IJBPAS, October, 2025, 14(10): 5664-5671

ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

COVISHIELD ADVERSE DRUG REACTIONS IMPACT ON PUBLIC HEALTH: A COMPREHENSIVE REVIEW

SHRADDHA S.L., PATEL P* AND THAKKAR J

Parul Institute of Pharmacy and Research, Faculty of Pharmacy, Parul University, Vadodara, Gujarat-391760

***Corresponding Author: Dr. Pinkal Patel: E Mail: pinkal.patel@paruluniversity.ac.in**

Received 26th April 2024; Revised 29th Aug. 2024; Accepted 21st Oct. 2024; Available online 1st Oct. 2025

https://doi.org/10.31032/IJBPAS/2025/14.10.9529

ABSTRACT

The World Health Organization proclaimed the coronavirus pandemic of 2019 in March 2020. As there is currently no cure for the illness, immunizations and following COVID-appropriate behavior guidelines have emerged as the main tactics being used to contain the epidemic. To guarantee the best possible health for the general public, it is imperative to evaluate each vaccine's safety profile, as many have been approved after successful clinical trials. This study aimed to review the adverse drug reactions (ADRs) related to the Covishield vaccine, with an emphasis on the incidence of adverse effects in vaccine recipients. The review report was conducted at a tertiary care center to evaluate the adverse events following Covishield vaccination.

Keywords: Coronavirus 2019, Adverse drug reactions, Post marketing Surveillance, Thrombosis with Thrombocytopenia Syndrome, Vaccination

INTRODUCTION:

The novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the cause of coronavirus disease 2019 (COVID-19). SARS is an RNA virus that can cause various illnesses in humans, from the common cold to severe and potentially fatal conditions like Middle East respiratory syndrome (MERS) and SARS **[1]**.

Wuhan, China, reported the first instance of the new coronavirus illness. Because of its

extremely contagious nature, the virus has expanded worldwide since its emergence despite significant efforts to limit it by the WHO and other countries **[2]**. COVID-19 has afflicted millions of individuals globally since humans have little to no immunity against a unique virus. As a result, several nations have put in place a variety of preventive measures, such as hand washing, wearing face masks, keeping social distance, and enforcing regional and national curfews to reduce the rate of transmission **[3]**. Antiviral drugs such as lopinavir or ritonavir, remdesivir, oseltamivir, and favipiravir are commonly used to treat COVID-19 infections, while their effectiveness in severe cases with high death rates is not assured. The cornerstone of care is symptomatic treatment, which emphasizes oxygen therapy and addresses a variety of problems. Severe respiratory distress is given special attention to reduce the risk of mortality. It may be required to use both invasive and non-invasive mechanical ventilation in cases of respiratory failure that is not responsive to oxygen therapy. Since COVID-19 does not yet have a specific drug, immunization is still the most important method of prevention and stopping the virus's spread **[4]**. Lockdowns were imposed to provide researchers a window of opportunity to create potent vaccinations or cures. Mortality and morbidity rates continued even after several drugs were repurposed for prevention and COVID-19 treatment. Nonetheless, there is hope for COVID-19 immunization of people thanks to the global development of numerous vaccines. India is a key player in the worldwide COVID-19 immunization initiative because it is the second most populous country and has large pharmaceutical production capabilities **[5]**. Covishield has been authorized for restricted emergency use by the drug regulatory authorities of India. Produced by the Serum Institute of India, Covishield is a recombinant replication-deficient chimpanzee adenovirus that carries the gene encoding the S protein antigen of SARS-CoV-2. It is one of the vaccinations that can be used in an emergency to possibly protect adolescents and older from contracting COVID-19. The immunization schedule consists of two doses, each of 0.5 ml, given four to twelve weeks apart. The objective of the subsequent investigation is to assess the incidence of adverse events after vaccination (AEFI) after the delivery of the initial and subsequent doses of Covishield and Covaxin. It also aims to evaluate the causes connected to these negative impacts.

SURVEILLANCE AND REPORTING:

The Covishield immunization program in India started on January 16, 2021, to vaccinate frontline and healthcare professionals first. It was then made available for use by the broader population,

including massive immunization campaigns **[6]**. Previous clinical trials associated adverse effects with the Covishield vaccine were documented. These include adverse reactions at the injection site, weariness, chills or fever, fever, headaches, nausea, vomiting, pain in the joints or muscles, flu-like symptoms, dizziness, decreased appetite, discomfort in the abdomen, enlarged lymph nodes, excessive perspiration, itching, or rash **[7]**. There is still a lack of knowledge regarding the general public's experience following vaccination. Studying the effects of the COVID-19 immunization can yield important information. These kinds of studies would not only assist allay fears about possible side effects after vaccination, but they would also boost vaccination safety confidence among the general public. In the end, this might hasten the COVID-19 vaccine campaign. Real-time post-marketing data on COVID-19 vaccines might provide valuable insights to drive regulatory decisions and shape public health initiatives aimed at maintaining a favorable benefit-risk balance, particularly as mass immunization programs get underway.

The necessity for ongoing safety monitoring is underscored by the COVID-19 vaccines, such as Covishield, which have been developed and distributed rapidly. Post-marketing surveillance is crucial for quickly identifying and reporting adverse effects because preclinical and early clinical trial data are inadequate. To improve continuing efforts to assure vaccination safety, this study aims to investigate the frequency, nature, duration, severity, and outcomes of adverse events recorded in recipients of the Covishield vaccine.

SPECIFIC FINDINGS ON COVISHIELD AND COVAXIN ADRS IN INDIA:

Table 1: The breakdown of the various adverse drug reaction kinds across the two vaccinations.

Name of ADR	Covishield (n)	Percentage	Covaxin (n)	Percentage	Total
Itching	0	0	1	4	1
Dizziness	3	4	1	4	4
Darkness under eye	1	1	0	0	1
Light-headednessq	0	0	1	4	1
Joint pain	1	1	1	4	2
Pain in legs	3	4	0	0	3
Haematuria	1	1	0	0	1
Chest pain	1	1	0	0	1
Vertigo	2	2	1	4	3
Anorexia	1	1	0	0	1
Loose motion	2	2	1	4	3
High temperature	34	40	5	19	39
Body ache	13	15	5	19	18
Abdominal pain	1	1	0	0	1
Injection site Bruise	0	0	1	4	1
Pain in vagina	1	1	0	0	1
Headache	6	7	1	4	7
Myalgia	1	1	2	8	3
Low B.P.	1	1	2	8	3
Weakness	6	7	2	8	8
Vomiting	4	5	0	0	4
Pain on left side of the body	1	1	0	0	1

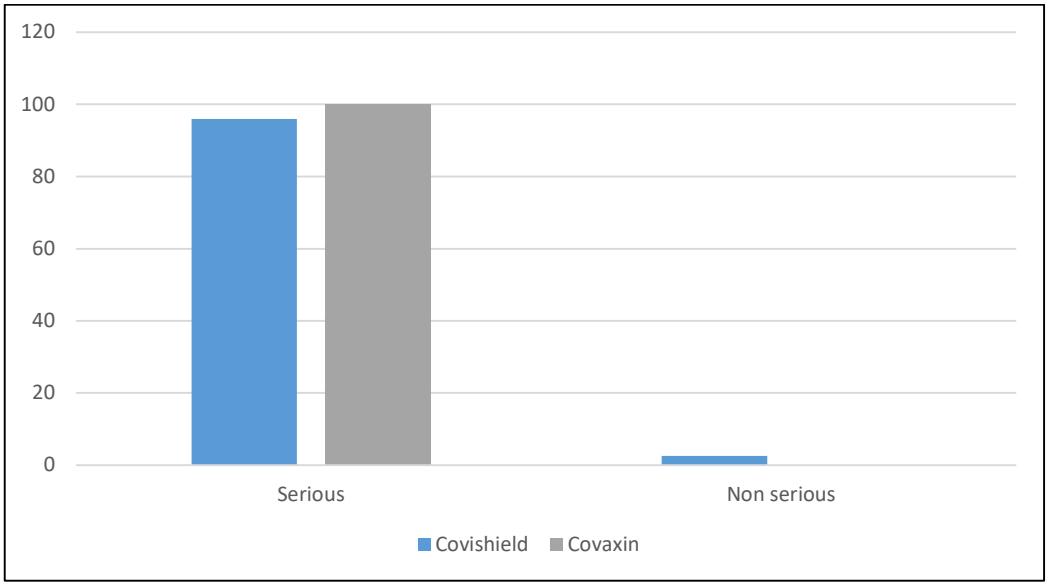

Figure 1: Adverse drug reaction distribution based on seriousness

Table 2: Distribution of unlisted adverse events in vaccines

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

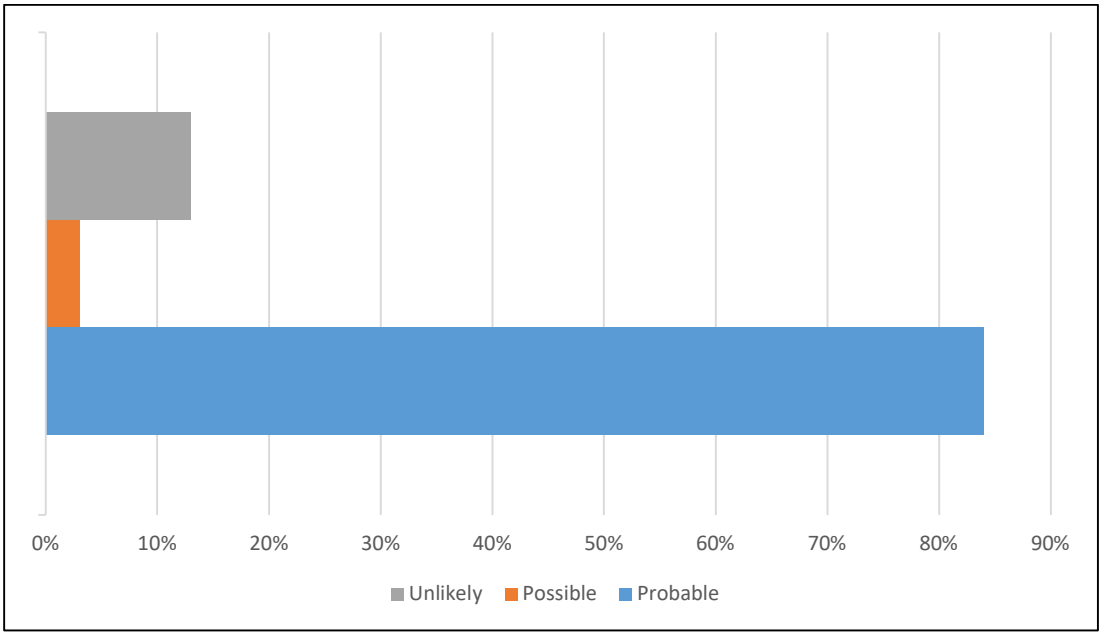

Figure 2: ADR distribution according to the judgment of causality

Table 3: Distribution of adverse events based on the two vaccines' respective causalities.

Classification as per WHO-UMC Scale	Covishield	Percentage	Covaxin	Percentage	Total	Percentage
Not Likely	03	4%	0	0%	3	3%
Potential	08	9%	07	27%	15	13%
Most likely	74	87%	19	73%	93	84%

ADVERSE DRUG REACTION OF COVISHIELD IN 2024:

The producer of Covishield has acknowledged a rare yet notable correlation between the vaccine and Thrombosis with Thrombocytopenia Syndrome (TTS), a condition marked by a decline in platelet levels and the formation of blood clots. The risk of TTS is categorically classified as "very rare" and "uncommon," with indicative symptoms including dyspnoea, chest or limb discomfort, petechiae or ecchymosis, cephalalgia, and paresthesia. Nonetheless, the probability of encountering TTS following the Covishield administration is reported to be exceedingly minute, with the Indian government emphasizing its insignificance relative to the total volume of doses administered **[8]**. Symptoms indicative of Thrombosis with Thrombocytopenia Syndrome (TTS) encompass a spectrum of serious manifestations, notably including intense and persistent headaches refractory to standard pain relief measures, blurred vision, cognitive impairment or seizure activity, facial or limb weakness, dyspnea or chest discomfort, acute abdominal pain, lower extremity edema, and unexplained petechial rash or bruising distant from the injection site. These symptoms typically manifest within a window spanning from 4 to 42 days following the administration of the initial dose of the vaccine.

With very few documented cases of thrombosis with thrombocytopenia syndrome (TTS) in India, the country's population has an extremely low chance of developing TTS after receiving the Covishield immunization. The safety and effectiveness of vaccinations like Covishield in preventing COVID-19 are highlighted by regulatory authorities, who also keep a close eye on uncommon side effects like TTS. It is crucial to emphasize that TTS, which includes immune thrombotic thrombocytopenia (VITT) generated by the vaccine, is an extremely unusual adverse effect that is mainly noticed following the first dose of the vaccination **[9]**. An investigation carried out within the cohort of healthcare personnel at a tertiary care establishment unveiled fever (24.64%) and myalgia (18.84%) as the prevailing adverse events after Covishield inoculation. The inquiry culminated in affirming the vaccine's safety, highlighting an exceptionally low occurrence of Adverse

Drug Reactions (ADRs). It accentuated the imperative of expeditious identification and intervention in the management of infrequent adverse effects such as Thrombosis with Thrombocytopenia Syndrome (TTS) **[10]**. These findings underscore the infrequent incidence of Thrombosis with Thrombocytopenia Syndrome (TTS) linked to Covishield in the year 2024, emphasizing its negligible risk, the favourable safety profile of the vaccine, and the critical significance of diligent monitoring and efficient management of adverse effects.

The vaccine was created by the prestigious Serum Institute of India (SII) in Pune and sold under the brand name Covishield in India. Following revelations on AstraZeneca's legal disclosure in a UK court, a person allegedly passed away after receiving the Covishield vaccination.

FREQUENCY AND NATURE OF SEVERE/SERIOUS ADVERSE EVENTS:

After COVID-19 vaccine administration, minor adverse events commonly reported encompass pyrexia, injection site discomfort, swelling, redness, headache, dizziness, vomiting, fatigue, and hypersensitivity reactions. However, more severe adverse events, such as Thrombosis with Thrombocytopenia Syndrome (TTS), characterized by the formation of large blood clots concomitant with reduced platelet counts, have been sporadically observed, occurring at a frequency of less than 1 in 100,000 vaccinated individuals post-administration of adenovector-based COVID-19 vaccines in India.

Drawing from adverse events documented during clinical trials and previous utilization of the same vaccine platform for other vaccines, specific adverse events are earmarked for meticulous monitoring during the introduction of novel vaccines. Termed Adverse Events of Special Interest (AESI), these events encompass myocarditis, pericarditis, encephalitis, myelitis, seizures, idiopathic thrombocytopenia, Guillain-Barre Syndrome, thrombosis with thrombocytopenia syndrome, and thrombosis.

Ongoing studies are actively monitoring the risk of specific events identified for potential association with the utilization of COVID-19 vaccines in India. Despite these considerations, based on the available evidence regarding safety and efficacy, COVID-19 vaccines have been discerned to possess a commendable benefit-to-risk ratio **[11]**.

Vaccines	Reaction	Time-to-Onset of Event	Frequency per Dose given
Covishield	Thrombotic Thrombocytopenia Syndrome (TTS)	3- 30 days	0.5 to 6.8 cases per 100 000 doses administered
	Thrombocytopenia	10 days (1-78 days)	8 per 1,000,000 doses administered

CONCLUSION:

The accumulated Adverse Drug Reaction (ADR) data spanning from the year 2020 to 2024 concerning Covishield in India paints a picture of its commendable safety profile, marked by a minimal incidence of severe adverse events. While the sporadic emergence of Thrombosis with Thrombocytopenia Syndrome (TTS) underscores the imperative for sustained vigilance, immediate reporting, and comprehensive evaluation of adverse reactions, it is imperative to acknowledge that the overarching advantages of Covishield in combating COVID-19 and averting fatalities eclipse the risks linked with this rare condition.

Preventive measures in the form of tracking, documenting, and examining Adverse Drug Reactions (ADRs) have been critical to ensuring the security and well-being of vaccine recipients. As vaccination efforts continue, preserving robust surveillance systems, promoting openness, and swiftly resolving any concerns about vaccine safety are critical cornerstones to preserve public confidence and support ongoing immunization efforts.

REFERENCE:

[1] Pandi-Perumal SR, Gulia KK, Gupta D, Kumar VM. Dealing with a pandemic: the Kerala Model of containment strategy for COVID-19. Pathogens and Global Health; 114 (5): 2020 232–3.

[2] Kaur SP, Gupta V. COVID-19 Vaccine: A comprehensive status report. Virus Research 2020 [Internet] https://pubmed.ncbi.nlm.nih.gov/32800805/

[3] Alwan NA, Burgess RA, Ashworth S, Beale R, Bhadelia N, Bogaert D. Scientific consensus on the COVID-19 pandemic: we need to act now. Lancet . 2020;396 (10260):e71–2.

[4] Singh N, Singh J, Bhandari V, Kumar R. A study of COVID-19 vaccine (COVISHIELD) pharmacovigilance in primary healthcare workers in Punjab, India. AMEI's Current Trends in Diagnosis & Treatment 2021;5 (1):6–11.

[5] Elegant NX. Why India Just Might Pull off 'the World's Largest Vaccination Program. Fortune.com January 2021[Internet] https://fortune.com/2021/01/15/india-covid-vaccine-registration-campaign/.

[6] Soni M. Day 100: How is India's Covid-19 Vaccination Drive Going? Hindustan times April 2021 [Internet] https://www.hindustantimes.com/india-news/day-100-how-is-india-s-

covid-19-vaccination-drive-going-101619325283656.html

[7] Serum Institute of India PVT. LTD. fact sheet for vaccine recipient approved for restricted use in emergency situation of chadox1 ncov- 19 corona virus vaccine (recombinant) covishield[tm] in prevention of covid-19 disease in individuals 18 years of age and older January 2021[Internet] https://www.seruminstitute.com/product_covishield.php

[8] Covishield's rare side effect: What is TTS, symptoms, risk factors explained, Times of India May 2024 [Internet] https://timesofindia.indiatimes.com/life-style/health-fitness/health-news/covishields-rare-side-effect-what-is-tts-symptoms-risk-factors-explained/photostory/109778749.cms

[9] The Healthy Indian Project. Fact Check: Are AstraZeneca's Covishield-vaccinated Indians susceptible to developing TTS. Hindustan times May 2024 [Internet] https://www.hindustantimes.com/india-news/fact-check-are-covishield-vaccinated-indians-susceptible-to-developing-tts-101714541409821.html

[10] Mittal A, Jain B, Varshney AM, Garg G, Sachan D, Singh RB. Adverse effects after first and second dose of covishield and covaxin: A longitudinal study. Journal of Family Medicine and Primary Care. 2022; 11 (11):7339–45.

[11] Ministry of Health and Family Welfare. ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI) Surveillance and Response 2024 [Internet]. Ministry of Health and Family Welfare 2024 January.