SOUTH AFRICAN SOCIETY
OF ANAESTHESIOLOGISTS (SASA)

Practice Guidelines 2018 Revision
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Previous publications and revisions

First published:
1987

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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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All contributors participated in revision of the full document.

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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

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


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.
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.
Acknowledgments

The South African Society of Anaesthesiologists (SASA) wishes to acknowledge with gratitude the unrestricted educational grants provided by MSD and EthiQal Medical Risk Protection that made the development, publishing, distribution and web hosting of this guideline possible.
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.¹ 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

** SOURCES:
1. CANADIAN ANAESTHESIOLOGISTS’ SOCIETY’S “GUIDELINES TO THE PRACTICE OF ANAESTHESIA” ON THE “RESPONSIBILITIES OF THE CHIEF OF ANESTHESIA”

² 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 includes ‘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 dieticians, 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 life support 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 national efforts 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 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\(^1\) 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, appendicectomy, 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 subspecialities 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.

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.

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.
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). 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)

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.

(Fore more details available on 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:

(Contd.)
▪ 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)

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)

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.hpcsa.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:

i. for which he or she is adequately educated, trained and sufficiently experienced, and
ii. 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:

i. Initial supervised training experience as previously discussed.

ii. 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.

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).

**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.

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.

Sources:
2. NEL S. FACTORS INFLUENCING ADVERSE EVENT AND ERROR REPORTING IN ANAESTHESIOLOGY; RESEARCH REPORT.
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.
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.”1

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.1

• 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),2,3 Ireland and the United Kingdom (UK),4 Europe5 and Australia.6

• 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.7

• “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.3,7-23 Complex memory, decision-making and alertness and attention are especially vulnerable to the effects of fatigue.7,8,14,19 Cognitive function deteriorates by 25% from baseline after 24 hours of wakefulness.24

• 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.7,25

• Fatigue-related depression and anger result in detachment and a lack of compassion for patients.26

• There is increased risk for the occurrence of errors, critical incidents, and accidents.7,27 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.10

- Fatigued workers can perform normally for short durations of attention if sufficiently motivated,28 but have a tendency to slow down work processes to maintain accuracy, leading to decreased productivity, known as the speed-accuracy trade-off.29

- 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.4

- 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.21 This level of impairment in a driving test could be shown after just three hours of additional wakefulness.20 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.10

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,20 or 7h:30 min according to other authorities.31

- Loss of sleep is cumulative.28,32 Failure to address this sleep debt contributes to earlier fatigue on subsequent rotation duties.14,28 It takes two consecutive nights of optimal sleep at the correct time to recover from significant sleep loss.4

- 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.4,7,33,34

- Work schedules longer than 12.5 hours contribute significantly to a risk of decreased vigilance, occupational injury, or a medical error.27

- Anaesthetic duties often do not allow for normal intake of food and liquid. Unrecognised hypovolaemia and hypoglycaemia contribute to fatigue.4
• 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.35

• Suggested corrective strategies include7:

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.”

Sources:
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. SaO₂, 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 perianesthesia 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.

Sources:
5. Association of Anaesthetists of Great Britain & Ireland (AAGBI) 2007: Assistance for the Anaesthetist
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.

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 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\textsubscript{2} 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)

<table>
<thead>
<tr>
<th>Equipment description</th>
<th>District hospital</th>
<th>Regional hospital</th>
<th>Tertiary hospital</th>
<th>Central hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthetic machine (basic)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Anaesthesia machine, with O₂, air and N₂O 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</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Anaesthetic work station</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>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, SPO₂, multi-gas analyser, spirometry, NMT, BIS or entropy</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Anaesthesia trolley, mobile</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Processed EEG depth of anaesthesia monitor (if not part of patient monitor)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Blood/fluid warmer</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Blood salvage system</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Cerebral oximeter (NIRS)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Diagnostic set, complete</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Equipment</td>
<td>2018</td>
<td>2017</td>
<td>2016</td>
<td>2015</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>------</td>
<td>------</td>
<td>------</td>
<td>------</td>
</tr>
<tr>
<td>Defibrillator, complete, mounted on mobile trolley (adult/paediatric paddles)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Defibrillator and external pacing</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Difficult airway management equipment</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Forced air warmer</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Fibre-optic laryngoscope</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucometer</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Haemoglobinometer/centrifuge (Hct)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>High-flow blood/fluid warmer</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Lactate meter</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Laryngoscope set, complete</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Jet ventilator</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Near Infrared Cerebral Oximetry (NIRS)</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-invasive cardiac output monitor</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>PCA, PCA pump or disposable pumps</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Peripheral nerve stimulators</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Platelet function monitor (Access to)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Point-of-care diagnostics (blood gas, electrolytes, glucose and lactate)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Pulse oximeter with HB (Access to)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Resuscitator, pulmonary, manual, adult, complete</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Resuscitator, pulmonary, manual, child/infant, complete</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Scale for swab weighing (Access to)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Syringe drivers</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Suction unit, mobile, 1 x 2-litre bottle/disposable bag, wall outlet</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Suction unit, mobile, 1 x 2-litre bottle/disposable bag, electrical</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>TCI syringe drivers (target-controlled intravenous anaesthesia)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>TEE</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transport ventilator</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Transport vital signs monitor</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Thromboelastograph</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Video bronchoscope</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Video laryngoscope (for district if high volume obstetrics)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Vital signs monitor with ECG, SpO$_2$, NIBP, temperature, capnography</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Vital signs monitor with ECG, SpO$_2$, NIBP, invasive pressures, temperature, multi-gas analyser</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Vital signs monitor: capnograph</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Vital signs monitor with SpO$_2$ and NIBP</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Volumetric infusion pump</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

**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**

**Premedication**

| Benzodiazepines | Lorazepam Midazolam |

**Induction agents**

| Propofol Etomidate Ketamine Thiopental |

**Volatile**

**Induction**

| Halothane Sevoflurane |

**Maintenance**

| Isoflurane |

**Muscle relaxants**

**Depolarisers**

| Suxamethonium |

**Non depolariser**

| Cisatracurium Vecuronium |

**Rapid sequence intubation**

| Suxamethonium Rocuronium |

**Reversal agents**

| Neostigmine with either atropine or glycopyrrolate |

**Analgesics**

**Oral**

| Paracetamol NSAIDs, e.g. ibuprofen |

**Intravenous**

| Fentanyl Morphine Ketamine |

**Postoperative**

| Morphine Tramadol Diclofenac IM |

**Fluids**

| Ringer lactate 0.9% NaCl |

**Sources:**

### Treating anaesthesia complications

<table>
<thead>
<tr>
<th>Condition</th>
<th>Treatment/Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malignant hyperthermia</td>
<td>Dantrolene</td>
</tr>
<tr>
<td></td>
<td>CVS support – adrenaline (epinephrine)</td>
</tr>
<tr>
<td>LA toxicity</td>
<td>Lipid emulsion (20%)</td>
</tr>
<tr>
<td>Acute hypotension</td>
<td>Ephedrine IV, 3–5 mg</td>
</tr>
<tr>
<td></td>
<td>Phenylephrine IV, 50–100 mcg</td>
</tr>
<tr>
<td>Acute hypertension</td>
<td>Alfentanil (obtund the hypertensive response)</td>
</tr>
<tr>
<td></td>
<td>Magnesium sulfate</td>
</tr>
<tr>
<td></td>
<td>Labetalol</td>
</tr>
</tbody>
</table>

### PONV

<table>
<thead>
<tr>
<th>Stage</th>
<th>Treatment/Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prophylaxis</td>
<td>Dexamethasone</td>
</tr>
<tr>
<td>Treatment</td>
<td>Ondansetron</td>
</tr>
<tr>
<td></td>
<td>Promethazine</td>
</tr>
</tbody>
</table>

### Regional neuraxial

<table>
<thead>
<tr>
<th>Type</th>
<th>Medication/Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spinal</td>
<td>Bupivacaine 0.5% (spinal use) plain or hyperbaric (+glucose)</td>
</tr>
<tr>
<td>Epidural</td>
<td>Bupivacaine 0.5%</td>
</tr>
<tr>
<td></td>
<td>Lidocaine 2% (preservative-free)</td>
</tr>
<tr>
<td>Regional blocks</td>
<td>Lidocaine 1% or 2%</td>
</tr>
<tr>
<td></td>
<td>Bupivacaine 0.5%</td>
</tr>
<tr>
<td>Topical anaesthesia</td>
<td>Lidocaine jelly</td>
</tr>
<tr>
<td></td>
<td>Lidocaine topical spray</td>
</tr>
<tr>
<td></td>
<td>Lidocaine/prilocaine, topical cream, 2.5/2.5%</td>
</tr>
<tr>
<td>Chronic neuropathic pain</td>
<td>Amitriptyline</td>
</tr>
<tr>
<td></td>
<td>Carbamazepine</td>
</tr>
</tbody>
</table>

### Emergency medication

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

<table>
<thead>
<tr>
<th>Type</th>
<th>Medication/Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac arrest</td>
<td>Adrenaline</td>
</tr>
<tr>
<td>Antidysrhythmics</td>
<td>Amiodarone</td>
</tr>
<tr>
<td></td>
<td>Dopamine</td>
</tr>
<tr>
<td></td>
<td>Dobutamine</td>
</tr>
<tr>
<td></td>
<td>Lignocaine</td>
</tr>
<tr>
<td></td>
<td>Verapamil</td>
</tr>
<tr>
<td></td>
<td>Adenosine</td>
</tr>
<tr>
<td>Bronchodilators</td>
<td>Salbutamol</td>
</tr>
<tr>
<td></td>
<td>Aminophylline</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>Hydrocortisone</td>
</tr>
<tr>
<td></td>
<td>Dexamethasone</td>
</tr>
<tr>
<td></td>
<td>Methylprednisolone</td>
</tr>
<tr>
<td>Vasopressor</td>
<td>Phenylephrine and ephedrine/etilephrine</td>
</tr>
<tr>
<td>Vasodilators</td>
<td>Labetalol</td>
</tr>
<tr>
<td></td>
<td>TNT</td>
</tr>
</tbody>
</table>
Antibiotics for prophylaxis

As per current recommendations²
- 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

<table>
<thead>
<tr>
<th>Category</th>
<th>Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalants</td>
<td>Sevoflurane, Desflurane</td>
</tr>
<tr>
<td>Analgesics</td>
<td>Alfentanil, Sufentanil, Remifentanil</td>
</tr>
<tr>
<td>Relaxants</td>
<td>Rocuronium, Atracurium</td>
</tr>
<tr>
<td>Other</td>
<td>Dexmedetomidine, Esmolol, Noradrenaline, Ketorolac, Paracetamol IV, Sugammadex</td>
</tr>
<tr>
<td>Chronic neuropathic pain</td>
<td>Gabapentin, Duloxetine, Pregabalin</td>
</tr>
</tbody>
</table>

Sources:

Sugammadex

SASA:3

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

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 pharmacovigilence (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.

**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:

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. 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, 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 happen 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

Sources:
4. Lundgren AC. Ampoule sharing – is it safe practice and is it best practice? Pipeline 2007;57:1
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.6

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.¹

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:**

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.²

• 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.¹

• 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.

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 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. Premedicant 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


- 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

Source:
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).1-4

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

*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.6-8

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.5

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.9,10

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 juxta-venous anatomy, reduction in procedure time and a reduction in serious complications.11,12

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.13-15 Ultrasound reduces the number of attempts, shortens the procedure time and increases the rate of successful cannulation.16 It may be particularly advantageous in patients with abnormal anatomy, low perfusion states or previous unsuccessful cannulation attempts.17

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.18

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.1

- 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.1,2,19-21
- May be used for the cannulation of subclavian and femoral veins.22,23
- Equivocal evidence supports the use of US for arterial cannulation.14

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.

Sources:


**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

<table>
<thead>
<tr>
<th>Hospital Type</th>
<th>Required Standards</th>
<th>Peri-Anesthetic Care and Monitoring Standards HIGHLY recommended</th>
</tr>
</thead>
</table>
| Level 1       | All that are HIGHLY RECOMMENDED | 1. Continuous direct presence in the anaesthetising location of a vigilant anesthesia professional.  
2. Appropriate “pre-check” of the anesthesia system, facilities, equipment, and supplies.  
3. Use of the relevant components of the WHO Safe Surgery Checklist  
4. Supplemental oxygen administered to all patients undergoing general anesthesia.  
5. Continuous use of pulse oximetry.  
6. Continuous monitoring of airway and ventilation by observing the bag and with a stethoscope.  
7. Confirmation of the correct placement of an endotracheal tube by auscultation.  
8. Continuous monitoring of the pulse by clinical examination and with a pulse oximeter.  
10. Continuous monitoring of tissue perfusion by clinical examination and with a pulse oximeter.  
11. Monitoring of non-invasive arterial blood pressure at appropriate intervals.  
12. Use of a disconnect alarm if mechanical ventilation is employed.  
13. Audible signals eg pulse oximeter, and alarms activated at all times.  
14. All patients should remain where anaesthetised until recovered or be transported safely to a specifically designated recovery location.  
15. Immediate availability of oxygen, suction, and a means of ventilation in Recovery.  
16. Continuous use of pulse oximetry until recovery of consciousness.  
17. Adequate pain relief including narcotics when needed. |
| Rural Hospital or a Health Center with a small number of beds; sparsely equipped operating room (OR) for “minor” procedures |                     |                                                                 |

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

<table>
<thead>
<tr>
<th>Hospital Type</th>
<th>Required Standards</th>
<th>Peri-Anesthetic Care and Monitoring Standards – HIGHLY recommended PLUS recommended</th>
</tr>
</thead>
</table>
| Level 2       | All HIGHLY RECOMMENDED (Table 1) PLUS these RECOMMENDED items | 1. Monitoring of inspired oxygen concentration with an instrument fitted with a low oxygen concentration alarm.  
2. Use of a device protecting against the delivery of an hypoxic gas mixture.  
3. Use of capnography to verify the correct placement of the endotracheal tube or other airway device and the adequacy of ventilation.  
4. Use of a continuous electrocardiograph.  
5. Continual measurement of temperature.  
6. Use of a peripheral neuromuscular transmission monitor when neuromuscular blocking drugs are given.  
7. Sufficient trained staff in the post-anesthesia recovery area to manage patients recovering from anesthesia and surgery. |
| District or Provincial hospital eg with 100-300 beds, with adequately equipped major and minor operating rooms |                     |                                                                 |
### Table 3: Characteristics and Clinical Practice Recommendations for Level 3 Hospitals

<table>
<thead>
<tr>
<th>Hospital Type</th>
<th>Required Standards</th>
<th>Peri-Anesthetic Care and Monitoring Standards – HIGHLY recommended PLUS recommended PLUS SUGGESTED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 3</td>
<td></td>
<td>1. Continuous measurement of the inspiratory and/or expired gas volumes, and of the concentration of volatile agents.</td>
</tr>
<tr>
<td>A Referral Hospital of 300-1 000 or more beds with basic intensive care facilities</td>
<td>All HIGHLY recommended (Table 1) PLUS recommended (Table 2) PLUS these items</td>
<td>2. Continuous measurement and display of arterial pressure in appropriate cases.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Use of continuous electronic temperature measurement.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Monitoring of urine output during prolonged procedures or when significant administration of intravenous fluids is anticipated.</td>
</tr>
</tbody>
</table>

### 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.

SOURCES:

2. Guidance on the provision of anaesthetic services for postoperative care. The Royal College of Anaesthetists; 2009.
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](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)

<table>
<thead>
<tr>
<th>Country</th>
<th>Doctors per 100,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indonesia (2012)</td>
<td>20</td>
</tr>
<tr>
<td>Thailand (2010)</td>
<td>39</td>
</tr>
<tr>
<td>South Africa (2013) - Econex</td>
<td>60</td>
</tr>
<tr>
<td>India (2012)</td>
<td>70</td>
</tr>
<tr>
<td>Brazil (2013)</td>
<td>189</td>
</tr>
<tr>
<td>China (2012)</td>
<td>194</td>
</tr>
<tr>
<td>Russia (2010)</td>
<td>431</td>
</tr>
<tr>
<td>Cuba (2010)</td>
<td>672</td>
</tr>
</tbody>
</table>

Source: World Health Organisation, 2014\textsuperscript{12}

Figure 7: Number of specialists\textsuperscript{13} per 100,000 citizens in developed countries and South Africa (2011)

Source: Eurostat, 2015; Econex, 2014
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 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).
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 Ethics¹ 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\(^2\) 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.\(^3\) 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 practice 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,\(^4\) 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.*\(^5\) 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.⁵

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

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:  

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\textsuperscript{11} 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.

\textbf{Sources:}

1. \url{http://policybase.cma.ca/POLICYPDF/PD04-06.pdf}
2. \url{http://www.asahq.org/publicationsAndServices/standards/10.pdf} (N/A)
3. \url{http://policybase.cma.ca/POLICYPDF/PD04-06.pdf}
4. \url{http://www.asahq.org/publicationsAndServices/standards/10.pdf} (N/A)
Appendix 4
National Policy for Patient Safety Incident Reporting and Learning in the Public Health Sector of South Africa

July 2016
Preamble

One of the greatest challenges today is to delivering safer and quality care in complex, pressurized and fast-moving healthcare environments. In such environments, things can often go wrong. Patient Safety Incident Reporting and Learning systems is used to identify these patient safety issues and therefore forms the cornerstone of patient safety strategies. By learning from these systems errors can be corrected to prevent reoccurrence to ensure that patient safety, quality of care and health outcomes of patients are improved.

The World Health Organization’s (WHO) World Alliance for Patient Safety developed the first draft guidelines for Adverse Event Reporting in 2005 with the vision that one day it may be possible for the bad experience suffered by a patient in one part of the world to be a source of transmitted learning that will benefit future patients in many other countries.

These guidelines are currently being updated and revised as WHO Guidelines for Patient Safety Incident Reporting and Learning Systems. Several initiatives are undertaken by the WHO to obtain inputs for these guidelines. One of the initiatives were to create an international platform for presenting and discussing experiences and the role of reporting and learning systems for patient safety by hosting the Inter-Regional consultation workshop on patients safety incident reporting and learning systems in Africa and Asia Pacific that was held in Colombo, Sri Lanka in March 2016. South Africa was privilege to attend this workshop. The recommendation from this workshop was that all countries should develop an effective and sustainable National level Patient Safety Incident Reporting and Learning System.

The Ministerial medico-legal Committee was established in 2014 as South Africa is currently experiencing an explosion in medical malpractice litigation which is not in keeping with the generally known trend of negligence in malpractice. The impact of medico-legal litigations threatens the vision of Government of achieving a long and healthy life for all South Africans. The Committee held a medico-legal summit on 9 and 10 January 2015, one of the recommendations of this summit was that a uniform National reporting System of adverse events related to patient safety must be implemented, this is in line with the recommendations of the WHO.
I believe that this policy is essential for realising the vision of the WHO as well as the Ministerial Medico-Legal committee. Every public health establishment must have a Patient Safety Incident Reporting and Learning system as stipulated in this policy. The emphasis should not only be on reporting as it is only one part of implementing an efficient system, if learning does not take place the data collected through reporting is of no use. Sir Liam Donaldson, WHO Envoy for Patient Safety stated that “To err is human, to cover up is unforgivable, but to fail to learn is inexcusable”.

Once the national Patient Safety Incident Reporting and Learning system is established, data from the system will be used to develop National action plans to improve patient safety to ensure that all South Africans receive safe health care.

Ms P Matsoso
Director General of Health
Date:
Acknowledgements

Developing the National Policy for Patient Safety Incident Reporting and Learning required specific technical expertise that was provided by a range of organisations.

My sincere gratitude to the committee members of the Ministerial Medico-legal Committee for organizing and hosting the first Medico-legal summit in January 2015 that set the background for this policy to be developed. These members also gave valuable inputs on the draft versions of the policy.

Being well aware that mentioning by name those that have contributed always carries the risk of also unknowingly excluding important names, the Department of Health nether less would like to extend special thanks dr. Valentina Hafner, consultant of the WHO on patient safety who volunteered to provide inputs on the first draft of the policy. She also provided valuable literature on the minimal information model for patient safety as well as highlighting new developments in the world of patient safety. Dr Neelam Dingra-Kumar, the WHO’s coordinator for Patient Safety and Quality Improvement, for inviting South Africa to attend the Inter- Regional consultation workshop on patients safety incident reporting and learning systems in Africa and Asia Pacific held in Colombo, Sri Lanka, where valuable lessons were learned.

Also a vote of thanks to the National Blood Service of South Africa, the Mental Health Directorate and the Pharmocovigilence unit within the National Department of Health for providing inputs on the various sections pertaining to the services that they govern.

A special word of thanks is also extended to our colleagues who made their contributions as heads of the provincial Quality Assurance units and units dealing with patient safety.
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POLICY FOR PATIENT SAFETY INCIDENTS REPORTING AND LEARNING

1. PURPOSE

The purpose of this policy is to provide direction to the public health sector of South Africa regarding the management of patient safety incident reporting, including the provision of appropriate feedback to patients, families/support persons and clinicians, and the sharing of lessons learned to prevent patient harm. A patient safety incident (PSI) is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. The use of the word “unnecessary” in this definition recognizes that errors, violation, patient abuse and deliberately unsafe acts occur in healthcare. These are considered incidents. In the context of this policy the term PSI will be referred to as an incident. This policy describes a national standardised system for managing PSIs to ensure that health facilities, district offices, provincial offices and the national office respond effectively to PSIs.

2. SCOPE

This Policy Directive:
- applies to all incidents that occur in public health establishments of South Africa
- is applicable to clinical staff and non-clinical staff
- describes roles and responsibilities in the incident management process
- articulates mandated reporting requirements from legal and policy perspectives, see section 5.4
- defines the timeframes within which incidents, and the results of the investigation of these incidents, are to be reported
- identifies the facility/district/provincial and national level processes for aggregation, analysis, learning and action on incidents

Compliance with this Policy Directive is mandatory for all Health Professionals working in public Primary Health Care establishments and Hospitals in South Africa.
3. MANDATORY REQUIREMENTS

All health facilities must have a system in place to manage PSIs according to the following principles:

3.1 Just Culture
Staff that reports patient safety incidents should be free from fear of victimisation solely for reporting PSIs. The Just Culture supports a “learning organisation” that investigates incidents instead of blaming individuals.

3.2 Confidential
The identities of the patient, reporter or institution should be kept anonymous and only known to staff directly involved in the management of a PSIs as well as managerial staff that are indirectly involved in the further management of the incident.

3.3 Timely
Reports are analysed promptly. Once the organisation is notified of a PSIs, investigation should be conducted immediately.

3.4 Responsive
Participating organisations commit to the immediate implementation of recommendations.

3.5 Openness about failures
Patients and their families/support persons are offered an apology and told what went wrong and why.

3.6 Emphasis on learning
The system is oriented towards learning from mistakes and consistently employs improvement methods for achieving this.
4. IMPLEMENTATION

All staff working in Primary Health Care Facilities and Hospitals are responsible to:

- report and record all patient safety incidents in line with the procedures to as stipulated in the procedural manual for Patient Safety Incident Reporting and Learning
- report all incidents that resulted in serious harm or death (Severity Assessment Code 1 incidents) within 24 hours to management or sub-district/district and provincial office
- commence and/or participate in the open disclosure process as appropriate
- participate in the investigation of incidents as required
- finalise Severity Assessment Code 1 incident reports within sixty working days
- participate in the implementation of recommendations arising from the investigation of incidents
- encourage colleagues to notify incidents that have been identified

All hospitals, district offices, provincial offices and national office must have a Patient Safety Committee.

The Committee’s main objective is to oversee the effective management of PSIs. These Committees do not need to be stand-alone committees but can form part of other committees that deals with clinical governance. The Terms of Reference of such combined committees must indicate in detail the functions the Committee will be performing in regard to the management of PSI reporting.
4.1 Terms of Reference for Hospital and Sub-district/ District Patient Safety Committees

- Develop a Standard Operating Procedure (SOP) to manage PSIs that is in line with the procedures as stipulated in the procedural manual for Patient Safety Incident Reporting and Learning.
- Monitor that health facilities adhere to the SOP for the management of PSIs.
- Management must report all Severity Assessment Code 1 incidents to the respective provincial office within 24 hours.
- Review PSI reports for all Severity Assessment Code 1 incidents that are reported. In cases where further investigation is required, investigate incident.
- Monitor that all Severity Assessment Code 1 incidents reports are finalised within 60 days.
- Monitor that recommendations are implemented to prevent reoccurrence of the incident.
- Conduct monthly meetings of which the minutes must be recorded.
- Compile and analyse statistical reports to identify trends.
- Submit monthly statistical reports to the respective provincial office.
- Make recommendations to improve patient safety according to trends identified.
- Disseminate lessons learned from PSI management.
- Sub-district/ district Patient Safety Committees must identify a staff member in all Primary Health Care facilities that will be responsible for the management of PSIs. These staff members must be trained on the management of PSIs.
- Implement guidelines and protocols that support staff and encourage an environment where incident notification and active management of incidents is fostered.
- Attend provincial Patient Safety Committee meetings when required.
- Ensure that regular training of staff on the management of PSIs takes place.
- Identify education needs emerging from PSI management.
4.2 Terms of Reference for Provincial Patient Safety Committees

- Develop a provincial protocol to manage PSIs that is in line with the procedures as stipulated in the procedural manual for Patient Safety Incidents Reporting and Learning
- Monitor that health facilities and sub-district/district offices adhere to provincial PSI protocol.
- Assist health facilities and sub-district/district offices to mitigate immediate consequences of PSI.
- Monitor that Severity Assessment Code 1 incidents are reported within 24 hours.
- Review PSI reports for all Severity Assessment Code 1 incidents that are reported. In cases where further investigation is required, investigate the incident.
- Monitor that all Severity Assessment Code 1 incident reports are finalised within 60 days.
- Monitor the implementation of recommendations to prevent reoccurrence of the incident.
- Conduct at least quarterly meetings of which the minutes must be recorded. Ad hoc meeting can be scheduled as needed.
- Compile and analyse provincial statistical reports to identify trends.
- Submit quarterly statistical reports to the national office.
- Disseminate lessons learned from PSI management
- Develop guidelines and protocols that encourage an environment in health facilities where incident notification and active management of incidents are fostered.
- Implement provincial system-wide initiatives to prevent similar future incidents.
- Facilitate the transformation of knowledge obtained through the statistical analysis of PSIs into protocols, guidelines and standard operating procedures.
4.3 Terms of Reference for National Patient Safety Committee

- Develop a national policy to manage PSI.
- Conduct quarterly meetings of which the minutes must be recorded.
- Monitor that provinces adhere to the policy to manage PSIs.
- Compile and analyse quarterly national PSI statistical reports.
- Implement national system-wide initiatives to prevent similar future incidents.
- Provide advice to the Minister for Health on issues of public concern and media or public attention.
- Provide an appropriate national response to new risks as they are identified.

5. Procedural manual for Patient Safety Incidents Reporting and Learning

The procedures to manage patient incident reporting and ensure learning are set out in the following procedural manual (see section 5.1 to 5.8) for patient safety incident reporting and learning.
5.1 Rationale for patient safety incident reporting and learning

Lapses in patient safety are a major health care quality problem. The occurrence of patient harm due to such lapses is remarkably common, causing many avoidable deaths each year. A large majority of these lapses are the unintended results of highly complex and imperfect health care delivery systems in which minor mishaps sometimes combine to cause harmful or disastrous results. Most of the unintended occurrences are related to whole system challenges. Professional errors, at risk behaviour and reckless misconduct or negligent behaviour also contribute to PSI. Appropriate preventative measures will reduce the number and severity of incidents.

The aim of PSI reporting is to improve patient safety by learning from failures of the health-care system so that the likelihood of a recurrence of the same event is significantly reduced.

All health-care professionals must report PSIs as soon as they become aware of it to ensure that optimal learning take place. PSIs must be recorded and analysed to identify whether improvements in the delivery system can be made.

Improved patient safety is demonstrated by, among others, improved patient satisfaction with health services, reduction of avoidable mortality, harm encountered during care, litigations and reduced health care costs.

5.2 Objectives for patient safety incidents reporting and learning

The objectives of the procedures for PSI reporting and learning are to:

- create a framework to guide the implementation of a PSI Management Reporting System
- standardise the definitions for PSIs
- standardise the degree of severity classification
• standardise the classification for PSIs by type, agent (cause) and outcome
• standardise the methodology for reporting, investigating and responses to PSIs
• ensure that statistical data on PSIs are readily available for planning and decision making
• prevent and or reduce harm to patients whilst undergoing medical care
• ensure that preventative measures are put in place to reduce the incidence of PSIs and prevent their reoccurrence
• continuously improve quality of care through the identification of all missed opportunities in ensuring optimal patient outcomes
• ensure appropriate communication with patients who have been harmed due to a PSI, including an apology if indicated

5.3 Definition of terms as used

Patient Safety: is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.

Incident: An incident can be a near miss, no harm incident or harmful incident (adverse event).

Near miss: is an incident which did not reach the patient.

No harm incident: is one in which an event reached a patient but no discernible harm resulted.

Harmful incident (adverse event): is an incident that results in harm to a patient that is related to medical management, in contrast to disease complications or underlying disease. Medical management includes all aspects of care from interaction with health care provider to discharge of a patient from medical treatment or health care facility.

Incident type: a descriptive term for a category made up of incidents of a common nature, grouped because of shared, agreed features
Harm: implies impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death, and may be physical, social or psychological.

Degree of harm: is the severity and duration of any harm, and any treatment implications, that result from an incident.

Severity Assessment Code 1: Serious harm or death that is/could be specifically caused by health care rather than the patient’s underlying condition or illness

Severity Assessment Code 2: Moderate harm that is/could be specifically caused by health care rather than the patient’s underlying condition or illness

Severity Assessment Code 3: Minor or no harm that is/could be specifically caused by health care rather than the patient’s underlying condition or illness

Error: the failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (error of planning). Errors may be errors of commission of omission, and usually reflect deficiencies in the systems of care.

Hazard: is a circumstance, agent or action with the potential to cause harm

System: a set of interdependent elements (people, processes, equipment) that interact to achieve a common aim.

Incident outcomes: all impacts upon a patient or an organisation wholly or partially attributable to an incident

Organisational outcome: the impact upon an organisation which is wholly or partially attributable to an incident.

Patient outcome: is the impact upon a patient which is wholly or partially attributable to an incident
**Resulting actions:** identify immediate or indirect action taken that relates to the patient or the organisation to improve the situation or prevent the reoccurrence of an incident.\(^1\),\(^2\)

**Minimal Information model:** refers to a minimal common architecture for the core concepts considered to be essential for information and comparison purposes of PSI reports\(^3\).

### 5.4 Legal and policy framework

The constitutional, legislative and policy framework for the policy is as follows:

#### 5.4.1 National Health Act no 61 of 2003

Section 47, subsection 1 of the National Health Act stipulates that all health establishments must comply with the quality requirements and standards prescribed by the Minister after consultation with the National Health Council. The quality requirements and standards contemplated in subsection (1) may relate to human resources, health technology, equipment, hygiene, premises, the delivery of health services, business practices, safety and the manner in which users are accommodated and treated.

#### 5.4.2 The National Health Amendment Act 12 of 2013

Section 78 of the Act states that one of the objectives of the Office of Health Standards Compliance (OHSC) is to protect and promote the health and safety of users of health services. A set of National Core Standards for Health Establishments were developed to realise this objective. The standards are structured into seven cross-cutting domains. The various standards relating to PSI are set out in domain 2 (Patient Safety, Clinical Governance and Clinical Care).

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\(^1\) World alliance for patient safety WHO draft guidelines for adverse event reporting and learning systems – from information to action 2005:7

\(^2\) Conceptual framework for the International Classification for Patient Safety, WHO, 2009: 15-16

\(^3\) WHO Working Paper. Preliminary version of Minimal Information Model for Patient Safety, Spring 2014: 4
5.4.3 Ethical rules for health practitioners

All health care practitioners are bound by ethical rules in their specific professional practice. As the gist of these rules has to do with the protection of their patients and the public at large, health professionals are thus held accountable for their professional acts and omissions.

A health care practitioner should always regard concern for the best interests or well-being of their patients as their primary professional duty. Health Care practitioners must treat patients with respect, keep information confidential and provide information to patients as required to ensure that they can make an informed decision when they have to give consent for procedures. Health care practitioners must also work with and respect other health-care professionals in pursuit of the best health care possible for all patients. The ethical rules guide judgment against unethical practices of health professionals⁴.

Public health workers are also subject to the Code of Conduct for Public Servants in which the expected relationship of the employee with the public is clearly defined.

5.4.4 The National Patients’ Rights Charter

The Patients’ Right Charter stipulates that users of health services have the right to a healthy and safe environment.

5.4.5 The Health Professions Amendment Act 29 of 2007

The Act regulates the mandatory reporting of procedure-related deaths. The act stipulates that the death of a person undergoing, or as a result of, a procedure of a 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 Inquest Act, 1992 (Act No. 145 of 1992), or the Births, Marriages and Deaths Registration Act, 1992 (Act No. 51 of 1992).

5.4.6 The Births and Deaths Registration Act 51 of 1992

The act provides for the notification of death by medical practitioners and authorised nursing practitioners in cases of death. A notice of death must be given within 72 hours of the death by the informant. The cause of death must be recorded as –

(i) “natural causes”, if satisfied that the death was due to natural causes;
(ii) “unnatural causes”, if satisfied that the death was due to unnatural causes; or
(iii) “under investigation” and the case number, if the death is still under investigation in terms of section 3 of the Inquests Act;

5.4.7 The Inquest Act (as amended)

The act regulates procedures in unnatural deaths by making provision for the holding of inquests in cases of deaths or alleged deaths apparently occurring from other than natural causes and for matters incidental thereto. Any person who has reason to believe that any other person has died and that death was due to other than natural causes, shall as soon as possible report to the South African Police Service, unless he has reason to believe that a report has been or will be made by any other person.

By definition it also requires referral to Forensic Pathology Services and performance of an autopsy. The consent of family members is not required in such cases, however the family/relatives of the deceased should be informed prior to the performance of the autopsy.

5.4.8 The Mental Health Care Act 17 of 2002

The act regulates procedures in regard to assisted and involuntary mental health care users, mentally ill prisoners and State patients that have absconded from a health establishment.

In cases where an assisted and involuntary mental health care user, State patient or mentally ill prisoner has absconded or is deemed to have absconded the head of the
health establishment may request assistance from the South African Police Services to apprehend and return the user to the health establishment concerned using Mental Health Care Act form number 25 (MHCA 25).

The health establishment must inform the South African Police Services of the estimated level of dangerousness of the mental health care user, State patient or mentally ill prisoner. If the mental health care user, State patient or mentally ill prisoner is apprehended in the vicinity of the health establishment, the South African Police Service must return the user immediately to the health establishment. Should the apprehension by the South African Police Service not take place in the vicinity of that health establishment, the mental health care user may be held in custody at the police station for a period of not more than 24 hours. During this time the head of the health establishment should take steps to ensure that a mental health care practitioner from a health establishment nearest to the police station provides treatment to the mental health care user.

Section 11, subsection one of the Mental Health Care Act also prescribes that every person, body, organisation or health establishment providing care, treatment and rehabilitation services to a mental health care user must take steps to ensure that i) users are protected from exploitation, abuse and any degrading treatment, ii) users are not subjected to forced labour and iii) care, treatment and rehabilitation services are not used as punishment or the convenience of other people. A person witnessing any form of abuse set in subsection one against a mental health care user must report this fact in the prescribed manner.

5.4.9 Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended

This act refers to the reporting of adverse drug reactions received by pharmaceutical manufacturers (license holders) from health professionals. Regulations 34 and 37 of the act stipulates that that license holders must report all adverse drug reactions (ADRs) associated with the use of registered medicines and any other safety data which arise during post-registration and post-marketing clinical trials to the office of the Registrar of Medicines via their pharmacovigilance unit. Health professionals are also encouraged to report suspected adverse drug reactions directly to the National Adverse Drug Event Monitoring Centre using the prescribed ADR reporting form.
Adverse drug reaction means a response to a medicine in humans or animals, 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.

The minimum information required when reporting an ADR is:
- an identifiable source (reporter) of the information. This should include the name or initials and address of the reporter and the reporter’s qualification
- an identifiable patient. A patient may be identified by surname and forenames (s) or initials of surname and forenames, or by reference number, or by age or gender
- suspected product(s)
- suspected reaction(s)

Information additional to the minimum should be actively sought and submitted as soon as it becomes available.

5.4.10 National Health Act No. 61, 2003 - Regulations relating to blood and blood products (no.r.179)

Sub-regulation (10) of the National Health act states that the South African National Blood Service (SANBS) must inform the Director-General of health or a person specifically designated by him or her, verbally immediately of any report received in terms of a blood transfusion that resulted in any serious or life threatening reaction or death and confirm such report in writing as soon as possible.

In order for SANBS to report the blood transfusion reactions that resulted in any serious or life threatening reaction or death to the Director-General, the Standards of Practice for Blood Transfusion in South Africa, 6th edition, September 2013, section 60.1.3 further states that the medical practitioner at the health establishment shall report any blood transfusion reactions as soon as possible in writing to the SANBS where the blood was obtained from. In the event of mortality or major morbidity, the report may be verbal initially and then subsequently in writing. A labelled blood sample must be obtained from the recipient and sent together with the blood-container, any attached transfusion set and intravenous solutions to the SANBS where the blood was ordered from. The prescribed form must also be completed and sent together with aforementioned.
The SANBS will investigate the incident and submit a report on the outcome of the investigation to the responsible medical practitioner or clinical manager at the health establishment who reported the incident to SANBS.

5.5 Situational analysis

5.5.1 Internationally

European data from the World Health Organization consistently show that medical errors and health-care related adverse events occur in 8% to 12% of hospitalisations.

Strategies to reduce the rate of adverse events in the European Union alone would lead to the prevention of more than 750 000 harm-inflicting medical errors per year, leading in turn to over 3.2 million fewer days of hospitalisation, 260 000 fewer incidents of permanent disability, and 95 000 fewer deaths per year⁵.

In the United States of America between 210 000 and 440 000 patients who go to the hospital for care suffer some type of preventable harm that contributes to their death yearly. That would make medical errors the third-leading cause of death in America, behind heart disease, which is the first, and cancer, which is second⁶.

In an Eastern Mediterranean and African study, almost one third of patients who suffered a harmful incident died. Another 14% sustained permanent disability, 16% sustained moderate disability, 30% were left with minimal disability and 8% of the patients’ harm could not be specified. The study also concluded that 34% of the observed incidents resulted from therapeutic errors. Others came from diagnostic errors (19%), surgical mistakes (18%), obstetrics (9%), neonatal procedures (8%), non-surgical procedures (5%), drug-related incidents (4%), fractures (2%), anaesthesia (0.5%) and falls (0.5%).⁷

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⁶ How many die from medical mistakes in U.S hospitals, Patient Safety exploring quality of care in the US, Sept 2013
⁷ Patient safety in developing and transitional countries, New insights from Africa and the Eastern Mediterranean, WHO, 2011: 5-6
5.5.2 Public Health Service in South Africa

National data on the occurrence of PSIs in public health establishments is not currently available. Therefore rapid assessment of the contents of provincial policies/protocols/guidelines to manage PSIs was conducted by the National Department of Health (NDOH) in June 2014. Eight of the nine provinces responded on the request by NDOH to avail their provincial policies/guidelines. One of the eight provinces that responded did not have an official approved provincial policy to manage PSIs as the province was still in the process of developing the policy. Wide variations were found in the management of PSIs amongst provinces. Categories of incident types also varied widely. Although some provinces used a few similar categories, no province used the same set of categories. There were also differences in the processes followed to manage PSIs as well as the forms used to capture PSIs. Some similarities were found in the manner in which adverse events were escalated to District and Provincial Offices if the PSIs were of a serious nature, had legal implications or appeared in the media. Five of the provinces used the “Safety Assessment Code (SAC)” matrix to risk rate PSIs. The majority of the provinces did not include templates to collect statistical data on PSIs in their policies/protocols/guidelines to manage PSIs.

5.6 Minimum Information Model

One of the long standing aspirations of the World Health Organization (WHO) was to turn the failures of health-care into global learning opportunities to accelerate and expand patient safety improvement. Weak patient safety cultures, together with the fear of punishment, prevent to some extent the reporting of PSIs. In addition, the scarcity of universally applicable and common standards for collecting, storing, classifying, analysing and interpreting incident reports as well as other clinical data is a significant barrier to effective reporting and learning. Therefore the WHO developed a tiered classification system in the form of an Information Model. There are three tiered classification models:

- first tier - Minimal Information Model (MIM)
- second tier - Intermediate Information Model
- third tier - Full Information Model.
The detail of the data collected increases as the tiers progresses. The Minimal Information Model may be seen as the first layer of a fuller local reporting system tailored to its own context.

For the South African context the MIM will be used as a starting point to strengthen effective reporting by identifying the key data features that can provide maximum meaningful learning.

In general, reporting systems aim to satisfy three main objectives:

- description (What happened)
- explanation (Why it happened)
- remedial (what were the reactions).

The MIM includes these three main objectives into the following classifications:

- incident identification
  - patient (a person who is a direct or indirect recipient of healthcare and involved directly or indirectly in the PSI)
  - time (date and time of day when the incident occurred)
  - location (physical environment in which a PSI occurs)
  - Agent(s) involved (agent with the potential to cause harm. It refers to the product, device, person or any elements involved in the incident with the potential to influence it)
- incident type (a descriptive term for a category made up of incidents of a common nature, grouped because of shared, agreed features)
- incident outcomes (all impacts upon a patient or an organisation wholly or partially attributable to an incident)
- resulting actions (identify immediate or indirect action taken that relates to the patient or the organisation to improve the situation or prevent the reoccurrence of an incident)
- reporter (person who collects and writes information about the incident)

The classes for the agents (contributing factor), incident type and incident outcome are defined by the WHO’s framework for the International Classification for Patient Safety.

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Safety (ICPS). The classes as set out by the WHO are very extensive, therefore the rapid assessment of the contents of provincial patient safety or adverse event policies/protocols/guidelines that were collected by the NDOH in June 2014 were used to reduce the concepts of each of the three classes for the South African context.

Table 1 set out the classification of the MIM and also provide a description of the classifications.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Description of classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Incident Identification</td>
<td></td>
</tr>
<tr>
<td>Patient</td>
<td>Name, Surname, Patient file, Gender, Age</td>
</tr>
<tr>
<td>Date and Time</td>
<td>Specific date and time when incident took place</td>
</tr>
<tr>
<td>Location</td>
<td>Ward, department, section where incident took place</td>
</tr>
<tr>
<td>Agents involved</td>
<td>See annexure A</td>
</tr>
<tr>
<td>b. Incident type</td>
<td>See annexure B</td>
</tr>
<tr>
<td>c. Incident outcomes</td>
<td>See annexure C</td>
</tr>
<tr>
<td>d. Resulting actions</td>
<td>Note down action implemented to prevent a similar incident from re-occurring</td>
</tr>
<tr>
<td>e. Reporter</td>
<td>Name and Surname, designation, contact details. Note that the anonymity of reporting should be considered at all level to increase adherence to the procedure. It is not recommended in cases where the incident result in legal action.</td>
</tr>
</tbody>
</table>

Table 1: Classification and description for MIM

5.7 Designation of members of Patient Safety Committees

The National policy to manage PSIs stipulates the terms of reference of the Patient Safety Committees that must be established at hospital, sub-district/district, provincial and national level. Sub district/district offices must identify a designated Patient Safety Champions in every Primary Health Care establishment.

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*Conceptual framework for the International Classification for Patient Safety, WHO, 2009: 32-47 and 90-95*
The members of these committees as set out in section 8.1 to 8.4 gives guidance to Patient Safety Committees on the designation of the members to include in their committees.

5.7.1 Designation of members for hospital Patient Safety Committees

Members of the Patient Safety Committee should be constituted by, but not limited to, staff members with the following designations:

- Chief Executive Officer
- Clinical Manager (Chairperson)
- Quality Assurance manager
- Nursing manager/s
- Representative of the Infection and prevention control section
- Complaints manager/Public relations officer
- Head of corporate services or representative of the Labour Relations division
- Representative of the Occupational health and Safety division
- On an ad-hoc basis:
  - Nursing Managers of areas where the incidents took place
  - Clinical Heads of areas where the incidents took place

5.7.2 Designation of members for sub-district/district offices Patient Safety Committees

Members should be constituted by, but not limited to, staff members with the following designations:

- District Quality Assurance manager (Chairperson)
- District manager
- Representative from district hospitals
- Member(s) of District Specialist Teams
- Representative of the Labour Relations division
- On an ad-hoc basis:
  - Facility Managers of health establishment where incidents took place
  - Managers of programmes
5.7.3 Designations of Patient Safety Committee members for provincial offices

Members should constitute, but is not limited to, staff members with the following designations:

- Head of Quality Assurance division/ and or designated person (Chairperson)
- Clinical specialists to be co-opted according to expertise required to give an opinion on the adverse event cases that will be presented
- Nurse expert
- Representative from the Legal Advisors division
- Representative from the Labour Relations division
- On an ad-hoc basis:
  - Chair persons of district/ sub district Patient Safety committees where the incident took place
  - Chair persons from hospital Patient Safety committees where the incident took place

The Committee can co-opt members as required based on the need.

5.7.4 Designations of Patient Safety Incident Committee members for national office

- Chief Director or Director for Hospital services
- Chief Director or Director for Primary Health Care
- Chief Director or Director for Quality Assurance (Chairperson)
- Chief Director or Director for Legal services
- Chief Director or Director for Monitoring and Evaluation
- Chief Director or Director for Policy Coordination and Integrated Planning

The Committee can co-opt members as required based on the need.
5.8 Management of patient safety incidents

Once a PSI has been identified a series of action steps must be followed to ensure the effective management of PSIs. These action steps are as follows:

1. Identifying PSIs
2. Immediate action taken
3. Prioritisations
4. Notification
5. Investigation
6. Classification
7. Analysis
8. Implementation of recommendations
9. Learning

The action steps are explained in detail in sections 5.8.1 to 5.8.9 and set out in figure 1 as a flow diagram.

5.8.1 Step 1: Identifying patient safety incidents

PSI prevention and or management can only happen if PSIs are detected in time. Although there are different mechanisms that may be used to detect PSIs, most managers get to know about PSIs in their own health establishments from tip-offs, media publications and law-suits or from complaints by patients and members of the public.

There are various ways that are used to detect PSIs without the need for additional costs. All PSIs must be reported in one central Patient Safety Incident Management Systems irrespective of the manner in which it was detected/identified. The following are some of the well-known PSI detection methods:

5.8.1.1 Patient safety incident reporting by health professionals

Most Patient Safety Incident Management Systems rely on detecting patient safety incidents through reporting by health professionals even though only a small number of PSIs are reported in this manner. Public health researchers have established that only 10 to 20 percent of errors are ever reported and, of those, 90 to 95 percent

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10 New South Wales Incident Management policy, 2014: 7-14
cause no harm to patients. Therefore information on PSIs are scanty in most establishments. The reasons for under-reporting vary, hence the need for seeking alternative options of detecting PSIs. The Just Culture philosophy must be developed within health establishments to enable a conducive environment to report PSIs.

5.8.1.2 Inpatient medical record review / retrospective patient record review (Clinical Audit).

Medical records of all patients admitted or treated at a specified service area (at a specified time) are reviewed by a selected team. The process of reviewing medical records follows a defined inpatient event. The Inpatient event may comprise of five to eight outcomes i.e. death, return to operating theatre within seven days, transfer from a general ward to an intensive care unit, unplanned readmission within six weeks after discharge, increased average length of stay in hospital, patient dissatisfaction, litigation cases, etc. The intended outcome of disease intervention is agreed upon i.e. delivery of a healthy neonate, full recovery from current illness, complete alleviation of pain, improved functionality of the body part or organ, etc. Once the outcome of disease (treatment or stay in health facility) has been identified by the team, all criteria related to treatment of the condition are examined. Health professionals’ notes are examined and compared among one another.

Another example of a structured tool that can be used to review records is the Institute for Healthcare Improvement (IHI) Global Trigger Tool for Measuring Adverse Events developed by the Cambridge Institute for Healthcare Improvements. The Trigger Tool methodology is a retrospective review of a random sample of inpatient hospital records using “triggers” (or clues) to identify possible adverse events. It is important to note, however, that the IHI Global Trigger Tool is not meant to identify every single adverse event in an inpatient record. The methodology, recommended time limit for review, and random selection of records are designed to produce a sampling approach that is sufficient to determine harm rates and observe improvement over time.

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12IHI Global Trigger Tool for measuring Adverse Events (UK version) Institute for Healthcare Improvement, 2008
5.8.1.3 Focus teams
Focus teams offer an opportunity for a very rich learning environment as members within the team discuss and develop ideas. Examples of focus teams are Morbidity and Mortality review committees, clinical audit teams, Quality Assurance committees, etc. conduct focused audit on patient safety.

5.8.1.4 External sources
Patients’ families and representatives, any concerned public member (who may have not been a patient but has observed an incident happening or heard about it) and the media, can also report adverse events. Reporting of incidents may be through Speak Up campaigns, complaint management system, public representatives (e.g. hospital boards or committees), etc. Once the PSI is reported, the health department is obliged to initiate proper investigations into the allegation.

5.8.1.5 Review of record on follow-up of patients
Bearing in mind that PSIs may occur or be recognized after patient’s discharge from health care facility, a specially formulated patient’s progress form is attached to a discharge summary report. Once the PSI is detected by the health professional during patient’s follow up, the form is completed and returned to the health care facility that initially treated the patient. The alleged PSI is investigated then appropriate corrective measures are implemented. Corrective measures may include recalling patient to a facility for further treatment.

5.8.1.6 Surveys on patients’ experience of care
Regular, well-structured surveys on patients’ perception of care provide valuable information on issues related to PSIs. Although they may seem to be generic and not pinpoint the actual location of incidents, surveys on patients’ perception of care help to direct and guide managers towards critical focus area (within the health care system) that should to be improved.

5.8.1.7 Safety walk rounds
Safety walk rounds consist of a core group of senior managers walking through the health facility on a regular basis. The rounds take place in six to eight service areas
of the health facility. Overall rounds should last for 60 or more minutes. During rounds, operational staff members, excluding their immediate managers, are asked questions about their knowledge of any PSIs using a safety rounds ‘toolbox’ – see Annexure D. All comments by the staff are recorded. The management team also conducts its own observations across all the service areas. After each walk round, the team meets for debriefing. All responses are collated, categorised into categories and prioritised according to severity and impact. Managers are delegated to resolve the identified safety concerns. The best way is to use an action plan to guide progress and evaluation. The managers are also expected to keep hospital executives informed of their progress and challenges that demand the intervention of senior managers. The summary of the safety walk rounds, including results of interventions, is presented at the monthly management meeting or any other regular platform designed by the health facility. The presentation of interventions may be presented in a narrative format or graphically.

5.8.1.8 Use data to identify and guide management of patient safety incidents

Many organizations have local, provincial and national information system e.g. District Health Information System from which analysis can be made. It is imperative that managers investigate negative trends using statistical data on PSIs and subsequently improve such performance. In addition to identifying PSIs, various important issues other than PSIs, e.g. technical expertise of data capturers, can be identified.

5.8.1.9 Research studies and findings

Research studies may include any patient safety related research study that might have been conducted over time. An individual, group or the health facility might have conducted the research. Research findings and recommendations are considered in Quality Improvement projects and are then implemented.

5.8.2 Step 2: Immediate action

Following identification of a PSI, it may be necessary to take immediate actions to mitigate the harmful consequences of the incident. These actions may include:

- providing immediate care to individuals involved in the incident (patient, staff or visitors) to prevent the harm from becoming worse
• making the situation/scene safe to prevent immediate recurrence of the event
• gathering basic information from staff while the details are still fresh in the minds of the involved clinicians
• notify South African Police Service (SAP), health establishment’s security or other institution where applicable

5.8.3 Step 3: Prioritisation

The purpose of prioritisation is to ensure that a standardised, objective measure of severity is allocated to each incident. The Severity Assessment Code (SAC) must be used to prioritise all notifications. The key purpose of the SAC is to determine the level of investigation and action required. Therefore the degree of harm suffered should be the key consideration. Experience has demonstrated that predicting the likelihood of recurrence is not helpful as it can be unreliable.

There are three classes in the SAC, classes 1, 2 and 3. SAC 1 includes incidents where serious harm or death occurred; SAC 2 includes incidents that caused serious harm and SAC 3 includes incidents that caused mild or no harm. See Annexure E that describes the SAC.

5.8.4 Step 4: Notification

According to the WHO PSI data must be recorded and analysed in order to improve patient safety. It is equally important to develop a response system and a reporting system to improve patient safety.

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13 New South Wales Incident Management policy, 2014: 9
14 Government of Western Australian Health Department: Clinical Incident management toolkit, 2012 (updated Feb 2014): 6
15 World alliance for patient safety WHO draft guidelines for adverse event reporting and learning systems – from information to action 2005: 54
5.8.4.1 Record keeping

All PSIs must be recorded as recordkeeping is crucial in the effective management of PSIs. Data on PSIs can be reported in unstructured or structured reports.

Unstructured reports on PSIs are more narrative. The contents of reported PSIs are determined by the reporters’ discussion with the person receiving the report. Although unstructured reports carry more information and clarity, more time is needed to make some inferences then decide on the applicable action to be taken. The unstructured reports are therefore, labour intensive and time consuming as compared to the highly structured reporting systems.

Structured reporting is usually done on an electronic information system. These types of reports are conducted in a highly structured manner and require specific information or narrative description of incidents. The highly structured reporting format may require a reporter to select options from pre-defined fields. The system ensures that reports are quickly entered, readily classified, aggregated, analysed and recommendations made available within a few minutes of reporting. The preliminary findings and recommendations are made available to the Head of the facility in question for further investigation and responsive measures. Countries such as Australia, Japan, England and some health organisations in South Africa have successfully implemented structured PSI reporting on electronic information systems.

Structured PSI reporting has proven to be more effective to manage PSIs than unstructured reporting especially when data is captured on an electronic information system. Therefore for the South African public health sector structured reporting is prescribed by means of using various prescribed forms and templates to record data on PSIs.

All PSIs must be recorded on a PSI reporting form, see annexure F as an example. Section A (notification) of the form must be completed by the manager of the section where the incident took place. If the incident is a SAC1 incident, submit section A to the district or provincial office for notification. Section B (statements by staff patient or significant other) of the form must be completed by the staff, patients or significant others that were present while the incident took place. Section C (investigation) of the form must be completed by the staff member(s) that has investigated the incident, in
most cases this would be the manager(s) of the section where the incident took place.

To enable health establishments to keep statistical data on PSIs, all PSIs must be recorded in a PSI register, see annexure G. The register is a written record that contains information on PSIs. The register can be in the form of a book or separate pages filed in a file that is clearly marked that it contains PSI registers. In cases where an electronic information system is used the minimum dataset must include all fields as indicated in the patient safety register.

5.8.4.2 Incident notification to Management

All SAC 1 incidents must be reported within 24 hours to the Provincial or District office depending on the line of reporting as determined by the specific province. The reporting of SAC 1 incidents is mandatory. PSIs with a SAC rating of 2 or 3 must be reported to executive management within the facility. The provincial, district and facility protocol or standard operating procedure to manage PSIs must include a flow diagram that details the process flow to be followed when reporting PSIs.

5.8.4.3 Initial notification to patient

Initial disclosure should take place as early as possible after the incident. Information should be provided to the patient and family in a clear and simple language, and the occurring error recognised and explained. The provider should share with the patient and/or their family or carer what is known about the incident and what actions have been taken to immediately mitigate or remediate the harm to the patient. The discussion should focus on the condition as it currently exists i.e. no assumptions and uncertain future actions should be communicated at this stage. It is the obligation of the health care organization to provide support or assistance as required to patients, family and health professionals involved. Patients, family and healthcare professionals often also require psychological support.

Disclosure involves health care providers as well as patients. Depending on the severity and impact of the PSI, people to be called and the venue for disclosure should be carefully decided on. The health care provider at the service site may
disclose some of the less serious PSI, such as close calls. More serious PSIs may be communicated in designated areas such as the duty room or manager’s office.

The following, depending on careful assessment of circumstances, may be communicated to the patient or representative:

- the facts of the harm and incident known at that time
- steps taken for ongoing care of the patient
- an expression of sympathy by the health care provider or organisation
- a brief overview of the investigative process that will follow including time lines and what the patient should expect from the analysis
- an offer of future meetings as well as key contact information
- time for patients and or representative to ask questions. Provide answers that you are sure of at the time. Where uncertain, promise to and seek answers for the patient
- where necessary offer practical and emotional support
- plan for future investigation and treatment required
- remedial action taken
- the relevant health professional involved can at this stage convey their apology in a sincere manner
- systems to support the health professionals involved must also be in place

5.8.5 Step 5: Investigation

All notified incidents require investigation at an appropriate level. The SAC applied in the prioritisation stage guides the level of investigation.

An investigative report should include:

- a detailed chronology of circumstances leading to the incident
- a summary of the interviews conducted with staff, patient or significant other
- root cause analysis that includes the actions to be taken
- conclusions by Patient Safety committee
- recommendations arising from the investigation

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16 The Pan American Health Organization adverse events policy and guidelines, December 2011: 7-8
PSIs must be investigated by means of systems Root Cause Analysis (RCA) to determine cause and then to ensure prompt improvement to prevent the same PSI from reoccurring. Underlying causes must be explored and solutions or corrective actions to improve the system must be identified. Remedial actions can include but is not limited to, appropriated training or education of staff members, correction of system failures and appropriate disciplinary action in cases where reckless behaviour was identified. Incidents where a health professional displayed reckless behaviour must also be referred to the relevant professional body for further management. See Annexure F, section C, number 2b of the PSI reporting form for a framework for RCA and action plans.

In cases where staff was found to be the cause of the incident the just culture must be applied. A just culture recognises that:

- human error and faulty systems can cause an error
- individual practitioners should not be held accountable for system failings over which they have no control
- competent professionals make mistakes
- even competent professionals will develop unhealthy norms (shortcuts, “routine rule violations”).

Although the Just Culture does not support the punishment of staff that made mistakes, it has zero tolerance for reckless behaviour. It supports coaching and education if the mistake was inadvertent, or occurred in a system that was not supportive of safety.

The Just Culture is founded on three behaviours, Human error, At-risk Behaviour and Reckless behaviour. Health Establishments should console those who commit human error, coach those who are guilty of at-risk behaviour and discipline those with reckless behaviour (see Table 2)\(^{17}\). In some cases where an incident is reported as a PSI the outcome of the investigation can also conclude that there no error occurred.

\(^{17}\)The ABC of the Just Culture: The path to building a dependable organization. Alejandro Alfonso Díaz, September 2011
A mechanism to assess individual versus system accountability has been developed by James Reason in his “Unsafe Acts” algorithm (Reason 1997), and is a practical method of ensuring a just assessments of individual acts based on the Just Culture. This algorithm was put into practical use for managers of health establishments by streamlining the process to four simple questions:

- Did the employee intend to cause harm?
- Did the employee come to work drunk or equally impaired?
- Did the employee knowingly and unreasonably increase risk?
- Would another similarly trained and skilled employee in the same situation act in a similar manner?

If the first three answers are “No” and the last “Yes” the origin of the unsafe act lies in the organisation, not the individual\(^1\)\(^8\).

The Just Culture model fosters increased safety in the delivery of healthcare by promoting transparency, fairness, communication and learning\(^1\)\(^9\).

Investigation of PSIs must be concluded within 60 working days from the occurrence of the incident. A PSI is viewed as concluded under the following circumstances:

- The case has been investigated and the committee for review of PSIs has concluded an outcome with recommendations.
- Written confirmation has been received that the establishment is being sued and therefore the case will be further managed by a court of law.

\(^1\) Fair and Just Culture, Team Behavior, and Leadership Engagement: The Tools to Achieve High Reliability. Health Services Research, August 2006

\(^1\)\(^9\) Patient Safety handbook, Barbary J Youngberg, 2012, Chapter 13:178
• The case has been referred to the Labour Relations section for further management.

In the last two instances although the case will be closed on the PSI Management Reporting System, the outcome of the investigations conducted by the relevant organisations/sections must be noted in the PSI reporting form once it has been concluded by either a court of Law or the Labour Relations section.

5.8.6 Step 6: Classification

A classification comprises of a set of concepts linked by semantic relationships. It provides a structure for organising information to be used for a variety of other purposes, including health establishment, district, provincial and national statistics, descriptive studies and evaluative research.

A uniform classification system according to the Minimal Information Model as described in section 5.6 ensures accurate data analysis. All PSIs must be classified according to the following classes:

• agents (contributing factors), see annexure A
• incident type, see annexure B
• incident outcome, see annexure C

5.8.7 Step 7: Analysis

Regardless of the objective of the Patient Safety incident Management Reporting System neither the act of reporting nor the collection of data will reduce the occurrence of PSIs unless the data are analysed and recommendations are made for change and these changes are implemented.

There are three indicators to monitor PSIs, PSI case closure rate, SAC 1 incident reported within 24 hours rate and PSI case closure within 60 working days rate. The data for these indicators must be collected from the PSI registers that must be completed on a monthly basis. The calculation of the indicators is set out in table 3.
Indicator name | Calculation of Indicator
--- | ---
Patient Safety Incident case closure rate | Total number of PSI case closed in the reporting month
 | Total number of PSI cases reported in the reporting month X 100
Severity assessment code (SAC) 1 incident reported within in 24 hours rate | Total number of SAC 1 incidents that were reported within 24 hours in the reporting month
 | Total number of SAC 1 incidents in the reporting month X 100
Patient Safety Incident case closure within 60 working days rate | Total number of PSI cases closed within 60 days in the reporting month
 | Total number of PSI cases closed in the reporting month X 100

Table 3: Calculation of Indicators for patient safety incidents

Health establishments must on a monthly basis submit reports to their district/provincial office. Provincial offices must report to the National Office quarterly. The data for the prescribed reporting templates can be submitted manually or electronically in cases where a web-based application is available.

The following statistical data must be recorded and submitted:

- data on classifications of agents involved, see annexure H
- data on classifications of incident type, see annexure I
- data on classifications of incident outcome, see annexure J
- indicators for PSIs, see annexure K

Statistical data for SAC 1 incidents must be kept separate from statistical data on SAC 2 and SAC 3 incidents.

In cases where an electronic information system is used to capture the data on PSIs, the data fields as indicated in the patient safety register must be used to populate the data onto annexures H to K.

5.8.8 Step 8: Implementation of recommendations

Recommendations from the investigations and reviews must be implemented to ensure the development of better systems to ensure improved practices. The Root Cause Analysis indicates the time frames as well as the staff responsible for
implementation, see annexure F, section C, number 2b (Framework for RCA and actions).

Patient Safety committees at various levels in the health system are responsible for ongoing monitoring that is required to ensure recommendations are addressed in a timely manner and to evaluate the success of any action taken to achieve improvement.

5.8.9 Step 9: Learning

The fundamental role of PSI reporting systems is to enhance patient safety by learning from failures of the health-care system. Reporting can lead to learning and improved safety through:

- the generation of alerts regarding significant new hazards,
- feedback and
- analyzing reports.

5.8.9.1 Alerts

Reports can provide sufficient data to enable analysts to recognize a significant new hazard and generate an alert. These alerts must be published as widely as possible to prevent the reoccurrence of the newly identified hazard.

5.8.9.2 Feedback

Feedback on the progress and outcome of the PSI is an important component of a successful Patient Safety Incident Management System. The patient as well as the staff must receive feedback on the management of PSIs.

Feedback to staff

To ensure that learning takes place it is essential that feedback is given to all staff on the results/outcomes of investigations in a timely manner. Feedback must be provided to staff involved in the incident and should occur as soon as possible,

World alliance for patient safety WHO draft guidelines for adverse event reporting and learning systems – from information to action 2005: 13
including after the completion of the RCA. The information to be provided is limited to that which is included in the final RCA report. This way staff involved in the incident will be informed of the conclusions reached by the team and of the recommendations arising from any investigation.

In order to close the loop and ensure learning, feedback must also be given to the broader group of clinical providers and managers within the organisation. This feedback will focus on the lessons to be learned by the organisation and system amendments that will provide a greater chance that the incident will not happen again. Such feedback and discussion could take place at; for example, ward meetings, mortality and morbidity review meetings.

Feedback should also include updates as the changes are made and improvements achieved as a result of these changes. This will also provide a level of accountability for implementation of the recommendations that come from the RCA.

**Feedback to the patient – post analysis disclosure**

Achieving a culture of patient safety requires open, honest and effective communication between the health care providers and patients. It is important that all avenues related to the occurrence of adverse events be fully investigated and made known to the patient, relatives or legal representative/s. Giving wrong information is dangerous and where there is suspicion of litigation, the facility should consult the legal representative of the provincial health department.

Patients lose trust, become anxious, fearful and angry when they sense that information is being withheld. Post analysis disclosure is reached when additional facts have been identified and the reasons for the adverse events are better understood.

Management may likely have a greater role to play at this stage and health care providers involved should be updated about the results of the analysis and encouraged to continue to participate in the discussions. Leadership or the legal counsel has to decide what information should be disclosed.
The following should be included in post analysis disclosure:

- the patient should be informed of improvement made to prevent similar events from recurring
- continued practical and emotional support should be provided as required
- re-enforcement, correction or update of information provided in previous meetings should be provided
- the patient/representative should be promised to be informed of further additional information as it unveils
- further expression of sympathy and, where necessary, regret that may include an apology with acknowledgement of responsibility for what has happened
- actions taken as a result of internal analysis that might have resulted in system improvement.

Other disclosure methodologies such as multi-patient and multi-jurisdictional disclosures, in instances where PSIs affected more than one patient, can be used to convey the message. Information provided should be as selective as possible to ensure that privacy and confidentiality of the patients is realised. Where PSIs involve more than one institution, representatives of both institutions from affected should collaborate throughout the process and send one common message.

Patients and or family members should not be sent from pillar to post while seeking answers on PSIs. Managers should not apportion blame and refer a patient/representative to other levels of care without assisting one to do so.

5.8.9.3 Analysing reports

Analysing report can reveal unrecognised trends and hazards requiring attention. Regular reports on trended aggregated data and outcomes of RCAs must be provided to the management team and clinical staff.

The most important function that a large reporting system can perform is to use the results of investigations and data analyses to formulate and disseminate recommendations for systems changes.
The series of action steps that must be followed to ensure the effective management of PSI is set out in the figure below (figure 1).

### Step 1: Identifying the Patient safety incident
- Reporting by Health professionals
- Inpatient medical record review
- Focused teams
- External sources
- Record review on follow-up of patients
- Patient Experience of Care Survey
- Safety walks
- Use of data
- Research studies

### Step 2: Immediate action taken
- Provide immediate care
- Make situation safe
- Gathering basic information
- Notify SAP and security where applicable

### Step 3: Prioritisation
- Severity Assessment Code (SAC) 1
- Severity Assessment Code 2
- Severity Assessment Code 3

### Step 4: Notification
- Record keeping: Patient Safety Incident (PSI) management form and PSI register
- Initial notification to province/district for SAC =1 and SAC =2&3 to management
- Initial notification (disclosure) to patient

### Step 5: Investigation
- Description of incident
- Interviews of staff members/patients
- Root Cause Analysis, includes actions to be taken
- Conclusion by Patient Safety Committee
- Recommendations

### Step 6: Classification
- Incident Identification: Patient, date and time, location, agent
- Incident type
- Incident Outcome
- Action
- Reporter

### Step 7: Analysis
- Analyse data according to type of incident
- Analyse data according to incident outcome
- Analyse data according to agent (cause) involved
- Calculate and analyse PSI indicators

### Step 8: Implementation of recommendations
- Health establishment Patient Safety Committee monitors implementation of recommendations
- Provincial/ district Patient Safety committee has an oversight function to monitor implementation of recommendations

### Step 9: Learning
- Feedback to patient / family (post analysis disclosure)
- Feedback to staff

**Figure 1: Action steps for the management of Patient Safety Incidents**
## Annexure A: Classification for agents (Contributing factors)

<table>
<thead>
<tr>
<th>Main classification</th>
<th>Sub classification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Staff Factors</strong></td>
<td>Cognitive Factors (e.g. Perception/understanding, knowledge based/problem solving (Failure to synthesise/action on available information), halo effects (is the cognitive bias where staff seen as knowledgeable or highly respected, opinions’ are followed blindly)</td>
</tr>
<tr>
<td></td>
<td>Performance Factors (e.g. Technical error in execution (physical – skill based), rule based (misapplication of good rules or application of bad rules, bias)</td>
</tr>
<tr>
<td></td>
<td>Behaviour (e.g. risky, reckless, sabotage/criminal act, attention issues (absentmindedness/forgetfulness, out of sight, out of mind, distraction), fatigue/exhaustion, overconfidence)</td>
</tr>
<tr>
<td></td>
<td>Communication Factors (e.g. language difficulties, communication methods, health literacy)</td>
</tr>
<tr>
<td></td>
<td>Patho-Physiologic/Disease Related Factors (e.g. problems with substance abuse other mental illness)</td>
</tr>
<tr>
<td></td>
<td>Emotional Factors</td>
</tr>
<tr>
<td></td>
<td>Social Factors</td>
</tr>
<tr>
<td><strong>2. Patient Factors</strong></td>
<td>Cognitive Factors (e.g. perception, understanding, knowledge based/problem solving (Failure to Synthesise/Action on available information), halo effects (is the cognitive bias where staff seen as knowledgeable or highly respected, opinions’ are followed blindly)</td>
</tr>
<tr>
<td></td>
<td>Performance Factors (Technical error in execution (physical – skill based), rule based (misapplication of good rules or application of bad rules, bias)</td>
</tr>
<tr>
<td></td>
<td>Behaviour (risky, reckless, sabotage/criminal act, attention issues (absentmindedness/forgetfulness, out of sight, out of mind, distraction), fatigue/exhaustion, overconfidence)</td>
</tr>
<tr>
<td></td>
<td>Communication Factors (e.g. language difficulties, communication methods, health literacy)</td>
</tr>
<tr>
<td></td>
<td>Patho-Physiologic/Disease Related Factors (problems with substance abuse other mental illness)</td>
</tr>
<tr>
<td></td>
<td>Emotional Factors</td>
</tr>
<tr>
<td></td>
<td>Social Factors</td>
</tr>
<tr>
<td><strong>3. Work/Environment Factors</strong></td>
<td>Physical Environment/Infrastructure</td>
</tr>
<tr>
<td></td>
<td>Remote/Long Distance from Service</td>
</tr>
<tr>
<td></td>
<td>Environmental Risk Assessment/Safety Evaluation</td>
</tr>
<tr>
<td></td>
<td>Current Code/Specifications/Regulations</td>
</tr>
<tr>
<td><strong>4. Organisational/Service Factors</strong></td>
<td>Protocols/Policies/Procedures/Processes</td>
</tr>
<tr>
<td></td>
<td>Organisational Decisions/Culture</td>
</tr>
<tr>
<td></td>
<td>Organisation of Teams</td>
</tr>
<tr>
<td><strong>5. External Factors</strong></td>
<td>Natural Environment</td>
</tr>
<tr>
<td></td>
<td>Products, Technology and Infrastructure</td>
</tr>
<tr>
<td></td>
<td>Services, Systems and Policies</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>Not specified in classification 1 to 5</td>
</tr>
</tbody>
</table>
## Annexure B: Classification for Incident Type

<table>
<thead>
<tr>
<th>Main classification</th>
<th>Sub classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Clinical Administration</td>
<td>Medical procedure performed without valid consent</td>
</tr>
<tr>
<td>2. Clinical process/procedure</td>
<td>Not performed when indicated</td>
</tr>
<tr>
<td></td>
<td>Performed on wrong patient</td>
</tr>
<tr>
<td></td>
<td>Wrong process/procedure/treatment performed</td>
</tr>
<tr>
<td></td>
<td>Performed on wrong body part/site/side</td>
</tr>
<tr>
<td></td>
<td>Retention of foreign object during surgery</td>
</tr>
<tr>
<td></td>
<td>Pressure sores acquired during admission</td>
</tr>
<tr>
<td></td>
<td>Maternal death</td>
</tr>
<tr>
<td></td>
<td>Neonatal death</td>
</tr>
<tr>
<td></td>
<td>Fresh still birth</td>
</tr>
<tr>
<td>3. Health Care associated infections</td>
<td>Bloodstream</td>
</tr>
<tr>
<td></td>
<td>Surgical Site</td>
</tr>
<tr>
<td></td>
<td>Pneumonia</td>
</tr>
<tr>
<td></td>
<td>Urinary drain/tube</td>
</tr>
<tr>
<td></td>
<td>Communicable diseases</td>
</tr>
<tr>
<td>4. Medication/IV fluids</td>
<td>Wrong dispensing</td>
</tr>
<tr>
<td></td>
<td>Omitted medicine or dose</td>
</tr>
<tr>
<td></td>
<td>Medicine not available</td>
</tr>
<tr>
<td></td>
<td>Adverse Drug Reaction</td>
</tr>
<tr>
<td></td>
<td>Wrong medicine</td>
</tr>
<tr>
<td></td>
<td>Wrong dose/strength administered</td>
</tr>
<tr>
<td></td>
<td>Wrong patient</td>
</tr>
<tr>
<td></td>
<td>Wrong frequency</td>
</tr>
<tr>
<td></td>
<td>Wrong route</td>
</tr>
<tr>
<td></td>
<td>Prescription Error</td>
</tr>
<tr>
<td>5. Blood or blood products</td>
<td>Acute transfusion reactions</td>
</tr>
<tr>
<td></td>
<td>Delayed transfusion reactions/events (including Transfusion Transmitted Infections)</td>
</tr>
<tr>
<td></td>
<td>Errors- wrong blood/blood products</td>
</tr>
<tr>
<td>6. Medical device/equipment/</td>
<td>Lack of availability</td>
</tr>
<tr>
<td>Fixtures</td>
<td>Failure/malfunction</td>
</tr>
<tr>
<td>7. Behaviour</td>
<td>Suicide/Intended Self Harm</td>
</tr>
<tr>
<td></td>
<td>Attempted suicide</td>
</tr>
<tr>
<td></td>
<td>Sexual assault by staff member</td>
</tr>
<tr>
<td></td>
<td>Sexual assault by fellow patient or visitor</td>
</tr>
<tr>
<td></td>
<td>Physical Assault by staff member</td>
</tr>
<tr>
<td></td>
<td>Physical assault by fellow patient or visitor</td>
</tr>
<tr>
<td></td>
<td>Exploitation, abuse, neglect or degrading treatment by fellow patient or visitor</td>
</tr>
<tr>
<td></td>
<td>Exploitation, abuse, neglect or degrading treatment by staff member</td>
</tr>
<tr>
<td></td>
<td>Wandering/Absconding/Missing</td>
</tr>
<tr>
<td>8. Patient accidents</td>
<td>Falls</td>
</tr>
<tr>
<td>9. Infrastructure/Buildings/Fixtures</td>
<td>Damaged/Faulty/Worn</td>
</tr>
<tr>
<td></td>
<td>Non-Existent/Inadequate</td>
</tr>
<tr>
<td>10. Resources/Organisational</td>
<td>Bed/Service Availability/Adequacy</td>
</tr>
<tr>
<td>Management</td>
<td>Human Resource/Staff Availability/Adequacy</td>
</tr>
<tr>
<td></td>
<td>Protocols/Policy/Procedure/Guideline/Availibility/Adequacy</td>
</tr>
<tr>
<td>11. Other</td>
<td>Any other incident not listed in classification 1 to 10</td>
</tr>
</tbody>
</table>
Annexure C: Classification for incident outcome

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PATIENT OUTCOME</strong></td>
<td></td>
</tr>
<tr>
<td>1. None</td>
<td>Patient outcome is not symptomatic or no symptoms detected and no treatment is required.</td>
</tr>
<tr>
<td>2. Mild</td>
<td>Patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (e.g., extra observation, investigation, review or minor treatment) is required.</td>
</tr>
<tr>
<td>3. Moderate</td>
<td>Patient outcome is symptomatic, requiring intervention (e.g., additional operative procedure; additional therapeutic treatment), an increased length of stay, or causing permanent or long term harm or loss of function.</td>
</tr>
<tr>
<td>4. Severe</td>
<td>Patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function.</td>
</tr>
<tr>
<td>5. Death</td>
<td>On balance of probabilities, death was caused or brought forward in the short term by the incident.</td>
</tr>
</tbody>
</table>

| **ORGANISATIONAL OUTCOME**                                                                               |
| 1. Property damage                                                                                       |
| 2. Increase in required resource allocation for patient | Increased length of stay, admission to special care area, additional treatment/tests, disrupted workflow/delays for other patients, additional staff required, additional equipment required |
| 3. Media attention                                                                                       |
| 4. Formal complaint                                                                                    |
| 5. Damaged reputation                                                                                   |
| 6. Legal ramifications                                                                                  |
| 7. Other                                                                                                |
### Annexure D: Safety Walk around toolkit.

<table>
<thead>
<tr>
<th>AREA</th>
<th>FOCUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care Delivery</td>
<td>- Any special training need&lt;br&gt;- Missed or delayed orders&lt;br&gt;- Any missing care delivery issue</td>
</tr>
<tr>
<td>Communication</td>
<td>- Missing test results&lt;br&gt;- Delayed test results&lt;br&gt;- Availability of policies or procedures</td>
</tr>
<tr>
<td>Environment</td>
<td>- Cleanliness&lt;br&gt;- Hand washing facilities&lt;br&gt;- Sanitary facilities&lt;br&gt;- Exposed electrical wires / broken glasses / broken walls / pilling paint&lt;br&gt;- Waste bins with plastic lining and lid</td>
</tr>
<tr>
<td>Equipment</td>
<td>- Availability of resuscitation / life saving equipment&lt;br&gt;- Functionality of resuscitation / life saving equipment&lt;br&gt;- Proper storage of resuscitation / life saving equipment&lt;br&gt;- Control list of resuscitation / life saving equipment</td>
</tr>
<tr>
<td>Intra-departmental transport</td>
<td>- Adequate communication between the departments e.g. porters, radiology, wards to wards, operating theatre and wards, etc&lt;br&gt;- Availability of processes for providing staff to accompany and or stay with patient</td>
</tr>
<tr>
<td>Medication</td>
<td>- Consistence naming of medications (generic vs trade names)&lt;br&gt;- Proper identification of patients&lt;br&gt;- Procedure for medicine administration&lt;br&gt;- Procedure for safekeeping of medication</td>
</tr>
<tr>
<td>Security</td>
<td>- Ability to distinguish patients from visitors&lt;br&gt;- Ability to distinguish different staff categories among disciplines&lt;br&gt;- Ability to control / monitor visitors and patients movement in / out of care areas</td>
</tr>
<tr>
<td>Staffing</td>
<td>- Staff patient ratio (consider acuity levels)&lt;br&gt;- Appropriate skill mix</td>
</tr>
</tbody>
</table>
### Annexure E: Prioritisation - Severity Assessment Code (SAC)

<table>
<thead>
<tr>
<th>SAC 1</th>
<th>SAC 2</th>
<th>SAC 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Actual/potential consequence to patient</strong></td>
<td><strong>Moderate harm</strong></td>
<td><strong>Minor or no harm</strong></td>
</tr>
<tr>
<td>Serious harm or death that is/could be specifically caused by healthcare rather than the patient’s underlying condition or illness</td>
<td>Moderate harm that is/could be specifically caused by healthcare rather than the patient’s underlying condition or illness</td>
<td>Minor or no harm that is/could be specifically caused by healthcare rather than the patient’s underlying condition or illness</td>
</tr>
<tr>
<td><strong>Type of event/incident</strong></td>
<td><strong>Incidents include but are not limited to the following:</strong></td>
<td><strong>Incidents include but are not limited to the following:</strong></td>
</tr>
<tr>
<td>• Procedure involving the wrong patient or body part resulting in death or major permanent loss of function</td>
<td>• Moderate harm resulting in increased length of stay (More than 72 hours to 7 days)</td>
<td>• Minor harm resulting in increased length of stay of up to 72 hours</td>
</tr>
<tr>
<td>• Retained instruments or other material after surgery</td>
<td>• Additional investigations performed</td>
<td>• No harm</td>
</tr>
<tr>
<td>• Wrong surgical procedure</td>
<td>• Referral to another clinician</td>
<td>• Only first aid treatment required</td>
</tr>
<tr>
<td>• Surgical site infections that lead to death or morbidity</td>
<td>• Surgical intervention</td>
<td>• Near miss that could have resulted in minor harm</td>
</tr>
<tr>
<td>• Suicide of a patient in an inpatient unit</td>
<td>• Medical intervention</td>
<td>• ADR that resulted in minor or no harm</td>
</tr>
<tr>
<td>• Death or serious morbidity due to assault or injury</td>
<td>• Moderate harm caused by a near miss</td>
<td>• Blood transfusion reaction that resulted in minor or no harm</td>
</tr>
<tr>
<td>• Nosocomial infections resulting in death or neurological damage</td>
<td>• ADR that resulted in moderate harm</td>
<td></td>
</tr>
<tr>
<td>• Blood transfusion that caused serious harm or death</td>
<td>• Blood transfusion reaction that resulted in moderate harm</td>
<td></td>
</tr>
<tr>
<td>• Medication error resulting in death of a patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Adverse drug reaction (ADR) that results in death or is life-threatening</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Maternal death or serious morbidity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Neonatal death or serious morbidity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Missing/swopped/abscond patient and assisted or involuntary mental health care user/mental ill prisoner/State patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Any other clinical incident which results in serious harm or death of a patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Action required</strong></td>
<td><strong>Action required</strong></td>
<td><strong>Action required</strong></td>
</tr>
<tr>
<td>• Notify management immediately</td>
<td>• Notify management within 24 hours</td>
<td></td>
</tr>
<tr>
<td>• Submit a notification to provincial/district office within 24 hours</td>
<td>• Conduct a formalised investigation</td>
<td></td>
</tr>
<tr>
<td>• Conduct a formalised investigation</td>
<td>• In cases of an ADR notify the National Adverse Drug Event Monitoring Centre of the Medicines Control Council (see annexure N, form ARF1). If the ADR was caused by Anti-retroviral drugs or medicines for the treatment of tuberculosis, it must also be reported to the National Pharmacovigilance Centre for Public Health Programs (see annexure O, form 31a).</td>
<td></td>
</tr>
<tr>
<td>• In cases of unnatural deaths, report it to the South African Police Service and refer to Forensic Pathological Services</td>
<td>• In cases where a Mental Health Care user was subjected to physical or other abuse, was exploited, neglected or received degrading treatment. Complete MHCA 02 (annexure M)</td>
<td></td>
</tr>
<tr>
<td>• In cases where an assisted or involuntary mental health care user, mentally ill prisoner or State patient has absconded, notify and request the South African Police Service to locate, apprehend and return the patient to the relevant health establishment. Complete MHCA 25 (annexure L) and submit to the relevant authority as indicated on the form</td>
<td>• In case of a blood transfusion reaction that did not cause serious harm or death, notify the blood transfusion service and submit</td>
<td></td>
</tr>
<tr>
<td>• In cases where a Mental Health Care user was subjected to physical or other abuse, was exploited, neglected or received degrading treatment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

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<table>
<thead>
<tr>
<th>Reporting requirement</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>In cases of an ADR notify the National Adverse Drug Event Monitoring Centre of the Medicines Control Council (see annexure N, form ARF1). If the ADR was caused by Anti-retroviral drugs or medicines for the treatment of tuberculosis, it must also be reported to the National Pharmacovigilance Centre for Public Health Programs (see annexure O, form 31a).</td>
<td></td>
</tr>
<tr>
<td>In cases of blood transfusion reactions notify the blood transfusion service where the blood was ordered from and submit the required documentation and samples, see annexure P.</td>
<td></td>
</tr>
<tr>
<td>Complete investigation and actions taken within 60 working days. Submit report to provincial/district office.</td>
<td></td>
</tr>
<tr>
<td>Complete investigation and actions taken within 60 working days. Submit report to management.</td>
<td></td>
</tr>
</tbody>
</table>
Annexure F: Patient Safety Incident Reporting form

**Section A** (notification) - to be completed by manager of section where incident took place. Submit section A to next level for notification for SAC 1 incidents

**Section B** (Statement by staff, patient or significant other) – to be completed by staff, patients or significant other that were directly involved while the incident took place

**Section C** (investigation) - to be completed by investigator(s) of the incident, in most cases this would be the manager(s) of section where the incident took place

**SECTION A - Notification**

<table>
<thead>
<tr>
<th>1. Type of Patient Safety Incident (PSI): Mark with an X</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Harm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Patient information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name and surname</td>
</tr>
<tr>
<td>Patient file number</td>
</tr>
<tr>
<td>Location (department/ward)</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Gender</td>
</tr>
<tr>
<td>Final Diagnosis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Staff involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name and Surname</td>
</tr>
<tr>
<td>Contact detail</td>
</tr>
<tr>
<td>Department</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Date of PSI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Time of PSI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. Date reported to next level if SAC = 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>8. No of days to report PSI with SAC = 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9. Method of detecting PSI: Mark with an X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported by health professional</td>
</tr>
<tr>
<td>Research studies</td>
</tr>
<tr>
<td>Surveys on patient experience of care</td>
</tr>
<tr>
<td>Inpatient medical review</td>
</tr>
<tr>
<td>Review of record on follow-up</td>
</tr>
<tr>
<td>External sources</td>
</tr>
<tr>
<td>Safety walk rounds</td>
</tr>
<tr>
<td>Focused teams</td>
</tr>
<tr>
<td>Use of data</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10. Short description of Patient Safety Incident (detailed information available under section B as reported by staff)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ref no:</td>
</tr>
</tbody>
</table>


11. Immediate resulting action taken to minimise harm

<table>
<thead>
<tr>
<th>Compiled by:</th>
<th>Designation:</th>
<th>Signature:</th>
<th>Date:</th>
</tr>
</thead>
</table>

12. Short description of Initial disclosure

<table>
<thead>
<tr>
<th>Compiled by:</th>
<th>Designation:</th>
<th>Signature:</th>
<th>Date:</th>
</tr>
</thead>
</table>

SECTION B- Statement by staff, patient or significant other

1. Statement by staff, patient or significant other: (Add sections for additional statements and information as needed)

<table>
<thead>
<tr>
<th>Statement 1:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compiled by:</td>
</tr>
</tbody>
</table>
## National Procedural Manual for Patient Safety Incident Reporting and Learning

### SECTION C - Investigation

<table>
<thead>
<tr>
<th>1. Category according to type – mark appropriate one with an X</th>
<th>2. Framework for Root Cause Analysis and implementation of action plans</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Clinical procedure</td>
<td>1. Staff</td>
</tr>
<tr>
<td>3. Health Care associated infections</td>
<td>Cognitive Performance</td>
</tr>
<tr>
<td>4. Medication / IV fluids</td>
<td>Behaviour Communication</td>
</tr>
<tr>
<td>5. Blood and blood products</td>
<td>Patho-Physiological / Disease</td>
</tr>
<tr>
<td>8. Patient Accidents</td>
<td>Emotional Social</td>
</tr>
<tr>
<td>Medical procedure performed without valid consent</td>
<td>2. Patient</td>
</tr>
<tr>
<td>Not performed when indicated</td>
<td>Cognitive Performance</td>
</tr>
<tr>
<td>Bloodstream</td>
<td>Behaviour Communication</td>
</tr>
<tr>
<td>Wrong dispensing</td>
<td>Patho-Physiological / Disease</td>
</tr>
<tr>
<td>Acute transfusion reactions</td>
<td>Emotional Social</td>
</tr>
<tr>
<td>Falls</td>
<td>3. Work / Environment</td>
</tr>
<tr>
<td>Performed on wrong patient</td>
<td>Physical Environmental / Infrastructure</td>
</tr>
<tr>
<td>Surgical site</td>
<td>Remote/ long distance from service</td>
</tr>
<tr>
<td>Omitted medicine or dose</td>
<td>Environmental assessment/safety Evaluation</td>
</tr>
<tr>
<td>Errors- wrong blood/ blood products</td>
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<td>Delayed transfusion reactions/ events</td>
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<td>(including Transfusion Transmitted Infections)</td>
<td>Protocols/Policies/ procedures</td>
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<td>9. Infrastructure/ Buildings/ Fixtures</td>
<td>Processes</td>
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<td>7. Behaviour</td>
<td>Organisational decisions/Culture</td>
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<tr>
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<td>Organisation of teams</td>
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<tr>
<td>10. Resources/ Organisational</td>
<td>5. External</td>
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<td>Wrong process/ procedure/ treatment performed</td>
<td>Products, Technology and Infrastructure</td>
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<td>Adverse Drug Reaction</td>
<td>Describe the factor that contributed to the event</td>
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<td>Describe the action plan to rectified the identified problem</td>
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<td>Person responsible for implementing the action plan</td>
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<td>Communicable diseases</td>
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<td>Wrong medicine</td>
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<tr>
<td>Suicide/Intended self harm</td>
<td>Exploitation, abuse, neglect or degrading treatment by staff member</td>
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<td>Bed/Service availability/ adequacy</td>
<td>3. Contributing factors</td>
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<tr>
<td>Human Resources/ Staff Availability/ Adequacy</td>
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<td>11. Other</td>
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<td>Wrong dose/ strength administered</td>
<td>5. Contributing factors</td>
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<td>Physical assault by fellow patient or visitor</td>
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<td>Fresh still born</td>
<td>3. Contributing factors</td>
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<td>Any other incident that does not fit into categories 1 to 10</td>
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<tr>
<td>Exploitation, abuse, neglect or degrading treatment by fellow patient or visitor</td>
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<tr>
<td>Protocols/Policy/procedure/guideline available/ adequate</td>
<td>4. Contributing factors</td>
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<td>Physical assault by fellow patient or visitor</td>
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<td>Exploitation, abuse, neglect or degrading treatment by staff member</td>
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### 3. Findings and recommendations by Patient Safety Committee

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<th>4. Conclusion</th>
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<td>Type of behaviour according to Just Culture: mark with a X</td>
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<tr>
<td>Patient outcome: mark with a X</td>
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<td>Referred to Labour relations</td>
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Compiled by: [Name]  
Designation: [Title]  
Signature: [Signature]  
Date: [Date]
Annexure G: Patient Safety Incident (PSI) register

HEALTH ESTABLISHMENT NAME: ____________________________________________ MONTH/YEAR_____________

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<th>SAC score</th>
<th>Reporting date of SAC 1 incidents</th>
<th># of working days to report SAC 1 incident</th>
<th>Summary of incident</th>
<th>Finding (all incidents) and recommendations by Patient Safety Committee</th>
<th>Class according to Incident type</th>
<th>Class according to agent</th>
<th>Incident outcome</th>
<th>Organisational outcome</th>
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<th>Type of closure</th>
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<th>Type of Behaviour</th>
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National Procedural Manual for Patient Safety Incident Reporting and Learning
### Annexure H: Statistical data on classification for agents (contributing factor)

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<td>Behaviour</td>
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<td>Communication factors</td>
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<td>Patho-Physiologic/Disease related Factors</td>
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<td>Emotional factors</td>
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<td>Social factors</td>
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<td>Cognitive factors</td>
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<td>Performance</td>
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<td>Behaviour</td>
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<td>Communication factors</td>
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<td>Social factors</td>
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<td>3. Work/Environment factors</td>
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<td>4. Organisational/Service factors</td>
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<td>Protocols/Policies/Procedures/</td>
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<td>Organisational decisions/culture</td>
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<td>Organisation of teams</td>
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<td>5. External Factors</td>
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<td>Products, technology and infrastructure</td>
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<tr>
<td>Services, systems and policies</td>
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<td>6. Other</td>
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* Total of agent in Column Q ÷ Grand Total of Column Q
Annexure I: Statistical data on classification according to type of Incident

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<td>2. Clinical process/ procedure</td>
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<tr>
<td>Performed on wrong patient</td>
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<tr>
<td>Wrong process/procedure/treatment performed</td>
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<td>Performed on wrong body part/site/side</td>
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<tr>
<td>Retention of foreign object during surgery</td>
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<td>Pressure sores acquired during admission</td>
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<td>Maternal death</td>
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<td>Neonatal death</td>
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<td>3. Health care associated infections</td>
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(including Transfusion Transmitted Infections)
Errors- wrong blood/ blood products

6. Medical devises/ equipment/ property
Lack of availability
Failure / malfunction

7. Behaviour
Intended Self Harm/Suicide
Attempted suicide
Sexual assault by staff
Sexual assault by fellow patient or visitor
Physical Assault by staff
Physical assault by fellow patient or visitor
Exploitation, abuse, neglect or degrading treatment by fellow patient or visitor
Exploitation, abuse, neglect or degrading treatment by staff member
Wandering/Absconding

8. Patient accidents
Falls

9. Infrastructure/ Buildings/ fixtures
Damaged/ Faulty/ Worn
Non-Existent/ Inadequate

9. Resources/ Organisational
Bed/Service Availability/Adequacy
Human Resource/Staff Availability/Adequacy
Protocols/Policy/Procedure/Guideline Availability/Adequacy

11. Other
Any other incident that does not fit into category 1 to 10

GRAND TOTAL

* Total of type in Column Q ÷ Grand Total of Column Q
### Annexure J: Statistical data on classification according to incident outcome

#### PATIENT OUTCOME

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#### ORGANISATIONAL OUTCOME

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<th>P</th>
<th>Q</th>
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<tbody>
<tr>
<td>Apr</td>
<td>May</td>
<td>Jun</td>
<td>Q1</td>
<td>Jul</td>
<td>Aug</td>
<td>Sept</td>
<td>Q2</td>
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<td>Q3</td>
<td>Jan</td>
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<td>Mar</td>
<td>Q4</td>
<td>TOT</td>
<td>AVG</td>
<td>%*</td>
</tr>
<tr>
<td>Property damage</td>
<td>Increase in required resource allocation for patient</td>
<td>Media attention</td>
<td>Formal complaint</td>
<td>Damaged reputation</td>
<td>Legal ramifications</td>
<td>Other</td>
<td>GRAND TOTAL</td>
<td></td>
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</tr>
</tbody>
</table>

* Total of outcome in Column Q ÷ Grand Total of Column Q
Annexure K: Statistical data on Indicators for Patient Safety Incidents

Name of Establishment/Province: ________________________________

Financial Year: ________________________________

<table>
<thead>
<tr>
<th>Column Name</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month:</td>
<td># PSI cases</td>
<td># PSI cases closed</td>
<td>% PSI cases closed (Column B/Column A)</td>
<td># PSI cases closed within 60 working days</td>
<td>% of PSI cases closed within 60 working days (Column D/Column B)</td>
<td># PSI SAC 1 incidents</td>
<td># SAC 1 incidents reported within 24 hours (Column F/Column G)</td>
<td></td>
</tr>
<tr>
<td>April</td>
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<td>Quarter 2</td>
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<tr>
<td>Quarter 3</td>
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<td>Quarter 4</td>
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<td>AVG</td>
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</tr>
</tbody>
</table>
FORM MHCA 25

DEPARTMENT OF HEALTH

NOTICE OF ABSCONDMENT TO SOUTH AFRICAN POLICE SERVICE (SAPS)
AND REQUEST FOR ASSISTANCE TO LOCATE, APPREHEND AND RETURN
USER

[Sections 40(4), 44(1) or 57(1) of the Act]

Surname of user.............................................................. ................................................... ..................................
First name(s) of user..............................................................................................................................
Date of birth................................................................. or estimated age.................................................
Gender: Male □ Female □
Occupation: ................................................ Marital status: S □ M □ D □ W □
Date if admission to health establishment : ...........................................................( name of establishment)
Address: .................................................................................................................................................
.................................................................................................................................................
.................................................................................................................................................
.................................................................................................................................................
Date of abscondment: ..............................................................
User is: (mark with across)
Assisted user □ Involuntary user □ State patient □ Mental ill prisoner □
Diagnosis on medical condition:
...........................................................................................................................................................
...........................................................................................................................................................
...........................................................................................................................................................
...........................................................................................................................................................
Estimation of likelihood of doing harm to self or others: (mark with a cross)
Little chance □ Reasonable chance □ High likely □ Extremely likely □
Circumstances of abscondment:
...........................................................................................................................................................
...........................................................................................................................................................
...........................................................................................................................................................
...........................................................................................................................................................
Attach full report (if available)

Your assistance in locating and apprehending the above user is appreciated

Print initials and Surname: .................................................................................................

Signature: ............................................................................................................................

(head of health establishment)

Date: ..............................................................

Place: .............................................................

[In case of an assisted or involuntary user: copy of this notice to be submitted to head of provincial department]

[In case of a state patient: copy of this notice to be submitted to Registrar or Clerk of the relevant Court official curator ad litem and head of national department]

[In the case of a mentally ill prisoner: copy of this notice to be submitted to head of the prison from where the user was initially transferred and to head of national department]
FORM MHCA 02

DEPARTMENT OF HEALTH

REPORT ON EXPLOITATION, PHYSICAL OR OTHER ABUSE, NEGLIGENCE OR DEGRADING TREATMENT OF A MENTAL HEALTH CARE USER

[Section 11(2) of the Act]

(All the information contained in this Form will be held strictly confidential).

I. ........................................................................................................................................

(name/s)

........................................................................................................................................

(address)

☐ hereby declare that I have witnessed exploitation, physical or other abuse, neglect or degrading treatment of the following mental health care user:

☐ hereby declare that I have been through exploitation, physical or other abuse, neglect or degrading treatment

A. Details of User (where known)

First Name and Surname of User..........................................................................................

Date of birth .................................. or estimated age ............................................................

Gender: Male ☐  Female ☐

Occupation ..................................  Marital status: S ☐  M ☐  D ☐  W ☐

Residential address: ................................................................. ................................................................. ................................................................. .................................................................

B. Name of health establishment or other place where the alleged incident occurred

................................................................................................................................................

Address: ................................................................. ................................................................. ................................................................. .................................................................

C. Date of incident ......................................................................................................................

D. Brief description of the User:

E. Description of the alleged incident:
OATH/AFFIRMATION

I certify that:

i. The deponent acknowledged to me that:
   a. He/she knows and understands the contents of this declaration;
   b. He/she has no objection to taking the prescribed oath;
   c. He/she considers the prescribed oath to be binding on his/her conscience;

ii. The deponent signed this declaration in my presence at ...................... on this .......... day of ......................... 20......
**Annexure N: Adverse Drug reaction and Product Quality Problem report form**

**ADVERSE DRUG REACTION AND PRODUCT QUALITY PROBLEM REPORT FORM**
*(Identities of reporter and patient will remain strictly confidential)*

**NATIONAL ADVERSE DRUG EVENT MONITORING CENTRE**
NADEMC
The Registrar of Medicines
Private Bag X 828
Pretoria, 0001

In collaboration with the WHO International Drug Monitoring Programme

---

**PATIENT INFORMATION**

Name (or initials): ...........................................................
Patient Reference Number: ...........................................
Sex: M F Age: ... DOB: ... Date/... Weight (kg) ... Height (cm) ...

**ADVERSE REACTION / PRODUCT QUALITY PROBLEM** *(tick appropriate box)*

<table>
<thead>
<tr>
<th>Adverse reaction</th>
<th>and/or Product Quality problem</th>
<th>Date of onset of reaction: ... Date/...</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Time of onset of reaction: ... hour/... min</td>
</tr>
</tbody>
</table>

**Description of reaction or problem (Include relevant tests/lab data, including dates):**

---

**1. MEDICINES / VACCINES / DEVICES (include all concomitant medicines)**

<table>
<thead>
<tr>
<th>Trade Name &amp; Batch No. (Asterisk Suspected Product)</th>
<th>Daily Dosage</th>
<th>Route</th>
<th>Date Started</th>
<th>Date Stopped</th>
<th>Reasons for use</th>
</tr>
</thead>
</table>

**ADVERSE REACTION OUTCOME (Check all that apply)**

<table>
<thead>
<tr>
<th>death</th>
<th>life-threatening</th>
<th>hospitalisation</th>
<th>Other</th>
<th>Recovered: Y N</th>
<th>Sequelae: Y N</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sequelae:</td>
</tr>
</tbody>
</table>

**Event reappeared on rechallenge:**

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
<th>Rechallenge not done</th>
</tr>
</thead>
</table>

**COMMENTS:** *(e.g. Relevant history, Allergies, Previous exposure, Baseline test results/lab data)*

---

**2. PRODUCT QUALITY PROBLEM:**

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Batch No</th>
<th>Registration No</th>
<th>Dosage form &amp; strength</th>
<th>Expiry Date</th>
<th>Size/Type of container</th>
</tr>
</thead>
</table>

**Product available for evaluation?: Y N**

**REPORTING HEALTHCARE PROFESSIONAL:**

NAME: ................................................................. QUALIFICATIONS: .................................................................
ADDRESS: ............................................................
Postal Code: ............ TEL: (........)..........................

Signature Date
This report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:
• medications (drugs, vaccines and biologicals)
• medical devices (including in-vitro diagnostics)
• complementary / alternative medicines (including traditional, herbal remedies, etc)

Report even if:
• you’re not certain the product caused the event
• you don’t have all the details

Please report especially:
• adverse drug reactions to newly marketed products
• serious reactions and interactions with all products
• adverse drug reactions which are not clearly reflected in the package insert.

Please report especially:
• suspected contamination
• questionable stability
• defective components
• poor packaging or labelling
• therapeutic failures

Important numbers:
Investigational Products and Product Quality Problems:
• fax: (012) 395-9201
• phone: (012) 395-9341

Adverse Events Following Immunisation:
• fax: (012) 395 8905
• phone: (012) 395 8914/5

Confidentiality: Identities of the reporter and patient will remain strictly confidential.

Your support of the Medicine Control Council’s adverse drug reaction monitoring programme is much appreciated. Information supplied by you will contribute to the improvement of medicine safety and therapy in South Africa.

PLEASE USE ADDRESS PROVIDED BELOW - JUST FOLD IN THIRDS, TAPE and MAIL

Postage will be paid by the Addressee
Posgeld sal deur die geadresseerde betaal word

BUSINESS REPLY SERVICE
BESIGHEIDSANTWOORDDIENS
Free Mail Number: BNT 178
Vryposnommer: BNT 178

DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID
REGISTRAR OF MEDICINES
REGISTRATEUR VAN MEDISYNE
PRIVATE BAG / PRIVAATSAK X828
PRETORIA
0001

No Postage stamp necessary if posted in the Republic of South Africa
Geen posseël nodig nie indien in die Republiek van Suid-Afrika gepos
### Patient Details:

<table>
<thead>
<tr>
<th>Patient Initials</th>
<th>Reference No</th>
<th>Age/ Age range</th>
<th>Gender</th>
<th>Pregnant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>M/F</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Allergy</th>
<th>Weight (kg)</th>
<th>Height (cm)</th>
<th>Estimated Gestational Age</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Race</th>
<th>Sub district</th>
<th>District</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coloured</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Description of Adverse Drug Reaction

Date of onset of reaction (dd/mm/yyyy)

Abdominal pain
Abnormal behavior
Anxiety
Back pain
Chills
Confusion
Depression
Diarrhoea

<table>
<thead>
<tr>
<th>Allergy</th>
<th>Abnormal behavior</th>
<th>Anxiety</th>
<th>Back pain</th>
<th>Chills</th>
<th>Confusion</th>
<th>Depression</th>
<th>Diarrhoea</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Description of Reaction or Problem (tick all that apply) – Attach additional information if required</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persistent muscle pain</td>
</tr>
<tr>
<td>Vision changes</td>
</tr>
<tr>
<td>Problems with breathing</td>
</tr>
<tr>
<td>Psychosis/hallucinations</td>
</tr>
<tr>
<td>Weight loss</td>
</tr>
<tr>
<td>Rash</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Ringing in the ears</td>
</tr>
<tr>
<td>Unusual bleeding</td>
</tr>
<tr>
<td>Unusual bruising</td>
</tr>
<tr>
<td>Unusual fatigue</td>
</tr>
<tr>
<td>Violent behavior</td>
</tr>
</tbody>
</table>

### Adverse Reaction Outcome/Intervention

ADR subsided after removing suspected drug
ADR reappeared after restarting drug
Discontinued suspected drug
Replaced by
Decreased dose
Treated ADR with
Other

### Laboratory Results

<table>
<thead>
<tr>
<th>Date</th>
<th>K+</th>
<th>Creat</th>
<th>eGFR</th>
<th>ALT</th>
<th>AST</th>
<th>Hb</th>
<th>Platelets</th>
<th>CD4</th>
<th>Viral Load</th>
<th>Lact</th>
<th>Other</th>
</tr>
</thead>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

### Medicines (And Concomitant Medicines, Including Herbal Products)

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Suspect drug/Trade Name</th>
<th>Dose</th>
<th>Interval</th>
<th>Route</th>
<th>Date started</th>
<th>Date stopped</th>
<th>Prescriber (Dr/Pharm/Nurse)</th>
</tr>
</thead>
</table>

### Concomitant Medical Condition(s)

- HTN
- DM
- KS
- Hep B
- PCP
- Esophageal Candidiasis
- Oropharyngeal Candidiasis
- Crypt Meningitis
- Renal dysfunction
- Hepatic dysfunction
- TB
- Other/s

### Reported By:

<table>
<thead>
<tr>
<th>Name</th>
<th>Highest Qualification</th>
<th>Designation</th>
<th>Email</th>
<th>Tel</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

**THIS REPORT IS NOT AN ADMISSION THAT THE REPORTER OR THE SUSPECTED DRUG(S) CAUSED THE ADR.**
Instructions on filling the ADR Report

A) Patient Details – All fields to be completed

B) Medicines (and Concomitant medicines, including herbal products) – All fields to be completed as per the example below:

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Suspect drug/Trade Name</th>
<th>Dose</th>
<th>Interval</th>
<th>Route</th>
<th>Date started</th>
<th>Date stopped</th>
<th>Prescriber (Dr/Pharm/Nurse)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZT</td>
<td>Retrovir</td>
<td>300mg</td>
<td>BID</td>
<td>PO</td>
<td>16-Oct-2014</td>
<td>NA</td>
<td>Doctor</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>Panado</td>
<td>1g</td>
<td>TDS</td>
<td>PO</td>
<td>16-Oct-2014</td>
<td>19-Oct-2014</td>
<td>Nurse</td>
</tr>
<tr>
<td>St John’s Wort</td>
<td></td>
<td>2 drops</td>
<td>TDS</td>
<td>PO</td>
<td>16-Sep-2014</td>
<td></td>
<td>Pharmacist</td>
</tr>
</tbody>
</table>

In the first column, please insert the accepted abbreviation of the name of the medicine or the name of the medicine the patient is taking (1 or AZT or zidovudine in the example), in the second column, insert the name of the drug suspected of causing the ADR, preferably its trade name (in this case the Trade name is Retrovir). You should then enter the dose, route of administration, the date started and stopped (where applicable) and the professional category of the prescriber namely, Doctor, pharmacist or nurse.

C) Adverse Drug Reaction – Please report any suspected ADR. Report even if you do not have all the details. Please tick ADRs presented in the form as appropriate. If they do not appear on the list, please complete in the section labelled other. Please provide as much detail as possible.

D) Laboratory Results – Please select the laboratory results and write the value. (BL = Baseline; Cur = Current). If they are not among the ones listed, there is a section provided for other lab results. Please complete in as much detail as possible.

E) Adverse Drug Reaction Outcome – Please complete the Intervention, action taken and patient outcome in all fields. A section is provided in cases where interventions, actions and outcomes other than those provided occur.

F) Relevant Clinical History – Please complete all fields in this section

G) Concomitant Medical Conditions – Please complete all fields in this section. If they are not among the ones listed, there is a section provided for other lab results. Please complete in as much detail as possible.

H) Reported by – Please complete all fields. Your contact details may be required in case of follow up to clarify information

Abbreviations

- AZT = Zidovudine
- 3TC = lamivudine
- ABC = Abacavir
- APV = amprenavir
- ATV = atazanavir
- d4T = stavudine
- ddC = zalcitabine
- ddi = didanosine
- DLV = delavirdine
- DRV = darunavir
- ETR = efavirine
- FPV = fosamprenavir
- FTC = Emtricitabine
- IDV = indinavir
- MVC = maraviroc
- Nfv = nelﬁnavir
- NVP = Nevirapine
- RAL = raltegravir
- SQV = saquinavir
- TDF = Tenofovir
- TPV = tipranavir
- R = Rifampicin
- H = Isoniazid
- E = Ethambutol
- Z = Pyrazinamide
- Km = Kanamycin
- Lzd = Linezolid
- TRD = Terizidone
- Pto = Protonamide
- Cs = Cycloserine
- Cfx = Ciprofloxacin
- Azi = Azithromycin
- Cot = Clarithromycin
- Km = Capreomycin
- Mfx = Moxifloxacin
- Cs = Cinolamine
- Gfx = Gatifloxacin
- Eto = Ethionamide
- ENF = Enfuvirtide
- RTV = ritonavir
- LPV = lopinavir
- PAS = para-aminosalicylic acid
- AmCl = Amoxicillin/Clavulanic Acid
- PAS24 = Experimental Nitroimidazole drug
Annexure P: Blood transfusion reaction form

South African National Blood Service
2 Constantia Boulevard, Constantia Kloof Extension 22, Roodepoort 1709
Toll Free: 0800 11 9031

TRANSFUSION REACTION FORM

Important: Please read this pamphlet before commencing the transfusion

Responsibilities of the Doctor Transfusing a Patient with Blood or a Blood Component:

1. Discuss the benefits and the potential risks of blood transfusion and obtain informed consent from the patient. All transfusions must be medically justifiable and alternatives to a blood transfusion need to be considered.
2. Check that the certificate of compatibility on the container has been completed correctly.
3. Ensure that the patient is satisfactorily identified as the correct patient for whom the blood or blood component in each unit is intended.
4. Verify that a pre-transfusion compatibility test has been carried out and ensure that a record is kept thereof. In case of extreme emergency, blood may be transfused without a pre-transfusion compatibility test provided that such a test is performed when possible, unless the doctor considers such a test impractical or unnecessary.
5. Inspect the container and the blood therein for any abnormalities before it is transfused, in order to ensure that the hermetic seal of the container is intact and shows no evidence of having been pierced. A container of blood shall not be entered/spiked by piercing the hermetic closure for preparing a suspension of packed red cells or removing a sample for testing or for any other purpose unless:
   • the entering/spiking of the container is carried out under conditions which conform with acceptable methods of asepsis;
   • the container of blood is kept at a temperature of 2 - 6°C from the time of entering/spiking until immediately prior to transfusion;
   • the transfusion is completed with 6 hours of the container being entered.
6. Check the expiry date on the unit of blood or blood component to ensure that it has not lapsed.
7. Ensure that each infused blood unit is retained at a storage temperature of 2 - 6°C for at least 48 hours after the completion of the transfusion.
8. In the event of a suspected transfusion reaction deliver a fully completed transfusion reaction form with the empty packs and administration set to the Blood Bank for the purpose of investigating the cause of an untoward reaction or death following the transfusion. (Refer to 8 below)
9. Report promptly to the Blood Bank any untoward reaction, or death of the patient as an apparent result of the transfusion.
10. Storage and transportation temperature:
   • Blood must be transported at (1 - 10°C)
   • Blood must be stored at 2 - 6°C until immediately before transfusion.
   • FFP must be transported and stored at less than - 18°C (minus).
   • Blood and blood products must NOT be immersed in hot water or heated except by using an approved warming device, the temperature of which must not exceed 37°C.
   • Blood must be infused within 4 – 6 hours of warming.
   • Blood must not be frozen
   • Platelets to be transported and stored at 20 - 24°C and continuously agitated until transfusion.

NB! All issued products must be transfused within 72 hours, if unused/not transfused, must be returned to the blood bank.

IN THE EVENT OF TRANSFUSION REACTION

1. Stop the transfusion immediately
2. Keep the patient open with normal saline using new administration set
3. Confirm if unit was intended for same patient
4. Contact the doctor in charge
5. Monitor temperature, pulse rate, BP, respiratory rate and urine output
6. Perform a dipstick on urine sample for haemoglobinuria
7. Contact the transfusion service for advice
8. Send to the Blood Bank as soon as possible:
   • This form fully completed
   • The suspect donor pack (and other previous blood or plasma packs, if any), the administration set and drip filter. (Do not empty the pack or remove drip set).
   • At least 5ml EDTA venous blood taken from the patient from a different site to the infusion, with precautions to avoid haemolysis and bacterial contamination.

TRANSMISSION REACTION CATEGORIES

<table>
<thead>
<tr>
<th>REACTION</th>
<th>SIGNS / SYMPTOMS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ANAPHYLACTIC REACTION</strong></td>
<td>Sudden onset. Symptoms include dyspnoea, hypotension/shock, facial and/or glottal oedema plus explosive GI symptoms. May lead to cardiac arrest/death.</td>
</tr>
<tr>
<td><strong>ACUTE HAEMOLYTIC REACTION (AHTR)</strong></td>
<td>Usually abrupt in onset and within 15 - 20 minutes after initiation of any red cell containing blood products. Fever, chills, nausea, vomiting, pain – flank back, chest, dyspnoea, hypertension, tachycardia, unexpected degree of anaemia, renal failure, DIC.</td>
</tr>
<tr>
<td><strong>BACTERIAL CONTAMINATION</strong></td>
<td>Usually rapid onset, about one hour post transfusion. Chills, fever, abdominal cramps, vomiting or diarrhoea, renal failure, renal failure, flushed skin, hypotension and shock.</td>
</tr>
<tr>
<td><strong>FEVERISH NON HAEMOLYTIC TRANSFUSION REACTION</strong></td>
<td>Onset usually with 1 – 2 hours after start of transfusion. Headache, myalgia, malaise, fever, chills, tachycardia and hypotension. Commonly found in multiparous or multi-transfused patients. Isolated fever &gt; 38°C or, a rise of 1°C from the pre-transfusion value.</td>
</tr>
<tr>
<td><strong>TRANSFUSION – RELATED ACUTE LUNG INJURY (TRALI)</strong></td>
<td>Rarely occurs within 2 hours of initiating transfusion. Dyspnoea, hypotension, fever, bilateral pulmonary oedema usually occurring within 4 hours of a transfusion.</td>
</tr>
<tr>
<td><strong>TRANSFUSION – ASSOCIATED CIRCULATORY OVERLOAD (TACO)</strong></td>
<td>Usually abrupt in onset and within 15 - 20 minutes after initiation of any red cell containing blood products. Fever, chills, nausea, vomiting, pain – flank back, chest, dyspnoea, hypotension, tachycardia, unexpected degree of anaemia, renal failure, DIC.</td>
</tr>
<tr>
<td><strong>DELAYED TRANSFUSION REACTION</strong></td>
<td>Extravascular Haemolytic Reaction: Caused by exposure to incompatible red cells in the presence of an atypical IgG antibody such as anti-Kell, anti-Duffy, etc. Severity variable ranging from mild to severe.</td>
</tr>
<tr>
<td><strong>ALLERGIC REACTION</strong></td>
<td>Usually mild. NO FEVER, itching, hives, urticaria, erythema. Limited to mucocutaneous symptoms only.</td>
</tr>
</tbody>
</table>

**Patient Information:***

**Signs and symptoms of TRALI:**

- Dyspnoea
- Hypotension
- Fever
- Tachycardia
- Pulmonary oedema

**Signs and symptoms of TACO:**

- Dyspnoea
- Hypotension
- Fever
- Tachycardia
- Pulmonary oedema

**Signs and symptoms of TRAR:**

- Fever
- Chills
- Nausea
- Vomiting
- Abdominal pain
- Tachycardia
- Hypotension

**Signs and symptoms of TRAR (DAF):**

- Fever
- Chills
- Nausea
- Vomiting
- Abdominal pain
- Tachycardia
- Hypotension
- Hemolysis

**Signs and symptoms of TRAR (DAF) (CRRT):**

- Fever
- Chills
- Nausea
- Vomiting
- Abdominal pain
- Tachycardia
- Hypotension
- Hemolysis
- Renal failure

**Signs and symptoms of TRAR (DAF) (CRRT) (DIC):**

- Fever
- Chills
- Nausea
- Vomiting
- Abdominal pain
- Tachycardia
- Hypotension
- Hemolysis
- Renal failure
- DIC

**Signs and symptoms of TRAR (DAF) (CRRT) (DIC) (ARDS):**

- Fever
- Chills
- Nausea
- Vomiting
- Abdominal pain
- Tachycardia
- Hypotension
- Hemolysis
- Renal failure
- DIC
- ARDS

**Signs and symptoms of TRAR (DAF) (CRRT) (DIC) (ARDS) (MODS):**

- Fever
- Chills
- Nausea
- Vomiting
- Abdominal pain
- Tachycardia
- Hypotension
- Hemolysis
- Renal failure
- DIC
- ARDS
- MODS

**Signs and symptoms of TRAR (DAF) (CRRT) (DIC) (ARDS) (MODS) (Necrosis):**

- Fever
- Chills
- Nausea
- Vomiting
- Abdominal pain
- Tachycardia
- Hypotension
- Hemolysis
- Renal failure
- DIC
- ARDS
- MODS
- Necrosis
**PATIENT INFORMATION**

Name of patient: ___________________________ Age: ___________________________
Surname: ___________________________ Gender: M [ ] F [ ]
Hospital name: ___________________________ Hospital number: ___________________________
Diagnosis (before transfusion): ___________________________
Indication for transfusion: ___________________________
Products transfused: ___________________________ Unit/Pack numbers: ___________________________
Was the blood warmed: ___________________________ How? ___________________________

**CATEGORY:**
- Haematology
- Oncology
- Medical
- Obstetrics/Gyn/Perinatal
- Anaesthetics
- Trauma
- Surgical
- Paediatric
- Orthopaedics

Brief medical history: ___________________________

**REACTION DETAILS**

Date of transfusion: / /  Time:  Volume transfused: ___________________________
Onset of reaction: Immediate [ ] < 1hr [ ] 1-2hrs [ ] < 6 hrs [ ] > 6 hrs [ ] >24 hrs [ ] Date: / /

**CLINICAL SIGNS AND SYMPTOMS**

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<td>Back pain</td>
<td>Joint/muscle pain</td>
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<td>Hypertension</td>
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<td>Shock</td>
<td>Restlessness/anxiety</td>
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<tr>
<td>Haematuria</td>
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</table>

Other relevant clinical information: ___________________________

**Treating doctor information**

Name: ___________________________ Contact no: ___________________________ Date: ___________________________

**Ward no: ___________________________ Signature: ___________________________**

**INCIDENT (For SANBS staff only)**

- Patient misidentification
- Product related
- Near miss event
- Other (Specify)

**Transfusion Reaction**

- FNHTR
- Minor allergic
- Severe allergic
- Anaphylactic shock
- Acute haemolytic reaction
- Delayed haemolytic reaction

**Incompatible transfusion**

**Delayed Serological Transfusion Reaction:** Specify new all antibody(ies) within 28 days of transfusion

**Specify:**
- TACO
- TAD
- Hypertensive
- PTP
- TA-GVHD

**Bacterial Contamination**

- Positive culture product
- Positive culture recipient

**TRALI**

- Unknown
- Other (Specify):

**RELATIONSHIP AND GRADING (HAEMOVIGILANCE – OFFICE ONLY)**

Relationship of reaction to transfusion
- Definite
- Probable
- Possible
- Doubtful
- Ruled out
- Not determined

Severity (Grade)
1. (non-severe)
2. (severe)
3. (Life-threatening)
4. Death
Not determined

Conclusion (Based on IHN definitions) ___________________________
Appendix 5
IUSS HEALTH
FACILITY GUIDES

Facilities for Surgical Procedures

Gazetted

30 June 2014
Task Team: A:15

supported by:

health
Department: Health
REPUBLIC OF SOUTH AFRICA

CSIR
our future through science
**Facilities for Surgical Procedures**

*“Facilities for Surgical Procedures” contains health facility guidance in four parts covering the infrastructure norms and standards for operating theatres and ancillary areas in healthcare facilities from primary healthcare to tertiary healthcare. It is to be read in conjunction with the full norms and standards suite and covers Policy and Service Context (Part A), Planning and Design (Part B), Accommodation Plans (Part C), User room requirements (Part D) and Examples (Part E)*

**Reference:** CSIR 59C1119 – A:15 - 001

**Authors:** IUSS N and S Task Group A:15

**Stakeholders:** National Department of Health, Provincial Departments of Health and Public Works


Accessing of these guides

This publication is received by the National Department of Health (NDoH), IUSS Steering Committee Chairman, Dr Massoud Shaker and Acting Cluster Manager: Health Facilities and Infrastructure Management, Mr Ndinannyi Mphaphuli. Feedback is welcome.

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Application and development process

These IUSS voluntary standard/guidance documents have been prepared as national Guidelines, Norms and Standards by the National Department of Health for the benefit of all South Africans. They are for use by those involved in the procurement, design, management and commissioning of public healthcare infrastructure. It may also be useful information and reference to private sector healthcare providers.

Use of the guidance in this documentation does not dissolve professional responsibilities of the implementing parties, and it remains incumbent on the relevant authorities and professionals to ensure that these are applied with due diligence, and where appropriate, deviations processes are exercised.

The development process adopted by the IUSS team was to consolidate information from a range of sources including local and international literature, expert opinion, practice and expert group workshop/s into a first level discussion status document. This was then released for public comment through the project website, as well as national and provincial channels. Feedback and further development was consolidated into a second level development status document which again was released for comment and rigorous technical review. Further feedback was incorporated into proposal status documents and formally submitted to the National Department of Health. Once signed off, the documents have been gazetted, at which stage documents reach approved status.

At all development stages documents may go through various drafts and will be assigned a version number and date. The National Department of Health will establish a Health Infrastructure Norms Advisory Committee, which will be responsible for the periodic review and formal update of documents and tools. Documents and tools should therefore always be retrieved from the website repository www.iussonline.co.za or Department webportal (forthcoming) to ensure that the latest version is being used.

The guidelines are for public reference information and for application by Provincial Departments of Health in the planning and implementation of public sector health facilities. The approved guidelines will be applicable to the planning, design and implementation of all new public-sector building projects (including additions and alterations to existing facilities). Any deviations from the voluntary standards are to be motivated during the Infrastructure Delivery Management Systems (IDMS) gateway approval process. The guidelines should not be seen as necessitating the alteration and upgrading of any existing healthcare facilities.

Acknowledgements

This publication has been funded by the NDoH

IUSS N&S task A:15: Tobias van Reenen, Edwina Fleming, Magda Coetzter, Zane Farina, Denise Sheard, Mirinda Coertzen
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OVERVIEW

This document outlines the policy and service context and attempts to illustrate the desired planning principles and design considerations of facilities for surgical procedures.

- **Part A** outlines the national and provincial service and policy context which are the basic determinants of the planning and design principles;
- **Part B** contains planning and design guidance, design considerations, functional relationships between hospital departments with respect to facilities for surgical procedures, and relationships within the unit itself;
- **Part C** develops these principles into a series of user room requirements;
- **Part D** contains room data sheets; and
- **Part E** includes some indicative equipment lists and case studies.

Parts C, D and E are intended to demonstrate how the principles prescribed in Part B can be applied in worked examples. Parts C or D, if used directly, are deemed to satisfy the principles developed in Part B, but are not the only acceptable solutions.

Case studies (Part E) provide illustrative worked solutions and should not be adopted without appropriate contextual adaptation.

While this document outlines design requirements and acceptance criteria which have an impact on clinical services, these requirements are prescribed within the framework of the entire IUSS set of guidance documents and cannot be viewed in isolation. The following documents should be complied with, together with this document:
## TABLE 1: IUSS: GNS REFERENCE DOCUMENTS

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**Colours Legend**

<table>
<thead>
<tr>
<th>Consultants</th>
<th>Administrators</th>
<th>Related documents</th>
</tr>
</thead>
</table>

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INFRASTRUCTURE UNIT SUPPORT SYSTEMS(IUSS) PROJECT  
Health Facility Guides: 
Facilities for Surgical Procedures [Gazetted, 30 June 2014]
1. INTRODUCTION

Surgical and diagnostic facilities range from procedure rooms, where minor procedures may be performed, to operating theatres where more complicated procedures are performed. These require a full medical team and need to occur in dedicated hospitals with dedicated areas designed for and equipped with special lighting, equipment and air-handling systems. This area of the hospital is usually contained in the Operating Theatre Unit (OTU), which provides a highly controlled environment for the operative and perioperative care of patients who are undergoing diagnostic and surgical procedures under anaesthesia or sedation.

2. Surgical procedures

Medical and surgical procedures are categorised according to their urgency, body system involved, department they are conducted in (e.g. dedicated operating rooms for specialised procedures such as orthopaedic, cardiac surgery, neurosurgery for which different equipment is used), type of procedure, degree of invasiveness and any special instrumentation that may be used (e.g. an endoscopic suite or catheterisation laboratory).

Surgical procedures are performed by a surgical team in a dedicated operating room and may be:

- Elective procedures: the patient chooses when and if to have the procedure.
- Required procedures: these need to be done but are not necessarily done immediately.
- Emergency procedures: these are often a matter of life or death and are required due to an urgent or traumatic event.

3. Surgical team members

The composition of the surgical team will depend on the surgery to be performed and may include:

- The surgeon, a qualified physician specialised in surgical procedures, who leads the team and is responsible for performing the surgery.
- The anaesthesiologist, a qualified physician specialised in anaesthesia, who is responsible for the safety of the patient during anaesthesia and for pain management. Anaesthesiologists are involved in all three stages of surgery (pre-operative, operative and post-operative).
- Nursing staff, which include:
  - the nursing staff involved in the care of the patient throughout the perioperative period;
  - the scrub person, who prepares the setup and assists the surgeon during surgery;
  - the circulating person, who supports the team and collects supplies; and
  - the anaesthetic assistant, who assists the anaesthetist.
4. Support staff

Support staff include:

- porters
- cleaners
- staff nurse
- clerks
- CSSD staff.

5. Patient care

The surgical team has the responsibility of caring for the patient during the perioperative period, which includes the pre-, intra- and post-operative management of the patient - i.e. care given to the patient before, during and after surgery.

- **Pre-operative care** is the preparation and management of the patient prior to surgery and occurs in both the inpatient ward and the holding area in the operating theatre unit.
- **Intraoperative care** is the management of the patient during the operative procedure whilst in the operating room. This period begins when the patient is transferred onto the theatre table in the operating room and ends when the patient is transferred to the recovery area. During this period the patient may be anaesthetised, prepped and draped, and the operation is performed.
- **Post-operative care** is the management of the patient after the procedure until discharge and includes care in the recovery area in the operating theatre unit and the inpatient facility.

6. Surgical disciplines

The most common surgical disciplines include:

- General surgery - this includes surgery by general surgeons, who operate on almost any part of the body and who refer patients to relevant specialists when other specialised surgery is required.
- Cardiothoracic surgery - the cardiothoracic surgical team performs procedures within the chest, including the heart and its valves, the lung, oesophagus, chest wall and blood vessels.
- Neurosurgery - the neurosurgical teams specialise in surgery to the nervous system, including the brain, spine, peripheral nervous system and their supporting structures.
- Oral and maxillofacial surgery - the maxillofacial surgical teams deal with surgical problems of the head and neck (i.e. the ears, sinuses, mouth, pharynx, jaw, etc.).
- Reconstructive and plastic surgery - this surgical team performs surgery on abnormal structures of the body due to injury, birth defects, infection, tumours or disease, as well as cosmetic surgery to improve a patient's appearance.
- Transplantation - this advanced surgical team performs surgery specific to organ-transplant techniques, such as heart-lung transplants, liver transplants and kidney/pancreas transplants.
- Urology and renal transplantation - this surgical team performs surgery related to the kidney, kidney stones, bladder, urethra and ureters.
- Gastrointestinal surgery - digestive tract (stomach, bowels, liver and gall bladder).

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• Vascular surgery - this involves diagnosis and treatment of arterial and venous disorders, such as aneurysms, lower-extremity revascularisation, and other problems.
• Paediatric surgery - this surgical team is specially trained to perform procedures on neonates, infants and children.
• Ear, nose and throat surgery - this team is specially trained for surgery procedures to the ear, nose and throat.
• Obstetric and gynaecological surgery - this surgical team will perform caesareans (both elective and emergency), hysterectomies, removal of ovaries and other female-specific surgical procedures.
• Ophthalmology - this involves surgical treatment related to procedures to the eyes.
• Orthopaedic surgery - this involves surgical treatment related to the musculoskeletal system.

7. Surgical techniques

These include the following:
• Open surgery - this requires a large incision to access the relevant area of skin and tissues to allow the surgeon direct access to the internal structures or organs involved (e.g. to remove an appendix.
• Laser surgery - this involves the use of a laser to allow the surgeon to precisely cut tissues instead of using a physical knife or scalpel. An example of its use would be in surgery to the eye and/or larynx.
• Microsurgery - this involves the use of an operating microscope positioned above a small incision, allowing the surgeon to visualise small structures such as those in the eye or nervous system.
• Robotic surgery - a surgical robot is used under the direction of the surgeon to control the instrumentation.
• Minimally invasive surgery (MIS) - this involves smaller incisions through the skin to insert a specially designed instrument into the body cavity or structure. The surgeon can see into the body through the use of associated devices. An example of MIS is the removal of the gall bladder.
• Reconstructive surgery - this involves the reconstruction of an injured, mutilated or deformed part of the body.
• Cosmetic surgery - this is performed to improve the appearance of an otherwise normal surface structure of the body.
• Transplant surgery - this involves the replacement of an organ or body part by removing the diseased organ and replacing it with a donated, healthy organ.
• Endoscopic procedures - this refers to any procedure using a device known as an endoscope, to look inside the body for medical, diagnostic or surgical purposes.¹
• Interventional radiology - these procedures take place in the diagnostic and interventional radiology department.

8. Additional guidelines available

• Department of Health (DoH), 1996. Regulation pertaining to control of private hospitals. (R158). South Africa: DoH.

9. Service Context

9.1. Hospital categories of service


TABLE 1: SURGICAL FACILITIES PER FACILITY CATEGORY

<table>
<thead>
<tr>
<th>District</th>
<th>Regional</th>
<th>Tertiary</th>
<th>Central Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>General surgery</td>
<td>General and specialist surgery</td>
<td>-Sub-speciality surgery</td>
<td>-Super specialties</td>
</tr>
<tr>
<td></td>
<td>-Orthopaedic surgery</td>
<td>-Orthopaedic surgery</td>
<td>-Transplants-Paediatric surgery</td>
</tr>
<tr>
<td></td>
<td>-Ophthalmology</td>
<td>-Ophthalmology</td>
<td>-Facilities for holding, surgery and recovery of</td>
</tr>
<tr>
<td></td>
<td>-Obstetric surgery</td>
<td>-Paediatric surgery</td>
<td>highly infectious patients</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-Oral and maxillofacial surgery</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>-Cardiothoracic surgery</td>
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<td>-Neurosurgery</td>
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<td></td>
<td></td>
<td>-Urology</td>
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<td></td>
<td></td>
<td>-Gastrointestinal surgery</td>
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<td>-Vascular surgery</td>
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<tr>
<td></td>
<td></td>
<td>-Obstetric and gynaecological surgery</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>-Facilities for holding, surgery and recovery of highly infectious patients</td>
<td></td>
</tr>
</tbody>
</table>
10. Determining the number of operating theatres (OTs) required

The following rules of thumb relate the number of operating theatres to the number of beds in a hospital:

- **1 OT per 50 inpatient beds**
- **or**
- **1 OT per 25 surgical beds.**

The *WHO Planning & Design Guide* proposes the following calculation method:

Multiply no of surgical beds by no of operating days/year

= no of surgical bed-days available / year  
  e.g. A = 160 x 260 = 48 000  

Divide A by average length of stay in surgical ward

= maximum no of surgical patients admitted / year  
  e.g. B = 48 000 / 4 = 12 000  

Divide B by actual no of working days

= no of surgical operations expected / day  
  e.g. C = 12 000 / 300 = 40  

Multiply C by average hours per operation

= No of OT hours / day  
  e.g. D = 40 * 3 = 120  

Divide D by actual no of working hours in the OT

= No of operating theatres required  
  e.g. D = 120 / 6 = 20  

Factor in occupancy rate

= Corrected no of operating theatres required  
  e.g. E = 20 * 75% = 15 theatres  

*Refer to:*  
*. Appendix 3 – Capacity Planning*
PART B - PLANNING AND DESIGN

1. Overview

This document illustrates the desired planning principles and design considerations with applied examples to support the planning process.

Part B contains planning and design guidance, design considerations, functional relationships between the OTU and hospital departments and relationships therein.

Workflow diagrams within departments are provided to assist in understanding the intradepartmental relationships in support of functional flow to ensure productive service delivery. Workflow diagrams are provided to explain the flow of:

- patients, clinical staff,
- support goods and services,
- maintenance staff, as well as
- the flow of the public through the OTU.

The detailed room diagrams with accompanying guidelines are provided to clarify an understanding of the different space requirements and room-specific specifications.

During the planning and design stages, it is important that input from staff, technicians, cleaning staff, reception staff, porters, equipment personnel, clinical and nursing staff be encouraged and sought. This would promote efficient and appropriate operational functions in the OT.

2. GENERAL PLANNING AND DESIGN REQUIREMENTS

The OTU is a specialised facility within the hospital where lifesaving or life-improving procedures are carried out on the human body by invasive methods under strict aseptic conditions in a controlled environment by specially trained personnel to promote healing and cure with maximum safety, comfort and economy. It is imperative that the OT is designed scientifically to ensure sterility, easy maintenance and effective utilisation.5

2.1. Objectives of the operating theatre unit

The primary objectives of an operating theatre unit can be summarised as follows:

- Patient-focused care;
- Successful surgical or diagnostic procedures for the patient;
- Preservation of patient dignity at all times;
- Maximising efficiency in terms of throughput and outcomes. Due to the complexity of the OTU, the procedures performed and the technical equipment required, this life-saving unit is a major cost

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centre within the hospital and, as such, must function efficiently and be designed to be utilised effectively; and

- Ensuring maximum standards of safety of the patient through:
  - safe anaesthesia,
  - promotion of a high standard of asepsis,
  - the creation of a “sterile” environment in the OT and the set-up room to reduce the risk of infection,
  - promoting clean equipment in the operating theatre, and
  - the use of sterile equipment during the procedure, including re-useable equipment that has been correctly sterilised;
- Recruitment, development and retention of appropriately skilled staff that is achieved through optimising working conditions and providing a working environment;
- Facilitation of coordinated services;
- Clean storage of consumables, medicine and equipment pertinent to the procedures to be performed;
- Provision of administrative functions to ensure that the OTU performs effectively by optimising utilisation of the OTs and staff time;
- Security for the patient, for staff and for equipment;
- Minimise maintenance;
- Ensure functional separation of spaces;
- Control of traffic flow within the OTU; and
- Infection control - exclusion of contamination from outside the theatre achieved by
  - limiting the number of people in the operating theatre,
  - control of the environment - temperature, humidity, and surface and airborne contamination levels are to be maintained within prescribed levels, and
  - the sterilisation of instruments and re-useable instruments used in the procedure.

2.2. Strategic planning considerations

Before proceeding with the planning and design of the OTU, it is important to clarify the following:

- The category of hospital and the levels of service required of that hospital.
- How many operating theatres will be required in the OTU.
- The type of procedures to be performed and the types of theatres required for those procedures.
- OT sizes required.
- OTU department location in relation to the rest of the hospital.
- Infection control – the hospital policies will determine the zoning within the department to an extent. Infection-control teams should be consulted from the onset of the planning and design process, and should remain members of the planning team throughout - from the business case to completion and occupation of the new or upgraded facility. Refer to the IUSS:GNS Infection prevention and control for further guidance.
- Structural implications with regard to existing or new structures. These relate to the load-bearing capacity, as well as noise and vibration concerns.
- Constraints created by a modular construction where a specific grid has been adopted.
- Theatre equipment requirements in terms of environmental quality, vibration, structure, electrical and mechanical.
- IT & communication requirements especially related to the digital theatres.
- Decontamination of equipment, medical devices and instruments for re-use is essential in an OT in order to reduce the risk of contamination. Refer to the IUSS:GNS Central sterile services department (CSSD).
2.3. **Infection-control policies and procedures**

The introduction of microbial contamination to the patient is the greatest risk in the operating theatre and must be the foremost focus of all design of spaces within these units, regardless of whether the space is a minor procedure room or specialist operating theatre. Surgical-site infections acquired during an operation can be fatal for the patient. To effectively reduce the risk of surgical infections, these areas and their environments must comply with strict policies and procedures.

These procedures are essentially common to all types of surgical facilities, especially with regard to:

- the operational procedures,
- the reprocessing of re-useable instrumentation and devices used for these procedures,
- infection control, and
- the cleaning and disinfection of the physical space.

“A clean operating room environment with sterile (or correctly decontaminated) equipment with restricted access and appropriately attired staff can go a long way to reducing the risks of surgical site infections”\(^6\).

2.4. **Healing environments\(^7\)**

Historically, operating theatre units have concentrated on designs that address only the technical aspects and the need for an uncontaminated, sterile or clean environment, with slim regard for the need to make patient and staff spaces pleasant and appealing. Today, a number of patients undergo surgery without a general anaesthetic, remaining conscious throughout the procedure. It is therefore important that the environment created within the OTU is soothing and encourages a healing environment. Design of the OTU environment needs to consider the needs of the theatre staff, potentially traumatised patients, guardians of minors and care for minors themselves. The evidence-based considerations and recommendations are discussed below.

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\(^7\) The Achieving Excellence Design Evaluation Toolkit (ADET), downloadable from the NHS Estates website (www.nhsestates.gov.uk) is an excellent tool to assist with design.
**Daylight**

Studies indicate that the majority of people prefer indoor spaces that are illuminated by sunlight (Van den Berg, 2005). Lack of natural light is one of the most common complaints made by OTU staff about their working environment. As daylight tends to be brighter and renders a natural spectrum of colours in an indoor space, it is important to try and design elements that allow natural light into the OTU. Illumination by natural daylight has benefits for both clinical outcomes and the wellbeing of occupants. Where natural sunlight is introduced into the operating theatre, potential problems of reflection on digital screens and glare at specific times of the day can arise. These problems need to be identified, understood and mitigated.

The following areas should be provided with natural light, whenever possible:

- Operating theatres
- Recovery unit
- Waiting area
- Staff room.

For more detailed information, refer to the IUSS document on “Hospital Design Principles”.

PHOTOGRAPH 1: OPERATING THEATRE (COURTESY OF RED CROSS CHILDREN’S HOSPITAL, CAPE TOWN)

PHOTOGRAPH 2: OPERATING THEATRE (COURTESY OF RED CROSS CHILDREN’S HOSPITAL)
Noise

Noise and sound attenuation is an aspect often overlooked in the design of the OTU. Special attention is required when detailing doors, ceilings and the selection of trolley-wheels, etc.). Quiet retreats are also important for staff to sit and rest in between cases. The unwanted propagation of sound and speech between adjacent rooms should be prevented though carefully considered design and the observation of acoustic principles.

Views

Windows in staff areas, recover

Where OTU areas are provided with views to the outside, these views should be well considered and should not be distracting to the theatre staff. External windows in operating theatres may create a pleasant indoor environment at the expense of the patient's privacy. For this reason, access to external areas that could provide sight into the theatre should be highly restricted. Windows installed in operating theatres should be flush and sealed on the inside. It is advisable to consider using double-glazed window panels with internal blinds which can be operated from inside the theatre.

Photograph 3: Setting-out Room (Courtesy of Red Cross Children’s Hospital)

Air quality

Air quality is critical in operating theatres. Air quality is quantified in terms of:

- Operative temperature
- Radiant temperature
- Humidity
- Airborne contamination (odour, biological and particulate)
- Air velocity.

These aspects are addressed in the IUSS:GNS Building engineering services guidance document and further in this document.

Patient privacy

When designing the OTU, it is important to consider views and lines of sight within the facility from the aspect of patient privacy. Patients are especially vulnerable in the OTU as, at times, they may be both unconscious and uncovered.

Artificial lighting

Artificial lighting needs to be carefully considered in the design of the OTU as each space has different requirements. The lighting needs to provide the level of illuminance required to suit the activities in the relevant space. Placement of fittings is crucial in all the patient areas including the recovery area, the holding
area, induction (anaesthetic) rooms, operating theatre and staff areas. Refer to the IUSS:GNS Building engineering services for guidance on lighting levels and quality.

2.5. Finishes

Refer to the IUSS:GNS Materials and finishes for a comprehensive specification of finishes.

Finishes, equipment and materials must be easy to maintain and clean, as well as observe infection-control principles. Materials should be selected to minimise maintenance and be sustainable, as well as compatible with their intended function. Special design consideration should be applied when planning spaces, corners, junctions, work tops, etc.

PHOTOGRAPH 4: RECOVERY AREA (COURTESY OF WATERFALL HOSPITAL)

2.6. Child-friendly environment

Children should be separated from adult patients in the OTU. Separate holding and recovery areas need to be provided for children when sharing theatres with adults. These spaces must allow for parents to accompany their children. The spaces for children must create a calm environment suitable to children.

2.7. Controlled access

The maintenance of a highly controlled environment in the OTU requires restricted and controlled access into the OTU. Automated sliding doors assist in the maintenance of the hygienic environment by limiting the touching of common-use surfaces. Openable windows in the OTU are not acceptable.

2.8. Control of waste

Waste generated in the OTU must be treated appropriately as it has considerable environmental impact.

Bio-medical waste raises considerable environmental, biological and social issues. It is beyond the scope of this guidance document to explore legal and safety issues at length.

The reader is referred to the IUSS:GNS Waste disposal and IUSS:GNS Hospital mortuaries guidance documents for more information on anatomical waste and limb disposal.
2.9. **Communications**

Planning should take into consideration the fact that telephones are required throughout the OTU to facilitate good communication. This needs to be planned in conjunction with the system to be used throughout the hospital. It is important that noise reduction is considered with regard to telephone ringtones, and a subtle flashing indicator light may be more appropriate.

Phones need to be easily accessible, especially in areas where patients wait, recover, etc.

2.10. **Storage**

Storage space for theatres is easily underestimated. Planning should ensure that, prior to design, storage requirements are sufficiently identified and included. Storage planning should include for large equipment such as additional theatre tables, anaesthetic machines, mobile machinery - as well as pharmaceutical supplies, instruments, linen and consumables. Each discipline in the OTU has specific storage needs.

Depending on the size of the OTU and hospital policy, storage can be in a series of separate rooms or can be managed from one point in a central area.

Pharmaceuticals are stored separately.

Shelving needs to be durable, washable, easily disinfected and have a hygienic finish to the surface.

Open-plan storage areas should be clearly delineated to help prevent overflow and creep of space used for storage. The flow of clean and dirty materials needs to be considered in the planning of storage areas. Where insufficient storage is provided, it is common for circulation space such as the “dirty” passages to become an ad hoc storage area, such as seen in the image to the right.

Public healthcare facilities are subject to lengthy procurement lead times. In order to maintain the requisite service levels, good management of these facilities demands the maintenance of high stock levels. For this reason it is normal for public health facilities to demand between two and three times the storage space of public hospitals.
3. Location

The OTU should be:

- located in an area accessible to the critical-care unit and supporting services like the CSSD, x-ray and laboratory;
- located away from traffic and other potential sources of disruptions and noise;
- located such that daylight must not distract lighting in the OT;
- located and arranged to prevent non-related traffic through the OTU;
- the OTU must be easily accessible from the emergency department, labour unit, surgical wards and ICUs;
- the Central Sterilising Services Department (CSSD) could be adjacent to the OTU, but should not be placed back-to-back or adjacent to a theatre room in order to prevent potential cross-contamination;
- the design of the OTU should allow for ease of access to the storage areas for delivery of OT consumables; and
- controlled access from an external corridor is highly desirable.

FIGURE 1: DEPARTMENTAL RELATIONSHIPS AND CRITICAL ADJACENCIES
4. **STERILE CORE PRINCIPLE**

The main principle behind the design of an OTU is the establishment of a *central sterile core*, which consists of the patient on the operating table, the surgeon and scrub nurse, the scrub room, the set-up room and induction room (where applicable).

The *clean zone* connects the OT via the clean passage to the holding and recovery areas and the store rooms that directly supply the OT. The clean zone separates the OT (sterile zone) from the potentially contaminated areas (the *general zone*) such as the offices, staff change areas, reception and the disposal areas (the *dirty zone*) such as the sluice and waste areas. In ultraclean theatres an additional ultraclean condition is established within the unidirectional airflow (laminar flow) zone.

**FIGURE 2: STERILE CORE CONCEPT**

The four zones (Figure 2) are areas of varying degrees of cleanliness in which the bacteriological count progressively diminishes from the outer to the inner zones (sterile core), and is maintained by a differential pressure gradient cascading from the inner zone (sterile core) to the outer zone. This pressure gradient is established and maintained by the ventilation system. For additional information on the design, classification and validation of the clean zones the reader is referred to the I/USS:GNS Building engineering services.

Important principles to incorporate in the planning and design include:

- Exclusion of contamination from outside the OT;
- Separation of clean areas from contaminated areas within the OTU; and
- Efficient, controlled traffic patterns within the OTU.
### TABLE 2: FUNCTIONAL ZONES

<table>
<thead>
<tr>
<th>ZONE</th>
<th>ACCOMMODATION SPACES</th>
<th>WORKING AREAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>GENERAL</td>
<td>External area waiting area, porters’ room</td>
<td>Unrestricted area outside the operating theatre where street clothing is worn.</td>
</tr>
<tr>
<td></td>
<td>Receiving lobby, unit manager’s office, reception, trolley bay (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Doctors’ offices, staff lockers area, ablutions, on-call rooms, staff change areas</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Training/meeting rooms</td>
<td></td>
</tr>
<tr>
<td>CLEAN ZONE</td>
<td>Storage support areas for theatres, nurses’ station, theatre clean passage, holding area and recovery area, staff rest areas</td>
<td>Semi-restricted area</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Restricted to authorised personnel only</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Theatre attire is worn</td>
</tr>
<tr>
<td>STERILE ZONE</td>
<td>Theatres, scrub area, set-up areas, induction room (anaesthetic room)</td>
<td>Restricted area where procedures are performed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Authorised personnel only</td>
</tr>
<tr>
<td>DIRTY ZONE</td>
<td>Dirty passages, dirty utilities, waste areas, clean up areas</td>
<td>Restricted area outside the operating theatre where street clothing is worn.</td>
</tr>
</tbody>
</table>
FIGURE 3: RELATIONSHIPS WITHIN THE OPERATING THEATRE UNIT

INFRASTRUCTURE UNIT SUPPORT SYSTEMS(IUSS) PROJECT
Health Facility Guides: Facilities for Surgical Procedures [Gazetted, 30 June 2014]
5. TRAFFIC FLOW PATHS

The OTU design must prevent cross-traffic of staff and supplies from the decontaminated/soiled areas to the sterile/clean areas. The use of facilities external to the operating theatre for soiled/decontaminated processing, clean assembly and sterile processing must be designed to move the flow of goods and personnel without compromising universal precautions or aseptic techniques in both departments.

The following are key planning principles for designing traffic flow paths in surgery units:

- Patient and materials routes should move progressively forward without unnecessarily looping back.
- Ensure pre-operative and post-operative patients do not meet at any point in the unit (except perhaps at the point of entry/exit).
- Eliminate crossover circulation points.
- Reduce double-handling of patients and supplies.
- Reduce patient and staff travel.

Modern theatre layouts tend to rely more on creating operational policies than physically separate routes to control traffic flow in the theatre unit. The advantage of this approach is that it offers opportunity for a more efficient design although the reliance on policies exposes this unit to risk from human error and discipline issues.

5.1. Patient flow pathway

The patient is collected from the inpatient unit (ward) by the theatre porter or brought to the theatre area accompanied by a nurse from the ward, ICU or emergency centre. At the OTU, the patient is brought through the access-controlled doors into the **OTU lobby area**, where the patient is transferred to the care of the OTU staff. At this point the patient may be transferred onto a theatre trolley if not already on one.

The patient is wheeled by the OTU staff through the second set of doors, across the red line into the **restricted OTU area**. The patient is kept in the holding area, cared for by the nursing staff, until called to theatre by the anaesthetist/surgeon.

The patient is wheeled into the **induction room**, or taken straight into the theatre where the anaesthetist is waiting to anaesthetise the patient. From the induction room, the patient is taken into the **operating theatre** and transferred to the theatre table. The surgeon performs the procedure on the patient once the anaesthetic is effective.

Upon completion of the operation, the patient is transferred onto the patient trolley, and then taken to the **recovery area** to be cared for by the nurses under the supervision of the anaesthetist.

Once the patient’s condition is stable, the patient is then wheeled out of the OTU red-line area into the lobby area and out into the external passage, then on to the **ward or ICU**. The patient may be handed over to and collected by the ward staff or taken to the ward or ICU by the theatre staff when discharge criteria have been met.
5.2. **Staff flow pathway**

The flow of staff involves a number of clearly defined personnel:

- Doctors
- Nursing staff
- Service staff.

All personnel entering and leaving the OTU must be fully gowned in correct theatre attire within the red-line area (clean and sterile zones). This requires that personnel wishing to enter the clean and sterile areas must first change and gown up in a change area before entering the red-line area. These change areas must be separated into male and female change areas.

Personnel exiting the red-line area will be required to remove the theatre gown, head and foot covers in the change areas prior to exiting the OTU.

For new facilities, the red-line area could be demarcated as running through the change rooms, thereby classifying the change rooms as an intermediate space or “grey” area between clean and non-clean areas. Grey areas should be serviced and operated as if they were within the clean area, but allow for the practicalities of transition between clean and non-clean areas. Staff toilets should not be located within change rooms, grey areas or red-line areas as this could entice staff to use their toilets while still dressed in theatre garb. The inclusion of showers within the change rooms should be considered only where staff may need to shower before leaving the OTU. Dedicated ablution facilities are preferred for this purpose.
5.3. Services flow pathway

The routes and method of transport of waste and contaminated items through the operating unit need to be carefully considered in how they pertain to cross-infection, contamination and patient views. A one-way flow of supplies into the operating room, and then of soiled goods and trash out of the operating room, is preferred. The shared use of a corridor for staff and patient access into the OR is acceptable, but this same corridor should not be used for delivery of sterile supplies into the OR. Sterile supplies and instruments should have a separate, dedicated pathway from the central sterile supply into the operating room without encountering staff or patient traffic, whether in scrubs or not.

A separate service corridor backing on to the theatres could be a solution. This corridor will link through to the CSSD and the dirty utility room, from which waste can be collected externally.

It may be helpful not to think of this corridor as a “dirty” corridor as it then frequently manages to live up to its name. The aesthetics, air quality and architectural finishes of this zone should be the same as for the clean passage.
6. GENERAL ZONE

The protective zone provides for:

- The admission and reception area with general overseeing of day-to-day operations, control of entry and exit from the OTU and completion of administrative tasks.
- Administrative and staff areas, including change rooms, office and administrative space.
- Offices for doctors and nursing staff.
- Overnight rooms for doctors and staff on call.

### TABLE 3: ROOM LIST FOR THE PROTECTIVE ZONE

<table>
<thead>
<tr>
<th>PROTECTIVE ZONE</th>
<th>Standard room</th>
<th>Non-standard room</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative offices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IT Switch Room</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Meeting Room – Large</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Office – Chief Anaesthetist</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Office - Chief Surgeon</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Office - Doctors</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Office – Unit manager</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Office – Sister</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Doctors on call rooms with en suite ablution</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Staff toilet</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
### PROTECTIVE ZONE

<table>
<thead>
<tr>
<th></th>
<th>Standard room</th>
<th>Non-standard room</th>
</tr>
</thead>
</table>

**Education and training**

Seminar room  

**Pre entrance to theatre unit**

Waiting  

**Entrance area**

Trolley park area  

Entrance lobby  

Office-porters (optional)  

Unit manager’s office  

Reception  

Bay – Personal Protective Equipment  

Restricted access area  

**Staff area**

Female change room with toilet & showers  

Male change room with toilet & showers  

---

### 7. Administration offices

Office space is to be provided as per the Gazetted office space norms.

The offices are to be located close to the entrance or exit and must be outside of the clean and sterile areas. Depending on the size of the OTU, office space may need to be provided for the:

- Chief anaesthetist
- Chief surgeon
- Doctors’ offices:
  - Principal specialist
  - Senior specialist
  - Registrars
- Anaesthetic secretary x 1
- Unit manager
- Operational managers
8. Seminar room

This is a standard seminar room for meetings and training, to be located within the office area.

Services include:

- Plugs for computers and a projector
- Data points
- Video and audio point

Consider:

- Chairs and a large table
- Screen
- Small lockable cupboard for equipment.

9. Overnight stay

The overnight stay is a room for staff on call that may need to rest while waiting to be called to the OTU. Provision should be made for single-bed units with a shower/toilet facility en suite, or for a shower/toilet facility to be shared between two separate bed units.

The doctors’ overnight rooms must be external and adjacent to the theatres with immediate access in the event of an emergency and shall be designed considering the following:

Services to include:

- Two double-socket outlets
- Telephone
- Data point
- Ablution with shower and toilet, either en suite per bed unit, or shared between two units.

Considerations:

- Privacy
- External window
- Bed and side table
- Desk with chair
- Mirror
- Cupboard for clothes.
10. Pre-entrance

10.1. Waiting area

Prior to entrance into the OTU there should be a waiting area for the patient’s escorts or family members to wait, should there be no such facility on the ward. A small counselling room off the waiting area should also be provided for doctors to speak privately with waiting family members.

10.2. Trolley park area

A trolley park area is required, where theatre policy requires patients to be fetched from the ward and transported on a theatre trolley to the theatres.

10.3. Entrance lobby

There should be one main entrance to the theatre unit which is access-controlled and through which staff pass and patients and supplies are carried. Disposals should be removed separately through an alternative exit that is controlled from reception. Entry should be controlled by an intercom system with CCTV linked to the theatre reception area. Staff access can be controlled by access cards. However, the type of access control chosen must not inhibit emergency escape from the theatre unit in the case of fire.

The entrance area should have two double automatic sliding doors to allow for the transfer of trolleys and patients on beds accompanied by clinical staff. A minimum clear door opening of 1800mm is required with the lobby passage area being a minimum of 3000mm wide x 4400mm long to allow for two beds to pass each other, as well as accompanying staff and equipment. The doors should be supplied with kick-plates and stainless steel door protectors. Provide clear demarcations on the floor for entrance control.

The entrance lobby should have the access-controlled door off the main passage that is operated from OTU reception desk within the OTU. The patient is wheeled through these doors into a lobby (interim space), where the staff from the OTU receive the patient from the ward staff. The patient is then wheeled through into the holding area over the red-line area, optionally through a second set of automated doors.

Important considerations include the following:

- There must be restricted access control over all persons entering and exiting the OTU.
- Glass sliding doors at entrance - first set.
- An optional separate glass sliding door into the theatre clean passage from the holding and recovery areas, providing some screening when necessary.
- A red line 50mm wide at the pre- and post-operative entrances, and after the staff change room.
- The interim space to receive patients should be 9m² minimum.

Refer to the case studies included in this document for examples.

10.4. Porters’ base

A porters’ base should have access to the main passage and the lobby area.

10.5. Unit manager’s office

The unit manager’s office should have a viewing window into the lobby to be able to monitor all patients, staff and other personnel entering and exiting the theatre unit. Access from the unit manager’s office into the theatre unit is also required.
10.6. Bay – personal protective equipment

An open storage bay for location of personal protective equipment such as gloves, gowns, overshoes, caps and masks should be located within the interim space of the entrance lobby, at the entrance to the OTU. The bay must be deep enough to allow storage of gloves, gowns, overshoes and masks. A minimum area of 2m² is required.

10.7. Reception

The reception area is the central area of communication for the theatre unit. The theatre clerk works from this desk and should have an unobstructed view of the main entrance, the waiting area, the lobby area as well as a view into the theatre unit and staff entrance from the change areas.

11. Staff areas

11.1. Change

Staff change rooms are for staff to change into appropriate operating-room attire, and to store their street clothing. Clinical staff encounter infection and handle contaminated instruments and dressings while in the OTU during the day, and therefore need to shower and change at the end of a shift (or during a shift, should the need arise).

Appropriate change rooms shall be provided separately for male and female personnel (nurse, doctors and technicians) working within the Operating Unit.

Staff change rooms should be adjacent to the theatres. Entrance to the staff change areas, prior to gowning and entering the operating-theatre suite, should be off the main passage external to the operating-theatre suite. These staff change rooms shall be arranged to encourage a one-way traffic pattern so that personnel entering from outside the surgical suite can change and move directly into the OTU red-line area (restricted area within the OTU).
Once inside the change room, staff collect clean gowns, caps and shoe covers before changing into their gowns. The change rooms shall contain adequate lockers, showers, hand basins and space for donning of surgical attire and shoes.

Once changed, staff are then permitted to exit the change room into the operating suite through a separate door.

After staff have completed their tasks within OTU, they exit through a door into the change area where they discard their gowns, caps and shoe covers before dressing and exiting through the door to the external passage.

The total area should be divided into male and female change areas and sized according to the number of staff in the operating-theatre suite.

A minimum of 8-9m² per operating theatre or 4m² for a single person, increasing by one m² for each additional person is required. Space provision should take into account peak numbers of full time staff, students and visitors at any one time.

Access will be required to showers, toilets and decontamination facilities.

Consider the following:

- Secure storage of personal property is essential.
- Full-length mirrors, towel rails, benches, hooks and rails, full-length lockers.
- Mobile bins for soiled laundry.
- Seating/benches to sit on while changing.
- Shelves for clean gowns, hats, footwear covers.
- The change room entrance door shall be provided with locks or electronic access devices to prevent the entry of unauthorised persons into the OTU.
- Hair-dryer outlet.
- Toilets. This is to be a room containing a toilet and hand basin.
  - Toilets shall be provided at the minimum ratio of one per operating room but no fewer than two in total (1 per 8 staff).
- Staff toilets should not be located within change rooms, grey areas or red-line areas as this could entice staff to use their toilets while still dressed in theatre garb.
- Showers shall be provided at the minimum ratio of one per two operating rooms, but no fewer than two. Provide:
  - a privacy latch
  - bench for clothes
  - hook for clothes
  - walls to be full height.
- The above toilets and showers are to be divided equally between male and female change rooms.
FIGURE 8: STAFF FLOW THROUGH CHANGE ROOMS

Passage external to operating theatre suite, connecting to other Departments

IN & OUT

MALE CHANGE

Theatre clothing

IN & OUT

FEMALE CHANGE

Theatre clothing

GREY ZONE

RED LINE AREA
12. Clean zone

The clean zone within the OTU separates the sterile core from the non-clean or contaminated areas and includes:

TABLE 4: CLEAN ZONE ROOM LIST

<table>
<thead>
<tr>
<th>Clean zone</th>
<th>Standard room</th>
<th>Non-standard room</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holding area – pre-operative</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Recovery area – post-operative</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Nurses’ station</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Clean passage</td>
<td></td>
<td>x</td>
</tr>
</tbody>
</table>

**Stores:**

- Clean linen x
- Equipment x
- Instruments x
- Pharmaceutical supplies x
- Surgical supplies x
- Anaesthetic supplies x
- Blood store x
- Equipment cleaning x
- Passage to operating theatres x
- Induction room x
- Bay - mobile equipment x
- Laboratory area x
- Medical gas storage x
- Bay - x-ray equipment x
- Anaesthetic workroom x

Standard rooms as indicated in the table above are described in the IUSS standard-room documents. Non-standard rooms are described below.
12.1. **Holding area – Pre-operative**

This space is for patients waiting to have surgery. The area is close to the entrance lobby but within the red-line restricted-access area.

Services to include:

- Hands-free wash hand basin - 1 per 6 bays
- Oxygen point - 1 per trolley
- Suction point - 1 per trolley
- Electrical points - 3 per trolley
- Emergency call system - 1 per trolley
- Lighting - 2000 lux

The patient-holding area should be as follows:

- Allow for trolley space, with curtain rails for privacy.
- The trolley cubicles must also be provided with intravenous fluid rails.
- The area must be supplied with shelves for patient folders and a cupboard.
- The patients must be clearly visible from the nurses’ station.
- There must be space for a resuscitation trolley.
- Light and good ventilation is important.
- Include a visibly positioned clock.

Minimum provision of one holding bay per theatre

Each patient-holding bay shall be a minimum of 9m².

A separate toilet is required off this area for patients.

**NOTE:** Children to be kept in a separate holding area, with a chair for parents accompanying the patient.

12.2. **Central nurses’ station**

The nurses’ station is the administrative base for the operating suite and an enquiry point for patients, staff and visitors. It provides for the coordination of patient care, observation, writing up of clinical notes, entering of data into computers, and the making and receiving of phone calls. The station must accommodate nurses, a clerk and doctors’ work space. From here the nurses must be able to observe patients in both the holding and recovery areas.

Services required include:

- Four telephones
- Data points
- Hands-free wash hand basin
- Nurse call system
- Power outlets for computer points, two central monitors, computer, fax and printer
- Light panel indicating which theatres are occupied
- Indication light showing gas per theatre
- Fire panel.

Special considerations include:

- The central nurses’ station should be positioned between the holding and recovery areas and should include a large counter facing patients in both holding and recovery bays.
• The nurses’ station should allow the nurses to have a view of the entrance as well.
• Work area to be provided for nurses and doctors to fill in forms and make notes.
• Wall-mounted wipe board and pin board.
• Engraved, wall-mounted aluminium OTU diagram, indicating fire exits.
• Workstation for computer, printer, fax machine, photocopier and telephone.
• Work surface and space for filing, shelves to accommodate files and stationery, with drawers and cupboards.
• All surfaces must be impervious and designed for easy cleaning.

12.3. Bay – resuscitation trolley

The resuscitation trolley bay is for the supervised holding of the resuscitation trolley and equipment.

The bay size should be a minimum of 2m² and must be deep enough to allow storage of the trolley without projection into the passage. The resuscitation trolley bay must be located adjacent to the nurses’ station and elsewhere if required, with direct access to the recovery and holding areas; rapid emergency access to the trolley from this area to patient areas is essential.

12.4. Recovery area – post-operative

The recovery area is for patients to receive care post-operatively prior to transfer back to the wards, and for patients to recover from the anaesthetic outside of the operating theatre.

• Minimum provision of one (or 1.5) bays per theatre
• Minimum floor area – 12 to 16m² per bay
• Minimum wall length – 3,45m

The recommended distance to the recovery area is a maximum of 65m from the operating theatres to a stage-1 recovery bay. This distance equates to a minute of travel time for the patient from the operating room to recovery, and is considered the maximum time a patient can be off fixed monitoring post-surgery.

(Ron Bridgefoot Principal - HASSELL)

Services include:

• Hands-free wash hand basin - 1 per 4 bays
• Oxygen point - 1 per bay
• Suction point - 1 per bay
• Electrical points - 4 per bay
• Emergency call system - 1 per bay
• Deep-bowl sink - 1
• Lighting - see IUSS BES guide
• A call/panic button - 1 per holding area

Consider:

• Space required for resuscitation trolley.
• Light and ventilation are important.
• All trolley bays in recovery must be provided with a curtain rail for patient privacy.
• Provide an x-ray viewing box / x-ray viewing screen (digital), and facilities to screen off the patient.
• The recovery area shall be within the restricted access area.
• If any post-operative imaging is to be done in this area, sufficient ionic radiation protection must be available for the bay walls and curtains.
• A separate area should be provided for children and breastfeeding mothers.

12.5. **Staff rest room**

The staff rest room is used by the staff for rest and relaxation during tea and meal breaks, especially where it is difficult for staff to use centrally located facilities.

The staff rest room must be located away from the operating theatre area.

Size is dependent on the number of staff using the facility. Allow 1.5m² per person, with a minimum area of 25m².

Services include:

- Double-bowl sink with drainage and hot and cold water.
- Microwave oven.
- 120ℓ fridge/freezer combination.
- Plug outlets for a kettle, microwave and fridge.
- Data outlets.

Considerations:

- Provide a general staff rest room and a separate quiet staff rest area.
- Facilities for food and beverage preparation and storage should be provided.
- Lounge chairs.
- Table and chairs.
- Where possible, the staff rest room is to be shared by all staff of the OTU.

**FIGURE 9: RELATIONSHIP DIAGRAM OF HOLDING/RECOVERY AREA AND NURSES’ STATION**
12.6. **Anaesthetic induction room (optional)**

The provision of anaesthetic rooms (induction rooms) immediately adjacent to the operating room depends on the facility and procedure type.

The anaesthetic induction room is for holding patients on mobile beds or trolleys prior to operative procedures at times when the operating theatre is not available. Local, regional or general anaesthetics can be administered in this area.

This should be a minimum of 16m².

The anaesthetic induction room should be directly connected to the operating/procedure room and may be shared between two operating theatres or procedure rooms. The anaesthetic induction room should be located en route between the entrance of the unit and the operating room.

Services include:

- Four PLUG outlets for equipment
- Vacuum
- Medical gas
- Oxygen.

Considerations:

- A countertop for the preparation of medication and for equipment.
- Cupboards for the storage of equipment and consumables.

12.7. **Storage**

With the impact of technology on the operating room size, more storage areas are required to house the technology when it is not in use.

12.8. **Bay – mobile equipment storage**

The mobile equipment storage bay is an open storage area for one or more items of mobile equipment in frequent use by the operating theatres, and will include the following:

- A blood-warming device needs to be available to all theatres
- A fluid-warming device (preferable in the setting-up room)
- Mobile scales
- Patient-lifting devices
- Portable x-ray equipment
- Camera equipment
- Plug-point space for charging.

---

The provision of anaesthetic rooms immediately adjacent to the operating room has also become a source of controversy. In many European hospitals the provision of the anaesthetic room has been removed in favour of holding areas. This is in response to the modern-day provision of better-equipped day-surgery suites, which have removed many of the minor procedural and short theatre-time cases from the inpatient theatre suite. The anaesthetic room therefore is no longer required as a holding area and, if the premedication can be delivered at ward level, the dwell time outside the operating room can be completed elsewhere. In a patient-focused environment, however, the anaesthetic room provides a soothing environment where carers can wait with the frail elderly or the very young and provide comfort right up to the point of intubation. (Ron Bridgefoot Principal of HASSELL)
12.9. **Blood store**

There shall be adequate provisions for refrigerated blood storage. This may be a blood-storage refrigerator in a dedicated room or in a shared space. The blood-storage area requires a minimum area of 5m².

The blood-storage area should be located with ready access to the OT and may be combined with a pathology room.

Services include:

- Two power outlets
- The blood refrigerator requires essential power supply.
- Considerations:
  - An area for preparation
  - Blood warmer.

12.10. **Laboratory area**

This is an area for preparation and examination of frozen sections which may be provided adjacent to the operating theatre, off the clean passage.

Services and furniture include:

- Stainless steel sink
- Suction point
- 4 x plug points
- Hands-free wash hand basin with elbow action taps
- IT connection
- Telephone
- Shelf for microscope
- Under-counter cupboards with worktop and space to write notes, look into microscope, work with frozen sections.
12.11. Medical gas storage

This area is for the main storage of medical gases, which must be outside the facility and reticulated internally to gas outlets. Provision shall be made for additional separate storage of sufficient reserve gas cylinders to complete at least one day's procedures.

12.12. Store – special instruments

This area is a secure room for the storage and holding of special instruments in a clean environment. This store requires a minimum area of 9m².

The store should be located close to the operating theatres and off the clean corridor.

Considerations:

- The store should be lockable.
- Stainless steel shelving is required.
- Store rooms are best designed in an elongated rectangular shape to allow easy access to all items.

12.13. Store – pharmaceutical

This is a secure room for the storage and holding of pharmaceutical items for use in the operating theatre. The room should be located off the clean passage with a dispensing counter for the issuing of pharmaceuticals upon request from staff from the operating theatres. Pharmaceuticals from outside the OTU should be delivered to this store area through an access-controlled door that connects to the external passage.

Minimum size: 9m²

Services include:

- Data points
- Plug points for computers
- Plug points for equipment
- A clinical-wash hand basin.

Considerations:

- The store should be lockable
- Stainless steel shelving is required
- Countertops for staff to work
- A hatch between the store and the clean passage to allow requisitions to be given and for the delivery of requested pharmaceuticals for specific procedures in the operating theatres.

PHOTOGRAPH 7: TYPICAL STORAGE WITHIN THE OPERATING THEATRE SUITE

12.15. Anaesthetic workroom

An Anaesthetic workroom may be provided for cleaning, testing and storing of anaesthesia equipment and should be located with direct access to circulation corridors and ready access to the operating theatres.

Services include:

- Sufficient power and data outlets and a medical gas panel for testing of equipment.
- A clinical hand-wash basin shall be provided within the room.
- Stainless steel wash trough with hand shower.
- Hands-free clinical wash hand basin.

Considerations

- The anaesthetic workroom shall contain workbenches, sink(s) and racks for cylinders.
- Provisions shall be made for separate storage of clean and soiled items.
- Work top area – stainless steel.
- Provide space for anaesthetic trolleys and other anaesthesia equipment.

12.16. Scope cleaning

This space is utilised for the cleaning, disinfection, sterilisation and storage of endoscopes and accessories.

The area is divided internally into a dirty area for the cleaning of used equipment and a clean area for the storage of cleaned, reprocessed equipment.

It is good practice for scope-cleaning and sterilisation to be performed in the CSSD and not in the OTU.

The dirty-area requirements include:

- The dirty area to be equipped with automated endoscope re-processors, with the required electrical supply and three water supplies – hot, cold and demineralised water.
- A deep-bowl stainless steel sink that is large enough to rinse and wash the endoscopes.
- A stainless steel work surface to be provided.
- Storage cupboards for special chemicals required (these are hazardous and must be handled and stored accordingly).

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• Suction.
• Clinical hand-wash basin with elbow taps, soap dispenser and hand-towel dispenser with disposal bin mounted on the wall.
• Signage to be mounted in a clearly visible spot, warning of any hazardous substances and processes and detailing procedures in the event of contamination.
• Extract ventilation at bench level is required to remove toxic vapours.
• Storage of personal protective equipment such as nitrate gloves, goggles, impermeable aprons and respiratory-protection equipment suitable for use when decontaminating endoscopes or mixing chemicals.

The clean area requirements include:

• Secure storage of flexible endoscopes and accessories both sterile and non-sterile.
• Vertical lockable cupboards to hang the flexible endoscopes.
• Storage for manuals, logging and charting supplies.

PHOTOGRAPH 8: SCOPE CLEANING ROOM IN OPERATING THEATRE SUITE (COURTESY OF RED CROSS HOSPITAL)

13. STERILE ZONE

The sterile zone comprises:

• The scrub-up/gowning room
• The set-up room
• The operating theatre (OT).

These rooms are directly adjacent to each other.
13.1. Scrub-up/gowning room

Each theatre should have a scrub room. The scrub-up/gowning room provides an enclosed, dedicated area for pre-operative scrubbing, gowning and gloving prior to entering the operating theatre. It is required that all entering the operating theatre should wear surgical scrubs and surgical masks.

The scrub-up/gowning room should be a minimum of 11m² per operating room (to allow sufficient space for a minimum of three people). The scrub room should be large enough to allow staff to scrub up, gown and circulate without risk of contaminating each other or contamination from the surrounding fittings.

The scrub area should be situated off the clean passage, in a separate room adjacent to, and in front of, the theatre entrance - i.e. the scrub-up area should be directly accessible from the OTU corridor and from the associated operating or procedure room.

Services include:

- The scrub area to be equipped with a double stainless steel scrub sink with elbow taps.
- Splash-limiting stainless steel basins or drainage trough.
- Hot and cold water.
- Wall-mounted clock.

Considerations:

- The activities of scrubbing and gowning/gloving should be separate within the space.
- Taps should be non-touch – automatically operated or foot operated.
- Taps should be high enough so that hands and elbows can be washed and rinsed under the taps.
- Taps must be able to be operated with elbow action.
- Provide shelves for replacement gowns, gloves, head cover and foot covers.
- Provide adequate space to gown.
- Antiseptic hand-washing liquid dispensers should be fixed to the wall above the scrub sinks. These should be elbow-action dispensers.
- The scrub sink and taps should be at a height that facilitates hand- and arm-washing.
- The design of the drainage must ensure that the floor does not become wet during scrub-up procedures.
- The floors must be anti-slip.
• Wall-mounted paper towels to be provided.
• Wall-mounted glove dispensers to be provided.
• Space for floor disposal bins that are foot-operated.
• The door between the scrub and theatre should be an automatic self-closing door (however, a door is not essential between the theatre and the scrub room unless the scrub is shared between two theatres).
• Splash-back to the sink to be a solid waterproof panel.

PHOTOGRAPH 9: SCRUB AREA EXAMPLES

PHOTOGRAPH 10: EXAMPLE: SCRUB AREA IN CLEAN CORRIDOR

The example above shows an installation where the scrub area is included in the common-use theatre passage. While this appears to be an appealing and economical design, it presents a potential infection-control risk. The common-use passage is not normally served by the same class of ventilation, does not enjoy the same hygienic finishes as the theatre, and is not validated as an aseptic area. This arrangement also removes the clean transition zone between common-use areas and the aseptic theatre environment. Staff are forced to enter and leave the theatre through the main theatre door during surgical cases, thus disrupting the aseptic environment established in theatre while in operation.
13.2. Set up/Setting out/Preparation

The set-up room is the clean workroom in the OTU where clean or sterile materials are held and arranged prior to use in the operating theatres. Instrument packs and other sterile packs required for the day surgery are delivered to the set-up room from CSSD. Here the scrub nurse will set up for a procedure, before the full surgical team are present, opening sterile items and instrument packs on trolleys to check that all the required equipment is present and sterile.

Each theatre should have a set-up room which is outside but adjacent to the operating theatre, and which has direct access to the operating theatre. Sharing of one set-up room between two operating theatres is acceptable, provided the layout and size of the room facilitates such sharing.

Set-up rooms may be combined with the sterile stock store with direct access to the operating theatre.

A minimum of 12m² per operating room (or 20m² where one set-up room is shared between two operating rooms) should be provided. Larger set-up rooms are required for operating rooms where organ-transplant surgery and orthopaedic surgery take place (more trolleys are required to be set up prior to operating).

The main functions for which facilities shall be provided are:

- Setting up of instruments and packs on trolleys prior to a procedure.
- Storage of sterile packs, instruments and materials to be used in the operating theatre.
- Holding of sterile supplies and packs.
- Storage of lotions in a special-purpose warming cabinet.
- Preparation of dressing and instrument trolleys.
- Storage of drugs, including scheduled drugs.

Considerations:

- This is a sterile area and should not be accessed by people not in full theatre attire.
- Space is required for assembly of trolleys prior to delivery to the operating room.
- The set-up room shall be positively pressured relative to adjoining rooms.
- Any worktop areas should be stainless steel.
- Doors into the theatre must be automated.
- Storage and suitable work surfaces.
- Doors in and out of the set-up room must be large enough to allow instrument trolleys fully set out to pass through without being contaminated.
- Work surfaces to be high enough to store 870mm-high trolleys beneath.

14. OPERATING THEATRES (Sterile Zone)

The operating theatre (OT) is central to the operating-theatre unit.

14.1. Essential principles of design for operating theatres

The OT is a specialised facility within the hospital where lifesaving or life-improving procedures are carried out on the human body by invasive or minimally invasive methods under strict aseptic conditions in a controlled environment, by specially trained personnel, to promote healing and cure with maximum safety, comfort and economy. It is imperative that OTs are designed scientifically to ensure sterility, easy maintenance and effective utilisation (Gupta, Kant and Chandrashekhar, 2005).
All aspects of the theatre must be focused on maintaining the concentration of the operating surgeon and team during the operation.

The standardisation of theatre layouts within an OTU will offer great value to the performance and efficiency of the theatre staff. Mirroring theatre layouts in order to economise on space usage is therefore not recommended.

**Infection prevention and control within the theatre**

This section serves to outline a few critical aspects of infection prevention and control as they pertain to surgery facilities. For a more detailed review of IPC measures and practices, the reader is urged to refer to the *IUSS Health Facility Guide: Infection Prevention and Control*.

![Diagram](image)

**FIGURE 11: ROUTES FOR SURGICAL SITE INFECTION IN THE OT**

The following direct contact routes for surgical-site infection are identified as:

**INSTRUMENTS**

Surgical Instruments are at risk of being contaminated prior to or during procedures by both contact and airborne routes. These contaminated instruments are considered to be a primary source of contact infection.

**CONSUMABLES**

Consumables are similarly at risk of becoming themselves contaminated, before being the agent by which contact contamination occurs.

**UTILITIES**

Utilities which are re-usable between procedures, and which may even be shared during simultaneous procedures, can harbour or transmit infection.
FIXED ROOM AND EQUIPMENT SURFACES

These surfaces shall be able to withstand the rigors of the regular cleaning and disinfection regimen prior to each invasive procedure.

THEATRE STAFF

Theatre staff are a major source of infectious particles and for this reason theatre practice, gowning and etiquette is of critical importance in reducing incidences of surgical-site infections.

AIRBORNE CONTAMINATION CAN HAVE THE FOLLOWING SOURCES:

THEATRE STAFF

It is estimated that a person walking can liberate as many as 5,000 bacteria per minute (Kowalski and Bahnfleth, 1998). Many of these particles can remain suspended in the air currents for extended periods and therefore have a great potential for surgical-site infection.

VENTILATION SYSTEMS

Inadequately designed or maintained ventilation systems can harbour, generate, liberate and distribute airborne contaminants widely. Well-designed ventilation systems can suppress, control and dilute airborne contaminants.

ENVIRONMENTAL

Airborne environmental contaminants are generally kept out of the surgery facility by the ventilation system. Where ventilation systems fail or are inadequate, viable and non-viable contaminants can enter the surgery facility and contaminate staff, equipment and the wound site directly.

SURGICAL-SITE INFECTIONS

Surgical-site infections result in a higher healthcare burden. It is estimated that surgical-site infections (SSI) double the cost of treatment through length of stay (LOS) alone. This estimate excludes re-admissions (Broex, et al., 2009).

SPACE SEPARATION AND DIFFERENTIATION WITHIN THE OPERATING THEATRE:

Surgical procedures pose a risk of infection to the patient, necessitating that the space to perform these procedures be carefully planned accordingly. These procedures should occur in areas which must provide adequate space to accommodate the patient, the surgical team while performing the procedure, and the equipment required for the procedure. The set-up of an operating theatre is primarily influenced by the aseptic principles that have to be applied.

In order to maintain good aseptic principles it is essential to divide the areas in and around the operating theatre into three working areas:

- The core or centre of the operating theatre/room is where the patient is situated and where the procedure is performed.
- The “sterile” circle is the area directly around the patient where the scrub nurses and surgeon(s) performing the procedure, using sterile instruments, stand and work. It includes any theatre staff directly involved in the procedure who are wearing sterile surgical attire, the operating table, other

---

accessory equipment and any furniture that is covered with sterile drapes, such as trolleys and stands.

- The unsterile area is where associated support staff (i.e. the anaesthetist, circulating nurse and students, etc.) are performing their duties within the operating theatre. While assisting “sterile” personnel, unsterile personnel must remain in the unsterile area and avoid crossing into or between sterile areas. They supply items to the scrub team attending the patient, move equipment around the theatre into place and monitor patient progress.

Generally, equipment, trolleys and members of the surgical team are on either side of the table, while the anaesthetic team and anaesthesia equipment is at the head of the table.

**FIGURE 12: WORKING AREAS WITHIN THE OPERATING THEATRE**
The equipment, supplies and people working within the immediate surgical field around the patient on the operating table (a 4m x4m envelope) are the area of greatest concern for infection control in the surgical environment. A carefully orchestrated workflow in, out of and within the operating theatre, is key to minimising the risk of contamination in this cleanest of patient-care environments. Anything that moves in and out of operating rooms, as well as the surgical suite as a whole, should be subject to rigorous control.  

14.2. Size and space allocation in operating theatres

- The shape of the room should be rectangular and as close to square as possible.
- The shorter side of the room should be a minimum of 80% of the longer side.
- The room should have splayed corners for ease of cleaning. The ventilation return/extraction duct is commonly placed behind the splayed corner.
- Space allocation must be large enough for correct techniques and small enough to minimise unnecessary movements of personnel, patients and supplies.
- The speed of the development of technology has had, and will have in future, significant implications for the design of OTs. “The challenge for planners and architects is to design surgical facilities that are not only functional but have sufficient flexibility to adapt to the changes and rapid developments in surgical technology” (HBN 26).”

• Size is very dependent on the equipment to be utilised within the OT. Anaesthetic machines, for example, have increased in size due to the number and complexity of the integral patient-monitoring systems.

PHOTOGRAPH 11: ANAESTHETIST TROLLEY IN THEATRE

14.3. Operating theatre sizes

TABLE 5: RECOMMENDED MINIMUM OPERATING THEATRE SIZES

<table>
<thead>
<tr>
<th>THEATRE</th>
<th>AREA</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor procedure</td>
<td>20-36 m²</td>
<td></td>
</tr>
<tr>
<td>General surgery</td>
<td>40 m²</td>
<td></td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>40 m²</td>
<td>May need to accommodate a ceiling fixed or mobile microscope.</td>
</tr>
<tr>
<td>Burns</td>
<td>40 m²</td>
<td></td>
</tr>
<tr>
<td>Cath lab</td>
<td>49 m²</td>
<td></td>
</tr>
<tr>
<td>Digital theatre</td>
<td>49 m³</td>
<td></td>
</tr>
<tr>
<td>ENT and scopes</td>
<td>49 m²</td>
<td>May need to accommodate a ceiling-fixed or mobile microscope.</td>
</tr>
<tr>
<td>General endoscopy</td>
<td>55 m²</td>
<td></td>
</tr>
</tbody>
</table>
The provision of multipurpose operating rooms can be considered to give flexibility in booking cases to any operating room. This generally means operating rooms of around 55m² to cater for a variety of equipment that now accompanies many of the general procedures. Advantages of a standard theatre size include the following (NHS Estates, 2004. HBN 26, Facilities for Surgical Procedures, UK):

- Flexibility, as a variety of surgical procedures can be performed in the same size of theatre, which leads to better utilisation of the theatre and less downtime.
- Both minimal and open surgery can be undertaken in the same theatre space.
- Orthopaedic surgery requires as many as seven trolleys for different sets of instruments during surgery, and requires a larger space to accommodate the additional items.
- In a number of facilities, patients are transferred from the theatre table to their beds. Beds are larger than the traditional trolleys and require more space to manoeuvre within the operating theatre.

### 14.4. Finishes and fixtures

**Ceilings**

Ceilings in the operating theatres should be smooth and monolithic. The surface finish must be washable and completely sealed. While a solid concrete slab is preferred, with services directly above the slab, this is not always possible - which results in a suspended ceiling with a ceiling void above. This requires access panels to be fitted to the ceiling and should be the sealable type. The ceiling void must be deep enough to allow maintenance to be carried out on equipment above the ceiling.

While acoustically absorbent ceiling finishes reduce noise, it is essential that infection risks are minimised and only smooth, easily washable surface finishes are applied to the ceiling soffit.

**Walls**

Walls in the operating theatre must be smooth, impervious, durable, washable and easily cleanable. Added protection needs to be applied in areas where damage to the surface of the wall is more likely.

**Floors**

Floors in the operating theatre have to be particularly hardwearing and durable, as they are subject to:

<table>
<thead>
<tr>
<th>THEATRE</th>
<th>AREA</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urology &amp; plastics</td>
<td>55 m²</td>
<td></td>
</tr>
<tr>
<td>Cardiothoracic</td>
<td>55 m²</td>
<td>May have to accommodate extra equipment like the heart-lung machine.</td>
</tr>
<tr>
<td>Orthopaedic</td>
<td>60 m²</td>
<td>Needs to accommodate x-ray image intensifier, different tables - e.g. fracture tables</td>
</tr>
<tr>
<td>Trauma</td>
<td>49 m²</td>
<td></td>
</tr>
<tr>
<td>Neurosurgery &amp; spinal</td>
<td>60 m²</td>
<td>May need to accommodate a ceiling-fixed or mobile microscope.</td>
</tr>
</tbody>
</table>
• machinery loads as equipment is pushed back and forth throughout the unit and stored or utilised in the theatres;
• Frequent washing and scrubbing, as cleanliness is critical and decontaminating the theatres after each operation is critical for infection-control purposes; and
• spillages, which occur during most operations; consequently floor finishes must be easily washable, stain-resistant and sustainable.

It is therefore important that floors finishes are:

• Slip-resistant
• Continuous with sealed joints at junctions
• Smooth
• Impervious
• Easily washable
• Wear resistant
• Hygienic.

Skirtings should be coved and should rise 100mm up the wall. Best practice is to have a continuous floor finish that continues up the wall with no joint between the floor and the skiriting. This allows for easy cleaning and discourages microbial colonisation.

The fixing of the floor finish to the underlying screed must be carefully carried out to the manufacturer’s specification to ensure good adhesion and so that the floor will withstand the heavy loads anticipated.

Where the theatre is under "laminar flow", the floor directly below the airflow hood should be a different colour, so that staff can differentiate the area covered by the hood within which the sterile trolleys must be kept, and where key staff should remain during the operation.

It is useful to also demarcate with different colours floor areas where essential equipment needs to be always placed - e.g. the emergency trolley.

**Doors and door frames**

Doors and frames need to be durable and able to withstand frequent impact from mobile equipment. Solid-core doors must be used.

Where glazed panels are fitted to the theatre doors, these should be opaque to protect patient privacy.

Automatic door openers that are foot- or elbow-operated should be fitted to the entrance doors to the theatre.

Since the main entrance to theatres isn’t through an anteroom, the operation of this door during operations can severely affect the integrity of the clean zone established in the theatre. While the presence of sliding doors in theatres presents a concealed mechanism which is virtually un-cleanable, and does not provide an adequate seal to assist with contamination control, swing doors also present a plethora of additional problems. The surge of air from swinging doors in theatres could disrupt the ultra-clean zone around the operating table, and the use of swinging doors in theatres with unidirectional airflow (UDAF) or laminar flow should be applied with caution. Sliding doors, when used, should be installed such that the door mechanism is not within the operating-theatre room.

**Windows**

Windows in the OTU should be weather-tight, durable, washable, and easily accessible for cleaning and maintenance.
Windows should have blinds installed which enable the OTU to be darkened as appropriate. These must be washable and easily maintained and of a material that does not encourage microbial colonisation. The positioning of windows is critical within the OTU, and should prevent glare, ensure maximum user comfort, provide views out while protecting internal privacy. See paragraph 0 “Views” for more information.

**Music**

Many theatre staff insist on music in theatres. For this reason it is advisable to install a CD player or AV receiver in the theatre panel, or at a similar discreet location. Where music players are permanently installed in theatres, their controls should be flush with the panel. AV receivers should not be limited to propriety hardware interfaces, but should accept multiple device types. A suitable consideration would be a wireless Bluetooth receiver supporting easy pairing with universal remote audio and volume controls. This would permit staff to bring their own portable media players and playlists for use with the system.

**Lighting**

Good lighting levels and quality are essential in operating theatres. In addition to irradiance, colour rendering and evenness are important factors. For details of lighting requirements for surgeries the reader is referred to the IUSS:GNS Building Engineering Services guidance document.

**Computer equipment**

Digital display of imaging results should be available to the surgeon at the operating table. For this purpose a display panel should be provided on a movable or retractable pendant. The inclusion of a conventional keyboard and mouse is not recommended. Should the imaging display system require a user interface, a decontaminable touch interface is recommended.

**Swab-count board**

Theatre policy requires safe checking and counting of swabs, needles and instruments before, periodically during, and after each case. This process requires the use of containers for used or contaminated swabs, and a count board and swabs will remain in the theatre throughout the case.

For this reason, a swab-count board should be accommodated in the theatre-layout planning. The swab-count board could include the stand with bins and racks to facilitate the counting and control of swabs and instruments.
Theatre warning light

A visual alarm panel should be included in the theatre. This panel should give an indication of any critical engineering system failure, such as ventilation or medical gases. Alarms to this panel should also be relayed to the nurses' station and engineering office. Non-critical alarms should be relayed only to the engineering office and nurses’ station as necessary. The theatre alarm panel should also give a visual indication of the theatre temperature. For information the reader is referred to the IUSS: GNS Building engineering services guidance document.

15. Theatre types

15.1. THE GENERAL-SURGERY OPERATING THEATRE

This operating theatre provides an aseptic environment in which to carry out surgical procedures under local, regional, general anaesthetic or sedation.

- The general-surgery operating theatre is located within the operating unit and away from through-traffic.
- Direct access is required to the holding bay/anaesthetic room, scrub room, exit bay/circulation corridor.
- Ready access is required to recovery, clean-up areas, sterilising bay, sterile store and CSSD.

STAFF CONTINGENT AND LOCATIONS

The surgeon normally stands on the patient’s right-hand side if it is open surgery; however, in the case of laparoscopic surgery the position varies. The surgeon may stand at the foot end of the table.

The scrub person stands opposite the surgeon, with the assistant surgeon.

The anaesthetist and assistant will be at the head of the theatre table.

The circulating person will be at any area that makes it easy to work in close proximity to the scrub team.

OVERHEAD SERVICES

Overhead services should include one central ceiling-mounted, dual-luminaire theatre light that should be securely fixed above the operating table.

Also, two services pendants, one for surgical and one for anaesthetic use, are to be securely fixed to the ceiling. These pendants shall be positioned such that they are readily accessible to either the surgeon or the anaesthetist, as appropriate. Retractable pendants shall be designed such that they accommodate the ergonomics of even the most diminutive nursing staff.

<table>
<thead>
<tr>
<th>General theatre services</th>
<th>Anaesthetic pendant</th>
<th>Surgical pendant</th>
</tr>
</thead>
<tbody>
<tr>
<td>230V socket outlets and connection to the UPS systems</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Oxygen</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>Medical vacuum points</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>
The table above details the anaesthetic and surgical pendants differently. Many surgical teams will prefer that both pendants are identical thus providing more flexibility in theatre configuration.

### WALL-MOUNTED SERVICES

A wall-mounted control panel is commonly provided and should include the following services:

- Radio or AV receiver
- Clock and stop-clock
- Telephone
- Sterile touch-screen-controlled computer
- Temperature controller
- The control panel could have a conventional x-ray viewing box or a 42” LCD screen (this may be on a fixture suspended from the ceiling).
- A swab board shall be mounted on one wall.
- An indicator light is required outside the entrance of the theatre to indicate whether the theatre is occupied.

It is essential that at least one wall be free from door openings and services that require frequent attention. This provides a quiet area for sterile equipment and scrubbed personnel, which is not compromised by frequent traffic. It is preferable for the adjacent wall to be free, or impinged upon only for exit from the operating room.

### ANAESTHETIC EQUIPMENT

The following anaesthetic equipment should be accommodated:

- Anaesthetic machine, with cardiac monitor
- Two or three drip stands
- Equipment positioning for endoscopic surgery
- Trolley with the anaesthetic-induction and -reversal drugs
- Trolley for the anaesthetist to work on
- Suction apparatus - may or may not be part of anaesthetic machine
- Records / computer to record patient data
- Waste-sharps container
- Chair.

### SURGICAL EQUIPMENT

The following surgical equipment should be accommodated:

- Digital display and recording system for patient’s records
• Two infusion pumps
• Three syringe pumps
• Blood warmer
• Feeding pump
• Operating table
• Suction apparatus
• Two kick-abouts
• Three to four instrument trolleys
• Three basin stands
• Mayo stand or table
• Diathermy machine
• Two small trolleys
  o 1 for the catheter
  o 1 for the telescope warmer
• Two endoscopy carts with
  o the camera system, video,
    light source and insufflators
• Equipment monitors for specialised equipment
• Writing worktop, with drawers for nursing staff
• Four chairs
• Sharps container
• Emergency call system.

**ADDITIONAL CONSIDERATIONS:**

• The scrub area and setting-up area may be shared by two adjacent theatres.
• The use of automatic, foot-operated, sliding doors for all theatre entrances is recommended.
• Passive infrared proximity sensors are not appropriate for activating theatre doors.
• An emergency call button linked to the sister's office should be accessible from within the theatres.
• All theatre electrical services should be on emergency backup supply. This includes a UPS and generator.

15.2. **THE OBSTETRICS OPERATING THEATRE**

This theatre is principally the same as a general theatre, save for the wall panel which includes services for two new-borns. This should include two separate sets in the panel, each with:

• Oxygen
• Vacuum
• Medical air
• Six plugs.

Two baby-resuscitation stations are to be located permanently adjacent to the theatre’s wall service panel.

15.3. **THE ORTHOPAEDICS OPERATING THEATRE: – ULTRACLEAN /LAMINAR FLOW**

**PERSONNEL REQUIRED IN THE THEATRE**

• Surgeon
- One or two assistant surgeons
- Scrub person - can be one or sometimes two
- The circulating person
- Anaesthetist
- Anaesthetic nurse or assistant
- Possible additions:
  - students
  - medical reps

The surgeon normally stands on the patient’s left-hand side or, depending on the type of surgery he will be doing, in another position. If it is surgery of the extremities, he will stand on the side to be operated on.

The assistant surgeon stands opposite the surgeon, next to the scrub person.

The circulating person is at the bottom and side of the table, and looks after the scrub team.

The scrub person stands opposite the surgeon, with the assistant surgeon.

The anaesthetist and assistant will be at the head of the theatre table.

**OVERHEAD SERVICES**

Overhead services should include one central ceiling-mounted, dual-luminaire theatre light that should be securely fixed above the operating table.

Also, two services pendants, one for surgical and one for anaesthetic use, are to be securely fixed to the ceiling. These pendants shall be positioned such that they are readily accessible to either the surgeon or the anaesthetist, as appropriate. Retractable pendants shall be designed such that they accommodate the ergonomics of even the most diminutive nursing staff.

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<th>Surgical pendant</th>
</tr>
</thead>
<tbody>
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<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Oxygen</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>Medical vacuum points</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Low-pressure medical air</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Nitrous oxide</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Anaesthetic-gas scavenging points</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>High-pressure medical air</td>
<td>-</td>
<td>2</td>
</tr>
</tbody>
</table>

Anaesthetic, wall-mounted and surgical equipment accommodation considerations are principally the same as for general theatres.
**UNIDIRECTIONAL AIRFLOW/ LAMINAR-FLOW PLENUMS**

- The plenum shall be fitted to the ceiling in the middle of the theatre.
- All metal work on the laminar flow unit shall be stainless steel or baked epoxy-coated mild steel.
- HEPA filters shall be terminally mounted at the unidirectional-airflow (UDAF) plenum.
- The UDAF screen shall be hinged such that the lighting and HEPA filters are serviceable from within the theatre.
- HEPA filters shall be removable into the theatre for testing and replacement. This protects the theatre from being directly exposed to the service-space environment during HEPA filter changes.
- The UDAF plenum shall include sealable upstream sampling ports for in situ filter-efficiency testing.
- The UDAF plenum shall include concealed lighting to achieve the required background lighting levels and quality.

![PHOTOGRAPH 13: EXAMPLE OF UDAF PLENUM ACCESS](image)

**EQUIPMENT:**

The equipment required in an orthopaedic theatre is similar to that of a general theatre, although the equipment trolleys are larger and more numerous to accommodate the specialist equipment. There may be as many as seven equipment trolleys for certain procedures.

**ADDITIONAL CONSIDERATIONS**

The "Plaster of Paris" or POP store room should be adjacent to the theatre and should include a stainless steel sink with hot and cold water and storage space for materials.

**15.4. THE CARDIOTHORACIC OPERATING THEATRE**

This theatre is principally the same as a general theatre, with the following considerations:

**PERSONNEL REQUIRED IN THE THEATRE**

- Surgeon
- One or two assistant surgeons
• One or two scrub persons
• One or two anaesthetists
• One or two anaesthetic assistants or nurses
• One circulating person
• Perfusionist.

The surgeon stands on the patient’s right-hand side during the procedure.

The assistant stands opposite the surgeon.

If there are two assistants, the other one will stand on the surgeon’s side, opposite the scrub person.

The scrub person stands next to the assistant surgeon, opposite the surgeon.

The anaesthetist is always at the top end of the operating table.

The anaesthetic nurse or assistant will be in close proximity to the anaesthetist at all times.

The perfusionist sits behind the surgeon, next to the heart-lung machine.

**OVERHEAD SERVICES**

The overhead services required are similar to that of a general theatre.

**ANAESTHETIC EQUIPMENT**

The following anaesthetic equipment should be accommodated:

• Anaesthetic machine, with cardiac monitor
• Two or three drip stands
• Small trolley for insertion of lines like the CVP, arterial line (ideal in induction room)
• Trolley with the anaesthetic induction and reversal drugs
• Trolley for the anaesthetist to work on
• Suction apparatus - may or may not be part of anaesthetic machine
• Records / computer to record patient data
• Monitors
• Infusion pumps
• Waste-sharps container
• Chair.

**SURGICAL EQUIPMENT**

The following surgical equipment should be accommodated:

• Operating table
• Three to four surgical instrument trolleys
• Small trolleys for insertion of a urinary catheter
• Basin stands - two or three
• Two kick-abouts
• Mayo stand or table
• Suction apparatus
• Three basin stands
• Mayo stand or table
• Diathermy machine
• Two small trolleys
  ▪ 1 for the catheter
- 1 for the telescope warmer
- Defibrillator machine
- Drip stand with sternal saw motor
- Special operating table which can be adjusted to any position needed
- More than one suction apparatus
- Four chairs
- Sharps container
- Emergency call system.

**PERFUSIONIST EQUIPMENT**

The following perfusionist equipment should be accommodated:

- Heart-lung machine
- Heater/cooler machine
- Intra-aortic balloon pump
- Arterial blood gas machine
- Ice machine (outside OR)
- The heat load of the perfusionist’s equipment (heart-lung machine, inter alia) must be considered.

**15.5. THE NEUROSURGERY OPERATING THEATRE**

This theatre is principally the same as a general theatre, save for the following considerations:

**PERSONNEL REQUIRED IN THE THEATRE**

- Surgeon
- One or two assistant surgeons
- One scrub person
- One anaesthetist
- One anaesthetic assistant or nurse
- One circulating person.

The surgeon and assistant stand at the head of the table.

The anaesthetist and anaesthetic machine will be at the side or at the foot end of the table.

The scrub person stands either between the surgeon and assistant, or on the right-hand side of the patient.

The circulating person is next to the sterile team, at the head end of the table.

The anaesthetic nurse or assistant will be in close proximity to the anaesthetist.

**OVERHEAD SERVICES**

Overhead services should include one central ceiling-mounted, dual-luminaire theatre light that should be securely fixed above the operating table.

Also, two services pendants, one for surgical and one for anaesthetic use, are to be securely fixed to the ceiling. These pendants shall be positioned such that they are readily accessible to either the surgeon or the anaesthetist, as appropriate. Retractable pendants shall be designed such that they accommodate the ergonomics of even the most diminutive nursing staff.
Consider that since the surgeon is at the head of the patient and the anaesthetist moves to the side of the patient, the anaesthetic pendant should be located to the side (side of the patient’s head).

**WALL-MOUNTED SERVICES**

The wall-mounted services required for this type of theatre are principally the same as for a general theatre.

**ANAESTHETIC EQUIPMENT**

The aesthetic equipment space requirements are principally the same as for a general theatre.

**SURGICAL EQUIPMENT**

The following surgical equipment should be accommodated:

- Operating table
- Two or three surgical instrument trolleys
- Suction apparatus
- Two or three basin stands
- Small trolley with shaving equipment
- Small trolley for inserting the urinary catheter
- Mayo stand or table
- Operating microscope
- Ultrasonic surgical aspirator for tumours
- Head rests like the Mayfield and the horseshoe
- Special operating table that can be adjusted to suit the particular procedure
- Two suction machines or apparatus
- Diathermy machine with both bipolar and monopolar settings.

**ADDITIONAL CONSIDERATIONS**

The surgical equipment utilised in this type of theatre can be highly sensitive to vibration. The theatre should therefore be appropriately isolated from vibration. Refer to the equipment installation requirements for acceptable limits.
15.6. THE OPHTHALMOLOGY THEATRE

This theatre is principally the same as a general theatre, save for the following considerations:

**STAFFING REQUIREMENTS**

Consider that the surgeon is at the head and the anaesthetist moves to the side of the patient; therefore the anaesthetic pendant is to the side (side of patient’s head).

**OVERHEAD SERVICES**

This theatre requires ceiling-mounted scopes. This demands that the ceiling structure be sufficiently supported to carry the additional load.

**ADDITIONAL CONSIDERATIONS**

The surgical equipment utilised in this type of theatre can be highly sensitive to vibration. The theatre should therefore be appropriately isolated from vibration. Refer to the equipment installation requirements for acceptable limits.

The following additional features need to be accommodated in the setting-up room:

- Washing and cleaning area for instruments.
- Storage space.
- Flash sterilisers are often requested for emergency sterilising of dropped utensils. This solution is not recommended, as these can create an additional maintenance and operational burden and risk. In addition, the responsibility of equipment sterilisation then shifts away from the CSSD to the theatre staff. It is recommended that the capacity for emergency sterilising is incorporated into the CSSD to ensure proper sterilisation processes are followed. The implementation of flash sterilisers as a convenience to supplant good operational planning is therefore not acceptable.

15.7. THE UROLOGY THEATRE

This theatre is principally the same as a general theatre, save for the following considerations:

**ADDITIONAL CONSIDERATIONS**

The surgical equipment utilised in this type of theatre can be highly sensitive to vibration. The theatre should therefore be appropriately isolated from vibration. Refer to the equipment installation requirements for acceptable limits.

Urology theatres usually function as a set of two theatres in tandem:

- The first theatre is a standard theatre.
- The adjacent theatre is used for imaging, and has a scope and x-ray table with x-ray – therefore it needs a water supply and drain to the table.
- The imaging room may require lead-lined doors for radiation protection. The hinges or sliding mechanism and closers of these doors should be designed to reliably manage the additional weight of these doors.

Where separate imaging rooms are not implemented and integrated imaging bays are used instead, the theatre architecture should incorporate ionising radiation-protective measures.

15.8. THE BRONCHOSCOPY THEATRE

This theatre is principally the same as a general theatre, save for the following considerations:
A scope-cleaning room is required near or attached to the theatre. This is detailed further on in this document.

- Flash autoclaves are often requested but are not recommended, as these can create an additional maintenance and operational burden. In addition, the responsibility of equipment sterilisation then shifts away from the CSSD to the theatre staff.
- A clean, ventilated storage cupboard is required for the drying and storing of scopes.

Since bronchoscopy theatres present a very high risk for airborne infection, these theatres should be maintained at a relative negative pressure with high ventilation rates. Recirculation ventilation is not recommended for these theatres; instead full fresh-air exhausted ventilation systems are recommended with special consideration for the control of contaminated exhaust discharge. The three elements of control are direction, dilution, and disinfection.

15.9. **THE PAEDIATRIC OPERATING THEATRE**

This theatre is principally the same as a general theatre, save for the following considerations:

- Consideration should be given to creating a warm welcoming environment for paediatric theatres.
- Waiting areas should be provided for mothers and family.
- OT tables shall not be fixed.
- Independent temperature control is required to reduce the risk of mortality in paediatric care.
  - The temperature range for paediatric theatres and induction rooms should be between 18°C and 28°C.

**CONTEXT CONSIDERATION**

- Paediatric theatre caseloads will vary from institution to institution and may be as high as 20-25%.
- Paediatric theatre cases treated within district hospitals should be limited to children over four years of age or 10kg.

15.10. **THE BURNS THEATRE**

This theatre is principally the same as a general theatre, save for the following considerations:

- The operating table should facilitate waste-water management during patient washing.
- Floor drains are not recommended within theatres as these can present a conduit for cross-infection between procedures and theatres.
- Two hoses should be available for patient wash.
- Temperature range = 22-28°C.
- Humidity range = 45-60% RH.

- Temperature and humidity display is required at the theatre control panel.

15.11. **DIGITAL OPERATING THEATRES**

Most modern theatres can be termed digital theatres as they now use digital imagery during surgery. An effective implementation of digital technology in theatres requires consideration of the following questions in planning:

- Which surgical team member needs to see what, and at what stage?
- Where are the images being recorded from, and where do they get recorded to?
- Is imaging equipment constantly used in the theatre for procedures?
If not, then mobile units could be considered.

Fixed or ceiling-mounted equipment could become an obstruction if it is not continuously utilised in the theatre in question.

16. Day surgery unit

Day-surgery units are defined as “self-contained, dedicated units, suitable for carrying out surgical procedures and treatments on adult and child patients whose discharge is planned for the same day as their admission”\(^\text{12}\)

Day-care services mainly include day surgery, endoscopy, and medical investigation and treatment.

Provision of a large theatre size is preferable to accommodate a variety of surgical procedures. The infrastructural requirements for a day-surgery unit theatre are principally the same as that of a general theatre.

16.1. Planning considerations

Design of the facility should accommodate the sequence outlined below, such that the patient progresses in one direction through the unit. Principal routes should be designed to minimise clashes between patients and services.

Patient-related activities occur in the following sequence:

- entering the unit
- reception and waiting
- pre-admission and assessment
- pre-operative preparation
- operation/procedure
- post-anaesthesia recovery
- pre-discharge recovery and care
- discharge and exit of the unit
- transfer to a larger theatre to accommodate scopes.

FIGURE 13: ONE-WAY PATIENT FLOW THROUGH DAY UNIT

Entrance and exit

Privacy is essential. Men and women should be attended to in separate areas, and children must be kept separate from adult patients. Continuous observation by the nursing staff is crucial.

16.2. Location

Day-theatre units should preferably be close to the OPD or adjacent to the theatres where the day theatre can share services with the main theatre unit.

16.3. Accommodation requirements

<table>
<thead>
<tr>
<th>Room</th>
<th>Standard</th>
<th>Non-standard</th>
<th>Comments</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entrance to day unit</td>
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<tr>
<td>Entrance</td>
<td></td>
<td>x</td>
<td>Refer to Item 9.1</td>
<td>Entrance</td>
</tr>
<tr>
<td>Waiting area with play area</td>
<td></td>
<td>x</td>
<td></td>
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</tr>
<tr>
<td>Reception</td>
<td></td>
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<tr>
<td>Pre-operative area</td>
<td></td>
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</tr>
<tr>
<td>Pre-admission assessment room</td>
<td></td>
<td>x</td>
<td>Consulting room configuration</td>
<td>Adjacent to waiting area</td>
</tr>
<tr>
<td>Change rooms for male patients</td>
<td></td>
<td>x</td>
<td>Change room area</td>
<td>Adjacent to assessment room</td>
</tr>
<tr>
<td>Change rooms for female patients</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient locker area</td>
<td></td>
<td>x</td>
<td></td>
<td>Adjacent to change areas</td>
</tr>
<tr>
<td>Male patient toilets and shower</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Room</td>
<td>Standard</td>
<td>Non-standard</td>
<td>Comments</td>
<td>Location</td>
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<tr>
<td>Female patient toilet and shower</td>
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<tr>
<td>Admissions room</td>
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<tr>
<td>Nurses’ station</td>
<td>x</td>
<td></td>
<td>Focal point within the pre-operative area</td>
<td>Adjacent to patient changing rooms, admissions rooms and patient sub-waiting areas.</td>
</tr>
<tr>
<td>Operating Theatre suite</td>
<td></td>
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</tr>
<tr>
<td>Pre-operative nurses base</td>
<td>x</td>
<td></td>
<td>Pre-operative area in theatre</td>
<td>Theatre area which may be separate to the main theatre block or attached to the main theatre block in the hospital. This should also be adjacent to the day ward area - pre- and post-op.</td>
</tr>
<tr>
<td>Pre-operative holding area</td>
<td></td>
<td>x</td>
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<td></td>
</tr>
<tr>
<td>Anaesthesia room</td>
<td>x</td>
<td></td>
<td>Theatre unit (refer to IUSS document re operating theatres)</td>
<td></td>
</tr>
<tr>
<td>Scrub-up and gowning</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating room</td>
<td>x</td>
<td></td>
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<tr>
<td>Set-up room</td>
<td>x</td>
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<tr>
<td>Mobile x-ray equipment bay</td>
<td>x</td>
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<tr>
<td>Post-operative recovery room</td>
<td>x</td>
<td></td>
<td>Post-operative area</td>
<td></td>
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<tr>
<td>Post-operative nurses’ station</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sluice room</td>
<td>x</td>
<td></td>
<td>Support services off theatre passage</td>
<td></td>
</tr>
<tr>
<td>Scope cleaning room</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment store</td>
<td>x</td>
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<tr>
<td>Dirty utility</td>
<td>x</td>
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<tr>
<td>Surgical store</td>
<td>x</td>
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<tr>
<td>Medicine cupboard</td>
<td></td>
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<tr>
<td>Equipment service room</td>
<td>x</td>
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<tr>
<td>Medical gas cylinder store</td>
<td>x</td>
<td></td>
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<td></td>
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<tr>
<td>Wheelchair/trolley park bays</td>
<td></td>
<td>x</td>
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</tr>
<tr>
<td>Room</td>
<td>Standard</td>
<td>Non-standard</td>
<td>Comments</td>
<td>Location</td>
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<tr>
<td>Anaesthetic-gas scavenging</td>
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<tr>
<td><strong>Post-operative recovery area</strong></td>
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<tr>
<td>Pre-discharge recovery area - trolleys</td>
<td></td>
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<td></td>
<td>Adjacent to the nurses’ station</td>
</tr>
<tr>
<td>Pre-discharge recovery area - chairs</td>
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<tr>
<td>Pre-discharge recovery area – nurses’ base</td>
<td>x</td>
<td></td>
<td></td>
<td>Adjacent to pre-discharge recovery area</td>
</tr>
<tr>
<td>Patient toilet (to accommodate a patient in a wheelchair)</td>
<td>x</td>
<td></td>
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</tr>
<tr>
<td>Clean utility</td>
<td>x</td>
<td></td>
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<tr>
<td><strong>Shared support areas</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Dirty utility</td>
<td>x</td>
<td></td>
<td></td>
<td>Located between pre-op, post-operative recovery and pre-discharge areas</td>
</tr>
<tr>
<td>Sluice</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cleaners’ room</td>
<td>x</td>
<td></td>
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<tr>
<td>Sterile pack store</td>
<td>x</td>
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<tr>
<td>Equipment store</td>
<td>x</td>
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<td></td>
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<tr>
<td>Clean linen store</td>
<td>x</td>
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<tr>
<td>*Or central store</td>
<td>x</td>
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<tr>
<td>Crutches and splint store</td>
<td>x</td>
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</tr>
<tr>
<td>Switch room</td>
<td>x</td>
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<tr>
<td><strong>Staff facilities</strong></td>
<td></td>
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<tr>
<td>Staff change for theatre - female</td>
<td>x</td>
<td></td>
<td></td>
<td>A separate staff area closely situated to the theatres</td>
</tr>
<tr>
<td>Staff change for theatre - male</td>
<td>x</td>
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<tr>
<td>Staff toilet female</td>
<td>x</td>
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<tr>
<td>Staff toilet male</td>
<td>x</td>
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</tr>
<tr>
<td>Staff locker area</td>
<td>x</td>
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</tbody>
</table>
17. IT Requirements

It is important that the design team understand the intra-dependencies of all the services within the OTU early during the design process. This includes collating and analysing the extensive information regarding the following equipment and services:

- medical gases
- oxygen and air
- suction
- data cables and data equipment
- surgical equipment.

These interdependencies will inform the IT requirements that need to be planned for. This is especially relevant in theatres where ready access to diagnostic imagery is used to assist in, and assess, procedural progress.

The incorporation of real-time imaging provided by MRI or CT-scanning during neurosurgical, cardiovascular or orthopaedic surgery demands larger operating rooms. In many tertiary hospitals specialised operating rooms of 65-80m² are in evidence.

Imaging equipment capable of performing 3D rotational angiography, CT-scanning and intravascular ultrasound enable open surgery and endovascular techniques to be employed simultaneously.

The challenge to the design team exists in understanding where and how this technology is to be located and to anticipate possible clashes between this and other services and circulation that may result.

The equipment that is installed in the specialised or hybrid theatres should not impede their use in more standard cases.

Communication between operating rooms and pathology and radiology can be implemented, enabling real-time consultation with other medical experts to provide a seamless and integrated delivery of care to the patient. (Ron Bridgefoot Principal HASSELL)

The use of IT and communications may now include voice-activated control of equipment and the room environment, robotic surgery, electronic patient records and CCTV for training and consultation.
18. Dirty Zone

The dirty zone includes the following areas:

- Dirty utility
- Sluice
- Wash-up areas (scopes)
- TSSU/CSSD
- Cleaner's room
- Scope-cleaning room.

18.1. Scope-cleaning room

Washing and hanging provision is required for scopes and equipment.

18.2. Sluice

This is a standard room of a minimum of 9m² and its documentation should be read in conjunction with the IUSS generic room documentation.

The sluice in the administration zone should be adjacent to the recovery area.

The sluice provides for:

- Cleaning and holding of used equipment for collection and sterilisation elsewhere
- Disposal of clinical and other waste and soiled linen
- Testing and disposing of patient specimens
- Decontamination and storage of patient utensils such as pans, urinals and bowls.

The sluice should include the following services:

- Hand-wash basin with elbow taps and gooseneck outlet in each room with splash-back, soap dispenser and paper-towel dispenser
- Automatic bed-pan washer, in all sluices
- Stainless steel sluice sink
- Two 230V socket outlets.
Storage space for the following should be accommodated:

- Clean bed pan and urinal drying racks
- Built-in cupboard
- Two run-abouts, two-bucket system
- Soiled linen area
- Bumper rails to prevent bins marking walls
- Storage for used CSSD supplies, urine testing, detergents, urinal covers
- Space for large bins
- Shelves for wash basins and buckets.

19. STRUCTURE

19.1. Ceiling Void / Engineering Space

When planning the OTU, the construction of the operating room’s ceiling detail bears some consideration. The ceiling structure above the operating theatre should be safely trafficable, without interrupting the operation below.

The designer has the option of creating a reinforced concrete slab and finishing the soffit to serve as the OT ceiling. This solution offers the advantage of providing a structural component to which the lights and pendants can be fixed directly. Unfortunately this solution requires very careful detailing and planning, as larger penetrations need to be created during the construction of the slab and they consume precious vertical space.

Sufficient space should be provided for uncompromised routing of services above the operating theatre. The interstitial engineering space should provide enough room for installing and maintaining services. It is therefore helpful to allow for sufficient headroom for maintenance staff.

Alternatively, a trafficable, flush-finished, monolithic and impervious ceiling constructed below the slab offers a more efficient solution. This solution requires that special structures need to be installed to support the lights, plenums and pendants.
Where ceiling void access is to be through the ceiling itself, access through removable lights is not recommended as these inevitably become damaged. Dedicated trapdoors should be installed outside of the clean zone so that maintenance staff do not need to re-enter the clean zone after being in the ceiling.

Smooth cornice details are recommended to aid cleaning. Floated ceilings are not recommended. No effluent or waste pipes should be routed in the space directly above any theatre.
PART C - ACCOMMODATION PLANS

The flexibility of this theatre design permits natural light into the operating room by the removal of the dirty corridor, which previously ran around the perimeter. Grouping operational rooms together into effective clusters enables stores and set-ups to become tailored to case types, and helps staff identify with their location. This is particularly important for large theatre floors to reduce travel times between stores and where there is little reference/orientation to outside views.

At the Gold Coast Hospital the operating rooms are positioned around a central sterile support area in clusters of eight. The operating rooms in turn were encircled by a peripheral patient transport corridor which enabled patients to see out. It is noted that in the Mackay Hospital Redevelopment the use of Case Carts enabled flexibility in the use of corridors because of the containment of used materials within the carts.
OVERVIEW: OPERATING UNIT - RELATIONSHIP OF COMPONENTS

- [Diagram of an operating unit with relationships of components]
<table>
<thead>
<tr>
<th>ROOM</th>
<th>COMMENTS</th>
<th>STANDARD</th>
<th>NON-STANDARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>GENERAL AREAS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Administrative offices</td>
<td>Outside of OTU</td>
<td></td>
<td></td>
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<tr>
<td>IT Switch room and UPS</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Meeting room - large</td>
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<td></td>
<td>x</td>
</tr>
<tr>
<td>Office – Chief anaesthetist</td>
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<td></td>
<td>x</td>
</tr>
<tr>
<td>Office - Chief surgeon</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Office – Doctors</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Office – Unit manager</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Office – Sister</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Doctors on call rooms with en suite ablation</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Staff toilet</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Education and training</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seminar room</td>
<td>20-30 places</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Library</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Study area</td>
<td>5 places</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Pre-entrance to operating theatre unit</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Public waiting area</td>
<td>Allow at least 4 chairs</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Wheelchair accessible toilet</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Counselling room</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Entrance area</td>
<td></td>
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</tr>
</tbody>
</table>
### Facilities for Surgical Procedures

#### Lobby
- Lobby

#### Porters’ base
- Porters’ base

#### Trolley park
- Trolley park

#### Unit manager’s office
- Unit manager’s office

#### Reception
- Reception

#### Bay – Personal protective equipment
- Bay – Personal protective equipment

#### Restricted access area

#### Staff area

#### Female change room with toilet & showers
- Female change room with toilet & showers

#### Male change room with toilet & showers
- Male change room with toilet & showers

#### Operating theatre suite

#### Clean area

<table>
<thead>
<tr>
<th>Room</th>
<th>Comments</th>
<th>Standard</th>
<th>Non-Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office</td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Patient holding bays</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Nurses’ station</td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Patient-recovery bays</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Clean utility for recovery</td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Clean passage to operating theatres</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Stores</td>
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<td></td>
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<tr>
<td>Clean linen</td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>- Equipment</td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>- Instruments</td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>- Pharmaceutical supplies</td>
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<td>x</td>
</tr>
</tbody>
</table>

*Health Facility Guides: Facilities for Surgical Procedures [Gazetted, 30 June 2014]*
<table>
<thead>
<tr>
<th>ROOM</th>
<th>COMMENTS</th>
<th>STANDARD</th>
<th>NON-STANDARD</th>
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<tbody>
<tr>
<td>Surgical supplies</td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Anaesthetic supplies</td>
<td></td>
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<td>x</td>
</tr>
<tr>
<td>Blood store</td>
<td></td>
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<td>x</td>
</tr>
<tr>
<td>Equipment cleaning</td>
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<td>x</td>
<td></td>
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<tr>
<td>Mobile equipment bays</td>
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</tr>
<tr>
<td>Emergency trolley</td>
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<td>x</td>
<td></td>
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<tr>
<td>Trolley</td>
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<td>Cleaners’ room</td>
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DRAWING 2: THEATRE AND CSSD PLAN (COURTESY OF MITCHELLS PLAIN [DISTRICT] HOSPITAL)

MPDH Architects in Association
DRAWING 3: THEATRE AND CSSD LAYOUT (COURTESY OF KING GEORGE V [DISTRICT] HOSPITAL)

Osmond Lange Architects
DRAWING 4: THEATRE LAYOUT (COURTESY OF EDENDELE [REGIONAL] HOSPITAL)
Facilities for Surgical Procedures [Gazetted, 30 June 2014]
REFERENCES


ACTS AND REGULATIONS

All local Municipal laws and regulations.

Any other applicable Laws or Regulations.


Regulations of the local Electricity Authority.


# LIST OF ABBREVIATIONS

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<th>Description</th>
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<tr>
<td>A &amp; E</td>
<td>Accident and Emergency Department</td>
</tr>
<tr>
<td>AHU</td>
<td>Air-handling Unit</td>
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<tr>
<td>CSSD</td>
<td>Central Sterile Supply Department</td>
</tr>
<tr>
<td>EMS</td>
<td>Emergency Medical Services</td>
</tr>
<tr>
<td>HCW</td>
<td>High Care Ward</td>
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<tr>
<td>HEPA</td>
<td>High Efficiency Particulate Air (filter)</td>
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<tr>
<td>ICU</td>
<td>Intensive Care Unit</td>
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<tr>
<td>NBR</td>
<td>National Building Regulations SABS 0400</td>
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<tr>
<td>NICU</td>
<td>Neonatal Intensive Care Unit</td>
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<tr>
<td>OT</td>
<td>Operating Theatre</td>
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<td>OTU</td>
<td>Operating Theatre Unit</td>
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<tr>
<td>SABS</td>
<td>South African Bureau of Standards</td>
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<tr>
<td>SANS</td>
<td>South African National Standards</td>
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<tr>
<td>SSO</td>
<td>Switched Socket Outlet</td>
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<tr>
<td>UDAF</td>
<td>Uni-directional Air Flow</td>
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<tr>
<td>UPS</td>
<td>Uninterrupted Power Supply</td>
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<tr>
<td>URS</td>
<td>User Requirement Specification</td>
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</table>
LIST OF DEFINITIONS

“central hospital” means a public hospital designated by the Minister of Health to provide health services to users from more than one province.

“health establishment” means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services.

“hospital” means a health establishment which is classified as a hospital by the Minister in terms of section 35 of the National Health Act.

“operating room” is a room within the operating suite in which surgical or other invasive procedures can be carried out.

“operating suite” refers to a suite of rooms within the demarcated area where surgical and other invasive procedures are carried out or where support to these procedures is provided.

“barrier isolator” refers to a device comprising a physical film separating an operator or clinician from a work process; The work process is maintained within an isolated environment which may be held at a positive or negative pressure.

"Central Sterile Supply Department (CSSD)" means a facility for the receiving, decontamination, preparation, packing, sterilising, storing and issuing of sterile and disinfected instruments and other reusable materials. This facility is also known as the "sterilisation and disinfection unit" (SDU).

"cleaners' room" means a room for the storage of cleaning equipment, the drawing of clean water and the disposal of dirty water, and the washing and drying of cleaning equipment. This room may be combined with the dirty utility room.

"clean air" means air that does not contain a considered contaminant.

"clean utility room" means a room for the storage of sterilised packs, dressings, sterile equipment and pharmaceutical supplies respectively; this area may also be used for a set-up area for ward procedures.

"considered contaminant" means any actual contaminant, surface or airborne, that may have a certain impact for which avoidance measures are taken.

"cross-contamination" refers to the contamination of any zone or surface by fomites, considered particulates aerosols, biological agents, fumes or gases originating from another zone or surface.

"cross-infection" refers to the spreading of an infection from one organism to another by cross-contamination.
"department" means a grouping of accommodation which has a specific function within a hospital; its area includes the associated internal or departmental circulation space.

"dirty utility room" means a room used for the collection and temporary storage of used equipment and general ward material; it can combine the activities of the sluice room, the soiled linen and waste room and the cleaners' room.

"emergency trolley/crash cart" means a mobile cart used for the storage of all appropriate resuscitation equipment and pharmaceuticals.

"equipment store" means a room used for the storing of monkey chains, traction kits and other general equipment.

"fresh air" means air drawn from the outside air of a building and contamination sources.

"high-care ward" refers to a ward for the care and management of specific types of patients requiring a minimum of eight hours of nursing care per patient day.

"holding area" means an area or room where pre-operative patients in transit to a procedure room/theatre are identified and continuously monitored by nursing personnel.

"induction room" means an area where patients are prepared for surgery/invasive procedures prior to being transferred to the operating theatre.

"intensive care unit" means a unit designed, staffed and equipped for the care and management of specific patients (e.g. medical, cardiac or post-operative) requiring a minimum of twelve hours of nursing care per patient day, or for the care of a patient who requires ventilation, continuous invasive monitoring, invasive care, or who is clinically unstable and whose life is at risk.

"main kitchen" means a facility suitably finished and equipped for the receipt, storage and preparation of meals, special diets and beverages.

"maternity unit" means a unit where antenatal care is provided, babies are delivered and postnatal care is given to mothers and infants.

"midwife obstetric unit (MOU)" means a maternity unit usually attached to a clinic or a community health centre (CHC), which is staffed by nursing sisters or midwives.

"milk kitchen" means an area for the preparation of feeds for babies which must be separate from the hospital kitchen or ward kitchen; it must contain a clinical-wash hand basin.

"mortuary" means a facility that receives, holds and allows for the identification of bodies of patients who died in the wards, theatre or casualty department, or who were dead on arrival at the facility.

"neonatal unit" means a facility for premature and new-born babies requiring incubation, specific care and monitoring.
"nurse station" means the control point for all activities in the patient-care areas.

"nursing unit or ward" means a unit with the facilities to accommodate patients as specified in this regulation.

"operating room" means a room within an operating-theatre suite in which surgical or other invasive procedures are carried out.

"operating suite" refers to rooms within the demarcated area where surgical interventions are performed or support is provided to these surgical activities;

"patient room" means a room where the patient can be accommodated.

"procedure room" means a room in which certain restricted procedures generally taking less than one hour can be performed without making use of general anaesthetic - e.g. endoscopies, procedures under local anaesthetic, such as suturing of lacerations, removal of skin lesions, biopsies, closed reductions and other similar procedures; may be situated outside the operating suite.

"recovery room/area" means the section of the operating suite specially set aside for the immediate post-operative recovery, resuscitation, nursing and special care of patients, until such time as such patients are considered to have recovered sufficiently to be safely removed from the operating suite.

"sluice room" means a room used for the emptying, cleaning and storage of bedpans and urine bottles; it can be combined with the activities of the soiled-linen and cleaners' rooms in the dirty utility room.

"specialised area" means any clinical area rendering specialised services such as intensive care, high care, or rehabilitation, for which additional space around the patient is required.

"soiled linen and waste room" means a room used for the collection and temporary storage of soiled linen and waste; may be combined with the dirty utility room.

"treatment room" means a room used for the treatment of patients in the wards, containing a clinical hand-wash basin.

“ventilation” means “The process of supplying air to or removing air from a space for the purpose of controlling air contaminant levels, humidity or temperature within the space” (ASHRAE Standard 62.1-2007, Section 3).

“validation” means the method of proving and documenting that an installed system or process performs reliably as intended and required.

“natural ventilation” means "Ventilation provided by thermal, wind, or diffusion effects through doors windows or other intentional openings in the building” (ASHRAE Standard 62.1-2007, Section 3).
"ward kitchen" means the room that forms an integral part of a nursing unit or units for the preparation of snacks and beverages; it also includes the area for the heating, storage and refrigeration of meals.

"uninterrupted power supply" means a battery system, which in the event of a normal mains supply failure will immediately provide the electrical supply for essential equipment and lighting.

"surgical" refers to a speciality in medicine that investigates or treats disease or injury by an operative procedure. Surgical procedures involve entering the body or body cavities by incision (breaking through the skin or other areas of the body)\(^\text{13}\). This may be to treat a disease or injury or to enhance body appearance or function.

“diagnostic” refers to a variety of observations and/or tests that can be performed in order to identify a particular disease or medical problem, and to providing the supporting evidence such as the cause - e.g. various types of endoscopy, cardiac stress tests, blood tests, x-rays etc.\(^1\)

ACKNOWLEDGEMENTS:

Documents of particular reference


Contributions at workshops:

<table>
<thead>
<tr>
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<tr>
<td>Department of Public Works and Transport</td>
<td>Western Cape</td>
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<tr>
<td>Edendale Hospital clinical and nursing staff</td>
<td>KwaZulu-Natal</td>
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<tr>
<td>King Edward VIII Hospital clinical and nursing staff</td>
<td>KwaZulu-Natal</td>
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<td>King George V Hospital clinical and nursing staff</td>
<td>KwaZulu-Natal</td>
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<tr>
<td>Inkhozi Albert Luthuli Hospital clinical and nursing staff</td>
<td>KwaZulu-Natal</td>
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<tr>
<td>Department of Health Infrastructure Department</td>
<td>KwaZulu-Natal and Western Cape</td>
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</tbody>
</table>

Hosted visits to:

- Red Cross Children’s Hospital, Cape Town
- Inkhozi Albert Luthuli Central Hospital, Durban
- King Edward Hospital, Durban
- King George V Hospital, Durban
- Edendale Hospital, Pietermaritzburg.
- Greys Hospital, Pietermaritzburg
- Lower Umfolozi War Memorial Hospital, Empangeni
- Ngwelezane Hospital, Empangeni
- Mitchells Plain Hospital, Cape Town
- Khayelitsha Hospital, Cape Town
- G. F. Jooste Hospital, Cape Town
- Worcester Hospital, Worcester
- Brits Hospital, Brits
- Waterfall Hospital, Midrand
- Royal Alexandra Hospital, Brighton
- Fiona Stanley Tertiary Hospital, Perth.
Appendix 6
“Towards Quality Care for Patients”

National Core Standards for Health Establishments in South Africa

National Department of Health
2011
National Core Standards for Health Establishments in South Africa

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Published Tshwane, South Africa

Further information regarding the National Core Standards and as well as copies can be obtained from:

Department of Health
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Tshwane
0001

Tel +27 (0) 12 395 8000 http://www.doh.gov.za

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The Department of Health would like to thank all contributors to the National Core Standards including, provincial colleagues, consultants, partners and donor agencies.

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### HEALTH ESTABLISHMENTS THAT ASSISTED WITH THE PILOT AND OTHER CONTRIBUTIONS

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<th>COMMUNITY HEALTH CENTRES &amp; CLINICS</th>
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<td>Galeshewe Day</td>
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<td>Nywara</td>
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<td>Kopanong – Kestell</td>
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The importance of providing quality health services is non-negotiable. Better quality of care is fundamental in improving South Africa’s current poor health outcomes and in restoring patient and staff confidence in the public and private health care system. If quality is defined as “getting the best possible results within available resources”, then these National Core Standards set out how best to achieve this.

A number of areas have been selected for fast track improvement. These essential areas include cleaner facilities, shorter waiting times, and better patient safety and care. In spite of some clear successes, more improvements are needed to ensure patients are provided with proper, decent health care. All managers at all levels are expected to ensure that these standards are met.

Simply reminding health care staff of their basic duty is not enough to achieve widespread and sustainable improvement in South Africa’s quality of care. The factors that contributed to the current situation must also be taken into account: poor management, a lack of accountability, a culture of mediocrity rather than excellence, demotivated staff, and even an erosion of professional ethics, are all to blame.

The root causes of these problems are varied and complex, therefore the system set in place to deal with them must be suitably comprehensive. Leadership is critical and the Department of Health intends to provide it throughout this process.

Developed with extensive input from many different partners, these standards speak to everyone. Most importantly they address staff caring for patients and the managers of clinics and hospitals, whether public or private. The National Core Standards reflect a vision for South Africa’s health services, rather than introducing a list of new requirements. They focus on what needs to be done to meet that vision.

Continuous assessment to ensure compliance with these standards will go a long way towards providing basic quality care. It will also mean that when an external audit team comes to measure compliance, all services should be good enough to meet quality standards.

Dr Aaron Motsoaledi (MP)
MINISTER OF HEALTH
South Africa faces an enormous challenge in transforming its health care delivery system - not only to meet citizens’ expectations of good quality care, but also to improve critical health care outcomes linked to the Millennium Development Goals.

The National Core Standards for Health Establishments have been expressly created as a statement of what is expected, and required, to deliver decent, safe, quality care. Through a national process of certification, an external body will formally assess each health establishment for compliance against these National Core Standards.

Where health establishments meet the standards, a process of continuous improvement will be encouraged to further enhance outcomes for patients. And for those not up to standard, the relevant governance structures and managers will be expected to make rapid improvements in service delivery to achieve compliance, or face progressive punitive measures.

The National Core Standards have been formulated through an extensive and participative consultation process. A diverse range of health care professionals and managers were involved, including the private sector and non-governmental organisations. Piloting and field testing has ensured that these standards are uniformly and universally acceptable, and applicable to the public and private sector, from the smallest rural clinic to the largest tertiary academic hospital. The National Core Standards have been based on the existing policy environment and tailored to South Africa’s health care context, while also reflecting international best practice and a strong evidence base.
However, the key challenge is to implement improvements at scale on the ground – to bridge the policy-implementation gap.

This gap is being addressed through a tool for managers, which makes clear what is expected of them both in terms of the systems that need to be in place and the outputs that should be delivered. It is hoped that this will achieve more than just better guidance – the tool is also provided so managers can assess themselves and close the gaps they find. It is believed that managers will be further incentivised by the knowledge that at some stage they will be assessed and held accountable by an external body. All of this is relevant not just for frontline managers in the establishments, but also for those who supervise and support them and whose job it is to enable them to deliver quality care.

Implementing these National Core Standards throughout every health care establishment in South Africa will take time and effort. To focus managers’ and supervisors’ efforts, six quality priorities have been identified for the first phase of implementation. These priorities reflect patients’ most pressing concerns regarding services, especially in the public sector.

Of these six priorities, improving the cleanliness of facilities is the most obvious and urgent. The others (reducing queues and waiting times, improving patient safety, preventing health facility acquired infections and ensuring availability of medicines through improved procurement and supply management) require process-based improvement strategies and a certain degree of process change over time. However, the last priority is a process of culture change: achieving more positive values and attitudes among staff and managers is part of a bigger shift – towards a future where a caring and positive attitude to patients and their families, as well as one another, is the norm.

Ms MP Matsoso
DIRECTOR GENERAL
NATIONAL DEPARTMENT OF HEALTH
1. Introduction

1.1 Policy context
The 10 Point Plan of the National Department of Health (NDoH) 2009-2014 makes provision for the “establishment of a quality management and accreditation body” and “improving the quality of health services”, as is also reflected in the Strategic Plan for 2009/12. One of the core outcomes of government is to ensure “a long and healthy life for all South Africans” through the achievement of the four specific areas in the Minister’s Performance Agreement with the President and spelt out in the Service Delivery Agreement negotiated with provinces and key stakeholders. These four performance areas are:

- Improve life expectancy
- Improve mother and child health and survival
- Reduce the impact of HIV/AIDS and TB
- Improve health system effectiveness

1.2 Legal context
The National Health Act, 61 of 2003 emphasises the need to foster good quality health services by developing structures to monitor the compliance of health establishments and agencies with health care standards. It provides for the creation of an Office of Standards Compliance as well as an Inspectorate of Health Establishments within each province. The Act further envisages a broad role for the Office of Standards Compliance in advising on health standards, revising or setting standards, monitoring compliance, reporting non-compliance, and advising on strategies to improve quality.

Amendments to aspects of this Act related to quality and compliance will align the legislative framework to the policy direction with the establishment of an independent body for certification of compliance, a clear process for setting of standards, and recognition of quality improvement as an intrinsic part of effective management.

2. Purpose of the National Core Standards
In fulfilling its strategic and legislative imperatives, the Office of Standards Compliance developed the National Core Standards for Health Establishments in South Africa, which will assist in setting the benchmark of quality care against which delivery of services can be monitored.

The main purpose of the National Core Standards is to:

- Develop a common definition of quality care which should be found in all health establishments in South Africa, as a guide to the public and to managers and staff at all levels;
- Establish a benchmark against which health establishments can be assessed, gaps identified and strengths appraised; and
- Provide for the national certification of compliance of health establishments with mandatory standards.

3. National Core Standards as a basis for quality
Quality can be defined in various ways.

Quality is getting the best results possible within the available resources (Policy on Quality in Health Care for South Africa, National Department of Health, April 2007); and

Quality is the level of attainment of health systems’ intrinsic goals for health improvement and responsiveness to legitimate expectations of the population. (World Health Organisation).
Quality has six dimensions according to the World Health Organisation: it should be effective, efficient, accessible, acceptable/patient-centered, equitable and safe.

In order to provide more detail to managers of establishments as to what this definition of quality means in practical terms, standards have been developed. A standard is a statement of an expected level of quality delivery. Standards reflect the ideal performance level of a health establishment in providing quality care.

These National Core Standards reflect the South African policy context and are based to a large extent on existing legislation, policies, guidelines and protocols (as reflected in the Bibliography), many of which are specific to the Department of Health. Others emanate from other relevant areas such as Treasury or the Department of Public Service Administration or the King guidelines on corporate governance. They therefore embody what managers are expected to be delivering in our health establishments, and do not embody new demands. Achieving compliance with these standards will assist in proactively putting the systems in place to avoid the most important risks to quality care or to reduce their impact.

What is important to note is that these standards are focused at health establishment level where delivery of care takes place. In Primary Health Care where some aspects of care are co-ordinated at the support levels (i.e. district, province, national, company corporate), these have been incorporated. Higher level support structures are specifically taken into account in assessing that the necessary governance and support functions, including strategic planning and oversight, are in place.

These particular standards do not cover other agencies or services such as community-based care, emergency medical services or private general practitioners, although such standards will be developed over time.

Standards are but one way of measuring performance. The use of standard clinical and other indicators as specified in the DHIS (District Health Information System) and the stipulated targets are a critical and complementary source of information and guidance. Non-routine information (for instance through surveys or surveillance systems) is another important mechanism for assessing quality and outcomes. Regular reporting on selected indicators as well as use of surveillance systems monitoring complaints and incidents will be used to identify high risk establishments requiring further investigation and support.

4. Background – how the National Core standards were developed

Responding to concerns regarding the multiplicity of different standards and guidelines for managers throughout the health system and the consequent difficulty in measuring performance against a common benchmark, a set of “Core Standards for Health Establishments” was launched in April 2008.

The standards and assessment tools were piloted in 2008 and again in revised form in March 2010 in a sample of public and some private hospitals and community health centres. These were purposively selected to cover all provinces and types of establishments.

Following these extensive pilots, significant technical input was used to revise the assessment tools and standards, including the introduction of a risk-based approach. An important part of the revision process has been the benchmarking of the standards against other accreditation systems.

The approach taken to the development of the standards has used a set of principles that reflect the overall policy direction of the Department, namely universality, relevance, validity, reliability and logic:

- **Universality** in terms of ensuring that the standards and assessment measures are generally applicable across all health care levels and settings – from public to private hospitals; from tertiary hospitals to primary health care facilities and from specialised to generalist care settings. (It must, however, be noted that certain standards or criteria may not be applicable in all contexts);

- **Relevance** in terms of ensuring that standards and assessment measures represent elements of care that are critical to the provision of safe, quality health care services in South Africa;
- **Validity and reliability** of what can be measured objectively and practically during an audit of a health establishment; and

- **Logic** through the arrangement and classification of criteria and measures into those concerned with inputs or systems, policies, procedures or processes and outputs, and as far as possible outcomes.

Many people have been consulted on, or contributed to, the development of the National Core Standards over the past two years, including quality managers from the National Department, the provinces and the private sector; experts in the various specialty fields such as pharmacy, management, infection control and health technology and infrastructure; partners in the form of non-governmental organisations and research councils, professional associations, organised labour, statutory bodies and consultants. (See Acknowledgements in Appendix).

### 5. Structure of the National Core Standards

The National Core Standards are structured into seven cross-cutting domains (see figure 1), with a domain being defined by the World Health Organisation as an area where quality or safety might be at risk.

Their layout is deliberate, in that the first three domains (Patient Rights, Safety, Clinical Governance and Care, and Clinical Support Services) are those domains that are involved directly with the core business of the health system of delivering quality health care to our users or patients.

The remaining domains (Public Health, Leadership & Corporate Governance, Operational Management and Facilities & Infrastructure) are essentially the support system that ensures the system delivers its core business, although our internal clients (our staff) are absolutely key in achieving this.

*Figure 1: Seven Domains of the National Core Standards*

![Diagram of seven domains](image)

The overall scope of each domain is reflected in Figure 2. Within each domain are sub-domains which further break down the domains into sub-sections or critical areas, which together describe the scope of that domain. The structure of the National Core Standards with domains and sub-domains is reflected in Figure 3: Structure of Domains and Sub-domains.
The domain of **Patient Rights** sets out what a hospital or clinic must do to make sure that patients are respected and their rights upheld, including getting access to needed care and to respectful, informed and dignified attention in an acceptable and hygienic environment, seen from the point of view of the patient, in accordance with Batho Pele principles and the Patient Rights Charter.

The **Patient Safety, Clinical Governance and Clinical Care** domain covers how to ensure quality nursing and clinical care and ethical practice; reduce unintended harm to health care users or patients in identified cases of greater clinical risk; prevent or manage problems or adverse events, including health care associated infections; and support any affected patients or staff.

The **Clinical Support Services** domain covers specific services essential in the provision of clinical care and includes the timely availability of medicines and efficient provision of diagnostic, therapeutic and other clinical support services and necessary medical technology, as well as systems to monitor the efficiency of the care provided to patients.

The **Public Health** domain covers how health facilities should work with NGOs and other health care providers along with local communities and relevant sectors, to promote health, prevent illness and reduce further complications; and ensure that integrated and quality care is provided for their whole community, including during disasters.

The **Leadership and Governance** domain covers the strategic direction provided by senior management, through proactive leadership, planning and risk management, supported by the hospital board, clinic committee as well the relevant supervisory support structures and includes the strategic functions of communication and quality improvement.

The **Operational Management** domain covers the day-to-day responsibilities involved in supporting and ensuring delivery of safe and effective patient care, including management of human resources, finances, assets and consumables, and of information and records.

The **Facilities and Infrastructure** domain covers the requirements for clean, safe and secure physical infrastructure (buildings, plant and machinery, equipment) and functional, well managed hotel services; and effective waste disposal.
### Domain 1. Patient Rights:
- 1.1 Respect and dignity
- 1.2 Information to patients
- 1.3 Physical access
- 1.4 Continuity of care
- 1.5 Reducing delays in care
- 1.6 Emergency care
- 1.7 Access to package of services
- 1.8 Complaints management

### Domain 2. Patient Safety - Clinical governance & Clinical Care:
- 2.1 Patient care
- 2.2 Clinical management for improved health outcomes
- 2.3 Clinical leadership
- 2.4 Clinical risk
- 2.5 Adverse events
- 2.6 Infection prevention and control

### Domain 3. Clinical Support Services:
- 3.1 Pharmaceutical services
- 3.2 Diagnostic services
- 3.3 Therapeutic and support services
- 3.4 Health technology services
- 3.5 Sterilisation services
- 3.6 Mortuary services
- 3.7 Efficiency management

### Domain 4. Public Health:
- 4.1 Population based service planning and delivery
- 4.2 Health promotion and disease prevention
- 4.3 Disaster preparedness
- 4.4 Environmental control

### Domain 5. Leadership & Corporate Governance:
- 5.1 Oversight and accountability
- 5.2 Strategic management
- 5.3 Risk management
- 5.4 Quality improvement
- 5.5 Effective leadership
- 5.6 Communications and public relations

### Domain 6. Operational Management:
- 6.1 Human resource management & development
- 6.2 Employee wellness
- 6.3 Financial resource management
- 6.4 Supply chain management
- 6.5 Transport and fleet management
- 6.6 Information management
- 6.7 Medical records

### Domain 7. Facilities & Infrastructure:
- 7.1 Buildings and grounds
- 7.2 Machinery and utilities
- 7.3 Safety and security
- 7.4 Hygiene and cleanliness
- 7.5 Waste management
- 7.6 Linen and laundry
- 7.7 Food services
Within each sub-domain are a set of standards which define what is expected to be delivered in terms of quality care and best practice. Linked to each standard are a number of criteria, which are the elements setting out the requirements to achieve compliance with the standard. Criteria are measurable and achievable as reflected in the measures.

**Figure 4: Structure of the National Core Standards**

The domains and sub-domains do not reflect how a health establishment is physically organised to deliver care. The standards have therefore been cross-referenced to all service areas (such as paediatric ward, MOU, infection control, theatre, or pharmacy) for purposes of assessment and in order for the assessment reports to provide each manager with a status report for each service area.

### 6. Measuring compliance

#### 6.1 The Assessment Tool and the Measures (contained in the data base)

To enable objective and comparable assessment of compliance, each criterion is broken down into measures which have been adapted to be context specific, e.g. PHC, private and public hospitals. Measures are the means or evidence for determining whether or not the criterion has been met. They examine direct observables i.e. aspects that can be seen, heard or felt by the assessors; and indirect observables such as analysis of policies, minutes of committees and patient record reviews, which, while they may not entirely demonstrate that a criterion is met, give reasonable assurance that it is. The measures form the basis for the assessment tool used for both self assessments and the compliance audit.

#### 6.2 Rating of measures – vital, essential and developmental

The component measures for each standard were classified according to a risk-rating approach, using a risk matrix adapted from that used by the Australian Capital Territory Government (2009) and assessing the severity of the impact as well as the likelihood of a risk occurring in each case.

Based on this risk rating the respective measures have then been placed in three risk levels:

- **Vital** measures are those that ensure that the safety of patients and staff are safeguarded so as not to result in unnecessary harm or death.

- **Essential** measures are those considered fundamental to the provision of safe, decent, quality care and are designed to provide an in-depth view of what is expected within available resources (for example: clinical risk management and quality improvement processes; or guidelines for maternity care).
- Developmental measures are those elements of quality of care to which health management should aspire to, in order to achieve optimal care. While non-compliance with these standards does not necessarily constitute a risk to patients, they form an integral part of a comprehensive quality health care system. Developmental standards enhance the health establishment’s ability to provide optimal care and reflect continuous improvement.

This risk-based approach allows an objective assessment of the impact of failure to comply with a standard in different areas. It also allows for more efficient reallocation of effort and resources within the current health care system to those standards where non-compliance poses extreme and/or high risks to the establishment’s health outcomes and patient or staff safety.

6.3 Reporting on compliance

The assessment tool produces reports on compliance with standards and gives a percentage score per domain, sub-domain or standard. The risk rating also informs the reporting of how compliance against the standards will be scored and reported, with weighting of results in accordance with the impact on patient care and safety. In addition the highest risk areas are also reported separately, to highlight the need for immediate corrective action to avoid potential catastrophic events.

7. The use of the Standards

The over-riding goal of the standards is to assist in improving the quality of care. The primary activity is therefore to ensure that the standards are disseminated throughout the health system and that compliance with them becomes the norm for staff and managers as a continuous improvement process is implemented (see figure 5).

7.1 Meeting standards

Standards are designed to be used by all managers and supervisors as a guide to expected service planning and delivery. Thus, compliance with standards and certification will be one of the requirements for increased management autonomy, formally reflected in the delegation of authority and ultimately in access to public funding through a system of national health insurance.
7.2 Measuring and enforcing compliance with standards

While self assessments can be used to improve the quality of care provided by the health care establishment, explicit regulation ensures that patients are safeguarded from life threatening situations that may arise from poor or non-compliance with minimum standards.

The National Core Standards for Health Establishments are part of the development of a new regulatory framework within the health sector. This regulatory framework will ensure that the health, safety and welfare of patients who use health establishments and the staff who care for them are protected through the enforcement of National Core Standards for quality.

To ensure compliance with National Core Standards, an independent body will undertake external audits of health care establishments. Audit reports issued by the body will assess the extent of compliance and will allow the independent regulator to issue certificates regarding the degree of compliance with standards, as stipulated by law, and take appropriate measures to enforce compliance.

The regulatory framework is designed to place emphasis on the inter-linkages between quality assurance (through regulation) and quality improvement in the implementation of quality standards. An initial self assessment undertaken by the health care establishment will provide a baseline for the health establishment to undertake remedial actions and implement quality improvement measures prior to a formal external audit of the degree of compliance. Once the external audit is completed, the health care establishment will also use the findings of the audit to implement further quality improvement initiatives.

7.3 Fast-track improvement to meet patients’ immediate expectations

It is expected that all establishments will ensure they are compliant with these standards. However, as improving quality is a process, not a once-off event, we have identified six critical areas where we are aware that many establishments (especially in the public sector) have much to improve. These are at the same time absolutely fundamental to the provision of safe, decent care.

Managers are therefore expected to ensure that they are compliant with these six fast-track areas in as short a time as possible (see also the document: “Fast Track to Quality”). These fast-track areas are a subset of the most critical standards and are largely reflected in the first 3 domains (see figure 6), namely:

1. Values and attitudes of staff
2. Cleanliness
3. Waiting times
4. Patient safety and security
5. Infection prevention and control
6. Availability of basic medicines and supplies
Figure 6: Six fast track priorities inter relationship with the National Core Standards

1. Patient Rights
2. Patient Safety, Clinical Governance & Care
3. Clinical Support Services
4. Public Health
5. Leadership & Corporate Governance
6. Operational Management
7. Facilities & Infrastructure

Patient Rights:
1. Values and attitudes
2. Waiting times
3. Cleanliness

Patient Safety, Clinical Governance & Care:
4. Patient safety
5. Infection prevention and control

Clinical Support Services:
6. Availability of medicines and supplies
Your right to dignity
Every patient has a right to

Healthy and safe environment
Participation in decision-making
Access to health care
Knowledge of one’s health
Insurance/medical aid scheme
Choice of health services
Treated by a named health care provider
Confidentiality and privacy
Informed consent
Refusal of treatment
A second opinion
Continuity of care
Complaints about health services
## Domain 1: Patient Rights

The domain of Patient Rights sets out what a hospital or clinic must do to make sure that patients are respected and their rights upheld, including getting access to needed care and to respectful, informed and dignified attention in an acceptable and hygienic environment, seen from the point of view of the patient, in accordance with Batho Pele principles and the Patient Rights Charter.

<table>
<thead>
<tr>
<th>Sub-domain</th>
<th>Standard</th>
<th>Criteria</th>
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</table>
| 1.1 Respect and dignity        | 1.1.1 Staff treat patients with care and respect, with consideration for patient privacy and choice | 1.1.1.1. Staff treat patients with courtesy and empathy and there is zero tolerance for abuse
1.1.1.2 Care provided maximises patient privacy
1.1.1.3 Mentally ill patients are managed and treated in the least restrictive or intrusive manner possible
1.1.1.4 Where possible, children are not separated from their parents and other relatives |
| 1.1.2 Patient satisfaction surveys and patient complaints are used to improve service quality | 1.1.2.1 Patient satisfaction surveys are conducted and analysed annually
1.1.2.2 Quality improvements at the health establishment are based on patient satisfaction surveys |
| 1.1.3 Patients are satisfied with the cleanliness and hygiene of the facility and with their accommodation. | 1.1.3.1 Patients are satisfied with the cleanliness and hygiene at the health establishment
1.1.3.2 Patients are satisfied with the linen, where provided
1.1.3.3 Patients are satisfied with the food, where provided
1.1.3.4 Patients have access to clean water in waiting areas |
| 1.2 Access to information for patients | 1.2.1 Patients are given the information they need regarding their treatment, their care after discharge, and their participation in research where relevant. | 1.2.1.1 Patients are informed of their rights and responsibilities, and any medical charges
1.2.1.2 Procedures are followed to get informed consent
1.2.1.3 All patients receive a discharge report (as required by the National Health Act 61 of 2003)
1.2.1.4 Where research projects are being conducted, ethical research guidelines are followed |
|                                 | 1.2.2 Information on services and service times is available, key service areas are clearly signposted and all staff are identifiable. | 1.2.2.1 Easy access to information on services is provided through the health establishment’s help desk
1.2.2.2 Key service areas of the health establishment are clearly signposted
1.2.2.3 Service operating times and visiting hours are clearly displayed at the entrance to the health establishment
1.2.2.4 Staff are easily identifiable |
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<tr>
<th>Sub-domain</th>
<th>Standard</th>
<th>Criteria</th>
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<tbody>
<tr>
<td><strong>1.3 Physical access</strong></td>
<td>1.3.1 Services are easy and safe to access including for the disabled</td>
<td>1.3.1.1 The health establishment is easy and safe to access</td>
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<td>1.3.1.2 There is easy access for persons with disabilities and the aged</td>
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<td>1.3.1.4 There are ablution facilities for persons with disabilities</td>
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<td>1.3.1.5 Information and facilities are available for hearing and visually impaired patients</td>
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<td><strong>1.4 Continuity of care</strong></td>
<td>1.4.1 Patients who need to be referred or transferred receive the care and support they need</td>
<td>1.4.1.1 An effective district health care referral policy and system is available, covering continuity of care, emergency care management, infrastructure and resources required</td>
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<td>1.4.1.2 Referrals are monitored to identify progress, trends and gaps in the system</td>
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<td>1.4.1.3 Patients are given information about referrals and specialist bookings</td>
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<td><strong>1.5. Reducing delays in care</strong></td>
<td>1.5.1 Waiting times and queues are managed to improve patient satisfaction and care, and serious patients are attended to first</td>
<td>1.5.1.1 Procedures are followed to manage queues and minimise waiting times</td>
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<td>1.5.1.2 Waiting times are monitored and improvement plans are implemented</td>
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<td>1.5.1.3 Patients receive their medicines on the day of their scheduled visit</td>
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<td>1.5.1.4 Patients are treated according to the severity and nature of their health condition or problem</td>
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<td>1.5.1.5 An efficient filing system is in place for patients’ records</td>
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<td>1.5.2 Waiting lists are kept as short as possible.</td>
<td>1.5.2.1 Waiting lists for elective procedures are efficiently managed</td>
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<td><strong>1.6. Emergency care</strong></td>
<td>1.6.1 Emergency patients are attended to, examined and stabilised appropriately and then referred or transferred if needed</td>
<td>1.6.1.1 Patient safety is ensured during handover from life support practitioners to health establishment staff</td>
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<td>1.6.1.2 Guidelines on examining and stabilising patients arriving at the accident &amp; emergency/PHC outpatient department are followed</td>
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<td>1.6.1.3 Health establishment closures and ambulance diversions are managed to minimise impact on patient care and ambulance services</td>
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<td>1.6.1.4 The emergency services provide a quality outcome for patients</td>
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<td><strong>1.7. Access to a package of services</strong></td>
<td>1.7.1 Services provided meet with national guidelines or licensing specifications.</td>
<td>1.7.1.1 Services at the health establishment meet national guidelines or licensing specifications</td>
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<td>Sub-domain</td>
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<td><strong>1.8. Complaints management</strong></td>
<td>1.8.1 Patients who wish to complain about poor service are helped to do so and their concerns are properly addressed</td>
<td>1.8.1.1 A clear procedure is used to deal with complaints</td>
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<td>1.8.1.2 Patients are made aware of the complaints procedure</td>
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<td>1.8.2 Complaints are used to improve service delivery</td>
<td>1.8.2.1 Complaints are recorded using a formal procedure</td>
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<td>1.8.2.2 Complaints are screened to ensure adverse events are identified and appropriately managed</td>
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<td>1.8.2.3 A procedure is in place for acknowledging, investigating and dealing with complaints</td>
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<td>1.8.2.4 Complaints are used to improve the quality of service delivery</td>
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<td>1.8.2.5 Complaints are addressed within nationally agreed timescales</td>
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</table>
## Domain 2: Patient Safety, Clinical Governance and Clinical Care

The **Patient Safety, Clinical Governance and Clinical Care** domain covers how to ensure quality nursing and clinical care and ethical practice; reduce unintended harm to health care users or patients in identified cases of greater clinical risk; prevent or manage problems or adverse events, including health care associated infections, and support any affected patients or staff.

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<thead>
<tr>
<th>Sub-domain</th>
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<th>Criteria</th>
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</table>
| **2.1 Patient care** | 2.1.1 Patients receive care and treatment that follows nursing protocols, meets basic needs and contributes to their recovery | 2.1.1.1 Procedures are in place to ensure delivery of basic care that optimises health outcomes  
2.1.1.2 There is evidence that care provided optimises health outcomes |
| **2.2 Clinical management of priority health conditions** | 2.2.1 Care provided contributes positively to national priorities, including the United Nations Millennium Development Goals for maternal and child health, HIV and Tuberculosis | 2.2.1.1 The latest guidelines are available for implementing strategic priority programmes or health initiatives  
2.2.1.2 There is evidence that the health establishment implements priority programmes or health initiatives according to the latest guidelines available  
2.2.1.3 A system is in place to regularly collect and analyse data on priority programmes/health initiative outcomes and to address any shortcomings |
| **2.3 Clinical leadership** | 2.3.1 Doctors, nurses and other health professionals constantly work to improve the care they provide through proper support systems | 2.3.1.1 Health professionals are appointed as heads of department/sections, with clear job descriptions and lines of accountability  
2.3.1.2 There is a formal supervision programme for health professionals  
2.3.1.3 Health professionals are responsible for setting up and managing a quality committee for the health establishment  
2.3.1.4 Quality committee reviews are used by health professionals to continuously improve patient care |
| **2.4 Clinical risk** | 2.4.1 Clinical risk identification and analysis takes place in every ward to prevent patient safety incidents | 2.4.1.1 A clinical risk policy and protocol for the health establishment is available which highlights the health establishment’s approach to the management of clinical risk  
2.4.1.2 A system is in place to monitor clinical risk and ensure control measures are carried out  
2.4.2.1. Procedures are in place for the care of patients who are terminally ill  
2.4.2.2 The manager of the health establishment ensures that where patients require observation for 72 hours the Mental Health Care Act No 17 of 2002 is complied with  
2.4.2.3 Frail and aged patients receive risk assessments, special observations and care as needed  
2.4.2.4 Patients belonging to high-risk groups, including violent, suicidal and mentally challenged patients, are kept safe |
## Domain 2: Patient Safety, Clinical Governance and Clinical Care

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<tr>
<th>Sub-domain</th>
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<tr>
<td><strong>2.4 Clinical Risk</strong></td>
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<td>2.4.2.5 High risk maternity patients are kept safe</td>
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<td>2.4. 2.6 Newborns and children are kept safe and secure</td>
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<tr>
<td>2.4.1 Clinical risk identification and analysis takes place in every ward to prevent patient safety incidents</td>
<td>2.4.1.1 A clinical risk policy and protocol for the health establishment is available which highlights the health establishment’s approach to the management of clinical risk</td>
<td>2.4.1.2 A system is in place to monitor clinical risk and ensure control measures are carried out</td>
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<td>2.4.3 Safety protocols are in place to protect patients undergoing high risk procedures such as surgery, medication administration, blood transfusions or resuscitations</td>
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<td>2.4.3.2 Appropriate safety measures are carried out in the operating theatre before and during surgery</td>
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<td>2.4.3.3 The safety of patients requiring resuscitation is assured</td>
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<td>2.4.3.4 The safety of patients receiving medication is assured</td>
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<td>2.4.3.5 Blood and blood products are administered safely</td>
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<td>2.4.3.6 Appropriate safety measures are in place for acutely ill patients in intensive care units</td>
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<td><strong>2.5 Adverse Events</strong></td>
<td>2.5.1 Adverse events or patient safety incidents are promptly identified and managed to minimise patient harm and suffering</td>
<td>2.5.1.1 The health establishment’s adverse events policy and procedure is available and in place</td>
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<td>2.5.1.2 The health establishment actively encourages reporting of adverse events</td>
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<td>2.5.2 Adverse events are routinely analysed and managed to prevent recurrence and learn from mistakes</td>
<td>2.5.2.1 A system is in place to monitor adverse events and carry out control measures</td>
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<td>2.5.2.2 Recommendations to prevent adverse events recurring are implemented and monitored</td>
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<td>2.5.2.3 Staff are constantly aware of risks in the environment</td>
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<td>2.5.2.4 The number of adverse events in the health establishment is monitored against relevant targets</td>
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<td><strong>2.6 Infection Prevention and Control</strong></td>
<td>2.6.1 An Infection Prevention and Control Programme is in place to reduce health care associated infections</td>
<td>2.6.1.1 An infection prevention and control policy outlines the health establishment’s approach to managing health care associated infections</td>
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<td>2.6.1.2 A qualified health professional is responsible for infection control</td>
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<td>2.6.1.3 A formal surveillance and reporting system is in place</td>
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<td>2.6.1.4 A formal system is in place to monitor infection prevention and control and ensure appropriate actions are taken to minimise infection rates</td>
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<td>2.6.1.5 The health establishment reports health care associated infections and notifiable diseases to appropriate public health agencies</td>
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<td>2.6.1.6 Staff and patients and, as appropriate, family and other caregivers, are educated on infection control practices</td>
</tr>
</tbody>
</table>
2.6 Infection prevention and control

2.6.1 An Infection Prevention and Control Programme is in place to reduce health care associated infections

2.6.1.1 An infection prevention and control policy is outlines the health establishment’s approach to managing health care associated infections

2.6.1.2 A qualified health professional is responsible for infection control

2.6.1.3 A formal surveillance and reporting system is in place

2.6.1.4 A formal system is in place to monitor infection prevention and control and ensure appropriate actions are taken to minimise infection rates

2.6.1.5 The health establishment reports health care associated infections and notifiable diseases to appropriate public health agencies

2.6.1.6 Staff and patients and, as appropriate, family and other caregivers, are educated on infection control practices

2.6.2 Specific precautions are taken to prevent the spread of respiratory infections

2.6.2.1 A programme for the prevention and control of respiratory infections is in place (eg for tuberculosis)

2.6.3 Standard precautions are applied to prevent health care associated infections

2.6.3.1 Standard precautions to prevent health care associated infections are actively implemented and applied in all clinical areas of the health establishment

2.6.3.2 Sharps are safely handled and disposed of

2.6.3.3 Effective hand washing is used to limit the spread of health care associated infections

2.6.3.4 Appropriate facilities are provided for patients with hazardous infections to reduce the risk of transmission

2.6.3.5 Equipment used by infected patients is safely disinfected

2.6.4 Strict infection control practices are observed in the designated infant feed preparation areas

2.6.4.1 Infant feeds are prepared to ensure safety of infants
DOMAIN 3: CLINICAL SUPPORT SERVICES
**Domain 3: Clinical Support Services**

**Clinical Support Services** covers specific services essential in the provision of clinical care and includes the timely availability of medicines, and efficient provision of diagnostic, therapeutic and other clinical support services and necessary medical technology, as well as systems to monitor the efficiency of the care provided to patients.

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<th>Sub-domain</th>
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<tbody>
<tr>
<td><strong>3.1 Pharmaceutical services</strong></td>
<td>3.1.1 Pharmaceutical services are licensed and are supervised by a registered pharmacist</td>
<td>3.1.1.1 The pharmacy is licensed by the Director General of the National Department of Health</td>
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<td>3.1.1.2 The pharmacy is registered with the South African Pharmacy Council (SAPC)</td>
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<td>3.1.1.3 A responsible pharmacist is in post and registered with SAPC</td>
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<td></td>
<td>3.1.2 Medicines and medical supplies are in stock and their delivery is reliable</td>
<td>3.1.2.1 All essential medicines are in stock (in accordance with applicable Essential Drugs List or formulary)</td>
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<td>3.1.2.2 Medical supplies required to care for patients are in stock</td>
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<td>3.1.2.3 Supply and delivery of medicines complies with contractual obligations</td>
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<td></td>
<td>3.1.2.4 Supply and delivery of medical supplies comply with contractual obligations</td>
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<td>3.1.2.5 Access to medicines is ensured during the health establishment’s operating hours</td>
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<td>3.1.2.6 Health professionals can access medicines when required urgently after hours</td>
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<td></td>
<td>3.1.3 Stock levels and storage of medicines and medical supplies are managed appropriately</td>
<td>3.1.3.1 Medicines are stored in compliance with the Pharmacy Act, Medicines and Related Substances Act, and relevant rules and regulations</td>
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<td>3.1.3.2 An up-dated computerised or manual (stock cards) inventory management system medicines is in place</td>
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<td>3.1.3.3 Schedule 5 and 6 medicines are controlled and distributed in accordance with the Medicines and Related Substances Act and Good Pharmacy Practice Guidelines</td>
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<td>3.1.3.4 Medical supplies comply with medicine supply management principles</td>
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<td>3.1.3.5 An up-dated computerised or manual (stock cards) inventory management system for medical supplies is in place</td>
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<td>3.1.4 Medicines are prescribed according to treatment guidelines and patients are educated to understand how and when to take them</td>
<td>3.1.4.1 There is a functional Pharmaceuticals and Therapeutics Committee in the health establishment or the district</td>
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<td>3.1.4.2 Medicine is dispensed in compliance with the Pharmacy Act (53 of 1974), Medicines and Substance Act (101 of 1965) and relevant regulations</td>
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<td>3.1.4.3 Advice is given to ensure patients adhere to therapy</td>
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<td>3.1.4.4 Prescribing complies with applicable guidelines and policies</td>
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<td>3.1.5 Reactions to drugs or severe side effects are reported and the patient is properly cared for.</td>
<td>3.1.5.1 A clear system is in place to manage adverse drug reactions</td>
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<td><strong>3.2 Diagnostic services</strong></td>
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<tr>
<td></td>
<td>3.2.1 Laboratory services are available and provide accurate results within agreed timescales</td>
<td>3.2.1.1 Laboratory services are available and results provided within agreed timescales</td>
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<td></td>
<td>3.2.1.2 The diagnostic laboratory results are accurate and reliable</td>
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<td>3.2.1.3 The laboratory and its staff have the equipment, consumables and protective gear needed to function effectively</td>
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<td>3.2.2 X-ray services are available and provide good quality reports or results within agreed timescales, and staff are protected from unintentional exposure</td>
<td>3.2.2.1 Radiology and related services (e.g. ultrasonography) are available and provided within agreed timescales</td>
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<td>3.2.2.2 Staff and patients are protected from unnecessary exposure</td>
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<td>3.2.2.3 Films and reagents are stored and disposed of according to guidelines</td>
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<td><strong>3.3 Therapeutic and support services</strong></td>
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<td></td>
<td>3.3.1 Blood for transfusion is available within an acceptable time</td>
<td>3.3.1.1 Blood and blood products are available to support care</td>
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<td>3.3.2.1 Patient treatment is holistic and includes comprehensive multi-disciplinary therapeutic programmes</td>
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<td>3.3.2.2 Patients are rehabilitated according to local clinical protocols, and receive required assistive devices</td>
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<td>3.3.2.3 Patients with existing or potential disabilities are referred as necessary, according to local clinical protocols</td>
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<td>3.3.2.4 Patients requiring social support are assessed, treated and referred according to local clinical protocols</td>
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<td><strong>3.4 Health technology</strong></td>
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<td></td>
<td>3.4.1 Medical equipment for safe and effective patient care is available and functional</td>
<td>3.4.1.1 Medical equipment meets minimum requirements for the appropriate level of care</td>
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<td>3.4.2.1 Staff are able to correctly use the medical equipment in the unit</td>
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<td>3.4.3.1 Critical devices are maintained to manufacturer requirements</td>
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<tr>
<td><strong>3.5 Sterilisation services</strong></td>
<td>3.5.1 Decontamination and sterilisation services are available and effective</td>
<td>3.5.1.1 A system is in place for decontamination of surgical instruments</td>
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<td>3.5.1.2 Suitably qualified staff manage the sterilisation department</td>
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<td>3.5.1.3 Clear lines of accountability exist for the decontamination cycle</td>
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<td>3.5.1.4 Sterilisation equipment meets legislative requirements</td>
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<td>3.5.1.5 All sterilisation failures are monitored</td>
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<td><strong>3.6 Mortuary services</strong></td>
<td>3.6.1 The mortuary has adequate storage and refrigeration</td>
<td>3.6.1.1 Policies and procedures guide all aspects of storage, removal and transportation of bodies</td>
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<td>3.6.1.2 Equipment for storage and transportation of bodies meet environmental hygiene standards</td>
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<td>3.6.1.3 Mortuary staff wear protective gear to prevent accident, injury or infection</td>
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<td><strong>3.7 Clinical Efficiency Management</strong></td>
<td>3.7.1 Clinical efficiency management systems ensure patients receive adequate, safe, quality health care</td>
<td>3.7.1.1 Effective and efficient case management systems are in place</td>
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<td>3.7.1.2 A process is in place to manage financial risks for payment of care and to protect patients from unnecessary costs</td>
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<td>3.7.1.3 Billing and case management systems ensure patients are not overcharged and can access benefits</td>
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Tobacco - deadly in any form or disguise.
## Domain 4: Public Health

**Public health** covers how health facilities should work with NGOs and other health care providers along with local communities and relevant sectors, to promote health, prevent illness and reduce further complications; and ensure that integrated and quality care is provided for their whole community, including during disasters.

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<tr>
<th>Sub-domain</th>
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<tbody>
<tr>
<td><strong>4.1 Population-based planning and service delivery</strong></td>
<td>4.1 Communities, as well as other government departments and sectors are involved in the planning and delivery of local health services</td>
<td>4.1.1 Feedback and forums are used to involve the public in the health establishment’s planning</td>
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<td>4.1.1.2 Management identify community health needs, poor health outcomes and reduced access in their catchment area or population</td>
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<td>4.1.1.3 Management works with local and district planners to improve the population’s health status through the district or local health plan</td>
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<td>4.1.1.4 Management collaborates with relevant government entities or departments to identify social determinants of disease</td>
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<td>4.1.1.5 Management collaborates with relevant authorities and stakeholders to ensure the establishment is accessible and clearly signposted</td>
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<td>4.1.2 Different health authorities work together effectively to improve service delivery to the community</td>
<td>4.1.2.1 Management collaborates with other relevant health services (e.g. ambulance services and private health providers) to deliver seamless services</td>
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<td>4.1.2.2 Health establishment staff provide outreach services to facilities, organisations and patients in their catchment area</td>
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<td><strong>4.2 Health promotion and disease prevention</strong></td>
<td>4.2.1 Health promotion and the prevention disease or of its further progression are emphasised as part of patient care</td>
<td>4.2.1.1 The health establishment provides health promotion and other disease prevention activities among at risk patients</td>
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<td>4.2.1.2 The health establishment provides effective treatment which avoids complications to at-risk patients</td>
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<td>4.2.1.3 The health establishment provides effective rehabilitation for at-risk patients</td>
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<td>4.2.1.4 The health establishment supports and/or participates in relevant community health promotion initiatives</td>
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</table>
| **4.3 Health emergencies and disaster preparedness** | 4.3.1 Emergency plans exist to protect public safety if there are significant disease outbreaks or other health emergencies | 4.3.1.1 Inter-sectoral plans for responding to possible health emergencies and disease outbreak are annually reviewed and updated  
4.3.1.2 The health establishment can demonstrate its capacity to respond promptly and effectively to disease outbreaks  
4.3.1.3 The health establishment has an annually updated disaster management plan, which includes health emergencies |
| **4.4 Environmental controls** | 4.4.1 Regulatory controls are in place to limit environmental damage and public health risks | 4.4.1.1 The incinerator complies with environmental regulations  
4.4.1.2 The incinerator emissions comply with license and registration requirements  
4.4.1.3 Procedures ensure that toxic chemicals, radioactive waste and expired medicines are disposed of safely |
### Domain 5: Leadership and Governance

The **Leadership and Governance** domain covers the strategic direction provided by senior management, through proactive leadership, planning and risk management, supported by the hospital board, clinic committee as well the relevant supervisory support structures and includes the strategic functions of communication and quality improvement.

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<tr>
<th>Sub-domain</th>
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</table>
| **5.1 Oversight and accountability** | 5.1.1 The national / provincial department or parent company oversees and supports the hospital or clinic. | 5.1.1.1 The Auditor General monitors compliance of the establishment  
*only applicable to the public sector*  
5.1.1.2 The provincial department or parent company provides guidance to the health establishment on matters related to governance |
| | 5.1.2 A functional governance structure is in place | 5.1.2 A governance structure is in place and functional at the health establishment (i.e. Hospital Facility Board, Community Health Forums and/or private sector equivalent) |
| | 5.1.3 The governance structure ensures quality care and good management is provided | 5.1.3.1 The governance structure ensures the strategic direction meets stakeholder needs  
5.1.3.2 The governance structure ensures quality of care, including patient safety, is properly monitored  
5.1.3.3 The governance structure ensures the health establishment's risks are identified and managed  
5.1.3.4 The governance structure ensures the financial sustainability of the health establishment  
5.1.3.5 The governance structure ensures the health establishment's human resources are effectively managed and developed  
5.1.3.6 The governance structure monitors senior management performance and compliance with ethical business practice |
| **5.2 Strategic management** | 5.2.1 The management structure is appropriate for the health establishment and has the authority to ensure efficient service delivery | 5.2.1.1 The health establishment has an appropriate management structure in place and is familiar to all staff  
5.2.1.2 The delegation of authority for the health establishment's manager details limits of authority  
5.2.1.3 Delegations of authority for financial, human resources and other processes are clearly documented and followed |
| | 5.2.2 Strategic plans set key priorities and operational plans show how the targets will be achieved | 5.2.2.1 A comprehensive strategic plan is in line with national/provincial or parent company strategic plans  
5.2.2.2 Operational plans are in line with strategic plans so as to meet service delivery objectives |
### Domain 5: Leadership and Governance

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<tbody>
<tr>
<td>5.2.3 Budget allocations and staffing</td>
<td>ensure services can be delivered as planned</td>
<td>5.2.3.1 The annual budget is developed as part of the strategic and</td>
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<td></td>
<td></td>
<td>operational plan to meet agreed priorities using available resources</td>
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<td></td>
<td></td>
<td>and capacity</td>
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<td>5.2.3.2 Efficiencies and savings are identified and included in the</td>
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<td></td>
<td></td>
<td>budget</td>
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<td>5.2.3.3 The human resource allocation plan ensures sufficient staff to</td>
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<tr>
<td></td>
<td></td>
<td>meet the health establishment's agreed service levels</td>
</tr>
<tr>
<td>5.2.4 Senior managers monitor</td>
<td>and evaluate operational plans to ensure the health establishment’s</td>
<td>5.2.4.1 The health establishment's performance is monitored against key</td>
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<td>targets are met</td>
<td>objectives in the operational plans</td>
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<td>5.2.4.2 Internal and external financial audits are carried out annually</td>
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<td>5.3 Risk management</td>
<td></td>
<td>5.3.1 Risks are regularly analysed and controlled</td>
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<td>5.3.1.1 Risks are actively monitored and managed to minimise or eliminate</td>
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<td>risk where possible</td>
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<td>5.3.2 Medico-legal incidents and cases are properly managed</td>
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<td>5.3.2.1 The establishment has appropriate insurance or other cover for</td>
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<td>medico-legal incidents and damages claims</td>
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<td>5.4 Quality improvement</td>
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<td>5.4.1 A quality improvement system is in place and monitored for</td>
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<td></td>
<td></td>
<td>effectiveness</td>
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<td>5.4.1.1 A committee guides and coordinates the quality assurance system</td>
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<td>5.4.1.2 Actions are taken on all quality improvement needs and their</td>
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<td></td>
<td></td>
<td>implementation is monitored</td>
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<td>5.5 Effective leadership</td>
<td></td>
<td>5.5.1 Senior managers make sure that plans are implemented and targets</td>
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<td></td>
<td></td>
<td>are met</td>
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<td>5.5.1.1 Key senior positions are filled by persons with appropriate</td>
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<td>competencies, qualifications, experience and knowledge</td>
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<td>5.5.1.2 Each senior manager’s responsibilities are defined in a current</td>
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<td>job description</td>
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<td>5.5.1.3 Performance management of senior managers is in line with</td>
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<td>strategic and operational plans</td>
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<td>5.5.2 Senior managers’ actions demonstrate their leadership and values</td>
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<td>5.5.2.1 Senior managers provide positive role models</td>
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<td>5.5.2.2 Leadership development is actively supported at all levels</td>
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<td>5.6 Communications and public relations</td>
<td></td>
<td>5.6.1 Staff are involved in improving services and are kept informed</td>
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<td></td>
<td>about these efforts</td>
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<td>5.6.1.1 A communication strategy ensures staff are informed about all</td>
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<td>relevant issues within and affecting the health establishment</td>
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<td>5.6.1.2 Staff actively participate in decisions about quality in the</td>
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<td>health establishment</td>
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<td>5.6.2</td>
<td>Public relations staff provide the public and the media with accurate and appropriate information when needed</td>
<td>5.6.2.1 A communication strategy ensures that the public are informed about all relevant issues within and affecting the health establishment</td>
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<td>5.6.2.2 A member of staff is responsible for performing the functions of communication officer</td>
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<td>5.6.2.3 Information about the health establishment, health-related issues, public concerns and queries is released in a timely and appropriate manner</td>
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<td>5.6.2.4 All publicity and information material includes up-to-date contact details and the customer call-centre number</td>
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<td>5.6.2.5 The health establishment does not divulge confidential information or patient identifiable data without prior consent (as per legislation)</td>
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<td>5.6.2.6 Access to information conforms to Section 51 of the Promotion of Access to Information Act 2 of 2000 through an accessible PROATIA Manual</td>
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**Domain 6: Operational Management**

Operational management covers the day-to-day responsibilities involved in supporting and ensuring delivery of safe and effective patient care, including management of human resources, finances, assets and consumables, and of information and records.

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<tr>
<td>6.1 Human resource management and development</td>
<td>6.1.1 Staff is managed efficiently and fairly, and recruitment, administrative and registration processes ensure safe and effective service delivery</td>
<td>6.1.1.1 The health establishment has the most up to date human resource policies and relevant legislation</td>
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<td>6.1.1.2 An approved staffing plan is in place, in accordance with occupancy rates, utilisation rates and patient profiles</td>
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<td>6.1.1.3 The health establishment follows staff recruitment and selection procedures</td>
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<td>6.1.1.4 Health professionals are registered and provide clinical services consistent with their qualifications</td>
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<td>6.1.1.5 Staff absenteeism, turnover and vacancy rates are monitored to identify and address trends</td>
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<td>6.1.1.6 A human resource retention strategy ensures adequate and motivated staff</td>
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<td>6.1.2 Staff performance is regularly reviewed against job descriptions or performance plans to ensure these are achieved</td>
<td>6.1.2.1 Staff responsibilities are defined in current job descriptions</td>
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<td></td>
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<td>6.1.2.2 Staff are involved in periodic reviews to appraise their performance and set objectives and targets</td>
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<td>6.1.3 Labour Relations policies are supported by sound employee relations to protect employee and employer rights</td>
<td>6.1.3.1 Labour Relations policies recognise employees' and employers' rights and are applied fairly and consistently</td>
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<td>6.1.4 A comprehensive programme for staff training and continuing professional development is in place</td>
<td>6.1.4.1 Staff are briefed on the health establishment and their specific responsibilities</td>
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<td>6.1.4.2 Staff receive ongoing in-service education according to their roles and responsibilities</td>
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<td>6.2 Staff welfare and employee wellness</td>
<td>6.2.1 Staff health and welfare is actively promoted</td>
<td>6.2.1.1 There is a zero-tolerance policy on violence and abuse towards staff and action is taken to support this</td>
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<td>6.2.1.2 Staff health and healthy lifestyle initiatives are promoted and supported</td>
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<td>6.2.2 Staff are protected from workplace hazards through effective occupational health and safety systems</td>
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<td>6.2.2.1 Responsibilities under the Occupational Health and Safety Act are in writing</td>
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<td>6.2.2.2 An active Health and Safety Committee ensures a safe working environment</td>
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<td>6.2.2.3 A medical surveillance plan is in place for at-risk staff, based on health risk assessments</td>
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<td>6.2.2.4 Measures are in place to minimise critical occupationally acquired injuries and diseases</td>
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<td>Sub-domain</td>
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<tr>
<td>6.3 Financial management</td>
<td>6.3.1 Expenditure is managed and monitored to ensure efficiency within legal frameworks</td>
<td>6.3.1.1 All financial processes are in line with the Public Finance Management Act or Generally Accepted Accounting Principles</td>
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<td>6.3.1.2 Procedures ensure that expenditure meets defined service needs for staff and other inputs</td>
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<td>6.3.1.3 Analysis of actual spend against budgets ensures continuity of services and prompt payment of suppliers</td>
</tr>
<tr>
<td>6.4 Supply chain and asset management</td>
<td>6.4.1 All tendering and purchasing is transparent and fair and reflects planned needs and budgets</td>
<td>6.4.1.1 Asset and equipment needs are identified in the annual plans and budgets and incorporated into procurement plans</td>
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<td>6.4.1.3 All local tendering and contracting processes comply with relevant legislation</td>
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<td>6.4.2 Assets are properly registered, managed and controlled to maximise use and reduce losses</td>
<td>6.4.2.1 A complete, accurate and updated asset register is available</td>
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<td></td>
<td></td>
<td>6.4.2.2 Maintenance and disposal of assets is managed effectively and efficiently</td>
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<td>6.4.2.3 Assets are monitored and variances addressed</td>
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<td>6.4.2.4 Risk of loss or theft is identified and managed</td>
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<tr>
<td>6.5 Transport and fleet management</td>
<td>6.5.1 The availability and safety of vehicles are assured through proper maintenance, licensing of drivers and monitoring of utilisation</td>
<td>6.5.1.1 All vehicles owned or used by the health establishment are licensed and maintained</td>
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<td>6.5.1.2 The health establishment ensures that all employed or contracted drivers have an appropriate licence</td>
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<td>6.5.1.3 Transport use is recorded and monitored to prevent misuse of vehicles</td>
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<tr>
<td><strong>6.6 Information management</strong></td>
<td>6.6.1 A health management information system collects, stores and provides data to meet management's needs</td>
<td>6.6.1.1 Staff have adequate IT hardware, skills and support to effectively use the systems provided</td>
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<td></td>
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<td>6.6.1.2 Computerised systems are functional and used where available</td>
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<td>6.6.1.3 Contingency plans for system failure or other challenges are available and known to staff and managers</td>
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<tr>
<td></td>
<td>6.6.2 Management uses information to inform decision-making and planning</td>
<td>6.6.2.1 The health establishment submits clinical, managerial and administrative information as required</td>
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<td></td>
<td>6.6.2.2 Managerial, clinical and administrative information is used to support decision-making and planning</td>
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<td></td>
<td>6.6.3 Confidential information is handled in line with data protection policies and legislation</td>
<td>6.6.3.1 Patient, personnel and other confidential records are archived securely and only accessed by authorised personnel</td>
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<tr>
<td></td>
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<td>6.6.3.2 Procedures for the disposal of confidential waste are followed</td>
</tr>
<tr>
<td><strong>6.7 Medical Records</strong></td>
<td>6.7.1 Patient information is accurately and completely recorded according to clinical, legal and ethical requirements</td>
<td>6.7.1.1 Patient records are complete and contain all legal and statutory requirements</td>
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<td></td>
<td>6.7.1.2 Patient's records are managed confidentially</td>
</tr>
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<td>6.7.2 An efficient system is in place to archive and retrieve medical or patient records</td>
<td>6.7.2.1 Dedicated, trained staff and appropriate systems are in place to manage the record archive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6.7.2.2 Processes and infrastructure for filing and retrieval of patient files ensure effective and efficient services</td>
</tr>
</tbody>
</table>
DOMAIN 7: FACILITIES AND INFRASTRUCTURE
The facilities and infrastructure domain covers the requirements for clean, safe and secure physical infrastructure (buildings, plant and machinery, equipment), functional, well managed hotel services and effective waste disposal.

<table>
<thead>
<tr>
<th>Sub-domain</th>
<th>Standard</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>7.1 Buildings and grounds</strong></td>
<td>7.1.1 The building meets all applicable regulations</td>
<td>7.1.1.1 The health establishment has been licensed annually against the R158 or R187 regulations * only applicable to the private sector</td>
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<td></td>
<td></td>
<td>7.1.1.2 The health establishment complies with infrastructure standards * only applicable to the public sector</td>
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<tr>
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<td>7.1.2 Infrastructure is appropriately used according to level of care</td>
<td>7.1.2.1 Available facilities are regularly checked to ensure they are fit for purpose</td>
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<td>7.1.2.2 The health establishment layout is planned or adapted to ensure it meets service and patient needs</td>
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<td>7.1.3 Waiting areas are convenient and provide adequate shelter and seating for patients</td>
<td>7.1.3.1 Waiting areas are appropriately located and adequate for the number of patients using them</td>
</tr>
<tr>
<td></td>
<td>7.1.4 Buildings are safe and adequately maintained</td>
<td>7.1.4.1 The health establishment holds regular, documented and comprehensive inspections of its physical facilities</td>
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<td></td>
<td></td>
<td>7.1.4.2 Maintenance is carried out promptly and efficiently by qualified personnel</td>
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<td>7.1.5 The health establishment is organised, furnished and equipped to meet patient needs and comfort</td>
<td>7.1.5.1 All areas are adequately furnished and provide an acceptable environment for patient care</td>
</tr>
<tr>
<td></td>
<td>7.1.6 Grounds are maintained to be safe and orderly</td>
<td>7.1.6.1 A regular maintenance programme ensures grounds are safe and attractive</td>
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<td>7.1.6.2 All pedestrian and vehicular access routes are maintained to ensure the smooth running of the health establishment</td>
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<td>7.1.6.3 Emergency vehicle access roads are kept clear</td>
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<tr>
<td><strong>7.2 Machinery and utilities</strong></td>
<td>7.2.1 Electrical power, water, sewerage and other internal bulk supply systems meet the needs of the establishment</td>
<td>7.2.1.1 Site and floor plans show the location and layout of the main services (e.g. water, sanitation and electricity)</td>
</tr>
<tr>
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<td>7.2.1.2 Routine and emergency electrical power services meet the needs of the health establishment</td>
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<td>7.2.1.3 Routine and emergency water supplies meet the needs of the health establishment</td>
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<td>7.2.1.4 The sewerage disposal system is functional and properly maintained</td>
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<tr>
<td>Sub-domain</td>
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<td>7.2 Machinery and utilities</td>
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<td>7.2.1.3 Routine and emergency water supplies meet the needs of the health establishment</td>
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<td>7.2.1.4 The sewerage disposal system is functional and properly maintained</td>
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<td>7.2.1.5 Appropriate ventilation is provided in theatres, patient accommodation and waiting areas</td>
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<td>7.2.1.6 Routine and emergency medical gas and vacuum systems meet the needs of the health establishment</td>
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<td>7.2.2 Operational plant, machinery and equipment is well maintained, fully functional and complies with regulations</td>
<td>7.2.2.1 Operational plant, equipment and installations are tested and properly maintained</td>
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<td>7.2.2.2 The operational plant, machinery and equipment is upgraded, replaced, decommissioned and disposed of according to a documented system</td>
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<td>7.2.3 A reliable internal and external telephone system provides routine and emergency back-up communication</td>
<td>7.2.3.1 The telephone system is functional and reliable</td>
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<td>7.2.3.2 A functional back-up system ensures communication if the telephone system fails</td>
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<td>7.2.3.3 Private telephone facilities are available for communicating confidential information</td>
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<td>7.2.4 A functional public communication system allows communication throughout the health establishment in the event of an emergency</td>
<td>7.2.4.1 A system is in place for alerting occupants in the event of an emergency</td>
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<td>7.2.4.2 Staff are briefed to react to emergency warnings</td>
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<td>7.2.4.3 All beds and ablution facilities have an emergency call system to alert the nursing staff</td>
</tr>
<tr>
<td>7.3 Safe and secure environment</td>
<td>7.3.1 People and property are actively protected from safety and security risks</td>
<td>7.3.1.1 Security systems safeguard the building, patients, visitors and staff</td>
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<td>7.3.1.2 The layout of security systems protect vulnerable patients</td>
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<td>7.3.1.3 Adequate internal and external lighting protects patients, visitors and staff</td>
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<td>7.3.1.4 All security incidents are reported and addressed</td>
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<td>7.3.1.5 Safety and security awareness is promoted among staff</td>
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<td>7.3.1.6 Current Local Fire Authority certificates show the health establishment complies with relevant fire safety regulations</td>
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<td>7.3.1.7 An emergency plan is available to show that patient well-being is protected at all times</td>
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<tr>
<td>7.4 Hygiene and cleanliness</td>
<td>7.4.1 The buildings and grounds are kept clean and hygienic to maximise safety and comfort</td>
<td>7.4.1.1 The health establishment is kept clean, including critical areas of public use (especially toilets) and areas for patient care</td>
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<tr>
<td></td>
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<td>7.4.1.2 Appropriate cleaning materials and equipment are available, and properly used and stored</td>
</tr>
</tbody>
</table>

Domain 7: Facilities and Infrastructure
### Sub-domain Standards

<table>
<thead>
<tr>
<th>Sub-domain</th>
<th>Standard</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>7.5 Waste management</strong></td>
<td>7.5.1 Waste management in the health establishment and surrounding environment complies with legal requirements, national standards and good practice</td>
<td>7.5.1.1 There is a current waste management policy and procedure</td>
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<td></td>
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<td>7.5.1.2 A designated and knowledgeable staff member ensures compliance with relevant waste management legislation and standards</td>
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<td></td>
<td>7.5.2 Health care risk waste (HCRW) is handled, stored and disposed of safely to reduce potential health risks and to protect the environment</td>
<td>7.5.2.1 The health establishment reviews its HCRW management every two years to identify the hazardous waste it generates and establish processes for its safe management</td>
</tr>
<tr>
<td></td>
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<td>7.5.2.2 Documented policies and procedures are available for the collection, handling, segregation, storage and disposal of HCRW</td>
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<td>7.5.2.3 A contract and service level agreement is in place with an approved and legally compliant waste removal service provider</td>
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<td>7.5.2.4 There are sufficient, accessible and appropriate waste disposal containers to handle all the HCRW generated</td>
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<td>7.5.2.5 Anatomical waste is disposed of legally while taking into account cultural preferences</td>
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<td>7.5.3 Management of general waste (e.g. office, kitchen, garden or household waste) ensures general cleanliness and the safety of staff and patients</td>
<td>7.5.3.1 General waste is stored and transported appropriately and securely, and removed promptly</td>
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<td>7.5.3.2 Sufficient numbers of suitable containers are conveniently located to allow safe disposal of waste</td>
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<tr>
<td><strong>7.6 Linen and laundry</strong></td>
<td>7.6.1 Linen and laundry services meet the needs of the hospital or clinic and safety standards</td>
<td>7.6.1.1 The laundry service is effectively managed and delivered (on-site or out-sourced) to meet the needs of the health establishment and laundry standards</td>
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<td>7.6.1.2 All laundry is handled in line with infection control and safety requirements</td>
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<td>7.6.1.3 The laundry has suitable equipment to meet the needs of the health establishment</td>
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<td>7.6.1.4 Adequate stocks of linen are maintained to ensure that items are always available</td>
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<tr>
<td>Sub-domain</td>
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<tr>
<td>7.7 Food services</td>
<td>7.7.1 Food services are provided to meet patients’ needs as well as safety standards</td>
<td>7.7.1.1 Policies and procedures guide all aspects of food procurement, storage, preparation and serving</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7.7.1.2 Food services are effectively managed and delivered (on-site or out-sourced) to meet the needs of the health establishment</td>
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<td>7.7.1.3 Patients are satisfied with food quality and presentation</td>
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<td>7.7.1.4 Food services provide patients with adequate and nutritious food and drink</td>
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<td></td>
<td>7.7.1.5 Policies and procedures are in place for infection control, safety and food hygiene</td>
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<td>7.7.1.6 Food services meet patients’ cultural, religious and dietary needs</td>
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<td>7.7.1.7 Equipment for the safe preparation of food is available</td>
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<td>7.7.1.8 Kitchens meet hygiene and environmental health standards</td>
</tr>
</tbody>
</table>
A. Bibliography

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Appendix 7

Western Cape Government
Health

To:
The DDG: Chief of Operations
The CFO
The Chief Director: Strategy and Health Support
The Chief Director: Health Programs
The Chief Director: People Management
The Chief Director: Infrastructure and Technical Management
The Director: Communications
The Deans: Health Sciences Faculties
Chairpersons: Provincial Clinical Governance Committees

CIRCULAR H 200 /2015

WESTERN CAPE DEPARTMENT OF HEALTH STANDARD OPERATING PROCEDURE (SOP) NO. A007: INFORMED CONSENT FOR MEDICAL AND SURGICAL PROCEDURES, INVESTIGATIONS AND SPECIFIC THERAPIES

This policy applies to all clinical health providers employed at Western Cape Government Health (WCGH) healthcare facilities.

Purpose of the policy:

- To establish Provincial policy and provide guidelines on how to obtain legal and ethically acceptable informed consent from patients attending provincial healthcare facilities for medical or surgical interventions, specific treatments and investigations.

This policy does not cover informed consent to participate in clinical research. Details of informed consent for patients recruited for clinical trials are determined by the Research Ethics Committee of the University under which the research project occurs.

Your cooperation is appreciated.

DR BETH ENGELBRECHT
HEAD OF HEALTH
DATE: 2015-12-04
# Informed Consent for Medical and Surgical Procedures, Investigations and Specific Therapies

**Policy compiled and approved by:**
The WCCH Theatre Efficiency Task Team

**Date:** Revised October 2015

## Policy Purpose

To establish Provincial policy and provide guidelines on how to obtain legal and ethically acceptable informed consent from patients attending provincial healthcare facilities for medical or surgical interventions, specific treatments and investigations.

This policy does not cover informed consent to participate in clinical research. Details of informed consent for patients recruited for clinical trials are determined by the Research Ethics Committee of the University under which the research project resorts.

## Target group

This policy applies to all clinical health providers employed at Western Cape Government Health (WCCH) healthcare facilities.

## Rationale and scope of policy

**Obtaining informed consent for a medical or surgical procedure or intervention is an important ethical and legal obligation on the part of all medical practitioners.**

This policy applies to all invasive procedures / major interventions, including those performed under local anaesthesia, spinal or epidural anaesthesia, procedural sedation or general anaesthesia – and specific non-anaesthetic procedures such as blood transfusion and HIV or Hepatitis testing.

A copy of the policy must be made available to all clinical healthcare professionals and other healthcare workers.
<table>
<thead>
<tr>
<th>Informed consent for elective / non-urgent emergency procedures (Continued)</th>
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<tbody>
<tr>
<td>b. If they are assisted mental healthcare users, a hierarchy of first-degree relatives may be approached to give consent as follows:</td>
</tr>
<tr>
<td>i) First-degree relatives may be approached in order of hierarchy, namely a spouse, biological parent, adult son or daughter, brother, sister or grandparent (Note that first-degree relatives who are currently involved in the patient's well-being may be the preferred source of consent).</td>
</tr>
<tr>
<td>ii) If no first-degree relative is contactable for an elective procedure, then the Department of Health's Head of the Legal Unit should be contacted on 021 483 3434 / 082 550 2612.</td>
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</tbody>
</table>

8. **Parents giving consent for children:** Any parent who is 12 years of age or older (the "minor parent"), may consent to the performance of a surgical operation on his or her child provided that the minor parent is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the surgical operation. The minor parent must be duly assisted by his or her parent or guardian.

Parents or legal guardians may therefore give consent for the performance of a surgical operation on his or her child:
- If the child is under the age of 12 years,
- If the child is over the age of 12 years, or older, but lacks sufficient maturity or the mental capacity to understand the benefits, risks and implications of the surgical operation.

A married person under the age of 18 is legally regarded as a major and is competent to grant consent for himself or herself and for his or her child. This may also apply to a minor who is financially independent.

Only a biological parent or a Court-appointed guardian may legally grant consent for non-urgent procedures on behalf of a child.

9. Any child of 12 years of age or older may give consent for any medical (non-surgical) treatment of himself or herself, provided that the child is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of such treatment. (For example: the prescription of oral contraceptives).

10. The procedure for obtaining consent for elective procedures on minors under 12 years of age, and those of 12-18 years not considered competent to provide informed consent when no parental guidance is available, is as follows:

   a. Every reasonable attempt must have been made to contact the parents at the address or telephone number given – in the event that this is unsuccessful, one must enquire with the police, neighbour or next of kin. A social worker should assist and document these attempts.

   b. If the above attempts are unsuccessful, consent may be given for minor children by an independent social worker at the provincial Department of Social Development. Contact details are: Tel: 021 483 4621; Fax: 021 483 4461.
17. Where consent is refused on religious grounds, please consult the medical ethic guidelines regarding "Religious or Religious Beliefs".

16. The legal validity of consent is subject to the requirements of Policy Points 1 to 6 above.

Procedure is prohibited.

15. Consent cannot be obtained for each operation, and the use of blanket consent forms to cover a large number of operations or multiple/separate procedures of the same kind is undesirable. Consent is valid for a limited period of time, and a new consent form must be completed and signed if the circumstances change or if the risks, benefits or details of the procedure remain the same.

14. It is not legally necessary to obtain consent from the patient's spouse for a permanent sterilization procedure.

13. Consent forms are not signed by the patient, only to affirm the identity of the person signing it. A witness does not sign to the consent to a document, only to affirm the identity of the person signing it.

12. Only in cases where consent is primarily the responsibility of the registered medical practitioner will the patient be informed that they have the option to perform the procedure. Consent may be obtained with the patient's refusal of consent. If such is required by law or the patient's best interests, even if this means doing so without parental consent. In an emergency, a minor child should be dealt with in the child's best interests. However, the informed social worker or any other social worker, may not give consent.

A department or health social worker or any other social worker, may not give consent.
1. **Patients 18 years and older**

In a medical emergency where the patient is unable to consent because of a decreased level of consciousness or other neurological impairment:

a. The attending doctor should obtain consent from the spouse or partner of the patient or, in the absence of such spouse or partner, a parent, grandparent, an adult child or an adult brother or sister of the patient, in the specific order as listed. This consent may be verbal/telephonic, but must be recorded on the consent form.

b. Where every effort has been made to contact the next of kin but without success, and an urgent/emergency procedure is required, the doctor should notify the relevant CEO/Manager medical services or delegate, of the need to obtain authority to proceed without consent. In the event that an emergency situation occurs after hours, contact the duty CEO/Manager medical services or delegate on call.

c. Junior doctors and those in training are strongly advised to seek and obtain the consensus opinion of a senior colleague before proceeding at his/her own discretion.

d. The doctor who performs the emergency operation must document the procedure in detail and complete the standard consent form, recording the name of the next of kin who has given consent or the name of the CEO/Manager medical services whom he or she has informed.

2. **Patients younger than 18 years of age**

Obtaining consent for emergency procedures on minors when parental consent is not available.

a. A duty CEO/Manager medical services may act "in loco parentis" on behalf of the minor child, and give consent to proceed. However, the onus rests on the attending doctor to assess and confirm the non-availability of a parent or legal guardian, and to arrange for the consent form to be signed by the CEO/Manager medical services. If the minor is over 12 years of age, the minor's assent should always be sought.

b. The operation for which telephonic consent is granted by the CEO/Manager medical services or delegate must be the operation that the attending doctor intends to perform, i.e. strictly and correctly defined.

c. The doctor who performs the emergency operation must document the procedure in detail and complete the standard consent form, recording the name of the CEO/Manager medical services who gives telephonic authority.
<table>
<thead>
<tr>
<th>Pregnancy</th>
<th>Terminated or Continued</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed</td>
<td>Consent for</td>
</tr>
<tr>
<td></td>
<td>Termination of Pregnancy</td>
</tr>
</tbody>
</table>

1. In terms of Section 6(1) of the Choice on Termination of Pregnancy Act, 1996 (Act 29 of 1996), the informed consent on Termination of Pregnancy may only be given in cases of medical indications (a) through (g) of Section 6 of the Act.

2. In the case of a minor seeking a termination of pregnancy, a medical practitioner or a registered midwife, or the case may be, shall advise such minor to consult with her parents, guardian, family member, or a friend before the pregnancy is terminated, provided that the advice given to the minor does not interfere with the minor's right to make decisions regarding her health.

3. In the case of a minor seeking a termination of pregnancy, a medical practitioner or a registered midwife, or the case may be, shall advise the minor to consult with her parents, guardian, family member, or a friend before the pregnancy is terminated, provided that the advice given to the minor does not interfere with the minor's right to make decisions regarding her health.

4. A minor requesting a termination of pregnancy shall provide complete part of the form “Statement by Minor Who Requests the Termination of her Pregnancy”.

5. At the time of signing consent for termination, the woman, including a minor female child, also signs consent for any further surgical procedure that may be required in the future to treat a complication of the termination.

6. The CEO of the medical services or delegate must be informed before the surgical induction of the termination of pregnancy on a minor.
Consent for the use of and/or blood products

Consent for HIV / HEP.B / HEP.C testing

1. The current prevalence of Human Immunodeficiency Virus (HIV) in South Africa carries an associated risk of this agent being transmitted via transfusion of donated blood and blood components, despite internationally standardised screening procedures in place at Blood Transfusion Services.

2. In view of the abovementioned risks, and in keeping with the patient’s right to self-determination, the Department of Health has been advised that blood transfusion requires the explicit, informed consent of the patient.

3. In obtaining the informed consent for transfusion, the material risk of transmitted infection should be clearly explained to the patient, as well as indications for and predicted benefits of the intervention.

4. It is suggested that the standard Consent to Medical Procedure form be completed prior to the transfusion and or procedure. The patient’s consent or refusal should be recorded in the block for that purpose.

5. In circumstances where the patient is not able to provide consent (e.g. life-threatening emergency, comatose patient, unaccompanied minor patient), the decision to proceed with transfusion should be made on clinical grounds alone and documented in the patient’s file.

6. Consent for HIV testing in WCGH facilities may be given verbally to the attending doctor once adequate pre-test counselling has taken place. This must be documented in the patient’s folder.

7. Children 12 years of age and older may consent to their own HIV test.

8. Should the HIV test be positive, a legal obligation exists for the doctor or other healthcare worker involved to inform the patient, provided the patient has indicated that he or she wishes to know the result, and to counsel him or her accordingly.

9. It is not policy to routinely check the HIV status of all patients having an operation or a procedure. Each case needs to be considered individually, taking into account the clinical features of the patient and the exact procedure planned. However, in the event that a healthcare worker suffers a needle stick injury or other exposure to blood or body fluids, the source patient needs to be approached to undergo tests for HIV / Hepatitis B / Hepatitis C. The patient must be asked if he or she consents and must be provided with pre- and post-test counselling.

If the source patient refuses permission or is unconscious, the attending doctor or registered nurse may not draw blood specifically for the HIV test without the patient’s consent. Instead, consider the following options:

a. Regard the source patient as HIV positive and treat the healthcare worker accordingly. An unconscious patient may be prepared to give consent once conscious.

b. Test an existing blood sample taken prior to the exposure incident, and, should the patient regain consciousness at any time, the
It is advised that, when completing the standard Consent to Medical Procedure form prior to the procedure, the patient or guardian should be asked to sign the block that reads, 'I consent to a sample of my blood being taken and tested for HIV, etc.'

a. Consent for HIV or Hepatitis testing must be obtained before the patient is made unconscious, unless there is a legitimate medical indication to do so while the patient is unconscious. If this sample may also be used for anonymous testing, it must be documented in the patient's medical record.

b. If no existing blood sample exists, but there is a legitimate medical indication to do another blood test, while the patient is unconscious, then this sample may also be used for anonymous testing.

c. If no existing blood sample exists, but there is a legitimate medical indication to do another blood test, while the patient is unconscious, then this sample may also be used for anonymous testing.

d. Offer test the source patient, but do not disclose the result (ie. anonymous testing). The source patient must agree to this and it should be documented in the patient's medical record.

e. If the source patient is legally incapable of giving consent (mentally ill or under 12 years of age), the basic guidelines for these patients apply.

f. It is advised that, when completing the standard Consent to Medical Procedure form prior to the procedure, the patient or guardian should be asked to sign the block that reads, 'I consent to a sample of my blood being taken and tested for HIV, etc.'
1. In accordance with Section 37(2) of the Criminal Procedure Act, 1977 (Act 51 of 1977) ("CPA"). a SAPS official can request a registered medical practitioner or registered nurse to take steps, including the taking of a blood sample in order to ascertain whether the body of a person, arrested upon any charge or released on bail, has any mark, characteristic or distinguishing feature or shows any condition or appearance.

Section 37 of the CPA further governs the powers of any police official to obtain fingerprints and/or a photographic image and/or request blood samples to be taken from accused or convicted persons. The situation may arise whereby a member of the South African Police Services ("SAPS") may attend a hospital in the event that such person is a patient at the hospital.

2. When a patient voluntarily consents to being fingerprinted and/or photographed, this must be recorded in the patient's folder and the police allowed to proceed.

3. If the patient refuses consent, the police may only proceed if the patient has been arrested and charged, or is already in custody.

4. If the police obtain the photographs or fingerprints without the healthcare facility and patient's consent, this must be documented in the patient's folder.

5. If the patient refuses consent, the police should be advised to wait until the patient is discharged or is formally arrested before attempting to obtain the evidence needed.

6. SAPS may request a medical practitioner or forensic nurse to draw blood from individuals arrested on suspicion of driving under the influence of alcohol or other substances. If the suspect does not co-operate, SAPS may use reasonable force to restrain him. The doctor or nurse may refuse to draw blood if, in his or her opinion, methods used by SAPS to restrain the suspect are unreasonable or potentially harmful.

<table>
<thead>
<tr>
<th>Consent for collection of forensic evidence / samples of body fluid on request from the South African Police Service</th>
</tr>
</thead>
</table>
| 1. In accordance with Section 37(2) of the Criminal Procedure Act, 1977 (Act 51 of 1977) ("CPA"). a SAPS official can request a registered medical practitioner or registered nurse to take steps, including the taking of a blood sample in order to ascertain whether the body of a person, arrested upon any charge or released on bail, has any mark, characteristic or distinguishing feature or shows any condition or appearance.

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<table>
<thead>
<tr>
<th>References and sources of information used in this policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children's Act, 2005 (Act 38 of 2005)</td>
</tr>
<tr>
<td>Choice on Termination of Pregnancy Act; 1996 (Act 92 of 1996)</td>
</tr>
<tr>
<td>Mental Health Care Act, 2002 (Act 17 of 2002)</td>
</tr>
</tbody>
</table>
CONSENT TO MEDICAL PROCEDURE

I, Dr ___________________________ have explained the nature, risks & possible consequences of the medical procedure to the undersigned patient or his/her legal guardian.

Signature _________________________ Date ______________

Circle whichever is applicable

<table>
<thead>
<tr>
<th>Procedure Explained</th>
<th>Personally</th>
<th>Via Interpreter</th>
</tr>
</thead>
</table>

Nature of procedure:

________________________________________________________________________

Where applicable indicate side of procedure (Right or Left)

Circle whichever is applicable

<table>
<thead>
<tr>
<th>TYPE OF ANAESTHETIC</th>
<th>Local</th>
<th>Spinal</th>
<th>General</th>
<th>Procedural Sedation</th>
</tr>
</thead>
</table>

CONSENT TO USE OF BLOOD and/or BLOOD PRODUCTS IF NECESSARY DURING THE COURSE OF THE PROCEDURE

Consent granted by Patient/Guardian: ___________________________ Signature ___________________________

Consent withheld by Patient/Guardian: ___________________________ Signature ___________________________

I consent to a sample of my blood being taken and tested for Hepatitis B and the Human Immuno Deficiency Virus (HIV) should contamination of a health care worker by my bodily fluids occur during the procedure.

Patient's / Guardian's Signature ___________________________

Full Name of Patient ___________________________ Signature/Thumb ___________________________

Print of patient ___________________________ Date ____________

I, the undersigned, hereby consent to the performance of, and understand the nature, risks and possible outcomes of the above procedure. The doctors who perform the above may carry out additional or alternative measures (including general anaesthesia) if considered necessary.

COMPLETE THIS SECTION IF CONSENT IS GIVEN BY A PERSON ON BEHALF OF THE PATIENT

Print Name ___________________________ Signature ___________________________ Date ____________

Relationship to patient ___________________________

Means by which consent was given: Personally ___________________________ Telephonically ___________________________

NAME AND SIGNATURES OF WITNESSES TO THE PATIENT'S / GUARDIAN'S SIGNATURE ON THIS DOCUMENT:

Witness 1
Print Name ___________________________ Signature ___________________________

Witness 2
Print Name ___________________________ Signature ___________________________

June 2010
### TOESTEMMING TOT MEDIÈSE PROSEDURE

<table>
<thead>
<tr>
<th>Omsirkel wat van toepassing is</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure verduidelik:</td>
</tr>
</tbody>
</table>

#### Aard van procedure:

Waar van toepassing, dui aan op watter kant is die procedure (Regs of Links)

#### Omsirkel wat van toepassing is

<table>
<thead>
<tr>
<th>Tyd Anestetikum:</th>
<th>Lokaal</th>
<th>Spinaal</th>
<th>Algemene</th>
<th>Procedurale Sedasie</th>
</tr>
</thead>
</table>

#### TOESTEMMING TOT DIE GEBRUIK VAN BLOED EN/OF BLOEDPRODUKTE, INDIEN NODIG, GEDURENDE DIE PROSEDURE

<table>
<thead>
<tr>
<th>Toestemming</th>
<th>Verleen deur</th>
</tr>
</thead>
<tbody>
<tr>
<td>pasiënt/voog:</td>
<td></td>
</tr>
</tbody>
</table>

Handtekening

### Ek gee toestemming dat 'n monster van my bloed getrek word en getoets word vir Hepatitis B en Mononucleosis (MIV), sommige gesondheidswerker gedurende die procedure met my liggelaarstaal in aanraking kom.

<table>
<thead>
<tr>
<th>Pasiënt/ Voog se handtekening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volle naam van pasiënt:</td>
</tr>
<tr>
<td>Handtekening/Duimdruk van pasiënt:</td>
</tr>
<tr>
<td>Datum:</td>
</tr>
</tbody>
</table>

### Ek, die ondergetekende, verleen hiermee toestemming tot die uitvoer van, en versam die aard, risiko's en moontlike gevolge van die bogenoemde procedure. Die dokter wat dit uitvoer, mag bykomende of alternatiewe maatreëls (insluitend algemene verdoving) uitvoer indien dit as noodsaaklik beskou word.

### VOLTOOI HIERDIE AFDELING INDIEN TOESTEMMING VERLEEN WORD DEUR 'N PERSOON NAMENS DIE PASiëNT

<table>
<thead>
<tr>
<th>Naam in drukskrif:</th>
<th>Datum:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handtekening:</td>
<td></td>
</tr>
</tbody>
</table>

#### Verhouding tot pasiënt

<table>
<thead>
<tr>
<th>Die wyse waarop toestemming verleen is:</th>
<th>Persoonlik</th>
<th>Telefoones</th>
</tr>
</thead>
</table>

#### NAME EN HANDTEKENINGE VAN GETUIES TOT DIE PASiëNT/VOOG SE HANDTEKENING OP HIERDIE DOKUMENT

<table>
<thead>
<tr>
<th>Getuie 1</th>
<th>Getuie 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naam en van in drukskrif:</td>
<td>Naam en van in drukskrif:</td>
</tr>
<tr>
<td>Handtekening:</td>
<td>Handtekening:</td>
</tr>
</tbody>
</table>

---

June 2010
ISIVUMELWANO SENKQUBO
YONYANGO

Mna, Gqirana

ndibucane sile ubume, unangicicweke neziphumo ozinokwama
zenkqubo yokunyanga ezi sigulane sityikitye apha ngasezantsi okanye umuntu osigcina ngokuselmethweni.

Utyikityo

Umhla

Faka isangqa kwefanilekeleyo

Indlela echaziweyo:  

Ngokwakho

Ngetoliki

Ubume benkqubo: 

Esikufunilane: 

Esomqalo 

Esiselelekeleyo: 

UHLIBHO LWESETHOMALALI SI ZINTLUNGU

Esiselelekeleyo

Indlela yokunyanga ngachiza
dilelebulali - zintungu

ISIVUMELWANO SOKUSETYENZiswa Kwegazi Okanye Imveliso Zegazi xa Kunemfuneko Ngexesha Lale NKQUBO.

Isivumelwano osiningezwe esigulana/ 

umuntu osigcinaayo:

Utyikityo

Utyikityo

Ndiyavumelana nokutshwa kwegazi 'am khonukuze kuvavan'ye intsholongo wane ye Hepatitis B nentsholongwane

ka gawulayo (HIV) xa kunekuthi omaye wabasabonzi achaphelenke kwincinci yomzima wam xa kusenziswa lenkqubo.

Esigulana / Umuntu osigcinaayo: Utyikityo

Amagama apheliso esigulana

Utyikityo/ ushicelo lukabhontsi 
wesigulana

Umhla

Mna, otyikityo apha ngasezantsi, 

diyakwumelana ngorwaziwa, kwaxe 

ndiyagqonda imeko. Ingicicweke kuyeze 

ziphumo ozinokwama zelenkqubo ingilinta.

Ongqoza abenza le njo ingentsha 

bangafumanisa izinto ezongazelele lwe 

okanye ezinye izinto (kubandakanywa izinto nje 

zothomala'lsa lintungu) xa 

kunokubonakala kuyifumela.

GCWALISA ELI CANDELO UKUBA ISIVUMELWANO SINIKRHELWE NGUMNTU OMELE ISIGULANE

Bhala igama

Umbila

Tyikitya

Uphudleleni kwesigulana

Indlela ekunikeleleni ngayo isivumelwano: 

Ubuqu

Ngemfeno - mfono

IGAMA NAMATYIKITYO AMANGQINA ESIGULANE / EYABANTU ABAGCINA ABANTWANA KOLUXWEBHU.

Ingqina loku - 1

Bhala Igama

Utyikityo

Inqina lezi - 2

Bhala Igama

Utyikityo

December 2010
Appendix 8
**Questionnaire**

<table>
<thead>
<tr>
<th>Have you ever had:</th>
<th>Yes</th>
<th>No</th>
<th>Details and therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>High blood pressure, a heart attack, angina, or chest pain?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rheumatic fever, a heart murmur, embolus, or irregular heart rate?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthma, bronchitis, pneumonia, emphysema, or TB?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any illnesses, coughs, cold or flu within the last 2 weeks?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have problematic snoring or sleep apnoea?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have thyroid problems, jaundice, hepatitis, or liver disease?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you or any close family members suffer with muscle weakness?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any bleeding/bruising problems or DVT’s or clots in the legs or lungs, Any</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>anticoagulant medication?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have any false or loose teeth, caps, crowns, or contact lenses?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you or any close family members have porphyria, malignant hyperthermia, or</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>scolion apnoea?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have heartburn, hiatus hernia, acid reflux, or stomach ulcers?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you received cortisone or steroid therapy – in the past or present?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are you pregnant?</td>
<td></td>
<td></td>
<td>If no – please provide the date of your last menstrual period</td>
</tr>
<tr>
<td>Do you drink alcohol daily</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do what you drink?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How many units per week?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For how many years?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you smoke?</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do what you smoke?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How many products per week?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For how many years?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

List any previous anaesthetics and operations you have had. Mention any problems you or close family members may have experienced.

List any medications you are taking at the present (legal, illegal, herbal or homeopathic)

List any allergic or unusual drug reactions:

Is there anything else you feel your anaesthetist should know about

Preoperative baseline vitals / measurements

<table>
<thead>
<tr>
<th>Heart rate</th>
<th>Systolic BP</th>
<th>Diastolic BP</th>
<th>Mean BP</th>
<th>Height</th>
<th>Weight</th>
</tr>
</thead>
</table>

**Anaesthesia consent**

For the vast majority of patients anaesthesia is safe and they experience no serious side-effects. However, some complications (such as nausea, sore throat and muscle pain) occur commonly. There are a number of more serious but rare complications that may also occur. It is common practice within the anaesthetic community not to discuss these possible problems with every patient as they are so rare that it would cause unnecessary anxiety for the majority of patients.

**Common risks:** Bruising at site of injection or drips. Nausea or vomiting. Sore throat and hoarse voice. Temporary muscle pain. Temporary headache and/or blurred vision.

**Uncommon risks:** Awareness of activity in the operating room during anaesthesia, particularly during emergency situations. Eye abrasions causing pain and requiring treatment. Damage to teeth or dental work, lips or tongue.

**Extremely rare risks:** Obstructions in the breathing passages, leading to difficulty breathing that cannot be easily controlled. Allergy to drugs causing wheezing, rash, and in rare cases – severe swelling, low blood pressure and cardiac arrest. Inherited muscle sensitivity to particular anaesthetic drugs (malignant hyperthermia). Heart attacks, strokes and pneumonia. Patients with diseases of the arteries, lungs, and smokers are at higher risk for these events.

**Regional anaesthesia:** Muscle weakness in the anaesthetised limb. Difficult passing urine after a lower body block. This returns to normal as the effect of the drug wears off, but a temporary urinary catheter may be needed. Headache, which is usually short-lived, but can be severe and may last several days. Damage to nearby blood vessels or organs – for example the lungs. Backache after spinal or epidural. This usually improves quickly, but occasionally can be lasting. There is a very small risk of infection or bleeding at the injection site, which may require antibiotic or surgical treatment. Rarely, nerves may be damaged, resulting in long-term weakness, pain, altered sensation or paralysis.

**Note:** There may be other unusual risks that have not been listed here. Please ask your Anaesthetist if you have any general or specific concerns about your case.

By signing below I certify that I have read the consent information on this page, or that the information has been read to me, and I acknowledge that I have discussed any aspects that remain unclear with my Anaesthetist.
<table>
<thead>
<tr>
<th>Date of procedure</th>
<th>List names of Anaesthetists</th>
<th>Signature</th>
<th>List grade</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>1: Intern</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2: Com serve</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3: MO &lt; 2 years</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4: MO ≥ 2 years</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5: Registrar</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6: Consultant</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time on table</th>
<th>Hh : mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery start</td>
<td>Hh : mm</td>
</tr>
<tr>
<td>Surgery completion</td>
<td>Hh : mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LMA</th>
<th>Nasal tube</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Un-cuffed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Oral ET tube</th>
<th>Un-cuffed</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>C &amp; L Grade</th>
<th>Pre O₂</th>
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</table>

<table>
<thead>
<tr>
<th>Introducer</th>
<th>Cricoid pres</th>
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</table>

<table>
<thead>
<tr>
<th>Fibreoptic aid</th>
<th>RSI</th>
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</thead>
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<table>
<thead>
<tr>
<th>WND check list</th>
<th>Cuff pressure</th>
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<th>Volatile - maint</th>
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</table>

<table>
<thead>
<tr>
<th>Airway</th>
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<th>Circle</th>
<th>Spinal</th>
<th>Epidural</th>
<th>Nerve block</th>
<th>Ultrasound</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Controlled</td>
<td>T-piece</td>
<td>Blunt-tip</td>
<td>Tuohy</td>
<td>Nerve stim</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pmax / Vol</td>
<td>Air</td>
<td>Rate</td>
<td>N₂O</td>
<td>Depth to epidural space (cm)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Peep</td>
<td></td>
<td></td>
<td></td>
<td>Epidural catheter in space (cm)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RSI</td>
<td></td>
<td></td>
<td></td>
<td>Notes</td>
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<table>
<thead>
<tr>
<th>Sat %</th>
<th>FiO₂</th>
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<tbody>
<tr>
<td></td>
<td>ET CO₂</td>
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<tr>
<td>Pmax/Tidal vol</td>
<td>T °C</td>
</tr>
<tr>
<td>CVP</td>
<td>Cet</td>
</tr>
<tr>
<td>Cet</td>
<td>Time</td>
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<table>
<thead>
<tr>
<th>Monitoring:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oximetry</td>
</tr>
<tr>
<td>ECG</td>
</tr>
<tr>
<td>NIBP</td>
</tr>
<tr>
<td>Capnograph</td>
</tr>
<tr>
<td>O₂ / Agent Analyser</td>
</tr>
<tr>
<td>Fluid warmer</td>
</tr>
<tr>
<td>Urine catheter</td>
</tr>
<tr>
<td>Eye &amp; pressure care</td>
</tr>
<tr>
<td>BIS/Entropy</td>
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<tr>
<td>MAP</td>
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<table>
<thead>
<tr>
<th>Events/Notes:</th>
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<tbody>
<tr>
<td>SBP</td>
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<table>
<thead>
<tr>
<th>Drugs:</th>
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<tr>
<td>Totals</td>
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<table>
<thead>
<tr>
<th>IV lines &amp; fluids:</th>
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<tbody>
<tr>
<td>Line 1</td>
</tr>
<tr>
<td>Line 2</td>
</tr>
<tr>
<td>Line 3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Blood loss:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine output:</td>
</tr>
<tr>
<td>Other loss:</td>
</tr>
</tbody>
</table>
### Recovery/ICU hand over

<table>
<thead>
<tr>
<th>Arrival time</th>
<th>Arrival B.P.</th>
<th>Arrival H.R.</th>
<th>Arrival SPO₂</th>
<th>Arrival temp</th>
</tr>
</thead>
<tbody>
<tr>
<td>hh : mm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Last opioid given:**

- Dose: ______________________ at hh : mm

**Blood loss**

<table>
<thead>
<tr>
<th>Event</th>
<th>ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>(total intraop)</td>
<td></td>
</tr>
</tbody>
</table>

**Urine output**

<table>
<thead>
<tr>
<th>Event</th>
<th>ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>(total intraop)</td>
<td></td>
</tr>
</tbody>
</table>

**WHO checklist?**

Y  N

### Intraoperative concerns / events

<table>
<thead>
<tr>
<th>Event</th>
</tr>
</thead>
</table>

**Ramsey Sedation Score**

1. Awake, anxious, agitated, restless
2. Awake, cooperative
3. Awake, responding to commands
4. Asleep, brisk response to loud noise or tap on forehead
5. Asleep, sluggish response to loud noise or tap on forehead
6. Asleep, no response

**Wong-Baker FACES Pain Scale**

- Y
- N

### Recovery room notes:

- Discharge criteria – mark whichever applicable

<table>
<thead>
<tr>
<th>All patients</th>
<th>Y</th>
<th>N</th>
<th>General anaesthesia</th>
<th>Y</th>
<th>N</th>
<th>Spinal anaesthesia</th>
<th>Y</th>
<th>N</th>
<th>Children</th>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain controlled?</td>
<td></td>
<td></td>
<td>Opening eyes and protruding tongue?</td>
<td></td>
<td></td>
<td>Sensation below umbilicus?</td>
<td></td>
<td></td>
<td>Fully responsive to simulation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea/ vomiting controlled?</td>
<td></td>
<td></td>
<td>Lifting head and arm?</td>
<td></td>
<td></td>
<td>C/S Uterus contracted?</td>
<td></td>
<td></td>
<td>PV bleeding noted?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescription chart checked?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Discharge criteria – mark whichever applicable

<table>
<thead>
<tr>
<th>All patients</th>
<th>Y</th>
<th>N</th>
<th>General anaesthesia</th>
<th>Y</th>
<th>N</th>
<th>Spinal anaesthesia</th>
<th>Y</th>
<th>N</th>
<th>Children</th>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time of discharge</td>
<td>hh : mm</td>
<td>Discharge temp</td>
<td>Pain score</td>
<td>Sedation score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Anaesthetic signature: ____________________________ Print name: ____________________________ Qualification: ____________________________
- Nursing signature: ____________________________ Print name: ____________________________ Designation: ____________________________
- Transferred to ward: ____________________________ by: ____________________________ at hh : mm
- Received by: ____________________________ Time: hh : mm Date: dd / mm / yy
## Appendix 9

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

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

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 ≥ 9/10 before discharge, unless there is a 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 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.

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Able to move 4 extremities voluntarily or on command</td>
<td>2</td>
</tr>
<tr>
<td>Able to move 2 extremities voluntarily or on command</td>
<td>1</td>
</tr>
<tr>
<td>Able to move 0 extremities voluntarily or on command</td>
<td>0</td>
</tr>
<tr>
<td>Able to deep breathe and cough freely</td>
<td>2</td>
</tr>
<tr>
<td>Dyspnoea or limited breathing</td>
<td>1</td>
</tr>
<tr>
<td>Apnoeic</td>
<td>0</td>
</tr>
<tr>
<td>BP* 20% of preanaesthetic level</td>
<td>2</td>
</tr>
<tr>
<td>BP* 20-50% of preanaesthetic level</td>
<td>1</td>
</tr>
<tr>
<td>BP* 50% of preanaesthetic level</td>
<td>0</td>
</tr>
<tr>
<td>Fully awake</td>
<td>2</td>
</tr>
<tr>
<td>Arousable on calling</td>
<td>1</td>
</tr>
<tr>
<td>Not responding</td>
<td>0</td>
</tr>
<tr>
<td>Pink (SaO2 &gt; 92% on room air)</td>
<td>2</td>
</tr>
<tr>
<td>Pale, dusky blotchy, (O2 required for SaO2 &gt; 90%)</td>
<td>1</td>
</tr>
<tr>
<td>Cyanotic (SaO2 &lt; 90% despite supplementary oxygen)</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td></td>
</tr>
</tbody>
</table>

**Sources:**
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 m² 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 m². 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 CO₂.

**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.

**Sources:**
