Vaccine related adverse event & strategy to handle it

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In news

Recently, Finland confirmed 1st adverse reaction to Pfizer/BioNTech Covid-19 vaccine

What is a vaccine-related adverse event?

- Any untoward medical event that follows immunization and that does not necessarily have a causal relationship with the usage of the vaccine.
- The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease
- Adverse events can range from minor side-effects to more severe reactions. They can be a cause of public concerns about vaccine safety.

Categories of adverse events

As per WHO, An adverse event following immunization (AEFI) are divided in 5 categories. They are:

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 defeat-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 and thus by its nature is preventable
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.

What is the strategy to handle adverse events of the COVID-19 vaccine?

The World Health Organization(WHO) gives the following guidelines to handle an adverse event of COVID-19 vaccine

- At the time of vaccine introduction, all countries should at a minimum have an AEFI surveillance system in place as described in the Global Manual on Surveillance of AEFI 3
- The AEFI surveillance cycle (Fig 1) outlines the different steps in identification, notification, reporting, investigation, data analyisis, causality assessment and feedback following all AEFI, including AEFI following Covid 19 vaccine.

Fig 1 AEFI surveillance cycle