Our Office Team

- Office manager
- Electronic health record (EHR) liaison
- Clinic nurse (Julie Williams)
- Clinic medical director (Dr. Mary Downs)
Learning Objectives

- To understand the steps of event analysis:
  1. Identify event
  2. Conduct investigation
  3. Analyze data
  4. Identify root cause and contributing factors
  5. Develop action plan

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
- **Root cause analysis***: A structured method used to analyze adverse events or near misses to identify problems and decrease the risk of future errors

Methodology

1. Identify Event
2. Investigate
3. Analyze
4. Identify Root Causes
5. Develop Action Plan

Event Investigation and Analysis Methodology

<table>
<thead>
<tr>
<th>Phase</th>
<th>I. Notification/Immediate/Interim Action</th>
<th>II. Investigation</th>
<th>III. Analysis</th>
<th>IV. Action Planning</th>
<th>V. Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>START</td>
<td>Notification of event</td>
<td>RCA?</td>
<td>Analyze data</td>
<td>Identify root causes</td>
<td>Develop preventative actions</td>
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<tr>
<td></td>
<td>Immediate/Interim actions for Patient Safety</td>
<td></td>
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<td></td>
<td>Implement Action Plan</td>
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<tr>
<td></td>
<td></td>
<td>No</td>
<td></td>
<td>Validation</td>
<td>Monitor and measure preventative actions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yes</td>
<td></td>
<td>No</td>
<td>Action effective?</td>
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<tr>
<td></td>
<td></td>
<td>No</td>
<td></td>
<td>Yes</td>
<td>Report findings</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>End</td>
</tr>
</tbody>
</table>

Enter event into database for tracking and trending if:
Chronic events
Event characteristics
Root Causes

Monitor and measure preventative actions

Report findings

End
Identification of Event

- The immediate response to an adverse event is to ensure the patient is safe and to alleviate any untoward effects of the event.

Identification of Event

- All adverse events and near misses should be reported immediately.
- All adverse events and near misses should be reported using a uniform procedure:
  - Who is supposed to report the event/near miss?
  - What form should be used?
  - When should the report be completed?
  - Who is supposed to get the incident report?

Timely and accurate reporting is the basis of effective responses.
Systems Thinking

Root cause analysis seeks to identify **systemic** or individual problems that contribute to an event

- These causes go deep enough to reveal the **system issues** underneath
- Once root causes are identified, they point to vulnerabilities and fixes at a **systems level**
- The **fixes at systems level** can prevent recurrences

Common Pitfalls

- **Investigation** not thoroughly done before **analysis** is attempted
- Analysis stops short of actual root causes
- Root cause is often identified as “**the person**” or human error
- Root causes not tied to corrective action plans that were identified
- Action plans focus on education of the **person or persons**
- Action plans not measured for effectiveness

If we don’t get to the root causes…

Then our action plans won’t fix the **systemic** problem…
Case Scenario

► Dr. Smith sees a female patient with complaints of nasal congestion and watery eyes. Dr. Smith prescribes Flonase nasal spray and orders a sinus CT scan

► When ordering the prescription in the EHR, she types “FLO” in the medication order screen and the EHR automatches Flomax, a medication for an enlarged prostate that is not approved by the Food and Drug Administration for women

► Without noticing the error, Dr. Smith selects the incorrect medication

Case Scenario (cont.)

► The patient fills the prescription and takes it as directed

► Flomax also has a side effect of hypotension. Several days after beginning the medication, the patient presents to the emergency room (ER) with dizziness and the error is discovered
Case Scenario (cont.)

- The patient returns to the health center as directed by the emergency room
- Dr. Smith examines the patient
- Results of sinus CT scan are not available
- Dr. Smith leaves for vacation

Case Scenario (cont.)

- Radiology calls the health center with abnormal CT results
- Receptionist writes the telephone report down and places it in Dr. Smith’s inbox
- Results of abnormal sinus CT scan are also emailed to Dr. Smith’s portal. Assigned covering provider for Dr. Smith is unaware CT results are pending for the patient
- **Delayed follow-up to the CT scan report** for a sinus mass; rule out squamous cell carcinoma
Investigation

Gather Information

- Physical evidence—locate, separate, investigate
- Interview—involved parties, witnesses, others with information
**Physical Evidence**

- Office medical record, ER medical record
  - Orders
  - Diagnostic tests
  - Lab results
  - Visit summary
  - Prescriptions
- Equipment, instructions, error codes
- Staff schedules
- Telephone records
- Photos, videos

**Interviews**

- Interviews are one of the primary ways we gather evidence about an accident/incident
- They can be structured, semistructured, or unstructured
- They often involve a person (witness) telling his or her story
Interview Tips

- Be an active listener
- Be courteous and open-minded
- Show limited emotion
- Don’t embarrass; reassure nervous interviewees
- Look for bias, but do not interrupt or criticize
- Keep interviewees on point
- Encourage interviewees to continue talking if they state they “don’t know anything” prematurely
- Ensure interviews are private and conducted one on one

Interviewees

- Office manager
- Dr. Smith (involved in the event)
- Dr. Miller (another physician in the practice)
- Dr. Downs (medical director)
- Nurse Adams (another nurse in the practice)
- EHR liaison
“The point of a human error investigation is to understand why actions and assessments that are now controversial, made sense to people at the time.”

— Sidney Dekker*

*Human factors and safety expert

Sample Interview Questions

- Can you explain to me in your words what happened?
- Have you ever been in this situation before?
- Did you do anything different in this situation than you have done before?
- Was there anything unusual about this visit or situation?
- Do you feel that when things don’t go right, you are able to speak about it freely?
- Can you describe your decision-making process?
- Do you feel like you had adequate training in the EHR?
Walk through the Event

- Good to elicit important details
- Helps probe staff perceptions (situational awareness) of the environment
- Helps interviewee to sketch out a diagram/flowchart of how things happened
- Helps remind the interviewees of event details they might have forgotten

Look at Safeguards/Barriers

- Safeguards/barriers are things that have been set in place to protect from harm, damage, or loss
- When investigating events/near misses/unsafe conditions, you must ask and seek to answer these important questions:
  - Was a safeguard present?
  - How did each defense/safeguard fail?
  - Why did they fail?
Are There Any Safeguards/Barriers?

What should have occurred:
- Physician selects “FLONASE”
- Were any safeguards present or did they fail?
- Is the drug highlighted or bolded in the list of choices to help the provider know which drug is being selected?
- Is there a follow-up dosing screen?
- Is there any alert for diagnosis/drug matches or male/female drug matches?
- Is there a pop-up screen to confirm the medication being prescribed?

Are There Any Safeguards/Barriers? (cont.)

What should have occurred:
- CT scan results should have been forwarded to assigned covering provider when physician was absent
- Were any safeguards present or did they fail?
- Is there a way to verify that results are forwarded in cases of absences?
- What is the process regarding coverage when a provider is on vacation?
- Was there an error message after the last upgrade?
Putting the Investigation Together

Develop a Timeline

- Based on data gathered and interviews
- Be as specific and detailed as possible
- Be sure to include precursor events
Simple Timeline

Monday
- Dr. Smith sees female patient with nasal congestion and watery eyes
- Dr. Smith tells patient she will prescribe FLONASE nasal spray
- Dr. Smith orders prescription in the EHR for FLOMAX
- Pharmacy order sent electronically to patient's retail pharmacy
- Dr. Smith orders sinus CT scan
- Patient picks up prescription at retail pharmacy
- Patient goes to outpatient Radiology for CT scan
- Patient takes FLOMAX for several days

Sunday
- Patient presents to ER with complaints of dizziness
- Patient returns to Health Center
- Patient seen by Dr. Smith
- CT scan report not available
- Dr. Smith leaves for vacation

Wednesday
- Radiology calls Health Center with abnormal CT report
- Report placed in Dr. Smith's inbox
- CT report mass identified rule out squamous cell carcinoma sent to Dr. Smith's e-patient list
- CT report not seen by covering provider

Analysis
Identify the Problem: The Problem Statement

- What happened?
- Who was involved?
- When did it happen?
- Where did it happen?
- Who was affected?
- How did it happen?

Develop a Problem Statement

The problem statement does not contain the “Why?”

“Why” will be discovered in the investigation
Problem Statement

1. Incorrect medication was prescribed for the patient
2. Recognition of abnormal sinus CT scan report was delayed

Analysis Steps

1. Identify and gather your root-cause analysis (RCA) team
2. Analyze the data for causal factors
3. Drill down to determine root causes
4. Prioritize the root causes
Multiple Tools and Thorough Analysis Can Help Identify Root Causes

- Timeline
- 5 WHYs
- Brainstorming
- Swarm analysis
- Causal Factor Diagrams
- Summary Form
- Joint Commission Framework

Brainstorming

- Based on the idea that collective thinking is better than individual thinking alone
- No idea is out of the question; some ideas will trigger others
- Ideas generated will not be discussed or analyzed at this time
- Ensure equal participation
- Document identified issues that are not related to the event but warrant attention at another time
5 Why’s

Steps to Answering the 5 “Why’s”:

■ Ask, “Why is this a cause of the original problem?”
■ For each new answer to the question, ask “why” again.
■ You will usually need to ask “why” 5 times (it may be more or less, but it’s usually 5).
■ How do you know when to stop? When you can no longer answer “why.”

5 Why’s Worksheet

<table>
<thead>
<tr>
<th>1</th>
<th>Problem from worksheet</th>
</tr>
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<tbody>
<tr>
<td>Incorrect medication was prescribed for the patient</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>2</th>
<th>Why is that happening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider did not review the drop down list of all medications that started with “FLO”</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3</th>
<th>Why is that?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider assumed that the correct medication was being prescribed</td>
<td></td>
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<table>
<thead>
<tr>
<th>4</th>
<th>Why is that?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Providers not cautioned about medication automatch in the EHR</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>5</th>
<th>Root Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocols or systems were not developed to require verification of prescriptions to intended medications before sending prescription to the pharmacy</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Action</th>
</tr>
</thead>
</table>
5 Why’s Worksheet

1. Problem from worksheet
   - Recognition of abnormal sinus CT scan report delayed

2. Why is that happening
   - Radiology report sent to ordering physician’s inbox but she was on vacation
     - Why is that?

3. Dr. trained that in her absence test results would automatically default to assigned covering provider for follow up
   - Why is that?

4. Sinus CT scan did not automatically default to assigned covering provider
   - Why is that?

5. Root Cause
   - Following the last upgrade, automatic default malfunctioned and was not reported

Identify Root Cause
Why Take Time to Identify Root Causes?

If you don’t have time to find the root causes now, do you have time to reinvestigate similar events because the root causes were not identified and fixed the first time?

Causal Factor Chain

Dr. Smith orders prescription in the EHR for FLOMAX

<table>
<thead>
<tr>
<th>Causal Factor</th>
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</tr>
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<tbody>
<tr>
<td>Root Cause</td>
<td>Root Cause</td>
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</table>
Causal Factor Chain

From problem to

Causal factors to

Root cause

Recognition of abnormal sinus CT scan report delayed

Causal Factor

Root Cause

Causal Factor

Root Cause

Abnormal sinus CT scan report delayed

Dr. Smith orders prescription in the EHR for FLOMAX

Because the provider did not review the drop down list of all meds that started with “FLO”

Provider assumed that the correct medication was being prescribed

Providers not cautioned about medication automatch in the EHR

Protocols or systems were not developed to require verification of prescriptions to intended medications before sending prescription to the pharmacy.
Causal Factor Chain

From problem to
Recognition of abnormal sinus CT scan report delayed
Causal factors to
Radiology report sent to ordering physician’s inbox but she was on vacation
Dr. trained that in her absence test results would automatically default to assigned covering provider’s inbox to follow up
Sinus CT scan did not automatically default to assigned covering provider
Root cause
Following the last EHR upgrade, the automatic default malfunctioned and was not reported

What Have We Learned from this Process?

<table>
<thead>
<tr>
<th>Before Training</th>
<th>After Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focused only on the individuals involved?</td>
<td>Look at the systems or workflow to help the individual (not blame the individual).</td>
</tr>
<tr>
<td>Decided that the pharmacy should have caught the error?</td>
<td>We can control and fix some of the processes or workflow. It is our responsibility to create safeguards in our office.</td>
</tr>
<tr>
<td>Jumped into coming up with solutions before thorough analysis?</td>
<td>We need to take the time to investigate and analyze—even if it takes multiple meetings.</td>
</tr>
<tr>
<td>Analysis may not have gotten to the root cause because we didn’t ask enough “why’s”?</td>
<td>Getting to the root cause will identify the systematic issues to help prevent future events.</td>
</tr>
</tbody>
</table>
Developing an Action Plan

Actions Should Be Tied Directly to Causal Factors and Underlying (Root) Cause

Sample Action Chain

Dr. Smith orders prescription in the EHR for FLOMAX

Because the provider did not review the drop-down list of all meds that started with "FLO"

Provider assumed that the correct medication was being prescribed

Providers not cautioned about medication automatch in the EHR

Protocols or systems were not developed to require verification of prescriptions to intended medications before sending prescription to the pharmacy

Recognition of abnormal sinus CT scan delayed

Radiology report sent to ordering physician’s inbox but she was on vacation

Dr. trained that in her absence test results would default to covering provider’s inbox to follow up

Sinus CT scan report did not automatically default to assigned covering provider

Following the last EHR upgrade, the automatic default malfunctioned and was not reported

Root Cause and Action Plans

Root Cause: Protocols or systems were not developed to require verification of prescription to intended medication before sending prescription to the pharmacy

■ Hardwired pop-up in EHR requires the physician to verify that the prescription has been matched against the intended medications before sending the prescription to the pharmacy

■ Updated protocol requires the provider to verify and document that the prescribed medications are correct

■ Office-wide education on updated protocols
Root Cause and Action Plans (cont.)

- Root Cause: Following the last EHR upgrade, automatic default malfunctioned and was not reported
  - Schedule IT to make the necessary changes in the EHR to ensure that the malfunction is fixed
  - Investigate EHR tracking system to address issue
  - Change the process for front desk and clinical staff on how to handle diagnostic results and who to contact when provider is not in the building
  - Educate providers and staff to “hand off” to covering providers

Take-away
ECRI Institute Clinical Risk Management Resources

- Event report interviews: https://www.ecri.org/Components/HRSA/Pages/PSRM5.aspx


- Event response toolkit: https://www.ecri.org/components/HRSA/Pages/EventResponseToolkit.aspx

Questions?

Clinical_RM_Program@ecri.org
(610) 825-6000, x5200

Thank You