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IP Indian Journal of Immunology and Respiratory Medicine

Journal homepage: https://www.ijirm.org/

Original Research Article

# Surveillance of Adverse Events Following Immunization (AEFI) - Post COVID 19 vaccination

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ARTICLE INFO

*Article history:*
Received 31-07-2021
Accepted 02-09-2021
Available online 29-09-2021

*Keywords:*
Vaccination
immunization
AEFI
COVID

ABSTRACT

Vaccination is a safe and effective way to prevent disease and save lives, but they may also produce some undesirable side effects which may affect the healthy individuals. Therefore, the monitoring of adverse events following immunization is necessary. Any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the use of the vaccine. The adverse event may be any unfavorable or unintended sign, an abnormal laboratory finding a symptom or a disease. AEFI surveillance studies helps to detect to identify a specific risk among the local population. In this study, we included 20 healthcare workers who were admitted in Gandhi medical college and hospital following immunization by Covid vaccination drive. No major AEFI was reported following vaccination. Our study concludes that proper counselling about the need for covid vaccination and the possible adverse events following vaccination would create an awareness among the public would prevent them from apprehension of second dose after developing AEFI following first dose.



## 1. Introduction

Immunization is one of the most effective public health interventions for protecting the individual and the public from vaccine-preventable diseases (VPDs).[1]

Incomplete and inadequate immunization in India against these communicable diseases results in substantial and unnecessary costs both in terms of hospitalization and treatment. The government of India as well as the World Health Organization (WHO) considers childhood vaccination as the priority, but there is not yet focus on adult immunization.[2]

Immunization has saved millions of lives. Modern vaccines are safe and effective. However, like other medicinal products, vaccines are not free from adverse reactions.[1]

### 1.1. Vaccination

Vaccine and vaccinology termed by “Edward Jenner” who also discovered smallpox vaccine .ie; variola vaccine. A vaccine is of activated and inactivated with its pathogen, pathogen when in enters host it creates defensive and precautionary effects of cells in our body [i.e.; immune system].[1]

#### 1.1.1. AEFI monitoring includes of 3 categories

1. Common minor or mild AEFI: includes local reaction such as redness, pain, itching and systemic reaction such as: fever, chill, headache.
2. Moderate AEFI: it is due to hospitalization makes significant disability.
3. Severe AEFI: this requires medical attention and may leads to disability or death.[2]

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https://doi.org/10.18231/j.ijirm.2021.039

AEFI Any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the use of the vaccine. The adverse event may be any unfavorable or unintended sign, an abnormal laboratory finding a symptom or a disease.[3]

*1.1.2. Types of AEFI:*[4]

1. Vaccine product-related reaction: an AEFI- that is caused or precipitated by a vaccine due to one or more of the inherent properties of vaccine product.
2. Immunization error-related reaction: an AEFI-that is caused by inappropriate vaccine handling, prescribing or administration and that thus by its nature, its preventable.
3. Immunization anxiety-related reaction: an AEFI-arising from anxiety about the immunization.
4. Coincidental event: an AEFI-that is caused by something other than the vaccine product, immunization error or immunization anxiety.

**Vaccine Reactions:**[5]

| **Minor reactions** | **Serious reactions** |
|---|---|
| Usually occur within a few hours of injection. | Usually do not result in long-term problems. |
| Resolve after short period of time and | Can be disabling. |
| Pose little danger. Local (or localized) | Are rarely life threatening. |
| Restricted or limited to a specific body part or region. (Includes pain, swelling or redness at the site of injection). | Include seizures, Seizure Uncontrolled electrical activity in the brain, resulting in convulsion, physical signs, thought disturbances, or a combination of symptoms and allergic reactions caused by the body's reaction to a particular component in the vaccine. |
| Systemic Relating to a system or affecting the entire body or an entire organism (e.g., fever). (Includes fever, malaise, muscle pain, headache, or loss of appetite). | |
| Severe reactions are a term including serious reactions but also including other severe reactions | |

## 2. Literature Review

Chandler RE (2020) stated that multiple vaccines to Covid 19 are currently being investigated either in traditional systems using known adjuvants or using currently unlicensed technologies, with regulatory bodies promising to fast-track approval procedures. Therefore, public confidence in vaccination programmes is at risk. Thus, monitoring AEFI plays a crucial role in immunization programmes.[6]

Kochhar S, Salmon DA (2020) stated that alongside preparations to ensure equitable access to the vaccines among people globally, preparations must be made within countries for Covid 19 vaccines safety surveillance on an urgent basis. Safety surveillance must be capable of investigating adverse events of special interest (AESI) and AEFI to determine a change in the benefit risk profile of the vaccine and to be able to anticipate coincidental events that might be attributed to the vaccine.[7]

Harris HP, et al., (2020) stated that the post licensure surveillance preparedness at both country and regional levels was urgent and that managing the info emic was critical. Therefore, AEFI surveillance will act as a roadmap to covid 19 vaccine benefit risk ratio.[8]

Joshi J et al., (2017) stated that the national immunization programme introduces newer vaccines for different age groups and coverage improves, the issues of vaccine hesitancy and confidence are likely to be raised more often and AEFI surveillance program will have to assume greater responsibility to comprehensively respond to the community concerns and sustain public confidence in vaccines.

Chakravarti SP et al., (2016) stated that vaccination of adults should become a new national health priority because of the economics involving disease treatment. Immunization minimizes morbidity and mortality. Unfortunately, the data on adult immunization is still scanty in India. Therefore, the approach to adult immunization is through raising awareness among the public and professionals.

Aim of this study was to monitor and report the adverse events occurring post immunization – COVID 19 vaccination. And the objective was to create awareness and preserve the public confidence in the immunization program.

## 3. Material and methods

A prospective observational cohort study was conducted in Gandhi Medical College, Secunderabad, Telangana, India for 3 Months that is from February – April 2021 with 20 as sample size (idea of inclusion was -all individuals taking COVID 19 vaccination of any type)

### *3.1. Study procedure*

#### *3.1.1. Review of patient*

The cases from the departments included in the study are reviewed.

#### *3.1.2. Enrollment of patient*

Based on inclusion and exclusion criteria.

#### *3.1.3. Collecting the data from patient*

A data collection form was designed which includes data such as age, gender, reason for hospitalization, past medical

history, past medication history and results of laboratory tests**.** A causality assessment scale developed by WHO is also included for the classification of AEFI.

### *3.1.4. Evaluate the safety of ongoing immunization*

### *3.2. Need of study*

1. Vaccination is a safe and effective way to prevent disease and save lives, but they may also produce some undesirable side effects which may affect the healthy individuals. Therefore, the monitoring of adverse events following immunization is necessary.
2. Adult immunization as a strategy has the broad potential to preserve and improve medical, social, and economic outcomes, including maintaining functional ability that benefits older adults, their families, communities, and countries.

### *3.3. Expected benefits of study*

1. Vaccine associated adverse events may affect the healthy individuals and should be promptly identified to allow additional research. Therefore, AEFI surveillance studies helps to detect changes in the frequency of adverse events, which may be an alert to consider the vaccine quality or to identify a specific risk among the local population.

## 4. Results

A total of 20 cases were collected which were all Adverse Event Following Immunization. All the cases were documented.

**Table 1:** Categorization of data based on gender.

| Gender | No. | Percentage (%) |
|---|---|---|
| Male | 5 | 25 |
| Female | 15 | 75 |

The above result indicates that female is majorly exposed to vaccine induced adverse events.

**Table 2:** Categorization of data based on age.

| Age Group (Years) | No. | Percentage (%) |
|---|---|---|
| 11-20 | 0 | 0 |
| 21-30 | 7 | 35 |
| 31-40 | 2 | 15 |
| 41-50 | 5 | 25 |
| 51-60 | 4 | 20 |
| 61-70 | 2 | 10 |
| 71-80 | 0 | 0 |
| >81 | 0 | 0 |

The above table shows that the age group 21-30years is the highest to get affected with this condition. the P-Value is <0.05, Hence the variables are found to be significant.

**Table 3:** Categorization of data based on cause of hospitalization.

| Cause of Hospitalization | No. | Percentage (%) |
|---|---|---|
| Respiratory system | 3 | 15 |
| Gastrointestinal system | 1 | 5 |
| Nervous system | 7 | 35 |
| Musculoskeletal system | 8 | 40 |
| Reproductive system | 0 | 0 |
| Cardiology | 0 | 0 |
| Nephrology | 0 | 0 |
| Others | 1 | 5 |

Most cases documented were associated with Musculoskeletal system (40%), followed by Nervous system (35%), followed by Respiratory system (15%). The P-Value is <0.001, Hence the variables are found to be significant.

**Table 4:** Categorization of data based on window period.

| Type of cycle | No. | Percentage (%) |
|---|---|---|
| <30 mins | 3 | 15 |
| Upto 1 hour | 0 | 0 |
| 2-3 hours | 6 | 30 |
| 4-6 hours | 6 | 30 |
| >12hours | 5 | 25 |

Based on window period highest probability was found to be 2-6 hours for any adverse event to begun. The P-Value is <0.001, Hence the variables are found to be significant.

**Table 5:** Categorization of data based on apprehension of second dose.

| Type of cycle | No. | Percentage (%) |
|---|---|---|
| Taken | 6 | 30 |
| Apprehension | 13 | 65 |
| Not taken upon medical advice | 1 | 5 |

About 65% of the patients were scared to take the second dose. The P-Value is <0.001, Hence the variables are found to be significant.

**Table 6:** Categorization of data based on Vitals after 30 minutes of vaccination.

| Vitals | No. | Percentage (%) |
|---|---|---|
| Stable | 15 | 75 |
| BP unstable | 2 | 10 |
| Temp unstable | 3 | 15 |

Most cases documented were stable (75%). The P-Value is <0.001, Hence the variables are found to be significant.

**Table 7:** Categorization of data based on AEFI (within 3 hours).

| Event | No. | Percentage (%) |
|---|---|---|
| Pain and Tenderness | 15 | 75 |
| Rashes/Pruritus/Malaise | 0 | 0 |
| Fever with Chills | 3 | 15 |
| Headache | 0 | 0 |
| Nausea /Vomiting | 3 | 15 |
| Giddiness/Fatigue | 4 | 20 |
| Seizures | 0 | 0 |
| Immunization related Anxiety | 0 | 0 |

Most cases documented were Pain and Tenderness (75%), followed by Giddiness/Fatigue (20%). The P-Value is <0.001, Hence the variables are found to be significant.

**Table 8:** Categorization of data based on AEFI (after 3 hours).

| Event | No. | Percentage (%) |
|---|---|---|
| Pain and Tenderness | 4 | 20 |
| Rashes/Pruritus/Malaise | 3 | 15 |
| Fever with Chills | 16 | 80 |
| Headache | 9 | 45 |
| Nausea /Vomiting | 0 | 0 |
| Giddiness/Fatigue | 12 | 60 |
| Seizures | 2 | 10 |
| Immunization related Anxiety | 3 | 15 |

Most cases documented were Fever with Chills (80%), followed by Giddiness/Fatigue (60%), followed by Headache (45%). The P-Value is <0.001, Hence the variables are found to be significant.

**Table 9:** Categorization of data based on length of hospital stay.

| Type of cycle | No. | Percentage (%) |
|---|---|---|
| Less than 3 days | 0 | 0 |
| 4-7 days | 14 | 70 |
| More than 7 days | 6 | 30 |

Length of hospital stay was 4-7 days (70%), followed by >7 days (30%). The P-Value is <0.001, Hence the variables are found to be significant.

**Table 10:** Categorization of data based on comorbidities:

| Comorbidities | No. | Percentage (%) |
|---|---|---|
| Yes | 6 | 30 |
| No | 14 | 70 |

Maximum no. of cases documented had no comorbidities (70%), rest Hypertension (15%), DM (8%). The P-Value is <0.001, Hence the variables are found to be significant.

**Table 11:** Categorization of data based on Covid history:

| Covid history | No. | Percentage (%) |
|---|---|---|
| Yes | 3 | 15 |
| No | 17 | 85 |

Maximum no. of cases documented had no covid history (85%), rest (15%) had Covid 19 positive. The P-Value is <0.001, Hence the variables are found to be significant.

**Table 12:** Categorization of data based on outcome

| Outcome | No. | Percentage (%) |
|---|---|---|
| Recovered | 20 | 100 |
| Recovering | 0 | 0 |
| Recovered with sequelae | 0 | 0 |

Most cases documented had fair recovery (100%). The P-Value is <0.05, Hence the variables are found to be significant.

## 5. Discussion

AEFI surveillance studies helps to detect changes in the frequency of adverse events which may act as an alert to identify various adverse events. In this study, we included 20 healthcare workers who were admitted in Gandhi medical college and hospital following immunization by Covid vaccination drive. Majority were female and were of the age group 21- 30 years (35%). Window period for occurrence of an adverse reaction was observed to be at least 2-6 hours after administration of vaccine. Their vitals were found to be stable after administration (30 minutes) of vaccine (in most of the cases). The documented cases had no known comorbid conditions. Most of them had no covid history, only 15% had reported to have a covid history.

The AEFI observed in most of the cases was within 2-6 hours of vaccination, that is fever with chills (80%), giddiness / fatigue (60%), headache (45%), rashes, seizures, and pain / tenderness in few cases. The cause of hospitalization was associated with musculoskeletal system (40%), nervous system (35%), and respiratory system (15%). All the patients admitted in the hospital due to AEFI recovered. The length of hospital stay on an average was 4-7 days. Nearly 65% of the patients failed to take the second dose of vaccine. Therefore, major apprehension for $2^{nd}$ dose was observed.

It was noted that major apprehension among subjects was due to lack of proper counselling after the occurrence of AEFI after first dose which led to slow vaccination drive and must have contributed to second wave of pandemic.

## 6. Conclusions

No major AEFI was reported following vaccination. It is observed that lack of proper counselling among patients led to apprehension of $2^{nd}$ dose. Our findings suggest that providing more information on the safety and efficacy of the new vaccines and counselling about the occurrence and management of AEFI can lead to better vaccination. Proper counselling of all the health care workers in the first place would help us to achieve good drive for successful vaccination.

## 7. Acknowledgment

None

## 8. Conflict of Interest

The authors declare that there are no conflicts of interest in this paper

## 9. Source of Funding

None

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**Cite this article:** Suhagiya P, Hakim J, Athmakuri D, Kuracha M, Chander T. Surveillance of Adverse Events Following Immunization (AEFI) - Post COVID 19 vaccination. *IP Indian J Immunol Respir Med* 2021;6(3):178-182.