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Mpox Outbreak and Vaccination Efforts

Global Trends and Future Outlook

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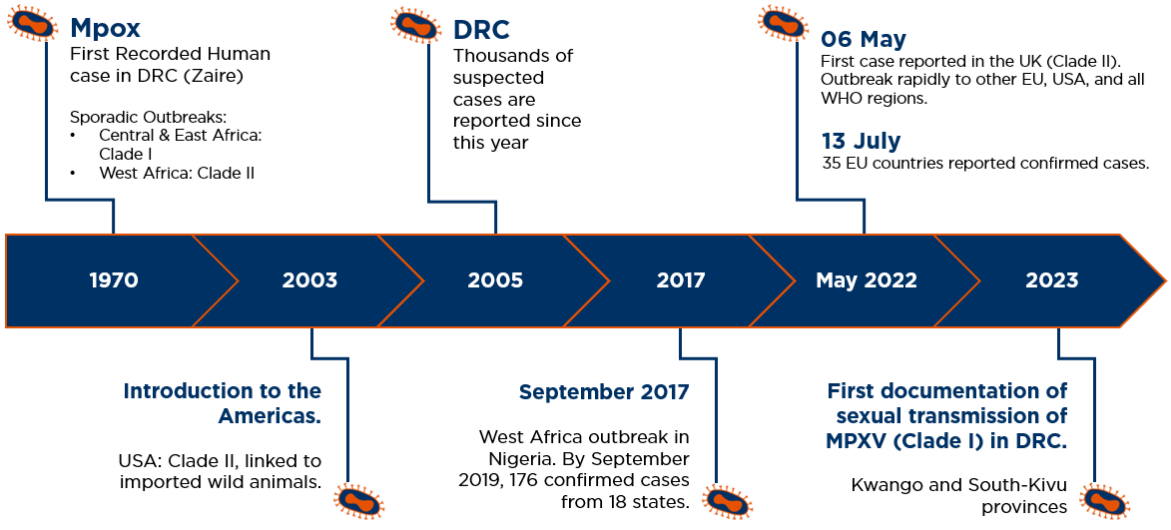
TRENDING TOPICS

The first reported human case of Mpox (formerly known as monkeypox) was a nine-month-old boy in the Democratic Republic of Congo in 1970 (see Figure 1 below). The increase in mpox incidence in humans in recent years has been temporally associated with declining population immunity to orthopox viruses after cessation of worldwide smallpox vaccination. Since then, cases of mpox have been reported sporadically in central and east Africa (clade I) and west Africa (clade II). Following a sudden outbreak in 2022, which rapidly spread across Europe, the Americas and then all six Word Health Organization (WHO) regions, WHO declared a public health emergency of international concern.

Figure 1: Timeline of Mpox Cases



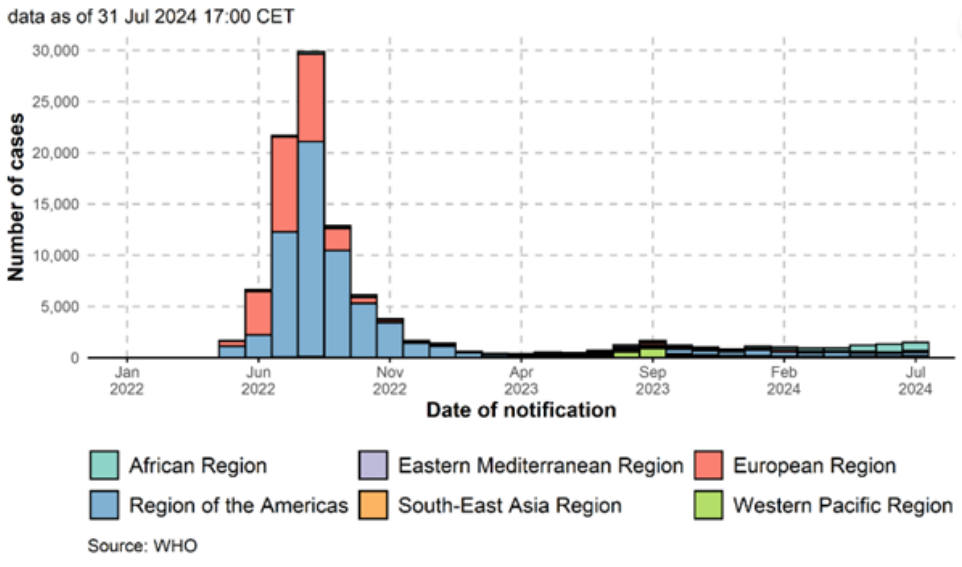
According to the African CDC epidemic intelligence report, 31st August 2024, Since the beginning of this year, a total of **5,265 confirmed cases, 18,737 suspected cases, and 617 deaths** (case fatality rate (CFR): 2.57%] of mpox have been reported from 13 African Union (AU) Member States (MS):[2]

- **Burundi** (281; 748; 0)
- **Central Africa Republic (CAR)** (48; 0; 1)*
- **Cote d'Ivoire** (28; 0; 1)
- **Gabon** (1; 0; 0)
- **Nigeria** (40; 0; 0)
- **South Africa** (24; 0; 3)
- **Democratic Republic of Congo (DRC)** (4,799; 17,801; 610)
- **Cameroon** (5; 34; 2)
- **Congo** (21; 154; 0)
- **Liberia** (6; 0; 0)
- **Kenya** (4; 0; 0)
- **Rwanda** (4; 0; 0)
- **Uganda** (4; 0; 0)

(confirmed cases; suspected cases; deaths)

Since 1 January 2022, cases of mpox have been reported to WHO from 121 Member States across all 6 WHO regions. As of 31 July 2024, a total of 103 048 laboratory confirmed cases and 186 probable cases, including 229 deaths, have been reported to WHO (see Figure 2 below).[3]

Figure 2: Number of global cases up to 31st Jul 2024 (WHO data)



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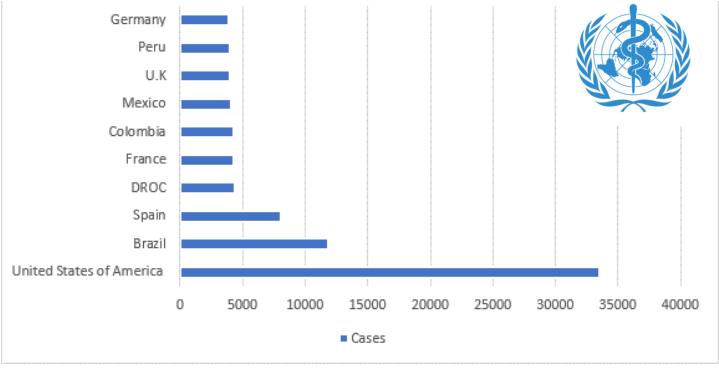
On the 13th of September 2024, WHO announced the **MVA-BN vaccine** as the first vaccine against mpox to be added to its prequalification list. The MVA-BN vaccine, also known as Modified Vaccinia Ankara-Bavarian Nordic, is a non-replicating smallpox vaccine and the only approved mpox vaccine in the EU/EEA, United Kingdom (under the brand name IMVANEX®), United States, Switzerland (as JYNNEOS®), and Canada (as IMVAMUNE®). It is approved for adults at risk of smallpox or mpox.[4]

Currently, only two African nations have granted Emergency Use Authorisation for the MVA-BN vaccine. However, the WHO prequalification, a service to assess the quality, safety and efficacy of medicinal products, will now accelerate ongoing procurement of mpox vaccines by governments and international agencies such as GAVI and UNICEF. MVA-BN joins the list of 269 vaccines already pre-qualified by WHO.

UNICEF and Africa CDC have indicated that there is an urgent need for sufficient vaccine to protect up to 1 million people in the high-risk areas of the DRC, while potentially up to 10-12 million doses could be required through 2025. In response Bavarian Nordic has prioritized the production of MVA-BN for the rest of the year to provide up to 2 million doses by year-end. In addition, Bavarian Nordic is exploring additional levers that could further expand the capacity. This includes looking to transfer manufacturing to other companies either in Africa or other parts of the world, and with further planned improvements in the manufacturing process, Bavarian Nordic has identified another 50 million doses that pending regulatory approvals and demand could be supplied during the next 12-18 months.[4]

It should be noted that in addition to MVA-BN, ACAM2000 a second-generation smallpox vaccine is approved by the FDA for immunization against smallpox and is made available for use against mpox under an Expanded Access Investigational New Drug Protocol, and third generation LC16m8 was licensed in 1975 in Japan for smallpox without age restriction and the indication was extended for the prevention of mpox in August 2022. Also developed is a fourth-generation vaccine known as VacΔ6 or OrthopoxVac. This relies on modification of the vaccinia virus genome through targeted deletion of genetic material responsible for encoding virulence proteins. In addition, other vaccines are under development – e.g. lipid encapsulated mRNA-based vaccines against diseases caused by orthopox viruses such as mpox and smallpox.[5]

Figure 3: 10 Most Affected Countries Globally since January 2022



As nations begin to receive MVA-BN, Nigeria being the first African nation to receive 10,000 doses in August 2024, it is imperative that systematic ongoing data collection during the deployment of vaccines is required to evaluate the effectiveness, safety and impact of mpox vaccination strategies.

Vaccines deployed during emergency situations, such as those for MPOX, require vigilant surveillance to detect any potential adverse effects that may not have surfaced during initial clinical trials. Post-marketing surveillance through systems like the Vaccine Adverse Event Reporting System (VAERS), active safety monitoring, and Phase IV clinical trials are critical elements to support identification of rare and/or long-term side effects. Continuous monitoring through aggregated safety data combined with core safety procedures such as signal detection and risk management, particularly in high-risk or vulnerable populations, ensure vaccine safety during mass global roll out.

As MPOX vaccination programs continue to expand globally, evaluating vaccine effectiveness through multiple observational studies, using information collected through surveillance platforms, electronic health records, and prospective studies is essential to monitor the real-world performance of all available vaccines. The assessment of how well these vaccines prevent infection, reduce disease severity, and limit transmission, especially as different viral strains emerge are part of continuous monitoring efforts by regulators and public partners. Though methods like cohort studies and case-control studies allow comparison of infection rates in vaccinated versus unvaccinated populations and provide valuable insights into vaccine effectiveness across diverse demographics, the potential for bias and confounding are important limitations to methods such as case control studies, and the results of a poorly conducted or incorrectly interpreted case-control study can mislead policies. [7]

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In addition to monitoring vaccine effectiveness and safety, it is vital to evaluate the broader public health impact of MPOX vaccination strategies. This includes assessing the effect of vaccines on transmission rates, achieving “depletion of susceptibles” or “herd immunity”, and their sustained role in outbreak management. Dynamic modelling, field studies, and routine healthcare data are invaluable in determining whether vaccination efforts are successfully reducing the spread of the virus. Furthermore, these insights help inform future vaccination strategies and resource allocation, particularly in areas exhibiting disparate levels of vaccine coverage.

Global health organizations, such as the WHO and Centers for Disease Control and Prevention (CDC), emphasize the importance of collecting comprehensive data during vaccine deployment. WHO has developed the Mpox outbreak toolbox, which includes standard case definitions, case report forms, case investigation forms, which aims to standardize case demographics, medical history, clinical presentation, exposure, and laboratory information.

Successful data collection practices from large-scale vaccination efforts, such as those implemented through the COVAX initiative during the COVID-19 pandemic, have demonstrated the importance of standardized and comprehensive data gathering. The COVAX initiative ensured equitable distribution of vaccines to low-resource countries while maintaining robust monitoring systems to track vaccine effectiveness, safety, and coverage. Whilst a similar approach is required for a global Mpox vaccination campaign, targeted strategies in Africa may be less effective due to the weak surveillance systems. In many areas, by the time a case is identified, the virus may have already spread to multiple locations, making containment efforts far more challenging. Furthermore, with limited testing capacity, many cases go undetected, and the true extent of the outbreak remains unknown. [6]

For more information about how PrimeVigilance can support your vaccine products, contact info@primevigilance.com

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