WWW.IJRPR.COM

International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

Vaccine Safety: A Brief Study on the Post-Marketing Surveillance of Covid-19 Vaccines in India

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A B S T R A C T

The advent of COVID-19 vaccines marked a critical milestone in the global fight against the pandemic. However, ensuring their safety remains paramount. This article presents a concise study on the post-marketing surveillance of COVID-19 vaccines in India, focusing on vaccine safety. Drawing upon data from various sources including regulatory agencies, healthcare providers, and public health authorities, this study evaluates the efficacy and safety profiles of COVID-19 vaccines in the Indian context.

Through a comprehensive review of adverse events following immunization (AEFI) reported post-vaccination, this study sheds light on the prevalence and severity of adverse reactions. Furthermore, it examines the mechanisms in place for monitoring and reporting adverse events.

By examining the challenges and opportunities in post-marketing surveillance, this study underscores the significance of continuous monitoring and evaluation to uphold the safety and efficacy of COVID-19 vaccines in India.

Keywords: COVID-19 vaccines, vaccine safety, post-marketing surveillance, adverse events, India

Introduction:

Post-marketing surveillance (PMS), also known as post-market monitoring or pharmacovigilance, is a system used by regulatory authorities, pharmaceutical companies, and healthcare professionals to monitor the safety and effectiveness of drugs, medical devices, and other healthcare products after they have been approved and made available to the public.

Post-marketing surveillance of COVID-19 vaccines in India involves a systematic process of monitoring and assessing the safety and effectiveness of vaccines after they have been approved and are being used in the general population.

COVID-19:

COVID-19, caused by the novel corona virus SARS-CoV-2, had been a global pandemic since early 2020. The virus can spread from an infected person's mouth or nose in small liquid particles when they cough, sneeze, speak, or exhale.

The majority of individuals infected with the virus typically endure mild to moderate respiratory illness and recover without needing specific medical intervention.

However, some individuals may experience more severe symptoms and necessitate medical attention. Common symptoms include fever or chills, Cough, Shortness of breath or difficulty breathing, new loss of taste or smell, Sore throat

It's worth noting that certain infected individuals may display no symptoms at all, while others might only exhibit mild symptoms, yet some could develop severe illness requiring hospitalization.

COVID-19 Vaccines:

India's vaccination drive against COVID-19 began on January 16, 2021. By March 4, 2023, the country had administered over 2.2 billion doses, including first, second, and booster doses.

Table 1- Cumulative doses administered across the Country: Total doses administered across the country as of March 4, 2023

Dose	Vaccination (Percentage of eligible population vaccinated)
Partially vaccinated	94.61 %
Fully vaccinated	87.81%

The vaccines initially approved for use in India were Oxford–AstraZeneca's Covishield and Bharat Biotech's Covaxin. These were later joined by Sputnik V (produced by Dr. Reddy's Laboratories and Serum Institute of India), Moderna, Johnson & Johnson, ZyCoV-D (developed by Zydus Cadila), and other candidates undergoing local clinical trials.

Adverse Event Following Immunization (AEFI) Reporting:

India has a well-established AEFI surveillance system where healthcare providers are required to report any adverse events occurring after COVID-19 vaccination. This includes monitoring for both common and rare adverse events to ensure the safety of the vaccines.

Integrated Vaccine and Immunization Surveillance System (IVISS): India has implemented the IVISS, a digital platform for real-time monitoring of vaccine distribution, logistics, and adverse events. This system helps track the uptake of COVID-19 vaccines across different regions and facilitates prompt action in case of any safety concerns.

National AEFI Committee: India has a National AEFI Committee responsible for reviewing and analyzing reports of adverse events following vaccination. This committee plays a crucial role in assessing the causal relationship between adverse events and COVID-19 vaccines and recommending appropriate actions, if necessary.

Collaboration with Global Surveillance Networks: India collaborates with global surveillance networks such as the WHO Global Vaccine Safety Initiative (GVSI) to share data and insights on vaccine safety and effectiveness. This collaboration helps India stay updated on international best practices and emerging trends in vaccine safety monitoring.

Public Awareness and Reporting: The Government of India conducts public awareness campaigns to encourage reporting of adverse events following COVID-19 vaccination. Citizens are informed about the importance of reporting any unusual symptoms or reactions after vaccination to ensure timely intervention and monitoring.

Regular Safety Reviews: Regulatory authorities in India conduct regular safety reviews of COVID-19 vaccines based on the available data from post-marketing surveillance. These reviews help identify any emerging safety signals and inform regulatory decisions, such as updating product labels or issuing safety advisories.

Ongoing Research and Evaluation: Post-marketing surveillance also involves ongoing research and evaluation studies to assess the long-term safety and effectiveness of COVID-19 vaccines in diverse populations, including vulnerable groups such as the elderly and individuals with comorbidities.

Common ADRs Reported:

Reported adverse events associated with COVID-19 vaccines vary depending on the specific vaccine and individual factors. Some of the commonly reported adverse events following COVID-19 vaccination and its severity range include:

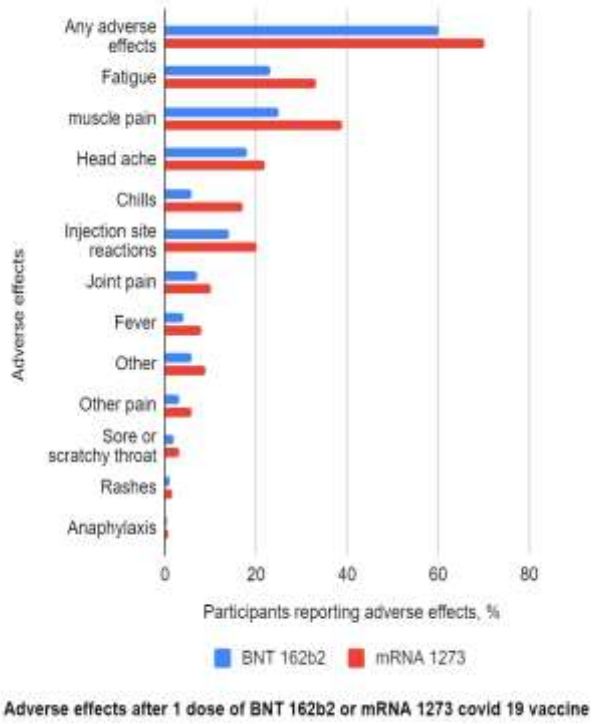

Fig 1.

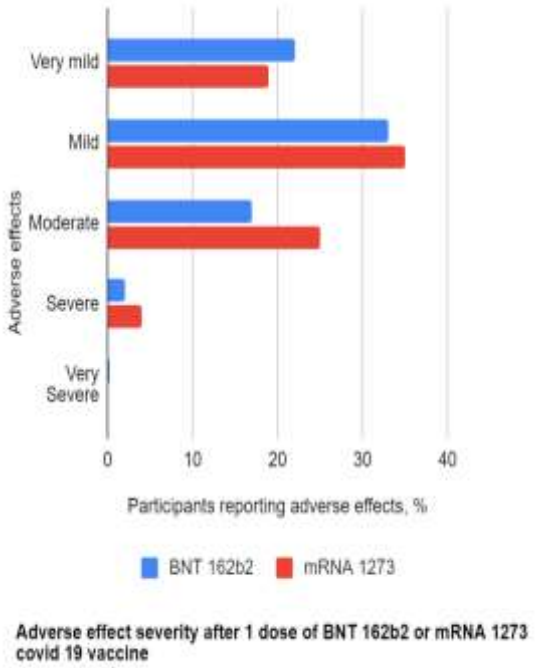

Fig 2.

BNT162b2: Pfizer-BioNTech COVID-19 Vaccine

It's important to note that the vast majority of adverse events following COVID-19 vaccination are mild and transient. The benefits of COVID-19 vaccination in preventing severe illness, hospitalization, and death far outweigh the risks of adverse events. Healthcare providers and public health authorities continue to closely monitor vaccine safety and provide guidance on vaccination recommendations.

Monitoring and Reporting of Adverse Drug Reactions (ADRs) in India:

Monitoring and reporting of ADRs involves systematic surveillance and documentation of negative or unintended reactions to medications. This process aims to identify potential safety concerns associated with drugs, assess their severity and frequency, and take appropriate measures to minimize risks and ensure patient safety. ADR monitoring and reporting contribute to the continuous improvement of drug safety standards and regulatory decision-making. The various mechanisms in India include:

Pharmacovigilance Programme of India (PvPI): PvPI is a national initiative established by the Indian Pharmacopoeia Commission (IPC) under the Ministry of Health and Family Welfare, Government of India to monitor and ensure the safety of medicines. The program is aligned with the World Health Organization's (WHO) Global Pharmacovigilance Programme and works in collaboration with international pharmacovigilance networks. PvPI facilitates the reporting, detection, assessment, and prevention of ADRs associated with pharmaceutical products marketed in India. It involves healthcare professionals, pharmaceutical companies, regulatory agencies, and patients in reporting suspected ADRs. PvPI also conducts pharmacovigilance training, promotes awareness, and disseminates information on drug safety to enhance the overall pharmacovigilance system in India.

Adverse Drug Reaction Monitoring Centers (AMCs): AMCs are designated centers responsible for receiving and processing ADR reports from healthcare professionals and consumers. These centers serve as frontline hubs for collecting, documenting, and analyzing reports of suspected ADRs from healthcare professionals, patients, and pharmaceutical companies. In India, Adverse Drug Reaction Monitoring Centers (AMCs) are established at various levels of healthcare institutions, including government hospitals, medical colleges, and private healthcare facilities. Some prominent AMCs include those affiliated with premier medical institutions such as All India Institute of Medical Sciences (AIIMS) in New Delhi, Post Graduate Institute of Medical Education and Research (PGIMER) in Chandigarh, and Christian Medical College (CMC) in Vellore.

Online Reporting Portal: PvPI operates an online reporting portal where healthcare professionals and consumers can submit ADR reports electronically.

Paper-based Reporting: Healthcare professionals can submit ADR reports using paper-based reporting forms provided by PvPI. These forms are available at healthcare facilities.

Consumer Reporting: PvPI encourages consumers, including patients and their caregivers, to report ADRs directly through designated channels.

Role of Health Professionals:

Health professionals serve as crucial guardians of public health, ensuring the safety of COVID-19 vaccines through a multifaceted approach. They meticulously administer vaccines, adhering to strict protocols to minimize errors and ensure proper dosage. Through proactive education, they address vaccine hesitancy and disseminate accurate information, fostering trust and confidence in vaccination. Health professionals vigilantly monitor vaccine recipients for any adverse reactions, promptly reporting any concerns to health authorities for further investigation. Their expertise in epidemiology and infectious diseases enables them to assess and mitigate risks associated with vaccine rollout. In collaboration with researchers and policymakers, health professionals play an indispensable role in safeguarding the safety and efficacy of COVID-19 vaccines, contributing to the collective effort to overcome the pandemic.

Conclusion:

Post-marketing surveillance of COVID-19 vaccines in India is a thorough and organized effort to ensure the safety and effectiveness of these vital interventions as they are distributed to the population. This surveillance framework, which relies on continuous monitoring, robust reporting mechanisms, rigorous data analysis, and collaborative efforts, has enhanced effective vaccination. By fostering transparency, accountability, and proactive engagement with stakeholders, this surveillance effort maintains public confidence in vaccination programs and safeguards public health in the face of evolving challenges posed by the pandemic.

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