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# "Assessing Post-Vaccination Symptoms in Adults: A Study on Covishield Immunization in Individuals Above 18 Years"

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**ABSTRACT**

This research investigates post-vaccination symptoms in adults following Covishield immunization in individuals aged 18 and above. The objective of the study is to comprehensively evaluate the prevalence and nature of adverse events associated with Covishield, a pivotal aspect in ensuring the vaccine's safety and efficacy. Utilizing real-world data, the research explores the spectrum of symptoms experienced by participants after vaccination, shedding light on the frequency and severity of reactions, with a particular focus on diverse demographic factors that may influence individual responses. Drawing on the insights gained from this study, it contributes valuable information to the broader discourse on vaccine safety and aids in refining strategies for effective immunization programs.

**Keywords** – Immunization, Vaccination, ESIC Hospital, Symptoms, adults, demographic

## Introduction

The emergence of COVID-19 has spurred a global effort to develop and deploy vaccines, with the Oxford-AstraZeneca Covishield vaccine standing as a pivotal player in this endeavor. As the vaccination campaigns progress, it becomes crucial to comprehensively evaluate the post-vaccination symptoms experienced by adults aged 18 and above. This observational study aims to contribute valuable insights into the Covishield immunization process, shedding light on potential side effects and their prevalence within this specific demographic.

Vaccination, as a cornerstone of public health, not only bolsters individual immunity but also plays a pivotal role in mitigating the spread of infectious diseases within communities. Covishield, a viral vector vaccine based on the adenovirus ChAdOx1, has demonstrated efficacy in preventing severe illness caused by the SARS-CoV-2 virus. However, understanding the nature and frequency of post-vaccination symptoms is imperative for ensuring the vaccine's safety and efficacy in real-world scenarios. Previous studies have highlighted the importance of monitoring adverse events following immunization (AEFIs) to refine vaccination strategies and enhance public confidence in the vaccination process (Shimabukuro et al., 2015).

This research builds on the existing body of knowledge by focusing specifically on adults aged 18 and above who have received the Covishield vaccine. The age-specific analysis is vital as vaccine reactions may vary across different demographic groups. By assessing post-vaccination symptoms, including common reactions such as pain at the injection site, fever, and fatigue, this study aims to provide a nuanced understanding of the vaccine's impact on adults, contributing to the ongoing discourse on vaccination safety and efficacy (Voysey et al., 2021). Such insights are instrumental not only for healthcare practitioners but also for policymakers striving to optimize vaccination strategies and public health interventions.

The COVISHIELD vaccine, utilized in India, was developed by the Serum Institute of India in alignment with the UK-developed vaccine by the Jenner Institute and the University of Oxford. Phase I/II blinded randomized controlled trials were conducted in the UK, Brazil, and South Africa in April 2020, utilizing randomization via the ChAdOx1nCoV-19 vaccine and reforming the MenACWY (standard meningococcal vaccine) due to testing. Neutralizing antibodies were observed at 91°C after the first dose and 100°C after the second dose. Phase II/III studies occurred in the UK from May to August 2020, encompassing participants across age cohorts (18-55, 56-69, and 70 or older), with similar timelines for all age groups. The COVISHIELD vaccination cycle comprises two separate doses of 0.5 ml each. Subsequently, a multicenter ICMR study was conducted at ESI Faridabad Hospital to evaluate the protection, safety, and immunogenicity of the whole-virion inactivated SARS-CoV-2 vaccine, SIV16B. Covishield's safety data are currently unavailable, rendering this study a follow-up to the ICMR study (SIV16B) (Voysey et al., 2021; Bhargava et al., 2021).

## Objective

This study is designed to comprehensively assess post-vaccination symptoms associated with Covishield in individuals aged 18 and above, considering both doses (dose 1 and dose 2). The safety profile of the Covishield vaccine within this age group will be closely examined to ensure the well-being of the vaccinated population. Another crucial aspect involves evaluating the rate of re-infection among enrolled subjects, shedding light on the vaccine's effectiveness over time. Additionally, the research aims to measure the quality of life post-vaccination, utilizing the WHOQOL questionnaire to gain insights into the overall well-being of individuals after completing both doses. Collectively, these objectives form the foundation for a comprehensive analysis of Covishield's impact on post-vaccination symptoms, safety, re-infection rates, and the subsequent quality of life for individuals aged 18 and above.

## Materials and sampling method

Study participants in this investigation included all individuals who received vaccines at the specified centres and provided consent for enrolment, with a particular emphasis on healthcare workers. The study's design involved a follow-up period of at least six months for the enrolled individuals. The study was conducted at ESIC Hospital in Faridabad (121001), focusing on a population of 100 healthy participants. The observational study spanned a duration of three months, during which subjects meeting specific inclusion criteria, such as being above 18 years of age, having no history of COVID, and displaying willingness to comply with study procedures, were considered for enrolment. Exclusion criteria were also defined, excluding individuals with recent vaccinations, those who were pregnant or breastfeeding, those with active HIV or hepatitis B or C, individuals with alcohol or drug addiction history, and those contraindicated for vaccination. The

study aimed to gather comprehensive data while considering the health and suitability of participants.

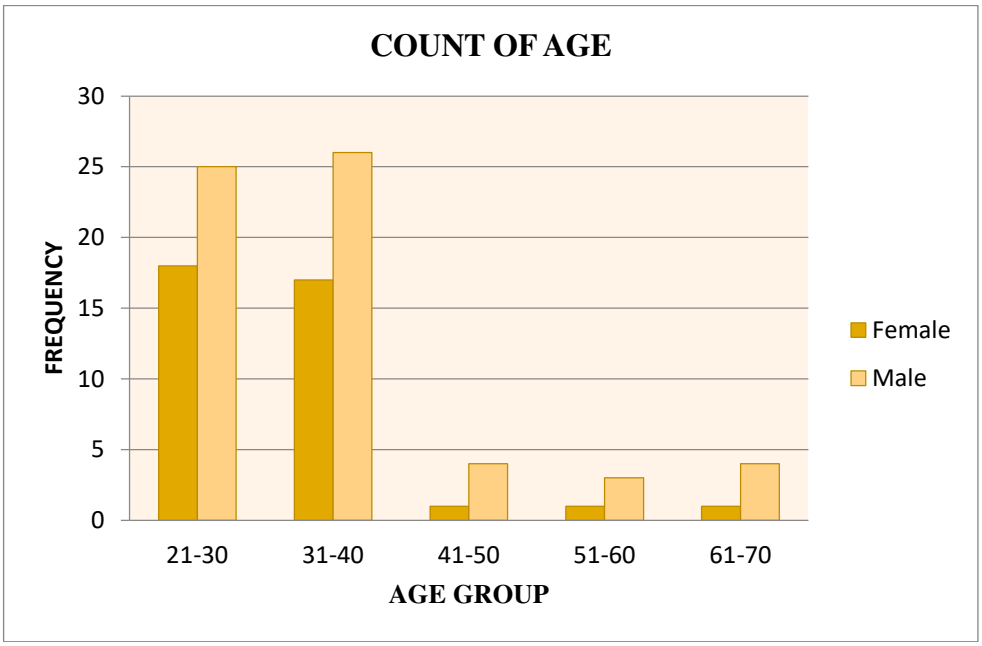
The subject selection criteria were stringent, ensuring that enrolled individuals met specific eligibility requirements. Inclusion criteria emphasized the age factor, absence of recent COVID history, and the willingness to provide informed consent and comply with study procedures. Exclusion criteria were equally thorough, considering recent vaccinations, pregnancy, specific diseases, substance addiction, and participation in other clinical trials. These criteria were implemented to maintain the integrity of the study and generate meaningful data on the post-vaccination experiences of healthcare workers over the designated observation period.

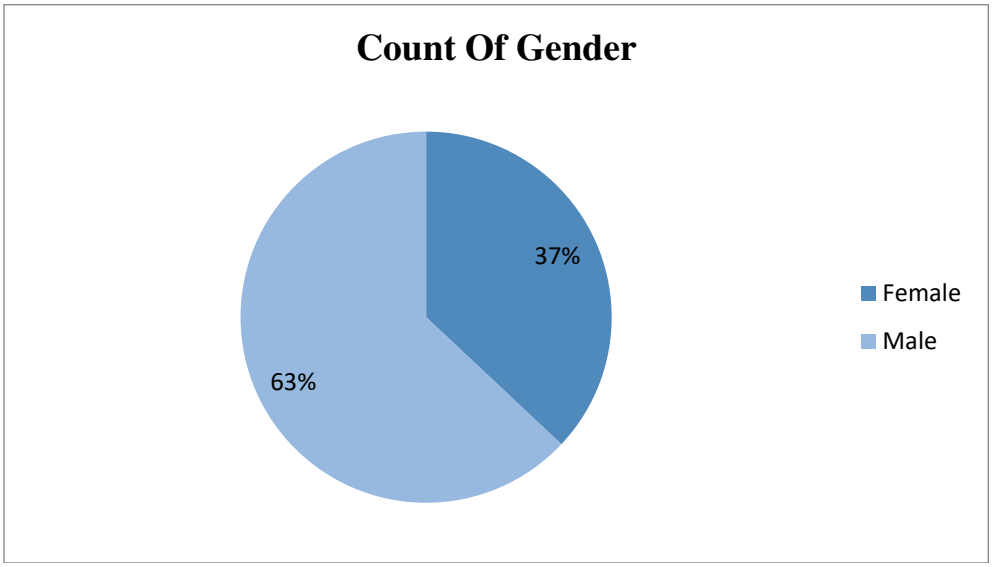
## Methodology

After taking informed consent, the subjects were vaccinated. On 2nd day a telephonic follow up were conducted with all vaccinated subjects who fulfill protocol specific inclusion/exclusion criteria. There were total 2 visits in the studied. Total duration of participation of the subject in the study was 12 weeks with follow-up. Safety assessments, physical examination, clinical examination, vital signs and adverse event monitoring were conducted on scheduled hospital visits. An unscheduled visits allowed at any time for any health related reason. If a patient wants to discontinue from the study then any time can discontinue the study.

## Observations

A total 100 subjects were enrolled in the study as per the eligibility criteria .Data of 100 subjects in this study were recorded ,age group above 18+ (Figure 1). Out of 100 subjects that were randomized for the study, 63 Subjects were male and 37 were female. Figure 2 shows the gender distribution.






A total of 100 participants, comprising 37 females and 63 males, underwent data analysis in this study. All 100 participants were administered the first dose of the Covishield vaccine. After the initial vaccination, 45% experienced fever, 17% had headaches, 1% reported coughing, and 7% suffered from a sore throat. None of the participants experienced a loss of smell or haemoptysis after the first vaccination. Additionally, 49% reported body ache, and 3% experienced diarrhea. During the period between the first and second doses, all 100 participants received negative results in the RT-PCR test. Subsequently, for the second dose, 12% experienced fever, 8% reported headaches, 1% had a cough, and 1% suffered from a sore throat. Similar to the first dose, no participants reported a loss of smell or haemoptysis. Additionally, 16% experienced body ache after the second vaccination.

Overall safety of subjects and result of questionnaire shows that the vaccine (covisheild) was safe for all age group participants which was above 18+ and subjects was happy from the Covishield vaccine, 73. 3% subjects was satisfied out of 100% with the vaccine after post vaccination.

## DISCUSSION

In this observational investigation, the safety of the Covishield vaccine for COVID-19 is demonstrated. The data presented indicates the effectiveness of the ChAdOx1 nCoV-19 vaccine against symptomatic disease, revealing a generally favorable safety profile for the ChAdOx1 vaccine from the Serum Institute of India. Adverse Events Following Immunization (AEFI) were observed in 50% of participants after the initial dose and approximately 20% after the second dose. The administration of four vaccines, including those from China's Sinovac, mRNA vaccines and AstraZeneca, involved a two-dose regimen separated by several days, aligning with the principle of multiple doses for immunization routines. The decision for multi-dosing was guided by the need for individuals to achieve the highest level of immunity in some cases, while in others, a second dose was necessary due to varied responses to a single dose. The COVID-19 vaccines were developed considering the understanding of SARS-CoV-2's binding mechanism and its glycoproteins. Covid 19 was detected by viral RNA from saliva or nasal pharyngeal swabs, and protection from viral infections was achieved by inducing mRNA cells to generate spike proteins, initiating antibody production.

Based on interim findings from this safety study, it can be inferred that the ChAdOx1 nCoV-19 coronavirus vaccine (recombinant), Covishield (Serum Institute of India), exhibits an overall good

safety profile. Younger individuals, females, and those with hypertension or a positive history of allergy or hypothyroidism are identified as having an increased risk of AEFIs, necessitating careful administration of vaccines to such individuals.

## Conclusion

The findings revealed a consistent median anti-spike IgG response across all age groups following the administration of Covishield vaccine via intramuscular injection within the deltoid region.
Among those who responded after the first dose, 51.15% reported adverse events, with fever (55.5%) being the predominant symptom, followed by body ache (49.9%), while cough and sore throat were less prevalent (2.0%). The onset of symptoms after the second dose occurred around 8.7 hours, lasting up to 120 hours, longer than the first dose. The mean duration of symptoms after the second dose was 1.8 days, higher than that of the first dose, with a maximum reported duration of 10 days. Systemic adverse events included fever, body ache, cough, and headache, reported by varying percentages of subjects. Notably, no reinfections from COVID-19 were observed among study participants during the study period.

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