Adverse Events Following Immunization

The goal of immunization is to protect the individual and the public from vaccine-preventable diseases. Although modern vaccines are safe, no vaccine is entirely safe without risk. Some people experience adverse events following immunization (AEFI) ranging from mild side effects to life-threatening but rare, illnesses. In the majority of cases, these events are merely coincidences; in others, they are caused by the vaccine or by an error in the administration of the vaccine, or anxiety-related reactions.

AEFI is any untoward medical occurrence that 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. i.e., a result of the vaccine or immunization process, or coincidental events that are not due to the vaccine or immunization process but are temporally associated with immunization.

There are five types of adverse events according to the Council for International Organizations of Medical Sciences/WHO cause-specific definition.

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 the vaccine product

2. Vaccine quality defect-related reaction - An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product including its administration device as provided by the manufacturer

3.Immunization error-related reaction - An AEFI that is caused by inappropriate vaccine handling, prescribing, or administration.

4. Immunization anxiety–related reaction - An AEFI arising from anxiety about the immunization

5. Coincidental event - An AEFI that is caused by something other than the vaccine product, immunization error, or immunization anxiety

Adverse Events Following Immunization Surveillance System in the National Immunization Program of Sri Lanka

The AEFI surveillance is an in-build monitoring mechanism consisting of experts from the central level to grass root level to evaluate and take necessary actions as early as possible for adverse events following immunizations.

Sri Lanka is the first country to establish an AEFI surveillance system in the region in 1996. A well-established network is available on the whole island covering all the immunization centers. The vaccines used in national immunization programs are extremely safe and effective. But no vaccine is perfectly safe and adverse events can occur following immunization. In addition to the vaccines themselves, the process of immunization is a potential source of adverse events.

The technology continues to improve with time, as do the quality, efficacy (level of protection), and effectiveness (disease reduction) of the vaccines utilized. With emerging diseases, the demand for new vaccines has increased. An increase in vaccine use (e.g., mass immunization campaigns) will lead to

more AEFIs. Surveillance of AEFIs is an effective means of monitoring immunization safety and contributes to the credibility of the immunization program. It allows for proper management of AEFIs and avoids inappropriate responses to reports of AEFIs that can create a sense of crisis in the absence of immunization safety surveillance. Presently, the program has been expanded by developing a more detailed reporting system and responding accordingly.

AEFI cases can be captured in different settings; In the field (Community), Immunization clinic or by a treating physician. All AEFI should be reported as soon as possible. All adverse medical events following immunization (irrespective of the cause) are needed to be reported to the Public Health staff (Midwife/ Public Health Inspector/ Public Health Nursing Sister/ MOH) or a Doctor. The necessary guidance and treatments are given if needed.

All the reported AEFI are compiled at the MOH level and sent to the Epidemiology Unit with a copy to Regional Epidemiologists monthly. In the event of the absence of any notified AEFI a “nil-report” is sent. A national database is maintained at the Epidemiology Unit. All deaths, serious and unusual (signal) events are investigated by MOH and informed to Epidemiology Unit directly. All deaths, selected serious events, and signals are evaluated and causality is assessed by the National AEFI Committee.


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