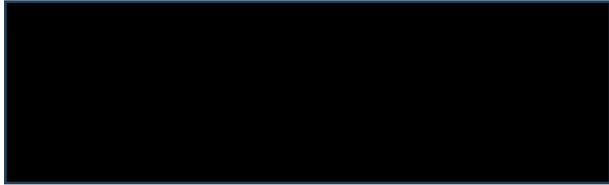




AUSTRALIAN
CATHOLIC
MEDICAL
ASSOCIATION

9 February 2021



Your Excellencies,

Re: Concerns of the Catholic Medical Association regarding currently available Covid-19 Vaccines

The Catholic Medical Association (“CMA”) is a national body created to provide support and voice for Catholic doctors. We have spent many hours analysing the available data particularly concerning the mRNA vaccines against the SARS-CoV-2 virus and related Covid-19 illnesses that are soon to be made available in Australia. Whilst we acknowledge the need for a safe and effective vaccine, our analysis reveals a number of concerns that have prompted us to write this letter to you.

It is essential that people are given accurate information about these vaccines so they may give informed consent (or refusal). Our greatest concern is that those wishing to conceive, either now or in the future, should be made aware of the very limited data regarding pregnancy issues, fertility effects and gonadal reproductive toxicology.¹ In addition, we strongly oppose any plan to employ coercive tactics to achieve vaccination of patients and healthcare workers.

As a leader of our Catholic Church, and a persuasive voice in Catholic healthcare, we seek your assistance to disseminate the information in this letter to Catholic health care agencies and the wider community to raise awareness, encourage discussion, and promote good health policies. Specific recommendations for next steps are set out in the conclusion of this letter.

Informed Consent

Doctors have a legal duty to provide patients with informed consent before providing treatment; specifically, we have a duty to inform patients of the material risks of an intervention and we

¹ That is to say, there are no published studies available that report on the histology in preclinical studies of animals’ testes, epididymides or ovaries. It should also be noted that the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (‘RANZCOG’) does not recommend routine use of Covid-19 vaccines in pregnancy. See, ‘Covid-19 Vaccination Statement’, Royal Australian and New Zealand College of Obstetricians and Gynaecologists (Statements and Guidelines) 26 January 2021 <<https://ranzcoг.edu.au/statements-guidelines/covid-19-statement/covid-19-vaccination-information>>.

have a duty to inform them of risks which we know or ought to know the patient will attach significance to when making a decision about whether to undergo the treatment.²

This legal duty arises from our ethical duty to respect the dignity and autonomy of patients as persons.³ In the current climate, there may be healthcare practitioners unaware of gaps in scientific research regarding these vaccines. In addition, doctors may need to feel reassured that information about these vaccines is coming from a trusted, credible source. We believe the following ten statements are a just representation of the limitations on these vaccines and can be relied upon by doctors when discussing the vaccine with their patients.

1. As the vaccines have been fast tracked in development, their safety is diminished.
2. As the vaccines are still under investigation, they are investigative or experimental.
3. There is no data to confirm the long-term safety of these vaccines.
4. Women of child-bearing age should be informed that the data of all marketed Covid-19 vaccines relating to reproductive toxicology is either absent, incomplete or inadequate according to established Guidelines on Reproductive Toxicology⁴ and Guidance for Industry for vaccine development.⁵ More specifically, patients to whom this warning applies should be informed that:
 - a. There have been mid-trimester miscarriage reports⁶ and an increased risk of prematurity⁷ associated with COVID-19 disease in pregnancy.
 - b. Significant inflammation on the maternal side of the placenta has been observed at microscopy in a well-documented case of mid trimester foetal demise in Covid-19 disease in pregnancy.⁸ This phenomenon was also seen in 40% of

² See *Rogers v Whitaker* (1992) 175 CLR 479; See also, Catholic Health Australia, Code of Ethical Standards for Catholic Health and Aged Care Services (2018) Pt 2 [1.5] <<https://www.cha.org.au/code-of-ethical-standards>>.

³ Catholic Health Australia (n 2) Pt 2 [1.3].

⁴ European Medicines Agency, 'ICH (R3) Guideline on Reproductive Toxicology: Detection of Toxicity to Reproduction for Human Pharmaceuticals' 17 February 2020 <<https://www.ema.europa.eu/en/ich-s5-r3-guideline-reproductive-toxicology-detection-toxicity-reproduction-human-pharmaceuticals>>.

⁵ US Department of Health and Human Services Food and Drug Administration Centre for Biologics Evaluation and Research, 'Guidance for Industry, Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Diseases Indications' (2006) <<https://www.fda.gov/files/vaccines,%20blood%20%26%20biologics/published/Guidance-for-Industry--Considerations-for-Developmental-Toxicity-Studies-for-Preventive-and-Therapeutic-Vaccines-for-Infectious-Disease-Indications.pdf>>.

⁶ National Vaccine Information Centre, Med Alerts (Search results from 1/29/21 release of VAERS Data) <[https://medalerts.org/vaersdb/findfield.php?EVENTS=on&PAGENO=3&PERPAGE=10&ESORT=NONE&REVERSESORT=&VAX=\(COVID19\)&VAXTYPES=\(COVID-19\)&SYMPTOMS=\(Exposure_during_pregnancy_%2810073513%29\)](https://medalerts.org/vaersdb/findfield.php?EVENTS=on&PAGENO=3&PERPAGE=10&ESORT=NONE&REVERSESORT=&VAX=(COVID19)&VAXTYPES=(COVID-19)&SYMPTOMS=(Exposure_during_pregnancy_%2810073513%29))>.

⁷ KR Woodworth, E O'Malley, V Neelam et al, 'Birth and Infant Outcomes Following Laboratory- Confirmed SARS-COV-2 Infection in Pregnancy – SET-NET, 16 Jurisdictions March 29-October 14,2020' (2020) 69(44) *CDC MMWR Morbidity and Mortality Weekly Reports* 1635.

⁸ D Baud, G Greub, G Favre et al, 'Second Trimester Miscarriage in a Pregnant Woman with Sars-CoV-2 Infection' (2020) 323 (21) *Journal of American Medical Association* doi:10.1001/jama.2020.7233.

maternal infections with Middle East Respiratory Syndrome⁹ and Severe Acute Respiratory Syndrome.¹⁰ In theory, therefore, there is concern that the vaccine may, by a similar molecular mechanism, establish an immune reaction to the placenta which could endure. To date, this has not been properly investigated.¹¹

- c. Concerns have been expressed about gaps in our knowledge of the effects of altered proportions of immune cells in pregnancy after Covid-19 vaccination.¹² Successful pregnancy depends on the correct balance of the body's immune cell responses. Disruption of this balance has been associated with foetal loss and prematurity.¹³ The mRNA vaccine data indicate an altered balance of these cells in a broad immune response¹⁴ following vaccination.
5. Patients who take the vaccines have a risk of vaccine-elicited Antibody-Dependant Enhancement, also called Pathogenic Priming. This is a phenomenon that can cause significant harm if the vaccine recipient is later exposed to the wild-type virus. Such enhanced disease possibility following immunization was acknowledged for Covid-19 vaccines¹⁵ as it had been well documented in previous trials of corona vaccines.¹⁶
6. Patients should be informed that beyond the usual temporary fever, chills and local site reactions associated with vaccines, there is an absence of detailed information regarding more serious adverse events observed such as an arrhythmia.¹⁷
7. Elderly patients should be informed that the pathophysiology of deaths following vaccination in the elderly is not yet clear.

⁹ G Favre et al, '2019-nCoV Epidemic: What about Pregnancies?'(2020) 395(10224) E40 *Lancet* doi: 10.1016/S0140-6736(20)30311-1.

¹⁰ SF Wong, KM Chow, TM Leung et al, 'Pregnancy and Perinatal Outcomes for Women with Severe Acute Respiratory Syndrome (2004) 19 (1) *American Journal of Obstetrics and Gynecology* 292 doi: 10.1016/j.ajog.2003.11.019.

¹¹ The Facts About Pfizer and BioNTech's COVID-19 Vaccine. https://www.pfizer.com/news/hot-topics/the_facts_about_pfizer_and_biontech_s_covid_19_vaccine

¹² SL Klein, P Creisher and I Burd. 'COVID-19 Vaccine Testing in Pregnant Females is Necessary' (2021) *Journal of Clinical Investigation* < <https://doi.org/10.1172/JCI147553>>.

¹³ S Saito, A Nakashima, et al. 'Th1/Th2/Th17 and Regulatory T-cell Paradigm in pregnancy' (2010) 63(6) *American Journal of Reproductive Immunology* 601.

¹⁴ EE Walsh, WR Frenck Jr, AR Falsey et al, 'Safety and Immunogenicity of Two RNA-Based Vaccine Candidates' (2020) 383 (25) *New England Journal of Medicine* 2439; U Sahin, A Muik, I Vogler et al, 'BNT162b2 induces SARS-Co-V-2-neutralizing Antibodies and T Cells in Humans' (2020) *medRxiv* <<https://www.medrxiv.org/content/10.1101/2020.12.09.20245175v1>>.

¹⁵ FP Polack, SJ Thomas, N Kitchin, 'Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine' (2020) 383 *New England Journal of Medicine* doi: 10.1056/NEJMoa2034577: 2603-2615.

¹⁶ SB Halstead and L Katzelnick, 'COVID-19 Vaccines: Should we fear ADE?' (2020) 222 (12) *Journal of Infectious Diseases*, doi: 10.1093/infdis/jiaa518: 1946-1950; J Lyons-Weiler 'Pathogenic Priming Likely Contributes to Serious and Critical Illness and Mortality in COVID-19 via Autoimmunity' (2020) 3 *Journal of Translational Autoimmunity* 100051, doi: 10.1016/j.jtauto.2020.100051; CT Tseng, E Sbrana E, N Iwata-Yoshikawa et al 'Immunization with SARS Coronavirus Vaccines Leads to Pulmonary Immunopathology on Challenge with the SARS Virus. *PloS one*' (2020) 7 (4) e35421 <<https://doi.org/10.1371/annotation/2965cfae-b77d-4014-8b7b-236e01a35492>>.

¹⁷ SL Klein, P Creisher and I Burd (n 12).

8. The interactions of COVID-19 vaccines with other medications are not known.
9. The vaccines which have used aborted foetal cell lines in their development should be identified to patients where the doctor knows or suspects this information would affect the patient's decision to undergo vaccination.
10. The vaccines may not prevent a person from transmitting Covid-19, rather they aim to prevent the vaccinated patient from becoming ill from the virus. Persons who are vaccinated against Covi-19 disease may develop asymptomatic infection and still be infectious for SARS-Co-V2 virus.

Any statement from Government authorities or other health care providers that these vaccines are safe without a qualification that their safety can only be understood in terms of short term safety, should be questioned. This is because it is not possible for health authorities to give assurances that these new vaccines will not cause long term health problems.

Mandatory vaccination

Given the above, we are concerned about the possibility of mandatory vaccination or coercive practices to achieve vaccination of patients and healthcare workers. Penalties and other repercussions from a person's informed refusal to be take these vaccines raise complex human rights issues about balancing unjust discrimination with concern for the common good.

Discussions about the reasonable accommodation of healthcare workers who refuse to take the vaccine cannot take place without first establishing the benefit of the vaccine to the community, its limitations and risks, and the number of healthcare workers likely to refuse vaccination. Accordingly, ventilating concerns about the risks and limitations of these vaccines is a necessary first step in trying to establish a baseline for rational public discourse.

Recommendation

As always, we want the Catholic Church to lead in times of adversity and the CMA is here to support the Church in this endeavour.

At this stage, our recommendation is that you consider the contents of this letter and co-ordinate a discussion amongst appropriate people in Catholic health agencies with the aim of obtaining an endorsement from them that the ten statements in this letter are fair and accurate representations of the currently known risks, limitations and unknowns of the vaccine that should be disclosed to patients. If such an endorsement were obtained, this information should be disseminated to employees of Catholic health agencies, and to the wider community for the purpose of informed consent.

We welcome the opportunity of discussing these matters with you in more detail and look forward to hearing from you at your earliest opportunity.

Yours faithfully,

The Australian Catholic Medical Association

