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4 November 2024

s 9(2)(a)

[redacted] [redacted]
Ref: H2024051358

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your follow up request under the Official Information Act 1982 (the Act) to the Ministry of Health – Manatū Hauora (the Ministry) on 10 September 2024. You requested:

> *Could you please provide me with the "literature review" and "proposed revised recommendation" mentioned in paragraph 4 of the May 27 memo as being provided to CV TAG by IMAC? I've inserted a screenshot below for clarity/convenience:*

Please find this information in the links below:

- www.tewhatuora.govt.nz/assets/About-us/Who-we-are/Expert-groups/COVID-19-Vaccine-Technical-Advisory-Group-CV-TAG/Pfizer-COVID-19-vaccine-in-pregnancy.pdf
- www.tewhatuora.govt.nz/assets/About-us/Who-we-are/Expert-groups/COVID-19-Vaccine-Technical-Advisory-Group-CV-TAG/Decision-to-use-the-Pfizer-mRNA-COVID-19-vaccine-for-group-three-and-general-population.pdf

> *Sorry one more thing - apologies for not including this in my email above, but can you please also provide the meeting minutes for the CV TAG meeting which took place to discuss the revised recommendation on 25 May 2021? This is also mentioned in the May 27 memo. I also request any correspondence, documents or other information related to this meeting.*
>
> *Hopefully sending two emails doesn't confuse things, please note my request above for the information provided to CV TAG by IMAC (mentioned in paragraph 4 of the May 27 memo) also. I consider the information requested in both of these emails to be relevant to my initial request."*

Information within scope of your request is itemised in Appendix 1 of this letter and copies of the documents are enclosed. The table in Appendix 1 outlines the grounds under which I have decided to withhold information. I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

Please note the information contained in document 5 titled '*COVID-19 and COVID-19 vaccines in pregnancy update*', was based on evidence available at the time that this summary was produced (21 May 2021). Hyperlinks are included throughout the summary, and in the section

headed ‘Website URLs for hyperlinks. Many of these hyperlinks now auto-redirect the reader to content that has been updated since the date that this summary was produced.

Please also note that documents 9 and 10 are held by the Ministry but are drafts and do not necessarily reflect the views of the Ministry nor the CV-TAG meeting held on 25 May 2021.

I trust this information fulfils your request. If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

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 Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Kristie Carter
Group Manager, Intelligence, Surveillance and Knowledge
Public Health Agency | Te Pou Hauora Tūmatanui

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	11 May 2021	CV Tag 11 May Minutes	Refused under section 18(d) of the Act as the information is publicly available here: https://fyi.org.nz/request/16691/response/65106/attach/5/H202112324%20documents%20redacted.pdf, please refer to pages 11-15.
2	20 May 2021	Overview of COVID-19 vaccines	Refused under section 9(2)(b)(ii) of the Act, as its release would likely unreasonably prejudice the commercial position of the person who supplied the information.
3	20 May 2021	Science overview of Janssen COVID-19 vaccine	
4	20 May 2021	Memo: Pfizer COVID-19 Vaccine – Decision to Use	Some information withheld under section 9(2)(c) of the Act, to avoid prejudice to measures to protect the health or safety of the public. Disclosing this info could lead to unwarranted public concern or misrepresentation, especially if the data is not contextualised. Information relating to the withheld appendix is publicly available here: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp.
5	21 May 2021	COVID-19 and COVID-19 vaccines in pregnancy - update	Released in full.
6	22 May 2021	Science overview of Pfizer COVID-19 vaccine	Refused under section 9(2)(b)(ii) of the Act, as its release would likely unreasonably prejudice the commercial position of the person who supplied the information.
7	23 May 2021	Summary of planned trials of COVID vaccines in children and adolescents	
8	25 May 2021	AGENDA: COVID-19 Vaccine Technical Advisory Group	Refused under section 18(d) of the Act as the information is publicly available here: https://fyi.org.nz/request/22426/response/85572/attach/5/H2023023312%20Appendix

			%201.pdf please refer to pages 20-21.
9	25 May 2021	Draft statement on Long-term effects of Pfizer vaccine (appendices to the agenda)	Released in full.
10	24 May 2021	Strawman Statement	
11	N/A	The effect of body mass index and arm size on intramuscular vaccine delivery and immunogenicity	Refused under section 9(2)(b)(ii) of the Act, as its release would likely unreasonably prejudice the commercial position of the person who supplied the information.

Memo

Pfizer COVID-19 Vaccine – Decision to Use

Date:	20 May 2021
To:	COVID-19 Vaccine Technical Advisory Group
From:	Allison Bennett, Manager, System Enablers, System Strategy and Policy
For your:	Advice

Purpose of report

1. This paper seeks to confirm if there is additional information available since initial rollout of the COVID-19 Pfizer vaccine that would impact on proceeding with the group three at scale and the general population roll out of the COVID 19 Pfizer vaccine

Background

2. Advice is provided to Cabinet on each vaccine cand date as it becomes available for use, without knowing if a future vaccine is going to be more suitable or effective. In order to make decisions given the uncertainty of uture candidate's availability, a Decision to Use framework was developed.

3. The Decision to Use Framework (please see Appendix One), is centred around the following four questions for making decisions on how to use COVID-19 vaccines, who to use them for and when to use them:

    a. what is the context that the decision is being made in?

    b. when do we need to make a decision?

    c. what are the key pieces of information that will build the foundations of our advice?

    d. what are he risks and benefits?

Decision to Use - Pfizer COVID-19 Vaccine

4. Following Medsafe's provisional approval of the Pfizer mRNA COVID-19 vaccine (Comirnaty, BNT162b2) for people 16 years and over on 3 February 2021, the COVID-19 Vaccine Technical Advisory Group (CV TAG) met on 4 February 2021 to provide the scientific and technical assessment of the Pfizer mRNA COVID-19 vaccine, including advice on who is to receive the vaccine.

5. The CV TAG completed a scientific and technical assessment of the Pfizer mRNA COVID-19 vaccine, in order to provide recommendations on its use for New Zealand's Vaccine Immunisation Programme.

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6. Advice was provided to Cabinet which recommended that we proceed with providing access to the Pfizer COVID-19 vaccine in line with the Sequencing Framework, noting the primary limitation of use in those 16 years and over, in line with the Medsafe approval.

7. It was noted that there were no exclusions, or limitations in the advice of the CV TAG that would materially impact on the implementation of the Sequencing Framework and Immunisation Programme.

Progressing to group three at scale and into the general population

8. It was noted that the Ministry of Health would provide further advice on the use of the Pfizer vaccine, alongside the other vaccines in our portfolio, before we start immunising people identified in group three at scale (group three includes people in the community most at r sk of serious illness and the workforces supporting them).

9. Given that we are progressing with group three at scale and then moving into the general population roll out in July, we wish to confirm with the CV-TAG if there is any new information since initial rollout of the Pfizer COVID-19 vaccine that would materially impact on the implementation of the Sequencing Framework and Immunisation Programme at this time. We have attached a summary of the safety data to support your discussion (Appendix Two)

10. The initial decision to use Pfizer for groups one and two was made on a basis that there would be further consideration of other candidat s in our portfolio by the time we were due to roll out to these groups, however, such regulatory decisions remain pending at this point in time.

11. Given the ongoing international context supply risks and increasing evidence around COVID-19 vaccines safety, efficacy and quality and uncertainty around duration, the need for boosters and managing variants of concern we will seek CV-TAG advice on managing these risks in the coming weeks.

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Document 4

Appendix One: Decision to Use Framework

DRAFT Vaccine Portfolio | Decision to use Framework

Our priority is to continue the health response to keep New Zealanders safe from the virus; and to drive the economic recovery from COVID-19.

Vaccine Strategy
Access to a safe and effective vaccine.

Decision Framework
Decide which vaccines to use that will best support the immunization Strategy and Programme

COVID-19 Immunisation Strategy and Programme
Make best use of the COVID-19 vaccines we purchase, while promoting equity and upholding Te Tiriti.

Objective — Ensure the best use of each of the COVID-19 Vaccines in our Portfolio

Decision Framework

1 Context
Q. In what context are we making the decision?

- Risk of COVID-19
- Public Health Measures
- Progress of the COVID-19 Immunisation Programme
- Managing portfolio risk

2 Decision Window
Q. When do we need to make a decision?

- Contract arrangements with suppliers | delivery schedules and purchase arrangements
- Regulatory approval
- Availability of information to support assessment
- Constraints | shelf-life, number of courses
- Understanding the information gaps

3 Inputs
Q. What are the key inputs that will build the foundations of our advice?

- Candidate
- Portfolio

Key sets of information, provided by a wide range of stakeholders that will support a robust assessment

- Equity
- Quality & Safety
- Implementation
- Population Coverage
- Customer Experience
- Fiscal

Advisory Group (Decision to Use)

IIAG

4 Assessment
Q. What are the risks and benefits

- Risks and Mitigations
- Benefits

Each vaccine, will vary: in the approach that is taken, the risks and benefits to use, not use, or wait.

4a Identify the approach
- Identify the approach taken, including who, when and how
- Identify choices that are required for each approach

4b 'Road-test' approach
- Understand the approach for each of the inputs and the sequencing framework / modelling
- Validate through consultation with expert advisory groups
- Assess against principles and objectives

4c Understand outcomes & risk
- Acceptable level of risk identified and agreed
- Establish best, worst and most likely impact

Impact for the Immunisation Programme

Principles

Minimise the health, social, economic and cultural harm of COVID-19 | Regional responsibility | Equal concern | Equity | Value | Legitimacy

Te Tiriti o Waitangi

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Appendix Two: Safety Data 24 May 2021

9(2)(c)

[redacted]

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Approved for release under the Official Information Act 1982

COVID-19 and COVID-19 vaccines in pregnancy- update.

This is an update of a summary of the evidence around the risks of COVID-19 in pregnancy and the advice and safety related to giving the vaccine in pregnancy.

COVID-19 disease

In pregnant people

During pregnancy, the immune system is downregulated to prevent an immune response against the fetal antigens. Particularly affected is the T cell (cellular) immune response that also plays an important role in the response to viral infection, along with the antibody (B cell) response. It is well recognised that pregnancy increases the risk of complications from a viral infection, such as influenza and varicella, and there is good evidence to show that this is also the case for COVID 19.

In pregnancy, COVID-19 carries a substantially increased risk of severe disease requiring intens ve care unit admission (ICU; over 18 times higher than pregnant women without COVID-19) and invasive ventilation support and death (over three times higher), although pregnant or recently pregnant people were not at increased risk of asymptomatic or mild disease[(1)] Risk of more severe disease was further increased by older maternal age, higher body mass index and the presence of pre-existing comorbidities, including diabetes and hypertension.[(1)]

A study in the UK found that maternal respiratory compromise due to COVID-19 resulted in caesarean delivery in almost six out ten of births and one in eight were delivered preterm.[(2)] In the US, the rates of preterm birth were nearly ten times higher (45% vs 5.2%) with severe COVID-19 compared with mild disease.[(3)]

In newborns

For babies of mothers with COVID-19, risk of preterm and neonatal ICU admission is increased, but not the risk of stillbirth or neonatal death. SARS CoV 2 infection in pregnancy does not appear to affect fetal growth, adverse neonatal outcomes or the rate of stillbirth.[(4)] The risk of SARS-CoV-2 infection from the mother to her newborn appears to be small.[(5)] However, a systematic review of SARS-CoV-2 infection in newborns found that, although most were asymptomatic (20%) or had mild (48%) or moderate (20%) signs of COVID-19. A higher proportion were severely unwell (12%), than seen in older children, with dyspnoea the most commonly reported sign.[(6)]

COVID-19 vaccines

Planning pregnancy

A recent non-peer-reviewed study found both SARS-CoV-2 infection and mRNA vaccine (Comirnaty®) induced anti-SARS-CoV-2 IgG antibodies were detected in the ovary follicular fluid and the levels correlated with serum IgG levels. No detrimental effect was seen in follicular function and oocyte quality biomarkers in patients undergoing oocyte retrieval attending an IVF clinic in Israel.[(7)]

In pregnancy

Although the mRNA COVID-19 vaccines were not specifically tested in pregnant people during their initial clinical trials, this is always the case, and key vaccines used in pregnancy (influenza and pertussis) were introduced without specific clinical trials. During preclinical studies in pregnant animals, no toxicity issues were identified for the mRNA vaccines for COVID-19 or for other vaccine candidates based on the same platform such as a Zika virus vaccine.[(8)] There are no specific safety reasons to exclude pregnant people since, based on how these vaccines work, they are unlikely to

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pose risk to a pregnant person or their unborn child. The mRNA COVID-19 vaccine (Comirnaty) does not contain live virus and is unable to give someone COVID-19. In addition, the mRNA in the vaccine cannot enter the nucleus of the cell, it does not interact with human genetic material and breaks down very quickly by the normal processes after entering the cell.

In most countries, any potential risk from the vaccine is balanced against a substantial risk of catching COVID-19 and significant risk of illness to the pregnant person and their infant. Risks are event higher for those with other underlying health conditions. As a result, in recent months more countries have recommended that COVID-19 vaccines be routinely used in pregnancy.

Ongoing safety surveillance and dedicated registers for pregnancy outcomes are monitoring those who have received COVID-19 vaccines in pregnancy (see below for latest data) in several countries There is an international push to get more vaccines developed specifically for use during pregnancy to protect mother and infant or to be tested during pregnancy.[9] Clinical trials have commenced testing these vaccines in pregnant and non-pregnant people, including one for the Comi naty® mRNA vaccine (NCT04754594). One challenge being faced for this type of clinical trial, in countries like the US where there is a high incidence of COVID-19, is that it has become unethical to give placebo and not the vaccine to all the participants (personal communication with Pfizer).

Recent data has shown a protective immune response in people who were vaccinated with mRNA COVID-19 vaccines in pregnancy and protective antibodies were transferred to the infant across the placenta (detected in cord blood at delivery) and in the breastmilk [10, 11] No severe adverse events or complications in pregnancy or in the newborn were observed.[10] The ntibody levels in pregnant and lactating participants were equivalent to those who were not pregnant. The immune response to the vaccine was greater than that to COVID-19 infection.[12] The optimal timing of vaccination is unknown; maternal and neonatal antibody levels wer directly correlated with time since vaccination.[11]

In people who are breastfeeding

All vaccines used on the New Zealand immunisation schedule can be given those who are lactating and breastfeeding. Although there is limited data about the use of the COVID-19 vaccines when breastfeeding, there is no plausible eason for any safety concerns. No intact spike protein enters breastmilk from the maternal circulation and free mRNA is destroyed very quickly by enzymes in the tissues and blood Any intact lipid nanoparticles present in the breastmilk are destroyed by the infant's gastrointestinal tract if ingested.[13]

By giving protection while breastfeeding, immunisation can reduce the risk of the spread of infection to the baby and k ep the mother well so they can fully look after their baby. Recent data has shown vaccination while breastfeeding provides protective antibodies for baby in breastmilk.[10, 12, 14]

Those who have delayed receiving COVID-19 vaccine in pregnancy, are highly recommended to receive it as soon as possible after delivery and do not need to suspend breastfeeding.

Safety surveillance data for COVID-19 vaccines given in pregnancy.

The safety of the mRNA COVID-19 vaccines when given in pregnancy is being monitored globally. The Centers for Disease Control and Prevention (CDC) in the US published data for 14 December 2020 to 28 February 2021 from the 'v-safe After Vaccination Heath Checker' (a smartphone-based reporting system), v-safe COVID-19 Vaccine Pregnancy Registry (linked to v-safe) and the Vaccine Adverse Event Reporting System (VAERS; a passive reporting system).[15] A total of 35,691 v-safe participants

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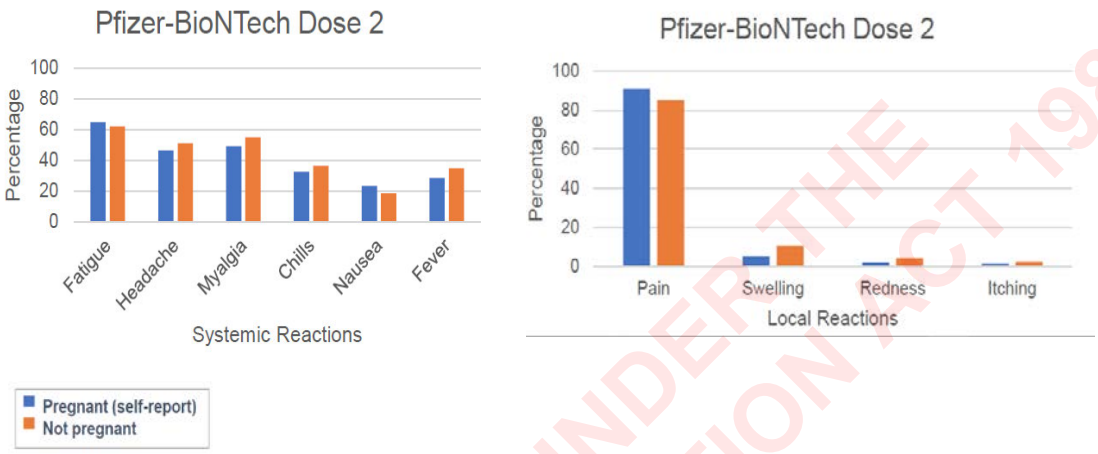
were pregnant at the time of vaccination and just under 4,000 enrolled in the v-safe pregnancy registry (see below).[15]

No significant difference were reported to v-safe between local and systemic reactions by pregnant and non-pregnant after the first or second dose of mRNA vaccine (see Figure 1 for data presented by author to CDC).[15, 16] As seen across all vaccine recipients, injection site pain was the most reported

Figure 1: V-safe systemic and local reaction reports on day 1 post-vaccination in self-reported pregnant and non-pregnant women aged 16-54 years (to 13 Jan 2021; presented by T Shimbukaro, 1 Mar 2021)



response (70-80%) with increasing incidence of fatigue, headache, myalgia and chills after dose 2 – these responses are identical to those reported in New Zealand (Medsafe AEFI reports) and during the pivotal clinical trial in non-pregnant people.[17]

The v-safe pregnancy register actively contacts participants who report they were pregnant at the time of COVID-19 vaccination. Once enrolled, they are contacted once per trimester, after delivery and when infant reaches 3 months of age to monitor for outcomes of interest. Preliminary data showed that compared with known background rates, there was no increase in risk of adverse pregnancy (miscarriage or still birth) or neonatal outcomes (preterm birth, small for gestational age, congenital abnormalities or neonatal death) was seen in those who were vaccinated in the third trimester of pregnancy (see Figure 2).[15, 18] The data is limited for those who were vaccinated earlier in pregnancy because the pregnancies are ongoing and not yet completed.

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Figure 2: V-safe pregnancy registry outcomes of interest in pregnant women vaccinated against COVID-19, as of 18 February 2021 (CDC, presented by T Shimbukaro, 1 Mar 2021)

Outcomes	Background rates*	V-safe pregnancy registry overall
Pregnancy outcome		
Miscarriage (<20 weeks)	26%	15%†
Stillbirth (≥ 20 weeks)	0.6%	1%
Pregnancy complications		
Gestational diabetes	7-14%	10%
Preeclampsia or gestational hypertension§	10-15%	15%
Eclampsia	0.27%	0%
Intrauterine growth restriction	3-7%	1%
Neonatal		
Preterm birth	10.1%	10%
Congenital anomalies‡	3%	4%
Small for gestational age^	3-7%	4%
Neonatal death	0.38%	0%

* Sources listed on slide 33; † 93% of these were pregnancy losses <13 weeks of age; § Pre-eclampsia or gestational hypertension diagnosed during pregnancy and/or during delivery; ‡ Congenital anomalies (overall) diagnosed after delivery only; ^ Birthweight below the 10th percentile for gestational age and sex using INTERGROWTH-21st Century growth standards

Reports to Vaccine Adverse Event Reporting System (VAERS) following vaccination in pregnant women (n=97) found no unexpected response, pregnancy or infant o tcomes with non-pregnancy specific adverse events and miscarriage rates reflected that of th background rates. Vaccine safety in pregnancy will continue to be monitored and bservational studies are ongoing.

One such observational study underway is called COVID-19 Vaccines International Pregnancy Exposure Registry (C-VIPER) to specifically evaluate obstet ic, neonatal and infant outcomes among women vaccinated pregnancy to prevent COVID-19 (NCT04705116).

Further data is anticipated, since as of 15 May 2021, over 270 million doses of COVID-19 vaccine (including 144 million doses of Pfizer and 115 m llion doses of Moderna mRNA vaccines) had been administered in the US in total The UK is also monitoring COVID-19 vaccinations given in pregnancy as part of the UK Vaccines in Pregnancy Surveillance Programme. The latest v-safe data (as of 17 May 2021) shows that almost 115,000 people using v-safe reported being pregnant when they received their COVID 19 vaccination (majority were given a mRNA vaccine) and nearly 5,000 were enrolled on the v-safe vaccine p egnancy registry.

Thrombosis with thrombocytopenia syndrome.

There have been r cent concerns around the risk of newly identified, very rare condition called 'thrombosis with thrombocytopenia syndrome' (TTS) occurring 4 to 20 days after the first dose of adenovirus viral vector COVID-19 vaccines (AstraZeneca and Janssen vaccines). Prior to applying preferred age restrictions, Australia saw six cases (five cases in women under 50 years of age and one aged >80 years) of TTS after around a million doses and the UK has reported 209 cases after 22 million doses of Vaxzevria (AstraZeneca vaccine) – both in the ballpark of one per 100,000 vaccine recipients.

Balancing the current risk from COVID-19 and the vaccine benefits, Australia prefers the mRNA COVID-19 vaccine (Comirnaty) for those aged under 50 years, although, those who have had a first dose of Vaxzevria may complete their immunisation with a second dose. People in the UK have a higher risk from COVID-19, and so age-related risk-benefit has resulted in a preference is to give mRNA vaccines in those younger than 30 years. For pregnant individuals of all ages, mRNA vaccine is

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preferred. No viral vector vaccines are currently approved for use in New Zealand to date, although both AstraZeneca and Janssen vaccines are part of the advanced purchase agreements and Medsafe continues to review the data for these. Note that this syndrome has not been associated with either of the mRNA COVID-19 vaccines.[19]

Conclusions

COVID-19 is associated with a significantly increased risk of preterm delivery and maternal mortality. Enhanced precautions to prevent SARS-CoV-2 infection in pregnancy are required. There is now a large body of evidence from real-life surveillance data with no safety concerns emerging around receiving COVID-19 vaccination in pregnancy with the mRNA vaccines. Decision-making needs to be balanced with the risk of severe disease, particularly in those with underlying health conditions o older age.

Most pregnant people in New Zealand have a very low risk of exposure to COVID-19. The current advice is that those who are at low risk of exposure to COVID-19 may choose to delay vaccination until after delivery. However, was there to be an outbreak of COVID-19 or if the borders open further later in the year, unimmunised pregnant people will be vulnerable to infection, and this change in risk as well as evolving data is likely to alter the current recommendations.

Current international recommendations

(note see below for URLs if hyperlinks are not accessible)

Australia and New Zealand

Royal Australian and New Zealand College of Obstetrics and Gynaecology (RNAZCOG)

[Updated 10 March 2021] "Although the available data do not indicate any safety concern or harm to pregnancy, there is insufficient evidence to recommend routine use of COVID-19 vaccines during pregnancy. However, if a pregnant woman meets the definition of being particularly vulnerable, then she should discuss the option of COVID-19 vacci ation with her obstetrician, GP and/or midwife. This is based on the observation that people with certain underlying medical conditions are at very high risk of experiencing se ious complic tions of COVID-19.

The most likely relevant groups of pregnant women include:

- Significant pre-exi ting medical conditions e.g. diabetes
- Solid organ transplant recipients
- Those with chronic respiratory conditions including cystic fibrosis and severe asthma
- Those who have homozygous sickle cell disease
- Those receiving immunosuppression therapies sufficient to significantly increase risk of infection
- Those receiving dialysis or with advanced chronic kidney disease
- Those with significant congenital or acquired heart disease

Pregnant workforce: RANZCOG recommends that, in settings of high community transmission, health care workers with direct patient contact, and other workers in areas of significantly increased risk of exposure to COVID-19, be allocated to lower risk duties that have reduced risk of exposure to patients with, or suspected to have, COVID-19 infection, working from home or leave of absence. RANZCOG recognises that pregnant women are, appropriately, often anxious about their own health and protective of their unborn baby. Where this is not possible to avoid exposure, pregnant workers who

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are in an at-risk work environment should be offered vaccination. All personnel should observe strict hygiene protocols and have full access to adequate Personal Protective Equipment (PPE).

General advice: All medical advice should be patient-centred and take into account each individual's personal considerations and preferences. In the absence of evidence on the safety or efficacy of the COVID-19 vaccines in pregnant women, the decision to receive vaccination rests solely with the pregnant woman following informed consultation with her midwife and/or doctor."

Canada

Society of Obstetricians and Gynaecologists of Canada

Consensus Statement [reaffirmed 4 May 2021]*:*

1. Pregnant individuals should be offered vaccination at any time during pregnancy or wh le breastfeeding if no contraindications exist.
2. The SOGC supports the use of all available COVID-19 vaccines approved in Canada in any trimester of pregnancy and during breastfeeding in accordance with regional eligibility.
3. The decision to be vaccinated is based on the individual's personal values as well as an understanding that the risk of infection and/or morbidity from COVID-19 outweighs the theorized and undescribed risk of being vaccinated during pregnancy o while breastfeeding.
4. Individuals should not be precluded from vaccination based on pregnancy status or breastfeeding.
5. Given that pregnant people are at increased ri k of morbi ity f om COVID-19 infection, all pregnant persons should be eligible to receive a COVID-19 vaccination.

United Kingdom

Public Health England: [updated 30 April 2021]

The COVID-19 vaccines available in the UK have been shown to be effective and to have a good safety profile. These vaccines do not contain live coronavirus and cannot infect a pregnant woman or her unborn baby in the womb. There is no known risk with giving inactivated virus or bacterial vaccines or toxoids during pregnancy o whilst breast feeding.

The Joint Committee on Vaccination and Immunisation (JCVI) has advised that pregnant women should be offered COVID-19 vaccines at the same time as people of the same age or risk group.

Evidence so far reviewed by the Medicines and Healthcare products Regulatory Agency (MHRA), the UK regulatory agency responsible for licencing medicines including vaccines, has raised no specific concerns for safety in pregnancy. Evidence on COVID-19 vaccines is being continuously reviewed by the World Health Organization and the regulatory bodies in the UK, USA, Canada and Europe.

A leaflet ha been produced by PHE to guide women of child-bearing age, currently pregnant or breastfeedi g. Pfizer and Moderna mRNA vaccines are the preferred vaccines for pregnant women of any age who are receiving their first COVID-19 dose.

Public Health England has also established surveillance (UK Vaccine in Pregnancy Surveillance programme) to monitoring inadvertent vaccination in pregnancy (to include COVID-19 vaccines, varicella, shingles and MMR).

Royal College of Obstetricians and Gynaecologists

COVID-19 Vaccines, pregnancy and breastfeeding [Q&As updated 14 May 2021]:

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- The latest advice [16 Apr 21] from the Joint Committee on Vaccination and Immunisation (JCVI) is that COVID-19 vaccines should be offered to pregnant women at the same time as the rest of the population, based on their age and clinical risk group. Women should discuss the benefits and risks of having the vaccine with their healthcare professional and reach a joint decision based on individual circumstances.
- You should not stop breastfeeding in order to be vaccinated against COVID-19.
- Women trying to become pregnant do not need to avoid pregnancy after vaccination and there is no evidence to suggest that COVID-19 vaccines will affect fertility.
- Having a COVID-19 vaccine will not remove the requirement for employers to carry out a risk assessment for pregnant employees, which should follow the rules set out in this government guidance.

A range of resources have been developed including an information sheet and decision aid for pregnant individuals.

One Q&A that may be considered for the recommendations in New Zealand is:

Q. When in pregnancy can I have the vaccine?

The vaccine should work whatever the stage of pregnancy you are in. The JCVI advises that women do not need a pregnancy test before vaccination, and that women planning a pregnancy do not need to delay pregnancy after vaccination.

However, as COVID-19 has more serious complications later pregnancy, some women may choose to delay their vaccine until after the first 12 weeks (which are most important for the baby's development) and plan to have the first dose at any time rom 13 weeks onwards.

As pregnant women are more likely to be seriously unwell and have a higher risk of their baby being born prematurely if they develop COVID-19 in their third trimester (after 28 weeks), women may wish to have the vaccine before their third trimester

United States

CDC: [updated 14 May 2021]
Pregnant people are more likely to get severely ill with COVID-19 compared with non-pregnant people. If you are pregnant, you can receive a COVID-19 vaccine. Getting a COVID-19 vaccine during pregnancy can p otect you from severe illness from COVID-19. If you have questions about getting vaccinated, a conversat on with your healthcare provider might help, but is not required for vaccination.

American College of Obstetrics and Gynecology (ACOG):[updated 28 Apr 2021]

- ACOG recommends that pregnant individuals have access to COVID-19 vaccines.
- COVID-19 vaccines should be offered to lactating individuals similar to non-lactating individuals.
- Individuals considering a COVID-19 vaccine should have access to available information about the safety and efficacy of the vaccine, including information about data that are not available. A conversation between the patient and their clinical team may assist with decisions regarding the use of vaccines approved under EUA for the prevention of COVID-19 by pregnant patients. Important considerations include:
    - the potential efficacy of the vaccine

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  - the risk and potential severity of maternal disease, including the effects of disease on the fetus and newborn
  - the safety of the vaccine for the pregnant patient and the fetus.
- While a conversation with a clinician may be helpful, it should not be required prior to vaccination, as this may cause unnecessary barriers to access.

Website URLs for hyperlinks

Australia and New Zealand

Medsafe COVID-19: Overview of vaccine reports: https://www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp

Statement: https://ranzcog.edu.au/statements-guidelines/covid-19-statement/covid-19-vaccinatio_-information

Canada

Consensus statement: https://www.sogc.org/common/Uploaded%20files/Latest%20News/SOGC_Statement_COVID-19_Vaccination_in_Pregnancy.pdf

UK

Public Health England Guidance: https://www.gov.uk/gove_nment/publications/safety-of-covid-19-vaccines-when-given-in-pregnancy/the-safety-of-c_vid_19-vaccines-when-given-in-pregnancy

Patient leaflet: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/965391/PHE_COVID-19_vaccination_guide_on_pr_gnancy_English_v3.pdf

Q&A: https://www.rcog.org.uk/en/guidelines-research-services/coronavirus-covid-19-pregnancy-and-womens-health/covid-19-vaccines-and-pregnan_y/covid-19-vaccines-pregnancy-and-breastfeeding/

Decision aid: https://www_rcog.org.uk/globalassets/documents/guidelines/2021-02-24-combined-info-sheet-and-decision-aid_pdf

United States

https://www.cdc_gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html

https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating_patients-against-covid-19

v-safe pregnancy registry: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html

References

1. Allotey J, Stallings E, Bonet M, Yap M, Chatterjee S, Kew T, et al. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis. BMJ. 2020;370:m3320.
2. Knight M, Bunch K, Vousden N, Morris E, Simpson N, Gale C, et al. Characteristics and outcomes of pregnant women admitted to hospital with confirmed SARS-CoV-2 infection in UK: national population based cohort study. BMJ. 2020;369:m2107.

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3. Lokken E, Huebner E, Taylor GG, Hendrickson S, Vanderhoeven J, Kachikis A, et al. Disease Severity, pregnancy outcomes and maternal deaths among pregnant patients with SARS-CoV-2 infection in Washington State. American Journal of Obstetrics and Gynecology. 2021.
4. Mullins E, Hudak ML, Banerjee J, Getzlaff T, Townson J, Barnette K, et al. Pregnancy and neonatal outcomes of COVID-19: co-reporting of common outcomes from PAN-COVID and AAP SONPM registries. Ultrasound Obstet Gynecol. 2021.
5. Walker KF, O'Donoghue K, Grace N, Dorling J, Comeau JL, Li W, et al. Maternal transmission of SARS-COV-2 to the neonate, and possible routes for such transmission: a systematic review and critical analysis. BJOG. 2020;127(11):1324-36.
6. Liguoro I, Pilotto C, Bonanni M, Ferrari ME, Pusiol A, Nocerino A, et al. SARS-COV-2 infection in children and newborns: a systematic review. European Journal of Pediatrics. 2020;179(7):1029-46.
7. Bentov Y, Beharier O, Moav-Zafrir A, Kabessa M, Godin M, Greenfield CS, et al. Ovarian follicular function is not altered by SARS-Cov-2 infection or BNT162b2 mRNA Covid-19 vaccination. medRxiv. 2021:2021.04.09.21255195.
8. Pardi N, Hogan MJ, Porter FW, Weissman D. mRNA vaccines - a new era in vaccinology Nat Rev Drug Discov. 2018;17(4):261-79.
9. Abu-Raya B, Maertens K, Edwards KM, Omer SB, Englund JA, Flanagan KL, et al. Global Perspectives on Immunization During Pregnancy and Priorities for Future Resea ch and Development: An International Consensus Statement. Front Immunol. 2020;11:1282.
10. Collier AY, McMahan K, Yu J, Tostanoski LH, Aguayo R, Ansel J, et al. mmunogenicity of COVID-19 mRNA Vaccines in Pregnant and Lactating Women. JAMA. 2021.
11. Rottenstreich A, Zarbiv G, Oiknine-Djian E, Zigron R Wolf DG, Porat S. Efficient maternofetal transplacental transfer of anti- SARS-CoV-2 spike antibodies after antenatal SARS-CoV-2 BNT162b2 mRNA vaccination. medRxiv. 2021 (Preprint):2021.03.11.21253352.
12. Gray KJ, Bordt EA, Atyeo C, Deriso E, Akinwunmi B, Young N, et al. COVID-19 vaccine response in pregnant and lactating women: a cohort study. American Journal of Obstetrics and Gynecology. 2021.
13. Drugs and Lactation Database (LactMed) COVID-19 vaccines. [Internet]Bethesda (MD): National Library of Medicine (US); 2006- [19 Apr 2021. Available from: https://www.ncbi.nlm.nih.gov/books/NBK565969/
14. Perl SH, Uzan-Yulzari A, Klainer H, Asiskovich L, Youngster M, Rinott E, et al. SARS-CoV-2-Specific Antibodies in Brea Milk After COVID-19 Vaccination of Breastfeeding Women. JAMA. 2021.
15. Shimabukuro TT, Kim SY, Myers TR, Moro PL, Oduyebo T, Panagiotakopoulos L, et al. Preliminary Findings of mRNA Covid 19 Vaccine Safety in Pregnant Persons. N Engl J Med. 2021.
16. Shimbabukuro T, CDC-COVID-19 Vaccine Task Force. COVID-19 vaccine safety update. March 2021. 2021 1 March 2021 Available from: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf
17. Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. 2020;383(27):2603-15.
18. Shimbabukuro T, CDC-COVID-19 Vaccine Task Force. COVID-19 vaccine safety update. Februa y 2021. 2021 27 January 2021.Available from: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-1-27-21.html
19. World Health Organization. Global Advisory Committee on Vaccine Safety (GACVS) review of latest evidence of rare adverse blood coagulation events with AstraZeneca COVID-19 Vaccine (Vaxzevria and Covishield) 2021 [updated 16 April 2021; cited 21 May 2021]. Available from: https://www.who.int/news/item/16-04-2021-global-advisory-committee-on-vaccine-safety-(gacvs)-review-of-latest-evidence-of-rare-adverse-blood-coagulation-events-with-astrazeneca-covid-19-vaccine-(vaxzevria-and-covishield))

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Draft statement on Long-term effects of Pfizer vaccine – for CVTAG review

Long-term safety of Pfizer vaccine

Medsafe independently reviewed the data on safety, quality and efficacy of the Pfizer vaccination and approved it for use. This approval followed the same rigorous process that is used for all previously approved medicines (including vaccines) currently licenced for use in New Zealand.

Based on the scientific understanding of how the Pfizer vaccine works, there have not been any long-term effects predicted. However, Medsafe continues to monitor any side effects of the Pfizer vaccine reported in New Zealand or from other countries where the Pfizer vaccine is in use. No long-term effects have been suggested from this monitoring.

Additional information on the Pfizer vaccine's long-term effectiveness, safety, and side effects is expected from ongoing clinical trials, including trials in pregnant women and children. Participants from the initial clinical trials are also being monitored for 2 years from their second dose of the Pfizer vaccine with regular follow-up visits until 2023. Data from these trials is shared by Pfizer/BioNTech with Medsafe and is being closely monitored.

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Strawman Statement

The new recommendation

We recommend that women/people who are pregnant are routinely offered COVID-19 vaccination at any stage of pregnancy. International surveillance data of large numbers of pregnant people indicate that there are no safety concerns with administering COVID vaccine in any stage of pregnancy. Furthermore, the risk of an adverse outcome from Covid-19 infection during pregnancy is significantly higher compared to non-pregnant adults. There is also evidence of antibody transfer in cord blood and breast milk which can offer protection to infants through passive immunity. Pregnant women/people are encouraged to discuss with their whānau and their LMC the decision to vaccinate or delay until after the baby is born.

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