Putting Patient Safety First: Trends in Adverse Drug Event Screening and Reporting

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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

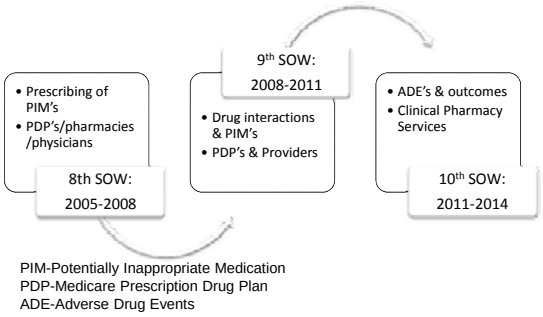
TECHNICIANS

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



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)?

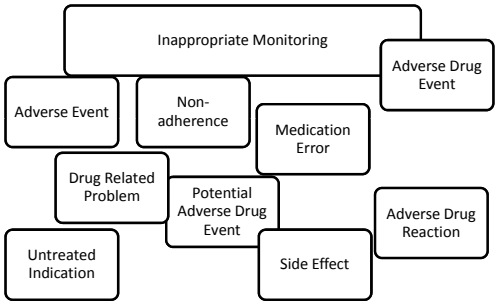
A. 770,000 people

Opportunity for Clinical Pharmacy Services

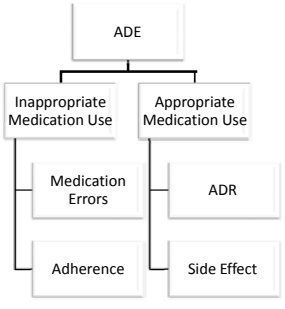
"Despite the high morbidity and mortality, physicians often do not recognize or appropriately treat instances of drug-related harm"

Nebeker, et.al. Clarifying Adverse Drug Events: A Clinician's guide to terminology, documentation, and reporting. Ann Intern Med. 2004; 140:795-801

"Tower of Babel" of Terminology



The Adverse Drug Event Family Tree



Definitions Related to Drug Related Harm: HARM OCCURRED

Term	Definition
Adverse event	Harm in a patient administered a drug that was not necessarily caused by a drug
Adverse Drug Reaction (ADR)	Harm caused by drug with normal use that is not expected
Adverse Drug Event (ADE)	Harm caused by the use of a drug or the inappropriate use of a drug

Adapted from: Nebeker, JR et .al. Clarifying Adverse Drug Events: A Clinician's Guide to Terminology, Documentation, and Reporting. Ann Intern Med. 2004; 140:795-801

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

TERM	DEFINITION
Potential Adverse Drug Event (pADE)	Circumstances that could result in harm by the use of a drug, but that did not result in harm to the patient

Adapted from: Nebeker, JR et .al. Clarifying Adverse Drug Events: A Clinician's Guide to Terminology, Documentation, and Reporting. Ann Intern Med. 2004; 140:795-801

True of False

- A potential adverse drug event did not result in patient harm

True of False

- A potential adverse drug event did not result in patient harm TRUE

Definitions Related to Drug Related Harm: **HARM MAY HAVE OCCURRED**

TERM	DEFINITION
Medication Error	Inappropriate use of a drug that may or may not result in harm
Side Effect	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)

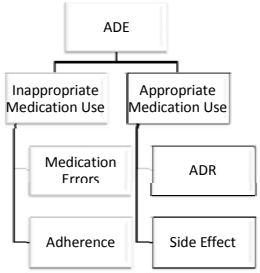
Adapted from: Nebeker, JR et .al. Clarifying Adverse Drug Events: A Clinician's Guide to Terminology, Documentation, and Reporting. Ann Intern Med. 2004; 140:795-801

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



Adverse Drug Events due to **Inappropriate Medication Use**

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

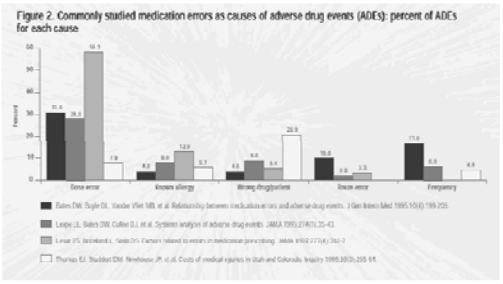
Kohl et al. To Err Is Human: Building a Safer Health System. Washington, DC: National Academy Press; 1991:1.
Weingart, et al. Epidemiology of medical error> British Medical Journal. 200; 320: 774-777
Hospital infections cause US billions of dollars annually. Centers for Disease Control and Prevention Website. Available at httP://www.cdc.gov/media/pressrel/r2k0306b.htm. Accessed July 22nd, 2012

Medication Errors

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

Bates, et al. The costs of adverse drug events in hospitalized patients. Journal of the American Medical Association. 1997; 277: 307-311

Medication Errors

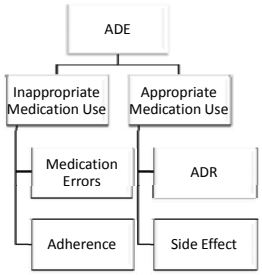


Reducing and Preventing Adverse Drug Events To Decrease Hospital Costs. Research in Action, Issue 1. AHRQ Publication Number 01-0020, March 2001. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/qual/aderia/aderia.htm

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

Arch Intern Med. 2008(116):565-71.
Am J Health-Syst Pharm. 1998(55)1:1127-33.



Adverse Drug ***Events*** due to Adverse Drug ***Reactions***

Adverse Drug Reactions

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

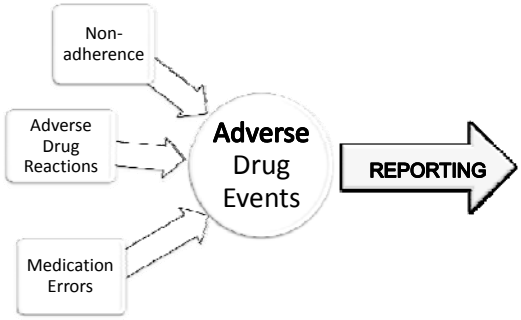
Institute of Medicine, National Academy Press, 2000
Lazarou J et al. JAMA 1998;279(15):1200–1205
Gurwitz JH et al. Am J Med 2000;109(2):87–94

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**

Johnson JA et al. Arch Intern Med 1995;155(18):1949–1956
Leape LL et al. N Engl J Med 1991;324(6):377–384
Classen DC et al. JAMA 1997;277(4):301–306

Adverse Drug Events (ADE)



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

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

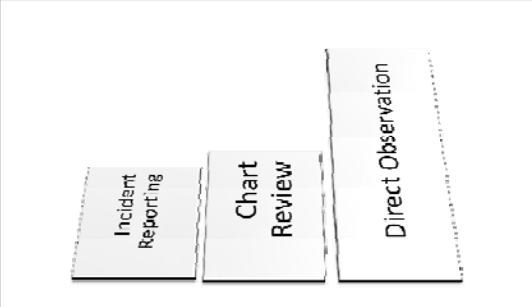
d. Trigger Tools

Meyer-Massetti C, Cheng CM, Schwappach DLB et al. Systematic review of medication safety assessment methods. Am J Health-Syst Pharm. 2011; 68:227-240.

Purpose: To compare the accuracy, efficiency, and efficacy of commonly used medication safety methods in proactive medication safety assessment.

Methods: Medical literature databases were search over a nine year period for any comparative study with at least two of four methodologies – incident report review, direct observation, chart review and trigger tool. Studies were included in the analysis if they included efficiency (effort and cost), and efficacy and provided numerical data.

Quantification of DRPs



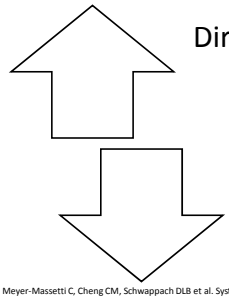
Meyer-Massetti C, Cheng CM, Schwappach DLB et al. Systematic review of medication safety assessment methods. Am J Health-Syst Pharm. 2011; 68:227-240.

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%

Meyer-Massetti C, Cheng CM, Schwappach DLB et al. Systematic review of medication safety assessment methods. Am J Health-Syst Pharm. 2011; 68:227-240.

Resource Utilization



Direct Observation

Chart Review

Incident Review

Trigger Tool

Meyer-Massetti C, Cheng CM, Schwappach DLB et al. Systematic review of medication safety assessment methods. Am J Health-Syst Pharm. 2011; 68:227-240.

Hanlon JT, Maher RL, Lindblad CI, et. al.
Comparison of methods for detecting potential adverse drug events in frail inpatients and outpatients. Am J Health-Syst Pharm. 2001; 58:1622-6

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.

Hanlon JT, Maher RL, Lindblad CI, et. al.
Comparison of methods for detecting potential adverse drug events in frail inpatients and outpatients Am J Health-Syst Pharm. 2001; 58:1622-6

Methods, cont

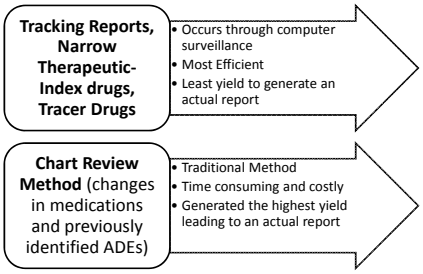
- Five ADE screening methods were used
  - Surveillance for tracer drugs,
  - Surveillance for narrow-therapeutic-index drugs
  - Screening for changes in medications
  - Screening for previously identified ADEs
  - ADE-tracking reports

Hanlon JT, Maher RL, Lindblad CI, et. al.
Comparison of methods for detecting potential adverse drug events in frail inpatients and outpatients Am J Health-Syst Pharm. 2001; 58:1622-6

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

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

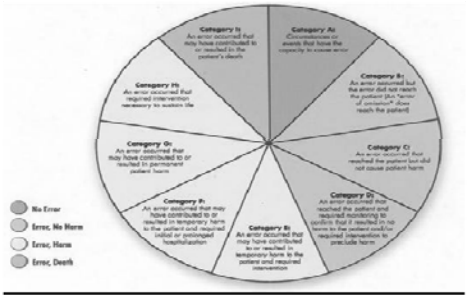
Hanlon JT, Maher RL, Lindblad CI, et. al.
Comparison of methods for detecting potential adverse drug events in frail inpatients and outpatients Am J Health-Syst Pharm. 2001; 58:1622-6



Audience Participation

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

National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP Index)



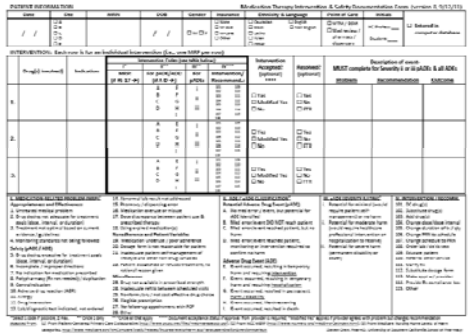
NCC MERP. accessed August 2012. www.nccmerp.org

Classifying Medication Errors NCC-MERP Index

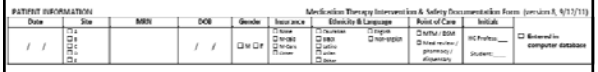
A circumstances exist for potential errors to occur
B an error occurred but did not reach the patient
C error reached the patient but did not cause harm
D patient monitoring required to determine lack of harm
E error caused temporary harm and some intervention
F temporary harm with initial or prolonged 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

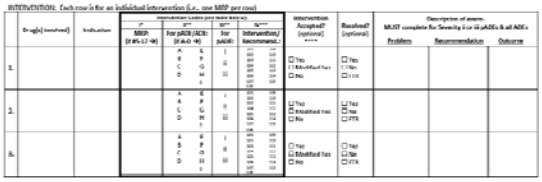


Patient Demographic Information



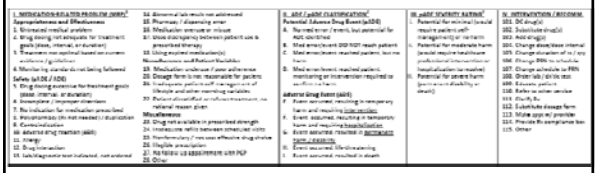
- Date of intervention
- Site
- Medical record number (MRN)
- Date of birth (DOB)
- Gender
- Insurance
- Ethnicity & Language

Intervention Documentation



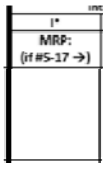
- One intervention per row
- Name(s) of drug(s) involved
- Indication(s) for drug
- Intervention codes

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)



I. MEDICATION-RELATED PROBLEM (MRP)[1]

Appropriateness and Effectiveness

1. Untreated medical problem
2. Drug dosing not adequate for treatment goals (dose, interval, or duration)
3. Treatment not optimal based on current evidence / guidelines
4. Monitoring standards not being followed

Safety (pADE / ADE)

5. Drug dosing excessive for treatment goals (dose, interval, or duration)
6. Incomplete / improper directions
7. No indication for medication prescribed
8. Polypharmacy (Rx not needed) / duplication
9. Contraindication
10. Adverse drug reaction (ADR)
11. Allergy
12. Drug interaction
13. Lab/diagnostic test indicated, not ordered
14. Abnormal lab result not addressed
15. Pharmacy / dispensing error
16. Medication overuse or misuse
17. Dose discrepancy between patient use & prescribed therapy
18. Using expired medication(s)

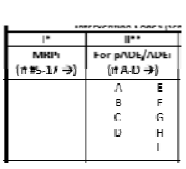
Nonadherence and Patient Variables

19. Medication underuse / poor adherence
20. Dosage form is not reasonable for patient
21. Inadequate patient self-management of lifestyle and other non-drug variables
22. Patient dissatisfied or refuses treatment, no rational reason given

Miscellaneous

23. Drug not available in prescribed strength
24. Inadequate refills between scheduled visits
25. Nonformulary / not cost effective drug choice
26. Illegible prescription
27. No follow-up appointment with PCP
28. Other

Intervention Codes ADE/pADE Classification



II. ADE / pADE CLASSIFICATION[1]

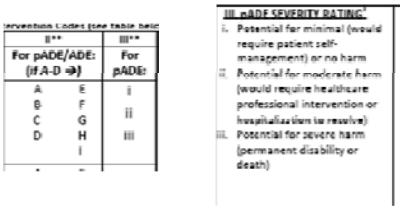
Potential Adverse Drug Event (pADE)

A. No med error / event, but potential for ADE 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 no harm

Adverse Drug Event (ADE)

E. Event occurred, resulting in temporary harm and required intervention
F. Event occurred, resulting in temporary harm and required hospitalization
G. Event occurred, resulted in permanent harm / disability
H. Event occurred, life-threatening
I. Event occurred, resulted in death

Intervention Code
Potential ADE Severity Rating



II** For pADE/ADE: (if A-D ➔)		III** For pADE:
A	E	i
B	F	ii
C	G	
D	H	iii
	I	

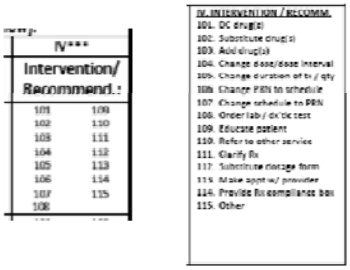
III. pADE SEVERITY RATING[2]

i. Potential for minimal (would require patient self-management) or no harm

ii. Potential for moderate harm (would require healthcare professional intervention or hospitalization to resolve)

iii. Potential for severe harm (permanent disability or death)

Intervention Code
Intervention/Recommendations

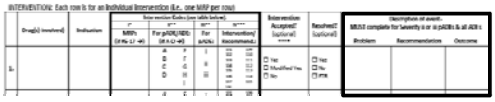


IV*** Intervention/ Recommend.*	
101	109
102	110
103	111
104	112
105	113
106	114
107	115
108	

IV. INTERVENTION / RECOMM.

101. DC drug(s)
102. Substitute drug(s)
103. Add drug(s)
104. Change dose/dose interval
105. Change duration of tx / qty
106. Change PRN to schedule
107. Change schedule to PRN
108. Order lab / dx tic test
109. Educate patient
110. Refer to other service
111. Clarify Rx
112. Substitute dosage form
113. Make appt w/ provider
114. Provide Rx compliance aid
115. Other

Description of Event



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

*Note: This has been edited from the manual to reflect the chart description.

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?

II. ADE / pADE CLASSIFICATION[2]

Potential Adverse Drug Event (pADE)

A. No med error / event, but potential for ADE identified
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Adverse Drug Event (ADE)

E. Event occurred, resulting in temporary harm and requiring intervention
F. Event occurred, resulting in temporary harm and requiring hospitalization
G. Event occurred, resulted in permanent harm / disability
H. Event occurred, life-threatening
I. Event occurred, resulted in death

Audience Participation

Based on patient case:

What ***severity*** would you classify this pADE?

III. pADE SEVERITY RATING[2]

i. Potential for minimal (would require patient self-management) or no harm

ii. Potential for moderate harm (would require healthcare professional intervention or hospitalization to resolve)

iii. Potential for severe harm (permanent disability or death)

MTI Pilot at NAH

PharmD Students trained on the MTI form

DRP screening occurred over 6 week period

Data compiled

MTI Pilot Results

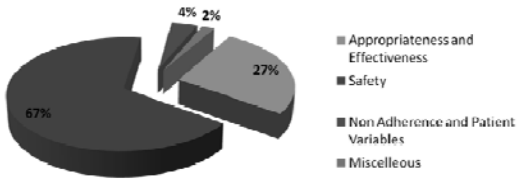
Time period: 6 weeks

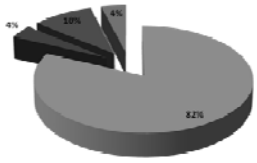
Total Number of patients: 50

Total Number of MRPs: 48

Patient Demographics	
Age	18-30 y/o : 4% (2) 31-50 y/o: 36% (18) >51 y/o: 60% (30)
Gender	Male: 56% (28) Female: 44 % (22)
Race	African-American: 34% (17) Caucasian: 12% (6) Hispanic: 54% (27)

MRP by Category





A- No med error or event, but potential identified

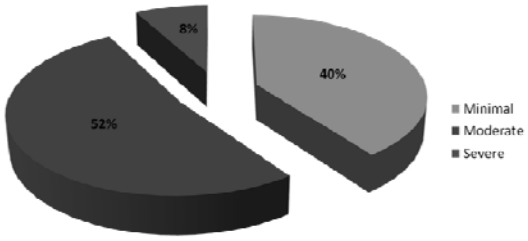
B-Med error/event DID NOT reach patient

C-Med error/event reached patient but no harm

D - Med error/event reached patient, monitoring or intervention required to confirm harm

pADE Classification

pADE Severity



Paradigm Shift

Safety Metrics

- Health Information System

Revised Clinical Intervention Tracking Module

Revise Clinical Intervention Module

Appropriate and Effectiveness Safety (pADE/ADE) Non Adherence and Patient Variables Miscellaneous	pADE/ADE Classification pADE Severity Rating

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

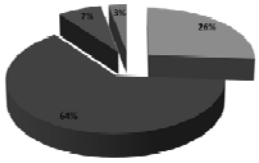
Time period: 4 week period	
Total Number of Clinical Interventions documented	636
Total Number of interventions sampled	69
Number of MRPs reviewed	69

MRP by Category

Safety (pADE/ADE)

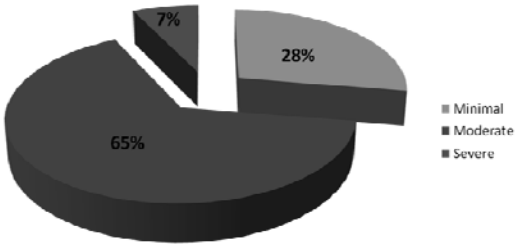
- Abnormal lab
- Allergy
- Contraindication
- Illegible Order
- Incomplete Order
- Order Clarifications
- Drug Dose Excessive for therapeutic Goals
- Therapeutic Duplication

pADE Classification



- A- No med error or event, but 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



Cost Avoidance

Occurrence Rate	3%
Average Cost of ADE	$ 2182
Yearly Projection of Med Intervention	7261
Estimated ADEs avoided (Annualized)	218
Estimated Savings	$ 475,298

Adapted from Medication Reconciliation Tracking Tool. John Hopkins University. Accessed at: http://www.ihi.org/knowledge/Pages/Tools/ReconciliationTrackingTool.aspx on 8/6/12

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:

m. Track and trend pharmacist interventions

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

Palmer K, Shane R Adding Value: Preventing Prescribing Errors through Pharmacist Interventions Utilizing a Severity Rating Scale http://www.ashpmedia.org/ppmi/case-studies.html, Accessed August 6, 2012.

ASHP PPMI Case Study

- Pharmacists document intercepted prescribing errors and their potential severity, utilizing the NCC MERP Index in the electronic health record.
- Analyzed Data used in numerous ways
  - Included in the hospital performance improvement program
  - Reported to P&T Committee and Medical Staff Committees
    - Physician Education
    - Medical Staff Credentialing process
  - Pharmacy Department
    - Clinical Skills Assessment for pharmacy residents
    - Shared with pharmacy staff on a routine basis

Palmer K, Shane R Adding Value: Preventing Prescribing Errors through Pharmacist Interventions Utilizing a Severity Rating Scale http://www.ashpmedia.org/ppmi/case-studies.html, Accessed August 6, 2012.

ASHP PPMI Case Study

- Outcome Measures
  - Demonstrated the value of clinical pharmacy services to the organization
  - Did not result in an increase FTE; however, it supported the need for pharmacist staffing throughout the patient care areas.

Palmer K, Shane R Adding Value: Preventing Prescribing Errors through Pharmacist Interventions Utilizing a Severity Rating Scale http://www.ashpmedia.org/ppmi/case-studies.html, Accessed August 6, 2012.

References

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3. Fattinger, et al. Epidemiology of drug exposure and adverse drug reactions in two Swiss deprtmetns of internal medicine. Br J Clin Pharmacol. 200;49:158-67
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5. Institute of Medicine. Committee on Identifying and Preventing Medication Errors. Preventing Medication Errors, Washington, DC: The National Academies Press 2006.
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8. Cullen DJ, Bates DW, Small SD, et al. The incident reporting system does not detect adverse drug events: A problem for quality improvement. *Journal on Quality Improvement* 1995;21(10):541-8.

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 _____ and an example of a(n)_____.

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