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REVIEW PAPER

Guidelines on Safe Sedation Practice for Non-Anaesthesiologists in Medical & Dental Clinics, Stand-Alone Ambulatory Surgical Centres, and Stand-Alone Endoscopy Suites in Singapore

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EXECUTIVE SUMMARY

- 1. The administration of sedation by non-anaesthesiologists for some procedures performed in medical/dental clinics, stand-alone ambulatory surgical centres and stand-alone endoscopy suites is practised in Singapore.**
- 2. A task force was initiated by MOH and led by the College of Anaesthesiologists, with representatives from the other Chapters and Colleges, to update the 2014 guidelines on the practice of sedation in medical/dental clinics, stand-alone ambulatory surgical centres and stand-alone endoscopy suites.**
- 3. As far as possible, the guidelines aim to guide non-anaesthesiologists in providing sedation safely to patients undergoing procedures in medical/dental clinics, stand-alone ambulatory surgical centres and stand-alone endoscopy suites. The guidelines do not cover the practice of palliative sedation or procedures done under sedation in hospitals such as its emergency departments, its ambulatory surgical centres, endoscopy suites or its clinics.**
- 4. These guidelines relate to the practice of sedation and focus on key areas such as training of non-anaesthesiologist sedationists, patient selection, monitoring of the sedated patients and the post-procedural management of such patients.**
- 5. We have included in this update the safe use of nitrous oxide in dental and medical clinics.**
- 6. This set of guidelines is based on careful consideration of the available evidence, professional regulations and other relevant information that has been developed through consultation with experts and practitioners. As guidelines, these do not override the healthcare professionals' rights and duty to make decisions that are in the best interests of each patient with their valid consent.**

1. INTRODUCTION

- 1.1 The aims of procedural sedation and analgesia are to ensure patient safety and comfort during the planned procedure. Options available range from minimal sedation through moderate sedation to deep sedation. ^(1,2,3,4)
- 1.2 Sedation can be performed either by an anaesthesiologist or a non-anaesthesiologist.
- 1.3 Non-anaesthesiologists shall limit their sedation techniques to achieve a level of minimal or moderate sedation as defined by the American Society of Anaesthesiologists (ASA). ⁽⁵⁾ However, moderate sedation for patients must only be undertaken by teams that have had adequate training and experience. Deep sedation can only be performed by an anaesthesiologist.
- 1.4 Adequate sedation is required for patient comfort and adequate monitoring of the sedated patient is necessary as morbidity has occurred from inadvertent excessive sedation. ^(6,7)
- 1.5 The use of propofol for sedation by non-anaesthesiologists is an area of concern as the drug has a low safety margin and may easily induce a deeper level of sedation than intended. Clinicians need to be adequately trained to recognize and rescue patients from these deep levels of sedation. In medical/dental clinics, standalone ambulatory surgery centres and standalone endoscopy suites, the **use of propofol should be limited to anaesthesiologists**. ^(8,9,10,11,12,13,14,15)
- 1.6 The purpose and need for sedation must be discussed with the patient or the legally responsible adult for patient under 21 years old prior to the procedure. Alternatives to moderate sedation must be offered and discussed. This shall include the option of having an anaesthesiologist perform the sedation. The option of General Anaesthesia can also be discussed with an anaesthesiologist.
- 1.7 Analgesia shall be given for painful procedures. Inducing a deeper level of sedation is not a substitute for adequate analgesia. Patients must be counseled on the possibility of some discomfort and pain during the procedure. Doses of sedatives and analgesics should be given in a titrated manner and kept to the minimum for patient comfort. If the patient is unable to tolerate the procedure under moderate sedation, then other options including having an anaesthesiologist perform the sedation should be discussed with the patient.
- 1.8 Proper and clear documentation must be maintained at all times before, during and after the procedure, including fitness for discharge.

2. DEFINITIONS

- 2.1 Sedation and analgesia result in a continuum of states ranging from minimal sedation (anxiolysis) to general anaesthesia as follows: ⁽¹⁵⁾ (Annex A)

Minimal Sedation (Anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway, ventilation and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia (“Conscious Sedation”) 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 without pharmacologic intervention.

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.

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 respiratory function or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

As sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, the proceduralist and/or sedationist (see definition below) must be able to rescue a patient whose level of sedation becomes deeper than initially intended.

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

Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. *The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level of sedation. It is not appropriate to continue the procedure at the unintended deeper level of sedation.*

2.2 Definitions of Medical Professionals and Medical Clinics

A **Medical Practitioner** refers to a person who is registered with the Singapore Medical Council (SMC) under the Medical Registration Act (Cap. 174).

A **Dental Practitioner** refers to a person who is registered as a Division I dentist under the Dental Registration Act (Cap. 76).

An **Anaesthesiologist** refers to a medical practitioner who is registered with the SMC on the Register of Specialists as an anaesthesiology specialist.

A **Registered Nurse (RN)** refers to a person who is registered as a registered nurse with the Singapore Nursing Board (SNB) under the Nurses and Midwives Act (Cap. 209).

Under the Private Hospitals and Medical Clinic (PHMC) Act (Cap. 248)*, **“Medical Clinic”** means any premises used or intended to be used by a medical practitioner, a dentist or

*References to the PHMC Act and Regulations will be superseded by the Healthcare Services Act (HCSA) and its Regulations when they come into force for Medical & Dental Clinics, Stand-Alone Ambulatory Surgical Centres and Stand-Alone Endoscopy Suites from mid-2022.

any other person:

- a) for the diagnosis or treatment of persons suffering from, or believed to be suffering from, any disease, injury or disability of mind or body; or
- b) for curing or alleviating any abnormal condition of the human body by the application of any apparatus, equipment, instrument or device requiring the use of electricity, heat or light, but does not include any such premises —
 - i. which are maintained by the Government or the National University of Singapore; or
 - ii. which form part of the premises of a licensed private hospital.

“Stand-Alone Ambulatory Surgical Centres” refer to medical clinics that are approved to provide ambulatory surgery as a special care service under Regulation 37 and Third Schedule of the PHMC Regulations*.

“Stand-Alone Endoscopy suites” refer to medical clinics that are approved to provide endoscopy as a special care service under Regulation 37 and Third Schedule of the PHMC Regulations*.

2.3 Terms used in guidelines

For the purpose of these guidelines, the following definitions are used:

A **Sedationist** refers to the person who administers the sedation and is responsible for monitoring of the patient during the procedure. Depending on the circumstances (*Annex B*), such a person may be an anaesthesiologist or medical/dental practitioner. Where the sedation is administered by a registered nurse (RN) with a valid practicing certificate (referred to as “nurse sedationist”), he/she shall only do so under supervision of the medical practitioner performing the therapeutic or diagnostic procedure, i.e. the proceduralist (see below) and the supervision must be in person. If a separate physician from the proceduralist is supervising the nurse sedationist, this must be done in-person on the condition the physician is competent and suitably qualified to provide sedation.

A **Proceduralist** refers to the medical/dental practitioner who performs the therapeutic or diagnostic procedure.

Neonates refer to persons from birth to 28 days old (inclusive).

Child/Paediatric refer to persons 12 years of age and below but **above 28 days**

Elderly refers to persons aged 65 years and above.

3. SCOPE OF GUIDELINES

3.1 All medical/dental clinics, stand-alone ambulatory surgical centres and stand-alone

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endoscopy suites, carrying out procedures that involve the practice of sedation by non-anaesthesiologists shall adhere to these guidelines, including the matrix in *Annex B* which summarises the personnel required and appropriate premises for various levels of sedation. The guidelines apply to procedural sedation for adult and paediatric patients in these clinics, unless otherwise specified. The guidelines do not cover the practice of palliative sedation or procedures under sedation in hospitals such as its emergency departments, its ambulatory surgical and endoscopy centres or its clinics.

- 3.2 The choice of sedatives and sedation techniques is dependent on the experience and preference of the individual non-anaesthesiologist sedationist, requirements or constraints imposed by patient factors, preference, the procedure and the risk of producing a deeper level of sedation than anticipated.
- 3.3 As it is not always possible to predict how each patient will respond to sedatives and analgesics, medical/dental practitioners intending to provide a given level of sedation must be able to rescue patients whose level of sedation becomes deeper than initially intended. Specifically, for moderate sedation, this means the ability to manage a compromised airway or hypoventilation.

4. ROLE OF SEDATIONIST / PROCEDURALIST

- 4.1 Only medical/dental practitioners who are qualified by education, training and/or accreditation as per institutional policy and procedures to administer moderate sedation shall administer the sedation or supervise a registered nurse to administer the sedation in medical/dental clinics, stand-alone ambulatory surgical centres and stand-alone endoscopy suites. ^(9, 16,17,18)
- 4.2 Where moderate sedation is administered, the practitioner performing the procedure (i.e. proceduralist) must be distinct from the person monitoring the patient (i.e. sedationist). The latter shall solely be involved in administering the sedation and monitoring the sedated patient and shall not perform any other tasks such as assisting with the procedure.
- 4.3 Deep sedation must not be administered in medical/dental clinics, stand-alone ambulatory surgical centres and stand-alone endoscopy suites unless it is administered by an anaesthesiologist.
- 4.4 Sedation must NOT be administered to neonates in medical/dental clinics, stand-alone ambulatory surgical centres and stand-alone endoscopy suites.

5. EDUCATION AND TRAINING

- 5.1 The sedationist must have adequate and specific training in:
 - a. Safe administration of sedation
 - b. Monitoring of patient under sedation
 - c. Management of complications arising from sedation
 - d. Proper documentation of sedation

- 5.1.1 The training may be:
- a. Part of relevant specialist training program
 - b. Fellowship (e.g. HMDP)
 - c. Specific training program not part of above (eg), Paediatric Sedation Advanced Life Support (PSALS) which provides training on paediatric advanced life support skills in sedation

See *Annex C: Aims and Objectives of Training in Sedation* ^(9, 17,18,19, 20)

- 5.2 All staff involved in sedation, including the proceduralist, shall be trained and shall maintain currency in Basic Cardiac Life Support (BCLS). Whenever moderate sedation is carried out in the absence of the anaesthetist, there must be a proceduralist, sedationist or another healthcare practitioner who is trained and current in airway management and advanced resuscitation skills (e.g. Advanced Cardiac Life Support (ACLS) or its equivalent) present in the premises and able to attend to the sedated patient immediately. This would not apply to minimal sedation involving either (a) less than or equal to 50% nitrous oxide (N₂O) in oxygen with no other sedative or analgesic medications by any route, or (b) a single, oral sedative or analgesic medication administered in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain. ^{2,4, 9,17, 18}
- 5.3 Where minimal to moderate sedation is administered to paediatric patients above the age of 28 days old, it is **mandatory** that the proceduralist or sedationist is competent and current in advanced resuscitation skills (e.g. Advanced Paediatric Life Support Course or its equivalent). ^(21,22)
- 5.3.1. If nitrous oxide is used for minimal sedation (as a single agent and ≤50% nitrous oxide) in paediatric patients, it is mandatory that the dental practitioner receive and keep current in the training of airway management and resuscitation skills including the use of a bag valve mask. Such hands-on training may be part of an advanced life support course or equivalent, or other accredited course that offers airway management skills training.
- 5.4 All nursing staff involved in the procedure must have a valid BCLS and be competent with basic resuscitation skills.

6. PATIENT SELECTION AND PRE-SEDATION ASSESSMENT

- 6.1 Sedation for procedures performed in medical/dental clinics shall be limited to uncomplicated procedures. In painful procedures, additional forms of pain relief should be considered rather than increasing sedation.
- 6.2 Patients must be properly evaluated by the medical/dental practitioner prior to the sedation. These should include 1) review of previous medical records and taking the relevant history from the patient or relatives; 2) a focused physical examination of the patient; and 3) review of available laboratory test results as indicated.
- a) Recommendations for Patient Evaluation (which include but are not limited to the following)

- Abnormalities of the major organ systems (e.g. cardiac, respiratory, renal, neurologic, sleep apnoea, metabolic, endocrine, congenital)
 - Conditions predisposing to aspiration (of stomach content) risk
 - Difficult airway
 - Adverse experience with sedation/analgesia, regional and general anaesthesia
 - Concomitant medications especially those that may interact with sedatives/analgesics
 - History of smoking, alcohol, substance abuse and/or drug allergies
 - History of prematurity (younger than 60 weeks postconceptional age) and apnoea of prematurity
 - Frequent exposure to sedation/analgesia
 - Presence of contraindications to sedation or drugs to be used in sedation (sedatives)
- 6.3 Patients with significant underlying conditions that are deemed to be at high risk of complications from sedation shall not be sedated by non-anaesthesiologists in medical/dental clinics, stand-alone ambulatory centres and stand-alone endoscopy suites.
- 6.4 Paediatric patients above the age of 1 year and assessed to be suitable as per 6.2 can be given medications for mild to moderate sedation in medical/dental clinics by a proceduralist/sedationist. ^(23,24,25) Sedation for paediatric patients above the age of 1 year in medical/dental clinics shall only be administered via the oral or inhalation route.
- 6.5 Paediatric patients above 28 days and below the age of 1 year and assessed to be suitable as per 6.2 can only be given Oral Syrup Chloral by proceduralist/sedationist.

7. PATIENT PREPARATION

- 7.1 A written informed consent for moderate sedation must be obtained from the patient or the legally responsible adult (e.g. for the patient under 21 years old). The consent form shall, at minimum, include the risks, benefits and alternatives to moderate sedation. *Counselling regarding discharge should be carried out prior to the procedure.* The possibility of reversal of the state of sedation and abandonment of the procedure in the event of complications must also be explained.
- 7.2 The patient or the legally responsible adult (particularly for a paediatric patient) shall be given an option to be sedated by an anaesthesiologist.
- 7.3 An adequate preoperative fasting period must be observed by the patient prior to the administration of any sedation. The period of fasting may vary with the age of the patient. Adequate fasting prior to the procedure and sedation is required as per fasting guidelines. ^(26,27,28)

Fasting Guidelines for adults & paediatric patients

(College of Anaesthesiologists Singapore Fasting Guidelines)

Ingested Material	Recommended Minimum Fasting Period (hours)
Clear liquids (e.g. water, fruit juices without pulp, carbonated beverages)	2 h
Breast milk	4 h
Infant formula	4-6 h
Non-human milk	6 h
Light meal (e.g. toast and clear liquids)	6 h
Fried, fatty food, meats	8 h

- 7.4 Prior to the administration of sedation, patients shall be advised that a prolonged period of impaired cognition may occur. The patient shall be advised about eating, driving, drinking, operate heavy or potentially harmful machinery or make legally binding decisions *while under the influence of the sedation*. If sedatives have been administered, the patient shall be advised that for safety reasons, a responsible adult must accompany him/her home.
- 7.5 A reliable continuous venous access shall be in place when intravenous sedation is used.
- 7.6 There should be a protocol established and maintained for immediate activation of Emergency medical services/ambulances for life-threatening complication.

8. INTRA-PROCEDURAL MONITORING OF SEDATED PATIENTS

- 8.1 During the procedure, all sedated patients must be monitored with respect to their vital signs, which shall include, but not limited to, the following:
- a) Clinical observation
 - i. Level of consciousness (e.g. For paediatric patients: a sedation scale to assess the depth of sedation intra-procedural and post-procedural) ^(29,30,31,32)
 - ii. Respiratory rate and pattern of breathing
 - b) Physiologic Monitoring
 - i. Continuous pulse oximetry ^(33,34,35)
 - ii. Continuous heart rate
 - iii. Blood pressure every 5 minutes
 - iv. Electrocardiography where appropriate ^(36,37,38)
 - v. End tidal carbon dioxide monitoring by continuous capnometry where appropriate ^(39,40,41,42)
- 8.2 Audible alarms and pulse oximeter tone on the physiologic monitors must be activated and switched on throughout the period of sedation.

9. POST-PROCEDURAL MANAGEMENT

- 9.1 After completion of the procedure, the patient must continue to be monitored at 15-minute intervals with respect to their vital signs as specified in section 8, and for adverse effects from either the procedure or sedation. The length of the post-procedural monitoring period/ recovery period must be commensurate with the perceived risk to the patient. ^(43,44,45)

Fitness for discharge of the patient should be authorized by the practitioner who administered the drugs or another appropriately qualified personnel.

Recommendations for discharge of the patient after sedation:

- a) Has been certified medically fit for discharge
 - b) Patent airway without respiratory depression
 - c) Return to baseline vital signs
 - d) Return to baseline motor function
 - e) Return to baseline level of consciousness
 - f) Adequate hydration and control of nausea and vomiting
 - g) Adequate pain control
 - h) A responsible adult to accompany patient home (it is preferable to have 2 accompanying adults if one adult is providing the transport for child who still requires car safety seat because of the risk of airway compromise if the child is left alone in the seat)
- 9.2 Verbal and written post-procedural instructions must be given to the patients and the responsible adult accompanying them at the time of discharge. These shall, at minimum, include instructions on the signs and symptoms of potential adverse outcomes. A 24-hour contact number in case of emergencies shall also be provided.
- 9.3 Good documentation practices must be in place to ensure the safe transfer of patients from the medical/dental clinic to an appropriate medical care facility should the need arise. A standardised operating protocol should be in place for emergencies arising from the sedation and the activation of emergency services.

10. MEDICAL FACILITIES

10.1 Equipment

The following must be available:

- a) Resuscitation equipment (that are age appropriate) which must be functional and effective at all times. See para 7.6 of the Specific Guidelines for Medical Clinics under

the PHMC Act (1980) and Regulations (1991)**.

- b) All drugs must be properly labelled with the expiry dates clearly shown.
- c) All physiologic monitors must be switched on and in full working order during the period that requires monitoring.
- d) Oxygen therapy equipment must be fully functional and provide an adequate supply of oxygen.
- e) All operating tables and patient trolleys must be able to be tilted in the head-down position.

10.2 Physical space

There must be a recovery area. The recovery area must be:

- a) Equipped with a patient's couch and the necessary resuscitative equipment such as oxygen apparatus (oxygen source and oxygen delivery devices), suction, defibrillator, pulse oximetry and other monitoring facilities;
- b) Adequate for staff movement while monitoring the patient and for the treatment of complications, if any.

10.3 There must be means of summoning emergency assistance when necessary (e.g. phone, intercom etc.).

11. SEDATIVE AGENTS

11.1 All proceduralists and/or sedationists must be fully familiar with the use and pharmacology of all sedative drugs, and the indications and contraindications for these medications. ^(46,47) All proceduralists and sedationists must demonstrate competence in the use of sedative agents and the recognition and management of complications from their administration. ^(48,49)

11.2 The choice of sedative drugs is largely operator dependent. The medications chosen by the proceduralists and sedationists remain bounded by the prescribing indications, contraindications and precautions set by Health Sciences Authority (HSA).

11.3 Where benzodiazepines are used either alone or in combination with an opioid for sedation, the proceduralists and sedationists shall comply with the Ministry of Health Clinical Practice Guidelines on the prescription of benzodiazepines (MOH Clinical Practice Guidelines 2/2008), where relevant.

11.4 When opioids are used, antagonists like Naloxone must be available and the proceduralists and sedationists shall comply with the National Guidelines for the Safe Prescribing of Opioids 2021⁵⁰. When benzodiazepines are used, antagonists like

Guidelines for Medical Clinics Under the PHMC Act (1980) and Regulations (1991)

*GL7.6 - Every medical clinic shall have:

- a) resuscitation facilities for emergencies and adverse reactions to any form of treatment provided;
- b) means to set up an intravenous infusion; and
- c) means to maintain a clear airway.

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Flumazenil must be available.

- 11.5 Sedation for paediatric patients in medical/dental clinics shall only be administered via the oral or inhalational route
- 11.6 A source of oxygen must be readily available. Patients shall receive oxygen throughout the period of the procedure and recovery. ^(51,52,53)

12. NITROUS OXIDE

12.1 Nitrous Oxide is commonly used as an anxiolytic agent for dental treatment in children and adults with dental fear and anxiety

12.2 Nitrous Oxide sedation use in Dentistry ^(54,55,56,57,58,59,60,61)

i. Indications

- A fearful and anxious patient
- Certain patients with special health care needs who cannot communicate
- A patient with prominent gag reflex
- A patient for whom profound local anaesthesia cannot be given
- A child who can comprehend and cooperate with the practitioner on the use of a face mask or prongs while undergoing a lengthy dental procedure

ii. Contraindications ⁽⁵⁴⁾

- Chronic obstructive pulmonary diseases
- Current upper respiratory tract infections
- Pneumothorax
- Bowel obstruction
- Recent middle ear disturbance/surgery within past week
- Recent neurosurgical interventions within past week
- Severe emotional disturbances or drug-related dependencies
- First trimester of pregnancy
- Treatment with bleomycin sulfate
- Methylene tetrahydrofolate reductase deficiency
- Cobalamin (vitamin B12) deficiency
- Inability to breathe through the nose ⁽⁵⁵⁾

12.3 Level of sedation ^(54,55)

a) Use of nitrous oxide for minimal sedation

- The use of nitrous oxide for minimal sedation is defined as the administration of nitrous oxide of $\leq 50\%$ with the balance as oxygen, without any other sedative,

opioid, or other depressant drug before or concurrent with the nitrous oxide to an otherwise healthy patient.

- Patients may become moderately sedated despite the intended level of minimal sedation; should this occur, the guidelines for moderate sedation apply.

b) Use of nitrous oxide for moderate sedation

- If nitrous oxide in oxygen is combined with other sedating medications, such as chloral hydrate, midazolam, or an opioid, or if nitrous oxide is used in concentrations >50%, this is considered moderate sedation, and the likelihood of deep sedation increases. In this situation, the practitioner is advised to institute the guidelines for moderate or deep sedation, as indicated by the patient's response.

12.4 Personnel

Nitrous oxide/oxygen inhalational sedation should only be administered by a dental practitioner trained in its use. The dental practitioner shall possess appropriate training and skills, and have proper facilities, personnel, and equipment to manage any reasonable foreseeable emergency. The practitioner is responsible for managing the potential complications associated with the intended level of sedation and the next deeper level.

12.4.1 Training for minimal sedation

a) Dental Practitioner who uses nitrous oxide for minimal sedation should receive training with the following didactic content:

- Physiology and pharmacology of nitrous oxide
- Effects of nitrous oxide
- Use of nitrous oxide for behavioral management: rationale and objectives
- Indications and contraindications
- Technique of nitrous oxide/oxygen administration
- Monitoring and documentation
- Recognition and management of adverse effects
- Facilities/personnel/equipment
- Occupational safety ⁽⁶¹⁾

b) Training on resuscitation skills follow that of section 5.2 and 5.3

c) Dental practitioner may receive training as:

- (i) Part of a relevant specialist training programme (accredited by the Singapore Dental Specialty Accreditation Board (DSAB)) which offers hands-on and didactics on nitrous oxide sedation in its curriculum (e.g NUS Paediatric dental trainees as part of Specialist Training Programme)
- (ii) Fellowship or post-graduate course (e.g. HMDP that provides

certification in sedation)

- (iii) Specific programme by trained medical/dental practitioner not part of the above (e.g. Nitrous oxide sedation CDE/CME programmes or part of the curriculum of basic dental degrees)
 - A documentation/proof (e.g. a letter of support from course director/faculty), including core syllabus, should be available upon request, as a record that the practitioner is competent in the use of nitrous oxide sedation and he/she has used nitrous oxide on at least 3 patients under supervision. Supervision may be given by dental practitioners in 12.4.1(c) (i and ii), or during the course by course director/faculty/instructors of 12.4.1(c)(iii).

12.4.2 Training for moderate sedation

- a) Dental practitioner who uses nitrous oxide for moderate sedation should receive relevant training as:
 - (i) Part of a relevant specialist training programme (accredited by the Singapore Dental Specialty Accreditation Board (DSAB)) which offers hands-on and didactics on nitrous oxide sedation as a moderate sedative agent in its curriculum
 - (ii) Fellowship/post graduate course (e.g. HMDP that provides certification in sedation)
- b) Training on resuscitation skills follow that of section 5.2 and 5.3.

12.5 All dental practitioners who use nitrous oxide at any sedation level should be trained in sedation equipment handling.

12.6 Dental auxiliary staff (including dental surgery assistant (DSA), oral health therapist (OHT), dental assistant (DA)) assisting dental procedures at any level of sedation must be competent with basic resuscitation skills (eg. Basic Cardiac Life Support (BCLS) or its equivalent) and have gone through hands-on training on sedation equipment handling.

12.7 Fasting is not required for patients undergoing minimal sedation using nitrous oxide. However, the practitioner may recommend that only a light meal be consumed in the two hours prior to the administration of nitrous oxide. ⁽⁵⁵⁾

12.8 Dental practitioners using nitrous oxide/oxygen for any level of sedation should adhere to the guidelines with regards to pre-sedation assessment, patient preparation, intra-operative monitoring of sedated patients, post-procedural patient management, compliance to having the relevant medical facilities, and keep proper documentations. (See section 6 to 10, and 14)

12.9 Equipment Requirement ^(54,55)

- a) When nitrous oxide is used to provide sedation, risks of chronic exposure should be considered and the following requirements must be satisfied.
- b) The inhalational equipment must have:

- (i) The capacity for delivering 100 percent, and never less than 30 percent, oxygen concentration at a flow rate appropriate to the child's size.
- (ii) A fail-safe system that is appropriately checked and calibrated: either a functioning device that prohibits the delivery of less than 30% oxygen or an appropriately calibrated and functioning in-line oxygen analyser with audible alarm
- (iii) An appropriate scavenging system to minimize room air contamination and occupational risk.
- (iv) A pre-procedural check of equipment for each administration of sedation must be performed. The system components, including the reservoir bag, should be inspected routinely for cracks, wear, and tears. Pressure connections should be tested for leaks when delivery system is turned on and each time a tank is changed.
- (v) A positive pressure oxygen delivery system suitable for patient being treated must be immediately available. The practitioner should only use dedicated purpose designed machines for the administration of nitrous oxide for dentistry that are maintained according to the manufacturers' guidance with regular documented servicing. This includes manufacturers recommended user maintenance, cleaning and infection prevention and control measure. Gas tanks/cylinders must be safely and securely stored.
- (vi) The design of the clinic must take into account that ventilation and scavenging of waste gases are sufficiently effective to meet with NEA standards.
- (vii) An emergency cart/kit must be readily accessible. Emergency equipment must be able to accommodate children of all ages and sizes. It should include equipment to resuscitate a non-breathing, unconscious patient and provide continuous support until trained emergency personnel arrive.
- (viii) There should be documentation that sedation equipment, monitors, delivery and scavenging systems is regularly maintained according to manufacturer's recommendations. All emergency equipment and drugs are checked and maintained on a regular scheduled basis.

13. PROPOFOL

13.1 Propofol (di-isopropylphenol) is a potent anaesthetic drug. It has been widely used for sedation in sub- anaesthetic doses. Overdose of the drug can lead to severe respiratory and cardiovascular compromise.

13.2 Propofol must only be administered by a medical practitioner trained in its use because it has:

- a) Potential to cause rapid and profound changes in the sedative/anaesthetic depth;
- b) No specific antagonist;
- c) Marked synergy with other sedative drugs;
- d) Resulted in deaths when infused at higher than recommended doses over a prolonged period of time.

13.3 Propofol shall **NOT** be used in medical/dental clinics unless it is

13.3.1 administered by anaesthesiologists; **and**

13.3.2 for the purposes of procedural sedation. (12,13,14,16,17,18,47,63,64,65)

14. DOCUMENTATION

14.1 Contemporaneous recording of monitored parameters and detailed records pertaining to the patient shall be properly kept. At minimum, these shall include the following:

- a) Names of all staff involved in the sedation and procedure;
- b) History, physical examination and investigations of the patient;
- c) Dosages and timing of drugs administered;
- d) Monitored vital signs at 5-minute intervals during the procedure and 15-minute intervals during recovery (electronic printout if available);
- e) Any adverse event(s) and interventions performed, including the dosages and timing of resuscitation drugs;
- f) Recovery status of the patient; and
- g) Fitness for discharge.

15. AUDIT

15.1 Facilities carrying out sedation and/or analgesia should have in place a system for audit of outcomes related to sedation and include these outcomes and any complications in quality assurance and peer review processes. These audits should form the basis of ongoing training, education and support of all team members involved in the care of patients undergoing sedation. (Refer to Annex D for sample checklist.)

15.2 Practitioners should report morbidity and mortality related to sedation according to jurisdictional requirements. These are particularly important when an intended sedation episode resulted in an adverse outcome.

ANNEX A: DEFINITIONS OF GENERAL ANAESTHESIA AND LEVELS OF SEDATION/ANALGESIA

	Minimal Sedation (Anxiolysis)	Moderate Sedation/Analgesia (Conscious sedation)	Deep Sedation/Analgesia	General Anaesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful response to verbal or tactile stimulation	Purposeful response after repeated or painful stimulation	Unarousable, even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

ANNEX B: SUMMARY OF PERSONNEL REQUIRED AND APPROPRIATE PREMISES FOR VARIOUS LEVELS OF SEDATION

Level of Sedation	Minimal Sedation	Moderate Sedation/ Analgesia	Deep Sedation/ Analgesia	General Anaesthesia	
Sedative Agents					
Propofol	Proceduralist and Sedationist must be 2 distinct persons – Proceduralist: (Medical / Dental Practitioner) Sedationist: (Anaesthesiologist)				Adult patients
Sedative drugs other than propofol	Proceduralist and Sedationist may be the same person	Proceduralist and Sedationist must be 2 distinct persons	Proceduralist and Sedationist must be 2 distinct persons –		
	Proceduralist (Medical/Dental practitioner)	Proceduralist (Medical/Dental Practitioner)	Proceduralist (Medical/Dental Practitioner)		
	Sedationist (same or different medical/dental practitioner)	Sedationist (Different Medical/Dental Practitioner or Registered Nurse administering sedative drugs under supervision in-person by the proceduralist or another physician)	Sedationist (Anaesthesiologist)		
Appropriate premises at which sedative agents can be used	All Medical / Dental Clinics			Standalone Ambulatory Surgical Centres /Standalone Endoscopy Suites	Paediatric patients above 28 days
	All Medical / Dental Clinics <i>*Sedation for paediatric patients in medical/dental clinics shall only be administered by oral or inhalational route. Please refer to section 6.4, section 11 and Annex C.</i>		Shall not be administered in medical / dental clinic setting		

ANNEX C: AIMS AND OBJECTIVES OF TRAINING IN SEDATION

The medical practitioner who aims to be certified to perform sedation safely shall have the requisite knowledge and skills.

TRAINING FOR MODERATE SEDATION

KNOWLEDGE

COMPETENCY DESCRIPTION

Can understand

- i. What is meant by conscious sedation as opposed to deep sedation and general anaesthesia
- ii. How to recognize the patient at risk e.g. difficult airway with high risk of airway obstruction that cannot be corrected without advanced airway management skills
- iii. the need for and means of monitoring the sedated patient including the use of commonly used sedation scales (eg Ramsay Sedation Scale, University of Michigan Sedation Scale, Children's Hospital of Wisconsin Sedation Scale)
- iv. the pharmacology of drugs commonly used to produce sedation
- v. how drugs should be titrated to effect and how the use of multiple drugs with synergistic actions can reduce the therapeutic index and hence the margin of safety
- vi. the importance of recognising the following when multiple drug techniques are employed:
 - Increased potential for adverse outcomes when two or more sedatives/analgesics are administered together and the importance of titrating them to effect
 - Knowledge of each drug's time of onset, peak effect, duration of action and potential for synergism leading to unpredictable responses
 - Can list which sedative drugs should not be given to the elderly with reasons
- vii. the risks associated with conscious sedation including [but not exclusively] those affecting the respiratory and cardiovascular systems
- viii. the particular risks of multiple drug sedation techniques
- ix. the risks of potential drug-drug interactions
- x. the unpredictable nature of sedation techniques in children
- xi. the different ranges of normal heart rates and respiratory rates among children of different age groups ^(65,66)
- xii. the pros and cons of sedation versus general anaesthesia in high risk patients.

Range of normal heart rates and respiratory rates ⁽⁶⁸⁾

Age	Respiratory Rate (breaths/min)		Heart Rate (beats/minute)	
	Low	High	Low	High
Infants (0 - <1 year)	<30	>60	<100	>160
Toddlers / Preschooler (1-5 years)	<20	>40	<80	>140
School going children (6-11 years)	<16	>30	<70	>120
Adolescents (12-17 years)	<12	>20	<60	>100

SKILLS

- i. the ability to select patients for whom sedation is an appropriate part of clinical management
- ii. the ability to explain sedation to patients and to obtain consent
- iii. the ability to administer and monitor intravenous sedation to patients for clinical procedures
- iv. the ability to recognize and manage the complications of sedation techniques appropriately, including recognition and correct management of loss of verbal responsiveness
- v. the ability to maintain airway in a deeply sedated patient
- vi. the ability to correctly administer oxygen and to recognise the different apparatus for oxygen therapy.
- vii. Competency with emergency airway management, which is fundamental for safe sedation practice and successful patient rescue. ⁽⁶⁹⁾

ANNEX D: PROCEDURAL SEDATION ADVERSE EVENT CHECKLIST

Adverse Events during Procedural Sedation (if any) Adapted from (69,70)

	NO
	YES (to duplicate form if present) (Can √ more than 1)
	Oxygen desaturation [require airway intervention] Lowest SpO2 measured _____ %
	Apnea [cessation of respiratory effort and requiring airway intervention]
	Partial airway obstruction [stridor, snoring or retraction AND required airway intervention(s)]
	Complete airway obstruction [Ventilatory effort with NO air exchange manifested by ALL of the following: a) Absence of upper airway (e.g. stridor or snoring) and breath sounds on auscultation b) Loss of CO2 waveform (when capnography is used) AND requiring airway intervention(s)]
	Laryngospasm [Complete airway obstruction WITH oxygen desaturation due to involuntary and sustained closure of the vocal cords preventing effective ventilation that REQUIRES positive pressure ventilation with or without neuromuscular blockade to overcome the symptom.]
	Clinically Apparent Pulmonary Aspiration [suspicion or confirmation of oropharyngeal or gastric contents in the trachea AND 1 or more of the following respiratory signs and symptoms in any of the 3 categories: (i) Physical signs: cough, crackles, decreased breath sounds, wheezing, tachypnoea or respiratory distress (ii) Oxygen requirement: desaturation requiring oxygen (iii) CXR: focal infiltrates, or consolidation]
	Vomiting No. of times _____ [requiring additional treatment and delay in discharge]
	Bradycardia [e.g. For the child - HR < the minimum expected normal rate for the age range and/or with evidence of poor perfusion and require intervention.]
	Hypotension [e.g. For the child - systolic BP < 5 th percentile for age AND required intervention]
	Myoclonus [involuntary brief contractions requiring an intervention /medication and interferes with procedure.]
	Generalised motor seizure
	Muscle rigidity [Involuntary muscle stiffening in extension that can be associated with shaking AND interferes with the procedure, requiring an intervention or administration of medications]
	Paradoxical response to sedation [unanticipated restless or agitation in response to sedation drugs during sedation AND results in administration of other sedative medication, delay in completion of procedure or discontinuation of procedure]

	<p>Unpleasant Recovery Reactions [abnormal patient behaviour during recovery phase requiring treatment or delay in patient discharge]. Tick either criteria:</p> <p>Inconsolable crying</p> <p>Delirium (state of severe confusion, altered mental)</p> <p>Agitation (restless, continuous activity)</p> <p>Nightmares</p> <p>Hallucinations (responds to sensory phenomena not physically present)</p> <p>Dysphoria (mood of restlessness, depression and anxiety)</p>
	Permanent neurological injury
	Death
	Others , please state:
	<p>Intervention (can tick more than 1):</p> <ul style="list-style-type: none"> <input type="checkbox"/> vigorous tactile stimulations <input type="checkbox"/> airway repositioning <input type="checkbox"/> suctioning <input type="checkbox"/> oxygen oral airway <input type="checkbox"/> bagged and mask assisted ventilation <input type="checkbox"/> intubation <input type="checkbox"/> administration of medication, please state: <input type="checkbox"/> Chest compression <input type="checkbox"/> IV fluids <input type="checkbox"/> physical restraints <input type="checkbox"/> Delayed discharge

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