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

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

2. Definitions

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

2.1 The continuum of procedural sedation and analgesia

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

Table I: The sedation continuum

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

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

2.2 Sedation endpoints

The American Society of Anesthesiologists (ASA) defines the following levels of sedation (Table I):[5]

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

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

2.2.1 Minimal sedation/anxiolysis

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

2.2.2 Moderate sedation/analgesia

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

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

2.2.3 Deep sedation/analgesia

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

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

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

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

2.2.4 General anaesthesia

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

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

The following statement by the ASA must be taken into consideration with every sedation procedure:[5]

"Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia ('Conscious Sedation') should be able to rescue patients who enter a state of Deep Sedation/Analgesia, whilst those administering Deep Sedation/Analgesia should be able to rescue patients who enter a state of General Anesthesia. Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified

practitioner corrects adverse physiological consequences of the deeper-than-intended level of sedation (i.e. hypoventilation, hypoxia and hypotension), and returns the patient to the originally intended level of sedation."

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

2.3 Non-dissociative sedation

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

2.4 Dissociative sedation

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

2.5 Sedation techniques

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

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

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

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

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

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

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

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

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

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

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

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

2.5.1 Basic or standard sedation

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

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

- inhalation of nitrous oxide (N_2O) in oxygen, where the concentration of N_2O must not exceed 50% in oxygen, or
- titrated intravenous doses of midazolam to a maximum dose of 0.1 mg/kg.

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

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

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

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

2.5.2 Advanced sedation

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

- any **combination** of drugs, administered by any route,
- any sedation administered by the intravenous route (e.g. propofol, etomidate, dexmedetomidine – with the exception of titrated doses of midazolam to a maximum of 0.1 mg/kg),
- any inhalational sedation (e.g. sevoflurane), with the exception of N_2O used as the sole agent in a concentration not exceeding 50% in oxygen, or
- any infusion techniques (i.e. target-controlled infusions [TCIs]).

Advanced sedation techniques:

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

2.6 Failed sedation

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

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

2.7 Prolonged sedation

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

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

3. Environment and clinical setting

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

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