Learning Objectives

2020 GSA Winter Forum

Matthew T. Popovich, PhD

ASA Director of Quality and Regulatory Affairs

Burden Reduction Myths and Opportunities: An Assessment of Recent Regulatory Actions Affecting Anesthesiologists

- Describe goals of federal regulatory policy on burden reduction as it relates to healthcare and patient safety
- 2. Identify three federal policy decisions related to burden reduction on the Quality Payment Program and Conditions of Physician Participation
- 3. Explain the impact standard setting organizations and medical society guidelines and standards have on facility accreditation, physician workflow, and regulatory burden

Ellen Basile, DO

Director, Pediatric Anesthesia, Department of Anesthesiology, Augusta University, Medical College of Georgia

Second Victim

- 1. Define second victim
- 2. Describe signs and symptoms of second event with potential outcomes from an event
- Review interventions and care options for second victims

Judith Handley, MD

Associate Professor, Department of Anesthesiology Augusta University, Medical College of Georgia

You've Been Served: Strategies to Survive a Medical Malpractice Suit

- 1. Discuss recent statistical trends in medical malpractice
- 2. Identify the key parts of the legal process involved in a medical malpractice case
- 3. Discuss specific physician experiences to a medical malpractice case
- 4. Identify strategies to decrease stress if involved in a medical malpractice case.

Michele Au, MD Physician Specialists in Anesthesia Emory – St. Joseph's Hospital, Atlanta

This Won't Hurt a Bit (and other white lies): Career, Family, and Balance in Anesthesia

- Address the stressors physicians face in timing and balancing the dual demands of clinical work and home responsibilities
- 2. Address the tension between the two stressors that can lead to burnout
- 3. Engage strategies to help other physicians better manage responsibilities, time and thought processes regarding these stressors

Dr. Francis Wolf, MD Assistant Professor of Anesthesiology, Emory University, School of Medicine

Topic 1: Rethinking Penicillin Allergies in the Perioperative Period: An Opportunity for Stewardship

- 1. Describe how a penicillin allergy listing impacts surgical patients
- 2. Cite the basis of cefazolin's lack of cross-reactivity with other beta-lactam agents
- 3. Describe a focused allergy assessment to determine the history of a severe delayed reaction
- 4. Describe the importance of a multi-disciplinary approach in perioperative antibiotic stewardship

Topic 2: Residual Paralysis: Is Our Silent Epidemic of Weakness Finally Over?

- 1. Provide the definition of residual neuromuscular blockade (rNMB)
- 2. Cite some of the main causes of rNMB
- Compare qualitative and quantitative nerve monitoring
- 4. Describe the advantages and limitations of sugammadex as a reversal agent

AGENDA

Friday, Ja	nuary 10	10:00a – 11:00a	You've Been Served: Strategies to Survive a				
4:00 - 6:30p	Registration Second Floor Landing (Azalea)		Medical Malpractice Suit Judith Handley, MD Associate Professor, MCG				
4:00 - 6:30p	Exhibit Assembly Azalea Prefunction	11:00a – 12:00p	Burden Reduction Myths and Opportunities: An Assessment of Recent				
4:30 - 6:30p	Board of Directors Meeting TBD		Regulatory Actions Affecting Anesthesiologists Matthew Popovich, PhD				
7:00 - 8:30p	Hospitality Suite Networking *see registration for location Hors d'oeuvres and refreshments		ASA Director of Quality and Regulatory Affairs				
8:00p	provided Dinner on Your Own or join Group Dinner	12:01 – 1:00p	Lunch/Exhibitor Conversations GSA Semi-Annual Business Meeting Azalea				
3.336	(self pay)						
Saturday.	January 11	1:00 - 2:00p	Topic 1: Rethinking Penicillin Allergies in the Perioperative Period: An Opportunity				
	take place in Azalea Ballroom unless		for Stewardship Topic 2: Residual Paralysis: Is Our Silent				
otherwise noted			Epidemic of Weakness Finally Over?				
			Francis Wolf, MD				
6:00a	Exhibit Assembly Azalea Prefunction		Emory University School of Medicine				
6:30 - 7:20a	Registration Second Floor Landing Breakfast with Exhibitors	2:00 – 2:10p	Resident Abstract Presentation Mayank Mehrotra MD (MCG)				
7:20 – 7:30a	Azalea Prefunction Welcome	2:10 – 2:20p	Chocolate/Caffeine Break				
	Dr. Steve Sween, MD GSA President Introductions	2:20 3:30p	Healthcare Policy Panel				
	Rachel Steckelberg, MD, MPH Dr. Philip Mills, DO	3:30p	GSA Committee Meetings				
	Winter Forum Activity Directors	4:30p	Committee Reports – General Session				
7:30 - 8:30a	This Won't Hurt a Bit (and other white lies): Career, Family, and Balance in	5:00 – 6:30p	Adjourn/Evening Hospitality				
	Anesthesia Michelle Au, MD	Sunday, Ja	anuary 12				
	Emory – St. Joseph's Hospital	8:30a 9:00 – 11:00a	Continental Breakfast Advocacy Workshop				
8:30 - 9:30a	Second Victim		(All are welcome to participate. There is				
	Ellen Basile, DO Director, Pediatric Anesthesia, MCG		no charge for this training. Please confirm your attendance at the registration desk on Friday or Saturday.)				
9:30 - 10:00a	Break with Exhibitors Azalea Prefunction		on may or Saturday.)				
9:30 - 11:00a	Resident Section Meeting						

Accreditation and Designation 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 Society of Anesthesiologists® and the Georgia Society of Anesthesiologists. The American Society of Anesthesiologists is accredited by the ACCME to provide continuing medical education for physicians.

The American Society of Anesthesiologists designates this live activity for a maximum of 6 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Disclaimer

The information provided at this activity is for continuing education purposes only and is not meant to substitute for the independent medical judgment of a healthcare provider relative to diagnostic and treatment options of a specific patient's medical condition.

Disclosure Statement

The American Society of Anesthesiologists remains strongly committed to providing the best available evidence based clinical information to participants of this educational activity and requires an open disclosure of any potential conflict of interest identified by our faculty members. It is not the intent of the American Society of Anesthesiologists to eliminate all situations of potential conflict of interest, but rather to enable those who are working with the American Society of Anesthesiologists to recognize situations that may be subject to question by others. All disclosed conflicts of interest are reviewed by the educational activity course director/chair to ensure that such situations are properly evaluated and, if necessary, resolved. The American Society of Anesthesiologists educational standards pertaining to conflict of interest are intended to maintain the professional autonomy of the clinical experts inherent in promoting a balanced presentation of science. Through our review process, all American Society of Anesthesiologists activities are ensured of independent, objective, scientifically balanced presentations of information. Disclosure of any or no relationships will be made available for all educational activities.

No speakers and/or planning committee members have indicated that they have relevant financial relationships with commercial interests to disclose:

Commercial Support

None

Claiming Credit for this Activity

Thank you for attending the **2020 Georgia Society of Anesthesiologists Winter Forum** on **January 11-12, 2020**. Please follow the directions below to complete the meeting survey, claim your credits, and print your certificate. *Note that this activity may not be loaded into the system until next week*.

- Click the following link and log in using your ASA credentials: https://education.asahq.org/totara/course/view.php?id=3607
- Complete the meeting survey, claim credits, and print your certificate.

OR

- Log in to the ASA Education Center at: http://education.asahq.org/.
- Once you have logged on to the ASA Education Center homepage, click the tab that says "MY COURSES" to select the link: 2020 Georgia Society of Anesthesiologists Winter.
- Complete the meeting survey, claim credits, and print your certificate.

NOTE: To retrieve your username and/or password, enter your email address at: https://www.asahq.org/member-center/forgot-password.

Please note: you must claim your credits for this course by November 30, 2019. You will NOT be able to claim credits after this date.

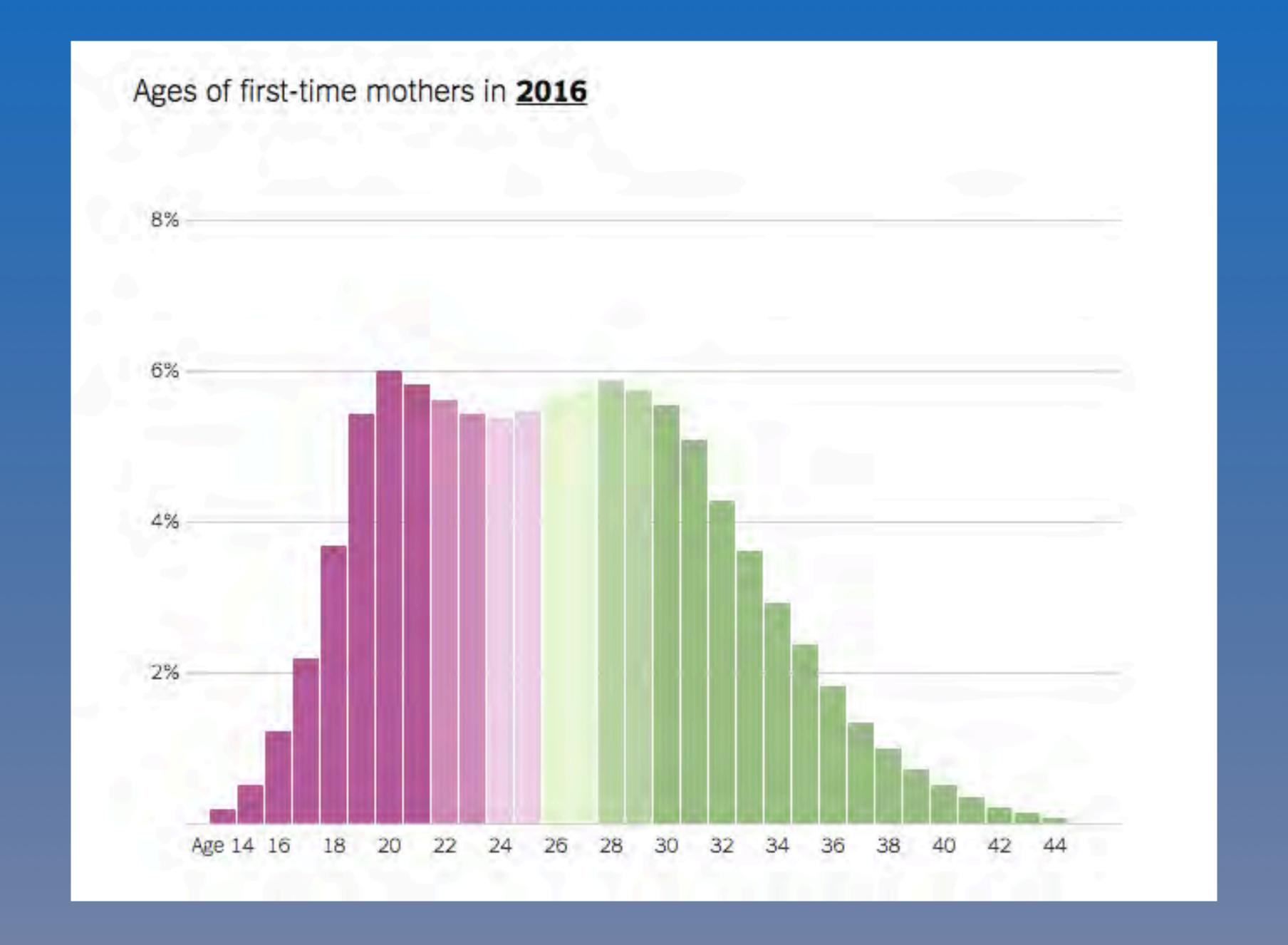
THIS WON'T HURT A BIT (AND OTHER WHITE LIES)

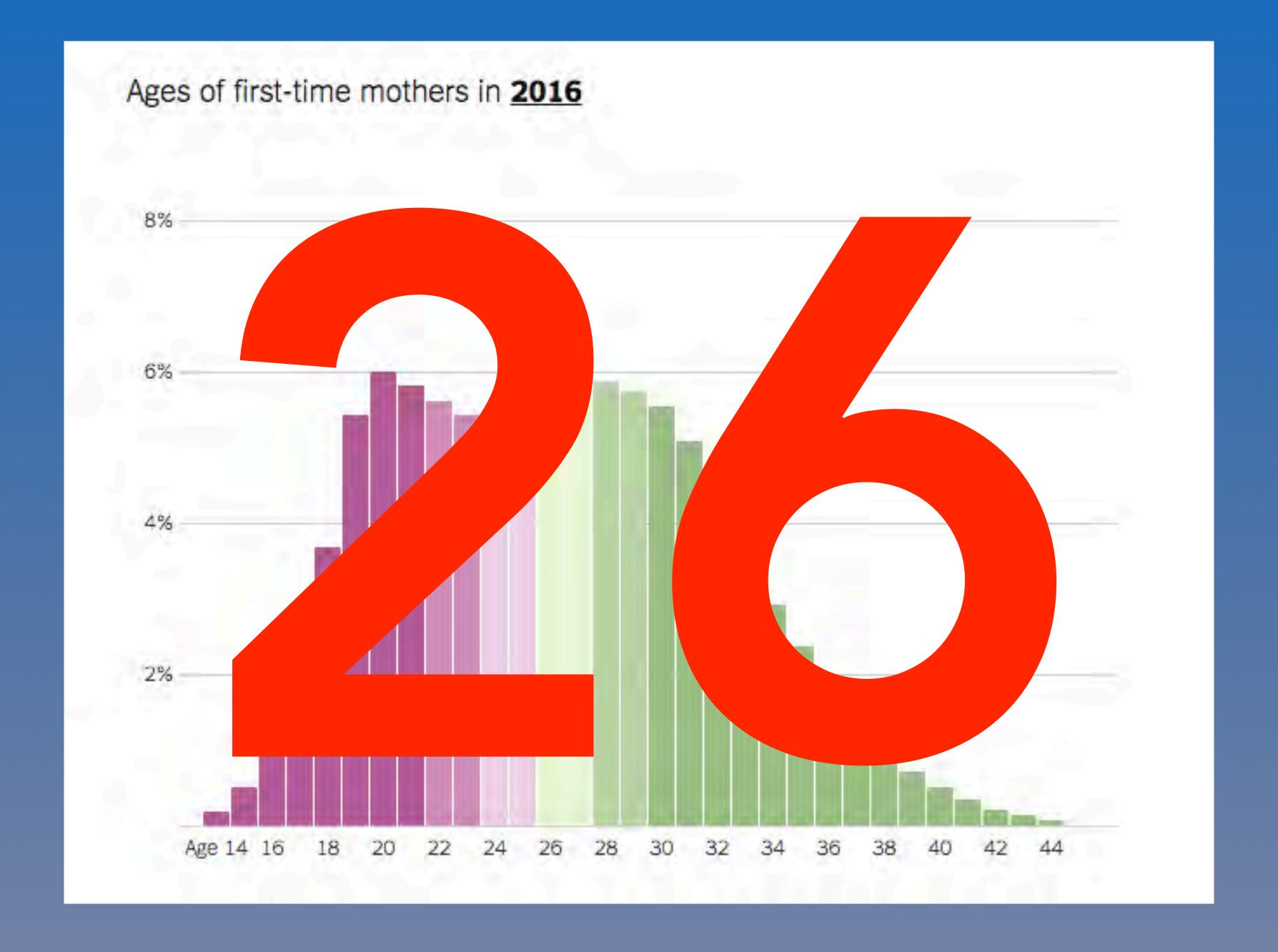
CAREER,
FAMILY, AND
BALANCED
ANESTHESIA



Michelle Au, MD, MPH
PHYSICIAN SPECIALISTS IN ANESTHESIA







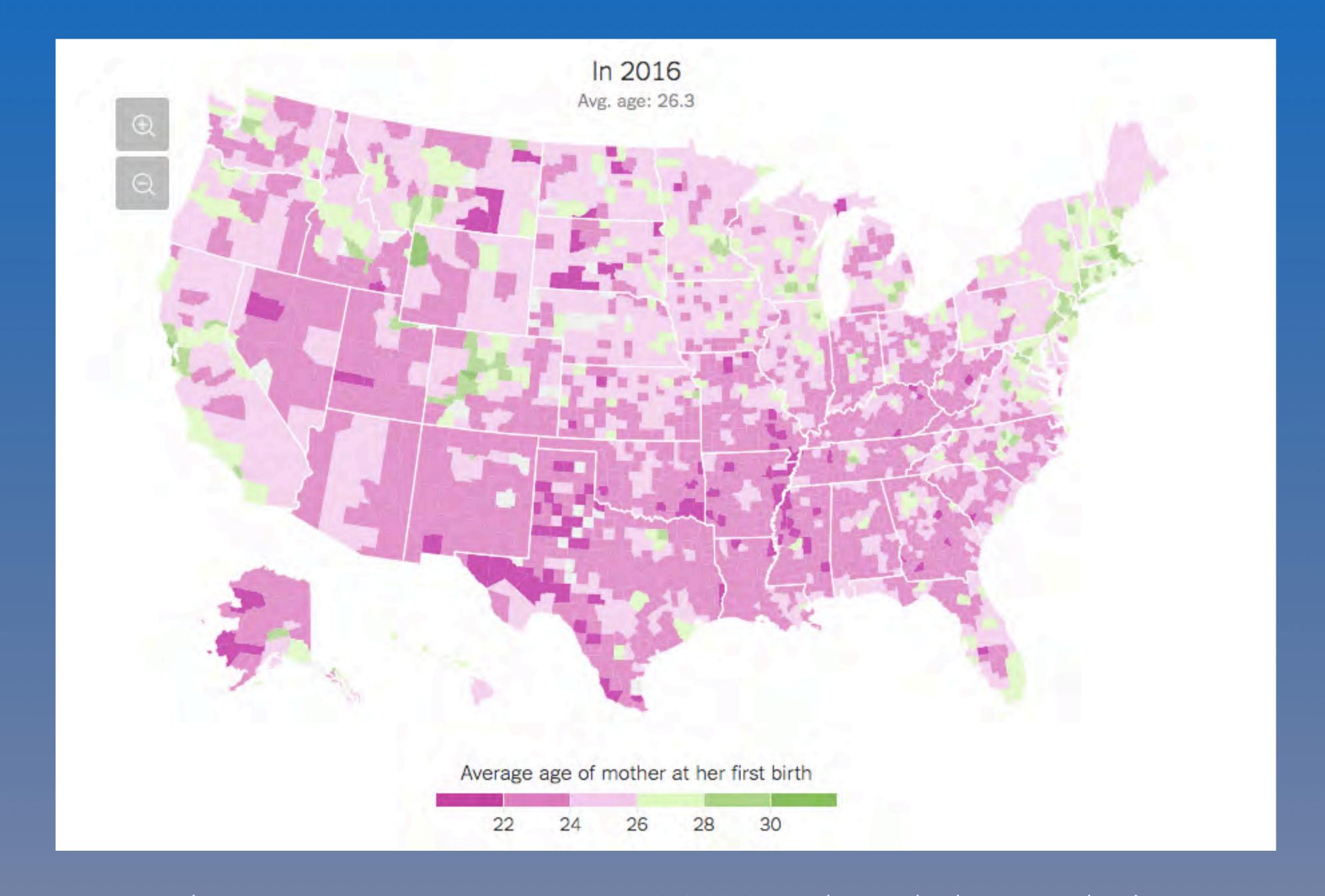


Table A-6: Age of Applicants to U.S. Medical Schools at Anticipated Matriculation by Sex and Race/Ethnicity, 2014-2015 through 2017-2018



The table below displays the self-identified racial and ethnic characteristics of applicants to U.S. medical schools from 2014-2015 through 2017-2018. The "Multiple Race/Ethnicity" category includes those who selected more than one race/ethnicity response. Please email datarequest@aamc.org if you need further assistance or have additional inquiries.

		2014-201			1	2015-2016			2016-2017*			2017-2018		
Mean Age of Applicants at Anticipated Matriculation		Matriculated		All	Matriculated		All	Matriculated		All	Matriculated		All	
		No	Yes	All	No	lo Yes		No	Yes	All	No Ye	Yes	All	
Women	American Indian or Alaska Native	27	25	26	26	24	25	27	24	26	27	25	26	
	Asian	24	23	24	24	23	24	24	23	24	24	23	24	
	Black or African American	26	24	25	25	24	25	26	24	25	26	24	25	
	Hispanic, Latino, or of Spanish Origin	25	24	24	25	24	24	25	24	24	25	24	24	
	Native Hawaiian or Other Pacific Islander	28	25	26	26	24	25	27	24	26	25	25	25	
	White	24	24	24	24	24	24	24	24	24	24	24	24	
	Other	24	24	24	25	23	24	24	24	24	24	24	24	
	Multiple Race/Ethnicity	25	24	24	25	24	24	25	24	24	25	24	24	
	Unknown Race/Ethnicity	25	24	24	25	24	24	25	23	24	25	24	24	
	Non-U.S. and Non-Permanent Resident	24	24	24	24	24	24	24	24	24	24	24	24	
	Total	25	24	24	25	24	24	25	24	24	25	24	24	
Men	American Indian or Alaska Native	26	26	26	27	25	26	27	25	26	25	25	25	
	Asian	24	23	24	24	23	24	24	23	24	24	23	24	
	Black or African American	27	24	26	27	24	26	26	24	26	26	24	26	
	Hispanic, Latino, or of Spanish Origin	25	24	25	25	24	25	25	24	25	25	24	25	
	Native Hawaiian or Other Pacific Islander	27	27	27	27	24	26	27	29	28	27	24	26	
	White	25	24	25	25	24	25	25	24	25	25	24	25	
	Other	25	24	24	25	24	25	25	24	24	25	24	24	
	Multiple Race/Ethnicity	25	24	25	25	24	25	25	24	25	25	24	25	
	Unknown Race/Ethnicity	25	24	25	25	24	25	26	25	26	26	24	25	
	Non-U.S. and Non-Permanent Resident	24	24	24	24	24	24	24	24	24	24	24	24	
	Total	25	24	24	25	24	25	25	24	25	25	24	24	

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		2014-2015			2015-2016			2016-20	2017-2018			
Mean Age of Applicants at Anticipat		1atriculated Yes		All	Matriculated No Yes		riculated	All	Matriculated		All	
				All			Yes	All	No	Yes	All	
Women	American Indian or Alask		25	26	26			24	26	27	25	26
	Asian		23	24	24			23	24	24	23	24
	Black or African Americ		24	25	25			24	25	26	24	25
	Hispanic, Latino, or of Spanish Origin		24	24	25			24	24	25	24	24
	Native Hawaiian or Other Pacific Islander		25	26	7			24	26	25	25	25
	White		24	24		4		24	24	24	24	24
	Other	A	24	24		23		24	24	24	24	24
	Multiple Race/Ethnicity	25	24	24		24		24	24	25	24	24
	Unknown Race/Ethnicity	25	24	7		24		23	24	25	24	24
	Non-U.S. and Non-Permanent Reside	24	24		A	24		24	24	24	24	24
	Total	25	24						24	25	24	24
Men	American Indian or Alaska	26	26						26	25	25	25
	Asian	24	23	24	24	23		23	24	24	23	24
	Black or African Ameri		24	26	27	24		24	26	26	24	26
	Hispanic, Latino, or of		24	25	25	24		24	25	25	24	25
	Native Hawaiian or Otl		27	27	27	24		29	28	27	24	26
	White	25	24	25	25	24	25	25 24	25	25	24	25
	Other	25	24	24	25	24	25	25 24	24	25	24	24
	Multiple Race/Ethnicity	25	24	25	25	24	25	25 24	25	25	24	25
	Unknown Race/Ethnicity	25	24	25	25	24	25	26 25	26	26	24	25
	Non-U.S. and Non-Permanent Resident	24	24	24	24	24	24	24 24	24	24	24	24
	Total	25	24	24	25	24	25	25 24	25	25	24	24

MATH TIME!

$$24 + 4 + 3 = 31$$
to
$$24 + 4 + 8 = 36$$
years old at end of training

healthline

FEMALE fertility TIMELINE











AGES 18-24

"best" age to procreate from a physical standpoint

AGES 25-30

chance of getting pregnant without intervention remains steady AGES 31-35

chances of conceiving are still high but odds will start to decline AGES 36-40

greatest reduction in fertility; risks of chromosomal issues with eggs are higher AGES 41-45+

chances of conceiving are low; body is preparing for menopause



SCREAMING INESIES ES









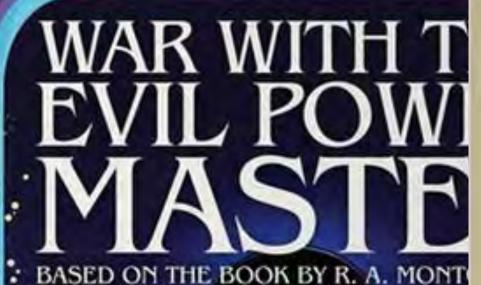


CHOOSE YOUR OWN ADVENTURE®

CHOOSE YOUR OWN AD

I or More Players

Page 15 1 or More Players





A COOPERATIVE ADVENTURE G/ BY PROSPERO HALL

BY KEN MCMURTRY

LKOM TO

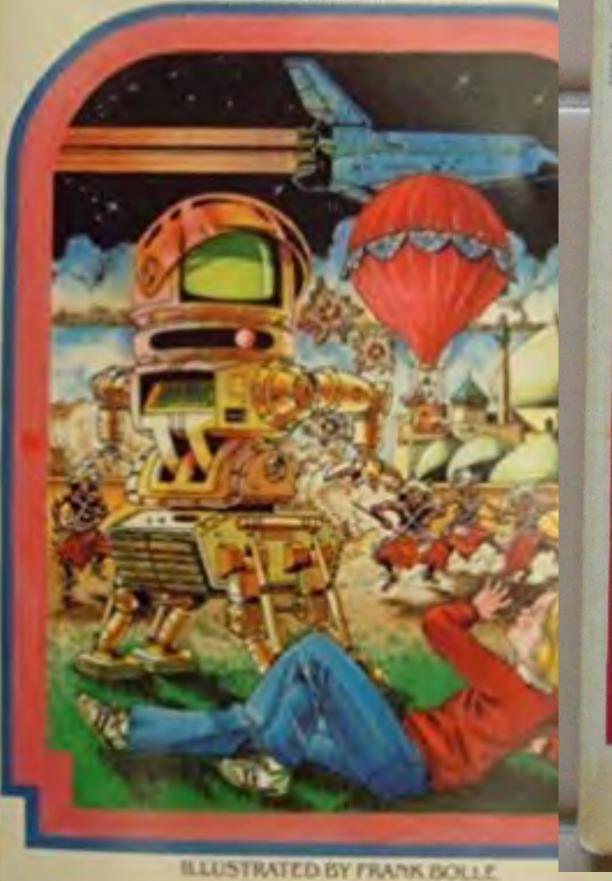
ENDINGS!

CHOOSE YOUR OWN ADVENTURE

STORY CHOOSE FROM 22 POSSIBLE EN

SUPERCOMPUT

BY EDWARD PACKARD

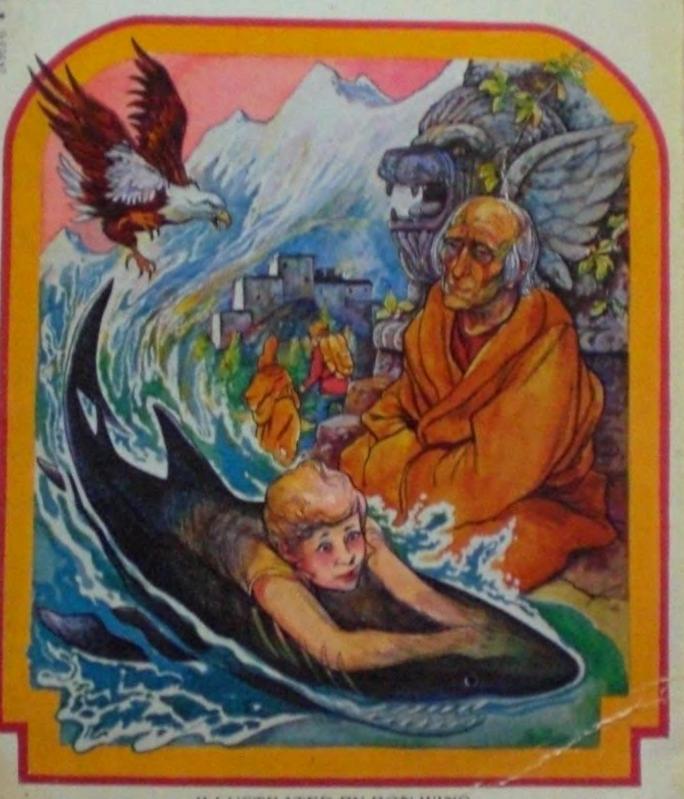


CHOOSE YOUR OWN ADVENTURE

YOU'RE THE STAR OF THE STORY! CHOOSE FROM 14 POSSIBLE ENDINGS

YOU ARE A SHARK

BY EDWARD PACKARD



ILLUSTRATED BY RON WING













"The patient comes first."

"Nothing is more important than family."

"Never show weakness."







THE ART OF TRIAGE

	URGENT	NON-URGENT							
IMPORTANT	DO IT NOW	SET A TIME AND DO IT LATER							
UNIMPORTANT	DELEGATE IT	GET RID OF IT							











PAY IT BACK



PAY IT FORWARD







michelleau@gmail.com



@scutmonkey



michelleaumd

SECOND WICTIM



ELLEN BASILE, DO

ASSOCIATE PROFESSOR

DEPARTMENT OF ANESTHESIOLOGY

CHILDREN'S HOSPITAL OF GEORGIA

AUGUSTA UNIVERSITY

DISCLOSURE

Under Accreditation Council for Continuing Medical Education Guidelines, disclosure must be made regarding <u>relevant</u> financial relationships with commercial interests within the last 12 months:

ELLEN ROARK BASILE, DO

DEPARTMENT OF ANESTHESIOLOGY
CHILDREN'S HOSPITAL OF GEORGIA
AUGUSTA UNIVERSITY

HAS NO RELEVANT FINANCIAL RELATIONSHIPS OR AFFILIATIONS WITH COMMERCIAL INTERESTS RELATED TO THIS TOPIC TO DISCLOSE.

MARIAH

GIRL DIES FOLLOWING TONSILLECTOMY

\$6 MILLION RECOVERY

PACU

FENTANYL

MONITOR ALARMS SILENCED

LACK OF NURSING ASSESSMENTS

ALBERT WU, MD JOHNS HOPKINS

MEDICAL ERROR: THE SECOND VICTIM BMJ. 2000 MAR 18;320(7237):726-7.

HEALTHCARE WORKER INVOLVED IN AN ADVERSE PATIENT OUTCOME...
WITH PREDICTABLE EMOTIONAL RESPONSE

SIGNS/ SYMPTOMS

RISK FACTORS

POTENTIAL OUTCOMES

RECOVERY PHASE

INTERVENTIONS/ TREATMENT OPTIONS

PREDICTABLE RESPONSE

THINK PTSD

RISK FACTORS

PEDIATRICS

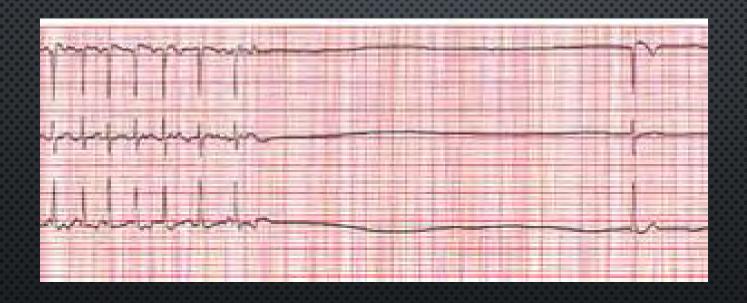


ASA 5/6

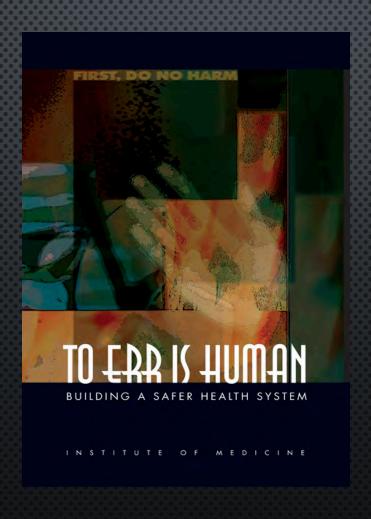
HONOR WALK



FIRST DEATH



MEDICAL ERROR



LAWSUITS



TRAINING



GOODNIGHT, SWEET PRINCE... AND FLIGHTS OF ANGELS SING THEE TO THY REST



OH SHIT



DENIAL

EGO

GUILT

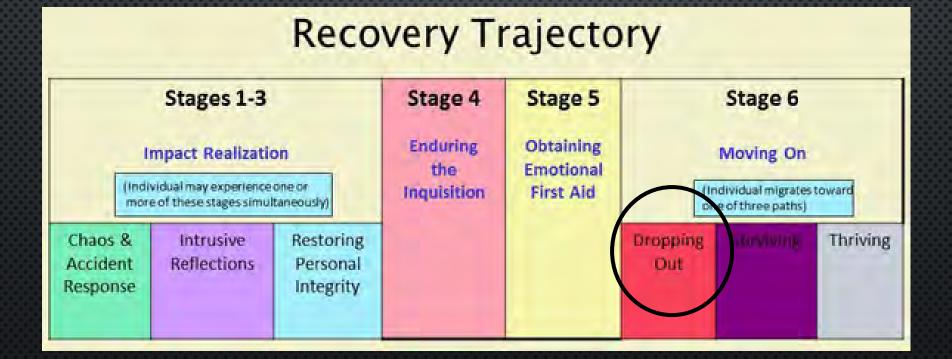
MEDICINE ASIDE

AIR FRANCE, FLIGHT 447-228 DEATHS

"DAMN IT, WE'RE GOING TO CRASH...

THIS CAN'T BE HAPPENING!"

STAGES OF RECOVERY





SUICIDE RATES PER 100,000

GENERAL PUBLIC 13.0

ARMY 23.8

Physicians 40

PHYSICIAN SUICIDE RISK

MALES 70% > THAN PUBLIC

FEMALES 250-400% > THAN PUBLIC

SPECIAL REPORT: SI AMONG SURGEONS

2011 SURVEY

7,905 SURGEONS RESPONDED

6.3% REPORTED SI
(3.3% GENERAL POPULATION)

SI AMONG SURGEONS

TOP THREE REASONS FOR SI

#1 + SCREEN FOR DEPRESSION

#2 BURNOUT

#3 MEDICAL ERROR IN PAST 3 MOS

SI AMONG SURGEONS

SURGEONS WHO REPORTED PERCIEVED MEDICAL ERROR

16.2% REPORTED SI

= 4 FOLD INCREASE

PAUL KALANITHI, MD

FOREWORD BY ABBAHAM VERGRESE

WHEN BREATH BECOMES



RECOGNIZED PROGRAMS

STANFORD

BRIGHAM AND WOMEN'S HOSPITAL

UNIVERSITY OF MISSOURI

SUSAN SCOTT, PhD, RN

University of Missouri Health System

FORYOU TEAM - PEER TO PEER

Survey questions adapted from her work

MITTS.ORG

MITSS

Medically Induced Trauma Support Services

YOU'RE NOT ALONE WE CAN HELP



"November 18, 1999 marks a day that changed my life for ever."

STRONGLY RECOMMENDED

24 HRS OFF –NO CLINCIAL DUTY

DEBRIEFING

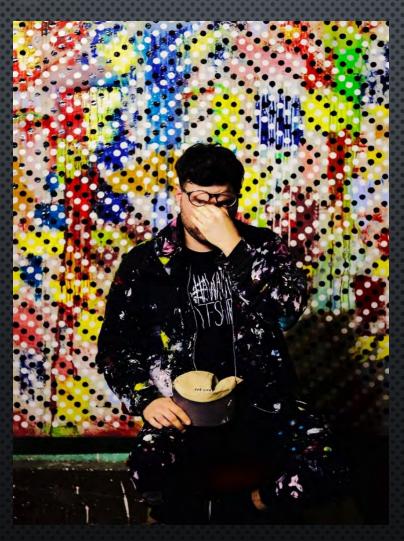
CAPTAIN SULLY



CONTACT INFO

EBASILE@AUGUSTA.EDU

QUESTIONS



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You've Been Served Strategies to Survive a Medical Malpractice Suit

Judith L.P. Handley M.D.

Associate Professor

Department of Anesthesiology and Perioperative Medicine

Children's Hospital of Georgia

January 11th, 2020

Relevant Disclosure and Resolution

Judith L.P. Handley, M.D.

I have no relevant relationships or affiliations with commercial interests to disclose

Learning Objectives

• Review recent statistical trends in medical malpractice.

• Identify the key parts of the legal process involved in a medical malpractice case.

• Discuss specific physician experiences and reactions to a medical malpractice case.

• Identify strategies to decrease stress if involved in a medical malpractice suit.

Some Interesting Information

2018 Medical Malpractice Payout Analysis

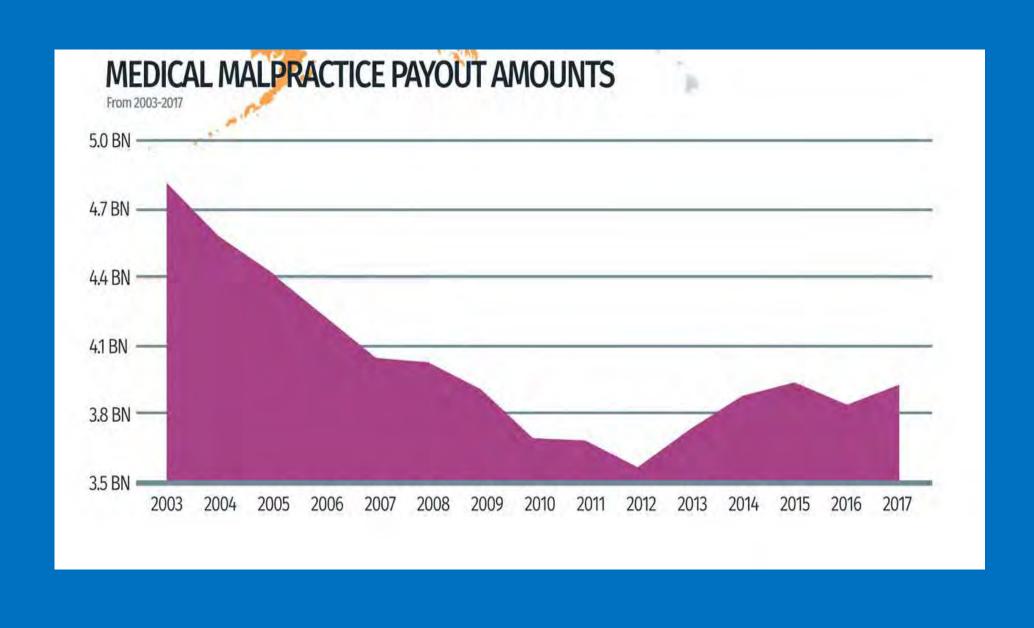
• Payouts in 2017 as reported to the National Practitioner Data Bank

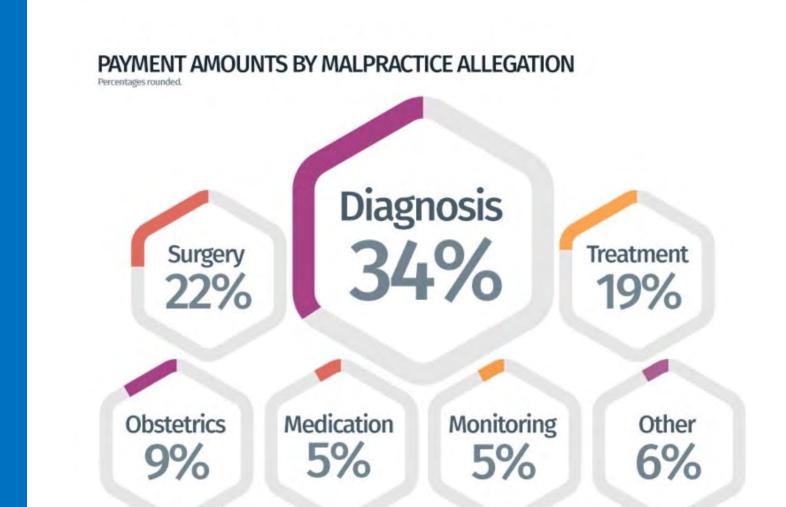
• 3.9 Billion total payouts

• Top States: New York, Rhode Island, New Jersey



• Bottom States: Wisconsin, South Dakota, Vermont







AVERAGE PAYMENT AMOUNTS

Payment amount by severity of the alleged outcome.

QUADRIPLEGIC, BRAIN DMG, LIFE CARE\$	1,029,105	MAJOR TEMPORARY \$214,407
MAJOR PERMANENT INJURY \$	600,797	CANNOT BE DETERMINED \$109,583
SIGNIFICANT PERMANENT INJURY\$	424,645	EMOTIONAL INJURY \$ 91,678
DEATH\$	374,530	MINOR TEMPORARY \$ 72,850
MINOR PERMANENT INJURY \$	236,057	INSIGNIFICANT INJURY \$ 34,333

Medscape Malpractice Report 2017

Methodology

Survey Method

Physicians were invited to participate in a 10-minute online survey.

Screening Requirements

Respondents were required to be practicing medicine in the United States.

Sample Size

A total of 4137 physicians across 25+ specialties met the screening criteria and completed the survey; weighted to the AMA's physician distribution by specialty.

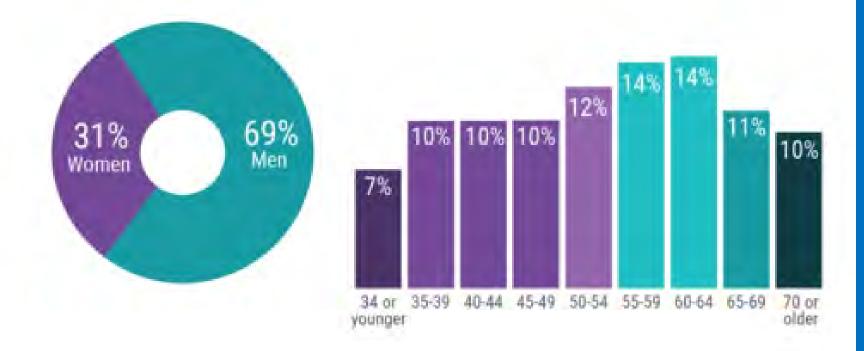
Recruitment Period

August 25 to October 6, 2017

Sampling Error

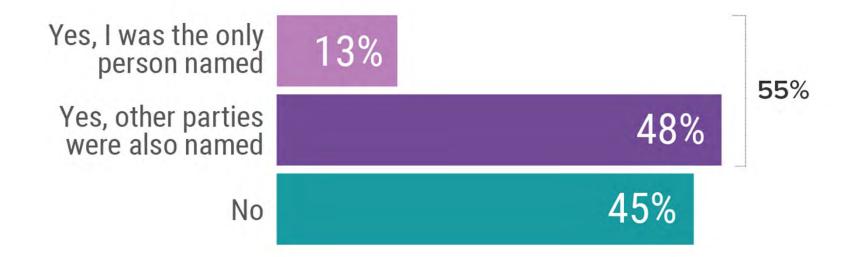
The margin of error for the survey was ± 1.52% at a 95% confidence level using a point estimate of 50%.

Demographics

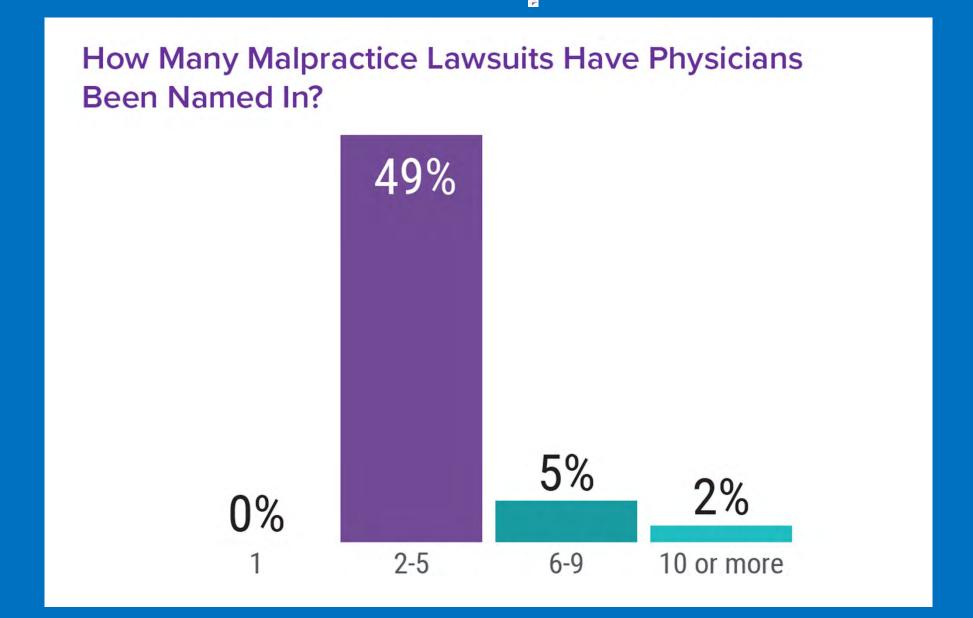


Was the Lawsuit Warranted? 89% No Unsure

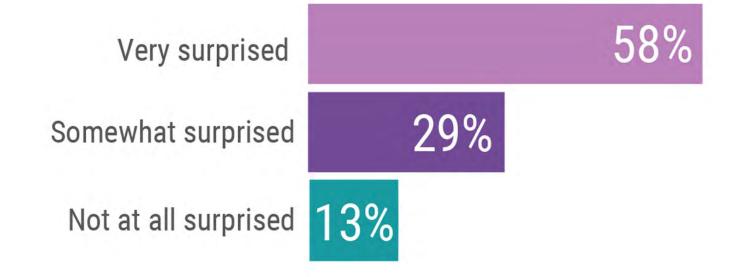
Have You Ever Been Named in a Malpractice Lawsuit?



Top 10 Specialties for Lawsuits Surgery 85% OB/GYN & Women's Health 85% Otolaryngology 78% Urology 77% Orthopedics 76% Plastic Surgery/Aesthetic Medicine 73% Radiology 70% Emergency Medicine 65% Gastroenterology 62% Anesthesiology 61%

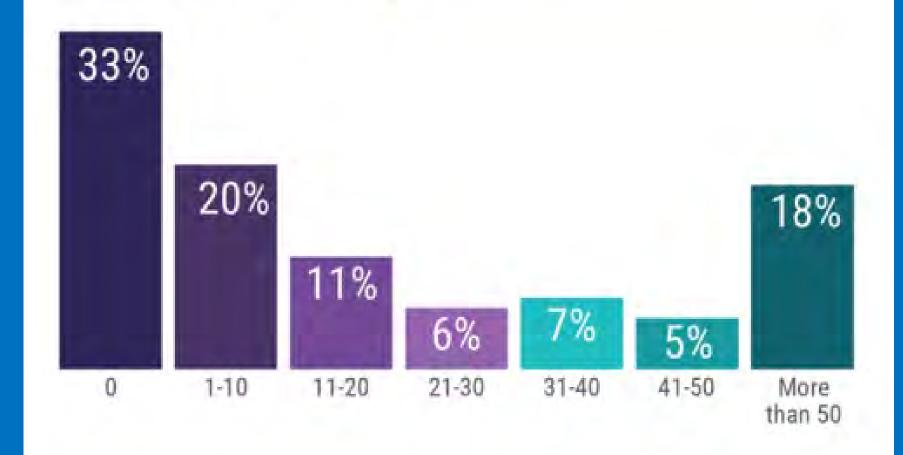


Were Physicians Surprised by the Lawsuit?



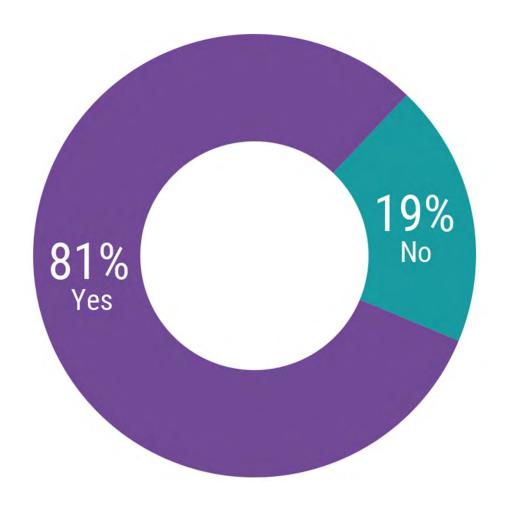
How Many Hours Did Physicians Spend on Their Defense? 33% 16% 16% 14% 12% 8% 2% 6-10 1-5 11-20 21-30 31-40 More than 40

How Many Hours Did Physicians Spend in Court and In Trial-Related Meetings?





Did Physicians Give Depositions?



Physicians' Advice About Deposition and Trial

Only be factual; answer questions, but don't volunteer information.

Trust your lawyer.

Try not to be intimidated.

Read all of the records, including the nursing notes.

Document everything in the patient encounter.

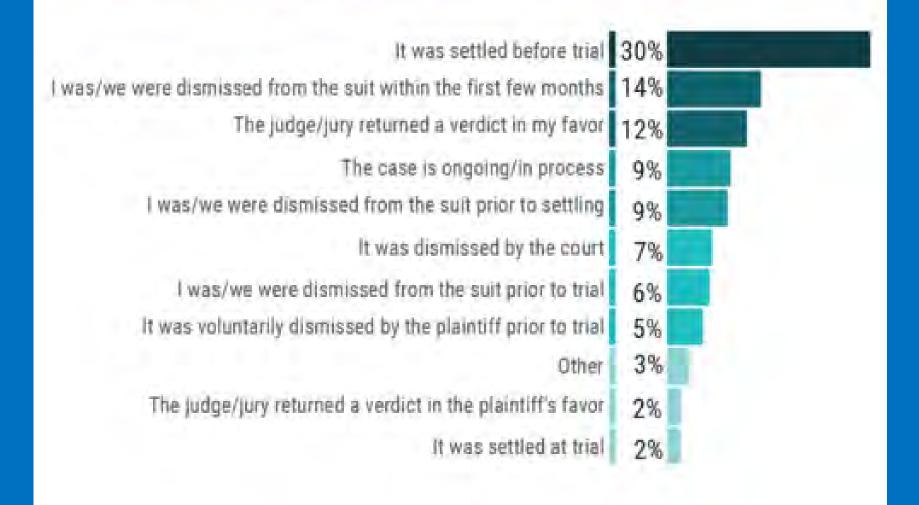
If you don't recall, say so. Don't guess.

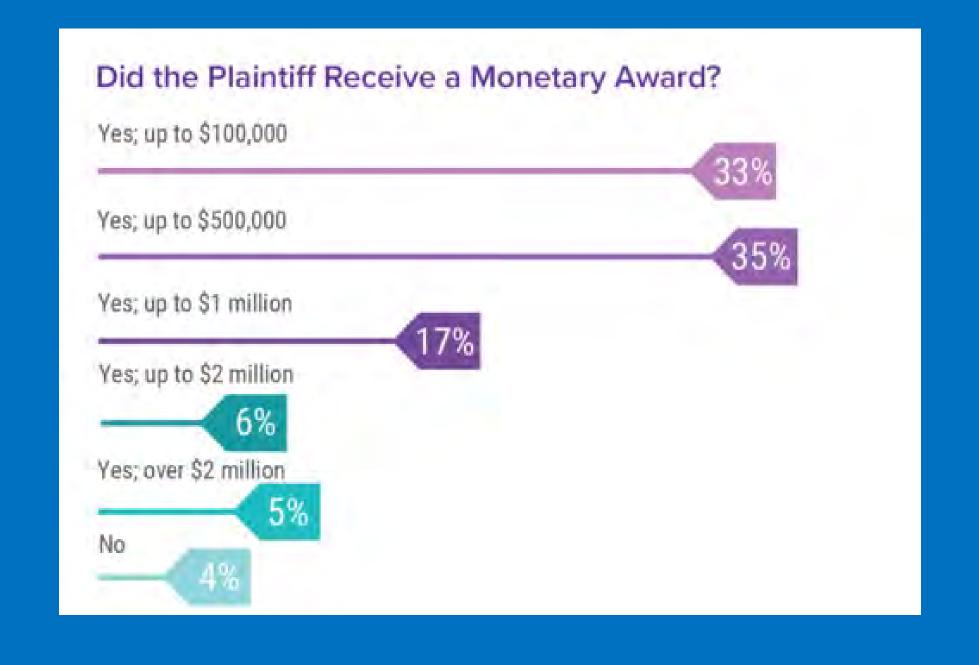
The plaintiff attorney is the enemy.

Stay focused.

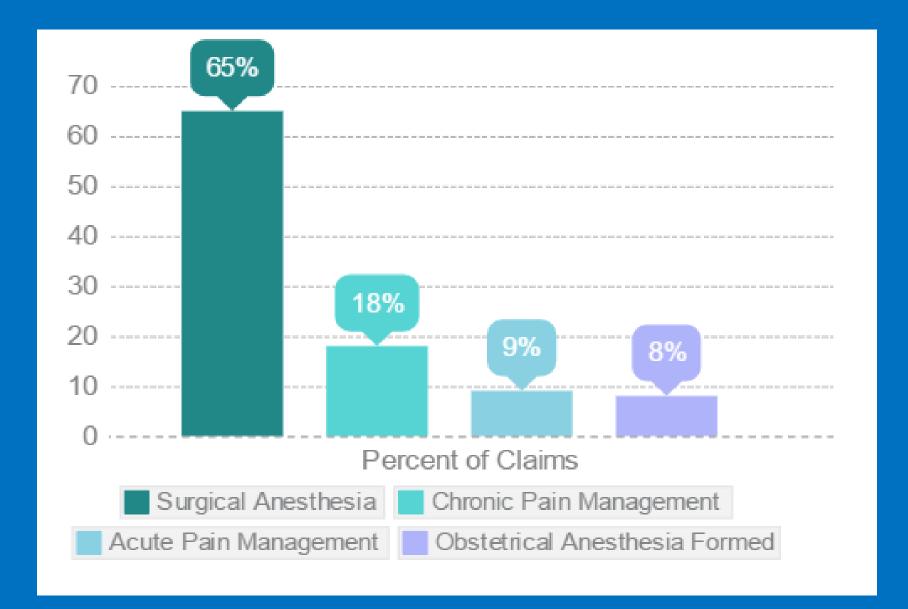
Just tell the truth and keep answers short.

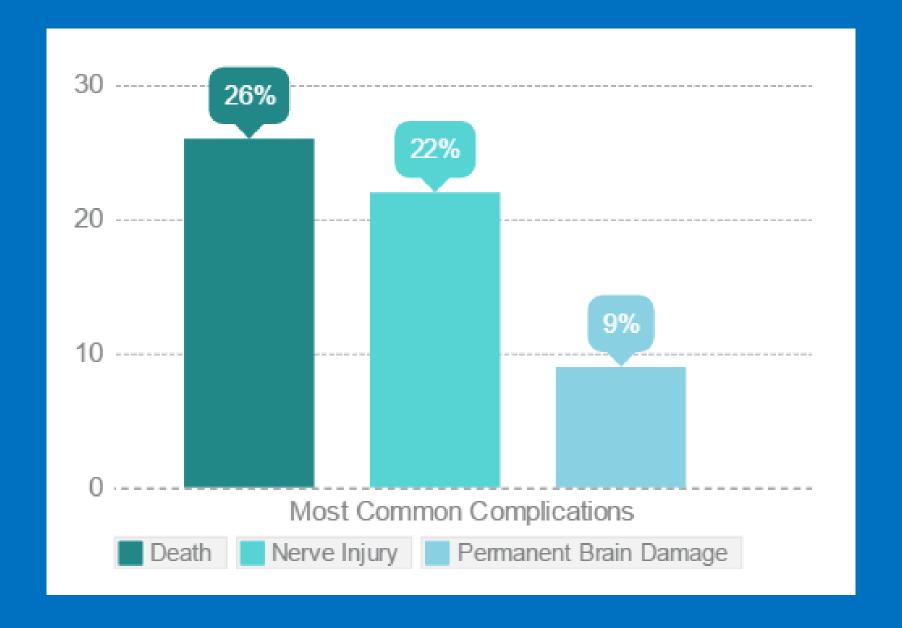
What Ultimately Happened With the Lawsuit?

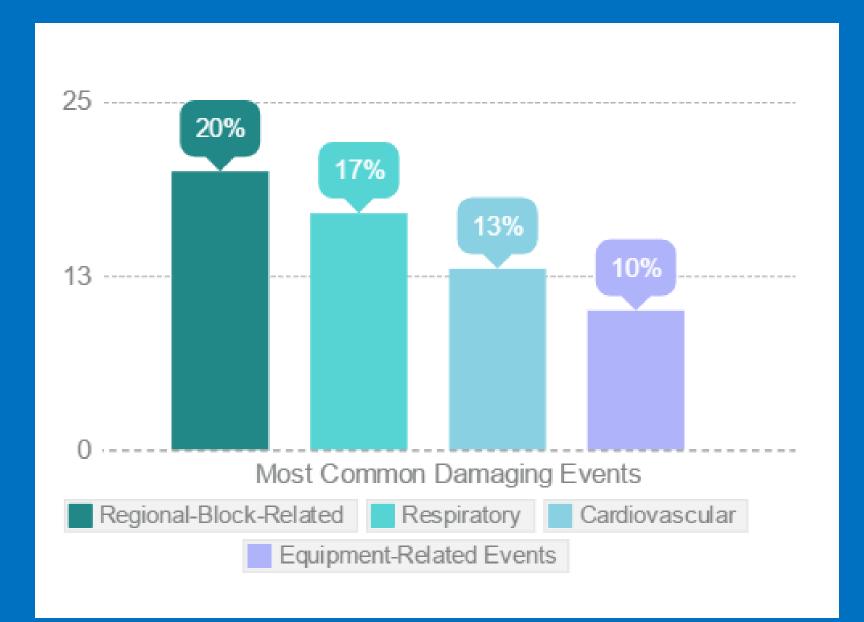


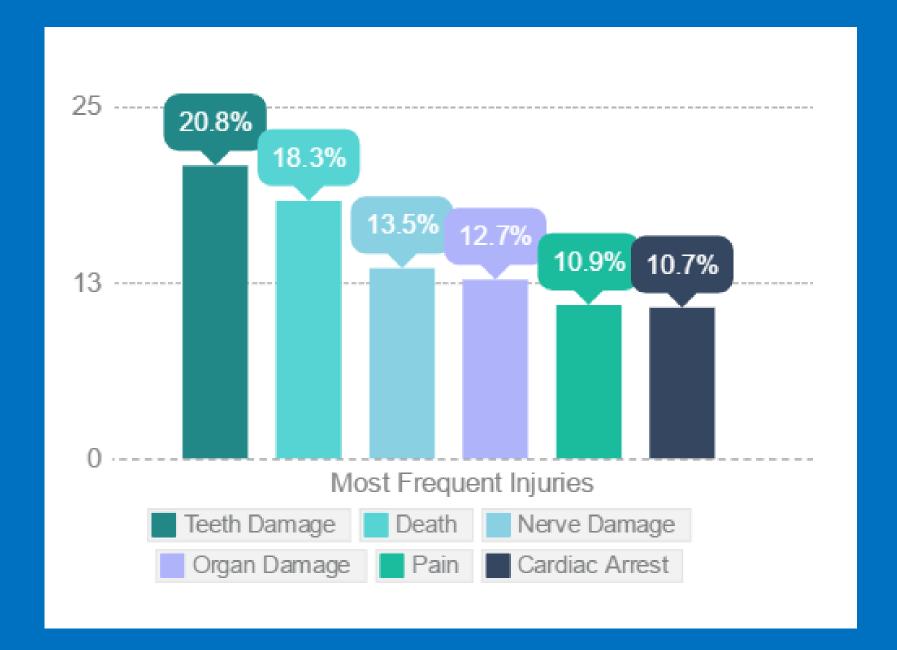


ASA Closed Claim Database









When It Becomes Your Turn

In the District Court of Oklahoma County
State of Oklahoma

CJ-2017-1955

Just Another Day in the OR on Call

• Ordinary call day assigned to a long case.

• Completed my "normal" preoperative assessment and discussion with family.



Nothing Unusual

Typical progression of case

Discuss ongoing issues with surgeon

End of Case



Risk Management IS Your friend

- Called in the morning to discuss events and status of the case.
 - Advise on how to approach family
 - Over the next 2 days spent a number of hours



Saying Your Sorry

- I'm sorry laws
 - Differ by state
 - Georgia protects all admissions of fault



Documentation

- The chart needs to be accurate and complete.
- Late entries are allowed
 - Timely, facts with no blame
- Electronic records
 - Forensic log can be requested
 - Technology fails



Emotional Time

• The OR environment after a case with an unexpected outcome occurs.

• You can't talk to anyone.

Discoverable







The Next Steps

• Received notice that a request for medical records had been received.

• Don't destroy, alter existing medical records



Legal Proceedings

In the District Court of Oklahoma County
State of Oklahoma

CJ-2017-1955

April 4th, 2017

Your Attorneys

• APIC

• Great law firms on retainer

• Met with the attorneys over the summer



Your Life Story

• Interrogatory: a written question which is formally put to one party in a case by another party and which must be answered.



Meet with Attorney

- Typed up your responses
 - Review closely, accuracy matters
- Likely will review the record
 - Client Attorney privilege

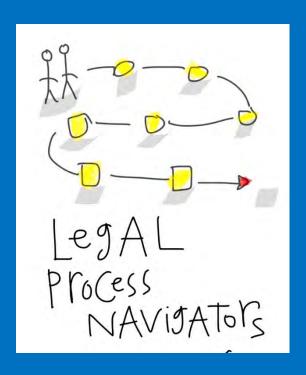


Legal Process

• Players in the Game

Plaintiff and attorney(s)

Defendant(s) and attorney



More Legal Stuff

Discovery

• Plaintiff's attorney will likely be consulting expert witness

• Laws regarding expert witnesses

• Be in communication



Deposition

• As depositions are given and released

• Review them with your attorney

• Prepare for your deposition

```
numerous times talking to different paralegais were serviced three, four times and they've served a song address and Cheryl's instructions was to go ahead with the file. That the Judge wouldn't notice it.

With the file. That the Judge wouldn't notice it.

Q. And the whole point of that was to keep the ith that file even though it was the wrong address?

A. Correct.
```



Preparation is KEY

- Many preparation sessions
- Some attorneys may videotape

- It is their job to get you ready
 - It's often unpleasant
 - Emotional



Make No Mistake

• Plaintiff's attorney IS not your friend

• This is a battle

• Again: Prepare



My Approach

• Off work for the couple of days before.

- Eliminated stress and distractions
 - Stayed at hotel
 - Pickup up by attorney



Star of the Show



Deposition

- Court will type your responses
 - Review it CAREFULLY
 - Be nit picky
 - Basis for questioning if it goes to trial

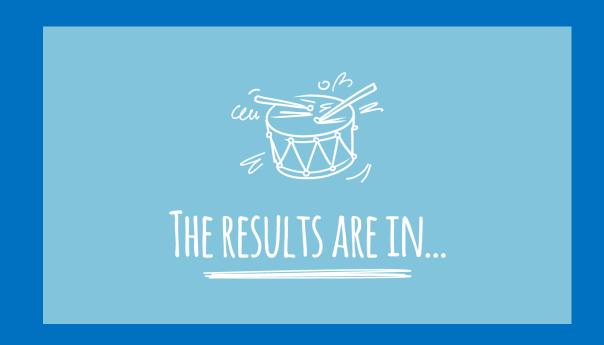


Possible Outcomes

• Dismissed

• Settlement

• Trial



Dismissed

• The plaintiff hereby dismisses this action without prejudice as to the defendant

• Judith L.P. Handley, M.D. only

Final Points

• It does not mean you are a bad clinician

• Reach out to available support systems

References

- Medscape Medical Malpractice Report 2017
- Diederich Healthcare 2017 Medical Malpractice Payout Analysis
- Oklahoma Court Filing CJ-2017-1955
- Brenner, IR. "How to Survive a Medical Malpractice Lawsuit: the physician's road map for success." 2010.

THANK YOU



Burden Reduction Myths and Opportunities: An Assessment of Recent Regulatory Actions Affecting Anesthesiologists

Matthew T. Popovich, Ph.D. | January 11, 2020



Disclosures

Matthew T. Popovich works for the American Society of Anesthesiologists® (ASA).



Learning Objectives

Describe

Describe the goals of federal regulatory policy on burden reduction as it relates to healthcare and patient safety.

Identify

Identify three federal policy decisions related to burden reduction on the Quality Payment Program and the Conditions of Participation.

Explain

Explain the impact that standard setting organizations and medical society guidelines and standards have on facility accreditation, physician workflow and regulatory burden.

ASA Quality and Regulatory Affairs



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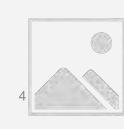
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Regulatory Affairs Specialist
Washington, DC



Claire Ostarello
Quality Associate
Schaumburg, IL



ASA Quality and Regulatory Affairs

QRA Expertise

- Accreditation organizations
- Conditions of Participation
- Advocate on non-payment federal regulatory issues
- Facilitate review of external standards and practice parameters
- Quality measure development
- Quality Payment Program
- Support registry reporting

ASA DC Office Expertise

- Payment policy (Payment and Practice Management)
- Alternative Payment Models (Payment and Practice Mgmt)
- Scope of Practice (Advocacy and State Affairs)
- Surprise Medical Billing (Advocacy and State Affairs)
- Federal opioid policy (Advocacy)



Trump Administration implemented long-standing policy goals to "reduce regulation" and "eliminate costs" associated with regulation.

- Any new regulation must be accompanied by eliminating two other regulations.
- Agencies must implement methods for identifying cost reductions.
- Agencies must be focused on burden reduction.



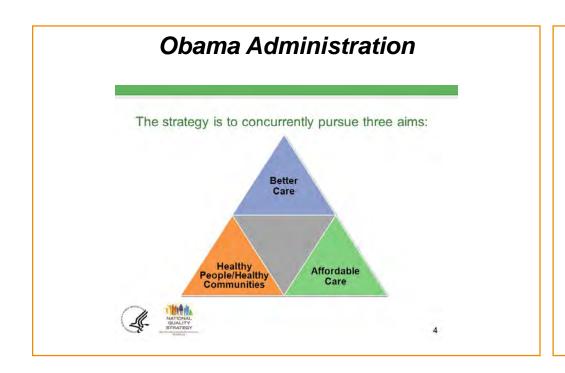


ASA priorities for burden reduction in 2017 included:

- Address disparities in Medicare payments for anesthesiologists.
- 2. Eliminate the negative adjustment to the value-based modifier (defunct after payment year 2018).
- Reduce number of measures required for the Physician Quality Reporting System (defunct after payment year 2018).
- 4. Eliminate burdensome surgical attire requirements that were not based on evidence; emphasis on accreditation standards based on evidence.
- 5. Eliminate of burdensome personal protective equipment requirements for drugs that are rarely, if ever, hazardous (USP <800>) to healthcare workers.
- Address rural pass through payments.



Administrations often use a simple framework or motto to guide their regulatory decision making.









Centers for Medicare & Medicaid Services (CMS) Goals Include:

- 1. Reduce unnecessary burden and cost
- 2. Increase efficiencies
- 3. Improve the beneficiary experience

Dr. Seema Verma, CMS Administrator:

Patients over paperwork is aimed at reducing "Regulations that are not contributing to patient safety, quality or program integrity but instead are only increasing our healthcare costs."

ASA successes in reducing burden have included:

- Continue Hardship Exemptions for QPP Promoting Interoperability (2017-)
- 2. Eliminated of the negative Value-based Payment Modifier (2018)
- 3. Removed of subjective pain-related CAHPS questions (2018)
- 4. Placed more anesthesiologists on opioid-related panels (2018-)
- 5. Supported unified infection prevention programs across health systems (2019)
- 6. Supported the unified Quality Assurance and Performance Improvement (QAPI) processes across health systems (2019)

CMS policy implications have been broad:

- 1. Increased minimum threshold for participation in MIPS
- 2. Revisions to Evaluation and Management Codes
- 3. Proposed revisions to the Stark Law and Anti-Kickback Regulations
- 4. Multiple requests for information (HIPAA, Supervision)
- 5. Changes to the H&P evaluations for inpatient and outpatient procedures (September 2019)
- 6. Preanesthesia evaluation in ambulatory settings (November 2019)

Burden Reduction for some does not mean burden reduction for all. ASA is increasingly concerned that "burden reduction" in many cases means burden transfer to anesthesiologists.

2019 Hospital and Ambulatory Conditions of Participation Changes

- Transfer of care agreements between ASC and hospital is optional
- H&P completion for ambulatory / outpatient settings can be set by local policy
- Emergency Preparedness training can be set by local policy
- Can set unified Infection Prevention policies and procedures across a health system
- Can set unified Quality Assessment and Performance Improvement procedures
- Decreased repetitive documentation for hospice healthcare workers

January 2020 *ASA Monitor* article includes further discussion on changes within the 2019 Hospital and Ambulatory Conditions of Participation Final Rule



But CMS and Health and Human Services have several positions that have not been resolved or are on the horizon that will impact anesthesiologists:

- 1. Electronic Health Records
- 2. Price Transparency
- 3. HIPAA Regulations
- 4. Stark and Anti-Kickback Updates
- 5. Presidential Order #13890: Protecting and Improving Medicare for Our Nation's Seniors

In 2020, ASA is focused on protecting physician-led care and the anesthesia care team model that protects patient safety and delivers quality care to patients.

Executive Order 13890 of October 3, 2019

Protecting and Improving Medicare for Our Nation's Seniors

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Purpose*. The proposed Medicare for All Act of 2019, as introduced in the Senate ("Medicare for All") would destroy our current Medicare program, which enables our Nation's seniors and other vulnerable Americans to receive affordable, high-quality care from providers of their choice. Rather than upend Medicare as we know it, my Administration will protect and improve it.

Sec. 5. Enabling Providers to Spend More Time with Patients. Within 1 year of the date of this order, the Secretary shall propose reforms to the Medicare program to enable providers to spend more time with patients by:

- (a) proposing a regulation that would eliminate burdensome regulatory billing requirements conditions of participation, supervision requirements, benefit definitions, and all other licensure requirements of the Medicare program that are more stringent than applicable Federal or State laws require and that limit professionals from practicing at the top of their profession;
- (b) proposing a regulation that would ensure appropriate <u>reimbursement by</u>
 Medicare for time spent with patients by both primary and specialist health
 providers practicing in all types of health professions; and
- (c) conducting a comprehensive review of regulatory policies that create disparities in reimbursement between physicians and non-physician practitioners and proposing a regulation that would, to the extent allowed by law, ensure that items and services provided by clinicians, including physicians, physician assistants, and nurse practitioners, are appropriately reimbursed in accordance with the work performed rather than the clinician's occupation.

Action Request: Feedback to HHS/CMS

CMS recently requested information on scope of practice:

- "Medicare regulations that require more stringent supervision than existing state scope of practice laws, or that limit health professionals from practicing at the top of their license."
- Concerned about the patient safety implications of any proposal that would remove physician supervision from the anesthesia care.
- Submit comments to CMS on the importance of safe, high-quality physician-led anesthesia care by JANUARY 17, 2020.
 - Visit: asahq.org/grassroots or text "CMSRequest" to 855-465-8659.

The general themes of burden reduction in the past three years has been:

- CMS and other agencies are making and implementing decisions that may alter your daily workflows and practice administration.
- Patients Over Paperwork is another term CMS uses for removing unnecessary or duplicative regulatory and billing requirements.
- Anyone can suggest a regulatory change to CMS.
- CMS has used the term "burden reduction" as a catchphrase for any change in regulation, regardless of whether burden is actually "reduced."

Quality Payment Program (QPP) pathways:

- Merit-based Incentive Payment System (MIPS)
 - Eligible clinicians and groups receive positive, neutral or negative payment adjustments
- Advanced Alternative Payment Models (Advanced APM)
 - Potential for 5% bonus for up to 6 years, depending on thresholds and definition

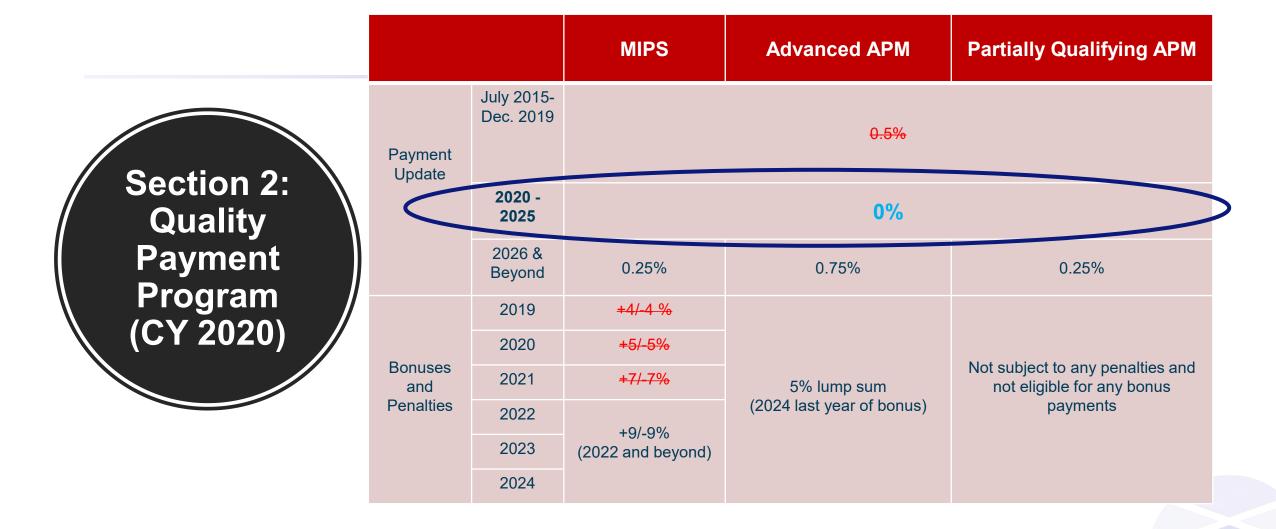
Quality Payment Program (QPP)

Merit-based Incentive Payment System (MIPS)

- Quality
- Cost
- Promoting Interoperability (PI)
- Improvement Activities (IA)

Alternative Payment Models (APMs)

- MIPS APMs
- Advanced APMs



For the 2020 QPP, CMS focused on:

- "Reducing clinician burden"
- Stabilizing MIPS scoring features
- Increasing data completeness for quality measures
- Requiring more documentation and physician involvement for receiving credit in the improvement activities component
- Encouraging ECs and Groups to join APMs

In general, the MIPS components are weighted the same in 2020 as they were in 2019.

Cost component must be 30% by reporting year 2022.

2022 Payment adjustment based on 2020 performance and participation = + / - 9%.

Component weights may change based on clinician special status.



Two examples about burden reduction and the Quality Payment Program.

- 1. Quality measures available for reporting (Meaningful Measures Initiative)
- 2. Improvement Activities attestation requirements (Burden Reduction)

Case Study #1: Meaningful Measures Initiative

CMS Goals Include:

- 1. Promote alignment across quality initiatives and programs to minimize burden.
- 2. Promote focused quality measure development toward outcomes that are meaningful to patients, families and providers
- 3. Identify highest priorities in improving healthcare
- 4. Assess how CMS delivers value better care, smarter spending, healthier communities.



Objectives for the meaningful measures initiative include a focus on measures that:

- Address areas that safeguard public health (think opioids)
- Are Patient-centered and meaningful to patients
- Are Outcome-based where possible
- Fulfill each program's statutory requirements
- Minimize documentation burdens
- Show significant opportunity for improvement
- Address population-based payment through alternative payment models
- Align across quality programs



Meaningful Measures Initiative Challenges

- 1. More than three dozen MIPS measures removed since 2017; dozens of Qualified Clinical Data Registry (QCDR) measures removed.
- CMS removed MIPS 426 and MIPS 427 anesthesiology transfer of care measures
- 3. Greater challenge for CMS to view anesthesia measures as meaningful to patients (few outcome measures, harder to attribute)
- CMS reluctant to approve new quality measures for MIPS (not unique to anesthesiology)

Meaningful Measures Initiative Opportunities

- 1. Approved MIPS 477: Multimodal Pain Management measure
- 2. Increased data completeness threshold from 60% to 70% of all cases
 - a. May demonstrate greater gap in performance
 - b. CMS sees this as a "burden reduction"
- 3. Implemented facility-based scoring for groups to have better opportunities to score higher in the quality and cost components

Anesthesiology Specialty Measure Set (2020) is:

- 1. MIPS #44: CABG: Preoperative Beta-Blocker in Patients with Isolated CABG Surgery
- MIPS #76: Prevention of CVC-Related Bloodstream Infections*
- 3. MIPS #404: Anesthesiology Smoking Abstinence* (Intermediate Outcome)
- 4. MIPS #424: Perioperative Temperature Management* (Outcome)
- 5. MIPS #430: Prevention of PONV Combination Therapy*
- 6. MIPS #463: Prevention of Post-Operative Vomiting (POV) Combination Therapy (Pediatrics)*
- 7. MIPS #477: Multimodal Pain Management*
- * designates a "high priority" measure

Case Study #2: MIPS Improvement Activities

- IA component has consistently been 15% of the total MIPS score
- Activities must be performed for a 90-day period
- Group must maintain documentation for six years
- Yes/No attestation through AQI
- Before 2020, only one person in a group had to complete the activity

Changes for 2020:

- 15 IAs were removed; seven were modified and two were added
- 50% of ECs in a practice must participate and report the same IAs

Improvement Activities there will be added in 2020:

- Drug Cost Transparency (Counseling to patients about cost of drugs)
- Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes

Improvement Activities that were modified or retired for 2020:

 Most changes reflected a consolidation of Qualified Clinical Data Registry-related and other improvement activities that were duplicative of other available improvement activities.

In 2020, CMS requires that at least 50 percent of a group's National Provider Identifiers (NPIs) must perform the same activity for any continuous 90 days in the performance period.

 CMS recommends large groups and multispecialty groups participate in "general improvement activities."

ASA and AQI, along with other specialty societies opposed this regulatory change noting that it is a burden increase.

- We are concerned that CMS will increase this threshold in the future
- We are concerned that CMS is infringing on the business objectives and individual goals of groups participating in MIPS

The top 5 Improvement Activities reported to AQI in 2018 were:

Activity ID	Improvement Activity
BE_13	Regularly assess the patient experience of care through surveys, advisory councils and/or other mechanisms.
PSPA_19	Implementation of formal quality improvement methods, practice changes or other practice improvement processes
BE_6	Collection and follow-up on patient experience and satisfaction data on beneficiary engagement
PSPA_7	Use of QCDR data for ongoing practice assessment and improvements
BE_1	Use of certified EHR to capture patient reported outcomes

Beneficiary Engagement – 13 ("BE_13") Improvement Activity

- <u>2019 Description</u>: Regularly assess the patient experience of care through surveys, advisory councils and/or other mechanisms.
- 2019 Validation/Documentation: Documentation (e.g. survey results, advisory council notes and/or other methods) showing regular assessments of the patient care experience to improve the experience, taking into account specific populations served and including them in this assessment, such as identified vulnerable populations. Surveys should be administered independently to the best extent possible.

Yes, CMS may audit on this criteria alone!

But wait!

That doesn't sound like burden reduction!

That sounds like a burden increase on my group!

We believe that by Year 4 (2020 performance year) of the Quality Payment Program, clinicians should be familiar with the improvement activities performance category. We believe that increasing the minimum threshold for a group to receive credit for the improvement activities performance category will not present additional complexity and burden for a group.

With over 100 improvement activities available for eligible clinicians to choose from in the improvement activities Inventory, which may be found at the Quality Payment Program website https://qpp.cms.gov/, that provide a range of options for clinicians seeking to improve clinical practice that are not specific to practice size, specialty, or practice setting. We believe that a group should be able to find applicable and meaningful improvement activities to complete that

would apply to at least 50 percent of individual MIPS eligible clinicians in a group.

Common Questions that a Group should ask about 2020 Improvement Activities choices:

- 1. What IAs reflect your current group initiatives and/or workflows?
- 2. Can more than 50% of your NPIs complete the task?
- 3. Can you document that the IA was completed?
- 4. Did you choose a minimum amount of IAs to complete to earn the 15% MIPS points?

The general themes of burden reduction and the Quality Payment Program in 2020 is:

- Stability in QPP program scoring
- Emphasis on opioid-related measures and improvement activities that reflect general public health needs
- Future opportunities to link quality with improvement activities
- Increased data completeness threshold for quality measures
- Increased emphasis on improvement activity data collection, implementation and documentation

Burden reduction can also occur regardless of government intervention – what can be done with standard setting bodies, infection control and non-government organizations?

Where are the challenges to and opportunities for anesthesiologist leadership?

- Director of Anesthesia Services (DAS) responsibilities in hospitals
- Surgical attire and "dangling" masks
- Disposable equipment and Infection Prevention
- The "one-hour rule" and US Pharmacopeia (USP) <797>
- Spiked IV bags
- Personal Protective Equipment and USP <800>
- History and Physical Assessments (H&Ps)
- Many other issues affecting anesthesiologists and their groups

CMS Conditions of Participation grant significant authority to Directors of Anesthesia Services (DAS).

§482.52 Condition of Participation: Anesthesia Services

If the hospital furnishes anesthesia services, they must be provided in a wellorganized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

Areas where anesthesia services may be furnished: operating room (inpatient and outpatient), obstetrical suite, radiology, clinics, emergency departments, psychiatry department, outpatient surgery areas, "special procedure areas" (e.g. endoscopy, pain management).

Features of the DAS routinely include:

- Authority and responsibility for directing the administration of all anesthesia services, including anesthesia and analgesia, throughout the hospital (including all departments in all campuses and off-site locations where anesthesia services are provided)
- Protecting patient safety
- Ensuring compliance with federal and state laws governing anesthesia services
- Understanding hospital administration priorities and goals
- Engaging different departments in developing policy
- Identifying evidence-based resources and practice parameters to support policy positions
- Evaluating appropriateness of quality assessment and performance improvement

Recent guidelines, training, practice parameters and other decision points that ASA members have faced as Directors of Anesthesia Services.

- Practice Parameters from other medical societies
 - Surgical Attire (Association of periOperative Regsitered Nurses AORN)
 - b. Procedural Sedation (Emergency Medicine)
- 2. Training requirements
 - a. Advanced Care Life Support training
 - b. Completion of educational training
- 3. Opportunities for common interests
 - a. Drug concentration standardization

ASA has been successful in reducing burden in several areas:

Engagement with external stakeholders:

- AORN on Surgical Attire revisions
- Society for Healthcare Epidemiology in America on Infection Control
- Joint Commission FAQs / Future Accrediting Organization FAQs

Member Resources:

- "Principles for Hospital-based Moderate Sedation, Analgesia and Anesthesia"
- ASA Practice Parameter on Surgical Attire
- Guide for Anesthesia Department Administration

But more work needs to be done:

- 1. Appropriate interpretation of surgical attire locally
- 2. Appropriate interpretation of USP <797> (Joint Commission)
- 3. Appropriate understanding of spiked IV bags (Joint Commission)
- 4. Removal of certain drugs for NIOSH Hazardous Drug list
- 5. Changes to the Conditions of Participation regarding History and Physical Examinations (H&Ps)
- 6. Collaborating with medical society stakeholders on burden reduction

In general, guideline development by external stakeholders affect anesthesiologist workflows each day.

- Director of Anesthesia Services is a position within hospitals and other settings that can and should set the tone for patient safety and use of evidence-based guidelines.
- ASA provides guidance documents and practice parameters that groups should use to develop policy.
- Contact Quality and Regulatory Affairs (QRA) at qra@asahq.org for additional areas where you believe we can reduce anesthesiologist burden

Learning Objectives

- Describe the goals of federal regulatory policy on burden reduction as it relates to healthcare and patient safety.
- Identify three federal policy decisions related to burden reduction on the Quality Payment Program and the Conditions of Participation.
- 3. Explain the impact that standard setting organizations and medical society guidelines and standards have on facility accreditation, physician workflow and regulatory burden.

QRA Contact Information / Questions

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ASA Website ("Quality Improvement"):

https://www.asahq.org/quality-and-practice-management/quality-improvement

Department E-mail Address: gra@asahq.org

Department of Anesthesiology

Rethinking Penicillin Allergies in the Perioperative Period: An Opportunity for Stewardship



Francis A. Wolf, MD
Assistant Professor, Department of Anesthesiology
Emory University School of Medicine

Disclosures: No conflicts of interest

Learning Objectives

- Describe how a penicillin allergy listing impacts surgical patients
- Cite the basis of cefazolin's lack of cross-reactivity with other betalactam agents
- Describe a focused allergy assessment to determine the presence of a severe delayed reaction
- Describe the importance of a multi-disciplinary approach in perioperative antibiotic stewardship

Stewardship / 'stu ərd ʃɪp, 'styu-/

(n) the responsible overseeing and protection of something considered worth caring for and preserving

DICTIONARY.COM UNABRIDGED
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a coordinated program that promotes the appropriate use of antimicrobials (including antibiotics), improves patient outcomes, reduces microbial resistance, and decreases the spread of infections caused by multidrugresistant organisms. https://apic.org/

Perioperative Antibiotics and SSI: Room for Improvement

- Inconsistencies:
 - Selection
 - Timing of the initial dose and subsequent doses
- Failed compliance linked to:
 - Increased risk of surgical site infection and post-operative sepsis

EUH Antibiotic compliance: overall and initial dosing



Date (Year/Month)

Major Changes in Our Approach to Perioperative Antibiotics

- 1. Primary responsibility for antibiotic selection transferred to Anesthesiology
- 2. Antibiotic standardization (recommendations from ID and pharmacy)
 - Cefazolin for most cases, cefuroxime in cardiothoracic cases
 - Active against common skin flora, bactericidal, rapid concentrations in tissues
 - Metronidazole added to cover gut flora
 - Vancomycin added if increased MRSA risk
 - Vancomycin or clindamycin as alternative agent
- 3. Most common agents made available in OR
- 4. Personalized feedback on compliance

Antibiotics Standardized by Surgical Case

Ordered Item DESC	Primary Antibiotic	Secondary Antibiotic	
Abdominal Aortic Aneurysm By/Endo Stent	Cefazolin	Vancomycin. Add Gent if abdominal aorta or groin incision	
Abdominal Aortic Aneurysm Bypass Graft	Cefazolin	Vancomycin. Add Gent if abdominal aorta or groin incision	
Abdominal Biopsy	Ask Proceduralist if Necessary		
Abdominal Exploration/Revision	Cefazolin + Flagyl	Clindamycin + Aztreonam	
Abdominal Fistula Tractotomy	Cefazolin + Flagyl	Clindamycin + Aztreonam	
Abdominal Fistula Tractotomy Lap	Cefazolin + Flagyl	Clindamycin + Aztreonam	
Abdominal I&D	Cefazolin + Flagyl	Clindamycin + Aztreonam	
Abdominal I&D w/Wound Vac	Cefazolin + Flagyl	Clindamycin + Aztreonam	
Abdominal Mass/Soft Tissue Excision	Ask Proceduralist if Necessary		
Abdominal Mesh Removal Cefazolin + Flagyl		Vancomycin + Aztreonam	
Abdominal Perineal Resection	Cefazolin + Flagyl Vancomycin + Aztreonam		
Abdominal Wall Reconstruction	Cefazolin + Flagyl	Clindamycin + Aztreonam	
Abdominal Wall Resection	Cefazolin	Vancomycin	

Dear Francis,

We are pleased to be providing your individualized monthly feedback on perioperative antibiotic prophylaxis. We appreciate your hard work and willingness to improve care to our patients.

Your overall compliance across sites (if applicable) for 11/01/2019 to 11/30/2019

Total # of Cases	Total Attributed Cases	Overall Compliance	Compliant with Initial Dose	Compliant with Redose
32	30	96.7 (29/30)	96.7 (29/30)	100.0 (8/8)

Dear Francis,

The Emory Healthcare Quality Committee changed how we define and monitor successful surgical antibiotic prophylaxis.

In our ongoing automated reviews, we identified a discrepancy in the antibiotic prophylaxis for one or more cases. We are providing the information below for your review:

MRN:

Patient Name:

Procedure: Arm Lesion Excision/Destruction

Anesthesia Start 2019-10-14 12:24:17

Surgery Start 2019-10-14 12:43:00

Surgery Stop 2019-10-14 13:46:00

Anesthesia Stop 2019-10-14 14:04:00

Reason: Failed Antibiotic Compliance On Initial Dose

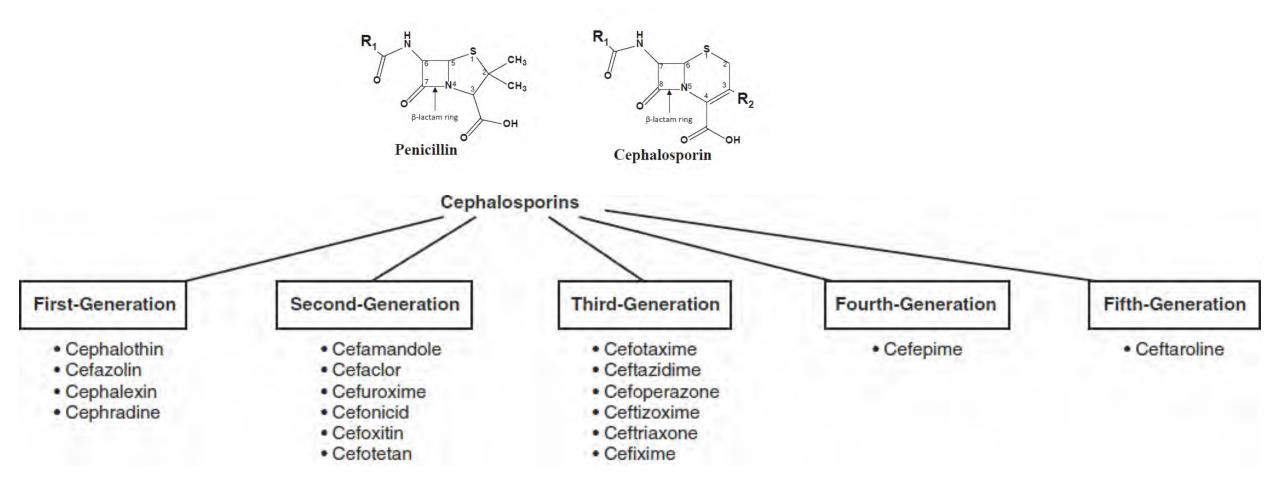
Explanation: CEFAZOLIN initial dose administered at 10-14-2019 12:54. This was outside of the compliance window 10-14-2019 11:43 to 10-14-2019 12:43.

What About Patients with a Penicillin Allergy?

 About 10% of the US population reports a penicillin allergy (Zhou 2016, Lee 2000, Shenoy 2019)

The exact reaction is rarely documented in the medical record

 Providers may avoid cephalosporins due to concerns about crossreactivity (Epstein 2016)



10% cross-reactivity?

Institutional guidelines:

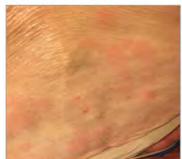
Use secondary antibiotic in cases of "severe" reactions

Types of Reactions

- Unknown
- Not a true allergy
 - Family history, GI symptoms
- Benign rash
- IgE mediated reaction
- Severe delayed reactions
 - Severe cutaneous adverse reaction (SJS, TEN, DRESS)
 - Serum sickness, drug fever
 - Organ specific injury (nephritis, hepatitis, hemolytic anemia)

IgE-mediated reactions

Onset minutes to hours into treatment course Raised off of the skin Pruritic Each lesion lasts <24 h Fades without scarring







Benign T-cell-mediated reactions

Onset days into treatment course Typically less pruritic than IgE-mediated reactions Each lesion lasts >24 h Fine desquamation with resolution over days to weeks







Severe T-cell-mediated reactions or severe cutaneous adverse reactions

Onset days to weeks into treatment course Blistering and/or skin desquamation Mucosal and/or organ involvement Usually requires hospitalization

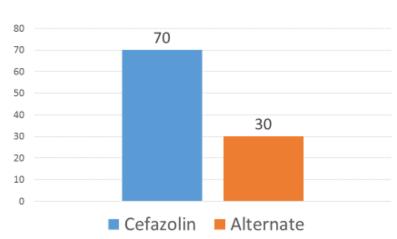




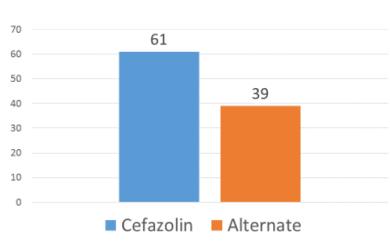


Antibiotic Selection in Patients with PCN allergy



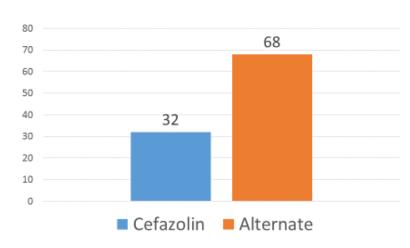






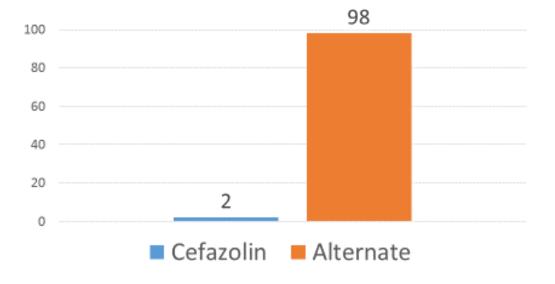
Survey of Emory anesthesia providers 2018 (n = 93)

Hives and Itching

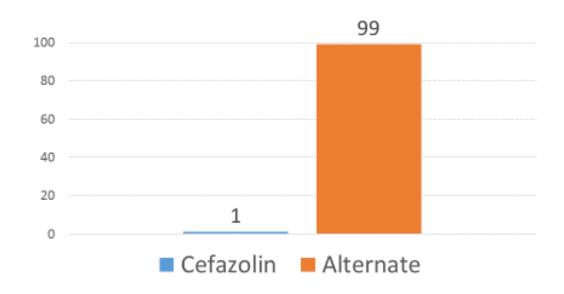


Antibiotic Selection in Patients with PCN allergy

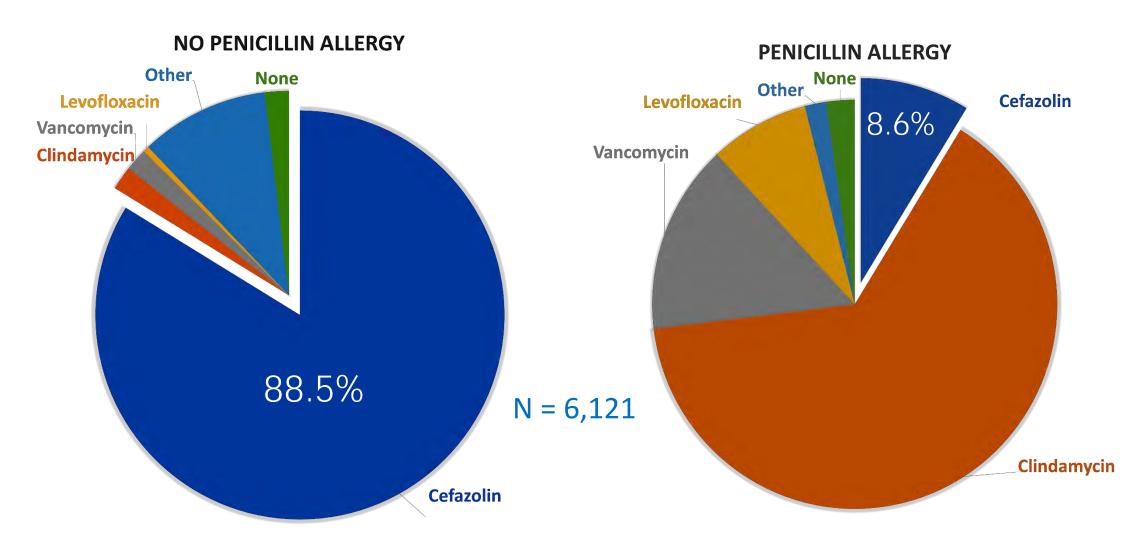




Severe Delayed Reaction



Prophylactic Antibiotic Selection: EUH Case Review 2013-2017



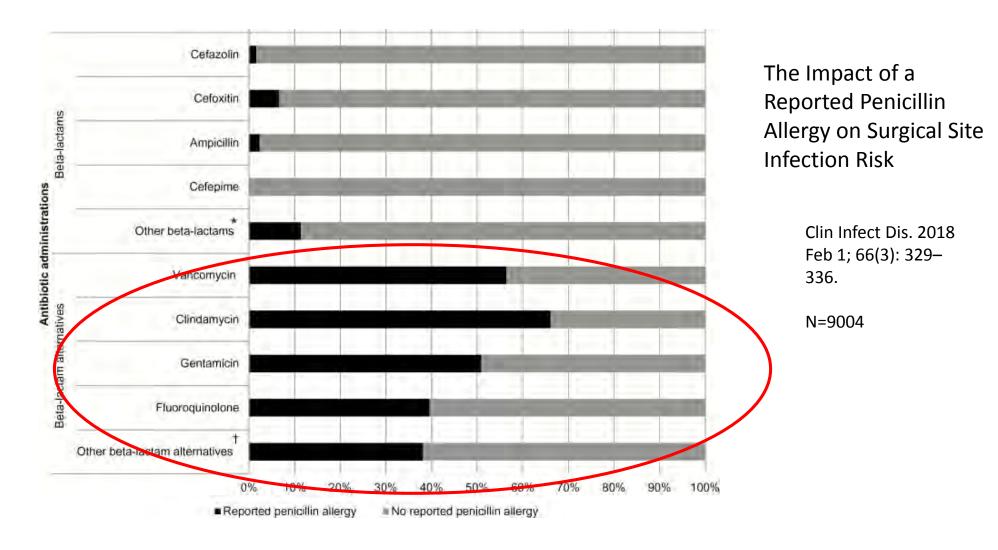
Langfitt, Mudda, Iorianni, Yao, Bowman, Lee, Amoateng, O'Reily-Shah, Lynde, Wolf. Compliance and Complications Associated with Penicillin Allergies in Surgical Patients. Presented at the ASA Annual Meeting, 2018 (Abstract presentation)

Patients with PCN Allergy Listing Receive Second-Line Antibiotics

	PCN ALLERGY (%)	NO PCN ALLERGY (%)	P-value
CEFAZOLIN	12.2	92.%	<0.001
CLINDAMYCIN	48.8	3.1	< 0.001
VANCOMYCIN	34.7	3.3	<0.001
GENTAMYCIN	24.0	2.8	< 0.001
FLOUROQUINALONES	6.8	1.3	<0.001

Blumenthal et al. The Impact of a Reported Penicillin Allergy on Surgical Site Infection Risk Clin Infect Dis. 2018 Feb 1; 66(3): 329–336.

Most Alternative Antibiotic Use is in Penicillin Allergic Patients



Key Fact 1

➤ Patients with a penicillin allergy listing are more likely to get second line agents

Due to concerns for cross-reactivity with cephalosporins

- 1. What are the consequences of second line agents?
- 2. Are the cross-reactivity concerns justified?

Reported Penicillin Allergy is Associated with Increased SSI

- Patients reporting a penicillin allergy had increased odds (adjusted odds ratio, 1.51; 95% confidence interval, 1.02–2.22) of SSI.
- Entirely mediated by receipt of alternative perioperative antibiotic
- NNT = 112-124 to prevent 1 SSI.



Blumenthal et. al. Clin Infect Dis. 2018 Feb 1; 66(3): 329–336.

Failed Compliance and SSI Associated with PCN Allergy Label

Failed compliance with first dose:

- 8.8% without a penicillin allergy
- 16.2% with a penicillin allergy (p = <.001)

	No PCN Allergy n=8503	PCN Allergy n=1445	P– Value
Superficial SSI, wound disruption	247 (2.9%)	62 (4.3%)	0.007
Deep or organ space infection, sepsis or septic shock	543 (6.4%)	114 (7.9%)	0.04
Any SSI or sepsis	725 (8.5%)	161 (11.1%)	0.002

Drawbacks to Common Second-Line Alternatives

Vancomycin:

- Not ideal coverage for:
 - MSSA, Strep species: SSIs 3.7% vs 1.3% of patients receiving cefazolin
- No gram negative coverage
- Prolonged infusion time, can cause delays or inappropriate timing
- Renal toxicity; need for drug levels
- "Red man syndrome"
- Often overly broad-spectrum

Clindamycin:

- Theoretically has MRSA coverage but:
 - Only 60% of isolates within the Emory system are susceptible
- Also increasing resistance for:
 - MSSA (75% susceptible)
 - Coag-negative staph (57% susceptible)
 - Strep species (70% susceptible)
- Increased *C. difficile* risk
- Microbiome disruption

Other Complications Associated with PCN Allergy

• C. Difficile risks: 23% increased odds

MRSA colonization or infection: 14% increased odds

• VRE colonization or infection: 30% increased odds

Patients with PCN "allergy" spent more days in the hospital compared to matched controls (n=51,582)

PCN "allergy" associated with increased healthcare costs

Macy E, Contreras R. Health care use and serious infection prevalence associated with penicillin "allergy" in hospitalized patients: a cohort study. J Allergy Clin Immunol 2014; 133:790–6.

Key Fact 2

➤ Second line antibiotics are associated with negative outcomes

Can we safely reduce our use of second line agents?

PCN Allergy is Less Common Than Thought

- 90% to 99% of patients reporting being allergic to penicillin can tolerate penicillins
 - misclassification of reaction: side effects, intolerances, preference, rash related to viral illness
 - natural waning of type I (IgE) allergy: 80% of patients become tolerant after a decade

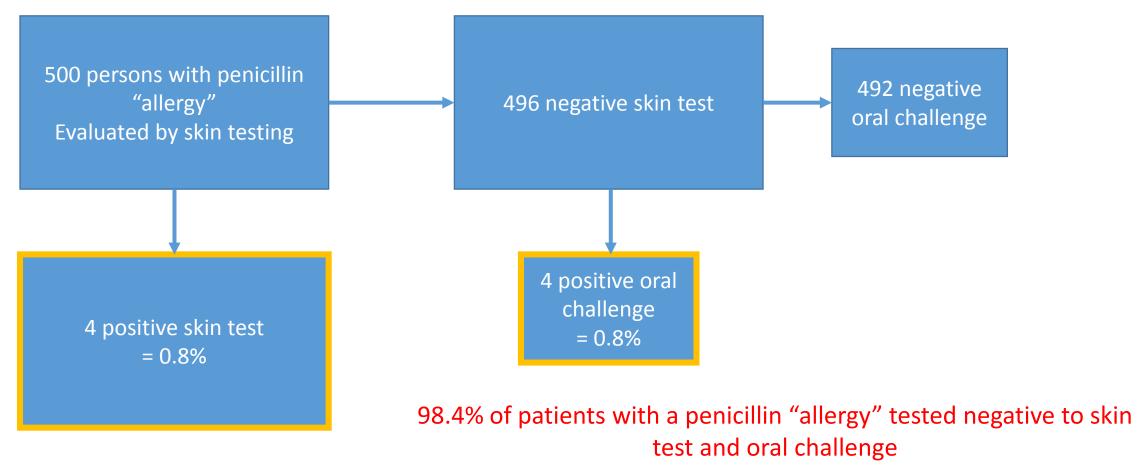


Blumenthal KG, Shenoy ES, Varughese CA, Hurwitz S, Hooper DC, Banerji A. Impact of a clinical guideline for prescribing antibiotics to inpatients reporting penicillin or cephalosporin allergy. Ann Allergy Asthma Immunol 2015;115: 294-300.e2

Original Article

Safely Diagnosing Clinically Significant Penicillin Allergy Using Only Penicilloyl-Poly-Lysine, Penicillin, and Oral Amoxicillin

Eric Macy, MS, MDa, and Eunis W. Ngor, MSb San Diego and Pasadena, Calif



Are You Sure You're Allergic?

Allergy & Immunology > Allergy

Patients Who Say They're Allergic to Penicillin Are Usually Wrong

— All "allergic" patients should be evaluated, review concludes



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Penicillin Allergy Less Common Than Thought: Study

Nov. 25, 2019, at 4:00 p.m.



an estimated 30 million Americans think they're allergic to this lifesaving drug when they are not.

Think You're Allergic to Penicillin? You're Probably Not

NEWS Oct 30, 2019 | Original story from University of Georgia

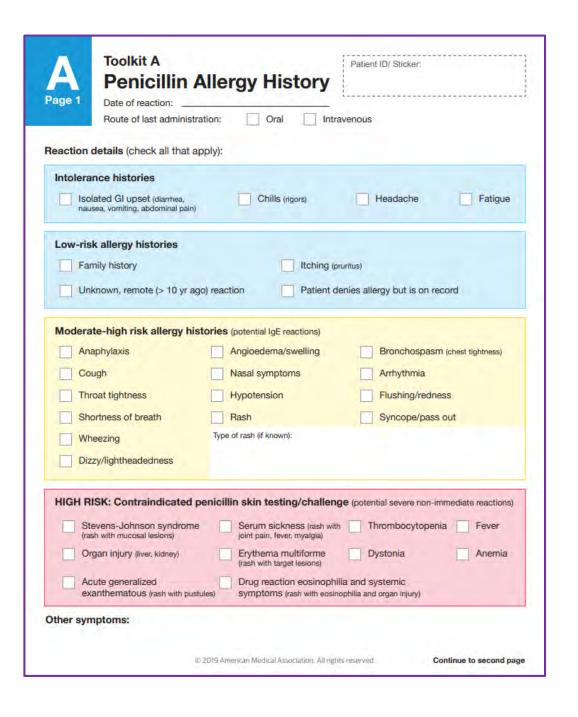
Key Fact 3

➤ Most patients with a penicillin allergy label do not have a penicillin allergy

Should we try to identify patients with "real" allergies?

Allergy History

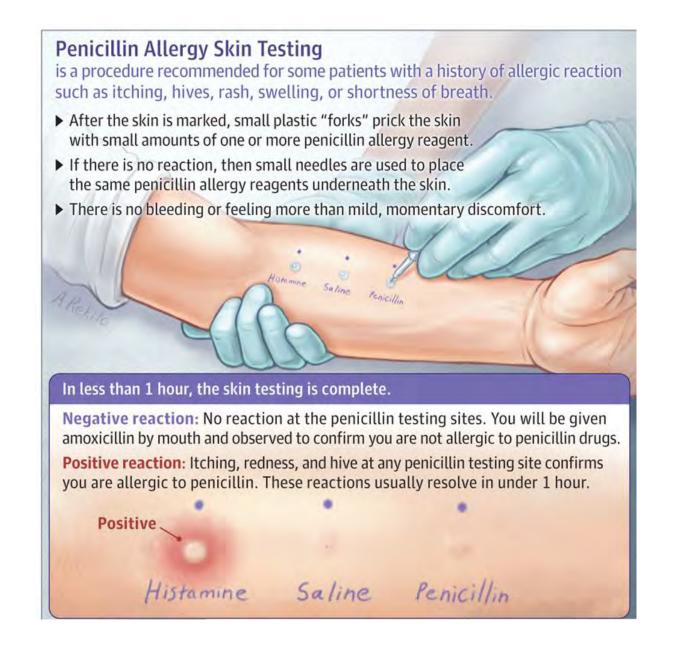
- Unknown
- Not a true allergy
 - Headache, isolated GI symptoms
- Benign rash?
- IgE mediated reaction
- Severe delayed reactions
 - Severe cutaneous adverse reaction (SJS, TEN, DRESS)
 - Serum sickness, drug fever
 - Organ specific injury (nephritis, hepatitis, hemolytic anemia)



What About Skin Testing?

- Fairly simple
- Effective
- Available
- Allows for de-listing

Testing for penicillin allergy is recommended by the CDC and multiple professional societies



Shenoy ES, Macy E, Rowe T, Blumenthal KG. Evaluation and management of penicillin allergy: a review [published January 15, 2019]. JAMA. doi:10.1001/jama.2018.19283



The effect of preoperative penicillin allergy testing on perioperative non-beta-lactam antibiotic use: A systematic review and meta-analysis

"preoperative testing protocols significantly decreased the rates of prescribing non-beta-lactam antibiotics compared with usual care (odds ratio 3.64 [95% confidence interval, 2.67-4.98]; p < 0.0001)."

Reilly, Clifford A.; Backer, Grant; Basta, Danielle; Riblet, Natalie B. V.; Hofley, Pamela M.; Gallagher, Megan C. Allergy and Asthma Proceedings, Volume 39, Number 6, November/December 2018, pp. 420-

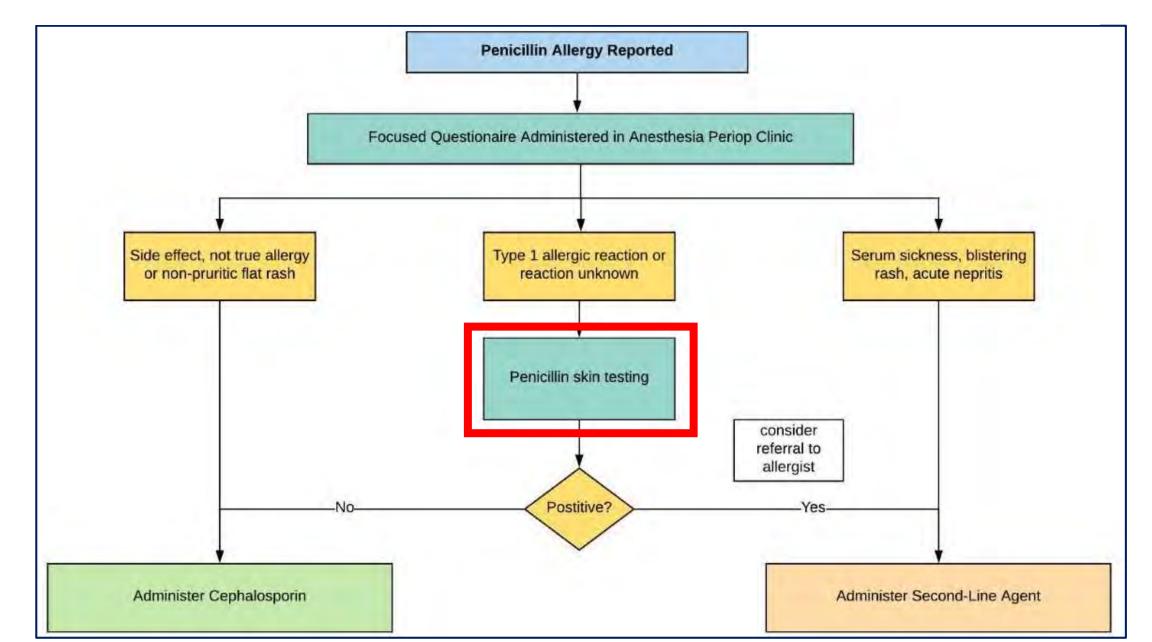
Safety and effectiveness of a preoperative allergy clinic in decreasing vancomycin use in patients with a history of penicillin allergy

Miguel Park, MD; Patricia Markus, RN; Damir Matesic, MD; and James T. C. Li, MD

Annals of Allergy, Asthma & Immunology 97(5) 681-687. 2006.

1,111 patients, 1,030 (93%) underwent skin testing for penicillin allergy. Forty-three (4%) had a positive skin test result to penicillin. 75% of patients received cefazolin, and only 149 (16%) received vancomycin compared with 30% historical controls (P < .01).

Proposal for New Approach



Barriers to Preoperative Skin Testing

- Logistics
- Time
- Training
- Materials
- Consent
- Documentation, communication
- Not all patients come through the Preop Clinic

Oral challenge is needed to confirm negative skin test (1 hour, can be harder to interpret)

Expert Consult...

What medications are you giving in the OR?

Mostly cefazolin, some cefuroxime

I don't think you need to bother with the skin testing

Why not?

Cefazolin is safe even in patients with severe IgE reactions to penicillin, including anaphylaxis

What?

SPECIAL ARTICLE

Misconceptions Surrounding Penicillin Allergy: Implications for Anesthesiologists

Leon Vorobeichik, MD,* Elizabeth A. Weber, MD, FRCPC,†‡ and Jordan Tarshis, MD, FRCPC*§

Anesth Analg. 2018 Sep;127(3):642-649.

Beta Lactam Antibiotics

Monobactam

J Allergy Clin Immunol Pract Vol 6 (1) Zagursky

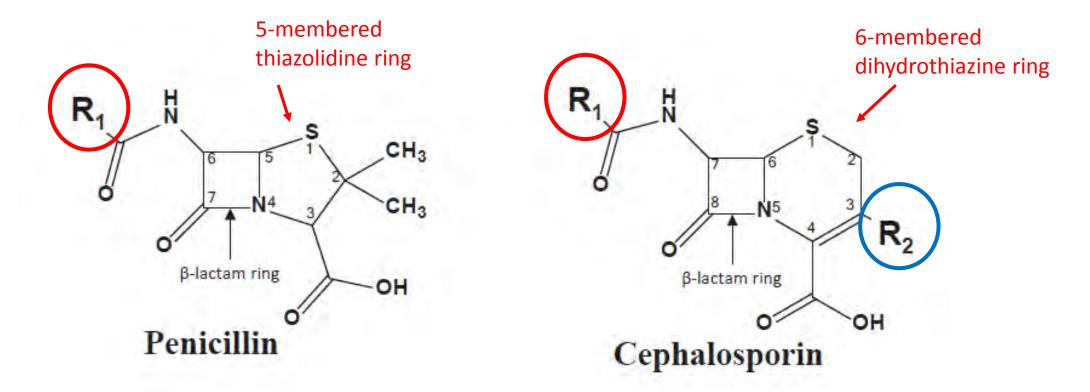
The Beta Lactam Ring is Not the Major Determinant of Allergies

Among patients with a positive PCN skin test who are exposed to carbapenem, the reaction rate was 0.8-1%

= Consistent with unique (separate) sensitivity

Skin and in vitro tests have established IgE response is directed towards the R1 side chain

Penicillin vs. Cephalosporin: Structure



the R1 side-chain is the major factor for cross-reactivity between cephalosporins and penicillins.

Key Fact 4:

Cross-reactivity among the beta lactams is based R side-chain similarity, not on the beta lactam ring.

Side Chain Cross-Reactivity Chart

	_	Penicillins					1st								2nd								3r	d			, -	_	4	th	5th			Mono				
										1,1				1.7									0												Cel	7.51		
		Nafcillin	Oxacillin	Dicloxacillin	Penicillin G / V	Piperacillin	Ampicillin	Amoxicillin	Cefadroxil	Cefatrizine	Cephalexin	Cefazolin	Ceftezole	Cephalothin	Cephapirin	Cefoxitin	Cefuroxime	Cefotetan	Cefprozil	Cefaclor	Cefonicid	Cefamandole	Cefoperazone	Ceftibuten	Cefdinir	Cefixime	Ceftriaxone	Cefditoren	Cefodizime	Cefotaxime	Cefpodoxime	Ceftazidime	Cefepime	Cefpirome	Ceftaroline fosami	Ceftolozane	Cefiderocol	Aztreonam
	Nafcillin																			1 8																		
	Oxacillin			r1																																		
	Dicloxacillin	- 1	r1																																		1	
PCN	Penicillin G / V					r1'	r1'	r1'	r1	r1	r1		9						r1	r1	r1	_ r1	r1'	-														
	Piperacillin			-	r1'		R1'	r1'	r1'	r1'	R1'								r1'	R1'	r1'	r1'	R1"															
	Ampicillin				r1'	R1'		r1'	r1	r1	R1								r1	R1	r1.	r1	r1'															
	Amoxicillin				r1'	r1'	r1'		R1	R1	r1'								R1	r1	r1	r1	R1'															
	Cefadroxil				r1	r1	r1	R1		R1	r1		-						R1	_r1	r1	r1	R1'														,	
	Cefatrizine				r1	r1'	r1	R1	R1		r1								R1	r1	r1	r1	R1'															
	Cenhalexin				r1	R1'	R1	r1	r1	r1									r1	R1	r1	r1	r1'															
1st	Cefazolin												R1r2																									
	Сепедоје								1		Co	R1r2												3.3														
	Cephalothin														R2	R1r2	r1'r2							- =						R2								
	Cephapirin													R2		r2	r2													R2			3. 3					
	Cefovitin								1					R1r2	r2		r1'R2) = (1.0	(4.0	- 1	12.3	r2	7							
	Cefuroxime													r1'r2	r2	r1'R2										r1"	R1"	R1"	R1"	R1"r2	R1"		R1"	R1"	r1"			
1.4	Cefotetan																				r2	R2	R2															
2nd	Cefprozil				r1	r1	r1	R1	R1	R1	r1									r1	-r1	r1	R1'] [
	Cefaclor		7		r1	R1'	R1	r1	r1	r1	R1								r1		r1	r1	r1'															
	Cefonicid				r1	r1	r1	r1	r1	r1	r1		K					r2	r1	r1		R1r2	r1'r2		< = 1								1					
	Cefamandole				r1	r1	r1	r1	r1	r1	r1				1			R2	r1	r1	R1r2		r1'R2							-							1 - 1	
	Cefoperazone		1		r1'	R1"	r1'	R1'	R1'	R1'	r1'		17.		Y .			R2	R1'	r1'	r1'r2	r1'R2					-		100		100		7.3			1		
	Ceftibuten																								R1'	R1'	R1'	R1'	R1'	R1'	R1'	R1'	R1'	R1'	r1'	r1'	R1'	R1'
11	Cefdinir																							R1'		R1'R2	R1'	R1'	R1'	R1'	R1'	R1'	R1'	R1'	r1'	r1'	R1'	R1'
	Cefixime														-)	r1"					1-11		R1'	RI'R2		R1'	R1'	R1'	R1'	R1'	R1'	R1'	R1'	r1	r1	R1'	R1'
0.1	Ceftriaxone																R1"							R1'	R1'	R1'		R1	R1	R1	R1	R1'	R1	R1	r1	r1	R1'	R1'
3rd	Cefditoren												7		,		R1"							R1'	R1'	R1'	R1		R1	R1	R1	R1'	R1	R1	r1	r1	R1'	R1'
	Cefodizime										-						R1"							R1'	R1'	R1'	R1	R1		R1	R1	R1'	R1	R1	r1	r1	R1'	R1'
	Cefotaxime													R2	R2	r2	R1"r2			-= (-	R1'	R1'	R1'	R1	R1	R1		R1	R1'	R1	R1	r1	r1	R1'	R1'
	Cefpodoxime								J E								R1"							R1'	R1'	R1'	R1	R1	R1	R1		R1'	R1	R1	r1	r1	R1'	R1'
	Ceftazidime																							R1'	R1'	R1'	R1'	R1'	R1'	R1'	R1'		ALC: UNKNOWN	R1'r2	r1	R1'	R1	R1
4.5	Cefepime					-							8				R1"							R1'	R1'	R1'	R1	R1	R1	R1	R1	R1'		R1	r1	r1	R1'r2	
4th	Cefpirome		1														R1"							R1'	R1'	R1'	R1	R1	R1	R1	R1	R1'r2	R1		r1	r1'	R1'	R1'
1	Ceftaroline fosamil																r1"							r1'	r1'	r1'	r1	r1	r1	r1	r1	r1	r1	r1		R1'	r1	r1'
5th	Ceftolozane																							r1'	r1'	r1'	r1'	r1'	r1'	r1'	r1'	R1'	r1'	r1'	R1'		R1'	R1'
	Cefiderocol								1															R1'	R1'	R1'	R1'	R1'	R1'	R1'	R1'	R1	R1'r2	-	r1	R1'		R1
Mono	Aztreonam							-	0							-				-				R1'	R1'	R1'	R1'	R1'	R1'	R1'	R1'	R1	R1'	R1'	r1°	R1'	R1	

1		Penicillins								
		Nafcillin	Oxacillin	Dicloxacillin	Penicillin G / V	Piperacillin	Ampicillin	Amoxicillin		
	Nafcillin									
	Oxacillin			r1						
	Dicloxacillin		r1		4					
PCN	Penicillin G / V					rt'	71"	17		
	Piperacillin		-		ri	100	R1"	ri		
	Ampicillin				11'	R1'		r1'		
	Amoxicillin				11"	rit!	r1"			
	Cefadroxil				rf	r1	ri	R1		
	Cefatrizine				11	11	ri	R1		
	Cephalexin				r1	R1'	R1	r1		
1st	Cefazolin									
	Ceftezole									
	Cephalothin									
	Cephapirin						-			
	Cefoxitin							-		
	Cefuroxime									
	Cefotetan									
2nd	Cefprozil				11	-r1	r1	R1		
	Cefacior		-		71	R1"	RI	r1.		
	Cefonicid				ri	r1	r1	r1		
	Cefamandole				rt	r1	rt	11		

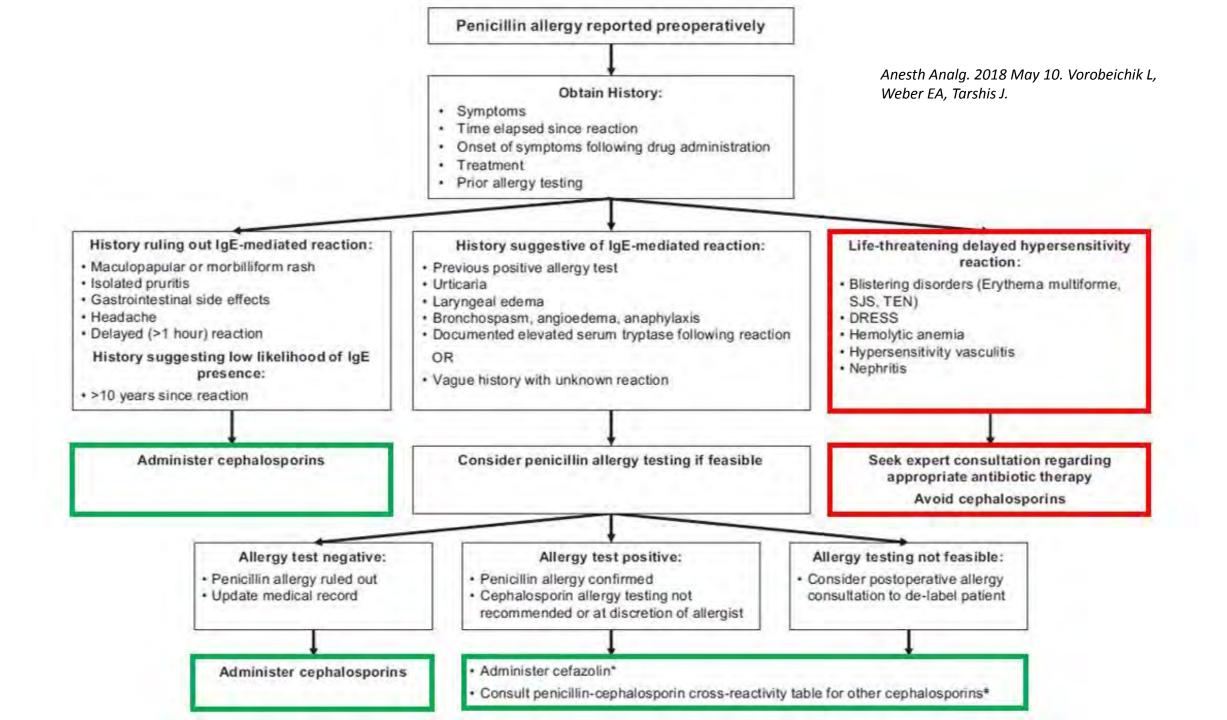
J Allergy Clin Immunol Pract. 2018 Jan -Feb;6(1):72-81.e1. Cross-reactivity in β-Lactam Allergy. Zagursky RJ, Pichichero ME.

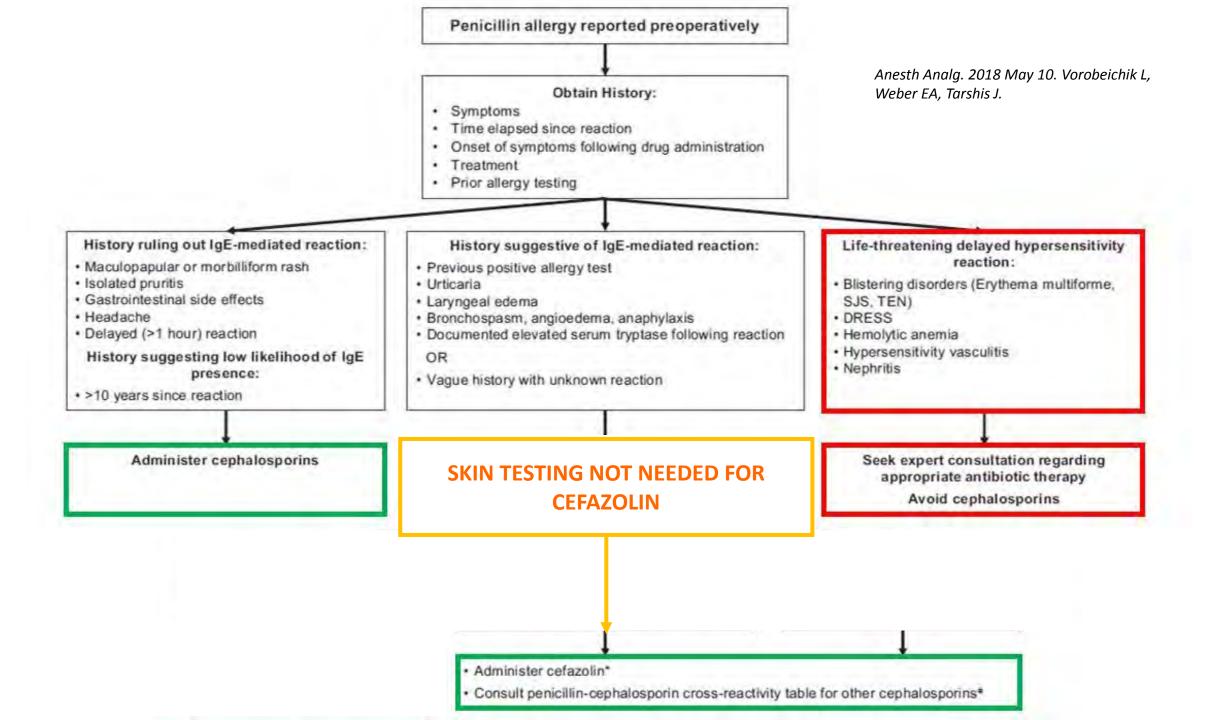
SPECIAL ARTICLE

Misconceptions Surrounding Penicillin Allergy: Implications for Anesthesiologists

Leon Vorobeichik, MD,* Elizabeth A. Weber, MD, FRCPC,†‡ and Jordan Tarshis, MD, FRCPC*§

"It is noted that **cefazolin** in particular demonstrates a **lack of cross-reactivity** with penicillins and other cephalosporins"





Safety Data: Macy et al

- Kaiser Permanente retrospective study of <u>cephalosporin</u> utilization over 2 years:
 - 949,323 received a cephalosporin
 - 13 had an anaphylactic reaction
 - = 0.001%
 - 65,915 patients had a penicillin allergy
 - 3 of these patients had anaphylaxis to a cephalosporin

= 0.0046%

Safety Data: Beltran et al

Cohort of 513 penicillin allergic surgical patients (624 cases)

Antibiotics Received (Courses)	Adverse Reactions	Rate
Cephalosporin* n=153	1 (hives, erythema)	0.6%
Clindamycin n=387	8 (rash or other effects	2%
Ciprofloxacin n=19	3 (rash or other side effects)	15.8%

^{*}Cefazolin, Cefoxitin

Anaphylaxis to Cephalosporins in Patients with Anaphylactic Reactions from Penicillins

•	Cephalexin,
	cefamandol and
	cefaclor all have R-
	side chain
	similarities with
	penicillins

Cephalothin preparations were contaminated with benzylpenicillin

Year, Reference	Age (years)	Sex	Reaction to penicillin	to penicillin (yes/no)	Cephalosporin	Reaction to cephalosporin
1965, Kabins et al (4)	47	F	Pruritis and angioneurotic edema	Yes	Cephalothin	Hypotensive, wheezing and unresponsive within 2 min
1966, Rothschild and Doty (23)	56	M	Pruritis and urticaria	No	Cephalothin	Apnea and hypotension within minutes
1966, Drug Letter (24)	40	F	Rash*	No	Cephalothin	Pruritis, dyspnea and angioneurotic edema
1968, Scholand et al (5)	65	М	Urticaria, angio- neurotic edema and dyspnea	Yes	Cephalothin	Wheezing and hypotension within 30 s
1968, Girard (6)	1 patient [†]		Anaphylaxis*	Yes	Cephaloridine	Mild anaphylactic shock*
1971, Petz (25)	2 patients†		Unknown*	No	Cephalothin	Anaphylaxis*
1974, Spruill et al (10)	59	M	Unknown*	Unknown	Cephalothin	Cardiac arrest within 5 mil
1980, Zeok and Tsueda (26)	1 patient [†]		Urticaria	No	Cephalothin	Hypotension, bradycardia diminished respiratory excursions and wheezing, generalized edema, urticaria
1989, Blanca et al (7)	22	F	Angioedema of the mouth and eyes	No	Cefamandole	Hypotension
1989, Blanca et al (7)	50	F	Hypotension, pruritis of the lips, breathing difficulties	Yes	Cefamandole	Hypotension, dysphonia, generalized pruritis, and upper airway obstruction
1989, Macnab (27)	35	F	Unknown*	No	Cephalexin and cephalothin	Urticaria, dyspnea, nausea and severe headaches
1999, Pumphrey and Davis (8)	76	F	Anaphylaxis to amoxicillin*	Yes	Cefaclor	Fatal anaphylaxis*
1999, Pumphrey and Davis (8)	3 patients†		Two allergic to amoxicillin and 1 allergic to penicillin*	Unknown	Unknown	Fatal anaphylaxis*
1999, Nordt et al (28)	32	F	Unknown*	Unknown	Cephalexin	Rapid onset of throat tightness and urticaria

^{*}No further details of the reactions were given; † Ages unknown. F Female; M Male

Key Fact 5:

➤ Cefazolin is predicted to be safe even in cases of IgE-mediated reactions to penicillin

Exception: Severe, Delayed Reactions

SCARS (Severe cutaneous adverse reactions)

DRESS

Blistering skin rashes

- Stevens-Johns Syndrome (SJS)
- Toxic endodermal necrolysis (TEN)

Organ-Specific Injury

- Hepatitis, nephritis
- Hemolytic anemia
- Serum sickness (joint pains)
- Drug fever

JAMA January 15, 2019

Severe T-cell-mediated reactions or severe cutaneous adverse reactions

Onset days to weeks into treatment course Blistering and/or skin desquamation Mucosal and/or organ involvement Usually requires hospitalization







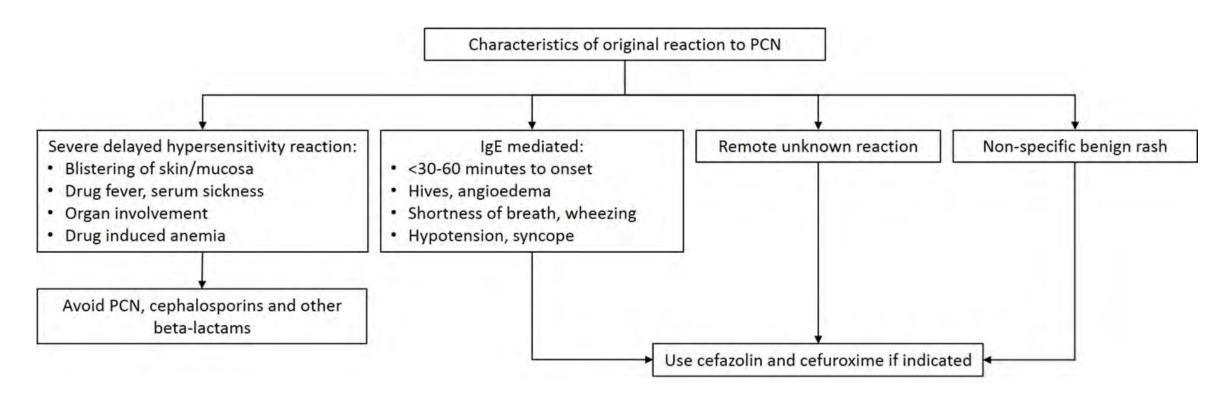
Mechanism for these reactions is unknown. Suggest avoiding all beta lactam agents

Key Fact 6

• In presence of severe delayed reaction, the mechanism is unknown and therefore many recommend avoiding all beta lactam agents.

• In the absence of a severe, delayed reaction, patients with a penicillin allergy can receive cefazolin and cefuroxime

Antibiotics for PCN Allergy, Approach 3.0



Emory's institutional algorithm for cefazolin/cefuroxime use in perioperative patients with reported allergy to penicillin.

Kuruvilla, et al. Journal of Allergy and Clinical Immunology: In Practice. In Press

Screening Tool for Severe, Delayed Reaction

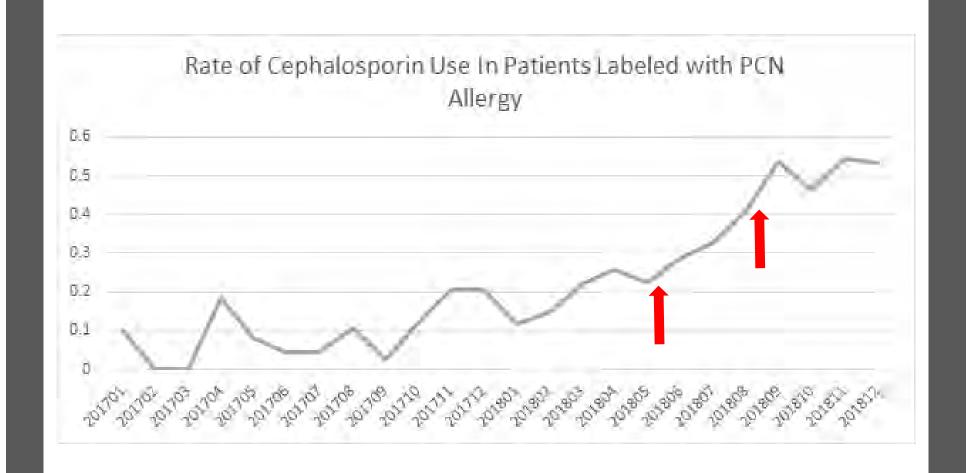
YES	NO	
		Did you have a severe skin reaction involving blisters on your skin and shedding or detachment of your skin? (SJS/TEN)
		Were you told you had Stevens-Johnson Syndrome or TEN?
		Did you have liver injury or hepatitis caused by the medication?
		Did you have kidney injury, nephritis or acute renal failure caused by the medication (acute interstitial nephritis)?
		Were you told you had hemolytic anemia caused by the medication? (Low hemoglobin or hematocrit or "blood counts" counts caused by penicillin)
		Did you have painful swollen joints caused by the medication (serum sickness)?
		Were you diagnosed with "drug fever"? (A fever caused by the antibiotic that developed about a week after starting the medication and then went away when you stopped the antibiotic?)
		Did you have a severe reaction involving the inside of your mouth, eye, or genital ulcers?

Figure 2. Questionnaire to assess for a history of a severe delayed hypersensitivity reaction to penicillin. If the patient answers yes to any of the above: avoid beta-lactam medications. If none of the above are checked: cefazolin and cefuroxime are expected to be safe.

New Protocol Implementation:

- Baseline survey with educational component
- Multidisciplinary group presentations including:
 - Anesthesia: Baseline data and knowledge survey results
 - Infectious Disease: Advantages to first-line antibiotic use
 - Allergy: Safety data for cefazolin use and the new protocol
- Electronic communications, updated guidelines
- Dept of surgery morning meetings
- Pharmacy meetings
- Ongoing informal education

Change in Practice at EUH



(cefazolin, cefuroxime)

Increased Use of First Line Antibiotics

Study Time Period	Mean Percentage of Penicillin-Allergic Patients Receiving Cefazolin/Cefuroxime
Baseline (1/2017 – 9/2017)	6.5%
Anesthesia managing antibiotics Survey of their allergy practice performed (10/2017 – 7/2018)	21.2%
Following educational session (9/2018 – 12/2018)	51.9%
Following Grand Rounds (1/2019-3/2019)	87.8%

• ANOVA utilized to compare the percentage of patients receiving a cephalosporin at baseline, after anesthesia control of antibiotics, and after both educational interventions, p<0.0001

New Process Review

Reviewed 24,629 cases before and after implementation of the new algorithm

PCN allergy 2296 = 9.3%

Chart review of all surgical patients with PCN allergy (n = 551) who was given a cephalosporin and received diphenhydramine or epinephrine (n=32)

- No immediate allergic reactions requiring epinephrine were identified.
- One case of delayed rash that did not require cephalosporin discontinuation
- Three patients received diphenhydramine for itching without rash

A streamlined approach to optimize perioperative antibiotic prophylaxis in the setting of penicillin allergy labels. Kuruvilla, Sexton, Wiley, Langfitt, Lynde, Wolf. Journal of Allergy and Clinical Immunology: In Practice. In Press https://doi.org/10.1016/j.jaip.2019.12.016

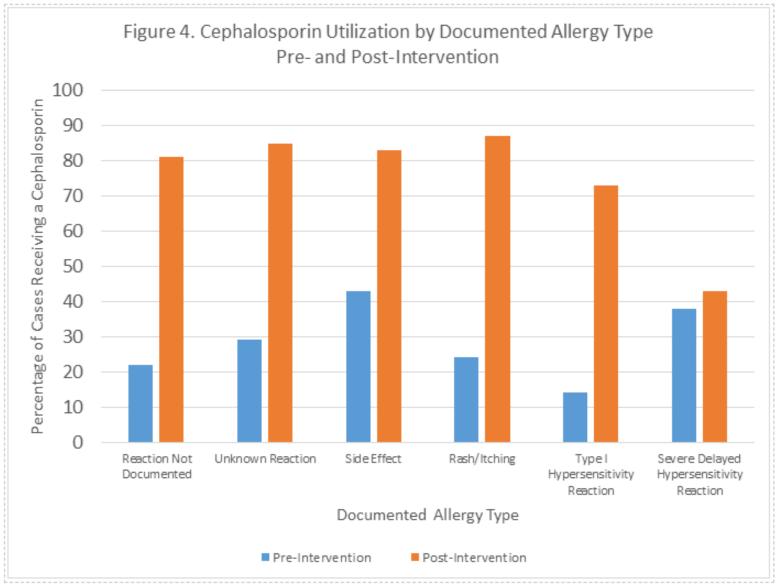


Figure 4. The percentage of penicillin-allergic surgical cases receiving a cephalosporin before and after algorithm implementation is shown, stratified by the type of allergic reaction documented in the patient's medical record.

Next Steps

- Assess impact on outcomes: SSI, C. Diff, cost
- Continue safety monitoring

Six Key Facts That Changed My Practice

- 1. Patients with listed penicillin allergy are more likely to get second line antibiotics
- 2. Second line agents are associated with negative outcomes
- 3. Most patients with a penicillin allergy label do not have a penicillin allergy

Six Key Facts That Changed My Practice

- Patients with listed penicillin allergy are more likely to get second line antibiotics
- 2. Second line agents are associated with negative outcomes
- 3. Most patients with a penicillin allergy label do not have a penicillin allergy
- Cross-reactivity among the beta lactams is based on side chain similarity
- 5. Cefazolin is safe even in cases of severe Ig-E reactions to penicillin
- 6. In presence of a severe <u>delayed</u> reaction, experts recommend avoiding all beta lactam agents.

In the absence of a severe <u>delayed</u> reaction, cefazolin can be used in patients with a penicillin allergy

Summary

Major Societies Agree - A New Approach to Penicillin Allergy Is Needed

- Patients with a penicillin allergy often get second line antibiotics due to concerns about cross-reactivity
- As a result, they may be at increased risk for SSIs and other complications
- A streamlined approach to that relies on ruling out a history of severe delayed reaction to PCN can allow for safe administration of first-line agents cefazolin or cefuroxime, without the need for skin testing.
- A multi-disciplinary team proved valuable in supporting this change in practice.
- The anesthesia team can take a leadership role in antibiotic stewardship

The Team

- Marybeth Sexton MD, MSc Infectious Diseases
- Zanthia Wiley, MD Infectious Diseases
- Merin Kurivilla, MD Allergy and Immunology
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- Terry Langfitt MD Anesthesiology (Resident)
- Joe Sharma MD Surgery
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Thank you





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Epstein RH, Jacques PS, Wanderer JP, Bombulie MR, Agarwalla N. Prophylactic antibiotic management of surgical patients noted as "allergic" to penicillin at two academic hospitals. A A Case Rep 2016; 6:263–7

Systematic review of professional liability when prescribing β -lactams for patients with a known penicillin allergy



Meghan N. Jeffres, PharmD *; Elizabeth A. Hall-Lipsy, JD, MPH †; S. Travis King, PharmD, BCPS (AQ-ID) ‡; John D. Cleary, PharmD, FCCP, BCPS (AQ-ID) §

Key Messages

- Patients labeled as penicillin-allergic are more likely to receive second line non-β-lactam antibiotics, experience higher rates of treatment failure, and incur higher antibiotic costs.
- Fear of litigation has been identified as a potential reason clinicians avoid using β-lactams in a patient with a penicillin allergy.
- Since 1959, 27 medical malpractice or negligence cases have been published in which a patient with a penicillin allergy received a β-lactam and experienced an adverse reaction.
- Defendants (providers) were found liable in 3 of 7 cases in which a penicillin-based antibiotic was prescribed to a patient with a known penicillin allergy.
- Defendants were not found liable in any cases in which a cephalosporin or carbapenem was prescribed excluding 1 case in which
 physicians settled out of court.
- Judges have cited a lack of scientific evidence demonstrating cephalosporins or carbapenems are contraindicated for patients with a penicillin allergy.



Residual Neuromuscular Blockade Is Our Silent Epidemic of Weakness Finally Over?



Strychnos toxifera (Curare) from Koehler's Medicinal-Plants 1887

Francis Wolf, MD
Assistant Professor, Department of Anesthesiology, Emory University School of Medicine

Disclosures: No conflicts of interest

Objectives

- 1. Provide the definition of residual neuromuscular blockade (rNMB)
- 2. Cite some of the main causes of rNMB
- 3. Compare qualitative and quantitative nerve monitoring
- 4. Describe advantages and limitations of sugammadex as a reversal agent

A STUDY OF THE DEATHS ASSOCIATED WITH ANESTHESIA AND SURGERY* BASED ON A STUDY OF 599,548 ANESTHESIAS IN TEN INSTITUTIONS 1948–1952, INCLUSIVE HENRY K. BEECHER, M.D., AND DONALD P. TODD, M.D.

FROM THE ANESTHESIA DEPARTMENT OF THE HARVARD MEDICAL SCHOOL AT THE MASSACHUSETTS GENERAL HOSPITAL, BOSTON

Table XIII. Total Incidence of "Curare" Use and Associated Death.
Total Number Anesthesias
Number Anesthesias in which "Curare" Used (1:14). 44,100
Frequency of Death Related to Anesthesia
Anesthesias Which Did Not Include "Curare" (266) 1:2100
Anesthesias Which Included "Curare" (118) 1:370

Most patients were not intubated and were breathing spontaneously

1954: Annals of Surgery

A 61 Year-Old, 80-kg Patient for Ventral Hernia Repair

- Rocuronium: 100 mg for case
- Reversal: 2 mg neostigmine from 2 twitches
- Extubated 10 minutes later
- On arrival in PACU was motionless and apneic
- Upper airway obstruction, low O₂ saturation
- Quantitative TOF reveals TOF ratio = 0.61

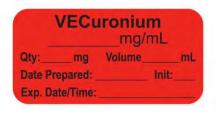


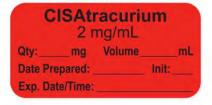
Residual neuromuscular blockade is the single biggest thing we do to harm our patients

-Glenn Murphy MD

Neuromuscular Blocking Drugs are (Still) Dangerous

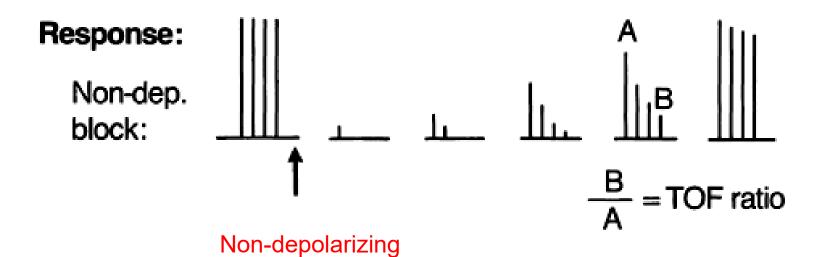
ROcuronium
10 mg/mL
Qty:___mg Volume___mL
Date Prepared: _____Init:__
Exp. Date/Time: ____





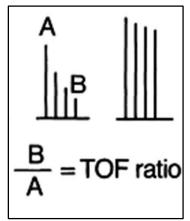


Train of Four Ratio



NMBD

Train of Four Ratio: Defining Weakness





1.0 or 100% = baseline

0.9 or 90% = full recovery

< 0.9 = residual weakness

<0.7 = residual weakness (older definition)

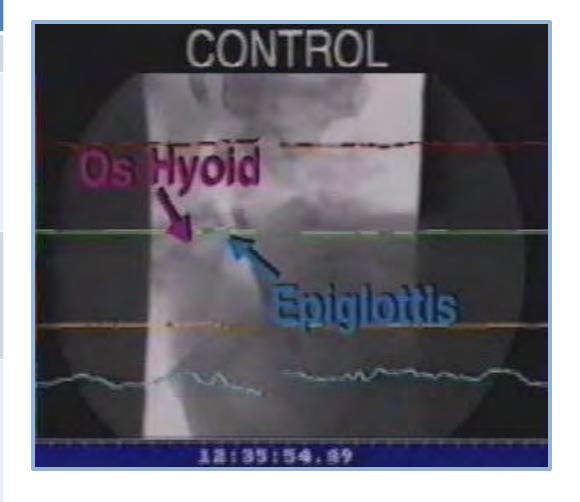
Train of four ratio < 0.9 = residual weakness

"residual paralysis"

"residual (neuromuscular) blockade"

"residual curarization"

TOF-R	Results of Weakness
≥0.9	No/little impairment
<0.9	Pharyngeal dysfunction Increased risk for aspiration Feelings of distress Diplopia Decreased upper esoph tone
<0.8	Impaired air flow Partial airway obstruction Decreased jaw clench Decreased FEV1
<0.7	 Impact on cough tongue protrusion sustained head lift lung volumes, inspiratory force, peak flows grip strength Impaired ventilatory response to hypoxia



Functional assessment of the pharynx at rest and during swallowing in partially paralyzed humans: simultaneous videomanometry and mechanomyography of awake human volunteers. Anesthesiology. 1997 Nov;87(5):1035-43.

Incidence of residual paralysis after extubation and in the PACU: 15-88%

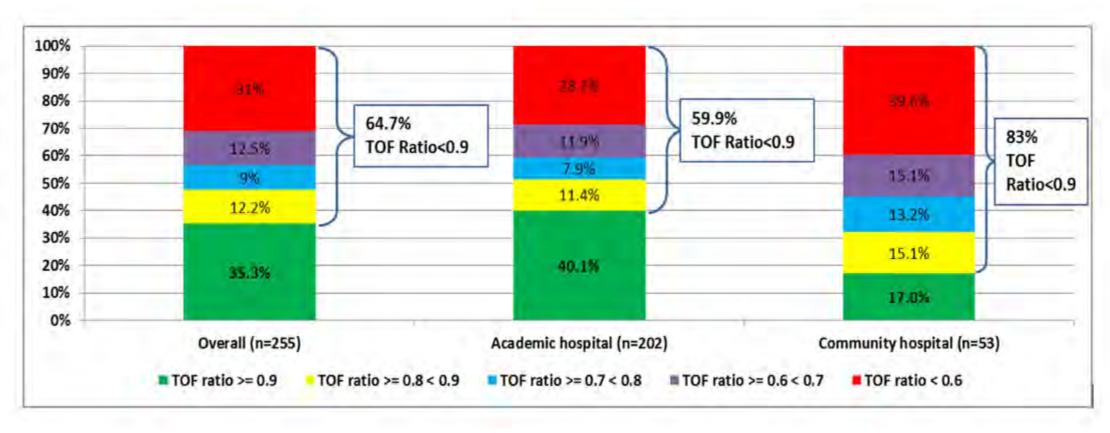
Table 1. Incidence of Residual Neuromuscular Blockade (2000–200

Author	Year	Number of patients	NMBD used	NM monitoring used (%)	Reversal used (%)	Site/time RNMB measured	Definition RNMB	Incidence RNMB	Type of anesthesia
Baillard et al. ²⁷	2000	568	Vecuronium	2	0	PACU	≈0.7	42% (AMG)	Inhalational
Bissinger et al. ²⁰	2000	83	Pancuronium	NS	100	PACU	<0.7	20% (AMG)	Inhalational and TIVA
Hayes et al. ²²	2001	148	Vecuronium Vecuronium	NS 41	100 68	PACU PACU	<0.7 <0.8	7% 64% (AMG)	Primarily inhalational
McCaul et al. ²⁸	2002	40	Atracurium Rocuronium Atracurium	41 41 50	68 68 100	PACU PACU Extubation	<0.8 <0.8 <0.7	52% 39% 65% (MMG)	NS
Gatio Bailla	<u> </u>					al in PAC			nal nal
ваша Debaene et al. ³	2003	526	Vecuronium	NS		DA OLI	-0.7	120/ /(10)	nat
	2000	420	veculomum	149	0	PACU	<0.7	16% (AMG)	Inhalational
			Rocuronium Atracurium	NS NS	0	PACU PACU	≈0.9	45%	Inhalational
	2005	218	Rocuronium Atracurium Vecuronium	NS NS 60	0 0 42	PACU PACU PACU	<0.9 <0.9	45% 3.5% (AMG)	Inhalational Inhalational
Baillard et al. ²¹			Rocuronium Atracurium	NS NS 60 60	0 0 42 42 100	PACU PACU PACU PACU Transfer to	<0.9 <0.9 <0.9 <0.9	45% 3.5% (AMG) 3.5% 36.7% (MMG)	Inhalational Inhalational Inhalational Inhalational
Baillard et al. ²¹ Kopman et al. ²⁴	2005	218	Rocuronium Atracurium Vecuronium Atracurium	NS NS 60 60	0 0 42 42	PACU PACU PACU PACU	<0.9 <0.9 <0.9	45% 3.5% (AMG) 3.5%	Inhalational Inhalational Inhalational
Baillard et al. ²¹ Kopman et al. ²⁴ Murphy et al. ³⁸	2005	21.8 60	Rocuronium Atracurium Vecuronium Atracurium Cisatracurium Rocuronium	NS NS 60 60 100	0 0 42 42 100 100	PACU PACU PACU PACU Transfer to PACU	<0.9 <0.9 <0.9 <0.9 <0.9	45% 3.5% (AMG) 3.5% 36.7% (MMG) 50.0%	Inhalational Inhalational Inhalational Inhalational Inhalational
Baillard et al. ²¹ Kopman et al. ²⁴ Viurphy et al. ²⁶ Viurphy et al. ²⁵	2005 2004 2004	218 60 70	Rocuronium Atracurium Vecuronium Atracurium Cisatracurium Rocuronium Pancuronium	NS NS 60 60 100 100 100	0 0 42 42 100 100 100	PACU PACU PACU PACU Transfer to PACU PACU PACU PACU	<0.9 <0.9 <0.9 <0.9 <0.9 <0.9	45% 3.5% (AMG) 3.5% 36.7% (MMG) 50.0% 83% (AMG) 29%	Inhalational Inhalational Inhalational Inhalational Inhalational Inhalational Inhalational
Baillard et al. ²¹ Kopman et al. ²⁴ Murphy et al. ²⁶ Murphy et al. ²⁵	2005 2004 2004 2005 2006	218 60 70 120 640	Rocuronium Atracurium Vecuronium Atracurium Cisatracurium Rocuronium Pancuronium Rocuronium	NS NS 60 60 100 100 100 100 11–12 11–12	0 0 42 42 100 100 100 100	PACU PACU PACU Transfer to PACU PACU PACU PACU Extubation PACU PACU PACU PACU	<0.9 <0.9 <0.9 <0.9 <0.9 <0.9 <0.9 <0.9	45% 3.5% (AMG) 3.5% 36.7% (MMG) 50.0% 83% (AMG) 29% 88% (AMG) 38–47% (AMG) 38–47%	Inhalational Inhalational Inhalational Inhalational Inhalational Inhalational Inhalational Inhalational Inhalational NS NS
Baillard et al. ²¹	2005 2004 2004 2005	218 60 70 120	Rocuronium Atracurium Vecuronium Atracurium Cisatracurium Rocuronium Pancuronium Rocuronium Rocuronium Atracurium Mivacurium	NS NS 60 60 100 100 100 100 11–12 11–12	0 0 42 42 100 100 100 100 25–26 25–26	PACU PACU PACU Transfer to PACU PACU PACU Extubation PACU PACU	<0.9 <0.9 <0.9 <0.9 <0.9 <0.9 <0.9 <0.9	45% 3.5% (AMG) 3.5% 36.7% (MMG) 50.0% 83% (AMG) 29% 88% (AMG) 38–47% (AMG)	Inhalational Inhalational Inhalational Inhalational Inhalational Inhalational Inhalational Inhalational NS

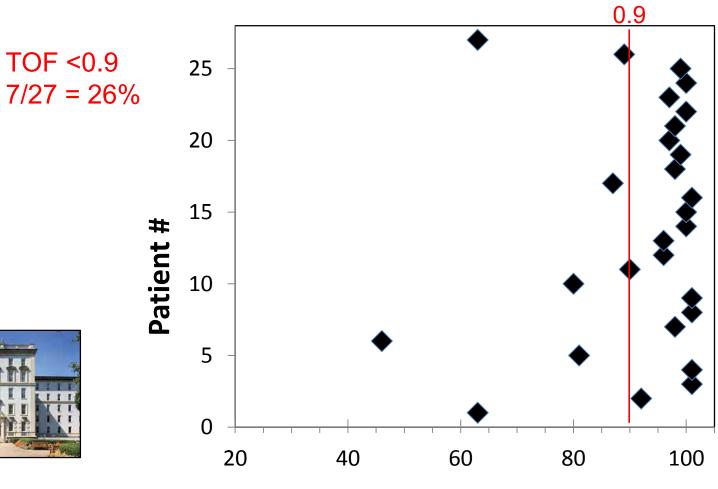
NMBD = neuromuscular blocking drugs; NM monitoring= neuromuscular monitoring; RNMB = residual neuromuscular blockade; TIVA = total intravenous anestnesia; NS = not stated.

Residual Curarization and its Incidence at Tracheal Extubation (RECITE)

rNMB at extubation: 64.7%



Residual Paralysis in the EUH PACU (2014)



TOF ratio (T4/T1) on arrival in PACU measured by AMG

Residual Paralysis is Associated with Critical Respiratory Events

- Airway Obstruction, Hypoxemia (Murphy 2004, 2008, Norton 2013)
- Aspiration, Respiratory Distress, Reintubation
- Longer PACU stays, diplopia, feelings of distress, inability to breathe deeply (Murphy 2004)

Anesthesia & Analgesia. 111(1):120-128, July 2010.

Murphy GS, Szokol JW, Marymont JH, Greenberg SB, Avram MJ, Vender JS. Anesth Analg. 2008;107:130–7

Butterly A, Bittner EA, George E, Sandberg WS, Eikermann M, Schmidt U. Br J Anaesth. 2010;105:304–9

Residual Paralysis and Critical Respiratory Events

- 202 PACU patients
- 30% had TOF < 0.9

	TOF < 0.9	TOF ≥0.9	P-Value
Airway obstruction	10%	2%	0.03
Mild-mod hypoxemia	23%	4%	<0.001
Severe hypoxemia	7%	1%	0.03
Inability to breathe deeply	38%	12%	<0.001

Norton. Rev Esp Anestesiol Reanim. 2013 Apr;60(4):190-6.

Critical Respiratory Events in the PACU

Table 4. Simple Logistic Regression Models Analyzing the Relationship Between Various Measures of Residual Neuromuscular Blockade and the Presence or Absence of Upper Airway Obstruction or Hypoxemia

Outcome	Variable	Regression coefficient	Standard error	Wald statistic	P	Odds ratio	95% CI
Upper airway	Intercept	1.220	0.910	_	_	_	
obstruction	Train-of-four ratio	-0.037	0.013	-2.963	0.003	0.96	0.94 to 0.99
Upper airway	Intercept	-3.831	0.939	_	-	()	
obstruction	Degree of NM blockade*	1.745	0.517	3.371	0.001	5.73	2.08 to 15.80
Severe	Intercept	2.509	0.939	_		-	_
hypoxemia	Train-of-four ratio	-0.047	0.012	-3.768	0.0002	0.95	0.93 to 0.98
Severe	Intercept	-2.487	0.539	-	_	1	
hypoxemia	Degree of NM blockade*	1.290	0.335	3.855	0.0001	3.63	1.88 to 7.00
Any	Intercept	4.431	1.129		_	_	
hypoxemia	Train-of-four ratio	-0.062	0.014	-4.463	< 0.0001	0.94	0.91 to 0.97
Any	Intercept	-2.265	0.491	_	-	-	-
hypoxemia	Degree of NM blockade*	1.744	0.339	5.151	< 0.0001	5.72	2.95 to 11.11

^{*} Degree of residual NM blockade classified as acceptable neuromuscular recovery = 0 (TOF ratio >0.90), mild-to-moderate = 1 (0.70 \leq TOF ratio \leq 0.90), or severe = 2 (TOF ratio <0.70).

Murphy, Anesth Analg 2008; 107:130 –7)

Critical respiratory event group	Control group	Difference (95% CI)	P
4 (9.5%)	38 (90.5%)	-81.0% (-90 to -66)	< 0.0001*
7 (16.7%)	4 (9.5%)	7.1% (-9 to 24)	0.366*
31 (73.8%)	0 (0%)	73.8% (59 to 85)	< 0.0001*
	event group 4 (9.5%) 7 (16.7%)	event group group 4 (9.5%) 38 (90.5%) 7 (16.7%) 4 (9.5%)	event group group Difference (95% CI) 4 (9.5%) 38 (90.5%) -81.0% (-90 to -66) 7 (16.7%) 4 (9.5%) 7.1% (-9 to 24)

Why Are Patients Weak?

- Limitations of nerve monitoring
- Limited effectiveness of neostigmine
- Timing and dose of reversal and extubation
- Deep paralysis/repeated dosing



Traditional (Qualitative) Monitor

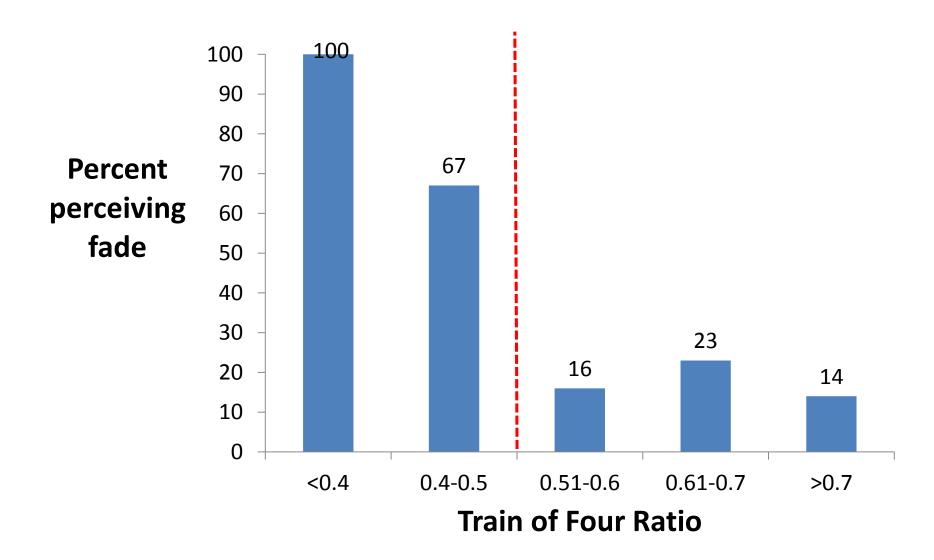
- No sensing function
- Clinician evaluates for fade
- Subjective



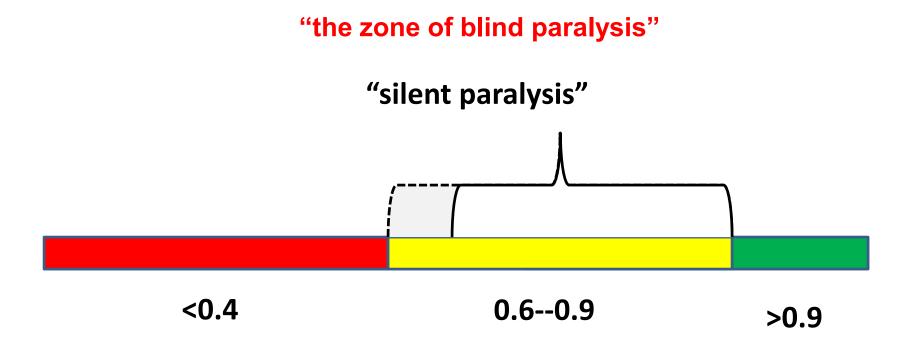
Quantitative Monitor:

- Additional sensor of acceleration, force, or EMG
- Provides numeric
 (objective) measure of fade

Experienced Anesthesiologists' (In)ability to Detect Fade on TOF



Residual Paralysis is Often Unrecognized



TOF Ratio

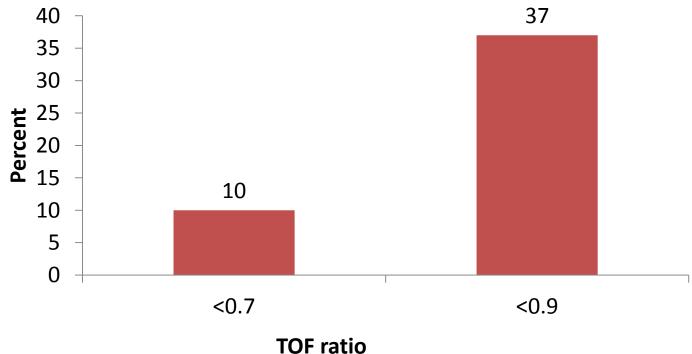
Six Pitfalls on the Way to Reversal with Neostigmine



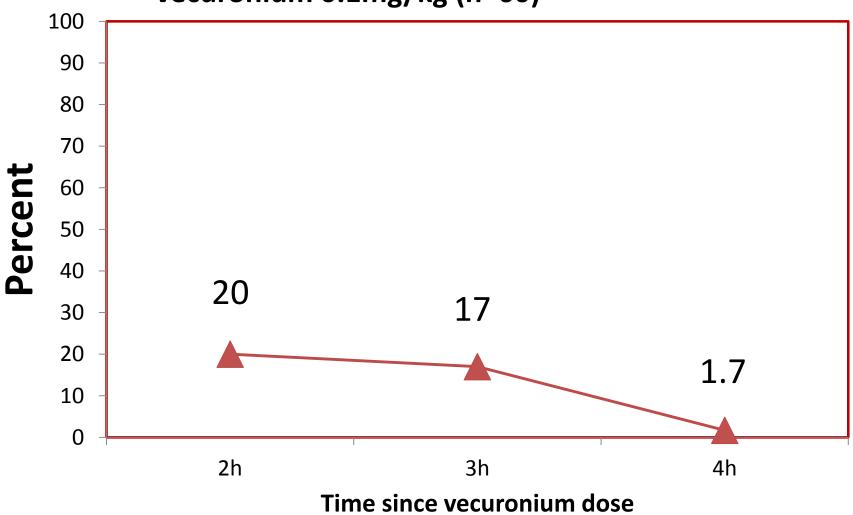
- 1. Relying on time alone
- 2. Relying on clinical tests
- 3. Using the facial nerve
- 4. Under-dosing
- 5. Allowing too little time
- 6. Use of qualitative monitors

Time Since Relaxation Does Not Reliably Exclude Weakness

Residual paralysis 2 hours after single intubating dose of intermediate acting neuromuscular blocking drug. N=239



Patients with TOF ratio <0.75 after single dose of vecuronium 0.1mg/kg (n=60)



Caldwell 1995 (adapted)

Clinical Tests Do Not Exclude Weakness

- Sustained head lift
 - 80-90% of healthy volunteers are able to maintain 5-second head lift with TOF 0.5 (Eikermann 2003, Pedersen 1990)
- Hand grip, leg lift, eye opening also possible with significant degree of residual paralysis
- (Masseter strength may indicate TOF ≥ 0.85)

Clinical Tests of Weakness

Table 2. Diagnostic Attributes of the Clinical Tests: Sensitivity, Specificity, Positive and Negative Predictive Values of an Individual Clinical Test for a Train-of-Four < 90%

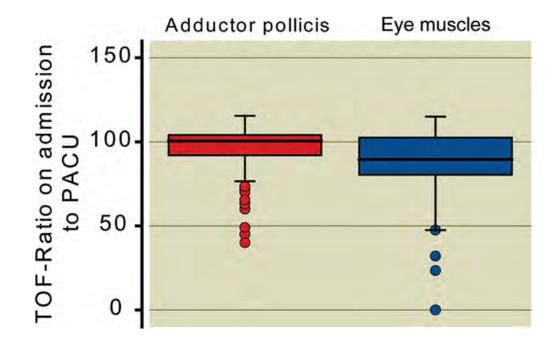
	Sensitivity	Specificity	Positive predictive value	Negative predictive value
Inability to smile	0.29	0.80	0.47	0.64
Inability to swallow	0.21	0.85	0.47	0.63
Inability to speak	0.29	0.80	0.47	0.64
General weakness	0.35	0.78	0.51	0.66
Inability to lift head for 5 s	0.19	0.88	0.51	0.64
Inability to lift leg for 5 s	0.25	0.84	0.50	0.64
Inability to sustained hand grip for 5 s	0.18	0.89	0.51	0.63
Inability to perform sustained tongue depressor test	0.22	0.88	0.52	0.64

Residual Neuromuscular Block: Lessons Unlearned. Part II: Methods to Reduce the Risk of Residual Weakness

Anesth Analg 2010;111:129 –40

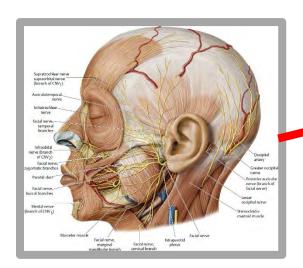
Ulnar vs Facial

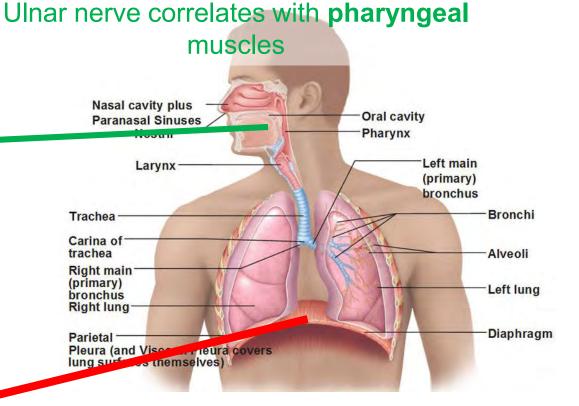
- Twitches return earlier at facial nerve compared to ulnar nerve
- Monitoring facial nerve results in higher incidence of residual paralysis (52% vs 22%, Thilen 2012):



Diaphragm vs. Pharynx







Facial nerve correlates with **diaphragm** (and larynx)

Dosing Neostigmine Reversal

- Full dose reversal = 50-70 mcg/kg
- Low dose reversal* = 20 mcg/kg

*Appropriate when TOF=4 with no fade, or TOFR ≥0.4

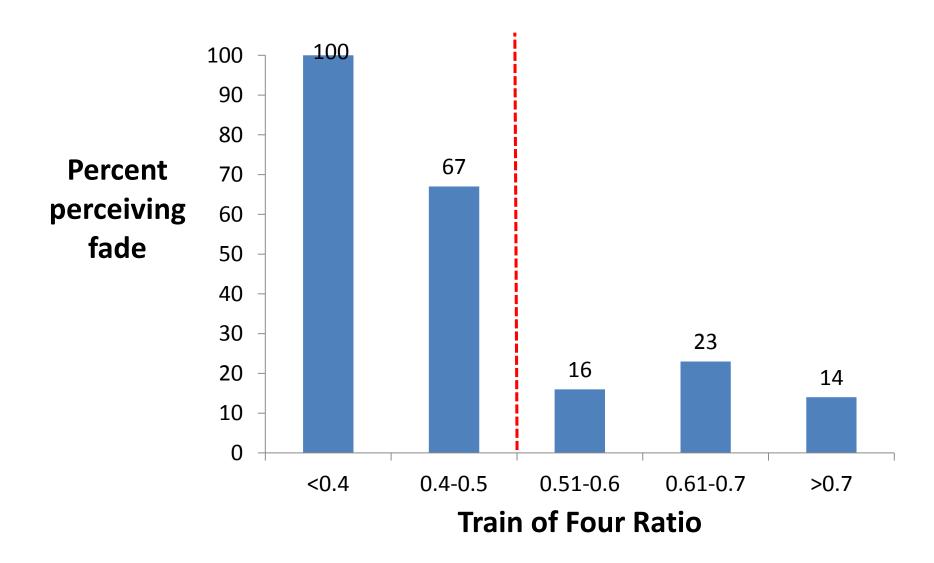
Time to Recovery Following Reversal

Number of twitches at time of reversal	Time to TOF ≥0.9 (minutes)
1	?
2	?
3	?
4	?

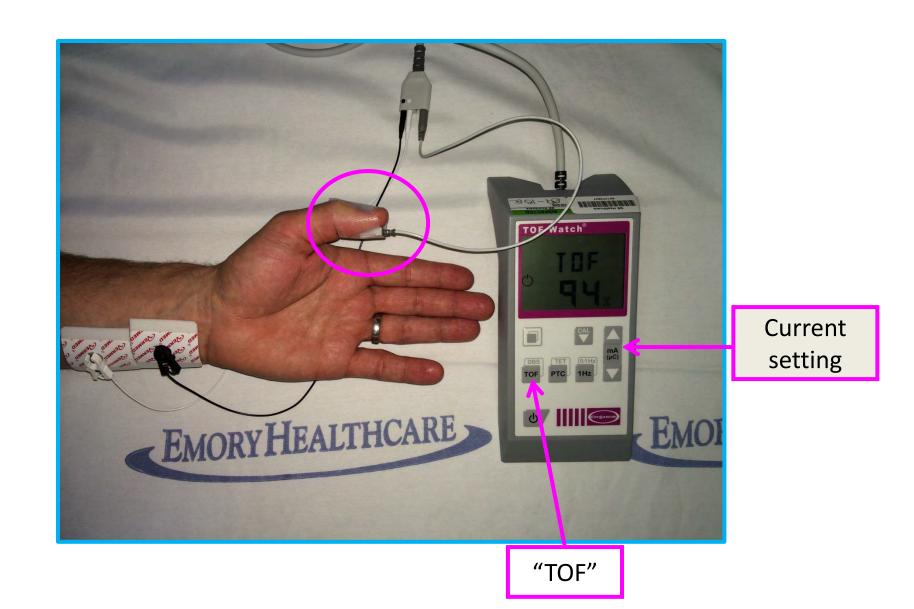
Time to Recovery Following Reversal

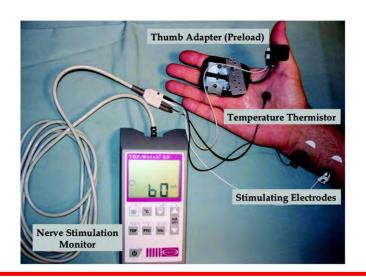
- Reversal from two twitches requires <u>at least 15 minutes</u>
 (Kopman 2004)
- Some patients reversed from two twitches will still have TOF
 <0.9 more than 30 minutes following reversal
- Unless you are using a quantitative monitor, you cannot reliably exclude residual paralysis using nerve stimulator and clinical assessment

Experienced Anesthesiologists' (In)ability to Detect Fade on TOF



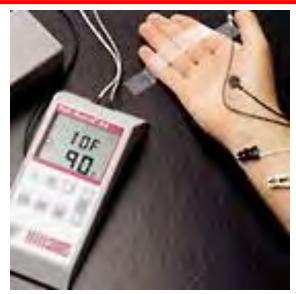
TOF Assessment with Accelerometer







Quantitative (objective) neuromuscular devices must be used to reliably detect TOF >0.4 to 0.6





Measuring Train of Four Ratio

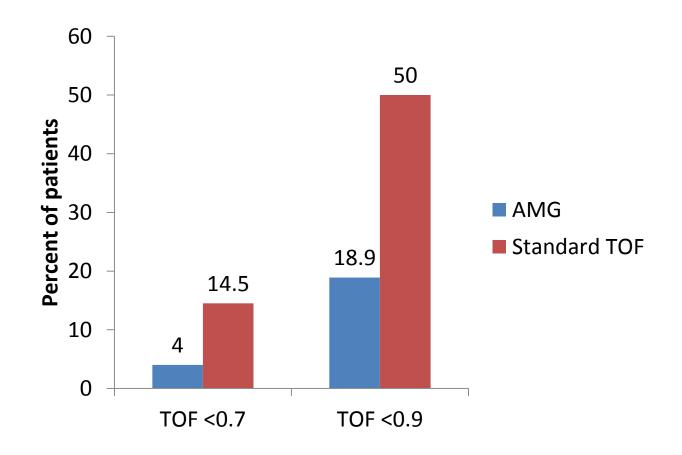
Monitor Type	Features
Mechanomyography (MMG)	"Gold Standard" Research applications only
Accelerometry (AMG)	Baseline TOF-R may be >100% (requires normalization) Requires unrestricted movement of thumb (or toe)
Electromyography (EMG)	Correlates well with MMG Can be used with arms tucked Disposable electrode (increased cost)
Cuff Device	Measures response in upper arm Overestimated recovery compared to EMG/AMG at ulnar nerv

Quantitative monitoring can reduce residual paralysis

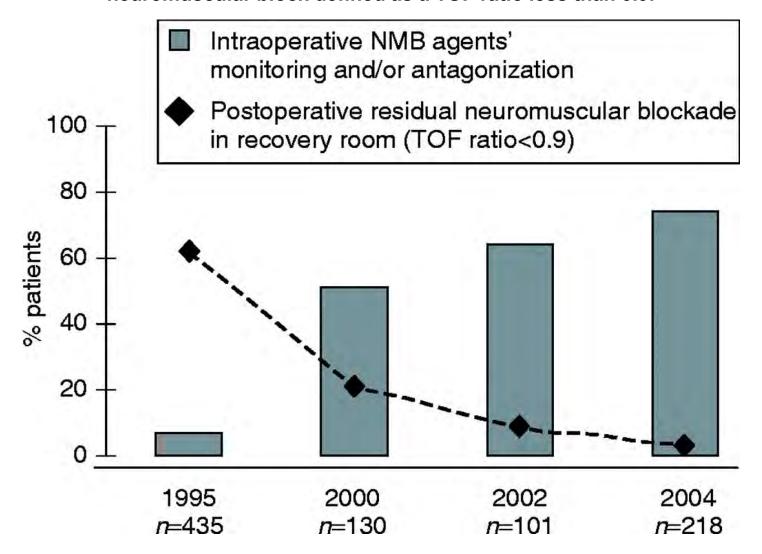


Intraoperative Acceleromyography Monitoring Reduces Symptoms of Muscle Weakness and Improves Quality of Recovery in the Early Postoperative Period

Glenn S. Murphy, M.D.,* Joseph W. Szokol, M.D.,* Michael J. Avram, Ph.D.,† Steven B. Greenberg, M.D.,‡ Jesse H. Marymont, M.D.,* Jeffery S. Vender, M.D.,§ Jayla Gray, B.A., Elizabeth Landry, B.A., Dhanesh K. Gupta, M.D.#



Evolution of intraoperative NMB agents' management and postoperative residual neuromuscular block defined as a TOF ratio less than 0.9.



ASA Guidelines on NMB Monitoring and Reversal:



Recommendations: Monitoring

Quantitative TOF monitoring should be routine when we reverse with neostigmine

(Anesth Analg 2010;111:129 –40)

Recommendations For Safer Neostigmine Reversal

- Monitor depth of blockade
- Use ulnar nerve rather than facial (for recovery)
- Reverse from at least two twitches (preferably 4)
- (Wait at least 15 minutes before extubating)
- Use a quantitative twitch monitor
- Use full dose reversal (50-70 mcg/kg) unless patient has 4/4 twitches with no detectable fade
- Withhold reversal only if normalized TOFR 90% or higher

First Human Exposure of Org 25969, a Novel Agent to Reverse the Action of Rocuronium Bromide

Francois Gijsenbergh, M.D.,* Steven Ramael, M.D.,† Natalie Houwing, M.Sc.,‡ Thijs van Iersel, M.D.§

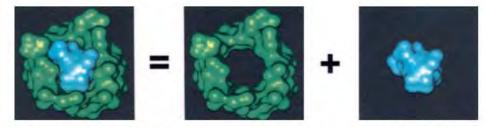
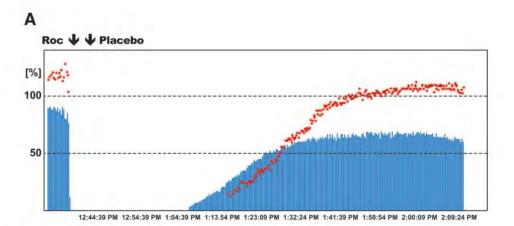
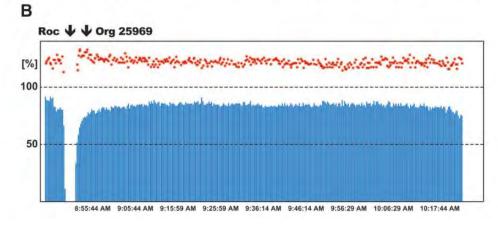


Fig. 1. X-ray crystal structures of Org 25969 (green) and rocuronium (blue) with filled van der Waals surface, showing that the two structures have many close contacts and are highly complementary to each other.





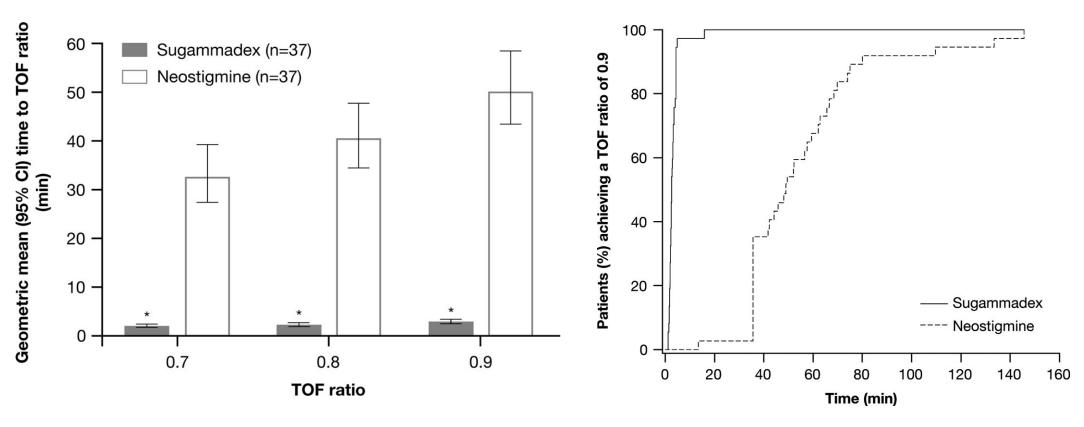
Sugammadex Dosing

Depth of Block	Dose	Time to TOFR >0.9 Minutes (range)
TOF = 2	2mg/kg	2 (0.9-5.4)
PTC = 1-2	4 mg/kg	3 (1.2-16.1)
2 min after RSI dose	16mg/kg	3 (1.2-10.6)

SIGNAL Study: PTC 1-2

• **Median time to recovery** TOF Ratio 0.9:

Sugammadex **2.7 min** (1.2-16 min) v neostigmine 49.0 min (13.3-145.7 min), p < 0.0001

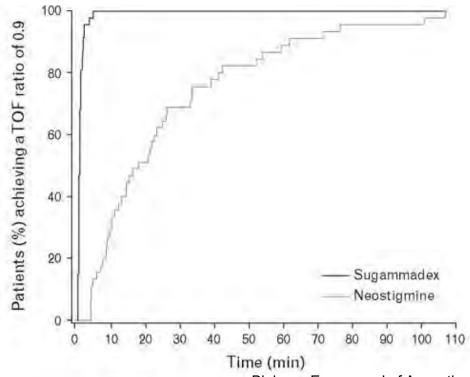


AURORA Study: TOF = 2/4

Median time to recovery

- TOF Ratio 0.9: Sugammadex 1.5 min v neostigmine 18.6 min, p < 0.0001
- TOF Ratio 0.8: Sugammadex 1.2 min v neostigmine 10.8 min, p < 0.0001
- TOF Ratio 0.7: Sugammadex 1.1 min v neostigmine 7.2 min, p < 0.0001

	Sugammadex (N = 48)	Neostigmine (N = 48)	P
Recovery of T ₄ /T ₁ ratio to 0	.9		
n	47 ^a	45 ^b	
Geometric mean (min)	1.5	18.6	< 0.0001
95% CI ^c	1.3-1.6	14.2-24.4	
Median (min)	1.4	18.5	
Range (min)	0.9-5.4	3.7-106.9	
Recovery of T ₄ /T ₁ ratio to 0	.8		
n	47 ^a	48	
Geometric mean (min)	1.2	10.8	< 0.0001
95% Cl ^c	1.1-1.3	8.5-13.7	
Median (min)	1.2	9.8	
Range (min)	0.9-3.4	2.7-67.9	
Recovery of T ₄ /T ₁ ratio to 0	.7		
n	47ª	48	
Geometric mean (min)	1.1	7.2	< 0.0001
95% CI ^c	1.0-1.2	5.8-8.9	
Median (min)	1.0	6.2	
Range (min)	0.7 - 2.7	2.4-41.1	



SPECTRUM Study: Emergency Reversal

Mean time to recovery

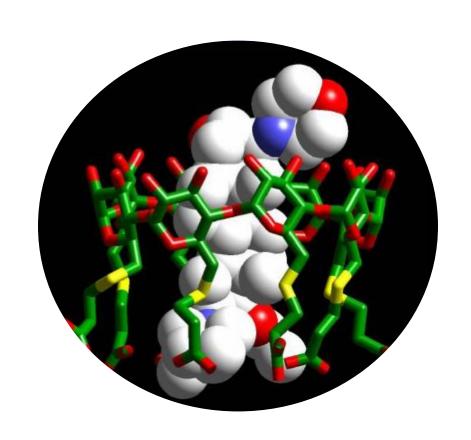
- Time to recovery of T1 to 10% of the baseline value
 - **4.4 min** rocuronium/sugammadex vs **7.1 min** succinylcholine, p < 0.001
- Time to recovery of T1 to 90% of the baseline value
 - **6.2 min** rocuronium/sugammadex vs **10.9 min** succinylcholine, p < 0.001

Table 1. Time (min) from Start of Administration of Neuromuscular Blocking Agent to Recovery of T₁ to 10% and T₁ to 90%

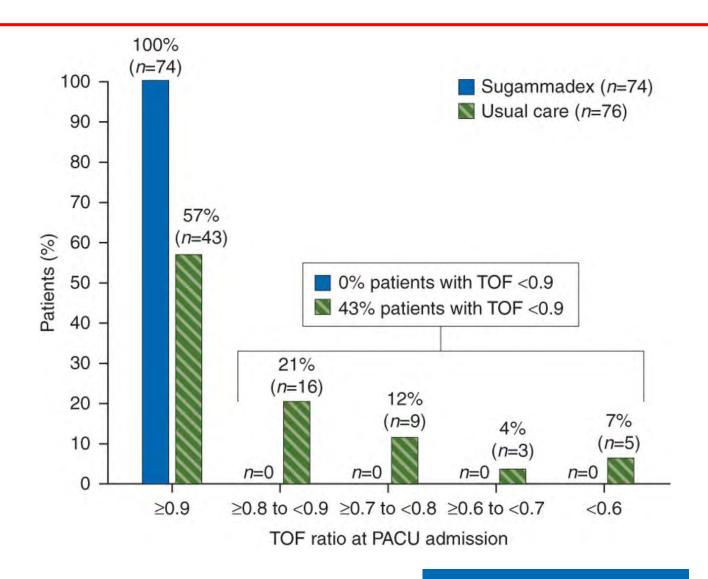
	Treatment Group		
	Rocuronium + Sugammadex* (n = 55)	Succinylcholine Only (n = 55)	
Recovery to T ₁ 10% (primary endpoint) Mean (SD) Median Min-max Recovery to T ₁ 90% Mean (SD) Median	4.4 (0.7) 4.2 3.5–7.7 6.2 (1.8) 5.7	7.1 (1.6)† 7.1 3.8-10.5 10.9 (2.4)† 10.7	
Min-max	4.2–13.6	5.0-16.2	

^{*} Protocol-specified sugammadex administration at 3 min after the start of rocuronium administration (mean [SD] 3.1 [0.2]; range 2.7 to 4.2 min). $\dagger P < 0.001$ between treatment groups.

Can Sugammadex Eliminate rNMB?



Residual paralysis 43% with usual care vs 0% with sugammadex





Format: Abstract -

Anesth Analq. 2013 Aug;117(2):345-51. doi: 10.1213/ANE.0b013c3182999672. Epub 2013 Jun 11.

Reversal with sugammadex in the absence of monitoring did not preclude residual neuromuscular block.

Kotake Y1, Ochiai R, Suzuki T, Oqawa S, Takaqi S, Ozaki M, Nakatsuka I, Takeda J.

<u>Reversal</u>	TOFR < 0.9	
None	13.0%	(2.8%-33.6%)
Neostigmine	23.9%	(16.2%-33.0%)
Sugammadex	4.3%	(1.7%-9.4%)

RESEARCH ARTICLE

Open Access

Usefulness of intra-operative neuromuscular blockade monitoring and reversal agents for postoperative residual neuromuscular blockade: a retrospective observational study



Gonzalo Domenech¹** Marías A. Kampel¹, María E. García Guzzo¹, Delfina Sánchez Novas¹, Sergio A. Terrasa² and Gustavo García Fornari¹

RNMB was present in 1.6% patients who received intra-operative quantitative NMB monitoring and 32% patients whose NMB was not monitored (P < 0.01).

Facial vs Ulnar Nerve

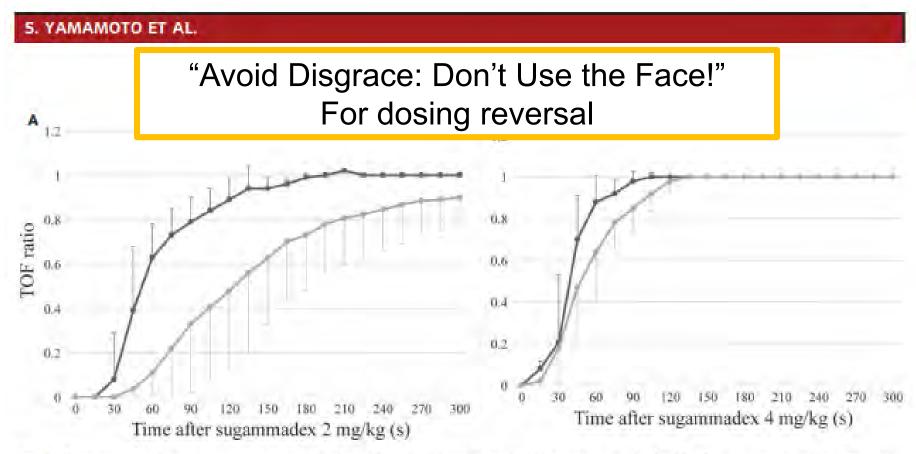
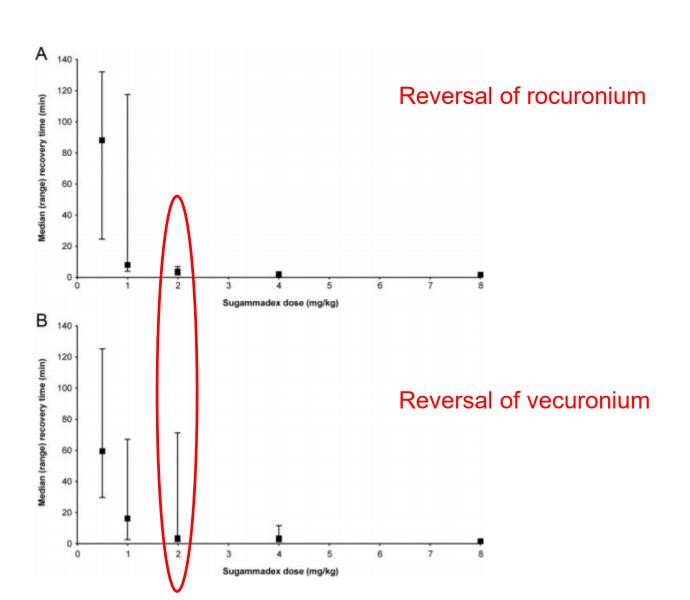


Fig. 2. Time course of facilitated recovery after a bolus of 2 mg/kg (A) and 4 mg/kg (B) sugammadex in the 20–60 y age group. A black line and a gray line show the response of the corrugator supercilii muscle and adductor policis muscle, respectively. Data are shown as mean and SD.

Rocuronium vs Vecuronium



Duvaldestin. Anesth Analg 2010;110:74-82

Sugammadex at EUH

- Added to formulary
- Established provider and patient education

Sugammadex (BRIDION) 100mg/ml: Key Information (3/2016) AVAILABLE FORMS 2ml vial (200mg/2ml) 5ml vial (500mg/5ml) Reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery Known hypersensitivity to sugammadex or any of its components Not recommended in patients with severe renal impairment (CrCl<30) or on dialysis · Not effective for reversal of non-steroidal neuromuscular blocking agents (cistatracurium, . Not approved for reversal of paralytics other than rocuronium and vecuronium Safety and effectiveness not established in patients ≤ 17 years of age (off-label use) . Dose and timing of sugammadex administration should be based on monitoring of twitch responses at the ulnar nerve. Dosing is based on actual body weight Train of four Post-tetanic count response at ulnar minutes after nerve =1-2 curonium 1.2mg/kg 16mg/kg Sugammadex dose 4mg/kg 2mg/kg Median time to full 2.7 1.4 rocuronium (range 0.9-5.4) (range 1.2 - 10.6) (range 1.2-16.1) 2.1 vecuronium ADMINISTRATION · Administer intravenously as a single bolus injection; injection may be given over 10 seconds into an existing intravenous line · Compatible with standard IV fluids including those containing dextrose · Physically incompatible with verapamil, ondansetron, and ranitidine (Do not mix sugammadex with these drugs) Anaphylaxis: Anaphylaxis has occurred in 0.3% of healthy volunteers (usually within 5 minutes) Cases of marked bradycardia have been observed within minutes after administration Monitor patient closely for at least 5 minutes after administration substitute for complete medication information. All content is for general information purposes only. The authors sense for complete inequation internations, or content is to general information purposes only. The authors ume no responsibility for, and make no guarantee regarding the accuracy of this information. You are encouraged onfirm any information provided here by referring to other, more complete and authoritative sources.

Emory Healthcare Department of Anesthesialogy: Information for Women Undergoing Anesthesia

Are you using hormonal birth control?

The following forms of hormonal birth control may be affected by medications used during anesthesia:

- . Oral contraceptive pills (also called OCP's, "the pill," or birth control pills)
- Birth control patch (also called a contraceptive patch or Ortho-Evra)
- · Vaginal contraceptive ring (NuvaRing)
- · Hormonal implants (Implanon or Nexplanon)

If you are using any of the methods of hormonal birth control listed above, some medications used during anesthesia could interfere with your birth control, making it less effective for preventing pregnancy:

- Aprepitant (Emend) is a medication that may be used to prevent nausea and vomiting.
- Sugammadex (<u>Bridion</u>) is a medication that may be used to reverse the effects of muscle relaxant medications used during anesthesia.

If you are given either of these two medications during anesthesia, you will need to use a second, non-hormonal method of birth control (such as condoms) as back-up for up to one month:

- · Second birth control method is required for 1 month after aprepitant
- · Second birth control method is required for 7 days after sugammadex

TELL your anesthesiologist if you are using hormonal birth control.

ASK your anesthesiologist if you have questions about effects on your birth control. We're happy to answer your questions.

NOTE: Hormonal injections (Depo-Provera, DMPA or <u>Lunelle</u>) and intrauterine devices (IUD's) are *not* likely to be affected by anesthesia medications. Other medications may interfere with hormonal birth control. Ask your healthcare provider if you have any questions about medications you are currently taking or may begin taking if you have concerns about their potential impact on your birth control.

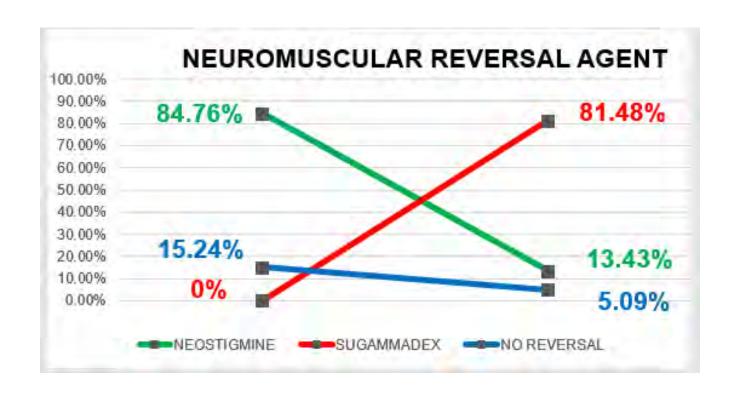
(3)

emoryhealthcare.org



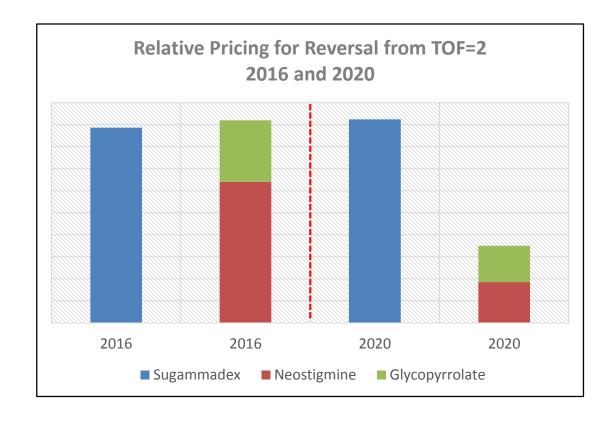
Sugammadex at EUH

- Available without restriction
- Reversal agent of choice



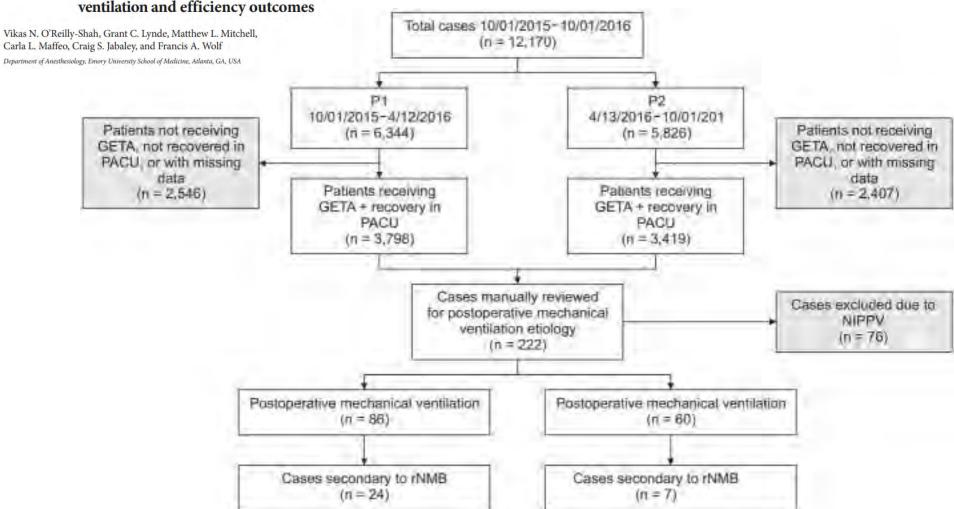
Sugammadex at EUH

- Available without restriction
- Reversal agent of choice
- Cost concerns





Initial experience with the unrestricted introduction of sugammadex at a large academic medical center: a retrospective observational study examining postoperative mechanical ventilation and efficiency outcomes



Early Signs of Reduced Mechanical Ventilation in the PACU

Table 2. Rates and Causes of Post-anesthesia Care Unit Mechanical Ventilation before (P1) and after (P2) the Introduction of Sugammadex into Clinical Care

Cause of PACU mechanical ventilation	Total	Pre (PI)	Post (P2)	Odds ratio of PACU mechanical ventilation in the post-introduction era versus the pre-introduction era (95% CI)	P value
Did not plan to extubate	32 (21.9%)	19 (22.1%)	13 (21.7%)	0.772 (0.373-1.551)	0.469
Hemodynamic	18 (12.3%)	6 (7.0%)	12 (20.0%)	2.030 (0.807-5.616)	0.134
Iatrogenic	16 (11.0%)	11 (12.8%)	5 (8.3%)	0.546 (0.182-1.451)	0.230
Neurological	18 (12.3%)	11 (12.8%)	7 (11.7%)	0.792 (0.297-1.992)	0.622
Respiratory	31 (21.2%)	15 (17.4%)	16 (26.7%)	1.124 (0.557-2.282)	0.108
rNMB	31 (21.2%)	24 (27.9%)	7 (11.7%)	0.339 (0.139-0.736)	0.005
All except rNMB	115 (78.8%)	62 (72.1%)	53 (88.3%)	0.938 (0.645-1.358)	0.733
All causes	146	86	60	0.767 (0.547-1.069)	0.118

Values are expressed as number (%). PACU: post-anesthesia care unit, rNMB: residual neuromuscular blockade. P values were derived by performing multiple variable logistic regression as described.

Sugammadex – Potential Benefits

- Reversal from deep and even profound blockade
- Faster, more reliable reversal
- Low rates of rNMB (~1-2%)
- Shorter PACU LOS
- Shorter time to extubation

Sugammadex Limitations

Areas of potential concern:

- Cases of bradycardia
- Only for use with rocuronium>vecuronium
- "Not recommended" in renal impairment (CrCl<30 or on dialysis)
- Prolongation of PTT/PT (effect on the lab assay)
- Decreased effectiveness of hormonal contraception?
 - Provide Preop Information and Discharge Instructions
- Hypersensitivity risks
- Cost

What is the Role of *Quantitative* Monitoring if We Have Sugammadex?

- Withhold reversal if spontaneous recovery is complete
- Increase use of neostigmine (e.g. patients with TOF3 or more)
- Reversal from very deep block (PTC=0)
- Assess suspected rNMB in OR and PACU
- Adjust dosing in obese patients?
- Precision dosing for rocuronium vs vecuronium at different levels of block

Summary

- Residual NMB is common after extubation when neostigmine is used for reversal
- Residual NMB can cause patient harm
- Use of quantitative monitoring can reduce rNMB
 - We should routinely use quantitative monitors of NMB when relying on neostigmine
- Sugammadex can reduce rNMB
 - When dosed correctly based on twitch assessment at the ulnar nerve
- If we employ quantitative monitoring combined with our available reversal agents we should be able to fully eliminate rNMB



Thank you



Michelle Au, MD, MPH

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Board-Certified Physician Anesthesiologist and professional writer. Fifteen years of front-line clinical experience and a strong interest in public health. Looking to expand my career into including more writing and public service, applying my deep knowledge and experience of the field into new challenges in narrative non-fiction, healthcare communication, and health policy.

PROFESSIONAL EXPERIENCE

PHYSICIAN SPECIALISTS IN ANESTHESIA, Emory-St. Joseph's Hospital, Atlanta, GA Attending Anesthesiologist, August 2008 – Present

- Diplomate of the American Board of Anesthesiology (2010)
- Direct management of patient care and supervision of a team of 75+ midlevel providers in the perioperative environment at a high-acuity tertiary care community affiliate of Emory University Hospital.
- Clinical Day Director in charge of OR scheduling, personnel and management, surgeon and nursing outreach, and daily hospital operations.
- Work environment included clinical management the operating rooms, intensive care units, endoscopy suites, radiology suites, the emergency department, and the preoperative testing clinic.
- 50-60 clinical hours a week while full-time, 30-40 hours a week part-time (since 2014)
- Expertise in major vascular and regional anesthesia, with expertise in ultrasound-guided peripheral nerve blockade
- Lead physician, physician mentorship team, charged with mentoring colleagues about interpersonal communication, teamwork skills, and effective group management technique
- Deep academic knowledge of the history and biologic effects of pharmacologic agents, with an interest in pain management and strategies for attenuating the national opioid epidemic

Professional memberships: American Society of Anesthesiology, Georgia Society of Anesthesiology, Medical Association of Georgia (Georgia Physicians Leadership Academy Class XII)

EDUCATION

COLUMBIA UNIVERSITY MAILMAN SCHOOL OF PUBLIC HEALTH New York, NY

Master of Public Health with focus in Healthcare Administration, August 2017-August 2019

- Graduation class speaker
- Led team to help build a community health center in rural Humacao, Puerto Rico at the Centro de Transformación Comunitaria in the aftermath of Hurricane Maria. Solicited donations, performed home health visits to assess community needs.

COLUMBIA UNIVERSITY MEDICAL CENTER, DEPARTMENT OF ANESTHESIOLOGY New York, NY

Post-Doctoral Residency Fellow, July 2005-June 2008

- Resident Education Committee
- Medical Student Curriculum Committee

COLUMBIA UNIVERSITY MEDICAL CENTER, DEPARTMENT OF PEDIATRICS New York. NY

Post-Doctoral Residency Fellow, July 2003-June 2005

COLUMBIA UNIVERSITY COLLEGE OF PHYSICIANS AND SURGEONS New York. NY

Doctor of Medicine, August 1999-May 2003

- **Awards:** Fellow of the Gold Humanism Honor Society, inducted May 2003, "In recognition of demonstrated clinical excellence, integrity, exemplary devotion to the service of others, and compassionate and respectful relationships with patients, families, and colleagues."
- **Clerkship Honors:** Pediatrics, Medicine, Neurology, Neurosurgery, Psychiatry
- Preclinical Honors: Psychiatric Medicine I and II, Endocrinology, Neuropathology
- Licensed to practice medicine in New York and Georgia

WELLESLEY COLLEGE

Wellesley, MA

BA Psychobiology, August 1995-May 1999

- Magna cum laude
- **Sherman Fairchild Foundation Research Grant** for work in Behavioral Neuroscience with Joanne Berger-Sweeney, Ph.D., studying the effect of neonatal monoaminergic depletion on the performance of learning and memory tasks in adult mice (1998-1999)
- **Beth Israel Deaconess Medical Center, Boston, MA,** Research Assistant, Institute for the Prevention of Cardiac Disease (1996)

LEADERSHIP

MEDICAL ASSOCIATION OF GEORGIA - GEORGIA PHYSICIANS LEADERSHIP ACADEMY

- Nominated by the Georgia Society of Anesthesiologists
- Focus on opioid epidemic risk mitigation in perioperative pain management

PUBLICATIONS

THIS WON'T HURT A BIT (AND OTHER WHITE LIES), Grand Central Publishing, 2011

- "An account of medicine, marriage and motherhood, executed with style and enough humor to offset the not-always-happy endings for patients...An upbeat memoir by a woman still imbued with the idealism to serve, but also to be there for her husband and two sons." (Kirkus Reviews)
- Editor: Grand Central Publishing, Hachette Book Group
- Agent: Sharon Bowers, The Miller Agency, NY

"One Flew Over,"

Wellesley Magazine, Endnote [publication date pending]

"Your Smartwatch: High-tech Health Tracker or Talisman?"

Emory Medicine Magazine, Spring 2019

"There's a Proven Public Health Strategy We Could Use to Encourage Vaccination" Slate, March 8, 2019

"Smartwatches Are Changing the Purpose of the EKG"

The Atlantic, February 7, 2019

"Humanely Told Stories of Lives Saved and Lost"

The Boston Globe, March 21, 2018

Arnold P. Gold Foundation, "The Big Picture"

Featured essay, July 11, 2001

PUBLIC SPEAKING

- Keynote speaker, Resident House of Delegates, American Society of Anesthesiology Annual Meeting (2019)
- Graduation speaker, Columbia University Mailman School of Public Health (2019)
- Visiting Professorship University of Florida, Jacksonville, Grand Rounds featured speaker (2017)
- Commencement address, Louisiana State University at Shreveport Health Sciences Center (2016)
- Commencement address, Wright State Boonshoft School of Medicine (2013)
- 2012: UC Davis School of Medicine, Wellesley College Hippocratic Society Annual Lecture (keynote speaker), 36th Annual Conference of the American Academy of Anesthesiologist Assistants (AAAA), South Carolina Medical Association annual meeting (keynote speaker)
- 2011: Iowa Writer's Workshop, Prairie Lights Bookstore, Atlanta History Center, Harvard Coop, Penn Book Center, Columbia University, <u>Georgia Society of the American College</u> <u>of Surgeons</u> Annual Meeting, Johns Hopkins University AMSA "Empowering Future Physicians" Conference, AJC Decatur Book Festival

RESEARCH

INWOOD HOUSE, New York, NY

- Development and implementation of a health education program assessing the effect of a smoking cessation initiative at a residential home for pregnant teenagers.
- Presented at the **Soros Service Program for Community Health (SSPCH) Research Symposium** on August 3, 2000

PERSONAL

Married to Joseph Walrath M.D., an oculoplastic surgeon in Atlanta GA. Mother of three. Strong medical Spanish, fluent in Cantonese.

Curriculum Vitae

Of

Matthew T. Popovich, Ph.D.

312-513-4948 (m) ● <u>mtpopovich@gmail.com</u> https://www.linkedin.com/in/matthewpopovich/

Work Experience

Director of Quality and Regulatory Affairs, American Society of Anesthesiologists November 2014 – Present Washington, DC

Quality Specialist, American Society of Anesthesiologists

May 2013 – November 2014 Washington, DC

Accreditation Consultant, National Association of Boards of Pharmacy

January 2012 – May 2013 Mt Prospect, IL

Pharmacy Quality and Safety Accreditation Manager, National Association of Boards of Pharmacy

June 2010 – August 2011

Mt Prospect, IL

Research Consultant, National Association of Boards of Pharmacy

February 2010 – June 2010

Mt Prospect, IL

Teaching Assistant and PhD Candidate, University of Illinois at Chicago – Department of History

August 2002 – August 2009

Chicago, IL

Graduate Archivist, University of Illinois at Chicago - Daley Library/Special Collections

January 2009 – August 2009, May 2005 - August 2005, February 2004 - August 2004 Chicago, IL

Education

Doctor of Philosophy (August 2009)

University of Illinois at Chicago – Department of History (Chicago, IL)

Dissertation: Boundaries of Progress: The Politics of Urban Annexation and Anti-Annexation,

1870-1930 (Defended July 2009)

Committee: Perry Duis, Ann Keating, Richard John, Leon Fink, Robert Johnston

Master of Arts (August 2004)

University of Illinois at Chicago – Department of History (Chicago, IL)

Bachelor of Arts (December 2001)

Purdue University, West Lafayette – Political Science and History

Non-Peer Reviewed Publications

- 1. Goldman, JM; Killoran, PV; Popovich, MT. "Federal initiatives to Improve Patient Safety through the Interoperability of Medical Devices, Data and Platforms Taking Shape." *ASA Monitor*. 11 2019; Vol.83, 54-56.
- 2. Rebello, E; Connolly, L; Hein, HAT; Popovich, MT. "Long-awaited United States Pharmacopeia (USP) General Chapter <797> Revisions Explained: The One-Hour Rule will No Longer be in Effect." *ASA Monitor*. 9 2019; Vol. 83, 70-71.
- 3. Dietrich, CC; Cammarata, BJ; Giordano, CR; Popovich, MT. "ASA Engagement with AORN Results in Surgical Attire Burden Reduction." *ASA Monitor*. 5 2019; Vol.83, 44-46.
- 4. Rebello, E; Connolly, LA; Popovich, MT. "Do No Harm: Finding Consensus on Medication Concentration Standardization." *ASA Monitor*. 03 2019; Vol.83, 18-19.
- 5. Connolly, LA; Popovich, MT; Quill, E. "Supporting ASA Members with Quality Management & Departmental Administration Initiatives." *ASA Monitor*. 03 2019; Vol.83, 12-13.

Book Chapters

Schmitz, D; Popovich, MT. "Quality Reporting: Understanding National Priorities, Identifying Local Applicability" in *Practice Management: Successfully Guiding Your Group into the Future*. Editors Stead, Stanley and Abouleish, Amr. *Anesthesiology Clin* 36 (2018) 201–216.

Presentations

- 1. Popovich, Matthew T. *Lifecycle of a Performance Measure*. ANESTHESIOLOGY 2019. Orlando. 22 October 2019.
- 2. Popovich, Matthew T. and Sharon K. Merrick. *MACRA & Regulatory Update* American Society of Anesthesiologists Practice Management 2019. Las Vegas. 19 January 2019.
- 3. Popovich, Matthew T. *Measuring Quality Data & Reporting*. American Society of Anesthesiologists Practice Management 2019. Las Vegas. 18 January 2019.

Expert Panels

- 1. National Quality Forum. Acute Pain Management Strategy Session. Washington, DC. 2 February 2017.
- 2. National Quality Forum. Measure IncubatorTM Strategy Session: Appropriate Pain Management. Washington, DC. 28 February 1 March, 2018.

Professional Workshops

1. Quality Reporting and Registries: Building Anesthesiology's Future. American Society of Anesthesiologists Anesthesiology Quality Meeting Pre-Conference. Schaumburg, IL. 15 November 2019.

Honors and Awards

March 2002 Phi Beta Kappa

Purdue University

Last Updated: December 28, 2019

GSA 2020 SUMMER MEETING











JULY 17-19

The Ritz Carlton Lodge at Lake Oconee Greensboro, GA