

Preoperative Medical Assessment

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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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Many patients contemplating ophthalmic surgery have medical conditions that could increase the risk of the procedure and anesthesia/sedation. To prepare for and reduce the risks as much as possible, patients undergo a preoperative medical assessment that usually includes a history and physical examination (H&P). Such an assessment has been mandated by CMS (Centers for Medicare and Medicaid Services). Regulations passed in 2019, however, give surgery centers more flexibility in determining who needs a preoperative H&P and when it must be performed; these new regulations are discussed in Part 2. Ophthalmologists may play a role in these determinations. They may also be performing the H&P themselves. This analysis provides information to guide decision making about the preoperative medical assessment.

Part 1: Assessing the patient's risks

Surgery and anesthesia both have inherent risk. These risks cannot be eliminated. Rather than "clear" patients for surgery, anesthesiologists, cardiologists, and other internal medicine specialists have worked to develop guidelines to identify the level of risk, optimize the patient's condition before surgery whenever possible, anticipate potential complications, and determine where surgery should take place.

The American College of Cardiology (ACC) and the American Heart Association (AHA) provide guidance for patients undergoing noncardiac surgery.¹ There are more than 50 million surgeries performed

¹ American College of Cardiology (ACC)/American Heart Association (AHA) 2014 Guidelines on Perioperative Cardiovascular Evaluation and Management of Patients Undergoing Noncardiac Surgery.

annually in the United States. Perioperative cardiac events occur in 1.4 to 3.9% of these procedures, and are the most common cause of morbidity and mortality. To determine the level of cardiac risk, the ACA and AHA recommend evaluating the procedure type and patient characteristics.

Procedural risk

Ophthalmic surgeries are generally considered low cardiac risk, since they are minimally invasive and lead to limited fluid shifts and cardiac stress. Cataract surgery is one of the two examples given of a low cardiac-risk procedure.

Patient risk: Anesthesia/sedation

Although not discussed in the ACA/AHA guidelines, each type of anesthesia or sedation has different risks. For example, the risk of hemorrhage is increased when anesthesia blocks are administered to patients with poorly-controlled hypertension, hemophilia, and those taking anticoagulant/antiplatelet medications. The need for general anesthesia, especially during prolonged vitreoretinal procedures, may increase the risk for some patients. Explain the type of anesthesia/sedation you prefer and why you feel this is the best option for the patient. If the patient is referred to another physician for the preoperative assessment, clarify what type of anesthesia/sedation is planned, and ask the physician to comment on it. If you will be administering the block, obtain informed consent for it.

Patient risk: Cardiac issues

Several organizations, including the ACA working in conjunction with the AHA, have developed risk calculators focused on ascertaining a patient's risk of a major adverse cardiovascular event—MACE—during surgery. One calculator, called the Revised Cardiac Risk Index (RCRI)², checks for the following conditions. Each one is given a point, and then the total MACE score is calculated, as seen in **Table 1**:

- **History of ischemic heart disease**
 - History of MI
 - History of positive exercise test
 - Current chest pain considered to be myocardial ischemia
 - Use of nitrate therapy
 - ECG with pathological Q waves
- **History of congestive heart failure**
 - Pulmonary edema, bilateral rales, or S3 gallop
 - Paroxysmal nocturnal dyspnea
 - CXR showing pulmonary vasculature reorganization
- **History of cerebrovascular disease**
 - Prior TIA or stroke
- **Preoperative insulin treatment**
- **Preoperative creatinine > 2mg/dL**

² Revised Cardiac Risk Index (RCRI) available at [https://www.thecalculator.co/health/Revised-Cardiac-Risk-Index-\(RCRI\)-Calculator-872.html](https://www.thecalculator.co/health/Revised-Cardiac-Risk-Index-(RCRI)-Calculator-872.html) (accessed 10/29/20).

Score	MACE risk	Recommendation
0	0.4%	May proceed to surgery if no acute coronary syndrome
1	0.9%	May proceed to surgery if no acute coronary syndrome
2	6.6%	Refer for further evaluation
3 to 6	11%	Refer for further evaluation

The patient’s risk for MACE increases slightly if one of these risk criteria is present, but the risk is still below 1%. Patients with two or more criteria have a significantly higher risk. Ophthalmologists may not have access to pertinent information about each of the MACE criteria. Instead, they can use these criteria to screen for increased risk, and refer patients with more than one to their PCP or cardiologist for a preoperative assessment that includes input on the safest site for the surgery (i.e., office vs. ASC vs. hospital).

Patient risk: Respiratory and other issues

The American Society of Anesthesiologists assesses risk in a way that includes respiratory function and social history. Their Physical Status (PS) classification system assigns patients to one of six categories.³ As a general rule, most patients undergoing eye surgery would fall into ASA PS I– IV.

ASA PS Classification	Definition	Examples
ASA I	A normal, healthy patient	<ul style="list-style-type: none"> • Healthy • Non-smoking • No or minimal alcohol use
ASA II	<p>A patient with mild, systemic disease</p> <p>Mild disease only without substantive functional limitations</p>	<ul style="list-style-type: none"> • Current smoker • Social alcohol drinker • Pregnancy • Obesity (30 < BMI < 40) • Well-controlled diabetes mellitus (DM) or hypertension (HTN) • Mild lung disease
ASA III	<p>A patient with severe systemic disease</p> <p>Substantive functional limitations</p>	<ul style="list-style-type: none"> • Poorly-controlled DM or HTN • COPD • Morbid obesity (BMI > 40) • Active hepatitis • Alcohol dependence or abuse • Implanted pacemaker

³ ASA Physical Status Classification System: www.asahq.org/clinical/physicalstatus.htm; accessed 10/29/20.

	One or more moderate to severe diseases	<ul style="list-style-type: none"> • Moderate reduction of ejection fraction • End-stage renal disease (ESRD) undergoing regularly scheduled dialysis • Premature infant postconceptual age < 60 weeks • History > 3 months of myocardial infarction (MI), cerebrovascular accident (CVA), transient ischemic attack (TIA), or coronary artery disease(CAD)/stents
ASA IV	A patient with severe systemic disease that is a constant threat to life	<ul style="list-style-type: none"> • Recent (< 3 months) MI, CVA, TIA, or CAD/stents • Ongoing cardiac ischemia or severe valve dysfunction • Severe reduction of ejection fraction • Sepsis • Disseminated intravascular coagulation • ARD (acute renal disease) or ESRD not undergoing regularly scheduled dialysis
ASA V	A moribund patient who is not expected to live without the operation	<ul style="list-style-type: none"> • Ruptured abdominal/thoracic aneurysm • Massive trauma • Intracranial bleed with mass effect • Ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes	

It is prudent to ask about the patient's ability to breathe effectively while recumbent, which may be compromised in patients with COPD, sleep apnea, or morbid obesity. The Cleveland Clinic has

determined that certain healthy patients ought not to be included in ASA PS I. These include patients with psychiatric disturbances, as well as the very young and very old.

Patient risks: Anticoagulant and/or antiplatelet medications

Patients who are on anticoagulant or antiplatelet medications can experience vision-threatening hemorrhage if these medications are continued, or MI or CVA if they are discontinued. These risk reduction measures can improve patient safety.

- 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, and document that physician's input.
- Obtain informed consent (<https://www.omic.com/anticoagulants-consent-form/>).
- Give the patient written preoperative instructions, if changes are planned, that clarify when to stop and restart.
- Address anticoagulant and antiplatelet medications in the pre- and postoperative orders.

Part Two: FAQs about preoperative medical assessments and H&Ps

The Centers for Medicare and Medicaid Services (CMS) mandates evaluations of patients before surgery. Until November 29, 2019, CMS required **all** patients to have 1) an H&P within 30 days of surgery, 2) an update to the H&P on the day of surgery, and 3) an anesthesia and procedure risk assessment (APRA) immediately prior to surgery. New CMS regulations allow hospitals and ambulatory surgery centers (ASCs) to determine which patients need a preoperative H&P as well as the timeline for it. When developing its written policies, the facility needs to consider the patient's age, diagnoses, type and number of surgeries to be performed at one time, all known comorbidities, planned level of anesthesia, and other criteria as needed for their patient population. Interpretive guidelines for the preoperative H&P and update were published on 2/20/20; guidance for how to assess patients who will not have preoperative H&Ps is forthcoming. There is no change to the anesthesia and procedure risk assessment.⁴

While ophthalmologists are medical doctors, as specialists they generally limit their care and treatment to ophthalmic conditions. Accordingly, most ophthalmologists do not perform the preoperative H&P themselves. Instead, they regularly refer the patient to the primary care physician (PCP) or other medical specialist for this evaluation. For similar reasons, ophthalmologists may not feel they can adequately update the H&P on the day of surgery or perform the APRA immediately before surgery.

⁴ State Operations Manual Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals Table of Contents (Rev. 200, 02-21-20) https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf; accessed 10/29/20.

Regardless of their comfort or competency level, ambulatory surgery centers (ASCs) may ask ophthalmologists to perform these evaluations. This is more likely to be the case if the ASC does not have anesthesiologists on site, since CMS Conditions of Participation state that a physician must perform the APRA. We provide recommendations about the ophthalmologist's role by answering questions that physicians have asked us on our Hotline.

Q: I have been conducting the preoperative H&P for years. What are the malpractice risks?

A: The primary purpose of the preoperative H&P is to determine if the chosen procedure and anesthesia are safe and appropriate for the patient, to help anticipate potential complications related to ophthalmic or medical comorbidities, and to determine the site of surgery. If a patient experiences an unanticipated outcome, he or she might allege that the assessment was negligent or failed to detect preexisting medical conditions. If you conduct these evaluations, make sure your H&P skills are up-to-date.

Q: My hospital has asked me to update the patient's preoperative H&P by conducting a physical assessment prior to surgery. I haven't done a preoperative H&P since my residency years ago, and don't feel competent to do one now. What should I do?

A: Your signature on the reassessment form indicates that you have conducted a history and physical examination, however brief. Ophthalmologists whose current competency does not include these skills should decline such requests, and work with the hospital administration to find alternative solutions, such as those described below.

Q: Does a physician have to perform the H&P update on the day of surgery?

A: No. CMS allows other "qualified practitioners" (QPs) to perform the outpatient H&P and the update to it at the ASC. CMS defines QPs as "those licensed practitioners who are authorized in accordance with their state scope of practice laws or regulations to perform an H&P and who are also formally authorized by the ASC to conduct an H&P. Other qualified licensed practitioners could include nurse practitioners [NPs] and physician assistants [PAs]."⁴

Q: The ASC where I operate has hired NPs and PAs to reassess the patient. The ASC wants me to cosign the evaluation. Is it risky for me to do that?

A: No. These practitioners are highly trained professionals whose scope of practice and workload regularly includes performing H&P examinations. OMIC has analyzed the liability risk for ophthalmologists when non-physicians such as Certified Registered Nurse Anesthetists (CRNAs) provide care.⁵ Physicians may be held vicariously liable for the actions of employees. When physicians supervise CRNAs who are not their employees, however, they are not necessarily liable for the CRNA's actions. Courts generally

⁵ Carol Poindexter, JD, and Kimberly Wittchow, JD, "Anesthesia and Sedation Risks and Precautions," *OMIC Digest* Summer/Fall 2004. Available at <https://www.omic.com/anesthesia-and-sedation-risks-and-precautions/>.

focus on the amount of control the physician exercises over the provider—whether the anesthesia provider is a CRNA or an anesthesiologist. While plaintiff attorneys might argue that the ophthalmologist’s signature on anesthesia orders, evaluations, or records is proof of control, they will need further evidence that the physician directed the actions of the CRNA to win their case. Similarly, simply cosigning the update to the patient’s condition does not make the ophthalmologist liable for the actions or omissions of the NP or PA.

Q: Does my signature imply that I am certifying the reassessment?

A: No. Your signature on a reassessment form acknowledges that another licensed provider has evaluated the patient’s medical condition. It does not imply that you are attesting to the accuracy or thoroughness of the examination in question. Once the NP or PA has completed the history and physical examination, read it, and write “Patient reassessed prior to surgery and cleared by _____ NP/PA” (include the provider’s name and title).

Q: Anesthesia providers perform a pre-anesthesia evaluation. Can the hospital use this to update the patient’s condition?

A: Many hospitals and surgery centers meet the CMS H&P update requirements in this way. Anesthesiologists and CRNAs have considerable expertise in conducting H&Ps and must evaluate the patient prior to administering sedation or anesthesia. Check the policy at each facility where you operate.

Q: Do I have to determine the patient’s ASA PS level?

A: No. The anesthesiologist or CRNA determines this during the pre-anesthesia assessment.

Q: What is the purpose of the APRA?

A: According to the CMS manual, the APRA is intended to “evaluate, based on the patient’s current condition, whether the risks associated with the anesthesia that will be administered and with the surgical procedure that will be performed fall within an acceptable range for a patient having that procedure in an ASC.”⁴ The Manual does not explain how to do this evaluation, but gives the ASA Physical Status Classification System as an example (this was discussed in detail in Part 1). CMS considers this system a standard tool for predicting morbidity and mortality in surgical patients. It explains that an ASC “that employed this classification system in its assessment of its patients might then consider, taking into account the nature of the procedures it performs and the anesthesia used, whether it will accept for admission patients who would have a classification of ASA PS IV or higher. For many patients classified as ASA PS level III, an ASC may also not be an appropriate setting, depending upon the procedure and anesthesia.”

Q: How can I reduce the risks of conducting the APRA?

A: Work with the ASC to develop a written policy on how best to conduct the APRA. Ask the CRNA to tell you the assigned ASA PS level and his or her assessment of the patient’s ability to undergo surgery at the ASC. Use this anesthesia assessment, along with your knowledge of the risks of the planned procedure, to determine whether the surgery may proceed.

Q: There are no anesthesiologists at the ASC where I operate. The ASC insists that I assess the patient immediately before surgery to evaluate the risk of anesthesia and the procedure. Do I have to perform this?

A: While NPs and PAs may conduct the preoperative H&P and the update to it, CMS stipulates that only a physician may perform this anesthesia and procedure risk assessment. CMS defines physicians as a doctor of medicine or osteopathy, doctor of dental surgery or dental medicine, doctor of podiatric medicine, doctor of optometry, or a chiropractor. If you are the only physician involved in your patient’s care, the ASC may ask you to do this. If you do not feel that you can, you may need to perform surgery at an ASC with an anesthesiologist.

The ophthalmologist, PCP, and anesthesia providers all have a vital role to play in ensuring that surgical care is safe. Working together, they can reduce the patient safety and liability risks.

Need confidential risk management assistance?

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