

Final Technical Report

for

Research Project

Follow-up study immunogenecity following COVID-19 vaccinations in Bhutan

Principal Investigator: Sangay Zangmo (Royal Centers for
Disease Control)

Co-Investigator(s): Sangay Zangmo (Royal Centers for Disease
Control)

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ANNEX 1**AF/01-016/07 Study Report Form**

Protocol No.: 2024.40.NNW		Protocol Title : Follow-up Immunogenecity study following COVID-19 vaccinations in Bhutan	
Principal Investigator:		<u>Sangay Zangmo</u>	
Phone number: 17336964		E-mail address :szangmo@health.gov.bt	
Sponsor's Name		<u>Khesar Gyalpo University of Medical Sciences</u>	
Address:		<u>Royal Centers for Disease Control, Thimphu, Bhutan</u>	
Phone : 17336964		E-mail :szangmo@health.gov.bt	
Study site(s):		<u>JDWNRH, Thimphu</u> Phuntsholing Hospital Paro Hospital	
Total Number of study participants : 887		No. of Study Arms:	
Number of participants who received the test articles:			
Study materials:		<u>Study questionnaire</u> Informed consent form Blood samples	
Treatment form:		NA	
Study dose(s): (if applicable).		<u>NA</u>	
Duration of the study		<u>1 year</u>	
Objectives:		Primary Objective: To determine the level of neutralizing antibodies to spike "S" proteins of SARS-CoV2 in the general population of selected sites in Bhutan. Secondary objectives: To determine other factors such as age, gender and existing comorbidities that may influence the level of antibodies to SARS-Cov2.	
Results: (Use extra blank paper, if more space is required.)		We sampled 883 individuals from the OPDs of 3 hospitals between February, 2025 to April, 2025. <u>Descriptive analysis:</u> The mean participants age was 45.7 ± 16.8, with a median 45 years. There were 533 females and 334 males.	

- 71.0% reported no prior COVID-19 infection, while 18.7% had a documented previous infection; infection status was unavailable for 10.3% of participants
- 46.3% of participants reported at least one comorbidity, whereas 53.7% had no reported comorbid conditions.
- Most participants had received four doses of COVID-19 vaccine (55.3%), followed by three doses (21.9%) and five doses (17.1%). Only 3.7% had received two or fewer doses
- There were at least 406 participants with known comorbidities at the time of sample collection, 69 of them reported a history of known COVID-19 infection in the past.

Serological analysis:

- Overall, mean antibody titre was 7039.9 with a median of 5953
- Higher titres were observed among individuals with higher doses of vaccines, however, the difference in antibody titres across vaccination dose groups was not statistically significant (Kruskal–Wallis $H = 7.72$, $p = 0.052$)
- Similarly, difference in the antibody titre among individuals with and without co-morbidities are not significant.

Conclusion:

No definitive protective antibody threshold exists for individuals. However, higher levels of antibody correlates to lower risk of infection and severity. As shown by studies, >54 IU/ml correlates to 50% protection in general population while 4-33 IU/ml correlates to 70% protection.

In Bhutan, high prevailing titres of antibody indicates a population that is at a higher protection level, but not of zero risk.

However, serological assays alone do not determine the level of individual immunity but rather helps understand population-level exposure, immunity trends, and risk, which helps shape public health strategy.

Signature of P.I.:

A handwritten signature in blue ink, appearing to be 'A. H.' with a stylized flourish.

Date: 27 April, 2026