Public Health England

The use of human and animal products in vaccines

Ensuring the safety and effectiveness of the vaccine programme

Contents

Ensuring the safety and effectiveness of the vaccine programme

Many pharmaceutical products and devices that are commonly used to treat illnesses, use animal-based products to perform important functions including fillers, diluents, capsules and lubricants[1].

As vaccines are generally complex biological products, a large number of animal derived products are often used in their manufacture.

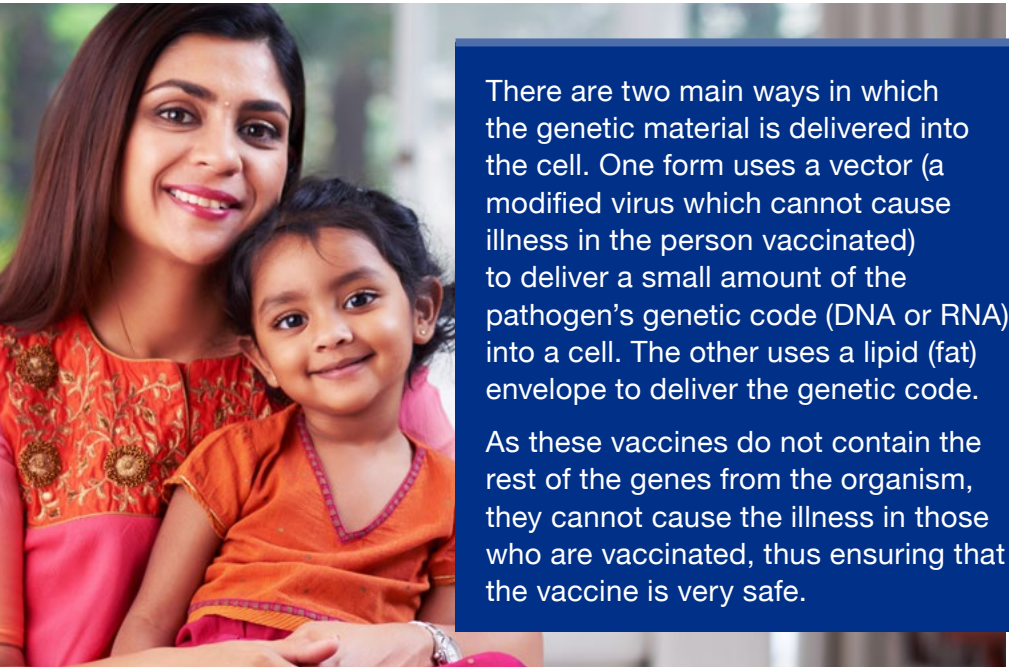
These products are essential to ensure the safety, potency and stability of the product and their use is highly regulated.

[1] Tatham Kate C, Patel Kinesh P. Suitability of common drugs for patients who avoid animal products BMJ 2014; 348 :g401

What are vaccines?

Vaccines are life-saving medicinal products, which are given to protect individuals against serious infections. Some vaccines contain small amounts of viruses or bacteria that have been inactivated by chemical treatment – these “killed” vaccines cannot cause the disease they prevent. Other vaccines contain micro-organisms which, although alive, are not able to cause serious disease (live attenuated vaccines). Vaccines may also be composed of purified fractions of these micro-organisms or even from selected components that are synthesised using DNA technology. All these vaccines are designed to safely protect people from potentially serious diseases.

Newer vaccines are also being used where genetic material is delivered into the host cells and the body’s own cells then generate a protein from the target organism.



There are two main ways in which the genetic material is delivered into the cell. One form uses a vector (a modified virus which cannot cause illness in the person vaccinated) to deliver a small amount of the pathogen’s genetic code (DNA or RNA) into a cell. The other uses a lipid (fat) envelope to deliver the genetic code.

As these vaccines do not contain the rest of the genes from the organism, they cannot cause the illness in those who are vaccinated, thus ensuring that the vaccine is very safe.

How are vaccines made?

Vaccines are usually made by growing cultures of the target virus or bacterium. Viruses need to grow in cells and so vaccine viruses are often grown in eggs (e.g. influenza) or in cell-lines derived from mammals, including humans.

These cell lines used to grow the virus will derive from a primary culture of cells from an organ of a single animal which has then been propagated repeatedly in the laboratory, often over many decades. For example, measles vaccine is grown in chick embryo cells and polio vaccines are grown in a mouse cell line. Another animal cell line, now being used to make egg-free flu vaccine, was derived in 1958 from the kidney of a cocker spaniel. Using these cell lines avoids any ongoing harm to animals.

The best-known human cell line is MRC5; these cells derive from the lung of a 14-week-old male fetus from a pregnancy that was terminated for medical reasons in 1966. This cell-line is used to grow viruses for vaccines against rubella, chickenpox and hepatitis A. Other fetal cell lines, collected in the 1970s and 1980s, have been used for other vaccines, including influenza and some of the new COVID-19 vaccines. No fetal material is present in the final vaccine.

The moral issues around the use of vaccines grown on fetal cell lines have been discussed within the Catholic Church. The Church notes that the cells lines are distant from the initial termination, and states that acceptance of such vaccines where there is no appropriate alternative does not signify cooperation with abortion[2].

Other vaccines are made in cells that have undergone genetic modification (recombination) so that they express the protein from the target organism. The cell lines used for these recombinant vaccines include yeast (hepatitis B vaccine) and insects (human papillomavirus vaccine).

Vaccines based on genetic material are an exception in that the DNA or RNA can be synthesised chemically. However, for some of these vaccines, cell-lines (animal or bacterial) may be required during development and products derived from animals (such as enzymes) may be used earlier in the production process.

[2] www.academyforlife.va/content/pav/en/the-academy/activity-academy/note-vaccini.html

What animal products are used to make vaccines?

Bacterial cultures and viral cell lines need to be grown in special liquid called “culture media”, as do the bacterial, insect or mammalian cells that are used to express recombinant proteins. This culture media provides numerous nutritious elements and growth factors that may have been obtained from materials of animal origin, such as serum, milk and milk derivatives, gelatine, meat extract or extracts from other muscular tissues. These components are used in the early stages of the manufacturing and are not present, or may only be present in trace amounts (residues) in the final vaccines. The products used in vaccine development are all are subject to careful safety and quality checks that are scrutinised by the independent regulators.

Animal enzymes are also used during the manufacture of vaccine viruses but subsequent washing, purification and dilution steps removes them from the final vaccine. One example is trypsin, normally derived from pigs, which is widely used during the manufacture of vaccines, usually being added to the final cell culture to activate the vaccine virus. Trypsin is also used during the manufacture of other medical products e.g. insulin and heparin. Although the enzyme is used as a raw material in the early steps of the vaccine manufacturing, it is then eliminated in the later steps of the manufacturing process.

Porcine trypsin in used in some injected influenza vaccines, and in vaccines against rotavirus, chickenpox and polio. It's use, and subsequent elimination from the vaccine, has been considered acceptable by some Muslim scholars[3]. The Eastern Mediterranean Region (EMRO) of the World Health Organisation (WHO) has a statement on their website about the use of porcine trypsin in oral polio vaccine (see next page)[4]. Although this vaccine is no longer used in the UK, similar considerations should apply to other vaccines.

Products that are used in the manufacture of a vaccine but which are not contained in the final vaccine are not generally listed on the Summary of Product Characteristics (The SmPC is a legal document approved by the independent regulators as part of the authorisation of each vaccine).

Residues should only be included in the SmPC if they are of known clinical relevance (for example antibiotics or components that are known cause allergies).

[3] The Eleventh Regular Session of the European Council of Fatwa and Research, Held at the Headquarters of the Islamic Association of Sweden, at the Islamic Centre, Stockholm Sweden. For the Period 1-7 Jumada I, 1424H (1-7 July 2003 AD). Fatwa 11/11.

[4] www.emro.who.int/polio/information-resources/oral-polio-vaccine-production.html

Polio Eradication Initiative

World Health Organization

Oral polio vaccine and its production

Background

Concern has been raised by some that the production of oral polio vaccine involves materials of porcine origin and that this might make the vaccine not halal for use by Muslims. The following is a description of stepwise production of the oral polio vaccine (OPV) which demonstrates that OPV does not contain any products of porcine origin or any other substance considered haram.

OPV production steps

1. There are no products of porcine origin in the seed material (cell lines and other biological reagents) used to make the oral polio vaccine.
2. There are no products of porcine origin in the oral polio vaccine itself.
3. A specific cell line is used to grow the polio vaccine virus to make the final vaccine.
4. In the preparation of these cells, a special product called Trypsin is needed to remove the cells from their container. The trypsin is an enzyme of porcine origin.
5. After the removal of the cells and before the virus for the vaccine is added, the Trypsin is completely washed and cleaned off from the cells.
6. The polio vaccine virus is then added to the cells to grow the virus for the vaccine. When the virus is ready, it is taken from the cells further cleaned and purified, and put into the vaccine vials.
7. At no time the final polio vaccine virus which is in the vaccine vial comes in contact with Trypsin nor any other porcine product.

Conclusion

There are no products, materials or contents of porcine origin in the oral polio vaccine.

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What animal products are added to vaccines?

Highly processed derivatives of animal materials are occasionally used in the finished vaccine product. These derivatives are called excipients, and perform an important function in ensuring the the vaccine is safe and effective. When an animal product is used as a constituent of vaccine, it will be listed in the SmPC.

Some chemicals – called adjuvants – are used to improve the immune response to vaccines. One example of an adjuvant that is derived from animals is “squalene” an oil that is extracted from a shark’s liver. This adjuvant is used in the influenza vaccine that is given to the elderly in this country where it improves the level of protection in an age group where responses to vaccines are normally reduced. Similar adjuvants are being looked at for one of the new COVID-19 vaccines.

Gelatine is another animal product used in some foods and in a very wide range of medicines, including many capsules, and some vaccines. Porcine gelatine is used in vaccines as a stabiliser – to ensure that the vaccine remains safe and effective during storage. Unlike the gelatine used in foods, the product used in vaccines is highly purified and broken down into very small molecules called peptides. In the UK, there are currently three vaccines that contain porcine gelatine: the nasal spray vaccine that protects children against flu, one of the two available MMR vaccines that protects against measles, mumps and rubella, and the live shingles vaccine that we use to protect older adults. The nasal flu vaccine has been tested using a sensitive test and porcine DNA was not detected.

Animal products are only ever used to ensure the safety and effectiveness of the vaccine. It is recognised that this may raise issues of acceptability for some people who do not consume animal products, or those whose faith avoids consumption of products from specific animals.

Despite this, many groups recognise the importance of vaccination and advise that vaccines containing prohibited substances can still be accepted. For example, one vegan group has produced detailed information on the various animal contents that are contained or used in vaccines[5].

In 2013, in relation to porcine gelatine in the nasal flu vaccine, PHE consulted the Jewish Kashrut and Medicines Information Service, who noted that porcine and other animal derived ingredients are acceptable in non-oral products including vaccines – even those administered via the nose.

The acceptability of porcine gelatine in vaccines has been considered by a number of Muslim scholars.

Some advice allows for the concept of transformation – istihala – which refers to the conversion of a forbidden substance into a substance with different properties and characteristics. The concept of istihala for porcine products is not accepted, however, by all Muslim legal schools.

Although one British scholar has ruled that porcine gelatine is acceptable[6], in 2013 the Scottish Government obtained a statement from Muslim Council of Scotland that ruled against the nasal flu vaccine.

Based on this diversity within the different faith groups, PHE has produced a leaflet explaining the issues around porcine gelatine in vaccines[7].

[5] www.veganfriendly.org.uk/health-fitness/vaccines
[6] www.britishfatwacouncil.org/2020/10/fatwa-on-flu-vaccine-containing-porcine-gelatine
[7] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/824013/PHE_vaccines_porcine_gelatine.pdf

Why can't we remove the animal content of vaccines?

Developing a vaccine is a complex process involving laboratory testing and clinical studies to ensure that it is both safe and effective. Vaccine manufacturers may use products that are known to perform well in other vaccines and choose one that is stable, good quality and available in sufficient volume.

Once the manufacturer has chosen a product for the vaccine, a substitution (for example by replacing an animal-based product with a plant based alternative) would usually invalidate the product licence, and could impact on the the vaccine's safety or effectiveness.

Extensive laboratory and clinical studies may then be required to show that the safety and effectiveness of the vaccine has not been affected. Because of this, developing a new safe and effective vaccine with a different content may take several years or may never happen.

Any new or modified vaccine product will then have to pass the independent regulator's rigorous safety and quality requirements.

In summary, even though animal products are used in the development of most vaccines, and some vaccines contain small amounts of animal products, the number of animals used in vaccine development and production is kept to an absolute minimum. Animals and animal products are only used when they are vital for ensuring that the vaccine is safe and effective and their use is highly regulated.

If you would like further information before making your decisions about vaccinations, you may wish to talk to your doctor or practice nurse. This is particularly important if you are at high risk of the diseases that these vaccines effectively prevent.

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