Patients residing in rural areas must spend the first 24 hours post-procedure within a reasonable distance of medical assistance, or must guarantee that they have access to a telephone in case of complications.

9. 4 Other

9.4.1 Practice appraisal protocol (Appendix 2)

The aim of the practice appraisal protocol is to ensure that the inspection is done by an appraised sedation practitioner or equivalent appointed body, e.g. COHSASA (Council for Health Service Accreditation of South Africa) and that the inspector is satisfied that the appraised clinic, practice, rooms 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.

9.4.2 Logbook

A logbook should be kept of cases performed under sedation. Adverse incidents and accidents should be documented, as well as the date when, and institution/association where, it was reported.

10. Safe sedation practice

It is beyond the scope of these Guidelines to review any specific sedation techniques in detail. These should be addressed by supervised clinical training. 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 sedation technique for an individual are:

- The risk-to-benefit ratio of the technique.
- The characteristics of the patient (ASA classification and risk assessment profile).
- The nature of the procedure being performed (painless or painful, major or minor).
- The qualifications, skills and experience of the sedation practitioner.
- The operator's understanding of sedation safety issues.
- The environment and clinical setting (premises, drugs and equipment).
- The availability of skilled personnel 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 the operating theatre).
- Contraindications.
- Evidence-based.
- The choice of sedation technique must be appropriate for 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 centered on the following:

- Appropriate patient selection and evaluation, with emphasis on a focused airway examination.
- Only ASA I and II patients qualify for sedation outside the operating theatre.
- Knowledge of the pharmacokinetics and pharmacodynamics of drugs.
- Administration of the minimal dose of drug necessary to make the patient safe and comfortable. This dose must have taken full effect before any additional dose is administered. The use of fixed doses or boluses is not recommended.
- Trained sedation practitioner, support staff, and facilities meeting the requirements for safe practice.
- Sedation practitioners must be able to manage, rescue and recover a patient who enters a deeper than intended level of sedation.

10.2 Pearls and pitfalls of safe sedation practice

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. 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 the following groups:

10.2.1 The elderly patient

- The initial dosage of the drugs should be reduced, and then titrated to effect.
- Since drugs take longer to take effect, they should be given longer in advance and given enough time before an assessment is made.
- Enough time should elapse between follow-up intravenous doses of sedatives/analgesics so that the peak effect of each dose can be evaluated before repeating the drug administration.
- Subsequent incremental doses should be reduced.
- When available, CO_2 monitoring by capnography is recommended.
- Drugs may linger for longer, so elderly patients should be monitored until complete recovery occurs.

10.2.2. The obese patient

- IV placement may be a challenge.
- NIBP monitoring may be difficult, since the cuff may not fit properly. Cuffs that are too small will overestimate true BP and too large cuffs will underestimate BP.
- Obese patients may suffer from gastro-oesophageal reflux disease and may be at risk of aspiration in spite of a nil per os status.
- Obese patients tend to have a reduced functional residual capacity. The tidal volume in supine position often falls below closing capacity of small airways, leading to atelectasis, increased ventilation/perfusion mismatching and impaired oxygenation. Therefore they have a tendency to desaturate faster than non-obese patients.
- 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.
- An increased risk of deep vein thrombosis and insulin resistance should be kept in mind.

10.2.3 The pregnant patient

The main concerns for the sedation practitioner are:

- The maintenance of foetal oxygenation.

  This is achieved through adequate maternal oxygenation and uterine perfusion. Sedatives and other drugs used during sedation may negatively affect maternal oxygen saturation, maternal cardiac output and uterine blood flow. Hypoxia and hypotension should be prevented at all costs. The possibility of aortocaval compression in the supine position should be kept in mind.
- Prevention of preterm labour.

Even though preterm labour may not be caused by the sedation process or the procedure itself, it remains a troublesome concern. The best strategy is to consult and involve the obstetrician well in advance of the procedure.

- Teratogenicity.

  Since the chances for teratogenicity during sedation are probably minimal to non-existent, pregnant patients can be reassured in this respect.

- Gastro-oesophageal sphincter tone are usually reduced and pregnant women often describe reflux symptoms. Depending on the type and duration of the procedure, general anaesthesia with airway protection should be considered.

10.3 Recovery

The patient must be allowed to recover from PSA in an appropriate and suitably equipped recovery room, with a healthcare professional trained in basic life support, monitoring him or her. 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.

11. Drugs used in procedural sedation and analgesia

There is no 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.

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 used for PSA can act in synergism when used in combination and it is suggested that the doses be reduced accordingly, and titrated in divided doses to effect. The sum of the incremental doses must not exceed the recommended maximum dose.

Where drug doses are not given in a weight-related dose (i.e. mg/kg), it must be assumed that it is the dose for a "standard" patient weighing 70 kg.

This guidance aims to promote good clinical practice through recommendations for the provision of sedation that is both safe and effective. It is not a recipe book for sedation techniques, nor how to do it. The guidance cannot replace training in specific sedation techniques that must include supervised clinical training.

This guidance is applicable to all patients receiving sedation to facilitate procedures, whether it is delivered in a surgery, in a community service clinic facility or in a hospital setting.