International Journal of Pharmacy and Pharmaceutical Sciences

Print ISSN: 2656-0097 | Online ISSN: 0975-1491 Vol 15, Issue 3, 2023

Original Article

ASSESSMENT AND ANALYSIS OF ADVERSE EVENTS FOLLOWING COVID-19 VACCINATION AMONG CHILDREN AGED 15-18 Y AT TERTIARY CARE TEACHING HOSPITAL, TELANGANA: A PROSPECTIVE OBSERVATIONAL STUDY

SWARUPA RANI KASUKURTHI[1], CHAKRADHAR T.[2], SRAVANI MARPAKA[3], N. KARUNASREE [4*]

[1]Department of Pharmacology, Osmania Medical College, Koti, Hyderabad, Telangana, India 500095, [2]Department of Pharmacology, Osmania medical College, Koti, Telangana, India 500095, [3]Adverse Drug Reaction Monitoring Centre-Osmania Medical College, Koti, Hyderabad, Telangana, India-500095, [4]Department of Pharmacology, Osmania Medical College, Koti, Hyderabad, Telangana, India 500095
Email: raja_narasimharao@yahoo.com

Received: 18 Jan 2023, Revised and Accepted: 06 Feb 2023

ABSTRACT

Objective: Government of India (GOI) has allowed vaccination for age group of 15-18 y. It is a positive step toward boosting immunization rates across the nation. As per guidelines, BBV152 vaccine, Bharat Biotech's "Covaxin" is approved for adolescents. The study was designed to evaluate adverse events following immunization (AEFI) among adolescents.

Methods: A prospective, observational survey was carried out among the first 315 beneficiaries (adolescents of age 15-18 y) for a period of 5 mo at Osmania medical college and hospitals. Within 24 h, 48-72 h, and two weeks following the first and second doses of Covaxin, active and passive surveillance using telephonic inquiry and documentation relating to adverse events was conducted. The prevalence of AEFI and its association with demographic factors have been identified. Collected data were analyzed using SPSS 25.

Results: The first 315 beneficiaries (Adolescents between the ages of 15 and 18) who received Covaxin were identified. All AEFIs reported were within the first 24-72 h of vaccination. AEFI incidence was higher in 1st dose (16.6%) when compared to 2nd dose (3.5%). No AEFIs were noted after 2 w. We found no association of AEFI with sex, age group, and past history of Covid as this finding is not significant ($p>0.05$).

Conclusion: Overall, Covaxin has a good safety profile in adolescents. Symptoms were transient and of low intensity. There were no documented severe and serious AEFI. It is obligatory for documentation as the AEFI profile will encourage vaccine adoption and lessen reluctance.

Keywords: Covid-19, Covaxin, Adolescents, AEFI

DOI: https://dx.doi.org/10.22159/ijpps.2023v15i3.47358. Journal homepage: https://innovareacademics.in/journals/index.php/ijpps.

INTRODUCTION

The ongoing COVID-19 pandemic, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), identified in December 2019 had severely impacted healthcare systems, social and economic progress throughout the world [1]. This dreadful Covid-19 disease accounts for 6.6 million deaths across the globe as of November 2022 [2]. Many global health organizations are consistently trying to come up with therapeutic treatments and prevention strategies. Researchers worked distinctly to increase effective and safer vaccines for COVID-19 infection.

COVID-19 first immunization phase in India was rolled-out on January 16, 2021, with priority given to frontline employees and healthcare professionals. Emergency Use Authorization (EUA) has been granted for two vaccines developed in India. A whole-Virion Inactivated Vero cell vaccine called Covaxin was created by Bharat Biotech in association with the Indian Council of Medical Research (ICMR), while a recombinant vaccine called Covishield (ChAdOx1nCoV-19) was created by Serum Institute of India in collaboration with Oxford-AstraZeneca [3, 4]. In Adults, Adverse Events Following Immunization (AEFI) incidents reported were minor [5] and gradually, the acceptance of vaccines increased as more than 80% of adult beneficiaries who were eligible for immunization received the first dose of COVID-19 vaccine and more than 50% received the second dose i.e., complete vaccination [6]. Based on Phase 2/3 trial, a 2 to 18-year-old child open-label, multi-center study demonstrating the effectiveness and safety of COVAXIN [7] which showed minor AEFIs, Subject Experts Committee of CDSCO had suggested for approving Bharat Biotech's COVAXIN as Emergency Use Authorization (EUA) for use in patients 2 to 18 y old.

Gradually, the Government of India (GOI) announced a nationwide mass vaccination drive for adolescent's 15-18 y of age from 3rd January 2022 [8]. It is crucial to demonstrate the safety of vaccination in the adolescent age group in a real-world scenario in India.

An adverse event following immunization (AEFI) is any undesirable medical outcome that may not necessarily have a causal connection to the use of the vaccine [9]. Based on severity and frequency, AEFIs are classified as Common minor AEFIs, which are self-limiting eg-fever, pain and swelling at the injection site, irritability, malaise, etc. Severe AEFIs are not minor but do not result in death, hospitalization, or disability. "Severe" is used to describe the intensity of a specific event (as in mild, moderate, or severe) and Serious AEFIs require hospitalization, results in persistent or significant disability/incapacity or a cluster, and death [10]. AEFI rates with BBV152 were lower compared to mRNA-based vaccines [11]. However, there is a paucity of data on the safety profile of Covaxin restricted to the adolescent subset. In order to control the ongoing pandemic, there is a need to create trust and confidence among the beneficiaries and extend the benefits of vaccination.

The present study aimed to identify and analyze the AEFIs among adolescents of the age group 15-18 y following COVID-19 vaccinations at our study site.

MATERIALS AND METHODS

Study site

The study site is Osmania medical college and General Hospitals.

Study design

A prospective observational study started from January 2022 to May 2022 among first 315 vaccine recipients. The first dose started from 3rd Jan 2022 to 25th Feb 2022. The second dose was administered after four weeks of the first dose. The two doses of Covaxin were

monitored for AEFI for a period of two weeks. The recipients were provided a leaflet containing information regarding vaccines, possible AEFI, and supportive medical care. The adverse events were cited from the WHO guidelines and information brochure advertised by the manufacturer [12].

Study participants

Inclusion criteria

Adolescents of age group 15-18 y (both boys and girls) who reported any adverse events (AEs) and provided consent from the accompanying guardian along with written assent of the adolescents were enrolled in the study. Beneficiaries with comorbidities like Diabetes, bronchial asthma, and thyroid disorders were also included, but none of them had the background.

Exclusion criteria

Age<15 and above 18 y were excluded. Adolescents without guardians and the recipients who refused to give consent/assent were not taken into the study.

Study process

Adverse event monitoring was done both actively and passively.

Active surveillance was done through telephonic inquiry and documentation related to adverse events was done within 24 h, 48-72 h, and after 2 w following the first and second doses of Covaxin.

Passive surveillance

Recipients were instructed to notify the surveillance team of any adverse reactions at the time of vaccination. The pamphlet provided emergency phone numbers in case they were needed.

Data sources/measurement

Data relevant to demography, and medical history, including the history of Covid positivity in the past, existing co-morbidities, concurrent drug history, and allergy to any stimuli was recorded. Information regarding the development of AEFIs, the severity of AEFIs, outcomes of AEFIs, and time to complete recovery was noted.

Sample size

According to the existing safety data from controlled settings, the general population's AEFI rate ranges from 12 to 21% [13, 14]. The study's main goal was to assess COVAXIN's safety profile in young people. Due to the absence of unique evidence to India and the assumption that 13% of clinically significant AEFIs occur on average, with a margin of error of 4%, the expected sample size for the present study was calculated to be approximately 290, it was intended to enroll at least 311 people, taking a drop-out rate of 10% into account.

Statistical analysis

Results were documented as frequencies as well as percentages for data such as incidence and severity of AEFIs. Chi-square test and P values were applied for dichotomous variables such as gender, age, and history of Covid to determine the association between different variables and the development of AEFIs. All the results were analyzed in Statistical Package for the Social Sciences (SPSS) version 25.

Ethical permission

The approval to conduct this study was obtained from the Institutional Ethics Committee (IEC) of Osmania Medical College and Hospitals with reference number.

[Ref. No. IEC/OMC/2022/M. No. (02)A cad–10] and written informed consent were taken from all the participants.

RESULTS

As per STROBE (Strengthening the Reporting of Observational studies in Epidemiology) guidelines, fig. 1 depicts the vaccination of subjects for the present study.

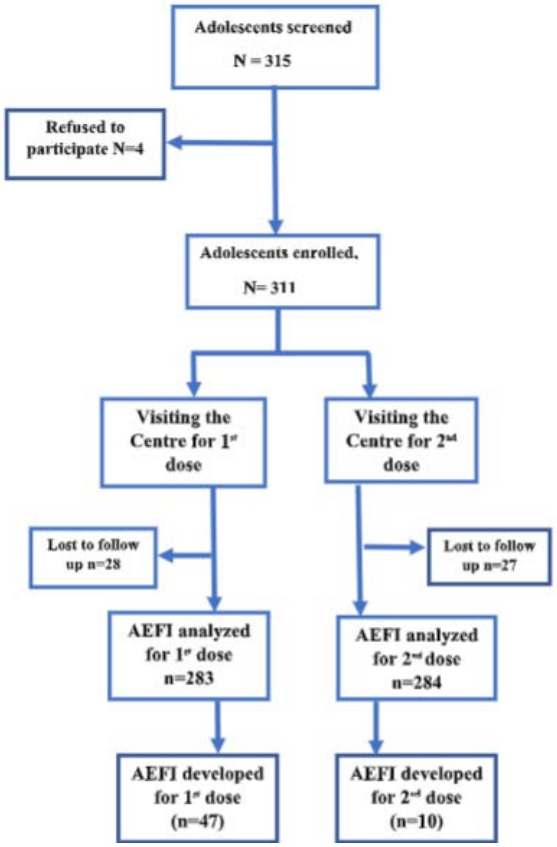
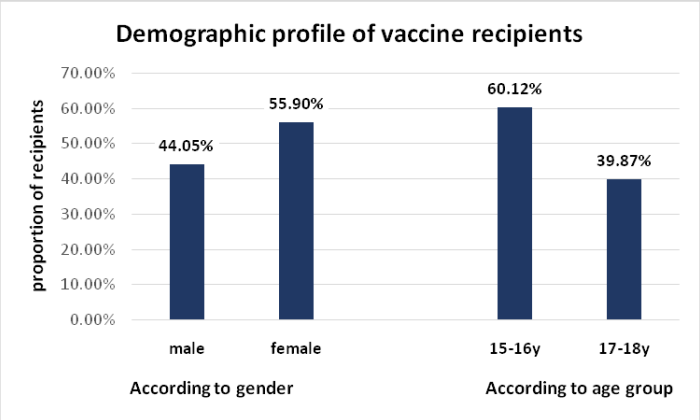


Fig. 1: STROBE flowchart showing enrolment of adolescents. AEFI adverse event following immunization, STROBE (Strengthening the Reporting of observational studies in Epidemiology)

Out of 311 participants enrolled, the majority of them i. e, 174(55.9%) were girls and the remaining 137(44.05%) were boys. 187(60.12%) and 124(39.87%) participants were in the age group of 15-16 y and 17-18 y, respectively. The demographic profile of vaccine recipients was categorized based on age and gender distribution, is shown in Graph 1.



Graph 1: Demographic profile of vaccine recipients

AEFIs after first dose in adolescents

Out of 311 enrolled vaccine recipients, only 283 participants were analyzed for the first dose. 47 (16.6%) developed AEFIs. All the adverse events reported were AEFIs of mild grade 1 severity (FDA grading scale). Common minor AEFIs reported were Swelling/pain/redness over the site of injection (n=14, 4.9%), Fever (n=12, 4.2%), Headache (n=5,1.76%), Feeling unwell (n=5,1.76%), Fatigue (n=1, 0.35%), Muscle ache (n=1, 0.35%), Nausea (n=3, 1.06%), Dizziness (n=1, 0.35%), Chills (n=2, 0.7%), Itching (n=2, 0.7%), Vomiting (n=1, 0.35%). Four types of minor adverse events were reported within 48-72 h as shown in table 1. No adverse events were reported after 2 w of the first dose of vaccination. Table 1 illustrates AEFIs after the first dose of vaccination.

AEFIs after second dose in adolescents

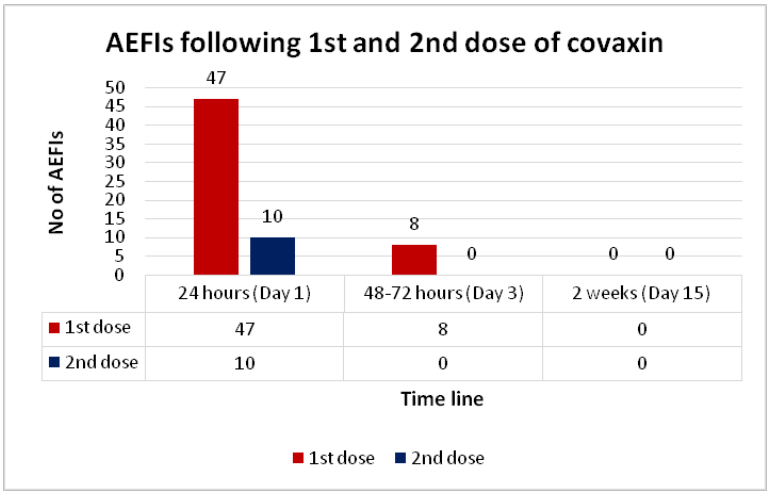
Out of 284 vaccine recipients, only 10 (3.5%) reported AEFIs within 24 h of 2nd dose of vaccination. No adverse events after 72 h and 2 w of the second dose vaccination. Adverse events reported during and after the second dose of vaccination were shown in table 2.

Table 1: AEFIs after the first dose of vaccination of Covaxin

Adverse events (mild) common minor AEFIs (N=283)	First 24 h (Day-1) No of cases (%)	48-72 h (Day-3) No of cases (%)	2 w of vaccination (Day-15) No of cases (%)
Fever	12 (4.2%)	4 (1.41%)	0 (0%)
Swelling/pain/redness over the site of injection	14 (4.9%)	3 (1.06%)	0 (0%)
Headache	5 (1.76%)	1 (0.35%)	0 (0%)
Feeling unwell	5 (1.76%)	1 (0.35%)	0 (0%)
Fatigue	1 (0.35%)	0 (0%)	0 (0%)
Muscle ache	1 (0.35%)	0 (0%)	0 (0%)
Nausea	3 (1.06%)	0 (0%)	0 (0%)
Dizziness	1 (0.35%)	0 (0%)	0 (0%)
Chills	2 (0.7%)	0 (0%)	0 (0%)
Itching	2 (0.7%)	0 (0%)	0 (0%)
Vomiting	1 (0.35%)	0 (0%)	0 (0%)

Table 2: AEFIs after the second dose of vaccination of Covaxin

Adverse events (mild) common minor AEFIs N=284	First 24 h (Day-1) No of cases (%)	48-72 h (Day-3) No of cases (%)	2 w of vaccination (Day-15) No of cases (%)
Fever	4(1.4%)	0 (0%)	0 (0%)
Swelling/pain/redness over the site of injection	3(1.05%)	0 (0%)	0 (0%)
Headache	1(0.35%)	0 (0%)	0 (0%)
Feeling unwell	0 (0%)	0 (0%)	0 (0%)
Fatigue	1(0.35%)	0 (0%)	0 (0%)
Muscle ache	0 (0%)	0 (0%)	0 (0%)
Nausea	1(10%)	0 (0%)	0 (0%)
Dizziness	0 (0%)	0 (0%)	0 (0%)
Chills	0 (0%)	0 (0%)	0 (0%)
Itching	0 (0%)	0 (0%)	0 (0%)
Vomiting	0 (0%)	0 (0%)	0 (0%)



Graph 2: AEFIs comparison in first and second doses of vaccination

Table 3: Association of AEFIs with age, sex, and history of covid disease

	AEFI first dose(n=283)				AEFI second dose(n=284)			
	Yes (N)	**No (N)**	**Chi-square**	**p-value**	**Yes (N)**	**No (N)**	**Chi-square**	**p-value (S/NS)**
Sex								
Female	26	124	0.1213	0.727	8	162	1.7499	0.185 (NS)
% of total	9.18%	43.8%			2.81%	57%		
Male	21	112			2	112		
% of total	7.4%	39.5%			0.7%	39.4%		
Total	47	236			10	274		
Age								
15-16	20	110	0.2598	0.610	7	140	1.381	0.239 (NS)
% of total	7.0%	38.8%			2.46%	49.2%		
17-18	27	126			3	134		
% of total	9.5%	44.5%			1%	47.1%		
Total	47	236			10	274		
H/o Covid								
Covid+ve	8	60	1.5159	0.218	2	56	0.001	0.973 (NS)
% of total	2.82%	25.2%			0.7%	19.7%		
Covid-ve	39	176			8	218		
% of total	13.7%	62.1%			2.81%	76.7%		
Total	47	236			10	274		

P>0.05–NS-Not Significant; P<0.05–S–Significant, We found no correlation of AEFI with sex, age group, and past history of covid (p>0.05)

AEFI with a history of covid-19

8 recipients (2.82%) and 2 recipients (0.7%) developed adverse events with a past history of Covid disease after the first dose and second dose of vaccination, respectively. All were minor and insignificant.

Association of adverse events with demographic variables

Adverse events according to sex, age groups and past history of Covid is elaborated in table 3.

DISCUSSION

There have been concerns about the effectiveness and safety of the vaccine campaign that was launched in India. Similar concerns were raised when a national immunization campaign for adolescents was launched in 2022 because of data indicating substantially fewer illnesses and COVID-19 symptoms among children [15]. Vaccines with a safety record, and subsequent effectiveness in preventing COVID-19, preventing severe forms of COVID-19, and preventing transmission serve as the most effective weapon to combat this pandemic. In India, schools and institutions have been physically closed for the past two years. Child vaccinations and COVID-19-appropriate behaviours may pave the way for their reopening in the future. As a result, the vaccination drive must be expanded to include youngsters while being strictly supervised for AEFI. To the best of our knowledge, this was the first study in South India assessing and analyzing AEFIs in adolescents of the age group 15-18 y.

In this research, we investigated AEFI among Covaxin recipients. Most of the adverse events reported were mild, common minor AEFIs (WHO-AEFI classification) such as fever, swelling/pain at the injection site, fatigue, headache, etc, observed within 24-72 h. This result was consistent with a previous study done by Parida *et al.* [16].

In this study, females reported higher AEFI than males, the result was similar to research conducted by Menni *et al.* [17], but the finding is not statistically significant (p=0.727) p>0.5. No gender difference was reported in a study done by Kamal *et al.* [18]. The proportion of AEFI was 16.6% after the first dose and 26.4% after the second dose. Our finding was further corroborated by a descriptive analysis using the WHO database [19].

Beneficiaries who received the first dose reported a higher AEFI (16.6%) compared to the second dose (3.5%). This finding was similar to a study conducted by Kaur *et al.* in North India [20] as they reported 40% and 16.6% of the AEFI among first and second dose beneficiaries, respectively. However, the sample size is higher compared to our study.

In our research, we did not discover any severe adverse events. In all the studies majority of the AEFIs are mild-moderate in nature. These

findings show that COVID-19 vaccinations have a greater safety profile. The common adverse events identified in our research were fever, pain at the injection site, myalgia, headache, and fatigue. Phase 2 trial of the BBV152 vaccine also reported the same common adverse events [21].

According to Government of India standards, people who have SARS-CoV2 infection are deferred from receiving vaccinations by three months. Therefore, we had only three participants with Covid infections in the last 3 mo, and the variable could not be analyzed further. Participants who had previously contracted SARS-CoV2 were shown to have a greater rate of reactogenicity [22, 23]. From table 3, beneficiaries with past history of Covid 19 developed were 8(2.82%) after first dose of vaccination and 2(0.7%) after the second dose of vaccination, we found no association as the results were statistically insignificant ($p=0.218>0.05$). The data reveals that Covaxin in adolescents majorly lead to minor AEFI, which was managed conservatively, did not require hospital admission, or precede to any long-term consequences.

LIMITATIONS OF THE STUDY

The study is limited by the relatively small sample size used to evaluate serious/rare AEFI. Telephonic follow-up approach was other limitation when compared with the direct observation made by physicians and strategies for retrieving data from clinical records.

The third wave of COVID-19, which was prevalent in the community at the time of adolescent vaccination, shares several clinical symptoms with some AEFIs, such as fever, headache, and fatigue.

The study's findings might not accurately reflect the frequency of adverse events, larger metacentric research is necessary to apply the findings to the general public.

CONCLUSION

Our study elucidates that Covaxin (BBV152) has a generally favourable safety profile and is well tolerated by adolescents. The symptoms were transient and of low intensity. There were no documented severe and serious AEFIs linked to vaccinations. There was a significant decrease in the incidence of AEFI after second dose when compared to first dose. It is obligatory for documentation as the AEFI profile will encourage vaccine adoption and lessen reluctance, particularly during the era of emerging variations of COVID-19 [24, 25]. Longer period follow-up could reveal further details regarding COVAXIN's long-term safety profile in young people. Studies of this kind highlight the necessity of careful AEFI reporting and monitoring, particularly for recently launched vaccinations to spot potential signals.

ACKNOWLEDGEMENT

The authors would like to acknowledge Osmania Medical College and NCC-PvPI, Indian Pharmacopoeia Commission (IPC), Ministry of Health and Family Welfare, Government of India (GOI) for the technical support. We extend our thanks to Dr. Sujith T for his assistance in the analysis. We also thank all adolescents who participated in the study and administrators for Data collection.

ETHICS APPROVAL

Approved by Institutional Ethics Committee of Osmania Medical College, [Ref. No. IEC/OMC/2022/M. No.(02)A cad–10] before the study was conducted.

FUNDING

No source of funding.

AUTHORS CONTRIBUTIONS

Dr. Swarupa Rani Kasukurthi conducted the research, drafted the manuscript and collected reference articles. Ms. Sravani Marpaka has planned and designed the concept of the study and co-drafted the manuscript. Dr. Chakradhar T and Dr. Karunasree N reviewed the manuscript.

CONFLICTS OF INTERESTS

Declared none

REFERENCES

1. Matta S, Chopra KK, Arora VK. Morbidity and mortality trends of covid 19 in top 10 countries. Indian J Tuberc. 2020 Dec;67(4S):S167-72. doi: 10.1016/j.ijtb.2020.09.031. PMID 33308665, PMC7543896.
2. Weekly epidemiological update on COVID-19-23; Nov 2022. Available from: https://www.who.int/publications/m/item/weekly epidemiological-update-on-covid-19-23 November 2022. [Last accessed on 25 Nov 2022]
3. ICMR: Indian Council of Medical Research. New Delhi; 2020. Available from: https://vaccine.icmr.org.in/index.php/website-policy. [Last accessed on 25 Nov 2022]
4. Fact sheet for vaccine recipients and caregivers; Jan 2021. Available from: https://www.bharatbiotech.com/images/covaxin/covaxin-factsheet.pdf. [Last accessed on 25 Nov 2022]
5. Srivastava RK, Ish P, Covid Vaccination Group S. The initial experience of COVID-19 vaccination from a tertiary care centre of India. Monaldi Arch Chest Dis. 2021 Mar 31;91(4). doi: 10.4081/monaldi.2021.1816, PMID 33794595.
6. Nath R. Safety profile of COVID-19 vaccination among adolescents in India-an initial experience. EpidemInt 2020;07(2):13-6. doi: 10.24321/2455.7048.202208.
7. Vadrevu KM, Reddy S, Jogdand H, Ganneru B, Mirza N, Tripathy VN. Immunogenicity and reactogenicity of an inactivated SARS-CoV-2 vaccine (BBV152) in children aged 2-18 years: interim data from an open-label, non-randomised, age de-escalation phase 2/3 study. Lancet Infect Dis. 2022 Sep;22(9):1303-12. doi: 10.1016/S1473-3099(22)00307-3. PMID 35717995, PMCID PMC9212880.
8. Mohfw GOI. Covaxin receives approval for emergency use in 12-18 y old children. Available from: https://www.mohfw.gov.in/pdf/GuidelinesforCOVID19VaccinationofChildrenbetween15to18yearsandPrecautionDosetoHCWsFLWsand60populationwithcomorbidities.pdf. [Last accessed on 25 Nov 2022]
9. Global manual on surveillance of adverse events following immunization; May 2016. Available from: https://www.who.int/publications/i/item/10665206144.WHO. [Last accessed on 25 Nov 2022].
10. MOHFW-GOI Universal Immunization Program (UIP) Revised AEFI guidelines: Executive summary. Available from: https://main.mohfw.gov.in/sites/default/files/Revised%20AEFI%20Guidelines%20Execute%20Summary.pdf. [Last accessed on 27 Nov 2022]
11. Frenck RW, Klein NP, Kitchin N, Gurtman A, Absalon J, Lockhart S. Safety, immunogenicity, and efficacy of the BNT162b2 covid-19 vaccine in adolescents. N Engl J Med. 2021 Jul 15;385(3):239-50. doi: 10.1056/NEJMoa2107456. PMID 34043894, PMCID PMC8174030.
12. Covaxin SMPC. Fact Sheet for Vaccine Recipient Approved for Restricted Use in Emergency by CDSCO. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/en/COVAXIN-SMPC_-BBIL.pdf and https://www.bharatbiotech.com/images/covaxin/covaxin-factsheet.pdf. [Last accessed on 27 Nov 2022]
13. Ella R, Vadrevu KM, Jogdand H, Prasad S, Reddy S, Sarangi V. Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBV152: a double-blind, randomized, phase 1 trial. Lancet Infect Dis. 2021 May;21(5):637-46. doi: 10.1016/S1473-3099(20)30942-7. PMID 33485468, PMC7825810.
14. Ella R, Reddy S, Blackwelder W, Potdar V, Yadav P, Sarangi V. Efficacy, safety, and lot-to-lot immunogenicity of an inactivated SARS-CoV-2 vaccine (BBV152): interim results of a randomised, double-blind, controlled, phase 3 trial. Lancet. 2021 Dec 11;398(10317):2173-84. doi: 10.1016/S0140-6736(21)02000-6. PMID 34774196, PMCID PMC8584828.
15. Gupta S, Malhotra N, Gupta N, Agrawal S, Ish P. The curious case of coronavirus disease 2019 (COVID-19) in children. J Pediatr. 2020 Jul;222:258-9. doi: 10.1016/j.jpeds.2020.04.062. PMID 32360416, PMCID PMC7189853.

16. Parida SP, Sahu DP, Singh AK, Alekhya G, Subba SH, Mishra A. Adverse events following immunization of COVID-19 (Covaxin) vaccine at a tertiary care center of India. J Med Virol. 2022;94(6):2453-9. doi: 10.1002/jmv.27655. PMID 35149993, PMCID PMC9088522.
17. Menni C, Klaser K, May A, Polidori L, Capdevila J, Louca P. Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID symptom study app in the UK: a prospective observational study. Lancet Infect Dis. 2021;21(7):939-49. doi: 10.1016/S1473-3099(21)00224-3. PMID 33930320, PMCID PMC8078878.
18. 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(Suppl 2):S283-8. doi: 10.1016/j.mjafi.2021.06.014. PMID 34334895.
19. Dutta S, Kaur RJ, Charan J, Ambwani S, Besi PS, Odontology F. Serious adverse events reported from the COVID-19 vaccines: a descriptive study based on WHO database. medRxiv Prepr Published online March 24; 2021. doi: 10.1101/2021.03.23.21253433.
20. Kaur U, Ojha B, Pathak BK, Singh A, Giri KR, Singh A. A prospective observational safety study on ChAdOx1 nCoV-19 coronavirus vaccine (recombinant) use in healthcare workers-first results from India. E Clinical Medicine. 2021;38:101038. doi: 10.1016/j.eclinm.2021.101038. PMID 34505032.
21. Ella R, Reddy S, Jogdand H, Sarangi V, Ganneru B, Prasad S. Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBV152: interim results from a double-blind, randomised, multicentre, phase 2 trial, and 3 mo follow-ups of a double-blind, randomised phase 1 trial. Lancet Infect Dis. 2021;21(7):950-61. doi: 10.1016/S1473-3099(21)00070-0. PMID 33705727, PMC8221739.
22. Joshi RK, Muralidharan CG, Gulati DS, Mopagar V, Dev JK, Kuthe S. Higher incidence of reported adverse events following immunization (AEFI) after first dose of COVID-19 vaccine among previously infected health care workers. Med J Armed Forces India. 2021 Jul;77Suppl 2:S505-7. doi: 10.1016/j.mjafi.2021.05.011. PMID 34334920, PMC8313055.
23. Mathioudakis AG, Ghrew M, Ustianowski A, Ahmad S, Borrow R, Papavasileiou LP. Self-reported real-world safety and reactogenicity of COVID-19 vaccines: a vaccine recipient survey. Life (Basel). 2021 Mar 17;11(3):249. doi: 10.3390/life11030249, PMID 33803014, PMC8002738.
24. Iyengar KP, Singh B, Vaishya R, Jain VK, Ish P. Should COVID-19 vaccination be made mandatory? Lung India. 2021 Jul-Aug;38(4):379-81. doi: 10.4103/lungindia.lungindia_181_21. PMCID PMC8272417, PMID 34259181.
25. Kunal S, Aditi, Gupta K, Ish P. COVID-19 variants in India: potential role in second wave and impact on vaccination. Heart Lung. 2021;50(6):784-7. doi: 10.1016/j.hrtlng.2021.05.008. PMID 34217989.