Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in adults: 2010

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Foreword

This is the fourth edition of the sedation guidelines of the South African Society of Anaesthesiologists (SASA).

The guidelines have undergone additional revisions since the publication of the third edition earlier this year. The document is specifically targeted at adult sedation. These guidelines must be seen as a work in progress, and the guidelines committee of SASA would appreciate input from colleagues from all sectors of medical practice. Please address your contributions and opinions to the SASA councillor responsible for practice guidelines, by e-mail to: sasa@uiplay.com. A formal review of these guidelines is due in 2015, and will take place at the discretion of SASA.

Acknowledgements

A SASA councillor, Dr Jenna Piercy from the University of Cape Town, was appointed to write these guidelines. She sought the help of Professor James Roelofse from the University of the Western Cape, who has extensive experience in the practice of sedation. After thorough research, and within a period of 18 months, they co-authored this state-of-the art document. SASA commends and thanks them for a superb, world-class document, which will no doubt serve to protect our patients. In addition, we trust that these guidelines will guide and educate both anaesthetic and non-anaesthetic colleagues.

Pieter Bettings
SASA President 2010

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Available online at: www.sajaa.co.za

Enquiries: editor@sajaa.co.za or sasa@uiplay.co.za or SASA, PO Box 1105, Cramerview, 2060, Gauteng, South Africa.

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Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in adults: 2010

All health care professionals participating in the assessment, administration, monitoring and recovery of patients requiring sedation are accountable for safe practice. *The patient is entitled to the same standard of care, whether the procedure is undertaken in a physician's office, a remote facility, or in an operating theatre.*

1. Introduction

These guidelines are for use by all medical practitioners and their teams, in order to provide safe sedation, analgesia and anxiolysis for adult patients. The objective is to develop the guidance provided by the South African Society of Anaesthesiologists (SASA) published in 2002. These guidelines are scheduled for review and modification in 2015, this process taking place at the discretion of SASA.

The guidelines are applicable to adult patients undergoing painful or non-painful diagnostic or therapeutic procedures, and are not applicable to:

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

1.1 Evidence

These guidelines are based on existing consensus statements, expert opinion, professional regulations, and published reports.

1.2 Objectives of procedural sedation and analgesia

The objectives of procedural sedation and analgesia (PSA) are to:

- 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 accomplished safely, reliably and effectively.
- Respect the rights of the patient at all times.
- 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. The provision of safe and effective PSA requires the regulation and education of sedation practitioners and teams, as well as patients.

1.3 Indications for sedation

Procedures that do not require neuromuscular blockade or unconsciousness are suitable for a PSA technique. PSA is standard practice in most countries, to facilitate the performance of various diagnostic and therapeutic procedures. PSA is currently being used in cardiology, dentistry, gastroenterology, radiology, dermatology, plastic surgery, and in the emergency medicine environment.

1.4 Risks to patient safety

Most procedures pose little risk to the patient. However, the administration of sedatives/analgesics may add to the risk. Adverse events during PSA most commonly occur due to drug-induced depression of respiratory function. Adverse events are more prevalent if a combination of drugs is used. Complications can be minimised by the training of practitioners in airway management. The maintenance and protection of the airway is a crucial part of safe sedation practice.

Adverse events and complications are more likely in non-hospital-based settings that do not meet the minimum requirements for safe sedation practice. Attention to environmental factors is essential for the safe practice of procedural sedation and is a basic requirement for ensuring a satisfactory outcome. Regular audits of the procedures, as well as all critical adverse events, should be performed, at least annually.

Adverse events may arise because of:

- Inadequate patient selection and poor preparation.
- The effects of sedatives/analgesics (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 sedationist to manage complications.
- The inability of the sedationist to rescue a patient from an unexpectedly or undesirably deep plane of sedation.
- Premature discharge of patients.

1.5 Clinical governance

Sedation practitioners should seek to regularly audit

their practice. There should be protocols available for the management of adverse events and complications. There should also be in-house training for the whole sedation team.

All practitioners involved in sedation practice should keep a logbook of cases performed.

It is recommended that all facilities undergo regular inspections to comply with quality assurance policies and procedures

2. Definitions

The definition of PSA encompasses a continuum of altered state of consciousness, varying from minimal sedation/ anxiolysis to deep sedation, as outlined below (Table I).

2.1 Sedation end points

2.1.1 Minimal sedation/anxiolysis

Minimal sedation/anxiolysis is a drug-induced state during which the patient responds normally to verbal commands. Cognitive function may be impaired, but ventilatory and cardiovascular functions are unaffected. Clinical monitoring alone may suffice in minimal sedation.

2.1.2 Moderate sedation/analgesia

Moderate sedation/analgesia was previously termed "conscious sedation". This is a drug-induced depression of consciousness during which the patient responds purposefully to verbal commands, either alone or accompanied by light, tactile stimulation. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

2.1.3 Deep sedation/analgesia

Deep sedation/analgesia 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. The ability to maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

In South Africa, deep sedation is considered part of the spectrum of general anaesthesia and should only be performed by doctors trained in the field of anaesthesia, in accordance with the *Guidelines for Practice* issued by SASA.

2.1.4 General anaesthesia

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 because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Table I: The continuum of sedation and sedation end points

	Minimal sedation/ anxiolysis	Moderate sedation/ analgesia *"conscious sedation"*	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

2.2 Continuum of PSA

PSA encompasses a continuum of altered state of consciousness ranging from anxiolysis (or minimal sedation) to deep sedation. If the patient fails to respond to verbal commands and/or light touch, the standard of care must be identical to that for general anaesthesia. Guidance on the care of the anaesthetised patient is provided in the publication *Guidelines for Practice* issued by SASA, and is not addressed in this document.

The response of individual patients to the administration of sedative-hypnotics is difficult to predict. The types of drugs used, the dosages administered, the additive effects of concomitant drugs and the patient's pharmacogenetic profile will all influence the depth of sedation. An unexpected progression of the depth of sedation must be anticipated, and practitioners must be able to rescue patients who enter a deeper level of sedation than intended.

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, loss of protective reflexes and general anaesthesia. With the use of non-dissociative drugs, the key to minimising adverse events/ complications is the careful titration of drugs to the desired effect.

2.4 Dissociative sedation

Dissociative sedation, produced with ketamine, 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 used for PSA, it does not

operate on the sedation continuum and should not lead to loss of consciousness.

2.5 Sedation techniques

2.5.1 Simple/basic sedation

Simple/basic sedation is induced by a single agent and not a combination of agents, for example:

- Oral, transmucosal or rectal drugs, e.g. benzodiazepines; or
- Inhalation of nitrous oxide (N_2O) in oxygen, where the concentration of N_2O must not exceed 50% in oxygen; or
- Titrated doses of intravenous midazolam, **to a maximum dose of 0.1 mg/kg**.

If the above drugs are used in combination, simple/basic sedation ceases, and the sedation technique is classified as "advanced sedation". When a simple sedation technique is insufficient, the depth of sedation **MUST NOT** be advanced, unless the patient is fasted and a dedicated sedationist is employed.

Simple sedation techniques include the use of concomitant simple analgesics.

2.5.2 Advanced sedation

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

- Any **combination** of drugs, administered by any route; or
- Any sedation administered by the intravenous route, e.g. propofol (with the exception of titrated doses of midazolam); or
- Any inhalational sedation (with the exception of N_2O used as the sole agent in a concentration of less than 50% in oxygen); or
- Infusion techniques, e.g. target controlled infusions (TCI).

2.6 Failed sedation

Failed sedation is defined as the failure to achieve a desired level of sedation, such that the procedure has to be abandoned, or the need arises to convert to general anaesthesia. Possible reasons for failed sedation include patient factors, drug factors, or procedure-related and operator factors. A previous episode of failed sedation may necessitate the provision of general anaesthesia for future procedures.

If PSA fails in the primary care setting or outside the operating room, there should be no intention to proceed to either deeper sedation or general anaesthesia. The procedure should be abandoned.

3. Preparation for sedation

3.1 Patient selection

Patients should be assessed in accordance with the American Society of Anesthesiologists (ASA) Physical Status Classification System (Table II). Only patients in ASA class I and II should be considered for sedation outside the operating room. Patients in ASA class III, IV or V require higher levels of monitoring and care. In these patients, procedures should only be undertaken by a sedationist who is trained in anaesthesia, in a fully equipped operating theatre, with a full range of emergency drugs and resuscitation equipment available.

Paediatric patients: See the SASA guidelines for sedation in paediatric patients.

Elderly patients: The elderly are more sensitive to the effects of sedatives and hypnotics, and the following precautions should be taken:

- The initial dosage of the drugs should be reduced, and then titrated to effect.
- A drug should be given a longer time to exert its effects before these are assessed.

Table II: ASA Physical Status Classification System

Class I	A normally healthy patient
Class II	A patient with mild systemic disease and no functional incapacity
Class III	A patient with severe systemic disease that limits activity, but is not incapacitating
Class IV	A patient with severe systemic disease that is a constant threat to life
Class V	A moribund patient not expected to survive 24 hours with or without an operation
"E"	An emergency procedure is denoted by the letter E following the class number

3.2 Informed consent

Written and verbal informed consent must be obtained and documented prior to the administration of sedative drugs. Informed consent must never be obtained after administration of sedative drugs. The nature of the procedure to be performed may not be changed after the patient has been administered a sedative drug.

Informed consent should include an explanation of the procedure, the proposed sedation technique and an explanation of the risks and benefits of appropriate alternatives. Patients must be informed of the possibility that the sedation may fail and that the procedure may have to be abandoned or performed under general anaesthesia at a later date. Consent must be obtained for both the procedure and the sedation (see Appendix 1).

The patient must be given the opportunity to ask questions.

3.3 Environment and clinical setting

Sedation should only be performed in an environment where the facilities, personnel, equipment and drugs required to manage emergencies are immediately available.

3.3.1 Facilities and equipment

If the procedure is to be performed outside the operating room, the minimal necessary facilities, equipment and drugs must include those detailed in Appendix 2.

3.3.2 Personnel

The sedation team must include a sedation practitioner, an operator, a trained person to monitor the patient, recovery personnel and support staff. Under specific circumstances, one person (the operator-sedationist) may perform the role of both operator and sedationist. These roles are further defined in Section 7.

Sedation practitioners and operators must only undertake procedures and interventions for which they have been specifically trained and for which they have proven competent. Personnel must have adequate, current experience in their roles, and must be involved in continuing professional development and education in order to maintain their skills. Sedation practitioners must be able to apply advanced life support techniques and manage, rescue and recover a patient who unexpectedly enters a deeper level of sedation than intended.

Sedation practitioners should have a good understanding of the pharmacokinetics and pharmacodynamics of the agents that they administer, including the pharmacology of the appropriate antagonists.

Sedation practitioners should be able to recognise and manage complications associated with the drugs in use.

Sedation practitioners should regularly audit their practice.

Sedation practitioners and all ancillary personnel must undergo periodic review of emergency resuscitation procedures and protocols. Documented in-house training should be implemented in all facilities involved in PSA.

4. Patient assessment

Patient preparation centres on giving information to the patient, and getting information from the patient. It is essential to evaluate the fitness of every patient for sedation outside the operating room. This evaluation entails:

- A recent **medical history** questionnaire (see Appendix 3). A detailed **sedation history** is vital, as previous failed attempts at sedation may indicate the need for general anaesthesia for future procedures. Special attention must also be paid to the **drug history** of the patient:
  - Psychotropic drugs (e.g. sedatives, anxiolytics, antidepressants and drugs used in the treatment of mania) may cause adverse drug reactions, particularly when used in combination with local anaesthetic agents during sedation.
  - Chronic medications (e.g. antihypertensive drugs) must be taken as usual on the day of sedation.
- A targeted **medical examination** must be performed, and special attention must be paid to the cardiovascular and respiratory systems. No patient should be considered for sedation without a thorough airway assessment.
- Written and oral **informed consent** must be obtained prior to the procedure. (See Section 3.2 and Appendix 1.)
- **Venous access** must be secured prior to sedation if the administration of intravenous sedatives is planned, and must remain in situ until the patient has fully recovered from the effects of the sedation.
- A **signalling system for pain or discomfort** should be established prior to the initiation of sedation.

5. Guidelines for fasting

If simple sedation techniques (see Section 2.5.1) are planned, fasting is recommended, but not mandatory.

If advanced techniques (including dissociative and non-dissociative techniques) or deep sedation are planned, standard anaesthetic fasting guidelines should be applied:

- Clear fluids: two hours.
- Solid food: six hours.

A “clear fluid” is defined as fluid which is non-particulate, and through which newsprint is visible.

If simple sedation techniques fail in a non-fasted patient, the procedure must be abandoned. In an emergency situation, a general anaesthetic with a rapid sequence induction may be considered.

6. Standards of monitoring

All members of the clinical team must be capable of monitoring the condition of the patient.

Prior to the commencement of sedation, baseline vital signs must be recorded. Clinical signs must be monitored at all times during the procedure and recovery period, until discharge from the facility. It is recommended that observations be recorded on a sedation monitoring chart (see Appendix 4). The sedation practitioner, or personnel designated to monitor the patient, must be in attendance at the patient’s side at all times, and must be able to recognise, and rescue the patient from, any complications.

Basic clinical monitoring must be provided during all levels of sedation and during the recovery period, and must include the documentation of:

- Level of consciousness (see Appendix 5).
- Breathing, ventilation and airway patency.
- Heart rate and rhythm.
- Oxygenation and colour.
- Pain.
- Anxiety levels.

Operator-dependent factors (e.g. airway manipulation, dose of administered local anaesthetic) and environmental factors (e.g. room temperature) must also be monitored.

6.1 Monitoring for minimal sedation/anxiolysis

The patient has intact cardiovascular and respiratory function, and protective reflexes. Although no further special care is needed, basic clinical monitoring is mandatory.

6.2 Monitoring for levels of sedation deeper than minimal sedation/anxiolysis

Advanced monitoring must be provided for all levels of sedation deeper than minimal sedation/anxiolysis. Basic clinical monitoring must be continued during the procedure and recovery period, until discharge from the facility. Monitoring should be commenced prior to the administration of sedation. Trained personnel, equipment for monitoring, and resuscitation drugs and equipment must be available throughout this period.

In accordance with international guidelines for levels of sedation deeper than minimal sedation/anxiolysis, the minimum mandatory monitoring equipment must include:

- A blood pressure monitor; **and**
- A pulse oximeter.

Capnography is the gold standard for the monitoring of ventilation. It is a more sensitive monitor for adequacy of ventilation than pulse oximetry. Capnography is not mandatory, but is advisable in the obese patient and in patients with respiratory problems. Capnography techniques using nasal cannulae and sidestream analysis are well tolerated by patients undergoing PSA.

With the use of multidrug techniques of sedation, it is advisable to use an electrocardiogram (ECG). Any patient with underlying cardiovascular disease should be monitored with an ECG.

7. Personnel

The level of care is determined predominantly by the degree of preservation of the protective airway reflexes and the risk of respiratory depression. At least two appropriately trained members of the sedation team should attend each patient.

7.1 Sedation practitioner (sedationist)

The **sedation practitioner (sedationist)** administers the sedative and analgesic drugs, and monitors the clinical effects of these drugs.

The sedation practitioner may either be:

- A dedicated sedationist, responsible only for the sedation and monitoring of the patient; or
- An operator-sedationist, responsible for both the administration of sedation and performance of the procedure.

7.2 Operator-sedationist

The **operator-sedationist** is responsible for both the administration of sedation and performance of the procedure.

The operator-sedationist may undertake the dual role of sedationist and operator **only if** simple sedation techniques are employed and the level of sedation does not progress beyond minimal sedation/anxiolysis. Furthermore, an operator-sedationist **must** be assisted by a second, appropriately trained person. This person must be present throughout the procedure and must be capable of monitoring the clinical condition of the patient and assisting the operator-sedationist in the event of a complication. This second person may have received only in-house training, provided that this training is fully documented.

An operator-sedationist must only use simple sedation techniques and must not administer combinations of drugs. A dedicated sedationist is required whenever advanced sedation is performed.

If the patient unintentionally enters a level of sedation deeper than minimal sedation/anxiolysis, monitoring of the patient **must be** performed by a second, medically trained person **(the observer)**.

7.3 Observer

An **observer** is required for monitoring the patient if the depth of sedation exceeds minimal sedation/anxiolysis at the hands of an operator-sedationist. The observer should have at least the equivalent of nursing training, and must be proficient at maintaining airway patency and the monitoring of vital signs. Such a person must be able to assist with ventilation if necessary.

All of the following roles must be filled by the attending personnel:

- Preprocedural screening, including patient evaluation, providing pre- and postsedation instructions and obtaining written informed consent (see Appendices 1, 6 and 7).
- Completing the preprocedural checklist (see Section 8.2 and Appendix 6).
- Prescribing and administering sedation.
- Patient monitoring (and rescue, where necessary).
- Performing the procedure.
- Recovery and discharge after the procedure (see Appendix 8).

7.4 Personnel requirements for each sedation endpoint

7.4.1 Qualifications and training requirements

Relevant qualifications and ongoing training remain the foundation of safe sedation practice. It is recommended that the persons administering sedation should:

- Have a primary, registered medical qualification.
- Have recognised knowledge and skills in the field of PSA. Formal teaching, simulation training, supervised cases and protocols can help to provide this.
- Have completed training in basic and advanced sedation techniques.
- Comply with SASA recommendations for safe sedation practice.
- Possess evidence of regularly updated qualifications in Basic Life Support (BLS) and Advanced Cardiac Life Support (ACLS).
- Possess evidence of continued professional development (CPD) in PSA.

7.4.2 Minimal sedation/anxiolysis

At this level of sedation, the sedation practitioner may also act in the role of the operator. However, in accordance with international guidelines, there must be a second person, separate from the operator, who is responsible for monitoring the patient.

7.4.3 Moderate sedation/analgesia

The patient's protective reflexes are maintained and the patient is able to respond appropriately. For this level of sedation, the following personnel are required:

- A **medical practitioner** who must:
  - Be trained in the presedation assessment of the patient and, specifically, in airway assessment.
  - Be trained in resuscitation, and must be experienced in advanced life support.
  - Understand the pharmacokinetics and pharmacodynamics of the administered drugs, including antagonists.
  - Be trained and experienced in the use of the drugs for moderate sedation and analgesia techniques.

At this level of sedation, the sedation practitioner may also act in the role of the operator. However, in accordance with international guidelines, there must be a second person, separate from the operator, who is responsible for monitoring the patient.

- A trained and dedicated **observer**, experienced in airway management and monitoring, is required to ensure that:
  - The patient remains conscious.
  - Respiratory function is adequate.
  - Vital signs are within normal limits.

The observer must be trained in basic life support.

7.4.4 Deep sedation/analgesia

Deep sedation/analgesia is part of the spectrum of general anaesthesia, and the standard of care must be identical to that for general anaesthesia.

7.4.5 General anaesthesia

Guidance is provided in the SASA publication *Guidelines for Practice*.

8. Documentation

8.1 Documentation before sedation

This process is aimed at gathering information from the patient, as well as giving information to the patient and his or her carers.

- The informed consent document must show that appropriate consent was obtained from the patient, or a responsible person (parent/guardian), according to local and international requirements (see Appendix 1).
- Information and instructions given to the patient and carer should include the aims, objectives and possible side effects of sedation. All information and instructions should be both verbal and written. The patient must be advised that oral sedatives must not be taken at home before sedation; all sedative drugs are to be administered at the facility for sedation (see Appendix 7).
- A recently completed medical history questionnaire should be evaluated by an appropriately trained sedation practitioner, and must be checked before the initiation of sedation for possible changes in the patient's condition (see Appendix 3).
- The name, address, and a telephone contact number of the carer/parent/guardian must be obtained and recorded.

8.2 Documentation immediately before sedation (the preprocedural checklist)

The aim of this document is to provide a final checklist before the start of the procedure or the sedation process. This is of particular importance if the patient was evaluated at an earlier consultation. A checklist is necessary to see if there has been any change in the condition of the patient that may affect the administration of sedation (see Appendix 6).

The sedation practitioner must sign the preprocedural checklist to ensure that the following information has been obtained and documented:

- Details of the patient.
- Details of the procedure (e.g. elective or emergency).
- Completion of the medical history questionnaire, which must be checked by the sedationist. Significant underlying surgical or medical disorders must be excluded, e.g. upper respiratory tract infection, allergies or sleep apnoea.
- Confirmation that the patient is fasted appropriately.
- History of previous sedation, including previous airway problems and contraindications to sedation.
- Physical examination and evaluation of the patient, including a full assessment of the airway.
- Details of chronic medication, including if the patient has taken the medication on the morning of the procedure.
- Details of the prescribed premedication, including details of the prescribing practitioner, the administering practitioner and the time of administration.
- Confirmation that the equipment, monitoring devices and drugs been checked.

8.3 Documentation during sedation

A sedation monitoring flow chart must be completed during the procedure (see Appendix 4). This must include the name, age and weight of the patient, and the route, dose and time of administration of any drugs. Vital signs must be recorded prior to the commencement of PSA (see Section 6). A contemporaneous clinical record should be kept and vital signs monitored and recorded at no greater than 10 minute intervals. In the case of a single operator-sedationist, a record may be regarded as contemporaneous if it is made immediately after the procedure.

8.4 Documentation during recovery

The vital signs must be monitored and recorded at least every 10 minutes until full recovery has occurred. The patient's clinical state must be documented immediately before discharge (see Appendix 8).

8.5 Documentation after discharge

The patient and carer must be supplied with written and verbal information with regard to postdischarge activities (see Section 11 and Appendix 7). This is an extremely important document, as it has medicolegal implications. If the procedure is performed as a day case, the patient must be escorted home by a responsible adult, who should stay with the patient for the rest of the day. Sedation must not be administered if an escort is not available. The patient and escort should be given the telephone number of a medical practitioner, hospital and ambulance service in the event of any procedure- or sedation-related problem.

9. Sedation techniques

Regardless of the technique chosen for the provision of PSA, the necessary components for safe sedation practice must include appropriate training and ongoing education of the PSA team, appropriate patient selection and the provision of a suitable and safe environment.

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 (e.g. ASA classification and risk assessment profile).
- The nature of the procedure being performed (e.g. painless or painful).
- The availability of skilled personnel to monitor and perform the procedure.
- The availability of skilled support staff to assist, should rescue be necessary.
- The environment and clinical setting (e.g. premises, drugs and equipment).
- The qualifications, skills and experience of the sedation practitioner.

9.1 Principles of safe sedation practice

These principles are centred on the following:

- Administration of the **minimal dose** of drug necessary to make the patient safe and comfortable.
- **Titration** of the drugs according to the individual's needs; there is no fixed dose, only a maximum dose.
- Knowledge of the **time of onset** of the drug's action.

Sedation practitioners must be able to manage, rescue and recover a patient who enters a deeper level of sedation than intended.

9.2 Sedation for painless procedures

Non-pharmacological and pharmacological techniques can be utilised. Behavioural management techniques should always be employed.

10. Drugs used in procedural sedation and analgesia

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 are synergistic when used in combination and it is *mandatory* 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*.

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

In general, the drugs selected for PSA should have duration of action in keeping with the duration of the procedure. Sufficient time for peak brain effect (the target site) must be allowed, to prevent overdose of sedatives.

SASA recommends that general anaesthetic induction agents (propofol, ketamine, etomidate) 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 sedation practitioners with anaesthetic experience who are trained in specific sedation techniques. Sedation practitioners using these drugs must have *at least* a qualification in ACLS.

10.1 Sedatives

Sedatives do not usually produce analgesia and should not be used alone for painful procedures. If sedatives are used, analgesics should be administered first to prevent pain, before using sedation. Sedative drugs should never be used to compensate for inadequate analgesia.

Some patients may become disinhibited, restless and uncooperative with the use of sedatives. This scenario is important to recognise, as it may lead to stacking. Stacking occurs when restlessness is interpreted as patient anxiety, resulting in the administration of additional doses of the sedative. This may cause an unanticipated deepening of sedation to an undesirable level.

Caution must be exercised when combining benzodiazepines, or other sedatives, with opioids. The effects of both categories of drugs are potentiated when used in combination, increasing the risk of adverse events and the progression to deeper levels of sedation.

10.1.1 Benzodiazepines

10.1.1.1 Midazolam

Midazolam is a short-acting benzodiazepine with sedative, anxiolytic, amnestic, anticonvulsant and muscle relaxant effects. It has no analgesic effect. Used in the recommended doses (Table III), the administration of midazolam should result in a conscious, compliant patient.

When administered in combination with other depressant drugs (especially opiates, with which it has a synergistic effect), or used on its own in higher than recommended doses, midazolam is likely to result in the loss of upper airway muscle tone. This may lead to obstruction, as well as respiratory depression and, possibly, cardiac depression.

Paradoxical excitement and agitation occur in up to 15% of patients. Giving additional doses may exacerbate the symptoms until unconsciousness and severe respiratory depression are induced. In such cases, an alternative agent should be used to avoid this. Ataxia and diplopia are other possible adverse effects associated with midazolam use.

Intranasal administration can be considered in certain cases (e.g. patients with learning difficulties). Intranasal midazolam causes a burning sensation, which can be reduced by the use of a mucosal atomisation device (MAD), and leaves a bitter aftertaste that may last for several days. Intramuscular administration is painful and not recommended.

The intravenous formulation can be given orally, mixed in a small volume of juice or paracetamol syrup to disguise the bitter taste. Once mixed, the shelf life is less than 24 hours. Tablets can be crushed and mixed in the same way to improve palatability.

Table III: Dosing schedule of midazolam

Route of administration	Dose	Recommended maximum dose	Time to peak effect	Duration of action
Oral	0.25-0.5 mg/kg	7.5 mg	10-30 minutes	60 minutes*
Buccal/ sublingual	0.25-0.3 mg/kg		10-15 minutes	20–60 minutes*
Intravenous	0.05-0.1 mg/kg to a maximum bolus of 2 mg**	3 mg	3-5 minutes	20–60 minutes*
Rectal	0.5-0.75 mg/kg		10-20 minutes	60 minutes*
Intranasal	0.2-0.3 mg/kg		10-15 minutes	20–60 minutes

* Dose-related

**Titrate to effect and repeat dose every 10 minutes until desired level of sedation is achieved, or recommended maximum dose is reached

10.1.1.2 Triazolam

Triazolam is a benzodiazepine which has been widely used for sedation/anxiolysis for intraoral procedures. It is a useful sedative for PSA, as it has no active metabolites and is effective via the sublingual or oral routes (Table IV).

Sublingual triazolam (0.125 mg) achieves clinical effect within 20 minutes.

Table IV: Dosing schedule of triazolam

Route of administration	Dose	Recommended maximum dose	Time to peak effect	Duration of action
Oral/sublingual	0.125–0.5 mg	0.5 mg	90-120 minutes	6 hours

If the patient becomes disinhibited and unmanageable after the administration of benzodiazepines, flumazenil, the specific benzodiazepine antagonist, should be given to reverse the action of the benzodiazepines. Elective or urgent procedures should be abandoned and rescheduled, to be performed under general anaesthesia at a later date. In an emergency situation, immediate conversion to general anaesthesia may be considered, if appropriate.

Flumazenil (Table V) reverses the sedative and respiratory depressant effects of benzodiazepines. It should be readily available whenever benzodiazepines are used. Its duration of action is approximately one hour, and resedation may occur if large doses of benzodiazepines have been administered. In such cases, the patient should be carefully monitored for at least two hours with a view to repeating the flumazenil dose. In an emergency, if intravenous access is not available, the intravenous dose can be given intranasally.

In patients taking benzodiazepines for seizures or behavioural disturbances, administration of flumazenil may precipitate these symptoms.

Table V: Dosing schedule of flumazenil

Dose	Titration interval	Recommended maximum dose	Duration of action
10 µg/kg over 30 seconds*	2 minutes*	1 mg/kg	1 hour

* Repeat dose until desired effect achieved, or recommended maximum dose is reached

It is not appropriate to administer flumazenil with the purpose of expediting the discharge of the patient from the sedation unit. Flumazenil should be reserved for use in inadvertent overdose, unanticipated deepening of sedation, or respiratory compromise. Its use may be considered if severe paradoxical reactions occur with benzodiazepines.

10.1.2 Non-benzodiazepine sedatives

10.1.2.1 α_2-agonists

α_2-agonists (e.g. clonidine, dexmedetomidine) are sedative analgesics with anxiolytic, but not amnestic, effects. Used in recommended doses, they have little to no respiratory depressant effects. Oral agents are particularly useful in combination with simple analgesics for painful procedures.

Clonidine can be administered via multiple routes but, for the purposes of procedural sedation, the oral route is recommended (Table VI).

Table VI: Dosing schedule of clonidine

Dose	Onset of action	Time to peak effect
1–5 µg/kg	20–40 minutes	60 minutes

Dexmedetomidine is a highly selective α_2-agonist (Table VII). It is a sedative, anxiolytic, hypnotic and sympatholytic, with analgesic properties. Dexmedetomidine is frequently referred to as the "ideal sedative", as it does not cause respiratory

depression, patients can be roused easily, and its effects mimic natural sleep more closely than other sedatives. It is administered by continuous intravenous infusion. **In South Africa, dexmedetomidine is only licensed for use in the setting of cardiac intensive care unit (ICU) for 24 hours after cardiac surgery in the intubated and ventilated patient**. In October 2008, the FDA in the USA approved the use of dexmedetomidine in general ICU, as a sedative for fibreoptic intubation, and for use in PSA. Side effects include profound bradycardia, sinus arrest and hypotension, particularly in patients with heart block or a high resting vagal tone. There have been reports of cardiac arrest associated with the use of dexmedetomidine. Dexmedetomidine may also cause a dry mouth and nausea.

Table VII: Dosing schedule of dexmedetomidine

Bolus dose	Maintenance infusion
0.5 µg/kg over 10 minutes	0.6 µg/kg/hour titrated to clinical effect (range = 0.2–1 µg/kg/hour)

10.1.2.2 Butyrophenones

Droperidol, a dopamine receptor antagonist, is a butyrophenone derivative with pharmacological and structural similarities to the neuroleptic haloperidol. Droperidol has sedative effects and is an excellent antiemetic, but it lacks analgesic properties. Side effects include hypotension, dysphoria and extrapyramidal movements. In high doses, droperidol prolongs the QT interval and may cause torsades de pointes and other malignant ventricular arrhythmias.

Droperidol is **not recommended** for use in PSA because of the occurrence of dysphoria, prolonged sedation and the risk of hypotension, particularly when used in combination with other sedatives, or in the elderly. The recommended dose for the prevention and treatment of nausea and vomiting is 10 µg/kg; exceeding this dose prolongs recovery and increases the occurrence of side effects.

10.2 Anaesthetic induction agents

10.2.1 Propofol

Propofol is a short-acting, intravenously administered sedative and hypnotic that can be used in small boluses titrated to effect, or as a continuous infusion (Table VIII and IX). TCI pumps are now available, allowing continuous, titrated administration.

Propofol is a very effective hypnotic and amnestic. However, it has a narrow safety margin, with deep sedation, airway obstruction and apnoea occurring rapidly and sometimes unpredictably.

Propofol should only be administered by an experienced sedationist, skilled in airway management. It must not be used if the operator is also acting as the sedationist.

Propofol causes pain on injection in up to 90% of cases. The combination with lignocaine (0.1 ml of 2% lignocaine per 1 ml of propofol) or tramadol (20 mg) may reduce this.

Prolonged infusions of propofol have been associated with propofol infusion syndrome (PRIS) and the development of fatal metabolic acidosis. The risk can be minimised by limiting propofol infusions to 80 µg/kg/minute (or 5 mg/kg/hour).

Propofol has no analgesic properties, and should be administered with an appropriate analgesic agent if a painful procedure is planned.

For initation of PSA, an infusion or slow bolus injection of propofol may be used. A rapid bolus injection can result in undesirable cardiorespiratory depression, including hypotension, airway obstruction, apnoea and desaturation. For maintenance of PSA, a variable rate infusion method is preferred to an intermittent bolus method.

Table VIII: Dosing schedule for bolus doses of propofol

Dose	Titration interval	Onset of action	Repeat dose	Duration of action
Bolus 0.5 mg/kg over 3-5 minutes*	1 minute	45–90 seconds	0.5 mg/kg	5-8 minutes

* In elderly or debilitated patients, the dose of propofol should be reduced to approximately 80% of the usual adult dose. This should be administered as a slow bolus over 3-5 minutes.

Table IX: Dosing schedule for infusion of propofol for PSA

Intravenous infusion	Target controlled infusion
2–4 mg/kg/hour titrated to clinical effect	Effect site concentration 1-2 µg/ml
In elderly patients, commence infusion at 1–2 mg/kg/hour	In elderly patients, recommended effect site concentration is 0.6-0.8 µg/ml

10.2.2 Ketamine

Ketamine is a phencyclidine derivative with an antagonistic action at the NMDA-receptor. The majority of pharmaceutical preparations are available as a racemic mixture.

The multiple actions and cardiovascular stability of ketamine make it a very useful agent for painful procedures. It induces a state of cortical dissociation with profound analgesia, sedation and amnesia, and is often referred to as a sedoanalgesic. Ketamine is sometimes associated with non-purposeful movements. This limits its use when total immobility is required (e.g. for CT or MRI scans).

Compared with other anaesthetic agents, there is relative preservation of airway reflexes and tone. However, with increasing doses, airway preservation cannot be guaranteed. Airway observation remains an essential part of monitoring regardless of the dose used. Rapid administration of boluses of ketamine may cause respiratory depression.

Ketamine stimulates the production of saliva and tracheobronchial secretions. Prophylactic coadministration of an antisialogogue (atropine or glycopyrrolate) may be used to diminish this troublesome side effect. However,

the concomitant use of an antisialogogue increases the occurrence of adverse events. With low dose ketamine, the use of an antisialogogue in adult patients is seldom necessary.

Emergence delirium may be associated with the use of ketamine in adults. Midazolam can be coadministered (≤ 0.05 mg/kg) to reduce the incidence of delirium, but will deepen and prolong sedation and increase the probability of apnoea.

The sympathomimetic action of ketamine may result in a tachycardia and hypertension. These side effects are rarely seen with the doses recommended for PSA.

Ketamine should be used with caution in the setting of head or eye injuries, as it may raise intracranial and intraocular pressure, particularly in patients who are hypercarbic. S^+ ketamine (Ketanest®), not yet available in South Africa, is not associated with an increase in intracranial or intraocular pressure. It is reported to be twice as potent as racemic ketamine.

Other reported reactions, such as ataxia, nystagmus, myoclonus, random limb movements and opisthotonus, are rarely clinically important with the doses of ketamine recommended for PSA.

Ketamine can be given via multiple routes (Table X), including intranasally. As is the case with most other drugs, this route is not recommended, as it can be distressing for the patient.

Table X: Dosing schedule of ketamine

Route of administration	Dose	Onset of action	Time to peak effect	Duration of action*
Oral	4–6 mg/kg as single agent, 2 mg/kg if used with other sedatives/ analgesics	> 5 minutes	30 minutes**	4–6 hours
Intravenous	0.5–1 mg/kg***	< 1 minute	3–5 minutes	5-10 minutes
Intramuscular	2–4 mg/kg	2–5 minutes	20 minutes	30 minutes**
Rectal	4–6 mg/kg	> 5 minutes	30 minutes**	30–120 minutes**
Nasal	5 mg/kg	10 minutes	20 minutes	1 hour

* Duration of action is prolonged if ketamine is administered with other sedatives/analgesics

** Dose-related

***Titrate to effect and repeat dose every 10 minutes, until desired level of sedation achieved

10.2.3 Etomidate

Etomidate produces sedation and anxiolysis, and is a useful agent for procedural sedation in patients who may be allergic to propofol (e.g. egg allergy). It has no analgesic properties, therefore the addition of analgesics for painful procedures is mandatory.

The side effects of etomidate include respiratory depression, myoclonus, nausea and vomiting and transient adrenal suppression. These side effects are seldom seen at the doses administered for PSA (Table XI).

Table XI: Dosing schedule of etomidate

Route of administration	Bolus dose	Continuous infusion	Onset of action	Duration of action
Intravenous	0.1 mg/kg titrated to effect, then 0.05 mg/kg every 3-5 minutes as needed	0.2–0.3 mg/ kg/hour	1 minute	10-15 minutes, full recovery within 30 minutes

10.3 Analgesics

10.3.1 Opioids

Opioids are analgesic drugs capable of inducing varying degrees of sedation and respiratory and cardiac depression, particularly when used in combination with other respiratory depressant drugs (e.g. midazolam). Although opioids may have sedative side effects, they **must not** be used to sedate patients for painless procedures.

Opioids potentiate the effects of other sedatives, and they cause dose-related depression of respiration and the central nervous system. When a sedative/opioid combination is used, the drug doses should be reduced and titrated. The sedationist must be trained and competent in the practice of rescue and resuscitation, should the need arise.

When given rapidly, opioids can induce chest wall and glottic rigidity. Opioids slow gastrointestinal motility and can induce nausea and vomiting.

Capnography is recommended when potent opioids are administered, and meticulous monitoring of respiratory and cardiovascular parameters throughout the procedure and recovery period is imperative. Whenever opioids are used for PSA, the specific antagonist naloxone must be immediately available.

10.3.1.1 Fentanyl and alfentanil

Fentanyl and **alfentanil** are potent short-acting opioids (Table XII and XIII). They have significant potential for respiratory and cardiac depression, particularly in combination with other respiratory depressant drugs. Practitioners administering these drugs intravenously should be experienced sedationists with airway management skills.

Fentanyl and alfentanil should not be used as sole analgesic agents, but rather to augment the effects of simple analgesics. When used in combination with other depressant drugs (such as midazolam), doses should be decreased and titrated to effect. Slow titration of small boluses will decrease, but not eliminate, the possibility of adverse events.

In patients at risk of upper airway obstruction, administration of fentanyl or alfentanil may precipitate this event and should be avoided.

Extreme care should be exercised in the postprocedural period, when the stimulus of the procedure has passed but the drug is still active and more likely to cause respiratory depression.

Table XII: Dosing schedule of fentanyl

Route of administration	Dose	Onset of action	Time to peak effect	Maximum dose	Duration of action
Oral/ transmucosal	5-15 µg/kg	15–30 minutes	30–45 minutes		1 hour*
Intravenous	0.25 µg/kg**	1-3 minutes	2–3 minutes	2 µg/kg	30 minutes*

* Dose-related

**Titrate to effect and repeat dose every 5 minutes, until desired level of analgesia is achieved

Alfentanil has a rapid onset and short duration of action, making it useful for short, painful procedures. Sedationists must take cognisance of this short duration of action when the drug is administered prior to the painful stimulus. Alfentanil should be titrated until the desired level of sedation is reached. If the procedure is expected to take longer than 2 minutes, an infusion should be commended. This should be terminated at the conclusion of the procedure. If a continuous infusion is maintained for > 30 minutes, the context-sensitive half-life is longer than that of remifentanil. The monitoring period after the infusion has been discontinued must be lengthened accordingly.

Table XIII: Dosing schedule of alfentanil

Bolus dose	Titration interval	Time to peak effect	Duration of action of bolus	Infusion rates
In divided doses, up to a maximum of 5 µg/kg*	1.5 minutes	90–150 seconds	< 5 minutes	10–12 µg/ kg/hour 0.25-1 µg/ kg/minute

* When administered as a bolus, the drug must be titrated according to effect

Take note that, when administering a bolus dose followed by a continuous infusion to maintain the peak effect site concentration for 10 minutes or longer, alfentanil no longer demonstrates a more rapid recovery than other opiates.

10.3.1.2 Sufentanil

Sufentanil is an extremely potent opioid analgesic (Table XIV). When used in balanced general anaesthesia, it is 5-10 times as potent as fentanyl. There are few reports of its use in PSA in the literature, as it is mainly reserved for use in the ICU setting in intubated and ventilated patients, or in patients undergoing general anaesthesia. Sufentanil is twice as lipophilic as fentanyl and is rapidly absorbed from the nasal mucosa. It is a useful analgesic when administered by this route.

Table XIV: Dosing schedule of sufentanil

Route of administration	Dose	Time to peak effect	Duration of action
Intranasal	1 µg/kg	20 minutes	> 60 minutes
Intravenous bolus	0.02 µg/kg	5.6 minutes	30 minutes
Intravenous infusion	0.2–0.4 µg/kg/ hour	6.5 minutes	240 minutes after a 2 hour infusion

10.3.1.3 Remifentanil

Remifentanil is an extremely potent, ultrashort-acting opiate. It is rapidly metabolised by tissue and red cell esterases. Remifentanil should not be used outside the hospital environment, and must not be administered by any personnel other than anaesthetists or highly trained sedationists. For PSA, a bolus dose must not be given and the dose, administered by continuous infusion, must not exceed 0.05 µg/kg/minute.

Naloxone is a specific opioid antagonist (Table XV). It will reverse the respiratory depressant effects and analgesic effects of opioids, and should be readily available whenever opioids are administered. Naloxone should only be used for severe respiratory depression or respiratory arrest, as reversal of analgesia may cause a profound sympathetic response. Since its duration of action is short, respiratory depression may recur, requiring additional doses. For this reason, monitoring should continue for at least two hours after the administration of naloxone. Once there has been a good clinical response to an intravenous dose of naloxone, additional administration of the total effective dose may be given as an intramuscular injection, thereby providing a depot of the drug and minimising the risk of a recurrence of respiratory depression. If intravenous access is not available, the initial doses may be given intramuscularly in an emergency.

Table XV: Dosing schedule of naloxone

NB These are the recommended doses for use in postoperative opioid respiratory depression, not the doses recommended for the treatment of opioid overdose.

Route of administration	Dose	Titration interval*	Maximum dose**	Duration of action
Intravenous	0.08-0.2 mg	2 minutes	10 mg	45 minutes

* Repeat dose until desired effect achieved or maximum dose reached.

**Postoperative respiratory depression should be reversed after administration of doses far lower than the maximum permissible dose.

If postoperative respiratory depression fails to respond to a dose of 0.4 mg, an alternative diagnosis should be sought.

10.3.2 Tramadol

Tramadol is an atypical opioid (Table XVI). It is an agonist at the µ-opioid receptor, but also inhibits reuptake of noradrenaline and serotonin. Its use with serotonergic agents (pethidine, fluoxetine, sertraline, clomipramine) is contraindicated, as such combinations may precipitate serotonin syndrome. Tramadol should not be administered with monoamine oxidase inhibitors, as this may result in potentiation of serotonergic and noradrenergic effects. Tramadol should not be administered with other µ-opioid receptor agonists, as their combined effects may antagonise each other.

Table XVI: Dosing schedule of tramadol

Route of administration	Dose	Maximum dose	Time to peak effect
Oral	50 mg	400 mg/day	40 minutes
Intravenous	1 mg/kg over 5 minutes	400 mg/day	20 minutes, with duration of action up to 9 hours

Tramadol can be used in combination with propofol for PSA for painful procedures, as it rarely causes respiratory depression.

10.3.3 Nitrous oxide

N_2O is an anaesthetic agent with analgesic properties. It is available in pure form or as Entonox®, premixed in a 1:1 (50% of each) ratio with oxygen.

In patients who can hold a mask, N_2O is an agent with a rapid onset and offset of action, and an excellent safety profile. The recommended dose is 50% (Table XVII) and, in most cases, it will need to be supplemented with, for example, local anaesthesia. If other sedatives are administered, respiratory depression must be anticipated.

Although N_2O is emetogenic, no clinically apparent cases of aspiration have been reported.

N_2O is only recommended in ASA I and II patients. In those with myocardial disease, it may cause myocardial depression and, in patients with respiratory disease, it may alter the response to hypoxia.

N_2O diffuses into air-filled cavities and should not be used in patients with chest injuries where pneumothorax is possible, in head injuries where pneumocranium is possible, or in those in whom bowel obstruction is suspected.

N_2O is best administered via a demand valve system connected to a cylinder of Entonox®. The sensitive demand valve is activated by inspiration, the rate of delivery of gas being determined by the strength of inspiration.

Scavenging should be available for such cases, and gas analysis of the circuit gas should be employed. If concentrations above 50% have been used, supplemental oxygen should be continued for several minutes after N_2O is discontinued, to counter the possibility of diffusion hypoxia.

Table XVII: Dosing schedule of nitrous oxide

Dose	Onset of action	Time to peak effect
50 % in oxygen	30–60 seconds	3–120 minutes

10.3.4 Local anaesthesia

Local anaesthetics should be considered wherever possible, bearing in mind that additional sedation or anxiolysis might be necessary. They can be used topically, for infiltration, or for local or regional nerve blocks.

EMLA® (Eutectic Mixture of Local Anaesthetics) is available as a cream or a patch. It requires an hour for full effect and can be used on intact or broken skin. EMLA® has a depth of penetration of 3-12 mm.

Alternatively, warming and alkalinising the local anaesthetic solution can reduce the sting on infiltration.

Local anaesthetics are cardiac depressants. Toxicity may occur if used in amounts exceeding the recommended dose.

10.3.5 Simple analgesics

Simple analgesics are analgesics that, in the recommended doses, do not cause sedation.

Paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs) are extremely useful, but the time to onset of action must be taken into consideration before a procedure is performed (Table XVIII).

Table XVIII: Dosing schedule of simple analgesics

Drug	Route of administration	Dose	Time to peak effect
Paracetamol	Oral	15–20 mg/kg	15–120 minutes
	Rectal	40 mg/kg	60–240 minutes
	Intravenous	15–20 mg/kg	30 minutes
Ibuprofen	Oral	7–10 mg/kg (400-800 mg every 4 hours)	120–240 minutes
Diclofenac	Oral	1–1.5 mg/kg	30–120 minutes
Ketorolac	Intravenous	0.5 mg/kg (10 mg every 8 hours)	60-120 minutes
	Intranasal	0.5 mg/kg (10 mg every 8 hours)	
Parecoxib	Intravenous	40 mg	Effective within 20 minutes,duration up to 9 hours

10.4 Novel therapies

"Ketofol" is a combination of ketamine and propofol and is fast gaining popularity in the field of PSA. There is synergism between propofol and ketamine, and combination therapy allows the use of lower doses of both drugs, thereby minimising side effects.

Ketofol can be prepared in a 1:1 ratio, consisting of 10 mg/ml ketamine and 10 mg/ml propofol in the same syringe. This equates to 5 mg/ml of ketamine and 5 mg/ml of propofol. A 70 kg patient can be given a bolus of 3 ml over 1-2 minutes. This should provide analgesia and sedation for 10-15 minutes.

Melatonin is a neurohormone produced by the pineal gland. It is synthesised from tryptophan via 5-hydroxytryptamine (serotonin). Melatonin is produced commercially by chemical synthesis, or from the pineal glands of cattle.

Melatonin induces natural sleep, with no known complications or risk of respiratory compromise. It has been used in the treatment of primary and secondary sleep disorders and the prevention and treatment of jet lag, and has been successfully used as a sedative for premedication in paediatric and adult patients. Melatonin provides anxiolysis and sedation. Unlike midazolam, it has minimal effects on cognitive and psychomotor skills after recovery.

Melatonin is administered as a sublingual preparation. Doses of 0.05 mg/kg of melatonin have been used to provide preoperative anxiolysis and sedation. The drug is most effective when administered during the period in which the patient would normally be asleep.

Trazodone is a triazolopyridine. It is mostly used for the treatment of depression, but also has sedative effects and has been used for sedating children with attention deficit hyperactivity disorder (ADHD). Trazodone can be used as an alternative if paradoxical reactions to midazolam have previously been recorded.

Zaleplon is a short-acting sedative/hypnotic with an ultrashort half-life. It binds selectively to the benzodiazepine site of the $GABA_A$ receptor, but has less residual central nervous system ("hangover") effects than the benzodiazepines. Zaleplon causes less anxiolysis but more profound hypnosis than the benzodiazepines, although it does not interfere with sleep architecture.

The pharmacokinetics of zaleplon makes it an ideal drug for PSA. It has an average onset of activity of 15 to 20 minutes after oral administration, an approximate duration of action of four hours, and is extensively metabolised in the liver. There are no active metabolites. Side effects include drowsiness and headache.

Zaleplon has been effectively used as a hypnotic for patients undergoing dental extractions, with 10 mg of oral zaleplon producing comparable anxiolysis to triazolam. Recovery from zaleplon is faster than recovery from triazolam.

11. Recovery and discharge criteria

The patient must be allowed to recover from PSA in an appropriate and suitably equipped recovery room, with a health care 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.

Criteria for discharge to home from the recovery room can be assessed using validated scoring tools such as the modified Aldrete scoring system (Table XIX) or the Modified Post Anesthesic Discharge Scoring System (MPADSS) (Table XX). Although the Aldrete score was not originally designed for use in ambulatory patients, it is commonly used to determine when patients are ready for discharge from the postanaesthetic care unit. The MPADSS was designed to determine home readiness after ambulatory surgery, and not specifically for assessing patients undergoing PSA.

Vital signs (blood pressure, heart rate, respiratory rate, oxygen saturation, level of consciousness, temperature and pain levels) must be measured and documented at regular intervals (See Appendix 8).

Table XIX: Modified Aldrete scoring system

	Score
Level of consciousness	
Fully awake	2
Arousable on calling	1
No response	0
Oxygen saturation (%)	
> 90% breathing room air	2
Oxygen required to maintain saturation > 90%	1
< 90% even when breathing oxygen	0
Circulation/blood pressure	
Systolic BP within 20 mmHg of presedation level	2
Systolic BP within 20-50 mmHg of presedation level	1
Systolic BP > 50 mmHg of presedation level	0
Movement/activity	
Able to move all extremities on command	2
Moves 2 extremities	1
Doesn't move extremities	0
Respiration	
Able to breathe and cough freely	2
Dyspnoea, shallow or limited breathing	1
Apnoea	0

When using the modified Aldrete score to evaluate the patient, he or she must score ≥ 9 before discharge home from the recovery room can be considered. In addition, a responsible person must accompany the patient home, and there must be no complications from surgery such as, for example, bleeding or vomiting.

Although still widely used, the modified Aldrete scoring system has been largely superseded by the MPADSS as a tool to determine home readiness (Table XX).

When using the MPADSS, patients are judged as fit for discharge when the score is ≥ 9 out of a maximum of 10.

It is no longer necessary to ensure that the patient is able to take in fluids orally, or that he or she has passed urine prior to discharge home. However, the patient must be advised to contact the responsible physician if unable to void urine within 6-8 hours of discharge from the sedation unit.

A responsible adult must accompany the patient home. Written and verbal instructions, including the contact details of a physician in the event of complications in the first 24 hours after sedation, must be issued to both the patient and the carer. The physician must be satisfied that aftercare is optimal before the patient is discharged.

Following the administration of PSA, the patient is not permitted to do any of the following for 24 hours:

- Drive a motor vehicle.
- Operate machinery.
- Drink alcohol.
- Sign any legal documents.

Table XX: Modified Post Anesthetic Discharge Scoring System

	Score
Vital Signs	
The vital signs must be stable and consistent with age and preoperative baseline	
BP and pulse within 20% of preoperative baseline	2
BP and pulse within 20-40% of preoperative baseline	1
BP and pulse > 40% of preoperative baseline	0
Activity level	
The patient must be able to ambulate at preoperative level	
Steady gait, no dizziness, or meets preoperative level	2
Requires assistance	1
Unable to ambulate	0
Nausea and vomiting	
The patient should have minimal nausea and vomiting before discharge	
Minimal: successfully treated with oral medication	2
Moderate: successfully treated with intramuscular medication	1
Severe: continues after repeated treatment	0
Pain	
The patient should have minimal or no pain before discharge	
The level of pain should be acceptable to the patient	
The pain should be controlled by oral analgesics	
The location, type and intensity of the pain should be consistent with anticipated postoperative discomfort	
Acceptability:	
Yes	2
No	1
Surgical bleeding	
Postoperative bleeding should be consistent with expected blood loss from the patient	
Minimal: does not require dressing changes	2
Moderate: up to two dressing changes required	1
Severe: more than three dressing changes required	0

Carers must be advised to seek immediate help in case of vomiting, strange and unusual behaviour, or any other symptom or sign that does not seem normal for the patient. Carers should also be instructed to look for any breathing difficulties. Medication must be administered as prescribed by the physician. The intake of food or fluids must be introduced slowly and only if the patient is fully awake. The patient must stay at home and rest quietly.

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

Consent to sedation and analgesia for medical/dental procedures

I have been fully informed and I declare the following:

1. I understand the nature of procedural sedation and analgesia, the purpose of the procedure and the risks involved. I understand that no guarantee can be given with regard to the results obtained.

   Procedural sedation and analgesia entails the administration of sedative and/or analgesic drugs to induce a reduced level of consciousness to such an extent that normal protective airway reflexes and spontaneous respiration are maintained, and cardiovascular function is unaffected. Procedural sedation and analgesia, together with regional/local anaesthesia, will put me/the patient in a relaxed state to make minor surgery possible. I understand that it is not a general anaesthetic and that I/the patient will not be unconscious, as I/the patient may have to respond to commands from the surgeon and/or the sedationist.

2. Unforeseen adverse events may arise during/after sedation that may require additional or different medications or treatment. I authorise the sedationist to treat such adverse events according to his/her professional judgement:

   Possible adverse events:
   - Unintended loss of consciousness
   - Drowsiness/dizziness
   - Shivering (4%)
   - Headaches (4%)
   - Postsedation nausea and vomiting (0.7%)

3. I give consent to the administration of such sedative and/or analgesic drugs as may be considered necessary or advisable by the practitioner responsible for this service.

4. I accept full and complete responsibility for actual and potential costs associated with procedural sedation and analgesia, and I accept full responsibility for the costs that have been explained to me. I agree to comply with the terms and conditions of payment.

5. I have had the opportunity to ask questions and I have been given the opportunity to choose alternative methods of treatment to my satisfaction.

6. I confirm that I have received written/oral instructions regarding the sedation, which I understand. I will abide by the pre- and postoperative instructions. I have completed a medical history questionnaire and have declared all drugs that I have taken during the last 6 months.

I, …… (patient/parent/guardian), of address

…… hereby authorise the following procedure/s

……

to be performed on (name of patient) …… utilising procedural sedation analgesia/local anaesthesia techniques under direction of Dr ……

Patient/parent/guardian signature ……

Witnesses: 1. …… 2. ……

Practitioner's declaration: I have explained the procedure of procedural sedation and analgesia, risks, alternatives and expectations to the patient/parent/guardian, and believe that he/she has been adequately informed and have consented.

…… ……

Practitioner's signature **Date**

Basic equipment and drugs for procedural sedation and analgesia in adults

All equipment should be checked regularly and stored in a mobile cupboard

Devices to administer oxygen and assist with ventilation	
Oxygen and oxygen tubing	Oxygen source must be reliable and able to provide at least 90% oxygen via a self-inflating positive pressure delivery system at 15 L/min for at least 60 minutes
Oxygen flow regulator	
Nasal prongs	
Venturi masks	To deliver 40% oxygen
Nebuliser and mask	
Self-inflating resuscitation bag with reservoir	
PEEP valve	
Catheter mount	

Airway devices and equipment	
Face masks	Selection of sizes
Laryngeal mask airways or similar supraglottic devices	Sizes 3–5
Range of cuffed endotracheal tubes	Sizes 5–8
Laryngoscope set	Two handles with long and standard blades, and spare batteries and bulbs
Water-soluble lubricant	
10 ml syringe for inflation of pilot balloon	
Tape or equivalent to secure endotracheal tube	
Oropharyngeal airways	Sizes 3–5
Nasopharyngeal airways	Sizes 6 mm and 7 mm
Stylets/introducers	Appropriately sized for endotracheal tubes
Magill forceps	

Monitoring equipment	
ECG monitor and cardiac defibrillator	With conductive paste, chest paddles and razor
Pulse oximeter	
Blood pressure monitoring device	Non-invasive, with appropriately sized cuffs
Stethoscope	
Thermometer	
Blood glucose testing device	
Selection of test tubes for blood biochemistry and full blood count	
Capnograph	Nasal prongs with capnography line strongly recommended, but not compulsory

Equipment with which to gain intravenous access	
Gloves	
Tourniquet	
Sterile gauze pads	
Alcohol skin wipes	
Intravenous cannulae	18–22 gauge
Sterile needles	
Assortment of syringes	1 ml – 50 ml
Sharps container	
Tape or equivalent to secure intravenous cannulae	

Equipment for the accurate infusion of drugs and fluids	
Infusion pumps	Intravenous fluid administration for simple sedation
Syringe drivers	Drug administration in advanced sedation
Intravenous administration sets	Must be compatible with infusion pumps
Stickers for labelling syringes	
Drip stands	
Intravenous fluids	Crystalloids and colloids

Hardware and miscellaneous equipment	
Source of suction	Including connection tubing
Suction catheters	Including catheters for suctioning endotracheal tubes, and Yankauer-type suction nozzles
Therapeutic heat source	
Cardiac arrest board	
Appropriate lighting	
Operating surface that can be tilted	
Urinary catheters	
Nasogastric tubes	
Means of summoning emergency assistance	
South African Resuscitation Council algorithms	Basic and advanced life support
Procedural documentation	

Recommended emergency drugs
Naloxone
Flumazenil
Adrenaline (at least 10 ampoules)
Atropine or glycopyrrolate
Ephedrine or phenylephrine (or other α-agonist)
Lignocaine
Glucose 50%
Hydrocortisone, methylprednisolone or dexamethosone
Promethazine (or other H1-antagonist)
Nitroglycerine spray
Aspirin
Salbutamol
Suxamethonium

Medical history questionnaire

Name			
Sex	Age	Height	Weight

Do you suffer from, or is there a history of, the following? Tick either "yes" or "no" and, if any answer is "yes", provide a detailed explanation.

	YES	NO
1. Cardiovascular disease		
High blood pressure		
If "yes", what was your last blood pressure reading?		
Heart failure		
Heart valve lesion, rheumatic fever, or congenital heart disease		
Dysrhythmia, palpitations (without exertion), or blackouts		
Shortness of breath when lying down, or walking on a level surface		
If any answer is "yes", please provide a detailed explanation:		
2. Central nervous system disorders		
Epilepsy, fits (convulsions), or dizziness		
Depression, or psychosis		
If any answer is "yes", please provide a detailed explanation:		
3. Blood disorders		
Anaemia, sickle cell disorder, or thalassaemia		
Abnormal bleeding associated with previous dental extractions, surgery or trauma, or do you bruise easily?		
If any answer is "yes", please provide a detailed explanation:		
4. Blood clots		
Episodes of thrombosis, or embolism of the legs or lungs		
If any answer is "yes", please provide a detailed explanation:		
5. Respiratory disease		
Do you smoke?		
History of snoring		
Lung disease, e.g. asthma, emphysema, or tuberculosis		
If any answer is "yes", please provide a detailed explanation:		
6. Endocrine disorders		
Diabetes mellitus		
If "yes", please give details of medication and degree of control of blood sugar:		
Thyroid problems		
Porphyria, or other metabolic disorders		
If any answer is "yes", please provide a detailed explanation:		
7. Liver disease		
Hepatitis, or jaundice		
Other liver disease		
If any answer is "yes", please provide a detailed explanation:		

	YES	NO
8. Kidney disease		
Renal disease or disorders, or renal failure		
If the answer is "yes", please provide a detailed explanation:		
9. Muscle disorders		
Myopathy, dystrophy or progressive weakness, or malignant hyperthermia		
If the answer is "yes", please provide a detailed explanation:		
10. Arthritis and orthopaedic problems		
If the answer is "yes", please provide a detailed explanation:		
11. Stomach problems		
Indigestion, heartburn, hernia, or ulcer		
If the answer is "yes", please provide a detailed explanation:		
12. Hereditary disease		
If the answer is "yes", please provide a detailed explanation:		
13. History of allergy in general, or allergic reactions to medications		
If the answer is "yes", please provide a detailed explanation:		
14. Previous admission to hospital		
If the answer is "yes", please provide a detailed explanation:		
15. Previous operations		
If the answer is "yes", please provide a detailed explanation:		
16. History of taking medication or drugs, including herbal remedies and recreational drugs		
If the answer is "yes", please provide a detailed explanation:		
17. Previous adverse or unpleasant reaction to anaesthesia		
If the answer is "yes", please provide a detailed explanation:		
18. Infectious diseases		
If the answer is "yes", please provide a detailed explanation:		
19. Airway problems		
If the answer is "yes", please provide a detailed explanation:		
20. Failed sedation		
If the answer is "yes", please provide a detailed explanation:		
21. Is there anything you would like to discuss, but would prefer not to write down?		
If the answer is "yes", please contact your sedationist and discuss this with him/her before the date of your procedure		

……

Signature (Patient/Parent/Guardian)

……

Date

Sedation monitoring chart

DAYCARE SEDATION RECORD																				
Date: Time in: Time out:																				
Patient name: File No:																				
DOB: Age: Weight: ASA I II III IV V E																				
Procedure: Operator: Sedation list: Recovery nurse:																				
Previous operations/sedation/GA: Complications: Allergies: Medical history: Medication:																				
Last oral intake: Fluids: Solids:																				
Premedication: Given at:																				
IV cannula size: 24G/22G/20G IV fluids: Site: Total fluids given:																				
TIME																				
O_2 %																				
N_2O %																				
RR																				
$EtCO_2$																				
SpO_2																				
BP 200																				
190																				
180																				
170																				
160																				
150																				
140																				
130																				
120																				
110																				
90																				
80																				
70																				
60																				
50																				
Heart rate •																				
Drugs																				
1																				
2																				
3																				
4																				
5																				
6																				

Sedation scoring system

Wilson Sedation Scale*

The level of consciousness can be assessed by using tools such as the Wilson Sedation Scale

Score	Description
1	Fully awake and oriented
2	Drowsy
3	Eyes closed but rousable to command
4	Eyes closed but rousable to mild physical stimulation (earlobe tug)
5	Eyes closed but unrousable to mild physical stimulation

*Wilson E, David A, MacKenzie N, Grant IS. Sedation during spinal anaesthesia: comparison of propofol and midazolam. Br J Anaesth 1990;64(1):48-52.

Preprocedural checklist

To be completed and signed by sedationist

Name:			Date of birth:		
Age:			Weight:		
Responsible doctor:			Sedationist:		
Procedure: Elective/Emergency/Urgent			Name of accompanying adult:		
Has the patient completed a medical questionnaire? Yes / No					
Has the patient been fully evaluated? Yes / No			Has the patient been physically examined and evaluated? Yes / No		
Sedation contraindication checklist					
Past sedation history Details:	Yes / No		Previous sedation satisfactory Details:	Yes / No	
Airway problems Details:	Yes / No		Previous failed sedation Reason:	Yes / No	
Raised intracranial pressure Details:	Yes / No		Previous complications of sedation Details:	Yes / No	
Sleep apnoea	Yes / No		Depressed level of consciousness	Yes / No	
Respiratory failure	Yes / No		Serious illness Details:	Yes / No	
Fasting time checklist					
Fasted for solids (including milk)			From:	(minimum 6 hours)	
Fasted for clear juice/water			From:	(minimum 2 hours)	
Significant underlying conditions (see medical questionnaire)					
Renal dysfunction	Yes / No		Cardiac dysfunction	Yes / No	
Hepatic dysfunction	Yes / No		Gastro-oesophageal reflux	Yes / No	
Respiratory dysfunction	Yes / No		Known allergies/drug reactions	Yes / No	
Chronic medication If yes, have they been taken today?	Yes / No Yes / No		Specify chronic medication:		
Premedication and monitoring					
Premedication prescribed and by whom:			Drug: Drug:	Dose: Dose:	Time: Time:
Premedication administered:	Yes / No		Name of person who administered premedication:		
Name of sedationist: Qualification:			Name of qualified attendant:		
Equipment checklist (tick if present)					
Pulse oximeter		NIBP		ECG	
Airway equipment		Oxygen		Drugs	
Resuscitation equipment		Temperature probe		Circulatory support equipment	

Signature of sedationist: ..... Date: .....

Name of sedationist (block letters): ..... Qualification: .....

Pre- and postsedation instructions for patients and carers

Please read the instructions carefully, and then fill in your details.

Dear Patient/Parent/Guardian,

You need to undergo a procedure/operation, and your doctor/dentist has chosen to do this under sedation. Please read the following information and instructions carefully. If anything is unclear, please contact your doctor/dentist at the following telephone numbers: …….

Presedation instructions

- If you suffer from any medical condition or take any acute or chronic medicine, you will need to inform your doctor/dentist before the procedure/operation. A medical history questionnaire has been included; please complete this and return it to your doctor/dentist before the procedure/operation. This is an important document, as it will help us to decide whether you qualify for the sedation that will have to be given for the procedure/operation. If you feel sick or unwell, please call your doctor/dentist so that he/she can decide whether it is necessary to postpone the treatment.
- Please wear comfortable clothes with loose-fitting sleeves.
- Do not eat anything for at least 6 hours before the procedure/operation. Clear fluids may be taken up to 2 hours before.
- If you take **chronic medication, please do so** on the day of the procedure/operation, after discussing this with your doctor/dentist.
- Please arrive in good time for your appointment, at least 30 minutes beforehand. In some cases, your doctor/dentist may feel that you will benefit from premedication to reduce your anxiety and make you feel relaxed. If this is the case, your doctor/dentist may request that you come earlier for your appointment so you can take the premedication.
- Please empty your bladder before the procedure/operation.
- An escort may remain with you until the sedation is underway and the procedure/operation is about to start. The escort will then be requested to leave the procedure/operation room.
- It may be necessary to put a drip/cannula in a vein in your hand or arm.

Postsedation instructions (aftercare of the patient)

- A responsible adult must take you home after the sedation, and you must remain in the company of a responsible adult for the remainder of the day. Sedation **will not** be given if you arrive without an escort.
- You may not drive, operate equipment or participate in any other activities that require alertness or coordination (e.g. swimming, cycling, etc) for at least 12 hours following the procedure/operation.
- If you are taking any regular medication, ask your doctor/dentist when you should take your next dose after the sedation.
- You should not experience nausea or vomiting after sedation. If you do vomit, and this happens more than once, please contact your doctor/dentist.
- Do not eat or drink if you are nauseous. Introduce any fluids or foods slowly after sedation. If you tolerate clear fluids, you may then progress onto solids.
- If you have not passed urine within 6-8 hours of being discharged, please contact the doctor/dentist at the telephone numbers provided.
- The sedation may result in amnesia (loss of memory). This is temporary, sometimes lasting for a few hours.

I, ……, the undersigned, have read and understood these pre- and postsedation instructions, and agree to contact the doctor/dentist if there is anything more that is not clear to me.

…… ……

Signature Date

We do not anticipate that you will have any adverse events or complications. Should you become concerned about anything, please contact:

Dr …… Telephone ……

Postoperative record and discharge criteria questionnaire

Name of patient:	**Date:**	
	Yes	**No**
Are the blood pressure and heart rate stable?		
Can the patient swallow and cough?		
Can the patient walk without feeling dizzy or faint?		
Is the patient nauseous?		
Is the patient breathing comfortably and of normal colour?		
Is the patient awake and appropriate?		
Has the operative site been checked and is bleeding controlled?		
Have written postoperative instructions been given and explained to both patient and carer?		
Is the patient pain free?		
Have possible complications been explained?		
Has a prescription been given or medication dispensed?		
Is there a responsible adult to accompany the patient?		

Monitoring																		
TIME																		
O_2 given																		
RR																		
SpO_2																		
Heart rate •																		
Temperature																		
BP 190																		
180																		
170																		
160																		
150																		
140																		
130																		
120																		
110																		
90																		
80																		
70																		
60																		
50																		
40																		
30																		

Patient has been assessed and is deemed fit for discharge at: (time and date)

Mode of transport home is:

Signature of recovery nurse:


SAPIENTIA ET ARTE CUSTODIMUS