

Adverse Event Following Immunization (AEFI) Surveillance in India: Position Paper of Indian Academy of Pediatrics, 2013

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Adverse event following immunization (AEFI) is a critical component of immunization program. The risk of AEFI with vaccination is always weighed against the risk of not immunizing a child. There is an evolving AEFI surveillance system in India for the vaccines delivered through 'universal immunization program' (UIP) of government sector, but the reporting remained suboptimal for long in the country, and there is almost no participation from private sector. The AEFI reporting from private sector will provide vital information on the safety of new and underutilized vaccines, not part of the UIP in India. The national guidelines are recently revised and updated. The Indian Academy of Pediatrics believes that pediatricians, especially in private sector have a crucial role to play with reporting of AEFI with newer/underutilized vaccines. Programmatic error, vaccine reaction, injection reactions, coincidental and unknown are the

five broad categories of AEFI for programmatic purposes. The serious AEFIs (death, disability, cluster and hospitalization) need to be reported immediately and investigated in detail as per the laid down procedures. Once a serious AEFI happens, primary or urban health centre should be immediately informed by the pediatricians practicing in rural or urban areas, respectively. This advocacy paper from the academy provides guidelines to practitioners on how to report cases, and suggests ways for IAP members to help in ongoing efforts of the government in improving AEFI surveillance in the country. The details about the diagnosis and management of known/expected AEFI with UIP and newer vaccines shall be published later.

Key words: *Adverse Event Following Immunization, Surveillance, Universal Immunization Program.*

Immunization against vaccine preventable diseases is one of the safest and the most cost effective interventions to improve child survival [1]. The advent and growing availability of new vaccines which target major childhood diseases such as pneumonia, meningitis and rotavirus have the potential to save an additional 1.7 million child lives. In India, with approximately 26 million infants born each year, hundreds of millions doses of vaccines are administered annually [2]. Although vaccines are proven to be extremely safe, there is a potential risk of a adverse reaction, as with any other drug or medication. Adverse Event Following Immunization (AEFI) is defined as 'a medical incident that takes place after immunization, causes concern and is believed to be caused by the immunization' [4-5]. This risk of AEFI with vaccination is always weighed against the risk of not immunizing a child. It is only when the benefit outweigh the risk, a vaccine is considered safe. However, even at a relatively low rate, because of the high absolute number of beneficiaries, there is risk of a few serious adverse events in the vaccinated children. This paper provides guidelines to practitioners both in private and government sector (including pediatricians) on how to report cases, and outline the steps needed to improve AEFI surveillance

and reporting by strengthening public private partnership in India.

IMPORTANCE OF AEFI

The vaccines are foreign for human bodies, given to healthy infants and children. In the natural process of developing immunity, a vaccine may cause fever, erythema, local pain etc. Besides, there is a slight risk of foreign body reaction to the components in the vaccines. These factors are likely to cause some concerns in the caregivers/parents. Whatever the cause, an AEFI may upset people to the extent that they may refuse further vaccination for their children. This may lead to the children much more likely to get a vaccine preventable disease, become seriously ill, disabled, and risk death. AEFI surveillance, therefore, helps to preserve public confidence in the immunization program [4]. Though, the majorities of AEFIs are mild, settle without treatment, and have no long term consequences; very rarely, serious adverse reaction can occur. The vaccination programs work in a 'paradox' meaning thereby that the focus of attention changes with the implementation of immunization program—when the vaccination coverage increases and disease burden reduces drastically, more cases of AEFI attract the attention of the people than the disease in the community [6].

AEFI SURVEILLANCE STRENGTHENING IN INDIA

AEFI surveillance in India started with the launch of Universal Immunization Program (UIP) in 1985. However, the AEFI reporting remained suboptimal for long in the country. In 2005/2006, the Government of India, with technical assistance from the World Health Organization/National Polio Surveillance Project India and other development partners, prepared the National AEFI Surveillance and Response Operational Guidelines [7]. These guidelines were widely disseminated across the country among medical officers in Government sector. Since then many national, state and district level AEFI surveillance workshops for immunization program managers have been conducted. The national guidelines were further revised and updated in 2010. These efforts have contributed in improving AEFI surveillance in India and the country reported the highest ever number of serious AEFI in 2010 (395 vs. 55 in 2006).

NATIONAL AEFI GUIDELINES IN INDIA

There are two sets of national guidelines available in India. The detailed version is called 'Operational Guidelines', and a shorter version is for 'Standard Operating Procedures' [8,9]. These guidelines, based upon World Health Organization suggested framework [4], were developed through a consultative process with various stakeholders, including various Government departments involved in immunization program, state government program managers, academic institutions, independent subject experts, Drug Controller General of India (DCGI) officials, development partners etc.

The AEFI reactions can broadly be classified as 'serious AEFIs' (death, disability, cluster and hospitalization) which need to be reported immediately and investigated as per the laid down procedures. The other, i.e. 'minor AEFIs' are reported through monthly reporting systems in UIP in Government of India. For the programmatic purpose, the AEFIs are classified in five broad categories of programmatic error, vaccine reaction, injection reactions, coincidental, and unknown [8,9].

HOW TO REPORT AEFI FROM PRIVATE SECTOR?

The majority of children in India receive immunization through public health facilities. However, it is estimated that approximately 10-20% of total immunization is provided through private sector and by pediatricians [10]. Moreover, the vaccines not part of the UIP in India are provided by the private sector only. There is an evolving AEFI surveillance system in India for UIP vaccines from government sector; however, the reporting from private sector is limited so far. It is important that AEFI from this sector are also reported and investigated, as per the laid

down national guidelines, which are applicable to private sector also. Additionally, the AEFI reporting from private sector will provide vital information on the safety of new and underutilized vaccines in India. Once a serious AEFI happens in the private sector at a clinic of pediatricians, in the rural area, she/he should immediately inform medical officer incharge of nearest primary health centre or other health facility. In the urban area, either she/he can inform medical officer In charge of nearest urban health centre or to the 'District Immunization Officer' (DIO). By all channel, the information should reach DIO as soon as possible.

The private practitioners (including pediatricians) should use the 'First Information Report' (FIR) form for reporting serious AEFI cases to the district officials. Once an AEFI is reported from private sector, the DIO and district AEFI committee members would then investigate the reported AEFI case. The pediatricians should help the investigation team in collection of all the related information.

It has come out from various interactions at different forums that the pediatricians, in general, are not aware and apprehensive about the existing AEFI reporting system and national guidelines on AEFI surveillance and response in India.

THE WAY FORWARD

Based upon the understanding of the AEFI surveillance and case investigation in India and a series of interactions with members of professional bodies, there are a few possible ways to strengthen AEFI reporting from private sector in India:

- *Stronger collaboration:* Considering a large number of pediatricians provide immunization service, their involvement in AEFI surveillance is crucial. A stronger collaboration between Government of India and Indian Academy of Pediatrics (IAP) will be a right platform to strengthen AEFI surveillance in India. The possible role of IAP can be as follows:
- Sensitizing members about AEFI surveillance in monthly IAP meetings and through their state and national level conferences
- Disseminating information through IAP publications
- Reporting AEFIs and supporting case investigation
- IAP members actively participating in district and state AEFI committee activities
- Supporting causality assessment at the state level.
- Conduct short sensitization meetings specifically

targeted at new /underutilized vaccines at district level through IAP/IMA network.

Online AEFI Reporting Platform for Private Practitioners

A possible solution for AEFI reporting from private sector is providing online platform through which practitioners can report from the comfort of their clinic. This platform may ask for First investigation report to be provided by private practitioner and then government counterpart can take lead and collaborate for further investigating and taking up the AEFI case investigation and reporting.

- IAP through its IAP Advisory Committee on Vaccines and Immunization Practices (ACVIP) has resolved to collaborate with the National AEFI program by suggesting the following measures:
 - Integrate IAP disease surveillance project (IDSURV) with AEFI reporting for a web based and integrated voice recording (IVR) reporting (already incorporated: www.idsurv.org).
 - The IDSURV program is fine-tuned to automatically send information to the concerned DIO/state immunization officer for prompt action.
 - In due course, SMS reporting shall also be integrated within the program for preliminary reporting but shall have to be followed up by proper FIR.
- The proposed 'public-private partnership' has been enthusiastically received by Ministry of Health, Government of India for prompt implementation.
- The public-private partnership envisages continuous monitoring by all the stake holders for a meaningful outcome.
- *Bringing the confidence amongst private practitioners:* Once the practitioners are sensitized about the AEFI surveillance, they might have higher confidence to report the cases. Inculcating confidence in the private practitioners will contribute to strengthen AEFI surveillance in India.

CONCLUSIONS

The immunization coverage in India is slowly increasing and additional new and underutilized vaccines are being

administered to the children by private practitioners. While there is a system for AEFI reporting from government sector in India based on the operational guidelines, there is limited awareness about the reporting system in the private sector resulting in inadequate reporting. There is, thus, a perceived need for improving AEFI surveillance in the private sector. This is possible through information dissemination and better collaboration with professional bodies and Government of India. The improved AEFI surveillance and reporting system in India will go in a long way to increase and retain the faith of the community in the existing and new vaccines and increasing the immunization coverage in India.

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