



GUIDELINES ON COVID-19 VACCINATION IN PREGNANCY AND BREASTFEEDING

Ministry of Health, Malaysia

Version 2

23rd June 2021



Updates

I	Safety and efficacy of MRA vaccines among pregnant and breastfeeding mothers
II	Recommendations on Oxford/AstraZeneca, Sinovac, CanSino and Janssen vaccines in pregnancy and breastfeeding
III	Mixing of different types of vaccines in pregnancy and breastfeeding
IV	Simultaneous/co-administration of other types of vaccines in pregnancy
V	Combined oral hormonal contraception and Oxford/AstraZeneca vaccine
VI	Flowcharts on pre & post vaccine assessment of antenatal mothers

Content

No	Title
I	Key recommendations
II	Summary of updates
III	Rationale for COVID-19 Vaccination in pregnancy
IV	Safety & efficacy of COVID-19 Vaccines among pregnant and breastfeeding mothers
V	Pre-pregnancy Care
VI	COVID-19 Vaccines and Fertility
VII	Timing of first vaccination dose in the antenatal period
VIII	Conceiving prior to completion of vaccination
IX	Simultaneous / co-administration of other types of vaccines in pregnancy
X	Vaccination and breastfeeding
XI	Combined Oral hormonal contraception and Oxford/AstraZeneca vaccine
XII	Vaccination after Covid-19
XIII	Care of women declining Covid-19 vaccination

Appendix	
I	Infographics on Covid-19 vaccination in pregnancy & breastfeeding
II	Consent form
III	Flowcharts on pre and post vaccination assessment
IV	Guidelines Committee

Key Recommendations

- 1) Pregnant mothers are considered vulnerable and are susceptible to severe COVID-19 infections, especially in the second and third trimester.
- 2) Front liners and those with underlying medical illnesses are at a higher risk of COVID-19 infections. Maternal age of ≥ 40 and BMI $\geq 40\text{kg/m}^2$ are among identifiable risk factors for severe COVID-19 infection in pregnancy.
- 3) COVID-19 vaccination should be advocated in pre-pregnancy care, especially for front liners and mothers with identifiable risk factors and also those seeking infertility treatment.
- 4) Although most pregnant mothers are asymptomatic, the need for ICU admission and mechanical ventilation are higher, particularly with infection by the newer variants of concern. Severe infections in pregnancy are associated with higher risk of pulmonary embolism, iatrogenic prematurity, stillbirth and maternal mortality.
- 5) Protecting pregnant mothers who are vulnerable, especially those with identifiable risk factors remain a health care priority for vaccination.
- 6) Based on virology principles, mRNA, vector-based and inactivated vaccines are not contraindicated among pregnant or breastfeeding mothers. Although evidence continues to emerge as more pregnant mothers are included in the study cohort, current data suggests that mRNA vaccines are the preferred option. Live vaccines are contraindicated in pregnancy.
- 7) The evidence with regards to mixing various types of vaccines and intervals are still being evaluated and until further evidence is available, is it best clinical practice to administer the similar type of vaccine especially among pregnant and breastfeeding mothers.
- 8) The benefits of COVID-19 vaccines with regards to neonatal protection continues to be evaluated. Current evidence suggests that other routine vaccinations such as Influenza and TDAP can also be safely administered simultaneously without a need for delay or interval between vaccines.
- 9) Routine pregnancy screening with urine pregnancy test prior to vaccination is not recommended. Vaccination of girls below the age of 18 should be based on an individualized risk assessment and approval by the Ministry of Health (MOH). The FDA has recently approved the use of the vaccines among those above 12 years of age.

Summary of Updates

1) Pregnant mothers remain a vulnerable group

As we continue to review the mortality and morbidity related to COVID-19 infection among pregnant and breastfeeding mothers in Malaysia, they remain a vulnerable group and it is our priority to vaccinate pregnant and breastfeeding mothers.

2) Safety of mRNA vaccines in pregnancy

Based on a recent publication using the “V-safe after vaccination health checker”, no safety signals were associated with mRNA COVID-19 vaccines. This is coherent with the MOH guidelines recommending the Pfizer vaccine among pregnant and breastfeeding mothers in Malaysia. The side effects reported were uncommon, mild, transient and treatable.

Ref: Shimabukuro TT, Kim SY, Myers TR, et al. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. N Engl J Med 2021; 384:2273-2282

3) Efficacy of vaccines in pregnancy and breastfeeding

Levels of antibody produced after vaccination with mRNA COVID-19 vaccine is comparable to non-pregnant mothers. This vaccine-induced immune response results in higher antibody titres than natural SARS-CoV-2 infection and is detectable in the cord and breast milk. Whether this confers any protective benefits remains to be seen.

Ref: Gray KJ, Bordt EA, Atyeo C, et al. Coronavirus disease 2019 vaccine response in pregnant and lactating women: a cohort study. Am J Obstet Gynecol. 2021; S0002-9378(21)00187-3. doi:10.1016/j.ajog.2021.03.023



4) First dose of the vaccine is to be administered between 14-33 weeks of pregnancy

Out of an abundance of caution, avoiding vaccination during the critical period of organogenesis in the first trimester is sensible. As the principle of vaccination is to confer protection before the vulnerable late second and third trimester, the current recommendation to administer the first dose of the vaccine during this period remains. The second dose can be administered beyond 33 weeks, based on the specific vaccine's schedule.

However, vaccination beyond 33 weeks is not an absolute contraindication and can be considered on a case-to-case basis, following individualized risk and benefit assessment.

5) Use of Oxford/AstraZeneca among pregnant and breastfeeding mothers

The Oxford/AstraZeneca vaccine is not contraindicated in pregnancy as it is not a live vaccine. It is best to discuss this with their doctors in order to weight the benefits and risks before making an informed decision.

Although there are no reported concerns with the use of Oxford/AstraZeneca vaccine among pregnant and breastfeeding mothers, there is less published data on this vector-based vaccine compared to the mRNA vaccine. Thus, mRNA-based vaccines such as Pfizer-BioNTech remain the preferred option.

In women who received their first dose of the Oxford/AstraZeneca vaccine and were later confirmed to be pregnant, the recommendation is to receive the second dose of the same vaccine, after 14 weeks of gestation. Vaccine-induced thrombotic thrombocytopenia risk (VITT) is highest following the first dose as compared to the second dose. Furthermore, there is limited evidence with regards to the benefits and implications of mixing different types of vaccines at the time of writing.

It is not contraindicated among breastfeeding mothers, and the WHO Strategic Advisory Group of Experts on Immunization (SAGE) interim guidelines on Oxford/AstraZeneca does not recommend discontinuation of breastfeeding following vaccination.

6) WHO interim guidelines on Sinovac in pregnancy

Coronovac, developed by Sinovac is recommended in pregnancy and breastfeeding mothers as the benefits outweighs the potential risk from the vaccine, despite the lack of safety data related to the use of Sinovac in pregnancy. In principle, live vaccines are contraindicated in pregnancy while Sinovac, being an inactivated vaccine is not.

However, the most robust data available involves the Pfizer-BioNTech mRNA vaccine, where more than 124,000 women were reportedly pregnant at the time of vaccination as of 14th June 2021. Of these, 5100 are involved and enrolled in a registry. The MOH currently recommends the mRNA vaccine as the preferred option, although this may change as new information and data are made available.

In women who have taken the Sinovac vaccine and were later confirmed to be pregnant, it is recommended to take the second dose after 14 weeks of gestation, as the vaccine is not contraindicated in pregnancy. The benefits, safety and efficacy of mixing vaccines in pregnancy is yet to be established.

Ref: World Health Organization. Interim recommendations on the use of inactivated Covid-19 vaccine, Coronovac, developed by Sinovac. 24th May 2021

7) CDC update on co-administration of anti-tetanus toxoid and COVID-19 Vaccines.

The initial recommendation was to defer COVID-19 vaccine for a minimum period of 14 days after administration of another vaccine, such as anti-tetanus toxoid (ATT). However, the experience following the COVID-19 vaccinations now demonstrates that the immunogenicity and adverse profiles are similar and tolerable. The updated CDC recommendations now states that co-administration of vaccines, including on the same visit is acceptable.

Ref: Centers for Disease Control Prevention. Interim clinical considerations for the use of Covid-19 vaccines currently authorized in the United States.



8) Pregnancy and fertility following vaccination

Existing literature remain consistent in stating that all types of COVID-19 vaccines do not affect fertility or future reproductive health. Women who have completed their vaccination can safely embark on pregnancy without delay. However, contraception is recommended between the first and second dose of vaccine.

9) Mixing vaccines and change of dosing interval

The implications of mixing different types of vaccines and changing of dosing interval is still being evaluated in clinical trials and until more robust evidence is available, it is reasonable to maintain the same type of vaccine for now. This is particularly sensible in pregnancy and breastfeeding. The COM-COV trial is one of a handful of trials evaluating the efficacy of mixing vaccines (heterologous schedule) and interim data has shown a higher reactogenicity with Oxford/AstraZeneca and Pfizer-BioNTech. However, the findings may not be applicable to pregnant women since the cohort involved patients above the age of 50.

Ref: Shaw R, Stuart A, Greenland M, et al. Heterologous prime-boost COVID-19 vaccination: Initial reactogenicity data. Lancet 2021. /doi.org/10.1016/S0140-6736(21)01115-6

10) Combined hormonal contraception and Oxford/AstraZeneca

The Faculty of Sexual Reproductive Healthcare (FSRH) of the Royal College of Obstetricians and Gynaecologists (RCOG), does not recommend discontinuation of combined oral hormonal contraception before or immediately after vaccination, in spite of the rare association between the Oxford/AstraZeneca vaccine and VITT. Temporary discontinuation does not render protection against the rare incidence of thrombosis yet increases the risk of unplanned pregnancies. If patients are concerned of their risk and medications, it is best to consult with their doctors first without discontinuing medications and existing contraceptive practices.



11) Vaccination for adolescent mothers above the age of 12 years

The pandemic has seen more than 1.6 million adolescents aged 12-17 in the United States being infected by SARS-CoV2 as of May 2021. This constituted 9% of infections in the country. The efficacy and immunogenicity with mRNA vaccine has already been demonstrated in a randomized clinical trial involving over 2200 adolescents aged 12-15 years old. In fact, as of 31st May 2021, 46,533 adolescents in this age group have been vaccinated in US. The CDC has since expanded the use COVID-19 vaccine to this age group.

The association with myocarditis and pericarditis remains rare and continues to be evaluated. Nevertheless, if an adolescent pregnant mother has significant identifiable risk factors in pregnancy and is flagged as high risk in pregnancy or during breastfeeding, the benefits of vaccinations should be discussed with the patient and family members or guardians. Standard requirement of consent for those below the age of 18 would apply.

Ref: US Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee. 10th June 2021.

Advisory Committee on Immunization Practices. ACIP Evidence to Recommendations for Use of Pfizer-BioNTech COVID-19 Vaccine under an Emergency Use Authorization.

12) Deployment of pregnant or breastfeeding front liners

Pregnant or breastfeeding front liners with no additional risk factors and who have completed their vaccination can continue to provide essential services. This includes direct involvement in managing COVID-19 patients up till the late third trimester as their services are critical with the surge in cases in the country.

13) Single dose vaccines in Malaysia – CanSino & Janssen Vaccines

Malaysia has recently granted conditional approval for the emergency use of two vaccines, produced by CanSino Bio and Janssen. Both are vector-based vaccines and therefore, not contraindicated in pregnancy. However, in view of the limited safety data in pregnancy, the preferred vaccine for pregnant and breastfeeding mothers remains the mRNA vaccine.

Rationale for COVID-19 Vaccination in pregnancy

Pregnant and recently pregnant women with COVID-19 infection are more likely to require intensive care unit admission (1.62, 1.33 to 1.96; $I^2=0\%$; 4 studies; 91606 women) and invasive ventilation (1.88, 1.36 to 2.60; $I^2=0\%$; 4 studies; 91606 women) as compared to non-pregnant women of reproductive age.¹

These findings were consistent with data from the ongoing prospective COV19Mx cohort in Mexico, where propensity score matching was used to adjust for other risk factors or co-morbidities. Amongst the 5183 pregnant and 5183 non-pregnant matched women, pregnant women had a higher odds of death (odds ratio (OR), 1.84; 95% CI, 1.26–2.69), pneumonia (OR, 1.86; 95% CI, 1.60–2.16) and ICU admission (OR, 1.86; 95% CI, 1.41–2.45) than non-pregnant women. The odds of intubation however, were similar (OR, 0.93; 95% CI, 0.70–1.25).²

Severe illness appears to be more common in the second and third trimester. In the UKOSS study, most women were hospitalized in their third trimester or peripartum (n = 342, 81%). The median gestational age at hospital admission was 34+0 weeks of gestation (interquartile range [IQR] 29–38 weeks).³ A retrospective multicentre study involving 190 women from France and Belgium also showed that women were five times more likely to be admitted to the ICU in the second half, compared to the first half of pregnancy.⁴

The overall rate of preterm birth was 17% (13 to 21%; 30 studies; 1872 women), although the majority were iatrogenic, including to facilitate ventilation. This was a 3-fold increase compared to pregnant women without disease.¹ In another cohort of 64 pregnant women with severe or critical COVID-19 disease, up to 75% of women delivered preterm.⁵ Spontaneous preterm birth rate was 6% (3% to 9%; $I^2=55\%$; 10 studies; 870 women).¹

Thus, vaccinating pregnant mothers with identifiable risk factors not only reduces maternal morbidity and mortality but also reduces fetal morbidity from preterm deliveries.

Safety and efficacy of COVID-19 vaccines among pregnant and breastfeeding mothers

Despite the lack of involvement of pregnant women in the initial clinical trials during development of COVID-19 vaccines, contemporary scientific knowledge indicates that COVID-19 vaccinations among pregnant and breastfeeding mothers are likely to be safe. There is no known risk with giving inactivated virus or bacterial vaccines or toxoids during pregnancy or whilst breast-feeding. Furthermore, pregnant women have been receiving vaccines such as tetanus toxoid, influenza and pertussis vaccination (TDaP) without demonstrable harm to the fetus.⁶

Both the Pfizer-BioNTech and Moderna are mRNA-based vaccines which builds “spike proteins”, mimicking the surface protein of SARS-COV-2 to trigger an immune response. These vaccines do not contain live SARS-CoV-2 and hence is not infective to the pregnant mother and her fetus.

Based on the recent New England Journal of Medicine (NEJM) publication using the V-safe after vaccination health checker, the study concluded that mRNA vaccines were safe to be used during pregnancy without any significant safety signals and this is coherent with the MOH guidelines recommending the Pfizer vaccine among pregnant and breastfeeding mothers in Malaysia. The side effects were uncommon, mild, transient and treatable.

Studies show that the efficacy of the mRNA vaccine is similar in pregnancy as compared to non-pregnant mothers. Although the vaccine induced immune response fared better as compared to those with natural COVID-19 infection, the risk of infection to the fetus is insignificant although the protective benefits remain to be evaluated.

Although there are no reported concerns with regards to the use of Oxford/AstraZeneca vaccine among pregnant and breastfeeding mothers, there is less experience with regards to the use of this vector-based vaccine as compared to the mRNA vaccine. Thus, Pfizer or the mRNA-based vaccine remains the preferred option based on the availability of safety data by the Ministry of Health, Malaysia.



If pregnant mothers are keen to take Oxford/AstraZeneca vaccines in pregnancy, while not contraindicated in pregnancy as it is not a live vaccine, it is best to discuss with their doctors as to weigh the benefits and risk before making an informed decision.

However, the Oxford/AstraZeneca is not contraindicated among breastfeeding mothers, and the WHO Strategic Advisory Group of Experts on Immunization (SAGE) interim guidelines on Oxford/AstraZeneca does not recommend discontinuation of breastfeeding following vaccination.

Coronavac, developed by Sinovac is recommended in pregnancy and breastfeeding mothers as the benefits outweighs the potential risk from the vaccine, despite the lack of safety data related to the use of Sinovac in pregnancy. In principle, live vaccines are contraindicated in pregnancy while Sinovac, being an inactivated vaccine is not.

However, the most robust data available involves the Pfizer-BioNTech mRNA vaccine, where more than 124,000 women were reportedly pregnant at the time of vaccination as of 14th June 2021. Of these, 5100 are involved and enrolled in a registry. The MOH currently recommends the mRNA vaccine as the preferred option, although this may change as new information and data are made available.

In women who have taken the Sinovac vaccine and were later confirmed to be pregnant, it is recommended to take the second dose after 14 weeks of gestation, as the vaccine is not contraindicated in pregnancy. The benefits, safety and efficacy of mixing vaccines in pregnancy is yet to be established.

Women who develop fever after vaccination should be counseled on taking acetaminophen, which is safety in pregnancy and does not alter the immunologic response towards COVID-19 vaccine.

Pre-pregnancy care

All women with identifiable risk factors should be advised to complete their vaccination before embarking on a pregnancy.

Routine pregnancy screening using urine pregnancy test prior to vaccination is not recommended. There are concerns that such measures may increase vaccine hesitancy and put off women against vaccination. It is essential to check for prior allergy risk and those declining vaccinations should be given more information on the benefits and safety of COVID-19 vaccination. Those who are considered vulnerable include:

Age \geq 40

BMI \geq 40kg/m²

Cardiac disease

Significant lung condition e.g. Tuberculosis/ Severe asthma

Moderate and severe renal diseases

Connective tissue diseases such as SLE, Sjogren's Syndrome

Severe anemia

HIV patients

Patients with liver diseases – including Hepatitis B patients on antiviral

Patients on immunosuppressive therapy

Organ transplantation (including bone marrow / stem cell)

Currently undergoing cancer treatment

History of splenectomy / Asplenia

Pulmonary embolism or other underlying medical diseases

COVID-19 Vaccines and Fertility

While fertility was not specifically studied in the clinical trials, no loss of fertility has been reported among trial participants or among the millions who have received the vaccines since their authorization. Furthermore, no signs of infertility appeared in animal studies.¹⁶

There are different viewpoints with regards to the need to postpone conception after vaccination. The American Society for Reproductive Medicine (ASRM) does not recommend delaying pregnancy attempts because of COVID-19 vaccination, including women undergoing fertility treatment. The European Society of Human Reproduction and Embryology (ESHRE) however, recommends a more cautious approach. It suggests postponing the start of assisted reproduction treatments (sperm collection, ovarian stimulation, embryo transfer) for at least a few days after the completion of vaccination (i.e., after the second dose) to allow time for the immune response to settle. It also adds that in the absence of information on the effect of the COVID-19 vaccine on oocytes and sperm, embryo implantation and early stages of pregnancy, and to allow time for antibody development, a more cautious approach could be considered (i.e., postpone the start of ART treatment for up to 2 months).^{17,18}

Front line workers, including non-healthcare workers who are at increased risk of repeated exposure to SARS-COV-2 due to the nature of their occupation, should ideally be vaccinated against COVID-19 particularly, if pregnant.

Timing of first vaccination dose in the antenatal period

Vaccinating women early in pregnancy in the setting of a pandemic offers increased emergent protection against the virus. However, such a strategy also potentially reduces the rate of protection towards the end of pregnancy. There is still uncertainty about the duration of protection after completion of the second dose vaccine.

Vaccinating women in the second half of pregnancy protects women against COVID-19 disease which has been associated with greater morbidity in the third trimester.

On the other hand, the first trimester is also a period of great uncertainty for some women and the risk of complications such as miscarriage is also highest. Despite the lack of evidence of harm on fetal/embryonal development from the developmental and reproductive toxicity (DART),⁸ out of an abundance of caution to avoid suspicion of connection, even coincidental, between pregnancy and fetal harm, in our opinion, it is reasonable to begin vaccination after the first trimester.

Conceiving prior to completion of vaccination

Women who conceive or find out about their pregnancy after the first dose of vaccination (and prior to the second dose) should be reassured about the overall safety of COVID-19 vaccines based on developmental and toxicity studies (DART).⁸ Based on the recent NEJM study, although rates of miscarriage was slightly increased, pregnancy complications such as gestational diabetes and preeclampsia, preterm birth, congenital anomalies and neonatal death were no higher than background rates.²²

Therefore, pregnant women could be given one of these three options:

Options	Recommendations
Defer second dose till 14 weeks of gestation	Although the manufacturer recommends an interval of no longer than 6 weeks for Moderna/Pfizer for optimal immune response, the UK Joint Committee on Vaccination and Immunization (JCVI) has recommended delaying the 3 week interval to up to 12 weeks, based on the short term effectiveness quoted below. ²³ This is in part, to facilitate rapid high level uptake of the vaccine
Omit second dose	Short term effectiveness of 52-89% has been reported after a single dose of vaccine, although the duration of this protection remains uncertain. ^{24,25}
Continue second dose as scheduled	If pregnant women are at high risk of severe disease or repeated exposure to SARS-COV-2, they may choose to continue receiving the 2 nd dose of vaccine as scheduled, based on the current safety data reported from v-safe. ²²



For those who have completed their first dose of the Oxford/AstraZeneca vaccine and were later confirmed to be pregnant, the recommendation is to take the second dose of the same vaccine after 14 weeks of gestation. Vaccine-induced thrombotic thrombocytopenia risk (VITT) is highest following the first dose as compared to the second dose. Furthermore, there is limited evidence with regards to the benefits and implications of mixing different types of vaccines at the time of writing.

Similarly, for mothers who have received the Sinovac vaccine and were later confirmed to be pregnant, it is recommended to delay the second dose beyond 14 weeks of gestation as the vaccine is not contraindicated in pregnancy while the benefits, safety and efficacy of mixing vaccines in pregnancy is yet to be established.

Simultaneous / co-administration of other types of vaccines in pregnancy

The initial recommendation was to defer COVID-19 vaccine for a minimum period of 14 days after administration of another vaccine, such as anti-tetanus toxoid (ATT). However, the experience following the COVID-19 vaccinations now demonstrates that the immunogenicity and adverse profiles are similar and tolerable. The updated CDC recommendations now states that co-administration of vaccines, including on the same visit is acceptable.

Similarly, in women who are Rhesus negative and have not been sensitized, anti-D immunoglobulins can be administered as per routine without a need to delay COVID-19 vaccination.

Vaccination and breastfeeding

Many lactating women fall into categories prioritized for vaccination, such as front-line health care workers. Both the WHO Interim Guidance on the use of mRNA-1273 (Moderna) and the Academy of Breastfeeding Medicine do not recommend cessation of breastfeeding for individuals who are vaccinated against COVID-19. Similar to pregnant mothers who were excluded from COVID-19 vaccine trials, there is currently little data for nursing mothers. However, there is little biological plausibility that the vaccine will cause harm and antibodies to SARS-CoV-2 in milk may protect the breastfeeding child.

The vaccine is made of lipid nanoparticles that contain mRNA for the SARS-CoV-2 spike protein, which stimulate an immune response, protecting the individual from COVID-19 illness. During lactation, it is unlikely that the vaccine lipid would enter the blood stream and reach breast tissue. If it does, it is even less likely that either the intact nanoparticle or mRNA would transfer into milk. In the unlikely event that mRNA is present in milk, it would be expected to be digested by the child and would be unlikely to have any biological effects.

While there is little plausible risk for the child, there is a biologically plausible benefit. Antibodies and T-cells stimulated by the vaccine may passively transfer into milk. Following vaccination against other viruses, IgA antibodies are detectable in milk within 5 to 7 days. Antibodies transferred into milk may therefore protect the infant from infection with SARS-CoV-2.¹⁵

A critical benefit to vaccinating pregnant mothers against pertussis and to a lesser extent, influenza in the third trimester is that the vaccine protects the infant for several months after birth by the transplacental transfer disease-specific serum immunoglobulin G. In this way, antenatal vaccination helps protect not only the mother but also provides neonatal protection. In contrast, the transfer of SARS-COV-2 maternal antibodies to the infant is inefficient when compared to vaccine-induced influenza antibodies. Therefore, it is unlikely that COVID-19 vaccination will provide protection to newborns. No vaccines are currently available to infants or young children.^{9,14}

Combined oral hormonal contraception &Oxford/AstraZeneca

The Faculty of Sexual Reproductive Healthcare (FSRH) of the Royal College of Obstetricians and Gynaecologists (RCOG), does not recommend discontinuation of combined oral hormonal contraception before or immediately after vaccination, in spite of the rare association between the Oxford/AstraZeneca vaccine and VITT. Temporary discontinuation does not render protection against the rare incidence of thrombosis yet increases the risk of unplanned pregnancies. If patients are concerned of their risk and medications, it is best to consult with their doctors first without discontinuing medications and existing contraceptive practices.

Vaccination after COVID-19 infection

Some degree of natural immunity is gained after infection with SARS-COV-2 virus. However, it is uncertain how long this immunity might last, although reinfection appears uncommon within 6 months of a PCR-confirmed SARS-COV-2 infection.¹³

Due to the potentially severe health risks posed by COVID-19 and its widespread extent, women who are at risk should still be considered for vaccination against COVID-19.

Care for women declining COVID-19 Vaccination

Women who are at risk but decline vaccination should have an opportunity for further discussion with an Obstetrician and Gynaecologist. This should be documented in their clinical notes. In addition, general measures for prevention of infection such as avoidance of crowds and unnecessary travel, use of a 3-ply mask in public areas, hand hygiene and compliance to standard operating procedures issued by the Ministry of Health should be reinforced.

COVID-19 VACCINATION IN PREGNANCY AND BREASTFEEDING

1 IS IT SAFE IN PREGNANCY?

There is increasing evidence that Covid-19 vaccination is safe in pregnancy.

2 WHO SHOULD GET VACCINATED?

All pregnant mothers are susceptible to severe complications from Covid-19. Therefore, vaccination is recommended particularly in women with risk factors such as age above 40, BMI above 40 or have underlying medical diseases.

3 WHEN SHOULD I GET MY VACCINE?

Ideally the first dose of Covid-19 vaccine should be given between 14 to 33 weeks. Feel free to consult your doctor if your pregnancy is outside this time frame for more information.

4 CAN I BREASTFEED MY BABY?

It is safe to breastfeed after receiving the Covid-19 vaccine as it does not contain live virus. Cessation of breastfeeding is therefore unnecessary.

5 DOES THE VACCINE PROTECT MY BABY FROM COVID-19 INFECTION??

Although antibodies have been found in breastmilk, we are unsure if this protects the baby from Covid-19 infection.

6 WHAT ARE THE SIDE EFFECTS?

Side effects are transient, uncommon and easily treatable. This includes pain at the injection site, headaches, chills, fatigue and muscle ache.

7 CAN I RECEIVE OTHER VACCINES SIMULTANEOUSLY?

Yes, you can receive other routine antenatal vaccines simultaneously.

8 IF I AM PLANNING TO GET PREGNANT, DO I NEED THE COVID-19 VACCINE?

Yes, since there is a higher risk of getting severe COVID-19 infection in pregnancy. It is recommended to complete vaccination before embarking on a pregnancy.

9 WHAT IF I PREVIOUSLY HAD COVID-19?

Vaccination is also recommended regardless of previous Covid-19 disease. If you have recovered more than 6 months ago, you are unlikely to have protective antibodies.

10 WHAT IF I HAVE ALLERGIES?

Women with severe allergies or previous anaphylactic reactions should consult a physician prior to receiving the vaccine.

Source: Guidelines on Covid-19 vaccination in pregnancy and breastfeeding.

CONSULT YOUR DOCTOR IF YOU HAVE
ANY QUESTIONS REGARDING COVID-19
VACCINATION IN PREGNANCY TODAY.



JUNE
2021



CONSENT FOR COVID-19 VACCINATION DURING PREGNANCY

Name of proposed intervention

COVID-19 Vaccination during pregnancy (Between 14 to 33 weeks of pregnancy)

Intended benefits

To reduce the risk of severe COVID-19 infection in pregnancy, particularly among high risk mothers

To reduce the risk of COVID-19 infection amongst pregnant frontline workers who are at increased risk of exposure to SARS-COV-2

Frequent Risks associated with COVID-19 Vaccination

- | | |
|-------------------------------|----------------|
| i) Pain at the injection site | iv) Fatigue |
| ii) Headache | v) Muscle ache |
| iii) Chills | |

**Your risk may be higher if you are known to have severe allergies or previous anaphylactic reasons. Consult your doctor first.*

Serious Risks

A) Maternal risk

Studies among non-pregnant women has shown that serious risks, including anaphylaxis and death from vaccinations are very rare. While there is a lack of safety data among pregnant mothers at this moment, there are no reasons to believe this would differ.

B) Fetal risk

No safety concerns have been found in experimental animal studies. However, there is no direct or long term safety data on COVID-19 vaccinations to the fetus.

Alternative options

I understand that I have the option to decline vaccination during pregnancy in view of safety concerns but this may increase my risk of having severe COVID-19 infections, especially if I am considered high risk, which includes ICU admissions, need for ventilation, stillbirth, prematurity and death.

Patient information

I have been given information and resources on COVID-19 including the benefits and risk of having vaccinations in pregnancy. I have been given sufficient time to make my informed decision. I also have been counselled on the various type of available vaccines and its benefits.

I hereby consent to have the COVID-19 vaccination during pregnancy.

Signature of Mother:

Name:

Identification No:

Signature of Doctor

Name:

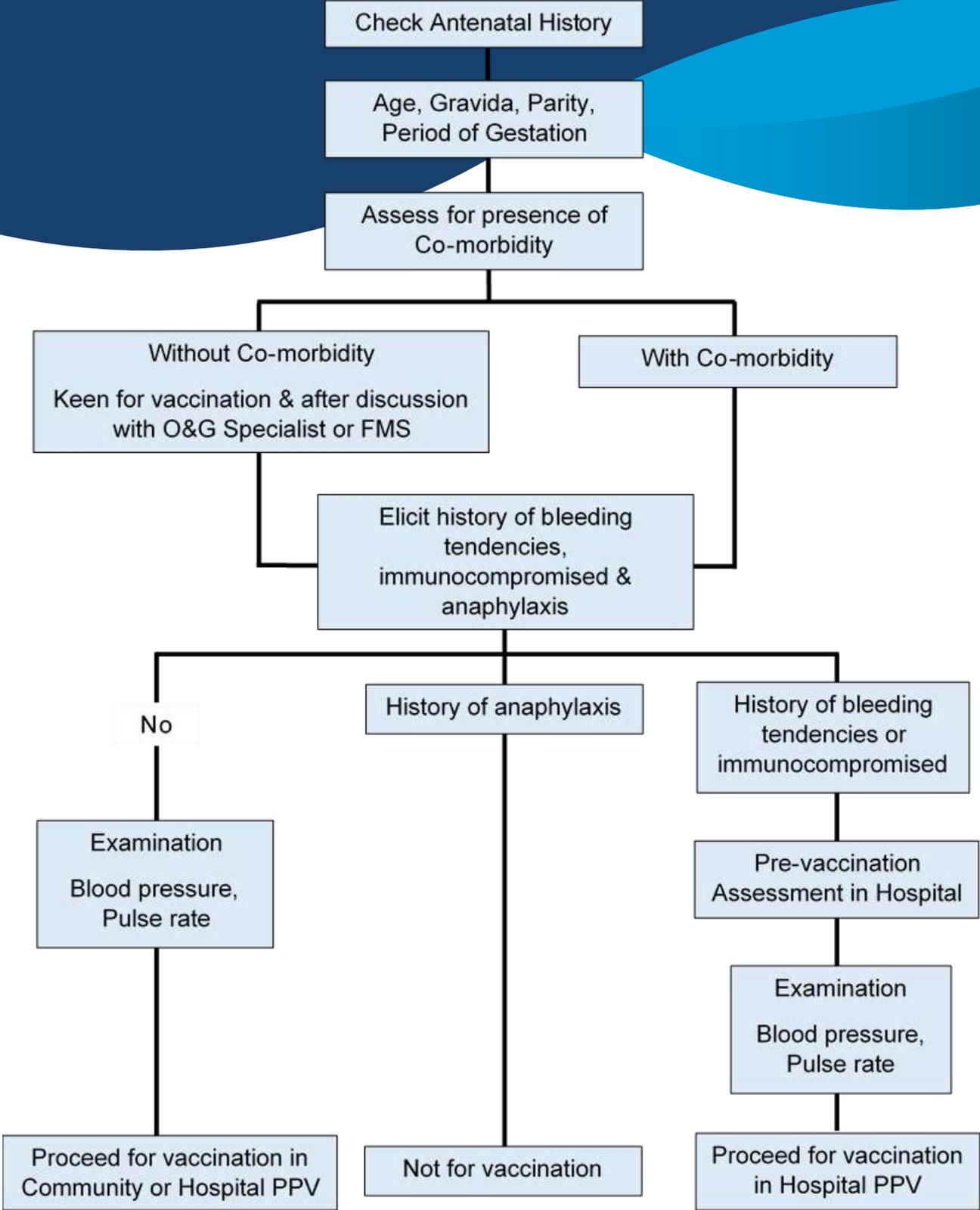
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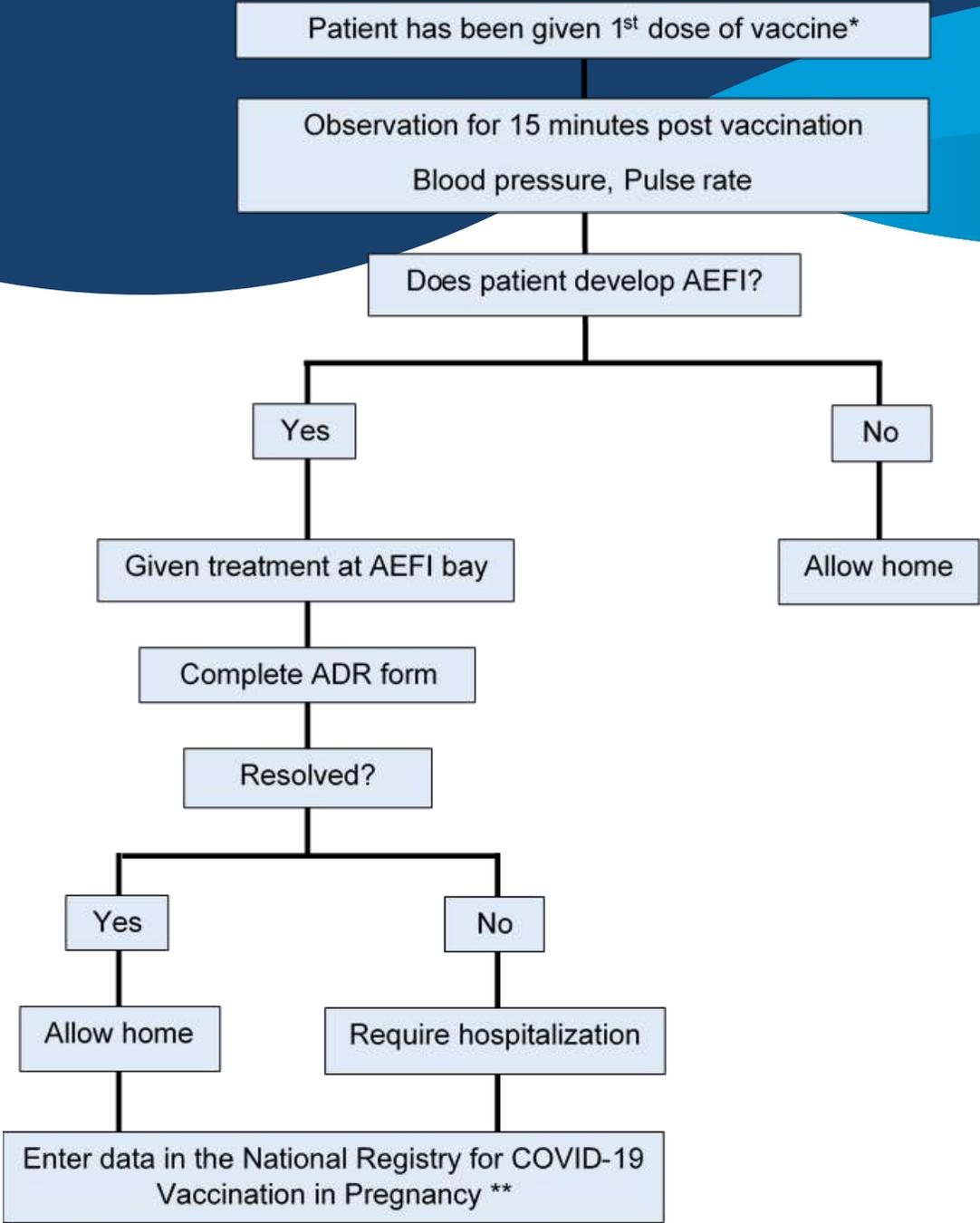
Translator (if required):

Date:

Flow Chart on Pre-vaccination Assessment for Antenatal Mothers on Presentation to Clinic or Hospital (1st Dose)



Flow Chart on Post-vaccination Assessment for Antenatal Mothers



*Any vaccine that has been approved for use in pregnancy by the Ministry of Health, Malaysia

**when available

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