ELSEVIER

Ambulatory Surgery 9 (2002) 173–177

Ambulatory Surgery

www.elsevier.com/locate/ambsur

National Guidelines

Guidelines for the accreditation of office-based surgery facilities☆

Glenda Rudkin *, Randall Sach

Australian Day Surgery Council, Suite 1, 2A Mona Road, Darling Point, NSW 2027, Sydney, Australia

Received 1 April 2001; accepted 1 June 2001

These guidelines have been prepared by the Australian Day Surgery Council to assist accrediting bodies to accredit office-based day surgery facilities. The Guidelines are intended as broad principles. Detail may be determined by the accrediting bodies. At some time in the future, health funds or other organisations may contribute to the costs of procedures performed in accredited office-based facilities.

Disclaimer

These guidellnes should not be construed as dictating the facilities required to safely perform any diagnostic or surgical procedures. The ultimate judgement of how, where and when a surgical procedure may be best performed must be made by the person who accepts overall responsibillty.

1. Contents

1.1. The Australian Day Surgery Council

The Australian Day Surgery Council, formerly the National Day Surgery Committee, was formed by the Australian Association of Surgeons and the Royal Australasian College of Surgeons which then incorporated the Faculty of Anaesthetists (now the Australian and New Zealand College of Anaesthetists) and the Australian Society of Anaesthetists. The Council also includes representatives of hospitals, private health funds and government. The Australian Day Surgery Council aims to promote day surgery of the highest possible standard.

Dr John Warden
Chairman
Australian Day Surgery Council
Suite 1, 2A Mona Road, Darling Point NSW 2027
Phone: 02 9363 4411
Facsimile: 02 9363 5001
Email: aas@enternet.com.au

Guidelines prepared by:

Glenda Rudkin:	ANZCA representative Australian Day Surgery council
Randall Sach:	RACS representative Australian Day Surgery Council

2. Introduction

2.1. Definition

Office-based surgery is defined as an operation(s) or procedure(s) carried out in a medical practitioner's office or outpatient department, other than as a service normally included in an attendance (consultation). it does not require or involve admission to a day surgery/procedure centre or to a hospital as an in-patient.

☆ With the expansion of Office based surgery in Australia, both the RACS and ANZCA consider it important that appropriate standards are defined to ensure quality control and patient safety in this area. This task has been delegated to the Australian Day Surgery Council to develop and provide guidelines for the accrediting bodies. These guidelines should be interpreted as principles only, with detail being the responsibility of the accrediting body.

* Corresponding author. Tel.: +61-2-9363-4411; fax: +61-2-9363-5001.

E-mail address: aas@enternet.com.au (G. Rudkin).

0966-6532/02/$ - see front matter
PII: S0966-6532(01)00114-7

Although there has been no formal recognition of office-based surgery, a significant group of minor operations/procedures are carried out in practitioner's consulting rooms.

The majority of these operations/procedures are carried out under local anaesthesia or without anaesthesia. However an increasing number are being carried out under sedation, with or without local anaesthesia.

2.2. Australian Practice Standards

The above broad spectrum of minor procedural activity is subject to currently accepted Australian practice standards. including those of infection control and occupational health and safety.

2.3. Accreditation of Office-based Surgery Facilities

Accreditation of office-based surgery facilities would best be the responsibility of accrediting organisations. The Australian Day Surgery Council has prepared these Guidelines to assist such organisations in the preparation of specific accreditation criteria.

Accreditation of office-based facilities should not be compulsory. The Guidelines are not intended to apply to simple procedures under local anaesthesia or without anaesthesia such as excision or biopsy of skin lesions, suture of lacerations, removal of sutures and surgical drains, and procedures carried out with topical (surface) anaesthesia, as consulting room services.

It is not envisaged that general anaesthesia will be undertaken as office-based surgery but, if a situation arose whereby general anaesthesia were to be performed in an office-based facility, this would require adherence to standards set by the Australian and New Zealand College of Anaesthetists.

These Guidelines should be interpreted as principles only with detail being the responsibility of the accrediting body.

The following requirements should be met for a facility to be accredited:

3. Part 1

3.1. Procedures performed under local anaesthesia alone

These Guidelines should be interpreted as principles only with detail being the responsibility of the accrediting body.

The following requirement should be met for a facility to be accredited:

1. **Physical facilities**
   (a) A dedicated procedure room, separate from any consulting room. This room should contain:
      - Adequate lighting to allow the procedure to be performed safely.
      - Non-slip, non carpeted flooring.
      - Adequate uncluttered floor space to access and perform resuscitation should this prove necessary.

   (b) A recovery area which is not part of the general waiting room or office.
   (c) Emergency lighting for the procedure room and recovery area.
   (d) Appropriate hand-washing facilities for pre-operative hand washing or scrub.
   (e) Regular and adequate cleaning.
2. **Equipment requirements**
   (a) An autoclave or access to sterile instruments from a sterile supply facility.
   (b) For an open procedure, proper provision for haemostasis should be available (e.g. electrosurgical unit).
   (c) Disposable single-use items, including sterile gloves and drapes, ampoules of local anaesthetic, needles, syringes, scalpel blades, and suture material.
   (d) Resuscitation equipment including:
      - A supply of oxygen and suitable devices for the administration of oxygen to a spontaneously breathing patient.
      - A means of inflating the lungs with oxygen (eg a range of pharyngeal airways and self-inflating bag suitable for artificial ventilation).
      - Adequate suction device.
      - Appropriate drugs for treating emergencies should include midazolam or diazepam, atropine and adrenaline.
      - A range of intravenous equipment.
      - Intravenous fluids and infusion sets.
      - Intravenous cannula.
3. **Approved procedures for the sterilisation of equipment and the maintenance of sterile operative fields**
   (a) Wherever possible single-use disposable items of equipment should be used, including syringes, needles and ampoules for injection. Any single-use article or instrument that has penetrated the skin, mucous membrane and/or tissue must be appropriately disposed of immediately after use or at the end of the procedure.
   (b) When re-usable items of equipment are used then provision must be made for:
      - Physical cleaning: this is a process for the removal of micro-organisms and biohazardous materials from the surface of an object. Thorough physical cleaning of instru-

ments to remove blood and other debris is essential if effective disinfection or sterilisation is to occur. Such physical cleaning must always be performed prior to the disinfection/sterilisation process.

- Disinfection: this is the process of eliminating all micro-organisms other than bacterial spores.
- Sterilisation: this is a process to destroy all forms of microbial life, including bacterial spores. The most effective and reliable form of sterilisation is by steam under increased pressure (autoclaving). Australian Sterilising standards AS 4187 and Standards for Endoscopic facilities and Services. All instruments, materials and medications introduced into the body tissue must be sterile. Such instruments may be pre-sterilised single-use items, or re-useable items, which have been sterilised before use. Instruments used for internal examinations of mucous membranes (eg vaginal speculum, rigid sigmoidoscopes and flexible endoscopes) must not have the capacity to transfer harmful micro-organisms between patients. They must therefore be sterilised or disinfected.

(c) All bio-chemical equipment must comply with Australian Standards AS-3551.

(d) Sterile drapes where necessary.

4. **Staff**

(a) Clinical support and facility responsibilities should be provided by appropriately trained personnel. Office staff should not be seconded for this purpose.

(b) All staff involved in the performance of procedures should have blood borne virus status assessed and maintain appropriate immunisation against Hepatitis B.

(c) All staff should be familiar with procedures to be followed in the event of a needle stick injury, which should be carefully documented.

(d) All staff should be trained in basic cardiopulmonary resuscitation procedures and the checking of equipment and emergency drugs used for resuscitation purposes.

(e) All staff must be conversant with a protocol for the management of patient collapse.

5. **Patient transfer**

(a) An arrangement should exist with a nearby accredited hospital for the transfer of patients in the event of unexpected serious or potentially serious developments.

6. **Medical records**

(a) An adequate anaesthetic and surgical record must be maintained. Separate documentation of each procedure should be maintained in a logbook, including date, time, duration, personnel involved in the procedure, and any associated problems or complications.

(b) Follow up arrangements and post-operative wound care must be clearly outlined to the patient, and written confirmation when appropriate.

7. **Waste disposal**

(a) Disposal of contaminated waste, including sharps, should be properly managed through an arrangement with a licensed contractor.

8. **General**

(a) An appropriate management structure, which has the ability to address continuous quality improvement (CQI) issues.

(b) Occupational health and safety guidelines for an operating theatre should be in place and followed. This should include fire safety and evacuation procedures.

(c) Documentation of regular staff training in cardio-pulmonary resuscitation, the use of emergency drugs, the care and maintenance of equipment.

4. Part 2

4.1. Procedures performed under local anaesthesia and sedation

Definition.

Sedation for diagnostic and surgical procedures (with or without local anaesthesia) includes the administration by any route or technique of all forms of drugs, which results in depression of the central nervous system.

All guidelines for procedures performed under local anaesthesia alone apply (See Part 1). In addition the following guidelines apply:

1. **Physical facilities**

(a) The complete facility should allow for:

- an admission and reception area;
- pre and post-operative patient holding areas;
- appropriate utility room;
- toilets suitable for disabled persons;
- refreshment facilities;
- vehicle access area.

2. **Procedure room**

(a)

- adequate size for procedure undertaken including adequate uncluttered floor space to perform resuscitation should this prove necessary;
- appropriate lighting, ventilation and suction;
- appropriate equipment for the procedure undertaken;
- an operating table or trolley which can be readily titled;
- quality of staff appropriate to the procedure undertaken.

3. **Recovery room**

(a)

- closely related to the procedure room with adequate lighting and adequate uncluttered floor space to perform resuscitation should this prove necessary;
- comfortable reclining seating for patients to complete recovery prior to discharge;

- patients supervised by appropriately trained nursing staff;
- ready access to resuscitation equipment, including oxygen and suction;
- patients should not leave the recovery room unaccompanied.

(b) Discharge area should include:
- wheel chair access;
- vehicle access area;
- ambulance access;

4. **Drugs and equipment**

(a) A supply of oxygen and suitable devices for the administration of oxygen to a spontaneously breathing patient.

(b) A means of inflating the lungs with oxygen (eg a range of pharyngeal airways and self-inflating bag suitable for artificial ventilation).

(c) Appropriate drugs for cardiopulmonary resuscitation and a range of intravenous equipment. Emergency drugs should include at least the following:
- adrenaline;
- atropine;
- dextrose 50%;
- lignocaine;
- naloxone;
- flumazenil.

(d) A pulse oximeter: continuous patient monitoring by pulse oximetry is required when intravenous sedation is used. Equipment must alarm when certain set limits are exceeded.

(e) Ready access to a defibrillator.

(f) An adequate suction device.

5. **Staff**

(a)
- Appropriately trained registered nurse should be present for theatre and/or recovery.
- There must be an appropriately trained assistant present during the procedure who shall monitor the level of consciousness and cardio-respiratory function of the patient and be competent in cardiopulmonary resuscitation.
- The operator may provide non-intravenous sedation and be responsible for care of the patient provided rational communication to and from the patient is continuously possible during the procedure.
- If at any time rational communication is lost, then the operator must cease the procedure and devote his/her entire attention to monitoring and treating the patient until such time as another practitioner becomes available to monitor the patient and take responsibility for any further sedation, analgesia or resuscitation.
- If intravenous sedative drugs are being administered an anaesthetist should be present.
- If loss of consciousness or loss of rational communication is sought as part of the technique, then an appropriately trained anaesthetist must be present to care exclusively for the patient.
- Techniques, which compensate for anxiety or pain by means of heavy sedation, must not be used unless an anaesthetist is present.
- The practitioner administering the sedation drugs requires sufficient basic knowledge to be able to:

  understand the actions of the drug or drugs being administered;

  detect and manage appropriately any complications arising from these actions. In particular doctors administering sedation must be skilled in airway management and cardiovascular resuscitation;

  anticipate and manage appropriately the modification of these actions by any concurrent therapeutic regimen or disease process, which may be present.
- A written record of the dosages of drugs and the timing of their administration must be kept as part of the patient's records. Such entries should be made as near the time of administration of the drugs as possible.
- A policy and procedure manual should be available to all staff.

6. **Patient assessment**

(a) The patient should be assessed before the procedure. Documentation should include:
- a concise medical history and examination (should include blood pressure measurement);
- informed consent;
- any instructions for preparation and discharge procedure.

(b) If the patient has any serious medical condition or danger of airway compromise, or is a young child or is elderly, then an anaesthetist should be present to monitor the patient during the procedure.

(c) Patient assessment can be assisted by:
- a standardised anaesthesia questionnaire;
- preliminary nurse assessment;
- prior surgical referral in cases of doubt as to suitability for office based surgery.

(d) Patient information in an understandable written format must include:
- general information about the processes followed in the office based facility;
- limited solid food may be taken up to six hours prior to sedation;

- unsweetened clear fluids totalling not more than 200 ml/h may be taken up to three hours prior to sedation;
- only medications or water ordered by the anaesthetist should be taken less than three hours prior to sedation;
- an H_2-receptor antagonist should be considered for patients with an increased risk of gastric regurgitation;
- the guidelines may be modified in some patients, particularly infants and small children, on advice from the anaesthetist.

7. **Selection guidelines**

(a) Procedures suitable for office-based surgery include those with:

- a minimal risk of peri-operative haemorrhage;
- a minimal risk of post-operative airway compromise.
- post operative pain controllable by outpatient management techniques.
- a rapid return to normal fluid and food intake.

(b) Patient requirements for office-based surgery include:

- a willingness to have the procedure performed together with an understanding of the process and ability to follow discharge instructions;
- physical status of ASA 1 or 11. Medically stable ASA 111 or IV patients may be accepted for office-based surgery following consultations with the anaesthetist concerned.
- In all cases, the ultimate decision as to the suitability of a patient for office based surgery is that of the surgeon and/or anaesthetist. The decision as to the type of anaesthesia must remain in the province of the anaesthetist and will be based on surgical requirements, patient considerations, the experience of the anaesthetist and the facilities in the office based surgery.

(c) Social requirements for office-based surgery include:

- a responsible person able to transport the patient home in a suitable vehicle;
- a responsible person at home for at least the first night after discharge from the facility;
- a responsible person is an adult who understands the instructions given to them and is physically and mentally able to make the decisions for the patient's welfare when appropriate.

8. **Discharge**

(a)

- The patient should be discharged only after an appropriate period of recovery and observation in the procedure room or in an adjacent area that is adequately equipped and staffed.
- Discharge of the patient should be authorised by the practitioner who administered the drugs, or another suitably qualified practitioner. The patient should be discharged into the care of a responsible adult to whom written instructions should be given. These should include emergency phone numbers.
- Should the need arise the patient must be transferred to appropriate medical care.

Selected Bibliography

Australian and New Zealand College of Anaesthetists Policy Documents: TE9, T1, T3, T4, T6, P4, P6, PS7, P9, P15, P19, P20, P21, P24, PS36.

Infection Control in Surgery, Policy Document, Royal Australasian College of Surgeons, July 1998.

Day Surgery. Report and recommendations of the Australian Day Surgery Council, Royal Australasian College of Surgeons, 1997.

Standards for Endoscopic Facilities and Services. February 1998 Gasroenterological Society of Australia and Gasteoenterological Nurses Society of Australia.

Reuse of Single-Use Medical Devices: Making Informed Decisions. ISBN 0-941417-52-2:ECR1 1996.

National Occupational Health and Safety Commission. Control of workplace hazardous substances: National code of practice for the control of workplace hazardous substances [NOHSC:0003 (1993)] and National model regulations for the control of workplace hazardous substances [NOHSC:0002 (1993)], Australian Government Publishing Services, Canberra.

Draft Crises management Manual. Cover ABCD. A Swift check. Australian patient Safety Foundation. GPO Box 400 Adelaide SA 5001. 1996.

Australian Council on Health Care Standards. (1990). Accreditation Guide-Day Procedure.

Australian Standard. Code of practice for cleaning, disinfecting and sterilising reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities. AS 4187-1994.

Australian Standard for Biomed AS3551.

ACORN Operating Room Nurses 1999.

Occupational Health, Safety & Welfare Regulations, 1995. Fire and Evacuation.