



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



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Date:	26 August 2021		
To:	Minister Joe Phaahla Honourable Minister of Health	From:	Ministerial Advisory Committee (MAC) on COVID-19 Vaccines

**THIRD UPDATE OF THE ADVISORY ON
RECOMMENDATIONS ON COVID-19 VACCINATION IN PREGNANCY**

Summary of update

- The advisory has been updated to include all pregnant women.

Problem Statement

Background

- Although the risk is small, pregnant and postnatal women are at increased risk of severe Covid-19 illness compared to their non-pregnant counterparts. They are also at increased risk of preterm birth and possibly other adverse obstetric outcomes.
- There is a growing body of safety evidence that supports the use of COVID-19 vaccines in pregnant women, but there remains uncertainty among clinicians and pregnant women about whether these vaccines can be safely used in pregnancy.

Points considered

COVID-19 in pregnancy

- In the largest US study comparing pregnant and non-pregnant women with COVID-19, pregnant women were significantly more likely to require intensive care and mechanical ventilation than non-pregnant women of the same age. Black women experienced a disproportionately higher number of deaths.
- Preliminary data from the South African Obstetric Survey Systems suggests that most COVID cases in pregnant women were diagnosed in the third trimester of pregnancy.

COVID-19 vaccination in pregnancy

- Animal studies using the Pfizer/BioTech and J&J/Janssen COVID-19 vaccines before or during pregnancy found no safety concerns.
- As is standard practice in the evaluation of new vaccines developed for the general population, pregnant and lactating women were excluded from initial COVID-19 vaccine trials (as from almost all trials of this kind), some women were subsequently found to have

been pregnant at the time of immunisation while others become pregnant soon after receiving the vaccine; the safety data from these cases has been reassuring.

- COVID-19 vaccines have been rolled out to millions of people worldwide and many pregnant women have been included in these rollouts, without concerning safety signals being identified. As of 22nd March 2021, more than 60 000 pregnant women have been registered on the US/CDC V-safe Registry Monitoring System.
- Clinical trials evaluating the safety and efficacy of COVID-19 vaccines in pregnancy are underway.
- BioNTech Vaccination does not appear to have any effect on the spontaneous abortion rate.
- The Pfizer/BioNTech vaccine is an mRNA vaccine that does not contain a live virus. Additionally, mRNA vaccines cannot interact with a person's DNA or cause genetic changes, as they do not enter the nucleus of the cell. The J&J/Janssen vaccine is a viral vector vaccine using non-replicating the relevant viral gene spliced into non-replicating viral vector. Thus far, no adverse pregnancy outcomes have been reported when the same viral vector was used in other vaccines and administered to pregnant women at any stage of pregnancy.
- A very rare thromboembolic event, referred to as thrombosis with thrombocytopenia syndrome (TTS) has been causally associated with the J&J COVID-19 vaccine. As of 7 May 2021, the US Food and Drug Administration (FDA) and the US CDC had reviewed 28 reports of TTS out of a total of more than 8 million vaccinations. An expert consultation of the COVAX Maternal Immunisation Committee concluded that there is no enhanced risk of TTS in pregnant women compared to non-pregnant women.
- A study evaluating the mRNA COVID-19 vaccine response in pregnancy and lactation enrolled 84 pregnant and lactating women. Eleven (13%) women received the first vaccine dose in the first trimester, 39 (46%) in the second trimester and 34 (40%) in the third trimester. The authors concluded that COVID-19 mRNA vaccines generated robust humoral immunity in pregnant and lactating women with immunogenicity and reactogenicity similar to that observed in non-pregnant women.
- In this study, vaccine-induced immune responses were significantly greater than the response to natural infection. Immune transfer to neonates occurred via the placenta and breastmilk.
- Adverse effects evaluated in this study included the risks of preterm birth, rates of pre-eclampsia and growth restriction. There were no cases of pre-eclampsia or growth restriction in women receiving the vaccine during pregnancy. One case of preterm birth was reported.
- WHO does not recommend pregnancy testing prior to vaccination.
- WHO does not recommend delaying pregnancy or terminating pregnancy because of vaccination.

References:

1. Maswime S. Global Research on Covid-19 and Pregnancy. Discovery Webinar. Youtube.com/watch?v=GwYUSxCL2sg. Accessed 29 March 2021
2. V-safe COVID-19 Vaccine Pregnancy Registry. www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html. Accessed 29 March 2021
3. Gray KJ, Bordt EA, Atyeo C, Deriso E, Akinwunmi B, Young B et al. COVID-19 vaccine response in pregnant and lactating women: a cohort study, AJOG 2021, doi: <https://doi.org/10.1016/j.ajog.2021.03.023>.
4. Update: Thrombosis with thrombocytopenia syndrome (TTS) following COVID-19 vaccination – US Advisory Committee on Immunization Practices (ACIP), 12 May 2021: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/07-COVID-Shimabukuro-508.pdf>.

5. Receipt of mRNA COVID-19 vaccines preconception and during pregnancy and risk of self-reported spontaneous abortions, CDC v-safe COVID-19 Vaccine Pregnancy Registry 2020-21. Research Square 2021. Accessed 23 August 2021 DOI: <https://doi.org/10.21203/rs.3.rs-798175/v1>

Recommendations

- COVID-19 vaccination is strongly encouraged for non-pregnant women contemplating pregnancy.
- COVID-19 vaccines using the Pfizer or the Johnson & Johnson vaccine should be offered to all pregnant women at any stage of pregnancy.
- Pregnant women with co-morbidities such as obesity, diabetes and hypertension in pregnancy should be prioritized for vaccination should vaccine supplies be limited.
- Health care professionals are encouraged to discuss the risks and benefits of the COVID-19 vaccination with their patients. These discussions should include the increased risk, albeit small, of severe disease in pregnant women when compared to non-pregnant women, reassurance about the growing evidence supporting the safety of vaccines in pregnant and breastfeeding women, the strong immune response following vaccination and the benefits of immune transfer to the neonate, and ongoing safety monitoring of vaccine use in pregnancy. Furthermore, they need to be informed that there are no known risks associated with other non-live vaccines given routinely to pregnant women.
- Consideration should be given to the option of availing the covid-vaccine to pregnant women at routine ante-natal visits. Not all clinicians are aware of the recommendations of the current VMAC advisory, and wider dissemination of guidance recommending the use of vaccines in pregnant women is required. Specifically, the Department of health and relevant professional bodies should ensure dissemination of these recommendations.

Thank you for consideration of this request.

Kind regards,



PROFESSOR BARRY SCHOUB

CHAIRPERSON: MINISTERIAL ADVISORY COMMITTEE ON COVID-19 VACCINES

DATE: 26 August 2021

CC:

- » **Dr S Buthelezi (Director-General)**
- » **Dr T Pillay (Deputy Director-General: Health Regulations and Compliance Management)**