

# Acute Pharyngitis in Time Sensitive Care Settings: The Case for Rapid, Accurate Diagnosis and Improved Care

Evidence-based Guidelines and  
the Impact on Patient Care

**July 29, 2021**  
**1:00-2:00 p.m. ET**

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COL-06607-01 07/21

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## MODERATOR



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Emergency Physician  
*Scripps Memorial Hospital*

## SPEAKERS



**Stanford T. Shulman, MD**

Virginia H. Rogers Emeritus  
Professor of Pediatric  
Infectious Diseases  
*Northwestern University  
Feinberg School of Medicine*

Chief Emeritus  
Division of Infectious Diseases  
*Ann & Robert H. Lurie  
Children's Hospital of Chicago*



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Medical Director and Founder  
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at multiple hospitals  
in MD and DE

# Learning Objectives

- Review the importance and challenges associated with diagnosis and treatment of Group A Strep (GAS)
- Discuss methods and share practical experiences of using rapid GAS tests in time-sensitive care settings
- Evaluate the latest guidelines for GAS pharyngitis diagnosis in the emergency department and primary care
- Examine the impact of rapid molecular testing on clinical decision making, patient care and operational workflows



# Polling Question #1

MOST of our Strep A testing is performed: (check all that apply)

- A. In-house – Antigen
- B. In-house – Molecular
- C. In-house – Culture
- D. Send-out all testing
- E. Send patient to reference lab for testing
- F. Other



# Group A Strep Pharyngitis



## **Stanford T. Shulman, MD**

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# Dr. Shulman Disclosures

- Speaker honorarium, Abbott



# Group A Strep Pharyngitis

# Group A Strep (GAS) Pharyngitis

“Strep throat” presents clinically as:

- Sudden onset tender, swollen anterior cervical nodes
- Fever, HA, red swollen tonsils +/- uvula, with or without exudates

**#1** bacterial cause of tonsillopharyngitis in adults and kids

Peak season in Winter and early Spring

Resistance:

- No reported cases with penicillin...
- Limited reports with Azithro /clarythro



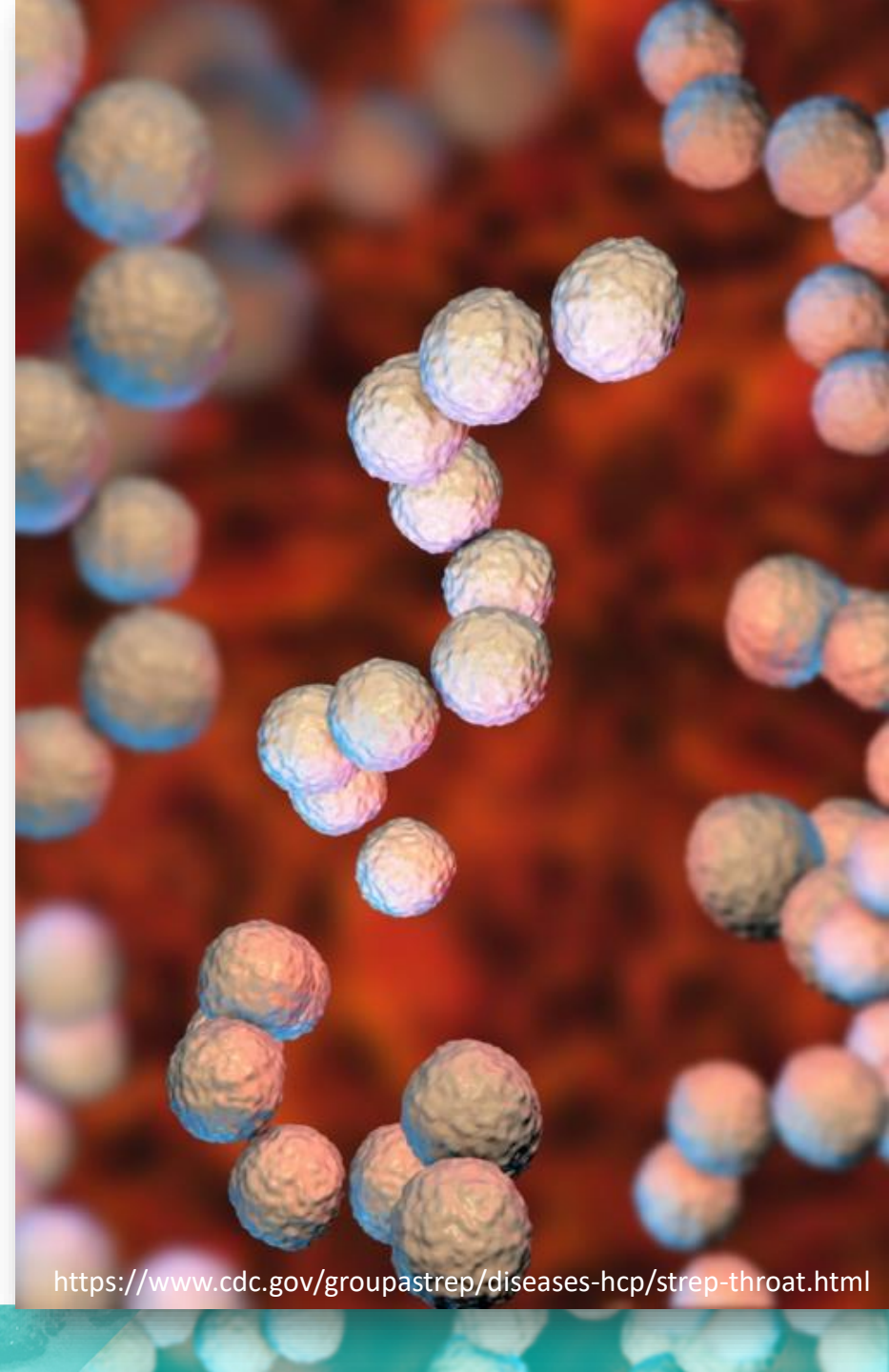


# Strep Throat is Typically Self-Limiting So Why Do We Test and Treat?

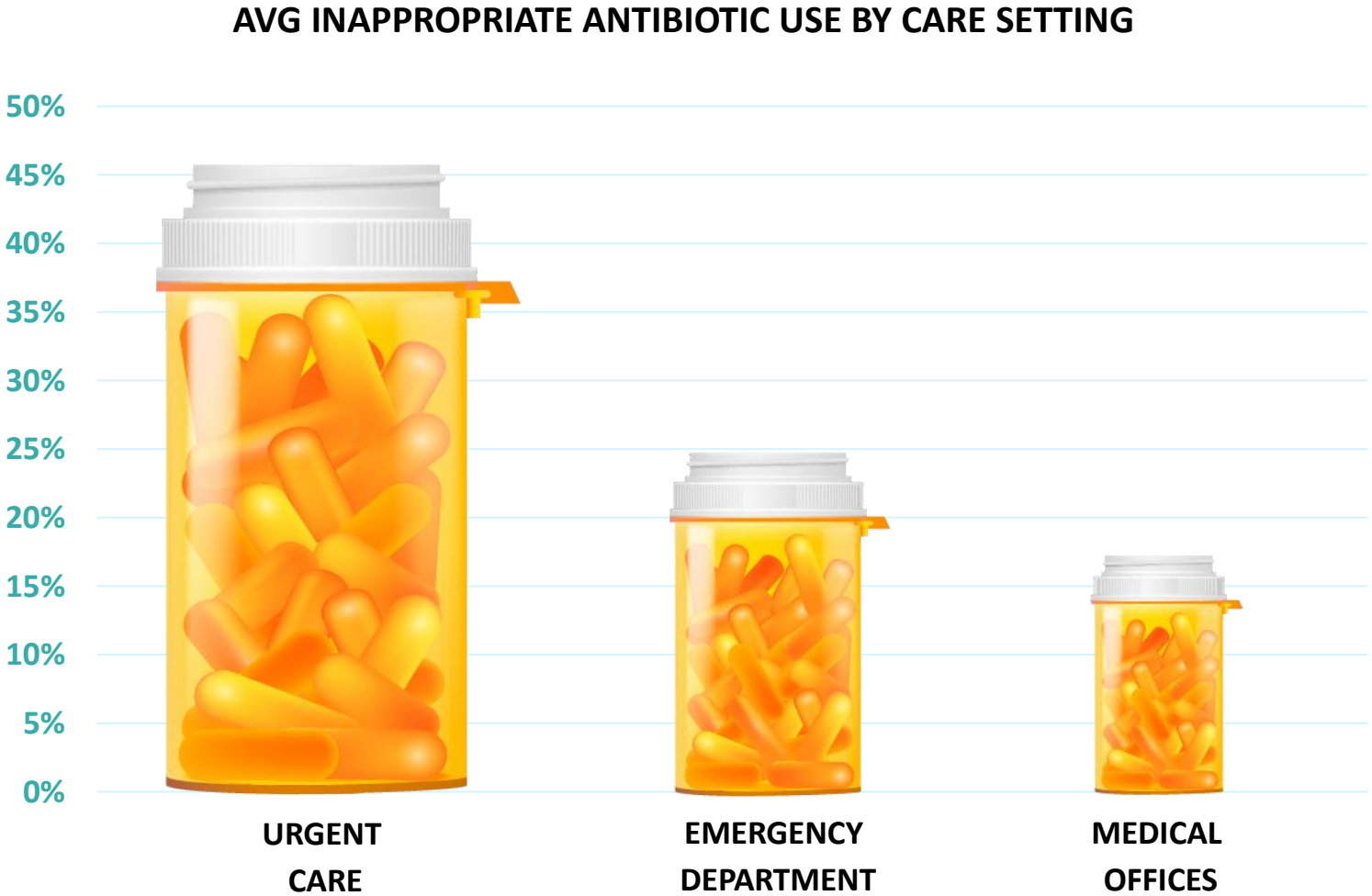
## TO PREVENT COMPLICATIONS

- Acute rheumatic fever
- Post-infectious glomerulonephritis
- Necrotizing fasciitis
- Streptococcal toxic shock syndrome
- Invasive GAS infection
- Abscesses

## PREVENT TRANSMISSION TO CLOSE CONTACTS



# Areas Most Prone to Inappropriate Antibiotic Use



Palms DL, et al. Comparison of Antibiotic Prescribing in Retail Clinics, Urgent Care Centers, Emergency Departments, and Traditional Ambulatory Care Settings in the U.S. *JAMA Intern Med.* 2018;178(9):1267–1269.

# American Academy of Pediatrics/Redbook

**DO NOT TRY TO DIAGNOSE WITHOUT LABORATORY CONFIRMATION**

**DO NOT TREAT WITH AB WITHOUT LABORATORY CONFIRMATION OF GAS**

**DO NOT TEST CHILDREN < 3-YEARS-OLD OR THOSE WITH OVERT VIRAL SYMPTOMS (COUGH, ORAL ULCERS, HOARSENESS, MAJOR NASAL CONGESTION [URI])**

POLL #1

Results

# American Academy of Pediatrics/Redbook (cont.)

## TESTING RECOMMENDATIONS AND CLINICAL PERSPECTIVES

### CULTURE

18-48 hours<sup>1</sup>

Not practical

“Gold standard”

### RADT (RAPID ANTIGEN DETECTION TEST)

Faster (10-20 mins)

High specificity<sup>1</sup>

Lower sensitivity<sup>1</sup> (83% - 88%)

**If POS: TREAT<sup>1</sup>**

**If NEG:<sup>1</sup>**

**Kids** = back-up test, usually culture

**Adults** = no back-up needed (very low risk)

### MOLECULAR

Potentially more rapid than RADTs  
(2 – 18 mins +)

Very high specificity<sup>1</sup> (~93 – 97%)

Very high sensitivity<sup>1</sup> (~96-99%)

Back-up test likely not necessary  
(only if indicated)

More costly than other tests

Too complicated for some POC?

*“Some studies suggest [rapid molecular tests] may be as sensitive as standard throat cultures...”<sup>1</sup>*

# 2012 Infectious Disease Society of America

RADTs discussed without mention of molecular assays

No routine studies recommended for children < 3-years-old

**Emphasis on selective swabbing of patients**

2018 IDSA and American Society for Microbiology (ASM)  
Joint Update on Lab Guidelines state:

*“Rapid, CLIA–waived methods for molecular group A Streptococcus testing provide improved sensitivity and may not require culture confirmation, though they have not yet been incorporated into consensus guidelines.”*

Shulman ST, et al. Clinical Practice Guideline for the Diagnosis and Management of Group A Streptococcal Pharyngitis: 2012 Update by the Infectious Diseases Society of America. Clinical Infectious Diseases 2012;55(10):e86–102.

Miller JA, et al. A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2018 Update by the Infectious Diseases Society of America and the American Society for Microbiology. Clin Infect Dis. 2018 Aug 31;67(6):e1–e94.



# Molecular Sensitivity Advantage vs. Antigen/RADT

**PRACTICALLY ELIMINATES FALSE POSITIVES/FALSE NEGATIVES**

## ANTIGEN/LATERAL FLOW

	SENSITIVITY	SPECIFICITY
Antigen (EIA) <sup>1</sup>	85.6	95.4

## MOLECULAR

	SENSITIVITY	SPECIFICITY
Abbott ID NOW™ <sup>2</sup>	98.5	93.4
Roche Cobas® LIAT® <sup>4</sup>	98.3	94.2
Cepheid GeneXpert® Xpress <sup>3</sup>	99.4	94.1
Mesa/ Thermo Fisher Accula™ <sup>5</sup>	96.2	97.5

<sup>1</sup>Cohen JF, et al. 2016, Issue 7. Art. No.: CD010502.

<sup>2</sup>ID NOW™ Strep A 2 Package Insert, IN734000 Rev.5.

<sup>3</sup>cobas® LIAT® Strep A Package Insert, 34-04030 Rev 4.

<sup>4</sup>Xpert® Xpress Strep A CLIA Waived Package Insert, 301-9326 Rev A.

<sup>5</sup>Accula™ FDA Summary K201269.

# Individual research and opinion pieces from reputable sources increasingly support molecular tests (NAATs)



AMERICAN  
SOCIETY FOR  
MICROBIOLOGY

Journal of  
Clinical Microbiology



CrossMark  
click for updates

## Point-Counterpoint: A Nucleic Acid Amplification Test for *Streptococcus pyogenes* Should Replace Antigen Detection and Culture for Detection of Bacterial Pharyngitis

Bobbi S. Pritt,<sup>a</sup> Robin Patel,<sup>a</sup> Thomas J. Kirn,<sup>b</sup> Richard B. Thomson, Jr.<sup>c,d</sup>

Division of Clinical Microbiology, Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, Minnesota, USA<sup>a</sup>; Departments of Pathology & Laboratory Medicine and Medicine, Rutgers Robert Wood Johnson Medical School, New Brunswick, New Jersey, USA<sup>b</sup>; Department of Pathology & Laboratory Medicine, NorthShore University HealthSystem, Evanston, Illinois, USA<sup>c</sup>; The University of Chicago Pritzker School of Medicine, Chicago, Illinois, USA<sup>d</sup>

Nucleic acid amplification tests (NAATs) have frequently been the standard diagnostic approach when specific infectious agents are sought in a clinic specimen. They can be applied for specific agents such as *S. pyogenes*, or commercial multiplex NAATs for detection of a variety of pathogens in gastrointestinal, bloodstream, and respiratory infections may be used. NAATs are both rapid and sensitive. For many years, *S. pyogenes* testing algorithms used a rapid and specific group A streptococcal antigen test to screen throat specimens, followed, in some clinical settings, by a throat culture for *S. pyogenes* to increase the sensitivity of its detection. Now *S. pyogenes* NAATs are being used with increasing frequency. Given their accuracy, rapidity, and ease of use, should they replace antigen detection and culture for the detection of bacterial pharyngitis? Bobbi Pritt and Robin Patel of the Mayo Clinic, where *S. pyogenes* NAATs have been used for well over a decade with great success, will explain the advantages of this approach, while Richard (Tom) Thomson and Tom Kirn of the NorthShore University HealthSystem will discuss their concerns about this approach to diagnosing bacterial pharyngitis.

Downloaded from http

# Rationale for Molecular in GAS Pharyngitis

70% of RADTs may require reflex culture testing	Adds significant burden on laboratory and health care system
Culture increases time to result	<ul style="list-style-type: none"><li>• Untreated patient may experience ongoing symptoms</li><li>• Clinicians may forgo recommended testing guidelines; 1) prescribe antibiotics based only on clinical features, or 2) test and prescribe antibiotics regardless of the test result</li></ul> <p><b>IMPACT:</b> Unnecessary antibiotic use, increased risk of antimicrobial resistance</p>
Issues with patient and healthcare provider satisfaction and other costs	Avoided by eliminating negative culture follow-up

# Are Some Molecular Tests Too Sensitive?

**ED patients** with sore throat<sup>1</sup>

3,634 RADT negative

2012-2013:

**8%** culture positive (false negative RADT)

2014-2015:

**16%** molecular positive

( $p < 0.0001$ )

Is molecular more sensitive than culture,  
or overly sensitive: 8% false positives?

350 asymptomatic children > 3 years old in  
**Primary Care**; immunization/well-child care<sup>2</sup>

**12%** culture positive

Probably carriers/harbor in respiratory tract,  
consistent with known carrier rate (can be >20-  
25% )

**20%** molecular positive ( $p < 0.0035$ )

8% false positive, carriers or molecular even better  
at picking up GAS pharyngitis

**IF NOT UTILIZED APPROPRIATELY, MOLECULAR TESTING MAY RESULT IN POTENTIAL OVERTREATMENT  
OF PATIENTS WITHOUT BONAFIDE GAS INFECTION AND NEGATE PRINCIPLES OF GOOD ANTIBIOTIC STEWARDSHIP.<sup>3</sup>**

<sup>1</sup>Tanz RR, et al. Caution Needed: Molecular Diagnosis of Pediatric GAS Pharyngitis. J Pediatric Infect Dis Soc. 2018 Aug 17;7(3):e145-e147.

<sup>2</sup>Tanz RR, et al. Highly Sensitive Molecular Assay for Group A Streptococci Over-identifies Carriers and May Impact Outpatient Antimicrobial Stewardship. Pediatr Infect Dis J. 2019 Aug;38(8):769-774.

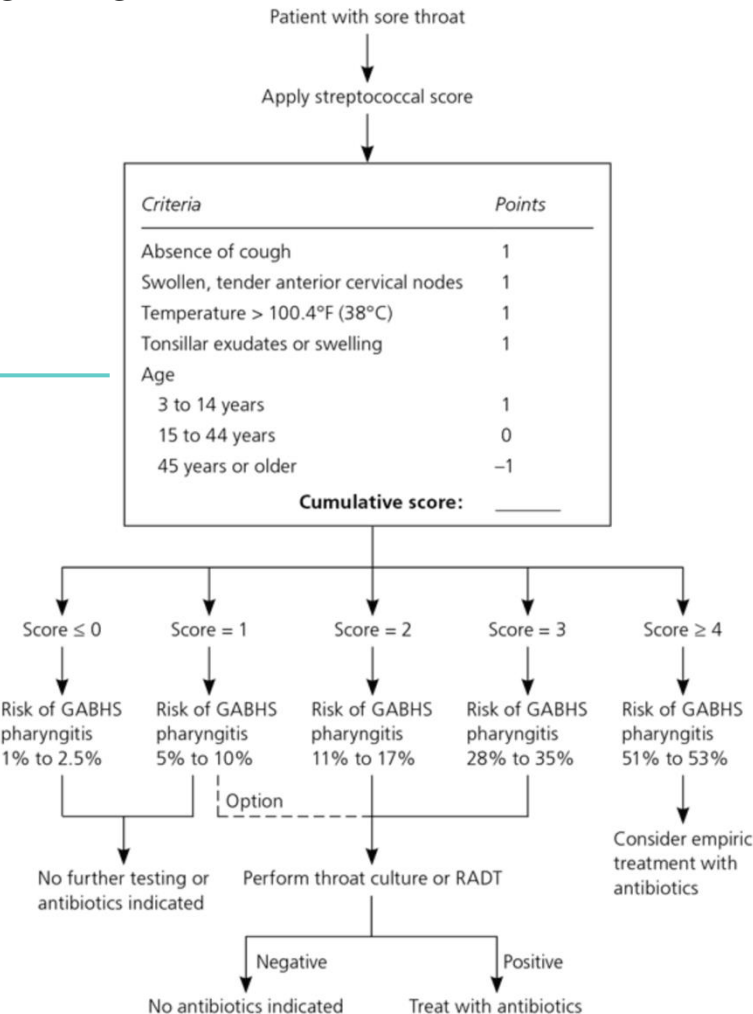
<sup>3</sup>Jaggi P, Leber A. Molecular Testing for GAS Pharyngitis: To Test or Not To Test, That Is the Question, *Journal of the Pediatric Infectious Diseases Society*, Volume 10, Issue 2, February 2021, Pages 65–67.

# Guide for Patient Selection for Testing

## PRE-TEST PROBABILITY SCORING SYSTEMS<sup>1</sup>

### CENTOR OR MODIFIED CENTOR (AKA MCISAAC)

**LOWER SCORE**  
**0,1,2**  
unlikely to have  
GAS pharyngitis



**HIGHER SCORE**  
**3,4+**  
more probable to have  
positive strep test

<sup>1</sup>Kalra MG, Higgins KE, Perez ED. Common Questions About Streptococcal Pharyngitis. Am Fam Physician. 2016 Jul 1;94(1):24-31. Erratum in: Am Fam Physician. 2017 Apr 1;95(7):414.

<sup>2</sup>Fine AM, Nizet V, Mandl KD. Large-Scale Validation of the Centor and McIsaac Scores to Predict Group A Streptococcal Pharyngitis. Arch Intern Med. 2012 June 11; 172(11): 847–852.

# Summary

- Updated guidelines regarding diagnostic testing for GAS pharyngitis are needed
- Future guidelines need to incorporate test performance (sensitivity/specificity), antibiotic stewardship, financial impact and timeliness of results





# Polling Question #2

Our current challenges with Strep A testing include: (select all that apply)

- A. Delayed diagnosis, unnecessary antibiotic use
- B. Culture send-outs, call-backs, charting
- C. Determining optimal testing for our setting
- D. Cost/Reimbursement
- E. CLIA/Regulatory compliance
- F. Other

# Acute Pharyngitis in Urgent Care and Emergency Medicine

Our Experience with Rapid Molecular Testing



**Ron Elfenbein, MD**

Medical Director  
*First Call Medical Center*

Emergency Physician Attending  
at multiple hospitals  
in MD and DE

# Disclosure

- Receiving speaker honoraria
- No financial ties to/interest in Abbott
- Use Abbott products in the urgent care, but not incentivized to own or operate





*Provide high-quality medical care experience  
that patients expect and deserve.*

*Our staff considers their work a success  
when every patient receives  
the best urgent care encounter possible.*

## Urgent Care

- Very competitive market
- Need to deliver quality care and establish yourself
  - Leverage every advantage
  - Elevate clinic from the rest
- How to stand out among the competition?
  - Offer superior products and services
  - Meet or exceed patient expectations

# A Significant Differentiator is our Testing

## PRIMARY OBJECTIVE

Perform POC tests that help OUR patient population:

Flu/GAS/RSV/COVID-19/INR/HA1C

- CLIA Waived
- Convenience
- Accuracy
- Speed/efficiency
- Patient demands
- ROI

# Why Molecular in Urgent Care?

You have one chance to do these tests

- Not repeat business
- Maximize antimicrobial stewardship
- Maximize Pt satisfaction
- Minimize staff burden/effort/cost (hidden and real costs)
- Manage ROI





# GAS Assessment Workflow in Urgent Care

## STANDING ORDER

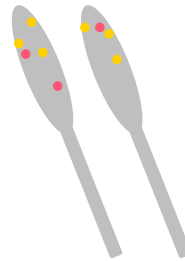


### SORE THROAT WITHOUT COUGH OR RUNNY NOSE:

Obtain swab sample (two if throat culture is protocol to prevent the need for a follow-up swab)

**All other patients**, including those who “just want to know”, **must be seen by the clinician first**

## RADT - NEGATIVE



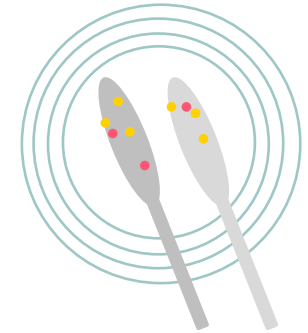
### THROAT CULTURE (CX):

**Children - Always**

**Adults - Consider** only with very high suspicion of group A strep pharyngitis (VERY rare)

OR

## NAAT - NEGATIVE (molecular)



### THROAT CULTURE:

**Children - Consider** only with very high suspicion of group A strep pharyngitis

**Adults: Never**

# Patient Workflow Comparison

## ANTIGEN TEST

- Collect two swabs (test and CX)
- All negatives need f/u CX
  - At BEST 86% sensitive
- Contact lab to arrange pick up
- Fill out paperwork PROPERLY
  - LOSE CONTROL over sample/situation
- F/u results
- Call patient/family with results

## MOLECULAR TEST

- One swab for Strep (no CX needed)
- VERY high sensitivity/specificity
- Simple, easy to use
- Rapid
- Control over entire process is YOURS
  - No calls, no delays, no “issues or problems”
  - No follow-up, no scanning

POLL #2

Results

# Quality of Sample is VERY Important

## SWABBING 101 TIDBITS

- Lay child down on exam table
- Hands over head, held by parents
- Your axilla on their belly, both hands free
- Tongue blade wedged between teeth flat, then turned 90 degrees
- Swab (be prepared to dodge the cough/spit/kicks/bites)



# Treatment

Amoxicillin x 10 days

Do **NOT** escalate to Augmentin-EVER!!!!

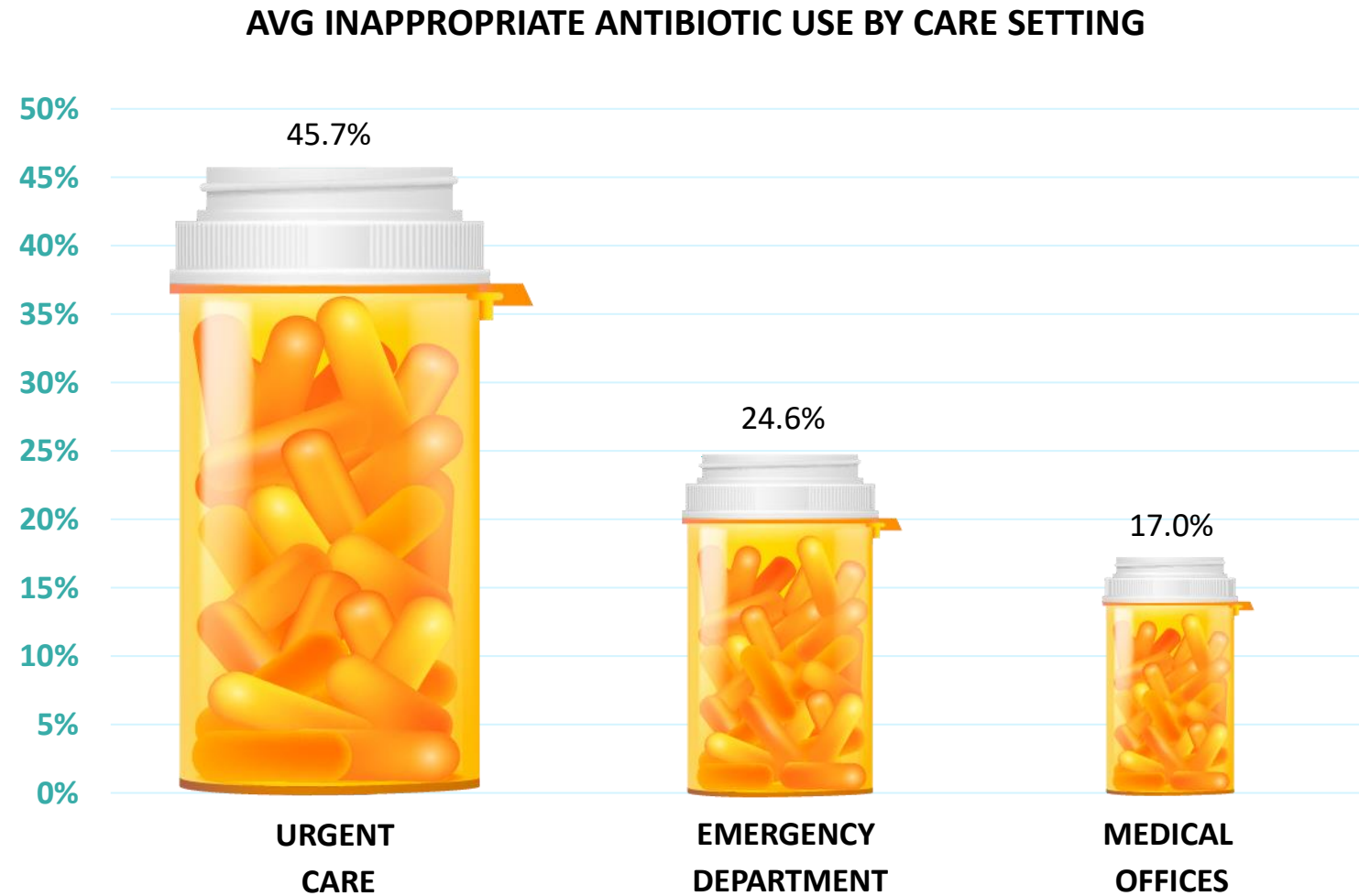
Penicillin allergy: narrow spectrum cephalosporins

Last resort: clindamycin, macrolides

*“There has **never** been a report of a clinical isolate of group A strep that is resistant to penicillin. However, resistance to azithromycin and clarithromycin is common in some communities.” - CDC*



# Areas Most Prone to Inappropriate Antibiotic Use





# Gotta Love the ER



“ ... and could I just see your insurance card?”

# Same Is True For Molecular in the ER

- Much more reliable results
- Potentially more cost effective
- MUCH faster TAT
  - Why ERs don't embrace POC technology?  
Molecular tests?
- HUGE satisfier (HCAPS)
- NO culture (HUGE savings)
- Obvious way (lab costs/time, etc..)
- Time lost following up/calls, etc..  
(mail/certified letters)
- Pt angst
- Misuse of antimicrobials



# Polling Question #3

Relative to GAS testing, we would like to:

- A. Do more molecular testing in-house
- B. Do more antigen testing in-house
- C. Do more Send-out testing
- D. Change test methods
- E. Keep testing as-is
- F. Other

Moving to Molecular



# Why Did We Make the Leap to Molecular?

- What things did we consider?
  - Cost
  - Ease of use/implementation/training
  - Instrument
  - Availability/storage of supplies
  - ROI (always need to consider this)
  - TAT
- Evaluation: Two CLIA waived molecular platforms
- Chosen method: ID NOW
  - **TAT** is fastest by a large margin
  - **Accuracy**
  - Overall **workflow**



# Molecular vs. Antigen Diagnostic Accuracy

PRACTICALLY ELIMINATES FALSE POSITIVES/FALSE NEGATIVES

## MOLECULAR “NAAT” TESTING



### Sensitivity / Specificity

GAS: 98.5% / 93.4%

Flu: 96-100% / 97%+

RSV: 98.6% / 98%

## ANTIGEN TESTING



### Sensitivity / Specificity

GAS: 86% / 95%

Flu: 54% / 98%+

RSV: 80% / 97%

NAAT, nucleic acid amplification test

<https://www.globalpointofcare.abbott/en/product-details/id-now-strep-a-2.html>

<https://www.globalpointofcare.abbott/en/product-details/id-now-influenza-ab-2.html>

<https://www.globalpointofcare.abbott/en/product-details/id-now-rsv.html>

Cohen JF, et al. 2016, Issue 7. Art. No.: CD010502.





Merckx J, et al. Ann Intern Med. 2017 Sep 19;167(6):394-409.

Chartrand C, et al. J Clin Microbiol. 2015. 53:3738 –3749.



# CLIA Waived Molecular Tests (NAAT) – Group A Strep

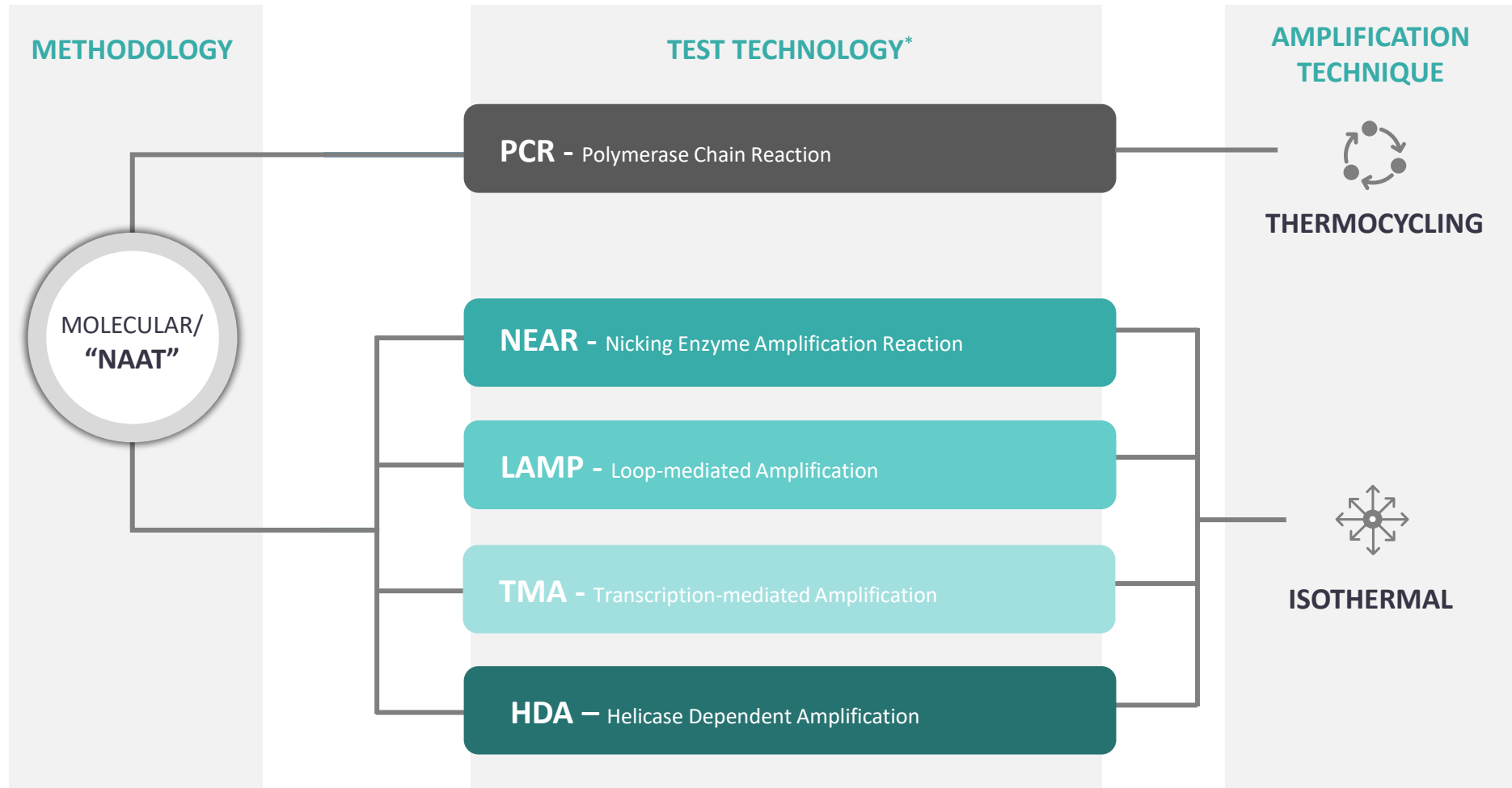
## BY TIME TO RESULT

	DEVICE	NAAT TYPE	POSITIVE RESULTS (MIN)	NEGATIVE RESULTS (MIN)	RESULT INTERPRETATION	CONFIRMS DX, NO CULTURE REQUIRED	SENSITIVITY	SPECIFICITY	PPA	NPA	MANUFACTURED
	Abbott ID NOW™	Isothermal	≥ 2	6	AUTO	✓	98.5	93.4	78.9 (PPV)	99.6 (NPV)	US
	Roche Cobas® LIAT®	PCR	~15	~15	AUTO	✓	98.3	94.2	88.1	99.2	US
	Cepheid GeneXpert® Xpress	PCR	≥ 18	24	AUTO	✓	99.4	94.1	85.3	99.8	US
	Mesa/Thermo Fisher Accula™	PCR	~30	~30	MANUAL/VISUAL	✗	96.2	97.5	93.8	99.8	CHINA

Currently available CLIA waived molecular tests for Group A Strep.

ID NOW Strep A 2 Package Insert, IN734000 Rev.5. cobas® Strep A Package Insert, 34-04030 Rev 4. Xpert® Xpress Strep A Package Insert, 301-9326 Rev A. Mesa Accula™ FDA Summary K201269.

# Molecular (NAAT) COVID-19 Test Technologies



NAAT, nucleic acid amplification test.

\*Multiple NAAT technologies amplify nucleic acids, not a comprehensive list.

CDC, [Nucleic Acid Amplification Tests \(NAATs\)](#), updated June 16, 2021. Accessed July 21, 2021.

POLL #3

Results

# Impact of Molecular on Our Practice



# Antimicrobial Stewardship Impact

**HUGE BENEFIT TO KNOWING IF POSITIVE OR NEGATIVE**

No waiting for GAS culture

No sending patient home with unnecessary Rx

Hold to fill

Antibiotic Rx for Strep reduced by **>25%**

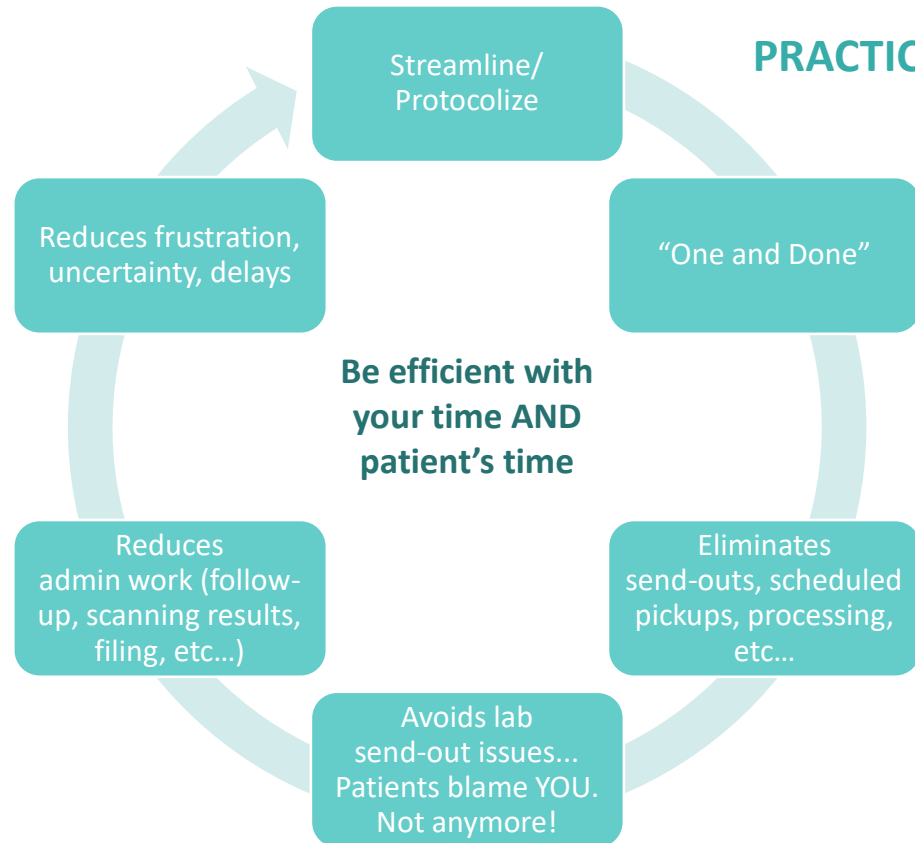
Easier to follow antiviral treatment guidelines

Pt's much more agreeable to treatment decision  
(Rx or no Rx)



# Workflow Analysis and Impact

Rapid and accurate molecular testing eliminates the need for follow-up strep culture



## TIME SAVINGS PER PATIENT

<b>5 – 10 mins</b>	In-clinic time
<b>&gt; 10 mins</b>	Calls/paperwork/ administrative burden
<b>&gt; 15 mins</b>	<b>Overall savings/patient</b>

## SATISFACTION

### Patients / Parents

Dx before leaving, time saved,  
no additional cx cost, etc....?

### Staff

Don't underestimate this

## REPUTATION

Increases "Street Cred"  
Separates you from the pack



# Financial Analysis

BASED ON THE CLINICAL BENEFITS AND OPERATIONAL VALUE



Conducted financial analysis



Considered 3 molecular tests for our practice



Independently evaluated 4 of our payors across each test



We found reimbursement was adequate

Financial analysis was based on our experience at our practice. Each practice will vary.

# Molecular Testing in Urgent Care



More expensive than antigen tests

Not ALL insurance covers (per encounter rate)

Initial time, energy, and effort to set up



Need molecular instrument



Need to stock both antigen AND molecular tests



More training (BUT SUPER, SUPER simple to operate)



Downside

# Molecular Testing in Urgent Care



Faster turn around time (get people in/out)



More accurate (eliminates false treatments, supports antimicrobial stewardship)



Eliminates need for follow-up testing (no culture, maintain control of process)



Saves money, time, staff involvement, staff work, patient effort



New technology, fancy instrument - patients love this



Easy to use and VERY reliable



HUGE patient satisfier



Separates your clinic from “the pack”  
Don’t underestimate this



# Clinical Cases



# PT CASE #1

---

7-year-old male presents with fever to 102, nausea and vomiting for 2-3 days getting worse. No sick contacts

**PMHX:** Non contributory, IMM UTD

**VITALS:**

- T- 101.7 (Tylenol given 2 hrs PTA)
- HR-122
- RR-31
- SPO2- 99%

**PE:**

- Overall tired looking, non-toxic
- Abd. Soft, mildly diffusely TTP
- Lungs CTA bil.
- Tachycardic
- NEG. TTP Mcburney's



# PT CASE #1 (CONT.)

---

## DDX:

Appendicitis, gastroenteritis, strep

## TESTS:

Strep A **NEG** by antigen test.  
CX sent. TAT 2-3 days

## D/C:

STRICT return precautions provided  
(appendicitis worry)





# PT CASE #1 (CONT.)

---

**2 DAYS LATER...**

**CX POS.** (False negative antigen test)

**Pt contacted by staff**

**Pt returned for RX**

## **DISPOSITION**

RX: Amoxicillin

Pt followed up in 2 days

Did well

## **IMPACT**

Call-back

MA time

Patient time and inconvenience

Delayed diagnosis



# PT CASE #2

---

6-year-old female presents with fever (Tmax 101.6), sore throat, malaise for 1 day.

- **PMHX:**

- 34 week SVB, IMM UTD, TTN

- **VITALS:**

- HR 128
- Temp 102.6
- RR 41
- SPO2-99% on RA

- **PE:**

- Lethargic appearing
- Warm
- Pos. anterior adenopathy
- Bil. Tonsilar exudate



# PT CASE #2

---

## DDX:

Strep, RSV, influenza

## TEST RESULTS:

- Neg flu
- Neg RSV
- Pos. Strep
  - Molecular test-answer in 3 minutes

## RX:

Amoxicillin, fluids, supportive care, D/C home

Patient did great

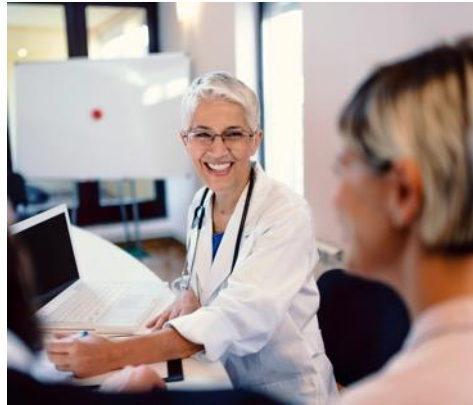
NO second swab, no call backs, no staff follow-up (other than usual “how are you feeling” next day call)





# Summary

- GAS is not always straight forward; don't treat without lab confirmed diagnosis
- RADT = culture negatives, 1 – 2-day delay in diagnosis, loss of control
- IDSA GAS guidelines have not been updated with statements on molecular use
- Rapid & accurate molecular strep A testing is GAME CHANGING; protocols and workflow align with time-sensitive care settings
  - No calls, no delays, no “issues or problems”
  - No follow-up, no scanning
- Inappropriate antibiotic use is a GLOBAL problem and stewardship is the responsibility of ALL clinicians



# Ron Efenbein, MD

Medical Director  
*First Call Medical Center*

Emergency Physician  
Attending at multiple hospitals  
in MD and DE



thank  
you :)

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# Q & A

## MODERATOR



**Ian Reilly, MD, FACEP**

Emergency Physician  
*Scripps Memorial Hospital*

## SPEAKERS



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