

SASES

The South African Society of Endoscopic Surgeons

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1 July 2014

South African Society of Endoscopic Surgery (SASES) Position Statement on the use of Equipment and Medical Devices in surgical settings

Who SASES is

SASES promotes high standards of endoscopic surgery in South Africa through training, conferences, workshops, education and sponsorships. It guides the HPCSA on credentialing, and issues Guidelines and Position Statements, such as these, to ensure quality of care and patient safety.

Laparoscopic / endoscopic surgery, also called minimally invasive surgery, has various benefits for patients, most of which also has cost benefits. These include that there is less postoperative pain, there is a shortened hospital stay, more rapid return to bowel function, a quicker return to normal activity, better cosmetic results and less diagnostic uncertainty. It is, also, the future of surgery.

Introduction

This statement confirms the position of SASES in relation to the procurement and availability of medical devices and medical equipment ("medical devices") required by surgeons in order to safely and effectively perform their professional duties, irrespective of the setting or sector (public or private). Ultimately, this statement serves to protect the interests of patients and ensure that the best possible care can be rendered in all circumstances.

The statement elaborates on three key principles:

- Quality of care and patient interest are paramount
- Practitioner clinical independence is inviolable
- There is a need for medical device regulations and interim measures

Although this statement is adopted for this type of surgery, the principles contained herein

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apply more widely.

Principle 1: Quality of care and patient interest paramount

Although it is recognised that healthcare has to be delivered in a cost-effective manner, "cheaper" is not always better when considering the choice of preferred medical devices. This matter is complicated by the absence of device regulations in South Africa.

Ethical Rule 27A of the HPCSA requires of practitioners to "at all times ... act in the best interests of his or her patients". This means ensuring that all equipment and devices used when treating patients are safe, of good quality, and perform as intended'. Concerning devices used in endoscopic surgery, **the surgeon is the person who would be able to assess whether a particular device performs as intended**, and whether its use is therefore in the **best interest of patients**.

Mechanisms should therefore exist in health facilities to allow practitioners to participate in new device procurement decisions and continuous evaluation of devices already procured. Health facilities should enter into contracts that mandate termination in cases where devices do not perform as intended.

The HPCSA and National Health Act require of practitioners to provide patients with treatment options, and to obtain their informed consent for the treatment thus chosen. Part of this process is a discussion on the **benefits, risks and costs of the options**. Although endoscopic procedures carry various benefits to the patients, practitioners would be obliged to discuss the risks associated with equipment and devices that are procured without their input.

In cases where practitioners deem the risk posed by available equipment to be high, practitioners will advise both the patient and the facility of such equipment-related risks in writing before the procedure. However, where the practitioner is faced with an underperforming device during a procedure, s/he will only be able to notify the facility of this failure after the procedure. This may occur if, for example, a new substitute suction device or energy source device is provided to the surgeon during surgery without prior warning of the discontinuation or the unavailability of its predecessor. In this setting the surgeon has no option but to use it and can only notify the facility after the procedure. In such circumstances the facility should take full responsibility in the event of any consequence (e.g. harm or inadequate treatment) flowing from such occurrence.

Ethical rule 23 of the HPCSA also requires that practitioners should offer "the best possible care at a cost-effective rate". Cost-effectiveness and lower prices are not equivalent terms. The issue is rendered more difficult by the absence of measurements of postoperative cost-savings in the medium- to longer term, which result from the avoidance of inferior technology. Earlier return to work and return to normal activities are examples of such unmeasured outcomes.

Medical schemes legislation authorizes, through managed care activities, the limitations on the use of devices used in healthcare. Schemes, however must abide by legislative requirements. These regulations require of medical schemes to fund "appropriate care" for Prescribed Minimum Benefits (PMBs). For all conditions (PMB or non-PMB), schemes should set benefits

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limits (e.g. protocols, disease caps and the likes), substantiated by **evidence-based medicine**. Within what would constitute evidence-based medicine, the scheme may “take into account” cost-effectiveness and affordability (budget impact). Surgeon input should be mandatory in this process. In these types of interventions the **individual clinical experience** of the surgeon is recognized by the law as valid. Input from experienced experts is usually referred to as the best available evidence and is used in the absence of treatment guidelines.

Not only the cost of the particular device should be considered, but also the longer-term effects of the use of cheaper devices. The risks posed by products not certified or licenced by reputable global authorities and/or products on which reports of inferior performance, safety-, maintenance-, support and/or operator/user difficulties have been reported, must also be considered prior to procurement, continuation of use and/or when entering into contracts with suppliers. Schemes must recognize and apply the definition of evidence-based medicine, which includes the experience of surgeons in this field.

Patients should be able to access appropriate, evidence-based care without facing medical scheme co-payments or penalties. Schemes should provide transparent evidence of how the cost-effectiveness (as opposed to the price) of devices has been evaluated when considering their availability for patients.

The Consumer Protection Act (CPA) creates strict (faultless) **liability for products**, including products used in the health sector. All in the supply chain, i.e. hospital / health facility, doctor-operator, as well as the importer or manufacturer share the legal liability for any harm caused by a device. As the entities closest to the consumer (the patient), both the practitioner and the hospital could face the brunt of a CPA claim.

If hospitals are unwilling or unable to ensure procurement, use and maintenance of equipment that are acceptable to practitioners, hospitals should indemnify practitioners from claims based on harm or inadequate treatment caused as a result of such equipment.

The **Office of Health Standards Compliance (OHSC)**, established in terms of the National Health Act, will soon start assessing all health facilities. One of the criteria of this assessment concerns devices. The assessment will focus on the use and maintenance of devices according to manufacturer standards, and the management and procurement of devices.

SASES urges the incorporation of quality and performance standards into the OHSC framework, as both a quality, and patient safety measures are core quality indicators. Mere compliance with manufacturer standards in itself does not ensure safe use, adequate and appropriate performance, and quality of care.

Principle 2: Practitioner clinical independence

Clinical independence is a fundamental principle of medical ethics, and forms the basis on which patients place their trust in practitioners. Patients trust that their doctors will use the best possible resources to afford them appropriate care. Practitioner choices of resources and equipment should not be swayed by improper external influences.

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The World Medical Association's 2008 Declaration on professional autonomy and physician clinical independence recognises the following –

“Hospital administrators and third-party payers may consider physician professional autonomy to be incompatible with prudent management of health care costs. However, the restraints that administrators and third-party payers attempt to place on clinical independence may not be in the best interests of patients.”

It states that practitioners –

“recognize that they must take into account the structure of the health system and available resources. **Unreasonable restraints** on clinical independence imposed by governments and administrators are not in the best interests of patients, not least because they can damage the trust which is an essential component of the patient-physician relationship”.

SASES therefore requires a reasonable system in both public- and private hospitals whereby the users and operators of medical devices, i.e. medical practitioners, have an adequate say in procurement decisions, in order to ensure that clinical independence are not unreasonably restrained and that patients can continue to place their trust in their doctors.

Principle 3: The need for medical device regulations and interim measures

The absence of medical device importer or manufacturer licensing and the **registration** of individual products has exacerbated the challenges practitioners experience in relation to medical devices and medical equipment. Currently, it is perfectly possible for any entity to import any device without any pre- or post-marketing regulatory controls, such as corrective action after equipment failures. There is currently no legal duty on any device importer or manufacturer to provide support- and/or maintenance services, and it is critical that **procurement decisions** favour entities that do provide such **support, training to operators and the necessary guarantees**.

In the absence of such a regulatory framework, SASES advises all health facilities to only procure from entities that are licenced (e.g. certified ISO 13485, SANS or FDA accreditation) and to ensure that products are registered by reputable regulators, such as the FDA, EU or in line with internationally aligned (IMDRF) jurisdictions. Proof of certification should be required. Companies should provide training and maintenance support as part of its service offering.

Furthermore, feedback from practitioners as to the performance, safety and quality of devices should be regularly and formally sought (e.g. through a device procurement advisory committee), corrective action taken and reported on.

Conclusion

SASES urges all stakeholders to use the principles espoused in this document as a guide and an agenda for further action. SASES members will, on their own, monitor the situation and report back to its Executive Committee as to the manner in which this matter is handled by facilities and practitioners alike.

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For further enquiries and comments, please contact SASES through its website:
<http://www.sases.org/contact-us/>.

Distribution

This Policy statement is distributed to:

Hospital groups, HASA, OHSC, Council for Medical Schemes, BHF, SAMA, SAPPF, Surgical- and related societies, SAMED (medical device trade association), Phango (patient representative organisation).

Bibliography

Consumer Protection Act, 2008

HPCSA Ethical Rules, 2006, as amended 2009 and 2013

General Regulations to the Medical Schemes Act, 1999, as amended

National Health Act, 2003

World Medical Association, 2008

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