilitarian response:** Consider short-term and long-ranging benefits and costs of Xtx
  - ▣ Probably would not justify public funds going towards Xtx
- **An egalitarian response:** Determine whether Xtx meets the needs of the least well-off
  - ▣ Depends on who is considered the least well-off and comparison groups before and after Xtx would become funded



# Virus & Public Health Problem

- Xtx poses risks to third parties (sexual partners, children, contacts) who have not consented to the procedure.
  - ▣ “when the recipient of a xenograft consents to the risk, he or she is, in effect, consenting to some risk to other parties” (268)
- Responses:
  - ▣ **Most restrictive** – prohibit risking third parties
  - ▣ **Utilitarian** – maximize net utility
  - ▣ **Egalitarian** – prioritize needs of who would be worst off
  - ▣ **Deontic** – check against prior binding obligations

# Veatch's Conclusion

- Xenotransplants/-grafts permissible if:
  - Do not violate natural law
  - Do not necessarily violate rights of animals
  - Patient/recipient is among the least well-off in society
  - Public health threat can be managed, does not violate other obligations or principles
  - Other bioethical obligations (consent, privacy) are met
- **Are these criteria too stringent or too lax?**
  - **Do you have unresolved concerns?**



M. Anderson

# Concerns re: Patient Rights

- **Confidentiality/privacy compromised** if long-term surveillance and monitoring needed to prevent public health crisis
  - **Can this be adequately addressed with consent forms? What about monitoring the patient's contacts?**
- **Role schism problem:** doctor serving as clinician AND researcher
  - “could lead to the urging of a patient to partake in a trial, when without such urging he or she would probably not take part” (206)

# Concerns re: Patient Rights

- Exploitation of vulnerable groups who otherwise will be denied organs
  - “because xenotransplants are notably less viable than their allotransplant counterparts, xenografts will be implants in those who are very ill but who cannot afford an allograft” (206)
- **Green screen** prevents uninsured and underinsured from having access to viable transplants
  - **Could Xtx provide a significant benefit to vulnerable patients? Or do you think the availability of these non-human organs would result in increased complacency and exploitation?**

# Animal Rights/Welfare

- Concerns about sentience and speciesist tendencies (a la Singer)
- Perhaps hierarchically order creatures “according to how far their struggle for life mirrors what we identify as human” (207)
  - ▣ **Does ranking non-humans in this manner make moral sense?**
  - ▣ **What if the only viable “donor” candidates are those who are close to us on the hierarchical scale?**

# Additional Sources

- FDA 2003 Guidelines:

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Xenotransplantation/ucm074354.htm>

- PHS 2001 Guidelines:

<http://www.fda.gov/biologicsbloodvaccines/guidancecomplianceinformation/guidances/xenotransplantation/ucm074727.htm>

- Timeline of Xtx research:

<http://www.pbs.org/wgbh/pages/frontline/shows/organfarms/etc/cron.html>

Questions? Comments?