National Hispanic Medical Association

VIRTUAL CHAPTER POLICY FORUM

NHMA Gulf Coast Chapter

Update on Latest Science on COVID-19: Results of Research Trials from Academic Centers in the Region & Response of Medical Training Programs

October 15, 2020
7:00 PM – 8:15 PM EDT
www.NHMAmd.org

@NHMAmd @NHMAmd.org

Welcome

Elena Rios, MD, MSPH, FACP
President & CEO
National Hispanic Medical Association
Washington, DC

- Encourage your patients to enroll and inform others about the clinical trials for COVID-19 Vaccines
  - www.CoronaVirusPreventionNetwork.org
  - www.COVIDVACCINESTUDY1.com

- **2020 Virtual Health Leaders and Scholars Awards Ceremony**
  - Thursday, November 19, 2020 from 8:00 PM- 10:00 PM ET
  - To register: https://bit.ly/NHHFCeremony2020
- **2021 NHMA National Hispanic Health Conference March 17- March 20**
  - To register: http://bit.ly/NHMAConference2021

Overview

Leornardo Seoane, MD, FACP
Co-Chair, NHMA Gulf Coast Chapter
Professor of Medicine
Chief Academic Officer, Ochsner Health

Housekeeping

- Presentations to be followed by 10-15 minute discussion
- Microphones will be muted
- Type questions in chat box
- Recording available next week at www.NHMAmd.org

To Claim CME Credit:

1. Visit www.ochsner.org/cme and select "CME Conference Portal"
2. Enter you email address and log in
3. Select "Click Here to show a list of conferences for self-registration and scroll down to "National Hispanic Medical Association Gulf South Chapter Meeting". Hit select. [LEAVE PASSWORD BLANK]
4. Enter your contact information and click "Save and Continue"
5. Enter the number of credits that you have earned, then check the box to confirm the credits.
6. You will then be able to print your certificate

You can visit this site to print your certificate(s) at any time for your records.

If you have any questions, please contact Kristin Tschirn at ktschirn@ochsner.org

COVID-19 Update

Leornardo Seoane, MD, FACP

Co-Chair, NHMA Gulf Coast Chapter

Professor of Medicine

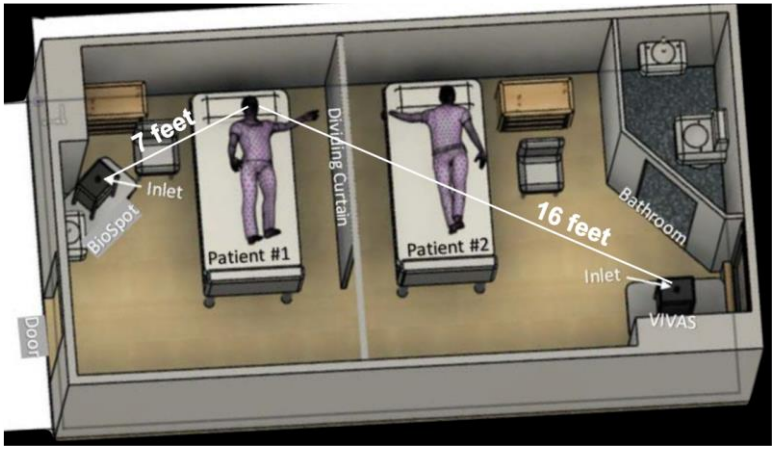
Chief Academic Officer, Ochsner Health

Objectives

- Prevention
  - Mask
  - Vaccines
  - Antibodies

Infectious SARS CoV-2 Aerosolized

- Air samples collected from COVID ward
- Live virus retrieved from air samples at 7 and 16 feet
- Neither patient submitted to aerosolized procedures



https://www.medrxiv.org/content/10.1101/2020.08.03.20167395v1.full.pdf

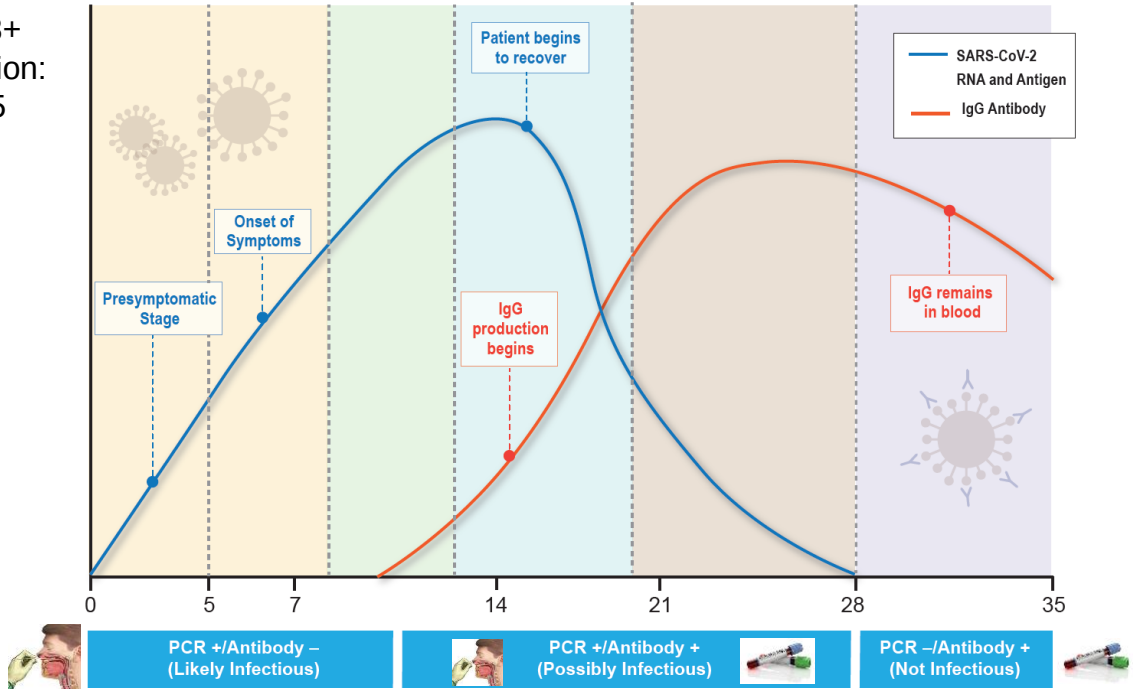
Mask Wearing May Reduce Severity of Disease

- Mask could lead to milder symptoms and more asymptomatic cases
- COVID Hamster model demonstrated increased severity with increased inoculum
- Case series of increased asymptomatic cases with mask wearing (Cruise ship, Food Plant, hospital wards)
- Decrease population death rates with mask wearing

Gandhi et al. J Gen Intern Med 2020

Baton Rouge Prevalence

Total 18+ population: 551,185



Unadjusted Prevalence %	**2.9%**	**1.0%**	**2.2%**
Projected infections	15,984	5,512	12,126
Asymptomatic	9,750 (61%)	3,417 (62%)	6,548 (54%)

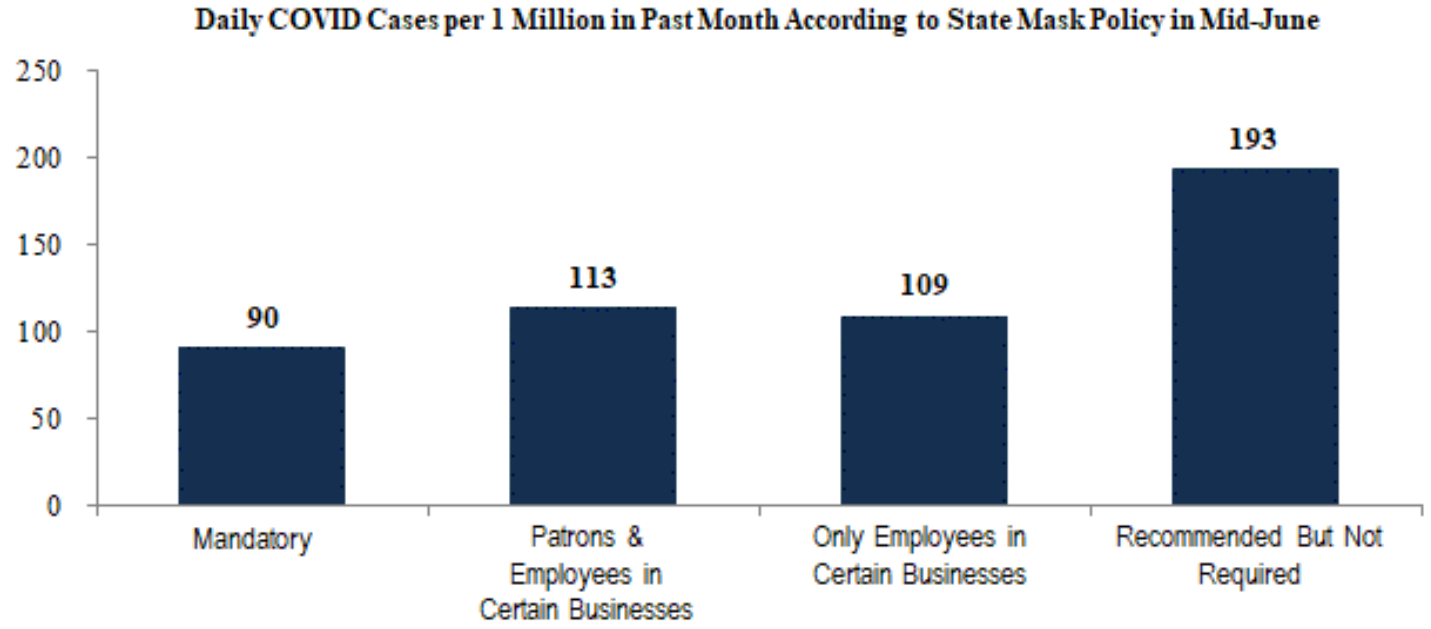
Two hair stylists with COVID-19 spent at least 15 minutes with 139 clients

EVERYONE WORE FACE COVERINGS NO CLIENTS ARE KNOWN TO BE INFECTED*

WEAR CLOTH FACE COVERINGS CONSISTENTLY AND CORRECTLY TO SLOW THE SPREAD OF COVID-19

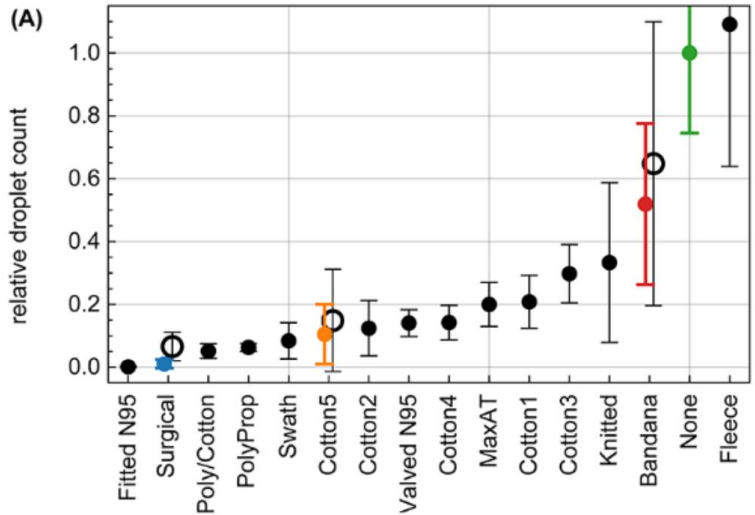
*No clients reported symptoms; all 67 customers tested had negative tests

Efficacy of Mask Mandates



Source: State health departments, National Governors Association

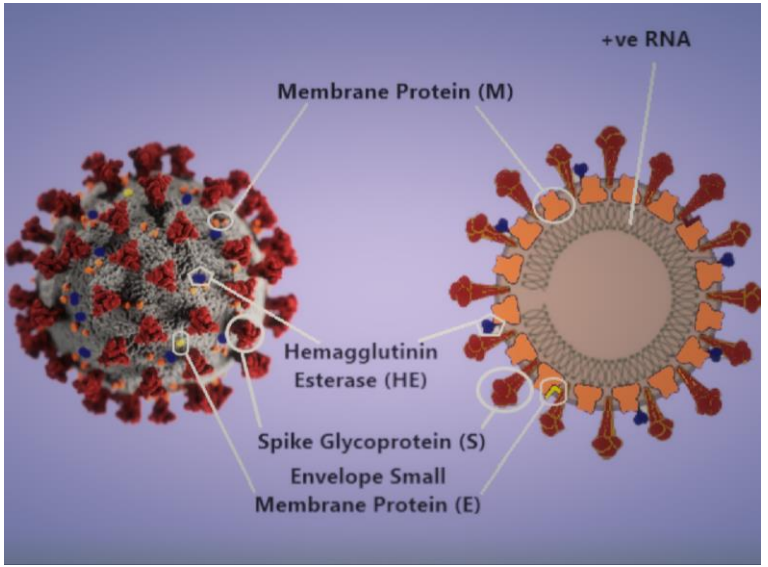
Not all Face Masks are Created Equal



https://advances.sciencemag.org/content/early/2020/08/07/sciadv.abd3083/tab-pdf

Vaccine, expose body to antigen, provoke immune response to block virus if person infected.

- Over 130 different candidates
  - 44 in clinical trials
  - Vast majority target "Spike" protein
- Virus inactivated or weakened
- Viral Vector
  - Replicating
  - Non-replicating
- Protein Based
  - Protein sub-unit
  - Virus like particles
- Nucleic Acid
  - DNA, RNA



Coronavirus Vaccines

UQ-CSL

****J&J Beth Israel**
Novavax
*ARCTURUS-Duke
*Imperial College/ Morningside

**Oxford-AstraZeneca
***Pfizer-BioNTech**
*Moderna-NIH
Novavax

**Russia: Sputnik V
**China: CanSinoBIO
China Sinovac
China Sinopharm

*mRNA Vaccine
** viral vector

Coronavirus Vaccine Tracker-New York Times, October 7,2020

Monoclonal Antibodies

- REGN-COV2
  - 2 humanized monoclonal antibodies targeting non-overlapping epitopes on spike protein
  - Animal Data
    - Prophylactically reduce viral load in upper and lower airways
    - Postinfectious dosing demonstrated increase viral clearance
  - Phase1/2/3 trials underway
    - 1:1:1 randomization 8g, 2.4g, placebo in non-hospitalized
    - Preliminary data ↓ time to alleviate symptoms

Monoclonal Antibodies Eli Lilly

- BLAZE-1 trial
  - 2 monoclonal Ab binding complementary regions of the spike protein
  - Primary end-point Decrease viral load (day11)
  - Improvement in symptoms
  - Lower rate of hospitalization and ER visits
- BIAZE-2 Phase 3 trial
  - LY-CoV555 antibody to prevent infection long term care facilities
- NIH ACTIV-2 and ACTIV-3
  - Ambulatory and hospitalized patients

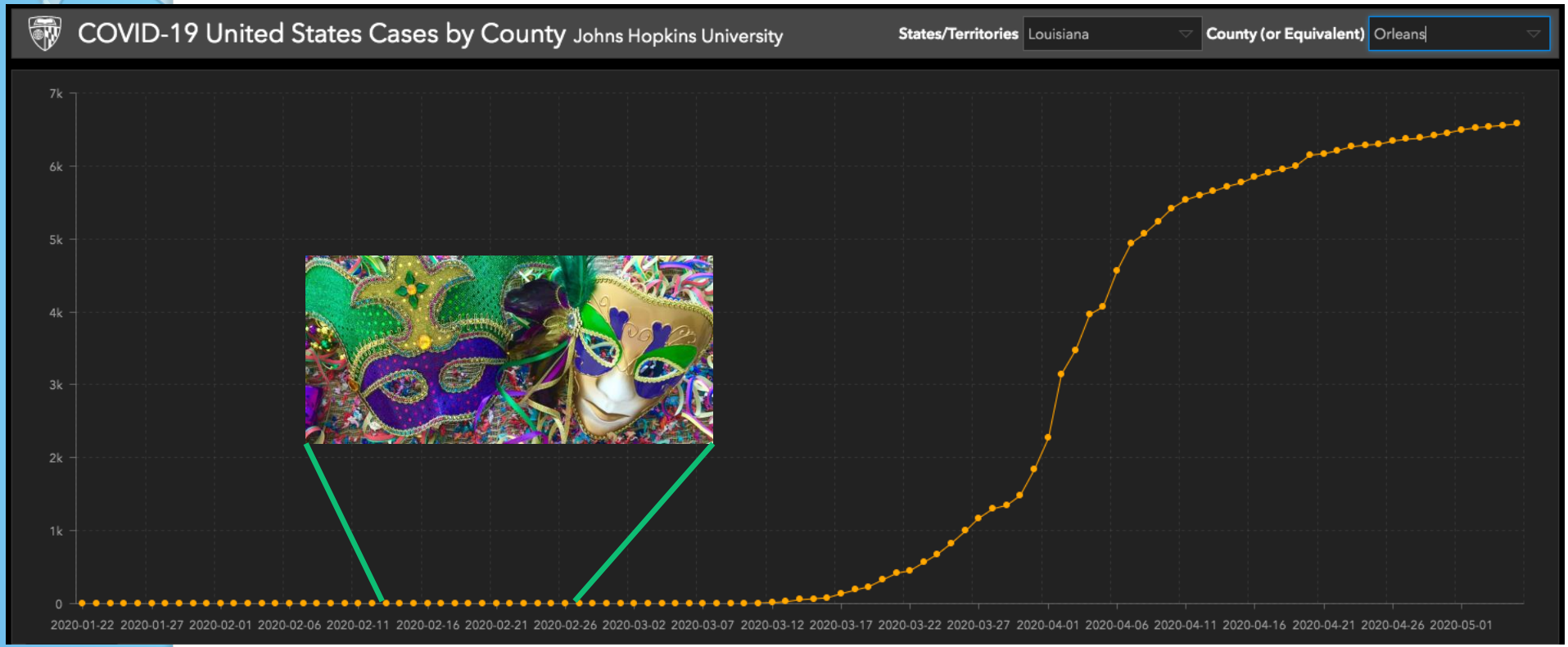
A Characteristic CXR Pattern in COVID-19

David L. Smith, MD
Associate Professor of Radiology
Associate Professor of Medicine
Associate Professor of Cell Biology & Anatomy
LSU Health New Orleans School of Medicine
Department of Radiology

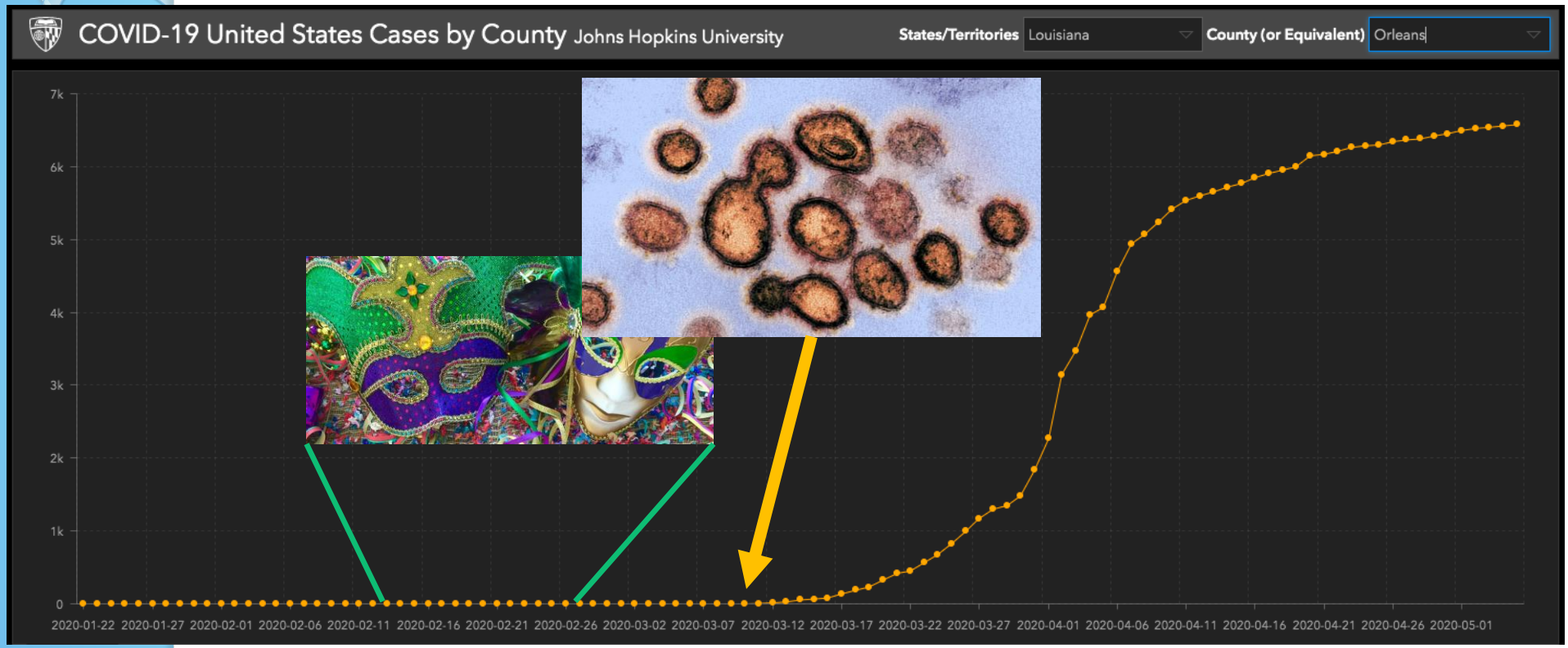
Disclosures / Conflicts of Interest:

None

COVID-19 cases in Orleans Parish

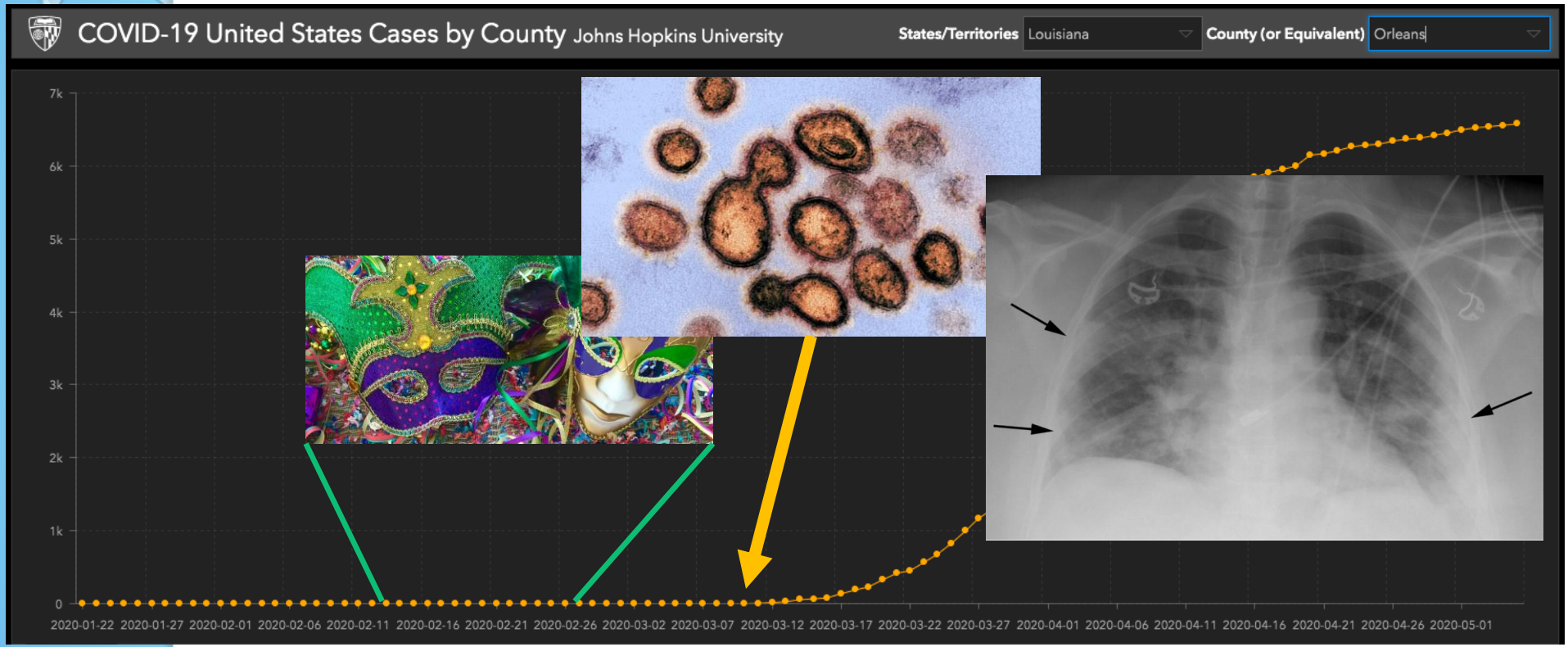


COVID-19 cases in Orleans Parish



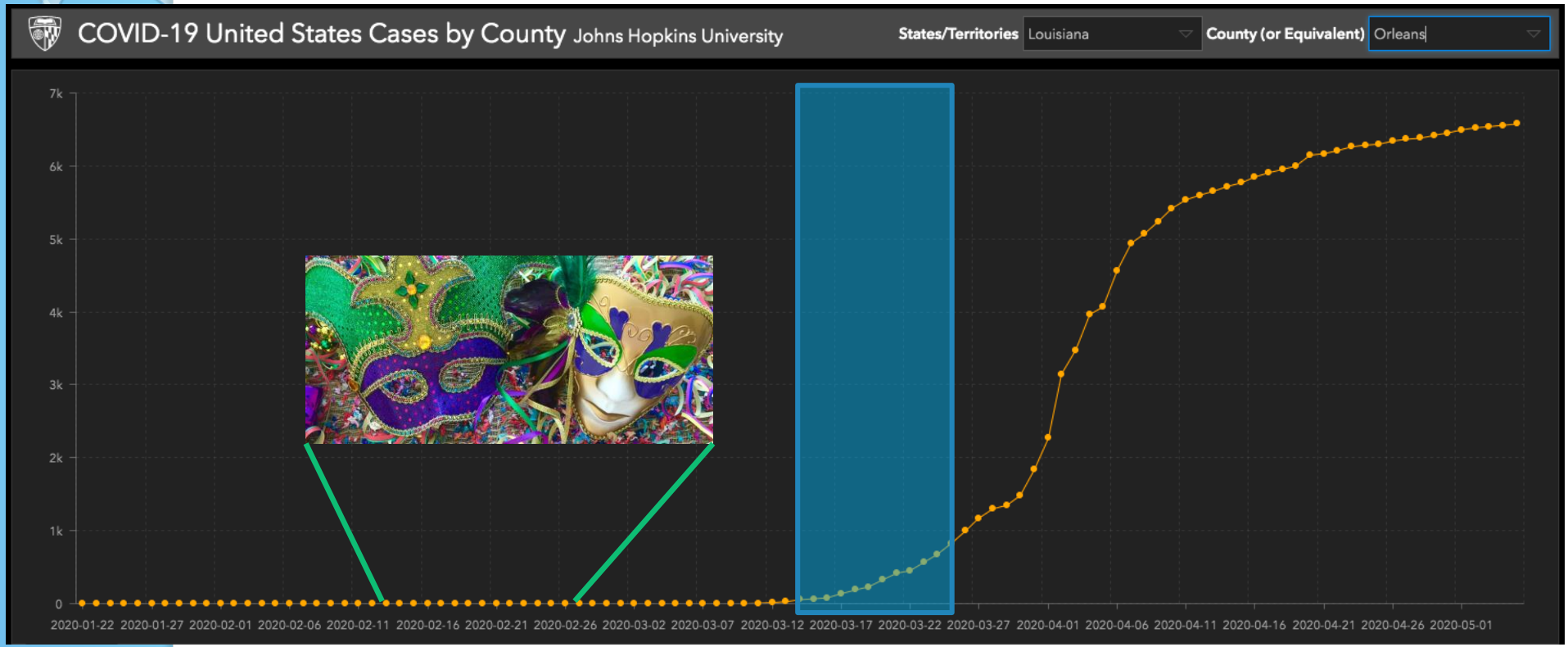
March 10

COVID-19 cases in Orleans Parish



March 10

COVID-19 cases in Orleans Parish



March 13 - 25

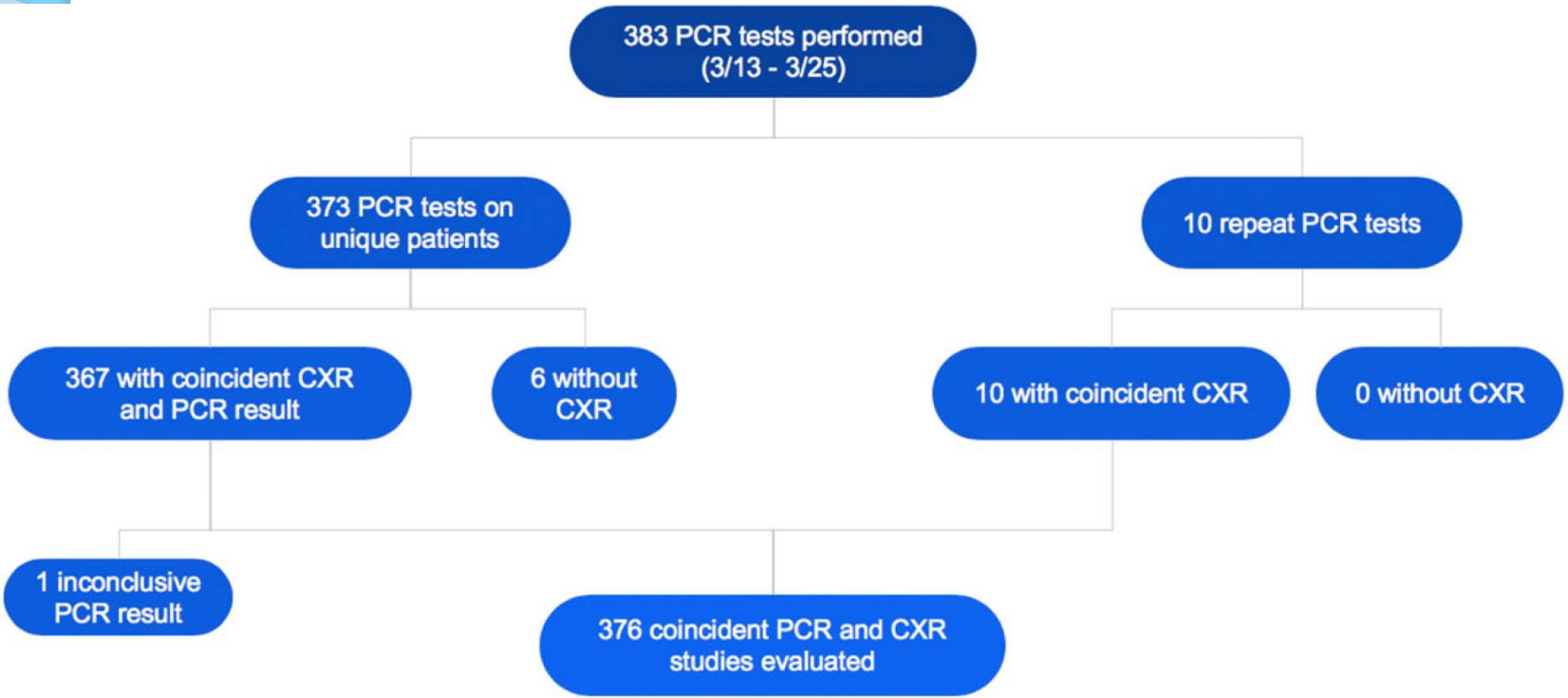

383 PCR tests performed (3/13 - 3/25)
373 PCR tests on unique patients
10 repeat PCR tests
367 with coincident CXR and PCR result
6 without CXR
10 with coincident CXR
0 without CXR
1 inconclusive PCR result
376 coincident PCR and CXR studies evaluated

Table 2: Chest Radiograph Characterization by Findings	
CXR Characterization	**CXR Findings**
Characteristic	Bilateral “patchy” and/or “confluent, bandlike” ground glass opacity or consolidation in a peripheral and mid-to-lower lung zone distribution
Nonspecific	Any pleuropulmonary abnormality other than the above
Negative	No radiographic abnormality

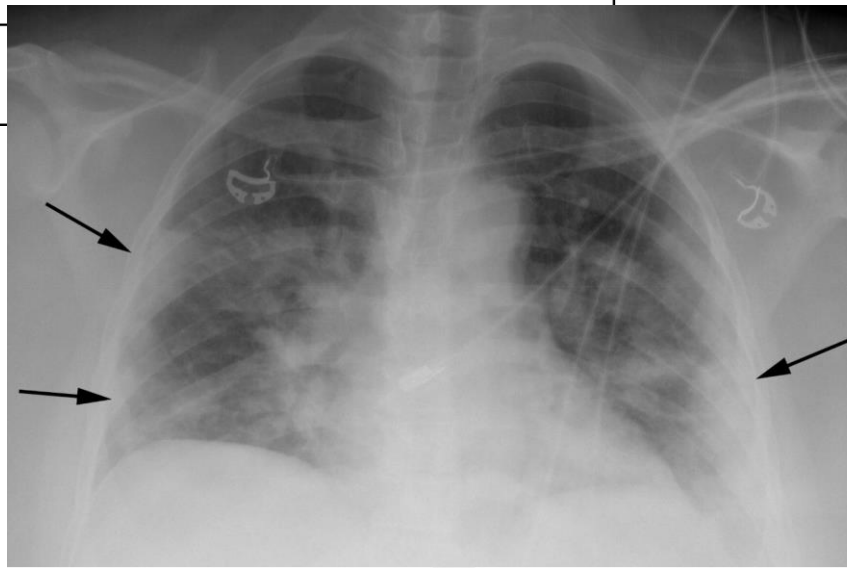


Table 3: Summary of Radiographic Findings			
CXR Findings	**PCR + (200)**	**PCR - (176)**	**Total (376)**
Characteristic Pattern	31	6	37
Nonspecific Pattern	114	101	215
Mass-like opacity	3	2	5
Upper-lobe predominant opacity	3	3	6
Diffuse opacity	21	19	40
Ill-defined bi-basilar opacity	40	30	70
Focal, unilateral opacity	47	41	88
Effusion(s)	0	6	6
Negative Radiograph	55	69	124

$p < 0.000001$

Sensitivity = 15.5%

Specificity = 96.6%

Positive Predictive Value = 83.8%

κ = “almost perfect”

Radiology: Cardiothoracic Imaging

Free Access

Original Research
Pulmonary Imaging

A Characteristic Chest Radiographic Pattern in the Setting of COVID-19 Pandemic

David L. Smith, John-Paul Grenier, Catherine Batte, Bradley Spieler

Author Affiliations

Published Online: Sep 3 2020 | https://doi.org/10.1148/ryct.2020200280

COVID-19 Diagnosis

Radiology: A Characteristic Chest Radiographic Pattern in the Setting of COVID-19 Pandemic

ACR Statement on Use of Computed Tomography (CT) and Radiography for Suspected COVID-19 Infection

The Fleischner Society - Role of Chest Imaging in Patient Management during the COVID-19 Pandemic: A Multinational Consensus Statement

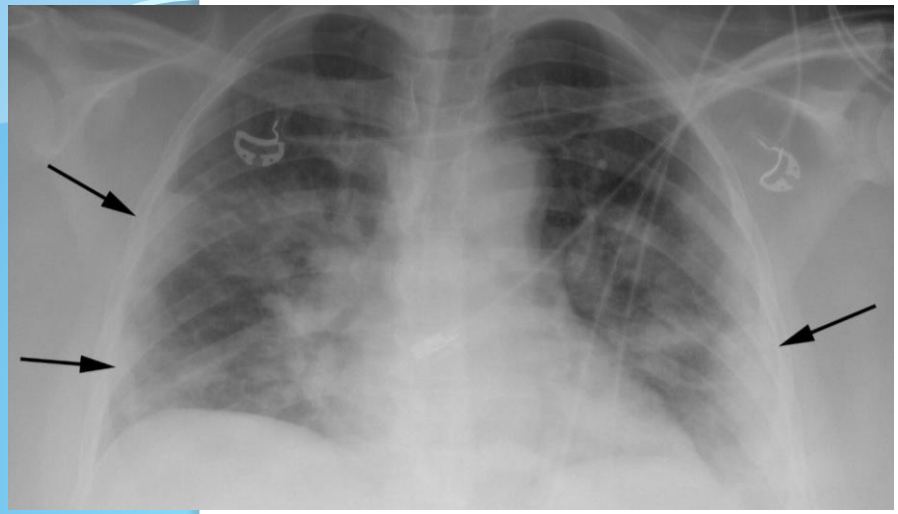
Radiological Society of North America Expert Consensus Statement on Reporting Chest CT Findings Related to COVID-19.
Endorsed by the Society of Thoracic Radiology, ACR and RSNA

Canadian Society of Thoracic Radiology and the Canadian Association of Radiologists' Statement on COVID -19

Royal Australian and New Zealand College of Radiologists - COVID-19 Essential Role of Clinical Radiology Services

(UK) Royal College of Radiologists position on the role of CT in patients suspected with COVID-19 infection

Society for Advanced Body Imaging (SABI) Webinar – COVID-19: Thoracic Imaging Findings and Recommendations



Thank you!

University Medical Center New Orleans
LCMC Health

LSU Health NEW ORLEANS

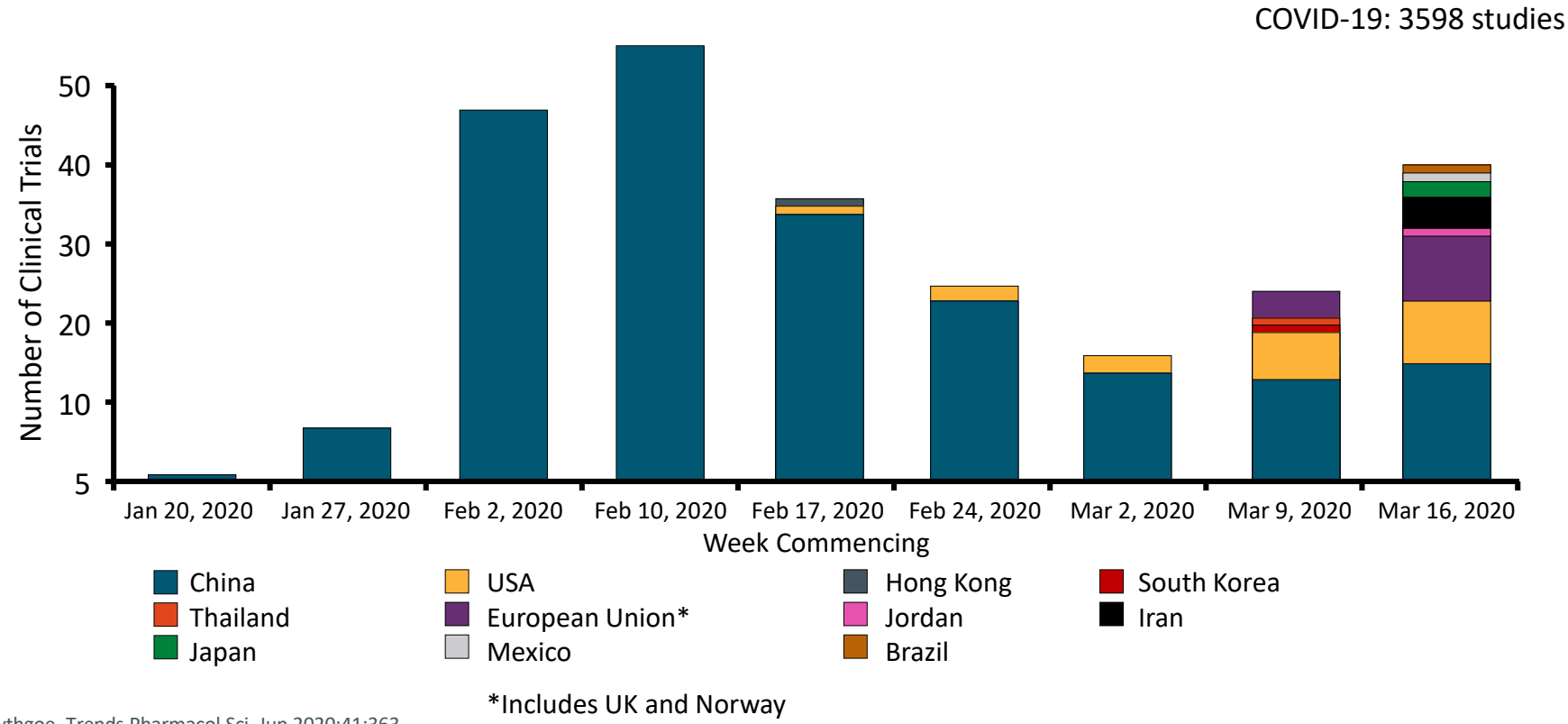
COVID-19 clinical trials that have impacted patient care

Julia Garcia-Diaz, MD, FACP, FIDSA

Director Clinical Infectious Diseases Research

University of Queensland/Ochsner Clinical Schoo

Geographic Distribution of Ongoing Clinical Trials for COVID-19



Lythgoe. Trends Pharmacol Sci. Jun 2020;41:363.

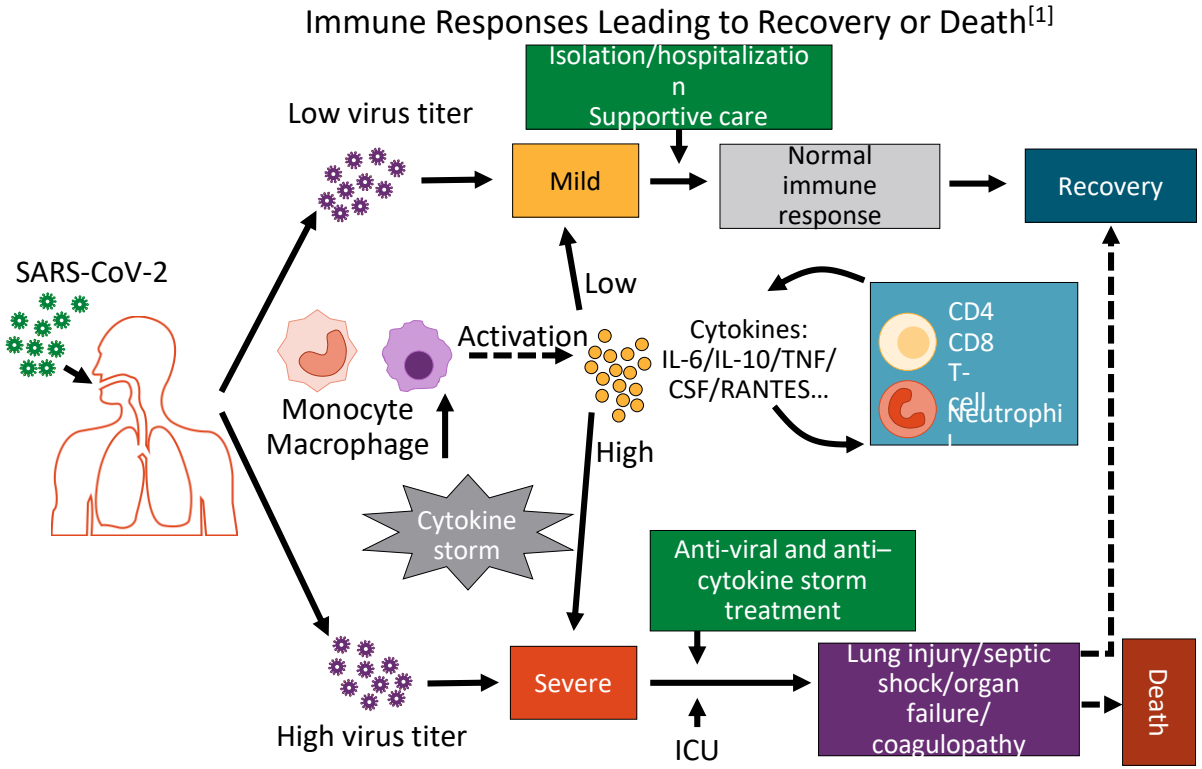
Key Therapeutic Classes Under Investigation for Treatment of COVID-19

Antivirals
Baloxivir
Convalescent plasma
Favipiravir
(Hydroxy)chloroquine
Interferon
Lopinavir/ritonavir
Nitazoxanide
Oseltamivir
Remdesivir
Ribavirin

Immunomodulators
Corticosteroids (eg, dexamethasone)
IL-1 inhibitors (eg, anakinra, canakinumab)
IL-6 inhibitors (eg, tocilizumab, sarilumab)
Intravenous immunoglobulin
JAK inhibitors (eg, baricitinib, ruloxitinib)

Barlow. Pharmacotherapy. 2020;40:416. McCreary. Open Forum Infect Dis. 2020;7:ofaa105. Sanders. JAMA. 2020;323:1824.

Immune Response to SARS-CoV-2



Adequate immune responses[2]

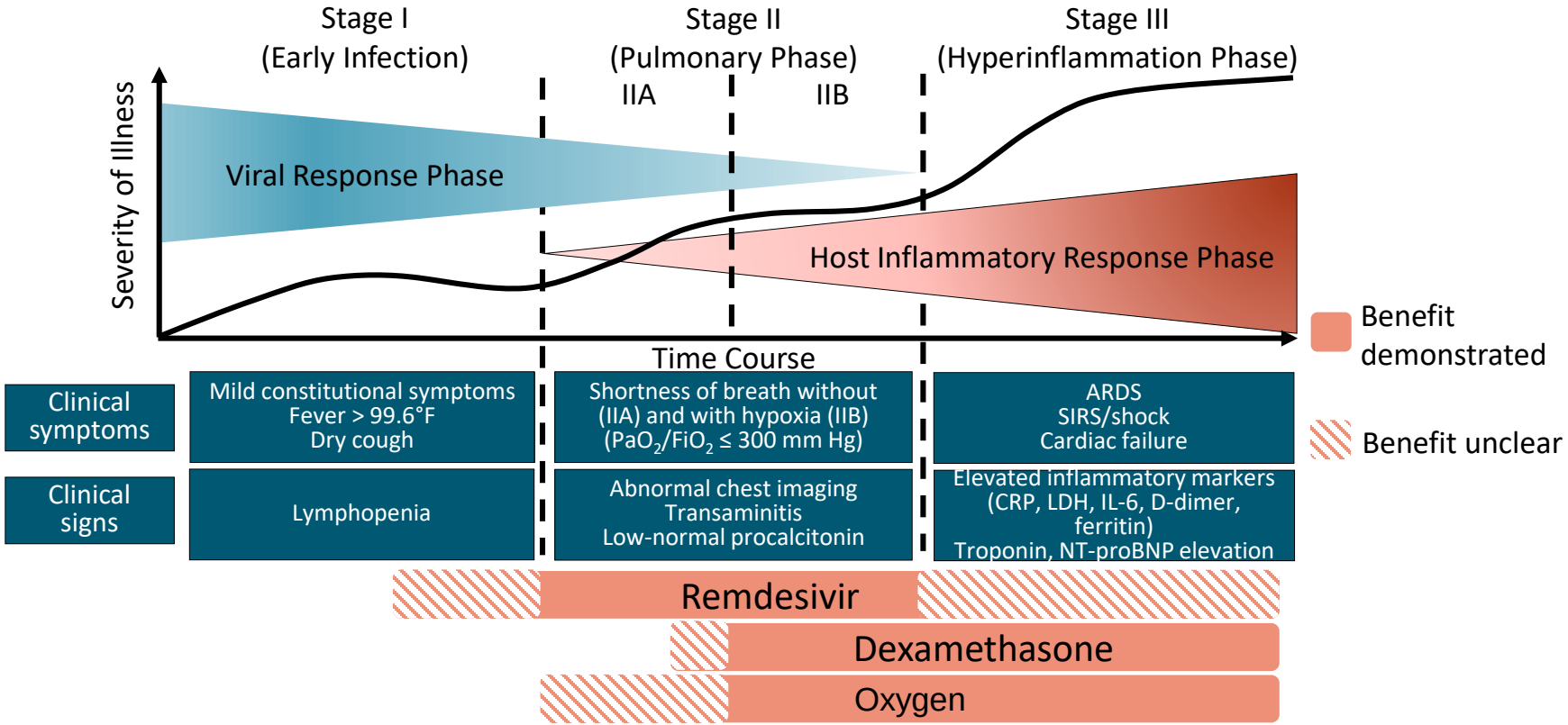
- Timely innate/adaptive responses
- Quick type 1 IFN response
- Activation of efficient antiviral response (clearance by macrophages)
- Activation of Th1 cells and B-cells for production of neutralizing antibodies

Inadequate immune responses[2]

- Delayed/limited type 1 IFN
- Endothelial cell death
- Epithelial/endothelial leakage
- Overactivation/exhaustion T-cells and NK cells
- Accumulation of activated macrophages → cytokine storm

1. Wang. J Leukoc Biol. 2020;108:17. 2. Sokolowska. Allergy. 2020;[Epub].

COVID-19 Therapies Predicted to Provide Benefit at Different Stages



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

Passive Immunization

- Monoclonal Antibodies
  - Produced in laboratories
  - Scalable
- Hyperimmune Immunoglobulins
  - Derived from plasma
  - Standardized product
- Convalescent Plasma
  - Plasma from recovered individuals
  - Batch-to-batch variability
  - Requires blood-type matching

Observational Data From the Expanded Access Treatment Protocol Sponsored by the Mayo Clinic

- Single-arm open-label protocol executed across 2807 acute care facilities in the US (April-July 2020)

  –N = 35,322 adults hospitalized with severe or life-threatening COVID-19 (52.3% ICU; 27.5% on mechanical ventilation)

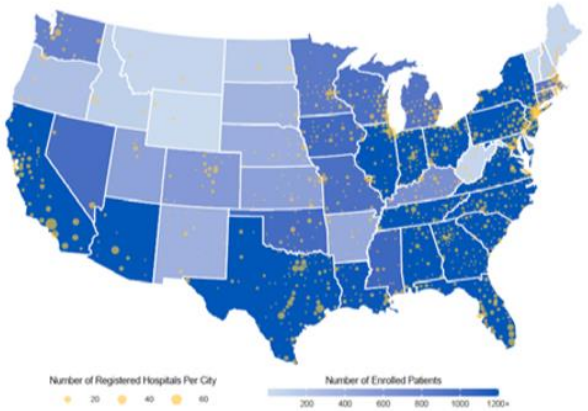
  –Transfused with ≥ 1 unit of human COVID-19 convalescent plasma

- Rates of 7-day mortality

  – **8.7% if transfused within 3 days of diagnosis vs 11.9% if ≥ 4 days (*P* < .001)**

  – 8.9% with “high-titer” plasma, 11.6% with “medium,” 13.7% with “low” (*P* = .048)

- Similar findings seen in 30-day mortality (21.6% vs. 26.7%, p<0.0001).

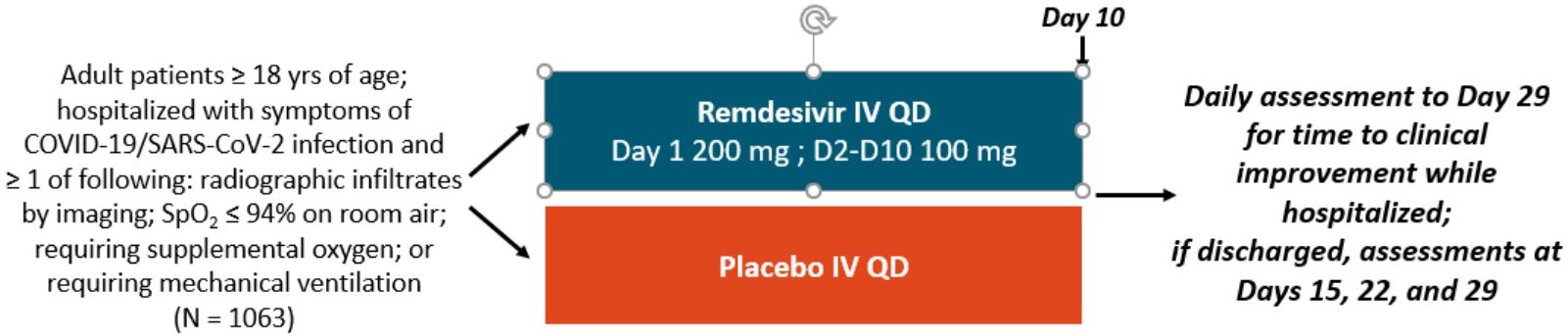


- Safety analysis in 20,000 patients reported serious AEs in < 1% of transfusions
- This data provided evidence that convalescent plasma is safe in hospitalized patients with COVID-19 and suggest earlier administration is more likely to reduce mortality

1. Joyner. May Clin Proc. 2020;95:1888. 2. NCT04338360. 3. Joyner. Mayo Clin Proc. 2020;95:1888.

Adaptive COVID-19 Treatment Trial (NIAID ACTT-1

Multicenter, adaptive, randomized, double-blind, placebo-controlled phase III trial



- Preliminary results from 1059 patients with data available after randomization

Outcome	Remdesivir (n = 538)	Placebo (n = 521)	HR (95% CI)	*P* Value
Median recovery time, days	11	15	1.32 (1.12-1.55)	< .001
Mortality by 14 days, %	7.1	11.9	0.70 (0.47-1.04)	NS

Beigel. NEJM. 2020;[Epub].

GS-US-540-5773: Remdesivir for 5 vs 10 Days for Hospitalized Patients With Severe COVID-19

- Randomized, open-label, multicenter phase III trial

Adults hospitalized with severe COVID-19; positive SARS-CoV-2 RT-PCR < 4 days prior to enrolment; $SpO_2 \leq 94\%$ on room air; pulmonary infiltrates on radiograph (N = 397)

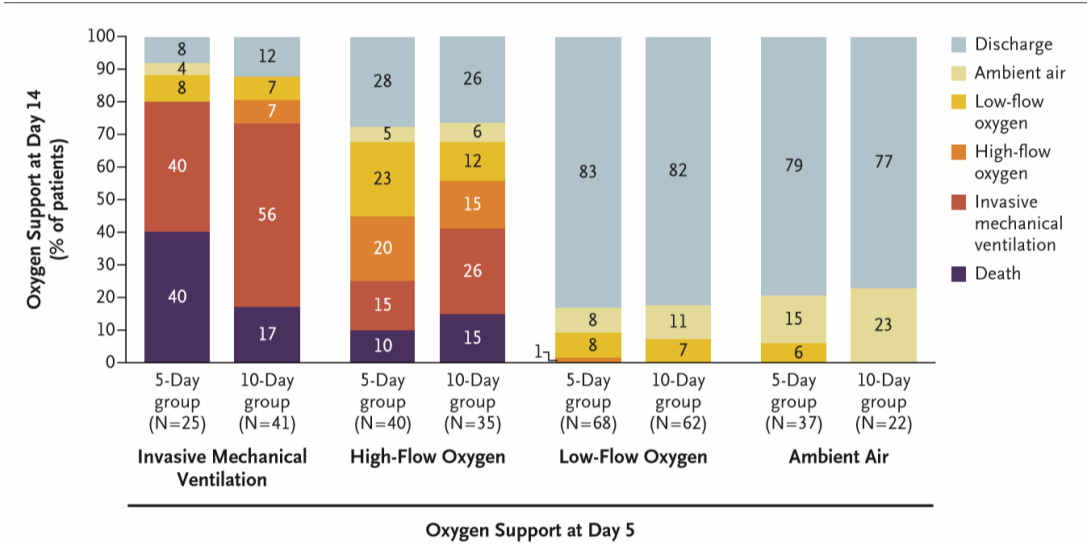
Day 5 | Day 10

Remdesivir
200 mg IV loading dose; 100 mg IV QD

Remdesivir
200 mg IV loading dose; 100 mg IV QD

Supportive therapy at clinician discretion

- 10-day vs 5-day OR for clinical improvement at Day 14: 0.76 (95% CI: 0.51-1.13)



Marks. IAS COVID-19. Abstr 11803.

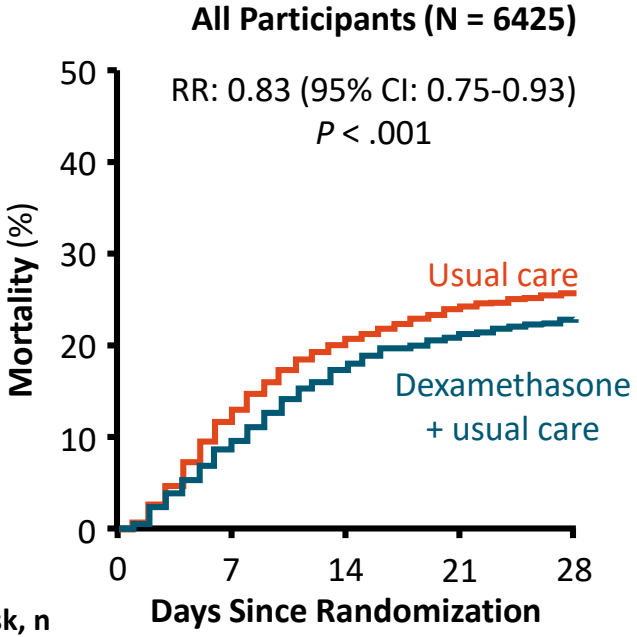
Randomised Evaluation of COVid-19 thERapY (RECOVERY) Trial Among Hospitalized Patients

- Hospitalized patients with clinically suspected or laboratory confirmed SARS-CoV-2
  - Initial recruitment was in patients ≥ 18 yrs of age but age limit was removed on 5/9/2020
- Patients randomized to usual care plus: no additional treatment, **lopinavir/ritonavir, dexamethasone, hydroxychloroquine, or azithromycin**
  - Factorial design with simultaneous allocation to no additional tx vs **convalescent plasma**
  - If progressive disease (hyper-inflammatory state), subsequent randomization to no additional treatment vs **tocilizumab**
- > 11,500 patients enrolled from > 175 NHS hospital organizations in the UK

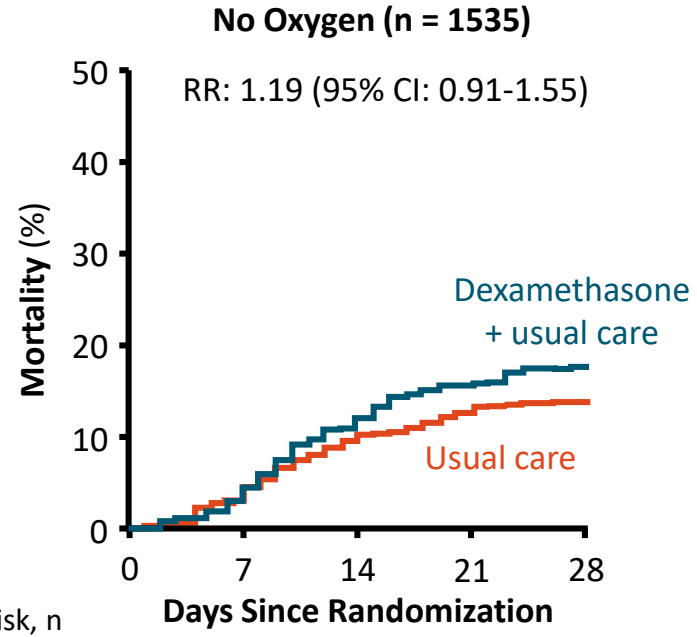
6/8/2020: recruitment to dexamethasone arm halted because sufficient patient numbers enrolled to establish potential benefit

https://www.recoverytrial.net. RECOVERY Collaborative Group. NEJM. 2020;[Epub]. NCT04381936.

RECOVERY Trial: Mortality With Dexamethasone + Usual Care vs Usual Care Alone



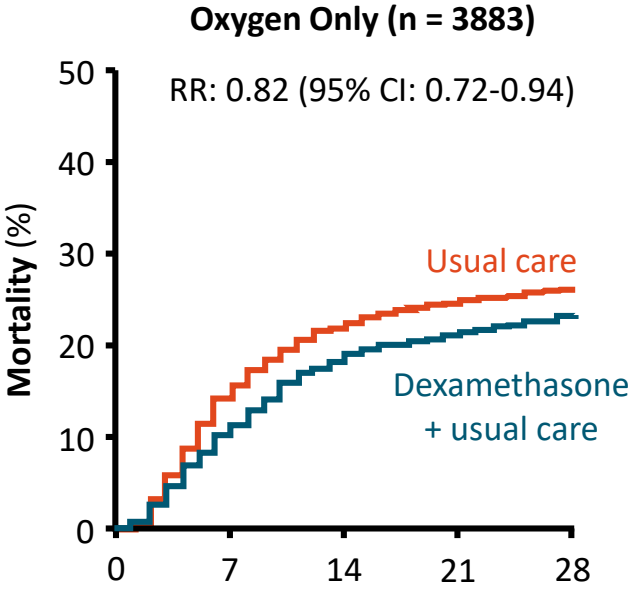
Patients at **Risk, n**					
Dexamethasone	2104	1903	1725	1659	1621
Usual care	4321	3754	3427	3271	3205



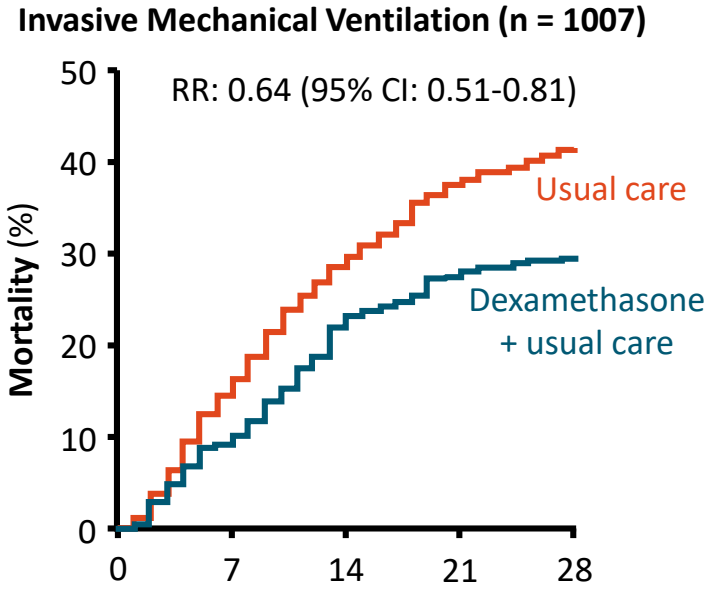
Patients at Risk, n					
Dexamethasone	501	478	441	421	412
Usual care	1034	987	928	897	889

RECOVERY Collaborative Group. NEJM. 2020;[Epub].

RECOVERY Trial: Mortality in Patients on Oxygen or Mechanical Ventilation ± Dexamethasone



Patients at Risk, n					
Dexamethasone	1279	1135	1036	1006	981
Usual care	2604	2195	2018	1950	1916



Patients at Risk, n					
Dexamethasone	324	290	248	232	228
Usual care	683	572	481	424	400

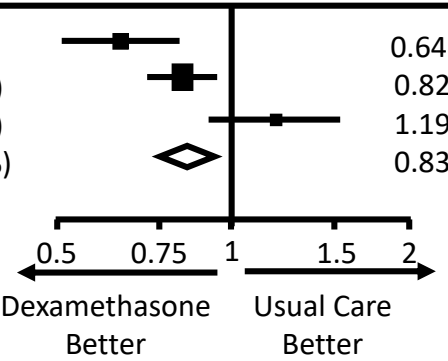
RECOVERY Collaborative Group. NEJM. 2020;[Epub].

RECOVERY Trial: Mortality at Day 28 (Primary Outcome)

- Addition of dexamethasone to usual care associated with **lower mortality** among subsets receiving invasive mechanical ventilation or oxygen alone but not in those receiving no baseline respiratory support

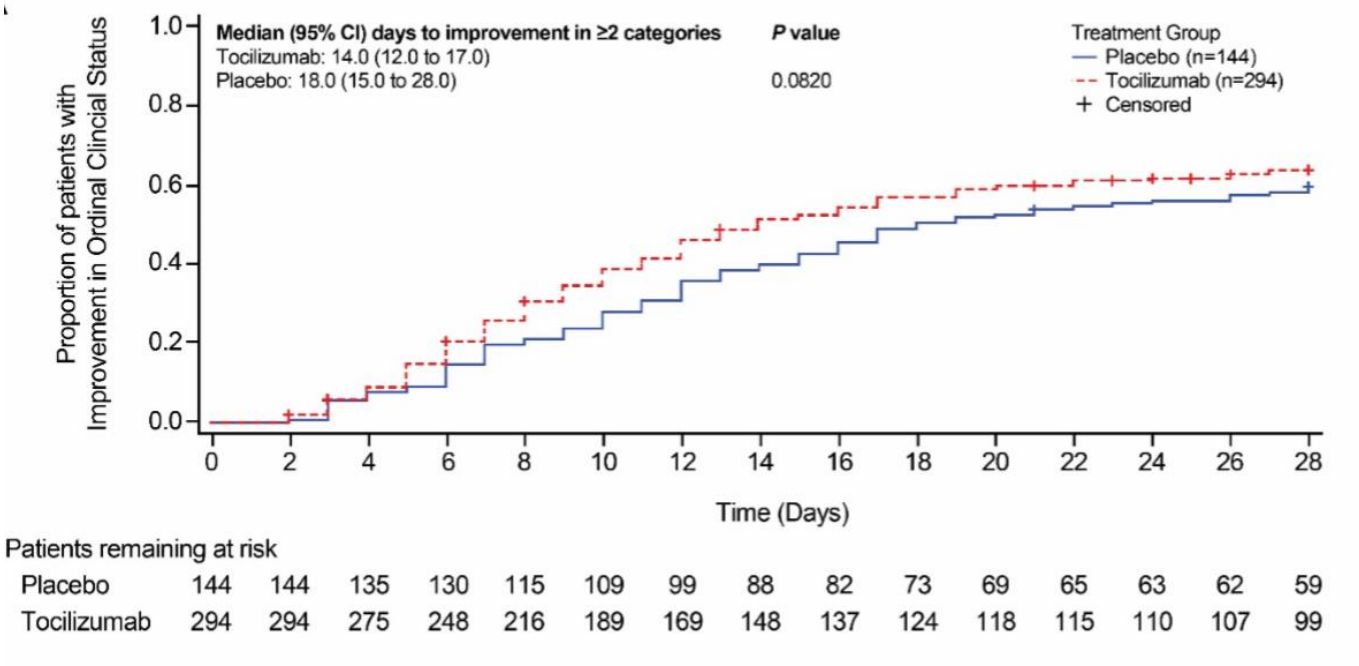
Respiratory Support at Randomization	**Dexamethasone + Usual Care**	**Usual Care Only**	**28-Day Mortality RR (95%CI)**	***P* Value**
Invasive mechanical ventilation	95/324 (29.3%)	283/683 (41.4%)	0.64 (0.51-0.81)	
Oxygen only	298/1279 (23.3%)	682/2604 (26.2%)	0.82 (0.72-0.94)	
No oxygen received	89/501 (17.8%)	145/1034 (14.0%)	1.19 (0.91-1.55)	
All patients	482/2104 (22.9%)	1110/4321 (25.7%)	0.83 (0.75-0.93)	< .001

Chi-square trend across 3 categories: 11.5



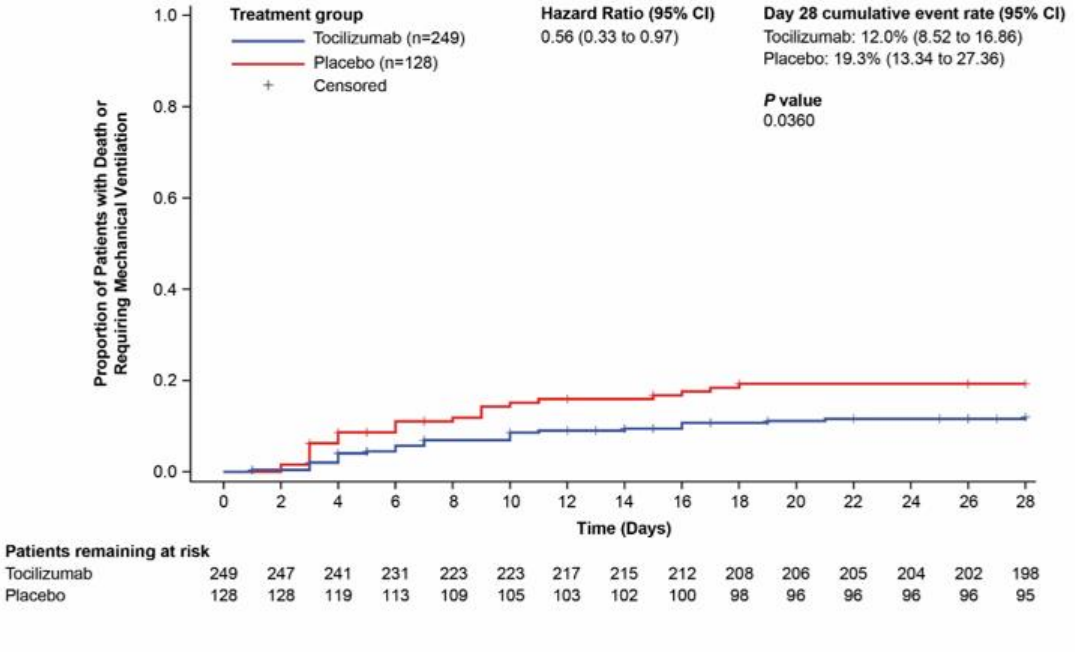
RECOVERY Collaborative Group. NEJM. 2020;[Epub].

COVACTA: Tocilizumab in hospitalized patients with COVID-19 pneumonia



Rosas I, et al. medRxiv 2020.08.27.20183442

EMPACTA (Evaluating Minority Patients with Actemra): Cumulative Proportion Plot of Time to Requiring Mechanical Ventilation or Death by Day 28 (modified-intent-to-treat population)



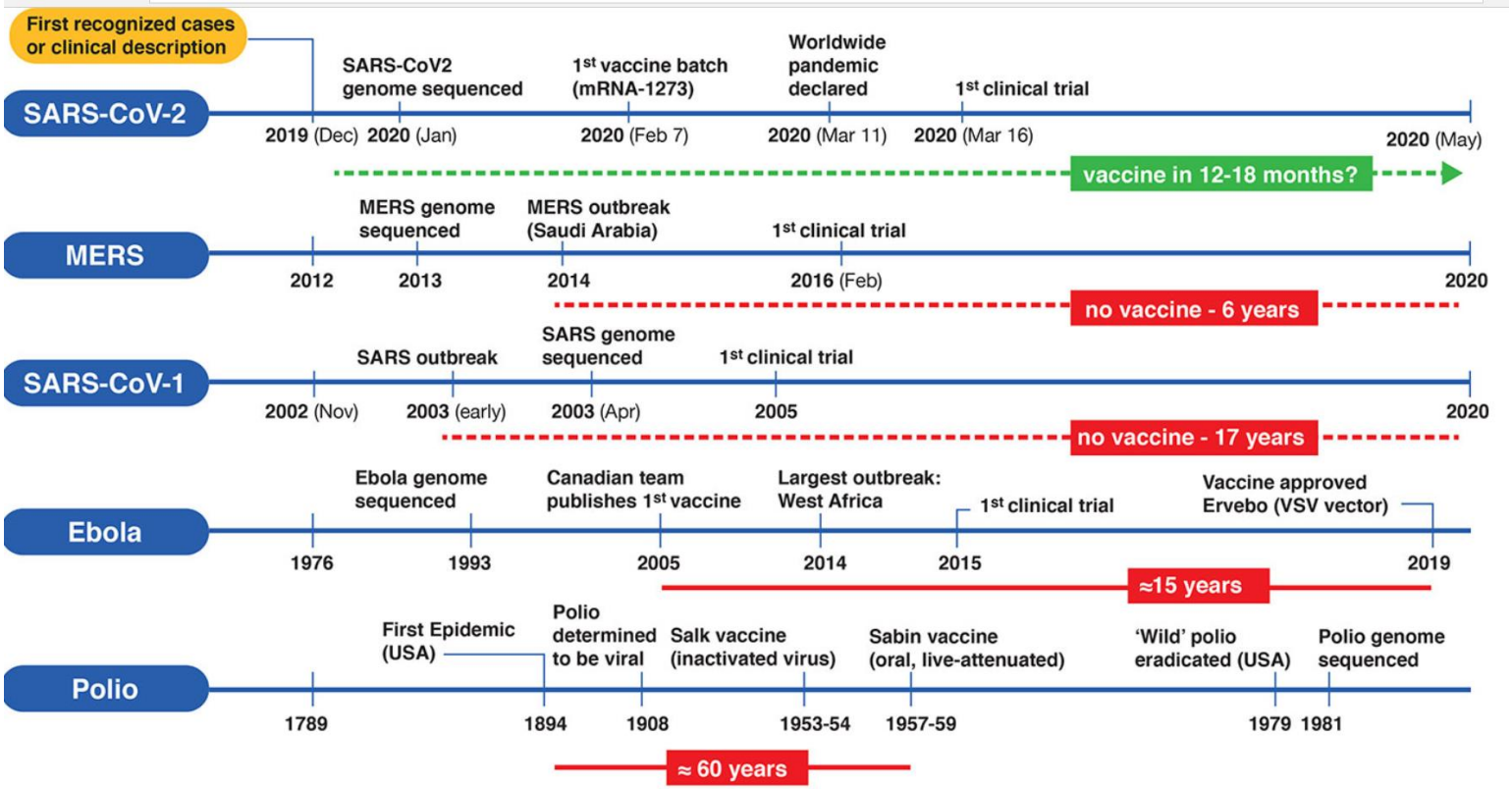
Hispanic/Latino: 56%

Black/African American: 14.9%

American Indian/Alaska Native: 12.7%

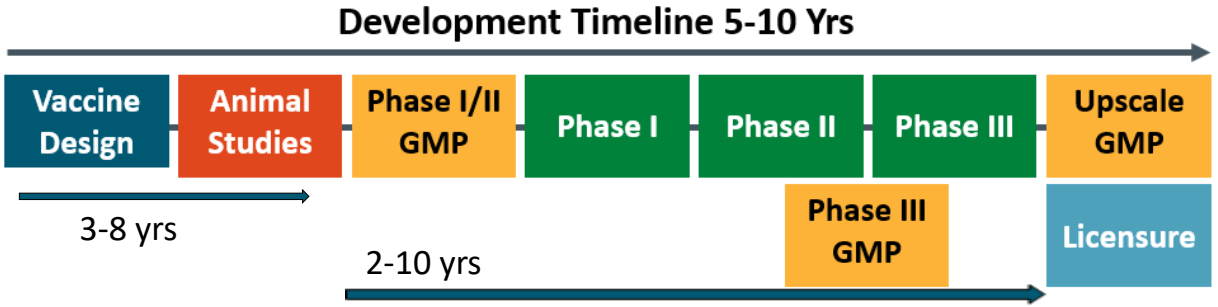
White: 12.7%

Salama C, et al. submitted

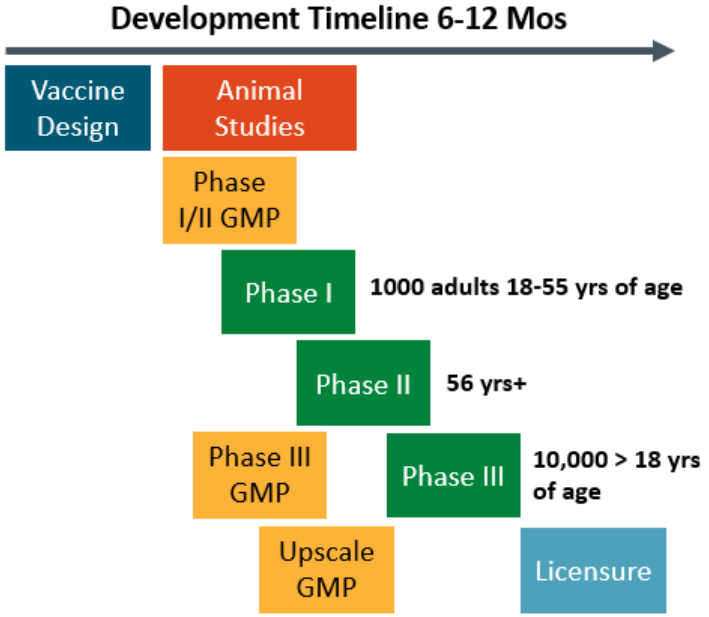


Funk. Frontiers in Pharmacology. 2020; 11:937.

SARS-CoV-2 Vaccine Clinical Trials



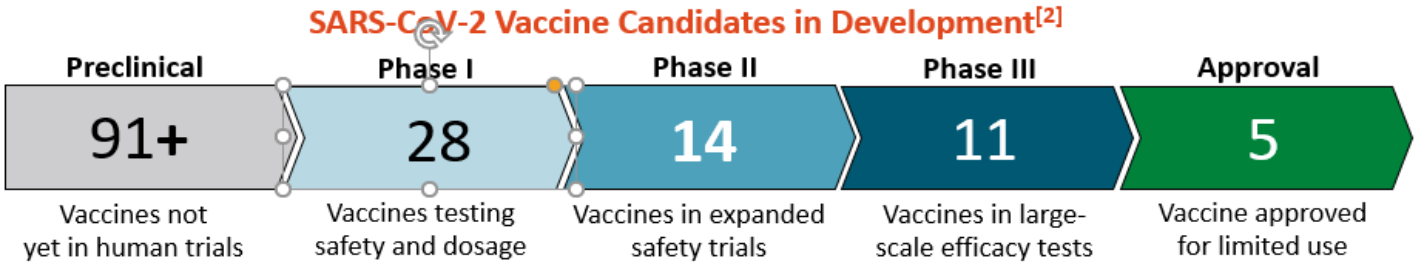
- International trial of Oxford vaccine: United Kingdom (19 sites), Brazil (6 sites), South Africa (6 sites)
- Phase II/III studies started at end of June: South Africa (6 sites, planned enrollment 2000); Brazil (3 sites, planned enrollment 10,000)
- Nonlinear trial progression with highly compressed time scale; first safety and immunogenicity data coming in from several vaccines



Pollard. ECCVID 2020.

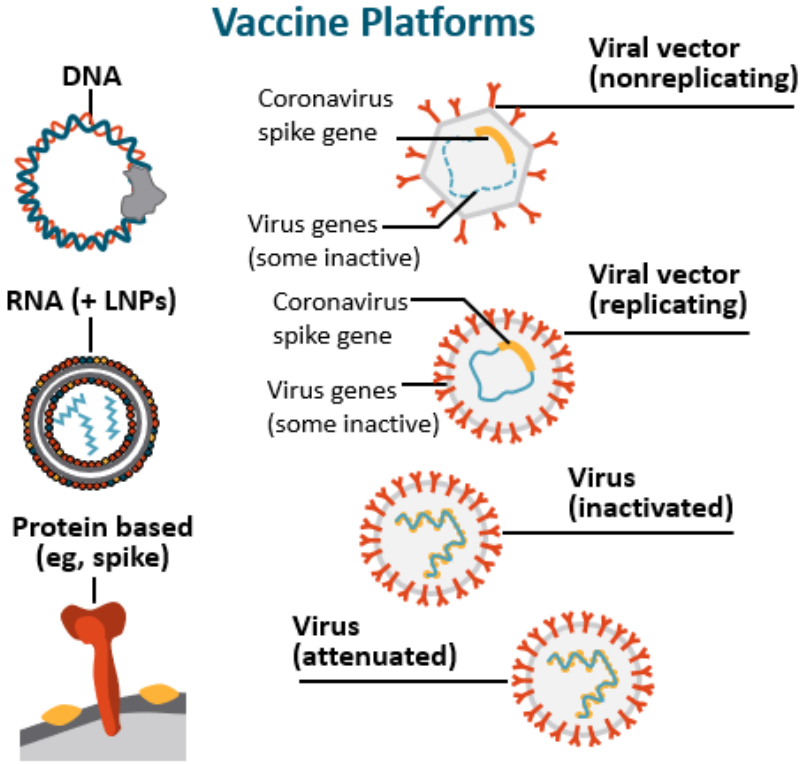
Development of Vaccines Against SARS-CoV-2

- 36 candidate vaccines in clinical development, 146 in preclinical stages[1]
- Anti–SARS-CoV-2 spike protein neutralizing antibody correlates with protection in macaques[2]
- Approaches under evaluation include spike protein nanoparticles with Matrix M, spike protein mRNA in lipid nanoparticles, spike protein DNA, adenovirus vectors (Ad5, Ad26)
- Oxford vaccine: SARS-CoV-2 spike protein in nonreplicating chimpanzee adenovirus (ChAdOx1)[3]



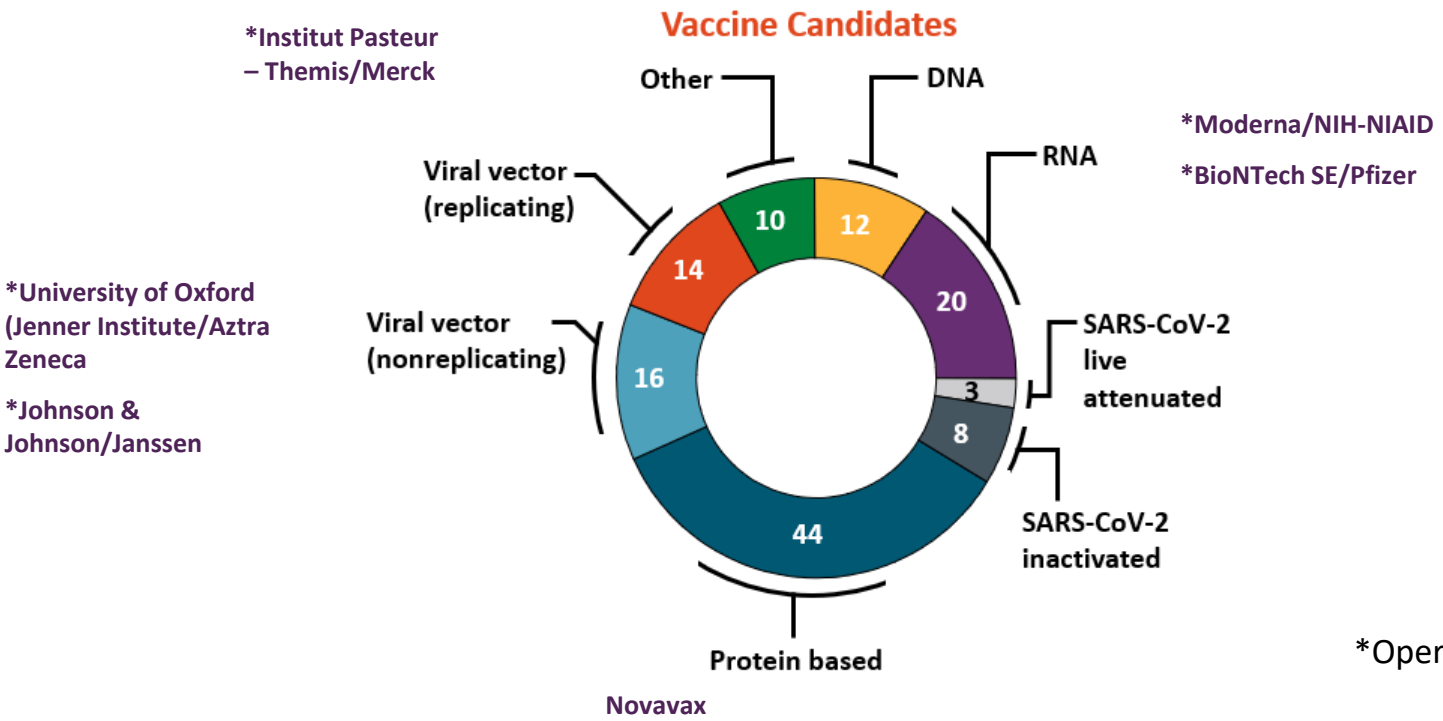
1. https://www.eccvid.org/media-790-news-regarding-covid-19-vaccines. 2. Yu. Science 2020;369:806. 3. Pollard. ECCVID 2020.

Vaccine Candidates in Development for SARS-Cov-2



Funk. Frontiers in Pharmacology. 2020; 11:937.

Vaccine Candidates in Development for SARS-Cov-2



*Operation Warp Speed

Funk. Frontiers in Pharmacology. 2020; 11:937.

Academics Response to Covid-19

G. Dodd Denton, MD MPH

Assistant Dean for Students

Ochsner Clinical School

OBJECTIVES

- At the end of this session, attendees will:
  - Describe options for virtual learning when patient contact is inadvisable
  - Discuss how clinically relevant learning objectives can be met via telephone triage experiences

MARCH 17, 2020 AAMC GUIDANCE

*"The AAMC strongly supports medical schools **pausing all student clinical rotations**, effective immediately, until at least March 31. First and foremost, this temporary suspension will allow medical schools a window of opportunity to develop and implement appropriate programs to fully educate all their students for their return to clinical rotations with (a) up-to-date information on COVID-19; and (b) appropriate steps in place to ensure their own and their patients' safety."*

PAUSED CLINICAL ROTATIONS

Ochsner Health had already prohibited student interaction with COVID-19 patients by March 13 and paused clinical rotations on Friday March 20 for 2 weeks

- Gradual resumption of face-to-face interactions
- Heavy virtual learning (zoom lectures, phone triage, virtual rounding)
- Full face-to-face interactions on pediatrics and psychiatry first, then others
- Complete **prohibition from student interaction with suspected or confirmed COVID-19 patients.**

VOLUNTEERISM DURING PAUSE

Five moderately large volunteer projects spontaneously arose (144 students participated; total of 3650 hours)

- **COVID-19 call center**
- **OB COVID-19 call center**
- **PCR lab**
- **MedVantage Clinic**
- **Family Communication Champions**
  - Students provided a communication bridge between inpatient hospitalists and families of admitted patients

COVID-19 CALL CENTER

Easily the largest volunteer project

Existing outpatient nursing telephone triage hotline rapidly became overwhelmed with COVID-19 calls (3 hour wait times).

From concept to implementation in 36 hours, students started answering calls and doing telephone triage

- 109 medical students volunteered for 1929 hours
- Completed 1958 patient encounters (19% of total calls)
- The average wait time dropped from 18:27 minutes to 1:01 minute

OB COVID-19 CALL CENTER

- Like the primary COVID-19 call center, the OBGYN call center also became overwhelmed with calls.
- Students joined nurse triage line with the following educational objectives
  - Improve effective communication with diverse patient groups
  - Work within a multi-disciplinary team
  - Gain skills in telehealth
  - Practice clinical reasoning around problems during pregnancy and post partum care

PCR LAB

Ochsner established the first in-house PCR testing laboratory for COVID-19 in the state of Louisiana.

Two students with extensive expertise running these PCR machines from their prior PhD work volunteered during the 2-week pause

Total of 254 volunteer hours!

Invaluable resource

MEDVANTAGE CLINIC

- Students joined a special clinic focused on under-served high utilizing patients, helping these patients learn how to do virtual visits
  - Gain skills in patient communication and telehealth
  - Practice screening for depression
  - Perform patient education on health issues, screening for COVID-19 symptoms, and advising patients on the importance of social distancing.

QUICK SHIFT TO VIRTUAL INTERVIEWS

In-person admission interviews became impossible for all medical schools

- Some announced admissions without interviews!

We adopted the Zoom videoconferencing software, including the Zoom breakout room feature

Social distancing, disinfection of interview rooms, and screening of all interviewers prior to entry into the interview space

By the end of June 2020, three full days of virtual interviews with 169 applicants had been completed

Informal comments from interviewers have been positive for both the virtual interviews and the Zoom videoconferencing software.

QUESTIONS?

National Hispanic Medical Association

VIRTUAL CHAPTER POLICY FORUMS

Thursday, September 10: Boston & Phoenix Chapters
Diabetes in the Latino/Hispanic Population–Challenges & Opportunities
7:00 PM - 8:15 PM ET

Wednesday, September 16: Chicago & Indianapolis Chapters
COVID-19 & Diversity in Health Care
7:00 PM - 8:15 PM ET

Wednesday, October 14: New York City & Philadelphia Chapters
COVID-19 Impacts on Latinos & Reflections from the Frontlines
7:00 PM - 8:15 PM ET

Thursday, October 15: Gulf Coast Chapter
Update on Latest Science on COVID-19: Results of Research Trials from Academic Centers in the Region & Response of Medical Training Programs
7:00 PM - 8:15 PM ET

Thursday, October 15: El Paso, Rio Grande Valley, & San Antonio Chapters
Impact of COVID-19 on Border Communities
2:00 PM - 4:00 PM ET

Tuesday, October 20: DC Metro Area Chapter
COVID-19 & Health Literacy
7:00 PM - 8:15 PM ET

Thursday, October 22: Miami Chapter
Physician Activists for Immigrants in Detention Centers
7:00 PM - 8:15 PM ET

Thursday, October 29: Northern & Southern California Chapters
COVID-19, Heart Disease, & Health Care Workforce
6:00 PM - 8:00 PM ET

Learn more about NHMA chapters here: http://bit.ly/NHMAPolicyForums2020