Monthly Healthcare Provider & Public Health Partner Webinar

Updates on COVID-19 and Other Emerging Public Health Issues

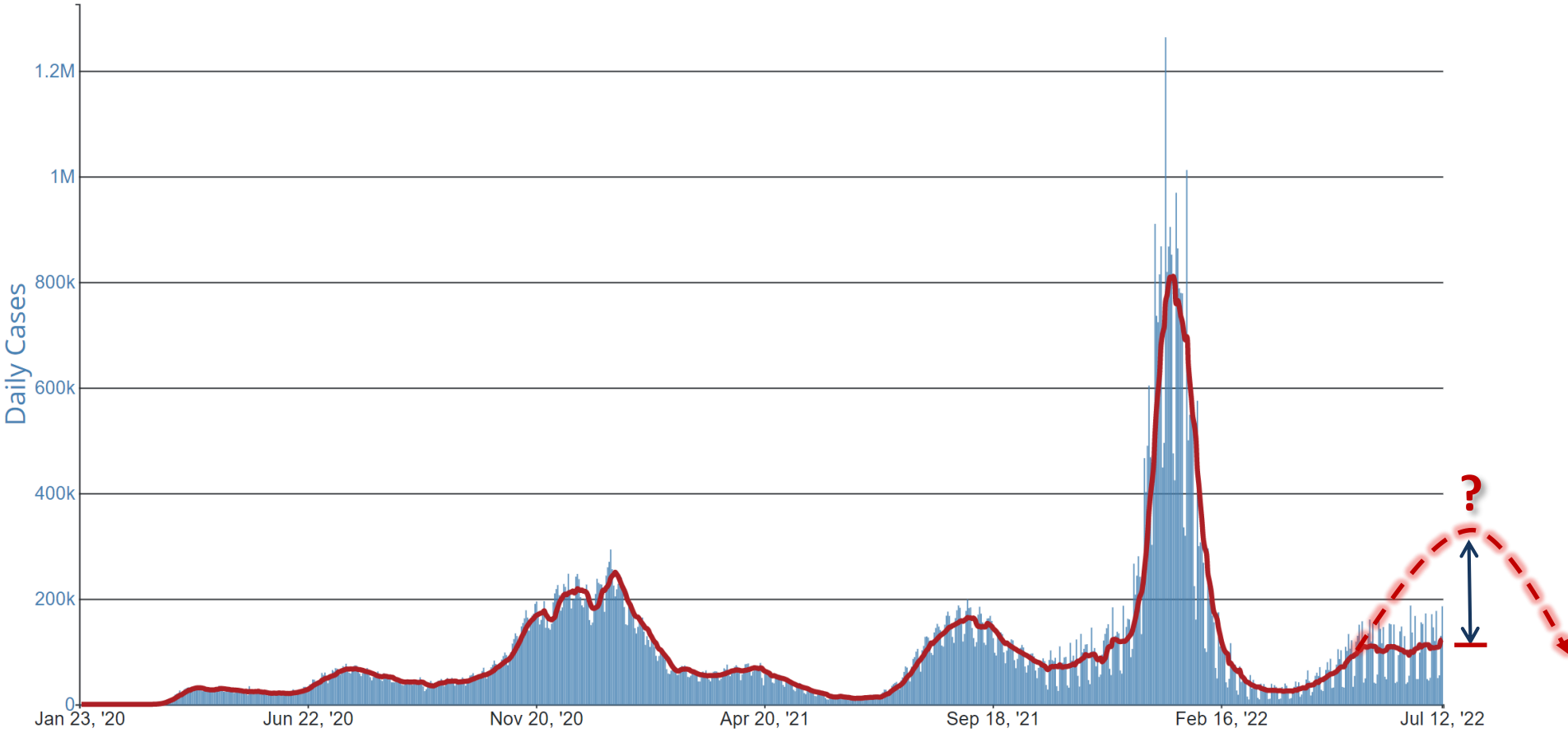
July 14, 2022

NH DIVISION OF
Public Health Services
Department of Health and Human Services

Agenda

- COVID-19 epidemiology
- COVID-19 vaccine recommendations
- Monkeypox virus outbreak
- Q&A

U.S. National Daily Incidence of COVID-19



https://covid.cdc.gov/covid-data-tracker/#trends_dailycases

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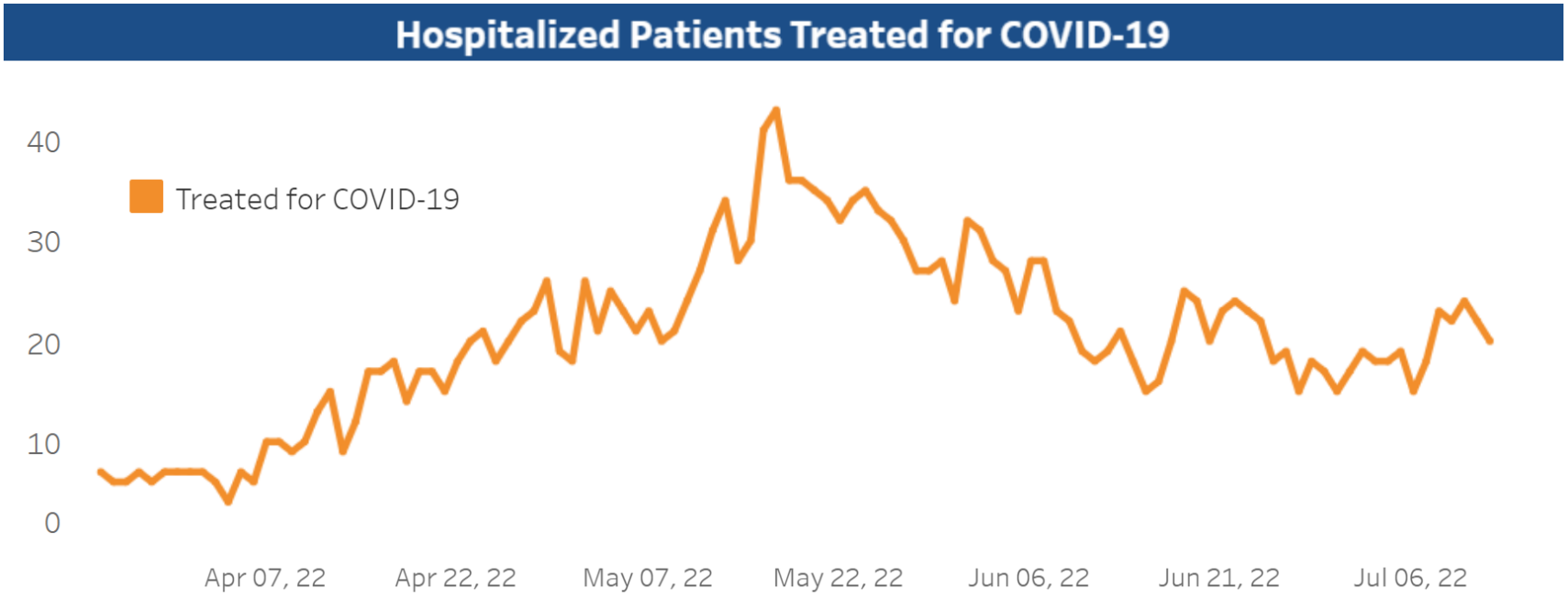
Number of People Hospitalized & Treated for COVID-19 in NH



https://www.covid19.nh.gov/dashboard/hospitals

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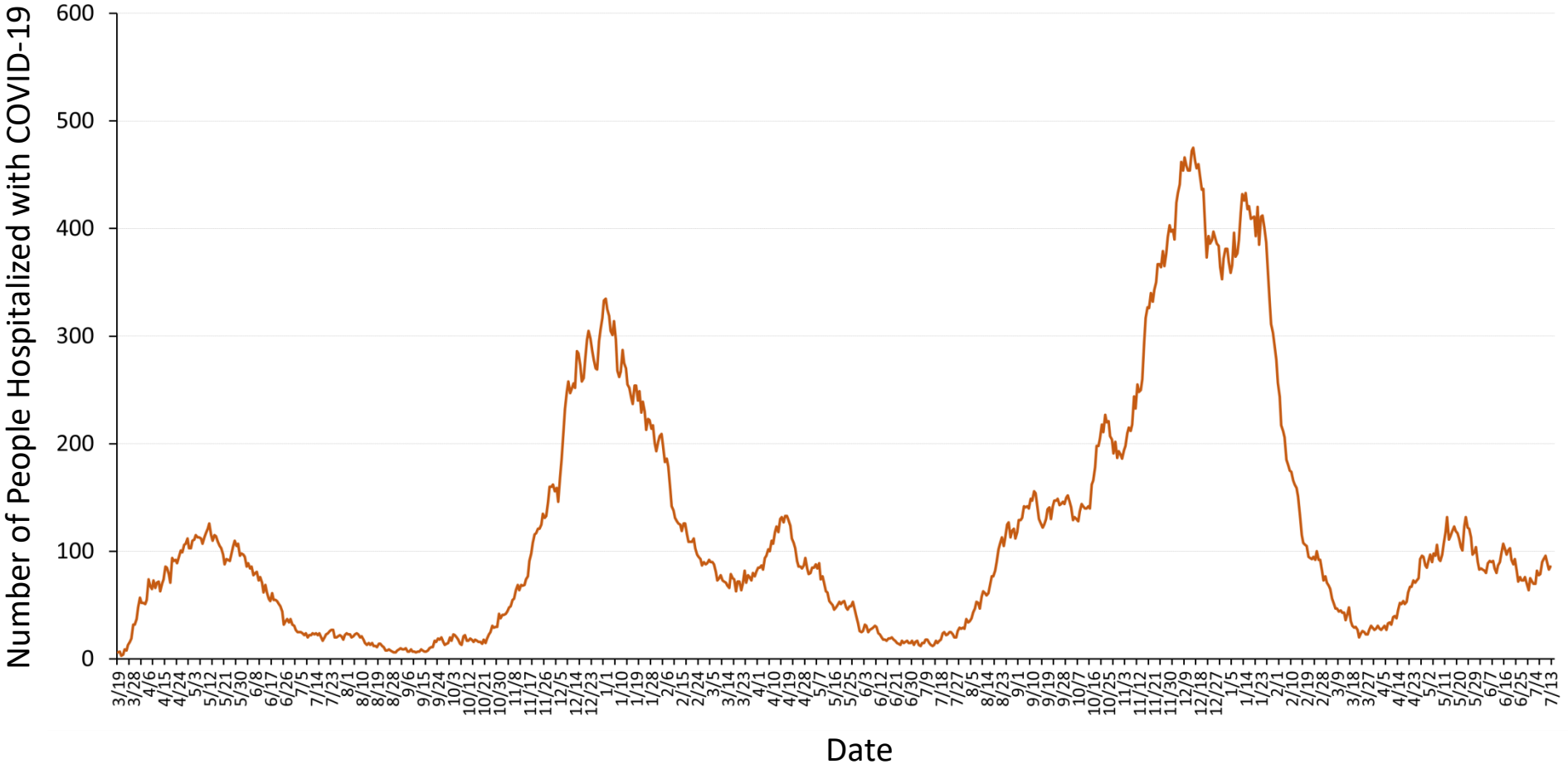
Number of People Hospitalized with COVID-19 Each Day in NH (Hospital Census)



https://www.nhha.org/index.php/whats-new/1545-coronavirus-disease-2019-covid-19-outbreak

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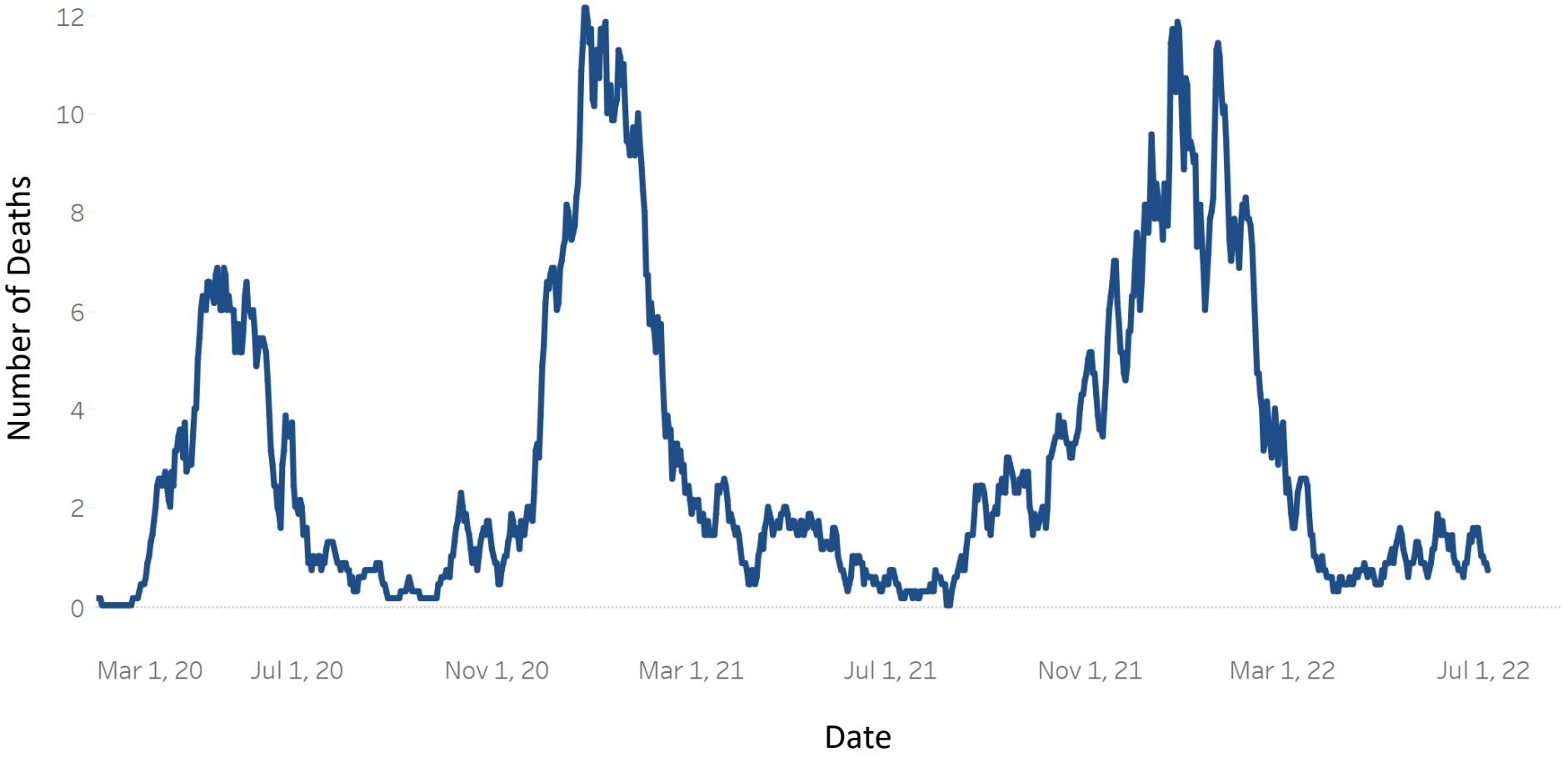
Average Number of COVID-19 Deaths per Day in NH (Based on Date of Death)



https://www.covid19.nh.gov/dashboard/trends

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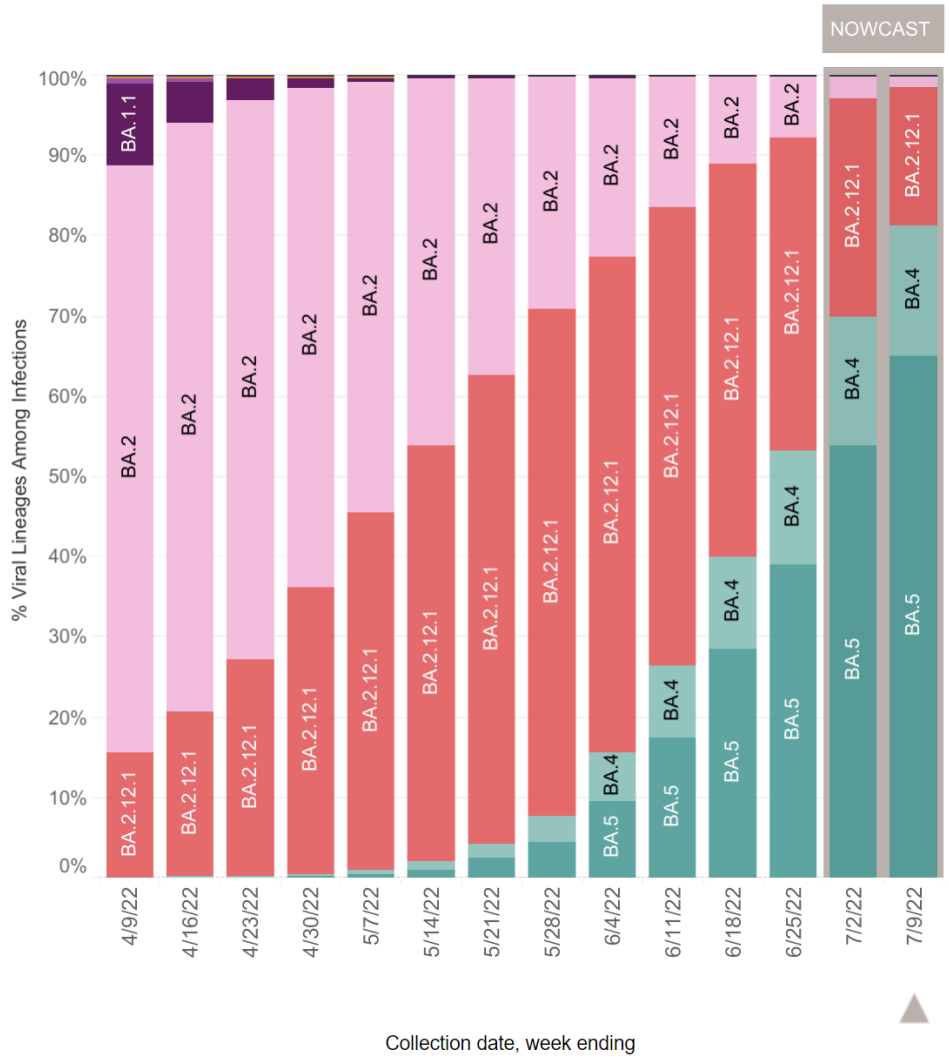
Variant Proportions in the U.S.

United States: 4/3/2022 – 7/9/2022



United States: 7/3/2022 – 7/9/2022 NOWCAST

USA

WHO label	Lineage #	US Class	%Total	95%PI
Omicron	BA.5	VOC	65.0%	62.2-67.7%
	BA.2.12.1	VOC	17.3%	15.7-19.0%
	BA.4	VOC	16.3%	14.5-18.3%
	BA.2	VOC	1.4%	1.3-1.6%
	B.1.1.529	VOC	0.0%	0.0-0.0%
	BA.1.1	VOC	0.0%	0.0-0.0%
Delta	B.1.617.2	VBM	0.0%	0.0-0.0%
Other	Other*		0.0%	0.0-0.0%

* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.
** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates
# AY.1-AY.133 and their sublineages are aggregated with B.1.617.2. BA.1, BA.3 and their sublineages (except BA.1.1 and its sublineages) are aggregated with B.1.1.529. For regional data, BA.1.1 and its sublineages are also aggregated with B.1.1.529, as they currently cannot be reliably called in each region. Except BA.2.12.1, BA.2 sublineages are aggregated with BA.2. BA.5.1 is aggregated with BA.5.

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

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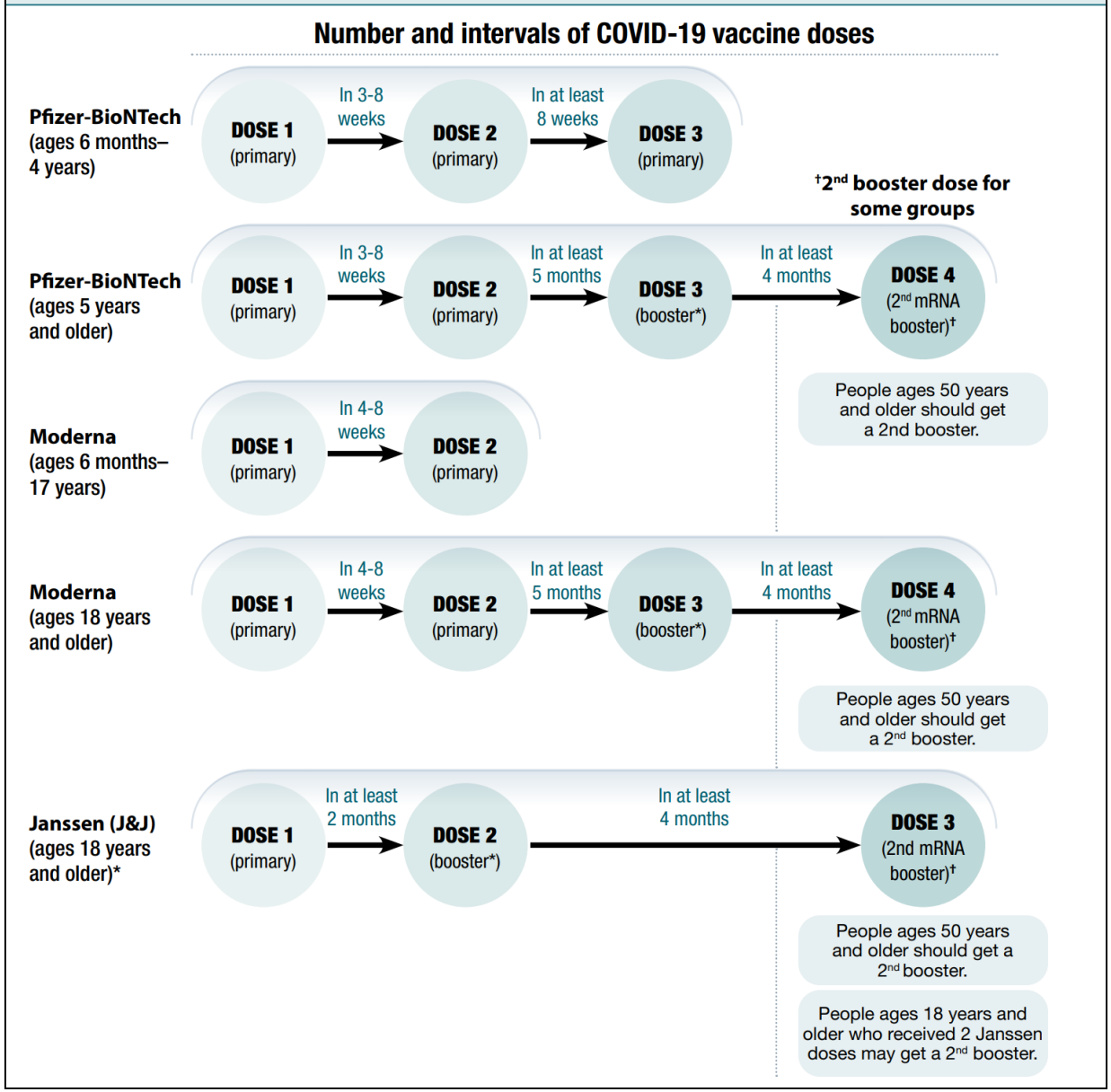
COVID-19 Vaccine Recommendations

COVID-19 Vaccine General Recommendations

- Everybody 6 months of age or older should get vaccinated with a primary series (either Pfizer-BioNTech or Moderna)
  - Number and timing of doses in the primary series depends on whether or not a person is moderate-severely immunocompromised
- Persons 5 years of age or older should also get at least a single booster dose
  - Exception: children and adolescents 5-17 years of age who received the Moderna primary series are not yet recommended for a booster (i.e., heterologous booster dosing is only authorized/recommended for persons 18 years of age or older) – this likely will change in the coming months
- Certain people are recommended to receive a 2nd booster dose now, including:
  - All persons 50 years of age or older
  - Persons 12-49 years of age who are moderate-severely immunocompromised

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

COVID-19 Vaccination Schedule for Most People



https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-vacc-schedule-at-a-glance-508.pdf

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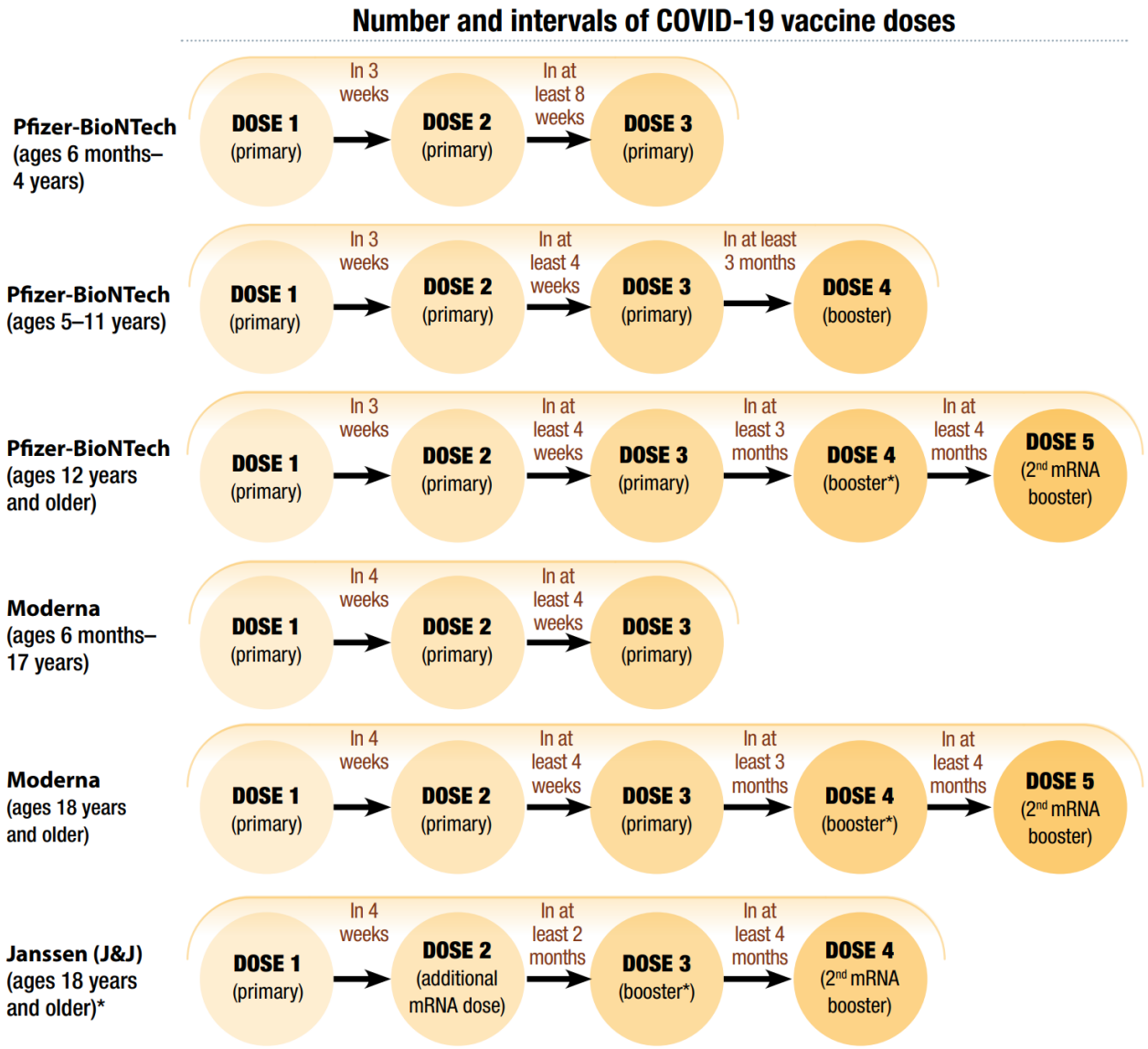
COVID-19 Vaccination Schedule for People Who Are Moderately or Severely Immunocompromised



https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-vacc-schedule-at-a-glance-508.pdf

Vaccination of Infants and Young Children

- Uptake of COVID-19 vaccination in children under the age of 5 years has been low so far in NH and nationally (~2000 doses administered to this age group in NH over the last ~3 weeks)
- As summer ends and children re-enter school or childcare, there will be additional opportunities to vaccinate
- Primary care providers should incorporate COVID-19 vaccination into well-child visits, and ensure children are both caught up on routine vaccinations AND COVID-19 vaccination
- Thank you to those providers/offices that have already enrolled to be COVID-19 vaccine providers

Transitioning from a younger to older age group

People should receive the recommended age-appropriate vaccine product and dosage based on their age on the day of vaccination. If a person moves from a younger age group to an older age group during the primary series or between the primary series and receipt of the booster dose(s), they should receive the vaccine product and dosage for the older age group for all subsequent doses.

FDA authorization allows for dosing options for certain age transitions for Pfizer-BioNTech COVID-19 Vaccine and Moderna COVID-19 Vaccine as described below. Refer to Table 1 for information about age-specific vaccine products and dosages.

Pfizer-BioNTech COVID-19 Vaccine

Children who will turn from age 4 years to 5 years: FDA authorization of the Pfizer-BioNTech COVID-19 Vaccine allows children who will turn from age 4 years to 5 years between any dose in the primary series to receive:

- A 2-dose primary series using the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 5–11 years

or

- A 3-dose primary series initiated with the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 6 months–4 years. Each of doses 2 and 3 may be with the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 6 months–4 years, **or** the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 5–11 years.

Children who will turn from age 11 years to 12 years: FDA authorization of the Pfizer-BioNTech COVID-19 Vaccine allows children who will turn from age 11 years to 12 years between doses in the primary series to receive, for any primary dose: (1) the Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 5–11 years or (2) the Pfizer-BioNTech COVID-19 Vaccine product authorized for people ages 12 years and older.

Moderna COVID-19 Vaccine

Children who will turn from age 5 years to 6 years: FDA authorization of the Moderna COVID-19 Vaccine allows children who will turn from age 5 years to 6 years between doses in the primary series to receive, for any primary dose: (1) the Moderna COVID-19 Vaccine product authorized for children ages 6 months–5 years or (2) the Moderna COVID-19 Vaccine product authorized for children ages 6–11 years .

Children who will turn from age 11 years to 12 years: FDA authorization of the Moderna COVID-19 Vaccine allows children who will turn from age 11 years to 12 years between doses in the primary series to receive, for any primary dose: (1) the Moderna COVID-19 Vaccine product authorized for children ages 6–11 years or (2) the Moderna COVID-19 Vaccine product authorized for people ages 12 years and older.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#timing-spacing-interchangeability

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States

Summary of recent changes (last updated June 30, 2022):

- New clinical considerations for coadministration of mRNA COVID-19 vaccines and orthopoxvirus vaccines

Reference Materials

- Summary Document for Interim Clinical Considerations (Updated 6/24/2022)
- Interim COVID-19 Immunization Schedule (Updated 6/24/2022)
- At-A-Glance COVID-19 Vaccination Schedule (NEW 6/24/2022)
- Moderna COVID-19 Vaccine for Children who Transition from a Younger to Older Age Group (NEW 6/24/2022)
- Pfizer-BioNTech for Children who Transition from a Younger to Older Age Group (NEW 6/24/2022)

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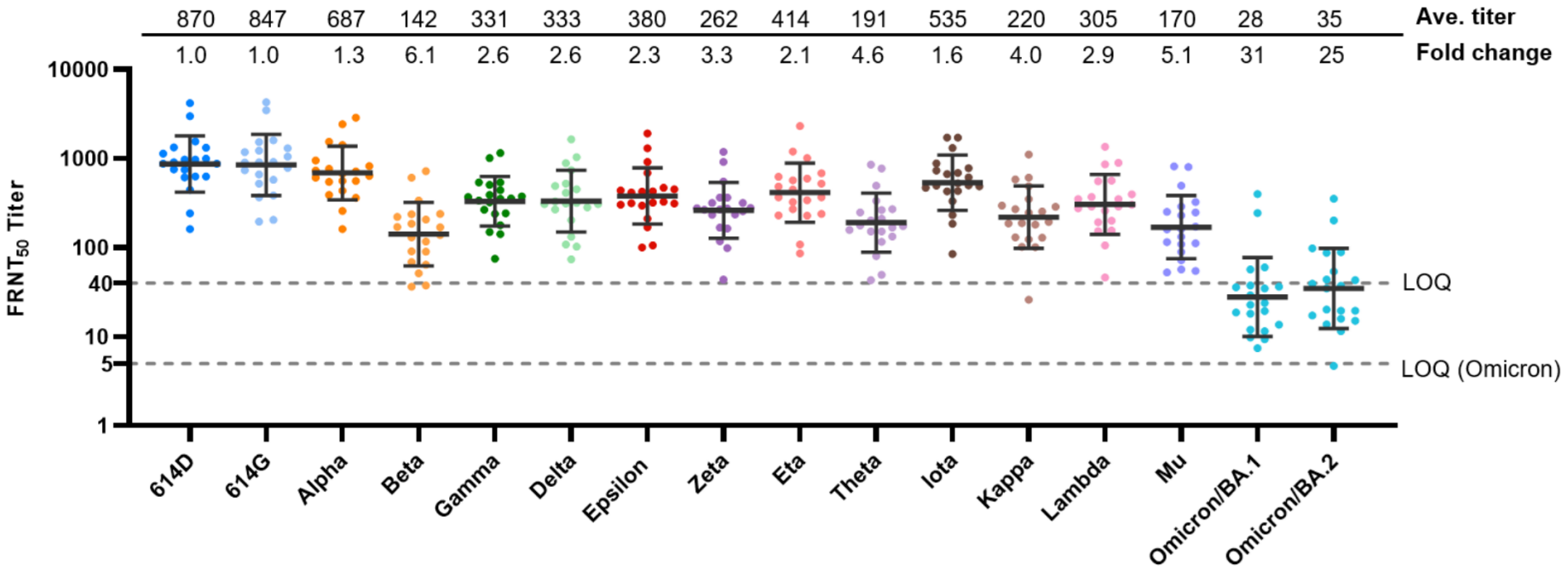
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Fall/Winter COVID-19 Vaccine Boosters

- June 28th the FDA VRBPAC met to discuss whether and how the SARS-CoV-2 strain composition of COVID-19 vaccines should be modified
- June 30th the FDA recommends adding an Omicron BA.4/5 spike protein component to the current vaccine to create a two-component (bivalent) COVID-19 booster vaccine for use starting fall 2022

Neutralizing Activity of mRNA Vaccine Sera Against SARS-CoV-2 Variants from Alpha to Omicron

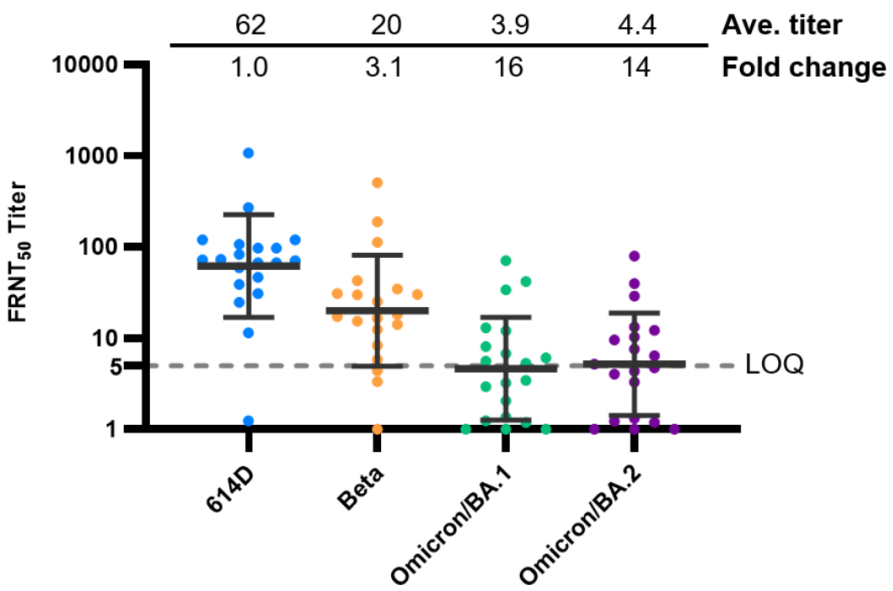


Sera from 2-6 weeks after completing second dose of Moderna (10 sera) and Pfizer-BioNTech (10 sera) vaccines, tested with recombinant SARS-CoV-2 reporter viruses

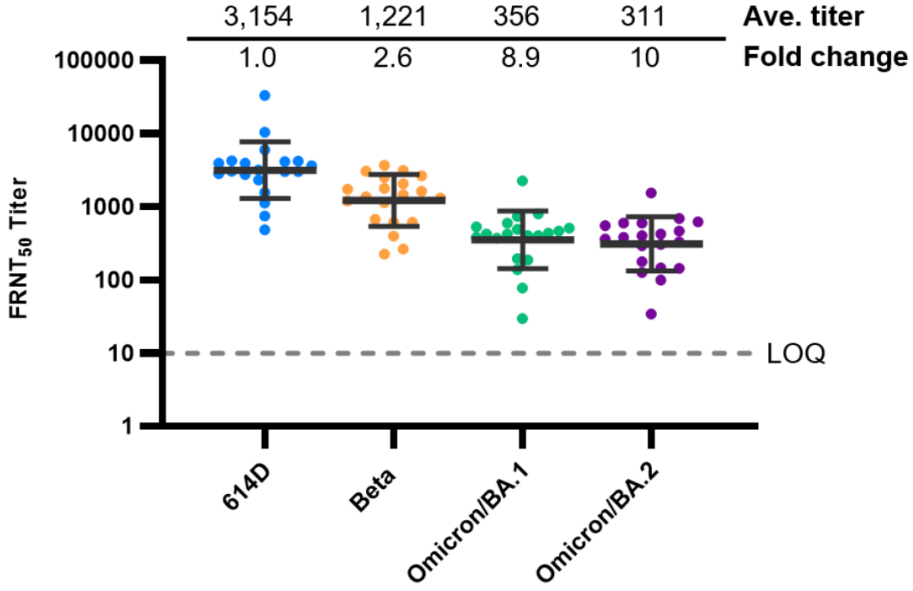
LOQ=Limit of quantitation. Zhou B, Davis T, Thornburg N, Wentworth D (CDC), *in publication*

https://www.fda.gov/media/159494/download

Booster Vaccination Enhances Neutralizing Antibodies Against SARS-CoV-2 Viruses Including Omicron



Sera from 6-7 months after completing second dose (pre-booster)



Sera from 2-6 weeks after completing third dose (post-booster)

LOQ=Limit of quantitation. Tested with Recombinant SARS-CoV-2 reporter viruses. Zhou B, Davis T, Thornburg N, Wentworth D (CDC), *in publication*

https://www.fda.gov/media/159494/download

Moderna COVID-19 Vaccine

- Analysis population: previously uninfected adults 18 years of age and older
- Vaccines evaluated:
  - mRNA-1273: monovalent, 50 µg mRNA encoding prototype S protein
  - mRNA-1273.214: bivalent, 25 µg each of mRNA encoding prototype or Omicron/BA.1 S protein

Neutralizing antibody GMT at 4 weeks after a 4th (2nd booster) dose

Neutralization Input Virus	mRNA 1273 GMT (95% CI) N=260	mRNA 1273.214 GMT (95% CI) N=334	GMT Ratio (95% CI) mRNA-1273.214/ mRNA-1273
Omicron/BA.1	1473 (1271, 1708)	2372 (2071, 2718)	1.75 (1.49, 2.04)
Ancestral (D614G)	5649 (5057, 6311)	5977 (5322, 6713)	1.22 (1.08, 1.37)

https://www.fda.gov/media/159495/download

Pfizer-BioNTech COVID-19 Vaccine

- Analysis previously uninfected adults 18-55 years of age
- Vaccines evaluated:
  - BNT162b2: monovalent, 30 µg mRNA encoding prototype S protein
  - BNT162b2 OMI: monovalent, 30 µg mRNA encoding Omicron/BA.1 S protein

Neutralizing antibody GMT at 1 month after a 4th (2nd booster) dose

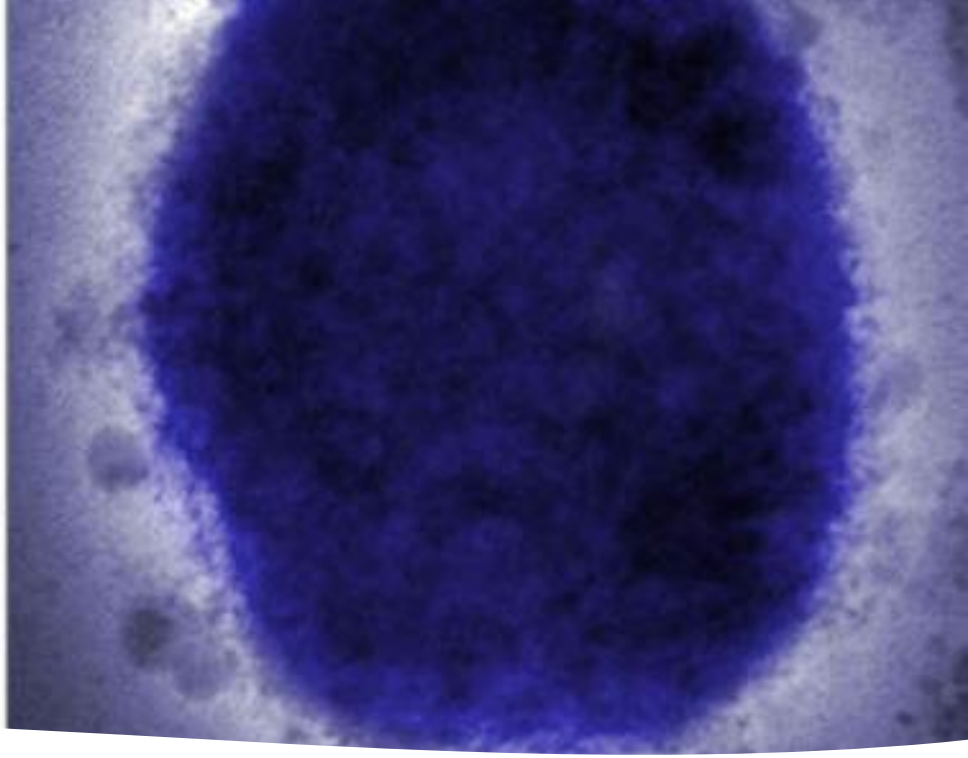
Neutralization Input Virus	BNT162b2 GMT (95% CI) N=141	BNT162b2 OMI GMT (95% CI) N=132	GMT Ratio (95% CI) BNT162b2 OMI/ BNT162b2
Omicron/BA.1	1100 (932, 1297)	1929 (1632, 2281)	1.75 (1.39, 2.22)
Ancestral (D614G)	12009 (10744, 13425)	11997 (10554, 13638)	Not Evaluated

https://www.fda.gov/media/159495/download

Fall/Winter COVID-19 Vaccine Boosters

- **It is likely that everybody will need boosters (ideally with an updated booster vaccine) as we enter the higher-risk winter period (and NH is planning for such a scenario)**
- COVID-19 vaccine boosters (not the primary series) are currently being updated to include BA.4 and BA.5 variants in a bivalent composition
- Right now people should be focused on completing their primary series and getting at least a single booster (if eligible and not already boosted) with the current COVID-19 vaccines
  - The Prime + Boost is still highly protective against severe disease
  - 1st booster is critically important for having the highest level of antibodies, longer durability of protection, and for expanding protection to cover emerging variants

Monkeypox

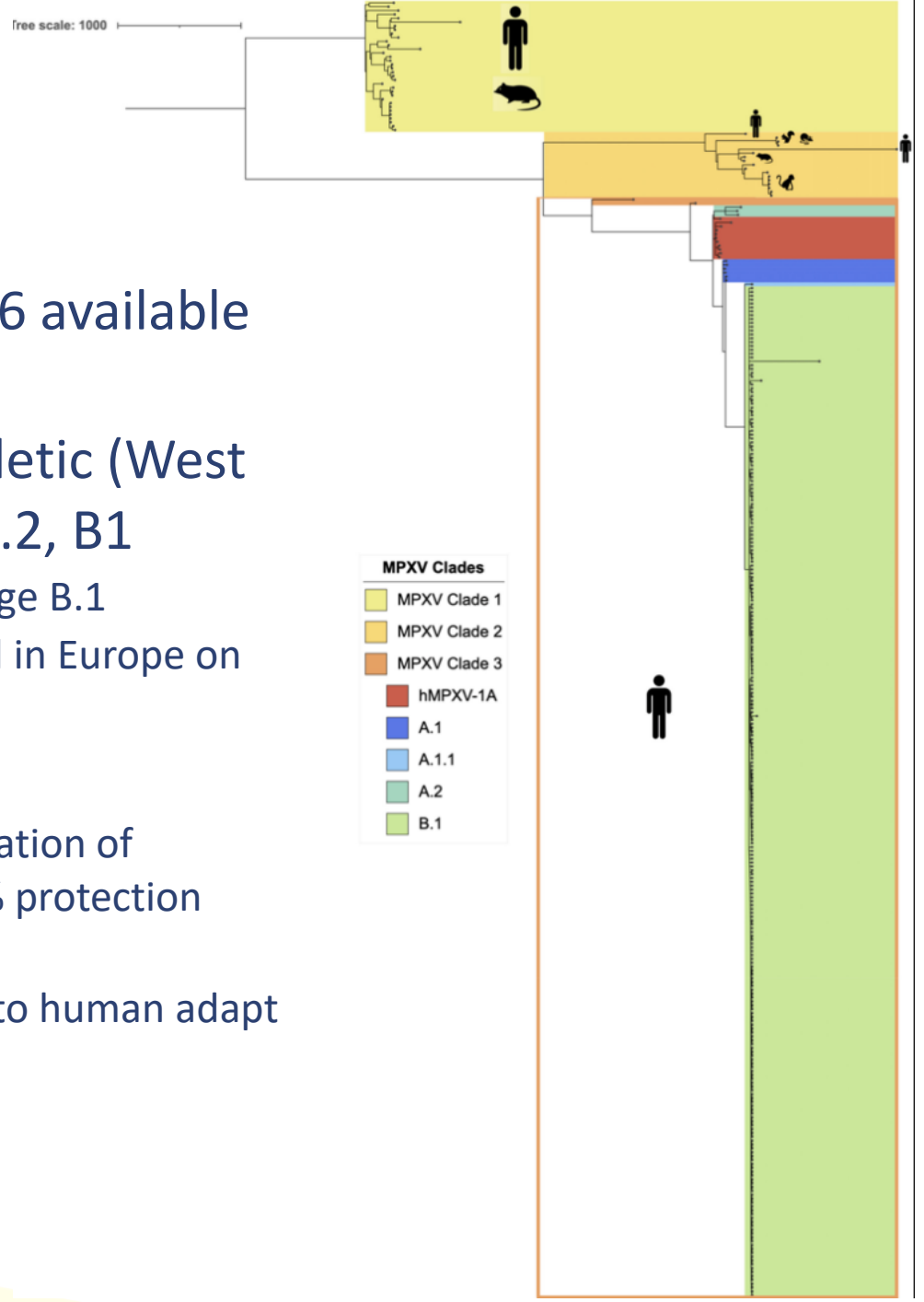


Monkeypox Background

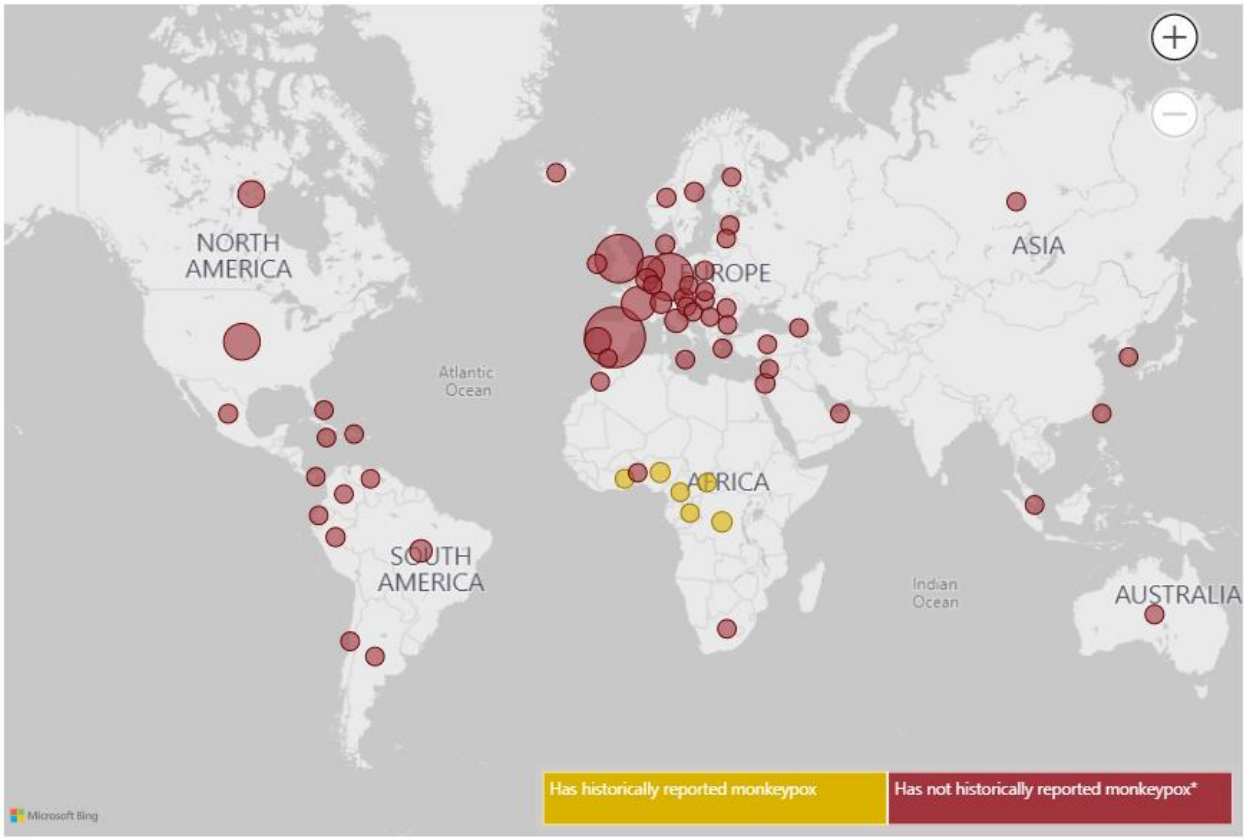
- **Endemic** as sylvatic zoonosis in central and western Africa
- **Epidemic** 2003 US MPX outbreak related to direct or indirect contact with infected animals (Gambian giant pouched rat)
- **Current** multiple intros to diverse countries from Nigeria (clade 3 [previously West African strain] with recent amplifying and superspreading events in Europe and North America
  - 4 MSM gatherings in Antwerp, Belgium; Quebec Province, Canada; Madrid, Spain; and Canary Islands
  - Sequences from 21 countries are almost all novel strain

New MPX Clade?

- Phylogenomic analysis of 286 available MPX genomes
- All grouped into 3 monophyletic (West African) clades: A.1, A.1.1, A.2, B1
  - All 2022 outbreak genomes in lineage B.1
  - Estimated that B.1 lineage emerged in Europe on 03/02/2022
- Hypothesized due to
  - Increased susceptibility due to cessation of smallpox vaccination in 1980's (85% protection against MPX)
  - Natural selective pressure on virus to human adapt
  - Superspreader events



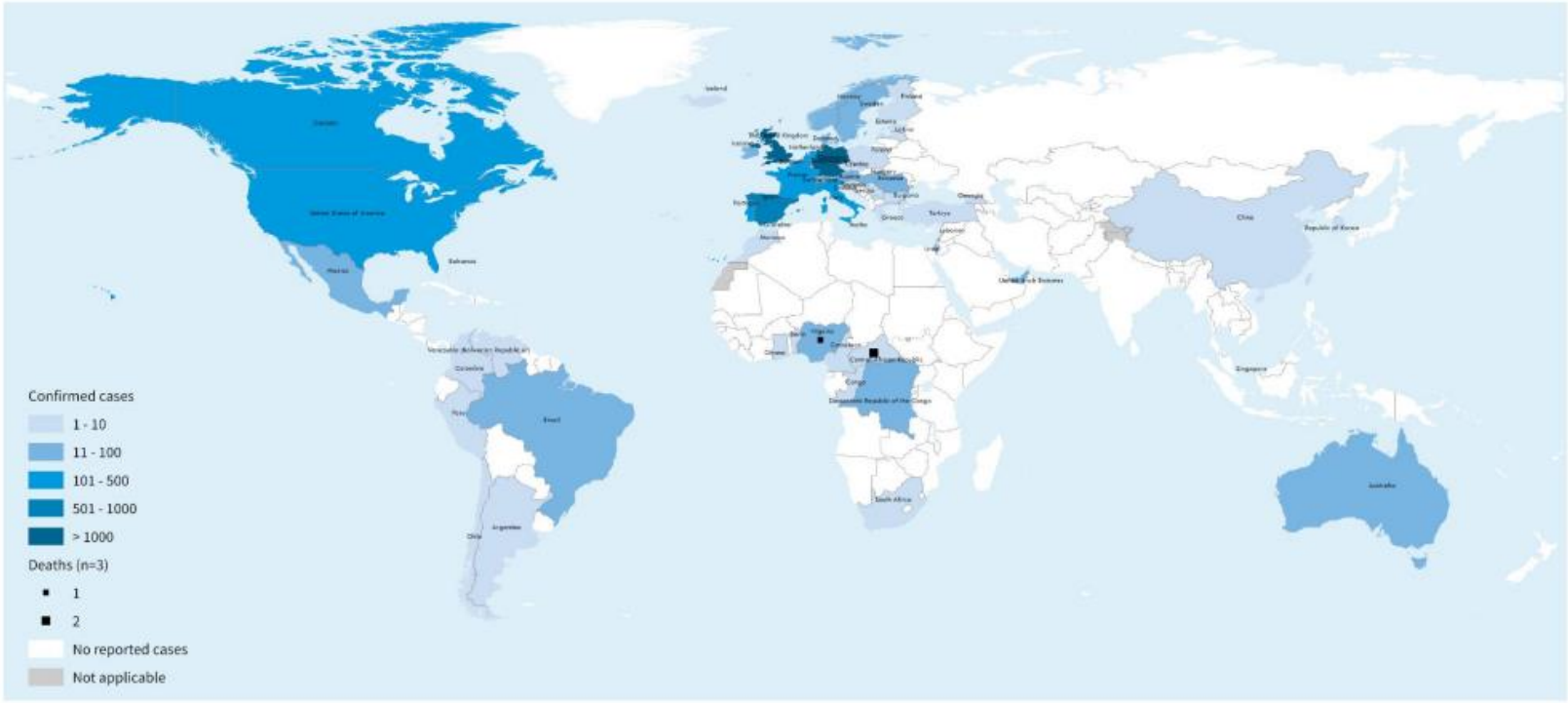
Global Situation Report (CDC)



In ~2m of circulation, >10,000 confirmed in 61 nonendemic countries

https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html

Global Situation Report (WHO)



The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization
Map Production: WHO Health Emergencies Programme
Map Date: 6 July 2022

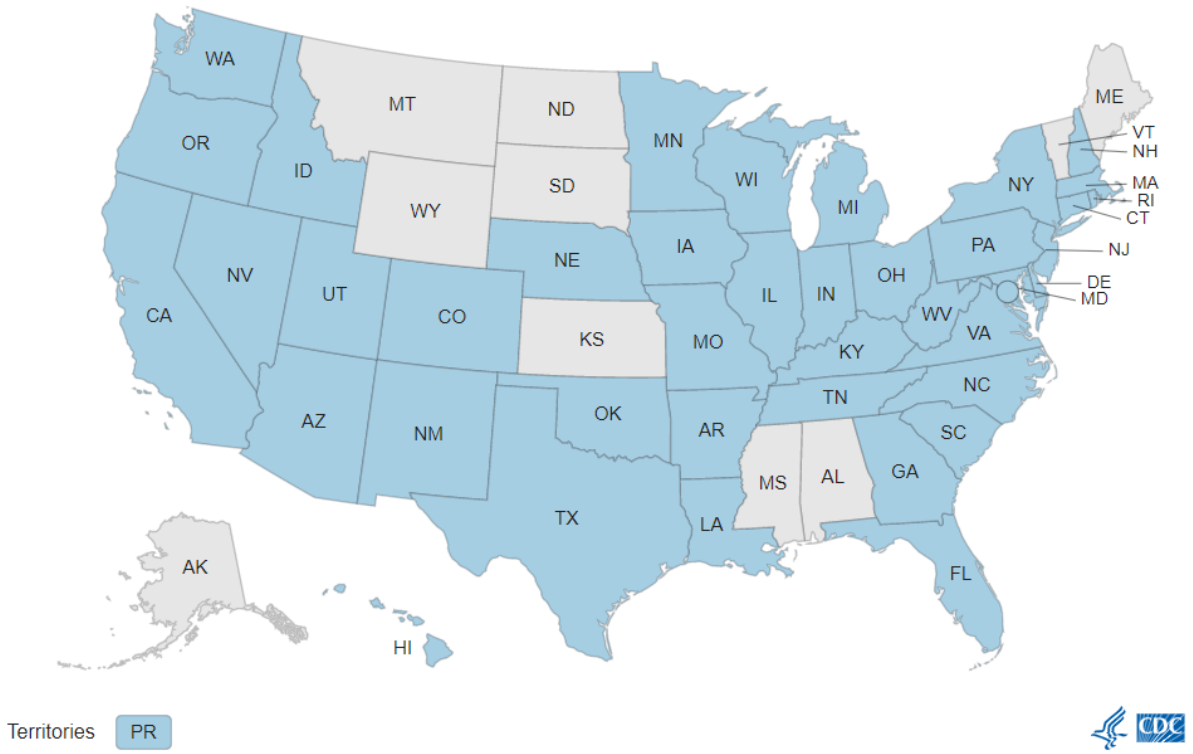
World Health Organization

Increasing; UK reports 15d doubling time

WHO is reconsidering PHIEC designation

WHO Situation Reports

US Case Count



5/19/2022 1st case in US; now ~1000 from 42 jurisdictions
#4 among nonendemic countries

https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html

US State Burden

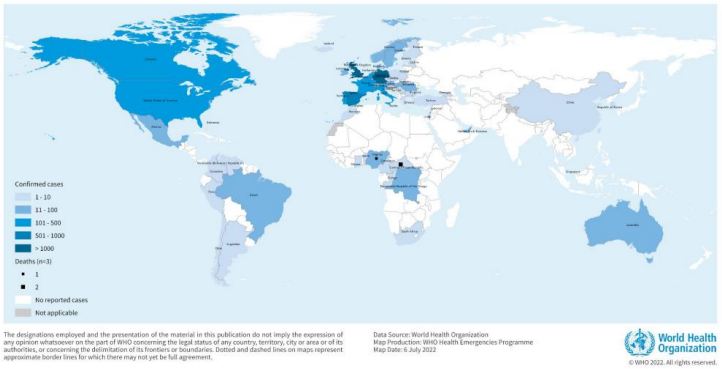
Case Count by State of Residence

State	Number of Cases
New York	158
California	150
Illinois	121
Florida	72
District Of Columbia	69
Georgia	48
Massachusetts	44
Texas	39
Pennsylvania	29
Virginia	25
Maryland	22
Washington	19
Colorado	16
New Jersey	11
North Carolina	10
Indiana	10

https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html

WHO Reported Demographics

- 99.5% males, median age 37y (interquartile range 31-43)
  - 79% of case are males 18-44yo
- Among cases reporting, 60% MSM
  - UK higher: 99% men, 97% MSM
  - Few sporadic cases have been reported in household members, nonsexual contacts, heterosexual contacts, and children
- 25 global cases reported to be health workers
  - Further investigation to determine if occupational exposure



WHO Situation Reports

UK Enhanced Investigations

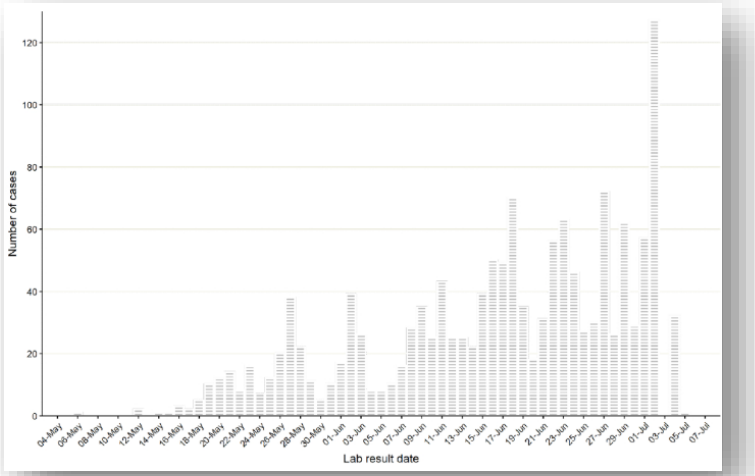


Table 3. Selected epidemiological metrics from enhanced surveillance questionnaires in confirmed monkeypox cases in England as of 6 July 2022

N=445, some metrics have slightly smaller denominators due to missing values

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%)
On HIV treatment (among living with HIV)	121 (99.2%)
Ever used PrEP (among HIV negative)	222 (79.3%)

[UK Situation]

Demographics of First 305 US Cases

- Median age: 36 years (range 20-76 years)
- Male sex at birth: 271
  - All for whom gender identity was reported, are cisgender men
  - MMSC[†]: 193/195(99%)
    Unknown: 76
- Female sex at birth: 5
  - Some cisgender women
  - Some transgender men
- No cases in children
- No deaths; some hospitalizations primarily for pain control

Any person, regardless of gender identity or sexual orientation, can acquire and spread monkeypox

Data will change pending ongoing investigations and additional cases*

[†]male to male sexual contact

June 29 COCA Call

Clinical Symptoms

- Skin rash or enanthem in all patients
- Lesions in different phases of development seen side-by-side
- Rash either scattered or diffuse; sometimes limited to one body site and mucosal area (e.g., anogenital region or lips/face)
- Presenting complaint sometimes anorectal pain or tenesmus; physical examination yields visible lesions and proctitis
- Prodromal symptoms mild or not occurring
- Fever, lymphadenopathy not occurring in all patients
- Some co-infections with sexually transmitted infections (STIs)

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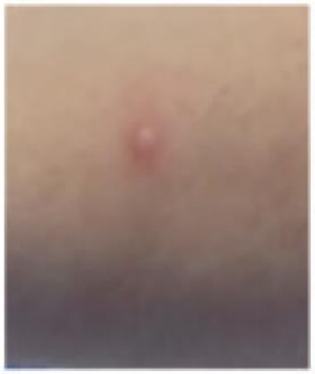
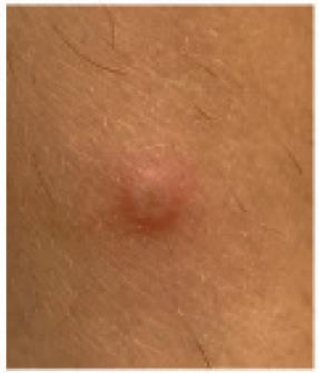
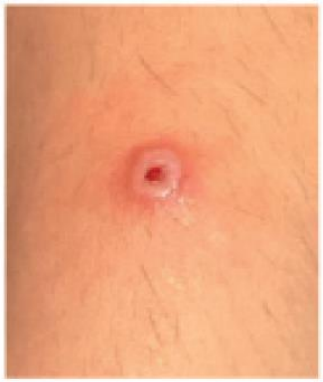
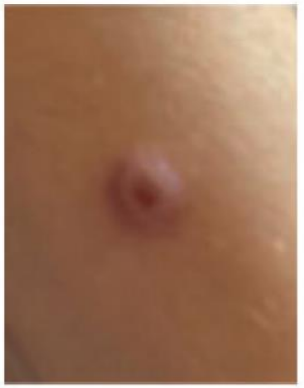
Global Clinical Features

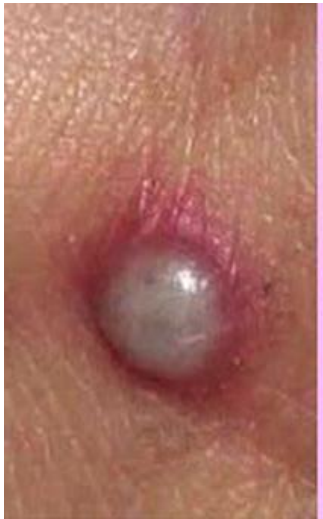








- Firm, deep-seated (vs. superficial, as seen with varicella), well-circumscribed, and sometimes umbilicated
  - Lesions in different stages of development
- “Atypical”: traditional symptoms F, LAD and centrifugal rash in same stage development



CDC Guidance to Clinicians

- Perform thorough skin and mucosal (e.g., anal, vaginal, oral) exam for rash
- Obtain swabs if
  - Observation of classic monkeypox rash OR
  - Observation of rash that could be consistent with monkeypox in persons with epidemiologic risk factors:
    - Contact with a person or people a) with similar appearing rash or b) with diagnosis of monkeypox
    - Close or intimate in-person contact with people in a social network experiencing monkeypox activity (e.g., men who have sex with men who meet partners through an online website, digital app or social event)
    - History of recent international travel to country currently with many cases
- Diagnosis of STI does not rule-out co-infection with monkeypox
- **Note:** any person, irrespective of gender identity or sexual orientation, can acquire and spread monkeypox.

June 29 COCA Call
monkeypox HAN

What Should You Do?

- When evaluating patients for monkeypox infection:
  - Place patient in private room with private bathroom
    - All not required unless conducting an aerosol generating procedure
  - Wear recommended PPE (see CDC's infection prevention guidance)
  - Take a detailed sexual history
  - Ask about travel
  - Ask about close or physical contact to person with similar skin lesions
  - Take detailed history of rash/lesions and any other symptoms
- If evaluating a patient for perianal/genital lesions, also screen for other STIs given high risk of concurrent infection (see The Lancet Preprint)
- Report suspected cases of monkeypox to NH DPHS at 603-271-4496
  - Nights and weekends call 603-271-5300 and ask for the on-call public health nurse

MPX Medical Countermeasures

Treatment

- Antivirals cidofovir, brincidofovir, tecovirimat IV or po in SNS
  - CDC TPOXX guidance used under CDC EA-IND protocol
- +/- vaccinia immune globulin (VIG)
- mAb development underway

Prevention: PEP and PrEP

- Jynneos: nonreplicating vaccinia vaccine; Bavarian Nordic A/S; branded as Imvanex in Europe and UK, as Imvamune in Canada
- ACAM2000: live replicating vaccinia vaccine; Emergent BioSolutions; > 100 million doses stockpiled

https://www.cdc.gov/vaccines/hcp/vis/current-vis.html

ACAM2000 and Jynneos

	ACAM2000	JYNNEOS
Vaccine virus	Replication-competent vaccinia virus	Replication-deficient Modified vaccinia Ankara
"Take"	"Take" occurs	No "take" after vaccination
Inadvertent inoculation and autoinoculation	Risk exists	No risk
Serious adverse event	Risk exists	Fewer expected
Cardiac adverse events	Myopericarditis in 5.7 per 1,000 primary vaccinees	Risk believed to be lower than that for ACAM2000
Effectiveness	FDA assessed by comparing immunologic response and "take" rates to Dryvax*	FDA assessed by comparing immunologic response to ACAM2000 & animal studies
Administration	Percutaneously by multiple puncture technique in single dose	Subcutaneously in 2 doses, 28 days apart

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Vaccine Contraindications

Contraindication	ACAM2000 Primary Vaccinees	ACAM2000 Revaccinees	ACAM2000 Household Contacts[1]	JYNNEOS
History or presence of atopic dermatitis	X	X	X	
Other active exfoliative skin conditions	X	X	X	
Conditions associated with immunosuppression	X	X	X	
Pregnancy	X	X	X	
Aged <1 year	X	X	X	
Breastfeeding	X	X		
Serious vaccine component allergy	X	X		X
Known underlying heart disease (e.g., coronary artery disease or cardiomyopathy)	X	X		
Three or more known major cardiac risk factors	X			

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Jynneos: Deeper Dive

- **JYNNEOS is a live virus vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating orthopoxvirus**
  - Also known as IMVAMUNE, IMVANEX, MVA
- **Licensed by FDA in September 2019**
- **Indication**
  - JYNNEOS is indicated for prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection
  - CDC is developing an Expanded Access Investigational New Drug Protocol to allow the use of JYNNEOS for monkeypox in pediatric populations

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Who Should Get PrEP?

- Clinical laboratory personnel who perform testing to diagnose orthopoxviruses, including those who use polymerase chain reaction (PCR) assays for diagnosis of orthopoxviruses, including Monkeypox virus
- Research laboratory workers who directly handle cultures or animals contaminated or infected with orthopoxviruses that infect humans, including Monkeypox virus, replication-competent Vaccinia virus, or recombinant Vaccinia viruses derived from replication-competent Vaccinia virus strains
- Certain healthcare and public health response team members designated by public health authorities to be vaccinated for preparedness purposes

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Evolving Vaccine Strategy: PEP++

- Vaccination of people with certain risk factors that make them more likely **to have been recently exposed** to MPX
- Vaccine supply severely limited: ~100 courses in NH
  - More expected in coming months: 1.1M in first half 2023
  - Allocation based on areas of highest transmission with population adjustment and weighted by population of MSM with HIV or eligibility for HIV PrEP
- Strategies to allocate in NH underway
  - Your input welcome

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Q&A