State-of-the-art 20
Mpox Symposium 25
3-5 December • Kinshasa • DRC

Mpox Vaccine : From Global Evidence to Africa's Strategic Imperative

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Kinshasa, 3 Dec 2025

PARTICIPANTS OF COORDINATION MEETING ON HEALTH INSTITUTION BASED SURVEILLANCE
FOR MONKEYPOX AND VIRAL HAEMORRHAGIC FEVERS,
SANKURU, LODJA, 10-12 JUNE, 1981

Why Mpox Vaccines Matter for Africa

- PHEIC and PHECs declarations
  - Persistent multi-country outbreaks /Increasing burden in Central Africa
  - concerns on the changing epidemiology of mpox in the DRC with increasing case counts, sexual contact-mediated clusters, and sustained human-to-human transmission driven by clade Ib.

- Equity in access – vaccines were used in the previous multi-country outbreaks

- WHO SRP/Africa IMST plan include response pillars mpox vaccination response

Smallpox Vaccination and Mpox:
Cross-protection from historic smallpox vaccination (DRC evidence)

Individuals born before 1980 vaccinated with first-generation vaccinia-based smallpox vaccines had a 5.2-fold lower mpox risk than unvaccinated persons (0.78 vs 4.05 per 10 000).

Corresponds to 80.7% pre-exposure vaccine effectiveness against mpox (95% CI: 68.2–88.4%).

Rimoin et al., PNAS, 2010

A study among 338 subjects found Dryvax, a first-generation vaccinia-based smallpox vaccine, was 85% effective against mpox.

Jezek et al., WHO Bulletin, 1988

Mpox vaccines landscape, effectiveness and safety

Licensed or under review:

- ACAM2000 – replicating, limited use
- MVA-BN (Jynneos/Imvanex) – non-replicating
- LC16m8 – Japan
- Next-gen MVA constructs in development

PREVENTIVE VACCINATION

- VE Estimate for 1-dose of MVA-BN: 76% (95%CI 65%-86%)
- VE Estimate for 2-dose of MVA-BN: 82% (95%CI 72%-92%)

POST EXPOSURE PROPHYLAXIS

- VE Estimate PEP with MVA-BN: 20% (95%CI -24%-64%)

GRADE with very low confidence for all estimates

- All mpox vaccines give local and systemic adverse events
- ACAM2000 has a higher SAE and myocarditis risk compared to third generation vaccines (LC16, MVA-BN)
- LC-16 is approved for use in children in Japan with a good safety profile
- MVA-BN is licensed for persons 18 and older.
- Graded certainty of evidence is low to very low

*** Smallpox and mpox (orthopoxviruses): WHO position paper, Aug 2024**
https://www.who.int/publications/i/item/who-wer-9934-429-456

SAGE Recommendations mpox outbreak response*

Vaccinate persons at high risk of exposure :

- members of a geographically defined area or community (e.g. village)
- sex workers; gay, bisexual, MSM or other individuals with multiple casual sexual partners;
- health workers at risk of repeated exposure
- contacts of persons with mpox in the household or in congregate settings (such as prisons, schools, health facilities or residential facilities)

Choose vaccine based on potential risks in vaccinees, e.g., avoid replicating vaccine in infants, pregnancy, Immuno-compromised persons.

Previous smallpox vaccination should not prevent mpox vaccination.

Collect data & Invest in research

Consider fractional dosing (more data needed).

Develop TPP with minimal criteria (which current vaccines meet) and preferred criteria for monkeypox vaccines

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How should mpox vaccines be used in DRC and its neighbouring countries?*

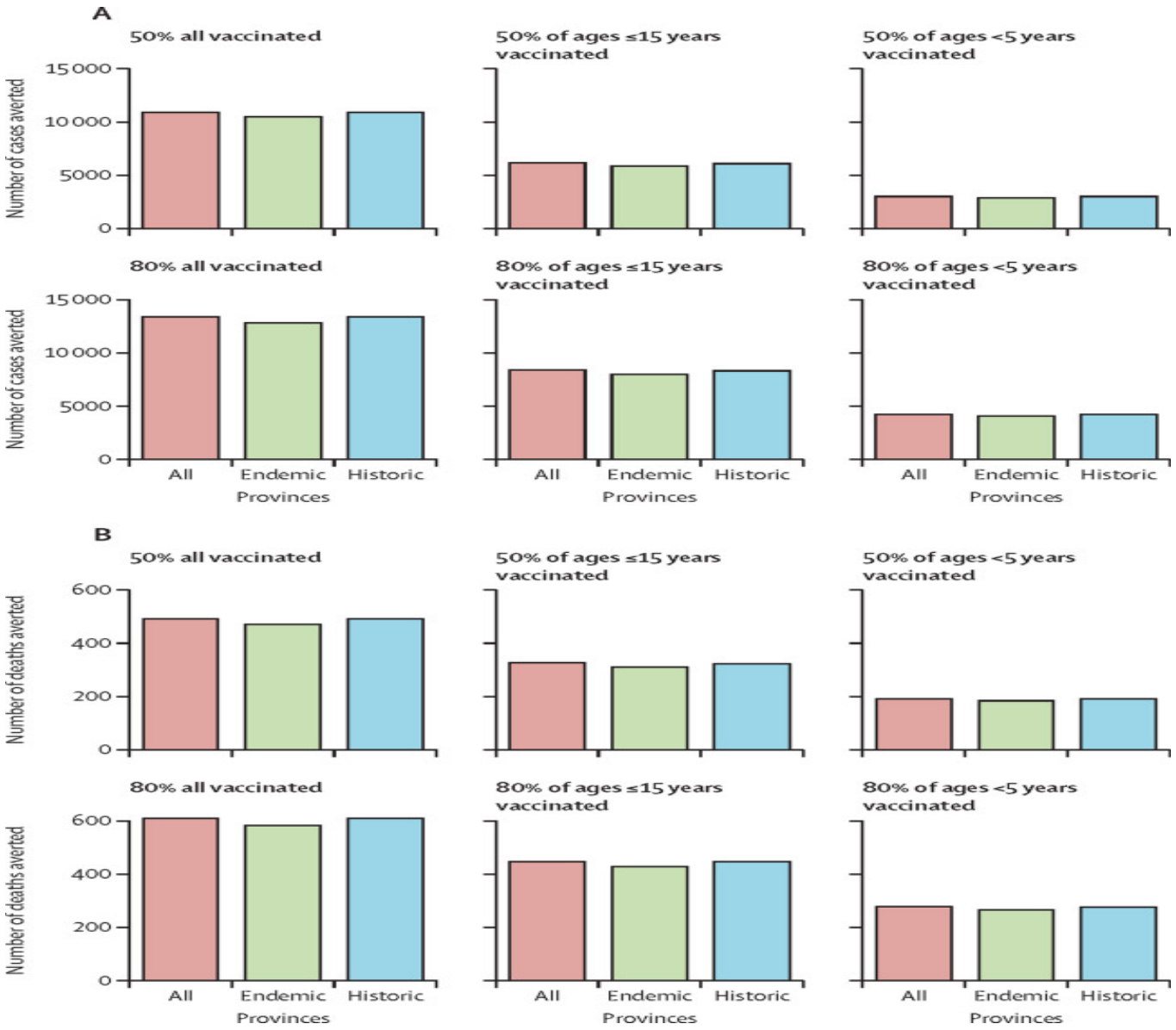
* Wayengera, Misaki

The Lancet Global Health, Volume 12, Issue 12, e1930

"If our intent is towards emergency deployment and use of the few available vaccine doses to interrupt transmission, priority groups should in fact be epidemiologically linked contacts of confirmed cases."

"The mechanical inclusion of at-risk groups such as sex workers, men who have sex with men, and people with multiple sex partners in the absence of a clear history of a recent exposure event deviates from what should be the immediate priority groups"

"In order for us to effectively use the few doses of vaccines available, it is important that we map the cases and their contacts, qualify the high-risk contacts, and target them for post exposure prophylaxis…"



Modelling vaccination approaches for mpox containment and mitigation in the Democratic Republic of the Congo -
Savinkina, Alexandra et al.
The Lancet, Vol 12, Issue 12, e1936 - e1944 – Dec 2024

"Without vaccination, our model predicted 14 700 cases and 700 deaths from mpox over 365 days.

Vaccinating 80% of children aged 15 years or younger in endemic provinces led to a 54% reduction in cases and a 71% reduction in deaths, requiring 26·6 million doses."

Vaccination Models outcomes: The **number of cases (A)** and **deaths (B)** averted via different vaccination scenarios

Recommendations from the Emergency Consultative Group

8 November 2024

1. There is no ground to say the mpox epidemic is under control. From the data, it is expected to increase again before stabilizing and initiating a downward trend toward the beginning of next year
2. Leverage the mpox opportunities to address other key public health issues such as measles
3. We need to take the opportunity of this crisis to build for the future - strengthen surveillance, pushing local manufacturing, decentralized testing, re-think health systems
4. Strengthen the data and evidence and build Africa CDC's capacity to drive data generation and analysis and influence policies and programmes
5. **It is time for bold action at this stage of the mpox response (e.g., vaccinate the entire Sud Kivu as ground zero of the Clade Ib outbreak)**

WHO / IMST guidance: strategize on deployment approaches for maximizing public health impact during the outbreak

Three phases:

1. STOP outbreak by vaccinating in **hot spots** those at highest risk of infection
2. EXPAND protection to those more vulnerable- after item 1 is completed
3. PROTECT for the future--when and if doses are available…

The people at risk of infection are the priority in a context of limited doses

”Vaccination in identified geographic areas" felt to use the vaccines with people of low or no risk

There are **1.91M** persons vaccinated with at least 1 dose of MVA-BN and LC16m8 mpox vaccines in 13 African countries (**73%** in DRC)

Children 1-17 years accounts for **30%** of total vaccinated

MVA-BN: 1,207,354 doses administered out of **1,940,130 received** (62%),

LC16m8: 775,862 doses administered out of **3,050,000 received** (25%)

Gavi mpox country delivery funding support: $12m

Country	Doses Administered	Doses Received	% Utilization
DRC	1,462,878	3,979,660	37%
Sierra Leone	185,008	273,500	68%
Uganda	193,958	361,480	54%
Angola	300	67,000	0%
Liberia	7,642	53,520	14%
Rwanda	31,729	45,520	70%
Nigeria	32,064	39,100	82%
Malawi	30,623	33,600	91%
Ghana	17,321	33,600	52%
Mozambique		26,990	0%
Guinea		20,000	0%
CAR	4,864	12,300	40%
Cote d'Ivoire	5,021	11,300	44%
Zambia		11,160	0%
South Africa	1,111	10,700	10%
Kenya	10,697	10,700	100%

Africa's Mixed Mpox Vaccination Experience –

Progress despite major supply, regulatory, and programmatic obstacles

Key Successes:

- Rapid implementation of targeted vaccination across multiple countries
- Good acceptance among frontline workers and identified high-risk groups
- Effective use of off-label strategies aligned with SAGE guidance (dose-sparing regimen, vaccination of children)
- Emerging effectiveness data to inform ongoing response efforts
- Alignment of Mpox vaccines with operational cost support

Key Challenges:

- Limited vaccine supply and delayed deliveries
- Suboptimal implementation of recommended strategies
- Weak pharmacovigilance systems
- Inadequate surveillance and contact tracing, reducing the effectiveness of targeted vaccination efforts
- Complex legal requirements governing the use of donated doses
- Competing public health priorities, sporadic cases patterns, and hesitancy amongst some key populations

Generating and using data for improved outbreak response and long term solutions on the role that vaccines can play

Vaccine Gaps from Panel Discussion *

- effectiveness studies, modifiers: HIV, malnutrition, other infections
- Data on post-exposure efficacy
- Fractional dosing, single dose efficacy
- Clade-specific data
- Collection of real world safety data via active surveillance, using standardized definitions
- Data to support vaccine use in special populations e.g., peds, IC, pregnancy
- Correlates of protection data to support other decisions
- Strategies: randomized deployment (e.g., 1 vs 2 doses, IM vs ID), ring vaccination immediate vs. delayed…
- Implementation: Phase I studies should be done in Africa. Africa is the only place to study multiple clades

* Mpox Research and Innovation , Scientific conference (29-30 August 2024), Aligning Mpox Research Response with Outbreak Response Goals

Defining Africa's Mpox Vaccine Agenda — Key Takeaways

Imported evidence cannot answer Africa's questions, Africa (DRC) is the epicenter of Clade I mpox

Outbreak-only vaccination is insufficient: align research agendas with outbreak response and long-term prevention strategies.

Policy must be grounded in African epidemiology: evidence generated in Africa will determine who to vaccinate, when, and with what products.

Expanding mpox vaccine pipeline: evidence -not product availability- must guide future vaccination policy.

Leverage continental and global partnerships to accelerate research, regulatory readiness, and access to vaccines tailored to all Clades