OFFICE-BASED ANESTHESIA: REQUIREMENTS FOR PATIENT SAFETY

INTRODUCTION

Thank you for honoring me with your Society's Heidbrink Award. It is a humbling truth, however, that as I look back on my 45 years of practicing anesthesia, I feel ill prepared to become clairvoyant regarding the newest and latest things that will advance our practices to the next level of patient care. Many changes have occurred in our practices over the past decades. These include technical, socioeconomic, and cultural changes. Also, for the most part, each subsequent change is a little more complex than its predecessor. However, the question remains: have changes been made for the betterment of patient care, or for the benefit of the healthcare industry?

THE GOOD OLD DAYS

As I reflect on my years of practicing anesthesiology and how I have had the opportunity to interact with you in the dental profession, I have come to realize that some of the more positive changes in our professions have focused on patient care. Furthermore, these positive changes have often evolved as a result of the changing culture of our practices as they relate to regulatory and socioeconomic forces. By virtue of our professional oaths, as well as statements of practice ethics, we can see that the changes of improved patient care are not all scientific, but are also directed toward improved patient safety. I will concentrate, therefore, on some areas of change in our practice over the past few decades that have enabled us to significantly improve patient safety.

A major impetus for changes in patient safety is a result of change in our society and its propensity for computers and the Internet. The Internet and the media are making the public much more knowledgeable and sensitive to our procedures and treatments. They are now self-educated experts in many areas of healthcare, especially attuned to the risks as well as the benefits. Our legal profession, politicians, and citizen advocate groups have also continually educated the public about

what they have a right to expect as a level of care and safety, and what their recourse is should there be adverse outcomes of treatment.

All consumers of healthcare question whether "all is safe" in their doctor's or dentist's office, and ask, "Who will see that it is safe?". In response, practitioners have established practice changes by their own volition and with the help of their professional organizations. Simultaneously, politicians have instituted government agencies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), as well as Health and Human Services regulations. This, in turn, has led to investigations and further development of rules and regulations related to patient safety. These external agencies define safe practices, then pass this information on to professional liability insurance companies, state licensing boards, and payors of health care with the mandate of compliance by the healthcare providers.

Compliance has now become a major focus of our practices, resulting in increases in administrative help in filling out a multitude of bureaucratic forms and consents. At the same time, reimbursement has become increasingly complex as the public and private payors request more and more documentation for determining qualifications for partial or full payment for services. The result has been further increase in practice expense; worse yet, failure to comply with all of these regulations subjects that practice and/or practitioner to legal action for malpractice or fraudulent billing activity.

PRACTICE AND IMPROVED PATIENT SAFETY

Fortunately there is significant improvement to patient safety through understanding and complying with many of those imposed rules and regulations. Generally speaking, there are 3 areas of practice where we need to ensure continued and effective patient safety.

Practice Location

It turns out that a major factor lending to some unsafe practices is practice location. When my generation of anesthesiologists entered practice our choice of location was exclusively in a hospital setting. In most hospital settings, the equipment, supplies, and supporting administrative and clinical staff were provided by the hospital. May I now take the liberty of contrasting that with the dental practice at the same time? My sense is that few to none of your practices were hospital-based, and

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that out of your practice income you had to provide for all of your needs: clinical and administrative staff, equipment, and office overhead. Furthermore, your standard of patient care depended solely on your personal training and practice ethics. Ergo, there were few risks of legal, fiscal, or regulatory agencies looking over your shoulders to judge the quality of your care.

Today, however, practice location impacts significantly on all of us. As surgical practices have become more intertwined, we find that more and more anesthesia services are being required in other areas of the hospital, ambulatory surgical centers, and what is euphemistically called office-based surgery. The result has been that anesthesiologists brought expectations about their hospital equipment, personnel, AND rules and regulations into the private office location.

Equipment and Personnel

Therefore, a change in practice location, as it relates to equipment and personnel, became an anesthesia issue. As surgical practices became ever more complex, there was an increasing need for the presence of an anesthesiologist or dedicated trained anesthesia provider. Understandably, a profession such as yours, responsible for providing all of its own safe anesthesia from time immemorial, would feel less pressure to adopt practice standards and requirements that the anesthesia community was endorsing. Probably, a major issue in this blending of practices was reaching agreement on the cost/benefit ratio for these practice changes. The office provider was confronted with increased costs through equipment and personnel needs and the anesthesia provider was faced with potential increases in medical liability, denied reimbursement, and mandatory practice standards. I'm happy to say that I believe our professional societies and their memberships have come together in a very respectful and professional way to develop some excellent practice guidelines, which have been emulated by a number of other professional groups. Having said that, there still remains the need to collaborate on the socioeconomic and ethical areas of our practices. The judgment of how well we are doing, regrettably, still rests in the hands of the auditing agencies, lawyers, patients, and the media.

Practice Standards, Policies, and Procedures

The inception of the third party scrutiny began in the mid-1960s, when health insurance companies and Medicare began to pay for health care instead of the patients themselves. Logically, they created certain requirements (aka, rules and regulations) for both patient

and provider if they were to qualify for reimbursement. As the science and technology and medicine grew along with an inflated national economy, the costs of health-care became increasingly unaffordable for the third-party payors as well as the patients. As the rules became more rigid, reimbursement began to decrease and compliance became an issue. Lawyers and auditors from the regulatory bodies emerged to investigate the alleged fraud that began to occur from the provider community. The media also began to explore and expose the ethical questions that arose about malpractice by some providers. The outcome was the realization on the part of the professional communities that they needed to do a better job of policing themselves. The major incentive, really, was a result of the increasing numbers of malpractice suits along with larger and larger settlements and the inflationary response on premiums by the malpractice insurance companies. All of this ultimately created the first of several recurring "malpractice insurance crises" across the country. Many insurance companies dropped their coverage of medical malpractice completely and others responded with prohibitive premium costs. This demand for improved quality of care resulted in many professional medical and dental societies writing standards of practice for the various aspects of their practices where the largest numbers of adverse circumstances had occurred. This activity did improve our level of patient care and led to the realization that it wasn't just a better therapeutic outcome, but also a decrease in adverse events, ie, increased patient safety, that was important. This in turn led to a return of insurance coverage and reduced premiums for many of the medical specialties.

Obviously, the creation of standards and guidelines is a large and complex area of our practices. I would, however, like to focus on 2 or 3 specific guidelines that are currently being advocated, scrutinized, and/or mandated by the public, legislatures, licensing boards, and pharmaceutical companies.

Competing professional groups, primarily the non-physician allied health care providers who are usurping more and more authority from the physician and dental professions, have also resisted our writing guidelines that impact on their current practices. The conflicts among the various healthcare providers is less about quality of care and more about independent practice, economic, and restraint of trade issues. Legislative bodies and the courts often have to resolve when patient safety is compromised by parties writing watered down guidelines in an attempt to cut costs and preserve income.

Guidelines for "Off-site" Sedation and Anesthesia. As mentioned earlier, more and more an-

esthesiologists have extended their practices into “off-site” (nonhospital) locations. First, ambulatory surgery centers were created for multispecialty surgical procedures not requiring postsurgical hospitalization. Anesthesiologists were usually involved in the creation of these entities so they had input (often financial) into equipment, supplies, employment of clinical personnel, and policies relating to pre, intra, and postoperative care. As other office-based practitioners (eg, oral surgeons, radiologists, dermatologists, and general surgeons) began to do more complex procedures, they chose to continue doing these procedures in their offices rather than transfer their procedural practices to ambulatory surgical centers or to expensive and crowded hospital operating rooms. A critical issue of this practice change focused around the need for varying degrees of patient sedation commensurate with the complexity of the procedures. As duration and intensity of procedures increased, so also did the need for deeper sedation, increased analgesia, and/or intermittent general anesthesia. Also, many of these patients had significant health problems and required constant monitoring. Logically, the need for trained people and appropriate equipment to monitor the levels of consciousness increased, commensurate with the pharmacologic side effects that lend to the increasing loss of cardiorespiratory and CNS reflexes. Since hospitals and ambulatory surgical centers already had most of the equipment, monitors, and surgical/anesthesia assistants available, it only required that guidelines for the safe administration of sedative and analgesic drugs be developed.

Guidelines for Conscious Sedation, Deep Sedation, and General Anesthesia. The earliest efforts at defining the levels of sedation occurred more than 2 decades ago. As hospital-based medical specialties, eg, radiology and cystoscopy, began to use more complicated equipment for more complex procedures, it became increasingly difficult for them to schedule such procedures in the surgical operating room where all of the surgical and anesthesia equipment and personnel were available. Conversely, trying to schedule such procedures in their areas using surgical and anesthesia personnel created tremendous logistical and scheduling conflicts. It became a form of “taking the mountain to Moses.” Not surprisingly, more and more often these specialists decided to do the procedure alone with their equipment and personnel with the rationale that many procedures were short enough and not sufficiently painful to justify their going to the ORs or to schedule anesthesia coverage. Unfortunately, many of those areas were too small and ill-equipped for good patient care and safety. As adverse events began to occur, it was the hospital medical staff committees on credentialing, op-

erating room policy, and professional liability that began to develop and implement various practice guidelines for conscious sedation in select practice circumstances and locations. Central to the success and enforcement of these guidelines was the need to train both physician and nonphysician providers in areas of sedation and anesthesia, especially as they relate to cardiorespiratory monitors, preoperative patient evaluation, and basic airway management. First, compliance was obtained through hospital privileges and provision of professional liability insurance. Within the past decade, the JCAHO has required hospitals and then ambulatory surgical centers to have established guidelines of sedation, with the requirement that all who participate in administration of sedation be certified as having been trained in same. As hospitals, professional liability insurance companies, and regulatory bodies reviewed the results of these guidelines, data emerged to suggest that there were fewer adverse events associated with these procedures, and even better, that improved patient safety translated into shorter length of stay in hospitals and reduced hospital costs.

In early 1990, the American Society of Anesthesiologists (ASA), through a Committee on Patient Safety, began an extreme review of closed malpractice claims relating to anesthesia practices. As certain areas of practice emerged as problematic, the committee referred their observations to another committee of ASA responsible for developing a number of practice parameters and standards for specific issues. Deliberations are made by an expert panel in each particular discipline. They have done extensive statistical review of the literature for the preceding years and made recommendations based on scientific findings. This patient safety activity has led to the very successful creation of the Anesthesia Patient Safety Foundation (APFS), which has captured the support and endorsement of not only other medical societies, but of the medical equipment and pharmaceutical industries, insurance companies, and federal agencies. Within the past 5 years, the American Medical Association has developed a similar patient safety program. The credibility of this foundation and the practice guidelines it has adopted has led to a number of other professional organizations such as the AMA and American College of Surgeons to adopt those guidelines for their practices as well.

Guidelines for Office-based Anesthesia. As more hospital-based surgical procedures became very complex and time consuming, (eg, liver and heart transplants), more specialties of medicine and dentistry began doing more routine surgical procedures in their offices. This rapid rise in office-based procedures also arose as an outgrowth of the escalating costs of health

care in general. Hospital costs became an unaffordable part of many health insurance policies and put stringent restrictions on the reimbursement of “elective” procedures. This was equally true of routine diagnostic studies. Elective plastic/cosmetic surgery was poorly covered by most insurance companies. Furthermore, inflated malpractice premiums forced many young practitioners to go without insurance. Economic survival for some resulted in their seeing more patients who were poorly evaluated for underlying medical problems and sometimes cared for in poorly equipped and staffed medical offices. Once again, the result was a compromise on patient safety with some patient mortality that caught the attention of the media as more and more complications resulted in newsworthy malpractice cases.

Coinciding with the economic push and bad publicity for office-based procedures was the increasing activity on the part of the anesthesia community and the traditional office-based practitioner community to increase the volume of their procedural practices in a safe, efficient, ethical, and affordable way. As discussed earlier, the critical area of patient safety is that of providing safe sedation to higher risk patients undergoing longer and more complex procedures requiring deeper levels of sedation up to and including varying periods of general anesthesia. Many office practices were not equipped with the necessary anesthetic and monitoring equipment for those kinds of procedures nor were they staffed with additional and trained personnel to provide safe sedation and anesthesia. Appropriately, more anesthesiologists included these office-based practice sites into their anesthesia practice (sometimes even as practice partners) and assisted those practitioners in developing guidelines for office-based anesthesia.

Once again, it was the public, patients, malpractice lawyers, and the media that brought enough pressure to bear that many state governments and regulatory agencies passed laws relating to office-based practices with emphasis on sedation and anesthesia care. The good news from this public outcry, which was directed at a few isolated practices, was that organized medicine (through its specialty societies) had already taken the lead in developing standards for office-based anesthesia, just as the standards were developed for sedation. Subsequent to the development of the “Guidelines for Office-Based Anesthesia” in 1999 by the ASA, the ADA and the AMA have also endorsed these guidelines in one form or another.

I would be remiss if I didn’t make special mention of the exemplary efforts in patient safety of your 2 organizations from the earliest days of the use of office sedation. You probably have more experience in this field than many of the medical specialties combined. I have read most, if not all, of the standards and guidelines put

out by the ADA, and also the extensive training you are required to have before doing all levels of sedation in your offices. The training courses and the certification you require of your practitioners exceed most of those required by hospitals and specialty societies. I’m certain your outstanding patient safety record is due, in large part, to your attention to these standards of safe practice.

Litigation and Reimbursement

I have saved the most confusing and frustrating issues involving our professional practices until last, and will only briefly address those that impact the physician-patient relationship as it relates to optimal patient care. Health care has become one of the greatest socioeconomic issues our society has had to deal with. It has determined presidential and governmental outcomes, whether it be Social Security, Medicare, or welfare. As we have extended our life expectancy to the mid-70s, we have a growing population of sicker people demanding more and more care and resources. (In Rwanda, the life expectancy is 50 years for female and 48 for males—they realize they cannot be immortal). The pressure to provide more and more service/care to more and more people for less and less reimbursement is gradually forcing the professional to cut corners and work longer hours, all with decreasing levels of reimbursement from third-party payors. In the meantime, office overhead, liability insurance, and payroll costs increase. It sounds exemplary, on paper, to become rigid about compliance with the rules and regulations of the watchdogs of healthcare, but it is pushing the limits of the profession to uphold the same high standards of care. We must work together to preserve our professional ethical standards of practice, *primum non nocere* (first do no harm), and refuse to care for any nonemergent patients unless we can do it safely and to the best of our ability.

CONCLUSION

I have endeavored to reflect on 45 years of my practice of anesthesia as it has touched on private and academic practice, as well as medical education for students, residents, CME, and third-world teaching programs. I have enjoyed being a part of medical and government politics at the state and national levels. Now I find myself involved in international societies and have the opportunity to make so many comparisons of each aspect of our various lives and cultures and to understand how health and life are viewed for all citizens of the world and not just for me.

Each healthcare provider, physician, dentist, and all other healthcare professionals have studied and learned how to apply their training to the betterment of their patients. As our immediate past president of ASA said this year in his address to our House of Delegates, "It's all about the patient." Our social, political, and professional energies should be directed toward protecting our rights to give up-to-date safe patient care. We must remember that quality of care requires up-to-date physical resources and the knowledge to give our patients our best. Patient safety is an increasing part of that care.

However, doing nothing might sometimes be the safest thing to do. Judgment and ethics must accompany a high level of knowledge. Quantity is not quality!

Thank you for inviting me to share these reflections with you. Wherever you are in your practice, keep up the good work in protecting and advocating our respective contributions to our patients' health. There is no better reward.

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