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*Cryphonectria parasitica* tendrils on chestnut tree bark (Photo: Ministry of Agriculture and Regional Development Archive, Ministry of Agriculture and Regional Development, Bugwood.org)



# Research Ethics Principles

B3 Summer Science Camp  
at Olympic High School

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# Ethical Principles

- Principles considered important to research in Biomedical Ethics
- Schools of Thought in Ethics
- Six Case Studies

# Respect for Autonomy

- The right of a person to make a decision for herself
  - Provide all pertinent information, properly explained (risks and benefits)
  - No undue influence: Threats and bribes
  - The person is responsible for seeking the information, understanding the information, finding an advocate if pressure is applied

# Moral status of individuals and Autonomy

- The ability to make an informed decision about the outcome of ones choices, for oneself and for society.
- An age limit is our customary standard.
- Exceptions include some types of mental illness or physical limitation.

# Non-maleficence (don't be evil)

- Do No Harm
  - The study cannot harm the person by adding something to their environment nor by removing something from their environment
- Monitoring is needed
  - Who should be watching?
    - Knowledgable experts? Community members?
- Mistakes are made and studies are cut short
  - How do you balance cost and benefit?
    - Individual? Society?

# Beneficence (do good)

- No study on humans should be performed that does not have the potential to enhance the welfare of humans.
  - Does this extend to animals? Does this extend to the environment?
- Different cultures regard doing good in very different ways.
- There may be longer-term consequences that are less good (the Green Revolution led to some of these debates, for example).

# Justice

- As much as you can, apply actions equally to all individuals and populations, so that everyone shares the risks and gets the benefits.
- The capabilities of individuals is inherently different – do we study children, are there special limits?
- Well-being can affect groups and society differently from specific individuals – how much does that affect the concept of justice or fairness?

# Schools of Thought - Utilitarianism

- The morally correct choice is the one that does the most good for the most people, and harms the fewest.
- Action is judged solely on outcome, not on intent
- Luck does not make your action morally good – it has to be deliberate. But you are not responsible for actions of others outside of your control.
- Good started out meaning happiness or pleasure, then became more a concept of well-being and self-realization.
- The reason for promoting the ‘good’ has to be the same for everyone



# Schools of Thought - Kant

- Kant believed that moral philosophy had to have a law that defined it.
  - There is a theoretical expression (similar to those describing physical laws) - but this one did not depend on observation and experiment.
    - This meant that truths had to be absolute
      - Interpretation might depend on the understanding of the people you were describing truth to.
- The Doctrine of Right – humans have an innate right to freedom
  - There are private rights (marriage and property)
  - There are public rights (the government can punish law-breakers)
- The Doctrine of Virtue
  - Right actions are so judged because general happiness increases
    - This could happen when good actions (proper duties) have been carried out or because bad actions have been avoided

# Morality

- Broad morality – choices made in daily life
- Particular morality – there is an ethical system guiding choices
  - A set of rules that is applied to carefully defined circumstances – you should be able to use logical rules to find a single good when an ethical dilemma arises.
    - Intuition and tradition often lack sufficient information to handle dilemmas that arise from new circumstances – or where two ideals are in conflict like Truth and Justice.
    - To apply the set of rules you must understand them thoroughly.
- **Pharmacists in private and professional roles - discuss**

# Case Study 1

- The Supreme Court on June 3 ruled that law enforcement authorities can take DNA samples from people arrested for serious crimes, such as violence or burglary.
- The justices rejected a 2012 decision by the Maryland Court of Appeals, which held that authorizing the sampling of DNA from people who had not been convicted is a breach of the Fourth Amendment right against unreasonable search and seizure.
- The practice is a valuable tool for investigating unsolved crimes, but the court justified the ruling on the grounds that it is a legitimate way to identify suspects.
  - “Taking and analyzing a cheek swab of the arrestee’s DNA is, like fingerprinting and photographing, a legitimate police booking procedure that is reasonable under the Fourth Amendment,” wrote Justice Anthony Kennedy for the majority.

# Counterarguments

- Justice Scalia challenged Kennedy's claim that the ruling was limited to serious offenses, and said that in practice, under the terms of the court's justification, DNA samples could be taken after any arrest.
  - "Make no mistake about it: because of today's decision, your DNA can be taken and entered into a national database if you are ever arrested, rightly or wrongly, and for whatever reason," said Justice Scalia.
  - Other critics are concerned that DNA sampling exposes people to as yet unpredictable privacy issues that will only be revealed as science decodes more of the genome.
  - "Once an individual's DNA sample is in a government database, protecting that information from future exploitation becomes more difficult," said the Electronic Privacy Information Center in a friend-of-the-court brief submitted earlier this year.

# Counter-counterarguments

- Justice Kennedy said that the information gleaned from DNA testing carried out by police is limited, and insisted that whether or not “the testing at issue in this case reveals any private medical information at all is open to dispute.”
- How much does Justice Kennedy know about the technologies for DNA fingerprinting, and for technologies for correctly recording and storing that data? (not much)

## Case Study 2

- Three hundred *supporters* of animal testing gathered in Milan to promote scientific research.
- The rally occurred after animal rights activists broke into a University of Milan lab where rabbits and mice were kept in April and destroyed years worth of work.
- The protest, held by the group Pro-Test Italia, emphasized the importance of greater public awareness about the benefits and conditions of animal research.
  - “I hope that, starting from today, public opinion understands who lies, because we are not assassins,” Gaia Gobbo, a graduate student in biotechnology at the University of Bologna, told *Nature*.

## Case Study 2 - Arguments

- Speakers explained the uses of animal research, while a group of about 30 animal-rights demonstrators counter-protested the event.
- The original Pro-Test group formed in the United Kingdom in 2006 in response to animal-rights protesters there.
- Pro-Test Italia was formed in September 2012 in response to a break-in at a dog-breeding facility in Brescia, Italy, in July by the same group of protesters who would later trash the University of Milan lab.

## Case Study 3

- Medical records – an individual is brought in suffering from a heart condition. He is a married, childless man. He has some slight physical abnormalities but they have not affected him for most of his life.
  - The heart condition has some unusual aspects to it, a lab workup has been requested by the attending physician, agreed to by the patient.
  - The results suggest a syndrome almost always seen in women, and for which some treatments seems to help. The physician has curiosity about the status of the patient and, without obtaining the consent of the patient, requests a karyotype, which tells which chromosomes someone has. The results come back indicating that this person has two 'X' chromosomes.
- Can the doctor use this information, tell the patient or his wife or the other physicians about these results?



# Case Study 3 - Arguments

- What are the implications of doing a genetic test?
- What are the implications of not telling someone the results of a genetic test?
- What are the implications to related family members of not communicating the results of a genetic test?

# Case Study 4

- A fertility clinic stores frozen embryos for couples looking to have babies. The clinic has been in operation for 10 years and has been very successful.
  - *In vitro* fertilization involves combining eggs and sperm in a Petri dish, identifying successful fertilizations, transplanting 1-3 in the womb of the female partner and storing the remaining embryos.
  - An advantage for couples whose families have a known genetic mutation is that early in development you can remove a cell and it will not harm the eventual fetus, so you can test for those that do not carry the bad allele.
  - The advantage to making multiple embryos is you can test several, just store the good ones, and if none of the first set successfully implant you can quickly try the others.
  - If the first set produces one or more live births, the couple may want to store the remainder to have a second or third child but this will not use all the embryos created.

# Case Study 4

- What is the right thing to do with the unused embryos?
  - Some couples will donate their embryos to completely infertile couples,
    - Not all are willing - they worry about the quality of care these strangers will give provide
    - There are a lot more embryos than couples
  - Donate the embryos to scientific research once they no longer intend to become parents
    - A majority of couples agree, especially when there has been a genetic illness in the family.
- How big is this problem?
  - There are 10,000 embryos frozen each year in the US.
- Who owns them?
  - Are they property or individuals
  - what is their state of moral virtue if they are individuals?.
- Courts mostly have said that no one can be *required* to be a parent
  - an embryo cannot inherit part of an estate.
- What are 5 things that could be done, and the ethical justification for the actions.

# Case Study 5

- Translational genomics is using a lot of tax dollars right now
  - Your genome sequence is being used to understand both what illnesses you *might* have and what treatments *might* be effective for you.
- One example would be the case of a drug that treats bone degeneration, called osteoporosis. This affects women more than men, but affects both.
  - Calcium leaches out of the bones, which become brittle and break easily. The spine can undergo compression fractures, leading to great pain, or just the act of coughing can cause ribs to break, which is very frightening.
  - There are several drugs that have been developed to treat this condition – they slow down the loss of calcium although they cannot cause it to be replaced.
- The drug we are considering has no side effects, but in order to work a patient would have to take it from puberty onwards, every day (sort of like a vitamin pill).
  - Not everyone needs this pill, but we don't yet know all the genetic causes of osteoporosis – a few people would know they need it, but most people would be unsure. For many people paying attention to your diet (making sure there is a lot of bio-available calcium) would be all the prevention required, but again, for some people this does not work.

# Case Study 5

- The drug company who developed this medication would like to require that people 25 and older take the medication. It is working with its home state legislature to enact this law.
  - This is not novel – many states required genetic testing of newborns since some conditions are preventable if you know about them immediately. The state may also required blood transfusions of minors, even if the parents don't agree, or a caesarean-section of a woman if her life is at risk or that of her fetus is at risk during a normal birth.
- What type of argument do you think the drug manufacturer will present to the legislature?
  - This is legislating to produce positive health benefits (for example, no smoking, or limiting soda drinks in schools) – should the government be involved in personal health decisions? Ever? Sometimes? When does social good overtake private reluctance?
- At what point should the government be allowed to intervene in health decisions? How would you allow people to opt out? What might the consequences be?
- If the law is put into effect, how would insurance companies likely respond? What should the legal consequences be for those who do not comply? How would you be able to tell that they had not complied?

# Case Study 6

- A patient who underwent gall bladder surgery was unable to pay a very large resulting bill. Since the surgery was successful and she was reasonably young with no other health problems she offered a swap to the hospital: one healthy kidney in return for no bill.
- The hospital declined, but she placed an ad in the local paper offering those in need of a kidney almost the same deal – pay for the test for a match, the transplant surgery and her bill and the kidney was yours.
- The ad ran because the newspaper did not realize that
  - Organ transplant is handled by licensed agencies – federal law prohibits buying or selling human organs and tissues, even your own.
  - Donation is allowed through the agencies under carefully controlled conditions.
  - Exceptions: men can be paid to donate sperm, women eggs or their services as a surrogate mother, and both can donate blood.

# Case Study 6

- Why does this create a dilemma?
  - Not nearly as many people offer organs for donation as need them.
  - Hospitals, doctors, insurance and drug companies make loads of money from transplants: the only people who don't profit are the ones taking the biggest risk.
    - You do want to make sure people understand the true risks to themselves,
    - You want to make sure they are not forced into doing something they really do not want to do.
- How might you encourage and reward organ donation without leading to real exploitation of the poorly educated or desperate?
  - Should death row prisoners be allowed to donate organs?
  - Should only family members be allowed to donate organs?
- Would this change your mind?
  - Even 'brain-dead' accident victims may feel pain
  - Some patients in a permanent coma are clearly *sensing* the environment, even if they don't respond.
  - Organs must be harvested before the *cells in the body* are dead and any kind of pain killer can affect transplant success - does complicate the ethics of our practice of 'only' allowing organ transplants from those who have been declared dead as the result of accident?