

# An assessment of AEFI COVID-19 vaccination in health care workers at a tertiary health care centre in central India

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Accepted 7 May, 2021

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## Abstract:

COVID-19 is a life-threatening universal public health emergency and the only hope to combat it is the COVID-19 vaccine. Different vaccines are available now, but their safety is a matter of concern people are eager to know what they can expect after getting vaccinated. The associated adverse effects of the COVID-19 vaccine may affect healthy individuals so monitoring them is an important aspect. Timely assessment can help to identify and take appropriate measures. Serious Adverse Effects Following Immunization (AEFIs) should also be promptly identified. India's first phase of COVID-19 vaccination started on 16 January 2021 with priority given to an estimated three crore healthcare workers (HCWs) and the frontline workers. In the present study, we assessed the AEFI of COVID-19 vaccine Covishield received by HCWs of our institute. For the first dose in the first phase of vaccination drive, 5,637 HCWs were vaccinated 32.28% of recipients experienced the symptoms Amongst those developing symptoms, 53.84% were males and 46.15% were females. Symptoms reported were fever (28.91%), myalgia (26.43%), cold and cough (8.16%), headache (6.74%), local pain/swelling at injection site (3.37%), fatigue (0.35%), diarrhea (0.08%) while other reported symptoms by few recipients were rigors (0.07%), joint pain (0.08%), nausea (0.07%). In 27% beneficiary symptoms subsided within 24 hours while in 1.28% symptoms lasted for 48 hours, in 4% recipients they lasted beyond 48 hours. In 0.70% of recipients, symptoms were severe. No unusual or unexplained symptom was observed. No serious adverse event was reported. No deaths were reported.

**Keywords:** Covishield, Covaxin, Sputnik V, Corona virus disease.

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## INTRODUCTION

We are in the midst of a universal public health emergency with the spread of the novel severe acute respiratory syndrome corona virus 2 (SARS-CoV-2), which causes corona virus disease 2019 (COVID-19). A safe, effective, accessible, and acceptable vaccine is critically needed to prevent the spread of COVID-19. The vaccine response includes the immune response and the likelihood of adverse events (AEs), AEs related to vaccines, including systemic, local, and laboratory value findings, are graded as mild, moderate, severe, and potentially life-threatening characterized as serious or involving emergency room or hospitalization (U.S. Food and Drug Administration, 2007). Data on vaccine AEs

may be collected through active solicitation by the researcher in a trial or through passive surveillance in a self-report submission to a national vaccine event reporting system by the vaccine recipient. In the latter case, the potential for underreporting and reporting bias exists.

## COVID vaccines for India

India's indigenous COVID-19 vaccine COVAXIN by Bharat Biotech has been developed in collaboration with the Indian Council of Medical Research (ICMR) and

National Institute of Virology (NIV) Pune, Maharashtra. It is an inactivated vaccine developed using Whole-Virion Inactivated Vero Cell-derived platform technology, with no sub-zero storage, no reconstitution requirement, and ready to use liquid presentation in multi-dose vials, stable at 2 to 8°C. The vaccine received DCGI approval for Phase I and II Human Clinical Trials in July 2020. Analysis from the National Institute of Virology indicates that vaccine-induced antibodies can neutralize the UK variant strains and other heterologous strains.

Another vaccine in use Covishield has been developed by the Oxford-AstraZeneca and is being manufactured by the Serum Institute of India (SII) Pune, Maharashtra. It uses the same technology as was used to prepare vaccines for viruses like Ebola -A chimpanzee adenovirus – ChAdOx1 modified to enable it to carry the COVID-19 spike protein into the cells of humans.

Both vaccines are a two-dose regimen, administered 6 to 8 weeks apart intramuscularly. Transportation and storage are easy. Both have shown satisfactory results ever since the inoculation started in India. The effectiveness of the Covishield vaccine is nearly 90% as per the global reports and Covaxin's 81% according to interim 3rd phase trial results (Cennimo, 2021). Top health officials in India have stated that both Covaxin and Covishield are effective against the mutated, UK/South Africa/Brazil virus.

A third corona virus vaccine has been approved for use in India. Russia's Sputnik V has been deemed to be safe and works in a way similar to the Oxford-AstraZeneca jab which is being made in India as Covishield. It has been given emergency use authorization in India amid a deadly second wave of infections when India overtook Brazil to become the country with the second-highest number of cases globally. It is being produced by Dr. Reddy's Laboratories. The volume of Sputnik V vaccine production in India will be gradually increasing and may surpass 50 million doses per month. It uses a cold-type virus, engineered to be harmless, as a carrier to deliver a small fragment of the corona virus to the body. Safely exposing the body to a part of the virus's genetic code in this way allows it to recognize the threat and learn to fight it off, without the risk of becoming ill. After being vaccinated, the body starts to produce antibodies especially tailored to the corona virus. The Sputnik jab uses two slightly different versions of the vaccine for the first and the second dose - given 21 days apart. They both target the corona virus's distinctive "spike", but use different vectors - the neutralised virus that carries the spike to the body. The idea is that using two different formulas boosts the immune system even more than using the same version twice - and may give longer-lasting protection. This gives around 92% protection against Covid-19 in late-stage trial results published in *The Lancet* (Jones and Roy, 2021).

Vaccines made by Pfizer and Moderna could become available for Indians as the government of India is

expanding its basket of vaccination. After being vaccinated, the body starts to produce antibodies especially tailored to the corona virus. This means that the immune system is primed to fight corona virus when it encounters it for real. Adverse event following immunization (AEFI) is defined as any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. Technological advances and continuously increased knowledge about vaccines have led to investigations focused on the safety of existing vaccines which have sometimes created a climate of concern. Vaccine-associated adverse events may affect healthy individuals and should be promptly identified to allow additional research and appropriate action to take place. Timely assessment is important to formulate recommendations for vaccination of particular groups and guidance for any groups that may be identified as more susceptible to serious AEFIs. It is also important for revising and updating screening procedures and to ensure that arrangements for treatment are put in place.

### Vaccination drive in India

Large-scale COVID-19 vaccination is the single most effective public health measure for lessening the corona virus disease (COVID-19) pandemic. Vaccination programs started in December 2020 in several countries. For this kind of unique mass vaccination drive, looking at the urgency and the pace of production of vaccines a strategy is designed by preferring the front line workers, medics, paramedics and other high-risk groups followed by the general public (Dooling et al., 2020).

India's first phase of COVID-19 vaccination started on January 16, 2021, with priority given to an estimated three crore healthcare workers and the frontline workers. The second phase of COVID-19 vaccination started on 1<sup>st</sup> March 2021 which included voluntary vaccination of those above 60 years of age and the under-50 population groups with co-morbidities, numbering around 27 crores. The government of India announced the third phase of vaccination of 18 years and above from 1<sup>st</sup> May 2021.

To tackle this pandemic vaccination is the need of the hour and because this particular vaccine is so new, people are eager to know what they can expect after getting vaccinated. National authorities and international bodies, including WHO, are closely monitoring for any unexpected side effects following COVID-19 vaccine use.

The Ministry of Health and Family Welfare India has asked the States to monitor the AEFI and start making arrangements to deal with any COVID-19 vaccine-related side-effects as one of the measures towards safe vaccine delivery among the masses (<https://www.mohfw.gov.in>).

In the present survey, we assessed the AEFI of the COVID-19 vaccine Covishield received as the first dose

in the first phase by HCWs in our institute to determine the safety of the vaccine and generate a database for medical science literature.

## METHODS

Data of after-effects of the first dose of the COVID-19 vaccine (Covishield) in the HCWs receiving the vaccine in a Government Medical College in central India was analyzed during the first phase of vaccination. The first phase of vaccination in the said institute was carried out from 16 Jan to 6 Feb 2021. This drive was preferably meant for high-risk health care workers (HCWs) of all age groups and both genders, class I to class IV, which included doctors and paramedical staff of all health stations of the entire city. Information regarding demographic details -name, age, gender of health care workers along with professional details and date of administration of vaccine was collected from the vaccination registration counter. The recipients were supervised for 30 min post-vaccination for a watch of hypersensitivity response. If the receiver is comfortable then he/she was allowed to leave the centre. Data on post-vaccination AEs were collected through passive surveillance in a self-report submission to a national vaccine event reporting system by the vaccine recipient. A web-based system was generated where the recipient was receiving daily health check-ins through the smart phone text messages for the first 7 days after vaccination. The HCW were asked to fill up following details:

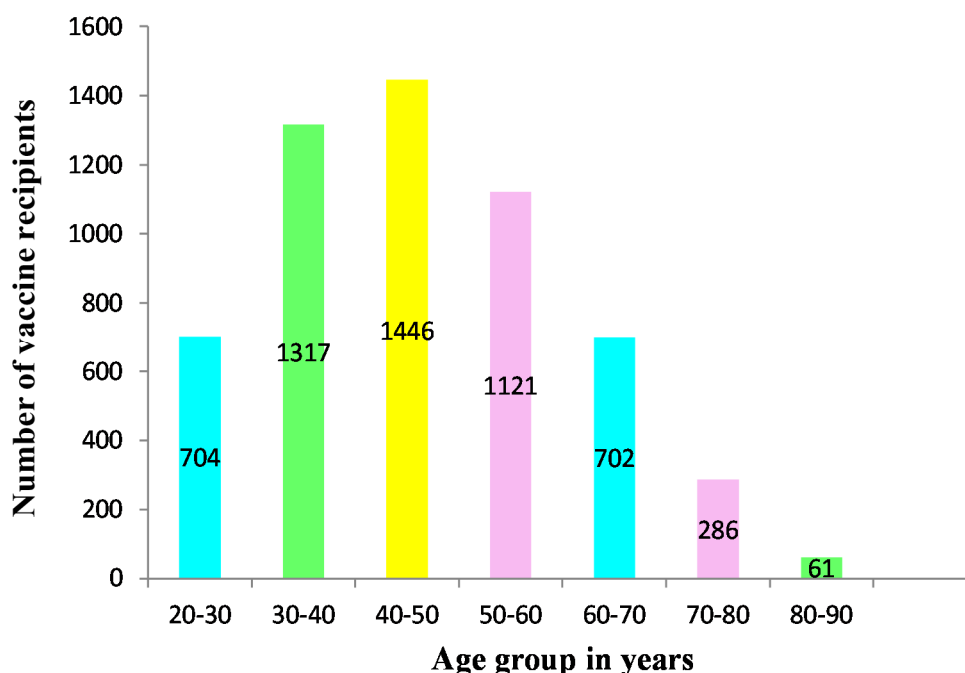
1. Nature of AEFI (signs and symptoms like fever, headache, nausea, vomiting, fatigue, body aches, cough, cold pain/swelling at the injection site at the site of injection, etc).
2. Type of AEFI (minor/severe/serious/death).
3. The time (in hours) of development of AE post-vaccination.
4. The duration (hours to days) for which it lasted.

5. If they needed hospitalization for managing their symptoms.

Microsoft office (excel) version 2010 was used for collecting, storing, and analyzing data. Descriptive analyses of data in terms of average and percentages were carried out.

## RESULTS

In our setup for the first dose in the first phase of the vaccination drive, 5637 HCWs were vaccinated. The participants' age ranged from 21 to 83 years, maximum in age group of 40-50 with a median age of 42 years (Figure 1). Amongst the recipients, 1820(32.28%) experienced the symptoms, 980 (53.84%) were men and 840 (46.15%) women. The most commonly reported symptoms after immunization in the recipients were mild fever in 1629 (28.91%), myalgia in 1490 (26.43%), cold and cough in 460 (8.16%), headache in 380 (6.74%), local pain and or swelling at the injection site in 190(3.37%), fatigue in 20 (0.35%), diarrhea in 5 (0.08%) while other reported symptoms by few recipients were rigors in 4 (0.07%) joint pain in 5 (0.08%), nausea 4 (0.07%). In 27% beneficiary symptoms subsided within 24 hours while in 1.28% symptoms lasted for 48 hours, while in 4% symptoms lasted beyond 48 hours. Only 4 (0.70%) of recipients demonstrated severe symptoms who required admission and observation but they were discharged after receiving treatment. No other unusual or unexplained symptom was observed. No serious adverse event was reported. No deaths were reported.



**Figure 1.** The number of vaccine recipients in different age groups.

## DISCUSSION

COVID-19 vaccines are designed to give the recipient immunity. Post-vaccination, he/she can have COVID-19 but the severity of the disease and duration of illness will be less. The vaccines can protect the person from death (<https://www.who.int>). It is common to experience some mild-to-moderate side effects when receiving vaccinations and is not a cause for alarm. This is because the immune system is instructing the body to react in certain ways: by increasing the blood flow so more immune cells can circulate, and it raises the body temperature to kill the virus. These side effects may affect one's ability to do daily activities, but they should go away in a few days. Some people have no side effects (<https://www.cdc.gov>). Experiencing no side effects does not mean the vaccine is ineffective (<https://www.who.int>; Lee, 2021; <https://medicalxpress.com>). It means everybody responds differently. According to the Centers for Disease Control and Prevention, a vaccinated person can have generalized symptoms like tiredness, headache, muscle pain chills fever nausea Injection site reactions. The local symptoms at the injection site like pain and or soreness, redness, swelling can be, on the arm where the shot is given. To reduce discomfort from fever one should drink plenty of fluids and dress lightly (Jayadevan et al., 2021). To reduce local symptoms, one should apply a clean, cool, wet washed cloth over the area, rest the arm and avoid any heavy lifting or activity.

In the present study for the first dose of first phase vaccination, 5637 HCWs received the shot. The recipients' age ranged from 21 to 83 years, with maximum 40-45 age group and a median age of 42 years. In the online survey, conducted between January 29 and February 4 by Rajeev Jayadevan, the respondents belonged to all age groups, from 20 years and those above 60 years were 17.5% (Jayadevan et al., 2021). In the present study, amongst the vaccine receivers, 32.28% developed post-vaccination symptoms. In a study on AEs of COVID-19 vaccines of different types in Indian set up by Dr. Rajeev Jayadevan et al., 65.9% HCWs developed at least one symptom (Jayadevan et al., 2021). The figure of our present study may not be the true reflection and more receivers would have developed the symptoms. We expect this underreporting because of the self-reporting submission system. Another reason for less reporting may be the AEs were manageable by the recipients. There has been apprehension about COVID-19 vaccines making people sick with the disease. But none of the approved vaccines contain the live virus, which means that these vaccines cannot make you sick with COVID-19 (<https://www.cdc.gov>). In the present assessment, the most common symptom reported is mild fever (28.91%) followed by myalgia (26.43%), these findings coincide with some surveys (Jayadevan et al., 2021). Other symptoms reported were cold and cough in 8.16%,

headache in 6.74%, local pain at the injection site in 3.37%, fatigue in 0.35%, diarrhea in 0.08%. These findings correspond to as opined by expert epidemiologists and executive director of the International Vaccine Access Center William Moss (<https://www.jhsph.edu>). Among the recipients experiencing the symptoms, 53.84% were men and 46.15% were women. This is in contrast to a general perception that women have more side effects of vaccines as compared to men. Preliminary data from the earliest vaccinations in December 2020 suggested that women reported more severe vaccine side effects than men (<http://medicine.yale.edu>). In February 2021, the CDC released data on adverse effects during the first month of the COVID-19 vaccine rollout, finding that while women received 61 percent of vaccine doses, 72 percent of the side effects reported to the agency were from women (<https://www.cdc.gov>). In a previous study with monovalent 2009 pandemic influenza A (H1N1) vaccines, it was found that females of childbearing age had higher rates of allergic reactions than males (Halsey et al., 2013).

Clinical research on many vaccines has shown differences between women and men: women exhibit a greater immune response that can facilitate vaccine efficacy, but they also experience more frequent and more severe AEs (Fink and Klein, 2018; Fischinger et al., 2019). Women are known to have stronger immune responses to foreign antigens (a benefit with infections and vaccines) and self-antigens (a susceptibility to autoimmune disease) than men (Fischinger et al., 2019). In the present study in 27% of the vaccine recipients, the symptoms did not prolong more than 24 hours while 1.28 % opined that their symptoms remained for 48 hours and in 4% symptoms lasted beyond the duration of 48 hours. According to the CDC, side effects usually start within a day or two of getting the vaccine, but they should also go away in a few days (<https://www.cdc.gov>). In 4 (0.70%) recipients symptoms were severe which required admission and observation but they were discharged after receiving treatment. Anaphylaxis to the mRNA COVID-19 vaccines is currently estimated to occur in 2.5 to 11.1 cases per 1 million doses, largely in individuals with a history of allergy (Shimabukuro et al., 2021). Blumenthal et al. (2021) prospectively studied Mass General Brigham (MGB) employees who received their first dose of an mRNA COVID-19 vaccine. In their survey anaphylaxis was confirmed in 0.025% of employees (Blumenthal et al., 2021). Allergic concerns contribute to vaccine hesitancy, however, the overall risk of anaphylaxis to an mRNA COVID-19 vaccine remains extremely low and largely comparable to other common health care exposures (Kim et al., 2014). Though allergic reactions have been reported in the literature, in the present survey no unusual or unexplained symptom was observed neither any serious adverse event was reported. The CDC based on passive spontaneous

reporting methods reports 0.025 to 0.11 per 10 000 vaccinations with serious adverse effects (Fischinger et al., 2019). CDC and FDA scientists have evaluated reports from people who experienced a type of severe allergic reaction anaphylaxis after getting a COVID-19 vaccine. Anaphylaxis after COVID-19 vaccination is rare and occurred in approximately 2 to 5 people per million vaccinated in the United States based on events reported to Vaccine Adverse Event Reporting System (VAERS) (<https://www.cdc.gov>). This kind of allergic reaction almost always occurs within 30 min after vaccination. Fortunately, vaccination providers have medicines available to effectively and immediately treat patients who experience anaphylaxis following vaccination. To date, the VAERS has not detected patterns in the cause of death that would indicate a safety problem with COVID-19 vaccines (<https://www.cdc.gov>). No deaths were reported in present study also.

## CONCLUSIONS

COVID -19 vaccines are new so monitoring AEFIs is a part of health care. In the present study we assessed the AEFI of COVID 19 vaccine - Covishield received by HCWs in our institute. Adverse effects were reported by 32.28% of recipients, more by females than males. In 27% respondents symptoms subsided within 24 hours while in 1.28% symptoms lasted for 48 hours, only in 4% of recipients, lasted beyond 48 hours. In 4 (0.70%) recipients symptoms were severe who required admission and observation but they were discharged after receiving treatment. In remaining receivers, the symptoms were mild and controllable. No unusual or unexplained symptom was observed. No serious adverse event was reported. No deaths were reported.

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**Citation:** Kavita M. Jaiswal KM, Dudhgaonkar S, Raghute L, Uike P, Kohli S, Anand I, 2021. An assessment of AEFI COVID-19 vaccination in health care workers at a tertiary health care centre in central India. *Microbiol Res Int*, 9(2): 46-50.

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