

## Communicating with Patients About Unanticipated Outcomes

*Claims Rx* has been exploring patient safety issues this year, with an overview of the Institute of Medicine (IOM)'s 1999 report, *To Err is Human: Building a Safer Health System* (January 2001) and guidance on responding to medical errors (February 2001). NORCAL has always encouraged its policyholders to communicate honestly with their patients about unanticipated outcomes and, this year, our Board of Directors endorsed the National Patient Safety Foundation's Statement of Principle, *Talking to Patients About Health Care Injury*. To further assist policyholders in this important task, we have developed the following *Nine Steps to Respond to Unanticipated Outcomes*.

These steps expand upon the guidelines that appeared in the February 2001 *Claims Rx*. They address the entire process of responding to unanticipated outcomes, from caring for the patient, through appropriate disclosure, to promoting healing for the health care provider. The steps are designed for hospital, group and individual physician office settings. If you are not the person in your setting who would execute a step(s), you will want to ensure that the responsibility is delegated to the appropriate individual(s).

### Nine Steps to Respond to Unanticipated Outcomes

An "unanticipated outcome" is 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.

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 always come first.*

#### 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 physician and the physician's contact information to family (e.g., family members, significant others, domestic partners and close friends with whom a patient chooses to share health information) and the health care team

#### 2. PRESERVE: Preserve the Evidence

- Sequester machinery (pumps, anesthesia machines) and preserve settings
- Sequester equipment (syringes, IV tubing, medication vials)
- Inform hospital risk manager
- Inform the chemical engineering or biomedical department, or supplier
- Acquire back-up equipment

#### 3. DOCUMENT: The Medical Record and Incident Report

##### Medical Record

- What to include:
  - "Known facts"<sup>1</sup> about unanticipated outcome
  - Care given in response

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<sup>1</sup> Many more facts may eventually be known than can be disclosed. "Known facts" refers to those objective facts, known to date, that are either documented in the medical record or learned through the event analysis (see footnote 2), and that can be disclosed without violating "confidentiality" (see footnote 3).

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- Disclosure discussion and names of witnesses (see Step 6)
- Treatment and follow-up plans
- What *not* to include:
  - Subjective feelings or beliefs
  - Speculation or blame
  - References to incident report forms or event analysis<sup>2</sup>
  - “Confidential”<sup>3</sup> information

### Incident Report

- Begin the event analysis by completing an incident report
  - Communicate “known facts”
  - Avoid speculation or blame
  - Preserve the confidentiality of the document
    - ❖ Do not place in medical record or discuss in medical record
    - ❖ Do not photocopy

### 4. REPORT: Complete Mandatory Reports if Required

- Inform hospital risk management, department chief, peer review as needed or if required
- Inform FDA if medical device or medication involved
- Inform coroner if needed or required by state law
- Inform Public Health Department and/or other government 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 (“confidential” document)

### 6. DISCLOSE: The Initial Disclosure Discussion

#### Why, Who, When, Where?

- *Why* disclose unanticipated outcomes?
  - Patient has right to know condition and make health care decisions
  - Improves doctor/patient relationship
  - Rebuilds trust between provider and patient/family
  - Supports quality of care
  - AMA Professional Code of Ethics<sup>4</sup>
  - JCAHO standards on patient safety and error reduction<sup>5</sup>
  - May be required by hospital staff by-laws, medical group policies and procedures, health plans, and health care organizations
- *Who* will inform patient?
  - Health care provider(s) involved in the unanticipated outcome
  - Provider(s) with responsibility for ongoing care
  - Person(s) with ability to answer questions

<sup>2</sup> The “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.

<sup>3</sup> 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. An attorney in your state should be consulted if you need legal guidance.

<sup>4</sup> See E-8.12 “Patient Information.” Index to the Code of Medical Ethics can be accessed from the Site Map at [www.ama-assn.org](http://www.ama-assn.org).

<sup>5</sup> Effective July 1, 2001. Available on the Web at [www.jcaho.org](http://www.jcaho.org), the Standards in Support of Patient Safety and Medical/Health Care Error Reduction outline changes pertaining to leadership, performance improvement, information management, patient rights, education, continuum of care and management of human resources.

- Persons involved in disclosure discussion may need assistance in preparing, coordinating or conducting discussion, depending upon:
  - ❖ Communication skills
  - ❖ Rapport with patient and family
  - ❖ Language barriers
- If event analysis reveals systems errors and/or involvement of multiple health care team members, contact event analysis team for advice on individual vs. group discussion and appropriate participants
- *When to inform patient and family?*
  - As soon as practicable after immediate health care needs addressed
  - Consider patient's physical and emotional readiness
  - Patient's permission needed to discuss care with family
- *Where to hold discussion?*
  - Consider privacy and health needs

### How to Disclose Unanticipated Outcomes

- Express empathy
  - 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

### National Patient Safety Foundation Adopts Statement of Principle

In an effort to encourage medical error disclosure, the National Patient Safety Foundation, an independent nonprofit research and education group formed to improve patient safety, recently adopted the following *Statement of Principle*.<sup>1</sup>

*When a health care injury occurs, the patient and the family or representative are entitled to a prompt explanation of how the injury occurred and its short and long-term effects. 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. They should be informed that the factors involved in the injury will be investigated so that steps can be taken to reduce the likelihood of similar injury to other patients.*

*Health care professionals and institutions that accept this responsibility are acknowledging their ethical obligation to be forthcoming about health care injuries and errors.*

*The National Patient Safety Foundation urges all health care professionals and institutions to embrace the principle of dealing honestly with patients.*

<sup>1</sup>National Patient Safety Foundation. *Talking to Patients About Health Care Injury: Statement of Principle*. Chicago: National Patient Safety Foundation, March 2001.

- Communicate only "known facts"
  - *What to communicate*
    - ❖ Objective information
      - ❖ Documented in medical record
      - ❖ Learned through the event analysis *unless* "confidential"
      - ❖ Adequate to ensure patient's understanding of unanticipated outcome and prognosis

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- ❖ If event analysis reveals systems errors and/or involvement of multiple health care 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
  - ❖ Conjectures or beliefs
  - ❖ “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 health care 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 health care team members and/or possible systems errors:
    - ❖ Inform patient that you can only comment on your own care
      - “I am not knowledgeable enough to discuss that aspect of your care...”
      - Contact event analysis team/risk manager/malpractice carrier for guidance on what is “confidential” and who will disclose specific information about the other provider’s care or systems issues
- Avoid speculation and blame
  - Cause(s) of unanticipated outcome may not yet be known
  - Unanticipated outcome not always preventable
    - ❖ May be result of disease process or risky life-saving treatment, or not preventable (e.g., some falls)
  - Unanticipated outcome not always due to negligence
  - Error, if one occurred, may not be cause of unanticipated outcome
- 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 care questioned
- Respond to patient’s complaints
  - Assure patient that the health care providers are dedicated to quality care and take patients’ complaints seriously

- Depending on size of practice/organization, refer to patient relations department or other responsible person in practice
  - Explain how to lodge complaint and provide forms if available
  - Do not offer opinion on need for lawsuit or worth of injury
- Respond to patient's questions about remedies<sup>6</sup> and refer settlement demands
    - Discuss immediately with organization's risk manager and with malpractice carrier
    - Inform patient that you are not in charge of claim resolution process but will contact appropriate people
  - 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? About your current condition?"
    - Address misunderstandings, confusion and information gaps as needed
  - Plan for follow-up care and more discussions and communicate the plan
    - If cause of unanticipated outcome or prognosis not yet known, assure patient/family additional facts will be shared when available
    - Give estimate of how long analysis process may take
      - ❖ Patient expectations may not be realistic
      - ❖ If expectations not met, can lead to breakdown of trust, fear of abandonment or cover-up, patient dissatisfaction, lawsuit
    - Make appointment for phone call and/or visit to update patient
      - ❖ "I will call you in two weeks to give you an update."
- Encourage patient/family to call if they have questions or haven't heard back from provider
  - Give name of contact person in hospital or practice

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

- Patient safety goal: make it hard for unanticipated outcome to occur, easy to detect, easy to respond and report
- Conduct event analysis. If in group, hospital or clinic, refer to individual or committee responsible for analysis
- Identify all causes of 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"
  - "Need to know" basis
  - Do not include or refer to in medical record
  - Do not photocopy

## 8. FOLLOW THROUGH: Subsequent Disclosure Discussion(s)

- Goal: meet ongoing health care needs and continue to address patient's/family's questions, concerns
- Keep promises: call back as promised or as needed
- Keep promises: hold subsequent disclosure discussion(s) 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

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<sup>6</sup> "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." See [www.npsf.org](http://www.npsf.org).

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- Begin subsequent disclosure discussion(s) by informing patient/family that care has been reviewed and that you are interested in continuing to discuss patient's/family's questions, concerns
- Follow guidelines on disclosure (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 Health Care Team

- Acknowledge effect on health care team members
  - Unanticipated outcomes disturbing to all involved
  - Many physicians question their judgment or ability after an unanticipated outcome, and wonder if they should have proceeded differently
  - Recognize need to share feelings about being involved in an unanticipated outcome with your family, friends, medical group or colleagues who were not involved in the event
  - Identify resources to help in healing
  - Allow time for resolution of feelings
  - View NORCAL video, *Surviving the Malpractice Suit: Physicians Tell Their Stories*
  - Participate in litigation stress workshop or group
- Distinguish sharing your feelings about the outcome from a discussion that includes the patient's medical information
  - A patient's medical information is confidential: health care providers
    - Informal discussions with colleagues and friends that include patient-specific information could be discoverable in the event of a medical malpractice lawsuit
  - Discuss medical information and facts of outcome/analysis *only with*:
    - Other members of patient's health care team on "need to know" basis 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
    - Defense attorney in event of litigation
- Avoid informal discussions of patient's medical information with colleagues, family, friends
- May share *feelings* about outcome
  - Refrain from mentioning names of patient or providers
  - Refrain from stating any specifics of the case
  - Refrain from speculation or blame
  - Possible scenarios and suggested wording
    - ❖ Surgery, procedure, anesthesia or medication
      - ❖ "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."

- ❖ Delay in diagnosis or treatment or ineffective treatment
  - ❖ “I had a very difficult time diagnosing a patient of mine, and treatment was delayed. I feel very bad 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.” ■

### For Further Information or Help

To discuss how to disclose a *specific unanticipated* outcome, call our Claims Department.

(800) 770-3414, Alaska

(800) 416-0791, San Francisco

(800) 356-5513, Pasadena

(800) 230-1004, Rhode Island

For help on *developing policies and procedures on disclosure, for education and training, or to give us feedback on these guidelines*, contact our Risk Management Department at:

560 Davis Street  
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## OSHA’s Revised *Bloodborne Pathogens Standard* Spurs Interest in Needle Stick Safety Resources

The *Needlestick Safety and Prevention Act*, which was passed by Congress and signed into law on November 6, 2000, called for revisions to the 1992 OSHA *Bloodborne Pathogens Standard*. The revisions, designed to reduce needlestick injuries among health care workers and others handling medical sharps, include:

- clarifying the requirement for employers to select safer needle devices as they become available (this requirement has been in effect since 1992);
- maintaining a sharps injury log (employers with 11 or more employees); and
- involving non-managerial employees in identifying and choosing the devices.

The revised *Bloodborne Pathogens Standard* was effective April 18, 2001; OSHA enforcement of the requirements for the injury log and employee selection of safer devices began in July 2001.<sup>1</sup>

In response to the updated standard, several policy-holders have inquired about needlestick safety resources, especially sample exposure control plans.

- The CAL-OSHA Web site contains a sample exposure control plan ([www.dir.ca.gov/dosh/dosh\\_publications/explan2.pdf](http://www.dir.ca.gov/dosh/dosh_publications/explan2.pdf)).
- The OSHA Web site has answers to frequently asked questions about needle sticks and a PowerPoint presentation in response to the newly enacted *Needlestick Safety and Prevention Act* ([www.oshaslc.gov/needlesticks/index.html](http://www.oshaslc.gov/needlesticks/index.html)).
- The Centers for Disease Control (CDC) Web site contains an article entitled: “Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis” ([www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm)). The article contains recommendations for the management of health care personnel potentially exposed to HBV, HCV or HIV, and recommendations for the contents of the occupational exposure report. The article also includes contact information for a number of organizations, including the National Clinician’s Postexposure Prophylaxis Hotline (PEpline).

<sup>1</sup> U.S. Department of Labor, Office of Public Affairs. Prevention is best medicine: OSHA announces outreach effort on needlestick prevention [press release]. May 9, 2001. From OSHA Web site: [www.osha.gov/media/oshnews/may01/national-20010509.html](http://www.osha.gov/media/oshnews/may01/national-20010509.html).

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