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REPORTED COVID-19 CASES IN THE UNITED STATES

Cumulative Cases – 92,655,110



Cases decreased by 15% from two weeks earlier

Source: New York Times 8-14-22

SARS-CoV-2 VARIANTS, US, CDC



Collection date, week ending

 mg
 BA.2.12.1, BA.2 sublineages are aggregated with BA.2.

 Sublineages of BA.4 are aggregated to BA.4. Sublineages of BA...

they currently cannot be reliably called in each region. Except

https://covid.cdc.gov/covid-data-tracker/#variant-proportions



Source: New York Times 8-14-2022

CDC COVID-19 COMMUNITY LEVELS



February 27, 2022

July 27, 2022



Source – https://covid.cdc.gov/covid-data-tracker/#countyview?list_select_state=all_states&list_select_county=all_counties&datatype=CommunityLevels&null=CommunityLevels

HOSPITALIZATIONS AND ICU ADMISSIONS FOR COVID-19 IN THE UNITED STATES



Hospitalizations decreased 3 % from two weeks earlier

Source: New York Times 8-14-22

COVID-19 DEATHS IN THE UNITED STATES

Cumulative Deaths – 1,033,195



Source: New York Times 8-14-22



DAILY COVID-19 VACCINATIONS IN THE UNITED STATES

Source: Our World in Data 8-14-22

COVID-19 VACCINATIONS IN THE UNITED STATES



Source: Our World in Data 8-14-22

COVID-19 BOOSTER DOSES IN THE UNITED STATES

CUMULATIVE DOSES ADMINISTERED 128.79 M



MONKEYPOX OUTBREAK: DAILY CASES, WORLDWIDE



Our World in Data - https://ourworldindata.org/monkeypox

MONKEYPOX OUTBREAK CURVE: DAILY CASES, UNITED STATES



Our World in Data - https://ourworldindata.org/monkeypox

2022 Monkeypox Outbreak, US



This Week's Pandemic and Epidemic News

- 1. CDC issued new, relaxed guidance for community COVID-19 prevention; these recommendations are not applicable to healthcare institutions..
- 2. DHHS issued a national research action plan to address long-COVID; the editorial staff of **JAMA** interviewed experts who suggested the plan was not adequate to address the issue.
- 3. A **New England Journal** study from Singapore demonstrated that two doses of the Pfizer-BioNTech vaccine in children 5 to 11 was 65.3% effective in preventing PCR-confirmed Omicron infection, and 82.7% effective in preventing Omicron-related hospitalization.
- 4. A **JAMA Network Open** paper from South Korea demonstrated that relaxation of restrictions for social gatherings was associated with an increase in transmission as was suspension of the need for vaccine passes.
- 5. A **JAMA Oncology** paper found a delayed third dose of Moderna vaccine substantially improved immune responses among patients with hematological malignancies and that patients with B-cell lymphoma and allogeneic hematopoietic stem cell transplant recipients need to be revaccinated after treatment or transplantation.
- 6. A Canadian study published in **Lancet** reported that the mRNA vaccines have a good safety profile in pregnancy.
- 7. A **Science Translational Medicine** paper demonstrated that Broadly neutralizing antibodies to SARS-related viruses can be readily induced in rhesus macaques.
- 8. A **New England Journal of Medicine** paper described the presentation, clinical course, and outcomes of polymerase-chain-reaction–confirmed monkeypox .
- 9. CDC and Our World in Data Monkeypox Situation Summaries..

References available in the chat

Panelists:



Dr. David Henderson NIH Consultant



Dr. Hilary Babcock BJC HealthCare



Dr. Kristina Bryant University of Louisville



Dr. David Weber UNC School of Medicine



SHEA TOWN HALL: MONKEYPOX UPDATE

David J. Weber, MD, MPH, FIDSA, FSHEA, FRSM (London) Sanders Distinguished Professor of Medicine, Pediatrics and Epidemiology Associate Chief Medical Officer Medical Director, Hospital Epidemiology



Disclosures: Consultancy; Pfizer, Merck, Sanofi, PDI, Germitec, Wellair All drugs/vaccines issues discussed consistent with FDA approvals or authorizations

MONKEYPOX: SUMMARY OF NEW INFORMATION

- Current outbreak largest ever recorded; however, outbreak may have plateaued; Outbreak due to a new clade (clade C)
- Reproductive number (Rho) = ~1.3 {COVID-19 initial Rho = 2-4; Omicron variants = 8-10}; main transmission mechanism
 is skin to skin contact (others: droplet requires prolonged exposure, fomites {shared eating utensils, contaminated
 bedding/clothes}, transplacental and congenital)
- Great majority of cases in men who have sex with men (MSMs); NC=~120 cases, at risk population in NC = 15,700
- Most patients in current outbreak have atypical symptoms compared to classic Monkeypox
- Testing: Available at health departments (free) & many commercial labs (capacity, ~70,000-80,000 tests per week)
- UNC-CH performing "in house" diagnostic tests for UNC Health: ~10 per day (capacity = 100/d); 78 tested performed to date, ~23% positive; turnaround time = 1-4 days (but usually results available in <24 hours); cost = ~\$250 per site tested
- Jynneos vaccine available for pre-exposure (PreP) and post-exposure prophylaxis (PEP)
 - UNC has provided PreP to our microbiologists performing Monkeypox testing
 - FDA has authorized ID administration at 1/5 dose to expand supply (based on limited data; one 2015 paper)
- Tecovirimat (TPOXX) available for treatment: UNC and CDC reliance agreement developed and signed by both parties



MONKEYPOX: ROUTES OF TRANSMISSION

- Animal-to-human via bite/scratch, direct contact, and indirect contact (cleaning cages, animal products)
- Human-to-human
 - Respiratory secretions (droplet transmission) prolonged face-to-face contact (no data regarding risk from patients with pneumonia)
 - Direct contact (skin-to-skin) with body fluids or body lesions
 - Indirect contact/fomites (drinking or eating from same dish, contact with contaminated linens)
 - Sexual: Direct contact, unknown if via semen or vaginal fluids
 - Vertical (transplacental) or at deliver (congenital): May lead to fetal demise
- Mortality: The case fatality rate for the Central African clade is 1-10% versus <3% for the West African clade
 - Likely an overestimate (biased by severity)
 - Currently outbreak expected mortality <1%; highest risk immunocompromised, pregnant women, young children
- UK Health Authority, 28 July 2022
 - Daily case growth rate has slowed
 - No confirmed cases of airborne transmission; Limited household transmission
 - Hospitalizations for severe pain, secondary bacterial infections
 - No deaths



Figure 1. Transmission of human monkeypox. In endemic countries, spillover events occur from zoonotic animal reservoirs into humans, potentially leading to limited outbreaks usually facilitated by close human contact. Outbreaks can also occur in nonendemic regions through introduction of the virus via human travel or importation of animals harboring the virus. Subsequent human-to-human transmission can then occur via household contacts and via other close contacts.

Titanji BK, et al. Open Forum Infectious Diseases 2022;21 June Bunge EM, et al. PLOS Neglected Tropical Diseases 2022:11 February; Reynolds MG, et al. Curr Opin Virology 2018;28:108-115; CDC Khalil A, et al. Ultrasound Obstet Gynecol 2022;2 June

MONKEYPOX TRANSMISSION: UNKNOWNS

- To what extent children, people with specific underlying conditions (including those that may cause immunocompromise, eczema or atopic dermatitis), or pregnant people are at risk of severe disease, as they have been with previous outbreaks of monkeypox.
- Whether people with immunosuppression have more Monkeypox virus present in body fluids.
- How often Monkeypox virus may be spread from respiratory secretions, or at what point during infection a person with monkeypox symptoms might be more likely to spread Monkeypox virus through respiratory secretions. As stated above, transmission during brief interactions has not been reported.
- If Monkeypox virus may be present in body fluids, including oral and respiratory secretions, urine, feces, and semen.
- Whether Monkeypox virus can be spread through semen or vaginal fluids. Viral DNA has been detected in semen.

Isolation and Prevention Practices for People with Monkeypox | Monkeypox | Poxvirus | CDC



	2018		2019	2019	2021			
	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	
Site of HCID unit	London	Liverpool	Newcastle	London	Liverpool	Liverpool	Liverpool	
Age range, years*	30-40	30-40	30-40	40-50	30-40	<2	30-40	
Sex	Male	Male	Female	Male	Male	Female	Female	
Transmission rank	Isolated	Index	Secondary	Isolated	Index	Secondary	Tertiary	
Country of acquisition	Nigeria	Nigeria	UK	Nigeria	Nigeria	UK	UK	
Smallpox vaccination history	None	None	MVA six days post- exposure or 12 days pre-illness	None	None	None	None	
HIV, hepatitis B, and hepatitis C status	Negative	Negative	Negative	Negative	Negative	Not tested (parents negative)	Negative	
Prodrome	Fever and night sweats (2 days)	Fever and groin swelling (4 days)	Coryzal illness (1 day)	Fever and headache (2 days)	None	None	None	
Lymphadenopathy	Yes	Yes	No	Yes	Yes	Yes	No	
Approximate maximum number of concurrent lesions	150	100	32	100	40	30	10	
Distribution of lesions	Face, scalp, trunk, limbs, palms, glans penis, and scrotum	Face, trunk, limbs, palms, soles, and scrotum	Face, trunk, hands (including nail bed), and labia majora	Face, scalp, trunk, limbs, penile shaft, palms, and soles	Face, trunk, limbs, palms, and penile shaft	Face, trunk, arms, and legs	Face, trunk, arms and hands	
Complications of illness	Low mood and emotional lability. Ulcerated inguinal lesion with delayed healing	Deep tissue abscesses, severe pain, and low mood	Conjunctivitis, painful disruption of thumbnail from subungual lesion	Ulcerated inguinal lesion with delayed healing	None	Pruritis and contact dermatitis from cleaning products	Low mood	
Specific management of complications	Clinical psychology input	Empiric broad- spectrum antibiotics, abscess drainage, and analgesia (including opiate and neuropathic agents)	Antibacterial eye drops	Empiric azithromycin	Nil specific	Calamine lotion and short course of antibiotics at the onset of dermatitis	Nil specific	
Monkeypox viral DNA dete	ected							
Blood	Yes	Yes	Yes	Yes	No	Yes	Yes	
Nose or throat swab	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Urine	Yes	Yes	Yes	Yes	No	No	No	
Antivirals received	Brincidofovir 200 mg (one dose) orally	Brincidofovir 200 mg (two doses) orally	Brincidofovir 200 mg (two doses) orally	None	None	None	Tecovirimat 600 twice daily for 2 weeks orally	
Day of illness treatment commenced†	7	6	7	-	+	C	5	
Complications of treatment	Transaminitis (peak ALT 331 U/L)	Transaminitis (peak ALT 550 U/L)	Transaminitis (peak ALT 127 U/L), nausea, and abdominal discomfort	-		-	None	
Duration of hospitalisation with monkeypox, days	26	27	35	39	13	22	10	
Outcome of monkeypox	Full recovery	Full recovery	Full recovery	Full recovery	Full recovery	Full recovery	Full recovery	

Table: Summary of the clinical course and response to treatment in seven patients with monkeypox

Skin and Soft Tissue Manifestations of Monkeypox



Figure 2: Skin and soft tissue manifestations of monkeypox

Skin and soft tissue features included: (A and D) vesicular or pustular lesions; (B and C) macular lesions involving the palms and soles; (D and E) a sub-ungual lesion; (F and G) more subtle papules and smaller vesicles; (H) and a deep abscess (arrow, image obtained during ultrasound-guided drainage).

Adler H, et al. Lancet ID 2022;24 May

Phylogenomic characterization and signs of microevolution in the 2022 multi-country outbreak of monkeypox virus

The largest monkeypox virus (MPXV) outbreak described so far in non-endemic countries was identified in May 2022. Here, shotgun metagenomics allowed the rapid reconstruction and phylogenomic characterization of the first MPXV outbreak genome sequences, showing that this MPXV belongs to clade 3 and that the outbreak most likely has a single origin. Although 2022 MPXV (lineage B.1) clustered with 2018-2019 cases linked to an endemic country, it segregates in a divergent phylogenetic branch, likely reflecting continuous accelerated evolution. An in-depth mutational analysis suggests the action of host APOBEC3 in viral evolution as well as signs of potential MPXV human adaptation in ongoing microevolution. Our findings also indicate that genome sequencing may provide resolution to track the spread and transmission of this presumably slow-evolving dsDNA virus.



Isidro J, et al. Nature Medicine 2022;24 June

2022 Monkeypox Outbreak, Global Map & US



11,177 Total confirmed monkeypox/orthopoxvirus cases

*One Florida case is listed here but included in the United Kingdom case counts because the individual was tested while in the UK.



Rare deaths (N=4, 2 due to encephalitis; US=0); hospitalizations infrequent (US, 8%) and most commonly for pain relief <u>https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html</u>

MONKEYPOX OUTBREAK CURVES: WORLDWIDE & US





Our World in Data - https://ourworldindata.org/monkeypox

Monkeypox Virus Infection in Humans across 16 Countries, 4/22-6/22

- Methods: International collaborative group of clinicians who contributed to an international case series to describe the presentation, clinical course, and outcomes of polymerase-chain-reaction–confirmed monkeypox virus infections.
- 528 infections diagnosed between April 27 and June 24, 2022, at 43 ٠ sites in 16 countries. Overall, 98% of the persons with infection were gay or bisexual men, 75% were White, and 41% had human immunodeficiency virus infection; the median age was 38 years. Transmission was suspected to have occurred through sexual activity in 95% of the persons with infection. In this case series, 95% of the persons presented with a rash (with 64% having <10 lesions), 73% had anogenital lesions, and 41% had mucosal lesions (with 54 having a single genital lesion). Common systemic features preceding the rash included fever (62%), lethargy (41%), myalgia (31%), and headache (27%); lymphadenopathy was also common (reported in 56%). Concomitant sexually transmitted infections were reported in 109 of 377 persons (29%) who were tested. Monkeypox virus DNA was detected in 29 of the 32 persons in whom seminal fluid was analyzed. 0 (13%) were hospitalized; the reasons for hospitalization were pain management, mostly for severe anorectal pain (21 persons); soft-tissue superinfection (18); pharyngitis limiting oral intake (5); eye lesions (2); acute kidney injury (2); myocarditis (2); and infection-control purposes (13). No deaths were reported.
- Microbiologically confirmed concomitant STI present, no./total no. screened (%) 109/377 (29): GC 32/377 (8), Chlamydia 20/377 (5), Syphilis 33/377 (9), Herpes simplex virus infection 3/377 (1), LGV 2/377 (1), Chlamydia and GC 5/377 (1), Other or not stated 14/377 (4)
- History of smallpox vaccination = 49 (9%)
- Suspected route of transmission, no. (%): Sexual close contact 504 (95), Nonsexual close contact 4 (1), Other or unknown 17 (3), Household contact 3 (1)
- Reported clinical features, no. (%): Rash or skin lesions 500 (95), Fever 330 (62), Lymphadenopathy 295 (56), Pharyngitis 113 (21), Headache 145 (27), Lethargy or exhaustion 216 (41), Myalgia 165 (31), Low mood 54 (10), Proctitis or anorectal pain 75 (14)
- Reported clinical features, no. (%): Rash or skin lesions 500 (95), Fever 330 (62), Lymphadenopathy 295 (56), Pharyngitis 113 (21), Headache 145 (27), Lethargy or exhaustion 216 (41), Myalgia 165 (31), Low mood 54 (10), Proctitis or anorectal pain 75 (14)
- Site of skin lesions, no. (%): Anogenital area 383 (73), Face 134 (25), Trunk or limbs 292 (55), Palms or soles 51 (10)
- Site of skin lesions, no. (%): Anogenital area 383 (73), Face 134 (25), Trunk or limbs 292 (55), Palms or soles 51 (10)
- Description of rash, no./total no. with rash reported (%): Vesiculopustular 291/500 (58), Macular 19/500 (4), Single ulcer 54/500 (11), Multiple ulcers 95/500 (19), Other 41/500 (8), No rash 28

Epidemiologic and Clinical Characteristics of Monkeypox Cases: US, 5/17/22-7/22/22

Assessment of Monkeypox using 1,195 case report forms

Summary

What is already known about this topic?

A global monkeypox outbreak began in 2022.

What is added by this report?

Among U.S. monkeypox cases with available data, 99% occurred in men, 94% of whom reported recent male-to-male sexual or close intimate contact; racial and ethnic minority groups appear to be disproportionately affected. Clinical presentations differed from typical monkeypox, with fewer persons experiencing prodrome and more experiencing genital rashes.

What are the implications for public health practice?

Public health efforts should prioritize gay, bisexual, and other men who have sex with men, who are currently disproportionately affected, for prevention and testing, address equity, and minimize stigma, while maintaining vigilance for transmission in other populations. Clinicians should test persons with rash consistent with monkeypox, regardless of whether the rash is disseminated or was preceded by prodrome. FIGURE. Monkeypox cases, by report date* — United States, May 17–July 22, 2022



TABLE 1. Characteristics of persons with monkeypox — United States, May 17–July 22, 2022

Characteristic (no. with available information)	No. (%)*	
Total	1,195 (100)	
Gender identity (1,195)		
Man	1,178 (98.7)	
Transgender man	3 (0.3)	
Woman	5 (0.4)	
Transgender woman	5 (0.4)	
Prefer not to answer	4 (0.3)	
Missing	0 ()	
Race and ethnicity (1,054)		
Asian, non-Hispanic	48 (4.6)	
Black, non-Hispanic	276 (26.2)	
White, non-Hispanic	428 (40.6)	
Hispanic	296 (28.1)	
Multiple races, non-Hispanic	6 (0.6)	
Missing	141	

* Percentages calculated using nonmissing data.

- 42% of persons with monkeypox with available data did not report the typical prodrome as their first symptom, and 46% reported one or more genital lesions during their illness; 41% had HIV infection.
 - Among 358 (30%) men (cisgender and transgender) with information on recent sexual behaviors and gender of sex partners available, 337 (94%) reported sex or close intimate contact with a man during the 3 weeks before symptom onset; 16 (4%) reported no such contact. Among 291 men who reported information about their male sexual partners during the 3 weeks preceding symptom onset, 80 (27%) reported one partner, 113 (40%) reported two to four partners, 42 (14%) reported five to nine partners, and 56 (19%) reported 10 or more partners. Among 86 men with information reported, 33 (38%) reported group sex, defined as sex with more than two persons, at a festival, group sex event, or sex party.

Philpott D, et al. MMWR 5 August 2022

Epidemiologic and Clinical Characteristics of Monkeypox Cases: US, May 17–July 22, 2022, CDC

	Ever experie	enced during illness	* (N = 1,007)	Initially experienced ⁺ (N = 461)		
	No. (%) ⁵			No. (%) ⁵		
Characteristic	Yes	No	No. missing	Yes	No	No. missing
Symptoms						
Rash	1,004 (100.0)	0 (—)	3	121 (41.6)	170 (58.4)	170
Fever	596 (63.3)	345 (36.7)	66	120 (41.2)	171 (58.8)	170
Chills	550 (59.1)	381 (40.9)	76	48 (16.5)	243 (83.5)	170
Lymphadenopathy	545 (58.5)	387 (41.5)	75	23 (7.9)	268 (92.1)	170
Malaise	531 (57.1)	399 (42.9)	77	24 (8.2)	267 (91.8)	170
Myalgia	507 (55)	415 (45)	85	13 (4.5)	278 (95.5)	170
Headache	469 (50.8)	454 (49.2)	84	27 (9.3)	264 (90.7)	170
Rectal pain	201 (21.9)	715 (78.1)	91	0()	291 (100.0)	170
Pus or blood in stools	184 (20.5)	713 (79.5)	110	0()	291 (100.0)	170
Abdominal pain	96 (11.5)	742 (88.5)	169	1 (0.3)	290 (99.7)	170
Rectal bleeding	90 (10.0)	810 (90.0)	107	0()	291 (100.0)	170
Tenesmus	90 (10.0)	809 (90.0)	108	2 (0.7)	289 (99.3)	170
Vomiting or nausea	83 (9.2)	817 (90.8)	107	0()	291 (100.0)	170
Rash sites						
Genitals	333 (46.4)	385 (53.6)	289	214 (55.7)	170 (44.3)	77
Arms	284 (39.6)	434 (60.4)	289	20 (5.2)	364 (94.8)	77
Face	276 (38.4)	442 (61.6)	289	94 (24.5)	290 (75.5)	77
Legs	265 (36.9)	453 (63.1)	289	18 (4.7)	366 (95.3)	77
Perianal	225 (31.3)	493 (68.7)	289	86 (22.4)	298 (77.6)	77
Mouth, lips, or oral mucosa	179 (24.9)	539 (75.1)	289	99 (25.8)	285 (74.2)	77
Palms of hands	157 (21.9)	561 (78.1)	289	13 (3.4)	371 (96.6)	77
Trunk	156 (21.7)	562 (78.3)	289	14 (3.6)	370 (96.4)	77
Neck	130 (18.1)	588 (81.9)	289	33 (8.6)	351 (91.4)	77
Head	97 (13.5)	621 (86.5)	289	8 (2.1)	376 (97.9)	77
Soles of feet	77 (10,7)	641 (89.3)	289	1 (0.3)	383 (99.7)	77

notoms and each among norsens with mankaymay United States May 17 July 22 2022

* Symptoms experienced up until the time of interview.

⁺ Symptoms reported by persons with monkeypox as their first symptoms during their illness or the body location where rash first appeared.

[§] Percentages calculated using nonmissing data.

Rash includes at least one lesion affecting the skin or mucous membranes.

- The most frequently reported signs and symptoms included rash (100%), fever (63%), chills (59%), & lymphadenopathy (59%)
- Among 291 persons with available information about their first symptoms, 58% reported at least one prodromal symptom; for the 42% of patients without prodromal symptoms, illness began with a rash.
- Among 104 persons with information on the number of lesions, 88% of cases involved fewer than 50 lesions.
- Among 339 persons with vaccination status available, 48 (14%) reported previous receipt of smallpox vaccine, including 11 (23%) who received 1 of 2 JYNNEOS doses during the current outbreak (one received 1 vaccine dose >3 weeks prior to symptom onset





CURRENT MONKEYPOX SYMPTOMS

Atypical features of current outbreak

- Presentation of only a few or even just a single lesion
- Absence of skin lesions in some cases, with anal pain and bleeding
- Lesions in the genital or perineal/perianal area which do not spread further
- Lesions appearing at different (asynchronous) stages of development
- The appearance of lesions before the onset of fever, malaise and other constitutional symptoms (absence of prodromal period).

- Novel manifestations of monkeypox are clearly linked to the location of mucocutaneous monkeypox lesions. Nearly all patients reporting peri-anal or rectal lesions reported pain and hospital admission has been required for patients with severe rectal pain with some having radiologically evident proctitis.
- Oropharyngeal symptoms (for example, tonsillitis, peritonsillar cellulitis or peritonsillar abscess or neck lymphadenopathy) have developed in some individuals causing pain or difficulty swallowing. Monkeypox lesions on external genitalia have caused severe swelling and pain and, in some cases, led to the development of paraphimoses. Cutaneous lesions have resulted in secondary bacterial infections of skin and soft tissues (cellulitis).
- Systemic symptoms including fever, lymphadenopathy and myalgia are common but in contrast to current understanding do not always precede mucocutaneous manifestations of monkeypox and approximately 10% of patients did not exhibit any systemic symptoms. Furthermore, 15 individuals (11.3%) have presented with a solitary cutaneous lesion with no subsequent skin lesions.

https://www.gov.uk/government/publications/monkeypox-outbreaktechnical-briefings/investigation-into-monkeypox-outbreak-inengland-technical-briefing-3

MEDICAL COUNTERMEASURES: VACCINE OPTIONS

Name	Indication	Dosing & Administration	Availability	Storage and Handling	Notes
XISO KNOWN AS: Imvamune Imvanex	FDA approved for prevention of smallpox & monkeypox in adults 18+ Individuals <18 can be treated under expanded access IND.	2 doses (0.5 mL each) administered 4 weeks apart. Subcutaneous injection	SNS request; ~ 72,000 doses in SNS and growing	Keep frozen at -25°C to -15°C (- 13°F to +5°F). Once thawed, the vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 8 weeks	Live attenuated virus vaccine; non-replicating modified vaccinia Ankara-Bavarian Nordic (MVA-BN) Ships frozen from SNS Can transport refrigerated for immediate/short term use Single dose vials; SNS does not provide ancillary supplies
<u>ACAM2000</u>	FDA approved for smallpox prevention in adults and pediatrics >1 y.o. Expanded access IND for monkeypox	1 drop of vaccine suspension via scarification using bifurcated needle. <u>CDC Training Videos for ACAM2000</u> <u>administration</u>	SNS Request; > 100 Million doses in SNS	Prior to reconstitution, store frozen at -15°C to -25°C (5°F to -13°F); may also be stored refrigerated at 2°C to 8°C (36°F to 46°F) for up to 18 months. Diluent stored at room temperature of 15°C to 30°C (59°F to 86°F).	Live vaccinia virus Myocarditis risk Contraindications for severe immunocompromise and peds <1. Only administered by trained individuals; previous vaccination recommended Counseling on covering wound and handling bandages 100 doses per vial; comes with diluent and 100 bifurcated needles:

Both options thought to be ~85% effective at preventing monkeypox.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES



transfer syringes not included.

Monkeypox Update: FDA Authorizes Emergency Use of JYNNEOS Vaccine to Increase Vaccine Supply, 9 August

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the JYNNEOS vaccine to allow healthcare providers to use the vaccine by intradermal injection for individuals 18 years of age and older who are determined to be at high risk for monkeypox infection. This will increase the total number of doses available for use by up to five-fold. The EUA also allows for use of the vaccine in individuals younger than 18 years of age determined to be at high risk of monkeypox infection; in these individuals JYNNEOS is administered by subcutaneous injection.

"In recent weeks the monkeypox virus has continued to spread at a rate that has made it clear our current vaccine supply will not meet the current demand," said FDA Commissioner Robert M. Califf, M.D. "The FDA quickly explored other scientifically appropriate options to facilitate access to the vaccine for all impacted individuals. By increasing the number of available doses, more individuals who want to be vaccinated against monkeypox will now have the opportunity to do so."



Comparison of Iyophilized versus liquid modified vaccinia Ankara (MVA) formulations and SC versus ID routes of administration in healthy vaccinia-naïve subjects

- Background: Modified vaccinia Ankara (MVA) is being developed as a safer smallpox vaccine and is being placed in the US Strategic National Stockpile (SNS) as a liquid formulation for subcutaneous (SC) administration at a dose of 1 × 10 8 TCID 50 in a volume of 0.5 mL. This study compared the safety and immunogenicity of the standard formulation, dose and route with both a more stable, lyophilized formulation and with an antigen-sparing intradermal (ID) route of administration.
- Methods: 524 subjects were randomized to receive either a full dose of Lyophilized-SC, a full dose of Liquid-SC or 20% (2×10⁷ TCID 50 in 0.1 mL) of a full dose Liquid-ID MVA on Days 0 and 28. Safety and immunogenicity were followed through 180 days post 2nd vaccination.
- Results: Among the 3 groups, the proportion of subjects with moderate/severe functional local reactions was significantly different (P = 0.0013) between the Lyophilized-SC group (30.3%), the Liquid-SC group (13.8%) and Liquid-ID group (22.0%) only after first vaccination; and for moderate/severe measured erythema and/or induration after any vaccination (P = 0.0001) between the Lyophilized-SC group (58.2%), the Liquid-SC group (58.1%) and the Liquid-ID group (94.8%) and the reactions lasted longer in the Liquid-ID group. In the ID Group, 36.1% of subjects had mild injection site skin discoloration lasting ≥6 months.
- After second vaccination Day (42–208), geometric mean of peak neutralization titers were 87.8, 49.5 and 59.5 for the Lyophilized-SC, Liquid-SC and Liquid-ID groups, respectively, and the maximum number of responders based on peak titer in each group was 142/145 (97.9%), 142/149 (95.3%) and 138/146 (94.5%), respectively. At 180 days after the 2nd vaccination, geometric mean neutralization titers declined to 11.7, 10.2 and 10.4 with only 54.3%, 39.2% and 35.2% of subjects remaining seropositive for the Lyophilized-SC, Liquid-SC and Liquid-ID groups, respectively. Both the Lyophilized-SC and Liquid-ID groups were considered non-inferior (primary objective) to the Liquid-SC group



Comparison of Iyophilized versus liquid modified vaccinia Ankara (MVA) formulations and SC versus ID routes of administration in healthy vaccinia-naïve subjects



Fig. 2. Maximum severity grade for reactogenicity collected by subjects in the Lyophilized-SC, Liquid SC and Liquid-ID groups for 15 days (Days 0–14) after each vaccination. Systemic reactogenicity events were graded using a functional scale of mild (present but easily tolerated), moderate (able to tolerate routine activity) with effort), and severe (unable to continue routine activity). Fever grading scale for oral temperature was mild $\geq 37.8 - 38^\circ$ C, moderate $\geq 38 - 39^\circ$ C, and severe (anable to continue routine activity). Fever is included in the systemic reactogenicity. Local injection site reactogenicity events other than erythema and induration were graded using a functional scale of mild (present but easily tolerated), moderate (able to tolerate routine activity) with effort), and severe (unable to continue routine activity). Local injection site erythema and induration were measured and graded as mild (<15ma), moderate (15-30 mm) or severe (>30 mm). * P<0.05, ** P<0.01.

Table 1a

BN PRNT per protocol population analysis: summary of number and proportion of responders with titers \geq 15, peak geometric mean titers (GMT), and number of subjects with \geq 4-fold rise by vaccination and visit.

Study visit day	Group					
	Lyophilized SC	Liquid SC	Liquid ID			
	Seroconversion, n/N (%) [95% CI]	Seroconversion, n/N (%) [95% CI]	Seroconversion, n/N (%) [95% C1]			
	GMT [95% CI]	GMT [95% CI]	GMT [95% C1]			
	≥4-fold rise n/N (%) [95% CI]	≥4-fold rise n/N (%) [95% CI]	≥4-fold rise n/N (%) [95% C1]			
Day 0 ^a	0/145 (0.0) [0.0, 2.5]	2/149 (1.3) [0.2, 4.8]	2/146 (1.4) [0.2, 4.9]			
	7.5 [,]	7.7 [7.4, 8.0]	7.7 [7.4, 7.9]			
	NA	NA	NA			
Day 14	60/145 (41.4) [33.3, 49.8] [°]	44/149 (29.5) [22.3, 37.5]	56/146 (38.4) [30.4, 46.8]			
	10.9 [9.9, 12.0] ^{№E}	10.0 [9.0, 11.1]	10.3 [9.3, 11.3] ^{NIE}			
	6/145 (4.1) [1.5, 8.8]	3/149 (2.0) [0.4, 5.8]	2/146 (1.4) [0.2, 4.9]			
Day 28 ^h	61/145 (42.1) [33.9, 50.5] [™]	39/149 (26.2) [19.3, 34.0]	68/146 (46.6) [38.3, 55.0]**			
	10.8 [9.9, 11.9] ^{№E}	9.6 [8.7, 10.6]	10.8 [9.9, 11.9] ^{NIE}			
	6/145 (4.1) [1.5, 8.8]	3/149 (2.0) [0.4, 5.8]	2/146 (1.4) [0.2, 4.9]			
Day 42	137/145 (94.5) [89.4, 97.6]	137/148 (92.6) [87.1, 96.2]	134/146 (91.8) [86.1, 95.7]			
	77.6 [62.3, 96.7] ^{NIE}	45.2 [36.4, 56.2]	54.4 [43.7, 67.8] ^{№E}			
	100/145 (69.0) [60.8, 76.4]	70/148 (47.3) [39.0, 55.7]	82/146 (56.2) [47.7, 64.4]			
Day 56	132/144 (91.7) [85.9, 95.6] ^{~~}	117/148 (79.1) [71.6, 85.3]	124/146 (84.9) [78.1, 90.3]			
	39.4 [31.9, 48.6] ^{ME}	23.4 [19.4, 28.3]	33.4 [27.2, 41.0] ^{NIE}			
	63/144 (43.8) [35.5, 52.3]	37/148 (25.0) [18.3, 32.8]	59/146 (40.4) [32.4, 48.8]			
Day 208	75/138 (54.3) [45.7, 62.8] [*]	56/143 (39.2) [31.1, 47.7]	50/142 (35.2) [27.4, 43.7]			
	11.7 [10.7, 12.8] ^{NIE}	10.2 [9.4, 11.0]	10.4 [9.4, 11.5] ^{NIE}			
	5/138 (3.6) [1.2, 8.3]	1/143 (0.7) [0.0, 3.8]	5/142 (3.5) [1.2, 8.0]			
Peak post vaccination 2	142/145 (97.9) [94.1, 99.6]	142/149 (95.3) [90.6, 98.1]	138/146 (94.5) [89.5, 97.6]			
	87.8 [71.2, 108.3] ^{NE}	49.5 [40.0, 61.3]	59.6 [48.1, 74.0] ^{NIE}			
	105/145 (72.4) [64.4, 79.5]	75/149 (50.3) [42.0, 58.6]	86/146 (58.9) [50.5, 67.0]			
Half Life [days]	69	92	77			

NIE: non-inferiority established. PRNT titers ≥15 and <75 were designated a titer of 15 by BN. Titer values of <15 (below limit of detection) were replaced by 7.5 (half the lower limit of detection) for analysis. Seroconversion was defined as PRNT value ≥15.

^a First vaccination.

^b Second vaccination.

⁶ Based on Day 42, 56, and 208. Accuracy of these 3-point estimates was compromised as many Day 208 observations for BN-PRNT were found below the lower limit of detection.

P<0.05.

*** P<0.001.



The effects of PEP smallpox vaccination on clinical disease presentation



Days Post-Exposure

(Percent of References that Reported Efficacious Post-Exposure Vaccination)

Fig. 1.

Post-exposure vaccination window extrapolated from historical epidemiology reports. A review of references that described post-exposure vaccination as providing partial or complete protection from, or attenuation of, smallpox symptoms during disease outbreaks was accomplished. The reported post-exposure vaccination windows were charted (gray bars) by the days post-exposure that efficacious vaccination was administered (black horizontal axis text). The percentage of references that indicated a benefit to post-exposure vaccination prior to each day post-exposure (gray horizontal axis text) were determined.





Ref 49 - MPXV-Macagues (intratracheal) : VACV-Elstree (intracutaneous)

Ref 50 - VACV-WR-BALB/C Mice (respiratory) : VACV-Elstree (scarification)

Ref 50 - VACV-WR-BALB/C Mice (respiratory) : MVA (intramuscular)

Ref 51 - ECTV-C57BL/6 Mice (respiratory) : VACV-Lister (intramuscular)

Ref 51 - ECTV-C57BL/6 Mice (respiratory) : MVA (intramuscular)

- Ref 51 ECTV-BALB/C Mice (respiratory) : VACV-Lister (intradermal tail scarification)
- Ref 51 ECTV-BALB/C Mice (respiratory) : VACV-Lister (intramuscular)
- Ref 51 ECTV-BALB/C Mice (respiratory) : MVA (intramuscular)
- Ref 51 ECTV-C57BL/6 Mice (respiratory) : MVA (intranasal)
- Ref 52 ECTV-C57BL/6 Mice (intranasal) : MVA (intranasal)
- Ref 52 ECTV-C57BL/6 Mice (intranasal) : MVA (intraveneous)
- Ref 53 ECTV-TLR9-/- Mice (respiratory) : MVA (intranasal)

Breakthrough infections after postexposure vaccination against Monkeypox

- Study: Observational analysis of all consecutive individuals vaccinated with IMVANEX[®] vaccine after a high-risk contact defined as close skin-to-skin or mucosal contact and/or indirect contact on textile or surface and/or droplets exposure defined by a contact at less than 2 meters during at least 3 hours with a PCR-confirmed Monkeypox patient.
- Most of the patients were men (91%, n=250) and men who have sex with men (88%, n=233). The vaccine was well tolerated with no severe adverse event. Among the 276 vaccinated individuals, 12 (4%) had a confirmed Monkeypox breakthrough infection with no severe infection. Ten out of 12 patients developed a Monkeypox infection in the five days following vaccination and two had a breakthrough infection at 22 and 25 days.

Thy M, et al. <u>https://doi.org/10.1101/2022.08.03.22278233</u>

Figure 1: Flow chart of early post-exposure vaccination against Monkeypox



Legends: MPX: Monkeypox

*MPX exposure: direct skin-to-skin or mucosal contact including sexual intercourse with a -confirmed monkeypox patient, indirect contact with a confirmed monkeypox patient through fomites (textiles or surfaces) and/or droplets exposure defined by a contact at less than 2 meters during at least 3 hours with a confirmed monkeypox patient

Figure 2: Delay between exposure, vaccination and confirmed Monkeypox infection in the 12 breakthrough infections



Legend: *Patient 6: Direct inoculation with a percutaneous needlestick

MONKEYPOX: INFECTION CONTROL IN HEALTHCARE SETTINGS

Summary of Changes (See: https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-healthcare.html)

- Added recommendations on how to monitor exposed patients and when they should be isolated.
- Added recommendations for assessing the risk of healthcare personnel (HCP) with monkeypox virus exposures, including how to monitor HCP and when to apply work restrictions. Updated the risk assessment table for HCP (see Table).
- Moved the entry addressing HCP wearing all recommended PPE from the low/uncertain category in the table to the table's preamble and described why self-monitoring remains recommended for these HCP.
- Changed intact skin contact with potentially infectious materials or surfaces from higher risk to intermediate risk
- Infection prevention and control personnel should be notified immediately of Monkeypox patients.
- A patient with suspected or confirmed monkeypox infection should be placed in a single-person room; special air handling is not required.
- Intubation, extubation, and any procedures likely to spread oral secretions should be performed in an airborne infection isolation room.
- Standard cleaning and disinfection procedures should be performed using an EPA-registered hospital-grade disinfectant with an emerging viral pathogen claim. Activities such as dry dusting, sweeping, or vacuuming should be avoided.
- To date, there have been no cases of Monkeypox transmitted by blood transfusion, organ transplantation, or implantation, transplantation, infusion, or transfer of human cells, tissues, or cellular or tissue-based products (HCT/Ps).
- Visitors to patients with monkeypox infection should be limited to those essential for the patient's care and wellbeing





- CDC. Isolation and Prevention Practices for People with Monkeypox. <u>https://www.cdc.gov/poxvirus/monkeypox/clinicians/isolation-procedures.html</u>
- CDC. Clinical Recognition. <u>https://www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html</u>
- CDC. Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during 2022 U.S. Monkeypox Cases. <u>https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html</u>
- CDC. Safer Sex, Social Gatherings, and Monkeypox. <u>https://www.cdc.gov/poxvirus/monkeypox/sexualhealth/index.html</u>
- CDC. Clinical Considerations for Monkeypox in People Who are Pregnant or Breastfeeding. https://www.cdc.gov/poxvirus/monkeypox/clinicians/pregnancy.html
- UNC-MC Monkeypox policies and guidelines: <u>https://uncmedicalcenter.intranet.unchealthcare.org/dept/Epidemiology/Pages/Monkeypox.aspx</u>
- UNC-Health Monkeypox guidelines: https://unchcs.intranet.unchealthcare.org/Pages/Monkeypox.aspx



Monkeypox in Children

So Many Questions

How many cases are there?

Who should we test?

What about post-exposure prophylaxis?

How are we going to manage exposures

in schools and daycare?



This Photo by Unknown Author is licensed under <u>CC BY-SA-NC</u>





Global Monkeypox Outbreak, 2022

Data in Children are Sparse



Analysis of 19305 total cases 0-17 years = 102 0-4 years = 26

https://worldhealthorg.shinyapps.io/mpx_global/

https://ourworldindata.org/monkeypox





First Pediatric Cases of Monkeypox in U.S.

2 cases

Washington, DC California Likely household exposure









INDIANAPOLIS—The Indiana Department of Health (IDOH) announced today that a total of 45 monkeypox cases have been reported across the state between June 18 and July 28, including two pediatric cases. No additional information about the cases will be released at this time due to patient privacy.





LONGBEACH

PRESS RELEASE



City of Long Beach Public Information Office 411 W. Ocean Blvd. Long Beach, CA 90802

8/2/2022

FOR IMMEDIATE RELEASE

Press Release # 080222-2

Subject: Long Beach Announces Pediatric Case of Monkeypox

Contact: Jennifer Rice Epstein 562.441.3590 Jennifer.RiceEpstein@longbeach.gov **Public Affairs Officer** Department of Health and Human Services

Long Beach, CA - The Long Beach Department of Health and Human Services (Health Department) has confirmed a presumptive case of monkeypox infection in a pediatric resident of Long Beach. Preliminary test results indicate that the child has tested positive for orthopoxvirus. Additional testing will be performed at the Centers for Disease Control (CDC) to confirm monkeypox. Given the positive test result, the Health Department is conducting an extensive contact investigation and offering vaccine to people who may have been exposed in order to prevent additional cases. The child was symptomatic but is now recovered.

This is a reminder that everyone, regardless of age or sexual orientation, can get monkeypox if they come into contact with the virus. This is a reminder that everyone, regardless of age or sexual orientation, can get monkeypox if they come into contact with the virus. Monkeypox can spread through close or prolonged skin-to-skin or face-to-face contact, including between household members. This can include hugging, kissing, cuddling, holding and feeding. It can also spread through contaminated materials, such as cups, bedding, clothing, towels and utensils. People with monkeypox isolating at

Monkeypox Data in California

Data are updated on Tuesdays and Thursdays. Last updated August 11, 2022.

Number of reported probable and confirmed monkeypox cases in California

Statewide Cases	Hospital
1,945	Yes
	No
	Missing/
	Age Grou
	Under 18
	18-24

122			
No	1,321	96.5	
Missing/Unknown	576	÷	
Age Group		Percent*	
Under 18 years	4	0.2	
18-24	116	6.0	
25-34	710	36.5	
35-44	682	35.1	
45-54	285	14.7	
55-64	128	6.6	
65 years and older	20	1.0	
Unknown		1200-00	

Percent*

35

48

ized

N







Clinical Considerations for Monkeypox in Children and Adolescents

Updated July 26, 2022 Print

Who this is for: Healthcare providers caring for children and adolescents less than ages 18 years in clinics, emergency departments, and hospitals in the United States.

What this is for: Considerations on clinical management of children and adolescents less than ages 18 years with exposure to monkeypox or concern for *Monkeypox virus* infection.

How to use: These considerations are intended to help U.S. clinicians and health systems develop a plan for managing children and adolescents with exposure to monkeypox, suspected monkeypox, or confirmed monkeypox.





Which Children Need Tested?

"Monkeypox should be considered when children or adolescents present with a <u>rash that could be</u> <u>consistent</u> with the disease, especially if <u>epidemiologic criteria</u> are present."

Monkeypox rash might look like

- Varicella
- Hand, foot and mouth disease
- Molluscum
- Allergic rashes (poison ivy!)

"Use clinical judgement"

https://www.cdc.gov/poxvirus/monkeypox/clinicians/pediatric.html





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Recommendations for Healthcare Providers on Diagnostic Testing

The public health response to monkeypox depends on timely and comprehensive laboratory testing and reporting of those results. Tests should be performed on persons for whom monkeypox is suspected based on clinical presentation and <u>epidemiologic criteria</u>. Positive diagnostic results from testing of skin lesion material for *Orthopoxvirus* or *Monkeypox virus* DNA in persons without epidemiologic criteria or known risk factors should be verified through repeat testing and/or confirmatory testing.

If there are no identified epidemiologic risk criteria for monkeypox infection, other possible causes of rash in adults should be considered, including secondary syphilis, herpes, and varicella zoster. In children without identified epidemiologic risk criteria for monkeypox, varicella zoster and molluscum contagiosum (MC) should be considered in the differential diagnosis. MC is an infection caused by a poxvirus (molluscum contagiosum virus) that is diagnosed more often in children than in adults. MC infection is usually a benign, mild skin disease characterized by lesions that may appear anywhere on the body. CDC's FDA-cleared non-variola virus test used within the Laboratory Response Network laboratories and most commercial laboratories, does not cross-react with molluscum contagiosum virus. In children and adolescents, as in adults, other potential etiologies of illness should be tested for in parallel with or before *Monkeypox virus* testing, based on clinical presentation and epidemiologic criteria.

https://emergency.cdc.gov/han/2022/han00471.asp





Monkeypox, Netherlands

10-year-old boy with no known exposures









Produced from live attenuated, non-replicating orthopox virus

Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN)

Expanded use authorization for subcutaneous use in children < 18 years No minimum age or weight per EUA

8.4 Pediatric Use

The safety and effectiveness of JYNNEOS have not been assessed in individuals less than 18 years of age. The FDA has granted an EUA for the emergency use of JYNNEOS for active immunization by subcutaneous injection for prevention of monkeypox disease in individuals less than 18 years of age determined to be at high risk for monkeypox infection. This authorization is based on safety and effectiveness data from clinical trials in adults and efficacy data from animal challenge studies and historical data with use of live vaccinia virus smallpox vaccine in pediatric populations.





Phase II study of measles MVA-mBN85B

Recombinant MVA-mBN85B expresses the F (fusion protein), H (hemagglutinin) and N (nucleoprotein) coding regions of the measles virus

Healthy children aged 6 months to 6 years

Investigational vaccine = 60

Controls =30

Vaccine safe and well tolerated

No SAEs





Mvabea (MVA-BN-Filo) is indicated for prevention of Ebola virus (Zaire ebolavirus species) disease

Safe and well-tolerated in individuals 1-17 years

Pain at infection site in 21%

Fatigue in 11%

Fever less common that in placebo group in young children

1-3 years of age (8%)

4-11 years of age (4%)

Reactions mild to moderate and last 1-3 days





Early bathing

Separation of person with monkeypox from newborn

If parent declines separation

No direct skin-to-skin contact

Newborn is fully clothed or swaddled

After contact, clothing or blanket should is removed and replaced

Infected person dons gloves and a fresh gown; all visible skin below the neck covered

Soiled linens should be removed from the area

Parent wears well-fitting source control (e.g. medical mask) during visit

Pump and discard breastmilk during infectious period

Isolate for 21 days

Post-exposure prophylaxis

Particularly for infants under 6 months of age, vaccinia immune globulin is alternative PEP modality



