IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

ADRs Report Of COVAXIN Vaccine

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ABSTRACT:

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The corona virus disease-19 (COVID -19) pandemic is a continuing global health crisis and the most difficult challenge we have faced in the most unusual ways. It has resulted in numerous fatalities and has had a significant impact on the global economy and financial markets. Vaccines are a new critical tool in the fight against this voracious beast. They have been released in a number of countries around the world. Although the vaccines' safety and efficacy have been discussed, we know very little about the post-vaccination experience outside of clinical trial settings. Adequate information about the vaccine' Adverse effects can educate the public, dispel myths, and increase vaccine acceptability.R1

. **Keywords:** Adverse effects, COVID-19, Covaxin vaccine clinical trial, Vaccine acceptability

INTRODUCTION:

Adverse drug reactions (ADRs) are a significant cause of morbidity and mortality worldwide. According to the definition provided by the World Health Organization, “an ADR is any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy.” The socio-economic and health consequences of ADRs have been highlighted in several studies.

While a majority of the studies cited above show prevalence of this problem in developed countries there is a paucity of accurate data from many developing countries like India.

Scrub are defined as the products used for the purposes Spontaneous (yellow card) reporting of ADRs remains the most widely used and cost- effective surveillance system and is the cornerstone of safety monitoring of drugs in clinical practice. It detects previously unrecognized adverse reactions and identifies risk factors that pre-dispose to drug toxicity and investigates causality.

In addition to identifying drug safety problems, it helps to facilitate risk-benefit judgments and comparisons within therapeutic categories. Intrinsic factors such as knowledge, attitude and practice can help in understanding the relationship of pharmacists with patients and other healthcare professionals and formulating strategies to encourage pharmacists to report ADRs

According to the 2011 census, India has the 2nd highest population in the world with over 1.21 billion people. Some of the ADRs are avoidable. Spontaneous reporting by healthcare professionals is a crucial step for preventing or reducing ADRs. The ADR reporting rate in India is below 1% compared to the worldwide rate of 5%. ADR management can cost the institution or the patient as much as US $15-150 in India. Given the lower rate in India, one of the reasons might be attributed to the awareness about pharmacovigilance and ADR monitoring among the Indian healthcare providers.R2

Concept of Pharmacovigilance

Definition:

According to WHO (WORLD HEALTH ORGANIZATION)

"Medicines and vaccines have transformed the prevention and treatment of diseases. In addition to their benefits, medicinal products may also have side effects, some of which may be undesirable and / or unexpected. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem".[R3]

OBJECTIVES:

- To monitor Adverse Drug Reactions (ADRs) in Indian population
- To create awareness amongst health care professionals about theimportance ADRreaction reporting in India
- To monitor benefit-risk profile of medicine
- Generate independent, evidence-based recommendations on thesafety of medicines
- Support the CDSCO for formulating safety related regulatorydecisions formedicines
- Communicate findings with all key stakeholders
- Create a national Centre of excellence a part with global drug safetymonitoring standards.[R4]

Types of Pharmacovigilance:

There are four important types of Pharmacovigilance such as:

- Passive surveillance
- Active surveillance
- Cohort event monitoring
- Targeted Clinical Investigations

i) Passive Surveillance-

Passive surveillance methods involve the usage of spontaneous adverse event reports voluntarily sent by healthcare professionals or patients to the marketing authorization holder or regulatory authority. Here, data related to the adverse reactions are collected in a central or regional database. The identity of the reporter remains anonymous, but patient-related details like country, age, gender, and pre-existing co- morbidities can be recovered from the reporting forms.

*Examples of spontaneous reporting systems include th*e –

1. FAERS (FDA Adverse Event Reporting System) database run by FDA
2. VigiBase™, the WHO Global Individual Case Safety Report (ICSR) database

ii) Active Surveillance -

This method aims to monitor certain specific drug-related adverse events and seeks to ascertain the number of adverse drug reactions entirely through a pre-planned process. It is commonly knownas toxicity monitoring or safety monitoring.

iii) Cohort Event Monitoring -

In this method, the surveillance study is planned prior to beginning the treatment with the medication. A group of people are exposed to a drug for a defined period and actively followed up duringtreatment.

Adverse events of the target drug or the events associated with one or more medicines taken with that drug are monitored.

iv) Targeted Clinical Investigations –

These kinds of investigations are performed to identify and characterize the adverse reactions related to a drug among special populations like people with some genetic disorders, pregnant women,and older people.[R5]

2] Pharmacovigilance Program of India(PvPI) ;

The purpose of the Pharmacovigilance Program of India is to collect, and analyse data to arrive at an inference to recommend regulatory interventions, besides communicating risks to healthcare professionals and the public.
The Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services under the aegis of Ministry of Health & Family Welfare, Government of India in collaboration with Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi has launched the nation-wide Pharmacovigilance programmer for protecting the health of the patients by assuring drug safety. The programmer is coordinated by the Department of Pharmacology at AIIMS as a National Coordinating Centre (NCC). The Centre will operate under the supervision of a Steering Committee.

Goal

To ensure that the benefits of use of medicine outweighs the risks andthus safeguard the health of the Indian population

Programmer governance and reporting structures

The Pharmacovigilance Programmer of India will be administered and monitored by the following two committees.

I. Steering Committee
II. Strategic Advisory Committee

Technical support will be provided by the following committees:

I. Signal Review Panel
II. Core Training Panel
III. Quality Review Panel.[R6]

List of "National Adverse Drug Monitoring Centres" (ADMCs):

1) Department of Pharmacology, R.G. Kar Medical College, Kolkata

2) Department of Pharmacology, R.G. Kar Medical College, Kolkata

3) Department of Clinical Pharmacology, Seth GS Medical College& KEM Hospital, Parel, Mumbai

4) Department of Clinical & Experimental Pharmacology, School ofTropical Medicine, Chaturanga Avenue, Kolkata

5) Department of Pharmacology, JIPMER, Pondicherry

6) Department of Clinical Pharmacy, JSS Medical College Hospital,Karnataka

Department of Pharmacology, Medical College, Guwahati.

Functions of Adverse Drug Monitoring Centres (ADMCs):

- ✓ To monitor the ADR
- ✓ To create awareness amongst health care professionals about the importance of ADR reporting
- ✓ To monitor benefit-risk profile of medicines

- ✓ Generate independent, evidence-based recommendations on the safety of medicines
- ✓ Support the CDSCO for formulating safety related regulatory decisions for medicines
- ✓ Communicate findings with all key stakeholders
- ✓ Create a national centre of excellence as par with global drug safety monitoring standards.[R8]

Mechanism of action of Covaxin:

The vaccine works by stimulating the immune system to produce antibodies against the inactivated SARS-CoV-2 strain. The vaccine is used, along with immune stimulants commonly known as vaccine adjuvants (Alhydroxiquim-II), to improve the immune response and provide longer-lasting immunity

The vaccine is similar to Corona Vac (the Chinese vaccine developed by Sinovac) in that it uses a complete infective SARS- CoV-2 viral particle consisting of RNA surrounded by a protein shell, but modified so that it cannot replicate.[R11]

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Side effects observed with COVAXIN include pain, swelling, redness and itching at the injection site, as well as body ache, weakness, stiffness, nausea, vomiting, fever, malaise and headache.

The other adverse effects may include:

- Severe allergic reaction.
- Difficulty in breathing.
- Swelling on the face.
- Swelling in the throat.
- Increased heartbeat.
- Rashes all over the body.
- Dizziness & weakness.

Some mild symptoms may occur like injection site pain, headache, fatigue, fever, body ache, abdominal pain, nausea and vomiting, dizziness-giddiness, tremor, sweating, cold, cough and injection site swelling. No other vaccine-related serious adverse effects have been reported.[R13]

Information about covaxin

Vaccination is the administration of a vaccine to help the immune system develop immunity from a disease. Vaccines contain a microorganism or virus in a weakened, live or killed state, or proteins or toxins from the organism. In stimulating the body's adaptive immunity, they help prevent sickness from an infectious disease. When a sufficiently large percentage of a population has been vaccinated, herd immunity results. Herd immunity protects those who may be immunocompromised and cannot get a vaccine because even a weakened version would harm them.

The effectiveness of vaccination has been widely studied and verified. Vaccination is the most effective method of preventing infectious diseases; widespread immunity due to vaccination is largely responsible for the worldwide eradication of smallpox and the elimination of diseases such as polio and tetanus from much of the world. However, some diseases, such as measles outbreaks in America, have seen rising cases due to relatively low vaccination rates in the 2010s – attributed, in part, to vaccine hesitancy. According to the World Health Organization, vaccination prevents 3.5–5 million deathsper year.

Began administration of COVID-19 vaccines on 16 January 2021. As of 2 December 2022, India has administered over 2.19 billion doses overall, including first, second and precautionary (booster) dosesof the currently approved vaccines. In India, 95% of the eligible population (12+) has received at least one shot, and 88% of the eligible population (12+) is

fully vaccinated.

India initially approved the Oxford–AstraZeneca vaccine (manufactured under license by Serum Institute of India under the trade name Covishield) and Covaxin (a vaccine developed locally by Bharat Biotech). They have since been joined by the Sputnik V (manufactured

under license by Dr. Reddy's Laboratories, with additional production from Serum Institute ofIndia being started in September, Modern vaccines, Johnson & Johnson vaccine and ZyCoV- D (a vaccine locally developed by Zydus Cadila) and other vaccine candidates undergoing local clinical trials.

According to a June 2022 study published in The Lancet, COVID-19 vaccination in India prevented an additional 4.2 million deaths from December 8, 2020, to December 8, 2021.

Over 80% of the population of India have a positive response for getting anti covid shots. India has one of the lowest vaccine hesitanciesin the world. There was vaccine hesitancyin the initial months of 2021, especially in rural India and among poor and tribal populations. Constant government and public awareness drastically reduced vaccinehesitancy.

Since May 2021, more than half of daily doses administered in India have been from rural parts. Vaccine centres in India have witnessed large number of people willing to get covid vaccine resulting in overcrowding and mismanagement. Many centres across India in months of April & May reported severe shortage of covid vaccines dueto large crowds turningup for vaccination. In cities like Mumbai, New Delhi, Bengaluru many people even after waiting for hours did not receive their covid vaccine due to shortage. Since July, vaccine supplyhas drastically increased thus India is vaccinating at a very fast [R14,15].

CONCLUSION:

Two-thirds of vaccinated peoples who completed the survey reported mild and short- lived post-vaccination symptoms. Tiredness, myalgia and fever were most commonly reported. These symptoms were consistent with an immune response commonly associated with vaccines, and correlated with the findings from previously published phase 2/3 trials. In 90% cases, the symptoms were either milder than expected or meeting the expectation of the vaccine recipient.

No serious events were reported. Symptoms were more common among younger individuals. There was no difference in symptoms among those who had a past history of COVID

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