1. Introduction

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

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

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

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

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

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

1.1 Evidence

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

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

1.2 Objectives of procedural sedation and analgesia

The following are the objectives of PSA:

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

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

1.3 Indications for sedation

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

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

1.4 Risks to patient safety

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

contributing to sedation-related adverse events, and sedation training is supported by all international sedation guidelines.[1]

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

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

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

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

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

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

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

Adverse events may occur because of the following reasons:

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

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

Complications or adverse events can occur:

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

1.5 Clinical governance

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

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

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

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

The following is also recommended:

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

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

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

2. Definitions

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