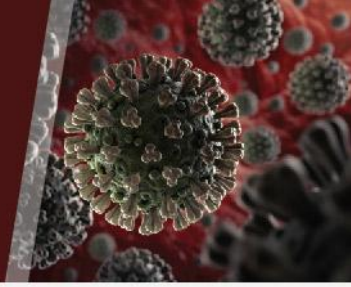
Ministry of Health
Vanuatu Government

Coronavirus (COVID-19)

Information Note:
AEFI surveillance protocol



LAST UPDATED: 20 October 2021

PROTOCOL FOR SURVEILLANCE OF ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI) FOR COVID-19 VACCINE

The Vanuatu Ministry of Health have proper protocols in place to investigate and report all non-serious and serious adverse events following immunisation (AEFI). Further information is provided below.

What are AEFI?

An AEFI is any medical incident that takes place after immunization and does not necessarily have a causal relationship with the use of vaccine.

Serious AEFI can be categorized into different groups as follows:

1. *Vaccine product-related reaction*: Caused by certain basic ingredients of the vaccine.
2. *Vaccine quality defect-elated reaction*: Caused by a flaw in the quality of the vaccine or in the administration device provide by the manufacturer.
3. *Immunization error-related reaction*: Occurs if the vaccine is not handled, prescribed, or administered in the correct way.
4. *Immunization anxiety-related reaction*: Happens if the client is worried about or scared of the vaccine or immunization process.
5. *Coincidental event*: Happens after immunization but is not caused by or related to the vaccine or immunization process.

How is an AEFI reported and investigated?

Stage 1: AEFI Notification

- The National Surveillance Unit has developed a notification form that clinicians (doctors and nurses) can use when either a serious or a non-serious AEFI is detected at community level and presents to a health clinic or hospital.
- Once the patient is received at the health clinic the priority of the nurse is to treat the patient and the nurse will have to fill in the notification form and refer the case to the provincial medical officer.
- The notification form is then reviewed by a medical officer (provincial or hospital) to determine if the investigation is required.

Stage 2: AEFI Investigation

The investigation of an AEFI case is usually conducted by a medical officer either at provincial level or at a hospital. The purpose of investigating an AEFI case is:

- To confirm the case diagnosis is correct.
- To collect details of the vaccine administered, such as name and batch number.
- To assess the immunization program and locate any errors.
- To find out if cases indicate a cluster and if so, what is the linking factor.

Stage 3: AEFI Investigation Review

Each province has its AEFI Review Committee comprised of a surveillance officer, hospital medical officer, risk communication officer and the treating medical officer for the serious AEFI case. The Committee will compile and review information prior to a causality assessment. The provincial surveillance officer should prepare a summary report of the serious AEFI which requires investigation and present it to the Committee for review.

Stage 4: Causality Assessment

Causality assessment is done at national level by the National Vaccine Safety Expert Advisory Group (NVSEAG), which is made up of experts in medicine, epidemiology, pharmacy and other relevant fields. The group systematically reviews all the data that has been collected and in the AEFI investigation form, and decides if there is a causal relationship between the adverse event and the vaccine/s received. All the recommendations and conclusion of the assessment will then be submitted to the National Drug and Therapeutics Committee (NDTC) and National Immunization Coordination Committee (NICC), and they will instruct the Demand Generation Working Group if required.

All these stages are carefully followed by the health officers to ensure that every serious AEFI is thoroughly investigated, and that the results of the investigation are discussed with the patient.