

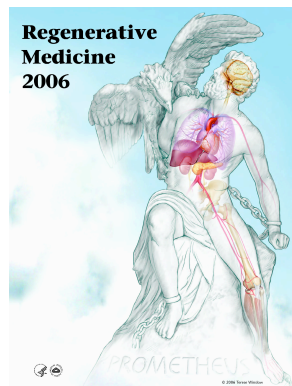
# Stem Cell Therapy

US275 Scientific Ethics  
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Regenerative medicine is the process of replacing or repairing human cells, tissues or organs to restore normal function.

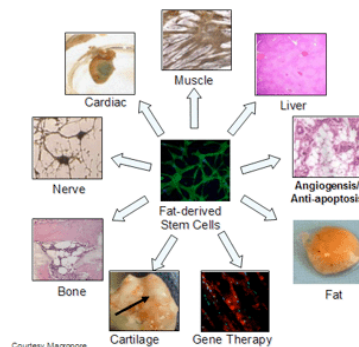
- Prometheus (Greek Titan)
  - chained to a rock
  - Zeus sent eagle to eat Prometheus' liver each day
  - Prometheus' liver regenerated daily enabling him to survive.



<http://stemcells.nih.gov/info/scireport/2006report.htm>

Veterinary medicine is currently using stem cell therapy to treat animals.

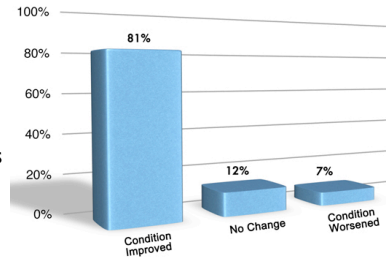
- Vet-Stem Regenerative Medicine
  - use autologous adipose-derived adult stem cells
  - treat traumatic and degenerative diseases
    - tendon and ligaments
    - osteoarthritis
    - osteochondral defects



<http://www.vet-stem.com/science.php>

# Veterinarians isolated stem cells from the animal's own fat.

- Vet collects fat from dog, cat, or horse
- Fat is processed to concentrate stem cells
- veterinarian injects the stem cells into affected area.
- results supported by double-blind placebo controlled studies.



Quality of life surveys of pet owner  
Vet-Stem Regenerative Veterinary Medicine

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# The majority of current human stem cell transplants are associated with bone marrow stem cells.

- treatment for cancers such as leukemia or certain blood diseases.
- adult stem cells
- repopulate body with healthy cells

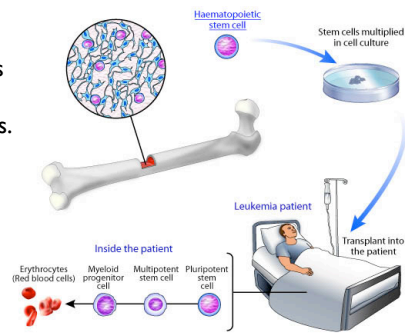


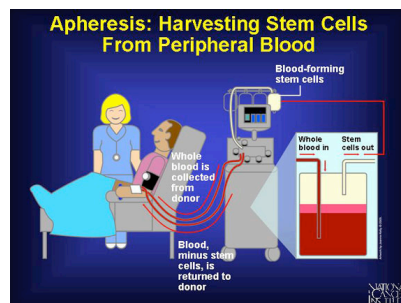
Illustration by Cell Imaging Core of the Center for Reproductive Sciences.

<http://stemcelltreatments.org/stem-cell-therapy/conditions/stem-cell-treatment-for-leukemia/bone-marrow-stem-cells-and-other-sources-for-leukemia-treatment/>

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# Apheresis is a method to isolate stem cells from peripheral blood.

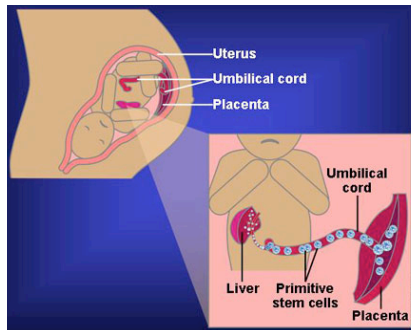
- donor receives growth factors to promote blood stem cells in the peripheral circulation.
- blood donation process that takes several hours.
- centrifuge spins the blood and separates the stem cells
- blood minus stem cells is returned to the donor.



<http://www.cancer.gov/cancertopics/understandingcancer/StemCells/AllPages/Print>

## Cord blood is a recent development for isolated immature blood stem cells.

- at birth, umbilical cord has many immature blood stem cells
- these cells can be isolated
  - protected and then frozen for later use



<http://www.cancer.gov/cancertopics/understandingcancer/StemCells/AllPages/Print>

## In November 2011, HEMACORD was approved by the FDA.

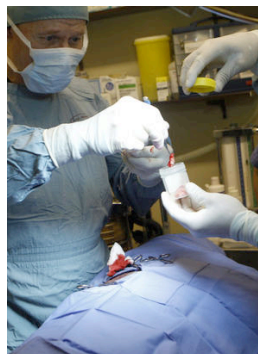
- Hematopoietic progenitor cells - cord (HPC-C) cell therapy
  - alternative to bone marrow transplants or peripheral blood
  - risks include graft-versus-host disease



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## Clinics in the United States provide stem cell therapy.

- follow “Good Tissue Practices”
  - viewed as blood and human tissue transplantation
- FDA currently allows
  - cells that are collected from the patient, and
  - infused into the patient on the same day with only “minimal manipulation”



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## Peyton Manning received adult stem cell injections to treat bulging disk in neck

- procedure done in Europe
- mesenchymal stem cells
  - isolated from fat cells
- injected into neck
  - regenerate damaged tissue



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## The first transplanted human organ grown from adult stem cells as a trachea.

- Donor trachea as a “skeleton”
  - now can use synthetic trachea (plastic similar to that used in soda bottles)
- “seeded” stem cells from patients bone marrow
- not currently approved in the U.S.
- 1st U.S. patient traveled to Sweden in 2011 for surgery.



Synthetic windpipe after stem cells have been incorporated, but before transplantation.  
<http://www.ucl.ac.uk/news/news-articles/1107/11070701>

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## Stem cells therapies are said to treat a wide range of diseases.

- if it treats everything,
  - it may be too good to be true
- stem cells are replacements for dead or damaged cells
  - many different cell types needed



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Without controlled clinical-trials, it will be impossible to determine if stem cells are effective.

- Placebo effect
- unclear of long-term outcomes
  - isolated reports of benign tumors



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## According to ClinicalTrials.gov on March 27, 2012...

- Phase I clinical trials
  - 1241
    - 152 not involving blood
- Phase II clinical trials
  - 2041
    - 285 not involving blood



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## According to ClinicalTrials.gov on March 27, 2012...

- Phase III clinical trials
  - 483
    - 124 not involving blood
- Phase IV clinical trials
  - 97
    - 3 not involving blood



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## Assignment

# Assignment

### **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.

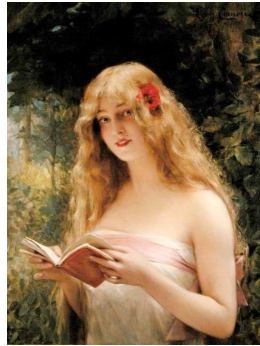
### **In your discussion group:**

*Should patients be allowed to make individual decisions to undergo unapproved stem cell treatments in the United States?*

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## Readings

Regenerative Medicine. (2006).  
Department of Health and Human  
Services. <http://stemcells.nih.gov/info/scireport/2006report.htm>



*The Beautiful Reader  
(La Belle Liseuse)*  
Leon Francois Comerre

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## Any Questions?

Email me at:  
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<http://www.vipitbullkennels.com/images/animated-question-mark.gif>

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