

# Patient Safety in Office-Based Surgery Facilities: I. Procedures in the Office-Based Surgery Setting

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### TASK FORCE STATEMENT

At the ASPS Annual Meeting in October of 2000, the ASPS Board of Directors convened the Task Force on Patient Safety in Office-based Surgery Facilities. The task force was assembled in the wake of several highly publicized patient deaths, increasing state legislative/regulatory activity, and a moratorium on all level II and level III office-based surgery in the State of Florida. The task force faced a daunting task.

The first area the task force focused on was collecting, evaluating, and reporting the health policies, accreditation standards, state legislation/regulation activities, and publications that influence the delivery of health care in office-based surgery facilities. With the information gathered, the task force produced several documents, starting with an accreditation crosswalk table that contrasted the office-based surgery standards of the three nationally recognized accrediting agencies. The task force also built a database to track state office-based surgery regulations, which was used as a resource to draft office-based surgery model legislation/regulation. The accreditation crosswalk and model legislation/regulation were placed on-line for members and have been widely distributed to national, state, and specialty medical organizations and state medical boards.

The second area the task force tackled was the development of office-based surgery guidelines. After an extensive review of the existing guidelines and scientific literature, it was deter-

mined that few materials met the scientific rigor necessary to establish clear standards of practice. Therefore, the task force determined that it would be more appropriate to develop office-based surgery practice advisories, which are defined as systematically developed reports intended to assist decision-making in areas of patient care in which scientific evidence is insufficient.<sup>1</sup> The advisory is based on the best information available and largely reflects the collective opinion of the members of the task force.

The task force included representatives from related plastic surgery organizations and the American Society of Anesthesiologists and included Ronald E. Iverson, M.D., chair; Jeffery L. Apfelbaum, M.D., American Society of Anesthesiologists representative; Jack G. Bruner, M.D., ASPS Liposuction Task Force representative; Bruce L. Cunningham, M.D., ASPS/PSEF Joint Outcomes Task Force representative; Richard A. D'Amico, M.D., ASPS representative; Thomas Joas, M.D., American Society of Anesthesiologists representative; Victor L. Lewis, Jr., M.D., ASPS Health Policy Analysis Committee representative; Dennis J. Lynch, M.D., ASPS representative; Noel B. McDevitt, M.D., ASPS Deep Vein Thrombosis Task Force representative; Michael F. McGuire, M.D., ASAPS representative; Calvin R. Peters, M.D., Florida Ad Hoc Commission on Patient Safety representative; Robert Singer, M.D., American Association for Accreditation of Ambulatory Surgery Facilities, Inc. representative; Rebecca S. Twersky, M.D.,

American Society of Anesthesiologists representative; and James A. Yates, ASAPS representative. I would like to thank members of the task force for the insights they brought to this process. The final document represents their significant contributions to these efforts. I would also like to recognize DeLaine Schmitz and Pat Farrell of the ASPS staff for their work in support of this project.

—*Ronald E. Iverson, M.D.*

#### INTRODUCTION

Our current health-care delivery system has become increasingly complex, making it possible to deliver health care which is technically superior to that previously offered. This is particularly true with regard to surgical services that are delivered in the outpatient setting. In fact, most surgical procedures are performed in one of three outpatient settings: hospital-based, free-standing ambulatory surgery centers, or office-based surgery facilities. The office setting, in particular, has many advantages for both the plastic surgeon and his or her patients. These advantages include greater control over the schedule, greater privacy for the patient, convenience, and increased efficiency and consistency in nursing staff and support personnel.

Even with the increased demand for ambulatory surgery services, little scientific evidence is available regarding patient safety issues in the ambulatory surgery setting and even less that specifically addresses the office setting. The majority of clinical research and scientific literature published on ambulatory surgery has been completed in the hospital-based ambulatory surgery setting. Research and published materials from the hospital-based ambulatory setting were used extensively in the development of this practice advisory; although the setting is not identical to that of the office, it is the most applicable.

Because many factors affect safe outcomes in the office setting, the Task Force determined that at least four advisories should be developed. The first, Practice Advisory for Procedures in the Office-based Surgery Setting, will be followed by advisories that address appropriate patient selection, anesthesia services, and pain management in the office setting.

The Practice Advisory for Procedures in the Office-based Surgery Setting, approved by the ASPS Board of Directors in November of 2001, identifies a variety of issues that are common to

most plastic surgery procedures but vary relative to the specific procedure performed. The numerous procedure-specific issues were divided into categories that include physiological stresses associated with surgical procedures, thromboprophylaxis measures, potential post-operative recovery problems, provider qualifications, and surgical facility standards. This advisory provides a synthesis and analysis of expert opinion, clinical feasibility data, open forum commentary, and consensus surveys.<sup>1</sup> It is based on the best information available and largely reflects the collective opinion of the members of the task force.

#### DISCLAIMER

Practice advisories are strategies for patient management developed to assist physicians in clinical decision-making. The Practice Advisory for Procedures in the Office-based Surgery Setting, based on a thorough evaluation of the current scientific literature and relevant clinical experience, describes a range of generally acceptable approaches to the diagnosis, management, or prevention of specific diseases or conditions. This practice advisory attempts to define principles of practice that should generally meet the needs of most patients in most circumstances. However, this advisory should not be construed as a rule, nor should it be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the appropriate results. It is anticipated that it will be necessary to approach some patients' needs in different ways. The ultimate judgment regarding the care of a particular patient must be made by the physician in light of all of the circumstances presented by the patient, the available diagnostic and treatment options, and the available resources.

This practice advisory is not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all facts or circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve. This practice advisory reflects the state of knowledge current at the time of publication. Given the inevitable changes in the state of scientific information and technology, periodic review and revision will be completed.

### PHYSIOLOGICAL STRESSES ASSOCIATED WITH SURGICAL PROCEDURES

There are few data to support the exclusion of specific procedures from the office setting. Nevertheless, the potential physiological stresses caused by hypothermia, intraoperative blood loss, liposuction in combination with multiple procedures, and the duration of the procedure(s) should be considered when selecting the appropriate facility setting.<sup>2</sup>

#### *Hypothermia*

Hypothermia can be a potentially serious complication of office-based surgery. Both regional and general anesthetics markedly impair the normal precise regulation of core body temperature. Hypothermia develops because the typical operating room environment is cold; however, it is anesthetic-induced impairment of thermoregulatory responses that contributes the most to this condition.<sup>3</sup> The degree of hypothermia is a significant concern with regard to infection and safety of anesthetic management. Studies indicate that hypothermia may directly impair neutrophil function or impair it indirectly by triggering subcutaneous vasoconstriction and subsequent tissue hypoxia.<sup>4</sup>

**Recommendation:** The office surgery suite must be equipped so that temperatures can be adequately monitored and adjusted; equipment should be available to warm the patient, including such cutaneous warming devices as Bair Huggers (Augustine Medical, Eden Prairie, Minn.), forced air warming blankets, and intravenous fluids warmers, as necessary. Without such hypothermia prevention measures, the procedures performed should be of short duration (1 to 2 hours) and limited to no more than 20 percent of the body surface area.

#### *Intraoperative Blood Loss*

Significant intraoperative blood loss can lead to an unstable condition in the patient postoperatively and an unplanned hospital admission.

**Recommendation:** Procedures on the average-size adult patient with 500 cc or greater anticipated blood loss should be performed only in facilities where adequate blood and blood components are readily available.

#### *Liposuction in Combination with Multiple Procedures*

The cumulative effect of multiple procedures performed during a single operation in-

creases the potential likelihood that complications may develop.<sup>5</sup> Nevertheless, many combined plastic surgery procedures are routinely and safely performed in office settings. Some combination plastic surgery procedures are more controversial. For example, restricting liposuction in combination with multiple unrelated procedures has been the topic of many debates. Certain measures have been implemented at the state level to address this issue with regard to liposuction. For instance, the State of Florida has determined that "Liposuction may be performed in combination with another separate surgical procedure during a single level II or level III operation, only in the following circumstances: when combined with abdominoplasty, liposuction may not exceed 1000 cc of aspirant; when associated with or directly related to another procedure, liposuction may not exceed 1000 cc of aspirant; and major liposuction (in excess of 1000 cc aspirant), may not be performed in a remote location from any other procedure" (Florida Board of Medicine 64B8-9.009 Rule. Standard of Care for Office Surgery, February 27, 2001). Some data support these limitations; however, the data tend to be anecdotal or in studies lacking the level of rigor necessary to establish clear standards of practice.<sup>5</sup>

**Recommendation:** The presumed benefits of combining procedures, particularly liposuction, must be weighed against the possibility of adverse events. It is the position of ASPS that liposuction can be performed safely in the office setting when done in accordance with ASPS recommendations to limit total aspirant (supernatant fat and fluid) to 5000 cc or less.<sup>6</sup> When large-volume liposuction is combined with certain other procedures, such as abdominoplasty, serious complications have arisen.<sup>5,6</sup> Therefore, it is recommended that such combination procedures be avoided.

#### *Duration of Procedure(s)*

In the selection of a plastic surgery procedure for the office setting, there are few prospective data and mostly conflicting opinions on the importance of surgery duration alone as a predictor of adverse outcomes. Most plastic surgery procedures typically performed in an ambulatory setting take longer than 1 hour to complete. These procedures include face lifts, rhinoplasties, breast reductions, mastopexies, liposuctions, and abdominoplasties. It is not uncommon for several plastic surgery proce-

dures to be performed during the same operative period, increasing the total duration of the surgery. In some studies, the duration of surgery does seem to correlate with adverse outcomes. In the anesthesia literature, Mingus et al.<sup>7</sup> suggest that any procedures extending beyond 1 hour correlate with a higher rate of postoperative admission. This may be a direct function of the procedure or it may relate to the procedure being more extensive than initially anticipated.

Fogarty et al.<sup>8</sup> compared three categories of reconstructive plastic surgery that often last longer than 6 hours: head and neck, breast reconstruction, and upper and lower limb surgery. Despite having a similar mean duration of surgery, the differences in postoperative complications among the three groups suggest that the duration of surgery alone is not a major determinant of postoperative morbidity and that the type of surgery performed and the patient's general health are more important predictors of outcomes. More extended procedures are likelier to produce postoperative nausea, vomiting, bleeding, and excessive pain, warranting overnight stay.<sup>2,9,10</sup> Several studies indicate that patients whose surgical procedure ended after 3 PM have a higher incidence of unanticipated admission than those whose surgery ended earlier.<sup>9</sup>

**Recommendation:** It is important to schedule long procedures sufficiently early in the day to allow for adequate recovery time before discharge.<sup>7</sup> If possible, the surgery should be completed by 3 PM to allow adequate time for recovery and discharge. Ideally, the overall duration of the procedure(s) should be completed within 6 hours. Although many plastic surgery procedures have proved safe in the office setting, attention to patient selection, intraoperative management, and postoperative care is of particular importance when procedures of longer duration are to be performed in the office setting.<sup>2,10,11</sup>

#### THROMBOPROPHYLAXIS MEASURES

The potential to develop deep vein thrombosis and pulmonary embolus remains a small but significant risk for surgical patients. Little information exists on the incidence of these events in office settings specifically. In 1998, the ASPS convened a task force to review this issue.<sup>12</sup> Various factors were identified that predispose a patient to deep vein thrombosis and pulmonary embolism. These include genetic

or acquired factors, antiphospholipid syndrome, and homocystinemia. Also, women with a current or recent history of contraceptive or postmenopausal hormone replacement use are at increased risk.

A careful diagnostic history is very important to identify the risk factors for deep vein thrombosis. The detailed personal history should include inquiries about a history of deep vein thrombosis, along with questions about unexplained episodes of syncope, dyspnea, or pleuritic pain that could indicate past pulmonary embolus or hypercoagulable states. A review of medications should be included, particularly with respect to contraceptives or replacement hormones. Of equal importance is a detailed family history of thrombotic events or hypercoagulable states, including any associated with hormone use.

During the physical examination, particular attention should be paid to edema, swelling, or other signs of venous insufficiency, especially in the lower extremities. Tenderness in an extremity in the absence of trauma, infection, or other obvious cause may signal an existing thrombotic problem. Skin discoloration, ulceration, and neuromuscular defects should be investigated. Laboratory screening is not recommended in the absence of physical symptoms or significant history. After the history, physical examination, and any pertinent laboratory screening, patients should be assigned a risk status of low, moderate, or high and thromboprophylaxis measures should be implemented accordingly.

#### *Risk Rating for Thrombosis or Embolism*

- **Low-risk:** Patients who face uncomplicated surgery and have no risk factors. These patients are usually under 40 years of age, although older patients undergoing short procedures may qualify.
- **Moderate-risk:** Patients 40 years and older who have no additional risk factors but who face procedures longer than 30 minutes. Patients who use oral contraceptives or are on postmenopausal replacement therapy are also at moderate or greater risk.
- **High-risk:** Patients over 40 years of age with at least one risk factor who face procedures over 30 minutes or longer under general anesthesia and/or have other risk factors.

*Thromboprophylaxis Measures for Risk Ratings*

- Low-risk: Comfortable positioning on the operating table with the knees slightly flexed. Constriction of the extremities and external pressure should be avoided.
- Moderate-risk: In addition to the recommendations for low-risk patients, intermittent pneumatic compression devices of the calf or ankle and frequent alteration of the operating room table are recommended. The devices should be in place before the induction of general anesthesia, and their use should be continued until the patient is awake and moving in the recovery unit.
- High-risk: In addition to all recommendations for low-risk and moderate-risk patients, both a hematology consultation and preoperative/postoperative pharmacologic antithrombotic therapy should be considered.

Recommendations: As part of the patient history and physical examination, attention should be paid to factors that predispose the patient to thrombosis or embolism, including:

- patient history, including the use of contraceptives and hormone replacement
- family history, with attention to past episodes of thrombosis or embolism
- genetic disposition to clotting disorders
- edema, swelling, or other signs of venous insufficiency in the lower extremities.

On the basis of this information, patients should be categorized as low-risk, moderate-risk, or high-risk, and thromboprophylaxis should be implemented accordingly.

#### POTENTIAL POSTOPERATIVE RECOVERY PROBLEMS LEADING TO UNPLANNED HOSPITAL ADMISSIONS

A review of 1971 postoperative cases by Levin et al.<sup>13</sup> found that 9.5 percent of unplanned hospital admissions resulted primarily from dizziness, pain, and nausea/vomiting. In their study, these symptoms were not correlated with the patient's age. Other studies have demonstrated that pain, in particular, may be dependent on the type of procedure, body mass index, or extent of the anatomical area of involvement. This may be attributable, in part, to large patients' not receiving adequate pain medication to compensate for their increased body mass. The same study found that when anesthesia lasts for more than 120 minutes, 20 percent of the patients suffer severe pain. In

plastic surgery procedures performed in an ambulatory setting, it has been found that liposuction and breast augmentation produce the most significant pain.<sup>14</sup> In fact, this study demonstrated that plastic surgery ranked fifth highest for procedures producing pain among all ambulatory surgery procedures.

Recommendation: Control of nausea/vomiting, dizziness, and pain is essential to postoperative recovery and discharge. Pain management should be correlated to body mass index and the procedure being performed. In addition, the patient should be sent home with sufficient medication to control pain and with adequate instructions on the use of this medication.

#### PROVIDER QUALIFICATIONS

The physician performing a given procedure, regardless of the location of the surgical facility, should have approved hospital privileges for the procedure and be qualified for examination by or be board-certified in a surgical specialty board recognized by the American Board of Medical Specialties, such as the American Board of Plastic Surgery.

#### SURGICAL FACILITY STANDARDS

Plastic surgery performed under anesthesia, other than minor local anesthesia and/or minimal oral tranquilization, should be performed in a surgical facility that meets at least one of the following criteria:

- accredited by a national or state-recognized accrediting agency/organization such as the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), the Accreditation Association for Ambulatory Health Care (AAAHC), or the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- certified to participate in the Medicare program under Title XVIII
- licensed by the state in which the facility is located.

#### CONCLUSIONS

As more complex plastic surgery procedures are performed in the office setting, the surgeon must implement a variety of measures to ensure patient safety. This practice advisory provides specific recommendations on how to safely address a variety of factors common to many plastic surgery procedures. Physiological

stresses associated with surgical procedures, such as hypothermia, intraoperative blood loss, liposuction in combination with multiple procedures, and duration of the procedure(s) are addressed. In addition, recommendations are provided in the areas of thromboprophylaxis, potential postoperative recovery problems, provider qualifications, and surgical facility standards. By implementing reasonable controls that are based on expert opinion and the best scientific information available, office-based surgery can be a safe and positive experience for both the patient and the physician.

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