COVID-19 Impact: Monoclonal Antibody Use in PALTC

This meeting will be recorded and will be available at www.fmda.org/journalclub.php

FMDA Journal Club

February 24, 2021
Corinne Bishop, RN, CRRN, CRNI; Christopher Lemelle, MD, MBA – Special Guests
Diane Sanders-Cepeda, DO, CMD – Host

Agenda

- COVID-19 State of the State
- Monoclonal Antibody Use in PALTC
- Open Discussion


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Home
Tracking
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By Region
Events & News
About
Tracking Home
Critical Trends
Global Map
U.S. Map
Data in Motion
COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)
Global Cases
112,229,910
Cases by Country/Region/Sovereignty
28,261,979 US
11,030,176 India
10,257,875 Brazil
4,153,735 Russia
4,146,756 United Kingdom
3,689,534 France
3,161,432 Spain
2,832,162 Italy
2,655,633 Turkey
2,410,409 Germany
2,233,589 Colombia
2,077,228 Argentina
2,052,266 Mexico
1,661,109 Poland
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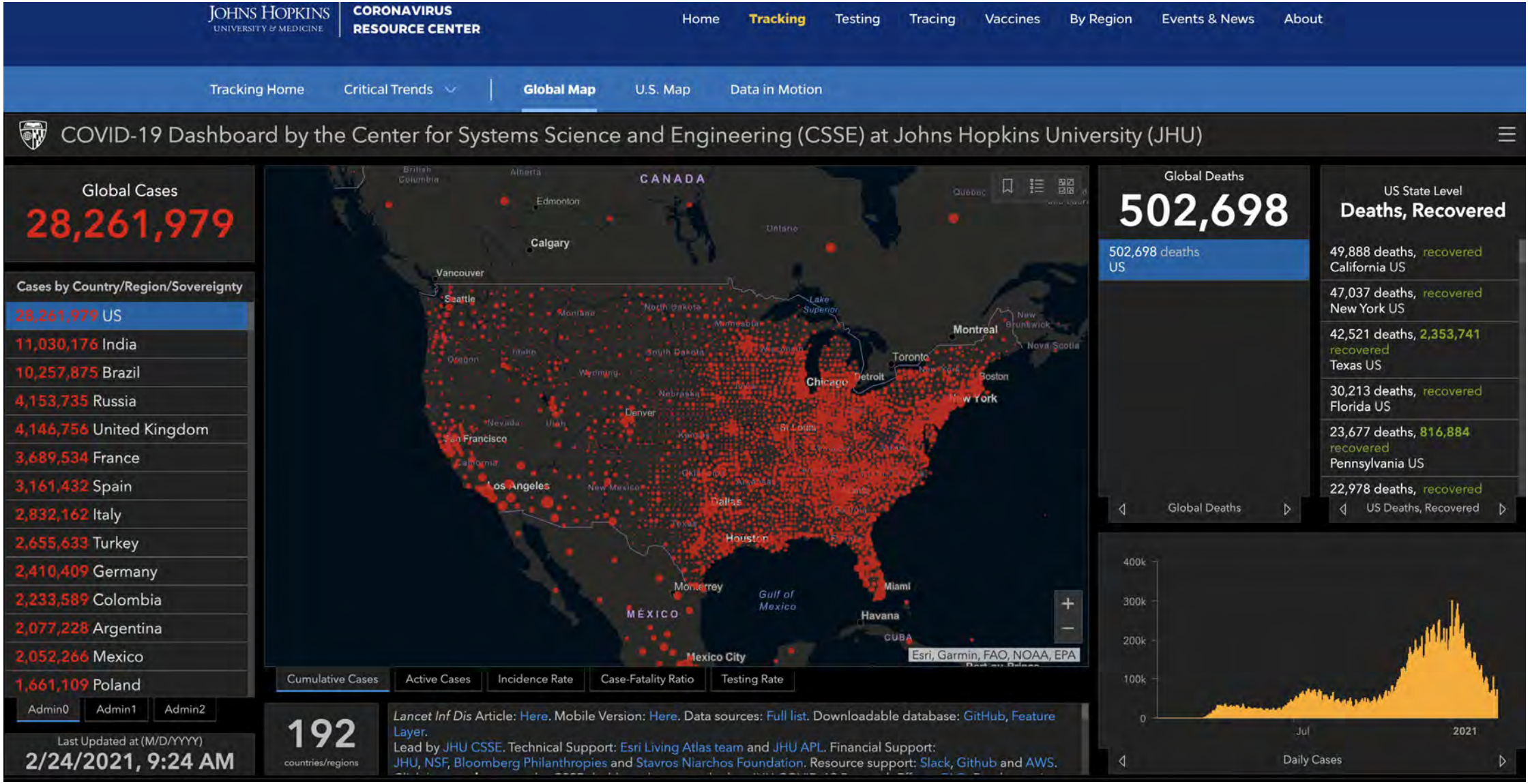
NORTH AMERICA
EUROPE
ASIA
AFRICA
SOUTH AMERICA
AUSTRALIA
North Pacific Ocean
North Atlantic Ocean
South Pacific Ocean
South Atlantic Ocean
Indian Ocean
Esri, FAO, NOAA
Cumulative Cases
Active Cases
Incidence Rate
Case-Fatality Ratio
Testing Rate
192
countries/regions
Lancet Inf Dis Article: Here. Mobile Version: Here. Data sources: Full list. Downloadable database: GitHub, Feature Layer.
Lead by JHU CSSE. Technical Support: Esri Living Atlas team and JHU APL. Financial Support:
JHU, NSF, Bloomberg Philanthropies and Stavros Niarchos Foundation. Resource support: Slack, Github and AWS.
Global Deaths
2,487,890
502,698 deaths US
248,529 deaths Brazil
181,809 deaths Mexico
156,567 deaths India
121,536 deaths United Kingdom
96,348 deaths Italy
Global Deaths
US State Level
Deaths, Recovered
49,888 deaths, recovered California US
47,037 deaths, recovered New York US
42,521 deaths, 2,353,741 recovered Texas US
30,213 deaths, recovered Florida US
23,677 deaths, 816,884 recovered Pennsylvania US
22,978 deaths, recovered
US Deaths, Recovered
2M
1.5M
1M
500k
0
Jul
2021
Daily Cases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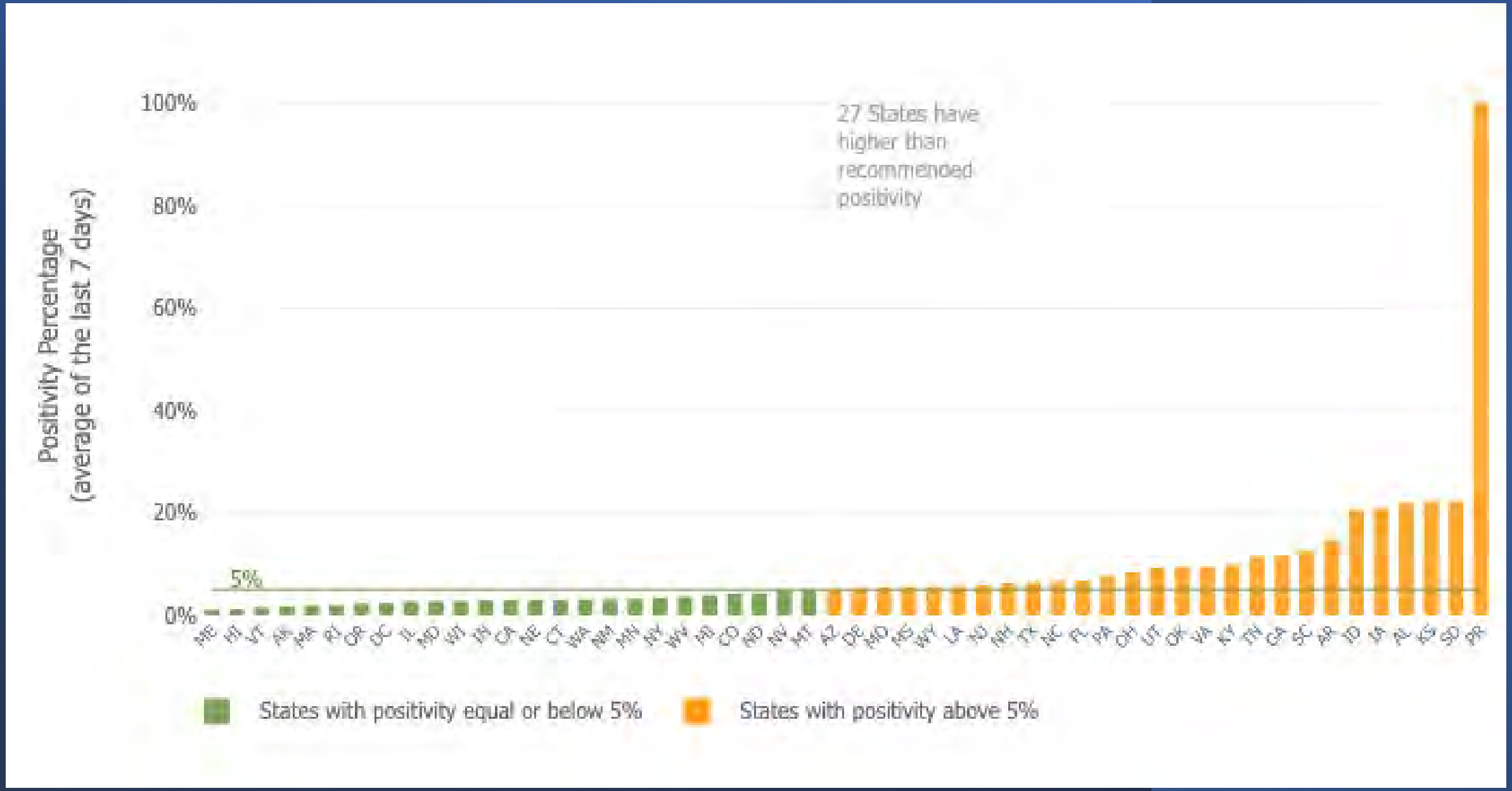

Positivity Percentage
(average of the last 7 days)
100%
80%
60%
40%
20%
0%
5%
27 States have higher than recommended positivity
States with positivity equal or below 5%
States with positivity above 5%

Florida's COVID-19 Data and Surveillance Dashboard

Florida Department of Health, Division of Disease Control and Health Protection

Select a County: STATE

Total Cases
1,878,533

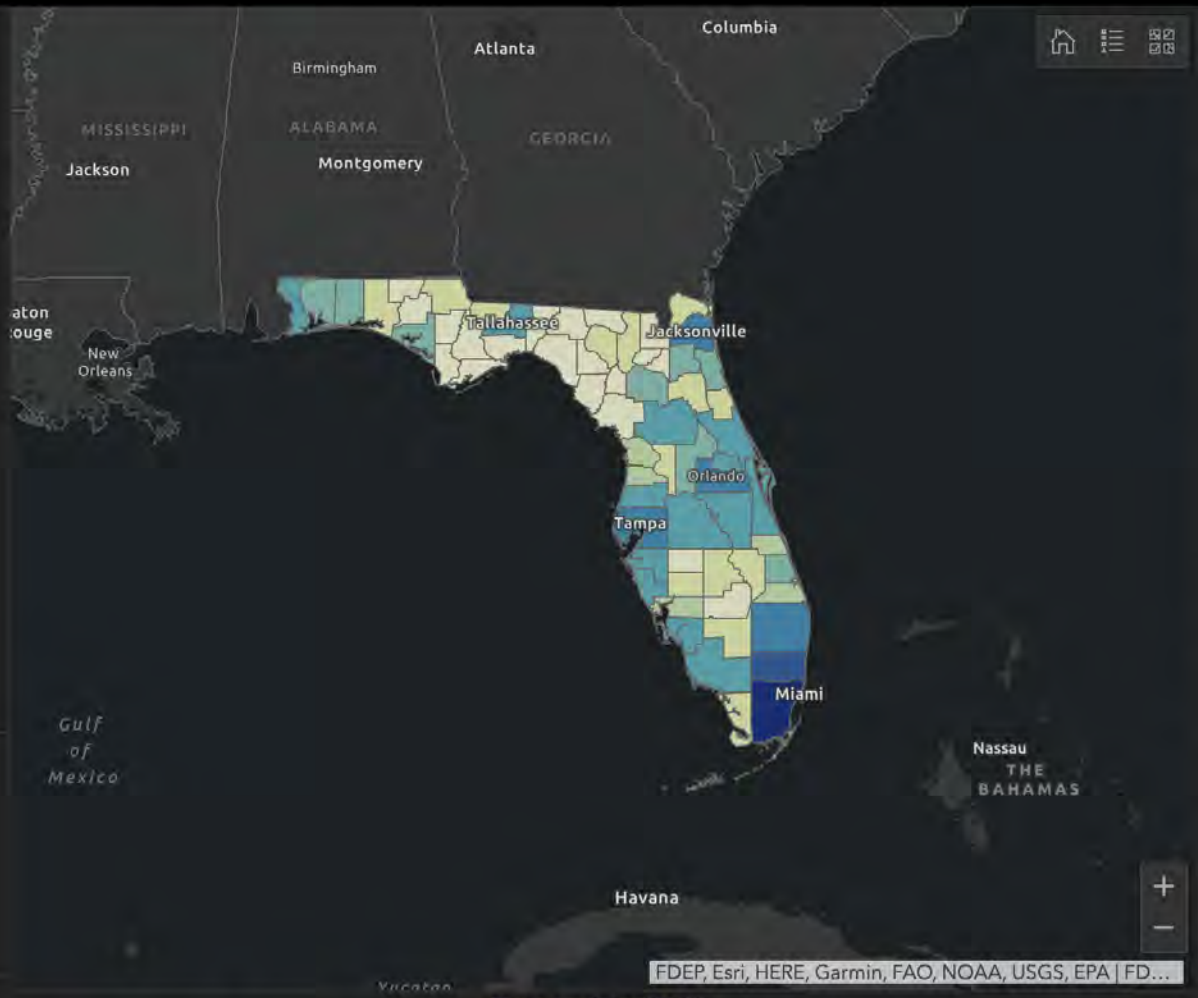
Cumulative Data for Florida Residents:

Positive Residents
1,844,228

Resident Hospitalizations
78,212

Florida Resident Deaths
30,213

Non-Resident Deaths
536



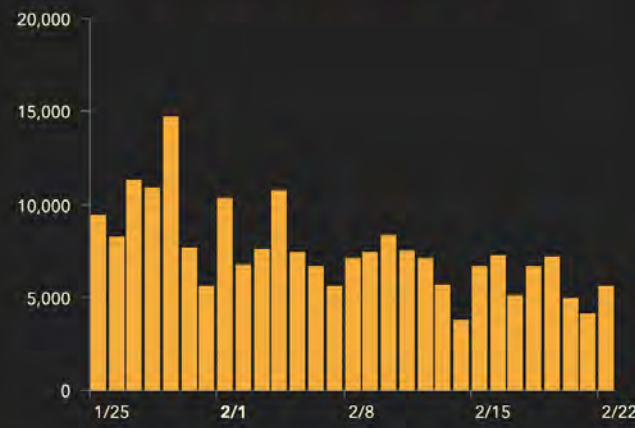
Data updated Daily

Comparison of counties is not possible because case data are not adjusted by population.

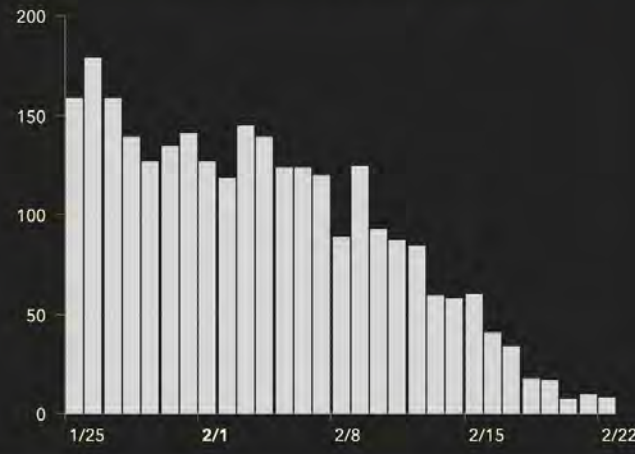
Click here to access and download data

Recent Data for Florida Residents (Last 30 Days):

New Cases of Residents by Day



Resident Deaths by Date of Death



The Deaths by Day chart shows the total number of Florida residents with confirmed COVID-19 that died on each calendar day (12:00 AM - 11:59 PM). Death data often has significant delays in reporting, so data within the past two weeks will be updated

Monoclonal Antibody Use in PALTC

Christopher Lemelle, MD, MBA
Strategy and Clinical Innovation, CVS/Omnicare

Corinne Bishop, RN, CRRN, CRNI
Infusion Nurse Specialist, Omnicare Pharmacy Services

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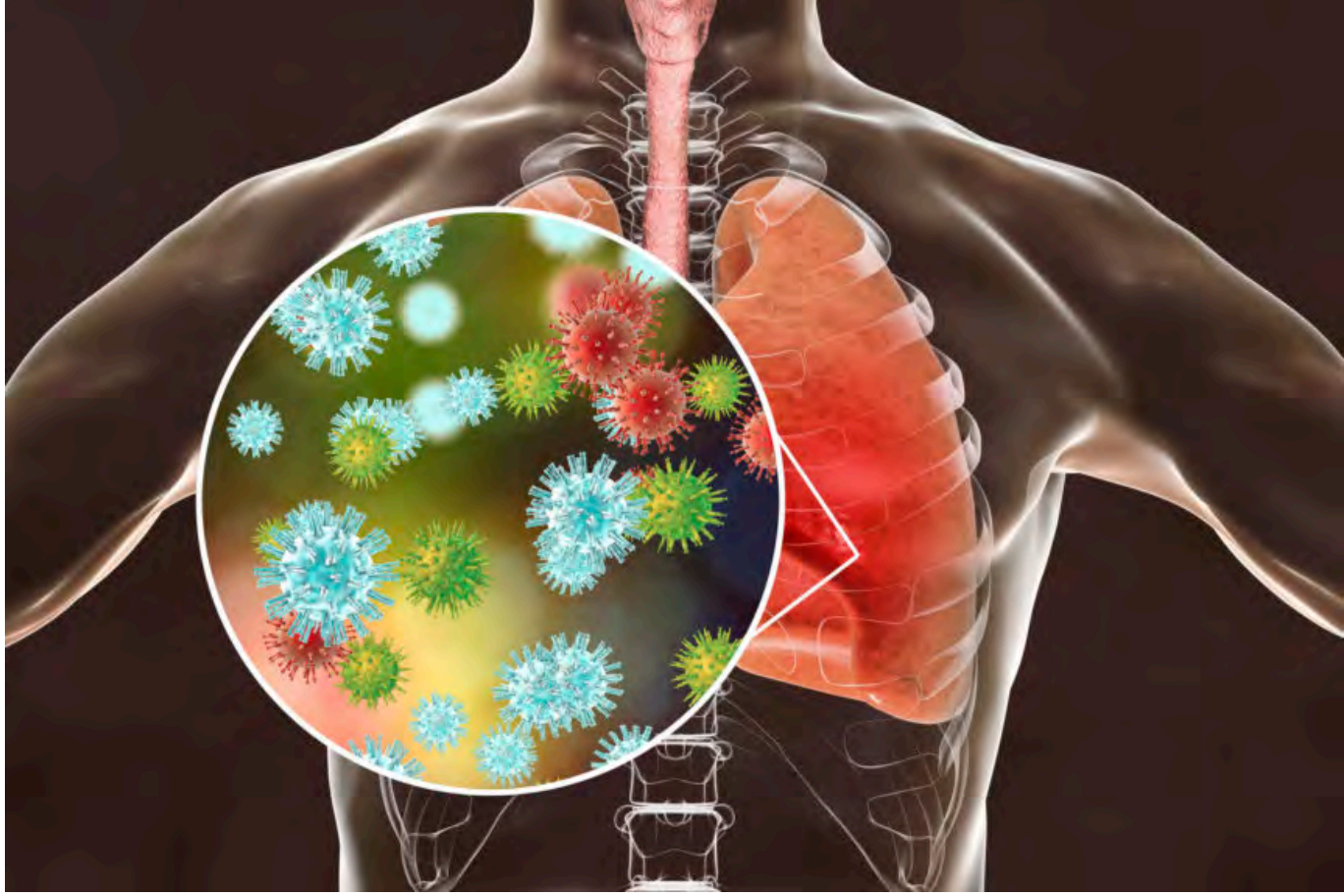

Monoclonal Antibody Update

Today's Objectives

I. Review current perspective and current research related to the use of Monoclonal antibodies

II. Discuss operational considerations when starting this treatment program in PALTC facilities

III. Describe the challenges and opportunities seen statewide and nationally with the delivery of this treatment in PALTC facilities

IV. Open Discussion

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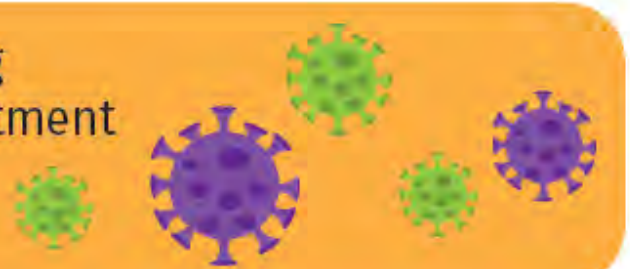
What are **MONOCLONAL ANTIBODIES?**

Monoclonal antibodies **(mAbs)** are antibodies developed in a laboratory to help our bodies fight infection.

Nearly **100** mAbs are FDA approved to treat health conditions including cancers and autoimmune diseases.

mAbs are also being studied for the treatment and prevention of COVID-19.



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Current COVID monoclonal antibody research is spares and largely focuses on Bamlanivimab +/- Etesevimab

The Blaze studies are a progressive series of studies with the latest, Blaze-4, focused on comparing efficacy of mono, combination, or placebo in patients diagnosed with mild to moderate SARS-CoV-2.

Blaze 4 Summary

Design: Randomized, placebo-controlled phase 2/3 trial at 49 US centers and 577 patients

Interventions: Bamlanivimab, Bamlanivimab + Etesevimab, or placebo IV infusions

Outcomes Measured:
Main- Viral load change at day 11
Secondary- Symptoms, need for hospital assessment, or death

Conclusions:
Main- Statistically significant reduction in viral load for combination (not for solo and placebo)
Secondary- Hospital readmission for placebo 5.8% vs average 1.5% in treated groups
Only 9 mild reactions and no deaths.

Source: https://jamanetwork.com/journals/jama/fullarticle/2775647

Operational Considerations

Monoclonal Antibody Allocation
Federal SPEED Program through ASCP

SPEED – Special Projects for Equitable and Efficient Distribution for the allocation of monoclonal antibodies

Direct allocation to long-term care pharmacies

Partners: American Society of Consultant Pharmacists and AMDA-The Society for Post-Acute and Long-Term Care Medicine

- Website: https://www.ascp.com/page/mab

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Bamlanivimab and Casirivimab/Imdevimab– Emergency Use Authorization (EUA)

- Patients categorizing as high risk must have at least one of the following criteria:
  - Body mass index (BMI) ≥ 35
  - Chronic kidney disease
  - Diabetes
  - Immunosuppressive disease
  - Currently receiving immunosuppressive treatment
  - Are ≥ 65 years of age

- Are ≥ 55 years of age AND have
  - Cardiovascular disease OR
  - Hypertension OR
  - Chronic obstructive pulmonary disease/other chronic respiratory disease

Emergency Use Authorization (EUA)- Patient Criteria

- Are 12 – 17 years of age **AND** have
  - BMI ≥ 85th percentile for their age and gender based on CDC growth charts
  - Sickle cell disease
  - Congenital or acquired heart disease
  - Neurodevelopmental disorders, for example, cerebral palsy
  - A medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)
  - Asthma, reactive airway or other chronic respiratory disease that requires daily medication for control

Monoclonal Antibody – **Restrictions**

- Monoclonal antibodies are **not** authorized for use in patients:
  - Who are hospitalized due to COVID-19
  - Who require oxygen therapy due to COVID-19
  - Oxygen dependent patients who require an increase in oxygen flow rate due to COVID-19 complications

Monoclonal Antibody and COVID-19 Vaccines

- If the patient has received monoclonal antibodies, they should not receive the COVID-19 vaccine for 90 days

- If the patient has received the COVID-19 vaccine(s) and subsequently tests positive for COVID-19, they can receive monoclonal antibodies

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-manufacturer%2Fpfizer%2Fclinical-considerations.html

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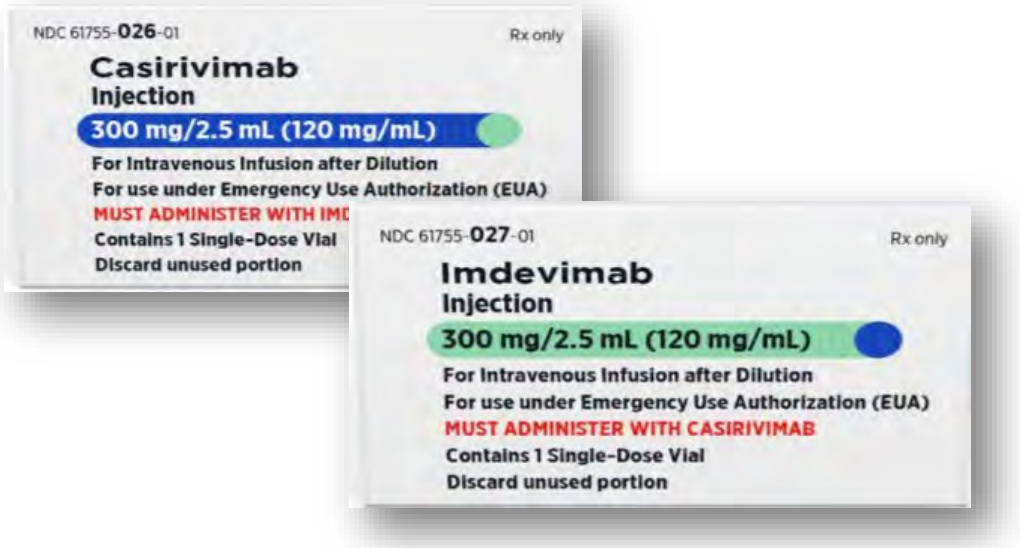
Bamlanivimab (Lilly)

Dose - 700 mg given as a one-time infusion
* EUA change : 100 ml/over 30 minutes

Casirivimab/Imdevimab (Regeneron)

Dose - 1200 mg of Casirivimab with 1200mg of Imdevimab combined in one infusion bag given as a one time infusion over a minimum of 60 minutes.

Monoclonal Antibodies should be administered as soon as possible after a positive COVID-19 test, and within 10 days of symptom onset



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Bamlanivimab and Etesevimab Combination

Emergency Use Authorization (EUA)

The authorized dosage is 700 mg bamlanivimab and 1,400 mg of etesevimab administered together as a single intravenous (IV) infusion as soon as possible after positive viral test for SARS-CoV-2 and within ten days of symptom onset.

Per the FDA: ***Lilly and authorized distributor(s) will ensure that the authorized bamlanivimab and etesevimab are distributed, as directed by the U.S. government***

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Bamlanivimab -Updated EUA

- Updated Patient Friendly Guide
- Updated HCP EUA - Mixing

100 mL NS to infuse over 30 minutes.

Rationale :

1. Concerns with a rapid infusion using the 16 minutes, as the nursing staff is more accustomed to infusing at a minimum of 30 minutes.
2. Using 30 minutes would require VS at the 1/2 point to identify potential infusion reactions before the entire dose is infused
3. If mixed in 50 ml and they fail to infuse the chaser bag the patient would lose 50 % of the dose .

Clinical and Operational Considerations

- ✓ Anaphylaxis Treatment
- ✓ Nursing Time- IV Access and Monitoring
- ✓ Exclusion Criteria
- ✓ Vaccination Timing
- ✓ Order Toolkit

This program has specific requirements which are largely constrained by facility labor capacity and capability, as well as provider hesitancy.

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Monoclonal Antibody – IV Access, Anaphylaxis and Infusion-Related Reactions

- Ensure peripheral **IV before ordering**
- There is a potential for serious hypersensitivity reaction, including anaphylaxis, with administration of monoclonal antibodies
- Anaphylaxis and infusion-related reaction orders must be obtained prior to infusion
- Anaphylaxis kit/medications must be readily available and will be supplied by the pharmacy
- If an infusion-related reaction occurs, consider slowing or stopping the infusion and administer appropriate medications and/or supportive care per prescriber's orders

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Monoclonal Antibody – Monitoring

- Monitor patient during administration and for at least one hour post infusion. Signs and symptoms of infusion-related reactions may include:
  - Fever
  - Chills
  - Nausea
  - Headache
  - Bronchospasm
  - Hypotension/ Hypertension
  - Angioedema
  - Throat irritation
  - Rash including urticarial
  - Pruritus
  - Myalgia
  - Dizziness
  - Diaphoresis
  - Difficulty breathing
  - Reduced oxygen saturation
  - Fatigue/weakness
  - Arrhythmia (e.g., atrial fib, sinus tachycardia, bradycardia)
  - Chest pain or discomfort
  - Altered mental status
- Monitor vital signs:
  - Prior to initiating infusion
  - Every 15 minutes during infusion
  - Every 15 minutes for one hour post infusion
- Resume COVID monitoring per facility protocol

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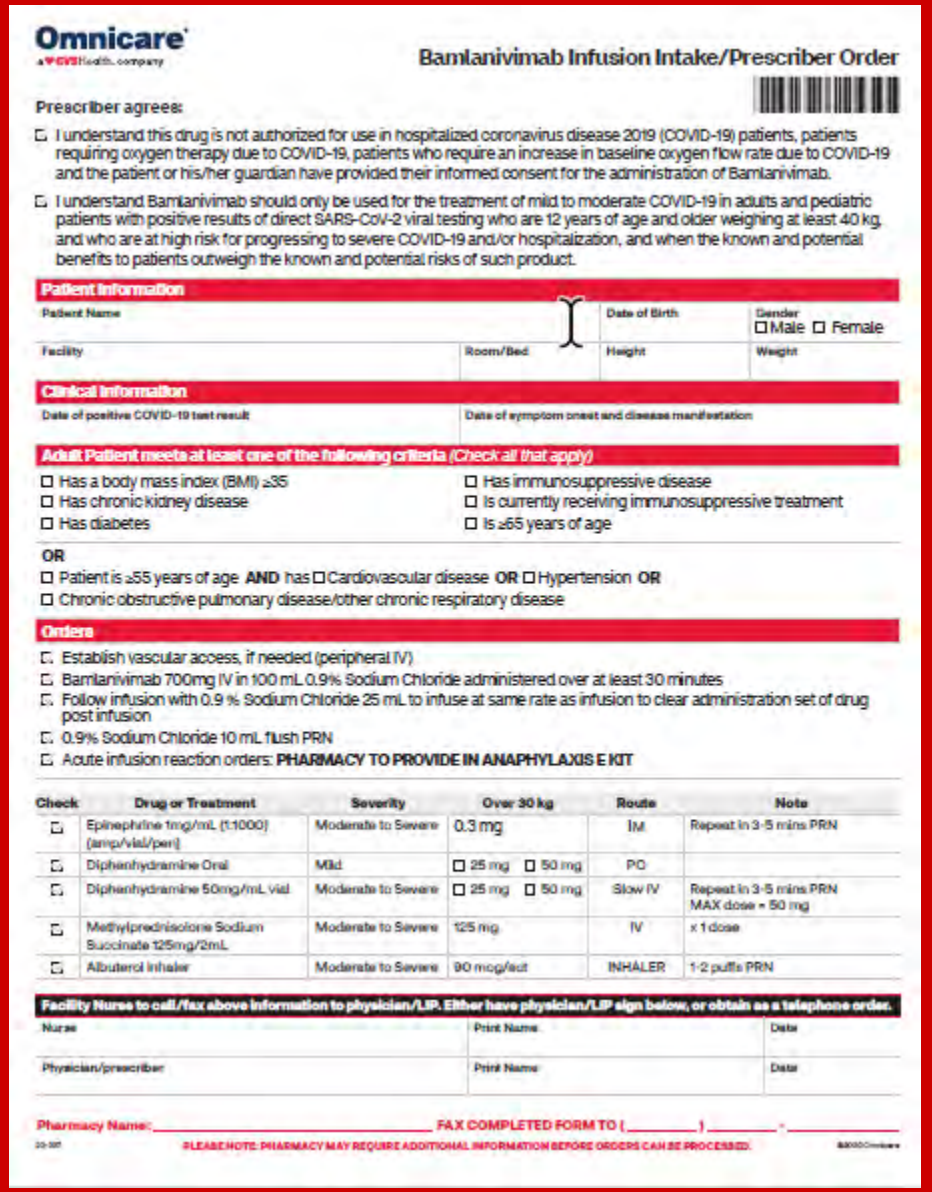
Monoclonal Antibody Tool Kit

- Monoclonal Administration Algorithm
- Intake Prescriber Order Form
- Nursing Care Plan
- Sample Consent Form
- Administration Flowsheet
- Facility Preparation Checklist
- Administration Procedure
- Skills Competency Checklist
- EUA Patient Fact Sheet
- EUA HCP Fact Sheet

*****Operation WARP SPEED *****



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Bamlanivimab Infusion Intake/Prescriber Order

Prescriber agrees:

☐ I understand this drug is not authorized for use in hospitalized coronavirus disease 2019 (COVID-19) patients, patients requiring oxygen therapy due to COVID-19, patients who require an increase in baseline oxygen flow rate due to COVID-19 and the patient or his/her guardian have provided their informed consent for the administration of Bamlanivimab.

☐ I understand Bamlanivimab should only be used for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization, and when the known and potential benefits to patients outweigh the known and potential risks of such product.

Patient Information

Patient Name		Date of Birth	Gender ☐ Male ☐ Female
Facility	Room/Bed	Height	Weight

Clinical Information

Date of positive COVID-19 test result	Date of symptom onset and disease manifestation

Adult Patient meets at least one of the following criteria (Check all that apply)

☐ Has a body mass index (BMI) ≥35
☐ Has chronic kidney disease
☐ Has diabetes
☐ Has immunosuppressive disease
☐ Is currently receiving immunosuppressive treatment
☐ Is ≥65 years of age

OR

☐ Patient is ≥55 years of age **AND** has ☐ Cardiovascular disease **OR** ☐ Hypertension **OR**
☐ Chronic obstructive pulmonary disease/other chronic respiratory disease

Orders

☐ Establish vascular access, if needed (peripheral IV)
☐ Bamlanivimab 700mg IV in 100 mL 0.9% Sodium Chloride administered over at least 30 minutes
☐ Follow infusion with 0.9 % Sodium Chloride 25 mL to infuse at same rate as infusion to clear administration set of drug post infusion
☐ 0.9% Sodium Chloride 10 mL flush PRN
☐ Acute infusion reaction orders: **PHARMACY TO PROVIDE IN ANAPHYLAXIS E KIT**

Check	Drug or Treatment	Severity	Over 30 kg	Route	Note
☐	Epinephrine 1mg/mL (1:1000) (amp/vial/pen)	Moderate to Severe	0.3 mg	IM	Repeat in 3-5 mins PRN
☐	Diphenhydramine Oral	Mild	☐ 25 mg ☐ 50 mg	PO	
☐	Diphenhydramine 50mg/mL Vial	Moderate to Severe	☐ 25 mg ☐ 50 mg	Slow IV	Repeat in 3-5 mins PRN MAX dose = 50 mg
☐	Methylprednisolone Sodium Succinate 125mg/2mL	Moderate to Severe	125 mg	IV	x 1 dose
☐	Albuterol Inhaler	Moderate to Severe	90 mcg/act	INHALER	1-2 puffs PRN

Facility Nurse to call/fax above information to physician/LIP. Either have physician/LIP sign below, or obtain as a telephone order.

Nurse	Print Name	Date
Physician/prescriber	Print Name	Date

Pharmacy Name: _____ FAX COMPLETED FORM TO (_____) _____ - _____

PLEASE NOTE: PHARMACY MAY REQUIRE ADDITIONAL INFORMATION BEFORE ORDERS CAN BE PROCESSED.

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Program Options

Three possible models

Infusion On-Site

Pro

- Complete control
- Infusion reimbursed at acute care rate ($358)

Con

- 2 hours of nursing time
- Need infusion capable staff

Transport to off-site infusion

Pro

- Relieves labor/capability constraints

Con

- Complex logistics
- Patient transport safety
- Loss of revenue/ reimbursement

Infusion On-Site with external partner

Pro

- End to end on site service

Con

- Variable cost (a few federal/state programs are free)
- Reliant on third party scheduling

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Best Practices

Education via live webexes for facility staff

Pre- educating Patients and Families on admission

Contract Infusion Nurse support (limited markets)

Vascular Access Support

Multiple infusions- grouping patients reduces labor constraint

- Create an Infusion Room on COVID unit
- No more than 3 patients at a time infused per RN
- Provide CNA to complete q 15-minute VS
- Identify 1 or 2 RNs in close geographic proximity to become mAb team

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Questions?


Open Discussion

The Florida Society For Post-Acute And Long-Term Care Medicine

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PHYSICIAN ORDERS FOR LIFE-SUSTAINING TREATMENT

Best Care Practices
In the Post-Acute & Long-Term Care Continuum

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