

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 followings:

- 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.

2.1 *Conscious Sedation*

Conscious sedation is a minimally depressed level of consciousness induced by the administration of pharmacologic agents in which the patient retains continuous and independent ability to maintain protective reflexes and a patent airway and to be aroused by physical or verbal stimulation.

No interventions are usually required to maintain a patent airway, spontaneous ventilation or cardiovascular function.

All conscious sedation techniques should provide a margin of safety that is wide enough to render loss of consciousness unlikely

2.2 *Deep sedation*

Deep sedation is a controlled state of depressed consciousness or unconsciousness from which the patient is not easily aroused; it may be accompanied by a partial or complete loss of protective reflexes, including the ability to maintain a patent airway independently and to respond purposefully to repeated or painful stimulation, and might be associated with inadequate spontaneous ventilation and/or impaired cardiovascular function.

Deep sedation can have similar risks to general anaesthesia, and can require an equivalent level of care.

2.3 *General Anaesthesia*

General anaesthesia is a controlled state of unconsciousness in which there is a complete loss of protective reflexes, including the ability to maintain a patent airway independently and to respond appropriately to painful stimulation, are associated with depression of respiration and disturbance of circulatory reflexes.

General anaesthesia is sometimes indicated during diagnostic or interventional medical or surgical procedures and requires the exclusive attention of an anaesthesiologist.

	Conscious Sedation	Deep Sedation	General Anaesthesia
Responsiveness	Purposeful* response to verbal or tactile stimulation	Purposeful* response following repeated or painful stimulation	Unarousable even with painful stimulus
Airway	No intervention required	Intervention may be required	Intervention required
Spontaneous Ventilation	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Usually maintained	Usually maintained	May be impaired

* Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

3 **General Principles**

3.1 The prescription of sedatives is the responsibility of a registered medical practitioner or dentist¹, who should observe the relevant law, rules and regulations governing them in

¹ **Medical Registration Ordinance (Cap 161)**: "registered medical practitioner" (註冊醫生) means a person who is registered, or is deemed to be so registered under the provisions of section 29; **Dentists Registration Ordinance (Cap 156)**: "registered dentist" (註冊牙醫) means a person whose name appears for the time being on the General Register, whether or not his name also appears on the Specialist Register.

particular the Dangerous Drugs Ordinance.

- 3.2 The registered medical practitioner or dentist is ultimately responsible for the sedative management, adequacy of the facility and staffing, patient assessment and preparation, recovery and discharge, diagnosis and treatment of emergencies related to sedation and providing equipment, drugs, documentation, training and protocol for patient safety.
- 3.3 The registered medical practitioner or dentist who prescribes or administers sedative or analgesic drugs that alter the conscious state of a patient must be prepared to manage the following potential risks:
 - 3.3.1 Depression of protective airway reflexes and loss of airway patency.
 - 3.3.2 Depression of respiration.
 - 3.3.3 Depression of the cardiovascular system.
 - 3.3.4 Drug interactions or adverse reactions, including anaphylaxis.
 - 3.3.5 Individual variations in response to the drugs used, particularly in children, the elderly, and those with pre-existing medical disease.
 - 3.3.6 Risks inherent in the wide variety of procedures performed under procedural sedation and/or analgesia.
 - 3.3.7 Risks associated with the combinations of opioids and sedatives that are synergistic in depressing consciousness, respiration and cardiovascular function.
 - 3.3.8 Unexpected extreme sensitivity to the drugs used for procedural sedation which may result in unintentional loss of consciousness, respiratory or cardiovascular depression.
- 3.4 An anaesthesiologist or an *appropriately trained*² medical practitioner or dentist must be present to monitor the patient throughout the procedure if:
 - 3.4.1 deep sedation is intended;
 - 3.4.2 the patient has any serious medical condition³, or is at increased risk of cardiovascular, respiratory or airway compromise during procedural sedation.

4 Patient Assessment & Preparation

All patients should be assessed before procedural sedation. The assessment should identify those patients with serious medical condition³, or those at increased risk of cardiorespiratory compromise as in 3.4.

Assessment should include:

² *appropriately trained* refers to those possessing the competencies mentioned in 5.4

³ **The American Society of Anesthesiologists's classification of physical status:**

P1	A normal healthy patient
P2	A patient with mild systemic disease
P3	A patient with severe systemic disease
P4	A patient with severe systemic disease that is a constant threat to life
P5	A moribund patient who is not expected to survive without the operation
P6	A declared brain-dead patient whose organs are being removed for donor purposes
E	Patient requires emergency procedure

Excerpted from American Society of Anesthesiologists Manual for Anesthesia Department Organization and Management 2003-04. A copy of the full text can be obtained from ASA, 520N Northwest Highway, Park Ridge, Illinois 60068-2573

- 4.1 a relevant medical history and examination;
- 4.2 an adequate explanation of the procedure and risks;
- 4.3 adequate instructions for preoperative preparation (e.g. fasting), postoperative care and discharge (e.g. a responsible person to escort and care for the patient after discharge). This is particularly important in ambulatory patients and/or outpatients.

Informed consent for sedation and/or analgesia and for the procedure should be obtained.

5 Staffing

In addition to the medical/dental and nursing staff/dental surgery assistant required for the procedure:

- 5.1 There must be adequate technical/nursing assistance as required.
- 5.2 Safety of the patient under sedation rests upon appropriate use of drugs, close monitoring and prompt resuscitation. It is good practice to have another appropriately trained medical/dental practitioner or qualified nurse/dental surgery assistant whose sole duty is to monitor the level of consciousness and cardio-respiratory status of the patient.
- 5.3 In the absence of dedicated personnel as specified in 5.2, the medical practitioner or dentist performing the procedure (operator) may provide and be responsible for the conduct of the patient's sedation, provided that rational verbal intercommunication to and from the patient or monitoring the patient's response to verbal commands is continuously possible during the procedure. If communication or response is lost at any time, the operator must devote the entire attention to monitoring and treating the patient until recovery or until such time as another appropriately trained medical practitioner/dentist becomes available.
- 5.4 Competency requirements for registered medical practitioners/dentists administering the sedation:
 - 5.4.1 Registered medical practitioners/dentists administering the sedation shall undergo the appropriate theoretical and practicum training, and demonstrate the following core competencies:
 - 5.4.1.1 Understanding of the sedation process and the safety aspects.
 - 5.4.1.2 Ability to perform quality assurance measures of sedation practice e.g. practice review, clinical audit, self assessment.
 - 5.4.1.3 Expertise in using various sedative agents, analgesic agents and their respective antagonists safely and appropriately, taking into consideration the physical condition of the patient.
 - 5.4.1.4 Ability to assess a patient's need, risks and suitability for sedation.
 - 5.4.1.5 Ability to recognize the various depths of sedation, monitor the level of consciousness, cardio-respiratory status and other physiological parameters.
 - 5.4.1.6 Ability to recognize and manage adverse effects of drugs used in sedation, including that of depressed conscious state, compromised airway, inadequate ventilation and oxygenation as well as unstable cardiovascular system.
 - 5.4.1.7 Ability to manage emergencies, rescue a patient from unintended deep

- sedation and manage the adverse effects listed in 5.4.1.6 thereof.
 - 5.4.1.8 Ability to lead/coordinate/initiate resuscitation of the patient. This requires the possession of Immediate life support skills, for example Basic and Advanced life support skills or equivalent
 - 5.4.1.9 Ability to assess recovery from sedation and discharge of patients.
- 5.4.2 Registered medical practitioners /dentists administering the sedation shall also comply with contemporary standards.
- 5.5 Competency requirements for qualified nurses/dental surgery assistants assisting in sedation process:
 - 5.5.1 Qualified nurses/dental surgery assistants assisting in sedation process shall undergo appropriate theoretical and practicum training, and demonstrate the following core competencies:
 - 5.5.1.1 General understanding of the sedation process and the involved drugs.
 - 5.5.1.2 Ability to recognize the adverse effects of drugs used in sedation
 - 5.5.1.3 Ability to recognize the various depths of sedation, monitor the level of consciousness, cardio-respiratory status and other physiological parameters.
 - 5.5.1.4 Ability to initiate immediate life support measures promptly and requiring the possession of immediate life support skills.
 - 5.5.2 Qualified nurses/dental surgery assistants assisting in sedation process shall comply with continuous education programmes, if appropriate.

6 Facilities & Equipment

All procedures should be performed in a location which:

- 6.1 is of an adequate area to carry out the procedure and resuscitation should this be required;
- 6.2 has adequate lighting and suction;
- 6.3 has a source of oxygen and suitable devices for administering oxygen to spontaneously breathing patients;
- 6.4 is adequately equipped for cardiopulmonary resuscitation, including a source of oxygen with a suitable delivery system and a means of inflating the lungs, drugs for resuscitation and a range of intravenous equipment and fluids (appendix 1);
- 6.5 drugs for reversal of benzodiazepines and opioids are available;
- 6.6 is equipped with a tilting operating table, trolley or chair unless it is technically impossible, whereby ready access to the above facilities for induction and recovery of sedation should be provided;
- 6.7 is equipped with a pulse oximeter and monitoring devices for measurement of vital signs;
- 6.8 permits ready access to an ECG and a defibrillator.

All the facilities and equipment mentioned above should be age appropriate. The hospital/clinic/facility concerned shall designate a registered medical practitioner or dentist to be responsible for facilities and equipment.

7 Technique & Monitoring

- 7.1 Reliable venous access should be in place for all procedures when deep sedation is intended.
- 7.2 As most complications of sedation are cardiorespiratory, doses of sedative and analgesic drugs should be kept to the minimum required for patient comfort, particularly for those patients at increased risk or with a slow circulation.
- 7.3 Monitoring of the patient's response to verbal commands wherever applicable and practicable must be routine. Loss of patient response to verbal commands indicates that there may have been loss of airway reflexes, respiratory and/or cardiovascular depression.
- 7.4 All patients undergoing procedural sedation must be monitored continuously with pulse oximetry and this equipment must give off visual and audible alarms when appropriate limits are transgressed.
- 7.5 There must be regular recording of pulse rate, oxygen saturation and blood pressure throughout the procedure in all patients.
- 7.6 According to the clinical status of the patient, other monitors such as ECG or capnography may be required

8 Oxygenation

- 8.1 Hypoxaemia may occur during procedural sedation and/or analgesia without oxygen supplementation. Oxygen administration diminishes hypoxaemia during procedures carried out under sedation with or without analgesia, and hence oxygen should be routinely available.
- 8.2 The incidence of hypoxaemia is so high in patients having airway or upper gastrointestinal tract endoscopies that supplemental oxygen should be considered for all such patients.
- 8.3 Pulse oximetry estimates and monitors arterial oxygenation continuously and must be used in all patients during procedural sedation.

9 Specialized Equipment for Nitrous Oxide Sedation

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

- 9.1 The equipment must have a minimum oxygen flow of 2.5 litres/minute and a nitrous oxide flow of not more than 10 litres/minute, or in machines so calibrated, a minimum of 30% oxygen in the gas mixture. The equipment must be able to administer 100% oxygen.
- 9.2 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.

- 9.3 The breathing circuit must have a reservoir bag, and a non-return valve to prevent re-breathing.
- 9.4 The breathing circuit must provide low resistance to normal gas flows, and be of lightweight construction.
- 9.5 Installation and maintenance of any gas system must be according to appropriate standards.
- 9.6 Servicing of equipment and gases must occur on a regular basis and at least annually.
- 9.7 An appropriate method for scavenging of expired gases must be in use.
- 9.8 A low gas flow alarm or other gas failure alarms, if appropriate.
- 9.9 Occupational safety hazards such as chronic exposure to nitrous oxide should be considered.

10 Documentation

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

11 Recovery & Discharge

- 11.1 The patient should be monitored for an appropriate duration after the procedure in an area, which is adequately equipped and staffed for recovery care.
- 11.2 After adequate assessment, patient discharge should be authorized by the registered medical practitioner or registered dentist providing the sedation; or by another registered medical practitioner or registered dentist with proper delegation and handover.
- 11.3 Outpatients
 - 11.3.1 An outpatient should have a responsible adult to escort him/her home.
 - 11.3.2 Written information including possible complications and how to obtain medical advice, if and when required, should be given on discharge.
 - 11.3.3 The patient should be advised not to drive or operate machinery or sign legal documents for at least 24 hours.
 - 11.3.4 All instructions should be written.

Appendix 1

Emergency drugs should include at least the following:

Adrenaline
Atropine
Dextrose 50%
Flumazenil
Naloxone (if opioids are used)
Emergency O₂ supply

References

The following references provide evidence to support the recommendations made in this document.

- 1 Hong Kong College of Anaesthesiologists. Guidelines for safety in sedation for diagnostic and minor surgical procedures. 2002
- 2 Australian and New Zealand College of Anaesthetists, Gastroenterological Society of Australia, Royal Australasian College of Surgeons. Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical or Surgical Procedures. 2008
- 3 Australian and New Zealand College of Anaesthetists, Gastroenterological Society of Australia, Royal Australasian College of Dental Surgeons. Guidelines on Conscious Sedation for Dental Procedures. 2003
- 4 Hong Kong Hospital Authority. Guidelines for Sedation of Children in Diagnostic and Therapeutic Procedures. 2000
- 5 American Society of Anesthesiologists. Continuum of depth of sedation. Definition of General Anesthesia and Levels of Sedation/Analgesia. 2004.
- 6 American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists (Gross JB et al.). Practice guidelines for sedation and analgesia by non-anesthesiologists. *Anesthesiology* 2002; 96: 1004-1017
- 7 American College of Radiology (Towbin et al.). ACR practice guideline for adult sedation/analgesia. 2005 <www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/iv/adult_sedation.aspx>
- 8 Standards for Conscious Sedation in Dentistry: Alternative Techniques. A report from the Standing Committee on Sedation for Dentistry. Faculty of Dental surgery, the Royal College of Surgeons of England. The Royal College of Anaesthetists 2007

- End -

Approved by EC on 17.12.2009
Endorsed by Council on 22.12.2009