NORCAL GROUP®

BEST PRACTICES

RISK MANAGEMENT **RESOURCE**

This exclusive resource was developed and is maintained by NORCAL Group's risk management team and is made available to members of the American Society for Interventional Pain Physicians (ASIPP) by Tom Wierzbowski of Willow Risk Advisors.

WILLOW
RISK ADVISORS, INC

AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS
ASIPP®

NINE STEPS TO RESPOND TO UNANTICIPATED OUTCOMES

BEST PRACTICES

RISK MANAGEMENT RESOURCE

NINE STEPS TO RESPOND TO UNANTICIPATED OUTCOMES

ABOUT NORCAL GROUP

The NORCAL Group of companies provide medical professional liability insurance, risk management solutions and provider wellness resources to physicians, healthcare extenders, medical groups, hospitals, community clinics, and allied healthcare facilities throughout the country. NORCAL Group includes NORCAL Mutual Insurance Company and its affiliated insurance companies. Please visit norcal-group.com/companies for more information.

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. Some of the steps may even occur simultaneously. In every instance, however, caring for the patient's immediate needs should always come first. When faced with the need to have a disclosure conversation with a patient or family, the physician may want to reach out to the facility risk manager or a risk management representative from his or her professional liability insurance carrier for assistance in preparing for the conversation.

By "unanticipated outcome," we mean a negative or unexpected result stemming from a diagnostic test, medical judgment or treatment, surgical intervention, or from the failure to perform a test, treatment or intervention. The unanticipated outcome may or may not be the result of error or negligence.

1. CARE: Take Care of the Patient

- Convey compassion for the patient's situation, focusing on the patient's needs
- Be available (or make sure an appropriate person is available) to the patient for questions in the immediate aftermath of the incident or event
- Address current healthcare needs
- Obtain necessary consults
- Assign primary responsibility for care, and communicate the identity of the physician in charge and the physician's contact information to family[1] and the healthcare team

2. PRESERVE: Preserve the Evidence

- Sequester devices/machinery (pumps, anesthesia machines, surgical stapler) and preserve settings
- Sequester equipment (syringes, IV tubing, medication vials)
- Inform hospital, facility or company risk manager
- Inform maintenance department or supplier
- Acquire back-up equipment

3. DOCUMENT: Document in the Medical Record

- What to include:
  - "Known facts"[2] about the unanticipated outcome
  - Care given in response
  - Disclosure discussion and names of those present for the discussion
  - Treatment and follow-up plans
- What not to include:
  - Subjective feelings or beliefs
  - Speculation or blame
  - References to incident report forms or Event Analysis[3]
  - "Confidential"[4] information
  - References to communications with malpractice carrier or attorney

4. REPORT: Complete Mandatory Reports if Required

- Begin the Event Analysis by completing an incident report
  - Record details about "known facts" in the report
  - Avoid speculation or blame
  - Treat as a confidential document
  - Do not place in medical record or discuss in medical record
  - Do not photocopy
- Inform hospital risk management, department chief, peer review or quality/safety committees as needed or if required
- Inform FDA if medical device or medication is involved
- Inform coroner as needed
- Inform Public Health Department and/or other governmental agencies as needed or if required

5. NOTIFY: Notify Claims Department of Your Malpractice Carrier

- Report any incident that could lead to claim, settlement demand, or lawsuit
- Do NOT use incident report form to notify carrier

6. DISCLOSE: The Initial Disclosure Discussion

Why, Who, When?

- Why disclose unanticipated outcomes?
  - Patients have a right to know about their condition and to make informed healthcare decisions
  - Improves doctor/patient relationship
  - Rebuilds trust
  - Improves quality of care
  - AMA Professional Code of Ethics calls for disclosure **(**Chapter 8: Opinions on Physicians and the Health of the Community (8.6 Promoting Patient Safety). 2016. Available at www.ama-assn.org/about-us/code-medical-ethics (accessed07.08.19.)
  - The Joint Commission Standards on Patient Safety and Error Reduction requirement
  - May be required by hospital staff bylaws, medical group policies and procedures, health plans, and healthcare organizations
  - May diminish liability risk
- Who will inform patient?
  - Physician(s) involved in the unanticipated outcome
  - Physician(s) with responsibility for ongoing care
  - People with ability to answer questions
  - People involved in a disclosure discussion may need assistance in preparing, coordinating or conducting a discussion, depending upon:
    - Communication skills
    - Rapport with patient and family

    - Language barriers
- When to inform patient and family?
    - As soon as practicable after immediate healthcare needs addressed
    - Consider patient's physical and emotional readiness
    - Choose a time that is convenient for the patient
    - Discussion should take as long as necessary; allot enough time in the physician's schedule to accommodate the discussion
    - Patient's permission needed to discuss care with family

Where, How and What To Disclose?

- Prepare for the conversation
    - Consider asking someone skilled in this type of conversation to accompany you or seek coaching to improve your communication skills
    - Consider consulting with the hospital's risk management or patient safety department or your liability insurance company for assistance
    - Prepare "talking points" that include (as appropriate):
        - The nature of the original medical problem and why treatment was pursued
        - Any information pertinent to the risk of a procedure that was provided to the patient during the informed consent discussion prior to the procedure being performed
        - A description of the procedure or treatment itself, including what (if anything) went wrong and how the healthcare team responded
        - An explanation of what has been done to care for the patient since the incident or event
    - Bring tools to describe how the unanticipated outcome occurred (e.g., diagrams, images, medical records, white board, etc.)
    - Anticipate difficult questions (e.g., "Did a medical device contribute to this injury? Why didn't you do [X]? Why did the other doctor tell me someone made a mistake?")
- Consider the "SEED" method – **S**etting, **E**mpathy, **E**ducation, **D**ocumentation

Setting

- Consider privacy and the patient's health needs
- Select a location that will provide for the patient's and family's comfort
- The physical area between the patient and the physician should be as open as possible (i.e., should not be sitting across a table from one another)

Empathy

- Exhibit "attending" behavior and actively listen to the patient
    - Sit at eye level with the patient
    - Keep an open posture, lean slightly forward; relax without crossing your arms, hunching your shoulders or bending your head down

  - Talk in a voice and tone that the patient understands, try to soothe the patient and empathetically relate to what is being said
  - Maintain eye contact
  - Indicate responsiveness with your facial expressions and gestures (nod, raise your eyebrows, smile, frown, etc. when appropriate)
  - Respond to the topics raised by the patient before you pursue your own disclosure agenda
  - Listen for at least a minute before interrupting
- Solicit and respond to patient's/family's feelings and questions
  - Contain your own emotional response
    - Focus on patient's needs
  - Convey receptive attitude
    - Open posture: arms uncrossed, concerned expression, eye contact, empathetic listening
  - Name and validate patient's concerns and feelings ("I can understand your anger…")
  - Avoid defensive or accusatory reaction if your care is questioned or criticized
- Convey compassion for patient's and family's pain and suffering
  - "I am sorry that you…" or "I am sorry for your…"
  - Focus on patient's and family's needs
  - **Avoid** "I am sorry that I…"
- Extend sympathy to family of deceased patient
  - May express verbally or in writing
  - May send flowers
  - May attend funeral

Education

- Communicate only "known facts"[5]
  - <u>What</u> to communicate
    - Objective information
      - Documented in medical record
      - Learned through the Event Analysis[6] _ **unless**"confidential"[7]
      - Adequate to ensure patient's understanding of unanticipated outcome and prognosis
      - The nature of the problem
      - The plan for corrective action
    - If Event Analysis reveals systems errors and/or involvement of multiple healthcare team members
      - Contact Event Analysis Team for advice on individual vs. group discussion and appropriate participants
      - Clarify what is "confidential" and who will discuss what with the patient/family

- What not to communicate
  - Subjective information
  - "Confidential" information, determined by state and/or federal law —possible examples include:
    - Results of protected Peer Review, Quality Assurance, Performance Improvement, or Risk Management Committees
    - Information provided in confidence by a third party
    - Confidential information about a healthcare organization or its operations
    - Health or employment information about a provider or employee
  - If asked to disclose "confidential" information
    - Inform patient/family that certain "confidential" information cannot be disclosed
      - "I know how important it is to you to understand what happened. Some information is confidential and can't be disclosed. What I can tell you is…"
  - If asked to comment on role/responsibility of other healthcare team members and/or possible systems errors
    - Inform patient that you can only comment on the care you provided for him/her.
      - "I am not knowledgeable enough to discuss that aspect of your care…"
    - Avoid blaming other physicians or other clinicians
    - Contact Event Analysis Team/Risk Manager/malpractice carrier for guidance on what is "confidential" and who will disclose specific information about another physician's care or systems issues
  - Avoid conjecture, speculation and opinions
    - Causes of unanticipated outcome may not yet be known
    - Unanticipated outcome is not always preventable
    - Unanticipated outcome may be result of disease process or risky life-saving treatment, or not preventable (e.g., some falls)
    - Unanticipated outcome is not always a result of negligence
    - Error, if one occurred, may not be the cause of unanticipated outcome
- Respond to patient's complaints
  - Assure patient that the physicians are dedicated to quality care and that they take patients' complaints seriously
  - Depending on size of practice/organization, refer to the Patient Relations Department, patient advocate or other responsible person in the practice/organization
  - Explain how to lodge complaint, and provide forms if available
  - Do not offer opinion on need for lawsuit or monetary value of a settlement for injury
- Respond to patient's questions about remedies and refer settlement demands to the appropriate department
  - Discuss immediately with organization's Risk Manager and with malpractice carrier

  - Inform patient you are not in charge of the claim resolution process and refer patient to contact appropriate people/department
- Verify patient's/family's understanding of 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 and your current condition?"
  - Address misunderstandings, confusion, information gaps as needed
- Plan for follow-up care and more discussions, and communicate the plan
  - If cause of unanticipated outcome or prognosis is not yet known, assure patient/family that additional facts will be shared when available
    - Give estimate of how long analysis process may take
    - Understand that patient expectations may not be realistic
  - If expectations are not met, this can lead to breakdown of trust, fear of abandonment or cover-up, patient dissatisfaction and/or lawsuit
  - Make appointment for phone call and/or visit to update patient
    - For example, "I will call you in two weeks to give you an update."
  - Encourage patient/family to call if he/she/they have questions or haven't heard back from you or other disclosure team member
  - Give your information or name and contact information of contact person in hospital or practice

Documentation

- See step 3 above for details on what to document in the medical record
- See steps 4 and 5 above for other mandatory reporting

7. ANALYZE: Analyze Unanticipated Outcome to Prevent Recurrence and/or Improve Future Outcomes

- Patient safety goal: make it hard for unanticipated outcomes to occur, easy to detect them, easy to respond and report
- Conduct an Event Analysis. If in group, hospital, or clinic, refer to individual or committee responsible for analyses
- Identify all causes of an event or "near miss"
- Develop and implement Corrective Action Plan (CAP) or refer to individual/committee responsible for CAP
- Keep Event Analysis documents and discussions "confidential"
- Do not include or refer to Event Analysis in medical record
- Do not photocopy Event Analysis documents
- If the Event Analysis confirms that an error contributed to the injury, the patient and the family or representative should receive a truthful explanation about the error. See the American Medical Association Code of Ethics, Opinion 8.6 – Promoting Patient Safety, available at www.ama-assn.org/about-us/code-medical-ethics (accessed 7/8/19).

8. FOLLOW THROUGH: Subsequent Disclosure Discussions

- Goal: meet ongoing healthcare needs and continue to address patient's/family's questions and concerns
- Keep promises: call back as promised or as needed
- Keep promises: hold subsequent disclosure discussions as promised or as needed
    - Determine the "Who, When, and Where" of the disclosure discussion based on current patient needs and latest results of Event Analysis
    - Begin subsequent disclosure discussions by informing patient/family that care has been reviewed and that you are interested in continuing to discuss patient's/family's questions and concerns
    - Follow guidelines on disclosure in Step 6
- Don't make promises that cannot be kept
    - Cannot provide Event Analysis documents
    - Cannot disclose "confidential" information
    - Cannot discuss others' roles and responsibilities unless authorized to do so by Event Analysis Team: don't speculate or blame

9. HEAL: Heal the Healthcare Team

- Acknowledge effects of unanticipated outcome on healthcare team members
    - Unanticipated outcomes are disturbing to all involved
    - Recognize need to discuss feelings about outcome/analysis with your family, friends, and colleagues
    - Identify resources to help in healing
        - Consider visiting the NORCAL Professional Wellness website for practical strategies for managing stress and preventing physician burnout related to unexpected outcomes: www.norcal-group.com/wellness (accessed 7/8/19)
    - Allow time for resolution of feelings
    - Participate in litigation stress workshops or groups, if available
- Distinguish between discussion of your feelings and discussion of facts of outcome/analysis
- Discuss facts of outcome/analysis only with:
    - Other members of patient's healthcare team for provision of care
    - Patient/family **unless** "confidential"
    - Participants in Event Analysis, Peer Review, Quality Assurance, Risk Management and other activities designed to improve quality of care
    - Malpractice carrier
    - Assigned defense attorney in the event of litigation
- Avoid informal discussions of **facts of outcome/analysis** with colleagues, family, friends
- You may share **feelings** about outcome/analysis with colleagues, family, friends

Endnotes/Definitions

1. By “family,” we mean family members, significant others, domestic partners, and close friends with whom a patient chooses to share health information.
2. Many more facts may eventually be known than can be disclosed. By “known facts,” we refer to those objective facts, known to date, which are either documented in the medical record or learned through the Event Analysis (see footnote 3) and which can be disclosed without violating “confidentiality” (see footnote 4).
3. “Event Analysis” includes any activity designed to evaluate the causes of unanticipated outcomes and improve patient outcomes in the future. Any incident with the potential to cause harm, including “near misses” and “close calls,” should be analyzed. Event Analysis activities include: completing and analyzing incident reports, peer review, quality assurance and performance improvement, risk management, and morbidity and mortality conferences. Depending upon state and/or federal law, documents and discussions produced during the Event Analysis may be legally confidential. For that reason, care should be taken to limit discussions to a “need to know” basis for the purposes of the Event Analysis, to avoid photocopying documents, and to refrain from referring to the analysis in the medical record.
4. Laws determining what discussions and documents are considered legally confidential — and thus not discoverable as evidence — vary from state to state; federal laws may also apply. We refer to such information as “confidential.” You may want to contact the Claims Department of your professional liability carrier for assistance. You should contact an attorney if you need legal guidance.
5. See note 2.
6. See note 3.
7. See note 4.