ISSN-2220-1181

SOUTH AFRICAN SOCIETY
OF ANAESTHESIOLOGISTS (SASA)

Paediatric Sedation Guidelines for Procedural Sedation and Analgesia

Foreword to the second edition of the SASA Paediatric Guidelines for Procedural Sedation and Analgesia

When the first edition of the Paediatric Procedural Sedation and Analgesia Guidelines was published in 2010, it was the culmination of over one year's worth of extensive inter-disciplinary consultation. This updated edition builds on the work of the first edition and includes a thorough revision and updating of the definitions of sedation, pharmacology and monitoring for paediatric procedural sedation and analgesia. It is the work of Professor James Roelofse and Dr Rebecca Gray with input from Professor Jenny Thomas and Dr Marianna de Kock.

Our aim with these guidelines is to provide a reference for good clinical practice for all health care practitioners who provide sedation and analgesia for children undergoing painful or non-painful therapeutic or diagnostic procedures. We also aim to promote good clinical governance in all matters concerning paediatric sedation whether a procedure is undertaken in a physician's office, a remote facility or an operating room. These guidelines are based on national and international peer-reviewed publications as well as on many years of paediatric sedation experience. The standards outlined in these guidelines are appropriate and achievable and will guarantee high levels of safety.

In the development of this new edition, the approach was to identify what is new in paediatric sedation and analgesia: new techniques, novel drugs and therapies, and to scrutinise other international paediatric sedation and analgesia guidelines; to revise some areas of practice – definitions, drug recipes; and learn from some of the changes made in the adult guidelines i.e. safety components of clinical governance and the need for log books, accreditation of practitioners and facilities, recommending the presence of an observer to monitor and help rescue patients during a critical event, and to recommend connected supervised clinical training in paediatric sedation and analgesia. Several definitions as well as Appendix 9 (Practice appraisal protocol) have been adapted directly from the adult guidelines and we thank the authors of these guidelines for permitting us to do this.

Accreditation for standards of practice for the provision of sedation and analgesia for children is necessary, and is imminent. Non-pharmacological strategies and psychological preparation are also important considerations for this practice. Each of these has been addressed in this document. One of the changes of this edition involves the removal of "recipes" of drug administration for particular procedures, as this information is part of the supervised clinical training programs which are offered in most provinces.

The term "sedation practitioner" will replace all previous terminology, and describes the health professional providing sedation analgesia to children. He or she requires adequate supervised clinical training in order to minimise risk to the patient. Sedation is not the same as anaesthesia, and this subject may be something we should address during our training of specialist anaesthesiologists.

We wish all readers success in the practice of this difficult but very necessary service to the children of South Africa.

Southern African Journal of Anaesthesia and Analgesia 2016; 22(1)(Supplement 5):S00-S00

South Afr J Anaesth Analg
ISSN 2220-1181 EISSN 2220-1173

Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in children

All health care professionals participating in the administration, monitoring and recovery of patients requiring procedural sedation and analgesia (PSA) or general anaesthesia are accountable for safe practice. *The patient is entitled to the same standards of care, whether the procedure is undertaken in a physician's office, a remote facility, or an operating theatre.*

1. Introduction

Providing safe and effective sedation of children requires child-appropriate equipment, drugs and monitors as well as thoughtful selection of patients suitable for sedation.

The aim of this document is to provide a reference that will enable all sedation practitioners to act within a framework to ensure patient safety and successful performance of procedures.

These guidelines are intended for use by all medical practitioners in order to provide safe sedation, analgesia and anxiolysis for children in all environments. Identification of those children unsuitable for PSA is crucial, and many of the sedation techniques utilised in adults are not recommended for paediatric practice.

These guidelines will:

- Define the terms used in PSA.
- Provide guidance on appropriate patient selection.
- Discuss drugs recommended for PSA.
- Specify equipment essential for PSA.
- Provide recommendations for monitoring, based on the sedation method utilised.
- Specify discharge criteria after PSA.
- Provide examples of the recommended documentation to complete and keep before, during and after PSA.

Attention to environmental factors is essential for the safe practice of PSA, and is also a basic requirement for ensuring a satisfactory outcome for both the patient and the procedure. It is recommended that an annual audit of the procedures performed be conducted, and that this process includes a review of all critical adverse events.

These guidelines are applicable to paediatric patients undergoing painful or non-painful diagnostic or therapeutic procedures. They are *not applicable to:*

- Patients requiring intensive care sedation.
- Prescription of sedation for palliative care.
- Sedation in the home setting.
- Premedication for patients undergoing general anaesthesia.
- Night sedation.

2. Objectives of procedural sedation and analgesia

PSA must provide a safe environment for the patient, and the result must be effective control of pain, anxiety and movement in children undergoing procedures. Decreased awareness and amnesia are added advantages.

In some circumstances, a short general anaesthetic may provide a quicker, more controllable, more reliable and safer option for the completion of the procedure/investigation. This would require skills, monitoring and environment appropriate to the administration of a general anaesthetic.

3. Clinical governance

Clinical governance is a system whereby healthcare organisations, providers, and sedation societies are accountable for continuously improving the quality of their services and safeguarding high standards of care. An environment must be created in which clinical excellence flourishes. The sedation practitioner should have a framework of accountability that will include clinical accountability for the maintenance of expertise, updating of knowledge and skills, clinical appraisal and the implementation of SASA guidance on procedural sedation and analgesia for children.

The sedation practitioner must have a plan for each sedation event for which he or she delivers a service. This should include details of the assessment protocols, the structure of the treatment

sessions, the roles of the team members and the systems in place for reporting adverse events. In-house training sessions for the entire sedation team should take place on an ongoing basis.

Practitioners involved in sedation practice should keep a comprehensive logbook of cases performed under sedation, and are required to keep a documentary record of adverse incidents and accidents. Sedation practitioners 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.

It is highly recommended that a sedation practice and facility in which the practice administers sedation, meet the basic standards outlined in Appendix 9 (Practice Appraisal Protocol) prior to administering sedation for the first time and that such an appraisal is carried out regularly.

It is recommended that:

- Facilities undergo regular inspections to comply with quality assurance policies and procedures.
- Records are kept of staff training for persons involved in administering sedation, as well as evidence of life support training i.e. Basic Life Support (BLS).
- Evidence should be available of the training of a sedation practitioner, including the possession of advanced life support certification e.g. Paediatric Advanced Life Support (PALS), Advanced Paediatric Life Support (APLS).

4. Definitions

The definition of PSA encompasses a continuum of altered state of consciousness, varying from minimal sedation and anxiolysis to deep sedation.

The response of individual patients to the administration of sedatives is difficult to predict. The drugs used, the dosages administered, the additive effects of concomitant drugs and the patient's pharmacogenetic profile will all impact on the depth of sedation. An unexpected progression of the depth of sedation must therefore be anticipated, and practitioners must be able to rescue patients who enter a deeper level of sedation than intended.

If the patient fails to respond to verbal commands and/or light touch, the standard of care must be identical to that for general anaesthesia. Guidelines for the care of the anaesthetised patient are provided in the publication *Guidelines for Practice* issued by the South African Society of Anaesthesiologists (SASA), and are not addressed in this document.

4.1 General anaesthesia

General anaesthesia 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 because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

4.2 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 to the desired effect.

4.3 Dissociative sedation

Dissociative sedation, produced by ketamine, causes a trance-like cataleptic state characterised by intense analgesia, amnesia, sedation, retention of protective reflexes (as deeper levels of sedation are reached, airway reflexes may be obtunded), spontaneous breathing and cardiovascular stability. It is believed that, when ketamine is administered in dissociative doses, it does not operate on the sedation continuum.

4.4 Sedation end points

4.4.1 Minimal sedation

Minimal sedation is a drug-induced state during which the patient responds normally to verbal commands. Cognitive function may be impaired, but ventilatory and cardiovascular functions are unaffected.

4.4.2 Moderate sedation

Moderate sedation is a drug-induced depression of consciousness during which the patient responds purposefully to verbal commands, either alone or accompanied by light, tactile stimulation. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate.

4.4.3 Deep sedation

> In accordance with the *Guidelines for Practice* issued by SASA, deep sedation is considered part of the spectrum of general anaesthesia, and should only be performed by those with *anaesthetic training*.

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. The patient may require assistance 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" in certain international sedation guidelines.

Safe sedation practice dictates that a patient in a deeply sedated state be in the care of a team including a dedicated sedation-trained anaesthetist or an appropriately trained sedation practitioner, a trained observer with life support training and the operator (performer of the procedure for which sedation is required).

4.5 Sedation techniques

The sedation practitioner should be aware that there are a variety of options available to manage anxiety in order to facilitate care of the patient. Procedural sedation and analgesia is just one option for the control of anxiety. The different options including behavioural management should be explained to patient/caregiver before a decision is made about which technique is used.

Sedation techniques should only be used by those sedation practitioners with the necessary theoretical, and supervised clinical training, and life support training.

4.5.1 Simple/standard sedation

Simple/standard sedation is induced by a single agent and not a combination of single agents, for example:

- Oral, transmucosal (excluding transmucosal dexmedetomidine) or rectal drugs, e.g. a small dose of an oral benzodiazepine, usually midazolam; or
- Inhalation of nitrous oxide (N_2O) in at least 50% oxygen; or
- A titrated intravenous dose of midazolam.

Sedation can no longer be considered simple or standard once additional agents become necessary, and the depth of sedation *may not* be advanced unless the patient is fasted.

Simple/standard sedation techniques can be used by operator sedation practitioners when all the requirements for safe practice have been met *e.g.* training, an observer to monitor and help with rescue if indicated, and premises that meet the requirements for safe practice.

4.5.2 Advanced sedation

Advanced sedation is induced by one of the following techniques:

- Any combination of drugs, administered by any route; or
- Any sedation administered by the intravenous route, using bolus or infusion techniques; or
- Any inhalational sedation (e.g. sevoflurane), with the exception of N_2O used as the sole agent in a concentration of less than 50% in oxygen.

Advanced sedation can include both dissociative and non-dissociative techniques.

Advanced sedation techniques should only be performed by those sedation practitioners who have had the necessary clinical and life support training.

Advanced sedation techniques require the attendance of a dedicated sedation practitioner and should not be performed by operator sedation practitioners.

4.6 Failed sedation

Failed sedation is defined as the failure to achieve the desired level of sedation, such that the procedure has to be abandoned, or the need arises to convert to general anaesthesia. Possible reasons for failure include inadequate pre-sedation assessment, patient factors, drug factors, or procedure-related and operator factors. A previous episode of failed sedation will necessitate that the child be carefully assessed, and consideration be given for the provision of general anaesthesia rather than sedation for future procedures.

4.7 Prolonged sedation

The aim of reducing costs and avoiding long theatre waiting times has resulted in an escalation in the demand for procedures to be performed outside the operating theatre. Frequently, these procedures are quite lengthy and may require the provision of moderate sedation and analgesia, or even deep sedation.

Sedation practitioners are increasingly faced with decisions about how long a patient can be kept safely sedated outside the operating theatre. Prolonged sedation in lengthy procedures carries increased risk and mechanisms must be instituted to ensure the safety of patients. Currently, there is no guidance for sedation practitioners on the definition of prolonged sedation. It is recommended that any sedation procedure in children lasting more than 1.5 hours for procedures performed outside the hospital should be defined as prolonged sedation. Any procedure lasting longer than 1.5 hours is probably best staged into two different procedures, although this approach may not be practical. The recommendation for a procedure that is expected to last more than 1.5 hours is to perform the procedure under general anaesthesia in the hospital.

4.8 Sedation for special needs in children

This is generally applicable to children whose disabilities affect the provision of care, and frequently applies to dental hygiene. Sedation for patients with disabilities must only be undertaken by trained sedation practitioners with experience in sedating patients with special needs. It may be extremely difficult to judge the level of sedation. Deeper levels of sedation are usually needed to treat this group of patients. Adaptations to the treatment protocol may be necessary e.g. more treatment sessions under sedation.

4.9 American Society of Anesthesiologists Physical Status Classification

The *American Society of Anesthesiologists (ASA) Physical Status Classification System* is tabulated below (Table I):

Table I: American Society of Anesthesiologists (ASA) Physical Status Classification System

Class I	A normal healthy patient
Class II	A patient with mild systemic disease and no functional incapacity
Class III	A patient with severe systemic disease that limits activity, but is not incapacitating
Class IV	A patient with severe systemic disease that is a constant threat to life
Class V	A moribund patient not expected to survive 24 hours with or without an operation
"E"	An emergency procedure is denoted by the letter E following the class number

4.10 Active upper respiratory tract infection

An active upper respiratory tract infection (URTI) is current or recent when 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
- If a parent/carer reports or is concerned that the child is sick

Airways remain reactive for up to six weeks following an URTI and any form of sedation is best avoided during this period.

5. Patient selection

No patient should be considered for sedation without a thorough focused assessment of the airway.

ASA class I and II patients are usually good candidates for sedation. However ASA II patients may become ASA III patients by the morning of the procedure. Children should be evaluated again immediately prior to the procedure:

No children under five years of age should be sedated by sedation practitioners who do not have extensive experience and training in the practice of sedation of young children. All sedation practitioners must have life support training.

Certain patients are *at increased risk for complications* and should at least be *assessed by a specialist anaesthetist with experience in sedation* or a *highly experienced and trained* paediatric sedation practitioner who need not be the sedation practitioner for the case, but will be available for consultation and, preferably, assistance. Strong consideration should be given towards sedating these patients in a **hospital setting.**

- Age < 1 year.
- Prematurity with residual pulmonary, cardiovascular, gastrointestinal or neurological problems, or significant anaemia.
- Children with congenital syndromes.
- Obesity (> 95th percentile body mass index (BMI) for age).
- Children who need an advanced sedation technique.
- A previous failed sedation.
- A previous over-sedation (unintentional deep sedation or general anaesthesia).
- Any known adverse effect (hyperactive or paradoxical response) or allergy to any of the sedation drugs.
- Any child who, following airway assessment, is suspected of having airway problems (see table II).
- Children with respiratory problems, including an active URTI, low oxygen saturation, and a weak cough or cry.
- Asthmatic children who are clinically wheezing or whose regular treatment includes more than inhalational short-acting $ß_2$–agonists and inhalational steroids.
- Children with cardiac problems, including congenital cardiac disease, cyanosis, congestive heart failure and undiagnosed murmurs.
- Neurological conditions, including poorly-controlled seizures, neuromuscular disease, central apnoea or an unstable cervical spine.
- Increased intracranial pressure.
- Severe behavioural problems.
- Uncontrolled gastro-oesophageal reflux or other conditions predisposing to reflux.
- Active vomiting.
- Haematological conditions, including coagulation disorders and sickle cell disease.
- ASA class III and IV.
- Parental reluctance.
- Children with malignancies.

In other patients, the sedation practitioner should be more *cautious* and have a low threshold for referring the patient to a more suitable institution if he or she does not feel comfortable performing the sedation. In these patients, even simple sedation may be problematic:

- Age: Children < 5 years.
- Acute or chronic altered mental state.
- Head injury.
- Communication problems.
- Autism.
- Severely delayed physical or mental milestones.
- Children on psychotropic drugs, including methylphenidate.
- Epilepsy.
- Controlled gastro-oesophageal reflux (i.e. GORD on treatment).

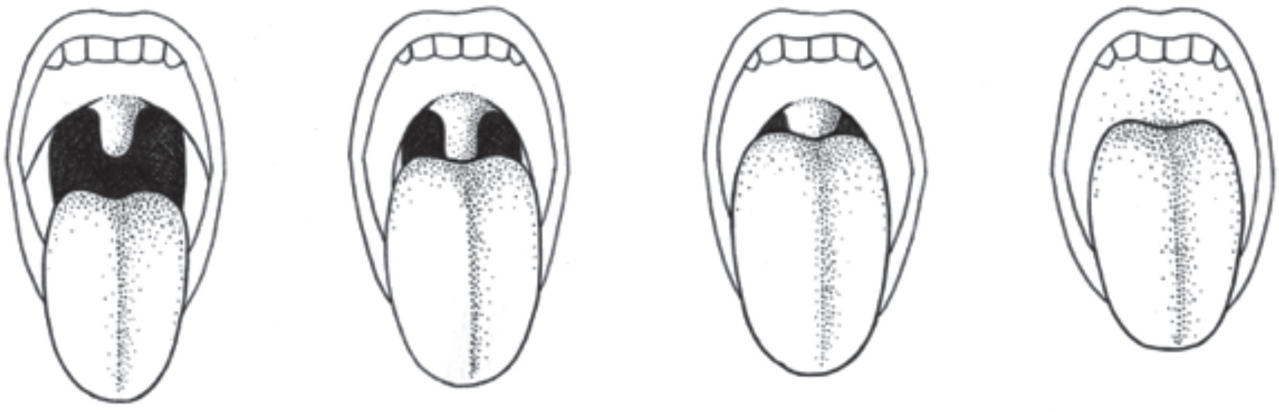
6. Pre-sedation patient assessment

Before sedation, a health evaluation, including a focussed airway examination see table II), should be performed on every child by an appropriately trained sedation practitioner. The ability to communicate with the child is essential, and identification of those children unsuitable for sedation is crucial.

It is useful to record the pre-sedation assessment on the pre-sedation medical history questionnaire (Appendix 1), as well as on the sedation monitoring chart (Appendix 5a).

This evaluation should include an assessment of:

- Age: caution with children < 5 years.
- Weight: appropriate for age.
- Birth and neonatal history.
- Prematurity.
- Fasting status.
- Full medical history:
  - » Relevant diseases, physical abnormalities, congenital syndromes.
  - » Behavioural problems, hyperactivity, mental retardation.
  - » Previous relevant hospitalisations.
  - » Previous negative experience (e.g. pain or necessity for restraint) in any medical/dental facility.
  - » History of sedation or general anaesthesia and any complications, including previous failed sedation.
  - » Allergies and previous allergic or adverse drug reactions.
  - » Medication (e.g. antiepileptic drugs, antiretroviral drugs):
    - Drug used, including dosage, time and route and site of administration of prescription drugs, over-the-counter drugs, herbal preparations or illicit drugs.
  - » Family history (e.g. porphyria, previous reaction to anaesthetic drugs).
  - » Risk of aspiration:
    - Reflux/regurgitation.
    - Patient not fasted (e.g. emergency procedure, trauma).
- Review of organ systems:
  - » Respiratory system:
    - Recent respiratory tract infection (see *Definitions 4.10*).
    - Snoring, apnoea.
  - » Cardiovascular system:
    - Activity level of child (effort tolerance).
    - Congenital cardiac disease.
  - » Behavioural problems or developmental delay.
  - » Congenital abnormalities and syndromes.
- Physical examination:
  - » Vital signs, including heart rate, blood pressure, respiratory rate and temperature.
  - » General examination.
  - » Airway assessment:
    - Observe from the front and side (lateral view) for abnormalities of the face, mouth, nose and neck, looking particularly for syndromic features:
      - Low-positioned or abnormal ears.
      - Facial (pre-auricular) tags.
      - Hypoplastic or receding chin.
      - Upper jaw overbite.
      - Lymphoid hyperplasia.
    - Mouth opening (three fingers of the child can be inserted):
      - Loose teeth.
      - Enlarged tongue.
    - Inspection of the pharynx:
      - Enlarged tonsils (approaching the midline or associated with snoring).
      - Mallampati classification (Figure 1).
    - Neck:
      - Flexion and extension.
      - Thyro-mental distance (distance more than the width of the three middle fingers of the child).
  - » Respiratory system:
    - Increased respiratory rate.
    - Use of accessory muscles.
    - Stridor.
    - Hoarseness.
    - Audible wheezing.
    - Productive cough.
    - Clubbing.
    - Cyanosis.



Class 1 Class 2 Class 3* Class 4*

*Class 3 and 4 not for sedation outside the hospital setting

(Diagrams by Helene Loon)

Figure 1: Mallampati classification for prediction of difficult intubation.

» Cardiovascular system:
  - Cyanosis.
  - Signs of heart failure.
  - The presence of a murmur; further assessment will be needed.

Table II: Specific airway factors that necessitate sedation in the hospital setting

- Obstructive sleep apnoea (OSA)
- Large tonsils approaching the midline, or associated with loud snoring
- Children who cannot lie flat because of airway obstruction
- Stridor
- Retropharyngeal masses
- Neck masses
- Tracheal deviation
- Mallampati class 3 or 4
- Neck mobility: decreased range of movement, including hydrocephalus with a large head
- Syndromic features (e.g. Pierre-Robin, Treacher-Collins)
  - Enlarged tongue
  - Micrognathia
  - Abnormal ears
- Masses within the airway
- Beware when children have malignancies: multiple level airway obstruction is possible

The evaluation must conclude with a risk assessment, as there may be factors (e.g. airway problems or obesity) that place the child at an increased risk of complications. These patients may warrant additional consultation or referral before sedation (see *Patient Selection*).

Record the name, address and telephone number (including an after-hours number) of the child's general practitioner or clinic.

Once it has been decided to proceed with sedation, valid informed consent should be obtained from a responsible person. This person could be the parent or guardian.

6. Valid informed consent

Information should be provided at an appropriate time when there is an opportunity to have a discussion, and for the patient/parent/guardian to be able to ask questions and understand the risks before consenting to sedation.

Alternatives to sedation, e.g. general anaesthesia or local anaesthesia, or local anaesthesia with behavioural management techniques, should be discussed with the patient and parent/guardian. If possible, this discussion should not occur immediately before the procedure in order for the parent/guardian to have sufficient time to digest the information and to formulate questions.

Valid written and verbal informed consent must be obtained and documented prior to the administration of sedative and analgesic drugs. Informed consent must never be obtained from the patient after the administration of sedative and analgesic drugs. The nature of the procedure to be performed may not be changed after a sedative and/or analgesic drug has been administered to the patient without getting new valid informed consent from the parent/guardian.

Valid informed consent should include an explanation of the procedure, the proposed sedation technique, costs, and an explanation of the risks and benefits of appropriate alternatives. Patients and parents/guardians must be informed of the possibility that the sedation may fail, and that the procedure may have to be abandoned or performed under general anaesthesia at a later date.

Consent must be obtained for both the procedure and the sedation (see Appendix 2). The sedation practitioner must ensure that the patient/person giving consent or representative understands the decisions that he or she is being asked to make. If use of suppositories/rectal medication is planned, it is recommended that consent should be obtained for this.

7. Guidelines for fasting

When simple sedation techniques (see *Definitions*) are planned, no fasting is necessary.

When N_2O (≤ 50%) is administered alone, no fasting is necessary.

If advanced techniques (including dissociative and non-dissociative techniques) and/or deep sedation (see *Definitions*) are planned, standard anaesthetic fasting guidelines should be applied:

- Clear fluids: two hours.
- Breast milk: four hours.
- Formula feeds and solid food: six hours.

Children should not have to fast for unnecessary lengths of time. Clear fluids should be administered up to two hours before the procedure. A "clear fluid" is defined as fluid which is non-particulate, and through which newsprint is visible.

In urgent cases, when a procedure cannot be postponed and simple sedation techniques are deemed unsuitable, a general anaesthetic with rapid sequence induction should be considered.

8. Administration of off-label and unlicensed drugs in paediatric practice

Off-label drug use: The use of licensed medications outside the conditions of the license.

Unlicensed drug use: The use of pharmaceutical products that have not been approved by any licensing authority of a specific country.

In paediatric practice in particular, the use of unlicensed drugs is common, and the preparation of drugs by non-pharmacists occurs frequently. This has resulted in the administration of medication "cocktails" in clinical practice.

This problem exists because the testing of drugs in clinical trials in children presents a dilemma: should children be spared the potential risks associated with clinical research? Also, is there

enough incentive for pharmaceutical companies to invest in the relatively small market for drugs developed for administration to neonates and infants?

But, the counterarguments to this line of thinking are that:

- Children may be harmed if administered drugs which have not been adequately tested.
- If extrapolated from adult doses, doses meant for children may be inadequate or toxic.
- The higher basal metabolic rate, organ immaturity, and pharmacodynamic and pharmacokinetic profiles may differ from adults.

Health care professionals looking after children:

- Are responsible for choosing the appropriate drug and dose.
- Are required to motivate and substantiate these choices by referring to international literature and guidelines.
- Should only make drug choices after considering:
  - Sound scientific data
  - Expert judgment
  - Professional literature.

The unlicensed or off-label use of medications is a common practice worldwide, and the situation in South Africa is no different. This is particularly relevant to paediatric practice, especially where neonates and infants are concerned.

Doctors are at risk of litigation when prescribing unlicensed and off-label drugs for their young patients, but can defend themselves by referring to international literature and guidelines. The package inserts of drugs are not medicolegal documents.

9. Drugs used in procedural sedation and analgesia

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 are synergistic when used in combination and it is mandatory 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 sedation practitioner must remember that there is no fixed dose, only a maximum dose.

9.1 Sedatives

9.1.1 Benzodiazepines

9.1.1.1 Midazolam

Midazolam is a short-acting benzodiazepine with sedative, anxiolytic, amnestic 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.

When administered in combination with other depressant drugs (particularly opiates, with which midazolam has a synergistic 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.

Paradoxical agitation occurs in up to 15% of patients. Giving additional doses of midazolam in an attempt to control the child will merely exacerbate the symptoms, until unconsciousness and severe respiratory depression are induced. In such cases, an alternative agent should be used. Ataxia, dystonia and diplopia are other possible adverse effects associated with midazolam use.

The intranasal route of administration is useful, particularly in children with special needs, however it may cause a burning pain as well as a bitter after taste which may last for several days. A single puff (10 mg/puff) of lignocaine spray prior to administration of intranasal midazolam may improve tolerability as will the use of an atomisation device.

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 is achieved.

The intravenous formulation can be given orally mixed in 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 and mixed in the same way.

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

9.1.1.2 Flumazenil

Flumazenil, the antagonist to benzodiazepines, reverses the sedative and respiratory depressant effects of midazolam, and should be readily available whenever midazolam is used (Table IV).

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 cases where flumazenil has been administered, the child should be carefully monitored for at least two hours, with a view to repeating the 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, administration of flumazenil may precipitate these symptoms.

9.1.2 Anaesthetic agents

9.1.2.1 Ketamine

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 limits 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 tone.

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 an URTI and will predispose to laryngospasm.

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 pre-procedural 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.

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

Previously contra-indicated 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.

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 for this route.

When used in combination with other sedative agents, and to decrease the likelihood of complications (respiratory depression

Table IV: Dosing schedule of flumazenil

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

* Repeat dose until desired effect achieved or maximum dose reached.

Table V: Dosing schedule of ketamine

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

* Dose-related
** Titrate to effect, repeating dose every three minutes until desired level of sedation achieved.
*** Infusion following bolus dose of 0.25–1 mg/kg

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

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.

and airway obstruction), the dose of ketamine should be reduced and titrated to effect, especially when administered intravenously.

9.1.2.2 Propofol

Propofol 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 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 sedation practitioner, preferably with anaesthetic training, who is skilled in the airway management of children, and in a facility that meets all of the criteria laid out in these guidelines (see Appendix 9). 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.

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

Propofol has no analgesic properties and, if a painful procedure is planned, an appropriate analgesic agent should also be given.

9.1.2.3 "Ketofol"

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

Used alone, this combination is adequate for minor medical and dental procedures. More painful procedures will require 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.

9.1.3 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.

9.1.3.1 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

9.1.3.2 Dexmedetomidine

Dexmedetomidine is a highly selective α_2-agonist providing sedation, anxiolysis, analgesia and sympatholysis. Dexmedetomidine is being used increasingly for sedation in children but this use is off-label owing to its lack of licence for this age group globally. 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.

Sedation mimics endogenous sleep and the EEG resembles that of natural non-rapid eye movement sleep. Patients sedated with dexmedetomidine, are rousable and alert when stimulated and

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
Intravenous (infusion)	0.2 - 1 µg/kg/hour			
Intranasal	1-4 µg/kg	15-30 minutes		55-100 min

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

interference with thermoregulation means that hypothermia can develop.

Transient hypertension, hypotension, bradycardia and sinus arrest are possible adverse events that may occur with dexmedetomidine use, especially with rapid loading doses (i.e. initial loading dose administered in less than 10 minutes), 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 and 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. 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. Ketamine (1 mg/kg) can be added to dexmedetomidine for sedation of painful invasive procedures.

9.1.4 Other sedative agents

9.1.4.1 Chloral hydrate and trichlorphos

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 by 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. Trichlorphos is structurally similar and can be used interchangeably with chloral hydrate. Chloral hydrate and trichlorphos are only available in oral form.

In the recommended doses (Table X), chloral hydrate is considered safe, although respiratory depression and airway obstruction can occur in predisposed patients. When higher doses (≥75 mg/kg) are used, or when chloral hydrate is combined with other depressant drugs, this is more likely. 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 combination of chloral hydrate with other agents is not recommended.

The sedative effects of chloral hydrate are unreliable in children 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.

9.1.4.2 Trimeprazine

Trimeprazine (Vallergan®), also known as alimemazine, 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). The long duration of action of trimeprazine makes it unsuitable for the out-patient or ambulatory setting.

Side effects include dry mouth, sweating, tachycardia, fever, rash, convulsions and coma. Rarely, instances of paradoxical excitation have been described.

Table XI: Dosing schedule of trimeprazine

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

9.1.4.3 Droperidol

Droperidol is a butyrophenone with sedative and antiemetic, but no anxiolytic, properties. Dysphoria and a "locked-in" feeling are more likely to occur if it is prescribed alone. For this reason, droperidol should only be used in combination with other sedatives, such as trimeprazine. 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 (Table XII below) for sedation fall well below this level and no specific cardiac monitoring is recommended for these patients.

Droperidol may be administered by the oral or intravenous routes (Table XII). It is a very effective antiemetic in low doses, with no associated sedation.

For the sedation of children, only the oral route is recommended, and then in combination with trimeprazine.

Because of its long duration of action, droperidol is not recommended for sedation for out-patient procedures.

Table XII: Dosing schedule of droperidol

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

9.2 Analgesics

9.2.1 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 or propofol). Opioids are not primarily sedative drugs, and the sedative action is a side effect.

9.2.1.1 Tilidine

Tilidine (Valoron®) is an intermediate-acting opioid available in droplet form. One droplet contains 2.5mg 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).

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.

9.2.1.2 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 sedation practitioners 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.

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 slower metabolism and excretion, and extreme caution should be exercised in this age group.

Extreme care should be exercised in the post-procedural period when the stimulus of the procedure has passed, but the drug is still active and more likely to cause respiratory depression.

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.

9.2.1.3 Remifentanil

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

9.2.1.4 Naloxone

Naloxone is a specific opioid antagonist that will reverse the respiratory depressant, as well as analgesic, effects of opioids, and should be readily available whenever opioids are used (Table XVI). It should only be used in cases of severe respiratory

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 0.5µg/kg, after 10 minutes if analgesia inadequate to maximum of 3µg/kg, titrated.
** Titrate to effect, repeating dose every three minutes until desired level of analgesia achieved or maximum dose reached.
*** Dose-related

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	10–12 µg/kg/hour

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.

9.2.2 Nitrous oxide

N_2O is an anesthetic 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_2O is an agent with a rapid onset and offset of action and an excellent safety profile. The recommended administered concentration is 50% (Table XVII). If a higher concentration is administered, this is classified as advanced sedation, with all the implications for monitoring of the patient attached to this level of sedation. For painful procedures, analgesia must be supplemented with, for example, local anaesthesia. If other sedatives are used, respiratory depression must be anticipated.

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

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.

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 strength 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.

Table XVII: Dosing schedule of nitrous oxide

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

9.2.3 Simple analgesics

Simple analgesics are analgesic drugs which have no sedative effects.

Paracetamol and non-steroidal 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.

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.

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

9.2.4 Local anaesthetics

Local anaesthetics should be considered wherever possible, bearing in mind that additional sedation or anxiolysis might be necessary. They 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.

Warming and alkalinising 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.

The toxicity of local anaesthetics are 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

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

10. Environment and clinical setting

Sedation should only be performed in an environment where the facilities, personnel, equipment and drugs required to manage emergencies are immediately available. Resuscitation equipment must be checked regularly and maintained. The facility must be equipped to meet all the requirements of safe sedation practice (see Appendix 9). Appropriate patient selection and adequate pre-procedure assessment will determine if the facility is adequate for each patient. Sedation practitioners must understand the limitations of working in the relative isolation of the out-of-hospital setting. Irrespective of the setting, the sedation team should have access to an in-patient facility to admit patients should a complication arise and have an arrangement in place for ICU transfer in the event of a complication.

Where the procedure will not be performed in a standard hospital operating theatre, the minimum necessary facilities must include an operating surface that can be tilted, and the equipment and disposables as listed below (Table XX).

Table XX: Checklist of equipment required for paediatric sedation and analgesia (Appendix 6)

Equipment to open and protect the airway	
Face masks	Size 0, 1, 2, 3 and 4
Laryngoscope set	Two handles with adult and paediatric blades, and spare bulbs and spare batteries
Endotracheal tubes	Uncuffed (sizes 2.5–5.5 mm) Cuffed (sizes 4.0 - 7.0 mm)
Water-soluble lubricant/ KY jelly	
10 ml syringe	
Tape, or equivalent, to tie endotracheal tube in place	
Oropharyngeal airways	Sizes 0-5
Nasopharyngeal airways	Sizes 4 - 7 If smaller sizes are not available one can use an endotracheal tube cut to size in nasopharynx
Equipment to confirm tracheal intubation	
Stethoscope	
End-tidal CO_2 monitoring	Desirable, particularly for longer, complex cases and when using advanced sedation techniques
Equipment for difficult intubation	
Introducers for endotracheal tubes/gum elastic bougie	Adult and paediatric stylets
Magill's forceps	Adult and paediatric
Laryngeal masks	Sizes 1.5–4
Equipment to deliver oxygen and ventilate patients	
Bag-valve ventilation devices with PEEP valve adaptor	Oxygen reservoir with adult, paediatric and neonatal masks
Oxygen delivery devices	Masks, nebulizer masks, nasal prongs (± CO_2 monitoring) and T-piece
Oxygen supply	The oxygen source must be reliable and able to provide at least 90% oxygen via a self-inflating positive pressure delivery system, at 15ℓ/minute for at least 60 minutes
Oxygen and oxygen tubing	With flow regulator and oxygen tubing for bag-valve device
Equipment to diagnose and treat cardiac dysrhythmias	
ECG monitor defibrillator	With conductive paste or pads, paddles, electrodes
Cardiac arrest board	
Equipment to gain intravascular access	
Tourniquets	
Alcohol skin wipes	
Sterile gauze pads	
Intravenous cannulae	18-24 G
Needles and syringes	1-50 ml syringes
Sharps container	
Paediatric intraosseous needles	
Tape	Appropriate strapping and dressings for paediatric intravenous access
Equipment for accurate infusion of drugs and fluids	
Infusion pumps	Intravenous fluid administration during simple sedation
Syringe drivers	Drug administration during advanced sedation
Intravenous administration sets	Administration sets and buretrols
Intravenous fluids	Crystalloids and colloids
Equipment for monitoring airway, breathing and circulation	
Stethoscope/praecordial stethoscope	
Pulse oximeter	Adult and paediatric probes
Non-invasive blood pressure monitoring device	Including paediatric and adult cuffs
Thermometer	Including low-reading capability
Blood glucose testing	
Capnograph	Desirable but not compulsory; nasal prongs with capnography line
Miscellaneous	
Drip stand, or equivalent suspension device	

Suction devices and suction catheters	Including catheters for suctioning endotracheal tubes, and Yankauer-type suction nozzles
Therapeutic heating source	Desirable for long cases
Universal precautions	Including gloves
Tilting operating surface or trolley	Capable of Fowler's and Trendelenberg positions
Procedure lighting	Adequate for intravenous access
Medication stickers	
South African Resuscitation Council algorithms *(www.resuscitationcouncil.co.za)*	Basic Life Support (BLS), Advanced Life Support (ALS) for adults and children, anaphylaxis management and choking
Resuscitation documentation record	

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

It is critical for a roving or mobile sedation practitioner to ensure, before commencing sedation, that all of this equipment is available.

11. Monitoring

Prior to the commencement of sedation, baseline vital signs must be recorded. Clinical signs must be monitored at all times during the procedure and recovery period, until the discharge of the patient from the facility. It is recommended that observations are recorded on a sedation monitoring chart (see Appendix 5a). The sedation practitioner, or personnel designated to monitor the patient, must be in attendance at the patient's side at all times until they are fully recovered from sedative and analgesic drugs, and must be able to recognise, and rescue the patient from, any complications.

Clinical monitoring (Appendix 4) as well as electronic monitoring should be used. Close and continuous observation of the child's face and chest wall motion is likely to aid in the early identification of problems, and must form the basis of all monitoring. This could be supplemented, but not be replaced, with monitoring devices. Regular communication with the patient will help in monitoring the level of sedation. If response to verbal commands and light tactile stimulation is lost, the patient requires the same level of care as that required for general anaesthesia

Clinical monitoring should include assessment and documentation of:

- Level of consciousness or depth of sedation (see Appendix 4, and the University of Michigan Sedation Scale);
- Breathing, ventilation and airway patency;
- The breathing pattern should be observed, as well as the movement of the chest and abdomen. Breathing should be rhythmic. Any signs of "sucking in" of the abdomen, rib retraction, use of accessory muscles and tracheal tug may indicate airway obstruction. The use of a precordial stethoscope may be useful. Noisy inspiration and/or expiration may be caused by partial airway obstruction;
- Neck extension is crucial for maintenance of the airway, and vigilance should be maintained for chin depression and neck flexion.
- Heart rate and rhythm.
- Blood pressure.
- Oxygenation and colour.
- Pain and degree of comfort.
- Anxiety levels and behaviour.
- The patient must be monitored for confusion, restlessness and agitation. This may indicate a possible adverse event, hypoxaemia, hypoglycaemia, or under-sedation or even over-sedation.
- Operator-dependent factors, e.g. airway manipulation and dose of administered local anaesthetic; and environmental factors, e.g. room temperature, must also be monitored.

11.1 Monitoring for minimal sedation

The respiratory and cardiovascular systems are usually unaffected. Intermittent assessment of the vital signs is appropriate.

11.2 Monitoring for moderate sedation

The respiratory and cardiovascular systems are usually unaffected. Basic clinical monitoring, e.g. responsiveness to verbal commands and light tactile stimulation, should be commenced prior to the administration of sedation, and must be continued during the procedure and recovery period until the patient has been discharged from the facility.

Trained personnel, monitoring equipment, as well as resuscitation drugs and equipment, must be available throughout this period. Continuous monitoring of pulse oximetry, heart rate and intermittent recording of the respiratory rate and blood pressure are recommended. This must be documented on a sedation monitoring chart (see Appendix 5a). Where moderate sedation is used, and continuous verbal contact with the patient maintained, electrocardiogram (ECG) monitoring is not essential. With the use of multi-drug techniques of sedation, it is advisable that an ECG is used.

Any patient with underlying cardiovascular disease should be monitored with an ECG. Capnography, the gold standard for the monitoring of ventilation, is a more sensitive monitor for adequacy of ventilation than pulse oximetry. It is not mandatory for moderate sedation, but is desirable in the obese patient and in patients with respiratory pathology. It is recommended that capnography should be used for deep sedation. Capnography techniques, using nasal cannulae, sidestream analysis and transcutaneous methods, are well tolerated by patients undergoing PSA.

It is not necessary to administer oxygen routinely to sedated patients. Nasal cannulae should be available.

11.3 Monitoring for deep sedation

Patients undergoing deeper levels of sedation require the same level of monitoring as patients receiving general anaesthesia.

12. Discharge

Premature discharge has been identified as a major contributing factor to severe morbidity and mortality in several post-sedation adverse event analyses.

Preparation for discharge starts in the recovery area. The recovery area should be staffed by a health care professional, capable of basic life support, who is responsible for monitoring no more than two patients simultaneously. A medical practitioner should assume overall responsibility for the patients in the recovery area, and should not leave the premises until the discharge criteria are met.

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 prolonged stays 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.

12.1 Discharge criteria: from the recovery area to the ward

A discharge scoring system (Table XXI, Appendix 5c) is recommended to establish readiness for discharge from the recovery area to the ward. The child should score at least 11 points prior to discharge. In addition, there should be no procedural or surgical complication (e.g. bleeding). Discharge cannot be permitted if the score for any individual category is zero.

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

12.2 Discharge criteria: from the health care facility to home

In addition to the criteria for discharge to the ward, prior to discharging the child home, the following criteria should be met:

- There are no surgical complications (e.g. bleeding after dental procedures).
- The child is able to take fluids orally.
- There is no nausea or vomiting.
- An analgesia management plan is in place.

The discharge questionnaire (Table XXII, Appendix 5d) can aid in determining if the patient is ready for discharge home.

Children may only be discharged home into the charge of a parent, guardian or other responsible person. This parent/guardian/responsible person must be given clear instructions,

Table XXI: Discharge scoring system

Physical sign	Clinical level	Score
Level of consciousness	Fully awake/alert/answers questions	2
	Rousable to verbal command	1
	No response	0
Respiration	Able to take deep breaths and cough adequately	2
	Shallow breathing with poor cough	1
	Apnoeic periods	0
Oxygen saturation	> 96% on room air	2
	Requires oxygen to maintain saturations > 90%	1
	Saturation < 90% with oxygen	0
Movement	Able to move all four extremities on command	2
	Able to move two extremities on command	1
	Not able to move extremities on command	0
Temperature	36–38 °C	2
	35.5–35.9 °C or 38.1–38.5 °C	1
	< 35.5 °C or > 38.5 °C	0
Pain	Minimal discomfort or pain	2
	Significant pain	0

Table XXII. Discharge questionnaire

	Yes	No
Fully awake and aware		
Breathes comfortably and is of normal colour		
Can swallow and cough		
Can walk without feeling faint, or able to move extremities		
Normothermic		
Has minimal discomfort or pain		
Not nauseated, or only minimal, on ambulation		
Operative site checked and bleeding controlled		
Able to take fluids orally		
Post-sedation instructions given and explained to parent/guardian/responsible person, including analgesia management plan		
Possible complications explained		
Prescription or medication given		
Suitably accompanied by parent/guardian/responsible person		

and must have access to a telephone. Instructions to be given to the parent/guardian/responsible person should include:

- 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 there is no difficulty in 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, 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/guardian/responsible person does not understand and agree to the above, the child is not ready for discharge.

13. Documentation required during procedural sedation and analgesia

- Documentation before sedation:
  - » Medical history questionnaire
  - » Informed consent
  - » Pre- and post-sedation instructions
- Documentation immediately before sedation:
  - » Pre-procedure checklist, including equipment check
- Documentation during sedation:
  - » Sedation monitoring chart, including practical clinical monitoring
- Documentation after sedation:
  - » Post-sedation monitoring chart, with discharge scoring system
  - » Discharge questionnaire

It is important to remember that, unless it has been written down, it never happened!

13.1 Documentation before sedation

- *Medical history questionnaire* (Appendix 1). This should be completed by the parent/guardian/responsible person and evaluated by the sedation practitioner. Prior to the commencement of sedation, and as part of the patient assessment, possible changes in the patient's condition should be sought and a risk evaluation performed.
- *Informed consent*. This document must show that appropriate consent was obtained from a parent/guardian/responsible person, according to local and international requirements (Appendix 2).
- *Pre- and post-sedation instructions.* It is useful to provide information (Appendix 3) to the parent/guardian/responsible person regarding the sedation process. This should include the aims, objectives and possible side effects of sedation. All information and instructions should be provided both verbally and in writing. In addition, the name, address and a telephone number (including after hours) of the parent/guardian/responsible person should be recorded.

13.2 Documentation immediately before sedation

The final points checked prior to commencing sedation should be documented. An evaluation of the child's condition, including any changes that took place after the completion of the medical history questionnaire should be written down. It is also important to record the details of the check for appropriate equipment in the sedation suite. This document may take the form of a pre-procedural checklist (Appendix 7).

13.3 Documentation during sedation

The sedation monitoring chart is a time-based document that includes the name, age and weight of the patient, as well as the route, time, and dose of administered drugs (Appendix 5a).

The chart must include information regarding the vital signs, which should be monitored and recorded at least every 10 minutes.

Before any sedative drug is administered, baseline documentation of all vital signs is necessary.

If capnography is utilised, the value of the end-tidal carbon dioxide concentration must be documented on the chart.

Adverse events and complications during sedation must be documented on the chart. Any action taken, and any escalation of care or requirement for hospitalisation, should be recorded.

To assess the level of consciousness, a variety of sedation scoring systems are available. It is advisable to use the simplest and most practical scoring system. The UMMS can be recommended (Appendix 4).

Any behavioural problems occurring during the sedation or recovery period should also be recorded on the form, and reported to the parent/guardian/responsible person.

13.4 Documentation after sedation

The vital signs must be monitored and recorded at least every 10 minutes, until full recovery has taken place (Appendix 5b).

Formal documentation of the patient's clinical condition must be performed before discharge from the facility (Appendix 5c and 5d).

Before the child is sent home, post-sedation instructions for the care of the child must be given to the accompanying parent/guardian/responsible person. It should be stressed that the child must not be left alone for at least the next 12 hours.

14. Adverse events accompanying procedural sedation and analgesia

Most procedures pose little risk to the patient. However, the administration of sedatives and analgesics may add to the risk. Adverse events during PSA most commonly occur as a result of drug-induced depression of respiratory function. Adverse events

are more likely if a combination of drugs (particularly three or more) is used.

Adverse events can also be related to poor patient rescue skills, inadequate monitoring and poorly-defined discharge criteria.

Complications can be minimised by training practitioners in airway management, because the maintenance and protection of the airway is a crucial part of safe sedation practice.

Adverse events and complications are more likely in non-hospital-based settings that do not meet the minimum requirements for safe sedation practice. Attention to environmental factors is essential for the safe practice of procedural sedation and is a basic requirement for ensuring a satisfactory outcome.

Audits of the procedures, as well as all critical adverse events, should be performed at least annually. An example of an adverse event reporting form is included in Appendix 8.

Adverse events may arise because of:

- Factors related to drugs:
  - » Drug interactions.
  - » Drug overdose, including local anaesthetic toxicity.
  - » Incorrect selection of drugs (e.g. opiates for painless procedures).
  - » Prescription errors, particularly with oral formulations.
  - » Drug combinations.
  - » Unanticipated (pharmacogenetic) responses to drugs.
  - » Unsupervised administration (e.g. by a parent at home).
  - » Lack of knowledge of the pharmacokinetics and pharmacodynamics of drugs.
- Factors related to skills:
  - » Inadequate clinical evaluation, especially of the airway, and inappropriate patient selection.
  - » Inadequate experience in paediatric sedation.
  - » Inadequate problem recognition.
  - » Inadequate appropriately-qualified support staff.
  - » Inability of the sedation practitioner to rescue a patient from an unexpected, or undesirable, deep level of sedation.
  - » Inadequate resuscitation skills.
- Factors related to the environment:
  - » Inadequate monitoring.
  - » Inadequate equipment
- Premature discharge, and not following discharge criteria.

15. Developing a sedation plan

Whenever possible, PSA should consist of both pharmacological and non-pharmacological strategies.

Non-pharmacological strategies include psychological preparation, nutritive and non-nutritive sucking, distraction, and basic physical measures, such as the application of ice or splinting, or a combination of these.

When providing procedure-specific recommendations, one must take into account the inter-individual variation in the reaction to drugs that are inherent in children. There is no fixed dose for any sedative agent in children, only a maximum dose.

Drug selection should depend on the requirements for the procedure:

- Analgesia
- Anxiolysis
- Sedation
- Amnesia
- Immobility

If a procedure is not painful, it is advised that agents such as ketamine or the opioids not be used routinely.

15.1 Psychological preparation of children for procedures

Preparing children and their families for procedures and medical events can significantly increase their confidence and their ability to cope with the experience.

Preparation should include all sensory information, a description of the sequence of events, and the expected duration of the procedure. When preparing the child, let him or her 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.

Talking to children is different from talking to adults. In order to provide helpful information, the child's developmental level, age, culture, and education should be taken into consideration. Young children have no sense of reason. "You will feel better after this medicine has been given" is of no apparent benefit to them; 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 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 at their level.

The caregiver plays a vital role in the hospitalisation of young children. They have an understanding of the child's needs and are best equipped to interpret the child's behaviors and reactions to, and in, the hospital. Frequent conversations with caregivers are crucial to success, and sufficient time should be made available for asking and answering questions.

By initially providing accurate and developmentally appropriate information, a family's level of uncertainty can be reduced, and their sense of control and involvement increased. This can lead to less emotional distress, and also result in the continuation of accurate information processing and the development of positive

coping strategies. The long-term benefits of this to the child, the parents and the medical staff cannot be underestimated.

16. Setting up a sedation service

When a sedation unit, facility or surgery is established, the following aspects deserve close attention in order to allow for the safe provision of sedation services, regardless of the sedation techniques employed:

- Environment
- Patient selection and patient assessment
- Training requirements
- Sedation practitioner: experience
- Sedation practitioner: ability to rescue
- Recordkeeping

16.1 Environment

The premises, the supporting facilities and equipment must be appropriate for the delivery of sedation services. The sedation unit/facility/surgery, which is outside the operating theatre, must comply with all contemporary standards for safe patient care. All providers of procedural sedation services are responsible for ensuring that the sedation facility in which care is delivered, is appropriate for the needs and safety of the sedation practitioners, patients and staff.

It is highly recommended that the sedation practitioner, as well as the owner of the premises, ensure that the premises are inspected and accredited by an independent recognised sedation authority to ensure that the necessary standards are in place. It is anticipated that this will soon be mandatory. It is recommended that the Society of Sedation Practitioners of South Africa (SOSPOSA) or the Council for Health Service Accreditation of Southern Africa (COHSASA) are contacted for evaluation of the sedation facility. The COHSASA or SOSPOSA evaluation should be repeated on a two-yearly basis.

At all times, the facilities must meet the professional standards for the provision of sedation, as set out in these guidelines. Appropriate equipment and drugs must be available, and in working order, when sedation is being provided and during the recovery period. Drugs and equipment must be appropriate, not only for the specific sedation technique used, but also for the treatment of adverse events and complications. Equipment must be maintained in accordance with the schedule described by the manufacturers. Records of the maintenance of equipment must be retained, and made available for subsequent formal inspection.

Access by the emergency services and the transfer of the patient must be permitted by the clinical setting.

16.2 Patient selection and patient assessment

Only patients classified as ASA I or II should be sedated outside the operating theatre. It must be noted that certain patients (e.g. the obese), who may be classified as ASA I or II according to clinical status, should actually be reclassified as at least ASA III and, as such, should be managed as higher risk patients. If sedation is planned for a procedure outside the operating room, such patients must be sedated by a highly experienced sedation practitioner.

Patient selection and assessment must be done before the procedure by trained health care professionals. The results of these examinations should be documented in the patient record. A focused airway examination of the patient is mandatory for any practitioner who plans paediatric sedation.

16.3 Qualifications and Training requirements

Relevant qualifications and ongoing training remain the foundation of safe sedation practice. It is recommended that sedation practitioners should:

- Have a primary, registered medical qualification;
- Have full registration with the HPCSA, as appropriate;
- Have formal training in standard and advanced sedation techniques, or be able to demonstrate equivalent experience and training, and also provide audit records of the safe administration of sedation drugs;
- Provide evidence of regular and recent sedation-related CPD activity appropriate to the sedation techniques that they will be providing;
- Have a logbook reflecting cases where sedation was performed, as well as the technique used;
- Comply with SASA recommendations for safe sedation practice;
- Have evidence of up-to-date qualifications in basic and advanced paediatric life support available.

16.4 Sedation practitioner: experience

The integrity of the sedation facility, and the effective selection and assessment of patients, is dependent on the experience of the sedation practitioner. Continuing professional development and supervised clinical training are crucial to maintain the link between the SASA guidelines on PSA and standards of practice at the facility. Regular updating of knowledge and skills is essential.

16.5 Sedation practitioner: ability to rescue

Patients may inadvertently progress to deeper levels of sedation. A sedation practitioner must be able to rescue a patient from an unintended deeper level of sedation.

16.6 Recordkeeping

It is recommended that the following documentation is completed:

- Valid informed consent.
- Medical history questionnaire.
- Pre-procedural checklist.
- Pre- and post-sedation instructions to patients and caregivers.

- Sedation monitoring chart (to include monitors used and drugs administered).
- Sedation scoring systems.
- Discharge criteria.
- Facility inspection and practice appraisal document.

All facilities providing sedation services must keep a register of procedures performed, with the sedation technique documented. Procedural sedation procedures should be the subject of regular audits, and all members of the sedation team should participate. The focus should be on the review of procedures, sedation techniques and processes. Records of the audit process and outcomes must be maintained and made available for inspection. Regular audits should be considered a core requirement for sedation providers involved in patient care.

Documentation and institutional protocols, including written informed consent, monitoring and written instructions for the care of the patient on discharge, must comply with the SASA recommendations on PSA for children

Appendix 1: Medical history questionnaire

Medical History Questionnaire

Name			
Sex	Age	Height	Weight

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
1. Cardiovascular disease		
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:		
2. Respiratory disease		
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:		
3. Central nervous system disorders		
Epilepsy, or fits (convulsions)		
Behavioural problems, attention deficit disorder, or developmental delay		
If any answer is "yes", please provide a detailed explanation:		
4. Blood disorders		
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:		
5. Endocrine disorders		
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 child's procedure		

…… ……

Signature (Parent/Guardian/Responsible Person) Date

…… ……

Signature (Patient, if possible) Date

Appendix 2: Valid informed consent

Valid informed consent to sedation and analgesia for medical or 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 (PSA) 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. PSA, 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 will not be unconscious, as he/she may 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, shivering, drowsiness, dizziness, headaches, 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 practitioner responsible for this service. This may include rectal medications/analgesia.

4. 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, local anaesthesia without sedation, or local anaesthesia with behavioural management techniques, to my satisfaction.

5. I confirm that I have received written/oral instructions regarding the sedation, which I understand. I will abide by the pre- and post-procedural instructions. I have completed a medical history questionnaire for my child and have declared all drugs that he/she has taken during the last 6 months.

6. If applicable, I accept full and complete responsibility for actual and potential costs associated with 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.

I, …… (patient/parent/guardian), of 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 sedation and analgesia, risks, alternatives and expectations to the patient/parent/guardian, and believe that they have been adequately informed and have consented.

…….. ……

Practitioner's signature **Date**

Appendix 3: Pre- and post-sedation instructions

Pre- and Post-sedation Instructions

Please read the instructions carefully, and then fill in your details and e-mail to: ……

Dear Patient/Parent/Guardian,

Your child needs to undergo a procedure/operation, and your doctor/dentist has chosen to do this under sedation. Please read the following information and instructions carefully. If anything is unclear, please contact your doctor/dentist:

Name of doctor/dentist: ……

Telephone/cellphone number: ……

E-mail address: ……

Pre-sedation instructions

- If your child suffers from any medical condition or takes any acute or chronic medicine, you will need to inform your doctor/dentist before the procedure. A medical history questionnaire has been included; please complete this and return by e-mail (if possible) at least 48 hours before the procedure. This is an important document, as it will help us to decide whether your child qualifies for the sedation that will have to be given for the procedure/operation.
- If your child is sick or unwell in any sense, please call your doctor/dentist so that he/she can decide whether it is necessary to postpone the treatment.
- Please ensure your child is dressed in comfortable clothes, with loose-fitting sleeves.
- Please ensure your child does not eat anything for at least 6 hours before the procedure. Breast milk may be taken up to 4 hours before, and water may be taken up to 2 hours before the procedure.
- If your child takes **chronic medication, please do give it** on the day of the procedure, after discussing this with the doctor/dentist.
- Please ensure that you and your child arrive in good time for the appointment, at least 30 minutes beforehand. In some cases, your doctor/dentist may feel that your child will benefit from premedication to reduce his/her anxiety and make him/her feel relaxed. If this is the case, the doctor/dentist may request that you come earlier for your appointment so that your child may be given the premedication.
- Please ensure that your child has emptied his/her bladder before the procedure.
- An escort may remain with the child until the sedation is underway and the procedure is about to start. The escort will then be requested to leave the procedure room.
- It may be necessary to put a drip/needle in a vein in your child's hand, arm or foot. Local anaesthetic ointment is available to apply beforehand. The doctor /dentist will discuss this with you and your child.

Post-sedation instructions (aftercare of the patient)

- A responsible adult must take the child home after the sedation. The child must remain in the company of this responsible adult for the remainder of the day. Sedation **will not** be given if the child arrives without an escort.
- Once at home, your child must rest quietly. Interfere as little as possible with your child's activities.
- Your child may not engage in activity or play with equipment that requires alertness or coordination (e.g. swimming, cycling) for at least 12 hours following the procedure. You should also keep your child away from potentially dangerous areas, like the kitchen, baths and pools of water.
- If your child is taking any regular medication, ask the doctor/dentist when you should give him/her the next dose after the sedation.
- The sedation may produce amnesia (memory loss). This is temporary, sometimes lasting for a few hours. After a dental procedure, be careful that your child does not bite his/her numb lip, as he/she will not be able to feel if it is painful.
- About 20% of children complain that they see double, or cannot see, after sedation. This is a temporary drug effect sometimes lasting for up to 6 hours.
- Some children are aggressive after sedation. This may be a drug effect. Ensure that your child is not left alone. Contact the doctor/dentist if you are worried about this.
- Introduce food and fluids slowly after sedation, as your child may feel nauseous and could vomit.

- Your child should not experience nausea or vomiting after sedation. If your child vomits **more than once,** please contact your doctor/dentist.
- Do not let your child eat or drink if he/she is nauseous. Your child may have clear fluids when instructed to do so by the doctor/dentist. If your child feels fine after having clear fluids, you may then progress to solids.

I, ……., the undersigned, have read and understood these pre- and post-sedation instructions, and agree to contact the doctor/dentist if there is anything else that is not clear to me.

…… ……

Signature (Parent/Guardian) Date

We do not anticipate that your child will have any adverse events or complications. Should you become concerned about anything, please contact the following, at these numbers:

Hospital Casualty Department: ……

Ambulance: ……

Dr ……

Telephone: ……

Cellphone: ……

Appendix 4: Clinical monitoring

Clinical monitoring for paediatric sedation

The clinical observation of level of consciousness, breathing, colour and behaviour or body language forms the basis of the monitoring of a sedated patient. It is to be supplemented by monitoring devices, as detailed in the guidelines.

Level of consciousness

Communication with the patient is of great importance.

Check for response to simple commands, e.g. "Open your eyes". Most children over one year of age should be able to follow this instruction. If there is no reaction to this request, check the patient for a response to light touch, e.g. eye opening. A lack of response to both of these instructions indicates a deep level of sedation. Watch for signs of increasing depth of sedation, e.g. the mouth falling open.

Breathing

Look at the colour of the skin and mucous membranes of the patient. This is best seen in the face. The baseline colour should be pink, with any variation on this, tending towards blue, indicating hypoxia.

Look at the breathing pattern, paying attention to the movement of the chest and abdomen. In the sedated patient, breathing should be rhythmic. "Sucking in" of the abdomen with chest expansion suggests partial or complete airway obstruction, and is known as "paradoxical respiration".

Listen to the movement of air from the patient's mouth and/or nose. A partially obstructed airway will result in noisy inspiration and/or expiration. This may sound like snoring or wheezing.

A praecordial stethoscope resting on the patient's chest will assist the sedation practitioner to assess breathing adequacy, particularly where visual assessment is obscured by drapes.

The likelihood of airway obstruction increases as the level of sedation deepens. This may be due to relaxation of the pharyngeal musculature or to the presence of obstructive tissue, such as adenoids or tonsils. Partial airway obstruction that is left untreated may result in hypoxia, and may progress to complete airway obstruction.

In the case of complete airway obstruction, no breathing sounds will be heard and paradoxical breathing will be present.

Behaviour

Confusion, restlessness and agitation may be signs of hypoxia, hypoglycaemia or over-sedation. These possibilities should be considered before administering further sedation.

Watch and listen for signs of pain (screaming, groaning, withdrawing) and anxiety (tachycardia, sweating, voicing anxiety).

In the older, co-operative child, a sign (e.g. hand squeezing or thumbs up or down) may be discussed before sedation is initiated. This can then be used by the child to communicate well-being or discomfort to the observer.

University of Michigan Sedation Scale (UMSS)

0 = awake and alert

1 = minimally sedated

Tired, sleepy, appropriate response to verbal conversation and/or sound

2 = moderately sedated

Somnolent/sleeping, easily aroused with light tactile stimulation or a simple verbal command

3 = deeply sedated

Deep sleep, rousable only with significant physical stimulation

4 = unrousable

Appendix 5a Sedation monitoring chart

SEDATION MONITORING CHART

Patient name	Heath Facility Sticker
Patient ID	
Date of birth	

ASA	1 2 3 4 5 E
Age	
Weight	

Premedication:	Time:

Date		Time in	
		Time out	
Monitors			
ECG		SpO_2	
BP		FiO_2	
Temp		$EtCO_2$	

Time																	
$Air/N_2O/O_2$																	Drug & Dose
1																	1
2																	2
3																	3
4																	4
5																	5
6																	6
Bloodpressure ↕ Pulse 200																	IV cannula size
180																	
160																	IV cannula site
140																	
120																	
100																	
80																	
60																	
40																	
20																	
RR																	IV Fluids
SpO_2																	
FiO_2																	
EtO_2																	
Temp																	
LOC																	

Health Facility
Procedure
Sedation Practitioner
Operator
Recovery nurse

Medical History
Previous operations/GA/Sedation
Medication
Allergies
Last oral intake Fluids Solids
Examination Airway Other systems
Comments

Critical event: Yes ☐ No ☐

Write details overleaf or on a critical incident reporting form

Sedation Practitioner Signature: _____

Appendix 5b Post-sedation monitoring chart

Post-sedation Monitoring Chart

	Admission	5 minutes	10 minutes	15 minutes	30 minutes	60 minutes	Discharge
Time							
O_2 given							
Respiratory rate							
SpO_2							
Heart rate							
Level of consciousness							
Temperature							
Comments							

Appendix 5c: Discharge scoring system

Discharge Scoring System

Physical sign	Clinical level	Score
Level of consciousness	Fully awake/alert/answer questions	2
	Rousable to verbal command	1
	No response	0
Respiration	Able to take deep breaths and cough adequately	2
	Shallow breathing with poor cough	1
	Apnoeic periods	0
Oxygen saturation	> 96% on room air	2
	Requires oxygen to maintain saturation > 90%	1
	Saturation < 90% with oxygen	0
Movement	Able to move all four extremities on command	2
	Able to move two extremities on command	1
	Not able to move extremities on command	0
Temperature	36-38°C	2
	35.5–35.9 °C or 38.1–38.5 °C	1
	< 35.5 °C or > 38.5 °C	0
Pain	Minimal discomfort or pain	2
	Significant pain	0

A score of 11 is sufficient for discharge from the recovery area to the ward. Discharge cannot be permitted if the score for any individual category is 0.

Appendix 5d: Discharge questionnaire

Discharge Questionnaire

	Yes	No
Fully awake and aware?		
Breathing comfortably and colour normal?		
Able to swallow and cough?		
Able to walk without feeling faint / able to move extremities?		
Normothermic?		
Has minimal discomfort or pain?		
Not nauseous, or only minimal on ambulation?		
Operative site checked and bleeding controlled?		
Able to take fluids orally?		
Post-sedation instructions given and explained to parent/guardian/ responsible person, including pain management plan?		
Possible complications explained?		
Prescription or medication given?		
Suitably accompanied by parent/guardian/responsible person?		

Patient has been assessed and is deemed fit for discharge home at: …… (time)

Mode of transport home: ……

Signature of recovery nurse: ……..…….

Date: ……..

Appendix 6: Checklist of equipment and drugs

Checklist of equipment required for paediatric procedural sedation and analgesia

Equipment to open and protect the airway	
Face masks	Size 0, 1, 2, 3 and 4
Laryngoscope set	Two handles with adult and paediatric blades, and spare bulbs and spare batteries
Endotracheal tubes	Uncuffed (sizes 2.5–5.5 mm)
	Cuffed (sizes 4.0–7.0 mm)
Water-soluble lubricant/KY jelly	
10 ml syringe	
Tape, or equivalent, to tie endotracheal tube in place	
Oropharyngeal airways	Sizes 0-5
Nasopharyngeal airways	Sizes 4 and 7 If smaller sizes are not available, one can use an endotracheal tube cut to size in nasopharynx
Equipment to confirm tracheal intubation	
Stethoscope	
End-tidal CO_2 monitoring	Desirable, particularly for longer, complex cases and when using advanced sedation techniques
Equipment for difficult intubation	
Introducers for endotracheal tubes/gum elastic bougie	Adult and paediatric stylets
Magill's forceps	Adult and paediatric
Laryngeal masks	Sizes 1.5–4
Equipment to deliver oxygen and ventilate patients	
Bag-valve ventilation devices with PEEP valve adaptor	Oxygen reservoir with adult, paediatric and neonatal masks
Oxygen delivery devices	Masks, nebulizer masks, nasal prongs ($\pm$ CO_2 monitoring) and T-piece
Oxygen supply	The oxygen source must be reliable and able to provide at least 90% oxygen via a self-inflating positive pressure delivery system, at 1.5ℓ/minute for at least 60 minutes
Oxygen and oxygen tubing	With flow regulator and oxygen tubing for bag-valve device
Equipment to diagnose and treat cardiac dysrhythmias	
ECG monitor defibrillator	With conductive paste or pads, paddles and electrodes
Cardiac arrest board	
Equipment to gain intravascular access	
Tourniquets	
Alcohol skin wipes	
Sterile gauze pads	
Intravenous cannulae	18-24 G
Needles and syringes	1-50 ml syringes
Sharps container	
Paediatric intraosseous needles	
Tape	Appropriate strapping and dressings for paediatric intravenous access

Equipment for accurate infusion of drugs and fluids	
Infusion pumps	Intravenous fluid administration during simple sedation
Syringe drivers	Drug administration during advanced sedation
Intravenous administration sets	Administration sets and buretrols
Intravenous fluids	Crystalloids and colloids
Equipment for monitoring airway, breathing and circulation	
Stethoscope/praecordial stethoscope	
Pulse oximeter	Adult and paediatric probes
Non-invasive blood pressure monitoring device	Including paediatric and adult cuffs
Thermometer	Including low-reading capability
Blood glucose testing	
Capnograph	Desirable but not compulsory; nasal prongs with capnography line
Miscellaneous	
Drip stand, or equivalent suspension device	
Suction devices and suction catheters	Including catheters for suctioning endotracheal tubes, and Yankauer-type suction nozzles
Therapeutic heating source	Desirable for long cases
Universal precautions	Including gloves
Tilting operating surface or trolley	Capable of Fowler's and Trendelenberg positions
Procedure lighting	Adequate for intravenous access
Medication stickers	
South African Resuscitation Council algorithms *(www.resuscitationcouncil.co.za)*	Basic Life Support (BLS), Advanced Life Support (ALS) for adults and children, anaphylaxis management and choking
Resuscitation documentation record	

Appendix 7: Pre-procedural checklist

Paediatric Pre-procedural Checklist

	Yes	No
1. Has the medical history questionnaire been completed?		
2. Has the child been evaluated by the sedation practitioner?		
3. Have there been any changes in the patient's medical condition since the first evaluation? If the answer is "yes", please provide details:		
4. Have contraindications for sedation been excluded?		
5. Has the child been examined for signs of an upper respiratory tract infection?		
6. Does the child have any allergies?		
7. Has the child fasted for the recommended period of time?		
8. Has written, valid informed consent been obtained?		
9. Has the child been administered premedication? If the answer is "yes", please provide details, including the name of the practitioner who ordered it:		
10. Has all equipment, including airway equipment, monitoring devices and drugs, been checked?		

…… ……...
Signature (Sedation practitioner) Date

Appendix 8: Critical incident reporting form

Critical Incident Reporting Form: Paediatric Sedation and Analgesia

General instructions

- A critical incident is any event which affects, or could affect, the safety of the patient. This event could be either preventable or unpreventable.
- Ensure identification of the patient and the sedation practitioner.
- Record the patient's demographic details: age, weight and state of health.
- Provide a simple description of events.
- For medicolegal purposes:
  - Do not assume culpability.
  - Simply provide a description of the sequence of events in your own words.
  - Include details which may have contributed to or minimised the event.
  - Suggest what could be done to prevent further events of this nature (e.g. monitors, drugs).
  - If more than one event occurred, provide a detailed report of each.
- State whether you think the event was avoidable: yes, no or undecided (maybe).

Classification of a critical incident

What was the cause of the event?	Circuitry		Equipment		Pharmacological	
Why did the event occur?	Factors that could have contributed to the event:					
	Factors that could have minimised the event:					
	Suggested corrective measures:					
Describe the sedation administered and the procedure performed:	Procedure:				Emergency	Elective
	Monitors:					
	Type of sedation:					
When and where did the event take place?	Time:	Day:		Month:		Year:
	Waiting area	Theatre	Procedure room		Recovery room	Ward
When were you alerted to the event?	Pre-sedation	Sedation induction	Sedation maintenance		Emergence	Recovery
Provide the patient's details:	Name:				ID:	ASA status 1 2 3 4 5 E
	Neonate	< 1 year		1-8 years		> 8 years
What was the immediate patient outcome?	Cardiac arrest	Major resuscitation		Minor resuscitation		Physical injury
What was the final patient outcome?	Awareness	Death	Major morbidity	Minor morbidity	Prolonged hospital stay	ICU or high care
Was the sedation practitioner debriefed?	Yes/No	Details:				

Critical incident report (including near-misses)

Patient details (or sticker):
Procedure:
Date and time of event:
Sedation practitioner present:

Brief and relevant details of the event: (Including nature of incident, action taken and final outcome)
Reporting sedation practitioner Name: Signed: Date:
Date of meeting where incident discussed:
Additional comments/further action taken:
Chairperson of the meeting: Name: Signed: Date:

Appendix 9: Practice appraisal protocol

This practice inspection protocol aims to ensure that the inspector (SOSPOSA) or appointed body, e.g. COHSASA, is satisfied that the appraised clinic, practice or facility can satisfactorily provide safe and effective sedation according to good practice. The inspection investigates essential areas, 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 sedation practitioner.

Ref	Topic	Yes	No
A	**General**		
1	Does the practice provide basic intravenous sedation, e.g. midazolam only?		
2	Does the practice provide advanced intravenous sedation techniques?		
3	Does the practice provide inhalation sedation?		
4	Do children aged 12 years and younger receive intravenous sedation at the practice?		
5	Are the sedation patients only ASA I or II?		
6	Does the practice only use operator sedation practitioners?		
7	Does the practice normally operate with a separate dedicated sedation practitioner?		
8	Is the practice in good standing with the HPCSA?		
B	Facilities		
1	Do the premises appear to be well maintained?		
2	Are the recovery and waiting areas separate?		
3	Is there good lighting and ventilation in all of the clinical areas?		
4	Is there access by the emergency services to the building?		
5	Is there access by the emergency services to the surgery?		
6	Is there space within the surgery to deal with an emergency?		
7	Is there space within the recovery area to deal with an emergency?		
8	Is there space within the surgery for the sedation practitioner to work effectively?		
9	Does the practice layout provide privacy for the sedation of patients?		
10	Are there facilities for a parent/caregiver to accompany their child while sedation is commenced?		
11	Can the dental or procedure chair be placed in the head-down tilt position, where applicable?		
C	**Sedation practice**		
1	Does the practice follow a recognised sedation protocol?		
2	Are patients normally assessed for suitability for sedation at a preceding appointment?		
3	Are possible options for anxiety and pain control explained to the patient/caregiver prior to obtaining consent for sedation?		
4	Do patients/caregivers have the opportunity to ask questions?		
5	Is pulse oximetry assessed and documented as part of the patient assessment?		
6	Is the patient monitored by a trained and experienced member of staff during sedation and recovery?		
7	Are recognised discharge criteria followed?		
8	Where are patients normally recovered?		
9	Does the sedation practitioner or trained staff discharge the patient?		
10	Are patients given a telephone number to call in case of problems or complications?		
11	Does the practice prohibit caregivers from remaining in the surgery during the procedure?		
12	Is there an agreed protocol with the local hospital and paramedics in case of an emergency?		
D	**Documentation**		
1	Are patients given written pre-operative instructions?		
2	Are patients given written post-operative instructions?		
3	Are the following noted and checked prior to sedation? • Medical, dental and social histories, and the medical history questionnaire • Previous sedations and general anaesthesia • ASA category • Fasting • Preoperative vital signs • Treatment required		

4	Is written valid consent obtained prior to sedation?		
5	Is a contemporaneous record (sedation flow sheet) kept of the administration of sedation?		
E	Equipment		
1	Is there equipment for the measurement of blood pressure and oxygen saturation values?		
2	Is there a dedicated Inhalation Sedation (IS) machine? Does this have the following? • Minimum delivery of 30% O_2 • Emergency N_2O 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	What is the date of the last service?		
8	Is a pulse oximeter available?		
9	Does the pulse oximeter have audible alarms?		
10	Is the equipment serviced according to the manufacturers' guidelines?		
11	What is the date of the last service?		
12	Is emergency oxygen available? What size cylinder? Is there a back-up supply or cylinder?		
13	Is there a self-inflating bag valve mask with reservoir bag, e.g. an Ambu® bag?		
14	Is there a pocket face mask, e.g. Laerdal® pocket mask, to provide assistance with ventilation?		
15	Is a set of nasal cannulae available?		
16	Is suction available and in working order? How often is suction cleaned and checked?		
17	Is backup suction available?		
18	Are laryngeal mask available in a range of appropriate sizes?		
19	Are Yankaeur® suckers available?		
20	Is a defibrillator available?		
21	Is an AED available?		
22	What is the date of the last service?		
23	Is the emergency equipment readily available? (SASA guidelines)		
F	**Drugs**		
1	Are emergency drugs available? (see SASA guidelines) Which ones do you have?		
2	Are all drugs (sedation and emergency) within their sell-by date?		
3	Is a designated person responsible for stock control?		
4	Are all emergency drugs readily available?		
G	**Staff**		
1	Names and qualifications of all dentists, doctors and nursing staff involved in sedation practice at this address. Do they all have life support training? Please supply details		
2	Can all staff demonstrate training in sedation, as well as a commitment to continuing professional education? Give details		
3	Can all assisting nurses demonstrate training in sedation?		
4	Can all recovery staff, if applicable, demonstrate training appropriate to their duties?		
5	Is all staff trained in at least Basic Life Support (BLS)?		
6	How often is emergency training provided? Give dates		
7	When was the last emergency training session? Is in-house training carried out?		
8	Is the facility suitable to provide moderate sedation and analgesia and to care for the patient slipping inadvertently into deep sedation?		
If "no" to the last question, the following observations would need to be addressed for successful practice appraisal:			