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.