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 such as of cutaneous pathology 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 endoscopecompatible 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

<b>Category</b> Critical	<b>Description</b> 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	<b>Level of disinfection</b> Such devices should be sterilised, defined as the destruction of all microbial life	<b>Methods of disinfection</b> 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

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

#### 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-sterilisants. 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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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: hospitalbased 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.<sup>1</sup>

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

#### 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

#### Level II

Minor or major surgical procedures in conjunction with oral, parenteral or intravenous sedation or under 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 of anaesthesia\*

#### Class A

Minor surgical procedures under topical and local infiltration blocks ± preoperative sedation, spinal, epidural, ganglion, regional or intravenous regional blocks excluded

#### Class B

Minor or major surgical procedures in conjunction with oral, parenteral or intravenous sedation, analgesic or dissociative drugs

#### **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.<sup>1</sup>

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 officebased 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.<sup>3-6</sup> 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, spermatocoele, testis biopsy, meatotomy, circumcision

J. THORACIC SURGERY: pleural aspiration, biopsy; intercostal block; remove superficial tumour; bronchoscopy, oesophagos-copy, 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, backup 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 bylaws, South African Bureau of Standards, Basic Conditions of Employments Act and Labour Relations Act. Please note that these acts represent minimum standard legislation. There is a definite interaction between the abovementioned statutes, common law, legal precedents, delictual and criminal liability and HPCSA ethical rules.<sup>1</sup>

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, radiofrequency 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.

#### More about...

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)<sup>1</sup> and many other national societies, e.g. the American Society of Anesthesiologists(ASA),<sup>2</sup> 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.<sup>3-6</sup> 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

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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.<sup>13,14</sup>

The South African Gastroenterology Society (SAGES) conscious sedation guidelines<sup>15</sup> 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 'preauthorisation'. SAGES is not prescriptive or proscriptive regarding OBA.

Formal training, certification and mentorship in OBA are mandatory.<sup>8</sup> 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-today 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-toconsumer advertising and marketing campaigns focused on doctors. The 'feefor-service-on-steroids' phenomenon is responsible, at least in part, for fuelling the enormous growth in the volume of hightechnology 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 videoendoscopy apparatus, and monitors), linen, drapes, reprocessing costs, and backup 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.<sup>1</sup>

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.<sup>2</sup> 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 septicaemia 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.<sup>3</sup>

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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.