Integrating Medication Safety in Pharmacy Practice

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Objectives

Pharmacist Objectives:
• List the key elements of a medication safety program
• Describe culture of safety and why it is necessary for a successful medication safety program
• Describe the medication management process and the role of medication safety in this process
• Explain the hierarchy of effectiveness of risk-reduction strategies
• Identify opportunities for proactive medication risk assessment

Pharmacy Technician Objectives:
• Explain the impact medication errors have on patient morbidity and mortality
• List key factors for medication errors
• Describe culture of safety and the reason it is necessary for a successful medication safety program
• Describe the medication management process and be able to identify opportunities to improve medication safety in this process
• Explain the difference between Failure Mode Events Analysis and Root Cause Analysis

Medical Error – 3rd Leading Cause of Death in the US

Medication Safety

“Medicine used to be simple, ineffective, and relatively safe. Now it is complex, effective, and potentially dangerous.”
– Professor Sir Cyril Chantler

• Medication safety is defined as freedom from preventable harm with medication use.
• Medication safety issues impact health outcomes and quality of life, length of stay in a healthcare facility, hospital admissions, re-admission rates, clinic and emergency room visits, and overall costs to the healthcare system.

Adverse Drug Event

An adverse drug event (ADE) is harm associated with any dose of a drug, whether the dose is “normally used in man” or not.
• Reversible ADE = harm caused by the use of a drug in the event of an error
• Non-reversible ADE = drug-induced harm occurring with appropriate use of medication.
• Medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm.

Relationship Between Medication Errors and ADEs

Adverse Drug Events (ADEs) and Medication Errors (MEs)

1. Medication Error
2. ADE
3. Reversible ADE
4. Non-reversible ADE
5. Reversible ME
6. Non-reversible ME

Adverse Drug Event (ADE) prevention is the key to reducing the risk of medication errors.
Impact of ADEs

- In inpatient settings, ADEs:
  - Account for an estimated 1 in 3 of all hospital adverse events
  - Affect about 2 million hospital stays each year
  - Prolong hospital stays by 1.7 to 4.6 days

- In outpatient settings, ADEs account for:
  - Over 3.5 million physician office visits
  - An estimated 1 million emergency department visits
  - Approximately 125,000 hospital admissions
  - Annually in the United States, 7,000 to 9,000 people die as a result of a medication error.
  - Cost associated with medication errors annually exceeds $40 billion

ADEs Likely to Increase

- Development of new medicines
- Discovery of new uses for older medicines
- Aging American population
- Increased use of medicines for disease treatment and prevention
- Expansion of insurance coverage for prescription medicines

The People Behind the Statistics

Pharmacy Compounding Error

For ~18 months, a young child had been receiving a 3 gram (20 mL) dose of tryptophan 150 mg/mL suspension by mouth at bedtime to treat a complex sleep disorder. A refill of the tryptophan prescription was ordered and picked up from the compounding pharmacy that had prepared the suspension in the past. That night, the child was given the usual dose of medication; the next morning, the child was found deceased in bed. A post-mortem toxicology test identified lethal levels of baclofen.

Look-Alike Sound-Alike Error

An outpatient pharmacy accidentally dispensed the antipsychotic thiothixene (Navane) instead of the prescribed anti-hypertensive medication amlodipine (Norvasc) to a 71 year old patient. The patient took the wrong medication for three months, leading to physical and psychological harm including ambulatory dysfunction, tremors, mood swings, and personality changes.

Drug Interaction Error

- Becki Conway was prescribed full doses of Lamictal and Depakote for bipolar disorder
- Pharmacy was alerted of drug interaction but filled the prescriptions and didn't counsel patient
- 2 weeks later, Becki went to urgent care due to sore throat, dry cough, runny nose, and chest pain
- Transferred to ED for cardiac workup; given Benadryl for rash and discharged home
- Went to a clinic the following day and provider recognized the drug interaction and Stevens-Johnson Syndrome
Second Victims
- Healthcare professionals who experience difficulties in coping with their emotions after a patient safety incident
- Often suffer from loss of confidence, fear of litigation or reputation damage, guilt, and anger
- Worst cases progress to PTSD or suicide
- Reported incidence of professionals who have experienced a negative emotional response following an incident range from 30% to 77%

Key Elements to Integrate Medication Safety
- Promote a Culture of Safety and Just Culture
- Acquire the Traits of High Reliability Organizations
- Know the basic key strategies for medication safety
- Know high-risk medications and populations in your practice setting and mitigate the risks

Medication Safety

Promote a Culture of Safety and Just Culture
- Culture is "How we do things here."
- Safety Culture is "How can we change HOW we do things to make care safer."
- A just culture is one that has a clear and transparent process for evaluating errors and separating events arising from flawed system design or inadvertent human error from those caused by reckless behavior, defined as a behavioral choice to consciously disregard what is known to be a substantial or unjustifiable risk.

Advisory Committee on the Safety of Nuclear Installations
- Having core values and behaviors that demonstrate a collective and sustained commitment to emphasize safety over competing goals. Such cultures value openness and mutual trust, provide appropriate resources for safe staffing, learn from errors, assess for weaknesses, display transparency and are accountable. The American Nurses Association

Culture of Safety
- The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization’s health and safety management. Advisory Committee on the Safety of Nuclear Installations
- Having core values and behaviors that demonstrate a collective and sustained commitment to emphasize safety over competing goals. Such cultures value openness and mutual trust, provide appropriate resources for safe staffing, learn from errors, assess for weaknesses, display transparency and are accountable. The American Nurses Association

Communication
- Foster a culture of open and respectful communication
  - Lead by example
  - Establish a code of conduct that specifies unacceptable behaviors and enforce it
  - Reward outstanding examples of collaborative teamwork, respectful communication, and positive interpersonal skills
  - Respectfully listen to staff and patients
  - Mindfulness throughout an organization considers, but moves beyond, events and occurrences.
  - If most of your interactions are related to negative situations, then there is room for improvement

Just Culture
- A just culture is one that has a clear and transparent process for evaluating errors and separating events arising from flawed system design or inadvertent human error from those caused by reckless behavior, defined as a behavioral choice to consciously disregard what is known to be a substantial or unjustifiable risk.

ASHP Policy 1021 Just Culture and Reporting Medication Errors
Just Culture

- Emphasizes learning rather than blame
- Learning from errors provides us with the opportunity to improve our systems, processes, and behavior
- Team members openly discuss and report events, process improvements or system issues without fear of reprisal
- Individuals are treated fairly
- Feedback and coaching of individuals is constructive
- Team members are held accountable for their performance in accordance with job responsibilities and organizational values

Just Culture

- Does not focus on the severity of the outcome
- Is not "blame-free" which means no one is accountable
- Does not tolerate conscious disregard of clear risks to patients
- Does not tolerate gross misconduct

Outcome Based Response

Do not respond to a situation based on the outcome.

Culture Killing Phrases

- "Who would do that..."
- "They should have known...."
- "Most people would have..."
- "Why would they think..."
- "No one else would..."
- Add your own....

Key Features of a Culture of Safety

- Blameless and voluntary reporting
- Perform detailed analysis of accidents and near misses
- Open communication and disclosure regarding safety and accidents
- Story telling, especially about ADEs
- Proactively prevent harm from occurring
- Top-down commitment to safety with accountability not simply limited to front-line providers
- Trust exists throughout the organization
- Focus on continuous improvements and system design

High Reliability Organizations

- Organizations that operate in complex, high-hazard domains for extended periods without serious accidents or catastrophic failures. The concept of high reliability is attractive for health care, due to the complexity of operations and the risk of significant and even potentially catastrophic consequences when failures occur in health care.
- Foster an environment of collective mindfulness – all workers look for and report small problems or unsafe conditions before they pose a substantial risk to the organization.
Traits of High Reliability Organizations

- Preoccupation with failure
- Reluctance to simplify
- Sensitivity to operations
- Deference to expertise
- Resilience

Preoccupation with Failure

- Everyone is aware of and thinking about the potential for failure
- Understand new threats emerge regularly from situations that no one imagined could occur, so all personnel actively think about what could go wrong and are alert to small signs of potential problems

- What does this look like?
  - Constantly share and de-stigmatize failure
  - Support innovation and new ideas
  - Identify what is working correctly – if a process fails, look at areas it is successful
  - Don’t quit after a few months – lead employees to see it is attainable

Reluctance to Simplify

- Resist simplifying their understanding of work processes and how and why things succeed or fail in their environment
- Seek underlying rather than surface explanations

- What does this look like?
  - Examine data/metrics
  - Willingness to challenge long-held beliefs
  - Ask questions and don’t stop at the surface

Sensitivity to Operations

- Constant awareness of how processes and systems affect the organization; what is and isn’t working

- What does this look like?
  - Transparency through improved communication and data sharing
  - Leadership involvement and rounding
  - Don’t assume

Deference to Expertise

- Listen to people who have the most developed knowledge of the task at hand, regardless of hierarchy or seniority

- What does this look like?
  - Do not say “I already know that.”
  - Redefine meetings – place and time
  - All staff are comfortable speaking up about potential safety problems

Resilience

- Assume the system is at risk for failure, and practice performing rapid assessments of and responses to challenging situations

- What does this look like?
  - Teams cultivate situation assessment and cross monitoring
  - Emphasize skill development
Key Strategies for Medication Safety

Medication Use Process

• Any step in the medication process from ordering the medication to monitoring after administration
  • Ordering/Prescribing
  • Transcribing
  • Dispensing
  • Administering
  • Monitoring

• Most medication errors occur during ordering/prescribing in both the inpatient and outpatient setting

Medication Safety Resources

Medication Safety Resources

• Summary of error rates:
  • Medication Use Process:
    • • Ordering/Prescribing
    • • Transcribing
    • • Dispensing
    • • Administering
    • • Monitoring

• Most medication errors occur during ordering/prescribing in both the inpatient and outpatient setting

Proactive Assessment: Failure Mode Effects Analysis (FMEA)

• Proactive analysis technique used to prevent problems before they occur
  • Designed to analyze potential failures of systems, subsystems of the system and the effects of the failures
  • The focus is what could go wrong versus what did go wrong

• Steps:
  • Identify high risk process and assemble team
  • Diagram the process in high-level steps
  • Brainstorm potential failures and what the effects may be
  • Prioritize failures in terms of criticality
  • Identify root causes of the failures
  • Redesign the process
  • Analyze and test the new process
  • Implement and monitor the redesigned process

Optimize Efficiency

• Maximize access to information
• Standardize
• Simplify
• Centralize error-prone processes
Safe Limits and Constraints
- Error-proof design
- Limit access or use
- Constraints and barriers

Reasonable Response
- Preparation to respond to errors
  - Immediate response
  - Event investigation and review

High-Risk medications and Patient Populations
- High-risk medications: Antidiabetic agents, oral anticoagulants, antiplatelet agents, and opioid pain medications account for more than 50% of ED visits for ADEs in Medicare patients.
- Polypharmacy—taking 5 or more medications—is one of the strongest risk factors for ADEs.
- Transitions of care—patients recently discharged from an acute care setting.
- Limited health literacy
- Cognitive conditions, such as memory problems
- Multiple providers prescribing medications

Populations at Higher Risk for ADEs
- Children (less than 18 yo)
  - 5% to 27% of all pediatric medication orders result in a medication error.
- Elderly (greater than 65 yo)
  - This group comprises only 12% of the US population, yet it accounts for ~30% of prescription drugs consumed in the US.
  - Estimates as high as 40% of medication orders for patients greater than 65 yo result in an error.

Look-Alike Sound-Alike Medications
High-Risk Medications
- High-risk (high-alert) medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these medications, the consequences of an error are clearly more devastating to patients.
- Mnemonic “A-PINCH”

Adverse Drug Events from Opioid Analgesics
- In 2013, the rate of opioid-related deaths involving opioid analgesics remained higher than the rate of deaths involving heroin, but the rate of deaths involving heroin had almost tripled from 2010.
- Goal: Identify ways to eliminate unnecessary prescribing of opioid analgesics without reducing the quality of care for patients who legitimately need pain management.

Adverse Drug Events from Insulin
- From 2007 to 2011, there were ~100,000 ED visits/year in the US for insulin-related hypoglycemia or insulin-related errors. Of these:
  - Nearly two-thirds of patients had symptoms of severe hypoglycemia, such as shock, seizures, or loss of consciousness.
  - About one-third of the emergency department visits resulted in hospitalization.
  - Older adults are most vulnerable to insulin-related hypoglycemia leading to emergency room visits and emergent hospitalizations.
- 1 in 5 insulin-treated patients 60 years or older visited the ED for insulin-related hypoglycemia over a 4-year period. Compared to the general population, older patients 60 years or older were 2.5 times more likely to have a hypoglycemic event or an error when taking insulin.
- Five times more likely to be hospitalized
- Meal-related mishaps and taking the wrong insulin product were the most common reasons for emergency room visits from insulin-related hypoglycemia or errors.

Adverse Drug Events from Anticoagulants
- Among older adults, oral anticoagulants are the most common causes of adverse drug events (ADEs) leading to emergency room visits and emergent hospitalizations.
- From 2013–2014, warfarin was the most frequently prescribed anticoagulant.
- Among the top 10 most common causes of ADEs resulting in emergency department visits among older adults:
  - Warfarin accounted for 32% of emergency room visits for all ADEs among older adults (≥65 years of age) and 36% of estimated emergent hospitalizations for all ADEs among older adults.
  - DOACs contributed to ~40% of oral anticoagulant bleeding visits.

Adverse Drug Events from Antibiotics
- Annually in 2013 and 2014, in the US, there were ~200,000 ED visits for adverse events related to antibiotics.
- Antibiotics are responsible for ~16% of ED visits for ADEs each year.
- Antibiotics are involved in more ED visits for ADEs than any other class of drugs in patients under 50 years old.
- In children less than or equal to 5 years old, antibiotics cause ~56% of ED visits for ADEs.
- ~82% of ED visits for ADEs from antibiotics are due to allergic reactions.

Prioritization: Ask Questions
- What are the most severe accidents that could happen?
  - High-risk medications
  - High-risk populations
  - Complex processes that are not utilized often
  - Emergency situations
  - Look-alike, sound-alike medications
- What do we do to prevent the worst accidents?
  - What are the existing safeguards in terms of technology, organizational systems, and staff?
  - Do these known risk management strategies reduce the risk of accidents?
  - Are there any lessons learned from other healthcare domains?
- What other systems or processes may be impacted by the accident?
  - Do those involved recognize potential dangers and do they have contingency plans?
  - What are the vulnerabilities in the system where the accident occurred?
- What can we do to improve?
Conclusion

• A safety culture is the foundation for medication safety
  • Focus on "how" rather than "who"
  • Build trust through consistency and avoiding responses based on outcomes
  • Avoid "killer phrases"

• Proactively assess
  • ISMP: Self Assessments and Quarterly Action Agendas
  • FMEA
  • Routinely review information from patient safety and medication safety organizations

• Join listserves applicable to your area of practice

• Understand the medication use process and think about the whole process when evaluating systems

• Apply safety strategies in system design

• Know high-risk populations and work to mitigate risk in these groups through better system design

• Know high-risk medications or situations and work to mitigate the risks

Questions?