ISSN-2220-1181

SOUTH AFRICAN SOCIETY
OF ANAESTHESIOLOGISTS (SASA)

SASA
Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in adults: 2020–2025

SOUTH AFRICAN SOCIETY OF ANAESTHESIOLOGISTS (SASA)

Please Note

SASA does not recommend the administration, prescription, or mixture of any medication outside of what is specified by the individual manufacturer and licensed for usage in South Africa, or as per their respective package insert and local registration. Should a medication be used off-label, SASA urges its members to ensure that all required and appropriate consent processes are followed prior to the administration of such medication, and that sufficient peer reviewed and accepted evidence exists to support the utilisation of such medication in this manner as constituting best practice.

In the case of any lipid emulsion, SASA further cautions its members to adhere to best practice in the preparation, management, administration, and any post-manufacture mixture of these emulsions, specifically. Package inserts are individualised per preparation and clearly outline safety recommendations and approved licensing of each medication. Mixing of lipid emulsions with additional medications can result in significant alteration and instability of the pharmacokinetics and dynamics of the original drugs. In addition, lipid emulsions carry a significant risk of bacterial contamination and therefore the preparation and administration thereof should maintain aseptic conditions.

SASA therefore strongly recommends that any medications used as mixtures or synergistic combinations be administered through separate syringes or mode of administration, and via a free-flowing intravenous line in order to avoid sedimentation, prolonged mixing due to stasis within the line, micelle formation, and inadvertent pharmacokinetic and/ pharmacodynamic denaturing.

CONTENTS

Foreword to the 2020–2025 edition of the SASA Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in adults

Writing guidelines on procedural sedation and analgesia is a formidable and challenging task. There are many disciplines and societies at international level now involved in writing guidelines and we need to be aware of what they see as important in their guidelines. We always need to identify new trends in sedation; for that we need to be involved at international level.

Our aim with these guidelines is to provide a guidance for safe sedation practice for all healthcare providers who are involved in sedation practice.

In this issue we have added adverse events and record-keeping, accreditation and the importance of simulation training to our recommendations under clinical governance. We would like our sedation practitioners to keep records and report adverse events to our societies, e.g. SOSPOSA, so that we all can benefit from the information we get.

It is also crucial that sedation practitioners keep their logbooks and update them regularly – "if it is not written down, it never happened".

All aspects of accreditation remain an important issue and we need to address this urgently. This forms an important part of safe sedation practice, also done at international level, and we need to follow this. The facilities where we work, especially outside the operating theatre, must meet the requirements for safe practice. It is our responsibility to see that this is the case. In the appendices there is a practice appraisal protocol that should be filled in by sedation practitioners doing sedation outside the operating theatre.

We do not cover sedation techniques in the guidelines. We believe sedation practitioners must learn the techniques with supervised clinical training.

Capnography for sedation outside the operating theatre will become a focus point in future. We are only supposed to be doing ASA I and II patients outside the operating theatre so there may be a feeling we do not need capnography. There is pressure to include capnography under monitoring as a minimum monitoring standard, like pulse oximetry and blood pressure monitoring.

Our appendices have been revised with more information on what patients need to know about sedation e.g. an example of a cover letter to the patient. This will include information to the patient, as well as information from the patient.

Sedation is today one of the fastest growing areas in anaesthesia care. Our research studies show a low incidence of side-effects, and a high incidence of patient satisfaction.

To all our readers we wish you a safe sedation journey.

Professor James Roelofse

jar@sun.ac.za

Dr Marí Jansen van Rensburg

mjvr@doctors.org.uk

SASA Sedation Guidelines 2020
(South African Society of Anaesthesiologists)

Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in adults: 2020–2025

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

The new guidelines replace the SASA guidelines, "Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in adults: 2015".

Reprint enquiries may be directed to: editor@sajaa.co.za and reprints@medpharm.co.za or SASA, PO Box 1105, Cramerview, 2060 and Medpharm Publications, PO Box 14804, Lyttelton, 0140.

Disclaimer
This is an official consensus document of The South African Society of Anaesthesiologists. While every effort has been made to ensure scientific accuracy, SASA and Medpharm shall not be responsible or in any way liable for errors, omissions or inaccuracies in this publication, whether arising from negligence or otherwise or for any consequences arising therefrom.

Medpharm® Publications
Published by Medpharm Publications for *The South African Society of Anaesthesiologists (SASA).*

SOUTH AFRICAN SOCIETY OF ANAESTHESIOLOGISTS (SASA)

Acknowledgements

The South African Society of Anaesthesiologists (SASA) wishes to acknowledge with gratitude the unrestricted educational grant provided by Medtronic that made the development, publishing, distribution and web hosting of this guideline possible.

Medtronic

Further, Together

1. Introduction

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

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

The guidelines are not applicable to:

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

1.1 Evidence

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

1.2 Objectives of procedural sedation and analgesia (PSA)

The objectives of procedural sedation and analgesia are to:

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

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

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

1.3 Indications for sedation

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

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

1.4 Risks to patient safety

Publications have highlighted a lack of formal training as contributing to sedation-related adverse events, and sedation training is supported by all international sedation guidelines.[1] The sedation practitioner must undergo theoretical training, as well as supervised clinical training. Regular update of knowledge is essential.

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

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

Adverse events may be categorised according to clinical importance:

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

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

Adverse events may occur because of:

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

Complications/adverse events can occur:

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

1.5 Clinical governance

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

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

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

The sedation practitioner must have a standard plan in operation for each sedation technique for which they deliver a service. This should include details of assessment protocols, structure of treatment sessions, roles of all team members and the systems in place for reporting adverse events. There should also be in-house training sessions for the whole sedation team.

All practitioners involved in sedation practice must keep a logbook of cases performed under sedation, and are required to document and report adverse incidents and accidents. Adverse events remain an area of serious concern. Sedation practitioners do not often report adverse events. It is recommended that adverse events be reported to societies involved in sedation practice.

It is recommended that:

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

2. Definitions

Sedation is a drug-induced depression of consciousness, with a continuum varying from minimal sedation/anxiolysis, moderate sedation and analgesia, dissociative sedation, to deep sedation, and finally general anaesthesia as outlined below (Table 1).

Table 1: The continuum of sedation and sedation endpoints.

	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

2.1 Sedation endpoints

The American Society of Anesthesiologists (ASA) defines three levels of sedation:[4]

2.1.1 Minimal sedation/anxiolysis

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

2.1.2 Moderate sedation/analgesia

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

There are societies which believe that dissociative sedation, i.e. using ketamine, should be part of the sedation continuum, falling between moderate and deep sedation/analgesia.

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. Deep sedation/analgesia may be accompanied by clinically significant ventilatory depression, assistance with maintaining a patent airway, and positive pressure ventilation. Cardiovascular function is usually maintained. This level of sedation is termed Monitored Anesthesia Care by some international sedation guidelines.

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

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

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

Guidance on the care of the patient under general anaesthesia is provided in the publication *Guidelines for Practice* issued by SASA, and is not addressed in this document.

<u>The following statement by the American Society of Anesthesiologists (ASA) must be taken into consideration with every sedation procedure:</u>

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

of sedation (i.e. hypoventilation, hypoxia and hypotension), and returns the patient to the originally intended level of sedation."[4]

It must be remembered that the level of consciousness is independent of the route of administration. Any level of PSA may be achieved via any route of administration.

2.2 Continuum of PSA

As PSA encompasses a continuum of altered state of consciousness ranging from anxiolysis (or minimal sedation) to deep sedation and analgesia, practitioners must always remember that the more drugs are used, the higher the possibility of changing the level of consciousness. Patients may reach a deeper than intended level of sedation.

The response of individual patients to the administration of sedatives, hypnotics or analgesics is difficult to predict because of individual drug variability. The types of drugs used, the dosages administered, the additive effects of concomitant drugs and the patient's pharmacogenetic profile will all influence the level of sedation or consciousness.

2.3 Non-dissociative sedation

Non-dissociative sedative drugs (including opioids, benzodiazepines, barbiturates, etomidate, dexmedetomidine and propofol) operate on the sedation dose-response continuum, where higher doses provide progressively deeper levels of sedation with possible respiratory and cardiovascular compromise, loss of protective reflexes and eventually 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. Titration eliminates guesswork.

2.4 Dissociative sedation

Dissociative sedation (seen with ketamine sedation/analgesia), causes a trance-like cataleptic state characterised by intense analgesia, amnesia, sedation, retention of protective reflexes, spontaneous breathing and cardiovascular stability. When ketamine is administered in doses appropriate for PSA, loss of consciousness is unlikely.

2.5 Sedation techniques

In order to optimise patient safety, sedation practitioners should only use the specific sedation techniques for which they have received formal training. This should include supervised clinical training.

Choice of techniques for sedation:

2.5.1 Basic/standard sedation

Basic/standard 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 intravenous doses of midazolam, to a maximum dose of 0.1 mg/kg.

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

If the above drugs are used in combination, basic/standard sedation ceases, and the sedation technique is classified as an advanced sedation technique. When a standard sedation technique proves to be insufficient, the depth of sedation **must not** be advanced, unless the patient is fasted and a dedicated sedation practitioner is employed.

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

The Academy of Medical Royal Colleges acknowledge that systemic analgesia in the form of a short-acting opioid, e.g. fentanyl, may be required in some patients to facilitate administration of local anaesthesia. Midazolam should carefully be titrated once the full effect of the opioid is clear and subsequent doses of opioid should be avoided.[5]

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 via any route, or
- any sedation administered via the intravenous route, e.g. propofol, etomidate, dexmedetomidine (with the exception of titrated doses of midazolam to a maximum of 0.1 mg/kg), 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, i.e. target controlled infusions (TCI).

2.6 Failed sedation

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

assessment of the patient, patient factors, i.e. anxiety, drug factors, or procedure-related and operator factors. A previous episode of failed sedation may necessitate the provision of general anaesthesia for future procedures.

2.7 Prolonged sedation

The aim to reduce costs and avoid long theatre waiting time has resulted in an escalation in the demand for procedures to be performed outside the operating theatre. Frequently these procedures are quite lengthy and may require the provision of moderate sedation and analgesia, or even deep sedation. Sedation practitioners are increasingly faced with decisions as to how long a patient can be kept safely under sedation outside the operating theatre. Prolonged sedation for lengthy procedures may involve risks, and mechanisms must be instituted to ensure the safety of patients. Currently there is no guidance for sedation practitioners regarding the definition of prolonged sedation. Sedation experts recommend that any sedation procedure lasting more than four hours for procedures performed outside the hospital should be defined as prolonged sedation. Any procedure lasting longer than four hours is probably best staged into two different procedures, although this approach may not be practical. The recommendation for a procedure expected to last more than four hours is to perform the procedure under general anaesthesia in-hospital.

3. Environment and clinical setting

Sedation practitioners must understand the limitations of working in the relative isolation of the out-of-hospital setting. The premises and supporting facilities where sedation is performed, must meet the requirements of safe sedation practice. Pre-procedure assessment and selection of patients will determine if the facility fulfils the requirements for each individual patient. The minimal required facilities, equipment and drugs for procedures to be performed outside the operating room, must include those detailed in Basic equipment and drugs for procedural sedation and analgesia in adults (Appendix 1).

Treatment areas must be large enough to enable adequate access for the sedation team. Furthermore, sedation should only be performed in an environment where staff, facilities, equipment and drugs meet requirements to manage emergencies. There must be enough room for managing medical emergencies. Resuscitation equipment must be available, maintained and regularly checked, especially before the start of the procedure. The equipment must be in working order and the drugs within their expiry date. Records of the maintenance of equipment must be retained and be made available for formal inspections. All surgeries are expected to have filled oxygen cylinders with appropriate attachments, as well as access to a defibrillator in case the patient needs resuscitation. The clinical setting must permit access for emergency services and the transfer of the patient, if necessary. Irrespective of the setting, the sedation team should have access to an intensive care setting, if possible.

The recovery facility may be either a dedicated recovery area or the treatment area may be used as such. Monitoring of patients must continue in the recovery area until patients have recovered from the effects of sedation. The recovery area must be equipped to facilitate the management of any sedation-related adverse events.

All providers of procedural sedation services are responsible to ensure that the sedation facility in which care is delivered, is appropriate for the needs and safety of the sedation practitioners, patients, and staff and that it is in line with guidelines and standards of care. The practice appraisal protocol (Appendix 2) serves as a benchmark for sedation practitioners to determine whether the location they work in, fulfils the requirements as set out in the guidelines.

The sedation practitioner, together with the owner of the premises, must also ensure that the premises are inspected and accredited by an independent recognised sedation authority. The focus should review the procedures, sedation techniques, and processes. Records of the audit process and outcomes must be maintained and be available for inspection. Regular audits should be considered as a core requirement for sedation providers involved in patient care. It is recommended that the Society of Sedation Practitioners of South Africa (SOSPOSA), or the equivalent body be contacted for evaluation of the sedation facility.

4. Valid informed consent to sedation and analgesia for medical/dental procedures (Appendix 3)

Valid, informed consent is a complex process. The GDC (General Dental Council, UK) gives valuable principles and standards for the dental team regarding consent for dental procedures.[6] It should be documented that appropriate consent was obtained from the patient, or a responsible person (parent/guardian), according to local and international requirements.

Before the process can be completed, information about the sedation and procedure must be provided in a clear and understandable way. This should happen at an appropriate time in order for the patient to be able to digest the information and formulate questions. The discussion should therefore, if possible, not occur immediately before the procedure or even on the day of the operation. It must never be obtained after administration of sedative and analgesic drugs. The nature of the procedure to be performed may also not be changed after sedative and/or analgesic drugs were administered to the patient.

Patients must understand the risks of sedation before consenting. Therefore, an explanation of the procedure, the proposed sedation technique and an explanation of the risks and benefits of the proposed technique should be explained. Patients must be aware 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.

Alternatives to sedation, e.g. general anaesthesia or local/regional anaesthesia, should be part of the discussion. Behavioural management techniques as an alternative to sedation, if relevant, should be discussed to ensure that the most suitable form of treatment is selected.

Consent must be obtained for both the procedure and the sedation. It is the responsibility of the sedation practitioner to ensure that the patient (or representative) understands the consequences of the decisions they are about to make. If the patient does not seem legally competent to give consent, e.g. special needs patients, consent will have to be obtained from someone with parental responsibility, i.e. the mother or father.

5. Patient assessment

Appropriate selection of patients for sedation is the first step of safe sedation practice. Each patient must specifically be assessed to determine his or her suitability for sedation outside the operating room. While the operator has the privilege of evaluating the patient beforehand, most sedation practitioners only meet the patient on the day of the procedure. The sedation practitioner should therefore assist and guide the operator in the evaluation of patients' suitability for sedation. It may be helpful to provide some guidance in the form of written notes to assist the operator in this process. Inappropriate patient selection is a recurring factor in sedation-related adverse events and poor outcomes.

Patient selection includes obtaining information from the patient as well as providing information to the patient. Whenever possible, pre-assessment should include retrieval and examination of previous records, i.e. medical, sedation, anaesthesia and surgical history.

The evaluation should include:

- A recent medical history questionnaire (Appendix 4). Details of previous sedations are vital, as previous failed attempts at sedation may indicate the need for general anaesthesia for future procedures. Enquire about previous problems with airway management as part of the suitability check for out-of-hospital procedures.
- Special attention to the drug history of the patient:
  - Chronic medication, e.g. antihypertensive drugs, anticoagulants, anti-diabetic drugs.
  - Psychotropic drugs (e.g. sedatives, anxiolytics, antidepressants, antipsychotics, anti-epileptics, and drugs used in the treatment of mania) may cause adverse drug reactions, particularly when used in combination with opioids and local anaesthetic agents during sedation.
  - Recreational drugs, especially since the relaxation of legislation on the use of marijuana.
- Special attention to airway assessment. Various airway evaluation scales are available to assist the sedation practitioner with evaluation of the airway, i.e. the Lemon Law[7] and upper lip

bite test (ULBT)[8] (Appendix 5). Studies showed that the upper lip bite test had a significantly higher specificity and accuracy than the modified Mallampati test.[8]

- Evaluation of the cardiovascular and respiratory systems by way of auscultation of the heart and lungs.
- Enquiry about previous abnormal laboratory tests.

Where indicated, a medical specialist should be consulted about the condition of the patient. If the patient was seen at an earlier appointment, a re-evaluation of the health status immediately before sedation and surgery is recommended.

Assessment should be done in accordance with the American Society of Anesthesiologists (ASA) Physical Status Classification System[9,10] (Table 2). However, while anaesthesia and sedation providers use the ASA classification to indicate a patient's overall preoperative status for anaesthesia and sedation, it may be misinterpreted as a classification to predict risk. It is important to realise that this is *not* a risk classification, but an evaluation of clinical status only.

Table 2: ASA (American Society of Anesthesiologists) Physical Status Classification System Modified[9,10]

Class I	Healthy patient, non-smoking, no or minimal alcohol use, no functional limitations
Class II	Patient with history of well-controlled mild systemic disease, e.g. diabetes mellitus, hypertension, no substantial functional limitations
Fragile ASA II patient	Patient *not controlled* on morning or afternoon of procedure, i.e. hypertensive, diabetic, asthmatic, obstructive sleep apnoea
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
Class VI	Clinically deceased patients
"E"	An emergency procedure is denoted by the letter E following the class number

ASA-E – Emergency operation for any of the above classes, e.g. ASA II-E.
ASA-P – In the pregnant patient any one of the above classifications can be modified, e.g. ASA II-P.
General anaesthesia should be considered in the light of a full stomach.

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. It is advised that these patients be done in-hospital.

Other patient groups that need special attention include:

- The elderly patient (also see 10.2.1):

  The upper age limit of patients suitable for procedures in the out-of-hospital setting should be determined on an individual basis. The decision is based on factors like the extent and duration of the procedure, comorbidities, chronic medication and whether there is aftercare at home. Patients $\geq$ 65 years should be carefully selected in terms of possible decreased

organ function and increased incidence of co-existent disease. These patients often have decreased reserves and may desaturate faster and have more cardiac events. There is a clear association between advanced age and reduction in the median effective dose for all drugs acting on the central nervous system. This increased sensitivity is irrespective of whether the drugs are administered orally, parenterally or by inhalation.

- The obese patient (also see 10.2.2):

  Obesity poses considerable challenges to the sedation practitioner, especially in the out-of-hospital setting. Even though these patients often have several associated comorbidities, pre-procedure assessment may be inadequate due to limited resources and the fact that most patients are seen on the day of the procedure. A sedentary lifestyle and limited physical activity may render assessment of cardiac function unreliable. The association between obesity and obstructive sleep apnoea limits the use of sedatives and opioids and increases risk in the light of early discharge requirements. Obese patients may also have restrictive lung disease with increased ventilation-perfusion mismatching and are therefore prone to desaturation, especially in the supine position. Due to other factors like an increased risk for deep vein thrombosis and insulin resistance, these patients may not be good candidates for out-of-hospital procedures and need to be carefully evaluated on a case by case basis.

- The pregnant patient (also see 10.2.3):

  There is very little information available on sedation in the pregnant patient. However, sedation practitioners should be familiar with the unique physiology of pregnancy, especially the way it affects the organ systems involved in sedation, i.e. respiratory, cardiovascular and gastro-intestinal.

- Paediatric patients: See the SASA Guidelines for sedation in paediatric patients.

6. Guidelines for fasting

Preoperative fasting for sedation is controversial. Some authorities, especially in dentistry and emergency medicine, consider it to be unnecessary. Airway reflexes are assumed to be maintained during minimal and moderate sedation, but may be lost during deep sedation.

If basic or standard sedation techniques (see 2.5.1) are planned, fasting is recommended, but not mandatory.

If advanced techniques (see 2.5.2), including dissociative and non-dissociative techniques, or deep sedation are planned, standard anaesthetic fasting guidelines are recommended:

- Clear fluids, apple juice: two hours.
- Solid food: six hours.

A "clear fluid" is defined as fluid without particles.

If basic/standard 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.

7. Standards of monitoring

The principles of monitoring are described by the Academy of Medical Royal Colleges in *Safe Sedation Practice for Healthcare Procedures*.[5] All the members of the sedation team must have a detailed knowledge of the monitoring equipment and interpretation of the information provided by the monitors.

Both clinical monitoring and electronic monitoring must be used. The sedation technique used, i.e. either basic/standard sedation, or advanced sedation, will determine what level of monitoring is required. For basic/standard techniques where only a single agent is used, the respiratory and cardiovascular systems are usually unaffected. Intermittent assessment of vital signs is appropriate, including clinical monitoring such as level of sedation, anxiety, colour of mucosa/skin and breathing patterns. For prolonged procedures, use of a pulse oximeter and non-invasive blood pressure monitor is mandatory. Should any advanced sedation technique be used, the level of sedation will determine the monitoring required, as set out below.

Clinical monitoring alone may suffice in minimal sedation.

The following should be monitored and documented when advanced sedation techniques are used:

- Anxiety levels and behaviour, such as confusion, restlessness and agitation.

This may indicate a possible adverse event, e.g. hypoxaemia, hypoglycaemia, under-sedation or even over-sedation, and should be monitored in all levels of sedation.

- Level of consciousness and depth of sedation.

Regular communication with the patient will assist in monitoring the level of sedation. Responsiveness to verbal command/light tactile stimulation is an important part of sedation, since loss of responsiveness indicates that the patient is entering deep sedation. Monitoring level of sedation must commence prior to the administration of sedation and must be continued during the procedure and recovery period, until discharge from the facility. Since patients may react in an unpredicted manner to a standard dose or drug, and since patients may drift in and out of different levels of sedation, monitoring of responsiveness should be part of every sedation.

Subjective monitoring scales, e.g. Wilson sedation scale or the UMSS (University of Michigan Sedation Scale) can be used (Appendix 6). It is suggested that sedation practitioners use the UMSS since the scoring system follows the levels of sedation on the sedation continuum.

The value of processed electroencephalogram monitors, i.e. bispectral index (BIS) monitoring for sedation outside the operating theatre, is debatable. It may be useful where deep sedation and analgesia are used.

- Pain and degree of discomfort.

When patients are not able to give a verbal response due to the demands of the procedure, e.g. dental work or procedures on the head and neck, a signalling system for pain or discomfort should be established prior to the initiation of sedation. In this way patients will be able to demonstrate whether they are in pain or discomfort, e.g. with a thumbs up, or thumbs down.

- Airway patency.

Relaxation of the mandible and involuntary opening of the mouth are early signs that the level of sedation is deepening. Noisy inspiration and/or expiration and snoring are indications of an obstructed upper airway and should be corrected with repositioning of the head and neck or lessening the sedation. A patient who starts snoring should be evaluated for complete airway obstruction. Sedation providers should be attentive to possible depression of the chin, e.g. during dental work, and flexion of the neck with deepening of sedation. Since airway patency is directly related to depth of sedation, monitoring of airway patency should be part of every level of sedation.

- Oxygenation and colour for all levels of sedation.

- Breathing, respiratory rate and ventilation.

The breathing pattern and movement of chest and abdomen should be observed for the duration of the procedure. Breathing should be rhythmic. Signs to watch out for are paradoxical breathing, rib retraction, use of accessory muscles, and tracheal tug which all may indicate airway obstruction.

Respiratory rate should be recorded intermittently, except when a capnograph is used, where it will be displayed continuously. The use of a precordial stethoscope may be useful if capnography is unavailable.

Since the effect of drugs on breathing and ventilation may be unpredictable and affect all levels of sedation, these should be monitored irrespective of the level of sedation.

Capnography, the so-called gold standard for the monitoring of ventilation, monitors the end-tidal concentration of carbon dioxide, which is believed to be a more sensitive monitor

to alveolar hypoventilation than pulse oximetry. Healthy patients, i.e. ASA I and II patients, do not require CO_2 monitoring, and since only ASA I and II patients qualify for sedation outside the operating theatre, the use of capnography outside the operating theatre is still controversial. Therefore, capnography is not mandatory for moderate sedation, but is highly recommended in fragile ASA II patients, the elderly, the obese patient, in patients with obstructive sleep apnoea, and patients with respiratory problems like COPD. For prolonged sedation, e.g. some plastic and dental procedures, it is highly recommended that capnography be used for deep sedation and analgesia as there may be a higher incidence of respiratory depression. Intention-to-treat analysis of studies[11] showed hypoxaemia incidence was not significantly lower in the additional capnography arm compared with standard monitoring. Additional capnographic monitoring of ventilatory activity resulted in improved detection of apnoea. A recent meta-analysis supported the use of capnography during PSA concluding that episodes of respiratory depression were 17.6-times more likely to be detected by capnography compared with standard monitoring.[12,13]

Capnography techniques using nasal cannulae, side-stream analysis, and transcutaneous methods are well-tolerated by patients undergoing PSA. Capnography must never replace clinical monitoring of ventilation/respiration.

- Heart rate and rhythm.

Pulse rate, as recorded by pulse oximetry, should suffice for most levels of sedation. In moderate sedation where continuous verbal contact with the patient is maintained, electrocardiogram (ECG) is not essential. However, for prolonged sedation or in fragile ASA II patients and the elderly, an ECG is indicated when advanced sedation techniques are used. Any patient with underlying cardiovascular disease should be monitored with an ECG.

- Non-invasive blood pressure (NIBP).

NIBP must be monitored at all levels of sedation, except maybe for minimal sedation/anxiolysis of short duration.

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

Minimum monitoring standards:

- ASA I and ASA II patients: pulse oximetry and NIBP.
- Fragile ASA II patients and deep sedation: pulse oximetry, NIBP, ECG and capnography.

Baseline vital signs must be recorded *prior* to the commencement of sedation. Thereafter, the patient must be monitored at regular intervals during the procedure and into the recovery period, until discharge from the facility. The patient must never be left alone or unmonitored until fully recovered from all sedative, analgesic and dissociative drugs.

It is recommended that observations be recorded on a sedation monitoring flow chart (Appendix 7). The sedation practitioner, or staff member designated to monitor the patient, must be in attendance at the patient's side at all times, and must be competent to recognise, and rescue the patient from any complications.

8. Personnel

Whenever a sedation is performed, there should be no less than two people present, i.e. the operator, performing the procedure, and an appropriately trained observer. If the operator also provides the sedation for the procedure, i.e. a single operator-sedation practitioner, the observer will be responsible for monitoring the patient under sedation and to assist the operator in the event of adverse events. If said operator expects of the observer to take part in the sedation, e.g. by topping up the sedation, the observer will only be responsible for monitoring the patient and providing sedation as requested by the operator. The observer will not be able to assist with the procedure and the operator takes full responsibility for the sedation as well as the procedure. This situation is only recommended for brief, minor procedures.[5]

For all other procedures, a three-person model is suggested:

- the operator,
- an assistant to the procedure, and
- a dedicated sedation practitioner.

8.1 The sedation practitioner (SP)

8.1.1 Qualifications and training requirements

Relevant qualifications and regular updating of knowledge and skills remain the foundation of safe sedation practice. It is recommended that the SP should:

- Have a primary, registered medical qualification.
- Have full registration with the HPCSA as appropriate.
- Have formal training in standard and advanced sedation techniques, or be able to demonstrate equivalent experience and training. Provision of audit records of safe administration of sedation drugs is also required.
- Provide evidence of regular and recent sedation-related CPD (continuing professional development) activity appropriate to the sedation techniques provided.
- Have a logbook, or equivalent, reflecting cases where sedation was done, as well as the technique used.
- Comply with SASA recommendations for safe sedation practice.
- Have evidence available of up-to-date qualifications in Basic Life Support (BLS) and Advanced Cardiac Life Support (ACLS).

8.1.2 The single operator-sedation practitioner (SP)

The term single operator-sedation practitioner defines a healthcare practitioner who provides the sedation and at the same time performs the required procedure. Since it may not be possible to pay full attention to monitoring the patient whilst performing the procedure, a second trained individual is necessary to assist the operator-SP in this role. According to the Academy of Medical Royal Colleges[5] the assistant of the operator-SP can fulfil this role for procedures less than 30 minutes.

It is recommended that the operator-SP should undertake the dual role of sedation practitioner and operator only when basic or standard sedation techniques are employed and the level of sedation does not progress beyond minimal sedation/anxiolysis. It is recommended that combinations of drugs not be administered. However, guidelines from the Intercollegiate Advisory Committee for Sedation in Dentistry[14] suggest that the operator SP can administer moderate sedation and analgesia with standard sedation techniques. An appropriately trained second person must be present throughout the procedure and must be capable of monitoring the clinical condition of the patient and assisting the operator-SP in the event of complications. This second person may have received only in-house training, including competency in airway rescue, provided that this training is fully documented.

8.1.3 The dedicated sedation practitioner (SP)

The dedicated sedation practitioner takes full responsibility for the administration of sedatives, analgesics, and/or dissociative drugs, and monitors the clinical effects of these drugs.

It is advised to use a dedicated SP:

- If the operator had no training in the administration of sedation.
- In fragile ASA II patients.
- In the elderly.
- In patients with comorbidities.
- If the procedure is expected to be prolonged.
- For complex surgical procedures.
- If advanced sedation techniques are to be used.
- For complex sedation techniques involving intravenous infusions, i.e. target controlled infusions.

SPs and operators must only undertake procedures and interventions for which they have been specifically trained and for which they have been proven competent.

Sedation practitioners (albeit single operator-SP or dedicated SP) should:

- Have a good understanding of the pharmacokinetics and pharmacodynamics of the agents that they administer, including the pharmacology of the appropriate antagonists (which should be reserved for emergency use).
- Understand the synergistic effects when combining drugs.
- Be able to recognise and manage complications associated with the drugs in use.
- Must be able to apply advanced life support techniques and manage, rescue and recover a patient who unexpectedly enters a deeper than intended level of sedation.
- Regularly audit their practice.

8.2 Observer and ancillary personnel

An observer is always required for monitoring the patient when a single operator-SP provides sedation, even for brief or simple procedures. 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 members of the sedation team must have received appropriate theoretical and supervised clinical training. Their knowledge and skills should continually be updated by way of medical education, attending in-house training sessions and airway certification as well as taking part in simulation training for the management of emergencies. In-house training can involve various innovations in the form of formal lectures, supervised clinical training, monitoring, simulation of emergencies, documentation, and recovery care. Evidence of in-house training must be documented and kept in the facility as proof of training/updating knowledge and skills which is an important medico-legal point.

All ancillary personnel must have a clear concept of their individual tasks. They must have adequate, current experience in their roles and must be involved in continuing professional development and education in order to maintain their skills.

The following tasks must be completed with every sedation:

- Pre-procedural screening, including patient evaluation, providing pre- and post-sedation instructions and obtaining written informed consent (Appendices 3, 4, 8 and 9).
- Completing the pre-procedural checklist (Appendix 11).
- Prescribing and administering sedation.
- Patient monitoring (and rescue, where necessary) (Appendix 7).
- Performing the procedure.
- Recovery and discharge after the procedure (Appendix 12).

8.3 Personnel requirements for each sedation endpoint (see 2.1)

The level of care is determined predominantly by the degree of preservation of the protective airway reflexes and the risk of respiratory depression.

8.3.1 Minimal sedation/anxiolysis

At this level of sedation the airway, cardiovascular function, and spontaneous breathing are unaffected. This level of sedation is suitable for the operator-sedation practitioner, but, in accordance with all international guidelines, there must be a second person, apart from the operator, who is responsible to help monitor the patient and help with rescue if needed. This is usually a level of sedation suitable for brief, simple procedures lasting less than 30 minutes.

8.3.2 Moderate sedation/analgesia (conscious sedation)

A level of sedation where the airway is usually maintained, cardiovascular function intact, and the patient is breathing spontaneously. For this level of sedation, the following personnel are required:

- A medical practitioner:
  - Trained in the selection, assessment and evaluation of the patient and, specifically, in airway assessment.
  - Trained in specific sedation techniques.
  - Trained in resuscitation and airway management, experienced in advanced life support.
  - With an understanding of the pharmacokinetics and pharmacodynamics of sedative, analgesic drugs, and dissociative agents, their possible synergistic effects and specific reversal antagonists. The sedation practitioner must demonstrate competency when using combinations of drugs.
  - Trained and experienced in the use of the drugs for moderate sedation and analgesia techniques.
  - With an understanding of the procedure to be undertaken: painful/non-painful, duration, requirements for immobilisation.

For procedures longer than 30 minutes it is recommended that a third person be present, an assistant to the procedure.

- 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.

For more complex procedures, where combinations of drugs are used, prolonged sedation, and in patients with comorbidities, a dedicated sedation practitioner must be present.

8.3.3 Deep sedation/analgesia

Deep sedation/analgesia is part of the sedation continuum and the standard of care must be identical to that for an unconscious patient.

It is advised that a dedicated practitioner who is trained in sedation practice and preferably with experience in anaesthesia, as well as a trained assistant be present. The sedation practitioner must have a valid advanced life support certification.

During deep sedation, intervention may be required to maintain the airway. Ventilatory efforts must be closely monitored as they may be inadequate, or even ineffective against a closed glottis.

8.3.4 General anaesthesia (GA)

GA is not part of the PSA spectrum, even though it is mentioned on the sedation continuum. Sedation practitioners must be able to rescue patients who slip unintentionally into unconsciousness.

Guidance for GA is provided in the SASA publication, *Guidelines for practice*.

8.4 Personnel requirements for sedation for adults with special needs

A **patient** with **special needs** can be defined as someone with medical, physical, psychological or social circumstances that require a different approach to treatment. Sometimes, those with special needs have physical limitations that make treatment, i.e. dental treatment, very difficult. Intravenous sedation is usually used to relieve anxiety, produce drowsiness, and offer an amnesic effect. Some patients may have to be admitted to a hospital the night before to have a sedative/hypnotic drug administered.

Sedation for patients with disabilities must only be undertaken by sedation practitioners with experience in sedating patients with special needs. It is sometimes necessary to use deeper levels of sedation in special needs patients. It may be extremely difficult to judge the level of sedation, so adaptations in treatment protocols may be necessary. Careful monitoring of the airway is mandatory. These cases should not be attempted by the single-operator SP and a dedicated SP should be employed.

9. Documentation required for procedural sedation and analgesia

Accurate documentation of all sedation processes is an important tool in the hands of the sedation practitioner. Documentation is crucial to protect the sedation practitioner in case of legal challenges. If it was not written down, it never happened.

9.1 Before sedation

Documentation is aimed at gathering information from the patient, as well as giving information to the patient or carers. Recorded information should include:

9.1.1 Valid informed consent to sedation and analgesia for medical/dental procedures (see Section 4 and Appendix 3)

9.1.2 Medical history questionnaire (Appendix 4)

A recently updated medical history questionnaire should be evaluated by an appropriately trained sedation practitioner, preferably before the day of the procedure. This must be re-checked before the initiation of sedation for possible changes in the patient's condition. The patient's weight and height must be indicated. In this way obese patients will be flagged and sedation practitioners may make an informed decision whether the patient is fit for sedation outside the hospital setting. Patients must be asked about significant underlying surgical or medical disorders, e.g. upper respiratory tract infection, allergies, sleep apnoea, and uncontrolled hypertension or diabetes mellitus. Use of chronic medication and drugs, including over-the-counter medications and recreational drugs, should be noted.

The name, address, and contact number of the carer/parent/guardian must be obtained and recorded. If there is no carer to provide aftercare to the patient, the sedation should be rescheduled.

9.1.3 Pre- and post-sedation instructions (Appendices 8 and 9)

Pre- and post-sedation instructions should be provided at the same time when the procedure is scheduled. This will give the patient/carer enough time to formulate questions and to organise an escort and transport as necessary.

Information and instructions given to the patient and carer should include the aims, objectives and possible side-effects of sedation. Information and instructions should be both verbal and written and must be given to both the patient and carer. 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 where the sedation will take place.

A responsible adult must accompany the patient home. Sedation must not be administered if an escort is not available. 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.

Contact details of a physician, hospital and ambulance service in the event of any procedure- or sedation-related adverse events in the first 24 hours after sedation, must be included in the instructions.

9.1.4 Cover letter to the patient/parent/guardian (Appendix 10)

It is recommended that every patient/parent/guardian receive a cover letter confirming the date, time and location of the procedure. This letter may also give an indication of the estimated fee for the sedation. An explanation of the forms that the patient/carer/guardian must complete will ensure that everything is in place on the day of the procedure.

9.1.5 Pre-procedural checklist (Appendix 11)

The aim of this document is to provide a final checklist before the start of the sedation process and procedure. 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. The checklist must be completed and signed by the sedation practitioner.

The sedation practitioner must ensure that the following information has been obtained and documented:

- Details of the patient, including ASA classification.
- Details of the procedure (elective or emergency).
- Completion of the medical history questionnaire, which must be checked by the sedation practitioner.
- Confirmation that the patient is fasted appropriately.
- History of previous sedation, i.e. failed sedation, previous airway problems and contraindications to sedation.
- Physical examination and evaluation of the patient, including a focused assessment of the airway.
- Details of chronic medication and whether the patient took any medication on the morning of the procedure, e.g. anti-hypertensives.

- Details of the prescribed pre-sedation medication, if any, with details of the prescribing practitioner, the administering practitioner and the time of administration.
- Confirmation that the facility, equipment, monitoring devices and drugs were checked for safe sedation practice (Appendix 2).

9.2 During sedation

9.2.1 Sedation monitoring flow chart

A sedation monitoring flow chart is a time-based document that must be completed during the procedure (Appendix 7). This includes the name, age, weight and fasting status of the patient, and the route, dose and time of administration of any drugs, including N_2O and O_2. Site of venous access and type and volume of intravenous fluids administered should be recorded. Information obtained from clinical and electronic monitoring should be shown at no longer than 10 minute intervals. Requests from the operator for deeper levels of sedation should be noted. Total dose of drugs given must be shown.

Adverse events and complications must be documented on the monitoring chart. Any resuscitation measures instituted, escalation of care, or hospitalisation must be recorded. Adverse events can be classified as critical, standard, or lesser adverse events. (See 1.4). Critical events warrant immediate reporting within sedation care systems, e.g. the sedation society, and automatic peer scrutiny for continuous quality improvement.

Any behavioural problems occurring during or after sedation must be recorded on the monitoring chart.

In the case of a single-operator SP, a record may be regarded as contemporaneous if it is made immediately after the procedure.

9.2.2 Sedation scoring systems (Appendix 6)

Sedation scoring systems are clinical tools to monitor the level of sedation. Even though these scoring systems are a practical way to determine the level of sedation, they have some drawbacks. They are all subjective and dependent on the interpretation by the individual sedation practitioner. In order to determine the level of sedation, the patient has to be stimulated, either verbally of physically – in other words, waking the patient up to evaluate the level of sedation. This defies the purpose of the sedation and may be disruptive to the procedure and the sedation process.

It may also be impossible to monitor response to verbal demand, e.g. in very young patients who are unable to understand or respond. Other groups that may be difficult to monitor include mentally handicapped patients and when language barriers are present.

Defining a 'purposeful response' is dependent on the interpretation of the sedation practitioner. Examples of a purposeful response may include responding to commands like opening the eyes, opening the mouth, taking deep breaths and pushing a painful stimulus out of the way.

As yet, the only clinical way to distinguish between moderate and deep sedation, is by loss of verbal response (or light tactile stimulation), i.e. between awake and asleep. Once verbal response is lost, it is impossible to determine whether the patient is under deep sedation or general anaesthesia. It is therefore better to aim to keep the patient awake (conscious), rather than asleep (unconscious) . Once verbal contact is lost, the patient may drift from deep sedation into general anaesthesia.

So, if anaesthesia is about keeping patients asleep, sedation is about keeping patients awake – this is especially true for procedures performed outside the hospital environment. This however is not always possible, since there are situations where deep sedation is required, e.g. in very painful procedures, very young patients, mentally handicapped patients and when complete immobility is required.

9.3 During recovery

9.3.1 Post-sedation monitoring chart

After the procedure is completed, patient monitoring must continue until the patient is fully recovered. Vital signs (blood pressure, heart rate, respiratory rate, oxygen saturation, level of consciousness and pain levels) must be measured and documented at regular intervals (Appendix 12).

9.3.2 Post-sedation instructions (See 9.1.3 and Appendix 9)

Post-sedation instructions must be provided at the time when the procedure is scheduled, so the patient/carer may have sufficient time to organise an escort, transport and time off as necessary.

9.3.3 Discharge scoring systems (Appendix 13)

Discharge scoring systems can be used to define and document a patient's clinical state immediately before discharge. These include validated scoring tools such as the Modified Aldrete Scoring System or the Modified Post Anesthetic Discharge Scoring System (MPADSS). 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 post-anaesthetic care unit. The MPADSS was designed to determine home-readiness after ambulatory surgery, and not specifically for assessing patients undergoing PSA.

When using the Modified Aldrete Scoring System to evaluate the patient, the patient 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, e.g. 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. 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 pass urine within 6–8 hours of discharge from the sedation unit.

9.3.4 Documentation after discharge

The physician must be satisfied that aftercare is optimal before the patient is discharged. A responsible adult escort, who is capable of looking after the patient unaided, must accompany the patient home after treatment under moderate sedation (conscious sedation) and remain with them as a minimum for the rest of the day. The responsibility of the escort extends to ensuring that the patient takes their normal prescribed medication and to contact the sedation practitioner in the case of adverse events. Both 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 adverse events.

Sedation must not be administered if an escort is not available.

An adult who receives only nitrous oxide/oxygen inhalation sedation (less than 50%) does not normally require an escort.

The patient and carer must be supplied with written and verbal information with regard to post-discharge activities. This is extremely important as it has medico-legal implications.

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.

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.

In general, the drugs selected for PSA should have a duration of action appropriate for 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, dexmedetomidine) 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 advanced sedation techniques. Sedation practitioners using these drugs must have *at least* a qualification in advanced life support.

Off-label and unlicensed drugs are sometimes used for adult PSA. Off-label drug use implies the use of licensed drugs outside the conditions of the license. Unlicensed drug use means the use of pharmaceutical products that have been approved by a licensing authority of a specific country. The unlicensed or off-label use of drugs is common practice worldwide, as well as in South Africa. Sedation practitioners are responsible for choosing the right drug and dose after careful consideration of expert opinion, scientific data on the drug(s), and what is published in the literature.

11.1 Sedatives

Sedatives do not produce analgesia and should not be used alone for painful procedures. 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 and other sedatives/analgesics. The effects of both categories of drugs are potentiated when used in combination, increasing the risk of respiratory compromise with possible airway obstruction, adverse events, and the progression to deeper levels of sedation. Titration remains a safe option in the administration of drugs.

Sedatives intended for procedural sedation include benzodiazepines (e.g. midazolam, diazepam, flunitrazepam, lorazepam, or temazepam) and dexmedetomidine. The most frequently used benzodiazepine is midazolam.

11.1.1 Benzodiazepines (BZDs)

The BZDs are the most commonly used sedative drugs in sedation practice and can be used by both operator-sedation practitioners for standard sedation techniques, and dedicated sedation practitioners as part of an advanced sedation technique.

11.1.1.1 Midazolam

Midazolam is a short-acting BZD with sedative, anxiolytic, amnestic, anticonvulsant and muscle relaxant effects. Since it has no analgesic effect, it should, when necessary, be combined with opioids during PSA.

It is the most commonly used benzodiazepine and has a clinical effect in 1–2 min, and a maximum effect after 13 min. Used in the recommended doses (Table 3), the administration of midazolam should result in a conscious, compliant patient.

Table 3: 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	7.5 mg	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	7.5 mg	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.
*** With elderly patients, it is advised that smaller intravenous doses must be titrated to effect.

The principal side-effect seen with intravenous administration of midazolam is that of respiratory compromise. Repeated doses should therefore be administered carefully to avoid complications such as airway obstruction and hypoxia. This is especially relevant in the elderly and patients with comorbidities. The drug should therefore be titrated to effect. The respiratory depression produced by midazolam has a synergistic relationship with the respiratory depression produced by other sedative drugs, especially the opiates. When used on its own in higher than recommended doses, midazolam administration is likely to result in the loss of upper airway muscle tone that may lead to airway obstruction. It produces minimal effects on the cardiovascular system in ASA I and II patients.

Paradoxical reactions, excitement and agitation occur in up to 15% of patients. Adding more midazolam may exacerbate the symptoms until severe respiratory depression and even unconsciousness 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. With severe side-effects like paradoxical reactions, the use of a BZD reversal agent, flumazenil, may be an option to administer to patients.

Nasal administration of drugs, like sedatives and analgesics, has become quite an exciting way of administering drugs. It can be considered in certain cases, e.g. needle phobias and special needs patients. The bioavailability of nasal midazolam is said to be about 80% which is superior to oral drugs.

Since intranasal midazolam can cause a burning sensation when administered, it is advised to use a mucosal atomisation device (MAD). Alternatively lignocaine 2% can either be administered before the intranasal midazolam or mixed with the solution to prevent burning of the nasal mucosae. Administration of midazolam may leave a bitter aftertaste that may last for several days. Careful selection of patients is necessary.

Intramuscular administration of midazolam 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.

11.1.1.2 Remimazolam

Remimazolam is a new benzodiazepine with a promising pharmacological profile, but still under evaluation in phase 3 trials.[15] It is metabolised by tissue esterases and has a rapid, more predictable offset of action than other clinically available benzodiazepines. Remimazolam has been developed for induction of anaesthesia and moderate or conscious sedation for minor invasive procedures. Remimazolam was found to be both faster acting and shorter lasting than midazolam, and showed a faster recovery time.

Remimazolam produces rapid dose-dependent sedation at doses from 0.075 mg/kg, with onset times of 1–3 min. It seems that remimazolam 0.075–0.20 mg/kg produces similar peak sedation to midazolam 0.075 mg/kg, but median recovery times at these doses ranged from 5 to 20 min, compared to 40 min for midazolam. This drug could be an exciting addition to the armamentarium of the sedation practitioner in future.

11.1.1.3 Buccolam

Buccolam is a new benzodiazepine that contains oro-mucosal midazolam in pre-filled oral syringes of 2.5 mg, 5 mg, 7.5 mg, and 10 mg. The solution, when administered, should be placed between the gums and cheek so that the drug is directly absorbed into the bloodstream.

11.1.1.4 Triazolam

Triazolam is a BZD which has been widely used for sedation/anxiolysis for intraoral procedures. The drug provides effective anxiolysis and amnesia. It is a useful sedative for PSA, as it has no active metabolites and is effective via the sublingual or oral routes (Table 4). Sublingual administration has been found to increase absorption by 28% over oral administration resulting in higher plasma concentrations at 1–2 hours. Sublingual triazolam (0.125–0.25 mg) achieves clinical effect within 20 minutes.

Table 4: 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

11.1.1.5 Temazepam

Temazepam is available exclusively for oral use. It has gained popularity in dentistry as an oral sedative for patients with learning difficulties. It has a half-life of 1.3–3 hrs, which means that it lasts longer than is ideal for an oral sedative for sedation. The drug is useful when administered by the operator-sedation practitioner in a dose of 20 mg two hours before the procedure.

Temazepam is also used for special needs patients, e.g. cerebral palsy, a dose 20 mg for hypnosis the evening before the procedure, and 20 mg an hour before procedural sedation.

Cimetidine, a H_2 receptor blocker, has been shown to increase blood levels of a metabolite of diazepam, and this has been implicated in delayed recovery. Temazepam is not affected by the H_2 receptor blockers; midazolam does not seem to be contraindicated in patients on H_2 receptor blockers.

If the patient becomes disinhibited and unmanageable after the administration of BZD, flumazenil, the specific BZD antagonist, should be considered to reverse the action of the BZD. 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.

11.1.2 Non-benzodiazepine sedatives

11.1.2.1 α_2-agonists

Two α_2-agonists, clonidine and dexmedetomidine, are used for sedation in clinical practice. They are sedative analgesics with anxiolytic, but not amnestic, effects. Used in recommended doses, they have minimal 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 5). It has a long duration of action as it is highly lipophilic.

In doses higher than those recommended for PSA, it can be used as an adjunct to lower the blood pressure and this may be requested by the surgeon for certain procedures. This practice should be carefully considered in the out-of-hospital environment. Clonidine may interact with various drugs, e.g. the antidepressants, and can cause rebound hypertension.

Table 5: Dosing schedule for clonidine

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

Dexmedetomidine is a highly selective α2-agonist (Table 6). 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 compromise and patients can be roused easily.

If needed for longer procedures, it needs to be administered by a slow initial bolus followed by a continuous infusion.[16] For adult patients, dexmedetomidine is generally initiated with a loading infusion of 1 (one) mcg/kg over 10 minutes. For patients over 65 years of age or those undergoing less invasive procedures such as ophthalmic surgery, a loading infusion of 0.5 mcg/kg over 10 minutes may be suitable. Maintenance dosing of dexmedetomidine should generally be initiated at 0.6 mcg/kg/hr and titrated to achieve desired clinical effect with doses ranging from 0.2 to 1 mcg/kg/hr for all procedures. The rate of the maintenance infusion should be adjusted to achieve the targeted level of sedation. It is best to individualise dexmedetomidine dosing and titrate to the desired clinical effect.

Caution is required with the administration of dexmedetomidine as cardiovascular changes related to speed of injection can occur. Side-effects include profound bradycardia, sinus arrest and hypotension, particularly in patients with heart block or a high resting vagal tone. Cardiac arrest associated with the use of dexmedetomidine has been reported. Dexmedetomidine may also cause a dry mouth and nausea.

In South Africa, dexmedetomidine is licensed for use where sedation is administered in an operating theatre in a hospital setting and an intensive care setting.

Combinations of ketamine and dexmedetomidine are becoming increasingly popular for in-hospital use for PSA. Dexmedetomidine is increasingly being used for nasal and buccal administration for PSA in children.

Table 6: Dosing schedule of dexmedetomidine

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

11.1.2.2 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 anti-emetic, 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.

11.2 Anaesthetic induction agents

11.2.1 Propofol

Propofol is a non-opioid, non-barbiturate, sedative/hypnotic drug and probably the most common and popular intravenous sedative agent. It has a rapid onset time of 30 to 60 sec and a short and predictable duration of action due to rapid equilibration between the blood and the brain. There is rapid redistribution of the drug to peripheral tissues and a rapid metabolic clearance from the blood. The half-life of propofol is 4.4 min. With the above characteristics, propofol is an ideal drug for PSA by trained sedation practitioners with airway certification.

Propofol can be used in small boluses titrated to effect. Due to its short context-sensitive half-time, it is a good drug to use as a continuous infusion, especially with the availability of TCI pumps (Table 7 and 8).

Propofol is a very effective hypnotic and amnestic. However, it has no analgesic properties. It is therefore usually combined with opioids during sedation for their synergistic effects. This may lead to significant cardiovascular depression and hypotension. Due to its narrow safety margin, deep sedation, airway obstruction and apnoea can occur rapidly and sometimes unpredictably. Patients must be carefully monitored.

Propofol should only be administered by an experienced sedation practitioner skilled in airway management and with anaesthetic experience. It is recommended that the drug not be used by an operator-sedation practitioner.

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) or ketamine 0.1 mg/kg injected intravenously before propofol administration, 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). In cases of prolonged sedation, patients must be carefully monitored for the development of PRIS.

For initiation 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.

Propofol is sterile, however it is a lipid-based emulsion, a vehicle known to support growth of micro-organisms. Sepsis and postoperative infection can occur as a result of unsafe practices, such as reuse of syringes on multiple patients, use of single-use medication vials for multiple patients, and failure to practise aseptic techniques.

Table 7: Dosing schedule for bolus doses of propofol

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

Table 8: 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

11.2.2 Ketamine

Ketamine is a phencyclidine derivative classified as an N-methyl-D-aspartate glutamate receptor antagonist (NMDA). Ketamine reduces the pre-synaptic release of glutamate, which is an excitatory neurotransmitter. The drug promotes central sympathetic stimulation and inhibition of neuronal catecholamine uptake.

Ketamine is available as a racemic mixture of two isomers, S (+) and R (-). This mixture is still used and very popular. Ketamine is, however, also available as a single isomer, S (+), Ketanest®.

Ketamine differs from other sedatives and has both analgesic and sedative characteristics. It can be used as the sole agent for painful procedures. It has a rapid onset of action (60–90 sec). Ketamine dissociates the thalamo-neocortical and limbic systems (emotional brain). The CNS is in effect dissociated from outside stimuli, i.e. pain, sight, sound (unpleasant experiences). The dissociative state caused by ketamine is characterised by sedation, intense analgesia, amnesia, intact protective reflexes, and stable cardiovascular parameters. These characteristics make ketamine such an attractive/safe and popular drug when used for procedural sedation.

The increasing popularity of ambulatory surgery has created a tremendous interest in ketamine for PSA. This is because of its short duration of action when used as boluses and in low doses, safety profile (used in small doses by the trained sedation practitioner), possibility of administration via many routes, the postoperative analgesic effects, and compatibility with other drugs. The drug has become a key component of advanced sedation techniques for medical and dental procedures. It must, however, be noted that the drug is not advised for use by single operator-sedation practitioners.

The multiple actions and cardiovascular stability of ketamine make it a very useful agent for painful procedures. Ketamine inhibits the catecholamine uptake, which exerts a sympathomimetic effect. It can increase the heart rate and blood pressure when higher doses are used. These side-effects are rarely seen with the doses recommended for PSA. Recent studies show that ketamine does not increase intracranial pressure at doses used for PSA.

Ketamine does not cause respiratory depression when titrated and injected slowly. Rapid intravenous administration may lead to intense respiratory depression. The laryngeal reflexes are usually intact with the doses used for PSA. What makes the drug extremely useful is its bronchodilatory properties. It is believed that ketamine protects against hypoventilation during deeper levels of sedation.

Ketamine stimulates the production of saliva and trachea-bronchial secretions. These effects are minimal with the low doses of ketamine recommended for PSA. There is no consensus on the use of prophylactic co-administration of anti-sialogogues and the concomitant use of a prophylactic anti-sialogogue is seldom necessary in adult patients. However, atropine may be a better drug than glycopyrrolate when administered with ketamine. Studies show a higher incidence of adverse events, e.g. nausea and vomiting, postoperative agitation, and airway obstruction when ketamine is used with glycopyrrolate.

Emergence of delirium may be associated with the use of ketamine in adults. Midazolam can be co-administered (≤ 0.05 mg/kg) to reduce the incidence of delirium.

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. Nausea and vomiting may occur, but are dose-dependent effects, and are more significant with intramuscular administration.

Ketamine can be given via multiple routes (Table 9), including intranasally. A burning sensation in the nose is possible, so lignocaine can be used before ketamine administration.

The versatility, efficacy, safety profile, and low cost of ketamine have promoted its widespread use and inclusion in the WHO list of "Essential Medicines" for a basic healthcare system.

Sedation practitioners must note that ketamine has become a very popular recreational drug.

Table 9: 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 or analgesics	> 5 minutes	30 minutes**	4–6 hours
Intravenous	0.5–1 mg/kg***	1.5 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 if necessary, until desired level of sedation achieved.

11.2.3 Etomidate

Etomidate is an intravenous drug that offers an alternative to provide procedural sedation, with maintenance of cardiovascular and respiratory function. Etomidate produces sedation and anxiolysis and is a useful alternative intravenous 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 recommended.

The side-effects of etomidate include myoclonus, nausea and vomiting and transient adrenal suppression. These side-effects are seldom seen at the doses administered for PSA (Table 10).

Table 10: 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

* About 0.1 ml/kg/hour titrated to effect.

11.3 Analgesics

11.3.1 Opioids

Opioids are analgesic drugs capable of inducing varying degrees of analgesia and sedation. Many different opioids are now available to relieve pain during procedures. Synthetic opioids such as alfentanil, fentanyl, sufentanil and remifentanil are extremely useful to supplement sedatives for short painful, and longer, procedures.

Respiratory and cardiac depression, particularly when used in combination with other respiratory depressant drugs (e.g. midazolam), may occur if not titrated to effect for PSA. Although opioids may have sedative side-effects, they **must not primarily** be used to sedate patients for either painless or painful procedures.

Opioids potentiate the effects of other sedatives, and 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 to effect. The sedation practitioner 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 down gastrointestinal motility and can induce nausea and vomiting.

Capnography is highly recommended when potent opioids are administered, and meticulous clinical 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.

11.3.1.1 Fentanyl and alfentanil

Fentanyl and alfentanil are potent short-acting opioids and probably the most popular drugs for use in PSA outside of the operating theatre (Tables 11 and 12). They have a safe and rapid onset and offset of effect, which are usually predictable and precise. They are easily titrateable and have reduced or rapidly reversible side-effects. Although short-acting opioids may be safely used in various applications, potential side-effects such as bradycardia, hypotension, respiratory depression, postoperative nausea and vomiting, and shivering are possible.

Short-acting opioids have significant potential for respiratory and cardiac depression, particularly in combination with other respiratory depressant drugs e.g. midazolam. Practitioners administering these drugs intravenously should be experienced sedation practitioners with airway management skills.

The doses of fentanyl and alfentanil, when used in combination with other depressant drugs (such as midazolam), should be decreased and titrated to effect. There is no specific dose, only a maximum dose. Slow titration of small boluses will decrease, but not eliminate, the possibility of adverse events. Monitoring of respiratory depressant effect remains crucial.

These drugs should not be used in patients at risk of upper airway obstruction since administration of fentanyl or alfentanil may precipitate this event and should be avoided. The short-acting opioids must also be used carefully in the elderly, the obese, and patients with obstructive sleep apnoea. Alternative analgesics are recommended.

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

Table 11: 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**	3– 6 minutes	2–3 minutes	2 µg/kg	30 minutes*

* Dose-related
** Titrate to effect and repeat dose every five minutes, until desired level of analgesia is achieved.

Alfentanil is an extremely popular short-acting opiate and can be used in small titrated boluses or as an infusion. If a continuous infusion is maintained for > 30 minutes, the context-sensitive half-time is longer than that of fentanyl. In this situation, the monitoring period after the infusion has been discontinued must be lengthened accordingly. The drug has a rapid onset and short duration of action, making it useful for short, painful procedures. Sedation practitioners must take cognisance of this short duration of action when the drug is administered prior to the painful stimulus. If the procedure is expected to take longer than 10 minutes, then either titrated bolus doses or an infusion technique can be used.

Table 12: 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.

11.3.1.2 Sufentanil

Sufentanil is an extremely potent opioid analgesic (Table 13). 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 intensive care 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 via this route.

Table 13: 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

11.3.1.3 Remifentanil

Remifentanil is an extremely potent, ultrashort-acting opiate that can be used in combination with hypnotic sedatives to provide sedation and analgesia. The drug is cleared by nonspecific blood and tissue esterases (whereas other short-acting opiates require hepatic clearance). Remifentanil should not be used outside the hospital environment, and must not be administered by any personnel other than anaesthetists or highly trained sedation practitioners with anaesthetic experience. For PSA, small bolus doses can be titrated, but with extreme care. The dose administered by continuous infusion must not exceed 0.05 µg/kg/minute.

Remifentanil when used with propofol for PSA should be administered in a separate syringe. Precise titration of remifentanil when used in combination with propofol should be achieved by using TCI.

Short-acting opiates commonly used for PSA outside the hospital environment:

The short-acting opioids have pharmacokinetic/pharmacodynamic profiles that are characterised by rapid onset and offset, enabling faster induction and emergence rates, making them excellent analgesic agents for PSA.

Onset and offset rates of short-acting opioids:

Pharmacokinetics	Remifentanil	Sufentanil	Alfentanil	Fentanyl
Onset	1.6 min	6.2 min	0.96 min	6.6 min
Offset: context-sensitive half-time	–6 min	30 min*	50–55 min*	> 100 min

* Context-sensitive half-time is the time required for a drug concentration in blood or at effect site to decrease by 50%; the above times are based on a 3-hour infusion. Of note is that alfentanil has a prolonged duration of action when used as a continuous infusion.

Opioids act in synergy with hypnotics and sedatives to produce a clinical effect and must be used carefully. Titration is recommended.

11.3.2 Tramadol

Tramadol is an atypical opioid (Table 14). It is an agonist at the µ-opioid receptor, but also inhibits re-uptake of noradrenaline and serotonin. Its use with serotonergic agents is contraindicated due to an increased risk of serotonin syndrome. Tramadol can be used in combination with propofol for PSA for painful procedures, as it rarely causes respiratory depression. Tramadol should be used with caution in patients taking psychotropic medication, and not be administered with 5HT3 receptor antagonists (e.g. granisetron, ondansetron).

Table 14: Dosing schedule of tramadol

Route of administration	Dose	Maximum dose	Time to peak effect
Oral	50–100 mg	400 mg/day	40 minutes
Intravenous	1–2 mg/kg over 5 minutes	400 mg/day	20 minutes, with duration of action up to 9 hours

11.3.3 Nitrous oxide (N_2O_2)

N_2O_2 is an anaesthetic agent with analgesic and sedative properties. It has a rapid onset and offset of action, and an excellent safety profile. Nitrous oxide is available in pure form or as Entonox®, premixed in a 1:1 (50% of each) ratio with oxygen.

The success of nitrous oxide sedation depends on appropriate titration of nitrous oxide to the individual patient's response and should be supported by behaviour management techniques.

Nitrous oxide sedation is very popular for use by operator-sedation practitioners for PSA and is usually used for brief, simple procedures. It is recommended that a second individual should monitor the patient and assist the operator-sedation practitioner. The recommended dose is between 20–50% (Table 15) and, in most cases, it will need to be supplemented, for example, with local anaesthesia. If other sedatives are administered, respiratory depression must be anticipated. Used in a concentration of < 50%, nitrous oxide produces minimal sedation and analgesia and at this concentration only clinical monitoring is necessary.

When used in a concentration of > 50%, nitrous oxide produces moderate sedation and analgesia or conscious sedation. The patient must then be monitored with a pulse oximeter and a blood pressure apparatus in addition to clinical monitoring. With concentrations above 50%, supplemental oxygen should be continued for several minutes after N_2O_2 has been discontinued in order to counter the possibility of diffusion hypoxia. N_2O_2 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 patients in whom bowel obstruction is suspected.

When nitrous oxide is used as a sole agent for sedation, fasting is not necessary and pulse oximetry is not routinely required.

Dedicated, purpose-designed machines for the administration of inhalation sedation should be used. Such machines must conform to current standards and be maintained according to manufacturers' guidance with regular, documented servicing. Dedicated inhalation sedation machines will not allow hypoxic levels of sedation.

Gas cylinders must be stored safely and be secured with regard to current regulations to prevent injury.

Scavenging of waste gases must be active and sufficient to fully conform to current safety standards.

Table 15: Dosing schedule of nitrous oxide

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

11.3.4 Methoxyflurane

Methoxyflurane is a highly potent inhalational anaesthetic agent. It was mostly abandoned from general anaesthesia for renal toxicity. It has however been reintroduced in clinical practice for use in procedural sedation as a self-administered analgesic. A simple hand-held inhalator device filled with a fixed 3 ml vial of methoxyflurane for 20–30 min is used. Even though the use of methoxyflurane is controversial, it is claimed that the occupational hazards and organ toxicity are negligible with the low dose used.[17]

11.3.5 Local/regional anaesthesia

A significant number of procedures for PSA are done under local/regional anaesthesia. The sedation practitioner must be aware of which local anaesthetic agent is used, the possible adverse events, and the dose administered by the surgeon. The effective use of local anaesthetic agents plays a significant part in the success of PSA. Local anaesthetic agents can be used topically, for infiltration, or for local or regional nerve blocks.

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

Warming and alkalinising the local anaesthetic solution can reduce the sting on infiltration.

EMLA® (Eutectic mixture of local anaesthetics of lidocaine 2.5% and prilocaine 2.5%) is available as a cream or a patch for topical anaesthesia usually before cannulation in extremely anxious patients. It requires up to two hours to achieve full effect and can be used on intact or broken skin. The patch is probably the best option for topical anaesthesia. EMLA® has a penetration depth of 3–12 mm.

EMLA® should not be used in patients allergic to any ingredient in EMLA® cream, e.g. patients allergic to the ester local anaesthetic agents or suffering from methaemoglobinaemia.

11.3.6 Simple analgesics

Simple analgesics are analgesics that, in the recommended doses, do not cause sedation. They are extremely useful agents for use by sedation practitioners as part of a PSA technique. They can be used pre-, intra-, and postoperatively.

Paracetamol and nonsteroidal anti-inflammatory drugs (NSAIDs) are commonly used, but the time to onset of action must be taken into consideration before a procedure is performed (Table 16.

It is sometimes indicated to use a weak opioid, e.g. tramadol, for patients that still have significant pain after taking paracetamol and the NSAIDs.

Table 16: 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	0.5–1 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

11.4 Antagonists

11.4.1 Flumazenil

Flumazenil (Table 17) reverses the sedative and respiratory depressant effects of BZDs. It should be readily available whenever BZDs are used. Its duration of action is approximately one hour, and resedation may occur if large doses of BZD 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 BZD for seizures or behavioural disturbances, administration of flumazenil may precipitate these symptoms.

Table 17: 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.

11.4.2 Naloxone

Naloxone is a specific opioid antagonist (Table 18). 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. 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. In an emergency, if intravenous access is not available, the initial doses may be given intramuscularly. It can also be administered intranasally.

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

Table 18: Dosing schedule of naloxone

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.

11.5 Novel therapies

11.5.1 Ketofol

Ketofol is a combination of ketamine and propofol, that can be administered together in the same syringe, or independently in two separate syringes, with the one following the other. The literature suggests that the combination can be safely mixed in the same syringe. There has been increasing interest in the mixture for PSA and the combination has become extremely popular.

Ketofol can be used as bolus for PSA for short procedures, or boluses combined with an intravenous infusion for longer procedures using TCI.

The combination of ketamine and propofol (ketofol) probably enables the use of lower doses of both drugs, thereby minimising adverse events like respiratory depression. Propofol mixed with racemic ketamine is popular for PSA. The optimal combination (ratio) and optimal infusion rate are the focus of research studies. It will probably depend on the level of sedation that is planned. It is advised to use as low as possible a dose of ketamine in the mixture. The addition of ketamine to propofol infusion will prolong recovery unless infusion rates are decreased.

Addition of ketamine to propofol infusion resulted in delayed recovery when a ratio of 1:1 was used.[18]

It is suggested that a 10:1 propofol-ketamine mixture provides the greatest benefit for continuous intravenous sedation in adults undergoing surgery. Better haemodynamic stability and faster recovery times will be achieved with this mixture. Lowering the ketamine concentration may also be associated with earlier discharge times.[19]

11.5.2 Melatonin

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, the prevention and treatment of jet lag, and successfully used as a sedative for premedication. 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.

11.5.3 Trazodone

Trazodone is a triazolopyridine. It is mostly used for the treatment of depression, but also has sedative effects. Trazodone can be used as an alternative if paradoxical reactions to midazolam have previously been recorded. An extended-release tablet is also available which should be used on an empty stomach at bedtime.

Usual adult dose

Immediate-release tablets: Initial dose: 150 mg per day in divided doses.
Extended-release tablets: Recommended starting dose: 150 mg once daily.

11.5.4 Zaleplon

Zaleplon is a short-acting sedative/hypnotic with an ultrashort half-life. It is chemically unrelated to the benzodiazepines, although it has similar effects due to its affinity for the same receptors on nerve cells. The drug 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 5–20 mg of oral zaleplon producing comparable anxiolysis to triazolam. Recovery from zaleplon is faster than recovery from triazolam.

Appendices

The authors would like to thank Dr André du Plessis and colleagues of Sedation Solutions, London, for sharing the contents of some of their information sheets for patients.

Appendix 1:
Basic equipment and drugs for procedural sedation and analgesia in adults

All equipment should be checked regularly and stored in a 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 alpha-agonist)
Lignocaine
Glucose 50%
Hydrocortisone, methylprednisolone or dexamethosone
Promethazine (or other H_1-antagonist)
Nitroglycerine spray
Aspirin
Salbutamol
Suxamethonium
Intralipid
Calcium-channel blocker e.g. nifedipine
Beta blocker e.g. esmolol
Selective alpha 1 adrenergic and non-selective beta-adrenergic receptor blocker e.g. labetalol

Reversal agents i.e. flumazenil, naloxone

Specific antagonists must be immediately available where a sedation practitioner administers opioid analgesics and/or benzodiazepines for PSA, regardless of the route of administration.
Reversal agents may be used for depression of ventilation/breathing to restore spontaneous breathing.
Naloxone is used to reverse opioid-induced respiratory depression.
Flumazenil is indicated to reverse benzodiazepine-induced respiratory depression.
After reversal, the patients must be monitored for a longer period of time in the recovery room to prevent re-sedation.

Appendix 2:

Practice appraisal protocol

REF	TOPIC	YES	NO
A	**GENERAL**		
1	Does the practice provide basic intravenous sedation e.g. midazolam only?		
2	Does the practice provide advanced intravenous sedation techniques (combination of drugs)?		
3	Does the practice provide inhalation sedation (IS)?		
4	Do children under 12 receive intravenous sedation at the practice? If yes, which drugs are used?		
5	Are sedation patients only ASA I or II? Do you do any fragile ASA II patients under sedation? Do you do any ASA III patients?		
6	Does the practice only use operator-sedation practitioners? Which drugs are they using for sedation?		
7	Does the practice normally operate with a separate sedation practitioner (dedicated)?		
8	Is the practice in good standing with the HPCSA?		
B	**FACILITIES**		
1	Do the premises appear to be well maintained?		
2	Are the recovery and waiting areas separate?		
3	Is there good lighting and ventilation in all clinical areas?		
4	Is there access for emergency services to the building?		
5	Is there access for emergency services to the surgery? Do you have a wheelchair available to transport patients?		
6	Is there space within the surgery to deal with an emergency?		
7	Is there space within the surgery for the sedation practitioner to work effectively?		
8	Does the practice layout provide privacy for sedation of patients?		
9	Can the dental chair be placed in the head-down tilt position where applicable?		
C	**SEDATION PRACTICE**		
1	Does the practice follow a recognised sedation protocol?		
2	Are patients normally assessed for suitability for sedation at a preceding appointment?		
3	Are the possible options for anxiety and pain control explained to the patient prior to obtaining consent for sedation?		
4	Do patients have the opportunity to ask questions?		
5	Are blood pressure and pulse oximetry assessed as part of the patient assessment and documented? Is capnography used in the practice?		
6	Is the patient monitored by a trained and experienced member of staff, during sedation and recovery?		
7	Are recognised discharge criteria followed?		
8	Where are patients normally recovered?		

9	Does the sedation practitioner or trained staff discharge the patient?		
10	Are patients given a telephone or cell phone number to call in case of problems or complications?		
11	Do all sedation patients have an escort? Do they leave for home by car/taxi?		
12	Does the practice prohibit patient escorts from remaining in the surgery during the procedure?		
13	Is there an agreed protocol with the local hospital and paramedics in case of an emergency?		
D	**DOCUMENTATION**		
1	Are patients given written preoperative instructions?		
2	Are patients given written postoperative instructions?		
3	Are the following noted and checked prior to sedation? • Medical, dental and social histories: medical history questionnaire • Previous sedations/general anaesthesia • ASA category • Fasting • Preoperative vital signs (including BP) • Treatment required • Information to the patient regarding the procedure		
4	Is written valid consent for sedation and the procedure obtained prior to sedation? Is this sometimes changed during sedation?		
5	Is a contemporaneous record (sedation flow sheet) kept of the administration of sedation?		
6	Do sedation practitioners keep a logbook or records of sedation cases?		
E	**EQUIPMENT**		
1	Is there equipment for measurement of blood pressures and oxygen saturation values?		
2	Is there a dedicated IS machine? Does this have the following? – Minimum delivery of 30% O_2 – Emergency N_2O cut-off		
3	Is the IS machine checked by a suitably trained and qualified member of staff prior to each session?		
4	Is there scavenging of waste gases?		
5	Is the IS machine serviced according to the manufacturers' guidelines?		
6	Is nitrous oxide stored according to current safety requirements?		
7	Date of last service?		
8	Is a pulse oximeter available? Is an ECG monitor available? Is a capnograph available? Are they all being used to monitor the patient?		
9	Does the pulse oximeter have audible alarms?		
10	Is the monitoring equipment serviced according to the manufacturers' guidelines?		
11	Date of last service?		
12	Is emergency oxygen available? What size cylinder? Is there a back-up supply/cylinder?		

13	Is there a self-inflating bag valve mask with reservoir bag (e.g. Ambu-bag)? Is there a 40% oxygen mask? Is there a rebreathing bag?		
14	Is there a pocket face mask (e.g. Laerdal pocket mask) to provide assistance with ventilation?		
15	Is there a set of nasal cannulae available?		
16	Is suction available and in working order? How often is suction cleaned and checked?		
17	Is back-up suction available?		
18	Is a laryngeal mask available?		
19	Are Yankauer suckers available?		
20	Is a defibrillator available?		
21	Is an AED available?		
22	Date of last service of monitoring equipment?		
23	Is the emergency equipment readily available? (see SASA guidelines)		
F	**DRUGS**		
1	Are emergency drugs immediately available? (see SASA guidelines) Which ones do you have?		
2	Are all drugs, sedation and emergency, in date?		
3	Is there a designated person responsible for stock control?		
4	Are all emergency drugs readily available?		
G	**STAFF**		
1	Names and qualifications of all dentists, doctors and nursing staff involved in sedation practice at this address. Do they all have airway certification. Please supply details.		
2	Can all staff demonstrate in-house training in sedation, as well as a commitment to continuing professional education? Give details.		
3	Can all nurses assisting demonstrate in-house training in sedation?		
4	Can all recovery staff (if applicable) demonstrate training appropriate to their duties?		
5	Are all staff trained in at least BLS (airway certification)?		
6	How often is emergency training provided? Give dates.		
7	When was the last emergency training session? Is in-house training done?		
8	The facility is suitable to provide moderate sedation and analgesia? If no, the following observations would need to be addressed for successful practice appraisal: _____ _____ _____ _____ _____ _____ _____		

Comments:

_____

_____

_____

_____

_____

_____

Assessed by: _____

Date: _____

Position/qualifications: _____

Signature: _____

Appendix 3:

Valid informed 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 entail 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 may or may not be unconscious, and that I/the patient may or may not have to respond to commands from the surgeon and/or the sedation practitioner.

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

   Possible adverse events include:

   - Unintended loss of consciousness
   - Drowsiness/dizziness
   - Unsteady gait
   - Shivering (4%)
   - Headaches (4%)
   - Double vision
   - Post-sedation 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 sedation 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, e.g. general anaesthesia, or local anaesthesia without sedation, or the use of local anaesthesia with behaviour management techniques, 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 and 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 has consented.

Practitioner's signature ……..……

Date……...……

Appendix 4:

Medical history questionnaire

Confidential medical history

This information is vital for us to ensure that we can make your conscious sedation (CS) safe. Please read and answer every question truthfully and provide us with details where needed.

Reference (Office Use Only)

Your Details

Title | Surname | First Name | Date of birth (DD/MM/YYYY)

Mobile or Landline | Email

Height | Weight | Occupation

Details of your GP or Consultant

Name and address of your specialist or doctor

Telephone | Email

Current medication

Please provide a full list of all prescription and / or alternative medication (including herbal) that you are currently taking.

Current medication

Please tick all boxes / conditions that apply to you and provide details.

General

- I am smoking __ cigarettes per day
- I stopped smoking __ years ago
- I consume about __ units of alcohol per week
- I am presently using recreational drugs
- I easily get skin rashes
- I've had a sedation before
- I've had general anaesthetics
- I've had a spinal or epidural anaesthetic

Women

- I am or could be pregnant
- I am taking oral contraceptives
- I am presently breast feeding

Allergies

- Penicillin
- Any other antibiotics
- Aspirin
- Painkillers
- Elastoplast
- Sedatives (please specify)
- Sleeping pills
- Latex
- Local anaesthetics
- Food allergy
- Anything else?

Have you or have you had any of the following conditions? Please provide details for all that apply!

- AIDS/HIV positive
- Anaphylaxis
- Anaemia / Low blood count
- Angina
- Anxiety
- Arthritis
- Artificial heart valve
- Asthma
- Blood disorders
- Breathing problems
- Bruising tendency
- Cerebral palsy
- Chest pains
- Convulsions
- Depression
- Diabetes (insulin dependent)
- Diabetes (Type II)
- Drug addiction
- Emphysema / COPD
- Epilepsy or seizures
- Excessive bleeding
- Excessive thirst
- Faints / Dizziness
- Frequent cough
- Frequent diarrhoea
- Frequent headaches
- Glaucoma
- Gout
- Haemophilia
- Hay fever
- Heart attack
- Heart failure
- Heart murmur
- Heart pacemaker
- Heavy snoring
- Hepatitis B or C
- Hereditary diseases
- High blood pressure
- High cholesterol
- Indigestion
- Irregular heartbeat
- Kidney problems
- Learning difficulties
- Leukaemia
- Liver disease
- Low blood pressure
- Low blood sugar
- Lung disease
- Muscle weakness
- Porphyria
- Psychiatric care
- Recent weight loss
- Reflux
- Rheumatic fever
- Sickle cell disorder
- Sleep apnoea
- Steroid medicine
- Stomach ulcers
- Stroke
- Swelling of limbs
- Thalassaemia
- Thyroid disease
- Yellow jaundice

- **Any other conditions not listed? Please note them below**

- **Please tick this box if there is anything you wish to discuss with your seditionist in confidence**

To the best of my knowledge, the questions on this form have been accurately answered. I understand that providing incorrect information can be dangerous to my (or the patient's) health. It is my responsibility to inform the office of any changes in medical status.

Name of Patient or Guardian	Date (DD/MM/YYYY)	Signature of Patient or Guardian

Appendix 5:

Evaluation of the airway for sedation

Lemon law[7]

L	Look externally for any malformations of the face
E	Evaluation 3-3-2: 3 fingers between upper and lower jaw to assess mouth opening; 3 fingers between the hyoid and chin; 2 fingers can fit in between hyoid and thyroid cartilage
M	Mallampati: look for position of uvula. If difficult to see, airway compromised
O	Obstruction: look for signs of obstruction e.g. wheezing, stridor
N	Neck mobility: evaluate flexion and extension of neck

Upper lip bite test (ULBT)[8]

ULBT is performed by asking the patient to **bite** the **upper lip**	
Class I	Lower teeth bite the upper lip above the upper vermilion border
Class II	Lower teeth bite the upper lip below the upper vermilion border
Class III	Lower teeth cannot bite the upper lip

Appendix 6:

Sedation scoring systems

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

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

University of Michigan Sedation Scale (UMSS)

University of Michigan Sedation Scale (UMSS)		
0	Awake and alert	
1	Minimally sedated	Patient drowsy, sleepy but rousable to verbal command
2	Moderately sedated	Patient may be sleeping, can be easily aroused by light tactile stimulation
3	Deeply sedated	Patient asleep, only rousable by significant physical stimulation, or repeated painful stimuli
4	Unrousable	No response with significant physical stimulation

Appendix 7:

Sedation monitoring flow chart

DAYCARE SEDATION RECORD		
Date:	Time in:	Time out:
Patient name:	File No:	ASA I II III IV V E
DOB:	Age:	Weight:
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																		

Appendix 8:

Pre-sedation instructions for patients/carers/guardians

If you are unable to comply with, or have any concerns regarding the instructions listed on this page, please contact your sedation practitioner, or our office, so that we can discuss how to best make adjustments for your particular requirements or circumstances.

- If you feel sick or unwell, please liaise with your doctor/dentist whether to postpone the treatment.
- Do not eat anything for at least 6 hours before the procedure/operation. Clear fluids (black tea/black coffee/apple juice) may be taken up to 2 hours before.
- Smoking and alcohol intake should be avoided for 24 hours before your appointment.
- The use of recreational drugs is not permitted for 48 hours prior to treatment.
- Please wear comfortable clothes with loose-fitting sleeves in order to be able to apply an electronic blood pressure cuff.
- Avoid wearing heavy make-up, nail varnish and jewellery.
- Wear flat shoes, as you may be slightly unsteady for a short while afterwards.
- Take any **chronic medication,** on the day of the procedure/operation, as ordered by your doctor/dentist. If taken, it must be taken at the usual times, along with a small amount of water, regardless of the restrictions on fluid intake noted above.
- Asthma sufferers should bring their inhalers.
- Diabetic patients should bring their blood glucose monitoring devices and take their blood glucose level the morning before the sedation. A low blood glucose level must be reported to the sedation practitioner.
- Patients with Obstructive Sleep Apnoea who use CPAP should bring their CPAP devices.
- Depending on the nature and duration of the surgery, contact lens wearers may have to remove their lenses. So, bring a contact lens container along, or wear spectacles if possible.
- 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. In this case, you may have to come earlier in order to take the premedication.
- Please empty your bladder before the procedure/operation.
- You must have an adult escort to accompany you home. The 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.
- If the sedation ends late in the day, it is advised that the escort remains with the patient until the following morning. Guidelines do not allow us to send you home on your own. If there is nobody to accompany you home we will unfortunately not be able to provide sedation.
- There must be arrangements in place for you and the responsible escort to travel home by private car or taxi rather than public transport.

Appendix 9:

Post-sedation instructions (aftercare) for patients/carers/guardians

- 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** proceed if you arrive without an escort.
- It can take up to 24 hours for the sedative drugs to be eliminated from your body and for you to recover from the effects of sedation (drowsiness, loss of memory, lack of awareness and coordination). Therefore, for at least 12 hours following the procedure/operation, you must not:
  - drive a vehicle (insurance will be void)
  - use electrical equipment, cook, or operate machinery
  - climb heights (e.g. ladders, scaffolding)
  - participate in any other activities that require alertness or coordination (e.g. swimming, cycling, etc.)
  - be in charge of children or dependent adults
  - make important decisions, or sign legal documents
  - use alcohol, sleeping tablets, tobacco, or recreational drugs
  - perform any complicated tasks
  - go back to work on the day of your sedation
- After the sedation you may continue your acute and chronic medication as ordered by your doctor/dentist.
- Discuss post-sedation breastfeeding with your doctor/dentist.
- You should not experience nausea or vomiting after sedation. If vomiting occurs 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 to solids.
- Do not consume any alcoholic drinks for the remainder of the day.
- 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.
- We trust that the enclosed information will answer all your questions. However, please phone your sedation practitioner or the practice if you are unsure about any information.

- Please complete the electronic feedback request that you will receive on the day after your appointment, as this will allow your sedationist to monitor your recovery.
- We do not anticipate any complications, but should you become concerned about anything, however trivial, please contact your sedationist or our office.

I, ……, the undersigned, have read and understood these pre- and post-sedation 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: ……

Appendix 10:

Cover letter to patient/parent/guardian

Dear Patient/Parent/Guardian,

Your doctor/dentist recommends that your/your child's procedure be performed under sedation. The procedure is scheduled for (date)……. at (time)……., at (address)……. The sedation will be performed by

Dr ……..……

The estimated fee for the sedation is (fee)……

You will receive the following documents:

1. **Confidential medical history questionnaire.**

Please read and answer every question truthfully and provide details where needed.

Please provide a full list of all prescription and/or alternative medication (including herbal) that you are currently taking.

The information required is vital, as it will assist us in deciding whether you qualify for sedation and to ensure a safe sedation. If you suffer from any medical condition, you will need to inform your doctor/dentist before the procedure/operation. Discuss with your doctor/dentist whether to take your acute or chronic medication on the day of the procedure.

2. **Consent form for the sedation.**

Kindly complete and sign.

3. **Instructions on how to prepare for the sedation.**

Please return these forms at your earliest convenience either by email or fax. Your booking can only be confirmed once the forms have been received. If anything is unclear, please contact your doctor/dentist at the following telephone numbers:

Tel: ……

Appendix 11:

Pre-procedural checklist

To be completed and signed by sedation practitioner

Name:		Date of birth:	
Age:		Weight:	
Responsible doctor:		Sedation practitioner:	
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: Dose: Time: Drug: Dose: Time:
Premedication administered: Yes / No	Name of person who administered premedication:
Name of sedation practitioner: 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 sedation practitioner:……Date:……

Name of sedation practitioner (block letters): ……

Qualification:……

Appendix 12:

Post-sedation monitoring chart 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 is behaviour 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:

Appendix 13:

Discharge scoring systems

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 pre-sedation level	2
Systolic BP within 20–50 mmHg of pre-sedation level	1
Systolic BP > 50 mmHg of pre-sedation 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

Modified Post Anaesthetic 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	2
Minimal: does not require dressing changes	1
Moderate: up to two dressing changes required	0
Severe: more than three dressing changes required	

References

1. Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018. A Report by the American Society of Anesthesiologists Task Force on Moderate Procedural Sedation and Analgesia, the American Association of Oral and Maxillofacial Surgeons, American College of Radiology, American Dental Association, American Society of Dentist Anesthesiologists, and Society of Interventional Radiology. Anesthesiology. 2018;128(3):437-479. https://doi.org/10.1097/ALN.0000000000002043.
2. Roback MG, Green SM, Andolfatto G, Leroy PL, Mason KP. Tracking and Reporting Outcomes Of Procedural Sedation (TROOPS): Standardized Quality Improvement and Research Tools from the International Committee for the Advancement of Procedural Sedation. British Journal of Anaesthesia. 2018;120(1):164-172. https://doi.org/10.1016/j.bja.2017.08.004.
3. Mason KP, Green SM, Piacevoli Q, International Sedation Task Force. Adverse event reporting tool to standardize the reporting and tracking of adverse events during procedural sedation: a consensus document from the World SIVA International Sedation Task Force. British Journal of Anaesthesia. 2012;108(1):13-20. https://doi.org/10.1093/bja/aer407.
4. American Society of Anesthesiologists: Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/ Analgesia. Approved by ASA House of Delegates on October 13, 1999 and last amended on October 23, 2019. Available at: https://www.asahq.org/standards-and-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedationanalgesia.
5. Academy of Medical Royal Colleges. Safe sedation practice for healthcare procedures. Standard and Guidance. October 2013. Available at: https://www.aomrc.org.uk/wp-content/uploads/2016/05/Safe_Sedation_Practice_1213.pdf.
6. General Dental Council. Standards for the Dental Team. London: GDC; 2013. Available at: https://standards.gdc-uk.org/Assets/pdf/Standards%20for%20the%20Dental%20Team.pdf.
7. Reed MJ, Dunn MJ, McKeown DW: Can an airway assessment score predict difficulty at intubation in the emergency department? Emergency Medicine Journal. 2005;22:99-102. https://doi.org/10.1136/emj.2003.008771.
8. Faramarzi E, Soleimanpour H, Khan ZH, Mahmoodpoor A, Sanaie S. Upper lip bite test for prediction of difficult airway: A systematic review. Pak J Med Sci. 2018;34(4):1019-1023. https://doi.org/10.12669/pjms.344.15364.
9. ASA Physical Status Classification System. American Society of Anesthesiologists. Archived from the original on 2010-10-08. Available at: https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system.
10. Fehrenbach and Associates. ASA Physical Status Classification System for Dental Patient Care 2020. Available at: http://www.dhed.net/ASA_Physical_Status_Classification_SYSTEM.html
11. Klare P, Reiter J, Meining A, et al. Capnographic monitoring of midazolam and propofol sedation during ERCP: a randomized controlled study (EndoBreath Study). Endoscopy. 2016;48(01):42-50. https://doi.org/10.1055/s-0034-1393117.
12. Waugh JB, Epps CA, Khodneva YA. Capnography enhances surveillance of respiratory events during procedural sedation: a meta-analysis. J Clin Anesth. 2011;23:189-196. https://doi.org/10.1016/j.jclinane.2010.08.012.
13. Hinkelbein J, Lamperti M, Akeson J, et al. European Society of Anaesthesiology and European Board of Anaesthesiology guidelines for procedural sedation and analgesia in adults. European Journal of Anaesthesiology (EJA). 2018;35(1):6-24. https://doi.org/10.1097/EJA.0000000000000683.
14. The dental faculties of the Royal Colleges of Surgeons and the Royal College of Anaesthetists. Standards for Conscious Sedation in the Provision of Dental Care. Report of the Intercollegiate Advisory Committee for Sedation in Dentistry. 2015. Available at: https://www.rcseng.ac.uk/-/media/files/rcs/fds/publications/dental-sedation-report-2015-web-v2.pd.
15. Pambianco DJ, Borkett KM, Riff DS, et al. A phase IIb study comparing the safety and efficacy of remimazolam and midazolam in patients undergoing colonoscopy. Gastrointest Endosc. 2016;83(5):984-992. https://doi.org/10.1016/j.gie.2015.08.062.
16. Venn RM, Karol MD, Grounds RM. Pharmacokinetics of dexmedetomidine infusions for sedation of postoperative patients requiring intensive care. Br J Anaesth. 2002;88:669-675. https://doi.org/10.1093/bja/88.5.669.
17. Jephcott C, Grummet J, Nguyen N, Spruyt O. A review of the safety and efficacy of inhaled methoxyflurane as an analgesic for outpatient procedures. Br J Anaesth. 2018;120(5):1040-1048. https://doi.org/10.1016/j.bja.2018.01.011.
18. Coulter FL, Hannam JA, Anderson BJ. Ketofol simulations for dosing in pediatric anesthesia. Pediatric Anaesthesia. 2014;24(8):806-12. https://doi.org/10.1111/pan.12386.
19. Cillo JE. Analysis of propofol and low-dose ketamine for adult outpatient dentoalveolar surgery. A prospective, randomized, positive-controlled clinical trial. Journal of Oral and Maxillofacial Surgery. 2012;70(3);537-543. https://doi.org/10.1016/j.joms.2011.08.036.