Ethical Issues in Epidemiology

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Contents

Lesson Plan ................................................................. 3
Teacher's Narrative ......................................................... 6
Transparencies ............................................................... 14
Student Handouts ............................................................ 51
Embedded Assessment (Student Version) .............................. 61
Embedded Assessment (Teacher's Discussion Guide) .............. 66
Lesson Plan

TITLE: Ethical Issues in Epidemiology

SUBJECT AREA: Social studies, science, health

OBJECTIVES: At the end of this module, students will be able to:

• Identify the ethical dilemmas inherent in research on human subjects
• Present arguments for and against research participation by human subjects
• Explain the role of an institutional review board (IRB) or human subjects review committee in protecting the rights of human subjects in public health research
• Recognize the rights of human research participants

TIME FRAME: Two to three class periods

PREREQUISITE KNOWLEDGE: The unit on clinical trials (Testing Ephedra: Using Epidemiologic Studies to Teach the Scientific Method) or equivalent training in clinical trials

MATERIALS NEEDED:

• Video clips from We All Have Our Reasons
• Internet access
• Handouts A–D; Embedded Assessment handout

To order a free copy of We All Have Our Reasons, contact:
CDC National AIDS Clearinghouse
Publications Ordering Service
P.O. Box 6003
Rockville, MD 20849-6003
Inventory No. V951
(800) 458-5231

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PROCEDURE: This instructional unit introduces students to some of the ethical issues facing epidemiologic research. The unit focuses on a contemporary research dilemma: clinical trials to test human immunodeficiency virus (HIV) vaccines in humans. Students will work through various in-class and homework activities as they grapple with the issues surrounding the administration of a test vaccine to protect persons from becoming infected with HIV. As an assessment strategy, students work in teams to review a fictitious HIV vaccine study protocol to evaluate whether it is ethical and adequately protects the rights of the intended research participants.

ASSESSMENT: See Embedded Assessment (Student Version) and Embedded Assessment (Teacher's Discussion Guide).

LINK TO STANDARDS:

Social Studies

• Social studies programs should include experiences that provide for the study of interactions among individuals, groups, and institutions.

• Social studies programs should include experiences that provide for the study of relationships among science, technology, and society.

Science

• Students should develop understanding of:

• Science and technology in local, national, and global challenges

• Understanding basic concepts and principles of science and technology should precede active debate about the economics, policies, politics, and ethics of various science- and technology-related challenges. However, understanding science alone will not resolve local, national, or global challenges.

• Progress in science and technology can be affected by social issues and challenges. Funding priorities for specific health problems serve as examples of ways that social issues influence science and technology.

• Individuals and society must decide on proposals involving new research and the introduction of new technologies into society. Decisions involve assessment of alternatives, risks, costs, and benefits and consideration of who benefits and who suffers, who pays and gains, and what the risks are and who bears them. Students should understand the
appropriateness and value of basic questions—“What can happen?”—“What are the odds?”—and “How do scientists and engineers know what will happen?”

• Science as a human endeavor

• Scientists have ethical traditions. Scientists value peer review, truthful reporting about the methods and outcomes of investigations, and making public the results of work. Violations of such norms do occur, but scientists responsible for such violations are censured by their peers.

Health

• Students will comprehend concepts related to health promotion and disease prevention.

Recommended References:


American College of Epidemiology’s *Ethical Guidelines*, http://www.acepidemiology.org/policystmts/EthicsGuide.htm
Teacher’s Narrative*

Part 1: Introduction

Tell students that the goal of this module is for them to understand how the ethical challenges of conducting a randomized controlled trial can be addressed. *(Transparency 1)* Tell students that the goal of this module is not for them to memorize the vocabulary of ethical randomized controlled trials.

Remind students that a randomized controlled trial (RCT) is “an epidemiologic experiment in which subjects in a population are randomly allocated into groups, usually called study and control groups, to receive or not receive an experimental preventive or therapeutic procedure, maneuver, or intervention.” *(Last JM. *A Dictionary of Epidemiology*. New York: Oxford University Press; 1995)* *(Transparency 2)*

Tell students that ethics is “ . . . a branch of philosophy that deals with distinctions between right and wrong—with the moral consequences of human actions. Ethical principles govern the conduct of epidemiology, as they do all human activities.” *(Last, *A Dictionary of Epidemiology)* *(Transparency 3)*

**OPTIONAL: Randomized Controlled Trials Versus Observational Studies**

Help students distinguish between the RCT study design and epidemiologic observational study designs. (In an RCT the experimental conditions are under the direct control of the investigator, whereas in observational studies [cohort, case–control and cross-sectional studies] “the investigator allows nature to take its course and merely observes the subjects and records, classify, counts, and analyzes the results.”) *(Last, *A Dictionary of Epidemiology)*. *(Transparency 4)* Help students identify the ethical concerns that arise in an RCT but not in observational studies. (In an RCT the investigator must consider the moral consequences of intentionally allocating subjects into different groups, at least one of which will be exposed intentionally to a treatment of questionable value and that may possibly do harm and another from which a potentially beneficial exposure will be intentionally withheld.)*

*For students who have completed A Mock Trial of Yellow Dye #5 or Case-Control Study as modules that could introduce students to observational studies*

Help students identify the ethical concerns that arise in an RCT. (In an RCT the investigator must consider the moral consequences of intentionally allocating subjects into different groups, at least one of which will be exposed intentionally to a treatment of questionable value and may possibly do harm and another from which a potentially beneficial exposure will be intentionally withheld.)

*Knowledge of the randomized controlled trial is required (see Testing Ephedra: Using Epidemiologic Studies to Teach the Scientific method)*
value and that may possibly do harm and another from which a potentially beneficial exposure will be intentionally withheld.)

Given the choices identified below, ask students to indicate their response to the question “How willing would you be to join a study of a vaccine to prevent HIV infection if that study was to start tomorrow?” by raising their hands.

- Definitely Not Willing
- Probably Not Willing
- Probably Willing
- Definitely Willing

Using a transparency pen, tally students’ willingness to participate in row 1 of the Willingness to Participate Transparency. (Transparency 5) (Students will be asked the same question two more times in the course of the unit. Do not erase the previous tallies. The results of the three tallies will be compared at the end of the unit.)

Start a List of Reasons (Handout A) why students would and would not participate in a study of a vaccine to prevent HIV infection on the chalkboard by:

- Asking students who are presently Probably Not Willing to participate in the RCT if they can identify the reason(s) why they would not participate.
- Asking students who are presently Definitely Not Willing to participate in the RCT if they can identify the reason(s) why they would not participate.
- Asking students who are presently Probably Willing to participate in the RCT if they can identify the reason(s) why they would participate.
- Asking students who are presently Definitely Willing to participate in the RCT if they can identify the reason(s) why they would participate.

Save this List of Reasons. It will be referred to and edited several times throughout the unit.

**OPTIONAL: Attitudes About Reasons for Participating in an HIV Vaccine Trial**

Have students explore reasons people may have for joining or not joining an HIV vaccine study by completing the Attitudes About Reasons for Participating in an HIV Vaccine Trial, an adaptation of an instrument created by Anne Coletti and others. (Handout AA) Potential HIV vaccine trial participants’ responses to the original instrument are in part the basis for their study “Randomized, Controlled Evaluation of a Prototype Informed Consent Process for HIV Vaccine Efficacy Trials,” which was published in the February 1, 2003, issue of the Journal of Acquired Immune Deficiency Syndromes.

Edit the List of Reasons that was begun above.
For homework ask students to read the booklet by the National Institute of Allergy and Infectious Diseases (NIAID) called *Understanding Vaccines: What They Are, How They Work*, at http://www.niaid.nih.gov/publications/vaccine/undvacc.htm *(Handout B)*

**Part 2: Informed Consent**

Ask a student to briefly summarize the booklet that was assigned for homework.

Review students’ answers to the following questions:

1. Would you have allowed your child to participate in Dr. Edward Jenner’s test of his smallpox vaccine? Why? Why not?
   
   *Students would probably not have allowed their children to participate in Dr. Edward Jenner’s test of his smallpox vaccine. Jenner intentionally injected the boy with fluid from a smallpox sore, which he believed would cause smallpox if his vaccine did not work.*

2. What are candidate vaccines?
   
   *Vaccines that seem promising but that have not been tested.*

3. What are subunit vaccines? What are their advantages and disadvantages?
   
   *Instead of using the entire microbe, the parts of the microbe that stimulate the immune system best are used as the antigens. Because fewer antigens are used, there is less chance of adverse reactions. Because only a part of the microbe is used, it should not be able to cause the infection. The process of identifying the best antigens can be difficult and time consuming.*

Given the choices identified below, again ask students to indicate their response to the question “How willing would you be to join a study of a vaccine to prevent HIV infection if that study was to start tomorrow?” by raising their hands.

- Definitely Not Willing
- Probably Not Willing
- Probably Willing
- Definitely Willing

Using a transparency pen, again tally students’ willingness to participate in row 2 of the Willingness to Participate Transparency. *(Transparency 5)*
Again, as described above, ask students in each of the four groups if they can identify the reason(s) why they would and would not participate and edit the List of Reasons accordingly.

Show the first 12 minutes of the *We All Have Our Reasons* videotape.

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Stop the videotape after the woman says:

“I can’t think of any information you could give me to make me want to take a vaccine to risk my life.” (Transparency 6)

Give attribution: *We All Have Our Reasons*, Community Perceptions of HIV Vaccine Research, University of Pennsylvania, Center for Studies of Addiction.

Refer to the List of Reasons and ask students to distinguish between those reasons that can be addressed with information and those that cannot.

Show the next 11 minutes of the *We All Have Our Reasons* videotape.

Stop the videotape after the man says:

“People need to know the background before they ever come in to do informed consent. They need to know what a clinical trial is. They need to know why they (clinical trials) have to be big. They need to know what the ethical problems are. They need to know what the risks of being in a vaccine trial are. Before they come into a clinic and hear about a specific trial or a specific product.” (Transparency 7)

Give attribution: *We All Have Our Reasons*, Community Perceptions of HIV Vaccine Research, University of Pennsylvania, Center for Studies of Addiction.

Ask students what they think the phrase informed consent means. (Transparency 8)

If the following issues are not discussed, raise them at the appropriate time.

- What does a potential RCT subject need to know in order to be truly informed?
• Are there groups of people who cannot give informed consent? Children? The mentally ill? Drug addicts?

• How does one determine when a potential RCT subject is truly informed?

• What does it mean to consent to do something?

• Can someone be coerced into consenting? If so, how?

• Are there groups of people who are more likely than others to feel coerced into participating in an RCT? Students? Prisoners? Those needing the incentive?

• Can someone who has given consent change his or her mind? If so, when?

Ask students to consider the following description of informed consent.

Voluntary consent is given by a subject (person or responsible proxy) for participation in a study . . . after being informed of the purpose, methods, procedures, benefits and risks, and, when relevant, the degree of uncertainty about the outcome. The essential criteria of informed consent are that the subject has both knowledge and comprehension, that consent is freely given without duress or undue influence, and that the right of withdrawal at any time is clearly communicated to the subject. (Last, A Dictionary of Epidemiology) (Transparency 9)

Ask students, if they knew the above about an RCT of an HIV vaccine, whether they would be more likely to participate in the trial.

Show students the cover of the Consent for Research Study that was created by Community Perceptions of HIV Vaccine Research, University of Pennsylvania, Center for Studies of Addiction, and funded by the NIAID/National Institutes of Health (NIH) HIV Prevention Trials Network: Vaccine Preparedness Study 1. (Transparency 10)

Give students the Consent for Research Study handout. (Handout C) Tell students you are going to show them 21 selected statements from the Consent for Research Study document. Ask them to identify what type of information from the list below each statement addresses and to assess whether or not this is accomplished. (Transparencies 11–31)

A Voluntariness

B Being informed about the purpose

C Being informed about the methods and procedures

D Being informed about the benefits and risks

E Being informed about the degree of uncertainty about the outcome
F Knowledge and comprehension
G Duress or undue influence
H Right of withdrawal at any time

Edit the List of Reasons that was begun above.

Using a transparency pen, again tally students’ willingness to participate in row 3 of the Willingness to Participate Transparency. (Transparency 5)

Again, as described above, ask students in each of the four groups if they can identify the reason(s) why they would and would not participate and edit the List of Reasons accordingly.

OPTIONAL: Informed Consent Quiz

Ask students to take the 10-item, true/false Informed Consent Quiz, a document created by Anne Coletti and others. (Handout CC) Responses to this instrument are in part the basis for their study “Randomized, Controlled Evaluation of a Prototype Informed Consent Process for HIV Vaccine Efficacy Trials,” which was published in the February 1, 2003, issue of the Journal of Acquired Immune Deficiency Syndromes.

Review students’ answers and address misconceptions.

Edit the List of Reasons that was begun above.

Part 3: Institutional Review Board (IRB)

“Rewind” the We All Have Our Reasons videotape and show the last 30 seconds of the previous clip again of the man saying:

“People need to know the background before they ever come in to do informed consent. They need to know what a clinical trial is. They need to know why they (clinical trials) have to be big. They need to know what the ethical problems are. They need to know what the risks of being in a vaccine trial are. Before they come into a clinic and hear about a specific trial or a specific product.” (Transparency 32)

Give attribution: We All Have Our Reasons, Community Perceptions of HIV Vaccine Research, University of Pennsylvania, Center for Studies of Addiction.

Remind students that ethics is “... a branch of philosophy that deals with distinctions between right and wrong—with the moral consequences of human actions. Ethical principles govern the conduct of epidemiology, as they do all human activities.” (Last, A Dictionary of Epidemiology) (Transparency 33)
Ask students to identify the moral consequences of an RCT of an HIV vaccine. Ask students what ethical problems need to be addressed if an RCT of an HIV vaccine is going to be done “right.”

Tell students that an **institutional review board** (IRB) is “the term used in the USA to describe the standing committee . . . that is charged with ensuring the safety and well-being of human subjects involved in research. The IRB is responsible for ethical review of research proposals. All research . . . that involves human subjects must be approved by an IRB or equivalent body.” (Last, *A Dictionary of Epidemiology*) **(Transparency 34)**

Tell students that at least one member of an IRB must be a nonscientist and have no affiliation with the institution doing the research.

Tell students that in the next class they will be divided into groups of five or six students, with each group assuming the role of an IRB. Each IRB will review a proposal for an RCT of an HIV vaccine to ensure the safety and well-being of the human subjects involved in the RCT. Tell students at the end of the class they will be asked to either approve or disapprove the proposal and, if their IRB disapproves, to tell the investigators what revisions are necessary in order to be re-reviewed by the IRB.

To prepare for their roles as IRB members, ask students to complete the IRB Preparation Assignment for homework. Give students the IRB Preparation Assignment handout. **(Handout D)**

- Click on “HERE,” go to the Human Participant Protections Education for Research Teams Web site and click on “ENTER.” **(Transparency 36)**
- Read the first three pages and “register for the course” at the bottom of page 3.
- Complete the “required fields” identified with a red asterisk and “Submit Registration.” (The student will need to create a password. The student should check “Completion Certificate only, no continuing education credits.” The student should enter the name of his or her high school for “Institution Name.”)
- Scroll to the bottom of the next page and click on “Proceed to the Main Menu.”
- Click on “The Basics” and study this section of the Web site.
- When finished, complete the “Exercise” and print the last page of this section of the Web site with the student’s “Results for exercise 2”

Tell students to complete the “Exercise,” print the last page of this section of the Web site with the “Results for exercise 2” and bring it to the next class. **(Transparency 37)**
Part 4: Embedded Assessment

This part of the module is an embedded assessment designed to determine the degree to which the teacher has taught and the students have achieved the goal of this module: to understand how the ethical challenges of conducting an RCT can be addressed.

Divide students into groups of five or six students and ask each group to assume the role of an IRB.

Give each student the Institutional Review Board Proposal. (Embedded Assessment)

Remind students that it is the responsibility of the IRB to ensure the safety and well-being of the human subjects involved in the RCT.

Tell students that at the end of the class each IRB will be asked to either approve or disapprove the proposal and, if their IRB disapproves, to tell the class what revisions are necessary in order to be re-reviewed by the IRB.

OPTIONAL: American College of Epidemiology’s Ethical Guidelines

For a more complete look at the ethical issues that confront epidemiologists and how they propose to address them, ask students to read the American College of Epidemiology’s Ethical Guidelines, at http://www.acepidemiology.org/policystmts/EthicsGuide.htm.