



Office-Based Surgery for Adults

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PURPOSE OF RISK MANAGEMENT RECOMMENDATIONS

OMIC regularly analyzes its claims experience to determine loss prevention measures that our insured ophthalmologists can take to reduce the likelihood of professional liability lawsuits. OMIC policyholders are not required to implement these risk management recommendations. Rather, physicians should use their professional judgment in determining the applicability of a given recommendation to their particular patients and practice situation. These loss prevention documents may refer to clinical care guidelines such as the American Academy of Ophthalmology's Preferred Practice Patterns, peer-reviewed articles, or to federal or state laws and regulations. However, our risk management recommendations do not constitute the standard of care nor do they provide legal advice. If legal advice is desired or needed, an attorney should be consulted. Information contained here is not intended to be a modification of the terms and conditions of the OMIC professional and limited office premises liability insurance policy. Please refer to the OMIC policy for these terms and conditions.

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Some ophthalmic surgical procedures can be safely performed in an office surgical suite. Others with higher risk profiles raise a number of concerns. If a patient experiences a serious complication or poor outcome and decides to sue the ophthalmologist, all aspects of the care will be questioned, including the decision to perform the procedure in the office.

The major concerns regarding in-office versus surgery center or hospital procedures revolve around the age and medical condition of the patient; the type of anesthesia; whether sedation is administered; the skills, training, and licensure of staff; the ability of the ophthalmologist and staff to respond to emergencies; and the availability of appropriate monitoring and resuscitation equipment.

Regardless of the setting of the surgery (office, ASC, or hospital), the same standard of care applies, and the safety of the patient should be the guiding principle in the decision-making process. **The following risk management recommendations are offered in order to promote patient safety and reduce the physician's professional liability risk.**

WRITTEN PROTOCOLS

- Establish written protocols for office-based surgery that address:

- Selection criteria (types of procedures, anesthesia (if any), sedation, patients, etc.)
- Immediate pre-procedure evaluation (i.e., reasons why surgery should be cancelled and/or moved to an ASC or hospital)
- Training and competency of staff
- Minimal staffing levels while patients are present (at least two, one of whom must be licensed)
- How to contact emergency medical personnel (e.g., “call 911”)
- Criteria and method for transferring a patient to the local hospital in the event of an emergency
- Emergency equipment
- Discharge evaluation and criteria

PROCEDURE SELECTION

- The procedure should be within the scope of practice and current competency of the ophthalmologist, and the monitoring and rescue capability of the staff and office.
- The procedure should be of a duration and complexity that will permit the patient to recover and be discharged home from the office.

PATIENT SELECTION

Patient selection criteria play a central role in the decision-making process. Our suggestions are based upon ophthalmic claims experience at OMIC and other professional-liability carriers, as well as a detailed review of pertinent clinical practice recommendations, laws, regulations, and accreditation requirements.

- **Recommendation: Limit office-based procedures with a risk of serious complications to patients with ASA Physical Status 1 or 2**
 - The American Society of Anesthesiologists (ASA) has a Physical Status Classification System that assigns a category after the physician completes a history and physical examination (see Resources section at the end of the document):
 - P1: normal, healthy patient
 - P2: mild systemic disease
 - P3: severe systemic disease
 - P4: severe systemic disease that is a constant threat to life
 - P5: a moribund patient who is not expected to survive without the operation
 - P6: a declared brain-dead patient whose organs are being removed for donor purposes
 - The ASA does not elaborate on what these classifications mean. The ophthalmologist must use professional judgment, and consult with an anesthesiologist or the patient’s primary care physician as needed, to determine if patients have particular ocular or medical comorbidities that require the services of an ASC or hospital. Particular attention should be paid to patients with hypertension or those with cardiovascular disease or its risk factors. For example, patients with more than one mild systemic disease may be considered ASA P3 (e.g., a patient with hypertension and diabetes that

- requires medication for control, or one with both hypertension and coronary artery disease, etc.).
- **ASA P3 patients should NOT have procedures with the potential for serious complications performed in an office setting.** We recommend that these patients be treated in an ASC or hospital setting, depending upon the severity and extent of their medical problems.
 - **Recommendation: Provide only minimal sedation/analgesia in the office setting**
 - The ASA guidelines note that because sedation is a continuum, it is not always possible to predict how an individual patient receiving sedation will respond. Sufficient qualified individuals must be present both to perform the procedure and to monitor the patient throughout the administration of sedation and recovery from it.
 - The ASA has defined levels of sedation/analgesia.
 - Minimal sedation (“anxiolysis”) is defined as “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.”
 - Examples of minimal sedation for ADULTS includes peripheral nerve blocks, local or topical anesthesia and either 1) less than 50% N₂O or 2) a single, oral sedative or analgesic medication administered in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain.
 - Moderate (“conscious”) sedation is defined as a “drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation.”
 - NOTE: reflex withdrawal from a painful stimulus is NOT considered a purposeful response
 - No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
 - Deep sedation/analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation.
 - NOTE: reflex withdrawal from a painful stimulus is NOT considered a purposeful response
 - 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.
 - **Moderate (“conscious”) sedation should NOT be administered in an office unless an anesthesia provider is present (i.e., an anesthesiologist or certified registered nurse anesthetist).**
 - Patients receiving moderate sedation risk slipping into deep sedation, where the ability to maintain ventilatory function may be impaired.

Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate.

- Most ophthalmic personnel lack the skill, training, and licensure to monitor and rescue patients receiving moderate sedation. Moreover, office surgical suites are rarely adequately equipped to monitor and rescue these patients.
- If moderate (“conscious”) sedation is administered, the office must have appropriate emergency and monitoring equipment. Please see OMIC’s Outpatient Surgical Facility Application for details.

MONITORING

- Monitor and document pulse and blood pressure before, during, and after the procedure.
- Carefully document any care given in response to changes in blood pressure readings or the clinical situation.
 - The major complication of any eyelid procedure is hemorrhage, which can lead to blindness. Hemorrhage is generally associated with uncontrolled hypertension. Even in healthy patients, blood pressure may suddenly spike to high levels during surgery. Such spikes would go unnoticed if the pressure were not monitored. Another serious result of uncontrolled hypertension is a cardiac event or stroke.
 - Patients with a history of hypertension or patients who present with an elevated blood pressure on no therapy may have an exaggerated blood pressure response to any noxious stimuli (i.e., pain with injection, epinephrine in the injection, and pain in surgery due to incomplete or ineffective local anesthesia).
 - Other painful stimuli such as bladder distention can also produce an abnormal blood pressure response.
 - Sedation will not eliminate this blood pressure response and should not be considered therapy for increased blood pressure.
- Reevaluate the decision to perform the procedure in the office if the preoperative blood pressure is elevated.
 - If the diastolic blood pressure is > 110 mm Hg, or the systolic pressure is > 200 mm Hg, cancel surgery and send the patient for treatment. Document the referral.
 - If the diastolic blood pressure is between 90 and 109 mm Hg, or the systolic pressure is between 160 and 200 mm Hg, strongly consider postponing elective surgery.
 - If the surgery is urgent, emergent, or the patient has traveled a long distance, consider admission to the hospital under the direct supervision of a medical team and an anesthesiologist.
 - To eliminate cancellation due to the “white coat syndrome,” surgeons may wish to allow patients five minutes in a quiet room, then retake the blood pressure.
- Consider using a pulse oximeter to measure oxygen saturation in the blood for more complicated procedures or for patients at higher risk. Examples of patients and procedures that might require pulse oximeter include:

- Patients receiving sedation
- Procedures that require extensive dissection
- Procedures of long duration (e.g., > than 30 minutes)
 - Patients in ASA PS 1, 2, or 3 undergoing only “minor” lid procedures (e.g., biopsy, skin tag excision) may not require pulse oximetry monitoring.
- The decision to discharge the patient to his or her home in the company of an adult should be made by the surgeon or registered nurse and based upon written discharge criteria (e.g., oriented, stable vital signs, minimal nausea and/or dizziness, able to maintain pre-procedure mobility).

EMERGENCY RESPONSE AND EQUIPMENT

- Anticipate, train staff to recognize, and be prepared to respond to the “worst case scenarios” associated with the procedure in question (e.g., hemorrhage and cardiopulmonary problems).
- Ensure that all staff members and ophthalmologists have at least met certification requirements for BLS (Basic Life Support) for Healthcare Providers.
 - See the Resources section, below, for information on BLS for Healthcare Providers courses given by the American Heart Association.
 - If an anesthesia provider administers moderate (“conscious”) sedation, the office should meet the post-procedure monitoring, discharge, and emergency response criteria detailed in OMIC’s Outpatient Surgical Facility Application.
- Ask the assistance of your hospital’s Pharmacy and Therapeutics Committee or Anesthesia Department in determining which emergency medications and equipment should be available. If only brief, “minor” procedures are performed, you may be advised that you do not need all of the equipment and supplies described here.
- On the outside of the emergency kit containing the medications, note:
 - Written instructions on administration (amount, dosage calculations if any, route, how often the dose can be repeated, etc.).
 - This is important since emergency medications are not frequently used by ophthalmologists, and memory is not reliable in an emergency.
 - Expiration dates
- If procedures with a higher risk profile are performed in the office, consider having an Automated External Defibrillator (AED).
 - Ensure that ophthalmologists and staff are trained and competent in its use. This training is provided during BLS for Healthcare Provider courses given by the American Heart Association.
 - Some offices already have a defibrillator, and do not need to acquire an additional AED.
 - If the office only performs brief, “minor” procedures such as skin tag excision and biopsies, an AED may not be required.
 - OMIC recognizes that the standard of care for emergency equipment is evolving. An AED affords an added margin of safety for all patients undergoing invasive procedures, and for those patients whose age predisposes them to cardiovascular problems. An AED may be a wise investment for the ophthalmologist. See the Resources section, below, for information on AEDs.

- If moderate sedation is administered, either a cardiac defibrillator or an AED is required.
- Resuscitative equipment should include suction, materials for starting IVs, and providing airway support (the ability to intubate is ideal, but, at a minimum, an Ambu bag and oxygen are required.)
- State-mandated guidelines regarding “in-office” surgery must be followed (e.g., in California and Florida).

RESOURCES

- American Society of Anesthesiologists www.asahq.org
 - ASA Physical Status Classification System, www.asahq.org/clinical/physicalstatus.htm, accessed 2/18/05
 - Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia , approved 13 October 1999, accessed 2/18/05, <http://www.asahq.org/publicationsAndServices/standards/20.pdf>
 - Office-Based Anesthesia Guidelines <http://www.asahq.org/Washington/oba.htm>
 - Basic Standards for Pre-Anesthesia Care, Basic Anesthesia Monitoring, and Post-Anesthesia Care <http://www.asahq.org/publicationsAndServices/standards/02.pdf>
 - Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists <http://www.asahq.org/publicationsAndServices/sedation1017.pdf>
 - Practice Guidelines for Preoperative Fasting and the Use of Pharmacological Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures <http://www.asahq.org/publicationsAndServices/npoguide.html>
- American College of Emergency Physicians www.acep.org
 - ACED AED Fact Sheet <http://search.acep.org:8080/PortalInABox460/portlets/autosuggest.jsp?username=e8e9e6e5f9e0f8&pib=true&threshold=50&numresult=10&defaultlogo=htm.gif&display=775&url=http%3A%2F%2Fwww.acep.org%2F1%2C2891%2C0.html&links=A&command=getoriginal>
- American Heart Association www.americanheart.org
 - BLS for Healthcare Providers <http://www.americanheart.org/presenter.jhtml?identifier=3011775>
 - AED Implementation Guide <http://www.americanheart.org/presenter.jhtml?identifier=3027225>

OMIC policyholders who have additional questions or concerns about practice changes are invited to call OMIC’s confidential Risk Management Hotline at (800) 562-6642, extension 641.

