Running a Sleep Lab during COVID

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Conflict of Interest Disclosures for Speakers

☐ 1. I do not have any relationships with any entities **producing, marketing, re-selling, or distributing** health care goods or services consumed by, or used on, patients, **OR**

☒ 2. I have the following relationships with entities **producing, marketing, re-selling, or distributing** health care goods or services consumed by, or used on, patients.

Type of Potential Conflict	Details of Potential Conflict
Grant/Research Support	Sleep SMART trial: Sleep for Stroke Management and Recovery Trial Funded by StrokeNET, University of Michigan REMEDE Trial: Phrenic Nerve Stimulation for Central Sleep apnea, Funded by Respicardia, Dr. Wilbur Su Axovant RVT-102-2002 of nelotarserin, REM Behavior Disorder Trial for symptomatic RBD in LBD, Funded by Axovant Prodromal LBD Research in RBD, with Dr. David Shprecher, Funded by the AZ Alzheimer's Consortium Idiopathic REM Behavior Disorder and the Sleep Profiler, NIH funded grant, Dr. David Shprecher, DO and Dan Levendowski NAPS consortium
Consultant	Jazz Pharmaceuticals, Eisai Neurology
Speakers' Bureaus	Jazz Pharmaceuticals, Harmony Biosciences, Eisai
Financial support	N/A
Other	N/A

☒ 3. The material presented in this lecture has no relationship with any of these potential conflicts, **OR**

☐ 4. This talk presents material that is related to one or more of these potential conflicts, and the following objective references are provided as support for this lecture:

Accreditation Statement

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of The American Academy of Sleep Medicine and The Virginia Academy of Sleep Medicine. The American Academy of Sleep Medicine is accredited by the ACCME to provide continuing medical education for physicians.

Outline

- Overview of the current AASM Mitigation Strategies
- Overview of COVID-19 testing options and strategies
- Discussion of how to implement mitigation strategies into the real world
- Discussion of future challenges and prospects in the COVID pandemic era

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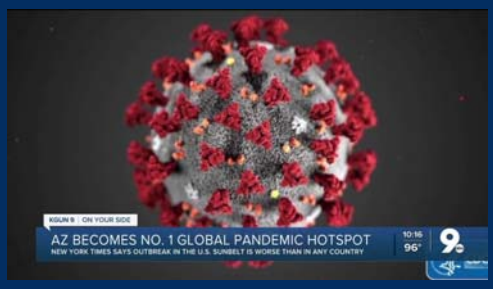

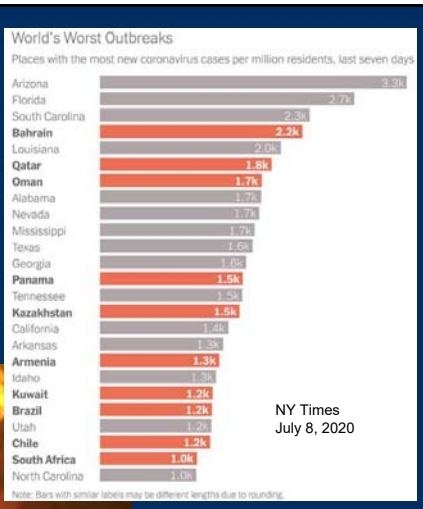

NY Times
July 8, 2020

THE UNIVERSITY OF ARIZONA
College of Medicine
Phoenix

AASM Mitigation Strategies with COVID

- The AASM strongly urges all sleep clinicians to implement the following strategies for the time period recommended for physical distancing by current federal guidance, i.e., until at least April 30, 2020:
- Postpone and reschedule in-lab administration of positive airway pressure (PAP) therapy (i.e., PAP titration studies and split night studies) except in emergencies, in which case, review the potential for aerosolization and ensure technologists use appropriate PPE. Avoid PAP use in the clinic setting due to the risk of aerosolization.
- Postpone and reschedule polysomnogram for children and adults except in emergencies.

https://aasm.org/covid-19-resources/

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AASM- Reopening Mitigation (April 27)

- Beginning May 1, 2020, the AASM advises sleep clinicians to implement the following strategies, depending on the local level of COVID-19 community spread reported by your state department of health and local health department. Sleep clinicians should be prepared to adjust operations as local conditions change, with the expectation that intermittent, short-term restrictions or closures may be needed in response to sudden increases in local community transmission.
- **COMMUNITY TRANSMISSION**
  - **SUBSTANTIAL**
    - **Large-scale community transmission, health care staffing significantly impacted, multiple cases within the communal settings**
  - **MINIMAL TO MODERATE**
    - **Multiple cases of COVID-19 in the community**
  - **NONE OR MINIMAL**

https://aasm.org/covid-19-resources/

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Community Transmission

Continuous monitoring of local prevalence, public health recommendations

	Substantial **Large-scale community transmission, staffing significantly impacted**	**Minimal to Moderate**	**None or Minimal**
PAP in clinical setting	Avoid		Resume as needed
PAP Tx–PSG	Consider empiric PAP	Emergencies only (PPE, AIIR)	
Dx-PSG	Restrict to emergencies; use PPE, SD	If not high risk for severe COVID illness	
Clinic appts	In-person if urgent - use PPE, SD Use telemedicine	If not high risk for severe COVID If no telemedicine option	
Visitors	Restrict and pre-screen		Usual policies
HSAT	Use specified parameters		

https://aasm.org/covid-19-resources/

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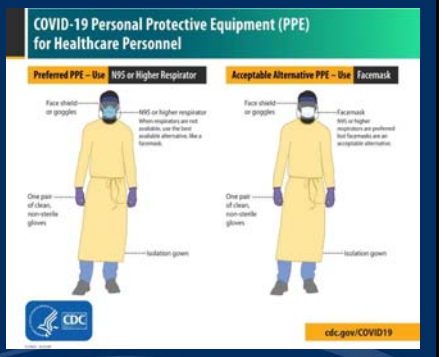
AASM- Reopening Mitigation (April 27)

- Procedures with a higher risk of aerosol transmission, such as positive airway pressure (PAP) titration, should be done with great caution, and staff should utilize appropriate PPE such as N95 respirators, gloves and face shields. Personnel with expected use of N95 respirators will need fit testing prior to use in accordance with OSHA 1910.134.
- Follow CDC's transmission based-precautions.



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Majority of the country

What will we do?

How will our labs survive financially?

How will we reschedule all these patients?

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Restarting in-lab Sleep testing

Checklist
- ✓SCREENING
- ✓INFECTION CONTROL
- ✓PPE
- ✓TESTING (COVID TESTING)

PNEUMONIC “SIP T”

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SCREENING

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Screening Patients and Staff

- **Patients** (symptoms, temperature, testing)
  - Pre-appointment
  - At time of appointment

- **Staff**
  - Temperature checks twice a day → send home if ↑
  - Flexible and/or reduced scheduling (some staff w/illness or quarantine)
  - Rest breaks if reduced staffing
  - Sick leave policies consistent with public health policies. Advise not to report to work when they are ill
    - -10 d of + COVID test; 20 d if IMC or hospitalized

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INFECTION CONTROL

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Infection Control

- Designate staff member to monitor state, local health dept updates (lab manager)
- Promote physical distancing
  - On-site (waiting rooms; check-in/checkout; spacing chairs; limit pt volumes; limit face-to-face time; instruct in advance)
  - Limit visitors
  - Implement online translation services
- Place signs
  - hand hygiene, respiratory hygiene, cough etiquette
- Ensure available, accessible PPE
- Review infection control procedures with staff frequently (CDC, manufacturers)

https://aasm.org/covid-19-resources/covid-19-mitigation-strategies-sleep-clinics-labs

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PROPER PPE

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Personal Protective Equipment (PPE)

- Actively monitor and secure PPE supplies
- At all times:
  - Staff: surgical face masks, N95
  - Patients: cloth covering or own surgical masks
- Follow state and federal guidelines regarding PPE use
- PAP: potential aerosol production
  - N95, gloves, gowns, face shields
  - Fit-test N95 respirators (OSHA 1910.134)

https://aasm.org/covid-19-resources/covid-19-mitigation-strategies-sleep-clinics-labs

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TESTING (COVID TESTING)

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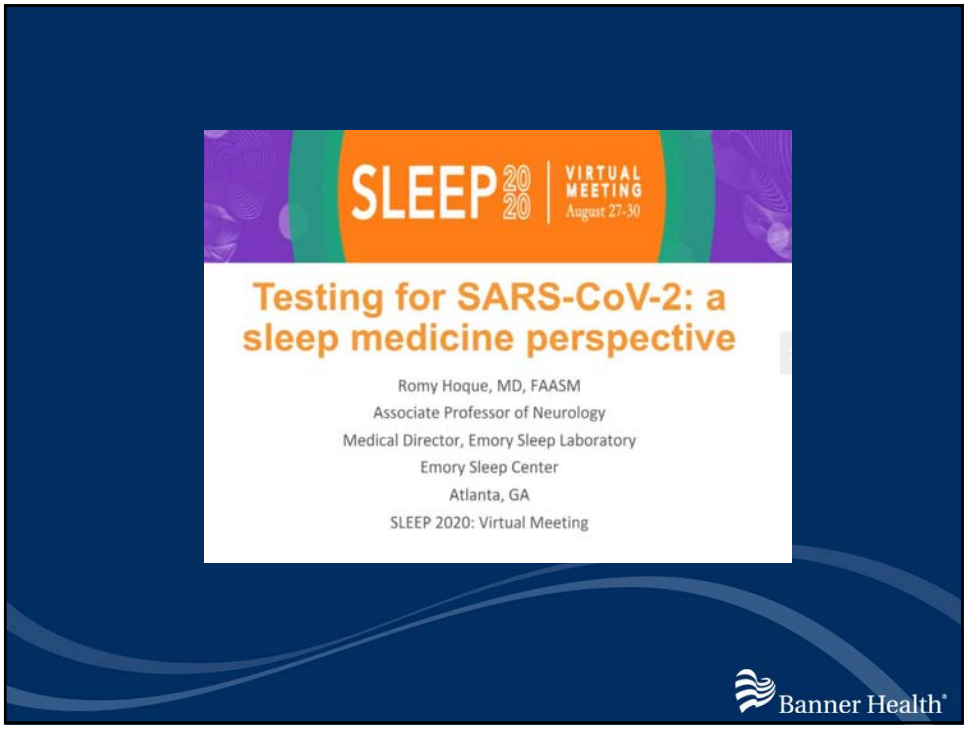

COVID-19 Testing: A Brief Overview

Two categories of testing

1) **Molecular diagnostic testing: detects amplified viral RNA**
   - **Nucleic acid amplification testing (NAAT)**
     - Reverse-transcriptase polymerase chain reaction (RT-PCR)
       - » Runtime: 1-3 hours
       - » Results take 1-3 days (longer in some areas)
       - » GOLD STANDARD
     - Other NAAT testing via Abbot ID now
       - » Runtime: 15 minutes
       - » Sensitivity compared to RT-PCR-50-80%
   - **Antigen testing** (rapid diagnostic testing), e.g Sofia SARS Antigen FIA
     - » Runtime: 15 minutes
     - » Detects non-amplified viral surface protein
     - » Immediate results, less sensitive than RT-PCR at low viral load
     - » Sensitivity compared to RT-PCR: 80%

2) **Serology testing: aka antibody testing**
   - Runtime: 4 hours
   - Does not detect virus, does not determine infectivity

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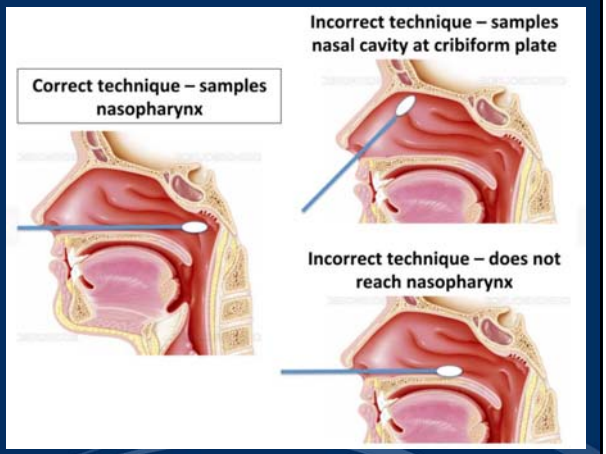
Nasopharyngeal Swab (NPS) technique

- Preferred method
- Per CDC, detection of SARS-CoV-2 viral RNA is better in narsopharynx samples vs throat samples
- Technique is important in lowering false negative tests



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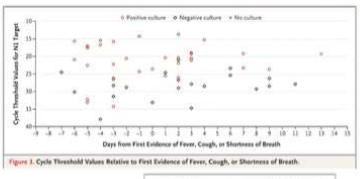
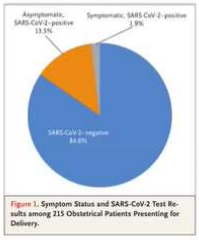
Who and When to Test for COVID

Asymptomatic Transmission

- Incubation period
  - Average 5 days, Range 1-14 days
- Window of Infectivity
  - 6 days prior – 9 days after sx onset
  - Peak 1-3 days prior to symptoms
- Mostly presymptomatic, ? asymptomatic transmission
- WA nursing home
  - 56% of PCR positive patients had no symptoms
- NYC All OB admissions
  - 15.4% positive- only 1.9% symptoms





Zou 2020 NEJM 382(12)
Li Science 2020
Ai Radiology 2020 Feb 26
Sutton NEJM 2020
Wei Morbidity and Mortality Weekly Report 2020 69 (14)
WHO Transmission Report 2 April 2020
Gandhi NEJM 2020
Arons NEJM 2020

Slide courtesy of Karin Johnson, MD, Yale Grand Rounds

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Can we trust negative testing?

- Analytic sensitivity
  - RT-PCR tests: 95%
  - Tested 239 COVID + samples — Sensitivity
    - CDC test — 100%
    - Abbott ID Now rapid testing — 85.2%
    - DiaSorin Simplexa — 89.3%
    - Roche cobas SARS-CoV2 test — 96.5%
    - Cepheid Xpress — 98.2%
  - 3.2% First negative test (183/5700 patients in NYC)
- Clinical sensitivity
  - 66-80% sensitivity of RT-PCR compared to Chest CT

Unpublished-Procop-Cleveland Clinic
Richardson JAMA 2020
Yang MedRxiv 2020 Feb 17

Slide courtesy of Karin Johnson, MD, Yale Grand Rounds

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Testing in previously + COVID pts

- What do you do with referrals for an in-lab PSG in those who have tested RT-PCR + for SARs-CoV-2 in the past but are currently asymptomatic?
- Per CDC guidelines, updated 7/7/20
- In persons recovered from COVID infection, a + RT-PCR during the 90 days after illness onset likely represents persistent shedding of the viral RNA rather than re-infection
  - Repeat testing is not useful
  - Recommendations: wait 10 days after + testing or 20 days after hospital discharge to ensure the pt is outside the infection window

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Other Considerations/Strategies

- HST's -- Reusable devices
  - Disinfect based on CDC/manufacturer's instructions
  - Consider removal from service for ≥72 hours
  - Disinfection before next use (use appropriate PPE)
- Consider fully disposable devices or components
- Service model that promotes physical distancing (e.g., mail delivery)
- Instruction via brochures, video or telemedicine

https://aasm.org/covid-19-resources/covid-19-mitigation-strategies-sleep-clinics-labs/

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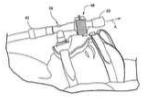
More considerations

Can we and should we try to minimize virus in air dispersion by PAP?



Infection control for nonvented mask
Patent CN1893994A

- Pre-exhalation filter setup
  - Will suboptimal non-vented mask options just increase leak around the mask negating the protection?
- Airborne Infection Isolation room (AIIR) for PAP (AASM rec)
  - Negative pressure rooms
  - HEPA filters in rooms

- Kryger & Thomas JCSM 2020
- Rutula Infect Control Hosp Epidemiol 1995 16(7): 391
- Mead Annals of Emergency Medicine 2004 44(6): 635
- Airborne Infectious Disease Management: Methods for Temporary Negative Pressure isolation www.health.state.mn.us/communities/ep/surge/infectious/airbornenegative.pdf

Ortolano et al. Filters reduce the risk of bacterial transmission from contaminated humidifiers used with CPAP for OSA. JCSM 2007 3 (7): 700-705

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Ongoing Factors that Determine your Mitigation Strategy

- Following COVID-19 Transmission levels
- COVID-19 viral testing capability
- PPE availability

- Risk management considerations
- Hospital Infection control regulations/policies

https://aasm.org/covid-19-resources/covid-19-mitigation-strategies-sleep-clinics-labs

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What do we do with the kiddos?

Pediatric Sleep Studies

- Should non-emergent kids get studies? When?
- Can home studies be used for kids? Down to what age?
- Is COVID-19 viral testing available and will it be too traumatic?
- Should parents get tested for COVID-19 virus too?
- Will kids be scared of techs in full PPE?

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Our Protocol

Joyce.lee-iannotti@bannerhealth.com

Banner University Medicine

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POLICY and PROCEDURE

TITLE: Center for Sleep Disorders: Referrals COVID-19 Workflow			
Number:		Version:	
Type: Administrative		Author:	
Effective Date: 05/21/20	Original Date: 05/20/20	Approval Date: 05/21/20	Deactivation Date:
Facility:			
Population (Define): Sleep Lab Staff			
Replaces:			
Approved by: Medical Director			

Patient Acceptance

Purpose To standardize method of referral from physicians and set criteria for patient acceptance to the Banner Health Sleep Centers.

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Policy

1. Referrals to the center will be made on a referral form and must be signed by the referring provider. The signed referral must NOT be older than 90 days from the date of signature to the date of study.
2. Patients may be directly referred to the sleep facility without the consultation of the Sleep Specialist prior to or within the three months following a sleep study ordered by a referring physician.
3. The Sleep Specialist will review all orders to determine if a patient should have a consult with the Sleep Specialist prior to a study. The Sleep Specialist will review all direct referrals to determine if the proposed evaluation conforms to the established AASM Practice Parameters, or if not, whether the evaluation is indicated for other reasons. The physician will complete and sign the chart review form or initial in the lower right corner of the referral that this has been reviewed to evidence compliance. The completed chart review form will be scanned into the medical record for each patient.
4. The facility will comply with the AASM "Practice Parameters for Indications for Polysomnography and Related procedures."
5. The patient will be tested with the approval of the Sleep Medical Director.
6. Indications for referral to Sleep Center:

Daytime sleepiness
Obstructive sleep apnea
Snoring
Narcolepsy with/without cataplexy
Witnessed apnea

Restless leg syndrome
Sleeping/napping during the day

Periodic leg movement disorder
Falling asleep while driving
Hypersomnia unspecified
Morbid obesity
Sleep related movement disorder unspecified

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Policy,
(continued)

7. The sleep center scheduler will call the patient to schedule their sleep study. Appointments will be staggered 10 minutes apart.
8. If the patient is referred for an in-lab split or titration study, the patient will also be scheduled for COVID testing. The sleep scheduler will schedule this appointment through Clockwise at a BUC (Banner Urgent Care) 72 hrs. prior to the sleep study appointment. Diagnostic studies with No PAP are not required to do COVID testing. A recommendation will be made to all potential PAP patients to self-isolate 72 hrs. prior to the sleep study after the COVID testing.
9. Twenty-four hours prior to the sleep study the scheduler will check Cerner for the COVID PCR results.
    - If the result is negative, the patient will continue with the sleep study.
    - The scheduler will ask the patient the COVID screening questions on the phone at time of confirmation and document them in Cerner.
    - If the result is positive, the sleep study will be cancelled. The referring provider and patient will be notified.
    - If the result is positive the patient can be rescheduled for the sleep study 14 days out if asymptomatic and 28 days out if symptomatic. They will be required to go through COVID testing again 72 hrs. prior to the rescheduled study.

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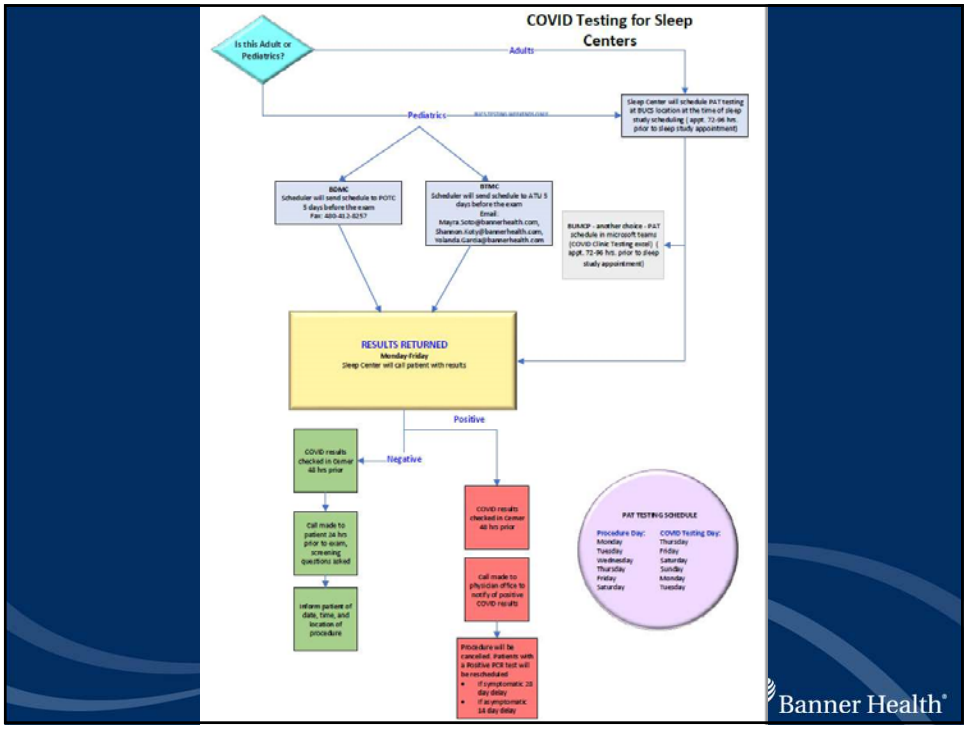

Banner PPE protocol:

- ✓ Doning and Doffing outside patient rooms
- ✓ N95 masks 3 nights in a row (unless soiled)
- ✓ Face shields wiped down with saniwipes after each patient
- ✓ PPE stored in brown bags in personal lockers

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10. The patient will arrive at the sleep center. If another patient is in the check-in area the patient will be asked to wait in their car until called to come in.
11. All Technologist will wear a surgical mask at the time of patient arrival. One mask per patient will be used. The mask will be placed in a paper bag (bag labeled with patient name) on a table outside of the patient room when the technologist is not in the patient room. The table outside of the patient room should include disinfectant wipes, the mask in the paper bag, and gloves.
12. A new set of gloves will be used each time the technologist greets/enters the patient room.
13. Once the patient is in the check-in area the technologist will ask the COVID screening questions again and the patient temperature will be taken. If the patient has symptoms or the temperature is over 100 F the patient will be asked to reschedule the sleep study.
14. If the patient is asymptomatic and doesn't have a fever they will be escorted to their room to proceed with the study.
15. The waiting area, pens, clipboards, doorknobs, furniture, printer (anything the patient touched) will be wiped down with a CDC approved disinfectant prior to the next patient arriving. Cleaning will be done according to the disinfectant's manufacturer recommendation.
16. After the study is finished, the patients will leave the center one at a time. After each patient leaves, the doorknobs and anything the patient touched will be wiped down with disinfectant.
17. The patient room furniture, doorknobs, and equipment will also be wiped down with disinfectant.
18. All paper referrals will be scanned into the patient's electronic medical record.
19. Patients will be excluded from direct referral or a laboratory-based sleep diagnostic study for reasons of medical instability, infection control issues, lack of medical necessity, or other issues identified by Medical Director on a case-by-case basis.
20. Age of patients served is facility dependent and ranges from newborn and greater.
21. Patients will be accepted as outpatients only. The Sleep Center will not take patients from the inpatient units or as a direct admit from the unit as we need all patients to be safe, medically stable, scheduled in advance, and established back to their sleep routine post hospitalization.
22. Patients who are in legal custody are not appropriate for the Sleep Center as appropriate studies cannot be accomplished with restraints.

COVID TESTING

INFECTIOUS DISEASES	09/24/2020 19:47 MST	09/24/2020 19:45 MST	05/09/2020 12:40 MST
BACTERIAL CULTURES			
Blood Culture			
VIRAL DIRECT DETECTION			
COVID-19 Patient Symptomatic?	Unknown *	No (Pre procedure	Yes
Source (NP Swab, OP Swab, Lower Resp)		NP Swab *	NP Swab
Coronavirus (COVID-19) SARS-CoV-2 RNA		Not Detected *	Detected * A
Coronavirus (COVID-19) SARS-CoV-2 IgG	Positive * A		

Event Date	Event	Result	Ref. Range	Trend
09/28/2020 15:39 MST	COVID-19 Patient Symptomatic?	No (Pre procedure test)		Trend
	COVID-19 Patient Symptomatic?	Unknown *		Trend
	Source (NP Swab, OP Swab, Lower Resp)	NP Swab *		Trend
	Coronavirus (COVID-19) SARS-CoV-2 RNA	Not Detected *	(Not Detected -)	Trend
	Coronavirus (COVID-19) SARS-CoV-2 IgG	Negative *	(Negative -)	Trend

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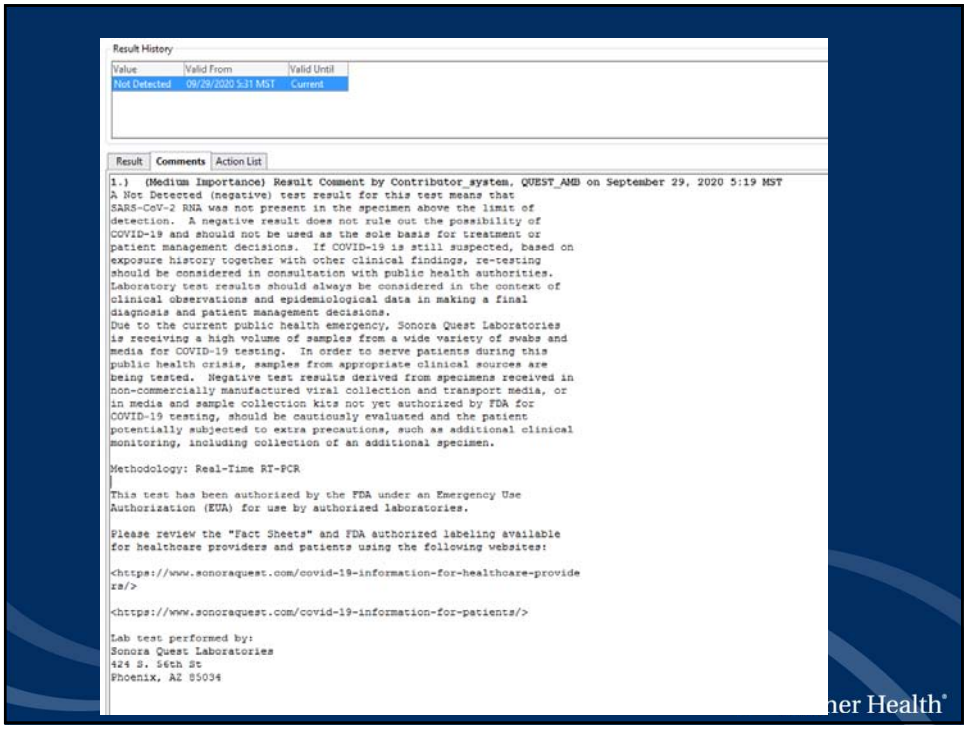

Result History

Value	Valid From	Valid Until
Not Detected	09/29/2020 5:31 MST	Current

Result | Comments | Action List

1.) (Medium Importance) Result Comment by Contributor_system, QUEST_AMB on September 29, 2020 5:19 MST
A Not Detected (negative) test result for this test means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection. A negative result does not rule out the possibility of COVID-19 and should not be used as the sole basis for treatment or patient management decisions. If COVID-19 is still suspected, based on exposure history together with other clinical findings, re-testing should be considered in consultation with public health authorities. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions.
Due to the current public health emergency, Sonora Quest Laboratories is receiving a high volume of samples from a wide variety of swabs and media for COVID-19 testing. In order to serve patients during this public health crisis, samples from appropriate clinical sources are being tested. Negative test results derived from specimens received in non-commercially manufactured viral collection and transport media, or in media and sample collection kits not yet authorized by FDA for COVID-19 testing, should be cautiously evaluated and the patient potentially subjected to extra precautions, such as additional clinical monitoring, including collection of an additional specimen.

Methodology: Real-Time RT-PCR

This test has been authorized by the FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories.

Please review the "Fact Sheets" and FDA authorized labeling available for healthcare providers and patients using the following websites:

<https://www.sonoraquest.com/covid-19-information-for-healthcare-provide rs/>

<https://www.sonoraquest.com/covid-19-information-for-patients/>

Lab test performed by:
Sonora Quest Laboratories
424 S. 56th St
Phoenix, AZ 85034

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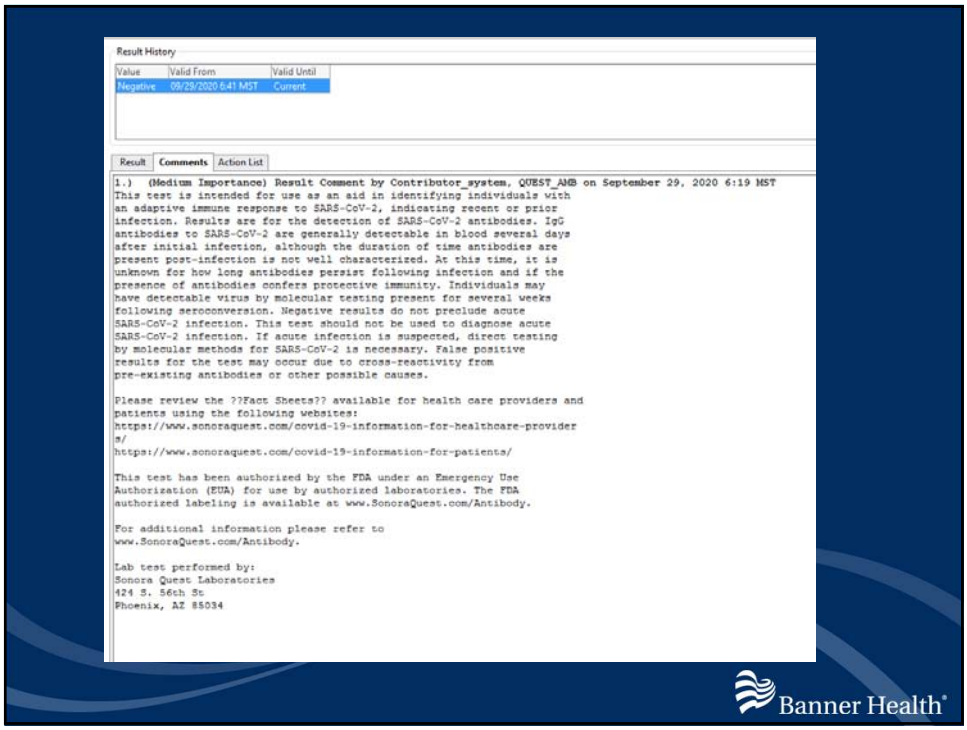

Result History

Value	Valid From	Valid Until
Negative	09/29/2020 6:41 MST	Current

Result | Comments | Action List

1.) (Medium Importance) Result Comment by Contributor_system, QUEST_AMB on September 29, 2020 6:19 MST
This test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Results are for the detection of SARS-CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Individuals may have detectable virus by molecular testing present for several weeks following seroconversion. Negative results do not preclude acute SARS-CoV-2 infection. This test should not be used to diagnose acute SARS-CoV-2 infection. If acute infection is suspected, direct testing by molecular methods for SARS-CoV-2 is necessary. False positive results for the test may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

Please review the ??Fact Sheets?? available for health care providers and patients using the following websites:
https://www.sonoraquest.com/covid-19-information-for-healthcare-provider s/
https://www.sonoraquest.com/covid-19-information-for-patients/

This test has been authorized by the FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories. The FDA authorized labeling is available at www.SonoraQuest.com/Antibody.

For additional information please refer to www.SonoraQuest.com/Antibody.

Lab test performed by:
Sonora Quest Laboratories
424 S. 56th St
Phoenix, AZ 85034

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Revised Scheduling protocol

- If the patient is an adult and a Split/HSAT was ordered the scheduler will look for the below diagnoses. If any of these are present, the patient will be rescheduled for an in-lab study in May 2020 or later.
  - O2 dependence
  - Severe comorbid COPD
  - Severe comorbid CHF
  - Neuromuscular disease
  - -BMI 55
  - -Recent seizures
- If the above comorbidities are not present and the patient is a candidate for a HSAT, the patient will be offered an HSAT. If the patient prefers an in-lab study they will be rescheduled for the in-lab.
- If the patient is an adult and an in-lab study was specifically ordered the chart will be reviewed by a medical director to see if the HSAT is an option.
- If patient is deemed an appropriate HSAT candidate, the ordering provider will be notified for a new HSAT order.
- Patients ordered as a titration study:
- The ordering physician will be contacted to consider cancelling the in-lab titration and starting an AutoPap device. If the ordering provider is not comfortable ordering a PAP device a sleep medicine consultation should be suggested. If the ordering provider feels the PAP titration is still needed, the patient should be rescheduled for a later date.
- All charts will be reviewed by the medical director prior to the patient coming in for the study

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Various home sleep study devices

Resmed Apnea Link

Watch PAT

THE UNIVERSITY OF ARIZONA College of Medicine Phoenix

Plexiglass installment for techs during HST tutorial

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HST drop box

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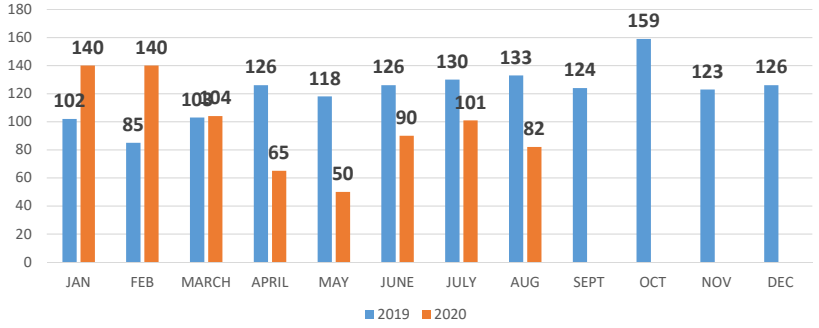
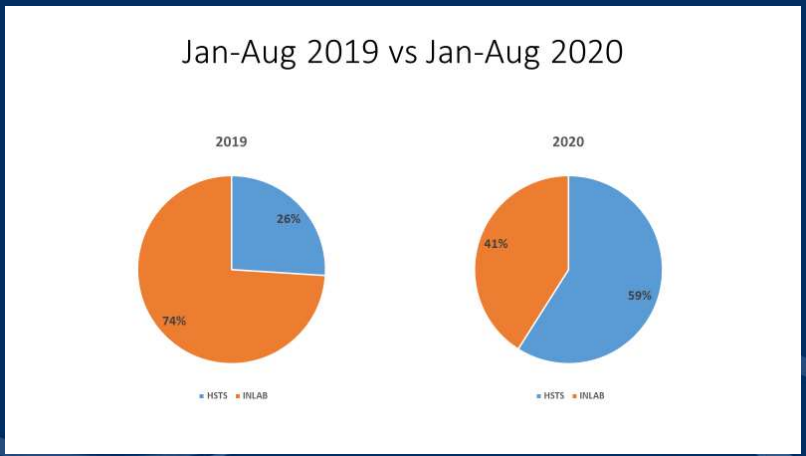
BUMCP Volume



COVD Trend Shift from In-Lab to HST



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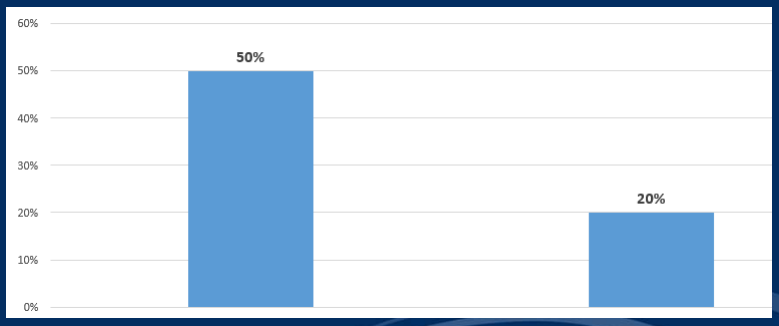
Last minute cancellations March-June 2020



Due to +COVID testing (20% pts failure to complete testing)

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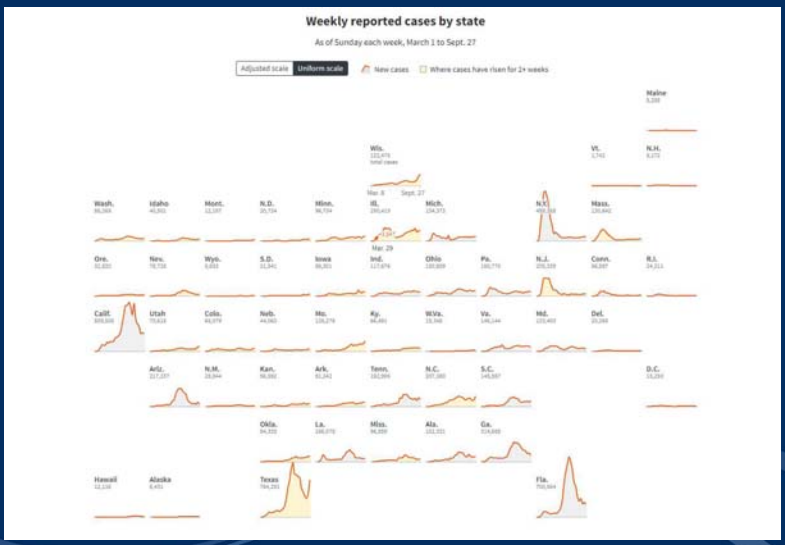
Numbers were reassuring…



https://graphics.reuters.com/HEALTH-CORONAVIRUS/USA-TRENDS/dgkvlgkrkpb/

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But…

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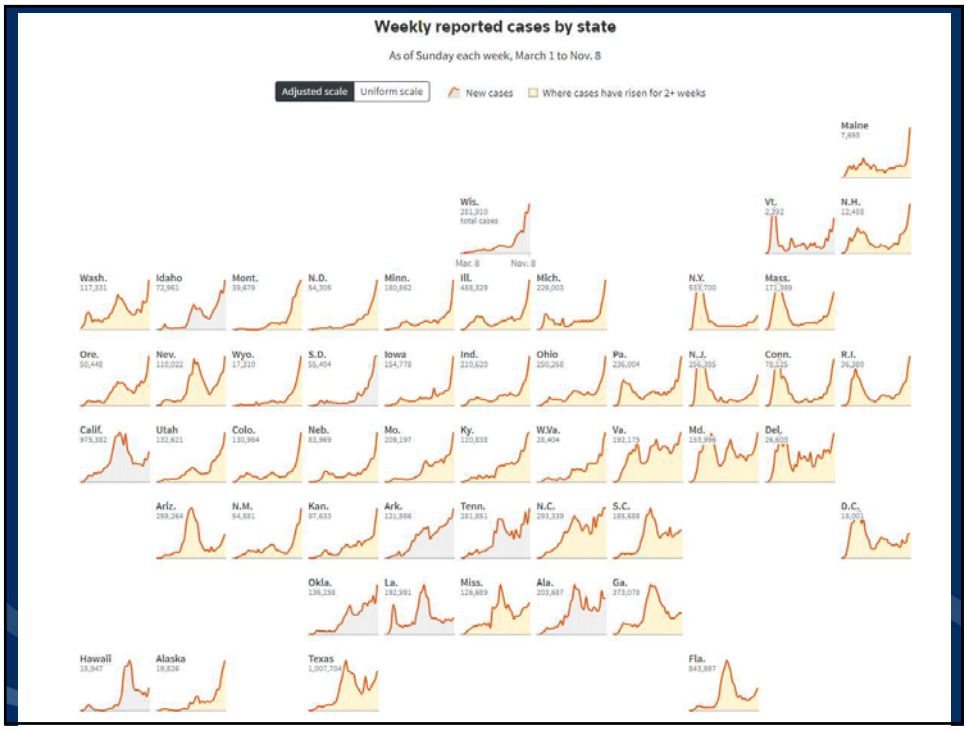
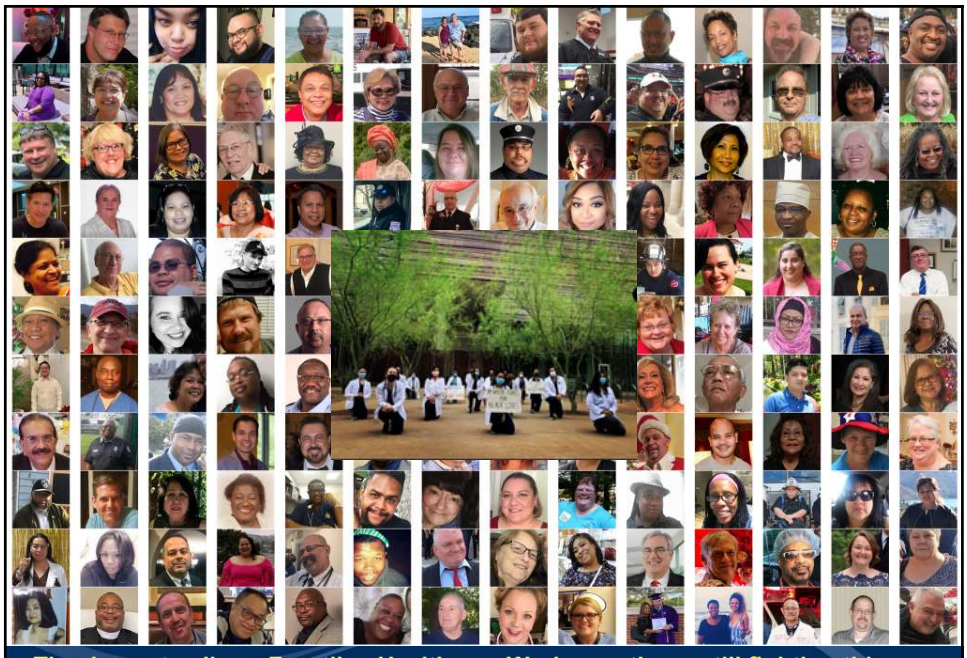


AASM COVID Task Force

- https://aasm.org/covid-19-resources/

Panelist: Indira Gurubhagavatula, MD, MPH

Dr. Gurubhagavatula is chair of the AASM COVID-19 Task Force and previously served as chair of the AASM Public Safety Committee, Occupational Sleep Wellness Committee, and Transportation Safety Task Force. She is an associate professor of medicine and director of the sleep medicine fellowship training program in the Division of Sleep Medicine of the Perelman School of Medicine at the University of Pennsylvania in Philadelphia. Dr. Gurubhagavatula also is an attending physician in the Corporal Michael Crescenz VA Medical Center.



Thank you to all our Frontline Healthcare Workers – those still fighting this fight and those we have lost

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Any Questions?

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