Screening for adverse drug events: a tool to improve safe medication use

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Disclosure

• I have no financial disclosures or conflicts of interest related to this presentation

• The Idaho State University ADE Screening Tools I will be presenting have been copyrighted by ISU but may be used for non-profit or academic uses

TD is a 69-year-old male with a history of atrial fibrillation, hypertension, dyslipidemia, depression, type II diabetes, and osteoarthritis. He is currently on metformin 500mg BID, glyburide 5mg BID, atorvastatin 20mg QHS, metoprolol succinate 50mg BID, hydrochlorothiazide 25mg QD, sertraline 50mg QD, and warfarin 5mg M/W/F and 2.5mg Tu/Th/Sa/Su. He presents today to pick up all of his prescriptions medications and a bottle of naproxen 220mg tablets. Which of the following best describes your role as the pharmacist?

A. As these medications are refills and the patient indicates he has no questions, simply ring TD up and provide him his medications.
B. Instruct patient that he should not take naproxen due to negative effects on kidney and possible risk of bleed.
C. Specifically inquire about hypoglycemia and bleeding adverse events, educate patient OTC products and ADEs, and provide recommendations to patient and provider to optimize drug therapy.
D. Instruct patient that he should talk to his doctor about switching warfarin to apixaban, glyburide to glimepiride, and increase dose of atorvastatin.

Objectives

• Describe the pharmacist’s role in preventing, identifying, and resolving adverse drug events.

• Review quality improvement techniques to improve safe medication use within your practice setting.

• Discuss an adverse drug event screening program that could be implemented in a pharmacy practice setting.

Which of the following best describes your primary practice site?

1. Chain retail pharmacy
2. Independent retail pharmacy
3. Staff hospital pharmacy
4. Clinical hospital pharmacy
5. Ambulatory care clinic
6. Other

ST, the director of pharmacy, wants to reduce medication errors across the hospital. She meets with the nurse manager and other stakeholders, and, together, they develop a process to improve the way the medications are verified prior to administration to patients. Their aim is to reduce medication administration errors by 50% by June 1, 2018 though the use of bar code scanning. They have a data collection strategy in place and have developed a flow diagram depicting the new approach to patient verification prior to medication administration. Which phase of the project have they just completed?

A. Plan
B. Do
C. Study
D. Act
Terminology

- **Adverse Drug Event (ADE)**
  - “an injury resulting from medical intervention related to a drug”
- **Adverse Drug Reaction (ADR)**
  - “harm directly caused by a drug at normal doses”
- **Potential Adverse Drug Event (pADE)**
  - “could result in harm by the use of a drug, but that did not result in harm to the patient”


Terminology

- **Medication Errors**
  - “any preventable even that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer”
- **Serious Adverse Event (SAE)**
  - Untoward medical occurrence that results in death, hospitalization or prolongation, persistent or significant disability, or is life threatening

National Coordinating Council for Medication Error Reporting and Prevention. Available at: http://www.nccmerp.org/about-medication-errors


Drug-Related Problems (DRP)

- “an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes”
- **AKA** – Medication-Related Problem (MRP); Medication Misadventure
- **Many different classification schemes**

Pharmaceutical Care Network Europe. Available at www.pcne.org


Classification of DRPs

- **Unnecessary drug therapy**
- **Needs additional drug therapy**
- **Ineffective drug**
- **Dosage too low**
- **Dosage too high**
- **Adverse Drug Reaction**
- **Medication Nonadherence**

The Problem

- Increasing medication use
  - ~60% of US population takes ≥1 prescription medication annually
  - ~15% take ≥5 prescription medications
- Significant increase in ADEs / ADRs reported to FDA
  - Rate outpacing increase in prescription use
- Significant underreporting of ADEs / ADRs


Burden of ADEs

- Over 50% of hospitalizations due to ADEs in older adults occur in patients >80 years old
  - ~2/3 of ADE hospitalizations related to unintentional overdose
- ~530,000 Medicare beneficiaries experience preventable ADE per year
  - Cost estimated at $887 million/year for Medicare
- Total costs ~$200 Billion/year


Budnitz et al. JAMA. 2006;296:1858-66.

Rates of Emergency Hospitalization for ADE in Older Adults in US

National Action Plan for ADE Prevention

1. Identify common, preventable, and measurable ADEs that may result in significant patient harm

2. Align efforts of Federal health agencies to reduce patients harms from these ADEs nationally

The Pharmacists Role

- “Despite the high morbidity and mortality, physicians often do not recognize or appropriately treat instances of drug-related harm”
- 35% of people taking prescription medications have not had medications reviewed for possible discontinuation

Pharmacist Accessibility

- Approximately 260,000 pharmacists in the US
- Between 59,000 and 67,000 community pharmacies in the US
- **13 billion** visits to a pharmacy per year
  - 275 million patient visits to a pharmacy each week
    - 4,000 patient visits a week per pharmacy
  - 92% of people live within 1.6 miles of a pharmacy
Each visit to a pharmacy represents a possible encounter!!

Does your pharmacy practice site have a method for ADE reporting?

A. Yes
B. No
C. Unsure

How often do you ask patients if they are having a specific adverse effect from a medication?

A. 0-25% of the time
B. 26-50% of the time
C. 51-75% of the time
D. 76-100% of the time

Community-based ADE Screening

Does your pharmacy practice site have a method for ADE reporting?

A. Yes
B. No
C. Unsure

How often do you ask patients if they are having a specific adverse effect from a medication?

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Community-based ADE Screening

• Brief checklists used to identify ADEs in community pharmacy settings
  – 5 questions; completed for 51 drug classes
  – 2,057 ADE/ADR checklists completed
  – Approximately 49% of patients reported an ADE / ADR to a top 200 medication
  • ~35% of ADEs confirmed by pharmacists as related to drug therapy

Community-based ADE Screening

“Developing short checklists based on common ADEs/ADRs that patients might experience may allow busy community pharmacists to identify whether an ADE/ADR is occurring and determine the causative agent, as well as assist other health care providers in optimizing medication therapy for patients.”
Methods of Surveillance

- Spontaneous reporting — “Direct Observation”
- Patient survey and questionnaires
- Electronic medical records — Chart review
- Computer-generated incidents
- ADE Monitors (“Trigger Tools”)

Causality Categorization Tools

- Jones’ algorithm
- Yale algorithm
- WHO Uppsala Monitoring Center (WHO-UMC)
- Adverse Drug Reaction Advisory Committee (ADRAC)
- Alerts Based on ADR Causality and Severity (ABACUS)
- Naranjo algorithm

### Adverse Drug Reaction Probability Scale

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Do Not Know</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are there previous conclusive reports on this reaction?</td>
<td>+1</td>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2. Did the adverse event appear after the suspected drug was administered?</td>
<td>+2</td>
<td>-1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3. Did the adverse event improve when the drug was discontinued or a specific antagonist was administered?</td>
<td>+1</td>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4. Did the adverse event disappear when the drug was readministered?</td>
<td>+2</td>
<td>-1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5. Are there alternative causes that could on their own have caused the reaction?</td>
<td>+2</td>
<td>-2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>6. Did the reaction disappear when a plausible was given?</td>
<td>-2</td>
<td>+1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>7. Was the drug detected in blood or other fluids in concentrations known to be toxic?</td>
<td>+1</td>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?</td>
<td>+1</td>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>9. Did the patient have a similar reaction to the same or similar drugs in any previous exposure?</td>
<td>+1</td>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>10. Was the adverse event confirmed by any objective evidence?</td>
<td>+1</td>
<td></td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Total Score: 12

### Naranjo Algorithm Interpretation

#### Causality

- **Certain**
  - Direct orlastname x causality: with plausible direct relationship to drug reaction
  - Cannot be explained by other drugs
  - Reaction was observed pharmacologically and pathologically

- **Probable**
  - Direct orlastname x causality: with reasonable direct relationship to drug reaction
  - Could also be explained by other drugs
  - No direct evidence of causality

- **Possible**
  - Direct orlastname x causality: without a direct relationship
  - Reaction was observed pharmacologically and pathologically

- **Unlikely**
  - Direct orlastname x causality: with a close to drug-related
  - Other drugs or other treatments

- **Conditional/Unclassifiable**
  - Direct orlastname x causality: with possible causality
  - More data for proper assessment needed

- **Unmonitored/Unclassifiable**
  - Report suggesting adverse reaction
  - Cannot be explained because of insufficient information
  - Data cannot be negated or verified

### Severity

- **Score**
  - 1: Mild
  - 2: Moderate
  - 3: Severe
  - 4: Life-threatening

#### ABACUS (Alerts Based on ADR Causality and Severity)

- **Causality**
  - No
  - Yes
  - Uncertain

- **Severity**
  - None
  - Mild
  - Moderate
  - Severe
  - Life-threatening

### WHO-UMC Causality Categories

- Available at: [https://www.who-umc.org/media/2768/standardised-case-causality-assessment.pdf](https://www.who-umc.org/media/2768/standardised-case-causality-assessment.pdf)
Tools to Identify DRPs in Outpatient Settings

- Institute for Healthcare Improvement Outpatient Trigger Tool
- START / STOPP Criteria
- Beer’s Criteria
- Tool to Improve Medication in the Elderly via Review (TIMER)
- Others?

IHI Outpatient Trigger Tool

- Developed in mid-2000s
- Several other IHI Trigger Tools
- 11 “clues” to possible adverse events
- Used to identify likely sources of adverse events upon brief chart review
- Only identifies adverse events related to commission

Hartwig ADR Severity Scale

<table>
<thead>
<tr>
<th>Level</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild (Level 1)</td>
<td>The ADR requires no change in the treatment with the suspected drug</td>
</tr>
<tr>
<td>Mild (Level 2)</td>
<td>The ADR requires that the suspected drug be withdrawn, discontinued or otherwise changed. No antibiotics or other treatment is required.</td>
</tr>
<tr>
<td>Moderate (Level 3)</td>
<td>The ADR requires that the suspected drug be withdrawn, discontinued or otherwise changed, and there is no increase in length of stay.</td>
</tr>
<tr>
<td>Moderate (Level 4)</td>
<td>Any level 3 ADR increases the length of stay by at least one day, or the ADR is the reason for admission.</td>
</tr>
<tr>
<td>Severe (Level 5)</td>
<td>Any level 4 ADR that requires intensive medical care.</td>
</tr>
<tr>
<td>Severe (Level 6)</td>
<td>The ADR causing permanent harm to the patient.</td>
</tr>
<tr>
<td>Severe (Level 7)</td>
<td>The ADR either directly or indirectly leading to the death of the patient.</td>
</tr>
</tbody>
</table>

ADR: Adverse drug reaction

QUALITY IMPROVEMENT TOOLS TO REDUCE ADVERSE DRUG EVENTS

Model for Improvement

1. What are we trying to accomplish? (AIM)

2. How will we know that a change is an improvement? (MEASURE)

3. What changes can we make that will lead to improvement? (CHANGE)


Plan

Plan: Plan the test, including a plan for collecting data.
- State the question you want to answer and make a prediction about what you think will happen.
- Develop a plan to test the change. (Who? What? Where? When?)
- Identify what data you will need to collect.
Do

- Run the test on a small scale.
- Carry out the test.
- Document problems and unexpected observations.
- Collect and begin to analyze the data.

Study

- Analyze the results and compare them to your predictions.
  - Complete, as a team, if possible, your analysis of the data.
  - Compare the data to your prediction.
  - Summarize and reflect on what you learned.

Act

- Based on what you learned from the test, make a plan for your next step.
- Adapt (make modifications and run another test), adopt (test the change on a larger scale), or abandon (don't do another test on this change idea).
- Prepare a plan for the next PDCA.

ADE Screening in Community Settings

https://pharmacy.isu.edu/ade

ADE Screening Project

- Collaboration between Qualis Health and Idaho State University College of Pharmacy
- Students **required** to complete ADE screenings when on community rotation
- Students **encouraged** to complete ADE screening when in other settings

Project Goals

- Reduce (Potential) Adverse Drug Events
- Improve Patient Engagement
- Encourage:
  - Communication between patients, pharmacists, and providers
  - Pharmacist and student pharmacist engagement with quality improvement activities to improve patient care
- Awareness:
  - Identify community best practices, innovations and strategies
  - Diffusion of innovations
Tools

- ADE Screening Instructions
- ADE Screening Algorithm
- Data collection methods
- Future trainings

Benefits of Collaboration

- Quality Improvement Expertise
- Pragmatic Student Engagement and Training
- Mutually Beneficial
  - Intersection of Research and Quality
  - Future project collaboration
Questions???