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

A NARRATIVE REVIEW ON PHARMACOVIGILANCE IN INDIA COVID-19 VACCINATION

[1]Ms. Saba S.Jagirdar,[2] Mr. Bhimashankar K .Bhui,[3] Mr. Sandeep V. Jadhav, [4]Dr .Vijaysinh U.Sable.

[1]Author, [2]Guide,[3]Co-Guide,[4]Principle.

Department of Pharmaceutics

Lokmangal College of Pharmacy, Wadala, Solapur

To ensure the safety and effectiveness of the vaccinations given, an effective vaccine pharmacovigilance system is necessary for the successful implementation of COVID-19 immunization programs in India. The Pharmacovigilance Programme of India and the National Expert Group on Vaccine Administration for COVID-19 have been instrumental in tracking and evaluating adverse events that occur after vaccination (AEFI). The collection, evaluation, and reporting of data on various adverse drug reactions linked to COVID-19 vaccinations has been made simpler thanks to these technologies. But there are a number of problems with India's vaccine pharmacy, including as slow data collection and underreporting. It is imperative to address these problems and promote proactive reporting by medical professionals and the general public in order to increase the effectiveness of the pharmacovigilance system. During the COVID-19 immunization campaign, India's vaccine pharmacovigilance efforts were largely obscured until the publication of this comprehensive review study. It also clarifies the significance of these initiatives in enhancing public trust in vaccinations. In addition to demonstrating the dedication to vaccine safety, the thorough reporting of AEFI assists legislators and medical experts in making decisions that will improve the immunization program as a whole.

Key words : COVID-19, PvPI, adverse effects, AEFI, Vaccine

Introduction

As of July 2023, WHO dashboards show that the COVID-19 pandemic has spread to devastating proportions, with 44 crore illnesses confirmed in India and over 5 lakh deaths [1]. All governmental organizations put preventative measures in place to stop the virus from spreading, including lockdown protocols, social distancing, sufficient sanitization, and face masks. In light of the growing waves of COVID-19 infections, the creation of the vaccine and its subsequent public distribution have been viewed as the most significant and effective prophylactic measures. Since the start of the pandemic, the COVID-19 vaccine has received a lot of attention globally [2].Although the creation of a vaccine usually takes many years, vaccinations were issued in

less than a year as a result of enhanced international collaboration, committed funding, the most recent vaccine technology, accelerated operational innovation, and regulatory procedures [3].

According to the evaluation conducted by the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC), India is among the countries with the most aggressive vaccination deployment objectives at this time. The nation first used Covishield and Covaxin, which were made by Bharat Biotech (BB) Ltd. and the Serum Institute of India (SII), respectively. India has given out 187 crore doses of the COVID-19 vaccine as of April 2022; the first and second doses have the potential to vaccinate around 100 and 85 crore individuals, respectively [4,5]. Public health has greatly improved as a result of vaccinations and communities all over the world getting benefits from them. Despite widespread vaccination acceptance and decades of use, there are still concerns among the public regarding vaccine safety, particularly in countries with high vaccination rates [6]. Nonetheless, there is still a good deal of public skepticism about the efficacy and safety of the COVID-19 vaccination [7]. There was doubt about the newly created COVID-19 vaccinations when they first came out, and this doubt was present in India as well. Based on existing studies, there are notable differences in vaccination aversion between Kuwait (76%) and Jordan (71%), Russia (45%), Poland, France, the United States, and the United Kingdom (44%, 41%, 21%, and 25%), respectively [8]. The WHO defined vaccine hesitancy as a "refusal or delay in accepting immunization 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 rumors that vaccinations may cause infertility and even death, and 23% of respondents felt that they were inappropriate for those with co-morbidities [11]. In order to determine the degree of vaccination hesitancy for COVID-19 in India, a research including 1638 people found About 37% of those surveyed refused to get the COVID-19 vaccination or were undecided. This corresponds to more than 200 million adults in our nation. In general, much of the research 71% of participants said they had at least one concern about vaccinations, with the majority frequent concerns about the vaccine's safety profile, possible adverse effects, as well as its efficacy [12]. When a wider population receives vaccines on a huge scale, They interact with a broad range of distinct pharmacogenetic individuals The adverse consequences of immunization programs may take several forms. Therefore, every unfavorable event—no matter how minor or large—needs to be strictly monitored. On the other hand, healthy individuals may have Adverse Effects Following Immunization (AEFI), which should be promptly identified to enable more research and the proper course of action. An adverse event that may or may not be connected to the vaccination's delivery is referred to as an AEFI. During the COVID-19 vaccine launch, the primary goal of vaccine safety monitoring was to promptly detect, investigate, and evaluate adverse events of special interest (AESIs) and adverse events of financial impact (AEFIs) that have significant medical implications. This proactive strategy attempted to minimize the negative impacts on people's health by ensuring a prompt and suitable reaction and immunization program. It also had a significant impact on maintaining the public's and healthcare professionals' faith in the immunization procedure [13]. In an effort to lower the number of vaccine-preventable fatalities, lessen the burden on the healthcare system, and facilitate the return to normalcy, the Indian government hastened the planning stages of one of the largest immunization campaigns in the world in late 2020. The Indian government produced a platform that held end-to-end processes from the manufacturer through every stage of the immunization process in a matter of months. Together with coordinating with several top stakeholders and requiring consensus building, this activity also needed staff to adjust to the new reality of working remotely and physically apart from one another. ..The establishment of the National Expert Group on Vaccine Administration for COVID-19, which has influenced

every facet of vaccine introduction in India, was a crucial first step in this endeavor. In order to create a unified and well-coordinated effort, the National Expert Group on Vaccine Administration for COVID-19 successfully established high-level coordination with 19 ministries at the federal level, 23 departments at the state and district level, and numerous developmental partners. More than 13.5 billion doses of the COVID-19 vaccine have been given globally since the World Health Organization (WHO) declared the pandemic on March 11, 2020 [1] [2]. At least 70.5% of people on the planet had gotten at least one dosage of the COVID-19 vaccination as of November 2023 [2]. At least 70.5% of people on the planet had gotten at least one dosage of the COVID-19 vaccination as of November 2023 [2]. This unprecedented situation highlights the urgent need for thorough vaccine safety monitoring since relatively uncommon adverse events linked to COVID-19 vaccinations might not be discovered until millions of people have received the shots. The Safety Platform for Emergency vaccinations (SPEAC) program developed a list of probable COVID-19 vaccine adverse events of special interest (AESI) in 2020 in advance of this historic worldwide launch of COVID-19 vaccinations [3]. The selection of AESI was based on their prior relationships to immunization, certain vaccine platforms or adjuvants, or viral replication during diseases of the wild type; theoretical issues with immunopathogenesis; or corroborating data from animal models employing platforms for potential vaccines [3]. Comparing the observed AESI rates after the start of a vaccination campaign with the anticipated (or background) rates based on historical periods prior to the vaccine roll out is one adaptable method for measuring AESI [4], [5]. When regulatory and public health organizations need to quickly examine a developing safety signal, these comparisons may be quickly performed and are crucial in the early identification of possible vaccination safety signals [4], [6]. The use of the ChAdOx1 (AstraZeneca COVID-19 vaccine) was halted on March 11 due to the identification of thrombosis with thrombocytopenia syndrome (TTS) as a safety signal, which was made possible in large part by observed versus (vs.) anticipated (OE) analysis in denmart and Norway [7], [8].

These assessments are beneficial not just in the first stages of widespread vaccine distribution but also as the immunization program develops, particularly if they can be carried out in a multi-nation setting. Following the Observed vs. Expected Analyses of COVID-19 Adverse Events of Special Interest Study Protocol [9], we carried out a global cohort study using data from ten sites in eight different countries that were a part of the special Global COVID Vaccine Safety (GCoVS) Project [10] of the Global Vaccine Data NetworkTM (GVDN®) [11]. Launched in 2021, the GCoVS Project is an international partnership of researchers and data sources from many countries, supported by the Centers for Disease Control and Prevention (CDC), with the aim of monitoring the safety of the COVID-19 vaccine.

Covid 19 vaccines in india:

The efforts to create vaccines coincided with the onset of the country's first wave of the epidemic. A specialist task force was established in April 2020 with the express purpose of carrying out in-depth research on COVID-19 vaccines in order to further and promote vaccine development. Several pharmaceutical firms started clinical studies for several COVID-19 vaccines during the pandemic, including as Zydus Cadila, BB, SII, and Dr Reddy's Laboratories. The vaccines Covishield, ZyCoV-D, Covaxin, and Sputnik V were among those being investigated. In January 2021, Covishield and Covaxin were approved for use in emergencies. Sputnik V was approved in April, while Moderna's mRNA-1273 was approved in the fourth week of June. Zydus Cadila's ZyCoV-D vaccine was approved in August. A number of other vaccines were undergoing various phases of clinical testing, such as Covovax (SII), BBV154 (BB), and Corbevax (Biological E Limited). Authorizations for the emergency use of Covovax, Sputnik Light, and Corbevax vaccines were obtained early in 2022 [14, 15]. India's massive COVID-19 immunization campaigns included the Covaxin and Covishield vaccinations by December 2021. Covishield was created by SII and AstraZeneca working together. The vaccination introduces certain genetic material into the body through the use of a harmless virus, or vector. Here, the vaccine employs a chimpanzee adenovirus that is replication-deficient—that is, it cannot reproduce itself efficiently and has

been altered to contain a genetic fragment—as the vector. This made it possible for the Spike protein's genetic code to be incorporated into the body by the vaccination. Covishield had permission toA number of other vaccines were undergoing various phases of clinical testing, such as Covovax (SII), BBV154 (BB), and Corbevax (Biological E Limited). Authorizations for the emergency use of Covovax, Sputnik Light, and Corbevax vaccines were obtained early in 2022 [14, 15]. India's massive COVID-19 immunization campaigns included the Covaxin and Covishield vaccinations by December 2021. Covishield was created by SII and AstraZeneca working together. The vaccination introduces certain genetic material into the body through the use of a harmless virus, or vector. Here, the vaccine employs a chimpanzee adenovirus that is replication-deficient—that is, it cannot reproduce itself efficiently and has been altered to contain a genetic fragment—as the vector. This made it possible for the Spike protein's genetic code to be incorporated into the body by the vaccination. Covishield had permission to active immunization in individuals aged 18 years and above, following a immunization schedule consisting of two doses. However, Bharat Biotech and the National Institute of Virology (NIV) of the Indian Council of Medical Research (ICMR) collaborated to create Covaxin, an indigenous COVID-19 vaccine. Covaxin was an inactivated vaccine made with Vero-cell-derived (certain cell lines used in labs to generate viruses) whole-virion inactivation (i.e., the entire virus was rendered inactive). In India, these two vaccinations were authorized for use in an emergency on January 3, 2021. On October 21, 2021, India achieved a significant milestone by giving out 100 crore doses of vaccines. The total number of vaccine doses delivered in India as of June 26, 2023, was 220.67 crore [5,16,17].

During the 2009 H1N1 swine flu pandemic and the ensuing vaccination campaign, we discovered that few countries' pandemic readiness plans adequately addressed vaccine safety monitoring. Public trust in the H1N1 vaccination was undermined by pharmacovigilance platforms' inability to establish or rule out connections between AEFIs and the vaccine. Global cooperation between scientists, medical and public health professionals, pharmaceutical and manufacturing companies, as well as increased capacity to analyze and report real-time incidents, are critical for ensuring effective pharmacovigilance of COVID-19 vaccines [18–20].

Vaccine pharmacovigilance in india:

The distribution of vaccinations requires robust pharmacovigilance systems, coordination of worldwide post-licensure surveillance, real-time information sharing, an open-source data repository, and a robust communication component [21]. The Indian Pharmacopoeia Commission (IPC) is the National Coordination Centre (NCC) for the Pharmacovigilance Programme of India (PvPI), operating under the Ministry of Health & Family Welfare since April 15, 2011. In order to inform regulatory interventions to the Central Drugs Standard Control Organization (CDSCO), the NCC's main duties include gathering, compiling, and analyzing data on adverse drug reactions (ADRs). Through PvPI Newsletters, the NCC also plays a crucial role in informing the public and medical professionals about the dangers connected with drugs [22, 23]. The primary goal of PvPI is to compile adverse event reports and provide regulatory bodies with the necessary tools to make wise judgments. This allows the authorities to then provide safety information to other organizations. Under the direction of the NCC, Adverse Drug Reactions Monitoring Centers (AMCs) are set up to make it easier for patients to report ADRs. By making it possible to identify uncommon ADRs that would not have come to light during clinical trial processes, these AMCs play a vital role [24]. The NCC provides labor and logistical assistance to guarantee the efficient reporting of ADRs and the seamless operation of AMCs. Currently, there are twelve regional training centers (RTCs) and over 250 active AMCs across the country as essential constituent of 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 vaccine. As a result, this integration strengthened the nation's reporting and surveillance systems for vaccination safety [25]. Regarding AEFI, India has two different sets of governmental guidelines. The longer version is referred to as the "Operational Guidelines," while the shorter version is called the "Standard Operating Procedures." These recommendations were created through a consultation process with a variety of

stakeholders, adhering to the World Health Organization's recommended approach [26]. The stakeholders included academic institutions, independent topic experts, representatives from the Drug Controller General of India (DCGI), development partners, and several government organizations involved in vaccination programs. Two general categories can be used to group AEFI responses. "Serious AEFIs" is the first category, which includes hospitalizations, deaths, and disabilities. Such instances need quick reporting and a methodical investigation that adheres to established protocols. The Universal Immunization Program (UIP) run by the Indian government uses monthly reporting systems to document the second categorization, known as "minor AEFIs." AEFIs are further divided into five major groups for programmatic purposes: coincidence incidents, vaccination responses, injection reactions, and unknown causes [27].

This was also made feasible by businesses' and governments' anticipation of the industrial growth of production, which was encouraged by the regulatory evaluation agencies' ongoing assessment procedures [1], [2]. The French Network of 31 Regional Pharmacovigilance Centers (RPVCs) made the promise to oversee the safe use of vaccines in this unusual scenario, even prior to the marketing authorizations.

- **What goals does our network have?**

i) prompt signal detection;

ii) openness regarding the safety profiles of COVID-19 vaccines;

iii) weekly expert report production made publicly accessible on the website of the French National Agency for Medicines and Health Products Safety (ANSM);

iv) responsiveness to inquiries from patients and medical professionals regarding possible side effects of these vaccines or symptoms associated with vaccination;

v) responsiveness with the general public, health care professional, hospitals and medical-social establishments.

Unprecedented communication to clarify and better illustrate why pharmacovigilance is both a chance and a necessary precondition for a policy pertaining to medications, including vaccines. This is the essence of French pharmacovigilance: it is both opulent and comprehensive, enabling a seamless transition from patient to signal to individualized patient and physician advice! This means that it is highly regarded globally, practical, and operational with its two complementary skills: medical and pharmacological knowledge linked to its two interdependent approaches (regional and national), in close proximity to the national organization "Agence nationale de sécurité du médicament et des produits de santé" (French National Agency for the Safety of Products and Medicines, ANSM [3], which had previously been heavily deployed in 2009 for the H1N1 vaccination [4], [5], [6], and more recently in 2019 with the careful pharmacosurveillance of potential COVID-19 therapy candidates [7]. The deployment of a vaccination during an epidemic period with the goal of vaccinating the entire population and the intense pharmacovigilance and surveillance of these vaccines still under conditional marketing authorizations are the main highlights of the first weeks of pharmacovigilance monitoring of COVID-19 vaccines in this unprecedented situation in France that we present in this special issue.

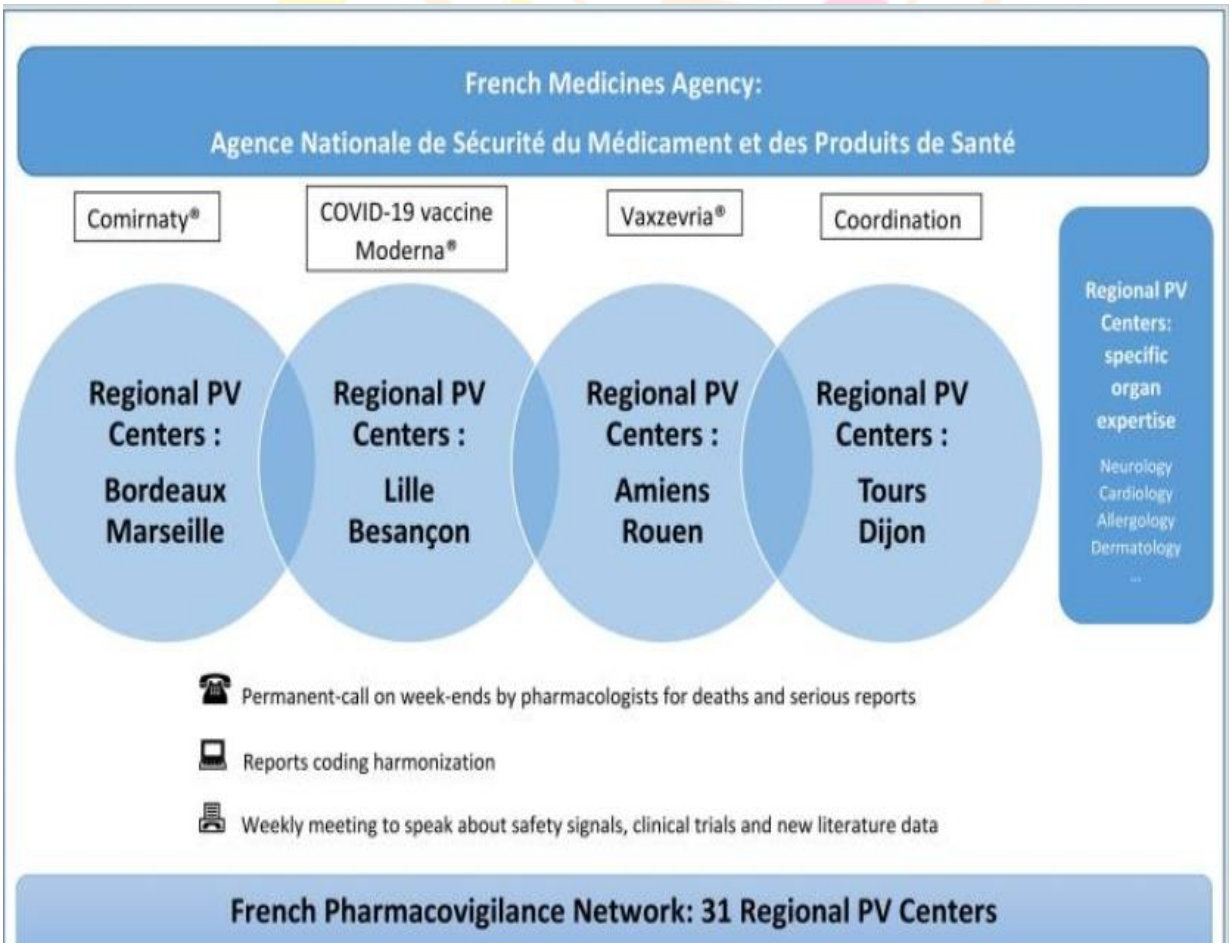
- **About french organization for the pharmacovigilance of covid-19 vaccines:**

A cross-disciplinary approach between the ANSM and the French pharmacovigilance network is necessary to analyze acute assessment and raise alerts, and as a result, the circuit has been adjusted to respond as effectively as possible to this unusual scenario. ANSM is the driving force behind this tight collaboration and strengthening of the pre-existing organization. Pharmacovigilance for COVID-19 vaccines is organized along

two dimensions, just like the vaccine's effect. The 31 Regional RPVCs' real-time study of all ADR notifications [14], [15], and [16] represents the individual dimension; the worldwide, scientific analysis of pharmacovigilance specialists from RPVCs and ANM represents the collective dimension. This task force represents pharmacovigilance in France. This arrangement permits real-time analysis and review. In addition to doing real-time ADR evaluations, each French vaccine's assigned pair of RPVCs regularly gathers and thoroughly examines all ADR data. Several RPVCs furthermore provide specialized organ knowledge (such as in neurology, cardiology, allergies, or dermatology) to effectively complete the assessment of ADRs.

Table. 1

Each Tuesday, ANSM receives a report detailing the level of proficiency attained by each pair of RPVCs for every vaccination. These expert reports collect information on the exposed population as well as quantitative and qualitative analysis of adverse drug reactions (ADRs) broken down by ADR type, age, and severity. For adverse events of interest (anaphylaxis, zona, Bell's palsy, etc.), qualitative, quantitative, and medical analysis are conducted in order to characterize them according to several parameters (age, gender, time to onset, etc.) and also to identify typical and/or serious pattern leading to potential safety signals. There are data displays for each week and the total. Then, in order to confirm safety signals, a conference is held every Thursday to examine the expert pharmacovigilance reports, which include important case reports, possible safety signals, and fresh



literature data in detail. In accordance with the European Medicines Agency (EMA), suitable risk minimizing measures would be released if a safety signal has been validated. At the EMA, national safety signals are activated. The ANSM website has comprehensive weekly reports that include summaries of noteworthy case reports [17]. Pharmacologists on permanent call on weekends are also arranged by the director of the pharmacovigilance centers to record and assess death and serious report occurrences seven days a week. Table 1 shows this entire organizational structureAccording to the World Health Organization (WHO), a vaccination is a biological preparation that triggers the body's immune system to mount an offensive against a specific

infection.[4] Although vaccines are generally thought to be safe, like any pharmaceutical treatments, they can occasionally cause adverse events (AEs), as shown in table 2.

Table 2: ADRs associated with various vaccines:

Research has shown that adverse outcomes after vaccination, even small ones, can have significant social and political consequences.[8] When media reports of adverse events (AEs) following vaccinations make headlines, public trust wanes and vaccination campaigns take a hit. This is the case because, in contrast to other pharmaceutical goods, vaccinations are administered to healthy individuals, primarily to the most vulnerable groups, such as children, and have a clear benefit.

The development and role in co-win:

The Indian government created Co-WIN to efficiently coordinate and oversee the countrywide COVID-19 immunization campaign. The impetus behind its creation was the necessity to address the unique obstacles posed by the vast scope and complex process of immunizing a population of more than 1.3 billion people. The main objectives of the platform were to provide a smooth and efficient vaccination process by simplifying the planning, enrollment, and supervision of vaccine dispensation across central and peripheral tiers. Along with maintaining precise and up-to-date data on vaccine distribution, recipients, and adverse events, Co-WIN also planned to let authorities properly assess the immunization campaign's progress and make well-informed choices. Co-WIN was merged with the World Health Organization-supported Surveillance and Action for Events Following Vaccination (SafeVAC) tool to manage AEFIs.

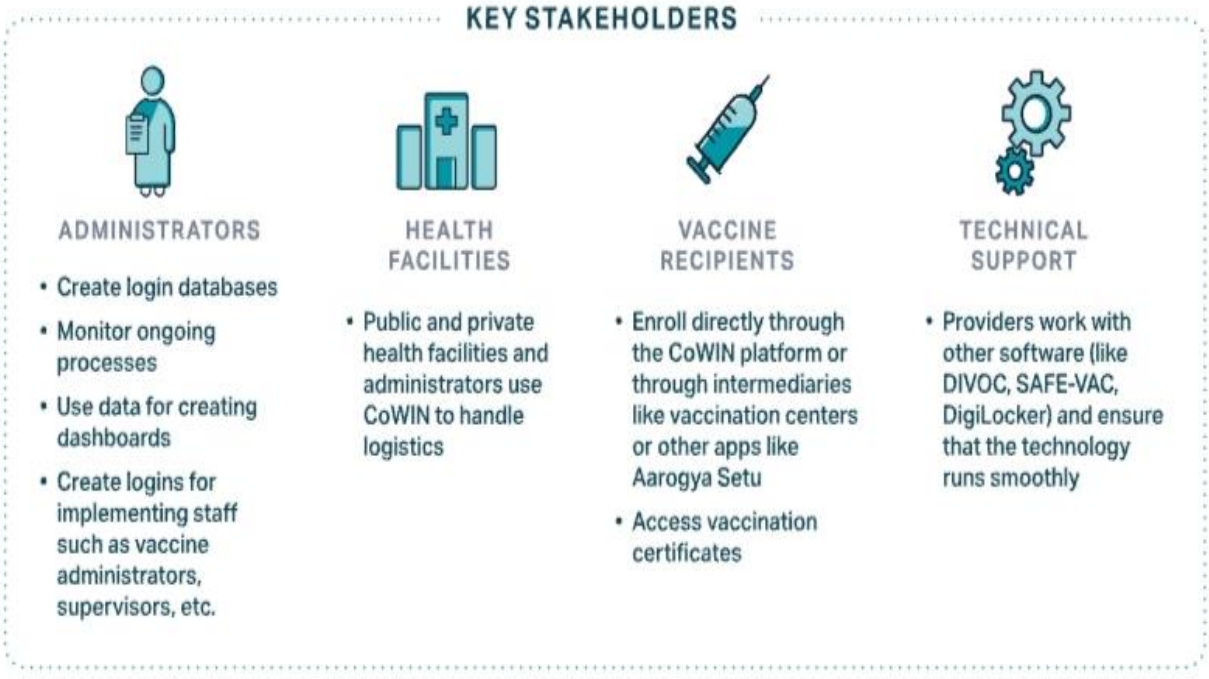
AEFIs were classified in three categories: mild, moderate and severe.

Vaccines	Adverse events	Onset interval
Rota virus	Intussusception	3-14 days
OPV	Vaccine-associated paralysis (AFP)	4-30 days
Tetanus	Brachial neuritis	2-28 days
BCG	Disseminated BCG infection	1-12 months
Hepatitis B	Anaphylaxis	0-1 h
Measles	Encephalopathy	6-12 days
DTP	HHE	0-48 h

Adverse events following immunization (AEFIs) related to vaccinations were documented in the Co-WIN system. A district immunization officer (DIO) or an administering vaccinator performed this. DIOs could access Co-WIN SafeVAC with a single login to fill out case report forms, preliminary case investigation forms, and final investigation forms for cases with significant or severe AEFIs, and then submit the necessary data. Additionally, every AEFI at planning units was tracked in AEFI registers and reported once a week. By

using suitable statistical techniques in conjunction with automated data mining, our strategy expedited the thorough investigation of AEFI cases. Consequently, any alarming patterns might be quickly identified [28, 29].

▪**What does co-WIN Do?**In order to facilitate a smooth vaccination delivery program, CoWIN links stakeholders from all points of the health care value chain, including cold storage locations, administrators, vaccinators, and verifiers (who confirm the identity of individuals undergoing vaccination); additionally, vaccine recipients are connected to both public and private vaccination facilities. The platform is accessible to users on desktop, tablet, and mobile devices, and it may be used for a range of purposes. The aforementioned graphic demonstrates a few of the ways that various stakeholders utilize CoWIN.



Key stakeholders and how they use CoWIN based on their roles.

AEFIs/ADRs reporting during covid-19 vaccines drive in india:

According to the 2015 guideline, AEFIs can be broadly categorized into three groups: (1) common minor AEFIs, which include fever, systemic symptoms, and local reactions;

(2) serious AEFIS, which are AEFIs that lead to hospitalization, death, or significant disability; and

(3) severe AEFIs, which are not minor reactions that also don't require hospitalization and don't result in disability or death. Like many other nations, India uses the passive reporting method.

The updated guideline places a strong emphasis on reporting all AEFI kinds. The medical officer in charge or any other reporter is required to report any serious AEFIs right away in a case reporting format. The report must be delivered to the district immunization officer (DIO) within a day. A monthly progress report is an alternative method of reporting AEFIs. All AEFIs, including both severe and small responses, must be reported in a format similar to the health management system on a monthly basis. Additionally, if no response is reported for the full month, the peripheral health worker must submit a nil report.

The guideline also places a strong emphasis on educating private participants about the current AEFI reporting system and inspiring them to submit similar reports. [16.21.22] A monthly progress report is an alternative method of reporting AEFIs. All AEFIs, including both severe and small responses, must be reported in a format similar to the health management system on a monthly basis. Additionally, if no response is reported for the full month, the peripheral health worker must submit a nil report. The guideline also places a strong emphasis on educating private participants about the current AEFI reporting system and inspiring them to submit similar reports. [16.21.22]

➥**Reporting and documenting AEFI requires collaboration, and the roles of several stakeholders are involved in a smooth information as follows:**

1. Workers in peripheral health

2. Officers of peripheral medicine 3. Independent contractors 4. DIOS 5. The state immunologist 6. The AEFI secretariat's role 7. The national AEFI committee's function Function of the holder of a marketing authorization (MAH). A group of impartial specialists evaluates the causality of AEFIs at various levels of the health administration. India established a National AEFI committee made up of impartial specialists to guarantee accurate and consistent causation determination for AEFIs that are reported across the country. An supervising National AEFI secretariat has been formed to oversee the evaluation of causation and to monitor the overall incidence of AEFIs. Moreover, a National AEFI Technical Collaborating Center was established to offer comprehensive support for the duration of this exercise. As soon as the COVID-19 vaccine was introduced in January 15, In 2021, a specialized team was established with the express purpose of evaluating the causal relationship between COVID-19 immunization and AEFIs. This subspecialty of medicine includes gynecologists, cardiologists, pulmonary medicine specialists, and neurologists. During the national AEFI committee meetings, the results of the causality assessments conducted by this expert team were discussed and eventually approved [30]. In a research by Gandhi et al. (2023), reports from causality assessments pertaining to major AEFIs were subjected to secondary data analysis. The Indian Ministry of Health & Family Welfare first released these reports. According to the results, 1112 causality assessment reports of Serious AEFIs associated with the COVID-19 vaccination had been made accessible in India as of March 29, 2022.711 instances (63.9%) of the 1112 major AEFIs needed hospitalization but eventually recovered, whereas 401 cases (36.1%) ended in mortality. Among the patients that were examined, 209 cases (18.8%) had thromboembolic events (TE). However, a reliable causal link between TE cases and the specific COVID-19 vaccination administered in India was not established. When it comes to the types of significant adverse events that cause illness, the majority were classified as Coincidental (578 cases, 52%) or Vaccine Product Related (218 instances, 19.6%). Reactions attributable to immunization anxiety accounted for 145 instances (13%). 53 instances (4.7%) were reported as uncertain or unable to be diagnosed, whereas a smaller fraction of cases (4, 0.4%) were characterized as responses linked to immunization errors [31]. In a tertiary care teaching institution, Basavraja et al., 2021 carried out another study, which Functions as an AMC

under PvPI, situated in South India. Healthcare workers (HCWs) and frontline staff who had received the COVID-19 vaccination at this specific institution made up the research population. Over the course of the investigation, a total of 11,656 doses of the COVID-19 vaccination were given at the study location; 9292 of these doses were associated with Covishield. According to the study, the incidence rate of AEFIs in the studied population was 3.48%, which was considerably higher than the 0.016% national incidence rate. Of the 445 AEFIs recorded in 269 participants, 433 happened after receiving the Covishield immunization, and 12 had something to do with Covaxin. After doing a causality evaluation, the research findings showed that 94.22% (n = 408) of the adverse events related to the Covishield vaccination were categorized as having a "consistent causal connection with immunization." In this group, 342 cases (78.98%) were classified as "reactions related to vaccination products," while 66 cases (15.24%) were classified as "reactions related to vaccination anxiety." Injectable site discomfort, swelling, redness, and itching were the most frequently reported adverse events (AEFIs) in the trial. These were followed by giddiness, fever, headache, and sneezing. Notably, all research participants recovered from their AEFIs without any long-term consequences, and none of the reported AEFIs were categorized as severe or significant [32]. A total of 1,264 adverse events following vaccination (AEFI) were found in healthcare professionals who got the Covishield vaccine, according to a different research. Of these, 31 AEFIs (2.5%) had an intensity ranging from moderate to severe, whereas 1,233 AEFIs (97.5%) were mild and self-limiting. Pain at the injection site (61.5%), weariness (23.5%), headache (20.2%), and fever (16.8%) were the most often reported adverse events. Other symptoms that were described were palpitations, myalgia, chills, nausea, vomiting, and dizziness. The study's observed adverse events closely matched those often documented for the Covishield vaccination. However, the investigation yielded no meaningful correlation between the recorded adverse events and the immunization. It is noteworthy that every AEFI was meticulously reported to the PvPI by the research. Furthermore, under PvPI, the Regional Training Center was quickly notified of all AEFIs by the institutional vaccine safety surveillance team [33]. According to a descriptive cross-sectional research carried out at the KCGMC, young persons between the ages of 18 and 45 reported voluntarily experiencing Adverse Drug Reactions (ADRs) for both the Covishield and Covaxin vaccinations at the ADR-monitoring center. These reports come from the Karnal District's various immunization facilities. A total of 1,21,195 recipients received the Covishield vaccination throughout the trial period, while 35,595 recipients received the Covaxin vaccination. 51 beneficiaries in all reported ADRs. Thirteen beneficiaries of the Covaxin group and 38 beneficiaries of the Covishield group experienced adverse drug reactions. The results of the study showed that there was no statistically significant difference in the incidence of adverse drug reactions (ADRs) between the two vaccinations during the course of the investigation ($p = 0.648$). A total of 85 adverse drug reactions (ADRs) were recorded among the individuals who reported ADRs; of these, 38 individuals received the Covishield vaccination, and 13 persons received the Covaxin vaccine. 51 healthcare professionals reported ADRs during the research period. With Covishield, only one beneficiary had a major adverse drug reaction (ADR) that required hospitalization and included hemorrhage, vaginal discomfort, vomiting, and fever. The patient recovered after therapy, and that same day, they were released from the hospital. During the whole investigation, no recorded deaths occurred. Fever made up 40% of the overall ADRs recorded in Covishield recipients, while bodily pains made up 15%. .. In contrast, fever and body pains made up 19% and 19% of the total ADRs in the group of ADRs recorded among Covaxin participants, respectively [34]. As part of the PvPI, a research was carried out at a Regional Training Center for Pharmacovigilance, which served as an AMC. Additionally, the DIO and the State Extended Programme on Immunization Officer (SEPIO) were notified of any serious AEFIs. Data gathered as a regular part of the ADR monitoring center's operations were used in this investigation. It included all AEFIs reported between January 10, 2021, and December 31, 2021, that were linked to COVID-19 vaccinations. Over 50,000 doses of the COVID-19 vaccine—41,462 doses of Covishield and 9,548 doses of Covaxin—were given out during this time. Following these vaccines, 330 side

effects were reported. Of these, 22 instances (6.67%) happened after the second dosage and 308 cases (93.33%) after the first dose. Just 6 cases (1.82%) of the reported AEFIs were classified as severe events, with 3 of those cases being designated as Adverse Events of Special Interest (AESI). Pain or discomfort at the injection site was the most common localized response among the reported AEFIs. The most typical symptoms of systemic AEFIs were headaches, myalgia (muscle pain), fever, and body pains or stiffness [35]. The previous discussion of Adverse Drug Reactions (ADRs) was supported by documentation found in case series studies or individual case reports. The fact that these ADRs were only disclosed to the PvPI, however, was not made clear. Rather, they were documented in published literature that provided insightful information on the prevalence and characteristics of certain adverse drug reactions (ADRs) associated with COVID-19 vaccines in India. Even though these case series and reports greatly advance medical knowledge, they might not be included in the official data that PvPI gathers. Numerous negative effects on the skin and other bodily systems have been reported following COVID-19 immunization. Cutaneous adverse drug reactions (CADRs) include any unwanted or inadvertent appearances, abnormal test findings, symptoms, or illnesses that develop after vaccination. CADRs are usually moderate and might include injection site responses or morphelliform eruptions. However, a few severe adverse drug reactions (CADRs) have also been reported, including Rowell syndrome and acute widespread exanthematous pustulosis. Purushottam et al. (2023) reported 18 cases of CADRs after receiving the COVID-19 vaccine. Of these cases, one person received the Covacxin vaccination and seventeen received the Covishield vaccine. The bulk of the fifteen CADR cases appeared within seven days of immunization, following either the first (10 cases) or second (8 cases) dosage of the vaccine. Acute urticaria, pityriasis rosea, leukocytoclastic vasculitis, herpes zoster, psoriasis exacerbations, eczema exacerbations, reactivation of herpes simplex virus 1 infection, and COVID arm were among the disorders covered by the recorded CADRs. A temporal link between the vaccine and the cutaneous reaction was established using the World Health Organization's causality assessment categorization, after a subset of individuals underwent histological examination. Within this categorization, all instances were assigned a B1 classification [38, 39]. Up till June 27, 2022, Garg et al. carried out a thorough systematic review and analysis using data from India. In all, 136 cases of severe neurological and mental side effects were documented from a sizable population of 2,000 million people who had received COVID-19 vaccinations. 64 distinct case reports or case series included descriptions of these adverse occurrences. Cerebral venous sinus thrombosis (VITT), post-vaccination herpes zoster, Guillain-Barre syndrome, and CNS demyelination were the most common adverse effects. Notably, immunological mechanisms were involved in the majority of these neurological issues. Ten individuals with VITT, a disorder defined by cerebral venous sinus thrombosis, were documented. However, given the broad reach of India's COVID-19 immunization campaign, the number of neurological and mental incidents that were recorded was assessed to be very small. Additionally, six distinct instances of mental adverse events were recorded in the trial. Functional neurological illnesses were identified among them; they resembled real neurological disorders, including dizziness, hemiparesis, movement problems, paraparesis, psychogenic nonepileptic seizures, and sensory symptoms. Misinformation about vaccinations on social media, stress from the epidemic, and increased psychological stress were all thought to be potential causes of these functional neurological illnesses. The analysis found that Indian recipients of the COVID-19 immunization experienced a number of significant neurological side effects. The total danger, though, didn't seem that high. Immune-mediated demyelination events of peripheral and central neurons were observed to be rather common, and most immune-mediated diseases had positive responses to immunotherapy. There have also been reported cases of herpes zoster, with a greater incidence rate seen after mRNA vaccinations. The evaluation clarified the significance of tracking and comprehending adverse events connected to COVID-19 immunization in order to maintain public health safety, especially in the face of data constraints [40].

Prevention and control of coronavirus:

Conclusion:

In conclusion The huge COVID-19 immunization campaign in India was implemented with the goal of protecting the populace against the epidemic. A strong pharmacovigilance system was put in place to constantly monitor Adverse Events Following Immunization (AEFI) in order to guarantee the effectiveness and safety of the vaccinations. The reporting of adverse events following vaccination to the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) and the Pharmacovigilance Programme of India (PvPI) has been a crucial component of the COVID-19 vaccination campaign. PvPI acts as the nation's primary location for gathering, compiling, and evaluating ADR data from different immunization facilities. The Indian AEFI Committee carefully examined the relationship between major AEFIs, supporting timely decision-making and the administration of suitable medical care. A systematic strategy to AEFI reporting was used in India to make sure that every adverse event was recorded, sorted, and examined. The gathered data were used to quickly spot any alarming patterns and facilitate evidence-based decision-making. The Indian government's Co-WIN platform played a key role in organizing and optimizing the vaccination procedure. Additionally, Co-WIN was connected with the World Health Organization-supported Surveillance and Action for Events Following Vaccination (SafeVAC) program. The AEFIs' monitoring and surveillance were improved by this integration. The PvPI discovered a number of systemic and cutaneous adverse drug reactions (ADRs) after COVID-19 immunization through diligent reporting. Although the majority of AEFIs were minor and self-limiting, some significant incidents were reported. The most often reported adverse drug reactions (ADRs) were fever, injection site soreness, headache, and weariness. Although there were reports of neurological and mental AEFIs as well, the total risk was still quite low in comparison to the enormous number of people who received vaccinations. Notwithstanding the endeavors to institute a resilient vaccine pharmacovigilance framework in

India, it is imperative to recognize a number of constraints. A significant obstacle is the underreporting of AEFI. A lack of reporting of several mild or self-limiting AEFIs might result in an insufficient knowledge of the overall safety profile of COVID-19 vaccinations. Real-time examination of ADR trends may also be hampered by insufficient or delayed data collection resulting from the passive nature of the reporting mechanism. The underreporting problem is exacerbated by the public's lack of awareness and understanding of AEFI reporting procedures. Furthermore, it is difficult to detect infrequent or delayed adverse effects as there is no specific surveillance mechanism in place for long-term safety monitoring following immunization. Improving vaccination pharmacovigilance in India and guaranteeing the ongoing safety and efficacy of the immunization campaign need addressing these constraints and encouraging proactive reporting and awareness among all stakeholders. In summary, the methodical tracking and documentation of adverse drug reactions (ADRs) in India played a crucial role in guaranteeing the security of COVID-19 vaccines and fostering public trust in the immunization campaign. In the continuous attempts to contain the epidemic and safeguard the health and welfare of the country's citizens, the pharmacovigilance system remained essential.

Reference:

1.World Health Organization. India: WHO Coronavirus disease (COVID-19) dashboard with vaccination data. Available from: https://covid19.who.int/region/searo/country/in.

2. Rodrigues CMC, Plotkin SA. Impact of vaccines; health, economic and social perspectives. Front Microbiol 2020;11:1526.

3. Agrawal G, Hermann R, Møller M, et al. Fast-forward: will the speed of COVID-19 vaccine development reset industry norms? Available from: https://www.mckinsey.com/industries/life-sciences/our-insights/fast-forward-will-the-speed-of-covid-19-vaccine-development-reset-industry-norms.

4. 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.

5. Geographic Insights. India COVID-19 vaccine tracker. 2021. Available from: https://geographicinsights.iq.harvard.edu/IndiaVaccine.

6. Larson H, de Figueiredo A, Karafillakis E, Rawal M. State of vaccine confidence in the EU 2018. A report for the European Commission. 2018. Available from: https://health.ec.europa.eu/system/files/2018-11/2018_vaccine_confidence_en_0.pdf.

7. Chandler RE. Optimizing safety surveillance for COVID-19 vaccines. Nat Rev Immunol 2020;20:451-2.

8. Sallam M. COVID-19 Vaccine hesitancy worldwide: a concise systematic review of vaccine acceptance rates. Vaccines (Basel) 2021;9:160.

9. Solís Arce JS, Warren SS, Meriggi NF, et al. COVID-19 vaccine acceptance and hesitancy in low- and middle-income countries. Nat Med 2021;27:1385-94.

10. Dhalaria P, Arora H, Singh AK, Mathur M, Ajai KS. COVID-19 vaccine hesitancy and vaccination coverage in India: an exploratory analysis. Vaccines (Basel) 2022;10:739.

11. Local Circles. Local Circles 11.5 crore Indian adults are still hesitant to take COVID vaccine. 2021. Available from: https://www.localcircles.com/a/press/page/localcircles-vaccine-hesitancy-survey.

12. Chandani S, Jani D, Sahu PK, et al. COVID-19 vaccination hesitancy in India: state of the nation and priorities for research. Brain Behav Immun Health 2021;18:100375.

13. CIOMS/WHO Working Group on Vaccine Pharmacovigilance. Definition and application of terms for vaccine pharmacovigilance. 2012. Available from: https://cioms.ch/wp-content/uploads/2017/01/report_working_group_on_vaccine_LR.pdf.

14. The New Indian Express. India gets fifth Covid vaccine as Johnson & Johnson's single-shot vaccine gets nod. 2021. Available from: https://www.newindianexpress.com/nation/2021/aug/07/india-gets-fifth-covid-vaccine-as-johnson--johnsons-single-shot-vaccine-gets-nod-2341527.html.

15. The Financial Express. Covid-19: Zydus Cadila's ZyCov-D vaccine gets nod for emergency use in India — here's everything you must know about country's sixth vaccine. 2021. Available from: https://www.financialexpress.com/lifestyle/health/covid-19-zydus-cadilas-zycov-d-vaccine-gets-nod-for-emergency-use-in-india-heres-everything-you-must-know-about-countrys-sixth-vaccine/2314938/.

16. Mohandas S, Yadav PD, Shete-Aich A, et al. Immunogenicity and protective efficacy of BBV152, whole virion inactivated SARS- CoV-2 vaccine candidates in the Syrian hamster model. iScience 2021;24:102054.

17. Serum Institue of India. fact sheet for vaccine recipient approved for restricted use in emergency situation of Chadox1 Ncov-19 Corona Virus vaccine (recombinant) Covishieldtm in prevention of Covid-19 disease in individuals 18 years of age and

older. 2021. Available from: https://www.seruminstitute.com/pdf/covishield_fact_sheet.pdf.

18. World Health Organization. Main operational lessons learnt from the WHO Pandemic Influenza A(H1N1) Vaccine Deployment Initiative. (2012). Main operational lessons learnt from the WHO pandemic influenza A(H1N1) vaccine deployment initiative. 2011. Available from: https://apps.who.int/iris/handle/10665/44711.

19. Mokdad AH, Hotez PJ, Orenstein WA. We have to get it right: ensuring success. EClinicalMedicine 2021;31:100690.

20. Naniche D, Hotez P, Bottazzi ME, et al. Beyond the jab: a need for global coordination of pharmacovigilance for COVID-19 vaccine deployment. EClinicalMedicine 2021;36:100925.

21. Sultana J, Mazzaglia G, Luxi N, et al. Potential effects of vaccinations on the prevention of COVID-19: rationale, clinical evidence, risks, and public health considerations. Expert Rev Vaccines 2020;19:919-36.

22. Kalaiselvan V, Thota P, Singh GN. Pharmacovigilance programme of India: recent developments and future perspectives. Indian J Pharmacol 2016;48:624-8.

23. Kalaiselvan V, Prasad T, Bisht A, et al. Adverse drug reactions reporting culture in pharmacovigilance programme of India. Indian J Med Res 2014;140:563-4.

24. Olsson S. The role of the WHO programme on International Drug Monitoring in Coordinating Worldwide Drug Safety Efforts. Drug Saf 1998;19:1-10.

25. Kumar Mall S, Dipa P, Goswami S, et al. Pharmacovigilance programme in India (PvPI): history, current scenario, future aspects and role in COVID-19. Asian J Res Pharm Sci 2022;205-9.

26. Immunization Focus World Health Organization Regional Office For The Western Pacific Manila. Immunization safety surveillance: guidelines for managers of immunization programmes on reporting and investigating adverse events following immunization. 1999. Available from: https://apps.who.int/iris/bitstream/handle/10665/208312/9290611820_eng.pdf?sequence=1&isAllowed=y.

27. Ministry of Health and Family Welfare. Revised AEFI guidelines: executive summary. Available from:https://main.mohfw.gov.in/sites/default/files/Revised%20AEFI%20Guidelines%20Execute%20Summary.pdf.

28. Ministry of Health and Family Welfare, Government of India. Guidelines for integration of Co-WIN with third-party applications developed by ecosystem partners. 2021. Available from: https://www.mohfw.gov.in/pdf/CoWINAPIGuidelinesFinal240521.pdf.

29. Singh K, Verma A, Lakshminarayan M. India's efforts to achieve 1.5 billion COVID-19 vaccinations: a narrative review. Osong Public Health Res Perspect 13;316-27.

30. Government of India, Ministry of Health & Family Welfare, Immunization Division. Causality assessment results of 88 reported serious adverse events following immunization (AEFI) cases following COVID-19 vaccination approved by national AEFI committee on 28th June 2021. 2021. Available from: https://main.mohfw.gov.in/sites/default/files/Englishnote.pdf.

31. Gandhi AP, Venkatesh U, Murali N. Serious adverse event following immunization and thromboembolic events associated with COVID19 vaccination: an analysis of nationwide causality assessment from India. Indian Heart J 2023;75:139-44.

32. 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 202;9:25151355211055833.

33. Sathyapalan DT, Moni M, Prasanna P, et al. Adverse events associated with Covishield vaccination among healthcare workers in a tertiary hospital in South India. Vaccine X 2022;12:100210.

34. Deb T, Beniwal A, Kamra N, Kaur M. ADR Profile of Covishield and Covaxin among young adults (18-45 year) in a district in northern India: a comparative study. Int J Toxicol Pharmacol Res 2022;12:187-94.

35. Jhaj R, Chaudhary D, Shukla AK, Yadav J. Stimulated reporting of adverse events following immunization with COVID-19 vaccines. Vaccines (Basel) 2022;10:2133.

36. Beatty AL, Peyser ND, Butcher XE, et al. Analysis of COVID-19 vaccine type and adverse effects following vaccination. JAMA Netw Open 2021;4:e2140364.

37. Gambichler T, Scholl L, Dickel H, et al. Prompt onset of Rowell's syndrome following the first BNT162b2 SARS-CoV-2 vaccination. J Eur Acad Dermatol Venereol 2021;35:e415-6.

38. Purushottam M, Rangappa V, Betkerur J, et al. Cutaneous adverse drug reactions (CADRs) to COVID-19 vaccines: a case series. Indian Dermatol Online J 2023;14:383-7.

39. World Health Organization. Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO classification. 2021. Available from: https://www.who.int/publications/i/item/9789241516990.

40. Garg RK, Paliwal V, Malhotra HS, et al. Spectrum of serious neurological and psychiatric adverse events in Indian COVID-19 vaccine recipients: a systematic review of case reports and case series. Neurol India 2023;71:209-27.

41. Our World in Data. Coronavirus (COVID-19) Vaccinations - Our World in Data 2023. https://ourworldindata.org/covid-vaccinations (accessed October 13, 2023).

42. Safety Platform for Emerging Vaccines S. D2.3 Priority list of adverse events of special interest: COVID-19. Brighton Collaboration; 2020. Available from: https://zenodo.org/records/6656179#.Y-0yxuyZOnN.

43. M.D.X. van der Boom, R. van Eekeren, F.P.A.M. van Hunsel Observed-over-Expected analysis as additional method for pharmacovigilance signal detection in large-scaled spontaneous adverse event reportingPharmacoepidemiol Drug Saf, 32 (2023), pp. 783-794, 10.1002/pds.5610 View at publisher View in ScopusGoogle Scholar

44. O. Mahaux, V. Bauchau, L. Van Holle Pharmacoepidemiological considerations in observed-to-expected analyses for vaccines Pharmacoepidemiol Drug Saf, 25 (2016), p. 215, 10.1002/PDS.3918 View at publisher View in ScopusGoogle Scholar

45. R. Li, B. Stewart, E. Weintraub Evaluating efficiency and statistical power of self-controlled case series and self-controlled risk interval designs in vaccine safety J Biopharm Stat, 26 (2016), pp. 686-693, 10.1080/10543406.2015.1052819 View at publisher View in ScopusGoogle Scholar

46. A. Pottegård, L.C. Lund, Ø. Karlstad, J. Dahl, M. Andersen, J. Hallas, et al. Arterial events, venous thromboembolism, thrombocytopenia, and bleeding after vaccination with Oxford-AstraZeneca ChAdOx1-S in Denmark and Norway: population based cohort study BMJ, 373 (2021), Article n1114, 10.1136/bmj.n1114 View at publisher View in ScopusGoogle Scholar

47. European Medicines Agency. Signal assessment report on embolic and thrombotic events (SMQ) with COVID-19 Vaccine (ChAdOx1-S [recombinant])-Vaxzevria (previously COVID-19 Vaccine AstraZeneca) (Other viral vaccines). 2021.

Google Scholar

48. Global Vaccine Data Network. Observed vs. expected analyses of COVID-19 vaccine adverse events of special interest study protocol. Version 1.4. Auckland (NZ): Global Vaccine Data Network; 2022. Available from: https://www.globalvaccinedatanetwork.org/sites/globalvaccinedatanetwork.org/files/2024-01/GVDN-observed-vs.-expected-analyses-of-COVID-19-vaccine-AESI-V1.4.pdf.

Google Scholar

49. Global Vaccine Data Network. Global COVID Vaccine Safety (GCoVS). Auckland (NZ): Global Vaccine Data Network; 2022 [accessed 2023 October 13]. Available from: https://www.globalvaccinedatanetwork.org/global-covid-vaccine-safety-gcovs.

Google Scholar

50. Global Vaccine Data Network. Auckland (NZ): Global Vaccine Data Network; 2023 [accessed 2023 October 13]. Available from: https://www.globalvaccinedatanetwork.org/.

Google Scholar

51. Global Vaccine Data Network. GVDN: Observed vs expected (OE) dashboard. Auckland (NZ): Global Vaccine Data Network; 2023 [updated 2023 December 8; cited 2023 December 13]. Available from: www.globalvaccinedatanetwork.org/Data-Dashboards.

Google Scholar

52. A. Phillips, Y. Jiang, D. Walsh, N. Andrews, M. Artama, H. Clothier, et al.

Background rates of adverse events of special interest for COVID-19 vaccines: a multinational Global Vaccine Data Network (GVDN) analysis Vaccine, 41 (2023), pp. 6227-6238, 10.1016/J.VACCINE.2023.08.079 View PDFView articleView in ScopusGoogle Scholar

53. K.E. Hanson, K. Goddard, N. Lewis, B. Fireman, T.R. Myers, N. Bakshi, et al. Incidence of Guillain-Barré syndrome after COVID-19 vaccination in the vaccine safety datalink JAMA Netw Open, 5 (2022), Article E228879, 10.1001/JAMANETWORKOPEN.2022.8879 View at publisher View in ScopusGoogle Scholar

54. World Health Organization. Statement of the WHO Global Advisory Committee on Vaccine Safety (GACVS) COVID-19 subcommittee on reports of Guillain-Barré Syndrome (GBS) following adenovirus vector COVID-19 vaccines n.d. https://www.who.int/news/item/26-07-2021-statement-of-the-who-gacvs-covid-19

55. subcommittee-on-gbs (accessed October 23, 2023). Government of India, Ministry of Electronics and Information Technology. UMANG. Accessed January 29, 2022. https://web.umang.gov.in/landing/

56. Government of India announces a liberalised and accelerated phase 3 strategy of Covid-19 vaccination from 1st May. Government of India, Ministry of Health and Family Welfare website. Accessed September 13, 2021. https://pib.gov.in/PressReleasePage.aspx?PRID=1712710

57. Government of India, Ministry of Health and Family Welfare. Guidance Note for CoWIN 2.0. Delhi: Government of India; 2021. Accessed September 13, 2021. https://www.mohfw.gov.in/pdf/GuidancedocCOWIN2.pdf

58. Introduction to DIVOC: Digital Infrastructure for Vaccination Open Credentialing. DIVOC website. Accessed September 13, 2021. https://divoc.egov.org.in/

59. Gangan SP. Maharashtra suspends Covid-19 vaccine drive till Jan 18 due to CoWIN app glitch. Hindustan Times. Updated January 16, 2021. Accessed September 13, 2021. https://www.hindustantimes.com/cities/mumbai-news/maharashtra-suspends-covid-19-vaccine-drive-till-jan-18-due-to-cowin-app-glitch-101610815929524.html

60. CoWIN update to allow for correction of personal details on vaccine certificate. Wire. June 9, 2021. Accessed September 10, 2021. https://thewire.in/health/cowin-update-to-allow-for-correction-of-personal-details-on-vaccine-certificate

APPENDIX

APPENDIX

Absrtact:-

To ensure the safety and effectiveness of the vaccinations given, an effective vaccine pharmacovigilance system is necessary for the successful implementation of COVID-19 immunization programs in India. The Pharmacovigilance Programme of India and the National Expert Group on Vaccine Administration for COVID-19 have been instrumental in tracking and evaluating adverse events that occur after vaccination (AEFI). The collection, evaluation, and reporting of data on various adverse drug reactions linked to COVID-19 vaccinations has been made simpler thanks to these technologies. But there are a number of problems with India's vaccine pharmacy, including as slow data collection and underreporting. It is imperative to address these problems and promote proactive reporting by medical professionals and the general public in order to increase the effectiveness of the pharmacovigilance system. During the COVID-19 immunization campaign, India's vaccine pharmacovigilance efforts were largely obscured until the publication of this comprehensive review study. It also clarifies the significance of these initiatives in enhancing public trust in vaccinations. In addition to demonstrating the dedication to vaccine safety, the thorough reporting of AEFI assists legislators and medical experts in making decisions that will improve the immunization program as a whole.

Key words: COVID-19, PvPI, adverse effects, AEFI, Vaccine