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).