Responding to unanticipated outcomes

Anne M. Menke, RN, PhD
OMIC Patient Safety Manager

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. 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.

Version 7/12/17

Dealing with unanticipated outcomes is one of the most difficult aspects of medical practice, especially if an error contributed to the result. While many physicians want to talk to their patients about adverse events, they may hesitate to do so for a variety of reasons. Some fear that disclosing complications may prompt a lawsuit. Others may lack the communication skills necessary to respond to a patient's anger and grief with compassion rather than defensiveness. When other health care providers or organizations are involved in a poor outcome, the ophthalmologist may feel conflicting loyalties or be concerned about the impact of a disclosure discussion on collegial relationships, referral patterns, or credentialing.

Regardless of their comfort level, ophthalmologists no longer control whether or not to disclose medical misadventures. Increasing numbers of medical groups, organizations, and health plans require that patients be informed of care outcomes as part of peer review and quality management, and as a recognition that patients have a need and a right to know about their own condition.

The best reason for disclosure, though, is the effect it has on the physician-patient relationship. Communicating in a sympathetic and non-defensive way with the patient or patient's family about the adverse outcome may help dispel much of the anger, confusion, and distrust. A patient's belief that he or she is not being told the whole story,

or is not being given the opportunity to ask the physician questions and vent feelings, often provokes a decision to seek the advice of an attorney and pursue a medical malpractice claim against the ophthalmologist. Indeed, studies have shown that patients who sued their physician often did so because their doctor did not help them understand the unanticipated outcome. Patients want their physician to do three things after poor outcomes: explain what happened, say he or she is sorry that the patient experienced the poor outcome, and take steps to prevent the same thing from happening to other patients.[1]

GUIDANCE FOR OPHTHALMOLOGISTS

OMIC has always encouraged its policyholders to communicate honestly and compassionately with their patients about care outcomes. These steps help ophthalmologists handle these difficult situations:

1. CARE. Take care of the patient.
2. PRESERVE. Preserve the evidence.
3. DISCLOSE. Conduct the initial disclosure discussion.
4. DOCUMENT. Document the outcome, disclosure discussion, and care.
5. REPORT. Complete mandatory reports if required.
6. CONTACT. Contact the Risk Manager for assistance.
7. NOTIFY. Notify the Claims Department if appropriate.
8. RESPOND. Respond to patient complaints and questions about remedies.
9. ANALYZE. Analyze the cause in order to improve future outcomes.
10. FOLLOW THROUGH. Conduct additional disclosure discussions as the EA progresses.
11. HEAL. Heal the health care team.

Key terms

Unanticipated outcome

This can be a negative or unexpected result stemming from a diagnostic test, medical judgment, treatment, or surgical intervention. At times, the failure to perform a test, treatment, or intervention affects the outcome.

Malpractice or maloccurrence?

Patients who experience unanticipated outcomes are often confused about the difference between a poor or unsatisfactory outcome—a maloccurrence—and malpractice. An unanticipated outcome may or may not be the result of error or negligence. Not all errors are the result of medical malpractice. The investigation may reveal that what initially appeared to be malpractice was instead either the result of the disease process itself, or a foreseeable or unpreventable complication of risky, even life- or vision-saving treatment.

[1] Vincent C, Young M, Phillips A, "Why do patients sue doctors? A study of patients and relatives taking legal action." *The Lancet*. 1994; 343: 1609-13.

An ophthalmic example may help clarify this distinction between malpractice and a maloccurrence. Rupture of the posterior capsule is a well-known complication of cataract surgery. The surgeon is not necessarily negligent if this occurs. He or she may be, however, if the ophthalmologist did not:

- Explain the potential complication to the patient as part of the informed consent process.
- Recognize and address the complication in a timely manner.
- Disclose and document the complication.
- Give adequate discharge instructions that address:
    - Diet, activity, wound care, and the follow-up appointment,
    - How to contact the surgeon,
    - What symptoms to report, and
    - The consequences of not informing the physician or seeking care (e.g., "These symptoms could indicate a serious infection or a retinal detachment. You could lose vision or go blind if these conditions are not treated promptly").

<u>Elements of negligence</u>

Plaintiffs (patients) must prove these elements in a medical malpractice lawsuit:

- Duty: a duty of care owed as the result of a physician-patient relationship.
- Negligence: a breach in the duty caused by the defendant's negligent act or omission (i.e., a deviation from the standard of care or SOC).
- Causation: a direct link between the defendant's negligent act or omission and an injury suffered by the plaintiff.
- Damages: pain and suffering, disability and disfigurement, past and future medical bills, lost wages, wrongful death, etc.

Patients who have experienced unanticipated outcomes want quick and clear answers about what happened. It takes time, however, to determine if an ophthalmologist breached the SOC, as the investigation includes a thorough analysis of the entire process of care, review of patient records, and consultation with medical experts who provide their opinions during sworn testimony. Many times, the investigation does not begin until the patient files a lawsuit, which can be years after the care.

<u>Event analysis (EA)</u>

EA leads to continuous quality improvement; it should take place as soon as possible after an event. The EA evaluates the causes of the unanticipated outcome in order to improve patient outcomes in the future. It can take many forms, and include discussions of patient safety issues with the Risk Manager of the facility or the physician's professional liability insurance company, review of incident reports, formal meetings of peer review, quality assurance, performance improvement, and risk management committees, as well as morbidity and mortality conferences.

<u>Confidential</u>

Some but not all types of EA are legally "confidential." Clarify the legal status of event analysis in your state and under federal law before embarking upon an EA to determine how to conduct the analysis and protect the confidentiality of documents and

discussions. You may need to focus on a patient safety issue instead of a specific case if there is no confidentiality protection available under state or federal law. Take steps to protect the confidentiality if there are such protections, such as limiting discussions to a "need to know" basis for the purposes of the EA, avoiding photocopying documents, and refraining from referring to the EA in the medical record. Most states require a "fair hearing" prior to taking action against a physician, such as restricting privileges. Medical staff by-laws generally stipulate the steps of the hearing process, including which aspects are confidential. Get legal advice before embarking on this kind of review so that you comply with all such requirements.

Possible examples of legally confidential material include:

- Results of formal peer review, quality assurance, performance improvement, or risk management committee reviews conducted pursuant to the facility's medical staff by-laws.
- Information provided in confidence by a third party.
- Details about an organization or its operations.
- Health or employment information about a provider or an employee.

For the purposes of this discussion, we refer to all such information as "confidential." Consult an attorney in your state for legal advice on what is "confidential" and how to protect the confidentiality of discussions and documents.

STEPS FOR RESPONDING TO UNANTICIPATED OUTCOMES

These steps address the entire process of responding to unanticipated outcomes, from caring for the patient, through appropriate disclosure, to promoting healing for the provider. Determine who has the education, training, and skills to perform each particular step.

The order in which these steps are completed may vary depending on the individual situation and/or the relevant institutional policies in effect at the time. In every instance, however, caring for the patient's immediate needs should come first. OMIC policyholders who need assistance completing a step are encouraged to contact our confidential Risk Management Hotline.

1. CARE. Take care of the patient.

- Address current health care needs.
- Obtain necessary consults.
- Assign primary responsibility for care.
- Communicate the identity of the primary treating physician and the physician's contact information to the team and the patient and family (by "family," we mean family members, significant others, domestic partners and close friends with whom a patient chooses to share health information. We will use the term "patient" to mean both the patient and family in the rest of this document).
- Obtain consent for new treatment needed in response to the outcome.

2. PRESERVE. Preserve the evidence.

- Sequester machinery (e.g., pumps, laser, and anesthesia machines) and preserve settings.
- Sequester equipment, such as syringes, IV tubing, and medication vials.
- Inform the facility's Risk Manager.
- Inform the chemical engineering/biomedical department or supplier if needed.
- Acquire back-up equipment.

3. DISCLOSE. Conduct the initial disclosure discussion.

- **Why, Who, When, Where?**

- *Why* disclose unanticipated outcomes?
    - The patient has the right to know about his/her condition and make decisions.
    - The information may be necessary to secure consent for treatment related to the unanticipated outcome.
    - Disclosure improves the physician/patient relationship, helps rebuild trust between the provider and the patient, and supports quality care.
    - Patients want to know.[2]
        - Nearly all patients (98 %) want to be informed of even a minor error; the more severe the outcome, the more they desire information.
        - The vast majority (92%) thought that physicians should inform them of complications. Only 60% of physicians thought this should occur.
        - Most (81%) wanted to know about future adverse outcomes associated with complications. Only 33% of physicians shared this preference.
    - Disclosure is consistent with the AMA Professional Code of Ethics,[3] the AAO Code and Principles of Ethics,[4] and Joint Commission standards on patient safety and error reduction.[5]
    - Hospital staff by-laws, medical group policies and procedures, health plans, and healthcare organizations may require disclosure.

- *Who* should inform the patient?
    - Health care providers involved in the unanticipated outcome.
    - Providers with responsibility for ongoing care.
    - People able to answer the patient's specific questions.

---

[2] American Society for Risk Management (ASHRM). Disclosure of unanticipated outcomes: the next step in better communication with patients (First of three parts). May 2003. ASHRM web site: www.ashrm.org. Accessed September 2004.
[3] See E-8.12 "Patient Information" and the Index to the Code of Medical Ethics at www.ama-assn.org.
[4] Code of Ethics of the American Academy of Ophthalmology, Principles of Ethics A 4, Communication with the Patient, "Open communication with the patient is essential." www.aao.org.
[5] See footnote 2.

- Assist participants in preparing, coordinating, or conducting the discussion. The type and amount of assistance depends on their communication skills, rapport with the patient and family, and language barriers.

- *When* should you inform the patient?
  - As soon as possible after providers address the patient's immediate healthcare needs.
  - When the patient is physically and emotionally ready.

- *Where* should you hold the discussion?
  - Consider the patient's privacy and health needs.

- **How to disclose unanticipated outcomes**

- Express sympathy.
  - Convey compassion for the patient's and family's pain and suffering.
    - Say "I am sorry that you …" or "I am sorry for your …"
    - Avoid "I am sorry that I …"
  - Focus on the patient's needs, not your own.
  - Extend sympathy to the family of a deceased patient orally or in writing, by sending flowers, or by attending the funeral.
- View the disclosure discussion as an opportunity to reestablish the therapeutic alliance and continue the informed consent discussion.
  - Review information presented about the risks during the preoperative informed consent discussion.
  - Help the patient understand what happened and how the outcome will affect his or her vision and health.
  - Focus on current treatment needs and goals.
  - Do not make promises that are unrealistic or lead to false hopes or expectations.
  - Honor the patient's request for a second opinion, and offer to facilitate finding someone to provide it.
- Communicate the facts about the unanticipated outcome.
  - Facts are objective information currently known about the unanticipated outcome contained in the medical record or learned during the EA.
  - Ask for help from the Risk Manager or EA team if more than one member of the team was involved or if the EA reveals systems errors (e.g., equipment malfunction, documentation errors, scheduling issues, etc.).
    - Identify the person responsible for discussing systems errors.
    - Determine whether to involve all involved providers or one provider at a time.
    - Clarify what each participant will discuss.
  - Identify "confidential" information.
- Solicit and respond to the patient's or family's feeling and questions.
  - Contain your own emotional response.
  - Focus on the patient's and family's needs.

    - Convey a receptive attitude with an open posture: arms uncrossed, concerned expression, eye contact, sympathetic listening, etc.
    - Name and validate the patient's concerns and feelings ("I can understand your anger…").
    - Stay calm if the patient raises concerns about your care.
- Verify that the patient understands the outcome and prognosis.
    - "This is upsetting news. I want to make sure that I have clearly communicated what we know so far. What is your understanding of what happened? Of your current condition?"
- Address misunderstandings, confusion, and information gaps as needed.
- Plan for follow-up care and more discussions, and communicate the plan.
    - Assure the patient that you will share additional facts when they become available. This is especially important when the cause of the unanticipated outcome or the prognosis is not known at the time of the initial discussion.
    - Give an estimate of how long the EA may take.
        - Help the patient have realistic expectations. Unrealistic or unmet expectations can lead to a breakdown of trust, fear of abandonment or cover-up, patient dissatisfaction, lawsuits, etc.
    - Make an appointment for a phone call or visit.
        - "I will call you in two weeks to give you an update."
    - Give the name of the contact person in the hospital or practice.
    - Encourage the patient to call if he or she has questions or hasn't heard back as promised.

- **<u>What NOT to communicate during a disclosure discussion</u>**

- Subjective information.
- Conjectures or beliefs.
- "Confidential" information
    - "I know how important it is to understand what happened. Some information is confidential. What I can tell you is …"
- Speculation and blame about the role you or other providers may have played in the outcome. Remember that the causes of the unanticipated outcome may:
    - Not be known yet.
    - Not be preventable.
    - Stem from a disease process.
    - Be a known complication of life- or vision-saving treatment.
    - Not be due to negligence.
    - Not be caused by an error, even if one did occur.
- Refrain from commenting on the role or responsibility of other team members or possible systems errors.
    - Off-hand, casual remarks made by members of the health care team raise liability concerns. A 1992 study found that "56% of families who said that the

advice of others prompted them to sue had been told by medical personnel prior to their filing a claim that the care provided had caused the injuries."[6]
        - Your comments about another provider's care can lead to a deposition or testimony at trial.
    - Inform the patient that you can only comment on your own care:
        - "I wasn't involved in that part of your care and don't have access to all of the records, so I can't comment on it. I'd be happy to discuss my care and your current condition."
    - Direct concerns about a provider's competency to the appropriate peer review committee or state board of medicine.

4. DOCUMENT. Document the outcome, disclosure discussion, and care.

- Include:
    - Objective facts currently known about the outcome,
    - Care given in response,
    - Disclosure discussion and names and relationship of those present during discussion, and
    - Treatment and follow-up plans.
- Do not include:
    - Subjective feelings or beliefs,
    - Speculation or blame,
    - References to incident report forms, EA activities, or "confidential" information.

5. REPORT. Complete mandatory reports if required.

- Inform the facility risk management, department chief, and peer review committee.
- Report medical device or medication complications that cause harm to the FDA.
- Contact the coroner if required by state law or facility policy.
- Inform government agencies such as Public Health as necessary.

6. CONTACT. Contact the Risk Manager for guidance.

- OMIC's Risk Managers can provide guidance on implementing these steps.
- We treat calls to our Hotline as confidential: the policyholder must give permission to share information about the outcome with the Claims or Underwriting Department.
- HIPAA regulations allow physicians to discuss protected health information (PHI) with their professional liability carrier. These discussions are part of healthcare operations. As such, physicians do not need to notify the patient or obtain the patient's authorization to release records.
- The Risk Manager gives risk management recommendations, not legal advice. Contact an attorney if you want legal advice.

---

[6] Hickson GB, Clayton WE, et al. Factors that prompted families to file medical malpractice claims following perinatal injuries. *JAMA* 1992; 267:1359-1363.

- The Risk Manager will advise the policyholder when to report a claim to the Claims Department. It is the responsibility of the policyholder to report the claim; the Risk Manager will not do so.

7. NOTIFY. Notify the Claims Department of your malpractice carrier.

- The policyholder triggers coverage for an unanticipated outcome by notifying the Claims Department.
- Report immediately any written notice, demand, cross-claim, or lawsuit (including an arbitration proceeding).
- Report any incident that is likely to lead to a claim, settlement demand, or lawsuit.
- Do not send the confidential facility incident report to Claims.

8. RESPOND. Respond to the patient's complaints and questions about remedies.

- Respond to patient complaints.
    - Acknowledge the complaint as quickly as possible. Failure to do so may further alienate the patient and prompt a lawsuit.
    - Speak to the patient yourself whenever possible.
    - Thank the patient for bringing the concern to your attention.
    - Assure the patient that you and other healthcare providers are dedicated to quality care and take complaints seriously.
    - Involve the patient relations or compliance department as needed.
    - Explain how to lodge a written complaint and provide forms if available.
    - Do not offer an opinion on care provided by others, the need for a lawsuit, or worth of the injury.
- Respond to patient's questions about remedies[7] and refer settlement demands.
    - You are not admitting liability if you waive or refund your own fees, or agree to pay for additional care.
    - The patient may still sue you if you do waive or refund fees, or pay for additional care.
    - Discuss requests for money immediately with the facility Risk Manager and/or malpractice carrier.
        - You do not have the authority to offer remedies for care provided by other physicians or the employees of the facility.
        - Follow the protocol at the facility and respect the terms of your liability insurance policy.
        - Get help if the patient wants you to pay for someone else's care.
    - Determine whether you are willing to waive or refund your fees.
        - Contracts with third-party payers (including Medicare) may limit your ability to waive co-pays or refund fees.

[7] "When an error contributed to the injury, the patient and the family or representative should receive a truthful and compassionate explanation about the error and the remedies available to the patient." The National Patient Safety Foundation's "Talking to Patients about Health Care Injury: Statement of Principle." March 2001. See www.npsf.org.

        - Violating contracts/regulations may subject you to allegations of insurance fraud and abuse.
        - Refer to the contract and follow its provisions.
        - Check with the plan to see if you must refund money it paid if you want to waive or refund the co-payment.
    - Check state reporting laws. Some states do not require you to report fee waivers, refunds, or payment for future care in response to an oral demand. Many states require you to report payments made in response to a written demand.
    - Ask OMIC's Risk Manager to review any letter you write to the patient in response to a request to waive or refund fees.
    - Contact OMIC's Claims Department if you want to pay for another provider's care, or if you want the patient to sign an indemnity release in exchange for a fee waiver, refund, or payment. We will ask an attorney in your state to draft the release.
- Contact the Claims Department if a patient presents you with a written demand for settlement. Inform the patient that you are not in charge of the claim resolution process but will contact the appropriate person at your professional liability carrier.
- Seek guidance from your attorney or the Claims Department on the need to report a refund or payment to the National Practitioner Data Bank (NPDB). Here is general information about NPDB reports.
    - Report a payment if you receive a written request for money, AND a business or corporate entity (including one comprised of a solo practitioner) makes the payment (see 45 C.F.R. § 60.3).
    - Do not report if you did not receive a written request.
    - Do not report a refund paid out of personal funds, even in response to a written demand (see NPDB Guidebook, pp. E-12, E 16).
    - Do not report a waiver of debt (i.e., the patient has not paid you yet).

9. ANALYZE. Analyze unanticipated outcomes to prevent recurrence and improve future outcomes.

- Here is how patient safety experts summarize their goals: they want to make it hard for unanticipated outcomes to occur, but easy for providers to detect, address, and report them.
- Clarify the legal status of EA and any requirements imposed by law or facility before beginning. Contact an attorney for legal advice on these issues.
- Maintain the confidentiality for formal meetings such as those organized under medical staff by-laws. Keep EA documents and discussions "confidential"
- Limit discussion of PHI when conducting an EA outside of a formal, legally "confidential" process.
    - Informal discussions with colleagues that include PHI could be discoverable in the event of a medical malpractice lawsuit.
    - Focus the discussion on the patient safety issue.

        - "We're meeting today to evaluate our appointment scheduling process. We want to see if patients who need urgent or emergent care could slip through the cracks."
        - "Our group is evaluating our protocol for endophthalmitis prophylaxis. Can you share with us what your group does?"
        - "What are your criteria for referring your patients to a retina specialist?"
        - "Our Quality Improvement meeting today will focus on procedures to prevent wrong site surgery."
- Develop a corrective action plan (CAP).
- Share the CAP with staff and other providers.
    - "Thank you for your help identifying vulnerabilities in our appointment scheduling process. Here is new procedure."
    - "I've changed my standing orders for cataract surgery. I will identify the operative eye with the word "right" or "left" instead of OD or OS."

10. FOLLOW THROUGH. Conduct additional disclosure discussions as the EA progresses.

- The goal of ongoing discussions is to meet the patient's current needs and address remaining questions and concerns.
- Keep promises: call back and meet the patient as promised or as needed.

11. HEAL: Heal the team.

- Invite team members to participate in the EA or help develop the CAP.
- Identify resources such as counselors and social workers.
- Acknowledge the impact of the unanticipated outcome on team members.
    - Many physicians question their judgment or ability after an unanticipated outcome and wonder if they should have proceeded differently. Explain that this is a normal reaction.
- Allow time for feelings to resolve.
- Recognize and honor need to share *feelings* about the unanticipated outcome with family friends, the medical group, or colleagues who were not involved in the event.
        - Here is some sample wording:
            - "A patient of mine had a very poor outcome. I want all my patients to get better and when they don't, I question my ability."
            - "I had a very difficult time diagnosing a patient of mine, and treatment was delayed. I feel very badly about this."
            - "The treatment I ordered for a patient of mine didn't work and the patient got worse. I am so discouraged I want to quit medicine."
        - Do not share the names of the patient or other providers, specifics of the case, or speculation about the cause. Failure to protect this information could lead to a lawsuit for breach of confidentiality.
- You may discuss PHI and "confidential" facts with other members of patient's current health care team if needed for care, participants in event analysis, peer review,

quality assurance, risk management, and other activities designed to improve quality of care, your malpractice carrier, and your defense attorney.
- Encourage participation in litigation stress workshops or groups.
- Avail yourself of the resources offered at the website of the Physician Litigation Stress Resource Center at www.physicianlitigationstress.org. The website includes articles about the physical and emotional toll of poor outcomes, as well as sources of support, links to information about tort reform, and a bibliography.

Unanticipated outcomes occur often. Getting help early and following this process can minimize the impact on you and the patient, and improve future care.

OMIC policyholders may obtain confidential advice through our Hotline. Please call 1.800.562-6642, option 4, or email us at riskmanagement@omic.com.