CSBQ Brief on COVID 19 vaccines on offer in Australia & New Zealand
Updated 21st September AD 2021

This is an updated briefing paper originally presented to the meeting of the LCANZ's *Commission on Social and Bioethical Questions* on the 1st September.

COVID-19 vaccines currently available in Australia

Vaxzevria (Astra Zeneca)

- Viral vector vaccine (genetically engineered virus vector system)
- Abortion-derived cell lines (HEK 293) used for its production and in laboratory testing

Cominarty (Pfizer)

- mRNA vaccine (genetic code for spike protein encased in lipid coat)
- Abortion-derived cell lines may have been used in laboratory testing

TGA approved and soon to be available in September 2021

Spikevax (Moderna)

- mRNA vaccine
- Abortion-derived cell lines may have been used in laboratory testing

Yet to receive TGA approval, but on the way (perhaps later in 2021)

Novavax (Biocelect)

- Protein vaccine (synthetic spike protein only)
- Abortion-derived cell lines may have been used in laboratory testing

COVID-19 vaccines currently available in New Zealand

Cominarty (Pfizer)

- mRNA vaccine (genetic code for spike protein encased in lipid coat)
- Abortion-derived cell lines may have been used in laboratory testing

Ethical concerns about the use of abortion-derived cell lines

- HEK293 (Human embryonic kidney cells), PERC6 (Primary human embryonic retinal cells) cell lines have been used in the production of some of viral vector COVID vaccines and in the testing of these vaccines. They may have also been used in the testing of the mRNA vaccines.
- Vaccines that have been produced using abortion-derived cell lines do not contain the same cells or tissues taken from the aborted child. However, they could not have been developed without those original cells from the abortion.
- Delving into the documentation available about how the organs and tissues from those abortions was 'harvested' is not for the faint hearted and is disturbing. It is a cause for great moral concern. This is particularly so because the practice of 'harvesting' organs during abortions for biomedical research continues to be practiced. The biomedical industry should be urged to use more ethically and morally acceptable methods for research and production of medicines and vaccines.
- HEK293, PER6 and other abortion-derived cell lines (such as Wi-28, MRC-5 cell lines) are used widely in biomedical research and the production of vaccines. They are also used in the production of monoclonal antibody therapy, some gene therapies, and increasingly in cancer treatments.
- HEK293 cell line is said to be preferred for its "easy maintenance, robustness, and ease of transfection."
- While navigating this vast field one finds that much of our modern medical scientific biomedical research has been touched in one way or another by the use of these abortion derived cell-lines.

Other ethical concerns regarding *Vaxzevria (*Astra Zeneca*)*

- A concern expressed is that the vaccine is a form of gene therapy, being a viral vector vaccine. This is a new type of vaccine 'platform' different from one of the traditional vaccination types such as whole virus, live attenuated vaccines. A whole virus live attenuated vaccine is one where the disease-causing virus is altered or "attenuated" to produce an immune response to the disease but the not disease itself. Examples include vaccines for MMR (Measles, mumps, rubella), chickenpox, and shingles.

In most of these vaccines, the genetic material inside the virus is not altered. However, in some others the genetic code of the virus is altered in some way to make it less "disease-causing."

- COVID-19 viral vector vaccines contain only the genetic material (RNA) for the spike protein of the virus and is inserted into a different, more "harmless" virus (e.g. a mammalian adenovirus). Hence, the genetic material is artificially produced in the laboratory and inserted into the vector virus. When injected into the human, this virus infects human cells, releasing the genetic material into them. The host human cell machinery is then used by the RNA to produce the viral spike protein. The spike protein is then released by the human host cell and recognized by the human immune system as a foreign substance. An immune response then results, mainly in the form of antibodies to provide protection against natural infection of the COVID-19 virus.
- A concern is that this vaccine is a form of gene therapy. Gene therapy is defined in various ways, but one simple definition is "the introduction of new genetic material into a cell in order to produce the expression of that gene". So, one could call this type of vaccination a form of gene therapy.
- It is worth noting that viruses themselves are essentially genetic material contained within a lipid, glycoprotein coat. A natural viral infection itself performs a type of gene therapy on the host it infects, whether it be the common cold, influenza or chickenpox. When a virus infects a cell, the viral genetic code is injected into that human cell and uses the host human cell's machinery to reproduce itself. However, because the COVID-19 virus and the COVID-19 vaccines contain RNA, this genetic code cannot be incorporated into the human genetic code which is DNA. They are incompatible with each other. Hence, no new genetic material will be passed on to the next generation.

- Another major concern has been the risk of Thrombosis with Thrombocytopenia Syndrome (TTS). This touches on the ethical concern of providing informed consent for vaccination. TTS is a particular type of blood clotting problem, usually the blood vessels of the brain and gastrointestinal system. It appears to be an immune mediated response to vaccination with *Vaxzeriva*. Two months ago it was estimated that out of six (6) million six (6) people are known to have died of TTS after receiving the 1st dose of *Vaxzeriva*. Certainly, more people have had TTS and survived (see risk table below). From a public health and medical point of view the occurrence of this complication is considered rare. In Australia, the definition of a rare disease is if it affects less than 5 in 10,000 people. It is a potentially very severe medical condition. Although not everyone dies from TTS, most require hospitalization, and some management in ICU. Some recover with long term medical complications. The risk of TTS, if you did not get it after the 1st dose, is a reduced to a 10th with the second dose. TTS occurs 4-42 days after the first dose, and there are recommendations from an Australian multidisciplinary panel on how to investigate and manage it early. It's also worth noting that blood clotting (in the brain, legs, lung) is also a known significant and not uncommon complication of severe/critical COVID disease, especially in those requiring ICU management. Not being vaccinated for COVID-19 does not remove the risk of getting a blood clot.

Age	Estimated risk of TTS per 100,000 AstraZeneca (Vaxzevria) vaccine doses (first dose)
<50 years	3.1
50-59 years	2.7
60-69 years	1.4
70-79 years	1.8
80+ years	1.9
*as at June 2021	

https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/learn-about-covid-19-vaccines/about-the-astrazeneca-vaxzevria-covid-19-vaccine#thrombosis-with-thrombocytopenia-syndrome-tts

As with all other vaccines, *Vaxzeriva*, *Cominarty* and *Spikevax* can also cause other side effects and complications. Usually these are pain and swelling at the injection site, general malaise, aches, fever, headache etc. The severity can vary from mild to more severe, and usually requires simple measures such as rest and simple analgesia.

Ethical concerns regarding mRNA vaccines (Pfizer's *Cominarty* & Moderna's *Spikevax*)

- As with *Vaxzeriva* there is a concern that mRNA vaccines are a form of gene therapy. The vaccine is genetic material (messenger RNA or 'mRNA') coding for the spike protein which is wrapped into a lipid (fat) coat.
- The COVID-19 mRNA vaccines and viral vector vaccines are new, but the research and technology is not so new. Research into these vaccine platforms has been ongoing for 30-40 years. One could say those who have been developing this technology have now found an opportunity to use it in the COVID-19 pandemic.
- The unanswered question is, will the introduction of only the genetic material coding the spike protein, without all the other genetic material that causes disease, bring about any unintended, harmful consequences? At present, we don't know, however it appears unlikely. Further follow up will determine this.
- mRNA vaccines and viral vector vaccines can be considered "human made viruses". They aim not to cause disease, but to bring about an immune response to protect against disease from natural infection.
- Advantages over viral vector vaccines
    - Quicker to produce, both in terms of research response to a new virus, and in mass production.
    - Given the relatively rapid spread of COVID-19 the desire for a rapid response is understandable.
- Advantages over protein vaccines
    - It's thought they produce a better immune response. The human immune system sees the mRNA vaccine more like a 'natural' viral infection compared with that of a protein-based vaccine (produced in the laboratory).
- The main serious medical side effects of mRNA vaccines have been myocarditis and pericarditis. These occur particularly in males and younger people, usually after the second dose. Myocarditis = inflammation of the heart muscle. Pericarditis = inflammation of the thin tissue lining of the heart with fluid accumulation around the heart. It appears that most cases are mild to moderate, requiring monitoring and supportive treatment in hospital. However, some deaths have been reported. From a population health perspective, the risk is considered rare. The CDCP (Centre for Disease Control and Prevention) states that over a thousand cases of myocarditis and pericarditis have been reported from 177 million doses given. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

  It is worth noting that myocarditis and pericarditis are themselves significant and common complications of moderate to severe COVID-19 disease.
- There have been concerns regarding the vaccine's effects on pregnancy and fertility. The Australia Government's Department of Health website states:

  The theory that COVID-19 vaccines cause infertility is based on the disproven idea that one of the spike proteins in COVID-19 and the Syncytin-1 protein (which help placenta development) are the same. They are *not.*
  https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/is-it-true/is-it-true-do-covid-19-vaccines-cause-infertility

  Currently there are 5 studies relating to pregnancy and COVID-19 vaccines on the COVID-NMA website register (covid-nma.com/vaccines/mapping). Time will tell if the COVID-19 vaccines have long-term effects on fertility and pregnancy.

  The Royal Australian & New Zealand College of Obstetricians and Gynaecologists (RANZCOG) advises that pregnant women are at a higher risk of developing COVID complications compared with non-pregnant women of the same age. These include; admission to hospital, ICU admission, and overall morbidity and mortality. There is an increased risk of premature birth, or the newborn requiring special care, and increased risk of stillbirth. Currently there is no evidence that COVID causes an increased risk of miscarriage. COVID vaccination reduces the risk of premature delivery if it protects infection in the mother.
  https://ranzcog.edu.au/statements-guidelines/covid-19-statement/information-for-pregnant-women

Concern about the pace of research and production of COVID-19 vaccines

- An understandable concern not to be dismissed. However, this needs to be understood in the context of a once in a hundred year pandemic.
- The sheer number of registered trials and published papers regarding COVID-19 is unprecedented. Given the volume and sense of urgency to respond to the pandemic, solid, sufficient peer review and analysis of the papers was always going to be an issue. It is an ongoing issue. Public availability of current registered, published and peer reviewed research (and those which are not) regarding COVID-19 is also unprecedented.
- A useful tool is the covid-nma.com website updated weekly, a collaboration of the *Cochrane Library* and the *WHO* (World Health Organisation).
- There has been concern that the COVID-19 vaccines remain experimental. On the one hand this is to be acknowledged. Previously, vaccines have been developed over years to decades. However, not all vaccinations are the same. Some vaccines are produced for disease processes that develop over many years. Hence, they take many years, even decades to research, produce and evaluate. On the other hand, respiratory viruses such as COVID-19 develop acutely, and the severity and breadth of spread of COVID-19 has required a more rapid response. The issue of our desire for a quick response is also a deeper issue requiring further and broader reflection and even repentance. However, the short to medium term efficacy and side effects of such vaccinations can be studied in a shorter time frame.

  All vaccinations, medications, medical products, and interventions (including surgical techniques) are continually reviewed and trialed. Recent reviews of many commonly performed and long established orthopaedic surgical practices have found a relative lack of evidence for their benefit. This is not to say that they are not beneficial. The issue is that there is a lack of evidence from what is considered the 'gold standard' in assessing a disease treatment, i.e. randomized controlled trials. A lot of what is done in medical practice is not as evidence-based as is commonly thought. This is not to undermine confidence in medical science and practice. But it also should keep medical science humble and readily open to scrutiny. It also highlights that the practice of medicine and of the other healing professions is both an art and a science. With this born in mind one could consider all medical treatments experimental.

  The following is a general description of clinical trial phases. Practically speaking, the present the COVID-19 vaccines in Australia area in the phase 3 to 4 category, given they are provisionally approved by the TGA (Therapeutic Goods Administration).

  - **Phase I clinical trials** are done to test a new biomedical intervention for the first time in a small group of people (e.g. 20-80) to evaluate safety (e.g. to determine a safe dosage range and identify side effects).
  - **Phase II clinical trials** are done to study an intervention in a larger group of people (several hundred) to determine efficacy (that is, whether it works as intended) and to further evaluate its safety.
  - **Phase III studies** are done to study the efficacy of an intervention in large groups of trial participants (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions (or to non-interventional standard care). Phase III studies are also used to monitor adverse effects and to collect information that will allow the intervention to be used safely.
  - **Phase IV studies** are done after an intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use over longer periods of time. They may also be used to investigate the potential use of the intervention in a different condition, or in combination with other therapies.

    https://www.australianclinicaltrials.gov.au/what-clinical-trial/phases-clinical-trials

Purpose of the COVID-19 vaccines

- There is clear evidence that both COVID-19 vaccinations available in Australia are effective (around 80%) in reducing moderate/severe/critical disease and mortality in the short, medium term. Long term efficacy is yet to be established. Booster doses may be required to maintain immunity.

- There is emerging evidence that vaccination also reduces the risk of transmission. That evidence is not as well established as it is for disease severity reduction.
    - A UK study suggests either vaccine reduces household transmission by 40-60%. Transmission in the home is the main driver of transmission generally. https://khub.net/documents/135939561/390853656/Impact+of+vaccination+on+household+transmission+of+SARS-COV-2+in+England.pdf/35bf4bb1-6ade-d3eb-a39e-9c9b25a8122a?t=1619601878136
    - An Israeli study showed that mRNA vaccine reduced nasal viral load. A higher nasal viral load is associated with a higher risk of transmission. https://www.nature.com/articles/s41591-021-01316-7

Other considerations

- Vaccination is a medical procedure with risks and benefits. Seek medical advice from your general practitioner and pastoral counsel and support from your pastor.
- Vaccination is one, significant part of the larger public health response to the COVID-19 pandemic. These include physical distancing, mask wearing, hand sanitizing, and isolating while sick. These will still play a key role in protecting the vulnerable including those who are vaccinated. Will the emphasis on vaccination alone lead to complacency with regard to these other "low tech", yet vital public health measures?
- How does the church respond to the concern of those outside and inside the church?
    - The church needs to consider its role as a public space, i.e. as a host for those outside of it, and where certain expectations are placed on it by government and society.
    - On the other hand, the church is also a place where God's Word reigns. In one way, the church is not a "safe space" to be in. Life in this world is filled with risks. It is dangerous to tread on God's holy ground unprepared by Him. His church is a refuge for the sick, the vulnerable, including those who cannot receive a vaccination for any reason, including conscientious reasons, whether we agree with them or not. What are the risks we are really concerned about, and the risks we should be concerned about?
- To whom does my body belong? St Paul writes:

  You are not your own, you have been bought at a price. Therefore honour God with your body (1 Cor 6:7)

  There is an unavoidable tension between God's gift of our personal bodily autonomy and God's gift of our responsibility to others all given under God's gracious rule. How do we apply this reality in the current COVID-19 pandemic?
- At the beginning of the pandemic in 2020 there was significant doubt as to whether an effective vaccine for COVID-19 would ever be available. Many in the church prayed that God's response to their many prayers would include a vaccine. To be vaccinated or not to be vaccinated is a question to be prayerfully considered. For many it is a struggle. It is good for all of us to recognize this. We have an opportunity to be humble, repent, thank God for all His gifts, eternal and temporal, including health, medical care, and each other (James 4:1-12). Those who are vaccinated, and those who are not vaccinated, are called to treat each other with patient love and care.

Some resources

https://lozierinstitute.org/update-covid-19-vaccine-candidates-and-abortion-derived-cell-lines/

https://lozierinstitute.org/a-visual-aid-to-viral-infection-and-vaccine-production/

https://s27589.pcdn.co/wp-content/uploads/2020/09/09.17.20-Fetal-Cell-Line-Fact-Sheet.pdf

https://lozierinstitute.org/a-visual-aid-to-viral-infection-and-vaccine-production/

https://covid-nma.com

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