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Review Article

One Health Bulletin

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Management of adverse events post–COVID–19 vaccination with Covaxin and Covishield: A literature review

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ABSTRACT

Covaxin and Covishield have been granted approval for emergency medical use in India due to the severity of COVID-19. Both vaccines are safe and effective and have a good immunogenic response. There is no difference between Covaxin and Covishield in terms of dosages and both can be administered as 0.5 mL (containing 6 mg of virus antigen for Covaxin and 5×10^{10} virus particles for Covishield) in the upper arm region. Covaxin and Covishield are designed for a two dose schedule, and it is advised that the second dose of Covaxin be administered 4-6 weeks after the first dose while 12-16 weeks after the first dose for Covishield. These vaccines may have several side effects such as swelling and itching at the injection site, joint pain, dizziness, headache, allergic reaction, increased heartbeat, and fever. Appropriate counselling and suggestion should be provided for any symptoms associated with vaccination so that post-vaccinated issues can be managed. Physician and community pharmacists may play a vital role in the management of adverse drug event associated with vaccines.

KEYWORDS: COVID-19; SARS-CoV-2; Covaxin; Covishield; Vaccine; Adverse events; Management

1. Introduction

As per the data published in drug discovery trends dated 1 March 2021 in the US suffering Bell's Palsy post-vaccination for COVID-19 in one of the trials went viral, few had the patience to wait for evidence on whether the condition was caused by the vaccine. In the corresponding Pfizer-BioNTech study, four vaccine recipients developed Bell's palsy, but no participants in the placebo group did. So there is a need to find out the compressive information about the phase 3 clinical trial conducted by Moderna. Despite the US and UK drug regulator's assurance that four cases in forty-thousand people who were part of the clinical trial were not enough data to press the panic button on a vaccine, fear had gripped enough people[1]. Regardless of whether future investigations scientifically determine that the cases of temporary facial paralysis attribute to the vaccine, many people have decided to delay their decision for vaccination. This may not be the last experience, as the world is engaged in an unprecedented attempt to vaccinate elderly population and more people with co-morbidities[2]. Considering the fact, this review article highlighted the post effects of two Indian vaccines i.e Covaxin and Covishield and the key role of the community pharmacist in the management of adverse drug associated with vaccines.

1.1. Two COVID–19 vaccines

1.1.1. Covaxin

It is an inactivated vaccine manufactured in collaboration of India's National Institute of Virology and Bharat Biotech, India. After the administration of Covaxin, it activates immune cells and later on develops antibodies against the virus. Two doses of Covaxin can be given to people. The vaccine needs to be stored at 2-8 ℃, with the

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How to cite this article: Kumar A, Shrivastava S, Tiwari P. Management of adverse events post-COVID-19 vaccination with Covaxin and Covishield: A literature review. One Health Bull 2022; 6. https://www.doi.org/10.4103/2773-0344.347378

Article history: Received 7 July 2021 Revision 28 April 2022
Accepted 5 May 2022 Available online 13 June 2022

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cold chain maintained throughout.

1.1.2. Covishield

Covishield was manufactured in collaboration of Serum Institute of India and Oxford-AstraZeneca which was made from weakened adenovirus. Post administration of Covishield activates the immune system to develop antibodies that minimizes the coronavirus infection. Two doses of the Covishield can be given in the interval of four to twelve weeks. Covishield needs to be stored at 2-8 ℃.

1.2. Coincidences masked in COVID vaccination

Because of the existing vulnerabilities in the health profile of those getting vaccines, the chance of health condition to be masked as vaccine side-effect is very high. These is what we call 'coincidental' event, random in nature, but it is often thought to be related to vaccines. It means that some people developed heart-attacks, strokes or other diseases that seemed to be related to the vaccine just because those events followed vaccination. As part of massive immunization programmes involving children, we have seen the potential of such scares to create vaccine reluctance in parents who inadvertently increase the health risks for their child by missing life-saving doses. In the case of a COVID-19 vaccine, vaccinating so many adults with vulnerable health profile in such a short span is uncharted territory, and two of the most important aspects are total transparency and full preparedness on our part to monitor, investigate and address side-effects of vaccinations[3].

2. Vaccine safety monitoring

According to the interim guidance of World Health Organization, there are three types of data sources used in immunisation programmes: 1) routine monitoring: periodic reports, electronic immunisation registries, and logistics management information systems are used to define routine monitoring; 2) periodic surveys: to assess aspects of service delivery and immunisation outcomes; 3) surveillance systems: these are designed to keep an eye out for adverse effect following immunisation.

2.1. Monitoring goals

It includes: 1) to track uptake and coverage by region, population groups, risk categories, dose and schedule completion; 2) to assess how our national policies prioritize at-risk groups based on age and environment (such as hospital and long-term care facility), and weather (temperature between 3 and 17 ℃ and absolute humidity between 1 and 9 g/m^3); 3) to give a personal immunisation certificate related to health, occupational, educational, or travel according to national policies; 4) to ensure that individuals can be tracked during the vaccination course, which is likely in the event of a multi-dose schedule, and limit the number of people who drop out.

2.2. Monitoring of Vaccines and supplies

It includes: 1) to track the delivery of vaccinations and auxiliary supplies such as syringes and personal protective equipment; 2) to track vaccine supplies so that no vaccination opportunities are missed; 3) to track vaccine wastage, especially in multi-dose vials; 4) to track the adequacy and fairness of vaccination; 5) to track the total number of doses distributed over a given period of time.

2.3. Monitoring of vaccination at work place

It includes: 1) prior to vaccination, heads of the government or commercial entities will examine site preparedness; 2) adherence to vaccination standard operating procedures, including beneficiary verification to ensure that only qualified beneficiaries are vaccinated; 3) human resource training status; 4) Adverse event following immunization (AEFI) management. India has had an extensive network of AEFI surveillance and monitoring system with over 700 district committees, as well as state level and national level panels for children over the past 10 years. And this time, we are dealing with adults, with many of them suffering chronic diseases, so cardiologists, pulmonologists, general physicians and neurologists were inducted into the national panel last month. More medical specialists are in the process of being inducted at the state and district levels[4].

3. Management of adverse reaction due to vaccines

Some people have no adverse effects after vaccinated while many notice side symptoms that may interfere with normal activities, which should subside in a few days. Anaphylaxis, myocarditis and pericarditis following COVID-19 immunization are uncommon. Patients should be screened prior to receipt of each vaccine dose, and those with a contraindication should not be vaccinated. Pre-vaccination questionnaire was there to assist in vaccination, and the side effects of the two vaccines are shown in Table 1.

In a government letter to all states and union territories, the Ministry of Health has clearly mentioned that only people over the age of 18 would be vaccinated in emergency situation. But

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Table1. Adverse events (AEs) (≥ 10%) of Covaxin and Covishield.

AEs	Covaxin (*n*=290)[5]	AEs	Covishield (*n*=1 639)[6]
Fever	48.3%	Pain at the injection site	91.0%
Bodyache	33.8%	Asthenia	74.3%
Headache	30.7%	Headache	68.7%
Pain at injection site	24.5%	Join pain	55.0%
Flue like syndrome	16.2%	Fever	47.5%
Join pain	16.2%	Sleep disturbance	29.8%
Cough	12.8%	Anxiety	12.0%
-	-	Swelling	10.7%

the clinical guidelines don't recommend vaccination for pregnant and lactating mothers because there are high chances of blood coagulation and other platelet disorder can be associated. It has been proposed that if required, the COVID-19 vaccine and other vaccines should be given at an interval of at least 14 days[7]. The second dose should also be of the same COVID-19 vaccine as the first dose due to the interchangeability of COVID-19 vaccines is not authorized[8].

The Ministry of Health has laid down certain precautions and contraindications for COVID-19 vaccination along with various fact sheets for both the vaccines (Covishield and Covaxin) which contained information pertinent to the vaccine-like platform, physical specifications, dosage, cold-chain requirements, contraindications, and AEFI[9]. Regarding the contraindications, the Ministry of Health highlighted the importance of vaccination for persons with a history of anaphylactic or allergic reaction to a previous dose of COVID-19 vaccine, and those with immediate or delayed allergy and anaphylaxis to the vaccine. There are several reports suggesting that if a patient having any illness, the vaccination may differ as per standard guidelines[10]. All people using anticoagulants should have their PT-INR checked before getting the vaccination. Those with a history of bleeding diathesis should be closely monitored.

Poor immune systems and HIV-associated patients are debarred. The Ministry of Health has asked states and union territories to prepare for such events and accordingly set up at least one AEFI center in each block[11]. If there were any severe adverse event associated during and after the vaccination, medical report and other anaphylaxis reaction should be addressed immediately and recorded for future reference[12]. Further, minor and severe anaphylaxis reactions were also recorded to minimize the adversity[13, 14].

The effective and safe distribution and administration of the COVID-19 vaccination program will require expert supervision and an affirmative action plan. With unique insight and expertise in medicines and the delivery, the role of pharmacists stands in contributing to the success of vaccination drive. In addition, a pharmacist may play a crucial role in the operational roles in the preparation, distribution system of vaccines, strategic planning, and administration of COVID-19 vaccines to the common people. Effective delivery of vaccination would be a great opportunity for the pharmacist[15]. To strengthen the pharmacist a training program can be organized and up-to-date specific information may be given to avoid misunderstanding and other vaccine-related questions can be addressed during training so that they may encourage more people for vaccine drive in a mission mode. At last but not least to safeguard pharmacists, their teams, and patients must be paramount and must be assured through sustaining COVID-safe practice environments [16,17].

4. Conclusions

There are several challenges which still remain even after vaccination. Indeed it's a great initiative that has been taken across the globe to vaccinate the people on mission mode. Covaxin and Covishield have been granted permission for emergency use only, still, there is a lot to do for the establishment of the molecules to minimize the adverse effect associated with existing vaccines. Apart from existing vaccines nasal vaccines of Bharat-Bio Tech, India could be a game-changer to eradicate the coronavirus. During the pre and post-vaccination, there is a need to address the side effect, in such case pharmacist may play a vital role in the management of side effects associated with vaccines. Being a drug expert and their relevant experience in the field definitely may help people who have been vaccinated. Pharmacists have their expertise and better understating of pharmacology, biochemistry, drug and drug interactions, drug and food interactions, etc. In this contrast, pharmacists may be helpful to manage severe adverse events.

Conflict of interest statement

The authors declare that they have no conflict of interest.

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Acknowledgements

The authors are grateful to the Dayananda Sagar University, Bangalore, Karnataka, India and ARKA JAIN University, Jamshedpur, Jharkhand, India for providing literature support to make this article success.

Funding

The study received no extramural funding.

Authors' contributions

Shrivastava S. was responsible for literature collection and writing the draft of this article. Kumar A reviewed the development process of each COVID-19 vaccines and evaluated the advantages and disadvantages of current vaccines. As the corresponding author, Tiwari P controlled the content of the whole review.

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