This unit explores the scientific and ethical issues involved in clinical HIV vaccine trials using human research participants. The unit begins by examining students’ current knowledge of HIV, and by reviewing HIV structure and transmission. Next, it familiarizes students with types of vaccines and with challenges related to creating an HIV vaccine. Students are encouraged to explore issues related to human research participants using basic ethical principles and historical case studies. Lastly, global issues regarding the pandemic are explored to give the students an understanding of cultural issues involved in the spread of HIV. This cultural context introduces students to ethical dilemmas inherent in the selection of human participants in global vaccine trials. The lessons culminate in having students design their own hypothetical HIV vaccine clinical trial, based upon knowledge of HIV structure, vaccine characteristics, human research participants considerations, and global contexts.

Length:
5 Lessons and a culminating assessment, spanning approximately 2 weeks, depending on the number of activities and depth of review

Target Audience: Grades 7-12

Washington State Standards Targeted

Systems 1.1.6 Characteristics of Living Things
1.2.6 Structure and Organization of Living System
1.2.7 Molecular Basis of Heredity
1.2.8 Human Biology

Inquiry 2.1.1 Questioning
2.1.2 Planning and Conducting Investigations
2.1.5 Communicating
2.2.2 Limitations of Science and Technology
2.2.4 Evaluating Methods of Investigation

Design 3.1.1 Identifying Problems
3.1.2 Designing and Testing Solutions
3.1.3 Evaluating Potential Solutions
3.2.2. Relationship of Science and Technology
## Correlation to National Science Standards: Grades 5-12

<table>
<thead>
<tr>
<th>Unifying Concepts and Processes</th>
<th>Lesson 1</th>
<th>Lesson 2</th>
<th>Lesson 3</th>
<th>Lesson 4</th>
<th>Lesson 5</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systems, order, and organization</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Evidence, models, and explanation</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Constancy, change, and measurement</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Evolution and equilibrium</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Form and Function</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
</tbody>
</table>

## Correlation to the National Science Standards: Grades 9-12

<table>
<thead>
<tr>
<th></th>
<th>Lesson 1</th>
<th>Lesson 2</th>
<th>Lesson 3</th>
<th>Lesson 4</th>
<th>Lesson 5</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Science as Inquiry</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abilities necessary to do scientific inquiry</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Understandings about scientific inquiry</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td><strong>Physical Science</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structure and properties of matter</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Chemical Reactions</td>
<td>●</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>●</td>
</tr>
<tr>
<td><strong>Life Science</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The cell</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Molecular basis of heredity</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Biological Evolution</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Interdependence of organisms</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Matter, energy, and organizations in living systems</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Behavior of organisms</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td><strong>Science and Technology</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abilities of technological design</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Understandings about science and technology</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td><strong>Science in Personal and Social Perspectives</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personal health and community health</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Science and technology in local, national, and global challenges</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td><strong>History and Nature of Science</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Science as human endeavor</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Nature of scientific knowledge</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Historical Perspectives</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
</tbody>
</table>
1. Why is there an HIV Pandemic?
2. Why is a vaccine needed to control the HIV pandemic?
3. How do vaccines usually work and why hasn’t an HIV vaccine been developed?
4. How has history influenced research with human participants, and how are ethics applied in current research?
5. Which factors should be considered when developing and conducting trials?

The student will be able to:
1. Relate the structure, and lifecycle of HIV to challenges in vaccine development.
2. Identify ethical issues in historic and current research trials using human research participants, and apply an understanding of those issues to the development of a student-designed research proposal.
3. Evaluate the factors influencing the spread of HIV, both between individuals and on a global scale.
4. Design elements of a research protocol for an HIV vaccine trial and evaluate that protocol using considerations of scientific accuracy, knowledge of human research participants testing, and ethical principles (autonomy, beneficence, and justice).

1. Basic facts about HIV structure, transmission, research, and treatments need to be understood as background to why an HIV vaccine is currently lacking.
2. Mutations in viruses force the immune system to adapt and respond; vaccines must also stimulate an immune response. Since there is no history of a human being naturally clearing an HIV infection, a vaccine must produce an immune response which is better than that currently produced by the body.
3. Selection of human research participants for experimental research must be done carefully based upon the goals of the research and consideration of the risks and benefits to specific individuals and participant populations.
4. Pandemics are influenced by global health issues, cultural diversity, environmental context, education levels and socio-economic conditions.
5. Scientists conducting inquiry and research using human research participants must consider ethical principles based upon both past historical practices and current guidelines and regulations.
6. Examining the ethics of human research participants research encourages the use of critical and logical thinking to form positions and viewpoints.
Credits

Teacher Curriculum Design Team
Elise Cooksley, Two Rivers School, North Bend, Washington
Kirk Einspahr, Chelan High School, Chelan, Washington
Shawna Hodge, Auburn Riverside High School, Auburn, Washington
Pat Lisoskie, Black Hills High School, Tumwater, Washington
Laurie Odegaard, Moses Lake High School, Moses Lake, Washington
Linda Peterson, Woodmore Elementary, Bothell, Washington

Collaborations to Advance Understanding of Science and Ethics (CAUSE)
Susanna Cunningham, PhD
Principal Investigator and Professor, Dept. of Biobehavioral Nursing and Health Systems, University of Washington
Susan Adler
Co-Principal Investigator and Executive Director
Northwest Association for Biomedical Research
Jeanne Chowning, MS
CAUSE Program Director, Education Director,
Northwest Association for Biomedical Research
Joan Griswold, MIT
Education Outreach Coordinator,
Northwest Association for Biomedical Research
Mark Windschitl, PhD
Co-Principal Investigator and Assistant Professor
School of Education, University of Washington

Consultants
Laura Bishop, PhD, Ethics Consultant and Program Coordinator
High School Bioethics Curriculum Project, Georgetown University
Lola Szobota, Professional Development Consultant and Ethics Trainer, District Science Supervisor, Northern Valley High School District, Demarest, NJ
LueRachelle Brim-Atkins, MA, Diversity Consultant, Brim Donahoe and Associates
Paula Fraser, MLS, Bellevue School District, PRISM Program
Curriculum Advisory Committee
Wylie Burke, MD, PhD, Professor and Chair, Department of Medical History and Ethics, University of Washington
Mel Dennis, PhD, Professor and Chair, Department of Comparative Medicine, University of Washington
Suzanne Holland, PhD, Associate Professor, Department of Religion, University of Puget Sound
Beverly Torok-Storb, PhD, Senior Scientist, Fred Hutchinson Cancer Research Center
Paul Robertson, PhD, CEO and Scientific Director, Pacific Northwest Research Institute
Pat Wasley, PhD, Dean, College of Education, University of Washington

Curriculum Review
Gail Broder, HIV Vaccine Trials Network,
George Counts, M.D., University of Washington, HIV Vaccine Trials Network
Renee Holt, HIV Vaccine Trials Network
Pushpa Jayaraman, Seattle Biomedical Research Institute
Kim Louis, Seattle HIV Vaccine Trials Unit
Madhumita Mahalanabis, Seattle Biomedical Research Institute

Project Funded By
This project was supported by a Science Education Partnership Award (SEPA) from the National Center For Research Resources, National Institutes of Health (1R25RR016284-O1A2). Its content is solely the responsibility of the authors and does not necessarily represent the official views of NCRR or NIH.

Cover and Design:
La Neu, graphic designer
Sharon Swanson, cover illustration
Lesson Overview

Lesson One
Six introductory activities designed to review and assess student knowledge of HIV transmission, structure, research, and treatment are presented. The first activity (Survey — Global Awareness of HIV) can be used as a pre-unit assignment; it may also serve as a post-unit discussion.

Lesson Two
This lesson focuses on the HIV life cycle using web-based animations. Students identify possible targets for vaccine action and justify their choices based on HIV science.

Lesson Three
This lesson introduces priorities and challenges in the development of HIV vaccines. Vaccine types are compared and contrasted, and students learn about the most appropriate approaches for an HIV trial.

Lesson Four
The history of research with human participants is explored. Students hypothesize rules for such research, which may be modified after examining landmark case studies. The ethical principles and guidelines explained in the Belmont report and the UNAIDS Guidance Document are introduced. These principles form the basis upon which research is currently reviewed and approved.

Lesson Five
Students will participate in an activity to explore global cultural and socio-economic issues. They will identify issues effecting the health and welfare of different populations by continent, including HIV infection and death rates. This information will be applied when students choose a location for their vaccine trials.

Lesson Six: Evaluation
The culminating project will allow groups of students to present vaccine trial proposals to the class. Students research additional information to prepare their presentations. Presentations are evaluated and one project is chosen to be funded. As an individual assessment, students will submit a paper based on their learning during the unit; HIV structure, vaccine types and challenges, human research participants considerations, and global issues.

Symbols

- video
- discussion
- hands-on
- on-line or web based
- homework