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.