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, is a popular addition to modern medical care.

These guidelines are compiled to ensure safe Procedural Sedation Analgesia (PSA) for adult patients. They are intended for use by all medical practitioners and their teams, who participate in sedation for diagnostic and therapeutic procedures, either painful or non-painful. They apply to PSA before, during and after the procedure. The objective is to develop the guidance provided by the South African Society of Anaesthesiologists (SASA) published in 2015. They are not intended to substitute supervised clinical training, nor are they intended 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. hospitals, freestanding clinics, physician, dental, and other surgeries.

The guidelines are not applicable to:

- Patients requiring intensive care sedation.
- The prescription of sedation and analgesia for palliative care.
- Sedation and analgesia for use in the home setting.
- Premedication for patients undergoing general anaesthesia.
- Night sedation.
- Analgesia during labour and delivery.
- Postoperative analgesia.

1.1 Evidence

The guidelines are based on existing consensus statements, expert opinion, professional regulations and peer-reviewed published research studies and reports.

1.2 Objectives of procedural sedation and analgesia (PSA)

The objectives of procedural sedation and analgesia are to:

- Respect the rights of the patient at all times.
- Reduce the patient's fear, anxiety and distress.
- Minimise physical discomfort and pain.
- Minimise psychological trauma.
- Pose minimal threat to the patient's safety.
- Allow the procedure to be completed safely, reliably and effectively.

- Maintain consciousness and patient cooperation.
- Maintain control of physiological parameters.
- Maintain a patent airway.
- Return the patient to a state in which safe discharge is possible.

Good sedation practice requires the use of pharmacological and non-pharmacological methods to manage pain and anxiety. Most procedures require the use of local, regional, or systemic analgesia. However, pharmacological methods alone do not negate the need for good communication skills and a sympathetic attitude. Patient reassurance at all times is crucial for a successful sedation technique.

1.3 Indications for sedation

PSA is standard practice in most countries, to facilitate the performance of various diagnostic and therapeutic procedures. Procedures that do not require neuromuscular blockade and where pain can be controlled either locally or systemically, without compromising patient safety, are suitable for a PSA technique. PSA is currently used by 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 sedation practitioner, and is determined by:

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

1.4 Risks to patient safety

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 sedation practitioner must undergo theoretical training, as well as supervised clinical training. Regular update of knowledge is essential.

Although the procedure itself usually poses little risk to the patient, the addition of sedation, administering sedatives/analgesics/dissociative agents, may add to the risk. The use of combination therapy may further increase the risk of adverse events. Respiratory depression is the most significant adverse event following administration of sedatives/analgesics, therefore the maintenance and protection of the airway is a crucial part of safe sedation practice. During sedation the patient is taken from maintaining his/her own airway to depending on the sedation practitioner to preserve the airway. A focused airway examination is therefore mandatory.

Various research and clinical studies have been done to clear 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 according to clinical importance:

- Lesser adverse events, i.e. a short period of oxygen desaturation.
- Standard or moderate adverse events, i.e. oxygen saturation lowest 75% or lasting longer than 60 seconds.
- Critical adverse events, i.e. death, permanent neurological injury, admission to hospital, CPR and tracheal intubation. These should be reported immediately to sedation care systems or professional societies and 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:

- Sedation practitioner not trained or inexperienced.
- Inappropriate patient selection, inadequate preoperative assessment and poor preparation.
- Procedure not suitable for sedation.
- The effects of sedatives/analgesics/dissociative drugs (especially if used in combination).
- Timing of administration of drugs.
- Inadequate knowledge of the pharmacokinetics and pharmacodynamics of drugs.
- Unanticipated pharmacogenetic response to drugs.
- Inadequate monitoring of the patient.
- The inability of the sedation practitioner to manage complications.
- The inability of the sedation practitioner to rescue a patient from an unexpectedly or undesirably deeper than intended level of sedation.
- Premature discharge of patients who have not met the discharge criteria after sedation.

Complications/adverse events can occur:

- Before sedation.
- During sedation, i.e. drug interactions, oxygen desaturation, itching, allergic reactions, obstruction of the airway, injuries.
- After sedation, i.e. delayed recovery, 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 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.

The sedation practitioner should have a framework of accountability that will include clinical accountability for processes such as evaluation of expertise, a clinical appraisal and implementation of SASA guidance on procedural sedation and analgesia.

The sedation practitioner must have a standard plan in operation for each sedation technique for which they deliver a service. This should include details of assessment protocols, structure of 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 whole sedation team.

All practitioners involved in sedation practice must 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. Sedation practitioners do not often report adverse events. It is recommended that adverse events be reported to societies involved in sedation practice.

It is recommended that:

- All facilities undergo regular inspections to comply with quality assurance policies and procedures.
- Sedation practitioners consider 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. They will receive a certificate of good standing. Documents are available on the SASA website (www.sasaweb.com).
- Records be kept of staff training with regard to sedation for persons involved in administering sedation, as well as evidence of airway certification, i.e. Basic Life Support.
- Evidence be available as to the training of a sedation practitioner, and possession of airway certification, i.e. Advanced Life Support.
- Records be kept of adverse events.
- Future initiatives and developments must involve incorporation of simulation into training, credentialing and maintenance of sedation skills. Simulation offers hands-on experience in management of medical emergencies for sedation practitioners.