



**health**

Department:  
Health  
REPUBLIC OF SOUTH AFRICA



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Date:	11 June 2021		
To:	<b>Acting Minister MT Kubayi-Ngubane, MP Honourable Minister of Health</b>	From:	<b>Ministerial Advisory Committee (MAC) on COVID-19 Vaccines</b>

**SECOND 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 pregnant women are at no greater risk of being infected by SARS-CoV-2, the woman and her infant are more likely to have complications from Covid-19.
- The College of Obstetricians and Gynaecologists of South Africa were approached to provide expert advice regarding COVID-19 vaccination of pregnant women.
- The following is the opinion received from the College which has also been endorsed by the Vaccine MAC, and which is aligned with WHO's guidance.
- An additional review is attached as an annexure.
- It must be noted that the evidence is continually evolving and as such this advisory may need to be updated should significant new information become available.

**Points considered**

- Pregnant and lactating women were excluded from initial COVID-19 vaccine trials; thus, data to guide vaccine decision-making are lacking. In the largest US study comparing pregnant and non-pregnant women, 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-positive pregnant women were diagnosed in the third trimester of pregnancy.

- Clinical trials evaluating the safety and efficacy of COVID-19 vaccines in pregnancy are underway and planned. As of March 22, 2021 more than 60 000 pregnant women have been registered on the US/CDC V-safe Registry Monitoring System.
- Animal studies using the Pfizer/BioTech and J&J/Janssen COVID-19 vaccines before or during pregnancy found no safety concerns.
- The Pfizer-BioTech vaccine is an mRNA vaccine that does not contain a live virus. Additionally, mRNA vaccines do not interact with a person's DNA or cause genetic changes, as it does not enter the nucleus of the cell. The J&J/Janssen vaccine is a viral vector vaccine using a modified version of a 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 in all trimesters of pregnancy.
- A recent study by Gray et al 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.
- 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.
- Continuous review of vaccine safety in pregnancy will be undertaken by the Vaccine MAC for all vaccines considered for or included in the National rollout.
- 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>.

## Recommendations

- COVID-19 vaccination is strongly encouraged for non-pregnant women contemplating pregnancy.
- COVID-19 vaccines using the Pfizer or the J&J vaccine should be offered to all pregnant women.
- 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 workers are encouraged to discuss the risks and benefits of the COVID-19 vaccination with their patients. These discussions should include currently inadequate safety data for the vaccines in pregnancy and breastfeeding women, the strong immune response conferred to mothers following vaccination and the benefits of immune transfer to the neonate. Furthermore, that there are no known risks associated with other non -live vaccines given routinely to pregnant women.

Thank you for consideration of this request.

Kind regards,



**PROFESSOR BARRY SCHOUB**

**CHAIRPERSON: MINISTERIAL ADVISORY COMMITTEE ON COVID-19 VACCINES**

**DATE: 11 June 2021**

**CC:**

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