SOCIETY FOR AMBULATORY ANESTHESIA

Outpatient • Office Based • Non-Operating Room

SAMBA 2022 ASC MEDICAL DIRECTORS & LEADERS VIRTUAL SUMMIT

SATURDAY, JANUARY 22, 2022

SYLLABUS

Jointly Provided by the American Society of Anesthesiologists (ASA) and the Society for Ambulatory Anesthesia (SAMBA).

Phone: (414) 488-3915 • Email: info@sambahq.org • www.SAMBAhq.org

PROGRAM INFORMATION

Target Audience
This meeting is designed for anesthesiologists, anesthesia providers, practitioners, nurses and administrators who work and specialize in ambulatory, office-based or non-operating room anesthesia.

About This Meeting
The purpose of this meeting is to educate and share information that is tailored to physicians, AHPs, Medical Directors, and Administrative staff who practice in Ambulatory Surgery Centers. Opportunities for questions and answers will be provided at the conclusion of each panel.

Registration
Registration for the 2022 ASC Medical Directors & Leaders Virtual Summit includes access to all sessions and the program syllabus. Note that all fees are quoted in U.S. currency. Registration for the meeting is available to members and non-members via SAMBA's website at www.sambahq.org.

Disclaimer
The information provided at this accredited 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.

Accreditation and Designation Statements
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 Society for Ambulatory Anesthesia (SAMBA).

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 4.50 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Commercial Support Acknowledgement
The CME activity is not supported by any educational grants from ineligible companies.

Special Needs
The Society for Ambulatory Anesthesia (SAMBA) fully complies with the legal requirements of the Americans with Disabilities Act and the rules and regulations thereof. If any attendee in this educational activity is in need of accommodations, please contact the SAMBA Executive Office at 414-488-3915.

Cancellation Policy
Cancellations received through January 15, 2022, will receive a full refund. Cancellation of a meeting registration must be submitted in writing. Refunds will be determined by date written cancellation is received at the SAMBA office in Milwaukee, WI.

OVERALL LEARNING OBJECTIVES

At the conclusion of this activity, participants should be able to:

- Discuss current clinical topics affecting outpatient care in ASCs during and post the COVID-19 pandemic.
- Discuss relevant administrative topics currently phased by medical directors in ASCs.
- Describe the current status of the ASC industry and market.
- Discuss compliance and legal risks faced by ASC medical directors.

PROGRAM SCHEDULE *(All Times Listed are in Eastern Time)*

Saturday, January 22, 2021

Moderated by: Arnaldo Valedon, MD, SAMBA-F & Leopoldo V. Rodriguez, MD, MBA, FAAP, FASA, SAMBA-F

10:00am - 10:30am
Welcome and Introductions
Leopoldo V. Rodriguez, MD, MBA, FAAP, FASA, SAMBA-F & Arnaldo Valedon, MD, SAMBA-F

10:30am – 11:00am
Duties of a Medical Director
Niraja Rajan, MD, FAAP, SAMBA-F

11:00am – 11:30am
Controlled Substances Diversion – is Your ASC at Risk?
Lea Schilit, MS, PharmD, CPh, RD

11:30am -12:00pm
Medical Cannabis: HR Updates and Liability
Salvatore Puccio, Esq

12:00pm – 12:30pm
Break

12:30pm – 1:00pm
Pediatric Outpatient Anesthesia: Current Issues
Rosalie F. Tassone, MD, MPH

1:00pm – 1:30pm
How to build a successful total joint program in your ASC
Rena M. Courtay, MBA, BSN, RN, CASC, CPPM, CNOR(e)

1:30pm – 2:00pm
Obesity in Outpatient Surgery
Stanford R. Plavin, MD

2:00pm – 2:30pm
CMS and Accreditation Updates
Cheryl Pistone, RN, BSN, MA, MBA & Tess Poland, RN, MSN

2:30pm – 3:00pm
Status of the ASC Industry Update
William Prentice

3:00pm – 3:30pm
Review of 2022 Updates Pertinent for Ambulatory Anesthesiologists
BobbieJean Sweitzer, MD, FACP, SAMBA-F, FASA

PROGRAM PLANNING COMMITTEE

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WellSpan Health
Hanover, PA

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SAMBA Meetings Committee Chair
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Associate Chief Medical Officer, Children's Wisconsin Surgicenter
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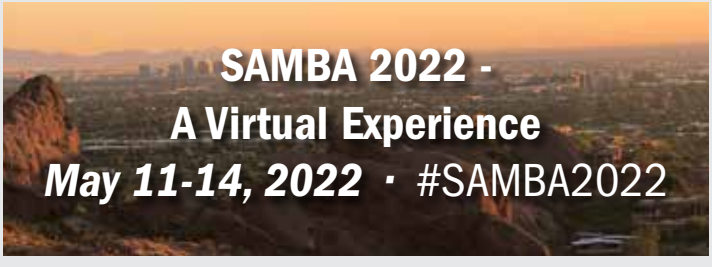
WellSpan Health
Hanover, PA

MARK YOUR CALENDAR AND BE SURE TO JOIN US AT FUTURE SAMBA MEETINGS!

Office-Based Anesthesia (OBA) Virtual Symposium
Saturday, March 19, 2022



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 accredited 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.

Disclosures
The following faculty, staff, and/or planning committee members have indicated that they have relevant financial relationships with commercial interests to disclose:

Name	Type of Relationship	Company
Leopoldo Rodriguez, MD	Consultant	AcelRx Pharmaceuticals
Leopoldo Rodriguez, MD	Consultant	Acacia Foundation
Arnaldo Valedon, MD	Other	ARC Medical

All relevant financial relationships for this activity have been mitigated.
All other planners, faculty, and staff have disclosed no relevant financial relationships with commercial interests.

CME CLAIM

To claim credit for the 2022 SAMBA Medical Directors & Leaders Virtual Summit

All communication is sent to the email on your ASA account. Please log into your ASA account and update your email if it has changed.

Follow the directions below to complete the meeting evaluation and claim credits. It is strongly recommended this be done within two weeks after the activity as the evaluation data is provided to the Society for Education in Anesthesia to plan future meetings.

ACCESSING THE WEBPAGE

Click the link below and log in using the email on your ASA account and password.

https://education.asahq.org/course/view.php?id=4180

CAN'T REMEMBER YOUR PASSWORD?

You can retrieve or set a new password by entering your email address at: https://www.asahq.org/member-center/forgot-password

NO LONGER HAVE ACCESS TO THE EMAIL ON YOUR ACCOUNT?

Contact ASA Member Services at (630) 912-2552 or email info@asahq.org.

Office Hours: Monday through Friday, 7:30 a.m. to 4:30 p.m. CT. Do not create a duplicate account.

NEED AN ASA ID NUMBER?

You may already have an ASA ID number. When an individual purchases a product or registers for any activity offered or jointly provided by the ASA, a record is created in our system. Staff will send an email from jpmeetings@asahq.org to create a free account for those who do not have an ASA ID number. This will allow access to the course page to complete an evaluation, claim credit, and print a certificate.

CLAIMING CREDIT

1. Complete the evaluation.
2. Click on the certificate, enter the credit you are claiming.
3. Print your certificate or save it as a PDF for your files.

If you experience difficulties logging in, don't hesitate to contact jpmeetings@asahq.org, and we will be happy to assist you. Do not create a duplicate account.

The deadline for claiming credit for this live activity is Dec. 31, 2022, 11:59 p.m. CT.

HANDOUTS

Duties of a Medical Director

Niraja Rajan, MD, FAAP, SAMBA-F

01/22/2022
10:30am – 11:00am Eastern

ASC Medical Directors & Leaders Virtual Summit
Saturday, January 22, 2022

Role of Medical Director in ASCs

Niraja Rajan MD
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nrajan@pennstatehealth.psu.edu

1

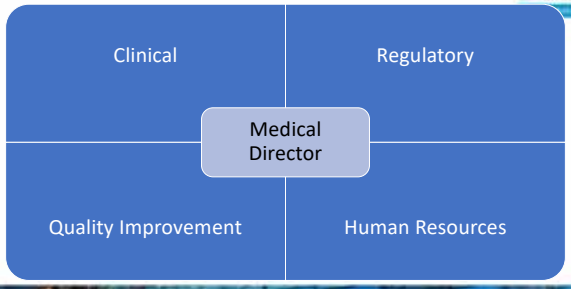
- I have no conflicts of interest

2

Objectives

- 1. Define the role of the Medical Director
- 2. Enumerate ways in which a Medical Director can enhance patient safety
- 3. Describe the medicolegal aspects of being a Medical Director

3



4

Clinical

- Scheduling
- Patient selection and screening
- Guidelines and best practices
- Infection control
- Patient safety

5

Regulatory

- Preparing for surveys/site visits
- Policy review and updates
- Protocol development
- Annual review of policies and procedures
- Maintaining compliance
- Pharmacy
- Laboratory

6

Surprise Medical Billing

- Good Faith Estimate
- Independent dispute resolution (IDR) process
- Patient-provider dispute resolution process
- Expanded rights to external review

7

Good Faith Estimate

- Prominently displayed
- Provided to patients upon request
- Includes charges for the primary service
- Also includes charges for services provided by other facilities or providers.
- Within one business day after scheduling when the primary item or service is scheduled at least three business days in advance or no later than three business days after scheduling when the primary item or service is scheduled at least 10 business days in advance; or
- Within three business days after an uninsured or self-pay consumer who has not yet scheduled requests a good faith estimate.

8

IDR process

- If the total billed charge(s) for a particular provider or facility is at least $400 higher than the combined good faith estimates of charges for that provider or facility.
- Within 120 calendar days of receiving the bill.
- Reviewed by a Selected Dispute Resolution (SDR) entity contracted with HHS

9

Quality Improvement

- Initiate QI projects
- Culture of safety
- Training and education of staff
- Conduct patient safety/infection control/QI meetings
- Reporting

10

Maintaining a Culture of Safety

- Conduct Patient Safety Leadership rounds
- Create a Reporting System
- Designate Patient Safety Officers
- Reenact Real Adverse Events from Your Hospital
- Train with simulated adverse events
- Involve Patients in Safety Initiatives
- Relay Safety Reports at Shift Changes
- Appoint a Safety Champion for Every Unit
- Create an Adverse Event Response Team

11

Human Resources

- Credentialing
- Privileging
- Staff competence evaluation and feedback
- Peer review
- Liaising and communication

12

Medical Director Arrangements: Fraud Alert

- The payments do not reflect fair market value for the medical director services to be performed
- The payments took into account the physicians' volume or value of referrals
- The physicians did not actually provide the services called for under the agreements.

13

Medical Director Agreement: Safe Harbor

- Agreement is set out in writing and signed by the parties.
- Agreement covers all services provided to the Center for the term of the agreement and specifies the services to be provided by the Medical Director.
- For periodic or part-time services, the agreement specifies exactly the schedule of such services, their precise length, and the exact charge.
- The term of the agreement is for not less than one year.
- The aggregate compensation is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.
- The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.
- The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

14

Vignettes

- While you are reviewing infection reports for the quarter you notice that all infections are from the same surgeon.
- A high volume urology surgeon at your ASC arrives 40 minutes late consistently on his OR days.
- While reviewing patient satisfaction surveys you notice a trend of patients complaining about long wait times for their procedure.
- A surgeon refuses to comply with the time-out process at your center.

15

Maintain neutrality

- Conflict is not bad
- Conflict is not good
- Conflict just "is what it is"
- Conflict is inevitable in any relationship or set of relationships
- Learn to embrace conflict in order to use it constructively

16

EASY: to engage

- Elicit information –"Tell me more", "Go on."
- Ask questions –"What led you to that conclusion?", "How do you feel about that now?"
- State the obvious –"Let me see if I have this right. You are saying . . ."
- You may be wrong in your interpretation –What seems obvious to you may not be the intended message.

17

Providing feedback

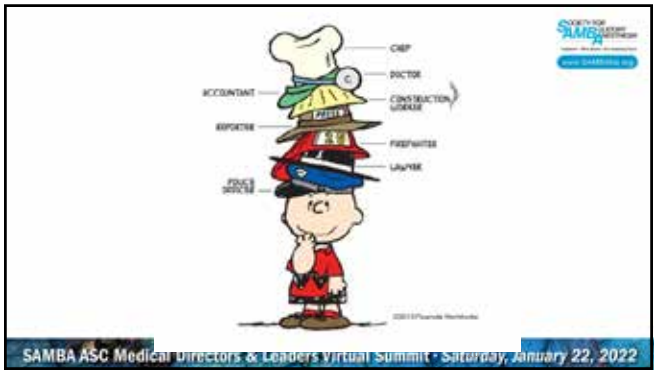
- Ask open ended questions
- Avoid asking why
- Remain solution focused
- It's not about being "right" –it's about behavioral change
- Be willing to negotiate

18

Expect the Distracting D's"

- Denial
- Dismissal
- Defensiveness
- Diminishment
- Disengagement

19



20

21

22

23

HANDOUTS

Controlled Substances Diversion- Is Your ASC at Risk?

Lea Schilit, MS, PharmD, CPh, RD

01/22/2022
11:00-11:30am Eastern

ASC Medical Directors & Leaders Virtual Summit
Saturday, January 22, 2022

Controlled Substances Diversion: Is Your ASC at Risk?

Lea Schilit, MS, PharmD, CPh, RD
Assistant Vice President
Clinical Pharmacy Services
HCA Ambulatory Surgery Division, Eastern Region

1

Learning Objectives

- Discuss rates of abuse in healthcare professionals and list examples of the most commonly diverted controlled substances. Recognize opportunities to divert in the ambulatory surgery setting and how diversion occurs
- Explain financial implications related to diversions and recent settlements
- Propose strategies for diversion prevention in your surgery setting
- Apply real diversion cases to help prevent or recognize diversion in your surgery center

2

Disclosures

Disclosure statement: the following individual has the following to disclose concerning possible financial or personal relationships with commercial entities (or their competitors) that may be referenced in this presentation.

- I have nothing to disclose

–Lea Schilit, PharmD, MS, CPh, RD, LD/N has nothing to disclose

3

Where are We At? What are the Current Statistics?

- ~841,000 people have died since 1999 from drug overdoses
- 100,306 overdose deaths from May 2020 to April 2021
  - 275 per day or 11 per hour
  - 28.5% increase since 2019 (78,056)

CDC Understanding the Epidemic
CDC Drug Overdose Deaths

4

COVID-19 and Overdose Deaths

- Synthetic opioids (fentanyl and primarily illicitly manufactured fentanyl), and methamphetamines primary driver of the increases in overdose deaths
- 78,056 overdose deaths in the U.S. from May 2020 to April 2021 due to opioids
  - Accounted for 75% of the total overdose deaths
- Most recorded overdose deaths in one year ever
  - 3x that of traffic accidents deaths and 2x that of gun deaths in same time period

CDC Overdose Deaths Accelerating During COVID-19
CDC Save Lives Now. Overdose Deaths have increased during COVID-19
Harvard School of Public Health. Drug Overdose Deaths hit record high.

5

Substance Abuse by Healthcare Professionals

- It is estimated that 10-15% of healthcare professionals will misuse drugs at some point in their career
- Higher rates of prescription drug use than the general public
  - Greater access to controlled substances
  - Tend to use drugs readily available in practice setting

Cohn MR, et al. *Hosp Pharm.* 2016.
Baldisseri MR. *Crit Care Med.* 2007.

6

Anesthesiologist Statistics

- Rate of substance abuse disorder for physicians ~10-14%
- Rate is 2.7 times greater for anesthesiologists than any other physician specialty
- 62% of anesthesia residency program directors report at least 1 resident with a substance abuse problem

Minn Med. 2010 Feb; 93(2): 46-9.
BJA Education. 2016 July; 16(7): 236-41.
Cohen MR, et al. *Hosp Pharm.* 2016.
Baldisseri MR. *Crit Care Med.* 2007.

7

Anesthesiologist Statistics

- Recovery rate: 74-90%; most return to practice (many in another specialty)
- It is estimated that "more than 400 drug-addicted anesthesiologists and residents may be working in operating rooms at this moment"

8

Certified Registered Nurse Anesthetist (CRNA) Statistics

- 1 of 10 practicing CRNAs are likely to misuse controlled drugs
  - Similar to rate of general public
- ~64% report poly-drug abuse

AANA Journal. 1999 April; 67(2): 133-40.
Substance Use Disorder in Nursing. NCSBN. 2011.

9

HOW EASY ARE WE MAKING IT?

10

11

12

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13

What is Wrong Here?

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14

Drugs of Choice

- December 2018, CDC reported that fentanyl had surpassed heroin as the drug most frequently associated with overdose deaths in the United States
  - 2011: Oxycodone
  - 2012-2015: Heroin
- Rate of drug overdose deaths related to fentanyl doubled each year from 2011-2016

Warnsley, L. NPR. Dec. 2018.

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15

Drugs of Choice: 2020 Diversion Data

- 82% of diversion events included one type of opioid
- Most common diverted controlled substances:
  - Oxycodone
  - Fentanyl
  - Hydrocodone

Drug Diversion Digest 2021

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16

Gaps in the Surgical Process

- Limited technology/automation
  - Electronic health records
  - Automated dispensing machines
  - Barcode medication administration
- Predominately paper charting
- Manual auditing
- Quick turn-over, fast-paced environment
- Controlled substances immediately available
- ↑↑↑ Narcotic waste and reconciliation process
- Contracted and, often, inconsistent staff

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17

Common Methods of Diversion

- Diverting pharmaceutical waste
- Inconspicuously switching out syringes or filling vials with saline or another substance
- Diluting medications
- Diversion from patients
- Blatant theft
- Falsification of documentation for medication administration

American Association of Nurse Anesthetists. Addressing Substance Use Disorder for Anesthesia Processionals. 2016.

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18

19

20

UTSW DEA Settlement

- On Dec. 15, 2016, a UTSW nurse overdosed on fentanyl diverted from UTSW's Clements University Hospital and was found deceased in a hospital bathroom
- 16 months later, on April 16, 2018, another nurse overdosed on diverted opioids, including fentanyl, and was found deceased in a different Clements Hospital bathroom
- Prompted a 3 year DEA and U.S. Attorney's Office investigation of UTSW's handling of controlled substances

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21

UTSW DEA Settlement

- Violated Controlled Substance Act (CSA) over a five-year period
- Failure to maintain effective controls to consistently detect and monitor suspected diversion
- UTSW did report certain instances of theft and loss to the DEA, it did not do so in a timely manner

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22

UTSW Diversion Settlement

- Did not properly document the dispensing and "wasting" of controlled substances
- Made errors in forms documenting the ordering, receipt, and distribution of controlled substances
- Violated certain recordkeeping and reporting obligations which included monitoring all controlled substance activity within its facilities
- UT Southwestern to Pay $4.5 Million
  - University of Michigan case was $4.3 million
  - Effingham Health System was $4.1 million

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23

UTSW DEA Settlement

- 3 year agreement between the DEA and UTSW
  - External auditor to conduct unannounced audits
  - Training program designed to help employees identify symptoms of addiction and signs of diversion
  - Employee compliance hotline that permits anonymous reporting of suspected drug diversion or drug impairment

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24

UTSW DEA Settlement

- Security cameras installation
- Database of employees who have been discharged or resigned because of drug diversion, and disclosing relevant information to requesting health facilities conducting pre-employment inquiries
- Permit DEA personnel to enter UTSW facilities at any time, without prior notice and without a warrant, to verify compliance

25

How Do We Protect our Patients and Staff from Diversion?

26

Strategies for Diversion Prevention

- Multi-disciplinary, medication diversion team
- Technology and automation
- Investigating variations in practices
- Diversion risk rounds
- Monitoring for program compliance
- Reconciliation processes for returned/wasted medications
- Accountability, Duty to report

27

Strategies for Diversion Prevention

- Conducting Root Cause Analyses
- Identify and close gaps
- Coaching and corrective action
- Segregation of duties
- Ensure appropriate chain of custody
- Preparing for next diversion
- Anesthesia staff education
- Annual diversion education and open communication

28

This is Reality

Recent Diversion Cases

29

Is that a Syringe in Your Pocket?

- Suspicious behavior reported
  - RN would always volunteer to stay late hours and for closing shifts
  - Only wanted to work in recovery
  - Lunch breaks out of the building and often came back late
- One shift arrived very early and within 15 minutes of shift starting, seen walking into the locker room with a syringe of hydromorphone

30

Is that a Syringe in Your Pocket?

- RN said went to locker room to get a pen→ forgot syringe was in pocket
  - "I'm a little concerned that this is going to go against me, especially since I had issues at my old employment over a similar event"
- Syringe sent for analysis and RN sent to drug screen
- RN asked if any medications may show on screen- stated takes Norco and Tramadol for back pain
  - States taken for ten years, thinks told manager

31

Is that a Syringe in Your Pocket?

- RN locker searched:
  - 2 (10 mL) syringes labeled Normal Saline (one was still in wrapper one was not)— these were sent for analysis
  - 4 (3 mL) empty syringes
  - 30 and 25 gauge needles

32

Is that a Syringe in Your Pocket?

- RN searched and on them :
  - 3 (3 mL) empty syringes
  - 2 (10 mL) syringes (one was still in wrapper)
  - 2 (22 gauge) needles
  - 2 filter needles
  - 1 vial of 100mcg/ml fentanyl (empty)
  - 1 vial of 2mg/mL Dilaudid (empty)

Remember this RN had only started their shift 15 minutes prior

33

Is that a Syringe in Your Pocket?

- Syringe containing hydromorphone concentration came back at 0.35 mg/mL
- RN was taken for drug testing→ those results were never posted or received
- RN was ultimately terminated from employment for breach of policy. She was also reported to the Board of Nursing and an initial notification to the DEA was also sent

34

Water or Fentanyl?

- Endo center- medication sample sent for routine testing- administrator who had access → maternity leave
- Months later pharmacist obtains results= fentanyl 1mcg/mL
- CRNA denied diversion, Medical Director sure the CRNA isn't diverting
- CRNA taken to testing center for drug screen and during ride admits diverting for past year

35

Water or Fentanyl?

- CRNA would go into room before everyone, draw up 1mL and put in empty water bottle in the room
- Then from vial would pull 2nd mL to give to the patient, then pull back on line 1 mL to show as waste
- Per CRNA started to divert because nurses never watched when wasting being done

36

Do You Count Your Propofol?

- Freestanding endoscopy center , ~2,000 cases/month
- CRNA 2 was taking over cases and propofol vials from CRNA 1, Propofol chain of custody count performed
  - Expected 20 vials but counted 21 vials

37

Do You Count Your Propofol?

- CRNA 1 put "extra" propofol vial in his pocket
- Both CRNA 1 & CRNA 2 signed the kit record attesting that 20 vials of propofol were present
- Anesthesia leadership approached CRNA 1 while they were taking a break in their car

38

Do You Count Your Propofol?

- Asked where missing propofol vial was located
  - CRNA stated that when the propofol count exceeds what is expected, CRNA keeps the extra vial in their bag in the car so that could use it if the was ever "under"
  - CRNA then produced 2 propofol vials
- Ad Hoc MDT Held, CRNA 1 was terminated and CRNA 2 had disciplinary action, Both propofol vials sent off for analysis and identification

39

A Change in Practice

- Endoscopy center
- CRNA with recent abdominal surgery
- Procedure nurses report to manager
  - Question if patients receiving medication
  - Noticed CRNA started using fentanyl and propofol
- Recovery nurses- patients coming into recovery wide awake despite receiving above medications
- Report to Pharmacist → Head Anesthesiologist → Drug Screen

40

Questions to Ask

- How are our centers at risk for an events like these?
- Do we have issues with waste witness/documentation issues? How can we improve on that?
- Are there ways someone could easily divert at our centers?

41

Questions to Ask

- Are there vulnerable areas (narcotic boxes/carts/cabinet locks) that need to be replaced?
- Do we openly discuss risk for diversion at our center?
- Do we provide annual diversion education?
- Diversion Drills?

42

Questions?

Lea.Schilit@hcahealthcare.com

43

References

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44

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45

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46

HANDOUTS

Medical Cannabis: HR Updates and Liability

Salvatore Puccio, Esq

01/22/2022
11:30am – 12:00pm Eastern

GW GARFUNKEL WILD, P.C. ATTORNEYS AT LAW

Medical (and Recreational Cannabis): HR Updates and Liability

Presented By:
Salvatore Puccio, Esq.
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1

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• Health Care Information and Technology	• Discharge Planning, Patient Rights and Elder Law
• HIPAA Compliance	• Personal Services and Estate Planning
• Corporate Reorganization & Bankruptcy	• Tax

2

FEDERAL OVERVIEW

- Under the Federal Controlled Substances Act (CSA), Cannabis Continues To Be Listed As A Schedule I Controlled Substance.
- A Schedule I Controlled Substance Is One In Which The Drug Or Substance:
  - Has a high potential for abuse;
  - Has no currently accepted medical use in treatment in the United States; and
  - There is a lack of accepted safety for use of the drug or other substance under medical supervision.

3

FEDERAL CANNABIS ENFORCEMENT EFFORTS

- In 1970, Congress Studied cannabis.
- Study Concluded That cannabis was NOT a Schedule I substance.
- Nevertheless, cannabis remained a Controlled Substance.
- 2009 AG Memo Relaxes Enforcement. Do Not Interfere With State Legalization.
- 2018 Memo of AG Sessions Places More Focus on Illegal Use.
- However, No Crackdown Since And Federal Prosecutions Down By 20%.

4

STATE LEGALIZATION

- As States Continue To Legalize Medical and Recreational Cannabis, Employers are Faces With Difficult, New Employment Scenarios.
- State Law On The Subject Conflicts With Federal Law.
- It Is Crucial To Understand Both, And Follow State Law Where Indicated.

5

WHERE DOES THIS LEAVE US?

- Still Not Permissible To Show Up At Work Under The Influence.
- Gaps In Employment Law And How To Treat Off-Duty Cannabis Use.
- Effect and Meaning of Cannabis Testing.
- Previously, Without A Specific Law Or Precedent, Employers Could Take Adverse Action For Positive Tests. Now, However, More Careful Consideration Is Required.

6

COMMON QUESTIONS TO CONSIDER

- May Employees Use Cannabis Recreationally Or Medically Outside Of Work?
- Are You Allowed To Test For Cannabis On A Pre-employment Drug Test?
- Can You Refuse To Hire An Applicant Who Tests Positive For Cannabis?
- May A Rejected Applicant Who Tested Positive For Cannabis Sue You?
- Is Cannabis Legal When Used For Medical Purposes Under Federal Law?
- Do You Have To Allow An Employee Who Uses Cannabis For Medical Purposes To Be Under The Influence At Work?
- Do You Have To Allow Medical Cannabis Use As A Reasonable Accommodation Under The Ada Or Your State Disability Law?

7

NEW YORK LAW

- The MRTA Allows Adults Aged 21 And Older To Possess, Purchase, Display, Obtain, And Transport Cannabis In Limited Quantities. The MRTA Takes Effect Immediately, Although The Sale Of Recreational-use Cannabis Is Not Expected To Become Legal For At Least Another Year.
- MRTA Amends Section 201-d Of The NYLL To Include Cannabis. This Now Protects Employees Off-duty Use Of Cannabis.
- Employees Still Cannot Be Under The Influence At Work.
- Employees Who Claim That Their Rights Are Violated Under Section 201-d Of The Nyll May File A Private Lawsuit For Equitable Relief And Damages.

8

NEW YORK LAW (CONT.)

- There are some limited exceptions to New York's law protecting off-duty cannabis use:
  - The employer's actions were required by state or federal statute, regulation or ordinance, or other state or federal government mandate;
  - The employee is "impaired" by the use of cannabis; or
  - The employer's actions would require such employer to commit any act that would cause the employer to be in violation of federal law, or would result in the loss of a federal contract or federal funding.
- "Impaired" means that the "employee manifests specific articulable symptoms while working that decrease or lessen the employee's performance of the duties or tasks of the employee's job position, or such specific articulable symptoms interfere with an employer's obligation to provide a safe and healthy work place, free from recognized hazards, as required by state and federal occupational safety and health law."

9

WHAT ABOUT TESTING?

- New York City Already Prohibits Drug Testing For Job Applicants, Unless Necessary Under Federal or State Law. New Laws, However, May Further Restrict Even That Limitation.
- No New York State Law Specifically Precluding Testing, But Limitations On Adverse Actions.
- No New Jersey Limitations On Testing, But Same Potential Limitations.
- Connecticut Limitations, Including Related To New Legalization Laws.
- Generally, Testing Is Permitted In Case Of Potential On-Site Use or Accidents.

10

ENFORCEMENT OF CANNABIS USE

- Recognized Talent Shortages.
- Nursing Shortages.
- Competition In The Market.
- Maintaining Consistency. Equal Treatment.
- Drug Testing Safety v. Non-Safety Positions.
- Zero-Tolerance Policy Limited Only Where Impairment Interferes With Job Or Statute.

11

CASE EXAMPLES

Physician Tests Positive:

- Physician Offered A Job At Your Business. You Test Her/Him For Drugs, Positive For Cannabis.
- Physician Says He Legally Used CBD To Treat Medical Issue.
- What Do You Do?
- What If Test Comes Back For THC And Physician Says I Legally Used cannabis Off-Duty In Colorado, Where It Is Legal?
- What About Reporting To Medical Board?
- What If It Was A Front Desk Receptionist?

12

CASE EXAMPLES (CONT.)

Accident On-Duty:

- An Employee Operating Safety Equipment Has An Accident.
- Policy Requires Drug Testing.
- Employee Tests Positive For THC. But You Cannot Tell When It Was Used From Test. What Do You Do?
- What Questions Should You Ask?
- What If You Trust This Employee, But Another Employee Had a Similar Situation And You Want That Person Terminated?

13

BEST PRACTICES

- Keep Cannabis Out Of Office, Same With Alcohol.
- Research And Careful Selection Of Type Of Test You Use And Stay On Top Of Developments In The Technology Of Testing.
- Consult A Local Lawyer About Relevant State Laws Before Setting Policies And Testing Rules.
- Educate Employees About The Company cannabis-use Policy And The Repercussions For Failed Tests, Including Random, Post-accident Or Reasonable Suspicion Tests. Handbook Topic.
- Questionable On Whether To Train Managers To Spot Signs Of Impairment. Caution!

14

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QUESTIONS?

15

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16

HANDOUTS

Pediatric Outpatient Anesthesia: Current Issues

Rosalie F. Tassone, MD, MPH

01/22/2022
12:30-1:00pm Eastern

ASC Medical Directors & Leaders Virtual Summit
Saturday, January 22, 2022

Pediatric Outpatient Anesthesia: Current Issues

Rosalie F. Tassone, MD, MPH
Envision Physician Services
Palms West Hospital and Palms West Children's Hospital

1

Objectives

- Review the updated guidelines for pediatric patients undergoing tonsillectomy
- Present discussion perspectives regarding NPO guidelines in pediatric patients
- Refresh recommendations regarding neuromuscular blockade in pediatric patients

2

I have nothing to disclose

3

Introduction

4

Starting at the End

- Population based retrospective cohort
  - Patients <18 years of age
  - Ontario 2014-2018
  - 3 days post surgery
- 83,468 surgeries
  - 2588 (3.1%) ED visit
  - 608 (0.7%) hospital admission


Open access Original research
BMJ Paediatrics Open
Emergency department use and hospital admission in children following ambulatory surgery: a retrospective population-based cohort study

5

Starting at the End

- Majority of ED visits for
  - **pain** and **bleeding**
- Majority of hospital admissions for
  - **bleeding, dehydration, pain**
- Most common surgeries
  - Tonsillectomy and cholecystectomy

Sawhney M, VanDenKerkhof EG, Goldstein DH, Wei X, Pare G, Mayne I, Tranmer J. Emergency department use and hospital admission in children following ambulatory surgery: a retrospective population-based cohort study. BMJ Paediatr Open. 2021 Nov 23;5(1):e001188. doi: 10.1136/bmjpo-2021-001188. PMID: 34901470; PMCID: PMC8611446.

6

Predictors of Unanticipated Admission

Pediatric Anesthesia

Pediatric Anesthesia ISSN 1155-5645

RESEARCH REPORT

Predictors of unanticipated admission following ambulatory surgery in the pediatric population: a retrospective case–control study

Amanda Whippey, Gregory Kostandoff, Heung K. Ma, Ji Cheng, Lehana Thabane & James Paul

Department of Anesthesia, McMaster University, Hamilton, ON, Canada

What is already known

- The rate of unanticipated admission following adult ambulatory surgery is almost 2% and can be used as a marker of patient safety, quality of care, and to identify appropriate patients for ambulatory surgery.
- Little is known about the incidence of and potential risk factors for unanticipated admission in the pediatric population.

What this article adds

- The incidence of pediatric unanticipated admission is low (0.97%) but significant.
- Anesthesia-related causes accounted for the majority of admissions.
- Predictive factors include age, ASA 3 class, type, duration, and time to completion of surgery as well as presence of OSA.

7

Predictors of Unanticipated Admission

- Case control study of ambulatory patients requiring unanticipated admission between 2005 and 2013
- Incidence of unanticipated admission was 0.97%
  - 47% (98) was anesthesia related
  - Hypoxia, pain, PONV
- Factors associated with unanticipated admission
  - Age <2 years
  - ASA 3 class
  - duration of surgery >1 h
  - completion of surgery >3 pm
  - orthopedic, dental, ENT
  - Intraoperative events
  - OSA

Whippey A, Kostandoff G, Ma HK, Cheng J, Thabane L, Paul J. Predictors of unanticipated admission following ambulatory surgery in the pediatric population: a retrospective case-control study. Paediatr Anaesth. 2016 Aug;26(8):831-7. doi: 10.1111/pan.12937. Epub 2016 Jun 1. PMID: 27247224.

8

Case presentation

- 14-year-old girl presents for adenotonsillectomy
- 5' 3" 75 kg BMI 29
- sleep disordered breathing
- PMH for mild asthma
- Meds- albuterol prn, oral contraceptives
- Clear nasal discharge for past 1 day
- Younger brother at home just recovered from URI

9

Guidelines for Tonsillectomy

Guidelines Executive Summary

AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY FOUNDATION

Clinical Practice Guideline: Tonsillectomy in Children (Update)—Executive Summary

Otolaryngology–Head and Neck Surgery
2019, Vol. 160(2) 187–205

DOI: 10.1177/0194599818807917
http://otojournal.org
SAGE

Ron B. Mitchell, MD[1], Sanford M. Archer, MD[2], Stacey L. Ishman, MD, MPH[3], Richard M. Rosenfeld, MD, MPH, MBA[4], Sarah Coles, MD[5], Sandra A. Finestone, PsyD[6], Norman R. Friedman, MD[7], Terri Giordano, DNP[8], Douglas M. Hildrew, MD[9], Tae W. Kim, MD, MEHP[10], Robin M. Lloyd, MD[11], Sanjay R. Parikh, MD[12], Stanford T. Shulman, MD[13], David L. Walner, MD[14], Sandra A. Walsh[4], and Lorraine C. Nnacheta, MPH[15]

10

Guidelines for Tonsillectomy

5. Indications for polysomnography	Before performing tonsillectomy, the clinician should refer children with obstructive sleep-disordered breathing (oSDB) for polysomnography (PSG) if they are <2 years of age or if they exhibit any of the following: obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidoses.	Recommendation
9. Perioperative pain counseling	The clinician should counsel patients and caregivers regarding the importance of managing posttonsillectomy pain as part of the perioperative education process and should reinforce this counseling at the time of surgery with reminders about the need to anticipate, reassess, and adequately treat pain after surgery.	Recommendation
10. Perioperative antibiotics	Clinicians should not administer or prescribe perioperative antibiotics to children undergoing tonsillectomy.	Strong recommendation against
11. Intraoperative steroids	Clinicians should administer a single intraoperative dose of intravenous dexamethasone to children undergoing tonsillectomy	Strong recommendation
12. Inpatient monitoring for children after tonsillectomy	Clinicians should arrange for overnight, inpatient monitoring of children after tonsillectomy if they are <3 years old or have severe obstructive sleep apnea (OSA; apnea-hypopnea index [AHI] ≥10 obstructive events/hour, oxygen saturation nadir <80%, or both).	Recommendation
13. Postoperative ibuprofen and acetaminophen	Clinicians should recommend ibuprofen, acetaminophen, or both for pain control after tonsillectomy.	Strong recommendation
14. Postoperative codeine	Clinicians must not administer or prescribe codeine, or any medication containing codeine, after tonsillectomy in children younger than 12 years.	Strong recommendation against

Mitchell RB, Archer SM, Ishman SL, et al. Clinical Practice Guideline: Tonsillectomy in Children (Update)—Executive Summary. *Otolaryngology–Head and Neck Surgery*. 2019;160(2):187-205. doi: 10.1177/0194599818807917

11

Opioid sparing anesthetics

- Codeine no longer routinely used
- Patients often sensitive to narcotics
- More opioid sparing approaches in literature
  - Ketorolac, dexmedetomidine, ketamine
  - However, some intraoperative narcotic use
- Peritonsillar local anesthetic injection

1) Aldamluji, N., Burgess, A., Pogatzki-Zahn, E., Raeder, J., Beloeil, H. and (2021), PROSPECT guideline for tonsillectomy: systematic review and procedure-specific postoperative pain management recommendations. Anaesthesia, 76: 947-961. https://doi.org.ezproxy.fau.edu/10.1111/anae.15289
2) Franz, AM, Dahl, JP, Huang, H, et al. The development of an opioid sparing anesthesia protocol for pediatric ambulatory tonsillectomy and adenotonsillectomy surgery—A quality improvement project. *Pediatr Anesth*. 2019; 29: 682– 689. https://doi.org.ezproxy.fau.edu/10.1111/pan.13662

12

ERAS in Adenotonsillectomy

Received: 18 May 2020 | Revised: 20 September 2020 | Accepted: 27 September 2020
DOI: 10.1111/coa.13655

ORIGINAL ARTICLE

WILEY

An enhanced recovery programme improves the comfort and outcomes in children with obstructive sleep apnoea undergoing adenotonsillectomy: A retrospective historical control study

Yu Zhang[1] | Dawei Liu[1] | Xiumei Chen[1] | Jiahai Ma[2] | Xicheng Song[1]

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Funding information
Taishan Scholars Program of Shandong Province; National Natural Science Foundation of China, Grant/Award Number: 81671907

Abstract

Objective: To explore the effects of an enhanced recovery after surgery (ERAS) programme on postoperative rehabilitation in children with obstructive sleep apnoea (OSA) during the perioperative period of adenotonsillectomy.

Design: A retrospective historical control study.

Setting: Service improvement project.

Participants: The study included 294 children with OSA (207 males, 187 females; age range, 2.5 years to 14 years) who underwent adenotonsillectomy.

Main outcome measures: The children who had undergone adenoidal ablation and bilateral tonsillectomy were divided into an ERAS group (208 patients) treated with the combined optimisation measures and a control group (186 patients) treated with traditional measures during the perioperative period. The postoperative incidence of complications, pain scores, anxiety scores and postoperative diets in the two groups were assessed.

Results: Patients in the ERAS group had significantly a lower overall complication rate and incidence of fever for 2 weeks of follow-up when compared to patients in the control group through the application of perioperative optimisation measures. Furthermore, patients in the ERAS group had less post-surgical pain, had better dietary intake at days 1, 3 and 7 after surgery and had lower preoperative anxiety scores after admission education and while waiting in the operation room.

Conclusion: The ERAS programme consisting of combined optimisation measures can reduce physical and psychological trauma during the perioperative period of adenotonsillectomy performed for children with OSA.

13

ERAS in Adenotonsillectomy

- 294 children with OSA
  - 208 in ERAS group, 186 controls
- ERAS protocol included
  - ERAS education, nutritional assessment,
  - Periop anxiety management,
  - Standardized anesthetic, multimodal pain management
  - Drink 10% glucose (5 mL/kg) 2 hrs before surgery
- ERAS patients had less pain, anxiety, complications

Zhang, Y, Liu, D, Chen, X, Ma, J, Song, X. An enhanced recovery programme improves the comfort and outcomes in children with obstructive sleep apnoea undergoing adenotonsillectomy: A retrospective historical control study. *Clin Otolaryngol*. 2021; 46: 249– 255. https://doi-org.ezproxy.fau.edu/10.1111/coa.13655

14

NPO guidelines

15

ASA current guidelines

- 2 hrs for clears
- 4 hrs for breast milk
- 6 hrs for formula, light meal
- 8 hrs for heavy meal

16

NPO concerns in children

- Instruction standardization
- Poor compliance
- Surgical case shuffling
- Aspiration risk
- Dehydration
- Patient and parent satisfaction
- Difficult IV access
- New studies related to gastric emptying

17

1 hour fast for clears?

Pro-Con Debate: 1- vs 2-Hour Fast for Clear Liquids Before Anesthesia in Children

Nicola Disma, MD,* Peter Frykholm, MD,† Scott D. Cook-Sather, MD, FCPP,‡ and Jerrold Lerman, MD, FRCPC, FANZCA§

See Article, p 578

Perioperative fasting guidelines are designed to minimize the risk of pulmonary aspiration of gastrointestinal contents. The current recommendations from the American Society of Anesthesiologists (ASA) and the European Society of Anaesthesiology and Intensive Care (ESAIC) are for a minimum 2-hour fast after ingestion of clear liquids before general anesthesia, regional anesthesia, or procedural sedation and analgesia. Nonetheless, in children, fasting guidelines also have consequences as regards to child and parent satisfaction, hemodynamic stability, the ability to achieve vascular access, and perioperative energy balance. Despite the fact that current guidelines recommend a relatively short fasting time for clear fluids of 2 hours, the actual duration of fasting time can be significantly longer. This may be the result of deficiencies in communication regarding the duration of the ongoing fasting interval as the schedule changes in a busy operating room as well as to poor parent and patient adherence to the 2-hour guidelines. Prolonged fasting can result in children arriving in the operating room for an elective procedure being thirsty, hungry, and generally in an uncomfortable state. Furthermore, prolonged fasting may adversely affect hemodynamic stability and can result in parental dissatisfaction with the perioperative experience. In this PRO and CON presentation, the authors debate the premise that reducing the nominal minimum fasting time from 2 hours to 1 hour can reduce the incidence of prolonged fasting and provide significant benefits to children, with no increased risks. (Anesth Analg 2021;133:581–91)

18

1 hour fast for clears: Pro

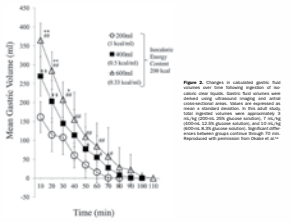
- Underlying concepts of preoperative fasting
  - ensure "safety" from aspiration
  - smooth and comfortable perioperative experience
- Often fasting times exceed recommended times
- Incidence of pulmonary aspiration is 0.6-9 cases/10,000 children undergoing anesthesia

Disma, Nicola MD*; Frykholm, Peter MD*; Cook-Sather, Scott D. MD, FCPP†; Lerman, Jerrold MD, FRCPC, FANZCA‡ Pro-Con Debate: 1- vs 2-Hour Fast for Clear Liquids Before Anesthesia in Children, Anesthesia & Analgesia: September 2021 - Volume 133 - Issue 3 - p 581-591 doi: 10.1213/ANE.0000000000005529

19

1 hour fast for clears: Pro

- During a fasting period of 1 hour, the greater part of any ingested fluid will empty from the stomach in healthy children
- Is endorsed and implemented already by some institutions and societies



Disma, Nicola MD*; Frykholm, Peter MD*; Cook-Sather, Scott D. MD, FCPP†; Lerman, Jerrold MD, FRCPC, FANZCA‡ Pro-Con Debate: 1- vs 2-Hour Fast for Clear Liquids Before Anesthesia in Children, Anesthesia & Analgesia: September 2021 - Volume 133 - Issue 3 - p 581-591 doi: 10.1213/ANE.0000000000005529

20

1 hour fast for clears: Con

- Often fasting times exceed recommended times
- Gastric emptying is complex
- In context of 1-hour fast pulmonary aspiration has increased to 12-18:10,000

Disma, Nicola MD*; Frykholm, Peter MD*; Cook-Sather, Scott D. MD, FCPP†; Lerman, Jerrold MD, FRCPC, FANZCA‡ Pro-Con Debate: 1- vs 2-Hour Fast for Clear Liquids Before Anesthesia in Children, Anesthesia & Analgesia: September 2021 - Volume 133 - Issue 3 - p 581-591 doi: 10.1213/ANE.0000000000005529

21

1 hr fast for clears: Con

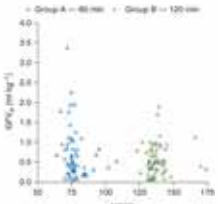


Figure 3. Variability of residual gastric fluid volume in children randomized to 1- vs 2-h fasts following clear liquids. Gastric fluid volumes were determined by blind aspiration of gastric contents. Median (IQR) fasting times were 76 min (73–79 min) for the intended 1-h fast cohort and 136 min (133–140 min) for the 2-h cohort. Note that none of the children actually fasted for the prescribed times. Volumes of the undefined clear liquids ingested were 5 mL/kg to a maximum of 150 mL. A disproportionate percentage (12%) of subjects fasting <2 h had residual gastric fluid volumes >1.25 mL/kg, the historical 95th percentile. GFV_0 indicates gastric residual volume. Reproduced with permission from Schmidt et al.[22]

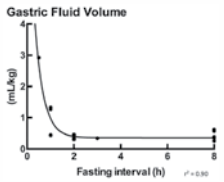


Figure 4. The relationship between the residual gastric fluid volume and the fasting interval. A tight exponential relationship was identified. Aggregate data plotted are that cited by Andersson et al.[21] Reproduced with permission from Lerman.[20]

22

1 hour fast for clears: Con

- Clear liquids of varying composition and unlimited volumes are INCONSISTENTLY and UNRELIABLY emptied from the stomach in 1 hr
- Focus on improving compliance of 2-hour fast

Disma, Nicola MD*; Frykholm, Peter MD*; Cook-Sather, Scott D. MD, FCPP†; Lerman, Jerrold MD, FRCPC, FANZCA‡ Pro-Con Debate: 1- vs 2-Hour Fast for Clear Liquids Before Anesthesia in Children, Anesthesia & Analgesia: September 2021 - Volume 133 - Issue 3 - p 581-591 doi: 10.1213/ANE.0000000000005529

23

Back to our case

- 14-year-old girl presents for adenotonsillectomy
- 5' 3" 75 kg BMI 29
- sleep disordered breathing
- PMH for mild asthma
- Meds- albuterol prn, oral contraceptives

24

Reversal of Neuromuscular Blockade

- Current literature with more attention toward reversal of neuromuscular blockade
- Full reversal not always achieved
- Sugammadex FDA approved in children
- Sugammadex vs Neostigmine
- Counseling patients on oral contraceptives who receive sugammadex about utilizing alternate form of contraception postoperatively

25

U.S. FOOD & DRUG

NDA 022225/S-008

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.
126 E. Lincoln Avenue, PO Box 2000
RY34-B188
Rahway, NJ 07065

Attention: Dori Glassner
Director, Global Regulatory Affairs

Dear Ms. Glassner:

Please refer to your supplemental new drug application (sNDA) dated and received, August 26, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Bridion (sugammadex) injection.

This Prior Approval supplemental new drug application proposes changes to the Package Insert based on data to fulfill the requirements of postmarketing requirement (PMR) 3003-8 in pediatric patients ages 2 to less than 17 years old. The data is from *Study P089 - A Phase 4 Double-Blinded, Randomized, Active Comparator-Controlled Clinical Trial to Study the Efficacy, Safety, and Pharmacokinetics of Sugammadex (MK-8616) for Reversal of Neuromuscular Blockade in Pediatric Participants.*

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

26

Sugammadex in children

RESEARCH REPORT

Sugammadex for reversal of neuromuscular blockade in pediatric patients: Results from a phase IV randomized study

- Randomized a total of 288 pediatric participants aged 2 to <17 years
  - sugammadex 2 mg/kg
  - sugammadex 4 mg/kg
  - neostigmine 50 µg/kg
- Recovery from rocuronium- or vecuronium-induced moderate neuromuscular blockade faster with sugammadex 2 mg/kg than with neostigmine
- Reversal of deep neuromuscular blockade with sugammadex 4 mg/kg was consistent with that of moderate neuromuscular blockade reversal

Voss, T, Wang, A, DeAngelis, M, et al. Sugammadex for reversal of neuromuscular blockade in pediatric patients: Results from a phase IV randomized study. *Pediatr Anesth.* 2021; 00: 1– 10. doi:10.1111/pan.14370.

27

Residual neuromuscular block

- impaired regulation of ventilation during hypoxia
- impaired pharyngeal function and airway protection
- is a risk factor for the development of postoperative pulmonary complications
- To assure normal vital muscle function and normal ventilatory regulation, an adductor pollicis TOF ratio of 0.90 should ideally be achieved before a patient is allowed to breath spontaneously after tracheal extubation
- This can only be reliably detected using objective monitoring techniques of neuromuscular function, such as accelometry or electromyography

Eriksson, Lars I. MD, PhD The Effects of Residual Neuromuscular Blockade and Volatile Anesthetics on the Control of Ventilation, Anesthesia & Analgesia: July 1999 - Volume 89 - Issue 1 - p 243-251 doi: 10.1213/00000539-199907000-00045

28

Residual neuromuscular block

- Monocentric prospective observational cohort
  - 291 patients ages >29 weeks and < 19 years
- Incidence of residual neuromuscular block
  - 48.2% in OR
  - 26.9% in PACU
- Pharmacological reversal of neuromuscular block was administered in 23.3% of patients
  - 41% of these after the TOF measurement in the OR (due to residual blockade)
- Quantitative monitoring of neuromuscular blockade should be implemented in all patients when NMBAs are administered

Klucka J, Kosinova M, Krikava I, Stoudek R, Toukalkova M, Stourac P. Residual neuromuscular block in paediatric anaesthesia. Br J Anaesth 2019;122(01):e1–e2

29

Reversal Agents and Postoperative Pulmonary Complications in Children

Association of Sugammadex or Neostigmine With Major Postoperative Pulmonary Complications in Children

Ralph J. Beltran, MD, Christian Mpody, MD, PhD, MBA, MPH, Olubukola O. Nafiu, MD, FRCA, MS, and Joseph D. Tobias, MD

- Propensity score-matched retrospective study using the Pediatric Health Information System (PHIS) dataset spanning the years 2016 and 2020
- Studied children <18 years who underwent elective, inpatient, noncardiac surgical procedures and received either neostigmine or sugammadex for reversal of NMB
- Primary outcome was major postoperative pulmonary complication, which we defined as the occurrence of either postoperative pneumonia or respiratory failure

30

Reversal Agents and Postoperative Pulmonary Complications in Children

- 33,819 children
  - 23,312 (68.9%) received neostigmine
  - 10,507 (31.1%) received sugammadex
- No evidence of a statistically significant association between the NMB reversal agent and the incidence of pulmonary complications
- Choice of NMB reversal agent does not appear to impact the incidence of major postoperative pulmonary complications

Beltran, Ralph J. MD; Mpody, Christian MD, PhD, MBA, MPH; Nafiu, Olubukola O. MD, FRCA, MS; Tobias, Joseph D. MD Association of Sugammadex or Neostigmine With Major Postoperative Pulmonary Complications in Children, Anesthesia & Analgesia: January 12, 2022 - Volume - Issue - 10.1213/ANE.0000000000005872 doi: 10.1213/ANE.0000000000005872

31

Sugammadex and hormonal contraceptives

- According to the package insert from Merck & Co, Inc.
- "5.6 Due to the administration of Bridion, certain drugs, including hormonal contraceptives, could become less effective due to a lowering of the (free) plasma concentrations."
- "7.3 In vitro binding studies indicate that Bridion may bind to progestogen, thereby decreasing progestogen exposure. Therefore, **the administration of a bolus dose of Bridion is considered to be equivalent to missing dose(s) of oral contraceptives containing an estrogen or progestogen**.
- **If an oral contraceptive is taken on the same day that Bridion is administered, the patient must use an additional, non-hormonal contraceptive method or back-up method of contraception for the next 7 days**."

32

Sugammadex and hormonal contraceptives

- Sugammadex may interfere with hormonal contraception
- Counsel patients about decreased effectiveness of hormonal contraceptives with use of sugammadex for reversal of neuromuscular blockade
- Revise informed consent
- Documentation

Sugammadex and Oral Contraceptives: Is It Time for a Revision of the Anesthesia Informed Consent?

To the Editor

Our institutions, along with many others across the country, have revised protocols to address potential issues for women on oral contraceptives who have received sugammadex in the perioperative period. According to the package insert from Merck & Co, Inc, "5.6 Due to the administration of Bridion, certain drugs, including hormonal contraceptives, could become less effective due to a lowering of the (free) plasma concentrations." The insert also states, "7.3 In vitro binding studies indicate that Bridion may bind to progestogen, thereby decreasing progestogen exposure. Therefore, the administration of a bolus dose of Bridion is considered to be equivalent to missing dose(s) of oral contraceptives containing an estrogen or progestogen. If an oral contraceptive is taken on the same day that Bridion is administered, the patient must use an additional, non-hormonal contraceptive method or back-up method of contraception for the next 7 days." Due to these warnings, it is our understanding that many anesthesiologists and their institutions have gone to great lengths to notify patients of this potential risk by providing both counseling and additional discharge paperwork suggesting alternative contraceptive use for this patient subset.

Interestingly, a similar potential risk exists with the administration of common perioperative antibiotics. The package insert for a common oral contraceptive ORTHO-NOVUM tablets (norethindrone/ethinyl estradiol) states, "Contraceptive effectiveness may be reduced when hormonal contraceptives are coadministered with antibiotics, anticonvulsants, and other drugs that increase the metabolism of contraceptive steroids." While some of the implicated medications include antibiotics that are frequently

Corda, David M. MD; Robards, Christopher B. MD Sugammadex and Oral Contraceptives: Is It Time for a Revision of the Anesthesia Informed Consent?, Anesthesia & Analgesia: February 2018 - Volume 126 - Issue 2 - p 730-731 doi: 10.1213/ANE.0000000000002677

33

Sugammadex and hormonal contraceptives

Informed Consent for Sugammadex and Oral Contraceptives: Through the Looking Glass

To the Editor

We read with interest Dr Corda and Robard's' recent letter to the editor regarding sugammadex and informed consent. While well intended, their assertion "a similar potential risk exists with the administration of common perioperative antibiotics" in terms of effect on contraceptive effectiveness is a misconception held by too many physicians. In fact, rifampin and rifabutin are the only antibiotics demonstrated to affect the metabolism of combined hormonal or progestin-only contraceptives. This is evidenced by World Health Organization recommendations[1] regarding broad-spectrum antibiotics and hormonal contraceptives, as well as recent reviews in the obstetrics literature.[2] Luckily, neither rifampin nor rifabutin is in common use perioperatively.

The more salient issue at hand is the use of sugammadex in women of childbearing age, many of whom take hormonal contraceptives. In vitro studies have demonstrated the ability of sugammadex to bind progestogen, and likely render that day's dose of hormonal birth control ineffective. This is the equivalent of a missed contraceptive dose. This then necessitates our patients use a nonhormonal birth control method for the next 7 days, which in turn requires the documentation of said recommendation. Discussions on this topic have focused on informed consent and appropriate documentation of this risk. What if we took a step back?

The approval of sugammadex has led to its widespread use—in our institution, I have encountered second-year anesthesia residents (CA-1s) who have never prepared a dose of neostigmine and glycopyrrolate. Admittedly, sugammadex is a highly effective and reliable agent. When

Webber AM, Kreso M. Informed Consent for Sugammadex and Oral Contraceptives: Through the Looking Glass. Anesth Analg. 2018 Sep;127(3):e52. doi: 10.1213/ANE.0000000000003608. PMID: 29979198.

34

- Women in their teens and 20s are about twice as likely as older women to have an unintended pregnancy while using birth control
- Adolescents with parents in tow may not be forthcoming regarding contraceptive use
- Consider using using neostigmine in lieu of sugammadex in these patients

Summary

- Choose your patients wisely
- Keep them hydrated
- Keep them strong
- Keep them informed
- Stay thoughtful in how you care for them

35

Questions

36

HANDOUTS

How to build a successful total joint program in your ASC

Rena M. Courtay, MBA, BSN, RN, CASC, CPPM, CNOR(e)

01/22/2022
1:00-1:30pm Eastern

ASC Medical Directors & Leaders Virtual Summit
Saturday, January 22, 2022

How to Build a Successful Total Joint Program in your ASC

Rena M. Courtay MBA, BSN, RN, CASC, CPPM, CNOR (e)
AVP Perioperative Ambulatory Surgery
Duke University Health System

1

Objectives

1. Discuss the landscape of Total Joint Arthroplasty
2. Recognize the benefits of moving total joint arthroplasty to the ambulatory surgery center
3. Discuss the keys to building a safe and successful total joint arthroplasty program in your ASC
4. Understand the payer landscape and the considerations for maximizing reimbursement
5. Identify outcome monitoring tools for your total joint arthroplasty program

2

Total Joint Arthroplasty Landscape in 2022

- Sg2, a healthcare strategy and advisory firm, projected 37 percent of total joint surgeries would be outpatient by 2022, with that number rising to 51 percent by 2026
- Total knee replacement became eligible for Medicare payment in the ASC setting in 2020, and Medicare added total hip replacements in 2021. Still waiting for Total Shoulder Arthroplasty to be added to the ASC list

3

ASC Total Joint Procedures

Year	2012	2013	2014	2015	2016	2017	2018	2019	2020
No. of ASC total joint procedures	5	37	359	1,096	2,325	3,498	5,409	9,226	14,281

The number of total joint procedures performed in ASCs has grown exponentially between 2012 and 2020 and has increased by 55 percent since 2019.

AAOS American Joint Replacement Registry 2021 Annual Report

4

Age of Patients

- Mean Age of Patients Undergoing Arthroplasty Procedures, 2012-2020 (N=2,171,930)
  - Total Knee Arthroplasty 67.0
  - Revision Knee Arthroplasty 65.5
  - Partial Knee Arthroplasty 64.4
  - Primary Total Hip Arthroplasty 66.1

AAOS American Joint Replacement Registry 2021 Annual Report

5

Case Breakdown

- Hip Arthroplasty – 81% are Primary THA (Total Hip Arthroplasty) and 35% of all TJA (Total Joint Arthroplasty) are Primary THA
- Knee Arthroplasty
  - Primary TKA (Total Knee Arthroplasty) makes up 52% of all TJA
  - Revision TKA – 4%
  - Partial Knee – 2%

AAOS American Joint Replacement Registry 2021 Annual Report

6

Benefits of Performing TJA in the ASC Setting

- Procedures are less invasive than they have been historically
- Cost – patients typically pay significantly less to have this done in an ASC
- Authorization – easier to get if done in an ASC
- Health and comfort of the patient
- Faster recovery
- Less chance of surgical site infection

7

Keys to Setting Up Your Outpatient TJA Program

- Physician Champion
- Multidisciplinary approach to planning
  - Anesthesia
  - Surgeons/PA's
  - Physician Office Staff
  - Clinical Staff
  - Managed Care
  - PT
  - ASC leadership

8

Key Items to Include in Plan

- Patient Education
  - Classes
  - Booklets
  - Videos
- Total Joint Coordinator
- Clinical Pathways
- Anesthesia
  - General
  - Spinal
  - Blocks (which kind)
  - Patient Selection Criteria

9

(Cont)

- Postoperative
  - Home Health?
  - Physical Therapy?
  - Overnight Stay
  - Home Considerations
- Equipment
- Financial Analysis
- Marketing

10

Arthroplasty CPT Codes

23472	TOTAL SHOULDER (GLENOID AND PROXIMAL HUMERAL REPLACEMENT)
27130	TOTAL HIP ARTHROPLASTY, ACETABULAR AND PROXIMAL FEMORAL PROSTHETIC REPLACEMENT, WITH OR WITHOUT AUTOGRAFT OR ALLOGRAFT
27446	UNI-KNEE ARTHROPLASTY, KNEE, CONDYLE AND PLATEAU; MEDIAL OR LATERAL COMPARTMENT
27447	TOTAL KNEE ARTHROPLASTY, KNEE, CONDYLE AND PLATEAU; MEDIAL AND LATERAL COMPARTMENTS WITH OR WITHOUT PATELLA RESURFACING

11

Tremendous Pricing Variability exists for Inpatient vs. ASC Procedures, Allowing for Value Generation in Case Migration

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12

Financial Considerations

Medicare

Uni-knee replacement : approximately $8500 inclusive of implant

Total Knee: $8600

Total Hip $8650

Total Shoulder still on inpatient only list

Establish pro-forma based on actual rates, actual projected costs, volume estimates, changes in patient flow assumptions (i.e. recovery care costs), etc.

Cases take 1-2 hours in the OR; 2-4 hours in recovery without overnight stay and then sent home with home health (nurses, PT, etc)

Confirm financial viability of Total Joints for Facility

13

Understand all of your costs:

- Pain Pump or Exparel
- Cement and cement mixer
- Drill rental (if you do not own)
- Laminar system hoods - disposable
- Instrument trays (can get vendors to bring in)
- Thrombin
- Can run $4000 and up for implants
- Other supplies: Approximately $1000-2000
- Length of stay - staffing

14

Payer Engagement

- Document all anticipated procedure costs, incl. physician-preferred implants
- Prepare documentation of *who* specifically will be performing those procedures, NPI#, and where they are doing them
  - Can use billing data to ID procedures where LOS < 2 days
  - Physician champions may be asked to contribute to payer discussions
  - Prepare data on projected volumes of selected procedures
- Gather Data:
  - Costing data – from Administrator
  - Patient Selection Criteria – prepared by Administrator & Physician(s)
  - Quality, Outcomes Data if available
- Engage major payers and determine which will be willing to reimburse at a profitable level for the center
  - Physician Champion and Anesthesia provider may need to engage

15

TJA Outcomes Monitoring

	Procedure								
Description:	Revision of Total Knee 27486	Partial Knee 27446	Total Knee 27447	Total Hip 27130	Total Shoulder 23472	Hemi Shoulder 23470	Event Total	Events per 1000 patients	% of Total Case Volume
admit < 30 days									
admit 30-90 days									
Admissions									
Return to OR < 30 days									
Return to OR 30-90 days									
Return to OR									
DVT's									
Falls*									
Pain									
SSI's**									
Superficial									
Periprosthetic Jt									
Event Total									
Patients Involved									
% of Procedure Case Volume									
Total Procedure Case Volume									

* Includes all falls and assisted to ground

** Per CDC definition - Infection that occurs after surgery in the part of the body where surgery took place. SSI can sometimes be superficial infection involving the skin only

Rate for Primary total Joint Procedures (DRG 470) 30-day Admission (all cause) is 3.91%. 90-day Admission (all cause) 5.23%. Source: Crimson Clinical Advantages Continuum of Care 2/17/19. The Complication of Care metric is based on the AHRQ (Agency for HealthCare Research and Quality) clofication system for complication codes.

16

Appendix – Sample Pt Selection Criteria

Patient Medical Factors:

- Must not have any systemic infection or communicable disease
- Must have ASA Physical Classification Score of 3 or less, and determined appropriate for procedure through collaboration of anesthesia provider and physician
- Obstructive Sleep Apnea (OSA) requires evaluation by anesthesia
- BMI < 40
- No known significant cardiac condition (i.e., Coronary Artery Disease, CHF, Uncontrolled hypertension, Arrhythmia, Pacemakers, AICD)
- No significant evidence of pulmonary disease (i.e., COPD)
- No significant history of significant GI issues – such as post-op ileus
- No significant history of liver disease – (i.e., Cirrhosis)
- No significant renal failure
- No significant hematology issues (i.e., HGB > 13)
- No significant elevation in Hemoglobin a1c
- No significant gyne-uro issues (History of urinary retention)
- No major neurological issues (History of dementia or post-op delirium), Prior CVA
- No history of major organ transplant
- No documented history of MRSA
- No history of malignant hyperthermia
- No active substance abuse or unmanaged chronic pain
- No poorly controlled anxiety or depression

These guidelines can be modified at any time and are at the discretion of the operating surgeon and anesthesia provider.

17

THANK YOU!

Rena Courtay

Cell (954)881-3757

Email: rena.courtay@duke.edu

18

HANDOUTS

Obesity in Outpatient Surgery

Stanford R. Plavin, MD

01/22/2022
1:30-2:00pm Eastern

ASC Medical Directors & Leaders Virtual Summit
Saturday, January 22, 2022

Obesity in Outpatient Surgery

Stanford R. Plavin MD
Principal
Ambulatory Anesthesia Partners
Atlanta, Georgia
splavin@technicalanesthesia.com

1

Obesity in Outpatient Surgery- Objectives

- Formally define and identify those patients considered to be obese
- Understand the additional anesthetic challenges that the obese patient presents when rendering care
- Provide a practical approach to risk stratification and the selection of appropriate patients for care in the Outpatient setting- either in the ASC or Office Based setting
- Discuss Perioperative and Postoperative strategies for the Obese Outpatient Surgery Patient

2

Definitions of Obesity

- Body Mass Index (BMI)- typically utilized
- Measurements of Central Obesity (Includes waist circumference and waist-to-hip ratio)
  - Corresponds to visceral adiposity- insulin resistance, dyslipidemia, increased CV risk
  - Waist circumference: Men > 102 cm (40 in); women >88 cm (35 in)
  - Waist-to-hip ratio: Men > 0.90; women >0.85
- Body Composition Measurements
  - Limited in obesity diagnosis: Men body fat >25% and in Women > 35%
- Not Just by weight alone as many used to do

3

4

Prevalence of Obesity- US and many countries

- Study group age 20 and older 2007 to 2016
- Obesity increased 33.7% to 39.6% of population
  - Men 32.2 % to 37.9%
  - Women 35.4% to 41.1
- Severe Obesity 5.7 to 7.7% an increase of over 35%
- Peak obesity occurs in those aged 40-60
  - 40.8% of men
  - 44.7% of women

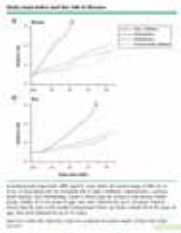
5

Size Matters…. Bigger Challenges Await

- Why the obese patient presents additional and unique challenges
  - Insulin Resistance and an array of metabolic and hemodynamic disorders
  - Type 2 DM more than 80% related to obesity
  - Lipid abnormalities
  - Systolic and Diastolic hypertension
  - LVH- high EDV and increased filling pressures
  - Obstructive Sleep apnea
  - Increased Systemic inflammation
  - Sympathetic Nervous System Activation
  - Endothelial dysfunction

6

BMI and the Risk of Disease



7

Big Issues… Big Concerns

8

Understanding the Anesthetic Challenges

- What's the Big Deal?
  - Preoperative process-
  - In person Pre-anesthetic evaluation
  - Setting the expectations for the patient
  - Airway – understanding the differences with obese patient
  - Physiologic changes and respiratory challenges
  - Pharmacokinetic and dosing of medications
  - Technical components of monitoring, access, predictability, and execution of the anesthetic plan
  - Regional? Neuraxial
  - Patient positioning
- Co-morbidities abound…

9

Physiological and Pharmacokinetic Changes

10

Before… During… After?

11

Considerations of LMA vs. ETT

- Degree and Distribution of Obesity
- Type and Length of surgery
- Patient Positioning
- Controlled Ventilation
  - BMI >40
  - Primary with Abdominal Obesity
  - Major Abd or Thoracic (not outpatient)
  - Surgery greater than 2 hours
  - Trendelenburg/head down/ Prone?

Consider 2nd generation SGAs

12

To do or Not to do….. That is **THE** question

- Decision to perform surgery on the obese patient in the Outpatient Setting: What would I do differently in another setting?
  - Information Needed: Data and Outcomes help guide decisions- BMI up to 40 has been shown to be equivocal risk; some up to 50…
  - **P-values** (Assign a value to each and create a checklist)
    - Process- Establish priorities and protocols- boundaries matter
    - Patient- evaluate thoroughly- Establish risk… Sedentary… active… motivated
    - Procedure –Single vs Multi-specialty, invasive, duration, postoperative pain management,
    - Place – Infrastructure, resources, proximity to tertiary care center, equipment
    - Personnel- staffing model, skillsets, care-team
    - Practitioners- MDA, CRNAs, RNs, LPNs, surgeons, procedures
    - Preparedness- Education of staff, Understanding the challenges, Planning in advance
    - Performance: Keep track of your outcomes

13

Standardization with Individualization®

- If yes is the answer….
- Perioperative and Postoperative challenges
  - ABC- trust the numbers
  - Positioning
  - Fluid management
  - Pain management
- Don't do this alone
- The more the merrier
  - Make sure you have what you need at the site
  - Make sure you have what you need at home
- The rules of engagement

14

Clinical case study….

- 57-year-old male with Type 2DM, HTN, mild OSA (AHI less than 10), compliant with CPAP, OA, and BMI of 46.8 presents for Left TKA, Limited Activity but No shortness of breath or chest pain
- Yes or No : P-values
- If yes, then what:
- If no, why not ?
- Action Plan:
  - Preop- set the parameters
  - Intraop - choices
  - Postop and beyond- resources at home and patient needs

15

Is there a right or wrong answer?

- Medical Directors are typically seasoned and experienced
- Provide oversight and pragmatism – "Trust your GUT"
- Facilitators but not Enablers
- Responsible and Trustworthy
- Checks and Balances- Authority and Governance
- Collaborate and Communicate
- Alignment is also key
- Understand your Audience

16

References and Resources

- Obesity as a risk factor unanticipated admissions after ambulatory surgery; Hofe RE, Kai T, Decker PA, Warner DO, Mayo Clin Proceedings; 2008;83(8):908
- Systematic Review of Same Day Lap Adjustable gastric band surgery; Thomas H, Agrawal S, Obese Surg, 2011 June;21(6):805-10
- Are morbidly obese patients suitable for ambulatory surgery?; Moon TS, Joshi GP, Curr Opin Anesthesiol. 2016, Feb;29(1): 141-5.
- Predictors of 30 Day Pulmonary Complications after Outpatient surgery: Relative Importance of BMI Weight classifications in Risk assessment; De Oliviera GS Jr., McCarthy, RJ etc; J Am Coll Surge 2017;225(2):312 Epub217 Apr23
- Additional upon request

17

References and Resources

- Effect of BMI on Perioperative Outcomes after Major Surgery: Results from the ACS-NSQIP 2005-2011; Sood A et al; World J Surg. 2015 Oct;39(10) 2376-85
- Body position and the effectiveness of mask ventilation in anaesthetised paralysed obese patients: A randomised cross-over study,Chang JE, Seol T, Hwang JY ,Eur J Anaesthesiol. 2021;38(8):825.
- Society for Ambulatory Anesthesia consensus statement on preoperative selection of adult patients with obstructive sleep apnea scheduled for ambulatory surgery;Joshi GP, Ankichetty SP, Gan TJ, Chung F ;Anesth Analg. 2012 Nov;115(5):1060-8. Epub 2012 Aug 10
- Anaesthesia and morbid obesity;Lotia S, Bellamy MC ;Continuing Education in Anaesthesia Critical Care&Pain. 2008;8(5):151.

18

Obesity in Outpatient Surgery- Objectives

- Formally define and identify those patients considered to be obese
- Understand the additional anesthetic challenges that the obese patient presents when rendering care
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19

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Saturday, January 22, 2022

Obesity in Outpatient Surgery

Stanford R. Plavin MD
Principal
Ambulatory Anesthesia Partners
Atlanta, Georgia
splavin@technicalanesthesia.com

20

Questions……

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21

HANDOUTS

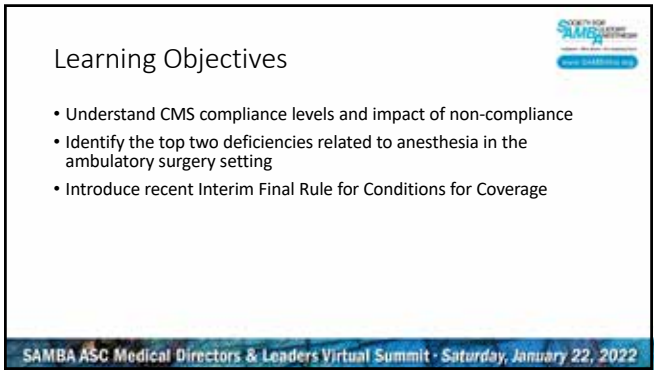
CMS and Accreditation Updates

Cheryl Pistone, RN, BSN, MA, MBA & Tess Poland, RN, MSN

01/22/2022
2:00-2:30pm Eastern


ASC Medical Directors & Leaders Virtual Summit
Saturday, January 22, 2022
Tess Poland, RN
Cheryl Pistone, RN
Compliance
CMS and Accreditation Updates

1


Learning Objectives
• Understand CMS compliance levels and impact of non-compliance
• Identify the top two deficiencies related to anesthesia in the ambulatory surgery setting
• Introduce recent Interim Final Rule for Conditions for Coverage
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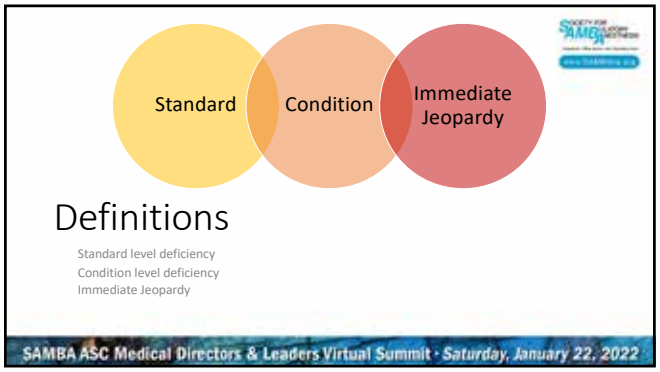
2


Standard
Condition
Immediate Jeopardy
Definitions
Standard level deficiency
Condition level deficiency
Immediate Jeopardy
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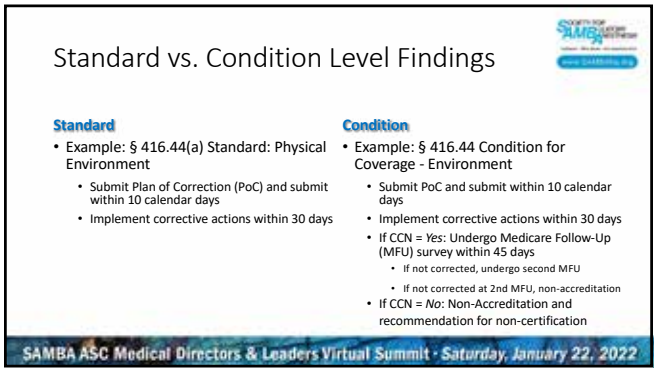
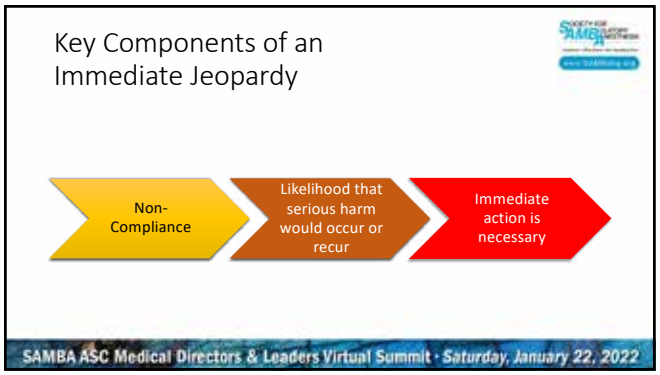
3


Standard vs. Condition Level Findings
Standard
• Example: § 416.44(a) Standard: Physical Environment
• Submit Plan of Correction (PoC) and submit within 10 calendar days
• Implement corrective actions within 30 days
Condition
• Example: § 416.44 Condition for Coverage - Environment
• Submit PoC and submit within 10 calendar days
• Implement corrective actions within 30 days
• If CCN = Yes: Undergo Medicare Follow-Up (MFU) survey within 45 days
• If not corrected, undergo second MFU
• If not corrected at 2nd MFU, non-accreditation
• If CCN = No: Non-Accreditation and recommendation for non-certification
SAMBA ASC Medical Directors & Leaders Virtual Summit · Saturday, January 22, 2022

4


Key Components of an Immediate Jeopardy
Non-Compliance
Likelihood that serious harm would occur or recur
Immediate action is necessary
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5


Top Immediate Jeopardy Deficiencies Related to Anesthesia
Safe Injection Practice
Emergency Equipment
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6

Safe Injection Practice

- Pre-filled syringes on anesthesia cart in procedure room
  - Prepared before OR was cleaned
  - Patient in room when syringes prepared for following patient
- Multidose vial opened and needle punctured in procedure room

7

Safe Injection Practice

- Cross contamination
- Cross infection
- Risk of medication errors
- Risk of liability
- Impacts patient outcomes

8

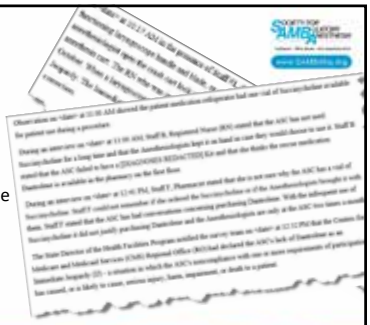
Emergency Equipment

- Non-functioning laryngoscope handle and blade
- No battery backup
- No backup laryngoscope
- No testing
- Lack of staff training and knowledge on use of equipment

9

Perfect Storm

- Resuscitative drugs present
- Staff unaware
- Pharmacist unaware
- Rescue kit/drugs not available
- Drills not conducted



10

CMS Update: Interim Final Rule

Vaccination Regulation: Enforcement of Rule Imposing Vaccine Requirement for Health Care Staff in Medicare- and Medicaid-certified Providers and Suppliers

QSO-22-07-ALL

11

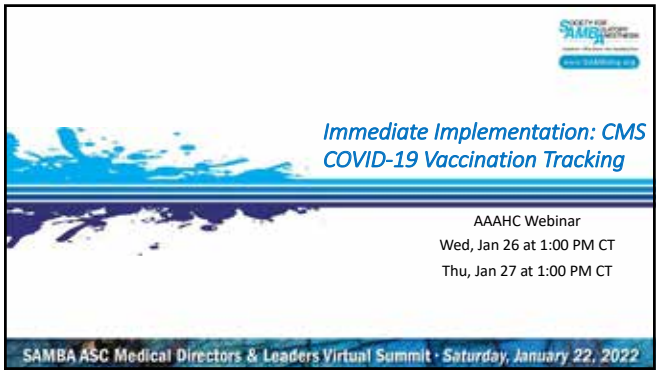
416.51 Condition for coverage—Infection control

(c) Standard: COVID-19 vaccination of staff

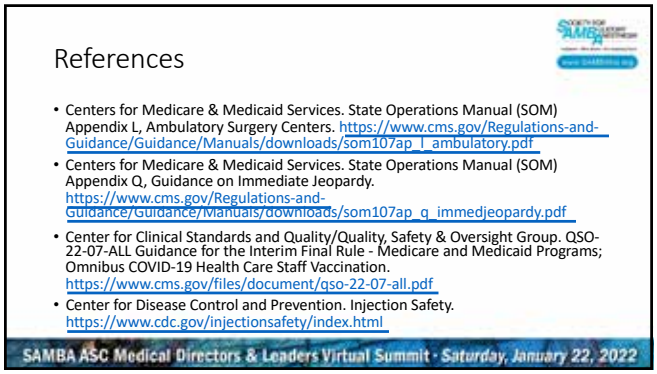
- Effective: Immediately
- Implementation Jan 27
- Implementation Feb 13: AL, AK, AZ, AR, GA, ID, IN, IA, KS, KY, LA, MS, MO, MN, NE, NH, ND, OH, OK, SC, SD, TX, UT, WV, WY
- Exclusion: TX

- Overview
  - Policy requirements
  - Vaccination requirements
  - Tracking and documentation
- Evaluating Compliance
  - Standard
  - Condition
  - Immediate Jeopardy

12


Immediate Implementation: CMS COVID-19 Vaccination Tracking
AAAHC Webinar
Wed, Jan 26 at 1:00 PM CT
Thu, Jan 27 at 1:00 PM CT
SAMBA ASC Medical Directors & Leaders Virtual Summit · Saturday, January 22, 2022

13


References
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Centers for Medicare & Medicaid Services. State Operations Manual (SOM) Appendix Q, Guidance on Immediate Jeopardy. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_q_immedjeopardy.pdf
Center for Clinical Standards and Quality/Quality, Safety & Oversight Group. QSO-22-07-ALL Guidance for the Interim Final Rule - Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination. https://www.cms.gov/files/document/qso-22-07-all.pdf
Center for Disease Control and Prevention. Injection Safety. https://www.cdc.gov/injectionsafety/index.html
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14


Q&A
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15

HANDOUTS

Status of the ASC industry Update

William Prentice

01/22/2022
2:30-3:00pm Eastern

HANDOUTS

Review of 2022 Updates Pertinent for Ambulatory Anesthesiologists

BobbieJean Sweitzer, MD, FACP, SAMBA-F, FASA

01/22/2022
3:00-3:30pm Eastern

ASC Medical Directors & Leaders Virtual Summit
Saturday, January 22, 2022

Review of 2022 Updates Pertinent for Ambulatory Anesthesiologists

BobbieJean Sweitzer, MD, FACP, F-SAMBA, FASA
President, SAMBA
Systems Director, Perioperative Medicine, Inova Health
Professor, University of Virginia

Bobbiejean.sweitzer@inova.org

1

Objectives

Audience members will be more familiar with:

1. Current regulatory changes.
2. Recent literature pertinent to ambulatory anesthesia, especially related to patient access.
3. 2022 implications of Covid-19 for ambulatory anesthesiology.

2

ASC Quality Reporting

- ✓The Ambulatory Surgical Center Quality Reporting (ASCQR) Program is a pay-for-reporting, quality data program administered by the Centers for Medicare & Medicaid Services (CMS)
- ✓ASCs report quality of care data for standardized measures to avoid payment penalty to annual payment updates to payment rates
- ✓ASCs not meeting ASCQR requirements have 2.0 percentage point reduction in annual fee update

https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ASC-Quality-Reporting

https://www.federalregister.gov/public-inspection/2021-24011/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment

3

2022 ASC Quality Measures for 2024 Payment

ASC #	Measure Name	Mandatory/Voluntary
ASC-9	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	Mandatory
ASC-11	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Voluntary
ASC-12	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy	Mandatory
ASC-13	Normothermia Outcome	Mandatory
ASC-14	Unplanned Anterior Vitrectomy	Mandatory
ASC-17	Hospital Visits after Orthopedic ASC Procedures	Mandatory
ASC-18	Hospital Visits after Urology ASC Procedures	Mandatory
ASC-19	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at ASCs	Mandatory
*New*ASC-20	COVID-19 Vaccination Coverage Among Health Care Personnel	Mandatory

4

2023 ASC Quality Measures for 2025 Payment

- ✓All of the previous ASC Quality Measures remain
- ✓Adding these:

ASC #	Measure Name	Mandatory/Voluntary
New ASC-1	Patient Burn	Mandatory
New ASC-2	Patient Fall	Mandatory
New ASC-3	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	Mandatory
New ASC-4	All-Cause Hospital Transfer/Admission	Mandatory

- ✓For 2023, CMS will require providers to submit measure data via the HQR System (formerly referred to as the QualityNet Secure Portal), rather than via claims
- ✓**Measures now required for ALL patients, not just Medicare patients**

5

2024 Changes

*NEW*ASC-15a-e	OAS CAHPS Measures	Voluntary

2025 Changes

ASC-11	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	*NEW*Mandatory
ASC-15a-e	OAS CAHPS Measures	*NEW*Mandatory

OAS (Outpatient and Ambulatory Surgery) CAHPS (Consumer Assessment of Healthcare Providers and Systems) measure is burdensome and many ASCs struggle to convince patients to complete any surveys, let alone lengthy 37-52 question surveys

https://www.ahrq.gov/cahps/index.html

6

CAHPS Surgical Care Survey Measures

Communication With the Anesthesiologist*

Q20 Did this anesthesiologist encourage you to ask questions?
Q22 Did this anesthesiologist answer your questions in a way that was easy to understand?
Q24 Did talking with this anesthesiologist during this visit make you feel more calm and relaxed?
Q25 Using any number from 0 to 10, where 0 is the worst anesthesiologist possible and 10 is the best anesthesiologist possible, what number would you use to rate all your care from this anesthesiologist?

Q3 Before surgery, did anyone in surgeon's office give you all the information you needed about your surgery?
Q10 During office visits before your surgery, did this surgeon spend enough time with you?
Q15 After you arrived at the surgical facility, did this surgeon visit you before your surgery?
Q31 After surgery, did this surgeon listen carefully to you?
Q36 During visits, were clerks and receptionists at the surgeon's office as helpful as you thought they should be?

7

Changes to the Inpatient Only List (IPO)

- ✓CMS maintains the IPO list, (a list of services that due to their complexity, CMS only pays for when performed in the inpatient setting
- ✓In 2021 CMS planned to eliminate the IPO list over 3 yrs, removing 298 services from the IPO list in the first phase of elimination
- ✓CMS received a large number of stakeholder comments that the IPO list serves as an important safeguard
- ✓CMS withdrew plans to eliminate the IPO list
  - ✓Adding back to the IPO list the services removed in 2021
  - ✓Did NOT add back to IPO CPT codes 22630 (lumbar spine fusion), 23472 (shoulder reconstruction), 27702 (ankle joint reconstruction) and corresponding anesthesia codes

8

ASC Covered Procedures List (CPL)

- ✓In 2021, CMS revised the long-standing safety criteria that were historically used to add procedures to the ASC Covered Procedures List (ASC CPL)
- ✓Adopted a notification process for surgical procedures that can be added to the ASC CPL
- ✓For 2022, CMS is reinstating the criteria for adding procedures to the ASC CPL that were in place in 2020
- ✓CMS is finalizing a nomination process, to begin March 2022, to allow external parties to nominate procedures to be added to ASC CPL
- ✓If CMS determines that a surgical procedure meets requirements to be added to ASC CPL, it will propose adding it to the ASC CPL for 2023

9

ASC Covered Procedures List (CPL) Changes

- ✓CMS added 267 surgical procedures to the ASC CPL beginning in 2021
- ✓Removing 255 of 258 procedures proposed for removal
- ✓3 codes proposed for removal but being retained are:
  - ✓CPT 0499T (Procedures Performed on Urethra)
  - ✓54650 (Repair Procedures on the Testis)
  - ✓60512 (Excision Procedures on the Parathyroid, Thymus, Adrenal Glands, Pancreas, and Carotid Body)

10

Public Reporting

- ✓Data collected through the ASCQR program is publicly reported so patients with Medicare and other consumers can compare the quality of care provided at an ASC
- ✓ The CMS Provider Data Catalog via data.cms.gov publishes information on the quality of care provided to patients
- ✓Data are generally refreshed bi-annually
- ✓CMS claims that publishing these data can improve facility performance by providing benchmarks for selected clinical areas and public view of facility data
  - ✓This has been challenged!
  - ✓Can the public truly rate medical decisions and quality?

11

ASC Requirement for Preop H&P

- ✓CMS no longer requires preop H&P within 30 days (or any time) before ambulatory procedures
- ✓CMS policy defers to ASC policies and operating physician's clinical judgement
- ✓Care should be "tailored to the patient and the type of planned surgery"
- ✓Still require "operating physician to document pre-existing medical conditions and appropriate test results" in the medical record
- ✓Presurgical assessments must include documentation of allergies
- ✓Still require that IF the H&P is done it must be in pt's record before the procedure
- ✓Anesthesia providers still required to do their "preoperative assessment"

12

"Surprise medical bills"

- ✓Difference between out-of-network fees and the amount covered by insurance after co-pays and deductible
- ✓Patients often assume that all providers—such as their anesthesiologist—are in-network because their surgeon is
- ✓Data indicates that >90% anesthesia claims are in patients' health plans or "in-network," (limits "surprise medical bills")
- ✓Federal No Surprises Act became law in Sept, 2021 in all 50 states
- ✓Ensures patients only responsible for in-network costs

13

It's a surprise bill if:

- ✓Patients do not sign a written consent alerting them that services are out-of-network and not covered by insurance
- ✓During a visit with a participating doctor, an out-of-network provider provides treatment
- ✓An in-network doctor sends a specimen, such as blood to an out-of-network laboratory
- ✓For any other health care services when referrals are required under the plan
- ✓AMA and AHA first filed lawsuit (ASA joined recently)

14

H.R.133: Consolidated Appropriations Act "No Surprises Act"

- ✓Created an independent dispute resolution (IDR) process
- ✓MDs & plans can negotiate a dispute resolution within 30 d
- ✓If no resolution they can use arbitration
- ✓Each party submits an offer and arbitrator chooses one
- ✓Same or similar disputed claims can be batched together
- ✓Arbitrator cannot consider CMS payor rates or billed charges
- ✓Arbitrator's decision final
- ✓Loser responsible for fees
- ✓For 90 days MDs & insurers cannot arbitrate for same service/s
- ✓MDs can batch cases & resubmit for arbitration after 90 days

15

Preoperative Care for Cataract Surgery: The Society for Ambulatory Anesthesia Position Statement

BobbieJean Sweitzer, MD, FACP, SAMBA-F, FASA,* Niraja Rajan, MD,† Dawn Schell, MD,‡ Steven Gayer, MD, MBA,§ Stan Eckert, MD,‖ and Girish P. Joshi, MBBS, MD, FFARCSI¶

Cataract surgeries are among the most common procedures requiring anesthesia care. Cataracts are a common cause of blindness. Surgery remains the only effective treatment of cataracts. Patients are often elderly with comorbidities. Most cataracts can be treated using topical or regional anesthesia with minimum or no sedation. There is minimal risk of adverse outcomes. There is general consensus that cataract surgery is extremely low risk, and the benefits of sight restoration and preservation are enormous. We present the Society for Ambulatory Anesthesia (SAMBA) position statement for preoperative care for cataract surgery. (Anesth Analg 2021;133:1431–6)

UpToDate revised their guidelines for patients having cataract surgery based on this SAMBA guideline

16

The importance of making it easy for patients to have cataract surgery

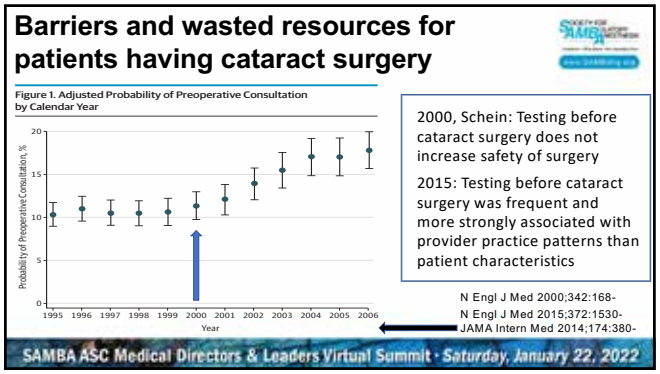
- ✓>20 million cataract extractions done worldwide annually
- ✓Cataracts are a common cause of blindness
- ✓Visual impairment is associated with increased mortality
- ✓Not being able to see impacts quality of life
- ✓Visual loss associated with cognitive impairment
- ✓Cataracts increase falls, hip fractures, car accidents, health care utilization, social isolation, dependency, nursing home placements and mortality

17

Improve patient satisfaction by improving sight!!

- ✓Patients are often elderly with comorbidities
- ✓Most cataracts done with topical or regional anesthesia
- ✓Require minimum or no sedation
- ✓ACC/AHA define cataract as only "truly low risk surgery" requiring NO cardiac risk assessment
- ✓Cataract surgery patients have a 0.014% chance of dying
- ✓It is unlikely that risk can be lowered
- ✓General consensus: cataract surgery is extremely low risk
- ✓Benefits of sight restoration and preservation are enormous

18


Barriers and wasted resources for patients having cataract surgery
Figure 1. Adjusted Probability of Preoperative Consultation by Calendar Year
Probability of Preoperative Consultation, %
Year
2000, Schein: Testing before cataract surgery does not increase safety of surgery
2015: Testing before cataract surgery was frequent and more strongly associated with provider practice patterns than patient characteristics
N Engl J Med 2000;342:168-
N Engl J Med 2015;372:1530-
JAMA Intern Med 2014;174:380-
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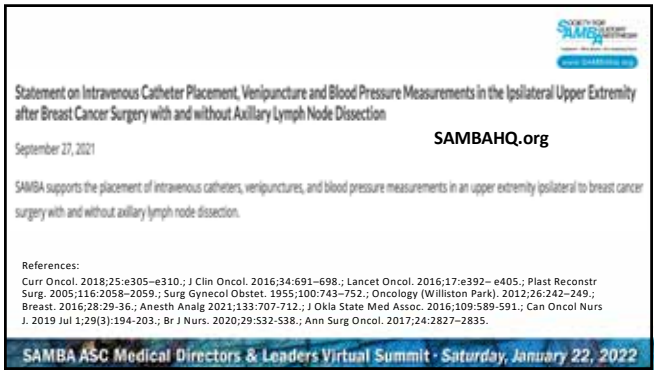
19


Statement on Intravenous Catheter Placement, Venipuncture and Blood Pressure Measurements in the Ipsilateral Upper Extremity after Breast Cancer Surgery with and without Axillary Lymph Node Dissection
SAMBAHQ.org
September 27, 2021
SAMBA supports the placement of intravenous catheters, venipunctures, and blood pressure measurements in an upper extremity ipsilateral to breast cancer surgery with and without axillary lymph node dissection.
References:
Curr Oncol. 2018;25:e305–e310.; J Clin Oncol. 2016;34:691–698.; Lancet Oncol. 2016;17:e392– e405.; Plast Reconstr Surg. 2005;116:2058–2059.; Surg Gynecol Obstet. 1955;100:743–752.; Oncology (Williston Park). 2012;26:242–249.; Breast. 2016;28:29-36.; Anesth Analg 2021;133:707-712.; J Okla State Med Assoc. 2016;109:589-591.; Can Oncol Nurs J. 2019 Jul 1;29(3):194-203.; Br J Nurs. 2020;29:S32-S38.; Ann Surg Oncol. 2017;24:2827–2835.
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20


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21