AETC AIDS Education & Training Center Program
Southeast Regional Conference 2023

What You Need to Know About the Prevention, Diagnosis and Treatment of Mpox

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Learning Objectives

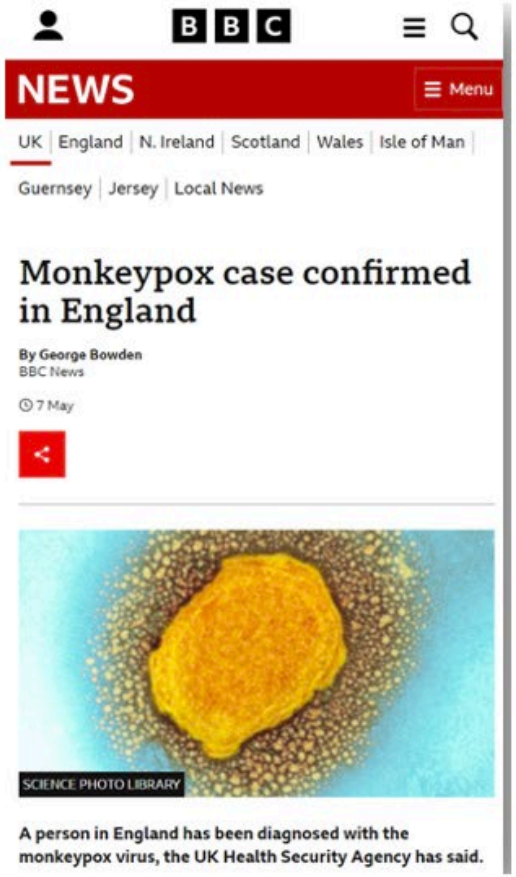
- Recognize the presentation of mpox
- Review how to diagnose mpox
- Develop familiarity with treatment options for mpox
- Compare the different vaccination options and prevention strategies for mpox
- Examine what has been learned since the start of the outbreak

Disclosures

- *None*

- *This program is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number U1OHA30535 as part of an award totaling $4.2m. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov.*
- *"Funding for this presentation was made possible by cooperative agreement U1OHA30535 from the Health Resources and Services Administration HIV/AIDS Bureau. The views expressed do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government. Any trade/brand names for products mentioned during this presentation are for training and identification purposes only."*

Mpox 2022



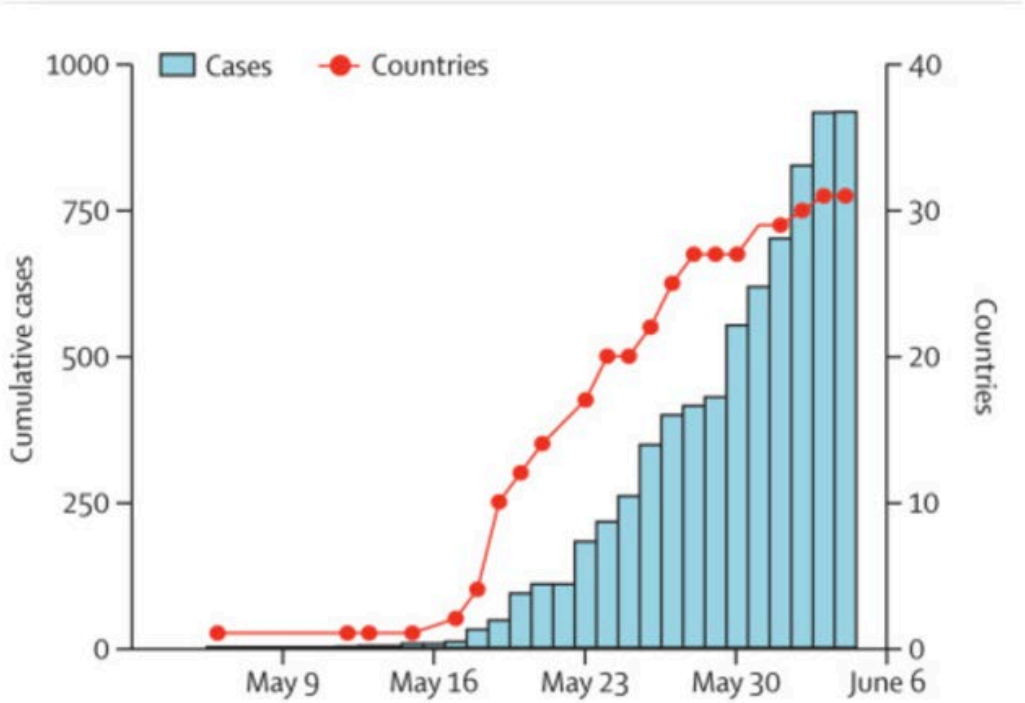
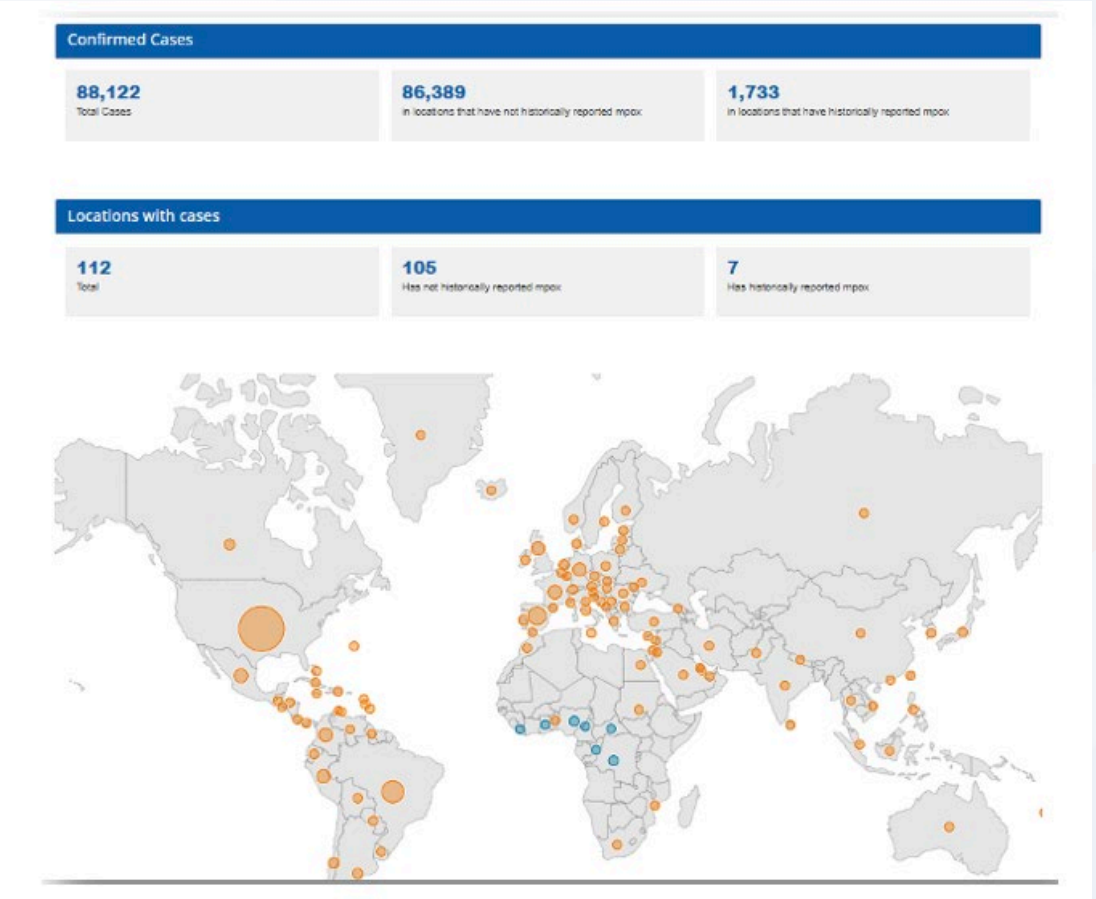


Figure Rapid expansion of the 2022 monkeypox outbreak

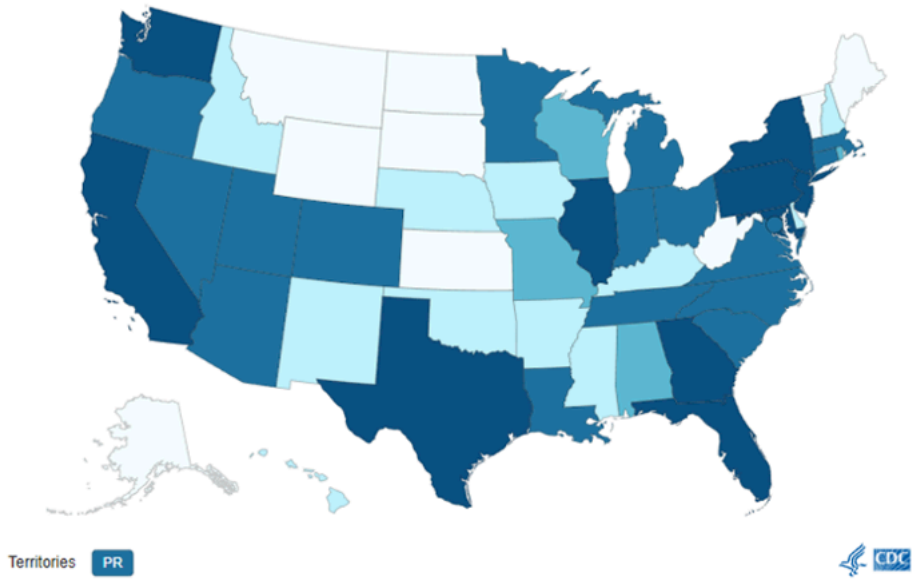
Kraemer MUG, Tegally H, Pigott DM, et al. Tracking the 2022 monkeypox outbreak with epidemiological data in real-time. *Lancet Infect Dis*. 2022;22(7):941-942. doi:10.1016/S1473-3099(22)00359-0

Epidemiology



https://www.cdc.gov/poxvirus/monkeypox/response/2022/index.html

Epidemiology



30,555 US Cases (7/5/23)

28,745 Men 94%

884 Women 3%

745 Age <20 2.4%

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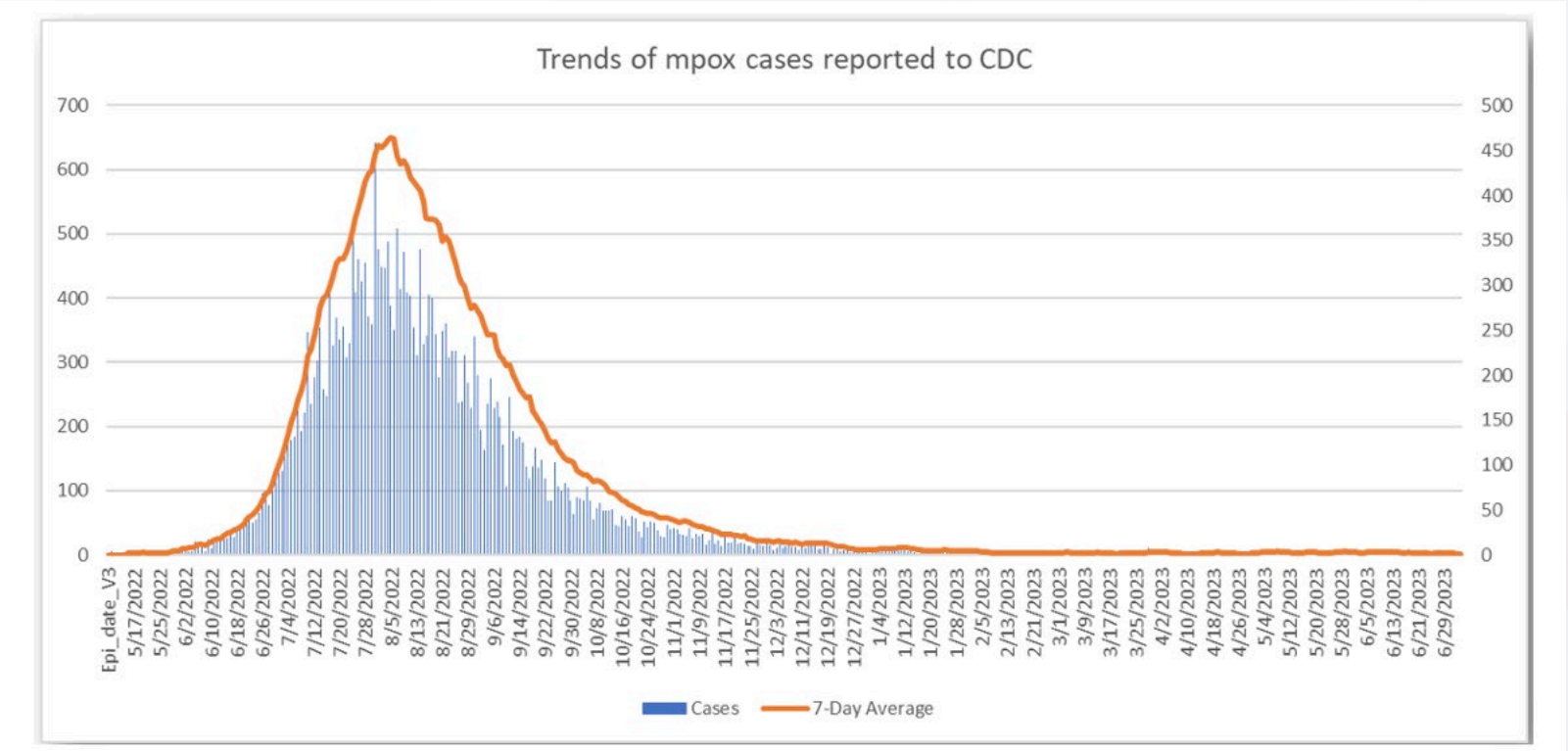
Current Epidemiology



https://www.cdc.gov/poxvirus/monkeypox/response/2022/mpx-trends.html

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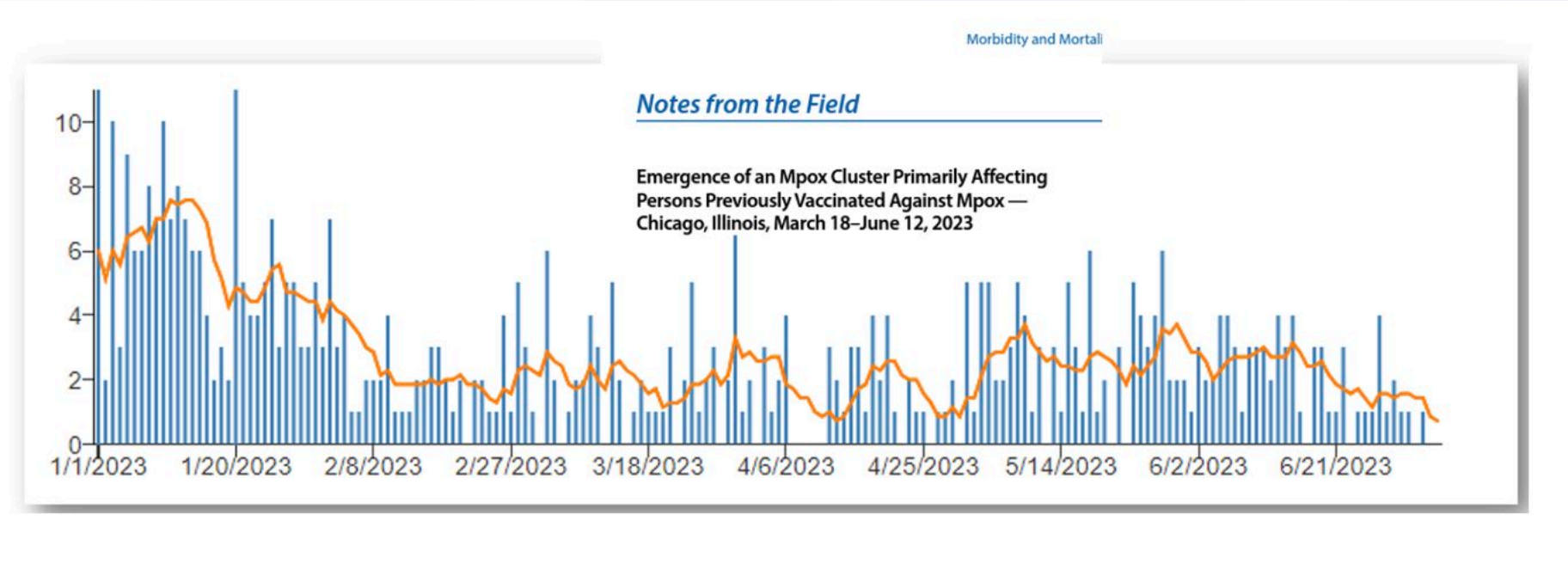
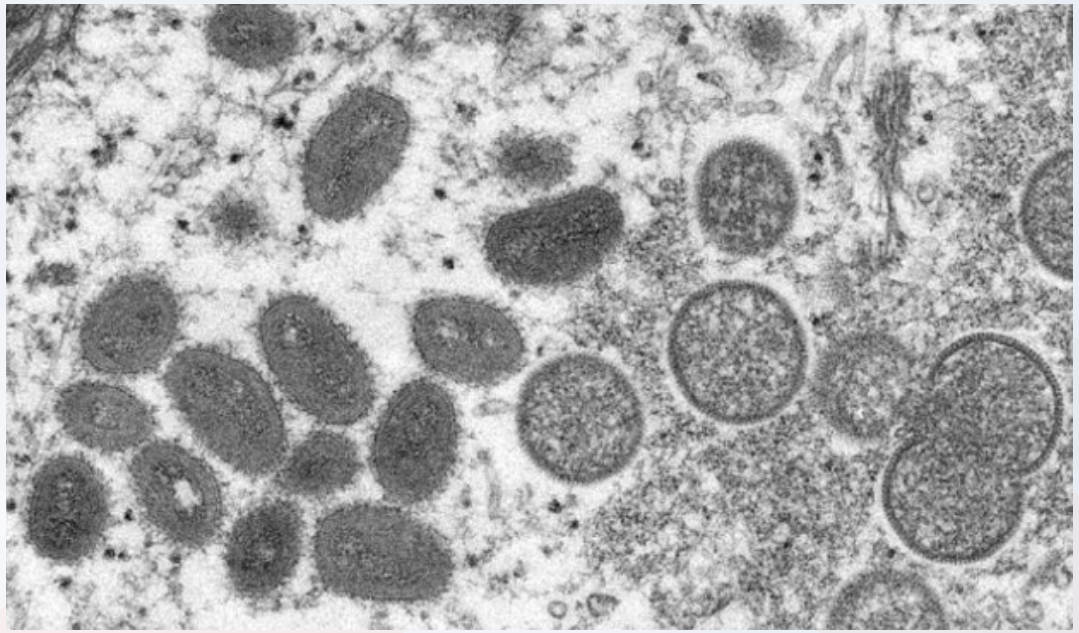


https://www.cdc.gov/poxvirus/monkeypox/response/2022/mpx-trends.html

What is Mpox?

- Poxvirus
  - Orthopoxvirus
  - Like smallpox! (but not)
- There are many other Orthopoxviruses
  - Variola (Smallpox)
  - Vaccinia
  - Cowpox
- Two virus clades
  - Clade 1 ~10% case fatality rate
  - Clade 2a ~1% case fatality rate
  - **Clade 2b ~ 0.2% case fatality rate**



Mpox Transmission

Not Easily Transmitted

Animal to Human

1. Direct contact with infected lesions or body fluids
2. Contaminated fomites
3. Bite and/or scratch
4. Ingestion of animal products

Mpox Transmission

Not Easily Transmitted

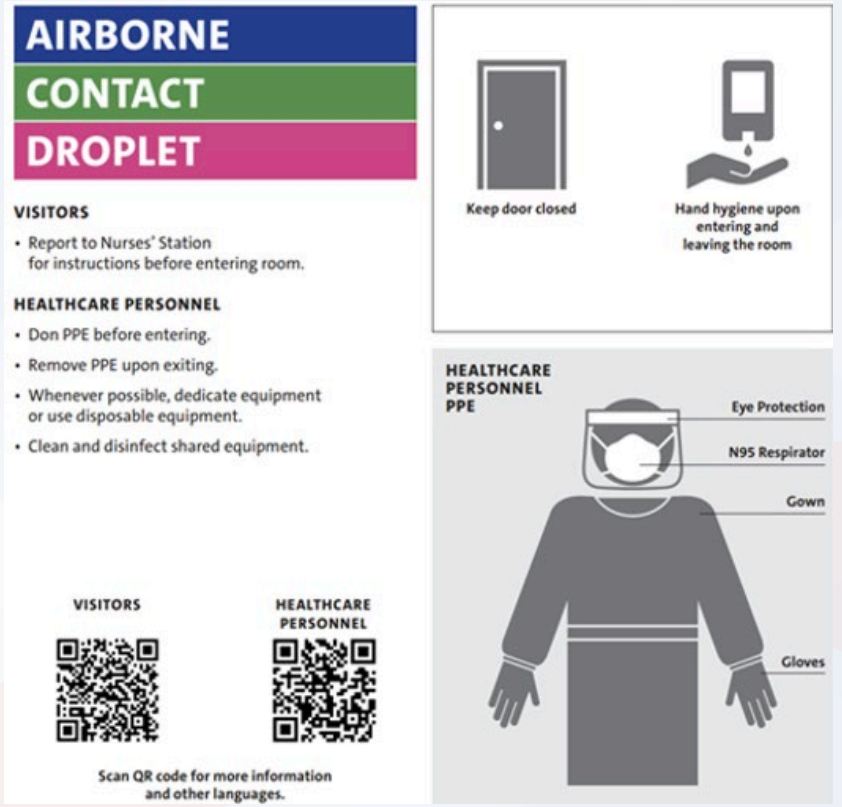
Human to Human

1. Direct contact with infected lesions or body fluids
2. Contaminated fomites
3. Exposure to respiratory secretions

Infection Prevention and Control of Mpox

Personal Protective Equipment (PPE)

- Gown
- Gloves
- Eye protection
- NIOSH-approved particulate respirator equipped with N95 filters or higher

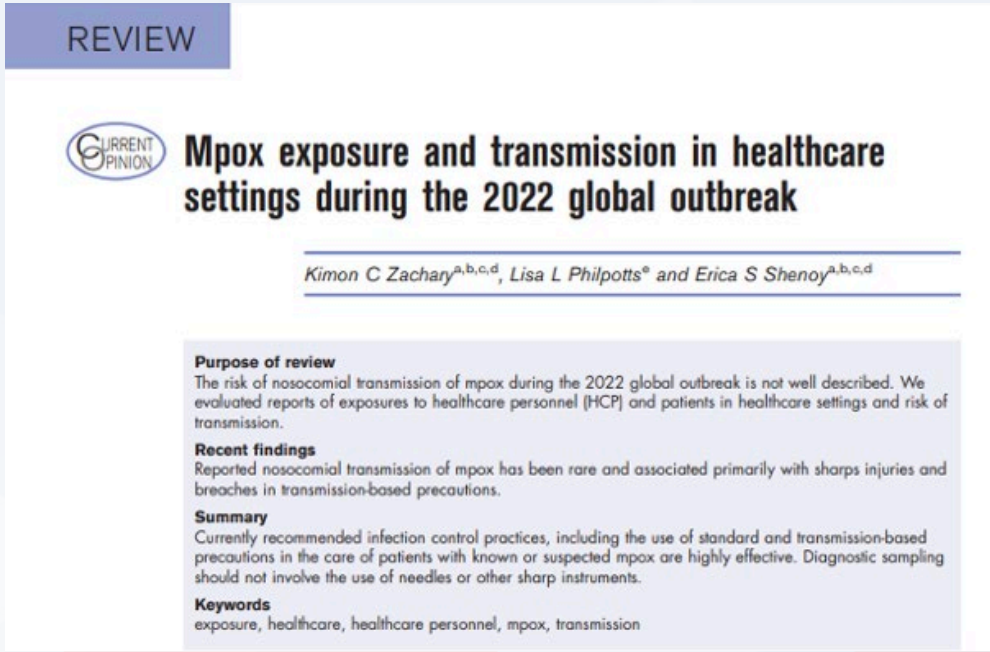


Transmission to Healthcare Workers is Rare

Personal Protective Equipment (PPE)

- 313 people
- Low use of recommended PPE
  - 23% used all PPE
- 12% received PEP (MVA vaccine)
- Monitored for 21 days

None acquired MPX



REVIEW

Mpox exposure and transmission in healthcare settings during the 2022 global outbreak

Kimon C Zachary[a,b,c,d], Lisa L Philpotts[e] and Erica S Shenoy[a,b,c,d]

Purpose of review
The risk of nosocomial transmission of mpox during the 2022 global outbreak is not well described. We evaluated reports of exposures to healthcare personnel (HCP) and patients in healthcare settings and risk of transmission.

Recent findings
Reported nosocomial transmission of mpox has been rare and associated primarily with sharps injuries and breaches in transmission-based precautions.

Summary
Currently recommended infection control practices, including the use of standard and transmission-based precautions in the care of patients with known or suspected mpox are highly effective. Diagnostic sampling should not involve the use of needles or other sharp instruments.

Keywords
exposure, healthcare, healthcare personnel, mpox, transmission

- Sharps injury was the most common route of acquisition among cases reported

Marshall et al MMWR 2022;71(38);1216-1219 Carvahlo et al Emerg Infect Dis 2022; 28(11) WHO Monkeypox Outbreak Global Trends, WHO.int, Zachary, K. , Philpotts, L. & Shenoy, E. (2023). Mpox exposure and transmission in healthcare settings during the 2022 global outbreak. *Current Opinion in Infectious Diseases*, *36* (4), 257-262. doi: 10.1097/QCO.0000000000000933.

Can I get Mpox ….?

Bus or Subway

Grocery Store

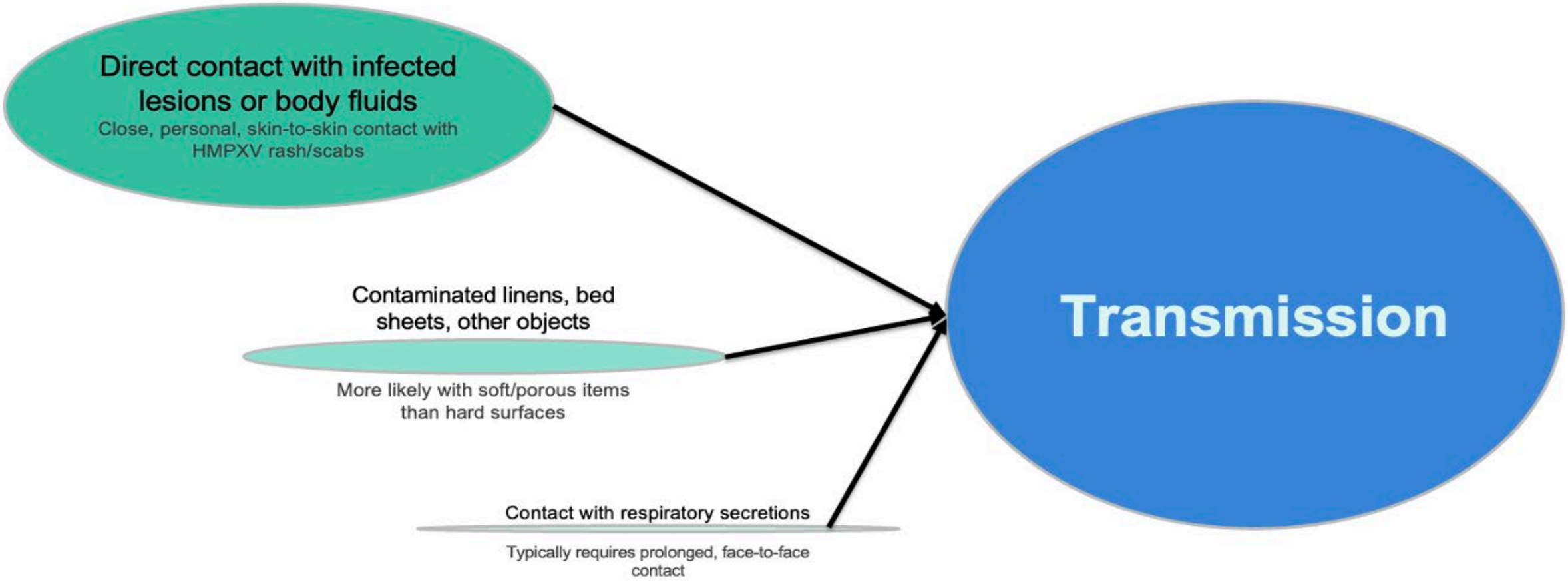
Clothing Store

Gym

Salon

Classroom

Mpox Transmission In The Real World



Mpox Transmission

Sexual Transmission

- Anatomic association between sexual practices and lesion location
  - **Proctitis 5x higher among those engaging in receptive intercourse then those not**

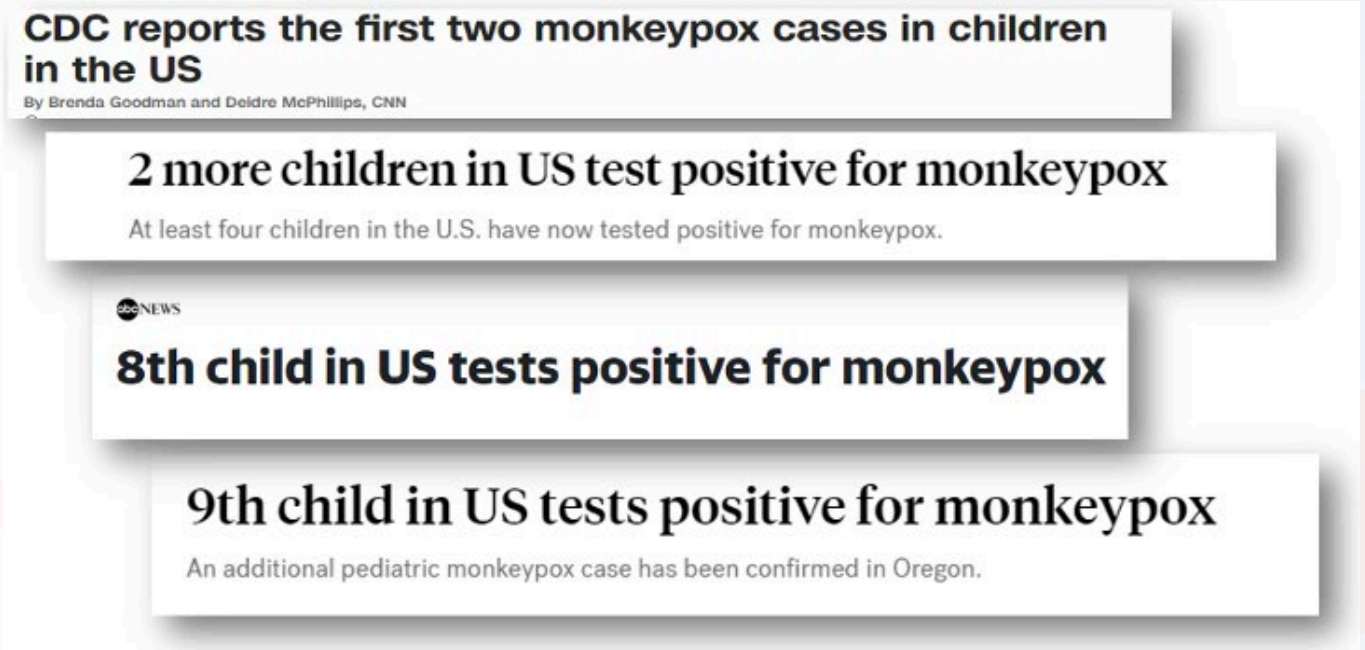
	MSM with receptive anal contact (n=108)	MSM without receptive anal contact (n=58)	Non-MSM sex (n=15)	Total (n=181)
Incubation period, days	8·0 (5·0–10·0)	7·0 (5·0–9·0)	6·0 (5·0–6·0)	7·0 (5·0–10·0)
Systemic symptoms before the rash	67 (62%)	16 (28%)	4 (27%)	87 (48%)
Presence of proctitis	41 (38%)	4 (7%)	0	45 (25%)
Throat PCR				
Not done	48 (44%)	16 (28%)	0	64 (35%)
Negative	11 (11%)	18 (31%)	6 (40%)	35 (19%)
Positive	49 (45%)	24 (41%)	9 (60%)	82 (45%)

Data are median (IQR) or n (%). MSM=men who have sex with men.

Table 3: Association between the presumed route of transmission and epidemiological, clinical, and virological factors

Mpox Transmission

As Numbers Increased, We Saw a Slow Expansion of the Epidemiology



30,555 US Cases (7/5/23)

884 Women 3%

745 Age <20 2.4%

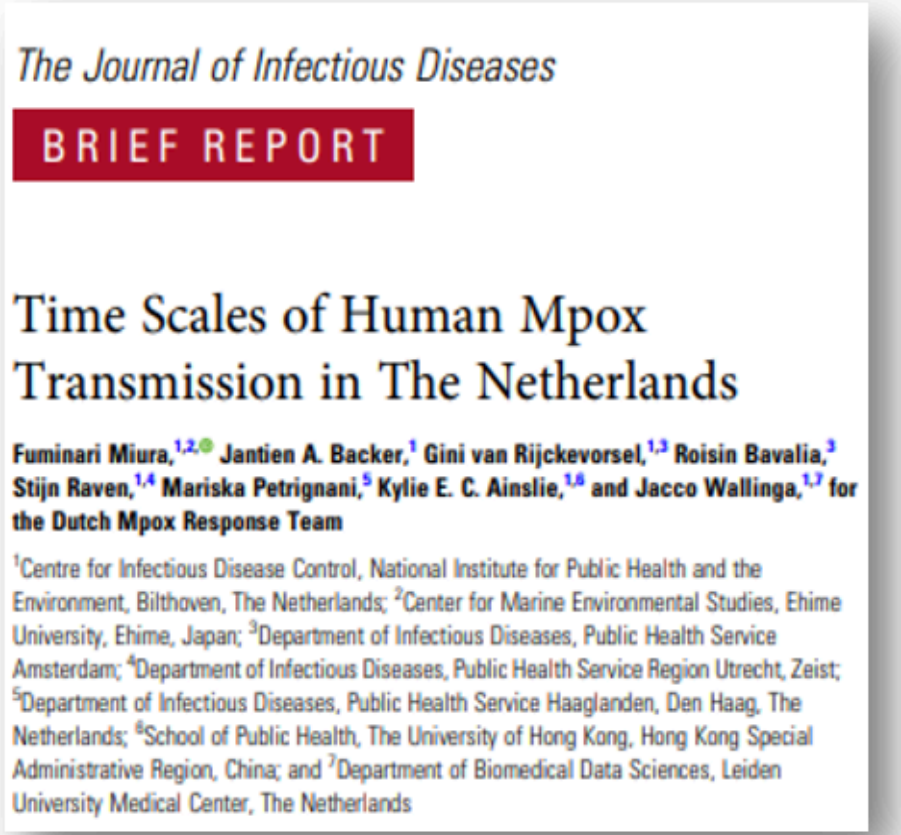
Mpox Pre-Symptomatic Transmission

RESEARCH ARTICLE

JOURNAL OF MEDICAL VIROLOGY WILEY

Presymptomatic viral shedding in high-risk mpox contacts: A prospective cohort study

Isabel Brosius[1] | Christophe Van Dijck[1,2] | Jasmine Coppens[1] | Leen Vandenhove[1] | Eugene Bangwen[1] | Fien Vanroye[1] | Jacob Verschueren[1] | The ITM MPOX Study Group | Sabine Zange[3] | Joachim Bugert[3] | Johan Michiels[4] | Emmanuel Bottieau[1] | Patrick Soentjens[1] | Johan van Griensven[1] | Chris Kenyon[1,5] | Kevin K. Ariën[4,6] | Marjan Van Esbroeck[1] | Koen Vercauteren[1] | Laurens Liesenborghs[1]



The Journal of Infectious Diseases

BRIEF REPORT

Time Scales of Human Mpox Transmission in The Netherlands

Fuminari Miura,[1,2] Jantien A. Backer,[1] Gini van Rijckevorsel,[1,3] Roisin Bavalia,[3] Stijn Raven,[1,4] Mariska Petrignani,[5] Kylie E. C. Ainslie,[1,6] and Jacco Wallinga,[1,7] for the Dutch Mpox Response Team

[1]Centre for Infectious Disease Control, National Institute for Public Health and the Environment, Bilthoven, The Netherlands; [2]Center for Marine Environmental Studies, Ehime University, Ehime, Japan; [3]Department of Infectious Diseases, Public Health Service Amsterdam; [4]Department of Infectious Diseases, Public Health Service Region Utrecht, Zeist; [5]Department of Infectious Diseases, Public Health Service Haaglanden, Den Haag, The Netherlands; [6]School of Public Health, The University of Hong Kong, Hong Kong Special Administrative Region, China; and [7]Department of Biomedical Data Sciences, Leiden University Medical Center, The Netherlands

Mpox Classic Presentation

Prodrome

- Fevers
- Chills
- Headache
- Malaise
- Myalgias
- Lymphadenopathy

Rash

- Days 1 to 3 (Before day 5)
  - Rash
  - Firm, deep-seated, well-circumscribed, sometimes umbilicated lesions
  - Starts on face and spreads to extremities, including palms & soles
  - Progresses through several synchronized stages
  - Can be painful
  - Can last up to 4 weeks

Mpox Classic Presentation

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Mpox Classic Presentation

Incubation 5-21 days → Prodromal Symptoms → Enanthem → Macules 1-2 days → Papules 1-2 days → Vesicles 1-2 days → Pustules 5-7 days → Scabs 7-14 days → Scabs fall off

Mpox Classic Presentation

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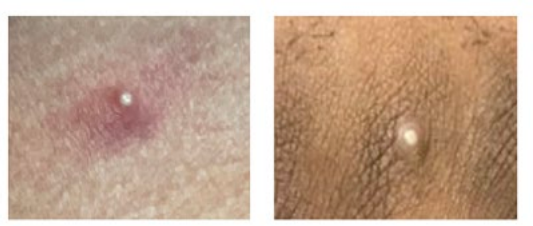

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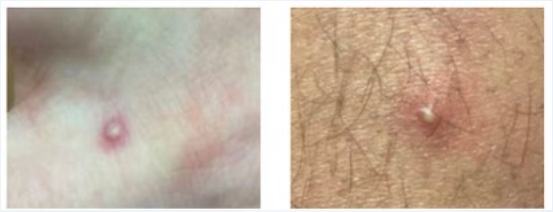

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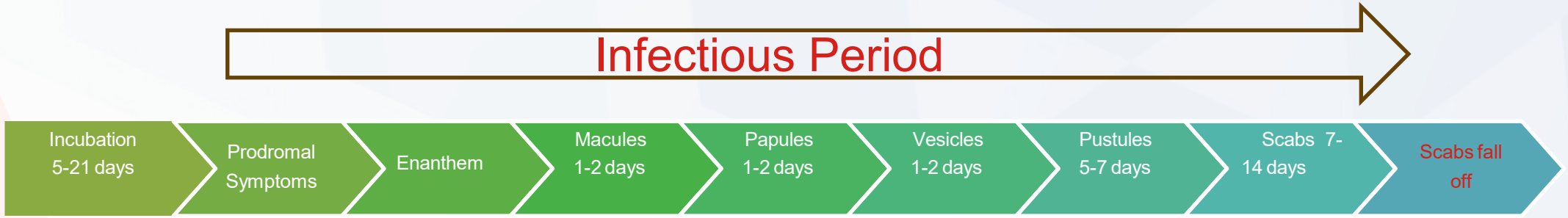

How Is Mpox Presenting During This Outbreak?

ORIGINAL ARTICLE

Monkeypox Virus Infection in Humans across 16 Countries — April–June 2022

J.P. Thornhill, S. Barkati, S. Walmsley, J. Rockstroh, A. Antinori, L.B. Harrison, R. Palich, A. Nori, I. Reeves, M.S. Habibi, V. Apea, C. Boesecke, L. Vandekerckhove, M. Yakubovsky, E. Sendagorta, J.L. Blanco, E. Florence, D. Moschese, F.M. Maltez, A. Goorhuis, V. Pourcher, P. Migaud, S. Noe, C. Pintado, F. Maggi, A.-B.E. Hansen, C. Hoffmann, J.I. Lezama, C. Mussini, A.M. Cattelan, K. Makofane, D. Tan, S. Nozza, J. Nemeth, M.B. Klein, and C.M. Orkin, for the SHARE-net Clinical Group*

Clinical features and novel presentations of human monkeypox in a central London centre during the 2022 outbreak: descriptive case series

Aatish Patel, Julia Bilinska, Jerry C H Tam, Dayana Da Silva Fontoura, Claire Y Mason, Anna Daunt, Luke B Snell, Jamie Murphy, Jack Potter, Cecilia Tuudah, Rohan Sundramoorthi, Movin Abeywickrema, Caitlin Pley, Vasanth Naidu, Gaia Nebbia, Emma Aarons, Alina Botgros, Sam T Douthwaite, Claire van Nispen tot Pannerden, Helen Winslow, Aisling Brown, Daniella Chilton, Achyuta Nori

Clinical presentation and virological assessment of confirmed human monkeypox virus cases in Spain: a prospective observational cohort study

Eloy José Tarín-Vicente, Andrea Alemany, Manuel Agud-Dios, Maria Ubals, Clara Suñer, Andrés Antón, Maider Arando, Jorge Arroyo-Andrés, Lorena Calderón-Lozano, Cristina Casañ, José Miguel Cabrera, Pep Coll, Vicente Descalzo, María Dolores Folgueira, Jorge N García-Pérez, Elena Gil-Cruz, Borja González-Rodríguez, Christian Gutiérrez-Collar, Águeda Hernández-Rodríguez, Paula López-Roa, María de los Ángeles Meléndez, Julia Montero-Menárguez, Irene Muñoz-Gallego, Sara Isabel Palencia-Pérez, Roger Paredes, Alfredo Pérez-Rivilla, Maria Piñana, Nuria Prat, Aida Ramirez, Ángel Rivero, Carmen Alejandra Rubio-Muñiz, Martí Vall, Kevin Stephen Acosta-Velásquez, An Wang, Cristina Galván-Casas, Michael Marks*, Pablo L Ortiz-Romero*, Oriol Mitjà**

Epidemiologic and Clinical Characteristics of Monkeypox Cases — United States, May 17–July 22, 2022

Weekly / August 12, 2022 / 71(32):1018-1022

On August 5, 2022, this report was posted online as an MMWR Early Release.

David Philpott, MD[1,2]; Christine M. Hughes, MPH[3]; Karen A. Alroy, DVM[3]; Janna L. Kerins, VMD[4]; Jessica Pavlick, DrPH[5]; Lenore Asbel, MD[6]; Addie Crawley, MPH[3]; Alexandra P. Newman, DVM[7]; Hillary Spencer, MD[1,4]; Amanda Feldpausch, DVM[8]; Kelly Cogswell, MPH[8]; Kenneth R. Davis, MPH[9]; Jinlene Chen, MD[10]; Tiffany Henderson, MPH[11]; Katherine Murphy, MPH[12]; Meghan Barnes, MSPH[13]; Brandi Hopkins, MPH[14]; Mary-Margaret A. Fill, MD[15]; Anil T. Mangla, PhD[16]; Dana Perella, MPH[6]; Arti Barnes, MD[17]; Scott Hughes, PhD[3]; Jayne Griffith, MPH[18]; Abby L. Berns, MPH[19]; Lauren Milroy, MPH[20]; Haley Blake, MPH[21]; Maria M. Sievers, MPH[22]; Melissa Marzan-Rodriguez, DrPH[23]; Marco Tori, MD[1,24]; Stephanie R. Black, MD[4]; Erik Kopping, PhD[3,25]; Irene Ruberto, PhD[26]; Angela Maxted, DVM, PhD[27]; Anuj Sharma, MPH[5]; Kara Tarter, MPH[28]; Sydney A. Jones, PhD[29,30]; Brooklyn White, MPH[31]; Ryan Chatelain, MPH[32]; Mia Russo; Sarah Gillani, MPH[18]; Ethan Bornstein, MD[1,4]; Stephen L. White, PhD[5]; Shannon A. Johnson, MPH[11]; Emma Ortega, MPHTM[12]; Lori Saathoff-Huber, MPH[17]; Anam Syed, MPH[5]; Aprielle Wills, MPH[3]; Bridget J. Anderson, PhD[7]; Alexandra M. Oster, MD[2]; Athalia Christie, DrPH[2]; Jennifer McQuiston, DVM[2]; Andrea M. McCollum, PhD[2]; Agam K. Rao, MD[2,8]; Maria E. Negrón, DVM, PhD[2,8]; CDC Multinational Monkeypox Response Team (View author affiliations)

Mpox Current Presentation

	16 Countries (NEJM) (N = 528)	Spain (Lancet) (N= 181)	London (BMJ) (N = 197)	United States (MMWR) (N= 1195)	Democratic Republic of the Congo (pre-print) (N = 216)
Demographics	**Male (>99%)** Female (0%) Trans (<1%)	**Male (97%)** Female (3%) Trans (---%)	**Male (100%)** Female (0%) Trans (0%)	**Male (98.7%)** Female (0.4%) Trans (0.7%)	Male (63.9%) **Female (36.1%)** Trans (---%)
Lesions	95%	100%	100%	100%	99.5%
Fever	62%	72%	61.9%	63.3%	0.5%
Chills				59.1%	44.9%
Lymphadenopathy	56%	85%	57.9%	58.5%	98.6%
Malaise	41%		23.4%	57.1%	85.2%
Myalgia	31%		31.5%	55.0%	
Headache	27%	53%	24.8%	50.8%	23.6%
Rectal Pain	14%	25%	36.0%	21.9%	
Sore throat		36%	16.8%		78.2%

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Mpox Current Presentation

Site of Skin Lesions	16 Countries (NEJM) (N = 528)	Spain (Lancet) (N= 181)	London (BMJ) (N = 197)	United States (MMWR) (N= 1195)	Democratic Republic of the Congo (pre-print) (N = 216)
Genitals	**73%***	**55%**	**56.4%**	**46.4%**	
Anus/perianal		**36%**	**41.6%**	**31.3%**	
Face	25%		36.0%	38.4%	
Trunks	55%**	57%**	35.5%	21.7%	
Limbs			37.6%	39.6%	
Hands/feet	10%	60%	28.4%	21.9%	
Perioral		28%		24.9%***	
Oropharyngeal		25%	13.7%		28.7%

Mpox Current Images

- We want to thank our patients for providing us permission to share their stories and images
- Some of the images on the next few slides will be graphic

Mpox Presentations

Presentations

- Genital lesions
- Proctitis
- Urethritis
- Pharyngitis
- Ocular disease
- Lymphadenopathy
- Bacterial superinfection
- Persistent/Progressive disease
- Encephalitis

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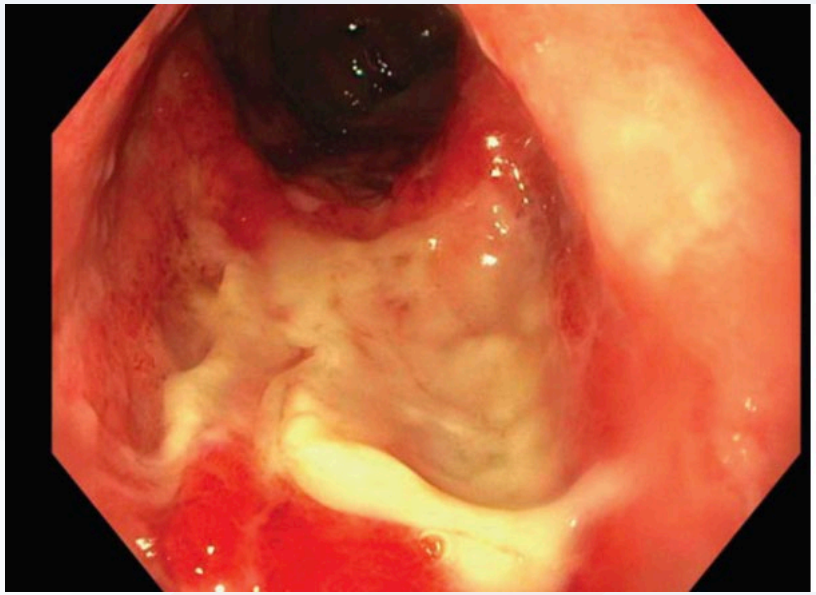

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Mpox Presentations

Presentations

- Genital lesions
- Proctitis
- Urethritis
- Pharyngitis
- Ocular disease
- Lymphadenopathy
- **Bacterial superinfection**
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Mpox Severe Presentations

Monkeypox Can Be a Severe Disease

Mpox in people with advanced HIV infection: a global case series

Summary

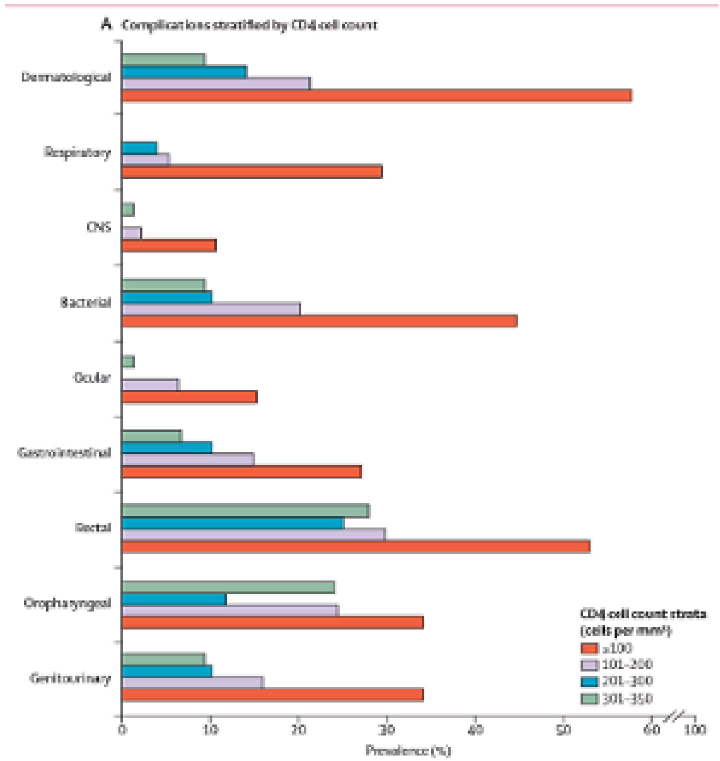
Background People living with HIV have accounted for 38–50% of those affected in the 2022 multicountry mpox outbreak. Most reported cases were in people who had high CD4 cell counts and similar outcomes to those without HIV. Emerging data suggest worse clinical outcomes and higher mortality in people with more advanced HIV. We describe the clinical characteristics and outcomes of mpox in a cohort of people with HIV and low CD4 cell counts (CD4 <350 cells per mm³).

Methods A network of clinicians from 19 countries provided data of confirmed mpox cases between May 11, 2022, and Jan 18, 2023, in people with HIV infection. Contributing centres completed deidentified structured case report sheets to include variables of interest relevant to people living with HIV and to capture more severe outcomes. We restricted this series to include only adults older than 18 years living with HIV and with a CD4 cell count of less than 350 cells per mm³ or, in settings where a CD4 count was not always routinely available, an HIV infection clinically classified as US Centers for Disease Control and Prevention stage C. We describe their clinical presentation, complications, and causes of death. Analyses were descriptive.

Findings We included data of 382 cases: 367 cisgender men, four cisgender women, and ten transgender women. The median age of individuals included was 35 (IQR 30–43) years. At mpox diagnosis, 349 (91%) individuals were known to be living with HIV; 228 (65%) of 349 adherent to antiretroviral therapy (ART); 32 (8%) of 382 had a concurrent opportunistic illness. The median CD4 cell count was 211 (IQR 117–291) cells per mm³, with 85 (22%) individuals with CD4 cell counts of less than 100 cells per mm³ and 94 (25%) with 100–200 cells per mm³. Overall, 193 (51%) of 382 had undetectable viral load. Severe complications were more common in people with a CD4 cell count of less than 100 cells per mm³ than in those with more than 300 cells per mm³, including necrotising skin lesions (54% vs 7%), lung involvement (29% vs 0%) occasionally with nodules, and secondary infections and sepsis (44% vs 5%). Overall, 107 (28%) of 382 were hospitalised, of whom 27 (25%) died. All deaths occurred in people with CD4 counts of less than 200 cells per mm³. Among people with CD4 counts of less than 200 cells per mm³, more deaths occurred in those with high HIV viral load. An immune reconstitution inflammatory syndrome to mpox was suspected in 21 (25%) of 85 people initiated or re-initiated on ART, of whom 12 (57%) of 21 died. 62 (16%) of 382 received tecovirimat and seven (2%) received cidofovir or brincidofovir. Three individuals had laboratory confirmation of tecovirimat resistance.

Interpretation A severe necrotising form of mpox in the context of advanced immunosuppression appears to behave like an AIDS-defining condition, with a high prevalence of fulminant dermatological and systemic manifestations and death.

Higher Complications With Lower CD4 Count



Mpox Presentations

Presentations

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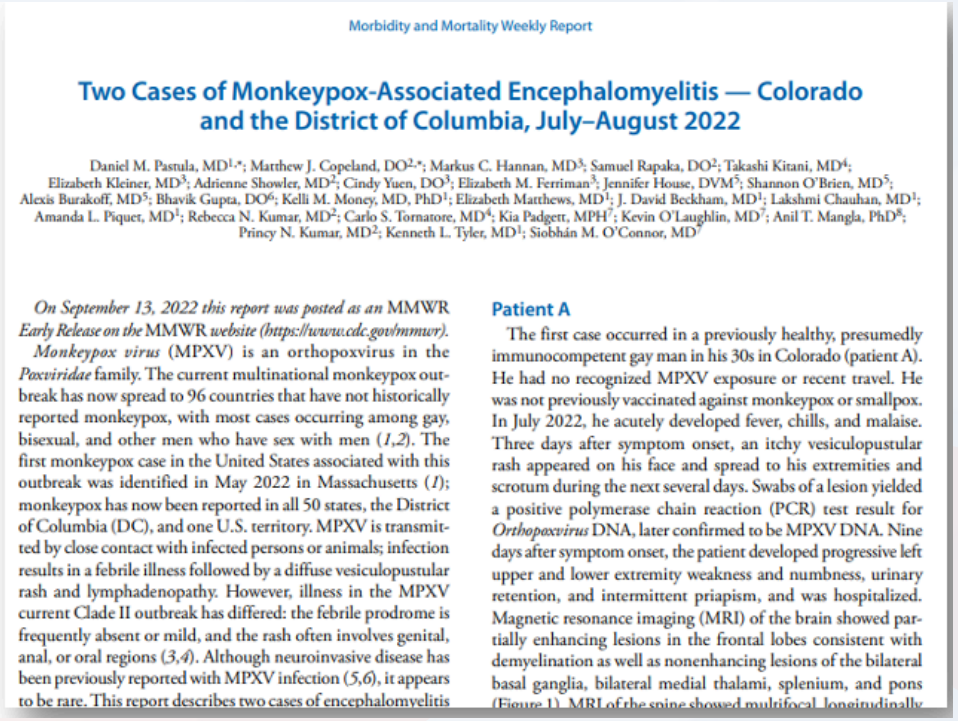


Morbidity and Mortality Weekly Report

Two Cases of Monkeypox-Associated Encephalomyelitis — Colorado and the District of Columbia, July–August 2022

Daniel M. Pastula, MD[1,*]; Matthew J. Copeland, DO[2,*]; Markus C. Hannan, MD[3]; Samuel Rapaka, DO[2]; Takashi Kitani, MD[4]; Elizabeth Kleiner, MD[3]; Adrienne Showler, MD[2]; Cindy Yuen, DO[3]; Elizabeth M. Ferriman[3]; Jennifer House, DVM[5]; Shannon O'Brien, MD[5]; Alexis Burakoff, MD[5]; Bhavik Gupta, DO[6]; Kelli M. Money, MD, PhD[1]; Elizabeth Matthews, MD[1]; J. David Beckham, MD[1]; Lakshmi Chauhan, MD[1]; Amanda L. Piquet, MD[1]; Rebecca N. Kumar, MD[2]; Carlo S. Tornatore, MD[4]; Kia Padgett, MPH[7]; Kevin O'Laughlin, MD[7]; Anil T. Mangla, PhD[8]; Princy N. Kumar, MD[2]; Kenneth L. Tyler, MD[1]; Siobhán M. O'Connor, MD[9]

On September 13, 2022 this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr).*

Monkeypox virus (MPXV) is an orthopoxvirus in the *Poxviridae* family. The current multinational monkeypox outbreak has now spread to 96 countries that have not historically reported monkeypox, with most cases occurring among gay, bisexual, and other men who have sex with men (*1*,*2*). The first monkeypox case in the United States associated with this outbreak was identified in May 2022 in Massachusetts (*1*); monkeypox has now been reported in all 50 states, the District of Columbia (DC), and one U.S. territory. MPXV is transmitted by close contact with infected persons or animals; infection results in a febrile illness followed by a diffuse vesiculopustular rash and lymphadenopathy. However, illness in the MPXV current Clade II outbreak has differed: the febrile prodrome is frequently absent or mild, and the rash often involves genital, anal, or oral regions (*3*,*4*). Although neuroinvasive disease has been previously reported with MPXV infection (*5*,*6*), it appears to be rare. This report describes two cases of encephalomyelitis

Patient A

The first case occurred in a previously healthy, presumedly immunocompetent gay man in his 30s in Colorado (patient A). He had no recognized MPXV exposure or recent travel. He was not previously vaccinated against monkeypox or smallpox. In July 2022, he acutely developed fever, chills, and malaise. Three days after symptom onset, an itchy vesiculopustular rash appeared on his face and spread to his extremities and scrotum during the next several days. Swabs of a lesion yielded a positive polymerase chain reaction (PCR) test result for *Orthopoxvirus* DNA, later confirmed to be MPXV DNA. Nine days after symptom onset, the patient developed progressive left upper and lower extremity weakness and numbness, urinary retention, and intermittent priapism, and was hospitalized. Magnetic resonance imaging (MRI) of the brain showed partially enhancing lesions in the frontal lobes consistent with demyelination as well as nonenhancing lesions of the bilateral basal ganglia, bilateral medial thalami, splenium, and pons (Figure 1). MRI of the spine showed multifocal longitudinally

https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7138e1-H.pdf

Mpox Current Presentations

- Prodrome
  - May or may not be present
  - May occur after rash or other symptoms
  - Non-skin lesions (i.e. proctitis) may be the presenting symptom

- Rash
  - Rash remains common but is presenting atypically
  - Starting in genital/perianal areas and mucous membrane involvement is common
  - Scattered or diffuse lesions OR localized to a specific body site
  - Lesions in different stages of progression seen side-by-side

A high index of suspicion is needed

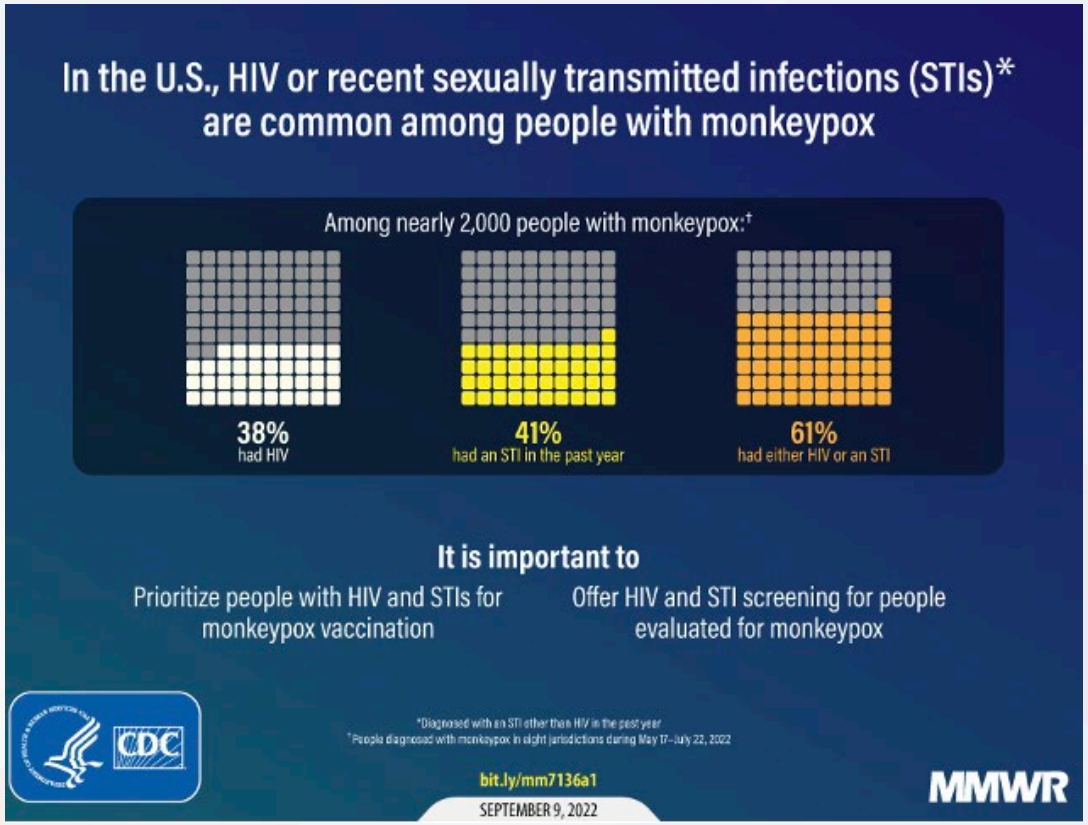
Differential Diagnosis for Mpox

- **Syphilis**
- Varicella
- **Herpes simplex virus**
- Molluscum contagiosum
- Other pox viruses
- Disseminated fungal infections
- **Disseminated gonococcal infection**
- **Enterovirus infection (Hand, Foot, and Mouth Disease (HFMD)**

- **Herpes simplex virus**
- **Syphilis**
- **Chancroid**
- **Lymphogranuloma venereum (LGV) Proctitis**
- **Gonorrhea**
- **Chlamydia (including LGV)**
- **Herpes simplex virus**
- **Syphilis**

Co-Infection with Other STIs

- 38% with co-existing HIV
- 41% had an STI in the past year



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Diagnosis of Mpox

Mpox DNA Identified In

- Seminal fluid
- Rectal swabs
- Urethral swabs
- Respiratory secretions
- Blood

Rapid communication

Open Acces

Isolation of viable monkeypox virus from anal and urethral swabs, Italy, May to July 2022

Like 0

Check for updates

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Davide Moschese[1], Giacomo Pozza[2], Davide Mileto[3], Andrea Giacomelli[2], Miriam Cutrera[3], Maria Vittoria Cossu[1], Maddalena Matone[1], Martina Beltrami[2], Federica Salari[3], Spinello Antinori[4], Alessandra Lombardi[3], Giuliano Rizzardini[1]

Hide Affiliations

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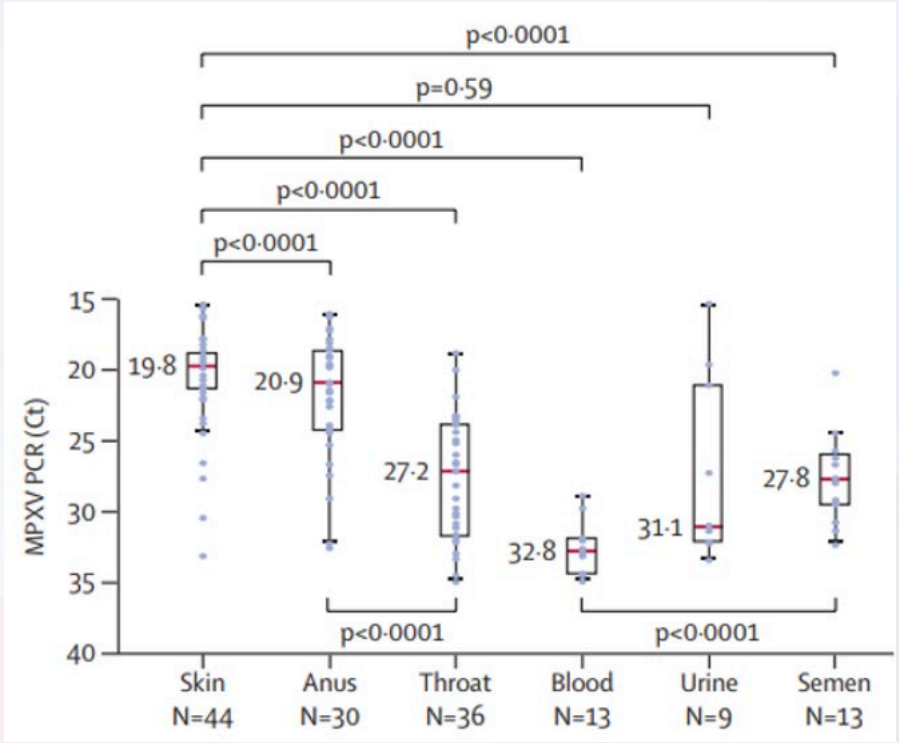
[4] Department of Biomedical and Clinical Sciences, Università degli Studi di Milano, Italy; III Division of Infectious Diseases, ASST Fatebenefratelli Sacco, Luigi Sacco Hospital, Milan, Italy.

Allan-Blitz, Lao-Tzu MD[1]; Klausner, Jeffrey D. MD, MPH[2]. Current Evidence Demonstrates Monkeypox is a Sexually Transmitted Infection. Sexually Transmitted Diseases: September 12, 2022 - Volume - Issue - 10.1097/OLQ.0000000000001705 doi: 10.1097/OLQ.0000000000001705, https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2022.27.36.2200675?emailalert=true#html_fulltext

Mpox Testing and Transmission

Viral loads in clinical samples of men with monkeypox virus infection: a French case series

Romain Palich, Sonia Burrel, Gentiane Monsel, Agathe Nouchi, Alexandre Bleibtreu, Sophie Seang, Vincent Bérot, Cécile Brin, Ariane Gavaud, Yara Wakim, Nagisa Godefroy, Antoine Fayçal, Yanis Tamzali, Thomas Grunemwald, Michel Ohayon, Eve Todesco, Valentin Leducq, Stéphane Marot, Vincent Calvez, Anne-Geneviève Marcelin, Valérie Pourcher

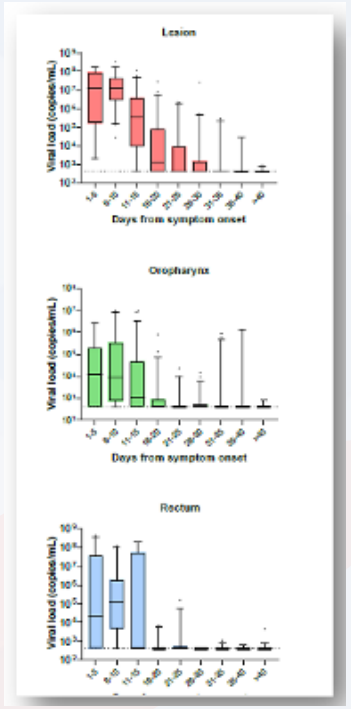


Palich R, Burrel S, Monsel G, et al. Viral loads in clinical samples of men with monkeypox virus infection: a French case series. *Lancet Infect Dis*. 2023;23(1):74-80. doi:10.1016/S1473-3099(22)00586-2

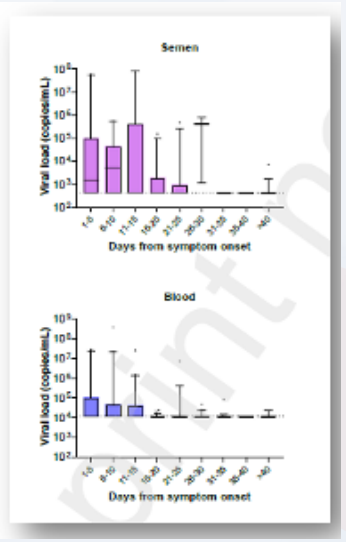
Diagnosis of Mpox

Time to Clearance

Location	Time to clearance in 50% of patients Days (95% CI)	Time to clearance in 90% of patients Days (95% CI)	Time to clearance in 95% of patients Days (95% CI)
Blood	5 (0 – 9)	23 (15 – 38)	34 (20 – 57)
Semen	11 (8 – 16)	43 (26 – 60)	60 (34 – 68)
Rectum	14 (11 – 22)	33 (24 – 60)	42 (27 – 76)
Pharynx	16 (13 – 19)	34 (27 – 43)	43 (32 – 60)
Lesion	25 (22 – 28)	41 (34 – 50)	47 (38 – 60)



Viral Loads



Suñer, Clara and Ubals, Maria and Tarín-Vicente, Eloy José and Mendoza, Adrià and Alemany, Andrea and Hernández-Rodríguez, Águeda and Casañ, Cristina and Descalzo, Vicente and Ouchi, Dan and Marc, Aurelien and Rivero, Ángel and Coll, Pep and Oller, Xènia and Cabrera, José Miguel and Vall-Mayans, Martí and Dolores Folgueira, María and Meléndez, María de los Ángeles and Agud-Dios, Manuel and Gil-Cruz, Elena and de León, Alexia Paris and Ramirez, Aída and Buhiichyk, Vira and Galván-Casas, Cristina and Paredes, Roger and Prat, Nuria and Sala Farre, Maria-Rosa and Bonet-Simó, Josep Maria and Farré, Magí and Ortiz-Romero, Pablo L. and Clotet, Bonaventura and Guedj, Jeremie and Cardona, Pere-Joan and Blanco, Ignacio and Marks, Michael and Mitja, Oriol and Group, The Movie Group, Viral Dynamics in Patients with Monkeypox Infection: A Prospective Cohort Study in Spain. Available at SSRN: https://ssrn.com/abstract=4248017 or http://dx.doi.org/10.2139/ssrn.4248017

Diagnosis of Mpox

Currently Approved For Diagnosis

- PCR from lesion swab
  - Local labs
  - Commercial labs
  - Public health labs

Serology

- IgM and IgG ELISA assays to *Orthopoxvirus* virus

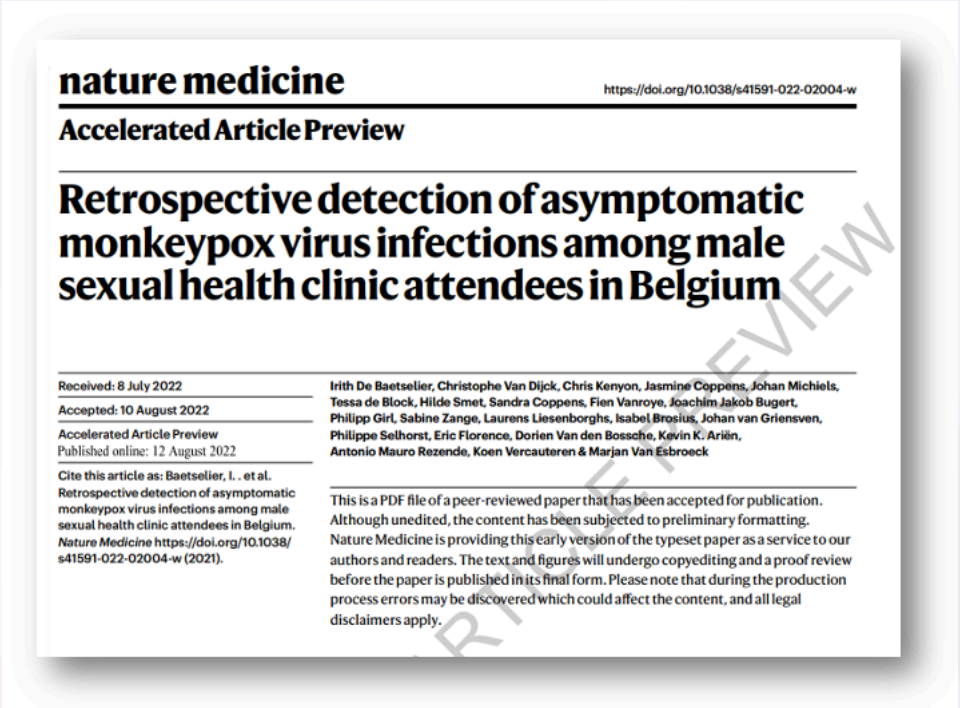
- IgM – ~5 days post rash onset
- IgG – ~8 days post rash onset

- Cross reacts with Vaccinia virus after receiving smallpox vaccination

- Not easily commercially available

Is Current Testing Enough?

- Retrospectively screened 224 samples collected for gonorrhea and chlamydia testing
- Monkeypox virus (MPXV) PCR assay
- 4 positives
  - 3 of 4 never developed any symptoms
  - All 3 had positive serology
  - 2 of 3 had culturable virus



nature medicine

https://doi.org/10.1038/s41591-022-02004-w

Accelerated Article Preview

Retrospective detection of asymptomatic monkeypox virus infections among male sexual health clinic attendees in Belgium

Received: 8 July 2022

Accepted: 10 August 2022

Accelerated Article Preview
Published online: 12 August 2022

Cite this article as: Baetselier, I. . et al. Retrospective detection of asymptomatic monkeypox virus infections among male sexual health clinic attendees in Belgium. *Nature Medicine* https://doi.org/10.1038/s41591-022-02004-w (2021).

Irith De Baetselier, Christophe Van Dijck, Chris Kenyon, Jasmine Coppens, Johan Michiels, Tessa de Block, Hilde Smet, Sandra Coppens, Fien Vanroye, Joachim Jakob Bugert, Philipp Girl, Sabine Zange, Laurens Liesenborghs, Isabel Brosius, Johan van Griensven, Philippe Selhorst, Eric Florence, Dorien Van den Bossche, Kevin K. Ariën, Antonio Mauro Rezende, Koen Vercauteren & Marjan Van Esbroeck

De Baetselier I, Van Dijck C, Kenyon C, et al. Retrospective detection of asymptomatic monkeypox virus infections among male sexual health clinic attendees in Belgium [published online ahead of print, 2022 Aug 12]. Nat Med. 2022;10.1038/s41591-022-02004-w. doi:10.1038/s41591-022-02004-w

Treatment of Mpox

- Supportive care
  - **Most patients fully recover**
  - Symptomatic treatment
- Antibody therapy
  - Vaccinia Immunoglobulin (VIGIV)
- Antiviral medications
  - Cidofovir
  - Brincidofovir
  - Trifluridine (eye disease)
  - Tecovirimat (EA-IND)

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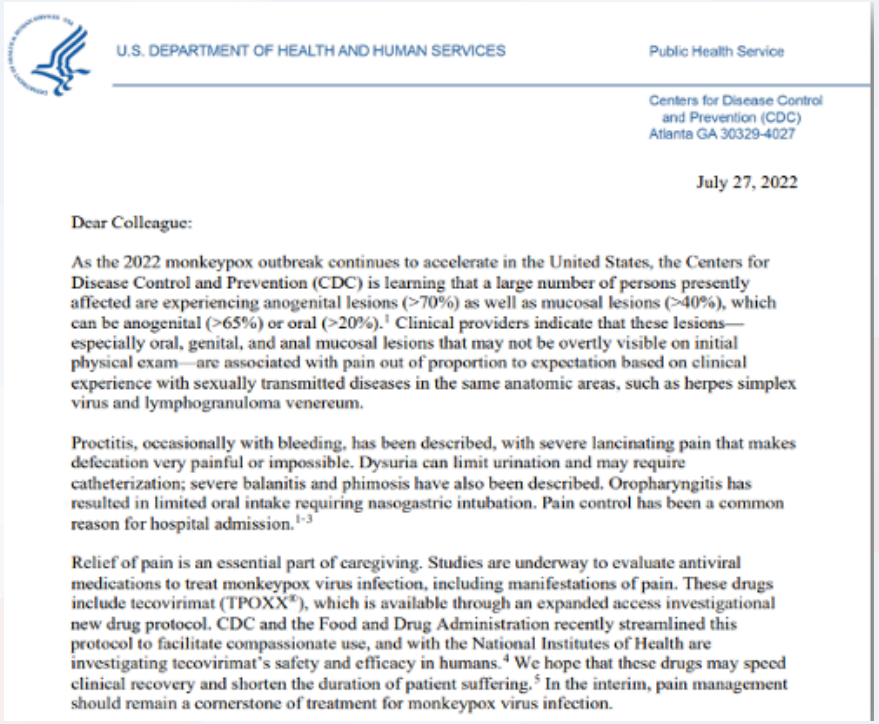
June 27 – CDC Dear Colleague Letter



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES — Public Health Service

Centers for Disease Control and Prevention (CDC)
Atlanta GA 30329-4027

July 27, 2022

Dear Colleague:

As the 2022 monkeypox outbreak continues to accelerate in the United States, the Centers for Disease Control and Prevention (CDC) is learning that a large number of persons presently affected are experiencing anogenital lesions (>70%) as well as mucosal lesions (>40%), which can be anogenital (>65%) or oral (>20%).[1] Clinical providers indicate that these lesions—especially oral, genital, and anal mucosal lesions that may not be overtly visible on initial physical exam—are associated with pain out of proportion to expectation based on clinical experience with sexually transmitted diseases in the same anatomic areas, such as herpes simplex virus and lymphogranuloma venereum.

Proctitis, occasionally with bleeding, has been described, with severe lancinating pain that makes defecation very painful or impossible. Dysuria can limit urination and may require catheterization; severe balanitis and phimosis have also been described. Oropharyngitis has resulted in limited oral intake requiring nasogastric intubation. Pain control has been a common reason for hospital admission.[1-3]

Relief of pain is an essential part of caregiving. Studies are underway to evaluate antiviral medications to treat monkeypox virus infection, including manifestations of pain. These drugs include tecovirimat (TPOXX®), which is available through an expanded access investigational new drug protocol. CDC and the Food and Drug Administration recently streamlined this protocol to facilitate compassionate use, and with the National Institutes of Health are investigating tecovirimat's safety and efficacy in humans.[4] We hope that these drugs may speed clinical recovery and shorten the duration of patient suffering.[5] In the interim, pain management should remain a cornerstone of treatment for monkeypox virus infection.

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Proctitis
- Stool softeners
- Lidocaine gel
- Sitz Baths
- Anti-inflammatory (if not bleeding)
- Gabapentin
- Avoid opioids if possible, but may be required

Genital Lesions
- Frequent bathing
- Keep it dry
  - Change clothes frequently
- If infected:
  - Wet to dry dressings
  - Antibiotic ointments
  - Systemic antibiotics

Oropharyngeal lesions
- Viscous lidocaine
- Salt water gargles
- Anti-inflammatory

Treatment of Mpox

- Supportive care
  - Most patients fully recover
  - Symptomatic treatment
- **Antibody therapy**
  - **Vaccinia Immunoglobulin (VIGIV)**
- **Antiviral medications**
  - **Cidofovir**
  - **Brincidofovir**
  - **Trifluridine (eye disease)**
  - **Tecovirimat (EA-IND)**

- Medical Countermeasures
  - - Severe disease
  - - Involvement of anatomic areas which might result in serious sequelae
  - - At risk of severe disease

Vaccinia Immunoglobulin (VIGIV)

- Supportive care
  - Most patients fully recover
  - Symptomatic treatment
- Antibody therapy
  - **Vaccinia Immunoglobulin (VIGIV)**
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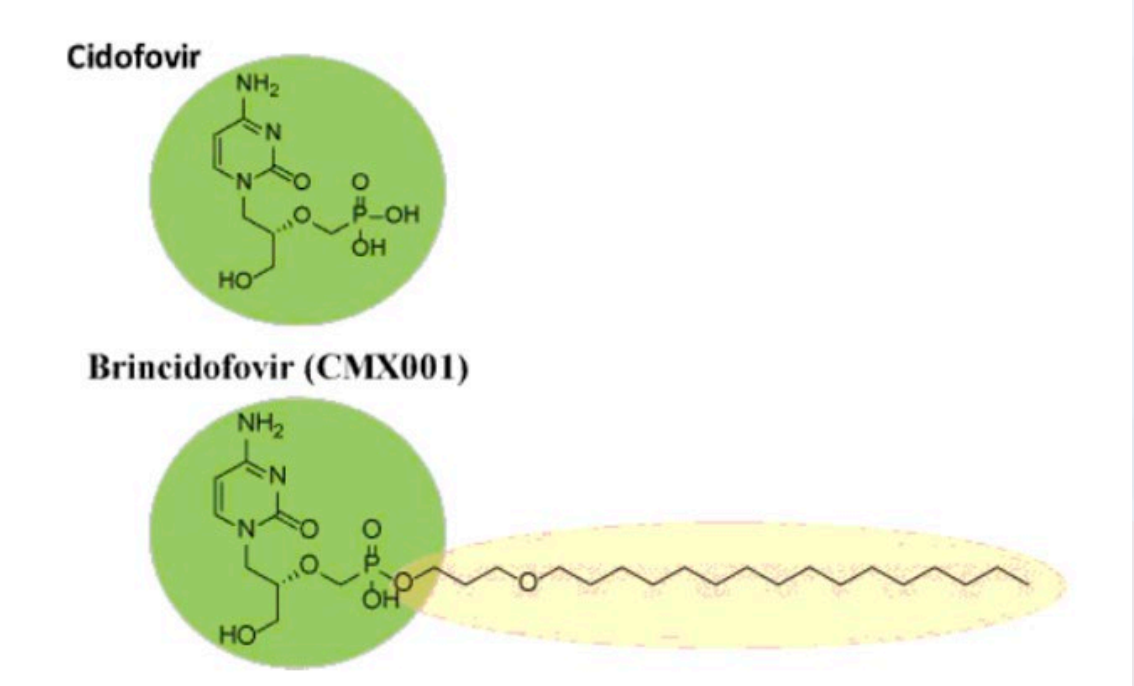


Treatment of Mpox

Clinical features and management of human monkeypox: a retrospective observational study in the UK

Hugh Adler, Susan Gould, Paul Hine, Luke B Snell, Waison Wong, Catherine F Houlihan, Jane C Osborne, Tommy Rampling, Mike BJ Beadsworth, Christopher JA Duncan, Jake Dunning, Tom E Fletcher, Ewan R Hunter, Michael Jacobs, Saye H Khoo, William Newsholme, David Porter, Robert J Porter, Libuse Ratcliffe, Matthias L Schmid, Malcolm G Semple, Anne J Turbridge, Tom Wingfield*, Nicholas M Price* on behalf of the NHS England High Consequence Infectious Diseases (Airborne) Network†

Summary

Background Cases of human monkeypox are rarely seen outside of west and central Africa. There are few data regarding viral kinetics or the duration of viral shedding and no licensed treatments. Two oral drugs, brincidofovir and tecovirimat, have been approved for treatment of smallpox and have demonstrated efficacy against monkeypox in animals. Our aim was to describe the longitudinal clinical course of monkeypox in a high-income setting, coupled with viral dynamics, and any adverse events related to novel antiviral therapies.

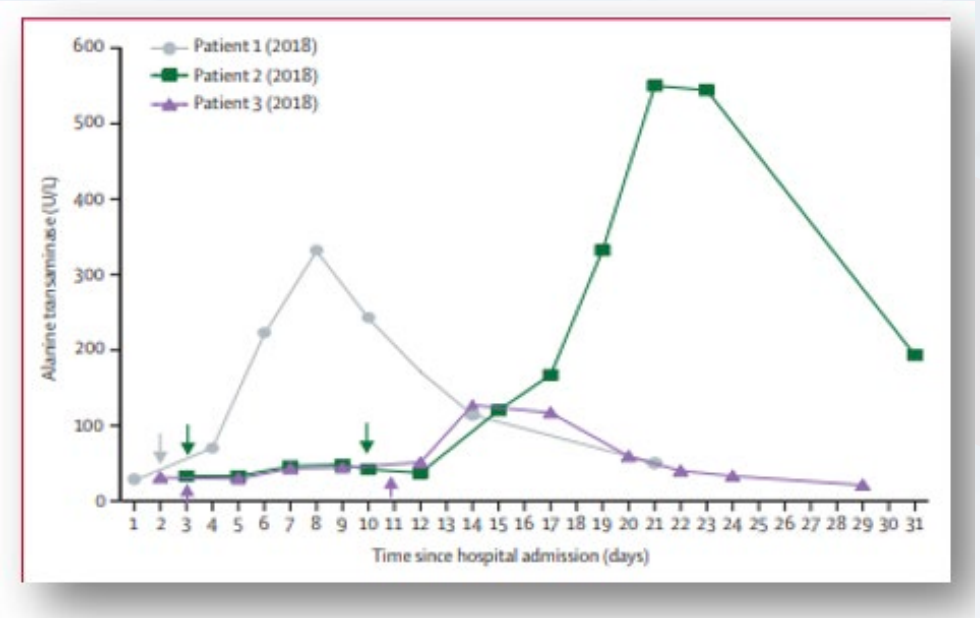
Methods In this retrospective observational study, we report the clinical features, longitudinal virological findings, and response to off-label antivirals in seven patients with monkeypox who were diagnosed in the UK between 2018 and 2021, identified through retrospective case-note review. This study included all patients who were managed in dedicated high consequence infectious diseases (HCID) centres in Liverpool, London, and Newcastle, coordinated via a national HCID network.

Findings We reviewed all cases since the inception of the HCID (airborne) network between Aug 15, 2018, and Sept 10, 2021, identifying seven patients. Of the seven patients, four were men and three were women. Three acquired monkeypox in the UK: one patient was a health-care worker who acquired the virus nosocomially, and one patient who acquired the virus abroad transmitted it to an adult and child within their household cluster. Notable disease features included viraemia, prolonged monkeypox virus DNA detection in upper respiratory tract swabs, reactive low mood, and one patient had a monkeypox virus PCR-positive deep tissue abscess. Five patients spent more than 3 weeks (range 22–39 days) in isolation due to prolonged PCR positivity. Three patients were treated with brincidofovir (200 mg once a week orally), all of whom developed elevated liver enzymes resulting in cessation of therapy. One patient was treated with tecovirimat (600 mg twice daily for 2 weeks orally), experienced no adverse effects, and had a shorter duration of viral shedding and illness (10 days hospitalisation) compared with the other six patients. One patient experienced a mild relapse 6 weeks after hospital discharge.

Lancet Infect Dis 2022
Published Online May 24, 2022
https://doi.org/10.1016/S1473-3099(22)00228-6
This online publication has been corrected. The corrected version first appeared at thelancet.com/infection on May 26, 2022

*Contributed equally
†Members are listed in the appendix
Tropical and Infectious Disease Unit, Liverpool University Hospitals NHS Foundation Trust, Liverpool, UK (H Adler PhD, S Gould MRCP, P Hine MRCP, M BJ Beadsworth MD, T E Fletcher PhD, Prof S H Khoo MD, L Ratcliffe MRCP, T Wingfield PhD); Department of Clinical Sciences, Liverpool School of Tropical Medicine, Liverpool, UK (H Adler, S Gould, P Hine, M BJ Beadsworth,

- First three patients were treated with oral brincidofovir ~7 after onset of rash
- All three patients developed elevated alanine transaminase and none completed the course of treatment



Trifluridine

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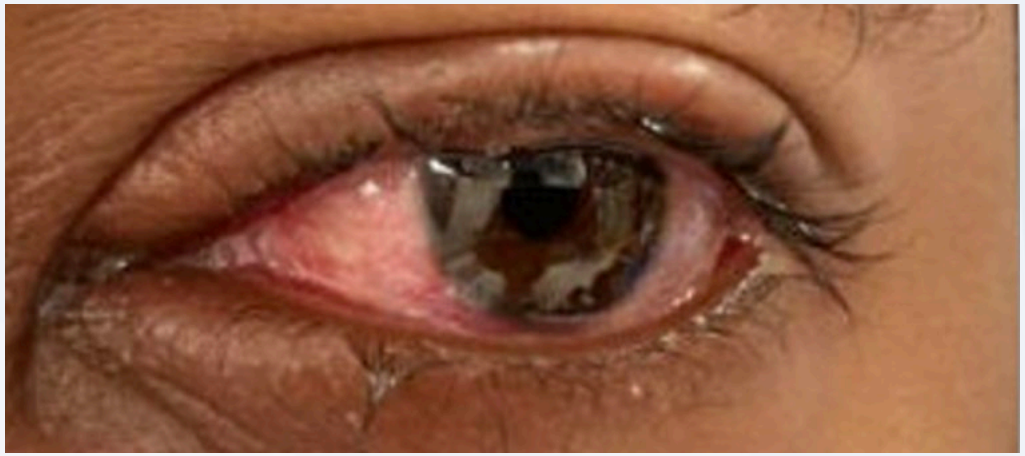

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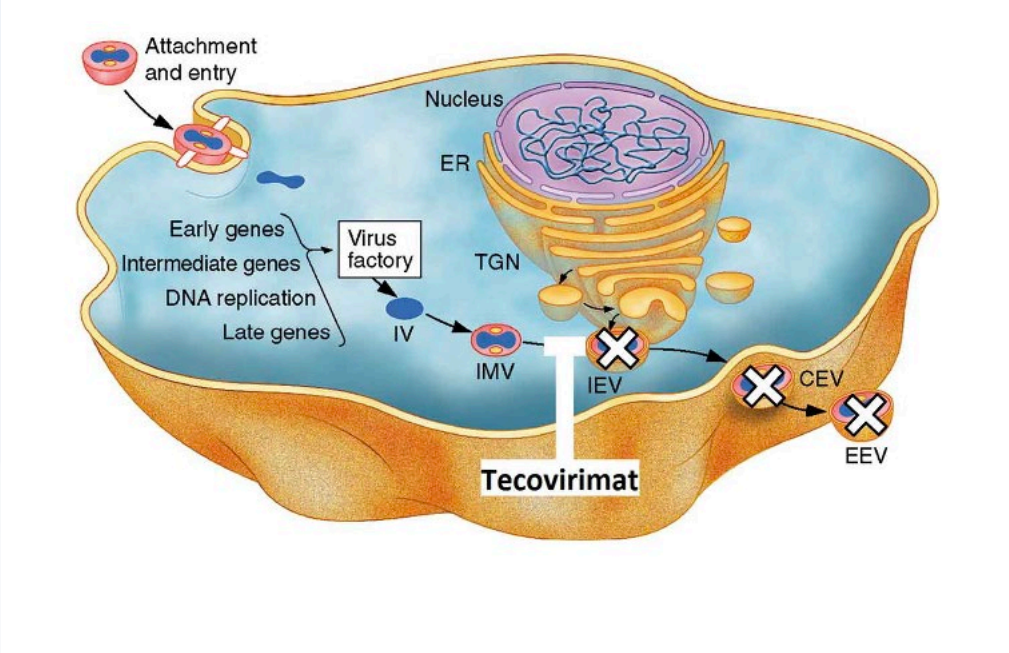

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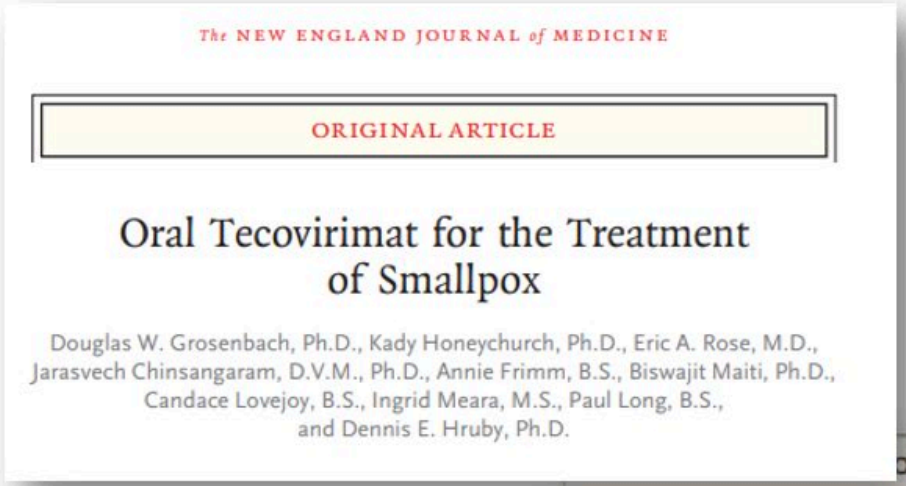
Tecovirimat



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Oral Tecovirimat for the Treatment of Smallpox

Douglas W. Grosenbach, Ph.D., Kady Honeychurch, Ph.D., Eric A. Rose, M.D., Jarasvech Chinsangaram, D.V.M., Ph.D., Annie Frimm, B.S., Biswajit Maiti, Ph.D., Candace Lovejoy, B.S., Ingrid Meara, M.S., Paul Long, B.S., and Dennis E. Hruby, Ph.D.

Occurred or Worsened during Receipt of Tecovirimat or Placebo in the Overall Summary Safety Population.

Type of Event*	Placebo (N=90)		Tecovirimat (N=359)		Total (N=449)	
	No. of Participants (%)	No. of Events	No. of Participants (%)	No. of Events	No. of Participants (%)	No. of Events
Any event	30 (33.3)	68	134 (37.3)	318	164 (36.5)	386
Event related to the trial agent	15 (16.7)	32	71 (19.8)	176	86 (19.2)	208
Event leading to discontinuation of trial agent	2 (2.2)	3	6 (1.7)	16	8 (1.8)	19
Serious events and events leading to death	0	0	1 (0.3)†	1	1 (0.2)	1

Grosenbach DW, Honeychurch K, Rose EA, Chinsangaram J, Frimm A, Maiti B, Lovejoy C, Meara I, Long P, Hruby DE. Oral Tecovirimat for the Treatment of Smallpox. N Engl J Med. 2018 Jul 5;379(1):44-53. doi: 10.1056/NEJMoa1705688. PMID: 29972742; PMCID: PMC6086581.

Tecovirimat

Clinical features and management of human monkeypox: a retrospective observational study in the UK

Hugh Adler, Susan Gould, Paul Hine, Luke B Snell, Weison Wong, Catherine F Houlihan, Jane C Osborne, Tommy Rampling, Mike BJ Beadsworth, Christopher JA Duncan, Jake Dunning, Tom E Fletcher, Ewan R Hunter, Michael Jacobs, Saye H Khoo, William Newsholme, David Porter, Robert J Porter, Libuse Ratcliffe, Matthias L Schmid, Malcolm G Semple, Anne J Tunbridge, Tom Wingfield*, Nicholas M Price* on behalf of the NHS England High Consequence Infectious Diseases (Airborne) Network†

Summary

Background Cases of human monkeypox are rarely seen outside of west and central Africa. There are few data regarding viral kinetics or the duration of viral shedding and no licensed treatments. Two oral drugs, brincidofovir and tecovirimat, have been approved for treatment of smallpox and have demonstrated efficacy against monkeypox in animals. Our aim was to describe the longitudinal clinical course of monkeypox in a high-income setting, coupled with viral dynamics, and any adverse events related to novel antiviral therapies.

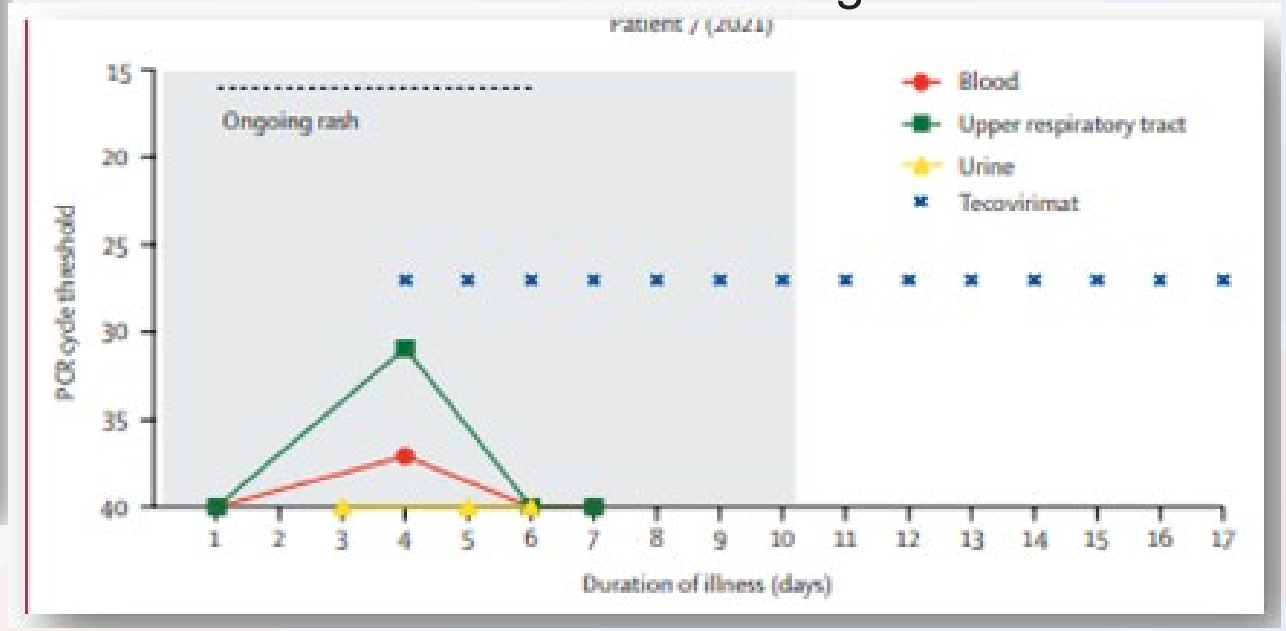
Methods In this retrospective observational study, we report the clinical features, longitudinal virological findings, and response to off-label antivirals in seven patients with monkeypox who were diagnosed in the UK between 2018 and 2021, identified through retrospective case-note review. This study included all patients who were managed in dedicated high consequence infectious diseases (HCID) centres in Liverpool, London, and Newcastle, coordinated via a national HCID network.

Findings We reviewed all cases since the inception of the HCID (airborne) network between Aug 15, 2018, and Sept 10, 2021, identifying seven patients. Of the seven patients, four were men and three were women. Three acquired monkeypox in the UK: one patient was a health-care worker who acquired the virus nosocomially, and one patient who acquired the virus abroad transmitted it to an adult and child within their household cluster. Notable disease features included viraemia, prolonged monkeypox virus DNA detection in upper respiratory tract swabs, reactive low mood, and one patient had a monkeypox virus PCR-positive deep tissue abscess. Five patients spent more than 3 weeks (range 22–39 days) in isolation due to prolonged PCR positivity. Three patients were treated with brincidofovir (200 mg once a week orally), all of whom developed elevated liver enzymes resulting in cessation of therapy. One patient was treated with tecovirimat (600 mg twice daily for 2 weeks orally), experienced no adverse effects, and had a shorter duration of viral shedding and illness (10 days hospitalisation) compared with the other six patients. One patient experienced a mild relapse 6 weeks after hospital discharge.

Lancet Infect Dis 2022
Published Online May 24, 2022 https://doi.org/10.1016/S1473-3099(22)00228-6
This online publication has been corrected. The corrected version first appeared at thelancet.com/infection on May 26, 2022

*Contributed equally
†Members are listed in the appendix
Tropical and Infectious Disease Unit, Liverpool University Hospitals NHS Foundation Trust, Liverpool, UK (H Adler PhD, S Gould MRCP, P Hine MRCP, M BJ Beadsworth MD, T E Fletcher PhD, Prof S H Khoo MD, L Ratcliffe MRCP, T Wingfield PhD); Department of Clinical Sciences, Liverpool School of Tropical Medicine, Liverpool, UK (H Adler, S Gould, P Hine, M BJ Beadsworth,

- One patient was treated with tecovirimat and experienced no adverse effects, and had a shorter duration of viral shedding and illness



Tecovirimat

- 549 patients (174 with intake and outcome)
- Received Tecovirimat May – Aug 2022
- 12 adverse events (3.5%)
  - Headache (3)
  - Nausea (2)
  - Visual disturbance (2)
  - Weakness (2)
  - Psychiatric disturbance (1)
  - None labeled as “serious”

Clinical Use of Tecovirimat (Tpoxx) for Treatment of Monkeypox Under an Investigational New Drug Protocol — United States, May–August 2022

Early Release / September 9, 2022 / 71

Kevin O'Laughlin, MD[1,A]; Farrell A. Tobolowsky, DO[1,A]; Riad Elmor, MS[1]; Rahsaan Overton, MPH[1]; Siobhán M. O'Connor, MD[1]; Inger K. Damon, MD, PhD[1]; Brett W. Petersen, MD[1]; Agam K. Rao, MD[1]; Kevin Chatham-Stephens, MD[1]; Patricia Yu, MPH[1]; Yon Yu, PharmD[1]; CDC Monkeypox Tecovirimat Data Abstraction Team (View author affiliations)

View suggested citation

Summary

What is already known about this topic?

Tecovirimat (Tpoxx) was approved by the Food and Drug Administration for treatment of smallpox based on data obtained from animal models; there are no safety or efficacy data regarding its use in patients with *Monkeypox virus* infection.

What is added by this report?

Among 549 patients with *Monkeypox virus* infection treated with tecovirimat under an Expanded Access Investigational New Drug protocol, 99.8% received it orally as an outpatient. Among 369 patients, few adverse events were reported.

What are the implications for public health practice?

Tecovirimat is generally well tolerated, and these data support continued access to treatment with tecovirimat during the current monkeypox outbreak.

Article Metrics

Altmetric:

184

News (30)
Blogs (2)
Twitter (122)
Facebook (1)

Citations:

Views:

Views equals page views plus PDF downloads

Metric Details

O'Laughlin K, Tobolowsky FA, Elmor R, et al. Clinical Use of Tecovirimat (Tpoxx) for Treatment of Monkeypox Under an Investigational New Drug Protocol — United States, May–August 2022. MMWR Morb Mortal Wkly Rep. ePub: 9 September 2022. DOI: http://dx.doi.org/10.15585/mmwr.mm7137e1.

Does Tecovirimat Work?

Cohort Studies

Case Report

Successful Outcome after Treatment with Cidofovir, Vaccinia, and Extended Course of Tecovirimat in a Newly-Diagnosed HIV Patient with Severe Mpox: A Case Report

Andres E. Martinez [1,2], Paola Frattaroli [1,2], Christine A. Vu [3], Lizy Paniagua [1,2], Joel Mintz [4], Andres Bravo-Gonzalez [5], Paola Zamudio [6], Astrid Barco [7], Aruna Rampersad [8], Paola Lichtenberger [1,2] and Jose A. Gonzales-Zamora [1,2,9,*]

Annals of Internal Medicine

OBSERVATIONS: CASE REPORTS

Monkeypox Virus-Associated Severe Proctitis Treated With Oral Tecovirimat: A Report of Two Cases

Letters

RESEARCH LETTER

Compassionate Use of Tecovirimat for the Treatment of Monkeypox Infection

LETTER TO THE EDITOR

JOURNAL OF MEDICAL VIROLOGY WILEY

Rapid improvement of severe Mpox lesions with oral tecovirimat

ORIGINAL RESEARCH

Annals of Internal Medicine

Tecovirimat Treatment of People With HIV During the 2022 Mpox Outbreak

A Retrospective Cohort Study

Jacob McLean, DO*; Kate Stoeckle, MD*; Simian Huang, MPH; Jonathan Berardi, FNP; Brett Gray, ANP, MPH; Marshall J. Glesby, MD, PhD†; and Jason Zucker, MD†

Does Tecovirimat Work?

- No evidence for a large effect of tecovirimat in **shortening healing time** and **viral clearance**.

Received: 23 February 2023 | Accepted: 2 June 2023
DOI: 10.1002/jmv.28868

RESEARCH ARTICLE

JOURNAL OF MEDICAL VIROLOGY WILEY

Effect of tecovirimat on healing time and viral clearance by emulation of a target trial in patients hospitalized for mpox

Valentina Mazzotta[1,2] | Alessandro Cozzi-Lepri[3] | Simone Lanini[1] | Annalisa Mondi[1] | Fabrizio Carletti[4] | Alessandro Tavelli[5] | Roberta Gagliardini[1] | Serena Vita[1] | Carmela Pinnetti[1] | Camilla Aguglia[1] | Francesca Colavita[2,4] | Paolo Faccendini[6] | Giulia Matusali[4] | Francesca Faraglia[1] | Alessia Beccacece[1] | Jessica Paulicelli[1] | Enrico Girardi[7] | Emanuele Nicastri[1] | Francesco Vaia[8] | Fabrizio Maggi[4] | Andrea Antinori[1]

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[8]General Direction, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy

Mazzotta V, Cozzi-Lepri A, Lanini S, Mondi A, Carletti F, Tavelli A, Gagliardini R, Vita S, Pinnetti C, Aguglia C, Colavita F, Faccendini P, Matusali G, Faraglia F, Beccacece A, Paulicelli J, Girardi E, Nicastri E, Vaia F, Maggi F, Antinori A. Effect of tecovirimat on healing time and viral clearance by emulation of a target trial in patients hospitalized for mpox. J Med Virol. 2023 Jun;95(6):e28868. doi: 10.1002/jmv.28868. PMID: 37306318.

Does Tecovirimat Generate Resistance?

AMERICAN SOCIETY FOR MICROBIOLOGY | Antimicrobial Agents and Chemotherapy

LETTER TO THE EDITOR
Month YYYY Volume XX Issue XX e00568-23

Identification of Tecovirimat Resistance-Associated Mutations in Human Monkeypox Virus - Los Angeles County

Jacob M. Garrigues[a], Peera Hemarajata[a], Abraar Karan[a,b], Naman K. Shah[a], Jemma Alarcón[a,c], Amy N. Marutani[a], Lauren Finn[a], Todd G. Smith[c], Crystal M. Gigante[c], Whitni Davidson[c], Nhien T. Wynn[c], Christina L. Hutson[c], Moon Kim[a], Dawn Terashita[a], Sharon E. Balter[a], Nicole M. Green[a]

[a]Los Angeles County Department of Public Health, Downey, California, USA
[b]Stanford University School of Medicine, Stanford, California, USA
[c]Centers for Disease Control and Prevention, Atlanta, Georgia, USA

KEYWORDS drug resistance, mpox, tecovirimat

1 **Resistance to anti-orthopoxviral drug tecovirimat (TPOXX®) during the 2022 mpox outbreak in**
2 **the US**
3
4 Todd G. Smith [a]*, Crystal M. Gigante [a], Nhien T. Wynn [a], Audrey Matheny [a], Whitni Davidson [a], Yong
5 Yang [a], Rene Edgar Condori [a], Kyle O'Connell [b,c], Lynsey Kovar [b,d], Tracie L. Williams [e], Yon C. Yu [f],
6 Brett W. Petersen [a], Nicolle Baird [a], David Lowe [a], Yu Li [a], Panayampalli S. Satheshkumar [a], and
7 Christina L. Hutson [a]

Todd G. Smith, Crystal M. Gigante, Nhien T. Wynn, Audrey Matheny, Whitni Davidson, Yong Yang, Rene Edgar Condori, Kyle O'Connell, Lynsey Kovar, Tracie L. Williams, Yon C. Yu, Brett W. Petersen, Nicolle Baird, David Lowe, Yu Li, Panayampalli S. Satheshkumar, Christina L. Hutson doi: https://doi.org/10.1101/2023.05.16.23289856

Does Tecovirimat Generate Resistance?

- MPXV F13L gene
  - Single amino acid changes are known to cause resistance
- 50 isolates from 26 patients were found to have a resistant phenotype
  - Severely immunocompromised patients
  - Multiple courses of TPOXX
- F13 mutations identified by **routine surveillance** have remained sensitive

Resistance to anti-orthopoxviral drug tecovirimat (TPOXX®) during the 2022 mpox outbreak in the US

Todd G. Smith [a]*, Crystal M. Gigante [a], Nhien T. Wynn [a], Audrey Matheny [a], Whitni Davidson [a], Yong Yang [a], Rene Edgar Condori [a], Kyle O'Connell [b,c], Lynsey Kovar [b,d], Tracie L. Williams [e], Yon C. Yu [f], Brett W. Petersen [a], Nicolle Baird [a], David Lowe [a], Yu Li [a], Panayampalli S. Satheshkumar [a], and Christina L. Hutson [a]

[a] Poxvirus and Rabies Branch, Division of High-Consequence Pathogens and Pathology, National Center for Emerging and Zoonotic Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd NE, Atlanta GA, 30333, USA

[b] Office of Advanced Molecular Detection, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd NE, Atlanta GA, 30333, USA

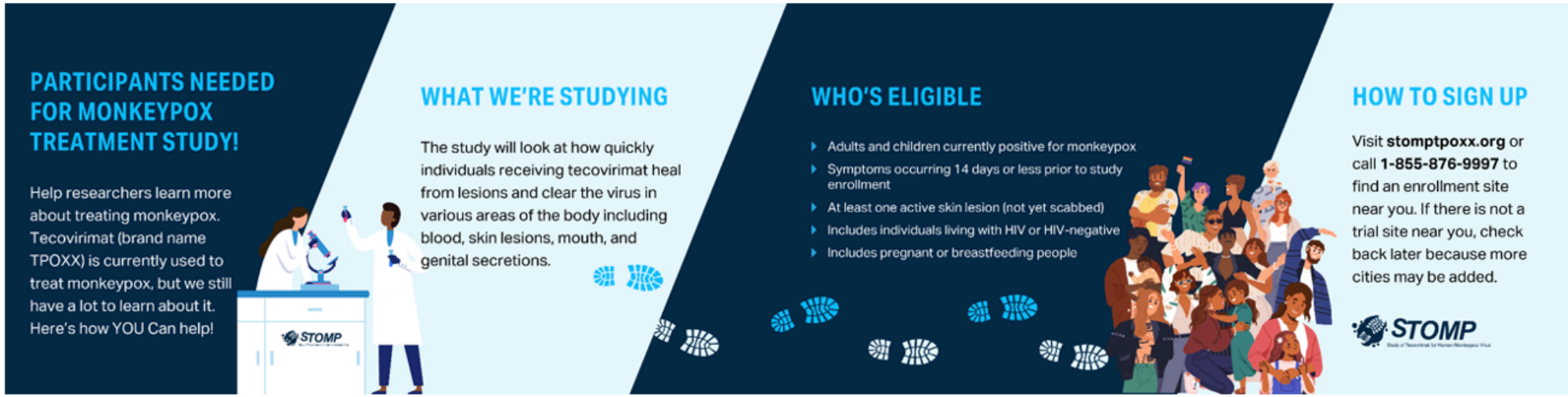
[c] Health Data and AI, Deloitte Consulting LLC, 1919 N. Lynn St, Arlington VA 22209.

Smith, Todd G, Crystal M Gigante, Nhien T Wynn, Audrey Matheny, Whitni Davidson, Yong Yang, Rene Edgar Condori, et al. 2023. "Resistance to Anti-Orthopoxviral Drug Tecovirimat (TPOXX®) during the 2022 Mpox Outbreak in the US." MedRxiv, January (January), 2023.05.16.23289856. https://doi.org/10.1101/2023.05.16.23289856.

Why We Need a Clinical Trial

- We don't know if tecovirimat (TPOXX) works to treat Mpox
- There are no human data to confirm that TPOXX is effective in treating Mpox
- Better understanding the potential for Mpox to develop resistance to TPOXX
- Patients deserve treatments that work
  - If TPOXX is not effective, we need to search for a new treatment
  - If TPOXX is effective, we need to ensure all people with Mpox have access to TPOXX

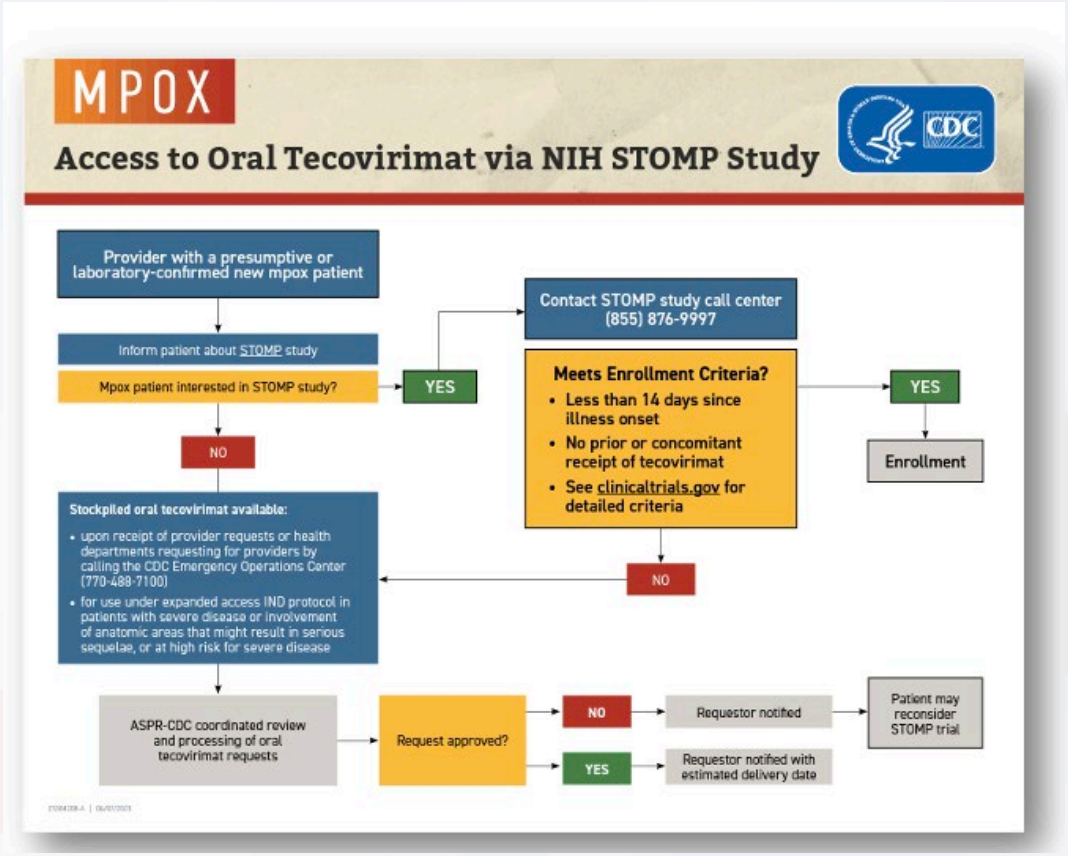
Ongoing Clinical Trial



STOMPTPOXX.ORG

How Can I Access Medical Countermeasures?

- Tecovirimat
  - Clinical Trial
  - CDC EA-IND
- VIGIV
  - CDC EA-IND
- Brincidofovir
  - FDA E-IND
- For more information:
  - https://www.cdc.gov/poxvirus/mpox/clinicians/treatment.html



Behavioral Change to Prevent Mpox

June 2022

Social Gatherings, Safer Sex and Monkeypox

Monkeypox is a disease caused by a virus not commonly seen in the United States. While we work to contain the current outbreak and study the virus, we want you to have information so you can make informed choices when you are in spaces or situations where monkeypox could be spread through close, intimate contact or during sex. There is a lot we still need to learn about monkeypox, and we will update this information as we learn more on www.cdc.gov/monkeypox.

What is monkeypox?

Monkeypox is a disease that can make you sick, including a rash, which may look like pimples or blisters, often with an earlier flu-like illness. Monkeypox can spread to anyone through close, personal, often skin-to-skin contact including:

- Direct contact with monkeypox rash, sores, or scabs from a person with monkeypox. We believe this is currently the most common way that monkeypox is spreading in the U.S.
- Contact with objects, fabrics (clothing, bedding, or towels), and surfaces that have been used by someone with monkeypox.
- Contact with respiratory secretions, through kissing and other face-to-face contact.

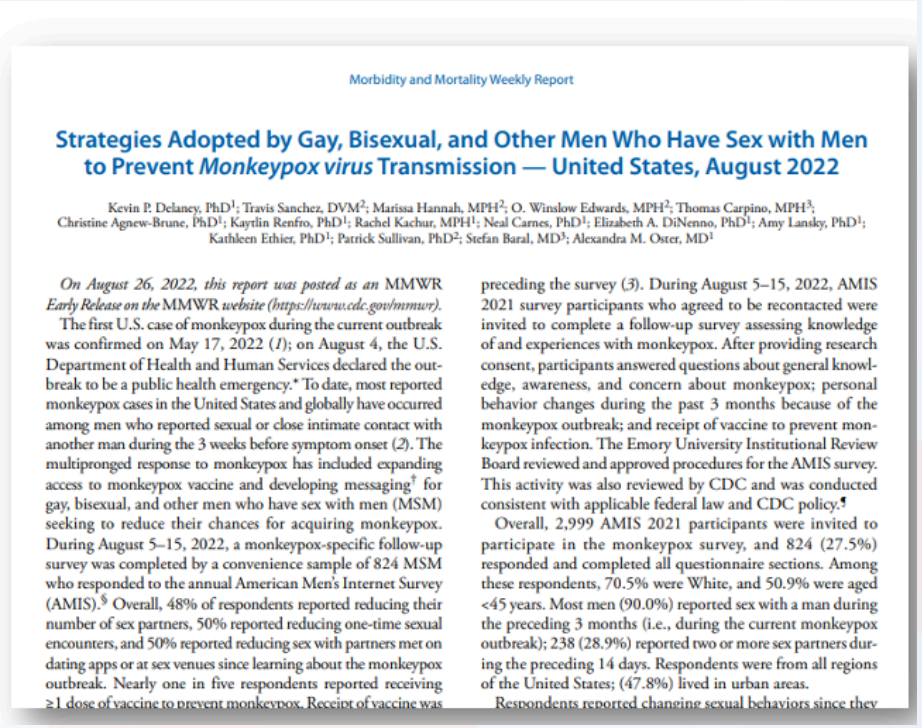
This contact can happen when you have sex including:

- Oral, anal, and vaginal sex or touching the genitals (penis, testicles, labia, and vagina) or anus (butt) of a person with monkeypox.
- Hugging, massage, and kissing.
- Touching fabrics and objects during sex that were used by a person with monkeypox and that have not been disinfected, such as bedding, towels, fetish gear, and sex toys.

https://www.cdc.gov/poxvirus/monkeypox/pdf/MPX_Social_Gatherings_Safer_Sex-508.pdf

Behavioral Change to Prevent Mpox

- ~50%
  - Decreased their number of partners
  - Decreased one-time sexual encounters
  - Decreased sex with partners met on apps or sex venues
  - Decreased group sex
- 42% - Decreased going to sex venues/events
- 35% - Decreased going to social events with close contact (dance parties / raves)



Morbidity and Mortality Weekly Report

Strategies Adopted by Gay, Bisexual, and Other Men Who Have Sex with Men to Prevent *Monkeypox virus* Transmission — United States, August 2022

Kevin P. Delaney, PhD[1]; Travis Sanchez, DVM[2]; Marissa Hannah, MPH[2]; O. Winslow Edwards, MPH[2]; Thomas Carpino, MPH[3]; Christine Agnew-Brune, PhD[1]; Kaytlin Renfro, PhD[1]; Rachel Kachur, MPH[1]; Neal Carnes, PhD[1]; Elizabeth A. DiNenno, PhD[1]; Amy Lansky, PhD[1]; Kathleen Ethier, PhD[1]; Patrick Sullivan, PhD[2]; Stefan Baral, MD[3]; Alexandra M. Oster, MD[1]

On August 26, 2022, this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr).*

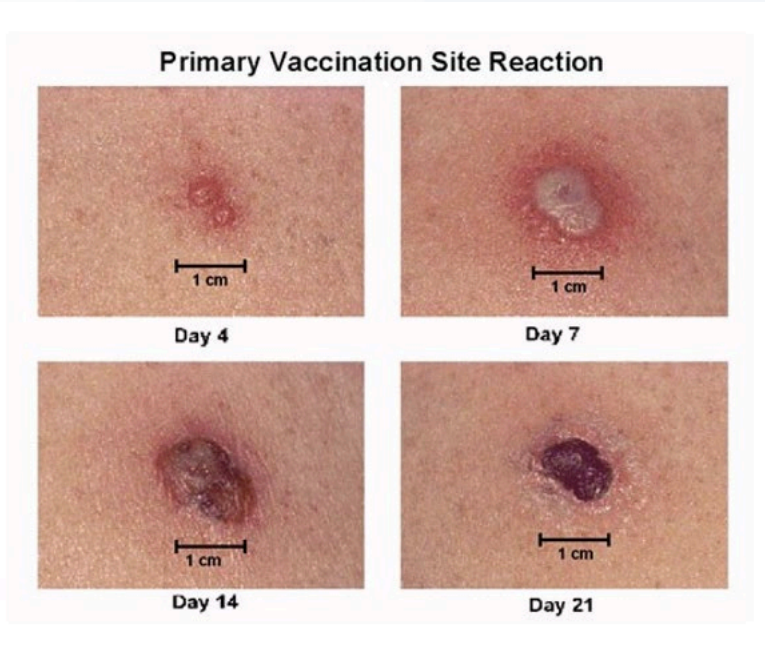
The first U.S. case of monkeypox during the current outbreak was confirmed on May 17, 2022 (*1*); on August 4, the U.S. Department of Health and Human Services declared the outbreak to be a public health emergency.* To date, most reported monkeypox cases in the United States and globally have occurred among men who reported sexual or close intimate contact with another man during the 3 weeks before symptom onset (*2*). The multipronged response to monkeypox has included expanding access to monkeypox vaccine and developing messaging† for gay, bisexual, and other men who have sex with men (MSM) seeking to reduce their chances for acquiring monkeypox. During August 5–15, 2022, a monkeypox-specific follow-up survey was completed by a convenience sample of 824 MSM who responded to the annual American Men's Internet Survey (AMIS).§ Overall, 48% of respondents reported reducing their number of sex partners, 50% reported reducing one-time sexual encounters, and 50% reported reducing sex with partners met on dating apps or at sex venues since learning about the monkeypox outbreak. Nearly one in five respondents reported receiving ≥1 dose of vaccine to prevent monkeypox. Receipt of vaccine was preceding the survey (*3*). During August 5–15, 2022, AMIS 2021 survey participants who agreed to be recontacted were invited to complete a follow-up survey assessing knowledge of and experiences with monkeypox. After providing research consent, participants answered questions about general knowledge, awareness, and concern about monkeypox; personal behavior changes during the past 3 months because of the monkeypox outbreak; and receipt of vaccine to prevent monkeypox infection. The Emory University Institutional Review Board reviewed and approved procedures for the AMIS survey. This activity was also reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.¶

Overall, 2,999 AMIS 2021 participants were invited to participate in the monkeypox survey, and 824 (27.5%) responded and completed all questionnaire sections. Among these respondents, 70.5% were White, and 50.9% were aged <45 years. Most men (90.0%) reported sex with a man during the preceding 3 months (i.e., during the current monkeypox outbreak); 238 (28.9%) reported two or more sex partners during the preceding 14 days. Respondents were from all regions of the United States; (47.8%) lived in urban areas.

Respondents reported changing sexual behaviors since they

Vaccination to Prevent Mpox?

Vaccinations



Current Vaccines

- ACAM2000
  - Live vaccinia virus
  - Lesion at the inoculation site
  - 1 injection
  - Booster every 3 years
  - FDA approved for >12 months
- JYNNEOS
  - Non-replicating virus
  - 2 injections, 4 weeks apart
  - Maximum immunity 14 days after second dose
  - FDA approved age >=18
    - EUA for age <18

Vaccination to Prevent Mpox?

Pre-Exposure Prophylaxis

- Should be given ASAP after exposure:
- Within 4 days to **prevent disease**
- 4 to 14 days to **reduce symptoms**
- **Note:** Vaccinia immune globulin (IND) available for patient's ineligible for vaccination for PEP

Pre-Exposure Prophylaxis

- Clinical and research lab workers
- Public health response team members
- **Epidemiological Risk Groups**

Does Vaccination Prevent Mpox?

How effective is vaccination?

- ~85% effective in preventing monkeypox

Int J Epidemiol. 1988 Sep;17(3):643-50. doi: 10.1093/ije/17.3.643.

The transmission potential of monkeypox virus in human populations

P E Fine [1], Z Jezek, B Grab, H Dixon

Affiliations + expand

PMID: 2850277 DOI: 10.1093/ije/17.3.643

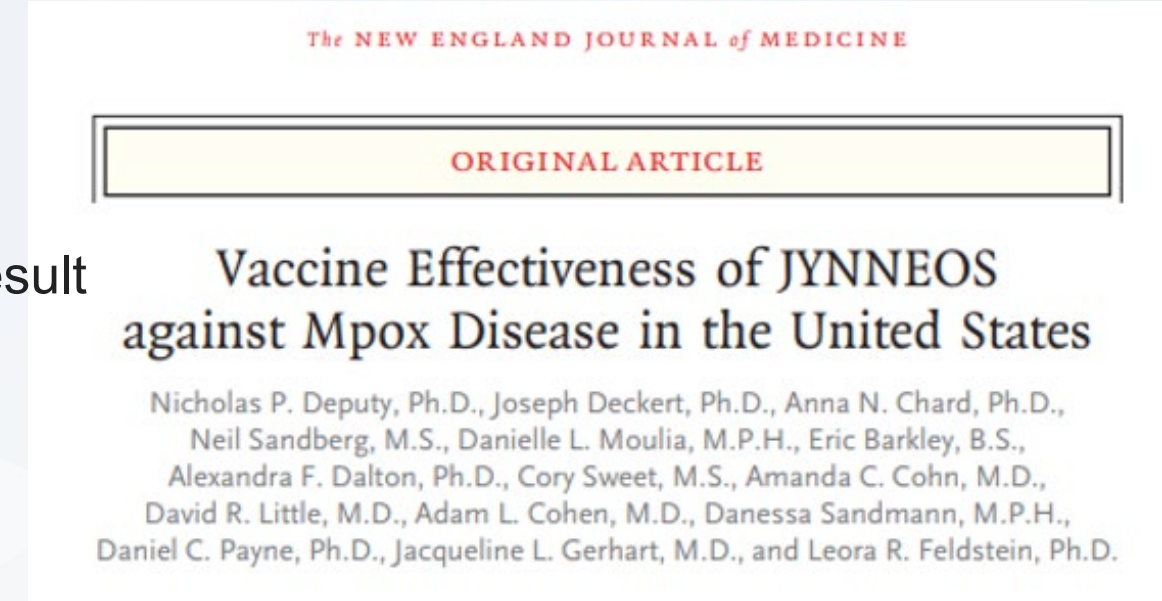
Abstract

Data on monkeypox in Zaire over the five years 1980-1984 are analysed to assess the protection imparted by past smallpox vaccination and the transmission potential of the virus in unvaccinated communities. Attack rates in individuals with and without vaccination scars indicated that smallpox vaccination (discontinued in 1980) imparted approximately 85% protection against monkeypox. It is predicted that monkeypox virus will continue to be introduced into human communities from animal sources, and that the average magnitude and duration of monkeypox epidemics will increase as vaccine-derived protection declines in the population. On the other hand, current evidence indicates that the virus is appreciably less transmissible than was smallpox, and that it will not persist in human communities, even in the total absence of vaccination. The findings thus support the recommendation of the Global Commission for the Certification of Smallpox Eradication to cease routine smallpox vaccination in monkeypox endemic areas, but to encourage continued epidemiological surveillance.

Fine PE, Jezek Z, Grab B, Dixon H. The transmission potential of monkeypox virus in human populations. Int J Epidemiol. 1988 Sep;17(3):643-50. doi: 10.1093/ije/17.3.643. PMID: 2850277.

Vaccine Effectiveness

- Case-control study
- Using the Cosmos database
- Cases - 2193
  - Mpox diagnosis code
  - Positive orthopox or Mpox virus lab result
- Controls - 8319
  - Incident HIV infection
  - Taking PrEP (new order or refill)


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Vaccine Effectiveness of JYNNEOS against Mpox Disease in the United States

Nicholas P. Deputy, Ph.D., Joseph Deckert, Ph.D., Anna N. Chard, Ph.D., Neil Sandberg, M.S., Danielle L. Moulia, M.P.H., Eric Barkley, B.S., Alexandra F. Dalton, Ph.D., Cory Sweet, M.S., Amanda C. Cohn, M.D., David R. Little, M.D., Adam L. Cohen, M.D., Danessa Sandmann, M.P.H., Daniel C. Payne, Ph.D., Jacqueline L. Gerhart, M.D., and Leora R. Feldstein, Ph.D.

Deputy NP, Deckert J, Chard AN, et al. Vaccine Effectiveness of JYNNEOS against Mpox Disease in the United States [published online ahead of print, 2023 May 18]. *N Engl J Med*. 2023;10.1056/NEJMoa2215201. doi:10.1056/NEJMoa2215201

Vaccine Effectiveness

- Adjusted vaccine effectiveness
  - 2 doses – 66%
  - 1 dose – 36%

Table 3. Estimated Vaccine Effectiveness against Diagnosed Mpox among Persons Seeking Health Care, According to Subpopulations of Interest, August 15 through November 19, 2022.

Subpopulation	Case Patients	Control Patients	Vaccine Effectiveness (95% CI)	
			Unadjusted	Adjusted*
	number		*percent*	
Men only†				
Unvaccinated, reference group	1792	6075		
Partially vaccinated	136	983	54.5 (45.0–62.5)	35.9 (21.6–47.6)
Fully vaccinated	25	335	77.3 (65.3–85.2)	64.8 (45.2–77.3)
Men only, 18–49 yr of age and without ACAM2000 vaccination†				
Unvaccinated, reference group	1561	4632		
Partially vaccinated	119	787	56.9 (46.7–65.2)	35.5 (19.1–48.6)
Fully vaccinated	23	247	73.4 (58.3–83.0)	58.7 (33.9–74.3)
Not immunocompromised				
Unvaccinated, reference group	1151	5368		
Partially vaccinated	102	932	47.0 (33.2–58.0)	40.8 (24.8–53.4)
Fully vaccinated	14	312	80.6 (65.5–89.1)	76.3 (57.7–86.8)

https://www.cdc.gov/poxvirus/mpox/clinicians/treatment.html

Vaccine Effectiveness

	2 doses	1 dose
Deputy , NEJM	66%	36%
Dalton, MMWR	86%	75%
Rosenberg, MMWR	76%	68%
Bertran, Lancet ID		76%
Sagy, Nature Medicine		86%

Re-infection and Post Vaccination Infection

Two individuals with potential monkeypox virus reinfection

Published Online April 6, 2023 https://doi.org/10.1016/S1473-3099(23)00185-8

See Online for appendix

Over 80 000 mpox (formerly known as monkeypox) cases have been confirmed worldwide and recovered individuals are considered protected against reinfection.[1–3] However, an individual with apparent reinfection has been recently reported.[4] In this Comment we describe two individuals with potential monkeypox virus reinfection at San Raffaele Hospital, Milan, Italy (figure; see appendix for details on testing and results).

The first individual is a 36-year-old man who has sex with men (MSM) who presented with asthenia, pharyngodynia, and fever with tenesmus and mucorrhoea on May 24, 2022, with symptom onset a week earlier, after attending a large gathering in Spain in early May, during which he had condomless oral intercourse and condomless anal intercourse with several partners. He is on antiretroviral therapy for a known HIV infection (1099 CD4⁺ cells per µL; HIV-RNA <20 copies per mL since 2015) and had no other medications or comorbidities.

He presented with a perianal ulceration, a pharyngeal lesion, and lymphadenopathy. Monkeypox virus PCR

CLINICAL PICTURE | VOLUME 401, ISSUE 10388, P1610, MAY 13, 2023

Second clinical episode of hMPX virus in a man having sex with men

Jeremy Zeggagh, MD • Olivier Ferraris, PhD • Maud Salmona, PhD • Arnaud Tarantola, PhD • Prof Jean-Michel Molina, MD • Prof Constance Delaugerre, PhD

Published: March 24, 2023 • DOI: https://doi.org/10.1016/S0140-6736(23)00509-3 • Check for updates

Howard Brown Health Identifies Monkeypox (Mpox) Resurgence

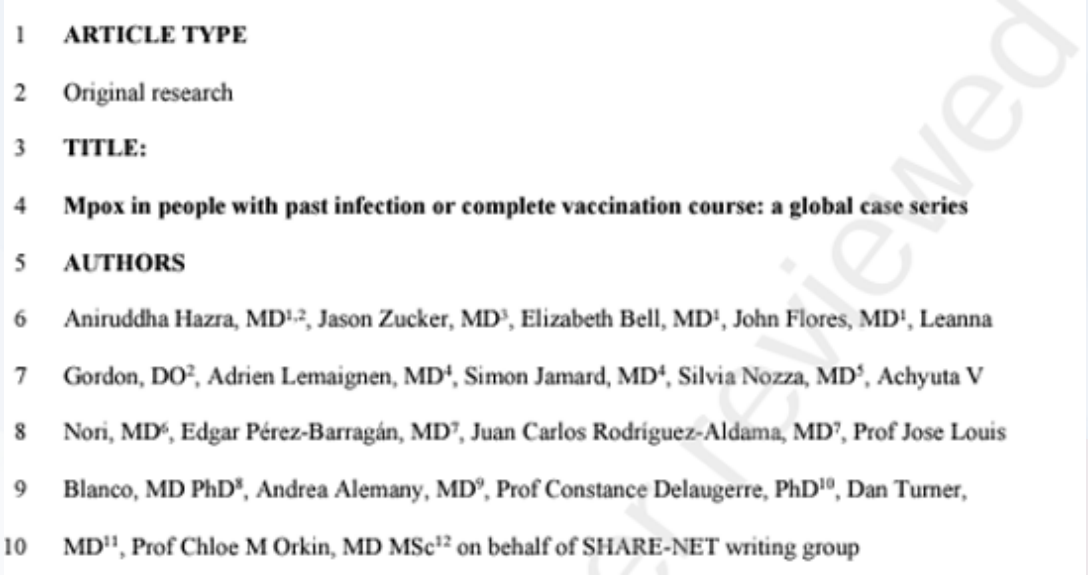
(Chicago, IL, May 5, 2023) – Howard Brown Health has identified a resurgence in cases of Monkeypox (Mpox) in the Chicago area. As of this morning, the agency has diagnosed seven new cases of mpox since April 17, with results from tests performed this week still pending.

In the nearly three months before April 17, the Chicago Department of Public Health only reported one new mpox case, diagnosed at Howard Brown. Last week's new case rate was the highest in Chicago since early November 2022 and was the highest weekly new case rate in any US region so far this year.

"We urge sexually active members of our community to receive the mpox vaccine. For example, unvaccinated people planning to attend International Mr. Leather at the end of May should receive their first dose of the mpox vaccination as soon as possible," said Dr. Patrick Gibbons, Chief Medical Director. "The more people who get vaccinated, the better protected the LGBTQ+ community will be from another outbreak of Monkeypox this year."

Re-infection and Post Vaccination Infection

- Less severe
  - Fewer confluent lesions
  - Diminished mucosal involvement
  - Reduced analgesia requirement
  - Fewer admissions



ARTICLE TYPE

Original research

TITLE:

Mpox in people with past infection or complete vaccination course: a global case series

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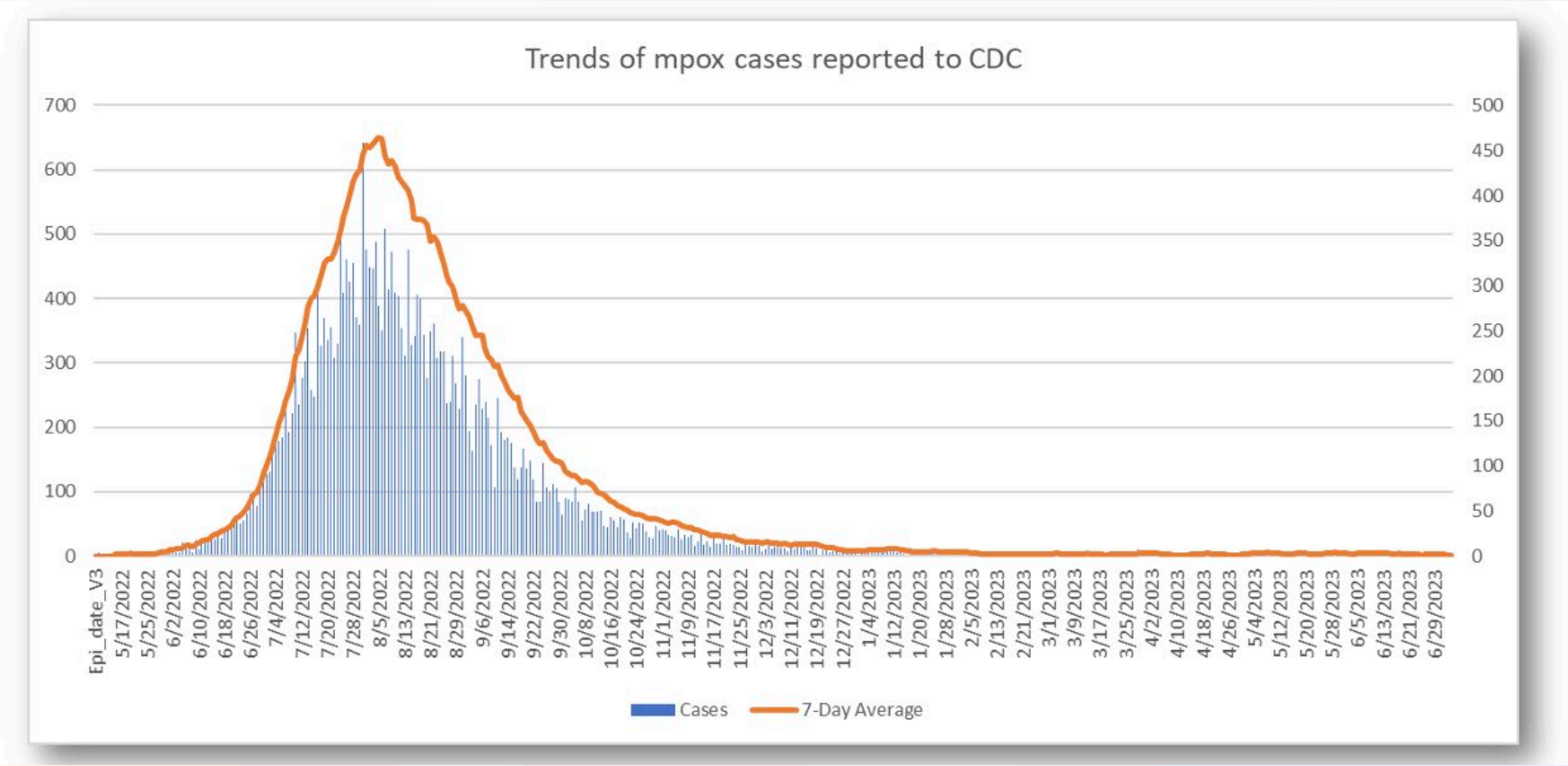
Hazra, Aniruddha and Zucker, Jason and Bell, Elizabeth and Flores, John and Gordon, Leanna and Lemaignien, Adrien and Jamard, Simon and Nozza, Silvia and Nori, Achyuta and Pérez-Barragán, Edgar and Rodríguez-Aldama, Juan Carlos and Blanco, Jose and Alemany, Andrea and Delaugerre, Constance and Turner, Daniel and Orkin, Chloe and Group, SHARE NET Writing, Mpox in People with Past Infection or Complete Vaccination Course: A Global Case Series. Available at http://dx.doi.org/10.2139/ssrn.4491622

Current Epidemiology



https://www.cdc.gov/poxvirus/monkeypox/response/2022/mpx-trends.html

Summary

- The current Mpox outbreak spread rapidly and can be serious
  - Cases are still occurring
- It is not presenting classically but is presenting commonly with genitourinary, rectal, and pharyngeal complaints
- Commonly looks like other sexually transmitted infections
  - Can present concurrently with other STIs so make sure to get complete STI testing
- We have supportive care and clinical trial options for all patients
- We have EA-IND treatment options for patients with severe disease
- More studies are needed to better understand the treatment options, and long-term outcomes of this disease
- **Have a low threshold to think about Mpox in your patients**
- **This disease can be stigmatizing and severe, patients are grateful for our support**

NYC STD Prevention Training Center (PTC)

The CDC-funded NYC STD Prevention Training Center at Columbia University provides a continuum of education, resources, consultation and technical assistance to health care providers, and clinical sites. www.nycptc.org

NEW YORK CITY STD HIV PREVENTION TRAINING CENTER

Didactic Presentations

Webinars, conferences, trainings and grand rounds presentations to enhance and build knowledge

Clinical Consultation Warmline

Clinical guidance regarding STD cases; no identifying patient data is submitted
www.stdccn.org

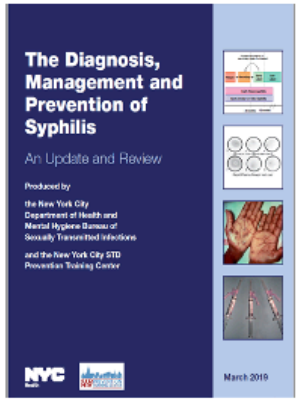
Technical Assistance

Virtual and on-site technical assistance regarding quality improvement, clinic implementation and best practices around sexual health provision

For more information please contact:
nycptc@cumc.columbia.edu

Resources

Clinical guidance tools regarding the STD treatment guidelines, screening algorithms and knowledge books, such as the **Syphilis Monograph**.
To download a copy please visit:
http://bit.ly/SyphilisMonograph2019PTC



ACTG AIDS CLINICAL TRIALS GROUP

STOMP
Study of Tecovirimat for Human Monkeypox Virus

IMPAACT
International Maternal Pediatric Adolescent AIDS Clinical Trials Network

ACTG A5418 STUDY POPULATION: SYMPTOMATIC MONKEYPOX VIRUS INFECTION	
RANDOMIZED ARMS: TPOXX vs. placebo (2:1)	OPEN LABEL TPOXX ARM
• Primary efficacy objective: To show that TPOXX reduces time to clinical resolution. • If progressing to severe or experiencing severe pain, then can move to open-label TPOXX	• Children, pregnant and breast-feeding people • Severe disease (hospitalized, ocular disease, facial lesions, complicated ulcers) • Severe skin disease or immune suppression
• IN PERSON enrollment and follow-up for 8 weeks with detailed virologic assessments, daily diary, and telemedicine • COMPLETELY REMOTE option is forthcoming in a version change • Up to 80 sites in US with possibility for international sites	

STOMPTPOXX.ORG	(855) 876-9997	NCT05534984
Website with list of active sites	Call center to connect to sites	See clinicaltrials.gov for details

Questions?

What You Need to Know About the Prevention, Diagnosis and Treatment of Human Monkeypox Virus

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Acknowledgments

The **National STD Curriculum** is funded by a cooperative agreement from the Centers for Disease Control and Prevention (CDC-RFA-PS20-2004). This project is led by the University of Washington STD Prevention Training Center and Infectious Diseases Education and Assessment (IDEA) Programs.

AETC Program National Centers and HIV Curriculum

- **National Coordinating Resource Center –** serves as the central web –based repository for AETC Program training and capacity building resources; its website includes a free virtual library with training and technical assistance materials, a program directory, and a calendar of trainings and other events. Learn more: https://aidsetc.org/
- **National Clinical Consultation Center –** provides free, peer-to-peer, expert advice for health professionals on HIV prevention, care, and treatment and related topics. Learn more: https://nccc/ucsf.edu
- **National HIV Curriculum –** provides ongoing, up –to-date HIV training and information for health professionals through a free, web –based curriculum; also provides free CME credits, CNE contact hours, CE contact hours, and maintenance of certification credits. Learn more: www.hiv.uw.edu