Endoscopist-Directed Propofol: Practical Considerations

Patrick D. Gerstenberger, MD, FASGE
Durango, Colorado
Regulatory Theater of the Absurd
*What happened to EDP*

Patrick D. Gerstenberger, MD, FASGE
Durango, Colorado
# Sedation Controversies

## Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical or Surgical Procedures 2008 (Review PS9)

- Australian and New Zealand College of Anesthetists
- Gastroenterological Society of Australia
- Royal Australasian College of Surgeons

## Sedation for Gastrointestinal Endoscopy 2008 (S3 Guideline)

- Endoscopy Section of the German Society for Digestive and Metabolic Diseases
- German Association of Gastroenterologists in Private Practice
- Surgical Work Group for Endoscopy and Sonography of the German Society for General and Visceral Surgery
- German Crohn’s Disease/Ulcerative Colitis Association
- German Society for Endoscopy Assisting Personnel
- German Society for Anesthesiology and Intensive Care Medicine
- Society for Legislation and Politics in Health Care
Sedation Controversies

- Safety
- Efficacy
- Economic
- Regulatory-Legal
Competing Interests Within GI

Endoscopist-Directed Propofol

Anesthesia Provider
Competing Interests Within GI

ASGE  ACG

AASLD  AGA
Regulatory Theater of the Absurd

What happened to EDP

- Propofol myths
- CMS Interpretive Guidelines:
  - What happened to EDP?
- Perspectives on endoscopic sedation
Propofol Myths

- Propofol produces rapid unpredictable changes in the level of sedation
- Propofol is unsafe for non-anesthesiologists because there is no reversal agent
- The propofol label precludes the supervision of propofol delivery by non-anesthesiologists
- Propofol increases procedure costs
## Sedation-Related Variable Costs

<table>
<thead>
<tr>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>** Patients**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EDOB</td>
<td>4,304</td>
<td>4,962</td>
</tr>
<tr>
<td>Female</td>
<td>2,266 (52.6%)</td>
<td>2,598 (52.4%)</td>
</tr>
<tr>
<td>Male</td>
<td>2,038 (47.4%)</td>
<td>2,364 (47.6%)</td>
</tr>
<tr>
<td>Age &gt; 65 years</td>
<td>27%</td>
<td>21%</td>
</tr>
<tr>
<td>** Procedures**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EGD (n)</td>
<td>1,265 (25.0%)</td>
<td>1,420 (24.7%)</td>
</tr>
<tr>
<td>Exam duration</td>
<td>8 minutes</td>
<td>8 minutes</td>
</tr>
<tr>
<td>Colonoscopy (n)</td>
<td>3,707 (73.4%)</td>
<td>4,267 (74.3%)</td>
</tr>
<tr>
<td>Exam duration</td>
<td>17 minutes</td>
<td>16 minutes</td>
</tr>
<tr>
<td>Cecal intubation rate</td>
<td>97%</td>
<td>98%</td>
</tr>
</tbody>
</table>

EDOB = endoscopist-directed benzodiazepine-opioid sedation  
EDP= endoscopist-directed propofol sedation (balanced propofol model)
## Sedation-Related Variable Costs

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EDOB</td>
<td>EDOB</td>
<td>EDP</td>
</tr>
<tr>
<td>Staff</td>
<td>$185.51</td>
<td>$204.51</td>
<td>$171.01</td>
</tr>
<tr>
<td>Medications</td>
<td>$2.81</td>
<td>$3.10</td>
<td>$4.66</td>
</tr>
<tr>
<td>Supplies</td>
<td>$38.32</td>
<td>$42.24</td>
<td>$57.86</td>
</tr>
<tr>
<td>Sum of Variable Costs</td>
<td>$226.64</td>
<td>$249.85</td>
<td>$233.53</td>
</tr>
<tr>
<td>Adjusted Net Variable Cost Reduction</td>
<td></td>
<td></td>
<td><strong>$16.32</strong></td>
</tr>
</tbody>
</table>

*Adjusted using CPI inflation calculator at Bureau of Labor Statistics [http://www.bls.gov/data](http://www.bls.gov/data) using the middle calendar year for each time interval as the basis for comparison

Includes costs associated with capnographic monitoring
Regulatory Theater of the Absurd

*What happened to EDP*

- Propofol myths
- CMS Interpretive Guidelines: What happened to EDP?
- Perspectives on endoscopic sedation
Endoscopist-Directed Administration of Propofol: A Worldwide Safety Experience

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*Division of Gastroenterology/Hepatology, Indiana University Medical Center, Indianapolis, Indiana; ‡Regenstrief Institute, Inc, Indianapolis, Indiana; §Gastroenterology Consultants, P.C., Medford, Oregon; ∥Capitol Gastroenterology Consultants Medical Group, Inc, Carmichael, California; Mugga Wara and Birndabella Endoscopy Centres, Brindabella Specialist Centre, Garran, ACT, Australia; ‡Department of Gastroenterology, Showa Inan General Hospital, Komagene, Japan; ¶¶Division of Gastroenterology, Department of Medicine, Mt Sinai Medical Center, New York, New York; ‡‡University Hospital of Basel, Department of Gastroenterology, Basel, Switzerland; §§Valdosta Medical Clinic, Valdosta, Georgia; §§§Stornont-Vail HealthCare, Topeka, Kansas; §§§§Reid Memorial Hospital, Richmond, Indiana; §§§Jeddah Center for Liver and Digestive Diseases, Erfan & Badege General Hospital, Jeddah, Saudi Arabia; §§§The Oregon Clinic, West Hills Gastroenterology, Portland, Oregon; §§§§Section of Gastroenterology, Department of Medicine, LSU Health Sciences Center, Shreveport, Louisiana; §§§§Rocky Mountain Gastroenterology Associates, Lakewood, Colorado; §§§§§Digestive Health Associates, Durango, Colorado; §§§§§§The Centre for Digestive Health, Nassau, Bahamas; §§§§§Clinica Anglo Americana, Lima, Peru; §§§§Northside Gastroenterology, Indianapolis, Indiana; §§§§§Deutsche Klinik Für Diagnostik, Wiesbaden, Germany; §§§§§Division of Gastroenterology, University of South Alabama College of Medicine, Mobile, Alabama; §§§§§Clinica Pediatrica, University of Trieste, Italy; §§§§§Department of Internal Medicine I, Klinikum Region Hannover Sloah, Hannover, Germany; §§§§North Mississippi Medical Center, Tupelo, Mississippi; §§§§§Department of Gastrointestinal Endoscopy, Fukui Kosei Hospital, Fukui, Japan; §§§§§§Wichita Falls Endoscopy Center, Wichita Falls, Texas; §§§§§§Stanton Medical Center, Yellowknife, Northwest Territories, Canada; and §§§§§Your GI Center, Lake Jackson/Pearland, Texas

Endoscopist-Directed Propofol

- 646,080 cases
  - 223,565 previously published
  - 422,424 previously unpublished
  - 28 centers in 10 countries

<table>
<thead>
<tr>
<th>Events</th>
<th>N</th>
<th>%</th>
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<tbody>
<tr>
<td>Endotracheal intubations</td>
<td>11</td>
<td>0.002</td>
</tr>
<tr>
<td>Permanent neurologic injuries</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Deaths</td>
<td>4</td>
<td>0.0006</td>
</tr>
<tr>
<td>Mask ventilations - total</td>
<td>489</td>
<td>0.086</td>
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</table>

### Sedation-Anesthesia Mortality

<table>
<thead>
<tr>
<th>Form of Sedation-Anesthesia</th>
<th>Mortality Rate per 100,000 cases</th>
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</thead>
<tbody>
<tr>
<td>Endoscopist-Directed Propofol (EDP)</td>
<td>0.6</td>
</tr>
<tr>
<td>Endoscopist-Directed Opioid-Benzodiazepine (EDOP)</td>
<td>8-11</td>
</tr>
<tr>
<td>General Anesthesia*</td>
<td>2-10</td>
</tr>
<tr>
<td>Monitored Anesthesia Care*</td>
<td>?</td>
</tr>
</tbody>
</table>

*Based on literature review

EDP mortality rate is lower than EDOP

EDP’s mortality rate is comparable to general anesthesia

Reported EDP Mortalities

- No deaths
  - ASA class I-II patients
  - Colonoscopy sedation

Economic Analysis

Cost of Substituting an Anesthesiologist

- $5.3 million/life-year saved
  - Assumes all deaths would have been prevented
  - Assumes no other deaths would have occurred

Standard cost-effectiveness threshold: $50,000-$100,000 per life-year saved

December 2009

Joint position statement
American Society for Gastrointestinal Endoscopy
American Gastroenterological Association
American College of Gastroenterology
American Association for the Study of Liver Diseases

Compares nonanesthesiologist-administered propofol (NAAP) to standard sedation
- Nurse-administered propofol sedation (NAPS)
- Balanced propofol sedation (BPS)

December 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

CMS

CENTERED for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

DATE: December 11, 2009
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Revised Hospital Anesthesia Services Interpretive Guidelines – State Operations Manual (SOM) Appendix A

Ref: S&C-10-09-Hospital

Memorandum Summary

- Hospital Anesthesia Services Requirements Clarified – The Centers for Medicare & Medicaid Services (CMS) is clarifying the interpretive guidelines (IGs) for the Hospital Condition of Participation (CoP) governing Anesthesia Services.
- Types of Anesthesia Services - The guidance indicates which types of anesthesia services are subject to the requirements governing administration of anesthesia specified at 42 CFR 482.52.
- Anesthesia Requirements - Further details on the pre-, intra- and post-operative anesthesia requirements are also provided.
Regulatory Radar
„Hepatitis C” Google Searches

LAS VEGAS SUN

Hepatitis C outbreak springs from Endoscopy Center of Nevada; 40,000 at risk

By Sun Staff · February 27, 2008 · 2:41 PM

News reference volume
Nevada ASC Problems

- January, 2008 identification of hepatitis C cluster caused by poor infection control practices in a Nevada ASC heightened concern

- Over 50,000 former patients were notified of potential exposure to infectious diseases
Nevada 2008 ASC Surveys

- Federal surveys conducted in 28 of the 51 Nevada ASCs
  - CDC developed infection control survey tool to assist surveyors
- 64% had condition-level problems
  - 18% (5 ASCs) terminated
FY 2008 ASC Pilot

• Maryland, North Carolina, Oklahoma

• Total of 68 ASCs surveyed

• Identified widespread deficiencies, particularly in infection control
“Propofol” Google Searches

Deceased June 25, 2009
CMS Interpretive Guidelines

Hospital Anesthesia Services

Anesthesia
• General
• Regional
• MAC
• Deep Sedation

To be given by anesthesiologist, CRNA or anesthesia assistant within scope of practice

Analgesia/Sedation
• Topical
• Local
• Minimal
• Moderate

To be given by appropriately trained medical professional within scope of practice

Rescue Capacity
Monitored Anesthesia Care (MAC)

- Deep sedation/analgesia is included in MAC
- “An example of deep sedation would be a screening colonoscopy when there is a decision to use propofol, so as to decrease movement and improve visualization for this type of invasive procedure. Because of the potential for the inadvertent progression to general anesthesia in certain procedures, it is necessary that the administration of deep sedation/analgesia be delivered or supervised by a practitioner as specified in 42 CFR 482.52(a)”.

Centers for Medicare & Medicaid Services
S&C-10-09-Hospital
December 11, 2009
Monitored Anesthesia Care (MAC)

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Centers for Medicare & Medicaid Services
S&C-10-09-Hospital
December 11, 2009
§ 482.52(a)

Anesthesia must be administered only by --

- (1) A qualified anesthesiologist;
- (2) A doctor of medicine or osteopathy (other than an anesthesiologist);
- (3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law
- (4) A certified registered nurse anesthetist (CRNA), as defined in §410.69(b) of this chapter, who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or
- (5) An anesthesiologist’s assistant, as defined in Sec. 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.
Revision of Revised Guidelines

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

DATE: December 11, 2009
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT Revised Hospital Anesthesia Services Interpretive Guidelines – State Operations Manual (SOM) Appendix A

Ref: S&C-10-09-Hospital
REVISED 2-05-2010

***Attached guidelines include corrections to figure on page 2 and monitored anesthesia care (MAC) section on page 3***

Centers for Medicare & Medicaid Services
S&C-10-09-Hospital
December 11, 2009
CMS Interpretive Guidelines

Hospital Anesthesia Services

Anesthesia
• General
• Regional
• MAC
• Deep Sedation

Analgesia/Sedation
• Topical
• Local
• Minimal
• Moderate

Rescue Capacity

To be given by anesthesiologist, qualified physician, CRNA or anesthesia assistant as specified at § 482.52(a)

To be given by appropriately trained medical professional within scope of practice

Centers for Medicare & Medicaid Services
S&C-10-09-Hospital
February 5, 2010
Can EDP Comply with the IGs?

Be an “anesthesia provider” under §482.52(a)

• Deep sedation privileges

Documentation requirements for anesthesia services

• Pre-anesthesia evaluation
• Post-anesthesia evaluation

This material is not intended to be and should not be relied upon as legal advice
Can EDP Comply with the IGs?

Policies and procedures

- Define deep sedation to be a form of anesthesia
- Define deep sedation providers to be anesthesia providers for deep sedation
- Define documentation requirements
  - Pre-anesthesia evaluation
  - Intra-procedure anesthesia record
  - Post-anesthesia evaluation
- Define how deep a sedation anesthesia provider may administer anesthesia by supervising the delivery of propofol by a registered nurse (RN)
- Define off-label drug use

This material is not intended to be and should not be relied upon as legal advice.
CMS Invokes FDA Label

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

MAR 5 - 2010

Dear Dr. Gerstenberger:

Thank you for your recent letter to the Centers for Medicare & Medicaid Services (CMS) expressing your concerns regarding the updated Interpretive Guidelines for the Medicare Hospital Condition of Participation governing anesthesia services. This guidance, which was issued via Survey and Certification memorandum S&C-10-09, dated December 11, 2009, does not change existing CMS requirements. The memorandum does provide clarification as to how existing regulations are applied as affected by the most up-to-date FDA label for propofol, which includes its indication as a type of anesthesia.

No change in existing requirements means no “rule making” under Administrative Procedures Act.

CMS letter from Thomas E. Hamilton
March 5, 2009
CMS Invokes FDA Label

In particular, with respect to the guidance indicating that use of propofol is considered monitored anesthesia care/deep sedation, including during endoscopic procedures, this language is based directly on Table 3 of the current Food and Drug Administration (FDA) label for DIPRIVAN (propofol) that lists the following approved indications for the use of propofol:

**Indications for DIPRIVAN Injectable Emulsion**

- Initiation and maintenance of Monitored Anesthesia Care (MAC) sedation
- Combined sedation and regional anesthesia
- Induction of General Anesthesia
- Maintenance of General Anesthesia
- Intensive Care Unit (ICU) sedation of intubated, mechanically ventilated patients.

Of note, this list does not include propofol as approved for the initiation and maintenance of moderate sedation/analgesia.
Thus, consistent with the FDA label, CMS views propofol when used for diagnostic or therapeutic procedures as a form of anesthesia – either general or MAC – and the practitioner who is performing the procedure must not administer propofol him/herself, nor delegate the administration of propofol to a licensed health care professional who is not qualified under our regulations to administer anesthesia.

Sincerely,

[Signature]

Thomas E. Hamilton
Director
February 2010

The Government’s Second Shot
February 2010

- Routine state recertification survey
- Endoscopic ambulatory surgery center using endoscopist-directed propofol sedation

**CFR §4416.42: G 050: Surgical Services**

Please be aware that your facility cannot be recertified for participation in the Medicare program without all CfC(s) being met. Immediate corrective action is required to remain in the Medicare program. We are recommending to the Centers for Medicare and Medicaid Services (CMS), that your provider agreement be terminated effective May 10, 2010, 90 days from the date of the survey, if your facility has not made the necessary corrections to come into substantial compliance with the CfC(s) by that date.
416.42 SURGICAL SERVICES

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

This CONDITION is not met as evidenced by: Based on observations, tracer methodology, interviews with staff and the facility Medical Director, medical record review, review of facility established protocols, review of training for staff and physicians, it was determined the Ambulatory Surgery Center failed to ensure that Registered Nurses were not responsible for the administration of the medication Propofol. Specifically, CMS (Centers for Medicare/Medicaid) expressly prohibits the administration of Propofol by staff other than qualified physicians or anesthesia providers.
CMS “Expressly Prohibits” EDP

ex·press·ly /ɪkˈspresli/ [ik-spres-lee]
–adverb

1. for the particular or specific purpose; specially: I came expressly to see you.
2. in an express manner; explicitly: I asked him expressly to stop talking.
Transparency in the Land of Oz

Who is that man behind the curtain?
CMS “Expressly Prohibits” EDP

“Based on the FDA-approved label for Diprivan (propofol) this drug is anesthesia and must be administered by someone qualified to do so, and that cannot be the same person who is performing the procedure.

We are getting lots of pushback from the gastroenterologists, many of whom prefer to have an RN under their supervision administering the drug. This is not acceptable.”

E-mail communication from:
Marilyn Dahl
Director, Division of Acute Care Services
Survey and Certification Group
CMSO/CMS
Can EDP Comply with the IGs?

- Be an “anesthesia provider” under §482.52(a)
  - Privileges to provide deep sedation
- Documentation requirements for anesthesia services
  - Pre-anesthesia and post-anesthesia evaluations
- Policies and procedures
- Anesthesia provider cannot be the endoscopist

This material is not intended to be and should not be relied upon as legal advice.
The Regulatory Targets

**Propofol**
- CMS invokes FDA label
- No indication for sedation
- No directing sedation while performing a procedure
- Training in general anesthesia

**Deep Sedation**
- Anesthesia service
- Requirements-
  - Anesthesia provider
  - Pre-anesthesia evaluation
  - Post-anesthesia evaluation
Is Off-Label Off-Limits?

**FDA**
- Drug Approval
- Drug Marketing

**CMS**
- Provider Payment
- Facility Certification
  - Conditions of Participation (CoPs)
  - Conditions for Coverage (CfCs)
- Hospitals
- ASCs
Off-Label Drug Use

- Regulatory authority
  - Food, Drug and Cosmetic Act of 1938 (FDCA)
  - FDA Modernization Act of 1997 (FDAMA)
- FDA approval is indication-specific
- Manufacturers’ promotion of off-label use is restricted
Off-Label Drug Use

- Physicians may legally prescribe approved drugs for off-label use
  - Up to 85% of prescribing in some fields
Estimated Numbers of Prescriptions for On-Label and Off-Label Uses of Medications in Various Functional Classes, 2001

Off-Label Drug Use

- Physicians may legally prescribe approved drugs for off-label use
  - Up to 85% of prescribing in some fields
  - May be sole therapy
  - May be therapy of choice
  - May be customary standard of care
  - Major role in drug therapy innovation
Implications of Off-Label Use

- Economic
- Regulatory
- Clinical
- Ethical
- Medicolegal
Authoritative Compendia

FDA-Labeled Indications (see details in DRUGDEX®)
- General anesthesia
- Monitored anesthesia care sedation
- Sedation for a mechanically ventilated patient, intensive care unit

Non-FDA Labeled Indications (see details in DRUGDEX®)
- Headache
- Intubation
- Procedural sedation
- Sedation

4.5.H Procedural sedation
1) Overview
FDA Approval: Adult, no; Pediatric, no
Efficacy: Adult, Effective; Pediatric, Effective
Recommendation: Adult, Class IIa; Pediatric, Class IIa
Strength of Evidence: Adult, Category B; Pediatric, Category B

MICROMEDEX accessed April 7, 2010
A View of the Propofol Label

“I should point out that the wording in the propofol labeling states 'should' not 'must' and therefore does not restrict usage by healthcare providers with training outside of anesthesia if they feel they are competent to handle the possible complications.”

Curtis J. Rosebraugh, MD, MPH
Director, Office of Drug Evaluation II, FDA
Testimony concerning fospropofol of July 21, 2008
The Second Regulatory Target

Deep Sedation

- Anesthesia service
- Requirements-
  - Anesthesia provider
  - Pre-anesthesia evaluation
  - Post-anesthesia evaluation
A Target or An Outcome?

Moderate

Deep
A Target or An Outcome?

Moderate

Deep
## Continuum of Sedation

ASA Sedation Continuum  
*Adoption by CMS redefines deep sedation*

<table>
<thead>
<tr>
<th></th>
<th>Moderate</th>
<th>Deep</th>
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</thead>
<tbody>
<tr>
<td>Responsiveness</td>
<td><em><em>Purposeful</em> response</em>* to verbal or light tactile stimulation</td>
<td><em><em>Purposeful</em> response</em>* after repeated or painful stimulation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Reflex withdrawal from a painful stimulus is not considered a purposeful response*
Deep sedation occurs frequently during elective endoscopy with traditional benzodiazepine-opioid sedation

- 80 ASA I-II outpatients

<table>
<thead>
<tr>
<th>ASA I-II Outpatients</th>
<th>Deep Sedation</th>
<th>Deep Sedation</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>All Observations</td>
<td>At Least Once</td>
</tr>
<tr>
<td>EGD (n=20)</td>
<td>26%</td>
<td>60%</td>
</tr>
<tr>
<td>Colonoscopy (n=20)</td>
<td>11%</td>
<td>45%</td>
</tr>
<tr>
<td>ERCP* (n=20)</td>
<td>35%</td>
<td>85%</td>
</tr>
<tr>
<td>EUS* (n=20)</td>
<td>29%</td>
<td>80%</td>
</tr>
<tr>
<td>Total</td>
<td>26%</td>
<td>68%</td>
</tr>
</tbody>
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*independent risk factors for deep sedation on multivariable analysis

Midazolam Dosing

3,707 colonoscopies performed with EDOB July 2004 –June 2006
Problems with the Continuum

- Depends on “responsiveness”
  - Subjective
  - Is it a valid surrogate marker?
    - Ventilatory risk
    - Cardiovascular risk
  - Is there acceptable interobserver reliability?
  - Practical limitations in application

- The continuum should be reformulated
  - Objective physiologic monitoring
    - Capnography

Green SM, Mason KP. Reformulation of the sedation continuum. JAMA. 2010 303:876-877
Regulatory Theater of the Absurd

What happened to EDP

Propofol myths

CMS Interpretive Guidelines:
-What happened to EDP?

Perspectives on endoscopic sedation
Is Moderate Sedation with Opioids-Benzodiazepines Feasible for the Future of Endoscopic Practice?

- High patient expectations
  - Painless screening procedures
  - Inadequate sedation
  - Informed consent
    - Withdrawal of consent
- High referring provider expectations
- Online patient ratings and comments
Is Moderate Sedation with Opioids-Benzodiazepines Feasible for the Future of Endoscopic Practice?

- Health system expectations
  - Measuring and benchmarking
    - Cecal intubation
    - Adenoma detection
    - Patient satisfaction
  - Pay for reporting/performance
    - Physician Quality Reporting Initiative (PQRI)
  - Public reporting
Is Moderate Sedation with Opioids-Benzodiazepines Feasible for the Future of Endoscopic Practice?

- Changing patient factors
  - Illicit drug use
  - Psychotropic drug use
  - Alcohol use
  - Prescription analgesic use
  - Obesity
Illicit Drug Use

U.S. Adults Aged 50-59
2002-2007

The 2002-2007 use rate in the U.S. is projected to double by 2020.


Source: 2002 to 2007 SAMHSA National Surveys on Drug Use and Health (NSDUHs).
Psychotropic Medication Use

1988-1994 compared to 1999-2002
Increased from 6.1% to 11.1%

Sample Wine Trend

Liters of ethanol per capita aged 15+

Prescription Analgesic Use

- NHANES* III 1988-1994
- Prevalence opiate analgesic use
  - 45-64 age males 3.4% (2.2-4.6 95% CI)
  - 45-64 age females 3.6% (2.4-4.8 95% CI)

*National Health and Nutrition Examination Survey
Obesity Trends Among U.S. Adults
1985

<10%

10-14%

No Data
What Next for EDP Practices?

2010

EDOP

Anesthesia Provider

Trend in Endoscopic Sedation
Necessity in Sedation

“Medical Necessity”

Endoscopist Experience and Skill

Patient Preference

Patient Factors

Regulatory Requirements

Procedural Difficulty

Patient Tolerance
Rodeo Endoscopy
New Sedation Paradigms?

Endoscopic Sedation

Anesthesiologist

CRNA

Physician Sedationist
New Sedation Paradigms?

Nonanesthesiologist Sedationist

- Endoscopist (second MD)
- Critical Care Physician
- Emergency Medicine Physician
- Internal Medicine Hospitalist
- Primary Care Physician
Conclusions

- Endoscopist-directed propofol sedation violates new U.S. Medicare facility mandates
- Serious questions exist regarding how these guidelines, which require dramatic and expensive changes in sedation practice, were conceived, communicated.
Conclusions

- EDP is a proven safe and cost-effective practice that should be allowed
- GI organizations should act aggressively to defend the evidence-based practice of endoscopic sedation and reject public policy actions that have no basis in scientific data
Conclusions

- The sedation continuum should be reformulated
  - Objective physiologic monitoring
- GI and anesthesia communities should work collaboratively to establish new training and practice guidelines for endoscopic sedation that support EDP
Conclusions

- New sedation paradigms are likely to evolve in response to regulatory actions and changing payment schemes
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