

National Primary Health Care Development Agency



Mpox Phase 2 Vaccination Rollout

Implementation Training

July 2025



NATIONAL PRIMARY HEALTH CARE DEVELOPMENT AGENCY



Agenda



S/N	Activity	Time	Duration	Responsible
1	Welcome and Registration	09:00 – 09:30am	30 mins	All
2	Opening Prayer (National Prayer)	09:30 – 09:40am	2 Mins	All
3	Introduction of Participants/ Roll call		8 mins	Moderator
5	Opening Remarks	09:40 – 09:45am	5Mins	Director DCI
6	Objectives and expected outcomes	09:45- 09:50am	5mins	Kyafi
7	Overview and epidemiology of Mpox disease in Nigeria	09:50- 10:10am	20mins	Odianoson
8	Introduction to Mpox Vaccination and service delivery	10:10 – 10:30am	20 mins	Adejoke/Ene
9	Discussion	10:30 -10:40am	10min	All
10	Cold chain requirements and Mpox vaccine handling for vaccination	10:40 - 11:10am	30 mins	Musbahu/Tochukwu/Bello
10	ACSM for Mpox Vaccination	11:10 –11:30am	20min	Abduljalal/Musa/ Margeret
12	M&E tools for Mpox Vaccination	11:30 -11:45 am	15 mins	Yazeed/Kyafi/Ekpo
13	Discussion	11:45- 11:55 am	10 mins	All
14	AEFI surveillance and Vaccine Safety monitoring	11: 55– 12:20pm	25 mins	Queenth/Dr Elemuwa/ Abdulazeez
15	Experience Sharing from Phase 1	12:20 -12:30 pm	10 mins	Cross River SIO Ms Eyomi
16	Provisions for the Mpox Vaccination	12:30 –12:45 pm	15Mins	Adejoke/Fatima/ Ezebilo/ Bassey
17	Discussions	12:45 – 13:00 pm	15 mins	All
18	Next Steps/Closing	13:00 – 13:05 pm	5 Mins	Head NPSIA



NATIONAL PRAYER



O God of all creation,

Grant this our one request,

**Help us to build a nation Where no man is
oppressed,**

And so with peace and plenty

Nigeria may be blessed





Objectives and Expected Outcomes



The Objectives of the Mpox Vaccine Introduction Training in Nigeria

1. To update the knowledge of EPI Managers and Health Workers on Mpox surveillance and epidemiology
2. To update the knowledge and skill of health workers on Mpox vaccination and delivery strategy
3. To update the knowledge and skill of health workers on the handling, storage, distribution, administration and waste management of the Mpox Vaccine
4. To update the knowledge and skill of health workers on risk communication, demand creation and mobilizing communities for Mpox vaccination
5. To update on the Management of AEFI and Cohort Event Monitoring for Mpox vaccination



Expected Outcomes of the Mpox Vaccine Introduction Training in Nigeria



1. EPI Managers and Health Workers are knowledgeable on Mpox disease
2. Health workers' knowledge and skills on Mpox vaccination and the delivery strategy is updated
3. Health workers' capacity is strengthened on the handling, storage, distribution, administration and waste management of the Mpox vaccine
4. Improved knowledge and skill of health workers on risk communication, demand creation and mobilizing communities for Mpox vaccination
5. Health workers updated on the current practices in surveillance, management of AEFI and Cohort Event Monitoring for the Mpox vaccine



*Thank
you*





Basic Facts on Mpox disease



What is Mpox(Monkeypox)?


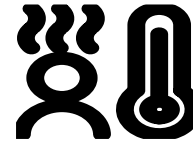







- Mpox is an illness caused by the Mpox virus.
- Mpox virus is a member of the Orthopoxvirus genus, which also includes smallpox, cowpox, etc
- It is a viral infection that can spread between people, mainly through close contact, and occasionally from the environment to people via things and surfaces that a person with mpox has touched
- In settings where the Mpox virus is present among some wild animals, it can also be transmitted from infected animals to people who have contact with them



Signs and symptoms of mpox



Category	Description	Pictorial representation of mpox symptoms
Common symptoms 	<ul style="list-style-type: none">▪ Rash lasting 2–4 weeks, resembling blisters or sores▪ Fever, headache, muscle aches, back pain, low energy, swollen lymph nodes▪ Rash can affect face, hands, feet, groin, genital, and anal regions▪ Lesions may also appear in mouth, throat, anus, rectum, vagina, or eyes▪ Number of lesions can range from one to several thousand	<p data-bbox="1694 221 2497 271">Pictorial representation of mpox symptoms</p> <div data-bbox="1732 357 1923 499"><p data-bbox="1732 521 1834 564">Fever</p></div> <div data-bbox="2025 349 2140 478"><p data-bbox="2025 506 2191 549">Back pain</p></div> <div data-bbox="2293 357 2420 478"><p data-bbox="2280 506 2382 549">Rash</p></div> <div data-bbox="1745 714 1847 835"><p data-bbox="1732 871 1911 913">Headache</p></div> <div data-bbox="2025 699 2140 821"><p data-bbox="2025 849 2165 942">Muscle ache</p></div>
Severe symptoms 	<ul style="list-style-type: none">▪ Inflammation of the rectum (proctitis) causing severe pain▪ Inflammation of the genitals causing difficulties urinating	

▪ Symptoms may resolve on their own with supportive care (pain/fever management) within a few weeks

▪ **Treatment for severe cases:** Hospitalization, supportive care, and antiviral medications may be required for severe mpox to reduce lesion severity and recovery time.]



Mpox has different modes of transmission, however it is primarily transmitted from person-to-person



Modes of transmission

1

Person-to-person transmission



- Spreads primarily through close contact (skin-to-skin, mouth-to-mouth, mouth-to-skin), including sexual contact, and face-to-face interactions (talking, breathing)
- Infectious until all lesions crust over, scabs fall off, and new skin forms (typically 2–4 weeks)
- Virus can persist on contaminated objects (clothing, bedding, surfaces); touching these can cause infection, especially with cuts or touching mucous membranes
- Can spread from parent to child during pregnancy, birth, or close contact

2

Animal-to-human transmission



- Occurs through physical contact with infected animals (monkeys, rodents) via bites, scratches, or activities like hunting and preparing meat
- Eating undercooked contaminated meat can also lead to infection
- Risk can be reduced by avoiding unprotected contact with wild animals and ensuring meat is thoroughly cooked.

3

Environmental transmission



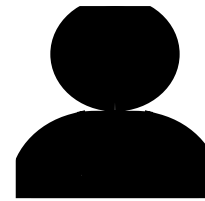
- Virus can persist on contaminated surfaces or objects
- Touching contaminated items and then touching eyes, nose, or mouth can lead to infection
- Cleaning and disinfecting surfaces and hand hygiene are crucial for preventing transmission from objects.



Who are the people at risk of getting infected?

Everyone is at risk of contracting Mpox because it affects all ages. However, health care workers have an additional job-related risk. Other groups with greater risk of severe disease include:

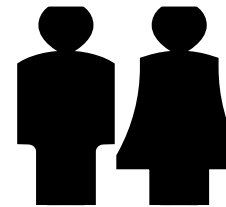
- Close contact with infected persons
- People with chronic illnesses – diabetes, heart disease, hypertension
- People with conditions that lower the body's immunity –e. g. HIV/AIDS
- People with high-risk sexual behaviors



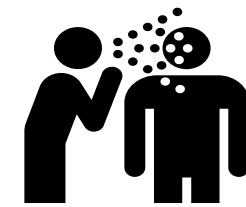
Healthcare workers



Immunocompromised people



People with high-risk sexual behaviors



Close contact with affected persons



General preventive measures



Strategies

Details

1

Self-Protection

- Avoid close contact with anyone who has mpox, including sexual contact
- Practice good hand hygiene: Wash hands frequently with soap and water or use an alcohol-based hand rub
- In areas with wild animals carrying mpox, avoid contact with sick or dead animals, and ensure meat is thoroughly cooked before consumption
- Use condoms as a precaution for 12 weeks (3 months) after recovery from mpox

2

Awareness and Communication

- Know the signs and symptoms of mpox and how it spreads
- Communicate openly with close contacts about any symptoms if the virus is spreading in your area or community

3

Health Management and Isolation

- Seek medical advice and isolate if you suspect you have mpox
- Isolate until fully recovered: Remain isolated until all lesions have crusted over, scabs have fallen off, and new skin has formed
- Follow local health guidelines on isolation and care at home or in a health facility

4

Post exposure prophylaxis

- Get vaccinated following contact with infected persons



Healthcare specific preventive measures for Mpox



Some healthcare specific preventive measures include:

- Wear appropriate personal protective equipment when handling mpox patients
- Wash hands thoroughly before and after patient contact and after touching contaminated surfaces
- Adhere to infection prevention guidelines, including safe handling of sharps and waste disposal
- Regularly disinfect surfaces and medical equipment used by patients
- Properly dispose of contaminated materials like PPE and beddings



Insert State Mpox surveillance data here





Basics Fact on the Mpox vaccine and how it works



Types of Mpox vaccines



There are currently three types of Mpox vaccine that have been approved:

1

MVA –BN (JYNNEOS)

- **Type:** Third-generation, non-replicating, live attenuated vaccine based on Modified Vaccinia Ankara (MVA)
- **Safety Profile:** Well-tolerated with fewer side effects, making it the preferred choice for healthcare workers and high-risk populations
- **Indications:** Recommended for individuals at high risk of exposure, including healthcare workers, close contacts, and at-risk community members.
Now approved for children 12 years and above (NGITAG yet to approve)
- **Manufactured by:** Bavarian Nordic

2

ACAM2000

- **Type:** Second-generation vaccine containing live vaccinia virus that replicates in humans
- **Safety Profile:** More side effects and contraindications compared to JYNNEOS, making it less commonly recommended
- **Indications:** Reserved for individuals at high risk where JYNNEOS is unavailable or contraindicated
- **Manufactured by:** Emergent Bio Solutions

- **Key considerations for healthcare workers:** The vaccine can also be administered after a person has been in contact with someone who has mpox (post-exposure prophylaxis). In these cases, the vaccine should be given less than 4 days after contact with someone who has mpox. The vaccine can be given for up to 14 days if the person has not developed symptoms



Types of Mpox vaccines



There are currently three types of Mpox vaccine that have been approved:

LC16

3

- **Type:** third generation minimally replicating): 1-dose widely used in children. Used in Japan in 2022 mpox outbreak.
- **Safety Profile:** Well-tolerated with fewer side effects, making it the preferred choice for healthcare workers and high-risk populations
- **Indications:** Recommended for individuals at high risk of exposure, including healthcare workers, close contacts, at-risk community members and children.
- **Manufactured by:** KM Biologic

While MVA-BN vaccine is indicated for use in a two full dose (0.5 mL/dose) vaccination series, WHO recommends that countries consider off-label use of a single dose of MVA-BN (0.5mL/dose) subcutaneously or fractional dosing (0.1mL/dose) administered intradermally in supply-constrained outbreak situations

In alignment with WHO SAGE recommendations, countries use MVA-BN vaccine dose-sparing options: single full dose and where feasible based on country context, one dose of intradermal fractional dosing to maximize the number of individuals who can be vaccinated.



How the Mpox vaccine works



- Monkeypox vaccines work by stimulating the immune system to recognize and combat the monkeypox virus
- There are currently three vaccines used for monkeypox prevention: MVA-BN (also known as Jynneos, Imvamune or Imvanex), ACAM2000, LC16
- All the vaccines were originally developed for smallpox but have shown effectiveness against monkeypox due to the genetic similarity between the viruses
- These vaccines are recommended for individuals at high risk of exposure, such as close contacts of confirmed mpox cases or those in communities with ongoing outbreaks
- When administered, the vaccine stimulates the body's immune system to produce antibodies against the Monkeypox virus. These antibodies are essential for recognizing and fighting off the virus if you are exposed



Vaccination delivery strategy



Background



- The Federal Government through the NPHCDA requested 10,000 doses of the Mpox vaccine from the United States Government, the request was granted and the Mpox vaccines have arrived Nigeria on the 27th August 2024.
- The request was made in response to the 2022 outbreak of Mpox in Nigeria where the country recorded a high number of cases of the Clade II type.
- With the declaration by the Africa Centre for Disease Control and Prevention (AfCDC) and the World Health Organization in August 2024 declared Mpox as a Public Health disease of Continental Security as the outbreak is spreading through Africa particularly East Africa with the more virulent strain of Clades Ib.
- **The vaccine is a preventive measure and targeted at limiting the outbreaks**
- Therefore, it is important that plans are in place to ensure adequate planning, equitable distribution, demand generation and judicious utilization of the vaccines across the targeted States as part of the FGoN and the NPHCDA's strategy of improving access to basic health services
- This training is aimed at efficiently deploying this vaccine.



Vaccination Strategy



- The vaccination strategy for this phase of vaccination is “Ring/targeted Vaccination” – this implies precision with vaccination targets (identify based on criteria)and their networks.
- The target group for vaccination in this phase are:
 - **Close contact of confirmed Mpox cases (within 42 days of infection of primary case)**
 - **Health workers (including laboratory and Support staff especially at infectious disease treatment centres)**
 - **Key populations with high risk of acquiring the disease (HIV infected persons, MSMs etc.)**
- It is essential that the target populations are linelisted and properly engaged prior to vaccination.



Vaccine administration



- **It is a 2 dose regimen vaccine (2nd dose 28 days after the 1st dose)-** *dose sparing measures allows for 1 dose to suffice.*
- Route of administration: the Jynneos vaccine is administered subcutaneously in the left upper arm
- Subcutaneously – angle 45⁰ over the Deltoid Muscle
- Wipe vaccination site with clean, wet gauze/ cotton wool before administration of vaccine.
- Do not rub vaccination site after injection.
- After administration, client to sit and be observed for at least 15 mins for AEFI before leaving vaccination site
- Vaccination will take place over 10 days per round



Vaccination team composition

- Two (2) categories of vaccination teams will be utilized: Fixed site team and Special team
- A fixed Site team: are teams that remain in designated health facilities to provide vaccination services
- Special teams are mobile and provide vaccination to target populations that have not reported to the health facility
- The fixed team is composed of 3 members - 1 vaccinators, 1 recorders, 1 mobilizer
- Special team is composed of 3 members – 1 vaccinator, 1 recorder, 1 mobilizer
- Each state is allotted Four (4) teams to carry out the Mpox vaccination over a period of 10 days



Criteria for team selection

	Team member	Criteria
	Vaccinator	<ol style="list-style-type: none">1. Must be a health worker licensed to give injections.2. 18 years and above3. Experience with giving vaccination is an advantage
	Recorder	<ol style="list-style-type: none">1. 18 years and above2. Ability to read and write3. Ability to communicate in English and the local language
	Mobilizer	<ol style="list-style-type: none">1. Must be above 18 years of age2. Ability to engage with target audience3. Experience engaging target population is an added advantage



Vaccination Site and Target population priorities

The Proposed vaccination sites to reach the target populations are:

- a. Infectious Disease (Mpox) treatment or referral facilities
- b. ART clinics
- c. Areas where priority groups for vaccination can be found (e.g special meeting sessions etc.).

It is expected that the **NOT** more than 2 fixed sites are selected and special teams are attached to the fixed sites.

The priority populations for preventive Mpox vaccination are

1. Close contacts of confirmed Mpox cases
2. Health workers (e.g Infectious Disease Hospitals, Laboratory staff etc.)
3. Persons with low immunity status
4. Person with high-risk sexual behavior

Vaccination is for persons 18 years and above in this instance



Roles and Responsibilities



	Role	Responsibility
1	Vaccinator	<ol style="list-style-type: none">1. Observe Infection, Prevention and control protocols/ SOPs2. Screen and educate client using key messages3. Vaccinate and tally client4. Observe for AEFI5. Collation and transmission of data to the LIO6. Collect and return vaccination materials to the LCCO7. Set up vaccination site8. The Vaccinator is the Supervisor for the team.
2	Recorder	<ol style="list-style-type: none">1. Fill the vaccination card for the vaccinated client2. Record the vaccination in the Mpox vaccination register including the unique client ID (for CEM follow up)3. Remind client to keep card securely
3	Mobilizer	<ol style="list-style-type: none">1. Ensure adherence to Infection Prevention and Control measures.2. Conduct temperature checks at the point of entrance.3. Ensure the orderly flow of clients at the vaccination sites.4. Participate in sensitization and dialogue meetings



Pre – Implementation activities includes resource quantification, stakeholder engagements, training of vaccination team and deployment of materials



Pre - Implementation

- Conduct stakeholder engagements with priority groups/ targets for vaccination to secure buy-in and support **including line listing eligible targets**
- Orientation of vaccination team on strategy and Interpersonal skill for vaccination of the priority groups.
- Quantify and deploy vaccine and other materials requirements to vaccination post/site
- **Ensure availability of additional resources at the vaccination post (job aids, IEC materials, etc)**



Implementation activities includes daily routine activities in relation to the vaccination of clients



Implementation

- Continued engagements with priority groups/ targets to ensure they receive the vaccines
- Check all materials for vaccination every morning before setting up or setting out.
- Remind Clients to report to the health centre / vaccination site **on their due date for the second dose of Mpox vaccine (28 days after first dose).**
- **Conduct an accountability check for vaccines and all materials after each session**

REMINd CLIENTS TO REPORT AEFI



Post Implementation includes daily routine activities in relation to the vaccination of clients



Post - Implementation

- Continued engagements with priority groups/ targets to ensure they report AEFI and keep the date for their next dose in view
- Ensure all relevant data and materials have been checked and returned to the appropriate place or person.
- Surveillance activities are continued and strengthened.



Key things to note

- A team is made up of vaccinator, Recorder and mobilizer
- Line listing clients before vaccination is a key step in Mpox vaccination.
- It is not a mass vaccination campaign but targeted.
- Ensure transmission of key messages to groups and informed consent
- The vaccine is a two-dose vaccine given 28 days apart.
- It is VERY essential to follow up clients to complete their second dose after 28 days



*Thank
you*





Vaccines and Logistics



Presentation Outline

Objectives

Expected Outcomes

Characteristics and Handling of **Jynneos (Mpox) vaccine**

Forecasting of **Jynneos (Mpox) vaccine**, Devices, PPE and CCE needs

Jynneos (Mpox) vaccine Storage, Transportation and Contingency Plan

Vaccine Accountability, Traceability and Reverse Logistics

TOR for the Vaccine Accountability Officers

Waste Management



Objectives



To build the capacity and knowledge of participants on:

1

The characteristics and handling of Jynneos (Mpox) vaccine

2

Requirement for Jynneos (Mpox) vaccine, devices, CCE and PPE

3

Receiving, storing, transporting Jynneos (Mpox) vaccine

4

Contingency Plans for Storage of Jynneos (Mpox) vaccine to ensure the maintenance of potency up to point of administration

5

Implementation of vaccine accountability, traceability, reverse logistics and waste management of Jynneos (Mpox) vaccines at all iSC levels



Expected Outcomes



At the end of the session participants should be able to:



Understand the characteristics and handling of the **Jynneos (Mpox) vaccine**



Estimate **Jynneos (Mpox) vaccine**, devices, CCE and PPE requirement for the vaccination exercise



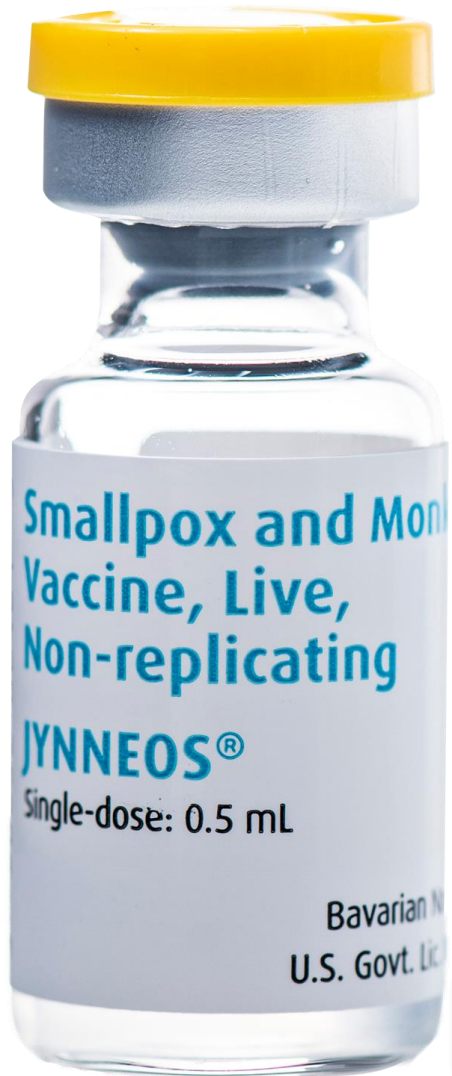
Properly receive, store and transport **Jynneos (Mpox) vaccine**



Implement the contingency plan to ensure the potency is maintained up to the point of administration



Implement Vaccine Accountability, Traceability, Reverse Logistics and Waste Management for **Jynneos (Mpox) vaccine** at all levels of the iSC








CHARACTERISTICS AND HANDLING OF JYNNEOS (MPOX) VACCINE

Please Note* the JYNNEOS (MPOX) VACCINE is also known as MVA-BN, i.e. Modified Vaccinia Ankara – Bavarian Nordic



Characteristics of Jynneos (MPox) vaccine (2/2)

Focus	Details
 Number of Doses/Vial	<ul style="list-style-type: none">1 doses per vial
 Schedule	<ul style="list-style-type: none">2 (Two) doses (0.5 mL each) 4 weeks (28days) apart.
 Storage	<ul style="list-style-type: none">Store in freezer between -25°C to -15°C up to label expiry date.Vaccine can be maintained at +2°C to +8°C for up to "60 days" (thaw only before distribution)Thawed Jynneos Vaccine cannot be refrozen
 Appearance	<ul style="list-style-type: none">When thawed, JYNNEOS is a milky, light yellow to pale white coloured suspensionPrior to administration, vaccine vial should be inspected for presence of partial discoloration. Vaccine "SHOULD NOT" be administered if present
 Administration	<ul style="list-style-type: none">Administered via subcutaneous route in the upper arm over the deltoid muscle



Please Note that the Jynneos (MPox) vaccine does not have a Vaccine Vial Monitor (VVM) hence strict temperature monitoring must be observed !



Handling of Jynneos (Mpox) vaccine (1/2)



- The vaccines must be stored in WHO PQS Freezers equipped with a Temperature Monitoring Device (RTMD) at all levels of the supply chain to maintain the temperature between -25°C to -15°C (National & State), +2 °C to +8°C (LGA & HFs)
- The temperature must be taken and charted twice daily, i.e. at beginning and close of work including weekends and public holidays at all levels of iSC
- Before administration, allow the vaccine to thaw and reach room temperature before use. The time the vaccine thawed must be noted and written on the vial
- During administration, the vaccine must be maintained at a temperature range of +2 °C to +8°C using conditioned ice packs and slit foam
- Before administering a dose of the vaccine, swirl the vial gently in an upright position for at least 30 seconds.
- Use a sterile needle and syringe to extract 0.5ml from the single-dose vial





Handling of Jynneos (Mpox) vaccine (2/2)



National Level

- The vaccine is stored in Walk-In-Freezer-Room (WIFR) at between -25°C and -15°C up to the expiration date

State Level

- The vaccine is stored in a **Walk-in-Freezer-Room** or **Ultra Cold Chain Equipment** at between -25°C and -15°C up to expiration date (uninterrupted power must be maintained)

Service Delivery Level

- The vaccine is stored in a **Solar Direct Drive (SDD) Refrigerator** at between $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ up to 60 days from the date of thawing
- If still frozen (from state level delivery), it must be thawed at room temperature before administration.
- Once thawed at $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ the vaccine must be administered with **60 days**

- Please Note that any vial of Jynneos (MPox) vaccine taken out of the CCE at -25°C and -15°C for vaccine administration cannot be refrozen
- Vaccines must be stored in WHO PQS CCE and maintained in the specified temperature



Appearance of Jynneos (Mpox) vaccine

Examples of normal appearance of MVA-BN of different age in comparison to a water sample (right side, without yellow cap) in front of a black (top) and white (bottom) background.

Comparison of a vial containing water (left) and MVA-BN (right)



The pictures below show examples of normal appearance of the MVA-BN (JYNNEOS) in terms of degree and appearance of particles that are observed.² The particles are more noticeable when viewed in front of a black background

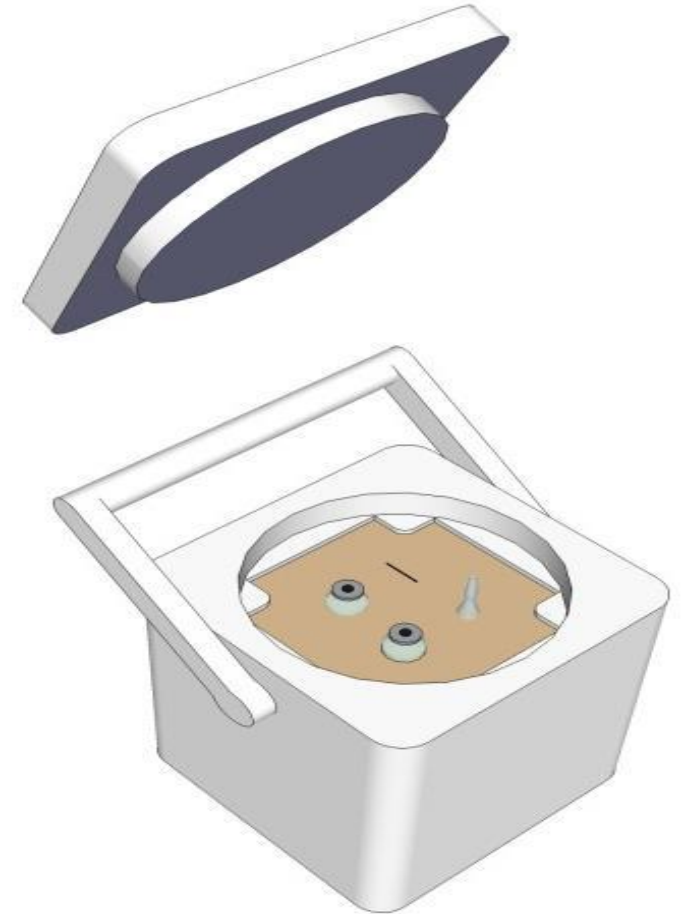




Securing Jynneos (Mpox) vaccine during sessions



- 1 Conduct vaccination in a shaded area
- 2 The vaccine carrier must remain closed and loaded with conditioned ice packs at +2 °C to +8°C throughout the process of immunization
- 3 Use the foam pad with slits above the vaccine carrier for vaccine vials before administration.





FORECASTING FOR Mpox VACCINES AND DEVICES, CCE AND PPE REQUIREMENTS



Forecasting of Mpox Vaccine, Devices, CCE and PPE Requirements



What is Forecasting?

- Forecasting is estimating the quantity of vaccines (doses), injection devices, cold chain equipment, and Personal Protective Equipment (PPE) required for a population over a specified supply period.
- Forecasting should ensure that the right quantities of bundled vaccines are estimated, adequately and timely supplied in good and acceptable quality at all levels.
 - ✓ National,
 - ✓ State
 - ✓ Service Delivery Point



Forecasting of Mpox Vaccine, Devices, CCE and PPE Requirements



Forecasting Parameters:

- Target population: **State Estimate**
- Doses per schedule: **2**
- Wastage rate: **5%**

Calculation of Wastage Factor = $100 / (100 - \text{wastage rate})$

Calculation of Vaccine Requirements based on Target Population method.

$$\text{Target Population (PT)} \times \text{\# of doses on the schedule (Dn)} \times \text{Wastage factor (Wf)} = \text{Total doses Required}$$

Note: The "expected coverage" is based on individual states estimated requirements shared with the National service delivery team



Estimating Mpox Vaccine Requirements using target population method



Example: Assuming the target population of a PHC is 500 persons, number of doses per schedule is 2, and expected Wastage rate is **5%** .

Calculate the quantity of *Mpox vaccines* required.

Calculation of Wastage Factor: $100 / (100 - \text{wastage rate (5\%)}) = 100 / (100 - 5) = 100 / 95 = 1.05$

Target Population (PT)	x	# of doses on the schedule (Dn)	x	Wastage factor (Wf)	=	Total doses required
500	x	2	x	1.05 (Wr 5%)	=	1,050

Number of Vaccine vials required are as follows for a given Service Delivery Point:

$$500 \times 2 \times 1.05 = 1,050 \text{ doses Required by the Service Delivery Point}$$

The vaccine is a single doses per vial, which means each vail is administer to an individual, therefore: **1,050 doses = 1,050 vials**



Calculating Devices (AD Syringes & Safety Box) Requirement...

Example: To calculate devices requirement for the Jynneos Mpox vaccines in the aforementioned example

- Where; Target population = 500 persons, Number of doses per schedule=2 and Wastage Rate for devices = **5%**.
- With a wastage rate of 5%, the Wastage Factor = $100 / (100 - \text{wastage rate}) = 100 / (100 - 5) = 100 / 95 = 1.05$

Calculation for AD syringes required

- **Number of AD syringes** = No. of vaccine doses (for the Mpox vaccine)

$$500 \times 2 \times 1.05 = \mathbf{1,050 \text{ AD syringes (0.5ml) required}}$$

- **Calculations for Safety Box Required**

$$\begin{aligned} & \text{Number of AD (0.5ml) syringes} / 100 \\ = & \quad 1,050 / 100 = 10.5 \text{ (11 Pcs)} \\ & \mathbf{11 \text{ Pcs of Safety Box required}} \end{aligned}$$



Calculation for PPE and CCE Requirements



PPE Requirement:

- Pack of face masks required = (No. of teams x No. of persons per team x No. of days of implementation) / 50
- Hand Sanitizer (250 ml) Needed = No. of teams x No. of persons per team

CCE Requirement:

- Vaccine Carriers requirements (Gio' Style) = No. of Teams x 2
- Ice packs requirements during vaccination = No. of Teams x 2 x 4
- **Cold Chain Storage Capacity requirement at LGA and HF levels**
= Total number of Doses x Packed Volume per Dose



Passive CCE types, capacity, and coolant requirements



Vaccine containers	Company Name	Manufacturer's ref	Vaccine storage volume (L)	No of coolant Packs	Coolant Pack Model (L) size
Large Cold box	B Medical System	RCW25	20	24	0.6
Vaccine Carriers	BLOWKING	BK VC 2.6 CF	2.6	4	0.6
	BLOWKING	BK VC 1.7 CF	1.7	4	0.3/0.4
	BLOWKING	VDC 24-CF	0.9	2	0.3/0.4

Note: Refer to instruction label on the CCE



TRANSPORTATION OF Mpox VACCINES



Transportation of Vaccine



Transporting the vaccines

- Transport vaccines only inside the passenger compartment of a passenger vehicle (not in the trunk or the bed of a truck, which may be too hot or too cold).
- Move transport containers directly into a vehicle that is already at a comfortable temperature.
- Secure transport containers (brace or strap them) to prevent unnecessary movement.
- Keep containers out of direct sunlight.
- Never leave the container unattended in the vehicle.



Transportation of JYNNEOS Mpox vaccines



- The Vaccine distribution to the Service Delivery Point will be strictly based on the target population to be immunized
- Vaccines will be transported from the national level to:
 - State level at -25°C to -15°C using cold boxes, frozen gel packs (or ratioed dry ice), and RTMDs.
 - Subsequently, transport from state cold stores to service delivery points will occur at $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ using:
 - either **cold boxes** (if the facility has an SDD refrigerator) or vaccine carriers and Geostyle[®] equipped with conditioned ice packs for vaccination teams.



Contingency Plans for Storage of Jynneos Mpox vaccine (SCS/SDP) 3/3



USE THIS PLAN IN THE EVENT OF POWER OUTAGE/ELECTRICAL DISRUPTION “OR” WIFR/UCC/CHEST FREEZER AT STATE LEVEL



Beyond wireless, in-built TMDs and 30 DTRs will be used for temperature monitoring

HAVE A PLAN READY

- Temperature Monitoring Devices for temporary vaccine storage and or transport.
- Bake and store enough “gel/icepacks” in a freezer at **-25°C**
- Identify a secondary (alternate) storage site in case of prolonged equipment downtime. The proximal site (“Onsite” or “Contiguous” to Storage Site) must have the recommended equipment such as WHO PQS WIFR/Chest Freezer/SDD Freezer

HAVE DESIGNATED 24HRS/7DAYS EMERGENCY CONTACTS PERSONS DETAILS

Primary emergency contact name and number: State or designated Technician/SIO/SCCO
 Secondary emergency contact name and number: ES/DPH
 Tertiary emergency contacts: NPHCDA RRT, NSCS Resident Engineer, Head Operations, DLHC

Key

→ Flow of events

The SDD Freezer will be monitored remotely, and email/SMS alerts will be sent to emergency contacts .

- Primary contact at **-22°C** (SCCO, VSL, iSC Supervisor, SC)
- Secondary contact at **-20°C** (SC, SIO, ES, HCH)
- Tertiary contact at **-18°C** (National Level. See contact list in subsequent slides)



1 Ensure 24/7 physical presence of designated personnel at the site where the WHO PQS WIFR/UCC/Chest Freezer is installed to ensure the equipment's temperature is maintained between -25°C to -15°C .

2 A Temperature monitoring device will be inserted in all WHO PQS WIFR/UCC/Chest Freezer to monitor the temperature of the vaccines to trigger proactive corrective measures.
 If power or cooling is disrupted and **the temperature goes below or above** the set Threshold i.e. **> -25°C** or **< -22°C**
 The designated staff will:

- Where applicable, Power the back-up generator or preferably the Automatic Transfer Switch (ATS) will be activated.
- Troubleshoot **WHO PQS WIFR** to ascertain if equipment downtime has or can be resolved

3 If the power outage/equipment malfunction persist and cannot be resolved, the on-site staff immediately moves vaccine as per protocol

3a If secondary (alternate) storage site is located “onsite” i.e. within the storage facility: Where applicable, Immediately transfer the vaccines into the pre-positioned vaccine carrier (Giostyle®) with appropriate gel packs onwards to the WHO PQS WIFR/UCC/Chest Freezer for safe storage.

3b If secondary (alternate) storage site is located “offsite”: Immediately transfer Vaccines to pre-positioned insulated cold Box(es) (B-Medical RCW 25), using frozen gel packs equipped with RTMD(s) for temporary vaccine storage and promptly transport to alternate storage site with available WHO PQS WIFR/UCC/Chest Freezer

Implement “a” or “b”



Tertiary level emergency contact details



S/N	Designation	Name	Phone Number	Email
1	Lead Resident Engineer (National Strategic Cold Store)	Engr. Mazila Luka	08024521764	luka.mazila@nphcda.gov.ng
2	Supply Chain "Rapid Response Team" (RRT)	State Logistics Focal Person	TBD	TBD
3		Dr. Yahaya Bello	08036168321	ybabbas@yahoo.com
4		Mr Azubike Tochukwu	08036432206	tochukwu.iv@gmail.com
5	Head of Operations (National Strategic Cold Store)	Mr Adagu Sanusi	07039282855	syadagu@gmail.com
6	Director Logistics & Health Commodities	Pharm. Tense Hauwa	08033930768	hauwatense@gmail.com

Please Note* that contact persons above are listed in order of first responder status



Vaccine accountability, Traceability , Reverse Logistics and waste Management



Vaccine accountability, Traceability and Reverse Logistics (1/2)



- Vaccines will be issued by batch numbers and clearly documented at both issuing and receiving stores
- Vaccine Accountability Officers (VAOs) i.e. SCCOs & Vaccination team Leads will be appointed at the following levels of iSC – State, and Service Delivery Point, with clear TORs to support Vaccine accountability.
- The VAOs will keep records of quantities and batch numbers of vaccines (and other commodities) and ensure physical count of all returned vials, both opened and unopened (reverse logistics).
- The VAOs will also review data on issuance, receipt and utilization of vaccines daily



Vaccine Accountability, Traceability and Reverse Logistics (2/2)



- **Reverse logistics** accounts for usable, unusable, punctured vials, and filled Safety Boxes from the vaccination points to the State Cold Store and ensures that all the vaccines can be **traced** using the batch numbers if the need arises.
- For “**equipped facilities**” where vaccine are stored the Service Delivery Point All empty, unusable, and usable vials will be evacuated to the State within **48hrs** after the completion of the vaccination exercise, in a **reverse order**.
- For “**unequipped facilities**” where vaccine are delivered on need basis based on scheduled clients, all empty, unusable, and usable vials will be evacuated to the State on the same day following the vaccination session, in a reverse order.
- The **empty and unusable vaccine vials** will be quarantined at the State Cold Store (SCS) and destroyed at the State level by **boil, crush, bury and encapsulation**, while used syringes in **filled safety boxes** isolated at holding point at the SCS will be **incinerated** at designated sites. *Waste management will be concluded within two weeks of the vaccination exercise.*



TOR for the Vaccine Accountability Officers (State & Service Delivery Point level)



The “SCCOs” and the “Vaccination Team Lead” will be the Vaccine Accountability Officers

Vaccine Accountability Officer (VAO) will be responsible for:

1. Recording of all Jynneos Mpox vaccine issued to the State/Service Delivery Point by batch number and other characteristics
2. Documenting the specific **batch numbers** issued to each State/Service Delivery Point site and ensuring quantity and batches received corresponds with what were issued within 24 hours of receipt.
3. Facilitating and providing guidance on selection, training, and overall guidance to Service Delivery Point Vaccine Accountability Officers (VAO).
4. Ensuring availability of paper-based Vaccine Accountability tools
5. Conducting a physical count of all the returned vials (open and unopened) and ensure the records, including batch numbers tally with the issues
6. Provide **daily stock balance** information ensuring First Expiry First Out (**FEFO**) principles are strictly adhered to in order to **mitigate vaccine expiries**
7. Harmonize state vaccine accountability records and follow up with team leads where discrepancies may arise.



TOR for the Vaccine Accountability Officers (Ward level)



1. Each day the Vaccination Team Lead records details of all vials given to each team (number of vials, batch number of each vial, team codes, the name, phone number of the team team and name of the health facility/vaccination site) in the Vaccine Accountability forms
2. At the end of each day, each vaccination team lead **MUST** return all used and unused vials to the collection point
3. The team lead checks and compares all vials returned with the recorded details (number of vials received against returned, batch numbers of vials, team codes (where applicable), etc.)
4. If details match, team lead reconciles the data and signs off for the day (hard copy).
5. The summary (hard copy) is then returned to the State Cold Store
6. The team lead **MUST** also reconcile number of clients immunized with the number of doses/vials used before transmitting data to the State
7. The team lead should also liaise with SCCO to understand the Health Facility/Site daily vaccine distribution plan.
8. The team lead should give daily feed back to the State VAO (SCCO)



Waste Management(1/2)



- Waste Management Committees (WMCs) will be activated at the **State, LGA and Ward** levels with clear TORs.
- The WMCs will develop waste management plans, suitable for their areas of responsibility
- The committees will be responsible for:
 - Identification of incineration facilities in the state
 - Identification of collection/holding points for wastes,
 - Proper documentation of wastes collected, especially for sharps
 - Designing an efficient waste transportation system where required,
 - Mobilization of required resources for waste management
 - Monitoring of waste management practices



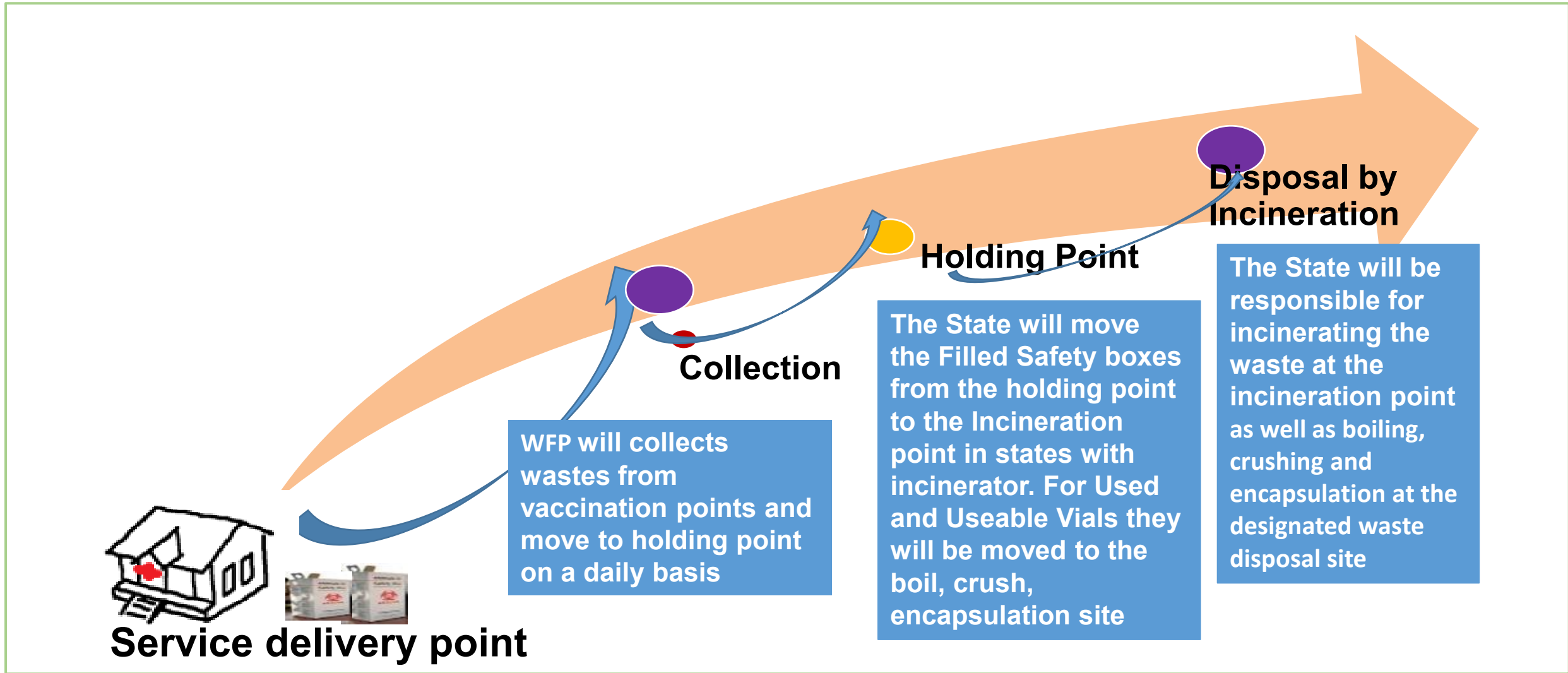
Waste Management(2)



- At the end of each daily vaccination session, all empty, unusable, and unopened vials will be retrieved and quarantined at the state cold stores.
- Filled safety boxes will be retrieved and quarantined at the LGA holding point for further waste management procedures.
- All empty/unusable vials will be retrieved for boiling, crushing, burying and encapsulation at state level.
- All filled safety boxes will be retrieved to the incineration sites for incineration.



Mpox Vaccine: Waste Disposal Management Flow





*Thank
you*





Risk Communication and Community Engagement/Demand Generation



Objectives of this Session



Understand the RCCE and demand generation strategy for the Mpox campaign



Equip state-level teams/trainers with key messages, and approaches for mobilization



Know your role in mobilization and community engagement



Learn how to handle rumors and misinformation



RCCE Goals for Mpox Response



Increase	Increase awareness about Mpox disease, transmission, and vaccine benefits
Drive	Drive demand for vaccination among eligible adults i.e., people 18 years and above
Promote	Promote preventive and protective behaviors, and reduce stigma
Build	Build trust through timely, transparent communication



Key Audiences



- **Primary:** Adults 18+, caregivers, youth, and high-risk groups – including health workers and people with weak immune systems.
- **Secondary:** Community leaders, religious leaders, schools, and healthcare workers
- **Influencers:** health workers, social media, mobilizers, town announcers, etc.



Usual concerns about vaccines



- Vaccine safety and effectiveness
- Fear of injections
- Fear of side effects
- Hesitancy due to misinformation and disinformation
 - **Misinformation:** includes false or inaccurate information spread unintentionally about mpox and the vaccine. For example, “the vaccine can cause mpox.”
 - **Disinformation:** deliberate false information spread with the intent to deceive or manipulate. For example, “mpox is a weapon to target specific populations.”
- Prioritization of specific age groups
- In some cases, the fear of stigmatization depends on the type of disease



Strategic RCCE Approaches



- Production and broadcast of 2 radio spots on:
 - Awareness and prevention
 - Reactive vaccination
- Production and dissemination of print materials: frequently asked questions, banners, and electronic posters.
- State-level townhalls with key stakeholders
- Mobilization by teams
- Social media promotions
- Leveraging mobilization and engagement structures to drive demand for mpox vaccine



Role of State ACSM/RCCE Teams



- Coordinate with all members of the team
- Effective dissemination of IEC materials
- Involvement of key stakeholders in the townhall meetings
- Raise awareness on mpox and vaccine benefits
- Share correct messages using simple words they can understand
- Track and report rumors and issues daily. Have a rumor tracking log.
- Listen to people's concerns and questions. Gently correct any false information.



Role of State ACSM/RCCE Teams



- Link people to nearby vaccination sites
- Identify opportunities for leveraging mobilization and engagement structures to drive demand for mpox vaccine
- Support daily review meetings and adapt messaging where necessary
- Train and supervise mobilizers
- Increase vaccine demand in eligible adults
- Promote healthy behaviors and reduce stigma



Special Considerations



Special considerations should also be given to:

- Internally displaced people (IDPs)
- Higher institutions of learning *because of the specific age group*
- Rural and slum areas
- Unique barriers (like hard-to-reach locations)
- People who already feel stigmatized
- Other vulnerable groups



Key Demand Generation Messages

- **Mpox is real** and spreads through close contact – anyone who is not protected can get it.
- **Symptoms** include fever, rash, swollen lymph nodes
- The vaccine is **safe, effective, and free**
- The vaccine is for people **18 years and above**.
- **Two doses** are required for **FULL protection. Return** to the health facility **for your second dose**.
- Get vaccinated at **designated health facilities** and **posts**
- **Continue to practice** hygiene and **avoid contact** with people showing symptoms of mpox.
- Keep your **vaccination card safe**.



Key Demand Generation Messages



- The mpox vaccine is **approved by WHO** for emergency use and is **authorised by NAFDAC**.
- **Trained healthcare workers** will administer the vaccine.
- Most people experience **mild reactions** to the mpox vaccine, such as pain, redness, or swelling at the injection site. **Serious side effects are rare**. However, **if you experience any severe reaction, return to the health facility for examination**.
- For **concerns and information**, **call** any of these toll-free lines: **NPHCDA 7722, NCDC 6232**



Monitoring, Rapid Feedback and Reporting Flow



Rumor tracking

- Establish community rumor tracking mechanisms
- Collect, verify, report, and timely respond to misinformation
- Use feedback loops to adjust messaging
- Engage trusted messengers for rebuttal and clarification

Monitoring and feedback

- Daily monitoring of mobilization activities
- Use of checklist and feedback forms
- Capture issues, hesitancy, and rumor trends
- Feed findings into coordination meetings for real-time decision-making
- Daily dashboard update and reporting template use



IEC Materials



Protect yourself and your loved ones
Get **Vaccinated** Against

MPOX (Monkeypox) today!



2 Doses = FULL protection and immunity
For everyone aged 18 and above

HERE

SAFE!
EFFECTIVE!
FREE!

#StopMpoxNow

For more information call these toll-free lines:
National Primary Health Care Development Agency (NPHCDA): 7722
Nigeria Center for Disease Control (NCDC): 6232

Keep your vaccination card safe!



Protect yourself and your loved ones
Get **Vaccinated** Against

MPOX (Monkeypox) today!



2 Doses = FULL protection and immunity
For everyone aged 18 and above

SAFE!
EFFECTIVE!
FREE!

Go to any government
health facility or vaccination
post near you for your
vaccination

Date:

#StopMpoxNow

For more information call these toll-free lines:
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Keep your vaccination card safe!



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#StopMpoxNow

For more information call these toll-free lines:
National Primary Health Care Development Agency (NPHCDA): 7722
Nigeria Center for Disease Control (NCDC): 6232

Keep your vaccination card safe!



FREQUENTLY ASKED QUESTION about **MPOX**
(Monkeypox) and the Vaccine



Protect yourself
and your loved ones

Get **Vaccinated** Against

MPOX (Monkeypox)

today!



Data Collection Tools



Background



Data Tools:

Refer to systems, technologies, and methodologies designed to collect, manage, analyse, and report data related to immunization/vaccination programs

These tools are crucial for-

- Tracking vaccination coverage
- Monitoring vaccine-preventable diseases
- Ensuring vaccine safety, and
- Optimizing vaccine distribution



Tally sheet



- This is a primary campaign data collection tool
- It is filled at the vaccination post by the vaccinator after every vaccination

MONKEY POX VACCINATION 20..... NIGERIA
TALLY SHEET FOR VACCINATION TEAMS

Instruction: To be filled by the Vaccinator. Use a separate tally sheet each day

Tick as appropriate Reactive Preventive

State: _____ LGA: _____ Ward: _____

Health Facility Name/post: _____ Vaccination Team code: _____ Date: _____

Age Group	Settlement 1 Name:		Settlement 2 Name:		Settlement 3 Name:	
	Male	Female	Male	Female	Male	Female
18-24 Years	o o o o	o o o o	o o o o	o o o o	o o o o	o o o o
	o o o o	o o o o	o o o o	o o o o	o o o o	o o o o
	o o o o	o o o o	o o o o	o o o o	o o o o	o o o o
	o o o o	o o o o	o o o o	o o o o	o o o o	o o o o
Sub Total						
25-40 Years	o o o o	o o o o	o o o o	o o o o	o o o o	o o o o
	o o o o	o o o o	o o o o	o o o o	o o o o	o o o o
	o o o o	o o o o	o o o o	o o o o	o o o o	o o o o
	o o o o	o o o o	o o o o	o o o o	o o o o	o o o o
Sub Total						
41-50 Years	o o o o	o o o o	o o o o	o o o o	o o o o	o o o o
	o o o o	o o o o	o o o o	o o o o	o o o o	o o o o
	o o o o	o o o o	o o o o	o o o o	o o o o	o o o o
	o o o o	o o o o	o o o o	o o o o	o o o o	o o o o
Sub Total						
50 Years & Above	o o o o	o o o o	o o o o	o o o o	o o o o	o o o o
	o o o o	o o o o	o o o o	o o o o	o o o o	o o o o
	o o o o	o o o o	o o o o	o o o o	o o o o	o o o o
	o o o o	o o o o	o o o o	o o o o	o o o o	o o o o
Sub Total						
Total						

MATERIAL RECEIVED, USED AND RETURNED

	Mpox (Vials) Vaccine	Syringes Auto	Safety Boxes	Vaccination Cards
1. Received				
2. Used &				
3. Returned				
4. Batch				

NUMBER OF AEFI CASES OBSERVED

	Serious	Non-Serious
Vaccination Post Supervisor Name/ Signature:		


Has AEFI Reporting Form been completed for each adverse event following immunization? Yes or No . Phone no _____




Vaccination card



- This tool is to be filled by the recorder and issued to the client after vaccination
- It serve as evidence of vaccination and should be returned to the post on the date of second dose vaccination



**FEDERAL MINISTRY OF HEALTH
NATIONAL PRIMARY HEALTH CARE DEVELOPMENT AGENCY**



Mpox Vaccination Card

<p>Part 1 <i>To be pre-filled by recorder</i></p>	<p>State: _____ LGA: _____ Ward: _____</p> <p>Settlement: _____ HF: _____ Name of Vaccinator: _____</p> <p>LIO's Phone Number : _____ Date of Vaccination: _____</p>
<p>Part 2 <i>To be filled by recorder at vaccination post</i></p>	<p>Name : _____ Age: _____ Sex: _____</p> <p>1st Dose Date: _____ Batch Number: _____ Expiry Date: _____</p> <p>2nd Dose Date: _____ Batch Number: _____ Expiry Date: _____</p>
<p>Part 3 <i>To be filled by supervisor in case of AEFI</i></p>	<p>AEFI Observed: _____</p> <p>Date of Onset: _____ Time of Onset: _____</p>



On-line Daily Call-in Data Template



- Used during the implementation stage of campaigns to collate daily immunization data
- It is collated and submitted by the state SIO/M&E officer
- Data collected from the call-in data template is used for daily data analysis and feedback to states



MPOX Vaccination Daily Call-In Template - Jynneos



Return	1st and 2nd Dose Vaccinations				Jynneos																						
SW	State	LGA	Number of vaccination sites	Oct-08																							
				1st Dose										2nd Dose										Vaccine Vials		Vials Returned	
				18-24 years		25-40 years		40-50years		Elderly (50 Years and Above)		AEFI		18-24 years		25-40 years		40-50years		Elderly (50 Years and Above)		AEFI		Received	Used	Empty	Unopened
				M	F			M	F	M	F	Serious	Non-Serious	M	F			M	F	M	F	Serious	Non-Serious				
1																											
2																											
3																											
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17																											
18																											
19																											
20																											
	TOTAL			0	0	0		0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	



Vaccination Register



- Used during the implementation stage of campaigns to collate daily vaccination data
- It is filled at the different vaccination post by the Team Supervisor/WFP
- Data collected is use to keep client vaccination details against subsequent visit

This Should be after every vaccination!!!



State Tallysheet Summary



- Used during the implementation stage of campaigns to collate daily immunization data
- It is collated and submitted by the SIO
- This sheet is used on a daily basis(1 sheet per day)



Mpox Vaccination Exercise - NIGERIA

State level Tallysheet Summary



Instruction: To be filled by SIO Use one sheet for each day

State _____

LGAs Visited _____

Date _____

Round _____

Day _____

S/N	Vaccination team Codes	Total No. of people (Vaccinated)								Mpox (Vials)			AD Syringes			Safety Boxes			Vaccination Cards			No. of AEFI Cases Reported				
		Male				Female				Vaccine																
		(18- 24ys)	(25 - 40 yrs)	(41 - 50 yrs)	Over 50 years	(18- 24ys)	(25 - 40 yrs)	(41 - 50 yrs)	Over 50 years	TOTAL	Received	Used or Wastage	Returned	Received	Used or Wastage	Returned	Received	Used or Wastage	Returned	Received	Used or Wastage			Returned	Minor	Major
1																										
2																										
3																										
4																										
5																										
6																										
7																										
8																										
9																										
10																										
11																										
12																										
13																										
14																										
15																										
Total																										

Remarks:

Note: Copy of this form should be sent to the state team. The LGA should file a copy centrally for future reference.

All sessions must be completed

STF Name _____ Signature _____



Daily Implementation Plan



- Daily implementation plan is a framework for planning of daily events
- It serves as a guide during implementation, and it **MUST** be used by all vaccination teams
- A DIP is developed during MP and updated just before implementation starts.
- The Ward Focal person and Team supervisors are responsible for updating DIPs
- Other persons involved in updating DIPs include:
 - Community leader
 - Religious leaders
 - Market woman leaders
 - Youth organization leaders



Visualization Dashboard



- Power BI will be used to visualize and use data for action during the campaign
- It provide up-to-date information on vaccination progress
- By visualizing key indicators like doses administered, target population coverage, and stock levels, the dashboard will support accountability and increase campaign visibility.
- The dashboard will help align efforts among logistics, field teams, and leadership by summarizing critical data (e.g., vaccine stock, demographic reach, site performance), ensuring coordinated, efficient vaccination delivery and follow-up.



Summary of Data Tools



S/N	Data Set	Data Tool	Responsible	Frequency	Timeline
1	Tally sheet	Vaccination tally sheet	Vaccinator	After vaccination	Intra campaign
2.	Card	Vaccination Card	Recorder	After vaccination	Intra campaign
3.	Register	Vaccination Register	Recorder	After vaccination	Intra campaign
5.	Mpox Supervisory Checklist	ODK	Supervisors	Daily	Intra campaign
6.	LGA Summary Sheet	Tally data	SIO/SM&E	Daily	Intra campaign
4.	Daily Call-In Data	Call-in data template (Google Link)	SIO/SM&E	Daily	Daily



*Thank
you*





Surveillance of Adverse Events Following Immunization with Mpox Vaccine



OBJECTIVES OF THE MEETING



At the end of the presentation participants will

1

Have a better understanding of vaccine Safety Surveillance System

2

Understand basic concepts of AEFI

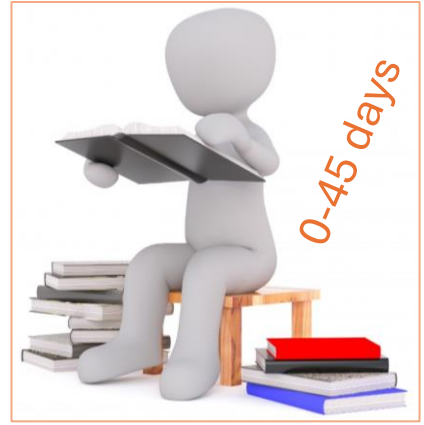
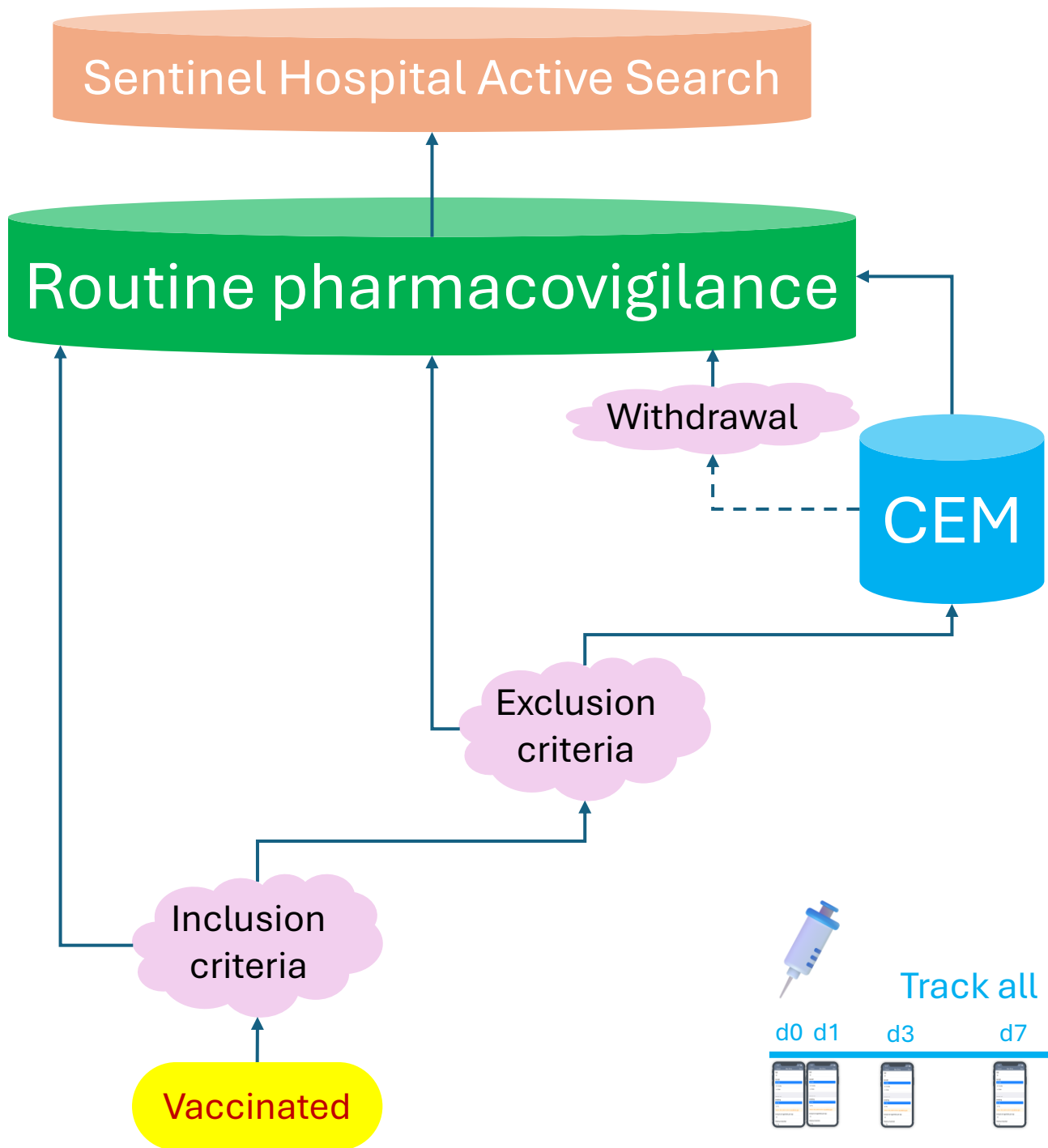
3

Be able to manage non serious and serious AEFI



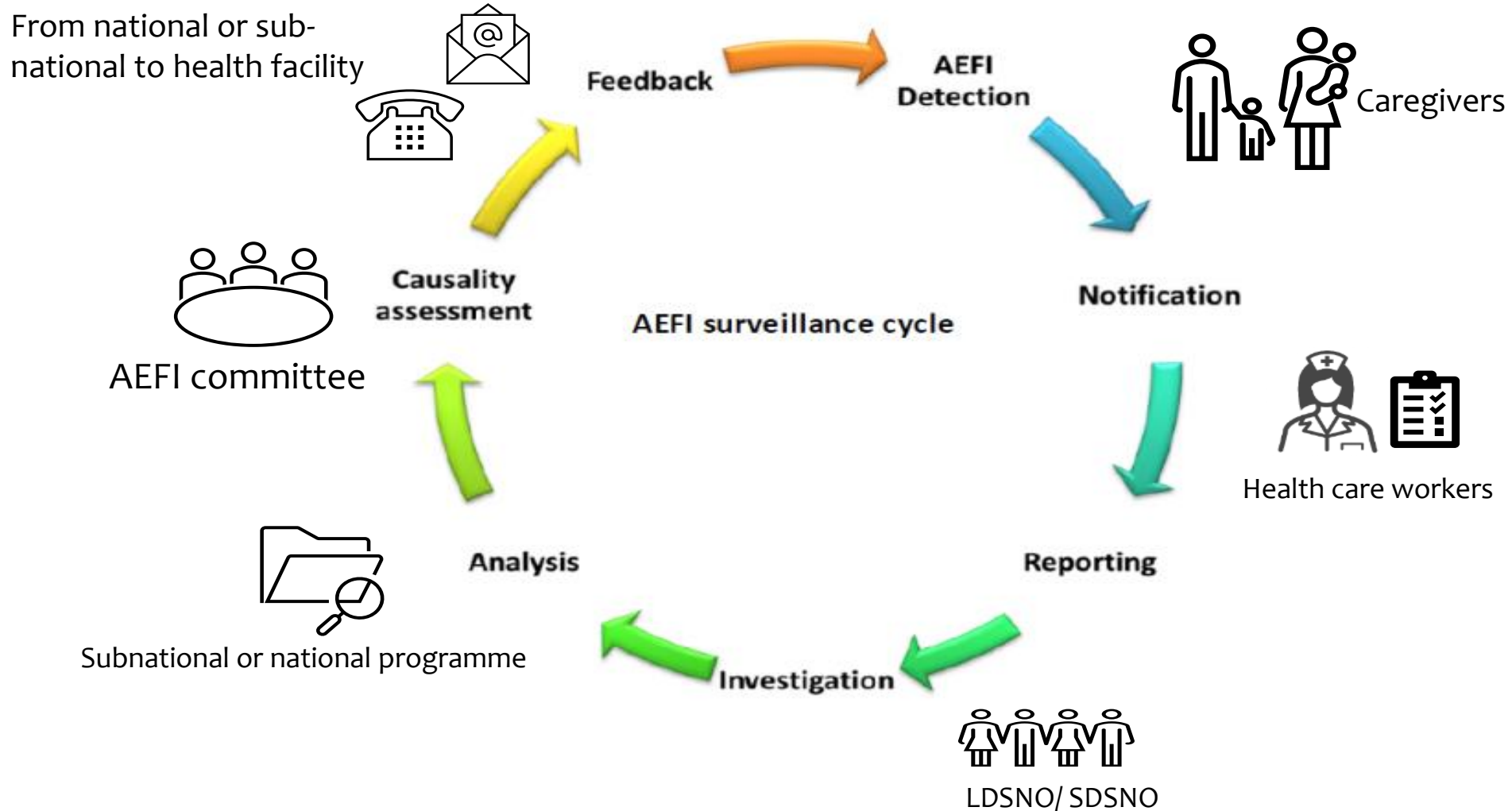
Safety Surveillance System

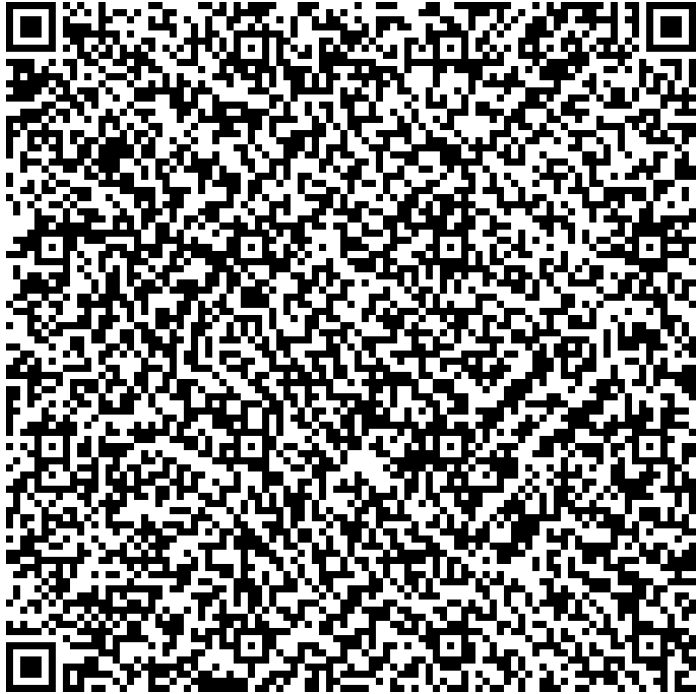
Mpox Vaccine





AEFI Cycle and Key Players





Cohort Event Monitoring

Enrol
Record reactogenicity
Follow up



Informed Consent

Fill ODK



	d0	d7	d14	d21	d28	exit
Informed Consent	✓					
Fill ODK	✓	✓	✓	✓	✓	✓



Vaccine Safety Surveillance of the Mpox vaccine recipients



Spontaneous reporting:

- All vaccine recipients can report Adverse Events Following Immunization (AEFIs) through the routine pharmacovigilance system, either detected during consultations or self-reported.
- Health workers complete a reporting form for all AEFIs; if serious, an additional investigation form is filled.
- The LGA Disease Surveillance and Notification Officer (DSNO) collects and enters the report into an electronic tool, while the paper form is sent to the state level.
- The state conducts performance monitoring on the paper reports, while electronic reports are validated at the national level and shared globally for vaccine safety analysis.
- Serious cases are referred to hospitals with relevant medical and investigation documents, and the investigation folder is shared with the national team.
- The National Expert Committee (NEC) clinically assesses serious AEFI cases and data for safety signals, which are then forwarded to decision-making bodies – NAFDAC and NITAG.



Vaccine Safety Surveillance of the Mpox vaccine recipients



Cohort Events Monitoring (CEM):

- Here, the person vaccinated from day 0 will be approached by an enroller who will inform them of the safety surveillance if he is willing to participate,
- The enrollee will sign a consent form and will also provide information on his prior conditions.
- A day after vaccination (day1) the enrollee will be called to see if he has any reactions (fever, pain at the site of injection. etc.).
- The enrollee will be called again on day 3, to monitor possible reactions again.
- Subsequently, the enrollees will be actively followed up until 5 weeks after each Mpox vaccine dose to see if they have visited any hospital. If a vaccinee visited a hospital for a condition other than accident, the hospital will be visited for collection of medical records and assessment.
- The file will be collected from the hospital and shared with the NEC for review, to determine if it is vaccine related.
- Enrollment of participants of participants will take place at each of the vaccination sites. Once the participant is enrolled, he will be followed up by house visits and/or phone calls.



Vaccine Safety Surveillance of the Mpox vaccine recipients



Sentinel hospital active search:

- Selected hospitals will be regularly visited for screening of hospital registers in active search of defined Adverse Events of Special Interest (AESI).
- The screening for AESI will cover the vaccination dates up to the forty-fifth day after the last person vaccinated.
- The potential cases will be line listed based on signs and symptoms by a Nurse using the combination of signs and symptoms.
- This is followed by the ascertainment of the case by a clinician using the Brighton Collaboration's case definition. The data abstraction will be done by the Nurse after ascertainment by the clinician using electronic tool.
- Finally, the data will be analyzed by the NPHCDA and shared with the NAFDAC.



Basic Concepts and Definitions



An Adverse Event Following Immunization (AEFI) is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine.

There are two broad classifications of AEFI.

1 Regulatory classification (Non serious AEFI and serious AEFI)

2

Cause specific classification – Five Categories

- *Vaccine Product related reaction, Vaccine quality defect related reaction, Immunization error related, Anxiety related reaction & Coincidental*

The adverse event may be any unfavorable, unintended sign, abnormal laboratory finding, or symptom or disease.



Basic Concepts and Definitions:



Regulatory classification

- **Non-Serious AEFIs**: An event that is not ‘serious’ and does not pose a potential risk to the health of the recipient (occurs within 2hrs of injection, resolves after a short period, poses little danger).

Serious AEFIs

is defined as an event causing a potential risk to the health/life of a recipient leading to

- **Hospitalization** or prolongation of existing hospitalization (*e.g., encephalopathy, seizures, aseptic meningitis*)
- **Persistent or significant disability or incapacity** (*e.g., paralysis*)
- **Life-threatening**
- **Congenital Malformations**
- **Death**

- ‘**Serious**’ is not synonymous with ‘**severe**’ (i.e., intensity or severity of the event)



Cause-specific classification of AEFI

	1	2	3	4	5
	Vaccine product-related reaction	Vaccine quality defect-related reaction	Immunization error-related reaction	Immunization anxiety-related reaction	Coincidental event
AEFI DEFINITION	Caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product	Caused by a vaccine due to 1 or more quality defects of the vaccine product including its administration device	Caused by inappropriate vaccine handling, prescribing, or administration	Arising from stress or anxiety about the immunization	Caused by something other than the vaccine product, immunization error, or immunization stress / anxiety
Example	Extensive swelling following DTP vaccination	Failure by the manufacturer to completely inactivate the germs (virus, bacteria etc.)	<i>Transmission of infection by contaminated multidose vial</i>	<i>Vasovagal syncope in an adolescent following vaccination</i>	<i>A fever after vaccination (temporal association) caused by a respiratory tract infection</i>



Likely side effects for Mpox Vaccine

Common side effects

- Local reactions – pain, redness, itching at the injection site
- Fatigue
- Headache
- Myalgia
- Nausea

Serious risk

- Very rare allergic reactions - lymphadenopathy



Management of AEFI



Management of non serious AEFI



Therapeutic remedies against fever and pain

- Paracetamol
- 15mg/kg every 6-8 h
- Maximum 4 doses / 24h

Non therapeutic remedies against fever

- Tepid sponging or warm bath
- Light cool clothing
- Oral rehydration

Non therapeutic remedies against local reactions

- Cold bandage applied to the injection site

 *Traditional medicines are to be avoided*

In case of worsening, take the patient to the nearest health facility with the vaccination card



Management of serious cases in health Facilities





*Thank
you*





Provisions for Mpox Vaccination



Each state will be provided with the following



- 4 teams – to cover multiple sites over the 10 days (teams may cover more than one site per day)
- Physical training at state level for vaccination team members
 - Tea break, lunch and transportation provided for team members and facilitators
- Transportation allowance -N20,000/day/team
- Supervision for State and LGAs team members (6 state – inclusive of the NPHCDA SC and 2 LGA supervisors)
- Vaccination post banner (1 per team) and publicity banners (4 per state)
- Data tools - *E -copies will also be made available*
 - Vaccination cards, Mpox Vaccine registers, Tally sheets, DIPs and Summary sheets



Vaccine logistics and health commodities distribution cost



- Intrastate Vaccine distribution cost including boat transport in riverine areas
- Transport Logistics for State Cold chain officer
- Fueling of generators
- Waste management (including transport to incineration sites and incineration, boiling etc.)



Vaccine Allocation



	STATE	VACCINE ALLOTTED
1	Rivers	1500
2	Ogun	1500
3	Kaduna	3000
4	Cross River	3000
5	Ondo	1500
6	Akwa Ibom	3000
7	Imo	2500
8	Edo	2500
9	Delta	2500
10	Plateau	2500
11	Benue	2000
12	Bayelsa	300
	TOTAL	25800



*Thank
you*





Next Steps



Next steps



- Submit details of vaccination team supervisors, and budget to Unicef to facilitate payments for logistics and other health commodities as needed for implementation.
- Work closely with surveillance team to identify hotspots and prioritize vaccination sites
- State level training of vaccination teams- 28th July 2025
- Engagement of Priority groups, key actors for Mpox vaccination – 24th – 29th July 2025
- Tentative Implementation date: 30th July 2025

Thank
you

