

Integrating Medication Safety in Pharmacy Practice

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Objectives

- Pharmacist Objectives:
 - List the keys 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 risk 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

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

Cause of Death	Number of Deaths
Heart disease	614,348
Cancer	591,699
Medical Error	251,454
Respiratory disease	147,101
Accidents	136,053
Stroke	133,103
Alzheimer's Disease	93,541
Diabetes	76,488
Influenza & Pneumonia	55,227
Kidney disease	48,146
Suicide	42,773

Medical errors are the 3rd leading cause of death in the United States.

Source: CDC, National Center for Health Statistics. Number of deaths for leading causes of death, 2014.

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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 facilities, hospital admissions, readmission rates, clinic and emergency room visits, and overall costs to the healthcare system.

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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.
 - Preventable ADE = harm caused by the use of a drug as the result of an error
 - Non-Preventable 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.

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Relationship Between Medication Errors and ADEs

Adapted from Figure 1 in Qual Saf Health Care 2004;13:306-314. doi: 10.1136/qshc.2004.010611

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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

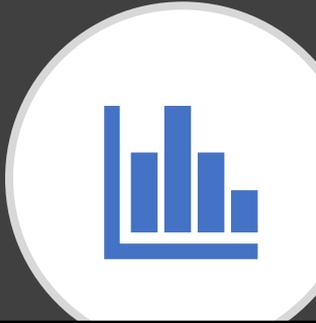
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ADEs Likely to Increase

- 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

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The People Behind the Statistics



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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.

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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.

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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.
- WARNING: SERIOUS SKIN RASHES**
See full prescribing information for complete clinical warnings.
Cases of life-threatening serious rashes, including fatal toxic epidermal necrolysis, have been reported with Lamictal. The rate of serious rashes is greater in patients with certain risk factors. Additional factors that may increase the risk of rash include (1):

 - concomitant use with valproate
 - starting the recommended initial dose of LAMICTAL
 - starting recommended dose escalation of LAMICTAL

Serious rashes are also caused by LAMICTAL; however, it is not possible to predict which patients will prove to be serious or life-threatening. LAMICTAL should be discontinued at the first sign of rash, unless the rash is clearly and drug-related. (S.1)
- 2 weeks later Becki went to urgent care due to sore throat, dry cough, irritated sinuses 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.



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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%

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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

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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*

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Culture of Safety

- Culture is "How we do things here."
- Safety Culture is "How can we change HOW we do things to make care safer?"

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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

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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

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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

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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

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Outcome Based Response

Do not respond to a situation based on the outcome.

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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....

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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

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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.

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Traits of High Reliability Organizations

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

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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

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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

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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

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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

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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

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Key Strategies for Medication Safety

Key strategies	Description
Failure mode effects analysis (FMEA) and self-assessments	Proactively identify risks and how they can be minimized
Workload design (Assigning functions and fail-safes)	Build in safeguards to prevent or respond to failure
Limit access or use	Use constraints (e.g. restriction of access or requirement for special conditions or authorization)
Maximize access to information	Use active means to provide necessary information when critical tasks are being performed
Constraints and barriers	Use special equipment or work environment conditions to prevent hazards from reaching patient
Standardize	Create clinically sound, uniform models of care or products to reduce variation and complexity
Simplify	Reduce number of steps in the process of handoffs (handovers) without eliminating crucial redundancies
Centralize error-prone processes	Transfer to external site to reduce distraction of staff with expertise, with appropriate quality control checks
Preparation to respond to errors	Have antidotes, reversal agents or remedial measures readily available and ensure staff are appropriately trained to manage an identified error

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Medication Use Process

- Any step in the medication process from ordering the medication to monitoring after administration
 - Ordering/Prescribing
 - Documenting
 - Transcribing
 - Dispensing
 - Administering
 - Monitoring
- Most medication errors occur during ordering/prescribing in both the inpatient and outpatient setting

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Medication Safety Resources

- Primary literature
 - Institute for Safe Medication Practices (ISMP)
 - <https://www.ismp.org/>
 - Purdue University has a medication safety program as well as a list of medication safety organizations with links
 - <https://medsafety.pharmacy.purdue.edu/medication-safety.html>
 - Pennsylvania Patient Safety Authority
 - <http://patientsafety.pa.gov/>
 - World Health Organization
 - The third WHO Global Patient Safety Challenge: Medication Without Harm
 - <https://www.who.int/patientsafety/medication-safety/en/>
 - Centers for Disease Control Medication Safety Program
 - <https://www.cdc.gov/medicationsafety/index.html>
 - forIOU at the University of Missouri is a great resource with information on **Secret Vectors**
 - <https://www.mhhealth.org/about-us/quality-care-patient-safety/office-of-clinical-effectiveness/foyou>

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Proactive Assessment: Failure Mode Effects Analysis (FMEA)

- Proactive analysis technique used to prevent problems before they occur
- Designed to analyze potential failures of systems, components 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

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Example: Failure Modes and Effects Analysis (FMEA) – Medication Dispensing Process

Steps in the Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1-10)	Severity (1-10)	Detectability (1-10)	Risk Profile (RPN)	Actions to Minimize or Eliminate Failure
Orders are written for their medications	This list does not be given per the physician's order of the patient.	Medication ordered may be available and ready to dispense in the pharmacy.	Patients may receive incorrect medication, incorrect dose of a dose or incorrect route.	8	8	1	64	Implement procedures to verify care plan to that of medication order and the patient as they occur.
Orders are written to discontinue or change the existing order	Orders are written to discontinue or change the existing order.	All doses remain for a 24-hour period and are not changed until the next order is received.	Patients may receive medications that have been discontinued or the concentration of a medication that has been changed.	10	8	5	400	Standardize with each of discontinued medications, including the concentration and volume, before per use. Use dispensing machine which has built-in information regarding current and discontinued medications prior to each administration.

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Optimize Efficiency

- Maximize access to information
- Standardize
- Simplify
- Centralize error-prone processes

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Safe Limits and Constraints

- Error-proof design
- Limit access or use
- Constraints and barriers

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Reasonable Response

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

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High-Risk medications and Patient Populations

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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

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Risk Factors for ADEs

- 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

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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"

High-risk medication group	Examples of medications
A. Anticoagulants	Antiplatelets Anticoagulants
P. Potassium and other electrolytes	Electrolytes of potassium, magnesium, calcium, phosphate, sodium chloride
I. Insulin	All insulins
N. Narcotics (opioids) and other analgesics	High-potency oral, injectable, rectal, and intrathecal opioids Parenteral "ultra-r" controlled and analgesic analgesics Benzocaine, for example, lidocaine, chlorbutol, propofol, propofol and other short-acting anesthetics
C. Chemotherapeutic agents	Chemotherapy Antibiotics Antifungals Antivirals
H. Insulin and anti-infectives	Insulin Erythropoietin, valganciclovir, acyclovir
Other	High-risk medicines identified at local health authority/healthcare level which do not fit the above categories

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Adverse Drug Events from Opioid Analgesics

- In 2013, the rate of overdose 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.
- In 2015, more than 15,000 people died from overdoses involving prescription opioids.
- Goal: Identify ways to eliminate unnecessary prescribing of opioid analgesics without reducing the quality of care for patients who legitimately need pain management.

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Adverse Drug Events from Insulin

- From 2007 to 2011, there were ~100,000 ED visits year in the US for insulin-related hypoglycemia or errors when taking insulin. Of these:
 - Nearly two-thirds of patients had symptoms of severe hypoglycemia, such as shock, seizures, or loss of consciousness.
 - Almost one-third of the emergency department visits resulted in hospitalization.
- Older adults are most vulnerable to insulin-related hypoglycemia leading to emergency room visits.
 - 1 in 8 insulin-treated patients 80 years or older visited the ED for hypoglycemia or errors. Compared to insulin-treated patients 45 to 64 years old, those 80 years or older were:
 - Twice as likely to visit the ED for insulin-related hypoglycemia 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.

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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 responsible for:
 - Warfarin accounted for 32% of emergency room visits for all ADEs among older adults (≥65 years of age), and 36% of emergent hospitalizations for all ADEs among older adults
 - Warfarin, rivaroxaban, and dabigatran were among the top 10 most common causes of ADEs resulting in emergency department visits among older adults
- In 2017:
 - Bleeding from oral anticoagulants resulted in approximately 235,000 emergency department visits
 - Older adults (≥65 years of age) were involved in ~ 80% of DOAC-related bleeding visits and 77% of warfarin-related bleeding visits
 - DOACs contributed to ~40% of oral anticoagulant bleeding visits

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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

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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 remaining vulnerabilities in terms of technology, organization/systems and staff?
 - Do these become more dangerous in certain circumstances?
 - Training of staff – tiers
 - What other systems or processes may be impacted by this?
- Is this a process that can be maintained?
 - Do those involved recognize potential dangers and do they have contingency plans?
- Transitions of care and hand-off between the HC team are vulnerable areas for accidents to occur. What can we do to improve this?

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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 list serves 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?

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