Unit 5:
Transplant Ethics

US275 Scientific Ethics
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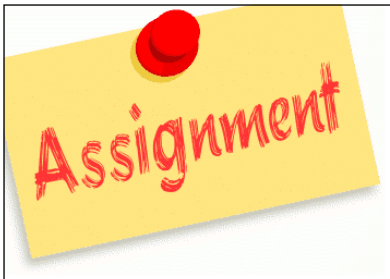
Organ Failure, Donation, and Transplantation.

- Describe why donor-recipient matching is crucial in organ transplantation.
- Describe the laws and procedures associated with organ donation.
- Explain the difference between an "opt-out" and an "opt-in" organ donation system.



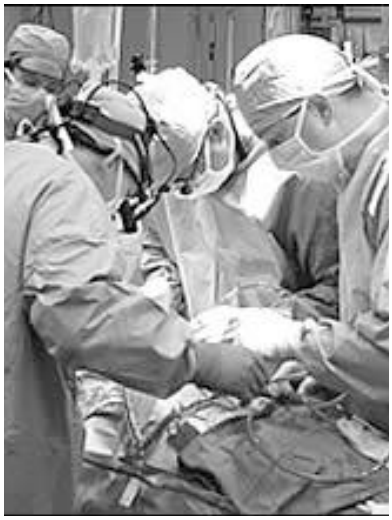
21. Who's organs are they?

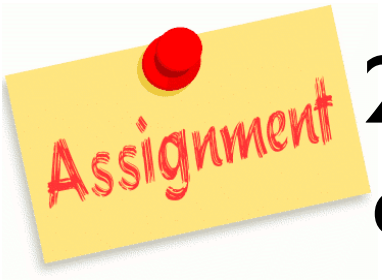
The United States currently has an "opt-in" organ donation system, where an individual after receiving informed consent makes a decision to be an organ donor. However in 2010 the New York State Legislature began considering an "opt-out" system, where everyone is presumed to be a potential donor unless they make an active decision to refuse.

<u>In your discussion group:</u>
Within your group discuss the ethical considerations between the opt-in and opt-out organ donation systems.

Alternatives to human organ transplants

- Describe how and when cell or tissue donation can be used instead of organ donation.
- Describe the risks and benefits of using animal organs for transplantation.





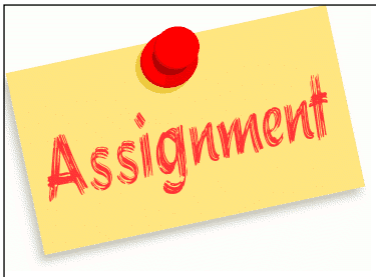
22. Xenotransplant costs and benefits.

There is an unknown level of risk of zoonotic infection associated with a xenotransplant, so research on the long-term effects must be monitored. Any patient that receives a xenotransplant agrees to continued restrictions and life-long medical monitoring. This agreement to these conditions violates the rights of an individual to withdraw as a research subject provided in the Declaration of Helsinki, the United States Office of Human Research Protections, and the U.S. Food and Drug Administration. An individual considering a xenotransplant is normally facing imminent death. Therefore, the patient is likely to feel some level of coercion to almost any condition in order to receive the desired life-extending treatment.

In your discussion group: Do the benefits to a recipient of a xenotransplant outweigh the costs to the patient and the risk to their family (and/or society) if a zoonotic disease develops?

Human Transplant Concerns

- Describe how decisions are made about what recipient receives a scarce donor organ.
- Describe different incentives might be used to increase the supply of donor organs.

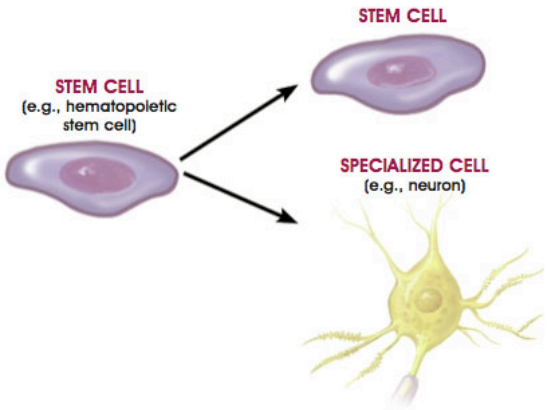


23. Trafficking of human organs.

<u>In your discussion group:</u>
Discuss with your group the following question: ***Currently many people die while waiting for an organ transplant. At the same time individuals in impoverished situations and their families could benefit from the financial incentives involved. If a person truly has the right to choose what happens to/with their body, should patients be able to purchase needed organs?***

Stem Cell Science

- Describe how stem cells can be used instead of organ or tissue transplants.
- Explain the difference between adult and embryonic stem cells.



24. When does the embryo/fetus become an individual that has a protected status?

The discussion around embryonic stem cells is often approached as to when human life begins. The egg and sperm cell are human and alive, so life is present at all stages. A better way to examine this question is to consider when human beings begin. To help in considering this question, please read "When do human beings begin? 'Scientific' myths and scientific facts" at http://www.all.org/abac/dni003.htm

In your discussion group, consider the question: When does the embryo/fetus become an individual that has a protected status?

Stem Cell Therapy

- Describe how stem cells are currently used for the treatment of veterinary disorders.
- Describe the use of stem cell treatments in the United States and abroad.

25. Waiting to die?

The process for determining if a new medical treatment is safe and effective often takes many years. Patients with terminal or degenerative conditions are unlikely to survive until the treatments become approved and available. Increasing numbers of patients with the financial resources travel to locations outside of the United States to seek out promising, but uncertain procedures. Patients that return to the United States are ineligible for future approved clinical studies and are potentially at risk for complications that physicians are unaware of. The FDA allows for limited emergency or "compassionate use" of unapproved treatments but this exemption is tightly restricted. In addition, while registering for a clinical trial will contribute to a better understanding of the treatment, but the patient may be in a control group that does not receive the stem cells.

In your discussion group:
Should patients be allowed to make individual decisions to undergo unapproved stem cell treatments in the United States?

Stem Cell Policies

- Describe the basic process of determining if a medical procedure is covered by insurance.
- Describe the laws, regulations, and guidelines for the development and research of embryonic stem cells.
- Describe the regulatory mechanisms involved with the use of human stem cells.

26. FDA - Watch dog or Pit

The Food and Drug Administrations primary role in monitoring and regulating drugs is to protect the public health from unsafe and/or unproven treatments. The FDA is in a precarious position between the developers of innovative treatments and physicians and patients seeking the most effective cures. The FDA is viewed as to lax when safety concerns develop with a previously approved medication, but too stringent when the need for additional safety and effectiveness data that is being slowly collected in clinical studies results in the delay in approval of a new drug. The knowledge of stem cell science and claims of miraculous stem cell cures race ahead of data from clinical trials, leaving the FDA to navigate through conflicting interests.

In your discussion group:
Review the articles on the court challenge between Regenexx and the FDA and the discuss with your small group, what criteria should the FDA use in determining whether or not to approve stem cell therapies.

Any Questions?

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