PBL Problem

Title: Ethical considerations on the use of vaccines

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Discipline: Biomedicine/Ethics

Target Audience: Undergraduate or Graduate

Keywords: Vaccination, Risk, Bioethics, Bioterrorism

Length of Time/Staging: 2-3 weeks (3 class periods)

Grading: Class Attendance/Participation
Group Evaluation
Individual Papers

Abstract:

This problem is designed to aid science students in understanding the ethical issues concerning the development and administration of vaccines. Part I is constructed to evaluate the perception of risk within a specific population (the classroom). Although the class may comprise of individuals with similar scientific backgrounds, the exercise should point out that not everyone might perceive the risk of being vaccinated in the same way. This “risk assessment” introduces the current problem of administering a new vaccine to society. The students are then presented with a hypothetical situation regarding an emerging disease. The class must form groups to discuss the social, cultural, and economic implications of applying a vaccine against such a disease. At the end of Part I students are given a reading assignment that is relevant for higher-level discussions during Part II. In Part III the students are presented with a twist in the hypothetical problem, followed by a real situation where they are asked to discuss the ethical considerations and a discussion of the rights of an individual to refuse vaccination.
The individual student’s progress will be assessed by class participation, a written assignment, and group evaluations.
Learning Objectives:

1. To identify all parties impacted by the employment of vaccines
2. To reflect upon all ethical considerations regarding vaccination
3. To understand all the considerations needed during the development of vaccines (graduate level)

Problem Content:

Part 1
Part 2
Part 3
Individual Assignment

Supporting Materials: References
Useful Materials
Useful Websites
Part I

Hand out introduction. Give about 5-10 minutes for the class to read it over.

Introduction

The Expanded Programme on Immunization was established in 1974 as an initiative to increase immunization programs throughout the world. Due to the efforts of this program, an estimated 3 million children a year are protected from potential life-threatening diseases. Ironically, opposition to vaccination manifested in this very same year in Scotland, due to an incorrect association between pertussis (whooping cough) vaccination and neurological damage. However, not all claims of vaccine-induced life-threatening events proved to be unfounded. For example, in 1952 the United States experienced as many as 20,000 cases of paralytic poliomyelitis; and in April of 1955, shortly after the Salk polio trial was proved to be successful, the government ordered the immunization of children. Unfortunately, two lots of polio vaccine from Cutter Laboratories were improperly inactivated and within a few days many cases of vaccine-induced paralysis were reported. Due to the “Cutter incident” and other similar events, our society may not always perceive vaccination as beneficial.

Risk Assessment Poll

Place students in random groups of 4-5 students. Give each group the following questions pertaining to vaccines and risk perception. Give group discussion time. Take a class poll by asking students to raise their hands based on the given question. This should take 15-20 minutes.

The following questions were derived from an article published by R.E. Spier in 2002:

Would you feel that a vaccine was more of a risk or less of a risk to you if:

1) the government mandated the use of a vaccine.
2) the risk was known and takes place in the near future after vaccination.
3) the risk was unknown and would probably take place many years after vaccination.
4) there was an alternate therapy or practice that substitutes for vaccination.
5) the vaccine was essential to your survival from disease.
6) the vaccine was mandatory for your specific line of work.
7) the risk was a rare disorder rather than a common one

To be handed out along with the next session after the poll:

The previous poll was created to emphasize the various perceptions that society may have concerning inoculation. Our society has not witnessed a widespread epidemic for a long time, and we have become desensitized to the effects of various diseases. Some individuals weigh the risk of a vaccine-induced event greater than the risk of contracting the actual pathogen. It is important to advise our society of examples such as the eradication of smallpox. To date, it is estimated that because of vaccination 350 million people have been spared the disfiguring effects of this disease.
Introduction of PBL problem. Give students 30 minutes to read and discuss the questions in groups. You could also incorporate a class discussion of the questions having each group report to the class on what they have discussed (20-30 min).

An Emerging Disease

For the purposes of this project we will propose the following hypothetical situation:

The newly discovered virus, named TJUV, recently emerged from an unindustrialized developing country. Researchers identified TJUV to be an RNA-based virus that is blood-borne and sexually transmitted; the extent of oral transmission, if present, is unknown. TJUV effectively evades the immune system and attacks the central nervous system, while slowly inactivating the immune system (for undergraduates, advise them that the virus is similar to HIV). Antibodies against TJUV have been found in patient serum; however, they are ineffective at clearing the virus. Life expectancy of the patient once antibodies are detected is approximately 2 years. The US and other industrialized countries determined the virus to be a great threat if an outbreak to the rest of the developed world was to take place. Therefore, the US launched an initiative to construct a vaccination program for the developing country. The indigenous people of this developing country do not have a word in their language for virus nor vaccine.

In your groups discuss the following questions:

1) Discuss the major individuals involved in the decision-making process concerning the research and development of vaccines.
2) What roles do each of these individuals take part in?
3) How do you think the developing country may react to an industrialized country administrating a vaccine to the developing country’s citizens?
4) Before the US employs a vaccine, the individual must sign an informed consent. Do you find any social or cultural implications with such a procedure?
5) Discuss the possible perception by the indigenous people of an oral vaccine versus an injected one.
**End of Part I Assignment:**

**Required Reading:** (Graduate and Undergraduate)


**Graduate Assignment:**

Consider the factors that may be required for the development of a vaccine against TJUV (animal models, format of delivery…). A discussion on this topic will resume during Part II.

**Recommended Reading:**


Part 2

At the graduate level a discussion may be led by the instructor to determine all factors that should be considered during the development of a vaccine (30 min)

For graduate and undergraduate classes: Form the same groups. Ask each question to all groups. Have them discuss and debate within the group using examples from the assigned reading. After each question have each group report to class. This could take up to 60 minutes.

Discussion Questions

1) What are the cost and benefits that must be considered when developing/administering a trial for a new vaccine?

2) Is it right that vaccines are tested in the developing world and then used in industrialized countries? Can this be justified if a certain disease is widespread in a certain area of the world?

3) What are the problems associated with vaccination and population control? Are these problems region specific?

4) How do we handle informed consent when we may be dealing with language/literacy barriers?

5) Removal of blood and tissue may be thought of as capturing the spirit of an individual. In some societies blood removal and needle insertion are taboo. How can this be addressed?

6) Should compensation be given to the source of the cell line from which the vaccine was created? Should the country that the vaccine trials were originated be compensated?

7) History of exposure of an individual’s immune system may be dissimilar between people in developing and developed countries. What kind of problems could this cause?

8) What are the implications of having a placebo control when not giving someone a vaccine could cause them to die from the disease?

9) Should we rely on “technical fixes” instead of vaccines when possible?

10) Why could vaccination be considered “sinful” to some people? Can we mandate a vaccine even if it goes against someone’s religious beliefs?
Part III

PBL problem revisited. Students should form the same groups as before. 10-15 minutes. should be given for this problems discussion in groups. You could also incorporate a class discussion of these questions having each group report to the class on what they have discussed (15 min).

Back to TJUV

For our hypothetical situation we will discuss the following problem:

The TJUV virus has been under study in many secure labs around the world. Researchers have discovered that the virus could be altered to become more readily airborne and used as a bioterrorist weapon.

1) Discuss whether the military should be vaccinated
2) Discuss if there were to be an outbreak whether everyone should be vaccinated
3) Do those individuals in a population who opted against vaccination have the rights to benefit from (herd immunity) the expense and the risks of vaccine-induced damage accepted by those who have been vaccinated?
4) Should vaccinated children be placed in the same classroom as their unvaccinated classmates?

15-20 minutes should be given to allow students to read and discuss the questions in groups. Have each group report back to the class about what their group has discussed.

In The News

In 1997, the military ordered all active personnel to be inoculated against anthrax. Again in January 2004, President Bush ordered all personnel to be vaccinated against smallpox and proposed that he himself would be vaccinated as well. Because of these mandates and others like them, some military men and women have opted to take an honorable discharge rather than risk any adverse effects of the vaccine.  

5) Discuss whether you believe it is ethical for the President of the United States to make such a mandate.
6) Discuss whether the risk of smallpox vaccination appears less if the President is willing to be vaccinated.
The following information should be given after the above discussion:

In Nigeria a ban on polio vaccinations led to a five-fold increase in the number of poliomyelitis cases. The ban was primarily due to a cultural misunderstanding that the vaccine caused AIDS or infertility. The ban has recently been lifted, however if the ban were to continue it would jeopardize the worldwide eradication of polio. Such a huge group of people with no immunity to polio may serve as a reservoir for new variants of the virus of which the world has never seen. Theoretically, if an outbreak of such a variant virus were to occur, it may even jeopardize the vaccinated individuals.

If time allows, discuss in groups whether the students’ answers for any of the above questions may change after learning about a real situation.(10-15 min.)
Final Assignment-Individual Paper

Each student must choose one paper topic for individual assessment. Paper length is the teacher’s discretion. Please emphasize outside research for this assignment and that multiple resources must be sited. Pass out group evaluation forms to be handed in with paper.

Topic 1

Should we develop a prophylactic or therapeutic vaccine to protect against HIV?

Topic 2

Discuss the possible implications for ONE of the following vaccine types. Use specific examples.

Vaccines against fertility, autoimmune diseases OR cancer.
Supporting Materials

References:

Useful Materials:


Useful websites:

- [www.childrensvaccines.com](http://www.childrensvaccines.com)
- [www.vaccinealliance.org](http://www.vaccinealliance.org)
- [www.vaccine.org](http://www.vaccine.org)
- [www.vaccinefund.org](http://www.vaccinefund.org)
- [www.who.int/vaccines](http://www.who.int/vaccines)