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.