Providence Medical Center

Saint John Hospital

St. Francis Health Center

Holy Rosary Healthcare

St. James Healthcare

St. Vincent Healthcare

Saint John's Health Center

St. Mary's Hospital

Duchesne Clinic

Saint Vincent Clinic

Marian Clinic

Marillac Clinic

Exempla Good Samaritan Medical Center

Exempla Lutheran Medical Center

Exempla Saint Joseph Hospital

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

Mary E. Homan, MA

9 November 2010
138th APHA
Annual Meeting

Sisters of Charity of Leavenworth Health System

We are a faith-based, mission driven healthcare organization.

Mary E. Homan, MA

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.

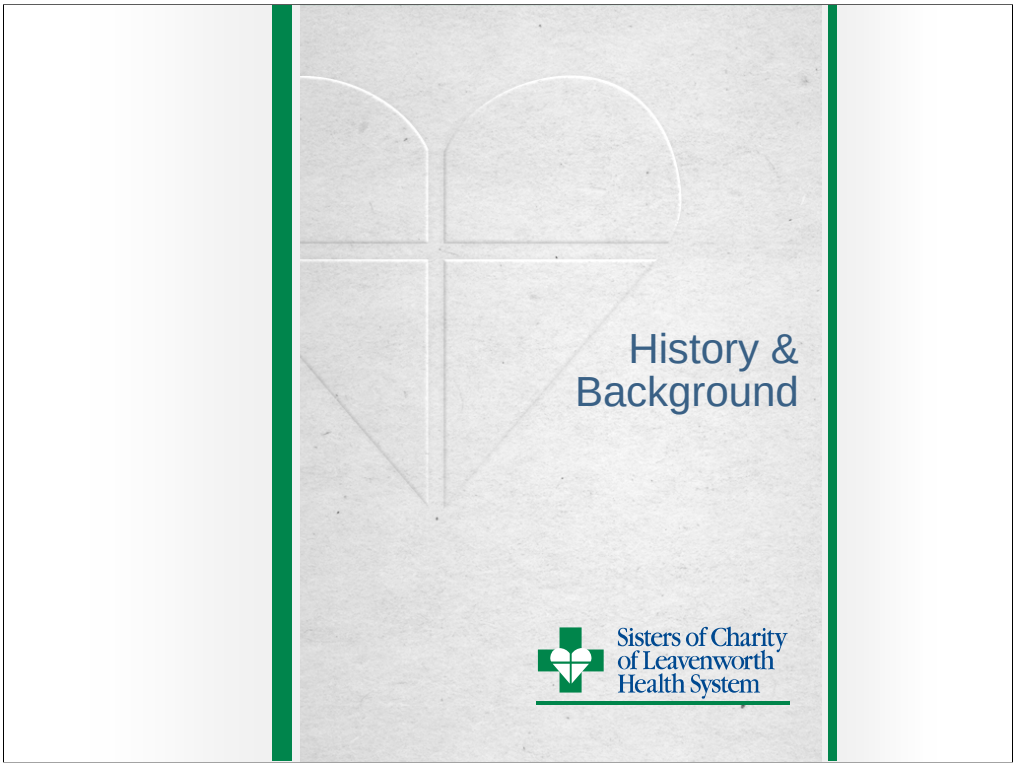
1. Beauchamp TL. Principles of Biomedical Ethics. 6th ed. New York: Oxford University Press; 2009.

Agenda

History and Background

Issue and Analysis

Recommendations


History &
Background
Sisters of Charity
of Leavenworth
Health System

Aborted Fetal Cell Lines

- WI-38[2] (1962)
  - Hayflick first reported[3] human diploid cells could be used for tissue culture vaccine manufacture for oral polio vaccines.[4]
  - Strain derived from lung cells from a female fetus of 3-months gestation.
- MRC-5[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[6] (1969)
  - Isolated directly from a tissue explant for a therapeutically aborted fetus because of laboratory-confirmed rubella.[7]

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.

3. L Hayflick, SA Plotkin, TW Norton, et al, "Preparation of Poliovirus Vaccines in Human Fetal Diploid Cell Strains," *American Journal of Hygeine* 75 (1962):240-258.

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."

5. Jacobs JP, Jones CM, Baille JP. Characteristics of a human diploid cell designated MRC-5. Nature. 1970 Jul 11;227(5254):168-170.

6. Plotkin SA, Farquhar JD, Katz M, Hertz C. Further studies of an attenuated rubella strain grown in WI-38 cells. Am. J. Epidemiol. 1969 Feb;89(2):232-238.

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[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

11. Richard Kent Zimmerman's "Ethical Analyses of Vaccines Grown in Human Cell Strains Derived from Abortion: Arguments and Internet Search," *Vaccine* 22 (2004): 4242.
12. Plotkin SA, Reef S. Rubella vaccine. In: Plotkin SA, Orenstein WA, eds. 1. *Vaccines* 4th ed. Philadelphia: WB Saunders; 2004:707–43.

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.

13. Cochi SL, Edmonds LE, Dyer K, Greaves WL, Marks JS, Rovira EZ, et al. Congenital 2. rubella syndrome in the United States, 1970–1985. On the verge of elimination. *Am J Epidemiol* 1989; 129:349–61.
14. Reef SE, Redd S, Abernathy E, Zimmerman L, Icenogle J. The epidemiology of rubella 3. and congenital rubella syndrome in the United States from 1998–2004: The evidence for absence of endemic transmission. *Clin Infect Dis* 2006; 43 Suppl 3:S126–32.

The Issue:

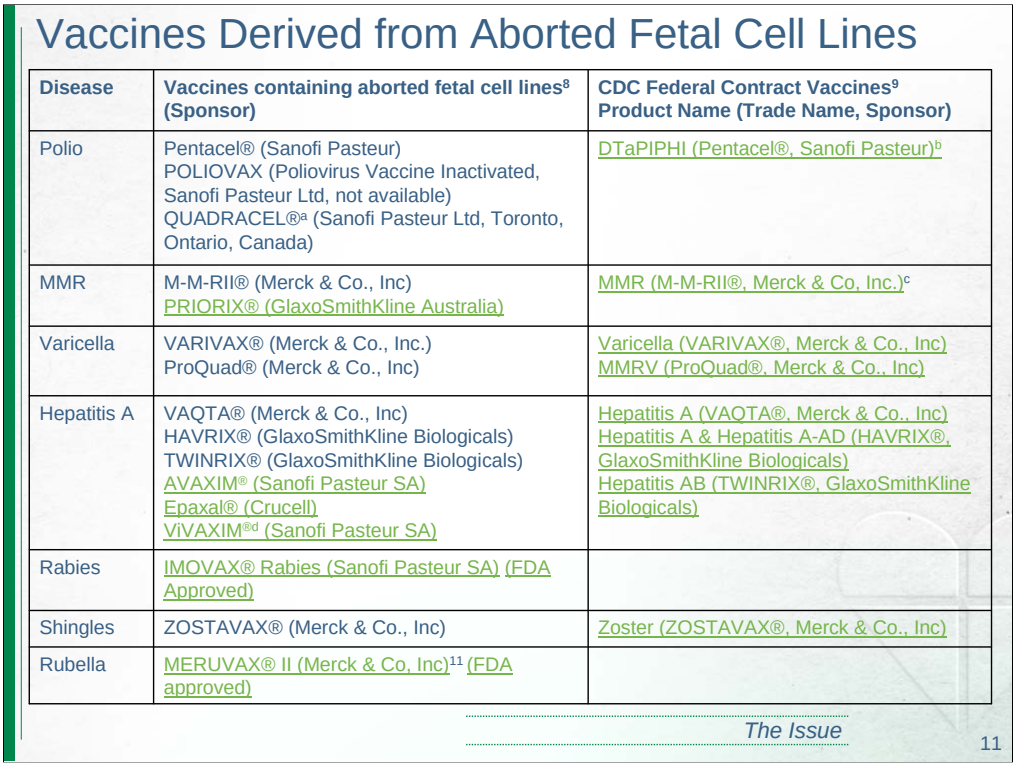
Immunizations and vaccine origin: What is a socially just public health response to ethical-moral concerns?

Sisters of Charity of Leavenworth Health System

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.”[15]

15. Salmon DA, Haber M, Gangarosa EJ, Phillips L, Smith NJ, Chen RT. Health consequences of religious and philosophical exemptions from immunization laws: individual and societal risk of measles. JAMA. 1999 Jul 7;282(1):47-53.



Vaccines Derived from Aborted Fetal Cell Lines

Disease	Vaccines containing aborted fetal cell lines[8] (Sponsor)	CDC Federal Contract Vaccines[9] Product Name (Trade Name, Sponsor)
Polio	Pentacel® (Sanofi Pasteur) POLIOVAX (Poliovirus Vaccine Inactivated, Sanofi Pasteur Ltd, not available) QUADRACEL®[a] (Sanofi Pasteur Ltd, Toronto, Ontario, Canada)	DTaPIPHI (Pentacel®, Sanofi Pasteur)[b]
MMR	M-M-RII® (Merck & Co., Inc) PRIORIX® (GlaxoSmithKline Australia)	MMR (M-M-RII®, Merck & Co, Inc.)[c]
Varicella	VARIVAX® (Merck & Co., Inc.) ProQuad® (Merck & Co., Inc)	Varicella (VARIVAX®, Merck & Co., Inc) MMRV (ProQuad®, Merck & Co., Inc)
Hepatitis A	VAQTA® (Merck & Co., Inc) HAVRIX® (GlaxoSmithKline Biologicals) TWINRIX® (GlaxoSmithKline Biologicals) AVAXIM® (Sanofi Pasteur SA) Epaxal® (Crucell) ViVAXIM®[d] (Sanofi Pasteur SA)	Hepatitis A (VAQTA®, Merck & Co., Inc) Hepatitis A & Hepatitis A-AD (HAVRIX®, GlaxoSmithKline Biologicals) Hepatitis AB (TWINRIX®, GlaxoSmithKline Biologicals)
Rabies	IMOVAX® Rabies (Sanofi Pasteur SA) (FDA Approved)	
Shingles	ZOSTAVAX® (Merck & Co., Inc)	Zoster (ZOSTAVAX®, Merck & Co., Inc)
Rubella	MERUVAX® II (Merck & Co, Inc)[11] (FDA approved)	

The Issue

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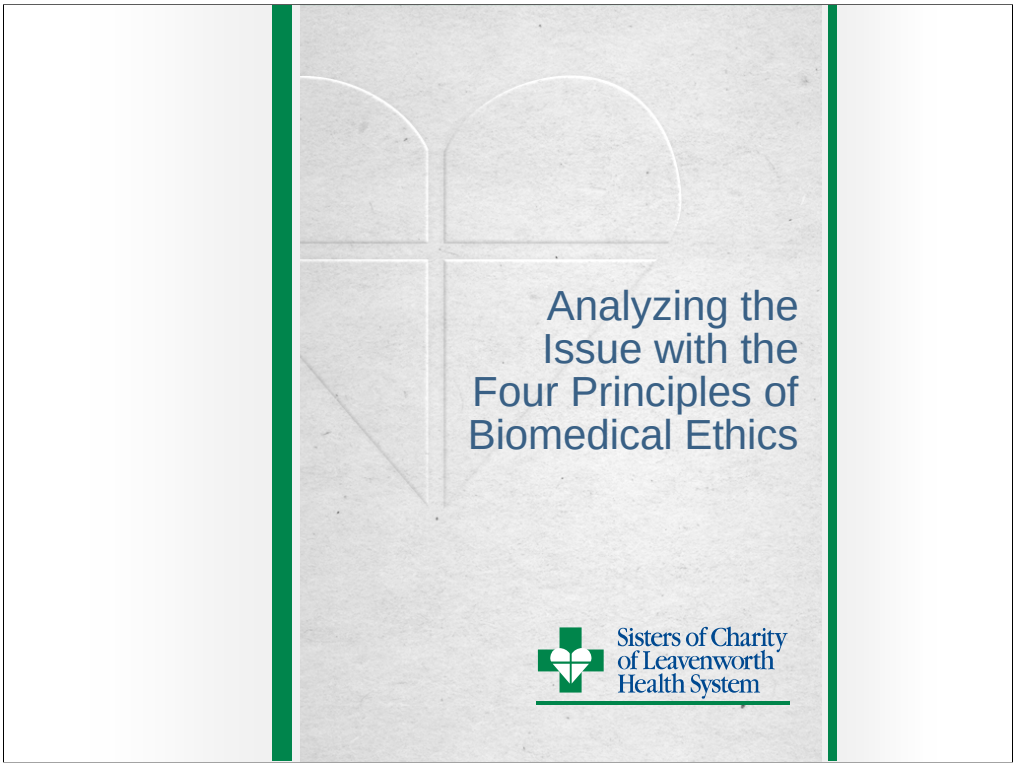
8. Children of God for Life. US and Canada Aborted Fetal Vaccines : In Pediatric Immunization Schedule Format [Internet]. 2009 Nov [cited 2010 Oct 24];Available from: http://www.cogforlife.org/vaccineList.pdf
9. Centers for Disease Control and Prevention. CDC Federal Contract Vaccines Availability, Packaging and NDC List [Internet]. Vaccines & Immunizations. 2010 Apr 21 [cited 2010 Oct 24];Available from: http://www2a.cdc.gov/nip/NDCVaccines/NDCVacc.asp
    a. Pertussis Vaccine – Acellular and Diphtheria and Tetanus Toxoids (Adsorbed) Combined with Inactivated Poliovirus Types 1, 2 and 3 (MRC-5 Cell), http://www.public.health.wa.gov.au/cproot/2205/2/QUADRACEL%20CMI%20for%20AUS.pdf
    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
10. "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


Analyzing the Issue with the Four Principles of Biomedical Ethics
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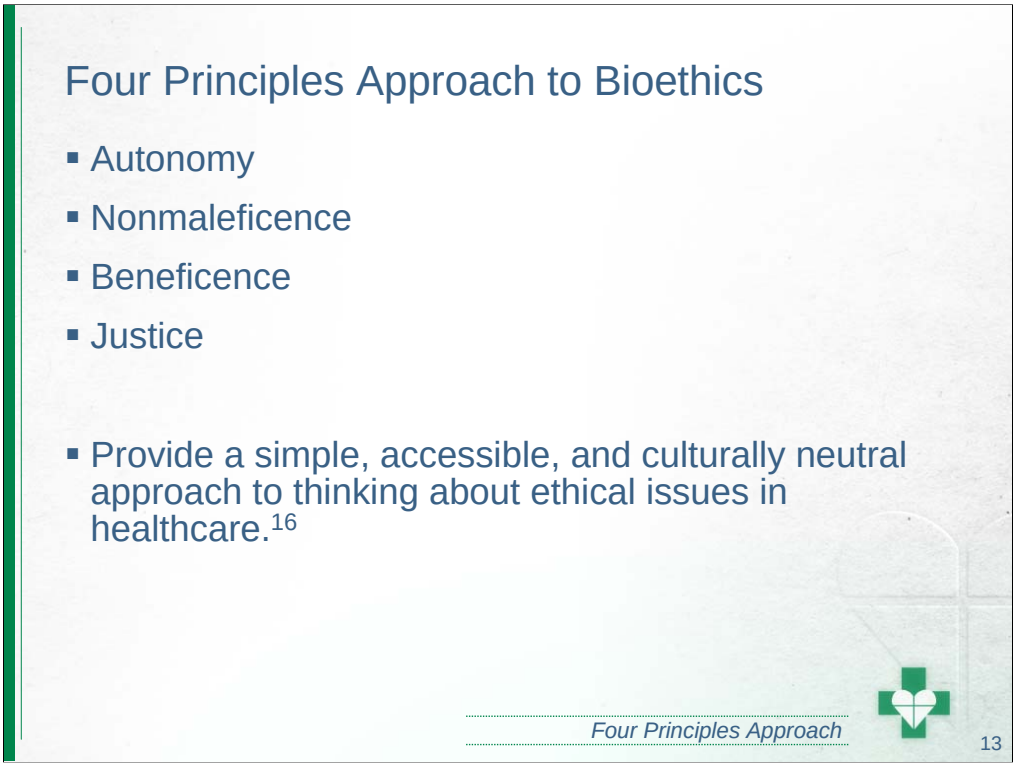
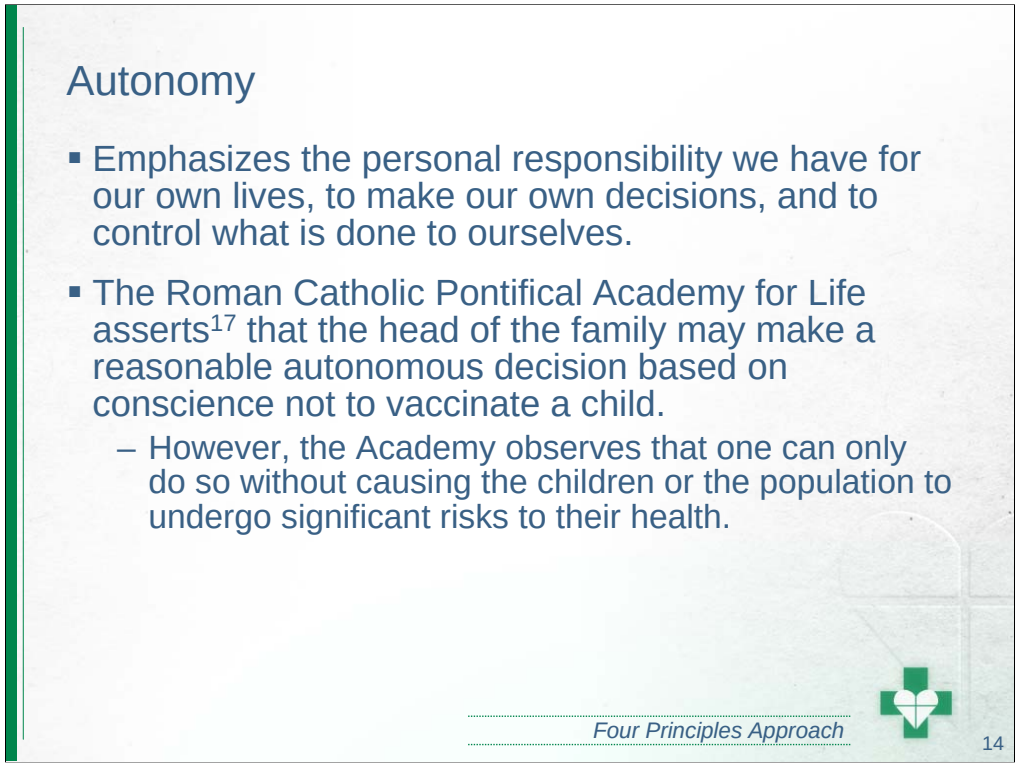


16. Gillon R. Medical ethics: four principles plus attention to scope. BMJ. 1994 Jul 16;309(6948):184-188.



17. Pontifical Academy for Life. Moral Reflections on Vaccines Prepared from Cells Derived from Aborted Human Foetuses [Internet]. 2005 Jun 5 [cited 2010 Oct 24];Available from: http://www.academiavita.org/template.jsp?sez=Documenti&pag=testo/vacc/vacc&lang=english

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.

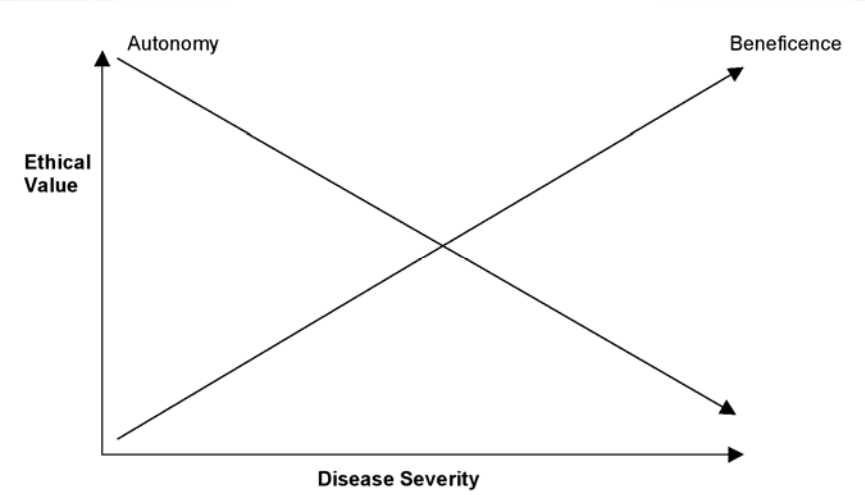
18. Anikeeva O, Braunack-Mayer A, Rogers W. Requiring influenza vaccination for health care workers. Am J Public Health. 2009 Jan;99(1):24-29.

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.

19. Maher DP. Vaccines, abortion, and moral coherence. Natl Cathol Bioeth Q. 2002;2(1):51-67.

Beneficence vs. Autonomy[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.

Four Principles Approach

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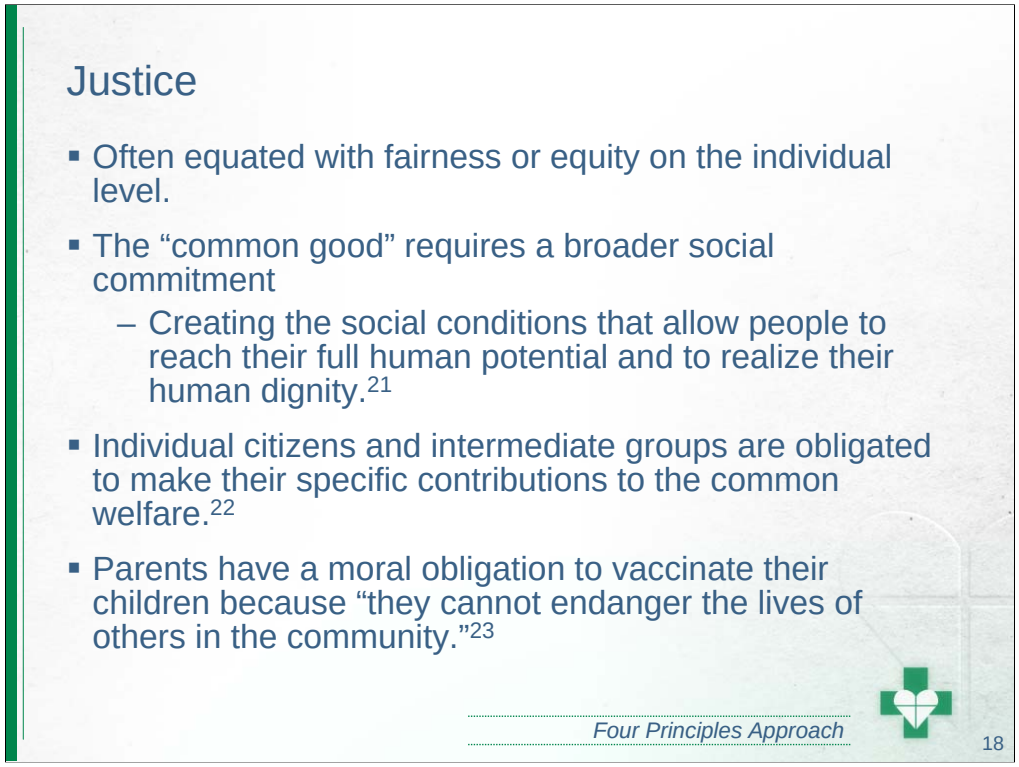
20. Field RI, Caplan AL. A proposed ethical framework for vaccine mandates: competing values and the case of HPV. Kennedy Inst Ethics J. 2008 Jun;18(2):111-124. “The interest in beneficence can be represented with a line that slopes in the opposite direction (Figure 1). When the risk of harm from a disease 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.”



21. Byron WJ. Ten Building Blocks Of Catholic Social Teaching. America. 1998 Oct 31;179(13):9-12.
22. Pope John XXIII, Encyclical Letter *Pacem en terris*, 11 April 1963, 53.
23. Signs of the Times. America. 2000 Mar 4;182(7):4.


Public Health and
Social Justice:
What is a socially just
public health response to
ethical-moral concerns?
Sisters of Charity
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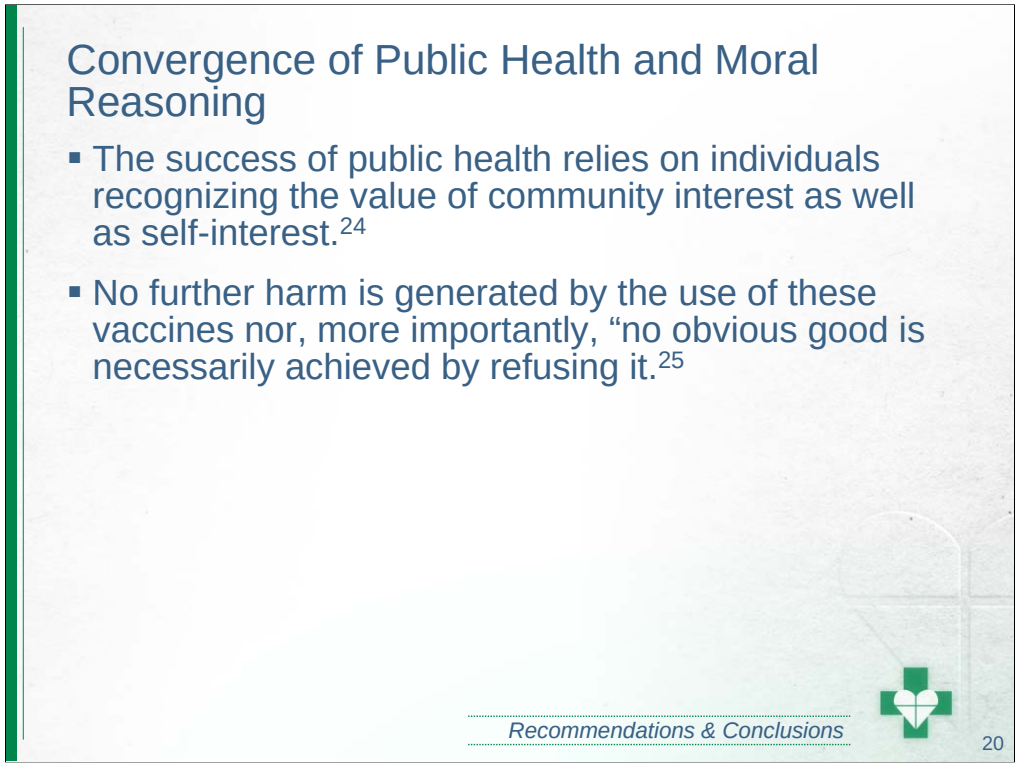
Health System



24. Kahn J. An unprotected public. Am J Bioeth. 2008 Jun;8(6):3-4.

25. Maher DP. Vaccines, abortion, and moral coherence. Natl Cathol Bioeth Q. 2002;2(1):51-67.

Recommendations

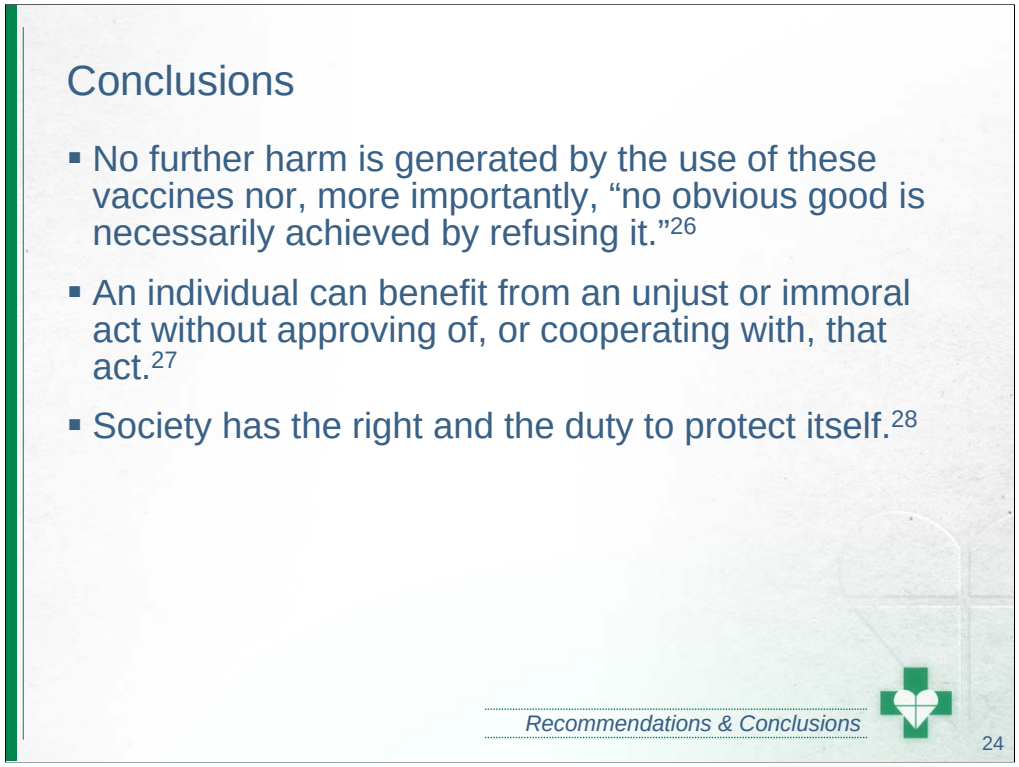
- Responsibilities of public health professionals
  - Translate and disseminate scientific and ethical aspects of vaccine development and immunization practices to the general public, legislators, religious groups, health care providers.
    - Share readily available statistics and figures reasonably 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.



26. Maher DP. Vaccines, abortion, and moral coherence. Natl Cathol Bioeth Q. 2002;2(1):51-67.
27. Schleppenbach G. The Moral Dimensions of Using Vaccines Originating in Induced Abortion [Internet]. Life Insight. 2000 Mar 17 [cited 2010 Oct 24];Available from: http://www.nebcathcon.org/column-life_insight.htm#3-17
28. Pope John Paul II. Evangelium vitae [Internet]. 1995 Mar 3 [cited 2010 Oct 24];Available from: http://www.vatican.va/holy_father/john_paul_ii/encyclicals/documents/hf_jp-ii_enc_25031995_evangelium-vitae_en.html

Questions

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