Global Science Research Journals Available Online at
www.globalscienceresearchjournals.org

Vol 2(1)

Review Article OpenAccess

Review on ADR Reporting of COVID-19 Vaccines

V. Asha jyothi*, G. Shireesha

Pharmacy Research,
St. Pauls college of pharmacy
Turkayamjal, Hyderabad
*Corresponding author: E-mail: ashajyothivadlapudi@gmail.com
Received 05 October, 2021; **Accepted** 19 October, 2021; **Published** 26 October, 2021

ABSTRACT

Adverse drug reactions (ADRs) are an established risk to medication use. As defined by the World Health Organization (WHO), an ADR is any response that is noxious and unintended, and that occurs at doses normally used in humans for the prophylaxis, diagnosis, therapy of disease, or for the modification physiological function. ADRs associated morbidity and mortality impose a burden to patient's health and health care costs. Unfortunately, not all ADRs can be identified in clinical trials, and so post-marketing surveillance is imperative in identifying and evaluating those risks associated with medication use . Spontaneous reporting of unusual or previously unpredicted ADRs by health care professionals (HCPs) can accordingly reduce such risk and promote the safe use of medications. The main advantage of spontaneous reporting is its ability to cover the entire population, which use a wide range of medications, thus identifying rare ADRs as early as possible. Nevertheless, only 6–10% of ADRs area actually reported to drug authorities in Europe, Canada and USA, making underreporting of ADRs a major limitation of spontaneous reporting. In an effort to strengthen the pharmacovigilance in India, government has initiated pharmacovigilance programme of India. Spontaneous reporting of adverse drug reaction is globally practiced it under pharmacovigilance programme. But the major drawback of this system is underreporting. The finding of study suggests a huge scope for improving the awareness about ADRs.

Keywords: Adverse drug reactions, Spontaneous reporting, Pharma covigilance.

INTRODUCTION

Adverse drug reactions (ADRs) are an established risk to medication use. As defined by the World Health Organization (WHO), "an ADR is any response that is noxious and unintended, and that occurs

at doses normally used in humans for the prophylaxis, diagnosis, therapy of disease, or for the modification of physiological function". Adverse Event is any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this medical product. An adverse drug reaction. distinguished from the adverse event by the former has a suspicion of causal relationship between the medicinal product and the reaction, i.e., judged as being at least possibly related to the reporting or the reviewing health professional, while the adverse event does not necessarily have such causal relationship. World Health Organization defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problems. In an effort to strengthen the pharmacovigilance in India, government has initiated pharmacovigilance programme of India (PvPI). Similarly, the Drug Controller General of India and Indian Council of Medical Research have established ADR monitoring centers in many hospitals in major cities of India. Despite these efforts and the presence of a large number of tertiary care facilities, pharmacovigilance is still in its infancy. The major reason behind this is poor understanding of the health-care professionals toward the existing pharmacovigilance program. ADRs associated morbidity and mortality impose a burden to patient's health and health care costs. Unfortunately, not all ADRs can be identified in clinical trials, and so post-marketing surveillance is imperative in identifying and evaluating those risks associated with medication use. Spontaneous reporting of unusual or previously unpredicted ADRs by health care professionals (HCPs) can accordingly reduce such risk and promote the safe use of medications. The main advantage of spontaneous reporting is its ability to cover the entire population, which use a wide range of medications, thus identifying rare ADRs as early as possible. Nevertheless, only 6–10% of ADRs are actually reported to drug authorities in Europe, Canada and USA, making underreporting of ADRs a major limitation of spontaneous reporting8. In India, the gross under-reporting of ADR is a cause of concern, the reasons for may be due to lack of trained staff and lack of awareness regarding detection, communication and spontaneous monitoring of ADRs among the health-care professionals (physicians, nurses, pharmacist and dentists). There is a requirement for constant training and enactment of regulations for ADR reporting among health-care professionals. Previously reported study has found that underreporting of ADR is related with shortcomings in the knowledge and attitude among health –care professionals. One of the major reasons of morbidity and mortality all over the world is adverse drug reactions (ADRs). Hence proper monitoring of ADRs is a necessity. In India all health care professionals including doctors, nurses and pharmacists can report an ADR by filling an ADR form of the central Drugs Standard Control Organization. It is important for healthcare professionals to know how to report and where to report an ADR. The active participation of healthcare professionals in the pharmacovigilance program can improve the ADR reporting. Egypt became a member in WHO International Program for Drug Monitoring in 2001, yet no solid steps were taken except in 2009 with the establishment of the Egyptian Pharmacovigilance Center (EPVC). EPVC roles include: receiving ADR reports, detecting safety signals, issuing regular newsletters with pharmacovigilance (PV)-related updates and conducting awareness workshops16. Spontaneous reporting in Egypt is a voluntary process, where pharmacists, among other HCPs, can send an ADR

report (yellow card) to EPVC's satellite centers in their respective region. These centers act as focal points to spread awareness with the Egyptian ADRs reporting process, through planning workshops for HCPs, including hospital pharmacists. Little is known about the Egyptian pharmacist attitude towards ADRs monitoring and barriers experienced by pharmacists considering the short-lived experience of PV in Egypt. Thus, the aim of this study is to assess the impact of awareness workshop, planned by the Cairo satellite center, on knowledge of hospital pharmacists and to identify the main factors (socio-demographic and professional, nature of ADR (that influence ADRs reporting) [1].

METHODOLOGY

Types of Adverse Drug Reactions 1

Type A effects

Augmented pharmacologic effects - dose dependent and predictable (medicine actions) are those which are due to (exaggerated) pharmacological effects. Type A effects tend to be fairly common, dose related (i. e. more frequent or severe with higher doses) and may often be avoided by using doses which are appropriate to the individual patient. Such effects can usually be reproduced and studied experimentally and are often already identified before marketing.

Type B effects

Bizarre effects (or idiosyncratic) dose independent and unpredictable (Patient reactions) characteristically occur in only a minority of patients and display little or no dose relationship. They are generally rare and unpredictable, and may be serious and are notoriously difficult to study. Type B effects are either immunological or non-immunological and occur only in patients, with - often unknown - predisposing conditions. Immunological reactions may range from rashes, anaphylaxis, vasculitis, inflammatory organ injury, to highly specific autoimmune syndromes. Also, non-immunological Type B effects occur in a minority of predisposed, intolerant, patients, e. g. because of an inborn error of metabolism or acquired deficiency in a certain enzyme, resulting in an abnormal metabolic pathway or accumulation of a toxic metabolite. Examples are chloramphenicol caused aplastic anemia and isoniazid caused hepatitis [2].

Type C effects

Chronic effects refer to situations where the use of a medicine, often for unknown reasons, increases the frequency of a spontaneous disease. Type C effects may be both serious and common (and include malignant tumors) and may have pronounced effects on public health. Type C effects may be coincidental and often concern long term effects; there is often no suggestive time relationship and the connection may be very difficult to prove.

Type D effects

Delayed effects (dose independent)

Carcinogenicity (e.g., immunosuppressants)

Teratogenicity (e.g., fetal hydantoin syndrome)

Type E effects: End-of-treatment effects

Type F effects: Failure of therapy1

Vaccine

A vaccine is a biological preparation that provides active acquired immunity to a particular infectious disease. Whereas, the Covid vaccine is defined as a vaccine intended to provide acquired immunity against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus causing coronavirus disease 2019 (COVID-19) [3].

Types Of Vaccines

As of June 2021, 18 vaccines are authorized by at least one national regulatory authority for public use

Two RNA vaccines

- Pfizer–Biotech
- Moderna,

Nine conventional inactivated vaccines

- BBIBP-CorV,
- Chinese Academy of Medical Sciences,
- CoronaVac,
- Covaxin,
- CoviVac,
- COVIran Barakat,
- Minhai-Kangtai,
- QazVac, and

- WIBP-CorV).

Five viral vector vaccines

- Sputnik Light
- Sputnik V
- Oxford–AstraZeneca,
- Convidecia, and
- Johnson and amp; Johnson)

Two protein subunit vaccines

- Epi Vac Corona and
- RBD-Dimer

In total, as of March 2021, 308 vaccine candidates are in various stages of development, with 73 in clinical research, including 24 in Phase I trials, 33 in Phase I–II trials, and 16 in Phase III development [4].

Mostly Used COVID-19 Vaccines In India

- Different covid -19
- The best covid -19 vaccines are the first one that is available to you.
- Covid-19 vaccines are safe and effective
- You may have side effects after vaccination, but there are normal
- It typically takes two weeks after you are fully vaccinated for the body to build protection(immunity) against the virus that causes covid-19

Covaxin

- Inactivation virus
- 2 shot vaccine
- 2nd dose after 28 days
- Efficacy of 70%-80%
- Developed by India
- Available in India
- Approved by 9 countries

Actions: When administrated immunity cells can still recognize the death virus, prompting the immune system to make antibodies against the pandemic virus.

Efficacy

In comparison to this, Bharat Biotech's Covaxin which has been recently found to be neutralizing against the UK variant has an efficacy rate of over 70 to 80% It must be four weeks interval between two doses

Side effects

- Redness, swelling, pains at the injection site
- Fever
- Sweating and or chills
- Body pains
- Nausea and vomiting
- Itching and rashes
- Headache

Indications: Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; loss of taste or smell of recent onset; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

Contraindication: You should not get COVAXIN if you: Had a severe allergic reaction to any ingredients of the vaccine. Had a severe allergic reaction after a previous dose of this vaccine. Currently have an acute infection or fever [5].

Precautions: This vaccine is unsafe who might be running with fever at the time of administration or on blood thinning medications, suffering from immune disorder, bleeding problem.

Covishield

- Viral vector (modern chimpanzee adeno)
- 2 shot vaccine
- 2nd dose after 84 days
- Efficacy of 70-90%
- Developed by UK, Sweden India
- Available in India
- Approved by 130+countries

Action: It is made from a weekend version of a common cold virus (knows as an adeno virus) from chimpanzees.

Efficacy

Serum institutions of India s Covishield vaccine. On the other hand, has an efficacy rate of over 70.4%. Its efficacy could reach up to 90 weeks apart. Dosing interval is stretched to 12 weeks or more.

Side effects

- Pain at the injection site
- Redness
- Swelling
- Head ache
- Nausea
- Vomiting
- Fever
- Muscle pain
- Body pain

Indications

The Covishield vaccine are L-Histamine, L-Histamine hydrochloride monohydrate, Magnesium chloride hex hydrate, Polysorbate 80, Ethanol, Sucrose, Sodium chloride, Disodium edentate dehydrate (EDTA), Water for injection, it pointed out [2].

Contraindication

Hypersensitivity

Precautions

Pre-existing allergy, blood thinning medications and one who is planning to conceive should advice to wait postponing their vaccination 3-4 weeks after corona virus.

Sputnik

- viral vector (modified adeno)
- 2 shot vaccination.
- 2nd Dose after 28
- Efficacy of 85-95%
- Developed by Russia
- Will be available in indie shortly

Action

The vaccine, also known as gram-covid Vac, is a combination of two different adenovirus (A26 and ad5). The adenovirus-viruses that causes covid -19 spike proteins, which prompts the body 10 make an immune response [2].

Efficacy

The Russian vaccine, sputnik v. recently approved by the drug controller general of indie (DCGI) has an efficacy rate of 91.5%. It has a high response in curbing the severity of the virus sputnik v must be given in two doses at 21 days interval [3].

Side Effects

- Head ach
- Fatigue
- Pain at the injection site
- Flu like illness

Indications: The Russian Sputnik V COVID-19 Vaccine (Gam-COVID-Vac) is indicated to build immunity to SARS-CoV-2, which causes COVID-19 disease.

Contraindication

- Hypersensitivity to any component of the vaccine, or a vaccine that has similar components; Components: Active substance: (1.0±0.5) × 1011 particles containing protein S gene of SARS-CoV-2 virus Excipients: polysorbate 80, magnesium chloride hex hydrate, EDTA disodium salt dehydrate, ethanol 95%, water for injection
- Pregnancy and breastfeeding, ask if the lady is trying to get pregnant. If she is, she has to wait for her period to get the vaccine.
- Patient below 18 years of age.

LITERATURE

Moderna

Action: The nucleoside-modified mRNA in the Moderna COVID19 Vaccine is formulated in lipid particles, which enable delivery of the nucleoside modified mRNA into host cells to allow expression of the SARSCoV2 Spike antigen. The vaccine elicits an immune response to the Spike antigen, which protects against COVID19.

Composition: Messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), trimethamine hydrochloride, acetic acid, sodium acetate trihydrate and sucrose.

Indications: Moderna COVID-19 Vaccine is authorized and recommended for people 18 years of age and older. All people for whom vaccination is indicated should receive 2 doses 28 days apart.

Contraindications: Contraindications to either of the mRNA COVID-19 vaccines: Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or to any of its components Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])*Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG) Persons with an immediate allergic reaction to the first dose of an mRNA vaccine should not receive additional doses of either of the mRNACOVID-19 vaccines. These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immune [1].

Efficacy

The Moderna vaccine requires two doses to be fully effective. it was found that up to 14 days after the first dose, the effectiveness was 50.8 percent. After that, it was about 92.1 percent. After the second dose, it takes about 2 weeks four your body to build full immunity. After that time period, the vaccine is approximately 94.1% effective [4].

Side effects

In clinical trials, reactogenicity symptoms (side effects that happen within 7 days of getting vaccinated) were common but were mostly mild to moderate22,23.

ADRs of covid-19 vaccines can be known by following process

Study Design

It is the main step to know the study type of research and the number of patients included in this study. This also includes the number of hospitals is surveyed. As per the covid-19, the study of patients information were shared by filling up the suspected ADR reporting form available at the pvpi, Ncc (IPC) website which is available in English, Hindi, and other vernacular Languages. Mobile application from Google play store named “ADRvPI”.24.

Table 1: ACCORDING TO DIFFERENT STUDIES OF SOME ARTICALS COVID-19 VACCINES ADRs .

VACCINE	ADRs	ADRs
COVAXIN	Pain at the injection site (24%)	Fever
	Swelling at the site of injection (3%)	Headaches

	Headaches (3%)	Fatigue
	Fatigue (3%)	Irritability
	Nausea and vomiting (2%)	Pain, swelling can both at the site of injection[26]
	Fever (2%)[25]	
COVISHILD	Myalgia and fatigue (69%)	Headache (52.6%)
	Fever (59%)	Fatigue (53.1%)
	Headache (46%)	Muscle or joint pain (44%)
	Flu-like symptoms (08%)	Fever (33.6%)
	Loose stools (03%)	Nausea (21.9%)
	Vomiting (01%).[27]	Chills (31%).[28]
SPUTNIK V	Pain at the site of injection (58%)	Fatigue (70%)
	Headache (42%)	Joint pain (46.4%)
	Hyperthermia (50%)	Headache (64.7%)
	Asthenia (24%)	Muscle ache (61.5%)
	Muscle and joint pain (24%)[29]	Chill (45.4%)
		Fever (15.5%)
MODERNA	Fatigue (70%)	Nausea, vomiting (23%)[30]
		Myalgia (61.5%)
	Headache (64.7%)	Arthralgia (46.4%)
	Muscle or joint pain (61.5%)	Chills (45.4%)
	Joint pain (46.4%)	Axillary swelling / tenderness (19.8%)
	Fever (15.5%)	
	Nausea and vomiting (23%)[31]	

CONCLUSION

This review purpose of gaining knowledge of ADRs reporting in covid -19 vaccines which decrease the mortality. This study helps for future reference for decreasing ADRs in the covid -19 vaccinated people.

AKNOWLEDGEMENT

Authors are very thankful to guide Dr. V. Asha Jyothi, St. Pauls college of pharmacy for providing necessary information, facilities and support.

REFERENCES

1. Gupta SK, Nayak RP, Shivaranjani R, Vidyarthi SK (2015) A questionnaire study on the knowledge, attitude, and the practice of pharmacovigilance among the healthcare professionals in a teaching hospital in South India. Perspect Clin Res 6: 45.

2. Sultana J, Cutroneo P, Trifirò G (2013) Clinical and economic burden of adverse drug reactions. J Pharmacol Pharmacother 4: 73.

3. Desai CK, Iyer G, Panchal J, Shah S, Dikshit RK (2011) An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. Perspect Clin Res 2: 129.

4. Khan SA, Goyal C, Chandel N, Rafi M (2013) Knowledge, attitudes, and practice of doctors to adverse drug reaction reporting in a teaching hospital in India: An observational study. J Nat Sci Biol Med 4: 191.

5. Hazell L, Shakir SA (2006) Under-reporting of adverse drug reactions. Drug safety. 29: 385-396.