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Virginia Crawford

By email: fyi-request-14914-94f036c5@requests.fyi.org.nz
Ref: H202102874

Dear Virginia Crawford

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 13 March 2021 for:

"...From the above, it is clear that the persons who received the placebo will NOT be followed up for the full two years indicated by the trial design, thus putting into question the validity of the trial as to the long term safety and efficacy of this vaccine. Furthermore, in regard to pregnant women, Dr Bloomfield has stated that women should seek the advice of their doctor or specialist as to whether to they should take the vaccine. Most doctors have absolutely NO IDEA of the pros and cons of this vaccine for pregnant women and are relying on the Health Department to advise them. Already there are many reports (in the USA) of spontaneous abortions occurring after vaccination with BNT162B2... Will the Health Department/Government make the public aware of the above issues? How many pregnant women have been vaccinated so far? Is a record being kept of them?"

The Comirnaty (Pfizer/BioNTech) COVID-19 vaccine is a mRNA vaccine. The vaccine works by delivering instructions for human cells to build the viral antigen, SARS-CoV-2 spike protein, which is then broken down after a few days. While there is no biological reason for this vaccine to cause problems in pregnancy, there is documented evidence of an increased risk of severe COVID-19 disease among pregnant women who are infected by the virus and adverse outcomes for their unborn children.

The Ministry is not specifically recording the number of pregnant women receiving the vaccine. However, there is a 'medical risk reason' field in the consent form and since vaccinations started, there have been two instances where people who mentioned pregnancy and were subsequently not vaccinated.

The Ministry acknowledges that pregnant women were not formally included in the initial clinical trials for the mRNA vaccine, although the Ministry is aware of a phase II/III clinical trial underway in the United States. A pregnancy register is being run internationally and more information will be available from vaccine use in pregnancy in other countries over the coming months. We recommend that pregnant women, their whānau and healthcare professionals discuss the risks associated and availability of safety data for COVID-19 vaccines. There is detailed advice for health professionals on COVID-19 vaccination, including for pregnancy (section 5.6.2), in a new chapter recently added to the Immunisation Handbook on 15 March 2021 at: <https://www.health.govt.nz/our-work/immunisation-handbook-2020/5-coronavirus-disease-covid-19>. Additional information about the

Pfizer/BioNTech vaccine and pregnancy is available on the Immunity Advisory Centre (IMAC) website:

- <https://www.immune.org.nz/sites/default/files/resources/Written%20Resources/COVID-19%20vaccination%20in%20pregnancy%20FINAL%2009032021.pdf>
- <https://www.immune.org.nz/sites/default/files/resources/Written%20Resources/COVID-19%20vaccination%20in%20pregnancy%20FINAL%2009032021.pdf>

I trust this information fulfils your request. Under section 28(3) of the Act you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely



Mathew Parr
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COVID-19 Vaccine and Immunisation Programme