

SEDATION
What's New for the
Anesthesiologist and
Non-Anesthesiologists?

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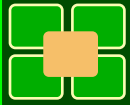
In the Past (PTP) (PTP = Prior to Propofol)

Local Standby



General Anesthesia

Characteristics of the Continuum of Sedation (circa 1992)



Conscious Sedation

Conscious

Cooperative

Protective reflexes
intact

Airway patent

Spontaneous ventilation

Excessive Sedation

Unconscious

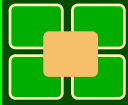
Non-responsive

Protective reflexes
depressed

Airway unprotected

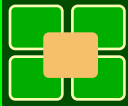
Depressed ventilation

Continuum of Sedation Ramsay (1974)



Ramsay Level	Description
Awake	
1	Anxious and/or agitated
2	Cooperative, oriented, and tranquil
3	Responds to commands
Asleep	
4	Brisk response to glabellar tap or loud auditory stimulus
5	Sluggish response to glabellar tap or loud auditory stimulus
6	No response

Ramsay et al. BMJ 1974;2:656-9.



Now: A Continuum of Techniques

- Local by Surgeon without an Anesthesiologist
- Dense regional with or without sedation
- Partial field block with sedation
- Deep sedation with or without block
- Unconscious sedation/ analgesia
- General anesthesia - spontaneous respiration
- General anesthesia - neuromuscular blockade
- General anesthesia - bypass/circulatory arrest

Conscious



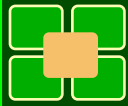
Unconscious

Or

Local Standby

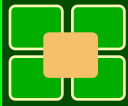


“Big Mac”



“Definitions”

- **Procedural Sedation = Moderate or Deep Sedation/ Analgesia**
- **Local Standby = Old term**
- **Conscious Sedation = Moderate Sedation**
- **MAC (Monitored Anesthesia Care) = “A continuum that can range widely and is not always predictable.”**
- **Light sedation, Just a “little” anesthesia, That white stuff, etc.**



ASA Position on MAC

- <http://www.asahq.org/publicationsAndServices/standards/23.pdf>
- Involvement of an anesthesiologist
- Pre-procedure visit, care during the procedure, post-procedure care
- Potential and ability to convert to GA
- Differences from “conscious sedation”
<http://www.asahq.org/publicationsAndServices/standards/35.pdf>



MAC-Monitored Anesthesia Care as delivered **ONLY** by an anesthesia provider

- **American Society of Anesthesiologists**

“MAC involves monitoring of multiple physiologic parameters...**anticipate** the need to progress to **general anesthesia**. In addition, the possibility that the surgical procedure may become **more extensive** than originally thought, and/ or result in unforeseen complications.”

Complications & Anesthetic Technique



Technique	# of Patients	Complications	Incidence
Local only	10,169	38	1/268
Local/sed.	10,229	96	1/106
General	61,299	513	1/120
Regional	1,936	7	1/277

1984 FASA Study of 87,000 patients in 40 freestanding ASC's



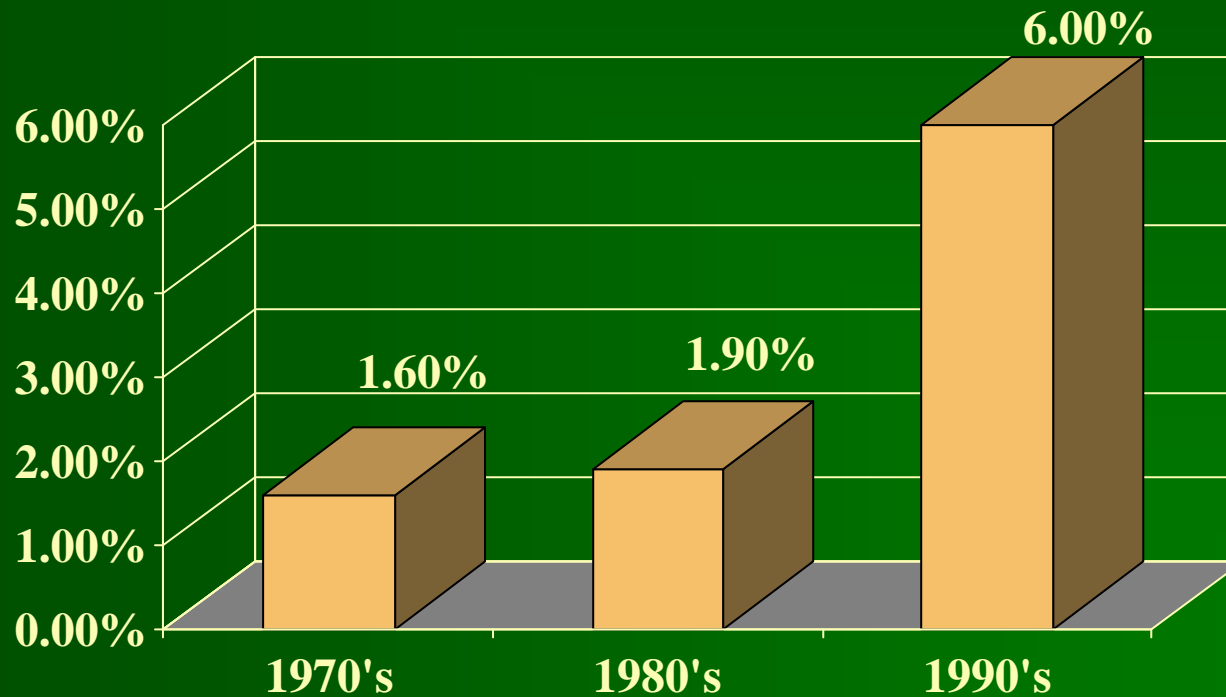
MAC Morbidity

- **JAMA 1998 study by Cohen (JAMA 1988;260:2859-63)**
100,000 Anesthetics
Highest mortality with MAC = 208/100,000
- **K. B. Domino in June 1997 ASA newsletter**
ASA Closed Claims Project
3791 closed malpractice claims
overall 2% were related to MAC



MAC - ASA Closed Claims

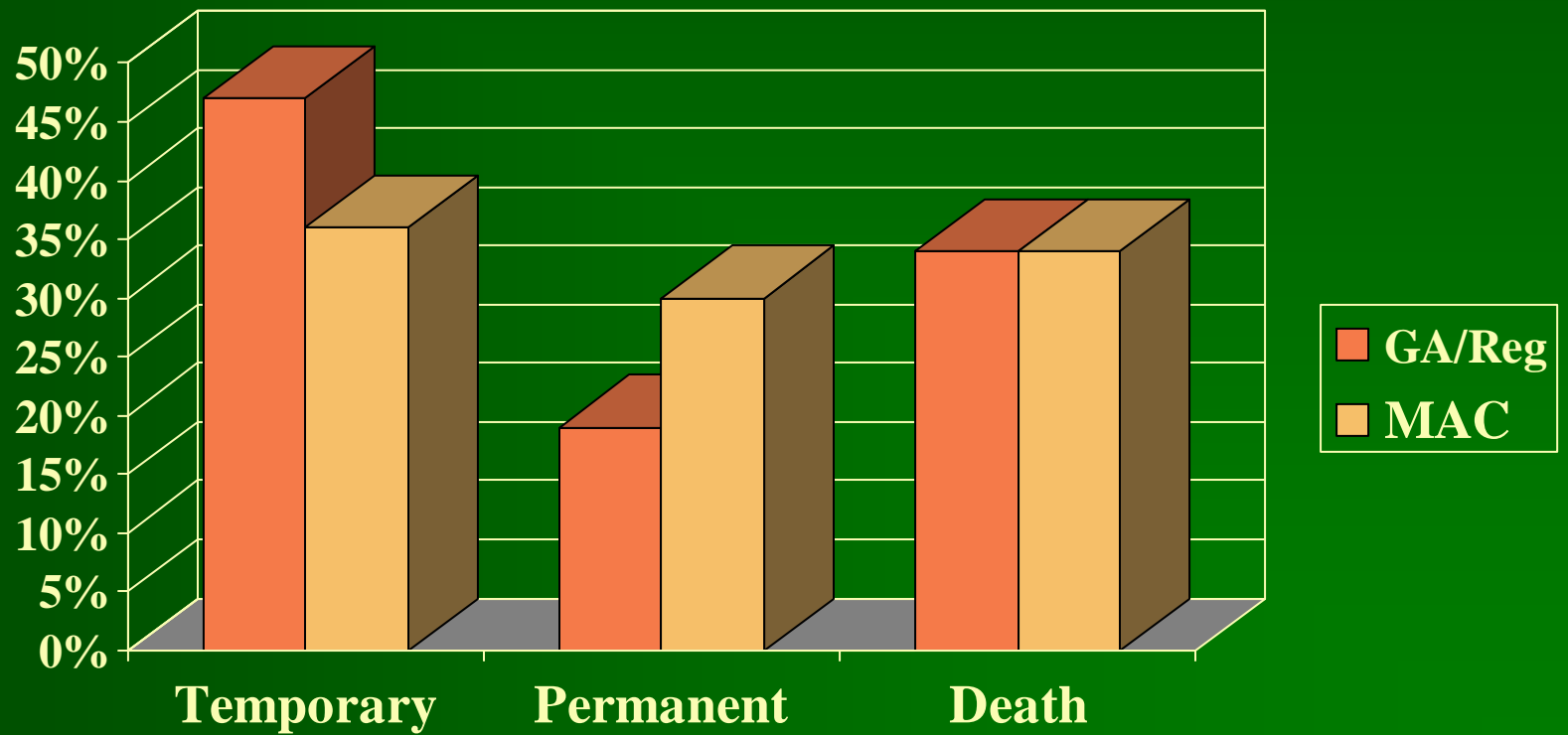
MAC claims as a percent of total



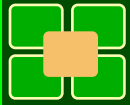


MAC - ASA Closed Claims

Distribution of Injury Severity



ASA Updated Reference Article on Sedation by Non-Anesthesiologists



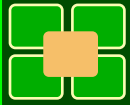
- Original article was in 1995, updated in 2002.
- Anesthesiology 2002; 96: 1004-17
- www.asahq.org/publicationsAndServices/sedation1017.pdf

ASA and JCAHO “Definitions”



- Minimal Sedation (Anxiolysis) = Normal response to verbal commands. Cognitive function and coordination may be impaired. Airway, ventilation, and cardiovascular functions are unaffected.
- Moderate Sedation/ Analgesia (Conscious Sedation) = Purposeful response (not reflex withdrawal from painful stimulus) to verbal or tactile stimulation. No airway intervention. Adequate spontaneous ventilation. Cardiovascular function is usually maintained.

ASA and JCAHO “Definitions”

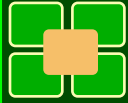


- Deep Sedation/ Analgesia = Purposeful response after repeated or painful stimulation. Airway intervention may be required. Spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
- General Anesthesia = Unarousable even with painful stimulus. Airway intervention often required. Positive pressure ventilation may be required. Cardiovascular function may be impaired.



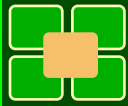
Propofol Package Insert

- **July 2002 Revised Version**
- **Bottom of first page in bold type under “Warnings”**
- **“For general anesthesia or monitored anesthesia care (MAC) sedation, propofol should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure.”**



Perils of Propofol

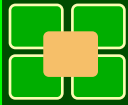
- **No analgesia whatsoever. Only hypnosis. Adding narcotic yields synergistic effects.**
- **ED 50 and ED 95 very widely spaced. Thus the need for close titration for each and every patient based on frequent assessment of level of consciousness.**
- **Dis-inhibition makes “conscious” sedation very difficult, pushing the patient to deeper levels of sedation (close to GA).**



Perils of Propofol continued

- When patients are deeply sedated they are candidates for developing laryngospasm and the need for emergent succinylcholine, mask ventilation, and intubation.
- Hypersalivation occurs in 12 % of cases.
- Examine your governmental “Nursing Board” for any “scope of practice” statutes.
- Primary cardiac inhibitor and vasodilator, very problematic in the dry, NPO patient (especially with coexisting cardiac disease)

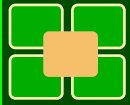
2004 ASA Statement on the “Safe Use of Propofol”



[www.ASAhq.org/publicationsAndServices/
standards/37.pdf](http://www.ASAhq.org/publicationsAndServices/standards/37.pdf)

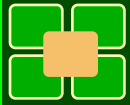
- Restates that sedation is a continuum and you must know how to do deep sedation to use propofol.
- Restates the warning on the FDA approved package insert.

Key Points in the ASA “Safe Use of Propofol”

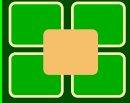


- Defines “Rescue” from the next sedation level
 - Airway management.
 - Return to the previous level of sedation.
 - Halt the procedure until the patient returns.
- Outlines equipment needed for monitoring and training of personnel.
- Contains a joint statement by ASA & AANA.

Privileging for Sedation for Non-Anesthesia Providers



- Moderate
 - <http://www.asahq.org/publicationsAndServices/standards/40.pdf>
- Deep
 - <http://www.asahq.org/publicationsAndServices/standards/39.pdf>



Recent ASA Pronouncements

- **10/2006 at meeting of ASA House of Delegates in Chicago**
- **“Because of the significant risk that patients who receive deep sedation may enter a state of general anesthesia, privileges to administer deep sedation should be granted only to practitioners who are qualified to administer general anesthesia or to appropriately supervised anesthesia professionals.”**



Gastroenterology and Propofol

Nurse Administered Propofol for Sedation (NAPS)

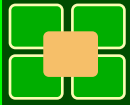
- **2004 - Joint statement from:**
 - American College of Gastroenterology (ACG)
 - American Gastroenterological Association (AGA)
 - American Society for Gastrointestinal Endoscopy (ASGE)
 - Society for Gastroenterology Nurses and Associates (SGNA)
- **The routine use of anesthesia providers for average risk patients for EGD and colonoscopy is not warranted.**
- **New CMS ASC payment system – 17% decrease in GI procedure reimbursement over 4 years.**

Gastroenterology and Propofol (continued)

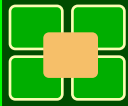


- GI physician-nurse teams using propofol for conscious sedation must be competent to do deep sedation and rescue from GA and severe respiratory depression.
- Must have a designated person other than the endoscopist to monitor and rescue.

Surgery Center of Southern Oregon Medford, Oregon



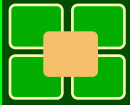
- **Since 1998 has trained 40 nurses in NAPS.**
- **“Perfect” safety record over 36,000 cases.**
- **ACLS and PALS certification.**
- **Competency program with 9 written exams.**
- **10 case OR rotation covering induction, emergence, gases, paralytics, reversal agents**
- **Perform 3 successful LMA insertions.**



NAPS training - continued

- **Perform heart, lung, and airway assessments.**
- **Annual 5 hour airway class and written exam.**
- **Observe NAPS by an RN for one week.**
- **Administer NAPS under direction of surgeon and an RN**
- **Complete annual airway modules, clinical competency program, airway management class, perform a case observed by the medical director.**

Supporting Documentation from Gastroenterology Literature



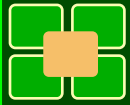
- 31 “Studies” demonstrate that this is safe.
- 9,152 cases of RN administered propofol with 7 cases of respiratory depression
- Seven years with 25,200 cases
 - 3 – Apnea
 - 3 – Laryngospasm
 - 1 - Aspiration
- 28,697 cases with 0.14% needing assisted ventilation (42 cases) with no intubation.



Ethicon Endo-Surgery Propofol Sedation Delivery System

- **Now in FDA trials**
- **Intent is to deliver “Moderate Sedation” and NOT “Deep Sedation”**
- **System monitors HR, BP, SpO2, RR via ETCO2, & ARM with closed loop feedback**
- **ARM – Automated Responsiveness Monitor**
- **Patient can respond purposefully to verbal commands, no airway intervention, with adequate spontaneous ventilation.**

Safeguards in a Facility Sedation Protocol for Non-Anesthesiologists



- **Training**
- **Documentation**
- **Auditing/ Oversight**
- **Quality Improvement**
- **P&T Committee or Pharmacy**

Safeguards in a Facility Sedation Protocol for Non-Anesthesiologists



■ Training

Pharmacokinetics and pharmacodynamics.

Avoid sedation drips or pumps.

Ability to rescue from next level of sedation.

ACLS, Airway course for nurses and MD proceduralists.

■ New AHA 4 hour “Airway Management” Course

“Designed for healthcare providers who must be proficient in using airway devices on adults in or out of hospital”

Bag-Mask Ventilation and Airway Adjuncts and LMA

Esophageal-Tracheal Combitube

ETT and ITD (Impedance Threshold Device)

Safeguards in a Facility Sedation Protocol for Non-Anesthesiologists



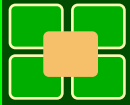
■ Documentation

OSA – ASA guideline and possible JCAHO NPSG.

Level of sedation (baseline, recording frequency).

SpO₂, RR (ETCO₂ ?), Responsiveness (Ramsay, OAAS), Airway intervention (chin lift, jaw thrust, nasal or oral airway, PPV by mask, LMA, OETT).

Safeguards in a Facility Sedation Protocol for Non-Anesthesiologists



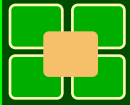
■ Auditing/Oversight

Facility certifies and routinely reviews sedation site leadership (nurses and MDs) CQI plans (volumes, events, code responders, training, equipment, space, nurse staffing, relationship to anesthesia department when sedation fails).

Random chart review

Unannounced observers from quality office

Safeguards in a Facility Sedation Protocol for Non-Anesthesiologists



- **Quality Improvement**

- Regular M&M conferences with nurses & MDs

- **P&T Committee or Pharmacy**

- Anesthesia representative on this committee

- Restrict drugs to “approved” locations

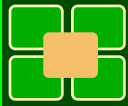
- Propofol (bolus, drip)

- Brevital

- Etomidate

- Dexmedetomidine (drip)

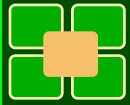
- Ongoing review of existing and new sedation drugs



Know the Nursing “Laws”

- **Board of Nursing, Interpretive Guidelines**
- **Scope of Practice Issues**
- **Can – Administer medications for moderate sedation. Monitor the patient.**
- **Cannot – Accept duties “that would interfere with patient monitoring”. Administer medications to induce deep sedation.**
- **Increase in States restricting RNs using propofol from 12 to now 22.**

Recent Developments at the Ohio Board of Nursing (9/07)



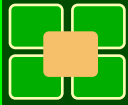
- **Only Moderate Sedation (defined by ASA)**
- **Must have 2nd nurse monitoring the sedation**
 - “The nurse ...should not engage in activities that would divert attention from the patient.”
- **Cannot “administer” deep sedation**
 - “The nurse should not engage in activities that are the practice of anesthesia care... Therefore should not administer medications to induce deep sedation and/or anesthesia.”



The “Bottom Line”

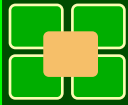
- “How much would an anesthesiologist or CRNA bill for a 20 minute case? Probably about \$200. Not much, but just enough to save a life.”
- Remember it is not about the money.
- It’s ALL about the money.

Payers and “Sedation” with Propofol For GI Procedures



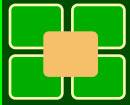
- **December, 2007 Aetna “new policy for MAC for GI endoscopy”.**
- **No routine coverage for MAC for GI procedures for patients with “no sedation-related risk factors.**
- **Pregnancy, age < 18, age > 65, high ASA status, airway risk (morbidly obese, OSA, ENT problems), difficult to sedate, drug or ETOH dependent, complex or long GI procedures, epilepsy.**

Payers and “Sedation” with Propofol For GI Procedures



- **Similar to Humana, WellPoint, and Health America**
- **No moves (yet) by United Healthcare**
- **Medicare usually only covers “high risk” cases (variable throughout U.S.)**
- **Will this cause patients to avoid colonoscopy?**
- **Wide regional differences – 77% get MAC in New York city, < 10% elsewhere with no differences in outcome.**

NOTES – Natural Orifice Transluminal Endoscopic Surgery



- **NOSCAR – Natural Orifice Surgery Consortium for Assessment and Research**
- **No laparoscopic ports (less pain, no scar).**
- **Access thru mouth, rectum, vagina, and possibly urethra.**
- **Transgastric peritoneoscopy for biopsy of liver or lymph nodes, Appendectomy, Herniorraphy, Cholecystectomy, GYN surgery**
- **Problems – Infection, closure of internal incisions, instrument development**

Always, Always, Remember...

First Do No Harm!!!

First!

First!

First!