About KePRO

- Quality improvement and care management organization
- Founded in 1985; headquartered in Harrisburg, PA
- Works with HRSA on Medical Malpractice Claims Reviews and Risk Management Services under a contract initiated in 2004.
- Provides risk management and patient safety technical assistance to section 330 FTCA deemed Health Centers and Free Clinics.
About ECRI Institute

- Independent, not-for-profit applied research institute focused on patient safety, healthcare quality, risk management
- Web site for HRSA grantees. Log in with user id and password at: www.ecri.org/clinical_RM_program
- Have not activated your User ID yet? E-mail us at: clinical_RM_program@ecri.org.
- 40-year history, 320 person staff
  - AHRQ Evidence-Based Practice Center
  - WHO Collaborating Center
  - Federally designated Patient Safety Organization
Objectives

- Identify reasons for having an effective internal event reporting system in health centers and clinics
- Recognize approaches for implementing an internal event reporting system as part of a health center or clinic risk management and patient safety plan
- Recall options for the flow of information for communication and action for reported events and near-misses
- Recognize strategies for implementing solutions to problems identified through event reporting systems for risk prevention and patient safety improvement
Why report events and near misses?
“You cannot manage what you do not know about...”
Why report events and near misses?

- Risk identification and loss reduction
- Prevention and improvement
- Education and learning
- Meet accreditation standards

National Patient Safety Goals
http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/
Key Definitions

- **adverse event**: an undesired outcome or occurrence, not expected within the normal course of care or treatment, disease process, condition of the patient, or delivery of services.

- **near miss**: an event or situation that could have resulted in an accident, injury, or illness but did not, either by chance or through timely intervention.

- **sentinel event**: an unexpected occurrence involving death or serious physical or psychological injury, ...serious injury specifically includes loss of limb or function.
Event Reporting Toolkit

**MODEL INTERNAL EVENT-REPORTING POLICY**

This model policy is intended as guidance to be adopted or adapted consistent with the internal needs of your organization. This policy is not to be viewed as required by ECRI Institute, KePRO, or HRSA.

**SUBJECT:** Adverse-Event and Near-Miss Reporting

**ADOPTION AND REVIEW DATES:**

**RESPONSIBLE DEPARTMENT:** Risk Management

**PHILOSOPHY AND PURPOSE:**

- [Organization name] endorses and supports a culture of safety and views adverse-event reporting as a means of improving systems and processes in providing healthcare services to all patients. In a continuing effort to promote a safe environment for patients, [organization name] will conduct a systematic program of adverse-event reporting. Reporting is nonpunitive, and all providers, employees, and volunteers are encouraged to report all patient and visitor events.

Supporting Toolkit Documents:

- Right click and choose "Save as" to save the files to your computer.

- Model Internal Event-Reporting Policy
- Event Reporting Barriers and Suggested Strategies
- Event Summary Tool
- Flow of Information Diagram
- Sample Action Plan Template
- Sample Data Collection Form
- Sample Event Report Narrative
# Event Reporting Toolkit

<table>
<thead>
<tr>
<th>Barriers to Event Reporting</th>
<th>Strategies for Overcoming Barriers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belief that someone else reported the event</td>
<td>Reporting systems should be able to identify duplications.</td>
</tr>
<tr>
<td>Lack of time to complete event report form</td>
<td>Design event report forms for ease of completion.</td>
</tr>
<tr>
<td>Lack of understanding of importance of reporting</td>
<td>Provide education about event reporting at orientation and annually thereafter; establish reporting as a performance expectation in job descriptions.</td>
</tr>
</tbody>
</table>
Event Summary Tool

Health Center/Clinic
Annual Report of Events 2010

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Number of Events</th>
<th>Patient Encounters</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Emergency in Health Center or Clinic</td>
<td>2</td>
<td>25000</td>
<td>0.01%</td>
</tr>
<tr>
<td>Communication Issues</td>
<td>20</td>
<td>25000</td>
<td>0.08%</td>
</tr>
<tr>
<td>Complaints</td>
<td>6</td>
<td>25000</td>
<td>0.02%</td>
</tr>
<tr>
<td>Diagnostic Test Problems</td>
<td>30</td>
<td>25000</td>
<td>0.12%</td>
</tr>
<tr>
<td>Documentation Issue</td>
<td>25</td>
<td>25000</td>
<td>0.10%</td>
</tr>
<tr>
<td>Falls</td>
<td>3</td>
<td>25000</td>
<td>0.01%</td>
</tr>
<tr>
<td>Handoff or Referral Problem</td>
<td>50</td>
<td>25000</td>
<td>0.20%</td>
</tr>
<tr>
<td>Incorrect Patient or procedure</td>
<td>1</td>
<td>25000</td>
<td>0.00%</td>
</tr>
<tr>
<td>Medication Errors</td>
<td>50</td>
<td>25000</td>
<td>0.20%</td>
</tr>
</tbody>
</table>
Event Summary Tool

Tool generates a graph with your added data
Flow of Information - Event Reporting

- Report initiated by individual who discovers, witnesses, or is notified of event
- Immediate
- Supervisor, Department Head
  - Obtain medical attention
  - Evaluate event
  - Impound equipment, supplies (if applicable)
  - Notify attending physician
  - Review, sign report
  - Notify family/responsible party (if applicable)
- Risk/Quality Management (Facility)
  - Review and analyze report
  - Assign severity index
  - Obtain clinical, nursing, engineering expertise - interdisciplinary team
  - Conduct investigation
  - Conduct root cause analysis (if applicable)
  - Determine if reportable under federal or state law
  - Track, trend data
  - Take corrective action / redesign
Algorithm: Categorizing Event Severity

NCC MERP Index for Categorizing Medication Errors Algorithm

- **Harm**
  - Physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

- **Monitoring**
  - To observe or record relevant physiological or psychological signs.

- **Intervention**
  - May include change in therapy or active medical/surgical treatment.

- **Intervention Necessary to Sustain Life**
  - Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

*An error of omission does reach the patient.*
## Event Reporting Toolkit

### Sample Data Collection Report

**CONFIDENTIAL EVENT REPORT (RM/QI Purposes only):**

<table>
<thead>
<tr>
<th>SEX:</th>
<th>N/A</th>
<th>Female</th>
<th>Male</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DAY OF WEEK:</td>
<td>Sunday</td>
<td>Monday</td>
<td>Tuesday</td>
<td>Wednesday</td>
</tr>
<tr>
<td></td>
<td>Thursday</td>
<td>Friday</td>
<td>Saturday</td>
<td>Unknown</td>
</tr>
<tr>
<td>PATIENT MENTAT</td>
<td>Oriented:</td>
<td>Yes</td>
<td>No</td>
<td>Unidentif</td>
</tr>
<tr>
<td></td>
<td>Sensory Impaired:</td>
<td>Yes</td>
<td>No</td>
<td>Unidentif</td>
</tr>
</tbody>
</table>

**SELECT ONLY ONE CATEGORY:**

<table>
<thead>
<tr>
<th>TREATMENT/PROCEDURE</th>
<th>EQUIPMENT/PRODUCT</th>
<th>FALLS</th>
<th>IN/BLOOD/MEDICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesia Problem</td>
<td>Disconnected/Dislodged</td>
<td>Assisted to Floor</td>
<td>Adverse Reaction</td>
</tr>
<tr>
<td>Application/Removal of Cast/Splint</td>
<td>Electrical Problem</td>
<td>Chair</td>
<td>Allergic Reaction</td>
</tr>
<tr>
<td>Aspiration</td>
<td>Implant</td>
<td>Exam Table</td>
<td>Container not Child</td>
</tr>
<tr>
<td>Body Fluid Exposure</td>
<td>Improper Use</td>
<td>Faint</td>
<td>Proof</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Outdated</td>
</tr>
</tbody>
</table>

**CHECK APPROPRIATE BOX IN DESIGNATED CATEGORY THAT BEST DESCRIBES THE EVENT**

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Event Reporting Toolkit

SAMPLE EVENT REPORT NARRATIVE

[Organization Name] Event Report (RM/QI purposes only – not part of patient medical record)

An adverse event or incident is defined, consistent with the [organization name] risk management as “an undesired outcome or occurrence, not expected within the normal course of care or treatment process, condition of the patient, or delivery of services.”

A near miss is defined as “an event or situation that could have resulted in an accident, injury, or death, but did not, either by chance or through timely intervention (e.g., a procedure almost performed on the wrong patient due to a lapse in verification of patient identification, but caught at the last minute by alertness of the nurse).”

○ Patient  ○ Visitor  ○ Other  Age_________ (days, months, years)

○ Female  ○ Male  Date of this report (mm/dd/yyyy)__________

Last name, first name of patient or other individual involved in event________________________
Event Report Information

- Date and time of the report
- Date and time of the event
- Location of the event
- Identification of people affected (e.g., patient, visitor, employee)
- Identity of people witnessing the event
- Identity of the physician to whom the event was reported (if applicable) and the physician’s response (e.g., orders given)
Event Report Information (cont)

- Brief, factual description of the event
- Key observations about the event or at the scene
- Manufacturer, model, and lot number of any medical device or pharmaceutical involved
- Condition of the people affected (including any complaints of injury, observed injuries, and a brief comment on any follow-up care)
Event Reporting Toolkit

4.0 Sample Response/Action Plan Template*

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PROPOSED ACTION</th>
<th>RESPONSIBLE PERSON(S)</th>
<th>ACTION DUE DATE</th>
<th>PROGRESS</th>
<th>COMMENTS</th>
</tr>
</thead>
</table>

*Sample Response/Action Plan Template* refers to a structured format to document the steps and progress of handling events.
Risk Management and Quality Improvement Functions Overlap in Patient Safety

**Risk Management**
- Risk Identifications (e.g., near-miss and adverse event reporting)
- Risk Control
- Claims Management
- Patient Relations and Disclosure
- Safety and Security
- Accreditation Compliance
- Mandatory Event Reporting
- Workers’ Compensation

**Overlapping Functions**
- Analysis of adverse and sentinel events and trends
- Root-Cause Analysis
- Proactive Risk Assessments
- Patient Complaint Handling
- Patient Safety Initiatives
- Board Reports
- Feedback to Providers and Staff
- Provider Credentialing
- Accreditation Issues
- Staff Education and Training
- Peer Review

**Quality Improvement**
- Quality Measures (e.g., indicators, dashboards, core measures)
- Benchmarking
- Best Practices/Clinical Guidelines
- Provider Performance and Competency
- Accreditation Coordination
- Patient Satisfaction
- Improvement Projects

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Other ways of discovering events

- Clinic safety rounds
- Anonymous reporting
- Reports of complications
- Claims
- Complaints

- Chart reviews using trigger tools
Implementing an Effective Event Reporting System

- Establish goals for system outcome
- Implement a “just culture”
- Assess existing systems
- Evaluate available systems
- Select and implement the system
- Monitor for effectiveness in identifying risks
Establish Goals

The ultimate goal of an event reporting system is to identify events and problem areas so that:

- The frequency of adverse events can be reduced
- The impact of adverse events (and potential impact of near misses) on patient outcomes can be mitigated
- The risk of liability claims can be reduced
- The occurrence of adverse events can be prevented altogether
Implement a just culture

- Non-punitive, yet accountable
- Open communication
- Fair-minded treatment
- Meaningful feedback on positive change
Assess existing systems

- Does the reporting system allow for ease of access and reporting by providers and staff?
- Does the report form include a listing of event types to prompt reporting of key events and near misses affecting patient safety?
- Does the system provide aggregate data for prioritization and trending information to evaluate systems and processes for safety and liability?
Evaluate available systems

- Use a task force
- Establish desired features
- Collect information on available systems
- Compare features, services, and costs
- Will it work in my health center or clinic?
Getting the most from Internal Event Reporting Systems

An effective event reporting system can enables the health center or clinic to:

- Act on significant errors or events quickly in an attempt to prevent or minimize harm
- Identify the cause of errors, near misses, and events so that recurrence can be prevented
- Analyze trends so that systems and practices can be improved
Event Investigation

- Follow up information to “fill in” the gaps
- Helps identify contributing factors
- Investigation interview
  - Web resources: “Event Investigation Tips”
- Refer to quality improvement/peer review for action
- Report serious/sentinel event in anticipation of litigation
Medical Record Documentation of Event

- Date and time of the event
- A factual account of what happened
- Name of provider notified and time of notification (if applicable)
- Patient’s condition after the event
- Any treatment or diagnostic tests rendered to the patient
Root Cause Analysis

- What exactly was the event or the chain of events that lead to the adverse event?
- What errors lead to it?
- What are the root causes?
- Did any errors relate to core system failures?
- Do they need redesign?
- What are lessons learned?

Tools and Resources

- The Joint Commission
  - http://www.jointcommission.org/SentinelEvents/Forms/

- National Patient Safety Agency
  - http://www.nrls.npsa.nhs.uk/resources/?entryid45=59847&
Failure Mode and Effects Analysis

- Identify the process to be evaluated
- Construct a detailed diagram of the process – a functional block diagram and/or flowchart
- Evaluate each step in the process and identify all potential failure modes (errors) and effects using a systems approach
- List potential effects of each failure mode
- Prioritize for action
- Deploy redesign strategy
FMEA Resources

- IHI

- American Society for Quality
Implementing solutions to identified problems

- Determine critical actions
- Resources needed
- Time frame for implementation
- Responsible individuals
- Potential impediments
- Countermeasures to impediments
Implementing solutions to identified problems (cont)

▶ Develop/Disseminate
  □ Education and lessons learned
  □ Safety alerts
  □ System modifications
  □ Monitor effectiveness
  □ Celebrate successes!

▶ Minnesota Adverse Event Measurement Guide
Success Story

- Reported vaccine mix-up
- Investigation of vials, cartons, and labels
- “Confirmation bias”
- Improved storage procedures
- Change in recording of lot numbers in vaccine log
Web Site Resources

Web site resources:

- CME courses in ECRI Institute eLearn system
- Guidance articles
- Self Assessment Questionnaire
- Standards and Guidelines
Challenges

Successes

Experiences
“Internal Event Reporting” program to be archived on Web site
Additional Questions?
clinical_RM_program@ecri.org
610-825-6000, ext. 5200
More info at:
www.ecri.org/clinical_RM_program
Thank You!