

Does This COVID-19 Pandemic Demand a Scale Up in AEFI Reporting in India?Sadhvika Kanagat¹, Abhijit Vinodrao Boratne², A. Suguna³, Sinthu Sarathamani⁴¹Postgraduate student, ²Professor and Head, ⁴Assistant Professor, Department of Community, Medicine, Mahatma Gandhi Medical College and Research Institute, Puducherry, Tamilnadu³Associate Professor, Department of Community Medicine, SRM Medical college Hospital & Research Institute, Trichy, Tamilnadu**Correspondence** : Dr. Sadhivika Kanagat, Email: sadhvikadoc@gmail.com**Abstract:**

The COVID-19 Pandemic has changed the global picture in the field of public health in the past few years. This critical time has made life very uncertain for everyone. Man has been constantly striving to discover measures to stop the spread of this deadly virus; the COVID-19 vaccine is one such endeavour. The fear and anxiety towards a new vaccine is high among the general public. With every new vaccination, constant monitoring and documentation of the vital happenings is very important. Thus, the reporting of Adverse events following immunization (AEFI) needs to be strengthened and implemented more efficiently to analyse the efficacy of this vaccination drive with respect to protection from the disease without causing any harmful adverse effects.

Key Words: Adverse Events following Immunization (AEFI), COVID-19 pandemic, Surveillance, Underreporting, Vaccines

Introduction:

The goal of immunization is to protect the individual and public from vaccine preventable diseases. However as with any biological product there are adverse events which follow immunization. WHO defines Adverse Events following Immunization (AEFI) as "Any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine". The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease." One of the most important needs for AEFI monitoring is to find rare, late effects of the vaccine which cannot be identified in the Pre- licensure trials of the vaccines. The data should be reported and maintained specific for each country; this will improve the local trust for global immunization programmes^[1]. India's Universal Immunization Programme (UIP), targets around 27 million new-borns and about 30

million pregnant women each year. India is the largest vaccine manufacturer and consumer among the developing countries, being a large consumer as well as manufacturer, India is expected to have a well-developed AEFI surveillance system.^[2]

The AEFI reporting in India takes place through a hierarchical process, starting from the subcentre to the PHC's and then to district and state headquarters followed by the national level finally.

Global Picture for AEFI Reporting

The AEFI reporting ratio trends were documented Globally around the six world health organisation regions and it was found that by 2015 60% of countries in the WHO Region of the Americas reported at least 10 AEFI per 100,000 surviving infants, followed by 55% in European Region, 43% in Eastern Mediterranean Region, 33% in Western Pacific Region, 27% in South-East Asia Region and 21% in African Region.^[3] Hence


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Table 1 : Modes of Reporting Adverse events following Immunization^[6]

Sr. No.	Country	AEFI Reporting Agency	AEFI Reporting mode (Offline: AEFI reporting form, Online or both)
1	United Kingdom	Medicines and Healthcare products Regulatory Agency & Commission on Human Medicines-yellow card	Both
2	United States of America (U.S.A)	Central Drugs Standard Control Organisation-IPC	Both
3	Australia	Therapeutic Goods Administration-Australian govt	Both
4	Singapore	HSA	Both
5	India	Central Drugs Standard Control Organisation - Indian Pharmacopeial Commission (IPC)	Both
6	Saudi Arabia	Saudi Food & Drug Authority (SFDA)	Both
7	New Zealand	Central Drugs Standard Control Organisation-IPC	Both
8	Sri Lanka	Cosmetics, Devices & Drug Regulatory Authority. (CDDA)	Offline
9	Canada	Canadian Adverse Events Following Immunization Surveillance System (CAEFISS)	Offline

worldwide the reporting of AEFIs increased but more work had to be done by the middle- and low-income countries. (Table 1)

AEFI Surveillance System in India

The AEFI surveillance system in India started along with the Universal Immunization Program (UIP) in 1985. The reporting has been satisfactory for quite a long time. In 2005-06 with the guidance of the world health organisation, the AEFI Surveillance and Response Operational Guidelines were formulated. These were circulated throughout the country among various medical officers and health workers. These guidelines have led to strengthening of our surveillance systems to a great level when compared to before. The AEFI surveillance program represents the country's initiative to deliver quality immunization programs with safe vaccines. The national AEFI guidelines were then revised in 2010, 2015 and presently under revision as in September 2020.^[4]

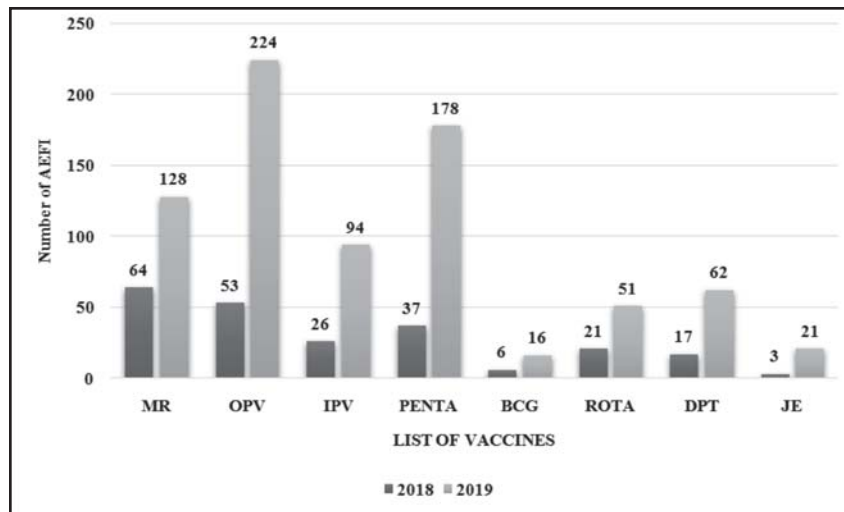
In India, there has been a five-fold increase in reporting of severe/serious AEFIs between

2012-2019 (ranging from 398 to 2662 cases). The average number of AEFIs per district has increased from 1.3 cases in 2015 to about 3.7 cases in 2019.^[6] The national quality assurance standards for AEFI Surveillance which was developed in 2016 led to various positive changes, however the gaps have not been completely filled and India is still one step backward in reporting when compared to the other countries.

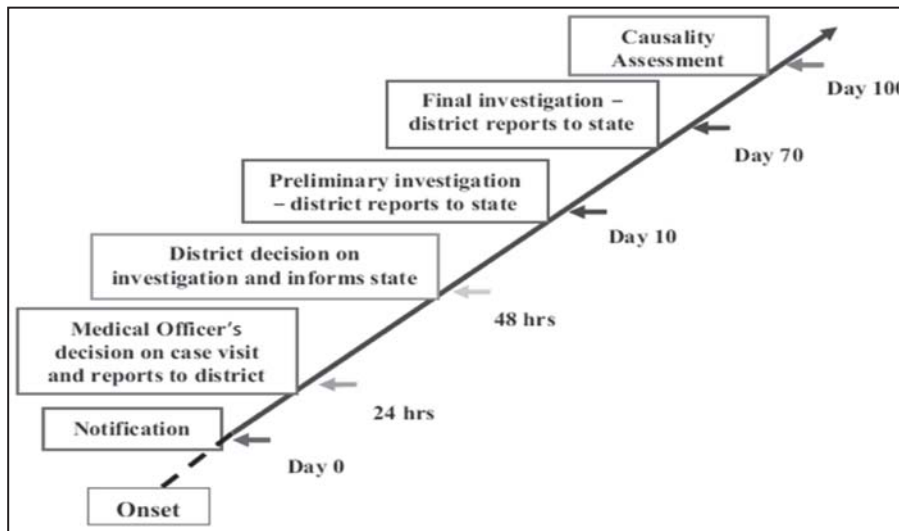
Reporting of AEFI:

The reporting of AEFIs happen by various modes in different countries. In India it happens in both offline and online mode. The immunization division of the ministry of health and family welfare is responsible for this. The National Health system resource Centre in the capital is functioning as the resource centre for AEFI.^[5] The offline mode of reporting is done by various forms such as the preliminary and final case investigation forms. These forms have to be filled out by the respective people and sent as per the timeline. Immediate medical management and investigations play a very crucial role in AEFI surveillance. Accurate causality

Figure 1 : Bar chart depicting the AEFIs with respect to Vaccines 2018 -19



Timeline of AEFI Reporting^[1]



assessment can be done only when proper investigations and history is collected. The online portal for AEFI reporting in India is the SAFE-VAC (Surveillance and Action for Events following Vaccination). This is a web-based application software which will help people at all levels to monitor the progress of reporting. The Co-Win portal which has been used for the covid vaccination drive has been integrated with the SAFE-VAC reporting for real time AEFI monitoring.^[7] There will be no loss of information in the process of transfer from district to state to national level. The reports of the causality assessment done by the state can be accessed by the programme managers and vaccinators, thus timely action can be taken.^[8]

Figure 1 has been interpreted by consolidating the AEFI data of the years 2018 and 2019 from the Ministry of health and family welfare website. There was no data for the year 2020 and data in the year 2021 was related to the covid vaccines and were very few to bring conclusions. It has been observed that the number of cases reported were higher in 2019 when compared to that of 2018. However, the data was not completely given for all the states in the website; hence it can either be understood as nil cases or underreporting. Thus, it would be easier to get a clear picture if the nil cases are also mentioned in the reports. More consolidated methods of report making would make comparisons easier and help in more efficient policy making.

Figure 2 : Bar chart depicting the AEFI'S with respect to states-2018

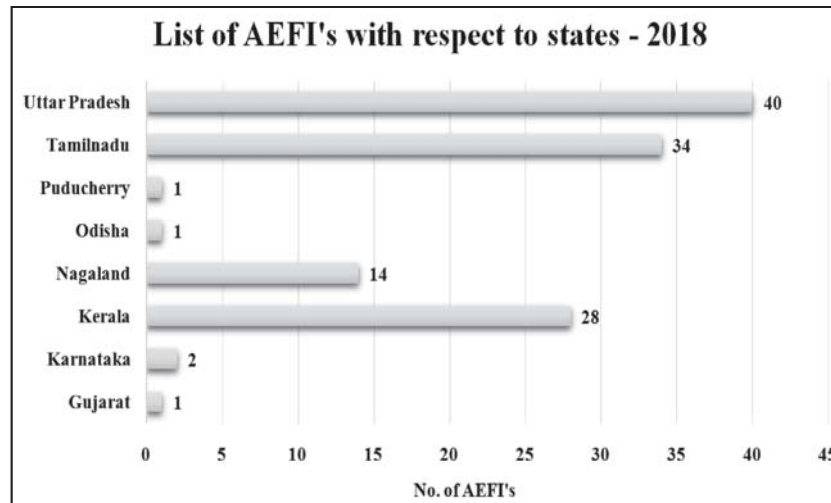
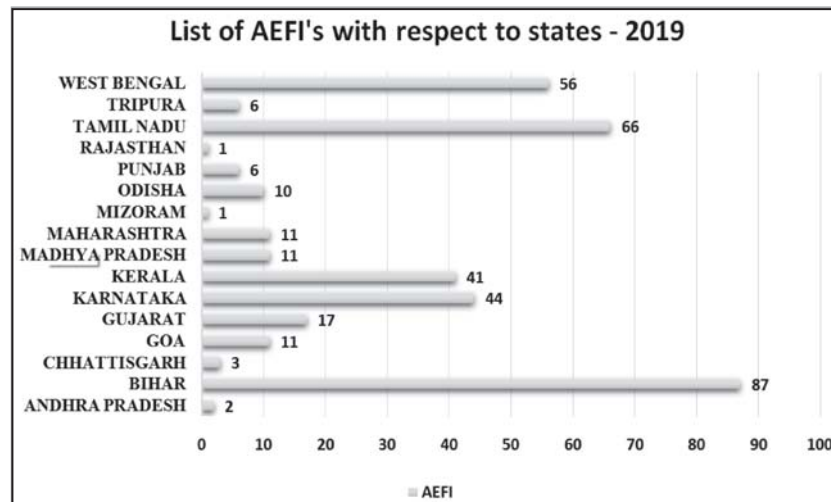


Figure 3 : Bar Chart depicting AEFI'S with respect to states -2019



Issues to be addressed:

About two third of the Indian districts do not report even a single case of AEFI. Some districts only report deaths. Under-reporting is one of the few major issues to be addressed. Reporting of AEFI following COVID vaccines have suddenly declined hindering us from gaining information regarding the efficiency of the vaccine.^[9] There is a lack of awareness about AEFI reporting among clinicians, health workers and paediatricians especially in the private sector. The PHC's lack AEFI registers and minor AEFIs are brushed aside and are not documented. Even if the cases are documented the investigations necessary for the reported cases are not done on time. The district AEFI committees have to conduct meetings more often and regulate the

reporting system with changing times. In spite of emergence of various reporting methods with technological advancement, these resources have not been utilized to the fullest potential.

Recommendations:

In the era of newly arising collaborative studies and scientific advancements, the investment in strategic reporting of AEFI is the need of the hour. Proactive communication methods and campaigns should be employed to convey knowledge about AEFIs to the stake holders and the general public. Reporting and documentation of AEFIs need to be looked at more closely. The Covid19 pandemic is making the routine things more demanding. As we are expecting India to be vaccinated against Coronavirus this year, it makes it doubly important

for India to strengthen the AEFI Surveillance system. With India being one of the largest vaccine manufacturers, achieving a system to cater the growing needs of the country is a major public health Challenge, but this is not unknown to India. With the help of innovative concepts, clear vision and stable communications at all levels starting from the primary health centre to the national AEFI committee we can bring a concrete AEFI reporting system. Using this COVID situation to our advantage, we can change AEFI reporting in India for the better.

Declaration:

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