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WHO Approves First Mpox Vaccine for Adults in Africa — Then Says Babies Can Get It, Too, Despite No Clinical Trials

By Dr. Suzanne Burdick

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The World Health Organization (WHO) today approved the first mpox vaccine for use in adults — and also said it can be used for babies, children, teens and pregnant women if they are in "outbreak settings where the benefits of vaccination outweigh the potential risks."

WHO's approval of Bavarian Nordic's vaccine will help governments and international agencies such as the Gavi, the Vaccine Alliance, and UNICEF, buy it, MedicalXpress reported.

The MVA-BN vaccine — short for "Modified Vaccinia Ankara-Bavarian Nordic" — is a smallpox/mpox vaccine. It is sold in the U.S. under the name Jynneos.

WHO **Assistant Director-General Yukiko Nakatani** said, "The decision can also help national regulatory authorities to fast-track approvals, ultimately increasing access to quality-assured mpox vaccine products."

Children's Health Defense (CHD) Chief Scientific Officer Brian Hooker called the WHO's approval of the shot for infants and children in Africa "a train wreck in the making."

Hooker told The Defender:

> "The safety profile is abysmal in adults (up to 2.1% serious cardiac events in clinical trials) and the vaccine has not been adequately tested for efficacy or safety in pediatric populations.
>
> "In other words, the WHO has no idea whether it will work nor do they know how much damage it will do. The WHO has again abandoned good public health principles and waved their magic vaccine wand on the mpox outbreak."

Dr. David Bell, a public health physician and biotech consultant, also criticized the WHO for overly focusing on mpox vaccines and neglecting to address broader public health issues in Africa.

> "So far this year, about 40,000 children have died from malaria in the DRC [Democratic Republic of Congo] alone, and similar numbers of people from malnutrition, tuberculosis and HIV/AIDs," Bell said.

Although these numbers "obviously dwarf" the number of mpox deaths, the WHO is

allocating fewer resources to addressing them.

Bell — who formerly served as a medical officer and scientist at the WHO — explained what he sees occurring:

> "We have become much better at detecting much rarer diseases such as mpox, and addressing these is certainly more lucrative for the growing industry feeding off the WHO's misinformation regarding rapidly rising pandemic risk.
>
> "However, it is clear that the people of DRC and Africa in general would benefit far more if WHO returned to impactful public health. There has been a move over recent years to a concentration on addressing the symptoms of diseases of poverty (which mpox is) with Western-developed commodities, rather than dealing with underlying causes.
>
> "This signals a return to colonialist-era approaches rather than evidence-based public health. It presumably reflects the way WHO is now funded, with increasing control from the private sector and a few large Western nations with large Pharma industries."

No Clinical Trials on Kids

In its press release, the WHO said the MVA-BN vaccine can be administered to adults over 18 as a two-dose injection four weeks apart but can also be given as a single dose "in supply-constrained outbreak situations."

> "While MVA-BN is currently not licensed for persons under 18 years of age," it said, "this vaccine may be used 'off-label' in infants, children and adolescents, and in pregnant and immunocompromised people."

The WHO called for more data on the vaccine's safety and efficacy in these situations.

The WHO Strategic Advisory Group of Experts on Immunization — which reviewed all available evidence and recommended the use of MVA-BN vaccine — noted in its Weekly Epidemiological Record reportthat "MVA-BN has not been specifically studied in clinical trials in children."

However, they said:

> "The same non-replicating MVA viral vector is used as a platform for other vaccines that include MVA-filo (Mvabea™) against Ebola virus disease (EVD).
>
> "The EVD vaccine is approved by the EU for adults and children aged 1 year and older. Data from 5 published studies on MVA-BN as a viral vector platform for the prevention of EVD, with a total population of 52 229 children, support the favourable safety profile of the product."

The authors of a new study — published Sept. 11 in The BMJ — presented results on MVA-BN's effectiveness in adult males but said nothing about children or pregnant women.

In 2023, researchers funded by the UK Health Security Agency looked at the health outcomes of 87 children who received a single dose of MVA-BN.

They reported that the vaccine was "well tolerated" but that larger studies needed to be

done to fully assess the shot's safety and efficacy in kids.

The Defender asked Bavarian Nordic for information about its mpox vaccine in pediatric populations but did not receive a response by the deadline.

The WHO's process for granting a drug "prequalification" approval for "emergency use listing" requires drugmakers to "commit to continue generating missing information to fulfill prequalification requirements."

"Once this information becomes available," the WHO said, "a PQ [prequalification] application should be submitted to complete the full process to achieve recommendation for international procurement in both emergency and non-emergency settings."

It is unclear how much pediatric safety and efficacy data Bavarian Nordic has collected so far and what it showed.

Mpox Vaccine Approved for U.S. Kids and Teens Since 2022

The U.S. Food and Drug Administration (FDA) in 2022 granted emergency use authorization for the vaccine for "in individuals less than 18 years of age determined to be at high risk for monkeypox infection."

Jynneos has been licensed for use in U.S. adults since 2019.

The Centers for Disease Prevention and Control (CDC)'s mpox vaccination website states that while teens and children at risk for mpox can receive Jynneos, it is not recommended for babies under 6 months.

The CDC also says Jynneos can be given to pregnant or breastfeeding women.

Although it remains unknown if Jynneos may pose risks to a developing fetus if taken during pregnancy, animal studies haven't shown any harm to developing fetuses when the vaccine was given to pregnant animals, the agency said.

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***Suzanne Burdick, Ph.D.**, is a reporter and researcher for The Defender based in Fairfield, Iowa.*

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