



**SOUTH AFRICAN SOCIETY  
OF ANAESTHESIOLOGISTS (SASA)**

**SASA paediatric guidelines for the  
safe use of procedural sedation  
and analgesia for diagnostic and  
therapeutic procedures in children:  
2021–2026**



## **SOUTH AFRICAN SOCIETY OF ANAESTHESIOLOGISTS (SASA)**

### **Please Note**

SASA does not recommend the administration, prescription, or mixture of any medication outside of what is specified by the individual manufacturer and licensed for usage in South Africa, or as per their respective package insert and local registration. Should a medication be used off-label, SASA urges its members to ensure that all required and appropriate consent processes are followed prior to the administration of such medication, and that sufficient peer reviewed and accepted evidence exists to support the utilisation of such medication in this manner as constituting best practice.

In the case of any lipid emulsion, SASA further cautions its members to adhere to best practice in the preparation, management, administration, and any post-manufacture mixture of these emulsions, specifically. Package inserts are individualised per preparation and clearly outline safety recommendations and approved licensing of each medication. Mixing of lipid emulsions with additional medications can result in significant alteration and instability of the pharmacokinetics and dynamics of the original drugs. In addition, lipid emulsions carry a significant risk of bacterial contamination and therefore the preparation and administration thereof should maintain aseptic conditions.

SASA therefore strongly recommends that any medications used as mixtures or synergistic combinations be administered through separate syringes or mode of administration, and via a free-flowing intravenous line in order to avoid sedimentation, prolonged mixing due to stasis within the line, micelle formation, and inadvertent pharmacokinetic and/ pharmacodynamic denaturing.

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## SOUTH AFRICAN SOCIETY OF ANAESTHESIOLOGISTS (SASA)

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## **Foreword to the third edition of the *SASA paediatric guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in children***

Our aim with these guidelines is to provide a reference for safe sedation practice for all healthcare providers who are involved in paediatric sedation. Paediatric sedation outside of the operating theatre remains a controversial issue. There are safety concerns regarding the intravenous administration of drugs in children, especially when a combination of drugs is used. It is well known that when more drugs are administered, there is a higher possibility of adverse events.

This edition of these guidelines gives guidance on how to do paediatric sedation safely. These guidelines also give information regarding the drugs that can be used for sedation. There is, however, no advice on paediatric sedation techniques. This must be learnt through supervised clinical training. We support international opinion that sedation practitioners doing paediatric sedation must be trained, have experience in sedation techniques and the necessary qualifications as stipulated in these guidelines.

Monitoring remains an important issue as far as paediatric sedation is concerned. There are clinicians that feel capnography must become part of the minimum monitoring standards, as it is believed to be a more sensitive monitor to alveolar hypoventilation than pulse oximetry. This is a valid argument for sedation in children where respiratory compromise is an important cause of morbidity. Many procedures are performed on children outside of a hospital, in facilities such as procedure rooms, which further emphasises capnography as a valuable monitoring method. Therefore, we highly recommend the use of capnography to monitor ventilation where available.

We want to emphasise again that procedures performed outside of a hospital operating theatre should only be for children with an ASA I or ASA II classification. Furthermore, the duration of an operation is also a consideration when the ASA classification is used. Children with ASA III or ASA IV classifications should only be operated on in a hospital operating theatre.

Accreditation is an important part of safe sedation practice and the accreditation of facilities where sedation is undertaken remains an important issue and needs to be addressed urgently. We emphasise again that it is unacceptable for sedation facilities to not meet the requirements of safe sedation practice. This issue is also addressed at international level and South Africa needs to follow suit. The facilities where we work, especially outside of operating theatres, must meet the requirements for safe practice. It is our responsibility to see that this is the case. Appendix 2 gives a practice appraisal protocol (PAP) that should be completed by sedation practitioners performing sedation procedures outside of a hospital operating theatre. You can

contact the Society of Sedation Practitioners of South Africa (SOSPOSA) for more information on this issue.

The appendices have been revised with more information on what patients need to know about sedation (e.g. a sample of a cover letter to the patient which includes information to the patient, as well as information from the patient).

We have had difficult times and are still threatened by COVID-19. Therefore, we include information on the management of COVID-19 and the impact it may have on procedural sedation.

We wish all our readers a safe sedation journey.

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**SASA Paediatric Sedation Guidelines 2021** (South African Society of Anaesthesiologists)

*Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in children: 2021–2026*

*All healthcare professionals involved in the administration of sedation and participating in the assessment, monitoring and recovery of children requiring procedural sedation and analgesia (PSA) are accountable for safe practice. The child is entitled to the same standard of care, whether the procedure is undertaken outside the hospital (primary care), in a physician's office, dental surgery, a remote facility or in an operating theatre.*

The new guidelines replace the SASA Paediatric Sedation Guidelines 2016, *Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in children.*



## 1. Introduction

Sedation as a means to facilitate challenging or painful procedures, or as a safe, cost-effective and time-saving alternative to general anaesthesia (GA), is a popular addition to modern medical care.

Provision of safe and effective sedation to children fulfils the need for performing non-invasive, painful or non-painful procedures outside of a hospital operating room, which otherwise would have to be added to already overbooked theatre lists. Working from a facility other than a hospital operating theatre demands the same level of care as provided within the hospital operating theatre.

The aim of this document is to provide a reference that will enable all sedation practitioners (SPs) who care for children, to act within a framework for safety to ensure patient wellbeing and successful completion of procedures.

These guidelines are intended for use by all medical practitioners and their teams who participate in sedation for diagnostic and therapeutic procedures in children, either painful or non-painful. The guidelines apply to procedural sedation and analgesia (PSA) before, during or after the procedure. The objective is to further develop the guidelines provided by the South African Society of Anaesthesiologists (SASA) published in 2016. These are neither intended to substitute supervised clinical training nor to be used as a recipe for the administration of sedatives, dissociative agents and analgesics. These guidelines are designed to be applicable to procedures performed in a variety of settings (i.e. hospital, freestanding clinics, or physician, dental and other surgeries) in order to provide safe sedation, analgesia and anxiolysis for children in all environments. Identification of children unsuitable for PSA is crucial, and many of the sedation techniques used in adults are not recommended for paediatric practice.

These guidelines are *not applicable* to the following patients:

- Children who require intensive care sedation.
- Children in need of sedation and analgesia for palliative care.
- Children receiving sedation and analgesia in the home setting.
- Children receiving premedication for GA.
- Children who require night sedation.
- Children who require postoperative analgesia.

### 1.1 Evidence

These guidelines are based on national and international peer-reviewed publications and reports, existing consensus statements, expert opinion, as well as many years of paediatric

sedation experience. The standards outlined in these guidelines are appropriate and achievable, and will guarantee high levels of safety.

## **1.2 Objectives of procedural sedation and analgesia**

The following are the objectives of PSA:

- To respect the rights of the child and parent/caregiver at all times.
- To provide an environment where the procedure can be completed safely.
- To reduce the child's fear, anxiety and distress.
- To provide effective pain control and prevention of movement.
- To decrease awareness and provide amnesia.
- To complete the procedure safely, reliably and effectively.
- To maintain the child's consciousness and cooperation.
- To maintain control of physiological parameters.
- To maintain a patent airway.
- To return the child to a state in which safe discharge is possible.

Medical practitioners should realise that in some circumstances, a short GA may be faster and safer, and a more controllable and reliable option for the completion of the intended procedure or investigation. GA should only be undertaken in an environment appropriate for the administration thereof, with the necessary qualified personnel available and sufficient monitoring in place.

## **1.3 Indications for sedation**

PSA is standard practice in most countries and is used to facilitate the performance of various diagnostic and therapeutic procedures. Procedures that do not require neuromuscular blockade and in which pain can be controlled either locally or systemically, without compromising patient safety, are suitable for PSA. PSA is currently used within various disciplines, such as cardiology, gynaecology, dentistry, gastroenterology, radiology, dermatology, plastic surgery and emergency medicine. The decision to perform PSA should be made by the primary clinician and the patient, not the SP, and is determined by the following:

- behavioural indicators (e.g. anxiety),
- procedural indicators, and
- treatment complexity.

## **1.4 Risks to patient safety**

Paediatric sedation poses unique challenges and pressures associated with the very specific needs of paediatric patients. Publications have highlighted a lack of formal training as

contributing to sedation-related adverse events, and sedation training is supported by all international sedation guidelines.<sup>1</sup>

The SP must undergo theoretical training, as well as supervised clinical training. It is essential that the SP updates their knowledge and skills regularly.

Although the procedure itself usually poses little risk to the child, the addition of sedation by administering sedatives, analgesics and/or dissociative agents, may add to the risk. The use of combination therapy may further increase the risk of adverse events. Respiratory compromise is the most significant adverse event following the administration of sedatives or analgesics. Airway management, therefore, is a crucial part of training because maintenance, protection and rescue of the airway is an integral part of safe sedation practice. During sedation, the child is taken from maintaining their own airway to depending on the SP to preserve their airway. A focused airway examination is thus mandatory.

Various research and clinical studies have been conducted to explain the terminology and definitions so that sedation-related adverse events can be easily identified (i.e. ranging from minimal to severe).<sup>2,3</sup>

Adverse events may be categorised as follows, according to clinical importance:

- Lesser adverse events (i.e. a short period of oxygen desaturation)
- Standard or moderate adverse events (i.e. lowest oxygen saturation at 75% or lasting longer than 60 seconds)
- Critical adverse events (i.e. permanent neurological injury, admission to hospital, CPR and tracheal intubation, or death)

Critical adverse events should be reported immediately to sedation care systems or professional societies and trigger automatic peer review.

The occurrence of adverse events and complications is more likely in non-hospital-based settings that do not meet the minimum requirements for safe sedation practice.

Adverse events may occur because of the following reasons:

- The SP is not trained or experienced in paediatric sedation.
- The patient selection is inappropriate, the preoperative assessment is inadequate or preparation is done poorly.
- The administration is unsupervised (e.g. premedication is administered at home).
- The child is unable or unwilling to cooperate.
- The procedure is not suitable for sedation.
- The sedatives, analgesics or dissociative drugs have adverse effects (especially if used in combination).
- The administration of the drugs is not timed correctly.

- The practitioners have inadequate knowledge of the pharmacokinetics and pharmacodynamics of the drugs.
- The patient has an unanticipated pharmacogenetic response to the drugs.
- The child is inadequately monitored.
- The SP is unable to recognise and manage complications.
- The SP is unable to rescue the child from an unexpectedly or undesirably deeper-than-intended level of sedation.
- The support staff is either not adequately trained or inexperienced in paediatric sedation.
- The child is prematurely discharged – they have not met the discharge criteria after sedation.

Complications or adverse events can occur:

- before sedation,
- during sedation (i.e. drug interactions, oxygen desaturation, itching, allergic reactions, obstruction of the airway or injuries), or
- after sedation (i.e. delayed recovery or amnesia).

### **1.5 Clinical governance**

Clinical governance is a system through which healthcare organisations and societies are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which clinical excellence will flourish.

All SPs are required to be registered as medical practitioners by the Health Professions Council of South Africa (HPCSA) and are required to comply with current safety regulations of the HPCSA.

The SP should have a framework of accountability that include clinical accountability for processes such as evaluation of expertise, clinical appraisal and implementation of SASA guidelines on PSA for children.

The SP must have a standard plan in operation for each sedation technique for which they deliver a service. This plan should include details of assessment protocols, structure of the treatment sessions, roles of all team members and the systems in place for reporting adverse events. There should also be in-house training sessions for the entire sedation team. All practitioners involved in a paediatric sedation practice should keep a logbook of cases performed under sedation and are required to document and report adverse incidents and accidents. Adverse events remain an area of serious concern as SPs do not often report adverse events. It is, however, recommended that adverse events be reported to societies involved in paediatric sedation practice.

The following is also recommended:

- All facilities must undergo regular inspections to comply with quality assurance policies and procedures.

- SPs must get an appraisal – a process which will be overseen by the Society of Sedation Practitioners of South Africa (SOSPOSA) and will follow a two-year cycle – upon which SPs will receive a certificate of good standing. Documents are available on the SASA website (<http://www.sasaweb.com>).
- Records of staff training with regard to sedation for staff members who are involved in administering sedation must be kept, as well as evidence of airway certification (i.e. Basic Life Support [BLS] training).
- Evidence must be available regarding the training of an SP, as well as evidence of airway certification (i.e. Paediatric Advanced Life Support [PALS] and Advanced Paediatric Life Support [APLS] training).
- Records of adverse events must be kept.

Future initiatives and developments must involve the incorporation of simulation into training, credentialing and maintenance of sedation skills. Simulation offers hands-on experience in the management of medical emergencies for SPs.

## 2. Definitions

The International Committee for the Advancement of Procedural Sedation (ICAPS) defines procedural sedation as follows: “The practice of procedural sedation is the administration of one or more pharmacological agents to facilitate a diagnostic or therapeutic procedure while targeting a state during which airway patency, spontaneous respiration, protective airway reflexes, and hemodynamic stability are preserved, while alleviating anxiety and pain”.<sup>4</sup>

### 2.1 The continuum of procedural sedation and analgesia

Sedation is considered on a continuum varying from minimal sedation or anxiolysis, moderate sedation and analgesia, dissociative sedation to deep sedation, and finally to GA as outlined below (Table I).

Table I: The sedation continuum

	<b>Minimal sedation/ anxiolysis</b>	<b>Moderate sedation/ analgesia</b>	<b>Deep sedation/ analgesia</b>	<b>General anaesthesia</b>
<b>Responsive- ness</b>	Responds to verbal stimuli	Purposeful response to verbal or tactile stimuli	Purposeful response only after repeated or painful stimuli	Unable to rouse
<b>Airway</b>	Unaffected	No intervention required	Intervention may be required	Intervention often required
<b>Spontaneous ventilation</b>	Unaffected	Adequate	May be inadequate	Frequently inadequate
<b>Cardiovascular function</b>	Unaffected	Usually maintained	Usually maintained	May be impaired

This implies that with an increase in drug administration (i.e. by increasing dosage or combining different drugs), the likelihood of advancing to the next level of sedation is increased. Patients may reach a deeper-than-intended level of sedation with accompanying adverse effects. The level of sedation is also affected by drug interactions and the individual's pharmacogenetic profile.

## **2.2 Sedation endpoints**

The American Society of Anesthesiologists (ASA) defines the following levels of sedation (Table I):<sup>5</sup>

1. minimal sedation or anxiolysis
2. moderate sedation/analgesia
3. deep sedation/analgesia, and
4. general anaesthesia.

In paediatric patients, these endpoints may be difficult to assess due to particular challenges of effective communication during the care of children, especially the young ones. Depending on the age and cooperation capabilities of the child, the amount of pain generated by the procedure and whether complete immobility is required, sedation endpoints in children tend to extend to the deeper end of the sedation continuum. An unexpected progression of the depth of sedation must therefore be anticipated and practitioners must be able to rescue patients who enter a level of sedation deeper than intended.

### **2.2.1 Minimal sedation/anxiolysis**

Minimal sedation/anxiolysis is a drug-induced state during which the patient responds normally to verbal commands. This level is sometimes referred to as “changing the mood” of the patient. Cognitive function and physical coordination may be impaired, but airway reflexes, and ventilatory and cardiovascular functions are unaffected.

### **2.2.2 Moderate sedation/analgesia**

Moderate sedation/analgesia is also termed “conscious sedation”. This is a drug-induced depression of consciousness during which purposeful response to verbal commands (either alone or accompanied by light tactile stimulation) is maintained. Interventions are not usually required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

There are societies that believe that dissociative sedation (i.e. using ketamine) should also be part of the sedation continuum and falls between moderate and deep sedation/analgesia.

### 2.2.3 Deep sedation/analgesia

Deep sedation is a drug-induced depression of consciousness during which patients cannot easily be roused, but may respond purposefully following repeated or painful stimulation. Reflex withdrawal from a painful stimulus is not considered to be a purposeful response. Deep sedation may be accompanied by clinically significant ventilatory depression. Assistance with maintaining a patent airway and positive pressure ventilation may be necessary. Cardiovascular function is usually maintained. This level of sedation is termed “monitored anaesthesia care (MAC)” in certain international sedation guidelines.

Transitioning through the planes of sedation/analgesia results in increased depression of the cardiovascular and respiratory systems and an increase in the likelihood of adverse events. The SP must be able to recognise and manage such complications promptly and effectively.

If a patient fails to respond to verbal commands and/or light touch, the standard of care must be identical to that for GA.

In South Africa, deep sedation and analgesia should only be performed by trained doctors with experience in the field of anaesthesia, in accordance with the SASA Practice Guidelines 2018 (available from <http://www.sasaweb.com>). This is especially true for sedation in children.

### 2.2.4 General anaesthesia

This is a drug-induced loss of consciousness during which patients cannot be roused, even by painful stimulation. The ability to maintain independent ventilatory function is impaired. Patients require assistance in maintaining a patent airway, and positive pressure ventilation may be required due to the depression of spontaneous ventilation or a drug-induced depression of neuromuscular function. Cardiovascular function may also be impaired.

Guidance on the care of a patient under GA is provided in the SASA Practice Guidelines 2018 (available from <http://www.sasaweb.com>) and is therefore not addressed in this document.

The following statement by the ASA must be taken into consideration with every sedation procedure:<sup>5</sup>

“Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia (‘Conscious Sedation’) should be able to rescue patients who enter a state of Deep Sedation/Analgesia, whilst those administering Deep Sedation/Analgesia should be able to rescue patients who enter a state of General Anaesthesia. 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 physiological consequences of the deeper-than-intended level of sedation (i.e. hypoventilation, hypoxia and hypotension), and returns the patient to the originally intended level of sedation.”

It is important to remember that the level of consciousness is independent of the route of administration. Any level of PSA may be achieved via any route of administration.

### **2.3 Non-dissociative sedation**

Non-dissociative sedative drugs (including opioids, benzodiazepines, barbiturates, etomidate and propofol) operate on the sedation dose–response continuum. Higher doses provide progressively deeper levels of sedation with possible respiratory and cardiovascular compromise, central nervous system depression and unconsciousness. With the use of non-dissociative drugs, the key to minimising adverse events is the careful titration of drugs until the desired effect is reached.

### **2.4 Dissociative sedation**

Dissociative sedation (as seen with ketamine sedation/analgesia) causes a trance-like cataleptic state characterised by intense analgesia, amnesia, sedation, retention of protective reflexes, spontaneous breathing and cardiovascular stability. When ketamine is administered in doses appropriate for PSA, loss of consciousness is unlikely. As stated earlier, some practitioners believe that dissociative sedation should be part of the PSA continuum, and would fit in between moderate and deep sedation.

### **2.5 Sedation techniques**

PSA is just one option to control anxiety in children. Depending on the requirements of the procedure, behavioural management is another possibility to explore before reverting to PSA. PSA should always include both pharmacological and non-pharmacological strategies.

Non-pharmacological strategies include psychological preparation, nutritive and non-nutritive sucking, distraction and scheduling the procedure during the child’s usual nap time.

Psychological preparation of children and their families for medical procedures and events can significantly increase both their confidence and their ability to cope with the experience.

Preparation should include a description of the sequence of events as well as the expected duration of the procedure. When preparing the child, let the child smell, touch and feel the items that may be used. For example, smell the alcohol swab, touch the wet swab and feel how cool it is to the touch.

When talking to children, take the child’s developmental level, age, culture and education into consideration. Young children have no sense of reason. Telling them that they will feel better

after taking the medicine is of no apparent benefit to them and they will remain fearful. Medical terminology should be avoided, and extensive explanation to both child and parents is usually necessary.

The use of pictures or actual equipment as aids is strongly recommended. Medical play also has considerable benefit. This is especially the case when the child is expected to undergo ongoing or repeated treatment. Looking down on or talking over a child should be avoided. Children are much more receptive to information when one is talking at their level.

The caregiver plays a vital role in the successful completion of procedures in young children. The caregiver has an understanding of the child's needs and may be best equipped to interpret the child's behaviours and reactions to medical procedures. Frequent conversations with caregivers are crucial to success and sufficient time should be made available for asking and answering questions.

Other basic physical measures, such as the application of ice or splinting or a combination of these, can be considered. These strategies should be discussed with the parent/caregiver before a decision is made as to which technique to use.

Pharmacological strategies must take into account the interindividual variation in the reaction to drugs that are inherent in children. Drug selection should be based upon the requirements for the procedure (i.e. analgesia, anxiolysis, sedation, amnesia or immobility).

If a procedure is not painful, it is advised that agents such as ketamine or opioids not be used routinely. However, small amounts of these agents can, through synergism, reduce the need for sedatives and hypnotics.

SPs' theoretical, supervised clinical and life support training should equate with the intended sedation technique. Since children may be uncooperative and unable to control movement during procedures, they often need deep sedation to ensure immobility. There is still no easy and objective measurement for the level of sedation and sedation scales are often not practical to use in children (Section 7.2). Children may, therefore, end up in deeper-than-intended levels of sedation, with airway obstruction and respiratory arrest. SPs may also yield to pressure from the proceduralist to enhance sedation to ensure immobility. SPs intending to practice sedation in children should be trained to rescue children from too deep levels of sedation.

### **2.5.1 Basic or standard sedation**

Basic or standard sedation can be defined as sedation induced by a single agent and not a combination of several agents, for example:

- oral, transmucosal or rectal drugs (e.g. a small dose of an oral benzodiazepine, usually midazolam),

- inhalation of nitrous oxide (N<sub>2</sub>O) in oxygen, where the concentration of N<sub>2</sub>O must not exceed 50% in oxygen, or
- titrated intravenous doses of midazolam to a maximum dose of 0.1 mg/kg.

**NB:** The use of propofol (or any other anaesthetic induction agent) is by definition an advanced sedation technique (Section 2.5.2).

If the drugs mentioned under basic or standard sedation are used in combination, or if additional agents become necessary to obtain the child's cooperation, basic or standard sedation ceases and the sedation technique is classified as an advanced sedation technique. When a standard sedation technique proves to be insufficient, the depth of sedation **must not** be advanced, unless the patient is *fasted* and a *dedicated SP* (Section 8.1.3) is employed.

Standard sedation techniques can include the use of concomitant simple analgesics, for example paracetamol.

Basic or standard sedation techniques can be used by operator-SPs when all the requirements for safe practice have been met (i.e. training, including supervised clinical training, an observer to monitor and help with rescue if indicated, and premises that meet the requirements for safe practice).

### 2.5.2 Advanced sedation

Advanced sedation can be defined as sedation induced by one of the following techniques:

- any **combination** of drugs, administered by any route,
- any sedation administered by the intravenous route (e.g. propofol, etomidate, dexmedetomidine – with the exception of titrated doses of midazolam to a maximum of 0.1 mg/kg),
- any inhalational sedation (e.g. sevoflurane), with the exception of N<sub>2</sub>O used as the sole agent in a concentration not exceeding 50% in oxygen, or
- any infusion techniques (i.e. target-controlled infusions [TCIs]).

Advanced sedation techniques:

- can include both dissociative and non-dissociative techniques,
- should only be performed by SPs who have had supervised clinical training and life support training in paediatric sedation, and
- require the attendance of a dedicated SP and should not be performed by operator-SP.

### 2.6 Failed sedation

Failed sedation is defined as the failure to achieve the desired level of sedation for the procedure to be completed safely, such that the procedure has to be abandoned or the need arises to convert to GA. Possible reasons for failed sedation include inadequate premedication

assessment of the child, patient factors (i.e. children with special needs), drug factors or procedure-related and operator factors. A previous episode of failed sedation may necessitate consideration for future procedures to be performed under GA instead of sedation.

## **2.7 Prolonged sedation**

The intention to reduce costs and avoid long theatre waiting times resulted in an escalation in demand for procedures to be performed outside of hospital operating theatres in primary care. Sometimes, these procedures are quite lengthy and often require the provision of deep sedation and analgesia in children. SPs are increasingly faced with the decision as to how long a child can be safely kept sedated outside of the hospital operating theatre, especially when using intravenous techniques. SPs themselves are concerned that they are sometimes faced with procedures in children which may last up to four hours in primary care.

Prolonged sedation for lengthy procedures, especially in children, carries increased risk. Mechanisms must be instituted to ensure the safety of the child. Currently, there is no guidance for SPs on the definition of prolonged sedation in children. It is recommended that in children, any sedation for procedures performed outside of a hospital and lasting more than 1.5 hours is considered prolonged sedation. Even though this approach may not be practical, these procedures should probably best be staged into two or more separate procedures. Alternatively, the recommendation for procedures expected to last more than 1.5 hours, is to perform the procedure under GA in-hospital.

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## **3. Environment and clinical setting**

SPs must understand the limitations of working in the relative isolation of the out-of-hospital setting. The premises and supporting facilities where sedation is performed, must meet the requirements of safe sedation practice. Preprocedure assessment and selection of paediatric patients will determine if the facility fulfils the requirements for each individual child. The minimal requirements for facilities, equipment and drugs for procedures to be performed outside of a hospital operating room, must include those detailed in *Appendix 1: Basic equipment and drugs for procedural sedation and analgesia in children*.

Treatment areas must be large enough to enable adequate access for the sedation team. Furthermore, sedation should only be performed in an environment where staff, facilities, equipment and drugs meet requirements to manage emergencies in children. There must also be enough room for managing medical emergencies. Resuscitation equipment suitable for children must be available, maintained and regularly checked, especially before the start of the procedure. The equipment must be in working order and the drugs within their expiry date. Records of the maintenance of equipment must be retained and be made available for formal inspections. During all surgeries, there must be filled oxygen cylinders with appropriate

attachments, as well as access to a defibrillator in case the child needs resuscitation. The clinical setting must permit access for emergency services and the transfer of the child, if necessary. Irrespective of the setting, the sedation team should have access to an intensive care setting.

The recovery facility may either be a dedicated recovery area or a treatment area that is used as such. Children must be continually monitored in the recovery area until they have completely recovered from the effects of the sedation. The recovery area must be equipped to facilitate the management of any sedation-related adverse events.

All providers of procedural sedation services for paediatric patients are responsible to ensure that the sedation facility in which care is delivered, is appropriate for the needs and safety of the SPs, paediatric patients and staff, and that it is in line with guidelines and standards of care. *Appendix 2: Practice appraisal protocol for paediatric sedation* serves as a benchmark for SPs to determine whether the location they work in fulfils the requirements as set out in the guidelines.

The SP, together with the owner of the premises, must also ensure that the premises are inspected and accredited by an independent, recognised sedation authority. The focus of the review should be on the procedures, sedation techniques and processes used. Records of the audit process and outcomes must be retained and made available for inspection. Regular audits should be considered a core requirement for sedation providers involved in patient care. It is recommended that SOSPOSA, or equivalent body, be contacted for accreditation and evaluation of the sedation facility.

Last but not least, is it imperative that all team members are sensitive to the need for maintaining a child-friendly environment. It may be necessary to make adjustments for the specific needs of paediatric patients.

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## 4. Valid informed consent to sedation and analgesia for medical or dental procedures

Valid informed consent (Appendix 3) is a complex process. The General Dental Council (GDC), UK, provides valuable principles and standards for the dental team regarding consent for dental procedures.<sup>6</sup> It should be documented that appropriate consent was obtained from the patient, or a responsible person (parent/caregiver), according to local and international requirements.

Before the process can be completed, information about the sedation and procedure must be provided in a clear and understandable way. This should happen at an appropriate time in order for the patient/parent/caregiver to be able to digest the information and formulate questions. The discussion should, therefore, if possible, not occur immediately before the procedure or even on the day of the procedure. Informed consent must never be obtained

after the administration of sedative and analgesic drugs. The nature of the procedure to be performed may also not be changed after sedative and/or analgesic drugs have been administered to the patient.

Patients/parents/caregivers must understand the risks of sedation before consenting. Therefore, an explanation of the procedure, the proposed sedation technique and the risks and benefits of the proposed technique should be given. Patients/parents/caregivers must be aware of the possibility that the sedation may fail and that the procedure may have to be abandoned or performed under GA at a later date.

Alternatives to sedation (e.g. GA or local/regional anaesthesia) should also be discussed. Behavioural management techniques as an alternative to sedation, if relevant, should be discussed to ensure that the most suitable form of treatment is selected.

Consent must be obtained for both the procedure and the sedation. It is the responsibility of the SP to ensure that the patient/parent/caregiver understands the consequences of the decisions they are about to make. If the child is not legally competent to give consent (e.g. underage or a child with special needs), it will have to be obtained from someone with parental responsibility (i.e. the mother or father, or legal caregiver).

A more difficult question to answer is *when* can a child give consent for a procedure. According to the Medical Protection Society (MPS), a child of 12 years or older may consent to medical treatment. For surgical treatment, a child of 12 years or older may consent with a parent or guardian's assent. The child must, however, have the maturity to understand the implications of the procedure.

As cited in the *Southern African Journal of Anaesthesia and Analgesia*,<sup>7</sup> children can give consent in the following situations: (i) for medical treatment, if they are older than 12 years of age, and if they have the maturity and capacity "to understand the benefits, risks, social and other implications of the treatment" – this is independent of parents' consent; or (ii) for surgical procedures, if they are 12 years of age and assisted by their parent or legal guardian (Form 34, or Form 35 if the child's parents themselves are aged 18 years and younger).

The planned usage of suppositories or rectal medication must also be explained carefully to the parents and consent be obtained ahead of time.

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## 5. Patient assessment

Appropriate selection of children for sedation is the first step to safe sedation practice. It is generally accepted that adults, through their lived experience, have the necessary coping skills to ensure safe and successful sedation. However, children of different age groups, and even children within the same age group, have different coping skills. The procedure to be

performed will largely determine what level of coping skills is required of the child. Every child must therefore specifically be assessed to determine their suitability for sedation outside of a hospital operating room.

Unfortunately, most SPs only meet the child on the day of the procedure. The operator has the privilege of evaluating the child during the first consultation. Therefore, the SP should assist and guide the operator in evaluating the child's suitability specifically for sedation. It may be helpful to provide some guidance in the form of printed or written notes to assist the operator in this process. Inappropriate patient selection is a recurring factor in sedation-related adverse events and poor outcomes.

It is recommended that, if at all possible, the SP should meet the child some time before the sedation to determine the child's cooperation capabilities and build rapport with the child. The pre-sedation visit should also be used to obtain information concerning the child, as well as providing information to the parent/caregiver. It is recommended that the information should be in the form of written notes for the parent/caregiver to refer back to as necessary.

If it is not practical to meet the child in person, it is advised that the parent/caregiver is contacted in advance of the sedation appointment to obtain and share information as set out above. The information should prepare the parent/caregiver and child for what to expect during the sedation, thereby facilitating communication and alleviating anxiety. This may be followed up with a phone call to the parent/caregiver to address any questions directly.

Whenever possible, previous records (i.e. medical, sedation, anaesthesia and surgical history) should be retrieved and examined.

The presence or absence of the parent/caregiver during the procedure needs to be discussed as well.

The evaluation of the child should include the following:

- A recent medical history questionnaire (Appendix 4). Details of previous sedations are vital, as previous failed attempts at sedation may indicate the need for GA for future procedures. Enquire about previous problems with airway management as part of the suitability check for out-of-hospital procedures.
- The drug history of the child, with special attention to:
  - chronic medication (e.g. asthmatic treatment, steroids and antihistamines for allergies, isotretinoin (Roaccutane), anti-diabetic drugs),
  - psychotropic drugs (e.g. anti-epileptics),
  - stimulants (e.g. methylphenidate), or
  - recreational drugs in teenagers, especially since the relaxation of legislation on the use of marijuana.

- An airway assessment – various airway evaluation scales are available to assist the SP with evaluating the airway, e.g. the Lemon Law<sup>8</sup> and Mallampati<sup>9</sup> classifications (Appendix 5). The Lemon Law aids the SP in identifying factors for a difficult airway.

During an airway assessment:

- Observe from the front and side looking for particularly syndromic features (e.g. low-positioned or abnormal ears and pre-auricular tags)
- Hypoplastic or receding chin
- Upper jaw overbite
- Loose teeth
- Enlarged tongue
- Enlarged tonsils (approaching the midline or associated with snoring)
- Flexion and extension of the neck
- Hoarseness
- Wheezing

An active upper respiratory tract infection (URTI) is a current or recent URTI, where two or more of the following symptoms or signs are still present:

- rhinorrhoea
- sore or scratchy throat
- sneezing
- nasal congestion
- malaise
- cough
- fever
- unexplained tachycardia
- a parent reports or is concerned that the child is sick

Airways remain reactive for up to six weeks following a URTI and reactive airways are prone to laryngospasm during PSA. Sedation is probably best avoided during this period.

An assessment must also include:

- an evaluation of the cardiovascular and respiratory systems by way of auscultation of the heart and lungs, and
- an enquiry about previous abnormal laboratory tests.

Where indicated, a paediatrician should be consulted about the condition of the child. If the child was seen at an earlier appointment, a re-evaluation of the health status immediately before sedation and surgery is recommended.

Assessment should be done in accordance with the *ASA physical status classification system*<sup>10,11</sup> (Table II). However, while anaesthesia and sedation providers use the ASA classification to indicate a child's overall preoperative status for anaesthesia and sedation, it may be misinterpreted as a classification to predict risk. It is important to realise that this is *not* a risk classification, but an evaluation of clinical status only.

**Table II: American Society of Anesthesiologists physical status classification system modified<sup>10,11</sup>**

<b>Class I</b>	A normal healthy patient, no functional limitations
<b>Class II</b>	A patient with a history of well-controlled mild systemic disease (e.g. diabetes mellitus, hypertension), no substantial functional limitations
<b>Fragile ASA II patient</b>	A patient not controlled on morning or afternoon of procedure (i.e. hypertensive, diabetic, asthmatic, obstructive sleep apnoea)
<b>Class III</b>	A patient with severe systemic disease that limits activity, but is not incapacitating
<b>Class IV</b>	A patient with severe systemic disease that is a constant threat to life
<b>Class V</b>	A moribund patient not expected to survive 24 hours with or without an operation
<b>Class VI</b>	Clinically deceased patients
<b>"E"</b>	An emergency procedure is denoted by the letter E following the class number

ASA-E – Emergency operation for any of the above classes (e.g. ASA II-E)

Only children in ASA Class I, II and fragile ASA II well-controlled, should be considered for sedation outside of a hospital operating theatre. It is possible for the ASA status to deteriorate from the time the child was initially evaluated to the time of the sedation (e.g. ASA II patients may become ASA III patients by the time of the procedure). Therefore, the recommendation is that children should be evaluated again immediately prior to the procedure.

Children in ASA Class III, IV or V require higher levels of monitoring and care. It is advised that procedures for these patients be done in-hospital.

Certain children are at increased risk for complications and it is imperative that these patients be recognised as such, during the preoperative assessment either in person, through the medical questionnaire or by telephonic consultation. Strong consideration should be given to sedating these children in a **hospital setting and should be determined on an individual basis**. Other factors may play a role (e.g. the extent and duration of the procedure, manner of transport and level of care at home).

Children at an increased risk for complications include, but is not limited to:

- Children younger than 3 years of age.
- Children with a history of prematurity with residual pulmonary, cardiovascular, gastrointestinal or neurological problems, or significant anaemia.
- Children with congenital syndromes.
- Children with obesity (> 95<sup>th</sup> percentile body mass index (BMI) for their age).  
*\*The association between obesity and obstructive sleep apnoea (OSA) limits the use of sedatives and opioids and increases risk in light of early discharge requirements. Children with restrictive lung disease are prone to desaturation – they must be evaluated on a case-by-case basis.*
- Children with previous failed sedation.
- Children with any known adverse reactions (hyperactive or paradoxical response) or allergy to any of the sedation drugs.
- Children who display severe behavioural problems or hyperactivity, or who are mentally challenged.
- Children whose parents are reluctant.

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## 6. Guidelines for fasting

Preoperative fasting for sedation is controversial. Some authorities, especially in dentistry and emergency medicine, consider it to be unnecessary. Airway reflexes are assumed to be maintained during minimal and moderate sedation, but may be lost during deep sedation. If basic or standard sedation techniques (Section 2.5.1) are planned, fasting is recommended, but not mandatory. If advanced techniques (Section 2.5.2), including dissociative and non-dissociative techniques, or deep sedation are planned, the following standard anaesthetic fasting guidelines are recommended:

- Clear fluids, apple juice: two hours. Some clinicians allow clear fluids even one hour before the procedure. A “clear fluid” is defined as fluid without particles.
- Breast milk: four hours.
- Formula feeds and solid food: six hours.

For a procedure to be completed safely, children often need deep sedation for which advanced sedation techniques may be required. When a basic or standard sedation technique is used in non-fasted children and fail, the technique should not be advanced. Rather, the procedure must be abandoned and rescheduled for a later time. In urgent cases, when a procedure cannot be postponed and simple sedation techniques are deemed unsuitable, a GA with rapid sequence induction should be considered.

Children should not have to fast for prolonged periods. Clear fluids should be administered up to two hours before the procedure. This may need some fine planning and good communication with parents/caregivers.

SPs must take note of the consensus statement on fasting before procedural sedation in adults and children by ICAPS.<sup>12</sup>

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## 7. Standards of monitoring

The principles of monitoring are described by the Academy of Medical Royal Colleges in *Safe Sedation Practice for Healthcare Procedures*.<sup>13</sup> All members of the sedation team must have detailed knowledge of the monitoring equipment and interpretation of the information provided by the monitors.

Clinical monitoring alone may suffice in minimal sedation. For all other levels of sedation, both clinical monitoring and electronic monitoring must be used. The sedation technique used (i.e. either basic or standard sedation, or advanced sedation) will also affect the level of monitoring required. For basic or standard techniques where only a single agent is used, the respiratory and cardiovascular systems are usually unaffected. Intermittent assessment of vital signs is appropriate, including clinical monitoring such as level of sedation, anxiety, colour of mucosa/skin and breathing patterns. For prolonged procedures, the use of both a pulse oximeter and a non-invasive blood pressure (NIBP) monitor are mandatory. Should any advanced sedation technique be used, the level of sedation will determine the monitoring required, as set out below.

### **7.1 Anxiety levels and behaviour, such as confusion, restlessness and agitation**

The SP should evaluate the child's cooperation, since this will impact the level of sedation needed for the procedure to be completed safely. An otherwise complacent child who becomes restless and agitated during the procedure, may indicate a possible adverse event (e.g. hypoxaemia, hypoglycaemia, under-sedation or even over-sedation). A full bladder can also cause restlessness, especially during longer cases.

### **7.2 Level of consciousness and depth of sedation**

Children often need deep sedation for procedures to be completed safely. Therefore, monitoring the level of sedation is of utmost importance and should be part of every sedation technique. Since a standard dose or drug in children may have an unpredictable effect, children may end up in a deeper-than-intended level of sedation. Regular communication with the child will assist in monitoring the level of sedation.

Sedation scoring systems were developed to monitor the level of sedation (e.g. the Wilson sedation scale or the University of Michigan Sedation Scale [UMSS]) (Appendix 6). It is suggested that SPs use the UMSS since the scoring system follows the levels of sedation on the sedation continuum.

Even though these scoring systems are a practical way to determine the level of sedation, there are some drawbacks. These scoring systems are all subjective and dependent on interpretation by the individual SP. Since loss of responsiveness to verbal command or light tactile stimulation is considered an indication that the child is under deep sedation (Table I and Appendix 6), the scoring systems rely on stimulating the child, either verbally or physically, in order to determine the level of sedation. This can be counterproductive, especially in children where the purpose of sedation is to induce a sedated and relaxed state to gain the child's cooperation. Stimulating the child at predetermined intervals to determine the level of sedation may also be disruptive to the procedure and the sedation process, and defy the purpose of the sedation. However, there is no other clinical way to determine the level of sedation. As the SP may be reluctant to stimulate the child, the child may enter deep sedation, and even GA, without the SP realising it. Sedation training and skill are indispensable to safely steer the process at this level of sedation. A child under deep sedation requires the same level of care as required during GA.

Interpreting a "purposeful response" is also dependent on the interpretation by the SP. Examples of a purposeful response may include opening the eyes, opening the mouth, taking deep breaths and pushing a painful stimulus out of the way. This, too, may be difficult to ascertain in children, especially young children who may not comprehend what is expected or how to respond. Other groups that may be difficult to monitor include mentally challenged children, children with autism or where language barriers exist.

The only clinical way to distinguish between moderate and deep sedation is by loss of verbal response (or light tactile stimulation), that is between awake and asleep. Once verbal response is lost, it is impossible to determine whether the patient is under deep sedation or GA. It is, therefore, better to aim to keep the patient awake (conscious), rather than asleep (unconscious). Once verbal contact is lost, the patient may drift from deep sedation into GA.

An easy rule is, if anaesthesia is about keeping patients asleep, sedation is about keeping patients awake – this is especially true for procedures performed outside the hospital environment. This, however, is not always possible since there are situations where deep sedation is required (e.g. in very painful procedures, very young patients, mentally challenged patients, or when complete immobility is required). The most important implication is to realise that as the depth of sedation increases so does the risk for cardiorespiratory events. Therefore, an experienced provider and extreme vigilance are required to perform these advanced techniques.

As far as electronic monitoring is concerned, the value of processed electroencephalogram (EEG) monitors (e.g. bispectral index [BIS] monitoring) for sedation outside of a hospital operating theatre is debatable. However, it may be useful where deep sedation and analgesia is used.

### **7.3 Pain and degree of discomfort**

Unlike adults, children may not be able to verbalise when they experience discomfort or pain. Close and continuous observation of the child's face and possible movement of extremities may aid as clues that the child is experiencing discomfort or pain.

In older children, when the demands of the procedure prohibit a verbal response (e.g. dental work or procedures on the head and neck), a signalling system for pain or discomfort should be established prior to the initiation of sedation. In this way, older children will be able to demonstrate whether they are in pain or discomfort (e.g. with a thumbs up or thumbs down).

### **7.4 Airway patency**

Relaxation of the mandible and involuntary opening of the mouth are early signs that the level of sedation is deepening. Noisy inspiration and/or expiration and snoring are indications of an obstructed upper airway and should be corrected by either repositioning the head and neck or lessening the sedation. A patient who stops snoring should be evaluated for complete airway obstruction. SPs should be attentive to possible depression of the chin (e.g. during dental work) and flexion of the neck with deepening of sedation. Since airway patency is directly related to depth of sedation, monitoring of airway patency should be part of every level of sedation.

### **7.5 Oxygenation and mucosal colour**

These should be observed continuously at all levels of sedation.

### **7.6 Breathing, respiratory rate and ventilation**

The breathing pattern and movement of the chest and abdomen should be observed for the duration of the procedure. Breathing should be rhythmic. Signs to watch out for are paradoxical breathing, rib retraction, use of accessory muscles and tracheal tug, which all may indicate airway obstruction. Stridor or coughing and bucking might be the earliest indication of laryngospasm and requires immediate action.

The respiratory rate should be recorded intermittently. When a capnograph is used, the respiratory rate will be displayed continuously. The use of a precordial stethoscope may be useful if capnography is unavailable.

Since the effect of drugs on a patient's breathing and ventilation may be unpredictable at all levels of sedation, these should be monitored irrespective of the level of sedation.

Capnography, the so-called gold standard for monitoring ventilation, monitors the end-tidal concentration of carbon dioxide, which is believed to be a more sensitive monitor to alveolar hypoventilation than pulse oximetry. Askar et al.,<sup>14</sup> in a systematic review and meta-analysis, showed that capnography monitoring reduced the incidence of hypoxemia during PSA. They

also suggest that applying capnography monitoring during PSA would reduce the incidence of hypoxic events.

However, healthy patients (i.e. ASA I and II patients) do not require CO<sub>2</sub> monitoring and since only ASA I and II patients qualify for sedation outside of a hospital operating theatre, the use of capnography in these instances is still controversial. Therefore, capnography is not mandatory for moderate sedation, but it is highly recommended in fragile ASA II children, obese children, children with OSA, and children with respiratory problems like asthma. For prolonged sedation (e.g. some plastic and dental procedures), it is highly recommended that capnography be used for deep sedation and analgesia, as there may be a higher incidence of respiratory depression.

Capnography techniques using nasal cannulae, side-stream analysis and transcutaneous methods are well-tolerated by children undergoing PSA. Even though capnography should never replace clinical monitoring of ventilation or respiration, it is highly recommended that capnography should be part of the standard minimum monitoring techniques in children.

### **7.7 Heart rate and rhythm**

Heart rate and rhythm are considered baseline vital signs and should be recorded on a sedation monitoring flow chart (Appendix 7) before the onset of the sedation. In moderate sedation, in ASA I and II patients, where continuous verbal contact with the patient is maintained, an electrocardiogram (ECG) is not essential and pulse rate, as recorded by pulse oximetry, should be sufficient. However, it may be very difficult to maintain continuous verbal contact with young children and an ECG, which is available on many of the current monitoring devices, should be used. For prolonged sedation or in fragile ASA II patients, ECG monitoring is indicated when standard or advanced techniques are used. Any patient with underlying cardiovascular disease should be monitored with an ECG.

### **7.8 Non-invasive blood pressure**

NIBP must be monitored at all levels of sedation, except maybe for minimal sedation or anxiolysis of short duration. It is important to ensure that the size of the NIBP cuff is appropriate for the age and weight of the child, to ensure accurate measurements.

### **7.9 Operator-dependent factors**

These factors may include airway manipulation, dose of administered local anaesthetic and environmental factors (e.g. room temperature) and must also be monitored.

### **7.10 Minimum monitoring standards**

- ASA I and ASA II patients: pulse oximetry and NIBP
- Fragile ASA II patients, prolonged sedation and patients under deep sedation: pulse oximetry, NIBP, ECG and capnography

Baseline vital signs must be recorded *prior* to the commencement of sedation. Thereafter, the child must be monitored at regular intervals during the procedure and the recovery period, until they are discharged from the facility. The child must never be left alone or unmonitored until fully recovered from all sedative, analgesic and dissociative drugs.

It is recommended that observations be recorded on a sedation monitoring flow chart (Appendix 7). The SP, or staff member designated to monitor the patient, must be in attendance at the patient's side at all times, and must be competent to recognise, and rescue the patient, from any complications.

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## 8. Personnel

Whenever sedation is performed, there should be no less than two people present (i.e. the operator who is performing the procedure and an appropriately trained observer). If the operator also provides the sedation for the procedure (i.e. a single operator-SP), the observer will be responsible for monitoring the child under sedation and to assist the operator in the case of adverse events. If the operator expects of the observer to take part in the sedation (e.g. by topping up the sedation), the observer will only be responsible for monitoring the patient and providing sedation as requested by the operator. The observer will not be able to assist with the procedure and the operator takes full responsibility for the sedation as well as the procedure. Since children often need deep sedation for procedures to be completed safely, this scenario is only acceptable for brief, minor procedures<sup>6</sup> and where minimal sedation with basic or standard techniques are used.

For all other procedures, especially when advanced sedation techniques are used, a three-person model should be followed, with a team consisting of:

- the operator with an assistant responsible to only help him,
- a dedicated SP, and
- an assistant for the SP.

### 8.1 The sedation practitioner

#### 8.1.1 Qualifications and training requirements

Relevant qualifications and regular updating of knowledge and skills remain the foundation of safe sedation practice. It is recommended that the SP should:

- have a primary, registered medical qualification,
- have full registration with the HPCSA as appropriate,

- have formal training in standard and advanced sedation techniques specifically for children, or be able to demonstrate equivalent experience and training (provision of audit records of safe administration of sedation drugs is also required),
- provide evidence of regular and recent paediatric sedation-related continuing professional development (CPD) activity appropriate to the sedation techniques provided,
- have a logbook, or equivalent, reflecting cases where sedation was done, as well as the technique used,
- comply with SASA recommendations for safe sedation practice in children, and
- have evidence available of up-to-date qualifications in BLS and APLS.

### **8.1.2 The single operator-sedation practitioner**

The single operator-SP is a healthcare practitioner who provides the sedation and at the same time performs the required procedure. Since it may not be possible to give full attention to monitoring the child while also performing the procedure, a second trained individual is necessary to assist the operator-SP in this role. According to the Academy of Medical Royal Colleges,<sup>13</sup> the assistant of the operator-SP can fulfil this role for procedures less than 30 minutes.

It is recommended that the operator-SP should undertake the dual role of SP and operator only when basic or standard sedation techniques are employed and the level of sedation does not progress beyond minimal sedation or anxiolysis. It is recommended that combination of drugs not be administered.

Since minimal or moderate sedation may not be sufficient to complete most procedures safely in young children, taking on the role of single operator-SP in young children is not recommended. Older children, who will cooperate and follow instructions, can safely be managed in this way if the operator and assistant are appropriately trained. The trained second person must be present throughout the procedure and must be capable of monitoring the clinical condition of the child and assisting the operator-SP in the event of complications. The second person may have received only in-house training, including competency in airway rescue, provided that this training is fully documented.

### **8.1.3 The dedicated sedation practitioner**

The dedicated SP takes full responsibility for the administration of sedatives, analgesics and/or dissociative drugs, and monitors the clinical effects of these drugs.

It is advised to use a dedicated SP in the following situations:

- The operator has no training in the administration of sedation in children.
- Fragile ASA II children.
- Children with comorbidities.

- The procedure is expected to be prolonged.
- The surgical procedures are complex.
- Advanced sedation techniques are to be used.
- Complex sedation techniques involving intravenous infusions (i.e. TCIs).

SPs and operators must only undertake procedures and interventions for which they have been specifically trained and for which they have been proven competent.

SPs (either single operator-SPs or dedicated SPs) should:

- have a good understanding of the pharmacokinetics and pharmacodynamics of the agents that they administer and specifically their use in children; this includes the pharmacology of the appropriate antagonists (which should be reserved for emergency use).
- understand the synergistic effects when combining drugs.
- be able to recognise and manage complications associated with the drugs in use,.
- be able to apply APLS techniques and manage, rescue and recover a child who unexpectedly enters a deeper-than-intended level of sedation.
- regularly audit their practice.

## **8.2 Observer and ancillary personnel**

An observer is always required for monitoring the child patient when a single operator-SP provides sedation, even for brief or simple procedures. The observer should have at least the equivalent of nursing training and must be proficient at maintaining airway patency and monitoring of vital signs. Such a person must be able to assist with ventilation if necessary.

All members of the sedation team must have received appropriate theoretical and supervised clinical training. Their knowledge and skills should continually be updated by way of medical education, attending in-house training sessions and airway certification, as well as taking part in simulation training for the management of emergencies. In-house training can involve various innovations in the form of formal lectures, supervised clinical training, monitoring, simulation of emergencies, documentation and recovery care. Evidence of in-house training must be documented and kept in the facility as proof of training or updating of knowledge and skills, which is an important medico-legal point.

Ancillary personnel must have a clear concept of their individual tasks. They must have adequate, current experience in their roles and must be involved in CPD and education in order to maintain their skills.

The following tasks must be completed with every sedation:

- Preprocedural screening, including patient evaluation, providing pre- and postsedation instructions and obtaining written informed consent (Appendices 3, 4, 8 and 9)

- Completing the preprocedural checklist (Appendix 11)
- Prescribing and administering sedation
- Patient monitoring (and rescue, where necessary) (Appendix 7)
- Performing the procedure
- Recovery and discharge after the procedure (Appendix 12)

### **8.3 Personnel requirements for each sedation endpoint (Section 2.2)**

The level of care is determined predominantly by the degree of preservation of the protective airway reflexes and the risk of respiratory depression.

#### **8.3.1 Minimal sedation or anxiolysis**

At this level of sedation, the airway, cardiovascular function and spontaneous breathing are usually unaffected. This level of sedation is suitable for the operator-SP, but in accordance with all international guidelines, there must be a second person, apart from the operator, who is responsible for monitoring the patient and helping with rescue, if needed. This is usually a level of sedation suitable for brief, simple procedures lasting less than 30 minutes. Clinical monitoring is extremely important. This level of sedation is often referred to as “changing the mood of the patient”.

#### **8.3.2 Moderate sedation/analgesia (conscious sedation)**

A level of sedation where the airway is usually maintained, cardiovascular function intact and the patient is breathing spontaneously. For this level of sedation, the following staff are required:

- An SP
  - trained in the selection, assessment and evaluation of the child for PSA, and specifically in airway assessment;
  - trained in specific paediatric sedation techniques;
  - trained in resuscitation and airway management in children and experienced in APLS;
  - with an understanding of the pharmacokinetics and pharmacodynamics of sedative, analgesic drugs and dissociative agents, their possible synergistic effects and specific reversal antagonists, as related to children – the SP must demonstrate competency when using combinations of drugs;
  - trained and experienced in the use of the drugs for moderate sedation and analgesia techniques in children;
  - with an understanding of the procedure to be undertaken: painful or non-painful, duration, requirements for immobilisation; and

- with an understanding of the value of monitoring the patient, and to never leave the patient unattended.
- A trained and dedicated observer, usually a nursing assistant, experienced in airway management and monitoring, to ensure that:
  - the child remains conscious;
  - respiratory function is adequate;
  - vital signs are within normal limits; and
  - the child is rescued from deeper-than-intended levels of sedation.
- An assistant to the SP is recommended for procedures longer than 30 minutes.

The observer must also be trained in BLS.

For more complex procedures, where combinations of drugs are used, prolonged sedation is required, or in children with comorbidities, a dedicated SP must be present.

### 8.3.3 Deep sedation/analgesia

Deep sedation/analgesia is part of the sedation continuum and the standard of care must be identical to that for an unconscious patient.

It is advised that a dedicated SP who is trained in paediatric sedation and preferably with experience in paediatric anaesthesia, as well as a trained assistant be present. The SP must have a valid APLS certification.

During deep sedation, intervention may be required to maintain the airway. Ventilatory efforts must be closely monitored as they may be inadequate, or even ineffective, against a closed glottis.

It is highly recommended that capnography is used to monitor ventilation.

### 8.3.4 General anaesthesia

GA is not part of PSA, even though it is mentioned on the sedation continuum. SPs must be able to rescue patients who unintentionally slip into unconsciousness.

Guidance for GA is provided in the SASA Practice Guidelines 2018 (available from <http://www.sasaweb.com>).

## **8.4 Personnel requirements for PSA in children who need special care**

Children who require special care (Section 10.2) include those with medical, physical, intellectual, psychological or social circumstances that require a different approach to treatment. They may have physical limitations, learning difficulties or movement disorders that make

treatment (e.g. dental treatment) very difficult. Intravenous sedation is usually used to relieve anxiety, produce drowsiness and offer an amnesic effect. Some patients may have to be hospitalised the night before to have a sedative or hypnotic drug administered.

Sedation for these children must only be undertaken by SPs with experience in sedating children with special needs. It is often necessary to use deeper levels of sedation. It may be extremely difficult to judge the level of sedation, so adjustments in treatment protocols may be necessary. Careful monitoring of the airway is mandatory. These cases should therefore not be attempted by the single-operator SP and a dedicated SP should be employed.

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## 9. Documentation required for procedural sedation and analgesia

Accurate documentation is crucial to protect the SP in case of legal challenges. If it was not written down, it never happened.

### 9.1 Before sedation

Documentation before sedation is aimed at obtaining information about the child, as well as providing information to the parent/caregiver.

Recorded information should include the following:

- *Valid informed consent to sedation and analgesia for medical or dental procedures (Section 4 and Appendix 3)*
- *Medical history questionnaire (Appendix 4)*

A recently updated medical history questionnaire should be evaluated by an appropriately trained SP, preferably before the day of the procedure. This must be checked again on the day of the procedure and before the initiation of sedation, for possible changes in the child's condition. It is important that the child's weight, and if available height, be indicated on the questionnaire, as drug dosages in sedation are calculated according to the weight of the child. This will also ensure that obese children are flagged beforehand, so that SPs may make an informed decision on whether the child is fit for sedation outside of a hospital setting. Significant underlying medical disorders (e.g. URTI, allergies, sleep apnoea, and uncontrolled asthma or diabetes mellitus) should be asked about. The use of chronic medication, including over-the-counter medications, should be noted.

The name, address and contact number of the parent/caregiver must be obtained and recorded. It is important to ensure that a responsible person will provide aftercare at home. If no-one is available, the sedation should be rescheduled.

- *Pre- and postsedation instructions (Appendices 8 and 9)*

Pre- and postsedation instructions should be provided at the time when the procedure is scheduled. This will give the parent/caregiver enough time to formulate questions and to organise transport and aftercare as necessary.

Information and instructions given to the parent/caregiver should include the aims, objectives and possible side effects of sedation. These should be provided both verbally and in written or printed form, and must be given to both the parent and the responsible caregiver. Parents/caregivers must be advised that oral sedatives must not be taken at home before sedation; all sedative drugs are to be administered at the facility where the sedation will take place.

It is important to ensure that a responsible *adult* will accompany the child home and will be available for aftercare at home. If such a person is not available, the sedation must be postponed. Parents/caregivers must be advised to seek immediate help in case of vomiting, strange and unusual behaviour, or any other symptoms or signs that does not seem normal. Parents/caregivers should be instructed to look for any breathing difficulties. The intake of food or fluids must be introduced slowly and only when the child is fully awake. Medication must be administered as prescribed by the physician. The child must stay at home and rest quietly.

Contact details of a physician, hospital and ambulance service must be included in the instructions, in the event of any procedure- or sedation-related adverse events during the first 24 hours after sedation.

- *Cover letter to the parent/caregiver (Appendix 10)*

It is recommended that every parent/caregiver receive a cover letter confirming the date, time and location of the procedure. This letter may also give an indication of the estimated fee for the sedation. An explanation of the forms that the parent/caregiver must complete will ensure that everything is in place on the day of the procedure.

- *Preprocedural checklist (Appendix 11)*

The aim of this document is to provide a final checklist before the start of the sedation process and procedure. This is of particular importance if the child was evaluated at an earlier consultation. A checklist is necessary to see if there has been any changes in the condition of the child that may affect the administration of sedation. The checklist must be completed and signed by the SP.

The SP must ensure that the following information has been obtained and documented:

- Details of the child, including ASA classification
- Details of the procedure (elective or emergency)
- The medical history questionnaire, which must be checked by the SP

- Confirmation that the child is fasted appropriately
- Confirmation that an adult will be responsible for aftercare at home
- History of previous sedation (i.e. failed sedation, previous airway problems and contraindications to sedation)
- Physical examination and evaluation of the child, including a focused assessment of the airway
- Details of chronic medication and whether the child took any medication on the day of the procedure (e.g. anti-epileptics, methylphenidate)
- Details of any prescribed pre-sedation medication at the facility, with details of the prescribing practitioner, the person administering the medication and the time of administration.
- Confirmation that the facility, equipment, monitoring devices and drugs were checked for safe sedation practice (Appendix 2).

## **9.2 During sedation**

### **9.2.1 Sedation monitoring flow chart**

A sedation monitoring flow chart (Appendix 7) is a time-based document that must be completed during the procedure. This includes the name, age, weight and fasting status of the child, and the route, dose and time of administration of any drugs, including N<sub>2</sub>O and O<sub>2</sub>. The site of venous access and type and volume of intravenous fluids administered should also be recorded. Observations obtained from clinical and electronic monitoring should be shown at no longer than 10 minute intervals. Requests from the operator for deeper levels of sedation should be noted. Total dose of drugs given must be shown.

Adverse events and complications must be documented on the monitoring chart. Any resuscitation measures instituted, escalation of care, or hospitalisation must also be recorded. Adverse events can be classified as critical, standard or lesser adverse events (Section 1.4). Critical events warrant immediate reporting within sedation care systems (e.g. the sedation society) and automatic peer review for continuous quality improvement.

Any behavioural problems occurring during or after sedation must be recorded on the monitoring flow chart.

In the case of a single-operator SP, a record may be regarded as contemporaneous if it is made immediately after the procedure.

## 9.2.2 Sedation scoring systems

Monitoring the level of sedation should begin at the start of the sedation, be continued throughout the procedure and into the recovery period, until the patient is discharged from the facility.

Owing to the lack of an affordable, reliable and validated electronic monitor for level of sedation, clinical monitoring, using sedation scoring systems (Appendix 6), is mandatory. These are clinical tools used to monitor the level of sedation (Section 7.2).

These scoring systems are subjective and dependent on the interpretation of the SP. In older children, loss of verbal contact is an indication that the child is entering deep sedation. In young children who lack communication skills, it may be very difficult to determine the level of sedation. Children may drift into GA, without the SP realising it. At this level of sedation, children must get the same care as children under GA, with special attention to maintaining an unobstructed airway.

## 9.3 During recovery

### 9.3.1 Postsedation monitoring chart

After the procedure is completed, monitoring must continue until the child is fully recovered. Vital signs (blood pressure, heart rate, respiratory rate, oxygen saturation, level of consciousness and pain levels) must be measured and documented at regular intervals on a postsedation monitoring chart (Appendix 12).

### 9.3.2 Postsedation instructions

Postsedation instructions (Appendix 9) must be provided at the time when the procedure is scheduled, so the parent/caregiver may have sufficient time to organise transport, time off or another responsible adult to stay with the child for the remainder of the day.

### 9.3.3 Discharge scoring systems

Discharge scoring systems (Appendix 13) can be used to define and document a child's clinical state immediately before discharge. These include validated scoring tools such as the modified Aldrete scoring system and the Modified Post Anaesthetic Discharge Scoring System (MPADSS). Although the Aldrete score was not originally designed for use in ambulatory patients, it is commonly used to determine whether patients are ready for discharge from the postanesthetic care unit. The MPADSS was designed to determine home-readiness after ambulatory surgery and not specifically for assessing patients undergoing PSA.

When using the modified Aldrete scoring system to evaluate the child, the score must be  $\geq 9$  before discharge from the recovery room can be considered. In addition, there must be no complications related to the procedure (e.g. bleeding or vomiting).

Although still widely used, the modified Aldrete scoring system has been largely superseded by the MPADSS as a tool to determine home-readiness. When using the MPADSS, patients are judged as fit for discharge when the score is  $\geq 9$  out of a maximum of 10.

It is no longer necessary for the child to be able to take fluids orally or pass urine prior to discharge. However, the parent/caregiver must be advised to contact the responsible physician if the child is unable to pass urine within 6–8 hours of discharge from the sedation unit.

#### 9.3.4 Documentation after discharge

The physician must be satisfied that aftercare at home is optimal before the child is discharged. A responsible adult, who is capable of taking care of the child unaided, must accompany the child home after treatment under sedation. A dedicated and responsible adult should remain with the child for the rest of the day and the responsibility of this caregiver at home extends to ensuring that the child takes the normal prescribed medication and to contact the SP in the case of adverse events. Both the accompanying adult and caregiver should receive the telephone number of a medical practitioner, hospital and ambulance service in the event of any procedure- or sedation-related adverse events. Sedation must not be administered if an accompanying adult or caregiver is not available.

The parent/caregiver must be supplied with written and verbal information with regard to postdischarge activities. This is extremely important as it has medico-legal implications.

Patients residing in rural areas must spend the first 24 hours post-procedure within a reasonable distance of medical assistance, or must guarantee that they have access to a telephone in case of complications.

### 9.4 Other

#### 9.4.1 Practice appraisal protocol

The aim of the practice appraisal protocol (Appendix 2) is to ensure that the inspection for accreditation of the facility is done by an appraised SP or equivalent body (e.g. SOSPOSA or the Council for Health Service Accreditation of South Africa [COHSASA]). The inspector must be satisfied that the appraised clinic, practice, rooms or facility meet the requirements for safe practice. The inspection investigates essential aspects such as governance, organisation, construction and equipment, as well as policies and procedures, including fire, safety, drugs, emergencies, staffing, training and unanticipated patient transfers in a practice setting to ensure patient safety and to reduce risk and liability to the SP.

## 9.4.2 Logbook

The SP must keep and complete a logbook of all cases done under sedation. Adverse incidents and accidents should be documented, as well as the date when, and institution or association where, these were reported. Logbooks are available on the SOSPOSA website for SPs to meet the requirements of safe practice and monitoring of children.

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## 10. Safe sedation practice

It is beyond the scope of this document to review any specific sedation techniques in detail as the same drugs are not used for all procedures. These should be addressed by supervised clinical training as well as updating of knowledge and skills. A variety of sedation techniques are available and practitioners may offer a combination of techniques. The pharmacology of sedative, analgesic and dissociative drugs will also not be discussed.

The main factors determining the choice of a sedation technique for a child are as follows:

- The risk-to-benefit ratio of the technique.
- The characteristics of the child (ASA classification and risk assessment profile).
- The nature of the procedure being performed (painless or painful, major or minor).
- The use of a sedative only or sedative as well as analgesics, as necessitated by the procedure.
- The qualifications, skills and experience of the SP, specifically for paediatric sedation.
- The operator's understanding of sedation safety issues relating to children.
- The environment and clinical setting (premises, drugs and equipment).
- The availability of skilled staff to monitor and perform the procedure.
- The availability of skilled support staff to assist, should rescue be necessary.
- The requirement for prolonged sedation (especially since more procedures are being done outside of a hospital operating theatre).
- The relevant contraindications.
- The use of evidence-based techniques.

The choice of sedation technique must be appropriate according to both the needs of the individual and the procedural requirements. It is recommended that the simplest techniques are implemented where possible.

### 10.1 Principles of safe sedation practice

These principles are centred on the following:

- Appropriate patient selection and evaluation, with an emphasis on a focused airway examination.
- Only ASA I and II children qualify for sedation outside of a hospital operating theatre.

- Children may be classified as fragile ASA II patients if not controlled on the morning or afternoon of the procedure (i.e. diabetic, asthmatic, obstructive sleep apnoea) – the condition must be controlled before sedation is started, where possible.
- Knowledge of the pharmacokinetics and pharmacodynamics of drugs, relating to children.
- Administration of the minimal dose of drug necessary to ensure the child's safety and comfort. This dose must have taken full effect before any additional dose is administered. The use of fixed doses or boluses is not recommended.
- SPs trained and experienced in paediatric sedation, support staff who understand the special issues relating to paediatric sedation, and facilities that meet the requirements for safe practice.
- SPs must be able to recognise and manage complications, and rescue and recover a child who enters a deeper-than-intended level of sedation.

The sedation technique should be tailored to the demands of the procedure. Considerations include whether the procedure is painless or painful; whether pain can be relieved by local or regional analgesia and whether systemic analgesics are needed; whether complete immobility is required and what the expected duration of the procedure is. The child's age and capability to cooperate will be crucial. Drug selection should be based on ease of dosing to reach and maintain the desired level of sedation and analgesia. Titration of drugs remains the safest way of administering drugs during PSA.

All advanced sedation techniques should include a working intravenous line for administration of rescue or emergency drugs.

Since airway obstruction and depression of ventilation are common negative effects of sedation, attention should be paid to positioning of the head and neck before the start of the sedation. A small pillow under the shoulders to extend the head and neck may minimise airway obstruction.

Sedation techniques need to be adjusted in children who require special care.

## ***10.2 Child groups requiring special care***

Children who may need special care during PSA include those with learning disabilities and other specific medical, emotional, mental or social impairments. These may impact the child's ability to understand, communicate and cooperate for safe treatment. Some children may have movement disorders, exhibiting sudden, uncontrolled movements making treatment impossible.

Children with special needs who require PSA may heighten anxiety in all members of the sedation team. Children are often very perceptive to this and may react negatively to the process of PSA. The presence of the parent/caregiver may be invaluable.

Good planning and consideration of several factors are required to decide on the best way to care for these children. The ability of the child to cooperate during the procedure will impact on the planned management. As much information as possible should be obtained from the parent/caregiver to best understand the child's needs. Simple questions about the child's reaction to previous procedures like dental examinations or obtaining blood samples, will give an indication of what to expect.<sup>15</sup>

For those who may not be able to cooperate during PSA and who require more complex or extended procedures, GA should be considered as a safe alternative. The patient may benefit from a single GA rather than multiple visits for PSA.

### 10.2.1 The obese child

- Intravenous placement of a cannula may be challenging.
- NIBP monitoring may be difficult since the cuff may not fit properly. Cuffs that are too small will overestimate true blood pressure, while cuffs that are too large will underestimate blood pressure.
- Obese children have a higher risk of gastro-oesophageal reflux disease and may be at risk of aspiration despite a nil per mouth status.
- Childhood obesity has a negative effect on variables such as FEV<sub>1</sub>, FVC and FEV<sub>1</sub>/FVC ratio. This may influence the child's response to episodes of hypoxia and hypercarbia.
- These children are at risk of undiagnosed obstructive sleep apnoea and may be at further risk of desaturation and apnoea during the recovery period.
- Calculating drug dosing may be problematic; drug dosing based on actual body weight will lead to overdose; dosing based on ideal body weight may be inadequate. Titration of drugs eliminates guesswork and is advisable.
- An increased risk of deep vein thrombosis and insulin resistance in these children should be kept in mind.

### 10.2.2 Children with cerebral palsy

Cerebral palsy is probably the most common disability in children. The aetiology is unknown in most cases. Children may have mild disease with normal intelligence but may also present with severe spasticity and intellectual disability. Common comorbidities include spasticity, scoliosis, gastro-oesophageal reflux and decubitus ulcers. Excessive drooling of saliva may lead to aspiration because of difficulty swallowing. Antisialagogues (e.g. atropine or glycopyrrolate) can be considered, but may thicken lung secretions. There is increased interest in using dexmedetomidine for sedation in children with cerebral palsy because of the neuroprotective effect.

PSA for children with cerebral palsy may be challenging when done outside of a hospital operating theatre. It is recommended that qualified, experienced SPs perform the sedation in these children.

### **10.2.3 Children requiring sedation for paediatric auditory electrophysiology**

Diagnostic paediatric auditory electrophysiology is sometimes done in small children. Testing includes measures such as the auditory brainstem response (ABR) and auditory steady state response (ASSR). Both procedures require children to keep extremely still during the recording. Testing can be done during natural sleep (children 0–6 months), procedural sedation with a variety of sedative drugs, and the use of GA. Single sedative agents (e.g. trimeprazine, chloral hydrate and promethazine) are sometimes used. Combination techniques (e.g. trimeprazine and droperidol, and midazolam and propofol) are also used by SPs.<sup>16</sup> These authors provide a comprehensive list of sedative drugs that could be considered. Monitoring of the children during sedation is extremely important.

### **10.2.4 Children with trisomy 21**

Children with trisomy 21 have several associated conditions that will influence the technique and method of sedation.

Macroglossia and a high incidence of OSA makes them vulnerable to developing partial or complete upper airway obstruction with the administration of sedative agents. Drugs which preserve airway tone, such as dexmedetomidine or ketamine, are useful in this group of children where moderate to deep sedation is required. Careful clinical monitoring with the assistance of capnography, where available, will aid in early detection of obstruction. This may be managed by cautious repositioning (see below), the use of a nasopharyngeal airway or may require the application of continuous positive airway pressure (CPAP).

Atlantoaxial instability may leave the cord vulnerable to injury with excessive flexion or extension. Careful positioning of the head in a neutral position is required once sedation is achieved. If there are any signs or symptoms of cord compression on presedation assessment, the child should be referred for investigation before any procedure is attempted.

Approximately 50% of children with trisomy 21 will have congenital heart disease. Children with suspected underlying heart disease should be referred for a cardiology evaluation. The sedation should be managed by an experienced SP. Only ASA I or ASA II patients should be done outside of a hospital operating theatre.

## 10.2.5 Paediatric sedation in the SARS-CoV-2 era

The possible transmission of SARS-CoV-2 infection to a member of staff during a procedure is of great concern to healthcare workers in the era of COVID-19. Procedural sedation which is administered intravenously without airway instrumentation, will enable procedures to be performed safely and without the risk of aerosolisation of respiratory droplets, and as such, may be preferable to the administration of a GA, where appropriate.

Where established safety protocols (such as those laid out in these guidelines) are followed by experienced SPs, a low incidence of interventions such as bag-mask ventilation, suctioning and unanticipated intubation during procedural sedation is reported.<sup>17-19</sup> Procedures and techniques sometimes required during procedural sedation (including airway repositioning, the use of an oropharyngeal airway and low-flow oxygen delivery via nasal cannulae) are not believed to be associated with significant aerosol generation.<sup>20</sup>

The following procedures are associated with a high potential risk of aerosol generation: open suctioning of airways, cardiopulmonary resuscitation (including bag-mask ventilation), and endotracheal intubation and extubation. Non-invasive ventilation (e.g. BiPAP, CPAP) and high-flow oxygen delivery are also believed to be aerosol-generating, while uncertainty exists around nebulisation and the use of inhaled nitrous oxide.<sup>21</sup> The risk of viral shedding during intranasal administration of medication by atomisation is unknown and this technique should be avoided in a patient with known or suspected COVID-19.<sup>22</sup>

With a focus on the mitigation of risk of transmission, it is recommended that all children referred for procedural sedation be screened both for symptoms according to the latest screening criteria (<http://www.sacoronavirus.co.za>) and for close contact with a confirmed COVID-19 positive patient in the preceding 14 days. The same screening should be applied to parents/caregivers. In addition to this, it is recommended that all elective sedation cases undergo testing for active SARS-CoV-2 infection. Elective procedures in SARS-CoV-2 positive patients should be postponed until 14 days after the resolution of symptoms.

**Where patients have been screened and tested negative** for the SARS-CoV-2 virus, sedation may proceed with current standard precautions:

- All healthcare workers present should wear a surgical mask, disposable gloves and a plastic apron over their work clothes.
- In cases where aerosol-generating procedures form part of the procedure (e.g. upper GI endoscopy or dental work), all healthcare staff attending to the patient during the procedure should wear an N95 mask and eye protection in addition to the protection described above.
- At the start of the case, the team should discuss plans for potential airway rescue. If airway rescue is required, team members should be comfortable with who will perform the various roles, and discuss which team members may step back. N95 masks and protective

eyewear should be at hand to be donned for any airway instrumentation. If airway rescue is anticipated, it may be prudent to don N95 masks from the outset, conscious of the need to protect PPE resources.

- The patient should wear a standard cloth or surgical mask but should take it off during the procedure for clinical monitoring purposes. Where capnographic monitoring is available, it is possible to apply the monitor and then put on a mask over it. Where the possibility exists, some capnographs can potentially accommodate a filter to be placed between the monitor and the patient.
- Thorough cleaning of all instruments and surfaces to take place between cases.

**Where patients have been screened and tested positive and the procedure is urgent** (required in a timely fashion to optimise treatment, cannot be delayed):<sup>23</sup>

**Symptomatic child:** The symptoms may range from mild with fever and gastro-intestinal (GIT) upset to severe with cardiac dysfunction in the case of multisystem inflammatory syndrome in children (MISC-C) (also referred to as paediatric inflammatory multisystem syndrome temporally associated with severe acute respiratory syndrome coronavirus 2 [PIMS-TS]).

- It is preferable to perform procedures on such children in an appropriately prepared operating theatre with full PPE for all staff.
- For procedures to be performed outside of a hospital operating theatre (such as in radiology), the area should be prepared as per SASA guidelines for the preparation of an operating theatre.<sup>24</sup>
- For procedures both in or out of theatre, it is recommended that referral is made to a specialist anaesthetist with experience in sedation or a highly experienced and trained paediatric SP.
- Natural airway sedation may remain the most appropriate technique to minimise viral transmission.
- Where possible, the patient should continue to wear a face mask during the procedure. This may be applied over nasal cannulae if necessary, with due consideration to clinical monitoring.

**Asymptomatic child:** The risk of transmission to healthcare workers remains and the procedure should be postponed unless urgent.

- In the case of urgent procedures, referral to a specialist anaesthetist with experience in sedation or a highly experienced and trained paediatric SP is recommended.
- Procedures that can be performed in an appropriately prepared operating theatre should be done so. In the case of procedures outside of a hospital theatre (such as radiology), the area should be prepared as per SASA guidelines for the preparation of an operating theatre.<sup>24</sup>
- Procedural sedation should be performed wherever possible to reduce the risk of viral transmission.

- Where possible, the patient should continue to wear a face mask during the procedure. This may be applied over nasal cannulae if necessary, with due consideration to clinical monitoring.
- Full PPE should be worn by all staff present for the procedure.

As our understanding of SARS-CoV-2 and COVID-19 is constantly evolving, these guidelines are expert opinion based on the best evidence available at the time of writing. Practitioners are urged to consult <http://www.sasacovid19.com> for updates to these guidelines.

### **10.3 Recovery**

The child must be allowed to recover from PSA in an appropriate and suitably equipped recovery room, with a healthcare professional trained in BLS. The staff-to-patient ratio should not be less than one recovery professional to two patients. A medical practitioner should assume overall responsibility for patients in the recovery area and may not leave the premises until discharge criteria are met (Section 9.3.3).

### **10.4 Discharge**

Premature discharge has been identified as a major contributing factor to severe morbidity and mortality in several postsedation adverse event analyses. When long-acting drugs have been used, there will be a delay to discharge readiness and a risk of re-sedation. These children will require a prolonged stay in the recovery area.

Depending on the facility where the PSA has been performed, discharge from the recovery area can be either to the ward and then home, or directly from the recovery area to home.

A separate, simple evaluation aid may be the ability of the child to keep their eyes open for 20 minutes after sedation in the recovery area, in a quiet environment where they are not being stimulated. Once the child is able to fulfil this criterion, they are usually fit to be discharged.

Children may only be discharged home into the charge of a parent, caregiver or other responsible person. This parent/caregiver must be given clear instructions and must have access to a telephone.

Instructions to be given to the parent/caregiver should include the following:

- Do not leave the child unattended at any time in a car seat. In a car, the child should be continuously watched to see that they have no difficulty breathing. In cases where the primary caregiver may be driving the car, it is strongly advised that a second adult is present to constantly supervise the child.
- Eating and drinking must be slowly initiated over the next few hours and only if the child is completely awake and alert.

- No play that requires coordination should be attempted for the next 12 hours (e.g. cycling, skating, swimming or climbing). The child should rest quietly at home.
- Supervise all playing and/or bathing for the next 12 hours. Do not leave the child alone at home.
- In case of vomiting, strange and unusual behaviour, or any other symptom or sign that does not seem normal for the child, seek immediate help or dial the provided telephone number.
- Give the medication as prescribed by the physician.

If the parent/caregiver does not understand and agree to the above, the child is not ready for discharge.

### **10.5 Follow up or patient satisfaction**

Following up on the wellbeing of the child within the week postoperatively is advisable, to receive feedback on the overall experience both of the child and of the parent/caregiver. Feedback aids in refining and improving the practice of paediatric PSA.

Evaluating patient satisfaction in children involves a multidimensional approach that entails different aspects of clinical care, safety and the absence or tolerable presence of certain known side effects, and in some settings, the cost of the procedure and sedation.<sup>25</sup> Macario et al.<sup>26</sup> concluded that the avoidance of postoperative nausea and vomiting was more important to some patients than the prevention of postoperative pain. Regular audit of the practitioner's practice is recommended and patient satisfaction could be included in future projects in a way tailored to the specific population applicable.

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## **11. Drugs used in procedural sedation and analgesia**

There is no one ideal drug for PSA available yet; therefore, combinations of drugs are often used. Most of the drugs used do not have both analgesic and sedative properties.

The intravenous route is often used because of the predictable onset and offset of action.

However, the placing of an IV cannula in children may be cumbersome and other modalities should be considered.

Inhalation sedation with N<sub>2</sub>O in oxygen is a longstanding and safe method to gain a child's cooperation and trust, especially in the dentist's office.

A useful technique in children is intranasal administration of sedation, especially when intravenous cannulation is challenging. It requires less cooperation and onset is faster than with oral sedation. The effect of drugs administered intranasally is more predictable due to direct absorption into the bloodstream and no first-pass metabolism. Sufficient cooperation can be

achieved within about 10 minutes, which allows for placement of the intravenous cannula. The intravenous route can then be used for the remainder of the sedation.

Oral sedation is an alternative for short, non-painful procedures. Owing to its unpredictability in terms of onset of action, effect and duration of action, it is seldom used as sole method for PSA. However, it is a useful route to administer premedication in order to obtain a child's cooperation for intravenous line placement. Some guidelines recommend that when only oral drugs are administered for sedation, intravenous cannulation is still mandatory.

Many of the maximum doses recommended here are lower than those quoted in the respective package inserts. This is because PSA frequently involves the administration of more than one type of drug. Drugs for PSA can act synergistically when used in combination and it is suggested that the doses be reduced accordingly and titrated to effect in divided doses. The sum of the incremental doses must not exceed the recommended maximum dose.

When administering drugs for PSA, the SP must remember that there is no fixed-dose, only a maximum dose. Drug dosages in children are usually calculated according to the child's weight. It is, therefore, important that the child's weight is documented on the sedation chart. If the child's weight is not available, the PAWPER tape can be used as a simple and reliable method of weight estimation in children and infants.

In general, the drugs selected for PSA should have a duration of action appropriate for the duration of the procedure. Sufficient time for peak brain effect (the target site) must be allowed, to prevent overdose of sedatives. Titration of administered drugs is deemed to be one of the single most important layers of safety. The SP must possess the relevant knowledge of the pharmacokinetics of each of the chosen sedatives used.

SASA recommends that GA induction agents (propofol, ketamine, etomidate, dexmedetomidine) and the short-acting opioids (fentanyl, alfentanil, sufentanil, remifentanil) should only be used by those formally trained in anaesthesia or intensive care medicine, or by experienced SPs with anaesthetic experience who are trained in specific advanced sedation techniques. SPs using these drugs in children must have *at least* a qualification in APLS.

In paediatric practice, the use of off-label and unlicensed drugs is common. Off-label drug use implies the use of licensed medicines outside the conditions of the license. Unlicensed drug use means using pharmaceutical products that have not been approved by any licensing authority of a specific country. Preparation of drugs by non-pharmacists occurs frequently and has resulted in the administration of medication "cocktails" in clinical practice. SPs are responsible for choosing the right drug and dose after careful consideration of expert opinion, scientific data on the drug(s), and what is published in medical literature.

## 11.1 Sedatives

### 11.1.1 Benzodiazepines

#### 11.1.1.1 Midazolam

Midazolam is a short-acting, water-soluble benzodiazepine with sedative, anxiolytic, amnesic and anticonvulsant properties. It has no analgesic effect. Used in the recommended doses (Table III), the administration of midazolam should result in a conscious, compliant child. It can be administered via various routes; used alone, as an oral agent, or as an intravenous sedative technique.

When administered in combination with other depressant drugs (particularly opiates, with which midazolam has a super-additive effect), or used on its own in higher than recommended doses, midazolam is likely to result in the loss of upper airway muscle tone with obstruction. Respiratory and cardiac depression are also possible consequences. Children predisposed to upper airway obstruction are particularly at risk. Ataxia, dystonia and diplopia are other possible adverse effects associated with midazolam use.

The reported incidence of paradoxical agitation is quoted as high as 15% in paediatric patients.<sup>27,28</sup> The most common causative agent is the benzodiazepines and these reactions more commonly occur within 3–6 minutes after administration.<sup>29</sup> The reaction was originally described as “behavioural toxicity” and includes symptoms such as agitation, aggression, excitement and excessive movement, characterised by confusion and disinhibition, and also includes sympathetic activation resulting in hypertension and tachycardia. The patient can be at risk of injuries to themselves as well as the staff around them.

The proposed management includes BLS guidelines and reassurance. If the patient is very agitated, pharmacological management is advised to abort the reaction using a dosage of flumazenil (Table IV). Smaller dosages (e.g. 5 mcg/kg) has also been described.<sup>30,31</sup> The literature also describes the usage of an alternative agent, such as ketamine. Additional dosages of midazolam are not recommended and increase the risk of unintended deeper levels of sedation which is associated with a greater risk of respiratory depression.

The intranasal route of administration is useful, particularly in children who need special care. However, it may cause a burning sensation, and a bitter after taste which may last for several days. A single puff (10 mg/puff) of lignocaine spray prior to installation of intranasal midazolam may improve tolerability, as will the use of an atomisation device. Mucosal Atomization Device (MAD®, LMA North America, San Diego, CA) is available and makes nasal administration easier and more acceptable.

Rectal administration could be considered in young children, but absorption may be unpredictable. Rectal administration may also be preferred in children who refuse oral medication. Parental consent should always be sought prior to administering medication via the rectal route. A paediatric feeding tube can be used to administer midazolam rectally.

Intramuscular administration is painful and is not recommended.

**Table III:** Sole agent dosing schedule of midazolam

Route of administration	Dose	Recommended maximum dose	Time to peak effect	Duration of action
Oral	0.25–0.5 mg/kg	7.5 mg	10–30 minutes	60 minutes*
Sublingual	0.25–0.3 mg/kg	0.3 mg/kg	10–15 minutes	20–60 minutes*
Intravenous	0.025–0.1 mg/kg**	1 mg	3–5 minutes	20–60 minutes*
Rectal	0.5–0.75 mg/kg	1 mg/kg	10–20 minutes	60 minutes*
Intranasal	0.2–0.3 mg/kg	0.3 mg/kg	10–15 minutes	60–120 minutes*

When used in combination with other drugs, doses should be decreased and titrated to effect

\* Dose-related

\*\* Titrate to effect, repeat dose every five minutes until desired level of sedation achieved

The intravenous formulation can be given orally mixed with a small volume of juice, cold drink or paracetamol syrup to disguise the bitter taste. Once mixed, the shelf life is less than 24 hours. To improve palatability, tablets can be crushed between two spoons and mixed in the same way.

When given intravenously, most children should require no more than 1 mg and, in combination with other depressant drugs,  $\leq 0.5$  mg is recommended. Titration to effect remains the best option.

#### 11.1.1.2 Flumazenil

Flumazenil is an imidazobenzodiazepine compound used clinically as a benzodiazepine antagonist. It reverses the sedative and respiratory depressant effects of midazolam by competitively antagonising GABA-receptors. Flumazenil should be readily available whenever midazolam is used (Table IV).

Flumazenil has a quick onset of action. The duration of action is approximately one hour and, if large doses of midazolam have been administered, re-sedation may occur at this point. In such cases, the child should be carefully monitored for at least two hours, with a view to repeat the flumazenil dose. In an emergency, if intravenous access is not available, the intravenous dose may be given intranasally.

In patients who are taking benzodiazepines for seizures or behavioural disturbances, or any other drugs that potentially lower the seizure threshold, administration of flumazenil may precipitate these symptoms.

**Table IV:** Dosing schedule of flumazenil

<b>Dose</b>	<b>Titration interval*</b>	<b>Maximum dose</b>	<b>Duration of action</b>
10 µg/kg over 30 seconds	2 minutes	1 mg/kg	1 hour

\* Repeat dose until desired effect is achieved or maximum dose reached

## 11.1.2 Anaesthetic agents

### 11.1.2.1 Ketamine

Ketamine is a popular and safe drug for procedural sedation. Ketamine is an N-methyl-D-aspartate glutamate receptor antagonist (NMDA agonist) which reduces the presynaptic release of the excitatory neurotransmitter, glutamate. The multiple actions and cardiovascular stability of ketamine make it a very useful agent for painful procedures. Used in high doses, it induces a state of cortical dissociation with profound analgesia, sedation and amnesia. Ketamine is sometimes associated with non-purposeful movements, which may limit its use when total immobility is required (e.g. for CT or MRI scans). In this instance, ketamine can be combined with other intravenous drugs (e.g. propofol) to prevent non-purposeful movements.

Compared with other anaesthetic agents, there is relative preservation of airway reflexes and muscular tone.<sup>32</sup>

Prophylactic co-administration of an anti-sialagogue (atropine 0.02 mg/kg orally or intravenously, or glycopyrrolate 0.01 mg/kg intravenously) is recommended to diminish the production of tracheobronchial secretions and saliva. The production of secretions can be particularly problematic in the presence of a URTI and will predispose to laryngospasm. The need for suctioning of secretions is often necessary.

The emergence delirium associated with ketamine in adults is less common in children and of a much smaller magnitude. It correlates significantly with the degree of preprocedural agitation. The addition of midazolam does not reduce the incidence of mild to moderate emergence agitation but will deepen and prolong sedation, increasing the likelihood of apnoea.<sup>33-35</sup>

The sympathomimetic action of ketamine may result in a tachycardia and hypertension.

Previously contraindicated in the context of head and eye injuries owing to concerns about raised intracranial pressure, ketamine is now accepted as safe in these patients. Other reported reactions (ataxia, nystagmus, myoclonus, random limb movements and opisthotonus) are rarely clinically important.<sup>33</sup>

Ketamine, as a single agent, can be used at subhypnotic doses to achieve an analgesic effect.

Ketamine can be given via multiple routes (Table V), including intranasally, but accurate pharmacodynamic information for children is not available.

When used in combination with other sedative agents, and to decrease the likelihood of complications (respiratory depression and airway obstruction), the dose of ketamine should be reduced and titrated to effect, especially when administered intravenously.<sup>34</sup>

Table V: Dosing schedule of ketamine

Route of administration	Dose	Onset of action	Time to peak effect	Duration of action
<b>Sedation</b>				
Oral	6–10 mg/kg	> 5 minutes	30 minutes <sup>†</sup>	4–6 hours
Intravenous (bolus)	0.25–1 mg/kg <sup>**</sup>	< 1 minute	3–5 minutes	10–15 minutes
Intravenous (infusion)	0.5–1 mg/kg/hour <sup>***</sup>	< 1 minute	3–5 minutes	10–15 minutes
Intramuscular	2–4 mg/kg	2–5 minutes	20 minutes	30–120 minutes <sup>†</sup>
Rectal	4–6 mg/kg	> 5 minutes	30 minutes <sup>†</sup>	30–120 minutes <sup>†</sup>
Intranasal	5 mg/kg	5–10 minutes	20 minutes	20–120 minutes
<b>Analgesia</b>				
Oral	4–6 mg/kg	> 5 minutes	30 minutes <sup>†</sup>	4–6 hours
Intravenous (infusion)	0.15–0.3 mg/kg/hour	< 1 minute	3–5 minutes	15 minutes

<sup>†</sup>Dose-related

<sup>\*\*</sup>Titrate to effect, repeating dose every three minutes until desired level of sedation achieved

<sup>\*\*\*</sup>Infusion following bolus dose of 0.25–1 mg/kg

### 11.1.2.2 Propofol

Propofol, a water-soluble phenol, is a short-acting, intravenously administered sedative hypnotic that can be used in small boluses titrated to effect (Table VI), or as a continuous infusion.

Propofol is a controversial drug in the non-operating theatre environment. Its rapid onset and offset make it attractive for PSA. However, it has a narrow therapeutic index with a small margin of safety when compared with the other sedatives outlined in these guidelines (e.g. midazolam and ketamine). Deep sedation, airway obstruction and apnoea occur rapidly and unpredictably. Children are particularly sensitive to repeated boluses of propofol.

Propofol should only be administered by an experienced SP, preferably with anaesthetic training, who is skilled in the airway management of children, and in a facility that meets all the criteria laid out in these guidelines (Appendix 1 and 2). It should only be used for brief procedures, as repeated doses or infusions are more likely to be associated with adverse events.

The use of capnography is highly recommended when propofol is used for sedation, due to the relatively high incidence of respiratory depression and airway obstruction. Supplemental oxygenation may mask this adverse event if oxygen saturation alone is monitored.

In up to 90% of cases, propofol causes pain on injection. Combination with lignocaine (0.1 ml 2% lignocaine/ml of propofol) will reduce this. Another option is to leave the tourniquet in place for 1 minute and give 1–2 ml of 2% lignocaine as pretreatment, before removing the tourniquet.<sup>36</sup>

Prolonged infusions (> 18 hours at > 4 mg/kg/hour) have been associated with fatal metabolic acidosis.

Propofol has no analgesic properties and an appropriate analgesic agent should also be given if a painful procedure is planned. However, the combination of propofol and other sedatives/analgesics will give rise to an increased risk of adverse events.<sup>34,37</sup> Advanced paediatric PSA with a combination of drugs should only be used by experienced SPs, with the ability to recognise and rescue unintended effects. Even though the incidence is very rare, the highest rate of intubation following serious adverse events in paediatric PSA is seen with propofol use (in a recent meta-analysis from cases in the emergency department).<sup>38</sup>

Table VI: Single agent dosing schedule of propofol

Dose	Onset of action	Duration of action	Repeat dose	Titration interval
0.3–0.5 mg/kg	45–90 seconds	5–8 minutes	0.5 mg/kg	1 minute

### 11.1.2.3 Ketofol

Ketofol is a combination of ketamine and propofol. The synergism between ketamine and propofol means lower doses of each drug can be used in combination, potentially decreasing the likelihood of side effects.

Used alone, this combination is adequate for minor medical and dental procedures. More painful procedures will require either deeper levels of sedation or the addition of further agents such as local anaesthetic.

The recommended preparation of ketofol for paediatric use is 50 mg ketamine with 90 mg propofol diluted to 10 ml. This results in a concentration of 5 mg/ml ketamine and 9 mg/ml propofol and, of this solution, 0.05 ml/kg is recommended (Table VII).

Both agents can have side effects, and airway vigilance is essential as the incidence is not necessarily lower in patients sedated with ketofol, compared to propofol alone.<sup>39</sup>

Providers need to be careful with repeating boluses as this could result in a high accumulative dosage of ketamine, ultimately prolonging the recovery from the sedation.<sup>40</sup>

The mixture of ketofol in a single polypropylene syringe has been shown to be compatible, both chemically and physically, at room temperature resulting in a predictable and stable concentration.<sup>41,42</sup>

**Table VII:** Dosing schedule of ketofol, consisting of ketamine 5 mg/ml and propofol 9 mg/ml

Route of administration	Dose	Onset of action	Duration of action	Repeat dose	Titration interval
Intravenous	0.05 ml/kg*	30–90 seconds	5–10 minutes	0.05 ml/kg	1–5 minutes

\* Ketamine 0.25 mg/kg and propofol 0.45 mg/kg

### 11.1.3 Alpha-agonists

Alpha-agonists are sedative analgesics with anxiolytic, but no amnestic, effects. When used in the recommended doses as single agents, these drugs have little to no respiratory depressant effects. Oral agents are particularly useful in combination with simple analgesics for painful procedures.

#### 11.1.3.1 Clonidine

Clonidine can be administered via multiple routes but, for the purposes of procedural sedation, the oral route is recommended (Table VIII).

**Table VIII:** Sole oral agent dosing schedule of clonidine

Dose	Onset of action	Time to peak effect
1–5 µg/kg	20–40 minutes	60 minutes

#### 11.1.3.2 Dexmedetomidine

Dexmedetomidine is a highly selective  $\alpha_2$ -adrenergic receptor-agonist providing sedation, anxiolysis, analgesia and sympatholysis, without respiratory suppression. Dexmedetomidine is being used increasingly for sedation in children, but this use is off-label owing to its global lack of licence for this age group. Dexmedetomidine is only recommended for use by those highly experienced in paediatric sedation and with anaesthetic training. It should only be used in an in-hospital setting.

Dexmedetomidine does not appear to have any effect on the respiratory system with airway patency and ventilation maintained.

Patients sedated with dexmedetomidine are rousable when stimulated as sedation mimics endogenous sleep and the EEG resembles that of natural non-rapid eye movement sleep. Dexmedetomidine causes interference with thermoregulation and the patient is at risk of developing hypothermia.

Transient hypertension, hypotension, bradycardia and sinus arrest are possible adverse events that may occur with dexmedetomidine use, especially with rapid loading doses, comorbid cardiac disease, younger patients with enhanced vagal tone, or when administered with other medications that possess negative chronotropic effects. Caution should be exercised with the loading dose (i.e. initial loading dose administered in not less than 10 minutes). It should be used with caution in younger children and avoided in those with cardiac disease.

Dexmedetomidine can be administered by intravenous bolus and/or infusion as well as intranasally, in which case it is best administered undiluted using an atomising device. Intranasal administration has the advantage of bypassing first-pass metabolism.<sup>43</sup> Dexmedetomidine can be administered via the buccal route using similar dosing to the intranasal route. However, this route is less effective than the intranasal route (Table IX). Ketamine (1 mg/kg) can be added to dexmedetomidine for sedation of painful invasive procedures.

Table IX: Dosing schedule of dexmedetomidine

Route of administration	Dose	Onset of action	Time to peak effect	Duration of action
Intravenous (bolus)	0.5–1 µg/kg over 10 minutes	5–10 minutes	15–30 minutes	60–120 minutes
Then intravenous (infusion)	0.2–1 µg/kg/hour	N/A	N/A	N/A
Intranasal	1–4 µg/kg	15–30 minutes	N/A	55–100 minutes

#### 11.1.4 Other sedative agents

##### 11.1.4.1 Chloral hydrate and trichlophos

Chloral hydrate is one of the oldest sedative-hypnotic drugs available. Despite its long track-record of use in this country, it is not registered for use in humans with the Medicines Control Council (MCC) of South Africa, but can be acquired for use provided a Section 21 application is made to the MCC. It has no analgesic properties and should be used for non-painful procedures only. Trichlophos is structurally similar and can be used interchangeably with chloral hydrate. Chloral hydrate and trichlophos are only available in oral form.

In the recommended doses (Table X), chloral hydrate is considered safe even though it has a very long half-life. Respiratory depression with airway obstruction can occur in predisposed patients. Therefore, chloral hydrate should never be administered by untrained personnel unable to manage unwanted events.

Extra care should be taken in children with conditions predisposing them to upper airway obstruction, such as tonsillar hypertrophy.<sup>37</sup> This is more likely to occur when higher doses

( $\geq 75$  mg/kg) are used, or when chloral hydrate is combined with other depressant drugs. Combination of chloral hydrate with other agents is therefore not recommended.

Other adverse effects include gastric irritation, nausea and vomiting. These effects are lessened by administration with food or water. Chloral hydrate has been shown to be more effective when taken on a full stomach.

The sedative effects of chloral hydrate are unreliable over the age of three years. In toddlers and infants, its duration of action may be prolonged. The degree of sedation is dose dependent. Postprocedural monitoring must continue until the level of sedation, without stimulation, is clearly decreasing.

In premature infants, the duration of action will be significantly prolonged and respiratory depressant effects will be evident at lower doses. It is not recommended for use in this group of patients.

Chloral hydrate is contraindicated in patients with porphyria.

Table X: Dosing schedule of chloral hydrate

Dose	Maximum dose	Onset of action	Time to peak effect	Duration of action
25–100 mg/kg	2 g	15–30 minutes	30–60 minutes	6–8 hours

#### 11.1.4.2 Trimeprazine

Trimeprazine (Vallergan®) is a long-acting phenothiazine derivative, which may be used on its own or in combination with other sedatives (e.g. droperidol). It is available in oral form and, due to erratic absorption, the onset time is variable (Table XI). Trimeprazine also poses unwanted anticholinergic side effects such as dry mouth, tachycardia and fever, but convulsions and coma are rarely seen. Instances of paradoxical excitation have been described.

The long duration of action of trimeprazine makes it unsuitable for the outpatient or ambulatory setting.

Table XI: Dosing schedule of trimeprazine

Dose	Onset of action	Duration of action
1–2 mg/kg	60–90 minutes	5–8 hours

#### 11.1.4.3 Droperidol

Droperidol is a butyrophenone with sedative and antiemetic, but no anxiolytic, properties.

It should only be used in combination with other sedatives, such as trimeprazine, due to commonly experienced dysphoria and “locked-in” feeling when prescribed alone.

Droperidol increases QT interval in a dose-dependent fashion among susceptible individuals and high doses of the intravenous form (usually in the setting of psychosis) have been associated with cardiac arrest. The doses recommended for sedation (Table XII) fall well below this level and no specific cardiac monitoring is recommended.

Droperidol may be administered by oral or intravenous routes (Table XII). For the purposes of paediatric sedation, only the oral route is recommended in combination with trimeprazine.

However, due to its long duration of action, droperidol should not be considered for outpatient procedural sedation.

In patients with established postoperative nausea and vomiting, droperidol is a very effective antiemetic in low doses, with no associated sedation.

Table XII: Dosing schedule of droperidol

Route of administration	Dose	Duration of action
<b>Sedation</b>		
Oral	0.05–0.2 mg/kg	2–6 hours
<b>Antiemetic</b>		
Oral or intravenous	10–20 µg/kg	6 hours

## 11.2 Analgesics

### 11.2.1 Opioids

Opioids are analgesic drugs that can induce varying degrees of sedation and respiratory and cardiac depression, particularly when used in combination with other respiratory depressant drugs (e.g. midazolam). Opioids are not primarily sedative drugs and the sedative action is a side effect.

#### 11.2.1.1 Tilidine

Tilidine (Valoron®) is an intermediate-acting opiate available in droplet form. One droplet contains 2.5 mg of the active ingredient. Tilidine is a sublingually administered opioid, with a side effect profile common to this group of drugs. It has a bitter taste and is best administered under the tongue or just inside the tooth margins. In bigger children, where the body weight is excessive for age, the dose of a “drop per year of age” may be used as a guide, and titration to effect is recommended (Table XIII).

Tilidine may not be used for analgesia during sedation per se, but it might have been given to the patient upon presentation to alleviate pain. Be mindful that it can lead to unintended deeper levels of sedation should the patient undergo PSA following its administration (e.g. a patient presenting to the emergency department for a fracture that requires sedation

for manipulation). Bhatt et al.<sup>34</sup> found an increased odds ratio of adverse events in a large prospective, multicentre cohort study where preprocedural opioid administration was used. This should not discourage the alleviation of preprocedural pain but alert the practitioner to be mindful of those agents already used.

Table XIII: Dosing schedule of tilidine

Dose	Time to peak effect	Duration of action
1 mg/kg*	45 minutes	4–6 hours

\* Number of drops = body weight/2.5

### 11.2.1.2 Fentanyl and alfentanil

Fentanyl and alfentanil are potent, short-acting opioids with significant potential for respiratory and cardiac depression, particularly when used in combination with other respiratory depressant drugs (Table XIV and XV). Practitioners administering these drugs should be experienced SPs with airway management skills. Meticulous monitoring of respiratory and cardiovascular parameters throughout the procedure and recovery period is imperative. Naloxone should be at hand.

Fentanyl and alfentanil should not be used as sole analgesic agents, but rather to augment the effects of simple analgesics. When used in combination with other depressant drugs, such as midazolam, doses should be reduced and titrated to effect. Slow titration of small boluses will decrease, but not eliminate, the possibility of adverse events. When combining fentanyl with either propofol or ketamine, the risk for adverse events and interventions are increased.<sup>34</sup>

In patients at risk of upper airway obstruction, administration of fentanyl or alfentanil may precipitate this event.

Neonates may experience prolonged sedation and respiratory depression because of a slower metabolism and excretion, and extreme caution should be exercised in this age group.

SPs should also be vigilant in the postprocedure period when the stimulus of the procedure has passed, but the drug is still active and more likely to cause respiratory depression.

Table XIV: Sole agent dosing schedule of fentanyl

Route of administration	Dose	Onset of action	Time to peak effect	Maximum dose	Duration of action
Intranasal	1–2 µg/kg*	10 minutes	15 minutes	3 µg/kg	1–2 hours
Intravenous	0.25 µg/kg**	Immediate	3–8 minutes	2 µg/kg	30 minutes***

When used in combination with other drugs, doses should be decreased and titrated to effect

\* Repeat doses of 0.5 µg/kg, after 10 minutes if analgesia is inadequate to a maximum of 3 µg/kg, titrated

\*\* Titrate to effect, repeating dose every three minutes until desired level of analgesia is achieved or maximum dose reached

\*\*\* Dose-related

Alfentanil has a rapid onset and short duration of action, making it useful for short, painful procedures. It should be titrated until the desired level of analgesia is reached (Table XV). If the procedure is expected to take longer than two minutes, an infusion should be initiated. This should be terminated at the conclusion of the procedure.

Table XV: Sole agent dosing schedule of alfentanil

Intravenous bolus dose	Titration interval	Duration of action	Infusion dose
0.5–1 µg/kg	2 minutes	< 5 minutes	0.5–1 mcg/kg/min

#### 11.2.1.3 Remifentanil

Remifentanil is currently not recommended for analgesia in children for PSA, especially outside of the hospital environment.

#### 11.2.1.4 Naloxone

Naloxone is a specific opioid antagonist that will reverse the respiratory depressant as well as analgesic effects of opioids. It should be readily available whenever opioids are used (Table XVI). It should only be used in cases of severe respiratory depression or respiratory arrest, as reversal of the analgesic effects may cause a profound sympathetic response. As the duration of action is short, respiratory depression may recur, requiring additional doses. For this reason, monitoring should continue for at least two hours after administration of naloxone. Once a response to the intravenous dose has been achieved, the additional total effective dose could be administered intramuscularly. In an emergency, if intravenous access is not available, the initial doses may be given intramuscularly.

Table XVI: Dosing schedule of naloxone

Dose	Titration interval*	Maximum dose	Duration of action
1–2 µg/kg	2 minutes	1 mg/kg	45 minutes

\* Repeat dose until desired effect achieved, or maximum dose reached

### 11.2.2 Nitrous oxide

N<sub>2</sub>O is an anaesthetic agent with analgesic properties. It is available in pure form or premixed in a 1:1 ratio with oxygen, known as Entonox®.

In older children who can hold a mask, N<sub>2</sub>O is very useful because of its rapid onset and offset of action and its excellent safety profile. The recommended administered concentration is 50% (Table XVII) and often used by the operator-SP in South Africa, especially in dentistry, as this concentration or less will produce minimal sedation.

If a higher concentration is administered, the sedation must be classified as an advanced sedation technique, with all the implications of monitoring the patient attached to this sedation technique. For painful procedures, analgesia must be supplemented with, for example, local analgesia. If other sedatives are used, respiratory depression must be anticipated.

$N_2O$  is only recommended in ASA I and II patients. In those with myocardial disease,  $N_2O$  may cause a detectable degree of myocardial depression and, in patients with respiratory disease it may alter the response to hypoxia.

$N_2O$  diffuses into air-filled cavities and should not be used in the following cases:

- chest injuries, with possible pneumothorax
- head injuries, with possible pneumocranium
- suspected bowel obstruction

Although  $N_2O$  is emetogenic, vomiting is rare and aspiration exceedingly so.

$N_2O$  is best administered via a demand-valve system connected to a cylinder of Entonox®. The procedure should be fully explained to the child, who should be able to hold the mask with the demand valve without assistance. The sensitive demand valve is activated by the child's inspiration, with the rate of delivery of gas determined by the force of inspiration.

In those children unable to operate a demand valve, a breathing circuit with continuous flow from an anaesthetic machine may be used. Scavenging should be available for such cases. To avoid the delivery of a hypoxic mixture when delivering  $N_2O$  other than as Entonox®, in-circuit gas analysis should be employed. If concentrations above 50% have been administered, supplemental oxygen should be administered for several minutes after  $N_2O$  has been discontinued to counter the possibility of diffusion hypoxia.

The cylinders and valve must be checked and maintained regularly, according to manufacturer's guidelines with documented servicing. Injury can be prevented by safe storage of these devices.

Table XVII: Dosing schedule of nitrous oxide ( $N_2O$ )

Dose (concentration administered)	Onset of action	Time to peak effect
50%	30–60 seconds	3 minutes
70%	30–60 seconds	3–5 minutes*

\*Deep sedation will result if the child does not hold the mask themselves

### 11.2.3 Methoxyflurane

Methoxyflurane is a potent inhalational fluorinated hydrocarbon. It has recently become available in South Africa after withdrawal in the 1970s due to concerns about postoperative acute kidney injury. It provides good analgesia in subanaesthetic doses, and offers great potential for the provision of analgesia and sedation in the prehospital emergency care setting.

It has been reintroduced in clinical practice for use in procedural sedation as a self-administered analgesic since it doesn't appear to be associated with nephrotoxicity when administered for short periods at these doses. Deeper levels of sedation may result when administered directly by the practitioner, which is often the case in younger patients. Self-titration with an inhaler for anticipatory analgesia is recommended.<sup>44-46</sup>

The use of methoxyflurane is controversial due to its possible negative effects on kidney function.

### 11.2.4 Simple analgesics

Simple analgesics are analgesic drugs that have no sedative effects.

Paracetamol and nonsteroidal anti-inflammatory drugs (NSAIDs) are extremely useful, but must be allowed time to take effect before a procedure is performed (Table XVIII). NSAIDs should be avoided in any child requiring fluid resuscitation, until good urine output is established. Additionally, also avoid if any other contraindications to NSAIDs are present.

Suppository formulations of these drugs do not consist of a uniform distribution of the active ingredient. As a result, they cannot be divided to administer smaller doses.

Always consider asking parental consent for analgesic (or any) suppository medication before administration as discussed under consent for procedures.

Table XVIII: Dosing schedule of simple analgesics

Drug	Route of administration	Dose	Time to peak effect
Paracetamol	Oral	20 mg/kg	100–120 minutes
	Rectal	40 mg/kg	60–240 minutes
	Intravenous*	15 mg/kg	50–60 minutes
Ibuprofen	Oral	10 mg/kg	120–240 minutes
Diclofenac	Rectal	1–1.5 mg/kg	30–45 minutes
Ketorolac	Intravenous	0.5 mg/kg	60–120 minutes

\*A loading dose of 20 mg/kg can be given if it is the first intravenous dose the patient receives

### 11.2.5 Local anaesthetics

Local anaesthetics should be considered wherever possible, bearing in mind that additional sedation or anxiolysis might be necessary. These can be used topically or by infiltration.

EMLA® (Eutectic Mixture of Local Anaesthetics) requires at least an hour for full effect. It can be used on intact or broken skin and penetrates to a depth of 3–12 mm. EMLA® stickers are also available and with the help of the provided documentation or a phone call prior to the procedure, it can be applied by caregivers at home 60–90 minutes prior to the procedure.

Warming and alkalising the solution of local anaesthetic may reduce the sting experienced on infiltration.

It must be noted that the local anaesthetics are membrane depressants and, if given in excessive doses, may depress the cardiovascular and respiratory systems. This is especially important in PSA for dentistry if a block does not take effect and further doses of local anaesthetic are given.

Note that toxicity is additive; if one drug is used in combination with another, the combined dose should not exceed the maximum safe dose of either drug (Table XIX).

**Table XIX:** Maximum safe doses of local anaesthetic drugs

<b>Drug</b>	<b>Dose with adrenaline</b>	<b>Dose without adrenaline</b>
Lignocaine	7 mg/kg	3 mg/kg
Bupivacaine	2.5 mg/kg	2.5 mg/kg

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## Appendix 1: Basic equipment and drugs for procedural sedation and analgesia in children

All equipment should be checked regularly and stored in a cupboard.

### Devices to administer oxygen and assist with ventilation

Oxygen and oxygen tubing	Oxygen source must be reliable and able to provide at least 90% oxygen via a self-inflating positive pressure delivery system at 15 L/min for at least 60 minutes
Oxygen flow regulator	
Nasal prongs	(± CO <sub>2</sub> monitoring)
Venturi masks	To deliver 40% oxygen
Nebuliser and mask	
Self-inflating resuscitation bag with reservoir for children	
PEEP valve	
Catheter mount	

### Airway devices and equipment

Face masks	Size 0, 1, 2, 3 and 4
Laryngeal mask airways or similar supraglottic devices	Sizes 1.5–3
Range of cuffed endotracheal tubes	Uncuffed (sizes 2.5–5.5 mm); Cuffed (sizes 4.0–7.0 mm)
Laryngoscope set	Two handles with adult and paediatric blades, and spare batteries and bulbs
Water-soluble lubricant	
10 ml syringe for inflation of pilot balloon	
Tape or equivalent to secure endotracheal tube	
Oropharyngeal airways	Sizes 0–5
Nasopharyngeal airways	Sizes 4 mm and 7 mm; if smaller sizes are not available, one can use an ET cut to size in nasopharynx
Stylets/introducers/gum elastic bougie	Appropriately sized for endotracheal tubes
Magill forceps	Adult and paediatric size

### Monitoring equipment

ECG monitor and cardiac defibrillator	With conductive paste or pads, paddles and electrodes
Pulse oximeter	Adult and paediatric probes
Blood pressure monitoring device	Non-invasive, with appropriately sized paediatric and adult cuffs

Stethoscope/precordial stethoscope	
Thermometer	Including low-reading capability
Blood glucose testing device	
Selection of test tubes for blood biochemistry and full blood count	
Capnograph	Nasal prongs with capnography line strongly recommended, but not compulsory

### Equipment with which to gain intravenous access

Gloves	
Tourniquet	
Sterile gauze pads	
Alcohol skin wipes	
Intravenous cannulae	24–18 G
Sterile needles	
Assortment of syringes	1–50 ml
Sharps container	
Paediatric intraosseous needles	
Tape or equivalent to secure intravenous cannulae	

### Equipment for the accurate infusion of drugs and fluids

Infusion pumps	Intravenous fluid and drug administration
Syringe drivers	Drug administration in advanced sedation
Intravenous administration sets	Paediatric administration sets and buretrol
Stickers, marker pen for labelling syringes	
Drip stands	
Intravenous fluids	Crystalloids and colloids

### Hardware and miscellaneous equipment

Source of suction	Including connection tubing
Suction catheters	Including catheters for suctioning endotracheal tubes, and Yankauer-type suction nozzles
Therapeutic heat source	Desirable for long cases
Cardiac arrest board	
Appropriate lighting	Adequate for intravenous access
Operating surface that can be tilted	Capable of Fowler's and Trendelenburg positions
Urinary catheters	

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Nasogastric tubes

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Medication stickers

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Means of summoning emergency assistance

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South African Resuscitation Council algorithms

Basic Life Support (BLS), Advanced Life Support (ALS) for adults and children, anaphylaxis management and choking

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Resuscitation documentation record

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**Recommended emergency drugs**

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Naloxone

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Flumazenil

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Adrenaline (at least 10 ampoules)

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Atropine or glycopyrrolate

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Ephedrine or phenylephrine (or other alpha agonist)

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Lignocaine

---

Glucose 50%

---

Hydrocortisone, methylprednisolone or dexamethasone

---

Promethazine (or equivalent H1-antagonist)

---

Salbutamol

---

Suxamethonium

---

Intralipid

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Calcium-channel blocker (e.g. nifedipine)

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Beta blocker (e.g. esmolol)

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Selective alpha-1 adrenergic and non-selective beta-adrenergic receptor blocker (e.g. labetalol)

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Reversal agents (i.e. flumazenil, naloxone)

Specific antagonists must be immediately available where an SP administers opioid analgesics and/or benzodiazepines for PSA, regardless of the route of administration.

Reversal agents may be used for depression of ventilation/breathing to restore spontaneous breathing.

Naloxone is used to reverse opioid-induced respiratory depression.

Flumazenil is indicated to reverse benzodiazepine induced respiratory depression.

After reversal, the patients must be monitored for a longer period of time in the recovery room to prevent re-sedation.

## Appendix 2: Practice appraisal protocol for paediatric sedation

REF	TOPIC	YES	NO
<b>A</b>	<b>GENERAL</b>		
1	Does the practice provide basic intravenous sedation, e.g. midazolam only?		
2	Does the practice provide advanced intravenous sedation techniques (combination of drugs)?		
3	Does the practice provide inhalation sedation (IS)?		
4	Do children aged 12 years and younger receive intravenous sedation at the practice? If yes, which drugs are used?		
5	Are sedation patients only ASA I or II? Do you do any fragile ASA II patients under sedation? Do you do any ASA III patients?		
6	Does the practice only use operator-sedation practitioners? Which drugs are they using for sedation?		
7	Does the practice normally operate with a separate sedation practitioner (dedicated)?		
8	Is the practice in good standing with the HPCSA?		
<b>B</b>	<b>FACILITIES</b>		
1	Do the premises appear to be well maintained?		
2	Are the recovery and waiting areas separate, or the procedure room used as the recovery room?		
3	Is there good lighting and ventilation in all clinical areas?		
4	Is there access for emergency services to the building?		
5	Is there access for emergency services to the surgery? Do you have a wheelchair available to transport patients?		
6	Is there space within the surgery to deal with an emergency?		
7	Is there space within the surgery for the sedation practitioner to work effectively and do resuscitation if necessary?		
8	Does the practice layout provide privacy for sedation of patients?		
9	Can the dental or equivalent chair be placed in the head-down tilt position where applicable?		
10	Are there facilities for a parent/caregiver to accompany their child while sedation is commenced?		
<b>C</b>	<b>SEDATION PRACTICE</b>		
1	Does the practice follow a recognised sedation protocol?		
2	Are patients normally assessed for suitability for sedation at a preceding appointment or during day of surgery?		
3	Are there possible options for anxiety and pain control explained to the patient prior to obtaining consent for sedation?		
4	Do parents/caregivers have the opportunity to ask questions?		

5	Are blood pressure and pulse oximetry assessed as part of the patient assessment and documented? Is capnography used in the practice?		
6	Is the patient monitored by a trained and experienced member of staff, during sedation and recovery?		
7	Does the practice prohibit parents/caregivers from remaining in the surgery during the procedure?		
8	Are recognised discharge criteria followed?		
9	Where are patients normally recovered?		
10	Does the sedation practitioner or trained staff discharge the patient?		
11	Are patients given a telephone or cell phone number to call in case of problems or complications?		
12	Does the practice ensure that all children have a responsible adult accompanying them home and to take responsibility for after-care at home? Which mode of transport will the child and accompanying adult use?		
13	Is there an agreed protocol with the local hospital and paramedics in case of an emergency?		
<b>D</b>	<b>DOCUMENTATION</b>		
1	Are parents/caregivers given written preoperative instructions?		
2	Are parents/caregivers given written postoperative instructions?		
3	Are the following noted and checked prior to sedation? Medical, dental and social histories: medical history questionnaire Previous sedations/general anaesthesia ASA category Fasting Preoperative vital signs (including BP) Treatment required Information to the patient regarding the procedure History of allergies		
4	Is written informed, valid consent for sedation and the procedure obtained prior to sedation? Is this sometimes changed during sedation?		
5	Is a contemporaneous record (sedation flow chart) kept of the administration of sedation?		
6	Do sedation practitioners keep a logbook or records of sedation cases?		
<b>E</b>	<b>EQUIPMENT</b>		
1	Is there equipment for measurement of blood pressures and oxygen saturation values?		
2	Is there a dedicated Inhalation Sedation (IS) machine? Does this have the following? - Minimum delivery of 30% O <sub>2</sub> - Emergency N <sub>2</sub> O cut-off		
3	Is the IS machine checked by a suitably trained and qualified member of staff prior to each session?		

4	Is there scavenging of waste gases?		
5	Is the equipment serviced according to the manufacturers' guidelines?		
6	Are the gases stored according to current safety requirements?		
7	Date of last service?		
8	Is a pulse oximeter available? Is an ECG monitor available? Is a capnograph available? Are they all being used to monitor the patient?		
9	Does the pulse oximeter have audible alarms?		
10	Is the equipment serviced according to the manufacturers' guidelines?		
11	Date of last service?		
12	Is emergency oxygen available? What is the size of the cylinder? Is there a back-up supply/cylinder?		
13	Is there a self-inflating bag valve mask with reservoir bag for children (e.g. Ambu-bag)? Is there a 40% oxygen mask? Is there a rebreathing bag?		
14	Is there a pocket face mask (e.g. Laerdal pocket mask) to provide assistance with ventilation?		
15	Is there a set of nasal cannulae available?		
16	Is suction available and in working order? How often is suction cleaned and checked?		
17	Is back-up suction available?		
18	Is a laryngeal mask available?		
19	Are Yankauer suckers available?		
20	Is a defibrillator available?		
21	Is an AED available?		
22	Date of last service?		
23	Is the emergency equipment readily available? (SASA guidelines)		
<b>F</b>	<b>DRUGS</b>		
1	Are emergency drugs immediately available? (see SASA guidelines) Which ones do you have?		
2	Are all drugs, sedation and emergency, in date?		
3	Is there a designated person responsible for stock control?		
4	Are all emergency drugs readily available?		
<b>G</b>	<b>STAFF</b>		
1	Names and qualifications of all dentists, doctors and nursing staff involved in sedation practice at this address. Do they all have airway certification? Please supply details.		

2	Can all staff demonstrate in-house training in sedation, as well as a commitment to continuing professional education? Give details.		
3	Can all nurses assisting demonstrate in-house training in sedation?		
4	Can all recovery staff (if applicable) demonstrate training appropriate to their duties?		
5	Is all staff trained in at least BLS (airway certification)?		
6	How often is emergency training provided? Give dates.		
7	When was the last emergency training session?		
8	Is the facility suitable to provide moderate sedation and analgesia? If no, the following observations would need to be addressed for successful practice appraisal:		

Comments:

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Assessed by: \_\_\_\_\_

Date: \_\_\_\_\_

Position/qualifications: \_\_\_\_\_

Signature: \_\_\_\_\_

## Appendix 3: Valid informed consent to sedation and analgesia for medical/dental procedures

I have been fully informed, and I declare the following:

1. I understand the nature of procedural sedation and analgesia, the purpose of the procedure and the risks involved. I understand that no guarantee can be given with regard to the results obtained. Procedural sedation and analgesia entails the administration of sedative and/or analgesic drugs to induce a reduced level of consciousness to such an extent that normal protective airway reflexes and spontaneous respiration are maintained, and cardiovascular function is unaffected. Procedural sedation and analgesia, together with regional/local anaesthesia, will put my child in a relaxed state to make minor surgery possible. I understand that it is not a general anaesthetic and that my child is not unconscious, and that my child may or may not have to respond to commands from the surgeon and/or the sedation practitioner.  
If the procedure cannot be safely completed under sedation, the procedure may have to be abandoned and rescheduled, to be performed under general anaesthesia.
2. Unforeseen adverse events may arise during/after sedation that may require additional or different medications or treatment. I authorise the sedation practitioner to treat such adverse events according to his/her professional judgement:  
Possible adverse events include:
  - Unintended loss of consciousness
  - Drowsiness/dizziness
  - Unsteady gait
  - Shivering
  - Headaches
  - Double vision
  - Postsedation nausea and vomiting
3. I give consent to the administration of such sedative and/or analgesic drugs to my child as may be considered necessary or advisable by the sedation practitioner responsible for this service. This may include rectal medication/analgesia.
4. I accept full and complete responsibility for actual and potential costs associated with procedural sedation and analgesia, and I accept full responsibility for the costs that have been explained to me. I agree to comply with the terms and conditions of payment.
5. I have had the opportunity to ask questions and I have been given the opportunity to choose alternative methods of treatment (e.g. general anaesthesia, or local anaesthesia without sedation, or the use of local anaesthesia with behaviour management techniques) to my satisfaction.
6. I confirm that I have received written/oral instructions regarding the sedation, which I understand. I will abide by the pre- and postoperative instructions. I have completed a medical history questionnaire on behalf of my child and have declared all drugs that my child took during the last 6 months.

I,..... (patient/parent/guardian), address

.....  
hereby authorise the following procedure/s to be performed

.....  
on (name of patient ).....

utilising procedural sedation and analgesia/local anaesthesia techniques under direction of

Dr .....

**Patient/parent/guardian signature**

.....

Witnesses:

1.....

2.....

Practitioner's declaration: I have explained the procedure of procedural sedation and analgesia, risks, alternatives and expectations to the patient/parent/guardian, and believe that he/she has been adequately informed and have consented.

**Practitioner's signature** .....

**Date**.....

## Appendix 4: Medical history questionnaire

Child's name	Age	Sex	Weight	Height
Parent/caregiver's name				

Does the child suffer from, or is there a history of, the following? Tick either “yes” or “no” and, if any answer is “yes”, provide a detailed explanation.

	YES	NO
<b>1. Cardiovascular disease</b>		
High blood pressure		
Heart valve lesion, rheumatic fever, or congenital heart disease		
Dysrhythmia, or fainting spells		
Shortness of breath when feeding, lying down, or walking on a level surface		
Episodes of blueness of lips/tongue/fingers/toes		
If any answer is “yes”, please provide a detailed explanation:		
<b>2. Respiratory disease</b>		
Do either of the parents smoke?		
History of snoring		
Breathing difficulties		
Lung disease (e.g. asthma, tuberculosis)		
If any answer is “yes”, please provide a detailed explanation:		
<b>3. Central nervous system disorders</b>		
Epilepsy, or fits (convulsions)		
Behavioural problems, attention deficit disorder, or developmental delay		
If any answer is “yes”, please provide a detailed explanation:		
<b>4. Blood disorders</b>		
Anaemia, sickle cell disorder, or thalassaemia		
Abnormal bleeding associated with previous dental extractions, surgery or trauma, or does the child bruise easily?		
If any answer is “yes”, please provide a detailed explanation:		
<b>5. Endocrine disorders</b>		
Diabetes mellitus		
If the answer is “yes”, please give details of medication and degree of control of blood sugar:		

**6. Liver disease**

Hepatitis, or jaundice

Other liver disease

If any answer is "yes", please provide a detailed explanation:

**7. Kidney disease**

Renal disease or disorders, or renal failure

If the answer is "yes", please provide a detailed explanation:

**8. Musculoskeletal disorders**

Muscle disorders (e.g. myopathy, dystrophy or progressive weakness)

Orthopaedic problems

If the answer is "yes", please provide a detailed explanation:

**9. Infectious diseases**

If the answer is "yes", please provide a detailed explanation:

**10. Stomach problems**

Reflux, or regurgitation

If the answer is "yes", please provide a detailed explanation:

**11. Previous admission to hospital**

If the answer is "yes", please provide a detailed explanation:

**12. Previous operations**

If the answer is "yes", please provide a detailed explanation:

**13. Previous adverse or unpleasant reaction to anaesthesia/sedation**

If the answer is "yes", please provide a detailed explanation:

**14. Previous problems or complications with sedation (e.g. failed sedation)**

If the answer is "yes", please provide a detailed explanation:

**15. History of allergy in general, or allergic reactions to medications**

If the answer is "yes", please provide a detailed explanation:

**16. History of taking medication or drugs, including herbal remedies and recreational drugs**

If the answer is "yes", please provide a detailed explanation:

**17. History of hereditary disease in the child's family (e.g. porphyria, or malignant hyperthermia)**

If the answer is "yes", please provide a detailed explanation:

**21. Is there anything you would like to discuss, but would prefer not to write down?**

If the answer is “yes”, please contact your sedation practitioner and discuss this with him/her before the date of your procedure.

.....  
Signature (Parent/Guardian/Responsible Person)

.....  
Date

.....  
Signature (Patient, if possible)

.....  
Date

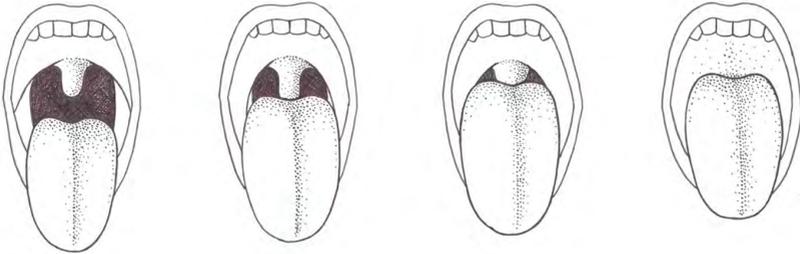
## Appendix 5: Evaluation of the airway for sedation

### Lemon law:<sup>8</sup>

<b>L</b>	Look externally for any malformations of the face
<b>E</b>	Evaluation 3-3-2; (3 fingers between upper and lower jaw to assess mouth opening; 3 fingers between the hyoid and chin; 2 fingers can fit in between hyoid and thyroid cartilage)
<b>M</b>	Mallampati; look for position of uvula. If difficult to see, airway compromised.
<b>O</b>	Obstruction, look for signs of obstruction (e.g. wheezing, stridor)
<b>N</b>	Neck mobility, evaluate flexion and extension of neck

### Mallampati classification for prediction of difficult intubation:<sup>9</sup>

The score is assessed by asking the patient to open his or her mouth as wide as possible.



1. Class I: Soft palate, uvula visible. Sedation can be done.
2. Class II: Soft palate, portion of uvula visible. Sedation can be done.
3. Class III: Soft palate, base of uvula visible. Not for sedation outside the operating theatre.
4. Class IV: Only hard palate visible (soft palate not visible). Not for sedation outside the operating theatre.

## Appendix 6: Sedation scoring systems

### Wilson sedation scale

Score	Description
1	Fully awake and oriented
2	Drowsy
3	Eyes closed but rousable to command
4	Eyes closed but rousable to mild physical stimulation (earlobe tug)
5	Eyes closed but unrousable to mild physical stimulation

### University of Michigan Sedation Scale (UMSS)

0	Awake and alert	
1	Minimally sedated	Patient drowsy, sleepy but rousable to verbal command
2	Moderately sedated	Patient may be sleeping, can be easily aroused by light tactile stimulation
3	Deeply sedated	Patient asleep, only rousable by significant physical stimulation, or repeated painful stimuli
4	Unrousable	No response with significant physical stimulation

## Appendix 7: Sedation monitoring flow chart

SEDATION RECORD																			
Health facility:				Date:				Time in:				Time out:							
Child's name:								File No:				ASA I II III IV V E							
DOB:			Age:			Weight:			ASA:										
Procedure:										Operator:									
										Sedation list:									
										Recovery nurse:									
Previous operations/sedation/GA:										Medical history:									
Complications:										Medication:									
Allergies:																			
Date/time of last oral intake:																			
Solids:						Breast milk:						Fluids:							
Presedation medication:																			
Drug:				Dose:				Route:				Time:				Given by:			
IV cannula size: 24G/22G/20G						Site:						IV fluids:				Total fluids given:			
TIME																			
O <sub>2</sub> %																			
N <sub>2</sub> O%																			
Level of Sedation:																			
RR																			
EtCO <sub>2</sub>																			
SpO <sub>2</sub>																			
Temp																			
BP 200																			
190																			

180																				
170																				
160																				
150																				
140																				
130																				
120																				
110																				
90																				
80																				
70																				
60																				
50																				
Heart rate: ECG/SpO <sub>2</sub>																				
Drugs/ Route																				TOTAL
1.																				
2.																				
3.																				
4.																				
5.																				

## Appendix 8: Pre-sedation instructions for parents/caregivers

If you are unable to comply with or have any concerns regarding the instructions listed on this page, please contact your sedation practitioner, or our office, so that we can discuss how to best make adjustments for your particular requirements or circumstances.

- If your child feels sick or unwell, please liaise with your doctor/dentist about whether to postpone the treatment.
- The child should not eat anything for at least 6 hours before the procedure/operation. Clear fluids (black tea/black coffee/apple juice) may be taken up to 2 hours before.
- Breastfeeding may be continued up to 4 hours before the procedure. Thereafter clear fluids may be offered up to two hours beforehand.
- The child should wear comfortable clothing with loose-fitting sleeves in order to be able to apply an electronic blood pressure cuff.
- The child should take any **chronic medication** on the day of the procedure/operation, as ordered by the doctor/dentist. If taken, it must be taken at the usual times, along with a small amount of water, regardless of the restrictions on fluid intake noted above.
- If the child has asthma, bring the inhaler with on the day of the procedure.
- Children with diabetes should bring their blood glucose monitoring devices and take their blood glucose level the morning before the sedation. A low blood glucose level must be reported to the sedation practitioner.
- Children with obstructive sleep apnoea who use CPAP should bring their CPAP devices.
- Please arrive in good time for the appointment, at least 30 minutes beforehand. In some cases, the doctor/dentist may feel that the child will benefit from premedication to reduce anxiety and aids with relaxation. In this case, you may have to come earlier in order for the child to take the premedication.
- Please let the child empty his/her bladder before the procedure/operation.
- The child must be accompanied home by an adult escort. The escort may remain with the child until the sedation is underway and the procedure/operation is about to start. The escort will then be requested to leave the procedure/operation room.
- A responsible adult must remain with the child for the rest of the day. This person will be responsible for ensuring that the child takes the normal prescribed medication and to contact the sedation practitioner in the case of adverse events. If there is nobody to stay with the child at home, we will unfortunately not be able to provide sedation.
- There must be arrangements in place for the child and the responsible adult to travel home by private car or taxi rather than public transport.

## Appendix 9: Postsedation instructions (aftercare) for parents/caregivers

- A responsible adult must take the child home after the sedation. An adult must take responsibility for the child's welfare at home and remain with the child for the remainder of the day. The child must never be left alone. Sedation **will not** proceed if these prerequisites are not in place.
- It can take up to 24 hours for the sedative drugs to be eliminated from the body and for the child to recover from the effects of sedation (drowsiness, loss of memory, lack of awareness and coordination). Therefore, for at least 12 hours following the procedure/operation, the child must not be allowed to:
  - climb heights (e.g. play structures)
  - participate in any other activities that require alertness or coordination (e.g. swimming, cycling, etc.)
  - go back to school on the day of sedation
  - be unsupervised in potentially dangerous areas, like the kitchen, bath and other pools of water.
- After sedation, the child may continue any acute and chronic medication as ordered by the doctor/dentist.
- The child should not experience nausea or vomiting after sedation. If vomiting occurs more than once, please contact the responsible doctor/dentist.
- The child should not eat or drink if any nausea is present. Introduce fluids or foods slowly after sedation. If the child tolerates clear fluids, solids may be presented.
- After a dental procedure, due to the effects of local analgesia, the child's lip may remain numb for some hours. Be sure that the child does not bite the lip accidentally, as the child will not experience any pain.
- About 20% of children complain of double vision after sedation. This is a temporary drug effect and may sometimes last for up to 6 hours.
- Some children become aggressive after sedation. This may be a drug effect. Ensure that the child is not left alone. Contact the doctor/dentist if you are worried about this.
- If the child did not pass any urine within 6–8 hours of being discharged, please contact the doctor/dentist at the telephone numbers provided.
- The sedation may result in amnesia (loss of memory). This is temporary, sometimes lasting for a few hours.
- We trust that this information will answer all your questions. However, please phone your sedation practitioner or the practice if you are unsure about anything.
- We do not anticipate any complications, but should you become concerned about anything, however trivial, please contact the sedation practitioner or our office.

I, ....., the undersigned, and parent/carer of .....(child's name) have read and understood these postsedation instructions, and agree to contact the doctor/dentist if there is anything more that is not clear to me.

Signature .....

Date .....

We do not anticipate that you will have any adverse events or complications. Should you become concerned about anything, please contact:

Dr .....

Telephone .....

## Appendix 10: Cover letter to parent/caregiver

Dear Parent/Caregiver

Your child's doctor/dentist recommended performing your child's procedure under sedation after discussing alternative options with you. The procedure is scheduled for (date)..... at (time)....., at (address).....

The sedation will be performed by Dr .....

The estimated fee for the sedation is (fee).....

You will receive the following documents:

### 1. Confidential medical history questionnaire

Please read and answer every question truthfully and provide details where needed.

Please provide a full list of all prescription and/or alternative medication (including herbal) that the child is currently taking.

The information required is vital, as it will assist us in deciding whether the child qualifies for sedation and to ensure safe sedation. If the child suffers from any medical condition, you will need to inform your doctor/dentist before the procedure/operation. Discuss with you doctor/dentist whether the child should take his/her acute or chronic medication on the day of the procedure.

### 2. Consent form for the sedation

Kindly complete and sign.

### 3. Instructions on how to prepare for the sedation

Please return these forms at your earliest convenience either by email or fax. The booking can only be confirmed once the forms have been received. If anything is unclear, please contact your doctor/dentist at the following telephone numbers:

Tel: .....

## Appendix 11: Preprocedural checklist

(To be completed and signed by sedation practitioner)

Child's name:	Date of birth:	Premature birth? Yes / No
Age:	Weight:	In hospital/Outside hospital
Responsible doctor:	Procedure: Elective/Emergency/Urgent	
Sedation practitioner evaluating child:	Was a medical questionnaire completed? Yes / No	
Has the child been fully evaluated? Yes / No    Date:	ASA Status:	
Name of parent/caregiver accompanying child:	Name of parent/carer responsible for aftercare:	
<b>Sedation contraindication checklist</b>		
Past sedation history?                      Yes / No Details:	Previous sedation airway problems?                      Yes / No Details:	
Previous sedation satisfactory?              Yes / No / NA Details:	Sleep apnoea?    Yes / No Reason:	
Previous sedation failed?                      Yes / No / NA Details:	Any syndromic features?                                      Yes / No Details:	
Previous sedation complications?          Yes / No / NA Details:	Serious illness?    Yes / No Details:	
<b>Fasting time checklist</b>		
Fasted for solids (including milk)?	From:	(minimum 6 hours)
Fasted for breast milk?	From:	(minimum 4 hours)
Fasted for clear juice/water?	From:	(minimum 2 hours)
Other significant underlying conditions (see medical questionnaire)		
Respiratory dysfunction?                      Yes / No	Hepatic dysfunction?    Yes / No	
Cardiac dysfunction?                              Yes / No	Gastro-oesophageal reflux?                                      Yes / No	
Known allergies/drug reactions              Yes / No	Renal dysfunction?    Yes / No	
Chronic medication?                              Yes / No If yes, have they been taken today? Yes / No	Specify chronic medication:	
<b>Premedication and monitoring</b>		
Premedication prescribed and by whom:	Drug:	Dose:                      Time:
	Drug:	Dose:                      Time:

Premedication administered: Yes / No		Name of person who administered premedication:			
Name of sedation practitioner: Qualification:		Name of qualified attendant:			
<b>Equipment checklist (tick if present)</b>					
Pulse oximeter	<input type="checkbox"/>	NIBP	<input type="checkbox"/>	ECG	<input type="checkbox"/>
Airway equipment	<input type="checkbox"/>	Oxygen	<input type="checkbox"/>	Drugs	<input type="checkbox"/>
Resuscitation equipment	<input type="checkbox"/>	Temperature probe	<input type="checkbox"/>	Circulatory support equipment	<input type="checkbox"/>

Signature of sedation practitioner: ..... Date: .....

Name of sedation practitioner (block letters): ..... Qualification: .....

## Appendix 12: Postsedation monitoring flow chart

Name of child:										Date:	
										Yes	No
Are the blood pressure and heart rate stable?											
Can the child swallow and cough?											
Can the child walk (if applicable) without feeling dizzy or faint?											
Is the child nauseous?											
Is the child breathing comfortably and of normal colour?											
Is the child awake and appropriate?											
Has the operative site been checked and is bleeding controlled?											
Have written postoperative instructions been given and explained to both parent and caregiver?											
Is the child pain free?											
Have possible complications been explained?											
Has a prescription been given or medication dispensed?											
Is there a responsible adult to accompany the child and who is responsible for aftercare at home?											
TIME											
O <sub>2</sub> given											
RR											
SpO <sub>2</sub>											
Heart rate											
Temperature											
Level of consciousness											
Pain											
BP 160											
150											
140											
130											
120											
110											
90											

80														
70														
60														
50														
40														
30														

Child has been assessed and is deemed fit for discharge at: \_\_\_\_\_ (time and date)

Mode of transport home is: \_\_\_\_\_

Name of responsible adult accompanying child home is: \_\_\_\_\_

Signature of recovery nurse: \_\_\_\_\_

## Appendix 13: Discharge scoring systems

Modified Aldrete scoring system: a score of 10 out of 10 means the child is fit for discharge.

	Score
<b>Level of consciousness</b>	
Fully awake	2
Arousable on calling	1
No response	0
<b>Oxygen saturation (%)</b>	
> 90% breathing room air	2
Oxygen required to maintain saturation > 90%	1
< 90% even when breathing oxygen	0
<b>Circulation/blood pressure</b>	
Systolic BP within 20 mmHg of pre sedation level	2
Systolic BP within 20–50 mmHg of pre sedation level	1
Systolic BP > 50 mmHg of pre sedation level	0
<b>Movement/activity</b>	
Able to move all extremities on command	2
Moves 2 extremities	1
Doesn't move extremities	0
<b>Respiration</b>	
Able to breathe and cough freely	2
Dyspnoea, shallow or limited	1
Breathing apnoea	0

Modified postanesthetic discharge scoring system

	Score
<b>Vital signs</b>	
<i>The vital signs must be stable and consistent with age and preoperative baseline.</i>	
BP and pulse within 20% of preoperative baseline	2
BP and pulse within 20–40% of preoperative baseline	1
BP and pulse > 40% of preoperative baseline	0
<b>Activity level</b>	
<i>The patient must be able to ambulate at preoperative level.</i>	
Steady gait, no dizziness, or meets preoperative level	2
Requires assistance	1
Unable to ambulate	0
<b>Nausea and vomiting</b>	
<i>The patient should have minimal nausea and vomiting before discharge.</i>	
Minimal: successfully treated with oral medication	2
Moderate: successfully treated with intramuscular medication	1
Severe: continues after repeated treatment	0

<p><b>Pain</b></p> <p><i>The patient should have minimal or no pain before discharge.</i></p> <p><i>The level of pain should be acceptable to the patient.</i></p> <p><i>The pain should be controlled by oral analgesics.</i></p> <p><i>The location, type and intensity of the pain should be consistent with anticipated postoperative discomfort.</i></p> <p>Acceptability:</p> <p>Yes</p> <p>No</p>	<p></p> <p></p> <p></p> <p></p> <p></p> <p></p> <p>2</p> <p>1</p>
<p><b>Surgical bleeding</b></p> <p><i>Postoperative bleeding should be consistent with expected blood loss from the patient</i></p> <p>Minimal: does not require dressing changes</p> <p>Moderate: up to two dressing changes required</p> <p>Severe: more than three dressing changes required</p>	<p></p> <p></p> <p>2</p> <p>1</p> <p>0</p>









