Putting Patient Safety First: Trends in Adverse Drug Event Screening and Reporting
Charlene A. Hope, PharmD, BCPS
Izabella Wentz, PharmD, FASCP - Moderator

Learning Objectives

PHARMACISTS
1. Differentiate between safety outcomes: adverse drug events, potential adverse drug events, medication side effects and medication errors.
2. Identify three different approaches to Adverse Drug Event screening.
3. Discuss current economic, clinical and humanistic outcomes associated with adverse drug events.
4. Evaluate a tool implemented across various patient care settings for potential Adverse Event screening.
5. Describe the types of therapeutic and safety measures that should be tracked to justify the expansion of clinical pharmacy services.

Learning Objectives

TECHNICIANS
1. Explain the difference between safety outcomes: adverse drug events, potential adverse drug events, medication side effects and medication errors.
2. Identify three different approaches to Adverse Drug Event screening.
3. Name the types of outcomes associated with Adverse Drug Events.
4. Review a tool implemented across various patient care settings for potential Adverse Event screening.
5. Name two therapeutic and safety outcome measures.

About Quality Improvement Organizations

- Telligen is the Medicare Quality Improvement Organization (QIO) for the state of Illinois, under contract with the Centers for Medicare & Medicaid Services (CMS).
  - Largest federal program dedicated to improving health quality at the community level
  - 1982: Peer Review Organizations (PRO’s) created by Congress
  - 1992: Medicare work of PRO’s redirected to Quality Improvement
  - 2002: Change of moniker to QIO to reflect mission
- Work in three year long “Statements of Work” to improve care provided to Medicare beneficiaries
- Provide technical assistance, resources and tools to providers and facilities throughout the state

QIO Medication Safety Initiatives

- 9th SOW: 2008-2011
  - Prescribing of PIM’s
  - Drug Interactions & PIM’s
  - PDP’s & Providers
  - ADE’s & outcomes
  - Clinical Pharmacy Services

- 8th SOW: 2005-2008
  - Prescribing of PIM’s
  - PDP’s/pharmacies

- 10th SOW: 2011-2014
  - PIM-Potentially Inappropriate Medication
  - PDP-Medicare Prescription Drug Plan
  - ADE-Adverse Drug Events

Check Point

How many people are injured or die in hospitals each year from adverse drug events (ADEs)?

A. 770,000
B. 220,000
C. 560,000
D. 1,200,000
Why do we care about ADE?

- Adverse drug events occur almost daily in medium-sized hospitals and outpatient settings
- 700,000 ED visits due to ADEs annually
- 120,000 hospitalizations due to ADEs annually
- $3.5 billion spent on ADE costs annually
- At least 40% of ambulatory ADE costs preventable
- ADE incidence rates: ranges from 2 per 100 admissions to 7 per 100 admissions (AHRQ)
- Can lead to permanent disability, depression, non-adherence, distrust in medical system and have a negative impact on quality of life.
- 770,000 people are injured or die in hospitals each year from adverse drug events (ADEs)

Check Point

How many people are injured or die in hospitals each year from adverse drug events (ADEs)?

A. 770,000 people

Opportunity for Clinical Pharmacy Services

“Despite the high morbidity and mortality, physicians often do not recognize or appropriately treat instances of drug-related harm”


“Tower of Babel” of Terminology

Definitions Related to Drug Related Harm:
HARM OCCURRED

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse event</td>
<td>Harm in a patient administered a drug that was not necessarily caused by a drug</td>
</tr>
<tr>
<td>Adverse Drug Reaction (ADR)</td>
<td>Harm caused by drug with normal use that is not expected</td>
</tr>
<tr>
<td>Adverse Drug Event (ADE)</td>
<td>Harm caused by the use of a drug or the inappropriate use of a drug</td>
</tr>
</tbody>
</table>

True of False

1. An ADR is always an ADE

True of False

1. An ADR is always an ADE

2. An ADE is always an ADR

Definitions Related to Drug Related Harm: HARM DID NOT OCCUR

<table>
<thead>
<tr>
<th>TERM</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential Adverse Drug Event (pADE)</td>
<td>Circumstances that could result in harm by the use of a drug, but that did not result in harm to the patient</td>
</tr>
</tbody>
</table>


 definitions Related to Drug Related Harm: HARM MAY HAVE OCCURRED

<table>
<thead>
<tr>
<th>TERM</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication Error</td>
<td>Inappropriate use of a drug that may or may not result in harm</td>
</tr>
<tr>
<td>Side Effect</td>
<td>A usually predictable effect of a drug that is not the intended effect, may be desirable, undesirable or inconsequential (not usually considered when reporting adverse events)</td>
</tr>
</tbody>
</table>

True or False

• Medication errors always result in patient harm

True or False

• Medication errors always result in patient harm
• Side effects are predictable effects of medications

Medical Errors

• Between 44,000-98,000 people die each year in hospitals due to medical errors.
• 2000 study in Australia: 50,000 people became disabled as a result of medical errors annually
• 2 million people suffer healthcare acquired infections which adds up to: 88,000 deaths, and a cost of $5 billion

Medication Errors

• 7000 deaths annually in the US, increase the annual operating costs of a 700 bed hospital by $3 million dollars

Adverse Drug Events due to Inappropriate Medication Use

Hospital infections cause $5 billions of dollars annually. Centers for Disease Control and Prevention Website. Available at [http://www.cdc.gov/media/pressrel/r2k0306b.htm](http://www.cdc.gov/media/pressrel/r2k0306b.htm). Accessed July 22nd, 2012


Non-Adherence

- Drug-Related Problems
  - Treatment failures due to possible non-adherence with medication regimen:
  - Total estimated cost is $100 billion annually
- Approximately 2 million hospital readmissions each year can be traced to non-adherence
- Approximately 125,000 Americans die each year because of non-adherence
- Intentional vs. non-intentional

Adverse Drug Reactions

- 2 million adverse drug reactions
- 100,000 fatalities
- One of the leading causes of death in the United States.¹

Adverse Drug Events (ADE)

Costs Associated with ADR

- $136 billion annual costs
- ADRs cause 1 out of 5 injuries or deaths per year to hospitalized patients
- Mean length of stay, cost and mortality for ADR patients are DOUBLE that for control patients

Pharmacist Role in ADR Reporting

ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting
It is the pharmacist’s responsibility and professional obligation to report any suspected ADRs.

ASHP PPMI
Optimal pharmacy practice models: Characteristics, requirements, and challenges
B19. Pharmacists should actively monitor for and report potential and actual adverse drug events

References:
- Classen DC et al. JAMA 1997;277(7):301–306
- Institute of Medicine, National Academy Press, 2000
- Classen DC et al. JAMA 1997;277(7):301–306
- The consensus of the Pharmacy Practice Model Summit. Am J Health-Syst Pharm. 2011; 68:1148-52
Check Point
Which of the following methods does your institution utilize to identify adverse events (ADE, ADRs and Medication Errors)? Choose all that apply.

a. Incident Reporting  
b. Direct Observation  
c. Chart Review  
d. Trigger Tools

Quantification of DRPs

Accuracy of DRPs

- Sensitivity, Specificity and Positive Predictive Value of the different DRP assessment methods varied greatly.
- Incident report review were generally more specific than other methods
- When compared to trigger tools, incident report review was consistently less sensitive.
- PPV of trigger tools ranged from 0% to 100%

Resource Utilization


Purpose
1. Compare the rates of potential ADEs identified from self-reports along and from self-reports combined with chart reviews.
2. Determine the number of potential ADEs identified from self-reports that were plausible ADEs
3. Determine the time required to apply various ADE-screening methods
4. Calculate the prevalence of chart ADE screens leading to ADE evaluations
5. Describe the interpreter reliability of ADE screens applied separately by a nurse and a pharmacist

Methods
Multi-centered, conducted at 11 Veteran Affairs Medical Centers (VAMCs)

Patients eligible if they were >65 years old, hospitalized on a medical or surgical ward for >48 hours, and were frail.

Methods, cont

• Five ADE screening methods were used
  – Surveillance for tracer drugs,
  – Surveillance for narrow-therapeutic-index drugs
  – Screening for changes in medications
  – Screening for previously identified ADEs
  – ADE-tracking reports

Table 1. Prevalence and Efficiency of Chart ADE Screens Assessed by a Pharmacist (n=50)

<table>
<thead>
<tr>
<th>Screening Method</th>
<th>% Positive ADE Screens Leading to ADE Summaries</th>
<th>Minutes Needed to Screen for Potential ADEs (Mean ± S.D.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADE-tracking reports</td>
<td>2</td>
<td>1.85 ± 3.47</td>
</tr>
<tr>
<td>Narrow-therapeutic-index drugs</td>
<td>4</td>
<td>2.68 ± 2.09</td>
</tr>
<tr>
<td>Tracer drugs</td>
<td>6</td>
<td>7.78 ± 4.40</td>
</tr>
<tr>
<td>Changes in medication</td>
<td>42</td>
<td>17.13 ± 9.65</td>
</tr>
<tr>
<td>Previously identified ADEs</td>
<td>52</td>
<td>10.71 ± 5.89</td>
</tr>
</tbody>
</table>

Audience Participation

How many sites currently reporting potential or preventable adverse drug events?

Classifying Medication Errors

NCC-MERP Index

A circumstances exist for potential errors to occur
B an error occurred but did not reach the patient
C error reached the patient but did not cause harm
D patient monitoring required to determine lack of harm
E error caused temporary harm and some intervention
F temporary harm with initial or prolonged hospitalization
G error resulted in permanent patient harm
H error required intervention to sustain the patient’s life
I error contributed to the patient’s death

NCC MERP. accessed August 2012. www.nccmerp.org
Proactive Screening Process

Patient Demographic Information
- Date of intervention
- Site
- Medical record number (MRN)
- Date of birth (DOB)
- Gender
- Insurance
- Ethnicity & Language

Intervention Documentation
- One intervention per row
- Name(s) of drug(s) involved
- Indication(s) for drug
- Intervention codes

Intervention Codes
- 4 parts to match columns in intervention section
  I. Medication-Related Problem (MRP)
  II. ADE/pADE Classification
  III. pADE Severity Rating
  IV. Intervention/Recommendation

Medication-Related Problem (MRP)

Intervention Codes ADE/pADE Classification
Intervention Code
Potential ADE Severity Rating

<table>
<thead>
<tr>
<th>Intervention Code</th>
<th>Potential ADE Severity Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Potential for minor harm</td>
</tr>
<tr>
<td>B</td>
<td>Potential for moderate harm</td>
</tr>
<tr>
<td>C</td>
<td>Potential for severe harm</td>
</tr>
<tr>
<td>D</td>
<td>None</td>
</tr>
</tbody>
</table>

Description of Event

- Provides clarification of event and likelihood of its association with the drug

Patient Case

RH is a 57 y/o Male admitted for right foot abscess, cellulitis, anemia, hypokalemia, and acute kidney injury
PMH: Seizures, Asthma, chronic back pain, Crohn’s Disease

Upon review of the patient medication profile, the pharmacist discovers that the patient has been receiving Sulfadiazine 500 mg po Q6hr instead of Sulfasalazine 500 mg po Q6hr. The physician was called and order was corrected.

Audience Participation

Based on patient case:

How would you classify the identified pADE?

What severity would you classify this pADE?
MTI Pilot at NAH

- PharmD Students trained on the MTI form
- DRP screening occurred over 6 week period
- Data compiled

MTI Pilot Results

Time period: 6 weeks
Total Number of patients: 50
Total Number of MRPs: 48

<table>
<thead>
<tr>
<th>Patient Demographics</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-30 y/o</td>
<td>4%</td>
<td>2</td>
</tr>
<tr>
<td>31-50 y/o</td>
<td>36%</td>
<td>18</td>
</tr>
<tr>
<td>&gt;51 y/o</td>
<td>60%</td>
<td>30</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>56%</td>
<td>28</td>
</tr>
<tr>
<td>Female</td>
<td>44%</td>
<td>22</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African-American</td>
<td>34%</td>
<td>17</td>
</tr>
<tr>
<td>Caucasian</td>
<td>12%</td>
<td>6</td>
</tr>
<tr>
<td>Hispanic</td>
<td>54%</td>
<td>27</td>
</tr>
</tbody>
</table>

MRP by Category

- Appropriateness and Effectiveness
- Safety
- Non Adherence and Patient Variables
- Miscellaneous

pADE Classification

- A: No med error or event, had potential identified
- B: Med error/event DID NOT reach patient
- C: Med error/event reached patient but no harm
- D: Med error/event reached patient, monitoring or intervention required to confirm harm

pADE Severity

- Minimal
- Moderate
- Severe

Revised Clinical Intervention Tracking Module

Safety Metrics
- Health Information System
### Revised Clinical Intervention Module

<table>
<thead>
<tr>
<th>Appropriate and Effectiveness</th>
<th>pADE/ADE Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety (pADE/ADE)</td>
<td>pADE Severity Rating</td>
</tr>
<tr>
<td>Non-Adherence and Patient Variables</td>
<td></td>
</tr>
<tr>
<td>Miscellaneous</td>
<td></td>
</tr>
</tbody>
</table>

#### Educate Pharmacists, APPE PharmD Students

- One on One orientation/training
- 1 hour presentation included as a part of site orientation (paper and computer)

### Updated Clinical Intervention Documentation

<table>
<thead>
<tr>
<th>Time period: 4 week period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of Clinical Interventions documented</td>
</tr>
<tr>
<td>Total Number of interventions sampled</td>
</tr>
<tr>
<td>Number of MRPs reviewed</td>
</tr>
</tbody>
</table>

### pADE Classification

- A: No med error/event, potential identified
- B: Med error/event did not reach patient
- C: Med error/event reached patient but no harm
- D: Med error/event reached patient, monitor/ag or intervention required to confirm harm

### pADE Severity

- 65% Minimal
- 28% Moderate
- 7% Severe

### Cost Avoidance

- Occurrence Rate: 3%
- Average Cost of ADE: $2,182
- Yearly Projection of Med Intervention: 7,261
- Estimated ADEs avoided (Annualized): 218
- Estimated Savings: $475,298

Adapted from Medication Reconciliation Tracking Tool, Johns Hopkins University. Accessed at: [http://www.ihi.org/knowledge/Pages/Tools/ReconciliationTrackingTool.aspx](http://www.ihi.org/knowledge/Pages/Tools/ReconciliationTrackingTool.aspx) on 8/6/12
ASHP PPMI Case Study

**ASHP PPMI Case Study**

**Adding Value: Prevention Prescribing Errors through Pharmacist Interventions Utilizing a Severity Rating Scale**

**Relevant PPMI Recommendation**

B24. Every pharmacy department should:

• Track and trend pharmacist interventions

• Primary Intended Outcome
  – Demonstrate clinical relevance, via use of a severity rating scale, of prescribing errors intercepted by pharmacists

References


Post Test Case Study

60-year-old Hispanic female who presents for diabetes MTM. She has been experiencing what she describes as “10 "really bad" hypoglycemic episodes since her last visit with her primary care provider. She claims that she has not changed her diet nor activity level. She checked her blood glucose levels during several of these episodes and the readings ranged from 60 to 70 mg/dL; she managed these episodes by consuming fruit juice or bread and rechecking her blood glucose every 15 minutes as directed. Upon completing your medication reconciliation, you find out that her dose of glyburide was recently increased from 10 mg BID to 20 mg BID.

Case Study Question

1. This adverse event is ____________________

a. inappropriate medication use, Side Effect
b. appropriate medication use, Non-adherence
c. inappropriate medication use, Medication Error
d. appropriate medication use, Adverse Drug Reaction
Assessment Question

2. Which of the following methods of screening for Adverse Drug Event events is considered to be the most time efficient?
   a. Direct Observation
   b. Trigger Report
   c. Chart Review
   d. Incident Reporting

Assessment Question

3. A Potential Adverse Event is a circumstance that could result in harm by the use of a drug, but that did not result in harm to the patient
   a. True
   b. False

Assessment Question

4. How many hospital re-admissions each year are due to non-adherence?
   a. 40,000
   b. 250,000
   c. 1 million
   d. 2 million

Assessment Question

5. The Medication Therapy Intervention Form incorporated the tracking of which safety outcomes?
   a. Potential Adverse Drug Events and Medication Errors
   b. Adherence and Adverse Drug Events
   c. Medication Errors and Adherence
   d. Potential Adverse Drug Events and Adverse Drug Events