



Guidelines for Safe Sedation for diagnostic and therapeutic procedures

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Content

	Page
1. Introduction	3
2. General principles for the safe use of sedatives	5
3. Patient Assessment and Preparation	6
4. Staffing	7
5. Facilities and Equipment	8
6. Technique and monitoring	9
7. Oxygenation	9
8. Specialized Equipment for Nitrous Oxide Sedation	10
9. Documentation	10
10. Recovery and Discharge of Patient	11
11. Appendix	11
12. Reference	14



1. INTRODUCTION

A minimum standard of safety measures is recommended for the sedation of patients to facilitate unpleasant diagnostic or therapeutic procedures, and Hong Kong Academy of Medicine (HKAM) has published a document “Guidelines on Procedural Sedation” in 2009. However, anaesthetic input is often requested for deep sedation, which at times could progress to general anaesthesia, or for patients with multiple co-morbidities, the guidelines below would, in some areas, recommend more stringent requirements than the HKAM ones. As there are conditions where general anaesthesia would be a better choice instead of sedation, considerations should be given to factors such as the length and invasiveness of the procedure, the positioning, the allowance of patient movement, the severity of pain induced, the risk of aspiration, the difficulty in rescuing and resuscitating the patient, the fragility of patient etc.

This document should be read in conjunction with the following Guidelines and Documents of the Hong Kong College of Anaesthesiologists: -

"Guidelines on Monitoring in Anaesthesia"[P1]

"Guidelines for Postanaesthetic Recovery care"[P3]

“Guidelines for Day case Surgery” [P5]

“Guidelines on the Pre-anaesthetic consultation” [P13]

"Recommended Minimum Facilities for Safe Anaesthetic Practice in Operating Suites"[T2]

"Recommended Minimum Facilities for Safe Anaesthetic Practice in Organ Imaging Units"[T3]

"Recommended Minimum Facilities for Safe Anaesthetic Practice in Delivery Suites"[T4]

“Minimum requirement for an Anaesthetic Record” [T6]

Hong Kong Academy of Medicine: “Guidelines on Procedural Sedation” 2009

1.1 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. While lack of memory of the distressing events and /or analgesia may be desired outcomes, lack of response to painful stimulation is not assured.

1.1.1 Conscious sedation (also called “Moderate sedation”) is defined as a drug-induced depression of consciousness during which patients are able to respond purposefully to verbal commands or light tactile stimulation; interventions to maintain a patent airway, spontaneous ventilation or cardiovascular function may, in exceptional situations, be required. All conscious sedation techniques should provide a margin of safety that is wide enough to render loss of consciousness unlikely.

1.1.2 Deep sedation is characterized by depression of consciousness that can readily progress to the point where consciousness is lost and patients respond only to painful stimulation. It is associated with loss of the ability to maintain a patent airway, inadequate spontaneous ventilation and/or impaired cardiovascular function, and has similar risks to general anaesthesia, requiring an equivalent level of care.

1.1.3 General anaesthesia is a drug induced state characterized by absence of purposeful response to any stimulus, with loss of protective airway reflexes. General anaesthesia is sometimes indicated during diagnostic or interventional medical or surgical procedures and requires the exclusive attention of an anaesthesiologist. (please also refer to appendix 3 for these definitions)

Sedation is not a set of discrete, well-defined stages but a continuum where there is a transition from complete consciousness through the various depths of sedation to general anaesthesia. With wide inter-individual responsiveness to sedative effect of drugs, such transition could be rapid and occur unexpectedly.

1.2 The necessity for a guideline for safety measures is based on the following:-

1.2.1 The protective reflexes are obtunded under sedation and airway obstruction may occur at any time;

1.2.2 A wide variety of drugs, with potential adverse interactions, may be given to the patient;

1.2.3 The difficulty in predicting absorption, distribution and efficacy of drugs, especially when not given intravenously;

1.2.4 Unpredictable individual variance in response to drugs, especially in



the elderly, the infirm and those with underlying medical diseases;

1.2.5 The possibility that excessive amounts of sedatives may be used to compensate for inadequate analgesia;

1.2.6 The duration of the pharmacological effect of the sedatives may outlast that of the procedure;

1.2.7 The facilities and staffing at the locations where procedures are performed are variable.

2. GENERAL PRINCIPLES FOR THE SAFE USE OF SEDATIVES

The following principles should be followed whenever sedative techniques are employed:

2.1 The prescription of sedatives is the responsibility of a registered medical practitioner ¹, who should observe the relevant law, rules and regulations governing them, in particular the Dangerous Drugs Ordinance.

2.2 The registered medical practitioner is ultimately responsible for the sedative management (includes ensuring adequate monitoring), adequacy of the facility and staffing, patient assessment and preparation, recovery and discharge, diagnosis and treatment of emergencies and complications related to sedation, and providing equipment, drugs, documentation, training and protocol for patient safety.

2.3 The medical practitioner providing the sedation should:

2.3.1 understand and be able to deal with the actions of the drugs being given as well as anticipate and modify dosages in the light of underlying disease processes and concurrent medications. Safety will be optimised only if practitioners use defined methods of sedation for which they have received formal training.

2.3.2 be familiar with the detection and management of possible complications and potential risks:

2.3.2.1 Depression of protective airway reflexes and loss of airway patency.

2.3.2.2 Depression of respiration.



2.3.2.3 Depression of the cardiovascular system.

2.3.2.4 Drug interactions or adverse reactions, including anaphylaxis.

2.3.2.5 Individual variations in response to the drugs used, particularly in children, the elderly, and those with pre-existing medical diseases.

2.3.2.6 The possibility of deeper sedation or anaesthesia being used to compensate for inadequate analgesia or local anaesthesia.

2.3.2.7 Risks inherent in the wide variety of procedures performed under procedural sedation and/or analgesia.

2.3.2.8 Unexpected extreme sensitivity to the drugs used for procedural sedation and/or analgesia, which may result in unintentional loss of consciousness, and respiratory or cardiovascular depression.

2.3.3 be skilled in airway management and cardiopulmonary resuscitation, relevant to the patient's age and condition.

2.3.4 participate in the quality assurance program of the facility.

2.4 If loss of consciousness or loss of rational verbal communications is likely, an anaesthesiologist must be present throughout the procedure.

2.5 If the patient has any serious medical condition, or at increased risk of sedation as assessed in 3.1, an anaesthesiologist should be present to monitor the patient throughout the procedure. In situations where an anaesthesiologist is involved in the monitoring of a patient, with or without prescribing any sedation, the care involved is termed "monitored anaesthetic care".

3. PATIENT ASSESSMENT AND PREPARATION

3.1 All patients should be assessed before sedation. The assessment should identify those patients with serious medical condition, or those at increased risk of cardiovascular, respiratory and/or airway compromise. The proper assessment of a patient before a procedure should include:

3.1.1 a relevant medical history, physical examination and, where applicable, investigation(s), looking into the current and co-existing problems, past medical and surgical problems, previous sedation and anaesthesia history, current medications (including non-prescribed medications), allergies, fasting status,



presence of false, damaged or loose teeth, or other evidence of potential airway problems as well as patient's exercise or functional status ;

3.1.2 an adequate explanation of the procedure and risks, including that of sedation. Informed consent for sedation and for procedure should be obtained.

3.2 Patients should be given adequate instructions (written ones) for preoperative preparation (e.g. fasting) and post-operative care (e.g. a responsible person to escort and care for the patient after discharge). This is particularly important in ambulatory patients and/or outpatients.

3.3 For elective procedures, fasting instructions same as general anaesthesia is usually followed. While some assume airway reflexes are maintained during conscious as well as minimal sedation, and lost during general anaesthesia, it is not clear where the point of loss of reflexes lies, or if such a point exists.

4. STAFFING

In addition to the medical and nursing staff required for the procedure, there must be other staff:

4.1 Another medical practitioner or a qualified nurse trained in resuscitation, whose sole responsibility is to monitor the level of consciousness and cardiorespiratory status of the patient.

4.1.1 This qualified nurse should meet the competency requirements listed in 5.5 of HKAM Guidelines on Procedural Sedation (2009).

4.2 Dedicated anaesthetic assistant as in HKCA T7 document should be available to anaesthesiologist.

4.3 Adequate technical/nursing assistance as required.

4.4 Provided rational verbal intercommunication to and from the patient is continuously possible during the procedure, the operator may provide the sedation and be responsible for the conduct of the patient's sedation.

4.5 If, at any time, communication is lost, then the operator must cease the procedure and devote his entire attention to monitoring and treating the patient until another medical practitioner is available to take responsibility for the patient's care.



5. FACILITIES AND EQUIPMENT

All procedures should be performed in a location which:

- 5.1 Is of an adequate area to carry out the procedure and resuscitation should this be required.
- 5.2 Has adequate lighting,
- 5.3 Has adequate suction source, suction catheters and handpiece.
- 5.4 Has a source of oxygen and suitable devices for administering oxygen to spontaneously breathing patients.
- 5.5 Is equipped with a means of inflating the lungs with oxygen (for example, a Bag-valve-mask resuscitator) together with ready access to a range of equipment for advanced airway management (e.g. masks, oropharyngeal airways, laryngeal mask airways, laryngoscopes, endotracheal tubes)
- 5.6 Is adequately equipped for cardiopulmonary resuscitation, including drugs for resuscitation and a range of intravenous equipment and fluids (appendix 1).
- 5.7 Is equipped with a tilting operating table, trolley or chair.
- 5.8 Is equipped with a pulse oximeter and monitoring devices for measurement of vital signs. Capnography should be readily available.
- 5.9 Permits ready access to a defibrillator
- 5.10 Has adequate number of electrical outlets for essential equipment
- 5.11 Has a means to summon emergency assistance.
- 5.12 Has a clinical emergency response plan to manage potential clinical deterioration. There should be written protocols for cardiopulmonary emergencies and other internal and external disaster such as fire, electrical power failure etc. Equipment, drugs and trained staff to implement the emergency response plan and protocols should be available.
- 5.13 Has a system to collect and regularly review the location's relevant sedation related information and incidents for quality assurance and auditing purposes

All the facilities and equipment mentioned above should be age appropriate, well maintained in working condition.



6. TECHNIQUE AND MONITORING

- 6.1 Reliable venous access should be in place for all procedures when sedation is used
- 6.2 Dose of sedative and analgesic drugs should be kept to the minimum required for patient comfort as most morbidity and mortality of sedation are related to cardio-respiratory complications of over-sedation.
- 6.3 Drugs and syringes should be clearly labelled
- 6.4 All patients undergoing procedural sedation and/or analgesia must be monitored continuously with pulse oximetry; and this equipment must give off visual and audible alarms when appropriate limits are transgressed.
- 6.5 There must be regular recording of pulse rate, arterial oxygen saturation and blood pressure throughout the procedure in all patients.
- 6.6 Depth of sedation need to be routinely monitored, typically by assessing patient's response to verbal commands or stimulation. When verbal responsiveness is lost and the patient becomes deeply sedated, same level of care as general anaesthesia is required.
- 6.7 When verbal communication is not maintained either because of the depth of sedation or the procedure, the patient should be monitored with capnography.
- 6.8 According to the clinical status of the patient, other monitors such as ECG may be required.

7. OXYGENATION

- 7.1 Oxygen administration diminishes hypoxaemia during procedures carried out under sedation /or analgesia, and should be used in all patients for as much of the procedure as possible.
- 7.2 Pulse oximeter enables the degree of tissue oxygenation to be monitored and must be used in all patients during procedural sedation and/or analgesia. If hypoxaemia is detected, staff should devote their whole attention to correcting this situation which may include ceasing the procedure until the hypoxaemia is corrected.



8. SPECIALIZED EQUIPMENT FOR NITROUS OXIDE SEDATION

When nitrous oxide is being used to provide sedation, the equipment must satisfy the following special requirements:

8.1 The equipment must have a minimum oxygen flow of 2.5L/minute and a nitrous oxide flow of not more than 10 L/minute, or in machines so calibrated, a minimum of 30% oxygen in the gas mixture. The equipment must be able to administer 100% oxygen.

8.2 The equipment must include an anti-hypoxic device which cuts off nitrous oxide flow in the event of an oxygen supply failure, and opens the system to allow the patient to breathe room air.

8.3 The breathing circuit must have a reservoir bag, and a non-return valve to prevent re-breathing.

8.4 The breathing circuit must provide low resistance to normal gas flows, and be of lightweight construction.

8.5 The installation and maintenance of any gas system must be according to appropriate standards.

8.6 Servicing of equipment and gases must occur on a regular basis and at least annually.

8.7 An appropriate method for scavenging of expired gases must be in use.

8.8 A low flow alarm or other gas failure alarms, if appropriate.

8.9 Occupational safety hazards such as chronic exposure to nitrous oxide should be considered.

9. DOCUMENTATION

9.1 The clinical record should include the names of staff performing sedation, with documentation of the history, examination and investigation findings.

9.2 A written record of the dosages of drugs and the timing of their administration must be kept as a part of the patient's records. Such entries should be made as near the time of administration of the drugs as possible.



9.3 This record should also note the regular readings from the monitored variables, including those in the recovery phase, and should contain other information as indicated in the College Guidelines for the Anaesthetic record [T6].

10. RECOVERY AND DISCHARGE OF PATIENT

10.1 The patient should be monitored for an appropriate duration after the procedure in an area, which is adequately equipped and staffed for recovery care.

10.2 If the recovery area is not where the procedure occurred, then there must be adequate and safe patient transfer facilities available.

10.3 After adequate assessment, patient discharge should be authorized by the registered medical practitioner providing the sedation; or by another registered medical practitioner with proper delegation and handover.

10.4 Adequate staffing and facilities must be available in the recovery area for managing patients who have become unconscious or who have suffered complications during the procedure.

10.5 A system should be in place to enable safe transfer of the patient to appropriate medical care facilities should the need arise.

10.6 Outpatients

10.6.1 An outpatient should have a responsible adult to escort him/her home.

10.6.2 Written information including possible complications and how to obtain medical advice, if and when required, should be given on discharge,

10.6.3 The patient should be warned not to drive or operate machinery or sign legal documents for at least 24 hours.

10.6.4 All instructions should be written.

¹ Medical Registration Ordinance (Cap 161):“registered medical practitioner” means a person who is registered, or is deemed to be so registered under the provisions of section 29

11. APPENDIX 1

Emergency drugs should include the following:



Adrenaline
Amiodarone
Atropine
Dextrose 50%
Flumazenil
Lipid Emulsion*
Naloxone
Portable emergency O2 supply

*Lipid emulsion should be available where local anaesthetics are used, unless lignocaine is the only local anaesthetics available

Appendix 2: ASA PHYSICAL STATUS CLASSIFICATION SYSTEM

(From <https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system> ,accessed 2 Jan,2017)

ASA PS Classification	Definition	Examples, including, but not limited to:
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 < BMI < 40), well-controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled



DM or HTN, COPD, morbid obesity (BMI ≥ 40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.

ASA IV

A patient with severe systemic disease that is a constant threat to life

Examples include (but not limited to): recent (< 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis

ASA V

A moribund patient who is not expected to survive without the operation

Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction

ASA VI

A declared brain-dead patient whose organs are being removed for donor purposes

*The addition of “E” denotes Emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)

Appendix 3



ASA CONTINUUM OF DEPTH OF SEDATION:

DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA

	<i>Minimal Sedation Anxiolysis</i>	<i>Moderate Sedation/ Analgesia ("Conscious Sedation")</i>	<i>Deep Sedation/ Analgesia</i>	<i>General Anesthesia</i>
<i>Responsiveness</i>	Normal response to verbal stimulation	Purposeful** response to verbal or tactile stimulation	Purposeful** response following repeated or painful stimulation	Unarousable even with painful stimulus
<i>Airway</i>	Unaffected	No intervention required	Intervention may be required	Intervention often required
<i>Spontaneous Ventilation</i>	Unaffected	Adequate	May be inadequate	Frequently inadequate
<i>Cardiovascular Function</i>	Unaffected	Usually maintained	Usually maintained	May be impaired

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response (pushing away the painful stimulus would be considered purposeful)

Excerpted from Continuum of Depth of Sedation. Definition of General Anesthesia and Levels of Sedation/ Analgesia of the American Society of Anesthesiology. From the ASA, 520N, Northwest Highway, Park Ridge, Illinois, 60068-2573, USA.

12. REFERENCE

- ANZCA PS09 2014 Guidelines on sedation and/or analgesia for diagnostic and interventional medical, dental or surgical procedures
- Hong Kong Academy of Medicine -Guidelines on procedural sedation 2009
- Royal College of Anaesthetists: Guidelines for the Provision of Anaesthesia Services (GPAS) Chapter 19. Guidance on the Provision of Sedation Services 2016
- Academy of Medical Royal Colleges: Safe Sedation Practice for Healthcare Procedures: Standards and Guidance. October 2013
- American Society of Anesthesiologists. CONTINUUM OF DEPTH OF SEDATION: DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA 2014