COVID-19 Update February 1, 2021

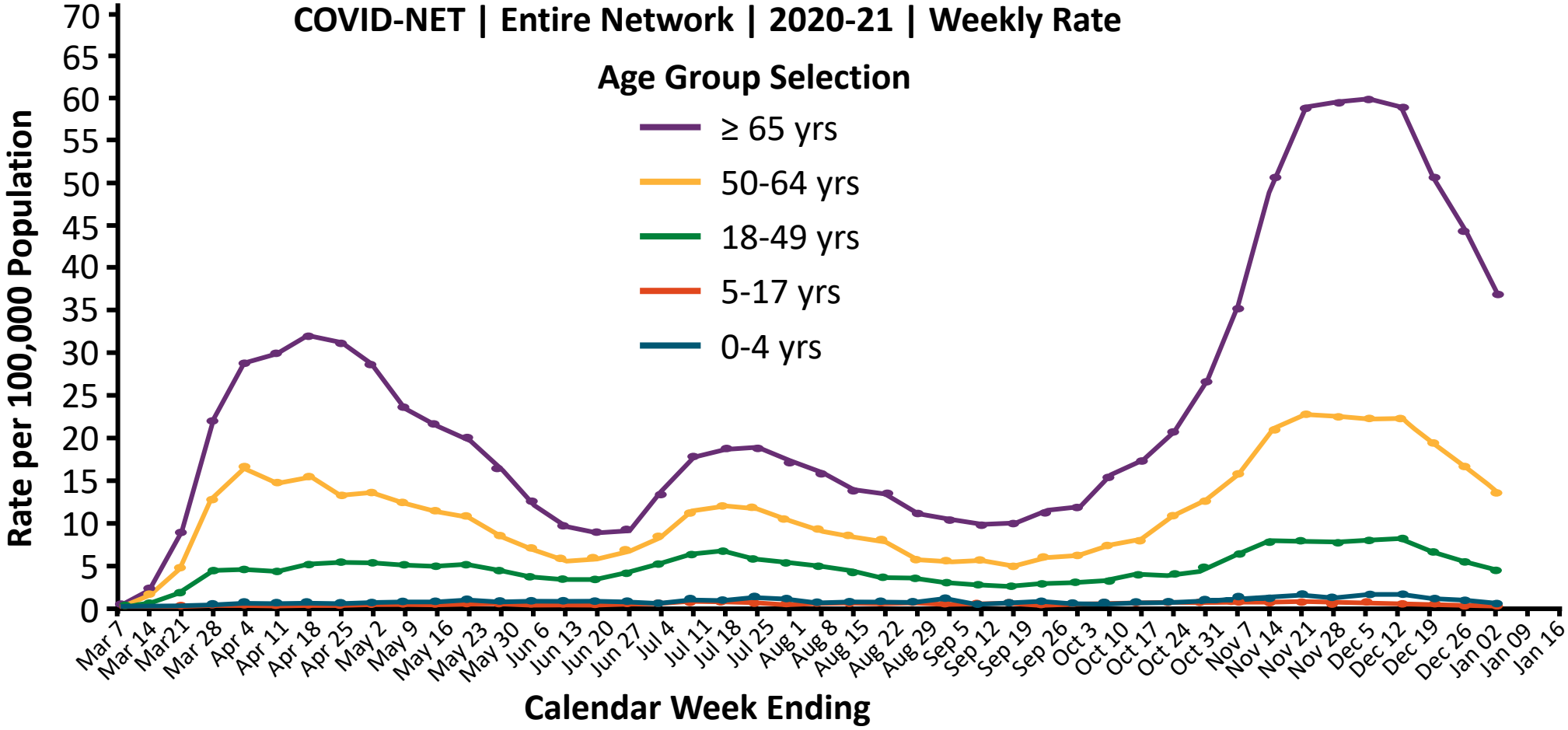
Jorge Mera, MD

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

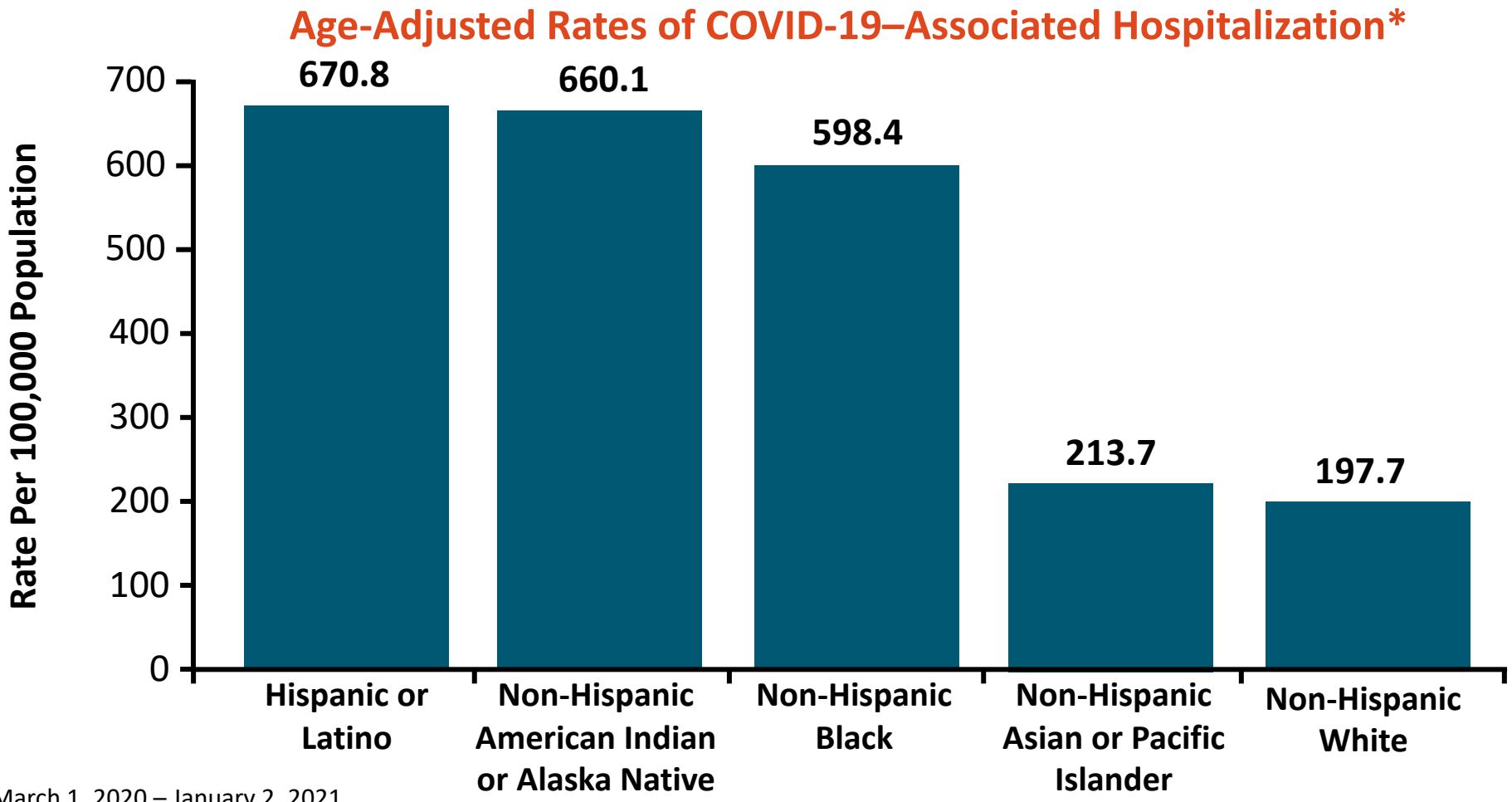


Covers ~ 10% of US population: 99 counties in 14 states (CA, CO, CT, GA, IA, MD, MI, MN, NM, NY, OH, OR, TN, UT)

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

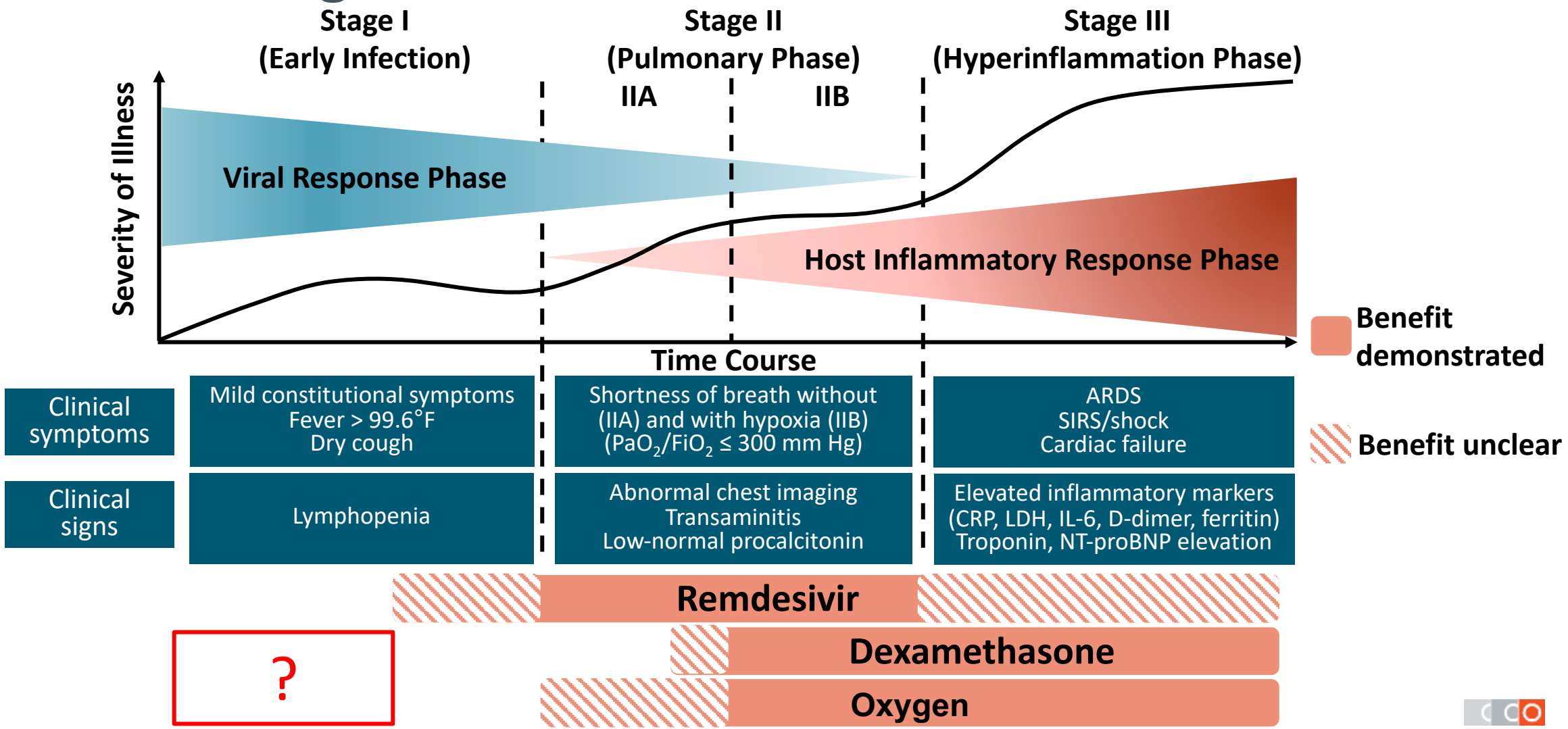
Recommended for 14 days, but can end early:

- 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.

https://covid19.dkbmed.com

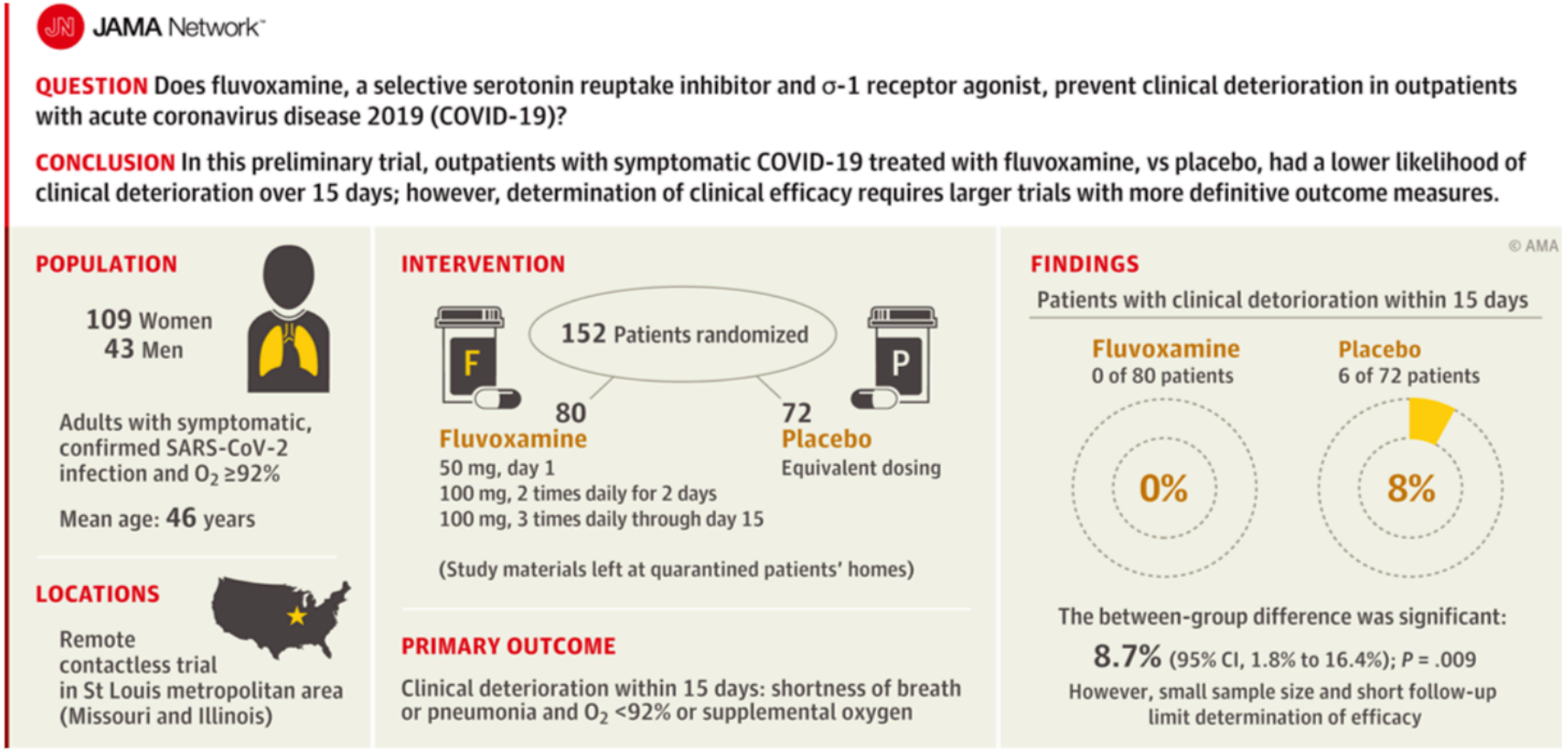
COVID-19 Therapies Predicted to Provide Benefit at Different Stages



Slide credit: clinicaloptions.com

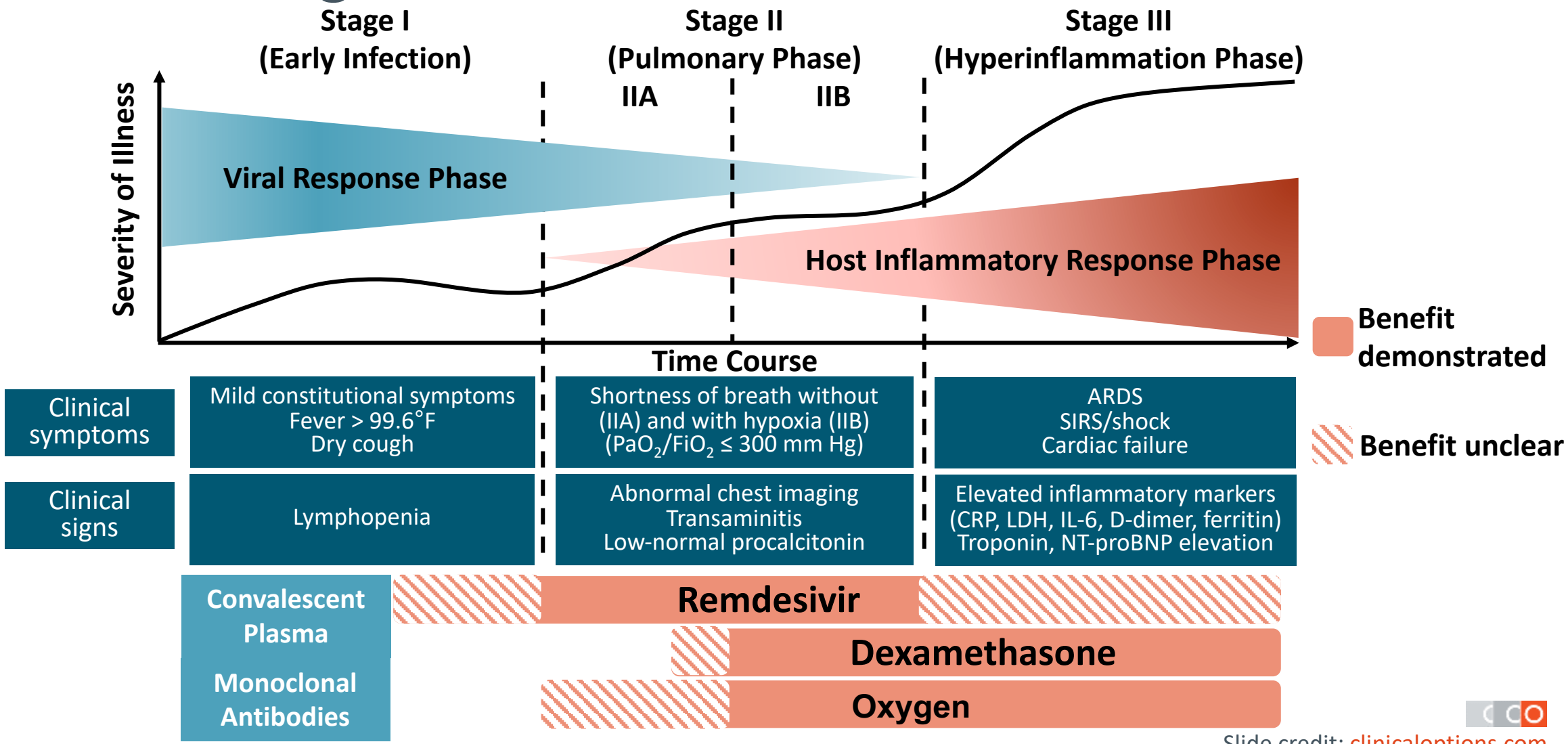
Siddiqi. J Heart Lung Transplant. 2020;39:405.

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



JAMA. 2020;324(22):2292-2300

COVID-19 Therapies Predicted to Provide Benefit at Different Stages



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Bamlanivimab

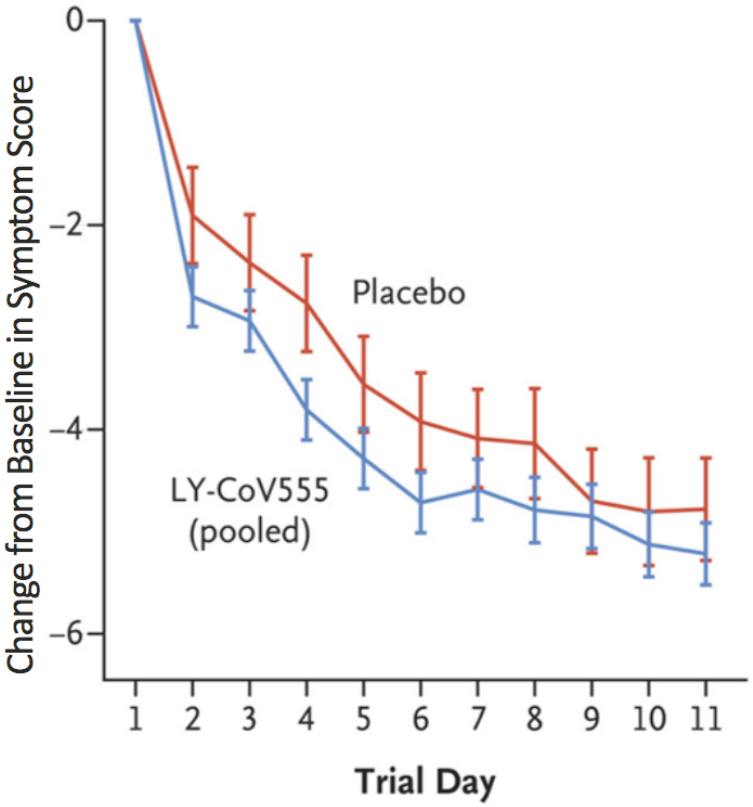


Table 3. Hospitalization.*

Key Secondary Outcome	LY-CoV555	Placebo	Incidence
	no. of patients/total no.		%
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.

Chen et al. N Engl J Med. 2020. DOI: 10.1056/NEJMoa2029849.

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)

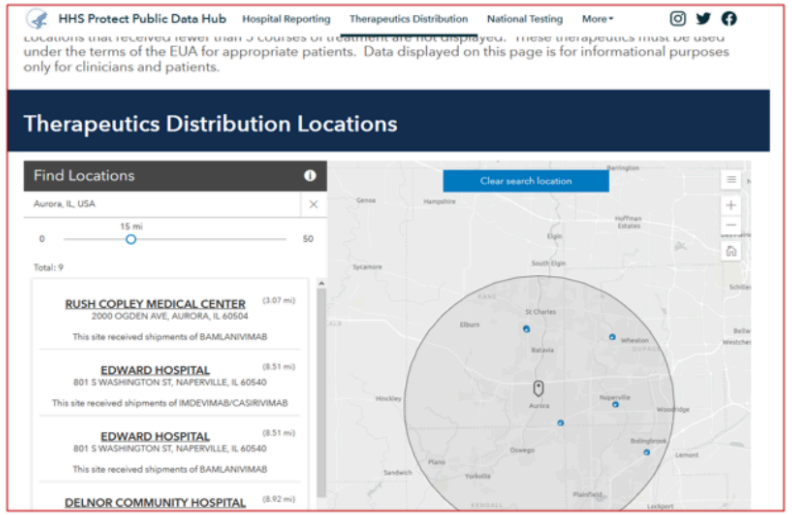
Nurse Staffing/Supply details…

- 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



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
Remdesivir + baricitinib	EUA	Hospitalized patients (≥2 yrs) requiring supplemental oxygen, invasive mechanical ventilation, or ECMO

Probably Better When Given Early

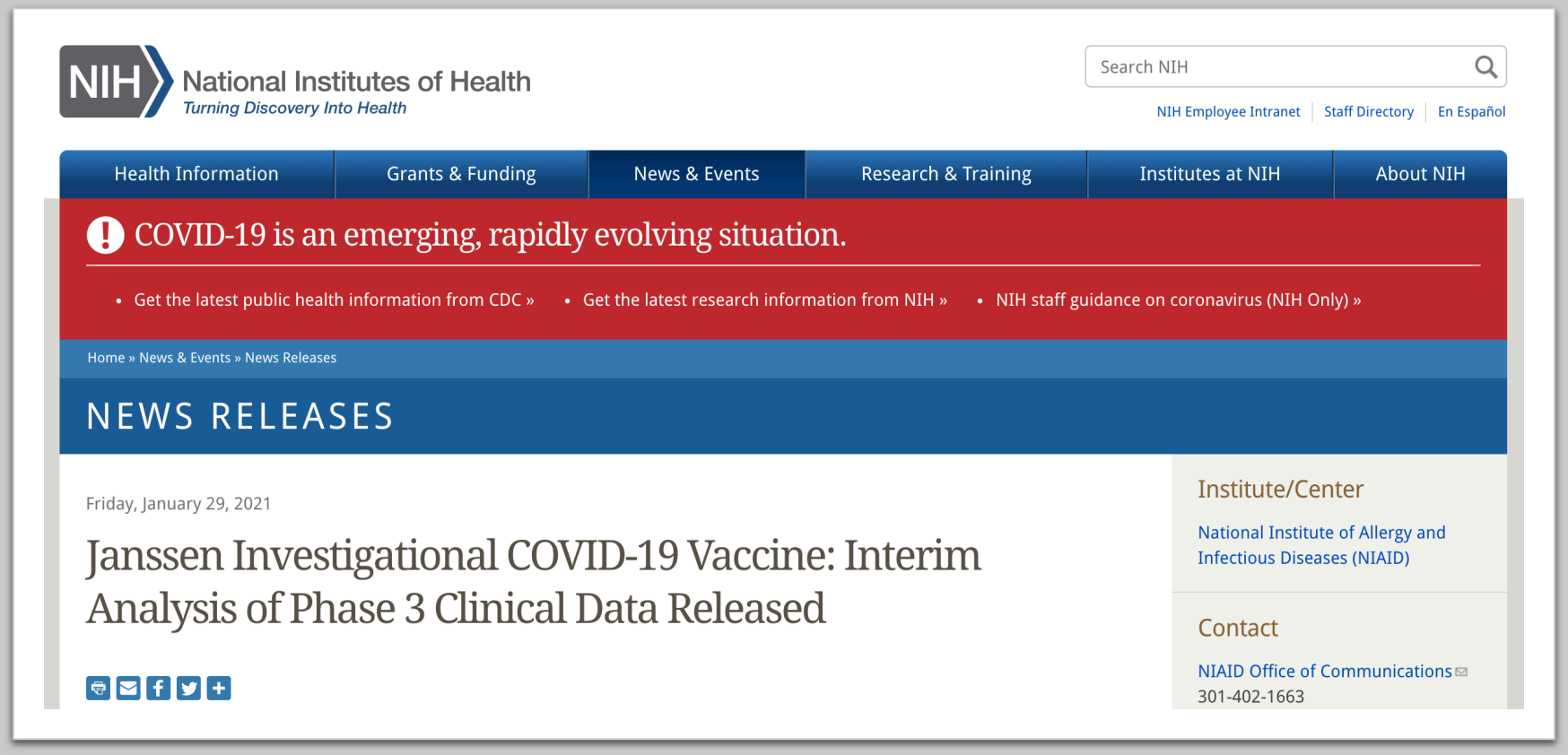
Key Ongoing Anticoagulation Trials for COVID-19

- 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.

Slide credit: clinicaloptions.com



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 a**ssessed 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