IJNRD.ORG ISSN : 2456-4184
INTERNATIONAL JOURNAL OF NOVEL RESEARCH AND DEVELOPMENT (IJNRD) | IJNRD.ORG
An International Open Access, Peer-reviewed, Refereed Journal

Adverse effect of Covishield after vaccination

[1]Deeksha Sahu, [2]Ashutosh Maurya, [3]Vinay Kumar Awasthi, [4]Kanhaiya Verma & [5]Arya Yadav

[1]Student of B. Pharm, [2]Student M. Pharm, [3]Student M. Pharm, [4]Student M. Pharm & [5]Student B. Pharm

[1]Department of Pharmacology
[1]M.G.B. Rajat College of Pharmacy and Management, Singhpur Gohila, Ambedkar Nagar, India
[2]Seth Vishambhar Nath Institute of Pharmacy, Deva Road Lucknow, U.P. India

Abstract: - The global rollout of COVID-19 vaccines has been crucial in combating the pandemic, with Covishield, the AstraZeneca/Oxford vaccine, being one of the widely administered vaccines. This abstract summarizes the adverse effects observed following Covishield vaccination. The data was collected from various clinical trials, post-marketing surveillance, and independent studies. Common side effects include mild to moderate reactions such as injection site pain, fatigue, headache, muscle pain, chills, fever, and nausea, typically resolving within a few days. More severe but rare adverse effects have been reported, including thrombotic events with thrombocytopenia, anaphylaxis, and Guillain-Barré Syndrome. The incidence of these severe reactions remains extremely low, and the benefits of vaccination in preventing COVID-19 outweigh the risks. Ongoing monitoring and research are essential to fully understand the long-term safety profile of Covishield and to ensure public confidence in vaccination programs. This review underscores the importance of continued vigilance and transparent reporting in vaccine safety to mitigate public health risks and enhance the global vaccination effort.

Keywords: COVID-19, Covishield, SARS-CoV-2, Immunisation, ADRs & Anaphylaxis

Introduction

Covishield: - It is a recombinant, replication-deficient chimpanzee adenovirus vector encoding SARS (Serene the encrypting the acute respiratory syndrome) – (COV-2 Spike (S) glycoprotein. The genetic material of part of corona virus is expressed which stimulates an Immune response.
According to the third phase experiment, covaxin showed effectiveness of nearly effectiveness of about 90%. Both vaccination & developed by India have so for proving satisfactory efficacy against several mutant variants of SARS-CoV-2.

Success rate of Covishield vaccine in India: - The effectiveness of first and second doses of Covishield were 71%, respectively. Against SARS-CoV-2 infection.

Approval of Covishield vaccine: - On 1 January 2021, the Drug controller General of India (DCGI) approved emergency use of the Oxford Astrazeneca Vaccine (trade name – "Covishield").

By severe acute respiratory syndrome – Coronavirus 2 caused is being infected covid-19 Including more than 150 countries, the impact of covid-19 was for-reaching worldwide. Thus, the disease a global pandemic was declared by the WHO.[1]

The simple, safe and effective way of preventing harmful diseases by the vaccination. The body's natural defence system to build resistance to the specific infection of strengthen the immune system through the vaccine administration.[2] BBV152 is the generic name of the covaxin. It is given as an intramuscular injection into the deltoid muscle of the upper arm in two doses with an interval of 4-6 weeks.[3] Pain, swelling, redness, itching, fever, headache, body pains, malaise, nausea, vomiting rashes are the common ADRS observed at Injection site. A recombinant replication-deficient chimpanzee adenovirus vector encoding the SARS CoVe-2 spike glycoprotein was covidshield. It is a viral vector vaccine. On the same patent technology as Astrazene -ca, it is developed by the serum institute of India.[4] ChAdOxt to-19 is the generic name of covidshield. (serum Institute of India), AZD 122 (Astrazeneca). This vaccine is administered intramuscularly into the deltoid muscle in two doses at a volume of 0.5 ml each with a time interval of 12-16 weeks.[5]

Tenderness, warmth, pain, redness, itching, swelling or bruising, being unwell, tired (fatigue), fever with or without chills Headache, feeling sick, nausea, joint pains or muscles ache are the ADRs observed on the injection site. According To WHO, Adverse drug reaction is "Any response to a drug which is noxious and unintended which occurs at normal doses used in man for prophylaxis, diagnosis or therapy of disease on the modification of the physiological function".[6]

An adverse event is "any unwanted medical occurrence during drug administration Corona virus is spread by the inhalation of respiratory aerosols direct human contact & via fomites.[7] And it is a highly infectious virus. There are some steps that can protect the individuals from getting infected- like- Social distancing, personal hygiene frequent hand washing is sanitizing using alcohol 61-70%) based hand-sanitizing zens & disinfection of the surfaces.[8]

The vaccine development includes pre-clinical, clinical (phase I, II) & manufacturing (phase IV) stages. Safety, immunogenicity & efficacy is assessed in a stepwise manner during the clinical stages. During phase IV (4), the comparative Clinical studies post-marketing surveillance are done.[9] For a safe & swift immunisation programme these steps are mandatory Similarly, a reporting mechanism needs to be in place for AE us which is both transparent and up to date. Sri Lanka has a post-vaccine surveillance system for children & a robust vaccination Programme.

An adult vaccination programme of this magnitude has never been implemented previously done vaccination strategy against the pandemic was quite different.[10]

It was required to conduct a post vaccine surveillance simultaneously among them since health care workers received the vaccine as a priority group.[11]

Based on WHO dashboards and death toll hitting 62 lakhs worldwide, COVID-19 pandemic has elevated to lethal proportions with 50 crore confirmed cases globally as of April 2022, all governmental organizations have followed preventive strategies yielding. [12,13]

Measures, social distancing, appropriate sanitization and face masking to restrain the spread of the virus. India advertised to be one of the countries with the largest vaccine roll-out targets directly administering vaccines according to the recommendations of National Expert Group on Vaccine Administration for COVID-19 (NEGVAC). [14,15]

India has produced 187 crores of total. COVID-19 vaccination deses with first and Second doses vaccination coverage to almost 100 & 85 crores respectively till April 2022.[16] The timeline of vaccination for priority population groups have been engraved.

The concern over the safety and efficacy of the COVID-19 vaccine approach high in the mind of the public.[17] Post vaccination surveillance is important to quantify the adverse events affiliated with COVID-19 vaccination for assessing Causality.

The adverse events that would follow such vaccination expenditure could be variable.[18] Adverse Effect following Immunization (AEFI) may influence healthy individuals & should be immediately identified to permit addition research and appropriate action to take place- Timely detection & reporting of adverse following covid-19 vaccination is the first step in assuring the continued safety of the vaccine, immunization sarfety surveillance & response. AEFI is Defined as an untoward medical occurence that may or may not have a causal association with the vaccine administration. [19,20]

Covaxin and covishield produced by Serum Institute of India & Bharat biobtech Ltd respectively were administered in the country.

Methodology: - A longitudinal study was conducted. For a period of 3 months in the adults above 18 yrs of age attending rural health training center (RHTC) either to receive their first & second dose of Covishield or covaxin.[21]

After vaccination, the participants were observed at the health facility for 30 min. For any AEFI & also followed up telephonic -cally on 7th day from vaccination.[22]

When participants were divided into two groups by mean age (≤40 and 40 ≥years) and parameters were compared, most systemic (fever, nausea, fatigue, itching) and all local AE were significantly more prevalent in the ≤40 age group.[23]

Two percent had reactions within the first 20 minutes. Anaphylaxis developed in 12 participants. History of anaphylaxis, drug or food allergy were reported in 0.6%, 2.8% and 6.7% respectively. However, previous history of allergy was not significantly related to immediate reactions or anaphylaxis following vaccination.[24] Despite having minor AE, 71.1% attended routine work while 0.2% required hospitalisation.

Study population & study periods- During the covid pandemic, the study was conducted among the faculty dentists working in four different tertiary care centers of Jaipur city (in Rajasthan) in May 2021.[25]

Aim: - To assess the safety of efficacy of ADRs with covid Vaccination in the South Indian Population.

Study design: - This was an observational, retrospective study.

Inclusion criteria: - Covishield received by all the faculty dentists working is 4 different tertiary care centers of Jaipur city. Those who gave their consent for participation in the study.[26]

Exclusion criteria: - Other health care workers (dental, hygienists, & technicians), resident doctors and internen students Those receiving vaccines other than covidshield or no vaccine.

Research tool: - A standardized questionnaire platforms' utilizing google forms was utilized so collect information about the participants.[27] The face value for the questionnaire was established by two subject experts, then it was pilot tested on 80 participants to check its validity & reliability.

Data analysis: - All the individual participants records were coded & kept confidential. For statistical analysis, IBM statistical package for the social sciences for windows version 17.0 software (IBM Corp, Armonk, NY, USA) was used. For demographic data, descriptive statistics such as frequency & % Were used. To find the associated risk factors for developing adverse effects following vaccination Fisher's exact & chi-square test were used.[28] The data on age, gender, vaccine type & ADRS was collected through telephonic interviews of and online question near was documented in the data collection form.

Results: - Out of 532 participants, 250 (47%) came for their first dose while 282 (53%) Came for second dose Maximum participation was seen by males & those belonging to age group 18-30 years in both the group.

In India two vaccines were approved by the central drugs standard control organisation (CDSCO) – Covishield and Covaxin. However, the vaccines are known to have Adverse Drug Reactions (ADR) to such as fever, body pains, headache, pain & swelling at the injection site.

Table 1: Gender-wise distribution of ADRs among beneficiaries who reported ADRs

Gender	Covishield	Percentage	Covaxin	Percentage	Total	Percentage
Male	19	50%	7	53.8%	26	51%
Female	19	50%	6	46.2%	25	49%

Table 2: Distribution of various types of ADRs among both vaccines

Name of ADR	Covishield (n)	Percentage	Covaxin (n)	Percentage	Total
Fever	34	40	5	19	39
Body ache	13	15	5	19	18
Weakness	6	7	2	8	8
Headache	6	7	1	4	7
Dizziness	3	4	1	4	4
Vomiting	4	5	0	0	4
Vertigo	2	2	1	4	3
Myalgia	1	1	2	8	3
Pain in legs	3	4	0	0	3

Gender	**Percentage (%)**	**Number (n=)**
Male	32.2	1646
Female	67.8	3469
Ethnicity		
Sinhalese	76.5	3873
Others	23.5	1187
Health care worker category		
Medical	17.6	898
Nursing	36.4	1855
Health care assistants	22.9	1169
Professions supplementary to medicine	4.2	216
Paramedical staff	2.7	135
Hospital office staff	3.5	179
Security officer	4.5	230
Hospital cleaning staff	4.8	246
Ambulance staff	0.5	24
Others	2.7	143
Pregnant	0.14	7
Breast feeding	2.1	110
Past infection (Positive PCR for SAR-CoV2)	1	52

Low b.p.	1	1	2	8	3
Loose motion	2	2	1	4	3
Joint pain	1	1	1	4	2
Itching	0	0	1	4	1
Neck pain	1	1	0	0	1
Pain in left sideof body	1	1	0	0	1

Pain in vagina	1	1	0	0	1
Injection site bruise	0	0	1	4	1
Light headedness	0	0	1	4	1
Hematuria	1	1	0	0	1
Improper wound healing	0	0	1	4	1
Left hand pain	0	0	1	4	1
Chest pain	1	1	0	0	1
Abdominal pain	1	1	0	0	1
Tightness in pre-existing nodule	1	1	0	0	1
Darkness under eye	1	1	0	0	1
Anorexia	1	1	0	0	1

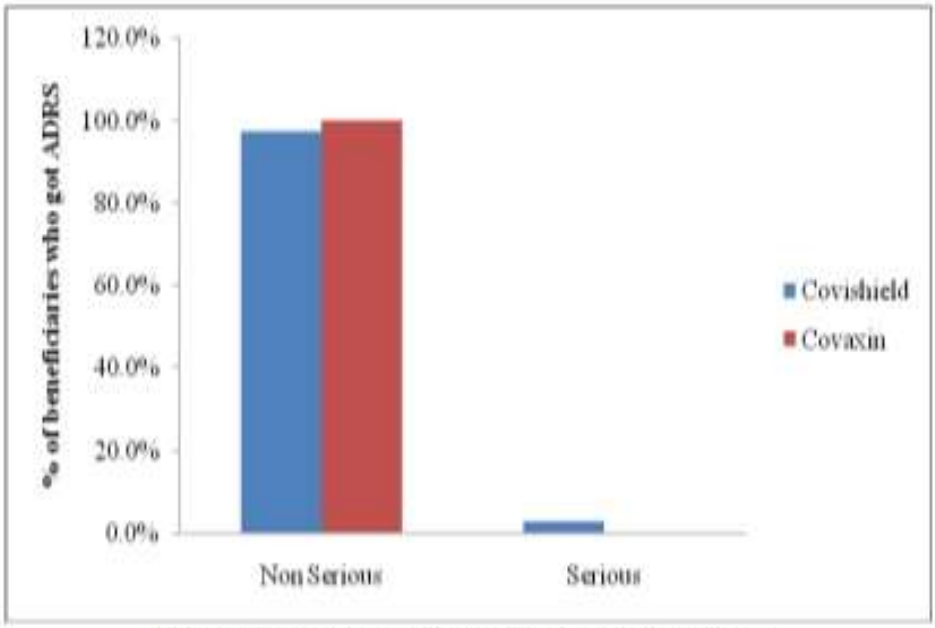

Figure 1: Distribution of ADRs as per seriousness.

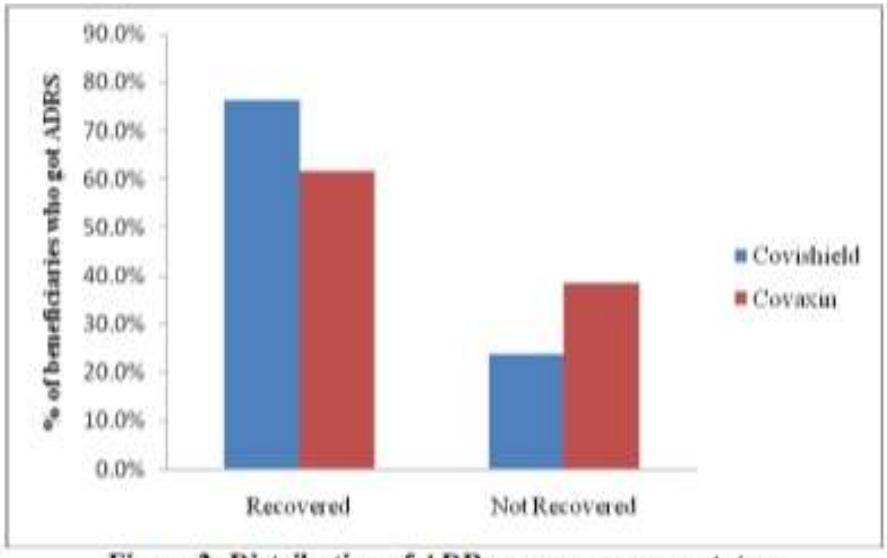

Figure 2: Distribution of ADRs as per recovery status.

Table 3: Distribution of unlisted adverse events in vaccines

Name of unlisted Adverse events	Frequency in Covishield	Frequency in Covaxin
Vertigo	2	1
Weakness	6	2
Pain in vagina	1	0
Injection site bruise	0	1
Light headedness	0	1
Hematuria	1	0
Improper wound healing	0	1
Chest pain	1	0
Tightness in pre-existing nodule	1	0
Darkness under eye	1	0

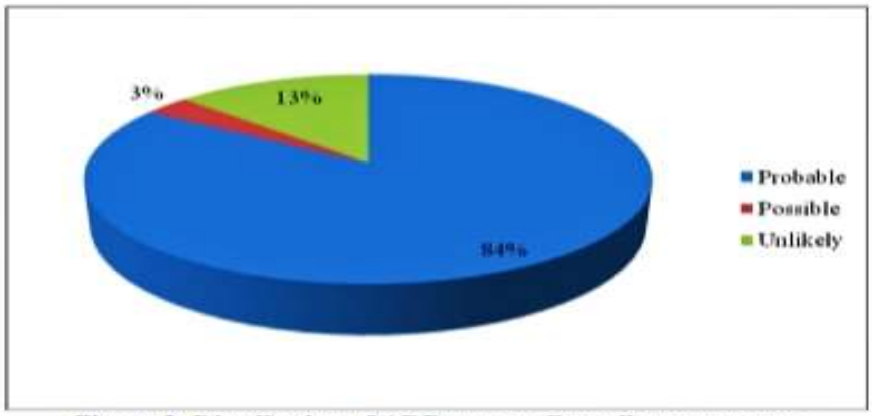

Figure 3: Distribution of ADRs as per Causality assessment

Table 4: Distribution of ADRs as per Causality assessment among both vaccines.

Classification as per WHO-UMC Scale	Covishield	Percentage	Covaxin	Percentage	Total	Percentage
Probable	74	87%	19	73%	93	84%
Possible	08	9%	07	27%	15	13%
Unlikely	03	4%	0	0%	3	3%

Discussion: - The present study was on the ADRS Caused by the vaccines against covid-19 infections. Followed by 46-60 yr, the ADRS were mostly seen in the age group of 18-30 yr.

In India has reported few ADRs associated with vaccination in a tertiary care hospital among health care workers. Those studies have shown that the first dose of vaccination shows a higher % of ADRS compared to the second dose of covishield, Similar results were seen in our study, where Covishield first dose showed a rat of ADRs of 49.9%. Followed by the second dose of 10.9%. “Fever, body pain, headache, vomiting, pain at the injection site, weakness, drowsiness, insomnia, chills, cold, cough, diarrhoea, allergy, dysuria, giddiness, chest pain, loss of appetite, throat pain, neck pain, stomach upset, eye irritation are the common ADRS caused by the covid vaccines. All the ADRS caused by these vaccines Where mild or moderate.[29]

Our study’s results have shown that the ADRS of covishield vaccination are fever, body pains, headache, weakness & pain at the injection, site in a higher % of the population.

Furthermore, an observational Study on surveillance of adverse events of covishield conducted by Dhanya Jose et al, A cross-sectional study conducted on ADRS of covishield by sukhpal kaur et al. In study, female gender was a critical risk factors, for post vaccination adverse effects. This report was along the side of the Other previous studies.

This report can be explained as younger individuals & females have stronger immune responses in compare with the elderly & male counterparts, respectively, they are wanted to develop more adverse effects of immense intensity 2

Concerning the severity of symptoms, most symptoms were mild (73.63%) & moderate (26.37%) & no severe side effects were norted. This report is like a study conducted in Wuhan which expressed most symptoms as mild to moderate in severity.

An average about 80.4% of the participants had not report their adverse effect while 21% participants have not known where & how to report their ADRS. This report highlights the requirement for training of our health-care workers on reporting of adverse effects following immunization. This will promotes strengthen active surveillance concurrently with the mass vaccination program of the government of India.

One of the limitations of this study is that the variations in the adverse events following different doses was not. Considered in detail as the present study deliberate to focus on the predictors that affects the adverse effects in respective of the dosing of the vaccination.

The investigation study conducted among HCWs in Sri Lanka, when there was no large-scale post-vaccination surveillance investigation.

The average age of the study population was 40.69 (±9.85) years, with an age range 18-63 years. study population was divided into two groups 10<40 years old, regarding the mean age. Between the two groups, profiles of adverse events were compared.

Two-thirds of the sample was female which imitated the increased proportion of female HCWs in government hospitals in the country, The priority was given to frontline healthcare workers & other stakeholders with the introduction of the vaccination programme to Sri Lanka.

Before it reached the public, this provided the Ideal setup to study adverse events among frontline workers.

A national vaccination programme required a safe vaccine & post – vaccine surveillance as an essential part of the programme. There are standard steps to follow when a vaccine is introduced for a newly emerged disease.

An average about 80.4% of the participants had not report their adverse effects while 21% participants have not these knowing where & how to Report their ADRS. This report highlights are the requirement for training of our health-care workers on reporting of adverse effects following immunisation. This will promote strengthen active surveillance concurrently with the mass vaccination program of the government of India.

One of the limitations of this study is that the variations in the adverse events following different doses was not. considered in detail as the present study deliberate eliberate to focus on the predictors that affects the adverse effects in respective of the dosing of the vaccination.

Conclusion: -

The conclusion emphasizes the overall safety profile of both vaccines, with no reported fatalities associated with their administration. This is a significant finding, as it underscores the vaccines' general safety and helps build public confidence in their use. Despite the lack of death reports, it is important to acknowledge the occurrence of one serious adverse event linked to the Covishield vaccine. This incident required the recipient to be hospitalized. However, the individual's swift recovery and discharge on the same day are reassuring, suggesting that even serious adverse events can be effectively managed with appropriate medical care.

Both vaccines were associated with common adverse drug reactions (ADRs) such as fever, body ache, and weakness. These reactions are typically mild to moderate in severity and are consistent with the expected immune response to vaccination. Such symptoms are common with many vaccines and indicate that the body is building

protection against the virus. The absence of significant differences in the prevalence of ADRs between the two vaccine groups is noteworthy. It suggests that both vaccines have a similar safety profile, which can be a critical factor in public health decision-making, especially in scenarios where vaccine choice might be driven by availability rather than preference.

The findings also highlight the importance of continuous monitoring and reporting of adverse events post-vaccination. This ongoing surveillance ensures that any potential risks are identified promptly and managed effectively. It also contributes to the overall understanding of vaccine safety, informing both healthcare providers and the public.

In conclusion, the data reinforce the safety of both vaccines, with no fatalities reported and manageable adverse events. The similarities in the occurrence of common ADRs between the two vaccines provide additional reassurance about their safety profiles. This information is crucial for healthcare professionals and the public as it supports the continued use of both vaccines in the fight against COVID-19, helping to prevent the spread of the virus and protect public health.

REFERENCES

1. Agrawal S, Gael AD, Gupta N. Emerging prophylaxis strategies against COVID-19. Monadic Arch Chest Dis. 2020;90 doi:10.4081/monaldi.2020.1289.
2. Shahriar S, Koly FJ. A cross-sectional study on Bangladeshi students regarding physiological challenges of online education. Pharm Educ. 2021;21:267-75.
3. Sohrabi C, Alsafi Z, O'neill N, Khan M, Kerwan A, Al-Jabir A, et al. World Health Organization declares global emergency:A review of the 2019 novel coronavirus (COVID- 19) Int J Surg. 2020;76:71-6.
4. Mohakuda SS, Nigam A, Rajesh K, Sanhedrin VK, Sharma H, Singh B, et al. Covishield India: Demystifying myths through an early multicenter safety Study. Am J Manage Care. 2021;27:e339-42.
5. Kamal D, Thakur V, Nath N, Malhotra T, Gupta A, Batlish R. Adverse events following ChAdOx1 nCoV-19 Vaccine (COVISHIELD) amongst health care workers: A prospective observational study. Med J Armed Forces India. 2021;77:S283-8.
6. [Last accessed on 2022 Jan 03]; (COVID-19) C, Health E, Disease H, Disease L, Management P, Conditions S. COVID Vaccine Booster: Everything You Need to Know. WebMD. 2022 Available
7. Konu YR, Gbeasor-Komlanvi FA, Yerima M, Sadio AJ, Tchankoni MK, Zida-Compaore WIC, et al. Prevalence of severe adverse events among health professionals after receiving the first dose of the ChAdOx1 nCoV-19 coronavirus vaccine (Covishield) in Togo, March 2021. Arch Public Health. 2021;79:207.
8. Sultana A, Shahriar S, Tamsin MR, Mim SR, Fatema KR, Saha A, et al. A retrospective cross-sectional study assessing self-reported adverse events following immunization (AEFI) of the COVID-19 vaccine in Bangladesh. Vaccines (Basel) 2021;9:1090.
9. Kumar D. R S, J S, Patel AE, R V. Covid-19 vaccination coverage and break through infections in urban slums of Bengaluru, India: A cross sectional study. medRxiv. 2021 doi:10.1101/2021.11.21.2126271
10. Kumar VM, Pandi-Perumal SR, Trakht I, Thyagarajan SP. Strategy for COVID-19 vaccination in India: the country with the second highest population and number of cases. Npj Vaccines 2021;6(1):60. Available from: http://www.nature.com/articles/s41541 -021-00327-2 л.

11. Ministry of Health and Family Welfare. Government of India. COVID-19 vaccines operational guidelines [Internet]; 2020 [cited 2021 May 19].
12. Available from https://main.mohfw.gov.in/sites/default /files/COVID19VaccineOG111Chapter16. pdf 7.
13. R.E. Chandler Optimizing safety surveillance for COVID-19 vaccines Available from: Nat Rev Immunol, 20 (8) (2020), pp. 451-452http://www.nature.com/articles/s41577-020- 0372-87
14. Ministry of Health and Family Welfare. CoWIN dashboard [Internet]. [cited 2022 Apr 22]. Available from: https://dashboard.cowin.gov.in/7.
15. Who (world health organization), Geneva 2020, draft land scape of COVID-19 candidate vaccines (Google scholar).
16. Basavaraja CK, Sebastian J, Ravi MD, John SB. Adverse events following COVID-19 vaccination: first 90 days of experience from a tertiary care teaching hospital in South India. Ther Adv Vaccines Immunother tracker 2021;9:25151355211055830. Available from: https://doi.org/10.1177/25151355211055 833 7.
17. Harvard.edu. Covid-19 vaccination tracker. Available from: https://geographicinsights.iq.harvard.edu/IndiaVaccine 7.
18. WHO. WHO coronavirus disease [Internet]. WHO; 2021. p. 1. Available from: https://covid19.who.int 7.
19. Klugar M, Road A, Mekhemar M, Conrad J, Buchbender M, Howaldt HP, et al. Side effects of mRNA-based and viral vector-based COVID-19 vaccines among German healthcare workers. Biology (Basel) 2021;10:752.
20. Jayadevan R, Shenoy RS, Anithadevi TS. Survey of symptoms following COVID-19 vaccination in India. medRxiv. 2021 doi:10.1101/2021.02.08.21251366.
21. Sangha T. A review of coronavirus disease-2019 (COVID-19). Indian J Paediatric 2020;87:281-6.
22. Kumar VM, Pandi-Perumal SR, Trakht I, Thyagarajan SP. Strategy for COVID-19 vaccination in India: The country with the second highest population and number of cases. NPJ Vaccines 2021;6:60.
23. Fact Sheet for Vaccine Recipient Approved for Restricted Use in Emergency Situation of Chadox1 ncov-19 Corona Virus Vaccine (Recombinant); 2021. Available from: [Last accessed on 2021 Jul 31].
24. Hartwig SC, Siegel J, Schneider PJ. Preventability and severity assessment in reporting adverse drug reactions. Am J Hosp Pharm 1992:49:2229-32.
25. Raid A, Pokhran A, Attia S, Klugarová J, Koščík M, Klugar M. Prevalence of COVID-19 vaccine side effects among healthcare workers in the Czech republic. J Clin Med 2021;10:1428.
26. Almufty HB, Mohammed SA, Abdullah AM, Merza MA. Potential adverse effects of COVID19 vaccines among Iraqi population; a comparison between the three available vaccines in Iraq; a retrospective cross-sectional study. Diabetes Metab Sydnor 2021;15:102207.
27. Zhu FC, Li YH, Guan XH, Hou LH, Wang WJ, Li JX, et al. Safety, tolerability, and immunogenicity of a recombinant adenovirus type-5 vectored COVID-19 vaccine: A dose-escalation, open-label, non-randomised, first-in-human trial. Lancet 2020;395:1845-54.
28. Menni C, Klaser K, May A, Polidori L, Capdevila J, Louca P, et al.
29. Voysey M, Clemens SA, Madhi SA, Wicks LY, Folegatti PM, Alley PK, et al. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: An interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. Lancet2021;397:99-111.