Guidelines for Safe Sedation for diagnostic and therapeutic procedures

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1. INTRODUCTION

A minimum standard of safety measures is recommended for the sedation of patients to facilitate unpleasant diagnostic or therapeutic procedures. 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]
“Guidelines on Monitored Care by an Anaesthesiologist” [P16]
"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.

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.

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, 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.

   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.

2.4 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);

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.

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 Adequate technical/nursing assistance as required.

4.3 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.

4.4 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 adequately equipped for cardiopulmonary resuscitation, including a source of oxygen with a suitable delivery system and a means of inflating the
lungs (e.g. Bag-valve-mask resuscitator), drugs for resuscitation and a range of intravenous equipment and fluids (appendix 1).

5.6 Is equipped with a tilting operating table, trolley or chair.

5.7 Is equipped with a pulse oximeter and monitoring devices for measurement of vital signs.

5.8 Permits easy access to a defibrillator.

5.9 Has adequate number of electrical outlets for essential equipment.

5.10 Has a system to collect and regularly review the location’s relevant sedation related information for quality assurance and auditing purposes.

All the facilities and equipment mentioned above should be age appropriate.

6. TECHNIQUE AND MONITORING

6.1 Reliable venous access should be in place for all procedures when sedation is used.

6.2 Drugs and syringes should be clearly labelled.

6.3 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.

6.4 There must be regular recording of pulse rate, arterial oxygen saturation and blood pressure throughout the procedure in all patients.

6.5 According to the clinical status of the patient, other monitors such as ECG or capnography may be required.

7. OXYGENATION

7.1 Oxygen administration diminishes hypoxaemia during procedures carried out under sedation or analgesia, and must 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 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

10.3 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

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

10.5 Outpatients

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

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

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

10.5.4 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

12. REFERENCE

- ANZCA Guideline on sedation and/or analgesia for diagnostic and interventional medical, dental or surgical procedures 2010
- Hong Kong Academy of Medicine - Guidelines on procedural sedation 2009