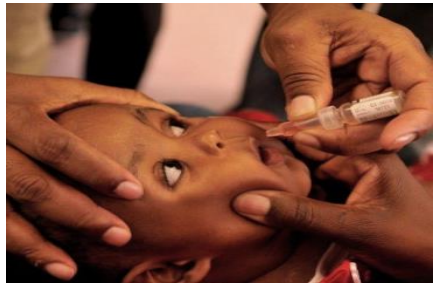
MPOX VACCINE ROLLOUT IN SOUTH AFRICA



EXPANDED PROGRAMME ON IMMUNISATION

MPOX VACCINATION TRAINING

11 MARCH 2024

Facilitators: EPI

Ms Elizabeth Maseti

Ms Phuti Mashiane

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Health
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2030 NDP

30 YEARS OF FREEDOM
South Africa 1994 - 2024

AGENDA & TOPICS

Chairperson: Ms E. Maseti – NDOH EPI Manager

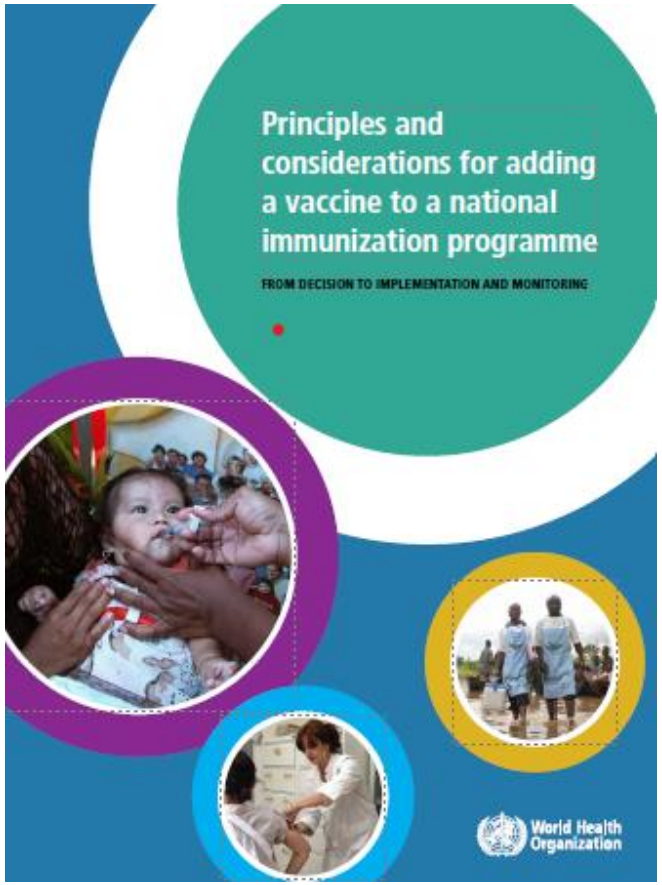
ITEM	TOPIC	RESPONSIBILITY
1	Vaccine Overview and Programme Related Matters	Dr Simangele Mthethwa: WHO VPD-NPO
2	Regulatory Issues, Procurement and Distribution	Ms Sisanda Mtatambi: National EPI Policy Specialist
3	Service Delivery Model	Ms Feni Motshwane: NDOH ISHP
4	Monitoring & Evaluation/Data management	Mr Thulasizwe Buthelezi: WHO Data Manager
5	Surveillance & Adverse Events Monitoring	Ms Ester Khosa-Lesola: WHO Surveillance officer
6	Social Mobilisation and Communication	Ms Nomkhosi Mokoena: RCCE

Outline

- Mpox Vaccine Workstreams
- Target Audience
- Overview of Mpox Disease
- National Advisory Group On Immunisation (NAGI) Recommendations
- Vaccine Estimates
- Service Delivery Platform
  - Vaccine Administration
  - Vaccine Sites
- Vaccine Supply And Procurement
  - Regulatory Issues, Procurement And Distribution
  - Cold Chain Management
  - Vaccine Stock & Wastage Management
- Information, Monitoring & Data Management
- Vaccine Safety Surveillance
- Risk Communication And Community Engagement (RCCE)

Mpox Vaccine Workstreams

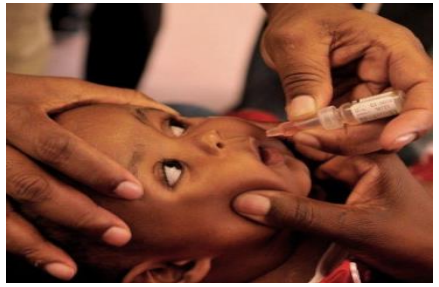
- Coordination and communication with provinces and other stakeholders
- Technical issues
- Service delivery model
- Regulatory issues, procurement and distribution
- Capacity building
- Data management
- Pharmacovigilance
- Demand generation



Target Audience

Training is intended for health workers involved in vaccination response to a Mpox outbreak.

- EPI Programme Managers
- Logisticians/Supply chain officers
- Cold Chain Managers
- Supervisors
- Health workers
- Hast Managers
- CDC managers
- Vaccination team members
- Field monitors
- Local partners supporting vaccination response



OVERVIEW OF MPOX DISEASE

What is Mpox?

Mpox (monkeypox) is a viral infectious disease which commonly manifests with a skin rash or mucosal lesions which can last 2–4 weeks, accompanied by fever, headache, muscle aches, back pain, low energy, and swollen lymph nodes.

There are two main Mpox virus strain (clades):

- Clade I - formerly central African or Congo Basin clade
  - Subclades Ia and Ib
  - Ib emerged in 2023 & is more severe
- Clade II - formerly West African clade
  - Subclades IIa and IIb

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Mode of Transmission

- Person-to-person, mainly through close contact
- Direct contact with contaminated material (such as clothing, bedsheets, used dressings, injection device, etc.)
- Transmitted from animal to person in endemic areas where the virus occurs in animal hosts
- Pregnancy, when virus can be passed on to the newborn baby.

WHO is at risk of Mpox

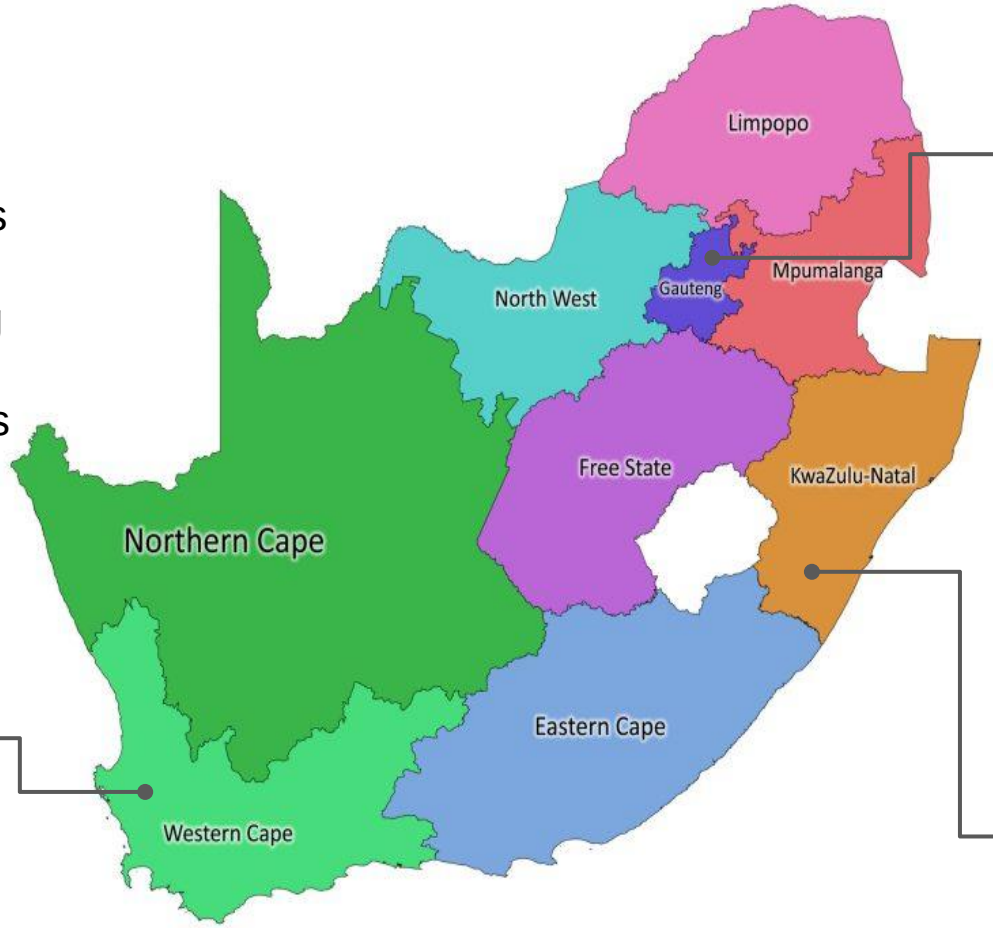
- People who have been in close contact with someone who has Mpox;
- Health and care workers, including clinical laboratory and health care personnel performing tests to diagnose Mpox;
- People who have multiple sex partners, including men who have sex with men;
- Sex workers of any gender and their clients;
- Mpox outbreak response team members.

Children, pregnant people and people living with HIV/weak immune systems are at higher risk for serious illness and death due to serious complications.

South Africa Mpox Outbreak Overview

28 confirmed cases

- May 2024 – February 2025
- 3 deaths (CFR:7%)
- 27 Males, 89% identifying as engaging in male-to-male sexual activities, 1 Female
- Age Distribution: 17- 43 years
- Over half of the cases occurred among people living with HIV (PLHIV)
- Currently no health disparities by race or ethnicity
- Last case confirmed on 8th February 2025
- Hotspots in each province
- Clade Ib and IIb reported



District	Subdistrict	Confirmed Cases
City of Johannesburg	Region F Region D	5
City of Tshwane	Region 6	3
City of Ekurhuleni	Nigel Tembisa	5 (1 Death, 37-year old)
Sedibeng	Midvaal	1
West Rand	Merafong	1

District	Subdistrict	Confirmed cases
City of Cape Town Metropolitan Municipality	Western	2

District	Subdistrict	Confirmed cases
eThekwini Metropolitan Municipality	eThekwini	8 (1 Death, 39-year-old)
uThukela	Alfred Duma ((Ladysmith)	1 (1 Death, 40-year-old)
Umzinyathi	Nquthu	1
uMgungundlovu	Msunduzi	1

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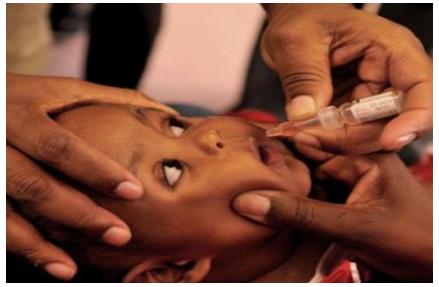


NAGI RECOMMENDATIONS

Phase 1
Control Phase (10 700 MVA-BN doses)

- **Pre-exposure vaccination**
- Gay, bisexual, or other men who have sex with men (GBMSM) and transgender people
  - At highest risk of MPXV exposure (people with a recent history of multiple sexual partners and those participating in group sex or sex-on-premises event)
  - In the districts with previously reported cases,
  - People at higher risk of severe mpox disease within these target populations (e.g., people with advanced HIV disease).
  - Health care workers participating in care of key population services should also be considered, as the risk is higher for those caring for infected patients.

Phase 1
Rapid outbreak response

- **Post-exposure vaccination following detection of new cases**

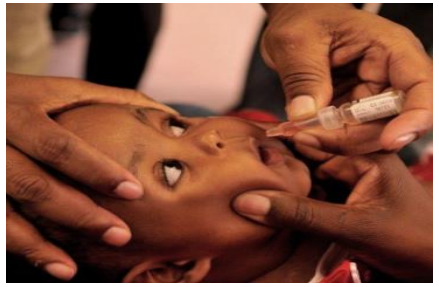
  A small stockpile should be maintained to be used for post-exposure vaccination of

  - close contacts (sexual contacts and household contacts),
  - health care workers
  - and laboratory workers as part of rapid outbreak response following detection of new cases.

Phase 2

This will be determined based on the epidemiological situation and on the uptake and acceptability of vaccination in phase 1.

- **Pre-exposure vaccination**
  - laboratory workers and frontline health care workers at high risk of exposure
  - sex workers in the districts with previously reported cases,
  - people with occupational risk through travel to high-risk areas in Africa (e.g., people working on mines, military personnel and humanitarian aid workers).



VACCINE ESTIMATES

Parameters for vaccine estimation

- **Data sources used**
  - South African Census 2022
  - South Africa Men's Health Monitoring Study-I and Study-II
  - Beyond Zero PSE project
  - Research studies
- **Parameters established based on these resources**

Parameters	MSM	TG
Estimated number of people [redacted]	66785	39775
Estimated highest risk of exposure	60%	40%
Estimated vaccine acceptance	50%	50%
Estimated programmatic reach / access	60%	40%
Estimated uptake of the 2nd vaccine dose	60%	60%

Vaccination of high-risk groups

- Vaccination to be offered in a staggered approach initially targeting GBMSM and transgender people at highest risk of exposure in districts with reported cases. Those considered at the highest risk are people with a recent history of multiple sex partners and those participating in group sex

- Vaccine estimations for GBMSM and TG at highest risk in the five metropolitan municipalities (Cape Town; Durban; Ekurhuleni; City of Johannesburg; Tshwane): **37 600 doses**

Estimations	MSM	TG	Total
Number of people reached and accepting vaccination	19 100	5 000	24 100
Number of vaccine doses	30 600	7 100	37 600

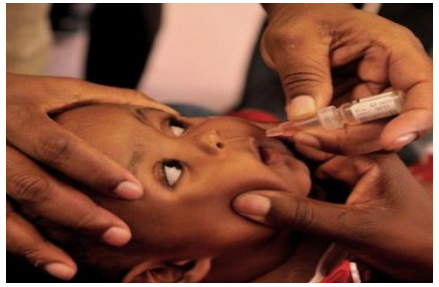
Note. Transgender persons include transmen, transwomen and non-conforming people. People reached is based on utilizing exiting facility- and community-based key population programmes for vaccine roll-out

- Health workers and laboratory staff at risk of repeated exposure: suggested to have **1000 doses for HCW** at frontline hospital that may get into contact with Mpox patients/body materials

Post-exposure vaccination of contacts

- Vaccination of contacts of persons with Mpox; this includes household contacts, sexual contacts, health workers with specific exposure to Mpox, and laboratory workers that handled Mpox specimens
- Estimated 5 contacts per index cases based on household survey and ratio of household vs non-household contacts – including HCW and laboratory staff

	100 cases	500 cases	1000 cases
Number of contacts	500	2500	5000
Vaccination uptake	200	1000	2000
Vaccine doses	320	1600	3200



SERVICE DELIVERY PLATFORM

Introduction

- A **solid service delivery platform** is necessary to increase access to and delivery of Mpox vaccines. Based on the **hotspot mapping**, strategic vaccination efforts will **focus on individuals at the highest risk of infection**, including close contacts of recent cases and healthcare workers, to interrupt transmission chains.
- Vaccination strategies include both post-exposure and pre-exposure approaches.

Vaccination aim: Stop the outbreak

X Not a mass campaign !

X Not a vaccine roll-out!

X Not a vaccine introduction!

It is an integrated, targeted outbreak control response

Vaccine deployment approach

This is not a vaccine introduction but vaccination to stop the outbreak (human to human) transmission

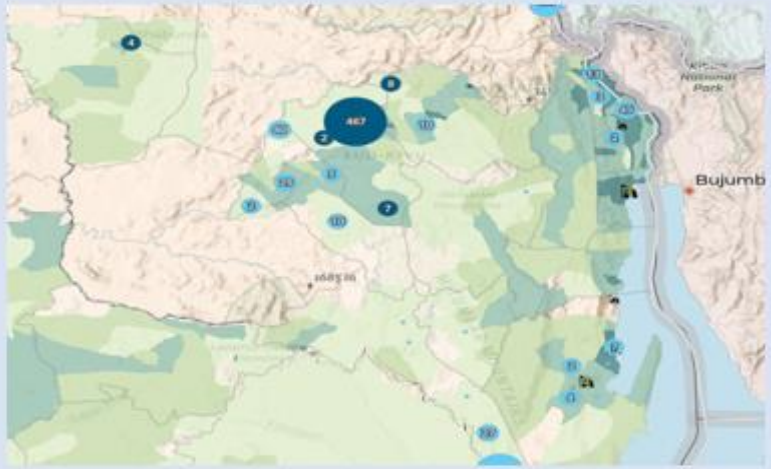
1. Understanding epidemiology at local level

WHERE CASES OCCURRED?

WHO & AGE GETS DISEASE?

2. Mapping "hot spots" & estimating size pops

WHERE ARE THE HOT SPOTS?



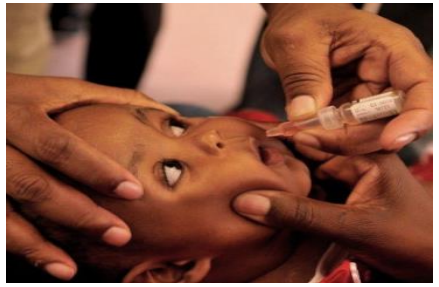
1. Areas with **high incidence** in previous 4 weeks
2. Areas with **confirmed cases** in previous 4 weeks
3. Areas with cases **in cities, IDPs or refugee camps, institutions** (schools, prisons, others
4. **"Newly infected areas"-** no cases before, not reported before

3. Planning the logistics & field operations

HOW TO REACH MOST AT RISK?

Vaccine deployment approach *(continued)*

- Targeted approach will be used
  - Adhering to principles of equity, inclusion, human rights, and dignity of all individuals
- Target Population
  - the target population, which is the population at high risk of infection.
  - the target facility where the key population accesses services: (drop-in centres, pop-in centres, and centres of excellence)
  - the target geographic area - districts which have reported a case of mpox



VACCINE ADMINISTRATION

Mpox Vaccine Schedule

- A delayed dose approach will be done in South Africa;
- Administering the MVA-BN vaccine in a **single dose (0.5 mL)** may be done in case of limited vaccine supply.
- Clients will receive the 2nd dose once more stock is available

Preparing for vaccination

What you need
- Screening tool for eligibility
- Vaccination register
- Vaccination card
- Vaccine
- Syringe and needle
- Sharps container
- Cotton ball

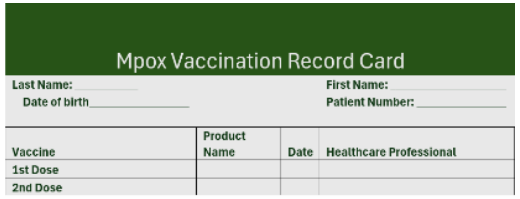
All patients must be screened for vaccine eligibility using the Mpox Pre-Vaccination Assessment Tool

Main supplies:

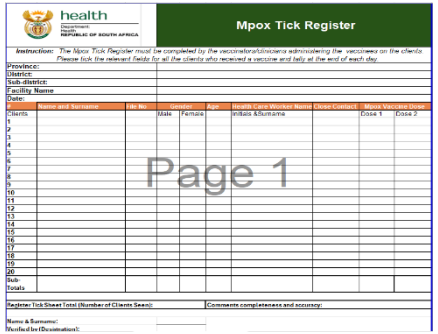
MVA-BN vaccine single-dose vial

Syringe: 1 or 2ml
Needle: 23G

Safety or biohazard box



Vaccination card



Mpox Vaccination Tick Register

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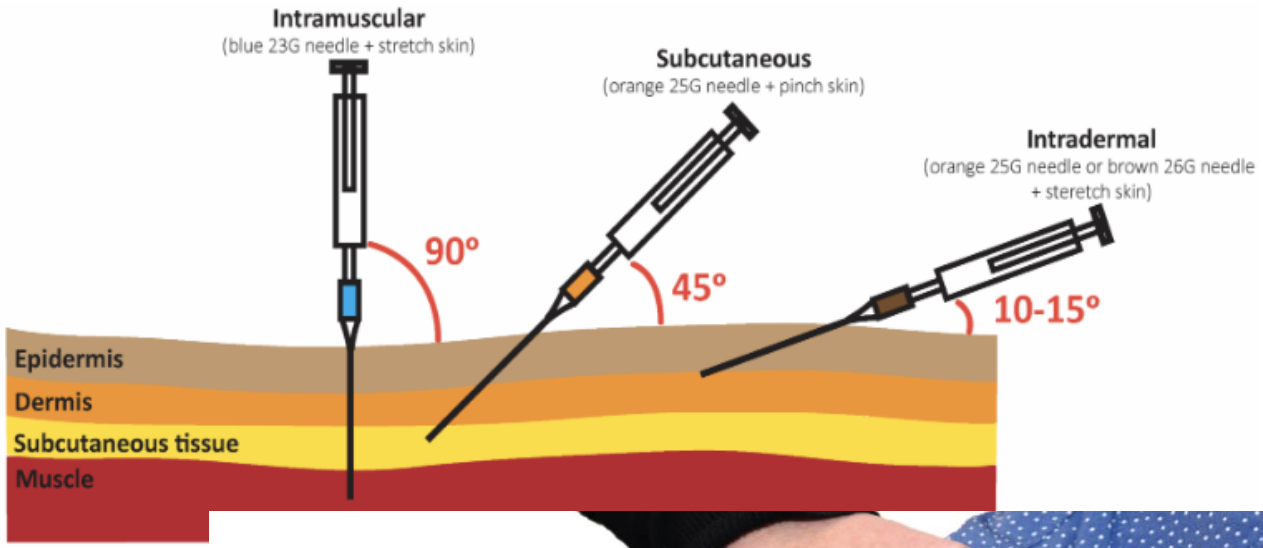
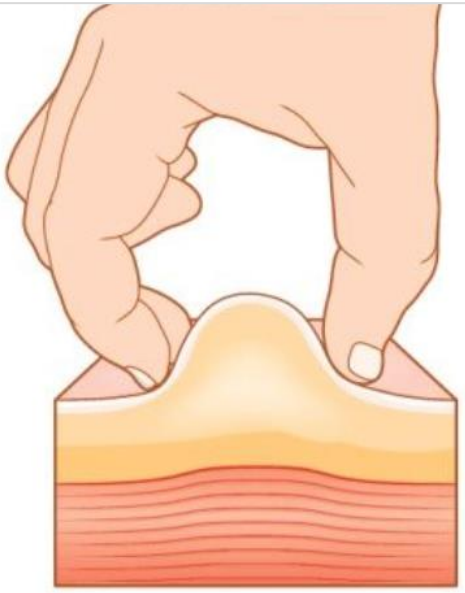
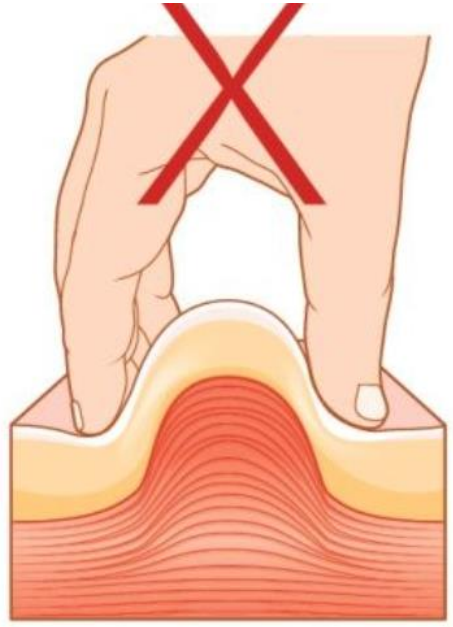
The Technique

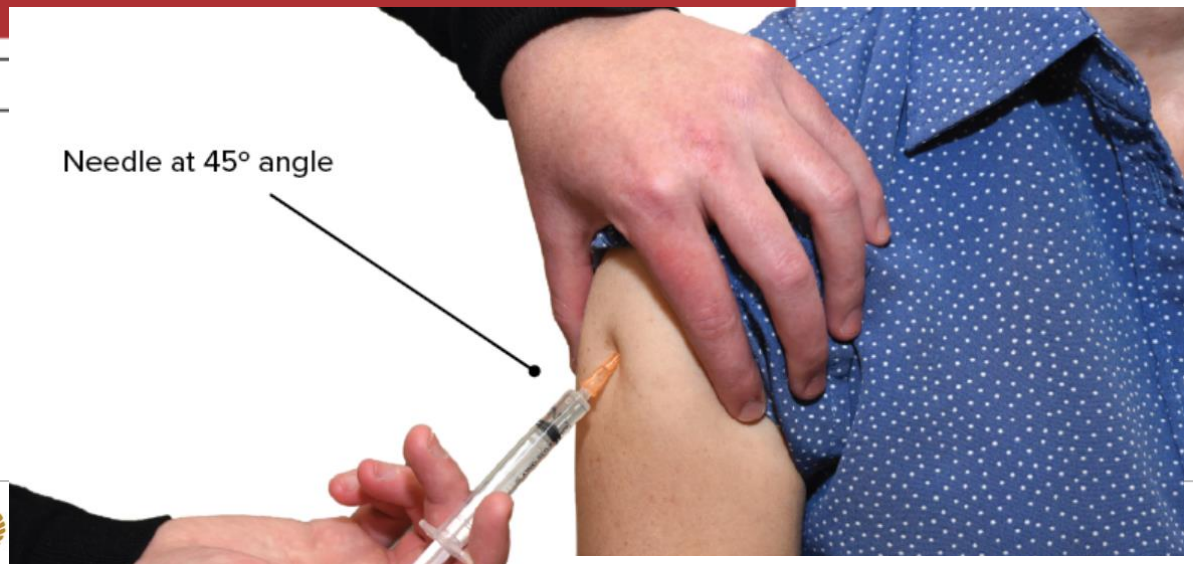


Lift the skin between thumb and 2 fingers with one hand, pulling the skin and fat away the underlying muscle



Incorrect technique





Subcutaneous injection

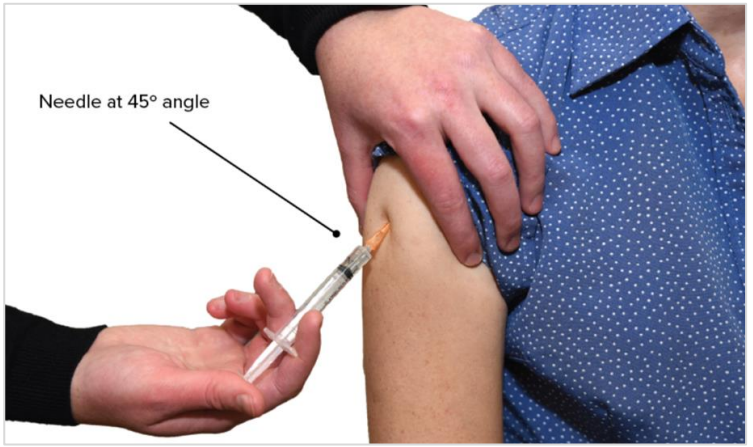
Preferred site: **fatty tissue in the upper arm**

Vaccine dose administration

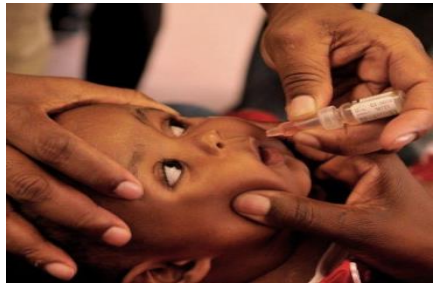
1. Take the number of vials required for the session.
2. Place the unopened vaccine vials in a vaccine carrier based on manufacturers instructions.
3. Thawed vaccine is ready to use. **Do not dilute**.
4. Swirl the vaccine vial gently for at least 30 seconds. **Do not shake**.
5. Visually inspect the vial.
    - Vaccine should appear as milky, light yellow to pale white colored suspension, free of particulate matter.
    - If discolored or containing any particulate matter, do not administer and safely discard the vial.
6. Open vaccine vial one at a time.

Vaccine dose administration *(continued)*

7. Draw up 0.5 ml of vaccine just before administration.
    - Use one vaccine vial per vaccinee
    - Do not prefill syringes with vaccine
    - Use the vaccine immediately after loading the syringe.
    - Use one needle to withdraw and administer vaccine
8. **Remember to wear gloves before touching the patient**
9. Administer the dose subcutaneously in the fatty tissue over in the upper arm.
10. Do not recap or remove the needle
11. Dispose of the used syringe and needle immediately in the safety/biohazard box.
12. Record administered dose on vaccination card and tally sheet.
13. Observe the vaccinee for up to 15 minutes for any reaction.



If injection site is dirty, cleanse the area with a cotton ball wet with water.



VACCINATION SITES

Service delivery site selection

- Provinces with Mpox cases GP, KZN and WC to finalise lists
- Sites selected by provinces based on:
  - Affected districts
  - Hotspot for key populations
  - Population size estimates
  - NGOs supporting key populations
  - Centers of service excellence for key populations
  - Mobile services for key populations
  - **NB: Sites to be reviewed post Executive Orders**

KZN Province vaccination sites

Public health clinics and hospitals in high transmission areas

- Priority facilities under operation Phuthuma at ETK District.
  1. Cato Manor CHC
  2. Hlengisiwe CHC
  3. Inanada CHC
  4. KwaDabeka CHC
  5. KwaMashu CHC
  6. Phoenix CHC
  7. Tongaat CHC
  8. PMMH Gateway
  9. Prince Cyril ZULU CDC
  10. Pinetown Clinic

KZN Province vaccination sites *(continued)*

Clinics that cater to populations at higher risk, such as LGBTQ+ health services, STI clinics, or HIV treatment centers.

CDC supported Implementing Partners

- Aurum
- HST
- TB/HIV Care

USAID Supported Implementing Partners

- TBD

Mobile health units that can reach underserved populations and provide vaccinations on the go

- Aurum: 2 mobile units (1 x eThekwini and 1 x Umgungundlovu)
- HST: TBD
- TBHIV Care: TBD

KZN Province vaccination sites *(continued)*

Clinics that cater to populations at higher risk, such as LGBTQ+ health services, STI clinics, or HIV treatment centers

Key population centres of excellence

- Addington CHC
- Eastboom CHC
- Walton Clinic
- KwaDukuza CHC

Facilities currently undergoing training

- Newcastle Gateway Clinic
- Empathe Clinic
- Sundumbili CHC

Gauteng Province Mpox service delivery sites

ORGANIZATION NAME/ Facility	POPULATION SERVED (MSM, FSW ETC)	SITE TYPE	District	District and sub-district/region	clinic	Site name and address	Site manager name, email and contact number
OUT LGBT Wellbeing	MSM	Clinic drop in centre	Johannesburg	Sub district B	Engage Men's Health	Engage Men's Health (DIC) 23 Glenhove Street, Melrose Estate	Maurice Greeves- 0740240546
OUT LGBT Wellbeing	MSM	Clinic drop in centre	Johannesburg	Sub district F	Engage Men's Health	Engage Men's Health (Braam Service Site) Reserve Street, Braamfontein	Maurice Greeves- 0740240546
GDOH	KEY POP FRIENDLY FACILITY	Clinic	Johannesburg	Sub district D	Itereleng CHC	Itereleng CHC, 5/6 Elias Motsoaledi Road	Rona Oldjohn, 011 989 0304/ 0824753943, Itireleng.Clinic@gauteng.gov.za,
GDOH	KEY POP FRIENDLY FACILITY	Clinic	Johannesburg	Sub district G	Stredford CHC	Stretford CHC, 15573 x2 Orange Farm Link Road Orange Farm	Fikile Dikolomela-Lengene,010 344 2990/ 0723714189, CHC, Stretford.CHC@gauteng.gov.za
GDOH	KEY POP FRIENDLY FACILITY	Clinic	Johannesburg	Sub district A	OR Thambo	OR Tambo, 353 Ingonyama Road, Ext 2, Diepsloot	Debbie Moloi,011 464 5005, 0605847220, ORTambo.Clinic@gauteng.gov.za
GDOH	KEY POP FRIENDLY FACILITY	Clinic	Johannesburg	Sub district C	Discoverers	Discoverers,35 Clarendon Drive, Discoverers, Roodepoort	Debby Sibanda,011 472 3648/0826002519, Discoverers.CHC@gauteng.gov.za
GDOH	KEY POP FRIENDLY FACILITY	Clinic	Johannesburg	Sub district D	Chiawelo	Chiawelo CHC,1753 Rihlampfu Street Chiawelo, Soweto	Sylvia Mvula,060 584 7213 010 345 4328, ChiaweloCHC.ChiaweloCHC@gauteng.gov.za
Wits RHI Key Populations	TGW	Clinic drop in centre	Johannesburg	Sub district F	Wits RHI Key Populations	Esselen Street, Hillbrow, 2001, Johannesburg. GPS: -26.190820040203327,	Nothando Madondo
GDOH	KEY POP FRIENDLY FACILITY	Clinic	Johannesburg	Sub district E	Alexandra CHC	Alexandra CHC, No. 33 arkwirght Avenue, Wynberg	nmandondo@wrhi.ac.za
GDOH	KEY POP FRIENDLY FACILITY	Clinic	West Rand	West Rand District Health Council, RandWest (Westonaria) Sub District	Bekkersdal West CHC	Bekkersdal West CHC, 3545 Khomo Ya Hlaba Street, Bekkersdal, 1779	011 358 5300
GDOH	KEY POP FRIENDLY FACILITY	Clinic	West Rand	West Rand District Health Council, Merafong Sub District	Carletonville Central	Carletonville Central, Eden Village, 3 Agnew Road, Carletonville, 2499	Sr Matlou Machaba, 073 837 0227, Matlou.Machaba@gauteng.gov.za
GDOH	KEY POP FRIENDLY FACILITY	Clinic	West Rand	West Rand District Health Council, Mogale Sub District	Krugersdorp Central	Krugersdorp Central Clinic, Cnr Commissioner and Fountain Street, Krugersdorp, 1740	Sr Sindi Mongae, 073 853 9694, Sindi.Mongae@gauteng.gov.za
AURUM POP INN	MSM AND TGW	Clinic drop in centre	Ekhurhuleni	Ekhurhuleni North	Aurum Pop Inn	21 Margarete avenue Kempton Park	Mpho Tafane, MTafane@auruminstitute.org +27 (0) 60 276 1163
GDOH	KEY POP FRIENDLY FACILITY	Clinic	Ekhurhuleni	Ekhurhuleni South	Jabulani Dumane CHC	Jabulani Dumane CHC, nguza str, vosloorus	Mr S Matchaba, '072 419 0359, Sandile.Matsaba@gauteng.gov.za
GDOH	KEY POP FRIENDLY FACILITY	Clinic	Ekhurhuleni	Ekhurhuleni East	Kwa-thema CHC	Kwa-thema CHC, 7001 Moshoeshoe str, kwa thema springs	Ms Moeketsi, 0832335751, Tshepiso.Moeketsi@gauteng.gov.za
GDOH	KEY POP FRIENDLY FACILITY	Clinic	Sedibeng	Sedibeng - Emfuleni	Market avenue	22 Market avenue Vereeniging	Monica Sekati - 073 225 6734 Monica.Sekati @gauteng.gov.za
GDOH	KEY POP FRIENDLY FACILITY	Clinic	Sedibeng	Sedibeng - Emfuleni	Zone 17	62064 Zone 17 Sebokeng	Dolly Moreetsi - 073 229 3696 Dolly.Moreetsi@gauteng.gov.za
GDOH	KEY POP FRIENDLY FACILITY	Clinic	Sedibeng	Sedibeng- Midvaal	Midvaal	45 Carvalho st Meyerton	Susan Myaka - 072 230 0085 susan.Myaka@gauteng.gov.za
AURUM POP INN	MSM AND TGW	Clinic drop in centre	Tshwane	TSHWANE 3	Aurum Pop Inn	Aurum Pop Inn, Loftus park shpping complex, 416 kirkness street, building A, 1st floor.	Pontsho Komane, PKomane@auruminstitute.org; +27 (0) 73 443 7174

Western Cape Province Mpox service delivery sites

- **Initial Phase:**
  - Commence at the Ivan Toms Centre for Men's Health, located at 1 Portwood Road, Greenpoint, Cape Town.
- **Expansion Phase:**
  - Depending on the vaccine allocation for the Western Cape and community uptake, the program will expand to additional clinics.

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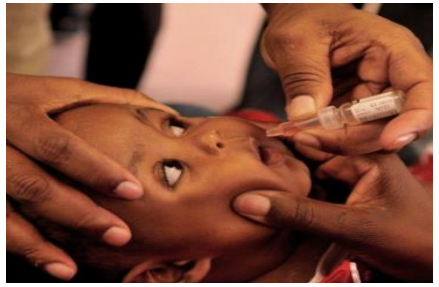
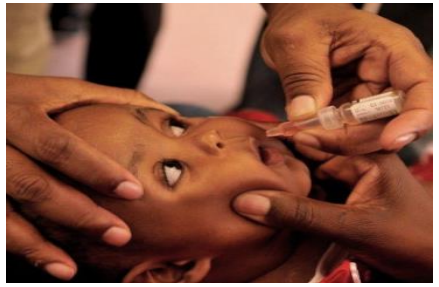


VACCINE SUPPLY AND PROCUREMENT



REGULATORY ISSUES, PROCUREMENT AND DISTRIBUTION

Mpox Vaccine Donation Update

- Africa CDC has donated a total of 10 700 doses of IMVANEX vaccine sourced from Luxembourg and Malta:

Batch Number	**448770**		
Manufactruing Date	16/09/2024		
Expiry Date	If stored at – 20°C	If stored at – 50°C	If stored at – 80°C
	31/08/2027	31/08/2029	31/08/2033

- Section 21 approval has been granted for 10 000 doses
- Application for the additional 700 doses in progress
- Submission for acceptance of donation has been submitted to DG
- Service provider to be appointed for importation, warehousing & distribution of the vaccine once submission has been approved
- **Lot Release conditions:** All imported lots will be subject to lot release by the South African National Control Laboratory (SANCL) as per SAHPRA Lot release guidelines.

Reporting of AEFI's

- **Bavarian Nordic** to supply summary periodic safety update report (simplified PSUR) (worldwide data) 6 weekly or 3-monthly to pvsubmission@sahpra.org.za.
- A summary of AEFIs must be reported to SAHPRA and the National Department of Health (NDoH) / EPI every two-weeks
- All **serious AEFI's** should be reported **within 24hrs** and
- All other AEFIs should be reported within 14 working days of identification.
- Patients and healthcare professionals can report AEFIs through the Med Safety App.

SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Section 21 Response Letter

10/15/2024 3:58 PM

Marione Schonfeldt

1112 Voortrekker Rd
Dr AB Xuma Building
Pretoria Townlands

marione.schonfeldt@vodamail.co.za

Dear Marione Schonfeldt,

REQUEST TO USE UNREGISTERED MEDICINE IN TERMS OF SECTION 21 OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965):

Your application dated **10/10/2024 8:33 AM** refers

A. ***STATUS: Approved***
B. ***APPLICANT: Marione Schonfeldt***
C. ***IMPORTING COMPANY: Biovac***
D. ***PATIENT/(S):***
E. ***UNREGISTERED MEDICINES:***

GENERIC NAME: Modified Vaccinia Ankara – Bavarian Nordic Live virus1 no less than 5 x 107 Inf.U*

TRADE NAME: JYNNEOS

F. ***QUANTITY: 5000 doses***
G. ***LETTER NUMBER: B-31231***

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MVA-BN Importation

Freight Forwarding from sourcing country

Arrival in South Africa

Customs clearance

SAHPRA approval
Import permit (DAFF permit)

Transport from airport to appointed Supplier's storage facility

Storage at central warehouse

MVA-BN Distribution from Supplier to selected Depots in GP, KZN and WCP

Appointed Supplier Warehouse

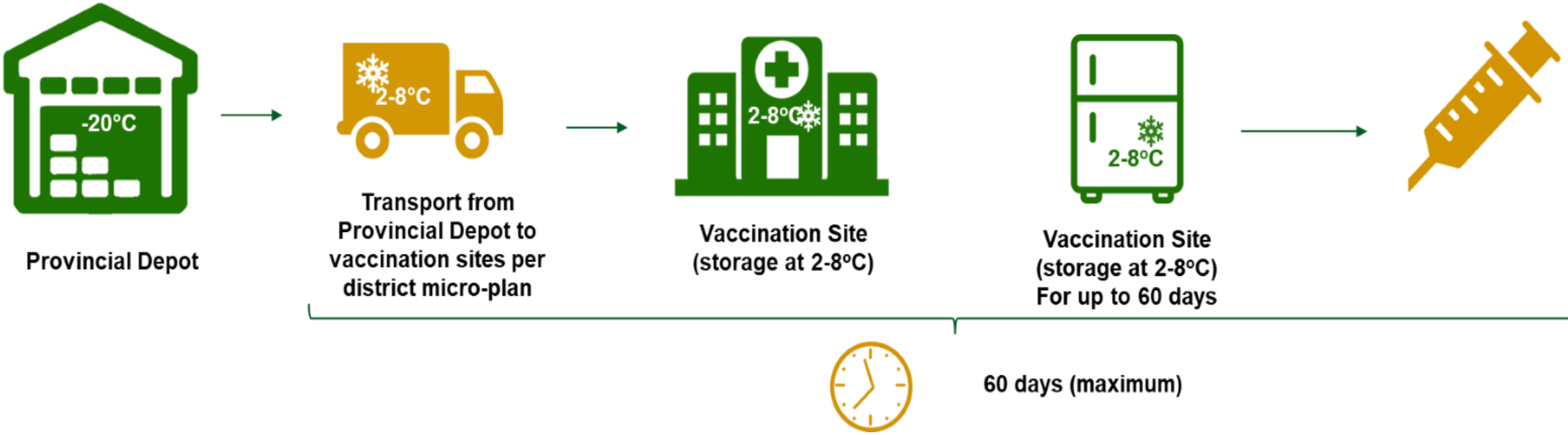
Transport from Supplier to Provincial Depot

Provincial Depot

Vaccine shelf life is up to 3 years at this storage temperature

Temperature range for -20°C is include -15°C to -25°C

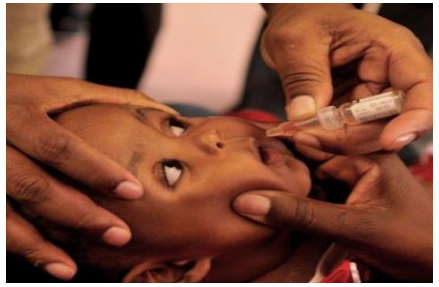
MVA-BN Distribution from Depots in GP, KZN and WCP vaccination sites



Use it within 2 months from thawing date, but not exceeding the original/ marked expiration date.

MVA-BN Vaccine Registration

Specification	MVA-BN
Different brands	**a. Jynneos®** **GENERICS** **b. Imvanex®** **c. Imvamune®**
Pharmaceutical form	Liquid frozen
Presentation	Single dose vial
Administration	Two doses (0.5ml)
Registered for	12 years and above
Storage	2ºC to 8ºC away from light for up to 2 months Can be stored at temperatures lower than -20ºC for up to 3 years
Reconstitution	Not required
Administration site	Subcutaneous SC/ upper arm (deltoid area)
Administration device	0.5 ml or 1ml syringe, with needle (23Gx1” or 0.6x25mm



COLD CHAIN MANAGEMENT

MVA-BN vaccine presentation

- Live non-replicating vaccine
- Prequalified as a single-dose vial
- Preservative-free suspension
- Delivered frozen in-country at -20°C
- Vaccine is ready-to-use once thawed
- **No dilution**

MVA-BN vaccine characteristics

Freeze Sensitivity	Light Sensitivity	Multidose vial policy	Vaccine Vial Monitor
• Never refreeze a vaccine vial once it has been thawed	• Store vials in the original package and protected from light	• N/A • Presented as a single dose	• N/A

MVA-BN vaccine packaging

Name	Secondary Packaging	Tertiary Packaging
Jynneos 	• Carton of 10 single-dose vials • Dimensions: 3.8 x 5.4 x 9.3 cm. • Cold chain volume: 19.08 cm3/dose	• Box containing 48 secondary cartons (480 vials/ 480 doses) • Dimensions: 12.4 x 24.6 x 39.2 cm.
Imvamune 	• Carton of 20 single-dose vials (20 doses) • Dimensions: 4.5 x 9.7 x 12.6 cm. • Cold chain volume: 27.50 cm3/dose	• Box containing 70 secondary cartons (1,400 vials/ 1,400 doses). ▪ Dimensions: 26.4 x 33.1 x 49.7 cm.

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Changing expiry dates as moved to different temperature ranges

- Vaccine is delivered to countries frozen with a longer shelf-life.
- Vaccine shelf life becomes shorter once it is thawed or stored in a refrigerator .
- It is important to track the remaining shelf life by updating the vaccine's new expiration date.
- Original expiration date printed on label must be respected **if it comes earlier** than the expiration date at +2°C to +8°C.

Frozen Vaccine	Thawed unopened vaccines
• 3 years shelf life • frozen vaccine stored at **-25°C to -15°C**	• **2 months* shelf life** • thawed vaccine stored at **+2°C to +8°C** • * from the date the vaccine was thawed and within the original/marked expiration date.

Dynamic labeling is the process of manually updating the vaccine's expiration date on the carton label. It is done immediately once the vaccine is taken out of the freezer to thaw or to be stored in a refrigerator.

Thawing frozen MVA-BN vaccine

DO NOT REFREEZE THE VACCINE ONCE THAWED!

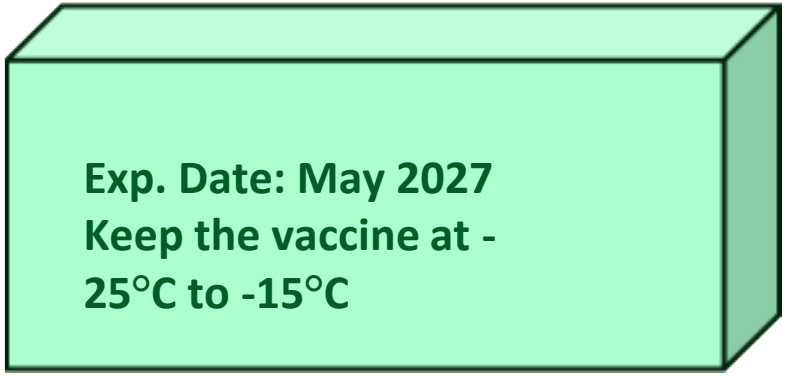
Thawing procedure if vaccine is FOR immediate use:

1. Keep vaccine vials in their original packaging, protected from light.
2. Take vaccine from freezer and bring to ambient temperature (+8 °C to +25 °C).
3. Ensure vaccine is placed in a secured location, do not expose to sunlight.
4. Allow vaccine to thaw completely – this may take about 5 to 10 minutes.
5. Apply dynamic labeling as indicated in slide: **“Application of dynamic labeling of expiration date”**
6. Ensure original expiration date remains visible and thawing date and new expiration date at +2°C to +8°C storage are visible and legible.
7. Keep vaccine in the refrigerator and use it within two months from thawing date.
8. Discard any unused vaccine at the end of the two-month period.

Dynamic labelling: Monitoring the remaining shelf-life of thawed vaccine

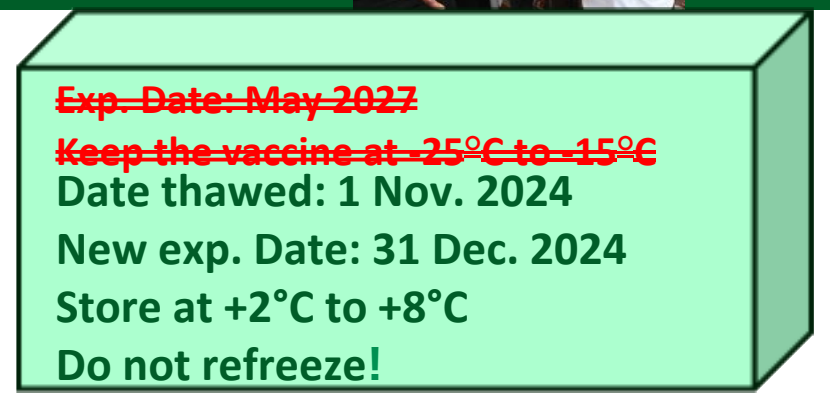
Key considerations:

- Keep the vaccine vials in original carton during storage.
- Keep the original expiration date printed on the carton readable.



- Ensure training of Depot staff to ensure implementation of dynamic labeling.
- Ensure responsible health workers at different levels are trained and provided with the required supplies to implement dynamic labeling.
  - **<u>Options</u>:** Use of permanent marker, waterproof stickers, printed labels, or color coding
  - Any of these options may be used to track the remaining shelf life once vaccine is moved from freezer to refrigerator.

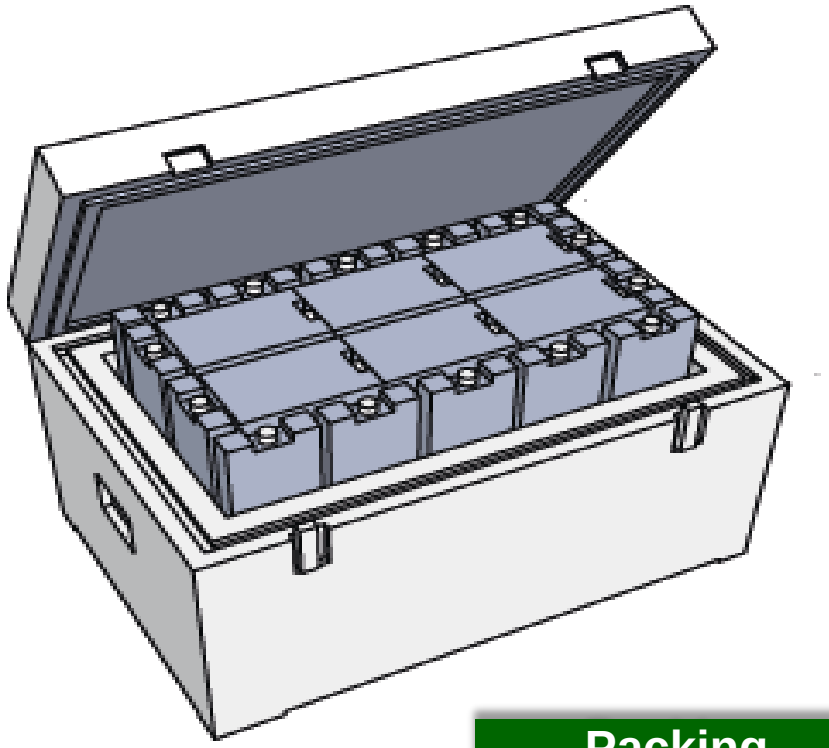
Dynamic labelling: Monitoring the remaining shelf-life of thawed vaccine



Key considerations:

- Once vaccine is moved from freezer to refrigerator, indicate the new expiration date at +2°C to +8°C on the carton.
- Remind to not refreeze thawed vaccine.
- Cross out expiration date at -25°C to -15°C on label but keep it readable.
- Printed expiration date at -25°C to -15°C storage should be respected if it comes earlier than the expiration date at +2°C to +8°C.
- Once vaccine is thawed, all necessary vaccine transport and use should take place within the next 2 months from thawing date.
- Any unused vaccine vials should be discarded 2 months after thawing date.

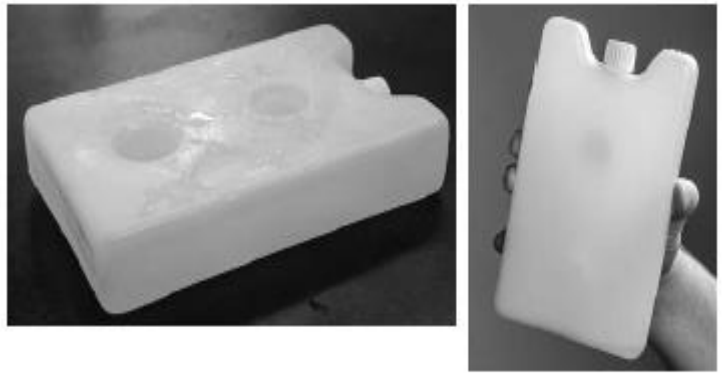
Packing vaccines for distribution



Packing System must be Validated

- Packing arrangements must be planned in advance and documented in an SOP
- Correct packing arrangements prevent vial breakages in transit
- Empty spaces inside the container must be filled with bubble wrap or suitable materials
- A continuous temperature monitoring device (CTMD) must be placed in the passive container
- A CTMD will monitor for freeze if storing freeze sensitive vaccines

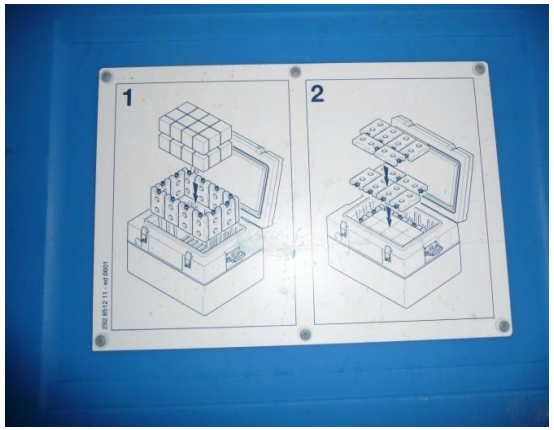
Conditioned Ice packs

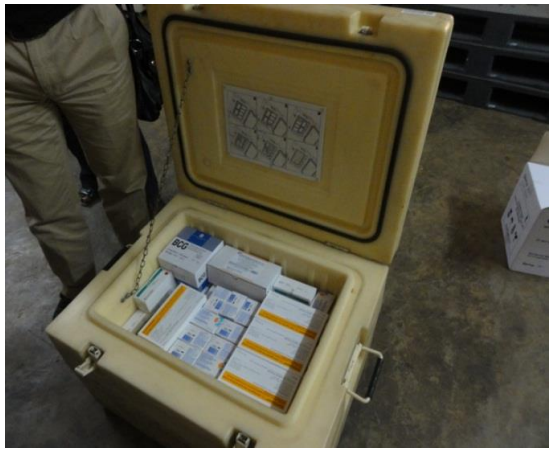


- Coolant-packs must be prepared correctly.
- If conditioned icepacks are not properly conditioned, freeze-sensitive vaccines will be exposed to sub-zero temperatures and may be damaged.
- Ice packs that have been removed from the freezer and left at room temperature until they begin to melt
- Mixture of water and ice at a temperature of about 0°C
- Eliminates the initial freezing risk without much reduction in cold life

Correct Vaccine Packaging Practices

- Pack prequalified vaccine carriers according to the manufacturers' instructions
- Use passive containers with published cold life at least as long as that required for longest planned trip
- Confirm minimum ambient temperature in transit does not fall below +5°C
- Pack a continuous temperature monitoring device with the vaccine load
- **Remember that MVA-BN vaccines that was distributed at 2-8°C should not be frozen again**.





Continuous Temperature Monitoring Devices

Only comprehensive temperature monitoring system can record the temperature history of vaccines passing through the supply chain

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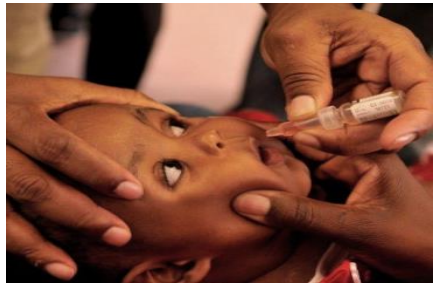
Ancillaries

- Syringes 1 syringe per dose, (1ml, 0,5ml)
- Needles suitable for subcutaneous vaccination: 1 needle per vial, 23g x 25mm
- Cotton wool balls (2 per number of vaccinees)
- A safety box for disposal of used syringes and needles (1 per 100 doses supplied)
- Viricidal disinfectant, e.g., Biocide
- PPE -3 ply surgical masks for vaccinators and boxes of gloves
- Sterile water for irrigation for sites with no running water
- Handwash and alcohol-based (70%) sanitizer



VACCINE STOCK & WASTAGE MANAGEMENT

Vaccine Stock Management

- MVA-BN vaccine will NOT be recorded on SVS
- Manual stock cards should be kept
- Facilities in selected districts should not order more than 1 month supply from the provincial depot
- The calculation of required doses should be based on the target population and session size:
- The estimated volume of vaccine required to reach the target population in these 3 provinces are 40 000 MVA-BN doses
- Initially only 10 700 doses will be available - 26, 75 % of the need
- Selected facilities should initially target only 26,75 % of the target population and order the vaccines for the 1st dose and the 2nd dose separately to ensure the expiry date at 2-8C can be utilized optimally.

Quantification

MVA-BN vaccine required (Clinic A) = number of persons in the target population (X) x wastage multiplication factor (1,05) x number of doses to be administered (2) x expected coverage (100%)

If X = 200

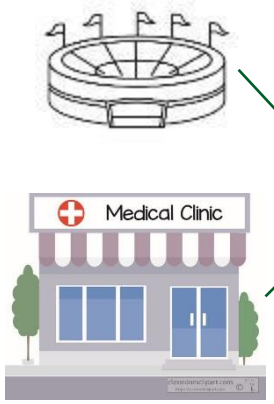
MVA-BN vaccine required (Clinic A) 1st dose = 200 x 1,05 x 1 x 1

= 210 doses required for the target population

Ensure stock on hand does not exceed a 1 month supply

Record keeping

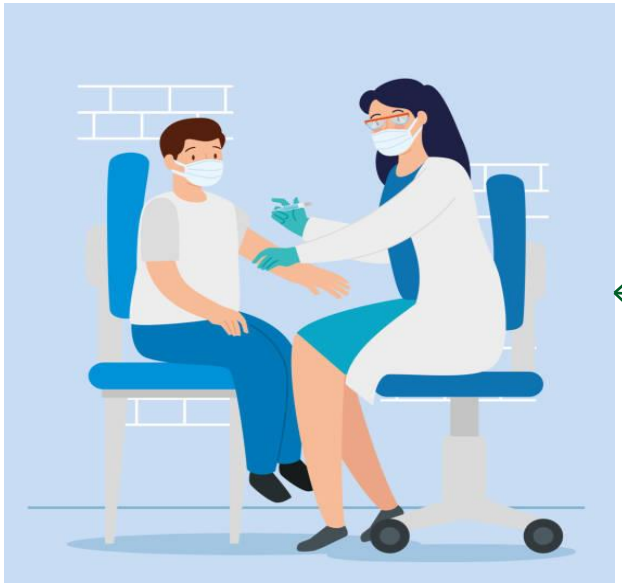
Record the number of vials

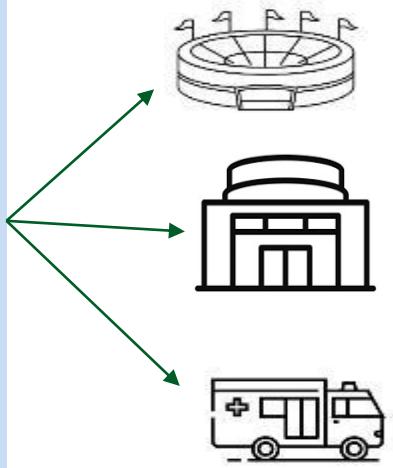


Medicine store-room or Pharmacy

Use Stock card

Vaccination Station





Record vaccine movement on a tally sheet or vaccine stock card

Stock Cards

- **The stock card is used to record and monitor orders, receipts issues and disposal of stock**
- **Transactions entered on stock cards:**
- **Receipts (+):** These include receipts from any supplier, such as the Hospital or another facility
- **Issues (-):** These include issued to the consulting rooms or other facilities. Goods returned to the Supplier should be recorded as an issue.
- **Stock adjustment (+/-):** After stock take of physical count the required adjustments are entered on the stock cards.
- **Vaccine wasted / disposed (-)**

ANNEXURE E: VACCINE STOCK CARD

VACCINE STOCK CARD												
Facility Name:												
Product:					Strength:				Presentation:			
ICN/NSN/Stock Number :					Issue Unit:				Max Stock Level:			
Order Frequency:			Lead Time:			Maximum Stock Factor:				Re-order Factor:		

Date	Start/ Opening Balance	Transaction Number	Quantity Ordered	Quantity Received	Quantity Issued	Issued To	No. of vials Discarded Unopened	No. of vials Opened for Use	Batch Number	Expiry date	End/ Closing Balance	Remarks and Initials

TOTAL MONTHLY ISSUES FOR USE IN OWN FACILITY

Financial Year	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Average Monthly Consumption
FY: /													
FY: /													

Calculating Vaccine Wastage

THE NUMBER OF **VACCINE DOSES** AND **NOT** THE NUMBER OF **VACCINE VIALS**

WILL BE USED IN ALL VACCINE WASTAGE CALCULATIONS

Wastage Calculations: Storage Level

- Should be calculated monthly using the physical stock cards.
- All discarded doses should be divided into the following categories in a loss/variance report:
  - Exposure to freezing
  - Exposure to heat
  - Expired vaccines
  - Damaged vaccines
  - Missing vaccine

ANNEXURE D: STOCK LOSS REPORT

STOCK LOSS / STOCK VARIANCE / EXPIRED STOCK REPORT								
Name of The Store			Financial Year:		Pharmacy Manager Signature:	Name Signature		
Month:		Document Number:			Authorized Person:	Name Signature		
ICN / NSN	Product Description		Unit	Quantity stock discarded/missing	The estimated value of discarded/missing inventory	Transaction number of the stock system	Remarks	
Nature of loss (indicate total quantity throughout the month)								
Quantity damaged during transit	Quantity damaged during storage	Quantity discarded due to VVM discard point	Quantity discarded due to Freezing	Quantity discarded due to Expiry	Quantity discarded due to Heat Exposure	Quantity discarded due to Breakage	Quantity discarded as Missing Inventory	Quantity discarded due to another reason
Recommendations for corrective actions and disposal								
Property Survey Board Submission List of documents attached to the report (photos, claim, laboratory analysis, batch & expiry dates…)								
Board of Survey Chairperson:			Signature:			Date Evaluated/Approved:		

Wastage Calculations: Storage Level

- The formula for calculating vaccine wastage at storage level:

$$\textit{Proportional vaccine wastage rate in unopened vials wastage} = \frac{\textit{Number of doses discarded}}{\textit{Start balance + number of doses received}} \times 100$$

- A large volume of vaccines is usually stored at these facilities
- Any cold chain failure would have a significant impact on vaccine availability at the lower levels of distribution.
- There is no acceptable wastage rate at the storage level, as vaccine wastage at this level is considered avoidable and should be zero

Wastage Calculations: Service Delivery Level

- Calculating wastage at service delivery level requires different data elements which should be collected while providing immunisation services
- A vaccine stock card is included in the guide, to ensure all relevant data elements are collected and could be used in all immunisation rooms, hospital wards where immunisation is provided.
- This include:

ANNEXURE E: VACCINE STOCK CARD

VACCINE STOCK CARD

Facility Name:												
Product:					Strength:				Presentation:			
ICN/NSN/Stock Number :					Issue Unit:				Max Stock Level:			
Order Frequency:			Lead Time:			Maximum Stock Factor:				Re-order Factor:		

Date	Start/ Opening Balance	Transaction Number	Quantity Ordered	Quantity Received	Quantity Issued	Issued To	No. of vials Discarded Unopened	No. of vials Opened for Use	Batch Number	Expiry date	End/ Closing Balance	Remarks and Initials

TOTAL MONTHLY ISSUES FOR USE IN OWN FACILITY

Financial Year	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Average Monthly Consumption
FY: /													
FY: /													

Wastage Calculations: Service Delivery Level

- The accurate collection of data should be ensured through the training and commitment of all relevant stakeholders including vaccinators, vaccine handlers, pharmacist assistants, pharmacists, and operational managers.
- When calculating the vaccine wastage, the data should be collected on the vaccine stock card (Annexure E) and converted to the number of **DOSES** (for Mpox 1 vial =1 dose) before wastage calculations are conducted

Always start by calculating vaccine usage

Wastage Calculations: Service Delivery Level

The formula for calculating vaccine usage at the service delivery point is as follows:

$$\text{Vaccine usage (rate)} = \frac{\text{Number of doses administered (a)}}{\text{Number of dose issued (b)}} \times 100$$

This data is collected on the tally sheet (a): The number of doses administered in the vaccination room or site

This data is collected on the stock card (b): The number of vials issued to the vaccination room / site

Wastage Calculations: Service Delivery Level

OR

$$\text{Vaccine usage (rate)} = \frac{\text{Number of doses administered}}{(\text{Number of usable doses at beginning of period}) + (\text{Number of doses received during period}) - (\text{Number of usable doses in stock at end of period})} \times 100$$

The challenge with calculating wastage in this way- **it does not indicate what proportion of the wastage was avoidable or unavoidable**

Vaccine Wastage Monitoring Tool

ANNEXURE G: SERVICE DELIVERY POINT MONTHLY REPORTING TOOL

VACCINE WASTAGE MONITORING TOOL FOR WARDS/IMMUNISATION ROOM

		Vaccine Name		
Facility Name		Reporting Period	*Month*	*Year*
District		Sub-district		
Average Monthly Live Births/ Target Population				

Date	Start Balance	Number of doses received	Number of doses discarded Unopened	Number of doses Opened for use	Number of children immunized	End Balance
	A	B	C	D	E	F= (A+B) - (C+D)

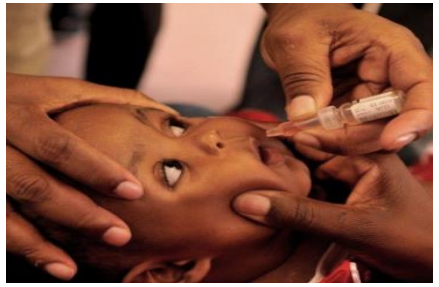
Monthly Facility Report

Rate	Formula	Monthly Result
Vaccine Usage Rate	H=(E x 100)/(A + B - F)	
Vaccine Wastage Rate (overall)	100 H	
Proportional wastage rate in unopened vials	(C x 100)/(A + B - C)	
Proportional wastage rate in opened vials	(D - E) x 100/D	
Unopened-vial-specific wastage rate	(C x 100)/(A + B - F)	
Opened-vial-specific wastage rate	(D - E) x 100/(A + B - F)	
Immunisation coverage rate	DHIS Data	

COMPLETED BY:

FULL NAME	DESIGNATION	DATE

For multi-dose vials, the data must be captured in doses instead of vials e.g. Measles: 1 vial = 10 doses



INFORMATION, MONITORING & DATA MANAGEMENT

Summary of Key Indicators

Category	Indicator	Disaggregation	Data Source
Vaccination Sites	Number of vaccination sites meeting compliance criteria	Public sector: province, district	MFL
	Number of sites approved for Mpox vaccination services	Public sector: province, district	MFL
Vaccinators	Number of vaccinators allocated per site	Public sector: province, district	Province/District
	Number of vaccinators trained for Mpox vaccination	Public sector: province, district	Province/District
Mpox Vaccine Supply Chain	Number of vaccines procured	National Department of Health	Supplier contracts, stock received at central stores
Mpox Vaccine Supply Chain	Number of vaccine doses distributed/allocated to sites	Public sector: province, district and vaccination site	Stock Visibility System
Mpox Vaccine Supply Chain	Percentage of sites reporting vaccine stock shortages	Public sector: province, district and vaccination site	Stock Visibility System
Vaccination Coverage	Percentage of people fully vaccinated against Mpox	Geographic coverage, age categories, gender, vaccine type and public vaccination sites	DHIS2

Summary of Key Indicators *(Continued)*

Category	Indicator	Disaggregation	Data Source
Vaccination Coverage	Proportion of the target population fully vaccinated against Mpox	Geographic coverage, age categories, gender, vaccine type, public health vaccination sites, beneficiary group	DHIS2
Dose Uptake	Rate of uptake for the first dose of the vaccine	Geographic coverage, age categories, gender, vaccine type, public health vaccination sites, beneficiary group	DHIS2
Drop-out	Drop-out rate between the first and second doses (for two-dose vaccines)	Geographic coverage, age categories, gender, vaccine type, public health vaccination sites, beneficiary group	DHIS2
Adverse Events Following Immunization	Number of vaccinated individuals reporting serious adverse events	Geographic coverage, age categories, gender, public health vaccination sites, beneficiary group	Vaccine AEFI system & SAHPRA
Post-vaccination Mpox Infection	Post-vaccination Mpox infection rate	Geographic location, cases, admissions, mortality	NMC

Mpox Vaccination Collection Tool: Vaccination Card

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MPOX VACCINATION RECORD CARD

VACCINEE DETAILS

Surname														
First Name(s)														
Identity Number/ Passport Number														
Next appointment date														

VACCINE DOSE	VACCINE NAME	MANUFACTURER	BATCH NUMBER	VACCINE DATE					
1st Dose									
2nd Dose									

VACCINATOR'S DETAILS

1st Dose	Surname	
	First Name(s)	
	Signature	
2nd Dose	Surname	
	First Name(s)	
	Signature	

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Mpox Vaccination Collection Tool: Register Cover page

MPOX TICK REGISTER	
Facility Name:	
District:	Sub-District:
Starting Date:	
Ending Date:	

Mpox Vaccination Collection Tool: Instructions to fill in the register

INSTRUCTIONS TO FILL IN

a	Month/Year	Enter the month and year in which the Mpox vaccination took place
b	Date	Enter the date on which the Mpox vaccination took place.
c	Name & Surname	Enter the Name of the client, followed by the Surname of the client.
d	Unique identifying number	Enter the full South African ID number of the client, a passport number for clients without a South African ID, Assylum seeker or Patient Folder Number.
e	Age	Enter the clients numeric age (a number) during the time of the vaccination
f	Gender	Write in full "Female" if the client is female and "Male" if the client is a male.
g	High risk population	Write the acronym of the relevant category as indicated by the client.
		MSM stands for a men who have sex with men.
		SW stands for an individual who provide sexual services for a fee.
		HCW stands for People with certain occupational risks, such as healthcare workers or laboratory personnel working with orthopoxviruses.
		II stands for Immunocompromised individuals
		Other: Stands for other higher risk group not included in the above categories
h	Contact of the confirmed case	Contacts of confirmed cases: Those who have had prolonged close contact with an individual diagnosed with mpox are typically recommended to receive the vaccine to prevent the spread of the virus.
i	Vaccine administrator	The clinicial who will be administering the vaccine
j	Comments	Enter any important information such as: any side effects

Mpox Vaccination Collection Tool: Register

Month: **Year:**

Row number	Unique identifier (Folder number ID/passport)	Name and Surname	Gender (Male/Female) F/M	Age	Address	Contact Number	High risk population					Contact of confirmed case	Date of first dose	Mpox Vacc first dose	Batch No	Date of second dose	Mpox Vacc second dose	Batch No	Vaccine administrator	Comment
							MSM	Sex workers	Health care worker	Immunocompromised individuals	Other									
1																				
2																				
3																				
4																				
5																				
6																				
7																				
8																				
9																				
10																				
11																				
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Total																				

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Mpox Vaccination Collection Tool: Monthly Summary

MONTHLY SUMMARY SHEET

Start a new page for a new month

MONTH & YEAR: _____

Indicators (data source)	Gender		Age	
	Male	Female	<18 years	>18 years
# MSM				
# Sex workers				
# Health care workers				
# Contact of the confirmed case				
# Immunocompromised				
# Other				
Total				

Complied by:

Name: _____ **Date:** _____ **Sign:**

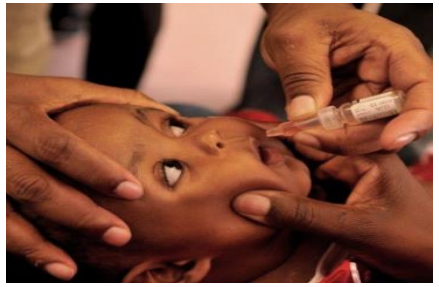
Reviewed by:

Name: _____ **Date:** _____ **Sign:**

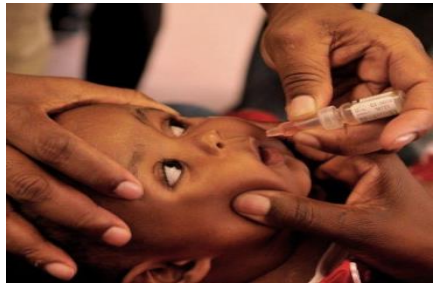
health
Department:
Health
REPUBLIC OF SOUTH AFRICA

2030 NDP

30 YEARS OF FREEDOM
South Africa 1994 - 2024



VACCINE SAFETY SURVEILLANCE



Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN): Vaccine Safety Surveillance

Presentation Outline

- Aim and objectives of **Adverse Events Following Immunisation** (AEFI) Surveillance
- Vaccine Safety Surveillance Types
- Vaccine Safety Surveillance Cycle in SA
- MVA-BN Surveillance
- MVA-BM Vaccine Profile
- Adverse Events Following Immunisation
- Causality Assessment Classification
- MVA-BN Vaccine AEFIs/Side Effects
- Contraindications
- Clinical Features of Anaphylaxis
- Anaphylaxis Management
- Management of AEFIs and AESIs
- Post–vaccination Recommendations
- Events related to immunisation-error
- Prevention of Immunisation Error-Related AEFI
- Case Reporting & Investigation
- Health Facility Pharmacovigilance Requirements
- AEFI Reporting
- Causality Assessment of AEFIs and AESIs
- Key Points for Communicating with MVA-BN Vaccine Recipients
- PV Surveillance Requirements
- Challenges in Vaccine Safety Surveillance
- Conclusion
- References

Presentation Outline

Aim:

- The purpose of monitoring adverse events following MVA-BN vaccine administration is to ensure safety, inform risk-benefit assessments, and continuously improve immunization practices

Specific Objectives:

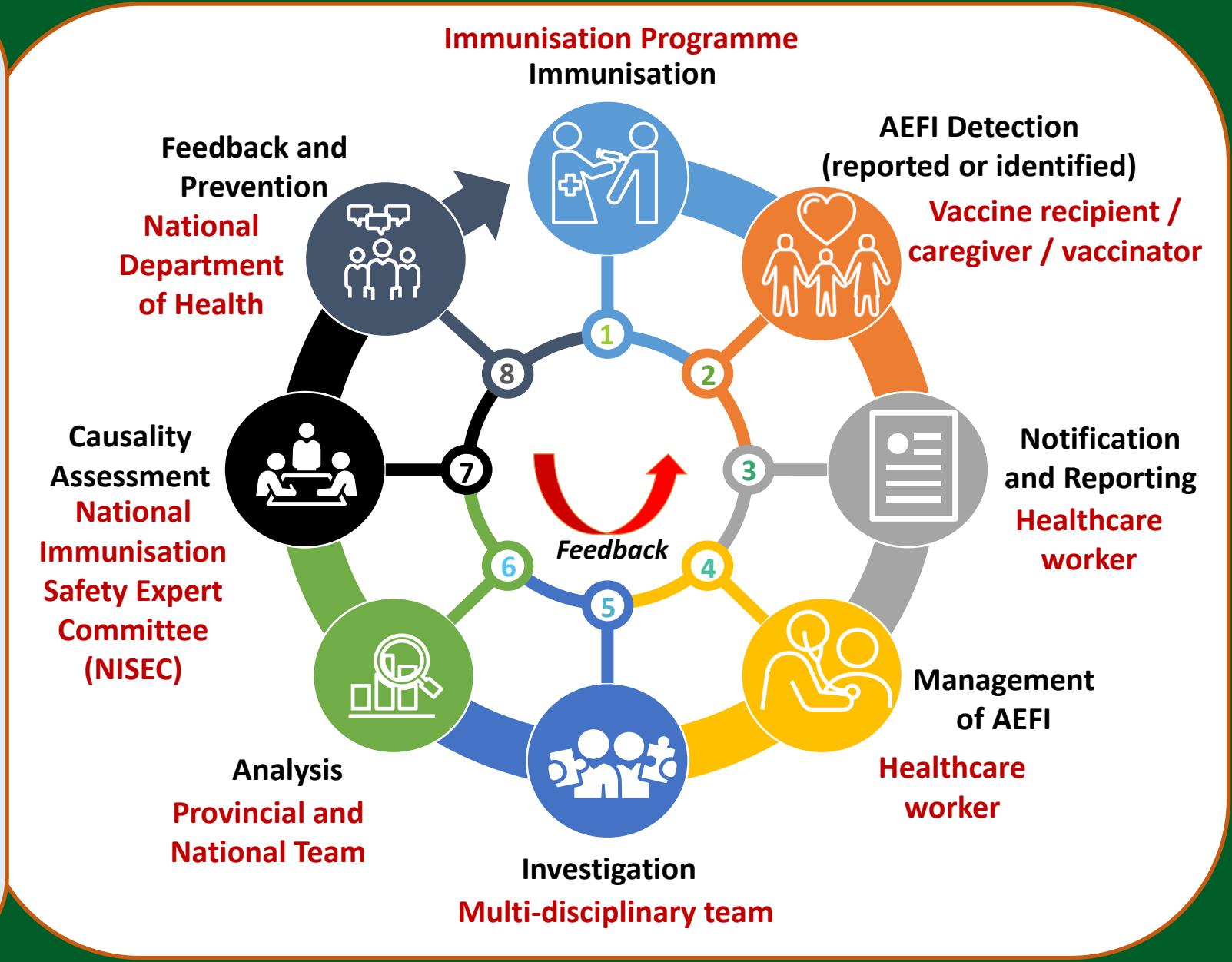
- Detection of Adverse Events
- Evaluation and Causality Assessment
- Risk Assessment
- Safety Monitoring
- Communication and Public Trust
- Strengthening Immunization Programs
- International Collaboration

Vaccine Safety Surveillance Types

- **Passive:** Relies on healthcare providers and public reports
- **Active:** Systematic follow-ups with vaccinated individuals
- **Enhanced**: Increased scrutiny during specific periods (e.g., outbreaks)
- **Pharmacovigilance:** Monitoring the effects of vaccines post-marketing and administering
- **Registry-Based:** Using health databases for monitoring
- **Community-Based Reporting:** Engaging the public for direct feedback

Vaccine safety surveillance cycle in SA

- Vaccine Manufacturing Industry
- South African Health Products Regulatory Authority (SAHPRA)
- National Department of Health (NDoH)
- World Health Organization (WHO)
- Ministerial Advisory Committees on Vaccines and Immunisation



MVA-BN Active Surveillance

- The National Department of Health does not plan to establish sentinel sites for active surveillance but will monitor AESIs through the existing safety network, as described in the *Vaccine Safety Surveillance in South Africa: Manual for Surveillance and Response to AEFI*
- AESIs will be recorded using standard forms and included in the national AEFI line list, with causality assessments conducted per WHO methodology using Brighton Collaboration case definitions

MVA-BN Vaccine profile

- **Clinical Trial Data**:
  - Over 7,800 participants; consistently showed a favorable safety profile
  - Extensive use during the 2022 mpox outbreak with over a million doses administered
  - Rare but serious effects: no significant myocarditis risk
- **Safety in Special Populations**:
  - Safe for immunocompromised individuals
  - Limited data but no safety concerns in pregnant and breastfeeding women
  - MVA-BN vaccine, is a non-replicating
    - ✓Cannot reproduce in human cells, making it safer for individuals with conditions like pregnancy compared to other live replicating vaccines
  - Well-tolerated in adolescents

AEFI: Definition

An AEFI is any untoward medical occurrence (unfavourable or unintended sign, abnormal laboratory finding, symptom or disease) which follows immunisation, and which does not necessarily have a causal relationship with the

usage of the vaccine.

Causality Assessment Classification

Consistent with causal association to immunisation

A. Consistent with causal association to immunization

- ☐ A1. Vaccine product-related reaction (As per published literature)
- ☐ A2. Vaccine quality defect-related reaction
- ☐ A3. Immunization error-related reaction
- ☐ A4. Immunization anxiety-related reaction (ISRR**)

A1 Vaccine product-related reaction

Individual's response to **inherent properties** of vaccine, even when vaccine has been prepared, handled and administered correctly

A2 Vaccine quality defect-related reaction

Caused or precipitated by vaccine, due to one /more **quality defects of the product**, including its administration device, provided by manufacturer

A3 Immunisation error-related reaction

Caused by inappropriate vaccine **handling, prescribing** or **administration**

A4 Immunisation stress-related reaction

Arising from **anxiety** about the immunisation and **fear** of **injection** e.g. fainting

Causality Assessment Classification

Inconsistent with causal association to the immunisation

C. Inconsistent with causal association to immunization

C. Coincidental

☐ Underlying or emerging condition(s), or conditions caused by exposure to something other than vaccine

Event caused by something other than the vaccine product, immunisation error or immunisation anxiety

Coincidental event

An event that happens after vaccination but is not caused by the vaccine or vaccination process

Implications for immunisation programme

- **Potential comorbidities** → especially in elderly e.g. hypertension, diabetes, heart disease
- Coincidental events can occur in **healthy individuals** without comorbidities
- **Newly** acquired or diagnosed **illness**
- **Spontaneous** occurrence of an event without known risk factors
- Other **exposures** to drugs or toxins prior to event
- Surgical or other **trauma** leading to a **complications**
- Estimate **population-based background rates**
  - Pre-specified adverse events of special interest
  - Mortality per age group / disease

MVA-BN Vaccine AEFIs/Side Effects

Common Side Effects

- Injection Site Reactions:
  - Redness, Swelling, Pain or tenderness, Induration (hardened area), Itching
- Systemic Reactions:
  - Fatigue, Headache, Muscle pain (myalgia), Nausea, Mild fever, Chills
- Less Common Side Effects:
  - Lymphadenopathy (swelling of lymph nodes)
  - Allergic Reactions: Rash or hives, Mild hypersensitivity reactions
  - Localized Skin Reactions: Bruising or discoloration at the injection site

Rare but Serious Side Effects

- Severe Allergic Reactions:
  - Anaphylaxis (immediate medical attention required if difficulty breathing or swelling occurs)
- Myocarditis or Pericarditis:
  - No significant increase was observed compared to the general population

Safety in Special Populations Immunocompromised Individuals:

- It is safe for individuals with weakened immune systems.
- Pregnant and Breastfeeding Women:
  - Data are limited, but the vaccine is considered safe when the benefits outweigh the risks.
- Children and Adolescents:
  - Well-tolerated with a safety profile similar to adults

Contraindications

- The **MVA-BN vaccine** should **not** be administered to individuals with known allergies to any of its components, including:
  - ✓**Chicken Protein**: Derived from the vaccine production process
  - ✓**Benzonase**: An enzyme used during manufacturing
  - ✓**Gentamicin**: An antibiotic used as a preservative

- Record: The individual's medical history and any potential contraindications

Clinical Features of Anaphylaxis

Acute onset of signs and symptoms:

- Urticaria (hives) or angioedema
- Bronchospasm, wheezing, dyspnoea, chest tightness
- Laryngeal oedema with upper airway obstruction or stridor
- Gastrointestinal symptoms such as nausea, vomiting, diarrhoea
- Hypotension and/or shock
- Dizziness, paraesthesia, syncope, sweating, flushing, dysrhythmias

Anaphylaxis Management

- The standard treatment guidelines for managing anaphylaxis are outlined in the *VACCINE SAFETY SURVEILLANCE IN SOUTH AFRICA: Manual for Surveillance and Response to Adverse Events Following Immunisation*
- The required items should be included in an AEFI management kit, along with the Case Reporting Forms (CRFs)
- Ensure anaphylaxis kits are also accessible at outreach sites
- All cases of anaphylaxis should be recorded immediately

Management of AEFI and AESIs

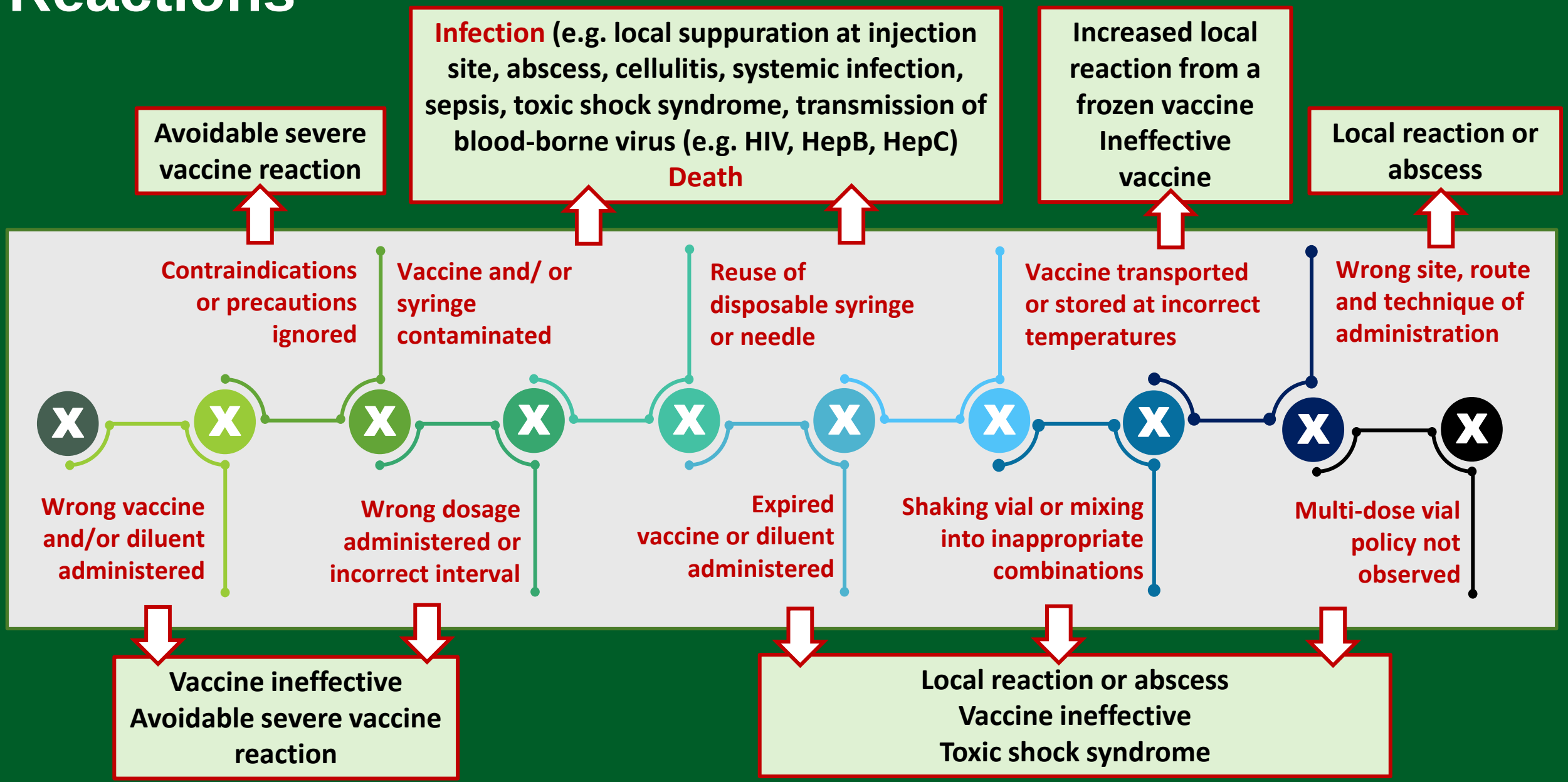
- AEFI/AESIs should be managed in line with the standard treatment guidelines
- The AEFI must be reported, and clinical records should be available at the time of AEFI/AESI investigation
- All vaccination teams have the capability, tools, knowledge, and access to the medicines and equipment needed to manage anaphylaxis should it happen

Post-Vaccination Recommendations

- **Monitor Symptoms**:
  - Most side effects resolve on their own, but medical advice should be sought if severe or prolonged reactions occur

- **Symptomatic Treatment**:
  - Over-the-counter pain relievers (e.g., Paracetamol or ibuprofen) for pain or fever
  - Cold compresses for injection site discomfort

Events Related to Immunisation Error-Related Reactions



Prevention of Immunisation Error-Related AEFI

Follow the manufacturer's recommendations and train healthcare providers on vaccine **preparation, route & technique of administration**.

Cold chain management:

- Check the **expiry-** or **manufacturing date.**
- Check for signs of **freezing**. Use conditioned ice packs for cooler boxes.
- Recommended temperature: between 2°C and 8°C.

NB: Do NOT use beyond specifications

Screen for:

- **contraindications** to vaccination e.g. previous anaphylaxis. If any contraindications → do NOT vaccinate
- confirm eligibility for approved age and risk categories
- **precautions** and determine if the benefits of the vaccine outweigh the risks. If any precautions → vaccinate with CAUTION

Accurate Administration:

- **Draw the vaccine into the syringe** just before vaccination and **do not touch** the **needle** to avoid contamination of the vaccine and/or the syringe
- Ensure the correct dose(0.5 mL subcutaneously)
- Use the appropriate site, such as the upper arm (deltoid)
- Administer MVA-BN subcutaneously

NB! Ensure documentation (i.e. maintain records) and communication

Establish clear protocols for reporting immunization errors

Quality Assurance, Audits Regular Inspections and Feedback Mechanisms:

- Conduct routine checks of vaccine storage facilities and administration sites
- Provide regular feedback to healthcare providers to correct practices and prevent future errors

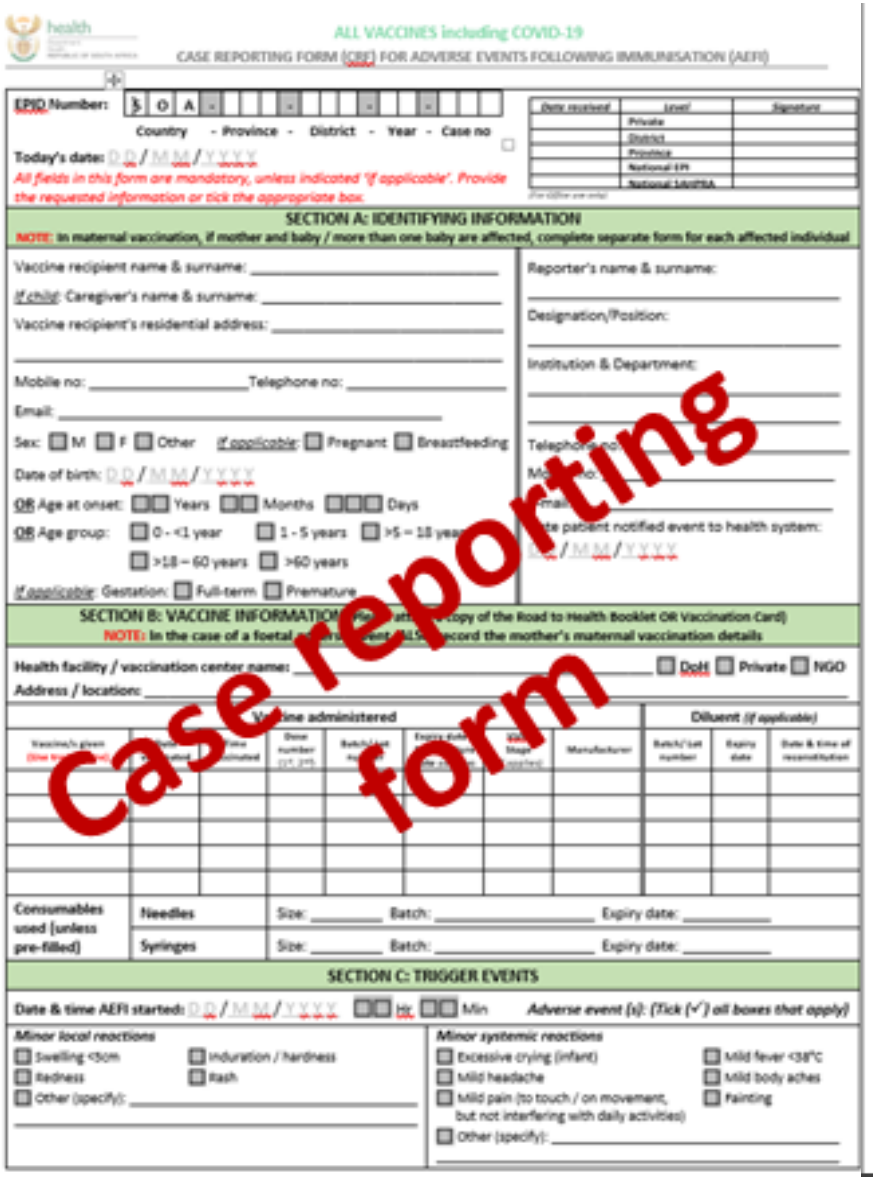
NB! If in doubt, contact your supervisor for clarification. Do not hesitate to report issues or concerns when identified.

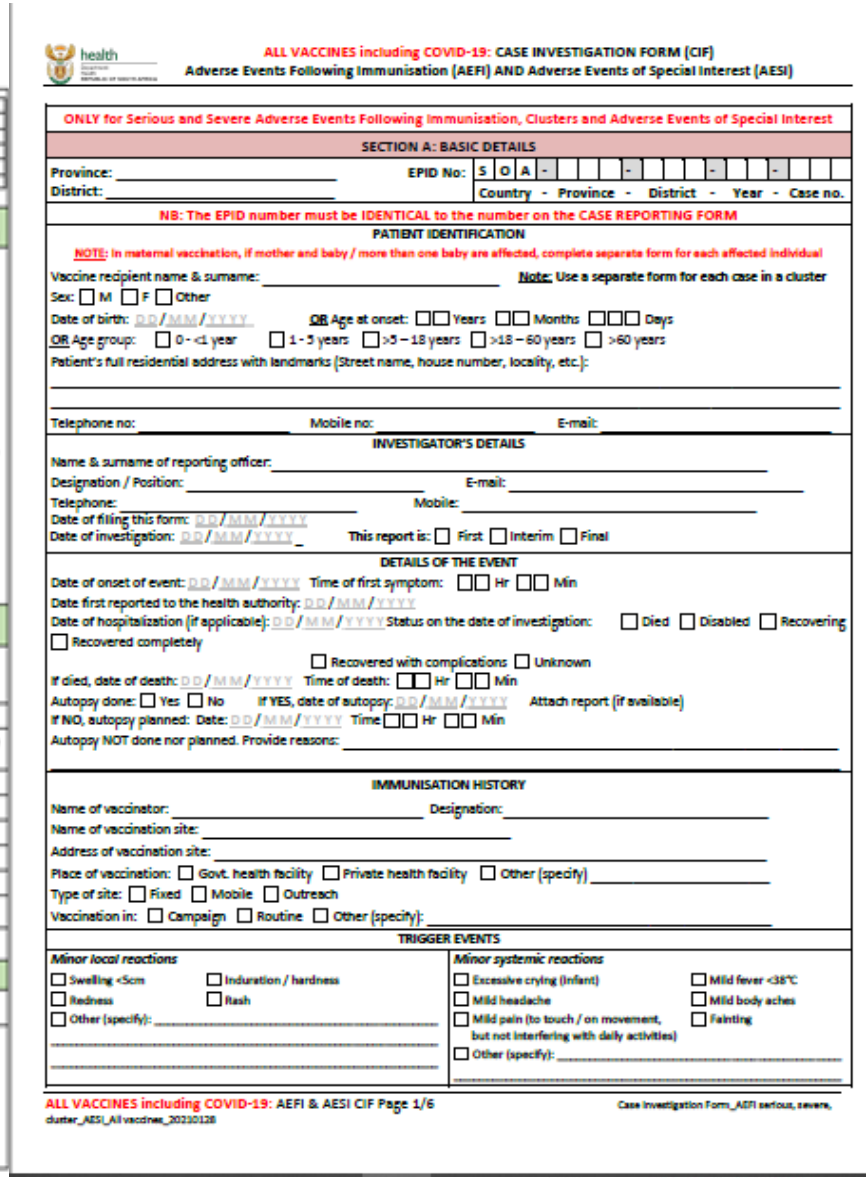
Post-Vaccination Recommendations

- The CIF collects clinical information to determine the certainty of reported AEFIs and AESIs

Med Safety App

Electronic reporting



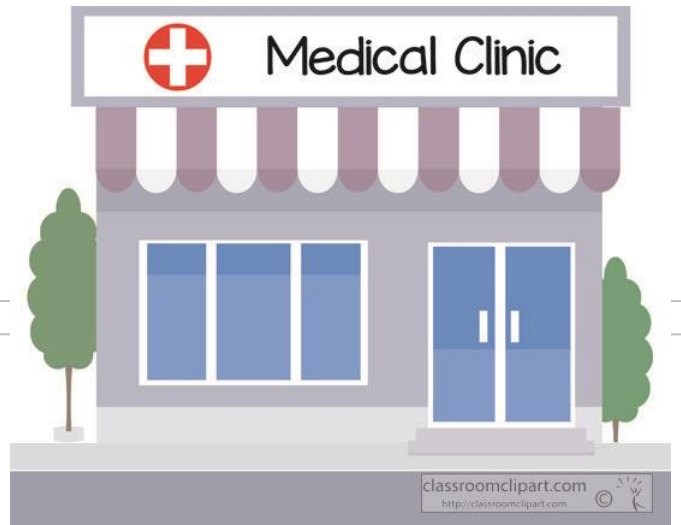


health
Department:
Health
REPUBLIC OF SOUTH AFRICA

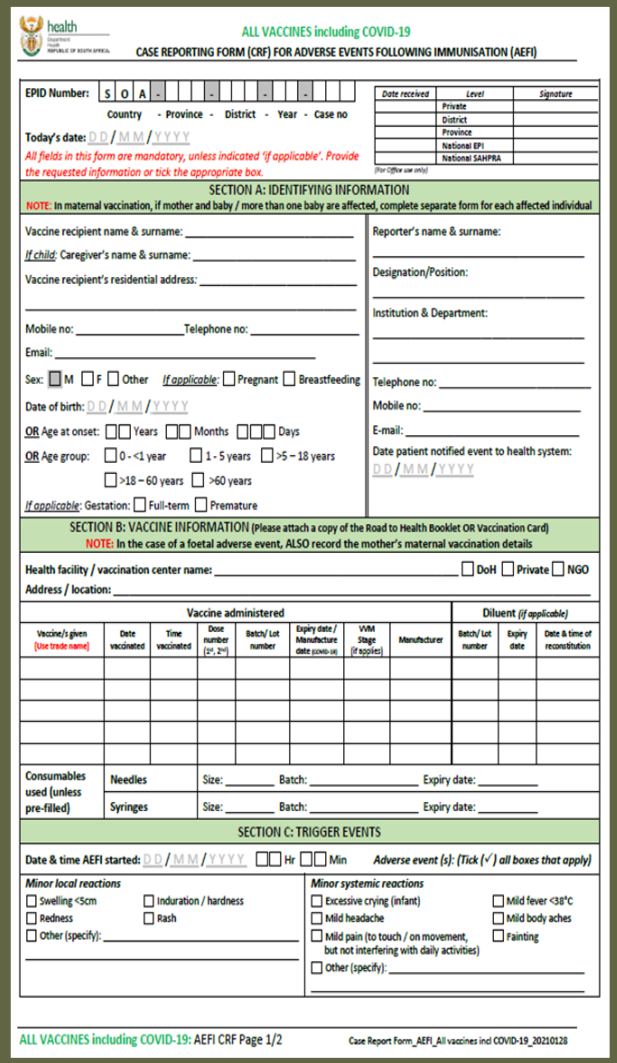
Health Facility Pharmacovigilance Requirements

Pharmacovigilance (PV) responsibilities:

- Vaccinee Counselling
- Identification of AEFI & AESI
- Treatment of AEFI & AESI
- Notification of AEFI & AESI
- Reporting of AEFI & AESI
- Providing feedback to the vaccinee, community



AEFI


ALL VACCINES including COVID-19
CASE REPORTING FORM (CRF) FOR ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

EPID Number: S O A - - - - - - - - - -
Country - Province - District - Year - Case no

Today's date: D D / M M / Y Y Y Y

All fields in this form are mandatory, unless indicated 'if applicable'. Provide the requested information or tick the appropriate box.

Date received	Level	Signature
	Private	
	District	
	Province	
	National EPI	
	National SAHPRA	

(For Office use only)

SECTION A: IDENTIFYING INFORMATION

NOTE: In maternal vaccination, if mother and baby / more than one baby are affected, complete separate form for each affected individual

Vaccine recipient name & surname:
If child: Caregiver's name & surname:
Vaccine recipient's residential address:
Mobile no: Telephone no:
Email:
Sex: M F Other If applicable: Pregnant Breastfeeding
Date of birth: D D / M M / Y Y Y Y
OR Age at onset: Years Months Days
OR Age group: 0 - <1 year 1 - 5 years >5 – 18 years >18 – 60 years >60 years
If applicable: Gestation: Full-term Premature

Reporter's name & surname:
Designation/Position:
Institution & Department:
Telephone no:
Mobile no:
E-mail:
Date patient notified event to health system: D D / M M / Y Y Y Y

SECTION B: VACCINE INFORMATION (Please attach a copy of the Road to Health Booklet OR Vaccination Card)
NOTE: In the case of a foetal adverse event, ALSO record the mother's maternal vaccination details

Health facility / vaccination center name: DoH Private NGO
Address / location:

Vaccine administered								Diluent (if applicable)		
Vaccine/s given (Use trade name)	Date vaccinated	Time vaccinated	Dose number (1st, 2nd)	Batch/ Lot number	Expiry date / Manufacture date (COVID-19)	VVM Stage (if applies)	Manufacturer	Batch/ Lot number	Expiry date	Date & time of reconstitution

Consumables used (unless pre-filled): Needles Size: Batch: Expiry date:
Syringes Size: Batch: Expiry date:

SECTION C: TRIGGER EVENTS

Date & time AEFI started: D D / M M / Y Y Y Y Hr Min *Adverse event (s): (Tick (✓) all boxes that apply)*

Minor local reactions
Swelling <5cm Induration / hardness
Redness Rash
Other (specify):

Minor systemic reactions
Excessive crying (infant) Mild fever <38°C
Mild headache Mild body aches
Mild pain (to touch / on movement, but not interfering with daily activities) Fainting
Other (specify):

ALL VACCINES including COVID-19: AEFI CRF Page 1/2 Case Report Form_AEFI_All vaccines incl COVID-19_20210128

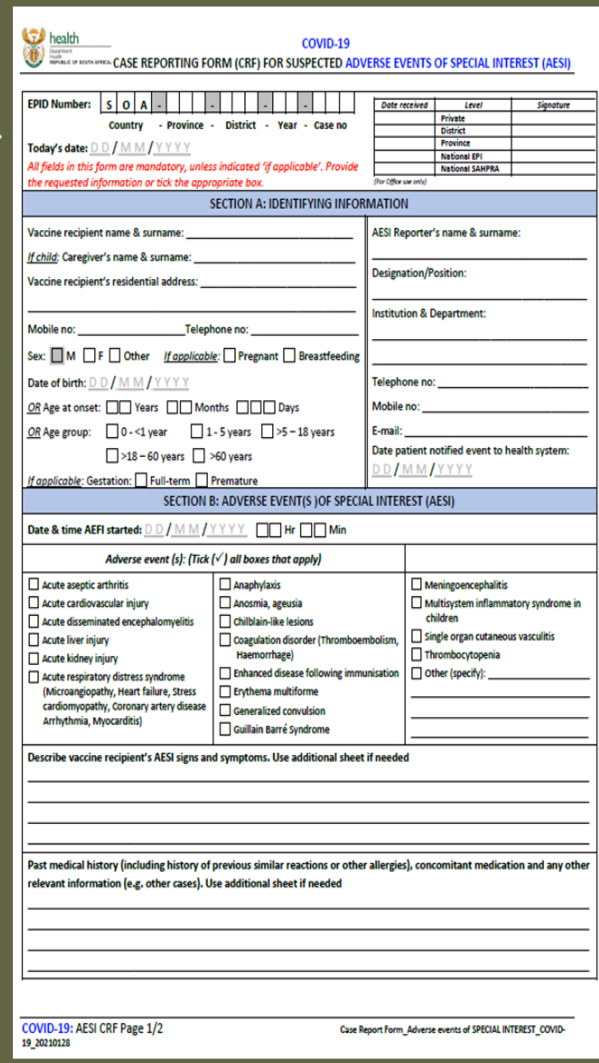
Paper-based reporting

Email all documentation to:
AEFI@health.gov.za

Med Safety App

Electronic reporting

AESI


COVID-19
CASE REPORTING FORM (CRF) FOR SUSPECTED ADVERSE EVENTS OF SPECIAL INTEREST (AESI)

EPID Number: S O A - - - - - - - - - -
Country - Province - District - Year - Case no

Today's date: D D / M M / Y Y Y Y

All fields in this form are mandatory, unless indicated 'if applicable'. Provide the requested information or tick the appropriate box.

Date received	Level	Signature
	Private	
	District	
	Province	
	National EPI	
	National SAHPRA	

(For Office use only)

SECTION A: IDENTIFYING INFORMATION

Vaccine recipient name & surname:
If child: Caregiver's name & surname:
Vaccine recipient's residential address:
Mobile no: Telephone no:
Sex: M F Other If applicable: Pregnant Breastfeeding
Date of birth: D D / M M / Y Y Y Y
OR Age at onset: Years Months Days
OR Age group: 0 - <1 year 1 - 5 years >5 – 18 years >18 – 60 years >60 years
If applicable: Gestation: Full-term Premature

AESI Reporter's name & surname:
Designation/Position:
Institution & Department:
Telephone no:
Mobile no:
E-mail:
Date patient notified event to health system: D D / M M / Y Y Y Y

SECTION B: ADVERSE EVENT(S)OF SPECIAL INTEREST (AESI)

Date & time AEFI started: D D / M M / Y Y Y Y Hr Min

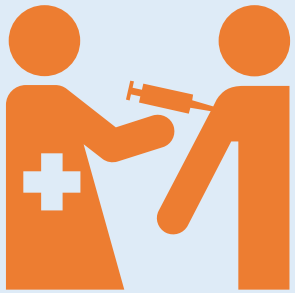
Adverse event (s): (Tick (✓) all boxes that apply)

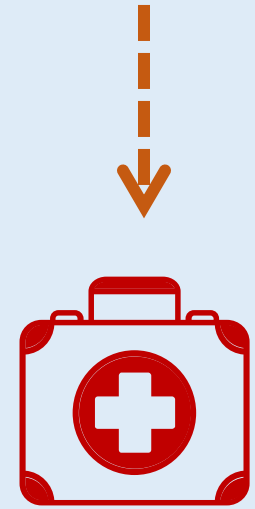
Acute aseptic arthritis
Acute cardiovascular injury
Acute disseminated encephalomyelitis
Acute liver injury
Acute kidney injury
Acute respiratory distress syndrome (Microangiopathy, Heart failure, Stress cardiomyopathy, Coronary artery disease Arrhythmia, Myocarditis)
Anaphylaxis
Anosmia, ageusia
Chilblain-like lesions
Coagulation disorder (Thromboembolism, Haemorrhage)
Enhanced disease following immunisation
Erythema multiforme
Generalized convulsion
Guillain Barré Syndrome
Meningoencephalitis
Multisystem inflammatory syndrome in children
Single organ cutaneous vasculitis
Thrombocytopenia
Other (specify):

Describe vaccine recipient's AESI signs and symptoms. Use additional sheet if needed

Past medical history (including history of previous similar reactions or other allergies), concomitant medication and any other relevant information (e.g. other cases). Use additional sheet if needed

COVID-19: AESI CRF Page 1/2 Case Report Form_Adverse events of SPECIAL INTEREST_COVID-19_20210128





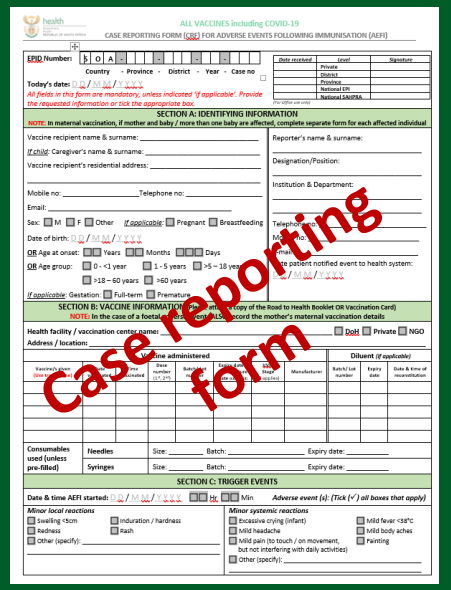
Adverse event of concern

Health facility

Med Safety App

MILD/MINOR EVENTS

Expected



Case reporting form

SEVERE EVENTS

Not expected

Arm is sore or red at the injection site

Fever/ chills

Headache

Fatigue

Muscle aches

Nausea

Investigated

Serious events

- Result in death
- Require inpatient hospitalisation
- Life threatening
- Result in persistent or significant disability/incapacity
- Congenital anomaly/birth defect
- Medically important event or reaction

Non-serious events

- Need clinical management
- Usually do not result in long-term problems

AEFI Reporting

AEFI Reporting:

- All AEFIs must be reported within 24 hours, following the procedures in the *Vaccine Safety Surveillance Manual*

AESI Reporting:

- Serious AEFIs are to be reported to SAHPRA and the NDoH/EPI within 24 hours

Patients and healthcare professionals can report AEFIs via the Med Safety App. Choose to report an AEFI not an ADR

- *For more information, visit the Med Safety App.*

District Requirements

District responsibilities:

- AEFI & AESI investigation
- Follow-up call centre
- District AEFI & AESI line list
- Allocation of EPID number to all cases
- Update cases on Vigilance hub
- Monitoring cases on Vigilance hub
- Providing feedback to the health care facility

health

ALL VACCINES including COVID-19: CASE INVESTIGATION FORM (CIF)
Adverse Events Following Immunisation (AEFI) AND Adverse Events of Special Interest (AESI)

ONLY for Serious and Severe Adverse Events Following Immunisation, Clusters and Adverse Events of Special Interest

SECTION A: BASIC DETAILS

Province: _____ EPID No: S O A - - - - - - - - - - - -
District: _____ Country - Province - District - Year - Case no.

NB: The EPID number must be IDENTICAL to the number on the CASE REPORTING FORM

PATIENT IDENTIFICATION

NOTE: In maternal vaccination, if mother and baby / more than one baby are affected, complete separate form for each affected individual

Vaccine recipient name & surname: _____ Note: Use a separate form for each case in a cluster
Sex: ☐ M ☐ F ☐ Other
Date of birth: DD/MM/YYYY OR Age at onset: ☐☐ Years ☐☐ Months ☐☐☐ Days
OR Age group: ☐ 0 - <1 year ☐ 1 - 5 years ☐ >5 – 18 years ☐ >18 – 60 years ☐ >60 years
Patient's full residential address with landmarks (Street name, house number, locality, etc.):
_____
_____
Telephone no: _____ Mobile no: _____ E-mail: _____

INVESTIGATOR'S DETAILS

Name & surname of reporting officer: _____
Designation / Position: _____ E-mail: _____
Telephone: _____ Mobile: _____
Date of filing this form: DD/MM/YYYY
Date of investigation: DD/MM/YYYY This report is: ☐ First ☐ Interim ☐ Final

DETAILS OF THE EVENT

Date of onset of event: DD/MM/YYYY Time of first symptom: ☐☐ Hr ☐☐ Min
Date first reported to the health authority: DD/MM/YYYY
Date of hospitalization (if applicable): DD/MM/YYYY Status on the date of investigation: ☐ Died ☐ Disabled ☐ Recovering ☐ Recovered completely
☐ Recovered with complications ☐ Unknown
If died, date of death: DD/MM/YYYY Time of death: ☐☐ Hr ☐☐ Min
Autopsy done: ☐ Yes ☐ No If YES, date of autopsy: DD/MM/YYYY Attach report (if available)
If NO, autopsy planned: Date: DD/MM/YYYY Time ☐☐ Hr ☐☐ Min
Autopsy NOT done nor planned. Provide reasons: _____

IMMUNISATION HISTORY

Name of vaccinator: _____ Designation: _____
Name of vaccination site: _____
Address of vaccination site: _____
Place of vaccination: ☐ Govt. health facility ☐ Private health facility ☐ Other (specify) _____
Type of site: ☐ Fixed ☐ Mobile ☐ Outreach
Vaccination in: ☐ Campaign ☐ Routine ☐ Other (specify): _____

TRIGGER EVENTS

Minor local reactions		*Minor systemic reactions*	
☐ Swelling <5cm	☐ Induration / hardness	☐ Excessive crying (Infant)	☐ Mild fever <38°C
☐ Redness	☐ Rash	☐ Mild headache	☐ Mild body aches
☐ Other (specify): _____		☐ Mild pain (to touch / on movement, but not interfering with daily activities)	☐ Fainting
		☐ Other (specify): _____	

ALL VACCINES including COVID-19: AEFI & AESI CIF Page 1/6
cluster_AESI_All vaccines_20210128
Case Investigation Form_AEFI serious, severe,

2030 NDP

30 YEARS OF FREEDOM
South Africa 1994 - 2024

District surveillance teams

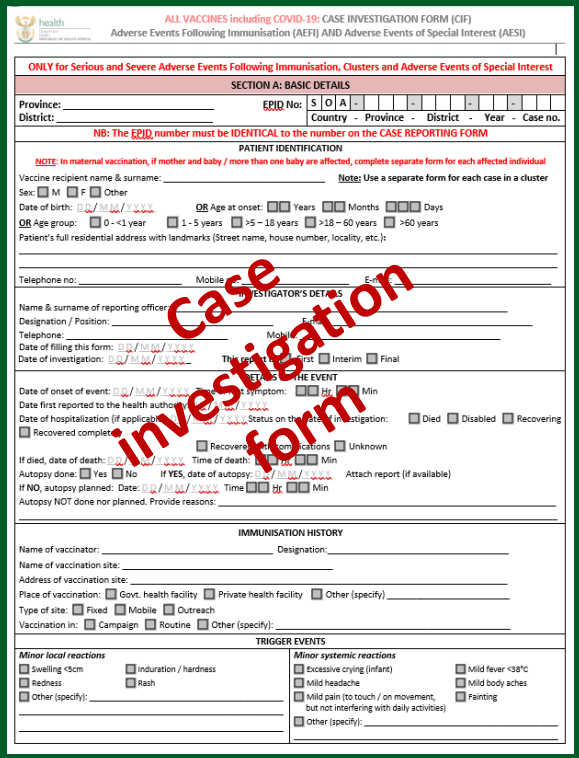
Multi-disciplinary

Case investigation

Investigation

Collect essential evidence:

- Personal details
- Vaccine administered
- AEFI experienced
- Dates of events
- Clinical notes
- Laboratory results
- Co-existing conditions
- Other medicines taken
- Previous allergies
- Autopsy report



NISEC SOUTH AFRICA National Immunisation Safety Expert Committee

Provincial AEFI Committee

Causality assessment

Causality assessment

Systematic review of data about AEFI case to determine the likelihood of a causal association between the event and the vaccine

Investigation of Events

- The district Investigation Team leads the response for AEFIs and AESIs requiring follow-up, starting investigations within 48 hours, and concluding within seven days
- Completed reports are submitted to the national AEFI coordinator and SAHPRA
- For complex cases, support may be sought from provincial and national levels, NISEC, WHO, and other partners

Provincial requirements

Responsibilities:

- Preliminary Causality assessment (PISEC)
- Provincial AEFI & AESI line list
- Update cases on Vigilance hub
- Monitoring cases on Vigilance hub
- Providing feedback to the district

Main responsibilities of Provincial AEFI Committees

- **Strengthen** AEFI **reporting** in the provinces
- Ensure maintenance of national **policy** and **standards**
- Ensure prompt and thorough **investigation** of severe and serious AEFI
- Carry out periodic **review** of AEFI for **trends** of non-serious AEFIs reported
- Respond to media and **community concerns** → allay fears regarding vaccine safety
- Ensure high **AEFI surveillance** standards→ ensure no serious AEFI are missed

Experts serving on the committee

- Assist in timely **assessment of causal association** between the vaccine and the event based on the WHO assessment and classification system
- Submit the **preliminary reports** of cases to the National Immunisation Safety Expert Committee (NISEC) for final independent assessment

National Requirements

Responsibilities:

- Causality assessment
- National AEFI & AESI line list
- Update cases on Vigilance hub
- Monitoring cases on Vigilance hub
- Providing feedback to the committee, provinces

Med Safety App

Reporting AEFI

1

- Complete case report form (CRF) for **ALL** detected AEFI and AESI cases
- Submit CRF within **24 hours** of detection or notification
- Complete line list

ALL cases of AEFI and AESI: Complete and submit CRF within 24 hours

2

AEFI and AESI Serious or severe cases and clusters

- Manage AEFI/AESI
- Arrange for case investigation by multi-disciplinary team, to be completed **within 48 hours**
- In case of a death, immediately inform District surveillance Officer via phone

3

- Case investigation by multi-disciplinary healthcare team in the district
- Submit completed CIF and documentation to District Surveillance Officer within **48 hours**

Conduct case investigation within 48 hours including the completed CIF

4

Line list Submit weekly

- Provincial AEFI Coordinators to submit updated line list on a weekly basis to the National AEFI Coordinator

5

- Follow-up on any outstanding documentation from the case investigation
- Submit for causality assessment by NISEC

Causality assessment completed by NISEC

6

Feedback and Prevention

- Follow-up on feedback from NISEC
- Communicate outcome of causality assessment with vaccine recipient
- Implement corrective measures in the case of programmatic errors

Causality Assessment of AEFIs and AESIs

- The National Immunisation Safety Expert Committee (NISEC) conducts causality assessments

- Since 2017, The NISEC's main purpose is to provide independent, authoritative, scientific advice and recommendations to the NDoH and SAHPRA on matters relating to immunisation safety and AEFI/AESI.

- The mandate of NISEC is therefore to review and assess serious and non-serious severe AEFI/AESI cases and AEFI clusters (serious and non-serious) submitted to the EPISA and SAHPRA

Communicating Points for MVA-BN Vaccine Recipients

- Acknowledge the Possibility of Adverse Events
- Emphasize the Vaccine's Safety Profile
- Contextualize Risk-Benefit Balance
- Set Clear Expectations
- Address Specific Concerns
- Build Trust Through Transparency
- Utilize Trusted Communication Channels
- Provide Reassurance on Monitoring and Response
- Counter Misinformation
- Encourage Open Dialogue
- Reinforce Key Messages
- Provide Resources and Support

Challenges in Vaccine Safety Surveillance

- Potential underreporting of adverse events
- Limited resources in rural healthcare facilities
- Variability in staff training and awareness levels
- Public scepticism and misinformation about vaccines
- Data management and analysis capabilities may be limited
- Need for continuous engagement and education efforts

Conclusion

- The vaccine is generally well-tolerated, with mild side effects being the most common
- The MVA-BN/JYNNEOS vaccine has demonstrated a favourable safety profile in both clinical trials and real-world use.
- Its safety profile makes it a preferred option for many populations, including those at higher risk of complications from live virus vaccines
- Ongoing safety surveillance is essential to promptly identify and address any potential adverse events, ensuring the continued safe use of the vaccine across diverse populations.
- Collaborative efforts across all levels are essential
- Encourage proactive engagement and reporting from all stakeholders
- Continuous monitoring strengthens confidence in vaccination programs

Key References

1. Brighton Collaboration Case Definitions(https://docs.google.com/spreadsheets/d/1QgF35nYcsaFN3DZTOtV_lP0TYqQzsDMUQBAd5M9brrM/edit#gid=1666959512)
2. VACCINE SAFETY SURVEILLANCE IN SOUTH AFRICA https://drive.google.com/file/d/1pY5qX9RFB8zxAhSSG0_tAJbZlk8uipT0/view?pli=1
3. JYNNEOS Package Insert: Provides comprehensive information on indications, dosage, administration, contraindications, and potential side effects. Drugs.com
4. European Medicines Agency (EMA) – Imvanex: Offers detailed insights into the vaccine's approval status, clinical efficacy, and safety profile within the EU. European Medicines Agency
5. Bavarian Nordic – MVA-BN Platform: Describes the vaccine's development, underlying technology, and its applications against various infectious diseases. Bavarian Nordic
6. Clinical Trial Data: Studies such as the Phase 2 randomized, open-label trial provide data on the vaccine's immunogenicity and safety across different populations. Clinical Trials
7. World Health Organization (WHO) Prequalification: In September 2024, WHO prequalified the MVA-BN vaccine, recognizing its safety and efficacy in preventing mpox. World Health Organization
8. WHO's causality assessment manual and a link to the WHO's eLearning course, can be accessed online at: https://gvsi-aefi-tools.org/.

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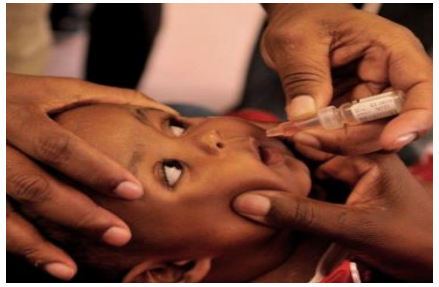


RISK COMMUNICATION AND COMMUNITY ENGAGEMENT (RCCE)

Introduction

- The objective of RCCE activities on the Mpox vaccination campaign is to **raise awareness** and to **increase uptake, thus improving coverage on the targeted audience/selected sites; key population.**
- Effective participation is to built on partnerships with targeted communities e.g. key population
- To reinforce positive health practices/behavioral change, discourage dangerous practices and foster community involvement and accountability.
- Key population group is involved as **partners** in planning, promoting, implementing and monitoring campaigns, develop a **stronger trust and ownership** in the health service
- Rumours and misinformation about vaccinations rapidly addressed through ***RCCE, planned and implemented on time.***

Social Mobilisation and Demand Creation

- Increase awareness of the vaccine rollout approach and the prioritisation of key population groups;
- Provide the public with timely, consistent, and accurate information on Mpox vaccines (availability, safety, timelines), to build and maintain trust, and counteract misinformation, myths, and misconceptions;
- Reduce vaccine hesitancy and public resistance to Mpox vaccines;
- Address misconceptions about any AEFI that may occur;
- Tackle perceptions of low infection risk in specific populations and
- Create an environment that supports the widespread adoption and maintenance of non-pharmaceutical interventions to reduce the risk of Mpox infection.

Effective RCCE/ACSM planning

- Planning for RCCE starts at high level to district (national, province & district)
- Activate sub-committees; communication, health promotion, ACSM, and external partners.
- Preparation for implementation and manage risks/crisis and timely respond to low uptake, vaccine hesitancy, misinformation, rumours and AEFIs
- Monitoring and Evaluation of RCCE activities
- Planning consists SIA **objectives** and be **aligned** with the timelines

RCCE/ACSM Committees

- Committees can be from any pre-existing structures established for previous SIAs or vaccine introductions (e.g., Covid-19, measles & Rubella vaccine)
- The committees at each level should be responsible for:
  - Providing **overall direction** to the RCCE activities;
  - Ensuring that the **coordination of RCCE activities** are implemented by appropriate entities;
  - **Reviewing, testing and approving** information materials;
  - **Monitoring the effectiveness** of RCCE activities and making any adjustments where required

Strategies for Advocacy and Social Mobilisation

- Use a **variety of channels which include meetings between various levels of government departments**, civil society organisations, key partners, news coverage to ensure commitment at all levels
- Use of **high placed officials and political leaders** at national and provincial levels (MEC for Health, Head of Departments etc.)
- **Sensitisation** of political, religious, faith –based , cultural, traditional and other local leaders.
- **Involvement** of the local private health sector, other departments, NGOs, CBOs, Higher Learning Institutions, community leaders and volunteers in planning and implementing the SIA
- Involvement of local schools and churches in community Mobilisation.
- Use of community meetings and Imbizos to create and heighten campaign awareness.

Community Mobilisation

Social mobilization/community engagement activities focus on conveying that;-

- the greatest number of people possible is needed to have good vaccine coverage
- the people specifically targeted (e.g., key population) and those who are specifically excluded for the campaign;
- the risks associated with not being vaccinated and with being vaccinated (e.g. AEFI);
- there is a plan to cover areas of most difficult access, where the diseases start; and the most vulnerable populations which have very little or no access to health facilities;,

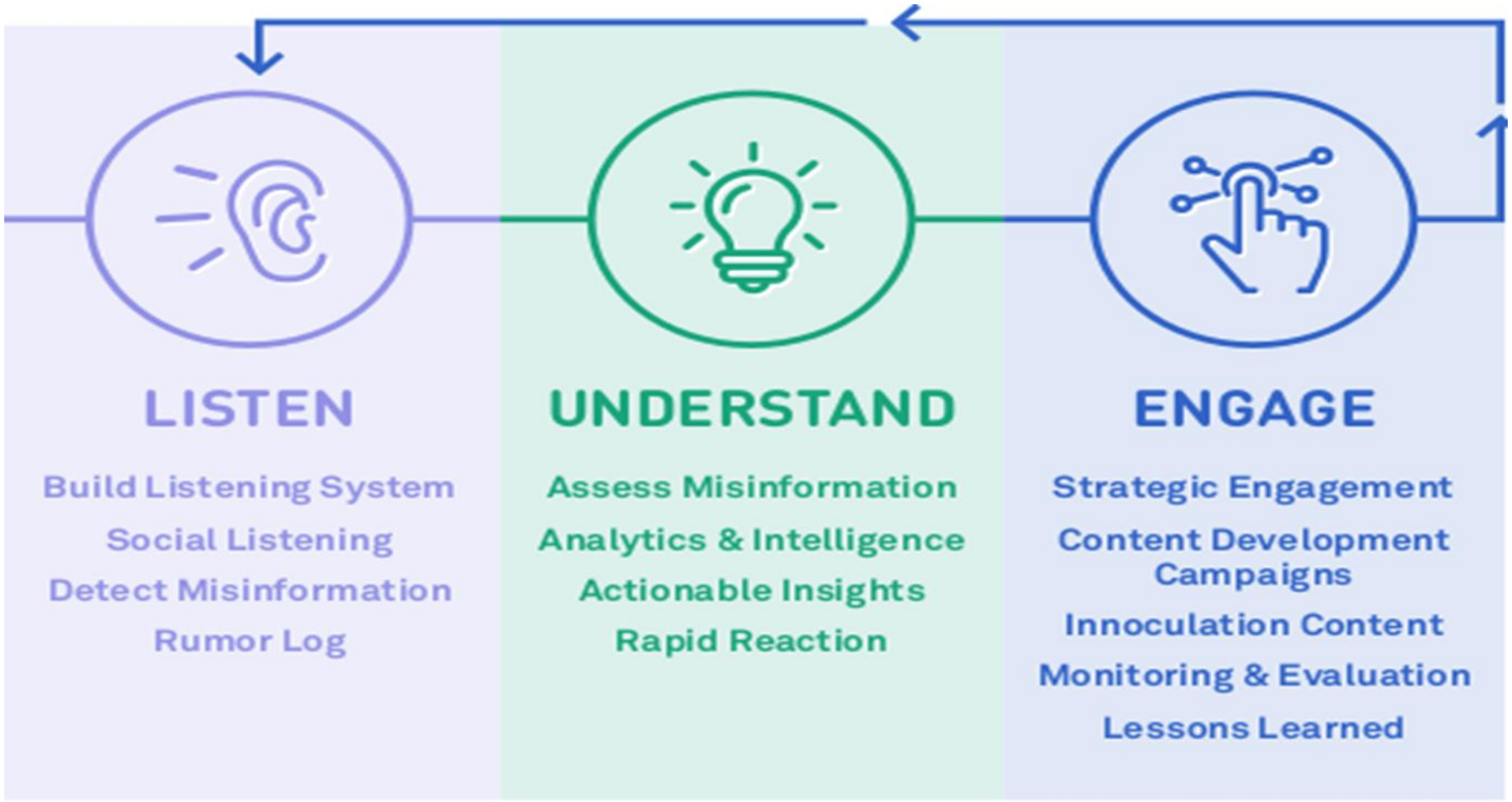
RCCE Activities

- Multiple channels to be used for communicating the rollout vaccine campaign in multiple channels:
  - Advocacy visits to community leaders (traditional, political leaders and civil society);
  - Conduct house to house visits;
  - Announcements at community events (sports and cultural events), school events, courts, ceremonies, public meetings, malls, markets, and transportation hubs;
  - Conduct visits at places of key population gatherings (pride month, YouTube channels etc);
  - Utilise Electronic media (Radios, TV, etc.);
  - Utilise the Social media – FB, Instagram, and others;
  - Utilise Printed IEC materials (Booklets, Posters, Brochures, Leaflets, and flyers).
  - Loudhailing, and
  - Utilising all key populations space

Rumours & Misinformation Management

- Specific or support messages such as the **target disease** , vaccine **safety**, mode of vaccine administration and **AEFI**s should be **transparent** and equally communicated **through**:
  - All communication channels
  - Theoretical questions and answers,
  - Social mobilization,
  - Home visits,
  - Health facility visits
  - Interpersonal communication

Rumours & Misinformation Management



Acknowledgment

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