

CME

The SA Journal of CPD
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SEPTEMBER 2009



Office-based surgery

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Office-based surgery

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Current interests are gastroenterology, colorectal conditions, laparoscopic surgery, health informatics, practice guidelines, reimbursement and coding.

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This issue of your *CME* introduces the theme of office-based surgery (OBS). Traditionally minor surgical procedures are performed in side-rooms in practitioners' offices. The modern concept of OBS pushes the envelope to encompass a wider range of ambulatory procedures. In concert with the more invasive nature of the procedures, office-based anaesthesia (OBA) has developed as a specialised field.

The increased utilisation of the office setting has been driven mainly by the high costs of hospitalisation and theatre. There is also a shortage of beds and theatre time. In the USA ambulatory surgical centres (ASC) or day-clinics have proliferated and offer a wide range of procedures. The glamorous Beverley Hills Dr 90201 plastic surgery centres are upmarket examples. Many other disciplines have developed office-based or ambulatory techniques, including endoscopy, infertility and other gynaecological procedures, and dental and maxillo-facial procedures.

While the expanded concepts of OBS and OBA may seem obvious developments, they are not yet ready for prime time in South Africa. Driven by financial incentives and patient demand, they may be burdensome to show profit. Doctor comfort and 'one-stop shop' practice is fraught with financial and legal constraints. Most funders refuse to reimburse out-of-hospital costs adequately. Nevertheless, some have seen the light and encourage office-based procedures. Quality of care, standards and accreditation are poorly addressed in South Africa.

The skills for the performance and management of OBS are not taught in university residency programmes. Additional private mentorship and training is mandatory and often acquired abroad, e.g. in the USA.

Our team of authors have assembled a set of practical articles to provide guidance to practitioners and their support structures. They present a conservative, safe and practical approach to OBS. They may have an aura of 'Americanism' but we are still very much in the dawning of a new era in South Africa and can but learn from the experiences and mistakes of our American and Australian colleagues, who have carefully documented guidelines and regulations.

Health care

Health care in South Africa is in a serious crisis and faces numerous, possibly insurmountable, challenges. These include the worldwide economic downturn, state health care suffering catastrophic implosion in many areas, health care worker shortages and strikes and threatened reformation with the voyeuristic potion of National Health Insurance (NHI).

Our private health care system is a mess because economic behaviours driving it are irrational, often perverse and counterproductive. Unchecked spiralling costs and dominance by medical schemes and administrators under the guise of managed health care (MHC) are some of the vices.

Government attempts at heavy-handed control of the private sector will have disastrous effects. Yet, health care is the social right of all citizens and the responsibility of the government to deliver. The ultimate goal is that of a sustainable, universally accessible NHI system, more privately insured lives (more members of medical insurance schemes) and a cost-effective private sector.

Marketplaces require consumers who demand better products at ever better prices and producers who are rewarded for supplying both. The health care marketplace, by contrast, is distorted by third-party reimbursement that does not reward rational behaviour by either consumers or producers, and in many cases actually penalises it.

- The consumer of the medical product is often not the purchaser of that product and has no motive to determine its real value.
- The producer of the medical product determines the need for the product and is paid more for producing more of it; the producer has no incentive to reduce cost.

Fee-for-service medicine is perverse; it rewards doctors and hospitals financially for overtreatment, heroic treatment, redundant treatment or for any treatment at all, regardless of the economic or scientific merit or outcome. Private health care in South Africa is a fragmented, disintegrated, uncoordinated disaster!

Managed care to the rescue? Aggressive intervention by emboldened or embattled third party payers (medical scheme and administrators), positioning themselves as the champions of medical necessity and clinical consistency, yet driven by their own financial self-interest, attempts to bring some predictability to the system. MHC is harsh medicine for health care's appalling economics and dreadful history – akin to a near-lethal dose of chemotherapy for a sick health-care market, palliating the cancer, but the system remains sick. They have exacerbated the confusion and complexity of the system by installing a pervasive, costly infrastructure of heavy-handed and cumbersome command-and-control systems. The primary goals have been to reduce direct costs associated with medical decision-making, regardless of quality, outcomes and even long-term economics. This harsh medicine works only because the patient is so desperately ill! A hard place just got harder.

Now ... rescue us from managed care! Guidelines designed to promote cost-effectiveness for an entire population seldom succeed. In glaring contrast to the intensity involved in the doctor/patient relationship, the MHC 'covered member' alliance is a nuisance. Why? Because administrators don't diagnose or treat people, they process them!

Hospitals are only slightly better, but are generally considered large, impersonal expensive machines through which people move when sick, guided not by the hospital's protocols, but by their physicians' training and instincts.

A dichotomous situation has developed: managed care operators have allegiance to their shareholders to maximise savings, but doctors are ethically sworn to their profession – to do what is best for every individual patient. We are generally revered for our clinical judgement, autonomy and moral authority – earned through years of training and personal sacrifices. Doctors

have an intellectual incumbency that will reign in the end, in stark contrast to the naked ambitions and hollow advertising of MHC marketeers.

The treatment plan^{1,2}

A holistic application of five interrelated forces may consummate health care reform, driving down health care costs, simplifying and streamlining the systems and promoting quality care:

- Risk assumption, to correct fundamental problems in health care consumption and market economics. This embodies capitation and other alternative reimbursement strategies.
- Consumerism, to neutralise distortions in the health system created by the self-interest and faulty paternalism of providers and MHC, to galvanise competition among providers.
- Consolidation, to scale health care infrastructure properly, mobilise capital,

spread risk across broader populations of patients and providers and allocate health care resources more efficiently.

- Integration, to correct the fragmentation and other infrastructural defects built into the medical delivery system.
- Industrialisation, to rationalise the haphazard use of services, increase economic predictability, improve quality and reduce costs.

More or less control? Competition and management must come from within the profession. When this transformation is complete, the answer to that most menacing of questions 'do you know who controls your health care?' will be, surprise, surprise, your doctor!

1. Kleinke JD. *Bleeding Edge. The Business of Health Care in the New Century*. Maryland: Aspen Publishers, 1998. <http://www.hs-net.com>

2. Grobler S. Beijing 2008 Olympic Games and ... 'Manto'; what do they have in common? *South African Gastroenterology Review* 2008; 6(2): 27-28.

Office-based surgery – why it is important

Office-based surgery can contain costs and improve outcomes for the patient.

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Ambulatory surgery seeks to offer improved patient outcomes and cost-containment benefits. Three organisational models have evolved: hospital-associated ambulatory surgery programmes, freestanding ambulatory surgery centres (ASC) and office-based surgery (OBS).

Surgery and anaesthesia have become much safer in the modern era. The changing scope of practice brings with it the refinement of skills and practices, development of new procedures and technologies and a paradigm shift of surgery to the office setting. This move promotes continuity of care, with a familiar patient, cost containment and improved outcomes for the patient and doctor.

In the USA, office surgery has grown rapidly, with some 10 million office procedures performed in 2005. However, the rapid growth of outpatient surgical centres coupled with poor regulation and some bad outcomes may have detracted from the ostensible advantages.

Definitions

Office or outpatient surgery/procedure: An operation or procedure carried out in a medical practitioner's office or outpatient department, other than a service normally included in a consultation, which does not require treatment or observation in a day surgery or procedure centre (facility) or unit, or as a hospital inpatient.

Day surgery/procedure: An operation or procedure, excluding an office or outpatient operation or procedure, where the patient would normally be admitted and discharged on the same day.

Ambulatory surgical centre (ASC): A facility primarily organised or established for the purpose of performing surgery

for outpatients ... and maintenance of a dedicated operating room. American accrediting agencies recognise centres for cosmetic and facial surgery, endoscopy, ophthalmology, laser eye surgery, oral and maxillofacial surgery, orthopaedic surgery, plastic surgery, podiatry clinics and multi-specialty surgery centres.

Day surgery/procedure – extended recovery: A patient treated in a registered day surgery or procedure centre (facility) or unit, free-standing or hospital-based, who requires extended recovery including overnight stay, before discharge.

Limited care accommodation: Hotel or hostel accommodation for day surgery or procedure patients where professional health care is available on a call basis.

In the USA, office surgery has grown rapidly, with some 10 million office procedures performed in 2005.

Scope of practice

- Surgery – skin, soft-tissue and muscle biopsy, minor breast surgery, liver biopsy, anorectal conditions, laparoscopy, orthopaedic manipulations and minor procedures
- Endoscopy

- Plastic and reconstructive surgery – (see more about ... article on p. 414 of this issue)
- ENT, ophthalmology
- Gynaecology and infertility
- Dental and maxillofacial procedures.



Competency

The skills for the performance and management of OBS are not adequately taught in state undergraduate or residency programmes in South Africa. Additional private mentorship and training is mandatory and often acquired abroad, e.g. in the USA. It is emphasised that the choice of patient, procedure and type of anaesthetic must remain the responsibility of the surgeon and/or anaesthetist.

History, clinical examination, pre-existing illnesses (e.g. diabetes, coronary artery disease, epilepsy, immunocompromised patient), active skin infections, allergies, bleeding disorders and current medications must be considered before performing a surgical procedure. Anticoagulants, salicylates, NSAIDs, clopidogrel and over-the-counter products (Procydin and the herb *Ginkgo biloba*) can complicate surgical procedures by increasing clotting time and forming haematomas even after a seemingly simple procedure.

The practitioner must have adequate knowledge and experience of a procedure, the equipment needed as well as indications, contraindications and complications before attempting any surgery. Informed consent, including the risks and benefits, must be confirmed.

Standard (universal) precautions

Due to the potential spread of HIV, standard infection control procedures such as hand washing, gloves and protective barriers to protect health care workers from blood-borne and body fluid-borne diseases are mandatory. The risk of developing hepatitis B virus (HBV) after blood and body fluid exposure is much greater than that of HIV. All health care providers not currently immunised against HBV should strongly consider hepatitis B immunisation. All staff should be familiar with procedures to be followed in the event of a needle-stick injury, which should be carefully documented.

Facilities and equipment

There are three levels of OBS depending on the complexity of anaesthesia and surgical procedures performed.

- Level I includes minor surgery performed under topical or local anaesthesia not involving drug-induced alteration of consciousness other than minimal preoperative anti-anxiety medications. This article deals only with level I office surgery, which requires training and equipment, but no accreditation.
- Level II procedures require mild-to-moderate sedation anaesthesia with postoperative monitoring.
- Level III procedures require deep sedation and analgesia. These issues are dealt with in subsequent articles.

The risk of developing hepatitis B virus (HBV) after blood and body fluid exposure is much greater than that of HIV.

Procedure room

Office surgery can be performed in individual examination rooms using mobile equipment, but is best performed in a designated procedure room large enough to allow easy access to the patient and storage for supplies and other equipment. The procedure room should be situated in an area away from the flow of heavy traffic to contain contaminated areas and ensure privacy. A sink with antiseptic soap for scrubbing, sterile and non-sterile gloves and

sharps container help maintain universal precautions.

The operating table, overhead lighting and procedure trays are the most basic and important items in the procedure room. The room should be designed and equipped to accommodate the physician performing the procedure and to handle many office emergency problems. Fixed mounted overhead lighting and other light sources such as gooseneck lamps and headlamps should be used. Additional equipment for the procedure room includes a suction device with tubing, catheters and tips and waste receptacles. For an open procedure, proper provision for haemostasis should be available (e.g. electro-surgical unit).

The procedure room should be situated in an area away from the flow of heavy traffic to contain contaminated areas and ensure privacy.

Most procedure rooms are designed to maintain a high level of antisepsis, not complete sterility. The level of antisepsis is based on the maintenance capabilities of the staff rather than absolute sterility such as that found in a hospital operating suite.

Surgical instruments and equipment can be kept in sterile surgical packs for efficiency. Accuracy and security are paramount in choosing surgical instruments. Although cost is becoming an important factor in their selection, high-quality instruments should be chosen for the surgeon's comfort. Most cutaneous procedures can be performed with basic instruments.

Surgical instruments should be cleaned and disinfected after the procedure. Hinged instruments such as scissors, haemostats and needle holders may be cleaned with an ultrasonic cleaner. The instruments are dried and placed back in the surgical tray along with new supplies to complete the surgical pack. The pack is then wrapped with surgical towels or autoclave paper, secured with autoclavable tape and autoclaved or sent to a sterile supply facility.

Single-use disposable items of equipment should be used wherever possible. These include syringes, needles and ampoules for injection, as well as a wide array of biopsy devices. Any single-use article or instrument

Importance of OBS

The operating table, overhead lighting and procedure trays are the most basic and important items in the procedure room.

that has penetrated the skin, mucous membrane or tissue must be appropriately disposed of immediately after use or at the end of the procedure.

Single-use disposable items of equipment should be used wherever possible.

Resuscitation equipment should be located either in the room or nearby to allow basic cardiopulmonary resuscitation. While there is some medico-legal responsibility, the major concern should be patient safety. All staff should be trained in basic cardiopulmonary resuscitation procedures, checking of equipment and emergency

drugs used for resuscitation purposes. All staff must be conversant with a protocol for the management of a patient who has collapsed. An arrangement should exist with a nearby hospital for the transfer of patients in the event of unexpected serious or potentially serious developments.



An adequate anaesthetic and surgical record must be maintained. Separate documentation of each procedure and scheduled drugs should be kept in a log book, including date, time, duration, personnel involved in the procedure and any associated problems or complications. Follow-up arrangements and postoperative wound care must be clearly outlined to the patient, with written instructions when appropriate.

Disposal of biomedical contaminated waste, including sharps, should be properly managed via an arrangement with a licensed contractor.

Occupational health and safety guidelines for an operating theatre should be readily

available and respected. This should include electrical, fire safety and evacuation procedures.

Summary

Office-based surgery is on the rise. Training, development of national standards and accreditation are essential.

Recommended reading

Australian Day Surgery Council, Royal Australasian College of Surgeons, Australian New Zealand College of Anaesthetists and the Australian Society of Anaesthetists. *Report and Recommendations on Office-based Surgery Development in Australia. Guidelines for Office-Based Surgery*. Revised 2004. http://www.surgeons.org/AM/Template.cfm?Section=Australia_Day_Surgery_Council&Template=/CM/ContentDisplay.cfm&ContentID=3431.

Chavez MC, Maker VK. Office surgery. In: Rakel RE, ed. *Textbook of Family Medicine*, 7th ed. Philadelphia Saunders Elsevier, 2007: 34.

Committee on Ambulatory Surgical Care, American College of Surgeons. *Guidelines for Optimal Ambulatory Surgical Care and Office-based Surgery*, 3rd ed. www.facs.org/ahp/kyOBSguide12-03.pdf

Committee on Quality Assurance in Office-Based Surgery. *A Report to: New York State Public Health Council and New York State Department of Health 2007*. http://www.health.state.ny.us/professionals/office-based_surgery/reports/docs/committee_on_quality_assurance.pdf

Department of Health Professions Quality Assurance Division Washington State. *Medical Quality Assurance Commission Policy/Procedure*. http://www.doh.wa.gov/hsqa/Professions/Medical/documents/OBS_guidelines.pdf

In a nutshell

- There has been a paradigm shift of surgery to the office setting.
- Additional mentorship and training are recommended.
- Anticoagulants can complicate seemingly simple procedures.
- Standard (universal) precautions are essential.
- A designated procedure room is preferred.
- Proper provision for haemostasis should be available.
- Surgical instruments must be cleaned and disinfected after the procedure.
- Single-use disposable items are recommended.
- There should be equipment and staff for cardiopulmonary resuscitation.
- Keep adequate records.
- Disposal of biomedical contaminated waste, including sharps, should be properly managed.
- Occupational health and safety guidelines must be respected.

Office-based endoscopy

Office-based endoscopy provides a good example of how to establish office-based surgery.

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This article aims to serve as a template for practitioners seeking to formally establish an office-based surgery and use an office-based endoscopy service (OBE) as an example. We have drawn from Gastroenterological Society guidelines and our local experience.^{1,2}

Scope of practice

- Gastrointestinal endoscopy – upper GI, small bowel, sigmoidoscopy, colonoscopy, including biopsy, ablation, dilatation
- Bronchoscopy
- ENT – rigid and fibre-optic endoscopy, laryngeal surgery^{3,4}
- Urology – flexible cystoscopy, ultrasound-directed prostate biopsy
- Gynaecology – hysteroscopy, endometrial biopsy (ablation, laparoscopy).

Reimbursement

In the current era of managed care there are formidable shifting relationships that we must deal with. The OBE offers greater comfort and satisfaction at a lower cost than traditional treatment facilities. Is it ethical for surgeons or gastroenterologists to own the facility in which they work, to self-refer and to charge for the use of the facility? Yes, but there are safety, quality-of-care and ethical constraints.

The current fee structure has lagged far behind endoscopy practice costs. Activities by legislative bodies and managed care organisations continue to stress the economic viability of the office environment. The initial investment in OBE can be daunting.

One effort currently underway is to ‘rebase’ practice costs and facility fees to reflect the actual costs of providing services (so-

called national health reference price list (NHRPL)) rather than on historic charges. An alternative proposal is to use the fees developed for hospitals and apply these to OBS and OBE as a classification system for grouping procedures for facility payment (assignments purportedly would be based on clinical characteristics and resource utilisation). Grouping and reimbursement levels are current issues being discussed by the National Health Insurance (NHI) task teams.

Activities by legislative bodies and managed care organisations continue to stress the economic viability of the office environment.

Along legislative lines, there are also impediments of outdated legislation, talks of Certificate of Need (CON) restrictions and the trend towards accreditation of facilities. Accreditation is a natural evolution as payers, managed care organisations and regulators place increasing emphasis on quality, safety and patient satisfaction. It will also become increasingly important, if not essential, for obtaining facility reimbursement.

Functional plan and architectural issues

Size and volume

It is important to have a clear understanding of the expected volume of procedures and the number of doctors sharing the facility.

Endoscopy

Separate space for cleaning equipment between procedures and a separate recovery area will avoid delays in room turnover. If many patients are 'first visits' on the day of their procedure, consultation space and time must be factored in. Endoscopic case mix can also influence volume.

Location

Locating in an existing professional building on your primary hospital 'campus' has several advantages over a totally free-standing facility. Patient trust may be higher when entering a professional hospital complex. In the event of a complication, response time is rapid. And since no hospital wants to lose your endoscopy business, the hospital can see some rental return. Corporate and hospital governance issues place additional pressure to ensure safety compliance.

There are also strong arguments for a free-standing, geographically separate facility: neutral turf, both politically and geographically, might be best.

Construction basics and work flow

Plumbing, air conditioning, sound proofing, ventilation and electricity are beyond the gambit of this article, but some basics are as follows:

- Construction costs for endoscopic space tend to be 2 - 3 times as expensive as standard office space. Several nuts-and-bolts issues will be dictated by local building codes and licensing requirements. Make sure you are aware of regulations.
- Adequate sound-proofing between endoscopy rooms, patient recovery area and waiting rooms is essential. The sounds related to endoscopy can be disturbing to patients waiting to undergo procedures, as well as those recovering.

- Temperature regulation is desirable. Waiting rooms have fully clothed people; pre-operation areas have nervous, undressed people; endoscopy rooms have sedated people and others hard at work with heat-generating equipment.
- The endoscopy rooms and endoscopy cleaning areas must be well-ventilated.
- The most desirable patient flow pattern is a simple, one-directional movement. Consider the movement flow in the procedure room – the number of people, where they stand, endoscope and monitors, beds and trolleys, supplies, cleaning facility.

Patient trust may be higher when entering a professional hospital complex.

- Patients often arrive for endoscopy anxious and confused. If possible, send careful instructions, and have signs posted in the immediate vicinity. There must be wheelchair, stretcher and bed access.
- The reception area must have adequate room for patients' families. As a general rule, 1 - 2 people accompany each endoscopy patient. Use individual chairs instead of couches; people do not like to sit with strangers in stressful situations. A toilet facility should also be available.
- The pre-op (prep) area should be private. IVs are started and patients are undressed. Nursing and doctor interviews are performed here. Bathrooms should be easily accessible.

The sounds related to endoscopy can be disturbing to patients waiting to undergo procedures, as well as those recovering.

- Consider the use of television or music in the reception and prep area.
- Procedure rooms have high electrical needs and the building must have power back-up in both procedure and recovery rooms. Dimmers are excellent, as well as spotlights over areas of paper work and biopsy handling. Telescopic lights or headlamps are useful.
- The endoscope cleaning area should be near the procedure room, and should be spacious and well-ventilated. The standard of practice is moving to automatic endoscope reprocessors, but they are expensive and require lots of space and hot water.
- The recovery area requires more planning than one might think. There must be adequate space for recovery beds. Time in recovery can be considerable and could create a 'log jam'. Until patients are fully recovered and exit this unit, there is no way to bring new patients through the system. A standard scenario may be as follows: patient goes from procedure to recovery room on a stretcher; once alert he/she sits up and gets dressed, then proceeds to a recliner before reaching full ambulatory status. This frees up the stretcher area and allows observation of nearly ambulatory patients prior to discharge.
- Have a transfer agreement with a hospital to handle emergency admissions.
- Strongly consider training and accreditation in advanced life support for doctors and staff.
- Do not compromise on quality of staff or endoscopic equipment simply for economic reasons. You must be at least as comfortable working in your OBE as you are at the hospital. The quality of care and quality improvement process should address all areas, including access, reception, procedures, storage, waste disposal, pathology, transfer policy, housekeeping, administration, clinical records, billing as well as continuing professional development (CPD).
- A note about the doctor's office: it is a great advantage to have the office area adjacent



Endoscopy

to the procedure room. The doctor can then easily go from seeing patients to performing procedures.

Checklist for office-based endoscopy set-up (office set-up)

(Note: these are illustrative and form the basis of local accreditation processes that are under development.)

Regulations

- All office-based endoscopy practices must adhere to local and state laws and regulations, including occupational health and safety and infection control.
- Endoscopes must be cleaned to a high level of disinfection. Reprocessing of endoscopes and other contaminated equipment should be done in a room separate from where endoscopic procedures are performed.
- There must be adequate ventilation.
- Regular staff orientation and refresher training on policy and procedures are important.
- There must be an appropriate plan for disposal of human waste, blood and other potentially infectious materials.
- Compliance must be monitored.

Good clinical practice

Any office endoscopy setting where a patient receives intravenous conscious sedation *must* comply with guidelines, accreditation and laws.

Indications/appropriateness

- Office-based procedures are to exclude: stent placement, endoscopic retro-grade cholangiopancreatography (ERCP), removal of a foreign body, therapeutic haemostatic control of acute bleeding, procedures deemed emergencies, procedures carrying a considerable risk of bleeding or major complication.
- Patients with an American Society of Anesthesiologists (ASA) score of IV are not eligible to undergo office endoscopy.
- Patients with an ASA score of III are further assessed for their appropriateness.

Physical environment

- There should be appropriate patient facilities which include disabled access.

- A private patient changing area is needed, as well as a storage locker or equivalent for patient belongings.
- The bathroom should not be in a common area.
- A waiting area for accompanying family or others should be provided.
- Acceptable patient privacy should be maintained at all times throughout the pre-procedure, procedure and recovery care.
- All patient records and materials must be filed in a safe and confidential area.

Patients with an ASA score of IV are not eligible to undergo office endoscopy.

Exam room criteria

The endoscopy room should be at least 10 m². One should be able to reduce illumination from ambient light, to fit a rolling stretcher through all doorways, and move freely on both sides of the patient. The doctor should have an unimpeded view of all monitoring equipment, and there should be sufficient storage for supplies and equipment, adequate ventilation, auditory and visual privacy, and a mechanism to summon additional assistance to the room.

The following equipment must be in the room, functioning and readily available: oxygen, endoscopes, suction, electronic

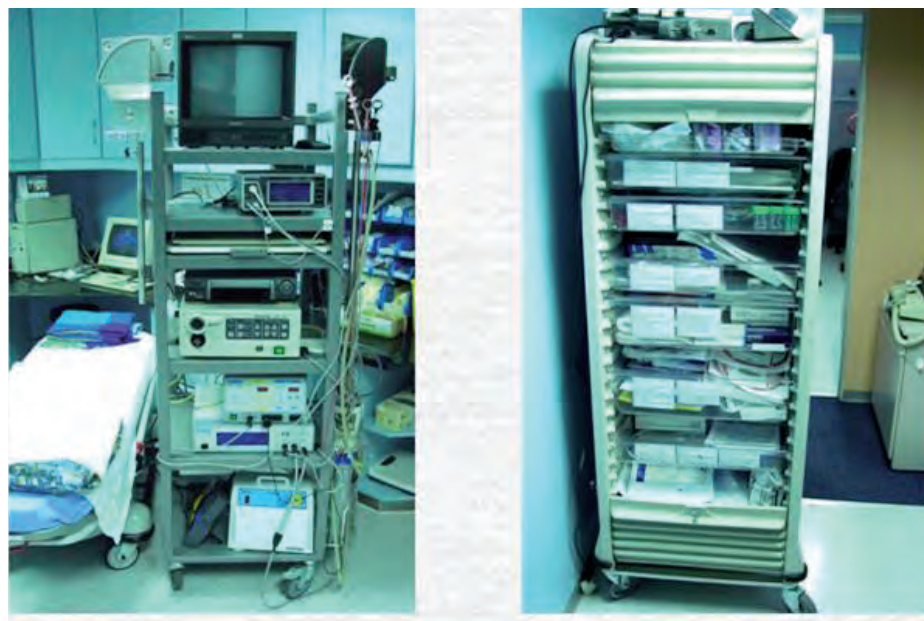
monitors of pulse, BP, oxygen saturation and ECG. There should be a written policy for equipment checks and maintenance and a log to monitor compliance.

Emergency supplies, equipment and procedures

- The following equipment should be functioning and readily available with properly trained staff: oxygen, suction, airway, laryngoscope, Ambu bag, defibrillator, electrocautery, power backup.
- The defibrillator must be checked at the start of each work day, and other equipment checked according to manufacturers' recommendations.
- Safety provisions must be in place to evacuate a patient.
- All medications and devices must be stored in a secure and environmentally controlled location.
- Relevant provisions of the Controlled Substances Regulations must be adhered to. Controlled substances must be stored in a double-locked cabinet and counted and signed for daily. Pharmaceutical agents must be monitored for date of expiration and a log must be kept.

Procedure information and documentation

- Patients are given face-to-face pre-procedure instructions.
- Informed consent must be taken by the doctor prior to the procedure and documented in the patient's medical record.
- There must be written discharge instructions.



- A medical record system must be kept and there must be a procedure for reporting results to the patient and referring doctor.

Administration of conscious sedation (sedation and analgesia)

- All patients should have a documented anaesthesia risk assessment.
- Conscious sedation should be administered in accordance with accepted policy.
- Intravenous access must be maintained until the patient has fully recovered.
- Reversal agents must be readily available.
- Once sedation has begun at least one certified doctor or nurse trained to monitor and assess the patient's well-being should be physically present in close proximity to the patient at all times.
- A trained assistant should be present in the room throughout the endoscopic procedure. If the procedure is particularly complex, so that the assistant's attention may become diverted from monitoring, a second assistant may be necessary.
- Pre-sedation and post-procedure stabilisation must include baseline heart rate, blood pressure, respiratory

rate and oxygen saturation, and ECG for high-risk patients.

- A registered nurse must be present in the recovery area at all times.
- Patients must be continuously monitored in the recovery area and should be discharged only after they have been assessed and all criteria have been met.
- Written discharge criteria are established to include: evaluation of responsiveness, vital signs, ability to tolerate fluids and swallow. Patients who have undergone conscious sedation must be accompanied by an adult upon discharge.

Documentation

Initial findings are documented in the patient chart on the day of the procedure. Subsequently, a signed report of the procedure should be completed. The report must include: date of procedure(s), procedure(s), extent of examination, duration, findings, tissue sampling, therapeutic intervention, procedure-related and sedation-related complications, limitations, copies of photographs or digital images.

Training and office management

- Doctor and staff must be properly trained and certified.

- To achieve quality assurance, regular peer review of the appropriateness of procedures performed and their outcomes should be done.
- A log or database of all procedures and outcomes should be kept. Recognised procedure-related and sedation-related complications must be tabulated and regularly reviewed.
- A written office policy and procedure manual must be maintained and updated.
- Staff should receive orientation and continuous training in all policies and procedures.

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In a nutshell

- Many endoscopic procedures are suitable for the office.
- There are challenging reimbursement issues.
- Calculate expected volume of procedures and number of doctors sharing.
- Plan work flow, access (including disabled) and trolleys and beds.
- The doctor should be able to easily move between seeing patients and doing procedures.
- Do not compromise on quality of staff or endoscopic equipment.
- Adequate sound proofing, ventilation and temperature regulation are important.
- The endoscope cleaning area should be separate and well-ventilated.
- The recovery area requires careful planning.
- There should be a transfer agreement with a hospital to handle emergency admissions.
- Accreditation of the facility is advisable.
- Training and accreditation in advanced life support for doctors and staff is necessary.
- There should be a checklist for an office-based endoscopy set-up.

Office-based anaesthesia

Successful office-based anaesthesia requires a particular set of skills and a knowledge base.

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Newer surgical and anaesthetic techniques have allowed a greater number of invasive procedures to be performed in non-hospital settings. Economic advantages and practitioner and patient convenience have driven the rapid growth of office-based surgery (OBS) and office-based anaesthesia (OBA). The advantages of OBS are personal attention, service, aftercare, ease of scheduling, greater privacy, lower cost, increased efficiency, decreased nosocomial infection, and consistency in nursing personnel. In the USA 17 - 24% of all elective ambulatory surgery is performed in the office setting. Data for South Africa are lacking, but there seems to be consistent growth in this area, as anaesthetists and sedationists are called upon more frequently to provide office-based services.

In the USA 17 - 24% of all elective ambulatory surgery is performed in the office setting.

Despite the allure of OBS and OBA, it is not suitable for every surgeon or appropriate for every patient or surgical procedure. OBA requires a different approach to anaesthesia in a hospital-based practice, and not all anaesthesia providers have the skill, knowledge base or personality to deal with the OBA environment. Compared with hospitals, office-based facilities currently have few or no regulations, little oversight, and insufficient control. The anaesthesiologist must carefully examine each practice to ensure safe perioperative care. It must be continuously emphasised that the standard of care in an office surgical suite should be no less than that in a hospital. Adequate informed consent is mandatory.¹

Sedation v. anaesthesia

Therapeutic sedation is a seamless continuum of an altered state of consciousness, varying from mild anxiolysis to anaesthesia. Patients may rapidly and often unpredictably move from one level to another with top-up doses, continuous infusions, combinations of drugs, or changes in level of stimulus. There is a wide intra- and inter-patient variation in response to a given dose of a given drug or drug combinations.

The South African Society of Anaesthesiologists (SASA) sedation guidelines (adult and paediatric) were published in 2002.^{2,3} Levels of sedation tabulated in Table I are easier to describe than to achieve. It is unusual for any patient to remain at one level of sedation for the entire duration of a procedure. Other terms have therefore replaced these rigid categories and reflect the continuum from anxiolysis to general anaesthesia as well as the importance of the analgesic component. Sedation is perhaps best termed 'sedation-analgesia' or 'monitored anaesthesia care' (MAC). These terms allow for the imprecision of sedation but, at the same time, demand a practitioner with sufficient skill to deal with the entire continuum of MAC and guidelines identical to those for the administration of general anaesthesia (GA).

There are wide indications for conscious sedation. These include procedures performed under loco-regional anaesthesia, lesser degrees of ophthalmic surgery, and painless diagnostic and therapeutic radiological procedures – particularly where co-operation, e.g. breath-holding, is required. The advantages are physiological stability and maintenance of airway patency and control. There are, however, circumstances better suited to deep sedation or GA, e.g. procedures with substantial fluctuating levels of stimulus (anal dilatation, uterine dilatation and curettage (D&C));

Table I. The continuum of sedation

	Anxiolysis	Light sedation (no opioid)	Deep sedation (or with opioid)	Anaesthesia
Responsiveness	Response to verbal stimuli	Purposeful response to verbal or tactile stimuli	Purposeful response only after repeated or painful stimuli	Unrousable
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

a procedure where patient resistance may reduce its success (endoscopy, reduction of dislocations); and procedures, even painless ones, on pre-adolescent children and patients with cognitive impairment.

There are wide indications for conscious sedation.

Tools of the trade

Personnel. A suitably trained sedationist, who may be the operator, is required. A dedicated anaesthetist is necessary for deeper sedation, high-risk patients, and other special cases. A suitably trained assistant is essential to monitor the patient, especially in major procedures – this person should do nothing else.

Monitoring and resuscitation equipment. This is necessary in the treatment and recovery areas – pulse oximetry, blood pressure, and ECG (in patients with cardiac disease or major cardiovascular risk factors). Intravenous access via a flexible cannula is mandatory. An operating surface that can be tilted, a defibrillator, oxygen, suction, equipment for the maintenance of airway, breathing and circulation, and emergency drugs are required.

Drugs for sedation and analgesia

Benzodiazepines. Midazolam is most commonly used owing to its rapid onset and short duration of action. Its elimination half-life is 1.5 - 3 hours. Amnesia is pronounced, even at sub-hypnotic doses. Suppression of respiratory drive occurs. Flumazenil is a competitive antagonist at the benzodiazepine receptor. Incremental doses of 0.2 - 1.0 mg IV are usually effective for reversal of all the effects of benzodiazepines. The duration of action varies from 15 minutes to 140 minutes, with re-sedation being a risk especially if longer-acting benzodiazepines are used. This short duration of action correlates well with that of midazolam.

Propofol. Propofol is increasingly being used owing to its very rapid onset and short duration of action. The half-life β is 30 - 60 minutes, but a third compartment with slower elimination half-life is also present, indicating the possibility of accumulation after very long infusions. The blood concentration for sedation is 1.0 - 2.5 $\mu\text{g/ml}$, and for anaesthesia 3.0 - 6.0 $\mu\text{g/ml}$. The recommended maintenance infusion rate of propofol varies between 100 and 200 $\text{mg}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$ for hypnosis and 25 - 75 $\text{mg}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$ for sedation. A 14%

incidence of excitatory phenomena is seen. Amnesia is not pronounced. Its anti-emetic effects are very advantageous, especially where opiates are used concomitantly. There is usually dose-related cardiovascular depression, and a combination with potent opioids may cause resistant bradycardia.

Ketamine. Ketamine is an *N*-methyl-*D*-aspartate (NMDA) receptor antagonist, causing dissociative anaesthesia, currently making a comeback in OBA owing to excellent analgesic properties with a low incidence of respiratory depression. It has a very wide therapeutic range. Laryngospasm is potentially a dangerous complication, but is rare and usually transient. Psychic side-effects may be troublesome, but can be minimised by the co-administration of a benzodiazepine or a similar hypnotic. Recovery may be delayed, especially if more than 2 mg/kg or 150 mg is given.

Opioids. Opioids are used primarily to provide analgesia in procedural sedation and analgesia. Although all these agents cause varying degrees of sedation, the effect is inconsistent, depending on the route and speed of administration and the agent used, and responses can vary greatly among individual patients. These agents are best considered as analgesics with the potential to supplement other primarily sedating drugs, such as the benzodiazepines. Although morphine and pethidine have both been used as analgesics in this setting, they have been largely replaced by shorter-acting opioids, particularly alfentanil (Rapifen) and remifentanyl (Ultiva). They can cause severe respiratory depression, bradycardia and muscle rigidity. Nausea and vomiting is often a problem.

Opioids are used primarily to provide analgesia in procedural sedation and analgesia.

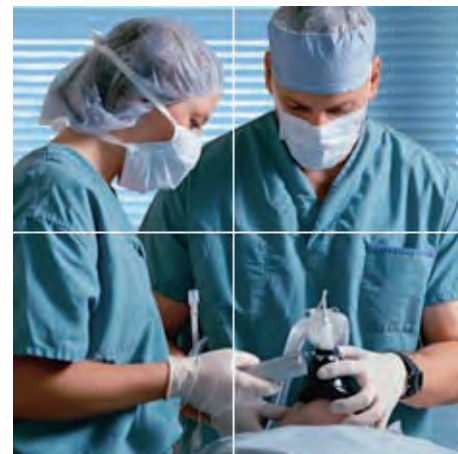
Nitrous oxide. Although not very useful at relatively high altitudes inland, it is widely used for sedation. Nitrous oxide has an onset of action of 3 - 5 minutes, with a duration of action of 3 - 5 minutes. It can be self-administered as a 50/50 $\text{N}_2\text{O}/\text{O}_2$ mixture. Nausea and vomiting occurs in 10 - 15% of patients. Another concern is diffusional hypoxia during the recovery phase.

Alpha₂agonists. These provide preoperative sedation and anxiolysis and decrease intraoperative anaesthetic requirements. Dexmedetomidine (PreceDEX) has a half-life of 2.3 hours. A unique type of sedation may be produced in which patients can be

aroused readily and then return to a sleep-like state when left alone. Higher infusion rates may, however, lead to complete loss of responsiveness. Amnesia develops at higher infusion rates. Their use in diagnostic or therapeutic settings in which a state of 'conscious sedation' is desirable has, however, yet to be studied rigorously. The only approved sedative indication for dexmedetomidine is for the intensive care treatment of postoperative surgical patients for up to 24 hours. Because of its sympatholytic and vagomimetic actions, dexmedetomidine is approved with a warning about hypotension, bradycardia and sinus arrest and can be used only in a monitored situation.

Techniques of sedation and analgesia

It is impossible to prescribe a generic approach to sedation-analgesia – procedure, patient and operator demand a unique approach. MAC remains more labour intensive and hands-on than most types of GA, because of the ease and rapidity of transition to lighter and deeper levels of sedation owing to the imprecision of the available monitors.⁴



Possible options are the following:

- intermittent physician/nurse-controlled bolus technique after an initial loading dose
- continuous infusion technique after a loading bolus or infusion
- target-controlled infusion (TCI)
- patient-controlled sedation (PCS)
- combinations of the above.

An intermittent bolus technique is probably the most frequently employed, particularly in brief procedures requiring no more than a few boluses. With prolonged surgery, this technique can become excessively tedious and labour intensive. Continuous infusions are applicable to

Office-based anaesthesia

virtually all commonly used agents. They are particularly indicated where drug boluses are associated with considerable adverse effects, e.g. dexmedetomidine and propofol (cardiovascular depression) and remifentanyl (respiratory depression). TCI employs a variety of algorithms and assumptions to construct a variable-rate infusion, designed to produce a constant plasma concentration of sedative agent. It is a more elegant technique than continuous infusion, but will only produce a perfect result in the prototype average patient. Some adjustment may still be required based on clinical or neurophysiological observation. PCS is a variant of the intermittent bolus technique.

Special monitoring in sedation-analgesia

Bispectral index monitoring. Numerous studies have been carried out in an attempt to correlate clinical sedation, hypnosis, amnesia and analgesia with neurophysiological indices, e.g. bispectral index monitoring (device that continually analyses EEG signals to assess level of consciousness). Bispectral index monitoring only describes the likelihood of sedation/non-responsiveness; there is no predictable relationship between bispectral index monitoring and analgesia.

Capnography. While pulse oximetry is a standard of care, it is really only an indicator of some forms of hypoxia. Desaturation may take some time to manifest in a patient with respiratory depression. Unfortunately, the shape of the oxygen-haemoglobin dissociation curve means that once hypoventilation-related hypoxia manifests, it evolves rapidly into a critical event. The inevitable co-existence of hypercarbia sets the scene for disaster via cardiac depression – predisposition to arrhythmias and a hyperadrenergic state.

Capnography produces an accurate real-time indication of arterial carbon dioxide. It is substantially more accurate than clinical observation or oximetry for the early detection of respiratory depression. Capnography is a standard of care in GA. However, it remains expensive, is fraught with technical limitations in the unintubated patient, and has remained peripheral to the clinical mainstream.



What to do with failed sedation?

It is in the nature of patients, procedures, and operators that a proportion of OBA will fail. An unco-operative, combative patient may be the result of inadequate or excessive sedation, or of the choice of a sub-optimal sedative approach for a stimulating procedure. The usual approach is to deepen sedation or add agents and, while this may be appropriate in the healthy young patient who requires a higher dose, it may be fatal in patients manifesting hypoxic or hypercarbic confusion from overdose. The question with failed sedation is whether to:

- Persist and risk patient dissatisfaction or injury and failure of the procedure.
- Deepen the sedation and complete the procedure and risk patient morbidity or death.

- Abandon the procedure, reverse the drugs, and re-schedule to an appropriate setting and methods. There really is only one correct answer, namely this final option.

Summary

While OBA is rapidly becoming more important in daily anaesthetic practice, one should remember that the main drive behind this is cost containment and patient comfort. It is our duty to ascertain that it is not done at the cost of reduced patient safety. Even pure conscious sedation requires the presence of a skilled and dedicated sedationist. The impact of a patient's physiological impairment on the kinetics of the drugs and of the drugs on the patient's physiology must be considered in advance, and a sedation-analgesia plan must be individualised.

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In a nutshell

- Different approach than that used in hospital-based practice.
- Potentially more risky environment.
- Standard of care in an office surgical suite should be no less than that in a hospital.
- Conscious sedation v. analgesia and monitored anaesthesia care must be considered.
- Monitoring and resuscitation equipment is essential.
- Midazolam is commonly used.
- Propofol is increasingly being used owing to its very rapid onset of action.
- Is ketamine making a comeback?
- Opioids provide analgesia, but can cause severe respiratory depression.
- Each procedure, patient and operator demand a unique approach.

Local anaesthetics: Characteristics, uses and toxicities

An understanding of local anaesthetics is essential to successful office-based surgery.

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Surgeons currently perform more and larger procedures in an ambulatory setting. Local anaesthesia is an important aspect of office-based surgery. Local anaesthetics (LAs) vary in their pharmacological properties and are used in various techniques of local anaesthesia administration, i.e. topical, infiltrative, epidural, spinal, and plexus block anaesthesia. A good working knowledge of local anaesthetics is required to enhance patient safety, experience and comfort.

Mechanism of action

LAs are membrane-stabilising drugs that reversibly decrease the rate of depolarisation and repolarisation of excitable membranes. They act by inhibiting sodium influx through sodium channels in neuronal cell membranes so that action potentials cannot arise and signal conduction is inhibited.

Nerves have differing susceptibilities to the effects of LAs, depending on diameter and myelination. Small-diameter unmyelinated fibres, such as type C pain fibres, are the most sensitive to LA-blocking effects, whereas heavily myelinated, thicker fibres, such as type A motor fibres, are less sensitive.

Pharmacology

LAs are composed of a lipophilic aromatic ring connected by an ester or amide chain to a hydrophilic or ionisable secondary or tertiary amine. Ester-linked LAs are generally shorter acting and are rapidly inactivated by plasma cholinesterase. Amide-linked LAs are metabolised in the liver by the cytochrome P450 enzyme system. More than 50% of amide-linked LAs are bound to plasma glycoproteins. Fluctuation in these protein levels influences metabolism.

The toxicity of LAs relates to plasma concentration. The more free LA in the body plasma, the more toxic it is.

Commonly used LAs are 1% or 2% lignocaine with or without adrenaline 1:100 000 or 1:200 000, and bupivacaine (Macaine) 0.25% or 0.5% with or without adrenaline. The search for less toxic, long-acting LAs was prompted by fatalities associated with the cardiovascular toxicity of bupivacaine. The 50:50 racemic mixture of bupivacaine consists of R- and S-isomers. The latter form, levobupivacaine (Chirocane), has less potential for CNS and

cardiovascular toxicity. Ropivacaine (Naropin), a pure S-isomer, invokes better sensorimotor dissociation at lower doses. Although ropivacaine may be associated with acute CNS and cardiovascular toxicity, the incidence appears to be rare.

LAs and vasoconstrictors

Adrenaline (via its alpha effects) prolongs LA effects by delaying uptake in the local vascular bed and diminishing potential systemic toxicity by slowing the rate of rise of LA blood levels. Adrenaline has a serum half-life of less than 1 minute, being rapidly metabolised by catechol-O-methyltransferase in blood, lung, liver, and elsewhere.

Prohibition of the use of LA with epinephrine for digital or other acral regions (e.g. ear, tip of nose) is an established surgical tradition. However, digital necrotic and ischaemic complications are extremely rare. Recent reviews have concluded that when used to effect a digital block, adrenaline-containing LAs are quite safe and provide intraoperative haemostasis and longer post-procedure pain relief. As always, good judgement is necessary – an insulin-dependent, diabetic vasculopathic patient with a finger laceration may not be the best candidate for the injection of adrenaline into the finger.

LAs are membrane-stabilising drugs that reversibly decrease the rate of depolarisation and repolarisation of excitable membranes.

Toxicities

Neurological toxicity manifests with agitation, restlessness, tremor and convulsions (presumably by depression of central cortical inhibitory pathways, leaving the excitatory pathways uninhibited). Depression of brain functions occurs at higher concentrations, leading to coma, respiratory arrest and death. Such high tissue concentrations may be due to very high plasma levels after intravascular injection of a large dose or direct exposure of the central nervous system (CNS) through the cerebrospinal fluid, e.g.

overdose in spinal anaesthesia or accidental injection into the subarachnoid space in epidural anaesthesia.

The most important part of managing LA toxicity is recognising it.

Cardiac toxicity results from direct depression of myocardial contractility and dysfunction of the autonomic ganglia. Myocardial contractility is greatly impaired owing to the conduction-blocking effects of LAs. Ventricular dysrhythmias from a LA overdose are rare, except in the case of bupivacaine, which can cause ventricular tachycardia and fibrillation. Cardiac side-effects are usually seen with very high serum concentrations and most often follow neurological manifestations.

Treatment

Inadvertent intravascular injection of LA is the fastest way to elevate serum LA levels and precipitate a reaction. The most important part of managing LA toxicity is recognising it. The first sign may be simple agitation. Under such circumstances, injection or infusion should be stopped immediately. Supportive measures, such as supplemental oxygen, positional change, monitoring of blood pressure, and oxygen saturation are all appropriate.

Treatment of CNS complications and toxicity is still controversial because no single remedy exists. CNS manifestations, such as seizures, have been treated successfully with benzodiazepines (e.g. diazepam 0.1 - 0.2 mg/kg IV, IM or per rectum), thiopental 2 mg/kg, or propofol (Diprivan) 1 mg/kg IV. Propofol can cause significant bradycardia, further compromising cardiovascular status. Avoid phenytoin (Epanutin) because it shares pharmacological properties with lignocaine and may potentiate toxicity.

Propofol is usually contraindicated when there is any evidence of cardiovascular toxicity.

Lipid rescue with lipid emulsion (e.g. 20% Intralipid) has been shown to reverse both neurological and cardiac toxic effects quickly and effectively. The mechanism of

action is not clear – the lipid may act as LA sink, rapidly decreasing the serum levels of the offending LA.

Weinberg's recommended dosing regimen in cardiac collapse secondary to LA toxicity unresponsive to standard therapy is: 1 ml/kg IV bolus over 1 minute, repeated twice at 3 - 5-minute intervals; then (or sooner if stable) convert to infusion at 0.25 ml/kg/min, continuing until haemodynamic stability has been restored. Increasing the dose beyond 8 ml/kg is unlikely to be useful. In practice, to resuscitate an adult weighing 70 kg, use a 500 ml bag of fat emulsion (e.g. Intralipid 20%). Give 70 ml stat IV, repeat up to twice and administer adrenaline if necessary or appropriate. Then, attach the fat emulsion bag to an administration set and infuse the rest over 15 minutes. Note that propofol is not a component of lipid rescue. It is formulated in a 10% lipid emulsion and therefore an overdose of propofol would be necessary to provide an adequate dose of lipid emulsion. Propofol is usually contraindicated when there is any evidence of cardiovascular toxicity.

Allergies to LAs are quite rare. True IgE allergic reactions can occur. Ester-linked LAs are most often linked to true anaphylaxis, usually due to a sensitivity to their metabolite, para-aminobenzoic acid (PABA), and do not result in cross-allergy to amides. Therefore, amides can be used as alternatives in these patients. Sulphites used to stabilise vasoconstrictors and methylparaben, a bacteriostatic agent similar to an ester linkage found in some LAs, can cause non-IgE-mediated allergic reactions.

There have been reports of prilocaine causing methaemoglobinaemia. Hydrolysis of prilocaine initially leads to the formation of o-toluidine products that can bind to haemoglobin and cause methaemoglobinaemia.

Most reactions not related to LA toxicity can be classified into psychosomatic responses and idiosyncratic reactions. Hyperventilation, tachycardia, or vagal episodes may well be due to anxiety.

Other local adverse effects of anaesthetic agents include neurovascular manifestations, such as haematoma, oedema, pain, blanching, infection, prolonged anaesthesia, facial paralysis and paraesthesias. These are caused by localised nerve damage. The risk of temporary or permanent nerve damage varies between different locations and types of nerve blocks. Permanent nerve damage after a peripheral nerve block is rare. Symptoms are very likely to resolve within a few weeks to months.

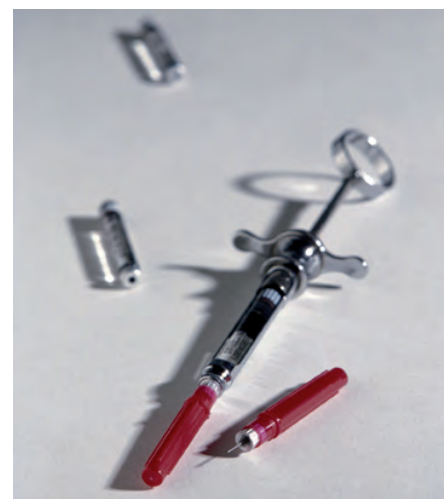
Dosing and administrative technique

Deciphering anaesthetic concentration and dilution

Concentration. Drug concentration is expressed as a percentage, i.e. grams per 100 ml (e.g. 1%=1 g/100 ml (1 000 mg/100 ml) or 10 mg/ml). (Bupivacaine 0.25%=2.5 mg/ml; lignocaine 1%=10 mg/ml.)

Dilution. When adrenaline is combined in an anaesthetic solution the result is expressed as a dilution (e.g. 1:100 000):

- 1:1 000 means 1 mg/1 ml (0.1%)
- 1:10 000 means 1 mg/10 ml (0.01%)
- 1:2 000 means 1 mg/2 ml (0.05%)
- 1:20 000 means 1 mg/20 ml (0.005%)
- 0.1 ml of 1:1 000 adrenaline added to 10 ml of anaesthetic solution = 1:100 000 dilution or 0.01 mg/ml
- 50 ml of lignocaine 1% with adrenaline 1:100 000 contains lignocaine 500 mg and adrenaline 0.5 mg.



Dosing guidelines

Dosing guidelines for LAs encompass generous margins of safety. Co-morbidities, anatomical location, surface area to be treated, concentration of the LA, addition of adrenaline, and rapidity of the infusion are all factors to consider in safe dosing guidelines (Table I). Reduced dosages are indicated in debilitated or acutely ill patients, very young children, geriatric patients and patients with liver disease or atherosclerosis.

Clinicians modify the formulations after manufacture by mixing, diluting and adding fresh adrenaline or bicarbonate to achieve their own particular cocktail.

pH plays an important role in LA function. Anything that alters the pH of the local tissue will affect the LA's ability to penetrate the cell membrane. With local infection

Table I. Local anaesthetic agents commonly used for infiltrative injection

Agent	Duration of action	Maximum dosage guidelines (total cumulative infiltrative injection dose per procedure)
Lignocaine without adrenaline	Medium (30 - 60 min)	4.5 mg/kg; not to exceed 300 mg
Lignocaine with adrenaline	Long (120 - 360 min)	7 mg/kg; not to exceed 500 mg
Bupivacaine without adrenaline (Macaine)	Long (120 - 240 min)	2.5 mg/kg; not to exceed 175 mg total dose
Bupivacaine with adrenaline	Long (180 - 420 min)	Not to exceed 225 mg total dose
Levobupivacaine (Chirocane)	Long (180 - 420 min)	150 mg (400 mg/24 h)
Ropivacaine (Naropin)	Long (120 - 360 min)	5 mg/kg; not to exceed 300 mg for minor nerve block

the environment is acidic, and the LA is charged and cannot pass through the cell membrane to exert its effect.

LAs are found on the surgeon's shelf as slightly acidic hydrochloride water-soluble salts. Injection of the drug results in a painful burning sensation. If 1 ml of an 8.4% solution of Na-bicarbonate is added to 9 - 10 ml of lignocaine the pH increases to 7.4. If a lignocaine-adrenaline solution is used, 2.0 - 2.5 ml of an 8.4% solution of Na-bicarbonate should be added. The burning effect disappears, patient comfort is improved, and the nerve block is speedier and lasts longer.

Plastic surgeons have developed so-called tumescent solutions, i.e. highly dilute solutions of LA, adrenaline and buffer to minimise blood loss, enhance removal of fatty tissue and improve patient comfort. Although formulations of tumescent solution vary, a typical mixture to be injected into the subcutaneous space would contain lignocaine 0.1%, sodium bicarbonate 12 mmol/l and adrenaline 1:1 000 000, usually warmed to body temperature. Using tumescent solution, lignocaine doses as high as 50 mg/kg have been administered without toxicity (although 35 mg/kg or lower is considered a safer dose).

Topical LAs

Topical LAs are used alone or in conjunction with an injectable LA. The absorption of topical LA is related to the concentration used, the amount of surface area covered, and the type of surface to which it has been applied. Systemic toxicity has been reported with the use of these compounds.

Lignocaine applied to a mucosal surface can lead to plasma levels approaching those reached with parenteral administration. Lignocaine 1% spray (Xylocaine) delivers 10 mg per pump dose. Care must be taken when using these compounds.

EMLA cream (2.5% lignocaine, 2.5% prilocaine) delivers maximal benefit after 30 - 60 minutes with an occlusive dressing. Systemic absorption, even of large amounts of EMLA on large surface areas, has been shown to be far below toxic levels. EMLA works very well in anaesthetising the skin before minor vascular access procedures and in superficial laser skin treatments.

Summary

LAs are compounds unparalleled in their ability to alleviate pain. Surgeons with a good understanding of the actions and toxicities of these medications, as well as the skill to deliver them, will find that the minor procedure room is an enjoyable, a comfortable and a safe place for their patients.

The risk of toxicity from LA use can be minimised by the following simple rules:

- Use the lowest concentration of LA required – diluting is allowed.
- Avoid direct injection into the intravascular space.
- Use adrenaline to slow absorption of LAs into the bloodstream to prolong anaesthetic effect and minimise blood loss.
- Modify the dose of LA/adrenaline for patients with risk factors for toxicity.
- Use enough LA to adequately anaesthetise the area of interest.

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In a nutshell

- A good working knowledge of local anaesthetics will enhance the patient's safety, experience and comfort.
- LAs are membrane-stabilising drugs that block nerve impulses.
- A low pH, e.g. in the case of infection, impairs LA efficacy.
- Adrenaline prolongs LA effects by delaying uptake from the injection site.
- The toxicity of LAs relates to plasma concentration.
- An overdose causes CNS and cardiovascular complications.
- L-bupivacaine and ropivacaine lessen CNS and cardiovascular toxicity.
- Lipid rescue has been shown to reverse both neurological and cardiac toxic effects.
- Allergies to LAs are quite rare.
- Dosing guidelines with a generous margin of safety are recommended.
- Reduce dosages in debilitated, acutely ill patients, in very young or old patients, and in patients with liver disease or atherosclerosis.
- Clinicians often modify the formulations post manufacture by mixing, diluting and adding fresh adrenaline or bicarbonate to achieve their own particular cocktail.

More about... office-based surgery

Minor anorectal surgery in the office

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Changing patterns of management options

This short article deals with modern-day selection of cases and procedure-room tactics in the management of benign anorectal diseases. Many conditions can be dealt with in the office, and most of the remainder can be treated on an ambulatory basis. Nevertheless, we need more patient and doctor education to shake off the old traditions.

Range of facilities

Previously, management of benign anal disease involved an office consultation and digital rectal examination. In many countries, (rigid) sigmoidoscopy would have been carried out in an operating room prior to surgical haemorrhoidectomy, fistulectomy, anal dilatation, etc.

Just as 'exploratory laparotomy' has virtually disappeared from the operating list due to the quality of pre-operative diagnostic assessment, so it should be possible to have made a management decision regarding benign anal disease by the time most patients leave the office. Indeed, the majority of patients will have been treated at the conclusion of the consultative process. No longer should (the majority of) haemorrhoids be removed surgically; most simple fistulae can be dealt with by a minor procedure involving a stay of no more than 2 hours; anal dilatation for fissure has been shown to damage the internal sphincter and a simple tailored sphincterotomy is completely amenable to day-patient management. A history of rectal bleeding should not automatically result in a colonoscopy, an examination under anaesthetic or a haemorrhoidectomy.

The office

The examination area should have available a range of proctoscopes, rigid sigmoidoscopes, haemorrhoidal banding, probes, local anaesthetic and instrumentation to allow excision of cutaneous pathology such as perianal haematomas, small skin tags, banding of haemorrhoids, simple haemorrhoidectomy, low fistulotomy, sphincterotomy and excision of anal warts, abscess drainage, etc. Additional lighting in the form of adjustable goose-neck or headlamps is recommended.

A simple diathermy machine and the facilities for instrument sterilisation such as an ultrasonic cleaner and a small autoclave can be accommodated.

An on-site office flexible sigmoidoscope is a very helpful asset, but a decision to acquire this instrument should be made on economic and geographical grounds.

The office is not a sterile environment but involves the use of equipment which has been sterilised to remove transmissible biological material.

Technical aspects

Potentially unsuitable patients are the obese and those with a bleeding risk. The more extensive the surgery, particularly below the dentate line, the greater the likelihood of pain; the more anxious patient will present a greater challenge with regard to the minimisation of postoperative discomfort.

Minor office procedures are carried out with no sedation or local anaesthetic infiltration (haemorrhoid banding) or under local anaesthesia (excision of tags or peri-anal haematomas). More extensive procedures involving anal skin, and particularly the internal sphincter, are optimally performed under local anaesthetic infiltration and intravenous sedation.

Surgical principles

Although anorectal procedures that are suitable for day surgery can be performed without bowel preparation, it is of benefit to provide oral bowel prep or to administer an enema on arrival to reduce the need for early postoperative evacuation and to lessen the chance of impaction following haemorrhoidectomy. If colonoscopy is to be performed, full bowel preparation is necessary.

The majority of day procedures can be performed with the patient sedated in the left lateral position, an assistant elevating the right buttock. Haemostasis should be assured prior to completion of the procedure.

Anaesthesia

Optimal anaesthesia is mandatory. Several techniques can be used: local anaesthesia, local infiltration analgesia with sedation, posterior perineal block, caudal block, epidural anaesthesia or general anaesthesia.

Technique of local anaesthesia

The skin is cleaned and disinfected with an antiseptic solution. The anaesthetic solution is injected subdermally and submucosally around the lesion to be treated, with a continuous motion of the needle or frequent aspiration to prevent intravascular injection. Injection into the muscle may be avoided depending on the depth of the lesion.

Posterior perineal block

Suggested mixture – 40 ml lignocaine 0.5%, adrenalin 1:100 000 (0.4 mg), 6 ml bicarbonate 8.4%. After subdermal infiltration at two sites anterior and posterior of the anal ring, the anococcygeal ligament is deeply infiltrated with 5 ml; 8 - 10 ml are injected into both ischioanal spaces while withdrawing the needle to anaesthetise the deep nerve endings. Through the anterior puncture in front of the anus, 5 - 10 ml solution is then infiltrated subdermally on each side at the level of the anal verge to secure superficial analgesia.

Summary

A simple paradigm shift has brought the management of many benign anorectal disorders within reach of a well-appointed office. However, most surgeons have not yet moved in this direction.

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Infection control and reprocessing

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Universal precautions and the 'chain of infection'

Safety and infection control are paramount in all surgical and endoscopic facilities. The high prevalence of hepatitis B, HIV, TB and resistant micro-organisms (e.g. MRSA) mandates universal precautions: every patient must be considered a potential source of infection and all surgical and endoscopic devices must be decontaminated and disinfected or sterilised according to protocol.

For a pathogen to be transmitted, all the links in the so-called 'chain of infection' need to be intact, viz. presence of viable micro-organisms, sufficient number of pathogens to initiate infection, host susceptibility to infection and entry of the pathogen through the typical portal (i.e. gastrointestinal pathogens through the gut, blood-borne pathogens through the bloodstream). If just one link is interrupted, infection cannot develop.

Infection control measures that may disrupt the chain of infection include:

- disinfection and sterilisation of medical equipment
- proper use of personal protective equipment
- personal hygiene

- engineering controls (ventilation, building design, clean water supply)
- cleaning and disinfection of environmental surfaces
- adequate administrative monitoring and support
- training and continuing education.

Every patient must be considered a potential source of infection and all surgical and endoscopic devices must be decontaminated and disinfected or sterilised according to protocol.

Spaulding classification for medical devices and level of disinfection

The widely accepted classification system proposed by E H Spaulding divides medical devices into categories based on the risk of infection with their use (Table I).

Importance of decontamination and cleaning

All reprocessing must be preceded by disassembly and cleaning to remove all inorganic and organic material from

the internal and external surfaces. This includes mechanical brushing, rinsing and exposure of all external and accessible internal components to a low-foaming, enzymatic instrument- or endoscope-compatible detergent. Ultrasonic cleaning may be needed to remove material from hard-to-clean areas. These methods reduce the 'bioburden' and are critical in allowing disinfection-sterilisation agents to work properly.

Disposable v. re-usable devices

It may be prudent to use disposable or single-patient use (SPU) items (e.g. drapes, sigmoidoscope, anoscope, biopsy instruments, endoscopic accessories), as they are supplied sterile, ready-to-use and carry a manufacturer and supplier guarantee. Re-using SPU medical devices is a widespread practice, but there are a number of potential hazards, including device failure, infection, inadequate labelling, etc.

The issue of safety and costs has been thrown into confusion by the spiralling costs of equipment and resistance from medical aids to pay the full cost of disposables. Costs are rarely clear-cut and not simply a matter of the purchase price. There are hidden costs associated with acquisition, stocking and disposal of SPU devices. Reprocessing costs include sterilisation, maintenance, replacement and indirect costs (additional instruments, training, administration, quality assurance). Potential costs may emanate from employee injury, patient injury and complications, as well as risk management, liability and litigation.

Quality control and training

There should always be sufficient numbers of trained staff and items of equipment

Table I. Spaulding classification for medical devices and level of disinfection

Category	Description	Level of disinfection	Methods of disinfection
Critical	A device that enters normally sterile tissue or the vascular system, e.g. surgical instruments, implants, needles, cardiac and urinary catheters, endoscopic biopsy forceps that break the mucous membrane barrier	Such devices should be sterilised, defined as the destruction of all microbial life	Steam autoclave, ethylene oxide gas, chemicals (e.g. glutaraldehyde, peracetic acid, Sterrad hydrogen peroxide gas plasma)
Semi-critical	A device that comes into contact with non-intact skin or mucous membranes and does not ordinarily penetrate sterile tissue, e.g. endoscopes, ventilator and anaesthesia circuits	At least high-level disinfection (HLD), defined as the destruction of all micro-organisms, mycobacteria, viruses, fungal spores, and some, but not all, bacterial spores	Boiling, moist heat or chemical. A limited number of disinfectants can be used for heat-labile equipment such as endoscopes, e.g. glutaraldehyde, ortho-phthalaldehyde (OPA), peracetic acid, hydrogen peroxide
Non-critical	Devices that do not ordinarily touch the patient or touch only intact skin, such as stethoscopes, BP cuffs, linen, basins, equipment and furnishings	These items may be cleaned by low-level disinfection	Hypochlorites, alcohol, iodine and other antiseptics

More about...

to allow enough time for thorough cleaning and disinfection. Personnel assigned to reprocessing must respect device-specific reprocessing instructions to carry out adequate cleaning and high-level disinfection or sterilisation procedures correctly. All personnel should receive information on the biological and chemical hazards associated with procedures using disinfectants-sterilants. Protective equipment (e.g. gloves, gowns, goggles, facemasks, respiratory protection devices) should be readily available to health care workers, and should be used as appropriate to protect them from exposure to chemicals, blood or other potentially injurious agents. It is important to monitor the efficacy of the disinfection-sterilisation procedures at prescribed regular intervals.

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Office-based plastic surgery – Beverley Hills Dr 90210?

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In recent years there has been a remarkable increase in the number of outpatient surgical procedures. Office-based plastic and cosmetic surgery has paralleled this growth. Ambulatory procedures are performed in three settings: hospital-based centres, free-standing ambulatory surgery centres, and office-based surgery (OBS) facilities.

The rise in outpatient surgery is partly due to the increasing cost of inpatient surgical services. Funders do not usually pay for cosmetic procedures. Hospitals are expensive, with major theatres costing more than R120 per minute, excluding consumables. They are often run as large corporations paying lip service to patient needs, but in reality treat patients as abstract commodities.

The advantages of OBS include patient convenience, privacy and comfort, greater control over the schedule, and increased efficiency and consistency of nursing and support personnel. Costs may be managed, but cost-cutting may detract from safety and quality.

Minor procedures with or without mild sedatives are commonly and safely performed in the office surgery. The

surgeon must implement a variety of organisational and logistic measures to ensure patient safety as more complex plastic surgery procedures (level II and III) are performed in the office setting. Procedures for which patients need deeper sedation or anaesthesia require the assistance of an anaesthetist or accredited sedationist and licensing of the facility as an 'unattached operating theatre unit'. A classification of OBS is set out in Table I.¹

Plastic surgery is the fastest growing medical specialty in the USA. Increasingly there is what has been called a 'Los Angelesation' of the world; almost everyone seems to want to look younger and more beautiful. The public love plastic surgery, even just reading about it in the popular press. Ambulatory plastic surgery centres are increasingly being used, are often boldly advertised, and are highly publicised commercial ventures.

'We treat everybody like a celebrity. Rodeo Drive Plastic Surgery is one of the best ... featured in TV, magazines, newspapers and international media. Many plastic surgery facilities treat you like an assembly line. They get you in, perform the surgery, get you out and they are done with you. But Rodeo Drive Plastic Surgery treats you different. They start out by putting your needs and desires first, and then provide excellent care and consultation after the surgery. Some of the services they provide are tummy tuck, liposuction, breast augmentation, face lift, brow lift, nose reshaping, chin rejuvenation, and Botox. So if you are wanting to have Beverly Hills Plastic Surgery please have it done right by professionals like those. <http://www.rodeodriveplasticsurgery.com/>'

But beyond the tabloid appeal plastic surgery is a multi-faceted surgical discipline. It is a medical specialty practised



Table I. Classification of office-based surgery

Levels of complexity	Class of anaesthesia*
Level I Minor surgical procedures under topical, local or infiltration block not involving drug-induced alteration of consciousness other than minimal sedation oral anxiolytic medications	Class A Minor surgical procedures under topical and local infiltration blocks ± preoperative sedation, spinal, epidural, ganglion, regional or intravenous regional blocks excluded
Level II Minor or major surgical procedures in conjunction with oral, parenteral or intravenous sedation or under analgesic or dissociative drugs	Class B Minor or major surgical procedures in conjunction with oral, parenteral or intravenous sedation, analgesic or dissociative drugs
Level III Surgical procedures requiring deep sedation/analgesia, general anaesthesia or major conduction blocks and support of vital bodily functions	Class C Major surgical procedures requiring general or regional block anaesthesia and support of vital bodily functions

*Adapted from the American College of Surgeons Guidelines for optimal ambulatory care and office-based surgery.¹

by highly trained doctors. It is based on solid foundations, follows logical principles, and is at the cutting edge of many exciting developments in medicine and health. Safety is of the utmost importance in office-based plastic surgery centres.

The American Society of Plastic Surgeons and American Society for Aesthetic Plastic Surgery mandate accreditation of office facilities.² They assembled a task force to develop OBS guidelines in the wake of several highly publicised patient deaths, increasing state legislative/regulatory activity, and a moratorium on all level II and III OBS in some states. The guidelines deal with the many factors that effect safe outcomes in the office setting, including appropriate patient selection, anaesthesia services, and pain management. The numerous procedure-specific issues address physiological stresses associated with surgical procedures (hypothermia, blood loss, liposuction in combination with other procedures, duration of procedure), thromboprophylaxis measures, potential postoperative recovery problems leading to unplanned hospital admission, provider qualifications, and surgical facility standards.³⁻⁶ The Association of Plastic and Reconstructive Surgeons of Southern Africa (<http://www.plasticsurgeons.co.za/default.asp>) strives to maintain standards in line with those of other international societies.

Conclusions

Recent increases in office-based cosmetic and aesthetic procedures have been stimulated in part by advantages of patient comfort, convenience and privacy. This rise has also been catalysed by the need for greater efficiency and cost containment. These goals should be realised in an environment that meets or exceeds the standards for patient safety established

for conventional hospital-based operating facilities and ambulatory surgery centres.

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Unattached operating theatres

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Many surgical specialties currently provide their patients with cost-effective surgical procedures that are performed safely in an office-based setting. The office surgery may at times be a more 'risky' environment for patients, compared with formal hospital theatres. Governance of these matters is clearly inadequate in South Africa and exposes the office operator to legal and ethical concerns. Organisation, construction and equipment, policies and procedures, including fire, safety, drugs, emergencies, staffing, training and unanticipated patient transfers are among the many issues that need to be considered.

The Regulations Governing Private Hospitals and Unattached Operating Theatre Units published under Government Notice No. R. 158 of 1 February 1980 and amendments are lengthy and onerous. The regulations stipulate a number of issues for theatres in both private hospitals and unattached facilities, but there is a poor distinction between private hospital and 'unattached theatres'. They do not address the practical and legal issues pertaining to

Table I. Scope of prescribed procedures carried out in unattached operating theatre units*

No prescribed procedures shall be carried out in unattached operating theatre units unless the necessary facilities, equipment and assistance are available for such procedures, for resuscitation and for postoperative care.

A. DENTISTRY: restorative dentistry, removal of teeth, minor oral procedures

B. GENERAL SURGERY: stitch wound & tendon; drain or remove superficial abscess, haematoma, nail, foreign body, tumour; sigmoidoscopy, colonoscopy; inject piles & varicose veins; paracentesis; minor anal surgery

C. PSYCHIATRY: ECT, narcoanalysis, electrostimulation, LP

D. ORTHOPAEDICS: reduction simple fractures, dislocations; manipulations, aspiration, injections; arthrography; carpal-tunnel release; suture tendon, nerve; remove ganglion

E. ENT: laryngoscopy; DPP; grommets, toilet of ears; cauterisation, remove foreign body, polyp; reduction nose fracture; tonsillectomy & adenoidectomy (no longer sanctioned); tracheotomy

F. O & G: EUA; incision, cauterise, biopsy vulva, cervix, endometrial; IUD; D&C; hysterosalpingogram; hormone implant, laparoscopy, sterilisation; Shirodkar; external version; other minor procedures

G. OPHTHALMOLOGY: EUA; corneal foreign body; probe tear duct; incision meibomian cyst; remove pterygium

H. DERMATOLOGY: diathermy, curettage, biopsy, removal warts, skin or mucous membrane lesions

I. UROLOGY: cystoscopy, urethral dilation, vasectomy, spermatocele, testis biopsy, meatotomy, circumcision

J. THORACIC SURGERY: pleural aspiration, biopsy; intercostal block; remove superficial tumour; bronchoscopy, oesophagoscopy, dilatation

K. NEUROSURGERY: EUA; LP, spinal drug administration, drainage; myelogram, angiogram, air encephalogram; nerve block; drain ventricle via existing burr hole or fontanelle; bone biopsy

L. PLASTIC SURGERY: plastic excision, repair small wound, scar, small skin grafts (under local anaesthetic)

M. MEDICINE: gastroscopy, bone marrow trephine/biopsy, paracentesis pleura/peritoneum

*Adapted from: Updated regulations governing private hospitals and unattached operating theatre units (published under Government Notice No. R.158 in *Government Gazette* No. 6832 of 1 February 1980 and amendments).

office-based surgery, endoscopy and the modern concept of ambulatory surgery centres.

- Definition: 'unattached operating theatre unit' means an operating theatre unit not owned or managed by the state, local authority, private hospital, hospital board or any other public body and not attached to a hospital or nursing home, and where a patient operated on may remain for a period not exceeding 12 hours.
- Prior approval and limited registration is provided, necessitating annual renewal.
- Detailed technical requirements for the facility, building, accommodation and equipment are contained in the regulations. Compliance with electrical specifications and provision of uninterrupted power supply (UPS, back-up generators) are common problem areas.
- A list of the scope of prescribed procedures carried out in unattached operating theatre units is summarised in Table I.

Additional governance matters are addressed in the Health Act and Medical Schemes Act, their regulations and amendments, other regulations governing patient care facilities, general hygiene and infectious diseases requirements, water supply, waste disposal, facilities regulation in terms of the Occupational Health and Safety Act, applicable Local Authority by-laws, South African Bureau of Standards, Basic Conditions of Employment Act and Labour Relations Act.

Please note that these acts represent minimum standard legislation. There is a definite interaction between the above-mentioned statutes, common law, legal precedents, delictual and criminal liability and HPCSA ethical rules.¹

The Medical Protection Society (<http://www.medicalprotection.org/southafrica/>) issued a warning that it may not be able to assist or provide indemnity cover in respect of complaints or claims arising from procedures performed in unregistered unattached theatres.

Most office-based surgery in South Africa is currently undertaken in doctors' rooms where no formal accreditation or licensing is held. This clearly exposes the practitioner and the owner of the facility to numerous legal and ethical risks. Legislation and governance processes are antiquated or lacking.

The Department of Health list of the scope of procedures in Table I is outdated. The South African Medical Association (SAMA)'s *Doctors' Billing Manual (DBM)* contains a long 'list of procedures that are often done in the doctors' rooms ...', but this list simply defines procedures that may not attract extra remuneration (modifier 0004). The SAMA Private Practice Committee has expressed the need to update this list as well as to develop consensus on the scope and standards of office-based surgery practice so as to avoid legal exposure.

A much wider range of procedures are performed or could be performed in the office surgery, particularly under a

combination of local and sedation or general anaesthetic techniques, e.g.:

- endoscopy: polypectomy, dilatation, stenting, placement of feeding tubes, vascular access, haemostasis and ablation of lesions, ENT endoscopic procedures
- general, orthopaedic, podiatry, neurosurgery and plastic surgery: more extensive procedures and rearrangements, liposuction, radio-frequency ablation, anorectal procedures (see the article on minor anorectal surgery in the office, p. 412 of this issue), ENT and ophthalmology
- obstetrics and gynaecology: hysteroscopy, suction biopsy, endometrial ablation, terminations, infertility procedures
- dental and maxillofacial procedures.

Practice guidelines for office-based surgery must be addressed by the national organisations representing practitioners, in co-operation with Department of Health, indemnity insurers, HPCSA and ISO Standards bodies, e.g. the International Organization of Standardization (ISO: <http://www.iso.org/iso/home.htm>) and their local representative, the South African Bureau of Standards (SABS: <https://www.sabs.co.za/>), and accreditation bodies such as the Council for Health Service Accreditation of Southern Africa (COHSASA: <http://www.cohsasa.co.za/html/accreditation.htm>). In the USA there are a host of state regulatory authorities and at least four accrediting organisations that constrain practices, e.g.

Medicare (<http://www.medicare.gov/>), Joint Commission on Accreditation of Healthcare Organizations (JCAHO: <http://www.jointcommission.org>), Accreditation Association for Ambulatory Health Care (AAAHC: <http://www.aaahc.org>) and the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF: <http://www.aaaasf.org/>).

These (to-be-developed) local guidelines must take cognisance of the following principles to assist practitioners who are considering or currently practise ambulatory surgery or other invasive procedures that require anaesthesia, analgesia or sedation in an office setting. While it is relatively easy to develop a set of criteria to certify a facility in which office surgery is to be performed, it is difficult to determine similar criteria or scope of practice definitions that can be used fairly and accurately to determine which physicians are qualified to use those facilities. Patients will benefit from systems based on best practice that ensure quality.²⁻⁴ There should be a focus on quality care and patient safety in the office. Practitioners and nurses should hold a valid licence or certificate and perform services commensurate with appropriate levels of education, training and experience and the scope of practice.

- Facilities should comply with all applicable state and local laws, codes and regulations pertaining to fire prevention, building construction and occupancy, including the disabled, occupational safety and health, drug supply, storage and administration, disposal of medical waste and hazardous waste. All premises must be kept neat and clean. Sterilisation of operating materials must be adequate.
- The procedure should be of a duration and degree of complexity that will permit the patient to recover and be discharged from the facility. Patients with co-morbidities may be at undue risk for complications and should rather be referred to an appropriate facility for the procedure and the administration of anaesthesia.
- The necessary equipment and personnel to manage emergencies resulting from the procedure and/or anaesthesia should be available. A written protocol must be in place for the safe and timely transfer of patients to a pre-specified alternative care facility when extended or emergency services are needed to protect the health or well-being of the patient. Pre-existing arrangements for definitive care of the patient shall be established, e.g. hospital admitting privileges or referral to appropriate specialist care.

Conclusions

In South Africa office-based surgery is a 'grey' area, largely devoid of formal practice standards. Accreditation guidelines are under development as this burgeoning 'ugly duckling' comes of age.

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Sedation and analgesia by non-anaesthesiologists

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The practice of office-based surgery (OBS), endoscopy and office-based anaesthesia (OBA) is continuously expanding and involves the management of a diverse population (adult and paediatric with or without co-morbidities) by numerous disciplines (surgical, medical, dental and maxillofacial).

Traditionally, anxiolysis and light sedation were administered by the operator or nurse assistant. Increasingly, however, more complex procedures demand the full attention of the operator and complete co-operation of the patient. Many of these procedures require deeper sedation, analgesia or anaesthesia by an anaesthesiologist or dedicated sedationist with the knowledge, skills and experience to ensure optimal results.

There is a grey area, fraught with controversy and 'turf battles', regarding use of deeper sedation, powerful agents such as propofol and opiates, or combinations of drugs by non-anaesthesiologists. The use of propofol has deeply divided gastroenterologists,



and gastroenterology and anaesthesia professional societies. Logistics in OBS and OBA require safety and rapid recovery. Safety and medico-legal liability are inextricably tempered by economic issues.

Guidelines for sedation and analgesia by the South African Society of Anaesthesiologists (SASA)¹ and many other national societies, e.g. the American Society of Anesthesiologists (ASA),² contain important caveats: '... concomitant use of opioids and deep sedation (mandates) a medical practitioner trained and experienced in advanced resuscitation skills be present throughout the procedure and recovery and should have no other responsibilities. This role should preferably be assumed by an anaesthetist ...'. The important corollary is that the practitioner must be able to 'rescue' patients from general anaesthesia as well as have advanced life-support skills and appropriate equipment to deal with cardiorespiratory emergencies.

Propofol is officially restricted for use as an anaesthetic agent for induction and maintenance of general anaesthesia and for sedation in ventilated patients. Nevertheless, there is a growing practice and supporting evidence that the operator, e.g. gastroenterologist, can cost-effectively and safely direct propofol sedation for routine procedures in average-risk patients.³⁻⁶ Combinations of intravenous sedative and analgesic agents are commonly administered by non-anaesthesiologists for OBS or OBA.⁷⁻¹² Drugs should be administered individually in small, incremental doses titrated to desired levels of analgesia and sedation.

Use of anaesthesiologist assistance for endoscopic procedures

The ASA guidelines warn that the presence of one or more sedation-related risk factors, coupled with the potential for deep sedation, may increase the likelihood

More about...

of adverse events. In this situation, if the practitioner is not trained in the rescue of patients from general anaesthesia, then an anaesthesiologist should be present.

Endoscopic procedures are significant cost drivers. Inherent costs of specialised equipment, over-utilisation and inappropriate level of facility (e.g. theatre) are among the factors. The routine assistance of an anaesthesiologist for monitored anaesthesia care (MAC) in average-risk patients undergoing routine endoscopic procedures is not warranted and is cost prohibitive.

Gastroenterology – endoscopy practice

Endoscopic practices vary widely regarding sedation in South Africa and world-wide. In France an anaesthesiologist must be present. Nurse sedationists are permitted in Germany and the USA. Propofol is popular in many European centres, notably in Switzerland.^{13,14}

The South African Gastroenterology Society (SAGES) conscious sedation guidelines¹⁵ view elective upper GI endoscopy and colonoscopy as outpatient, day-clinic or office procedures, requiring conscious sedation. With deference to published guidelines, the responsibility rests with the endoscopist to decide on appropriate protocols. In the setting of private practice this may involve 'pre-authorization'. SAGES is not prescriptive or proscriptive regarding OBA.

Formal training, certification and mentorship in OBA are mandatory.⁸ An online educational resource is recommended (<http://www.sedationfacts.org/>).

Conclusion

Our commitment to patients is that they have access to medically necessary technologies, pharmaceuticals and services delivered by appropriately trained health care professionals in a cost-effective environment that promotes safety, patient comfort and quality of care. Office surgery and anaesthesia are ready for 'prime time'.

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When the cheque is not in the mail!

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A major impediment to office-based surgery (OBS) is that reimbursement by funders is seldom guaranteed. Medical scheme payment generally derives from member savings portions or day-to-

day benefits. OBS is largely performed where funds have become depleted, for conditions that are not covered by funders (e.g. cosmetic surgery, large co-payments in hospital facility), or for needy people unable to afford medical insurance. Unbecomingly, OBS is born out of pathos – embattled doctors attempting to assist cash-strapped patients, often cutting costs and quality – an endeavour fraught with ethical and legal pitfalls and hardly ever profitable for the provider. There is seldom an incentive to perform procedures in the office setting, other than an impecunious client who cannot afford hospital-based surgery. Very few schemes pay more for office-based procedures.

Hospital-based payment systems contribute to the high cost, poor quality and lack of accountability that characterise the current health care delivery system. Equipment and pharmaceutical suppliers are paid only if their products are used. Consequently, they engage in direct-to-consumer advertising and marketing campaigns focused on doctors. The 'fee-for-service-on-steroids' phenomenon is responsible, at least in part, for fuelling the enormous growth in the volume of high-technology and costly services provided to beneficiaries. One of the biggest problems in traditional care is that no one is held accountable for the quality or cost of the entire package of services delivered to a beneficiary during an episode of care or for chronic disease. Worse still, no one is held responsible for keeping beneficiaries healthy!

Tariff-setting in South Africa in the doldrums

We have stagnated since third-party payers started calling the shots and the competition commissioner reined in the abilities of service providers to negotiate fees. The surrogate replacement process to determine a cost-based Reference Price List (RPL) has turned out to be slow, laborious, expensive and flawed. Our painstaking private practice cost studies have been vilified by the Department of Health (DoH). The most basic of concepts, that of tiered consultations, has been stalled for more than five years. It will take many years before a new tariff schedule is established.

Hospital facilities and anaesthetists command time- and complexity-based remuneration. However, funders do not pay for oxygen or its administration, e.g. an oxygen mask in the office setting. General and specialised equipment (e.g. diathermy, ultrasound, and video-endoscopy apparatus, and monitors), linen, drapes, reprocessing costs, and back-

up equipment (uninterruptible power supply (UPS), generators, resuscitation and emergency apparatus) are poorly remunerated, if at all. We should demand a facility fee similar to that paid to hospitals for use of their facilities.¹

Calculation of costs and remuneration for medical equipment should take into account capital or investment costs (including accessories, trade-up options, incentives) and operation and maintenance (O&M) expenditures (staff, training, floor space, insurance, running costs, consumables, repairs) for the useful lifespan of the equipment, including a reasonable return on investment (ROI) and medical inflation. The utilisation (number of uses per day or month) determines the per procedure cost. The DoH has prescribed formulas to derive the so-called reference price, but insist on utilisation of not less than 65% of a working day per item.² Using their calculations, a pelvic ultrasound procedure would only be paid a paltry R38! (Personal communication – Chris Archer, South African Private Practitioners Forum (SAPPF)). This is clearly untenable, even more so if more than one of a range of office-procedure devices are held.

There are major stumbling blocks in brokering remuneration and a new coding and billing structure. Non-implementation of cost-based reference pricing threatens the sustainability of private practice in South Africa. Both the SAPPF and the Hospital Association of South Africa (HASA) have had to resort to the courts in an attempt to get the DoH to agree to reasonable terms of engagement and to try to expedite changes.

Prescribed Minimum Benefits demystified

Some respite has been afforded our patients. Prescribed Minimum Benefits (PMBs) are guaranteed benefits that a medical scheme has to cover. In terms of the Medical Schemes Act, PMBs cover the costs related to 'the diagnosis, treatment

(inpatient and outpatient), and care of ...':

- any emergency medical condition
- a limited set of ± 270 medical conditions (called the Diagnosis and Treatment Pairs (DTPs), listed in the Act)
- the 25 Chronic Diseases List (CDL) conditions.

The full list of PMB conditions is available on the Council for Medical Schemes (CMS) website: <http://www.medicalschemes.com/>.



A member is entitled to PMBs regardless of the medical scheme option. The medical scheme must pay in full for all relevant consultations and appropriate special investigations or procedures that have yielded the positive PMB diagnosis from its risk pool and not the member's medical savings account. If the scheme initially paid for these from a savings account, the member should request the scheme to reverse the costs to the risk pool, since PMB-related services may never be paid from savings accounts. If funds were depleted and the client paid 'out of pocket', the scheme must reimburse the client.

Complications arising from conditions that are non-PMBs may be a PMB condition if the complication itself is listed under these conditions. Some conditions are excluded from cover, such as cosmetic surgery and examinations for insurance purposes, but if a member contracts septicemia or wound

sepsis after bariatric or cosmetic surgery, the scheme has to provide cover in full for a complication that is a PMB condition.

ICD-10 codes facilitate the easy identification of PMBs by service providers and funders. It is important to ensure that diagnosis information provided is correct to guarantee that benefits are paid out from the correct benefit pool. Many funders try to thwart the process by demanding that a PMB must first be formally registered. This is contrary to the spirit of the law – a valid, clinically appropriate ICD code in an account should unlock the benefits. Practitioners should counter this by charging their usual private rates for procedures that are subjected to such onerous extraneous administration. Schemes have no option but to pay whatever we charge, or face a complaint to the CMS.

PMBs are under review to expand the list of conditions covered considerably and to align the regulations with the National Health Insurance (NHI) reformation.

Feasibility

Office-based surgery is financially onerous under the current general fiscal economic downturn and the prevailing below-cost returns that practitioners have to endure. It behoves the astute practitioner to perform a feasibility study and market analysis to determine the viability of their business venture. Expert advice should be obtained from an experienced financial advisor.³

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single suture

The right fat might keep off the flab – or diabetes

Some extra fat may benefit people who need to lose weight, or fight diabetes, as long as it is the right kind of fat.

Brown fat, unlike normal white fat which stores the energy obtained from food, turns into heat, suggesting that it could be used as a weight-loss aid. Bruce Spiegelman, from the Dana-Faber Cancer Institute in Boston, and colleagues have shown that foreskin cells from mice can be changed into brown fat cells. When these cells are injected into mice, they burned sugar that would otherwise have been stored. A virus containing the gene that codes for two molecular switches that are essential for turning skin cells into brown fat was used to trigger the change.

Kajimura S, et al. *Nature* 2009; published online 29 July.

September 2009 – Office-based surgery

CPD questionnaires must be completed online via www.cpdjournals.org.za. After submission you can check the answers and print your certificate. Questions may be answered up to 6 months after publication of each issue.

LOCAL ANAESTHETICS: CHARACTERISTICS, USES AND TOXICITIES

1. Choose one correct statement wrt ropivacaine and levobupivacaine:

- A. They are more potent than bupivacaine
- B. Less prone to CNS toxicity
- C. R-isomers of bupivacaine
- D. Known to cause intense vasodilatation
- E. More selective in blocking motor nerve fibres.

2. Which one of the following agents is safe and useful in treating CNS and cardiac toxicity resulting from overdose of local anaesthetic:

- A. Propofol
- B. Phenytoin
- C. Amiodarone
- D. Lipid emulsion
- E. Adrenaline.

3. True (A) or false (B) – fill in only block A or B:

Adrenaline is absolutely contraindicated in digital nerve blocks.

OFFICE-BASED ANAESTHESIA

4. Choose one correct statement wrt to midazolam in office sedation and analgesia:

- A. Is commonly used for sedation owing to its rapid onset and short duration of action
- B. Amnesia and analgesia are pronounced, even at sub-hypnotic doses
- C. Suppression of respiratory drive seldom occurs
- D. Flumazenil is a non-competitive antagonist at the benzodiazepine receptor
- E. Flumazenil is a competitive antagonist at the benzodiazepine receptor with duration of action varying from 140 to 250 minutes.

5. Choose one correct statement wrt office anaesthesia drugs:

- A. Propofol has no anti-emetic effect
- B. There is a wide intra- and inter-patient variation in response to a given dose of a given drug or combinations
- C. Ketamine has excellent analgesic properties, but respiratory depression and laryngospasm are common side-effects
- D. Opioids can all cause severe respiratory depression, but have powerful anti-emetic properties
- E. Dexmedetomidine (PreceDEX) has recently been approved as an agent of choice in office sedation.

6. True (A) or false (B) – fill in only block A or B:

Office-based anaesthesia requires a different approach to that used in the hospital-based practice, but all anaesthetists are trained to deal with this environment.

OFFICE-BASED ENDOSCOPY

7. Choose one correct statement wrt office endoscopic procedures:

- A. They are very well reimbursed
- B. Accreditation and training are important prerequisites, but are poorly applied in South Africa
- C. It is the ideal environment for placement of oesophageal stents
- D. ASA II patients are not suitable for office endoscopy
- E. A marked increase in gynaecological hysteroscopy and endometrial ablation has been endorsed by funders and SASOG.

8. Choose one correct statement wrt suitable office endoscopy set-up:

- A. A certificate of need must be obtained prior to attempting office endoscopy
- B. Oxygen is expensive, seldom reimbursed and only used if really necessary
- C. Two trained assistants must be present in the room throughout the endoscopic procedure
- D. Resuscitation equipment must be available on call from a nearby hospital
- E. Informed consent must be taken by the doctor prior to the procedure and documented in the patient medical record.

9. True (A) or false (B) – fill in only block A or B:

Check the defibrillator at the start of each work day.

MINOR ANORECTAL SURGERY IN THE OFFICE

10. Choose one correct statement wrt minor anorectal procedures in the office:

- A. Full bowel prep is essential
- B. Proper anorectal evaluation is seldom possible in the office

- C. Rubber band ligation above the dentate line usually is very painful and requires anaesthetic block
- D. The majority of procedures are performed in the lithotomy position
- E. Assurance of haemostasis should be carefully achieved prior to completion of the procedure.

11. True (A) or false (B) – fill in only block A or B:

Caudal block is easy to learn and commonly used in anorectal surgery.

INFECTION CONTROL AND REPROCESSING

12. Choose one correct answer wrt reprocessing of devices:

- A. Most modern disinfectants are effective as they are able to penetrate biofilm build-up
- B. High-level disinfection is defined as the destruction of all microorganisms, mycobacteria, viruses, all fungal and all bacterial spores
- C. Re-use of disposable devices is a widespread and safe practice
- D. It is important to monitor the efficacy of the disinfection-sterilisation procedures at prescribed regular intervals
- E. Re-usable devices are usually cheaper in the long run compared with disposables.

13. True (A) or false (B) – fill in only block A or B:

Sterilisation of flexible endoscope is the standard of practice.

OFFICE-BASED PLASTIC SURGERY – BEVERLY HILLS DR 90210?

14. Choose one correct statement wrt office-based plastic surgery:

- A. Safety is of the utmost importance
- B. All procedures require the assistance of an anaesthetist
- C. Liposuction is a simple procedure that is ideally suited for the plastic surgery office
- D. Licensing is necessary, as an 'unattached theatre' is required for all surgery
- E. Most face-lifts can be accomplished in the office under local anaesthetic.

15. True (A) or false (B) – fill in only block A or B:

Most medical schemes will pay for cosmetic surgery as long as it is performed in the plastic surgeon's office.

UNATTACHED OPERATING THEATRES

16. Choose one correct statement wrt the regulations governing private hospitals and unattached operating theatre units:

- A. They were initially published in the Government Gazette in 1990
- B. They stipulate prior approval and annual renewal of operating licence
- C. They carry a comprehensive list of procedures that may be performed in the office setting
- D. They sanction postoperative overnight stay
- E. They are updated annually to govern modern safe office surgery and anaesthesia.

17. True (A) or false (B) – fill in only block A or B:

Separate Regulations in the Health Act describe standards for office-based surgery.

SEDATION AND ANALGESIA BY NON-ANAESTHESIOLOGISTS

18. Choose one correct statement wrt sedation and anaesthesia and analgesia:

- A. The official stance of the Anaesthetic Society of South Africa is that the concomitant use of opioids and sedation drugs targeted for deep sedation or anaesthesia should be restricted to anaesthetists.
- B. Propofol has excellent hypnotic and analgesic properties.
- C. An anaesthetist must be present at all endoscopic procedures performed under sedation.
- D. Light sedation is adequate for all colonoscopies.
- E. Cost is always more important than safety.

19. True (A) or false (B) – fill in only block A or B:

Propofol is officially restricted for use as an anaesthetic agent for induction and maintenance of general anaesthesia and for sedation in ventilated patients.

WHEN THE CHEQUE IS NOT IN THE MAIL!

20. True (A) or false (B) – fill in only block A or B:

Equipment costs in the office setting are adequately covered in the RPL calculations.