





COVID-19 vaccination training for healthcare workers

Module 4: Adverse events following immunisation (AEFI) monitoring for COVID-19 vaccination

Use of the Med Safety App for AEFI reporting 3 May, 6 May, 10 May and 13 May 2021





Overall objectives of today's session

- To provide a short overview of the Med Safety App for reporting an adverse event following immunisation (AEFI)
- To provide hands-on experience using the Med Safety App
 - Download
 - Navigation
 - Reporting an AEFI
- To answer participants' questions posted to the Knowledge Hub or live during the session





Poll 1: Have you watched any of the Med Safety App videos available on the Knowledge Hub or SAHPRA website?



- A. YES all of them
- B. Some of them
- C. None





Poll 1 results









A. YES

- B. Attempted, but unsuccessful
- C. NO





Poll 2 results







Poll 3: Have you heard anything about the Med Safety App in the media?



- If YES, select the option which provided you with the most useful information
- A. Yes, social media (Facebook, Twitter, Instagram)
- B. Yes, radio
- C. Yes, TV
- D. Yes, newspaper
- E. Yes, online news
- F. No





Poll 3 results







Why report and investigate an adverse event following immunisation (AEFI) and an adverse event of special interest (AESI)?



WHO is responsible and WHEN to report an AEFI?

- All health care workers **providing immunisation** services
- Health workers providing clinical treatment of AEFI and AESI in health centres, hospitals, etc.
- Vaccine recipients who report AEFI
- Researchers conducting clinical trials or field trails







Case reporting form for AEFI

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Med Safety App



ALL VACCINES including COVID-19: AEFI CRF Page 2/2

ZA_AEFI_CRF_NISEC_Jan 2021

Background on the Med Safety App



South Africa







What can we do with the Med Safety App?

- Report suspected AEFI and adverse drug reactions (ADRs) electronically
 → Replaces the need for paper forms → better data quality
- Public can report
 - ADRs for medicines
 - AEFI (coming soon)
 - → Minimise under-reporting
- Reported cases can be updated with additional information
- Build a watch list of medicines
- Real time data visibility

 \rightarrow View number of reports received in WHO database of suspected ADRs/AEFI

 \rightarrow Track drug-related safety information





Safety signals or rare events



- **Safety signal** = when information becomes available from one or multiple sources
 - Could potentially be associated with the vaccine
 - Considered to be of sufficient likelihood to justify investigation or verification
- Requires large populations who received a particular vaccine \rightarrow pool data
- Signals → reviewed by committee of experts from the four countries



Features of the Med Safety App?

Med Safety App

- Mobile application free download
- Available for **Android** and **iOS** devices
- Electronic reporting of
 - Adverse drug reactions (ADRs) for medicines
 - Adverse events following immunisation (AEFI)
- Can be used by both healthcare professionals and the public
- Keep you up-to-date with information → Drug safety news
- Can function offline without internet connection
 - Create reports and submit when connected
 - Access newsfeed offline

Preferred

method of

reporting for

AEFI and

ADRs

Where and how to download the Med Safety App

- Access download instructions and information videos about the App:
 - Knowledge Hub
 - <u>http://medsafety.sahpra.org.za/</u>
- Questions or challenges experienced with the use of the App:
 - Email: adr@sahpra.org.za
 - Helpline: 012-5010311(weekdays; office hours)

What resources are available?

What resources are available?

African Union Smart Safety Surveillance (AU-3S) Programme

Instructions to download and use the Med Safety App

Table of Contents

- 1. About the Med Safety App
- 2. How to download the Med Safety App
- 3. Opening the Med Safety App for the first time
- 4. How to navigate the Med Safety App
- 5. How to navigate the reporting forms
- 6. <u>How to use the Med Safety App to report a side effect to a vaccine (for healthcare professionals)</u>
- 7. How to use the Med Safety App to report a side effect to a vaccine (for the public)
- 8. <u>How to use the Med Safety App to report a side effect to a medicine (for healthcare professionals)</u>
- 9. How to use the Med Safety App to report a side effect to a medicine (for the public)

SMART SAFETY

JRVEILLANCE

Document:

How to download

and use the App

to report an

AEFI or ADR

Hands-on demonstration on how to use the Med Safety App for reporting an AEFI

Med Safety

App

Search for "Med Safety"

App Store (iOS devices)

Google Play (Android devices)

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The Med Safety app makes it easy to report adverse effects to medicines.

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You might also like

Install Med Safety

Open Med Safety App for first time

Download display

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Vaccine details

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Reaction details

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Reaction details

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01 May 2021	\checkmark
Is the reaction still occurring, or has it Recovered/resolved	resolved? *
If the reaction has resolved, when did the stop?	reaction
02 May 2021	~
Add	

Adverse event outcome	Definition
Recovered/resolved	The patient has fully healed from the reaction without any
	lasting effects
Recovering/resolving	The patient is in the healing process and displaying clear
	positive signs of recovery but has not yet fully healed
Not recovered/not	The patient has not yet healed from the reaction and is not
resolved	yet showing clear positive signs of recovery
Recovered/resolved with	The patient has healed from the reaction but there are lasting
sequelae	effects or implications as a result of the reaction
Fatal	The patient has passed away (upon selecting this option, you
	must include the patient's date of death and indicate whether
	an autopsy was done)
Unknown	The patient's status is not known

Indicate the outcome of the reaction

Reaction details

Add other reactions "Add" if reaction is not on the list

* C 1 16:41 **Reaction details** Cancel Save 27 / 20000 Did the reaction(s) lead to: Disabling/Incapacitating Life threatening Caused/prolonged hospitalization Congenital anomaly/birth defect Results in death Medically significant BACK NEXT > 冒 Ø 000 Products News Watch List Report More $\langle 1 \rangle$ С

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Past medical history (including history	of similar	SENT REPORTS	PENDING REPORTS	
reaction or other allergies), concomita and dates of administration (exclude t treat reaction) other relevant informati cases).	nt medication hose used to on (e.g. other	Report 1 Report Date:02 May 202	1 1	
Known epilepsy on Epilim 500mg	twice daily			
	10			Upon submission
Submit report Would you like to submit this report? NO YES				Message in the App to
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IMPORTANT!!

Review the updated Module 4 materials available on the Knowledge Hub

Make use of the Med Safety App resources available on the Knowledge Hub and the SAHPRA website

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ANY QUESTIONS?

THANK YOU

