

Hospital Policy – Medical Affairs & Physicians Engagement

Procedural Sedation

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Objective

- 1.0** To detail the risk management strategies adopted by the hospital for patients (including children) who are given medications with the intent of inducing sedation for the performance of clinical procedures and to provide safeguards to manage unintentional progression into deep sedation.

Scope

- 2.0** This policy applies to all Medical Practitioners credentialed with the hospital and to all nursing staff in clinical areas where patients are given sedation for procedures. This policy is not intended to apply in the following settings:
- Administration of medication intended for deep sedation (refer definition 5.4.3).
 - General Anaesthesia (refer definition 5.4.4).
 - When medications are given at or below dosages recommended for pre-medication or minimal sedation (anxiolysis) (refer definition 5.4.5).
 - Management of pain before, after or unrelated to a diagnostic or therapeutic procedure.
 - Sedation used during the placement or maintenance of an artificial airway (e.g. Mechanical ventilation).
 - A single oral sedative or analgesic medication administered in doses appropriate for the unsupervised treatment of insomnia, anxiety or pain.

Policy

- 3.0** Policy
- 3.1** Sedation for patients undergoing procedures within the hospital may be administered by Credentialed Medical Practitioners who have been granted specific privileges for Procedural Sedation by the hospital.

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3.2 The Medical Practitioner administering the procedural sedation 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 Medical Practitioner should observe the relevant law, rules and regulations governing them in particular the Dangerous Drugs Ordinance.

3.4 The hospital recognises the fact that sedation used for the purpose of reducing discomfort to the patient for therapeutic or diagnostic procedures is not without risk because:

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

3.5 Hospital privileges to perform Sedation for Procedures

3.5.1 To administer Sedation for Procedures in the hospital, a Credentialed Medical Practitioner must meet the relevant competency requirements set down by the Hong Kong Academy of Medicine (refer to Appendix A).

3.5.2 Medical Practitioners, other than Anaesthesiologists, who apply for credentialing and who wish to be privileged for Procedural Sedation must demonstrate that they have an understanding of this policy.

3.5.3 Medical Practitioners, other than Anaesthesiologists, not credentialed as Paediatricians, and who have not been granted specific privileging in Sedation for Procedures in Paediatric Patients, shall not be permitted to order parenteral sedation for children.

3.6 Patient Education and Consent For Procedural Sedation

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3.6.1 The Medical Practitioner administering the procedural sedation shall be responsible for educating the patient (or other appropriate person if the patient is incapacitated or is a child, and unable to understand) on the risks, potential complications and alternatives of the planned sedation.

3.6.2 Informed consent for sedation and/or analgesia and for the procedure should be obtained. This consent shall form part of the Consent for Operation or Procedure form.

3.7 Assessment of Patient Prior to Procedural Sedation

3.7.1 All patients should be assessed before procedural sedation to confirm patient's suitability. The assessment should identify those patients with a serious medical condition¹ and/or those at increased risk of cardiorespiratory compromise (refer to para in 3.9.2).

3.7.2 Assessment should include:

- a relevant medical history and examination.
- an adequate explanation of the procedure and risks.
- 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.

3.7.3 The assessment shall be documented in the patient's medical record.

3.8 Technique

3.8.1 Medical Practitioners administering the sedation shall comply with contemporary standards and only use techniques and drugs commensurate with their training and experience.

¹ **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

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3.8.2 As most complications of sedation are cardiorespiratory, doses of sedative and analgesic drugs should be titrated according to patient response, especially for those patients at increased risk or with a slow circulation.

3.8.3 Oxygenation

3.8.3.1 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.

3.8.3.2 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.

3.8.3.3 Pulse oximetry estimates and monitors arterial oxygenation continuously and must be used in all patients during procedural sedation.

3.9 Monitoring During Procedural Sedation

3.9.1 All patients receiving sedation for a procedure shall have an appropriately trained assistant/nurse (refer to Appendix A) present to monitor and document the patients' condition during the procedure.

3.9.2 The attending Doctor must arrange to have an anaesthesiologist or an appropriately trained medical practitioner (refer to Appendix A) present to monitor the patient throughout the procedure if the patient has any serious medical condition, or is at increased risk of cardiovascular, respiratory or airway compromise during procedural sedation (refer to para 3.7.1).

3.9.3 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.

3.9.4 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.

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

3.9.6 According to the clinical status of the patient, other monitors such as ECG or capnography may be provided at the request of the Medical Practitioner administering the procedural sedation.

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- 3.9.7** The Medical Practitioner administering procedural sedation shall remain within the hospital premises until the patient has recovered from the sedation, is stable and breathing well.

3.10 Staffing

- 3.10.1** In addition to the medical and nursing staff required for the procedure there must be adequate technical/nursing assistance as required.
- 3.10.2** It is also good practice to have another appropriately trained medical practitioner or qualified nurse (refer to Appendix A) whose sole duty is to monitor the level of consciousness and cardio-respiratory status of the patient.
- 3.10.3** In the absence of additional dedicated personnel as specified in 3.10.2, the Medical Practitioner 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 becomes available.

3.11 Facilities & Equipment

- 3.11.1** All procedures should be performed in a location which has:
- adequate area to carry out the procedure and resuscitation should this be required;
 - adequate lighting and suction;
 - a source of oxygen and suitable devices for administering oxygen to spontaneously breathing patients; and
 - adequate provision to call for help.
- 3.11.2** The location will also be 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;
 - a pulse oximeter and monitoring devices for measurement of vital signs; and
 - ready access to an ECG and a defibrillator.

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3.11.3 The location must also be 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.

3.12 Specialised Equipment for Nitrous Oxide Sedation

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

- 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;
- 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;
- breathing circuit must have a reservoir bag, and a non-return valve to prevent re-breathing and provide low resistance to normal gas flows, and be of lightweight construction;
- installation and maintenance of any gas system must be according to appropriate standards;
- servicing of equipment and gases must occur on a regular basis and at least annually;
- appropriate method for scavenging of expired gases must be in use; and
- have low gas flow alarm or other gas failure alarms, if appropriate;

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

3.13 Documentation

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

3.13.2 A written record of medications administered, the dosages 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.

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3.13.3 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.

3.13.4 These can be documented in either the Sedation Record Form, the Anaesthesia Record Form or (in the case of procedures performed at the Radiology Dept.), the Radiology Care Record.

(Note: The option to document on the Anaesthesia Record Form applies only to Anaesthesiologists.)

3.14 Recovery and Discharge following Procedural Sedation

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

3.14.2 After adequate assessment, patient discharge should be authorised by the Medical Practitioner administering the procedural sedation; or by another Medical Practitioner with proper delegation and handover.

3.14.2 Discharged Home

3.14.2.1 In addition, patients who are to be discharged home following sedation for procedures should:

- have a responsible adult to escort him/her home;
- be advised not to drive or operate machinery or sign legal documents for at least 24 hours;
- be provided with written Post Procedure Discharge Advice, including information on possible complications and how to obtain medical advice, if and when required; and
- a 24-hour emergency contact telephone number provided.

3.14.2.2 All instructions should be provided verbally to the patient and in written form.

3.15 Adverse events monitoring

3.15.1 Adverse events occurring or following a procedure done under Sedation shall be reported through the Hospital Incident Reporting system.

3.15.2 HIR's relating to performance or compliance to hospital policy shall be tabled for discussion at the Patient Safety & Clinical Risk Management Subcommittee of the Clinical Governance Committee.

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Guideline

4.0 Emergency drugs

4.1 At least the following emergency drugs for resuscitation must be available at the location:

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

Reference

5.0 References

5.1 Legislation and Regulations

5.1.1 Cap 161 Medical Registration Ordinance

5.2 GHK Documents

5.2.1 SOP_GMA_006 Safe Anaesthetic Practice

5.3 JCI Standards

5.3.1 ASC.3 *Policies and procedures guide on the care of patients undergoing moderate and deep sedation.*

5.3.2 ASC.5.1 *The risks, benefits, and alternatives are discussed with the patient, his or her family, or those who make decisions for the patient.*

5.3.3 PFR.6.4 *Informed consent is obtained before surgery, anaesthesia, use of blood and blood products and other high-risk treatments and procedures.*

5.4 Definitions

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- 5.4.1 Sedation** 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

- 5.4.2 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

- 5.4.3 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.

- 5.4.4 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.

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- 5.4.5** Minimal Sedation (Anxiolysis) A drug induced state during which patients respond normally to verbal commands. Although cognitive function and co-ordination may be impaired, ventilatory and cardiovascular function are unaffected.

5.5 Others

5.5.1 Guidelines of the Hong Kong College of Anaesthesiologists:

- Guidelines on Monitoring in Anaesthesia.
- Guidelines for Post Anaesthetic Recovery Care.
- Recommended Minimum Facilities for Safe Anaesthetic Practice in Operating Suites.

(available at http://www.hkca.edu.hk/ANS/standard_publications/guidelines.htm)

Appendix

6.0 Appendix

- 6.1** *Appendix A* Hong Kong Academy of Medicine Guidelines on Procedural Sedation – Competency Requirements

Hong Kong Academy of Medicine Guidelines on Procedural Sedation (December 2009)

Competency requirements for registered medical practitioners 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 recognise the various depths of sedation, monitor the level of consciousness, cardio-respiratory status and other physiological parameters.
 - 5.4.1.6 Ability to recognise 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.

Competency requirements for assistant/nurse 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 recognise the adverse effects of drugs used in sedation
 - 5.5.1.3 Ability to recognise 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.