ROYAL AUSTRALASIAN COLLEGE OF SURGEONS

RESPONSE TO REGULATION OF CERTAIN COSMETIC SURGICAL PROCEDURES UNDER THE PRIVATE HEALTH FACILITIES ACT 1999 DISCUSSION PAPER - QUEENSLAND

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ABOUT THE ROYAL AUSTRALASIAN COLLEGE OF SURGEONS (RACS)

The Royal Australasian College of Surgeons (RACS) is the leading advocate for surgical standards, professionalism and surgical education in New Zealand and Australia. RACS is a not-for-profit organisation that represents more than 7000 surgeons and 1300 surgical trainees and international medical graduates across New Zealand and Australia. It also supports healthcare and surgical education in the Asia-Pacific region and is a substantial funder of surgical research.

RACS provides training in nine surgical specialties, cardiothoracic surgery, general surgery, neurosurgery, orthopaedic surgery, otolaryngology head and neck surgery, paediatric surgery, plastic and reconstructive surgery, urology and vascular surgery. RACS plays an active role in the setting of standards of surgical care, the training of surgeons and their participation in continuing medical education throughout their lifetime of surgical practice.

RACS purpose is centred on excellence in patient care, and we endeavour to give consideration to the full effects of reform measures on patient care and service provision across all areas. We believe that the primary objective of any medical intervention should be to benefit the patient, and that patient safety is paramount.

BACKGROUND

Private health facilities are a vital component of the health system in Queensland, managing almost half of all hospital admissions.

These facilities are primarily regulated by the *Private Health Facilities Act 1999* (the Act) and associated subordinate legislation. The act provides a framework for protecting the health and wellbeing of people receiving health services at private health facilities. This is achieved by requiring compliance with a robust licensing regime, and compliance with standards to protect patient safety.

At present, there is no overarching regulation of cosmetic procedures performed in this way in Queensland. With the expansion of the types of complex procedures available, and increasing volumes of procedures being performed outside of the hospital setting, the Department of Health considers a risk is being posed to patients that can be straightforwardly addressed by drawing these procedures back within the regulatory framework.

The Act requires that procedures involving the use of general epidural or spinal anaesthetic, and sedation resulting in more than simple sedation, be performed in a licensed private health facility. However, many of the cosmetic surgical procedures that are currently carried out no longer require an anaesthetic, or are performed under sedation at levels that would not bring them within the Act's regulatory framework. Rather, many cosmetic surgical procedures may now be carried out under simple sedation and/or local anaesthetic.

This means that while the medical practitioners performing cosmetic procedures are subject to relevant standards and guidelines issues by the MBA, the facilities carrying out the procedures are not always subject to the standards required by the Private Health Facilities Act 1999 Regulation.

RESPONSE

We commend the Queensland Government for initiating measures to strengthen the regulation of cosmetic surgery, as recent events have shown that patients who are often unaware of differences in safety and quality standards have been exposed to unacceptable risks in some practices. RACS is particularly concerned that patients may be undergoing major surgical procedures in unlicensed facilities without any form of oversight or adherence to standards.

The RACS position is that all facilities providing surgical services require oversight to maintain a minimum level of safe practice, and that regulation should be based on the credentials of the practitioner and the level of sedation, rather than the procedure that is undertaken. This is very relevant in the case of office-based facilities, which are not required to be licensed in any Australian

jurisdiction, and for which there are no national standards. This is a particular concern and needs to be addressed.

The Australian and New Zealand College of Anaesthetists (ANZCA) and the New South Wales Agency for Clinical Innovation (ACI) have well developed standards on safe procedural sedation and these should be considered as part of any regulatory changes. Where they are consistent, we encourage the Government to consider how it can implement these changes more broadly, as procedural sedation is practiced in other specialties apart from plastic and cosmetic surgery.

Facilities where daytime surgical procedures are carried out under 'conscious sedation' are not required to be licensed or accredited. This is clearly a risk to the public.

Procedural sedation may often be administered to low risk patients without incident, however there appears to be an extended list of higher risk procedures that are being undertaken under 'conscious sedation'. It is essential that practitioners who administer sedation, and those who supervise recovery, have the appropriate skills and resources to manage potential risks.

RACS proposes that the definition of a surgical and/or anaesthesia private health facility be broadened to include all procedures requiring intravenous sedation of any type. Consideration should also be given to whether procedures conducted using large volumes of local anaesthetic or nerve blocks should be restricted to licensed facilities. This is not intended to affect the practice of minor surgical procedures being carried out in doctors' rooms under local anaesthesia.

Regulation of office based facilities

The Australian Government developed the National Safety Quality Health Service Standards to guide the accreditation of healthcare facilities and provide nationally consistent standard of care that consumers could expect from health service organisations[1], however there are no standards covering office-based facilities, and this is a deficiency of the system.

Accreditation is generally linked to reimbursement for service[2], and cosmetic procedures are not recognised by Medicare, nor do health insurers necessarily pay benefits for these types of procedures or the hospital costs associated with them.[3]

Office-based facilities such as private rooms, where many cosmetic procedures are undertaken, are not defined in QLD legislation. It is expected that the volume and types of procedures conducted in these settings will increase as surgical techniques and sedation methods improve. Again, this is a substantial risk to the public.

Nationally consistent requirements for office-based facilities should be developed and implemented and there should be independent accreditation of the facilities, with a particular focus on sedation level, credentialing of clinical staff, infection control, sterile supply, and clinical waste management.[4] New Zealand has standards for office-based facilities which may be an appropriate starting point.[5][6]

RECOMMENDATION

RACS does not support the creation of a new class of surgery within the cosmetic procedures group; however greater oversight of the appropriate credentialing of facilities, including appropriate credentialing of practitioners is needed.

If any type of intravenous sedation is required to perform a procedure, then the surgery should only be undertaken in a licensed facility. This generally means a larger operation which requires the resources and oversight found in a larger facility.

Key points

The Royal Australasian College of Surgeons recommends:

- Regulation of private health facilities based on a level of sedation rather than the procedure performed;
- That procedures requiring intravenous sedation, excluding dental, only be performed in an accredited and licensed day surgery or hospital;
- Procedures conducted using large volumes of local anaesthetic or nerve blocks, which may reach toxic levels be restricted to licensed facilities;
- Cosmetic surgical operations should only be performed by practitioners who are registered surgical specialists;
- Development and implementation of nationally consistent requirements for office-based facilities including independent accreditation of facilities, credentialing of clinical staff, infection control, sterile supply and clinical waste management.

[1] Australian Government. Australian Commission on Safety and Quality in Healthcare. Accreditation and the NSQHS standards; 30 Apr 2015. Accessed 29 March 207. Available from: https://www.safetyandquality.gov.au/our-work/national-standards-and-accreditation/

[2] Private Health Insurance (Accreditation) Rules 2011, 3 Jan 2013.

[3] Australian Government. Private Health Insurance ombudsman. Plastic and Reconstructive surgery: Policy Exclusions and restrictions; 31 August 2010. Accessed 29 March 2017. Available from http://www.ombudsman.gov.au/publications/brochures-and-fact-sheets/phio/plastic-and-reconstructive-surgery

[4] Bartholomeusz, F.A.H.: The need for regulation of office-based procedures closing a regulatory gap to ensure patient safety in all surgical procedures. Editorials MJA. 2012. Available from http://www.mja.com.au/system/files/issues/196_08_070512/bar10410_fm.pdf

[5] Standards New Zealand. NZS 8164:2005 – Day-stay Surgery and Procedures. Wellington, New Zealand. 6 May 2005.

[6] Standards New Zealand. NZS 8165:2005 – Rooms/Office-based Surgery and Procedures. Wellington, New Zealand. 6 May 2005.