Disclosure of Adverse Events

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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RISK ISSUE

Disclosure of an adverse event or unanticipated outcome is important for patient safety, patient trust, patient right to autonomy to make decisions about treatment, continuity of care among providers, and to provide empathy. Studies have shown that transparency and empathy can strengthen the physician-patient relationship and potentially reduce the chance of litigation. There are legal and ethical considerations to be aware of when communicating to patients about the details of adverse events.

BACKGROUND

An adverse event is an outcome that would not be expected during the usual course of treatment and may have been caused by a human or system error. When an adverse event occurs there may be a tendency to deny, become defensive, or make assumptions before learning the facts. This is not beneficial to patients, physicians, or staff.

ASSESSMENT

Patients expect and deserve timely and full disclosure of adverse events and assurance that, if preventable, something is being done to avoid recurrence. Additionally, offering empathy and saying you are sorry the event occurred can reduce anger and begin healing. Obstacles exist that impede

disclosure, such as fear of retaliation, lack of training, culture of blame, and fear of litigation. Disclosure doesn't necessarily stop individuals from pursuing litigation, but withholding information could be a catalyst for litigation and potentially inflate the case value.

If the investigation reveals that a medical error occurred, the error should be documented in the medical record and disclosed to the patient. Examples of errors requiring disclosure include wrong procedure, wrong site, wrong medication, wrong dose, wrong lens, etc. Patients need information pertinent to their health to make informed treatment decisions. Adverse events may require additional treatment or awareness of potential future side effects to report for follow up care.

Expressions of sympathy are not admissible as evidence of negligence in most states. Most state apology laws protect providers who empathize with the patient's situation, but not necessarily providers who admit an error. Check your specific state laws concerning apologies and discuss your disclosure plan with a risk management consultant.

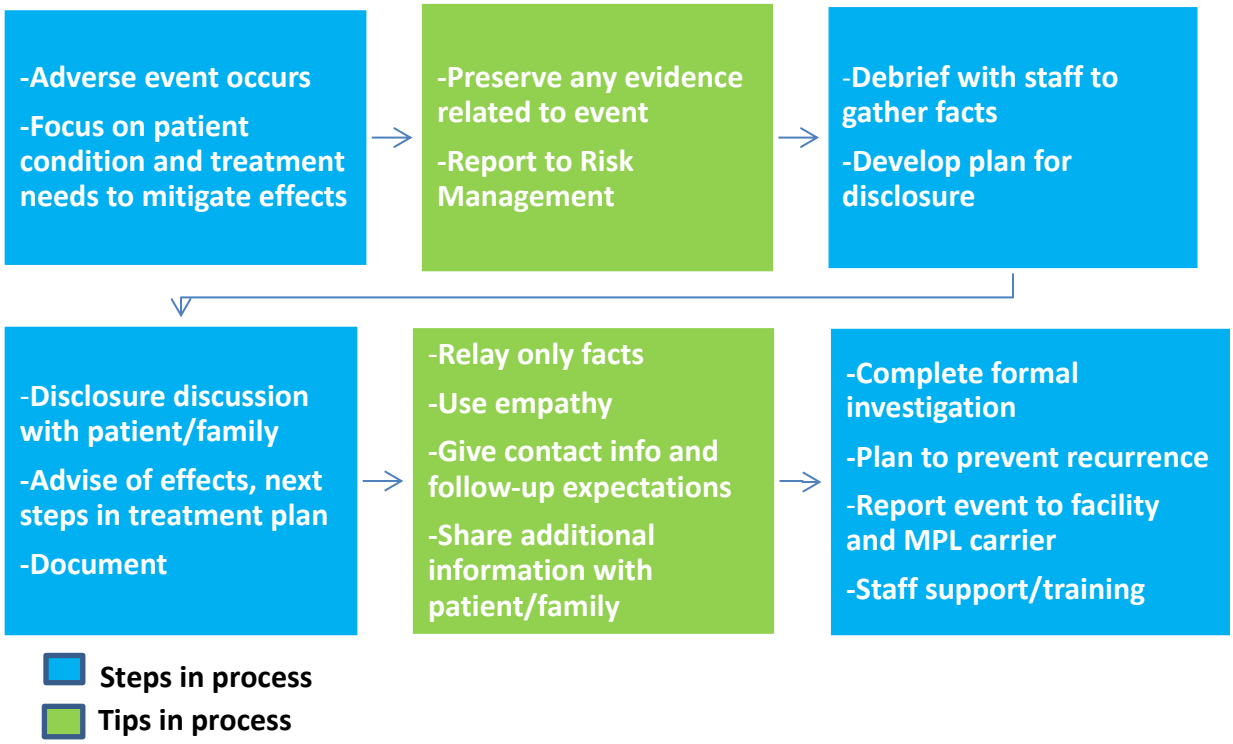
DISCLOSURE PROCESS STEPS

1) **Focus** on patient's condition and treatment needs.
2) **Preserve any evidence** related to the event (example: equipment, devices, medication, packaging).
3) **Contact** Risk Management for advice.
4) **Debrief** with the staff involved to gather facts.
5) **Develop** a disclosure plan.
6) **Disclose** the facts of the event to the patient and/or family.
   - **Who**-attending/treating physician; other members of health care team can be included
   - **What**-known facts only; do not hypothesize, blame others, or admit negligence; use plain language
   - **When**-as soon as possible after the event
   - **Where**-in a confidential setting
   - **How**-with empathy, understanding, and transparency
     - Example: "I understand this was not the outcome we all hoped for. I can only imagine how difficult this must be for you. I'm reviewing what happened and will keep you informed as I learn more." NOT "I'm sorry, I made a mistake."
7) **Advise** of possible short-term or long-term effects of any injury resulting from the event and next steps in the treatment.
8) **Share** your contact information and follow-up time frames to set expectations and alleviate concerns.
9) **Document** disclosure communication with the patient and/or family in the medical record.
10) **Perform** a **Root Cause Analysis**
   - Let the patient know there will be a formal investigation and that you will provide updates.
   - Internally investigate how the event occurred.
   - If an error occurred:
     - Create a plan to prevent it from happening again.

- Assure the patient that steps are being taken to prevent a recurrence of the error.

11) **Report** the incident to the facility and your medical professional liability (MPL) carrier.
12) **Offer support to staff** affected by the event – Second victims.

DISCLOSURE PROCESS MAP



RISK MANAGEMENT RECOMMENDATIONS

- Develop and implement policies and procedures to provide a clear approach to identify, disclose, and report adverse events. *See Disclosure Process Steps and Map, above.*
- When an adverse event occurs, follow the policies and procedures you have enacted.
- Facilitate training for staff on disclosure process steps.
- Remember that disclosure is an ongoing process; provide updated information to the patient and/or family.
- Create a culture of safety that encourages staff to report adverse events without fear of retaliation.

RESOURCES

1) ASHRM Disclosure Unanticipated Events White Paper
2) AHRQ Adverse Event Checklist
3) AHRQ Disclosure Checklist
4) AHRQ Disclosure of Errors

5) AHRQ CANDOR
6) Disclosure of Adverse Events: A Guide for Clinicians
7) The Role of Apology Laws in Medical Malpractice
8) Institute for Healthcare Improvement - Respectful Management of Serious Clinical Adverse Events White Paper

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.