



**ASPR**

# **COVID-19 Monoclonal Antibody (mAb) Therapy Real-World Effectiveness and Implementation**

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# NDMS



## Nationwide Medical Response System

- Supplements state and local medical resources during declared disasters or major emergencies

## Key functions

- Medical response (medical, veterinary, fatality)
- Aeromedical evacuation



# mAb Infusion Field Site Locations



**El Centro Regional Medical Center**  
El Centro, CA



**TMC HealthCare**  
Tucson, AZ



**Sunrise Hospital and Medical Center**  
Las Vegas, NV

# ASPR/NDMS Field mAb Efforts

- Implementation of COVID-19 monoclonal antibody therapy (mAbs) at three US medical centers
- Real-world effectiveness evaluation of COVID-19 mAbs
- Infusion Capacity Calculator (*coming soon*)

# Eligibility Criteria

- Laboratory-confirmed COVID-19
- Within 10 days of symptom onset
- $\geq 12$  years of age & weight  $\geq 40$  kilograms

# Eligibility Criteria

## Plus, at least one of the following:

- Body mass index  $\geq 35$
- Chronic kidney disease
- Diabetes mellitus
- Immunosuppression
- $\geq 65$  years of age
- $\geq 55$  years of age AND  
Cardiovascular disease, hypertension, or chronic obstructive pulmonary disease / respiratory disease
- 12 – 17 years of age AND  
High BMI, heart disease, neurodevelopment or medical equipment dependence, or chronic lung disease

# mAb Effectiveness Evaluation

- **Objective:** Quantify the effect of mAb treatment on COVID-19
- **Design:** Retrospective cohort analysis at Tucson Medical Center in Tucson, Arizona, supported by ASPR/NDMS
  - Poverty rate 23%; median household income 69% national average
- **Approach:** Electronic medical record review February 2021

# Definitions

- **Controls (untreated):** (+) patients 7/1/20 – 12/20/20, screened retrospectively for eligibility
- **Cases (treated):** bamlanivimab monotherapy at infusion site 1/7/21 – 1/15/21
- **Outcome:** COVID-19-related ED visit or hospitalization following (+) SARS-CoV-2 result within 30 days



# Results

- 875 (+) patients 7/1/20 – 12/20/20, prior to mAb availability
  - 547 (63%) ineligible
  - 328 (37%) eligible but untreated (**controls**)
- 270 eligible and treated patients 1/7/21 – 1/15/21 (**cases**)
- 598 mAb-eligible COVID+ patients (**the cohort**)
  - 61% female; 10% non-White; 39% Hispanic ( $p > .05$ )
  - 53% > 65 years (untreated patients 3 y younger)

# Baseline Risk Factors

Risk Factor	Untreated (N = 328)	Treated (N = 270)	P-value
Hypertension	53.7%	20.4%	<0.01
Cardiovascular Disease	21.6%	7.4%	<0.01
BMI $\geq$ 35	10.7%	4.1%	<0.01

# Unadjusted Results

- ED visits or hospitalization within 30 days
  - Untreated 39/328 (11.9%)
  - Treated 5/270 (1.9%)
  - $p < 0.01$
- No adverse events

# Adjusted Results (Logistic Regression)

- Treatment effect: aOR 0.18 (0.06, 0.44)
  - 82% risk reduction (56%, 94%)
- BMI  $\geq$  35: aOR 6.44 (2.48, 16.71)

# mAb Effectiveness Conclusions

- Single infusion of bamlanivimab effective at decreasing hospital presentation by 80%
- BMI  $\geq 35$  remained significant in adjusted models (aOR = 6.44)
- Treated patients had fewer co-morbidities, suggesting potential healthcare access differences

# mAb Implementation Conclusions

- mAb infusion site processes can be implemented with limited staff and physical resources
  - Require one nurse or other medical provider per 5 patients
- Sites most effective when integrated into pre-existing infrastructure
  - Effective model depends upon local community
- EUAs shape implementation requirements and therapy uptake

# Infusion Capacity Calculator

- In development
- Combines results from effectiveness and implementation studies
- Allows users to estimate infusion capacity based on available materiel (e.g., infusion beds and bays) and personnel (e.g., nurses)

# Monoclonal Antibody Infusion Throughput Calculator

This tool can be used estimate the operational capacity of an infusion center to provide monoclonal antibody therapy for patients with COVID-19.

Users provide inputs for the number of infusion beds, number of staff, scheduling policies, and expectations for number of patients.

Selected inputs are matched to scenarios for which treatment times and the numbers of patients able to be treated have been estimated. The outputs provided can provide insight into the staffing and space requirements needed to treat expected patient populations of different sizes.

Enter inputs for nurse and clinical support staff who will work in the infusion center. These two roles are primary drivers of the capacity of an infusion center. Other roles, such as physicians, pharmacists, registration, testing, and referral may be needed to implement an infusion center, but are not listed as inputs for this tool.

## Physical Capacity

How many infusion beds or bays will be operational? ⓘ

15

## Process

Will infusion appointments be scheduled or walk-in? ⓘ

Scheduled

On a typical day, how many hours will the infusion center be open? ⓘ

12

On a typical day, what is the expected patient demand? ⓘ

30

## Check-in

How many clinical staff will support the check-in process (including checking vital signs and confirming patient eligibility for infusion)? ⓘ

2

## Infusion

How many nurses (RNs) will support the infusion process? ⓘ

3

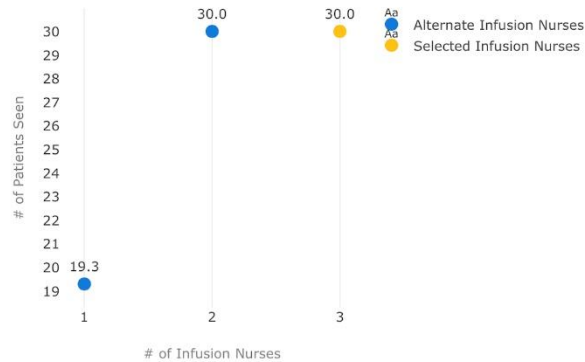
How many non-nurse clinical staff (e.g paramedics) will support the infusion process? ⓘ

0

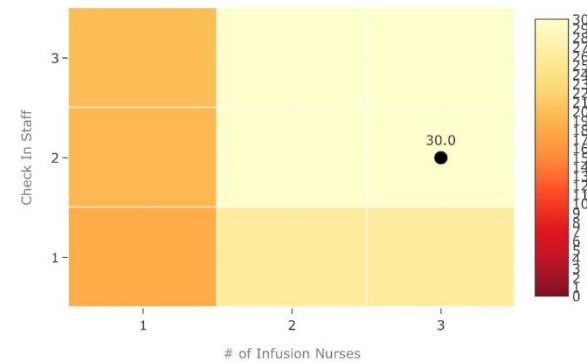


<b>Number of patients seen during infusion center hours:</b>	<b>30.0</b>	
<b>Average patient time (hours) for an infusion appointment to be completed (check-in to departure):</b>	Avg. Time	95% CI
	<b>2.82</b>	<b>( 2.81, 2.84 )</b>
Percent of infusions completed within 3 hours:	70.1874%	
Percent of infusions completed within 4 hours:	97.431%	
Percent of expected patients able to be seen by end of day:	100.0%	

Expected Patients vs Infusion Nurses



Patients Seen based on Check In Staff vs # of Infusion Nurses



X-Axis Field  
# of Infusion Nurses

Y-Axis Field  
Check In Staff

# mAb Manuscript Pre-Prints

## Real-world Effect of Monoclonal Antibody Treatment in COVID-19 Patients in a Diverse Population in the United States

## Implementation of SARS-CoV-2 monoclonal antibody infusion sites at three medical centers in the United States: Strengths and challenges assessment to inform COVID-19 pandemic and future public health emergency use

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### Real-world Effect of Monoclonal Antibody Treatment in COVID-19 Patients in a Diverse Population in the United States

© Kaitlin Rainwater-Lovett, John T. Redd, Miles A. Stewart, Natalia Elias Calles, Tyler Cuff, Mike Fang, Mark J. Pangiglo, Anastasia S. Lambrou, Jonathan K. Thornhill, Christopher Bradburne, Samuel Imbriciale, Jeffrey D. Freeman, Michael Anderson, Robert Kadlec  
doi: <https://doi.org/10.1101/2021.04.08.21254705>

This article is a preprint and has not been certified by peer review [what does this mean?]. It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice.

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#### ABSTRACT

**Background** Monoclonal antibodies (mAbs) against SARS-CoV-2 are a promising treatment for limiting the progression of COVID-19 and decreasing strain on hospitals. Their use, however, remains limited, particularly in disadvantaged populations.

**Methods** Electronic health records were reviewed from SARS-CoV-2 patients at a single medical center in the United States that initiated mAb infusions in January 2021 with the support of the U.S. Department of Health and Human Services' National Disaster Medical System. Patients who received mAbs were compared to untreated patients from the time period before mAb availability who met eligibility criteria for mAb treatment. We used logistic regression to measure the effect of mAb treatment on the risk of hospitalization or emergency department (E.D.) visit within 30 days of laboratory-confirmed COVID-19.

**Results** Of 598 COVID-19 patients, 270 (45%) received bamlanivimab and 328 (55%) were untreated. Two hundred and thirty-one patients (39%) were Hispanic. Among treated patients, 5/270 (1.9%) presented to the E.D. or required hospitalization within 30 days of a positive SARS-CoV-2 test, compared to 39/328 (12%) untreated patients (p<0.001). After

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### Implementation of SARS-CoV-2 monoclonal antibody infusion sites at three medical centers in the United States: Strengths and challenges assessment to inform COVID-19 pandemic and future public health emergency use

© Anastasia S. Lambrou, John T. Redd, Miles A. Stewart, Kaitlin Rainwater-Lovett, Jonathan K. Thornhill, Lynn Hayes, Gina Smith, George M. Thorp, Christian Tomaszewski, Adolphe Edward, Natalia Elias Calles, Mark Amox, Steven Plerta, Tiffany Plurdi, Victoria Callahan, Adam Tewell, Helga Scharf-Bell, Samuel Imbriciale, Jeffrey D. Freeman, Michael Anderson, Robert P. Kadlec  
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#### ABSTRACT

**Background** The COVID-19 pandemic caught the globe unprepared without targeted medical countermeasures, such as therapeutics, to target the emerging SARS-CoV-2 virus. However, in recent months multiple monoclonal antibody therapeutics to treat COVID-19 have been authorized by the U.S. Food and Drug Administration (FDA) under Emergency Use Authorization (EUA). Despite these authorizations and promising clinical trial efficacy results, monoclonal antibody therapies are currently underutilized as a treatment for COVID-19 across the U.S. Many barriers exist when deploying a new infused therapeutic during an ongoing pandemic with limited resources and staffing, and it is critical to better understand the process and site requirements of incorporating monoclonal antibody infusions into pandemic response activities.

**Methods** We examined the monoclonal antibody infusion site process components, resources, and requirements during the COVID-19 pandemic using data from three initial infusion sites at medical centers in the U.S. supported by the National Disaster Medical

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