3. ANAESTHESIA EQUIPMENT AND ANAESTHETISING FACILITIES

3.1 Facilities

2022 review by P Bettings

Introduction

The requirements for healthcare facilities providing surgical services are described in the Infrastructure Unit Support Systems (IUSS) Health Facility Guides: Facilities for Surgical Procedures (Gazetted 30 June 2014 – Appendix B) that supersedes regulation R158 on Infrastructure and should be interpreted in conjunction with the current National Core Standards (NCS) Regulations (Appendix A[iv]).

Please note: Recommendations have been adopted to accommodate the legislation providing for the designation of hospitals as Gazetted on 2 March 2012 by the National Department of Health (NDoH), “Regulations relating to categories of hospitals” in which hospitals are designated according to the number of beds, the staffing skills and registration of both medical and nursing staff, ability to provide critical care, and the outreach and support services that the facility undertakes and receives.

District hospital (Level 1)

This category is divided into small (50–150 beds), medium (150–300 beds) and large (more than 300 beds). District hospitals provide a 24-hour service staffed by general practitioners and clinical nurse practitioners, on an inpatient, ambulatory and emergency basis. A district hospital receives outreach and support from general specialists based at regional hospitals.

Regional hospital (Level 2)

It has between 200–800 beds and provides 24-hour service in internal medicine, paediatrics, obstetrics and gynaecology, and general surgery, with additional services in at least one of the following: orthopaedic surgery, psychiatry, anaesthesia, and diagnostic radiology. Services include trauma and emergency services, and the facility must provide short-term ventilation in a critical care unit. A regional facility receives referrals from several district hospitals in its geographic area and should receive outreach and support from tertiary hospitals.

Tertiary hospital (Level 3)

It has 400–800 beds, provides the services of a regional hospital, and has subspecialties of internal medicine, paediatrics, obstetrics and gynaecology, and general surgery. The critical care unit will provide intensive care under the supervision of a specialist or specialist intensivist. Tertiary hospitals receive referrals from regional hospitals and may provide training for healthcare professionals.

Central hospital (Level 4)

It has a maximum of 1 200 beds and provides tertiary services. In addition, it provides central referral and national referral services, must conduct research, must provide training for healthcare professionals, and must be the main teaching platform for a medical school.

Specialised hospital

It has a maximum of 600 beds and provides specialised services like psychiatry, infectious diseases, tuberculosis or rehabilitation services.

Private facilities

The Health Act (2012) only provides for “for-profit” and “not-for-profit” categories of private hospitals. For the purposes of these guidelines, the committee regards most private healthcare facilities with inpatient beds to meet the criteria of at least a regional hospital. Therefore, the facility needs to meet the applicable standards.

Stand-alone, day-care facilities

Stand-alone, day-care facilities providing sedation and anaesthesia in a theatre must be equipped to the level expected of a regional hospital.

Facilities for office-based sedation

Facilities that provide office-based sedation only must be equipped according to the standards required in the SASA “Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in adults: 2021.” (Appendix C)

Note:

• Where hospitals provide a combination of levels of care, the facilities and equipment must meet the requirements for the higher level of care.
• Private practitioners should familiarise themselves with requirements by some hospital groups/facilities for facility agreements and electronic record keeping. (Appendix D).

3.2 Equipment

2022 review by G Davies, A Reed and D Shmukler

• Every item on the list of essential equipment should be available at every site where anaesthesia is provided, even if anaesthesia is only provided occasionally.
• Essential items are equivalent to a mandatory standard of care.
• Recommended/desirable items should be available where resources allow and if appropriate for the surgical/anaesthesia services delivered.
• Private facilities will generally be equipped at the level of regional (level 2) hospitals, except where these facilities provide specialised services (e.g., cardiothoracic surgery, shoulder surgery, etc.) where they will need to meet the requirements for tertiary/central (level 3/level 4) hospitals.
• Day surgery and office-based facilities are discussed in the relevant portion of the practice guidelines (Appendix E).

• It remains the duty of the anaesthesia provider to ensure that all relevant anaesthesia equipment required in the perioperative period is available, in working order and appropriate for the case being performed.

Anaesthesia equipment

• Essential anaesthesia equipment requirements will differ between institutions depending on the nature of the surgery undertaken and the surgical services offered. The availability of maintenance and repair services is also a key consideration when procuring anaesthesia equipment. Referral hospitals are usually in large centres and must meet higher standards.

• Regional (Level 2) hospital requirements will include most of the recommended equipment.

• Tertiary (Level 3) and central/specialised hospital requirements must include all items listed as “Recommended”.

An oxygen-failure device with an audible alarm, preferably continuous, must be fitted to the anaesthesia machine.

Appropriate flow controllers for all available gases:

• The flow meter for oxygen must be accurate to 100 ml/minute or less for flows up to 1 l/minute and accurate to 500 ml/minute for higher oxygen flows.

• Where there is a sequence of gas control knobs, oxygen must be positioned on the right, as seen from a position facing the machine.

• Oxygen must always be the final gas delivered to the common gas pathway.

• Machines with electronic flow controllers must have a manual device for oxygen delivery, independent of electrical supply.

• One volatile delivery system that can deliver accurate, controllable partial pressures of volatile anaesthesia agents at varying fresh gas flows, and under the full range of normal clinical conditions. The graduations of the control should not exceed 0.5 minimum alveolar concentration (MAC) and should provide at least three times the MAC of the selected agent.

The breathing system pressure relief valve should be set to 6 kPa/60 cm H₂O.

An oxygen flush system, delivering at least 35 l/minute of oxygen to the machine outflow and controlled by a prominent, recessed, non-lockable button.

Outflow point connector of 22 mm International Organization for Standardization (ISO) standard male taper.

These components must be mounted on a rigid frame that maintains the flow meters in a vertical position and the volatile delivery system in a level position.

The mounting frame for a mobile anaesthesia machine must be sufficiently stable to prevent it from being accidentally tipped over. All ancillary monitoring equipment should be mounted on a suitable horizontal surface, or securely attached to the machine.

Oxygen analyser with an audible low-concentration warning device which should be adjustable, but with a minimum of 18%.

Where a potentially hypoxic gas mixture could be delivered, a hypoxic guard must be fitted to ensure a minimum oxygen concentration of 25%.

High-pressure gas supply master/slave switches, whereby low oxygen pipeline or cylinder pressure cuts off hypoxic gas sources (fail-safe device).

All major theatres must have a pipeline supply of medical air. SASA recommends a medical air supply for all new operating theatres.
theatres, including theatres for minor procedures/occasional use.

Appropriate delivery system for the supply of compressed air.

Gas delivery systems capable of delivering accurately proportioned fresh gas mixtures at flow rates down to 250 ml/minute. It should be noted that low flow anaesthesia using a fresh gas flow less than the patient’s minute ventilation, mandates the use of real-time capnography and anaesthetic agent analysis (AA). SASA recommends anaesthetic AA at all sites.

Breathing circuits

**Essential items**

- A suitable breathing system for adult patients fitted at all junctions with ISO-standard tapered fittings.
- Paediatric anaesthetic breathing systems must be available in institutions where children might be anaesthetised.
- One set of face masks per machine in a suitable range of sizes that are appropriate for the patient population.
- Ready availability of sufficient stock of single-use, Guedel-type oral airways, available in every size, for all patients to be anaesthetised on any given day in each operating theatre.
- Complete set of supraglottic/laryngeal mask airways per theatre complex, as appropriate for the caseload (e.g., full range of adult sizes (3–5) for adults or paediatric sizes (1–2½) for children.
- An appropriate range of different endotracheal tube sizes with standard connectors which are immediately available.
- Breathing circuit pressure gauge.
- A self-inflating resuscitation bag (Ambu® or similar), with reservoir bag and adaptors/oxygen cylinder for administering supplementary oxygen.
- A ventilator suitable for the cases anaesthetised at that location.

**Recommended items**

- Anaesthesia workstation with central processing unit controlling electronic flow meters, electronic vaporisers and integrated multi-mode anaesthesia ventilator, e.g., rising bellow or piston-driven, with integrated patient monitoring and a circle breathing circuit with a carbon dioxide absorber.
- Venturi® injector for airway inflation within the theatre complex.

Ancillary equipment per theatre

**Essential items**

Laryngoscopes (preferably with fibre-optic light carrier and light-emitting diode light source)

Two functional handles with
- Full range of adult blade sizes, preferably Macintosh pattern.
- Appropriate range of paediatric laryngoscope blades when providing paediatric anaesthesia.

Video-assisted laryngoscope (considered essential in all large level 1, level 2 and level 3 hospitals and high turnover obstetric units).

Magill adult and paediatric endotracheal tube-introducing forceps.

Nonmetallic or plastic-coated, malleable endotracheal tube-introducing stylettes.

Inflating device (syringe and a cuff pressure manometer) for endotracheal tube cuffs.

Two kidney dishes as receivers for clean and dirty oral and endotracheal instruments.

Designated difficult airway management trolleys with appropriate equipment should be in every theatre complex.

Anaesthesiologist’s chair on wheels with backrest.

A wall clock with a sweep second hand or digital equivalent should be present in each theatre.

Suction unit for exclusive use by the anaesthesiologist, generating a minimum negative pressure of 50 kPa at a minimum airflow of 25 l/minute into a reservoir bottle of at least one-litre capacity. Adequate length of suction tubing and an appropriate range of cannulas/catheters for oral and endotracheal suction.

Anaesthesia and surgical suction bottles should be graduated for volume.

A monitor-defibrillator with adult and infant electrodes per theatre suite must be available. The ability to provide external cardiac pacing is desirable in all age groups, including neonates and paediatric patients.

Operating table with Trendelenburg-position controls at the head of the table.
- Two lateral padded straight arm supports.
- Appropriate padding and equipment for the positioning of patients to prevent injury.

Drug trolley for exclusive use by the anaesthesiologist.

Topical anaesthesia spray.

Two intravenous (IV) infusion poles.

An appropriate selection of IV fluids and IV cannulas must be available.

In-line warmer for blood and IV fluids.

Pressure infuser for both 500 ml (blood) and 1 000 ml IV bags.

Infusion devices: volumetric pumps and/or syringe drivers.

A pair of strong scissors.

A method of securing the anaesthesia breathing system to the operating table.

Warming blankets/convection warmers for use in the theatre. Availability of warming blankets/convection warmers is an absolute requirement for neonates and infants.

Where infants and small children are to be anaesthetised, a full range of the necessary paediatric equipment (as outlined above) must be available.

Electrical generator backup for hospital and/or theatre complex.

Uninterruptible power supply (UPS) or battery backup for life-support equipment.
In the event of a power outage (failure of main Eskom power supply), the following guidelines should be followed:

1. If the theatre complex only has one electrical backup system (generator/UPS), current elective cases should be completed as soon as possible, and all other cases postponed until the main power is restored. Urgent emergency cases may continue (See Appendix F[iii]).

2. If a theatre complex has a second backup power supply, e.g., a second generator or UPS unit, elective cases can continue if it is verified that the second backup supply has adequate capability for the duration of the power outage.

3. Equipment battery backup is not deemed to be a second backup power supply as the duration of the battery supply is not dependable enough to continue with an elective list.

**Recommended items**

A telephone in each theatre for communication.

Individual illumination of the anaesthesiologist’s area, including an emergency backup, battery-powered illumination source.

Blood salvage system.

High-flow blood/fluid warmer.

Syringe drivers programmed to administer target-controlled IV anaesthesia.

Intermittent pneumatic calf compressors and related consumables.

Low amperage peripheral nerve stimulator to assist with regional anaesthesia techniques per theatre suite.

Equipment for patient-controlled analgesia (PCA).

Transportable ventilator and monitor.

Video-assisted or normal light source fibre-optic bronchoscope.

A rigid bronchoscope (this need not be for exclusive use by the anaesthesiologist) with attachments for ventilating apnoeic patients (available in the theatre suite).

All electrical equipment should be able to operate from batteries, particularly when a reliable emergency electrical supply is not available.

**Monitors**

**Essential items**

A stethoscope.

A multi-parameter vital signs monitor, incorporating and displaying:

- An electrocardiogram (ECG) channel with 3- and/or 5-lead ECG monitoring. The unit must incorporate a diathermy filter.
- Heart rate: Derived from ECG, pulse oximetry or non-invasive blood pressure (NIBP) readings.
- An automated electronic NIBP module displaying systolic, mean, and diastolic blood pressure (BP), with an appropriate range of cuffs.
- Pulse oximetry, displaying oxygen saturation and a plethysmograph.
- Anaesthetic agent analyser and capnography, displaying end-tidal anaesthetic agent concentrations and CO₂ in mmHg, kPa or a percentage, and a capnograph.
- Patient temperature for oropharyngeal, oesophageal, rectal, bladder or tympanic use, reading 22–42 °C minimum range.
- Alarms: adjustable alarm limits for all parameters.

**Oxygen monitor** (inspired and expired), with a low-limit alarm (may be incorporated in the multi-parameter vital signs monitor or the anaesthesia machine).

Whenever an automatic ventilator is used, a breathing circuit pressure monitor with high- and low-limit alarms must be incorporated.

A peripheral nerve stimulator to monitor neuromuscular function when muscle relaxants are used, with double burst stimulation, train-of-four and post-tetanic count facilities.

A point-of-care (POC) device to estimate blood glucose.

A POC device to measure haemoglobin and/or haematocrit.

A thermometer that permanently displays the operating theatre temperature.

**Recommended items**

Invasive pressure module for intra-arterial/IV pressure monitoring incorporated in the multi-parameter vital signs monitor or anaesthesia machine.

Portable ultrasound device for guided nerve blocks and vascular access.

Blood gas analyser.

Transportable vital signs monitor.

Scale for weighing swabs.

Processed electroencephalogram (EEG) depth of anaesthesia monitor.

Non-invasive cardiac output monitor.

Coagulation monitoring device. (Essential in a theatre where heparin is used, e.g., cardiac surgery, vascular surgery).

Transoesophageal echocardiography equipment.

Near-infrared spectroscopy (NIRS) cerebral oximetry monitor.

See Table I for essential equipment list (anaesthesia).
Table I: Essential equipment list

<table>
<thead>
<tr>
<th>Equipment description</th>
<th>District hospital</th>
<th>Regional hospital</th>
<th>Tertiary/central hospital</th>
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</thead>
<tbody>
<tr>
<td>Anaesthesia machine (basic)</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Anaesthesia machine, with O₂, air and N₂O flow meters, with vapourisers, anaesthesia rising bellow ventilator, absorber and closed circuit, masks, suction unit, aneroid BP apparatus (with obese, adult and child cuffs) and oxygen monitor</td>
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<tr>
<td>Anaesthesia workstation</td>
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<tr>
<td>Anaesthesia workstation: CPU controlled with electronic flow meters, electronic controlled vapourisers, integrated multi-mode ventilator (rising bellow or piston-driven), may include integrated patient monitor with ECT, ST-segment analysis, NIBP, invasive pressure, pulse oximetry, multi-gas analyser, spirometry, NMT, BIS or entropy</td>
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<tr>
<td>Anaesthesia trolley, mobile</td>
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<tr>
<td>Processed EEG depth of anaesthesia monitor (if not part of patient monitor)</td>
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<tr>
<td>Blood/fluid warmer</td>
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<tr>
<td>Blood salvage system</td>
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<tr>
<td>Cerebral oximeters (NIRS)</td>
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<tr>
<td>Diagnostic set complete</td>
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<td>Defibrillator, complete, mounted on a mobile trolley (adult and paediatric paddles)</td>
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<tr>
<td>Defibrillator with external pacing</td>
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<tr>
<td>Difficult airway management equipment</td>
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<td>Forced-air warmer</td>
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<td>Fibre-optic laryngoscope</td>
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<td>Glucometer</td>
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<td>Haemoglobinometer/centrifuge (Hct)</td>
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<td>High-flow blood/fluid warmer</td>
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<tr>
<td>Intermittent pneumatic calf compressors</td>
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<td>Jet ventilator</td>
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<tr>
<td>Laryngoscope set, complete</td>
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<tr>
<td>Non-invasive cardiac output monitor</td>
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<tr>
<td>PCA pump (reusable or disposable)</td>
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<tr>
<td>Peripheral nerve stimulator</td>
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<td>Platelet function monitor (access to)</td>
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<tr>
<td>POC diagnostics (blood gas, electrolytes, glucose and lactate)</td>
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<td>Portable ultrasound</td>
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<tr>
<td>Pressure infusion devices (for blood, 500 ml and 1 000 ml fluid bags)</td>
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<tr>
<td>Pulse oximetry – advanced (Hb, non-invasive cardiac output, etc.) (access to)</td>
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<td>Resuscitator, pulmonary, manual, adult, complete</td>
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<tr>
<td>Resuscitator, pulmonary, manual, child/infant, complete</td>
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<td>Scale for weighing swabs (access to)</td>
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<td>Syringe drivers</td>
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<tr>
<td>Suction unit, mobile, 1x 2-litre bottle / disposable bag, wall outlet</td>
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<td>Suction unit, mobile, 1x 2-litre bottle/disposable bag, electrical</td>
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<td>TCI syringe drivers (for TCI anaesthesia)</td>
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<td>Trans-oesophageal echocardiography</td>
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<tr>
<td>Transport ventilator</td>
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<tr>
<td>Transport vital signs monitor</td>
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<tr>
<td>Thromboelastography (access to)</td>
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<td>Video bronchoscope</td>
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<tr>
<td>Videolaryngoscope (for district, if high volume obstetrics)</td>
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<tr>
<td>Vital signs monitor: capnograph</td>
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<tr>
<td>Vital signs monitor with ECG, SpO₂, NIBP, temperature, capnography, multi-gas analysis, invasive BP</td>
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<tr>
<td>Vital signs monitor with ECG, SpO₂, NIBP, temperature, capnography, multi-gas analysis</td>
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<tr>
<td>Vital signs monitor with SpO₂ and NIBP</td>
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<tr>
<td>Volumetric infusion pump</td>
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Recovery room equipment

An area within the theatre suite, preferably with easy access from each theatre, must be provided for the recovery of patients from anaesthesia before discharge to the wards.

Equipment and drugs

Each bed space should be provided with:

1. An oxygen flow meter with attachment for oxygen tubing for mask or nasal prongs.
2. A hook, or pole, for suspension of IV fluids.
3. Suction equipment, including a receiver, tubing, a rigid handpiece and a range of suction catheters, including Yankauer.
4. An automated NIBP monitor with appropriately sized cuffs.
5. A stethoscope.
6. A pulse oximeter.

Within the RR, there must be:

1. A range of devices for the administration of oxygen to spontaneously breathing patients.
2. A self-inflating manual resuscitator, e.g., Ambu® bag or similar, able to deliver 100% oxygen and allow manual ventilation. A minimum of two per recovery room complex is required.
3. Equipment and drugs for airway management and endotracheal intubation.
4. Emergency drugs.
5. A range of IV equipment and fluids.
6. Drugs and equipment for acute pain management.
7. A range of syringes and needles.
8. An ECG monitor.

There should be immediate access to:

1. A monitoring defibrillator, preferably with pacing capability.
2. A blood warmer.
3. A thermostatically controlled warming cupboard for IV solutions.
4. A refrigerator for drugs and blood.
5. A procedure light.
6. A range of appropriate anaesthesia and emergency drugs.
7. A surgical tray for procedures, including tracheostomy and chest drains.
8. POC access to diagnostic services, e.g., blood glucose, blood gases and radiology.
9. A peripheral nerve stimulator.
10. Other equipment as appropriate to the patient’s condition, e.g., wire cutters.
11. A ventilator.

The recovery trolley or bed must:

- Have a firm base and mattress.
- Tilt from either end, both head up and head down, to at least 15 degrees.
- Be easy to manoeuvre.
- Have functional and accessible brakes.
- Have provision for the patient to be able to sit up.
- Have straps or side rails capable of being dropped below the base or easily removed.
- Include provision for a pole from which IV solutions may be suspended.
- Include provision for monitoring, mounting portable oxygen cylinders, underwater seal drains and suction apparatus for use during transport.

Routines for checking, cleaning, servicing and storage of equipment

Any institution at which anaesthesia is administered must provide efficient and reliable maintenance and repair services for all anaesthetic equipment. A suitable mechanism must exist whereby faulty essential equipment can be replaced immediately.

Regular sterilising, cleaning, and housekeeping routines for the care of anaesthesia equipment should be established in accordance with the SASA Guidelines for Infection Control in Anaesthesia in South Africa 2021 (Appendix G).

Service by an appropriately certified organisation or persons should be carried out on a regular and appropriate basis. Life-support equipment should be serviced by a manufacturer-approved license-holder company at intervals recommended by the manufacturer.

To promote maximum safety in relation to service procedures, the following points are important prerequisites:

- Individual anaesthetic machines should be clearly identified, either by the maker’s serial number, or preferably by a hospital marking. This identification must extend to all the readily removable components, such as canisters and vaporisers, so that the performance and checking of these can be followed without confusion.
- A record of service procedures performed on each machine, signed by the person responsible for the service, must be provided to the appropriate hospital personnel, e.g., department of anaesthesia, anaesthetic technical staff or theatre nursing staff, depending on local circumstances.
- In newly built operating theatres, where operating suites have undergone major structural alterations, before the commissioning of the area, all new and existing gas lines are pressure-tested, followed by gas flow and purity testing. This must be carried out by a third party licensed to install, and test medical gas lines.
- When any medical gas installation is tested, the persons that should be present are the mechanical engineer from public works/hospital group, the mechanical engineer from health infrastructure, the hospital/facility engineer; the medical engineer; the medical gas engineer and the third party doing the testing.
• The installation of new or altered gases requires certification once the installation is completed and deemed operational.
• Adequate time must be available for service personnel to perform regular and emergency servicing without compromising safety.
• Storage facilities should be available for nitrous oxide and oxygen within the operating theatre suite. This storage area should fulfil the criteria described in the appropriate South African Bureau of Standards (SABS) Code of Practice.

3.3 Low flow anaesthesia guidelines

2022 new addition by E Welch

The delivery of anaesthesia gases in the most efficient, economical, and environmentally friendly manner is a requirement of modern anaesthesia practice. This practice requires an understanding of the physics of the delivery system and the properties of the agents being used. It is an appropriate technique for the current administration of most volatile-based anaesthetics.

Definition

Low flow anaesthesia is anaesthetic gas delivery using a fresh gas flow less than the patient’s minute volume.

Classification of fresh gas flow rates

High-flow: greater than 4 litres per minute
Moderate flow: 2–4 litres per minute
Low-flow: less than 2 litres per minute
Basal flow: 250–500 ml per minute

250 ml/min is the minimal basal oxygen requirement for metabolic processes at rest in a normothermic patient and must therefore be administered as 100% O₂.

Equipment

Anaesthesia delivery system

Standard anaesthesia equipment as per SASA guidelines with an emphasis on:

• Anaesthesia machine capable of delivering accurate, fresh gas flow of less than 1 L per minute
• Flow meters capable of increments of less than 100 ml
• Leak of fewer than 100 ml on machine and circuit check done immediately before the case
• Carbon dioxide absorber
• Circle system with unidirectional flow valves

Monitoring

• Standard routine monitors as required for any anaesthetic (ECG, pulse oximeter, BP and other monitoring according to the case)
• Inspired oxygen monitor
• Capnography
• Agent analyser
• Ventilatory pressure and tidal volume

CO₂ absorber

• Canister containing between 450 ml and 3 L of carbon dioxide absorbent that undergoes a colour change when exhausted (Soda lime or Baralyme undergo a colour change when exhausted).
• When the absorber is exhausted, a rise in the inspired CO₂ (F_iCO₂) is seen on the capnograph.
• Absorber must be changed once F_iCO₂ is greater than 4 mmHg (0.5 kPa)

Volatile delivery

• Vaporiser out of circuit
• Desflurane, isoflurane and sevoflurane are the agents of choice
• Older, soluble, highly metabolised agents like halothane and enflurane cannot be delivered at high enough concentrations to be easily delivered with flows less than 1 L
• Poorly metabolised gases like desflurane may accumulate during lengthy procedures at very low flows
• The use of nitrous oxide is not recommended when using low flows as it increases the risk of hypoxia

Gas delivery

• Gas delivery using a standard anaesthetic machine
• Flow meters must be able to deliver flows from 250 ml to 10 L per minute
• Flow meters must be graduated to measure accurately at flows less than 1 L, preferably in 50 ml to 100 ml increments

Closed circuit

• Often called a circle system as gas flow is in a single direction from machine to patient and back from patient to machine
1. Oxygen

**What to give**

- A minimum of 250 ml of oxygen is needed to meet the basic metabolic requirements of a normothermic, awake patient at rest. The delivery of at least this amount of oxygen per minute is required in an anaesthetised patient. This replacement will be constant, provided the metabolic rate remains constant. At flows of less than 1 L per minute, a F\textsubscript{O\textsubscript{2}} of at least 50% is recommended. If the monitored F\textsubscript{O\textsubscript{2}} decreases, the minimum amount of oxygen delivered will need to be increased.

- All circuits have a *small leak* that will usually be detected by the preoperative machine check (most machines will allow a leak of fewer than 40 ml per minute to pass this test). In addition to the gas loss from sampling lines and uncuffed tubes, this leak needs to be added to the minimal amount of gas delivered. Most people are comfortable with a minimum of 300–500 ml per minute fresh gas flow.

2. Volatiles are delivered from a vaporiser out of circuit. This gas replaces metabolised and absorbed volatile agent and gas vented to the atmosphere. A variable replacement is needed as it depends on the solubility and amount of agent metabolised.

3. **N\textsubscript{2}O**, when used as an adjuvant anaesthetic agent, must always be added to at least 250 ml of oxygen. Saturation occurs quickly, and metabolism is minimal, so N\textsubscript{2}O will start to accumulate over time. It is not recommended to use nitrous oxide with low flow.

4. **Air** is often added to flows above 250 ml of oxygen to avoid complications from using 100% oxygen, provided the F\textsubscript{O\textsubscript{2}} is maintained.

**Unidirectional valves**

- Circuit requires two unidirectional valves that move freely with low resistance to flows down to less than 250 ml
- Valves must delineate the circuit’s inspiratory and expiratory limb, allowing flow to occur through the circuit in one direction only without mixing inspiratory and expiratory gases

**Oxygen delivery**

- Inspiratory and expiratory oxygen concentration needs to be monitored constantly
- Hypoxia can occur due to inadequate fresh gas flow, delivery of a low F\textsubscript{O\textsubscript{2}}, changes in patients' metabolic rate, and dilution by accumulating gases such as N\textsubscript{2}O, CO\textsubscript{2}, CO, and methane

**Set up of the circuit**

- Fresh gas must be delivered into the reservoir bag or ventilator bellows and not directly into the circuit
- Gas is delivered to the patient and returned via the CO\textsubscript{2} absorber in a circular pattern using a ‘closed system’. The same gas is continuously recycled with small amounts released from the ventilator or breathing valve to allow for additional fresh gas to be introduced, with one-way valves producing unidirectional flow around the circuit.

**How to do it**

The basic principle is that it takes a long time for any change in gas concentration to occur at low flows. The lower the fresh gas flow, the longer this change takes.

**What to give**

1. **Oxygen**: A minimum of 250 ml of oxygen is needed to meet the basic metabolic requirements of a normothermic, awake patient at rest. The delivery of at least this amount of oxygen per minute is required in an anaesthetised patient. This replacement will be constant, provided the metabolic rate remains constant. At flows of less than 1 L per minute, a F\textsubscript{O\textsubscript{2}} of at least 50% is recommended. If the monitored F\textsubscript{O\textsubscript{2}} decreases, the minimum amount of oxygen delivered will need to be increased.

2. All circuits have a *small leak* that will usually be detected by the preoperative machine check (most machines will allow a leak of fewer than 40 ml per minute to pass this test). In addition to the gas loss from sampling lines and uncuffed tubes, this leak needs to be added to the minimal amount of gas delivered. Most people are comfortable with a minimum of 300–500 ml per minute fresh gas flow.

3. Volatiles are delivered from a vaporiser out of circuit. This gas replaces metabolised and absorbed volatile agent and gas vented to the atmosphere. A variable replacement is needed as it depends on the solubility and amount of agent metabolised.

**Maintenance of anaesthesia**

- Due to the metabolism and absorption of volatile agents, the concentration of volatile agent in the entire system will slowly decrease over time. While the circuit receives low fresh gas flow, the absorbed and metabolised agent is not completely replaced; the result is a further decrease in alveolar volatile concentration. This may result in the patient becoming aware.
- Therefore, a higher vaporiser setting than the desired end-tidal agent concentration is needed.

**Principles of altering gas concentrations**

The following are the principles behind establishing or changing any gas concentration using low flow:

1. The entire circuit comprises about 6 L—the tubing makes up about 1.5 L, the ventilator or rebreathing bag about 2 L, the carbon dioxide absorber 2 L, and the patient’s tidal volume 0.5 L.

2. The aim is to obtain a constant concentration of volatile agent throughout this 6 L at the MAC value we require.

3. This 6 L needs to be changed five times to reach a steady gas state, so a total of 30 L of circuit gas needs to be changed.

4. If we introduce the volatile agent at 1 L per minute, it will take 6 minutes to change all the gas in the circuit once, and 6 x 5 = 30 minutes to reach steady state. At 250 ml, it takes 120 minutes to reach steady state.

5. One can also speed this up by setting a greater volatile concentration than is desired until the agent is at the required concentration on the agent analyser.

**Starting a case**

Use the above principles at the beginning of a case. The circuit contains no volatile agent. The aim is to saturate it with a certain MAC of volatile agent in a patient who will awake quickly from the initial dose of the induction agent.

- Following an initial IV and opiate induction.
- Fresh gas flow of 2 L/minute and desflurane at 12% or sevoflurane at 4% until the end-tidal agent concentration reaches the desired concentration (6% desflurane or 2% sevoflurane).
- Lower fresh gas flow to 250–500 ml and monitor oxygen and volatile concentration. Adjusting the vaporiser as needed.

**Changing gas concentration**

- Using the above principles shows that changing the concentration of volatile to a higher or lower MAC while at low flow can take quite a long time.
- Rapid changes in concentration can be achieved by increasing the fresh gas flow to 2 litres.

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• Minimally metabolised agents like desflurane, isoflurane and sevoflurane require a vaporiser setting of 10–20% higher than required to accommodate for this but may also start to accumulate over time.
• An agent analyser eliminates this guesswork.
• Nitrous oxide in a closed circuit will start to accumulate over time as it is minimally metabolised, resulting in hypoxia.

Switching off
1. The same principles apply to wakening the patient at the end of the procedure. If the volatile agent is switched off and low fresh gas flow maintained, the patient can take between 10 and 20 minutes to wake up while the volatile concentration slowly decreases.
2. A fresh gas flow of 6 L will rapidly flush the circuit of residual volatile agent.

Paediatrics
In paediatric anaesthesia, the same principles apply but use smaller bore tubing, size-appropriate filters and cuffed tubes.

Troubleshooting
1. Hypoxia – due to low delivered $F_O_2$, dilution from other gases, increased metabolic rate.
2. Tachycardia – due to rapid changes in gas concentration with desflurane (the rule is fresh gas flow x volatile concentration should be less than 24, i.e., $2 L \times 12\% = 24$).
3. Overdose – due to prolonged high fresh gas flow and high vaporiser setting.
4. Awareness – due to circuit leak or low vaporiser setting.
5. Hypercapnoea – carbon dioxide absorber exhaustion.
7. Low circuit volume – due to leaks in the circuit and can lead to inadequate ventilation as bellows and reservoir bag are not refilled, hypoxia and awareness.

3.4 Medication
To be reviewed in 2026

Essential Drugs Programme
To provide equal access to medicines for all South Africans, whilst improving the supply of listed items at a lower cost, the Essential Drugs Programme (EDP) of South Africa was established in terms of the National Drug Policy (NDP) in 1996.

The World Health Organization (WHO) defines essential medicines as those that satisfy the priority healthcare needs of the population. Essential medicines must always be available within health systems in adequate quantities, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.

In the health objectives of the NDP, the government of South Africa clearly outlines its commitment to ensuring the availability and accessibility of medicines for all people.

The criteria for selecting essential medicines in South Africa were based on the WHO guidelines for drawing up a national EML. Essential medicines are selected with due regard to disease prevalence, evidence of efficacy and safety, and comparative cost.

The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations. It happens by means of the ministerial appointment of a National Essential Medicines List Committee (NEMLC), which draws up and revises the national list of essential medicines for three levels of care: primary health care, secondary and tertiary hospital level.

Table II summarises current recommendations of essential drugs for anaesthesiology. The list indicates agents that should be available to provide safe anaesthesia at regional hospital level.

Table II: Summary of current recommendations of essential drugs for anaesthesiology

<table>
<thead>
<tr>
<th>Premedication</th>
<th>Benzodiazepines</th>
<th>Lorazepam</th>
<th>Midazolam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Induction agents</td>
<td>Propofol</td>
<td>Etomide</td>
<td>Ketamine</td>
</tr>
<tr>
<td>Volatiles</td>
<td>Induction</td>
<td>Halothane</td>
<td>Sevoflurane</td>
</tr>
<tr>
<td>Maintenance</td>
<td>Isoflurane</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muscle relaxants</td>
<td>Depolarisers</td>
<td>Suxamethonium</td>
<td></td>
</tr>
<tr>
<td>Non-depolariser</td>
<td>Cisatracurium</td>
<td>Vecuronium</td>
<td></td>
</tr>
<tr>
<td>Rapid sequence intubation</td>
<td>Suxamethonium</td>
<td>Rocuronium</td>
<td></td>
</tr>
<tr>
<td>Reversal agents</td>
<td>Neostigmine with either atropine or glycopyrrolate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Analgesics</td>
<td>Oral</td>
<td>Paracetamol</td>
<td>NSAIDs, e.g. ibuprofen</td>
</tr>
<tr>
<td>IV</td>
<td>Fentanyl</td>
<td>Morphine</td>
<td>Ketamine</td>
</tr>
<tr>
<td>Postoperative</td>
<td>Morphine</td>
<td>Tramadol</td>
<td>Diclofenac IM</td>
</tr>
<tr>
<td>Fluids</td>
<td>Ringer’s lactate</td>
<td>0.9% NaCl</td>
<td></td>
</tr>
<tr>
<td>Treating anaesthesia complications</td>
<td>Malignant hyperthermia</td>
<td>Dantrolene</td>
<td></td>
</tr>
<tr>
<td>CVS support – adrenaline (epinephrine)</td>
<td>LA toxicity</td>
<td>Lipid emulsion (20%)</td>
<td></td>
</tr>
<tr>
<td>Acute hypotension</td>
<td>Ephedrine IV, 3–5 mg</td>
<td>Phenylephrine IV, 50–100 mcg</td>
<td></td>
</tr>
</tbody>
</table>

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The drugs listed are the minimum requirement for safe anaesthesia that should be available in all facilities.

In addition, see Table III for a list of highly desirable drugs in regional, tertiary and central hospitals.

<table>
<thead>
<tr>
<th>Table III: Drugs which are highly desirable in regional, tertiary and central hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inhalants</strong></td>
</tr>
<tr>
<td><strong>Analgesics</strong></td>
</tr>
<tr>
<td><strong>Relaxants</strong></td>
</tr>
<tr>
<td><strong>Other</strong></td>
</tr>
</tbody>
</table>

**Chronic neuropathic pain**
- Gabapentin
- Duloxetine
- Pregabalin

**Off-label drug use**

Off-label prescription and/or use refers to the prescription or use of a medicine or medical device outside of its approved label, i.e., outside of the indication for which the manufacturer has submitted studies to the satisfaction of regulators and which has therefore not been proven at all or to the level at which it would satisfy regulators to register the product for that particular indication or use.

Medicines are not always tested or registered for certain patient groups or diseases. Medicines are sometimes used in contexts or for conditions other than for which they have been registered. Medicines registration processes in South Africa are sometimes slower than those in other markets, and sometimes, there are no alternatives available to patients.

Medicines (and medical devices) are registered based on their safety profile being acceptable, and on their proven efficacy (or performance).

Off-label use of medicines may be indicated if sufficient evidence (defined as peer-reviewed acceptance of indication) exists for such use. Medicines are often used in such a manner in the paediatric population.

Under South African law, informed consent should be provided for the specific healthcare intervention. The World Medical Association (WMA) requires that, in the case of off-label prescriptions, the patient must be informed about the character of the prescription.

The Consumer Protection Act (CPA) requires patients to be informed of the nature of the specific goods or services they are to receive, and the conditions under which they are to be provided. Furthermore, this information is to be provided in plain language, which means that the patient should understand what an off-label prescription and use means.
The National Health Act (NHA) requires the patient to be informed about the benefits, risks and consequences of, in this case, off-label use. The CPA has more stringent tests in relation to warnings about risks and requires that the patient’s attention be drawn to the specific risks conspicuously, and where there is a risk that is ‘serious’ or ‘unusual’, that the consent be provided in writing.

Where there are no alternatives available to patients, or where off-label use is, in the opinion of the profession, the best for certain patients, this fact should be explained to the patient as well.

It must be borne in mind that, under consumer legislation, the practitioner shares the legal liability for any possible harm that results from the use (or off-label use) of a product with all others in the supply chain. This harm may be because the product is unsafe, due to product failure or due to inadequate instructions or warnings being issued.

The CPA states that goods must be “reasonably suitable” for the purpose for which they were intended. Products registered for specific indications in other jurisdictions may be easier to justify as “reasonably suitable” than those not registered anywhere for the particular indication and/or with limited data on their safety and efficacy.

Due to pharmacovigilance (postmarketing surveillance) requirements on pharmaceutical companies (similar provisions exist for medical device companies), practitioners are advised to contact the medical departments of such companies to enquire as to the recorded safety profile of the product when used off-label, as well as whether there is information available on whether the product is, or could be, reasonably suitable for the off-label purpose.

**Ampoule labelling standard**

**SASA deems the standard SANS 44/2014: Labelling of small-volume (50 ml or less) parenteral drug containers, as essential and to be adopted.**

The key feature of this standard is that labels will be much more legible in the clinical arena. The standard focuses on font size, text legibility and orientation, text contrasts, ordering of label content, and language. It mandates the use of the drug’s generic name on the label and states that, if used, the trade name may not exceed the size of the generic name. To create space for clearer labelling on small ampoules, English is now the only mandatory language. The standard also recommends that, where applicable, manufacturers should part of the label utilise the colours specified for identifying specific drug classes on syringe labels, as per the SABS SANS 26825.

**Substitution of medicines and devices**

The substitution of health goods occurs in resource-constrained settings because of healthcare priorities in formularies and treatment guidelines. Legislation relating to substitution in health care (and in general consumer goods) impacts this practice.

The WMA has serious concerns about the practice of substitution.

There is a difference between generic and therapeutic substitution, with generic substitution generally permitted by South African law, but therapeutic substitution is not. The WMA recommends that national medical associations lobby for therapeutic substitution to be declared illegal, where the practitioner does not issue a new and valid prescription.

Drug therapy should be individualised based on a complete clinical patient history, current physical findings, all relevant laboratory data, and psychosocial factors.

Where generic products are on the market, the WMA recommends that practitioners ensure that there are quality assurance laboratory data, and psychosocial equivalence.

The Medicines and Related Substances Act only permits generic substitution within the criteria set by the section 22F:

1. Pharmacists must inform patients with a prescription for dispensing of the benefits of the substitution.
2. When substitution has taken place, the pharmacist must take reasonable steps to inform the prescriber of such substitution.
3. Pharmacists may dispense the generic instead of the prescribed medicine, unless expressly forbidden by the patient.
4. The prescriber has written in their own hand on the prescription the words “no substitution” next to the item prescribed.
5. The retail price of the generic is higher than that of the prescribed medicine.
6. The product has been declared not substitutable by the South African Health Products Regulatory Authority (SAHPRA).
7. Although there was, in the past, a list of non-substitutable products issued by SAHPRA, the current list only contains rules relating to biologics. SASA, however, strongly recommends that practitioners who deem that the generally accepted circumstances under which substitution should not take place, are present in a particular case, should ensure that a non-substitutable order is issued to clearly indicate the opinion of the practitioner.

The CPA also prohibits the substitution of any goods without the consent of the consumer (patient).

Therefore, the WMA, the Medicines Act, and the CPA, read with the NHA, make it clear that:

1. Information must be provided on drug choices and the patient’s condition to enable the practitioner to select medicines carefully.
2. Once the patient consents to the medicine selected, that medicine should not and cannot be changed without the patient's consent.

3. In the case of therapeutic substitution, practitioners should re-evaluate the patient and the options and issue a new prescription.

The WMA and South African postmarketing surveillance of medicines require that all adverse drug reactions (ADRs) or therapeutic failures be reported. This is and should also be the case in instances of generic substitution.

The WMA recommends that practitioners document ADRs and report it to appropriate drug regulatory authorities.

The WMA recommends that medical practitioners and pharmacists cooperate within the definitions set by their respective roles, making it clear that the practitioners assess and prescribe based on an assessment of the patient's pharmacological needs. It furthermore states that pharmacists have the role of "reviewing prescription orders to identify interactions, allergic reactions, contraindications and therapeutic duplications." They should, however, discuss "concerns with the prescribing physician, but the pharmacist should not change the prescription without consulting the prescriber".

SASA recommends that, in the practical theatre setting, the practitioner be able to issue an advanced instruction to the hospital pharmacist that generic substitution would not be indicated for a particular patient or patient group, and that a specific medicine should therefore be available in theatre.

SASA does not support the practice where third parties, even if they are pharmacists, contact patients to recommend therapeutic or generic substitution.

National Pharmacovigilance Programme

SAHPRA is responsible for ensuring the safety, efficacy and quality of all medicines used by the South African public. The National Pharmacovigilance Programme is coordinated by SAHPRA and has a dedicated unit, The National Adverse Drug Event Monitoring Centre (NADEMC), in Cape Town, which monitors the safety of all registered medicines in South Africa.

What is pharmacovigilance?

Pharmacovigilance is defined as the science and activities concerned with the detection, assessment, understanding and prevention of adverse reactions to medicines (i.e., ADRs). This activity aims to improve the safe and rational use of medicines, thereby improving patient care and public health.

What is an adverse drug reaction?

SAHPRA defines an ADR as a response to a medicine that is noxious and unintended, including lack of efficacy, and which occurs at any dosage and can also result from overdose, misuse, or abuse of medicine.

Who should report adverse drug reactions?

All healthcare workers, including doctors, dentists, pharmacists, nurses, and other health professionals, are encouraged to report all suspected adverse reactions to medicines (including vaccines, X-ray contrast media, traditional and herbal remedies), especially when the reaction is not in the package insert, potentially serious or clinically significant.

What happens to a report?

All ADR reports are entered into a national ADR database. Each report is evaluated to assess the causal relationship between the event and the medicine. A well-completed ADR/product quality form submitted could result in any of the following:

- additional investigations into the use of the medicine in South Africa;
- educational initiatives to improve the safe use of the medicine;
- appropriate package insert changes to include the potential for the reaction, and
- changes in the scheduling or manufacture of the medicine to make it safer.

ADR reporting aims to reduce the risks associated with using medicines and ultimately improve patient care.

Will reporting have any negative consequences on the health worker or the patient?

An ADR report does not constitute an admission of liability or that the health professional contributed to the event in any way. The outcome of a report, together with any important or relevant information relating to the reaction, will be sent back to the reporter as appropriate. The details of a report are stored in a confidential database. The names of the reporter or any other health professionals named on a report and that of the patient will be removed before any details about a specific ADR are used or communicated to others. The information is only meant to improve the understanding of the medicines used in the country.

Is the event possibly an adverse drug reaction?

The following factors should be considered when an ADR is suspected:

- What exactly is the nature of the reaction? (Describe the reaction as clearly as possible and, where possible, provide an accurate diagnosis.)
- Did the reaction occur within a reasonable time relationship to starting treatment with the suspected medicine? (Some reactions occur immediately after administration of a medicine while others take time to develop.)
- Is the reaction known to occur with the medicine as stated in the package insert or other reference? (If the reaction is not documented in the package insert, it does not mean the reaction cannot occur with that medicine.)
- Did the patient recover when the suspected medicine was stopped? (Some reactions can cause permanent damage, but most reactions are reversible if the medication is stopped.)
- Did the patient take the medicine again after the reaction abated (i.e., rechallenge)?
- If so, did the same reaction occur again? (In most situations, it is not possible or ethical to rechallenge the patient with the same medicine. If such information is available or if such a rechallenge is necessary, recurrence of the event is a strong indicator that the medicine may be responsible.)
• Can this reaction be explained by other causes, e.g., underlying disease/s; other medicine/s; toxins or foods? (It is essential that the patient is thoroughly investigated to decide the actual cause of any new medical problem. A medicine-related cause should be considered when other causes do not explain the patient’s condition.)

What types of reactions should be reported?

The following ADRs should be reported:
• all ADRs to newly marketed drugs or new drugs added to the EML,
• all serious reactions and interactions,
• ADRs that are not clearly stated in the package insert, and/or
• all adverse reactions or poisonings to traditional or herbal remedies.

Report even if you are not certain that the medicine caused the event.

What product quality problems should be reported?

The following product quality problems should be reported:
• suspected contamination,
• questionable stability,
• defective components,
• poor packaging or labelling, and/or
• therapeutic failures.

How can adverse drug reactions be prevented from occurring?

Some ADRs are unavoidable and cannot be prevented. However, most ADRs can be prevented by following the basic principles of rational use of medicines.

How are adverse drug reactions reported?

1. Reporting of suspected ADRs can be done via the eReporting link on the SAHPRA website (https://www.sahpra.org.za). Alternatively, an ADR/product quality report form should be completed and emailed to adr@sahpra.org.za. The form can be obtained from the SAHPRA website. Report forms may also be accessed via the following website: http://www.mccza.com.

2. The National Adverse Drug Event Monitoring Centre
C/o Division of Pharmacology, University of Cape Town, Observatory, 7925 
(021) 447 1618; Fax: (021) 448 6181

Ampoule sharing

Ampoule sharing (Appendix F[iii]) is prevalent in public and private sector anaesthesia practice and refers to withdrawing multiple doses of drug from a single-use ampoule. This practice mostly relates to “expensive drugs” and paediatric anaesthesia – an attempt at cost saving in the first instance, and time-saving or convenience in paediatric cases. From the clinical governance point of view, there is little doubt that ampoule sharing is certainly not in our patients’ best interests. The inability to maintain sterility once an ampoule is opened, the risk for cross infection with subsequent sepsis, the possibility of mistakes in labelling or administration, and the risk of theft from an open ampoule negate the small cost benefit of sharing a single large ampoule between patients.

• SASA deems the standard SANS 44/2014: Labelling of small-volume (50 ml or less) parenteral drug containers, as essential and to be adopted.
• The WMA recommends that practitioners document ADRs and report it to appropriate drug regulatory authorities.
• The WMA recommends that medical practitioners and pharmacists cooperate within the definitions set by their respective roles, making it clear that the practitioners assess and prescribe based on an assessment of the patient’s pharmacological needs. It furthermore states that pharmacists have the role of “reviewing prescription orders to identify interactions, allergic reactions, contraindications and therapeutic duplications.” They should, however, discuss “concerns with the prescribing physician, but the pharmacist should not change the prescription without consulting the prescriber”.
• SASA recommends that, in the practical theatre setting, the practitioner be able to issue an advanced instruction to the hospital pharmacist that generic substitution would not be indicated for a particular patient or patient group, and that a specific medicine should therefore be available in theatre.

Bibliography

• Logan M. Breathing systems: effect of fresh gas flow rate on enflurane bja/73.6.775.
• Lundgren AC. Ampoule sharing – is it safe practice and is it best practice? Pipeline. 2007:57:1


