

## 5. THE ANAESTHETIC PERIOD

Consideration of 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.

### 5.1 Delegation of care

2022 review by A de Goede and T Hlongwane

The anaesthetist's primary responsibility is to the patient currently under their care. **The anaesthetist shall always remain with the patient throughout the conduct of all general anaesthesia, major regional anaesthesia, and procedural sedation and analgesia (PSA) until the patient is transferred to the care of personnel in an appropriate care unit.**

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

An anaesthetist 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 lifesaving emergency care to another patient. That person's only responsibility would be to monitor the patient during the anaesthetist's absence and to keep the anaesthetist informed until returning to the theatre. In this situation, the anaesthetist remains responsible for the patient's care and must inform the operating room team.

An intraoperative handover of care between two anaesthetists should be documented in the anaesthesia record and follow a structured protocol. **It is unacceptable for one anaesthetist to simultaneously administer general anaesthesia, major regional anaesthesia, or moderate to deep procedural sedation (as classified in the SASA Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in adults: 2020–2025 and the SASA paediatric guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in children: 2021–2026) on more than one patient.**

Where only mild procedural sedation is administered, and provided an additional appropriately trained, qualified, and accredited individual, approved by the healthcare institution, is in constant attendance with each patient receiving care, it may be acceptable under these specific circumstances for one anaesthesia provider to supervise more than one patient.

In an obstetric unit, it is acceptable for one anaesthesia provider to supervise more than one patient receiving regional analgesia

for labour, but only once the patient has been assessed to be stable and handed over to a qualified and experienced registered maternity unit nurse for monitoring.

The anaesthetist remains primarily responsible for extubation of the patient

### 5.2 Perioperative temperature management

To be reviewed in 2026

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.

Monitoring patient core temperature is strongly recommended during cases of general and neuraxial regional anaesthesia lasting 30 min or longer.

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

To be reviewed in 2026

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

#### Vascular access

Based on available evidence, using real-time US during internal jugular (IJ) cannulation improves success and reduces the incidence of complications associated with the insertion of central venous catheters (CVC).

In adults, complications during performance of femoral vein (FV) cannulation are less severe than those that occur with subclavian (SC) and IJ vein cannulation. US guidance for FV access may improve the success rate and reduce complications for FV cannulation. However, this benefit may be more important with novice operators, paediatric patients, or patients with difficult anatomical landmarks. It should be noted that prolonged FV cannulation is associated with a higher incidence of DVT. An individualised and holistic patient risk-benefit assessment for site and type of line should always be considered.

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

Static US with skin marking is useful for identifying vessel anatomy and thrombosis but may not improve cannulation success or reduce complications as real-time US needle guidance does.

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

Current published evidence implies that adult and paediatric patients may benefit from using US when placing intra-arterial pressure monitoring lines. US reduces the number of attempts, shortens the procedure time and increases the rate of successful cannulation. It may be particularly advantageous in patients with abnormal anatomy, low perfusion states or previous unsuccessful cannulation attempts.

The cost-effectiveness of using US, 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.

It is thus the opinion of SASA that, based on currently available evidence, the following recommendations relating to US-guided vascular access can be made:

1. Support its use whenever available for the cannulation of IJ veins. There is clear, high-quality evidence that the use of US is superior to a landmark technique.
2. It may be used for the cannulation of SC and FVs.
3. Equivocal evidence supports the use of the US for arterial cannulation.

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

## Transthoracic echocardiography

Focused assessment using TTE may be an invaluable peri-operative extension to the clinical examination, and the skill can be acquired relatively easily. It should, however, not be seen as replacing a complete echocardiographic examination by an experienced operator if the indication for a thorough examination exists.

The use of US 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 with 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 anaesthetist's skill. This is a specific skill, but certainly not outside of a member's normal capability to assimilate. No different mechanism of staying abreast of technology is needed for US 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.

It is thus the opinion of SASA that, based on currently available evidence, the following recommendations relating to US-guided vascular access can be made:

- Support its use whenever available for the cannulation of IJ veins. There is clear, high-quality evidence that the use of US is superior to a landmark technique.
- It may be used for the cannulation of SC and FVs.
- Equivocal evidence supports the use of the US for arterial cannulation.

## 5.4 Monitoring and care standards

### To be reviewed in 2026

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 2–3 standards in these tables.

Please note that international levels of care do not exactly correlate to South African levels of care. This table should be merely used as a guideline.

Table VI: Characteristics and clinical practice recommendations for Level 1–3 facilities

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

Level 2 hospital	Required standards	Peri-anaesthetic care and monitoring standards – <i>highly recommended plus recommended</i>
District or provincial hospital, e.g. with 100–300 beds, with adequately equipped major and minor operating rooms	All <b>highly recommended</b> (Level 1) <b>plus</b> these <b>recommended</b> items	<ol style="list-style-type: none"> <li>1. Monitoring of inspired oxygen concentration with an instrument fitted with a low oxygen concentration alarm.</li> <li>2. Use of a device protecting against the delivery of a hypoxic gas mixture.</li> <li>3. Use of capnography to verify the correct placement of the endotracheal tube or other airway device and the adequacy of ventilation.</li> <li>4. Use of a continuous electrocardiograph.</li> <li>5. Continual measurement of temperature.</li> <li>6. Use of a peripheral neuromuscular transmission monitor when neuromuscular blocking drugs are given.</li> <li>7. Sufficient trained staff in the postanaesthesia recovery area to manage patients recovering from anaesthesia and surgery.</li> </ol>
Level 3 hospital	Required standards	Peri-anaesthetic care and monitoring standards – <i>highly recommended plus recommended plus suggested</i>
A referral hospital of 300–1 000 or more beds with basic intensive care facilities	All <b>highly recommended</b> (Level 1) <b>plus</b> recommended (Level 2) <b>plus</b> these items	<ol style="list-style-type: none"> <li>1. Continuous measurement of the inspiratory and/or expired gas volumes, and of the concentration of volatile agents.</li> <li>2. Continuous measurement and display of arterial pressure in appropriate cases.</li> <li>3. Use of continuous electronic temperature measurement.</li> <li>4. Monitoring of urine output during prolonged procedures or when significant administration of intravenous fluids is anticipated.</li> </ol>

## 5.5 Prevention of wrong-side surgery

### 2022 review by M Blackburn

Wrong-side procedures are classified as '*never events*'. However, they still occur at an unacceptable rate. As integral members of the surgical team and advocates for patient safety, anaesthesia providers are critical to processes that aim to prevent these.

Of note, it is estimated that wrong-side **blocks** are performed with an incidence 10 times those of wrong-side **procedures**. The factors below contribute to this.

Table VII: Factors that contribute to wrong-side procedures

#### Physician factors

- High-pressure environment
- Fatigue
- Lack of clear hierarchy/responsibility
- Staff change during the procedure
- Failure to check or mark site

#### Patient factors

- Sedated/confused or block sited after induction
- Similar patient names
- Language/communication barriers
- Abnormal anatomy
- Multiple blocks in the same patient
- Haemodynamic instability leading to distraction

#### Procedural factors

- Change in patient position
- Change in order of theatre list
- Wrong site marked
- Marking erased
- Distractions – verbal, phone call, teaching, etc.

While the WHO checklist (Appendix I) offers some protection from wrong-side procedures, it is recommended that further safeguards are put into place. The attending anaesthetist should take the following steps to prevent incorrect side procedures:

1. Verbally confirm the site and side of the surgery with the patient during the preanaesthesia consultation and document the discussion and confirmation of site/side against the booked procedure.

2. Ensure that the correct side is marked clearly. While this is primarily the responsibility of the consenting surgeon, as patient advocates, it falls to anaesthesia providers to confirm that this has been done. Options include:

- Indelible marker – consider marking the actual needle insertion site – be aware that this **may** lead to confusion with previously placed surgical side markers, so ensure this is clearly marked as a block site.
- Brightly coloured armband (of a colour different to those typically used by nursing staff)—visible at all times before skin incision—not necessarily on the limb to be operated on but lateralised to the correct side and visible.

## Prevention of incorrect side block performance

Previously, the 'STOP before you block' model was developed to reduce the risk of wrong site/side blocks. However, the number of incidents was not significantly decreased. The model has been adjusted in the interim and has been produced as a 'Prep, Stop, Block' model.

The model is presented as a standard operating procedure (SOP) and has the following steps:

### Prep

1. The performing anaesthetist **prepares** the local anaesthetic solution in a clearly marked syringe with a suitable block needle. This is then handed off to the assistant, out of reach of the person doing the block.
2. The anaesthetist then cleans and drapes, making sure to leave the previously placed mark visible.

### Stop

1. The **stop** moment happens after preparation is completed. When ready, the anaesthetist announces that all preparation is completed, and they are ready to block.
2. At this stage, the anaesthetist and the assistant view the surgical site mark and verbally confirm the correct side, and the assistant reconciles this with the consent form.

## Block

1. Only after the correct side is confirmed does the assistant hand the prepared tray to the anaesthetist, who immediately performs the **block**.
2. Any delay or interruption requires beginning the process from step 1.

The most important aspect of this updated model is that it is performed **immediately** before needle placement. The Prep, Stop, Block approach was devised by Regional Anaesthesia United Kingdom (RA-UK). It is currently endorsed by the Royal College of Anaesthetists (RCOA), Safer Anaesthesia from Education (SAFE), Royal College of Surgeons and the Association of Anaesthetists of Great Britain and Ireland (AAGBI).

## General

It is critical to appreciate the role of distraction in the performance of checklist-based procedures like the WHO and anaesthesia safety checklists – should these be interrupted for any reason, the checklist should be started from the top. Extreme care should be taken if the patient is to be positioned in positions other than supine after induction. Ultimately the creation and curation of strong team dynamics in the operating theatre will go a long way toward decreasing the risk of wrong-side procedures in the context of the provision of medical and surgical care.

## 5.6 Records

**2022 review by R Davids, C Lundgren, A Roux, D Shead and N Zimmelman**

SASA supports the following WFSA standards:

- A record of the details of each anaesthetic (preoperative assessment, anaesthetic plan, intra- and postoperative course) should be made (highly recommended).
- 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 anaesthesia care.

## Anaesthesia records

A full contemporaneous record relating to the continuum of anaesthetic care, i.e., records relating to preanaesthesia, intraoperative and postanaesthesia care, 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 BP should be recorded at least every five minutes. O<sub>2</sub> saturation must be monitored continuously and should be recorded at frequent intervals for all patients. End-tidal carbon dioxide concentration must be constantly monitored and recorded at frequent intervals. Reasons for deviation from these charting guidelines should be documented in the anaesthetic 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 anaesthesia record should include the patient's level of consciousness, heart rate, BP, O<sub>2</sub> saturation, and respiratory rate as first determined in the PACU.*

All practitioners must 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 if patient confidentiality is maintained.

The HPCSA states that "healthcare practitioners should enter and maintain at least the following information for each patient consulted":

- Personal (identifying) particulars of the patient.
- The bio-psychosocial history of the patient, including allergies and idiosyncrasies.
- The time, date, and place of every consultation.
- The assessment of the patient's condition.
- The proposed clinical management of the patient.
- The medication and dosage prescribed (all prescriptions must comply with the provisions of the Medicines Act and regulations).
- Details of referrals to specialists, if any (including the reports from such specialists, or any other conversations had with such specialists).
- 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 SAHPRA, compulsory.
- Test results.
- Imaging investigation results.
- Information on the times the patient was booked off from work and the relevant reasons.
- Where applicable, written proof of informed consent or some record or note in the patient file that consent has been obtained.

The entity holding and processing the information must consider and adhere to the following:

- The patient is entitled to see data being stored.
- The information being collected and processed must be adequate and necessary in view of the purpose to which the patient has consented.
- The holder of the information is obliged to ensure the accuracy, quality and security of the information they hold.
- Haemodynamic printouts or electronic data collected by facilities concerned as documentation of patient vital signs during anaesthesia can only be collected with the patient's and anaesthetist's prior consent.

Each record and printout must possess clear identifiable patient details. Any patient data collected that would reasonably be considered to be part of the patient-doctor notes may only be reviewed by or shared with any party other than the clinician or patient directly with prior written consent of the patient and, when shared, with notification to the clinician concerned (and this includes any legal representatives of facility groups).

## Ownership of records

- The information on a health record belongs to the patient.
- 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 than as is determined by law.
- The entity referred to above is the person/persons legally holding the patient's record.
- For state practice, standard documents approved by the authority, e.g., provincial administration, are used.
- Outside of the public sector, records on personally owned stationery guarantees the anaesthetist's ownership of the record. *SASA recommends that anaesthetists in private practice, as far as is permissible, enter medical records onto personally owned stationery.*
- All recorded patient information, both written and digital, should be preceded by an informed consent process.
- The patient has a right to the information as contained in their record and may petition under the Promotion of Access to Information Act (PAIA) for a copy of said record.
- *SASA recommends that where records are made available to patients, the responsible practitioner personally discloses/ explains the shared information.*
- The only acceptable grounds for refusal of access to patients' records is if access might cause serious harm to their physical or mental wellbeing.

## Signing of records and official documents

- Practitioners are, through the ethical rules, obliged to sign official documents and instructions generated by them. According to the HPCSA's ethical rules, this signature must be accompanied by the initials and surname of the practitioner in block letters. This also validates the instruction or record and the date it was issued.
- Sick certificates must comply with the requirements of the ethical rules. They can only include the diagnosis in a lay person's language if the patient has provided written consent to such disclosure.

## The anaesthetist's prescription

The HPCSA's ethical rule 23 stipulates that the medical practitioner "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, considering 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:

1. Diagnoses should precede prescriptions.
2. Prescriptions must be clinically indicated.
3. Patients must be informed of the medicines available to them.

Ethical rule 27A requires practitioners to respect patients' choices, and read with the NHA, requires practitioners to give 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 that:

1. Schedule 2, 3 or 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.
2. Schedule 5 substances shall not be repeated for longer than six months, and only if the authorised prescriber has indicated on the prescription the number of times and the intervals at which it may be dispensed. Where the 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.
  - Schedule 6 substances shall not be repeated without a new prescription being issued.
  - Schedule 7 or 8 substances may only be acquired by the Director-General, who may 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:

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

10. the International Classification of Diseases code (ICD code) should be stated where a prescription is to be funded by a third-party funder.

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.

A prescription constitutes an order to a pharmacist to dispense medication to a patient or guardian who will then administer the medication and/or a delegation of authority to a registered nurse to dispense/administer a medication to a patient on the medical practitioner's behalf. A prescription per patient is not required for drugs directly administered by the anaesthetist perioperatively. It is, however, incumbent on the anaesthetist to accurately record all drugs administered to each patient (time, dosage, route and relevant information).

Regulation 28 also requires pharmacists to verify the authenticity of telephonic, faxed, or electronic prescriptions, requiring that it 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 indicate the diagnosis on the prescription where the patient consents.

Practitioners should not demand any valuable consideration in return for prescribing 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.

## Records of incident and death reporting

The requirements for reporting adverse incidents (an institutional process) and death (a statutory process) are discussed in the Peer review and Incident Reporting sections of these Guidelines.

South African law requires any death considered unnatural to be reported for medicolegal investigation. Unnatural death related to anaesthesia is provided for in the Health Professions Act. In July 2008, a revised version of this statutory obligation came into effect with the proclamation of the Health Professions Amendment Act.

Previously the law stated that "the death of a person whilst under the influence of a general anaesthetic or local anaesthetic, or of which the administration of an anaesthetic has been a contributory cause, shall not be deemed to be a death from natural causes as contemplated in the Inquests Act 58 of 1959, or the Births, Marriages and Deaths Registration Act 81 of 1963". This has now been amended and states 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 Inquests Act 58 of 1959, or the Births and Deaths Registration Act 51 of 1992".

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 (The current South African [SA] procedure-related death notification [PRDN] instrument), the GW7/24 form (Report of person whose death is associated with the administration of an anaesthetic or a diagnostic or therapeutic procedure), originally published in the 1970s.
- Relevant documents from the patient's file.

## Maternal deaths

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 and completion of the maternal death notification form (MDNF) 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 maternal deaths occurring during pregnancy and childbirth. This also includes deaths occurring within 42 days of termination of pregnancy, irrespective of the duration of the pregnancy.

## Integrated reporting of an adverse incident and procedure-related death

It is recommended that the processes of adverse incident and procedure-related death reporting is 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 recommended that supervisors or other colleagues guide less experienced providers to ascertain that the record contains all relevant information. This may be facilitated in the process of adverse incident reporting, as described by the NDoH in their **policy document**, 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 (Ensuring that relevant information is included) the anaesthetic record AND the full report is added to the GW7/24.
    - iv. It is recommended that individuals and institutions participate in the collection of adverse event data using the tool developed by the NDoH, 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

### The Perioperative Shared Health Record and Integration with a Perioperative Clinical Registry

The Perioperative Shared Health Record (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 – a clinician-driven platform inclusive of all physician service providers. The PSHR will allow for individual practice benchmarking. Using appropriate governance mechanisms, the Perioperative Clinical Registry will allow for clinician-driven quality assessment and research.

The final results of this were published in the 2019 South African Health Review, and SASA continues to engage with all stakeholders on this and other platforms.

### 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 NHA, PAIA and POPIA all address the right to confidentiality and the circumstances under which disclosure would be authorised. Record-keeping is critical in risk management in medical practices and health establishments. The following section is informed by **POPIA**.

#### Summary of the act

- to promote the protection of personal information processed by public and private bodies;
- to introduce certain conditions so as to establish minimum requirements for the processing of personal information;
- to provide for the establishment of an Information Regulator to exercise certain powers and to perform certain duties and functions in terms of this Act and the Promotion of Access to Information Act, 2000;
- to provide for the issuing of codes of conduct;
- to provide for the rights of persons regarding unsolicited electronic communications and automated decision making;
- to regulate the flow of personal information across the borders of the Republic; and
- to provide for matters connected therewith.

#### Types of data and information that are protected

1. According to the 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 names, addresses, and similar personal information, as well as financial and biometric information and the likes are protected by POPIA. 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 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, documents or reports, x-rays, prescriptions, laboratory test results, certificates, clinical research records, etc. are included in the definition of information that is protected.
4. Information relating to health is considered "special information" within POPIA, attracting greater expectations for confidentiality.

#### Patient consent to disclosure

1. POPIA and NHA state that patients may consent to disclose their information, but such consent must be in writing. The HPCSA ethical rules require consent to be 'explicit'. **SASA recommends that consent to disclosure be made in writing.**
2. Third-party access: Under the terms of POPIA, the arrangements around third-party access to patient information broadly match the guidelines set out by the HPCSA. This means that patient consent is essential.
3. Exceptions to consented disclosure of personal information must align with NHA 2003, particularly sections 15 and 16.
4. Please note that both the NHA and POPIA provide automatic exemption on the sharing of information for the purposes of providing the service. This specifically includes sharing clinical information with the healthcare team providing care to the patient and the information required to be shared to bill for services provided. Please note that this exemption **does not** extend beyond this, such as sharing clinical information with family members, or information gathered for clinical and/or other research. **Although billing processes are implicitly included in the permissions, it is recommended that patients be made aware that you use an external billing company,** if this is the case, and that you will be submitting an invoice to their medical scheme. The **SASA Green Consent Form** includes such a statement.

#### Legal requirement or court order to disclose

- The NHA also authorises disclosure if a law explicitly requires disclosure. For example, notifiable diseases are declared as such by 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.
- The same applies if someone obtains a court order – such an order may compel the disclosure of the information.
- Practitioners may rely on ethical principles to not disclose under these circumstances. They 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

- Each entity collecting and recording personal information is bound by the provisions of POPIA, and each entity must preserve the confidentiality of the information it holds in its possession. Entities cannot share information without the patient's written consent, and the entity must ensure that the receiving party has the same or similar protections for confidentiality in place.
- POPIA advocates that all personal information held must be protected from loss, damage or unauthorised destruction, and unlawful access. The legal expectation is the implementation of reasonable technical and organisational measures to ensure information protection.
- 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 must be adhered to by both, i.e., two separate sets of forms may be required to give effect to consent to disclosure, and there may be two sets of policies relating to how health records are handled, shared, etc.

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

No personal information may be collected, recorded, stored, reworked or otherwise dealt with, without compliance with the following criteria as set by POPIA, all of which the patient must consent/agree to:

- The patient must know that their information is collected, reworked, stored, or disseminated ("processing").
- 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.
- The patient must know if there will be further processing of their information (e.g., a record used for health research purposes, inclusion in any clinical review panels, even if internal, etc.).
- 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. See section 16 of POPIA for the required duration of record keeping.
- Should the practitioner share information with another entity to provide services (such as a billing agency), the practitioner remains the "responsible party" in terms of the definitions within POPIA. The other entity becomes the "operator" in POPIA terms. It is essential that the responsible party has a written agreement in place with the operator that addresses confidentiality and confirms that the operator is POPIA compliant. If the operator is an international organisation (as is

the case if your information is stored through companies like Google or Amazon), the international company must comply with legislation equivalent to or more stringent than POPIA. Most international companies, including Google and Amazon, comply with General Data Protection Regulations (GDPR) in Europe, which is considered sufficient.

- The confidentiality requirements extend to any staff working for a clinician. It is expected that employment contracts for staff exist and explicitly include confidentiality clauses. It is also required that staff are trained in POPIA and that such training is recorded.
- Failure to comply with POPIA may lead to complaints lodged with the Information Regulator, resulting in civil and/or criminal prosecution.

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

- 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.
- 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.
- The HPCSA requires that records be kept in non-erasable ink, erasure fluid should not be used, and changes should be made on the original, erroneous document, with a signature and date next to the amendment.
- 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.

### Children and confidentiality

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.

### Additional POPIA requirements

1. The promulgation of POPIA has created some specific additional requirements for every entity. This is based on the entity being a juristic entity. In the public sector, the hospital is likely to be the juristic entity, and it would be the responsibility of the hospital management to ensure compliance with these requirements. In the private sector, each juristic entity would be required to comply. This would, therefore, apply to every partnership, association, solus practitioner or individual member of an association if the association is not a legal or juristic entity.
2. Over and above the items outlined above, the specific requirements include, but are not limited to:
  - i. A PAIA Manual (a template is available from SASA [sasa@sasaweb.com](mailto:sasa@sasaweb.com)) and its lodging with the Information Regulator

- ii. The designation and registration with the Information Regulator of an Information Officer (which would likely be the practitioner themselves)
- iii. The training of the Information Officer for their role and a record of such training
- iv. A data breach policy, whereby the steps that will be taken in the event of such a breach are outlined. This must include how the affected people will be notified of the breach.

### Example of policy document

This document is only available as part of the online publication of the SASA Practice Guidelines 2022 Revision.

- A record of the details of each anaesthetic (preoperative assessment, anaesthetic plan, intra- and postoperative course) should be made (highly recommended).
- 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 anaesthesia care.
- SASA recommends that anaesthetists in private practice, as far as is permissible, enter medical records onto personally owned stationery.
- SASA recommends that where records are made available to patients, the responsible practitioner personally discloses/explains the shared information.
- 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 (The current South African [SA] procedure-related death notification [PRDN] instrument), the GW7/24 form (Report of person whose death is associated with the administration of an anaesthetic or a diagnostic or therapeutic procedure), originally published in the 1970s.
  - Relevant documents from the patient's 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 and completion of the maternal death notification form (MDNF) with the entire maternity team.
- It is recommended that the processes of adverse incident and procedure-related death reporting is integrated for the following reasons:
  1. To improve the quality of record keeping.
    - i. It is recommended that supervisors or other colleagues guide less experienced providers to ascertain that the record contains all relevant information.
    - 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 (Ensuring that relevant information is included) the anaesthetic record AND the full report is added to the GW7/24.

iv. It is recommended that individuals and institutions participate in the collection of adverse event data using the tool developed by the NDoH, or a similar tool.

2. To facilitate root-cause analysis and the institution of quality improvement programmes.

- SASA recommends that consent to disclosure be made in writing.
- Although billing processes are implicitly included in the permissions, it is recommended that patients be made aware that you use an external billing company.

### Bibliography

- American Society of Anesthesiologists Task Force on Central Venous Access, Rupp SM, Apfelbaum JL, Blitt C, et al. Practice guidelines for central venous access: a report by the American Society Of Anesthesiologists Task Force On Central Venous Access. *Anesthesiology*. 2012;116(3):539-73. <https://doi.org/10.1097/aln.0b013e31823c9569>.
- Aouad MT, Kanazi GE, Abdallah FW, et al. Femoral vein cannulation performed by residents: a comparison between ultrasound-guided and landmark technique in infants and children undergoing cardiac surgery. *Anesth Analg*. 2010;111(3):724-8. <https://doi.org/10.1213/ane.0b013e3181e9c475>.
- Barrington MJ, Uda Y, Pattullo SJ, Sites BD. Wrong-site regional anesthesia: review and recommendations for prevention? *Curr Opin Anaesthesiol*. 2015;28(6):670-84. <https://doi.org/10.1097/aco.0000000000000258>.
- Dobson G, Chow L, Filteau L, et al. Guidelines to the practice of anesthesia – revised edition 2021. *Can J Anaesth*. 2021;68(1):92-129. <https://doi.org/10.1007/s12630-020-01842-x>.
- Dobson G, Filteau L, Fuda G, et al.; on behalf of Canadian Anesthesiologists' Society. Guidelines to the practice of anesthesia – revised edition 2022 [Internet]. ©2022. Canadian Anesthesiologists' Society. Available from: <https://www.cas.ca/en/practice-resources/guidelines-to-anesthesia>. Accessed 21 Jul 2022.
- Fragou M, Gravvanis A, Dimitriou V, et al. Real-time ultrasound-guided subclavian vein cannulation versus the landmark method in critical care patients: a prospective randomized study. *Crit Care Med*. 2011;39(7):1607-12. <https://doi.org/10.1097/ccm.0b013e318218a1ae>.
- Gao Y-B, Yan J-H, Gao F-Q, et al. Effects of ultrasound-guided radial artery catheterization: an updated meta-analysis. *Am J Emerg Med*. 2015;33(1):50-55. <https://doi.org/10.1016/j.ajem.2014.10.008>.
- Grebenik CR, Boyce A, Sinclair ME, et al. NICE guidelines for central venous catheterization in children. Is the evidence base sufficient? *Br J Anaesth*. 2004;92(6):827-30. <https://doi.org/10.1093/bja/ae1134>.
- Gualtieri E, Deppe SA, Sipperly ME, Thompson DR. Subclavian venous catheterization: greater success rate for less experienced operators using ultrasound guidance. *Crit Care Med*. 1995;23(4):692-7. <https://doi.org/10.1097/00003246-199504000-00018>.
- Hansen MA, Juhl-Olsen P, Thorn S, Frederiksen CA, Sloth E. Ultrasonography-guided radial artery catheterization is superior compared with the traditional palpation technique. *Acta Anaesthesiol Scand*. 2014;58(4):446-52. <https://doi.org/10.1111/aas.12299>.
- Health Professions Council of South Africa. Guidelines for good practice in the health care professions – guidelines on the keeping of patient records. Booklet 9. Pretoria: Health Professions Council of South Africa; 2016. Available from: [https://www.hpcs.co.za/Uploads/Professional\\_Practice/Conduct%20%26%20Ethics/Booklet%209%20Keeping%20of%20Patient%20Records%20September%20202016.pdf](https://www.hpcs.co.za/Uploads/Professional_Practice/Conduct%20%26%20Ethics/Booklet%209%20Keeping%20of%20Patient%20Records%20September%20202016.pdf). Accessed 22 Jul 2022.
- Hilty WM, Hudson PA, Levitt MA, Hall JB. Real-time ultrasound-guided femoral vein catheterization during cardiopulmonary resuscitation. *Ann Emerg Med*. 1997;29(3):331-6; discussion 337. [https://doi.org/10.1016/s0196-0644\(97\)70344-5](https://doi.org/10.1016/s0196-0644(97)70344-5).
- Health Professions Council of SA Ethical Rule 2006, as amended. Available from: [https://www.hpcs.co.za/Uploads/Professional\\_Practice/Ethics\\_Booklet.pdf](https://www.hpcs.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf). Accessed 3 Aug 2022.
- Iwashima S, Ishikawa T, Ohzeki T. Ultrasound-guided versus landmark-guided femoral vein access in pediatric cardiac catheterization. *Pediatr Cardiol*. 2008;29(2):339-42. <https://doi.org/10.1007/s00246-007-9066-2>.

- Kumar A, Chuan A. Ultrasound guided vascular access: efficacy and safety. *Best Pract Res Clin Anaesthesiol.* 2009;23(3):299-311. <https://doi.org/10.1016/j.bpa.2009.02.006>.
- Lamperti M, Bodenham AR, Pittiruti M, et al. International evidence-based recommendations on ultrasound-guided vascular access. *Intensive Care Med.* 2012;38(7):1105-17. <https://doi.org/10.1007/s00134-012-2597-x>.
- Mallory DL, McGee WT, Shawker TH, et al. Ultrasound guidance improves the success rate of internal jugular vein cannulation. A prospective, randomized trial. *Chest.* 1990;98(1):157-60. <https://doi.org/10.1378/chest.98.1.157>.
- McGee DC, Gould MK. Preventing complications of central venous catheterization. *N Engl J Med.* 2003;348(12):1123-33. <https://doi.org/10.1056/nejmra011883>.
- Milling TJ, Rose J, Briggs WM, et al. Randomized, controlled clinical trial of point-of-care limited ultrasonography assistance of central venous cannulation: the third sonography outcomes assessment program (SOAP-3) Trial. *Crit Care Med.* 2005;33(8):1764-9. <https://doi.org/10.1097/01.ccm.0000171533.92856.e5>.
- Moeti T, Padarath A, editors. *South African Health Review 2019*. Durban: Health Systems Trust; 2019. Available from: [https://www.hst.org.za/publications/South%20African%20Health%20Reviews/SAHR\\_2019\\_14012020\\_Updated%20web.pdf](https://www.hst.org.za/publications/South%20African%20Health%20Reviews/SAHR_2019_14012020_Updated%20web.pdf). Accessed 21 Jul 2022.
- National Institute For Clinical Excellence (NICE). Guidance on the use of ultrasound locating devices for placing central venous catheters NICE; 2002. Available from: <https://www.nice.org.uk/guidance/ta49/resources/guidance-on-the-use-of-ultrasound-locating-devices-for-placing-central-venous-catheters-pdf-2294585518021>. Accessed 21 Jul 2022.
- National Institute for Clinical Excellence. Guide to the methods of technology appraisal. NICE; 2004. Available from: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/191504/NICE\\_guide\\_to\\_the\\_methods\\_of\\_technology\\_appraisal.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/191504/NICE_guide_to_the_methods_of_technology_appraisal.pdf). Accessed 21 Jul 2022.
- Safe Anaesthesia Liaison Group (SALG), Regional Anaesthesia UK (RAUK). *Stop Before You Block* [Internet]. c2022. RA-UK. Available from: <https://www.ra-uk.org/index.php/stop-before-you-block>. Accessed 17 Jan 2022.
- Schummer W, Köditz JA, Schelenz C, Reinhart K, Sakka SG. Pre-procedure ultrasound increases the success and safety of central venous catheterization. *Br J Anaesth.* 2014;113(1):122-9. <https://doi.org/10.1093/bja/aeu049>.
- Shiloh AL, Savel RH, Paulin LM, Eisen LA. Ultrasound-guided catheterization of the radial artery: a systematic review and meta-analysis of randomized controlled trials. *Chest.* 2011;139(3):524-9. <https://doi.org/10.1378/chest.10-0919>.
- Shiver S, Blaivas M, Lyon M. A prospective comparison of ultrasound-guided and blindly placed radial arterial catheters. *Acad Emerg Med.* 2006;13(12):1275-9. <https://doi.org/10.1197/j.aem.2006.07.015>.
- The Republic of South Africa. Government Gazette, 10 April 2003. No. R. 510. General regulations made in terms of the Medicines and Related Substances Act, 1965 (Act No. 1010 of 1965), as amended. Available from: [https://www.gov.za/sites/default/files/gcis\\_document/201409/24727b.pdf](https://www.gov.za/sites/default/files/gcis_document/201409/24727b.pdf). Accessed 22 Jul 2022.
- The Republic of South Africa. Government Gazette, 17 January 2008. No. R. 511. Section 48 of the Health Professions Amendment Act, 29 of 2007. Available from: [https://www.gov.za/sites/default/files/gcis\\_document/201409/a29-07.pdf](https://www.gov.za/sites/default/files/gcis_document/201409/a29-07.pdf). Accessed 17 Jan 2022.
- The Republic of South Africa. Government Gazette, 19 June 2006. Vol 492. Children's Act 38 of 2005. Available from: [https://www.gov.za/sites/default/files/gcis\\_document/201409/a38-053.pdf](https://www.gov.za/sites/default/files/gcis_document/201409/a38-053.pdf). Accessed 21 Jul 2022.
- The Republic of South Africa. Government Gazette, 20 July 2007. No. R. 636. Section 1 of the Regulations regarding the rendering of Forensic Pathology Service. Available from: [https://www.gov.za/sites/default/files/gcis\\_document/201409/30075n.pdf](https://www.gov.za/sites/default/files/gcis_document/201409/30075n.pdf). Accessed 17 Jan 2022.
- The Republic of South Africa. Government Gazette, 23 July 2004. Vol 469. The National Health Act 61 of 2003. Available from: <https://www.gov.za/documents/national-health-act>. Accessed 22 Jul 2022.
- The Republic of South Africa. Government Gazette, 26 November 2013. Vol 581. Protection of Personal Information Act 4 of 2013. Available from: [https://www.gov.za/sites/default/files/gcis\\_document/201409/3706726-11act4of2013protectionofpersonalinforcorrect.pdf](https://www.gov.za/sites/default/files/gcis_document/201409/3706726-11act4of2013protectionofpersonalinforcorrect.pdf). Accessed 21 Jul 2022.
- The Republic of South Africa. Government Gazette, 3 February 2002. Vol 416. Promotion of Access to Information Act 2 of 2000. Available from: [https://www.gov.za/sites/default/files/gcis\\_document/201409/a2-000.pdf](https://www.gov.za/sites/default/files/gcis_document/201409/a2-000.pdf). Accessed 21 Jul 2022.
- The Republic of South Africa. Government Gazette, 6 May 1992. Vol 323. The Births and Deaths Registration Act 51 of 1992. Available from: [https://www.gov.za/sites/default/files/gcis\\_document/201409/a511992.pdf](https://www.gov.za/sites/default/files/gcis_document/201409/a511992.pdf). Accessed 17 Jan 2022.
- The Republic of South Africa. Union Gazette Extraordinary, 3 July 1959. The Inquests Act 58 of 1959. Available from: [https://www.gov.za/sites/default/files/gcis\\_document/201505/act-58-1959.pdf](https://www.gov.za/sites/default/files/gcis_document/201505/act-58-1959.pdf). Accessed 17 Jan 2022.
- The Republic of South Africa. Section 56 of the Health Professions Act 56 of 1974. Available from: [https://www.hpcs.co.za/Uploads/Legal/Legislation/health\\_professions\\_ct\\_56\\_1974.pdf](https://www.hpcs.co.za/Uploads/Legal/Legislation/health_professions_ct_56_1974.pdf). Accessed 17 Jan 2022.
- The Republic of South Africa. The Medicines and Related Substances Act (previously Drugs Control Act) 101 of 1965 Medicines. Available from: [https://www.gov.za/sites/default/files/gcis\\_document/201505/act-101-1965.pdf](https://www.gov.za/sites/default/files/gcis_document/201505/act-101-1965.pdf). Accessed 22 Jul 2022.
- Troianos CA, Hartman GS, Glas KE, et al. Guidelines for performing ultrasound guided vascular cannulation: recommendations of the American Society Of Echocardiography And The Society Of Cardiovascular Anesthesiologists. *J Am Soc Echocardiogr.* 2011;24(12):1291-318. <https://doi.org/10.1016/j.echo.2011.09.021>.
- Troianos CA, Hartman GS, Glas KE, et al. Guidelines for performing ultrasound guided vascular cannulation. *Anesth Analg.* 2012;114(1):46-72. <https://doi.org/10.1213/ane.0b013e3182407cd8>.
- Troianos CA, Jobes DR, Ellison N. Ultrasound-guided cannulation of the internal jugular vein. A prospective, randomized study. *Anesth Analg.* 1991;72(6):823-6. <https://doi.org/10.1213/0000539-199106000-00020>.