Monkeypox Outbreak 2022 Epidemiology, Clinical Presentation, Treatment, & Prevention

Tristan McPherson, MD
Health Systems Support Branch, Therapeutics
Medical Director, Viral Hepatitis
New York City Department of Health and Mental Hygiene
August 18, 2022

The information presented is based on current knowledge and is subject to change.



Objectives

At the conclusion of this presentation, participants will be able to:

- •Describe the epidemiology of the 2022 monkeypox outbreak, with a focus on New York City
- •Recognize the most common clinical presentations of monkeypox infections in the 2022 outbreak
- •Identify the indications for treatment of monkeypox infections and understand the regulatory process for accessing these medications
- Summarize clinical and public health resources available for monkeypox testing and vaccination



Background and current outbreak



Background

- Monkeypox is a previously uncommon zoonotic disease caused by the monkeypox virus, an Orthopoxvirus
- Historically human cases limited to central and western African countries
- Prior to the 2022 global outbreak, nearly all human monkeypox cases outside of Africa were linked to international travel to central and western Africa, or animals imported from west Africa
 - U.S. 2003: 47 human cases from contact with infected pet prairie dogs housed near rodents from Ghana. This was the first time human monkeypox was reported outside of Africa
 - U.S. 2021: Two travel-associated cases among residents of Texas and Maryland infected while visiting Nigeria



Current Outbreak

- Since May of 2022, sustained person-to-person transmission in multiple countries including the US
- At this time, primarily among men who identify as gay, bisexual, and other men who have sex with men
- Transmission occurring through prolonged direct contact, including sexual and intimate encounters

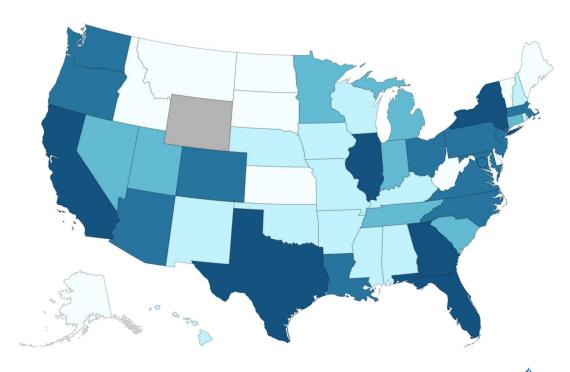


SITUATION REPORT IN NEW YORK STATE As of August 17, 2022

NEW YORK STATE - 2,675 CASES

- 2483 in New York City
- 67 in Westchester County
- 39 in Suffolk County
- 27 in Nassau County
- 8 in Erie County
- 8 in Orange County
- 7 in Dutchess County
- 7 in Monroe County
- 6 in Rockland County
- 3 in Albany County
- 3 in Sullivan County
- 3 in Tompkins County
- 2 in Columbia County
- 2 in Ulster County
- 1 each in Broome, Chemung, Greene,
 Niagara, Onondaga, Putnam, Schenectady,
 Seneca, St. Lawrence, and Tioga Counties

U.S. - 12,689 CASES*











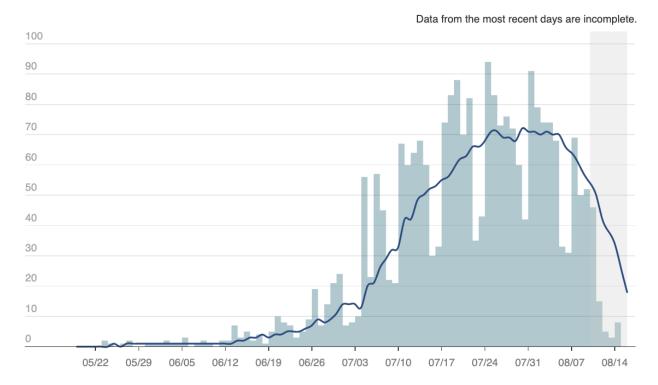
Cases of Monkeypox by Date of Diagnosis, NYC

• Total Cases: 2,483 (as of August 17)

Daily New Cases

This chart shows the number of monkeypox cases that have been diagnosed each day since the NYC outbreak began in June.

The below data will be updated every weekday.



Data updated each weekday at 10 a.m.

NYC Demographic Data As of August 11, 2022 (N = 1,989 cases)

,	,	•
Borough	Bronx	310
	Brooklyn	472
	Manhattan	917
	Queens	276
	Staten Island	13
	Unknown	2
Age	0-17	0
	18-24	101
	25-34	833
	35-44	733
	45-54	239
	55-64	76
	65-74	5
	75-84	1
	85 plus	0
	Unknown	1
Gender	Men	1,938
	Transgender/Non-binary	32
	Women	11
	Unknown	8

Race/Ethnicity	Asian or Pacific Islander	74
	Black	498
	Hispanic	595
	White	550
	Other	19
	Missing	253
Sexual Orientation	LGBQ+	1,392
	Straight	77
	Unknown	520
Citywide		1,989

Updated: August 11 at 10 a.m.

Unknown = missing or pending case investigation



Clinical presentation



Clinical Presentation

- Current cases have atypical features
- Rash still characteristic; but often starting in genital and perianal areas or orally
 - Depending on when patient presents, progression of lesions may not appear characteristic, especially if lesions are in the early stages
 - Sometimes not disseminating to other parts of body and lesions may be in different stages
 - Location likely reflective of points of contact
- Proctitis may be initial complaint
- Prodromal symptoms
 - May be mild, not present, not detected or appear after rash
 - Fever, headache, myalgia, lymphadenopathy, night sweats, chills













Photo credit: UK Health Security Agency



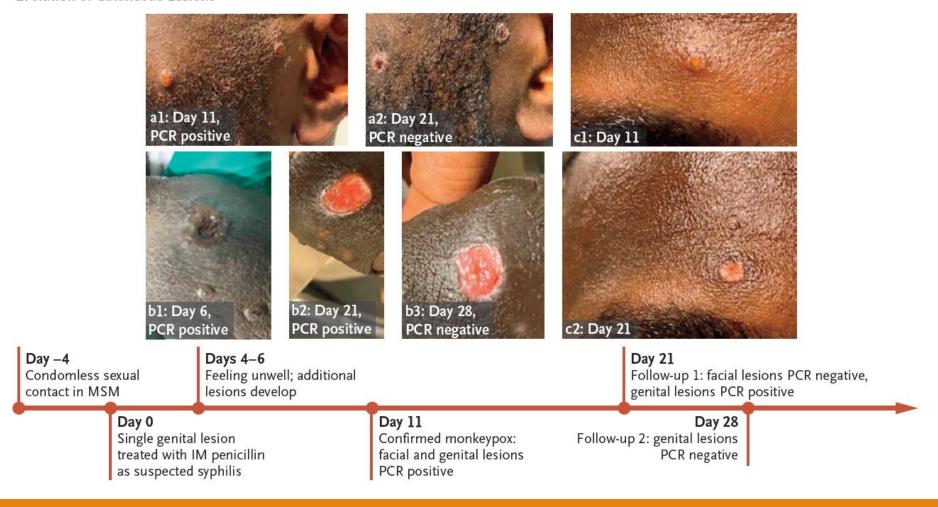
- 98% gay or bisexual men, median age 38 years, 75% White, 41% with HIV
- Sexual activity presumed route of transmission for most (95%)
- Rash in 95%
- 64% <10 lesions, 73% anogenital lesions, 41% mucosal lesions, 54 (%) single genital lesion
- Systemic features preceding rash included
- Fever (62%), lethargy (41%), myalgia (31%), headache (27%) and lymphadenopathy (56%)
- Concomitant sexually transmitted infections for 29%
- Among 23 patients with clear exposure history, median incubation 7 days (range 3 to 20 days)



- Antiviral treatment given to 5% of patients
- Hospitalization for 70 (13%) for
 - 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).
- Monkeypox viral DNA detected in semen of 29 of 32 patients



Evolution of Cutaneous Lesions

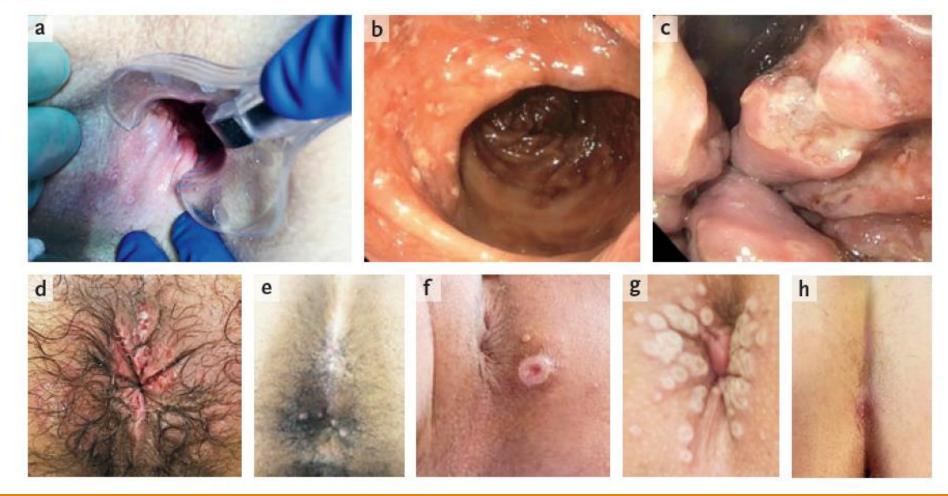








Perianal, Anal, and Rectal Lesions



Clinical Presentation

- Most individuals have a self-limited disease course managed with supportive care
- This includes medicines or other clinical interventions to control itching, nausea, vomiting, and pain
- Some lesions can be extremely painful and can cause scarring
- Proctitis can progress to become severe and debilitating which may require prescription medication
- Complications can include pneumonitis, encephalitis, sightthreatening keratitis, and secondary bacterial infections, strictures due to scarring particularly anogenital tissue



Testing



Updates on Testing

- Submit specimens through commercial laboratories if possible
 - Testing for NY residents now available at 5 commercial laboratories
 - <u>LabCorp</u>, <u>Mayo Clinic Laboratories</u>, <u>Aegis Science</u>, <u>Sonic Healthcare</u>, <u>Quest Diagnostics</u>
 - NYS and NYC Public Health Laboratories continue to offer testing for State and City residents with expanded capacity



How to Test

- ALWAYS refer to individual lab websites for lab-specific specimen collection and submission criteria, which may differ
 - Typical specimen is a swab of a lesion or lesions
 - Package specimens correctly
 - Appropriate identifiers on specimen containers
 - Remember some labs require DRY swabs and others may accept specimens in VTM





Monkeypox viral DNA Detection Bodily Fluids and Mucosal Sites

- •12 MSM patients, with a median age of 38.5, four people living with HIV with undetectable viral load
- •Additional bodily fluid and mucosal tissues swab specimens collected at time of diagnosis with active monkeypox infection
- Monkeypox viral DNA detected in multiple specimens
 - Saliva (12/12), rectal swabs (11/12), nasopharyngeal swabs (10/12), semen (7/9), urine (9/12) and feces 8/12)
- Detection of viral DNA does not equate to infectious virus
- Similar findings from previous study by Italian researchers
- Authors suggest possibility of transmission through sexual fluids or saliva and recommend more research



Management and Treatment



Updated Interim NYC Guidance for Treatment of Monkeypox

- Released July 2, 2022; updated August 2, 2022
 - https://www1.nyc.gov/assets/doh/downloads/pdf/cd/monkeypox-treatment-guidance-interim.pdf
- Provides instruction on supportive care and symptom treatment for providers
- Elaborates on clinical indications in which treatment with tecovirimat might be considered
- Revised step by step instructions for prescribing or obtaining tecovirimat for patients in NYC



Treatment

Skin lesions

- Keep clean and dry when not showering or bathing to prevent bacterial superinfection
- Pruritus managed with oral antihistamines and inert, anti-irritant topical agents such as calamine lotion or petroleum jelly

Oral lesions

- Compounds such "magic" or "miracle" mouthwashes (prescription solutions used to treat mucositis) to manage pain
- Oral antiseptics to keep lesions clean (e.g., chlorhexidine mouthwash)
- Topical benzocaine/lidocaine gels for temporary relief, especially to facilitate eating and drinking, but limit to recommended doses



Treatment

- Nausea and vomiting
 - Anti-emetics as appropriate

- Diarrhea
 - Managed with appropriate hydration and electrolyte replacement
 - Anti-motility agents not generally recommended given the potential for ileus



Treatment

- Proctitis can occur with or without internal or external lesions
 - May be manageable with appropriate supportive care
 - Can progress to become severe and debilitating
 - Stool softeners such as docusate should be initiated early.
 - Sitz baths may calm inflammation
 - Over the counter pain medications such as acetaminophen or NSAIDs
- Pain from proctitis may require prescription medications
 - Balance use with the possibility of side effects, like constipation
- Proctitis may be accompanied by rectal bleeding
 - Observed to be self-limited but should be evaluated by a healthcare provider



Tecovirimat for Treatment

- Tecovirimat (TPOXX) is an antiviral medication approved by FDA to treat smallpox disease
 - Oral capsule and IV formulations
 - Can be given on outpatient basis
- CDC-held Emergency Access Investigational New Drug (IND)
 Protocol allows use of tecovirimat for primary or early empiric treatment of monkeypox in people of all ages
- Available through the NYC or NYS Health Departments to any prescriber able to complete components of the IND



Tecovirimat for Treatment - When to Consider

Severe disease

• E.g., hemorrhagic disease, sepsis, encephalitis

Lesion location or type

 Confluent lesions, or lesions in anatomical areas at special risk of scarring or stricture, such as those near or directly involving the eye, mouth, rectum, or urethra





Tecovirimat for Treatment - When to Consider

- Complications
 - e.g., proctitis (particularly with tenesmus, challenges in pain control, or rectal bleeding)

- High risk of severe disease
 - Immunocompromised, pediatric populations, history or presence of atopic dermatitis or other active exfoliative skin conditions and pregnant or breastfeeding people





Tecovirimat - NYC Experience

Experience in NYC to date:

- More than 30% meet criteria for tecovirimat
- Most common indication is severe proctitis
 - Other indications include painful anal or penile lesions, bacterial superinfection, painful oral lesions
- Prescribed for over 750 patients
- Significant improvement reported after just a few days of starting treatment
- No significant adverse events reported
 - Some reports of headache and nausea



Tecovirimat - How to obtain Treatment

- The CDC's IND protocol was recently simplified to make it easier for any provider to prescribe tecovirimat
 - Allows the use of telemedicine for all patient encounters (initial and follow-up visits) as long as the patient can submit the signed consent form electronically.
 - Treatment with tecovirimat can begin upon receipt of the medication and after obtaining informed consent. No pre-registration is required for clinicians or facilities.
 - Fewer forms are required under the IND, and they can all be returned to CDC after treatment begins.





Prescribing Tecovirimat

- Revised overview and step by step instructions for prescribing or obtaining tecovirimat for patients in NYC
 - https://www1.nyc.gov/assets/doh/downloads/pdf/cd/monkeypoxtreatment-guidance-interim.pdf
 - Health Advisory #16: Accessing Tecovirimat for People with Monkeypox
- Obtaining tecovirimat for patients in New York State



2022 Health Advisory #16: Accessing Tecovirimat for People with Monkeypox

- Many people with monkeypox in New York City (NYC) have developed complications including proctitis, which can progress to become severe and debilitating, and lesions in anatomical sites at risk of scarring or other permanent sequelae. Supportive care, including pain control, is a mainstay of treatment.
- Tecovirimat (TPOXX) is an antiviral medication available through the Centers for Diseast Control and Prevention (CDC) that is being used to treat monkeypox infection under <u>CDC's Expanded Access Investigational New Drug (IND) protocol</u>. To date, tecovirimat has been prescribed for over 400 patients in NYC.
- Recently the FDA and CDC simplified this protocol so that treatment with tecovirima
 can begin upon obtaining <u>informed consent</u> from the patient. No pre-registration is
 required and evaluations can be done by telemedicine. Additional forms must be
 submitted to CDC after initiating treatment.
- Providers are urged to take the necessary steps to prescribe tecovirimat when indicated
 for the patients that have a positive test result (or are awaiting test results and have a
 clinically compatible illness). NYC providers who want to prescribe tecovirimat and can
 adhere to the IND protocol can email MPXtherapeutic@health.nvc.gov for information
 on free delivery to patients or to request supplies for a pharmacy at their facility.
- For more information about monkeypox, visit the NYC Department of Health and Mental Hygiene's Monkeypox Information for Providers webpage.

August 2, 202

Dear Colleagues,

The number of people diagnosed with monkeypox continues to rise in New York City (NVC), the US and other countries, On July 23, 2022, the World Health Organization declared MPX a Public Health Emergency of International Concern; on July 28, the New York State Department of Health declared monkeypox an Imminent Threat to Public Health and, on July 29, the State declared a <u>State Disaster Emergency</u>; and on July 30, the NYC Department of Health and Mental Hygiene (Health Department) declared monkeypox a <u>Public Health Emergency</u>, and on August 1, the City declared a <u>State of Emergency</u>.



Tecovirimat - Prescribing in NYC

- •In NYC, to prescribe tecovirimat
 - First obtain the <u>Informed Consent Form</u>
 - Then email the NYC Health Department at MPXtherapeutics@health.nyc.gov to receive an automated reply with instructions including how to arrange to have individual prescriptions delivered to the patient by the NYC pharmacy courier service.
 - Complete and submit to CDC the required <u>Patient Intake Form</u> and <u>FDA Form</u>
 1572 Enrollment Form
 - Conduct two follow-up visits and submit the required <u>Clinical Outcome Forms</u> to CDC
 - Report life-threatening or serious adverse events associated with tecovirimat



Clinical Considerations for Treatment and Prophylaxis in People with HIV

- Unknown if people with HIV have different incubation or prodromal phase of illness
 - Two historical case series found no difference in patients with HIV compared to those without HIV
- European countries where most patients are on antiretroviral treatment (ART)
 have noted no deaths or excess hospitalizations thus far among monkeypox
 patients with HIV
- Patients with advanced or uncontrolled HIV may have a higher risk for more severe or prolonged disease
- Vaccination, medical treatment and close monitoring are a priority
 - Patients taking ART should continue treatment; if not they may start ART
 - Patients can receive tecovirimat, though some <u>interactions with ART</u> may occur
 - Patients can receive JYNNEOS vaccine



Clinical Considerations for People Who are Pregnant or Breast/Chest feeding

- It is unknown if pregnant people are more susceptible to monkeypox virus or if infection is more severe in pregnancy. However, smallpox, also an orthopoxvirus, was associated with more severe illness during pregnancy, including hemorrhagic complications and death.
- Adverse pregnancy outcomes, including spontaneous pregnancy loss and stillbirth, have been reported in cases of confirmed monkeypox infection during pregnancy
- Monkeypox virus can be transmitted to the fetus during pregnancy or to the newborn by close contact during and after birth
- Must separate baby from parent to prevent transmission
- Breast feeding may be delayed unknown if virus is present in breast milk



Clinical Considerations for People Who are Pregnant or Breast/Chest feeding

- Can treat with tecovirimat though with limited data in pregnancy
- Reach out to LHD if encounter a case in pregnancy
- No fetal effects seen at high doses in animal studies
- Seen in breast milk at high doses in animal studies
 - Levels in breast milk may not treat infant for monkeypox
- Can receive vaccine
 - Animal studies show no effects on pregnancy no human data



Clinical Considerations for Monkeypox in Children and Adolescents

- Disease is usually mild and self limited but can be severe
 - Especially in those with history of dermatitis or exfoliative skin conditions
 - Under the age of 8 years
 - Immunocompromised
- Keep skin lesions covered and prevent children from scratching lesions or touching their eyes may result in auto-inoculation
 - Optimal fluid intake should be encouraged, particularly with extensive skin involvement causing additional fluid losses
- Can treat with tecovirimat though should monitor kidney function
- Vaccine is now available for those age <18 yo under Emergency Use Authorization (EUA)



Prevention and Vaccination



Prevention

- Avoid sex and other intimate contact with multiple or anonymous partners.
- If someone does have sex or other intimate contact, the following can help reduce risk:
 - Reduced number of partners, especially those that or anonymous or whose recent sexual history is unknown.
 - Ask partners if they have monkeypox symptoms or feel sick. If person or partners are sick, especially if they have a new or unexpected rash or sore, do not have sex or close physical contact.
 - Avoid sex parties, circuit parties and other spaces where people are having sex and other intimate contact with multiple people.
 - If someone does have sex or other intimate contact while sick, they should cover all rashes and sores with clothing or sealed bandages. This might reduce spread from contact with the rash or sores, but other methods of transmission might still be possible.
 - Since it may be possible the virus can be transmitted through semen, use latex condoms during sex.
- Do not share towels, clothing, fetish gear, sex toys or toothbrushes.
- Wash hands, fetish gear and bedding. Sex toys should be washed after each use or sex act.



Vaccination

- The JYNNEOSTM vaccine is licensed by the U.S. Food and Drug Administration as a 2 dose-series for the prevention of monkeypox in people ages 18 and older with EUA for those <18.
- Not indicated for people who have been previously diagnosed with monkeypox, or have active symptoms that may be due to monkeypox
- No real-world data on how well JYNNEOS protects people from monkeypox or how well the vaccine will prevent monkeypox in the current outbreak
- Remind patients who are vaccinated to continue other prevention measures such as avoiding sex and other close physical contact with people who have symptoms of monkeypox, or if they develop symptoms of monkeypox



Vaccination

- Available for post-exposure prophylaxis (PEP) following a recent exposure to a person with monkeypox
- CDC recommends PEP within 4 days from the exposure to prevent disease; if given between 4-14 days after the exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease
- Two PEP strategies:
 - Known contact of a suspected or confirmed monkeypox case
 - Arranged by the Health Department
 - Expanded PEP (PEP++) for persons who are not a known contact but may be at greater risk for recent exposure based on behavioral/epidemiological criteria
 - Offered by appointment at vaccine clinics



NYC Health Department Vaccine Clinics - PEP++

- Goal of PEP++
 - Reduce number of people with severe illness
 - Interrupt ongoing transmission
- Due to the rapid increase in cases and limited supply of vaccine, the Health Department has prioritized first doses for PEP++ so more people receive some protection
- This single-dose strategy is consistent with the monkeypox vaccine strategy in the UK and Canada, and based on the available scientific evidence
- Once supply increases, the Health Department will contact people who received first dose to schedule a second dose appointment
- The delay of the second dose should not affect the immune response to the second dose



Health Department Vaccine Clinics - PEP++

- People age 18 or older who meet all of the following criteria are eligible to get vaccinated at a Health Department clinic:
 - Gay, bisexual, or other man who has sex with men, and/or transgender, gender nonconforming, or gender non-binary
 - Have had multiple or anonymous sex partners in the last 14 days
 - Do not have symptoms of monkeypox, or were not diagnosed with monkeypox
- People should especially consider vaccination if:
 - Their partners are showing symptoms of monkeypox
 - They met recent partners through online applications or social media platforms (such as Grinder, Tinder or Scruff), or at clubs, raves, sex parties, saunas or other large gatherings
 - They have a condition that may increase their risk for severe disease



Resources



NYC Health Department Resources

Show your pride!
Stay healthy and keep your community safe.
The monkeypox information you need to know right now.

Ver esta página en español

Monkeypox (Orthopoxvirus)

Cases in NYC

As of June 23, 30 people in New York City have tested positive for orthopoxvirus. likely monkeypox.

Most of these people have had mild illness, have not been hospitalized and have their own. Even with mild illness, the rash and sores from monkeypox can be itch

Anyone can get and spread monkeypox. The current cases social networks of gay, bisexual and other men who have se currently at greater risk of exposure.

If you have a new or unexpected rash or other <u>symptoms of</u> provider.

Vaccination

Vaccination is available for people who may have been rece Eligible people can get the two-dose vaccine at the Chelsea Tuesday, Thursday, Friday and Sunday, between 11 a.m. an recommended

Note: All vaccination appointment slots have been filled thro Unfortunately, walk-in vaccinations will also not be available additional supply from the CDC to meet the high demand. C appointments for the following week.

Learn more about vaccination eligibility and how to make an

Monkeypox Outbreak Palm Card (PDF)
 Other Languages: Español

¡Manténgase sano para un verano de diversión!

Obtenga la información sobre la

e necesita saber la vacunación ara usted.

información, h/monkeypox, e el código QR.

Get the monkeypox information you need to know now, and find out if vaccination is right for your

MAC

you need to know now, and find out if vaccination is right for you.

Stay healthy for

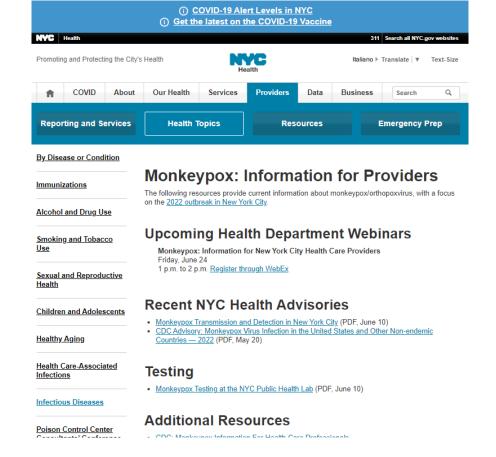
a summer of fun!

For more information, visit nyc.gov/health/monkeypox, call 311 or scan the QR code.



6.21.22

MAC



nyc.gov/monkeypox

https://www1.nyc.gov/site/doh/providers/health-topics/monkeypox.page



THANK YOU



Managing People with Suspected or Confirmed Monkeypox

- Patients awaiting test results should isolate in a room or area separate from other household members and pets.
 - If the result is negative, they can discontinue isolation.
 - If the result is positive, they must continue to isolate until all lesions have resolved, the scabs have fallen off, and a fresh layer of intact skin has formed.
- While isolating patients should:
 - Stay at home as much as possible and avoid nonessential visitors in the home.
 - Do not engage in physical sexual activity with others.
 - If leaving the home (e.g., for medical care or for physical activity), maintain a safe distance from others, cover up all skin lesions, and wear a well-fitting surgical mask.
 - Detailed home isolation guidance can be found on the CDC Clinician FAQ webpage under question 10 "When a patient is isolating in their home, what should they do?"



Management of Contacts

- People with a high or intermediate exposure risk (e.g., sexual or close physical contact):
 - Daily symptom monitoring for 21 days from the date of the last exposure
 - Postexposure prophylaxis vaccination arranged through the Health Department
- People with a low exposure risk:
 - Daily symptom self-monitoring for 21 days from the date of the last exposure



Infection Control

- Apply standard precautions for all patient care, including for patients with suspected monkeypox
- Place patients with suspected or confirmed monkeypox infection in a single-person room special air handling is not required
- Keep door closed if safe to do so
- Health care workers who enter the patient's room should use gown, gloves, eye protection (i.e., goggles or a face shield that covers the front and sides of the face) and a respirator (e.g., N95 or higher)
- Perform procedures likely to spread oral secretions in an airborne infection isolation room
- Standard cleaning and disinfection procedures should be done using an EPA-registered hospital-grade disinfectant with an emerging viral pathogen claim



Health Care Workers and Monkeypox

- PrEP not routinely recommended for health care workers who care for patients with, or suspected to have, monkeypox
- Among the cases identified in the US to date, none have been heath care workers exposed in a health care setting
- Appropriate PPE will protect HCWs from potential exposures,
- Healthcare providers exposed to a person with monkeypox patient should stay alert for symptoms, especially within the 21-day period after the last date of care
- Notify Infection control, occupational health



Public Health Response

- Ample testing capacity at 5 commercial labs that can test >50,000 specimens weekly
 - <u>LabCorp</u>, <u>Mayo</u>, <u>Aegis Science</u>, <u>Sonic Healthcare</u> and <u>Quest</u>
- Testing for Orthopoxvirus at Wadsworth Center (and NYC PHL)
 - Positive results = probable cases presumed to be monkeypox
 - Then may be then confirmed monkeypox by CDC testing
 - Rapid review of additional tests to expand provider testing capacity
 - Wadsworth has additional capacity as well with prior DOH approval
- Supporting local health departments with tools and consultation for case investigation and contact tracing/monitoring



Updates on Testing – NYC Public Health Laboratory

- Submit specimens through commercial laboratories when possible
- Continues to offer testing for NYC residents
- •Soon will be accepting swabs stored in viral transport media (VTM) in addition to dry swabs. An announcement will be sent via the eOrder application
- •Courier services will not be available starting August 19. Providers and facilities will need to arrange their own transportation of specimens for monkeypox testing to PHL



Clinical Presentation

- Infectious once symptoms begin (whether prodromal or rash symptoms) and isolation precautions should be continued until all lesions have resolved, the scabs have fallen off, and a fresh layer of intact skin has formed
 - Typically, 2-4 weeks
- May be confused with sexually transmitted infections (STI) or other conditions, however the diagnosis of an STI does not exclude monkeypox as a concurrent infection may be present



Summary of 197 Monkeypox Patients From London

Systemic illness reported among 86.3%, most common symptoms were; fever (61.9%), lymphadenopathy (57.9%), and myalgia (31.5%)

- 61.5% developed systemic features before the onset of mucocutaneous manifestations
- 38.5% after
- 13.7% at the same time

Other complaints included rectal pain (36.0%), sore throat (16.8%), penile edema (15.7%), oral lesions (13.7%) and tonsillar signs (4.6%)

31.5% of patients had a concomitant sexually transmitted infection

Hospitalization for 10.2% of patients, primarily for management of symptoms

most commonly rectal pain and penile swelling

