# COVID-19 VACCINE SAFETY SURVEILLANCE IN VANUATU IN THE FIRST THREE MONTHS OF IMPLEMENTATION, 2021.

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Holiday Inn, Port Vila
23 – 24 September 2021

# INTRODUCTION

- Prior to the 2021 COVID-19 Vaccinations starting, there were no Immunisation safety surveillance systems in place in Vanuatu.
- The number and type of adverse events following Immunisation was unknown in Vanuatu
- Maintaining public trust in vaccine safety is crucial, all healthcare providers should be aware of all aspects of AEFIs and remain prepared to respond to public concerns (WHO,2015).



https://iris.wpro.who.int/bitstream/handle/10665.1/12620/9789290617457_eng.pdf

# Adverse Events Following Immunisation (AEFI)

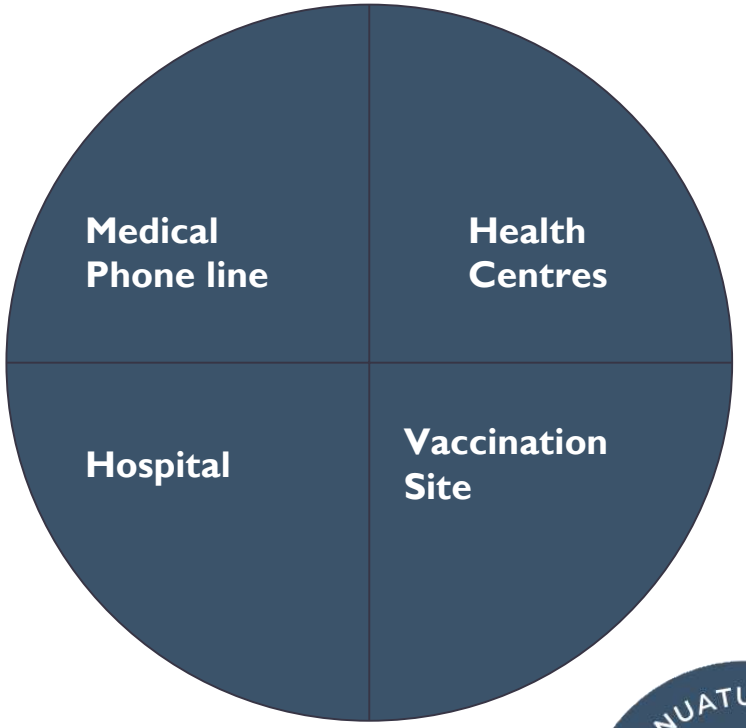
(AEFI) is any unforeseen medical occurrence which follows immunization. It may not necessarily have a causal relationship with vaccine usage

An AEFI Notification can be serious or non-serious

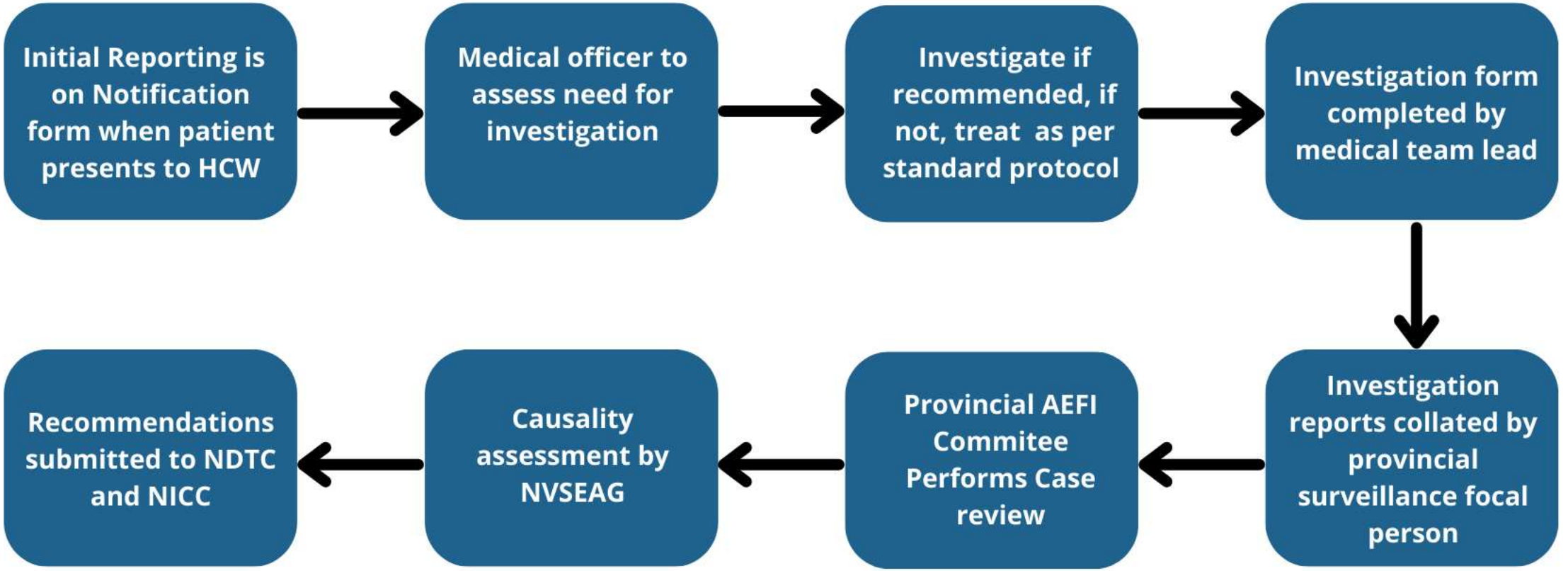
https://iris.wpro.who.int/bitstream/handle/10665.1/12620/9789290617457_eng.pdf

# METHODS

- Establishment of passive surveillance system guidelines
- Creation of AEFI forms, reporting channels and database
- Training of healthcare workers
- Collation of data to find reporting rate by Vaccine and Epidemiological Week



# AEFI Reporting Process



# AEFI Notification report

## AEFI Notification Report

**Surveillance, Research and Emergency Response Unit, Ministry of Health Vanuatu**

COVAX ID: _____
(data entry officer to enter)

**SECTION 4: DESCRIPTION OF ADVERSE EVENT/S**

| TIME: Number of Hours/Days after Vaccination | | | |
|---|---|---|---|
| | ☐ Anxiety | | *These are common non-serious AEFIs* |
| | ☐ Red, Itchy Rash<br>☐ Swollen eyes & face<br>☐ Noisy Breathing or Stridor<br>☐ Fast pulse<br>☐ Hypotension<br>☐ Abdominal cramps or nausea<br>☐ Vomiting or nausea<br>☐ Loss of Consciousness<br>☐ Numbness<br>☐ Hyperventilation | ☐ Other immediate adverse event (describe): | *These may be serious AEFIs* |
| | ☐ Injection site tenderness or pain<br>☐ Headache<br>☐ Dizziness<br>☐ Muscle pain<br>☐ Nausea<br>☐ Chills<br>☐ Fever *Recorded temperature:*<br>☐ Joint pain<br>☐ Generally feeling unwell | | *These are common non-serious AEFIs* |
| | ☐ Shortness of breath<br>☐ Chest pain<br>☐ Swelling in the leg<br>☐ Persistent abdominal pain<br>☐ Severe and persistent headaches<br>☐ Rash (tiny blood spots or bruising) | | *These may be serious AEFIs* |

**SECTION 7: MEDICAL OFFICER REVIEW**

***Give form to medical officer for review.***

- ***If vaccinated person is at vaccination centre or mobile clinic, review is required by the team lead of the medical team.***
- ***If vaccinated person is hospitalised, review is required by a senior medical officer.***
- ***If vaccinated person is at a health service (not hospital), review is required by a provincial medical officer***

| | |
|---|---|
| **Final Recommended action** | ☐ No further investigation required.<br>☐ AEFI Investigation required. If in hospital inform clinical surveillance officer if in rural health centre inform provincial surveillance focal point immediately.<br>***(AEFI Investigation is required if the AEFI is serious meaning; results in death, is life-threatening, requires hospitalization, results in persistent or significant disability, requires intervention to prevent permanent damage, is part of a cluster or is causing concern)*** |

➔ ***Return form to provincial surveillance unit.***

**SECTION 8: PROVINCIAL LEVEL TO COMPLETE**

| | | |
|---|---|---|
| **AEFI Investigation required?** | ☐ No | ☐ Yes |
| **AEFI Investigation initiated by provincial team?** | ☐ No | ☐ Yes |
| **Date investigation was initiated?** | | |
| **Has the national surveillance unit been informed?** | ☐ No | ☐ Yes |

➔ ***Please scan and send to MOH surveillance unit.***

# AEFI Investigation Report

## AEFI Case Investigation Report

Surveillance, Research and Emergency Response Unit, Ministry of Health Vanuatu

COVAX ID: _____

| *Relevant medical details* | | |
|---|---|---|
| Currently pregnant? | ☐ Yes ☐ No ☐ Unknown | Weeks: |
| Currently breastfeeding? | ☐ Yes ☐ No ☐ Unknown | |
| Past history of similar event? | ☐ Yes ☐ No ☐ Unknown | |
| History of allergy to vaccine, drug or food? | ☐ Yes ☐ No ☐ Unknown | |
| Adverse event after previous vaccination (s? | ☐ Yes ☐ No ☐ Unknown | |
| Pre-existing illness (30 days) / congenital disorder? | ☐ Yes ☐ No ☐ Unknown | |
| History of hospitalization in the last 30 days, with cause? | ☐ Yes ☐ No ☐ Unknown | |
| Patient currently on concomitant medication? (If yes, name drug, indication, doses & treatment dates) | ☐ Yes ☐ No ☐ Unknown | |
| Family history of any disease (relevant to AEFI) or allergy | ☐ Yes ☐ No ☐ Unknown | |
| **For infants** | | |
| The birth was: | ☐ Full term ☐ Pre-term ☐ Post-term | Weeks: |
| Birth weight: | | |
| Delivery procedure: | ☐ Normal ☐ Assisted (forceps, vacuum, etc) | ☐ Caesarean ☐ With complications Description: |

| SECTION 3. VACCINATOR DETAILS | |
|---|---|
| Type of site | ☐ Fixed ☐ Mobile vaccination clinic ☐ Other: |
| If fixed, name of site: | Name:<br>Address:<br>Telephone: |
| If fixed, type of site: | ☐ Hospital ☐ Clinic ☐ Dispensary ☐ Aid post |
| If mobile, where was vaccine administered? | |
| Name of vaccinator | |
| Profession of vaccinator: | ☐ Doctor ☐ Nurse ☐ Other: |

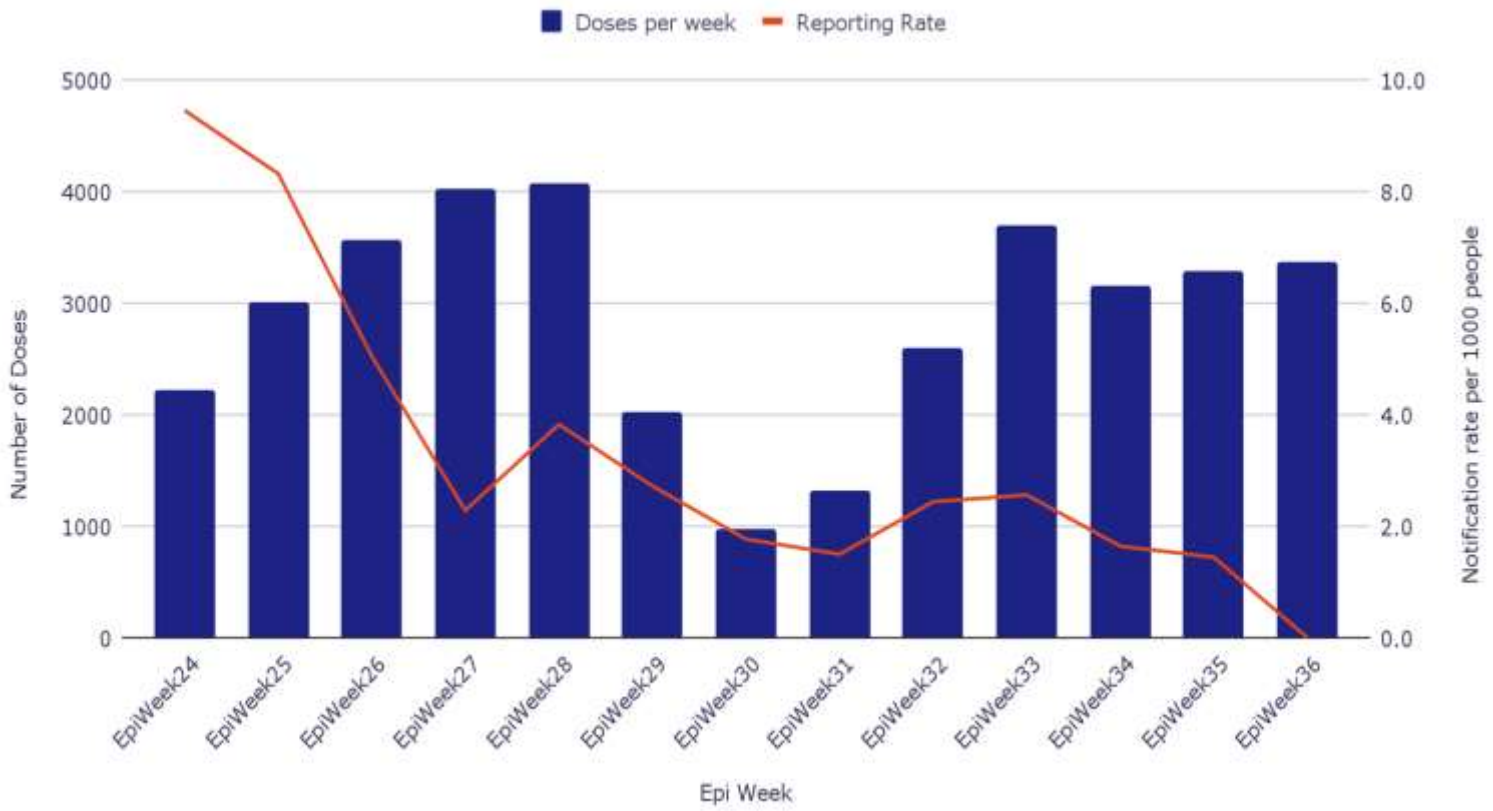
| SECTION 8. IMMUNISATION PRACTICES AT THE PLACE (S) WHERE CONCERNED VACCINE WAS USED | | |
|---|---|---|
| Complete this section by asking and/or observing practice. | | |
| Specify key findings/additional observations and comments: | | |
| Are AD syringes used for immunisation? | ☐ Yes ☐ No ☐ Unknown | |
| If no, specify the type of syringes used: | ☐ Glass ☐ Recycled disposable | ☐ Disposable ☐ Other: |
| Reconstitution procedure (complete only if applicable): | | |
| Same reconstitution syringe used for multiple vials of same vaccine | | ☐ Yes ☐ No ☐ n/A |
| Same reconstitution syringe used for reconstituting different vaccines | | ☐ Yes ☐ No ☐ n/A |
| Separate reconstitution syringe for each vaccine vial | | ☐ Yes ☐ No ☐ n/A |
| Separate reconstitution syringe for each vaccination | | ☐ Yes ☐ No ☐ n/A |
| Are the vaccines and diluents used the same as those recommended by the manufacturer? | | ☐ Yes ☐ No ☐ n/A |
| *Specify key findings/additional observations and comments:* | | |

| SECTION 9. COLD CHAIN AND TRANSPORT | |
|---|---|
| At the last vaccine storage point: | |
| Is the temperature of the vaccine storage refrigerator monitored | |
| If Yes, was there any deviation outside of 2 – 8°C after the vaccine was placed inside | ☐ Yes ☐ No ☐ Unknown |
| If yes, provide details of monitoring separately | ☐ Yes ☐ No ☐ Unknown |
| Was the correct procedure for storing vaccines, diluents and syringes followed | ☐ Yes ☐ No ☐ Unknown |
| Was any other item (other than EPI vaccines and diluents) in the refrigerator or freezer | ☐ Yes ☐ No ☐ Unknown |
| Were any partially used reconstituted vaccines in the refrigerator | ☐ Yes ☐ No ☐ Unknown |
| Were any unusable vaccine (expired, no label, VVM at stages 3 or 4, frozen) in the refrigerator | ☐ Yes ☐ No ☐ Unknown |
| Were any unusable diluents (expired, manufacturer not matched, cracked, dirty ampoule) in store | ☐ Yes ☐ No ☐ Unknown |

# Results 1; Table showing Reporting rate (per 1000 doses) of each vaccine as vaccination progresses

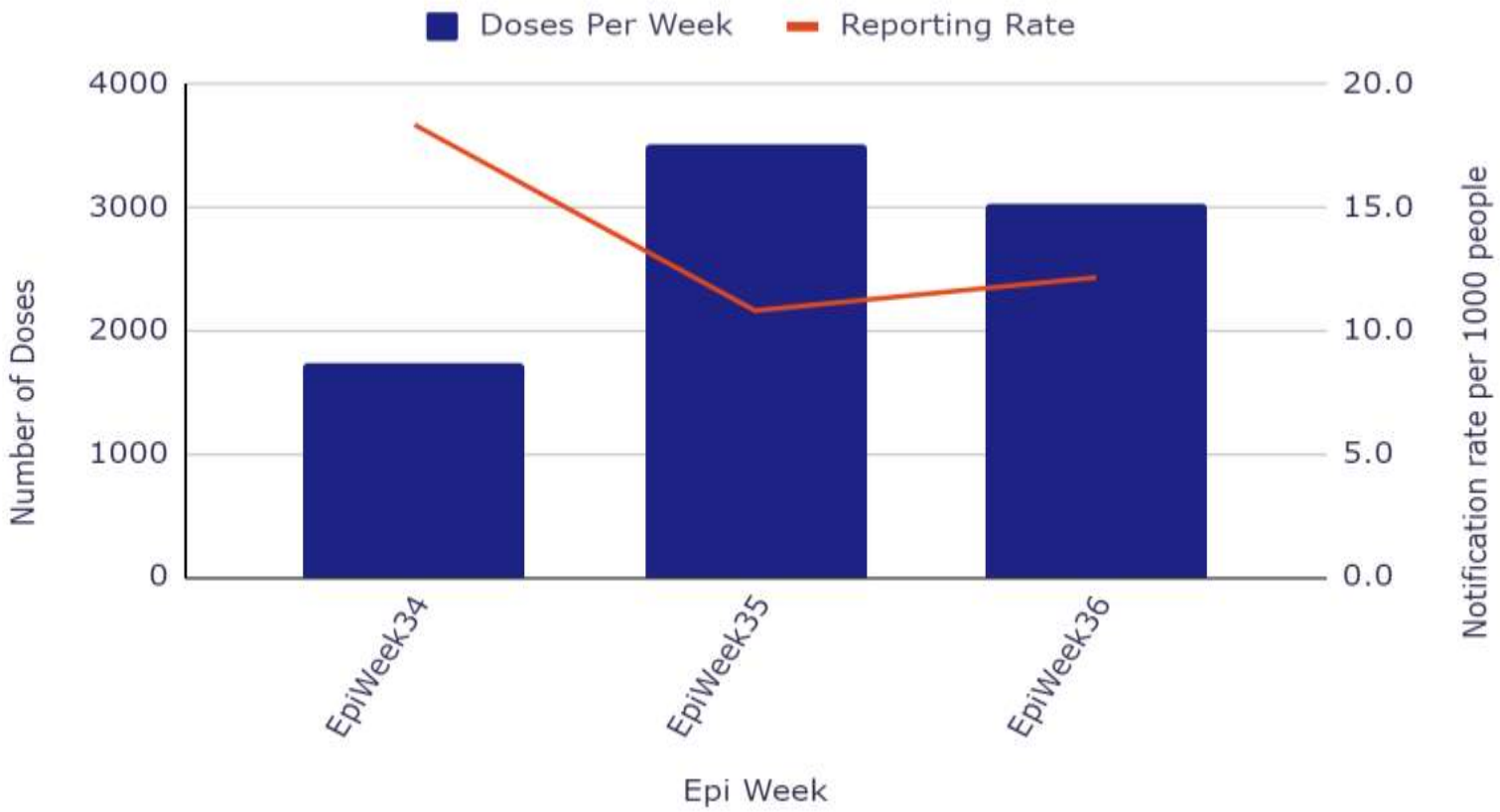
| Epidemiological Week | Total Doses Administered | AstraZeneca Reporting rate | Sinopharm Reporting rate |
|---|---|---|---|
| **23** | 1650 | 8.5 | 0.0 |
| **24** | 5146 | 8.3 | 0.0 |
| **25** | 7369 | 9.9 | 0.0 |
| **26** | 10374 | 8.3 | 0.0 |
| **27** | 13938 | 4.8 | 0.0 |
| **28** | 17,960 | 3.0 | 0.0 |
| **29** | 22,041 | 3.7 | 1.5 |
| **30** | 24,062 | 3.0 | 0.4 |
| **31** | 25,039 | 1.0 | 0.0 |
| **32** | 26357 | 3.8 | 0.0 |
| **33** | 28960 | 3.1 | 0.0 |
| **34** | 32661 | 2.7 | 0.0 |
| **35** | 35,815 | 1.9 | 0.0 |
| **36** | 39,094 | 1.5 | 0.0 |

# RESULTS 2; Reporting rate by Epi week for SHEFA province



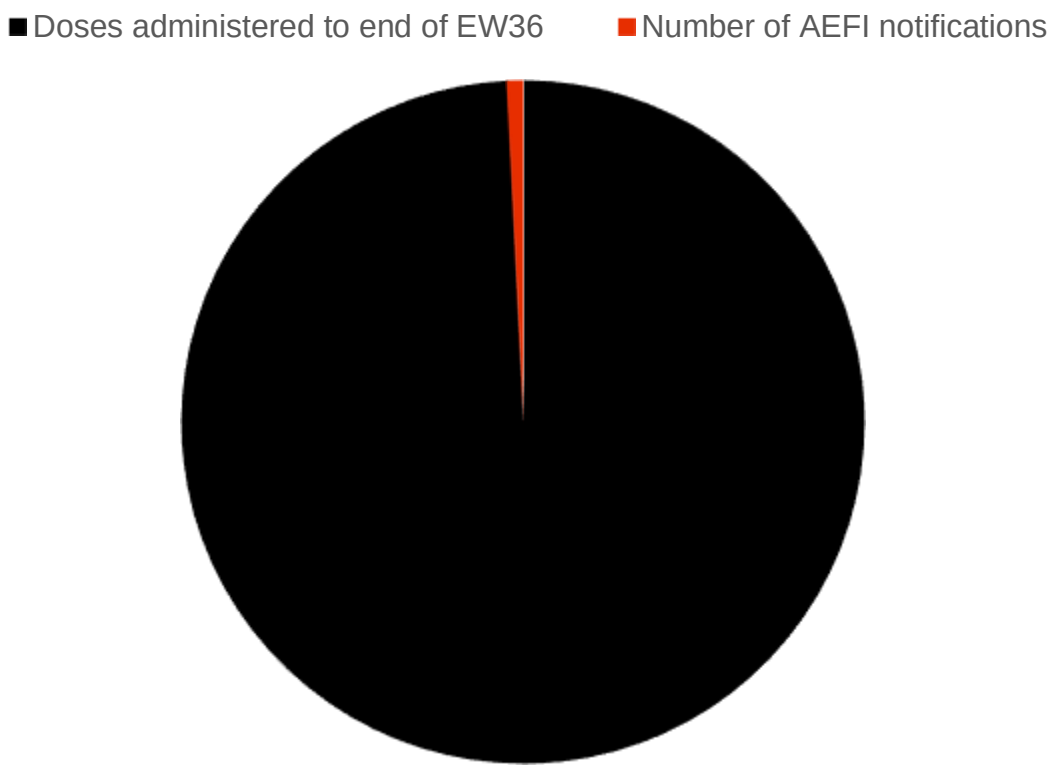

- Initial reporting rates were high in initial stages but progressively declined

# RESULTS 3; Reporting rate by Epidemiological week for SANMA




- Initial reporting rates were high but have decreased after the first three weeks

# RESULTS 4; Proportion of doses given for which there was an AEFI report within the first 3 months of COVID-19 vaccination campaign



# AEFI causality assessment classifications completed between 2nd June to 5th September 2021

| Causality Conclusions | AstraZeneca | Sinopharm | Total |
|---|---|---|---|
| Vaccine-product related | 0 | 0 | 0 |
| Vaccine quality defect-related | 0 | 0 | 0 |
| Immunization error-related | 0 | 0 | 0 |
| Inconsistent causal association to immunization (coincidental) | 7 | 1 | 8 |
| Immunization anxiety-related | 1 | 0 | 1 |
| Indeterminate - insufficient evidence | 0 | 0 | 0 |
| Indeterminate - conflicting trends | 0 | 1 | 1 |
| Unclassifiable | 0 | 0 | 0 |

# DISCUSSION

- SHEFA AEFI reporting rate is 3.7 per 1000 and that is inline with Australia's (2.7 per 1000) and New Zealand (3.9 per 1000).
- Decline of reporting rate is expected to continue as vaccination awareness increases.
- Vanuatu COVID-19 Immunisation program is safe.



https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-09-09-2021
https://www.medsafe.govt.nz/COVID-19/safety-report-26.asp

# RECOMMENDATIONS / IMPLICATIONS

- Continue to strengthen AEFI surveillance.
- Emphasize the need to report AEFIs from other vaccines.

# ACKNOWLEDGEMENTS


- Dr Caroline Van Gemert
- Dr Tessa Knox Bellamy & Dr Matt Cornish
- Dr Phillippe Guyant
- MOH Surveillance unit
- Provincial Surveillance Focal Points