

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 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. Consult an attorney if legal advice is desired or needed. 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.

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 can help you promote patient safety and reduce your professional liability risk.

WRITTEN PROTOCOLS

- Establish written protocols for office-based surgery that address:
 - Selection criteria (types of procedures, anesthesia, 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)
 - Discharge evaluation and criteria
 - 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 and protocols

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. Please see “Preoperative assessment” at [\[insert link\]](#) for a detailed analysis of how to assess cardiac and respiratory risk, and of CMS regulations on preoperative history and physical examinations.

- **Recommendation #1: Limit office-based procedures to patients with ASA PS I and II if there is a risk of serious operative complications.**
 - The American Society of Anesthesiologists (ASA) has a Physical Status Classification System¹ that assigns a category after the physician completes a history and physical examination. The first three categories of patients are discussed here as they are the ones most likely to undergo ophthalmic surgery. The examples given are those of the ASA.
 - PS I: Normal, healthy patient
 - Non-smoking
 - No or minimal alcohol use
 - PS II: Mild systemic disease
 - Current smoker
 - Social alcohol drinker
 - Pregnancy
 - Obesity (30 < BMI < 40)
 - Well-controlled diabetes mellitus (DM) or hypertension (HTN)
 - Mild lung disease
 - PS III: Severe systemic disease
 - Poorly controlled DM or HTN
 - Active hepatitis
 - Alcohol dependence or abuse

¹ ASA Physical Status Classification System www.asahq.org/clinical/physicalstatus.htm; accessed 10/29/20.

- Implanted pacemaker
 - Moderate reduction of ejection fraction
 - End stage renal disease
- 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 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.*
- **Recommendation #2: ASA PS III patients with the potential for serious systemic or ocular complications should have their surgery at an ASC or hospital.**
- **Recommendation #3: Manage patients on anticoagulant and/or antiplatelet medications.**
 - Determine whether the patient is on anticoagulant and/or antiplatelet medications.
 - Take these medications into account when deciding whether to use an anesthetic block.
 - Explain the pros and cons of continuing vs. temporarily stopping the medications.
 - Discuss any planned change in anticoagulant or antiplatelet medication with the provider who prescribed them.
 - Give the patient written preoperative instructions, if changes are planned, that clarify when to stop and restart.
 - Obtain informed consent (<https://www.omic.com/anticoagulants-consent-form/>).
- **Recommendation #4: Obtain informed consent for anesthesia and sedation.**
 - Inform patients of your recommendations for sedation and/or anesthesia.
 - Document the decision-making process and consent discussion.
- **Recommendation #5: Provide only minimal sedation/analgesia in the office setting.**
 - The ASA guidelines² 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."

² ASA Continuum of Depth of Sedation: <https://www.asahq.org/standards-and-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedationanalgesia>

- 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.
 - Although not discussed in the ASA document, there are FDA-approved systems for patients to self-administer a 50/50 mix of oxygen and N₂O. These delivery systems are often used for oculofacial procedures in an office setting.
 - 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.
- **Recommendation #6: 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 should have appropriately trained personnel and resuscitative equipment, as discussed more fully below.
- **Recommendation #7: Be prepared to manage complications of anesthetic blocks.**

- OMIC has settled lawsuits related to the administration of local and retrobulbar blocks in the office.³
- Patients have experienced globe perforations, hemorrhage, and death from brainstem anesthesia.
- Be prepared to perform procedures such as lateral canthotomy and CPR with bag mask respirations.
- Consider early referral to ophthalmic sub-specialists for ocular complications, and urgent referral to a hospital for other anesthesia complications.

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. Uncontrolled hypertension can also lead to 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.

³ Morley M, Menke AM, Nanji KC. Ocular Anesthesia-Related Closed Claims from Ophthalmic Mutual Insurance Company 2008 to 2018. *Ophthalmology*; 2020; 127: 852-858. [https://www.aaojournal.org/article/S0161-6420\(19\)32371-1/fulltext](https://www.aaojournal.org/article/S0161-6420(19)32371-1/fulltext); accessed 10/30/20.

- 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 moderate (conscious) sedation
 - Procedures that require extensive dissection
 - Procedures of long duration (e.g., > than 30 minutes)
 - Patients in ASA PS I, II, or III 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 clinical 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 clinical 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.
- 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.)
- Ask the assistance of your hospital’s Pharmacy and Therapeutics Committee or Anesthesia Department in determining which emergency medications and additional equipment should be available.
- 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.
- State-mandated guidelines regarding “in-office” surgery must be followed (e.g., in California and Florida).

RESOURCES

- American Society of Anesthesiologists (all accessed on 10/26/20) www.asahq.org
 - ASA Physical Status Classification System: www.asahq.org/clinical/physicalstatus.htm.
 - Continuum of Depth of Sedation: <https://www.asahq.org/standards-and-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedationanalgesia>
 - Office-Based Anesthesia Guidelines: <https://www.asahq.org/standards-and-guidelines/guidelines-for-office-based-anesthesia>.
 - Basic standards for anesthesia care:
 - Pre-Anesthesia Care: <https://www.asahq.org/standards-and-guidelines/basic-standards-for-preanesthesia-care>
 - Basic Anesthesia Monitoring: <https://www.asahq.org/standards-and-guidelines/standards-for-basic-anesthetic-monitoring>
 - Post-Anesthesia Care: <https://www.asahq.org/standards-and-guidelines/standards-for-postanesthesia-care>
 - Documentation: <https://www.asahq.org/standards-and-guidelines/statement-on-documentation-of-anesthesia-care>
 - Statement on Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists: <https://www.asahq.org/standards-and-guidelines/statement-of-granting-privileges-for-administration-of-moderate-sedation-to-practitioners>
- American Heart Association (accessed 10/30/20): www.americanheart.org
 - BLS for Healthcare Providers <https://cpr.heart.org/en/cpr-courses-and-kits/healthcare-professional/basic-life-support-bls-training>
 - AED Implementation Guide: <https://cpr.heart.org/en/training-programs/aed-implementation>.

Need confidential risk management assistance?

OMIC-insured ophthalmologists, optometrists, and practices are invited to contact OMIC’s Risk Management Department at (800) 562-6642, option 4, or at riskmanagement@omic.com.