Office Accreditation Experiences With 3 Accrediting Agencies and Suggestions for Changes in Private Oral and Maxillofacial Surgery Facility Evaluations

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Historically, oral and maxillofacial surgeons have had considerable autonomy in operating their offices. Oral and maxillofacial surgeons have had a singular history of safety, training, and success in outpatient anesthesia in their offices. However, preventable patient morbidity and mortality in private office-based surgical facilities of a variety of professions have brought increased scrutiny to the office environment. The present report describes the experiences of 3 oral and maxillofacial surgeons with 3 accrediting agencies in obtaining office accreditation and offers recommendations to be considered for the future of our specialty in terms of private office certification.

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Two trends have occurred during the past 20 to 25 years that have brought the topic of office accreditation to the minds of stakeholders (ie, doctors, patients, regulators, legislators, and the public). One dominant trend has been the tremendous shift from the inpatient setting to the outpatient setting for a variety of procedures. The other important trend has been the low rate, but steady incidence, of seemingly preventable patient harm and death in the outpatient setting, which also occurs with inpatient experiences. High-profile cases have increased public awareness of preventable medical errors.[1-3] In addition, traditionally, accountability in office-based medicine and dentistry has been lacking compared with other surgical forums. Many states are considering recommending office accreditation to permit even minimal sedation, in addition to more esoteric modalities. The American Dental Society of Anesthesia Web site, as well as the American Association for the Accreditation of Ambulatory Surgical Facilities (AAAASF) Web site, has a state by state listing of current and proposed state regulations. A few states (eg, New York and Nevada, where we practice) have enacted legislation mandating office accreditation by 1 of the 3 national accrediting bodies for physicians performing more than minimal sedation.

In New York State, bills S6052-A and A7948-A[4,5] were enacted in June 2007 and gave a 2-year period in which to meet the new requirements. The regulation was the culmination of a 13-year process that examined the quality of care in the outpatient setting. Committees[6] were appointed to examine the quality of care in the outpatient setting. However, the only dentist on the commission was a pediatric dentist in academia. Ten years earlier, similar recommendations for more regulation of the outpatient setting had been made by the commission but had not been taken up by the then-acting governor. At the more recent point, when the commission made recommendations, then Governor Spitzer quickly adopted the recommendations and enacted the regulation. Dually licensed oral and maxillofacial surgeons (OMSs) were subject initially to the mandated accreditation, and dentally licensed OMSs were not. Our state societies sought an exemption from the legislation and, after a 2-year effort, were eventually exempted from the regulation by the New York State Department of Health the week before the deadline for compliance. Dual-degree OMSs do not need to meet the regulation as long as they practice within the scope of their dental license. Believing that the consequences of failure in

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achieving the exemption was too great and the outcome too uncertain to risk not becoming accredited, 3 of us pursued accreditation independently. In addition, 3 of us are officers with the New York State Society of Oral and Maxillofacial Surgery and wanted to determine what challenges and costs would be entailed to achieve compliance.

In Nevada, a similar office-based surgery law[7] was passed in June 2009. As reported in the *Journal of the American Dental Association* editorial *Cottages no More* in August 2009,[8] 100% of Nevada's medically licensed population are now subject to onerous statutes requiring national accreditation, as well as annual reporting of all nonlocal anesthetics delivered, scheduled and unscheduled facility inspections, penalties ranging from permit revocation to a fine as great as $1,000.00/day, and inspection costs yet to be determined. All this came to fruition after no historical physician facility regulation whatsoever.

Ironically, the impetus for this legislation was not an anesthetic mishap, but an allegation of an endoscopy center lapse in infection control that has yet to be proved in court. We believe that although preventable iatrogenic disease transmission likely occurred, the upcoming trial will replace the initial theory involving contaminated intravenous medications with a more realistic one of inadequately sterilized endoscopy instruments. Regardless, as is often the case, the litigation-fueled public outcry from the sensational allegations prompted legislators to "do something," and do something the legislators did.

Significantly, dentists were excluded from the new legislation, because it was recognized that dentistry, owing to the visionary leadership of several iterations of Nevada State Society of Oral and Maxillofacial Surgery leadership, had been self-regulating facilities since the early 1980s using an OMS societal paradigm, based on the original of such programs developed in Southern California in the 1970s. Over the years, the voluntary societal examinations in Nevada evolved to mandatory Nevada State Board of Dental Examiners evaluations and were well established when the endoscopy center allegations were first made public.

For dentally licensed OMSs in Nevada, nothing has changed. However, medically licensed OMSs must now acquiesce to the new statutes. Dually licensed Nevada OMSs are wrestling with the issue of being accredited by their dental licensure but still being subject to the medical sovereignty rules. At least 1 OMS has dropped his medical licensure to take full advantage of the time-tested and well-proven dentally related statutes alone.

The present report describes and reviews the experience of 3 of us (D.T., V.N., and T.K.) in achieving accreditation from 3 different accrediting bodies: the Joint Commission (JC), Association for the Accreditation of Ambulatory Health Care (AAAHC), and AAAASF. In addition, we have reported on the effect of the Nevada office-based surgery law in that state. Finally, we have appealed to the leadership and membership of the AAOMS to consider further developing and enhancing the facilities standards by which OMSs deliver outpatient anesthesia in an attempt to avoid losing our ability to offer input on what type of regulations best suits our specialty.

Experience With the JC (David Todd)

I had been vaguely familiar with office accreditation but did not know the details when I began to explore the process. I attended several meetings at which representatives from the JC, AAAHC, and AAAAHF gave an overview of the process, and I bought several accreditation manuals. I became convinced, and remain convinced, that the best method to accomplish accreditation with these entities is through the use of a consultant. Although becoming accredited could be achieved without a consultant, I believe the time required would be prohibitively high. Even working with our consultant, I have estimated that it took me 55 to 60 hours of my time, with a similar time investment from key staff members, to complete the process. My consultant, whom I found very valuable, only works with the JC; thus, I chose this organization to become accredited.

The direct costs of my accreditation were about $24,000, in addition to the time investment and loss of office time. The consultant costs were $12,500, the survey and 1 year of accreditation was $6,900, "credentialing" of me and my certified registered nurse anesthetist was $1,500, and minor equipment changes cost $2,000. The minor equipment changes included more locked cabinets to store medications, locks on closet doors, a new mini refrigerator to store medications, a new crash cart that could be locked, and new batteries for the emergency lighting system. The emergency batteries for the lighting system were still working and testing fine, but the accreditation required they be changed annually.

The JC has 9 chapters[9] (Table 1), which are composed of "standards" and "elements of performance." The standards are descriptions of how the JC wants tasks and goals to be completed, and the elements of performance list the requirements for those tasks. I have included this lengthy list to show the extent of the requirements from this process. The standards closely follow requirements set out by the Center for Medicare and Medicaid Services for management and payment of the inpatient hospital setting, nursing home, and ambulatory surgery facility. Although the JC has had an office-based accreditation program in place for 8 years, our office was only the 400th office

Table 1. JC CHAPTERS

Management of human resources
Improving practice performance
Management of information
Management of medication
Provision of care, treatment, and services
Patient ethics, rights, and responsibilities
Surveillance, prevention, and control of infection
Environment of care
Leadership

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accredited by the JC nationally. The process with the JC is very paperwork intensive and very bureaucratic. Our consultant came to my office for 5.5 days, and we reviewed several chapters at each visit. Our consultant brought a manual with templates on a compact disk for the various policies that were written to meet the standards and elements of performance for the JC. Customizing the policies to try to fit what I do as an oral and maxillofacial surgeon (OMF) was often a frustrating process. Many standards are designed for large institutions with multiple departments and many layers of staffing. Many standards seem designed to show quality, without actually being able to create quality. Table 2 lists our index for our policies and gives an example of the tasks of complying with the JC standards.

One of the most important concepts to understand about office accreditation is that it is an ongoing process. The office must live the "accreditation lifestyle." The standards keep evolving and changing, which means adapting to those changes over time. In addition, regular tasks are required that must be completed on a daily, weekly, monthly, quarterly, and yearly basis. One process that we developed was a "task calendar" (Table 3) listing the various tasks to be accomplished on a regular basis. Assigning staff to perform these regular tasks and documenting them is time-consuming and, initially, very difficult to incorporate into the office routine. Even after a routine has been established, it is easy to defer these tasks because they never seem urgent.

To become accredited, a survey is performed by a surveyor who has undergone training for the role. The first survey occurs on a scheduled date and only examines the policies and procedures that have been created for the accreditation. In addition, 2 patients are "traced" through the office from entry and greeting to discharge. Our survey took place on a day reserved for that process. The surveyor was a very pleasant internal medicine doctor who came to our office at 8 AM and left at 5:45 PM. She outlined a plan for the day, and then she "traced" 2 patients whom we had treated under deep sedation in the office that day. The observation includes all aspects of the care those patients received. The rest of the day involved reviewing our policies and procedures to meet compliance with the standards. She talked to the staff as much or more than she interacted with me. We had 3 minor deficiencies we had to correct.

One deficiency involved not having the proper documentation for 1 of our staff. The staff member had the certification but did not have the document in her file proving her certification. A second deficiency was not labeling the basin on the surgical tray as being for saline. We had put nothing else in the basin, but the standard requires every container to be labeled. The third deficiency involved not having a second control thermopile test for our autoclave. We were performing regular tests, but we did not have a control for the test being performed.

Once accredited, the JC will return sometime between the end of the second year and the end of the third year, with only a 3- to 5-day notice of the visit. The second survey and subsequent surveys are more difficult for offices, because all patient care and procedures occurring within the interval from the first survey are open for review. In addition, all changes made in the standards must be continually updated and modified. When I reviewed my experience with the JC, I found myself frustrated with a process that often seemed inappropriate for a small office (I am a solo practitioner with 6 staff members). The JC accreditation process was designed from their experience meeting the Center for Medicare and Medicaid Services requirements and from experience in dealing with large staffs with multiple department levels in the nursing home and hospital environment. A small office does not have a human resources department, an infection control officer, a medical director, an Occupational Safety and Health Administration compliance officer, an environmental safety officer, and so forth. It is an ideal goal to have the same standard of care whether for a large hospital, nursing home, or small office, but how to accomplish this task?

I have provided some examples from each chapter to help the reader understand where frustration can occur in trying to meet the accreditation standards.

HUMAN RESOURCES

How does one credential oneself? For a solo practitioner, this is a process one must perform for accreditation. One must list the procedures one is competent to perform and then "credential" oneself as able to perform them. In addition, an outside agency must independently review all licenses and certificates to ensure they are legitimate. The credentialing of staff is slightly easier but also involves some imprecise measures of competency. Independent documentation of

Table 2. POLICY MANUAL INDEX

- Human resources
  - Documentation required for nonphysician and LIP hiring
  - Job descriptions and orientation checklist
  - Age-related competency and performance evaluation page
  - Staff education
  - Credentialing and privileging
  - Recredentialing and reprivileging
  - Medical staff focused review
- Improving practice performance
  - Quality and performance improvement plan
  - Patient satisfaction survey
  - National Patient Safety Goals
  - Sentinel events
  - Root cause analysis
  - Failure effects mode analysis
- Management of information
  - Medical records protection and availability
  - Confidentiality and agreement
  - Medical record content
  - Medical record review tool
  - Verbal and written orders
  - Tracking and locating medical records
- Management of medication
  - Controlled drug management
  - Safe medication practices
  - Decreasing medication errors
  - Medication errors
  - Medication error reporting form
  - Medication reconciliation form
  - Medication read back process
  - Medication administration
  - Medication administration labeling/procedure
  - Medication preparation
  - Range and "as-needed" (PRN) orders
  - "Look alike/sound alike" medication
  - Emergency crash carts
- Provision of care, treatment, and services
  - Patient eligibility
  - Patient assessment, reassessment, and allergies
  - Child abuse and domestic violence reporting
  - Education plan and education of patient and family
  - Pain assessment, pain assessment in children
  - Pain scale examples
  - Emergency care
  - Waived testing
  - Discharge policies
- Practice ethics, patient rights, and responsibilities
  - Code of ethics
  - Conflict of interest
  - Decision making
  - Patient rights
  - Patient participation
  - Refusal of care
  - Unanticipated outcome
  - Patient complaints
- Surveillance, prevention, and control of infection
  - Infection control plan
  - Surgical wound infections
  - Communicable infections
  - Infection control strategies
  - Sharps injury form
  - Employee injury and illness
  - Standard precautions
  - Hand hygiene
- Environment of care
  - Patient safety plan
  - Clinical practice guidelines
  - Standing orders
  - Security management plan
  - Hazardous management plan
  - Emergency management plan, drills
  - Fire safety
  - Fire drill
  - Fire safety in oxygen-enriched environment
  - Emergency power systems
  - Maintenance and repair of patient equipment
  - Required life support equipment
- Leadership
  - Provision of patient care
  - Communication process
  - Levels of care
  - Patient safety plan

Abbreviation: LIP, licensed independent practitioner.

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licensing and credentialing seems to be a waste of money but must be done at the beginning of accreditation and then every 2 years. I do not understand why the New York State license is not proof enough

Table 3. TASK CALENDAR EXAMPLES

- Daily
  - Refrigerator temperature check
  - Emergency cart check
- Weekly
  - Emergency generator log
  - Anesthesia checklist
  - Ultrasonic/Codex
  - Clocks
  - Eyewash station flush
  - QI data
  - Autoclave/thermopile
- Monthly
  - Chart reviews
  - Fire extinguisher
- Quarterly
  - Data review
  - Fire drills
  - Medical emergency drills
- Biannually
  - Environmental/safety survey
  - Trace gas analysis
- Yearly
  - Staff appraisals
  - Employee certification
  - Batteries for emergency lighting

Abbreviation: QI, quality improvement.

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that I have a New York State medical and dental license. The documentation of staff education and meetings was relatively easy, but time-consuming.

IMPROVING PRACTICE PERFORMANCE

Some aspects of the chapter on improving practice performance were easy to accomplish but, again, were time-consuming. Internal and external review of the medical records, patient satisfaction surveys, and documentation of these responses is time-consuming and recurrent, monthly and quarterly. The national patient safety goals are laudable and relatively easy to implement. Sentinel events (terminology for a major medical error), root cause analysis (analysis of the cause of the error), and failure effects mode analysis (analysis of a process before an adverse event to identify risk points) are exercises also listed in this chapter.

MANAGEMENT OF INFORMATION

The management of information chapter has a lot of paper governance that is easy to accomplish but time-consuming. I do like the verbal and written order policies that require verbal orders to be transcribed and read back before performing. This helps to prevent errors and makes the staff more accountable.

MANAGEMENT OF MEDICATION

The management of medication chapter had a beneficial effect on medication dispensing and improved our practice in terms of preparation, dispensing, and documentation of the medications. It is a good idea to identify the "look alike/sound alike" medications. However, although we put the policies in place, we found few medications of concern for a specialty practice, such as ours. An area of considerable work has been the medication reconciliation policy, for which each medication that the patient is taking must be listed, as well as the reason, route, dose, frequency, and so forth. This only applies to patients in our practice undergoing sedation or general anesthesia, but it has proved very time-consuming for our staff and has often involved multiple telephone calls to other providers and pharmacies to determine what medications the patients are taking. For patients classified as American Society of Anesthesiologists Class I, this has been easy to perform. For some patients classified as American Society of Anesthesiologists Class II and III, this can be a difficult task to complete.

PROVISION OF CARE, TREATMENT, AND SERVICES

I liked the surgical site marking required in the Provision of Care chapter, and we implemented marking of radiographs electronically to help prevent incorrect tooth extraction. The remainder of the chapter seems to be mainly paperwork, without much benefit toward improving one's practice. Developing educational plans for our patients, documenting pain levels, waived testing (glucometer) staff training and assessment, and the policies for potential victims of abuse seemed to be minimally helpful.

PRACTICE ETHICS, PATIENT RIGHTS, AND RESPONSIBILITIES

Because of the chapter on practice ethics, each patient is asked to read and document that they have read a biography of myself and my key staff, our Health Insurance Portability and Accountability Act policy, a program called "Speak Up" to prevent medical errors, and a patient rights and responsibilities brochure (in addition to our health form and insurance information form). The reaction to patients from this effort has been negative, with many feeling overwhelmed and many feeling we were too "legalistic." Considerable paperwork is devoted to conflicts of interest, decision making, patient rights, refusal of care, and dealing with patient complaints and has been unhelpful.

SURVEILLANCE, PREVENTION, AND CONTROL OF INFECTION

The Surveillance, Prevention, and Control of Infection chapter is a difficult chapter to complete. An infection control officer must be appointed (probably the surgeon), and monitoring policies for risks of infection and strategies to limit infection risk must be created. I found it difficult to find specific data to compare our practice with the "national standards." The remainder of the policies include standard precautions, Sharps injury policies, hand washing, and so forth.

ENVIRONMENT OF CARE

Safety plans, a hazardous management plan, and emergency management plans add considerable paperwork. The emergency policies documenting everything from flood to volcano and rape in the office to bomb threats seem almost silly. None of these policies mandate emergency drills of the sort mandated by our office anesthesia evaluation (OAE) program, such as laryngospasm, airway obstruction, angina, and so on. Some policies seem almost incredible. We were required to test our emergency lighting system and document they were functioning once a month. In addition, the emergency lighting batteries must be changed annually. My electrician has informed me that the batteries are rated for a 7-year lifespan. Given that we have no overnight capability and have outdoor windows in every room and skylights, as well as a natural gas-fired electrical generator with critical circuits wired to it, I found this policy surprising. I appreciated the require-

ment for all equipment to be inspected annually but had already been doing this as a part of the OAE.

LEADERSHIP

The leadership chapter seemed easy to complete, but again seemed to add nothing of value to the practice. Mission statements, value statements, and practice guidelines are inserted to describe the practice to the JC but are ideas inherent to the practice itself.

Experience With the AAAHC (Victor Nannini)

My practice consists of 2 offices approximately 20 minutes apart and includes 7 oral and maxillofacial surgeons. We have full-scope practice, including cosmetic surgery, performed by 2 of our dual-degree licensed surgeons. When New York State passed the New York State Public Health Law Section 230-d Office-Based Surgery, we were concerned that we might be out of compliance once the law went into effect; therefore, my partners and I elected to have our 2 offices accredited by 1 of the 3 national agencies selected by the state government. One of our partners attended a seminar with the AAAHC. He was impressed with their program and believe strongly that we would be able to fulfill their criteria in a timely fashion.

The AAAHC produces a yearly manual[10] that provides standards that apply to one's particular specialty in medicine and dentistry. The manual includes 24 chapters of compliance (Table 4); however, not all chapters apply to oral and maxillofacial surgery. In our case, 13 of the 24 chapters were applicable. Because our knowledge of this process was extremely limited, we elected to hire a consultant who was familiar with the standards associated with this organization. The consultant spent 1 day in our office, surveying our facilities, asking questions about our administrative policies, and formulating a plan for us to implement. This was performed approximately 5 months before our on-site survey. At the initial visit, it was our impression that our offices had been performing sterilization, administration, emergency drills, and anesthesia extremely well. This was supported by our consultant, with some minor corrections. However, the paperwork and procedural plans to actually document that the practice was performing these tasks were inadequate. These were sent to us online by the consultant and included administrative and clinical manuals (Table 5). These manuals had to be adapted to our particular organization, making the appropriate corrections, and implementing these into our daily functions. A medical director was assigned whose responsibility was to oversee that the procedures and administrative tests were performed according to the standards provided by the manuals. This person met with the administrative staff weekly; reviewed each page of the manuals; assigned tasks to be performed by the medical staff, including emergency drills, employee evaluations, pharmaceutical services, office inventory, credentialing of medical staff, quality improvement, evaluation of clinical records, anesthesia services, financial records, and risk management. This process took approximately 5 months, and although the facility size requirements were not an issue, the zoning and fire code requirements and handicapped access were all issues we had to address.

An application of significant detail was required by the AAAHC. This was more than 100 pages and required many hours of work. I did find completing the application helpful in preparing for the survey, because in the process, each of the chapters and their standards were covered. This was completed approximately 2 months before our on-site examination.

To make the appropriate changes, including the consulting fees and facility upgrades, cost our practice approximately $50,000, in addition to the time investment and loss of patient visits. This included a consultant fee of $15,000; an application fee of $635;

Table 4. ASSOCIATION FOR THE ACCREDITATION OF AMBULATORY HEALTH CARE CHAPTERS

Chapters that apply to office-based surgery organizations (core chapters)
Chapter 1—Rights of patients
Chapter 2—Governance
Chapter 3—Administration
Chapter 4—Quality of care provided
Chapter 5—Quality management and improvement
Chapter 6—Clinical records and health information
Chapter 7—Previously professional improvement
Chapter 8—Facilities and environment
Chapter 9—Anesthesia services
Chapter 10—Surgical and related services
Chapter 15—Pharmaceutical services
Adjunct chapters
Chapter 11—Overnight care and services
Chapter 12—Dental services
Chapter 13—Emergency services
Chapter 14—Immediate/urgent care services
Chapter 16—Pathology and medical laboratory services
Chapter 17—Diagnostic and other imaging services
Chapter 18—Radiation oncology treatment services
Chapter 19—Occupational health services
Chapter 20—Other professional and technical services
Chapter 21—Teaching and publication activities
Chapter 22—Research activities
Chapter 23—Managed care organizations
Chapter 24—Health education and health promotion

Data from 2010 Accreditation Guidebook for Office-Based Surgery.[10]

Table 5. TABLE OF CONTENTS FOR ADMINISTRATIVE MANUAL

1. Statement of mission, goals objective, including short- and long-range plan
2. Rights and responsibilities of patients
3. Governance
   - Governing body
   - Organizational chart
4. Administration
   - Performance evaluation and wage and salary guidelines
   - Purchasing and inventory control
   - Accounts receivables
5. Quality of care provided
   - Patient care policies and procedures
   - Medical staff rules and regulations
   - Credentialing policy
   - Guidelines for ambulatory procedure
   - Medical records policy
   - Pathology policy
   - Specimen exemption list
   - Communicable disease policy
   - Patient self-determination
   - Recording of cases of elder abuse and/or neglect
   - Treatment of minors
   - Translation policy
6. Quality improvement
   - Risk management policy
   - Impaired health care professional
   - Incapacitated health care professional
   - Adverse incident reports
7. Professional improvement
   - In-service education
8. Facilities and environment
   - Internal and external disaster plan
   - Safety rules and guidelines
   - Disaster preparedness: fire safety
   - Floor plan for evacuation routes
   - Disaster preparedness: bomb threat
   - Disaster preparedness: flooding
   - Disaster preparedness: wind event
   - Handling spills
   - Water supply policy
   - Preventative maintenance policy
   - Transfer patient policy
   - Cardiopulmonary resuscitation policy
   - Electrical defibrillation policy
   - Patient–practitioner call system after discharge policy
   - Pharmacy services
   - Blood transfusion policy
   - Smoking policy

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our survey fee of $6,120; credentialing of our 7 surgeons; changes to our buildings, including moving fire pull alarms to accommodate people in wheelchairs, signage changes to accommodate potential ambulance arrival, double-locked medication boxes, placement of appropriate fire extinguishers, staff meetings and drills; the purchase of mini refrigerators, and electrical changes, including anesthesia power backup and bell ringing for handicapped patients requiring assistance entering our building. Our consultant returned approximately 2 months after the first visit to review all facility changes, administrative and clinical manuals, and to run a mock survey. This required an entire day and limited the amount of patient contact. Overall, I found our consultant very helpful and, in the long run, invaluable as to the success of our accreditation process. Without her analysis and guidance, it is doubtful we would have been successful.

Our survey was performed during a 2-day period in May 2009. It was performed by a facial cosmetic surgeon. Again, our office had limited patient treatment for these 2 days. I found the surgeon extremely knowledgeable regarding the standards and extremely reasonable in his understanding of outpatient practice. He was very professional and supportive of our approach to the process. All aspects of our facility were evaluated, and the staff members were questioned on the emergency procedures and administrative tasks. We were required to demonstrate procedures on 2 patients, showing our anesthesia techniques, time-outs, equipment used, procedure performed, and recovery with discharge instructions and Aldrete scale. He reviewed our administrative and clinical manuals, employee evaluations, sterilization techniques, 30 charts of sedation, staff credentialing and evaluation, financial records, and emergency drills performed.

At the end of the second day, our evaluator sat down with the administrative staff most involved in the accreditation process and reviewed the findings and provided us with a survey report that covered each chapter of the AAAHC manual. For each chapter, numerous criteria must be met. For each of those, a compliance rating is given. This will be substantial compliance, partial compliance, noncompliance, or not applicable. Along with these compliance ratings, the surveyor can include supporting and summary comments. For us, some included items he found quite acceptable and others needed adjustment. Most of our deficiencies were found in some of the paperwork we had not provided, including a lack of a written grievance policy in both offices, and some problems in charting with reconciliation of medications (6 of 30 charts reviewed). We also did not have a Clinical Laboratory Improvement Amendments of 1988 waiver, required if laboratory testing is provided. We perform human chorionic gonadotropin testing for women of childbearing age scheduled to undergo general anesthesia.

The survey report was sent to the AAAHC and reviewed by the Board of Directors. This group completes the process and makes the final decision regarding the length of accreditation. The AAAHC will provide an accreditation of 6 months, 1 year, or 3

years or, in some cases of noncompliance, a deferred accreditation. They also reserve the right to reinspect an office before the accreditation period because of a significant complaint or adverse event or as a routine audit of 5% of their accredited facilities. We were fortunate enough to receive a 3-year accreditation. However, we always have the possibility of an audit, for which we will have approximately 1 week to prepare. This requires us to daily be in full compliance with the AAAHC standards. In 3 years, when our certification expires, we will be required to follow the 2012 standards and will be responsible for all activities, including charting, medication reconciliation, emergency drills, employee evaluations, minutes of meetings, accreditation of staff, and reporting of adverse events. Unlike our initial survey, all paperwork and charts will be subject to review for the 3-year period. Also, whenever the accreditation term has expired, the practice will be subject to another fee to re-evaluate the organization. Therefore, if one has received a 6-month accreditation, one could be subject to another survey fee. I have included 2 chapters from our survey of the 12 of 24 required for most oral and maxillofacial surgery organizations to give examples of what I believe were the positive and negative connotations for our specialty.

CHAPTER 1—RIGHTS OF PATIENTS

An accreditable organization recognizes the basic human rights of patients.[3]

We all want to treat our patients with respect and dignity. To comply with this chapter, we were required to have patient satisfaction surveys, Health Insurance Portability and Accountability Act forms in every patient chart, locked facilities of the patient charts, patient rights statements presented at both offices, an after-hour telephone number with referral to 911 if life-threatening emergencies occurred, patient responsibility statements, patient financial responsibility statements, and characteristics of our marketing material. Despite the significant paperwork, this seemed reasonable and should be a part of every oral and maxillofacial surgery office. However, we were deficient in the category of advance directives. We have a policy of not accepting advance directives, but did not have a policy of asking every patient whether they had advance directives. Because, for the most part, our patients are healthy, requiring advanced directives for all patients seemed excessive. However, according to the AAAHC, this is a New York Board of Health requirement, not a requirement of the AAAHC. We were also required to have a written grievance policy posted for patients to read. It was not posted in our satellite office, and we had to make this correction.

CHAPTER 2—GOVERNANCE I

An accreditable organization has a governing body that sets policy and is responsible for the organization.[3]

The governing body is a list of the owners and controlling parties in charge of the organization. With small practices, significant paperwork is required, including mission and goal statements, organizational charts showing the relationship between the governing body and various staff administrators and the Medical director; written policies on pediatric patients, including those practitioners who have Pediatric Advanced Life Support (required to be present when pediatric patients are treated); all written minutes of meetings held by the governing body, including any legal or ethical matters concerning the organization; and quality improvement studies and financial records. We were required to have an affiliation with a local hospital for the possible transfer of patients. We were required to have a pharmacy to oversee all drug purchases. A risk management policy must be in place, annual training for staff to meet Occupational Safety and Health Administration requirements, and a documented written policy on adverse incidents, and completed documentation with follow-up and analysis of how to prevent future occurrences. Again, the basic premises of these policies are good, and I believe have made our organization better. However, paperwork involved to show that each of these policies has not only been implemented, but also maintained, is enormous.

CHAPTER 2—GOVERNANCE II, CREDENTIALING AND PRIVILEGING

Credentialing and privileging is a subchapter that describes the credentialing and privileging requirements to provide patient care by our health professionals.[3]

Credentialing is probably 1 of the more difficult processes to comply with, because it seems excessive for most practices. A written credentialing policy must be in effect, including criteria to be appointed or reappointed, along with peer review. All procedures performed in the office must be written out, and each practitioner will request credentials for each. Queries to educational institutions that the practitioner attended, to all government agencies, including the National Practitioner Data Bank, and proof of liability must be documented. This must be performed every 2 years. In addition to the initial efforts and expense to credential each practitioner, a yearly evaluation must be performed that includes the number of patients treated, infection rate, and patient satisfaction results. For single practitioners, I found it ridiculous to credential one's self, especially when few checks and balances are in place.

There is no question that when one is required to specifically consider one's particular practice and how daily operations are performed, significant benefits will result from undergoing the accreditation process. I believe that our organization has improved and that we are more accountable to both our patients and ourselves. However, many of the bureaucratic policies required often appeared redundant and could be considered wasteful in an office setting as small as ours. Credentialing the doctors in a small group appears to be a significant waste of time, especially if they have already been credentialed at hospitals. As can be seen in Table 5, listing the contents for the administrative manual, many policies seem impractical for small groups. Also, tremendous stress is placed on the staff to consistently provide documentation regarding quality improvement, drug reconciliation, emergency drills, chart documentation, employee evaluation, maintenance of facilities, and staff accreditation. Also, the increased expenses must be considered when determining the cost/benefit ratio of this process.

The trend in health care toward increased outpatient treatment will undoubtedly lead to government standards of some sort, such as evidenced by the Government Accountability Office recommendation to the US Department of Health and Human Services.[4] This might require accreditation by national associations. I believe that a compromise between these rigid standards, which appear to work for large organizations and ambulatory centers, and standards suitable for those of us who practice on a much smaller scale, can be accomplished. We should concentrate on optimizing patient safety with strong anesthesia guidelines and with some of the administrative aspects to ensure these guidelines are followed.

Experience With AAAASF (Tim Kelling)

The AAAASF was started in 1980 for the purpose of providing physicians practicing outpatient-based surgery with parenteral anesthesia an option to become accredited for the truly ambulatory setting. Currently, AAAASF has accredited more than 1,000 ambulatory surgery facilities across the United States. From the historical evolution of each agency, I believed that the AAAASF would be the most appropriate choice for accreditation of my practice.

The process of accreditation with the AAAASF can be divided into 3 steps. The entire process took about 3 months. I would estimate that about 5 to 10 hours weekly was devoted solely to the accreditation process. In total, I devoted approximately 80 to 100 hours to the accreditation process, not taking into account a similar investment of time by my office manager. In addition, the surgical assistants spent time with general office organization and helped with the execution of the various elements of the accreditation checklist.

Step 1 involved the application process. We contacted the AAAASF and they sent to the office a "Procedures Manual."[11] Within the manual were various forms to be completed, identifying the practitioner, location, a facility director, Health Insurance Portability and Accountability Act agreement form, along with some other basic information. Each practitioner's license was required, along with his/her board status. A copy of the letter from the hospital granting privileges, with a specific list of the privileges, was required. A basic floor plan of the facility was also needed. Finally 6 completed AAAASF Random Case Peer Review forms, a list of any complications ("unanticipated sequelae"), and the disposition of those complications from a semiannual review were mandatory. These case reviews were submitted on forms provided by the AAAASF. All information can be mailed or sent by facsimile to the AAAASF. The application also required a declaration of the class type of anesthesia for which to be accredited. Class A is local anesthesia. Class B is parenteral anesthesia without the use of propofol. Class C-M allows for the use of propofol. Class C allows for general anesthesia either induced by inhalational anesthetics or a total intravenous anesthetic approach that would likely include propofol.

The application process involved the expense of $1,105 per office (this fee must be paid yearly for each office), accompanied by the optional purchase of a DVD for $950. The DVD provided Word documents that, with minor modifications, could be used for some of the various written protocols required by the "Procedures Manual" (Table 6). This manual was essentially the "cookbook" for meeting all the requirements of accreditation. Questions that arose during the process of satisfying each requirement within the

Table 6. PROCEDURE MANUAL CHAPTERS FOR AMERICAN ASSOCIATION FOR THE ACCREDITATION OF AMBULATORY SURGICAL FACILITIES

General environment
Procedure room environment, policy, and procedures
Postanesthetic procedure recovery area environment, policies, and procedures
General safety in facility
Intravenous fluids and medications
Medical records
Quality assessment/quality improvement
Personnel
Anesthesia
Inspection and self-evaluation

Todd et al. Office Accreditation Experiences. J Oral Maxillofac Surg 2011.

manual were generally answered by the support staff at the AAAASF. Because of the manual, DVD, and accessibility of the AAAASF staff, it was not necessary to hire a consultant for the accreditation process. Although expensive, I found the DVD useful but could have managed without it.

Step 2 involved the execution of the various elements of the "Procedures Manual." This process took approximately 2 months and involved several late nights at the office poring over the manual page by page and chapter by chapter, checking off items. Most requirements in the manual related to anesthesia were already in place because of the AAOMS' mandated anesthesia evaluation. However, this only constituted a very small percentage of the overall checklist. The incorporation of the requirements in the manual in the day-to-day practice was not so much difficult as time-consuming. Written protocols were required for almost every office scenario. For example, protocols were required for bomb threat, tornado, office intruder, special considerations for pediatric patients, room cleaning, and equipment maintenance, to name just a few. We contacted the local ambulance company to evaluate the office for accessibility. This was also done to "prove" that the surgical room dimensions could accommodate the emergency personal, stretcher, necessary equipment, and so forth. The expenditures for office improvement included hospital grade outlets, redundant equipment for sterilization, monitors, lights and surgical suction with battery backup, and construction of doorways to definitively separate the clinical areas from clerical areas. New flooring and painted walls that were easily washed were also needed. Tile required a special nonsilicone-based sealant. Any instrument requiring electricity for patient use was tested by a biomedical technician and required annual evaluation. The office upgrades and expenditures totaled approximately $35,000 to $40,000 for the 2 offices.

Step 3 was the actual inspection, which costs $950 per office. This was followed by a verbal confirmation of accreditation after the accrediting board has met. It can take up to 1 month before confirmation of the accreditation. A surprisingly nondescript certificate of accreditation was sent to each office, indicating a 3-year term and the "class of anesthesia" allowed until the next inspection. However, each 6 months, the submission of peer review and unanticipated sequelae paperwork is required to remain in good standing. Generally, in a group practice setting, this peer and complication review is easily done. As with the JC and AAAHC, ongoing maintenance of the accreditation checklist that will come under scrutiny at the 3-year reaccreditation visit is needed. The AAAASF does not make any surprise or unannounced visits for reaccreditation. The event of office mortality or mortality within 30 days of surgery at the office will trigger an unscheduled re-evaluation of accreditation compliance, preceded by mandatory reporting of that event to the AAAASF.

The standard office inspection took about 1 day for each office. The inspector was a surgical peer who had gone through the same accreditation process. This provided a necessary dose of realism during the inspection. In my case, the physician was a retired plastic surgeon. He was reasonable and realistic. All inspectors have undergone a training program provided by the AAAASF. When the accrediting agency was notified that the office was ready for inspection, an inspector was chosen by the AAAASF, and both parties communicated with each other and arranged for the actual inspection. On arrival to the office, the inspector took a basic tour of the office. No patients were involved in the evaluation. The inspector evaluated the physical space, equipment, medications, emergency policies, and the volumes of policies, protocols, and procedures. A senior surgical assistant, myself, and the office manager were available for questions. I spent the least amount of time answering minor questions compared with my office manager and surgical assistant. All the policies and procedures were organized in a series of binders. My office manager helped navigate this information. During his walk-through, he asked questions about the office cleaning protocols, sterilization, and organization of the rooms. Our surgical assistant was on-hand to answer such questions. The inspector reviewed approximately 6 charts per doctor randomly selected from recent complications that had been encountered in the practice, as well as a basic evaluation of record keeping. If any deficiencies were noted during the inspection process, an opportunity was provided to correct these deficiencies immediately. He did not cite any deficiencies during our inspection but asked that 1 policy sheet on basic life support be clarified. He had completed the evaluation of 1 office within about 4 hours and then decided to also evaluate our other office on the same day. The accreditation inspection started at 8 AM and was complete for both offices by 4:30 PM. We were notified of our passing status about 2 weeks later; however, from the inspector feedback, we had no doubt about the success of the accreditation inspection.

The overall process of accreditation seemed fair and reasonable in retrospect. The paperwork aspect of accreditation was clearly the most onerous aspect of the process. It was my impression that the process for AAAASF accreditation was more manageable than the process for the others, with a similar overall expense, less the consultant. Reflecting on the process as a whole, clear positive and negative aspects were present that would be useful to review for comparison with the other accrediting agencies.

Regardless of the agency, initial accreditation is expensive and time-consuming but, also, quite useful. Therein lies the conundrum of accreditation. Accreditation provided a mechanism for organization of the office at all levels not otherwise possible without the incentive of accreditation and the templates provided by the various agencies.

The sum total in my estimation was positive. The most positive aspects of the experience with the AAAASF was the dose of realism provided by a manageable manual of requirements and the office review by a medical/dental peer, which I believe differed from the other 2 accrediting agencies. A specific useful aspect of the accreditation with the AAAASF was the introduction of the "time-out" pause before beginning a surgical procedure. Although easy to put in place without accreditation, it was not until the accreditation process that this was truly put in place in my offices. As we can all attest, the busyness of a day can result in mistakes. If a procedural pause was a part of each surgery, this could all but eliminate some types of surgical errors. An example of our office time-out routine follows: "This is Joe Smith. He is 18 years old. Joe has no allergies. He has a history of mild asthma. He has no history of anesthetic difficulties. The adult size mask is on the Ambu bag. He is here for the extraction of the upper right third molar, the upper left third molar, and lower right third molar. There is no lower left third molar. I repeat, there is no lower left third molar." This can done by any member of the surgical/anesthesia team for all to hear. Other positives included written protocols for infection control, such as cleaning spills with blood-borne pathogens, procedure rooms, instruments, and so forth, such that all employees, whether experienced or new, very clearly understand the sequence and manner in which these tasks should be performed. The Occupational Safety and Health Administration manual for the office was improved. The Material Safety Data Sheets requirements were updated. Simple mechanisms for monitoring drug expiration and defining very clearly the management and inventory process for controlled substances were improved. Accreditation requires battery backup or generator power for monitors, suction, automated external defibrillator/defibrillator, and lighting. For instance, when was the last time you tested your battery backup? I found that about 50% of the backup batteries were corroded or no longer working. These were changed, with a policy in place for unplugging during the night and recharging during the day to spare battery life and confirm working order daily. Standardization of patient recovery was also a benefit of the accreditation checklist. However, a registered nurse is required for patient recovery, unless the OMS wants to allow the patient to recover to established Aldrete protocols for discharge. Recently, the AAAASF has relaxed this requirement. Surgical assistants who have advanced credentials provided by the AAOMS Anesthesia Assistant Program would eliminate the registered nurse requirement for patient recovery.

Another requirement was to provide procedures for power failure, emergency evacuation of the office, fire drills, and incapacitation of the surgeon. These were just a few of the emergencies for which written protocols were required and that I found beneficial. Some of the emergencies I had not even thought about before I began this process. Emergency lighting and exit signs must be operational in the event of a power outage. In my offices, I found, to my surprise, that many of these things were nonfunctional.

The problem with accreditation, however, is that although many specific useful aspects have been included, many seemingly wasteful and pointless requirements have also been included. One example is the requirement of a disposable grounding pad when using unipolar electrocautery. The Elman electrocautery unit, which many OMSs use does not have a disposable pad. Another is a nonsilicone-based sealer on tile floors if tile is present in the surgical areas. Speaking from experience, whatever the sealer is, it does not last for very long. Additionally, the initial accreditation expense is accompanied by recurring expenses. Every 3 years, the inspection and annual office fee to maintain accreditation for 2 offices will cost about $8,000. A biomedical inspection of every electric device used in the procedure rooms for patient care is required. This includes the electrical outlets, breakers, monitors, automated external defibrillator/defibrillator, electrocautery, curing lights, and so forth and is a recurring yearly expense related to accreditation. This would be particularly expensive for large offices with multiple rooms and/or locations. Outlets cost $10 to $20 each. Other items were $25 to $100 each for inspection. Another expenditure is the requirement for the staff to wear dosimetry badges for radiation exposure. To date, no one in my office has registered anything but negligible.

Typically, most OMSs have succinylcholine on hand for the rare laryngospasm that might require administration to break the spasm. It is written that any agents with any potential for malignant hyperthermia must be accompanied by an immediate supply of 12 vials of dantrolene sodium and another 24 vials obtainable within 15 minutes. The shelf life of dantrolene is rather short, and a vial costs $72. This generally equates to the disposal of at least 12 vials on an 18-month basis or the waste of $1,000. My office has eliminated succinylcholine and switched to rocuronium as a rescue agent for laryngospasm to avoid the need for dantrolene. The rapidity of onset is not as

quick as with succinylcholine, but it is a reasonable option nonetheless.

Finally, a prerequisite for accreditation with the AAAASF is the requirement to have hospital privileges. The specific privilege list at the hospital dictates the allowable procedures in one's office. The multiple policy and procedures that must be in written form for accreditation were so tedious and so numerous that multiple 3-ring binders were needed to collate the information. However, once these policies have been written and in place, they are finished, with only a few modifications needed in the future.

In speaking with my colleagues, it seemed the AAAASF was the most reasonable in their policy and paperwork requirements. In general, it was also my impression that the AAAASF would be less expensive to start fresh with accreditation compared with the other agencies. The AAAASF clearly required less ongoing maintenance to maintain accreditation. The actual office visit for the examination was also less intrusive and seemingly more fair than that by other agencies.

I plan to maintain my accreditation with the AAAASF, although the process has some very clear disadvantages. In the end, the process was worth the accreditation in my estimation. It made my office more organized, and, as a result, I believe this has translated to better and safer patient care.

Oral and maxillofacial surgery might be at a crossroads with regard to our office-based delivery of anesthetic services. Many states are considering requiring additional regulation on anesthesia delivery in the outpatient setting. New York State and Nevada are 2 examples where legislation has been enacted that have affected dually licensed OMSs who practice in those states. The specialty has had an excellent safety record[12-17] and has had a unique history of training and providing safe and accessible anesthesia for our patients using the operator-anesthetist/office anesthesia team model. Most other specialties of dentistry, general practitioners, and other medical specialties have no similar background of training and safety. The stakeholders (patients, the public, regulators, and legislators), however, evidently seem to view all office-based anesthesia providers with a single lens and desire a single standard of care. An adverse event by a medical or dental provider in 1 area of the United States will receive media attention across the country. The OAE program[18] has served AAOMS members well but has some inherent problems. First, the OAE is peer reviewed. Many stakeholders view any industry that regulates itself with some suspicion and view outside review and supervision as more desirable. Second, the compliance with the OAE from state to state has been quite variable. Some states require the OAE as a part of their anesthesia certificate program, with 100% compliance. Many other states, however, have had 40% to 60% compliance within a given period. How can we state we are regulating ourselves with such low compliance on record? Finally, we believe that the OAE is simply not rigorous enough at this time to protect our profession from more regulation and oversight. A review of Tables 1 to 6 will demonstrate how differently the accreditation process is from our OAE program. The time has come for our leadership and membership to design a program that will satisfy the stakeholders and our membership that we are performing safe and accountable office-based anesthesia. We believe we are only 1 adverse event away from losing the ability to give input for our future of anesthesia delivery.

In addition, major practical questions come to mind secondary to the New York and Nevada experience. For instance, what exactly will the new legislation do for the citizens of these 2 states? Will the quality of care in the outpatient setting be improved over time? What is the effect of the cost burden because of these regulations to practitioners and patients who reside in these states? What will be the effect of access to care because of these cost burdens? Will practitioners choose other states to practice where such requirements do not exist? These are difficult questions to answer, and, realistically, no one knows the answers. It has been widely recognized that the dental model is remarkably efficient and second to none as far a positive results, all at a significant fiscal and temporal savings compared with the new, frankly experimental, medical model.

We all believe some aspects of the accreditation process improved our practices. We also believe, however, that if we have a choice in oral and maxillofacial surgery to shape our future, the current accreditation process is not the model that should be used to improve patient safety and increase accountability to the public and regulators for the future. Although various aspects of the accreditation program were beneficial, a large portion seemed to be bureaucratic paperwork that did not improve patient care and safety and missed what we would consider essential elements of our OAE program. The policies were designed for large institutions with multiple staff layers and to meet the Center for Medicare and Medicaid Services requirements. Clearly, some states have viewed the 3 accrediting agencies as the most desirable methods to increase the standards for anesthesia delivery.

What other avenues are available? One might be to work with the 3 accrediting bodies to tailor the process to meet the needs of the OMS. Who knows better about what OMSs do than an OMS? This is an approach that has been taken by the New York State Society of Oral and Maxillofacial Surgery. The New

York State Society of Oral and Maxillofacial Surgery worked with the AAAASF to develop an accreditation process that meets our needs and satisfies their requirements. The AAAASF was chosen because it was the most open to the idea of developing such a process. The AAAASF was amenable to developing specialty specific modifications and was more able to do so, because it had developed a better understanding of the operator-anesthetist model. Another avenue might be to further develop the OAE process to include a more stringent program that could then be administered by an independent group that could have some input or oversight by the AAOMS to meet the members' needs. Much as the American Board of Oral and Maxillofacial Surgery is to board certification, the process of accreditation could be peer driven in an equally stringent and formal way. This process could take some time to develop and would incur development costs. Currently, a committee created by the AAOMS is examining the options for moving forward with a variety of scenarios.

The experience in New York, Nevada, and other states, where increasing regulations have appeared, is a warning to our specialty that times are changing with regard to the attitudes of stakeholders toward outpatient anesthesia. The nation seems to have entered a period of increased public acceptance of unprecedented government intervention in many aspects of our lives. In addition, with budgets in many states with historic deficits, the income from inspection and licensing fees might seem more appealing than ever to state regulatory agencies.

Organized OMSs need to act quickly to lead the discussion of safety in our offices and increase the standards by which we operate. No doubt, some members will question the threat to our specialty and will oppose increasing our requirements. We believe that if we do not act, we might very well lose the ability to provide meaningful input for our profession. Once regulation is in place, it requires considerable financial and political effort to retroactively mold the process and will inevitably lead to compromise on key issues. This phenomenon has been seen in New York State with the scope of practice. It is time for our specialty to lead and take action on this vital aspect of every OMS practice.

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