

Office-Based Surgical and Medical Procedures: Educational Gaps

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ABSTRACT

Over the past decade, the number of procedures performed in office-based settings by a variety of practitioners—including surgeons, gastroenterologists, ophthalmologists, radiologists, dermatologists, and others—has grown significantly. At the same time, patient safety concerns have intensified and include issues such as proper patient selection, safe sedation practices, maintenance of facilities and resuscitation equipment, facility accreditation and practitioner licensing, and the office staff's ability to deal with emergencies and complications. An urgent need exists to educate practitioners about safety concerns in the office-based setting and to develop various educational strategies that can meet the continued growth of these procedures. This review outlines educational needs and possible solutions such as simulation exercises and education during residency training.

INTRODUCTION

With diminishing healthcare reimbursement and a growing consumer demand, a large portion of healthcare delivery has shifted from in-hospital settings to

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outpatient facilities and more recently to physicians' offices. Often called the Wild West of healthcare, office-based procedures continue to increase at a rapid pace, with an estimated 12 million procedures performed in 2009 alone.¹ The office setting offers improved access and convenience for both providers and patients. Office-based practices are typically more cost effective than other practice settings, and they are not subject to the same local, state, and federal regulations as hospitals or ambulatory surgical centers (ASCs). However, we continue to observe that the procedures being performed in offices are increasing in variety and complexity. Patients have more comorbidities, and office personnel are often unprepared to deal with complications. Office procedures also have caught the public's attention because of highly publicized malpractice claims and fatalities. In addition, there has been a dramatic increase in the number of deaths of young, healthy patients undergoing routine procedures such as dental surgery, endoscopy, laser hair removal, liposuction, and other aesthetic surgery.²

OVERVIEW OF SAFETY CONCERNS

From 1995 to 2005, the number of elective procedures performed in ambulatory settings doubled to 10 million.³ Medical practitioners in private offices perform 10%-12% of ambulatory procedures. Many office-based providers deliver care outside of their scope of practice, a trend known as "practice drift." These practitioners often complete weekend courses, enabling them to operate outside their specialty for certain procedures. Hospitals usually do not recognize such certifications, so the out-of-scope procedures tend to be concentrated in the office setting. As a result, office-based proceduralists are more vulnerable to practice drift and may not be fully capable of responding to complications.

In spite of being disproportionately impacted by practice drift, office-based practices are largely unregulated. Currently, there is no federal oversight of medical offices. Unlike hospitals and ASCs,

medical office suites are subject to few, if any, regulations by state or local authorities. In fact, only 27 states require accreditation of office-based practices.⁴ As of now, only 28 states have any guidelines or regulations pertaining to office-based facilities. Moreover, a vast majority of offices lack accreditation by one of the major accrediting agencies (American Association of Ambulatory Surgical Facilities, Accreditation Association for Ambulatory Health Care, and The Joint Commission); only 21 states mandate accreditation.⁵ Whether office procedures are performed with or without an anesthesia care provider, a wide range of concerns has been identified, including patient and procedure selection, perioperative management, complication management, and patient recovery. Non-patient-related issues include unqualified proceduralists and surgeons performing procedures outside of their scope of practice, substandard facilities, and a lack of qualified office personnel.⁵

To date, little in the literature has addressed office-related morbidity and mortality. The database of the American Society of Anesthesiologists (ASA) Closed Claims Project (a medical liability and quality control initiative) currently includes only 37 office-related cases, likely because of a 3- to 5-year time lag between occurrence and entry into the database.⁶

Procedures performed in office suites entail potential harm to patients. For example, from March to July 2000, patients in Florida experienced 9 adverse events, 4 of which involved deaths during office-based surgery.³ According to a study by Vila et al,⁷ the relative risk of an adverse event was 12.8 times greater in office-based procedures than in ASCs. Furthermore, the relative risk of death was 11.8 times higher in office settings than in other outpatient institutions.⁷ The findings of Vila et al prompted Florida officials to issue a moratorium on certain types of procedures performed in the office. However, the study has methodological shortcomings. Adverse events, including deaths, were compiled from incidents occurring in both registered and unregistered offices, but the total number of procedures observed came only from registered centers. This discrepancy may have inflated the likelihood of adverse events from office-based practices. Contrary to the results of Vila et al, a prospective study by Coldiron et al⁸ demonstrated no additional risk of death in offices compared to other ambulatory sites. Clayman et al⁹ also confirmed the safety of medical offices, as long as procedures are performed in an accredited facility by proceduralists who are credentialed for the same procedures in hospitals.

Keyes et al¹⁰ examined more than 1.1 million cases from 5,000 accredited offices. This retrospective study recorded 23 deaths; pulmonary embolism caused 13 of these deaths, prompting further investigation and leading to specific guidelines to address frequent complications. Although a superficial analysis of Keyes et al would suggest that the proportion of office-based adverse events is low, this number reflects only a small fraction of all existing offices (accredited and unaccredited). Unaccredited sites were not studied,¹⁰ and adverse events in those offices might not be documented or reported.

A study by Schaefer et al¹¹ highlighted many lapses in infection control at outpatient surgery centers. The study did not specifically address office-based proceduralists. However, the review was based on a sampling of 68 facilities in 3 states, demonstrating a noteworthy attempt by the Centers for Medicare and Medicaid Services (CMS) to use standardized tools for assessing safety practices at ambulatory settings.

In another effort to standardize clinical care practices in the ambulatory surgery setting, CMS mandated the use of a surgical safety checklist in all CMS-accredited ASCs. The initiative began in January 2012. Although noncompliance will not be financially penalized, such refusal will be publicly reported. Private payers and malpractice insurers could then use this information when determining payment policies for medical providers. In addition, office-based proceduralist practices are facing increased pressure from commercial insurers trying to institute what frequently appear as arbitrary medical necessity and prior authorization policies.

What is certain is that when adverse events occur in office suites, they are more severe than in conventional settings. This observation is well documented. Based on data from the ASA Closed Claims Project, office-based liability claims involved 3 times more deaths than ASCs.¹² Moreover, the analysis suggested that 46% of these incidents could have been prevented by improved monitoring and patient selection. In contrast, only 13% of liability claims in other ambulatory settings were deemed avoidable. The most common mechanism of injury cited was respiratory depression, underscoring the importance for all medical specialists to be wary of the potential adverse ramifications of office-based practice. Absent government oversight, office-based practitioners—such as podiatrists, dentists, oromaxillofacial surgeons, gastroenterologists, radiologists, obstetricians and gynecologists, urologists, plastic surgeons, and anesthesiologists—must exercise their professional responsibility to guarantee patients the highest standards of quality and safety.

IMPROVING EDUCATION AND TRAINING OF THE PRACTITIONER

One obstacle to reducing the performance variation in office-based procedures is a lack of proper education and training. Some practitioners and staff may not have the skills to select appropriate patients or to monitor sedated patients in the office setting.¹³ Another possible barrier could be that providers are underresourced; they might not have the supplies, drugs, staff, and equipment to prevent or reverse complications.¹⁴ Discrepancies in performance may occur because of incomplete use of existing medical knowledge; providers may not be consistently using best medical practices.

Many possible ways exist to tame this Wild West of healthcare and improve patient safety. One editorial pointed out that according to the Agency for Healthcare Research and Quality, only about 10% of patient safety studies are performed in outpatient settings.¹⁵ The authors called for “creating a culture of safety” in the outpatient setting, acknowledging that this setting is often “fragmented and disorganized and lacking in clear leadership.” The authors advocated for data collection on outpatient safety risks through the improved reporting of events and near misses from front-line clinicians.¹⁵

Over the past decade, professional organizations such as the ASA and the American Society of Plastic Surgeons have generated recommendations and guidelines to improve office safety. Options frequently discussed include requiring the practitioner to have board certification to perform specific high-risk procedures; requiring each office to have a manual of standards and policies; mandating office accreditation as part of board certification (if practitioners intend to perform office procedures); requiring practitioners to have admitting privileges at a nearby hospital; developing a credential program for performing a given procedure in both the office and the hospital; and moving toward greater oversight by local, state, and federal agencies. In addition, surgeons and anesthesiologists are attempting to collect ambulatory outcomes data.^{16,17} Professional societies have many potential opportunities to standardize patient care and provider qualifications.

Healthcare providers must be properly educated about safety in performing office-based procedures. Obtaining and maintaining office accreditation is one approach to standardizing the quality of care that patients receive. To fill the vacuum created by a dearth of regulation, organizations such as The Joint Commission, the American Association of Ambulatory Surgical Facilities, and the Accreditation Association for Ambulatory Health Care have taken the lead.

While each credentialing group has a different set of standards, they share several key features that every office-based practice should follow. All healthcare providers must be licensed and operate within their scope of practice. Personnel should be proficient in cardiopulmonary resuscitation, and at least 1 physician should be certified in advanced cardiac life support. Medical gases should be transported and stored in compliance with government regulations; waste gases must be scavenged in a manner that is consistent with Occupational Safety and Health Administration regulations. Lastly, any purchase or application of controlled substances must adhere to local, state, and federal laws.

Preoperative Evaluation and Postoperative Recovery

To augment safety in office settings, medical practitioners should receive education about appropriate preoperative care management. One of the major challenges in preoperative care is patient and procedure selection.⁴ Medical providers should evaluate patients along the following parameters: (1) past medical history, especially of morbid obesity, obstructive sleep apnea, or difficult airway; (2) family history of malignant hyperthermia or other metabolic disorders; (3) current medications; (4) drug or latex allergy; (5) deep vein thrombosis risk and prophylaxis regimen; (6) assessment of time and nature of last oral intake; and (7) psychological status, especially a history of drug or alcohol abuse. If patients do not meet acceptable criteria, physicians must take appropriate precautions and reassess the decision to proceed with the procedure. In some cases, patients may not be candidates for sedation/anesthesia in the office-based setting.¹⁸

Appropriate safety processes must be in place for the entire perioperative period. The structural aspects of the office suite should be conducive to patient safety. Rooms should be appropriately lit and ventilated. Suites should be spacious to enable the staff to secure the airway of a patient or perform cardiopulmonary resuscitation, if necessary. Medical offices must be equipped with fire extinguishers and a sprinkler system, and a defibrillator for emergency cardiac situations should be immediately available. Practitioners who provide sedation and anesthesia should also be prepared to manage malignant hyperthermia; their facilities should always have a readily accessible supply of dantrolene and necessary equipment. Through interspecialty collaboration, the Society for Ambulatory Anesthesia and the Malignant Hyperthermia Association of the United States have developed guidelines for the transfer of suspected malignant hyperthermia patients from the

office to the hospital.¹⁹ Local anesthetic toxicity precautions should also be taken, and appropriate supplies must be available to treat toxicity.²⁰ If sedation/analgesia is being administered, proper provider training and adherence to safe sedation practices are necessary.^{21,22}

Additionally, postoperative care has room for improvement. The patient recovery area should be adequately staffed with proper electronic monitoring systems. All patients should have a responsible adult present to escort them home. Pain, nausea, and vomiting are common factors that preclude timely discharge from the office.⁴ Consequently, medical providers must be cognizant about the need for optimizing pain control and mitigating postoperative nausea and vomiting. One plausible mechanism for decreasing recovery time is opting for short-acting sedative/anesthetic agents that minimally affect cardiovascular and respiratory status. Another approach is to increase the use of local anesthetics via infiltration or regional blocks. These types of pain control agents would decrease the use of postoperative opioids.

By decreasing patient recovery times, improved postprocedure care could also unleash efficiency gains for office-based proceduralists. Because the capacity of recovery rooms is fixed, prolonged stays in the recovery room often disrupt workflow and impede room turnovers.²³ Better postoperative care could address these bottlenecks and increase patient throughput, thus generating additional volume and revenue.

Simulation and Other Strategies

While all of the above approaches should cut the incidence of adverse outcomes, some complications will occur. As part of a comprehensive risk management strategy, office-based practitioners should develop and implement emergency contingencies and establish transfer agreements with local hospitals for complications, ensuring that patients can be readily admitted to better-resourced facilities during an emergency.³

The full integration of pre-, intra-, and postoperative care is critical to maximize safety and performance in office-based settings. Healthcare providers must continuously practice the above measures to ensure their integration into the patient experience. Consequently, simulation learning can play an important role in incorporating best practices into workplace operations. The military, airline, and hospital sectors have all successfully used the simulation strategy.²⁴ Simulations of emergent situations are risk-free opportunities to teach crisis management to the clinicians and staff involved in patient care. For

simulations to be effective, they should emphasize role assignments, teamwork, communication, and proper equipment use. All team members should take part in simulations because medical offices tend to be freestanding facilities where supplies, equipment, and personnel are constrained.

A variety of training scenarios would enhance a team's stock of skills. Possible exercises could address fires, medication errors, equipment failures, respiratory emergencies (eg, pulmonary embolism, pneumothorax, aspiration), teamwork communication, adverse cardiovascular events (eg, malignant hyperthermia, myocardial infarction, arrhythmia), and code status situations (eg, unknown code status, advanced cardiac life support). Such conditions represent some of the most frequently encountered complications in the office-based practice. Simulations of such events would give medical providers experience to sharpen their clinical and decision-making skills that in turn will raise performance, reduce errors, and improve outcomes when adverse situations occur.

Simulation experiences help providers develop confidence in delivering clinical care and coordinating activities as a team. By promoting the flow of communication between team members, simulation activities can enhance morale and create a workplace environment that fosters mutual respect. These improvements could lessen the costly turnover of highly qualified staff and increase operational efficiency in the current healthcare environment.^{25,26}

A simulation program is never complete without participant feedback. A debriefing session should always follow a simulation. Participants evaluate their individual performance as well as that of their peers. Typically, a debriefing session will also involve a screening of a video recording of the simulation session that allows the participants to identify potential areas of improvement.

The proliferation of office-based interventions has without a doubt increased the education requirements for medical providers. Therefore, it is vital for medical interns, residents, and fellows to receive adequate exposure to office-based procedures. Medical residencies should incorporate office-based practice into the graduate medical education curriculum to help ensure that future physicians have the skills necessary to practice in all healthcare settings.

CONCLUSIONS

The office-based proceduralist practice remains the Wild West of healthcare. The lack of government oversight and the hodgepodge of credentialing requirements mean that there is no standardization of safety and quality for medical offices. Office-based medical providers should be aware of accreditation

issues, care management, and simulation learning if they are to demonstrate superlative quality. Medical staff in office-based outpatient suites can certainly provide safe, effective, efficient, timely, patient-centered care. But this goal can only be achieved if clinicians and staff are properly trained to deliver such care.

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Epitoma

The authors of this study from Harvard Medical School and Drexel University College of Medicine highlight the significant growth of office-based procedures being performed by many practitioners in various specialties, particularly over the past 10 years. Many of these procedures were previously performed in an operating room as part of an outpatient or limited admission status. This work details many of the potential gaps in patient safety as these procedures migrate from the operating room to the office setting. The educational process presented is vital for both residents in training as well as established practitioners. This review article outlines educational needs and possible solutions (such as simulation exercises) to avoid potential lapses in patient safety.

—Guest Editor Ronald G. Amedee, MD

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