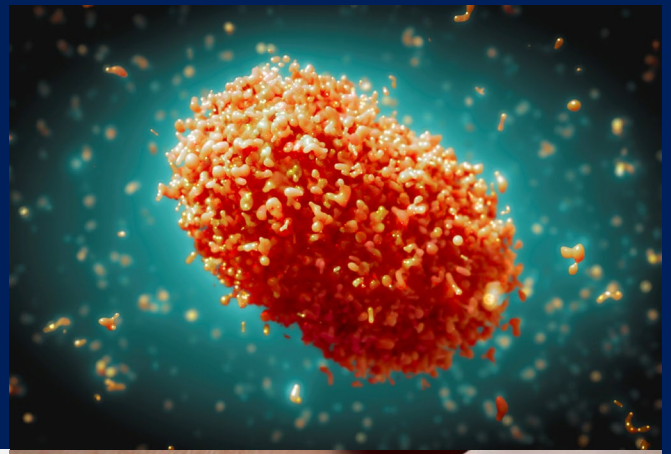
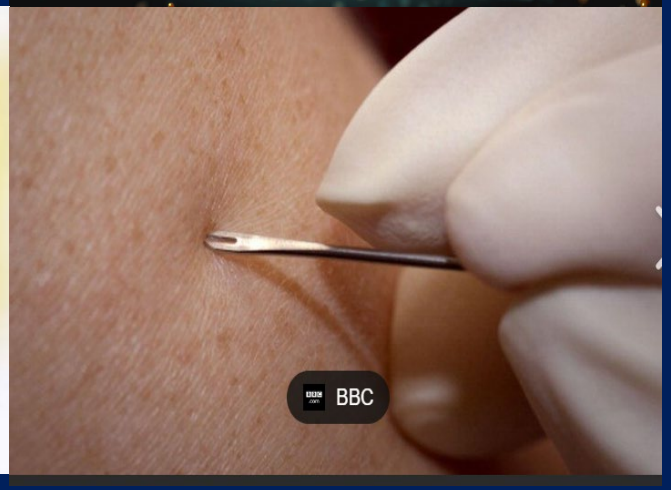
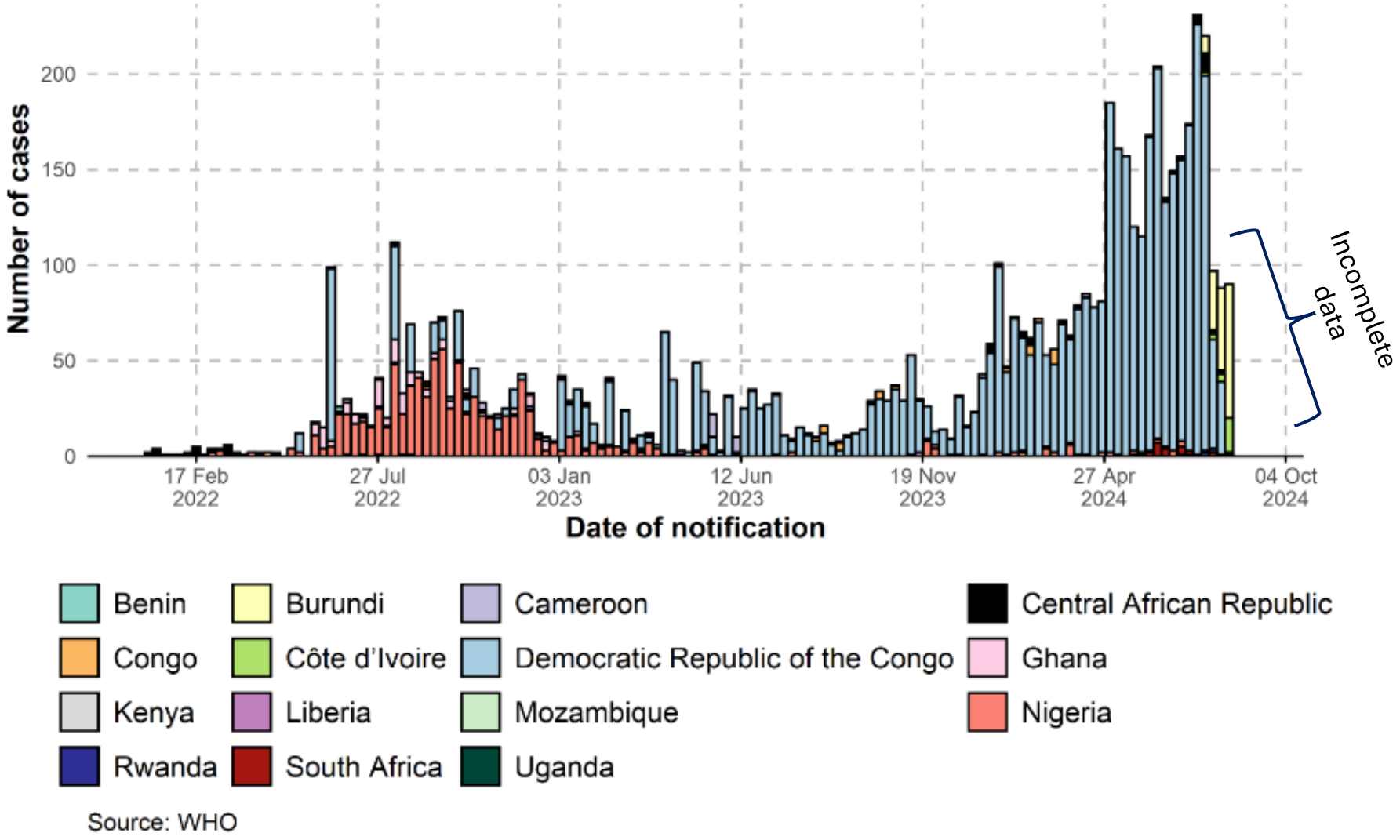
Status of mpox outbreaking the African Region and use of mpox vaccines





WHO African region epi curve, confirmed cases as of 25 Aug



Source: WHO

Total confirmed cases as of 25 August 2024 since 2022

7 658

Total confirmed deaths as of 25 August 2024 since 2022

54 (CFR = 0.7%)

Total confirmed cases and deaths from 01 Jan - 25 Aug 2024
Cases = 5281
Deaths: 32 (CFR = 0.6%)

World Health Organization
African Region

African countries actively affected as of 25 August 2024

Newly affected or re-affected countries in July / August 2024

- Burundi
- Rwanda
- Uganda
- Kenya
- Cote d'Ivoire
- Liberia
- Gabon
- Republic of Congo
- Nigeria
- Central Africa Republic
- South Africa

Suspected cases are being investigated in other countries.

World Health Organization
African Region

Newly affected countries with Clade 1b

- **Emerged in 2023** and has been spreading through sustained human-to-human transmission in eastern DRC since September 2023, in absence of zoonotic exposure.
- Detected **in six other countries: Burundi, Rwanda, Kenya, Uganda, Sweden,** and **Thailand**.
- Current estimated **Case Fatality Ratio is 0.7%** in **DRC***.
- **All mpox types of transmission still continue to occur**, but sexual contact has amplified the transmission quickly in certain networks and areas.
- **Drivers of transmission: human-to-human close contact**, including sexual contact, as well as other mpox modes of transmission.
- No deaths have been reported so far outside of DRC

Country	# confirmed cases	Distribution
Burundi	231	Dispersed in the country
Rwanda	4	3 in capital; 1 in border district
Uganda	4	Multiple districts
Kenya	2	PoE with Tanzania
Sweden	1	Travel history to Africa
Thailand	1	Travel history to Africa

**Available data from South Kivu for Epi Weeks 1-34*

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African Region

Complexities in understanding mpox transmission

- **Unknown** animal **reservoir**
- **Unclear** contribution of **zoonotic and human-to-human transmission** in African setting
- Different **distribution** of **MPXV clades** and **subclades**
- **Low sequencing** available in the African Region to monitor emerging strains
- Unclear human-to-human **transmission dynamics** in different settings
- **Different** age groups and **demographics** are affected in different geographical areas making the **comparison** of severity and outcomes **complex to interpret**
- **Multiple concurrent outbreaks**, with different characteristics are ongoing in endemic and newly affected provinces of the **DRC**
- Affected areas in the eastern part are also affected by **conflict and insecurity** which **hinder surveillance and response** activities

Standing recommendations

Standing recommendations for mpox issued by the Director-General of the World Health Organization in accordance with the International Health Regulations (2005) (IHR)

21 August 2023

"States Parties are recommended to develop and implement national mpox plans that build on WHO strategic and technical guidance, outlining critical actions to sustain control of mpox and achieve elimination of human-to-human transmission in all contexts through coordinated and integrated policies, programmes and services."

World Health Organization
African Region

Vaccines and other countermeasures are included, importantly, the DG's standing recommendations on mpox

States Parties are recommended to

A. Have national mpox plans integrated into broader health systems. Capacities that have been built in resource-limited se… …nd among marginalized groups should be sustained.

B. Strengthen and sustain testing and surveillance capacity and ensure that new cases of mp…

C. Protect communities through communication and engagement; continu… …on.

D. Invest in research to better understand mpox disease… …proved vaccines, tests, and treatments.

E. Provide travelers with i… …fore, during and after travel and refrain from implementing travel-related h… …sting for travelers.

F. Deliver o… …tients, integrated within HIV and STI programmes, with access to treatments and measures to protect hea… …givers.

G. Work towards equitable access to safe, effective and quality-assured vaccines, tests and treatments for mpox.

Extended to August 2025

World Health Organization
African Region

Vaccines & immunization are a critical component of the overall strategic framework for mpox control

Components

C1 | Emergency coordination
Strengthen emergency operations and coordination between Member States and stakeholders for public health response appropriate for the local context and integrated with key health services

C2 | Collaborative surveillance
Monitor and share information to improve collective understanding of how an outbreak is evolving, identify specific risk, and inform response measures

C3 | Community protection
Raise awareness and empower communities to adopt protective measures.

C4 | Clinical care
Provide safe and quality clinical care for individuals and prevent infections in health and community settings

C5 | Countermeasures
Improve access to effective diagnostics, vaccines and therapeutics for mpox

C6 | Research
Drive the cross-cutting research agenda in all areas

Objectives

1. Achieve control of mpox outbreaks with focus on groups at risk in each context
2. Advance mpox research and access to countermeasures
3. Minimize zoonotic transmission of monkeypox virus

Goal

Stop mpox

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African Region

Vaccine products are currently licensed across various countries for use against mpox, but are not *prequalified*

Product	Description	Dosing	Administration / presentation	Where licensed	Indicated age group
MVA-BN	Non-replicating vaccinia-based vaccine, 3rd generation	Two doses four weeks apart	Needle and syringe (subcutaneous or intradermal administration) Liquid frozen or freeze-dried	Canada, EU, USA, UK, Switzerland	Canada, EU, UK: 18+ US: 18+ <18 under EUA
LC16	Minimally replicating vaccinia-based vaccine, 3rd generation	Single dose regimen	Bifurcated needle, percutaneous route/administration Freeze-dried Multidose vials	Japan	No limitations
ACAM2000	Replicating vaccinia-based vaccine, 2nd generation	Single dose regimen	Bifurcated needle, percutaneous route/administration Freeze-dried Multidose vials	USA (Emergency investigational new drug), Australia, Singapore	16+
OrthopoxVac	Non-replicating, vaccinia-based vaccine, 4th generation	Single dose regimen	Needle and syringe (intradermal administration) Freeze-dried	Russian Federation	18 to 60 years
CJ-50300	Live replicating, 2nd generation	Single dose regimen	Bifurcated needle Freeze-dried Multidose vials	Republic of Korea (Emergency Use Authorization)	20 to 60 years

Additional details not currently available / under ascertainment

World Health Organization
African Region

Mpox vaccines in the African Region

- Vaccines currently not prequalified or have emergency use listing (EUL)
- WHO DG triggered the process for EUL for mpox vaccines, which will accelerate vaccine access in the African Region
- EUL also enables partners including Gavi and UNICEF to procure vaccines for distribution

R&D: evidence gaps remain on the use of mpox vaccines

Category	Evidence gap	Note
Safety	Safety during pregnancy and breastfeeding	No data
	Surveillance and monitoring of serious adverse events, including in subpopulations	No safety signals to date
	Safety in immunocompromised persons, including advanced HIV, persons with autoimmune disease	HIV not a contra-indication
	Further safety profile in persons below the age of 18 years, including in young children	LC16 licensed for children; MVA-BN-filo approved for children; MVA-BN study 12-18 years underway
Immunogenicity & effectiveness	Immunogenicity and VE in persons below the age of 18 years, including in young children	Studies proposed, RCT needed
	Vaccine effectiveness over time, need for booster	13 observational studies show 82% for 2 doses (MVA)
	Correlates of initial protection and correlates of durability of protection	Smallpox immunity gap globally
	Assessment and reporting of breakthrough infections	Expected for VE of 82%
Epidemiology	Evidence on risk factors for mpox exposure, especially in LMICs	Need to strengthen surveillance, descriptive epi
	Evidence on severity of disease, including in children, especially in LMICs	Need case-based surveillance, clinical characterization, causes of death
	Evidence on modes on transmission in LMICs, including in children	Multi-disciplinary, One Health approach
	Seroprevalence studies	Needed to assess background risk
	Duration of protection following natural exposure	Occasional re-infection documented

Studies are on-going to close these evidence gaps

Study	Location(s)	Sponsor	Product	Description
Cluster-randomization phase 3 vaccination trial to evaluate the efficacy and safety of the LC16	DRC	INRB / MSPHP (DRC); MHLW (Japan)	LC16	Open-label phase III vaccine trial to test the efficacy and safety of the LC16 vaccine in population and region where mpox occurs
SMART (Smallpox vaccine for Mpox for Post-Exposure Prophylaxis: A Cluster Randomized Controlled Trial)	Nigeria (DRC, Uganda)	McMaster University (Canada)	MVA-BN	A pragmatic, adaptive, multi-site, double-blind, cluster-randomized trial where households with one or more persons confirmed to have mpox (index) will be randomized to smallpox vaccine or control.
Non-inferiority study of MVA in children from 2 to less than 12 years of age compared to adults	TBD	Bavarian Nordic	MVA-BN	Open-label, comparative, multi-center immunogenicity and safety study in children compared to adults
Randomized controlled trial to assess the efficacy of LC16 in population HIV+, PrEP, MSM	Colombia	KM Biologics	LC16	Parallel open-label sequential randomized controlled trial
REMAIN Prospective cohort (18 years and older)	Multi-sites	Fundación FLS de Lucha Contra el Sida	MVA-BN	Observational trial to assess effectiveness of MVA-BN in Spain and Latin American countries
A two-staged phase 2 randomized, open-label trial	USA	NIAID	MVA-BN	Comparison of the immunogenicity and safety of MVA-BN in adolescents aged 12-17 years to adults aged 18-50 years
SEMVac Safety and effectiveness MVA-BN in at risk population	Germany	TBD	MVA-BN	Multicenter prospective cohort study in adults at risk

Several pathways exist for regulatory assessment of available vaccine products

#	Pathway	First steps	Benefits	Considerations
1	**WHO Emergency Use Listing/ Prequalification Procedure**	• DG decision required to allow opening of Expression of Interest (EoI) • WHO would then open EoI	• Unlocks UNICEF / Gavi procurement & support • Single entry to all Member States	• Requires specific emergency context • Indemnification and liability issues must be addressed
2	**Use under RCTs / research protocols (randomization non deployment)**	• NRA / Ethics Committees approve an mpox study protocol	• Quicker access • Opportunity to close clinical data / evidence gaps in target groups (e.g. children)	• Requires political decisions based on public health needs
3	**Stringent Regulatory Authority (SRA)-facilitated National Regulatory Authority (NRA) review**	• Country must request support from SRA • SRA shares assessment reports and /or engages in joint review with NRA	• Enables access to currently indicated age groups for possible outside of the clinical trials	• Requires safety monitoring outside of controlled clinical trial • More difficult to collect clinical data to close data gaps • Must be done for each country

NOT EXHAUSTIVE

Countries can access available mpox products through several mechanisms

#	Mechanism	Flow	Description
1	**Direct procurement**	Manufacturer to country	Countries that have the requisite policy, regulatory and financial capacity procure vaccines directly from manufacturers
2	**Pooled procurement**	Manufacturer to 3rd party to country	Global / regional initiatives to aggregate demand across countries for combined procurement from manufacturers (ex. PAHO Revolving Fund, HERA)
3	**Coordinated donations**	Country (or manufacturer) to 3rd party to country	Global / regional initiatives to accept donations from countries / partners / manufacturer for subsequent redistribution
4	**Bilateral donations**	Country to country	Countries with supply to spare donate doses (and materials) to requesting countries

NOT EXHAUSTIVE

What should countries who want to use mpox vaccines do next?

- Discuss with **national immunization technical advisory groups (NITAGs)**

- Begin **regulatory approval*** for bringing new vaccines in country
  - National regulatory authority
  - Ethics review committee

- Consider research protocols as way to incorporate vaccination into the response and close key knowledge gaps

*The African Vaccine Regulatory Forum (AVAREF) platform in WHO AFRO is being used to facilitate the authorization of vaccines

World Health Organization
African Region

THANK YOU

Obrigada

MERCI

NITAG support hub: Vaccinology webinar series for NITAGs in Africa

SAGE recommendations for mpox

Dr Judith van Holten

SAGE secretariat

28 August 2024

World Health Organization

Mpox vaccine and immunization recommendations

- In response to the global mpox outbreak, interim guidance on mpox vaccines and immunization was endorsed by SAGE and published in November 2022
- In the last year, additional epidemiological data has been obtained from the African setting
- New information has become available regarding the safety and vaccine effectiveness of MVA-BN
- SAGE considered this for the 2024 updated mpox vaccine and immunization recommendations
- These updated mpox vaccine recommendations are now published in a position paper which combines SAGE endorsed smallpox vaccine recommendations developed in October 2023

Smallpox and mpox vaccine position paper WER9934-eng-fre.pdf (who.int)

World Health Organization

Recommendation mpox outbreak response[1]

- Vaccination is **recommended for persons at high risk of exposure to mpox in an outbreak**. The identification of populations at risk of exposure is limited in some settings by currently available epidemiological data. This is particularly the case for communities affected by zoonotic transmission. In studies involving men who have sex with men, pre-exposure vaccination with one or two doses of smallpox/mpox vaccine was demonstrated to be effective against mpox. Effectiveness of post-exposure vaccination is less certain, which may be linked to the predominantly sexual mode of transmission in available studies. To allow the greatest flexibility with respect to local risk assessment, varied modes of transmission and response options, populations to consider for vaccination may include:
    - **based on local epidemiology**, members of a geographically defined area or community (e.g. village), including children, with a documented high risk of exposure to mpox;
    - sex workers; gay, bisexual or other men who have sex with men (MSM) with multiple sexual partners; or other individuals with multiple casual sexual partners;
    - **health workers at risk of repeated exposure**; clinical laboratory and health care personnel performing diagnostic testing for mpox or providing care, and outbreak response team members (as designated by national public health authorities).
    - **contacts of persons with mpox**, ideally within four days of first exposure.[2] Contacts may include children, others in the household or in congregate settings (such as prisons, schools, health facilities or residential facilities)

1. Outbreak definition: occurrence of two or more laboratory confirmed (or one laboratory confirmed and one or more epidemiologically linked cases) of mpox in nationally or locally defined geographic areas

2. Criteria to define risk of exposure in this context include e.g. direct skin-to skin physical contact, contact with contaminated materials such as clothes or bedding. Vaccination ideally up to 14 days in the absence of symptoms.

Choice of vaccines for immunocompetent non-pregnant individuals

- WHO recommends that for immunocompetent non-pregnant individuals, non-replicating vaccine (MVA-BN), minimally replicating vaccines (LC16m8), replicating cell-culture derived vaccinia-based vaccines (e.g. ACAM2000) or equivalent vaccines that meet WHO standards for quality, are appropriate for use.
- Specific considerations, including potential off-label use, apply as to vaccine choice for special population groups (see recommendation on vaccine choice for special populations).

Choice of vaccine for special populations - infants, children and adolescents

- For infants, children and adolescents, where consideration is given to vaccination, non-replicating (MVA-BN) or minimally replicating (LC16m8) vaccines may be used.
    - LC16m8 is approved for use in children in Japan. However, LC16m8 is contraindicated in pregnancy and in immunocompromised children and adolescents, including in uncontrolled advanced HIV.
    - While MVA-BN is currently not licensed for persons under 18 years old, this vaccine may be used in infants, children and adolescents when the benefits of vaccination outweigh the potential risks in the context of an outbreak. The use of MVA-BN in children constitutes an “off-label” product use.
    - Replicating vaccine (such as ACAM2000) should not be used in infants.
    - WHO recommends further collection of data on vaccine safety and effectiveness for these populations.

Choice of vaccine for special populations - pregnancy

- During pregnancy, where consideration is given to vaccination, non-replicating vaccine (MVA-BN) should be used.

Replicating vaccine (such as ACAM2000) and minimally replicating vaccine (such as LC16m8) should not be used in pregnancy. Administration of MVA-BN in pregnancy constitutes “off-label” use.

Choice of vaccine for special populations – immunocompromised persons

- For immunocompromised individuals for whom replicating (such as ACAM2000) or minimally replicating (LC16m8) vaccine is contraindicated, non-replicating vaccine (MVA-BN) should be used; likewise for individuals for whom there are warnings or precautions because of immunosuppressive therapies or proliferative skin conditions (e.g. atopic dermatitis), non-replicating (MVA-BN) vaccine should be used.

- Immunocompromised persons include those with active cancer, transplant recipients, immunodeficiency, and active treatment with immunosuppressive agents. They also include people living with HIV with a current CD4 cell count of <200 cells µl.

Vaccination schedules and dosing

Based on the risk profile and the available vaccine data, WHO recommends “off-label” use of a single dose or intradermal fractional dosing* of MVA-BN in supply-constrained outbreak situations. WHO emphasizes the need to collect further data on vaccine safety and effectiveness in these circumstances.

*one fifth of a dose (0.1mL) administered intradermally

Vaccination in previously vaccinated individuals

The duration of protection of vaccinia-based mpox vaccines is not fully characterized and may vary between vaccine products. WHO recommends that individuals who are eligible for vaccination should be vaccinated irrespective of documented previous smallpox vaccination and/or visible smallpox vaccine scar. For individuals previously vaccinated with mpox vaccines, an individual benefit-risk assessment should be done.

Thank you

World Health Organization

MPOX Outbreak vaccines rollout: Evidence to Recommendation Process for NITAGs (example of PICO questions)

Dr Sidy Ndiaye, Immunization Officer,
AFRO/UCN/VPD

Acknowlegment : joint effort from NITAGs support partners : TFGH, NISH, US/CDC and WHO

Broad policy question 1: Should country X recommend mpox vaccines for populations in the community at high risk* of mpox during the current outbreak?

Population	Populations in the community at high risk* of exposure to mpox in an outbreak setting (e.g. close contacts or members of "key" populations) in outbreak regions
Intervention	Administration of **the licensed^ or WHO pre-qualified** mpox vaccine (MVA-BN [Two doses], LC-16 [One dose]) or ACAM2000 (One dose)
Comparison	No vaccination
Outcomes	Reduction in incidence of mpox infection and complications (hospitalization or death)
PICO Question	In persons at high risk of mpox in the community during an mpox outbreak, what is the evidence that mpox vaccine is safe and can reduce the incidence of infection, hospitalization, and death?

- *Populations in the community at high risk*: To be defined based on epidemiology of mpox in the outbreak setting (e.g. household contacts of cases and contacts of contacts, other members of the local community, contact with live or dead wild animals, persons with multiple casual sexual contacts, frontline workers such as customs workers, persons working at borders with affected countries etc.).
- ^ mpox vaccines currently under Emergency Use Listing (EUL)

Broad policy question 2: Should country X recommend mpox vaccines for healthcare workers and frontline workers at high risk of being exposed during the current outbreak?

Population	Healthcare workers and frontline workers** at high risk of exposure to mpox.
Intervention	Administration of the licensed^ or WHO pre-qualified mpox vaccine (MVA-BN [two doses], LC-16 [one dose]) or ACAM2000 (one dose)
Comparison	No vaccination
Outcomes	Reduction in incidence of mpox infection and complications (hospitalization or death)
PICO Question	In healthcare and frontline workers at high risk of mpox during an outbreak, what is the evidence that mpox vaccine is safe and can reduce the incidence of infection, hospitalization, and death?

** **Health care and frontline workers**: For example, health workers at risk of repeated exposure; clinical laboratory and health-care personnel performing diagnostic testing for mpox or providing care; and outbreak response team members (as designated by national public health authorities)., etc.

Specific consideration when developing criteria table and collecting evidence

Identification of **Risk Groups** and prioritization:

Surveillance: Epidemiologic features and serotypes

Vaccine Efficacy and Safety: Suitability, monitoring, and data collection

Vaccine Access and Equity: Ensuring equitable access and preventing disparities

Values and Preferences: Target populations and healthcare workers

Resources: Mobilization for quick vaccine rollout

NITAG operation:

- **Extending working group membership** to Environmental and animal health experts, health ethics
- Working with the **National regulatory agency, safety committee** (as ex-officio member)
- **leveraging in on the COVID-19 experience** in providing timely recommendation, supporting the advocacy, training of health professional, Media briefing; …
- **Updating the recommendation** considering new evidences and mpox outbreak evolution.

Mpox Outbreak Vaccine Rollout
Evidence to Recommendations (EtR) Process for NITAGs

- Resources to support NITAGs
  - Developing PICO Question(s)
  - Developing Evidence Tables – PICO Specific
    - 7 Criteria Domains
    - Examples developed in consultation with WHO, US CDC experts
    - Domain 1 – Problem
    - Domain 2 – Benefits and Harms
    - Domains 3-7 – in resource materials
  - Additional Information
    - Vaccines available – General characteristics, Safety/Efficacy, Use in different age groups
    - Worksheet for considering risk groups to vaccinate
  - All EtR resource materials available - to be updated as appropriate

  - Primary Source - WHO Position Paper – Smallpox and Mpox (Orthopoxviruses) - August 2024 Immunization, Vaccines and Biologicals (who.int)

Evidence to Recommendations
Seven Criteria Domains

Evidence to Recommendations Criteria Table
Domain 1: Problem

Element	Categories of Evidence
1.1 Burden of disease	• Incidence of morbidity & mortality • Age-specific morbidity and mortality • Risk groups • Serotype distribution • Disease occurrence over time • Changes in epidemiology over time
1.2 Clinical characteristics of the disease	• Signs and symptoms of disease • Severe forms • Long-term complications of disease • Medical management of disease
1.3 Use and Costs of Health Care	• Primary/secondary/tertiary care implications • Short- and long-term use of healthcare (e.g., treatments, hospitalization)
1.4 Alternative preventive and control measures	• Alternative preventive and control measures (e.g., health education, hygiene) and their effectiveness, costs, practicality
1.5 Regional and international considerations	• Existence of regional and global recommendations • Disease potential for international spread and pandemic risk

PICO-Specific Evidence Table

Example - Mpox

Policy Question: Should country X recommend mpox vaccines for populations in the community at high risk* of mpox during the current outbreak?

PICO Question: In persons at high risk of mpox in the community during an mpox outbreak, what is the evidence that mpox vaccine is safe and can reduce the incidence of infection, hospitalization, and death?

Domain 1: Problem

Element	Categories of Evidence	PICO-Specific Evidence to Collect	Priority	Sources of Evidence
1.1 Burden of disease	☐ Incidence of morbidity & mortality ☐ Age-specific morbidity and mortality ☐ Risk groups ☐ Serotype distribution ☐ Disease occurrence over time ☐ Changes in epidemiology over time			
1.2 Clinical characteristics of the disease	☐ Signs and symptoms of disease ☐ Severe forms ☐ Long-term complications of disease ☐ Medical management of disease			
1.3 Use and Costs of Health Care	☐ Primary/secondary/tertiary care implications ☐ Short- and long-term use of healthcare (e.g., treatments, hospitalization)			
1.4 Alternative preventive and control measures	☐ Alternative preventive and control measures (e.g., health education, hygiene) and their effectiveness, costs, practicality			
1.5 Regional and international considerations	☐ Existence of regional and global recommendations ☐ Disease potential for international spread and pandemic risk			

PICO-Specific Evidence Table

Example - Mpox

PICO Question: In persons at high risk of mpox in the community during an mpox outbreak, what is the evidence that mpox vaccine is safe and can reduce the incidence of infection, hospitalization, and death?

Domain 1: Problem

Element	Categories of Evidence	PICO-Specific Evidence to Collect	Priority	Sources of Evidence
1.1 Burden of disease	☒ Incidence of morbidity & mortality	Incidence, hospitalizations and deaths due to mpox before and during outbreak	Critical	Surveillance (country), AFR CDC, WHO AFRO Rapid review (NISH/UCT)
	☒ Age-specific morbidity and mortality	Age specific incidence, hospitalizations, mortality		
	☒ Risk groups	Risk groups (severe disease) – immunocompromised, pregnant and breast-feeding women, young children Persons at risk during outbreaks – laboratory staff and clinical persons treating disease, key populations (commercial sex workers, MSM, persons with multiple casual sex partners, transgender), outbreak response team and frontline workers, congregate settings (prisons, etc)		Persons at risk during outbreaks to be defined by country MOH/govt
	☒ Serotype distribution	Mpox virus clade, genomic sequences		
	☒ Disease occurrence over time	Incidence prior to outbreak and time course during outbreak		
	☒ Changes in epidemiology over time			
1.2 Clinical characteristics of the disease	☒ Signs and symptoms of disease	Skin rash (systemic, genital), fever, lymphadenopathy, headaches, etc	Critical	WHO SAGE, Mpox Website; AFR CDC; country information
	☒ Severe forms	Severe systemic rash, secondary sin lesions, encephalitis, hepatitis, pneumonitis, hospitalization, death		
	☒ Long-term complications of disease	? Skin scarring, corneal and facial scarring impaired vision/blindness, sexual impairment		
	☒ Medical management of disease	Prevention secondary infection, ? other; ? antivirals		

PICO-Specific Evidence Table

Example - Mpox

PICO Question: In persons at high risk of mpox in the community during an mpox outbreak, what is the evidence that mpox vaccine is safe and can reduce the incidence of infection, hospitalization, and death?

Domain 1: Problem (continued)

Element	Categories of Evidence	PICO-Specific Evidence to Collect	Priority	Sources of Evidence
1.3 Use and Costs of Health Care	☒ Primary/secondary/tertiary care implications ☒ Short- and long-term use of healthcare (e.g., treatments, hospitalization)	Clinic care, hospital care, ? ICU	Critical Important	Country information
1.4 Alternative preventive and control measures	☒ Alternative preventive and control measures (e.g., health education, hygiene) and their effectiveness, costs, practicality	Infection prevention/control – isolation, handwashing, gloving/gowning, clinical care; surveillance, contact tracing, self monitoring; health education, hygiene, ? other	Critical	Country information
1.5 Regional and international considerations	☒ Existence of regional and global recommendations ☒ Disease potential for international spread and pandemic risk	WHO SAGE, RITAG recommendations, emergency committee, EPR/TAG statements Substantial risk of cross border transmission – neighboring countries, distant travel (IHR, Africa CDC)	Critical	WHO SAGE, AFR CDC, WHO AFR

PICO-Specific Evidence Table

Example - Mpox

PICO Question: In persons at high risk of mpox in the community during an mpox outbreak, what is the evidence that mpox vaccine is safe and can reduce the incidence of infection, hospitalization, and death?

Domain 2: Benefits and Harms

Element	Categories of Evidence	PICO-Specific Evidence to Collect	Priority	Sources of Evidence
2.1 Vaccine characteristics	☒ Vaccine presentation, formulation, dosage, and route of administration ☒ Administration schedule and possibility of co-administration with other vaccines and drugs ☒ Flexibility of vaccination schedule ☒ Cold chain and logistic requirements	MVA-BN (non-replicating)(2 dose –SQ or ID , 4 weeks apart); LC-16 (minimally replicating)(1 dose, percutaneous with bifurcated needle) ACAM-2000 (replicating, 1 dose, bifurcated needle) # doses/vial No data re. Co-administration with other vaccines MVA-BN – 18+ yrs; <18 EUA; LC-16 – all ages; unsuitable for immunocompromised, pregnant, proliferative skin diseases ACAM2000 – immunocompetent adults: unsuitable for immunocompromised, pregnant, proliferative skin diseases, infants < 1yr Liquid frozen (MVA-BN) or freeze dried (MVA-BN, LC-16)	Important	WHO SAGE August 2024 Vaccine Product package inserts
2.2 Safety	☒Type, consequences and frequency of short and long-term adverse events following vaccination ☒ Risk groups or risk factors for adverse events ☒ Contraindications or precautions	Type, consequences and frequency of adverse events following vaccination during clinical trials - Local or muscle pain, redness, swelling, headache, fatigue No serious AEFI identified for MVA-BN, LC-16; ACAM2000-Myopericarditis – 20.1/100000 doses LC-16, ACAM2000 - immunocompromised, pregnant persons, proliferative skin diseases ACAM2000 – infants < 1 yr	Critical	WHO SAGE Meta-analyses 2022, 2024 Vaccine package inserts Country information

PICO-Specific Evidence Table
Example - Mpox

PICO Question: In persons at high risk of mpox in the community during an mpox outbreak, what is the evidence that mpox vaccine is safe and can reduce the incidence of infection, hospitalization, and death?

Domain 2: Benefits and Harms (continued)

Element	Categories of Evidence	PICO-Specific Evidence to Collect	Priority	Sources of Evidence
2.3 Efficacy and effectiveness	☒ Vaccine efficacy/effectiveness and types of specific protection ☒ Critical determinants of the immune response associated with protection ☒ Duration of protection and waning of immunity in general and risk groups ☒ Interference regarding protection or immunity with other vaccines	MVM-BN , ACAM2000 , LC16 efficacy, effectiveness for primary preventive vaccination for high-risk population of exposure (by age, previous vaccination with Small pox vaccine) Determinants of vaccine efficacy and effectiveness in populations with underlying conditions such as immunocompromised, malnutrition, pregnant women ...] Efficacy and effectiveness when co-administrated with other vaccines (YF, MR, DPT booster) Duration of protection and waning of protection in high risk population Efficacy only shown for 12 + months; neutralizing antibodies persist many years Booster doses q. 2-5 yrs depending on exposure.	Critical	WHO SAGE recommendations Meta-analyses for SAGE MVA-BN – pre-exposure – 76 % (1 dose), 82% (2 doses); post-exposure – 20% Immunocompromise – 51-70% efficacy LC-16, ACAM2000 – protective in non-human primates; neutralizing antibody in 95% (naïve, 80-95% previously vaccinated
2.4 Vaccine indirect effects	☐ Herd immunity/protection ☐ Potential negative population impact of emergence of non-vaccine serotypes	No information available		

Mpox Vaccines - General Information

PICO Question: In persons at high risk of mpox in the community during an mpox outbreak, what is the evidence that mpox vaccine is safe and can reduce the incidence of infection, hospitalization, and death?

Product	Description	Dosing	Administration	Presentation	Indicated Age Groups	Where Licensed
MVA-BN	Non-replicating vaccinia-based vaccine, 3rd generation	Two doses four weeks apart	Needle and syringe (subcutaneous or intradermal administration)	Liquid frozen or freeze-dried ? Single dose vial	18+ yrs; < 18 yrs EUA (US)[1]	Canada, EU, USA, UK, Switzerland
LC-16	Minimally replicating vaccinia-based vaccine, 3rd generation	Single dose	Bifurcated needle, percutaneous route/administration	Freeze-dried Multidose vials	No limitations	Japan
ACAM2000	Replicating vaccinia-based vaccine, 2nd generation	Single dose	Bifurcated needle, percutaneous route/administration	Freeze-dried Multidose vial	16 + yrs	USA (Emergency investigational new drug), Australia, Singapore

1. EUA - Emergency Use Authorization (United States)

Source: WHO Position Paper – Smallpox and Mpox (Orthopoxviruses)(August 2024) Immunization, Vaccines and Biologicals (who.int)

Mpox Vaccines - Safety and Efficacy

PICO Question: In persons at high risk of mpox in the community during an mpox outbreak, what is the evidence that mpox vaccine is safe and can reduce the incidence of infection, hospitalization, and death?

Product	Description	Adverse reactions	Serious Adverse Reactions	Efficacy	Immunogenicity	Duration	Source:
MVA-BN	Non-replicating	Frequent minor local and systemic AEFI	? myocarditis 4.77/million doses (not higher than background)	Pre-exposure 1 dose – 76% (64%-88%) 2 dose – 82% (72%-92%) Post-exposure 20% (-24%-64%)	>= 98%	Not studied; Booster 2-5 yrs	WHO SAGE 2024
LC-16	Minimally replicating vaccinia based	Frequent minor local and systemic AEFI	None identified	No human data 100% Protective against lethal challenge – mice, rabbits, monkeys	90-100% take rate 100% seroconversion (naïve) 60% previously vaccinated	Not studied	WHO SAGE 2024
ACAM2000	Replicating vaccinia-based vaccine	Frequent minor local and systemic AEFI	Myopericarditis – 20.1 per 100,000 doses Generalized vaccinia (<1 per 100,000 doses)	No human data 100% Protective against lethal challenge in animals	~100% take rate (healthy 18-29 yrs) 97% seroconversion (naïve) 76% in previously vaccinated	Not studied	WHO SAGE 2024

Source: WHO Position Paper – Smallpox and Mpox (Orthopoxviruses))(August 2024) [Immunization, Vaccines and Biologicals (who.int)]

Mpox Vaccines - Choice of Mpox Vaccines For Different At-Risk Populations (WHO SAGE 2024)

PICO Question: In persons at high risk of mpox in the community during an mpox outbreak, what is the evidence that mpox vaccine is safe and can reduce the incidence of infection, hospitalization, and death?

Product	Description	Adult (> 18 yrs) Immunocompetent	Infant, child, adolescent < 18 yrs	Pregnant women	Immunocompromised (including persons living with HIV)	Other – Atopic Dermatitis
MVA-BN	Non-replicating	++	++ (US EUA)[1]	+ (off label use)	++	++
LC-16	Minimally replicating vaccinia based	++	++	Contraindicated	Contraindicated	Contraindicated
ACAM2000	Replicating vaccinia-based vaccine	++	- Contraindicated < 1 yr	Contraindicated	Contraindicated	Contraindicated

Source: WHO Position Paper – Smallpox and Mpox (Orthopoxviruses))(August 2024) [Immunization, Vaccines and Biologicals (who.int)]

Considerations for Mpox Vaccine Recommendations
(Domain 1 – Problem/Disease Burden) – Worksheet (Draft)

PICO Question: In persons at high risk of mpox in the community during an mpox outbreak, what is the evidence that mpox vaccine is safe and can reduce the incidence of infection, hospitalization, and death?

Outbreak Situation	Risk Group	Notes	Geographic considerations	Estimated Risk	Risk complications	Vaccination Strategy
		Risk defined per national/local epidemiology	Risk defined per national/local incidence, epidemiology	Risk defined per national/local epidemiology		Primary Prevention vs. Post-Exposure
Non-Outbreak	Laboratory workers	Exposure to orthopox viruses				
	Outbreak response team	Potential exposure to orthopox viruses				
Prevention – Outbreak	Contacts of cases					Post-exposure
	Health workers involved in outbreak	HW, laboratorians, persons with clinical contact with cases; lab laboratory specimens, contaminated materials				
	First responders/ frontline workers involved in outbreak	Potential contact with cases, contaminated materials				
	Sexually active with casual partners (e.g.	MSM, sex commercial workers, heterosexuals with multiple casual partners				
	Children	<5 yrs			++	
		5-18 yrs				
	Immunocompromised				+++	
	Congregate settings	Eg. prisons, boarding schools, etc				
	Pregnant women				++	

Mpox Outbreak Vaccine Rollout
Evidence to Recommendations (EtR) Process for NITAGs

Questions ?

Dr Sidy Ndiaye, Immunization Officer, AFRO/UCN/VPD

Dr. Stephen Hadler– Senior Advisor, Task Force for Global Immunization

Acknowledgement: Joint effort from NITAGs support partners : TFGH, NISH, US/CDC and WHO

TOPIC

mpox outbreak and ongoing response efforts – a focus on the NITAGs in the African region

Susanne Noll
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28 August 2024

nish-africa.org

nish@uct.ac.za

VACFA vaccines for africa

NISH National Immunization Technical Advisory Group (NITAG) Support Hub

Library guide on Mpox

Library Guides OR LibGuides are a content management and information sharing system

LibGuides are user-friendly, efficient electronic resources that can meet the information needs of our users, in our case NITAG members online.

Susanne Noll, 28 August 2024

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Databases used

Pubmed

EbscoHost

Academic Search Premier, Africa-Wide Information, CINAHL, Health Source - Consumer Edition, Health Source - Nursing/Academic Edition, MEDLINE, APA PsycArticles, APA PsycInfo

Google Scholar

Library guide on Mpox

MeSH Terms and keywords used
PICO

Population : all African countries

Africa [MeSH]

OR

Africa OR African OR Algeria OR Angola OR Benin OR Botswana OR "Burkina Faso" OR Burundi OR “Cabo Verde” OR Cameroon OR Cameroun OR "Canary Islands" OR "Cape Verde" OR "Central African Republic" OR Chad OR Comoros OR Congo OR "Cote d'Ivoire" OR "Democratic Republic of Congo" OR Djibouti OR Egypt OR Eritrea OR eSwatini OR Ethiopia OR Gabon OR Gambia OR Ghana OR Guinea OR Guinea- Bissau OR "Ivory Coast" OR Jamahiriya OR Kenya OR Lesotho OR Liberia OR Libya OR Madagascar OR Malawi OR Mali OR Mauritania OR Mauritius OR Mayotte OR Morocco OR Mozambique OR Namibia OR Niger OR Nigeria OR Principe OR Reunion OR Rwanda OR “Saint Helena” OR “Sao Tome” OR Senegal OR Seychelles OR “Sierra Leone” OR Somalia OR “St Helena” OR Sudan OR Swaziland OR Tanzania OR Togo OR Tunisia OR Uganda OR “Western Sahara” OR Zaire OR Zambia OR Zimbabwe

Library guide on Mpox

MeSH Terms and keywords used

PICO

Intervention : Monkeypox"[MeSH Terms] OR "Monkeypox virus"[MeSH Terms] OR "Monkeypox"[Title/Abstract] OR "monkey pox"[Title/Abstract] OR "MPOX"[Title/Abstract] OR "MPX"[Title/Abstract] OR "MPXV"[Title/Abstract] OR "hMPXV"[Title/Abstract] OR (("Orthopoxvirus"[MeSH Terms] OR "Orthopoxvirus"[Title/Abstract] OR "Poxviridae Infections"[MeSH Terms] OR "Poxviridae"[Title/Abstract] OR "poxvirus*"[Title/Abstract] OR "Smallpox"[Title/Abstract] OR "Smallpox"[MeSH Terms] OR "Variola virus"[MeSH Terms] OR "Variola virus"[Title/Abstract] OR "Smallpox Vaccine"[MeSH Terms] OR "smallpox vaccine LC16m8"[Supplementary Concept]

Comparison : no comparison

Outcome: safety OR efficacy OR treatment OR impact OR “reduction in disease” OR morbidity OR mortality

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Library guide on Mpox

Result lists showed that there is very little research done until now:

1. Only a few African countries are affected
2. Most papers are from the WHO or SAGE
3. Under the term “Mpox vaccines” no results, only under “Mpox” as one keyword

We urgently need research information from all of you and your institutions, so that we can learn from each other how to confront this dreaded disease. We plead with you to share and distribute experiences , knowledge ad practices that you encounter along this challenge

Susanne Noll, 28 August 2024

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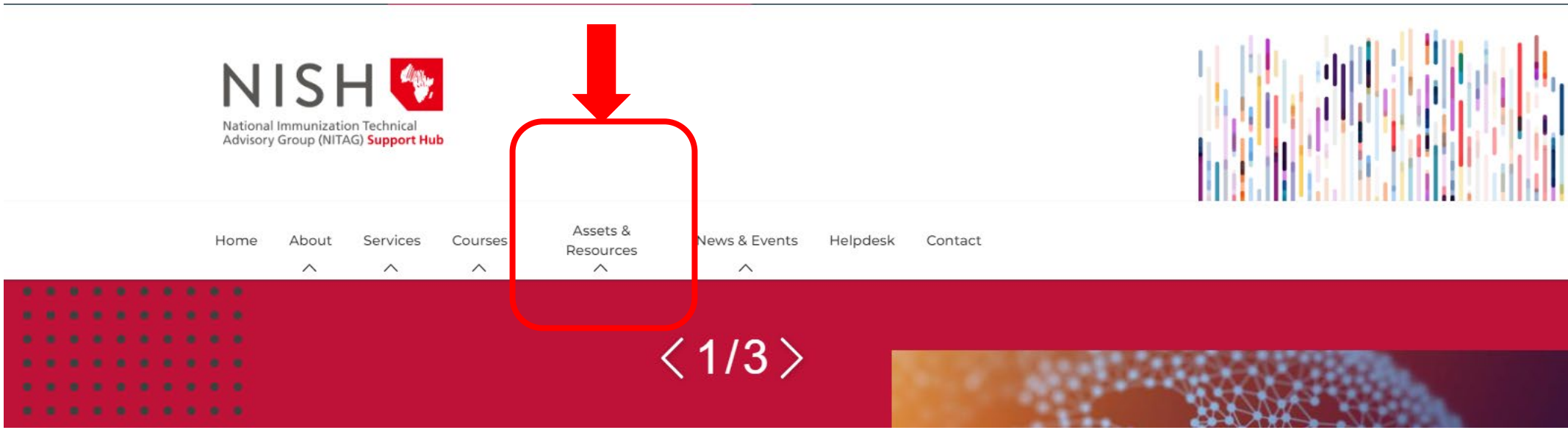
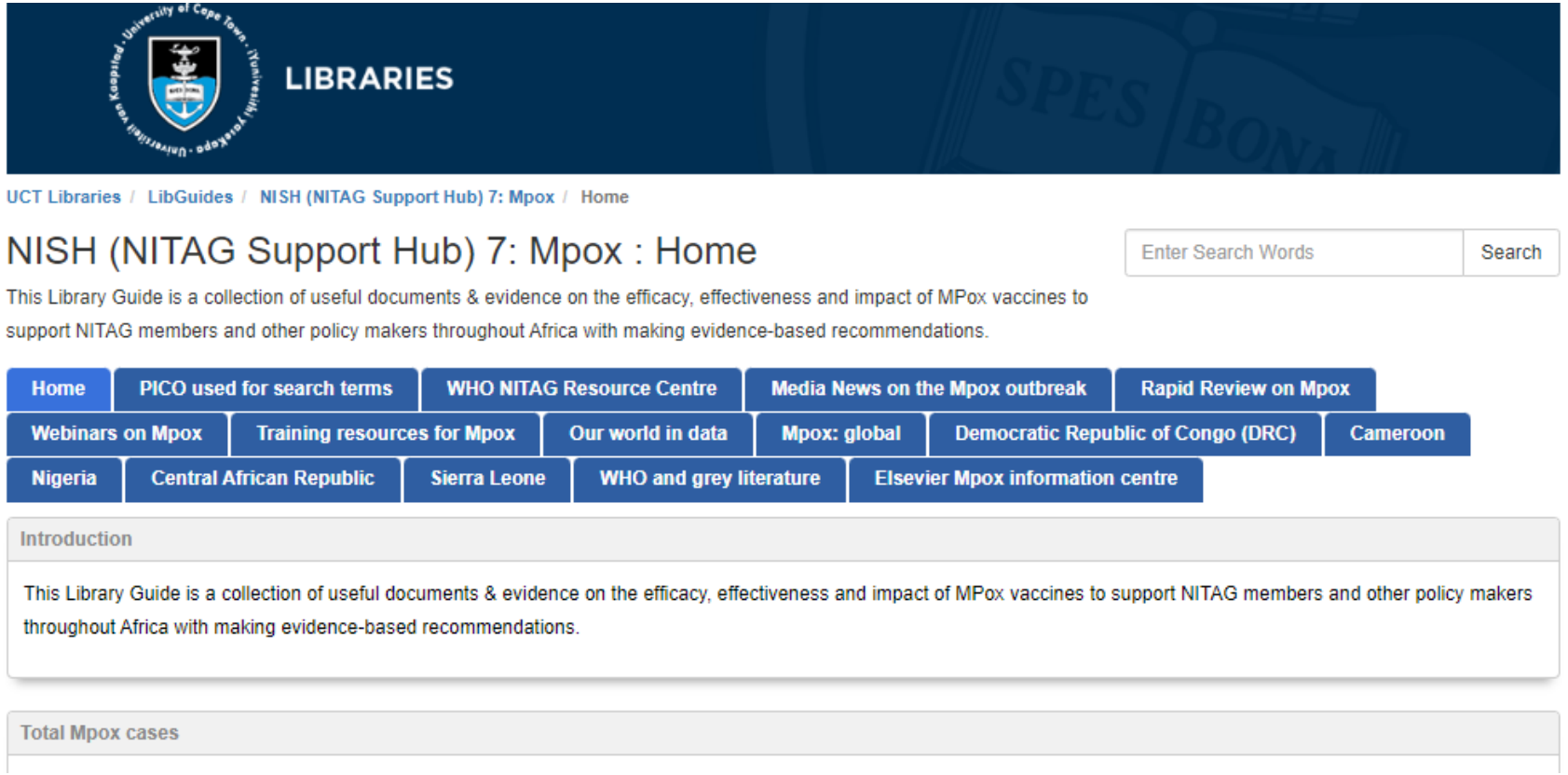
Where to find it?

NISH website: www.health.uct.ac.za/nish



This is where you find it

This is what it looks like



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Introduction

This Library Guide is a collection of useful documents & evidence on the efficacy, effectiveness and impact of MPox vaccines to support NITAG members and other policy makers throughout Africa with making evidence-based recommendations.

Total Mpox cases

Tabs

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Total Mpox cases

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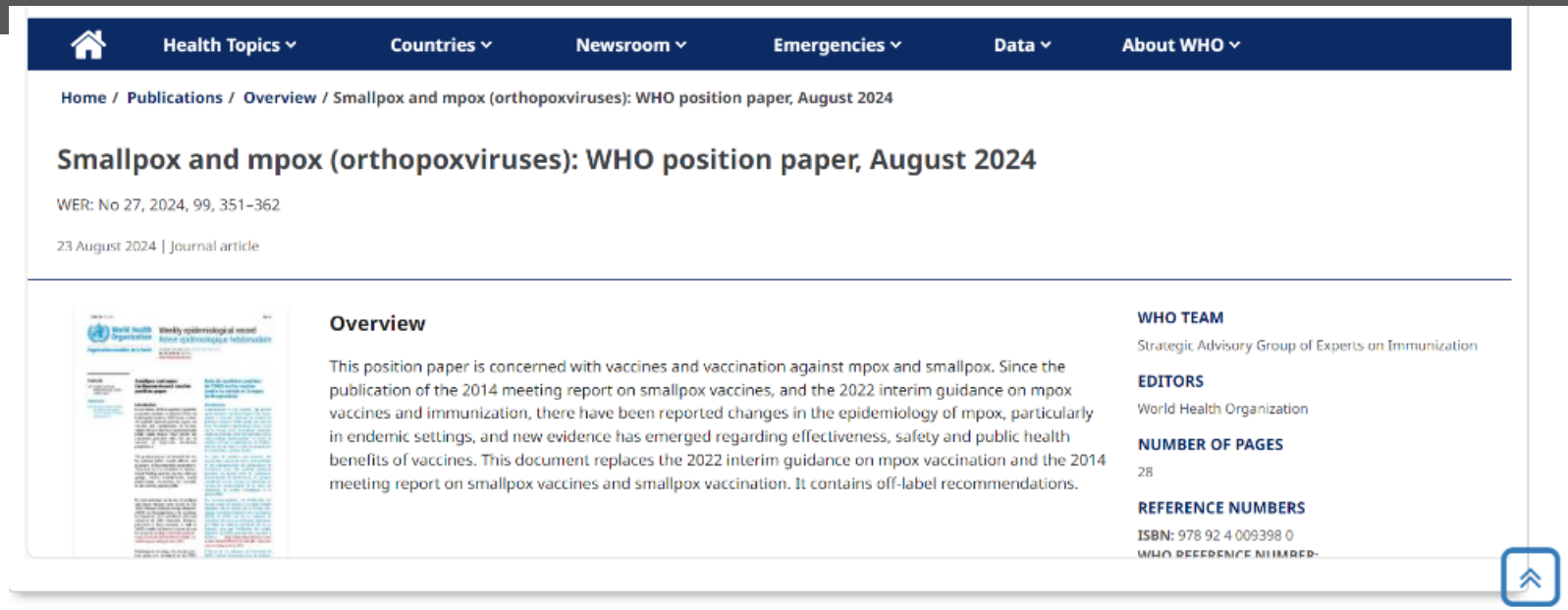

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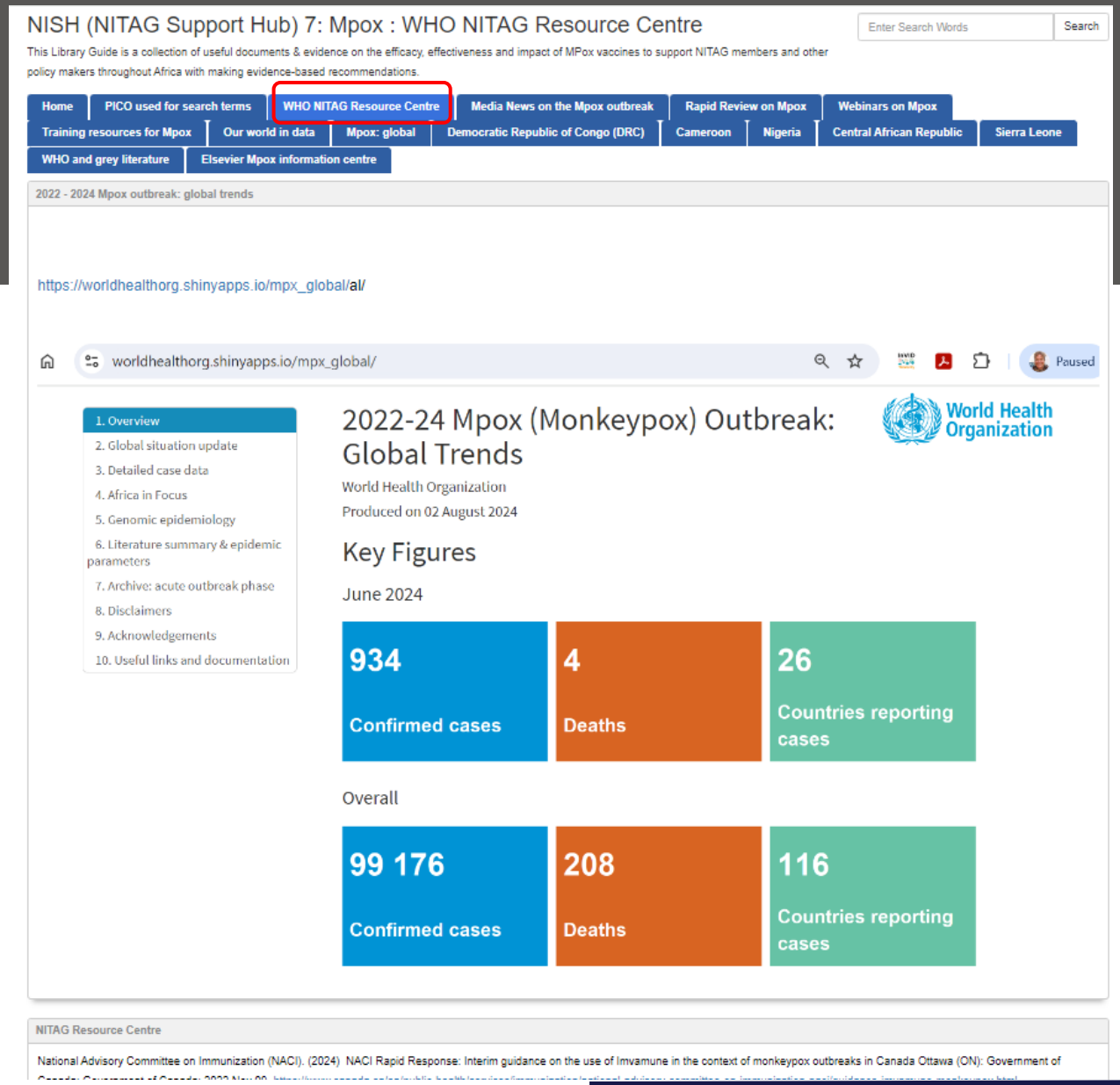
WHO NITAG Resource Centre



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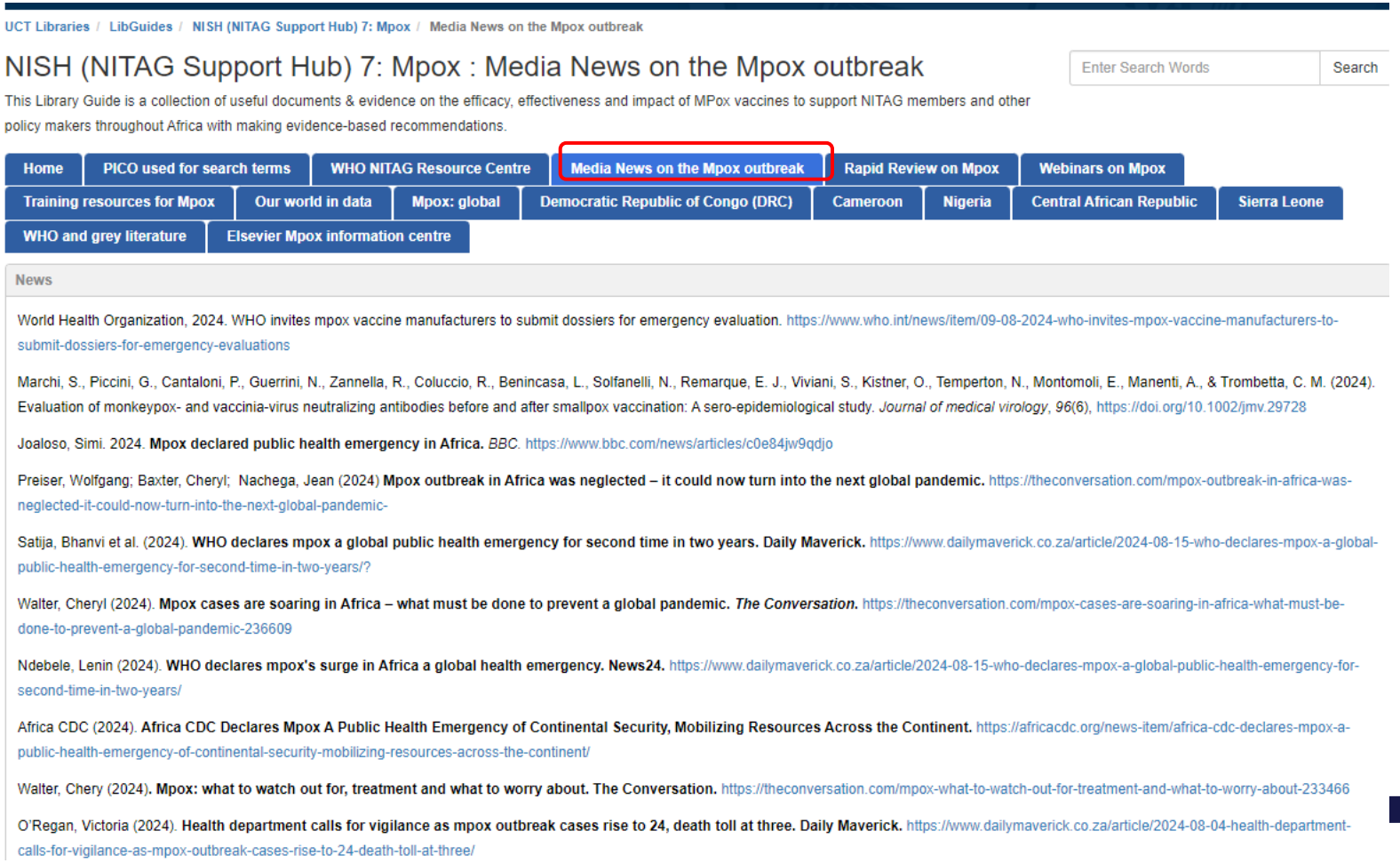
Media News on Mpox outbreak



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News

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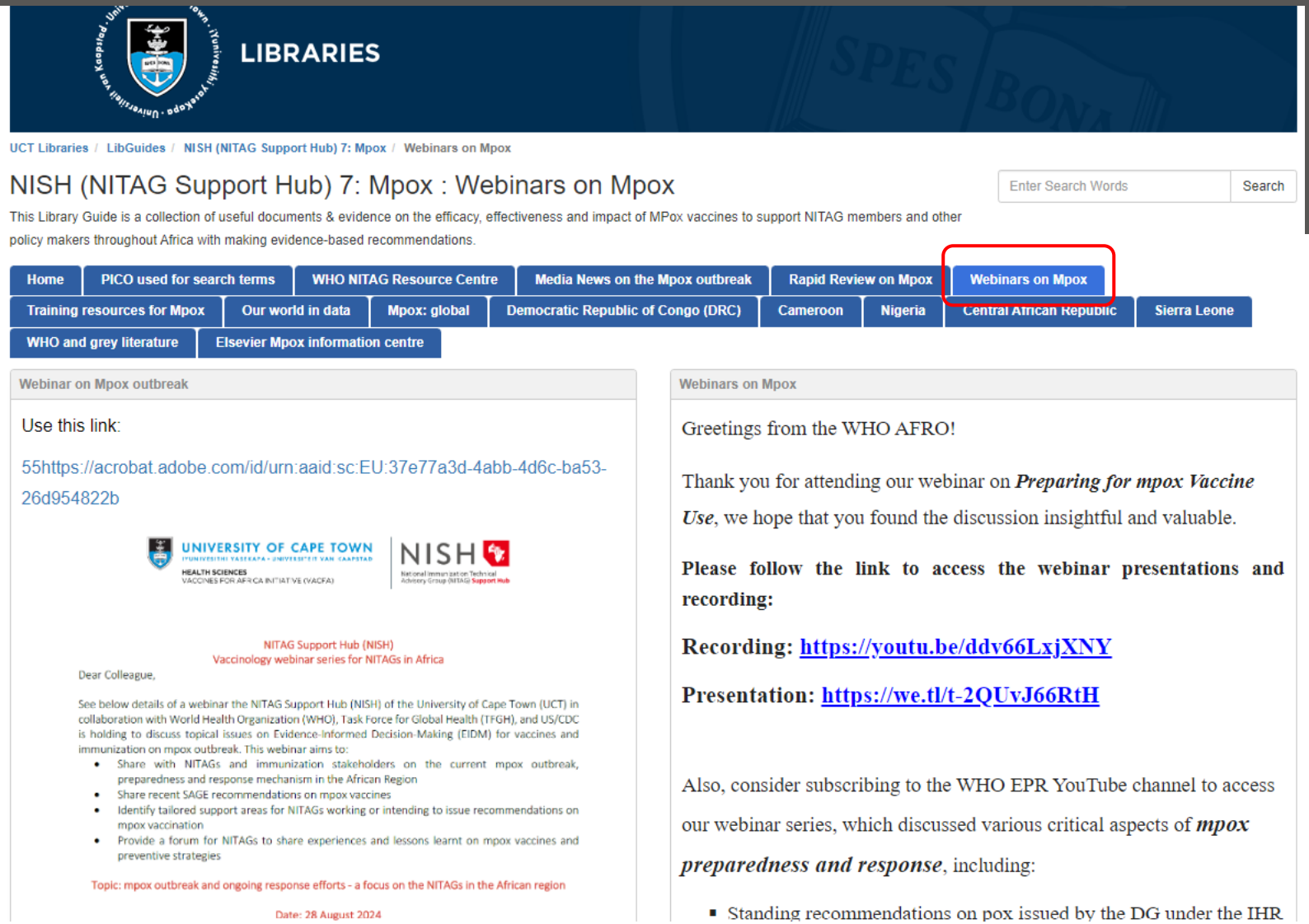
Webinars on Mpox



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Webinar on Mpox outbreak

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UNIVERSITY OF CAPE TOWN
HEALTH SCIENCES
VACCINES FOR AFRICA INITIATIVE (VACFA)

NISH
National Immunization Technical Advisory Group (NITAG) Support Hub

NITAG Support Hub (NISH)
Vaccinology webinar series for NITAGs in Africa

Dear Colleague,

See below details of a webinar the NITAG Support Hub (NISH) of the University of Cape Town (UCT) in collaboration with World Health Organization (WHO), Task Force for Global Health (TFGH), and US/CDC is holding to discuss topical issues on Evidence-Informed Decision-Making (EIDM) for vaccines and immunization on mpox outbreak. This webinar aims to:

- Share with NITAGs and immunization stakeholders on the current mpox outbreak, preparedness and response mechanism in the African Region
- Share recent SAGE recommendations on mpox vaccines
- Identify tailored support areas for NITAGs working or intending to issue recommendations on mpox vaccination
- Provide a forum for NITAGs to share experiences and lessons learnt on mpox vaccines and preventive strategies

Topic: mpox outbreak and ongoing response efforts - a focus on the NITAGs in the African region

Date: 28 August 2024

Webinars on Mpox

Greetings from the WHO AFRO!

Thank you for attending our webinar on ***Preparing for mpox Vaccine Use***, we hope that you found the discussion insightful and valuable.

Please follow the link to access the webinar presentations and recording:

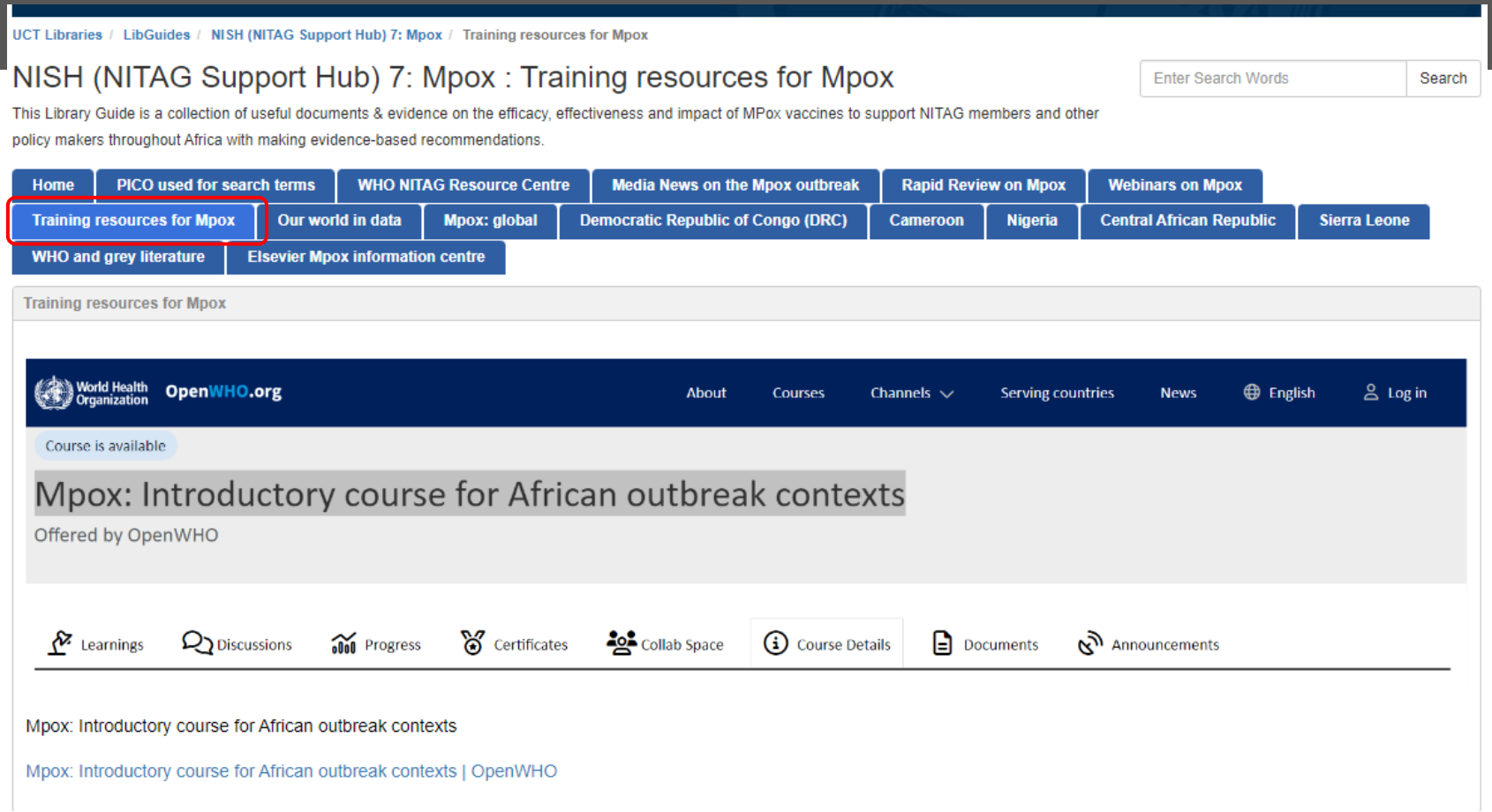
Recording: https://youtu.be/ddv66LxjXNY

Presentation: https://we.tl/t-2QUvJ66RtH

Also, consider subscribing to the WHO EPR YouTube channel to access our webinar series, which discussed various critical aspects of ***mpox preparedness and response***, including:

- Standing recommendations on pox issued by the DG under the IHR

Training resources on Mpox



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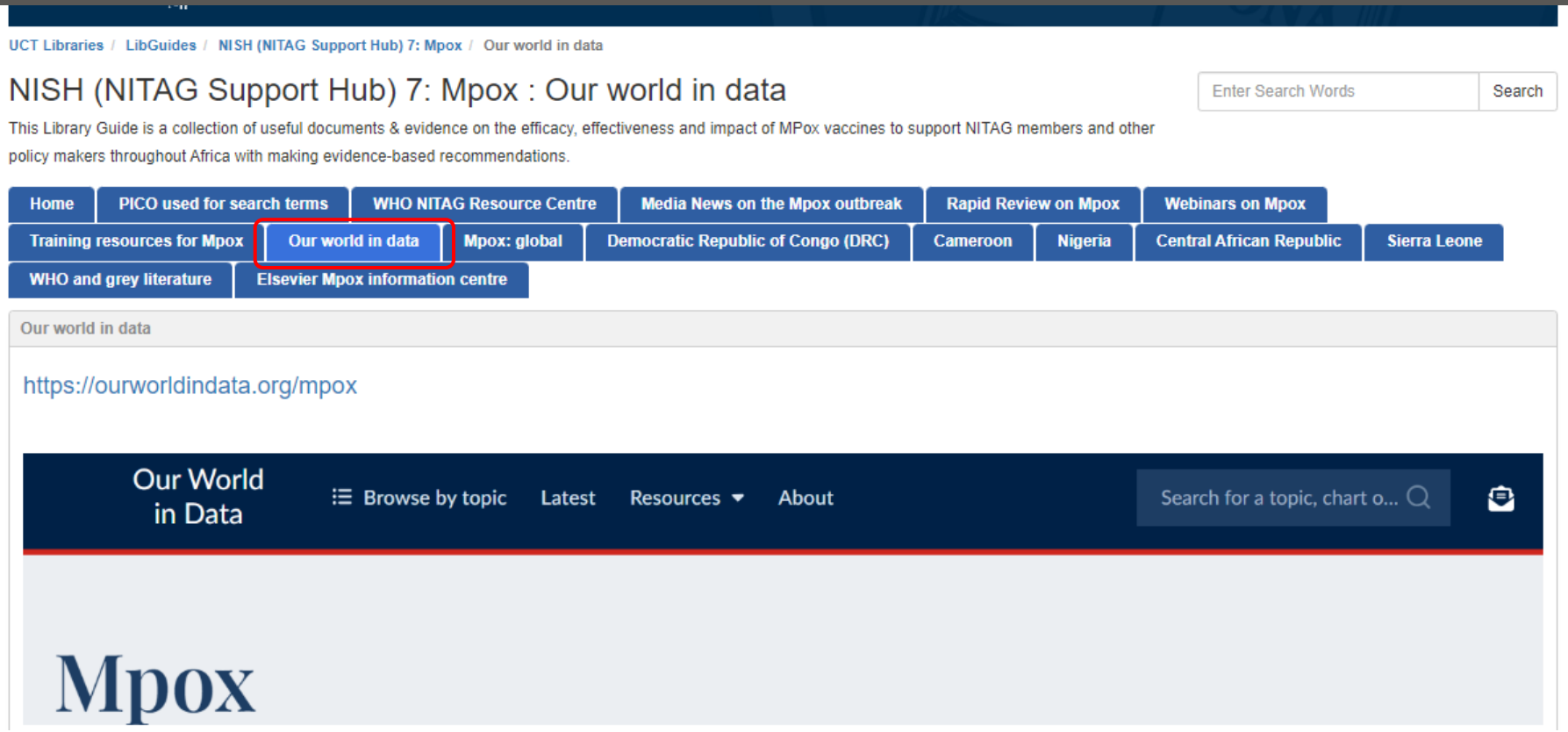
Our World in Data



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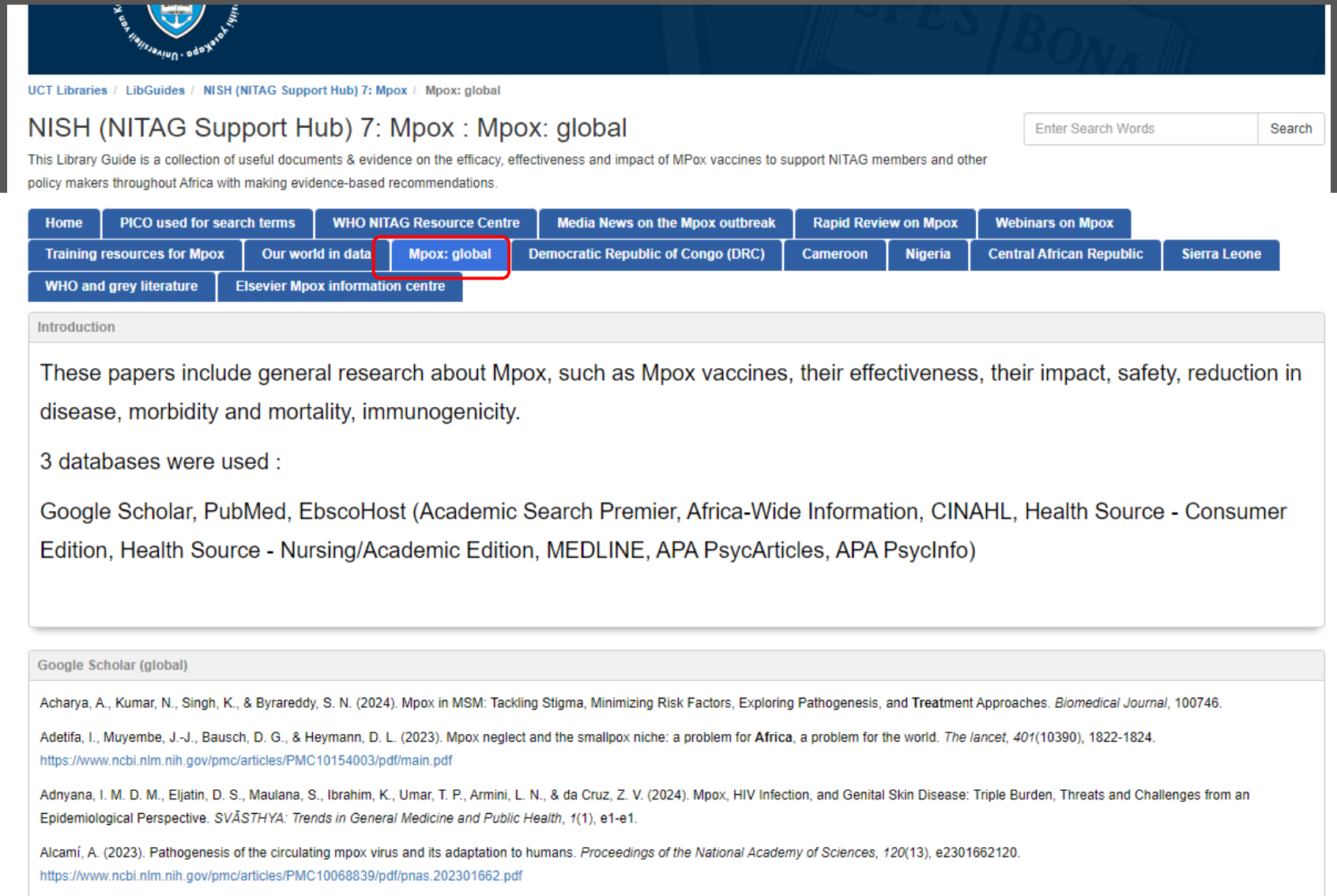
Mpox Global



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Introduction

These papers include general research about Mpox, such as Mpox vaccines, their effectiveness, their impact, safety, reduction in disease, morbidity and mortality, immunogenicity.

3 databases were used :

Google Scholar, PubMed, EbscoHost (Academic Search Premier, Africa-Wide Information, CINAHL, Health Source - Consumer Edition, Health Source - Nursing/Academic Edition, MEDLINE, APA PsycArticles, APA PsycInfo)

Google Scholar (global)

Acharya, A., Kumar, N., Singh, K., & Byrareddy, S. N. (2024). Mpox in MSM: Tackling Stigma, Minimizing Risk Factors, Exploring Pathogenesis, and **Treat**ment Approaches. *Biomedical Journal*, 100746.

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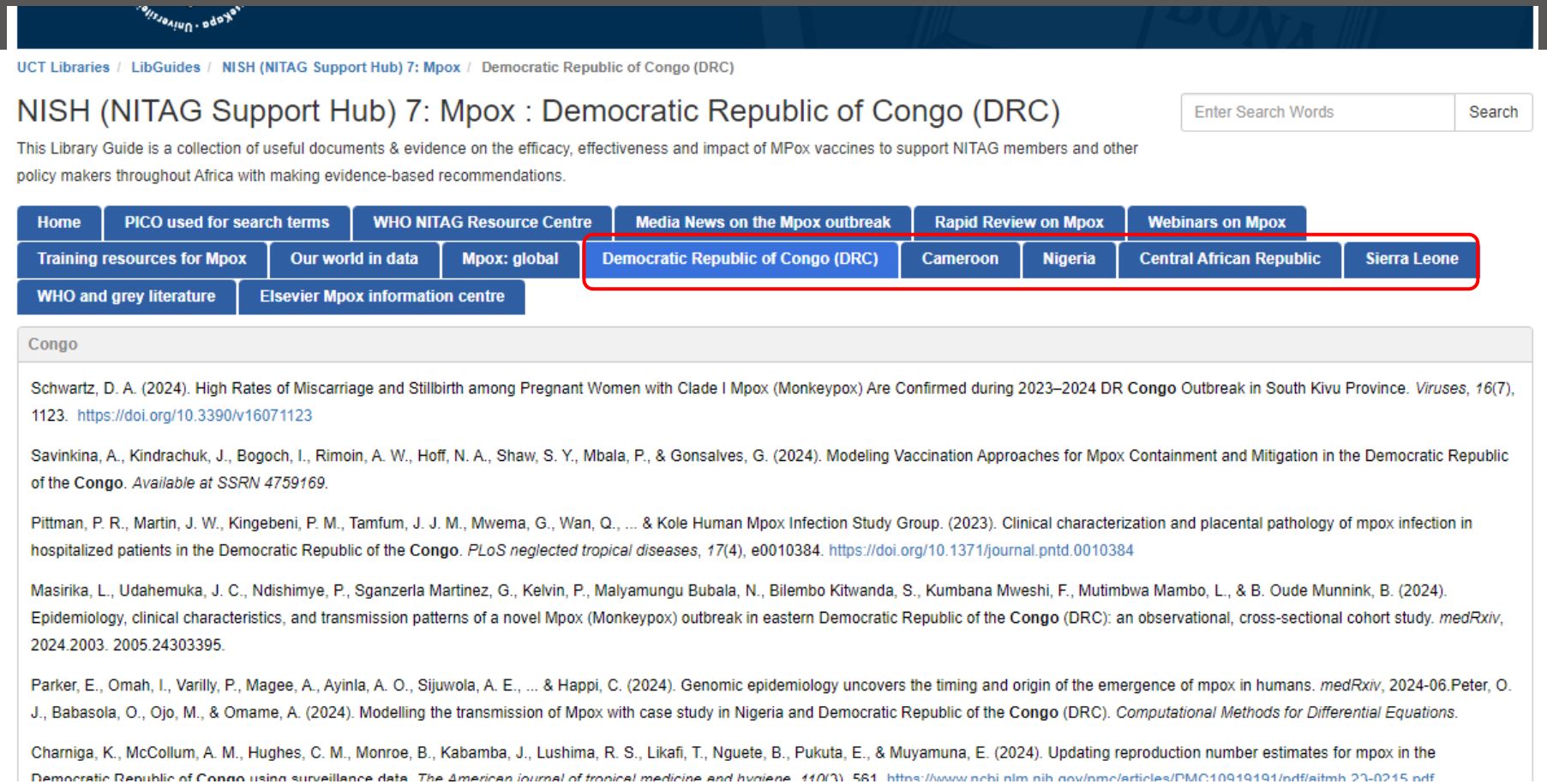
Mpox in African Counties



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Congo

Schwartz, D. A. (2024). High Rates of Miscarriage and Stillbirth among Pregnant Women with Clade I Mpox (Monkeypox) Are Confirmed during 2023–2024 DR **Congo** Outbreak in South Kivu Province. *Viruses*, *16*(7), 1123. https://doi.org/10.3390/v16071123

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WHO and grey literature sources

Home | PICO used for search terms | WHO NITAG Resource Centre | Media News on the Mpox outbreak | Rapid Review on Mpox | Webinars on Mpox
Training resources for Mpox | Our world in data | Mpox: global | Democratic Republic of Congo (DRC) | Cameroon | Nigeria | Central African Republic | Sierra Leone
WHO and grey literature | Elsevier Mpox information centre

Toolkits

WHO. 2024. Mpox outbreak toolbox. https://www.who.int/emergencies/outbreak-toolkit/disease-outbreak-toolboxes/mpox-outbreak-toolbox

Grey literature

WHO. 2024. WHO Director-General declares Mpox outbreak a public health emergency of international concern.

WHO Mpox (monkeypox) outbreak; 2022. Avalaible from: https://www.who.int/emergencies/situations/monkeypox-oubreak-2022.

WHO recommends new name for monkeypox disease. Avaiilable from: https://www.who.int/news/item/28-11-2022-who-recommends-new-name-for-monkeypox-disease.

World Health Organization. (2023). *Responding to the global mpox outbreak: ethics issues and considerations: a policy brief, 19 July 2023* (No. WHO/Mpox/Outbreak_response/Ethics/2023.1). World Health Organization. https://iris.who.int/bitstream/handle/10665/371405/WHO-Mpox-Outbreak-response-Ethics-2023.1-eng.pdf?sequence=1

World Health Organization. (2024). *Regional Mpox Bulletin: 11 August 2024*. Regional **Mpox** Bulletin: 11 August 2024

World Health Organization (2024). *Strategic framework for enhancing prevention and control of **mpox** 2024-2027* . Strategic framework for enhancing prevention and control of **mpox** 2024-2027

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NISH (NITAG Support Hub) 7: Mpox : Elsevier Mpox information centre

Enter Search Words | Search

This Library Guide is a collection of useful documents & evidence on the efficacy, effectiveness and impact of MPox vaccines to support NITAG members and other policy makers throughout Africa with making evidence-based recommendations.

Home | PICO used for search terms | WHO NITAG Resource Centre | Media News on the Mpox outbreak | Rapid Review on Mpox | Webinars on Mpox | Training resources for Mpox | Our world in data | Mpox: global | Democratic Republic of Congo (DRC) | Cameroon | Nigeria | Central African Republic | Sierra Leone | WHO and grey literature | Elsevier Mpox information centre

Elsevier Health Care Hub

Mpox Explained

Mpox Explained | Organization Websites | What Our Clinicians Reading | Drug Monographs | Patient Education | Trial ClinicalKey →

https://elsevier.health/en-US/monkeypox/home

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Thank you

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UGANDA NATIONAL IMMUNISATION TECHNICAL ADVISORY GROUP (UNITAG) MPOX WORKING GROUP

PRESENTATION AT THE NISH-WHO WEBINAR

ON MPOX OUTBREAK

28/08/2024

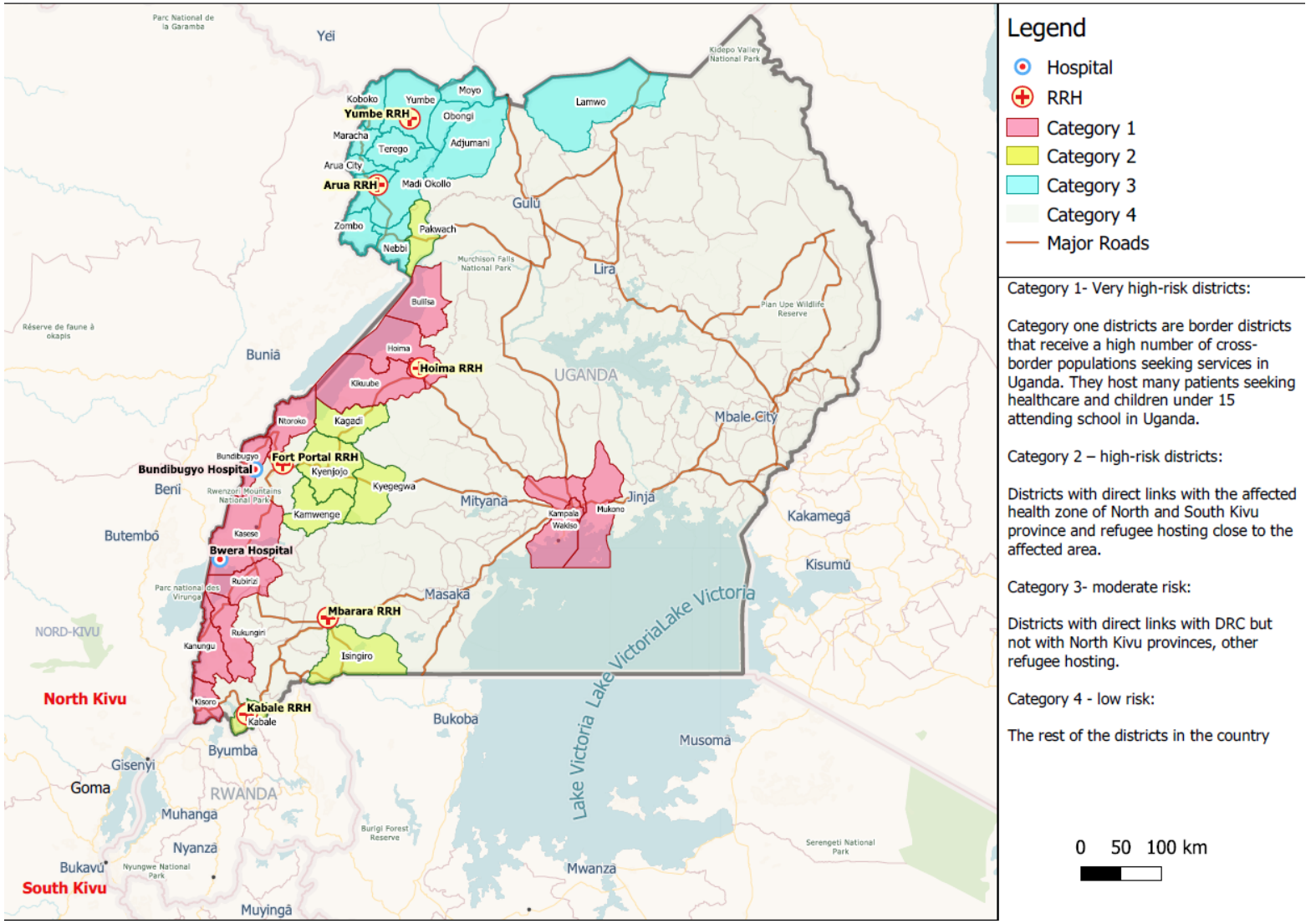
PROF. DAVID MEYA

CHAIR UGANDA NITAG MPOX WORKING GROUP

Uganda Mpox Risk mapping and classification

The considerations and assumptions for risk categorization

- *The proximity to epicenters,*
- *Trade and regional transportation hubs*
- *Refugee host communities*
- *Population movements*
- *Districts providing social services: health care & education.*



Context to Mpox Transmission for Uganda

- Uganda borders DRC with a lot of human interactions and **porous borders**
- Communities in Uganda share social, cultural and economic ties with communities in DRC
- 17 of 142 districts in Uganda share a border with DRC with 5 districts hosting DRC refugees
- Ugandan army troops deployed in Eastern DRC
- Long distance truck drivers ply the region in the interconnected routes (DRC-Kenya-South Sudan-Rwanda & Uganda)
- Proportion of HIV viral load suppression among persons living with HIV in the 23 districts ranges from 75.9-82.8% below the recommended 95% (UNAIDS 95-95-95 targets)

MoH Advice request to UNITAG on Mpox

- On 26th July 2024, The MoH wrote to the UNITAG requesting for advice to consider Mpox vaccines for prevention of Mpox Transmission among high risk groups in Uganda

- This followed a confirmation of 2 initial Mpox cases in Bwera Kasese District, which is linked to a new variant clade Ib which is responsible for upsurge of cases in DRC

-

- To date, Uganda has confirmed 5 Mpox cases – 2 cases epidemiologically linked to DRC and 3 new confirmed cases in non border districts **not linked to the initial cases**

- The Chair UNITAG convened a Full UNITAG meeting on 9th Aug, where the MoH request was presented to members for consideration

- An Mpox working Group was constituted and held the first meeting on 15th Aug 2024. Reviewed available evidence using ETR framework

UNITAG Mpox Working Group Composition

- 6 Core NITAG Members, Specialties include;
  - Medicine , Public Health &Epidemiology (1),
  - Medicine & Surgery (1) doubles as the Chair, Clinical Care Sub Pillar under Case Management Unit, Ministry of Health,
  - Vaccinology & Immunology (2),
  - Community Health & Behavioral Sciences (1)
- 3 Ex-officio Members - Uganda National Expanded Program for Immunisation (UNEPI,MOH) & Head Surveillance and Epidemics Incident Commander
- 2 Liaison Members- Representatives of WHO and UNICEF
- 2 Co-opted Experts - National Drug Authority -Drug Regulation and Pharmaco-vigilance and member of AEFI Committee, and Uganda Virus Research Institute - Biomedical Laboratory Technology & Head of Data Analysis for Mpox

Mpox Policy Questions & considerations

1. Should Uganda use a vaccine against Mpox for high-risk populations to halt community transmission?

   Key considerations: WHO recommendations, alternative preventive control measures

2. Which population groups should be targeted for vaccination? How will they be prioritized if supply is limited?

   Key considerations: Populations at risk of severe disease outcomes -considering modelling different scenarios using available data to guide selection of high-risk groups, ethical guidelines

Mpox Policy Questions & Considerations

3. Which vaccine products, if any, should Uganda use to halt community transmission?

   Key considerations: Availability, Affordability, Ease of administration- training needs, Efficacy, cold chain requirements, safety & AEFI monitoring requirements, WHO recommendations

4. What mode of introduction should be used? WHO EUL with a Research Component.

   Key considerations: WHO EUL, timelines, NDA approvals, donor conditions

5. Social Considerations: Targeted populations, ethics, Health communication

   Key Considerations; leveraging Ebola and COVID 19 response experience, Sex work and MSMs are illegal in Uganda

Next steps: Mpox Evidence Collection

- Local Epidemiology data- Incidence Management team presentations
- WHO/SAGE recommendation report and position paper on Mpox
- Draft recommendation report for consideration by the Full NITAG committee

THANK YOU

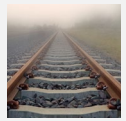
Épidémie de Mpox et efforts de réponse en cours – un focus sur les GTCV de la région africaine.

GTCV-République Démocratique du Congo

28 Août 2024

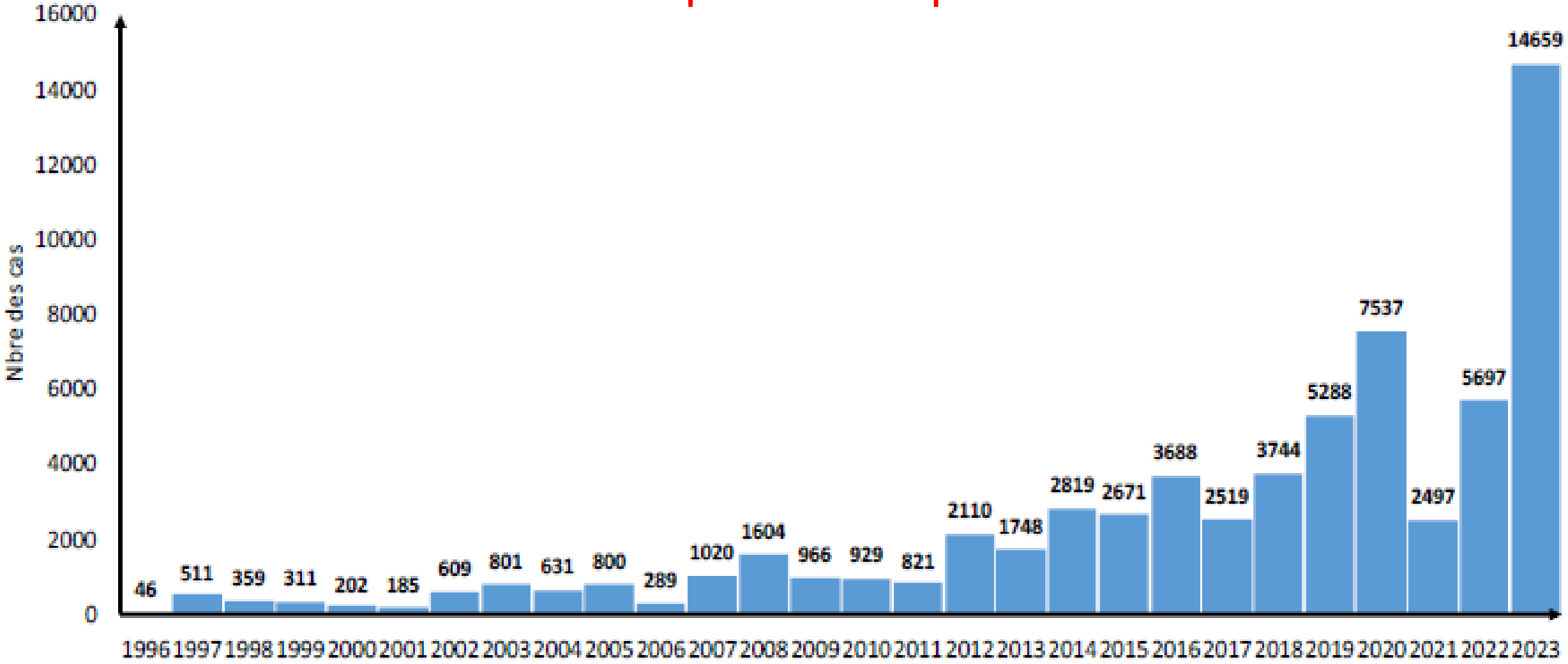
Pour GTCV-RDC, Professeur Dr Abdon Mukalay, Président a.i.,

Plan

- Contexte
- Lancement de la question politique du vaccin MPox
-  Parcours vers la publication de la recommandation sur le vaccin MPox
- Expérience de mise en œuvre
- Leçons sur les recommandations relatives au vaccin contre la COVID-19

Contexte

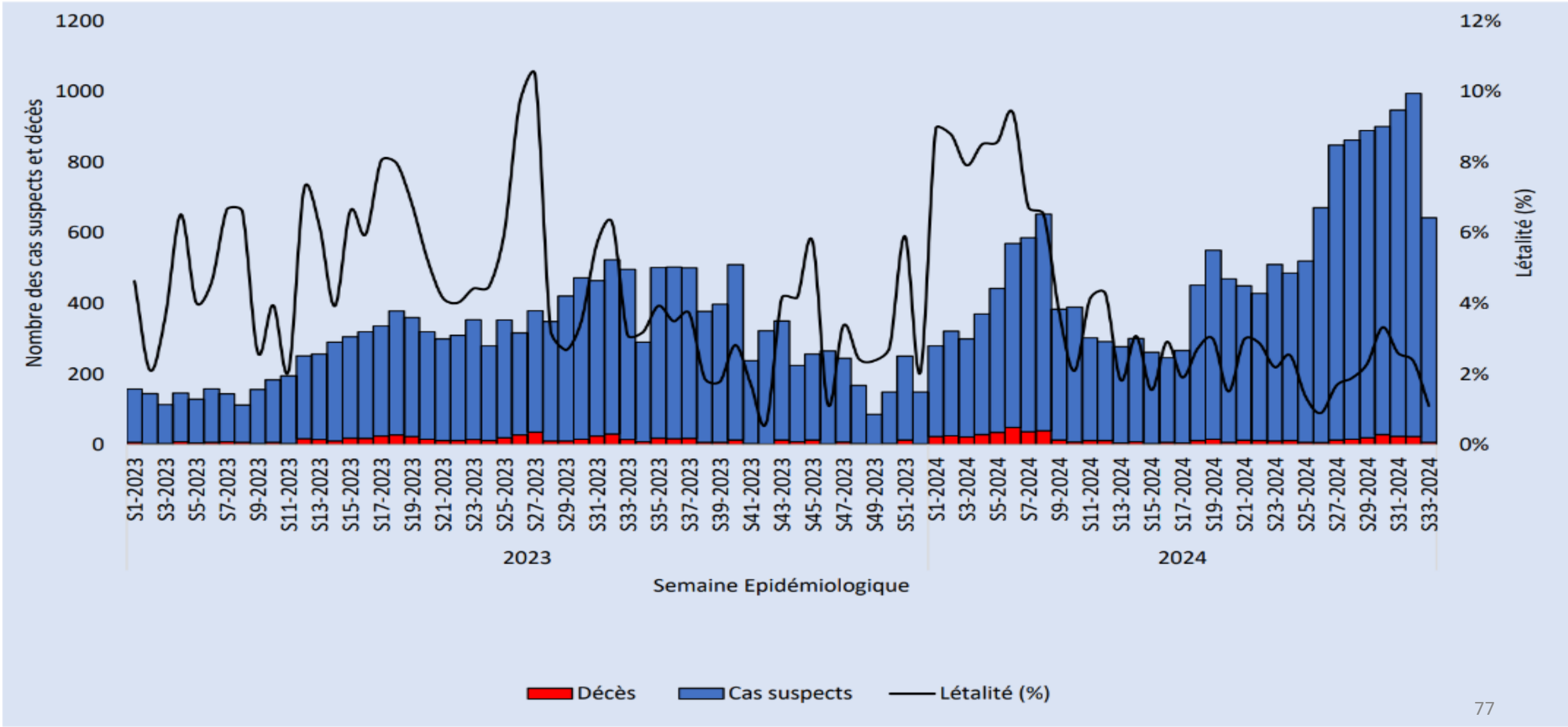
Evolution des cas suspects de Mpox en RDC de 1996 à 2023



(PNLMPX & FHV)

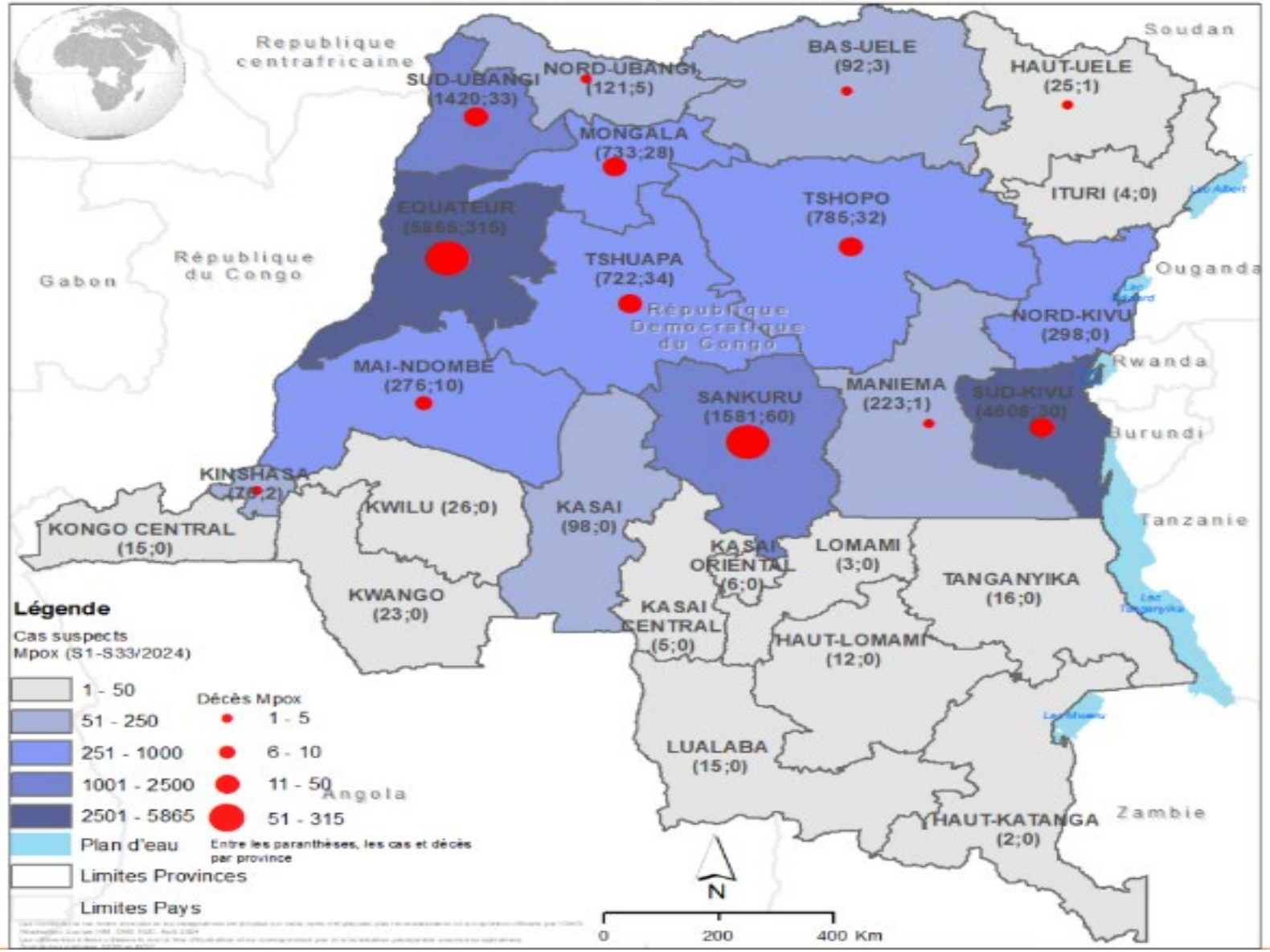
Contexte

Evolution des cas suspects, décès et létalité de Mpox en RDC, S1-S52 2023 à S1-S33 2024 (sources : Base IDS S33 & INSP)



Contexte

Répartition spatiale des cas suspects, décès de Mpox dans les provinces affectées de la RDC de S1 à S33 2024 (n=17342)



Lancement de la question politique du vaccin MPox

Devant cette situation alarmante, le MSPHP, par l'entremise de la Direction du PEV (N/Réf: PEV/DIR/023/NZW/2024 du 30/01/2024), a adressé une requête au GTCV, lui demandant « **d'examiner les données probantes et de formuler des recommandations stratégiques relatives à l'utilisation des vaccins en fonction du contexte national en session du vendredi 26 au samedi 27 janvier 2024** ».

Parcours vers la publication de la recommandation sur le vaccin MPox

* Déclaration de conflit d'Intérêt

*« Dans les populations exposées au risque de Mpox en RDC, lequel, parmi les vaccins existants peut donner les meilleurs résultats ? »

*Deux groupes de travail constitués:

Groupe 1: Vaccination, 7 membres,

Groupe 2: Cadre de recommandation générique (références des données probantes), 6 membres

Parcours vers la publication de la recommandation sur le vaccin MPox

- Documentation rendue disponible par le PEV, l'OMS et le Programme National de Lutte contre le Monkeypox et Les Fièvres Hémorragiques Virales (PNLMPX-FHV)
- Recherche systématique sur Internet à travers Medline / PubMed, Cochrane, Google Scholar et les bases de données sanitaires de l'OMS, CDC, etc.
- Analyse critique des Publications pertinentes contenant des données probantes
- Evaluation de la qualité scientifique des documents publications/données probantes grâce aux outils ad hoc (GRADE, AMSTAR, RCA);

Parcours vers la publication de la recommandation sur le vaccin MPox

- Les études sélectionnées sur base des effets de l'intervention (innocuité et efficacité de la vaccination) ont été retenues selon un modèle de leurs niveaux hiérarchiques de preuve scientifique. Pour les données probantes "critiques", soit les critères d'innocuité, d'efficacité et d'efficience, et ensuite pour l'épidémiologie de la maladie, y compris l'immunité collective suite à la vaccination,
- Données "importantes" se rapportent aux questions programmatiques (faisabilité) et les autres restantes représentent des données "non critiques".

Parcours vers la publication de la recommandation sur le vaccin MPox

- Discussion et mise en commun des travaux des deux groupes en plénière ;
- Délibération à huis clos sans les autres membres (Secretariat, ex-officio)
- Et, enfin la prise de décision concertée.
- Le processus appliqué pour l'élaboration de la note de recommandation suit le modèle de l'OMS proposé aux GTCV (OMS, SIVAC).

Expérience de mise en œuvre

PEV a utilisé cet avis du GTCV pour contribuer à la demande des vaccins à GAVI, aux USA et aux autres partenaires.

Cet avis sert aussi à la communication des risques et engagement communautaire

Leçons sur les recommandations relatives au vaccin contre la COVID-19

- ✓Commencer tôt la communication des risques et engagement communautaire.
- ✓Associer tôt la population
- ✓Lutter contre l'infodémie ou les antivaccinations
- ✓Mener des études sur la résistance à la vaccination
- ✓Collaborer avec l'OMS, les nations et partenaires pour la disponibilité des vaccins

- **OMS** World Health Organization
- **NISH: NITAG Support Hub (NISH) of the University of Cape Town (UCT),**
- **Task Force for Global Health (TFGH),**
- **US/CDC**
- **Ministère SPHPS/PEV**

Thank you,

Obrigado,

Merci beaucoup!