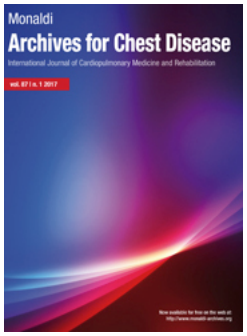

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Unveiling vaccine safety: a narrative review of pharmacovigilance in India's COVID-19 vaccination

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Abstract

In India, a robust vaccine pharmacovigilance system is essential to the effective implementation of COVID-19 immunization programs, ensuring the safety and efficacy of the administered vaccines. The National Expert Group on Vaccine Administration for COVID-19 and the Pharmacovigilance Programme of India have played vital roles in monitoring and analyzing adverse events following immunization (AEFI). These tools have made it easier to gather, assess, and report information about different adverse drug reactions connected to COVID-19 vaccines. However, there are several issues with India's vaccination pharmacovigilance, including underreporting and sluggish data gathering. To improve the efficiency of the pharmacovigilance system, it is crucial to address these issues and encourage active reporting by healthcare professionals and the general public. This insightful review article serves as a critical resource for shedding light on India's vaccine pharmacovigilance efforts throughout the COVID-19 vaccination drive. It also elucidates how these efforts are pivotal in bolstering public confidence in vaccines. The comprehensive coverage of reported AEFI not only showcases the commitment to vaccine safety but also helps healthcare professionals and policymakers make informed decisions to enhance the overall vaccination program.

Key words: COVID-19, AEFI, PvPI, ADR, vaccine, pandemic.

Introduction

According to WHO dashboards, the COVID-19 pandemic reached devastating proportions with confirmed 44 crore infections in India as of July 2023 and a death toll of over 5 lakhs [1]. To stop the virus from spreading, all governmental organisations implemented preventive measures such as lockdown procedures, social withdrawal, adequate sanitization, and face masking. The development of the vaccine and its subsequent distribution amongst the populace has been seen as the most important and efficient preventative tool in the face of rising waves of COVID-19 infections. The COVID-19 vaccine has been a top focus worldwide since the pandemic began [2]. Vaccine development typically takes several years, but thanks to improved international cooperation, dedicated finance, the current vaccine technology, sped-up operational innovation and regulatory processes, vaccines were released in less than a year [3]. As

per the assessment by the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC), India stands out as one of the nations with the most ambitious targets for vaccine deployment at present. During the initial stages, the country utilized Covishield and Covaxin, produced by the Serum Institute of India (SII) and Bharat Biotech (BB) Ltd. respectively. As of April 2022, India has provided 187 crores of COVID-19 vaccine doses, with the first and second doses covering about 100 and 85 crores of people, respectively [4,5]. Vaccines have significantly improved public health and communities all over the world are getting benefits from them. Concerns among the public about vaccine safety have been noted, despite broad vaccine acceptance and decades of usage, especially in nations with high immunisation rates [6]. However, there persists a notable level of public unease concerning the safety and effectiveness of the COVID-19 vaccine [7]. The emergence of recently developed COVID-19 vaccines encountered scepticism on a global level, and this scepticism was also evident within India. The available research indicates that vaccine reluctance differs significantly between Kuwait (76%) and Jordan (71%), Russia (45%), while Poland, France, the United States and the United Kingdom reported 44%, 41%, 21%, 25% vaccine reluctance respectively [8]. Immunisation hesitance was described by the WHO as a "delay in acceptance or refusal of vaccination despite the availability of vaccination services." In a study conducted by Solis Arce et al., it was found that India exhibited an acceptance rate of 84%, surpassing the figures from the United States (64.6%) and Russia (30.4%). The findings also highlighted that the willingness to receive vaccinations can be attributed to a desire for personal defence against COVID-19. However, concerns about potential side effects emerged as the primary reasons for hesitancy [9]. Yet, in India, a significant proportion of the population eligible for vaccination exhibits hesitancy towards COVID-19 vaccines [10]. For example, a survey conducted in October 2021 by Local Circles estimated that more than 75 million individuals who were eligible showed vaccine hesitancy. 16% said vaccine effectiveness against novel COVID-19 variants was one of the concerns, along with 23% people concerned about the rumour that potential death and infertility can occur following vaccination, and 23% individuals perceived unsuitability for individuals with co-morbidities [11]. To gauge the extent of COVID-19 vaccine hesitancy in India, a study conducted on 1638 adults revealed that 37% of the respondents were either unsure or declined to receive the COVID-19 vaccines. This translates to over 200 million

adults across our country. Overall, a majority of the study participants (71%) expressed at least one concern regarding vaccines, with the most common worries revolving around the safety profile of the vaccine, its potential side effects, and its effectiveness [12]. When vaccinations are widely distributed to a larger population, they come into contact with a sizable diverse pharmacogenetic pool. The unfavourable outcomes of such immunisation initiatives could vary. As a result, there needs to be strict surveillance of all adverse events, whether small or significant. As an alternative, Adverse Effects Following Immunisation (AEFI) may afflict healthy people and should be quickly recognised in order to facilitate further study and appropriate response. AEFI is described as an unfavourable medical event that may or may not be related to the administration of the vaccine. The main objective of vaccine safety monitoring during the rollout of COVID-19 vaccines was to swiftly identify, examine, and analyze AEFIs and Adverse Events of Special Interest (AESIs) that carry considerable medical significance. This proactive approach aimed to ensure a swift and appropriate response, thereby minimizing the adverse effects on individuals' health and immunization programs. Additionally, it played a crucial role in upholding the confidence and trust of healthcare professionals and the general population in the vaccination process [13].

This article serves as a narrative review, aiming to explore relevant literature published in the English language within the timeframe of 2020 to 2023. Searches were performed on PubMed and Google Scholar. The search terms utilized encompassed a range of relevant terms related to the topic, such as "COVID-19," "coronavirus," "SARS-CoV-2," "COVID," "vaccination," "immunization," "adverse effects," "adverse events," "complications," "India", “pharmacovigilance” and “AEFI”. These keywords were searched individually or in combination to gather pertinent information. The collected results were then meticulously assessed for their relevance to the topic. Any duplicate studies and those providing insufficient or irrelevant information were excluded. In this paper, we examine the Adverse Drug Reactions (ADRs) associated with COVID-19 vaccines in India and explore the pharmacovigilance programs overseeing these vaccinations within the country.

COVID-19 vaccines in India

The vaccine development endeavours aligned with the beginning of the initial wave of the pandemic within the nation. In April of 2020, a specialized task force was formed with the specific aim of conducting dedicated research on COVID-19 vaccines, with the intention of promoting and advancing vaccine development. Amid the pandemic, several pharmaceutical companies, including Dr Reddy's Laboratories, BB, SII, and Zydus Cadila, embarked on clinical trials for a range of COVID-19 vaccines. Among the vaccines under examination were Covishield, ZyCoV-D, Covaxin, and Sputnik V. Covishield and Covaxin obtained emergency use authorization in January of 2021, and in April followed the approval of Sputnik V. Moderna's mRNA-1273 received approval in the 4th week of June, succeeded by Zydus Cadila's ZyCoV-D vaccine in August. Additional vaccines, including Corbevax (Biological E Limited), BBV154 (BB), and Covovax (SII) were in diverse stages of clinical trials. Early in 2022, Covovax, Sputnik Light, and Corbevax were granted vaccine emergency use authorizations [14,15].

By December 2021, India had implemented two vaccines, Covaxin and Covishield, for its extensive COVID-19 vaccination efforts. Covishield was developed through a collaboration between SII and AstraZeneca. The vaccine utilizes a harmless virus (vector) to deliver specific genetic material into the body. In this case, the vaccine uses a replication-deficient (this virus cannot replicate itself effectively and is modified to carry a piece of genetic information) chimpanzee adenovirus as the vector. This allowed the vaccine to introduce the genetic code for the Spike protein into the body. Covishield was authorized for active immunization in individuals aged 18 years and above, following a two-dose vaccination regimen. On the other hand, Covaxin crafted in partnership between Bharat Biotech and the Indian Council of Medical Research (ICMR)-National Institute of Virology (NIV), was an indigenous COVID-19 vaccine. Covaxin was a vaccine that was inactivated and formulated using the whole-virion inactivated (meaning the whole virus was inactivated) Vero-cell-derived (specific cell lines used in laboratories for growing viruses) These two vaccines garnered emergency use authorization in India on January 3, 2021. 21st October 2021, marked the day when India accomplished an impressive milestone by administering 100 crore vaccine doses. As of June 26, 2023, the total number of vaccine doses administered in India reached 220.67 crore [5,16,17].

We learned during the H1N1 swine flu pandemic of 2009 and the subsequent vaccination campaign that few nations' pandemic preparation strategies appropriately handled vaccine safety monitoring. Pharmacovigilance platforms were unable to confirm or rule out relationships between AEFIs and the H1N1 vaccine, which weakened public confidence in the vaccine. To ensure effective pharmacovigilance of COVID-19 vaccines, global collaboration between scientists, medical and public health professionals, and pharmaceutical and manufacturing businesses, as well as expanded capacity to analyse and report real-time incidents, are of the utmost importance [18-20].

Vaccine pharmacovigilance in India

Strong pharmacovigilance systems, global post-licensure surveillance coordination, real-time information sharing, an open-source data repository, and a strong communication component are necessary for the rollout of vaccines [21]. Since April 15, 2011, under the Ministry of Health & Family Welfare, the Indian Pharmacopoeia Commission (IPC) has been serving as the National Coordination Centre (NCC) for the Pharmacovigilance Programme of India (PvPI). The NCC's primary responsibilities encompass the collection, collation, and analysis of Adverse Drug Reactions (ADRs) data to inform regulatory interventions to the Central Drugs Standard Control Organization (CDSCO). Additionally, the NCC plays a pivotal role in communicating risks associated with medications to healthcare professionals and the public through PvPI Newsletters [22,23]. PvPI's central aim is to gather adverse event reports and empower regulatory authorities to make accurate decisions, subsequently conveying safety information to different organizations. To facilitate the collection of ADRs from patients, Adverse Drug Reactions Monitoring Centres (AMCs) are established under the NCC's supervision. These AMCs serve a crucial purpose by enabling the identification of rare ADRs that might not have surfaced during clinical trial programs [24]. The NCC extends support in logistics and manpower to ensure the smooth functioning of AMCs and the effective reporting of ADRs. Presently, about 250 operational AMCs and twelve regional training centres (RTC) exist nationwide as essential constituents of the PvPI. While the AEFI-surveillance system in India has been operational since its establishment in 1986, it was officially incorporated into the PvPI back in 2015 to oversee adverse events associated with

vaccines. This integration subsequently bolstered the surveillance and reporting mechanisms for vaccine safety within the country [25].

In India, two distinct sets of national guidelines exist concerning AEFI. The more comprehensive edition is recognized as the 'Operational Guidelines,' whereas a more succinct variant is denoted as the 'Standard Operating Procedures.' These guidelines were developed following the recommended framework outlined by the World Health Organization [26], and were developed through a consultative process involving various stakeholders. The stakeholders included various Government departments engaged in immunization programs, state government program managers, academic institutions, independent subject experts, officials from the Drug Controller General of India (DCGI), and development partners. AEFI reactions can be broadly classified into two categories. The first category is 'serious AEFIs,' which comprise instances of death, disability, and hospitalization. Such cases necessitate immediate reporting and investigation following the prescribed procedures. The second classification, referred to as 'minor AEFIs,' is documented using monthly reporting systems within the Universal Immunization Program (UIP) under the Government of India. For programmatic purposes, AEFIs are further classified into five broad categories, namely programmatic errors, vaccine reactions, injection reactions, coincidental events, and unknown causes [27].

The development and role of Co-WIN

Co-WIN was developed by the Indian Government to effectively manage and streamline the nationwide COVID-19 vaccination drive. Its inception was driven by the need to tackle the distinct challenges arising from the extensive scale and intricate nature of inoculating a populace exceeding 1.3 billion individuals. The platform's core aims encompassed streamlining the preparation, enrollment, and supervision of vaccine dispensation across central and peripheral tiers, thus guaranteeing a seamless and effective vaccination procedure. Co-WIN also aimed to maintain accurate and real-time data on vaccine distribution, recipients, and adverse events, allowing authorities to make informed decisions and effectively track the progress of the vaccination campaign. To oversee AEFIs, Co-WIN was combined with the Surveillance and Action for Events Following Vaccination (SafeVAC) application, supported by the World Health Organization. AEFIs were classified into three categories: minor, severe, or serious. Post-

vaccination occurrences of adverse events following immunization (AEFIs) were recorded within the Co-WIN system. This was done either by a district immunization officer (DIO) or an administering vaccinator. Through a single login, DIOs could access Co-WIN SafeVAC to complete case report forms, preliminary case investigation forms, and final investigation forms for serious or severe AEFIs cases, and subsequently submit the required information. Moreover, at planning units each AEFI was recorded in AEFI registers and reported on a weekly basis. This approach streamlined the detailed analysis of AEFI cases, achieved through automated data mining along with the application of appropriate statistical methods. As a result, any concerning trends could be rapidly pinpointed [28,29].

AEFIs/ADRs reported during COVID-19 vaccination drive in India

The causality assessment of AEFIs is conducted at different tiers of the administration of health by a team of independent experts. A National AEFI committee comprising independent experts, to ensure consistent and accurate causality determination for reported AEFIs nationwide was set up by India. To monitor the overall incidence of AEFIs and also to supervise the evaluation of causality, an overseeing National AEFI secretariat has been established. Furthermore, for this entire process, a National AEFI Technical Collaborating Centre was instituted to provide comprehensive support. Upon the initiation of the COVID-19 vaccination campaign in India on January 15, 2021, a dedicated team was formed specifically to conduct assessments of causality for AEFIs arising from COVID-19 vaccination. This specialized group comprises medical experts including neurologists, specialists in pulmonary medicine, cardiologists, and gynaecologists. The findings from the causality assessments carried out by this specialized team were deliberated upon and subsequently endorsed during the sessions of the national AEFI committee [30].

In a study by Gandhi et al. (2023), a secondary data analysis was performed on causality assessment reports regarding serious AEFIs. These reports originally were published by the Ministry of Health & Family Welfare of India. The findings indicated that up until March 29, 2022, a total of 1112 causality assessment reports had been made available in India regarding Serious AEFIs related to COVID-19 immunization. Among these serious AEFIs, 992 cases (89.2%) were reported among individuals who received

Covishield, while 120 cases (10.8%) occurred in COVAXIN vaccine recipients. Out of the 1112 serious AEFIs, 401 cases (36.1%) resulted in fatalities, and 711 cases (63.9%) required hospitalization but ultimately recovered. Out of the scrutinized cases, 209 (18.8%) recorded thromboembolic events (TE). Nonetheless, a consistent causal connection between TE cases and particular COVID-19 vaccine used in India wasn't confirmed. Concerning the nature of serious AEFIs, the majority were categorized as either Coincidental (578 cases, 52%) or Vaccine Product Related (218 cases, 19.6%). Immunization Anxiety-related reactions accounted for 145 cases (13%). A smaller subset of cases (4, 0.4%) were categorized as reactions related to Immunization Errors, while 53 cases (4.7%) were recorded as indeterminate or unable to be classified [31].

Another study was conducted by Basavraja *et al.,* 2021 at a tertiary care teaching hospital, which functions as an AMC under PvPI, situated in South India. The study population comprised healthcare workers (HCWs) and frontline workers who had received COVID-19 vaccines at this particular hospital. Throughout the study duration, a cumulative sum of 11,656 doses of COVID-19 vaccines was administered at the study location, with 9292 of these doses being attributed to Covishield. The study revealed that the incidence rate of AEFIs among the study population was 3.48%, significantly higher than the national incidence rate of 0.016%. Among the total 445 AEFIs reported among 269 subjects, 433 occurred following Covishield vaccination, while 12 were associated with Covaxin. Upon completing the causality assessment, the study revealed that 94.22% (n = 408) of AEFIs associated with the Covishield vaccine were classified as having a 'consistent causal connection with immunization.' Within this category, there were 342 cases (78.98%) labeled as 'vaccine product-related reactions' and 66 instances (15.24%) categorized as 'immunization anxiety-related reactions.' The most common AEFIs reported in the study were injection site pain, swelling, redness, and itching, followed by giddiness, fever, headache, and sneezing. It is noteworthy that none of the reported AEFIs was classified as severe or serious, and all participants in the study population recovered from their AEFIs without any lasting effects [32].

Similarly, another study identified a total of 1,264 adverse events following immunization (AEFI) among healthcare workers who received the Covishield vaccine. Among these, 1,233 AEFIs (97.5%) were mild and self-limiting, while 31 AEFIs (2.5%) were of moderate to severe intensity. The most frequently reported AEFIs included pain

at the injection site (61.5%), fatigue (23.5%), headache (20.2%), and fever (16.8%). Other reported AEFIs encompassed myalgia, chills, nausea, vomiting, dizziness, and palpitations, among others. The observed AEFIs in the study were consistent with those commonly reported for the Covishield vaccine. Nonetheless, the study did not discover any substantial association between the observed AEFIs and the vaccine itself. It is worth noting that the study diligently reported all AEFIs to the PvPI. Additionally, the institutional vaccination safety surveillance team promptly communicated all AEFIs to the Regional Training Centre under PvPI [33].

A descriptive cross-sectional study conducted at the KCGMC reported Adverse Drug Reactions (ADRs) for both Covishield and Covaxin vaccines, occurring among young adults aged 18-45 years, have been reported voluntarily at the ADR-monitoring centre. These reports originate from diverse vaccination centres within Karnal District. During the study period, a total of 1,21,195 beneficiaries were vaccinated with Covishield, and 35,595 beneficiaries were vaccinated with Covaxin. A total of 51 beneficiaries reported ADRs. Out of the Covishield group, 38 beneficiaries reported ADRs, while in the Covaxin group, 13 beneficiaries reported ADRs. The study's findings revealed that there was no statistically significant distinction in the occurrence of ADRs between the two vaccines throughout the study period ($p = 0.648$). Among the individuals who reported ADRs, a combined total of 85 ADRs were documented among those who received the Covishield vaccine (n=38), while 26 ADRs were recorded among recipients of the Covaxin vaccine (n=13). During the study period, 51 healthcare workers reported ADRs. Only 1 beneficiary experienced a serious ADR (haematuria, pain in the vagina, vomiting, fever) with Covishield, requiring hospitalization. After receiving treatment, the individual experienced recovery and was discharged on the same day. There were no reported fatalities throughout the course of the study. Among the ADRs reported in Covishield beneficiaries, fever accounted for 40% of the total ADRs, and body aches comprised 15%. In contrast, within the group of ADRs reported among Covaxin recipients, fever accounted for 19% of the overall ADRs, while body aches constituted another 19% [34].

A study was conducted at a Regional Training Centre for Pharmacovigilance, which functioned as an AMC as part of the PvPI. Serious AEFIs were additionally reported to the State Extended Programme on Immunization Officer (SEPIO) and the DIO. This study utilized data collected as a routine component of the ADR monitoring center's

operations. It encompassed all AEFIs attributed to COVID-19 vaccines reported between January 10, 2021, and December 31, 2021. During this period, over 50 thousand COVID-19 vaccine doses were administered, with 41,462 doses of Covishield and 9,548 doses of Covaxin. Out of these vaccinations, 330 adverse events following immunization (AEFIs) were reported. Among these, 308 cases (93.33%) occurred after the first dose, and 22 cases (6.67%) were after the second dose. Of the reported AEFIs, only 6 cases (1.82%) were categorized as serious events, including 3 cases identified as Adverse Events of Special Interest (AESI). Among the reported AEFIs, the most frequent localized reaction was pain or tenderness at the injection site. The most common systemic AEFIs included symptoms such as fever, body ache or stiffness, myalgia (muscle pain), and headaches [35].

The Adverse Drug Reactions (ADRs) discussed ahead were documented either as individual case reports or as part of case series studies. However, there was no specific mention that these ADRs were reported exclusively to the PvPI. Instead, they were recorded in published literature offering valuable insights into the occurrence and characteristics of particular ADRs related to COVID-19 vaccines in India. While these case reports and case series contribute significantly to medical knowledge, they may not be included in the official data collected by PvPI.

After COVID-19 vaccination, a range of adverse events affecting the skin and the broader body systems have been documented. Cutaneous adverse drug reactions (CADRs) encompass any undesirable or unintended manifestations, atypical laboratory results, symptoms, or ailments that arise subsequent to immunization. Typically, CADRs are mild and may include reactions at the injection site or morbilliform eruptions. Nevertheless, a handful of severe Cutaneous Adverse Drug Reactions (CADRs), such as Rowell syndrome and acute generalized exanthematous pustulosis, have also been recorded in correlation with COVID-19 vaccination [36,37].

Purushottoam et al. (2023) documented a total of 18 instances of CADRs subsequent to COVID-19 vaccination. Out of these cases, 17 individuals received the Covishield vaccine, while 1 individual received the Covaxin vaccine. The CADRs occurred after either the first (10 cases) or second (8 cases) dose of vaccination, with the majority (15 cases) appearing within <7 days post-vaccination. The documented CADRs encompassed various conditions including acute urticaria, pityriasis rosea,

leukocytoclastic vasculitis, herpes zoster, psoriasis exacerbations, eczema exacerbations, reactivation of herpes simplex virus 1 infection, and COVID arm. Selected cases underwent histopathological testing, and a chronological connection between the cutaneous reaction and vaccination was established using the World Health Organization causality assessment classification. All cases were categorized as B1 within this classification [38,39].

Garg et al. conducted a comprehensive systematic review up until June 27, 2022, analyzing data within India. They reported a total of 136 cases involving serious neurological and psychiatric adverse events among a substantial population of 2,000 million individuals who had received COVID-19 vaccines. These adverse events were described in 64 separate case reports or case series. The most frequent adverse events included CNS demyelination, Guillain-Barre syndrome, post-vaccination herpes zoster, and VITT (cerebral venous sinus thrombosis). Notably, the majority of these neurological complications were immune-mediated in nature. VITT, a condition characterized by cerebral venous sinus thrombosis, was reported in ten patients. Yet, considering the extensive scope of India's COVID-19 vaccination initiative, the reported instances of neurological and psychiatric events were deemed comparatively limited. The study also documented six separate occurrences of psychiatric adverse events. Among these, functional neurological disorders were observed, resembling true neurological disorders such as hemiparesis, movement disorders, paraparesis, psychogenic nonepileptic seizures, sensory manifestations, speech disorders, and dizziness. Social media misinformation about vaccines, along with pandemic-related stress, and heightened psychological stress were considered possible reasons for these functional neurological disorders. The review identified several serious neurological complications following COVID-19 vaccination in Indian recipients. However, the overall risk appeared to be minimal. Instances of immune-mediated central and peripheral neuronal demyelination events were notably prevalent, and the majority of immune-mediated disorders demonstrated favourable responses to immunotherapy. Cases of herpes zoster were also documented, with a higher occurrence rate observed following the administration of mRNA vaccines. Despite data limitations, the review shed light on the importance of monitoring and understanding adverse events associated with COVID-19 vaccination to ensure continued public health safety [40].

Conclusions

In India, the COVID-19 vaccination drive was a massive undertaking aimed at safeguarding the population against the pandemic. To ensure the safety and efficacy of the vaccines, a robust pharmacovigilance system was established to closely monitor Adverse Events Following Immunization (AEFI). The essential aspect of the COVID-19 vaccination campaign has been the reporting of adverse events following vaccination to both the Pharmacovigilance Programme of India (PvPI) and the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC). PvPI serves as the central repository for collecting, collating, and analyzing ADR data from various vaccination centres across the country. Indian AEFI Committee diligently assessed the causality of serious AEFIs, aiding in prompt decision-making and appropriate medical interventions. AEFI reporting in India followed a structured approach, ensuring that all adverse events were documented, categorized, and analysed. The data collected were utilized to identify any concerning trends swiftly and enable evidence-based decisions. The Co-WIN platform, developed by the Indian Government, was instrumental in managing and streamlining the vaccination process. Co-WIN was additionally integrated with the Surveillance and Action for Events Following Vaccination (SafeVAC) application, supported by the World Health Organization. This integration served to enhance the surveillance and monitoring of AEFIs. Through vigilant reporting, the PvPI identified various cutaneous and systemic ADRs following COVID-19 vaccination. While most AEFIs were mild and self-limiting, some serious events were documented. The most frequent ADRs reported were fever, pain at the injection site, headache, and fatigue. Neurological and psychiatric AEFIs were also recorded, although the overall risk remained minimal compared to the large population vaccinated. Despite the efforts to establish a robust vaccine pharmacovigilance system in India, several limitations need to be acknowledged. One major challenge is underreporting of AEFI. Many mild or self-limiting AEFIs may go unreported, leading to an incomplete understanding of the overall safety profile of COVID-19 vaccines. Additionally, the passive nature of the reporting system may result in delayed or incomplete data collection, hindering real-time analysis of ADR trends. Limited awareness and knowledge among the public about AEFI reporting processes further contribute to the underreporting issue. Furthermore, the absence of a dedicated surveillance system for long-term safety monitoring after vaccination makes it

challenging to identify rare or delayed adverse events. Addressing these limitations and promoting active reporting and awareness among all stakeholders is crucial in enhancing vaccine pharmacovigilance in India and ensuring the continued safety and effectiveness of the vaccination drive. Overall, the systematic monitoring and reporting of ADRs in India were crucial in assuring the safety of COVID-19 vaccines and instilling public confidence in the vaccination drive. The Pharmacovigilance system continued to play a pivotal role in the ongoing efforts to combat the pandemic and protect the health and well-being of the nation's population.

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