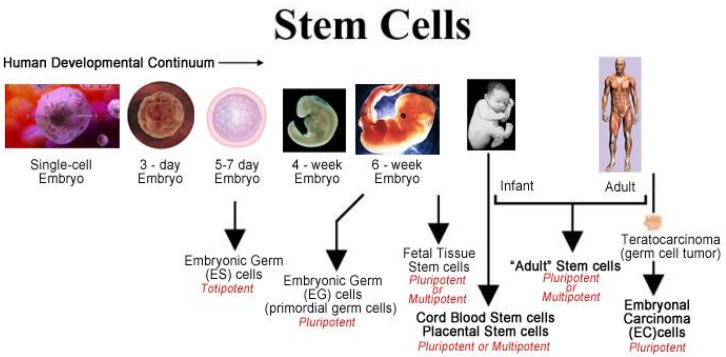
Ethics of Human Stem Cell Research & Vaccination

Stem Cell Biology

What are stem cells?

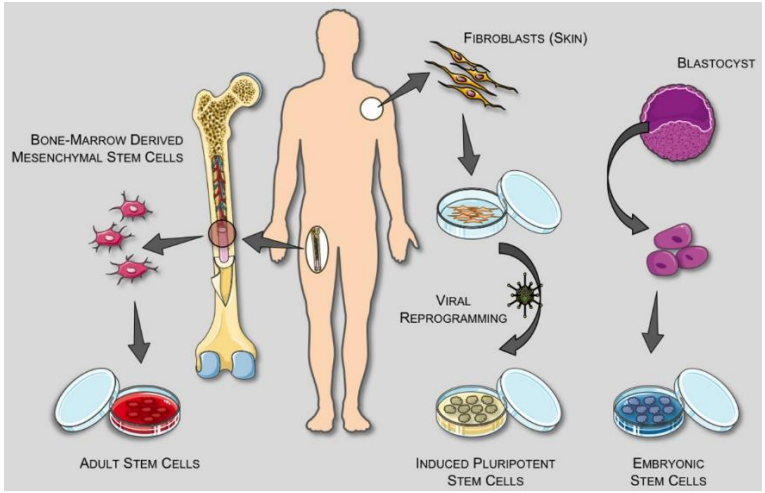
Stem cells are cells that have the remarkable potential to develop into many different cell types in the body. Serving as a sort of repair system for the body, they can theoretically divide without limit to replenish other cells for as long as the person or animal is still alive. When a stem cell divides, each "daughter" cell has the potential to either remain a stem cell or become another type of cell with a more specialized function, such as a muscle cell, a red blood cell, or a brain cell.

- NIH Website (http://stemcells.nih.gov/)

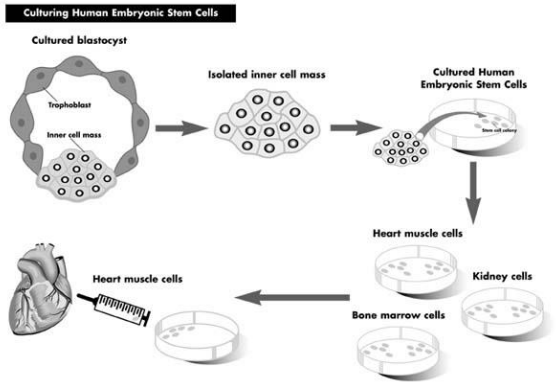


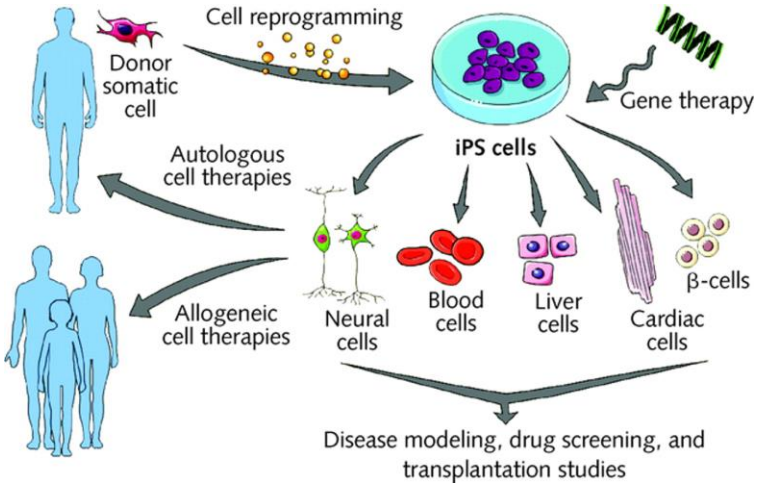
- A fertilized egg is considered **totipotent**, meaning that its potential is total; it gives rise to all the different types of cells in the body.
  - ➔ Totipotent cells could theoretically be used to regenerate any tissue in the body
- **Pluripotent** stem cells can give rise to any type of cell in the body except those needed to develop a fetus.
- Stem cells that can give rise to a small number of different cell types are generally called **multipotent**.

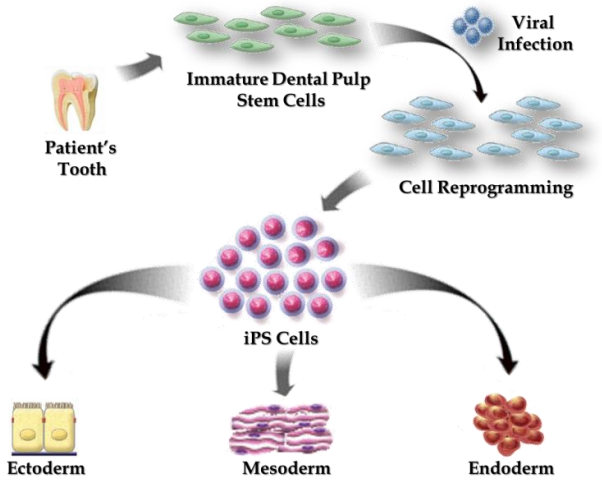
Embryonic & adult stem cells



Stem Cell Biology



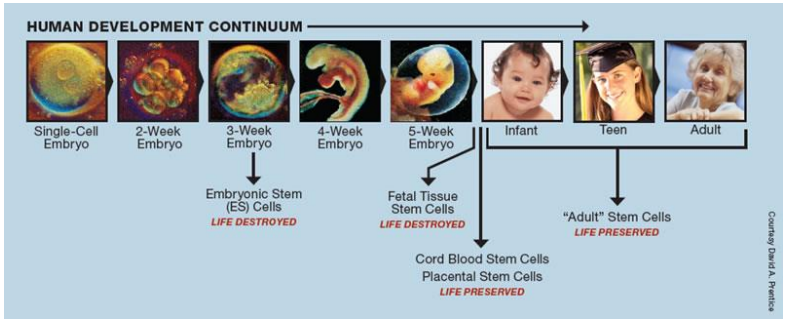




Stem Cell Biology

For the first time researchers reconstitute a complete organ. New bladders were made by growing bladder cells from the patients on a biodegradable scaffolding.

- Reported in the *Lancet* (April, 2006)

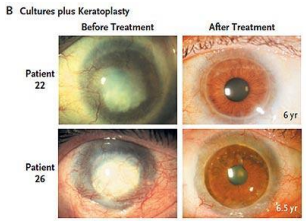


Stem Cell Biology

For the first time researchers reconstitute a complete organ. New bladders were made by growing bladder cells from the patients on a biodegradable scaffolding.

- Reported in the *Lancet* (April, 2006)

Success stories



Stem cells were taken from the limbus in the patient's own eye, cultured, and then grafted back on the eye
(Rama et al, 2010)

Umbilical cord stem cells therapy for a cerebral palsy boy

- Human embryonic stem cell (hESC) research offers great promise of cures for otherwise incurable conditions: juvenile diabetes, spinal cord injuries, Alzheimer's, Parkinson's

Consequentialism vs. Deontology

- Deontological moral theories maintain that the rightness of wrongness of an action is dependent on its conformity to certain fundamental rules ➔ What are the fundamental rules?
- Deontological Case
  - Utility does not trump basic rules or ethical rules
  - If the embryo is a human, then it has a right to life
  - It cannot be destroyed any more than we could intentionally kill a few children to save many others.

    - **Deontological** ethics or **deontology** is the normative ethical position that judges the morality of an action based on the action's adherence to a rule or rules. It is sometimes described as "duty" or "obligation" or "rule"-based ethics, because rules "bind you to your duty."

Consequentialism vs. Deontology

- Consequentialist moral theories maintain that the rightness or wrongness of an action is dependent on its consequence
  - How do we measure these consequences?
  - Consequences for whom?
- Benefits of hESC research potentially far outweigh the costs
  - Financial cost of the disease
  - Cost of suffering with the disease
- Embryos would have been destroyed anyway
  - About 400,000 frozen embryos in the United States alone
- Isn't it better to put these embryos to some good use rather than just destroy them?

    - **Consequentialism** is the class of normative ethical theories holding that the consequences of one's conduct are the ultimate basis for any judgment about the rightness or wrongness of that conduct.

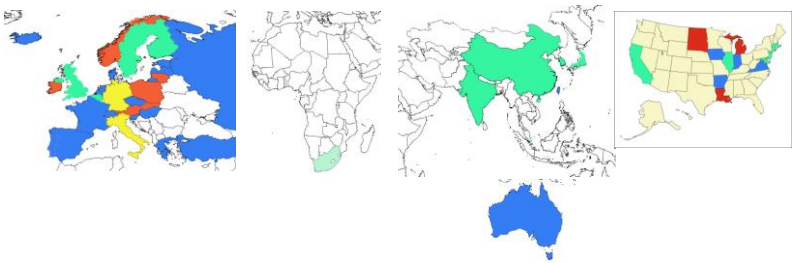
When is it human?

- At what point does this entity become a human being with a right to life?
  - The point of conception
  - The point of implantation
- Early candidates for such morally significant points of demarcation include:
  - the initial appearance of the primitive streak (19 days),
  - the beginning of the heartbeat (23 days),
  - the development of the brain waves (48 days),
  - the point at which essential internal and external structures are complete (56 days) and
  - the point at which the fetus begins to move around (12-13 weeks).

Stem Cell Ethics

Experimentation on human embryos violates the standards of the Nuremberg Code for research involving human subjects:

- No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur…
- Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability ,or death.



- The Restrictive Option: Prohibits human embryo research; does not explicitly permit research with existing human embryonic stem cell lines (shown in red)
- The Permissive Option: Accepts the production of human embryos for research purposes through in vitro fertilization and/or nuclear transfer (cloning) (shown in green)
- The Moderate Option: Permits the derivation of new human embryonic stem cell lines but only through the use of remaining embryos from infertility clinics (shown in blue)
- The Compromise Option: Permits research with existing human embryonic stem cell lines but not the derivation of new stem cell lines through the destruction of human embryos (shown in yellow)

National Institutes of Health Guidelines on Human Stem Cell Research

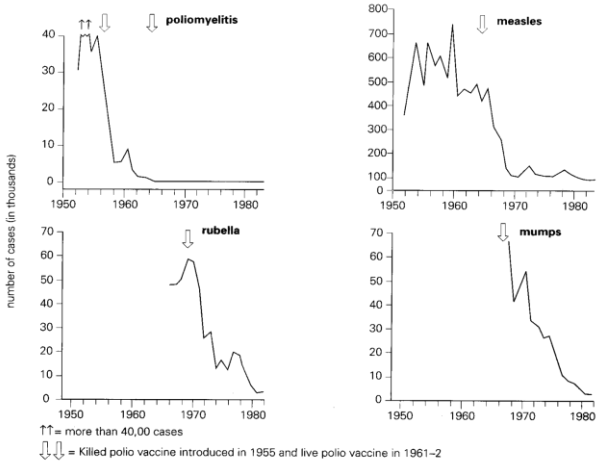
effective on July 7, 2009

- Responsible research with hESCs has the potential to improve our understanding of human health and illness and discover new ways to prevent and/or treat illness.
- Individuals donating embryos for research purposes should do so freely, with voluntary and informed consent.

Vaccine

- Types of vaccines
  - Live vaccines
  - Attenuated live vaccines
  - Inactivated (killed vaccines)
  - Toxoids
  - Polysaccharide and polypeptide (cellular fraction) vaccines
  - Surface antigen (recombinant) vaccines.

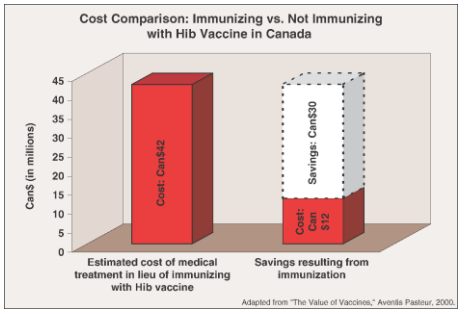
Decrease of viral infections
after vaccination programmes in Germany



Medical Microbiology, MOSBY, S. 444

Immunization can save money

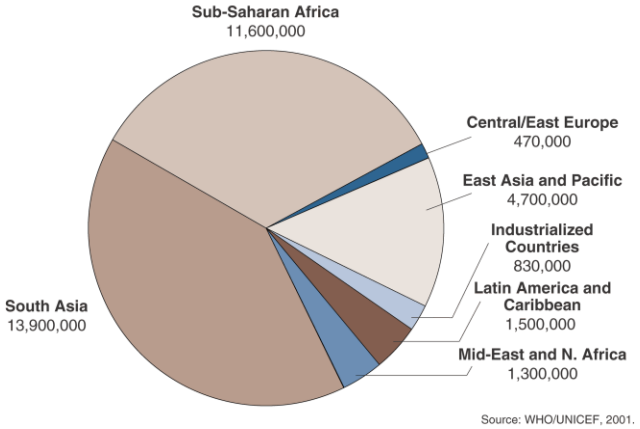
- Immunization is one of the most cost-effective health interventions.
- Investing in vaccines SAVES more money than it costs.



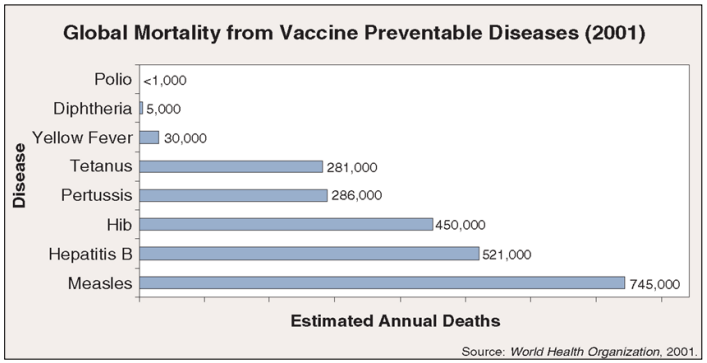
Immunization can protect the unprotected

- When immunization coverage is high, it can prevent viruses and bacteria from circulating.
- The more children in a community that are fully immunized, the more everyone is safe.

34 million children are not fully immunized



2.3 million still die each year



Side effect of Vaccine (examples)

- Side effects of Hib (*Haemophilus influenza)* vaccine:
  - About 1 in 4 children redness, warmth, or swelling where the shot was given
  - About 1 in 20 had a fever over 101
- PCV (Pneumococcal Conjugate)vaccine side-effects:
  - About half of children were drowsy after the shot, had a temporary loss of appetite, or had redness or tenderness where the shot was given
  - About 1 in 3 had swelling where the shot was given
  - About 1 in 3 had a mild fever
  - About 1 in 20 had a higher fever (over 102.2°F).
  - Up to about 8 in 10 became fussy or irritable
  - Life-threatening allergic reactions from vaccines are very rare

Some beliefs

- Vaccines Are Unsafe
- Decline in disease is not a result of immunizations
- Vaccines are not effective
- Infectious diseases are benign and self-limiting
- MMR vaccine causes Autism

Bioethical Theories and Vaccine

- Deontologic: Do I have a duty to be vaccinated?
  - Contribution to decreased transmission and herd immunity
  - Contribution to personal health – does it reduce work loss and hospitalizations?
- Utilitarian: Will my vaccination bring the most happiness
  - Cost-effectiveness needs clarified
  - Quality of life issue – adverse local effects and side effects versus personal and societal benefit

Bioethical Theories and Vaccine

- Principle Approach:
  - Autonomy – freedom to accept or refuse

    Implication is knowing consumer preferences
  - Beneficence – implication is for recipients to know personal benefits and reduced transmission
  - Non-maleficence – “do no harm” - implications are vaccine safety and quick appraisal via VAERs (**Vaccine Adverse Event Reporting System**) of potential adverse reactions, coverage in VICP (**Vaccine Injury Compensation Program)**
  - Justice – access so all can afford vaccination and continued safety research so that no group bears extra burden of adverse effects