



**SOUTH AFRICAN SOCIETY  
OF ANAESTHESIOLOGISTS (SASA)**

# **Practice Guidelines 2018 Revision**



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# INFORMATION

## Previous publications and revisions

First published:

1987

Revisions:

1990

1999

2006

2012

## Future revision

Suggested future revision:

2020

Suggested topics for future revision:

Scope of anaesthesia practice for Family Medicine Physicians

Informed consent procedures, responsibilities and proposed forms

Low flow gas requirements

Anaesthesia outside a hospital facility

Anaesthesia for day/ambulatory surgery

Position statement on non-physician anaesthetists

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## **Acknowledgements**

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Thank you to all the individuals, named and unnamed, who have contributed even in a small way to the Practice Guidelines over the years.



## List of Abbreviations

SASA	South African Society of Anaesthesiologists
CSA	Canadian Standards Association
CAS	Canadian Anesthesiologists' Society
WFSA	World Federation of Societies of Anaesthesiologists
HPCSA	The Health Professions Council of South Africa
ICU	Intensive Care Unit
ESMOE	Essential Steps in the Management of Obstetric Emergencies
ASA	American Society of Anesthesiologists
CPD	Continuing Professional Development
SAMA	South African Medical Association
WMA	World Medical Association
NPA	Non-physician Anaesthesia Provider
CMSA	Colleges of Medicine of South Africa
PACU	Postanesthesia Care Unit
NHA	National Health Act
PCR	Perioperative Clinical Registry
PSHR	Perioperative Shared Health Record
POPI	Protection of Personal Information Act, 2013
MDNF	Maternal death notification form
MCC	Medicines Control Council
BCEA	Basic Conditions of Employment Act
SANC	South African Nursing Council
RR	Recovery Room
APPSA	Association of Perioperative Practitioners of South Africa

SATS	South African Theatre Sister
ENT	Ear, Nose and Throat
MAC	Minimum Alveolar Concentration
ISO	International Standards Organisation
AA	Agent Analysis
UPS	Uninterruptable power supply
EEG	electroencephalogram
NIRS	Near Infrared Spectroscopy
EDP	Essential Drugs Programme
NEMLC	National Essential Medicines List Committee
NMT	Neuromuscular Transmission
ADR	Adverse Drug Reaction

## **Source publications and documentation**

1. The International Standards for a Safe Practice of Anaesthesia 2010, as endorsed by the World Federation of Societies of Anaesthesiologists (WFSA).

### **SOURCES:**

MERRY AF, COOPER JB, SOYANNWO O, ET AL. INTERNATIONAL STANDARDS FOR A SAFE PRACTICE OF ANESTHESIA. CAN J ANESTH. 2010;57(11):1027-1034.

WORLD FEDERATION OF SOCIETIES OF ANAESTHESIOLOGISTS (WFSA) [HOMEPAGE ON THE INTERNET]. AVAILABLE FROM: [HTTP://WWW.ANAESTHESIOLOGISTS.ORG](http://www.anaesthesiologists.org)

2. The Guidelines to the Practice of Anesthesia by the Canadian Anesthesiologists' Society, Revised Edition 2018, Canadian Journal of Anesthesia, Volume 65, Number 1
3. SASA Guidelines for Infection Control, SASA Sedation Guidelines, SA Acute Pain Guidelines, SA Society of Regional Anaesthesia Guidelines, Paediatric Sedation Guidelines for Procedural Sedation and Analgesia and SASA High Spinal Anaesthesia Guidelines.
4. National Department of Health documents as referred to in the text and/or added as appendices

## **Errata**

Errata will be published in the online version of the Revision on [www.sasaweb.com](http://www.sasaweb.com).

## Disclaimer

While every effort has been made to ensure scientific accuracy, SASA shall not be responsible or in any way liable for errors, omissions or inaccuracies in this publication, whether arising from negligence or otherwise or for any consequences arising therefrom. These guidelines are designed to provide a guide to the minimum standards considered best clinical care. However, every clinician retains responsibility for the care of the patient and must exercise independent clinical judgement.



## SOUTH AFRICAN SOCIETY OF ANAESTHESIOLOGISTS (SASA)

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# INTRODUCTION

The vision of the South African Society of Anaesthesiologists (SASA) is to lead the science and practice of safe anaesthesia to the highest standard and to ensure the sustainability of anaesthesia services in South Africa. SASA members subscribe to a Code of Conduct for Anaesthesia Professionals (Appendix 1).

The aim of the SASA Practice Guidelines is to set the standard for the practice of safe anaesthesia in the context of the South African healthcare system. The standard should be applicable to all sectors of this, often considered fragmented, system. In the public sector the head of the department of anaesthesia in a hospital or facility carries the burden of ensuring that the anaesthesia services provided in the department comply with standards of safe anaesthesia care. This responsibility should include awareness on standards, practice guidelines and regulatory requirements, establishing and enforcing written policies, peer review processes, monitoring quality of anaesthesia care and liaising with other stakeholders.<sup>1</sup> In the private sector, each individual practitioner carries an equivalent responsibility. SASA aims to guide and support individual practitioners or practices, regardless of sector, in performing their professional duties towards our patients.

The 2018 Revision is therefore extensive, in response to changing demands of the healthcare system and anaesthesia work environment:

- The previously published **SASA Position Statements** have been incorporated in the current Revision, as well as statements circulated in the SASA newsletter and other correspondence:
  - Responsible use of healthcare resources\*\*
  - Personal information and health data: confidentiality and access
  - The anaesthetist's prescription
  - Workload
  - Off-label drug use
  - Substitution of medicine and devices
  - Ampoule sharing
  - Use of ultrasound in anaesthesia

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#### SOURCES:

1. CANADIAN ANESTHESIOLOGISTS' SOCIETY'S "GUIDELINES TO THE PRACTICE OF ANESTHESIA" ON THE "RESPONSIBILITIES OF THE CHIEF OF ANESTHESIA"

\*\* CONSTITUTION OF THE REPUBLIC OF SOUTH AFRICA  
HPCSA ETHICAL RULES, 2006, AS AMENDED

- **Anaesthesia workforce – professional status, training, certification and accreditation, personnel, skills shortage (Appendix 2):** The latter appendix provides context to changes in this revision regarding issues such as scope of and support staff for the practice of anaesthesia, in the sections mentioned.
- **Records and statistics:** Safety and quality of care go hand-in-hand, and due consideration to the cost of anaesthetic care may then contribute to the value of care bestowed upon our patients. Unfortunately, most of the reports received by SASA on factors affecting safety and quality of care are anecdotal in nature. The Society has an ethical mandate to record and interpret information on the safety and quality of perioperative care in South Africa – a mandate that we ask all our members to contribute in fulfilling. We hope that, in future, revision of the Practice Guidelines will be based on evidence of care practices collected across all sectors and levels of care in the South African healthcare system.
- **Peer review and incident reporting:** The cost of health care is escalating worldwide, and medico-legal litigation contributes to an unprecedented level of expenditure in all areas of health care. This prompted the SA Ministry of Health to institute, amongst other initiatives, the Health Market Enquiry by the Competition Commission, and to investigate ways to mitigate medico-legal litigation. The profession and SASA have a role to play in supporting these initiatives.
- **Facilities, equipment and drugs:** The National Health Act stipulates that “every health care provider must inform” a patient of their health status, the range of diagnostic procedures and treatment options generally available, as well as the benefits, risks, costs and consequences of each. They should also be informed of their right to refuse health services, provided that the implications, risks, obligations of such refusal have been explained.
- **Professional well-being (Appendix 3):** As individual practitioners, we have the ethical and moral obligation to deliver the best care possible, but this includes attending to our own personal and professional well-being. As a profession, we have the obligation to take care of each other.

## Terminology

The contributors to the 2018 SASA Practice Guidelines Revision deemed it necessary to distinguish in the document between the two following categories of statements:

- Statements on circumstances, processes, equipment, drugs, etc. that are considered **essential** – wording to this effect also include's 'minimum standard', 'mandatory' or 'required'. Provision of anaesthesia care at a level lower than those outlined as **essential** for elective surgical procedures is unsafe and unacceptable.
- Statements on circumstances, processes, equipment, drugs, etc. that are considered **recommended** - wording to this effect also include 'desirable'. Stronger language – adding the word 'highly' – may be used to indicate that a circumstance, process, equipment or drug is deemed essential in an environment of best practise, and a goal that should be achieved as soon as possible. The goal always in any setting is to practise to the highest possible standards, preferably exceeding those prescribed if possible.

*\*\*The South African Constitution guarantees everyone the right of access to health care, which right has to be progressively realised within the available resources of the country. The Health Professions Council of South Africa (HPCSA) Ethical Rules require considerations of cost-effectiveness in healthcare provision. Healthcare resources include financial resources, infrastructure and equipment, as well as human resources. Financial resources can take the form of insurance- or medical scheme premiums, out-of-pocket contributions and taxation and budgetary allocations made to the health sector. All these resources have to be valued and optimally utilised.*

- *Healthcare practitioners should speak out where resources are not optimally utilised or where resources are directed away from healthcare service provision into non-essential areas of spending.*
- *There should be plans in place to systematically ensure that backlogs in infrastructure are addressed, maintenance and procurement of equipment are optimised and that quality of care is enhanced. These plans should be transparent, and healthcare practitioners should participate in the development thereof. Anaesthesia providers have an important role to play to ensure that infrastructure, equipment and quality of care are addressed.*

### SOURCES:

CONSTITUTION OF THE REPUBLIC OF SOUTH AFRICA  
HPCSA ETHICAL RULES, 2006, AS AMENDED

- *Health facilities should create mechanisms where proposals that impact the standard of care can be discussed prior to finalisation. Provision should also be made for complaints and disclosures, without penalty, to disclosing practitioners. Healthcare practitioners should not be victimised for raising healthcare resource concerns and/or for requiring participation in plans and decision-making relating to resource allocation.*
- *Every healthcare practitioner has to ensure that his/her recommendations to patients take into account the resource implications for both the patient and the system, and s/he should disclose the limitations being placed on care due to resource constraints, to the patient. Resource limitations may place rational and defensible limits to the care options available to patients. These limitations must be transparent, open to challenge and not detract from ensuring quality care.*
- *Treatment guidelines, protocols and policies should be based on best clinical practice, taking into consideration concerns of cost-effectiveness of the intervention and the affordability to the specific funding mechanism. Patients should, however, never have to receive sub-optimal care, or face under-servicing as a result of resource limitations. Resource limitations should not override the right of access to health care being meaningful.*

Although a disclaimer is added to this document, the Society is not ignorant of the fact that the standards set here can be, and have been, interpreted in a number of ways by individuals outside of the profession. It is however crucial that the Society continues to lead the way in guiding the profession of anaesthesia and related services in South Africa, which is the aim of this document. The Practice Guidelines will always be a work in progress, a guide that must stay relevant in changing social and economic circumstances. Comment on the Practice Guidelines can be sent to the SASA Office via email, and will be considered during the next revision, or included as erratum where applicable.



# GENERAL STANDARDS

## Section I: Professional status

South Africa suffers from a skills shortage of medical personnel in general (doctors and nurses) and specialist anaesthesiologists in particular (see Appendix 2). SASA is a professional society dedicated to addressing issues arising from anaesthesia practice, and can utilise specialist resources to consider and provide guidance on the provision of anaesthesia care by all anaesthesia providers. It is crucial that the SASA Practice Guidelines define the scope of practice for all existing and proposed categories of providers contributing to the anaesthesia workforce to maximise both patient care and the use of scarce resources.

In medicine, including anaesthesia, teamwork is emphasised. A proposed ideal surgical team would include:

- Surgeons
- Surgeon assistants
- Anaesthesiologists
- Anaesthesia assistants
- Nursing personnel (scrub nurse, floor nurse etc)
- Clinical technicians
- Clinical anaesthesia technologists
- Cleaners
- Theatre administration
- Porters

In addition, ward personnel and allied professions such as dietitians, physiotherapists and occupational therapists may form part of the team. This team may function in different compositions in different situations.

### ***Duties of an anaesthesia provider***

The practice of anaesthesia is unique in the provision of healthcare services, in that:

- Providers are often not based at one facility and have to commute between different facilities.
- Providers are true service providers and have little control over their daily bookings.
- Providers, as a group, may be faced with more emergency situations than other clinicians.
- Providers may have less time to establish rapport with the patient preoperatively.
- Anaesthesia is procedure-associated.

- The anaesthesia provider usually does not make the primary diagnosis.

The duties of the anaesthesia provider include:

- Maintaining personal knowledge and skills.
- Providing anaesthetic services or supervising trainees who provide anaesthetic services.
- Anaesthesiologists or anaesthetists may be directly responsible for only one anaesthetic procedure at any specific time, unless acting in a supervisory capacity.
- When a local anaesthetic technique is used for pain relief without concomitant surgery, e.g. labour epidural, the responsibility for patient supervision may be delegated to a suitably trained paramedical or nursing officer.
- Carrying out preoperative risk assessment and risk management for all types of patient and surgery.
- Supervising the recovery room activities.
- Participating in postoperative management where appropriate.
- Managing and/or supervising the management of patients in the Intensive Care Unit (ICU).
- Providing services related to the management of acute pain.
- Providing services related to resuscitation and advanced airway management in adults and children.
- Taking responsibility for supervising the maintenance of anaesthetic, monitoring and other life-support equipment relevant to anaesthesiology and critical care. This must take place in conjunction with a suitable technical or biomedical engineering service.
- Taking responsibility for the safe use of anaesthesia-associated drugs.
- Providing anaesthetic services that relate to obstetrics, including pain relief in labour.
- Providing procedural sedation services in and out of hospital.
- Keeping full documentation and records of the anaesthetic that was administered to patients.
- Obtaining informed consent to all invasive procedures, including those performed under local anaesthesia, spinal- or epidural anaesthesia, procedural sedation or general anaesthesia; and specific non-anaesthesia interventions such as blood transfusion or HIV testing.

Further duties may include:

- Maintaining personal and professional well-being.
- Providing services related to the management of chronic pain and consulting in pain clinics.
- Providing consultative anaesthetic and ancillary services.
- Carrying out administrative, educational and managerial duties, locally and/or regionally.

- Providing information and training on methods of handling mass casualties, trauma and basic lifesupport techniques to:
  - Paramedical staff
  - Interested community groups (particularly basic life support)
- Contributing to the activities of professional associations.
- Auditing and reviewing quality of care and participating in hospital-based, regional and/or nationalefforts to improve patient safety.
- Participating in theatre complex management.
- Carrying out reviews and investigations on drugs, equipment, methods of clinical management and physiological and pharmacological matters that are relevant to anaesthesiology and intensive care.
- Providing and/or taking part in advisory services to hospital committees, health commissions and other organisations for the improvement of healthcare services.

## ***Anaesthesia providers***

### **Introduction**

In view of the risks involved in the provision of anaesthesia services, and the possibility of simple errors that result in severe negative outcomes, such as hypoxic brain damage and death, the scope of practice for the various classes of medical practitioner should be defined. This section attempts to categorise physician anaesthesia providers based on training and experience. The scope of practice should not vary according to the facility level of care. HPCSA regulations regarding training and accreditation are only restated to provide context or when alternative recommendations are made. The two main groups of relevance are **independent practice** and **supervised practice**.

### *Supervised Practice*

This speaks to the practice of a medical practitioner who does not meet local requirement/ equivalent for anaesthetic training. These may, for instance, be doctors from overseas who have not done the South African two-month anaesthetic intern program programme. It is **recommended** that he/she should receive direct supervision by a diplomate anaesthetist, or, if none available, an anaesthetist designated as intern supervisor (see below).

### *Interns*

An intern is a doctor in training.

An intern relies on the undergraduate curriculum for training in anaesthesia at medical school. It is **recommended** that undergraduate teaching outcomes in anaesthesia at different training institutions should be standardised.

He or she should receive a minimum of supervised anaesthesia training of two months (four to six months is **desirable**). We emphasise here the HPCSA training requirements<sup>1</sup> with regards to supervision:

*Adequate supervision: Constant supervision of the intern is of critical importance. The most acceptable form of "adequate" supervision is the presence of a specialist anaesthesiologist or a registrar in anaesthesiology. In the absence of a specialist, the supervisor should preferably possess the Diploma in Anaesthesia of the Colleges of Medicine of South Africa, or at a minimum, have three (3) years full-time experience of administering anaesthesia as a medical officer. Irrespective of the qualification, the constant presence of the senior physician on a one-to-one basis, is strongly recommended.*

It is considered **mandatory** that the intern is trained in the anaesthetic module of the ESMOE (Essential Steps in the Management of Obstetric Emergencies) training programme.

### *Community service medical officers*

Community service doctors are often required to administer anaesthesia because no other trained medical practitioner is available. A community service doctor relies on both undergraduate and internship training in anaesthesia. Provision of anaesthesia must be supervised.

It is **recommended** that supervision in a training institution is done by either an anaesthesiologist or a diplomate anaesthetist. It is also **recommended** that the period is extended for six months in institutions accredited for Diploma in Anaesthesia training. It is **recommended** that supervision is done by a diplomate anaesthetist at all other facility levels of care.

It is **recommended** that a logbook be kept of all supervised completed cases.

### *Independent practitioners*

#### *General practitioners*

SASA **recommends** that general practitioners who have had no additional training in anaesthesia and rely on undergraduate, internship and community service training when performing anaesthesia services, should not be involved in the independent administration of anaesthesia.

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SOURCE:

1. HPCSA HANDBOOK ON INTERN TRAINING

The only exception to this would be in a dire emergency, where a patient of American Society of Anesthesiologists (ASA) class VE requires urgent anaesthesia and no other clinician trained in anaesthesia is available. As soon as is feasible, every effort should be made to transfer the patient to a centre where more specialized care is available.

To gain experience when there is no recourse to supervised training, it is **advised** that a newly qualified general practitioner join SASA as an associate member, in order to benefit from guidance and contact with diplomate anaesthetists and specialists and CPD activities in the local SASA branch and nationally.

It should be noted that that proof of experience in anaesthesia care may be required in peer-review processes or medico-legal investigations, and SASA therefore **recommends** keeping a register (logbook) of cases prior to and after being registered as an independent practitioner with the HPCSA.

The general practitioner should always inform a patient that he or she is not an experienced anaesthetist or anaesthesiologist.

*Diplomate anaesthetists with less than 3 years full-time anaesthesia practice or 'experienced' anaesthetists without DA*

'Experience' for non-diplomate anaesthetists here is defined as at least 3 years of anaesthesia practice and at least 75% of working time spent in anaesthesia. This experience may be limited to certain surgical categories or anaesthesia domains, e.g. obstetric anaesthesia, and this category of practice is therefore included here. It is **highly recommended** that evidence of Continuing Professional Development (CPD) activities in the anaesthesia field relating to this practice be kept.

The training requirement for a diplomate anaesthetist is a minimum of six months supervised practice in an accredited institution. The Diploma in Anaesthesia is awarded by the College of Anaesthetists of SA (CASA) on fulfilment of the training requirements and passing an examination administered by CASA.

The diplomate anaesthetist is eligible for the independent practice of both general and regional anaesthesia in fit and healthy patients (ASA class I) and patients with controlled systemic disease (ASA class II). Patients with poorly-controlled systemic disease or functional limitation should only be anaesthetised in consultation with a specialist anaesthesiologist (ASA class III), i.e. with a supervisor. The nature of the surgery must not be major.\*

It is reasonable to expect the diplomate to provide safe anaesthesia for fit and healthy paediatric patients over the age of two years, providing the practitioner has maintained the necessary skills and the nature of the intended surgery is minor and elective. If that is not the case, supervision or referral should be sought.

In an emergency, or where no alternative exists, the diplomate may, in consultation with a specialist anaesthesiologist, administer anaesthesia to patients with severe systemic disease (ASA class IV and V). This constitutes supervised practice.

\*Surgical severity or grading is done according to the definitions used with large international and national studies on surgical outcomes (i.e. not facility or outcome specific):

*Minor surgery would include procedures lasting less than 30 minutes performed in a dedicated operating room, which would often involve extremities or body surface, or brief diagnostic and therapeutic procedures, e.g. arthroscopy without intervention, removal of small cutaneous tumour, diagnostic proctology, biopsy of small lesions, etc.*

*Intermediate procedures are more prolonged or complex and may pose the risk of significant complications or tissue injury. Examples include laparoscopic cholecystectomy, arthroscopy with intervention, bilateral varicose vein removal, tonsillectomy, inguinal hernia repair, breast lump resection, haemorrhoidectomy, appendectomy, partial thyroidectomy, cataract surgery, uvuloplasty, minimally invasive repair of vaginal prolapse, vaginal hysterectomy, tendon repair of hand, fixation of mandibular fracture, etc.*

*Major surgical procedures are expected to last more than 90 minutes and include major gut resection, major joint replacement, mastectomy, extensive head and neck tumour resection, abdominal aortic aneurysm repair, major vascular bypass procedure, procedures involving free flap to repair tissue defect, amputation, total thyroidectomy, cystectomy, trans-urethral resection of prostate, resection of liver tumour, carotid endarterectomy, nephrectomy, total abdominal hysterectomy, spinal discectomy, etc.*

#### *Experienced diplomate anaesthetists*

Experienced diplomate anaesthetists may have extensive experience in certain surgical categories or types, but not in others. If experienced, and receiving at least 75% of income from anaesthesia OR spending at least 75% of their time providing anaesthesia care, the diplomate may be responsible for ASA III patients or patients undergoing major surgery in this field. It is important that the provider realises that peer review for this practice will be subject to assessment at the level of a specialist.

#### *Specialists in training (registrars)*

The anaesthetic registrar is permitted to administer anaesthesia under specialist supervision. This supervision must take place at a ratio of 2:1, i.e. two registrars to each specialist. In circumstances in which the anaesthesia is classified as "low risk", this ratio may be extended to 4:1, and if "high risk", 1:1.

*Specialist anaesthetists (anaesthesiologists)*

The specialist anaesthesiologist can be expected to provide anaesthesia services independently to all patients, irrespective of the state of health or co-existing disease (ASA classes I, II, III, IV and V). It behoves the individual practitioner to confine his or her practice to those areas in which he or she has maintained the necessary advanced skills. This applies particularly to the subspecialties of cardiac, thoracic, neuro- and paediatric anaesthesia.

## **Section II: Professional Organisations**

The South African Society of Anaesthesiologists (SASA) has been functioning independently as a professional body, “leading the science and practice of safe anaesthesia at the highest standard and ensuring the sustainability of anaesthesiology services”, as described in its Constitution. The objectives are the efficient functioning of the key business units, namely Education, Private Practice, Public Sector, Regulation, and Special Interest Groups. More information on the SASA Constitution is available at [www.sasaweb.com](http://www.sasaweb.com).

SASA previously functioned as a group within the South African Medical Association (SAMA) and remains affiliated to SAMA. More information on SAMA is available at [www.samedical.co.za](http://www.samedical.co.za).

SASA has full membership status of the World Federation of Societies of Anaesthesiologists (WFSA) and is a member of the African Regional Section within the WFSA. More information is available at [www.anaesthesiologists.org](http://www.anaesthesiologists.org).



## Section III: Training, Certification and Accreditation

### **Background**

Education and training of anaesthesia care providers in South Africa needs to take cognisance of the social setting within which such practice occurs, making them sensitive to both the system and individual needs. Such education and training must be patient-centred, allow for reflective learning to take place and foster lifelong learning by the practitioners. Further, the adequacy of training in respect of preset goals and competencies being achieved, is seen to be of greater importance than just the actual period of the training. Consequent upon completion of appropriate education and training, practitioners need to be certified for an appropriate level of practice. Such practitioners must then register with the Health Professions Council of South Africa (HPCSA).

### **Education and training**

Education and training in anaesthesia involves four key role players:

- HPCSA – regulations and accreditation
- University – academic (teaching and learning, training, research)
- Departments of Health – clinical training platforms and training posts
- Colleges of Medicine of South Africa (CMSA) – assessments/examinations

Education and training in anaesthesia is expected to occur at any healthcare facility (hospitals) where anaesthesia is delivered. Formal, accredited education and training in anaesthesia, however, may only occur at HPCSA-accredited hospitals. Criteria for such accreditation is determined by the HPCSA ([www.hpcsa.co.za](http://www.hpcsa.co.za)). Each training institution/site needs to be accredited for training in that particular discipline and for that particular competency.

### **Diploma in Anaesthesia (DA)**

The purpose of the Diploma in Anaesthesia is to encourage postgraduate training and raise the standards of practice of anaesthesia by evaluating candidates at the level (of safe) good, practical general practitioner anaesthetists.

#### **i. Sites**

- Anaesthesia training in fulfilment of the DA(SA) examination regulations may be undertaken in.
- Anaesthesia training posts under the supervision of university departments in teaching hospital complexes, as well as in teaching hospital equivalents or in university satellite departments of non-teaching hospitals.

- Post-internship anaesthesia training posts at any of the list of 38 hospitals throughout South Africa.
- Post-internship anaesthesia posts at 2 hospital sites in Zimbabwe.

(Full list of hospital sites available at CMSA website [https://www.cmsa.co.za/view\\_exam.aspx?QualificationID=46](https://www.cmsa.co.za/view_exam.aspx?QualificationID=46))

#### ii. Time

The candidate must for six months have held a post-internship qualification to practise medicine, which is registered or registrable with the Health Professions Council of South Africa. Community service doctors are eligible to be trained and write this examination during their year of community service.

#### iii. Portfolio/Logbook

All trainees are encouraged to keep a detailed portfolio of their training and experience. Except in the case of certified supervised training at a teaching or CMSA-approved hospital, a completed logbook is required to substantiate training and/or credit points claimed.

#### iv. Supervision

A designated supervisor, either a specialist anaesthesiologist or a diplomate, is responsible for training. The level of supervision varies according to the experience of the trainee and the complexity of patients managed. In the early stages, in-theatre or on-site supervision is mandatory. When the trainee is assessed as having achieved a level of competence, the supervision may then be off-site, with the proviso that the supervisor is readily available for complex cases and emergencies.

#### v. Assessments

- Trainees are expected to be continually evaluated by supervisors during their training, such evaluation focussing on knowledge, skills, attitudes and behaviours achieved.
- The final assessment occurs as the DA examination under the auspices of CMSA.

(More details available on [https://www.cmsa.co.za/view\\_exam.aspx?QualificationID=46](https://www.cmsa.co.za/view_exam.aspx?QualificationID=46))

### **Fellowship training for specialist anaesthesiologist**

#### i. Sites

- Training may only take place in an HPCSA-accredited academic department in a teaching hospital under the control of a university with a Faculty of Health Sciences or Medical School.
- The following eight anaesthesiology departments affiliated to universities across the country have been accredited by HPCSA to train specialist anaesthesiologists:

- Sefako Makgatho Health Sciences University
  - Stellenbosch University
  - University of Cape Town
  - University of KwaZulu-Natal
  - University of Pretoria
  - University of the Free State
  - University of the Witwatersrand
  - Walter Sisulu University
- Each of these university departments consists of one or more training sites, such sites being either accredited for full-time training or as a satellite site where only part of the training may be conducted. The HPCSA accredits all facilities involved in training against a set of predetermined criteria every five years.
  - Each trainee trains against a specific training number awarded to the training institution by the HPCSA.

#### ii. Time

Anaesthesiology trainees are required to spend a minimum duration of education and training equal to 48 months in an HPCSA-accredited registrar post under the control of an academic teaching department in a teaching hospital.

#### iii. Portfolio/Logbook

All trainees must keep a detailed portfolio of their training and experience, including a logbook. The portfolio is inspected periodically by the supervisor.

#### iv. Supervision

Trainees function under supervision of specialist anaesthesiologists at the training institution. The level of supervision varies according to the experience of the trainee and the complexity of patients managed. When the trainee is assessed as having achieved a level of competence, the supervision may be off-site, with the proviso that the supervisor is readily available for complex cases and emergencies. In more specialised domains (such as anaesthesia for cardiac surgery) constant, on-site supervision is necessary.

#### v. Assessments

Trainees are expected to be continually evaluated by supervisors during their training, such evaluation focussing on knowledge, skills, attitudes and behaviours achieved as per the College of Anaesthetists curriculum.

The formal assessment under the auspices of CMSA incorporates a Part 1 basic sciences examination and a Part 2 theory and clinical examination.

#### vi. Master of Medicine Research

Each trainee must complete a research project as part of their training. Such research is conducted under the auspices of the university academic department.

(More details available on [https://www.cmsa.co.za/view\\_exam.aspx?QualificationID=1](https://www.cmsa.co.za/view_exam.aspx?QualificationID=1))

### Sub-speciality training

#### *Critical Care*

The only sub-speciality domain that is fully accredited for training postanaesthetic specialisation is critical care. Such training may only occur in an accredited intensivist-run ICU under the auspices of a university and may either be full-time over a two-year period or part-time over a four-year period. The final assessment occurs as the Fellowship (previously Certificate) in Critical Care examination under the auspices of CMSA.

(More details available on [https://www.cmsa.co.za/view\\_exam.aspx?QualificationID=69](https://www.cmsa.co.za/view_exam.aspx?QualificationID=69))

#### *Pain Medicine*

A submission has been made to the HPCSA for accreditation of this sub-specialty.

### **Certification**

- Certification in respect of competencies is collectively completed by the training facility and the CMSA.
- The trainee needs to be evaluated and certified as having met the requirements of the training programme by the supervisor/director of training.
- The trainee needs to complete the requisite assessment by CMSA to be certified as a diplomate anaesthetist, specialist anaesthesiologist or a critical care sub-specialist.

### **Registration**

The HPCSA defines criteria and processes for registration of practitioners.

It is essential that all practitioners must:

- be registered in the appropriate category prior to embarking on clinical practice
- only practice within the scope defined by their registration category
- ensure that their registration is current

- participate in and record Continuing Professional Development (CPD) activities to maintain current knowledge.

SASA **recommends** that CPD activities should be appropriate to the practitioner's area of expertise and/or experience, and be recorded as such.

(More detail available from [www.hpcs.co.za](http://www.hpcs.co.za))

## **General**

### **Practice**

In terms of anaesthetic practice it is permissible for a practitioner to perform, except in an emergency, only a professional act:

- for which he or she is adequately educated, trained and sufficiently experienced, and
- under proper conditions and in appropriate surroundings.

### **Emergency**

For all categories of practitioners, if the emergency warrants urgent action to prevent morbidity or mortality, and there is no access to an appropriately trained healthcare practitioner, then it is permissible for the practitioner to intervene to the best of his/her ability, as long as no further harm is done in keeping with the ethical principle of "*primum non nocere*".

### **Experience**

Experience should also be viewed from two perspectives:

- Initial supervised training experience as previously discussed.
- Ongoing experience.

With highly specialised procedures, a minimum number of procedures need to be performed annually on a regular basis to remain proficient.

## Section IV: Records and Statistics

The WFSA Standards states:

*A record of the details of each anesthetic should be made and preserved with the patient's medical record (HIGHLY recommended\*). This should include details of the pre-operative assessment, the anesthetic plan, intra- and the post-operative course. It is recommended that individuals, departments, and regional and national groups collect cumulative data to facilitate the progressive enhancement of the safety, efficiency, effectiveness, and appropriateness of anesthesia care.*

\*I.E. MANDATORY/ESSENTIAL

### **Anaesthesia case records**

A full contemporaneous record of the anaesthetic technique, patient responses to anaesthesia and other pertinent medical information relating to the anaesthetic should be made by the practitioner delivering an anaesthetic. Any anaesthesia-related complications should be documented in the patient file.

The following has been adopted from the Canadian Anesthesiologists' Society guidelines, with permission:

*All monitored physiologic variables should be charted at intervals appropriate to the clinical circumstances. Heart rate and blood pressure should be recorded at least every five minutes. Oxygen saturation must be monitored continuously and should be recorded at frequent intervals for all patients. End-tidal carbon dioxide concentration must be monitored continuously and recorded at frequent intervals if the trachea is intubated. Reasons for deviation from these charting guidelines should be documented in the anesthetic record. Monitors, equipment, and techniques, as well as time, dose, and route of all drugs and fluids should be recorded. Intraoperative care should be recorded.*

*The anesthesia record should include the patient's level of consciousness, heart rate, blood pressure, oxygen saturation, and respiratory rate as first determined in the postanesthesia care unit (PACU).*

It is imperative that all practitioners provide and maintain documentation to support the execution of any tasks as set out in these *Practice guidelines* in as much detail as is practical and useful. The practitioner may be required to submit this information to named authorities willingly, provided that patient confidentiality is maintained.

### **The anaesthetist's prescription**

The HPCSA's ethical rule 23 stipulates that medical practitioners "shall not engage in or advocate the preferential use or prescription of any medicine or medical device which ... would not be clinically appropriate or the most cost-effective option" and that such prescription or supply shall be based on "the diagnosis of the patient concerned through a personal examination of the patient or by virtue of a report by another practitioner under whose treatment the patient

is or has been and such medicine or medical device is clinically indicated, taking into account the diagnosis and the individual prognosis of the patient, and affords the best possible care at a cost-effective rate compared to other available medicines or medical devices and the patient is informed of such other available medicines or medical devices". This ethical rule means that:

- Practitioners may prefer certain products over others, provided that –
  - Prescriptions should be preceded by diagnoses;
  - Prescriptions must be clinically indicated; and
  - Patients must be informed of the medicines available to them.

Ethical rule 27A requires of practitioners to respect patients' choices, and, read with the National Health Act, (NHA), requires of practitioners to put to patients the options generally available to them.

Ethical rule 17 requires all prescriptions to be issued under the personal and original signature of the medical practitioner. The format of a prescription, i.e. whether on a separate sheet entitled "prescription" or whether in the form of a medicines record as kept by anaesthetists in theatre, is not prescribed.

The Medicines and Related Substances Act 101 of 1965 (the Medicines Act) stipulates the conditions under which the various scheduled medicines may be prescribed and supplied to the public. Section 22A determines, in particular that –

- Schedule 2, 3 or Schedule 4 substances may only be repeated if the person who issued the prescription has indicated thereon the number of times it may be dispensed, but not for longer than six months;
- a Schedule 5 substance shall not be repeated for longer than six months, and then only if the authorised prescriber has indicated on the prescription the number of times and the intervals at which it may be dispensed;
- where a Schedule 5 substance is used for –
  - its anxiolytic, anti-depressant or tranquillising properties, it shall not be prescribed for longer than six months unless the authorised prescriber has consulted a registered psychiatrist before issuing a new prescription; or
  - its analgesic properties, it shall not be prescribed for longer than six months unless the authorised prescriber has consulted another medical practitioner, before issuing a new prescription;
- a Schedule 6 substance shall not be repeated without a new prescription being issued;

- the Director-General may authorise the use of any Schedule 7 or Schedule 8 substance in order to provide a medical practitioner therewith on the prescribed conditions for the treatment or prevention of a medical condition in a particular patient.

Regulation 28 of the General Regulations to the Medicines Act requires certain particulars to be on a prescription or order for a medicine:

- the name, qualification, practice number and address of the prescriber;
- the name and address of the patient;
- the date of issue of the prescription or order;
- the approved name or the proprietary name of the medicine;
- the dosage form;
- the strength of the dosage form and the quantity of the medicine to be supplied;
- in the case of a prescription, instructions for the administration of the dosage and frequency of administration;
- the age and sex of the patient; and
- the number of times the prescription may be repeated.

In SASA's opinion, the medicines record in theatre constitutes a lawful format in which regulation 28 is complied with, provided that the information set out above is included in the record.

Regulation 28 also requires of pharmacists to verify the authenticity of telephonic, faxed or electronic prescriptions, requiring that it must be followed by the original prescription or order within seven working days.

Regulation 28 also stipulates that the prescriber must keep records of the diagnosis relevant to the prescription and where the patient consents, indicate the diagnosis on the prescription.

Practitioners should not demand any valuable consideration in return for prescribing particular products and/or for supporting suppliers of medicines.

Prescription data shall only be made available to third parties (even if through intermediaries such as switching or clearing houses and software companies) with the patient's informed consent that data may be passed on, and reworked by other companies.

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SOURCES:

GENERAL REGULATIONS GNR 510 OF 10 APRIL 2003 TO THE MEDICINES ACT

HPCSA ETHICAL RULES, 2006, AS AMENDED

MEDICINES AND RELATED SUBSTANCES ACT 101 OF 1965

NATIONAL HEALTH ACT 61 OF 2003



## ***Records of incident and death reporting***

The requirements for reporting of adverse incidents (an institutional process) and death (a statutory process) is discussed in the Section on Peer Review and Incident Reporting in these Guidelines.

It is **essential** that the following documentation is completed and made available to the State pathologist who will perform the autopsy in the instance of a procedure-related death:

- Contemporaneous anaesthetic record and notes;
- GW7/24 medicolegal form;
- Relevant documents from patients' file.

In cases of a **maternal death** where an anaesthetic was involved, the following is **essential**:

Completion of the same documentation as with a procedure-related death PLUS completion of the maternal death notification form (MDNF) together with the entire maternity team.

Definition: The maternal mortality ratio (MMRatio) is the annual number of female deaths per 100 000 live births from any cause related to or aggravated by pregnancy or its management (excluding accidental or incidental causes). The MMRatio includes deaths during pregnancy, childbirth, or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, for a specified year.

It is **recommended** that the processes of adverse incident and procedure-related death reporting are integrated for the following reasons:

1. To improve the quality of record keeping
  - a. The anaesthetic record, whether in electronic- or printed/handwritten format, should be the basis of all record-keeping contributions from the anaesthesia provider.
    - i. It is however **recommended** that less experienced providers are guided by supervisors or other colleagues to ascertain that the record contains all relevant information. This may be facilitated in the process of adverse incident reporting, as described by the National Department of Health (NDoH) in their policy document (see Appendix 4), with regards to Step 4 to 7: Notification, Investigation, Classification and Analysis.
    - ii. It is **highly recommended** that the anaesthetic record is attached to the GW7/24 medical report to the forensic investigator in case of a procedure-related death.
    - iii. It is also **highly recommended** that the names of senior colleagues that reviewed (ensured that relevant information is included) the anaesthetic record AND the full report are added to the GW7/24.

- iv. It is **recommended** that individuals and institutions participate in collection of adverse event data using the tool developed by the National Department of Health, or a similar tool.
  - b. Incorporating record keeping in a standard workflow process for incident reporting may improve the quality of the record.
2. To facilitate root-cause analysis and the institution of quality improvement programmes.

### ***Aggregated clinical data and registries***

At the time of revision of these Guidelines, the Health Market Inquiry of the Competition Commission of South Africa had published a discussion document and call for submission entitled *Health outcome measurement and reporting: Improving the cost and effectiveness of clinical care in a competitive private healthcare sector in South Africa*, to which SASA has responded. The substance of the document and comments at the forum discussion subsequent to receipt of submissions clearly validated the establishment of the Perioperative Clinical Registry (PCR) by Safe Surgery SA (a SASA initiative – see [www.ansa.org.za](http://www.ansa.org.za)).

#### **The Perioperative Shared Health Record (PSHR) and Integration with a Perioperative Clinical Registry (PCR)**

The PSHR is a web-based platform administered by Safe Surgery SA (SSSA) that enables patient-centred information exchange between different members of the care team for a patient undergoing a surgical procedure. Central to its function is its interoperability – the ability to integrate with other data sources using similar health data standards, or to integrate existing electronic case- or administrative perioperative information. It will contribute to the basic dataset for a Perioperative Clinical Registry (PCR) – a clinician-driven platform inclusive of all physician service providers. The PSHR will allow for individual practice benchmarking. The PCR, using appropriate governance mechanisms, will allow for clinician-driven quality assessment and research.

### ***Personal information and health data: confidentiality and access***

The ethical duty of healthcare professionals to preserve patient confidentiality is intrinsically related to the trust that patients place in practitioners. Laws such as the National Health Act, Promotion of Access to Information Act and the envisaged Protection of Personal Information Act all address the right to confidentiality and the circumstances under which disclosure would be authorised. Record-keeping is a critical part of risk management in medical practices and health establishments.

## Types of data and information that are protected

1. According to the National Health Act (NHA) all information about a person's stay and/or visit to a health establishment, as well as information relating to his/her health status, treatment and care are confidential. This includes information provided by the patient, as well as information generated by healthcare professionals (e.g. prescriptions, notes in a patient file, etc.)
2. In addition, all name, address and similar personal information, as well as financial and biometric information and the likes are protected by the Protection of Personal Information (POPI) Bill. Information that is truly de-identified and cannot be relinked to an identifiable person is excluded from this protection. However, consent must be obtained from a person whose information starts out (e.g. is collected) as identifiable information, and then subsequently becomes de-identified. The person must know that his/her information will be reworked, and what the purpose of that reworking will be.
3. The above means that all recordings, written and/or typed notes, typed notes and documents or reports, x-rays, prescriptions, laboratory test results, certificates, clinical research records, etc. are included in the definition of information that is protected.

## Patient consent to disclosure

4. The NHA states that patients may consent to the disclosure of their information, but such consent must be in writing. The HPCSA ethical rules require consent to be 'explicit'. SASA recommends that consents to disclosure be made in writing.

## Legal requirement or court order to disclose

5. The NHA also authorises disclosure if there is a law that explicitly requires disclosure. For example, notifiable diseases are declared as such by a law and disclosure to the specific authorities can then be made. Another example is the medical schemes regulation that requires disclosure of an ICD-10 code on a bill to a medical scheme.
6. The same applies in the event that someone obtains a court order – such order may compel the disclosure of the information.
7. Practitioners may rely on ethical principles to not disclose under these circumstances, and may even challenge the constitutionality of the court order or the law that authorises or requires the disclosure.

## The anaesthesiologist and other practitioners and facilities

8. Each entity collecting and recording personal information is bound by the provisions of POPI and each entity must preserve the confidentiality of the information it holds in its possession. Information cannot be shared by entities without –
  - the patient's written consent; and

- ensuring that the receiving party has the same or similar protections for confidentiality in place.
- 9. In the public sector the employees of a hospital are bound with the hospital in relation to matters of confidentiality, disclosure and information processing. In the private sector the practitioners and the hospital are two different legal entities and the provisions of consent and similar protections have to be adhered to by both, i.e. two separate sets of forms may be required to give effect to consents to disclosure, and there may be two sets of policies relating to how health records are handled, shared, etc.
- 10. The NHA states that professionals can, without the patient's consent, share information if it is necessary and in the patient's best interest. This would normally occur within the context of the therapeutic team. In order to align with POPI, SASA proposes that hospital and practitioner forms disclose this legal mandate to patients.

### **Collection, use, dissemination and reworking of information**

- 11. No personal information may be collected, recorded, stored, reworked or otherwise dealt with, without compliance with the following criteria as set by POPI, all of which the patient must consent/agree to –
  - a. The patient must know that information about him/her is collected, reworked, stored or disseminated ("processing").
  - b. The patient must know what the purposes of the processing are, and such purposes must be lawful (e.g. a research protocol must be in place, or the information is collected and sent on based on the provisions of the Medical Schemes Act, etc.). The description of these purposes must be clear and delineated, and not overbroad and vaguely described.
  - c. The patient must know if there will be further processing of his/her information (e.g. a record that is used for purposes of health research, etc.).
  - d. The duration for which the record will be kept: Normally records would have to be destroyed after they have served the purpose(s) for which they were created, reworked or stored.
- 12. The HPCSA states that "healthcare practitioners should enter and maintain at least the following information for each patient consulted":
  - a. Personal (identifying) particulars of the patient.
  - b. The bio-psychosocial history of the patient, including allergies and idiosyncrasies.
  - c. The time, date and place of every consultation.
  - d. The assessment of the patient's condition.
  - e. The proposed clinical management of the patient.

- f. The medication and dosage prescribed (all prescriptions must comply with the provisions of the Medicines Act and regulations).
  - g. Details of referrals to specialists, if any (including the reports from such specialists, or any other conversations had with such specialists).
  - h. The patient's reaction to treatment or medication, including adverse effects, bearing in mind that the Medicines Act makes the reporting of adverse events to the manufacturer of the product, or directly to the MCC, compulsory.
  - i. Test results.
  - j. Imaging investigation results.
  - k. Information on the times that the patient was booked off from work and the relevant reasons.
  - l. Written proof of informed consent, where applicable, or some record or note in the patient file that consent has been obtained.
13. Furthermore, the entity holding and processing the information must consider or adhere to the following:
- a. The patient is entitled to see what information is being held on him/her.
  - b. The information being collected and processed must be adequate and necessary in view of the purpose to which the patient has consented. This means that no "additional" or "nice to know" information can be collected or reworked.
  - c. The holder of the information is under a duty to ensure the accuracy, quality and security of the information held by them.

#### **Information storage: duration, type/nature and destruction**

14. The HPCSA requires records to be stored for at least seven years, and for children's records to be kept until they reach maturity (18 years of age). The NHA requires records to be stored for 20 years.
15. The HPCSA permits storage in electronic format. It should, however, be borne in mind that unless reputable electronic storage mechanisms are used, the document's authenticity might be placed in dispute.
16. The HPCSA requires that records should be kept in non-erasable ink and erasure fluid should not be used, and that changes should be made on the original, erroneous, document, with a signature and date next to the amendment.
17. The words "no substitution" next to a line item on a prescription may not be electronic or affixed by a stamp, and must be in the practitioner's own handwriting.

18. Sick certificates must comply with the requirements of the ethical rules, and can only include the diagnosis in lay person's language if the patient had provided written consent to such disclosure.

### **Ownership of records**

19. The information on a health record belongs to the patient.
20. The record itself, however, belongs to the entity. However, this does not give the entity the right to disclose the information contained in the record in any manner other as is determined by law (i.e. with the patient's written consent, or on the basis of a law or court order), provided that the patient understands what the purpose of such disclosure is, how the information will be used, etc.

### **Signing off of records and official documents**

21. Practitioners are, through the ethical rules, obliged to sign official documents and instructions generated by them. This signature must, according to the HPCSA Ethical Rules, be accompanied by the initials and surname of the practitioner in block letters. This also serves to validate the instruction or record, and the date at which it was issued.

### **Children and confidentiality**

22. Both the HPCSA ethical rules and the 2005 Children's Act award children the right to confidentiality from the age of 12 years onwards, insofar as treatment is concerned. With surgical interventions, as the parents/legal guardians support the child in reaching the decision, they would have to have access to the child's personal information.

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#### **SOURCES:**

NATIONAL HEALTH ACT, 2003

CHILDREN'S ACT, 2005

PROTECTION OF PERSONAL INFORMATION BILL (VERSION NOVEMBER 2012)

PROMOTION OF ACCESS TO INFORMATION ACT, 2000

HPCSA ETHICAL RULES 2006, AS AMENDED

HPCSA BOOKLET 8, RECORD-KEEPING, 2008

## Section V: Peer Review and Incident Reporting

**Clinical governance** is defined as a system through which health services are responsible and accountable for:

- Continuously improving services;
- Safeguarding high standards of care;
- Ensuring the best clinical outcomes for patient care.

The system of governance includes the following aspects of clinical risk management:

- Mortality and morbidity reviews;
- Adverse events and near misses reporting and reviews. Note: a near-miss defines a hazard or unsafe situation that has the potential to cause harm, but does not. An adverse event describes actual harm that occurs to the patient.
- Patient record reviews and peer reviews;
- Clinical audits on various aspects of the anaesthetic processes in various anaesthetic practices, measuring compliance with best practice.

**Peer review** is a function of the Society's Regulation Business Unit, and peer review-related enquiries are facilitated through the SASA website.

The SA National Department of Health's Policy on **Adverse Event Reporting** is available (Appendix 4).

An **adverse event** can be defined as harm, an injury or complication associated with medical treatment. This may or may not be as a result of error. A **near-miss** is a possible injurious event that is intercepted before it reaches the patient.

Errors can be categorised as serious or minor, and may be as a result of an error by a doctor, or by another member of the health team or a systems error.

When documenting events around a medical error, the documentation needs to be factual and exhaustive. It is essential to avoid speculation regarding cause or blame.

Should a **death** occur, then the following applies:

The Health Professions Amendment Act of 2007 states the following:

"Death of a person undergoing a procedure of therapeutic, diagnostic or palliative nature or of which any aspect of such a procedure has been a contributory cause, shall not be deemed to be a death from natural causes as contemplated in the Inquests Act, 1959 (Act 58 of 1959), or the Births, Marriages and Deaths Registration Act, 1963 (Act 81 of 1963)."

This means that all doctors and nurses who work in operating theatres need to be made aware of the law, and that all unnatural (perioperative) deaths must be reported, regardless of the sentiments of the medical team and/or the next of kin.

This same group of medical personnel needs to be instructed to the effect that all unnatural deaths must be reported, regardless of the length of time that has elapsed since the administration of the anaesthetic. Documents regarding the report are discussed in the previous section of these guidelines.

It is strongly advised that one's indemnity insurance company should be notified immediately, particularly in cases where the death has been sudden and unanticipated.

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SOURCES:

1. MERRY AF, COOPER JB, SOYANNWO O, ET AL. INTERNATIONAL STANDARDS FOR A SAFE PRACTICE OF ANESTHESIA. *CAN J ANAESTH.* 2010;57(11):1027-1034.
2. NEL S. FACTORS INFLUENCING ADVERSE EVENT AND ERROR REPORTING IN ANAESTHESIOLOGY; RESEARCH REPORT.
3. *QUAL MANAG HEALTH CARE.* 2016 OCT; 25(4):213–218.
4. PSNET AHRQ PATIENT SAFETY NETWORK. ADVERSE EVENTS, NEAR MISSES, AND ERRORS.
5. LUNDGREN AC. PERI-OPERATIVE DEATHS IN TWO MAJOR ACADEMIC HOSPITALS IN JOHANNESBURG, SOUTH AFRICA; PHD THESIS.
6. IMPROVING PATIENT SAFETY — FIVE YEARS AFTER THE IOM REPORT DREW E ALTMAN, PHD, CAROLYN CLANCY, MD, AND ROBERT J BLENDON, ScD *N ENGL J MED* 2004; 351:2041-2043 NOVEMBER 11, 2004DOI:10.1056/NEJMp048243.



## Section VI: Workload

*“A sufficient number of trained anaesthesia professionals should be available so that individuals may practise to a high standard without undue fatigue or physical demands. Time should be allocated for education, professional development, administration, research and teaching.”<sup>1</sup>*

### Definitions and scope

- This position statement was compiled in response to concerns raised about the working conditions of junior doctors and trainees practising anaesthesia in state hospital settings. It is accepted that other issues are also relevant, including age, experience, level of training, supervision, complexity of surgery and the need to allow for conditions conducive to study in tertiary settings while providing a cost-effective sustainable medical service appropriate to a developing country.
- The primary concern is patient safety. Thereafter, physician well-being is considered.<sup>1</sup>
- These recommendations refer to routinely rostered duty hours that are performed at the place of work, whether on standby or on actual procedures. Standby hours from home are not specifically considered.
- Guidelines are available for the United States of America (USA),<sup>2,3</sup> Ireland and the United Kingdom (UK),<sup>4</sup> Europe<sup>5</sup> and Australia.<sup>6</sup>
- Fatigue is defined as: “inability or unwillingness to continue effective performance of a mental or physical task” and is a summary descriptor for the varied effects and labels used to describe the cognitive, behavioural, and physiological outcomes of sleep loss and circadian disruption.<sup>7</sup>
- “Vigilance” is comprised of alertness, selection of information and conscious effort.

### The effects of fatigue

- The impact of fatigue on performance has been investigated extensively among pilots and medical personnel.<sup>3,7-23</sup> Complex memory, decision-making and alertness and attention are especially vulnerable to the effects of fatigue.<sup>7,8,14,19</sup> Cognitive function deteriorates by 25% from baseline after 24 hours of wakefulness.<sup>24</sup>
- Known performance effects include reduced attention and vigilance with attention lapses, impaired memory and decision-making, slowed cognitive throughput, prolonged reaction time with lowered optimal responding, lapses in attention to detail, errors of omission, compromised problem solving, reduced motivation and disrupted communications.<sup>7,25</sup>
- Fatigue-related depression and anger result in detachment and a lack of compassion for patients.<sup>26</sup>
- There is increased risk for the occurrence of errors, critical incidents, and accidents.<sup>7,27</sup> However, it should be noted that no study has proved that fatigue on the part of healthcare

personnel causes errors that systematically harm patients. While individual allegations exist, they are still considered isolated incidents.<sup>10</sup>

- Fatigued workers can perform normally for short durations of attention if sufficiently motivated,<sup>28</sup> but have a tendency to slow down work processes to maintain accuracy, leading to decreased productivity, known as the speed-accuracy trade-off.<sup>29</sup>
- Numerous anaesthetic-specific skills have been shown to deteriorate as fatigue progresses. These include dural puncture, ECG interpretation and mathematical calculation, intubation, needle-stick injuries, syringe swap/wrong drug, overdosage and underdosage.<sup>4</sup>
- Compared to the impairments associated with ethanol ingestion, performance on a hand-eye tracking task declined such that the impairment was equivalent to a blood alcohol level of 0.05% after 17 hours of wakefulness.<sup>21</sup> This level of impairment in a driving test could be shown after just three hours of additional wakefulness.<sup>20</sup> At 24 hours of sustained wakefulness, the impairment in psychomotor function was equivalent to a blood alcohol concentration of 0.1%. The legal blood alcohol limit for operating a motor vehicle in South Africa is 0.05%.
- It is important to note that objective impairment occurs long before subjective awareness of fatigue. Self-regulating work and rest periods is highly unreliable.<sup>10</sup>

### ***Factors that contribute to fatigue***

1. Workload (volume and turnover of patients)
2. Patient acuity and complexity of procedures undertaken
3. Sleep deprivation
4. Age of provider
5. Breaks between cases and lists
6. Changes in the scheduling of providers

### ***Prevention and correction strategies***

- On average, the adult human requirement for sleep appears to be greater than 8 h (8 h:14 min) per 24-hour period,<sup>30</sup> or 7h:30 min according to other authorities.<sup>31</sup>
- Loss of sleep is cumulative.<sup>28,32</sup> Failure to address this sleep debt contributes to earlier fatigue on subsequent rotation duties.<sup>14,28</sup> It takes two consecutive nights of optimal sleep at the correct time to recover from significant sleep loss.<sup>4</sup>
- There is a reduced tolerance to night shift work with increasing age (manifesting as prolonged recovery times), and this needs to be taken into consideration by the call roster set-up.<sup>4,7,33,34</sup>
- Work schedules longer than 12.5 hours contribute significantly to a risk of decreased vigilance, occupational injury, or a medical error.<sup>27</sup>
- Anaesthetic duties often do not allow for normal intake of food and liquid. Unrecognised hypovolaemia and hypoglycaemia contribute to fatigue.<sup>4</sup>

- The Basic Conditions of Employment Act 75 of 1997 (BCEA) gives clear conditions for acceptable work hours. However even junior medical personnel are exempt from this protection on the basis of their income in excess of R115 572 per annum. There is a view that financial reward adequately compensates workers for adverse working conditions, presumably since higher income implies seniority and choice. Neither of these apply to junior medical personnel. From both the patient safety and physician well-being perspectives, financial compensation of individuals cannot be supported as a corrective strategy. Providing funding for increased staff levels would be more appropriate.<sup>35</sup>
- Suggested corrective strategies include<sup>7</sup>:
  1. Controlled work hours in conjunction with improved handover strategies.
  2. Observation of fatigue alleviation strategies:
    - a. Day sleeps before a night shift
    - b. Naps of at least 40 minutes when feeling excessively fatigued and before driving home
    - c. Improved structuring of call and shift rosters

[Advisory: caffeine consumption improves alertness but may impair rest and nap breaks. Potent medications to maintain alertness such as amphetamines are not recommended.]

3. Scheduling of providers
  - a. Plan work activities not to exceed 80 hours per week averaged over a six-week period.
    - i. Consecutive duties should allow for a minimum rest period of 10 hours between them.
    - ii. Continuous shifts on call not to exceed 16 hours at a time when the main activity is the provision of anaesthesia. Where the nature of activity allows for intermittent application, such as in ICU, a shift may continue for a maximum of 24 hours.
  - b. The work schedule must provide for non-clinical activities including personal development, maintenance of professional competency (CME credits), contribution to enhancing the profession and competency of the fraternity, and compliance with requirements of continued registration (range 10–25% of available time).
  - c. Scheduling plan to ensure availability and appropriateness of supervision for junior providers.
4. Equipment checking discipline.
5. Adequate and appropriate personnel to workload ratios.
6. Conducive work environment.
7. Exposure to after-hours work must conform to recommended rest periods.

## Recommendation

These recommendations pertain to call duty hours that are performed at the place of work.

Given the limited information available, and drawing from guidelines in other industries where vigilance with rapid and accurate reaction is of primary importance, continuous on-call duty of less than 12.5 hours is suggested, more than 17 hours is to be discouraged, and excess of 24 hours to be condemned. Consecutive duties should allow for an adequate rest period in proportion to the hours worked between them.

We acknowledge that these recommendations are frequently disregarded in the interest of patient care. The following quote from the ASA guidelines guide practice regardless of the duty hours: "Anaesthetists have a duty of care, wherever possible, to not provide out of hours emergency services for procedures that they do not routinely perform, do not feel clinically competent to perform or do not have clinical privileges to perform. An anaesthetist must ensure that at no time, as a result of his or her on-call roster commitment, do they undertake clinical duties if physical or mental fatigue, stress or ill health, alone or in combination, might interfere with safe patient care."<sup>2</sup>

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## **Section VII: Personnel**

The availability of appropriate assistance (including nurses and/or technicians) to the anaesthetist is considered to be of fundamental importance to the safe conduct of anaesthesia. Research has shown that skilled assistance with anaesthesia-specific training can minimise harm from adverse incidents; conversely, inadequate assistance has been shown to contribute to or fail to mitigate harm during perianaesthesia periods.

**SASA strongly recommends** that adequate assistance should be always and immediately available at any site where an anaesthetist is expected to provide sedation and or anaesthesia. This includes remote locations like cardiac catheterisation lab, radiology suites etc. The assistant to the anaesthetist is an essential member of the staff establishment in all locations where anaesthesia is administered. Hospital managers have to understand the critical importance of anaesthetic assistance and the hazards due to the lack of trained and competent assistance. Staff establishments and allocation practices should allow for provision of an assistant to the anaesthetist for every case where anaesthesia is administered. The anaesthetic assistant must be immediately available before and during induction, maintenance and emergence of anaesthesia. The assistant should have no other obligations or duties during these periods.

### ***Nursing Staff***

Anaesthetists and anaesthesiologists in both the private and public sector of South African health care rely heavily on the assistance of nursing staff in caring for patients in the perianaesthesia period. SASA is committed to participate in discussions with stakeholders (Association of Perioperative Practitioners of SA and SA Nursing Council) to define the principles of safe perioperative care, quality of perianaesthesia assistance and postanaesthesia care. Care of these patients takes place in a variety of settings for procedures including, but not limited to, surgical, obstetric, diagnostic, therapeutic, and pain management at outpatient and inpatient settings. The nature of anaesthesia practice has advanced and become increasingly complex in the past two to three decades due to the expanded knowledge in anaesthesia, significant innovations in equipment, technology and new pharmacotherapeutics. Concurrently surgical procedures have become more complex, more patients with high acuity, critical and complex diseases are being anaesthetised. The practice of anaesthesia is a specialised field of medicine; as such it should be practised by healthcare personnel with appropriate training, skills and knowledge which are complementary to that of the anaesthetic physician to administer safe anaesthesia. Safety is an urgent healthcare priority to all stakeholders in the health system.

In South Africa there is no formal or accredited training for anaesthetic nurses, however appropriate training must be undertaken in order to provide effective and safe support to the anaesthetist. This responsibility should lie with the hospital, nursing management, theatre managers and operating theatre nurse specialist (scrub sister) in each respective theatre.

## ***Management and supervision/Organisation of anaesthetic services***

An appropriately trained and experienced senior registered nurse of the theatre/anaesthetic team should be appointed as the supervisor of anaesthetic services in larger hospitals with numerous multidisciplinary theatres as well as offering remote location anaesthesia and where a number of anaesthetic assistants are employed. SASA **recommends** that the training, experience and competencies of such a senior nurse encompass at least those of anaesthesia nurse assistants and recovery room personnel – see below. The chief anaesthetic sister will have an administrative role whose task involves: planning and preparing, prioritising, providing and maintaining standards, and identifying and utilising resources; collaborating with multidisciplinary team members, exchanging information, to ensure efficient running of anaesthetic services.

### **Organisation**

- Monitors quality and safety standards of anaesthetic care throughout the facility.
- Ensures that written policies on the practice of anaesthesia are available and applied.
- In conjunction with biomedical engineering or health technological department organise and co-ordinate the servicing and repair of equipment.
- In co-operation with the department of anaesthesia or anaesthetists practicing in that facility, assist with capital equipment budget by conducting equipment needs assessments and procurement plan.
- Keep supply inventory and ensure adequate supplies of sundries and pharmaceuticals.
- Teaching, training and assessment of anaesthetic nurses and other ancillary staff.
- Systematic rostering of anaesthetic assistance: ensures safe anaesthesia care by allocating personnel with appropriate experience and competency to handle the specific needs relating to the patient, complexity of anaesthetic and procedure involved.

## ***Anaesthesia nurse assistants***

### **Role**

The anaesthetic nurse works in collaboration with the anaesthetist in the preparation and safe delivery of general, sedation, regional or local anaesthesia. The anaesthetic nurse is involved in preoperative, intraoperative, and postoperative anaesthesia care. They prepare the theatre for the day and check anaesthesia machines, monitors, drugs, materials, and all equipment related to anaesthesia procedures. They may be involved in pre-assessment, consent check and transport to theatre. The anaesthetic nurse assists the anaesthetist in the administration of general and regional anaesthesia to all ages and categories of patients and surgical procedures. The nurse also protects the patient and provides emotional and psychological support during this critical period. They should handover care to a recovery room nurse.

## Core responsibilities

### 1. Provide a safe perioperative environment

- a. Ensure clean environment and equipment.
- b. Adequate replenishing and organisation of stock and theatres.
- c. Checking and preparing monitors and all anaesthesia-related equipment.
- d. Prepare equipment, medicines and fluids.
- e. Observe all medico-legal requirements, ensure accurate record-keeping and adherence to schedule drug policies.

### 2. Assist the administration of safe and high quality anaesthetic

- a. Have applied knowledge in anaesthetic techniques, pharmacology and surgical procedures.
- b. Understand the potential implications of surgery and anaesthesia for individual patients as well as physiological responses to anaesthesia and surgery.
- c. Maintain and develop competence and performance throughout working life.
- d. Competently support and assist the anaesthetist.
- e. Monitor, recognize & recognise and assist in an emergency.
- f. Knowledge and care of anaesthetic-related equipment.

### 3. Be a patient's advocate

- a. Be the patient's voice.
- b. Ensure patient's dignity and rights are respected at all times.
- c. Ensure patient-centred approach.

### 4. Uphold reputation of nursing and theatre/department at all times

- a. Professionalism
  - Diligence, organisation, efficiency
  - Leadership
  - Communication
  - Confidentiality
- b. Responsibility and reliability
  - Personal accountability
  - Punctuality
  - High level of commitment
- c. Attitude
  - Enthusiasm



d. Teamwork

## 5. Identify healthcare needs, help develop new, better efficient systems

- a. Situational awareness
- b. Be proactive
- c. Participate in audits and research

### Qualifications, training requirements and core competencies

The anaesthetic nurse is a member of the theatre team and can be a registered nurse or enrolled nurse regulated by the South African Nursing Council (SANC). South Africa has no specific accredited anaesthesia nurse training and, hence, there are currently no national, defined core competencies that an individual must attain before considered a trained competent anaesthetic nurse. The operating theatre nurse specialist (scrub sister) is expected to be the most knowledgeable and experienced member of personnel amongst the nursing team with regards to theatre management (including aspects of the anaesthesia service) since she should apply critical thinking, planning, clinical judgment and implementation underpinned by scientific, biomedical and technological knowledge obtained from her theatre training. SASA notes that there have been various in-hospital training programmes to specifically train anaesthesia nurse assistants. However, the training of anaesthesia assistants varies widely throughout SA. It is the view of SASA that the lack of a national standard could be contributing to errors or near-misses during the perianaesthesia period.

### *Recommendations*

In the interim the hospitals, nursing managers, operating theatre nurse specialists must ensure that staff delegated to be anaesthesia assistants are competent and undergo training. The hospital and operating theatre managers, in collaboration with anaesthesiologists/department, must have a training programme, curriculum design and course content, teaching and assessment of anaesthesia assistant trainees. The anaesthetic department or anaesthetist should be available for support and guidance to determine the required knowledge, technical and non-technical skills of a competent anaesthetic nurse. Trainee assistants must be supervised until they are assessed to be safe to work independently.

### The scope of clinical practice includes:

- Pre-assessment and preparation of patient (with parent/caregiver) prior to surgery.
- Validation of preoperative assessment information on day of surgery.
- Checking and preparing theatre; anaesthetic machine and equipment according to theatre list and anaesthetist preferences.
- Ensuring availability of anaesthetic agents, resuscitation drugs and other drugs in theatre.

- Assistance in the delivery of anaesthesia/sedation/analgesia.
- Continuous patient assessment, monitoring and intervention in a holistic manner in theatre.
- Professional handover to recovery room personnel.

### **Core competencies**

The nurse shall demonstrate competence based on applied knowledge and ongoing practise of skills to perform the role of the anaesthetic nurse:

The expected knowledge base will include the following:

- Comprehensive types of anaesthesia techniques and their principles.
- Applied clinical pharmacology relating to anaesthesia/surgical intervention.
- Applied anatomy and physiology relating to anaesthesia/surgical intervention (airway, respiratory, cardiovascular, central nervous, thermoregulatory systems, pain and nausea and vomiting)).
- Knowledge of surgical and anaesthetic procedures to be performed and how they affect the patient.
- Analysis and utilisation of invasive and non-invasive monitoring data.
- Cardiopulmonary resuscitation, respiratory care, and other acute emergency care.
- Age/medical condition-specific competencies e.g. paediatrics, geriatrics, cardiothoracic, neurosurgery, ENT.
- Equipment required for anaesthetic procedures.
- Function, care, cleaning and maintenance of anaesthetic equipment.
- Principles of infection control and waste management.
- Resource management.
- Medico-legal requirements.
- Good communication and professionalism.

### ***Recovery room nurse***

The purpose of a recovery room/postanaesthetic unit in a theatre suite is to provide a safe handover of an anaesthetised patient, whether it be general, regional or sedation, for safe monitoring, observation and care by efficient, competent and trained nursing staff. This prevents and diminishes the occurrence of adverse events postoperatively and assists in the management of safe anaesthesia. Please note that the discharge of a postanaesthetised patient from the recovery room (RR) remains the responsibility of the anaesthesia provider and the length of stay in the RR is determined by such.

It is the responsibility of the institution to ensure that staff members who are appointed to the recovery room are trained and competent. Unfortunately, there is no current standardised curriculum for recovery room training available in South Africa. SASA is currently looking at the possibility of supporting the development of such a curriculum in collaboration with the nursing fraternity and the Association of Perioperative Practitioners of South Africa (APPSA).

SASA guidelines for recovery room nursing must be read in conjunction with the guidelines of SATS/APPSA for Anaesthetics and Recovery Room Nursing Guidelines.

## Role

The RR must be prepared and checked daily by RR staff according to policy, equipment and safety rules. A written policy regarding the checking of equipment and drugs must be available. The RR nurse must ensure that all the necessary equipment is available, checked and in working order. Specific roles of nurses must be identified daily/more often when necessary.

A specific area must be allocated for paediatric cases, prepared and in working order.

The patient is handed over to the RR nurse by the anaesthetist, assisted by the anaesthetic nurse, and the scrub sister.

- The patient should be identified during the hand over.
- The RR nurse should take note of the procedure, condition of the patient, anaesthetic given, pain control needed and any other specific orders (written/verbal) given by the anaesthetist or scrub sister (surgeon).
- The RR nurse should not accept full responsibility for the patient if not satisfied with the condition of the patient or until the patient is extubated, unless otherwise expressly agreed with the anaesthetist. Extubation remains the responsibility of the anaesthetist.
- All monitors, e.g. SaO<sub>2</sub>, BP, pulse, capnograph should be connected and observations should be documented. The RR nurse must be vigilant in monitoring physical changes and assessing their significance.
- Life-threatening situations and anaesthetic-related problems should be recognised, acted on and reported to the anaesthesia provider, e.g. return of protective reflexes, circulation/haemodynamic shifts, varying levels of consciousness, nausea and vomiting, pain level and airway dysfunction.
- The effect of all interventions must be evaluated.
- Pain control as prescribed by the anaesthesia provider should be administered.
- The RR nurse provides continuity through responsible discharge and professional hand over of the patient to the ward staff only after verbal communication with and written consent of the anaesthetist.

The RR nurse should also:

- Safeguard the patient against injury.
- Prevent medico-legal incidents.
- Communicate with the patient about any complaints, fears or anxiety and provide psychological support.
- Protect the dignity and privacy of the patient at all times.
- Keep accurate records.
- Practice correct waste management.

All RR personnel should update and maintain their professional knowledge and skills.

### Competence

- All RR staff should be adequately trained in recovery room procedures and the identification of adverse events.
- The RR nurse must be able to assess and identify anaesthetic-related problems regarding the airway, haemodynamic system or protective reflexes as well as the different stages of postanaesthesia recovery.
- An applied knowledge of anatomy and physiology of the airway is compulsory and relevant to airway management with the acquired skills of direct laryngoscopy, intubation and placement of a Guedel airway. The RR nurse should also be able to maintain an airway with bag and mask ventilation.
- The RR nurse should be able to assess breathing and identify upper airway obstruction, hypoventilation, apnoea, bronchospasm and aspiration.
- An applied knowledge of pharmacology is necessary, e.g. anaesthetic agents, analgesic drugs, cardiovascular drugs and effects.
- All RR staff must be aware of the existence and position of the emergency alarm, which should be checked daily.
- Knowledge of emergency procedures, protocols and CPR is compulsory.

### Experience

- A registered nurse proficient in anaesthesia and recovery room nursing should be in charge and manage the RR.
- Special situations/patients e.g. critically ill/paediatric/geriatric patients should be recovered by a competently trained RR nurse.
- All inexperienced staff should work under direct supervision of qualified staff.

## Staffing requirements

- The recovery room must be adequately staffed during functional operation of the theatre unit.
- A registered or enrolled nurse, who is trained and competent in recovery room care, must be present at all times.
- An appropriately trained registered nurse who is experienced and competent in recovery room work should be in charge.
- The ratio of nursing staff who are trained in recovery room care to patients needs to be flexible to provide:
  - no less than one nurse/two patients
  - one to each patient who has not recovered protective reflexes.
- Ideally, a ratio of 2:1 nurse/patient in compromised or critically ill patients should be sought. One nurse must take care of the patient, while the second should document and monitor observations.
- Special adjustments should be made for paediatric and geriatric patients as well – two nurses per patient until calm with full return of protective reflexes.
- An appointed and competent nurse should take responsibility for daily checks of the resuscitation trolley, drugs and equipment. A recheck should be done after use as well. The checks should be recorded.

Please note that the RR nurse should always act in the best interest of the patient. The patient must never be left unattended and always treated with respect. Confidentiality remains of the utmost importance. Noise and traffic in the RR should also be kept to a minimum.

It is **advisable** that continuous education and evaluation of knowledge and skills of anaesthesia and recovery room personnel are maintained to support safe anaesthesia and minimise medico-legal/adverse incidents.

## *Clinical technologists*

In South Africa the clinical technologists working in theatre have completed a national diploma or a biotechnology degree in clinical technology specialising in critical care, hence they are known as Critical Care Clinical Technologists (CCTs). They are registered and regulated by the Health Professions Council of South Africa (professional board of radiography and clinical technology). Their knowledge and skills allow them to apply scientific and technological information to perform diagnostic, therapeutic and life-support procedures, operate various anaesthesia-related equipment. They are indispensable members of the anaesthetic team.

## **Roles**

- To assist the anaesthetist in the preparation of the operating room and patients for anaesthesia, and operative or diagnostic procedures.
- To assist the anaesthetist with intraoperative monitoring and care of patients.
- To assist with the postoperative care and monitoring of patients.
- To function as part of the multidisciplinary team in the operating department.
- Assist during interhospital transfer of critically ill and ventilated patients.
- In conjunction with the chief anaesthetic sister, and health technology department assist in the procurement, checking, servicing and care of equipment.

We recommend that all hospitals with a number of theatres have a designated clinical technologist available. They must be immediately available to all major cases with numerous perianaesthesia procedures. They must be available 24 hours a day to provide equipment and therapeutic support, for example operating a cell-saver or point-of-care testing devices.

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2. KLUGER M, BUKOFZER M, BULLOCK M. ANAESTHETIC ASSISTANTS: THEIR ROLE IN THE DEVELOPMENT AND RESOLUTION OF ANAESTHETIC INCIDENTS. *ANAESTHESIA AND INTENSIVE CARE* 1999;27:269-274
3. DOBSON ET AL. GUIDELINES TO THE PRACTICE OF ANAESTHESIA. REVISED EDITION 2018, CANADIAN JOURNAL OF ANESTHESIA VOLUME 65:76-104
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## Section VIII: Facilities, Equipment and Medications

### *Introduction*

Modern practice of safe anaesthesia demands certain basic facilities and equipment for the safe administration of anaesthesia.

Medical practitioner preference is based on experience, skills and being trained on, in particular, the use of specific equipment. In many cases it is in the best interest of the patient for the anaesthetist to use products they are familiar with, and on which they have been trained. This should be disclosed during discussion with the patient.

The availability, or not, of certain equipment may be based on the procurement practices of the specific health facility within which the medical practitioner works. Practitioners should be involved in procurement and supply chain management processes, to ensure that equipment choices are rational, appropriate and in the best interest of the facility's general patient population.

Where appropriate equipment or medicine choices are not available, practitioners must register their objection to this fact and confirm such objection in writing to the facility manager. The limitations on options available to patients should be disclosed, in order to reduce the risk of the practitioner being held liable for any harm that may ensue as a result of the non-availability of appropriate goods.

Consumer protection legislation makes all in the supply chain of medicines and/or devices, possible jointly and strictly liable for any harm caused by the medicine or device. Care should therefore be exercised so that the choice is not solely based on the practitioner's choice, but on the practitioner providing information to the patient, to which the patient consents.

The HPCSA's ethical rule 23 recognises that medical practitioners may prefer certain products over others, provided that –

- Choices are exercised on the basis of the patient's diagnosis;
- Chosen products are clinically indicated; and
- Patients have been informed of the options available to them.

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#### SOURCES:

CONSUMER PROTECTION ACT 68 OF 2008

HPCSA ETHICAL RULES, 2006, AS AMENDED

NATIONAL HEALTH ACT 61 OF 2003

## Facilities

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 5) that supersedes regulation R158 on Infrastructure, and should be interpreted in conjunction with the current National Core Standards (NCS) Regulations (Appendix 6).

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, "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.

1. *District hospital.* This category is divided into small (between 50 and 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.
2. *Regional hospital.* Has between 200 and 800 beds and provides a 24-hour service in internal medicine, paediatrics, obstetrics and gynaecology and general surgery; with additional services in at least one of orthopaedic surgery, psychiatry, anaesthetics and diagnostic radiology. Services are described to include both 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.
3. *Tertiary hospital.* Has 400–800 beds, provides the services of a regional hospital, and in addition 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.
4. *Central hospital.* 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 of healthcare professionals, and must be the main teaching platform for a medical school.
5. *Specialised hospital.* Have a maximum of 600 beds and provide specialised services like psychiatry, infectious diseases, tuberculosis or rehabilitation services.



The 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, and the facility therefore needs to meet the applicable standards.

Where hospitals provide a combination of levels of care, the facilities and equipment must meet the requirements for the higher level of care.

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

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: 2015.”

## ***Equipment***

Every item on the list of essential equipment should be available at every site where anaesthesia is provided even if only occasionally.

Some of the items listed under “Desirable” in the following document may only be indicated as part of a central or specialised hospital’s requirements.

Day-care and office-based facilities should adhere to all the “Essential” requirements.

### **Anaesthetic equipment**

Standards must be influenced by the nature of the surgery undertaken, and to some extent by the quality of the service offered by the institution, and the availability of maintenance and service facilities. Referral hospitals are usually in large centres and must meet higher standards.

**Regional, tertiary, central and specialised hospital requirements must include all items set out under “Desirable”.**

#### *Anaesthetic mixture components*

The anaesthetic machine must not be capable of delivering a hypoxic mixture of gases under any circumstances.

**Essential** items considered to be a minimum requirement for the safe conduct of anaesthesia include:

Gas sources exclusively from cylinders must have:

- Pin-index yokes with pressure-reducing valves for both oxygen and nitrous oxide. These should be marked with the name or the chemical symbol of the gas and colour-coded in accordance with international standards.
- Pressure indicators for oxygen must be available.
- One nitrous oxide cylinder and one full spare per machine, or one medical air cylinder and one full medical air cylinder spare, per machine.
- Two oxygen cylinders and two full spares per machine.

A suitable spanner or key must be available for opening and closing gas cylinders, even where the cylinders have finger-control knobs. The spanner should be attached to the anaesthesia machine. Gas sources from pipelines with back-up cylinders must have:

- SASA recommends that all new facilities must be provided with piped medical air, in addition to oxygen and nitrous oxide.
- Noninterchangeable wall points and connectors for nitrous oxide, oxygen and any other gases, conforming to national standards.
- Colour-coded pipeline hoses capable of withstanding pressures of up to 1 000 kPa affixed to anaesthetic machines by noninterchangeable fittings. Colour-coding according to international standards: oxygen (white), nitrous oxide (blue) and medical air (black).
- Pressure indicators for each line, either outside the operating theatre, or in the gas pipeline before the anaesthetic machine. (SANS 7396-1:2009 Medical gas pipeline system).
- Non-return valves fitted at the machine connection point of the pipeline.
- One back-up cylinder with pin-index yoke for oxygen.
- One spare oxygen cylinder.
- A suitable spanner or key must be available for opening and closing gas cylinders, even where the cylinders have finger-control knobs. This should be attached to the anaesthesia machine.
- Medical air pipelines should be fitted with a water trap.

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

Appropriate flow controllers for all available gases:

- The flow meter for oxygen must be accurate to 100 ml/minute 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 is capable of delivering accurate, controllable partial pressures of volatile anaesthetic 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 oxygen flush system, delivering at least 35 l/minute of oxygen at the machine outflow and controlled by an obvious, recessed, nonlockable button.

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

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

- The mounting frame for a mobile anaesthetic 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 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 pipeline or cylinder pressure of oxygen cuts off hypoxic gas sources (fail-safe device).

Pipeline supply for medical air in all major theatres.

Appropriate delivery system for the supply of accurate flows 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 patients minute ventilation, mandates the use of real-time capnography and anaesthetic agent analysis (AA). SASA recommends AA at all sites, and expects that the next revision will make the availability of AA mandatory.

## Breathing circuits

**Essential** items considered to be a minimum requirement for the safe conduct of anaesthesia include:

- 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.
- Full set of supraglottic/laryngeal mask airways per theatre complex.
- 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.

**Desirable** items considered not absolutely essential on a basic machine, but normally considered desirable for the safe conduct of anaesthesia

- 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 considered to be a minimum requirement for the safe conduct of anaesthesia include:

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

- Two adult, preferably Macintosh® pattern with all size blades.
- Appropriate range of paediatric laryngoscope blades when anaesthesia might be provided for children.

Magill® adult and paediatric endotracheal tube-introducing forceps.

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

Anaesthesiologist's chair on wheels with backrest.

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

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 cannulae/catheters for oral and endotracheal suction.

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

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

A monitor-defibrillator with adult and infant electrodes per theatre suite must be available. A pacing facility is desirable.

Operating table with Trendelenburg-position controls at the head of 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 anaesthetic spray.

Two intravenous (IV) infusion poles.

A pair of strong scissors.

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

Anaesthetic and surgical suction bottles should be graduated for volume.

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

Warming blankets/convection warmers for use in theatre. This 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.

Infusion devices: volumetric pumps and/or syringe drivers.

In-line warmer for blood and IV fluids.

Pressure infusor for 500 ml (blood) or 1 000 ml IV bags.

Electrical generator back-up for hospital and/or theatre complex.

Uninterruptable power supply (UPS) or battery back-up for life-support equipment. In the case of a power outage (failure of main Eskom power supply) the following guideline should be followed:

- If the theatre complex only has one electrical back-up 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.
- If a theatre complex has a second back-up power supply, e.g. second generator or UPS unit, elective cases can continue as long as it is verified that the second back-up supply has adequate capability for the duration of the power outage.
- Equipment battery back-up is not deemed to be a second back-up power supply as the duration of the battery supply is not dependable enough to continue with an elective list.

*Desirable items considered not absolutely essential on a basic machine, but normally considered items considered not absolutely essential on a basic machine, but normally considered desirable for the safe conduct of anaesthesia*

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

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

Video-assisted laryngoscope.

Individual illumination of the anaesthesiologist's area, including emergency back-up, battery-powered illumination source.

Peripheral nerve stimulator to assist with regional anaesthetic techniques per theatre suite.

Syringe drivers programmed to administer target-controlled intravenous anaesthesia.

Blood salvage system.

High-flow blood/fluid warmer.

Transportable ventilator and monitor.

Equipment for patient-controlled analgesia.

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

A telephone in each theatre for communication.

## Monitors

**Essential** items considered to be a minimum requirement for the safe conduct of anaesthesia include:

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 or noninvasive blood pressure or invasive pressure readings.
- An automated electronic noninvasive blood pressure module displaying systolic, mean and diastolic blood pressure, with an appropriate range of cuffs.
- Pulse oximetry, displaying oxygen saturation and a plethysmogram.
- Capnograph, displaying end-tidal CO<sub>2</sub> in mmHg or Kpa, or a percentage and a capnogram.
- Temperature for oesophageal, rectal, bladder or tympanic use, reading 22–42 °C minimum range.
- Alarms: Adjustable alarm limits for all parameters.

Oxygen monitor of the gases (inspired and expired), with a low-limit alarm at least (may be incorporated in the device outlined in 3.4.2).

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 (may be incorporated in the device outlined in 3.4.2) with double-burst stimulation, train-of-four and post-tetanic count facilities.

A point-of-care device to estimate blood glucose.

A point-of-care device to measure haemoglobin and/or haematocrit.

A thermometer that permanently displays the operating theatre temperature.

**Desirable** items considered not absolutely essential on a basic machine, but normally considered desirable for the safe conduct of anaesthesia

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

Anaesthetic gas analyser.

Oesophageal stethoscope.

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

Processed EEG Depth of Anaesthesia Monitor.

Noninvasive cardiac output monitor.

Portable ultrasound device for guided nerve blocks and vascular access.

Transoesophageal echocardiography equipment.

Near Infrared Cerebral Oximetry (NIRS) monitor.

Blood gas analyser.

Transportable vital signs monitor.

Scale for weighing swabs.

See Table I for essential equipment list (anaesthesia).

**Table I.** Essential equipment list (anaesthesia)

<b>Equipment description</b>	<b>District hospital</b>	<b>Regional hospital</b>	<b>Tertiary hospital</b>	<b>Central hospital</b>
Anaesthetic machine (basic)	X	X	X	X
Anaesthesia machine, with O <sub>2</sub> , air and N <sub>2</sub> O flow meters, with vaporisers, anaesthesia rising bellow ventilator, absorber and closed circuit, masks, suction unit, aneroid blood pressure apparatus (with obese, adult and child cuffs) and oxygen monitor	X	X	X	X
Anaesthetic work station		X	X	X
Anaesthesia workstation: CPU controlled with electronic flow meters, electronic-controlled vaporisers, integrated multi-mode anaesthesia ventilator (rising bellow or piston driven), with integrated patient monitor with ECG, ST-segment analysis, NIBP, invasive pressures, SPO <sub>2</sub> , multi-gas analyser, spirometry, NMT, BIS or entropy			X	X
Anaesthesia trolley, mobile	X	X	X	X
Processed EEG depth of anaesthesia monitor (if not part of patient monitor)		X	X	X
Blood/fluid warmer	X	X	X	X
Blood salvage system			X	X
Cerebral oximeter (NIRS)			X	X
Diagnostic set, complete	X	X	X	X



Defibrillator, complete, mounted on mobile trolley (adult/paediatric paddles)	X	X	X	X
Defibrillator and external pacing		X	X	X
Difficult airway management equipment	X	X	X	X
Forced air warmer	X	X	X	X
Fibre-optic laryngoscope		X	X	X
Glucometer	X	X	X	X
Haemoglobinometer/centrifuge (Hct)	X	X	X	X
High-flow blood/fluid warmer		X	X	X
Lactate meter	X	X	X	X
Laryngoscope set, complete	X	X	X	X
Jet ventilator		X	X	X
Near Infrared Cerebral Oximetry (NIRS)			X	X
Non-invasive cardiac output monitor		X	X	X
PCA, PCA pump or disposable pumps		X	X	X
Peripheral nerve stimulators	X	X	X	X
Platelet function monitor (Access to)			X	X
Point-of-care diagnostics (blood gas, electrolytes, glucose and lactate)		X	X	X
Portable ultrasound for nerve blocks and vascular access		X	X	X
Pressure infusion device (for blood, 500 ml and 1 000 ml vacotainers)	X	X	X	X
Pulse oximeter with HB (Access to)			X	X
Resuscitator, pulmonary, manual, adult, complete	X	X	X	X
Resuscitator, pulmonary, manual, child/infant, complete	X	X	X	X
Scale for swab weighing (Access to)		X	X	X
Syringe drivers	X	X	X	X
Suction unit, mobile, 1 x 2-litre bottle/disposable bag, wall outlet	X	X	X	X
Suction unit, mobile, 1 x 2-litre bottle/disposable bag, electrical	X	X	X	X
TCI syringe drivers (target-controlled intravenous anaesthesia)		X	X	X
TEE			X	X
Transport ventilator		X	X	X
Transport vital signs monitor		X	X	X
Thromboelastograph			X	X
Video bronchoscope			X	X
Video laryngoscope (for district if high volume obstetrics)		X	X	X
Vital signs monitor with ECG, SpO <sub>2</sub> , NIBP, temperature, capnography	X	X	X	X
Vital signs monitor with ECG, SpO <sub>2</sub> , NIBP, invasive pressures, temperature, multi-gas analyser		X	X	X
Vital signs monitor: capnograph	X	X	X	X
Vital signs monitor with SpO <sub>2</sub> and NIBP	X	X	X	X
Volumetric infusion pump	X	X	X	X

BIS: Bispectral Index, CPU: central processing unit, ECG: electrocardiogram, HB: haemoglobin, Hct: haematocrit centrifuge, NIBP: noninvasive blood pressure, NIRS: near-infrared spectroscopy, NMT: neuromuscular transmission, N<sub>2</sub>O: nitrous oxide, PCA: patient-controlled anaesthesia, SPO<sub>2</sub>: blood oxygen saturation, TCI: target-controlled infusion, TEE: transoesophageal echocardiography

## **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:

- An oxygen flow meter and nipple.
- Suction equipment, including a receiver, tubing, a rigid hand piece and a range of suction catheters, including Yankauer®.
- An automated noninvasive blood pressure monitor with appropriately sized cuffs.
- A stethoscope.
- A pulse oximeter.
- Means of measuring body temperature.

Within the recovery room there must be:

- A range of devices for the administration of oxygen to spontaneously breathing patients.
- A self-inflating manual resuscitator, e.g. Ambu® bag, in order to deliver an oxygen-enriched mixture to inflate the lungs. A minimum of two per recovery room complex is required.
- Equipment and drugs for airway management and endotracheal intubation.
- Emergency drugs (see Section IV, paragraph 4).
- A range of intravenous equipment and fluids.
- Drugs and equipment for acute pain management.
- A range of syringes and needles.
- An electrocardiogram monitor.
- Patient-warming devices.

There should be immediate access to:

- A monitoring defibrillator, preferably with pacing facility.
- A blood warmer.
- A thermostatically controlled warming cupboard for intravenous solutions.
- A refrigerator for drugs and blood.
- A procedure light.
- A range of appropriate drugs.
- A surgical tray for procedures, including tracheostomy and chest drains.

- Point-of-care access to diagnostic services, e.g. blood glucose, blood gases and radiology.
- A peripheral nerve stimulator.
- Other equipment that is as appropriate to the patient's condition, e.g. wire cutters.
- 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.
- Contain 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 of being easily removed.
- Include provision for a pole from which intravenous 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 anaesthetics are given must provide an efficient and reliable maintenance and repair service 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 anaesthetic equipment should be established in accordance with the SASA Guidelines for Infection Control in Anaesthesia in South Africa 2014.

Servicing 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, licence-holder company.

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 that are 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, prior to 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: mechanical engineer from public works/hospital group, mechanical engineer from health infrastructure, hospital/facility engineer; medical engineer; 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 made available for service personnel to perform both regular and emergency servicing without safety being compromised.

Storage facilities should be available for nitrous oxide and oxygen in the sterile area. This storage area should fulfil the criteria described in the appropriate South African Bureau of Standards Code of Practice.

## **Drugs**

### **Essential Drugs Programme (EDP)**

To provide equal access to medicines for all South Africans, whilst improving supply of listed items at 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 be available within health systems at all times 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 availability and accessibility of medicines for all people.

The criteria for the selection of essential medicines in South Africa were based on the WHO guidelines for drawing up a national Essential Medicines List. Essential medicines are selected with due regard to disease prevalence, evidence on 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, and happens by means of 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 gives an indication of agents that should be available to provide safe anaesthesia at regional hospital level.

**Table II.** Summary of current recommendations of essential drugs for anaesthesiology<sup>1</sup>

<b>Premedication</b>	
Benzodiazepines	Lorazepam Midazolam
<b>Induction agents</b>	
	Propofol Etomidate Ketamine Thiopental
<b>Volatiles</b>	
Induction	Halothane Sevoflurane
Maintenance	Isoflurane
<b>Muscle relaxants</b>	
Depolarisers	Suxamethonium
Non depolariser	Cisatracurium Vecuronium
Rapid sequence intubation	Suxamethonium Rocuronium
Reversal agents	Neostigmine with either atropine or glycopyrrolate
<b>Analgesics</b>	
Oral	Paracetamol NSAIDs, e.g. ibuprofen
Intravenous	Fentanyl Morphine Ketamine
Postoperative	Morphine Tramadol Diclofenac IM
Fluids	Ringer lactate 0.9% NaCl

SOURCES:

1. STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LIST FOR SOUTH AFRICAN HOSPITALS – LEVEL ADULTS, CHAPTER 12. PRETORIA: THE NATIONAL DEPARTMENT OF HEALTH, 2015

### Treating anaesthesia complications

Malignant hyperthermia	Dantrolene CVS support – adrenaline (epinephrine)
LA toxicity	Lipid emulsion (20%)
Acute hypotension	Ephedrine IV, 3–5 mg Phenylephrine IV, 50–100 mcg
Acute hypertension	Alfentanil (obtain the hypertensive response) Magnesium sulfate Labetalol

### PONV

Prophylaxis	Dexamethasone Ondansetron Promethazine
Treatment	Metoclopramide Promethazine, deep IM, 25–50 mg

### Regional neuraxial

Spinal	Bupivacaine 0.5% (spinal use) plain or hyperbaric (+glucose)
Epidural	Bupivacaine 0.5% Lidocaine 2% (preservative-free)
Regional blocks	Lidocaine 1% or 2% Bupivacaine 0.5%
Topical anaesthesia	Lidocaine jelly Lidocaine topical spray Lidocaine/prilocaine, topical cream, 2.5/2.5%
Chronic neuropathic pain	Amitriptyline Carbamazepine

### Emergency medication

*In addition to drugs used to provide anaesthesia, the following need to be available*

Cardiac arrest	Adrenaline
Antidysrhythmics	Amiodarone Dopamine Dobutamine Lignocaine Verapamil Adenosine
Bronchodilators	Salbutamol Aminophylline
Corticosteroids	Hydrocortisone Dexamethasone Methylprednisolone
Vasopressor	Phenylephrine <b>and</b> ephedrine/etilephrine
Vasodilators	Labetalol TNT

Antibiotics for prophylaxis	<i>As per current recommendations<sup>2</sup></i> Cefazolin Metronidazole Gentamicin Clindamycin
Others	Sodium bicarbonate Calcium chloride/gluconate Beta blocker (propranolol, atenolol) Digoxin Furosemide Mannitol
Reversal agents	Dextrose 50% Oxytocin  Naloxone Flumazenil

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 drugs which are highly desirable in regional, tertiary and central hospitals.

**Table III.** Drugs which are highly desirable in regional, tertiary and central hospitals

Inhalants	Sevoflurane Desflurane
Analgesics	Alfentanil Sufentanil Remifentanil
Relaxants	Rocuronium Atracurium
Other	Dexmedetomidine Esmolol Noradrenaline Ketorolac Paracetamol IV Sugammadex
Chronic neuropathic pain	Gabapentin Duloxetine Pregabalin

SOURCES:

- STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LIST FOR SOUTH AFRICA HOSPITALS – LEVEL ADULTS. CHAPTER 11. PRETORIA: THE NATIONAL DEPARTMENT OF HEALTH, 2015

## Sugammadex

### SASA:<sup>3</sup>

1. Does not support any specified limitations with respect to the use of Sugammadex. Its use should be guided by the clinician's patient assessment and responsible use in the clinical circumstance.
2. Supports and encourages responsible, sparing use of Sugammadex limited to patients, who in the clinician's opinion:
  - a. Will benefit from the drug clinically intra-/postoperatively and/or
  - b. Will benefit from the favourable profile of reversal in the case of emergencies/difficult airways.
3. Emphasises that the use and dose of Sugammadex should be guided by quantitative neuromuscular transmission (NMT) monitoring as a minimum for all patients (as for all patients who receive neuromuscular blocking agents). Such monitoring should be made available in all facilities where neuromuscular blocking agents are used.
4. Does not encourage the routine use of Sugammadex as it is not sustainable at the current cost in the South African context. Routine use is likely to result in limited availability and/or specified indications (limitations) to its use.
5. Advocates that the use of neostigmine and an anti-cholinergic agent for reversal of the majority of patients is still considered applicable acceptable practice for the majority of patients who ordinarily require reversal. Appropriate timing and communication between the anaesthetic and surgical team is essential.
6. Is of the opinion that SASA members will continue to practise in the best interest of their patients, both clinically and financially, to ensure sustainable excellence in the delivery of anaesthesia in their respective sectors.
7. Recommends that Sugammadex be readily available for responsible usage within all facilities where reversal of neuromuscular blockade may be required.

## 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 for certain diseases. Medicines are sometimes used in contexts or for conditions other than for which they have

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### SOURCES:

3. POSITION STATEMENT ON THE USE OF SUGAMMADEX, 29 SEPT 2015



been registered. Medicines registration processes in South Africa are sometimes slower than those in other markets; and in some cases, 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.

In all instances 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 of 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 off-label prescription and use means.

The National Health Act requires the patient to be informed about the benefits, risks and consequences of, in this case, the 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 in a conspicuous manner, 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 the 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 as a result of the product being 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 that are registered for specific indications in other jurisdictions may be easier to justify as "reasonably suitable" than those that are not registered anywhere for the particular indication and/or with limited data on their safety and efficacy.

Due to pharmacovigilance (post marketing 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.

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SOURCES:

MEDICINES AND RELATED SUBSTANCES ACT 101 OF 1965

NATIONAL HEALTH ACT 61 OF 2003

HEALTH PROFESSIONS COUNCIL OF SA ETHICAL RULE 2006, AS AMENDED

WORLD MEDICAL ASSOCIATION ON THE RELATIONSHIP BETWEEN PHYSICIANS AND PHARMACISTS IN MEDICINAL THERAPY OF 1999, AS AMENDED IN 2010

## Ampoule labelling standard

SASA deems the standard SANS 44/2014: Labelling of small-volume (50 mL or less) Parenteral Drug 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 generic name of the drug 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 on part of the label utilise the colours specified for identifying specific drug classes on syringe labels, as per the SABS standard (South African National Standards) SANS 26825.

## Substitution of medicines and devices

The substitution of health goods occurs in resource-constrained settings, and comes about as a result of healthcare priorities made in formularies and treatment guidelines. Legislation relating to substitution in health care (and in general consumer goods) impact on this practice.

The WMA has serious concerns about the practice of substitution.

There is a difference between generic and therapeutic substitution, with generic substitution in general being permitted by South African law, but therapeutic substitution 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 procedures in place to ensure their lot-to-lot bioequivalence and their chemical and therapeutic 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; and
3. Pharmacists may dispense the generic instead of the medicine prescribed, unless –
4. expressly forbidden by the patient to do so;

5. the prescriber has written in his or her own hand on the prescription the words “no substitution” next to the item prescribed;
6. the retail price of the generic is higher than that of the prescribed medicine;
7. the product has been declared not substitutable by the MCC.

Although there was, in the past, a list of non-substitutable products as issued by the MCC 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 World Medical Association, the Medicines Act and the Consumer Protection Act, read with the National Health Act, make it clear that:

1. Information must be provided on drug choices and the patient’s condition, to enable the practitioner to carefully select medicines options.
2. Once the patient gives his or her consent to the medicine selected, that medicine should not and cannot be changed without the consent of the patient.
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 post-marketing surveillance of medicines require that all adverse drug reactions or therapeutic failure be reported. This is and should also be the case in instances of generic substitution. The WMA also recommends that the practitioner “document this finding and report it to appropriate drug regulatory authorities”.

The WMA recommends that medical practitioners and pharmacists cooperate within the definitions as 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**

The Medicines Control Council (MCC) has a responsibility to ensure the safety, efficacy and quality of all medicines used by the South African public. The National Pharmacovigilance Programme is coordinated by the MCC 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. adverse drug reactions or ADRs). The ultimate goal of this activity is to improve the safe and rational use of medicines, thereby improving patient care and public health.

### **What is an Adverse Drug Reaction (ADR)?**

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

### **Who should report ADRs?**

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 adverse drug reaction/product quality form submitted could result in any of the following:

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#### **SOURCES:**

CONSUMER PROTECTION ACT 68 OF 2008

MEDICINES AND RELATED SUBSTANCES ACT 101 OF 1965

NATIONAL HEALTH ACT 61 OF 2003

WORLD MEDICAL ASSOCIATION STATEMENT ON DRUG SUBSTITUTION, 2005

WORLD MEDICAL ASSOCIATION ON THE RELATIONSHIP BETWEEN PHYSICIANS AND PHARMACISTS IN MEDICINAL THERAPY OF 1999, AS AMENDED IN 2010

- 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.

The purpose of ADR reporting is to reduce the risks associated with the use of medicines and to ultimately improve patient care.

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

An adverse drug reaction 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 ADR?**

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

1. What exactly is the nature of the reaction? *(Describe the reaction as clearly as possible and where possible provide an accurate diagnosis.)*
2. 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.)*
3. Is the reaction known to occur with the particular medicine as stated in the package insert or other reference? *(If the reaction is not documented in the package insert, it does not mean that the reaction cannot occur with that particular medicine.)*
4. 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.)*
5. 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.)*
6. 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 what the*

*actual cause of any new medical problem is. 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 adverse drug reactions should be reported:

- all ADRs to newly marketed drugs or new drugs added to the EDL;
- all serious reactions and interactions;
- ADRs that are not clearly stated in the package insert;
- 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 product quality problems should be reported?**

The following product quality problems should be reported:

- suspected contamination;
- questionable stability;
- defective components;
- poor packaging or labelling;
- therapeutic failures.

### **How can ADRs 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 ADRs reported?**

An Adverse Drug Reaction/Product Quality Report Form should be completed in as much detail as possible before returning it by fax or post to any of the addresses provided below. Additional forms can be obtained by contacting the MCC at these addresses. Report forms may also be accessed via the following website: <http://www.mccza.com>.

#### **1. The Registrar of Medicines**

Medicines Control Council, Department of Health, Private Bag X828  
Pretoria, 0001  
Tel: (021) 395 8003/8176; Fax: (012) 395 8468

#### **2. The National Adverse Drug Event Monitoring Centre (NADEMC)**

C/o Division of Pharmacology, University of Cape Town,  
Observatory, 7925  
(021) 447 1618; Fax: (021)

## Ampoule sharing

Ampoule sharing is prevalent in both public and private sector anaesthesia practice and refers to the use of withdrawing multiple doses of drug from a single-use ampoule.<sup>4</sup> This practice mostly relates to “expensive drugs” and paediatric anaesthesia – an attempt at cost saving in the first instance, and time saving or for 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 ampule 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.

The risks of infection-related complications with drugs such as propofol clearly outweigh any benefit. An appraisal of 58 studies regarding propofol-related infections, including 20 outbreaks involving 144 patients and 10 deaths,<sup>5</sup> identified syringes, micro-droppers, vials, and IV stopcock dead space as the most frequently encountered reservoirs of extrinsically contaminated propofol, with previously used vials being the most common culprits. Of the infection outbreaks, hepatitis-C contributed 18.1%, hepatitis-B 4.2%, *Candida albicans* 21.5% and bacteria 47.2% (Gram-positive 27.1%, Gram-negative 20.1%). The incidence of contaminated syringes was approximately 6% in ICUs and operating rooms. The authors point out that these reports were all from industrialised countries (USA, UK, Europe, Australia and Taiwan) and they were of the opinion that propofol-related infections are under-reported. No reports from developing or low-income countries have been forthcoming where the problem is likely to be much greater due to economic restraints and lack of awareness leading to reuse of syringes, ampoules and vials.

The cost-saving argument is skewed in that although it is requested that the costs of one ampoule is shared amongst two or three patients, this rarely happens as hospital accounting systems do not allow for this. Consequently either only one patient gets charged for the whole ampoule that has been shared, or all the patients get charged for one ampoule. Neither of these is fair or acceptable, for obvious reasons. When cost containment comes with the risk of unsafe practice, it’s not worth it. Similarly in the public sector, the perceived or real cost saving comes at the price of safe anaesthetic practice. Financial pressures or a simple wish not

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### SOURCES:

4. LUNDGREN AC. AMPOULE SHARING – IS IT SAFE PRACTICE AND IT IS BEST PRACTICE? PIPELINE 2007;57:1
5. ZORILLA-VACA A, AREVALO JJ, ESCANDON-VARGAS K, SOLTANIFAR D, MIRSKI MA. INFECTIOUS DISEASE RISK ASSOCIATED WITH CONTAMINATED PROPOFOL ANESTHESIA, 1989-2014. EMERG INFECT DIS. 2016 JUN; 22(6): 981–992. DOI: 10.3201/eid2206.150376

to be wasteful, however noble, cannot advocate or endorse the practice of sharing single-use ampoules between multiple patients; this is not considered “best practice”.

Containers of which the contents are designed to be used for more than one patient must be labelled in such a way as to indicate the intended multiple usage. This should not be construed as including the preparation in pharmacy of individual prepared syringes.<sup>6</sup>

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SOURCES:

6. CHAMBERS A, ALLAN C, BIRKS R, COLLETT B, CURRAN J EDWARDS C, FITZWILLIAMS B, ET AL CONTROLLED DRUGS IN PERIOPERATIVE CARE. AAGBI. 2006.



# PERIANAESTHETIC CARE AND STANDARDS

## Principles of anaesthetic care

As discussed under General Standards, anaesthesia should be administered only by medical practitioners with appropriate training in anaesthesia.

The *sine qua non* of the safe conduct of anaesthesia is the physical presence of such a practitioner constantly in attendance during anaesthesia. Furthermore, the anaesthesiologist should be readily available during the period of recovery from anaesthesia until such time as the patient is deemed fit for transfer from the recovery area. Only in exceptional circumstances should the anaesthesiologist physically leave the operating room, and then only if continued supervision has been handed over to another suitably qualified medical person. In addition, the operating team should be informed that the anaesthesiologist will temporarily be out of the room and that continued monitoring will be performed by a substitute.

Every patient who presents for anaesthesia should undergo a general medical assessment by a medical practitioner, preferably by the doctor scheduled to give the anaesthetic. In order to provide safe anaesthesia the anaesthetist needs to understand the patient, the diseases and treatment of the patient and the demands of surgery and anaesthetic intervention. It is the responsibility of the anaesthesia practitioner to engage other members of the surgical team in care of the patient in such a way that the improved communication results in every effort being made to improve the quality of care and to prevent the patient from being harmed. An example of a tool to be used to enhance this communication process is the World Health Organization Safe Surgery Checklist (<http://www.who.int/patientsafety/safesurgery/>). This simple checklist was shown repeatedly to enhance patient safety.<sup>1</sup>

## Preanaesthesia care

### *Preoperative consultation*

- These standards apply to all patients who receive general or regional anaesthesia, sedation or monitored anaesthesia care. Under unusual circumstances, e.g. extreme emergencies, these standards may be modified. When this is the case, the circumstances shall be documented in the patient's record. At a minimum, a focused preoperative evaluation of airway, lungs and heart must be carried out and vital signs documented.
- An anaesthesiologist shall be responsible for determining the medical status of the patient, developing a plan of anaesthesia care and acquainting the patient or the responsible adult

#### SOURCES:

1. LAU CSM, CHAMBERLAIN RS. THE WORLD HEALTH ORGANIZATION SURGICAL SAFETY CHECKLIST IMPROVES POST-OPERATIVE OUTCOMES: A META-ANALYSIS AND SYSTEMATIC REVIEW. *SURGICAL SCIENCE*, 2016, 7, 206-217

with the proposed plan and all aspects relating thereto, including financial implications and scheduling. Appropriate informed consent for anaesthesia should be obtained.

- Information is obtained by reviewing the medical record, interviewing the patient in terms of the medical history, previous anaesthesia experience, drug therapy, current disease and aspects that may influence perioperative decisions, physical examination and results from special investigations, medical tests or consultations.
- Further consultation or investigations may be ordered at this stage, and specific preparation may be implemented. Any evaluations, tests and consultation should only be performed if there is reasonable expectation that the benefit will outweigh the risk. Potential benefits may include a change in timing and content of anaesthetic management which would improve safety or better utilisation of resources. There is no place for “routine special investigations” and only indicated investigations should be ordered. Results should also be reviewed before the anaesthetic. Unnecessary testing may lead to patient harm.<sup>2</sup>
- The responsible anaesthesiologist shall verify that the above has been properly performed and documented in the patient’s record.
- Preoperative assessment should take place early in the patient’s journey so that all requirements for essential resources and obstacles can be anticipated before the day of the operation. Patients with high severity of disease and/or high invasiveness of surgery should be evaluated before the day of surgery. Patients with low severity of disease and medium or low invasiveness of surgery could be evaluated on or before the day of surgery.<sup>1</sup>
- Ideally, the anaesthetist who will actually give the anaesthetic should visit the patient before the operation.
- Sufficient time must be made available in the patient care pathway for the anaesthetist to cover the essential points of preoperative assessment. Job plans should incorporate adequate programmed activities for preoperative anaesthetic visiting and assessment. Whenever possible, a preoperative consultation should be performed in a formal setting. Nevertheless, this might not always be practical or possible. Therefore, there can be no geographical or time limitation as to when or where this preoperative consultation should take place.
- At the time of the preoperative consultation, premedicant drugs should be prescribed in writing and signed for on the appropriate document by the anaesthesiologist or the individual taking the anaesthesiologist’s orders. Such premedicant drugs may include those for night sedation, pain management and therapy of underlying disease. This prescription should be available for other persons in the perioperative team to prevent incompatible or duplicate treatment administration.

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SOURCE:

2. ROIZEN MF. MORE PREOPERATIVE ASSESSMENT BY PHYSICIANS AND LESS BY LABORATORY TESTS. *N ENG J MED.* 2000;342:204–5

## Clinical assessment

### *Medical history*

The information should be obtained and recorded by the anaesthesia provider by taking a formal history, which may be supplemented with a questionnaire. Electronic/internet questionnaires to elicit patient information may be helpful to provide the anaesthetist with information, but must be supplemented by a face-to-face encounter and examination. The patient's history should include previous or present illnesses, previous anaesthesia and/or surgery and problems/complications, current and recent drug therapy, unusual reactions to drugs, family history as it pertains to anaesthesia and any further information deemed necessary for the assessment of the individual patient. The patient's ASA physical status category should be documented.

### *Physical examination*

The above history should be supplemented by a full physical examination at the time of the preoperative consultation. This includes evaluation of the airway and appropriate systems.

Additional information that might be necessary should be included, e.g.:

- Accurate measurement of the patient's weight and height should be provided.
- Clinical assessment of cardiovascular and respiratory status should be carried out as considered appropriate by the anaesthesiologist.
- Blood pressure reading should be taken.
- Further systemic examination should be conducted, as is relevant.
- Side-room urine examination should be undertaken, if indicated.

### *Preoperative testing*

Preoperative tests should not be carried out routinely. They should be ordered selectively (balancing risk and costs against benefits, taking the invasiveness of surgery into account) to guide optimising of perioperative management. Indications should be documented and based on information from medical records, history and physical examination. Unless the patient's condition changes significantly, results of tests carried out up to six months before the procedure should be acceptable.

When ordering special investigations is considered it should be considered if results would change management. If not, it is not useful and will only add to costs. Unnecessary duplication of information should also be avoided e.g. information gained from a cardiac echogram in some clinical scenarios make the need for an ECG and chest X-ray unnecessary.

### *A 12-lead electrocardiograph*

is not routinely indicated, but in the case of a history that is suggestive of cardiac or pulmonary disease may be indicated in the following circumstances or when symptomatic:

- Recent myocardial infarction or angina.
- Congenital heart disease.
- Arrhythmia, particularly if symptomatic.
- Any previous heart disease or condition predisposing to cardiovascular disease.
- Longstanding hypertension.
- History of dyspnoea, blackouts and palpitations.
- Poorly controlled diabetes.
- Older age.
- Chronic respiratory disease.
- Other risk factors.

### *A chest X-ray*

should be available where:

- Clinical examination indicates lung pathology with remaining functional impairment.
- There is a history of haemoptysis.
- There is a recent history of thoracic injury.
- Clinical grounds to suspect pulmonary hypertension.
- Other indications.

### *Preoperative haemoglobin*

should not be carried out routinely, but may be indicated by:

- Type and invasiveness of surgery.
- Liver disease or renal disease.
- Clinical anaemia.
- Extremes of age.
- Bleeding.
- Other haematological diseases.

### *Other special investigations*

Other special investigations, such as electrolytes, blood sugar, blood urea and creatinine, coagulation studies, pulmonary function tests, functional tests of cardiac function and an echocardiography should be considered in the light of the findings of the preoperative assessment.

### **Consent and explanation**

- Informed consent must be obtained.
- SASA **highly recommends** that a facility- or provincial policy guide the processes/procedures for obtaining informed consent (an example of such a policy can be found as Appendix 7 – with permission). SASA further **recommends** that anaesthesia-specific consent forms related to all aspects of the anaesthesia service is available (an example of such a form can be found as Appendix 8 – with permission).
- The patient or guardian needs to be fully informed regarding all aspects of the planned anaesthetic procedure, including the financial implications. A written fee estimate may be required to facilitate this communication.
- The anaesthesiologist may need to confirm that appropriate arrangements have been made regarding scheduling of the procedure.
- The patient's fears need to be allayed and information and reassurance given. The anaesthetic technique must be discussed with the patient or caretaker.
- Only the more common and relevant risks of the anaesthetic procedure need to be explained to the patient and/or his or her family, as is appropriate. Explanation of risks should not necessarily include rare and uncommon outcomes that will incur undue anxiety. However, catastrophic outcomes, e.g. death or paralysis, should be mentioned, even if extremely rare.
- Explanations and answers to questions posed by the patient should be frank, but must be tailored according to:
  - The ability of the patient to grasp the implications fully.
  - The patient's existing medical knowledge and medical background.
- It is preferable that a written information sheet with simple information on fasting, anaesthesia, and pain relief is provided to elective patients before hospital admission.
- The patient is entitled to know the qualifications and experience of the anaesthesia provider. SASA **recommends** that the patient is informed about this during the preoperative consultation. .

## Telephonic and electronic prescription of premedication drugs

While it is generally accepted that the ideal is to visit all patients in the ward before prescribing premedicants, it may be in the patient's best interests to prescribe these telephonically. For example, patients may only be admitted on the day of surgery while a busy surgical list is already in progress. This makes it difficult, if not impossible, for the anaesthesiologist to visit the patient prior to the patient's transfer to the operating suite. In such circumstances, it may be desirable or even essential to prescribe some form of anxiolytic or other premedication. Premedication drugs may be ordered telephonically if the patient's detailed history, as well as other admission criteria, such as age, weight and gender, is made available to the anaesthesiologist and if the patient is being attended to by registered nurses who will have the patient under observation. In these circumstances, overall responsibility will remain that of the anaesthesiologist, and he should refrain from telephonic/electronic prescriptions if it is not appropriate.

### **Preoperative fasting**

The following fasting guidelines have been adopted from the Canadian Anesthesiologists' Society, with permission:

*Fasting policies should vary to account for age and preexisting medical conditions and should apply to all forms of anesthesia, including monitored anesthesia care. Emergent or urgent procedures should be undertaken after considering the risk of delaying surgery vs the risk of aspiration of gastric contents. The type and amount of food ingested should be considered in determining the duration of fasting.*

*Before elective procedures, the minimum duration of fasting should be:*

- *Eight hours after a meal that includes meat or fried or fatty foods;*
- *Six hours after a light meal (such as toast and a clear fluid) or after ingestion of infant formula or non-human milk;*
- *Four hours after ingestion of breast milk (no additions to pumped breast milk are allowed);*
- *Two hours after clear fluids.*

*Unless contraindicated, adults and children should be encouraged to drink clear fluids (including water, pulp-free juice, and tea or coffee without milk) up to two hours before elective surgery.*

### Further information

South African Society of Anaesthesiologists' webpage. Available from: [www.sasaweb.com](http://www.sasaweb.com)

On the American Society of Anesthesiologists' webpage. Available from: [www.asahq.org/](http://www.asahq.org/):

- Basic standards for preanaesthesia care.
- Statement on routine preoperative laboratory and diagnostic screening.

- Practice advisory for preanaesthetic evaluation.

On the Royal College of Anaesthetists' webpage. Available from: <http://www.rcoa.ac.uk/>:

- Guidelines for the provision of anaesthetic services (July 2004), Chapter 3.

Regarding airway assessment:

- <http://www.asahq.org/~//media/For%20Members/Practice%20Management/PracticeParameters/DifficultAirway.ashx>
- <http://tinyurl.com/cgbow6w>
- [www.das.uk.com/guidelines/downloads.html](http://www.das.uk.com/guidelines/downloads.html)

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SOURCE:

1. AMERICAN SOCIETY OF ANESTHESIOLOGISTS TASK FORCE PRACTICE FOR PREANESTHESIA EVALUATION. ANESTHESIOLOGY. 2012;116(3):552-538.

## **Care of patients under anaesthesia**

Consideration to principles of safe anaesthesia care provision is given elsewhere in the document as it pertains to professionalism, equipment and monitoring, medication, etc. The following are guidelines on issues not addressed elsewhere.

### ***Preparation for Anaesthesia***

Before beginning anaesthesia, the anaesthesia provider must ensure that

1. An explanation of the planned anaesthetic procedure, including recognized risks and alternative techniques, has been provided and documented;
2. An adequate review of the patient's condition has been performed;
3. All equipment that is expected to be required is available and in working order, including the equipment required for supporting core temperature management (patient core temperature 36–37°C);
4. A reserve source of oxygen under pressure is available;
5. All drugs and agents that are expected to be required are correctly identified; and
6. The manufacturers' recommendations concerning the use, handling, and disposal of anaesthetic equipment and supplies have been considered.

### ***Delegation of Care\****

The anaesthesia provider's primary responsibility is to the patient receiving care. (The definition of an anaesthesia provider is discussed elsewhere in this guideline). The anaesthesia provider shall remain with the patient at all times throughout the conduct of all general, major regional, and procedural sedation and analgesia (PSA) until the patient is transferred to the care of personnel in an appropriate care unit.

If the attending anaesthesia provider leaves the operating room temporarily, he/she must delegate care of the patient to another anaesthesia provider. When the attending anaesthesia provider delegates care to an anaesthesia assistant (untrained physician, nurse, technician, etc.), the attending anaesthesia provider remains responsible for the anaesthetic management of the patient at all times. Before delegating care of the patient to an anaesthesia assistant, the anaesthesia provider must ensure that the patient's condition is stable and that the anaesthesia assistant is competent, experienced, familiar with the operative procedure and the operating room environment and equipment. The attending anaesthesia provider must remain immediately available when care is delegated to an anaesthesia assistant.

An anaesthesia provider may briefly delegate routine care of a stable patient to a competent person who is not a trained anaesthesia provider only under the most exceptional circumstances, e.g., to provide life-saving emergency care to another patient. That person's only responsibility would be to monitor the patient during the anaesthesia provider's absence and to keep the anaesthesia provider informed until he/she returns. In this situation, the anaesthesia provider remains responsible for the care of the patient and must inform the operating room team.



An intraoperative handover of care between two anaesthesia providers should be documented in the anaesthesia record and follow a structured protocol.

It is unacceptable for one anaesthesia provider to simultaneously administer general anaesthesia, major regional anaesthesia, or moderate to deep procedural sedation (as classified in the SASA Procedural Sedation Guidelines) on more than one patient. Nevertheless, it may be appropriate in specific circumstances for one anaesthesia provider to supervise more than one patient where only mild procedural sedation is administered, provided an appropriately trained, qualified, and accredited individual, approved by the healthcare institution, is in constant attendance with each patient receiving care. In an obstetric unit, however, it is acceptable to supervise more than one patient receiving regional analgesia for labour.

Due care must be taken to ensure that a suitably trained person adequately observes each patient following an established protocol. When an anaesthesia provider is providing anaesthetic care for an obstetric delivery, a second appropriately trained person should be available to provide neonatal resuscitation.

It is unacceptable for a single physician to administer a general anaesthetic and simultaneously perform a diagnostic or therapeutic procedure.

### ***Perioperative Temperature Management\****

Monitoring patient core temperature is strongly recommended during cases of general and neuraxial regional anaesthesia lasting 30 min or longer. In the absence of surgical or patient indications for intraoperative hypothermia, active patient warming systems, control of the operating room ambient temperature, and other methods, should be used to target a central core temperature of 36–37°C.

### ***Guidelines on the use of ultrasound in anaesthesia***

The use of ultrasound (US) has added greatly to patient safety, and is sufficiently pervasive in both the training of anaesthetists and usage among SASA members to warrant the drafting of some guidance.

#### **Vascular access**

On the basis of available evidence, use of real-time ultrasound during internal jugular (IJ) cannulation improves success, and reduces the incidence of complications associated with the insertion of central venous catheters (CVC).<sup>1-4</sup>

Complications during femoral vein (FV) cannulation in adults are less severe than those that occur with subclavian (SC)<sup>5</sup> and IJ vein cannulation. Ultrasound guidance for FV access may

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SOURCE:

\* CANADIAN ANESTHESIOLOGISTS' SOCIETY GUIDELINES

improve the success rate and reduce complications for FV cannulation, although this benefit may be more important with novice operators, in paediatric patients, or in patients with difficult anatomical landmarks.<sup>6-8</sup>

Obese and coagulopathic patients should have ultrasound screening of the SC vein before attempted cannulation to identify vessel location and patency. If real-time ultrasound is not used as the initial technique for SC vein cannulation, it should be used as a rescue device.<sup>5</sup>

Static ultrasound with skin marking is useful for identifying vessel anatomy and thrombosis but may not improve cannulation success or reduce complications, as does real-time ultrasound needle guidance.<sup>9,10</sup>

The major advantages of ultrasound-guided venous access are correct identification of the target vessel, confirmation of successful cannulation, avoidance of inadvertent arterial puncture and damage to juxtavenous anatomy, reduction in procedure time and a reduction in serious complications.<sup>11,12</sup>

Current published evidence implies that both adult and paediatric patients may well benefit from the use of ultrasound during the placement of intra-arterial pressure monitoring lines.<sup>13-15</sup>

Ultrasound reduces the number of attempts, shortens the procedure time and increases the rate of successful cannulation.<sup>16</sup> It may be particularly advantageous in patients with abnormal anatomy, low perfusion states or previous unsuccessful cannulation attempts.<sup>17</sup>

The cost effectiveness of the use of ultrasound, particularly during CVC has been studied and well described. The calculated cost of managing potential complications outweighs the cost of incorporating this technology into the practice of anaesthesiology.<sup>18</sup>

It is thus the opinion of SASA that, based on current available evidence, the following recommendation relating to ultrasound guided vascular access can be made.<sup>1</sup>

- Support its use whenever available for the cannulation of internal jugular veins. There is clear high quality evidence that the use of US is superior to a landmark technique.<sup>1,2,19-21</sup>
- May be used for the cannulation of subclavian and femoral veins.<sup>22,23</sup>
- Equivocal evidence supports the use of US for arterial cannulation.<sup>14</sup>

There have already been a number of cases where adverse incidents have occurred and the affected doctors were specifically questioned as to whether they used ultrasound. If the answer was in the negative, their cases were deemed less likely to be defensible and against international best practice. Such cases have led to an essential precautionary application of ultrasound.

## **Regional anaesthesia**

Refer to SASRA Guidelines

## Transthoracic echocardiography

Focused assessment using transthoracic echocardiography may be an invaluable perioperative extension to the clinical examination, and the skill can be acquired relatively easily. It should however not be seen as replacing a full echocardiographic examination by an experienced operator if the indication for a full examination exists.

The use of ultrasound is now standard such that it is included in the training of anaesthesiologists from the outset. There have also been, and will continue to be, many CPD programmes and courses for people to get up to date in the latest usage and available equipment. Technology is advancing, in all areas, including new drugs and other equipment. It is part of the daily maintenance of an anaesthesiologist's skill. This is a specific skill, but certainly not outside of a member's normal capability to assimilate and no different mechanism of staying abreast of technology is needed for ultrasound over any other form of advancement in the field of medicine.

It is now an expected standard skill of an anaesthesiologist and should be included as part of the basic skill set. There should, therefore, be no different or additional accreditation required.

There is additional work required in applying this skill in practice and an anaesthesiologist should be able to be reimbursed for this additional time and skill, applied in the interests of patient safety.

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## ***Monitoring and Care standards***

The following tables have been taken from the International Standards for the Practice of Safe Anaesthesia.

Please note that facilities in South Africa where anaesthesia is delivered should comply with Hospital Level 2 and 3 standards in these tables. Also note that ‘highly recommended’ is seen as **essential** for the purposes of the SASA Practice Guidelines. Items in Table 1 are therefore essential and items in Table 2 (including continuous temperature monitoring and NMT monitoring) are strongly recommended for perioperative monitoring in South African district hospitals.

**Table 1:** Characteristics and Clinical Practice Recommendations for Level 1 facilities

Hospital Type	Required Standards	Peri-Anesthetic Care and Monitoring Standards <b>HIGHLY recommended</b>
<p><u>Level 1</u></p> <p>Rural Hospital or a Health Center with a small number of beds; sparsely equipped operating room (OR) for "minor" procedures</p>	<p>All that are <b>HIGHLY RECOMMENDED</b></p>	<ol style="list-style-type: none"> <li>1. Continuous direct presence in the anaesthetising location of a vigilant anesthesia professional.</li> <li>2. Appropriate "pre-check" of the anesthesia system, facilities, equipment, and supplies.</li> <li>3. Use of the relevant components of the WHO Safe Surgery Checklist</li> <li>4. Supplemental oxygen administered to all patients undergoing general anesthesia.</li> <li>5. Continuous use of pulse oximetry.</li> <li>6. Continuous monitoring of airway and ventilation by observing the bag and with a stethoscope.</li> <li>7. Confirmation of the correct placement of an endotracheal tube by auscultation.</li> <li>8. Continuous monitoring of the pulse by clinical examination and with a pulse oximeter.</li> <li>9. Availability of a defibrillator.</li> <li>10. Continuous monitoring of tissue perfusion by clinical examination and with a pulse oximeter.</li> <li>11. Monitoring of non-invasive arterial blood pressure at appropriate intervals.</li> <li>12. Use of a disconnect alarm if mechanical ventilation is employed.</li> <li>13. Audible signals eg pulse oximeter, and alarms activated at all times.</li> <li>14. All patients should remain where anaesthetised until recovered or be transported safely to a specifically designated recovery location.</li> <li>15. Immediate availability of oxygen, suction, and a means of ventilation in Recovery.</li> <li>16. Continuous use of pulse oximetry until recovery of consciousness.</li> <li>17. Adequate pain relief including narcotics when needed.</li> </ol>

**Table 2:** Characteristics and Clinical Practice Recommendations for Level 2 Hospitals

Hospital Type	Required Standards	Peri-Anesthetic Care and Monitoring Standards – <b>HIGHLY recommended PLUS recommended</b>
<p><u>Level 2</u></p> <p>District or Provincial hospital eg with 100-300 beds, with adequately equipped major and minor operating rooms</p>	<p>All <b>HIGHLY RECOMMENDED</b> (Table 1) <b>PLUS</b> these <b>RECOMMENDED</b> items</p>	<ol style="list-style-type: none"> <li>1. Monitoring of inspired oxygen concentration with an instrument fitted with a low oxygen concentration alarm.</li> <li>2. Use of a device protecting against the delivery of an hypoxic gas mixture.</li> <li>3. Use of capnography to verify the correct placement of the endotracheal tube or other airway device and the adequacy of ventilation.</li> <li>4. Use of a continuous electrocardiograph.</li> <li>5. Continual measurement of temperature.</li> <li>6. Use of a peripheral neuromuscular transmission monitor when neuromuscular blocking drugs are given.</li> <li>7. Sufficient trained staff in the post-anesthesia recovery area to manage patients recovering from anesthesia and surgery.</li> </ol>

**Table 3:** Characteristics and Clinical Practice Recommendations for Level 3 Hospitals

Hospital Type	Required Standards	Peri-Anesthetic Care and Monitoring Standards – HIGHLY recommended PLUS recommended PLUS SUGGESTED
Level 3  A Referral Hospital of 300-1 000 or more beds with basic intensive care facilities	All HIGHLY recommended (Table 1) <b>PLUS</b> recommended (Table 2) <b>PLUS</b> these items	<ol style="list-style-type: none"> <li>1. Continuous measurement of the inspiratory and/or expired gas volumes, and of the concentration of volatile agents.</li> <li>2. Continuous measurement and display of arterial pressure in appropriate cases.</li> <li>3. Use of continuous electronic temperature measurement.</li> <li>4. Monitoring of urine output during prolonged procedures or when significant administration of intravenous fluids is anticipated.</li> </ol>

## Care of patients recovering from anaesthesia

### General principles

- Recovery from anaesthesia must take place under appropriate supervision in an area designed for this purpose.
- This area should either be in the theatre itself, or close to where the anaesthetic was administered.
- The staff members who work in this area must be appropriately trained. When the need arises, staff must be able to contact the anaesthesiologist or his or her designate promptly. See Section VII under General Standards
- It is desirable for patients to have regained consciousness and to be in a stable state before they are transported any distance.
- If patients have to be transported within and from the operating suite when not fully recovered, they must be moved on a suitably designed trolley or bed capable of a head-down tilt. The bed or trolley should be provided with oxygen, a means of inflating the patient's lungs, equipment for suctioning and an appropriate monitor. The patient must be accompanied by staff to be able to deal with problems which may occur during transport.

### Transfer from theatre to recovery room

It must be noted that the safe transfer of the anaesthetised patient from the theatre to the recovery room is of the utmost importance.

- A roller board should be used if available and the patient transferred from the theatre bed to trolley/bed in a gentle manner.
- An adequate amount of staff should be available to transfer the patient from the theatre bed to the patient trolley/bed.
- All lines and equipment should be handled with care.

- The oxygen mask, filter and suction tip of the patient should accompany the patient to the recovery room.
- An intravenous infusion stand should be available on all trolleys/beds.
- The dignity and privacy of the patient should be protected at all times.
- The bed should be tidy and clean.
- All trolleys/beds should be fitted with safety straps or cot sides. These should be in working order.
- The anaesthetic nurse/specifically appointed person should assist the anaesthetist with the transfer of the patient to the recovery room.

### ***Management and supervision***

Written protocols for safe management should be established.

A written daily routine for checking the equipment and drugs must be established.

Observations should be recorded at appropriate intervals and at the very least should include state of consciousness, colour, respiration, oxygen saturation, pulse and blood pressure and level of pain. The record should form part of the patient's clinical notes.

All patients should remain in the recovery room until the anaesthesiologist considers it safe to discharge them from the recovery room according to validated criteria, which include return of protective airway reflexes, stable cardiovascular and respiratory function, full reversal of neuromuscular blockade, absence of nausea and vomiting, and absence of pain.

The anaesthesiologist is responsible for:

- Supervising the recovery period and authorising the patient's discharge.
- Accompanying the patient to the recovery room and adequately handing him or her over to the nursing staff who will document the patient's condition on arrival and subsequent course in recovery.
- Providing appropriate written and verbal instructions and information to the recovery room staff for each case.
- Specifying the type of apparatus and the flow rate to be used in oxygen therapy.
- Remaining in the facility until the patient meets the criteria detailed below, or delegating this responsibility to another anaesthesiologist or intensivist (after providing appropriate information to such doctor).

## ***Guidelines for the handover of postoperative patients to the staff of the theatre recovery area:***

The responsibility of the anaesthetist does not end with the handover to the recovery staff and he or she or an appointed designate should be available in the theatre complex until it can be reasonably assumed that the anaesthetic has worn off.

- The anaesthetist must formally hand over care of a patient to a recovery room nurse or other appropriately trained member of staff.
- The patient should be breathing spontaneously and oxygen saturation should be appropriate.
- The patient should have recovered from the neuromuscular blocker, as determined by the return of the train-of-four or by appropriate clinical signs of recovery, vis-à-vis head lift or hand squeeze.
- The patient should be haemodynamically stable. If excessive blood loss has occurred, the anaesthetist should remain with the patient until adequate volume resuscitation has occurred and appropriate measures to test haemoglobin level and the ordering of homologous blood have been carried out.
- The patient should have adequate control of pain and postoperative nausea and vomiting.

Airway patency remains the responsibility of the anaesthetist until the patient is able to maintain his or her own airway. Patients should not be left unattended with an airway device in situ. If airway maintenance is delegated, it remains the responsibility of the anaesthetist. It is also his or her responsibility to ensure that any person to whom airway care is delegated is capable of safe airway management. If the anaesthesiologists delegate extubation of the patient to recovery room staff, the patient must be informed and consent to that during the preoperative consent procedure. The anaesthetist should authorise discharge from the recovery area to the ward. The patient should not be discharged until he or she has regained control of his or her airway, is haemodynamically stable and is able to communicate adequately. If the modified Aldrete score is used to assess the patient prior to discharge, it is reasonable to expect that the patient will score 2/2 for each of the five categories, unless there is good reason for failure to meet these criteria. If the patient requires admission to an intensive or high care unit, the anaesthetist should remain in attendance until the transfer has taken place, and handover to the appropriate intensive care personnel has occurred.

The time when the responsibility of the anaesthetist for a particular patient ends is unclear, and is not possible to determine precisely. However, it is reasonable to expect an anaesthetist to be in attendance, or at least available, until the patient has fully recovered from the anaesthetic and until the anaesthetist is satisfied that there are no sequelae from delivery of the anaesthetic. In addition, if the patient is to be handed over to other medical personnel, it is the responsibility of the anaesthetist to ensure that the patient is stable, that the medical personnel are competent



to take over the management of the patient, and that the handover is carried out clearly and concisely to ensure continuity of information. See recovery room poster as Appendix 9.

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# APPENDICES

## Appendix 1

### SASA Member Code of Conduct for Anaesthesia Professionals

#### *Health Professions Council Guidelines*

SASA expects its members to adhere to all Health Professions Council of South Africa (HPCSA) rules and regulations regarding good professional and ethical practice. This document is to be read in conjunction with the HPCSA guidelines pertaining to good practice, ethical rules, etc. (<http://www.hpcsa.co.za/conduct/ethics>). This incorporates the Generic Ethical Rules, Good Practice Guidelines, Patients' Rights Charter, and other relevant guidelines.

#### *Oath of Care*

Anaesthesia professionals are bound by the shared spirit and principles underlying the various oaths subscribed to by newly qualified healthcare professionals (i.e. revised Hippocratic Oath, and others). This social contract holds healthcare providers to a strict code of professional and personal conduct, forming the pillars of the SASA Code of Conduct for Anaesthesia professionals.

The practice of anaesthesia has its own, inherently unique demands and challenges regarding the nature of patient interaction, standards of care, quality of service delivery, safety requirements, and inter-collegial relationships. This Code of Conduct outlines the commitment every SASA member makes to ethical practice.

#### *Basic Components of Ethical Practice*

An anaesthesia professional has ethical responsibilities to:

- i. Patients
- ii. Colleagues and community
- iii. Him-/herself
- iv. Healthcare fraternity
- v. Workplace

#### **I: Responsibilities to patients**

1. Always place the patient's interests foremost.
2. Be truthful to patients.

3. Appreciate and respect the patient's supreme rights in medical decision-making, appropriate to the patient's developmental capacity and medical circumstances. Medical knowledge and skills should never be used to coerce or restrain patients with adequate decision-making capacity.
4. Appreciate that patients are extremely vulnerable in the perioperative period. Take care of the patient's physical and psychological wellbeing. The patient's right to dignity, privacy, and comfort is paramount. Patients should be treated with respect at all times, regardless of the state of consciousness.
5. Honour confidentiality regarding medical and personal information.
6. Honour and respect religious and cultural beliefs and be sensitive in this regard in the provision of treatment.
7. Provide appropriate postanaesthesia care, as and when applicable.
8. Provide emergency care for all patients, irrespective of the patient's financial status.

## **II: Responsibilities to colleagues and community**

1. Promote respectful and cooperative relationships with colleagues and healthcare workers to the benefit of patients.
2. Consult with colleagues as and when appropriate.
3. Cooperate and participate with colleagues to improve the quality and efficiency of anaesthesia care, and medical care in general.
4. Advise and assist impaired/suspected impaired colleagues within the boundaries of your own abilities, to the benefit of patients.
5. Immediately and adequately address any dangerous/negligent practices that potentially endanger patients and/or healthcare personnel. This includes reporting a colleague to the relevant authority, sooner rather than later.
6. Participate in keeping potentially dangerous substances secure from illicit use.

## **III: Responsibilities to yourself**

1. Maintain competence and skill as is necessary in your particular practice.
2. Take responsibility for your own mental and physical wellness.
3. Seek timeously assistance, evaluation and care when in doubt about your own health and wellness.
4. Seek timeous assistance and support when in doubt about your own clinical competence, be this in general, case or skill(s) specific.
5. Modify or cease practice when incapacitated in any way that has the potential to be detrimental to patients.

6. Take responsibility for your personal financial protection and wellbeing, preventing financial needs from interfering with clinical decision-making.

#### **IV: Responsibilities to the healthcare fraternity**

1. Refrain from seeking or accepting potentially compromising donations, gifts, or sponsorships from any source.
2. Avoid placing yourself in a position of perversity, potential position of perversity, or potentially perceived perversity.
3. Declare all donations, gifts, or sponsorships where the potential exists for undue influencing, or perceived influencing. This is specifically expected from faculty at events, conferences, and congresses. Any interest, whether perceived as a direct influence on the topic or not, should be declared at the start of a presentation.
4. Adhere to ethical and consistent billing practices, refraining from overreaching and overservicing practices. Additionally, appreciate your responsibility as an anaesthesia professional in seeking cost-saving treatment mechanisms.
5. Appropriately inform patients regarding cost and your billing practices, where possible, in order for the patient to make an informed financial decision.
6. Refrain from participating in exploitative financial relationships.

#### **V. Responsibilities in the workplace**

1. Dress appropriately and always maintain yourself in a clean, dignified and presentable manner.
2. Treat your co-workers with respect, including colleagues, nursing staff, cleaners, porters, etc.
3. Refrain from using inappropriate and derogatory language and behaviour, in whatever situation.
4. Maintain absolute professional conduct in theatre and in the workplace and refrain from doing anything that may make co-workers unhappy or uncomfortable.

This Code of Conduct represents the principles, values, and norms to be practised and maintained by all anaesthesia professionals as SASA members. The purpose of the code is to provide a clear framework within which SASA members are expected to conduct themselves. Continuous self and peer assessment against this Code of Conduct serve the best interest of patient and practitioner, contributing towards a healthy and prosperous anaesthesia community in South Africa.

## Appendix 2

### A Scarce Skill: Anaesthesia Services in South Africa

#### Specialist anaesthesiologists in SA

South Africa has an overall skills shortage, a problem significantly visible in the healthcare sector. The figure below published in 2015 by Econex on behalf of the Hospital Association of South Africa expresses the number of doctors per 100 000 citizens in various countries in 2013.

Figure 6: Country comparison - All doctors per 100,000 citizens (2010 or latest year available)

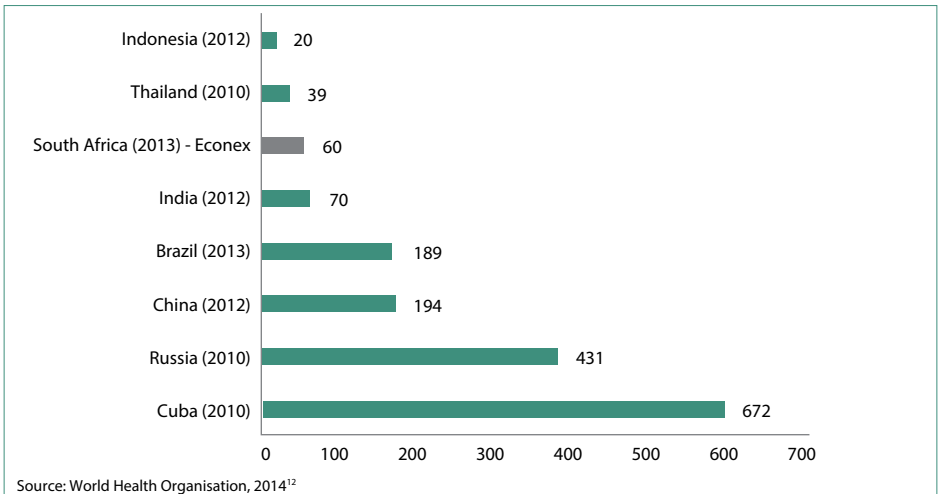
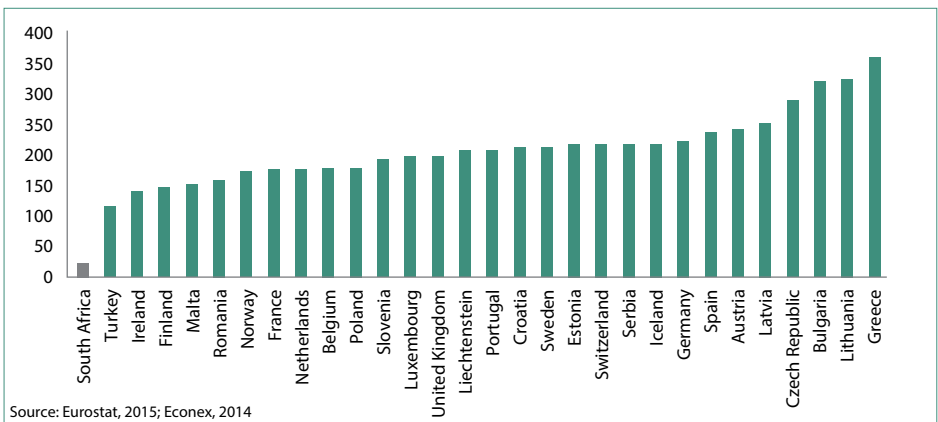
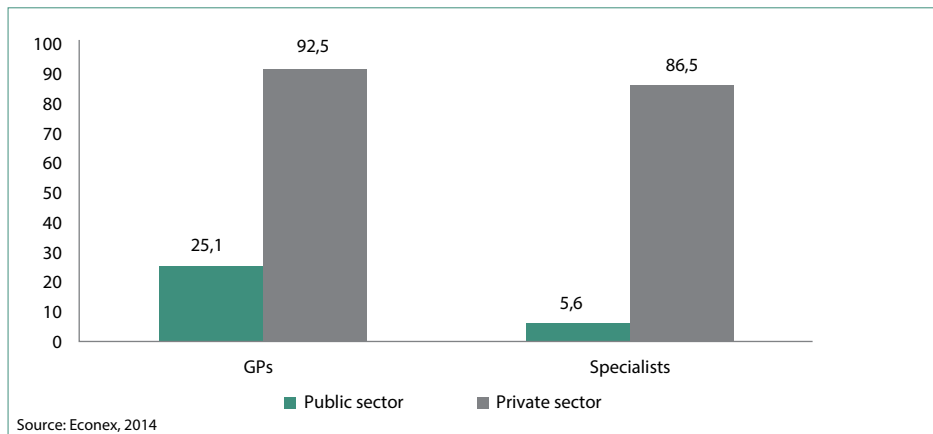


Figure 7: Number of specialists<sup>13</sup> per 100,000 citizens in developed countries and South Africa (2011)



On average South Africa has far fewer doctors per 100 000 population than any other BRICS (Brazil, Russia, India, China and South Africa) country – by 10 when compared to India and less than half of that of Brazil.

**Figure 3:** Number of doctors in the public sector per 100,000 citizens, relative to the number of doctors in the private sector per 100,000 beneficiaries (2013)



Importantly, from a SASA perspective, as a majority specialist representative society, the number of specialists per 100 000 citizens paints a woeful picture. When compared with multiple Organization for Economic Cooperation and Development (OECD) countries and resource rich countries providing forms of national health insurance, the South African workforce of specialists is one eighth to one tenth of countries whose public health systems are considered to function effectively under a national health insurance scheme.

When considering public vs. private sectors, there remains a considered opinion that a high capacity workforce exists in the private sector that may, or is likely to, be able to meaningfully work and cope with the shortfall of service available in the public sector. While various options may exist to attempt to address such a shortfall, the figure above indicates that approximately 86.5 specialists per 100 000 citizens exist currently in the privately insured/funded market of 8 800 000 lives. When assessing this number in conjunction with the prior figure it is clear, that at this ratio in the private sector, the number of specialists to population ratio remains less than half of almost all OECD countries’ ratios that provide social national health insurance.

This skills shortage has a significant impact on the number of people receiving surgery, especially in the public sector in South Africa. The comment published in *The Lancet* by Dare, Onajin-Obembe and Makasa, on the perioperative patient outcomes in the African Surgical

Outcomes Study: (ASOS): a 7-day prospective observational cohort study by Biccard et al, quantifies this issue for Africa:

“In the study countries, the average provider-to-population density of specialist surgeons, anaesthetists, and obstetricians (another core surgical indicator) was around 30 times lower than the recommended global minimum.”

Although the main aim of Biccard and colleagues’ study<sup>6</sup>.was to quantify surgical outcomes, the most alarming finding was how few people actually received surgery. Surgical volume (the number of operations per 100 000 population) is an indicator of met need for surgical care. The ASOS findings suggested that this is unacceptably low in Africa. Among the 25 countries who contributed data, only a median 212 operations (IQR 65–578) were done per 100 000 catchment population. These numbers are 20 times lower than the crucial surgical volume required to meet a country’s essential surgical needs each year (defined as 5 000 operations per 100 000 people).<sup>4</sup>

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SOURCE:

BICCARD, BM, MADIBA, TE, KLUYTS, H-L ET AL. PERIOPERATIVE PATIENT OUTCOMES IN THE AFRICAN SURGICAL OUTCOMES STUDY: A 7-DAY PROSPECTIVE OBSERVATIONAL COHORT STUDY. LANCET. 2018; (PUBLISHED ONLINE JAN 3.) [HTTP://DX.DOI.ORG/10.1016/S0140-6736\(18\)30001-1](http://dx.doi.org/10.1016/S0140-6736(18)30001-1)

# Appendix 3

## SASA Statement on Professional Well-being

### Professional Wellness

#### 1. Introduction

All healthcare workers have an ethical duty to strive to stay healthy.

The Health Professions Council of South Africa Guidelines on Good Ethical Practice under “Duties to Themselves” focus on maintaining sound professional knowledge and skills and a good professional practice.

Internationally, the importance to maintain personal health and psychological well-being is well recognised. The onus on achieving professional well-being rests not only on the individual, but also on institutions, fellow practitioners and the healthcare team.

Professional well-being not only applies to anaesthesiologists (as mentioned in this appendix), but to all anaesthesia providers.

This guideline is adapted from the Canadian Anesthesiologists’ Society’s: “The Healthy Anesthesiologist”. Hence the data provided are mainly from Canada and the USA. At present, we do not have any data on South African physicians, anaesthesiologists and anaesthesia providers.

The Canadian Medical Association’s Code of Ethics<sup>1</sup> states that a physician has “Responsibilities to Oneself”, namely:

*10. Promote and maintain your own health and well-being.*

*53. Seek help from colleagues and appropriately qualified professionals for personal problems that might adversely affect your service to patients, society or the profession.*

*54. Protect and enhance your own health and well-being by identifying those stress factors in your professional and personal lives that can be managed by developing and practicing appropriate coping strategies.*



The American Society of Anesthesiologists' Guidelines for the Ethical Practice of Anesthesiology<sup>2</sup> states:

*IV. Anesthesiologists have ethical responsibilities to themselves.*

*1. The achievement and maintenance of competence and skill in the specialty is the primary professional duty of all anesthesiologists. This responsibility does not end with completion of residency training or certification by the American Board of Anesthesiology.*

*2. The practice of quality anesthesia care requires that anesthesiologists maintain their physical and mental health and special sensory capabilities. If in doubt about their health, then anesthesiologists should seek medical evaluation and care. During this period of evaluation or treatment, anesthesiologists should modify or cease their practice.*

All physicians experience occupation-related stress to some degree; however, this may be particularly significant for anaesthesiologists.<sup>3</sup> The provision of anaesthesia has become safer over the years, and the public expects a successful outcome even though many patients undergoing anaesthesia are older, sicker, and subjected to more and more complex procedures than in the past. Anaesthesiologists practise in a high-stress environment, with multiple demands from patients, families, other physicians, co-workers, and administrators.

The anaesthesiologist of the 21st century is expected to be up-to-date on the latest literature and practicepractise evidence-based medicine, to be vigilant at all times when a patient is under his/her care, and to maintain a compassionate demeanor throughout – no small demands on any human being. The anaesthesiologist is also subjected to additional stressors – such as long and unpredictable working hours, minimal relief breaks, exposure to chemical and radiation hazards, noise pollution, and a lack of natural light.

One area of potential stress for anaesthesiologists, fortunately rare, is the occurrence of a death or other catastrophic event while the patient is under the care of the anaesthesiologist. This is particularly stressful when the event is unexpected and the patient was previously healthy. Anaesthesiologists may handle such crises in a variety of ways. The training of the anaesthesiologist includes the medical aspects of these situations (resuscitation, invasive procedures, etc.), but may not prepare the anaesthesiologist for the emotional stress that ensues. All too frequently the impact of these events become internalised by the anaesthesiologist,<sup>4</sup> and may lead to long-term sequelae, such as anxiety or depression. In many institutions there are limited systems in place to support the anaesthesiologist, either immediately, or in the longer term. In private practice, there are none.

Fatigue is a major issue for anaesthesiologists. The Association of Anaesthetists of Great Britain and Ireland (AAGBI) states that: *Every anaesthetist carries a personal obligation to provide a safe and effective service and should be aware of the problem of fatigue.*<sup>5</sup> Many comparisons have

been drawn over the years between the practice of anaesthesiology and the airline industry, but, unlike pilots, there has been no standardised approach to limit the number of working hours of anaesthesiologists. In some countries, legislation restricts the number of hours that pilots and truck drivers may work, but very few countries have laws for physicians. In South Africa, working hours for healthcare practitioners are not regulated. For the present, it is up to the individual anaesthesiologist, supported by his department and institution, to ensure that he/she is able to work without undue fatigue. In private practice, the responsibility of fatigue prevention rests solely on the anaesthesiologists.

Anaesthesiologists, like everyone, get older inevitably bringing on a diminution of faculties – physical, mental, and special sensory. This may be counterbalanced to some degree by the wisdom that comes with experience. There is much variation between individuals in the ageing process. Furthermore, a senior anaesthesiologist may be highly capable of functioning in some arenas, e.g. elective anaesthesia or education, yet be excessively stressed in others, e.g. managing the 2 a.m. ruptured aortic aneurysm. The AAGBI recommends that: *there should be a review of on-call responsibilities for anaesthetists over 55 years of age.*<sup>5</sup>

Anaesthesiologists are at particular risk for certain illnesses. They are more prone to addictions and suicide than other physicians.<sup>6-10</sup> They represent about 3% of physicians, yet they account for 20–30% of drug-addicted physicians.<sup>4</sup> The addiction rate in anaesthesiologists and other anaesthesia providers has been estimated in the 10–20% range<sup>8</sup>range.<sup>8</sup> Compared with internists, anaesthesiologists have been shown to have a higher incidence of suicide (RR 1.45).<sup>7</sup>

The ethical responsibilities to promote and maintain the health of anaesthesiologists can be considered in three main areas: personal responsibilities, institutional responsibilities, and individual responsibilities towards other healthcare workers, trainees and colleagues.

## **2. Personal Responsibilities of the Anaesthesiologist**

The ethical requirement to promote and maintain one's own health and well-being must address physical, mental, and emotional health. The anaesthesiologist should strive to stay healthy, but most will be faced with health and wellness challenges over many years in practice. As noted, anaesthesiologists are particularly prone to stress in the workplace, are subject to fatigue, and are at higher risk for addictions and suicide.

Anaesthesiologists should:

- 2.1. Be aware of the general and specific health issues that may impact their professional life.
- 2.2. Be aware of their own issues with health and wellbeing.
- 2.3. Seek appropriate help if concerned about their own physical, mental, emotional, or special sensory health.

- 2.4. Be particularly aware of the issue of fatigue, and if this is leading to unsafe practice, this should be addressed with the department and institution.
- 2.5. Avoid commitment to such a quantity of clinical work that they are affected by excessive fatigue.
- 2.6. Agree to limit or modify their practice if patients or co-workers are being placed at risk until significant personal healthcare issues are resolved.
- 2.7. Maintain adequate disability insurance so that they may attend to personal health or well-being without major financial penalty.

### ***3. Responsibilities of the Institution***

For the purposes of this document, the term “Institution” refers to the Health Authority, Hospital, Faculty and/or Departmental Administration that has jurisdiction over the provision of anaesthesia and the practice of anaesthesiologists. It is recognised that there are other authorities, such as regulatory authorities, that have jurisdiction over the anaesthesiologist and that have a stake in promoting physician wellness.

Institutions have multiple responsibilities relating to anaesthesia and the practice of anaesthesiologists. First and foremost, they have a duty to ensure that anaesthesia is delivered in a safe, ethical and caring fashion. All of these elements may be influenced by the health and well-being of the anaesthesiologist, and all are essential. For example, an anaesthesiologist capable of delivering safe anaesthesia, but who, as a result of personal stresses, is consistently rude to patients and disruptive to co-workers is not acceptable.

Institutions also have responsibilities to their employees and to the anaesthesiologists that practice in their facilities. In particular, the institution has a duty to promote a healthy work environment. With very rare exceptions, support must be provided to anaesthesiologists and other employees who seek help with health and wellness issues.

- 3.1. Institutions should have a formal policy and approach to promoting wellness of physicians, that takes into account the special needs of different practitioners, including anaesthesiologists.
- 3.2. Institutions should be supportive of any anaesthesiologist who seeks help with health or wellness issues, whether they be physical, mental, or emotional.
- 3.3. Institutions should have a formal policy addressing alcohol and drug abuse amongst employees and physicians, including anaesthesiologists.
- 3.4. Anaesthesiologists seeking support or help from the institution should be treated in a confidential manner.

- 3.5. Institutions should refer the support of the unwell anaesthesiologist to another agency, such as a physician support group or appropriate healthcare professionals.
- 3.6. Notwithstanding the above, institutions should consider the safety of patients and staff as their first priority, and may be required to place limits on the practice of an anaesthesiologist until the health issue has been resolved.
- 3.7. Institutions should not be obliged to continue to support an anaesthesiologist who consistently declines to seek help with a well-documented health or wellness problem that is preventing consistent delivery of safe, ethical, and caring anaesthesia.
- 3.8. A healthy work environment for anaesthesiologists should be supported by institutional policies, e.g. by the provision of adequate rest breaks, availability of healthy nutrition, provision of comfortable on-call sleep rooms, and an on-call schedule that does not lead to excessive fatigue.
- 3.9. Institutions should have a protocol in place to support staff, physicians, and anaesthesiologists who are involved in the care of patients who die or experience some other catastrophic event in the operating room or related areas.
- 3.10. Institutions should provide a flexible working schedule for anaesthesiologists, that takes into account the physiological stresses that affect anaesthesiologists of different ages.
- 3.11. Anaesthesiologists with disabilities who are able to function safely and effectively within a defined scope of practice should be supported by the institution.

### Individual Responsibilities towards Healthcare Workers, Trainees, and Colleagues

Many of the above recommendations apply to other healthcare workers, trainees, and colleagues. The ethical anaesthesiologist has a role in helping such individuals who have significant health or wellness problems that are impacting the safe, ethical, and caring delivery of medical services to patients. The American Society of Anesthesiologists states<sup>2</sup>:

*II. Anesthesiologists have ethical responsibilities to medical colleagues.*

*4. Anesthesiologists should advise colleagues whose ability to practice medicine becomes temporarily or permanently impaired to appropriately modify or discontinue their practice. They should assist, to the extent of their own abilities, with the re-education or rehabilitation of a colleague who is returning to practice.*

Anaesthesiologists are not, with a few exceptions, experts in providing the care that a colleague with health or wellness issues may require. They do have a role, however, in being aware of these concerns as they may relate to a colleague, in encouraging the colleague to seek appropriate

help, in reporting unsafe conditions, and in supporting a colleague who is in a recovery phase from an illness or wellness issue.

- 3.1. Anaesthesiologists should be broadly aware of the warning signs of significant illness, addiction, or excessive stress in a healthcare worker, trainee, or colleague.
- 3.2. Anaesthesiologists should approach a colleague if seriously concerned about health or wellness. The colleague should be encouraged to seek help and advice from an appropriate source.
- 3.3. Notwithstanding the above, if the anaesthesiologist is aware that patients and/or staff are being placed at risk, there is a duty to report such conditions to the appropriate authority, such as a Department Head or to SASA in private practice situations.
- 3.4. Anaesthesiologists should be supportive of healthcare workers, trainees, or colleagues who have sought help with a health or wellness problem, and are recovering, or undergoing treatment or rehabilitation for that problem.
- 3.5. Anaesthesiologists should respect the confidentiality of healthcare workers, trainees, or colleagues who have health or wellness issues.

#### **4. Legal responsibilities**

The South African HPCSA Guidelines on Ethical Rules<sup>11</sup> in addition stipulate the:

##### ***Reporting of impairment or of unprofessional, illegal or unethical conduct***

25. (1) A student, intern or practitioner shall –

(a) report impairment in another student, intern or practitioner to the board if he or she is convinced that such student, intern or practitioner is impaired;

(b) report his or her own impairment or suspected impairment to the board concerned if he or she is aware of his or her own impairment or has been publicly informed, or has been seriously advised by a colleague to act appropriately to obtain help in view of an alleged or established impairment, and

(c) report any unprofessional, illegal or unethical conduct on the part of another student, intern or practitioner.

This is a legal requirement.

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14. [HTTP://WWW.HPCSA.CO.ZA/CONDUCT/ETHICS](http://www.hpcsa.co.za/conduct/ethics) BOOKLET 2: GENERAL ETHICAL RULES.

## Appendix 4

### ***National Policy for Patient Safety Incident Reporting and Learning***

This document is only available as part of the online publication of the SASA Practice Guidelines 2018 Revision on [www.sasaweb.com](http://www.sasaweb.com)

# Appendix 5

## *IUSS Health Facilities Guides*

This document is only available as part of the online publication of the SASA Practice Guidelines 2018 Revision on [www.sasaweb.com](http://www.sasaweb.com)



# Appendix 6

## *National Core Standards*

This document is only available as part of the online publication of the SASA Practice Guidelines 2018 Revision on [www.sasaweb.com](http://www.sasaweb.com)

## Appendix 7

### *Example of consent policy document*

This document is only available as part of the online publication of the SASA Practice Guidelines 2018 Revision on [www.sasaweb.com](http://www.sasaweb.com)

## Appendix 8

### *Example of consent form*

This document is only available as part of the online publication of the SASA Practice Guidelines 2018 Revision on [www.sasaweb.com](http://www.sasaweb.com)

## Appendix 9

### Guidelines for the handover of postoperative adult patients to the staff of the theatre recovery area

S	T	A	M	P	E	D
<b>Stable</b> Patients in all respects	<b>Tell</b> the recovery staff about preoperative and intraoperative condition/problems	<b>Airway</b> secured	<b>Muscle</b> relaxants adequately reversed	<b>Pain</b> and nausea under control	<b>Ensure</b> that fluids and haemoglobin are adequately replaced	<b>Discharge</b> the patient from recovery room

The responsibility of the anaesthetist does not end with the handover to the recovery staff. The anaesthetist, or an appropriate, designated person, should be available in the theatre complex until it can be reasonably assumed that the anaesthetic has worn off.

15. The anaesthetist must formally hand over care of a patient to a recovery room nurse or other appropriately trained member of staff.
16. The patient should be breathing spontaneously and oxygen saturation should be appropriate.
17. The patient should have recovered from the neuromuscular blocker as determined by the return of the train-of-four or by appropriate clinical signs of recovery (for example head lift or hand squeeze).
18. The patient should be haemodynamically stable. If excessive blood loss has occurred, the anaesthetist should remain with the patient until adequate volume resuscitation, the haemoglobin level has been checked, and blood products have been ordered if necessary.
19. The patient should have adequate control of pain and postoperative nausea and vomiting.
20. Airway patency remains the responsibility of the anaesthetist until the patient is able to maintain his/her own airway. Patients should not be left unattended with Guedel® oral airways in situ. If airway maintenance is delegated, it remains the responsibility of the anaesthetist. It also is his or her responsibility to ensure that any person to whom airway care is delegated is capable of safe airway management.

The anaesthetist should authorise discharge from the recovery area to the ward. The patient should not be discharged until he or she has regained control of his or her airway, is haemodynamically stable and is able to communicate adequately. If the modified Aldrete score is used to assess the patient prior to discharge, the patient must score  $\geq 9/10$  before discharge, unless there is a good reason for failure to meet these criteria. If the patient requires admission

**ALDRETE SCORE**

Should be 2/2 for each parameter depending on circumstances and at least 9/10 prior to discharge from the recovery area.

Able to move 4 extremities voluntarily or on command	= 2	ACTIVITY
Able to move 2 extremities voluntarily or on command	= 1	
Able to move 0 extremities voluntarily or on command	= 0	
Able to deep breathe and cough freely	= 2	RESPIRATION
Dyspnoea or limited breathing	= 1	
Apnoeic	= 0	
BP* 20% of preanaesthetic level	= 2	CIRCULATION
BP* 20-50% of preanaesthetic level	= 1	
BP* 50% of preanaesthetic level	= 0	
Fully awake	= 2	CONSCIOUSNESS
Arousable on calling	= 1	
Not responding	= 0	
Pink (SaO <sub>2</sub> > 92% on room air)	= 2	COLOUR
Pale, dusky blotchy, (O <sub>2</sub> required for SaO <sub>2</sub> > 90%)	= 1	
Cyanotic (SaO <sub>2</sub> < 90% despite supplementary oxygen)	= 0	
Total		

to an intensive or high care unit, the anaesthetist should remain in attendance until the transfer has taken place and handover to the appropriate personnel has occurred.

The time at which the responsibility of the anaesthetist for a particular patient ends is not possible to determine precisely. It is reasonable to expect an anaesthetist to be in attendance, or at least available, until the patient has fully recovered from the anaesthetic and until the anaesthetist is satisfied that there is no sequelae from the delivery of the anaesthetic. In addition, if the patient is to be handed over to other medical personnel, it is the responsibility of the anaesthetist to ensure that the patient is stable, that the medical personnel are competent to take over the management of the patient, and that the handover is done clearly and concisely to ensure continuity of information.

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# Appendix 10

## Structural and Organisational Recommendations for Intensive Care Units in South Africa

### ***Introduction***

The recommendations in this document should be used as a guideline for the provision of ideal conditions for the care of critically ill patients. It is accepted that some of these are only feasible in certain training institutions. Nevertheless, other centres should aspire to the recommendations set out in this document.

These guidelines for intensive care units have been formulated to assist in the practice and provision of critical care for clinicians, hospital administrators and developers. Critical care, or intensive care, describes the highest level of continuing patient monitoring and treatment. The intensive care unit (ICU) is a specially designated area where facilities for the care of critically ill patients is concentrated, and where the level of care and supervision is considerably more sophisticated than that in the ordinary ward. These units may be multidisciplinary, dealing with all types of critically ill patients; or specialised, dealing with specific groups of patients, e.g. general surgical patients, neuro- or cardiac surgical patients and coronary care or paediatric patients. The level of care and facilities that are required vary depending on the patient mix. This determines the staffing, equipment, services and other facilities that are required in specific ICUs.

### ***Categories of intensive care units***

#### **Category 1 (high care)**

Patients who are admitted to this category of ICU require intensive monitoring/clinical interventions, which include:

- Patients with fluid, electrolyte or metabolic disturbances, e.g. diabetic ketoacidosis, postoperative monitoring.
- Patients with drug overdose that does not require positive pressure ventilation.
- Patients with neuromuscular weakness that does not require positive pressure ventilation.
- Patients with single-organ dysfunction that does not require active support.
- The provision of epidural analgesia.
- The care of patients recently discharged from a higher level of care.

## Category 2 (specialised organ support unit)

Patients who are admitted to this category of ICU require slightly less care than category 3 patients and may include, but are not limited to, those who:

- Require active organ support.
- Have single-organ failure.
- Have a specific need that requires continuous monitoring and observation.

## Category 3 (intensive care unit facility)

This category of ICU has the potential to offer the highest degree of patient care and the type of patient who is admitted to this unit may include, but is not limited to, those:

- With multiple-organ failure.
- Requiring multidisciplinary intervention.
- Requiring ventilation with second organ failure.
- Requiring renal replacement therapy with second organ failure.
- Haemodynamically unstable patients.
- Requiring Extra Corporeal Membrane Oxygenation (ECMO).

An ICU may admit patients with lesser disease acuity than they are designated to accept. However, on occasion, an ICU may admit patients of greater disease acuity than they are designated to accept. If the facilities and staff are not available for advanced care, transfer to a higher category ICU should be arranged, once the patient is deemed to be stable enough for transport. Isolation facilities must be available in all categories of ICU for patients who have multi-resistant organisms or communicable diseases.

### ***Staffing of intensive care units***

Levels of staffing by qualified medical, nursing, and ancillary and support personnel should be appropriate to the patient mix, severity of illness, and level of intervention. Mechanisms must be available for rapid effective communication between staff members within the unit, and those providing backup services.

Ward rounds should take place at least twice a day in order to provide adequate senior guidance. Rounds should take place at the same time each day and one round a day should be multidisciplinary.

## Medical staff

### *Category 1 intensive care unit*

1. 24-hour specialist cover. Specialists should have higher training.

### *Category 2 intensive care unit*

1. 24-hour specialist cover. Specialists should have higher training.
2. A registered medical practitioner must be available in the unit within minutes if necessary.

### *Category 3 intensive care unit*

1. Requires a full-time medical director who is registered by the Health Professions Council of South Africa (HPCSA) for independent practice in the subspecialty of Critical Care. The director's professional activities should be devoted to no less than 80% of the time to intensive care. The director's responsibility includes control of staff, admission and discharge policies, individual patient care, overall management of protocols and staff, quality control and audit function (issues of maintenance of accreditation), a supervisory role, liaison with hospital management, selection of admissions to the unit, arranging of training and research programmes, maintaining of records and equipment, and general supervision of the daily running and forward planning of the ICU.
2. The director of the ICU is assisted by clinicians registered by the HPCSA for independent practice in the subspecialty of Critical Care, and by additional specialists.
3. Care should be led by a Registered Intensivist, as the Closed Unit model of care has been shown to improve morbidity and mortality.
4. 24-hour specialist availability is essential. These individuals should either be subspecialists in critical care or have an acceptable higher qualification in anaesthesia, surgery, internal medicine, emergency medicine, obstetrics and gynaecology or paediatrics. Specialists must be immediately available 24-hours a day and should be physically present within 30 minutes if necessary. Specialists must undertake twice daily ward rounds and must not be responsible for delivering other services whilst covering the ICU when allocated to the on-call roster.
5. Specialist work patterns should be designed to deliver continuity of care. The specialist to patient ratio should not exceed between 1:8 – 1:15.
6. There should be on-site, 24-hour availability of a registered medical practitioner. This person must be available immediately and must not be committed to other duties.



## Nursing staff

Appropriate levels of nurse staffing should be determined on a shift-by-shift basis by consultation between the senior nurse and the critical care physician in charge, either directly, or through the use of unit-based policies. Staffing arrangements should be flexible to allow matching of supply with variable demand. An operational manager is responsible for the functioning and quality of the nursing care in the unit. Units must not contract more than 20% of nurses from an agency per shift when they are not their own staff.

### *Category 1 intensive care unit*

1. Nurse to patient ratio 1:2.
2. Control nurse should be trained in intensive care.

### *Category 2 intensive care unit*

1. Nurse to patient ratio 1:1.
2. At least 25% of the nurses should be trained in intensive care.

### *Category 3 intensive care unit*

1. ICU nurse to patient ratio between 1.5:1 and 2:1, depending on the number of category 3 patients. (This means that there is always one registered nurse with each patient.)
2. Not less than 50% of nurses with intensive care nurse training

### *Nursing assistants*

The above ratio of nurses to patients may be slightly decreased if nursing assistants are employed to wash patients, as runners and to assist nursing staff in other ways. However, they should not take over patient care responsibilities or monitoring responsibilities.

## Clinical technologists

Clinical technologists registered with the HPCSA, should be available 24 hours a day to provide equipment and therapeutic support. This includes:

- Care, maintenance and decontamination of ICU equipment.
- Operation of ICU equipment.
- Setting up and calibration of equipment, e.g. ventilators, pressure transducers, cardiac output monitors, oximetry and gas analysers.
- Performing blood gas analysis, oximetry and electrolyte measurement.
- Education of nursing and paramedical staff in user care and the operation of equipment.

## **Physiotherapists**

A physiotherapist who is experienced in ICU work (a minimum of six months' experience in an acceptable ICU) should be available on a 24-hour basis.

## **Pharmacists**

Category 3 ICUs should have a critical care pharmacist available to consult during normal working hours.

## **Radiographers**

An experienced radiographer who can provide mobile X-ray facilities should be available in all categories of ICUs.

## **Microbiologists**

Input from clinical microbiologists must be available daily.

## **Other healthcare professionals**

- Dietetic support should be available daily, particularly for patients on parenteral and tube feed nutrition.
- Speech and language therapists and occupational therapists should be available for patients when indicated.
- Social workers should be available to help with social and financial problems of patients and their dependents.

## **Secretaries, clerks and cleaners**

- Secretarial and clerical assistance should be available to manage patients' records and administrative issues. A ward clerk should be available for filing, taking calls and assisting with visitors.
- A cleaning team must be available to provide a 24-hour cleaning service, they must be familiar with infection control protocols and the handling of hazardous materials and waste.

## ***Design of intensive care units***

### **Facilities**

#### *Siting*

The ICU should be situated close to the departments from which patients are admitted, such as emergency and trauma units, recovery rooms and operating theatres. It should be easily

accessible to support areas, such as laboratory services, sterilising units, radiographic facilities and other diagnostic and treatment areas. Its design should incorporate the use of outside windows, providing lighting and views for both patients and staff.

### *Size*

Of the total number of acute beds in a hospital, 2–8% should be intensive care beds. These should be grouped into units of 8–12 beds for convenient management. There should be at least 20 m<sup>2</sup> of floor area for each bed in open-plan areas, with at least 2.5 m of unobstructed corridor space beyond the working area. In many instances, separate cubicles are preferable and should be a minimum of 25 m<sup>2</sup>. A minimum of one isolation cubicle should be available for every five ICU beds.

### *Lighting*

Maximum use should be made of outside windows. Artificial lighting should be of the correct colour and temperature and should have a facility to provide regional dimming and lighting over single beds only.

### *Hand basin*

One basin with hot and cold running water per two beds. Elbow taps or similar should be installed.

### *Bedside storage*

A cupboard with shelves for the storage of small amounts of disposable equipment (i.e. drugs, wound dressings).

### *Management base*

A central station should be provided where the following facilities are available:

- Two telephones per 3–4 beds.
- Central monitoring/telemetry
- Audible signals should be adjustable in intensity, and should have visual signals.
- Appropriate computer and IT availability to access laboratory results, radiology etc.
- Drug storage and administration facilities.
- Facilities for the storage of notes.
- An emergency trolley.
- Electrical sockets.
- Refrigeration storage.

- Storage for emergency medical equipment.

#### *Storage facilities*

These should be situated outside the patient area to accommodate: ventilators, drip stands, monitoring apparatus, syringe drivers, portable suction apparatus, linen and other equipment.

#### *Additional areas*

Additional areas required include equipment and consumable stores, utility rooms, a sisters' office, doctors' office, staff lounge, doctors' bedroom, laboratory, workshop, relatives' rooms, reception area, cleaners' room, seminar room, receptionist's office, dirty utility rooms, clean utility rooms, patient lavatories and showers, staff change rooms, lockers and shower facilities. The kitchen should be adequate to provide light meals for staff.

A private interview room must be available for discussions with relatives, dealing with bereavement issues and family interaction.

#### **Additional support services**

- Chemistry laboratory.
- Microbiology laboratory.
- Haematology service.
- Sterilising service.
- Pathology service.
- Blood bank

### **Equipment**

#### **Monitoring equipment**

For the early detection of abnormalities that require correction, high and low alarm limits should be determined and set appropriately for specific interventions, e.g. airway pressure, blood pressure, heart rate, oxygen saturation and end-tidal CO<sub>2</sub>.

#### *Electrocardiogram monitor*

One per bed

#### *Pressure monitor/transducers*

- ICU category 1 (one channel per bed)
- ICU category 2 (two channels per bed)
- ICU category 3 (three channels per bed)

*Non-invasive blood pressure monitoring device*

One per bed

*Oximetry*

One per bed

*Capnography*

- ICU categories 1 and 2 (available when needed).
- ICU category 3 (one per bed) Glucometer device One per unit

*Thermometers or temperature probes*

One per bed

### **Organ system support equipment**

*Ventilators with appropriate humidification devices*

- ICU category 2 (1 per bed)
- ICU category 3 (1.5 per bed)

*Continuous positive airways pressure devices*

*Capacity for non-invasive ventilation*

*High-flow nasal oxygen*

*Renal replacement therapy/haemoperfusion*

*Plasmapheresis*

*Intra-aortic balloon pump*

*Capability for measuring cardiac output*

*Capability for performing bronchoscopy*

*Extra-corporeal membrane oxygenation*

### **Other equipment**

*Beds*

- These must be able to tilt both head up and head down, move up and down (40–90 cm minimum), and break in the middle to allow patients to sit up and facilitate mobilisation. Preferably, they should be electrically operated, as well as have a manual assist or hydraulics for easy movement. They must be mobile with a suitable locking mechanism and must allow unimpeded access to the head of the bed for intubation, resuscitation and the insertion of central venous lines. Bed safety rails must be continuous and run the full length of the bed.

- A combination of Infusion pumps and syringe drivers must be available for intravenous fluid and drug administration.
- ICU category 1: 2 per bed
- ICU category 2: 4 per bed
- ICU category 3: 8 per bed

#### *Suction*

(to provide a negative pressure of 75 kPa and maintain a flow of 40 l/minute)

Two per bed.

#### *Emergency intubation trolley*

- One per unit, to carry:
  - Manual resuscitator (bag-valve-mask)/catheter mount/facemasks.
  - Selection of different sizes of oropharyngeal airways.
  - Naso-pharyngeal airway.
  - 2 laryngoscope handles (with a selection of small, medium and large blades and spare batteries).
  - Selection of endotracheal tubes.
  - Laryngeal mask airway.
  - Endotracheal tube introducer/gum elastic bougie.
  - Strapping for endotracheal tubes.
  - Bacterial filter.
  - Magill forceps.
  - Lignocaine spray.
  - KY Jelly.
  - Nasogastric tubes.
  - A pair of scissors.
  - Surgical blades.
  - Disposable gloves.
  - Safety glasses.
  - Surgical masks.
  - Oxygen masks and/or nasal cannulae.
  - Tracheostomy tape.
  - Yankauer suction tube and flexible suction catheters.
  - Appropriate drugs for intubation and resuscitation.

- Syringes, needles and alcohol swabs.
- Infusion sets, intravenous cannulae and transparent adhesive dressing.
- Resuscitation fluids.
- Emergency chest drain pack.
- Defibrillator/external pacing device with pads, paddles and electrodes  
One per unit
- Procedure light (pivot light of high intensity for special procedures)
- Forced air convective warming devices must be available
- Haemoglobinometer
- Urine-testing apparatus
- Ophthalmoscope and bedside investigational apparatus
- A flexible fibre-optic bronchoscope
- Low pressure suction apparatus
- Blood warming device
- Stethoscope (one per bed)
- A wall clock with a sweep second hand that is clearly visible from each bed space.
- Spirit levels
- Transport monitor
- Transport ventilator
- Ultrasound machine with an appropriate selection of probes
- Equipment for the provision of subglottic suction
- 12-lead ECG machine
- Intracranial pressure monitoring
- Provision for the safe disposal of sharps

## **Services**

### **Lighting**

Natural daylight, preferably with a view, must be utilised as much as possible for both patients and staff. Artificial light should be of daylight quality. Facilities for suitable dimming for night lighting should also be available. Individual bed lighting should be available for use at night.

### **Electricity**

The electricity should be 220-volt, single phase, with a single common earth ground. All outlets to the patient areas should be on the same phase. The patient area should be served by a maintained standby power source with the highest priority rating. There should be less

than five seconds interruption when switching to the standby source. The standby generator should be tested at least once every month. Separate protected battery power sources may be required for emergency lighting, computers, ventilators and other sensitive equipment.

## Medical gases

### *Oxygen*

Medical oxygen should be available at a pressure of 4 bar/400kPa. This pressure should be maintained when a flow of 50 l/minute at each outlet is in use at the same time. There should be two banks of cylinders or two tanks with automatic changeover controls with a visible and audible indication of failure in any part of the supply.

### *Compressed air*

Filtered oil-free medical air at a pressure of 4 bar should be available, and this pressure should be maintained with a flow of 50 l/minute at each outlet when all of them are in use. The supply should be governed by a fail-safe tandem system of providing compressed air.

## Vacuum

The ICU should have a central vacuum supply that can generate a negative pressure of 75 kPa and be capable of maintaining 40 l/minute air flow at each suction outlet when all outlets are in use.

ICU category 1: two inlets per bed

ICU categories 2 and 3: two inlets per bed

## Air conditioning

The unit should be air conditioned to allow a choice of temperature from 16–27 °C and a choice of humidity from 25–95%. Patient areas should have at least three changes of air per hour. A thermometer and hygrometer are necessary to monitor air conditioning in each room. Isolation rooms should be ventilated with reversible positive/negative airflow with at least 15 air changes per hour.

## Electricity points

These should have a pilot light indicating that the circuit is live (no more than four points per fuse):

ICU category 1: six per bed

ICU categories 2 and 3: sixteen sockets per bed

An alternative electrical supply must be available at all times in the event of a power failure.



## Mounts for monitors and equipment

Rails should be able to carry 20 kg every 60 cm. Some rails must be below the electrical sockets.

## Hanging intravenous sky hooks (or equivalent)

Two per bed

Electricity points, gas outlets and wall mounted equipment rails must be distributed on both sides of the bed.

## ***Diagnostic and investigational facilities***

### Biochemistry laboratory (24-hour availability)

Full serum chemistry

Full urinary chemistry

Blood gas laboratory

- ICU category 1: must be available immediately.

### Microbiology laboratory (24-hour availability)

### Haematology laboratory (24-hour availability)

Full blood counts.

Coagulation testing, including viscoelastic testing

### Diagnostic radiology

Routine radiography (24-hour availability)

Ultrasound investigation

- ICU category 1: daytime availability
- ICU categories 2 and 3: 24-hour availability

Computed tomography scanning

- ICU category 1: daytime availability
- ICU categories 2 and 3: 24-hour availability

Magnetic Resonance Imaging

- ICU category 3: 24-hour availability

Radioisotope scanning (daytime availability)

Angiography

- ICU category 1: daytime availability
- ICU categories 2 and 3: 24-hour availability

### ***Protocols and policies***

Protocols and policies for common ICU activities, unit-specific procedures and interventions, should be established, reviewed and practised. Such protocols and policies should be available in the unit to which staff may refer. These documents should include but are not limited to:

Admission, discharge and transfer criteria.

Infection control and antibiotic stewardship policies, including:

- Isolation of infected patients
- Sterilisation, changing and disposing of equipment
- Cleaning of the unit

Tracheal intubation and extubation.

Bundles for the management and care of invasive devices.

### ***Audit and continuous quality improvement***

There should be regular objective audits of:

- Structure
- Processes
- Outcomes from the perspectives of staff, patients, relatives and hospital administrators.

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