General tips for presentation

- Rehearse beforehand which presenters will talk about which slides. Feel free to interject while another presenter is speaking if you think of another important point, but structure is important to keep students focused!
- Don’t talk down to the students – treat them as equals! Try to appreciate everyone’s opinions (say stuff like, “that’s a really great point”); point out differences in people’s opinions to demonstrate the “grayness” of bioethics; ask for students to participate in the conversation without forcing them to
- Avoid steering the conversation toward unrelated topics; however interesting they might be, your time will likely go over (this presentation tends to run about 80 minutes with student participation and the activity)
- Try not to be biased in your comments.
Ethics and Policy-Making in Stem Cell Research

Presented by UC Berkeley’s STELA:
The Science, Technology, Ethics, and Law Working Group

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Intros!

- We introduce STELA as an organization
- We introduce ourselves (names, majors, why interested in stem cell research)
- We explain our goals for today:
  - Help bridge the gap between science and policy (it *is* possible to care about both; ourselves as examples!)
  - Give you a tool kit to start thinking about bioethical problems (maybe so you can think about some of these issues when you are old enough to vote)
  - We will be challenging you, but only to help you consider an issue from multiple angles; we do not intend to give you the “right” answers
What is ethics? (ask class)

- First, can anybody tell me what “ethics” is? (call on people)
- Here is the definition:
  - **Ethics**: “the rules of conduct recognized in respect to a particular class of human actions or a particular group/culture” – explain in common terms
What is Bioethics? (ask class)

- Now, anyone have an idea what bioethics might be? (call on people)
- Bioethics: “a field of study concerned with the ethics and philosophical implications of certain biological and medical procedures, technologies, and treatments, as organ transplants, genetic engineering, and care of the terminally ill” – explain in common terms
A classic bioethical decision

- Let’s get started thinking about how to approach a sample bioethical problem
- There is one heart available for transplant (all equal standing on waiting list, will die if don’t get transplant)
- Who should get the heart? – scenario 1
  - An average 17-year old girl, studies hard, active in school, has not yet experienced much of life
  - A 40-year-old school principal, is divorced and has no kids, but has a lot of people at the school depending on him
  - An 70-year-old woman with 5 children and 7 grandkids, who has dedicated her life to volunteer work with the poor and has led a fulfilling life
  - WHAT DO YOU THINK AND WHY? (ask people to vote for their choice by showing hands)
A classic bioethical decision

- Let’s imagine we have the same 3 people, but with different personalities/lifestyles.
- Now, who should get the heart? – scenario 2
  - 17 year old girl is now a heroin addict, has been in and out of jail since she was 13
  - 40 year old school principal has eaten fast food all his life, hasn’t made much effort to be heart-healthy
  - 70 year old woman is all alone; her family all died long ago
- DOES YOUR OPINION CHANGE? (if someone raises their hand, ask why their opinion changed)
- SO: What’s the point? – bioethical problems are complicated, require consideration of many factors and then a decision on which ones are most important; decisions depend on the situation at hand; bioethics is NOT black-and-white!
Basic Bioethics Principles

- We’re going to explain some basic bioethical principles in order to guide you in making bioethical decisions on complicated issues, like the heart-transplant issue.
- First, we want to suggest that you write some of this down, or try to remember them, because they will be useful later in our presentation!
- RESPECT for people’s rights (ASK STUDENTS for each principle if anyone can give a definition before offering the ones here)
  - Individuals have autonomy, or the right to make decisions about their own actions freely and without coercion
  - Individuals have dignity – we should respect people for the simple reason that they are fellow human beings (i.e. we cannot treat other human beings like pigs or trees!)
  - (pick out a person in class) Example: You can exercise your autonomy by deciding whether or not to do your homework tonight → it’s your decision
- BENEFICENCE: Benefits must be proportionate to risks
  - (pick out another person in class) Example: If you are going to risk talking to the guy or girl you like, you must foresee some benefit, like getting a prom date. Otherwise it wouldn’t be worth the risk of embarrassment!
  - In researching treatments, potentially harmful side effects must be weighed against the potential benefits; there should be an equal balance
Basic Bioethics Principles

- **JUSTICE**: The even distribution of benefits and risks throughout society
  - Let’s take this classroom as an example: I can’t just say that this random half of the class gets to have chocolate cake for lunch while the other half has to eat cauliflower. The benefits of eating chocolate cake aren’t distributed fairly. (it might be fair, however, to offer cake as a reward for acing the next test – this judgment is based on something!)
  - The same applies to biomedical research - Groups (racial, ethnic, gender, etc) should potentially benefit and/or potentially be exposed to risk at the same rate as other groups, unless there is something else that justifies unequal distribution (refer to “acing the test”)

- **NONMALEFICENCE**: Do no harm
  - Example: While it might be interesting to see what happens to your kneecap if we smashed it with a crowbar, we know that would cause harm to you, so couldn’t do that (even though it might be interesting scientifically)
  - Experiments should not be performed on humans if we know they will produce harm. If it becomes apparent that the experiment is harming the human participants, the study must stop.
What kinds of people actually deal with these issues on a daily basis?

Internal Review Boards (IRB’s): All universities, hospitals, and other research institutions have them. They are councils of scientists, administrators, and community members that approve the ethics of research involving human subjects BEFORE a project can start.

President’s Council on Bioethics: Who has heard of this? (ask) Created in 2001 to advise the United States president on ethical issues surrounding technology and medicine.

Independent Citizens’ Oversight Committee: This is specific to CA, and they oversee the ethical issues of what’s happening in stem cell research here in CA. The group is diverse, ranging from people involved in the sciences to people more like us, who are just interested in stem cell research ethics.

The point here, is to demonstrate that there are groups of people who spend a lot of time, some even have full-time jobs, that are dedicated to bioethics and even the ethics of stem cell research.
Some recent stem cell policy…

- **August 2001:**
  - President Bush declared that moral risks outweighed potential benefits in using left-over embryos from IVF clinics
  - Federal funding could only be used for research on stem cell lines already created from embryos because:
    - “The life and death decision has already been made”
  - The executive order applied only to *federally-funded* research
    - Did not ban new embryonic stem cell research all together
    - It can still be funded privately (just no government grants)
Some recent stem cell policy…

- 2002 President’s Council on Bioethics report “Human Cloning and Human Dignity”
  - Discussed laboratory-cloned embryos (NOT from IVF clinics; make sure students see the distinction) for research, including stem cell research
  - Majority of members said there was a “lack of sufficient scientific evidence to sustain claims of the unique value of cloned embryos for the desired research”
  - Therefore, they recommended policy of strict regulation of embryonic cloning
  - BUT, opinions varied
Some recent stem cell policy...

- November 2004 Proposition 71:
  - California voted in favor of spending $3 billion over the next ten years to fund stem cell research and dedicated facilities for scientists at CA universities and other advanced medical research facilities throughout the state.
  - This is PUBLIC money in the form of bonds.
Some recent stem cell policy...

- July 2006 U.S. House and Senate
  - Passed a bill to extend funding for research on NEW embryonic stem cell lines, beyond those already in existence at the time of Bush’s 2001 Executive Order
    - Mandated that consent be given by embryo donors at IVF clinics
  - In response, Bush VETOED the bill on the basis of respect for the moral integrity of the embryos
    - Launched “snowflake babies” campaign (explain that he invited children that were born from adopted embryos to the white house in order to demonstrate to the public that leftover embryos could in fact become children and should not be used for research)
M: Who should really decide?

- Recent history has shown that diverse stakeholders have influenced stem cell research policy.
- Who knows what a stakeholder is? (ASK)
  - President Bush (ban on generating/researching new embryonic stem cell lines)
  - Congress (passed bill to extend federal funding to the generation of and research on new embryonic stem cell lines; bill was vetoed by Bush)
  - California voters (voted in favor of Proposition 71, establishing the California Institute of Regenerative Medicine, which would allow state funding to go toward embryonic and human stem cell research)
- So there has been a mix of stakeholders that have gotten involved; can you think of anyone else who might be a stakeholder?
Who should really decide? (this slide not in presentation)

- Who has the right to decide the fate of stem cell research? – other possible stakeholders (suggest these if class has no ideas, ask if they think these are good ideas)
  - Government parties (the President; Congress; Supreme Court)?
  - Voters?
  - Couples donating the excess embryos for research?
  - Other couples looking to adopt excess embryos?
  - Religious leaders?
  - Stem cell researchers?
  - Bioethicists?
  - Disease advocacy groups?
Can someone tell me the 4 bioethical principles?

Can someone think of a situation where you might want to put them to use?

Let’s now start discussing some issues where many stakeholders have different opinions (so compromises are necessary) and where we might want to use our bioethical principles.
What issues are we discussing today?

- We will tackle some current issues, including:
  - The use of leftover embryos from IVF clinics for embryonic stem cell research
  - How we decide which diseases we should do research on – and you’ll help make the decision! (we have an activity planned)
What is an IVF clinic?

- Can anyone tell me what this is, based on what you know or what was gone over yesterday in the science presentation?
- An in-vitro fertilization clinic is a place where a couple can go after difficulty conceiving a child.
- Woman’s eggs are extracted and man contributes sperm.
- Woman’s egg fertilized in-vitro (outside her body) to generate embryos which are then inserted into her uterus to generate pregnancy.
Why are there left-over embryos?

Because IVF procedure generates many embryos in order to increase chances of success, there are left-over embryos that the couple chooses not to use.

These often get thrown out by IVF clinic.

BUT, instead, stem cells can be derived from these embryos.
When stakeholders collide: Current IVF embryo policy

- President Bush and others object to use of leftover IVF embryos because of their potential to be adopted by other couples, even though by June 2005 only 80-100 had ever been adopted (out of 400,000)
  - Students may ask, Why don’t more people adopt embryos? – expensive; timely; can be an invasive procedure; children that have already been born still need parents, which is often a motive in adopting; mother has to carry child 9 months before she can have the child
- Most of the stem cell policies in recent history have dealt with the use of embryos from IVF clinics (use of adult stem cells is far less controversial)
- Based on your gut feeling, which is ethically “right” for the embryos? (TAKE A VOTE)
  - Throwing out extra embryos (destroying them),
  - Saving the embryos on the chance that they could be adopted, OR
  - Using embryos for biomedical research (also destroying them)?
- NOW LET’S USE OUR BIOETHICAL PRINCIPLES. REVOTE!
- Let’s take, for example, the principle of justice – if we save the embryo for adoption, one couple benefits by becoming parents; maybe their family would also benefit by this new baby’s life. But if we use it for research, it’s possible that this embryo could lead to therapies/cures that benefit hundreds or thousands of different people.
- ALSO: some people might argue that the couple has a RIGHT (principle of respect) to have a child, and this overrides any social justice we might consider
- ASK: Does anyone have any thoughts on which situation holds more “justice”? (important: embryo actually being adopted or supplying cures/treatments are both POTENTIAL SITUATIONS; neither is guaranteed to happen, even if embryo is saved for that purpose)
The use of IVF embryos is not the only issue stem cell research is currently facing!

- The use of embryos in stem cell research is a “hot topic” and in the news a lot lately, but it’s not the only policy issues we ought to be thinking about.
- For example, some other questions policy-makers must tackle in the coming years:
  
  - How do we decide which diseases to do research on?
  
  - How do we make sure that all citizens receive equal access to the treatments, given that the research is funded with government (public) money?
    - This highlights the idea of justice as well.
When CA voters voted in favor of Prop 71, they approved a HUGE amount of funding for stem cell research therapies for diseases.

The only research that CIRM/ICOC approves must be intended to do research on stem cell-based cures or therapies for diseases.

Hopefully you heard about some applications of stem cell research yesterday in the science presentation – can anyone give an EXAMPLE?

But *what diseases in particular* do we do stem cell research on? How do we distribute the funding across the hundreds/thousands of diseases?
Proposition 71

- The California Institute of Regenerative Medicine (CIRM) was established when CA voters voted in favor of Prop 71 in the November 2004 election.

- What CIRM does:
  - Decides what research institutions get public money for stem cell research.
  - Research must have the goal of curing or improving major diseases, injuries, and “orphan diseases”.
    - Orphan diseases = rare diseases, usually life-threatening or chronically debilitating, not being heavily researched.
    - Examples: Tay-Sachs Disease (explain how disease affects you, age group it affects, mortality rate, etc.).
What diseases do we do stem cell research on first?

- Some would argue that muscular dystrophy, a disease that causes the muscles to deteriorate, should be a priority because people with the disease are likely to die by age 20.
- They argue that spinal cord injuries should not be as much of a priority because they cause paralysis, but death is not as common.
What diseases do we do stem cell research on first?

- The **Independent Citizen’s Oversight Committee (ICOC)** governs CIRM. This committee includes representatives of groups that advocate for (or support) people with:
  - Spinal cord injuries
  - Alzheimer’s disease
  - Type II diabetes
  - Multiple sclerosis or amyotrophic lateral sclerosis
  - Type I diabetes
  - Heart disease
  - Cancer
  - Parkinson’s disease
  - Mental illness
  - HIV/AIDS

- This doesn’t necessarily mean that these are the only diseases that will be researched, but it probably means that they have a better chance of getting researched because organized groups of people have come together and used resources like time and money to get themselves a voice on this committee.

- Notice: none of these are “orphan diseases.”

- How do we make sure attention is paid to them as well?
Common concerns in funding decisions:

- **Number of people with the disease.**
  - Is it relatively rare or very common in CA’s population?

- **The particular groups that suffer from the disease.**
  - Is it more common among women vs. men, in a certain geographical region (ex, southern california), does it affect a particular socioeconomic class, does it affect only young children? Or, instead, does it affect all types of people equally?

- **Severity of the disease.**
  - Does it cause prolonged pain or is it short-lived? What type of suffering does it cause? Can you recover from the disease or is it life-long?

- **Disease mortality.**
  - Does the disease decrease the patient’s quality of life yet allow them to survive, or will it cause certain death?

- **Average age at death.**
  - If death *will occur* without treatment, how old are the patients usually when they die? (ex, 5 years old versus 80 years old – does this make a difference?)

- **Already available therapies or treatments.**
  - Example, for diabetes: there already exists insulin therapy for some forms of diabetes. Does it make sense to do stem cell research on a cure/therapy for this, or should we divert stem cell research funding to diseases that don’t already have therapies available?
Class Activity: What diseases should we do research on?

- Divide into small groups (3-5 people)
- Discuss the following, referring to the bioethics principles that we discussed yesterday and earlier:
  - Which criteria are most important?
  - Number them 1-6 (the first thing on your list would be the criteria you would evaluate FIRST if you were deciding on funding)
    - write down HOW YOUR GROUP COMPROMISED and WHAT YOU BASED THE DECISION ON (gut feeling, bioethical principles, knowledge from other sources, etc)
  - Additional questions:
    - Look back at the list of disease groups on the ICOC. Do the diseases on the list meet your criteria? Are there any diseases you think should be added to or removed from the list?
    - Are there any other criteria you think should be considered?
    - How might various stakeholders (members of the public) react to your decision?

- At the end of group talks, come back together as a class. Write most important and least important from each group on the board. Have them give their reason. Note if there was a large variation in group decisions or
Take-home thoughts...

- Even though the issue of whether or not an embryo should be used for stem cell research has been in the news a lot, it’s not the only ethical issue.
- In fact, the type of analysis we did today is really what is happening in California today.
- A diverse group of women and men, from all racial and ethnic groups, and from various backgrounds, will be needed to make sure that these decisions reflect all of our interests and that we can come up with a policy solution that will satisfy all of our concerns in the most fair manner.
- We hope we’ve given you some tools to start thinking about such complex problems that our country and state will probably be deciding on in the years to come.
Thank you!