

**NYU Grossman
School of Medicine**

Unproven Interventions During Public Health Crises



The Case of Tecovirimat (TPOXX) for Mpox and the
Tension Between Access and Evidence-Generation

Monday, May 22nd at 12:45 pm - 2:15 pm



JOHNS HOPKINS
SCHOOL *of* MEDICINE



STOMP

Study of Tecovirimat for Human Monkeypox Virus



Disclosures

- ▶ No Relevant Disclosures

Our Panelists

▶ **Ali Moody**

- Program Operator/Peer Navigator & Patient Advocate at AIDS ACTION Baltimore

▶ **Elizabeth Anne Gilliams MD, MS, MSc**

- Medical Director of Sexually Transmitted Infections (STI) Services at Baltimore City Health Department; Instructor of Medicine at Johns Hopkins School of Medicine

▶ **Hayley Belli PhD**

- Assistant Professor of Biostatistics at NYU Grossman School of Medicine; Co-Chair of Ethics & Real-World Evidence (ERWE) research project

▶ **Matthew M. Hamill MBChB, PhD, MPH, MSc**

- Assistant Professor of Medicine at Johns Hopkins School of Medicine; Clinical Chief for Sexually Transmitted Infections (STI) Services at Baltimore City Health Department; Co-developer of AIDS Clinical Trials Group's (ACTG) Study of Tecovirimat for Human Mpox Virus (STOMP) protocol

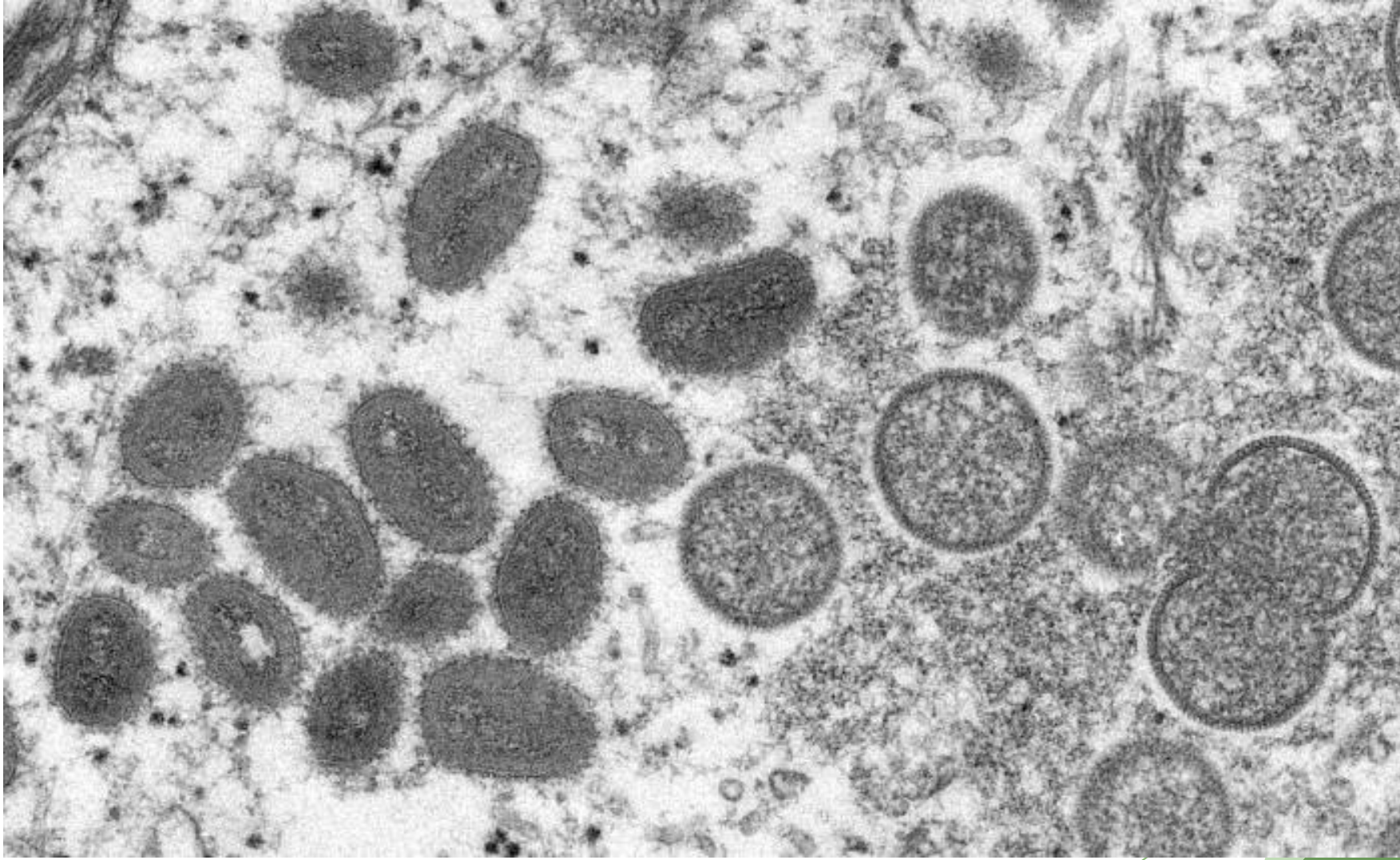
▶ **Alen Agaronov ScD (Moderator)**

- Postdoctoral Fellow of Medical Ethics at NYU Grossman School of Medicine

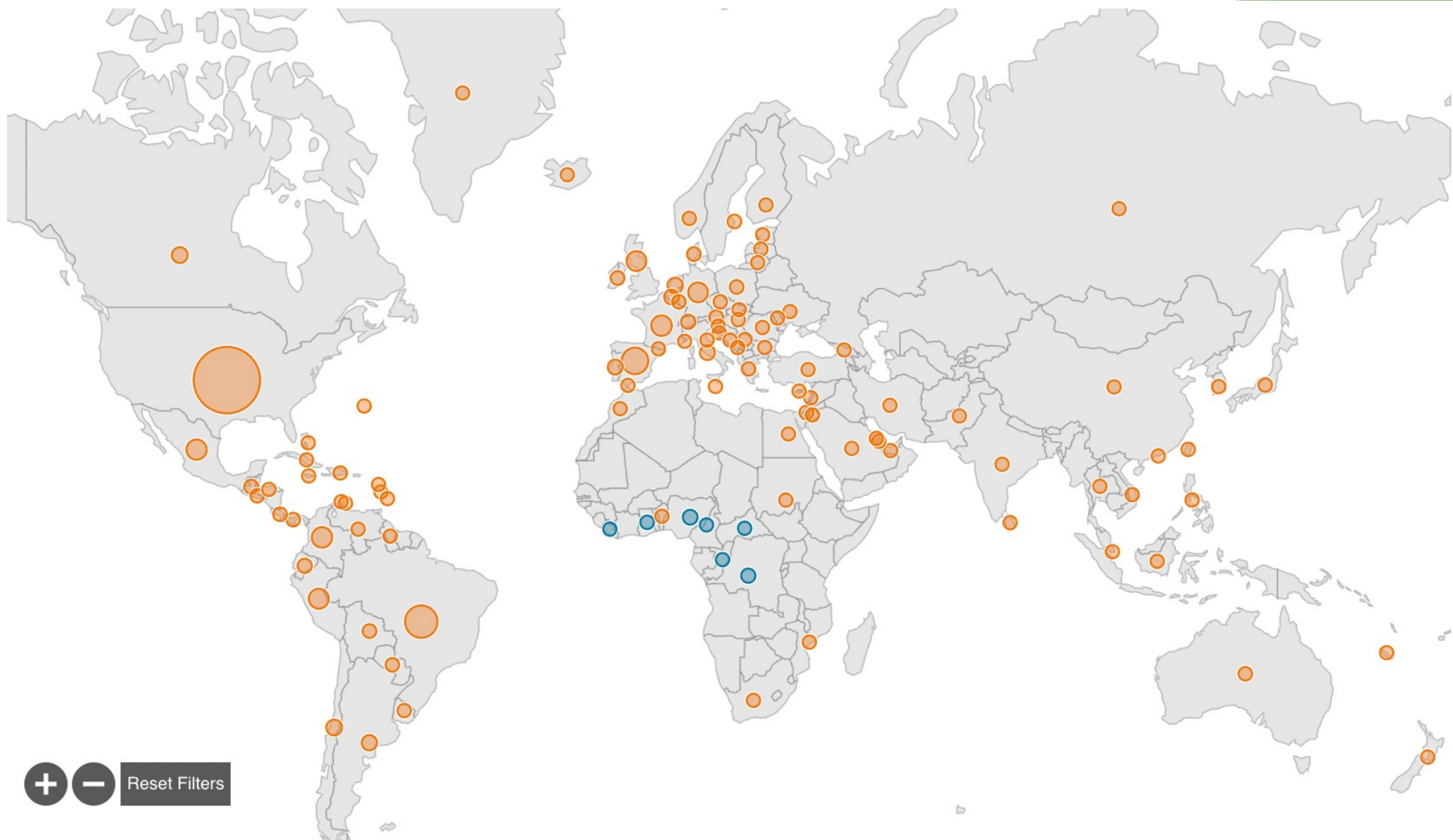
What's Ahead

- ▶ Case overview
- ▶ Panelist case presentations
- ▶ Moderated discussion
- ▶ Moderated audience Q&A
- ▶ Closing remarks

What is mpox?



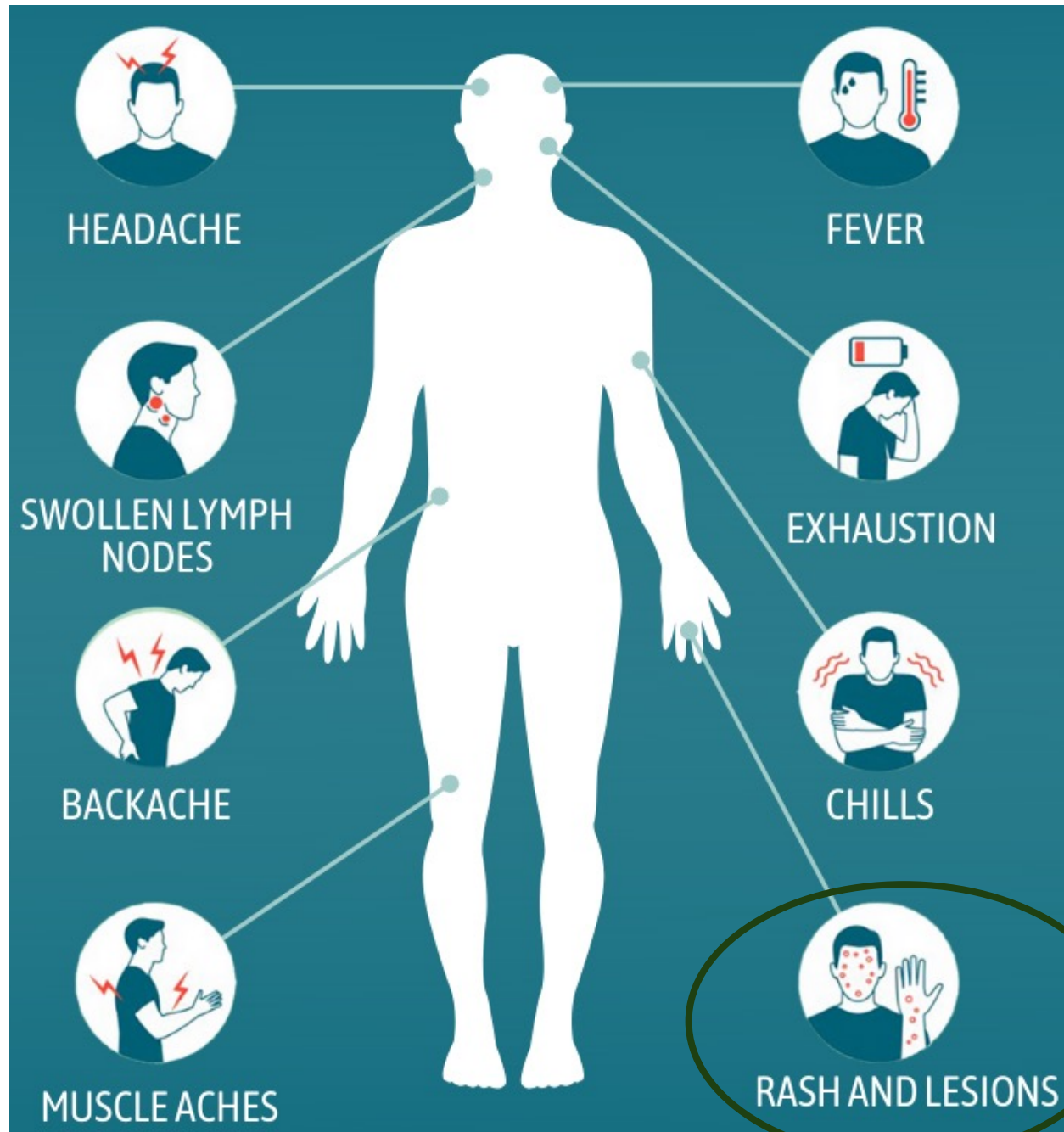
CDC, 2003,
<https://phil.cdc.gov/Details.aspx?pid=22664>



Legend

● Has not historically reported mpox

● Has historically reported mpox



HEADACHE



FEVER



SWOLLEN LYMPH
NODES



EXHAUSTION



BACKACHE



CHILLS



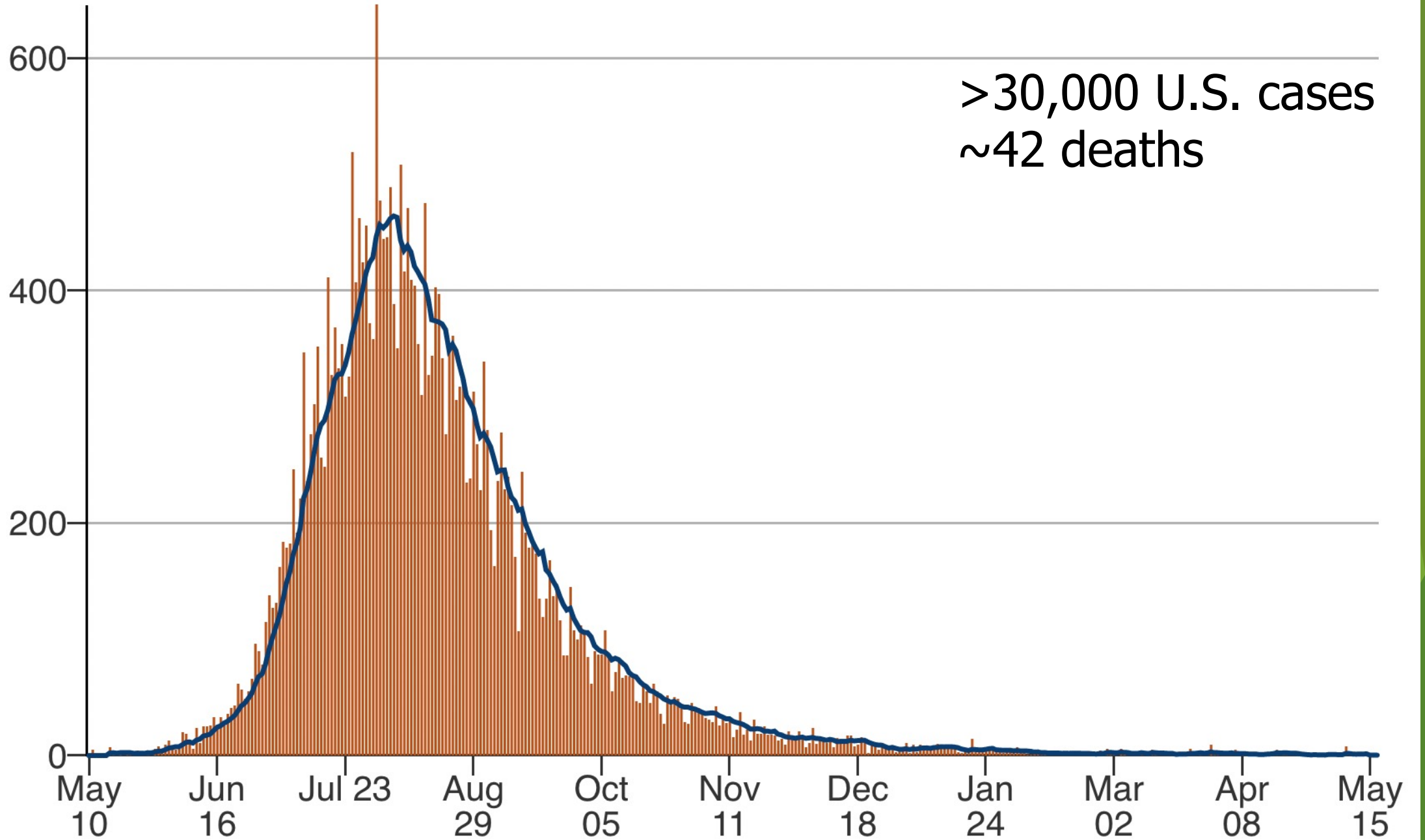
MUSCLE ACHES



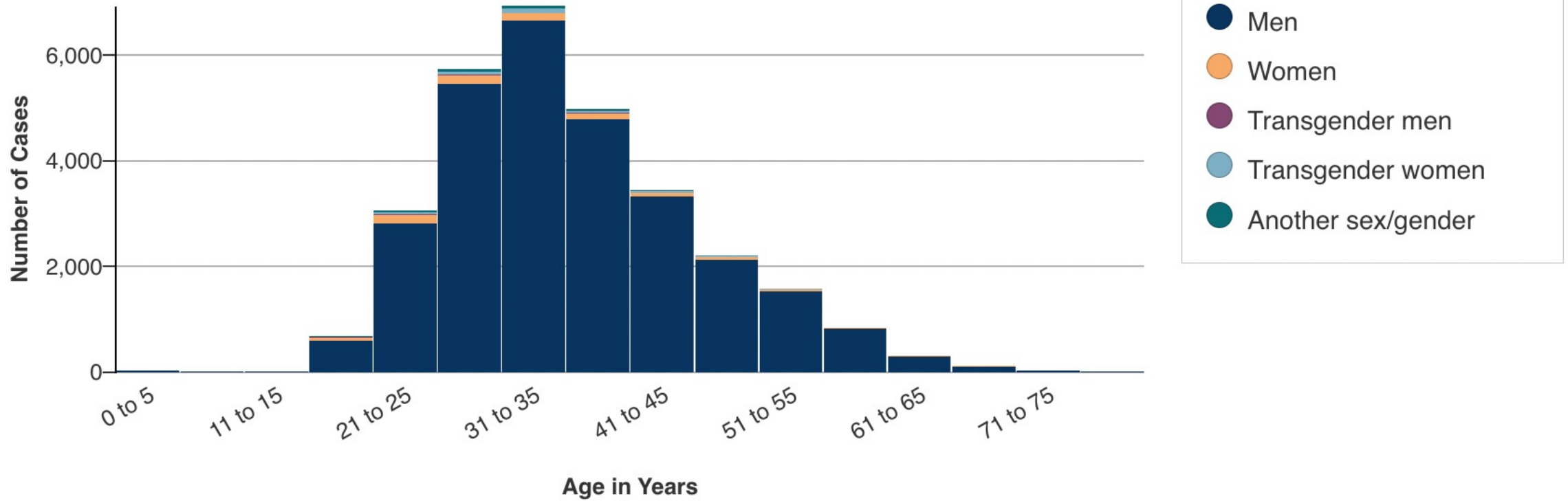
RASH AND LESIONS



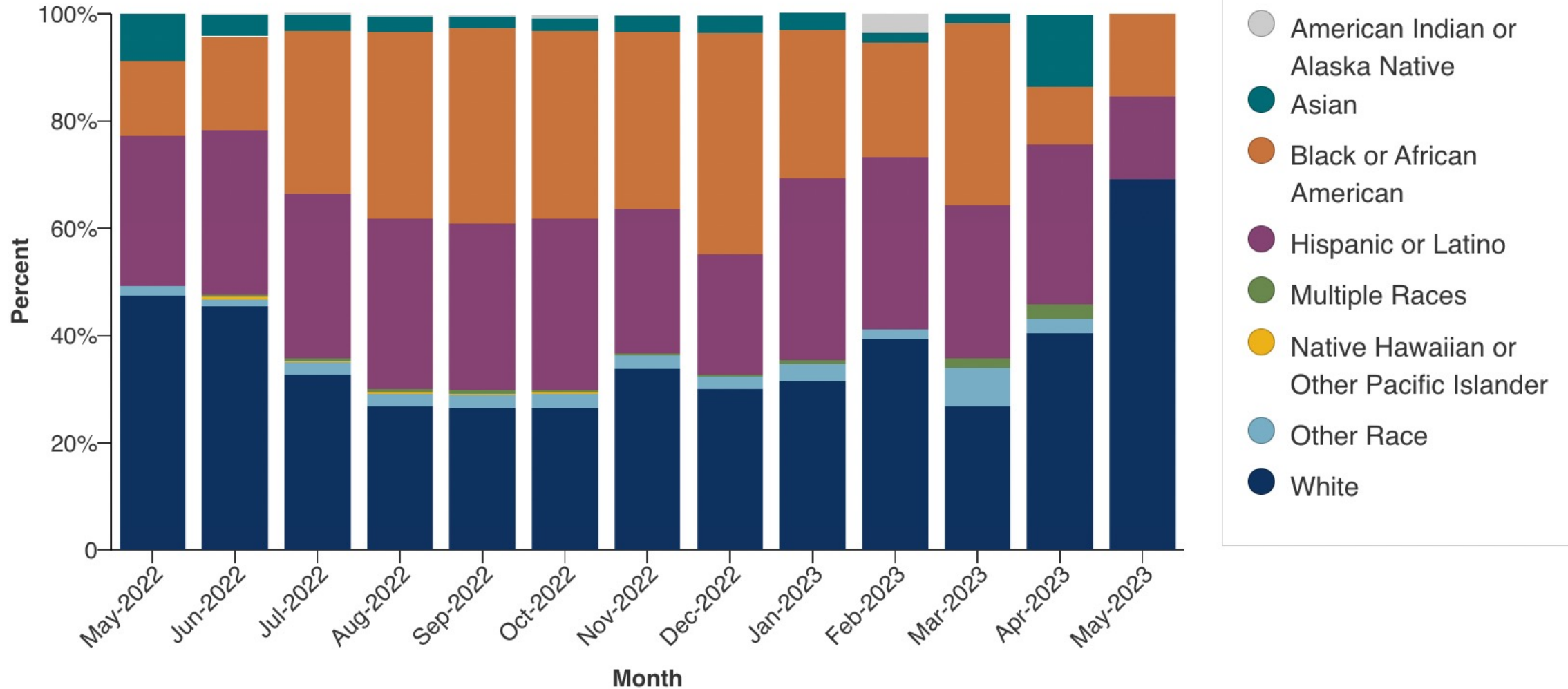
Number of Cases

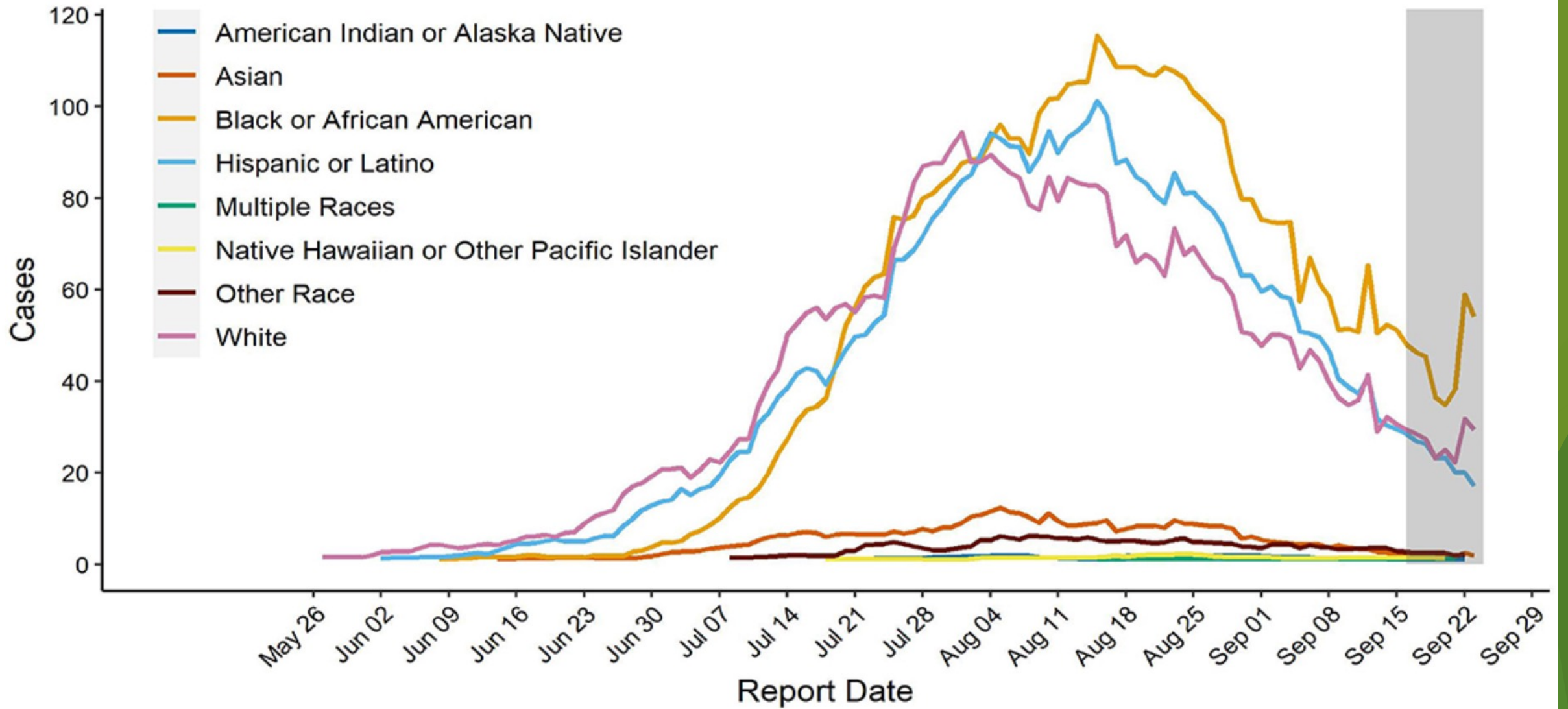


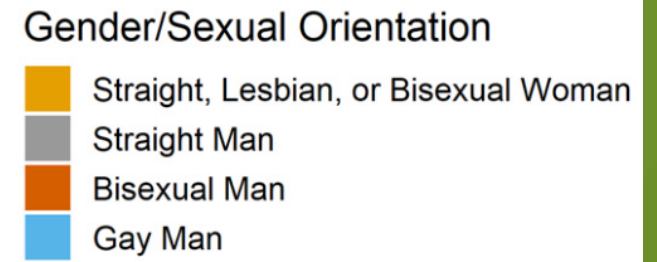
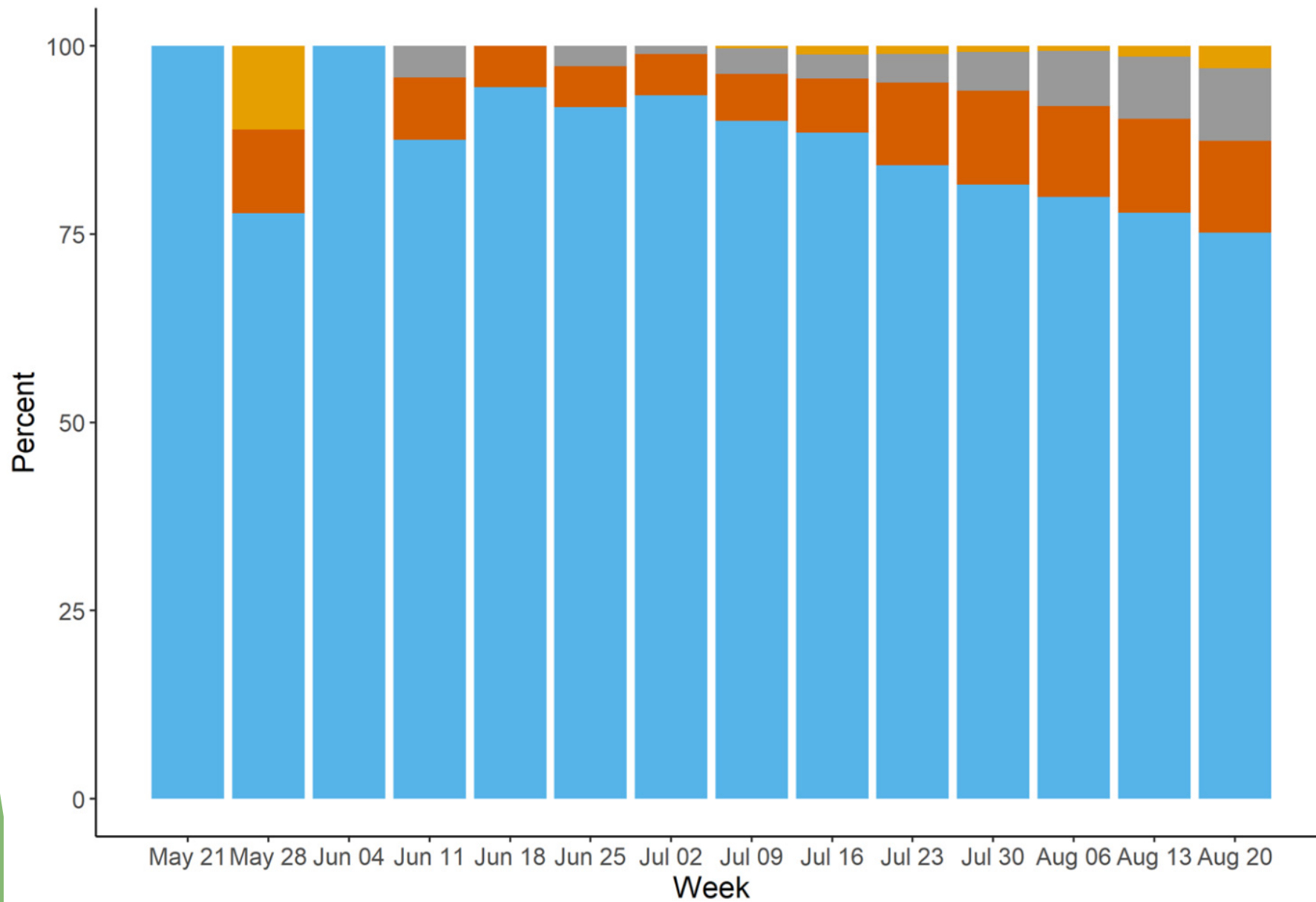
Mpox cases reported to CDC: Age and Gender

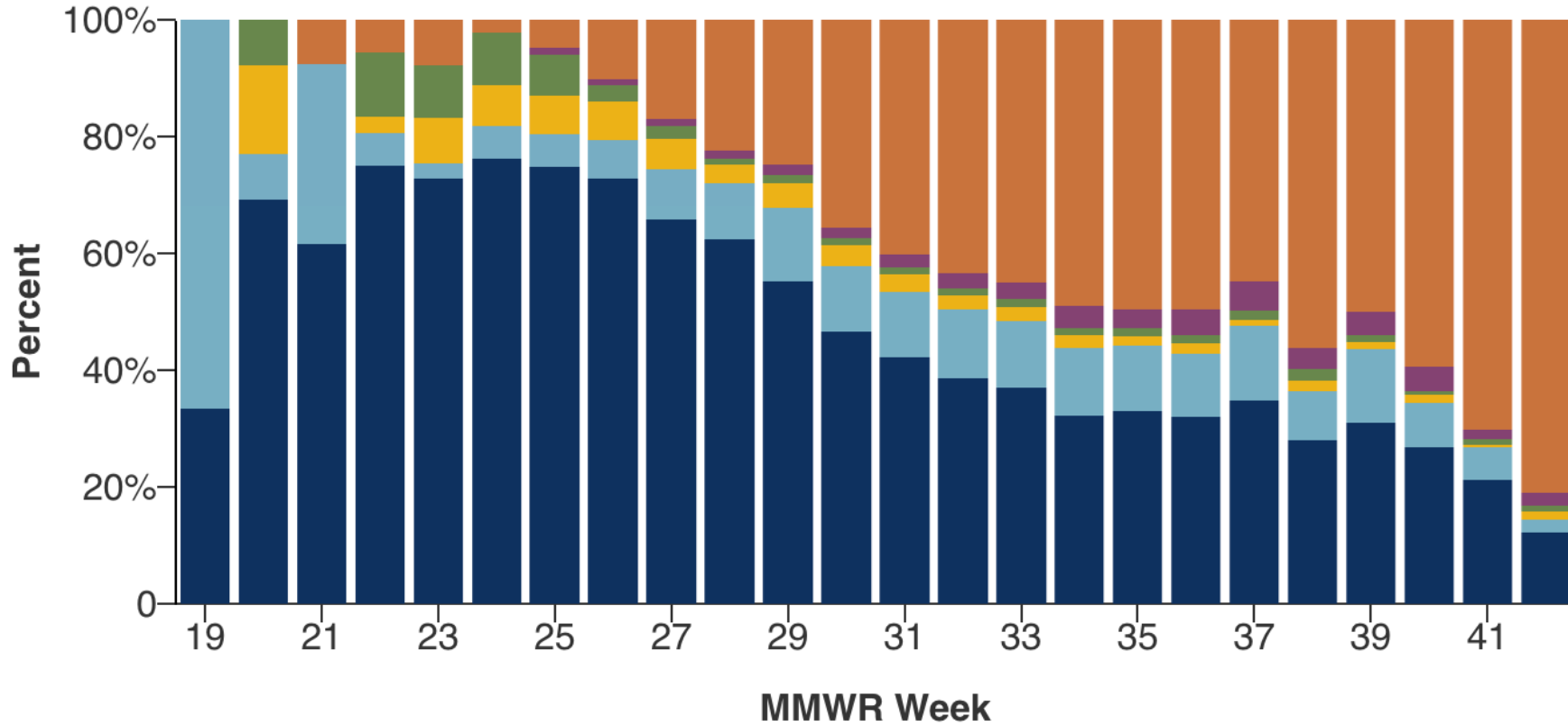


Proportion of All Cases by Race and Ethnicity by Month



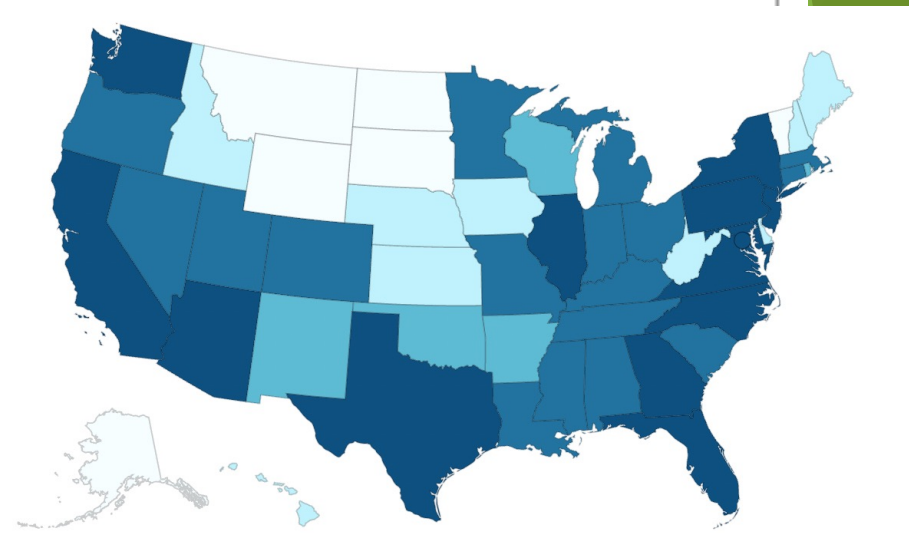
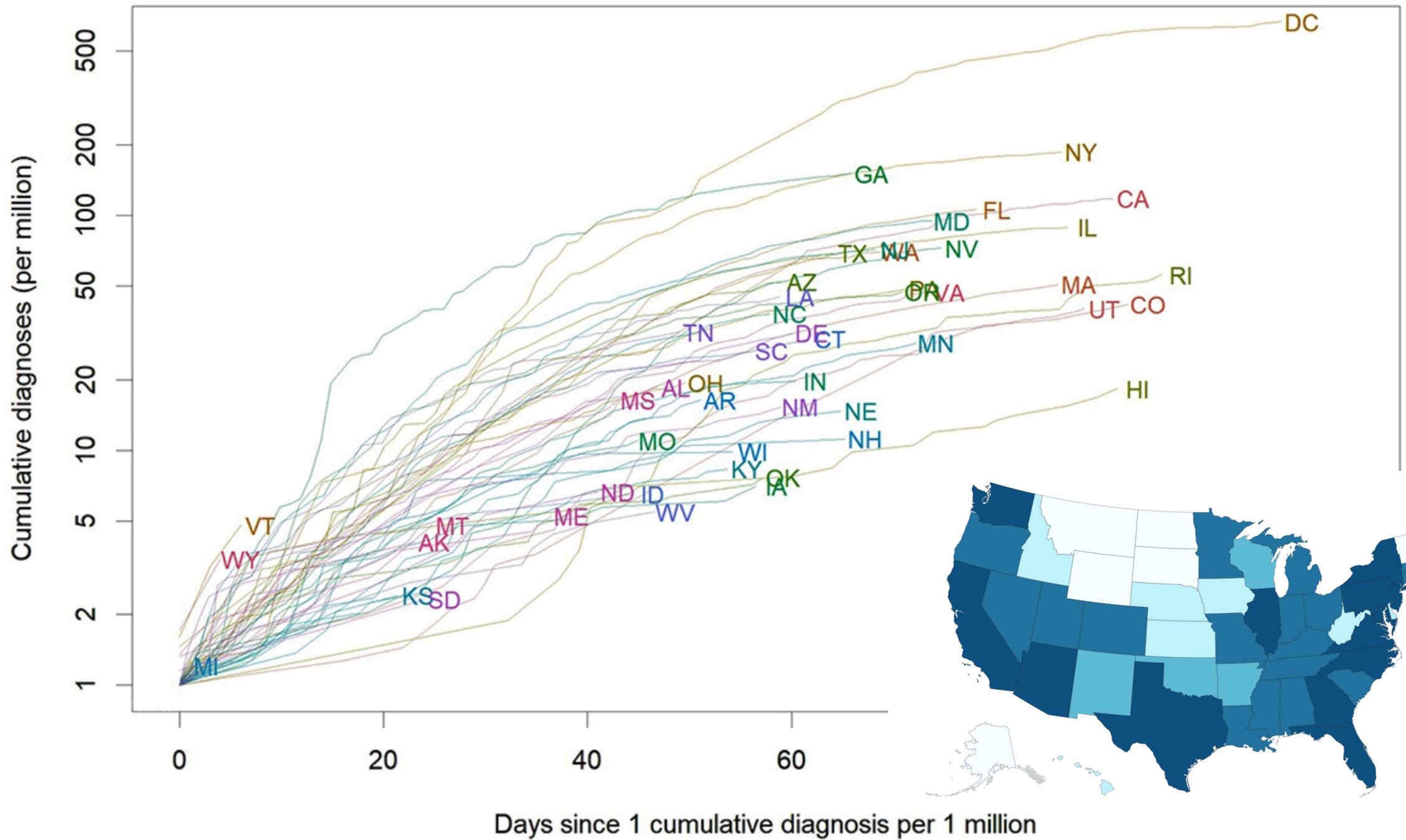






- Recent partners exclusively men
- No recent sexual partners
- Gender of all partners unknown/not specified
- Recent partners include men and other genders
- Recent partners exclusively women or other genders (no men)
- Missing sexual contact history





What is TPOXX?



TPOXX (Tecovirimat) – Antiviral

- Oral/IV
- **Not FDA-approved for mpox**
 - EMA-approved for smallpox, cowpox, mpox
 - FDA-approved for **smallpox** (“Animal rule”)
 - Safety: 359 healthy human volunteers
 - Efficacy: Primates w/mpox and rabbits w/ rabbitpox



JYNNEOS - Vaccine

- Bavarian Nordic
- FDA-approved for smallpox and mpox in adults in 2019

What is expanded access?

Access to Investigational Products

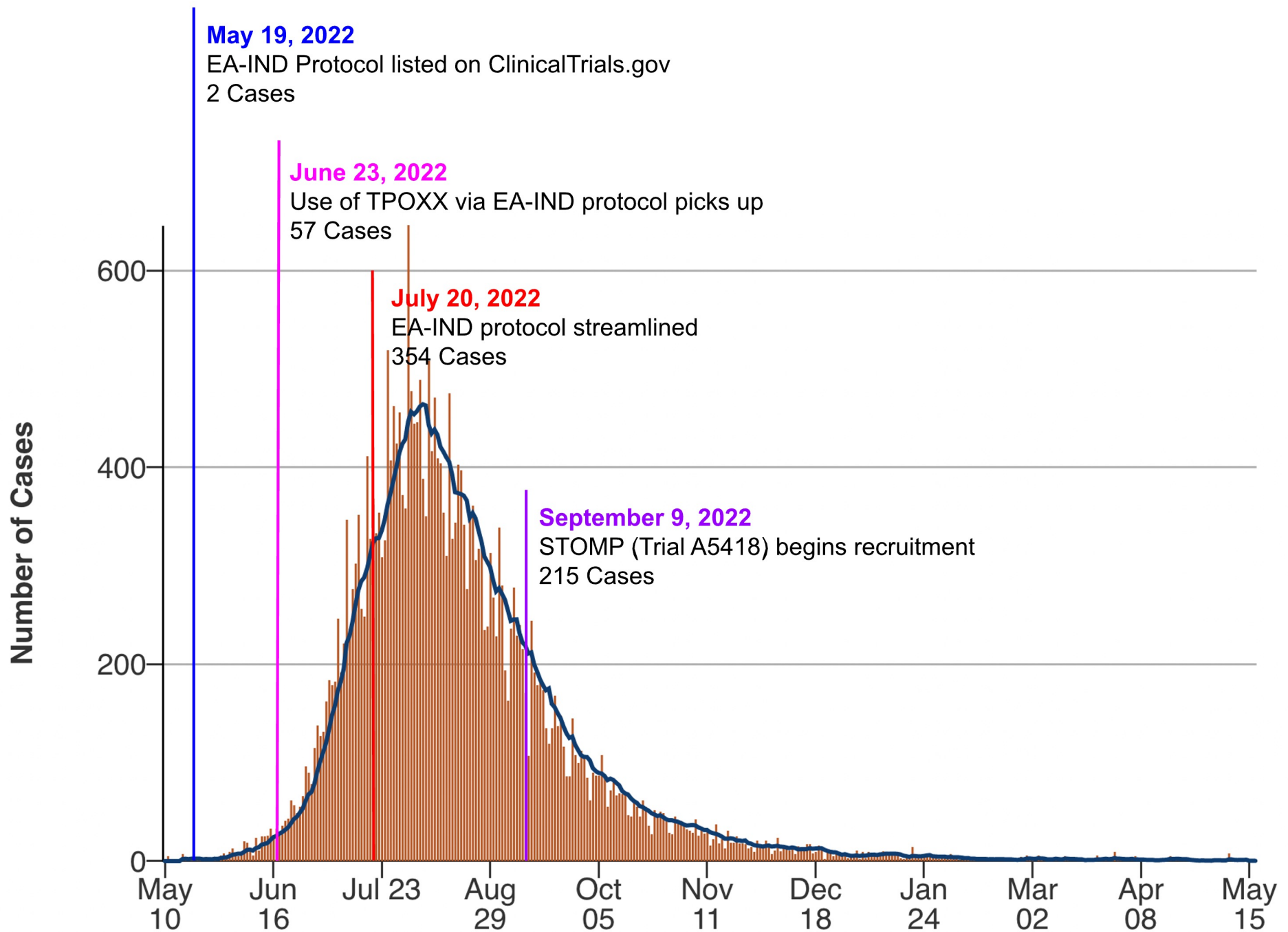
▶ Expanded Access (“Compassionate Use”)

- ▶ “IND Protocol” (HHS, FDA, CDC, BARDA, SIGA)

Other:

- ▶ ~~Clinical Trial~~ →
- ▶ ~~Emergency Use Authorization~~
- ▶ ~~Right to Try~~
- ▶ ~~Off-Label Use~~ →





AIDS Action Baltimore

Ali Moody

Program Operator/Peer Navigator & Patient Advocate at AIDS ACTION Baltimore



AIDS Action Baltimore

- ▶ AIDS Action Baltimore, Inc. (AAB) is dedicated to providing patient services for all people in Baltimore City.
 - ▶ The oldest CBO serving Baltimore over 34 years
 - ▶ Emergency financial assistance
 - ▶ HIV education, testing assistance
 - ▶ Navigation support for healthcare linkage
 - ▶ Retention in care, medication adherence, and access support
 - ▶ HIV prevention services, including outreach efforts and pre-exposure prophylaxis (PrEP) medication access

www.aidsactionbaltimore.org

Mpox and Baltimore

- ▶ **Quarterly Town Hall** on HIV and other public health topics that impact people living with HIV.
- ▶ **September 2022** - First Town Hall on Mpox
 - ▶ Information on mpox wasn't fully flushed out.
 - ▶ The Gay male community was in a panic about acquiring mpox.
 - ▶ No vaccines were available in Baltimore.
 - ▶ TPOXX as a treatment may have been available at this time but this information would have went over the general public's head.
 - ▶ Fear
 - ▶ Misinformation
 - ▶ Stigma
- ▶ **November 2022** - Second Town Hall on Mpox
 - ▶ AAB partnered with Baltimore City Health Department (BCHD) to make vaccines available at the Town Hall.

AAB Town Hall, March 2023

- ▶ **March 2023** - Hosted an **“MPOX Update”**
 - ▶ Where are we now?
 - ▶ New infections in Baltimore dropping.
 - ▶ False sense of safety because media no longer talking about mpox.
- ▶ People don't know the difference between the TPOXX treatment and the JYNNEOS vaccine.
 - ▶ TPOXX isn't on the community radar because prevention was the target conversation to the public.
- ▶ Hard to get vaccines in Baltimore City from July 2022 to February 2023. Unclear why vaccines were primarily available in Baltimore County.
 - ▶ Getting access to those location sites was even harder for those who didn't drive.

Baltimore Queer and Gay Community

- ▶ Businesses discriminated against LGBT+ community
 - ▶ Misinformation in the media (e.g., groups most affected, targeted sub-cultures, homophobia, and ignorance)
 - ▶ It got a little scary here in the DMV.
- ▶ Gay Male Baltimore community was proactive when it came to navigating clinical care of mpox and the outcomes that were happening.
 - ▶ When one of us got information on vaccines that information was share with everyone's networks.
 - ▶ If individuals didn't have access to a car people were carpooling to appointments.
- ▶ Uptick in individuals disclosing their mpox status online and documenting their experience on outlets like Facebook and Tic Tok.
 - ▶ I believe this helped with the stigma of MPOX.

Where are we now?

- ▶ People still don't know what mpox is and how it will affect them in the future.
- ▶ Little public interest in learning about mpox due to messaging around Gay men.
- ▶ The broader community is perhaps more interested in the prevention of mpox over its treating.
- ▶ Need more transparency around TPOXX and its efficacy for the general public.
- ▶ Uptick of infections in Chicago...
 - ▶ More question than answers ahead...



Sexually Transmitted Infections Services at Baltimore City Health Department

Elizabeth Anne Gilliams MD MS MSc

Medical Director for STI Services, BCHD Sexual Health Clinics
Clinical Associate, Johns Hopkins School of Medicine



Brandon M. Scott
Mayor, Baltimore City

Mary Beth Haller
Interim Commissioner of Health, Baltimore City

@Bmore_Healthy 
BaltimoreHealth 

health.baltimorecity.gov

Disclosures

Also on the study team for STOMP/ ACTG A5418 at JHU



Brandon M. Scott
Mayor, Baltimore City
Mary Beth Haller
Interim Commissioner of Health, Baltimore City



May- June 2022: Clinic preparedness

- Clinical Recognition
- Operational adaptations
 - Visit workflow & infection control
 - Testing via Maryland Dept of Health lab
 - Coordination with contact tracing

Lengthy patient visits (2 hours) and significant documentation burden

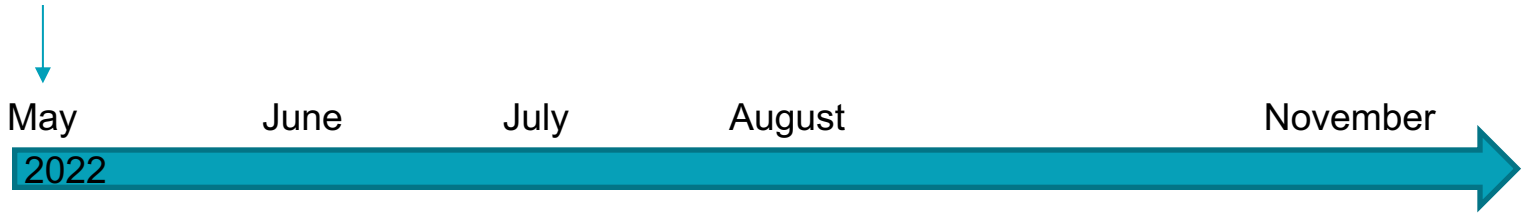


Brandon M. Scott
Mayor, Baltimore City
Mary Beth Haller
Interim Commissioner of Health, Baltimore City



Tecovirimat: an evolving process

CDC & MDH
communications
about awareness,
testing, tecovirimat

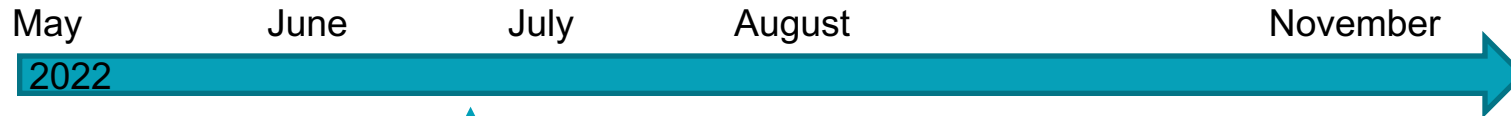


Brandon M. Scott
Mayor, Baltimore City
Mary Beth Haller
Interim Commissioner of Health, Baltimore City



Tecovirimat: an evolving process

CDC & MDH
communications
about awareness,
testing, tecovirimat



- First BCHD cases tested
- Who is eligible for tecovirimat?
- Case by case tecovirimat consideration with CDC, MDH, BCHD
- Drug shipped to clinic
- EA-IND requirements

- *Provider's CV and FDA investigator form (2 pages)*
- *IRB Reliance agreement (2 pages)*
- *Informed consent (4 pages)*
- *Patient intake form (6 pages)*
- *Day 1-7 clinical outcome form (3 pages)*
- *Day 8-14 clinical outcome form (3 pages)*
- *Day 21 clinical outcome form (3 pages)*
- *Drug accountability form (3 pages)*

26 pages



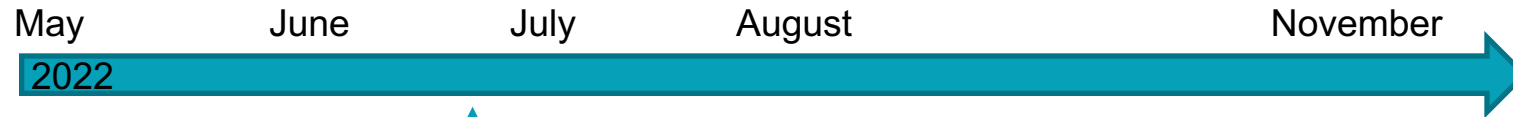
Brandon M. Scott
Mayor, Baltimore City
Mary Beth Haller
Interim Commissioner of Health, Baltimore City



Tecovirimat: an evolving process

CDC & MDH
communications
about awareness,
testing, tecovirimat

- Cases at peak
- CDC/MDH permits shipment of batches of tecovirimat to clinics



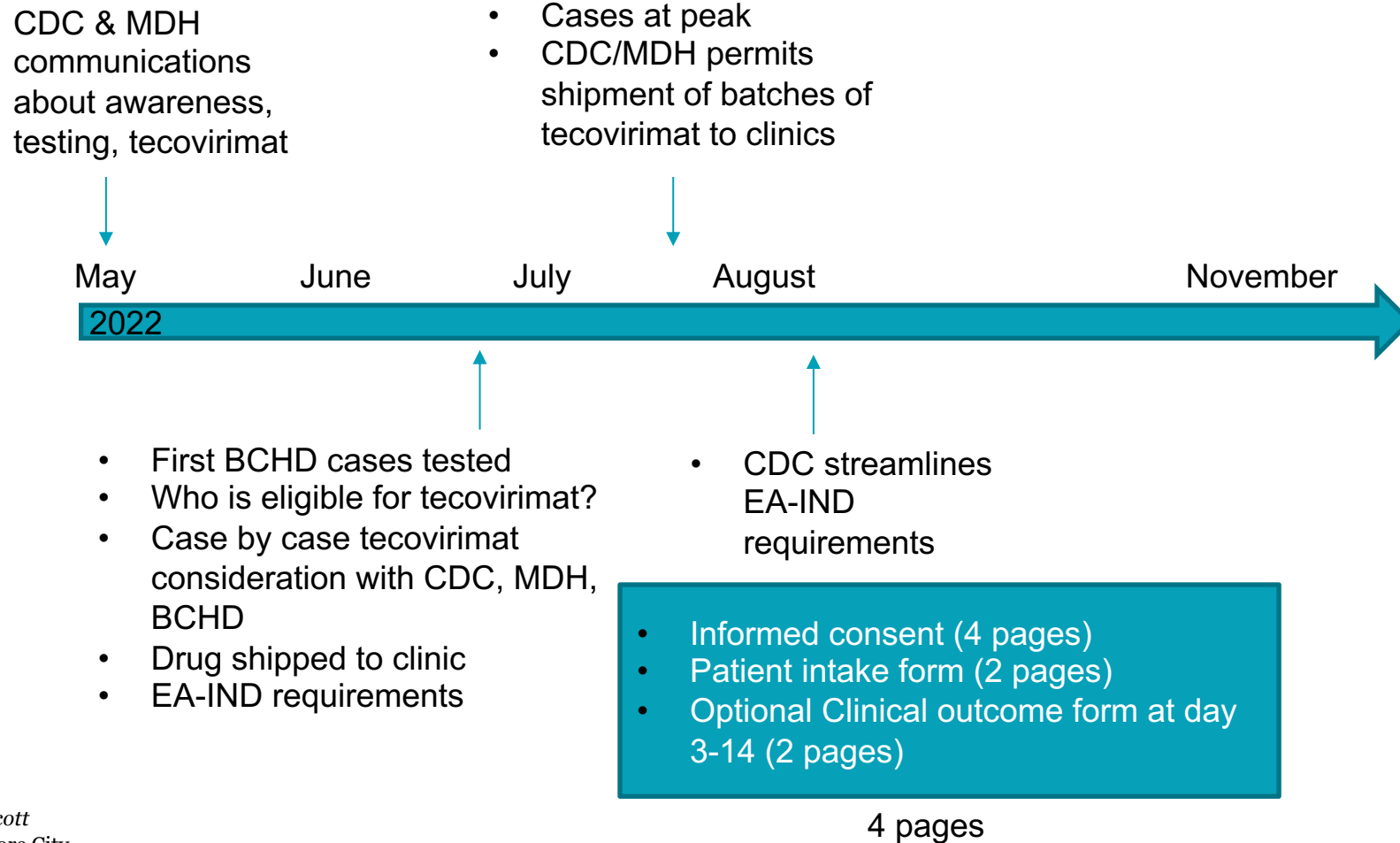
- First BCHD cases tested
- Who is eligible for tecovirimat?
- Case by case tecovirimat consideration with CDC, MDH, BCHD
- Drug shipped to clinic
- EA-IND requirements



Brandon M. Scott
Mayor, Baltimore City
Mary Beth Haller
Interim Commissioner of Health, Baltimore City



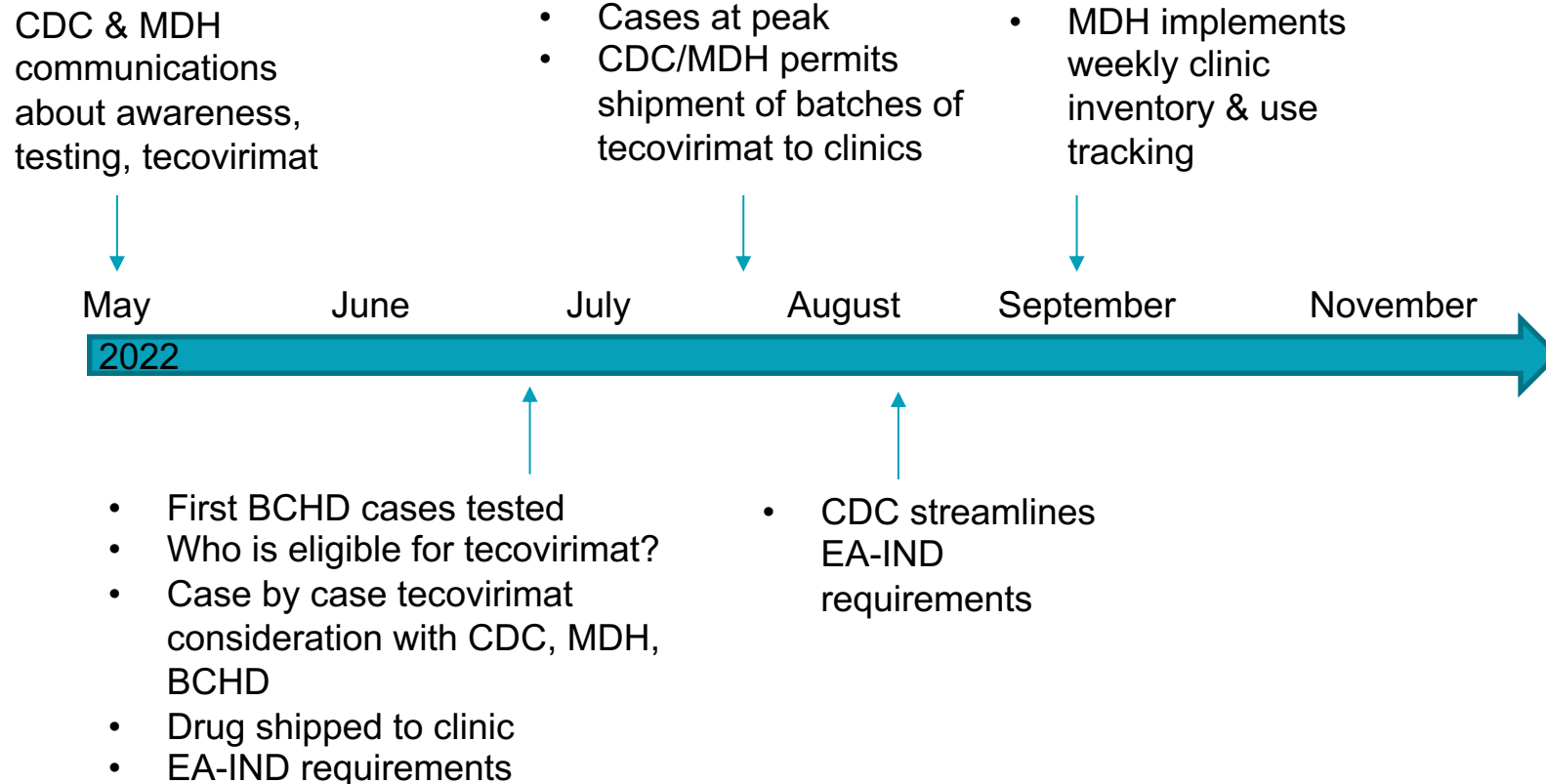
Tecovirimat: an evolving process



Brandon M. Scott
Mayor, Baltimore City
Mary Beth Haller
Interim Commissioner of Health, Baltimore City



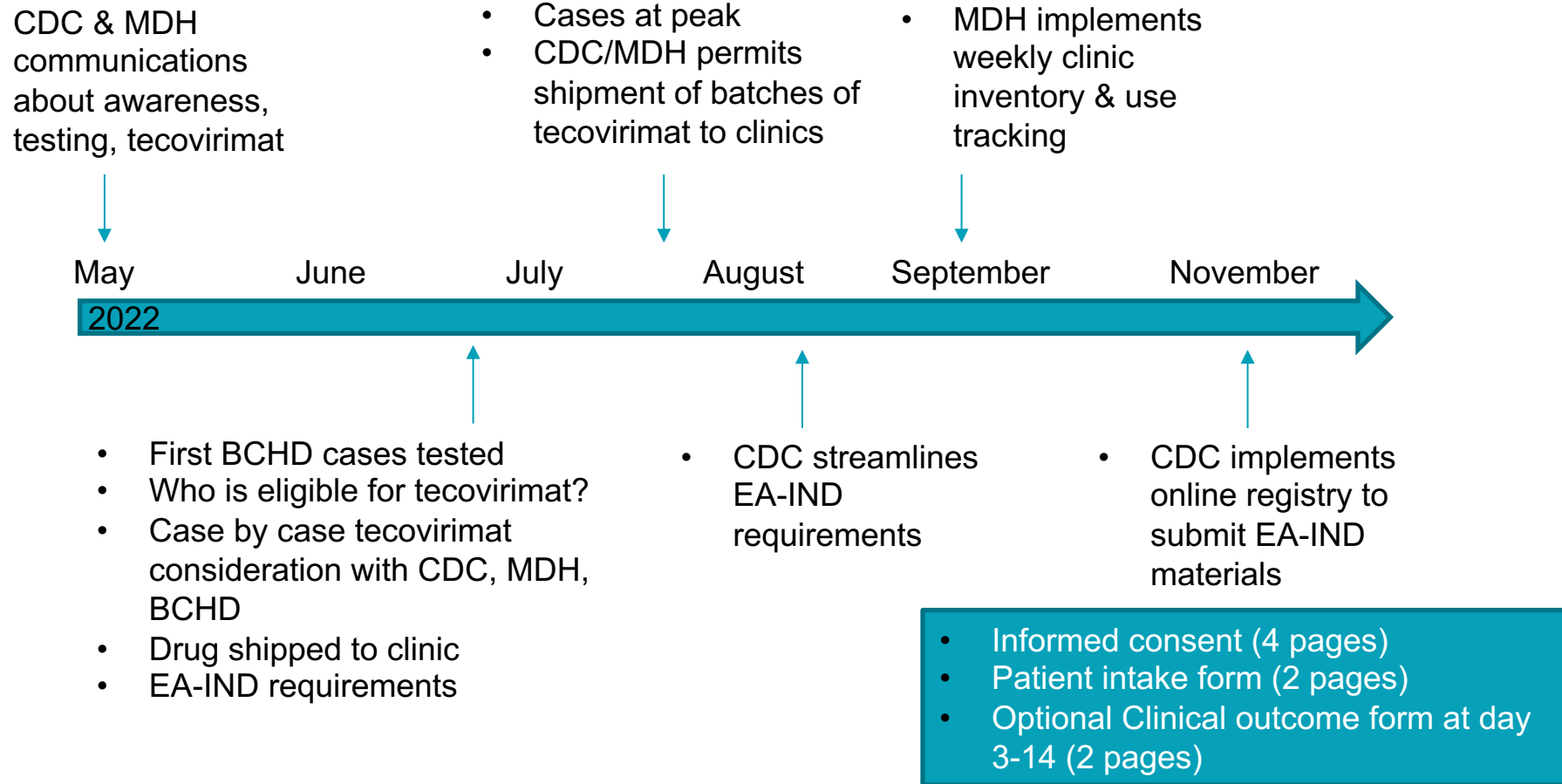
Tecovirimat: an evolving process



Brandon M. Scott
Mayor, Baltimore City
Mary Beth Haller
Interim Commissioner of Health, Baltimore City



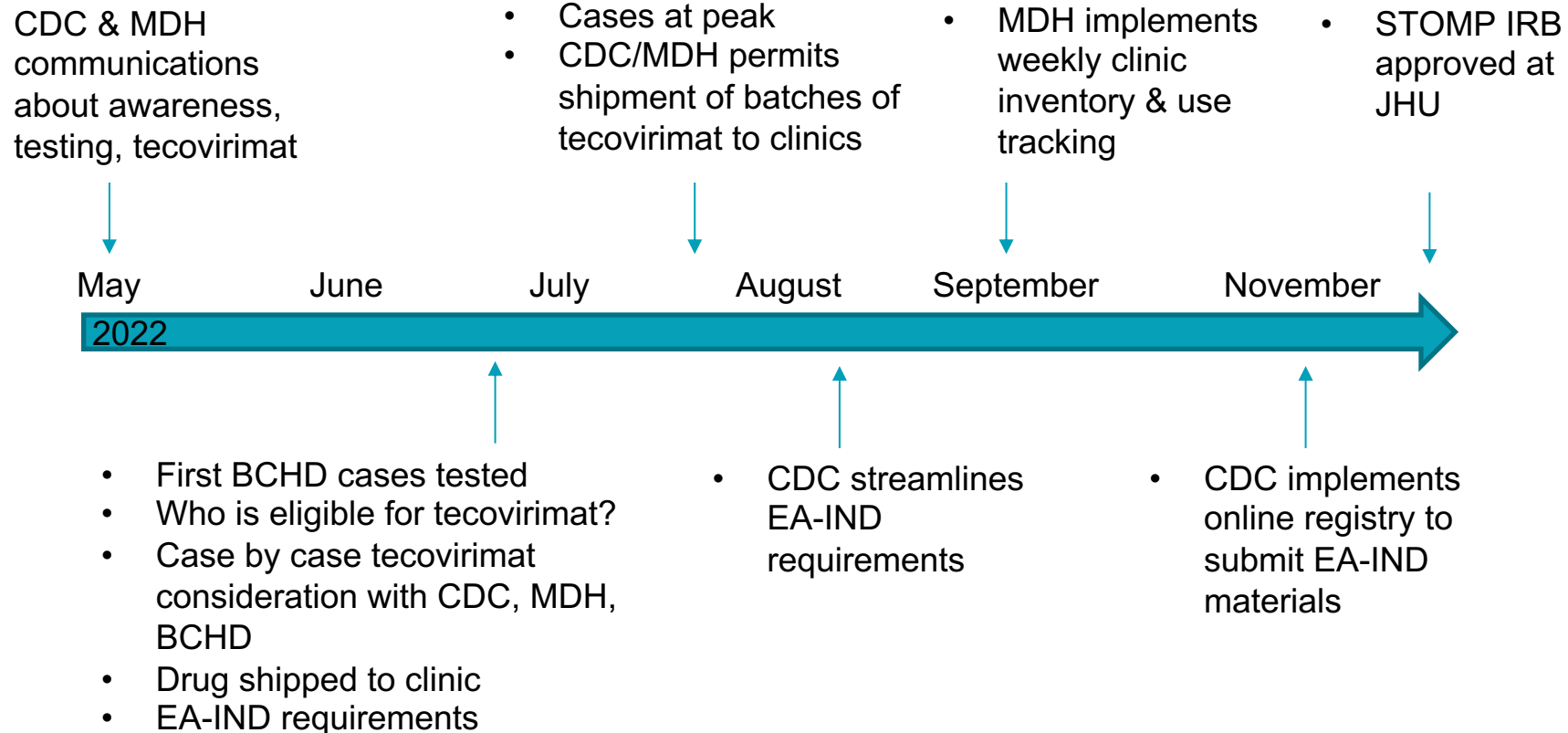
Tecovirimat: an evolving process



Brandon M. Scott
Mayor, Baltimore City
Mary Beth Haller
Interim Commissioner of Health, Baltimore City



Tecovirimat: an evolving process



Brandon M. Scott
Mayor, Baltimore City
Mary Beth Haller
Interim Commissioner of Health, Baltimore City



Patient counseling on tecovirimat

- *All tecovirimat was offered under EA-IND (not study)
- Few concerns about safety
- Almost all eligible patients were willing to try
 - Even if efficacy not well defined



Brandon M. Scott
Mayor, Baltimore City
Mary Beth Haller
Interim Commissioner of Health, Baltimore City



Where do we go from here?

- Continue to stock tecovirimat at clinics
- Efficacy still unclear
- How can procedures for EA-IND be made sustainable for providers?
 - Major access equity concerns



Brandon M. Scott
Mayor, Baltimore City
Mary Beth Haller
Interim Commissioner of Health, Baltimore City



CDC Tecovirimat Expanded Access Investigational New Drug (EA-IND) Protocol

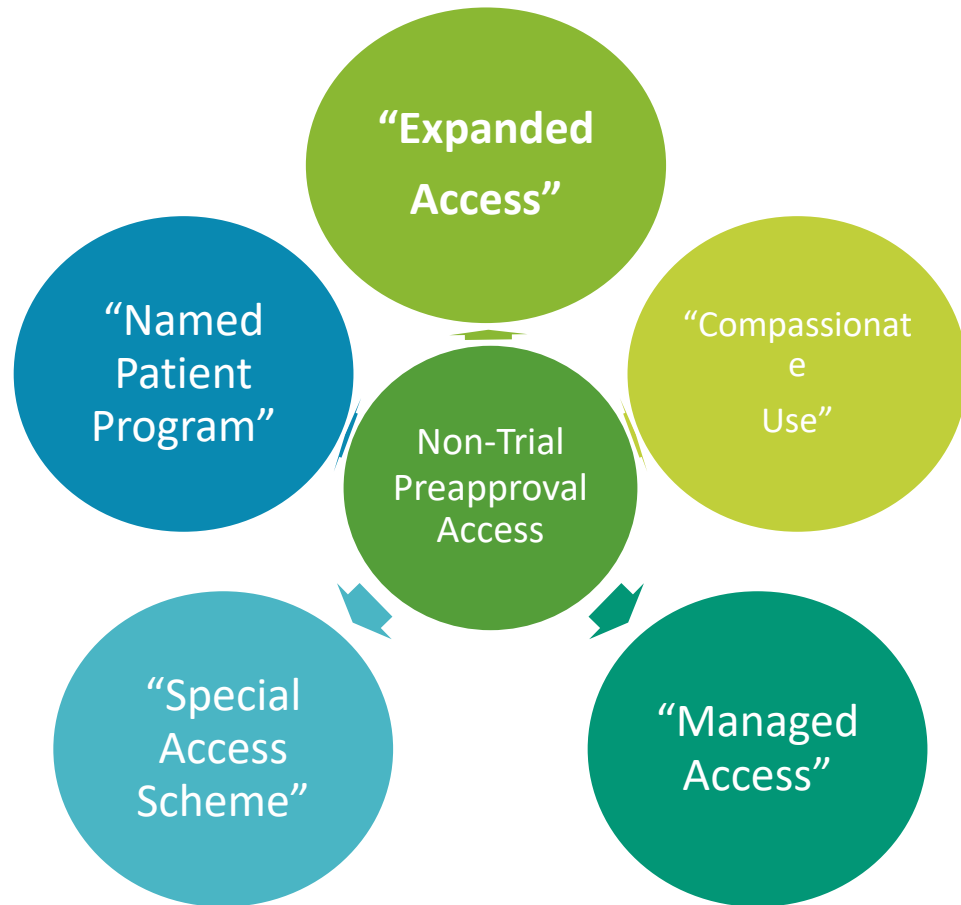
Hayley Belli PhD

Assistant Professor of Biostatistics at NYU Grossman School of Medicine
Co-Chair of Ethics & Real-World Evidence (ERWE) research project Member of
Working Group on Compassionate Use & Pre-Approval Access (CUPA)

Disclosures

- ▶ Member of the New York City Observational Study of MPOX Immunity (NYC OSMI) study team
 - ▶ Role: Co-Investigator/Statistician

Expanded Access terminology and stipulations



- ▶ *Mechanism that enables patients with an unmet medical need to gain access to an unapproved medical product when they are unable to enter a clinical trial*
- Serious or life threatening condition
- No approved alternative available
- Cannot interfere with clinical development
- Positive benefit/risk assessment for patient

How do people access medical products before regulatory approval?

- ▶ **Clinical Trials [research]**. In the case of unapproved medical products, trials are intended to learn about safety & efficacy of product; used to support regulatory decision-making]
- ▶ **Non-Trial Preapproval Access [treatment]**
 - ▶ Expanded Access
 - ▶ Right to Try
 - ▶ Emergency Use Authorization

Let's briefly set aside EA...

What are "Real World Data"
and "Real World Evidence?"

According to the FDA

Real World Data (RWD)

- ▶ Data relating to patient health status &/or the delivery of health care routinely collected from a variety of sources:
 - ▶ Electronic health records (EHRs)
 - ▶ Medical claims & billing data
 - ▶ Mobile & wearable devices
 - ▶ Product & disease registries
- ▶ In EA, myriad possibilities for what can be considered RWD: lab values, functional outcomes, patient-reported outcomes, etc.

Real World Evidence (RWE)

- ▶ Clinical evidence regarding the usage & potential benefits or risks of a medical product derived from analysis of RWD

Important to differentiate that RWD is derived from sources outside of randomized controlled trials (RCTs)

Promises and pitfalls of collecting RWD from Expanded Access programs in public health emergencies

- ▶ EA is intended for treatment not research
- ▶ RWD collected from EA may be of value by
 - ▶ Providing safety information
 - ▶ Generating hypotheses or inform the design of an RCT
 - ▶ Identifying biomarkers
 - ▶ Determining characteristics for stratification when randomizing in an RCT
 - ▶ Providing valuable data in the rare disease space where there are few patients
 - ▶ Providing valuable data in situations where RCTs are not feasible
 - ▶ Enhancing generalizability of RCTs as supplemental data
- ▶ When evaluating efficacy, the data always must be fit for purpose and collected using rigorous methods

Information for Healthcare Providers: Tecovirimat (TPOXX) for Treatment of Mpox

Updated February 28, 2023 [Print](#)

On This Page

[STOMP Clinical Study Information](#)

[Summary of Recent Changes](#)

[Tecovirimat \(TPOXX\) IND Online Registry](#)

[Tecovirimat IND Protocol](#)

[Institutional Review Board \(IRB\) Approval](#)

[How to Obtain Tecovirimat](#)

EAP should never hinder RCT enrollment!



STOMP Clinical Study Information

Providers should inform patients about the [Study of Tecovirimat for Human Mpox Virus \(STOMP\)](#) [↗](#) for their voluntary participation. If enrollment in STOMP is not feasible for a patient (e.g., a clinical trial site is not geographically accessible), tecovirimat use under CDC's expanded access protocol should be in concert with [CDC's guidance for treatment](#). [Demographics of patients receiving tecovirimat under the EA-IND are available on CDC's website](#).

Findings from TPOXX EA-IND protocol

- ▶ From May-August 2022, 549 patients with virus treated with tecovirimat under EA protocol, 369 patients with outcome forms including hospitalization data for 331 patients.
- ▶ “Tecovirimat is generally well tolerated, and these data support continued access treatment with tecovirimat during current outbreak.”
- ▶ “No control group was available for comparison; therefore, no conclusions can be drawn regarding the effectiveness of tecovirimat to treat monkeypox based on these data.”

Study of Tecovirimat for Human Mpox Virus (STOMP) Protocol

Matthew M Hamill MBChB PhD MPH MSc

Assistant Professor of Medicine at Johns Hopkins School of Medicine
Clinical Chief for STI Services at Baltimore City Health Department
Co-Developer of AIDS Clinical Trial Group's (ACTG) STOMP protocol



STOMP

Study of Tecovirimat for Human Monkeypox Virus



JOHNS HOPKINS
SCHOOL *of* MEDICINE

Disclosures

- ▶ Consulting
 - ▶ Roche diagnostics
 - ▶ GSK
- ▶ Writing royalties
 - ▶ Clinical Care Options
 - ▶ UpToDate

Tecovirimat for mpox - a very brief history

- ▶ 2018, Tecovirimat approved to treat **smallpox** by the under the “Animal Rule”
 - ▶ This rule allows findings from animal studies to support an FDA approval when human trials are not possible
 - ▶ No smallpox circulating to test Tecovirimat against a real-world infection, the drug qualified for this rule and was approved to treat smallpox
- ▶ The 2018 approval did not include **mpox**
 - ▶ CDC and FDA collaborated in 2022 to establish an Expanded Access—Investigational New Drug (EA-IND) pathway for Tecovirimat for use to treat mpox in the event of an outbreak



Study of Tecovirimat for Human Monkeypox Virus

STOMP [About the Study](#) [Participating Research Sites](#)

Call Center: 1-855-876-9997 (U.S. only)

NOW ENROLLING REMOTELY ACROSS THE UNITED STATES!

Call today for more information: 1-855-876-9997



Think you
might have
Monkeypox?

WE
NEED

YOUR
HELP!



1-855-876-9997



*Stock photo. Posed by model.

ACTG & STOMP protocol

- ▶ AIDS Clinical Trials Group (ACTG), established in 1987
- ▶ ACTG is the largest HIV clinical trials organization in the world and has conducted major trials that have advanced the standard of care for people living with HIV in the United States and around the world
- ▶ The ACTG is funded by the National Institutes of Health (NIH) through the National Institute of Allergy and Infectious Diseases (NIAID)
- ▶ The scientific priorities of the ACTG network include research to:
 - Identify strategies to **cure and/or achieve a functional** cure for HIV
 - Improve the **diagnosis** and **treatment** of **tuberculosis**, especially in those co-infected with HIV
 - Identify strategies to cure **infectious hepatitis**
 - Prevent or improve the treatment of, **non-infectious co-morbidities** and evaluate novel interventions targeting HIV Infection
 - Improve the **treatment for viral related malignancies** in HIV-infected adults

STOMP and other mpox protocols

- ▶ STOMP to enroll 530 people <https://clinicaltrials.gov/ct2/show/NCT05534984>
- ▶ 2 randomized arms TPOXX or placebo (2:1)
 - ▶ Double blind
 - ▶ If deterioration --> open label arm and receive TPOXX
 - ▶ Started 9/12/2022
 - ▶ EA-IND May 2022
- ▶ The third arm is open label
 - ▶ People with more severe mpox infection
 - ▶ people who have immune suppression
 - ▶ children
 - ▶ pregnant people
- ▶ Other studies
 - ▶ PLATINUM (UK)
 - <https://www.platinumtrial.ox.ac.uk/> (paused 3 April 2023)
 - ▶ PALM initiated in 2018 in DRC (NIAID and the DRC Ministry of Public Health), N=450, phase 2. 1:1
 - Started Oct 2022
 - ▶ CAR EA (Clade 1) (12/2021 - 2/2022)

Steps to Register and Access Electronic Patient Intake and Clinical Outcome Forms

Register Online

- Register as participating providers and facilities to be covered under the CDC-held TPOXX IND protocol.
- The electronic Form FDA 1572 can be completed through the online registry if it was not previously submitted to CDC.



Complete Verification

- Upon registration, the provider will receive the first email from "CDC TPOXXIND <noreply@dcipher.cdc.gov>" confirming registry as a participating provider to prescribe, dispense, and/or administer TPOXX under the CDC-held IND.
- Please complete the brief verification steps included in the email to access the electronic Patient Intake and Clinical Outcome Forms.



Grandfathered Providers

- A provider who has submitted TPOXX IND forms to CDC with a valid email address **prior** to online registry activation on 10/28/2022 ("grandfathered providers") automatically received the verification email described in step 2.
- Any provider who did not receive this email must register through the [TPOXX IND Online Registry](#).

Access Patient Intake Form (Required)

- Upon verification, a provider will receive a second email with a secure link to electronically fill out the Patient Intake Form.
- The secure link can be accessed multiple times to complete the form for each patient treated.
- For each patient treated with TPOXX, providers must submit the completed form to CDC within 7 days of therapy initiation.
- **Note:** For security reasons, the form must be completed and submitted in one sitting.



Access Clinical Outcome Form (Optional)

- Upon verification, a provider will receive a third email with a secure link to electronically fill out the Clinical Outcome Form.
- The secure link can be accessed multiple times to complete the form for each patient treated.
- For each patient treated with TPOXX, providers are requested to submit the form to CDC within 7 days of the last patient follow up.
- **Note:** For security reasons, the form must be completed and submitted in one sitting.

For any questions regarding the TPOXX IND Online Registry and/or electronic forms, please email regaffairs@cdc.gov.

www.cdc.gov/poxvirus

CS 534280-K | 1/31/2023

▶ N Engl J Med. 2022 Dec 15;387(24):2294-2295. doi: 10.1056/NEJMc2210015. Epub 2022 Nov 30.

Tecovirimat for Monkeypox in Central African Republic under Expanded Access

Festus Mbrenge¹, Emmanuel Nakouné¹, Christian Malaka¹, Josephine Bourner², Jake Dunning², Guy Vernet¹, Peter Horby³, Piero Olliaro³

Affiliations + expand

PMID: 36449745 PMID: PMC10117058 DOI: 10.1056/NEJMc2210015

Design considerations

- ▶ Lots of discussions about randomization ration, 2:1 chosen to increase chance of active drug
- ▶ Discussions around open label and switch from randomized to open label
- ▶ Dose 600mg 359 healthy adults (18-79 years)
 - ▶ 336 participants received at least 23 of 28 doses of 600 mg tecovirimat in a twice daily regimen for 14 days [Gibson and Leibowitz 2019]
 - ▶ 59% female, 69% White, 28% Black/African American, 1% Asian, and 12% Hispanic or Latino ethnicity
 - ▶ Ten percent of the participants were 65 or older
- ▶ STOMP trial sites initially all existing ACTG sites in the US
 - ▶ Expansion outside of ACTG
 - ▶ Expansion outside of US: Peru, Brazil, South Africa, Mexico

<https://actgnetwork.org/studies/a5418-study-of-tecovirimat-for-human-monkeypox-virus-stomp/>

Evidence of tecovirimat efficacy

- ▶ Efficacy of tecovirimat in nonhuman primate (monkeypox (name in 2018)) and rabbit (rabbitpox) models
 - ▶ The minimum dose of tecovirimat required in order to achieve more than 90% survival in the monkeypox model was 10 mg per kilogram of body weight for 14 days
- ▶ CAR 600 mg BID
- ▶ EA-IND n= 549 (5/2022 - 8/2022)
- ▶ Among 369 patients, few adverse events were reported

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

Weekly / September 16, 2022 / 71(37);1190–1195

On September 9, 2022, this report was posted online as an MMWR Early Release.

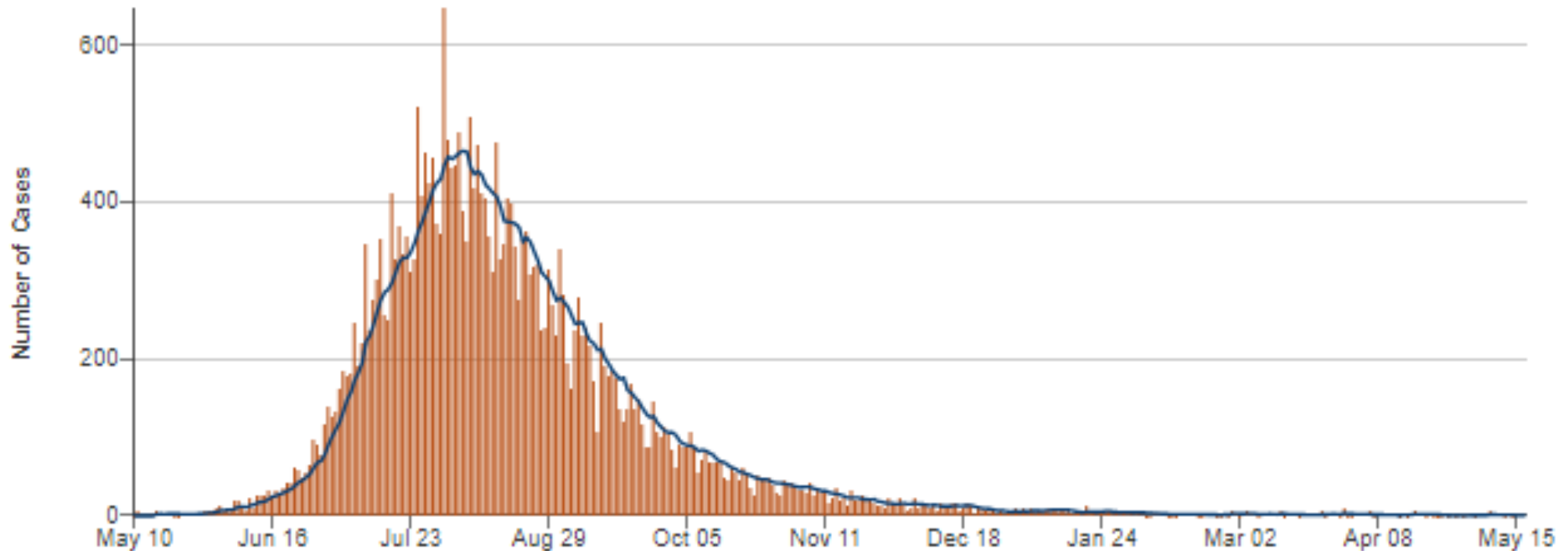
Kevin O’Laughlin, MD¹*; Farrell A. Tobolowsky, DO¹*; Riad Elmor, MS²; Rahsaan Overton, MPH¹; Siobhán M. O’Connor, MD¹; Inger K. Damon, MD, PhD¹; Brett W. Petersen, MD¹; Agam K. Rao, MD¹; Kevin Chatham-Stephens, MD¹; Patricia Yu, MPH¹; Yon Yu, PharmD¹; CDC Monkeypox Tecovirimat Data Abstraction Team ([VIEW AUTHOR AFFILIATIONS](#))

- ▶ STOMP if >120 kg dose is 600mg BID
 - ▶ Participants will be seen weekly through day 29
 - ▶ Participants will be seen at day 57 to assess for possible recrudescence of infection (i.e., new lesions occurring after initial resolution of disease)

STOMP status

- ▶ Continuing recruitment
- ▶ Slow

Daily Mpox Cases and 7 Day Daily Average



Moderated Discussion

The background features abstract, overlapping geometric shapes in various shades of green, ranging from light to dark. The shapes are primarily triangles and polygons, creating a dynamic and layered visual effect. The colors transition from a pale, almost white-green on the left to a deep, forest green on the right.

TABLE 2. Clinical outcomes abstracted from outcome forms of patients with *Monkeypox virus* infection who received tecovirimat (Tpoxx) under the Food and Drug Administration–regulated Expanded Access Investigational New Drug protocol (N = 369) — United States, May–August 2022

Outcome (no. unknown or missing)	No. (%)
Hospitalized (38)	
Yes*	23 (6.9)
Intensive care unit*	2 (0.6)
No	308 (93.1)
Outcome† (52)	
Recovered without sequelae	189 (59.6)
Recovered with sequelae	41 (12.9)
Not yet recovered	87 (27.4)
Days to subjective improvement§ (114)	
Median, days (IQR)	3.0 (2–4)
Adverse event¶ (29)	
Yes	12 (3.5)
No	328 (96.5)
Median no. of days to follow up after treatment initiation (IQR)**	
During treatment: assessment A (day 1–7)	6 (4–7)
During treatment: assessment B (day 8–14)	10 (8–13)
Posttreatment: assessment C	21 (20–23)
Assessment A (day 1–7) (156)	213 (57.7)
New lesions (22)	
Yes	25 (13.1)
No	166 (86.9)
All lesions crusted and healed with new layer of skin (59)	
Yes	49 (31.8)
No	105 (68.2)
Assessment B (day 8–14) (187)	182 (49.3)
New lesions (19)	
Yes	22 (13.5)
No	141 (86.5)
All lesions crusted and healed with new layer of skin (25)	
Yes	78 (49.7)
No	79 (50.3)
Assessment C (posttreatment) (225)	144 (39.0)
New lesions (7)	
Yes	3 (2.2)
No	134 (97.8)
All lesions crusted and healed with new layer of skin (11)	
Yes	119 (89.5)
No	14 (10.5)

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

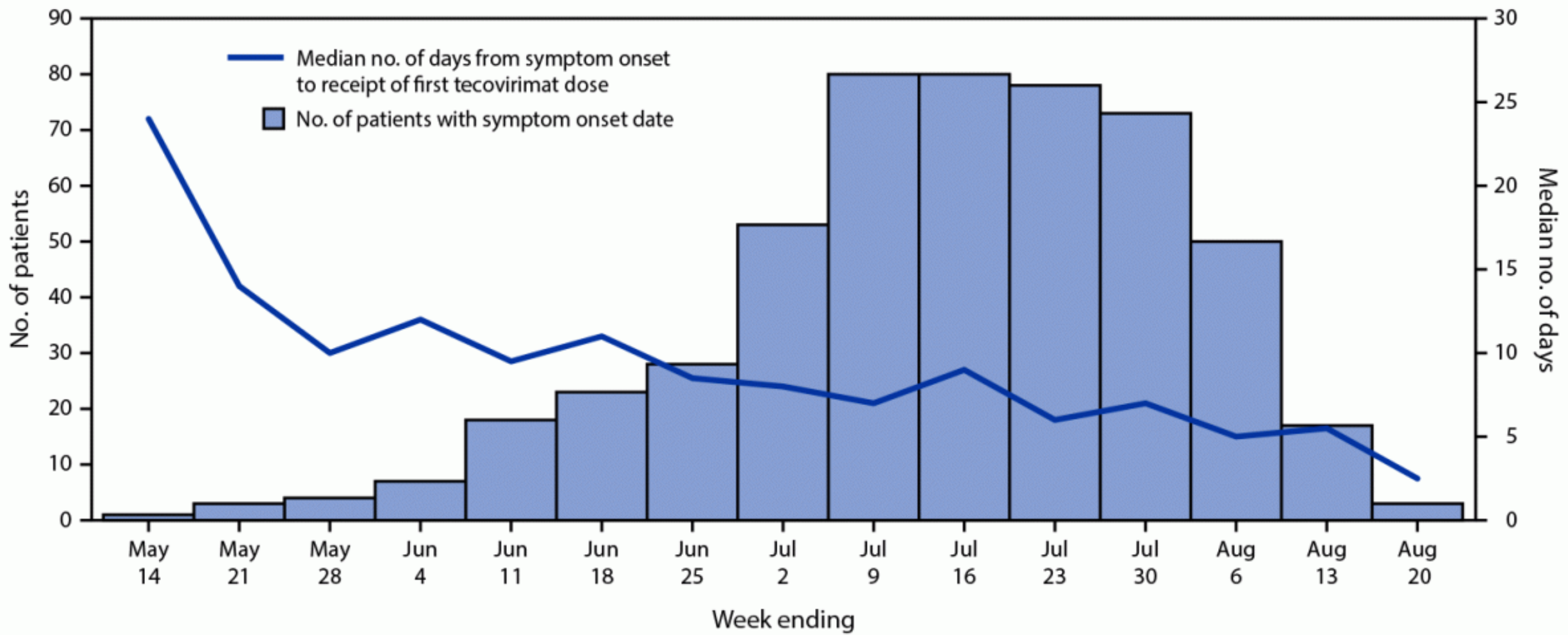
Background. Monkeypox virus (MPV) infection is a zoonotic disease caused by MPV. In 2022, monkeypox virus infection was first reported in the United States. The Food and Drug Administration (FDA) approved an investigational new drug protocol for the use of tecovirimat (Tpoxx) for the treatment of monkeypox virus infection. This report describes the clinical outcomes of patients who received Tpoxx under the FDA-regulated expanded access investigational new drug protocol.

Methods. We conducted a retrospective cohort study of patients who received Tpoxx under the FDA-regulated expanded access investigational new drug protocol for monkeypox virus infection in the United States from May 1, 2022, to August 31, 2022. Data were collected from electronic medical records, patient questionnaires, and clinical notes. The primary outcome was the proportion of patients who were hospitalized. Secondary outcomes included the proportion of patients who were in intensive care, the proportion of patients who were recovered without sequelae, the proportion of patients who were recovered with sequelae, the median number of days to follow up after treatment initiation, the proportion of patients who had adverse events, and the median number of days to follow up after treatment initiation.

Results. A total of 369 patients were enrolled in the study. The median age was 38 years (range, 18–84 years). The majority of patients were male (80.5%). The majority of patients were from the United States (98.1%). The majority of patients were from the Washington, DC, metropolitan area (50.1%). The majority of patients were from the United States (98.1%). The majority of patients were from the Washington, DC, metropolitan area (50.1%).

Conclusions. The majority of patients who received Tpoxx under the FDA-regulated expanded access investigational new drug protocol for monkeypox virus infection were hospitalized. The majority of patients who received Tpoxx under the FDA-regulated expanded access investigational new drug protocol for monkeypox virus infection were recovered without sequelae. The median number of days to follow up after treatment initiation was 3.0 days. The majority of patients who received Tpoxx under the FDA-regulated expanded access investigational new drug protocol for monkeypox virus infection did not have adverse events.

Keywords: Monkeypox virus; tecovirimat; expanded access; investigational new drug protocol; United States; May–August 2022.





Gay, bisexual, and other men who have sex with men are taking steps to protect themselves and their partners from mpox.



48%
reduced number of sex
partners



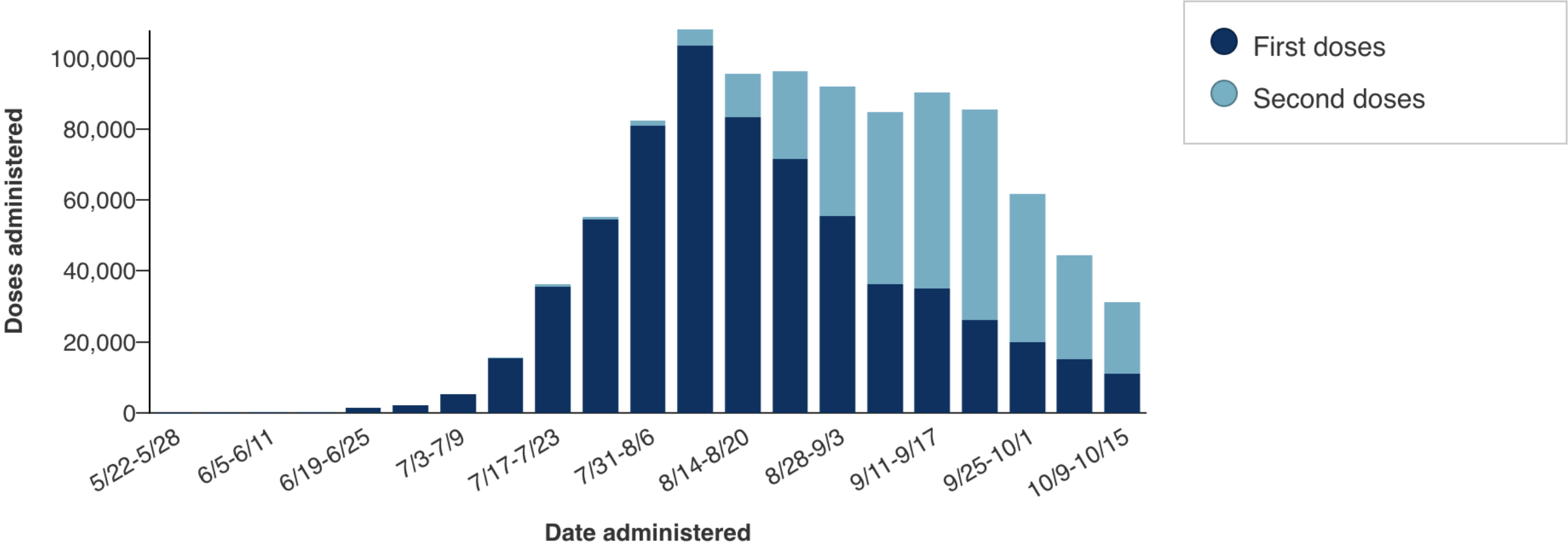
50%
reduced one-time sexual
encounters

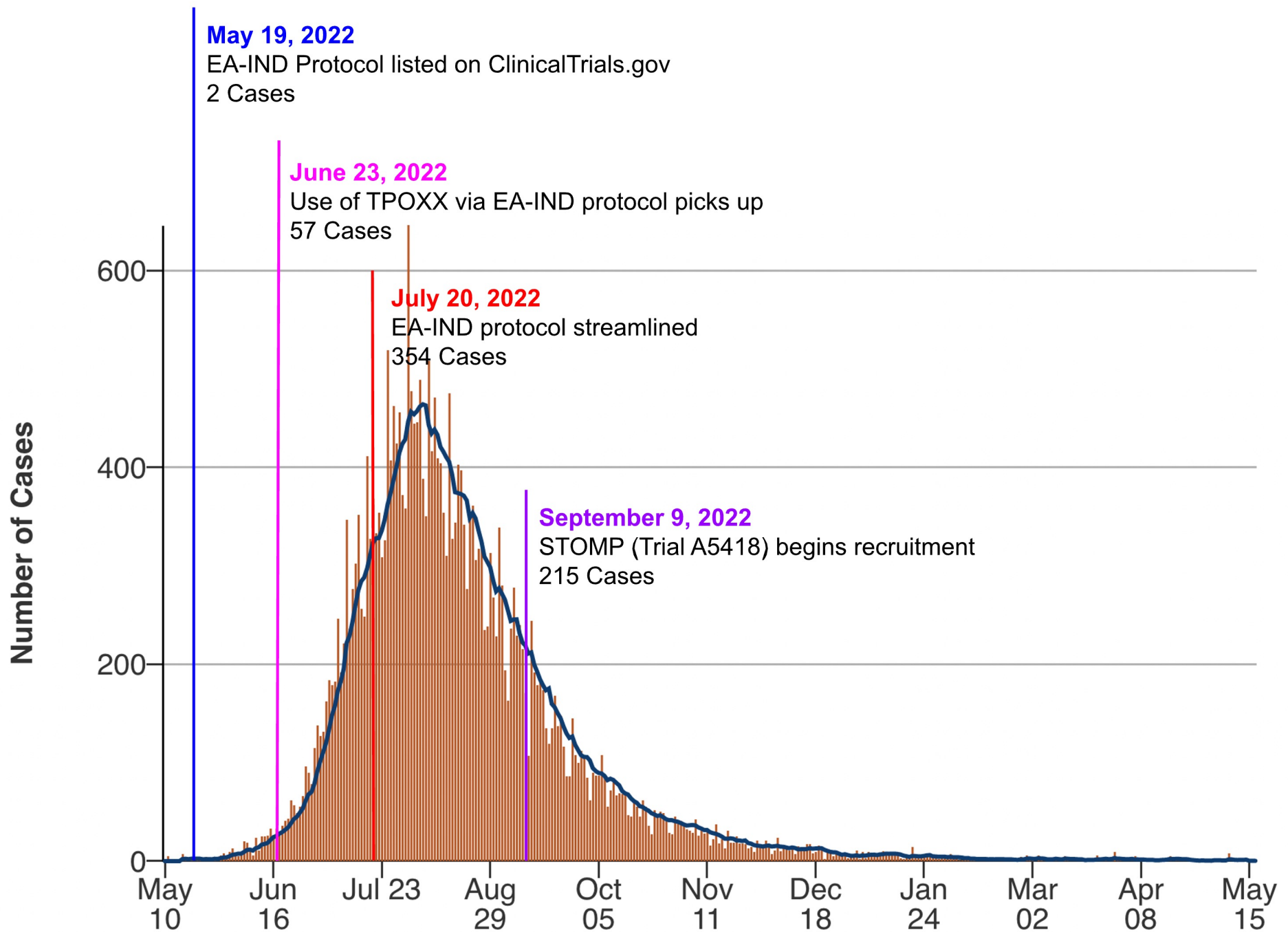


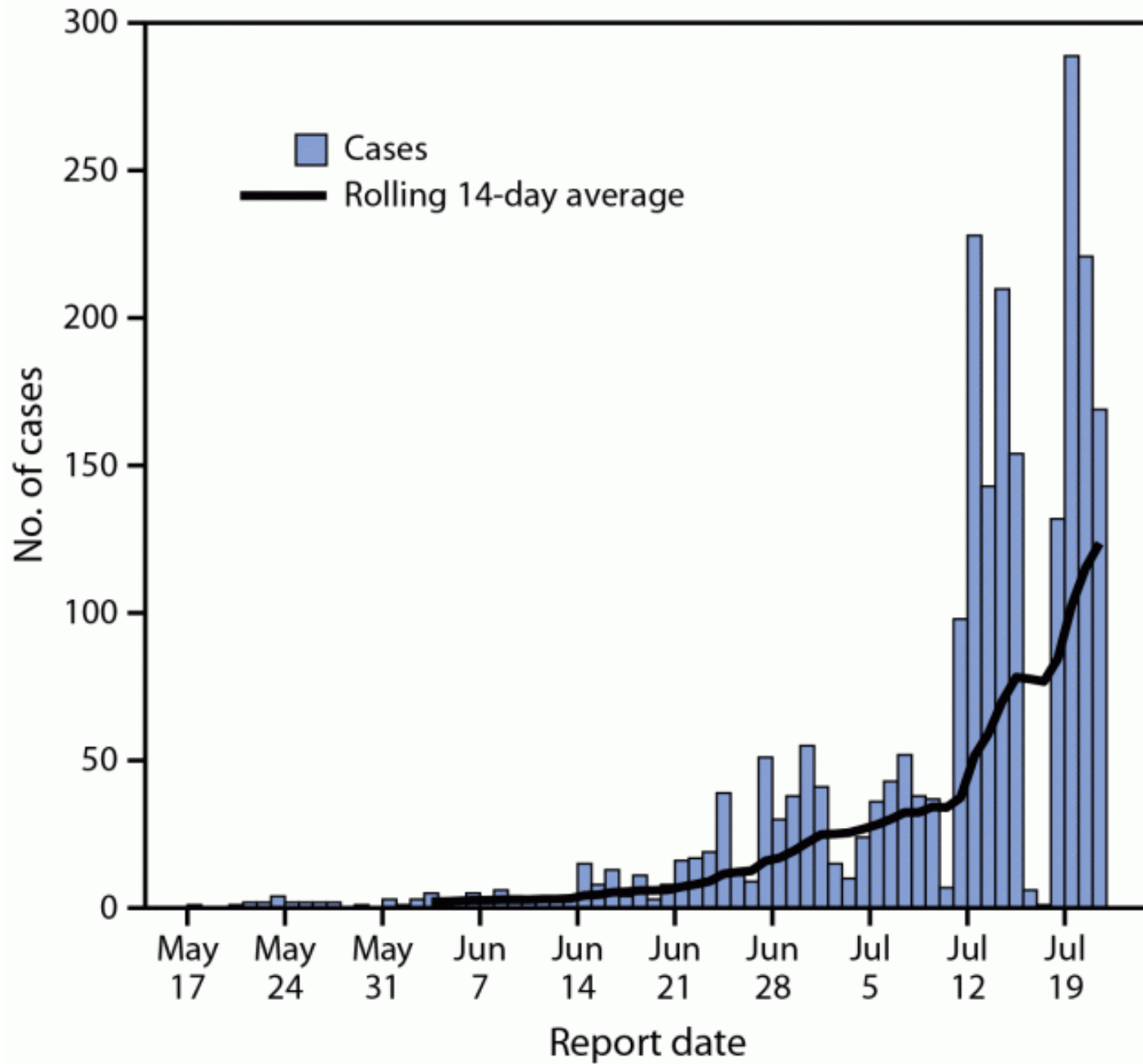
50%
reported reducing sex with
partners met on dating apps
or at sex venues

Monkeypox Vaccine Administered, by Dose Number and Date of Administration

Data Reported to CDC as of October 21, 2022







FORBES > INNOVATION > HEALTHCARE

CDC Issues New Mpox Alert After 12 Confirmed Cases In Chicago

Bruce Y. Lee Senior Contributor @

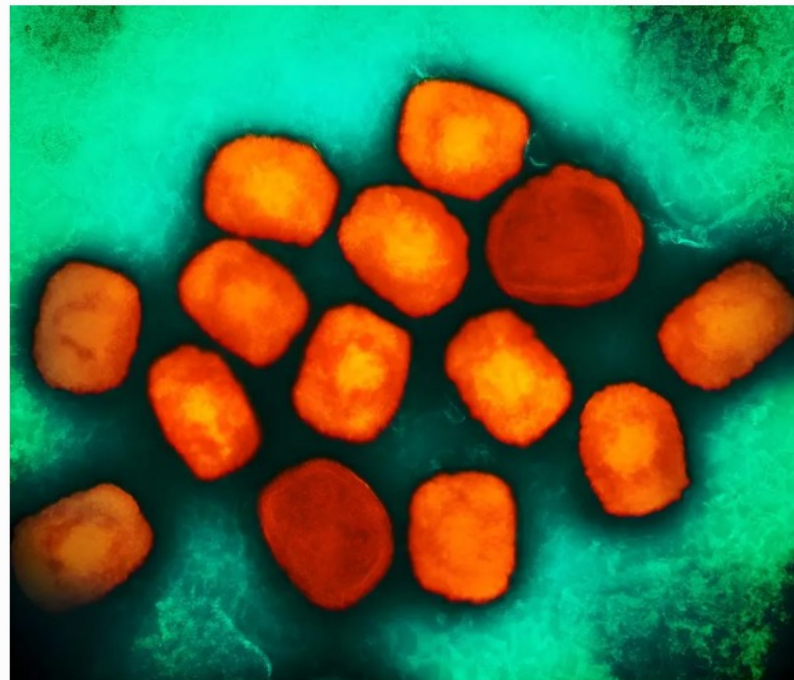
I am a writer, journalist, professor, systems modeler, computational and digital health expert, avocado-...

Follow

0

May 17, 2023, 09:42am EDT

Listen to article 8 minutes



The Chicago Department of Public Health (CDPH) reported what they called a "resurgence of mpox." ... [+] BSIP/UNIVERSAL IMAGES GROUP VIA GETTY IMAGES

Closing Remarks

The background features a complex, abstract design of overlapping, semi-transparent green polygons. The colors range from light, pale greens to deep, dark forest greens. The shapes are angular and layered, creating a sense of depth and movement. The overall composition is modern and clean, with the text 'Closing Remarks' positioned on the left side of the slide.



JOHNS HOPKINS
SCHOOL of MEDICINE



**AIDS
ACTION
BALTIMORE**

Thank you to the SCT
Planning Committee

Thanks to Lisa Aguado!

