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GENOVA SANREMO FAST TRACK CITIES

Il vaiolo delle scimmie: problema risolto o solo dimenticato?

UNIVERSITÀ DEGLI STUDI DI GENOVA

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Conflitto di interessi

- In merito a questa presentazione non ho conflitti di interesse da dichiarare
- Non ho ricevuto alcun supporto nel preparare questa relazione

Vaiolo delle scimmie = mpox

- **On of 28 November 2022, WHO recommended using the name *mpox* as a new name for *monkeypox*. The words will be used synonymously for one year while the term *monkeypox* is phased out.**

Problema risolto o solo dimenticato ?

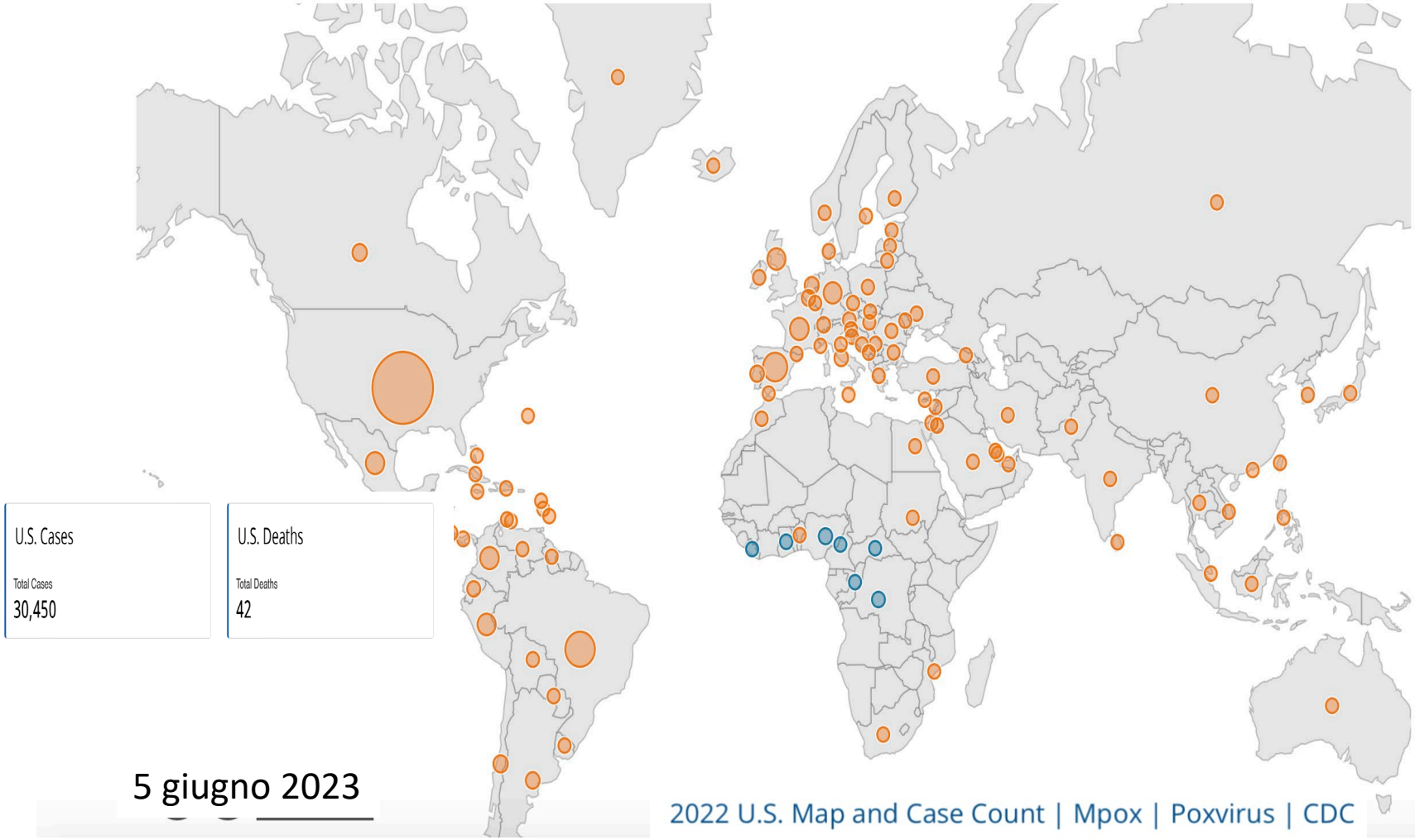
- Epidemiologia
- Virus
- Manifestazioni cliniche
- Farmaci
- Vaccino
- Futuro

Confirmed Cases

87,545
Total Cases

85,962
in locations that have not historically reported mpox

1,583
in locations that have historically reported mpox



5 giugno 2023

Country (110 locations)	Cases	Deaths
United States	30286	38
Brazil	10890	15
Spain	7546	3
France	4128	0
Colombia	4089	0
Mexico	3937	4
Peru	3785	20
United Kingdom	3738	0
Germany	3692	0
Canada	1478	0
Chile	1437	2
Netherlands	1262	0
Argentina	1124	2
Italy	957	0
Portugal	951	0
Nigeria	822	9
Belgium	793	2
Switzerland	552	0
Ecuador	530	3
Democratic Republic of the Congo	439	0
Guatemala	404	0
Austria	327	0
Bolivia	265	0
Israel	262	0
Sweden	260	0
Ireland	228	0
Poland	215	0
Costa Rica	213	1
Denmark	196	0
Panama	189	0
Australia	144	0
Ghana	124	4
Paraguay	119	0

Mpox: Daily confirmed cases

7-day rolling average

Our World in Data

LINEAR LOG

Confirmed Cases

87,545	85,962	1,583
Total Cases	in locations that have not historically reported mpox	in locations that have historically reported mpox

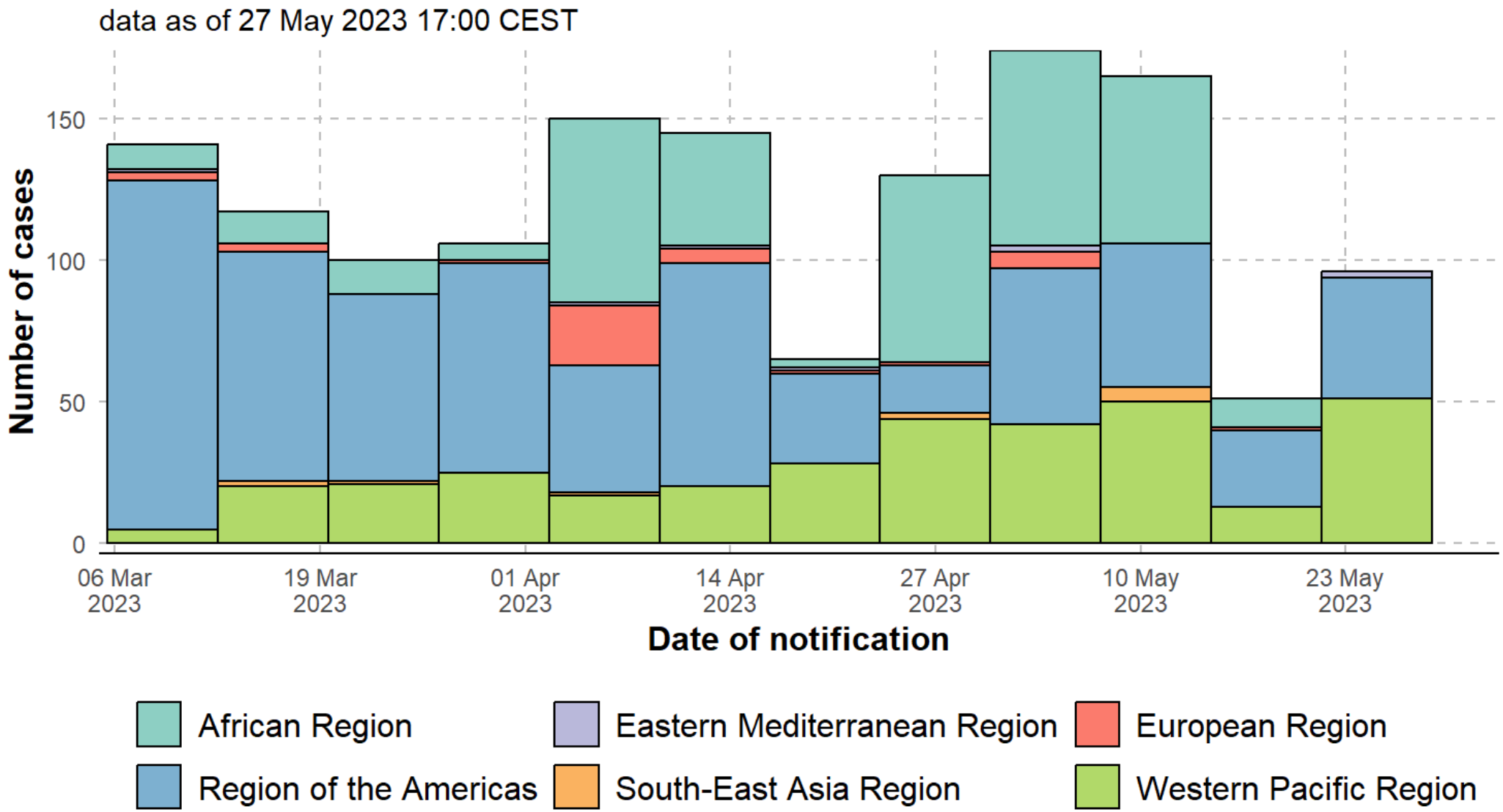
Source: World Health Organization

CC BY

May 1, 2022 — May 30, 2023

CHART | MAP | TABLE | SOURCES | DOWNLOAD

Epidemic curve shown for cases reported up to 28 May 2023 to avoid showing incomplete weeks of data.



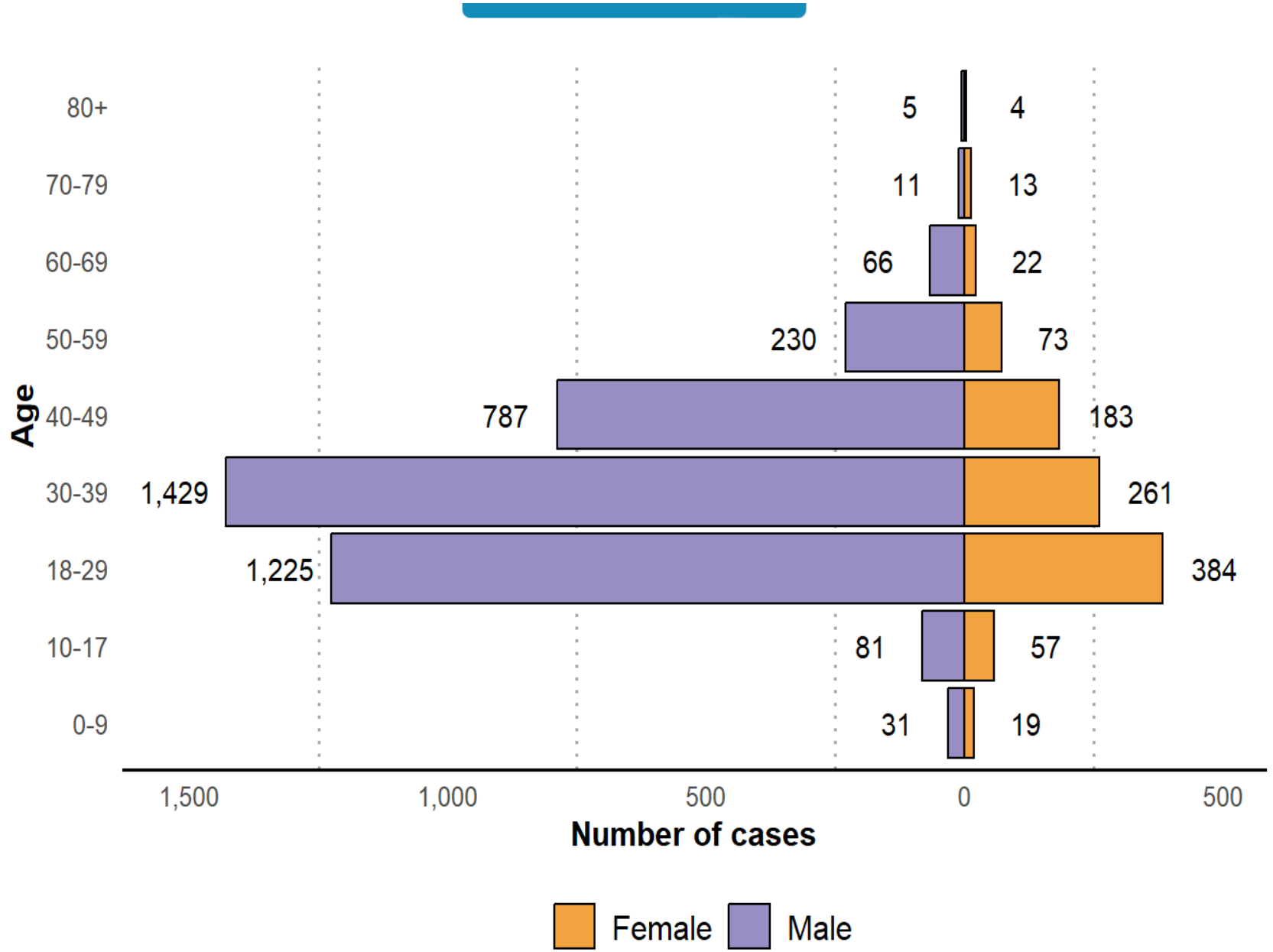
Source: WHO

Total mpox cases, by WHO region

From 1 Jan 2022. Data as of 30 May 2023

	Total Confirmed Cases	Total Probable Cases	Total Deaths	Cases in the last 3 weeks[1,2]	Cases in the preceding 3 weeks[1,3]	3-Week % change in cases[1,4]
Region of the Americas	59,413	1,098	114	121	128	−5%
European Region	25,902	0	7	1	7	−86%
African Region	1,794	0	20	69	109	−37%
Western Pacific Region	608	0	0	114	92	24%
Eastern Mediterranean Region	90	0	1	2	2	0%
South-East Asia Region	51	0	1	5	2	150%
Total	87,858	1,098	143	312	340	−8%

[1] Using most recently complete international standard week (Monday - Sunday)
[2] 08 May 2023 to 28 May 2023
[3] 17 Apr 2023 to 07 May 2023
[4] 17 Apr 2023 to 28 May 2023



Source: WHO
4,881 cases with age-sex data

Case profiles

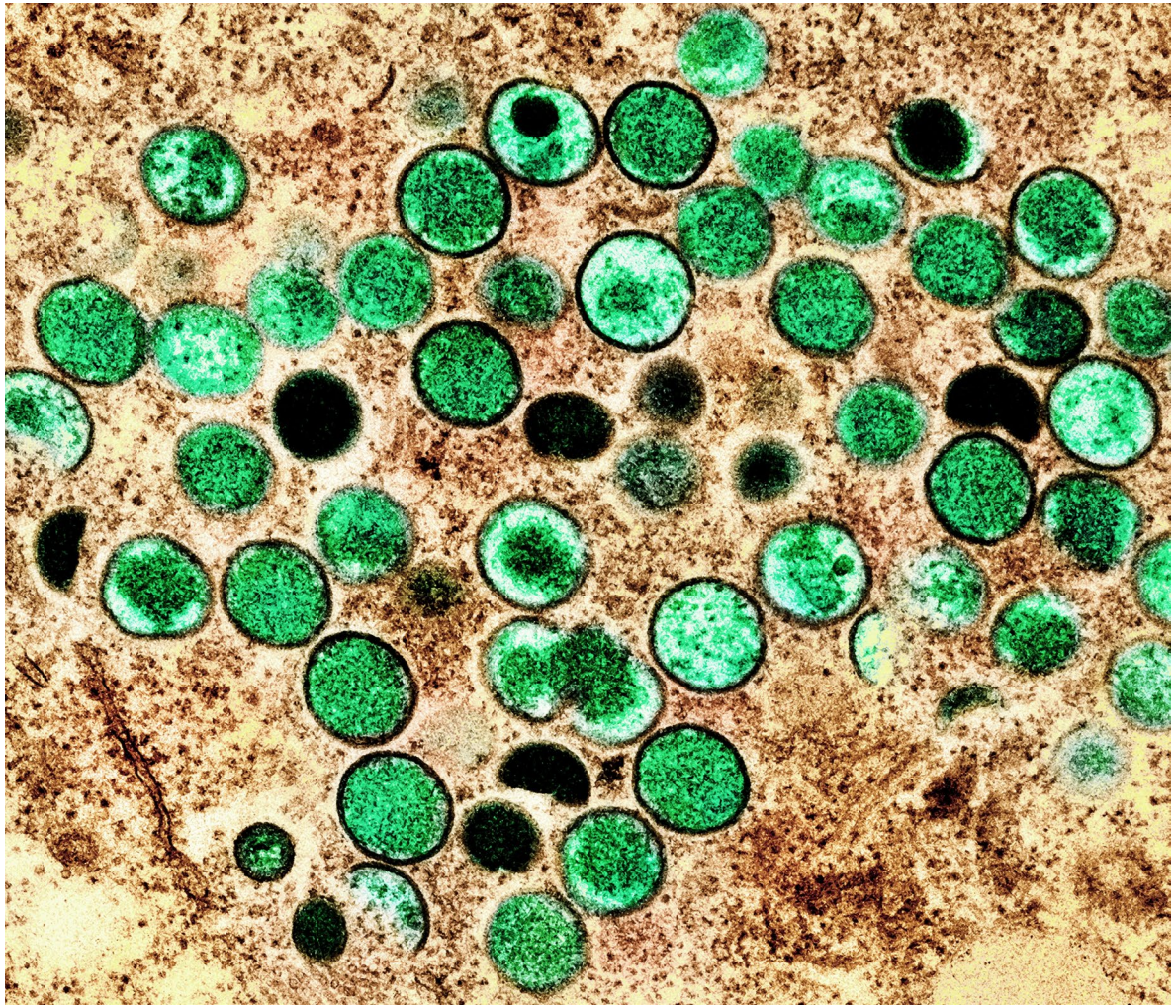
From March 06 2023 to May 26 2023

	Reported values[1]		Unknown or Missing Value
	Yes	No	
Men who have sex with men	269 (86.8%)	41 (13.2%)	334
HIV-Positive	95 (64.6%)	52 (35.4%)	497
Health worker	14 (11.0%)	113 (89.0%)	517
Travel History	49 (12.2%)	351 (87.7%)	244
Sexual Transmission	137 (80.6%)	33 (19.4%)	474
Hospitalised[2]	84 (35.1%)	155 (64.9%)	405
ICU	2 (1.6%)	123 (98.4%)	519
Died	0	218 (100.0%)	426

[1] Note given true proportions of variables, yes reporting may be common than no reporting

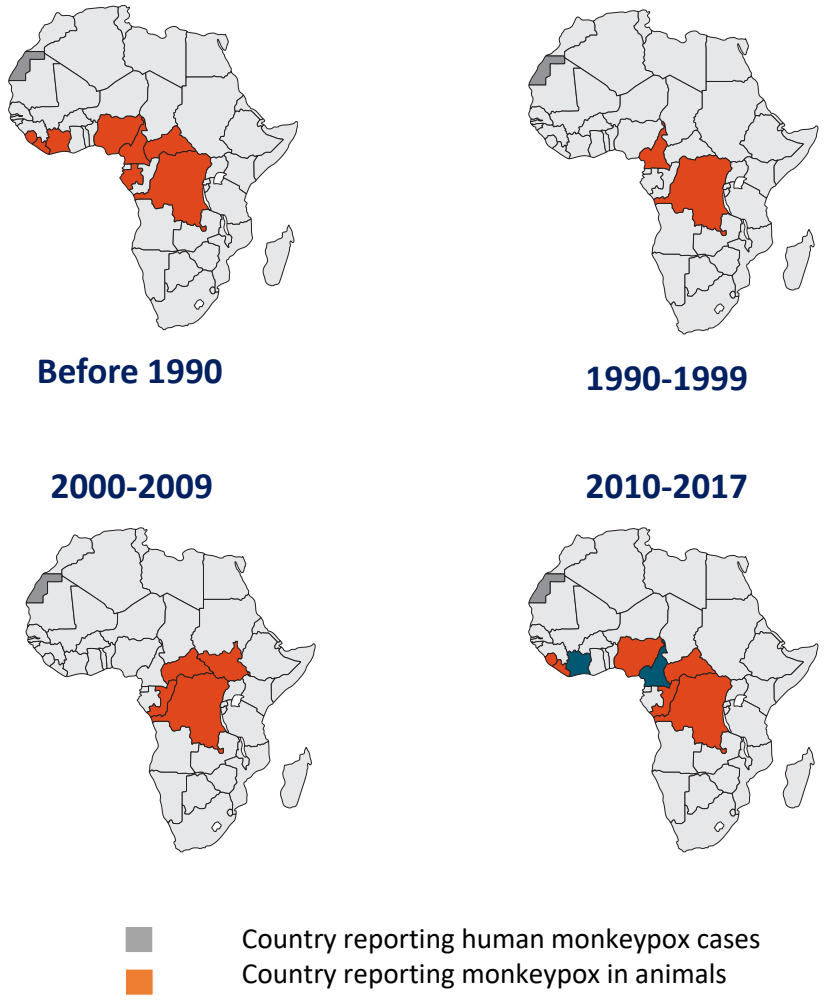
[2] May be hospitalised for isolation or medical treatment

Il Virus



Monkeypox History

- First described in monkeys used for research in 1958[1]
- First human case in 1970
- Transmitted to humans by infected animals (mostly rodents)
- Countries in Central and West Africa experienced “endemic” outbreaks
- 2017 outbreak in Nigeria suggested that **sexual transmission** may have occurred[2]



1. cdc.gov/poxvirus/monkeypox/about/index.html.
2. Ogoina. PLoS One. 2019;14:e0214229. 3. Durski. MMWR. 2018;67:306.

Mpox virus diveded into two main clades

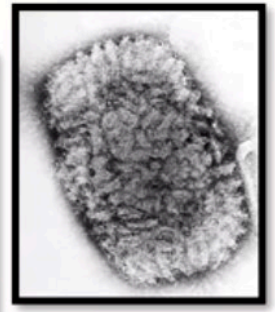
Clade I

- Formerly Congo basin clade
- More virulent (CFR ~10%)

Clade II

- Formerly West African clade
- Less virulent (CFR <1%)
- 2022 outbreak strain is sub-clade IIb

Source: Likos *et al*. J Gen Virol, 2005. Chen *et al*. Virology 2005. CFR = case fatality rate.



urnal of General Virology (2005), 86, 2661–2672 DOI 10.1099/vir.0.81215-0

A tale of two clades: monkeypox viruses

Anna M. Likos,[1]† Scott A. Sammons,[1]† Victoria A. Olson,[1] A. Michael Frace,[1] Yu Li,[1] Melissa Olsen-Rasmussen,[1] Whitni Davidson,[1] Renee Galloway,[1] Marina L. Khristova,[1] Mary G. Reynolds,[1] Hui Zhao,[1] Darin S. Carroll,[1] Aaron Curns,[1] Pierre Formenty,[2] Joseph J. Esposito,[1] Russell L. Regnery[1] and Inger K. Damon[1]

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Virology 340 (2005) 46 – 63
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Virulence differences between monkeypox virus isolates from West Africa and the Congo basin

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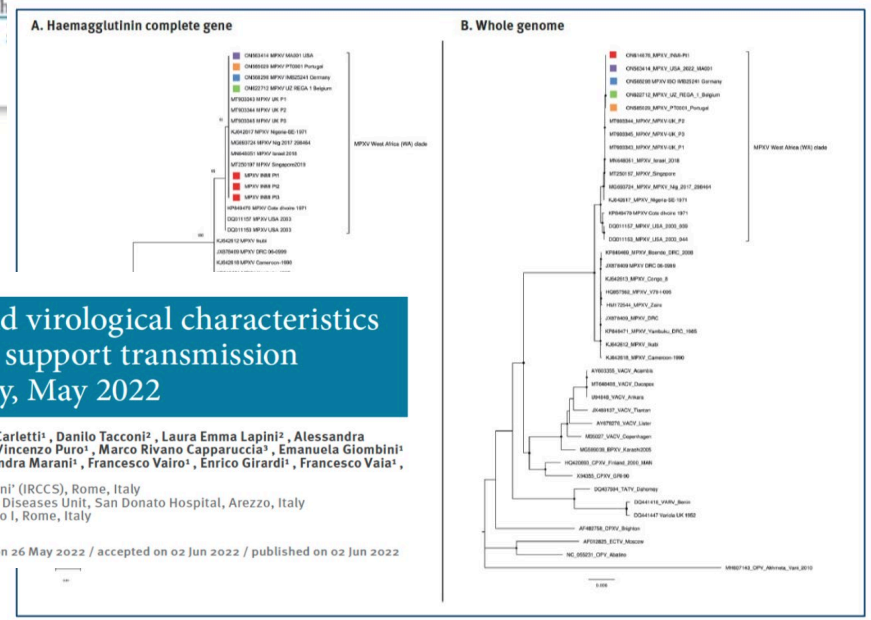

RAPID COMMUNICATIONS

Epidemiological, clinical and virological characteristics of four cases of monkeypox support transmission through sexual contact, Italy, May 2022

Andrea Antinori[1], Valentina Mazzotta[1], Serena Vita[1], Fabrizio Carletti[1], Danilo Tacconi[2], Laura Emma Lapini[2], Alessandra D'Abramo[1], Stefania Cicalini[1], Daniele Lapa[1], Silvia Pittalis[1], Vincenzo Puro[1], Marco Rivano Capparuccia[3], Emanuela Giombini[1], Cesare Ernesto Maria Gruber[1], Anna Rosa Garbuglia[1], Alessandra Marani[1], Francesco Vairo[1], Enrico Girardi[1], Francesco Vaia[1], Emanuele Nicastri[1], the INMI Monkeypox Group[4]

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2. Department of Specialised and Internal Medicine, Infectious Diseases Unit, San Donato Hospital, Arezzo, Italy
3. Infectious and Tropical Disease Unit, AOU Policlinico Umberto I, Rome, Italy
4. The members of the group are listed under Collaborators

Article submitted on 26 May 2022 / accepted on 02 Jun 2022 / published on 02 Jun 2022

Clade II b Mpox outbreak

- **Disproportionately affecting MSM**
- **Partecipation in gathering event**
- **Transmission during sexual contact**

Clinical and epidemiological characteristics, monkeypox patients, Italy, May 2022 (n = 4)

Characteristics	Patient 1	Patient 2	Patient 3	Patient 4
Sex	Male	Male	Male	Male
Age (years)	30s	30s	30s	30s
Sexual behaviour	MSM	MSM	MSM	MSM
Previous STIs	Hepatitis C, syphilis	Syphilis	Syphilis, hepatitis B	Hepatitis A[a]
HIV status	Positive	Negative on PrEP	Positive	Negative on PrEP
Recent sexual exposure	Yes	Yes	Yes	Yes
Systemic symptoms	No	Fever	Fever	Myalgia
Days from systemic symptoms to appearance of lesion	NA	3	3	2
Localisation of skin lesions	Genital, thorax and calf area	Anal, back, legs and foot sole	Anal, head, thorax, legs, arms, hand, and genital area	Genital and pubic area
Evolution of lesions	Asynchronous	Asynchronous	Asynchronous	Asynchronous

Table 1. Demographic and Clinical Characteristics of the Persons with Monkeypox.*

Characteristic	All Persons (N=528)
Median age (range) — yr	38 (18–68)
Sex or gender — no. (%)	
Male	527 (>99)
Female	0
Trans or nonbinary	1 (<1)
Sexual orientation — no. (%)†	
Heterosexual	9 (2)
Homosexual	509 (96)
Bisexual	10 (2)
Race or ethnic group — no. (%)†	
White	398 (75)
Black	25 (5)
Mixed race	19 (4)
Latinx	66 (12)
Other or unknown	20 (4)
HIV positive — no. (%)	218 (41)
HIV negative or status unknown — no. (%)	310 (59)
Use of preexposure prophylaxis against HIV — no./total no. (%)	176/310 (57)
Foreign travel in month before diagnosis — no. (%)‡	147 (28)
Continent of travel — no./total no. (%)	
Europe	132/147 (90)
North America	9/147 (6)
Australasia	0/147
Africa and Middle East	2/147 (1)
Central and South America	2/147 (1)
Not stated	2/147 (1)
Known to have undergone STI screening — no. (%)	377 (71)
Microbiologically confirmed concomitant STI present — no./total no. screened (%)	109/377 (29)
Gonorrhea	32/377 (8)
Chlamydia	20/377 (5)
Syphilis	33/377 (9)
Herpes simplex virus infection	3/377 (1)
Lymphogranuloma venereum	2/377 (1)
Chlamydia and gonorrhea	5/377 (1)
Other or not stated	14/377 (4)
HIV test taken — no./total no. with previously unknown or negative HIV status (%)	122/310 (39)
New HIV infection diagnosis — no./total no. (%)	3/122 (2)
Sexual history not known — no./total no. (%)	122/528 (23)
Median no. of sex partners in previous 3 months (IQR)	5 (3–15)
"Chemsex" reported in the previous month — no. (%)	106 (20)
Reported attendance at a sex-on-site event in the previous month — no. (%)	169 (32)
Known hepatitis infection — no. (%)	
Hepatitis B virus surface antigen positive	6 (1)
Hepatitis C virus antibody positive	30 (6)
Hepatitis C virus RNA positive	8 (2)
Reported history of smallpox vaccination — no. (%)	49 (9)

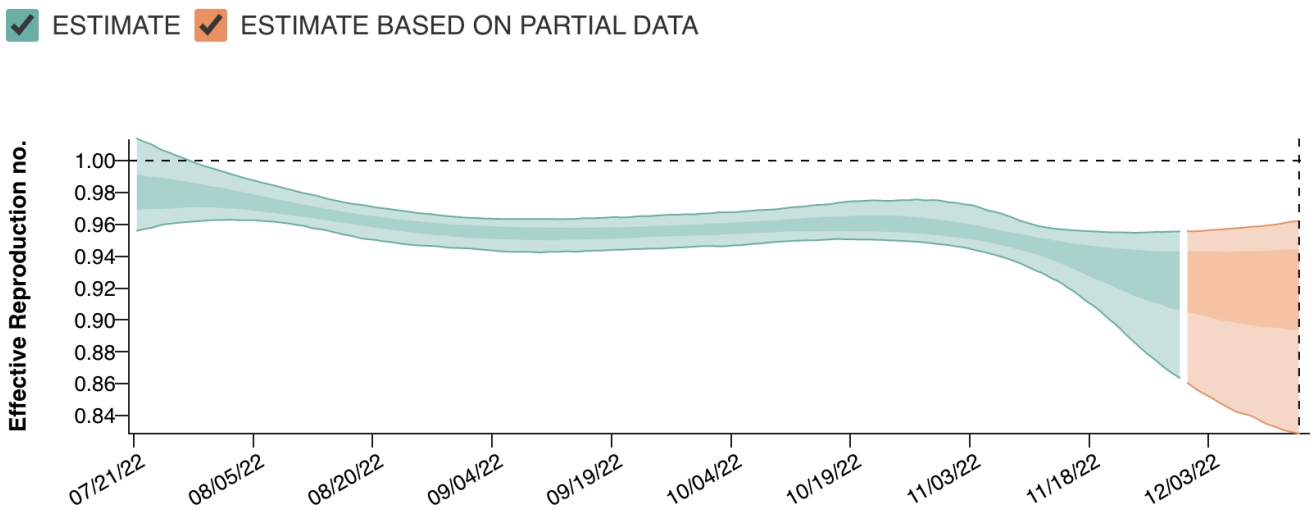
Antinori et. al. Eurosurveillance, 2022; Thornill et al. NEJM, 2022

Why such an outbreak?

Increasing susceptibility since the end of smallpox vaccination

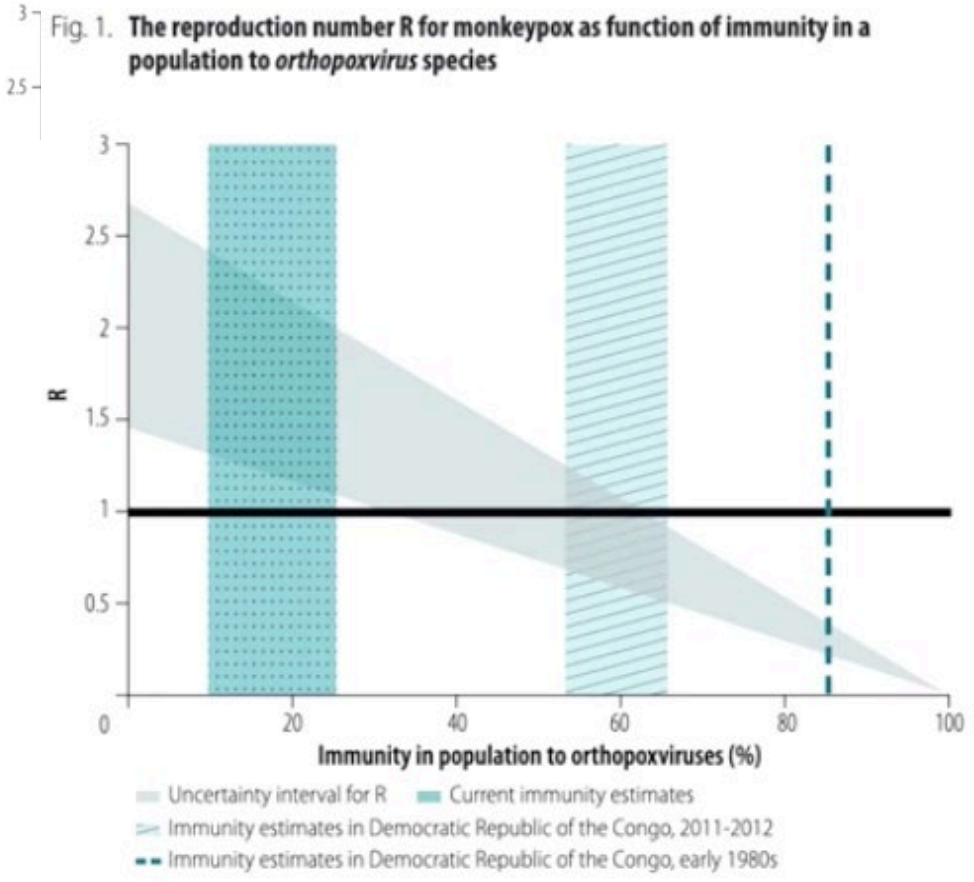
Fig. 1.

In the absence of immunity: there is a risk of outbreak if the number of contacts > 13.7



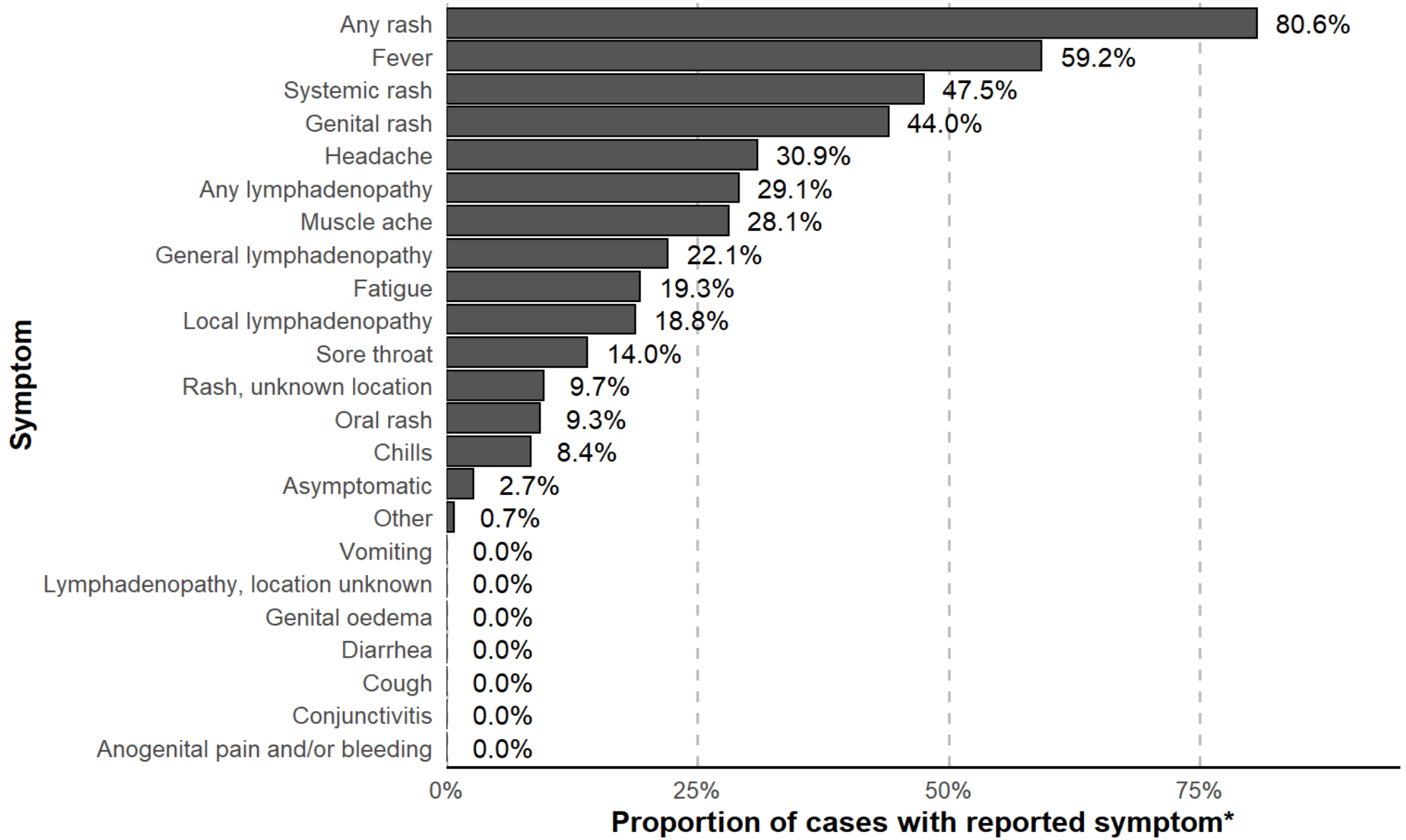
The graph shows the effective reproduction number (Rt) estimation over time based on complete data (green) or partial data (orange). The most recent data are considered incomplete due to delays in reporting mpox cases. As a result, there is more uncertainty associated with the most recent Rt estimates.

- Rt > 1 means the epidemic is **growing**
- Rt < 1 means the epidemic is **shrinking**
- Shading represents the 50% and 90% credible intervals (uncertainty in the estimates)



Reynolds et col cur Op Virol 2012 ; Grant et col BWHO 2022

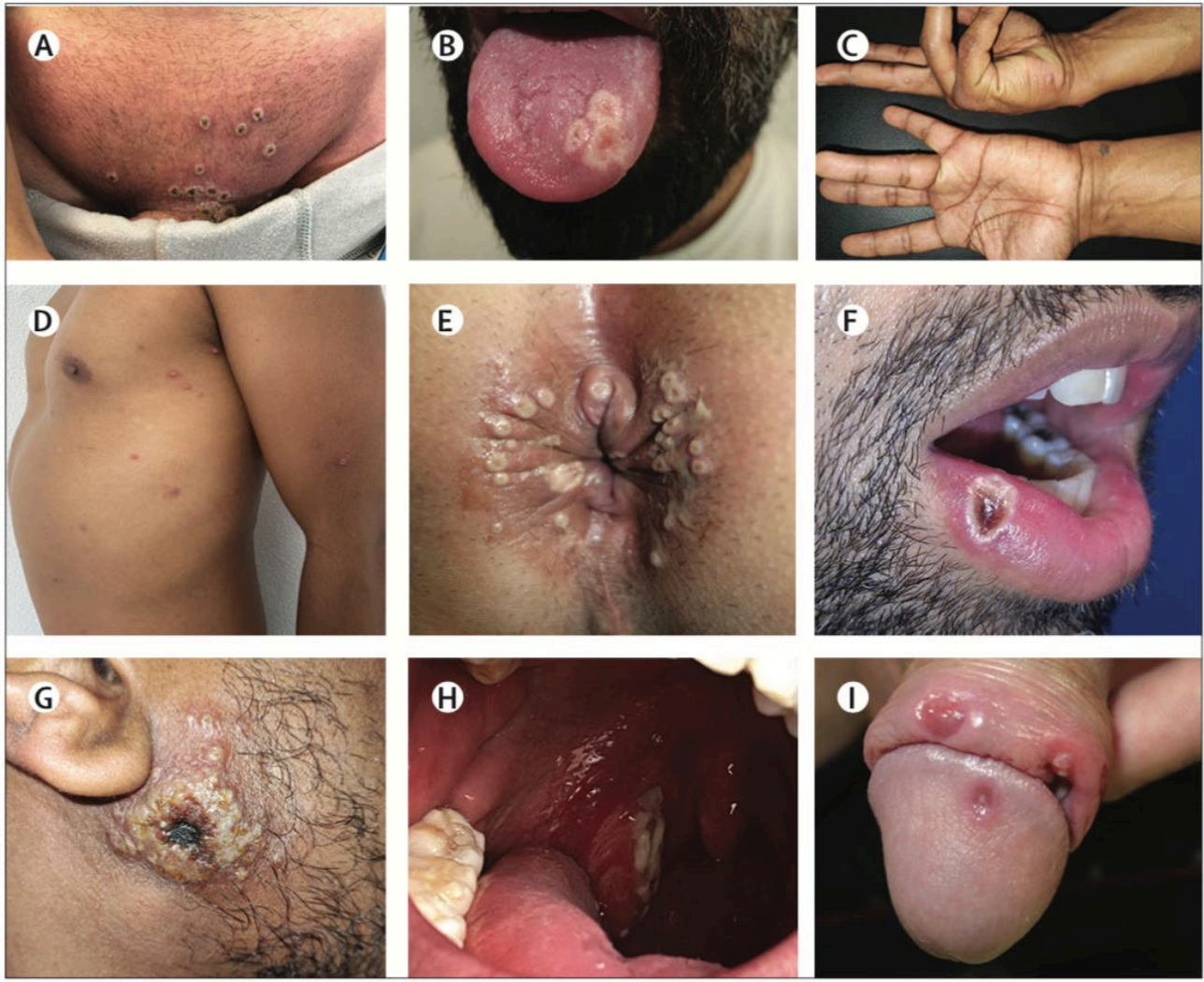
Clinica


Symptom
Any rash
Fever
Systemic rash
Genital rash
Headache
Any lymphadenopathy
Muscle ache
General lymphadenopathy
Fatigue
Local lymphadenopathy
Sore throat
Rash, unknown location
Oral rash
Chills
Asymptomatic
Other
Vomiting
Lymphadenopathy, location unknown
Genital oedema
Diarrhea
Cough
Conjunctivitis
Anogenital pain and/or bleeding
80.6%
59.2%
47.5%
44.0%
30.9%
29.1%
28.1%
22.1%
19.3%
18.8%
14.0%
9.7%
9.3%
8.4%
2.7%
0.7%
0.0%
0.0%
0.0%
0.0%
0.0%
0.0%
0.0%
0%
25%
50%
75%
Proportion of cases with reported symptom*

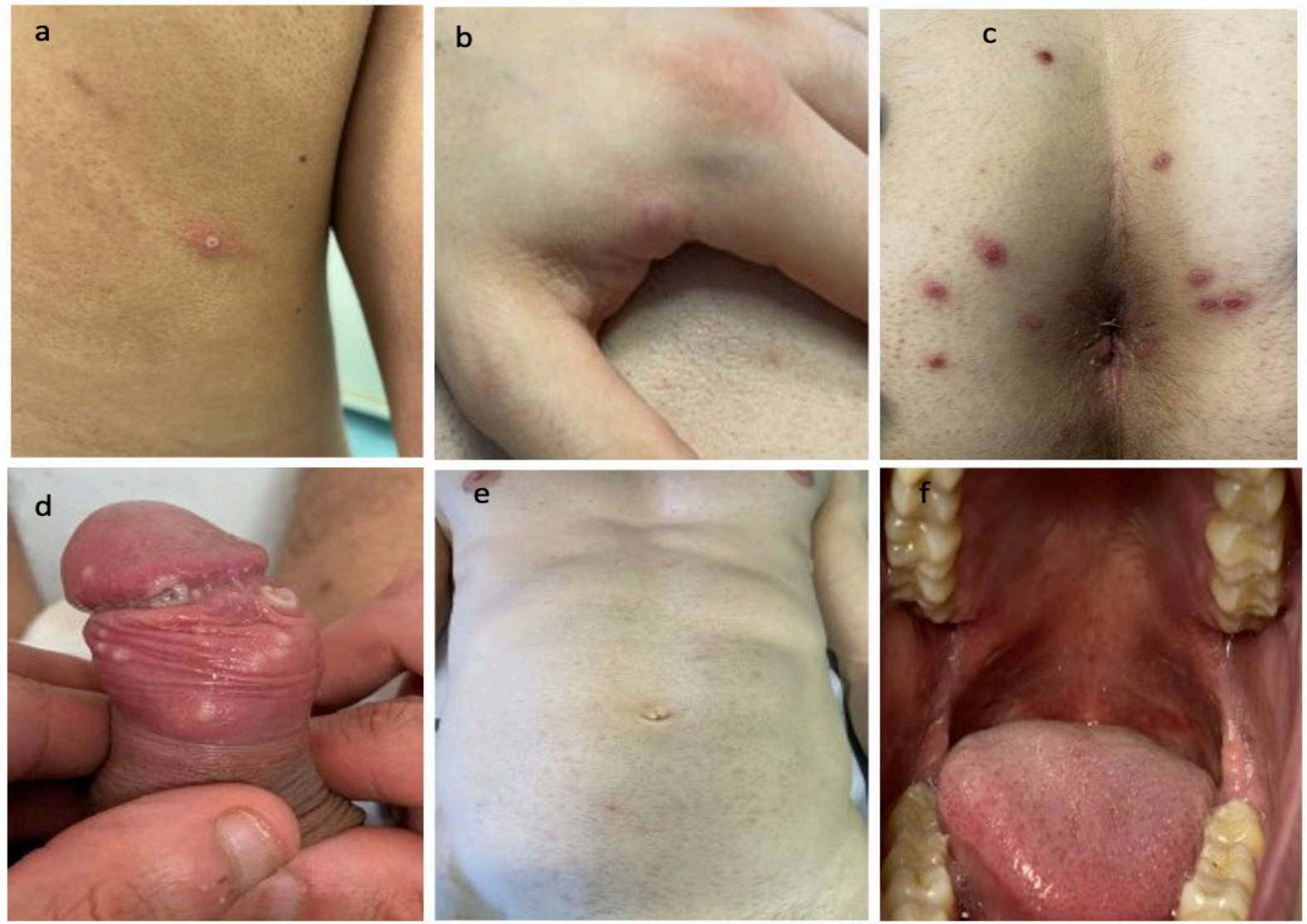
Source: WHO

Clade II b Mpox outbreak: clinical characteristics

- **Fewer 'prodromal' symptoms:** absent or follow rash onset
- **Rash:**
  - Lower burden of lesions
  - Distribution more centrifugal than centripetal
  - Affects both skin and mucosa (anal, genital, oropharynx)



Tarin-Vicente et al. Lancet, 2022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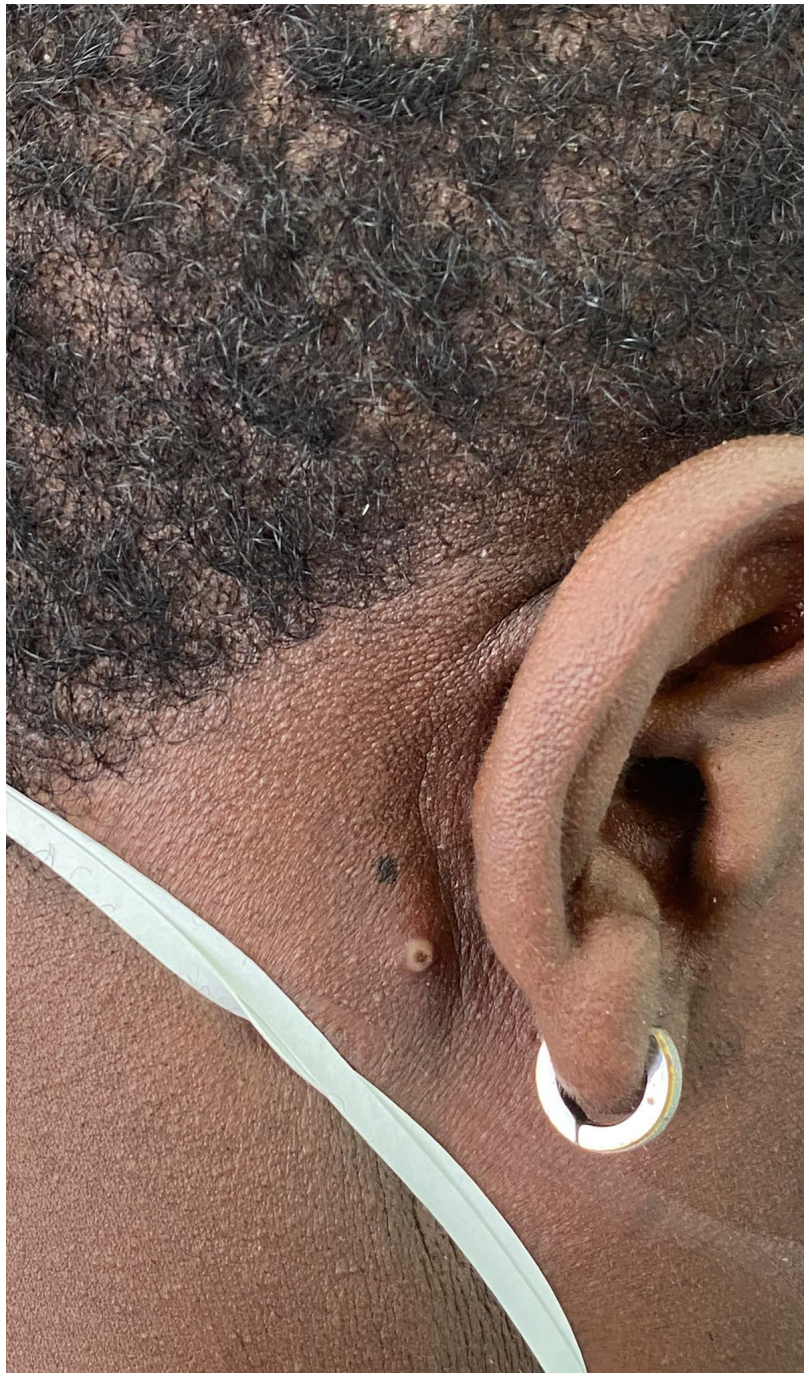
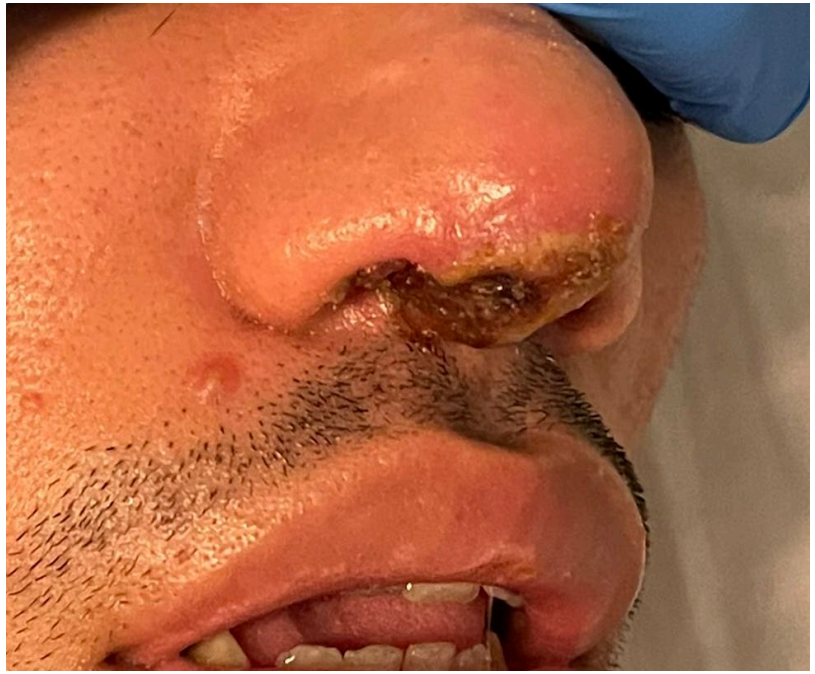
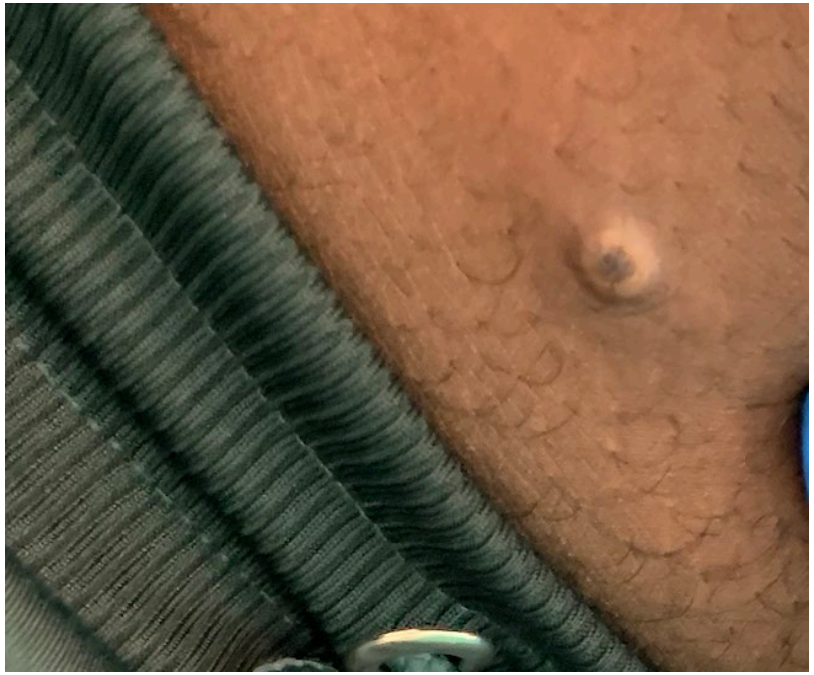
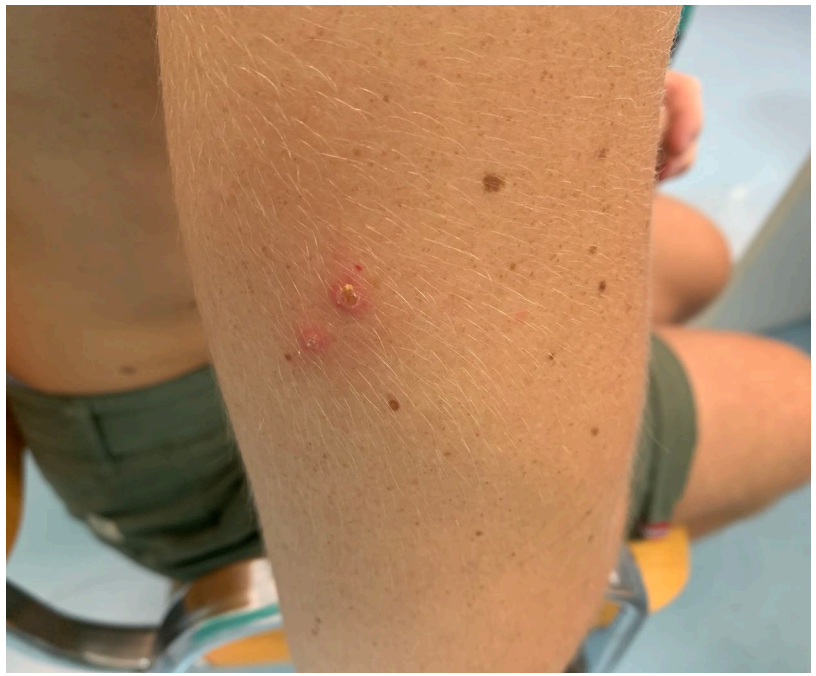
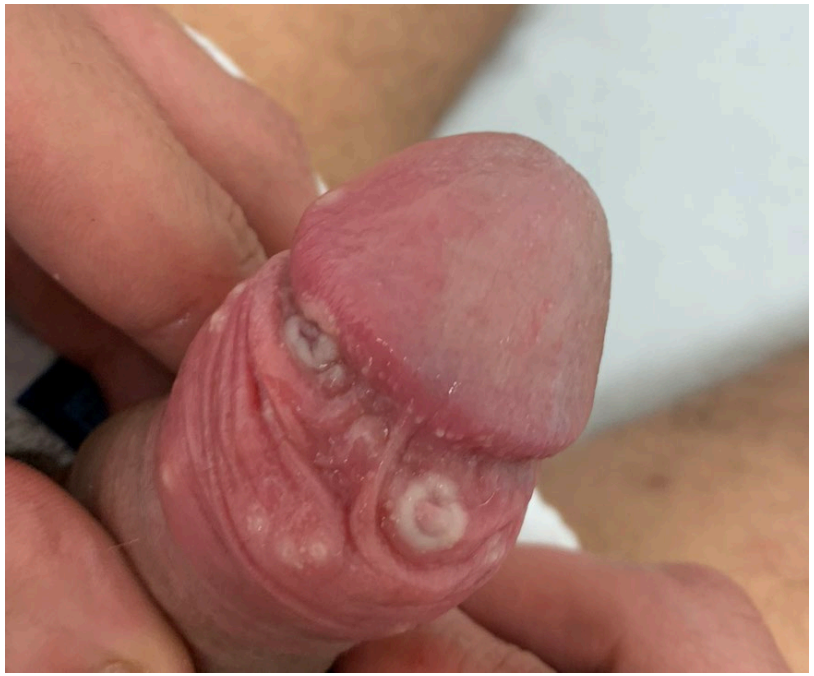
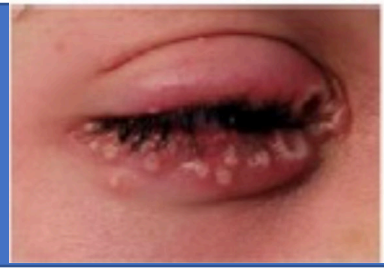






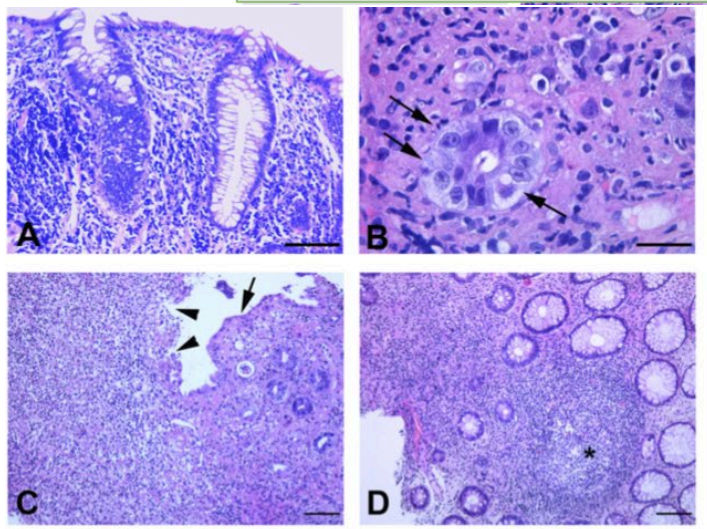
Clade II b Mpox outbreak: clinical characteristics

- ***Mucosal involvement*** leading to complication and possible sequelae is reported in about ***40%*** of cases.
- Frequent locations are:
  - Rectal mucosa
  - Oropharinx
  - Ocular mucosa
  - Genital mucosa

Ocular involvement in monkeypox: Description of an unusual presentation during the current outbreak



Lymphofollicular lesions associated to Monkeypox Virus proctitis



	Patient 1	Patient 2	Patient 3	Patient 4
Epithelium erosion/ulcer	/	+	+	/
Crypt distortion	Mild	Moderate	Mild	Focal
Edema	+	+	+	+
Fibrosis	+	+	/	/
Acute inflammation	Mild	Marked	/	/
Lymphoplasmacytic infiltration	Mild	Moderate	Mild	Mild
Reactive follicular hyperplasia	+	+	+	+
Mucin depletion	Mild	Mild/moderate	Mild	/

Thornill et al. NEJM 2022; Patel et al. BMJ 2022; Tarin Vicente et al. Lancet 2022; Mazzotta et al. Jour of Inf, 2022; Mazzotta et al, IJID 2022; Pinnetti et al, manuscript submitted

Mpox in PLWH: characteristics in MPOX large series, 2022

Table 2. Demographic and Clinical Characteristics of Persons with HIV Infection in the Case Series.*

Characteristic	Persons with HIV Infection (N=218)
Median age (range) — yr	39 (21–62)
Male sex — no. (%)	218 (100)
Sexual orientation — no. (%)	
Homosexual	212 (97)
Heterosexual	2 (1)
Bisexual	4 (2)
Median CD4 cell count (IQR) — cells/mm³	680 (513–861)
Missing CD4 cell-count data — no. (%)	33 (15)
HIV viral load — no./total no. with data (%)	
<50 copies/ml	180/190 (95)
<200 copies/ml	185/190 (97)
Missing HIV viral load data — no. (%)	28 (13)
Known to be taking ART — no. (%)	210 (96)
ART regimen among those taking ART	
Backbone — no./total no. (%)	
Tenofovir-based three-drug regimen	102/210 (49)
Abacavir-based three-drug regimen	20/210 (10)
Zidovudine-based three-drug regimen	2/210 (1)
Two-drug regimen	48/210 (23)
Missing or unknown	38/210 (18)
Third agent — no./total no. (%)†	
Integrase inhibitor	129/210 (61)
NNRTI	31/210 (15)
bPI	11/210 (5)
Missing or unknown	39/210 (19)

Thornill JP, et al. NEJM, 2022

PLWH represent about 40% in large series, with median CD4 count > 500 cells/mmc and with controlled viremia in more than 95%.

The clinical presentation and severity of monkeypox appeared similar among persons with or without HIV infection, but in almost all those in our series who had HIV infection, HIV was well controlled, with a median CD4 cell count of 680 cells per cubic millimeter.

What about the immunocompromised?

	Number of participants (n=156)
Age	35 (30-44)
Gender	
Male	153 (98%)
Female	3 (2%)
Trans or non-binary	0
Sexual orientation*	
Gay men, bisexual men and other men who have sex with men	139/155 (90%)
Heterosexual men	13/155 (8%)
Heterosexual women	2/155 (1%)
Ethnicity or race	
White	105 (67%)
Black	12 (8%)
Latinx	11 (7%)
South Asian	6 (4%)
Other	14 (9%)
Unknown	8 (5%)
HIV status	
HIV positive	47/155 (30%)
On antiretroviral therapy	41/47 (87%)
Most recent HIV-1 viral load <200 copies per ml	40/47 (85%)
Median CD4 cells per mm³	510 (349-828)
No CD4 cell count in preceding 12 months	12/47 (26%)
CD4 cell count <350 cells per mm³	9/47 (19%)
Viral hepatitis infection	
Hepatitis B surface antigen positive	3/112 (3%)
Hepatitis C virus antibody positive	2/116 (2%)
Hepatitis C virus RNA positive	0
Reported history of smallpox vaccination	
Ever	3 (2%)
During current pandemic before diagnosis	2 (1%)
Charlson comorbidity index (median, range)	0 (0–8)
Immunosuppression at time of infection	10 (6%)

Data are n (%), n/N (%), or median (IQR), unless otherwise indicated. Differing denominators reported are due to missing data. *Data for one bisexual woman are not presented in the table.

Table 1: **Demographic and clinical background of individuals admitted to hospital with monkeypox virus infection**

Fink DL, et al. Lancet Infect Dis, 2022

Check for updates

Received: 15 November 2022 | Accepted: 6 February 2023

DOI: 10.1002/jmv.28560

RESEARCH ARTICLE

JOURNAL OF MEDICAL VIROLOGY WILEY

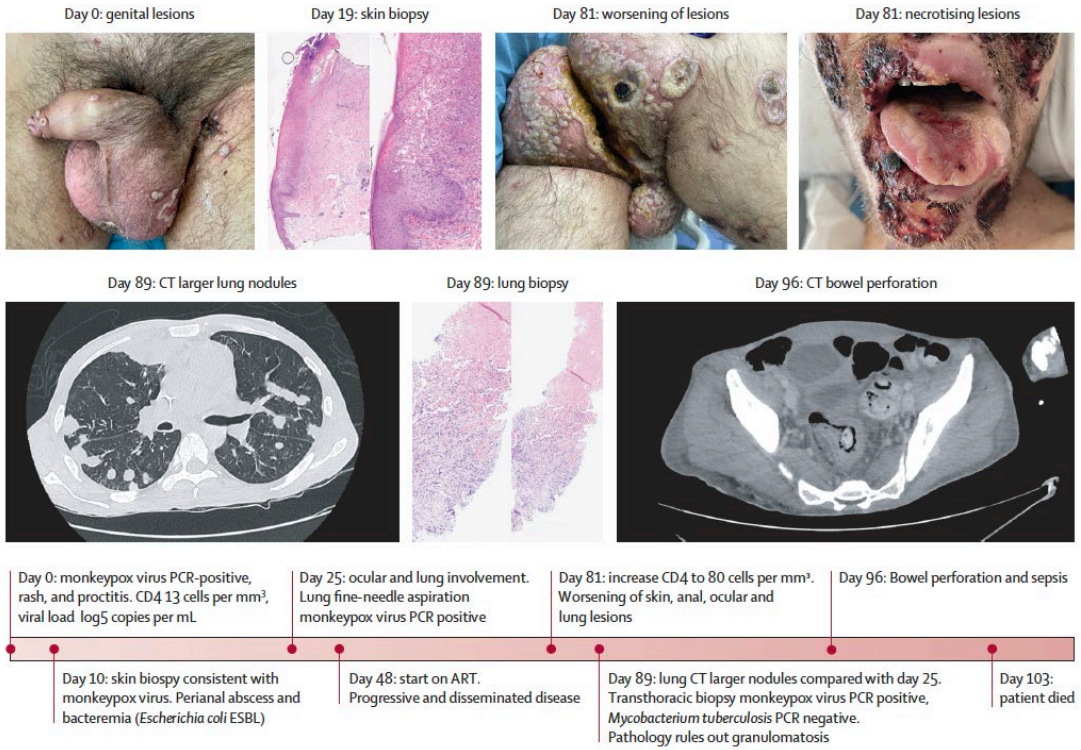
Monkeypox outbreak in Genoa, Italy: Clinical, laboratory, histopathologic features, management, and outcome of the infected patients

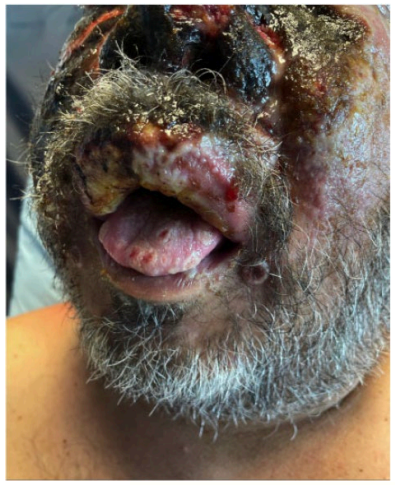
Giulia Ciccarese[1] | Antonio Di Biagio[2,3] | Bianca Bruzzone[4] | Antonio Guadagno[5] | Lucia Taramasso[2] | Giorgio Oddenino[6] | Giorgia Brucci[2,3] | Laura Labate[2,3] | Vanessa De Pace[4] | Mario Mastrolonardo[1] | Francesco Broccolo[7] | Giacomo Robello[6] | Francesco Drago[6] | Matteo Bassetti[2,3] | Aurora Parodi[6]

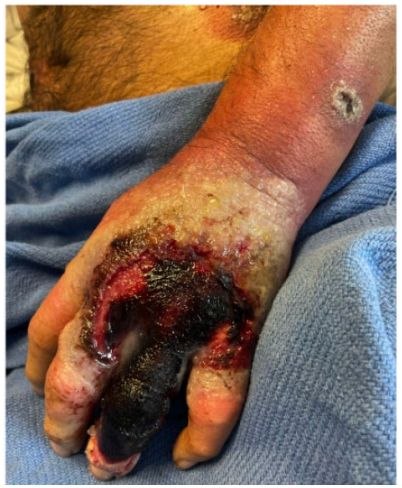
10969071, 2023, 2, Downloaded from https://onlinelibrary.wiley.com/doi/10.1002/jmv.28560 by University Degli Studi Di Genova, W

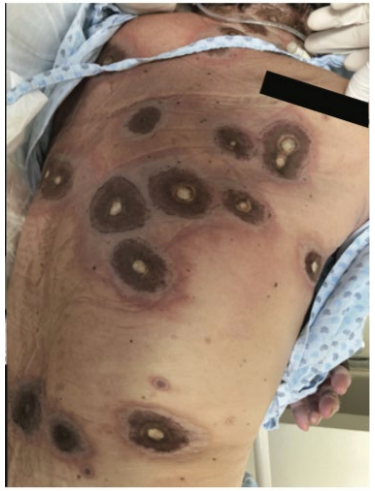
Mpox disease progression in patients with very low CD4 count and high HIV-RNA

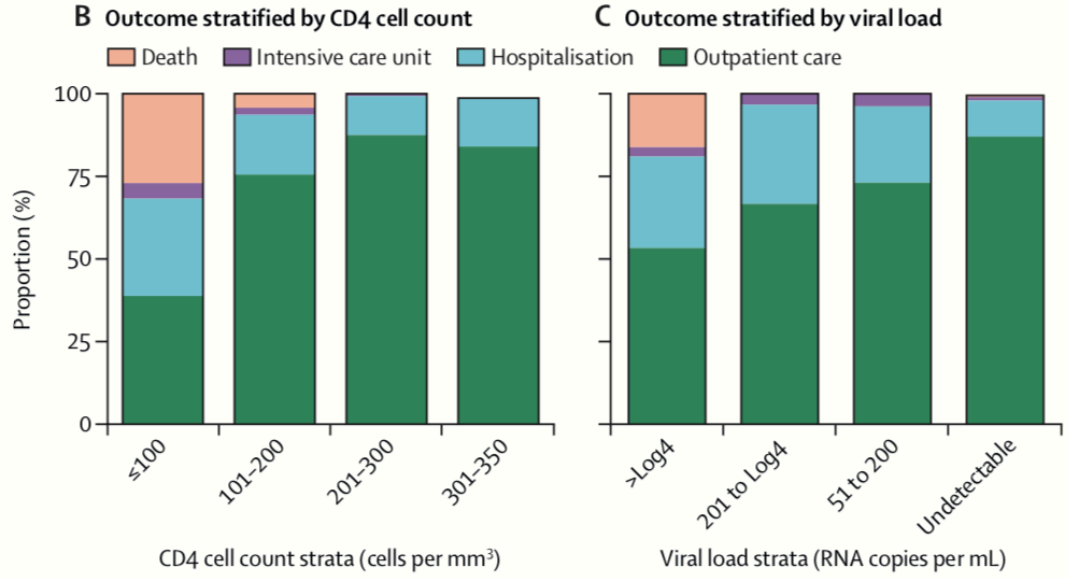
Interpretation A severe necrotising form of mpox in the context of advanced immunosuppression appears to behave like an AIDS-defining condition, with a high prevalence of fulminant dermatological and systemic manifestations and death.











Fulminant mpox as an AIDS-defining condition: useful or stigmatising?

Mitjà O, et al. Lancet, 2023; Govind et al. CID, 2022.

Antivirali

Therapy

- According to CDC reccomendations[2], treatment should be considered for use in people who have the following clinical manifestations:
  - ***Severe disease***
  - Involvement of anatomic ***areas which might result in serious sequelae***
- Treatment should also be considered for use in people who are ***at high risk*** for severe disease (immunocompromised, as PLWH; pediatric <1yr; pregnant or breastfeeding; People with a condition affecting skin integrity.

- Hemorrhagic disease
- Large number of lesions
- Confluent lesions
- Necrotic lesions
- Severe lymphoadenopathy
- Involvement of multiple organ systems
- Requiring hospitalization

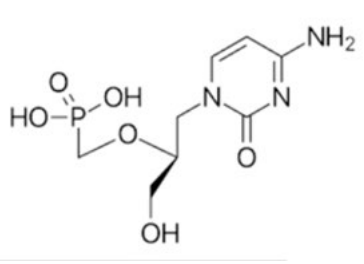
[2]CDC Interim Clinical Guidance for the Treatment. https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html.

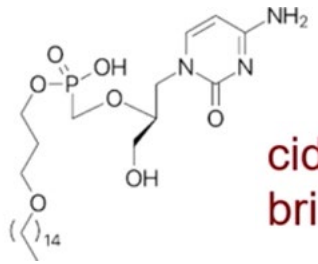
Viral Life Cycle and available therapeutics

Brincidofovir= oral DNA polymerase inhibitor approved for the treatment of smallpox in the US.
liver toxicity, risk of birth defects, risk of cancer, and risk of male infertility.
common side effects :diarrhea, nausea, vomiting, and abdominal pain.

Vaccinia Immune Globulin (VIG) is licensed by the FDA to treat complications of vaccinia vaccination. The effectiveness of VIG against smallpox and mpox is uncertain, and VIG has not been trialed in humans for smallpox or mpox.

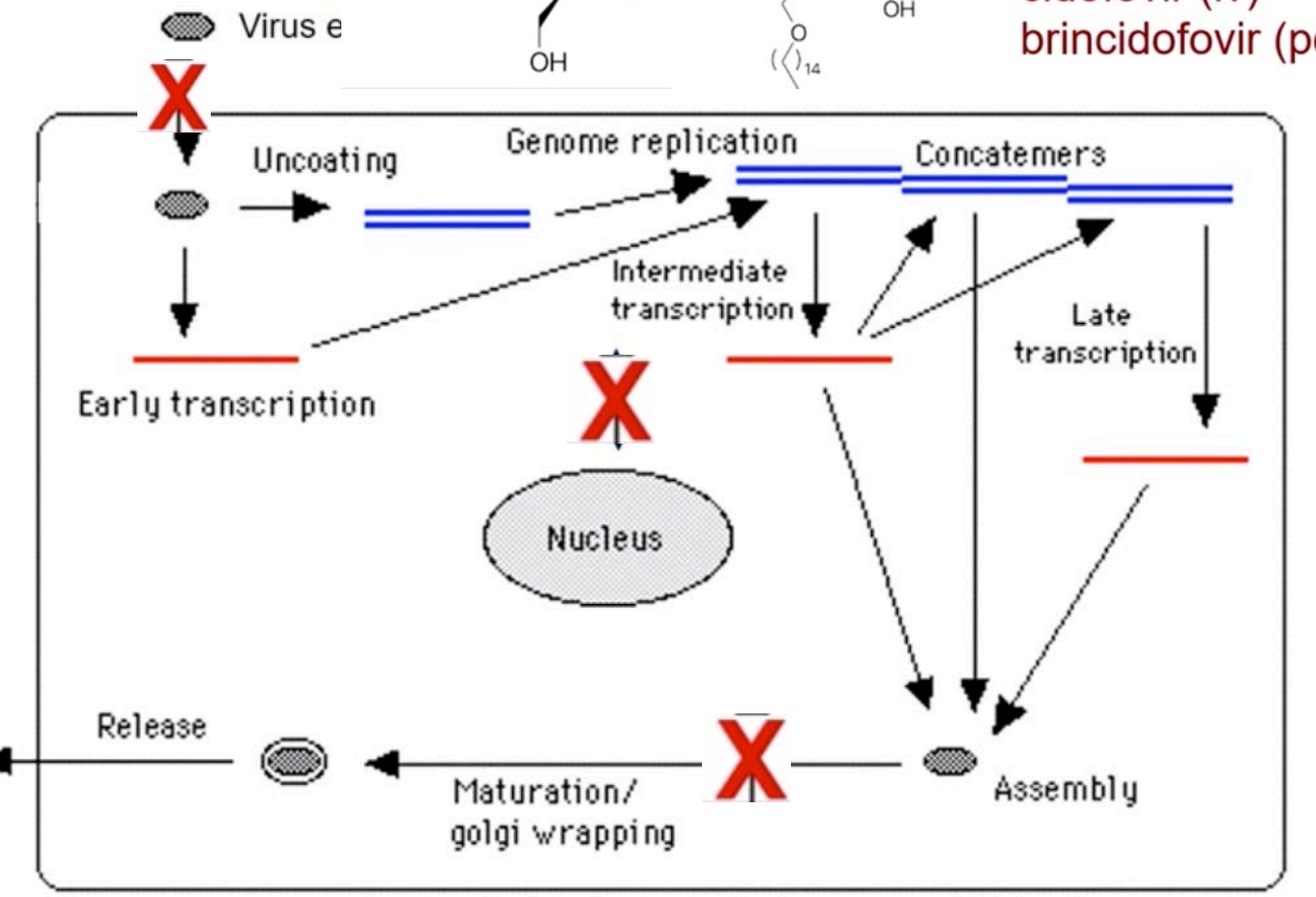
VIG-IV

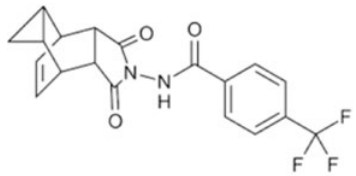




cidofovir (iv)
brincidofovir (po)

Normal saline and probenecid should be given concurrently with cidofovir





tecovirimat
(po or iv)

Tecovirimat inhibits viral envelope protein VP37, thus blocking viral maturation as well as the release of the virus from infected cells. TCV has unknown efficacy against the mpox virus

Monkeypox virus infection on the nose successfully treated with cidofovir in a newly diagnosed HIV patient

Laura Labate [1], Giorgia Brucci [1], Giulia Ciccarese[3], Bianca Bruzzone[4], Valentina Ricucci[2], Stefanelli Federica[2], Emanuele Delfino[2], Lucia Taramasso[2], Matteo Bassetti[1,2], Antonio Di Biagio[1,2]

Corresponding author: Giorgia Brucci

1 Dipartimento di Scienze Della Salute (I
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4 Hygiene Unit, Ospedale Policlinico Sa

Keywords MPXV, HIV, syphilis, cidofo

Figure 1. Nasal lesions at the hospital admission

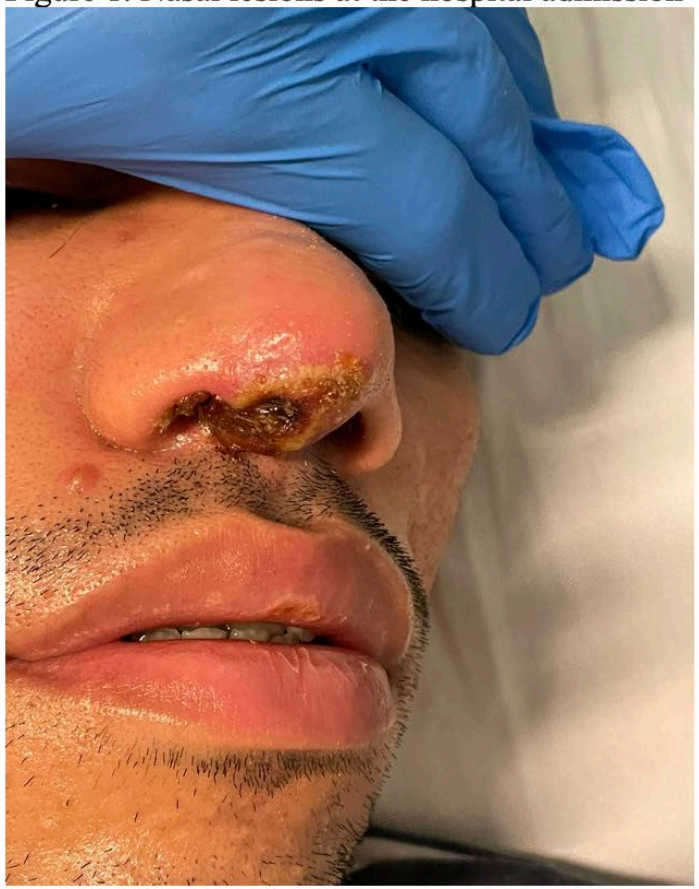

Figure 2. Nasal lesion at the one month follow up visit

2022

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Research Letter

ONLINE FIRST FREE

August 22, 2022

Compassionate Use of Tecovirimat for the Treatment of Monkeypox Infection

Angel N. Desai, MD, MPH[1]; George R. Thompson III, MD[1]; Sonja M. Neumeister, MPH[1]; Anna M. Arutyunova, BS[1]; Katelyn Trigg, MPH[1]; Stuart H. Cohen, MD[1]

Author Affiliations | Article Information

JAMA. Published online August 22, 2022. doi:10.1001/jama.2022.15336

Table. Clinical Characteristics of Patients With Monkeypox Infection Treated With Tecovirimat

Patient	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Smallpox vaccination history	Unk	Unk	No	No	No	No	No	Unk	Unk	Unk	Unk	No	No	No	Unk	No	Unk	Jynneos	Jynneos	No	Jynneos	Remote	No	Jynneos	Unk
HIV,[a] hepatitis B, hepatitis C status	HIV	None	None	None	None	HIV	HIV	HIV	None	HIV	HIV	None	HIV	None	None	HIV	None	None	None	None	None	None	None	None	HIV
Systemic symptoms	None	Fever, backache, fatigue	Nausea, chills, myalgias	Fever	Fatigue	Fever, fatigue	Fever, backache, headache, diarrhea, chills	None	Malaise, fever	Fever	Fever, sore throat, itching, fatigue	Fever, headache	Fever, headache	Headache, shoulder and neck pain	Headache, hoarseness	Fever, fatigue, headache, constipation, sore throat	Fever, headache, nausea, fatigue	Fever, myalgia, headache, sore throat	Fever, chills, urethritis	Fever	Fever, sore throat, back pain	Fever, sore throat	Fever, chills, night sweats	Fever, chills, fatigue, painful bowel movements	Fever
Lymphadenopathy	None	None	None	None	Inguinal	Inguinal and neck	None	None	Neck and inguinal	Cervical	Neck and inguinal	Right inguinal	None	None	Inguinal	Inguinal	None	Inguinal	None	Inguinal	Cervical, inguinal	Cervical	None	Inguinal	None
No. of lesions	10-100	<10	<10	10-100	<10	10-100	10-100	<10	10-100	10-100	10-100	10-100	>100	10-100	<10	<10	10-100	<10	<10	<10	<10	<10	<10	10-100	<10
Genital lesions	Perianal	Perianal	Genital	Genital	Genital	Perianal	Perianal	Genital	Genital	No	Genital	No	Perianal and genital	Genital	Genital	Perianal	Genital	Genital	Perianal	Genital	Perianal and genital	Genital	Genital	Genital	Perianal
Distribution of other lesions	Chest, eyelid, right hand, right knee, shoulder	Face, neck, arms		Scalp, face, forearms, hands, chest, back, legs, buttocks		Face, abdomen, groin, back, legs	Neck, arms, head, legs, abdomen, back		Face, back, arms, hands	Entire body	Throat, chest, arm, abdomen, hand, buttocks	Scalp, face, neck, abdomen, arms, back	Entire body	Arms, scalp		Arm, chest, face	Chest, back	Face, arm, chest	Arm, thigh	Chest	Wrist, chest	Arms, legs	Chest, back, arm, shin	Head, arms, legs, foot	Chest, back, arms, legs
Symptom onset to tecovirimat initiation, d	24	17	6	8	15	6	9	16	10	12	9	14	10	16	7	7	6	12	12	7	19	14	13	10	22
Days of tecovirimat therapy	14	14	14	14	14	14	14	14	21[b]	14	14	14	14[b]	14	14	14	14	14	14	14	14	14	14	14	14
7-Day self-reported outcomes[c]	Rec	Rec	Rec	No new lesions	No new lesions	No new lesions	Rec	No new lesions	New lesions	No new lesions	No new lesions	No new lesions	No new lesions	No new lesions	Rec	No new lesions	Rec	No new lesions	Rec	No new lesions	No new lesions	Rec	No new lesions	Rec	Rec
21-Day self-reported outcomes[c]	Rec	Rec	Rec	Rec	Rec	Rec	Rec	Rec	New lesions	Rec	Rec	Rec	Rec	Rec	Rec	Rec	Rec	Rec	Rec	No new lesions	Rec	Rec	Rec	Rec	Rec
Adverse effects at day 7	Backache, fatigue	None	None	None	Headache, nausea	None	Hand burning, weak nails	None	Fatigue, nausea, itching, headache	Fatigue	Fatigue, itching	None	None	Nausea, headache	None	Fatigue	None	Headache, diarrhea	None	None	Fatigue	Headache	Fatigue, nausea	Dry skin	Diarrhea

Abbreviation: unk, unknown.

[a] Patients with HIV were receiving antiretroviral therapy and confirmed or reported to be virologically suppressed.

[b] Dose increased on day 10 (patient 9) and day 7 (patient 13) due to delayed clinical response and borderline weight-based dosing.

[c] Recovered (rec): all lesions self-reported as crusted or fallen off; new lesions: development of new lesions; no new lesions: no new lesions reported but not yet recovered.

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Volume 9, Issue 8
August 2022

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JOURNAL ARTICLE

Tecovirimat for the Treatment of Human Monkeypox: An Initial Series From Massachusetts, United States

Wilfredo R Matias, Jacob M Koshy, Ellen H Nagami, Victor Kovac, Letumile R Moeng, Erica S Shenoy, David C Hooper, Lawrence C Madoff, Miriam B Barshak, Jennifer A Johnson, Christopher F Rowley, Boris Julg, Elizabeth L Hohmann, Jacob E Lazarus ✉
Author Notes

Open Forum Infectious Diseases, Volume 9, Issue 8, August 2022, ofac377, https://doi.org/10.1093/ofid/ofac377
Published: 27 July 2022 **Article history**

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Abstract

A large, ongoing multicountry outbreak of human monkeypox has the potential to cause considerable morbidity and mortality. Therapeutics for the treatment of smallpox, a related *Orthopoxvirus*, may be used and affect the natural history of monkeypox. We present 3 patients from our hospitals treated with tecovirimat, a pan-*Orthopoxvirus* inhibitor currently available under an expanded access investigational new drug protocol for monkeypox.

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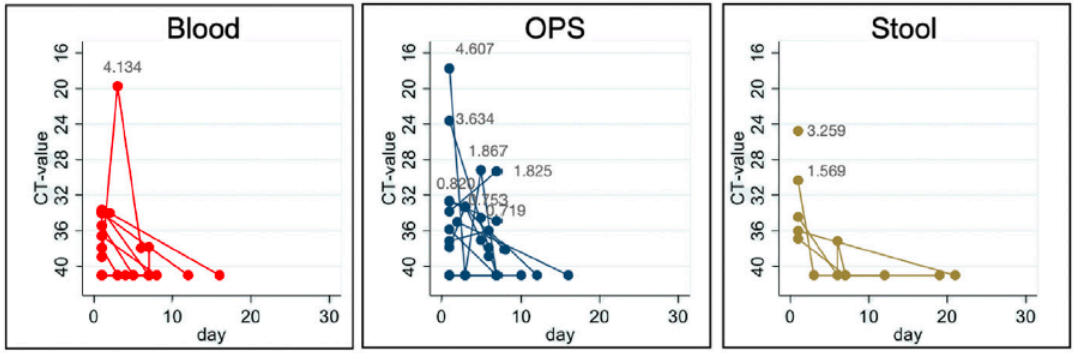
Clinical experience with use of oral Tecovirimat or Intravenous Cidofovir for the treatment of Monkeypox in an Italian reference hospital

A. Mondi, R. Gagliardini, V. Mazzotta et al.



Tecovirimat and cidofovir are potential options for MPX but limited data are available. Use of antivirals appears to be safe and might be considered, until further results will become available.

with a median Ct of 39 (IQR 37-41). In almost all patients, a progressive decline in viral load was observed over the course of treatment. Most biological samples were negative at the last available observation. DdPCR results approximately mirrored the viral shed-

TECOVIRIMAT effectiveness: real world data

Results of **emulation of a parallel trial design** with the target population of **41 patients admitted to the hospital for mpox (19 TCV-treated and 22 untreated)**.

Original cohort	21-day failure (%)	95% CI*		Recovery days	95% CI*	
Tecovirimat arm[$]	8.3	0.0	33.3	8.4	1.9	9.2
No Tecovirimat arm	22.2	0.0	55.9	11.7	7.6	12.7
Differences[1]	*-13.9*	*-5.2*	*+21.0*	*-3.3*	*-8.8*	*+0.4*

Emulated cohort	21 day failure (%)	95% CI*		Recovery days	95% CI*	
Kaplan-Meier						
Tecovirimat arm	12.5	0.0	50.5	14.7	12.5	14.9
No Tecovirimat arm	15.4	0.0	31.4	14.7	12.4	14.9
Differences[2]	*-2.9*	*-29.2*	*+33.5*	*-0.01*	*-0.11*	*+0.13*
Weighted Kaplan-Meier						
Tecovirimat arm	9.8	0.0	45.4	14.7	12.5	14.9
No Tecovirimat arm	13.9	0.0	29.3	14.7	12.4	14.9
Differences[3]	*-4.1*	*-29.2*	*+30.8*	*-0.02*	*-0.11*	*+0.12*

Potential Ct changes (log2 scale) over T1-T2[$] and ATE[&] from fitting a linear regression model

	Mean in treated with tecovirimat (95% CI)	Mean in untreated (95% CI)	ATE[*] (95% CI)	p-val
Treated vs. Untreated				
IPWs	0.25 (-0.02, 0.53)	0.41 (0.08, 0.73)	-0.16 (-0.64, 0.33)	0.52
Double Robust	0.38 (0.13, 0.64)	0.41 (-0.01, 0.84)	-0.03 (-0.58, 0.53)	0.92
Regression adjustment	0.38 (0.00, 0.76)	0.37 (0.01, 0.74)	0.01 (-0.56, 0.57)	0.97

Tecovirimat seems to be not effective in shortening healing time and viral clearance. Actually, the use of tecovirimat should be restricted to the clinical trial setting.

Mazzotta V, et al. ECCMID 2023 (OP)

TECOVIRIMAT: concerns

Tecovirimat

- Approved for smallpox (not monkeypox)
  - Thus, need for signed consent under CDC EAP
- Low barrier to resistance
  - Resistant mutation easily identified in cell culture
  - F13L amino acid substitutions detected in a tecovirimat-treated individual with progressive vaccinia virus infection
  - F13L amino acid substitutions detected in monkeypox virus infected, tecovirimat-treated NHP that succumbed to disease

Many of the resistance pathways require only a single amino acid change in VP37 to cause a substantial reduction in tecovirimat antiviral activity.

U.S. FOOD & DRUG ADMINISTRATION

Table: Orthopoxvirus VP37 Amino Acid Substitutions Associated with Tecovirimat Resistance

Resistance Analysis Study	Amino Acid Substitutions
VP37 amino acid substitutions associated with high-level phenotypic resistance to tecovirimat in cell culture (defined as ≥10-fold increase in EC50 value) in vaccinia virus, cowpox virus or camelpox virus	**Single amino acid substitutions:** H238Q, N267D/S, G277C, D283G/Y, A290V, D294V, A295E, L302P/Q **Combinations of amino acid substitutions:** F25V+I372N, L178S+Y258C, N179H+D283G, H194N +303insSVK, N267D+I309T, N267S+I317V, G277C+I372N, D280G+D294G, A290V+L315M, K68N+Y258C+T308S, W2C+D225A+Y258C+D280G
VP37 amino acid substitutions detected in mpox virus infected, tecovirimat-treated nonhuman primates that succumbed to disease	H238Q, N267del/I/D/S/K, R268G, D280Y, A290V, A295E, L297ins, I372N/ILKIKNRK (mutation of stop codon and extension of reading frame)
VP37 amino acid substitutions detected in a tecovirimat-treated individual with progressive vaccinia virus infection	A290V, L315M

[1]Due to the conserved nature of VP37, tecovirimat resistance-associated substitutions in one orthopoxvirus are expected to apply to other orthopoxviruses.

Vaccino

- MVA-BN (virus vaccinico vivo Ankara modificato, non replicante, prodotto dalla *Bavarian Nordic*), è un vaccino di terza generazione, indicato per la prevenzione del vaiolo e del vaiolo delle scimmie nei soggetti a partire dai 18 anni di età, ad alto rischio di infezione.
- Il nome commerciale del prodotto attualmente disponibile in Italia è JYNNEOS (gli altri nomi commerciali dello stesso prodotto sono IMVANEX e IMVAMUNE)

Ministero della Salute
DIREZIONE GENERALE DELLA PREVENZIONE SANITARIA
Ufficio 5 – Prevenzione delle Malattie trasmissibili e Profilassi Internazionale
Viale Giorgio Ribotta, 5 - 00144 Roma

- persone gay, transgender, bisessuali e altri uomini che hanno rapporti sessuali con uomini (MSM), che rientrano nei seguenti criteri di rischio:

i) storia recente (ultimi 3 mesi) con più partner sessuali;
e/o
ii) partecipazione a eventi di sesso di gruppo;
e/o
iii) partecipazione a incontri sessuali in locali/club/cruising/saune;
e/o
iv) recente infezione sessualmente trasmessa (almeno un episodio nell'ultimo anno);
e/o
v) abitudine alla pratica di associare gli atti sessuali al consumo di droghe chimiche (Chemsex).

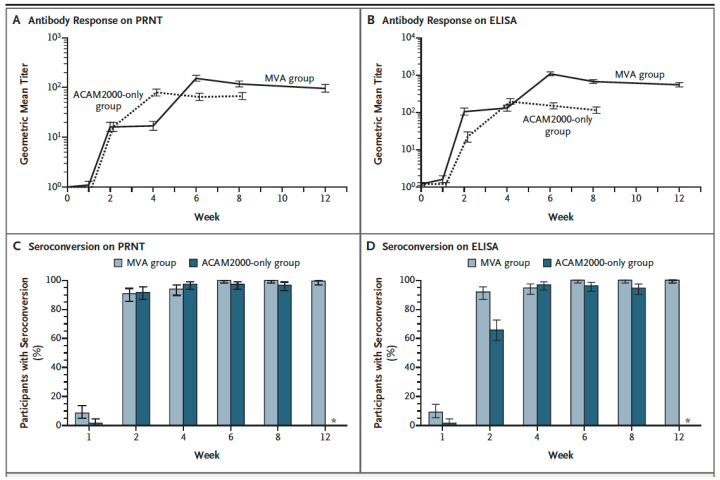
Vaccines

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 NOVEMBER 14, 2019 VOL. 381 NO. 20

Phase 3 Efficacy Trial of Modified Vaccinia Ankara as a Vaccine against Smallpox

Phillip R. Pittman, M.D., Matthew Hahn, M.D., HeeChoon S. Lee, M.D., Craig Koca, M.D., Nathaly Samy, M.D., Darja Schmidt, Ph.D., Joachim Hornung, Heinz Weidenthaler, M.D., Christopher R. Heery, M.D., Thomas P.H. Meyer, Ph.D., Günter Silbernagl, M.Sc., Jane Maclennan, B.Sc., and Paul Chaplin, Ph.D.



CONCLUSIONS

No safety concerns associated with the MVA vaccine were identified. Immune responses and attenuation of the major cutaneous reaction suggest that this MVA vaccine protected against variola infection. (Funded by the Office of the Assistant Secretary for Preparedness and Response Biomedical Advanced Research and Development Authority of the Department of Health and Human Services and Bavarian Nordic; ClinicalTrials.gov number, NCT01913353.)

letters to nature

Immunogenicity of a highly attenuated MVA smallpox vaccine and protection against monkeypox

Patricia L. Earl[1], Jeffrey L. Americo[1], Linda S. Wyatt[1], Leigh Anne Eller[2], J. Charles Whitbeck[3], Gary H. Cohen[3], Roselyn J. Eisenberg[3], Christopher J. Hartmann[4], David L. Jackson[4], David A. Kulesh[4], Mark J. Martinez[4], David M. Miller[4], Eric M. Mucker[4], Joshua D. Shamblin[4], Susan H. Zwiers[4], John W. Huggins[4], Peter B. Jahrling[4] & Bernard Moss[1]

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FDA NEWS RELEASE

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

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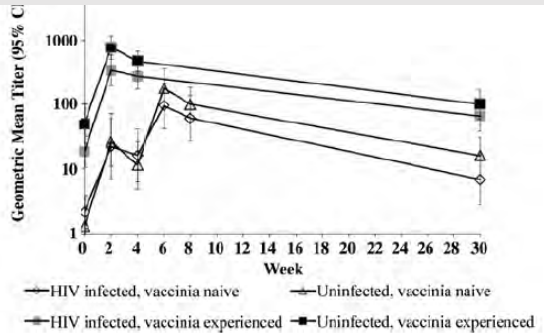
For Immediate Release: August 09, 2022

BHIVA British HIV Association

Based on the data outlined and experience with other vaccines, we recommend:

- People with HIV who are vaccinia-naïve (i.e. never immunised against smallpox) are advised that vaccination will not be protective immediately; protection will be about **80% by 2 weeks after one vaccine dose and about 95% by 2 weeks after a second dose**, i.e. maximum protection will take 6 weeks assuming two doses are given 28 days apart.
- People who have received smallpox vaccination in the past can expect >90% protection within 2 weeks after a single vaccine dose and close to 100% within 2 weeks after a second dose.
- All people with HIV should receive two full vaccine doses. While vaccine supplies are limited, people with a CD4 cell count <200 cells/mm^3 or persistent viraemia should be prioritised to receive a full first vaccine dose, and to receive a second full vaccine dose as soon as available. The CD4 count cut-off will be kept under review.
- People with detectable viraemia should be supported to achieve viral suppression to maximise vaccine efficacy.

MVA was well tolerated and immunogenic in all subjects. Antibody responses were **comparable** between uninfected and HIV-infected populations



Greenberg RN *et al. J Infect Dis* 2013;
Overton ET *et al. Open Forum Infect Dis* 2015.

Reduced Risk for Mpox After Receipt of 1 or 2 Doses of MPOX Vaccine Compared with Risk Among Unvaccinated Persons

To examine the incidence of monkeypox among persons who were unvaccinated and those who had received ≥1 Smallpox and Monkeypox Vaccine, Live, Nonreplicating vaccine dose, 5,402 reported monkeypox cases occurring among males¶ aged 18–49 years during July 31–September 3, 2022, were analyzed by vaccination status across 32 U.S. jurisdictions.** **Average monkeypox incidence (cases per 100,000) among unvaccinated persons was 14.3 (95% CI = 5.0–41.0) times that among persons who received 1 dose of JYNNEOS vaccine ≥14 days earlier.**

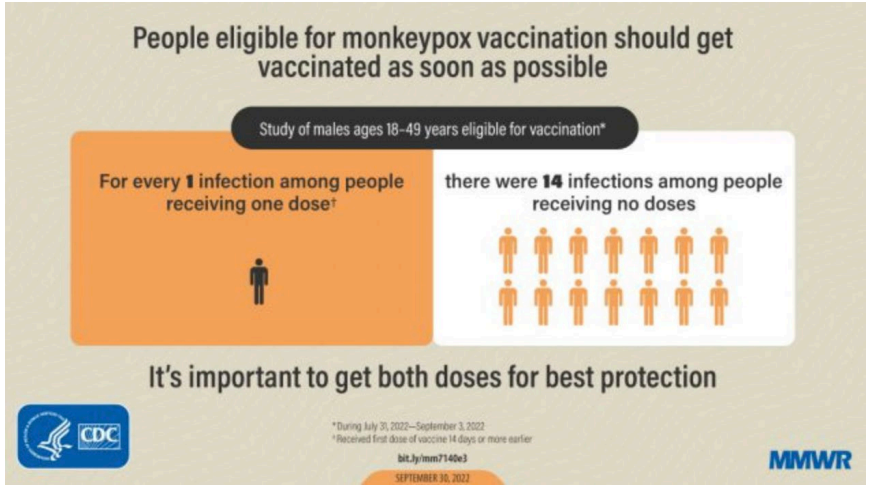
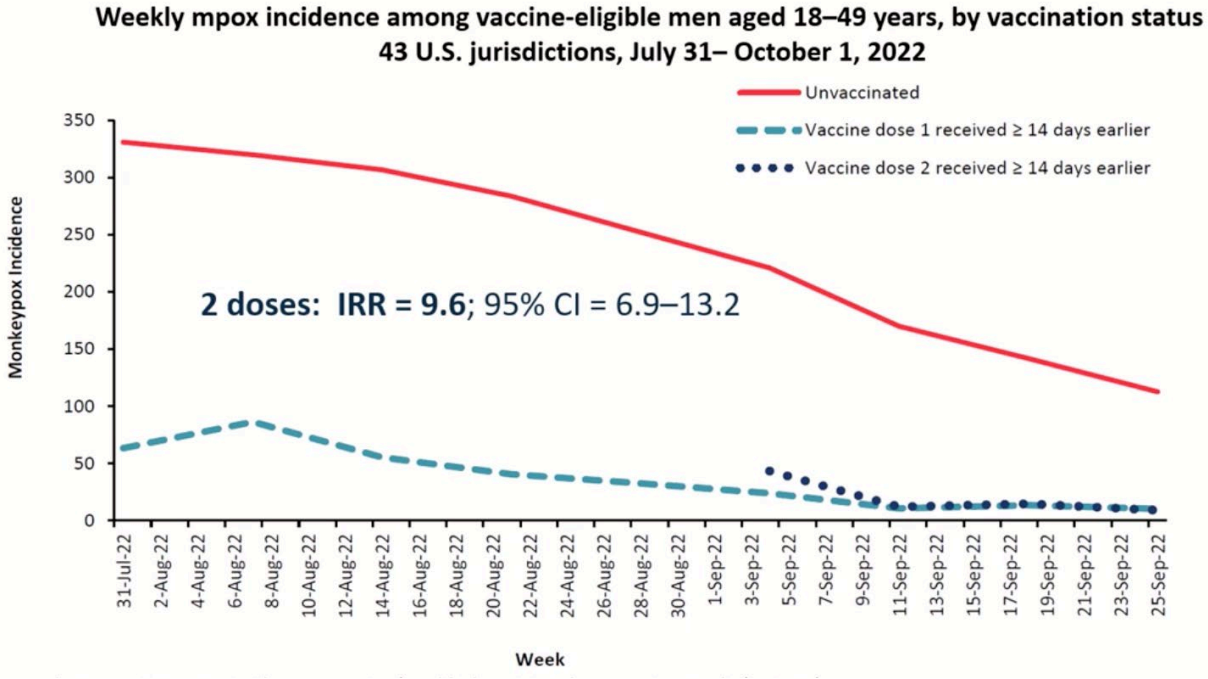


TABLE 1. Mpox cases among men* aged 18–49 years, by vaccination status,† and JYNNEOS vaccination coverage, by week (N = 9,544) — 43 U.S. jurisdictions,§,¶ July 31–October 1, 2022

Characteristic	No. (%) by week beginning									
	Jul 31	Aug 7	Aug 14	Aug 21	Aug 28	Sep 4	Sep 11	Sep 18	Sep 25	Total
Total mpox cases**	**1,823**	**1,649**	**1,450**	**1,250**	**1,035**	**854**	**605**	**494**	**384**	**9,544**
Vaccination status										
Unvaccinated	1,621 (88.9)	1,422 (86.2)	1,250 (86.2)	1,068 (85.4)	889 (85.9)	744 (87.1)	546 (90.2)	440 (89.1)	340 (88.5)	**8,320 (87.2)**
Vaccinated	202 (11.1)	227 (13.8)	200 (13.8)	182 (14.6)	146 (14.1)	110 (12.9)	59 (9.8)	54 (10.9)	44 (11.5)	**1,224 (12.8)**
Vaccination date known (n = 1,224)										
No	40 (19.8)	30 (13.2)	31 (15.5)	36 (19.8)	25 (17.1)	24 (21.8)	9 (15.3)	10 (18.5)	13 (29.5)	**218 (17.8)**
Yes	162 (80.2)	197 (86.8)	169 (84.5)	146 (80.2)	121 (82.9)	86 (78.2)	50 (84.7)	44 (81.5)	31 (70.5)	**1,006 (82.2)**
Illness onset relative to dose 1 of vaccination†† (n = 1,006)										
0–13 days after dose 1	141 (87)	145 (73.6)	112 (66.3)	86 (58.9)	62 (51.2)	30 (34.9)	24 (48)	9 (20.5)	5 (16.1)	**614 (61)**
≥14 days after dose 1	21 (13)	52 (26.4)	57 (33.7)	60 (41.1)	59 (48.8)	56 (65.1)	26 (52)	35 (79.5)	26 (83.9)	**392 (39)**
Illness onset relative to dose 2 of vaccination†† (n = 392)										
Before dose 2	21 (100)	48 (92.3)	50 (87.7)	46 (76.7)	47 (79.7)	36 (64.3)	13 (50)	18 (51.4)	16 (61.5)	**295 (75.3)**
0–13 days after dose 2	0 (—)	4 (7.7)	4 (7.0)	11 (18.3)	8 (13.6)	8 (14.3)	7 (26.9)	6 (17.1)	1 (3.8)	**49 (12.5)**
≥14 days after dose 2	0 (—)	0 (—)	3 (5.3)	3 (5.0)	4 (6.8)	12 (21.4)	6 (23.1)	11 (31.4)	9 (34.6)	**48 (12.2)**
JYNNEOS vaccination coverage (%)										
1 dose§§	5.7	10.4	16.9	24.6	30.9	36.2	40.2	42.9	45.5	**NA**
2 dose¶¶	0.1	0.2	0.3	0.8	2.1	4.7	8.4	12.7	17	**NA**



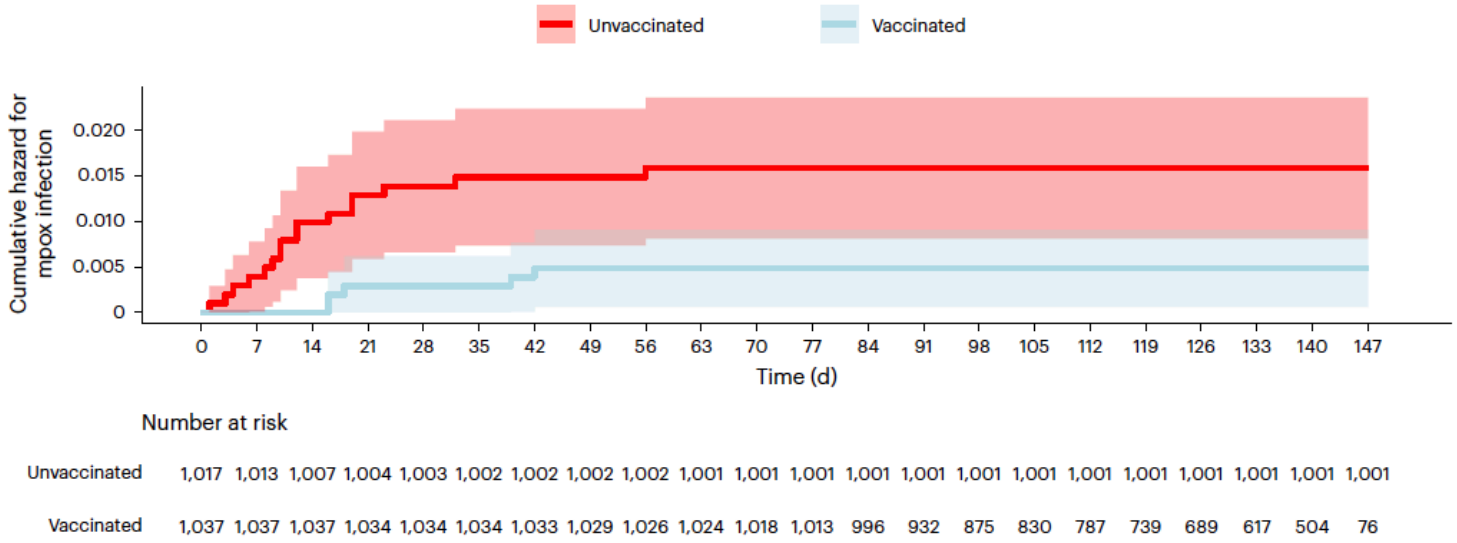
Payne et al. MMWR 2022.

Real-world effectiveness of a single dose of mpox vaccine in males

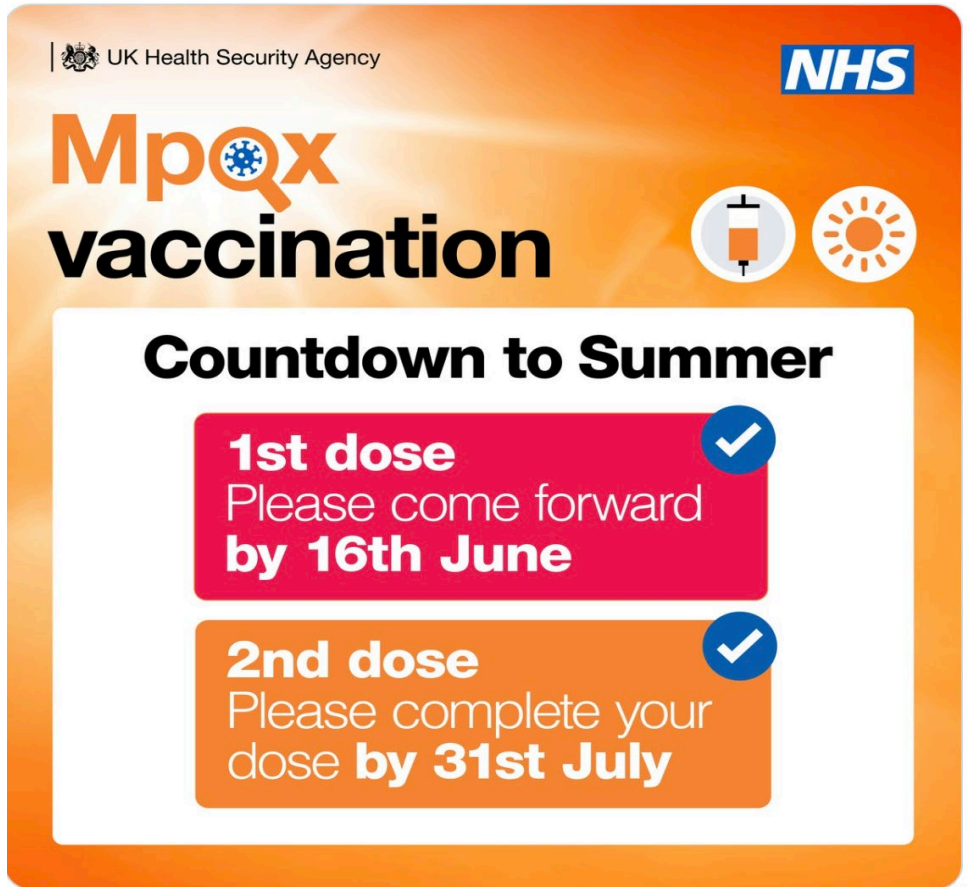
Table 2 | Association of participant characteristics and MPXV infection

Variables	Results of the univariable[a] models	Results of the multivariable[b] model
	HR (95% CI)	HR (95% CI)
Vaccination	0.30 (0.11, 0.83)	0.14 (0.05, 0.41)
Tel Aviv District	3.11 (1.05, 9.23)	3.98 (1.29, 12.33)
HIV-PrEP use[c]	0.97 (0.39, 2.41)	
Purchase of PDE5 inhibitors[c]	1.84 (0.67, 5.02)	2.14 (0.76, 5.99)
History of HIV/AIDS	0.87 (0.34, 2.24)	
Any syphilis infection	1.89 (0.76, 4.67)	1.11 (0.39, 3.18)
Chlamydia or NE gonorrhea in recent[c] rectal PCR	2.15 (0.72, 6.39)	
Chlamydia or NE gonorrhea in recent[c] urine PCR	3.38 (1.00, 11.48)	
Chlamydia or NE gonorrhea in recent[c] pharyngeal PCR	0.95 (0.22, 4.09)	
Chlamydia or NE gonorrhea in any recent[c] STI PCR	2.09 (0.84, 5.19)	2.53 (0.98, 6.52)
Recent[c] syphilis infection	3.58 (1.05, 12.15)	3.20 (0.78, 13.17)

In an analysis of 2,054 male individuals who met vaccine eligibility criteria, 1,037 (50%) were vaccinated during the study recruitment period and completed at least 90 d of follow-up. During the study period, **5 and 16 infections were confirmed in vaccinated and unvaccinated individuals, respectively.** The **adjusted vaccine effectiveness was estimated at 86% (95% confidence interval, 59–95%).**



Sagy YW, et al. Nat Med, 2023



Mpox (monkeypox)

Gay and bisexual men urged to get vaccinated against mpox as new cases reported

Mpox vaccine is effective, but two doses needed for best protection

Liz Highleyman | 31 May 2023 | Estimated reading time 9 minutes

Recent French mpox cluster includes fully vaccinated patients

News brief | *April 6, 2023*

French officials recently posted an **update** on an mpox cluster in the Center-Val de Loire region, with 17 cases reported since the first of the year, including 14 since March 1. All occurred in men who have sex with men who had several partners but didn't attend any common events.

Five of the patients had received two mpox vaccine doses in 2022. Also, five had received one smallpox dose during childhood, plus one dose in 2022.

Given the high proportion of vaccinated people in the cluster, 59%, Public Health France and its regional partners investigated the development, finding that the proportion of vaccinated cases is higher than the 25% observed at the national level between October and February.

"It is appropriate to await the results of real-life efficacy studies which will allow better interpretation of these data. To date, there is little perspective on the efficacy of 3rd generation vaccines against mpox infection," Public Health France said in its statement.

In other mpox developments, the European Centre for Disease Prevention and Control (ECDC) and the World Health Organization (WHO) European regional office yesterday posted a joint **update** on mpox, which reported 28 new cases from 7 countries since the last update 4 weeks ago. Sixteen of the cases are part of the French cluster. Six were from Spain. Other countries reporting cases are Portugal, the Netherlands, Switzerland, Greece, and Malta.

Santé publique France

Eléments nouveaux depuis le dernier bilan du 24 janvier 2023

- Survenue de 17 cas groupés de mpox en région Centre-Val de Loire
- 1 autre cas déclaré hors de ce cluster
- Les caractéristiques des cas recensés restent inchangées

Ce bilan inclut les cas confirmés biologiquement par PCR ou non. Ces derniers incluent les cas probables (signes cliniques évocateurs + contact à risque d'un cas confirmé) et les cas possibles (signes cliniques évocateurs + exposition à risque d'infection).

Au niveau international et du fait de différences dans les protocoles de surveillance selon les pays, les cas confirmés biologiquement restent l'indicateur de référence pour comparer les situations épidémiologiques entre pays.

Mpox '*as prevention*'

Monkeypox vaccination—an opportunity for HIV prevention

CrossMark

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HIV testing was offered to 2,185 people receiving mpox (formerly monkeypox) vaccination, who reported not being HIV positive. Among them 390 were current PrEP users, and 131 had taken PrEP in the past. Of 958 individuals consenting testing, six were newly diagnosed with HIV. Two patients had symptomatic primary HIV infection. None of the six patients had ever taken PrEP. Mpox vaccination represents an important opportunity for HIV testing and counselling about risk reduction and PrEP.

Conclusion

Our data show that the mpox vaccination campaign represents an important opportunity to take contact with people at high risk of HIV and other STIs. We recommend that everyone undergoing mpox vaccination should be offered HIV testing and, if they are negative, counselled about HIV/STI risk-reduction measures including PrEP.

Rapid communication

Results of an interventional HIV testing programme in the context of a mpox (formerly monkeypox) vaccination campaign in Latium Region, Italy, August to October 2022

Silvia Pittalis[1,*], Valentina Mazzotta[1,*], Nicoletta Orchi[1], Isabella Abbate[1], Roberta Gagliardini[1], Elisabetta Gennaro[1], Augusto Faticoni[1], Pierluca Piselli[1], Gabriella Rozera[1], Stefania Cicalini[1], Fabrizio Maggi[1], Enrico Girardi[1], Francesco Vaia[1], Andrea Antinori[1], Vincenzo Puro[1]

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Table

Characteristics of individuals newly diagnosed with HIV infection at time of mpox vaccination, National Institute for Infectious Diseases, Rome, Italy, 8 August–28 October 2022 (n = 6)

Characteristics	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Age range in years	30–39	20–29	40–49	40–49	30–39	40–49
Practice of chemsex	No	No	No	No	No	No
Previous STIs	Urethral gonorrhoea	Urethral gonorrhoea	Secondary syphilis; acute hepatitis A	Acute hepatitis B; latent syphilis	None	None[a]
Duration since last negative HIV test	<1 year	None	ca 3 years	<1 year	ca 5 years	ca 2 years
Previous PEP, if so year	Yes, 2015	No	No	No	No	No
Lymphocytes $CD4^+$ count in cells/mL	720	413	181	743	672	383
HIV viral load in copies/mL, (detection range 30–10,000,000)	2,155	>10,000,000	133,544	27,519	14,214	641,632
Type of infection and estimate of time of infection [8]	Recent infection (<1 year)	Symptomatic PHI (<1 month)	Advanced, late diagnosed (>1 year)	Symptomatic PHI (>1 month <6 month)	Chronic infection (>1 year)	Chronic infection (>1 year)
Symptoms/signs before the diagnosis	Not reported	Fever, myalgia and diarrhoea up to 6 days before	Not reported	Diffuse macular cutaneous rash, swollen neck lymph nodes, feeling of fever and fatigue ca 3 months before	Not reported	Not reported

PEP: post-exposure prophylaxis for HIV; PHI: primary HIV infection; STIs: sexually transmitted infections.

[a] Latent syphilis at the time of HIV diagnosis.

Future directions

- Mantain global ***surveillance*** and clinical vigilance of resurgence of clade Iib infections as well as novel ***introductions of new clades***
- Utility of non-lesion ***specimen for diagnosis***
- Detection of ***standardized antibodies testing***
- ***Complete randomized clinical trials*** of therapeutics (e.g. tecovirimat)
- Treatment strategies for those with severe ***immunodeficiencies***
- Need for additional therapeutics
- Increase ***vaccination uptake*** among at.risk persons
- Establish ***effectiveness and durability of immunity*** from vaccination and natural infenction, especially among immunosuppressed people
- Characterization of recurrence (***reinfection/relapse***)

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