

COVID-19 Update

February 1, 2021

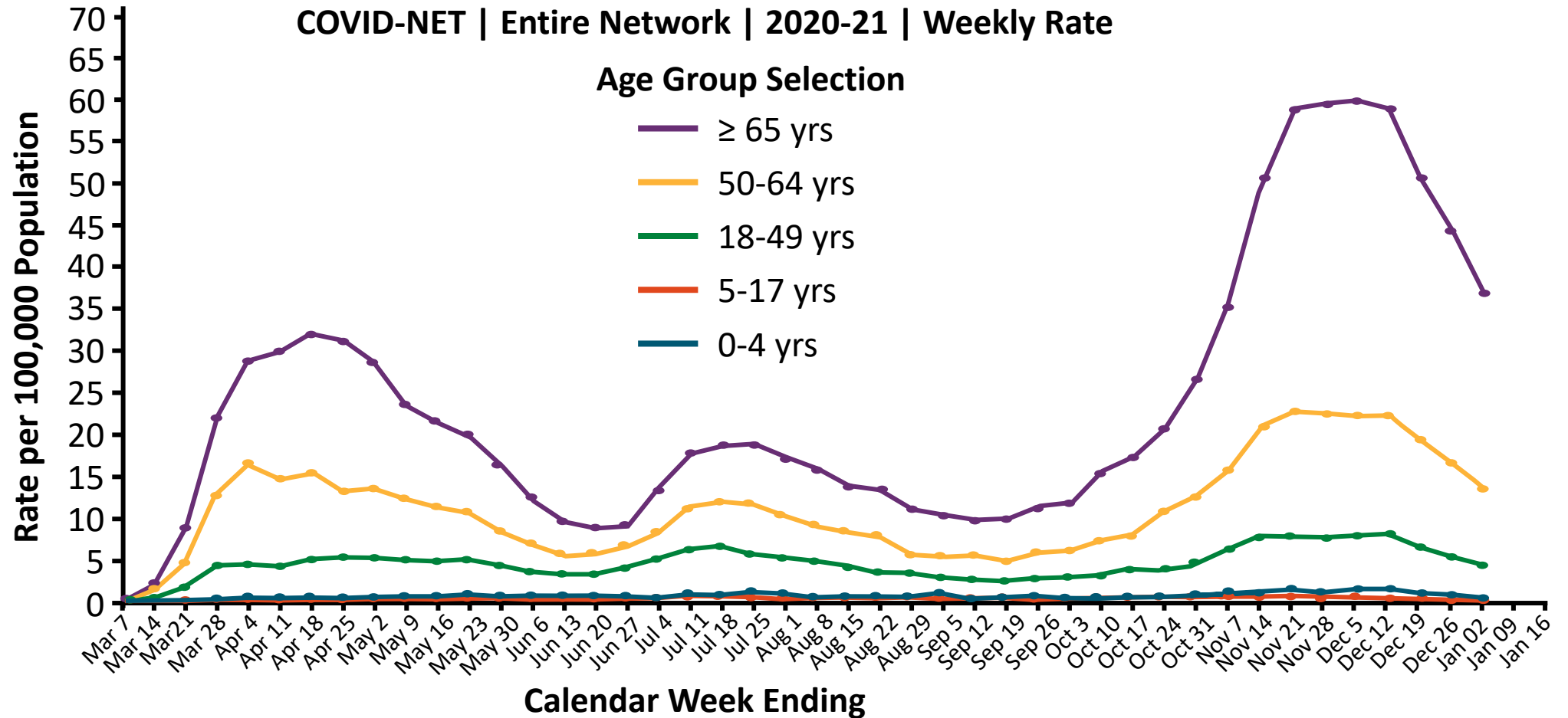
Jorge Mera, MD

Whitney Essex, APRN

Outline

- Risk factors for hospitalization due to COVID-19
- Management of COVID-19 in the outpatient setting
 - Focus on monoclonal antibodies
- New Vaccine

COVID-NET: Lab-Confirmed COVID-19–Associated Hospitalization Rates Stratified by Age



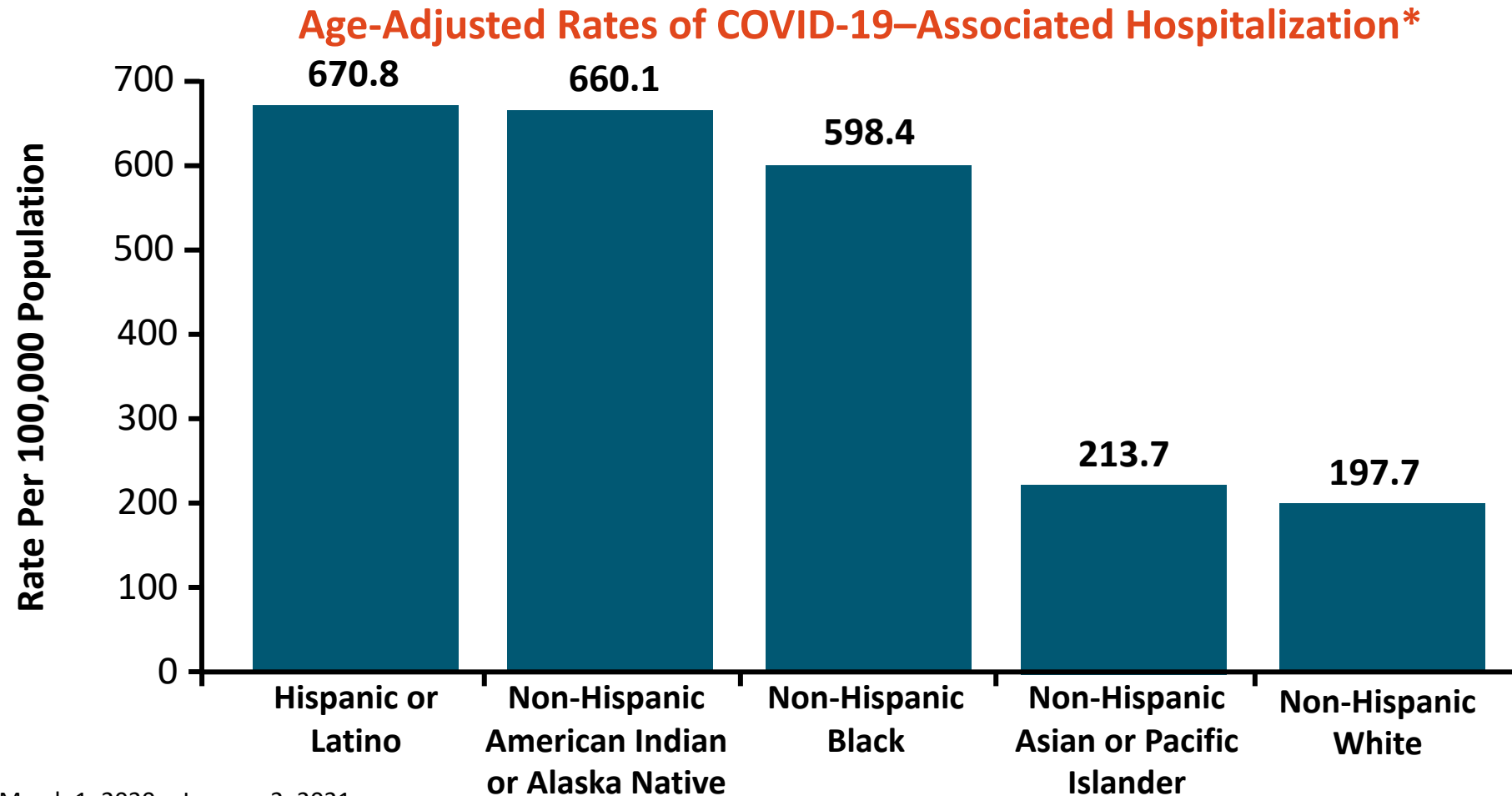
Covers ~ 10% of US population: 99 counties in 14 states (CA, CO, CT, GA, IA, MD, MI, MN, NM, NY, OH, OR, TN, UT)

https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html

Slide credit: clinicaloptions.com



COVID-NET: COVID-19–Associated Hospitalization by Race and Ethnicity



*Data from March 1, 2020 – January 2, 2021.

Covers ~ 10% of US population: 99 counties in 14 states (CA, CO, CT, GA, IA, MD, MI, MN, NM, NY, OH, OR, TN, UT).

<https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>



Slide credit: clinicaloptions.com

Home Care

- Monitor symptoms
- Supportive care
- Infection prevention and control measures

Isolation for People with COVID-19

May be discontinued under these conditions:

- At least 10 days since symptom onset, *and*
- At least 24 hours since resolution of fever without fever-reducing meds, *and*
- Other symptoms have improved

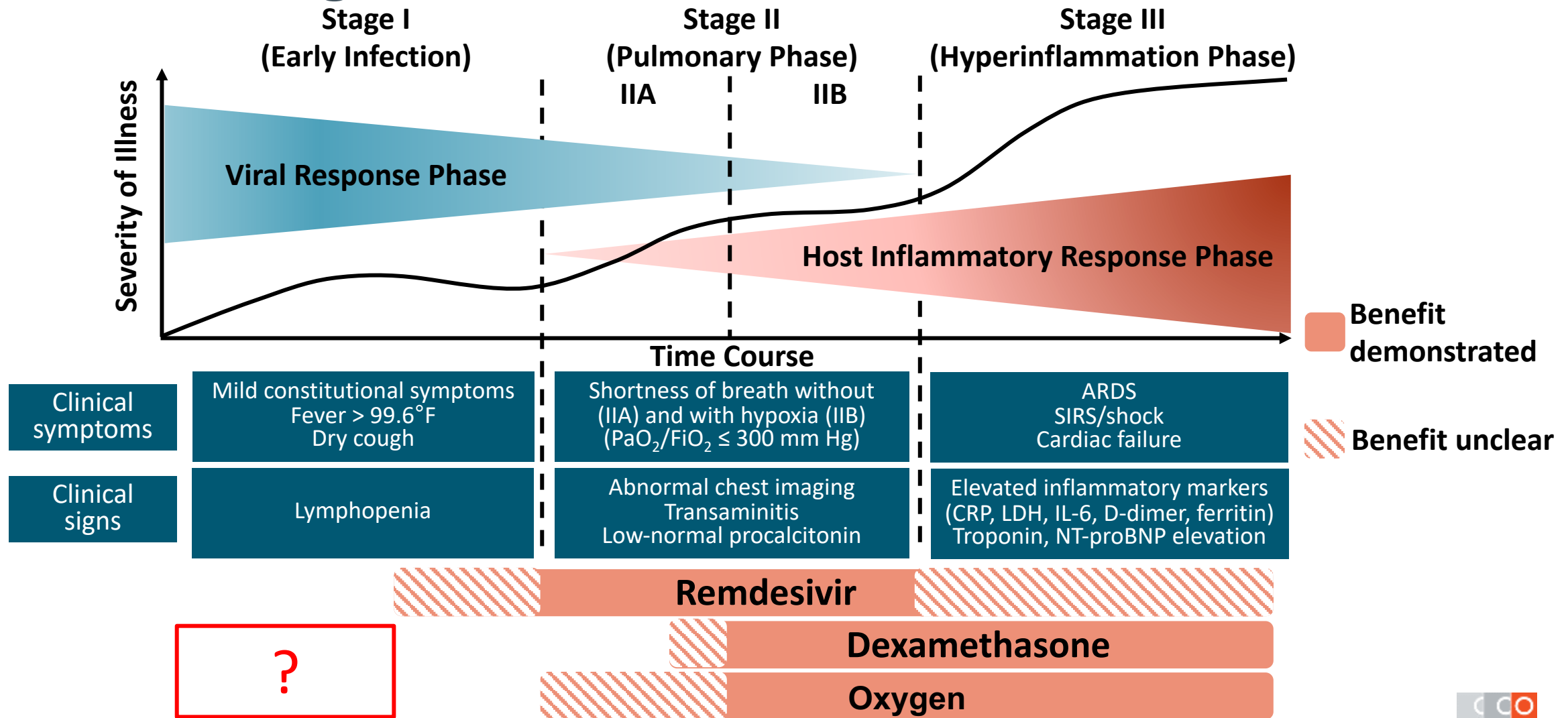
Quarantine for Close Contacts

Recommended for 14 days, but can end early:

- After day 10 without testing if no symptoms
- After day 7 if testing is negative and no symptoms

Symptom monitoring and masking through day 14 still required.

COVID-19 Therapies Predicted to Provide Benefit at Different Stages



Fluvoxamine vs Placebo and Clinical Deterioration in Outpatients With Symptomatic COVID-19: A Randomized Clinical Trial



QUESTION Does fluvoxamine, a selective serotonin reuptake inhibitor and σ -1 receptor agonist, prevent clinical deterioration in outpatients with acute coronavirus disease 2019 (COVID-19)?

CONCLUSION In this preliminary trial, outpatients with symptomatic COVID-19 treated with fluvoxamine, vs placebo, had a lower likelihood of clinical deterioration over 15 days; however, determination of clinical efficacy requires larger trials with more definitive outcome measures.

POPULATION

109 Women
43 Men



Adults with symptomatic, confirmed SARS-CoV-2 infection and $O_2 \geq 92\%$

Mean age: 46 years

LOCATIONS

Remote contactless trial in St Louis metropolitan area (Missouri and Illinois)



INTERVENTION



(Study materials left at quarantined patients' homes)

PRIMARY OUTCOME

Clinical deterioration within 15 days: shortness of breath or pneumonia and $O_2 < 92\%$ or supplemental oxygen

FINDINGS

Patients with clinical deterioration within 15 days

Fluvoxamine
0 of 80 patients



Placebo
6 of 72 patients

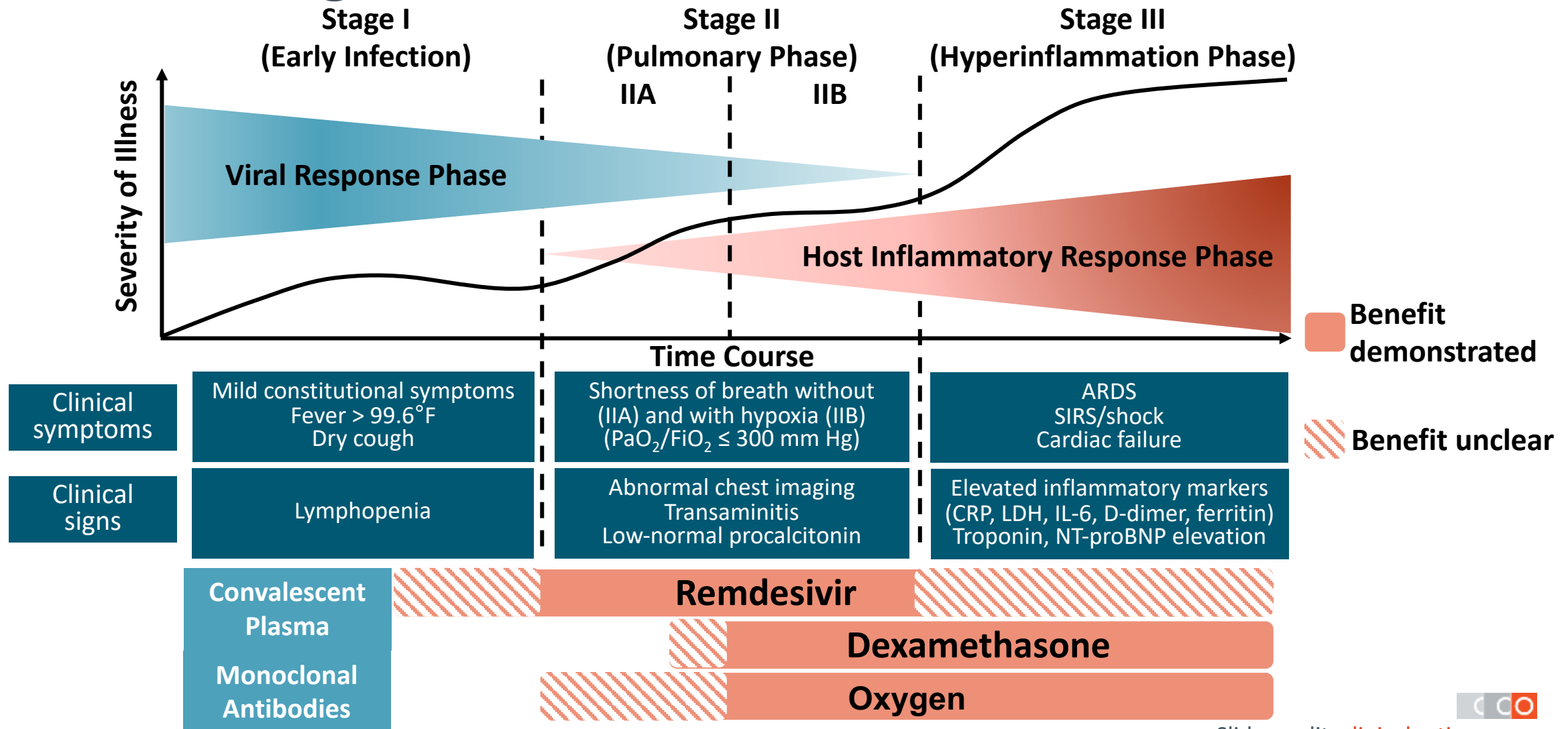


The between-group difference was significant:

8.7% (95% CI, 1.8% to 16.4%); $P = .009$

However, small sample size and short follow-up limit determination of efficacy

COVID-19 Therapies Predicted to Provide Benefit at Different Stages



Bamlanivimab

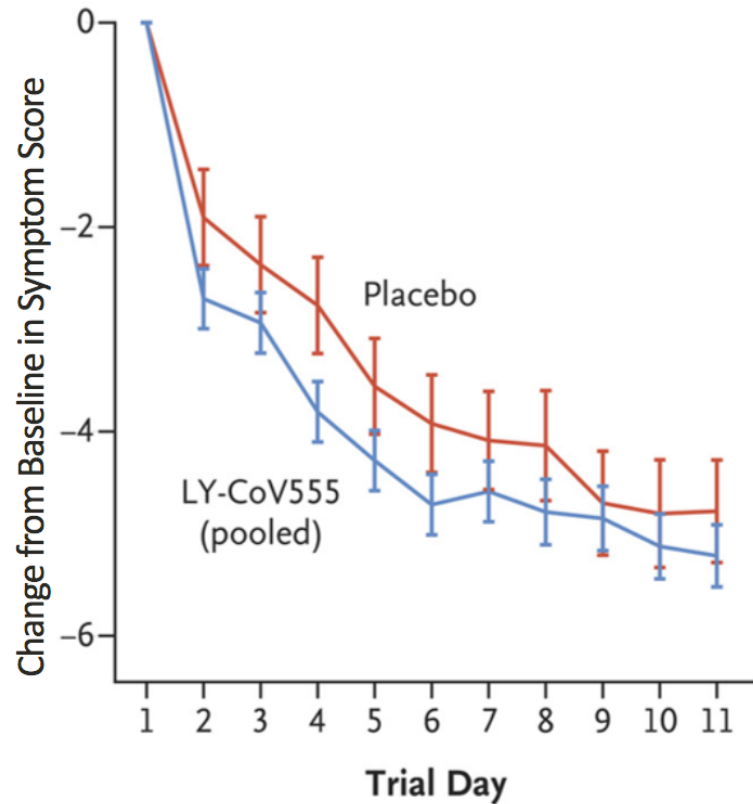


Table 3. Hospitalization.*

Key Secondary Outcome	LY-CoV555 <i>no. of patients/total no.</i>	Placebo	Incidence
			%
Hospitalization		9/143	6.3
	700 mg, 1/101		1.0
	2800 mg, 2/107		1.9
	7000 mg, 2/101		2.0
	Pooled doses, 5/309		1.6

* Data for patients who presented to the emergency department are included in this category.

Bamlanivimab

Our Experience

Jorge Mera, MD, FACP

Whitney Essex, APRN-CNP

Pre-Visit Process

List

List of COVID-19 patients is generated by IT (twice daily at our site)

Call

Call – Nurse calls eligible patient to explain/offer treatment

- As soon as possible after test result available
- Bamlanivimab can be given within 10 days of symptom onset

Confirm

Confirm – make sure patient understands that appointment will be 3-4 hours

Day of Visit

- Patient arrives – Nurse performs intake, including O2 Sat (~10 minutes)
- Prescriber:
 - Confirms eligibility with patient
 - Explains EUA (~15 minutes) – provides copy of fact sheet
 - Orders IV Start and confirms IV access prior to ordering bamlanivimab
 - Place order for bamlanivimab – informs pharmacy
- Pharmacy prepares bamlanivimab – delivers to clinic (~30 minutes)
 - Bamlanivimab is stored in refrigerator
 - Room temperature for administration
 - More "infusion reactions" if too cold

Day of Visit continued... and Follow up

- Nurse starts infusion
 - Use inline filter
 - Can be by gravity or pump
 - Confirms monitor (or self-monitors)
 - Monitor VS during and after infusion (per site protocol – q15 min, q30 min)
- Follow-up 1-3 days after via phone, Day 14 to confirm serious adverse events (hospitalization)

Nurse Staffing/Supply details...

- Nursing
 - Time Intensive
 - IV start
 - Nurse to patient ratio – 1:4 per 8 hour shift
 - With a separate monitor
 - With 2 rooms
 - Nurse to patient ratio – 1:2 per 8 hour shift
 - With no monitor
 - With 1 room
- Supplies
 - Typical IV Infusion supplies **except**: *PVC infusion set containing 0.2 or 0.22 micron polyethersulfone (PES) in-line filter*

Things to Consider

- ACLS trained staff required (at least 1)
- Crash cart or similar present
- Other meds available for in-clinic administration
 - Ondansetron, IV Fluids (NS), Acetaminophen, Ibuprofen, etc.
- Patient is present for up to 4 hours (and they are sick L)
 - Snacks, drinks, blankets, etc.
- Monitoring – many ways to do this
 - Tablets
 - Congregate observation room
 - One-on-One



Finding Antibodies



The screenshot shows the website for the National Infusion Center Association. The header includes the logo and navigation links: About Us, Membership, Education, Advocacy, Resources, Community, Infusion Center Locator, Annual Meeting, and Member Login. The main heading is "Infusion Prescribers" with a sub-heading "Welcome! Here you can find resources for healthcare providers ordering COVID-19 antibody infusions." Below this is a large blue section titled "COVID-19 Antibody Treatment Locator" with a sub-heading "Prescribers can use our COVID-19 Locator Tool to find infusion centers administering COVID-19 antibody therapies. If results do not populate for your state, please try widening the search radius. Otherwise, contact your state health department, as your state may not have opted into our locator program yet." A "Search the Locator" button is at the bottom.

The screenshot shows the "Therapeutics Distribution Locations" page on the HHS Protect Public Data Hub. The page includes a disclaimer: "LABORATORIES THAT RECEIVED LOWER THAN 3 CATEGORIES OF DISTRIBUTION ARE NOT DISPLAYED. THESE THERAPEUTICS MUST BE USED UNDER THE TERMS OF THE EUA FOR APPROPRIATE PATIENTS. DATA DISPLAYED ON THIS PAGE IS FOR INFORMATIONAL PURPOSES ONLY FOR CLINICIANS AND PATIENTS." The main heading is "Therapeutics Distribution Locations". Below this is a "Find Locations" section with a search bar set to "Aurora, IL, USA" and a radius of 15 miles. A map shows a circular search area around Aurora, IL. A list of locations is displayed on the left:

Location	Distance
RUSH COPLEY MEDICAL CENTER 2000 OGDEN AVE, AURORA, IL 60504 This site received shipments of BAMLANIVIMAB	(3.07 mi)
EDWARD HOSPITAL 801 S WASHINGTON ST, NAPERVILLE, IL 60540 This site received shipments of IMDEVIMAB/CASIRIVIMAB	(8.51 mi)
EDWARD HOSPITAL 801 S WASHINGTON ST, NAPERVILLE, IL 60540 This site received shipments of BAMLANIVIMAB	(8.51 mi)
DELNOR COMMUNITY HOSPITAL	(8.92 mi)

[Covid.infusioncenter.org](https://www.covid.infusioncenter.org)

<https://protect-public.hhs.gov/pages/therapeutics-distribution#distribution-locations>

Treatment Eligibility

Treatment	Status	Eligibility
Monoclonal antibodies: Bamlanivimab Casirivimab + imdevimab	EUA	Outpatients (≥ 12 yrs) with confirmed COVID at risk for severe disease, based on established criteria, within 10 days of symptom onset; Excluding: patients requiring oxygen because of COVID
Remdesivir	Approved	Patients (≥ 12 yrs and ≥ 40 kg) requiring hospitalization
Dexamethasone	Off label	Patients requiring supplemental oxygen
Convalescent plasma	EUA	Hospitalized patients Probably Better When Given Early
Remdesivir + baricitinib	EUA	Hospitalized patients (≥ 2 yrs) requiring supplemental oxygen, invasive mechanical ventilation, or ECMO

Key Ongoing Anticoagulation Trials for COVID-19

- Multi-trial international platform assessing **therapeutic anticoagulation with IV unfractionated heparin or SC LMWH** vs **standard pharmacologic thromboprophylaxis** in COVID-19 patients without a medical indication for blood thinners
- As of December 2020, based on deliberations across oversight boards, enrollment of **critically ill** COVID-19 patients requiring ICU support paused^[1]
 - Therapeutic AC drugs did not reduce need for organ support; potential for harm could not be excluded
 - Recruitment of moderately ill hospitalized COVID-19 patients still ongoing

Trials Involved

REMAP-CAP^[2,3]

ACTIV-4 ACUTE^[4,5]

ATTACC^[6]

1. <https://www.nhlbi.nih.gov/news/2020/nih-activ-trial-blood-thinners-pauses-enrollment-critically-ill-covid-19-patients>.

2. NCT02735707. 3. <https://www.remapcap.org/>. 4. NCT04505774. 5. <https://fnih.org/sites/default/files/final/activ-4a.pdf>. 6. NCT04372589.



! COVID-19 is an emerging, rapidly evolving situation.

- [Get the latest public health information from CDC »](#)
- [Get the latest research information from NIH »](#)
- [NIH staff guidance on coronavirus \(NIH Only\) »](#)

[Home](#) » [News & Events](#) » [News Releases](#)

NEWS RELEASES

Friday, January 29, 2021

Janssen Investigational COVID-19 Vaccine: Interim Analysis of Phase 3 Clinical Data Released



Institute/Center

[National Institute of Allergy and Infectious Diseases \(NIAID\)](#)

Contact

[NIAID Office of Communications](#) 
301-402-1663

COVI-19 Vaccine Update

Janssen Investigational
COVID vaccine:
Ad.26.COV2.S or
JNJ-78436725

- This is a recombinant vector vaccine that uses a human adenovirus to express the SARS-CoV-2 spike protein
- The adenovirus used in this vaccine has been modified, so that it can no longer replicate in humans and cause illness.
- A **single injection** and can be stored in a **refrigerator for months**
- The interim analysis **assessed 468 cases of symptomatic COVID-19 among 44,325** adult volunteers in Argentina, Brazil, Chile, Colombia, Mexico, Peru, South Africa, and the United States
- The vaccine was reportedly **66% effective** at preventing moderate and severe COVID-19 at 28 days post-vaccination among all volunteers, including those infected with an emerging viral variant

Janssen
Investigational
COVID vaccine:
Ad.26.COV2.S
or JNJ-
78436725

- **Moderate COVID-19 was defined** as laboratory-confirmed SARS-CoV-2 plus either one of the following:
 - Evidence of pneumonia
 - Deep vein thrombosis
 - Difficulty breathing
 - Abnormal oxygen saturation or a respiratory rate equal to or greater than 20
 - Two or more signs or symptoms suggestive of COVID-19, such as cough, sore throat, fever or chills
- **Severe COVID-19 was defined** as laboratory-confirmed SARS-CoV-2 plus evidence of clinical signs at rest indicative of severe systemic illness, respiratory failure, shock, significant organ dysfunction, hospital intensive care unit admission or death

Janssen Investigational COVID vaccine:
Ad.26.COV2.S or JNJ-78436725

- **Geographic variations of protection** for combined endpoints of moderate and severe disease:
 - 72% in the United States; 66% in Latin American countries; 57% in South Africa, 28 days post-vaccination.
- The investigational vaccine was reportedly **85% effective in preventing severe/critical COVID-19** across all geographical regions.
- Overall, there were 16 deaths in the placebo group, and 3 deaths in the vaccine group.
- **No deaths related to COVID-19 were reported in the vaccine group**, while 5 deaths in the placebo group were related to COVID-19