Vaccines – the facts from Viva!

Legally, all medicines (including vaccines) in the UK must be tested on animals before they are deemed safe for human use; either by the UK Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA), which covers most European countries, including the UK. Furthermore, many vaccines are produced using animal-based systems (eg eggs, cell cultures and serum) and most contain ingredients derived from animals.

On the other hand, vaccines are an effective way to prevent infectious diseases and have been pivotal in reducing the incidence of polio, tetanus, whooping cough and measles. They prevent a huge burden of disease and death in the world. If we didn't have vaccines, even more medication would be required to treat the increased number of people suffering with infectious diseases. By reducing the need for antibiotics, they may also help combat the development of antibiotic-resistant superbugs.

Vaccines were developed in the 1700s to combat smallpox, a very nasty, highly infectious deadly disease, which killed one in four of those infected. The pustules "smelled like rotting flesh." A British woman, Lady Mary Wortly Montagu, had lost her favourite brother to smallpox and when she travelled to Istanbul, noticed that people had "beautiful, unmarked skin." She discovered that families were being inoculated against smallpox with the material from pustules via a large needle into their veins. It largely worked, preventing smallpox from killing so many. She brought back the idea of inoculation to England. Later, in 1798, Edward Jenner developed the more sophisticated vaccine against this disease. Although Jenner achieved all the fame, it was Lady Mary's efforts which laid the groundwork for the eventual worldwide eradication in the 1970s of one of the deadliest diseases known to humans.

Other diseases such as rubella, polio, measles, mumps, chickenpox and typhoid are nowhere near as common as they were a hundred years ago thanks to widespread vaccination programmes. For example, The Global Polio Eradication Initiative was established in 1988 when polio was endemic in 125 countries causing some 350,000 clinical cases per year. Polio (poliomyelitis) is an infectious disease, causing paralysis in one in every 200 people infected. It mainly affects children under five. Today, the number of polio cases have been reduced by more than 99 per cent and polio remains endemic in only three countries – Pakistan, Afghanistan and possibly Nigeria. For more information see here.

Vaccine-derived polioviruses

In August 2020, the WHO declared Africa free of wild-type polio. However, there have been cases of vaccine-derived polio, in Africa and Asia, caused by a live virus from oral polio vaccines. In rare cases, the weakened virus can mutate into a form capable of causing new outbreaks. This has happened in a number of developing countries where the oral vaccine is used due to its low cost. Western countries use a more expensive, injectable vaccine which contains an inactivated virus. Outbreaks have occurred when the weakened vaccine-virus is excreted (in urine or faeces) by a vaccinated person and then picked up, through

contaminated food or water, by people who have not been vaccinated. So, it particularly affects countries with poor sanitation and low vaccination rates.

The WHO says, as of September 2020, 1,271 people around the world have caught vaccine-derived polio in the last decade. Polio once paralysed some 75,000 children a year across Africa alone. A new vaccine that cannot genetically mutate is in development.

For more information see here.

Although vaccines have undoubtedly saved millions of human and companion animals' lives, like all medicines they do not come without their major downsides. The biggest being animal testing, unfortunately still required by UK law.

Most vegans are seriously conflicted about the idea of taking non-vegan medicines. For some, the decision can be a cause of considerable distress. Here, we lay out some of the facts for you so that you can make an informed choice.

Herd immunity

When large numbers of a population are immunised, it reduces the risk of exposure for everyone in the community, including vulnerable people who are ill or have a weakened immune system. This is called 'herd immunity' and requires most people to opt in for it to be effective. Opting out of vaccination programmes increases the risk of outbreaks. For example, the drop in uptake of the MMR vaccine has led to outbreaks of measles occurring in countries that had previously been declared free of the disease – including the UK. So while some see vaccination as a personal choice, there is a social responsibility too – protecting yourself and your community.

From a health perspective, the benefits of vaccination far outweigh any slight risk; children are much more likely to be harmed by diseases, such as measles, than by the vaccine that prevents it. If vaccine uptake falls, disease rates will rise and the demand for medicines will increase and as all medicines are tested on animals, avoiding vaccines won't necessarily benefit animals.

Viva! believes that you should not put yourself and others at risk and should take the medicines you need but of course we also want vaccines and other medicines to be produced without using animals; not tested on them and not containing animal-derived ingredients. There have been some developments in this area and Viva! would like to encourage and support that further.

You can ask your GP or pharmacist to check and provide you, if possible, with medication that does not contain animal products such as gelatine or lactose.

You can look up the ingredients used in a medicine you have been prescribed here: http://www.medicines.org.uk/emc/.

For more information about vaccines, see the NHS pages on Why vaccination is safe and important and Who should have the flu vaccine?

Supplementary notes

Covid-19 vaccines

The Oxford-AstraZeneca Vaccine – ChAdOx1 nCoV-19

The Oxford-AstraZeneca Vaccine is made from a virus (ChAdOx1), which is a weakened version of a common cold adenovirus that causes infections in chimpanzees. The virus for the vaccine is grown in human kidney cells in labs.

The virus has been altered so that it is impossible for it to cause infection in humans. Genetic material (DNA) has been added that is used to make "spike" proteins from the Covid-19 coronavirus (SARS-CoV-2). This protein is found on the surface of SARS-CoV-2 and helps it infect human cells. Vaccinating with ChAdOx1 nCoV-19 prompts the body to develop an immune response to the spike protein that helps to prevent infection from the actual SARS-CoV-2 virus if you are exposed to it later.

Ingredients: One dose (0.5 ml) contains: COVID-19 Vaccine (ChAdOx1-S* recombinant) 5 × 10^10 viral particles (vp) *Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike glycoprotein. Produced in genetically modified human embryonic kidney (HEK) 293 cells. This product contains genetically modified organisms (GMOs).

The other (non-animal derived) ingredients are:

- L-histidine
- L-histidine hydrochloride monohydrate
- magnesium chloride hexahydrate
- polysorbate 80 (E 433)
- ethanol
- sucrose
- sodium chloride
- disodium edetate dihydrate
- water for injections

Pfizer/BioNTech COVID-19 vaccine BNT162b2

The Pfizer/BioNTech vaccine BNT162b2 is an mRNA vaccine. The active ingredient is messenger RNA that carries instructions for making the virus's spike protein. The mRNA is synthetic, not taken from an actual virus. It is delivered in a tiny sphere of fatty material suspended in saline solution and injected into muscle in your upper arm. The mRNA is then taken up by specialist immune cells, which follow its instructions to make the spike protein, just as they would do if they had become infected with the SARS-CoV-2 virus.

Ingredients: The active substance is BNT162b2 RNA. After dilution, the vial contains 6 doses, of 0.3 mL with 30 micrograms mRNA each. This vaccine contains polyethylene glycol/macrogol (PEG) as part of ALC-0159.

The other (non-animal derived) ingredients are:

- ALC-0315 = (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)

- ALC-0159 = 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide
- 1,2-Distearoyl-sn-glycero-3-phosphocholine
- cholesterol
- potassium chloride
- potassium dihydrogen phosphate
- sodium chloride
- disodium hydrogen phosphate dihydrate
- sucrose
- water for injections

Spikevax (previously Covid-19 vaccine Moderna)

This is also an mRNA vaccine.

Ingredients: The vaccine contains polyethylene glycol/macrogol (PEG) as part of PEG2000-DMG. One dose (0.5 mL) contains 100 micrograms of messenger RNA (mRNA) (embedded in SM-102 lipid nanoparticles). Single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2.

The other (non-animal derived) ingredients are:

- Lipid SM-102 (heptadecan-9-yl 8-{(2-hydroxyethyl)[6-oxo-6-(undecyloxy)hexyl]amino}octanoate)
- Cholesterol
- 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)
- 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000 DMG)
- Trometamol
- Trometamol hydrochloride
- Acetic acid
- Sodium acetate trihydrate
- Sucrose
- Water for injections

Ingredients for other (non-Covid) vaccines

Gelatine

Gelatine from pigs (porcine gelatine) is used in some live vaccines as a stabiliser to protect viruses against the effects of temperature. There have been a small number (one in every two million) of cases of allergic reaction to vaccines containing gelatine. Members of Muslim or Jewish religious communities, as well as vegans, may be unwilling or reluctant to use vaccines that contain gelatine from pigs. In the UK, there are three vaccines that contain porcine gelatine:

- Fluenz Tetra the nasal spray vaccine that protects children against flu
- MMR VaxPro a vaccine that protects against measles, mumps and rubella (Priorix, the other MMR vaccine does not contain gelatine)
- Zostavax the vaccine that protects older adults against shingles (Varilrix, the other chickenpox vaccine does not contain gelatine)

More information can be found in the NHS leaflet Vaccines and porcine gelatine.

Squalene

MF59 is an adjuvant – it boosts the immune response to a vaccine. It is used in one vaccine licensed in the UK: Fluad, a flu vaccine introduced in the 2018-19 flu season for adults over 65. The main ingredient is squalene, a naturally-occurring oil found in humans, plants and animals. The squalene in MF59 comes from purified fish oil. One dose contains 9.75 milligrams of squalene (there are 1,000 milligrams in a gram). It does not appear to be in any of the influenza vaccines marketed in the UK for the 2020 to 2021 season (ingredients were checked using www.medicines.org.uk/emc/).

Egg protein (ovalbumin)

The viruses for flu vaccines are usually made by injecting different flu virus strains into an egg where the viruses then enter the egg cells, recombine and makes new strains. Scientists look through the new strains to select the one that best-suits the features they are looking for to make the next flu vaccine. This is done every year to keep pace with the new and emerging flu viruses. The irony here is that if everyone went vegan, the source of these new viruses (largely poultry and pig farms) would vanish. In the UK, flu viruses for the nasal flu vaccine Fluenz Tetra and a number of inactivated flu vaccines are grown in fertilised hens' eggs. For more information about ovalbumin (egg protein) in flu vaccines see here.

Egg allergy is quite common in children under five, affecting around 60,000 children in the UK. The Joint Committee on Vaccination and Immunisation has advised that most children with an egg allergy can be safely vaccinated with the nasal flu vaccine because the ovalbumin content is very low (less than 0.024 micrograms per 0.2 ml dose). However, children who have a history of severe anaphylaxis to eggs, which has previously needed treatment in hospital, should be referred to a specialist for immunisation.

The measles and mumps viruses are grown on a cell culture containing chick embryo cells rather than in eggs (see Animal cell cultures below) so there is not enough egg protein in the MMR vaccine to cause allergic reactions and children with severe egg allergies are no longer told to avoid the MMR vaccine.

Vaccines, like other medicines, may contain other ingredients, some of which are not suitable for vegans (such as lactose – the sugar in cow's milk). You can access the list of ingredients for medicines here: http://www.medicines.org.uk/emc/.

Active ingredients for vaccines

The part of a vaccine that triggers our immune system to respond is called the active ingredient and is often an attenuated or inactivated virus that looks like the real thing to our immune system, but is not as harmful. There are a number of ways to grow these, one of which is known as cell culture – a general term used for when cells, from animal or plant tissues, are grown artificially in a laboratory.

For animal cells, the animal (or person) they originated from may have died years ago. In order to grow them, the temperature must be right and they need feeding with what is called growth medium. A typical cell culture medium is composed of amino acids (the building blocks of protein), vitamins, inorganic salts, glucose and serum (see FBS below) as a source of growth factors and hormones.

FBS – foetal bovine serum – used in some growth media, is extracted from the hearts of live calf foetuses taken from pregnant dairy cows during slaughter. FBS is commonly harvested by means of a cardiac puncture without any form of anaesthesia. Foetuses are exposed to pain and/or discomfort, so the practice of foetal blood harvesting is inhumane. Manufacturers of cell-cultured lab meat, for example, are experimenting with plant-based media. Some have stated that they have already achieved this and others are hopeful that they will too. For more general information see here.

Animal cell cultures

Viruses for the following UK vaccines are grown on animal cells:

- The polio part of the 6-in-1 vaccine (Infanrix Hexa), the pre-school booster vaccines (Repevax, Infanrix IPV and Boostrix-IPV) and the teenage booster vaccine (Revaxis).
- The Rotavirus vaccine (Rotarix)

Viruses for these vaccines are grown on Vero cells – a cell line started in the 1960s using kidney cells from an African green monkey.

- One of the Inactivated flu vaccines (Flucelvax Tetra)

The virus for this vaccine is propagated in Madin Darby canine kidney (MDCK) cells, this cell line originates from cells taken from the kidney of an adult Cocker Spaniel in 1958.

- The measles and mumps parts of the MMR vaccines (MMRVaxPro and Priorix) are produced in chick embryo cells.

Human cell cultures

In the UK, human cell cultures are used to grow viruses for these vaccines:

- the rubella part of both MMR vaccines (MMRVaxPro and Priorix)
- the shingles vaccine (Zostavax)
- both chickenpox vaccines (Varivax and Varilrix)

The cell strains currently used (WI-38 and MRC-5) were started in the 1960s using lung cells taken from two aborted foetuses. The abortions were legal and agreed to by the mothers and were not performed for the purpose of vaccine development.

Recombinant DNA technology

Recombinant vaccines are made using bacteria or yeast cells – so no animals are involved. A small piece of DNA is taken from a flu virus, for example, and inserted into another virus which is used to carry that DNA into the bacteria or yeast cells so that they can produce

large quantities of it for the vaccine (usually a single protein or sugar). This 'antigen' is produced in bulk, collected, purified and used to make a recombinant flu vaccine. See more about recombination methods here.

To make the hepatitis B vaccine, some DNA from the hepatitis B virus is inserted into the DNA of yeast cells which are then able to produce one of the surface proteins from the virus. This is purified and used as the active ingredient in the vaccine. Proteins for the HPV vaccine, part of the MenB vaccine and the hepatitis B part of the 6-in-1 vaccine are produced using a similar technique.

Recombinant influenza (flu) vaccines in the US are produced this way. This method does not use hens' eggs in the production process and could be faster than egg-based vaccines in the event of a pandemic or shortage of eggs. It also avoids changes that can occur when viruses are grown in eggs, which can affect how well vaccines works – and obviously avoids the egg allergy issue.

Recombinant DNA technology is potentially the most vegan-friendly way of producing a vaccine as it is feasible to develop one without using any animal ingredients at all.

RNA vaccines

How do they work? A short section of RNA, copied from the virus, is synthesised in a lab. This is injected into the body and enters the cells. There, it acts as an instruction manual for our cells to produce a protein (antigen) that looks like one found on the surface of the coronavirus. The immune system recognises the antigen as a foreign substance in the body and launches a response. Antibodies are produced to fight the invader. If we later encounter the real virus, the immune system will be primed and ready to respond. That's how vaccines work – giving your body a heads up on an imminent threat.

There have been claims on social media that "RNA vaccines enter your DNA." This is not true and shows a lack of understanding of basic biology. Professor Jeffrey Almond of Oxford University says: "Injecting RNA into a person doesn't do anything to the DNA of a human cell." DNA is our genetic blueprint. In the body, DNA is transcribed into a molecule called RNA, which is translated into protein. "DNA makes RNA makes protein" is the central dogma of biology. Along with other types of vaccines, RNA vaccines are being developed to combat Covid-19. Again, these are not to be grown in eggs.

Animal testing

National and international regulations currently require that new medicines are tested on animals before being licensed for use. Around five million animals including mice, rats, fish, chickens, rabbits, dogs and primates are used across the EU for this purpose each year.

The Covid-19 vaccine and animal research

Vaccine trials

The UK Medical Research Council says that animal experiments testing a Covid-19 vaccine in mice began as early as February 2020 in London. Vaccines have since been tested in ferrets,

(which are used because they have the right receptor cells in their lungs that permit infection), and monkeys (macaques) and pigs (because their immune systems share significant similarities to that of humans).

Human trials are also underway. Under normal circumstances, the MRC says, animal research must be completed before human trials can start, but because similar vaccines have worked safely in trials for other diseases, the work has been accelerated and is happening in parallel. This begs the question; why are animal experiments even deemed necessary? Viva! is anti-vivisection from an animal cruelty, philosophical and scientific standpoint. Many scientists agree that experiments on animals often fail to accurately mirror outcomes in humans (eg thalidomide and Vioxx). An increasing number of researchers would prefer to see new technologies used and to that end, there has been progress with human cell and tissue cultures, 3-D bioprinters (used to create human tissues for *in vitro* testing) and advanced computer-modelling techniques.

Antibody therapy

Your immune system produces antibodies when it encounters foreign substances such as viruses and bacteria, they are part of the natural immune response and their job is to neutralise the perceived threat. A variety of animals are now being used to produce antibodies that may combat Covid-19.

Mice bred for studying the 2003 SARS outbreak, that express the human receptor ACE2 in their cells, are being used to research antibodies that may be effective against different coronaviruses including SARS-CoV-2, the virus that causes Covid-19. The next step will be to test them in monkeys, because, says the MRC, human antibodies are more likely to interact with other components of the immune system in species that are more closely related to us than mice.

Hamsters also express the ACE2 receptor in their lungs. According to AnimalResearch.Info "After infection, hamsters appear to lose weight, become lethargic, their fur is tousled, their posture is hunched and they develop rapid, jerky breathing. SARS-CoV-2 is found in large quantities in the lungs and intestines of animals. And these clinical manifestations are reminiscent of upper and lower respiratory infection in humans."

Genetically modified cows, previously modified to carry a human gene that produces antibodies, are being injected with part of the SARS-CoV-2 virus to trigger an immune response. When they have produced enough antibodies, scientists will "harvest" their blood plasma (the liquid part of blood that carries cells and proteins around the body) and separate the antibodies from it to create a therapeutic drug. Sheep in Australia are also being used to produce antibodies against Covid-19.

These are just some examples of the research being conducted around the world. For more information see here.