

Patient Safety in the Office-Based Setting

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Learning Objectives: After studying this article, the participant should be able to: 1. Discern the importance of the physician's office administrative capacity. 2. Recognize the necessity of a system for quality assessment. 3. Assess which procedures are safe in the office-based setting. 4. Know the basic steps to properly evaluate patients for office-based plastic surgery.

Background: At least 44,000 Americans die annually as a result of preventable medical errors. Medical mistakes are the eighth leading cause of death in the United States, costing between \$54.6 billion and \$79 billion, or 6 percent of total annual national health care expenditures. Office-based procedures comprise a 10-fold increase in risk for serious injury or death as compared with an ambulatory surgical facility.

Methods: This article reviews the literature on office-based patient safety issues. It places special emphasis on the statements and advisories published by the American Society of Plastic Surgeons' convened Task Force on Patient Safety in Office-Based Settings. This article stresses areas of increased patient safety concern, such as deep vein thrombosis prophylaxis and liposuction surgery.

Results: The article divides patient safety in health care delivery into three broad categories. First, patient safety starts with emphasis at the *administrative* level. The physician or independent governing body must develop a *system of quality assessment* that functions to minimize preventable errors and report outcomes and errors. Second, the *clinical* aspects of patient safety require that the physician evaluate whether the procedure(s) and the patient are proper for the office setting. Finally, this article gives special attention to *liposuction*, the most frequently performed office-based plastic surgery procedure.

Conclusions: Patient safety must be every physician's highest priority, as reflected in the Hippocratic Oath: *primum non nocere* ("first, do no harm"). In the office setting, this priority requires both administrative and clinical emphasis. The physician who gives the healing touch of quality care must always have patient safety as the foremost priority. (*Plast. Reconstr. Surg.* 117: 61e, 2006.)

Primum non nocere, "first, do no harm."—

Hippocratic Oath

According to the Institute of Medicine,¹ 44,000 to 98,000 Americans die annually as a result of preventable medical errors. Even using the lower of these estimates, medical mistakes become the eighth leading cause of death in the United States, more than motor vehicle accidents, breast cancer, or acquired im-

mune deficiency syndrome.¹ The annual cost of preventable adverse events lies between \$54.6 billion and \$79 billion annually. This cost accounts for 6 percent of total national health care expenditures, more than the entire cost of caring for people infected with human immunodeficiency virus and living with acquired immune deficiency syndrome.¹ The cost of medical mistakes is even more staggering when one considers the expenses associated with malpractice litigation, which encompass increased physician malpractice premiums² as well as intangible expenses, such as additional testing performed primarily to avoid legal repercussions as opposed to optimal patient care.

Health care knowledge and science have advanced more rapidly than the physician's ability to deliver them safely and effectively. Technological advances, especially in anesthesia, allow surgeons to perform in office-based facilities proce-

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dures that were once reserved only for hospital operating rooms or ambulatory surgery centers.³ The demand for increased privacy, convenience, and efficiency³ precipitated an explosion of outpatient procedures, from 10 percent of all surgical procedures in 1979⁴ to 80 percent today, with a fourth of these procedures performed in the physician's office.³ The privacy and convenience benefits, however, have come at a startlingly high cost to patient safety.

According to *U.S. News and World Report*, the office-based setting comprises a 10-fold increase in risk for serious injury or death as compared with an ambulatory surgical facility.^{5,6} Needless deaths related to liposuction hint at the significant dangers of office-based cosmetic surgery.⁷ Notwithstanding these dangers, only 12 states have laws on office surgery.⁶ That is, while surgical procedures moved from hospitals to office-based settings, the corresponding transfer of regulatory oversight did not follow, prompting some to label office surgery as the "Wild, Wild West of health care."⁸

Outpatient plastic surgery can be safe,⁹ as demonstrated by Byrd et al. in their 5316 consecutive case review, which found a complication rate of less than 1 percent.³ Further multiple studies have shown outpatient complication rates between 0.33 and 0.7 percent, with the occurrence of death at approximately 0.002 percent.¹⁰ Indeed, many if not most of the office-based plastic surgery injuries arise from physicians practicing outside their medical training.¹¹ Recognizing safety as a top priority, in 2002 the American Society of Plastic Surgeons' Board of Directors convened the Task Force on Patient Safety in Office-Based Surgery Facilities.¹²⁻¹⁵ The task force has published several statements and advisories to help assist physicians in clinical decision-making,¹² emphasizing patient safety as the foremost concern in the practice of plastic surgery.

This continuing medical education article attempts to highlight and summarize these recent patient safety practice statements and advisories. The principles defined here are not intended to be construed as rules. They are not inclusive or exclusive, nor are they intended to serve as the standard of medical care, which may change with new information. The ultimate judgment regarding the care of a patient lies with the physician, who must consider all the circumstances presented.¹² "We must continue to be physicians first, always putting patient safety

first. . . Patient safety is our priority and *primum non nocere*, 'do no harm,' is our motto."¹⁶

This article organizes patient safety health care delivery in a threefold manner. First, patient safety starts at the *administrative* level, with the qualified physician's or independent governing body's recorded emphasis on patient safety. This emphasis requires a documented *system of quality assessment* that effectively functions to minimize preventable errors and includes regular reporting of outcomes and errors. Second, the clinical aspects of patient safety mandate the careful *evaluation of procedures and patients for office-based surgical procedures*. The physician must assess the risks inherent in each procedure or combination of procedures to determine whether the office-based setting is safe. The physician must also appraise each patient's medical risk factors and capacity to undergo anesthesia. Finally, because liposuction is the most frequently performed office-based plastic surgery procedure, this article gives *liposuction safety* individual attention.

ADMINISTRATION

Patient safety improvement is the surgeon's responsibility and, through the surgeon's leadership, should be passed on to the office staff. Office-based surgical procedures should only be performed in accordance with written policies that clearly set forth a focus on patient safety and document the hierarchy of responsibility and oversight. The physicians must obtain and maintain appropriate qualifications and training for the procedures they perform.

Governance

Office-based surgical practices require policies that describe the organization's structure. The medical director, governing body, or solo practitioner must procure these policies, which should include employee obligations, accountabilities, and supervision. Furthermore, such policies should have quality health care and patient safety as a primary focus. They should also include a patient's bill of rights, which should reflect an emphasis on patient respect, privacy, and confidentiality.^{4,17,18}

Physician Qualifications

The physician performing office-based surgery must obtain and maintain certification by one of the boards recognized by the American Board of Medical Specialties, the American Osteopathic

Association, or an approved state medical board. The physician should attain such licensure within 5 years of completing an approved residency training program.¹⁶ Perhaps most importantly, the physician must perform only those procedures for which he or she was trained and which are within the obvious scope of the certifying board.^{9,17}

SYSTEM OF QUALITY ASSESSMENT

The patient safety problem, according to the Institute of Medicine, lies not with bad physicians working in good systems but with good physicians working in bad systems. Office-based practitioners should develop a *system* of quality care with an emphasis on continuously improving patient safety.¹

A system of quality care involves the maintenance of the appropriate facilities, equipment, personnel, protocols, and procedures. The facility and personnel must be properly accredited and licensed, and the equipment should be regularly inspected and maintained. Emergency and transfer protocols must be in place, as should be procedures for medical records, informed consent, and discharge. Anesthesia should be administered under direct physician supervision, unless state law specifically provides otherwise. Physicians should report adverse events and outcomes as part of their quality care improvement and patient safety initiative.

Surgical Facility Standards

The facility must be accredited by the American Association for Accreditation of Ambulatory Surgery Facilities, the Accreditation Association for Ambulatory Health Care, the Joint Commission on Accreditation of Healthcare Organizations, AOS, or a state-recognized entity such as the Institute for Medical Quality or Medicare certified under Title XVIII.⁹

Emergency and Transfer Protocols

A system of quality assessment must have written policies that describe protocols for handling emergency situations, including not only medical emergencies but also other foreseeable disasters (e.g., fire, power outage, and so on) or acts of God. The medical director, governing body, or solo practitioner must ensure appropriate employee training for these protocols and must secure immediate availability of cardiopulmonary resuscitation equipment.^{4,9,17}

Written protocols should further include measures for timely and safe transfer of patients to a

prespecified alternate nearby care facility. The physician performing office-based procedures must have admitting privileges at such facility or a transfer agreement with another physician who has admitting privileges at such facility. Alternatively, the physician must maintain an emergency transfer agreement with the nearby facility. The physician may show competency by maintaining core privileges at an accredited or licensed hospital or ambulatory surgical center for the procedures performed in the office.^{9,16}

Personnel

An effective quality assessment system incorporates office personnel who are appropriately licensed or certified and who have the necessary erudition and expertise to deliver the facility's services. Such personnel must have clearly specified responsibilities with fitting and patient supervision.^{4,17} Personnel with advanced resuscitative technique training (advanced cardiac life support or pediatric advanced life support) must be available until all patients have been discharged. All personnel should maintain basic cardiopulmonary resuscitation training.^{16,17}

Informed Consent

According to insurance industry data, "failure to inform" is one of the most common secondary claims in malpractice lawsuits.¹⁹ Thus, the American Society of Plastic Surgeons developed the "Statement of Principle on Informed Consent," which details the information that should be discussed with and understood by the patient and documented by both physician and patient. Informed consent should include the type and risks of anesthesia; "the details of the surgery, benefits, possible consequences and side effects of the operation, potential risks and adverse outcomes as well as their probability and severity; alternatives to the procedure being considered and their benefits, risks, and consequences; and the anticipated outcome."²⁰

If a patient watches a video, reads a brochure, or views before-and-after photographs of other patients, the physician should thoroughly document such educational processes, as signed consent forms may not be helpful in defending claims without evidence of other documented educational processes.²¹ For specific procedures, the physician should provide uniform preoperative and postoperative patient education.⁹

Medical Records

Medical records should be decipherable, correct, inclusive, available, and up to date. They should include the history, physical examination, progress notes, relevant laboratory information, procedural reports, such as radiographs and/or magnetic resonance imaging scans, and important exchanges with other medical personnel. The records must emphasize allergies and adverse drug reactions.⁴ The physician should document and update medical records contemporaneously with the patient visit or procedure and should include patient comments, whether they are positive or negative.²¹ Finally, medical records are confidential; the quality assessment system must include dictates that protect patient information from illicit, unsanctioned, or unintended abstraction, intrusion, alteration, destruction, or divulgence.⁴

Discharge

Patient discharge is the surgeon's and/or anesthesiologist's responsibility. The patient can be discharged only upon fulfilling physician-defined and -written criteria that encompass stable vital signs, alertness and orientation (baseline status), voluntary movement, controlled pain, minimal nausea/vomiting, and the ability to tolerate by mouth. Written discharge instructions should include an emergency telephone number^{4,18} (Table 1).

Reporting Adverse Events

Many physicians do not report their errors because of the justified fear of liability.¹ Lack of reporting is an obstacle to peer review, which is key to improving patient safety. Consequently, the American Society of Plastic Surgeons/Plastic Surgery Educational Foundation and the American Board of Plastic Surgery joined forces to create TOPS, or Tracking Operations and Outcomes for Plastic Surgery, a Health Insurance Portability and Accountability Act-compliant Web-based collection database that compiles plastic surgery procedures and outcomes information. The database information is an internal quality control mechanism for the strict purpose of reducing morbidity and mortality and improving quality control and patient care. Because information reported to TOPS is confidential and is not discoverable or admissible as evidence in a court of law, physicians need not fear liability for reporting their adverse events.

TOPS is an incentive-based program: the plastic surgeon submitting data can earn up to 30 category 1 continuing medical education credits

Table 1. Recovery and Discharge Criteria after Sedation and Analgesia

Each patient-care facility in which sedation-analgesia is administered should develop recovery and discharge criteria that are suitable for its specific patients and procedures. Some of the basic principles that might be incorporated in these criteria are enumerated below.

General principles

1. Medical supervision of recovery and discharge after moderate or deep sedation is the responsibility of the operating practitioner or a licensed physician.
2. The recovery area should be equipped with, or have direct access to, appropriate monitoring and resuscitation equipment.
3. Patients receiving moderate or deep sedation should be monitored until appropriate discharge criteria are satisfied. The duration and frequency of monitoring should be individualized depending on the level of sedation achieved, the overall condition of the patient, and the nature of the intervention for which sedation/analgesia was administered. Oxygenation should be monitored until patients are no longer at risk for respiratory depression.
4. Level of consciousness, vital signs, and oxygenation (when indicated) should be recorded at regular intervals.
5. A nurse or other individual trained to monitor patients and recognize complications should be in attendance until discharge criteria are fulfilled.
6. An individual capable of managing complications (*e.g.*, establishing a patent airway and providing positive pressure ventilation) should be immediately available until discharge criteria are fulfilled.

Guidelines for discharge

1. Patients should be alert and oriented; infants and patients whose mental status was initially abnormal should have returned to their baseline status. Practitioners and parents must be aware that pediatric patients are at risk for airway obstruction should the head fall forward while the child is secured in a car seat.
2. Vital signs should be stable and within acceptable limits.
3. Use of scoring systems may assist in documentation of fitness for discharge.
4. Sufficient time (up to 2 h) should have elapsed after the last administration of reversal agents (naloxone, flumazenil) to ensure that patients do not become resedated after reversal effects have worn off.
5. Outpatients should be discharged in the presence of a responsible adult who will accompany them home and be able to report any postprocedure complications.
6. Outpatients and their escorts should be provided with written instructions regarding postprocedure diet, medications, activities, and a phone number to be called in case of emergency.

From the American Society of Anesthesiologists' "Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists" (*Anesthesiology* 96: 1004, 2002).

(up to 5 hours for each month). It also gives the plastic surgery practice the ability to follow patients over time and create reports that will help the practice negotiate hospital privileges and managed care contracts. Most important, TOPS is a program designed to enhance patient safety in plastic surgery by allowing physicians to learn from their collective mistakes.²²

Another program is the American Association for Accreditation of Ambulatory Surgery Facilities'

Internet-based quality improvement and peer review program. To participate in the program, the participant must meet certain minimum standards, including maintaining a quality improvement program that monitors, evaluates, and improves patient care; that responds to recurrent problems in the facility; and that assures that the director of the facility is aware and is addressing reported problems. At least six cases or 2 percent of a facility's cases must be reviewed by an independent physician every 6 months for the facility to be accredited. All cases must be reported to the program, with all adverse events cited.¹⁰

For reporting purposes, the American Society of Plastic Surgeons, American Association for Accreditation of Ambulatory Surgery Facilities, Accreditation Association for Ambulatory Health Care, and the Joint Commission on Accreditation of Healthcare Organizations agree that an adverse event includes death, unplanned hospitalization or transport, and "other serious events." "Other serious events" encompass any event, occurrence, or situation involving the clinical care of a patient that compromises patient safety and results in unanticipated injury requiring the delivery of additional health care services to the patient.²³

Anesthesia and Analgesia

The physician is primarily responsible for providing and supervising anesthesia and analgesia. A certified registered nurse anesthetist or other qualified health care provider may administer anesthesia⁹ but only under direct physician supervision, unless state law specifically provides otherwise.⁴ The surgeon should follow the American Society of Anesthesiologists' "Guidelines for Office-Based Anesthesia,"¹⁷ "Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists,"¹⁸ and "Guidelines for Preoperative Fasting"²⁴ (Table 2).

The operating room environment is founded on interaction and communication among the members of the surgical team, which includes anesthesiologists or anesthesia personnel, support staff, and the surgeon. This environment should emphasize patient safety. The surgical team should periodically evaluate its performance in peer review and morbidity conferences.⁹

Facilities and Equipment

The facility should be outfitted with the appropriate medical equipment, materials, and drugs necessary to provide anesthesia, recovery ministrations, cardiopulmonary resuscitation, and provisions for potential emergencies.⁴ Anesthesia

Table 2. Summary of American Society of Anesthesiologists Preprocedure Fasting Guidelines

Ingested Material	Minimum Fasting Period†
Clear liquids‡	2 hours
Breast milk	4 hours
Infant formula	6 hours
Nonhuman milk§	6 hours
Light meal	6 hours

From the American Society of Anesthesiologists' "Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists" (*Anesthesiology* 96: 1004, 2002).

* These recommendations apply to healthy patients who are undergoing elective procedures. They are not intended for women in labor. Following the Guidelines does not guarantee a complete gastric emptying has occurred.

† The fasting periods apply to all ages.

‡ Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee.

§ Since nonhuman milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.

|| A light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.

equipment should include suctioning apparatus, appropriately sized airway equipment, means of positive-pressure ventilation, intravenous equipment, pharmacologic antagonists, basic resuscitative medications, and, in the event of deep sedation, defibrillator equipment¹⁸ (Table 3). Facilities that dispense anesthesia must also have readily available back-up support in case of failure for all vital equipment, such as anesthesia equipment and the oxygen delivery system.⁹ Appropriate equipment must be available to allow proper documentation and monitoring in accordance with the American Society of Anesthesiologists' "Standards of Basic Anesthetic Monitoring."⁴

Furthermore, the operating facility should have the basic patient safety devices, such as "humidifiers, oximeters, capnography, warming blankets, and pneumatics/compression leg garments."⁹ It must also have appropriate "fire-fighting equipment, signage, emergency power capabilities, and lighting."⁴ All operative equipment should be inspected, maintained, and tested on a regular basis as recommended by the manufacturer.^{4,17}

The personnel, equipment, and procedures must be adequate to handle potential medical and other emergencies.⁴ Such emergency preparedness includes the requirement that key operative personnel are certified in advanced cardiac life support and regularly participate in continuing medical education regarding advances in outpatient surgery.⁹

Table 3. Emergency Equipment for Sedation and Analgesia

Appropriate emergency equipment should be available whenever sedative or analgesic drugs capable of causing cardiorespiratory depression are administered. The lists below should be used as a guide, which should be modified depending on the individual practice circumstances. Items in brackets are recommended when infants or children are sedated.

Intravenous equipment

- Gloves
- Tourniquets
- Alcohol wipes
- Sterile gauze pads
- Intravenous catheters [24–22-gauge]
- Intravenous tubing [pediatric “microdrip” (60 drops/ml)]
- Intravenous fluid
- Assorted needles for drug aspiration, intramuscular injection [intraosseous bone marrow needle]
- Appropriately sized syringes [1-ml syringes]
- Tape

Basic airway management equipment

- Source of compressed oxygen (tank with regulator or pipeline supply with flowmeter)
- Source of suction
- Suction catheters [pediatric suction catheters]
- Yankauer-type suction
- Face masks [infant/child]
- Self-inflating breathing bag-valve set [pediatric]
- Oral and nasal airways [infant/child-sized]
- Lubricant

Advanced airway management equipment (for practitioners with intubation skills)

- Laryngeal mask airways [pediatric]
- Laryngoscope handles (tested)
- Laryngoscope blades [pediatric]
- Endotracheal tubes
 - Cuffed 6.0, 7.0, 8.0 mm ID
 - [Uncuffed 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 mm ID]
- Styler (appropriately sized for endotracheal tubes)

Pharmacologic Antagonists

- Naloxone
- Flumazenil

Emergency medications

- Epinephrine
- Ephedrine
- Vasopressin
- Atropine
- Nitroglycerin (tablets or spray)
- Amiodarone
- Lidocaine
- Glucose, 50% [10 or 25%]
- Diphenhydramine
- Hydrocortisone, methylprednisolone, or dexamethasone
- Diazepam or midazolam

From the American Society of Anesthesiologists’ “Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists” (*Anesthesiology* 96: 1004, 2002).

OFFICE-BASED SURGERY PROCEDURE SELECTION

The surgeon must consider the risk factors associated with certain procedures when deciding whether such procedures should be performed in the office-based setting. Hypothermia and intraoperative blood loss can lead to patient instability. Liposuction in combination with multiple proce-

dures increases the likelihood of complications, as can extended procedure duration. The risk of deep vein thrombosis and pulmonary embolus is small but still significant, and factors such as nausea, vomiting, pain, and dizziness are common occurrences that can lead to unplanned hospital admissions. The physician must consider these risks factors cumulatively when deciding whether procedures are appropriately suited for the office-based setting.

Hypothermia

Factors contributing to hypothermia include (1) the typical cold operating room environment, (2) the unclothed/unprotected patient, (3) unwarmed intravenous fluids, and (4) the potential anesthetic-induced impairment of thermoregulatory responses. The office surgery suite must have adjustable temperatures that can be appropriately monitored. Warming equipment, including “cutaneous warming devices (Bair Huggers), forced air warming blankets, and intravenous fluid warmers,” should also be available.¹² If such anti-hypothermia measures are not available, the duration of the procedure should be limited to less than 2 hours and no more than 20 percent of the body surface area should be exposed.¹²

Intraoperative Blood Loss

If the anticipated blood loss is more than 500 cc for an average patient, the procedure should be performed only where adequate blood components are immediately available.¹²

Duration of Procedure

Some studies indicate that increased surgery length correlates with higher postoperative admission rates,^{12,25} while others demonstrate that the type of surgery performed and the general health of the patient are better indicators of outcome.^{12,26} Another study suggests that the type of anesthesia used most closely correlates with hospital admission.^{12,27} Extended procedures that end after 3 pm^{12,27} and that are associated with increased incidences of postoperative nausea, vomiting, inflammation, and bleeding may require an overnight stay.²⁸

Consequently, the overall duration of the procedure should be less than 6 hours. For longer operations, special attention should be paid to “patient selection, intraoperative management, and postoperative care.”¹² Longer procedures should also be completed by 3 pm to allow adequate recovery time.^{12,27}

Liposuction

Large-volume liposuction combined with other procedures, such as abdominoplasty, can cause serious complications. Death associated with isolated lipoplasty is rare (0.0021 percent, or one per 47,415), but the mortality rate increases significantly when lipoplasty is combined with other procedures. When combined with nonabdominoplasty procedures, the lipoplasty mortality rate increases to 0.0137 percent, or one per 7314; when combined with abdominoplasty, with or without other procedures, the lipoplasty mortality rate increases to 0.0305 percent, or 1 per 3281.²⁹ The presumed benefits of combined procedures must thus be weighed against potential untoward events. Regardless of the number of procedures, the surgeon should restrict total aspirant to 5000 cc in the office-based setting.¹² Liposuction is discussed in greater detail below.

Thromboprophylaxis Measures

Although deep vein thrombosis and pulmonary embolism are among the most widespread complications of surgical procedures, most plastic surgeons (up to 60 percent in certain procedures)³⁰ do not use any form of prophylaxis.³¹ The incidence of deep vein thrombosis could reach as high as 18,340 cases annually.³¹ Hypercoagulable inheritable conditions include factor V Leiden mutation, hyperhomocysteinemia, prothrombin gene mutation, proteins C and S deficiency, antiphospholipid antibodies (or lupus anticoagulant) and antithrombin III deficiency, dysfibrinogenemia, polycythemia vera, and heparin-induced thrombocytopenia. Nonheritable risks factors of deep vein thrombosis include surgery, increased age, malignancy, previous miscarriages, pregnancy, oral contraceptives, smoking, postmenopausal hormone replacement therapy, previous thromboembolism, heart failure, obesity, and paralysis.^{12,32}

The physician must identify the patient's risk factors for deep venous thrombosis by obtaining a detailed patient history and physical examination. The physician should use a comprehensive system or model to assess the patient's thromboembolic risk. One such risk assessment model is shown in Figure 1.³² This model divides risk factors into "exposing" and "predisposing."³² The physician sums these risk factors and provides the patient with an overall score. On the basis of this score, the physician assigns the patient to a risk group as follows:

- Low risk (one factor):
 - younger than 40 years old, no risk factors, uncomplicated surgery

- Moderate risk (two factors):
 - any age, uncomplicated surgery, additional risk factors
 - ages 40 to 60 years, no risk factors
 - younger than 40 years old, major surgery, no risk factors
- High risk (three factors):
 - uncomplicated surgery and older than 60 years or additional risk factors
 - major surgery and older than 40 years or additional risk factors
- Highest risk group (four factors or more)
 - 40 or older, major surgery, and history of venous thromboembolism, cancer, or hypercoagulable state; hip or knee arthroplasty; hip fracture surgery; major trauma; or spinal cord injury³²

The surgeon then provides prophylaxis based on the patient's thromboprophylaxis risk assessment (see Fig. 1).³²

- Low risk:
 - flexion of the knees at a 5 degree angle to maximize blood flow through the popliteal veins
 - ambulate three times daily
- Moderate risk:
 - low-risk thromboprophylaxis plus:
 - use of intermittent pneumatic compression stockings with elastic compression stockings (placed before anesthesia induction and continued at all times when the patient is not ambulating)
 - frequent alteration of operating room table
- High risk:
 - low-risk and moderate-risk thromboprophylaxis plus:
 - consideration of preoperative and postoperative antithrombotic therapy (low-molecular weight heparin in patients without extensive dissection)^{12,31}
- Highest risk:
 - low risk through high risk plus:
 - enoxaparin (Lovenox) 40 mg subcutaneously once daily postoperatively (first dose 12 hours after operation)³²

Potential Postoperative Recovery Problems Leading to Unplanned Hospital Admissions

Almost 10 percent of unplanned hospital admissions result from dizziness, pain, nausea, and vomiting.³³ Larger patients may need more pain and nausea medication to compensate for their increased mass. The physician should correlate pain management with body mass index, including home medications to control postdischarge pain.¹²

Step I. Total = _____

Exposing Risk Factors			
Check the box corresponding to each condition			
1 Factor	2 Factors	3 Factors	5 Factors
Minor surgery <input type="checkbox"/>	*Major surgery <input type="checkbox"/>	Previous myocardial infarction <input type="checkbox"/>	Hip, pelvis, or leg fracture <input type="checkbox"/>
	Immobilizing plaster cast <input type="checkbox"/>	Congestive heart failure <input type="checkbox"/>	Stroke <input type="checkbox"/>
	Patient confined to bed for > 72 hrs <input type="checkbox"/>	Severe sepsis <input type="checkbox"/>	Multiple trauma <input type="checkbox"/>
	Central venous access <input type="checkbox"/>	Free flap <input type="checkbox"/>	Acute spinal cord injury <input type="checkbox"/>

*Major surgery is defined by the use of general anesthesia or any procedure lasting longer than 1 hour.

Step II. Total = _____

Predisposing Risk Factors		
Check the box corresponding to each condition		
Clinical Setting	Inherited	Acquired
Age 40 to 60 (1 Factor) <input type="checkbox"/>	Any genetic hypercoagulable disorder (3 Factors) <input type="checkbox"/>	Lupus anticoagulant (3 Factors) <input type="checkbox"/>
Age > 60 (2 Factors) <input type="checkbox"/>		Antiphospholipid antibodies (3 Factors) <input type="checkbox"/>
History of DVT/PE (3 Factors) <input type="checkbox"/>		Myeloproliferative disorders (3 Factors) <input type="checkbox"/>
Pregnancy or < 1 month postpartum (1 Factor) <input type="checkbox"/>		Heparin-induced thrombocytopenia (3 Factors) <input type="checkbox"/>
Malignancy (2 Factors) <input type="checkbox"/>		Hyperviscosity (3 Factors) <input type="checkbox"/>
Obesity > 20% IBW (1 Factor) <input type="checkbox"/>		Homocystinemia (3 Factors) <input type="checkbox"/>
Oral contraceptive / hormone replacement therapy (1 Factor) <input type="checkbox"/>		

Step III. Total Step I and Step II = _____ Factors

Step IV. Orders

1 Factor	Low risk	Ambulate patient TID <input type="checkbox"/>
2 Factors	Moderate risk	Intermittent pneumatic compression stockings with elastic compression stockings on at all times when not ambulating <input type="checkbox"/>
3-4 Factors	High risk	Intermittent pneumatic compression stockings with elastic compression stockings on at all times when not ambulating <input type="checkbox"/>
> 4 Factors	Highest risk	Intermittent pneumatic compression stockings with elastic compression stockings on at all times when not ambulating <input type="checkbox"/> + 1. Enoxaparin (Lovenox) 40mg SQ once daily post op <input type="checkbox"/>

For 1 : Give first dose 12 hours Post Op

Signature _____
Print Name _____

Date/Time _____
Pager # _____

Fig. 1. From Davison, S. P., Venturi, M. L., Attinger, C. E., Baker, S. B., and Spear, S. L.: Prevention of venous thromboembolism in the plastic surgery patient. *Plast. Reconstr. Surg.* 114: 43e, 2004.

OFFICE-BASED SURGERY PATIENT SELECTION

The history and physical examination are among the most important steps a surgeon can take to ensure appropriate patient selection for an office-based procedure. They allow the physician to determine the most appropriate time and facility setting for the surgery, and they also provide vital information that helps guide the physician and medical staff with intraoperative and postoperative patient monitoring.¹³

History and Physical Examination

The physician must attain the patient's health, social, and family history, as well as ascertain whether there are any allergies (e.g., to drugs, latex, tape) or medications being used (including nonprescription drugs)¹³ (Fig. 2). The physician must acquire a review of body systems and document all comorbidities or infirmities (e.g., diabetes, cardiac disease, and respiratory disease). The physician or the physician's designee must perform a thorough physical examination and document the patient's age, weight, height, appearance, and vital signs and the name of the responsible adult to assist with postoperative instructions and care¹³ (Fig. 3).

Preoperative Tests

The history and physical examination will provide the physician with the necessary knowledge to order further testing, which should include the following:

- Electrocardiogram for patients over 45 years of age
- Electrocardiogram at any age when known cardiac conditions are present
- Complete blood cell count with chemistries as needed for anemia, diabetes mellitus, hypertension, and diuretic therapy
- Pregnancy test for all women of childbearing age unless documented surgical sterilization exists.¹³

American Society of Anesthesiologists' Physical Classification Rating

On the basis of the patient's history, physical examination, review of systems, laboratory testing, and/or medical specialist's evaluation, the physician should select the patient's American Society of Anesthesiologists' physical classification rating¹⁶: 1, normal healthy patient; 2, patient with mild systemic disease; 3, patient with severe sys-

temic disease; and 4, patient with severe systemic disease that is a constant threat to life.

Patients classified as types 1 and 2 are candidates for ambulatory and office-based surgical procedures; type 3 patients are candidates for an office-based procedures with local anesthesia (with or without sedation); and type 4 patients are only candidates for office-based operations with local anesthesia and without sedation¹³ (Table 4).

LIPOSUCTION SAFETY

Liposuction deserves special consideration, as it is the most frequently performed plastic surgery procedure.^{14,34} Currently, few scientific data exist to guide maximal safe allowances of wetting solution volumes.³⁵ There is no doubt, however, that complication risks increase with lipoaspirate volume and with treatment of multiple anatomic locations.³⁶

Large-Volume Liposuction

The American Society of Plastic Surgeons' Committee on Patient Safety, in its "Practice Advisory on Liposuction," defines large-volume liposuction as more than 5 liters of lipoaspirate taken in one operation.^{14,37} Such liposuction induces substantial fluid alterations.¹⁴ The "tumescent technique," in which 2 to 3 cc of wetting solution are infiltrated for every 1 cc of anticipated lipoaspirate, leaves behind 50 to 70 percent of the infiltrated volume, which can potentially result in fluid overload.^{13,14,38} Wetting solution infiltration greater than 70 ml/kg is more likely to cause such overload, which can present as increased blood pressure, jugular vein distension, and bounding pulses¹⁴ (70 percent of subcutaneous infiltrate is presumed to be intravascular),³⁹ as well as cough, dyspnea, lung crackles,^{33,40} and pulmonary edema.^{14,41,42} These complications require extended observation and potential diuresis.¹⁴

The surgeon should use the total lipoaspirate (fluid plus fat removed) to track liposuction volume, and should perform large-volume liposuction in a hospital setting. An appropriate facility with qualified and competent staff must monitor postoperative vital signs and urinary output. The physician should decide whether the patient's best interests dictate separate staged procedures. The surgeon can safely combine limited liposuction with additional plastic surgery procedures, but should not join large-volume liposuction with such procedures because of the risk of severe complications.¹⁴

Name: _____ Date: _____

SOCIAL

Age: _____ Sex: M F Married: Y N Occupation: _____
 Responsible Adult Available to Assist During Recovery Period Y N Relationship: _____

HABITS

Smoke: Y N Amount: _____ Coffee/Tea/Cola: Y N Amount: _____
 Alcohol: Y N Amount: _____ Daily Exercise: Y N Amount: _____

MEDICATIONS: List dose or number of pills per day
 Prescription Drugs

Non Prescription (Vitamins; Herbs)

Regular Aspirin Use: Y N Dosage & frequency: _____
 NSA (Advil, Motrin, Ibuprofen): Y N Dosage & frequency: _____
 Cortisone Injections Past Year: Y N Date(s) and injection location: _____

Drug Allergy: Y N List drug(s) and type of reaction: _____

Latex Allergy: Y N Tape Allergy Y N

FAMILY HISTORY: Have any blood relatives ever had the following problems:

Abnormal Bleeding: Y <input type="checkbox"/> N <input type="checkbox"/>	Coronary Surgery: Y <input type="checkbox"/> N <input type="checkbox"/>	Kidney Disease Y <input type="checkbox"/> N <input type="checkbox"/>
Abnormal Clotting: Y <input type="checkbox"/> N <input type="checkbox"/>	Diabetes: Y <input type="checkbox"/> N <input type="checkbox"/>	Tuberculosis: Y <input type="checkbox"/> N <input type="checkbox"/>
Anesthetic Problems: Y <input type="checkbox"/> N <input type="checkbox"/>	Heart Attack: Y <input type="checkbox"/> N <input type="checkbox"/>	Other Serious Illness: Y <input type="checkbox"/> N <input type="checkbox"/>
Cancer: Y <input type="checkbox"/> N <input type="checkbox"/>	Hypertension: Y <input type="checkbox"/> N <input type="checkbox"/>	

Please describe questions with a "Yes" answer: _____

PERSONAL PAST HISTORY: Have you ever had:

Abnormal Bleeding: Y <input type="checkbox"/> N <input type="checkbox"/>	Asthma: Y <input type="checkbox"/> N <input type="checkbox"/>	Hypertension: Y <input type="checkbox"/> N <input type="checkbox"/>
Abnormal Clotting: Y <input type="checkbox"/> N <input type="checkbox"/>	Diabetes: Y <input type="checkbox"/> N <input type="checkbox"/>	Sleep Apnea: Y <input type="checkbox"/> N <input type="checkbox"/>
Acid Regurgitation: Y <input type="checkbox"/> N <input type="checkbox"/>	Fainting Spell: Y <input type="checkbox"/> N <input type="checkbox"/>	Snoring: Y <input type="checkbox"/> N <input type="checkbox"/>
Anemia: Y <input type="checkbox"/> N <input type="checkbox"/>	Heart Attack: Y <input type="checkbox"/> N <input type="checkbox"/>	Weight Change past 12 Mo.: Y <input type="checkbox"/> N <input type="checkbox"/>
Angina: Y <input type="checkbox"/> N <input type="checkbox"/>	Hepatitis: Y <input type="checkbox"/> N <input type="checkbox"/>	Other Serious Illness: Y <input type="checkbox"/> N <input type="checkbox"/>

Please describe questions with a "Yes" answer: _____

Have you ever received a transfusion? Y N If yes, what year? _____

Have you been tested for HIV? Y N If yes, what year _____ Test results: positive negative

Do you wear: Contact lenses: Y N Eye glasses: Y N Hearing aid: Y N Dentures: Y N

Previous Surgery, year and type of procedure: _____

Indicate the type(s) of anesthesia received in the past, list any complications / reactions you experienced:

- Local anesthesia - (complications/reactions): _____
- General anesthesia -(complications/reactions): _____
- Spinal / Epidural - (complications/reactions): _____

Date last seen by Primary Care Physician: _____

Primary Care Physician (name) _____ (telephone) (_____) _____
 (address) _____

WOMEN PATIENTS ONLY:

Number of pregnancies _____ Number of children _____ Last menstrual period _____ Did you breast feed? Yes No

Fig. 2. From Iverson, R. E., and Lynch, D. J. Patient safety in office-based surgery facilities: II. Patient selection. *Plast. Reconstr. Surg.* 110: 1785; discussion 1791, 2002.

Name: _____ MRN: _____ Date: _____

Completed by Physician

REVIEW OF SYSTEMS

Loose Dental Devices:	Y <input type="checkbox"/> N <input type="checkbox"/>	Chest Pain:	Y <input type="checkbox"/> N <input type="checkbox"/>
Neck Mobility Problem:	Y <input type="checkbox"/> N <input type="checkbox"/>	Irregular Heart Beat:	Y <input type="checkbox"/> N <input type="checkbox"/>
Short Neck:	Y <input type="checkbox"/> N <input type="checkbox"/>	Vomiting:	Y <input type="checkbox"/> N <input type="checkbox"/>
Cough:	Y <input type="checkbox"/> N <input type="checkbox"/>	Difficult Voiding:	Y <input type="checkbox"/> N <input type="checkbox"/>
Shortness of Breath:	Y <input type="checkbox"/> N <input type="checkbox"/>	Seizure:	Y <input type="checkbox"/> N <input type="checkbox"/>
Recent Upper Respiratory Infection:	Y <input type="checkbox"/> N <input type="checkbox"/>	Current Pregnancy:	Y <input type="checkbox"/> N <input type="checkbox"/>
Normal Menstrual Period:	Y <input type="checkbox"/> N <input type="checkbox"/>	Black Out:	Y <input type="checkbox"/> N <input type="checkbox"/>
Stroke:	Y <input type="checkbox"/> N <input type="checkbox"/>	Obesity:	Y <input type="checkbox"/> N <input type="checkbox"/>

Comments: _____

PHYSICAL EXAM

Height: _____ Weight: _____ Blood Pressure: _____ Pulse: _____ Temp: _____

GENERAL STATUS COMMENT

HEENT: _____ Vision: _____ Pharynx: _____ Dental Devices: _____
 Pulmonary: _____
 Heart: _____
 Abdomen: _____
 Extremity: _____
 Neurologic (if applicable): _____

Comments _____

LABORATORY (if applicable)

H/H: _____	WBC: _____
PT: _____	Chest X-Ray: _____
Mammogram: _____	EKG (Pt over 40): _____
Pregnancy Test: _____	Sodium Chloride: _____
Potassium: _____	CO ₂ : _____
BUN: _____	Creatinine: _____

Comments _____

DIAGNOSES

1. _____
2. _____
3. _____

ASA CLASSIFICATION

- P1 A normal healthy patient
- P2 A patient with mild systemic disease
- P3 A patient with severe systemic disease
- P4 A patient with severe systemic disease that is a constant threat to life

FACILITY SELECTED

- Office-based Surgical Facility
- Ambulatory Surgery Center
- Hospital
-

Fig. 3. From Iverson, R. E., and Lynch, D. J. Patient safety in office-based surgery facilities: II. Patient selection. *Plast. Reconstr. Surg.* 110: 1785; discussion 1791, 2002.

Table 4. ASA Physical Classification Rating**ASA 1: A fit patient with no underlying systemic disease and taking no medications, e.g.:**

- A 43-yr-old woman for bilateral breast enhancement
- A 32-yr-old man for cosmetic rhinoplasty
- A 16-yr-old girl for earlobe reconstruction from congenital anomaly
- A 26-yr-old man for back lipoma excision

ASA 2: A patient with mild systemic disease, i.e., slightly limiting organic heart disease, mild diabetes, essential hypertension or anemia, obesity (by itself), chronic bronchitis, or any healthy individual under 1 year or over 70 years old, e.g.:

- Patients who smoke, drink alcohol frequently or excessively, or use street drugs
- Patients who are obese
- Patients who have any of the following, but under control without systemic compromise: diabetes, hypertension, asthma, gastroesophageal reflux disease, peptic ulcer disease, hematologic disorders, arthritis, neuropathy
- Patients with anatomical abnormalities of significance to health, such as hiatal hernia, difficult airways, nondebilitating heart anomaly, Down syndrome
- Patients with mild psychiatric illness that is under control, such as depression, anxiety disorder, and bipolar disorder
- Patients with a remote history of coronary artery disease and no other systemic illnesses whose progress afterward showed no further chest pain and documented good exercise tolerance
- A 4-month-old infant for cleft palate repair
- A 73-yr-old woman for bilateral breast enhancement
- A 21-yr-old woman for breast augmentation with truncal obesity
- A 43-yr-old woman for bilateral breast enhancement who smokes and has chronic obstructive pulmonary disease
- A 32-yr-old asthmatic man for cosmetic rhinoplasty

ASA 3: A patient with a systemic disease or multiple significant mild systemic diseases, organic heart diseases, severe diabetes with vascular complications, moderate-to-severe degrees of pulmonary insufficiency, angina pectoris, or healed myocardial infarction, e.g.:

- Any third-degree or fourth-degree burn patient who is hemodynamically stable and undergoing graft surgery
- A 16-yr-old woman for earlobe reconstruction after congenital anomaly, with a symptomatic ventricular septal defect
- A 26-yr-old man for back lipoma excision, with controlled end-stage renal disease
- A 53-yr-old man for liposuction, who is hypertensive and has occasional chest pain
- A 32-yr-old man for cosmetic rhinoplasty, who frequently has sickle cell crisis, with hematocrit of 16.

ASA 4: Organic heart disease showing marked signs of cardiac insufficiency, persistent anginal syndrome, active myocarditis, advanced degrees of pulmonary, hepatic, renal or endocrine insufficiency, e.g.:

- A 71-yr-old woman for bilateral breast enhancement under general anesthesia who is asthmatic, smokes, and has chronic obstructive pulmonary disease
- A 16-yr-old girl for earlobe reconstruction from congenital anomaly, with a cyanotic heart anomaly
- A 53-yr-old man for liposuction, who is hypertensive and has had congestive heart failure within the past 6 months

ASA, American Society of Anesthesiologists.

From Iverson, R. E., and Lynch, D. J. Patient safety in office-based surgery facilities: II. Patient selection. *Plast. Reconstr. Surg.* 110: 1785; discussion 1791, 2002.

The surgeon must carefully monitor the perioperative and postoperative fluid intake and output. The surgeon is responsible for communicating with the anesthesia care provider about fluid manage-

ment, which encompasses accounting for maintenance requirements, preexisting deficiencies, aspirated tissue removal, and third-space losses. Hemoglobin measurements may help confirm blood loss estimates, although such estimates can be inaccurate, especially in the setting of acute loss and potential hemodilution because of the wetting solution. Accurate fluid management will guide the physician in postoperative care, including patient warming, blood restoration, postanesthesia administration, and safe discharge measures.¹⁴

Liposuction Anesthesia

Anesthetic agents added to liposuction wetting solutions provide the benefit of postoperative analgesia. These agents, however, warrant caution. Bupivacaine is poorly reversed, is rapidly absorbed, and has a long half-life.⁴³ Toxic effects include cardiac arrhythmias, seizures, respiratory depression, and coma, and they can be lethal if the anesthetic agent is injected intravascularly.¹⁴

Unlike bupivacaine, lidocaine is more easily reversed, and up to 7 mg/kg can be injected with epinephrine into subcutaneous fat.^{44,45} Still, lidocaine toxicity has been associated with liposuction-related deaths.⁷ Toxicity presents with dizziness, agitation, lethargy, tinnitus, metallic taste, perioral paresthesias, and slurred speech.¹⁴ Lidocaine plasma levels peak at 10 to 12 hours after infiltration of wetting solution.⁴⁶ To decrease the risk of lidocaine toxicity, the task force recommends (1) using smaller concentrations of lidocaine in the wetting solution, (2) using the superwet technique rather than the tumescent technique, and (3) not using lidocaine with general or regional anesthesia.¹⁴

The task force further recommends that surgeons avoid epinephrine use in patients with “pheochromocytoma, hyperthyroidism, severe hypertension, cardiac disease, or peripheral vascular disease.”¹⁴ The physician should try to keep epinephrine dosing below 0.07 mg/kg,¹⁴ although higher doses have been reported to be safe.⁴⁷

Plastic surgeons should utilize the American Society of Anesthesiologists’ “Guidelines for Sedation and Analgesia”¹⁸ (Table 5). General anesthesia is safe for the office setting and is especially useful for complex or long operations due to precise dosing.¹⁴ Moderate sedation or analgesia (intravenous or oral) is also safe and adjunctively augments the patient’s level of comfort.¹⁴ Because of the possibility of vasodilation, hypotension, and fluid overload, however, the physician should avoid the use of epidural and spinal anesthesia in liposuction procedures.^{14,48}

Table 5. Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia

	Minimal Sedation (anxiolysis)	Moderate Sedation/Analgesia (conscious sedation)	Deep Sedation/Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful* response to verbal or tactile stimulation	Purposeful* response after repeated or painful stimulation	Unarousable, even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

Minimal Sedation (anxiolysis) = a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia (conscious sedation) = a drug-induced depression of consciousness during which patients respond purposefully* to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

Deep Sedation/Analgesia = a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully* following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia = a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering *Moderate Sedation/Analgesia (Conscious Sedation)* should be able to rescue patients who enter a state of *Deep Sedation/Analgesia*, while those administering *Deep Sedation/Analgesia* should be able to rescue patients who enter a state of general anesthesia.

* Reflex withdrawal from a painful stimulus is not considered a purposeful response.

Developed by the American Society of Anesthesiologists; approved by the ASA House of Delegates October 13, 1999.

From the American Society of Anesthesiologists' "Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists" (*Anesthesiology* 96: 1004, 2002).

Liposuction Patient Selection

Liposuction is a surgical procedure. The surgeon must assess the liposuction patient with standards that are the same as those used for any surgical patient, including a complete preoperative history and a physical examination. Unfortunately, the same patient population that stands to benefit the most from large-volume liposuction also carries the most significant inherent surgery risks, including "poor wound healing, infection, deep venous thrombosis, and sleep apnea."¹⁴ Because of these risks, liposuction is not a treatment for the severely obese patient (body mass index greater than 30).¹⁴

CONCLUSIONS

To function at our best, we must place patient safety as our highest priority. In the office setting, this priority means vigorous administrative emphasis as well as an effective quality assessment system (including peer review). It means diligently assessing whether the procedure and the patient are proper for the office setting, notwithstanding the influences of cost, privacy, efficiency, and profitability. The physician who gives the healing touch of quality care must always have patient safety as the foremost priority. "In the end, putting patient safety first simply comes down to being a

caring physician and exercising prudent judgment in the care of our patients. When in doubt, do not do it!"¹⁶

Pride goeth before destruction, and before honour is humility.—St. Augustine; *City of God*, Book 14:13

GLOSSARY

Advanced cardiac life support

Recertification depends on the individual state but is usually required every 3 years. At least one person on the surgical team should be qualified and present until all patients are discharged.

Adverse event

An injury caused not by the underlying patient condition but rather by medical management.²

Ambulatory surgery center

A licensed and accredited freestanding or hospital-based facility with an organized professional staff that provides surgical services to patients who do not require an inpatient bed.⁴

Deep sedation/analgesia

A drug-induced depression of consciousness during which patients cannot easily be aroused but respond purposefully to repeated or painful

stimuli. The patient may or may not be able to independently maintain ventilatory function. Patients may require assistance with patent airway maintenance, but they usually maintain cardiovascular function¹⁸ (Table 5).

Error

The failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).⁴⁹

External ultrasound assistance

Delivers adjunctive ultrasound through an external paddle in coordination with liposuction. The clinical benefits of external ultrasound assistance are in question.⁵⁰

General anesthesia

A drug-induced loss of consciousness during which patients are not arousable even by painful stimuli. The patient often will not maintain independent ventilatory function and often will require assistance with patent airway maintenance and positive pressure ventilation. Cardiovascular function may be impaired.¹⁸

Minimal sedation (anxiolysis)

A drug-induced state during which a patient responds normally to verbal commands. The patient usually maintains ventilatory and cardiovascular functions, although the induced state may cause cognitive function and/or coordination impairment.¹⁸

Moderate sedation/analgesia (conscious sedation)

A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are usually required to maintain a patent airway, and spontaneous ventilation is usually adequate. Cardiovascular function is usually maintained.¹⁸

Institute of Medicine

A nonprofit organization created for the purpose of providing unbiased, evidence-based, and authoritative information and advice concerning health and science policy to policy-makers, professionals, leaders in every sector of society, and the public at large. It is a component of the National Academy of Sciences. The Institute works outside the framework of government to

ensure scientifically informed analysis and independent guidance. The Institute of Medicine's mission is to serve as adviser to the nation to improve health.¹

Negligent adverse event

A preventable adverse event that satisfies legal criteria (i.e., whether the care provided failed to meet the standard of care reasonably expected of an average physician qualified to take care of the patient in question).⁵¹

Office-based surgery

Surgery and other procedures performed in the office of a licensed physician.⁴

Outpatient surgery

Surgery performed in any regulated or unregulated freestanding or hospital-based facility, clinic, or office that is organized for the purpose of providing care to patients without hospital admission.⁴

Outpatient surgery facility

Any facility, clinic, office, licensed ambulatory surgical center, or hospital where outpatient surgery and/or other procedures are performed.⁴

Pediatric advanced life support

Pediatric advanced life support is required only if the office-based procedure involves neonates, infants, or children.

Preventable adverse event

An adverse event attributable to error.⁵² More than two-thirds of adverse events are preventable.⁵¹

Quality of care

The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.⁵³

Tracking Operations and Outcomes for Plastic Surgery, or TOPS

A shared initiative between the American Society of Plastic Surgeons/Plastic Surgery Educational Foundation and the American Board of Plastic Surgery to gather plastic surgery procedures and outcomes information. The information is an internal quality control mechanism for the strict purpose of reducing morbidity and mortality

rates and improving quality control and patient care. The information is confidential and is not discoverable or admissible as evidence in a court of law. Moreover, by participating in TOPS, the plastic surgeon can earn up to 30 category 1 continuing medical education credits (up to 5 hours for each month that data are submitted).²²

OFFICE-BASED SURGERY CHECKLIST

DISCLAIMER: The following is not meant to be an inclusive checklist. Rather, it is merely a guide for the reader to help formulate an idea of whether he or she may or may not be compliant with the basic quality care and patient safety criteria for office-based surgical procedures.

Administration

Governance and Physician/Personnel Qualifications

- Does my office have a written policy that describes the organization's structure, including medical director or governing body?
- Does my office have a written policy that describes employee responsibilities and accountabilities, and does such policy clearly delineate supervisory personnel?
- Have the physicians, nurses, and staff personnel in my office obtained and maintained the appropriate licensures, and are they performing procedures and duties within the obvious scope of such licensures and training?
- Does my office have a written policy on a patient's bill of rights, one that clearly emphasizes quality of care and patient safety?
- Is everyone in my office current and knowledgeable about our written policies?
- Does my office have a method for tracking which personnel have and have not read these policies and the last time the policies were read?

System of Quality Assessment

Surgical Facility Standards

- Is my facility accredited by the American Association for Accreditation of Ambulatory Surgery Facilities, Accreditation Association for Ambulatory Health Care, Joint Commission of Accreditation of Healthcare Organizations, or AOS, or is it certified by a state-recognized entity such as the Institute for Medical Quality or Medicare?

Emergency and Transfer Protocols

- Does my office have a written policy describing protocols for handling emergency situations?
 - Fire
 - Power outage
 - Weather disaster (tornado, flood, earthquake, and so on)
 - Cardiac/respiratory arrest
- Do these emergency protocols include measures for timely and safe transfer of patients to a prespecified, alternate, nearby care facility?
- Does my office have admitting privileges with, or a transfer agreement to admit to, a nearby care accredited or licensed hospital or ambulatory surgical facility? Alternatively, does my office have a transfer agreement with another physician who has such privileges?

Advanced Cardiac Life Support and Pediatric Advanced Life Support

- Is everyone current?
- Do I have someone who is advanced cardiac life support–qualified available until all patients are discharged?
- If I work on neonates, infants, or children, do I have someone who is pediatric advanced life support–qualified available until such patients are discharged?
- Do all of my personnel maintain basic cardiopulmonary resuscitation training?

Adverse Event Reporting

- Does my office have a quality care Health Insurance Portability and Accountability Act–compliant method and policy for tracking and reporting adverse events?
- Does this tracking and reporting protocol also allow me to create reports and follow patients over time, so that I will be better able to negotiate hospital privileges and managed care contracts?
- Do I periodically evaluate my office's quality care and patient safety performance in peer review and morbidity conferences, and do I have a method for documenting such evaluations?

Anesthesia and Analgesia

- Do I have a readily available copy of the American Society of Anesthesiologists' "Guidelines for Office-Based Anesthesia"?

- If I administer sedation or analgesia or supervise such administration by a nonanesthesiologist, do I have a readily available copy of the American Society of Anesthesiologists' "Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists"?
- Do I know or have a copy of the American Society of Anesthesiologists' "Guidelines for Preoperative Fasting"?
- Do I have a readily available copy of the American Society of Anesthesiologists' "Standards of Basic Anesthetic Monitoring"?
- Do I know and have documented in my policies and protocols my state's current legislation regarding the delivery of anesthesia by a certified registered nurse anesthetist or other qualified health care provider?
- Do I have a written policy that describes the importance of communication between myself and the anesthesiologist or anesthesia personnel as well as support staff?

Facilities and Equipment

- Is my facility equipped with the appropriate medical equipment, supplies, and pharmacological agents necessary to provide the procedures and associated recovery services, including cardiopulmonary resuscitation and other emergency services?
- Does my facility have a back-up power delivery system?
- If I administer or supervise anesthesia delivery, does my facility have the necessary anesthesia equipment?
- Does my office's anesthesia, sedation, and analgesia equipment allow for proper documentation and monitoring in accordance with the American Society of Anesthesiologists' "Standards of Basic Anesthetic Monitoring"?
- Does my facility have basic safety devices?
 - Humidifiers
 - Oximeters
 - Capnography
 - Warming blankets
 - Forced air warmers
 - Pneumatics/compression leg garments
- Does my facility have the appropriate firefighting equipment, signs, emergency power capabilities, and lighting?
- Do I have an effective system that routinely documents the appropriate inspection, main-

tenance, and testing of my equipment as recommended by the manufacturer?

Informed Consent

- Do I have a detailed informed consent that follows the American Society of Plastic Surgeons' "Statement of Principle on Informed Consent"?
- Does my informed consent include the necessary information?
 - Details of the surgery
 - Details of the anesthesia
 - Benefits of the surgery
 - Possible consequences and side effects of the surgery
 - Potential risks and adverse outcomes as well as their probability and severity
 - Alternatives to the procedure being considered and their benefits, risks, and consequences
 - Anticipated outcome
- Does my informed consent allow me to individually document the patient education process, including whether the patient watched any videos, viewed before-and-after photographs of other patients, or read any brochures?
- Do I have uniform preoperative and postoperative patient education for specific procedures?

Medical Records

- Are my medical records legible, accurate, complete, and current?
- Do they include the history, physical examination, progress notes, operative reports, laboratory reports, x-ray reports, and communications with other medical personnel?
- Do my medical records highlight allergies and adverse drug reactions?
- Do I document and update my medical records contemporaneously with the patient visit or procedure?
- Do I routinely include patient comments in my medical records, regardless of whether such comments are positive or negative?
- Are my medical records confidential? Do I have written protocols in place that protect patient information from loss, tampering, alteration, destruction, and unauthorized or inadvertent disclosure?

Discharge

- Do I discharge my patients only after they have fulfilled defined written criteria?
- Before I discharge a patient, do I document stable vital signs, responsiveness, orientation, voluntary movement, controlled pain, and minimal nausea and vomiting?
- Do my written discharge instructions include postprocedure diet, medications, activities, and an emergency telephone number?
- Do I document that I discharged my patient only in the presence of a responsible adult who accompanied them home and who is able to report any postprocedure complications?

SYSTEM OF EVALUATION FOR OFFICE-BASED SURGICAL PROCEDURES

For each patient, the physician should have a protocol system that allows the physician to record whether such procedure can safely be performed in the office-based setting. This system should provide a checklist that considers the risk factors inherent in the prospective procedure(s), including hypothermia, intraoperative blood loss, liposuction, thrombolytic, and embolism hazards, and potential postoperative recovery problems.

Hypothermia

- Do I have the necessary equipment for the office-based surgical procedure that I am considering?
 - Cutaneous warming devices (Bair Huggers)
 - Forced air warmers
 - Intravenous fluid warmers
- If I do not have such equipment, will the procedure be limited to 2 hours and 20 percent of the total body surface area?

Intraoperative Blood Loss

- Does my record system allow me to document that the procedure is expected to involve 500 cc or less of blood loss?

Duration of Procedure

- Will the procedure be less than 6 hours in duration?
- If it is a longer procedure, will it end before 3 pm and consequently provide sufficient recovery time for my patient?

Thrombosis and Embolism Risks

- Does my history protocol allow me to systematically document the patient's thrombosis and embolism risks?
 - History of deep vein thrombosis
 - Unexplained episodes of syncope, dyspnea, or pleuritic pain
 - Hypercoagulable states
 - Medications such as contraceptives and replacement hormones
 - Family history with emphasis on past episodes of thrombosis and embolism
- Does my physical examination protocol allow me to systematically document the patient's thrombosis and embolism risks?
 - Unexplained skin discoloration or ulceration
 - Unexplained edema or swelling
- Does my protocol provide laboratory screening if the history or physical examination so indicates?

Thromboprophylaxis

- Does my protocol allow me to assign the patient a venous thrombosis or embolism risk status of low, moderate, high, or highest?

Potential Postoperative Recovery Problems Leading to Unplanned Hospital Admissions

- Have I provided adequate pain medication, including home medication, based on the patient's body mass index?
- Have I adequately controlled my patient's nausea, vomiting, and dizziness?

SYSTEM OF PATIENT EVALUATION FOR OFFICE-BASED SURGICAL PROCEDURES

The physical examination and medical history are among the most important patient safety assessment steps. The surgeon should have a systematic protocol to determine whether the patient is appropriate for the office-based procedure.

Physical Examination and History

- Does my physical examination include all the necessary information that I need to adequately assess whether the patient can safely undergo the office-based procedure?
 - Patient's health history
 - Social history

- Family history
- Allergies (drug, latex, tape)
- Medication regimen (including nonprescription drugs)
- Patient's age, weight, height, appearance, and vital signs
- Comorbidities, especially:
 - Diabetes
 - Cardiac disease
 - Respiratory conditions

Preoperative Tests

- Electrocardiogram for patients over 45 years old or at any age if cardiac conditions are known
- Complete blood cell count with chemistries as needed for anemia, diabetes mellitus, hypertension, and diuretic therapy
- Pregnancy test for all women of childbearing age, unless there is documented surgical sterilization

American Society of Anesthesiologists' Physical Classification Rating

- Does my protocol allow me to document the patient's American Society of Anesthesiologists' physical classification rating?
 - 1, normal healthy patient
 - 2, patient with mild systemic disease
 - 3, patient with severe systemic disease
 - 4, patient with severe systemic disease that is a constant threat to life
- Does my protocol categorize the patient's candidacy for ambulatory and office-based surgery?
 - Type 1 and 2 patients are candidates for ambulatory and office-based surgery
 - Type 3 patients may be candidates for an office-based surgical procedure with local anesthesia (with or without sedation)
 - Type 4 patients are only candidates for office-based procedures with local anesthesia and without sedation

LIPOSUCTION

Large-Volume Liposuction

- If I am performing a combination of procedures that includes liposuction, have I carefully weighed the benefits of performing all the procedures contemporaneously against the potential adverse consequences?

- Notwithstanding the number of procedures, is the total aspirant limited to 5000 cc?
- Does my postliposuction surgery protocol allow me to document the signs of volume overload?
 - increased blood pressure, jugular vein distension, and full bounding pulses
 - cough, dyspnea, lung crackles, and pulmonary edema
- Do I have the necessary qualified and competent staff that can effectively monitor my liposuction patient's postoperative vital signs and urinary output?
- Have I created a documented system that promotes communication with the anesthesia care provider about fluid management?
- Does this documentation system include accounting for:
 - maintenance requirements
 - preexisting deficits
 - intraoperative losses of aspirated tissue
 - third-space losses
 - preoperative and postoperative hemoglobin measurements

Liposuction Anesthesia

- Have I adequately added preemptive and prolonged local anesthesia to my liposuction wetting solutions?
- Is my staff trained to recognize the toxic affects of Marcaine, including cardiac arrhythmias, seizures, respiratory depression, and coma?
- If I use lidocaine with epinephrine, is such dosing limited to 7 mg/kg when injected into subcutaneous fat?
- Is my staff trained to recognize lidocaine toxicities, including light-headedness, restlessness, drowsiness, tinnitus, metallic taste, lip numbness, and slurred speech?
- Before using lidocaine, have I considered the factors that contribute to lidocaine toxicity, including drug absorption rate, drug interactions, fluid management, and prothrombotic factors?
- Do I take the necessary patient precautions to avoid lidocaine toxicity by:
 - limiting the lidocaine to smaller concentrations in the wetting solution
 - using the superwet technique rather than the tumescent technique
 - not using lidocaine with general or regional anesthesia¹⁴

- Do I avoid the use of epinephrine in patients with pheochromocytoma, hyperthyroidism, severe hypertension, cardiac disease, or peripheral vascular disease?
- Do I attempt to limit the epinephrine dosage to 0.07 mg/kg?
- Do I utilize the American Society of Anesthesiologists' "Guidelines for Sedation and Analgesia"?
- Do I avoid the use of epidural and spinal anesthesia in liposuction procedures?

Liposuction Patient Selection

- Have I performed a complete preoperative history and physical examination on my liposuction patient?
- Have I adequately warned my patient of the inherent risks of surgery, including poor wound healing, infection, deep venous thrombosis, and sleep apnea?
- For severely and morbidly obese patients (body mass index > 30), have I thoroughly informed them that liposuction is not a treatment for them and recommended that they seek other surgical counseling for the possibility of gastric banding (restrictive) or gastric bypass (malabsorptive) procedures?

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