



The need for regulation of office-based procedures

Closing a regulatory gap to ensure patient safety in all surgical procedures

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Health services are delivered in a variety of settings, including public and private hospitals, day surgeries and practitioner offices. Office-based surgery has been practised safely in the United States for many years,¹ and has been embraced by surgical specialties such as otolaryngology,² vascular surgery,³ general surgery including endoscopy, and plastic and reconstructive surgery including cosmetic procedures. However, unlike hospitals and day surgeries, office-based settings do not have regulations and quality controls in place to ensure that acceptable levels of care are implemented and monitored.

Public and private hospitals, day procedure centres and day hospitals must be accredited and comply with statutory requirements that differ considerably between Australian states but have similar safety and quality objectives. Despite overall good safety in office-based settings in the absence of such regulations, many adverse events have been reported in the US⁴ and Australia. Several American authors have championed the cause of office-based surgery, pointing out that over-regulation or loss of office surgery would have a tremendous impact on the management of common surgical procedures.⁵ However, given the increasing complexity

of surgery undertaken at these sites, lack of regulation of office-based surgery poses an unacceptable risk to patient safety. Further, patients are largely unaware of the inherent differences in safety and quality standards and controls that apply to surgical procedures performed at hospitals and day procedure centres compared with doctors' offices.

While office-based surgery is generally safe and cost-effective,¹ there is clearly a gap in quality and safety systems and regulations that needs to be closed. Nationally consistent requirements for office-based facilities should be implemented. These requirements should include independent accreditation of the facilities, credentialling of clinical staff, infection control, sterile supply, and clinical waste management. Building and facility issues and minimum quality and audit requirements must also be included. In the US, duration of anaesthesia has been shown to be an indicator of morbidity and mortality in office-based facial plastic surgery.⁶ Another study has shown that significant changes in haemodynamic status occur during office-based endoscopic surgery.⁷ Therefore, the scope and type of procedures that are to be accredited in office-based settings must also be carefully considered.

With regard to the practitioners who perform procedures, a two-tiered system has evolved in Australia. A contingent liability is placed upon hospitals and measures are taken by their medical advisory committees to test registrants to meet credentialling and scope-of-practice requirements. This system is open to all registrants who are recognised by the Australian Medical Council. However, similar credentialling of practitioners does not occur in the office-based setting.

Regulation of office-based procedures will also protect health care workers. Practical techniques to enhance the safety of health care workers in office-based surgery have been well documented. These techniques can be preoperative (organising the surgical field, considering alternative treatments for high-risk patients), intraoperative (safe handling and transferring of sharp instruments, working without using sharps, protecting from back-spray injuries) and postoperative (proper disposal of used sharps).⁸ All these techniques should be incorporated into a simple system of accreditation for office-based facilities.

A recent report prepared under the auspices of the Australian Health Ministers' Conference highlights the increasing number of cosmetic surgical procedures being performed in office-based settings.⁹ The report suggested a national framework to safeguard consumers based on five

interdependent elements: the procedures, the promotion of the procedures, the practitioner, the patient, and the place.⁹

Having regard to these recommendations, the Australian Society of Plastic Surgeons (ASPS) has made a submission to the Australian Commission on Safety and Quality in Health Care. The ASPS has recommended that a modified version of the American Association for Accreditation of Ambulatory Surgery Facilities International Class A standards¹⁰ should be used as the template for accreditation of office-based surgical facilities in Australia. These standards cover the general environment of the office-based setting and the specific environment of the procedure room, including equipment, infection control, emergency protocols, hazardous agents, medications, medical records, and provision for quality assessment and quality improvement. The standards should be supplemented by a transparent and robust credentialling process for the practitioners who provide services within these facilities.

There is no doubt that the safety of the Australian public is of paramount importance within our health care system. An urgent need exists for Australian regulatory authorities to rectify the lack of regulation in this burgeoning area of medical practice and provide a nationwide system of accreditation for office-based surgical facilities.

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