9.4.2 Logbook

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

10. Safe sedation practice

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

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

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

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

10.1 Principles of safe sedation practice

These principles are centred on the following:

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

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

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

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

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

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

10.2 Child groups requiring special care

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

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

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

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

10.2.1 The obese child

- Intravenous placement of a cannula may be challenging.
- NIBP monitoring may be difficult since the cuff may not fit properly. Cuffs that are too small will overestimate true blood pressure, while cuffs that are too large will underestimate blood pressure.
- Obese children have a higher risk of gastro-oesophageal reflux disease and may be at risk of aspiration despite a nil per mouth status.
- Childhood obesity has a negative effect on variables such as FEV1, FVC and FEV1/FVC ratio. This may influence the child's response to episodes of hypoxia and hypercarbia.
- These children are at risk of undiagnosed obstructive sleep apnoea and may be at further risk of desaturation and apnoea during the recovery period.
- Calculating drug dosing may be problematic; drug dosing based on actual body weight will lead to overdose; dosing based on ideal body weight may be inadequate. Titration of drugs eliminates guesswork and is advisable.
- An increased risk of deep vein thrombosis and insulin resistance in these children should be kept in mind.

10.2.2 Children with cerebral palsy

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

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

10.2.3 Children requiring sedation for paediatric auditory electrophysiology

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

10.2.4 Children with trisomy 21

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

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

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

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

10.2.5 Paediatric sedation in the SARS-CoV-2 era

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10.3 Recovery

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

10.4 Discharge

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

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

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

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

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

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

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

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

10.5 Follow up or patient satisfaction

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

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

11. Drugs used in procedural sedation and analgesia

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

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

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

Inhalation sedation with N_2O in oxygen is a longstanding and safe method to gain a child's cooperation and trust, especially in the dentist's office.

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

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

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

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

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

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

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

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