

#### Main Points of Discussion

- COVID-19 in Peds
- Contact Info for CDC questions
- Further Questions on Monoclonal Antibody
- Topics for Conversation
- Questions

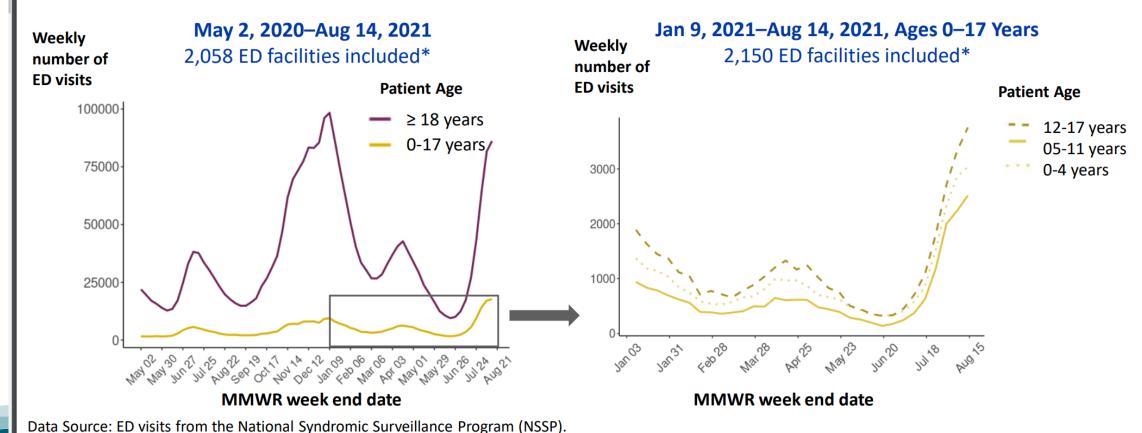


# **High-Level Summary**

- Children and adolescents are susceptible to SARS-CoV-2.
- Children tend to have fewer respiratory symptoms than adults.
- From prospective cohort and household transmission studies, infection rates are similar across age groups; children can transmit SARS-CoV-2 to others and with similar efficiency as adults.
- Children have lower rates of hospitalization and mortality compared to adults.



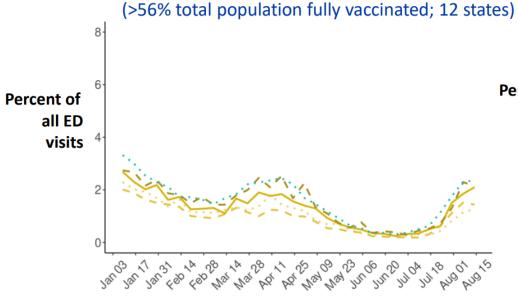
# U.S. Emergency Department (ED) Visits in Patients Diagnosed with COVID-19 by Age in a Sample of Reporting Facilities\*



<sup>\*</sup>Counts include only the subset of the 5,225 NSSP facilities with consistent reporting to NSSP and with high quality diagnosis codes throughout the time period. Fewer than 50% of facilities in California, Hawaii, Iowa, Minnesota, Oklahoma, and Ohio report to NSSP.

### U.S. Emergency Department (ED) Visits for COVID-19 in Children and Young Adults, by State Vaccination Rate; Jan 9-Aug 14, 2021

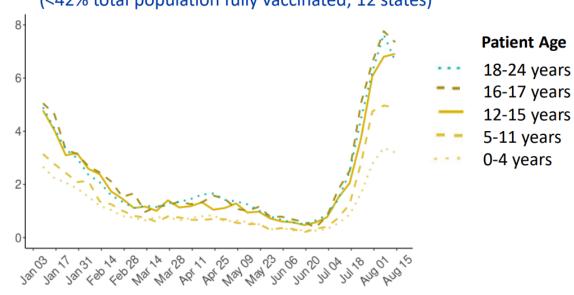
#### ED visits in quartile of states with highest vaccination rates\*



#### Percent of all ED visits

#### **ED** visits in quartile of states with <u>lowest</u> vaccination rates\*\*

(<42% total population fully vaccinated; 12 states)



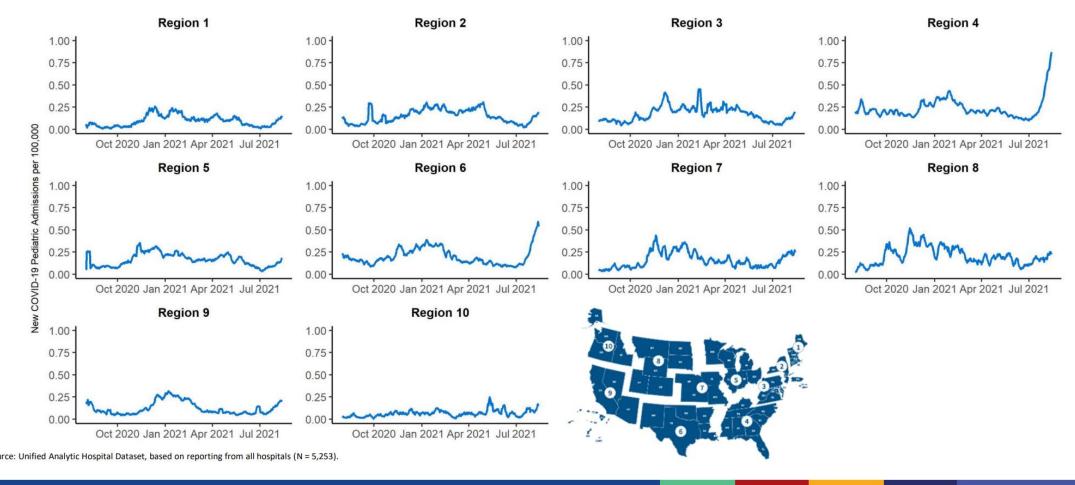
#### MMWR week end date

MMWR week end date

Data Source: ED visits from the National Syndromic Surveillance Program (NSSP). Fewer than 50% of facilities in CA, HI, IA, MN, OK, and OH report to NSSP. \* Highest vaccination states: VT, MA, ME, CT, RI, MD, NJ, NH, WA, NM, NY, OR.

\*\* Lowest vaccination states: AL, MS, WY, AR, LA, ID, GA, WV, TN, ND, OK, SC. Two states; WY and OK excluded because they did not have consistent data.

# New Admissions of Pediatric Patients with Confirmed COVID-19 per 100,000 Population, August 1, 2020–August 13, 2021, HHS Regions



# Parents Are Most Likely To Trust Pediatricians To Provide Reliable Information About The COVID-19 Vaccine For Children

Percent of parents who say trust each of the following **a great deal** or **a fair amount** to provide reliable information about the COVID-19 vaccines for children:

	Total parents	Democrats	Independents	Republicans	
Their child's pediatrician	78%	88%	82%	74%	
The CDC	66%	89%	69%	44%	
Their local public health department	62%	84%	64%	45%	
Their health insurance company**	58%	71%	60%	48%	
Their employer*	53%	65%	57%	44%	
Their child's school/daycare	44%	60%	42%	33%	
Other parents	38%	42%	40%	33%	

NOTE: \*Among those who are employed and not self-employed. \*\*Among those who are insured. See topline for full question wording.

SOURCE: KFF COVID-19 Vaccine Monitor: Parents And The Pandemic (Jul. 15-Aug. 2, 2021).

KFF COVID-19 Vaccine Monitor



# All Policy Considerations for School Plans Should Start with the Goal of Keeping Students Safe and Physically Present in School

- All students and staff who are eligible for a COVID-19 vaccine should get vaccinated.
- Families should make sure their children are up to date on all vaccines.
- All children over the age of two and all adult staff should wear face masks, regardless of whether they are vaccinated.
- Research shows if we follow public health precautions and using a multi-layer approach – getting vaccinated, universal mask use, distancing, testing, ventilation, cleaning and disinfecting – there is very low spread of COVID in schools.
- Schools should be prepared to offer resources to support student's mental health.







## **CDC-IDSA Partnership: Clinical Management Call Support**

#### FOR WHOM?

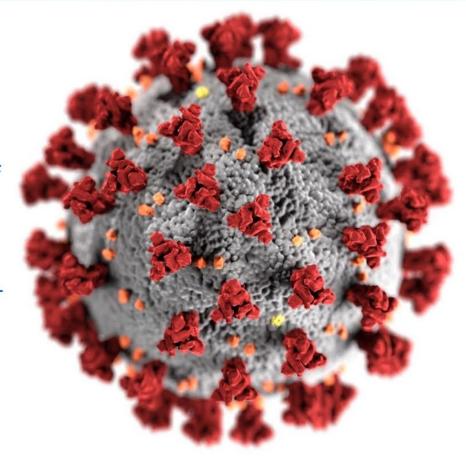
Clinicians who have questions about the clinical management of COVID-19

#### WHAT?

 Calls from clinicians will be triaged by CDC to a group of IDSA volunteer clinicians for peer-to-peer support

#### HOW?

- Clinicians may call the main CDC information line at 800-CDC-INFO (800-232-4636)
- To submit your question in writing, go to www.cdc.gov/cdc-info and click on Contact Form







cdc.gov/coronavirus

#### **COVID-19 Monoclonal Antibodies Side-By-Side**

	Casirivimab/Imde	vimab (Regeneron)	Bamlanivimab/Etesevimab (Eli Lilly & Co)			Sotrovima				
Available at UNC?	YES (p.	referred)	NO (use paused by FDA, 25 June 2021)			David Weber				
Authorized Use	Post-exposure prophylaxis in those not fully vaccinated but at high risk for progression to severe disease	Treatment of mild-moderate COVID-	oderate COVID-19 in adults and pediatrics (≥12 years, ≥40 kg) who present within <b>10 days</b> of a positive SARS-CoV-2 viral test wh <del>o are at high risk for progress</del> COVID-19  NOT authorized for inpatient <u>admitted for</u> COVID-19							
Clinical Data Updated 06/2021	Select Data from COV-2067 (Phase I  • n = 4,567 patients (3,067 CAS/IM  • Incidence of COVID-19 related he at day 29 → 3.2% PLB vs 1% CA 0.001)  • Time to syx resolution: 14 days P	ID, 1,500 PLB); tx w/in 3 days ospitalization or death from any cause AS/IMD (Δ -2.2%; RRR 0.69; p<	Select Data from BLAZE-1 (Phase III)  N = 769 patients (511 BAM/ETE, 258 PLB); tx w/in 4 days  Incidence of COVID-19 related hospitalization or death from any cause at day 29 → 6% PLB vs 0.8% BAM/ETE (Δ -5.2%; RRR 0.86; p<0.001)  COVID-19 related deaths: 4 deaths (PLB) vs 0 (p<0.01)			Select Data from COMET-ICE (Phase I/ II/ III)  • n = 583 patients (291 sotrovimab, 292 PLB); tx w/in 5 days  • Incidence of COVID-19 related hospitalization or death from any cause at day 29 → 7% PLB vs 1% CAS/IMD (Δ -6%; RRR 0.85; p< 0.01)  • COVID-19 related deaths: 1 death (PLB) vs 0 (p<0.01)				
Variant Activity	WHO Nomenclature         Lineago/Spike Substitution           Alpha         8.1.1.7           Beta         8.1.351           Gamma         P.1           Epsilon         8.1.427/8.1.429           lota         8.1.526           Kappa         8.1.617.1/8.1.617           Delta         8.1.617.2	No change No change No change No change No change	WHO Nomenclature Alpha Beta Gamma Epsilon lota Delta	Lineage/Spike Substitution  8.1.1.7  8.1.351  9.1  8.1.427/8.1.429  8.1.526  8.1.617.2	Fold Reduction in Susceptibility  No change  215  >46  9  31  No Change (ETE component only)	WHO Nomenclature Alpha Beta Gamma Epsilon lota Delta	Lineage/Spilke Substitution  8.1.1.7  8.1.351  P.1  8.1.427/8.1.429  8.1.526  8.1.617.2	Fold Reduction in Susceptibility  No change  No change  No change  NOT DETERMINED  NOT DETERMINED  NOT DETERMINED		
EUA Approved Dosing	1200 mg (600 mg CAS, 600 mg IMD) OR 1200 mg (600 mg CAS, 600 mg I Post-exp ppx only: 600 mg q4weeks	700 mg BAM IV and 1400 mg ETE IV x1 dose			500 mg sotrovimab IV x 1 dose					
Supplied As	Concentrated solution, preservative fi • <u>CAS/IMD</u> : 600 mg/600 mg (10 ml	Concentrated solution, preservative free  Bamlanivimab: 35 mg/mL (20 mL vial)  Etesevimab: 35 mg/mL (20 mL vial)			Concentrated solution, preservative free  Sotrovimab: 62.5 mg/mL (8 mL vial)					
Vial Storage	Store under refrigeration; protect from	Store under refrigeration; protect from light			Store under refrigeration; protect from light					
Preparation*	IV Prep: Dilute 10 mL co-formulated chloride SubQ prep: N/A, dilution not required	Dilute 20 mL BAM and 40 mL ETE in 100 mL 0.9% sodium chloride			Dilute 8 mL sotrovimab in 50-100 mL 0.9% sodium chloride					
IV Stability after dilution	36 hours under refrigeration 4 hours at room temperature		24 hours under refrigeration 7 hours at room temperature (includes infusion time)			24 hours under refrigeration 4 hours at room temperature (includes infusion time)				
Infusion Details*	Infusion time [IV Only]: 21 minute     Observation time [IV and SubQ]:     Equipment: infuse through in-line	Infusion time: 31 minutes     Observation time: 60 minutes     Equipment: infuse through in-line or add-on 0.2/0.22 micron filter			Infusion time: 30 minutes; flush with 9.9% NaCH to ensure delivery     Observation time: 60 minutes     Equipment: infuse through in-line or add on 9.2 micron filter					

<sup>\*</sup> Can be diluted to different final volume per EUA; preparation and administration in this chart reflects practice at UNC Health as built into the EHR (Epic)

# RCT OF BAMLANIVIMAB FOR PRE- AND POST-EX PROPHYLAXIS, NURSING HOMES & ASSISTED

- Goal: To determine the effect of bamlanivimab on the incidence of COVID-19 amongresidents and staff of skilled nursing and assisted living facilities.
- Methods: RCT, single-dose (4200 mg), phase 3 trial, of residents and staff of 74 skilled nursing and assisted living facilities in the US with at least 1 confirmed SARS-CoV-2 index case; 1175 participants enrolled 8/2 to 11/20/20
- Results: The prevention population comprised a total of 966 participants (666 staff and 300 residents) who were negative at baseline for SARS-CoV-2 infection and serology (mean age, 53.0 [range, 18-104] years; 722 [74.7%] women). Bamlanivimab significantly reduced the incidence of COVID-19 in the prevention population compared with placebo (8.5% vs 15.2%;odds ratio, 0.43 [95% CI, 0.28-0.68]; P < .001; absolute risk difference, -6.6 [95% CI, −10.7 to −2.6] percentage points). Five deaths attributed to COVID-19 were reported by day 57; all occurred in the placebo group. Rates of AEs: Bam = 20.1%, Placebo = 18.9%.
- Conclusion: Among residents and staff in skilled nursing and assisted livingfacilities, treatment during August-November 2020 with bamlanivimab monotherapy reduced the incidence of COVID-19 infection.

## Other topics for Conversation

- 3<sup>rd</sup> doses in moderate to severe immune suppression
  - Care Gaps firing in EPIC
- 3<sup>rd</sup> doses anticipated recs coming September
  - Will open vaccine clinics at Goodrich and Anaheim in September
- Flu vaccine has arrived including high dose flu vaccine
- We are making COVID-19 vaccine binders for each clinical site
- Any issues with giving COVID-19 vaccines in clinic?
- Higher demand for URI/COVID Testing
  - We will be opening testing centers, Next week Goodrich, 2 weeks Anaheim
- Questions about kids going back to school?



- CDC COCA Calls
- IDSA/Clinician Calls Every Other Week
- SHEA Weekly TownHall

# Questions?

