CDC/IDSA Clinician Call

July 23, 2022

Welcome & Introductions

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Vice President, Clinical Affairs & Guidelines
Infectious Diseases Society of America

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Professor of Medicine
Harvard Medical School
Director of HIV Clinical Svcs & Education, Massachusetts General Hospital
Past Chair, HIVMA

- 90th in a series of calls, initiated in 2020 as a forum for information sharing among frontline clinicians caring for patients with COVID-19.
- The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.
- This webinar is being recorded and can be found online at www.idsociety.org/cliniciancalls.

Monkeypox: Updates on Testing, Vaccination & Treatment

SITUATION UPDATE

John T. Brooks, MD
Chief Medical Officer
Monkeypox Response
U.S. Centers for Disease Control and Prevention

DIAGNOSTICS & TESTING

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Chief Medical Officer
Monkeypox Response
U.S. Centers for Disease Control and Prevention

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Laboratory and Testing Task Force Lead
CDC Multi-National Monkeypox Response 2022
Branch Chief, Poxvirus and Rabies Branch

VACCINATION

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Harvard Medical School
Director, Sexual Health Clinic
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TREATMENT

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U.S. Food and Drug Administration

Brett W. Petersen, MD, MPH
Captain, U.S. Public Health Service
Deputy Chief, Poxvirus and Rabies Branch
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Mary Foote, MD, MPH
Medical Director
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Q&A/DISCUSSION

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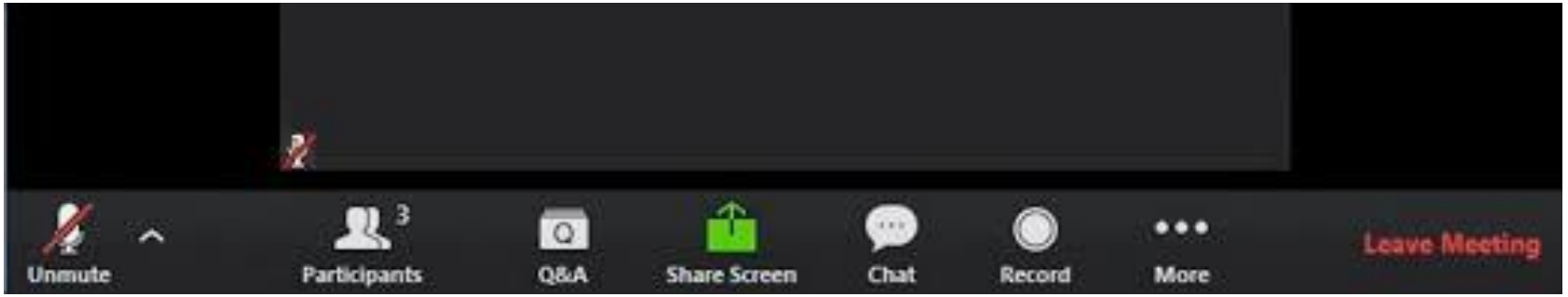
Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button



Situation Update

John T. Brooks, MD

MONKEYPOX

Situation Update

John T. Brooks MD
Chief Medical Officer
CDC Monkeypox Response

MONKEYPOX

Monkeypox virus

- **Monkeypox is a rare disease caused by infection with monkeypox virus**
- ***Monkeypox virus* belongs to the *Orthopoxvirus* genus**
  - *Orthopoxviridae* genus includes *Variola virus* (which causes smallpox), *Vaccinia virus* (used in the smallpox vaccine), and *Cowpox virus*
- **First discovered in 1958 following two outbreaks of a pox-like disease in colonies of monkeys kept for research (hence the name 'monkeypox')**
- **Specific animal reservoir unknown, but likely small African mammals**

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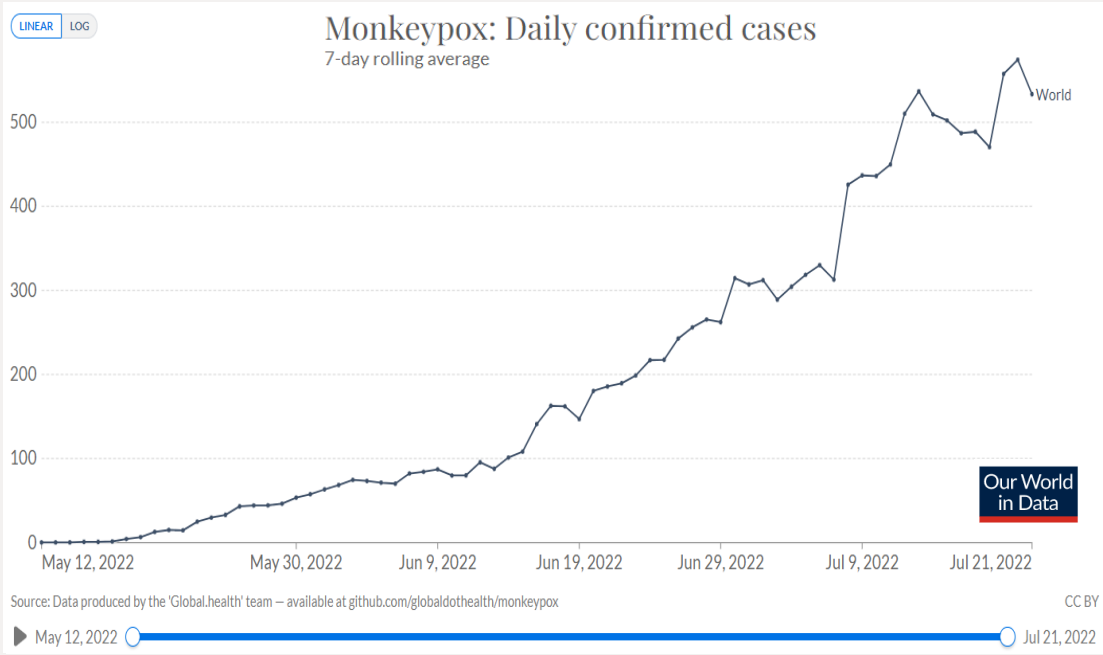
Worldwide Trend in Cases



Selected epidemiological metrics from enhanced surveillance questionnaires in confirmed monkeypox cases in England as of 6 July 2022 (N=445)

Metric	N (%)
Gay, bisexual, or men who have sex with men	427 (96.2%)
Travel abroad prior to symptom onset (21 days)	136 (30.6%)
Age under 30 years	86 (21.5%)
History of STI in the last year	233 (53.7%)
One or no sexual partners in last 3 months	67 (15.7%)
10+ sexual partners in last 3 months	134 (31.3%)
Living with HIV	123 (29.5%)

Source: Monkeypox - Our World in Data and Investigation into monkeypox outbreak in England: technical briefing 3 - GOV.UK (www.gov.uk)

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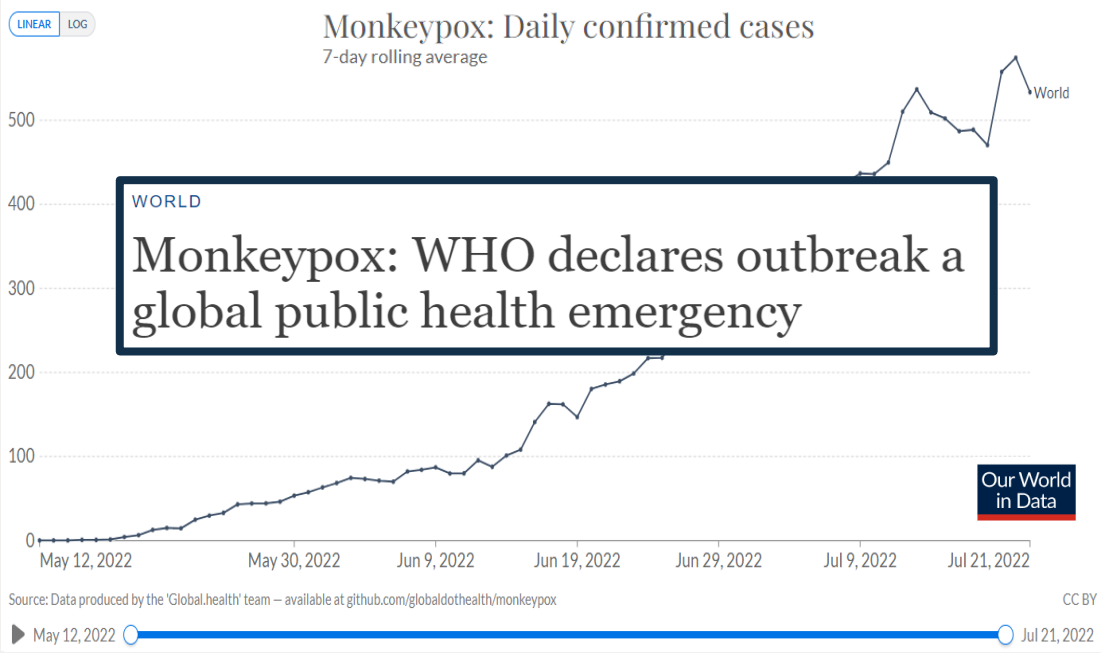
Worldwide Trend in Cases



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Source: Monkeypox - Our World in Data and Investigation into monkeypox outbreak in England: technical briefing 3 - GOV.UK (www.gov.uk)

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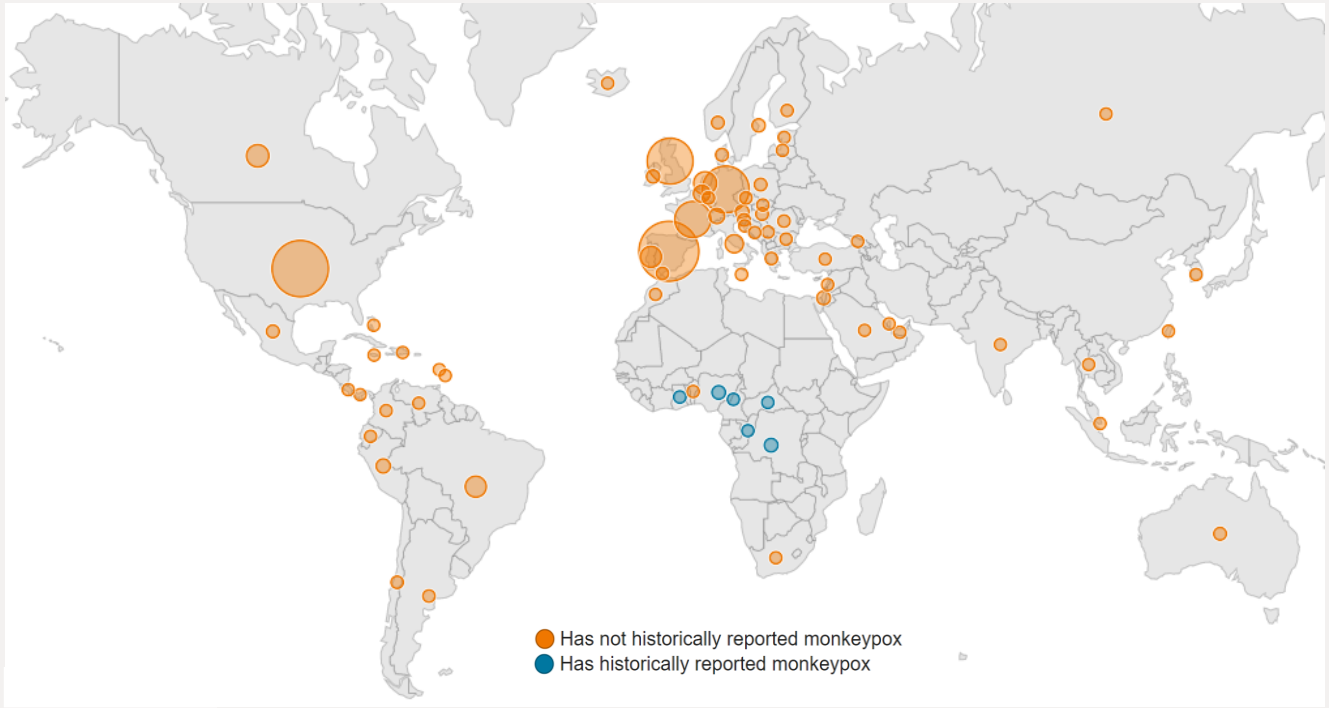
Case Count: 16,836 July 22, 2022

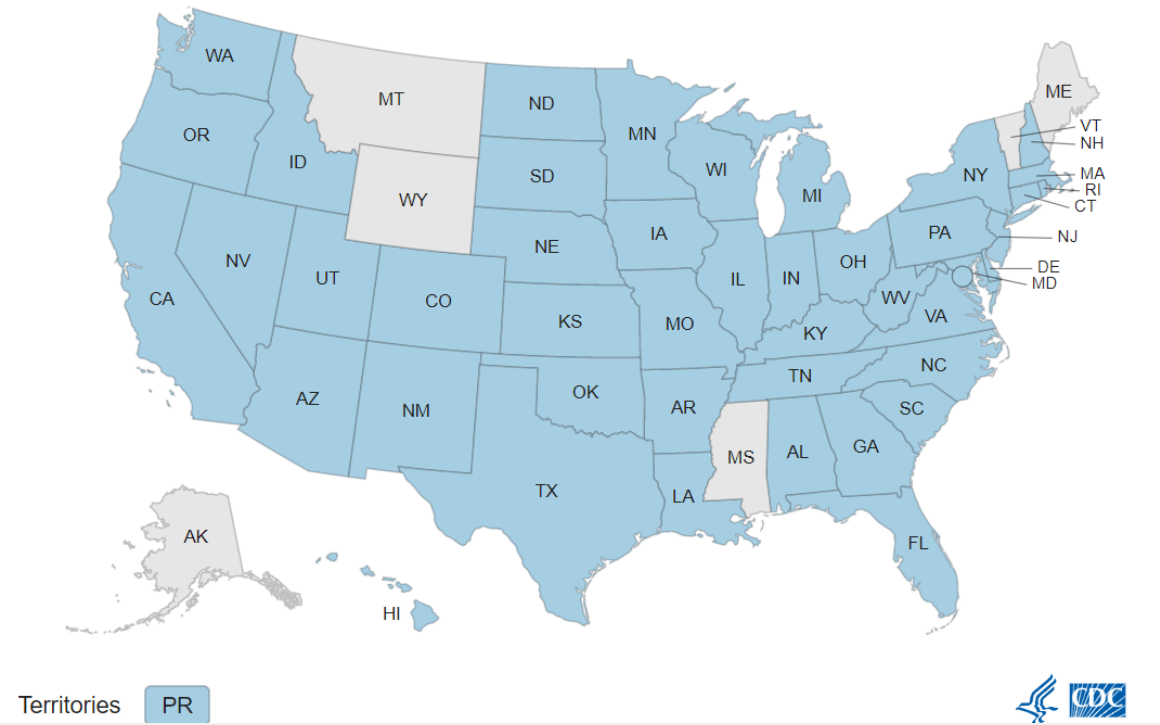


COUNTRY	COUNT
Spain	3,125
United States	2,891
Germany	2,268
United Kingdom	2,208
France	1,567
Netherlands	712

Source: [2022 Monkeypox Outbreak Global Map | Monkeypox | Poxvirus | CDC]

MONKEYPOX

Case Count: 2,891 July 22, 2022

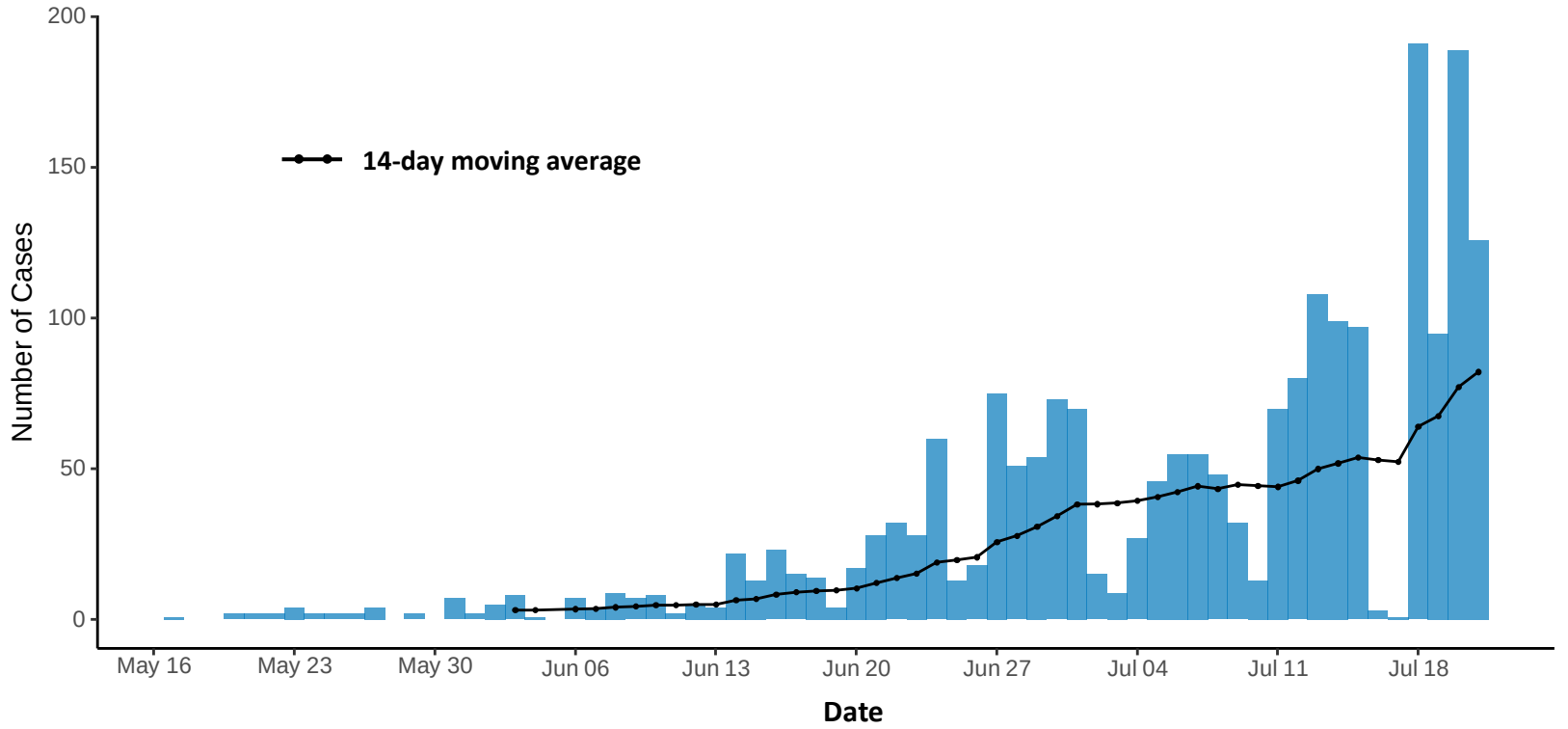


STATE	COUNT
New York	900
California	356
Florida	247
Illinois	238
Georgia	211
District of Columbia	110

Source: [2022 U.S. Map & Case Count | Monkeypox | Poxvirus | CDC]

MONKEYPOX

Case Count: 2,891 July 22, 2022



Source: [2022 U.S. Map & Case Count | Monkeypox | Poxvirus | CDC]

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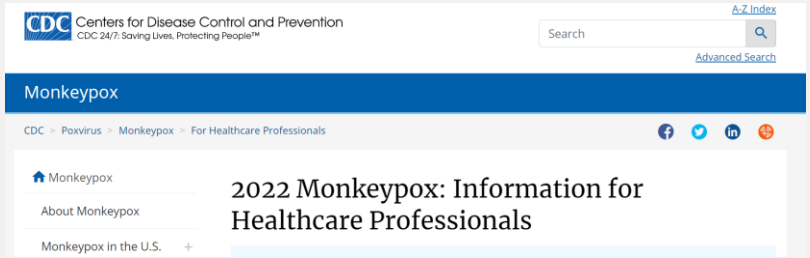
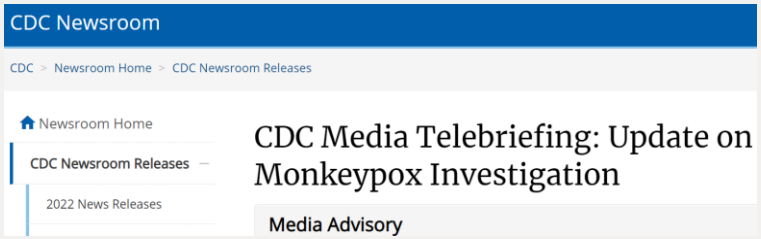
What is CDC Doing?

- Providing advice to state and local health departments
- Supporting diagnostic testing at Laboratory Response Network labs and CDC
- Providing frontline healthcare providers and public health officials with information on symptoms and how to manage illness



- Keeping public, clinicians informed with updated information on CDC website, social media, and via media briefings
- Working closely with community partners and raising awareness with multiple partners in LGBTQIA+ community
- Seeking public health partners' feedback
- Consulting with other countries



Diagnostics & Testing

John T. Brooks, MD
Christy Hutson, PhD, MS

MONKEYPOX

Diagnosis and Testing

John T. Brooks MD
Chief Medical Officer
CDC Monkeypox Response

Christy Hutson, PhD, MS
Chief, Poxvirus and Rabies Branch
Centers for Disease Control and Prevention

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Clinical Illness: 'Classic'

- **Incubation period:** 5–13 days on average (range 4–17 days)
- **Prodrome:** fever, malaise, headache, weakness, and lymphadenopathy that may be generalized or localized to several areas (e.g., neck and armpit)
- **Rash: appears shortly *after* prodrome starts**
  - Typically lesions develop simultaneously and evolve together on any given part of the body
  - Four stages – macular, papular, vesicular, to pustular – before scabbing over and resolving
  - Well-circumscribed, deep seated with umbilication, painful
  - When disseminated tend to be centrifugal: more on arms, legs, hands, feet
  - Can involve palms and soles
- **Illness duration is typically 2–4 weeks**

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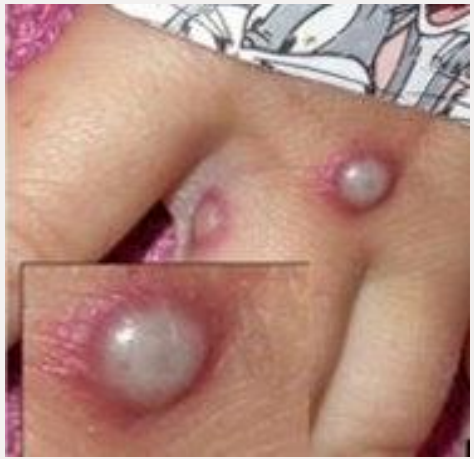
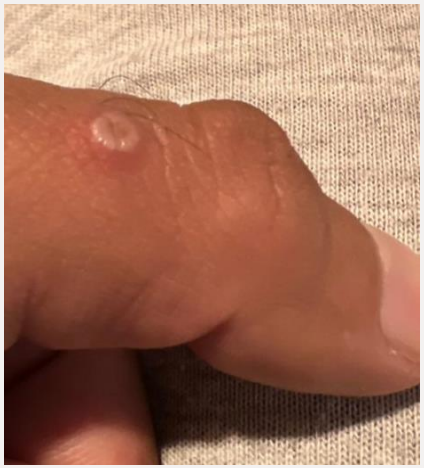
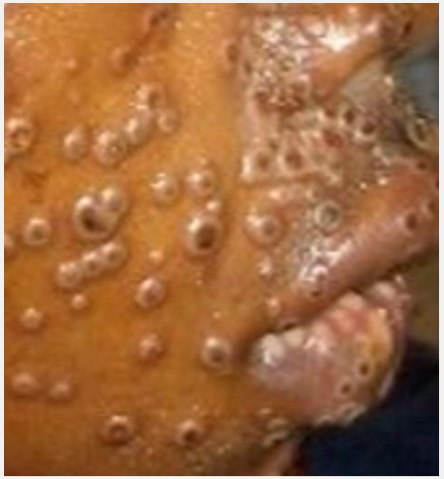
Clinical Illness: 'Classic'





Lesions observed during 2003 U.S. monkeypox outbreak



Lesions observed in endemic countries

Source: https://www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html

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Clinical Illness: '2022'

- Pattern: **scattered or localized** to a body site rather than diffuse
- **Rash often starts in mucosal areas** (e.g., genital, perianal, oral mucosa) and may not develop simultaneously in all body areas
  - **Proctitis**: anorectal pain, tenesmus, and rectal bleeding; associated with visible perianal vesicular, pustular, or ulcerative skin lesions and proctitis
  - **Oropharyngitis**: complicated by tonsillar swelling, abscess, dysphagia
- "Prodromal" symptoms can be absent or follow rash onset

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Clinical Illness: '2022' Lesions

Characteristic	(N = 528)
No. of skin lesions — no. (%)	
<5	207 (39)
5–10	131 (25)
11–20	112 (21)
>20	56 (11)
No lesions or missing data	22 (4)
Mucosal lesions present — no. (%)	217 (41)
Site of mucosal lesions — no./total no. (%)	
Anogenital only	148/217 (68)
Oropharyngeal only	50/217 (23)
Anogenital and oral	16/217 (7)
Nasal and eye	3/217 (1)

Source: Thornhill 2022, N Engl J Med

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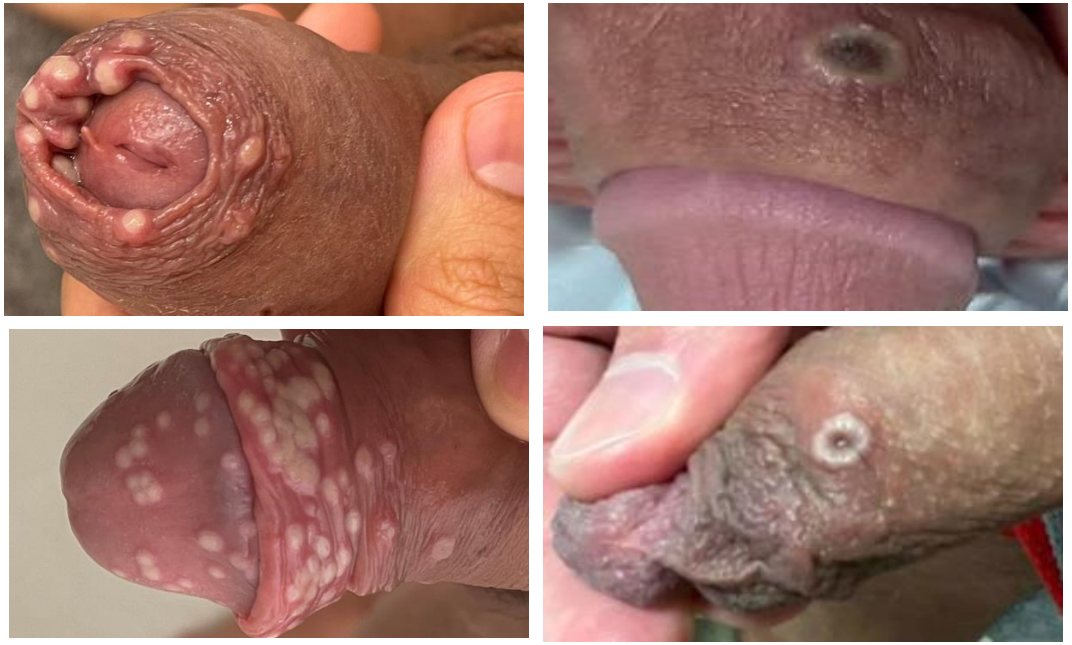
Clinical Illness: '2022' Lesions

Penile Lesions



Sources: Basgoz 2022, N Engl J Med; Jang 2020, J Korean Med Sci. Others courtesy of BW Furness with patient consent.

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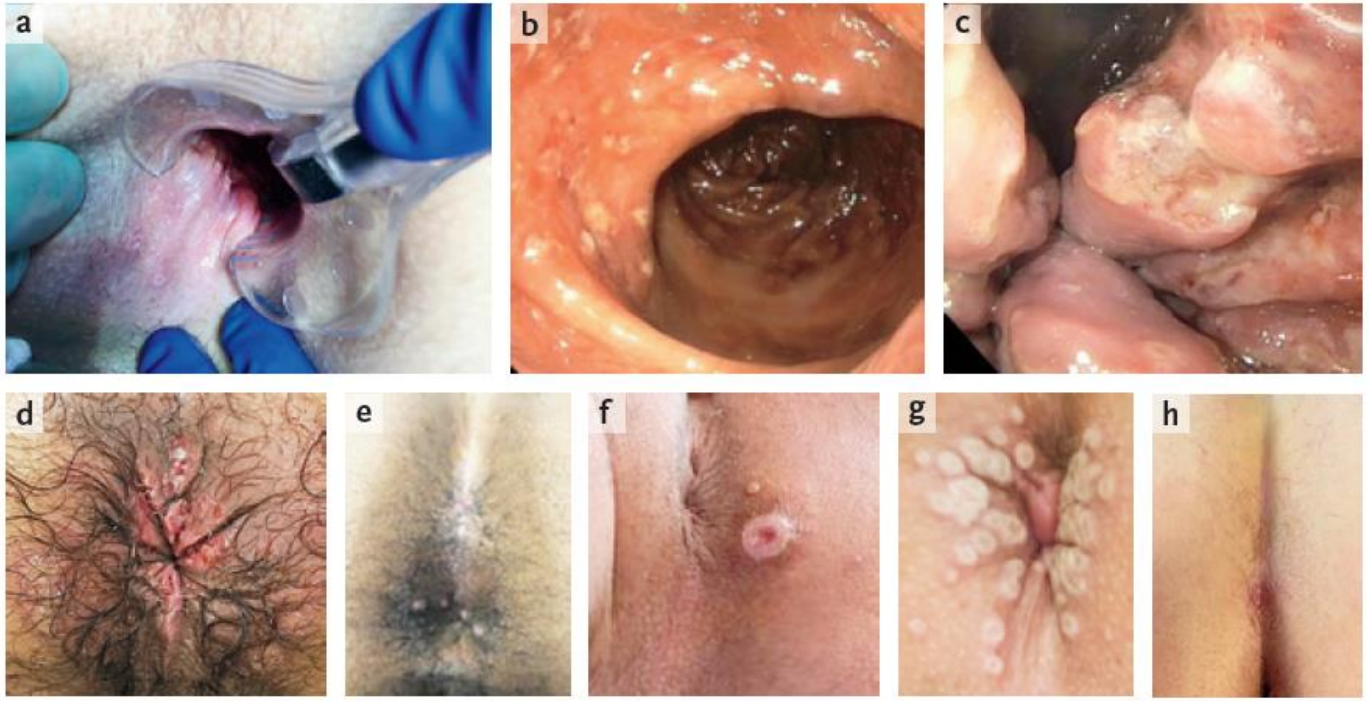
Clinical Illness: '2022' Lesions

Perianal, Anal, and Rectal Lesions



Source: Thornhill 2022, N Engl J Med

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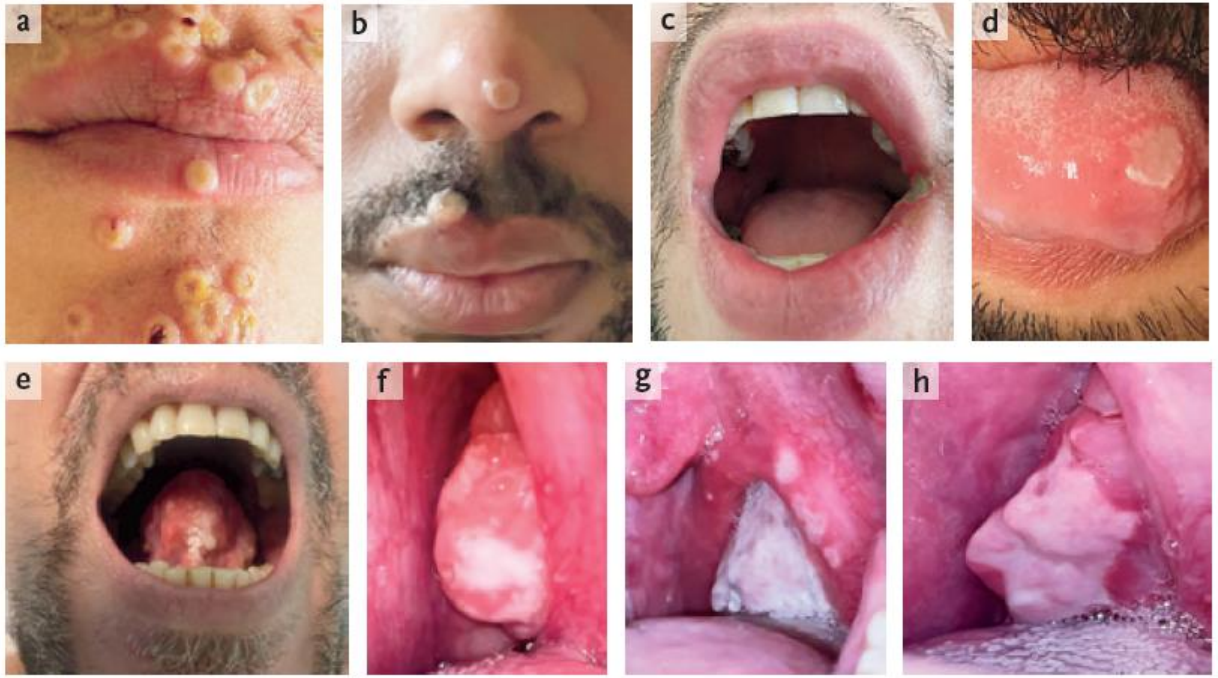
Clinical Illness: '2022' Lesions

Oral and Perioral Lesions



Source: Thornhill 2022, N Engl J Med

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Transmission

- **Spread person-to-person through:**
  - **Direct contact** with the infectious rash, scabs, or body fluids
  - **Respiratory secretions** during prolonged, face-to-face contact, or during intimate physical contact, such as kissing, cuddling, or sex
  - **Touching items (such as clothing or linens)** that previously touched the infectious rash or body fluids
  - **Through placenta** in an infected pregnant person to their fetus
- **Patients are infectious once symptoms begin (whether prodromal or rash symptoms) and remain infectious until lesions form scabs, scabs fall off, and a fresh layer of skin forms**

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Examination and Diagnosis

- **Collect a complete sexual and travel history for <u>past 21 days</u>**
  - Consider possibility of foreign or domestic animal or animal product contact
- **Perform a thorough skin and mucosal examination** (e.g., genital, anal, oral) in a room with *good lighting*
- **If rash present, consider a broad differential** (e.g., syphilis, varicella zoster, herpes simplex, molluscum contagiosum), especially if the person has epidemiologic risk factors for monkeypox infection in the current outbreak
- **Evaluate for STIs per the 2021 CDC STI Treatment Guidelines**
  - Persons with monkeypox have had STIs including acute HIV

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If you suspect you have a case…

- **Obtain specimens**
  - https://www.cdc.gov/poxvirus/monkeypox/clinicians/prep-collection-specimens.html
  - NB: testing in population with low prevalence more likely to have falsely positive results
- **Notify health department and your facility's infection control team**
  - Can be helpful with contact tracing and identifying person eligible for post-exposure prophylaxis
- **Consider consultation for treatment (contact health department)**
  - Antivirals (tecovirimat, cidofovir, brincidofovir)
  - Vaccinia immune globulin

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Testing for Suspect MPX Cases

- US Laboratory Response Network (LRN) labs (10,000 tests/week)
  - LRN labs (located within the state public health labs) perform CDC's FDA cleared non-variola Orthopoxvirus (NVO)-specific PCR test
  - Send samples to CDC for MPX-specific PCR and sequencing
- Commercial laboratory testing is now available (70,000 additional tests/week)
  - 40,000 testing capacity per week using CDC NVO test
  - 30,000 tests of commercial MPOX-specific laboratory test
- Current testing capacity is at 80,000 tests per week

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Testing for Suspect MPX Cases

- Specimen type
  - Recommended specimen type is skin lesion material
    - Swab of lesion from any part of the body is acceptable, if there is a visible lesion
  - Specifics on the acceptable lesion specimen type accepted within the LRN and commercial laboratories may vary
  - https://www.cdc.gov/poxvirus/monkeypox/clinicians/prep-collection-specimens.html
- Specimen collection
  - Use two sterile synthetic swabs (such as polyester, or nylon) per lesion
  - Swab each lesion vigorously to collect adequate DNA
  - It is not necessary to de-roof the lesion before swabbing
  - Approximately 3 lesions per patient are suggested
    - From different locations on the body or from lesions which differ in appearance
- Probable MPX: positive OPX PCR
- Confirmed MPX: positive MPX-specific PCR or sequence analysis

Vaccination

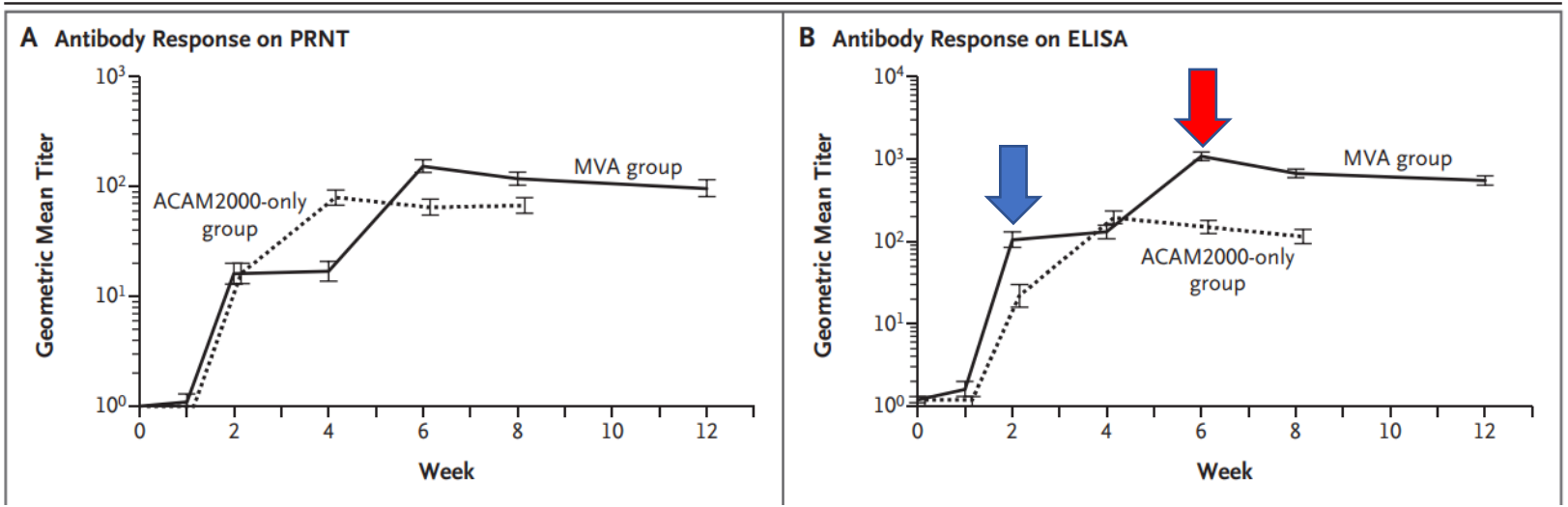
Kevin Ard, MD, MPH

JYNNEOS

- Replication-deficient *Vaccinia* virus
- Licensed as a series of two subcutaneous injections, 4 weeks apart
- Recommended by the Advisory Committee on Immunization Practices as pre-exposure prophylaxis for laboratory and other personnel with occupational exposure to orthopoxviruses
- Booster doses recommended every 2 years for those with exposure to monkeypox
- The only contraindication is severe allergy to a vaccine component.
- Side effects include injection site reactions; serious side effects are rare.
- The vaccine can be given to people with HIV and immunocompromising conditions.

Rao AK, et al; MMWR; 2022

Antibody response with JYNNEOS are non-inferior to those with ACAM2000.



Antibody titers at 2 weeks (ie, after a single dose) are similar between JYNNEOS and ACAM2000.

Peak antibody titers are achieved at 6 weeks (ie, 2 weeks after the second dose).

Pittman PR, et al; N Engl J Med; 2019

Post-exposure (PEP) vaccination strategies

- There are no efficacy data on PEP with JYNNEOS for the current outbreak.
- Vaccination may:
  - Prevent disease if given within 4 days of exposure
  - Reduce disease severity if given between 4-14 days of exposure
- 2 related strategies
  - **PEP** for people with a confirmed exposure to monkeypox through public health investigation, contact tracing, or risk exposure assessments
  - **PEP++** for people with presumed exposure to monkeypox
    - Know a sexual partner within the past 14 days was diagnosed with monkeypox
    - Have had multiple sex partners in the past 14 days in an area with monkeypox

www.cdc.gov/poxvirus/monkeypox/clinicians/faq.html#Eligible-mpox

Common questions

How effective is a single dose of JYNNEOS?

- Unknown, but antibody titers are similar to those of ACAM2000 at 14 days, when that vaccine is thought to show efficacy.

What is the maximum acceptable interval between the first and second doses?

- Unknown, but a dose given later would presumably still have a boosting effect

When after vaccination does protection begin?

- Unknown, but in a macaque model of monkeypox, protection occurred with a viral challenge 4 days after vaccination.

Pittman PR, et al; N Engl J Med; 2019 Earl PL, et al; Proc Natl Acad Sci U S A; 2008

Massachusetts General Hospital experience

- Began offering vaccination for PEP++ on July 7, 2022
- Available by calling for an appointment
- More than > 350 calls/day; initial supply rapidly committed
- Key considerations:
  - Managing demand
  - Providing other services (STI testing, HIV PrEP) or not
  - Fostering equity

Treatment

Adam Sherwat, MD

Brett W. Petersen, MD, MPH

Mary Foote, MD, MPH

Jason E. Zucker, MD, MSc

Tecovirimat: A Regulatory Perspective

Adam Sherwat, M.D.
Office of Infectious Diseases
Center for Drug Evaluation and Research
Food and Drug Administration

7/23/2022

Disclaimer

- The reviews expressed are those of the speaker and do not necessarily reflect official policy of the FDA.

Tecovirimat and the "Animal Rule"

Background

- Tecovirimat is an antiviral drug that inhibits viral spread to uninfected cells by directly and specifically targeting the orthopoxvirus protein F13 (VP37) which is involved in producing extracellular enveloped virions
- Tecovirimat was approved for the treatment of smallpox disease under a regulation known as the "Animal Rule"
- The Animal Rule allows for approval of drugs when human efficacy studies are not ethical and field trials to study the effectiveness of drugs or biological products are not feasible
- Under the Animal Rule, efficacy is established based on adequate and well-controlled studies in animal models of the human disease or condition of interest

Tecovirimat and the "Animal Rule"

Establishing Efficacy

- Conducting clinical trials to study tecovirimat for the treatment of smallpox is neither feasible nor ethical
  - Smallpox is an eradicated disease
  - Exposing study participants to variola virus (smallpox virus) is not ethical
- Scientific/logistical constraints with the use of variola virus in animal models
- Efficacy was established based on studies of non-human primates infected with monkeypox (MPX) and rabbits infected with rabbitpox (RPX)
- These studies demonstrated improved survival in animals that received tecovirimat compared to animals that received placebo

Table 6: Survival Rates in Tecovirimat Treatment Studies in Cynomolgus Macaques and NZW Rabbits Exhibiting Clinical Signs of Orthopoxvirus Disease

	Treatment Initiation[a]	Survival Percentage (# survived/n)		p-value[b]	Survival Rate Difference[c] (95% CI)[d]
		Placebo	Tecovirimat		
Cynomolgus Macaques					
Study 1	Day 4	0% (0/7)	80% (4/5)	0.0038	80% (20.8%, 99.5%)
Study 2	Day 4	0% (0/6)	100% (6/6)	0.0002	100% (47.1%, 100%)
Study 3	Day 4	0% (0/3)	83% (5/6)	0.0151	83% (7.5%, 99.6%)
	Day 5		83% (5/6)	0.0151	83% (7.5%, 99.6%)
	Day 6		50% (3/6)	0.1231	50% (-28.3%, 90.2%)
NZW Rabbits					
Study 4	Day 4	0% (0/10)	90% (9/10)	< 0.0001	90% (50.3%, 99.8%)
Study 5	Day 4	NA[e]	88% (7/8)	NA	NA

[a]Day post-challenge tecovirimat treatment was initiated
[b]p-value is from 1-sided Boschloo Test (with Berger-Boos modification of gamma = 0.000001) compared to placebo
[c]Survival percentage in tecovirimat treated animals minus survival percentage in placebo treated animals
[d]Exact 95% confidence interval based on the score statistic of difference in survival rates
[e]A placebo control group was not included in this study.
KEY: NA = Not Applicable

Tecovirimat and the "Animal Rule"
Establishing Safety

- Approvals under the Animal Rule still require establishing an adequate safety database like any other new drug or biologic product
- The safety of tecovirimat was evaluated in 359 healthy adult subjects ages 18-79 years in a placebo-controlled clinical trial
- Adverse reactions occurring in ≥ 5% of subjects receiving tecovirimat included headache (12%) and nausea (5%)
- No deaths or SAEs were considered related to tecovirimat

Tecovirimat and the "Animal Rule"
Dose Selection

- To select an effective dose, tecovirimat exposures achieved in healthy human subjects were compared with those observed in the animal models of MPX and RPX infection at the doses associated with maximum effectiveness
- For tecovirimat, the selection of a maximum human dose was constrained by neurologic findings in animal toxicology studies
- Despite this, tecovirimat exposures achieved in healthy humans at the recommended dose are higher than the therapeutic exposures in the relevant animal models

Post-Marketing Studies

- Uncertainties inherent in “Animal Rule” approvals
- The applicant must conduct postmarketing studies, such as field studies, to verify and describe the drug's clinical benefit and to assess its safety when used as indicated when such studies are feasible and ethical
- Applicants must include as part of their application a plan or approach to postmarketing study commitments in the event such studies become ethical and feasible

Why Was Tecovirimat Not Approved for Treatment of Monkeypox?

- Monkeypox disease did not meet the Animal Rule requirement that human efficacy studies are not ethical and field trials to study the effectiveness of drugs or biological products are not feasible
- At the time of tecovirimat approval, there were parts of the world (including the Democratic Republic of the Congo) where monkeypox disease was endemic and clinical trials could be conducted

Thank You

References

- Guidance for Industry: Product Development Under the Animal Rule

https://www.fda.gov/media/88625/download

- Guidance for Industry: Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention

https://www.fda.gov/media/132623/download

- Chan-Tack, K.M., Harrington, P.R., Choi, S.Y., Myers, L., O'Rear, J., Seo, S., McMillan, D., Ghantous, H., Birnkrant, D., Sherwat, A.I., 2019. Assessing a drug for an eradicated human disease: US Food and Drug Administration review of tecovirimat for the treatment of smallpox. Lancet Infect. Dis. 19, e221–e224.

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Monkeypox Treatment

Brett W. Petersen, MD MPH
Captain, U.S. Public Health Service
Deputy Chief, Poxvirus and Rabies Branch
Centers for Disease Control and Prevention

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Treatment Considerations for Monkeypox

- Many individuals infected with monkeypox virus have a mild, self-limiting disease course in the absence of specific therapy

- The prognosis for monkeypox depends on multiple factors such as previous vaccination status, initial health status, and concurrent illnesses or comorbidities

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Treatment Considerations for Monkeypox

- **Persons who should be considered for treatment following consultation with CDC might include:**
  - Persons with severe disease (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalization)
  - Persons who may be at high risk of severe disease:
    - People with immunocompromising conditions (e.g., HIV/AIDS, leukemia, lymphoma, generalized malignancy, etc.)
    - Pediatric populations, particularly patients younger than 8 years of age
    - Pregnant or breastfeeding women
    - People with a history or presence of atopic dermatitis, people with other active exfoliative skin conditions
    - People with one or more complication
- **Persons with monkeypox virus aberrant infections that include its accidental implantation in eyes, mouth, or other anatomical areas where monkeypox virus infection might constitute a special hazard (e.g., the genitals or anus)**

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Clinical Considerations for Treatment and Prophylaxis in People with HIV

- People with advanced HIV or who are not virologically suppressed with antiretroviral therapy can be at increased risk of severe disease related to monkeypox virus infection
- Post-exposure prophylaxis and antiviral treatments are available for persons exposed to monkeypox or with monkeypox virus infection
- Antiviral treatments have few interactions with antiretroviral therapy
- Vaccination with JYNNEOS is considered safe for people with HIV

https://www.cdc.gov/poxvirus/monkeypox/clinicians/people-with-HIV.html

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Tecovirimat

- Tecovirimat is an antiviral medication developed to treat smallpox
  - Also known as TPOXX or ST-246

- Oral capsule and IV formulations approved by FDA in July 2018 and May 2022, respectively
- Available from the Strategic National Stockpile as an oral capsule formulation or an intravenous vial

- Indication
  - Tecovirimat is indicated for the treatment of human smallpox disease in adults and pediatric patients weighing at least 3 kg

  - CDC-held Expanded Access Investigational New Drug (EA IND) Protocol allows use of Tecovirimat for Non-Variola Orthopoxvirus Infection (e.g., monkeypox)

https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208627s000lbl.pdf

MONKEYPOX

Tecovirimat EA-IND

- EA-IND provides an umbrella regulatory coverage
  - Clinicians and facilities do not need to request and obtain their own INDs
  - Provides liability coverage under the PREP Act for compensation to patients if injured via the Countermeasure Injury Compensation Program
- Treatment with TPOXX can begin upon receipt of the medication and after obtaining informed consent
  - No pre-registration is required for clinicians or facilities
- Forms requested under the EA-IND can all be returned to CDC after treatment begins
- CDC IRB serves as the central IRB for review and approval of the EA-IND
  - Determined that its use does not constitute research involving human subjects and federal-wide assurance requirements do not apply
  - For facilities requiring a reliance agreement, CDC IRB will provide a pre-signed reliance agreement for facilities to sign documenting reliance on CDC IRB (huma@cdc.gov)

https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html

MONKEYPOX

Revised Tecovirimat EA-IND

- Reduced number of case report forms from 6 forms (17 pages) to 2 forms (6 pages)
- Changed all patient assessments to virtual (via telemedicine) or in-person
- Reduced required assessment and follow-up visit to 3 time points that could be done via telemedicine visits
  - Patients would be assessed prior to treatment, once during the 14-day therapy, and once after completion of treatment

MONKEYPOX

Revised Tecovirimat EA-IND

- Required
  - Informed Consent Form
  - Patient Intake Form
  - FDA Form 1572: One signed 1572 per facility
  - Clinical Outcome Form
  - Serious Adverse Events MedWatch Form
- Optional Photos and Samples
  - Photos of lesions
  - Lesions samples for resistance testing
  - Pharmacokinetic samples for testing
  - Clinical laboratory parameters (hematology, chemistry, and urinalysis parameters)
- Optional Patient Diary and Instructions
  - Patient diary
  - Instructions for mixing TPOXX capsules with food

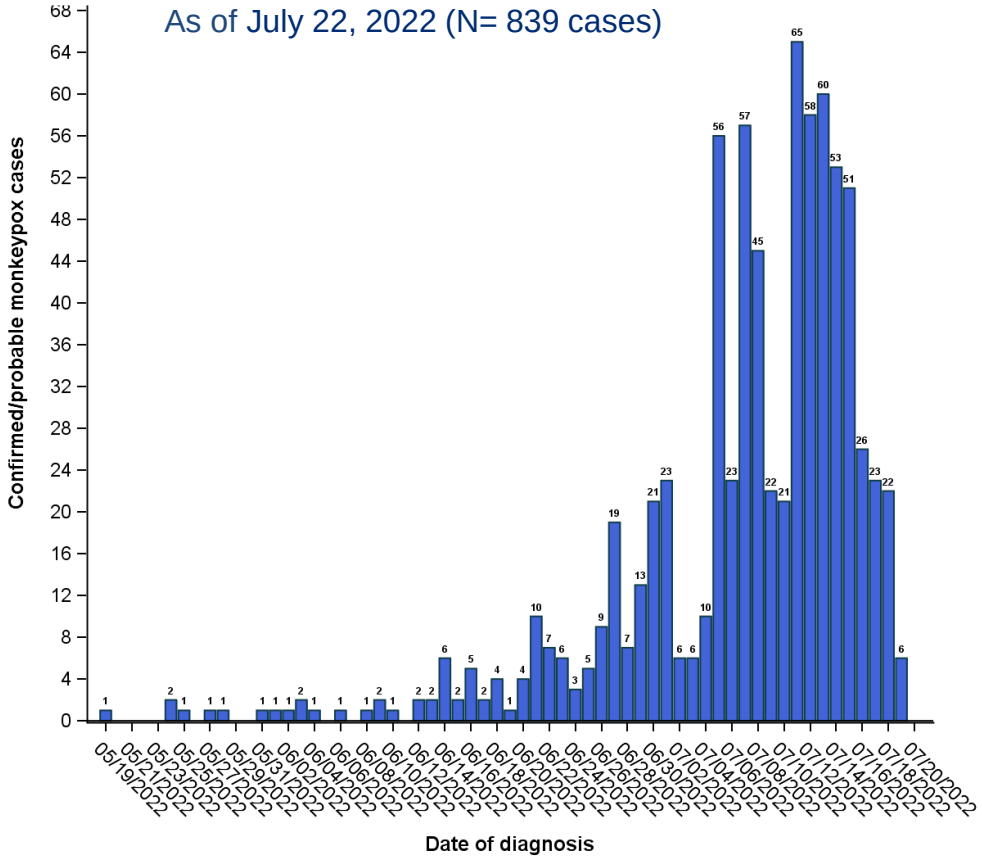
Other Treatment Options

- VIGIV is licensed by FDA for the treatment of complications due to vaccinia vaccination
- Cidofovir (also known as Vistide) is an antiviral medication that is approved by the FDA for the treatment of cytomegalovirus (CMV) retinitis in patients with Acquired Immunodeficiency Syndrome (AIDS)
- CDC-held Expanded Access Investigational New Drug Protocol allows use of VIGIV and Cidofovir for Non-Variola Orthopoxvirus Infection (e.g., monkeypox)

CLINICAL PRESENTATION AND MANAGEMENT OF MONKEYPOX: THE NEW YORK CITY EXPERIENCE

Mary Foote, MD, MPH
New York City Department of Health and Mental Hygiene

Cases of Monkeypox by Date of Diagnosis, NYC



NYC Demographic Data

As of July 21, 2022

Age	
Median Age (range)	35 (20-69)
Unknown	0 (0.0%)
Gender	
Men	765 (98.3%)
Women	1 (0.1%)
TGNCNB	9 (1.2%)
Unknown	3 (0.4%)

Sexual Orientation	
LGBQ+	406 (52.2%)
Straight	13 (1.7%)
Unknown	359 (46.1%)
Race/Ethnicity	
Hispanic/Latino	180 (23.1%)
Asian/Pacific Islander	33 (4.2%)
Black/African American	133 (17.1%)
White	230 (29.6%)
Other	2 (0.3%)
Unknown	200 (25.7%)

TGNCNB = transgender, gender nonconforming and nonbinary
Unknown = missing or pending case investigation

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

NYC Health

Treatment and pain management

Clinical Presentation

- No known mortality for the current outbreak, **but morbidity higher than expected**
- **Severe presentations can be debilitating with potential for long-term sequelae**
  - Proctitis (with or without ulcers) – tenesmus, bleeding, severe pain
  - Urethritis (urethral ulcers) – dysuria, hematuria
  - Pharyngitis (pharyngeal ulcers) – dysphagia, odynophagia
  - Balanitis/balanoposthitis
  - Perichondritis
  - Bacterial superinfection
    - Penile/testicular, pharyngeal, testicular lesions
- **Co-infections are common**
  - GC, chlamydia, syphilis, HSV, acute HIV, VZV

NYC Health

Supportive Care

- Gastrointestinal symptoms
  - Managed with appropriate hydration and electrolyte replacement
  - Antiemetics as needed
  - Anti-motility agents not generally recommended given the potential for ileus

- 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

https://www1.nyc.gov/assets/doh/downloads/pdf/cd/monkeypox-treatment-guidance-interim.pdf

NYC Health

Supportive Care

- 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
    - Topical anesthetics (e.g., dibucaine cream, lidocaine gel)

- Pain from proctitis and genital lesions 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

https://www1.nyc.gov/assets/doh/downloads/pdf/cd/monkeypox-treatment-guidance-interim.pdf

NYC Health

Tecovirimat – NYC Experience

Experience in NYC to date:

- Prescribed for ~215 patients
- About 20-25% meet criteria for tecovirimat
- Most common indication is severe proctitis
  - Other indications include painful anal or penile lesions, bacterial superinfection, painful oral lesions
- Significant improvements reported after just a few days of starting treatment
- No significant adverse events reported

https://www1.nyc.gov/assets/doh/downloads/pdf/cd/monkeypox-treatment-guidance-interim.pdf

NYC Health

Role of the Local Health Department

- Provider education and outreach
- Information and technical assistance via dedicated email
- A treatment navigation team follows up to give interim treatment guidance and support with:
  - Submitting the IND in order to prescribe tecovirimat directly
  - Assistance in referring the patient to another provider
- Once enrolled in IND – facilitate tecovirimat requests from the strategic national stockpile
- City supply managed by partner pharmacy – home delivery to patients
- Providers asked to submit brief REDCap form for each patient treated

https://www1.nyc.gov/assets/doh/downloads/pdf/cd/monkeypox-treatment-guidance-interim.pdf

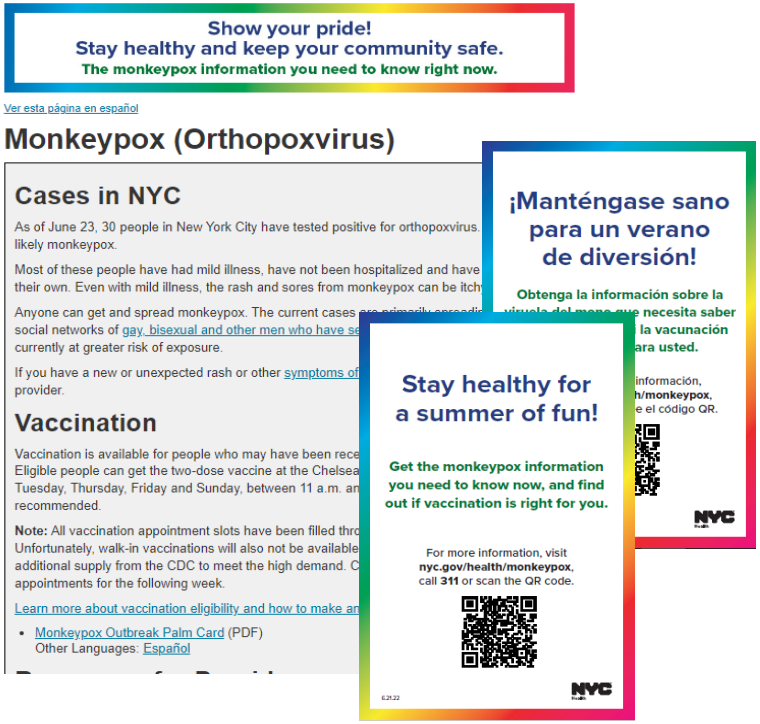
NYC Health

Challenges –Treatment Access

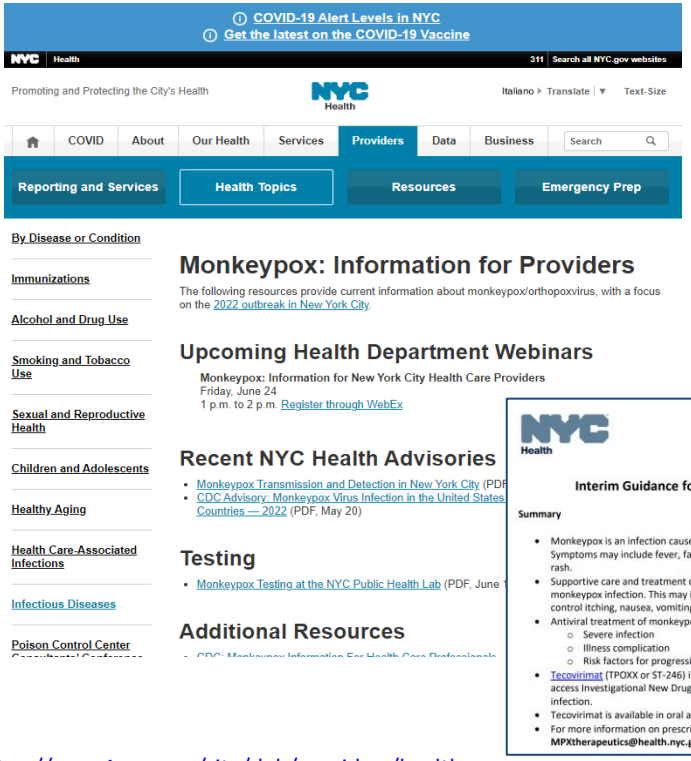
- Demand high, but patients not getting linked to treatment in timely manner
- Very few providers/facilities have enrolled to prescribe
  - Extensive and time-consuming paperwork and documentation needed for IND protocol
  - No reimbursement process
  - Heavy reliance on academic medical centers with research programs
- Equity concerns
  - Limited access for patients that are rural, uninsured or without primary care provider
  - Many safety net systems with fewer resources to scale up treatment under IND requirements

NYC Health

NYC Health Department Resources



nyc.gov/monkeypox



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

NYC Health

THANK YOU

Treating Monkeypox Patients in NYC

Jason Zucker, MD
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Assistant Medical Director, NYC STD Prevention Training Center
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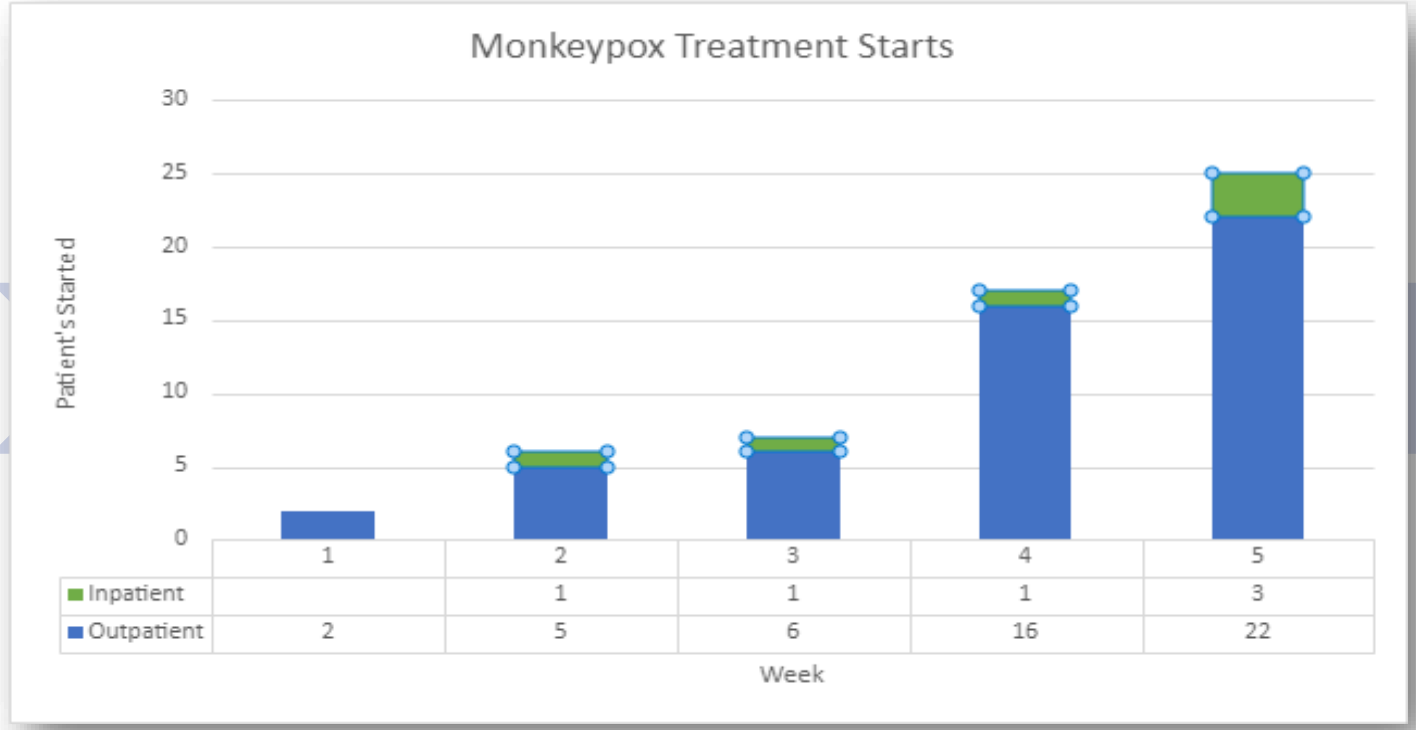
7/23/2022
Twitter: @Jason10033

The Columbia Monkeypox Treatment Program



July 23, 2022

51 Outpatients

6 Inpatients

The Columbia Monkeypox Treatment Program

Treatment Team From Day 1

1. Chief, Division of ID - Magdalena Sobieszczyk
2. Program coordination – Brett Gray and Mascha Elkind
3. Research nurse – Arianna Pazmino
4. Laboratory – Jennifer Chang, Meredith McNairy
5. Research Pharmacy - Elnaz Anjom
6. Scheduling – Dionna Thomas, Lynette Marte

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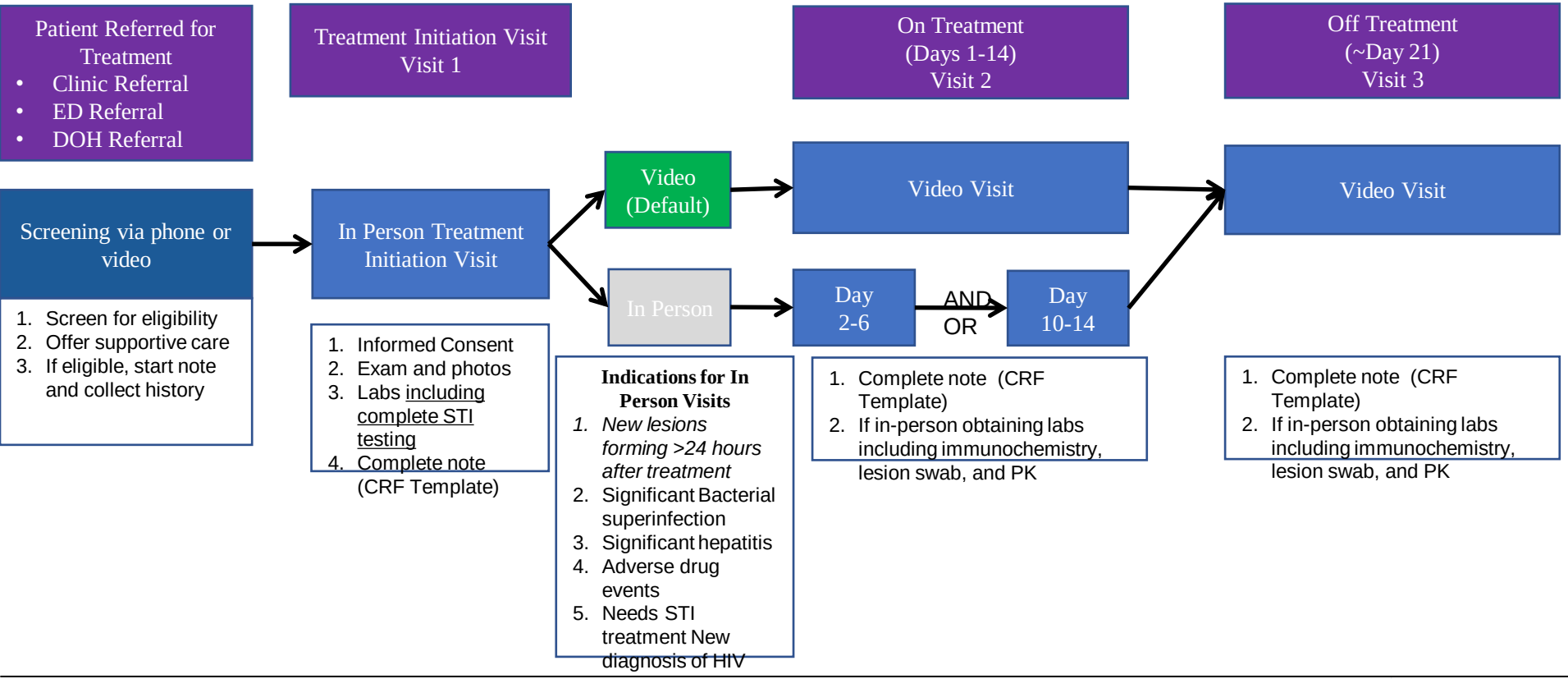
5. Research Pharmacy - Elnaz Anjom
6. Scheduling – Dionna Thomas, Lynette Marte

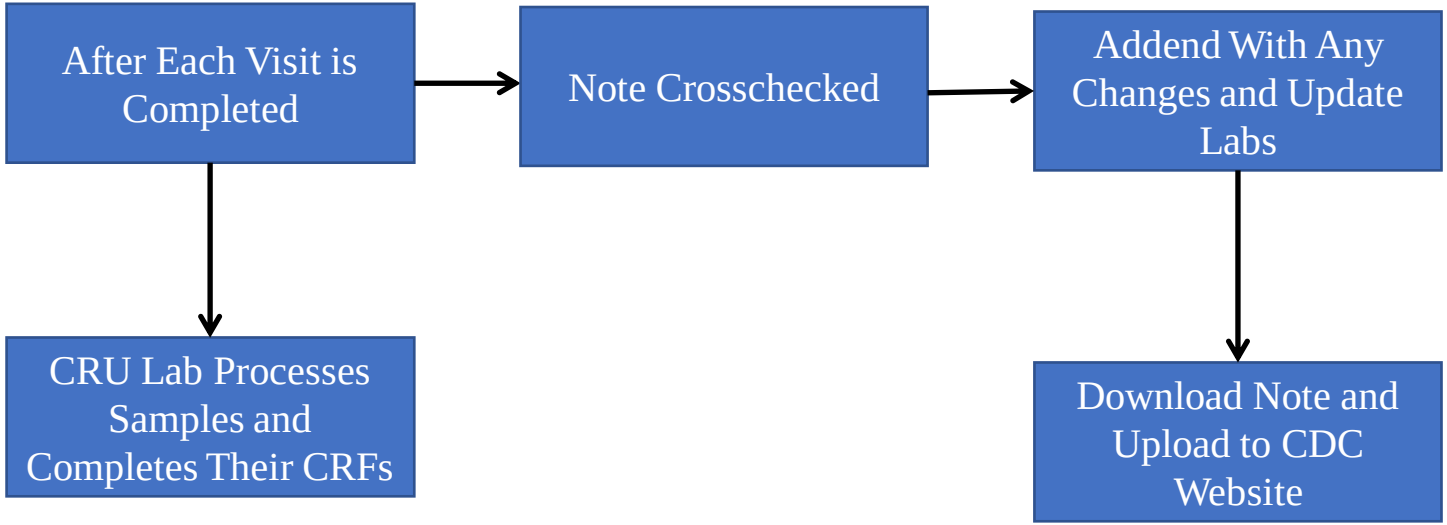
Providers Expanded Over Time:

1. Jason Zucker
2. Hanna Catan
3. Jacob McLean
4. Matt Scherer
5. Eddie Perez
6. Shauna Gunaratne
7. Caroline Carnevale
8. **Entire ID division!**

Outpatient Treatment Pathway



Monkeypox CRF, Special Labs, and Data Management



Key Points From Our Experience

- It takes a team to treat patients with Monkeypox
  - Ask for sub-specialty assistance (Dermatology, Colorectal Surgery, Gastroenterology, Urology, Wound Care, ENT, Ophthomology)
- Offer supportive care while waiting for treatment
- An in person visit is beneficial:
  - Get complete STI testing as STI co-infection is common
    - HIV, GC, CT, RPR, HSV, Hep C
- Bacterial superinfection is common and bacterial cultures are helpful to direct therapy
    - MRSA, MSSA, GAS, Klebsiella, Enterococcus
- Pictures are helpful for monitoring progress
- **This disease can be severe and patients are grateful for our support**

Q&A/DISCUSSION

Selected Resources

Situation Update:

- Slides 8 & 9 - https://ourworldindata.org/monkeypox and https://www.gov.uk/government/publications/monkeypox-outbreak-technical-briefings/investigation-into-monkeypox-outbreak-in-england-technical-briefing-3#fig5
- Slide 10 - https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html
- Slide 11 & 12 - https://www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html

Diagnostics & Testing:

- Slide 17 - https://www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html
- Slide 25 - https://www.cdc.gov/std/treatment-guidelines/default.htm
- Slide 26 - https://www.cdc.gov/poxvirus/monkeypox/clinicians/prep-collection-specimens.html

Treatment:

- Slide 45 - https://www.fda.gov/media/88625/download
    - https://www.fda.gov/media/132623/download
- Slide 49 - https://www.cdc.gov/poxvirus/monkeypox/clinicians/people-with-HIV.html
- Slide 50 - https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208627s000lbl.pdf
- Slide 51 - https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html
- Slide 57 - https://www1.nyc.gov/site/doh/health/health-topics/monkeypox.page
- Slides 60 - 63 - https://www1.nyc.gov/assets/doh/downloads/pdf/cd/monkeypox-treatment-guidance-interim.pdf
- Slide 65 - https://www1.nyc.gov/site/doh/providers/health-topics/monkeypox.page

THANK YOU

We want to hear from you!

Please complete the post-call survey.

A recording of this call, slides and the answered Q&A will be posted at
www.idsociety.org/cliniciancalls

-- library of all past calls available --

Contact Us:

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Deirdre Lewis (dlewis@idsociety.org)