Immunizations and vaccine origin: What is a socially just public health response to ethical-moral concerns?

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The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months:

No relationships to disclose
Learning Objectives

- Identify the ethical issues surrounding immunization.
  - Explain moral objections to certain CDC recommended vaccines.
- Articulate public health’s role in promoting vaccination coverage.
  - Apply the four principles of Beauchamp & Childress\(^1\) to the issue.
- Equip public health professionals with tools of moral reasoning to bridge the gap between science and religious understandings of childhood vaccination.

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Agenda

History and Background

Issue and Analysis

Recommendations
Aborted Fetal Cell Lines

- **WI-38** (1962)
  - Hayflick first reported human diploid cells could be used for tissue culture vaccine manufacture for oral polio vaccines.
  - Strain derived from lung cells from a female fetus of 3-months gestation.

- **MRC-5** (1967)
  - Developed from lung cells from a 14-week-old male fetus by Jacobs.
  - Essentially utilized the technology developed by Hayflick but at a different chemical value.

- **RA 27/3** (1969)
  - Isolated directly from a tissue explant for a therapeutically aborted fetus because of laboratory-confirmed rubella.

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2. From the 38th fetus in the series from women who had no family history of cancer, a cell strain was cultured from the lung which had optimal characteristics of cell growth and viral susceptibility. Plotkin SA. Vaccine production in human diploid cell strains. Am. J. Epidemiol. 1971 Oct;94(4):303-306.


4. Note: these abortions were not procured for the sake of the research or the development of vaccinations. “The decision to abort was independent of the desire to make use of fetal tissue. In other words, the abortions would have taken place whether or not the cell-line research would have followed.” See Maher DP. Vaccines, abortion, and moral coherence. Natl Cathol Bioeth Q. 2002;2(1):51-67. See also National Network for Immunization Information. Human Fetal Links with Some Vaccines [Internet]. 2008 [cited 2010 Oct 24]. Available from: http://www.immunizationinfo.org/issues/vaccine-components/human-fetal-links-some-vaccines “The cellular biologists who made the cell cultures did not induce the abortions.”


7. “The virus that led to the only rubella vaccine available in the United States and that is widely used overseas (Meruvax II, Merck) came from tissues obtained at the time of an abortion performed on a rubella virus-infected mother.” National Network for Immunization Information. Human Fetal Links with Some Vaccines [Internet]. 2008 [cited 2010 Oct 24]. Available from: http://www.immunizationinfo.org/issues/vaccine-components/human-fetal-links-some-vaccines
1962-1965 Rubella Epidemic\textsuperscript{11,12}

- Estimated 12.5 million rubella cases occurred in the United States.
- 2,000 cases of encephalitis
- 11,250 therapeutic or spontaneous abortions
- 2,100 neonatal deaths
- 20,000 infants born with Congenital Rubella Syndrome.
  - 11,600 children with deafness
  - 3,580 cases of blindness in children
  - 1,800 cases of mental retardation in children


Rubella after Vaccine Licensure

- Number of reported cases of CRS in the United States has declined 99%, from 77 cases in 1970 to one imported case in 2004.\(^{13,14}\)

- During 1998–2004, 28 cases of CRS were reported to the National Congenital Rubella Syndrome Registry (NCRSR).
  - Five of these were in infants born during 2001–2004.
  - 26 (93%) of the 28 cases occurring during 1998–2004 in which the mother’s country of birth was known, the mother was born outside the United States.
  - Of the 24 CRS cases with known import status occurring during this time, 12 (50%) were imported.

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The Issue:

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The Issue

- Right-to-life groups have advocated for religious exemptions to mandatory vaccinations because of the process used to originally obtain these cell lines.
  - Such groups call for parents' moral obligation to refuse certain vaccinations for their children.

- Researchers affiliated with the National Immunization Program state that parents who claim philosophical and/or religious exemptions “may create some risk to the community because unvaccinated or undervaccinated persons may be a source of transmission.”

Vaccines Derived from Aborted Fetal Cell Lines

<table>
<thead>
<tr>
<th>Disease</th>
<th>Vaccines containing aborted fetal cell lines* (Sponsor)</th>
<th>CDC Federal Contract Vaccines* Product Name (Trade Name, Sponsor)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polio</td>
<td>Pentacel® (Sanofi Pasteur) POLIOVAX (Poliovirus Vaccine Inactivated, Sanofi Pasteur Ltd., not available) QUADRACEL® (Sanofi Pasteur Ltd., Toronto, Ontario, Canada)</td>
<td>DTaPPHi (Pentacel®, Sanofi Pasteur)*</td>
</tr>
<tr>
<td>MMR</td>
<td>M-M-Rll® (Merck &amp; Co., Inc.) PRIORIX® (GlaxoSmithKline Biologicals)</td>
<td>MMR (M-M-Rll®, Merck &amp; Co., Inc.)*</td>
</tr>
<tr>
<td>Varicella</td>
<td>VARIVAX® (Merck &amp; Co., Inc.) ProQuad® (Merck &amp; Co., Inc)</td>
<td>Varicella (VARIVAX®, Merck &amp; Co., Inc) MMRV (ProQuad®, Merck &amp; Co., Inc)</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>VAQTA® (Merck &amp; Co., Inc) HAVRIX® (GlaxoSmithKline Biologicals) TWINRIX® (GlaxoSmithKline Biologicals) AVAXIM® (Sanofi Pasteur SA) Epaxal® (Crucell) VIVAXIM® (Sanofi Pasteur SA)</td>
<td>Hepatitis A (VAQTA®, Merck &amp; Co., Inc) Hepatitis A &amp; Hepatitis A-AD (HAVRIX®, GlaxoSmithKline Biologicals) Hepatitis AB (TWINRIX®, GlaxoSmithKline Biologicals)</td>
</tr>
<tr>
<td>Rabies</td>
<td>IMOVAX® Rabies (Sanofi Pasteur SA) (FDA Approved)</td>
<td></td>
</tr>
<tr>
<td>Shingles</td>
<td>ZOSTAVAX® (Merck &amp; Co., Inc)</td>
<td>Zoster (ZOSTAVAX®, Merck &amp; Co., Inc)</td>
</tr>
<tr>
<td>Rubella</td>
<td>MERUVAX® II (Merck &amp; Co., Inc) (FDA Approved)</td>
<td></td>
</tr>
</tbody>
</table>


   b. Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine Combined

   c. Measles, Mumps, and Rubella Virus Vaccine Live

   d. Combined purified Vi Polysaccharide Typhoid and Inactivated Hepatitis A vaccine

Analyzing the Issue with the Four Principles of Biomedical Ethics
Four Principles Approach to Bioethics

- Autonomy
- Nonmaleficence
- Beneficence
- Justice

- Provide a simple, accessible, and culturally neutral approach to thinking about ethical issues in healthcare.16

Autonomy

- Emphasizes the personal responsibility we have for our own lives, to make our own decisions, and to control what is done to ourselves.

- The Roman Catholic Pontifical Academy for Life asserts that the head of the family may make a reasonable autonomous decision based on conscience not to vaccinate a child.
  - However, the Academy observes that one can only do so without causing the children or the population to undergo significant risks to their health.

Nonmaleficence

- Imposes the obligation not to harm someone intentionally or directly.
- In 2009, Anikeeva et al proposed that in the case of mandatory influenza vaccinations, nonmaleficence may be interpreted to mean that health care workers are duty-bound not to place patients at undue risk.\(^{18}\)
- Therefore, it would seem possible that a parent, recognizing the risk that certain viruses have on unborn fetuses would choose then to vaccinate their own child out of a duty to protect the unborn.

Beneficence

- Positive expression of nonmaleficence.
- Not simply the personal ethics of choosing to use a vaccine derived from fetal cell lines.
- The evident health benefits that must be considered are not just those of one’s own children but also those of the greater community to which the children belong.¹⁹
- Engages a positive obligation to advance the health interests and welfare of others, to assist others in their choices to live life to the fullest.

20. Field RI, Caplan AL. A proposed ethical framework for vaccine mandates: competing values and the case of HPV. Kennedy Inst Ethics J. 2008 Jun;18(2):111-124. “The interest in beneficence can be represented with a line that slopes in the opposite direction (Figure 1). When the risk of harm from a disease is low, there is little need to help those who are susceptible. As the risk increases in terms of the severity of the disease, the interest in intervening on their behalf, for example by forcing them to receive a vaccination, rises along with it.”
Justice

- Often equated with fairness or equity on the individual level.

- The “common good” requires a broader social commitment
  - Creating the social conditions that allow people to reach their full human potential and to realize their human dignity.²¹

- Individual citizens and intermediate groups are obligated to make their specific contributions to the common welfare.²²

- Parents have a moral obligation to vaccinate their children because “they cannot endanger the lives of others in the community.”²³

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Public Health and Social Justice:
What is a socially just public health response to ethical-moral concerns?
Convergence of Public Health and Moral Reasoning

- The success of public health relies on individuals recognizing the value of community interest as well as self-interest.24
- No further harm is generated by the use of these vaccines nor, more importantly, “no obvious good is necessarily achieved by refusing it.”25

Recommendations

- Responsibilities of public health professionals
  - Translate and disseminate scientific and ethical aspects of vaccine development and immunization practices to the general public, legislators, religious groups, health care providers.
    - Share readily available statistics and figures reasonably understandable to ordinary people.
    - Be candid about the risks and benefits surrounding immunizations.
    - Understand and respect the religious beliefs underlying immunization issues.
    - Engage public groups in ethical dialogue.
Recommendations

- Responsibilities of health care providers
  - Supply accurate information so parents and guardians may make informed decisions.
  - Be candid about the risks and benefits surrounding immunizations.
  - Notify patients and their decision-makers of the vaccine’s components.
  - Have readily available statistics and figures reasonably understandable to ordinary people.
  - Understand and respect the religious beliefs underlying the issue.
Recommendations

- Responsibilities of parents and guardians
  - Seek accurate information from medically appropriate sources.
  - Ask the physician about the vaccine, its components, side-effects, and other aspects.
  - Understand what their religious tradition actually teaches about the issue.
  - Encourage the development of ethical vaccines.
Conclusions

- No further harm is generated by the use of these vaccines nor, more importantly, “no obvious good is necessarily achieved by refusing it.”

- An individual can benefit from an unjust or immoral act without approving of, or cooperating with, that act.

- Society has the right and the duty to protect itself.


Questions

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