

Response to Reviewer 2 Comments

Pregnant and lactating are generally excluded from clinical trials for ethical reason because of concerns about drugs toxicity for mothers and children. The principle of preventive measures applied is sometimes against the benefit for pregnant women particularly when the risk associated to the disease outweigh the toxicity risk of the new and innovative drug. As expected, clinical trials on COVID-19 vaccine at first excluded pregnant and lactating women. Evidences of worse outcomes in pregnant women with COVID-19 lead to shift in clinical trial practices toward inclusion of pregnant women. This paper describes inconsistencies existing across countries, regarding policies on the inclusion of pregnant women in vaccine trials.

Point 1: The study was based on data available on internet that may induce information bias for countries with health policies information available online. This point need to be address at least in the discussion.

Response 1: We have addressed this comment by adding lines 213-215

Our analysis was based on policy documents available on the internet which have the potential to bias the analysis. We may have excluded countries whose policy documents were not accessible on the internet.

Point 2: The procedure of reviewing the retrieved documents is not detailed. Who were the reviewers and were there cross review of the documents?

Response 2: Thank you we have clarified this on lines 93, 97-99 and 117.

RSC led the country by country internet searches in Southern Africa

RSC and BN reviewed the documents independently. All the authors met regularly via zoom and e-mail and reviewed selected documents and discussed the broad themes.

reviewed by RSC and cross reviewed by BN

Point 3: The materials used in this analysis are not clearly detailed by country. The documents used for each countries needed to be detailed in term of number and type for each country

Response 3: We have inserted a table, lines 110-112

Table 1: COVID-19 vaccination policies and official statements by country

Country	Policy guideline source and year	Type
South Africa	Guidance on the use of the Janssen Ad26.COV2.S (COVID-19) vaccine in pregnant and lactating women. South African Health Products Regulatory Authority (SAHPRA) "Vaccination of Pregnant and Breastfeeding Women" DIRECTOR GENERAL HEALTH. REPUBLIC OF SOUTH AFRICA 25th June 2021. VACCINATION OF PREGNANT AND BREASTFEEDING WOMEN.DIRECTOR GENERAL HEALTH. REPUBLIC OF SOUTH AFRICA. 29 August 2021 https://www.gcis.gov.za/vaccine-guideline	Policies and guidelines
Angola	https://www.angop.ao/en/noticias/saude/minsa-preve-vacinar-10-mil-profissionais-do-pre-escolar/ Official Portal of the Government of the Republic of Angola - News - NEW DECREE IN FORCE https://governo.gov.ao/ao/noticias/em-24-horas-2/	Official statements on social media and government websites
Botswana	PUBLIC NOTICE ON THE ADMINISTRATION OF COVID-19 VACCINE SECOND DOSE.7 June 2021. https://web.facebook.com/OFFICIAL.MOH.W.BW/photos/a.928167567330306/1955246084622444/?_rdc=1&_rdr https://web.facebook.com/OFFICIAL.MOH.W.BW/photos/a.459580184189049/1972711179542601/?_rdc=1&_rdr	Official statements on social media and government websites
Eswatini	Good evening Eswatini. 2 573 people... - Eswatini Government Facebook	Official statements on social media and government websites
Lesotho	No policy found on pregnant women and vaccines	
Madagascar	No policy found on pregnant women and vaccines	
Malawi	https://web.facebook.com/malawimoh/posts/306245058354441?_rdc=1&_rdr https://www.nyasatimes.com/pregnant-women-can-now-get-covid-19-vaccine-ministry-of-health/	Official statements on social media and government websites
Mozambique	https://covid19.ins.gov.mz/vacina-covid-19/	Official statements on social media and government websites
Namibia	National deployment and vaccination plan for COVID 19 vaccines. Republic of Namibia. February 2021 https://m-partners.facebook.com/watch/?v=440512974037719&_rdr https://web.facebook.com/photo/?fbid=792232671449738&set=a.147401944250814&_rdc=1&_rdr	Policies and guidelines Official statements on social media and government websites
Tanzania	https://web.facebook.com/wizaraafyatz/posts/4491598857527213?_rdc=1&_rdr	Official statements on social media and government websites

Zambia	https://web.facebook.com/mohzambia/posts/statement-on-covid-19-in-zambialusaka-wednesday-12th-may-2021our-country-has-off/1906336979540950/?_rdc=1&_rdr https://web.facebook.com/mohzambia/photos/a.773733439467982/2076455569195756/?_rdc=1&_rdr https://web.facebook.com/mohzambia/photos/a.773733439467982/1997860320388615/?_rdc=1&_rdr	<u>Official statements on social media and government websites</u>
Zimbabwe	https://www.herald.co.zw/covid-19-vaccines-safe-for-pregnant-women/	<u>Official statements on social media and government websites</u>

Point 4: The results focused on South Africa what about Namibia which seems to also have an explicit policy about vaccine in pregnant women? The comparison of the policies between South Africa and Namibia may be interesting

Response 4: Thank you for the comment. We have added details on Namibia's policies and guidelines, lines 163-168

Namibia on the other hand, issued the National Deployment and Vaccination Plan for COVID 19 vaccines in 2021 [34] and adopted the World Health Organisation Strategic Preparedness and Response Plan for the African Region, with the Namibian Ministry of Health and Social Services leading the programme on case management, infection prevention and control, risk communications, tracking the spread of COVID-19, and encouraging people including pregnant and lactating mothers to get vaccinated [35]

Point 5: In describing the context, the authors should list the COVID-19 clinical trials ongoing in the countries included in the analysis

Response 5: We have added the text on lines 46-49

Early COVID-19 clinical trials for example clinical trials on the effectiveness of BNT162b2 vaccine against Omicron variant and the efficacy of the ChAdOx1 nCoV-19 vaccine against the B.1.351 variant in South Africa excluded this population [12, 13].