

Procedural Sedation Opportunities & Challenges

Dr. Y F Chow

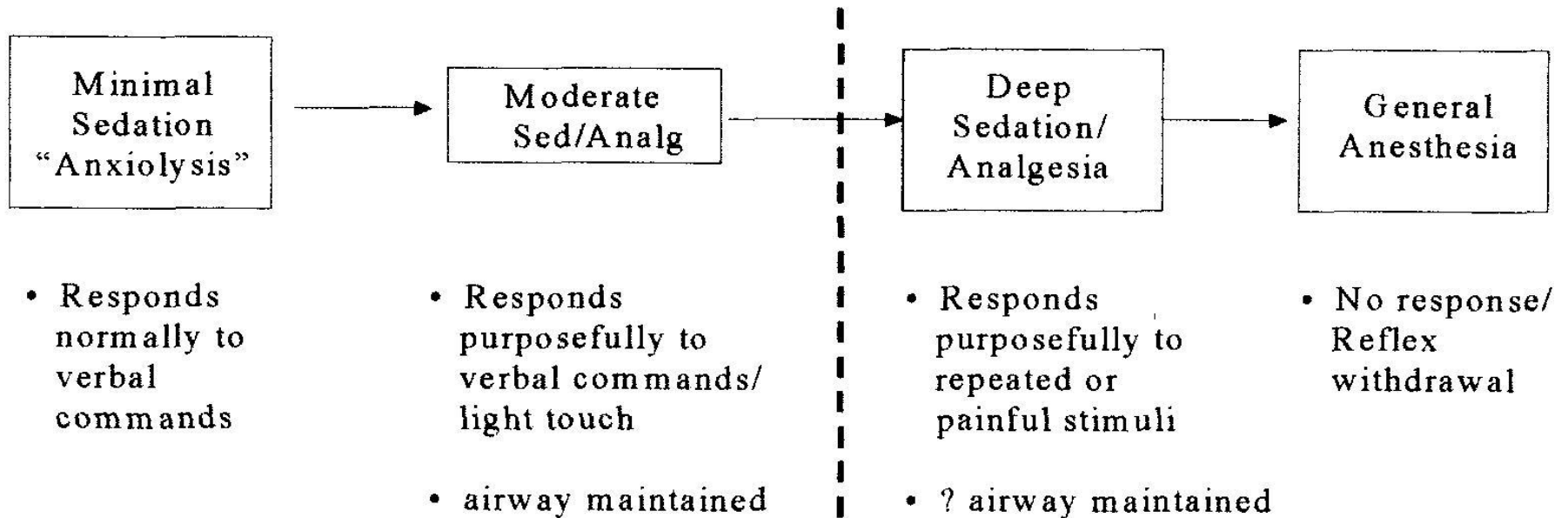
Chief of Service, Dept of Anaes & OT Services, QEH

HA Convention 2013

Sedation Definition

- “Depression of the central nervous system and/or reflexes by the administration of drugs by any route to decrease patient discomfort without producing unintended loss of consciousness”
- Difficult and confusing

ASA & JCAHO Continuum of Sedation



Loss of consciousness with its attendant risk of loss of protective reflexes may occur rapidly and unexpectedly

The Sedation Continuum

Alert-anxious

Alert-calm (anxiolysis)

Drowsy but clear mentation (sedation)

Eyes open; speech slurred

Eyes closed but answers questions appropriately

Opens eyes to voice; is confused

Oxygen desaturation on room air

Opens eyes to pain; responds purposefully

Eyes closed; moans and withdraws from pain

Moans to pain. Nonspecific motor response to pain

CO₂ retention

Oxygen desaturation on 2 L O₂

No response to pain

Bradypnea-poor gag reflex

Apnea-hypotension

Death

What happened when
sedation went wrong?

First Do No Harm!

- “...there are some patients we cannot help, there are none that we should harm...”

Stahl

Dr. Ken

US: Dentist's Sedation Death

- Four-year-old Javier Villa, who died after having his teeth drilled, was treated by dentists "who were incompetent and grossly negligent in sedating or monitoring the boy," according to a dental expert cited in court documents.

Death, Greed at the Dentist: American Children at Risk

abc **NIGHTLINE** Page 2 of 2
July 12, 2012

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"Pain-free dentistry can mean tens of thousands of dollars of extra income in your pocket annually, and as much as half a million extra in your pocket at retirement," wrote Dr. Michael Silverman, a dentist who runs a company that offers weekend-long training sessions for dentists on the use of oral sedation.

A national spokesperson for the American Academy of Pediatric Dentistry, Dr. Indru Punwani of the University of Illinois, said a weekend course is "inadequate" for preparing dentists to deal with emergencies that can arise through the use of oral sedatives.

2 Firefox | 2013_HA_Sedation | Study_Colon

UK

The National Reporting and Learning Service received 498 patient safety incidents between November 2004 and November 2008 where the dose **midazolam** prescribed or administered to the patient was inappropriate. Three incidents resulted in death.

Doctors Imprisoned / Struck off

- Abortion doctor is **imprisoned** for killing (SCMP 31 Oct 03)
Gynaecologist gets two years for ‘crass stupidity’ leading to woman’s death. The court heard Dr S injected Mrs. C with Remifentanyl, a pain killer he had never used before, while preparing her for an abortion. Mrs. C **died of an overdose of Remifentanyl**. Mr. Justice J said yesterday ‘I find it difficult to understand why you **did not at least consult an anaesthesiologist** before you did what you did on Jan 8’.
- Plastic surgeon **struck off register** over woman’s liposuction death (SCMP 21 Dec 09)
The ruling against Dr L was made after he was found guilty yesterday on three charges – that he was **unfamiliar with resuscitation procedures, unfamiliar with sedation safety guidelines and failed to provide sufficient resuscitation facilities at his clinic.**

Medical manslaughter on the rise - Casebook September 2008 - MPS

- ... *Doctors* making medical mistakes resulting in the *death* of their patients can now face criminal charges and spend time behind bars...



Sedation is Easy?

- Should be but the statistics indicate otherwise
- More dangerous than general anaesthesia
 - Limited large scale audit
 - Many anecdotal reports
 - 1 in 2000 30 day mortality (CVS / RS)*

*Quine MA. Prospective audit of UGI endoscopy : safety, staffing and sedation methods. Gut 1995; 36: 462-7

Pino RM 2007

Table 4 Events associated with procedural sedation

Event	Number of cases (%)
SpO ₂ < 90%	31 (0.12)
Systolic blood pressure < 20% baseline	28 (0.1)
Apnea or use of naloxone or flumazaniil	31 (0.12)
Nausea/vomiting	30 (0.11)
Cardiac arrest	17 (0.06)
Death	2 (0.007)
Pain/anxiety	31 (0.12)
Anesthesia assistance	28 (0.01)

Closed Claims Study US sedation in comparison with GA

- Older and sicker patients
- Elective eye surgery (21%) or *facial plastic surgery* (26%)
- More than 40% of claims involved death or permanent brain damage
- Respiratory depression from absolute or relative overdose of opioids
- *Over HALF of claims judged preventable*
 - better monitoring , increased vigilance and audible alarms

(Cote CJ et al Paediatrics 2000)

- Cardiopulmonary complications **50% of all**
- Cardiopulmonary incidents 2 per 1000 cases for GI endoscopic sedation
- Higher incidents for pediatric sedation (>10%)
- Risk factors:
 - Inadequate monitoring
 - Inadequate resuscitation
 - Inadequate evaluation
 - Medication errors
 - Inadequate recovery

Common Concerns:

- Inadequate knowledge
 - Drugs / techniques
 - Resuscitation (airway management)
- Patient selection
 - Pre-procedural evaluation
- Inadequate monitoring / multi tasking
- Unreasonable expectations
 - Physicians & patients

Procedural Sedation Guidelines



Issue date: December 2011

Sedation in young people

Sedation for diagnostic and therapeutic procedures in people

NICE Clinical Guideline Development

ADA American Dental Association
www.adanet.org

Guidelines for the safe use of procedural sedation and general anaesthesia

Original Clinical Review Committee Approved 2008 Revisions Approved 2010

SPECIAL ARTICLE
November 2012, 30(1)

Practice Guidelines for the Safe Use of Sedation and General Anesthesia in Children: An Updated Report

Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in children: 2010



Official Recognition by
The Official Journal of the South African Society of Anaesthetists

SAJAA

South African Journal of Anaesthesia and Analgesia
Volume 10(1) 2010

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and General
Anesthesia in
Children: 2010
The American
Society of Anesthesiologists
Task Force on
Sedation and
Anesthesia
Task Force
Members:
Richard D.
Lerman, MD, FA
Richard D. Lerman, MD, FA
Richard D. Lerman, MD, FA
Richard D. Lerman, MD, FA
Richard D. Lerman, MD, FA
Richard D. Lerman, MD, FA
Richard D. Lerman, MD, FA
Richard D. Lerman, MD, FA
Richard D. Lerman, MD, FA
Richard D. Lerman, MD, FA

drug-induced intracranial pressure
medical, dental or surgical procedures. Task



HKAM Guidelines on Sedation

- serves to recommend and ensure a minimum standard of safety measures for the sedation of patients to facilitate unpleasant diagnostic or minor surgical procedures across the different discipline

Hong Kong Academy of Medicine Guidelines on Procedural Sedation

1 Introduction

Sedation for patients undergoing diagnostic or therapeutic procedures could be undertaken by Fellows of different Colleges. Sedation is not without risk. This Guideline of the Hong Kong Academy of Medicine (the Academy) serves to recommend and ensure a minimum standard of safety measures for the sedation of patients to facilitate unpleasant diagnostic or minor surgical procedures across the different disciplines.

The risks of sedation include the following:

- 1.1 The protective reflexes are obtunded under sedation and airway obstruction may occur at any time.
- 1.2 A wide variety of drugs, with potential adverse interactions, may be given to the patient.
- 1.3 The difficulty in predicting absorption, distribution and efficacy of drugs, especially when not given intravenously.
- 1.4 Unpredictable individual variance in response to drugs, especially in the elderly, the infirm and those with underlying medical diseases.
- 1.5 The possibility that excessive amounts of sedatives may be used to compensate for inadequate analgesia.
- 1.6 The sedation may outlast the procedure.
- 1.7 The facilities and staffing at the locations where procedures are performed are variable.

This document has drawn reference from current literature and various other guidelines included in the reference section. It is also advised to be read in conjunction with the following guidelines of the Hong Kong College of Anaesthesiologists (available at http://www.hkca.edu.hk/ANS/standard_publications/guidelines.htm), which will be updated from time to time:

- 1.8 Guidelines on Monitoring in Anaesthesia
- 1.9 Guidelines for Postanaesthetic Recovery Care
- 1.10 Recommended Minimum Facilities for Safe Anaesthetic Practice in Operating Suites

2 Definition

Sedation is the depression of the central nervous system and/or reflexes by the administration of drugs by any route to decrease patient discomfort without producing unintended loss of consciousness.

Sedation is not a set of discrete, well-defined stages but a continuum where there is the transition from complete consciousness through the various depths of sedation to general anaesthesia. Loss of consciousness with its attendant risk of loss of protective reflexes may occur rapidly and unexpectedly.

Implementation of guidelines
is a different story

Many stakeholders for sedation...

- GI physicians / surgeons
- Radiologists
- Emergency physicians
- Cardiologists
- Paediatricians
- Dentists
- Plastic, aesthetic surgeons
- Eye...

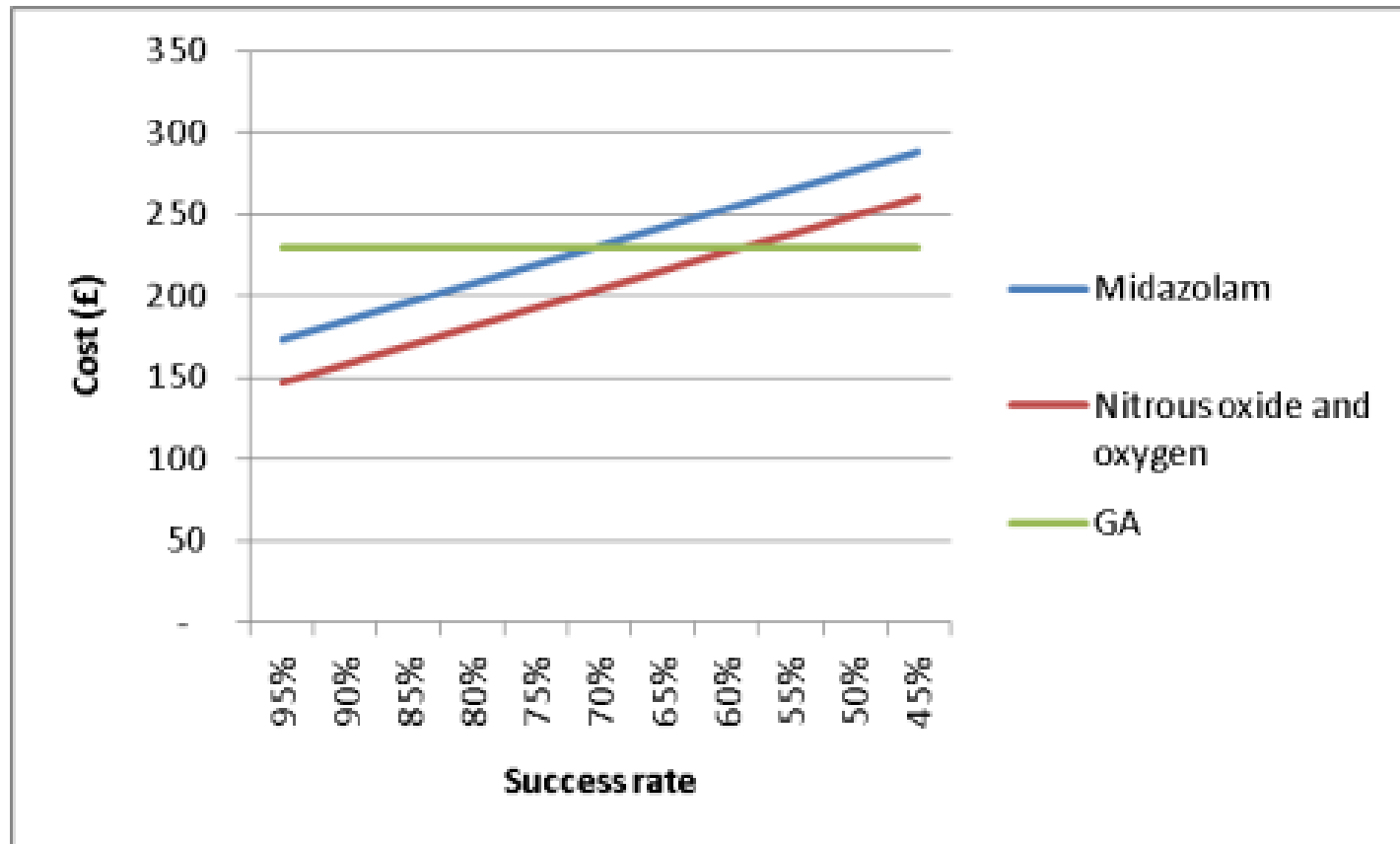
Implementation of Guidelines

- Benefits:
 - Improve training
 - Improve delivery of sedation
 - Increase success of sedation; less general anaesthesia used
 - Sedation is less expensive than general anaesthesia
- Drivers: sentinel events, hospital accreditation
- Barriers: resource / cost impact: training, additional equipment

Benefits

Sedation is cheaper than general anaesthesia

Figure 1 Change in cost relative to success rate



National costing report: sedation in children and young people (December 2010)

Sedation in primary care can:

- Alleviate pressure on hospital services
- Decrease avoidable hospitalization
- Freeing up hospital capacity and productivity
- Reduce waiting lists
- Less expensive

Potential savings

- Higher success rate of sedation
- Reduce risk of procedure, reduce no of adverse events
- Primary care settings

Drivers

JCI Requirement: Sedation Policy

- Scope of sedation
- Qualified personnel to practice sedation: education, training, credentialing
- Sedation location, equipment and monitoring
- Documentation
- Sedation guidelines

ACHS and sedation

Inadequate monitoring
for procedural sedation

- Taskforce to risk stratify sedation procedures set up
- New system to regulate paediatric procedural sedation implemented
- Additional staff to enforce HKMA sedation guideline recruited
- Education and training of frontline staff on safe use of sedation drugs conducted

Barriers

- a range of healthcare professionals: eg primary care: dental and GP; secondary care in hospital, using a wide range of techniques in different clinical settings: inpatients, outpatients, elective or emergency
- Staff turnover
- Difficult to estimate training needs
- Staff replacement costs while attending training
- Ongoing costs for CPD



Editorial

Safe sedation?

In the recent (2010) revision of the

paediatrics and dentistry have heightened concerns recently and the RCoA has been collaborating with

ments of different target levels of sedation because of subtle inconsistencies in the document. For exam-

- Guideline implementation still a major problem
- About one in seven hospitals had sedation committee / lead clinician for sedation
- Training needs for non-anaesthetists, safe limits of practice and governance framework are to be defined

HA Experience

Procedural Sedation Task Force in HA

**1st Meeting of Procedural Sedation Task Force to be held on 12 July 2011
at 10:00 am in Multi-function Room, Oasis, Centre of Health Protection**

Agenda

- 1. Welcome all members**
- 2. Confirm Membership**
- 3. Background of Task Force**
- 4. Discussion on the impact on the practice of procedural sedation safety associated with the “Guideline on Procedural Sedation” promulgated by HKAM**
- 5. Review on the appropriate strategy to enhance procedure sedation safety in HA**
- 6. Any Other Business**

*11 July 2011
Hospital Authority*

Strategies

- Develop / Adopt policy for local sedation practice with clusters variation
- Risk stratification approach
- Enhance training of staff
- Enhance monitoring equipment eg ETCO₂
- Additional resources via annual plan bidding
- Establish quality assurance programme

Endoscopies Which May Require Sedation in HA 2012: 104940

- GI: 70000
 - ERCP: 7500
 - Bronchoscopy: 7000
 - Cystoscopy: 7500
 - Others:
-
- Age < 19: 1230

Sedation need is increasing

- Local anaesthetic procedures
 - “Office” based, dental, plastic
- Minimally invasive surgery
 - Radiology
 - Catheter labs
- Diagnostic / screening
 - Endoscopy

Anaesthetists impossible to do all
the sedation work

Medical Inflation

[CBS News Staff /](#)

CBS News/ March 20, 2012, 5:48 PM

Study: Colonoscopies often come with costly, unnecessary sedation



istockphoto

(CBS/AP) Dread getting a colonoscopy? You're not alone - which is why lots of people are sedated before the procedure. But a new study suggests too many people are getting extra, unnecessary sedation, racking up nearly \$1 billion annually in health care costs.

[PICTURES: 10 myths about colon cancer](#)

What's more, most of the patients utilizing anesthesiologists to monitor sedation are considered low-risk patients who don't need the extra help, the study authors said.

Training Programmes



Hospital Authority Commissioned Training Program

Enhancing Safety in Sedation Workshop for HA Staff 2012

The Enhancing Safety in Sedation Workshop aims to provide the essential information, knowledge and skills to ensure a safe environment for procedural sedation. The Workshop will highlight important safety precautions with a key focus on the management of serious adverse events. The Workshop will take the format of web-based lectures, small groups problem-based discussions and hands-on medical simulation.

**Enhancing Sedation Safety Course
2013-14**

Instructor Manual

Hong Kong College of Anaesthesiologists



Over 300 HA Doctors and 200 Nurses were trained (2010-2012)

Statements	Minimum	Maximum	Mean	Std. Deviation
I learned things that were relevant to my practice	3.00	5.00	4.29	0.55
This course will help me work more safely	2.00	5.00	4.35	0.54
I will change my practice as a result of this workshop	2.00	5.00	4.03	0.67
I shall recommend this workshop to my colleague	3.00	5.00	4.29	0.57

- 1: strongly disagree to 5: strongly agree
- Mean perceived change of level of competence: 0.96 +/- 0.66
- Nurses perceived more relevant to practice and more likely to change practice

Cluster Local Practice Change



Kowloon Central Cluster
Hospital Authority
Queen Elizabeth Hospital

Procedural Sedation Guidelines

Document No.	KCC/KC/CCE/SPS/GL/001		
Department	KCC Workgroup on Safe Practice of Sedation		
Type of document	Guideline	Version	OCT2009
First Issue Date	SEP2009	Document Owner: Dr. Y F CHOW (COS, Anaes & OTS) Signature:	
Last Review Date	OCT2012		
Effective Date	SEP2009	Approval Officer: Hospital Management	
Next Review Date	OCT2014	Committee	



Safety First

- Define a minimum standard for the conduct of sedation
 - Properly trained personnel
 - No multi-tasking i.e. the person doing the sedation and observation cannot be the person assisting the procedurist
 - Availability of resuscitation equipment & drugs in the suite
- Audit and Feedback

Future?

Johnson & Johnson



**FDA Grants Premarket Approval (PMA)
for the SEDASYS® System for
Healthy Patients Undergoing Sedation
During Routine Colonoscopy and
EGD Procedures**

**- Reduces risks associated with
oversedation, facilitates faster patient
recovery and increases physician
satisfaction -**

Thank You