



Elsevier has created a [Monkeypox Information Center](#) in response to the declared public health emergency of international concern, with free information in English on the monkeypox virus. The Monkeypox Information Center is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its monkeypox related research that is available on the Monkeypox Information Center - including this research content - immediately available in publicly funded repositories, with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the Monkeypox Information Center remains active.



Contents lists available at ScienceDirect

# International Journal of Surgery

journal homepage: [www.elsevier.com/locate/ijso](http://www.elsevier.com/locate/ijso)

## FDA approved vaccines for monkeypox: Current eminence

Dear Editor,

Monkeypox is caused by the monkeypox virus, a member of the Orthopoxvirus genus in the family Poxviridae. It was declared a global public health emergency by the World Health Organization (WHO) on June 23, 2022 [1]. Monkeypox is usually a self-limiting illness, with symptoms lasting anywhere from two to four weeks. Fever, headache, muscular pains, back discomfort, fatigue, and enlarged lymph nodes are the most typical symptoms. A two-to three-week-long rash may follow or accompany these symptoms. Rashes may appear on the face or body parts such as palms/feet/soles of feet or eyes/mouth/throat/groin/anal areas. There might be as few as one or as many as several thousand lesions. Before the lesions fall off and a new layer of skin grows on top of the old one, lesions are flat and liquid-filled before they become crusted and dry. Difficult situations may happen. The case fatality rate has been hovering around 3–6% recently.

Humans get monkeypox via touching an infected person or animal and by handling infected objects. The monkeypox virus spreads through close contact with lesions, bodily fluids, respiratory droplets, and contaminated bedding. In tropical rainforests of central and west Africa, monkeypox is a zoonotic viral disease sometimes transmitted to other places. It is possible to get monkeypox by touching someone with a rash of a monkeypox patient, including via sexual intercourse, close physical contact, skin-to-skin contact, or oral-to-oral contact. Monkeypox patients remain contagious until the lesions have crusted over, the scabs have gone off, and a new layer of skin has developed below. When an infected individual comes into contact with contaminated items such as clothes, bedding, towels, gadgets, or other surfaces, they may spread the monkeypox virus to the environment. Anyone who comes into contact with these contaminated objects risks contracting the disease.

Eating or drinking food or liquids that have been in touch with the mouth may transmit the virus and breathe in airborne particles. Avoid being in close contact with anybody who has been diagnosed with monkeypox or with any animals that may be carrying the virus. Disinfect any areas that may have been contaminated by a virus from a contagious person regularly and clean such places.

The JYNNEOS (Brand name: Imvamune and Imvanex) as smallpox and monkeypox vaccination is indicated for individuals 18 years of age and older at high risk of infection. Two 0.5 ml doses of Jynneos should be administered four weeks apart. BioShield (BARDA, BioShield) collaborated with the U.S. government to create Jynneos smallpox/monkeypox vaccine to protect adults, especially those with compromised immune systems and those at high risk of adverse effects to standard smallpox vaccinations based on reproducing the virus [2]. JYNNEOS - STN: BL 125678/20 was amended by the FDA on June 21, 2021. J07BX is the ATC code. ImvaNEX and Imvamune are trademarks for the MVA-BN® vaccination in the European Union and Canada, respectively [3]. The European Medicines Agency (EMA) human

medicines committee (CHMP) proposed expanding the use of Imvanex to protect adults against monkeypox illness on July 22, 2022. In both monkeypox and smallpox, the vaccine's usage is based on human and animal immunogenicity findings and animal protection against the virus. According to Committee for Medicinal Products for Human Use (CHMP), these trials show that Imvanex effectively protects people against monkeypox illness [4].

The response to the Monkeypox outbreak was released by the U.S. Department of Health and Human Services (HHS) on July 21, 2022 [5]. HHS has produced and distributed more than 191,000 vaccines to state and local health authorities for free this year. The federal government will have access to more than 6.9 million doses by the middle of 2023, considering doses previously supplied to the Strategic National Stockpile (SNS), those awaiting a delivery from the provider, and replacement doses.

Cells from chicken embryo fibroblasts are used to make the JYNNEOS (MVA-BN) vaccine. Replication-competent poxvirus strains may infect humans and create an infectious virus that can be transferred to other people. As a result, replication-deficient vaccinia Ankara (MVA) strains do not induce clinical infection because they do not generate infectious viruses in people. As a result, poxvirus strains with poor reproduction provide a far lower risk of adverse effects than strains with good replication.

As a result of the outbreak of monkeypox, the U.K Health Security Agency (UKHSA) revealed its vaccination plan on June 21, 2022. Vaccines for smallpox are thought to protect against monkeypox since monkeypox is linked to the virus that causes smallpox. As a result, the Joint Committee on Vaccination and Immunization recommended that GBMSM to be vaccinated as soon as possible to people with the most significant risk of infection owing to many contacts. Although there is some indication that MVA-BN may prevent or change illness in monkeypox virus-infected contacts, the data is somewhat limited. The first-generation vaccinia-virus-based smallpox vaccination was 85% successful in preventing monkeypox in the past, according to the WHO. Vaccines are effective in protecting patients against monkeypox if taken before exposure. As a result, those exposed to monkeypox and who have not received the smallpox vaccination in the previous three years should be vaccinated. According to the CDC, a person's protection against monkeypox will be more effective if they obtain the vaccination as soon as possible.

People at high risk for smallpox and monkeypox infection may get the FDA-licensed Smallpox (Vaccinia) Vaccine, which has the patented ACAM2000 and Sanofi Pasteur Biologics Co. manufactures the vaccine [6]. The Strategic National Stockpile (SNS) now has a second-generation smallpox vaccine that has been approved and is ready for deployment if smallpox is used as a lethal biological weapon.

Multiple punctures deliver ACAM2000 as a single dose of live virus

<https://doi.org/10.1016/j.ijso.2022.106896>

Received 12 August 2022; Accepted 5 September 2022

Available online 8 September 2022

1743-9191/© 2022 IJS Publishing Group Ltd. Published by Elsevier Ltd. All rights reserved.

preparation through the percutaneous route as a single dosage. Unlike other vaccines, ACAM2000 is delivered distinctly. Pricks are made on the upper arm using a two-pronged stainless steel (or bifurcated) needle that has been submerged in the vaccination solution. A “pock” or localized infection develops when the virus multiplies in the injection site. The presence of a red, itchy, painful patch three to four days after immunization shows that the vaccine was effective; that is, there has been “a take.” A little scar is left behind when a blister forms at the location of the vaccine and then dries up, creating a scab. This scab comes off in the third week. An individual’s immune system is stimulated by the vaccination to produce antibodies and cells in the blood and other organs that may aid the body in fighting off an actual smallpox infection should they ever come into contact with it. As a result, those who get the ACAM2000 vaccine must take steps to prevent the vaccine virus from spreading.

As a lyophilized preparation of pure live virus, ACAM2000 may be used. Each ACAM2000 vaccine vial contains about 100 doses after reconstitution (0.0025 mL/dose). According to the plaque test in Vero cells, the vaccine virus concentration ranges from 1.0–5.0 × 10<sup>8</sup> plaque-forming units (PFU)/mL or 2.5–12.5 × 10<sup>5</sup> PFU/dose. Including 2% albumin USP and trace levels of neomycin and polymyxin B, the product comprises all these ingredients. If this injection lesion becomes infected with a virus, it may spread to other body regions and individuals. People who get ACAM2000 immunization must take care to prevent the vaccine virus from spreading and are considered fully protected after 28 days. Vaccination against smallpox or monkeypox, on the other hand, almost often results in very minimal side effects, such as a low fever, weariness, swelling of glands, redness, and itching at the site of vaccination. These vaccinations, on the other hand, come with more substantial side effects. ACAM2000’s side effects may be severe in certain patients, such as those with compromised immune systems. Talk to your doctor if you are unsure whether you should take ACAM2000. The older vaccination, Jynneos, has a lower risk of side effects and adverse outcomes. Still, the approval of vaccines is based on an emergency basis; there have been no clinical trials arranged for them; therefore, we need to wait for the ideal vaccine for treatment of monkeypox.

Furthermore, in light of the present monkeypox outbreak, a ring vaccination approach for the high-risk group seems preferable to mass immunization with smallpox vaccinations. As a result, determining the appropriate target population for accessible vaccinations based on risk and benefit analysis is a critical challenge for the immunization program. Furthermore, the target population should be assessed from the perspective of the jurisdiction’s epidemiological status, as well as the most recent findings on the monkeypox virus’s transmission dynamics, severity, and mortality [7].

#### Ethical approval

Not applicable as no animal study was conducted.

#### Sources of funding

No funding.

#### Author contribution

Hitesh Chopra, Manish Dhawan, Talha Bin Emran conceptualized and designed the manuscript, participating in drafting the article and/or acquisition of data, and/or analysis and interpretation of data; Shabana Bibi, Atif Amin Baig, Ajay Singh Kushwah, Manpreet Kaur and Talha Bin Emran edited and revised the manuscript critically. All authors critically revised the manuscript concerning intellectual content and approved the final manuscript.

#### Trial register number

1. Name of the registry: Not applicable.
2. Unique Identifying number or registration ID: Not applicable.
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): Not applicable.

#### Guarantor

Talha Bin Emran.

#### Provenance and peer review

Not commissioned, internally peer-reviewed.

#### Data statement

All data are available in the manuscript.

#### Declaration of competing interest

Authors declare that they have no conflicts of interest.

#### References

- [1] WHO, Director-general declares the ongoing monkeypox outbreak a public health emergency of international concern, n.d. <https://www.who.int/europe/news/item/23-07-2022-who-director-general-declares-the-ongoing-monkeypox-outbreak-a-public-health-event-of-international-concern>. (Accessed 29 July 2022).
- [2] JYNNEOS | FDA. <https://www.fda.gov/vaccines-blood-biologics/jynneos>. (Accessed 29 July 2022).
- [3] Considerations for monkeypox vaccination | monkeypox | poxvirus | CDC, n.d. <https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html>. (Accessed 25 July 2022).
- [4] EMA recommends approval of Imvanex for the prevention of monkeypox disease | European Medicines Agency, n.d. <https://www.ema.europa.eu/en/news/ema-recommends-approval-imvanex-prevention-monkeypox-disease>. (Accessed 29 July 2022).
- [5] FACT SHEET: U.S. Department of health and human Services response to the monkeypox outbreak | HHS.gov, n.d. <https://www.hhs.gov/about/news/2022/07/21/fact-sheet-us-department-of-health-and-human-services-response-to-the-monkeypox-outbreak.html>. (Accessed 29 July 2022).
- [6] ACAM2000 smallpox vaccine — precision vaccinations, n.d. <https://www.precisionvaccinations.com/vaccines/acam2000-smallpox-vaccine>. (Accessed 25 July 2022).
- [7] S.L. Kwon, S. Ban, J. Shin, H. Bae, H. Park, G.Y. Kwon, Monkeypox vaccination in the Republic of Korea: identifying the high-risk target group, *J. Kor. Med. Sci.* 37 (29) (2022 Jul 25) e239, <https://doi.org/10.3346/jkms.2022.37.e239>. PMID: 35880509; PMCID: PMC9313979.

Hitesh Chopra

Chitkara College of Pharmacy, Chitkara University, Punjab, India

E-mail address: [chopraontheride@gmail.com](mailto:chopraontheride@gmail.com).

Manish Dhawan

Department of Microbiology, Punjab Agricultural University, Ludhiana,

141004, Punjab, India

Trafford College, Altrincham, Manchester, WA14 5PQ, UK

E-mail address: [dhawanmanish501@gmail.com](mailto:dhawanmanish501@gmail.com).

Shabana Bibi

Department of Biosciences, Shifa Tameer-e-Millat University, Islamabad,

Pakistan

E-mail address: [shabana.bibi.stmu@gmail.com](mailto:shabana.bibi.stmu@gmail.com).

Atif Amin Baig

Unit of Biochemistry, Faculty of Medicine, Universiti Sultan Zainal Abidin,

Kuala Terengganu, 20400, Malaysia

E-mail address: [atifameen01@gmail.com](mailto:atifameen01@gmail.com).

Ajay Singh Kushwah, Manpreet Kaur

Amar Shaheed Baba Ajit Singh Jujhar Singh Memorial College of Pharmacy,

BELA, Ropar, Punjab, India

E-mail addresses: [kushwah\\_ph05@yahoo.co.in](mailto:kushwah_ph05@yahoo.co.in) (A.S. Kushwah), [ks.manpreet1007@gmail.com](mailto:ks.manpreet1007@gmail.com) (M. Kaur).

Department of Pharmacy, Faculty of Allied Health Sciences, Daffodil International University, Dhaka, 1207, Bangladesh

Talha Bin Emran\*

Department of Pharmacy, BGC Trust University Bangladesh, Chittagong, 4381, Bangladesh

\* Corresponding author. Department of Pharmacy, BGC Trust University Bangladesh, Chittagong 4381, Bangladesh.  
E-mail address: [talhabmb@bgctub.ac.bd](mailto:talhabmb@bgctub.ac.bd) (T.B. Emran).