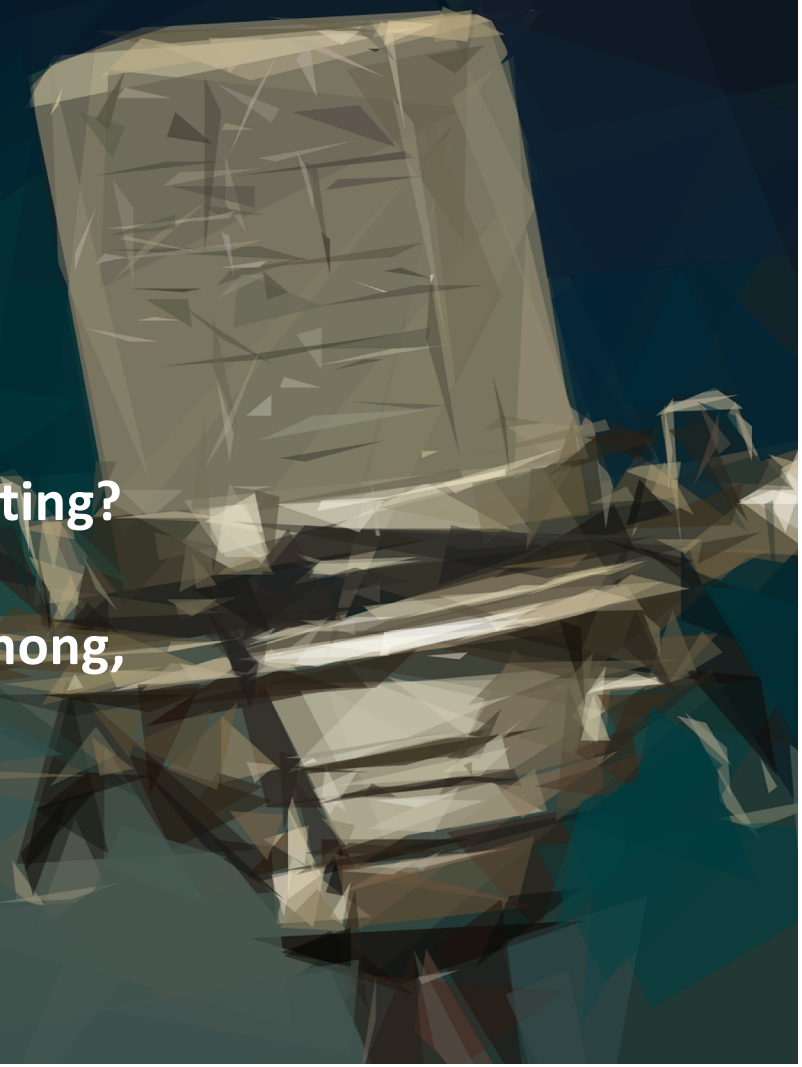
Community Conversations

Sunday, April 19
Tonight's Topic: What's Happening with Testing?

Tonight's Panelists: Drs. Kim Yu, Anthony Chong, Ted O'Connell, Raul Ayala and Lee Ralph



CALIFORNIA ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR CALIFORNIA

A Few Ground Rules

We are live streaming on CAFP's FaceBook page so please remember others may hear your comments.

Please feel free to type in questions or comments on Facebook. We'll be watching the box to triage for our host, panelists and moderator.

We are pleased to offer 1 AAFP Prescribed Credit for this live activity. To claim your credit go to: https://www.surveygizmo.com/s3/5533539/CAFP-Community-Conversations-Survey

We'll do our best to get to as many questions/comments as possible, and apologize in advance if we don't get to you. We will be saving the Chat Box and will try to respond during the week.

Disclosure

- The CAFP Committee on Continuing Professional Development is responsible for management and resolution of conflict for any individual who may have an influence on content, who has served as faculty, or who may produce CME/CPD content for the CAFP.
- It is the policy of CAFP to ensure independence, balance, objectivity, scientific rigor, and integrity in their continuing education activities.
- All individuals in a position to control content for this activity have indicated they have no relevant financial relationships to disclose.

Our Objectives for Tonight's Conversation

- Discuss the current testing issues in California communities
- Analyze opportunities to address testing in your community
- Answer questions about POCUS, antibody testing, contract tracing and more.

COVID-19 Testing in Independent Primary Care Practices in California

Kim Yu, MD, FAAFP

Regional Medical Director, California, Aledade

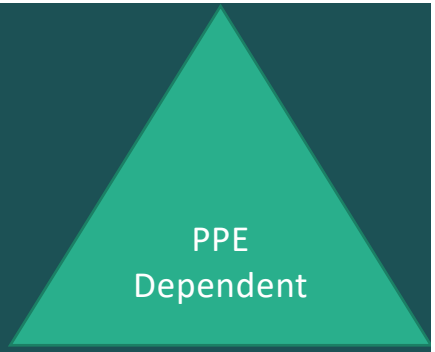
kyu@aledade.com @drkkyu

Testing at Primary Care Practices

Nationally, four weeks in, 4 out of 5 primary care practices continue to experience sustained high levels of stress. (QUICK COVID-19 PRIMARY CARE SURVEY – PCPCC/Larry Green Center)

- Persistent lack of personal protective equipment (58%) and tests (>50%)
- Separate group of 58% rely on used and homemade PPE
- 29% of clinicians report no capacity for COVID-19 testing and 39% have only limited capacity
- Reports of testing differences around the country

Current Testing Options in California



- Drive through specimen collection at practices – send out to labs for testing
- Specimen collection at offices – send out to labs for testing
- Health department testing – county dependent – changes frequently
- Hospital run testing/drive throughs
- Verily Project Baseline - High-risk individuals can complete the screener to see if they qualify for testing through this program. Potential participants need internet access and a Google account. Available in Sacramento, San Jose, San Mateo, Stockton, Lake Elsinore, Sherman Oaks, Long Beach, San Francisco, and Salida; >18y, able to drive
- https://www.projectbaseline.com/study/covid-19/

Types of Tests

Currently **no** FDA approved or cleared diagnostic tests for COVID-19.

Currently available testing is FDA-authorized under Emergency Use Authorization (EUA), which is invoked during circumstances that justify emergency use of in vitro diagnostics.

All diagnostic tests authorized under EUA are given one of three classifications: “H” and “M” are authorized for use in CLIA-certified laboratories only (and therefore require specimen send out to a designated lab) while “W” are deemed to be CLIA-waived for use in patient care settings (and therefore can be performed point-of-care). For a complete list of all currently authorized diagnostic tests for COVID-19 and associated EUA classifications, please see the FDA webpage.

Test results			Clinical Significance
RT-qPCR	IgM	IgG	
+	–	–	Patient may be in the window period of infection.
+	+	–	Patient may be in the early stage of infection.
+	+	+	Patients is in the active phase of infection.
+	–	+	Patient may be in the late or recurrent stage of infection.
–	+	–	Patient may be in the early stage of infection. RT-qPCR result may be false-negative.
–	–	+	Patient may have had a past infection, and has recovered.
–	+	+	Patient may be in the recovery stage of an infection, or the RT-qPCR result may be false-negative.

Table of Existing Send-Out (Reference Laboratory) Tests for SARS-CoV-2 (COVID-19): Medical diagnostic testing which is performed at a remote location (typically a CLIA-certified lab). While send out testing can be more time consuming, send out testing offers a wider range of available studies. In some instances, send out tests may offer improved sensitivity and specificity, as compared to analogous point of care options.

	Send Out Testing (Reference Laboratory Testing)	
Type of Test	rRT-PCR	Serological (IgM/IgG)
Associated Lab/ Test Platform	There are many available tests. Common examples include: - cobas SARS-CoV-2 (used by LabCorp and Quest Diagnostics, though not exclusively) - Abbott RealTime SARS-CoV-2 (used by Viracor)	Cellex qSARS-CoV-2 IgG/IgM Rapid Test (this is the only FDA authorized serology test, but exclusively for CLIA certified labs)
Preliminary Data on Sensitivity/ Specificity	There is insufficient data to make broad or conclusive claims about sensitivity / specificity. In addition, analytical performance is dependent on the specific assay used. Preliminary Data: cobas SARS-CoV-2: Positive Percent Agreement: 100% (50/50) 95% CI [92.9%, 100%] Negative Percent Agreement: 100% (100/100) 95% CI [96.3%, 100%][2] Abbott RealTime SARS-CoV-2: Positive Percent Agreement: 100% (60/60) 95% CI [94%, 100%] Negative Percent Agreement: 100% (31/31) 95% CI [88.8%,100%][3]	Positive Percent Agreement: 93.8% (120/128) 95% CI [88.2%, 96.8%] Negative Percent Agreement: 96.0% (240/250) 95% CI [92.8%, 97.8%][4]
Description of Test[5]	Detects nucleic acid (RNA) from SARS-CoV-2 in upper and lower respiratory tract specimens during the acute phase of infection.	Measures the amount of antibodies (e.g. IgG/IgM) or proteins present in the blood generated from immune response to infection (does not detect virus itself).
Time of Results	Dependent on testing location, typically 1-4 days after specimen collection.	Dependent on testing site, hours to days (10-15 min once in lab)

	CLIA-Waived Point-of-Care-Testing (OK to perform in office settings)		
Type of Test	Molecular Rapid Diagnostic Test* **Note: The examples listed in this table are the only available tests with an EUA "W" classification (CLIA-waived). There are many commercially available molecular point-of-care tests for SARS-CoV-2 that are authorized for use in CLIA-certified/reference laboratories.*		
Test Name	Abbott Diagnostics Scarborough, Inc ID NOW COVID-19	Mesa Biotech Inc. Accula SARS-CoV-2 Test	Cepheid Xpert Xpress SARS CoV-2
Preliminary Data on Sensitivity/ Specificity	*ID NOW COVID-19 Test Agreement with the Expected Results by Sample Concentration* *2X Limit of Detection = 20/20 (100%) 95% CI [83.9%, 100%]* *5X LoD = 10/10 (100%) 95% CI [72.3%, 100%]* *Negative = 30/30 (100%) 95% CI [88.7%, 100%]*[9]	*Accula SARS-CoV-2 Evaluation with Throat/Nasal Swab Samples* *2X Limit of Detection = 20/20 (100%)* *5X LoD = 7/7 (100%)* *10X LoD = 2/2 (100%)* *50X LoD = 1/1 (100%)* *Negative = 30/30 (100%)*[10]	*Xpert Xpress SARS-CoV-2 Test Agreement with the Expected Results by Target Concentration* *2X Limit of Detection = 20/20 (100%) 95% CI [83.9%, 100%]* *5X LoD = 5/5 (100%) (No CI due to sample size)* *Negative = 30/30 (100%) 95% CI [88.7%, 100%]*[11]
Description of Test[12]	Uses isothermal nucleic acid amplification technology for the qualitative detection of SARS-CoV-2 viral nucleic acids.	Qualitative, visual detection of nucleic acid from the SARS-CoV-2.	Rapid, real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2.
Hardware Required	Requires Abbott ID-NOW hardware (likely to add significant cost)	Cassette included in test kit	GeneXpert II, IV, XVI, Infinity 48, Infinity 80, and Xpress Systems
Time of Results	As little as 5 minutes for positive result, 15 for negative	As little as 30 minutes	As little as 45 minutes
Method of Collection[13]	NP (nasopharyngeal)		

Other testing options(serology, non-PCR, PCR requiring hardware, mail in testing):

Manufacturer	Type of Test	Sensitivity	Specificity	Tests per Pack	Compatibility
Henry Schein / SD Biosensor	IgM/IgG - serology	81.80%	96.60%	1?	POC test - device included in kit
Henry Schein / BioMedomics	IgM/IgG - serology	88.66%	90.63%	20	POC test - device included in kit
Cellex	IgM/IgG - serology	94.12%	95.79%	20/50/100	POC test - device included in kit
Co-Diagnostics	PCR	100%	100%	100	Compatible with most PCR machines
Atilia Biosystems	Isothermal			100	Requires RT-qPCR machine but does not require antigens - “dry test”. Specific PCR machines here
PerkinElmer	PCR				PerkinElmer Viral DNA/RNA 300 kit H96 and Chemagic™ 360 are recommended but it is unclear if they are REQUIRED
DiaCarta	PCR	96.70%	100%	24/48/480	Uses: Thermo Fisher QuantStudio 5 or 7500 Fast Dx, Bio-Rad CFX 384
LabCorp	PCR - mail in test	Roche has commented that it cannot release sensitivity and specificity data as there has not been enough time to conduct standard clinical testing.			Mail in test - 2-4 day turnaround after specimen pickup. Lab corp uses the Roche produced PCR test.
Quest Diagnostics	PCR - mail in test				Mail in test - 2 day turnaround (as of 4/14/20). Quest uses the Roche produced PCR test
Viracor	PCR - mail in test	95.24%	97%		Viracor uses the Abbott produced PCR assay test (not the ID NOW test)

Concerns with Serological Rapid POC Tests

- Not WHO recommended currently for clinical diagnosis
- Not FDA approved for clinical diagnosis
- Multiple Coronaviruses identified not just COVID19
- High false positive rate with low prevalence
- Immunity not proven after illness

All current POC serological tests say the following on their PI: "This test has not been reviewed by the FDA. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in those individuals. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E."

Stanford study April 2020 – Prevalence 2.24-3.37% in Santa Clara county. If true reflection of prevalence, the positive predictive value is less than 50%, meaning 50% of tests would be false positives!

Adjuncts to Diagnosis

Use of Chest X-ray – abnormal in 60-77%
Use of POC-US – B lines, rocket sign, areas of consolidation
Use of Chest CT Scan – abnormal in 86-95%

1014 hospitalized patients with suspected COVID-19 in Wuhan, China:
Both serial RT-PCR testing and chest CT

RESULTS:

- 59% (n = 601) of the patients had positive RT-PCR results
- 88% (n = 888) had positive chest CT scans.
- In patients with negative RT-PCR results, 75% (n = 308) had positive chest CT findings.
- Using RT-PCR results as reference standard, the sensitivity, specificity, and accuracy of chest CT in diagnosing COVID-19 were 97% (n = 580), 25% (n = 105), and 68% (n = 685), respectively
- The positive predictive value was 65% (n = 580) and the negative predictive value was 83% (n = 105).
- Initial RT-PCR pharyngeal swab sensitivity ranged from 66%-80%

Who Should Get Tested

The CDC has outlined general principles on the prioritization of patients for testing, including:

Priority 1: Hospitalized patients and symptomatic healthcare workers

Priority 2: Patients at highest risk of complication of infection ● Symptomatic patients in long- term care facilities ● Symptomatic patients age 65 and older ● Symptomatic patients with underlying conditions ● First responders with symptoms

Priority 3: Individuals in the surrounding community of rapidly increasing hospital cases to decrease community spread and ensure health of essential workers ● Critical infrastructure workers with symptoms ● Symptomatic patients who do not meet any of the above categories ● Health care workers and first responders ● Individuals with mild symptoms in communities experiencing high COVID-19 hospitalizations

As of right now, CDC indicates that Asymptomatic patients should not be prioritized.

Evolving Role of Primary Care in COVID-19 Pandemic Response:

Other countries have achieved remarkable results through proactive, broadly applied testing and contact tracing (when people who have had recent close associations with positive patients are contacted, tested and advised to stay home). We may see the day when Family Physicians are asked to participate in local, State or nationwide containment efforts. Appropriate PPE is essential; please do not place yourselves at risk by testing without appropriate PPE.

SARS-CoV-2 Testing:
Diagnostic and Serology

Anthony Fatch Chong, MD

Chief Medical Officer, Scripps Coastal Medical Center, San Diego

Diagnostic Tests

Testing options at Scripps Health

- Abbott POCT
- Halogic tests
- Quest Labs

Current limitation – Supplies for the tests

- Swabs
- Test reagents

Prioritization of Testing Given Resource Limitations

- Inpatient/admitted patients
- Patients with severe symptoms where result will impact treatment and management
- Pre-op clearance for urgent surgeries or care (chemotherapy) or OB
- Potentially clearance for return to work if symptom-based algorithm is not enough
- Avoid testing in asymptomatic or mildly symptomatic patients

Serology Tests – IgM and IgG

- WHO recommends not to use any POC serology tests
- No FDA approved serology tests
- FDA has approved an Emergency Use Authorization (EUA) for 4 tests

- Bottom line:
  - No clear understanding on how to interpret the results of any test yet
  - Not well studied for accuracy or validity
  - Not ready to use in your prctice

NEWS • News

San Diego County shuts down private coronavirus testing site offered by OC clinic

The COVID-19 tests, also offered outside the Westminster Mall, could put public health at risk, San Diego health officials say

Healthcare workers tend to a driver in line at a drive thru Coronavirus (COVID-19) testing site at the Westminster Mall in Westminster, CA, on Monday, Apr 6, 2020. The site, run by Elevated Health, is doing nasal testing for $125 and antibody testing for $75. (Photo by Jeff Gritchen, Orange County Register/SCNG)

- A lot of vendors approaching physician offices
- Unproven tests
- Not FDA approved
- Unclear cost vs. benefits for patients

What Does the EUA Mean?

Cannot use the result for diagnosis or treatment

- Not FDA cleared or approved for general use
- No clinically important decisions should be made based on the results
- Only available at authorized labs
- No permitted ads or promotion that this test is safe or effective for the detections of the SARS-CoV-2 virus

What's the Big Deal?
And Serology Test Will Help, Right?

False Negative

- Unclear what a positive IgM means
- If the sample is done <7 days of symptoms, sensitivity is about 38%

False Positive

- Unclear if a positive means that the patient is protected from a reinfection
- Possible cross-reactivity to other coronavirus subtypes

For Up-to-Date COVID-19 Info

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  - COVID-19: Practice

Respond to Coronavirus (COVID-19)

Support your practice and patients with the latest information on coronavirus.

Updated April 17, 2020

The Financial Relief for Family Physicians page breaks down financial relief programs.

Things are changing rapidly. Follow our Daily Updates page to see what's new each day.

Telehealth & Virtual Care Tools

Telehealth and virtual care are critical ways of delivering patient care in the pandemic.

Here's what you need to know to make it work for your practice, from selecting technology to understanding payment options.

View Resources

Continuing Medical Education

New education opportunities can support you during the pandemic.

Earn CME credit on these activities and access additional COVID-19 education resources.

See Activities

Practice Management

Practicing during the pandemic requires different ways of working.

Find guidance on non-urgent visits, coding and payment, PPE, testing and quality reporting.

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Telehealth Resources

Medicare Policy

Download the PDF

Medicaid Policy

(includes policy related to MCPs)

DCHS Medi-Cal Information

Download the PDF

Statement from State Insurance Commissioner

Notice re: Telehealth During COVID-19 State of Emergency (March 30, 2020)

Gov. Newsom's Executive Order re: HIPAA

Access the Governor's Executive Order suspending HIPAA-related penalties related to good faith use.

AAFP's Telehealth Resources

VISIT FOR MORE

Physicians Foundation

The Physicians Foundation Announces The Telehealth Initiative to Improve Access to Quality Health Care (March 19, 2020)

CAFP Community Conversation

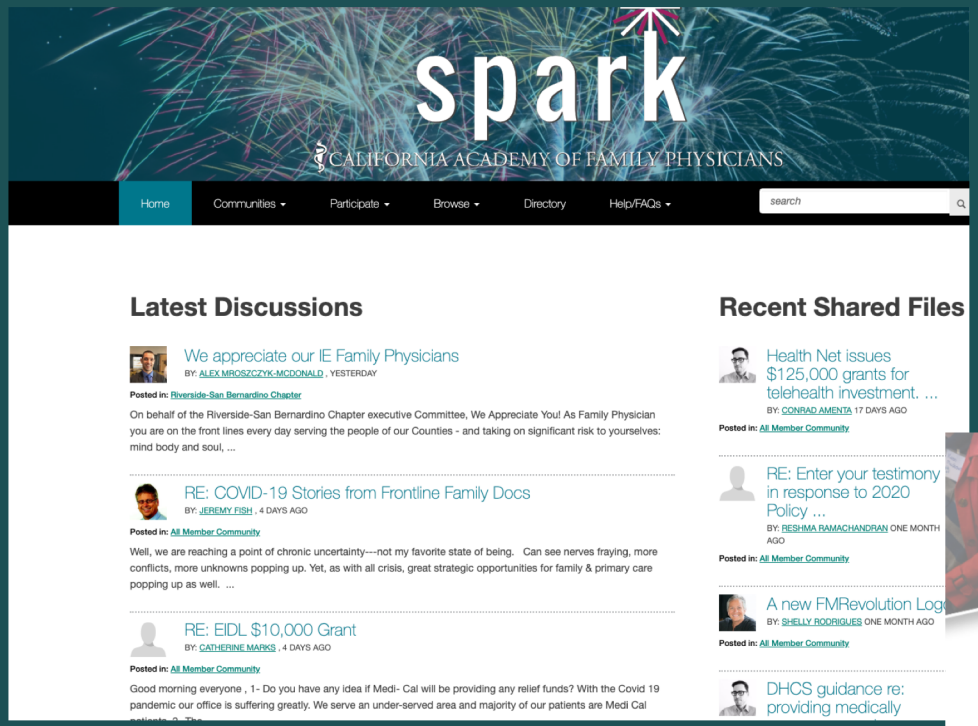
Topic: Dos and Don'ts of Telehealth (Five CAFP members representing diverse practices in California)

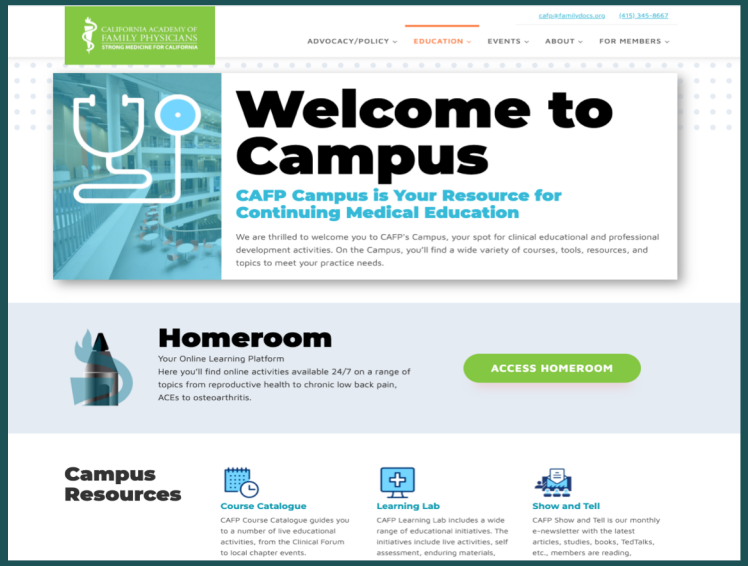
WATCH VIDEO

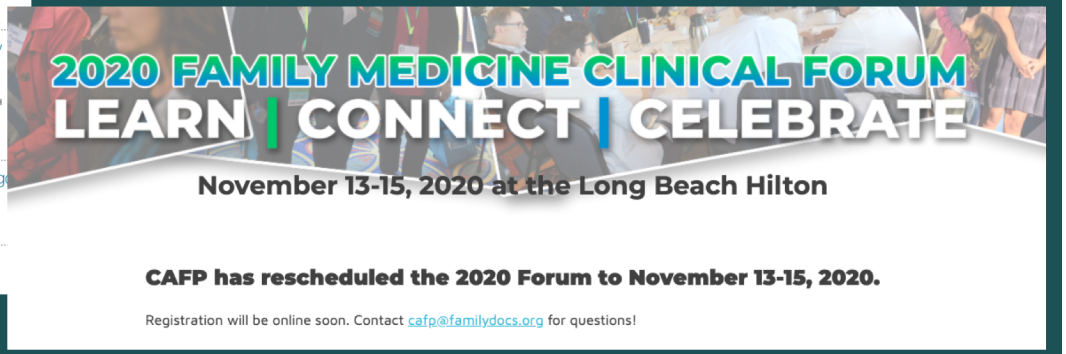
Texas AFP

Texas Family Doc Talk, Episode 2: The big telemedicine show.

Ask and Answer … Earn CME







Next week …

Adia Scrubb, MD, MPP

- PGY3, John Muir FM Residency Program
- CAFP Foundation 2019 Susan Hogeland, CAE Health Policy Fellow
- Presenting her fellowship project

“I am Not My ACEs score: Screening for Resilience in the Setting of Adverse Childhood Experiences”

Thank You!

See you next Sunday!

April 26, 7:30-8:30 pm

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