Stem Cells: Ethical and Regulatory Issues

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What is a stem cell?

A single cell that can replicate itself, or...

differentiate into many cell types.

Image prepared by Catherine Twomey for National Academies, Understanding Stem Cells: An Overview of the Science and Issues
Life begins at the petri dish!

Even the human embryos are divided...

Cloning for research!
Stem Cell Ethical Issues

• Blastocysts as a potential human life
• Nuclear transfer technology and the possibility of human reproductive cloning
• Research use of human-animal ‘chimeras’ might alter our definition of ‘human’
• The rights of the donors of the genetic material
• Making gametes from stem cells
• Equitable use of stem cell products
• Access to unproven therapies
Human Blastocyst

0.1-0.2mm diameter. Day 4-5 post fertilization.

Source: NIH website
Moral Status of the Embryo

• Utilitarian view (Bentham, J.S. Mill)
  – Stem cells have the potential to create the “greatest good for the greatest number.” Uncertain fate of blastocysts.
  – Promoting happiness is moral and curing disease produces happiness.
  – Problem: Moral relativism?

• Deontological view: A matter of moral rules and duties (Kant)
  – Every one has a right to expect not to be destroyed for the benefit of another.
  – Embryos have these rights too. Therefore, destruction of an embryo is immoral.
  – Problem: Are users of ESCs complicit?
The trick will be to separate the nuclei.
Moral Status of the Embryo
When Does an Individual Life Begin?

• At conception -- Roman Catholic view since Pope Pius IX in 1869, reinforced in 2008 by Vatican document "Dignitas Personae."
  – Along with abortion, ESCs are a moral and political issue of importance to many Fundamentalist-Evangelical Protestants. Reliance on Biblical text.

• Many other religious views place beginning of personhood later
  – Aristotle to Thomas Aquinas. “Quickening” as part of the Christian (Protestant) tradition.
  – Islam and Judaism; traditional 40-120 days, respect for healing.
  – Buddhism and Hinduism; reincarnation, karmic implications, sacrificial traditions, centrality of compassion.
Will There Ever Be Another You?

A Special Report on Cloning
Human Reproductive Cloning

- Opposed by the National Research Council as “dangerous and likely to fail.”
- Opposed by all reputable scientific organizations
- Already regulated by the FDA
- Bills twice passed House to ban research (criminal penalties) but died in Senate
Long-awaited. Scientists have used somatic cell nuclear transfer to produce embryonic stem cells from a type 1 diabetes patient.
SCNT Current Status

• Theoretical approach to custom design stem cell products and minimize rejection
• Works in rodents and large mammals (sheep, dogs) but claims of human SCNT success from South Korea in 2005 now discounted as fraudulent
• Successful human SCNT reported in 2013, from diabetes patient in 2014
• Restore *Homo neanderthalensis*?
Stem Cell to Gamete

Nature 491:535-6, 2012
Chimeras: Myth or Mad Science?

Chimeras are organisms composed of stable combinations of cells derived from different species.
Chimera Issues

- Can human embryonic stem cells differentiated into brain cells and inserted into mouse brain make the mouse think like a human?
- Outcome If human stem cells were inserted into developing non-human embryo?
- Self-imposed rules: No breeding of recipient animals; No inter-species blastocysts.
hESC Ethical Issues

• Blastocysts as a potential human life
• Nuclear transfer technology raises the possibility of human reproductive cloning.
• Research use of human-animal ‘chimeras’ might alter our definition of ‘human’.
• Defining the rights of the donors of the genetic material.
Views of IVF Patients

• Lyerly and Faden, Science (2007) 317:46
• 1244 survey respondents
  – 1020 with stored embryos
• Proportion likely to donate for:
  – infertility research 63%
  – disease or injury research 62%
  – stem cell research (derivation) 60%
  – to infertile couple 22%
  – thaw and discard 22%
Stem Cell Professional Regulation

• Guidelines from National Academy of Sciences, ISSCR, other scientific groups
• California and other state standards
• Consensus on key points:
  – Altruistic and consented donations of genetic materials
  – Provenance of cells and tissues
  – No reproductive cloning, no reproducing chimeras
  – Local oversight (SCROs)
STEM CELL POLICY QUIZ

• T/F: Congress has never passed a law limiting either cloning OR embryonic stem cell research
• T/F: Congress limits stem cell research primarily through budget allocations
• What is the Dickey-Wicker Amendment?
• T/F: The SCOTUS ruled that the D-W amendment does not apply to ESC research
Current Federal Policy

- 1995 NIH appropriation amendment (Dickey-Wicker) prohibits federal funding to create or destroy human embryos for research. Renewed annually. Legal issues resolved.
- President G. W. Bush 2001 limitations on funding lifted by President Obama in 2009. NIH registry (5/2014): 279 lines eligible for funding, 38 pending/draft, 66 not approved.
- 2005 law promotes umbilical cord blood banking as an alternative to ESCs.
Current Federal Policy Does NOT Affect:

• Legality of embryonic stem cell research
• Legality of research using somatic cell nuclear transfer
• Authority of states to expand, fund, limit or prohibit stem cell research
States with permissive stem cell **Legislation** or **Executive Orders**

States **limiting research** (criminal) on embryonic or fetal materials

2010
California Proposition 71: “Stem Cell Research and Cures Initiative”

- Authorizes $3 billion toward stem cell research (an annual spending limit of $350 million).
- Creates "California Institute for Regenerative Medicine."
- Establishes constitutional right to conduct stem cell research.
- Prohibits state funding of human reproductive cloning.
- Passed Nov. 2004 with 59% statewide, 52% in Orange County.
- $99.95 million to UCI thus far
UCI Human Stem Cell Research Oversight (hSCRO) Committee

- Appointed October 2005
- 9-10 members (stem cell science, clinical investigation, fertility medicine, ethics, science policy, community reps)
- Policy and scientific review. About 300 reviews so far, about a third were new. 36 ongoing.
- Coordinates with IRB, IACUC and other oversight bodies
UCI hSCRO:
Issues Considered To Date

- Provenance of cell lines; original consent for donation of materials; research restrictions in consent
- Use of pluripotent and differentiated human cell lines in animals
- Donation of blastocysts
- Donation of oocytes
- Derivation of cell lines including parthenogenesis and SCNT
- Genetic reprogramming of adult cells
- Generation of gametes from ESCs
WE ARE HERE FOR THE FREEDOM OF CURE WITH STEM CELLS BECAUSE IN ITALY OUR POLITICIANS WANT TO DESTROY OUR HOPES

“NOI SIAMO QUI PER LA LIBERTÀ DI CURA CON LE CELLULE STAMINALI PERCHE’ IN ITALIA I NOSTRI POLITICI VOLGONO DISTRUSSERE LE NOBILI SERRANZE!”
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