The Importance of Reporting Adverse Drug Reactions and Creating a Culture of Safety

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Objectives

• Describe Adverse Drug Reactions (ADR) and the importance of reporting for patient safety
• Illustrate the benefit of successful reporting, and how to implement a reporting system and utilize reporting tools
• Explain the importance of a successful ADR reporting program within the hospital to help create a culture of safety
What is an ADR?

- Harmful, unintended reaction to medication that occurs at doses normally used for treatment
  - *World Health Organization*
ADR (ASHP)

- Undesirable experience associated with the use of a medication that may result in:
  - discontinuing the drug
  - changing the drug therapy
  - modifying the dose
  - necessitates admission to a hospital or prolongs stay
  - necessitates supportive treatment
  - significantly complicates diagnosis
  - negatively affects prognosis
  - results in temporary or permanent harm, disability, or death
Side Effects

• Expected, well-documented reactions
• Results in little or no change in patient management
Reporting of Medication Events

**Adverse Drug Events**
- Medication error
- Medication administration error
- Inappropriate dose reduction/increase

**Adverse Drug Reactions**
- Harm caused by drug therapy at normal clinical dose and during normal use
  - Includes allergic reactions
  - Includes drug product and vaccine issues
Steps to Implementing an ADR Reporting Program

- Educate
- Monitor and Investigate
- Communicate
Part 1 - Education

• Do our nurses/staff understand what an ADR looks like, and when to report?
• Do our nurses/staff understand the value in reporting ADRs?
• Do our nurses/staff know where/how to report an ADR?
Why Aren’t ADRs Reported?

- Lack of knowledge about the reporting systems or perceived difficulty
- Uncertainty about whether or not a drug is the cause of an adverse event
  - Concern about medical liability or professional disciplinary action
- Lack of time or high workload
- Lack of understanding about why it is important to report
- Complacency (believing that serious ADRs are well documented when the drug is released in the market)
Are ADRs Always Preventable?

- Majority of preventable ADRs occur at prescribing and monitoring stages.
Who is most at risk for ADRs?

- Elderly
- Patients taking multiple medications
- Patients taking medications from specific classes:
  - Antidiabetics and hypoglycemic agents
  - Cardiovascular drugs
  - Psychotropics
  - Anticonvulsants
  - Antineoplastics
  - Corticosteroids
What Costs are Associated with ADRs?

- Ambulatory-setting cost impact of drug-related problems estimated at $76.6 billion in 1995.
- Cost estimated at $177.4 billion in 2000.
  - New prescriptions
  - Doctors visits
  - Admission to hospital
  - ED visit
  - LTC admission
Why are there so Many???

• 75% of patient visits result in a prescription

• Medicare Patients
  – 89% take a prescription medicine daily
  – 46% take greater than 5 prescriptions chronically
  – 54% take meds prescribed by 2 or more doctors
  – 5% obtain an Rx from Canada/Mexico

• ADRs increase exponentially with greater than 4 prescriptions
How Do We Report an ADR?
Part 2 – Monitor and Investigate

• Monitor reporting and evaluate for ADRs
  – Provide follow up to reporter
• Investigate potential trends using medication-use evaluation (MUE)
• Identify unreported ADRs through Trigger Tool
Reporting Increase

ADR Events Reported

2014

2015

Magruder Hospital
It's How We Care
Investigate Trends

![Graph showing total ADRs reported (Jan-Aug) and total Ciprofloxacin ADRs.](image-url)
Investigate through MUE

• A process focused on evaluating and improving the usage of a medication, with the goal of improving patient outcomes

• Analyze prescribing trends
  – Examine guidelines, treatment protocols, and standards of care for specific medication and medication-use processes, based on data from recent literature

• Collect data and evaluate usage
Indications an MUE is Needed

- Increase in ADRs or medication errors
- Multiple occurrences of treatment failure
- Pharmacy intervention consistently necessary
- Expensive medication
Interpreting the Data

• Develop and implement plans for improvement of the medication-use process based on MUE findings (if indicated)
• Recommend changes (if any) or suggest alternatives to current prescribing
• After changes implemented, continue to collect data
Ciprofloxacin MUE

- By August of 2015, 14 ADRs reported
  - 6 related to infusion of Ciprofloxacin.

- Ciprofloxacin is being infused over 60 minutes in the ED, but infusion time appears to be increased in Med/Surg and ICU to 90-120 minutes.
## Ciprofloxacinc MUE

<table>
<thead>
<tr>
<th>Total Ciprofloxacin Doses in 2014</th>
<th>175</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients Given in ED and Admitted</td>
<td>99</td>
</tr>
<tr>
<td>Patients Given in ED and Discharged</td>
<td>43</td>
</tr>
<tr>
<td>Patients Given Ciprofloxacin in Med/Surg</td>
<td>20</td>
</tr>
<tr>
<td>Patients Given in Surgery</td>
<td>2</td>
</tr>
</tbody>
</table>
Ciprofloxacin MUE

• No Levaquin ADRs have been reported

• Giving Levaquin for all 175 doses of Cipro dispensed in 2014, would create a cost increase of $10.27 for ciprofloxacin 200mg and $134.46 for 400mg = total increase of $144.73

<table>
<thead>
<tr>
<th>Cost of Levaquin (levofloxacin)</th>
<th>Cost of Cipro (ciprofloxacin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>250mg/50mL bag</td>
<td>$2.04</td>
</tr>
<tr>
<td>500mg/100mL bag</td>
<td>$2.98</td>
</tr>
<tr>
<td>750mg/150mL bag</td>
<td>$26.76</td>
</tr>
</tbody>
</table>
Ciprofloxacin MUE

• Can increase infusion time with no disruption in efficacy

• Antibiogram shows greater susceptibility to Levaquin then Ciprofloxacin for all areas except pseudomonas

• Diagnoses most prevalent (UTI and divertulitis) also indicated with Levaquin
MUE Recommendations

• Increase infusion time from 60 minutes to 90 minutes
  – ED patients being admitted 70% so will not need to worry about infusion time lengthening stay

• Remove Ciprofloxacin from pre-built order sets for prescribers
  – Propose utilizing Levaquin instead of Cipro for UTI, diverticulitis, and when appropriate
Monitor Results

• Since implementing recommendations, 1 ADR related to ciprofloxacin
  – Utilized Smart Pump software to determine pre-programmed infusion rate was overridden and infused at 60 minutes
Increase Reporting

• Use Smart Pump software for trends of infusion rates being consistently overridden
  – Evaluate if any overrides created infusion-related ADRs
Increase Reporting

- Examine patients who were given antidotes
- Was this given as an antidote for an ADR?
  - Was it reported?

<table>
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<tr>
<th>Trigger</th>
<th>Process identified</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1: Diphenhydramine</td>
<td>Hypersensitivity reaction or drug effect</td>
</tr>
<tr>
<td>T2: Vitamin K</td>
<td>Over-anticoagulation with warfarin</td>
</tr>
<tr>
<td>T3: Flumazenil</td>
<td>Oversedation with benzodiazepine</td>
</tr>
<tr>
<td>T4: Droperidol</td>
<td>Nausea/emesis related to drug use</td>
</tr>
<tr>
<td>T5: Naloxone</td>
<td>Oversedation with narcotic</td>
</tr>
</tbody>
</table>
Increase Reporting

• Create an ADR committee charged with increasing and monitoring ADR reporting
  – Promotes interdisciplinary problem solving

• Inservices held with all departments to educate (food always works!)
Part 3 - Communication

• Disseminate information from P&T Committee
• Share data with nursing staff
  – Value of reporting is realized when changes are implemented as a result
• Communicate through meeting/newsletter
Internal Reporting Mechanism

- Contrast Monitoring (Radiology)
- Spontaneous Drug Product Issues
- Pharmacist Review of Orders
- Retrospective Drug Monitoring
- Medication Use Evaluations
- Retrospective Identification in coding

ADR Reporting Program
Creating a Culture of Safety

• Just Culture addresses behavior and analyzes systems and workflows in place when evaluating errors
• Encourages reporting of events and coaching at-risk behaviors, non-punitive response
• Open dialogue promotes discussion among departments
Staff feel like their mistakes are held against them when an event is reported, it feels like the person is being written up, not the problem. Staff worry that mistakes they make are kept in their personnel file.

Nonpunitive response to errors.
Staff will freely speak up if they see something that may negatively affect patient care.

Staff feel free to question the decisions or actions of those with more authority.

Staff are afraid to ask questions when something does not seem right.

**COMMUNICATION OPENNESS**

- **Composite Score**
  - 2008
  - 2010
  - 2012
  - 2014
  - 2016
  - National
  - 6-24 Beds

- **Staff will freely speak up if they see something that may negatively affect patient care**
  - 2008
  - 2010
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We are given feedback about changes put into place based on event errors. We are informed about errors that happen in this unit. In this unit, we discuss ways to prevent errors from happening again.
Conclusion

• Reporting of ADRs is vital for patient safety
  – Work to minimize preventable ADRs
• Successful program can help identify problems and lead to positive change
References

- Adverse Drug Reactions by Joan B. Tarloff, PhD
- ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting
- Transitions of Care: Pharmacy Technicians Role in Helping to Reduce Readmissions
- Pharmacists Underreport Adverse Drug Reactions Due to Inadequate Training Rachel Lutz
  Published Online: Thursday, November 6, 2014 See more at:
- Pharmacists Underreport Adverse Drug Reactions Due to Inadequate Training - See more at: