Ethically compromised vaccines in New Zealand

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Ethically compromised vaccines are vaccines where the virus used in the manufacture of the vaccine has been cultured in a cell line developed from tissue grown from an aborted foetus. In New Zealand, an ethically compromised vaccine is the only vaccine available for Chicken pox (varicella), shingles (zoster), Hepatitis A, and rubella (which is part of the MMR – measles, mumps, rubella – vaccine). The poliovirus vaccine component of Quadracel, and Poliacel, is ethically compromised. However, there are a number of ethically uncompromised vaccines approved for use where the poliovirus component is grown in African green monkey kidney cells (Vero). The rabies vaccine, Verorab, is not as ethically compromised and is the preferred option to Mérieux Inactivated Rabies Vaccine (MIRV) which is an ethically compromised vaccine. This article lists the ethically compromised vaccines available in New Zealand, and explains why they are ethically compromised. It also explains when and why vaccination should still be accepted even when the only available vaccine is ethically compromised.

Medsafe (New Zealand Medicines and Medical Devices Safety Authority) is responsible for the regulation of vaccines (and other medical needs). Through the examination of the globally available data they ensure that approved vaccines are safe for use by the New Zealand population. Vaccines are assessed in view of a risk balance benefit to the population. [1]

Immunisation against rubella and the polioviruses are part of the New Zealand immunisation schedule. Chicken pox, Hepatitis A and rabies although not part of the immunisation scheme have vaccines approved for use in New Zealand as these vaccines may need to be administered for protection against an occupational health risk or to prevent a health risk whilst travelling outside New Zealand.

Ethically compromised vaccine production

The virus used in the production of some vaccines is cultured in cell lines known as human diploid cells. These cells lines were originally developed from tissue from an aborted foetus. Vaccines are ethically compromised by this connection to abortion. The most commonly utilised cell lines are WI-38 (Wistar Institute) and MRC-5 (Medical Research Council).[2]

WI-38 was derived from lung tissue from a three month gestation foetus in 1964.[3] The parents, living in Stockholm, chose to abort the child as they felt that they had too many children.[4] The MRC-5 cell line was derived from the normal lung tissue of a fourteen-week-old foetus that was aborted in 1966. This abortion from a twenty-seven-year-old mother was for 'psychiatric reasons.'[5] Stocks of cells are not replenished from repeated abortions.[6]

Pontifical Academy for Life – Moral Reflections on Vaccines

In 2005, the Pontifical Academy for Life issued *Moral Reflections on Vaccines Prepared from Cells Derived from Aborted Human Foetuses*. Drawing upon the Catholic principle of cooperation in wrongdoing, this statement reaches three important conclusions. First, when a choice exists between one vaccine which is ethically compromised and another vaccine which is not ethically compromised, the Pontifical Academy states that we have a "grave responsibility" to use the vaccine which is not ethically compromised. Second, when only ethically compromised vaccines are available, the Academy calls on health professionals and health consumers alike to put "pressure on the political authorities and health systems so that other vaccines without moral problems become available." Finally, until ethically uncompromised vaccines are developed, the Pontifical Academy for Life supports the use of even these ethically compromised vaccines so as to prevent serious health risks particularly for children and pregnant women.[7]

Ethically Compromised Vaccines Available in New Zealand [8]

Rubella

The rubella vaccine which is given as part of the combined MMR (mumps measles and rubella) vaccine and which is administered at fifteen months and four years is an ethically compromised vaccine. The virus for the vaccine is cultured in a human diploid cell line.[9] Rubella is a highly contagious disease with transmission between people occurring through respiratory secretions. In developed countries the average number of transmissions from a single case of rubella is between three and eight. The ready transmission of rubella means it is very difficult to avoid the infection in pregnant women. Further if a pregnant woman is infected, the risk of infection of her unborn baby is very high (about 95%). Congenital rubella syndrome involves serious consequences for the unborn child, including congenital heart disease, cataracts and deafness, along with other problems.[10]

Vaccines manufactured with viruses cultured in non-human cell lines have not proved to be as effective or safe as the ethically compromised vaccines against rubella.[11] Due to the serious health risks which would otherwise be faced by children, pregnant women and particularly the unborn

children of pregnant women, the Pontifical Academy for Life encourages vaccination with rubella vaccine even though this vaccine is ethically compromised.[12]

Polio

Vaccination against polio is often carried out in combination with other childhood vaccines at six weeks, three and five months. A booster is given at four years of age.

There are a number of poliovirus vaccines approved for use in New Zealand that are considered ethically uncompromised. The polioviruses component of the Infanrix hexa/ penta or Infanrix-IPV, and Boostrix-IPV all distributed by GlaxoSmithKline are grown in Vero cells, as are the polioviruses component in the Sanofi Pasteur vaccines, IPOL, Adacel Polio and Pediacel. However, the Sanofi Pasteur vaccines, Quadracel, and Poliacel contain polioviruses that have been cultured in the human diploid cell line, MRC-5. Thus, Quadracel and Poliacel are considered ethically compromised. Like Infanrix-IPV Quadracel vaccinates against diphtheria, tetanus, pertussis and the polioviruses. Infanrix –IPV can replace Quadracel and is not an ethically compromised vaccine. [13]

Although polio has been eradicated from all but three countries globally, vaccination must continue until global eradication and cessation of vaccination is declared.[14] Poliovirus is spread by the faecal oral route and travellers must be re-vaccinated if travelling to an endemic country if they have not been vaccinated in the previous ten years. Previous generations remember the devastation of polio epidemics which are now essentially unheard of today. One in 200 infections leads to irreversible paralysis, usually in the legs. More extensive paralysis can result in quadriplegia and in the most severe cases, bulbar polio, where the poliovirus attacks the nerve cells of the brain stem, reducing breathing capacity. Among those paralysed, 5% to 10% die when their breathing muscles become immobilized. Around 40% of people who survive paralytic polio may develop post-polio syndrome 15–40 years after the original illness.[15]

Although there are a number of ethically compromised poliovirus vaccines available in New Zealand they are not routinely offered as part of the immunisation schedule. Infanrix-hexa and Boostrix-IPV which are not ethically compromised, are the two vaccines listed on the New Zealand immunisation schedule, thus the issue of being offered vaccination with an ethically compromised poliovirus vaccine is unlikely. However, if you are seeking to vaccinate with a poliovirus vaccine that is not on the schedule check the information available from the manufacturer to ascertain the cell line that the polioviruses were cultured in for the production of the vaccine. If the cell line is a human diploid cell line, an alternative ethically uncompromised vaccine should be accessed where possible.

Chicken Pox (Varicella) and Shingles (Zoster)

Varicella (chicken pox) vaccine is not part of the routine immunisation schedule in New Zealand, however it is recommended for children aged 12 months to 12 years.[16] McCartney and Burgess suggest that cost and the concern of adding another injection to the immunisation schedule have influenced the decision not to include chicken pox on the immunisation schedule in New Zealand.[17]

Varicella and zoster vaccines (combined or individual) approved for use in New Zealand are considered ethically compromised as part of the production process for the vaccines includes culturing in a human diploid cell line.[18] The potential for a latent infection[19] with varicella virus meant that much caution was taken during the development and trialling of the varicella vaccines as it had to be not only efficacious but also safe.[20]

Chicken pox is often thought of as a mild childhood infection, often more of an inconvenience. However, a varicella infection in a pregnant woman can be as devastating as a rubella infection. Intrauterine infection may cause a spontaneous abortion, premature delivery or stillbirth.[21] Features of congenital varicella syndrome (CSV) may include: limb hypoplasia, neurological abnormalities, ocular anomalies, and low birth weight. Intrauterine or early postnatal infection can cause neonatal varicella infection. Infection manifested within five days before or two days after delivery is serious as it may become disseminated and a 20% mortality rate has been reported.[22] Infection with varicella can also be more severe in adults than in children.[23] The Pontifical Academy's statement supported vaccination against rubella because of the serious health risks which would otherwise be faced by children, pregnant women and particularly unborn children. The same conclusion applies to chicken pox: it is recommended that immunisation with the varicella vaccine is undertaken even though this vaccine is ethically compromised.

Zoster (shingles) vaccination is recommended for persons in the 60-79 year old age group. Zoster vaccination is estimated to prevent up to 50% of the cases of shingles (re-activation of the chicken pox virus in later life), and two-thirds of post-herpetic neuralgia (damage to the nerves after an outbreak of shingles) in this age group. If shingles does occur, then the duration of the episode and the severity of the pain are diminished by up to 60% if a person has received the zoster vaccination. The risk for transmission of zoster to household contacts is approximately 15.5%.[24] The need to be vaccinated with zoster should be discussed with a medical practitioner. Some people may decide to abstain from this ethically compromised vaccine if they can do so without posing a serious threat either to their own health or to the health of others.

Hepatitis A

Hepatitis A vaccine is not part of the New Zealand immunisation schedule. In New Zealand, Hepatitis A vaccination is recommended for chronic carriers of Hepatitis B and C, people with chronic liver disease and certain

occupational groups particularly those that could be exposed to faecal material.[25]

Due to the difficulty in culturing and obtaining high yields of the Hepatitis A virus, vaccine production for Hepatitis A was modelled on the practice of producing vaccines in human diploid cell lines.[26] Hepatitis A vaccines, are therefore ethically compromised as the virus is cultured in MRC-5 for vaccine production.[27] The current vaccine has an almost 100% efficacy, which means that research into this virus is now a low priority and therefore does not attract the levels of funding of other Hepatitis viruses.[28]

Hepatitis A is usually spread via the faecal-oral route, and transmission by an infected person to others in the home occurs easily. An infection with Hepatitis A can often result in hospitalisation. The death rate is approximately 3-6 deaths per 1,000 cases.[29]

Thus, immunisation with Hepatitis A vaccine is to be encouraged in circumstances where it is needed, and if travel is undertaken to an area of high prevalence or poor sanitation.

Rabies

The Rabies vaccine (Mérieux Inactivated Rabies Vaccine (MIRV)) manufactured by Sanofi Pasteur Pty Ltd is an ethically compromised vaccine grown in human diploid cells.[30] The rabies vaccine, Verorab manufactured by Sanofi-Pasteur is cultured on the Vero cell line. However, the initial culturing of the virus was in WI-38.[31]

As death is always the outcome from a bite or scratch from an infectious animal, then vaccination with rabies vaccine should be encouraged for travellers who will be spending prolonged periods (i.e. more than one month) in rural areas of rabies endemic regions. Although the rabies virus used in the production of the Verorab vaccine was initially cultured on a human diploid cell the vaccine is manufactured using Vero cell line, thus it is considered the less ethically compromised of the two approved rabies vaccines in New Zealand and should be sourced and used if rabies vaccine is required. In the event of exposure to rabies, vaccination should never be refused even if only an ethically compromised vaccine is the only vaccine available.

Rabipur Inactivated Rabies Virus Vaccine, manufactured by CSL Biotherapies/Novartis Vaccines is available in Australia and is manufactured from virus grown in purified chick embryo cell. Thus, it is not ethically compromised.[32] This vaccine is not available in New Zealand; however, re-evaluation of the available vaccines for rabies could consider the approval of Rabipur to provide an ethically uncompromised choice when providing rabies vaccination.[33]

Conclusion

In the statement of the Pontifical Academy for Life, the Catholic Church calls for the development of ethically uncompromised vaccines. Until such vaccines are available, however, the Church encourages vaccination to protect the general population and especially children, pregnant women and unborn children from serious health risks. Vaccination is a contribution to the best possible health care and wellbeing for all in our community.

The information in this article is subject to change as immunisation schedules may vary and alternative vaccines may be introduced. To check whether a vaccine is ethically compromised, consult the vaccine manufacturers' product description. This should include the cell line or method of culturing of the virus in the vaccine. Any vaccine that is cultured in human diploid cells, most often MRC-5 or WI-38, or in a cell line described as human embryonic is ethically compromised.

Summary of Recommendations

Disease	Vaccine	Recommendation
Rubella	Ethically compromised – no alternative	Vaccinate
Polio	Quadracel – Ethically compromised	Use uncompromised vaccine if available
	Poliacel – Ethically compromised	Use uncompromised vaccine if available
	Infanrix-IPV – ethically uncompromised	Vaccinate
	Infanrix hexa/penta – ethically uncompromised	Vaccinate
	Boostrix-IPV – ethically uncompromised	Vaccinate
	Pediacel – ethically uncompromised	Vaccinate
	IPOL – ethically uncompromised	Vaccinate
	Adacel Polio – ethically uncompromised	Vaccinate
Chicken Pox (varicella)	Ethically compromised – no alternative	Vaccinate
Shingles (zoster)	Ethically compromised – no alternative	Discuss with medical practitioner
Hepatitis A	Ethically compromised – no alternative	Vaccinate
Rabies	MIRV – Ethically compromised	Use uncompromised vaccine if available
	Verorab – ethically uncompromised	Vaccinate

Endnotes

1 Medsafe, New Zealand Medicines and Medical Devices Safety Authority, "Home," Medsafe, http://www.medsafe.govt.nz/

2 Pontifical Academy for Life (PAL), "Moral Reflections on Vaccines Prepared from Cells Derived from Aborted Human Fetuses," *National Catholic Bioethics Quarterly* 6, no. 3 (2006): 541-550 at 543. (NCBQ). In his cover letter, the then-President of the Pontifical Academy for Life, then-Bishop (now Cardinal) Elio Sgreccia notes that the statement was approved by the Congregation for the Doctrine of the Faith. The statement is also available at Children of God for Life (CGL), http://www.cogforlife.org/vaticanresponse.pdf. The two records of the statement differ in that the third footnote in the NCBQ version is missing from the CGL version. As a result, all subsequent footnotes are numbered differently in the two versions of the statement. In this article, we cite the NCBQ version of the PAL statement.

3 Rene Leiva, "A Brief History of Human Diploid Cell Strains," *The National Catholic Bioethic Quarterly* 6, no. 3 (2006): 443-451 at 445.

4 Pontifical Academy for Life, 542; Leiva, 445.

5 Pontifical Academy for Life, 543.

6 Immunise Australia Program, "Myths and Realities," Australian Government, Department of Health and Ageing, http://www.health.gov.au/internet/immunise/publishing.nsf/Content/uci-myths-guideprov

7 For a detailed explanation of the PAL statement see Kevin McGovern and Kerri Anne Brussen, "Ethically Compromised Vaccines and Catholic Teaching," *Chisholm Health Ethics Bulletin* 17, no. 2 (Summer 2011):1-9 at 3-6. That article discussed both vaccination and the PAL statement in detail. The present article sets out setting out specific conclusions about the various vaccines which are available in New Zealand.

8 In footnote 8 of its statement, the Pontifical Academy for Life discusses alternatives to ethically compromised vaccines from a global perspective. In contrast, this article discusses ethically compromised vaccines and possible alternatives from a New Zealand perspective. Some vaccines which are available globally are not approved for use in New Zealand.

9 Medsafe, New Zealand Medicines and Medical Devices Safety Authority, "Rubella Vaccines," Medsafe, http://www.medsafe.govt.nz/search/query.asp?qu=rubella+vaccine&FreeText=&sc=%2F&RankBase=448&pg=2

10 Pontifical Academy for Life, 541-2; Stanley A. Plotkin, "The History of Rubella and Rubella Vaccination Leading to Elimination," *Clinical Infectious Diseases* 43, Suppl 3 (2006): S166, S164.

11 Plotkin, S165-6.

12 Pontifical Academy for Life, 548; McGovern and Brussen, 6.

13 Medsafe, New Zealand Medicines and Medical Devices Safety Authority, "Polio Vaccines," Medsafe, http://www.medsafe.govt.nz/search/query.asp?qu=polio+vaccine&FreeText=&sc=%2F&RankBase=256&pg=2

14 World Health Organisation, "Poliomyelitis," World Health Organisation, http://www.who.int/mediacentre/factsheets/fs114/en/index.html

15 Polio Eradication Program, "Polio and Prevention," World Health Organisation, http://www.polioeradication.org/Polioandprevention.aspx. Post polio syndrome is progressive muscle weakness, severe fatigue and pain in the muscles and joints.

16 Ministry of Health, *Immunisation Handbook 2011*, (New Zealand Government: Wellington), 2011, 326.

17 Kristine K. McCartney and Margaret A. Burgess, "Varicella Vaccination in Australia and New Zealand," *Journal of Infectious Diseases* 197, Suppl 2 (2008): S191-195 at 193.

18 Medsafe, New Zealand Medicines and Medical Devices Safety Authority, "Varicella Vaccines," Medsafe, http://www.medsafe.govt.nz/search/query.asp?qu=varicella++vaccine&FreeText=&sc=%2F&RankBase=731&pg=2

19 Latent infection is due to the survival of the varicella virus in the cranial nerve ganglia, dorsal root ganglia, and autonomic ganglia along the entire neuraxis. Many years later, generally when an individual becomes immunocompromised, the varicella virus reactivates and causes a wide range of neurologic disease, including zoster (shingles). See Niklaus H. Mueller, "Varicella Zoster Virus Infection: Clinical Features, Molecular Pathogenesis of Disease, and Latency," *Neurologic Clinics* 26, no. 3 (2008): 675-697 at 675-76.

20 Michiaki Takahashi et al, "Development of Varicella Vaccine," *The Journal of Infectious Diseases* 197, Suppl 2 (2008): S41-44 at S41; Anne A. Gershon and Samuel I. Katz, "Perspective on Live Varicella Vaccine," *The Journal of Infectious Diseases* 197, Suppl 2 (2008): S242-245 at S242-3.

21 Gulam Khandaker et al, "Congenital and neonatal varicella: impact of the national varicella vaccination programme in Australia," *Archives of Disease in Childhood* 96 (2011): 453-456 at 453; Eileen Wilson, "Varicella vaccine Exposure during Pregnancy: Data from 10 Years of the Pregnancy Register," *Journal of Infectious Diseases* 197, Suppl 2 (2011): S178-S184 at S178.

22 Khandaker, 453.

23 Ministry of Health, 320.

24 National Centre for Immunisation Research and Surveillance, "Herpes Zoster," *FactSheet* (2009): 1-7 at 2.

25 Ministry of Health, 313-4.

26 Annette Martin and Stanley M. Lemon, "Hepatitis A Virus" From Discovery to Vaccines," Hepatology 43, no. 2, Suppl 1 (2006): S164-S172 at S164-5, Julien Peetermans, "Production, quality control and characterization of an inactivated hepatitis A vaccine," *Vaccine* 10, Suppl 1 (1992): S99-101 at S99-100.

27 GlaxoSmithKline, "Havarix, Twinrix," GlaxoSmithKline, http://www.gsk.com.au/products_vaccines.aspx; Sanofi Pasteur "Our Travel Range, Food and Water Borne Disease," Sanofi Pasteur, http://www.sanofipasteur.com.au/sanofi-pasteur2/front/index.jsp?siteCode=AVPI_AU&codeRubrique=74&lang=EN; CSL biotherapies, "VAQATA," CSL biotherapies, http://www.cslbiotherapies.com.au/s1/cs/aucb/1196562673365/Web_Product_C/1196562642888/ProductDetail.htm

28 Martin and Lemon, S164-5; Peetermans, S99-100.

29 Centers for Disease Control and Prevention, "Vaccine Information Statement–Hepatitis, A vaccine," Centers for Disease Control and Prevention, http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hep-a.pdf

30 Medsafe, New Zealand Medicines and Medical Devices Safety Authority, "Rabies Vaccines," Medsafe, http://medsafe.govt.nz/profs/datasheet/m/merieuxinj.pdf

31 Medsafe, New Zealand Medicines and Medical Devices Safety Authority, "Rabies Vaccines," Medsafe, http://medsafe.govt.nz/profs/datasheet/v/verorabinj.pdf; Sanofi Pasteur Representative, e-mail message to authors, April, 18, 2012.

32 CSL Biotherapies, "Rapibur," CSL Biotherapies, http://www.cslbiotherapies.com.au/docs/990/630/Rabipur%20PI%20-%20approved%20Nov2010.pdf

33 This vaccine might not be suitable for everyone as there have been some serious allergies reported with vaccines manufactured from chicken embryos. For this, see Pontifical Academy for Life, footnote 8.

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