Summary of Amendment

Version 2.1  (Effective Date: 1st January 2020)

Since the Guidelines are applicable to adult patients only (as stipulated in point b. of the Preamble), a minor amendment for improving clarity is made on Page 1 in the paragraph after Section 1.1.7, as below:

“The focus of this set of Guidelines is on the use of “conscious (moderate) sedation”. In addition, the safety standards in this document are applicable to both adult and paediatric patients only. .”
Preamble

As the statutory body responsible for postgraduate medical education and specialist training in Hong Kong, the Hong Kong Academy of Medicine (the Academy) has been promoting improvement in professional standards of practice across different specialties. The “Guidelines on Procedural Sedation” was published by the Academy in 2009 with the aim to promote safe and evidence-based practices in procedural sedation.

In order to keep abreast of the latest development in procedural sedation, this set of “Guidelines on Procedural Sedation” has undergone revisions by a dedicated working group, and endorsed by the Academy’s Education Committee, that drew references from relevant guidelines recognized locally and internationally (as listed in the Reference section). Key changes from the 2009 version of the Guidelines are highlighted below:

a. The focus of the Guidelines is explicitly stated to be that on the use of “conscious (moderate) sedation”;

b. It is clarified that the Guidelines are applicable to adult patients only (aged 18 or above);

c. Definitions of conscious (moderate) sedation, deep sedation and general anaesthesia have been updated; “conscious (moderate) sedation” is clearly differentiated from “minimal sedation”;

d. Staffing requirements for procedural sedation have been reviewed and updated, with a clear emphasis that an appropriately trained staff is required for the monitoring of vital signs and procedural complications (in addition to the person performing the diagnostic and/or therapeutic procedure);

e. The provision of capnography for patient monitoring is considered necessary for high-risk patients receiving conscious (moderate) sedation or any deeper level of sedation where sudden unexpected loss of consciousness may occur;

f. The importance of the careful determination of drug dosages when administering intravenous conscious (moderate) sedation is emphasized and stipulated;

g. The necessity of proper training is explicitly stated in the Guidelines. Practitioners administering conscious (moderate) sedation should have received relevant training recognized by the Academy or its Colleges, in order to be equipped with the necessary competency requirements as specified;

h. It is specified that a mechanism should be in place for regular review and monitoring to ensure that sedations procedures are conducted to an appropriate standard.

This set of Guidelines is for guidance only and not intended to be prescriptive. Ultimately it is the clinical judgment of relevant practitioners on how to make use of the Guidelines, having regard to all relevant clinical circumstances.
1 Purpose of the Guidelines

Sedation is not without risk. This set of Guidelines of the Academy serves to recommend a minimum standard of safety measures when performing conscious (moderate) sedation for patients across different disciplines in order to mitigate the risks of sedation as far as is possible. A number of factors could affect the risks of sedation, which include, but are not limited to, the following:

1.1.1 The protective reflexes are obtunded under sedation and airway obstruction may occur at any time.

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

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

1.1.4 Unpredictable individual variance in response to drugs, especially in the elderly, the infirm, and those with underlying medical diseases.

1.1.5 The possibility that excessive amounts of sedatives may be used to compensate for inadequate analgesia.

1.1.6 The sedation may outlast the procedure.

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

The focus of this set of Guidelines is on the use of “conscious (moderate) sedation”. In addition, the safety standards in this document are applicable to adult patients only. Meanwhile, it is recommended to read this set of Guidelines in conjunction with the following guidelines issued by the Hong Kong College of Anaesthesiologists which are updated from time to time:

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


Individual specialties may usefully specify additional standards for specific areas of practice. However, subject to the approval by the Education Committee of the Academy, such additional standards should always be additive to and never subtract from those set out in this set of Guidelines.
2 Definitions

2.1 General
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.

The following are definitions of different sedation-related states.

2.2 Minimal sedation
Minimal sedation (or anxiolysis) is a drug-induced state during which the patient responds normally to verbal commands. Cognitive function and physical co-ordination may be impaired, but airway reflexes, and ventilatory and cardiovascular functions are unaffected.

2.3 Conscious (Moderate) Sedation
Conscious (Moderate) sedation is not minimal sedation. It is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

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

2.4 Deep Sedation
Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

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

2.5 General Anaesthesia
General Anaesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug induced depression of neuromuscular function. Cardiovascular function may be impaired.

General anaesthesia is sometimes indicated during diagnostic or interventional medical or surgical procedures, and requires the exclusive attention of an anaesthesiologist.
2.6 A comparison of characteristics across different states is listed below:

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

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

3 General Principles

3.1 This Guideline refers to procedural sedation under the target state of conscious (moderate) sedation only. This level of sedation may be achieved through careful titration of drug according to effect, and is considered a safe target state as airway, ventilation and cardiovascular functions are normally adequate and maintained. This Guideline does not apply to intended deep sedation or higher. When verbal responsiveness is lost and the patient becomes deeply sedated, ventilation may be inadequate and airway interventions may be required. In a state of deep sedation, the patient will require the same level of care as for general anaesthesia. (Refer to 3.6)

3.2 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 particular the Dangerous Drugs Ordinance.

3.3 The registered medical practitioner or dentist is ultimately responsible for the management of sedation, 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 ensuring patient safety.

3.4 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 or complications:

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.
3.4.1 Depression of protective airway reflexes and loss of airway patency.
3.4.2 Depression of respiration.
3.4.3 Depression of the cardiovascular system.
3.4.4 Drug interactions or adverse reactions, including anaphylaxis.
3.4.5 Individual variations in response to the drugs used, particularly in children, the elderly, and those with pre-existing medical diseases.
3.4.6 Risks inherent to the wide variety of procedures performed under procedural sedation and/or analgesia.
3.4.7 Risks associated with combinations of opioids and sedatives that are synergistic in depressing consciousness, respiration and cardiovascular function.
3.4.8 Unexpected extreme sensitivity to the drugs used for procedural sedation which may result in unintentional loss of consciousness, and respiratory or cardiovascular depression.
3.4.9 Risks associated with a patient with any serious medical condition\(^2\), or who is at increased risks of cardiovascular, respiratory and/or airway compromise during procedural sedation.

3.5 In general, medical / dental practitioners administering conscious (moderate) sedation should be able to manage patients who enter a state of deep sedation, whilst those administering deep sedation should be able to manage patients who enter a state of general anesthesia.

3.6 An anaesthesiologist or an appropriately trained medical or dental practitioner must be present to monitor the patient throughout the procedure if:
   (i) deep sedation is intended;
   (ii) the patient has any serious medical condition, 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 condition\(^2\), and/or those at increased risks of cardiorespiratory compromise as stated in section 3.4.9.

Assessment should include:
4.1 a relevant medical history (including medication and allergy history).
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.
4.4 an examination of the airway, respiratory and cardiovascular status, and other systems as indicated by the history.

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\(^2\) The American Society of Anesthesiologists’s classification of physical status (2014):

- **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

Reference: [https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system](https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system)
4.5 an assessment of whether conscious (moderate) sedation is appropriate (e.g. history of past sedation, setting of the institute) and whether conscious (moderate) sedation may be inadequate for some painful, complex, or more prolonged procedures.

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

It is preferred that the person doing the above patient assessment is the same person responsible for administering the sedation. If this is not possible, there should be a mechanism in place to ensure appropriate communication and handover. The one responsible for administering the sedation should understand well, and be satisfied with, the patient’s condition, and have checked the pre-sedation assessment be adequate or else a reassessment of the patient is required.

5 Staffing

5.1 In addition to the person responsible for the procedure, there must be:

5.1.1 An appropriately trained staff (registered medical practitioner / registered dentist / qualified nurse / dental surgery assistant) in monitoring vital signs and procedural complications,

5.1.2 Technical / nursing assistance as required.

5.2 Competency requirements for registered medical practitioners/dentists responsible for the sedation:

5.2.1 Registered medical practitioners/dentists responsible for the sedation shall undergo appropriate theoretical and practicum training recognized by HKAM or its Colleges (Appendix 2), and demonstrate the following core competencies:

5.2.1.1 Understanding of the sedation process and relevant safety aspects.

5.2.1.2 Ability to perform quality assurance measures of sedation practice e.g. practice review, clinical audit, self-assessment.

5.2.1.3 Expertise in using various sedative agents, analgesic agents and their respective antagonists safely and appropriately, taking into consideration the physical condition of the patient.

5.2.1.4 Ability to assess a patient's needs, risks and suitability for sedation.

5.2.1.5 Ability to recognise the various depths of sedation, monitor the level of consciousness, cardio-respiratory status and other physiological parameters.

5.2.1.6 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 function.

5.2.1.7 Ability to manage emergencies, rescue a patient from unintended deep sedation and manage the adverse effects listed in section 5.2.1.6 thereof.

5.2.1.8 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 the equivalent.

5.2.1.9 Ability to assess recovery from sedation and determine fitness for discharge of patients.

5.2.1.10 Registered medical practitioners/dentists responsible for the sedation shall also comply with contemporary standards in conducting conscious (moderate) sedation.
5.3 Competency requirements for qualified nurses/dental surgery assistants assisting in sedation process:

5.3.1 Qualified nurses/dental surgery assistants assisting in sedation process shall undergo appropriate theoretical and practicum training, and demonstrate the following core competencies:

5.3.1.1 General understanding of the sedation process and the involved drugs.
5.3.1.2 Ability to recognise the adverse effects of drugs used in sedation.
5.3.1.3 Ability to recognise the various depths of sedation, monitor the level of consciousness, cardio-respiratory status and other physiological parameters.
5.3.1.4 Ability to initiate immediate life support measures promptly.

5.3.2 Qualified nurses/dental surgery assistants assisting in sedation process shall comply with continuous education programmes, where appropriate.

5.3.3 The person providing sedation should ensure that the sedation is safely administered and monitored and that the associated risks are recognized and duly responded to.

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, a means of inflating the lungs, a supply of drugs for resuscitation, and a range of intravenous equipment and fluids;
6.5 is equipped with drugs for the reversal of benzodiazepines and opioids;
6.6 is equipped with a tilting operating table, trolley or chair unless it is technically impossible, wherein ready access to the above facilities for induction and recovery of sedation should be provided;
6.7 is equipped with a pulse oximeter and devices for the monitoring of vital signs;
6.8 is equipped with 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 the above facilities and equipment.

There must be an area for post-sedation recovery which is equipped with a patient couch and the necessary resuscitative equipment such as oxygen apparatus, suction, defibrillator, pulse oximetry and other monitoring facilities; and should have adequate physical space
for staff movement while monitoring the patient and for the treatment of complications, if any.

7 Technic...
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
10.1 The clinical record should include the names of staff performing sedation and documentation of the history, examination and investigative findings. A written record of the dosages of drugs used 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, during the procedures and the recovery phase, and should contain other information as indicated, such as details on sedation-related complications and any resuscitative procedure.

11 Recovery & Discharge
11.1 The patient should be monitored for an appropriate duration after the procedure in an area that is adequately equipped and staffed for recovery care and monitoring of patients, especially those who have become unconscious or suffered complications during the procedure.

11.2 After adequate assessment, patient discharge should be authorised 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 Facility where procedural sedation is administered on a regular basis is recommended to adopt a set of standard discharge criteria in order to facilitate a consistent and reliable assessment and a safe discharge.
11.4 Outpatients
   11.4.1 An outpatient should have a responsible adult to escort him/her home.
   11.4.2 Written information including possible complications and how to obtain medical advice, if and when required, should be given on discharge.
   11.4.3 The patient should be advised not to drive or operate machinery or sign legal documents for at least 24 hours following the end of the procedure.
   11.4.4 All instructions should be in writing.

12 Training
12.1 The underlying premise is that safety will be optimised only if practitioners use defined methods of sedation for which they have received proper training. Irrespective of educational background, the competencies required for safe sedation and, crucially, for managing patients from sedation-related adverse events, must be the same. Practitioners administering conscious (moderate) sedation as described in this set of Guidelines should have received relevant training recognized by the HKAM or its Colleges so as to be equipped with necessary competency requirements as given in Section 5.2 and 5.3. Details of the principles and guidelines for recognition of sedation-related training are given in the Appendix 2.

13 Regular Review
13.1 Respective organizations engaging practitioners for carrying out procedural sedation should establish a regular review mechanism to monitor the adequacy and appropriateness of sedation process conducted, with the aim to strive for continuous improvement of the practice.

14 References
1. Safe Sedation Practice for Healthcare Procedures: Standards and Guidance. (Published by Academy of Medical Royal Colleges, 2013)
2. Guidelines on sedation/or analgesia for diagnostic and interventional medical, dental or surgical procedures (Published by Australian and New Zealand College of Anaesthetists (ANZCA), 2014)
3. Guidelines on Sedation for Diagnostic and Interventional Procedures (Hong Kong East Cluster, Hospital Authority, 2015)
4. Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018 (Published by the American Society of Anesthesiologists, 2018)
## Appendix 1

### 15 Membership of the Working Group

<table>
<thead>
<tr>
<th><strong>Convener (HKAM):</strong></th>
<th>Prof. Gilberto Leung</th>
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<td><strong>Members:</strong></td>
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<tr>
<td>Hong Kong College of Anaesthesiologists</td>
<td>Dr. John Low</td>
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<td></td>
<td>Dr. Samantha Lee</td>
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<td>College of Dental Surgeons of Hong Kong</td>
<td>Dr. Wong Yiu Kai</td>
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<td>Hong Kong College of Physicians</td>
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<td>Dr. So Sheung On</td>
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<td>Dr. Hui Yee Tak</td>
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<td>Hong Kong College of Radiologists</td>
<td>Dr. Danny Cho</td>
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<td>Dr. Wong Kam Hung</td>
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<tr>
<td>The College of Surgeons of Hong Kong</td>
<td>Prof. Wong Kwok Chu</td>
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16 Principles and Guidelines for Recognition of Sedation-related Training

1. The following principles should be adopted by the Colleges when vetting the applications:

A. Training programmes or courses provided or organized / co-organized by the Academy or its constituent Colleges (inclusive of relevant training for specialist trainees) will be recognized by default (i.e. exempted from the vetting process), based on the understanding that such programmes or courses are designed according to the competency requirements specified in the Section 5.2 and Section 5.3 of the Guidelines, with proper approval by the relevant College’s Council and Education Committee of the Academy.

B. Training courses organized by entities other than the Academy or its constituent Colleges will need to go through the vetting process in order to be recognized by the Academy. Training organizers are required to submit relevant details to the Academy, including but not limited to the following:
   1. Structure of the training programme
   2. Training contents
   3. List of faculties and respective qualifications
   4. Learning objectives
   5. Provision of practicum, if any
   6. Means of assessment
   7. Duration of course
   8. Level of qualification / certification

Note: Training organizers are also recommended to refer to relevant international guidelines during the development of training contents, e.g. the exemplar core curriculum for the safe use of conscious sedation (Appendix 1 of the “Safe Sedation Practice for Healthcare Procedures: Standards and Guidance” published by Academy of Medical Royal Colleges, 2013)

C. A Vetting Committee comprising representatives from different Colleges will be established (as given in the following page), which will be responsible for vetting of training programmes or courses for recognition as required by the “Guidelines on Procedural Sedation”. The Committee will make recommendations to the Education Committee (EC) of the Academy on the suitability of such training courses and hence whether they should be recognized as proper training. The recommendations would be considered and approved by the EC of the Academy.

D. Vetting is preferably completed beforehand. Retrospective applications for vetting, if needed, should be made no later than 3 months after the course is held. Rerunning of recognized courses is exempted from the vetting process provided that there is no substantial change in course structure and content.
Appendix 2

Vetting Committee for Recognition of Sedation-related Training

A. Terms of Reference
   1. To vet applications for recognition of sedation-related training courses organized by entities other than Academy Colleges, with reference to the principles and guidelines approved by the Academy.

   2. To make recommendations to the Education Committee of the Academy on whether such training courses are considered suitable for recognition by the Academy as proper training in the context of procedural sedation.

   3. To regularly review the vetting mechanism / criteria, report to the Education Committee of the Academy, and seek its advice on any matters associated with the vetting process.

B. Proposed Membership
   Members are appointed by the Education Committee of the Academy, with the following composition:

   Chairman: To be elected by and from among members
   Members: One representative from each of Academy Colleges
             (as nominated by respective Colleges wishing to do so)
             One representative from HKJC ILCM

C. Term of Office
   Two years

D. Meeting frequency
   Every 6 months, or on need basis. Business can be transacted and approved via circulation by the rule of simple majority (and the casting vote by the Chairman in case of equal vote, if needed).