UWTASP tele-antimicrobial stewardship program | echo

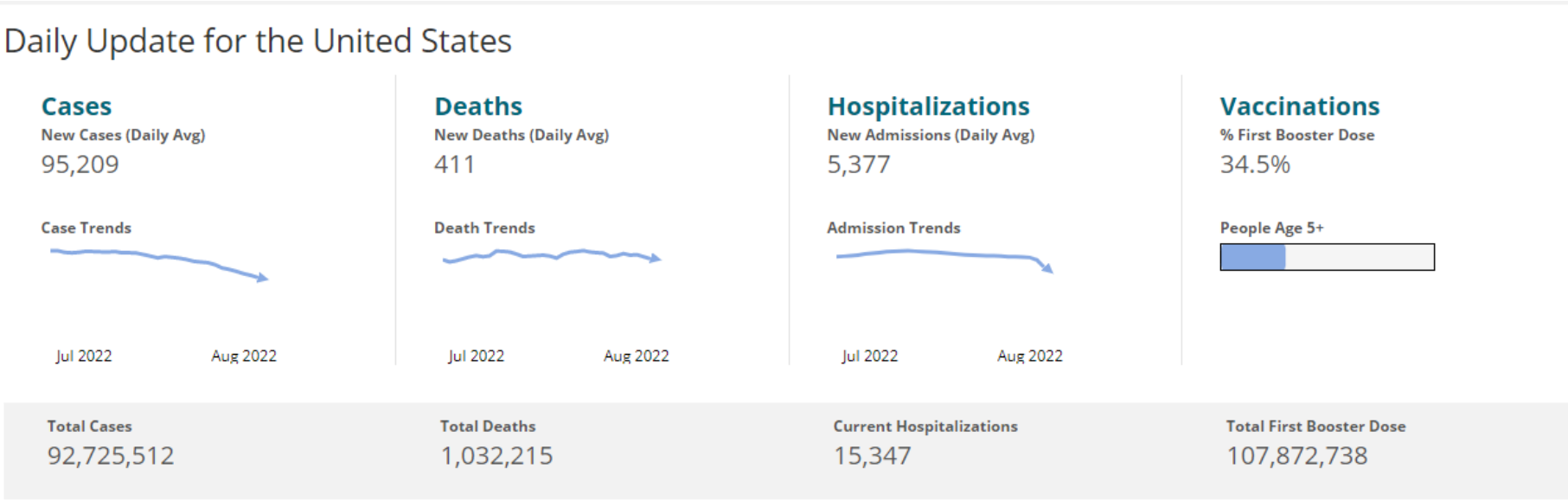
August 16, 2022

Agenda

- Speaker: *PandemicS Update*
- COVID19
- MPV

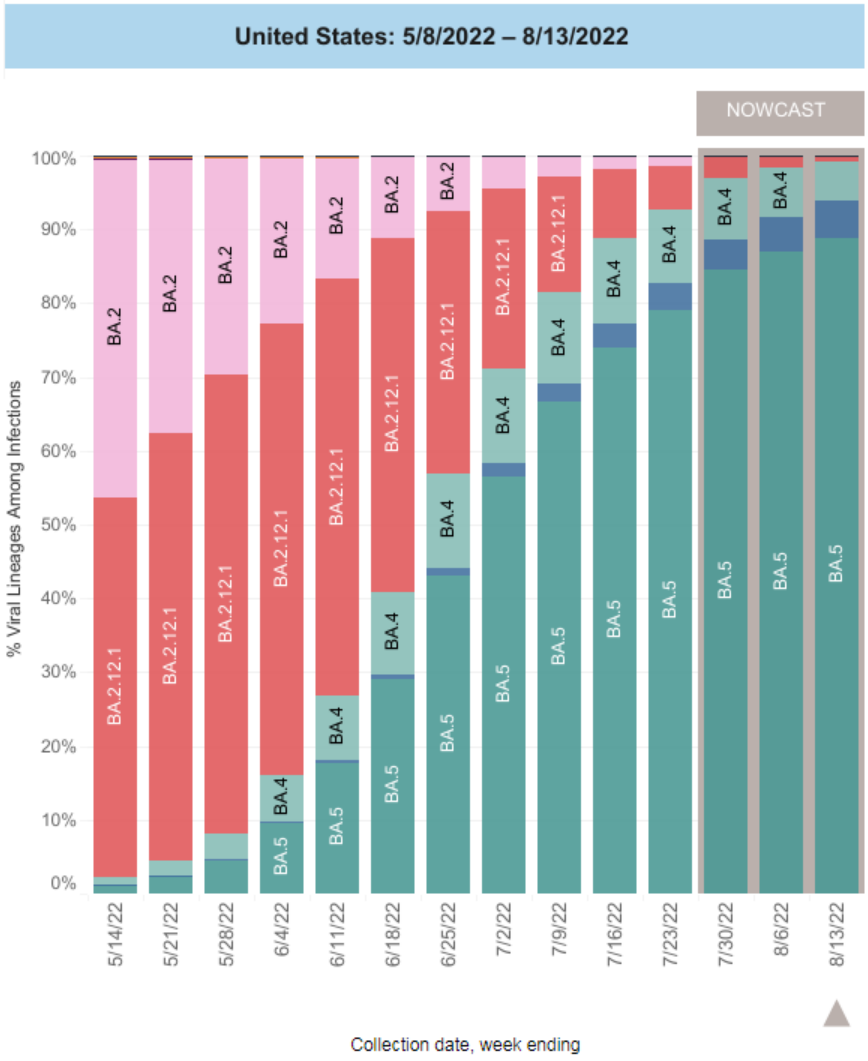
COVID19

COVID 19 – what are the trends



https://covid.cdc.gov/covid-data-tracker/#datatracker-home

COVID 19 – Circulating variants



United States: 8/7/2022 – 8/13/2022 NOWCAST

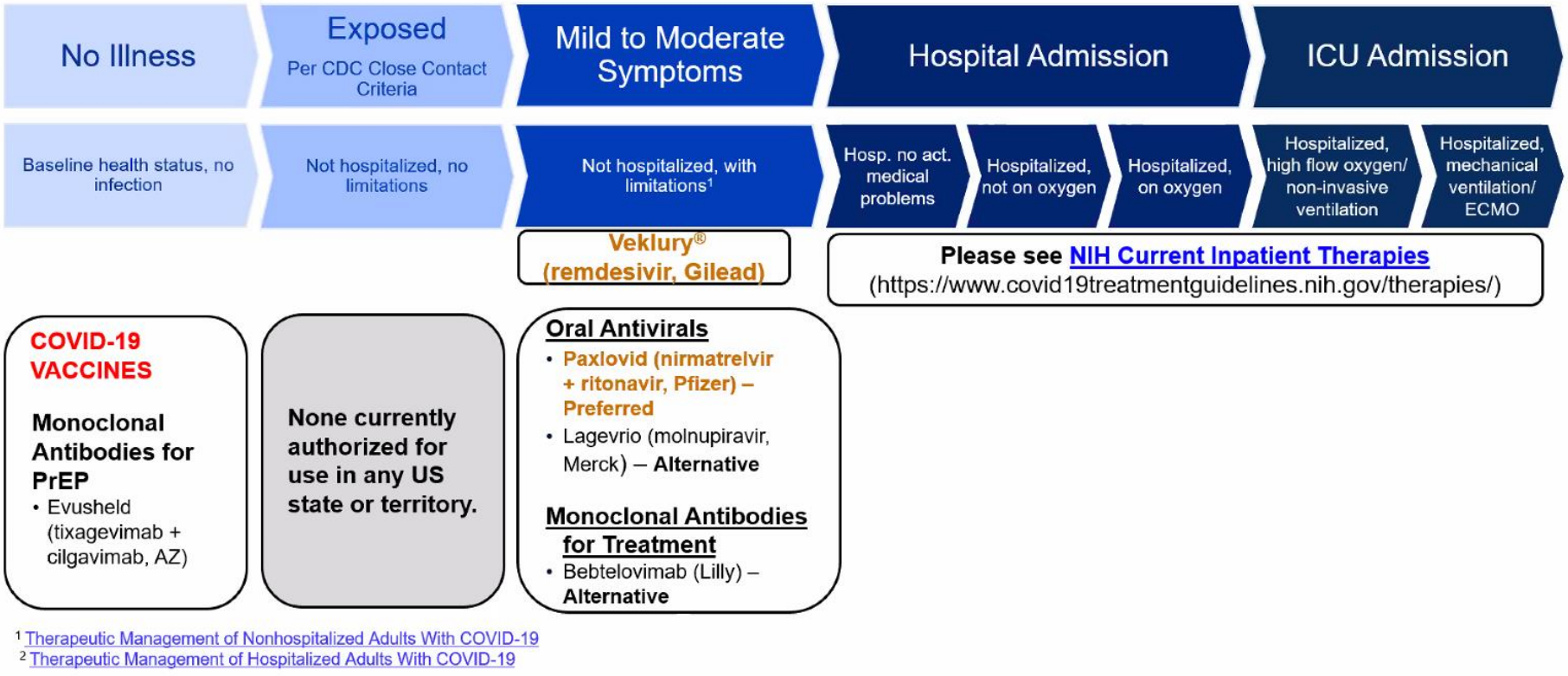
USA

WHO label	Lineage #	US Class	%Total	95%PI
Omicron	BA.5	VOC	88.8%	87.5-90.0%
	BA.4	VOC	5.3%	4.9-5.7%
	BA.4.6	VOC	5.1%	4.1-6.4%
	BA.2.12.1	VOC	0.8%	0.7-0.9%
	BA.2	VOC	0.0%	0.0-0.0%
	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. Sublineages of BA.4 are aggregated to BA.4. Sublineages of BA.5 are aggregated to BA.5.

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

Currently available treatments



[1] Therapeutic Management of Nonhospitalized Adults With COVID-19
[2] Therapeutic Management of Hospitalized Adults With COVID-19

Activity against variants

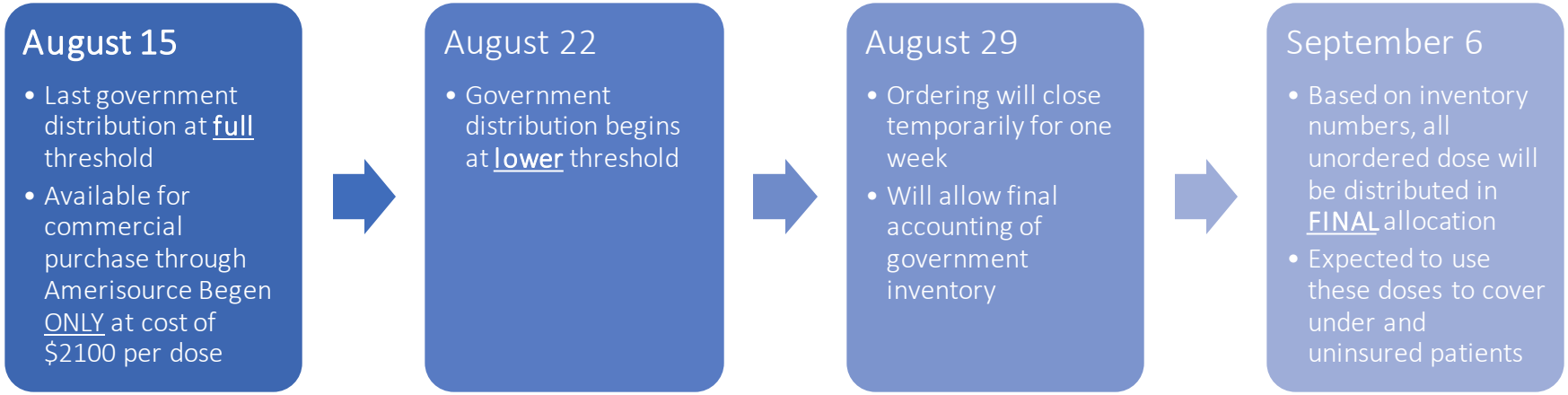
Bebtelovimab

Table 3: Authentic[a] SARS-CoV-2 Neutralization Data for Bebtelovimab

Lineage with Spike Protein Substitution	Country First Identified	WHO Nomenclature	Key Substitutions Tested[b]	Fold Reduction in Susceptibility
B.1.1.7	UK	Alpha	N501Y	No change[c]
B.1.351	South Africa	Beta	K417N, E484K, N501Y	No change[c,d]
P.1	Brazil	Gamma	K417T, E484K, N501Y	No change[c]
B.1.617.2/AY.3	India	Delta	L452R, T478K	No change[c,d]
B.1.427/B.1.429	USA (California)	Epsilon	L452R	No change[c]
B.1.526*	USA (New York)	Iota	E484K	No change[c]
B.1.1.529/BA.1	South Africa	Omicron	G339D + S371L + S373P + S375F + K417N + N440K + G446S + S477N + T478K + E484A + Q493R + G496S + Q498R + N501Y + Y505H	No change[c,d]
BA.1.1	South Africa	Omicron [+R346K]	BA.1 + R346K	No change[c]
BA.2	South Africa	Omicron [BA.2]	G339D + S371F + S373P + S375F + T376A + D405N + R408S + K417N + N440K + S477N + T478K + E484A + Q493R + Q498R + N501Y + Y505H	No change[c,d]
BA.2.12.1	USA	Omicron [BA.2+L452Q]	BA.2 + L452Q	No change[c]
BA.4	South Africa	Omicron [BA.4]	G339D + S371F + S373P + S375F + T376A + D405N + R408S + K417N + N440K + L452R + S477N + T478K + E484A + F486V + Q498R +	No change[c]

https://www.fda.gov/media/156152/download

New change: Bebtelovimab going commercial



- Medicare product reimbursement = $2,394
- Does not qualify for 340B pricing

Paxlovid – Info on rebound

- Viral and symptom rebounds can occur in both treated and untreated
- Viral load tends to be higher in paxlovid rebound patients
- Per CDC, isolation should be restarted after the onset of rebound symptoms or a positive test result
- No evidence that additional treatment is needed

https://www.nature.com/articles/d41586-022-02121-z
https://emergency.cdc.gov/han/2022/pdf/CDC_HAN_467.pdf
CDC Isolation and Precautions for people with COVID-19

Paxlovid rebound+: Stay tuned for more information

August 5, 2022: FDA creates post-authorization for Pfizer to conduct clinical trials in patients with COVID-19 rebound, evaluating:

A subsequent 5-day course in patients with rebound

Different treatment durations in immunocompromised patients

Action item: Re-dose Evusheld

- Evusheld can be given at the same dose (300 mg of tixageviman and 300 mg of cilavimab) **every 6 months**

- Repeat dosing should be timed from the date of the ***most recent**** Evusheld dose

*2/24/22 - the FDA revised Evusheld emergency use authorization (EUA) to change the initial dose for pre-exposure prophylaxis: increased the initial authorized dose from 150mg/150mg to 300 mg/300mg of tixagevimab and cilagavimab. FDA authorizes revisions to Evusheld dosing | FDA

https://www.fda.gov/media/154701/download

Monkeypox

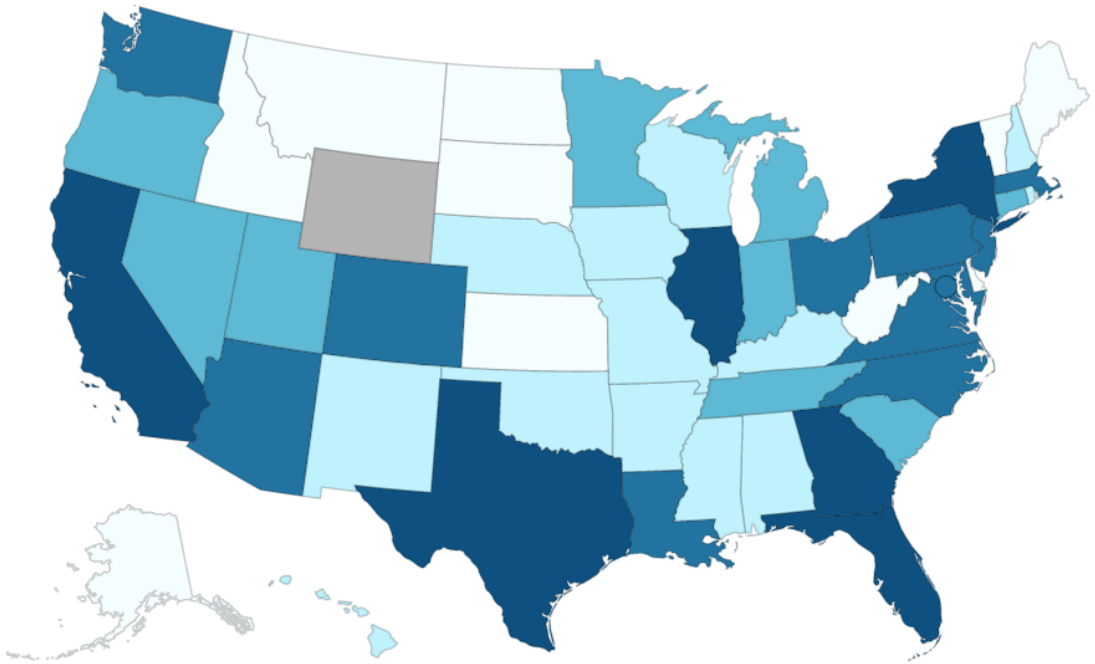
Epidemiology

"Data as of 15 Aug 2022 2:00 PM EDT"

Print

11,890 Total confirmed monkeypox/orthopoxvirus cases

*One Florida case is listed here but included in the United Kingdom case counts because the individual was tested while in the UK.



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

Vaccine Update

8/9/22: FDA Approved Intradermal Route via EUA

Table 2. Vaccination Schedule and Dosing Regimens for JYNNEOS Vaccine

JYNNEOS vaccine regimen	Route of administration	Injection volume	Recommended number of doses	Recommended interval between 1st and 2nd dose
Alternative regimen				
People age ≥18 years	ID	0.1 mL	2	28 days
Standard regimen				
People age <18 years	Subcut	0.5 mL	2	28 days
People of any age who have a history of developing keloid scars	Subcut	0.5 mL	2	28 days

JYNNEOS Vaccine | Monkeypox | Poxvirus | CDC

JYNNEOS SC and ID immunogenicity was evaluated using 4 different assays.

Immunogenicity

Assay	SC peak titer	ID peak titer	Difference	97.5% CI
SLU PRNT	8.37	8.36	0.005	0.43, 0.44
BN PRNT	5.63	5.90	-0.27	-0.77, 0.23
SLU ELISA	9.66	9.52	0.14	-0.21, 0.49
BN ELISA	9.59	9.57	0.02	-0.31, 0.35

Plaque reduction neutralizing titers (PRNT); St Louis University (SLU); Bavarian Nordic (BN) plaque reduction titers; Enzyme linked immunosorbent assay (ELISA)

https://emergency.cdc.gov/coca/calls/index.asp

Reactogenicity

Reactogenicity event	SC (%) N=166	ID (%) N=190
Feeling Tired	49.7	51.3
Muscle Aches	41.3	30.4
Headache	43.1	41.4
Nausea	21.6	23.0
Change in Appetite	15.0	20.4
Chills	12.6	14.7
Joint Pain	9.0	17.8
Pain at injection site	91.0	65.4
Erythema at injection site	81.4	99.5
Induration at injection site	69.5	99.5
Itchiness	48.5	89.0
Underarm pain	18.0	20.9
Underarm swelling	6.0	10.5

https://emergency.cdc.gov/coca/ppt/2022/081122_slides.pdf

Intradermal Information

Video on Administering JYNNEOS Intradermally

VIDEO

How to administer a JYNNEOS vaccine intradermally

Video Length: 00:00:55

Watch Video

Vaccine Prep info graphic

Patient Fact Sheet

JYNNEOS Vaccine | Monkeypox | Poxvirus | CDC

Vaccine FAQs

Q: My patient received the smallpox vaccine as a child. Should I still give JYNNEOS?

- **A** If the smallpox vaccination was given more than 3 years prior, patients should receive JYNNEOS if they meet the eligibility criteria.

Q My patient developed monkeypox infection either before they could get vaccinated or in the middle of their two-dose series. Should I give them any additional JYNNEOS doses?

- **A** The current recommendation is NO unless the patient is immunosuppressed.

Q My patient received their first dose of JYNNEOS vaccine subcutaneously. Can they get their second dose intradermally?

- **A** Yes. Administration routes are considered interchangeable.

Q My patient received their first dose of JYNNEOS vaccine more than 28 days ago. Do I need to restart their vaccine series or give extra doses?

- **A** No. The second dose should be administered as soon as possible (beyond the minimum interval of 24 days) but there is no need to restart the series or add doses of the second vaccine is given late.

Q Can pregnant or breastfeeding people receive the JYNNEOS vaccine?

- **A** While there are no data in people who are pregnant or breastfeeding, animal data do not show evidence of reproductive harm; **pregnancy and breastfeeding are not contraindications** to receiving JYNNEOS. Given concern for adverse events in pregnancy with monkeypox and risk of severe infection in neonates and infants, pregnant and breastfeeding persons who have monkeypox or have had a high-risk exposure should consider receiving JYNNEOS vaccination