Medication Safety

AHMED ABDELMAGEED, PHARMD

Objectives

- At the conclusion of today's talk you should be able to:
  - Discuss the risks associated with the medication use system
  - Describe the FDA's role in patient safety
  - Describe AHRQ and its role in patient safety
  - Describe ISMP's role in patient safety
  - Describe JCAHO role in patient safety

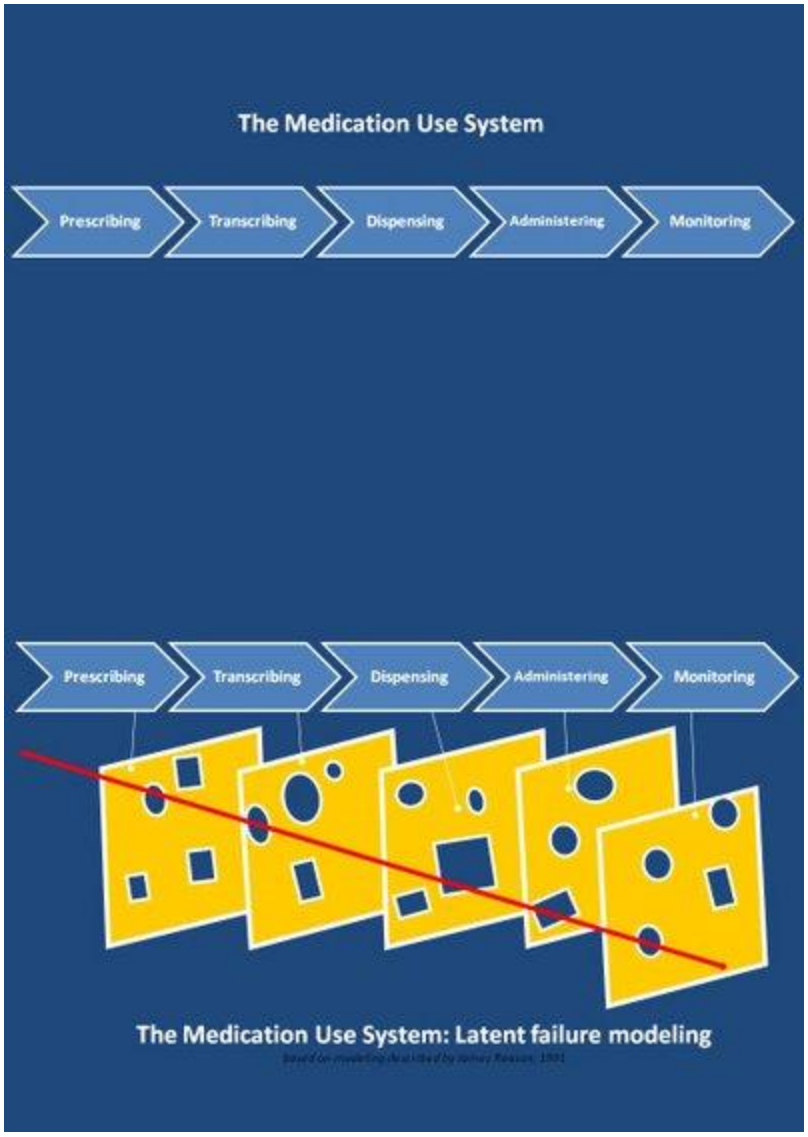
Dead By Mistake

- http://www.youtube.com/watch?v=6q38tAkmJs8&feature=related

Let's Do The Numbers

- It is a virtual certainty that patients admitted to the hospital will receive multiple medications and each administration occurrence carries with it the risk of error or misadventure.
- 300 patients per day
- Over the course of a one year = 109,500 patient days
- Each patient received 10 medications twice a day
- The opportunity for drug error would occur 2,190,000 times.
- Finally, assume that this hospital has a true 99.9% medication accuracy rate
- Yearly medication errors would be 2,190
- Study of 36 medical facilities, the true error rate was determined to be 14.6%
  - 319,740 medication errors

The Medication Use System



Orders are written by the prescriber

Orders are taken off the chart by a unit clerk and placed in a receptacle for delivery to pharmacy

Transportation or pharmacy picks up the order and brings to pharmacy

Orders are first reviewed by a pharmacy technician who triages the priority of the order

Order is placed into the pharmacy computer usually by a technician

Order is reviewed by a pharmacist

Order is approved and label is generated

Order is prepared and made ready for delivery back to the nursing unit

Order is transported by pharmacy or retrieved by nursing

Order is placed into patient unit dose bin or brought to the patient's room for administration

Order is checked against the original order

Medication is brought to the patient and patient identification is verified

Patient is administered the medication

Documentation of administration is made by nurse

Who is Responsible?

- Federal agencies, such as FDA, the Drug Enforcement Agency (DEA), the Agency for Health Care Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), and others
- Drug developers, manufacturers, and distributors
- Pharmacies, hospitals, and other healthcare entities (including those operated by the Federal government and the states)
- Healthcare professionals, including physicians and physician assistants, dentists, pharmacists, nurses, and their professional societies
- State regulatory bodies, including professional licensure and oversight boards
- Healthcare insurers
- Patients, caregivers, consumers, and organizations representing their interests

Food and Drug Administration

- The Food and Drug Administration (FDA) is the oldest comprehensive consumer protection agency in the U. S. federal government
  - FDA's modern regulatory functions began with the passage of the 1906 Pure Food and Drugs Act
- FDA is the federal agency responsible for ensuring that
  - Foods are safe, wholesome and sanitary;
  - Human and veterinary drugs, biological products, and medical devices are safe and effective;
  - Cosmetics are safe;
  - and electronic products that emit radiation are safe.
- FDA also ensures that these products are honestly, accurately and informatively represented to the public
- The FDA is also responsible for advancing the public health

FDA (Cont'd)

- As many as 3 billion prescriptions are written annually
- Too many people, however, suffer unnecessary injuries, even death, as a result of preventable medication errors or misuse
  - More needs to be done to protect the public from preventable harm from medication use
- *Improper medication use increases the risk of harm from medication, often resulting in hundreds of thousands of injuries or deaths each year. Many of these injuries and adverse events could have been prevented with currently available knowledge*
  - 1.5 million preventable adverse drug events occur within the healthcare system each year.
    - The costs of these preventable adverse drug events has been estimated to exceed $4 billion annually.
  - One study found that more than 9,000 children were accidentally exposed to prescription opioid drugs between 2003 and 2006.
    - It is estimated that 60,000 emergency department visits occur each year as a result of unsupervised ingestion of medications by children under 12 years of age.

Safe Use Initiative

Through this initiative, FDA seeks to partner and collaborate with relevant stakeholders to measurably reduce preventable harm from medications, thereby improving patient health. FDA proposes to identify, using a transparent and collaborative process, specific candidate cases (e.g., drugs, drug classes, and/or therapeutic situations) that are associated with significant amounts of preventable harm. Cases will be carefully analyzed for their potential for coordinated FDA/stakeholder actions to better manage related risks and reduce harm

U.S. Department of Health and Human Services
Food and Drug Administration
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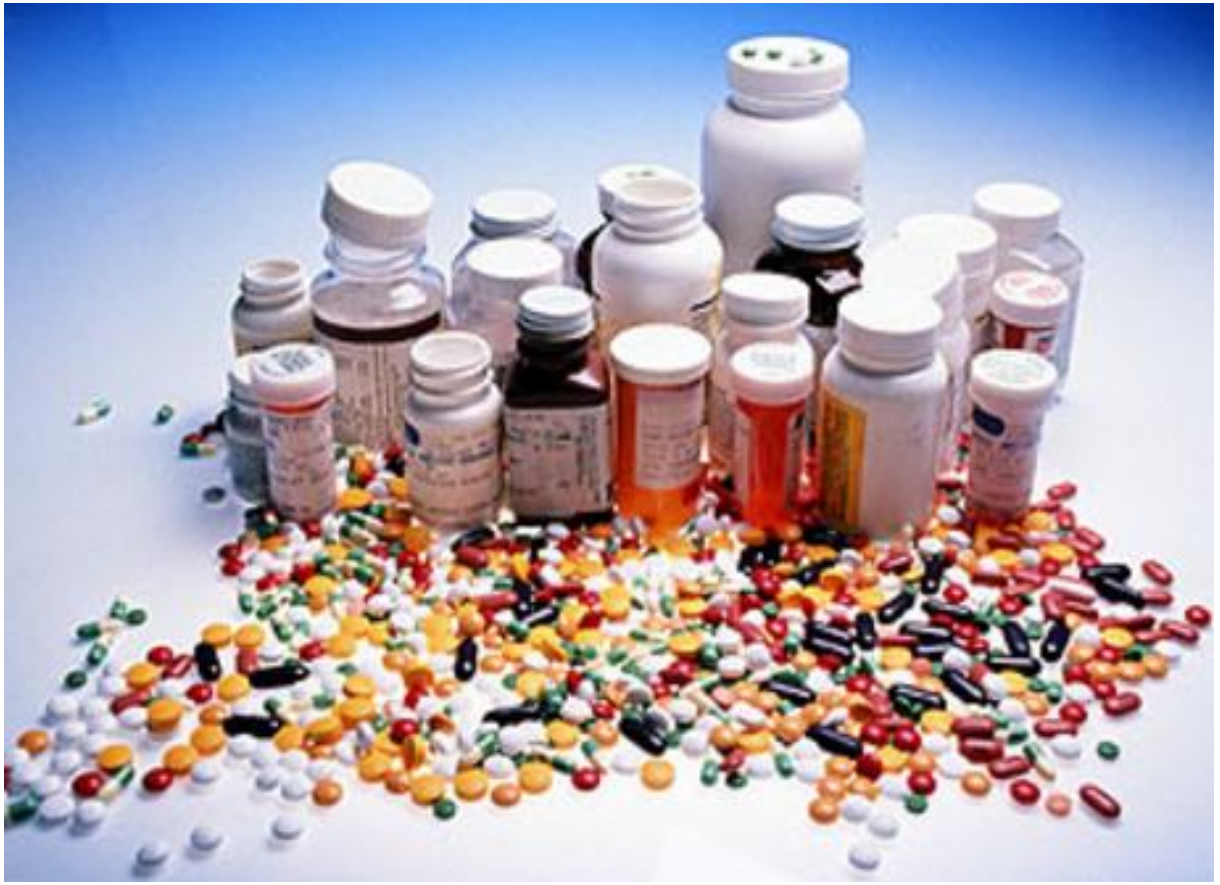
All medications have inherent risks

Some of the risks are unavoidable

while others can be avoided and managed



Unavoidable Risks

- Unavoidable medication risks result from gaps in current knowledge. There are also unavoidable risks from known side effects of medication. These risks are present even when all parts of the medication use process are optimally executed

- Sources
  - Gaps in current knowledge –
    - Risks from taking a medication that are not known to the medical scientific community
  - Unpreventable known side effects –
    - Risks from taking a medication that cannot be avoided, even when all parts of the medication use process are executed optimally.

Manageable Risks

- Manageable medication risks come from four broad sources
  - Medication errors
  - Unintended or accidental exposure
  - Intentional misuse, abuse and self-harm
  - Manageable, but small, risks from drug quality defects

- Medication Error – A mistake that occurs anywhere in the medication use process. Broad categories of medication errors include:
  - Informational errors in prescribing
  - Informational errors by patients and consumers
  - Procedure and process errors – mistake or mix-up during processes associated with use

Manageable Risks (Cont'd)

- Unintended, or accidental, exposures –
  - These occur when an individual, often a child, is exposed to a medication accidentally
- Intentional misuse, abuse, and self-harm –
  - Using a medication in a non-medical context introduces a variety of potential risks and can result in significant harm
- Drug Quality Defect –
  - Risks introduced by drug quality problems. These risks are very small

Risk Management

- Historically, FDA regulation has focused on maintaining drug quality; premarket evaluation of drug safety and effectiveness; appropriate drug labeling; drug advertising and promotion; and post-market surveillance for unexpected side effects.
- In 1999, FDA published regulations for a new standardized format for OTC drug labels, intended to relay the most important use information in an organized fashion
- In 2006, FDA issued a regulation that revised the content and format of prescription drug package inserts. The goal was to better manage the risks of medication use, reduce errors, and prevent side effects
- FDA has already launched several medication risk reduction projects that could benefit from collaboration with relevant stakeholders.
  - *Refer to Safe Use Initiative*

Health and Human Services

- The Department of Health and Human Services (HHS) is the United States government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves

- HHS' Medicare program is the nation's largest health insurer, handling more than 1 billion claims per year.
  - Medicare and Medicaid together provide health care insurance for one in four Americans

- HHS works closely with state and local governments, and many HHS-funded services are provided at the local level by state or county agencies, or through private sector grantees

- Also included in the Department is the Office of Public Health and Science, the Office of the HHS Inspector General and the HHS Office for Civil Rights.

Agency for Healthcare Research and Quality

- The Agency for Healthcare Research and Quality (AHRQ) is the lead Federal agency charged with improving the quality, safety, efficiency, and effectiveness of health care for all Americans
  - Oversees the operations of the Patient Safety Task Force
- Overall focus is:
  - Safety and quality
  - Effectiveness
  - Efficiency
- AHRQ supports health services research that will improve the quality of health care and promote evidence-based decision making
  - Provides enhanced quality assessment tools that can be used to highlight potential quality concerns and track changes over time
- AHRQ is committed to improving care safety and quality by developing successful partnerships and generating the knowledge and tools required for long-term improvement

AHRQ (Cont'd)

- AHRQ identifies strategies to improve health care access, foster appropriate use, and reduce unnecessary expenditures by:
  - Supporting research on ways to reduce health care disparities
  - Conducting an ongoing nationwide survey of about 15,000 households each year
  - Working in partnership to build a multi-State health data system
  - Providing financial support and technical assistance to researchers
- AHRQ supports improvements in health outcomes by:
  - Supporting researchers and research networks
  - Supporting projects that test and evaluate successful methods that translate research into practice
  - Supporting Evidence-based Practice Centers that review and synthesize scientific evidence
  - Translating the recommendations of the U.S. Preventive Services Task Force into resources for providers, patients, and health care systems
  - Supporting more than 90 projects in a multi-year effort to improve patient safety

AHRQ-PSNET

- **AHRQ Patient Safety Network (PSNet)** is a national web-based resource featuring the latest news and essential resources on patient safety
- The site offers weekly updates of patient safety literature, news, tools, and meetings ("What's New"), and a vast set of carefully annotated links to important research and other information on patient safety ("The Collection")
- AHRQ PSNet provides powerful searching and browsing capability, as well as the ability for diverse users to customize the site around their interests (My PSNet)
- It also is tightly coupled with AHRQ WebM&M, the popular monthly journal that features user-submitted cases of medical errors, expert commentaries, and perspectives on patient safety.

ISMP

- Institute for Safe Medication Practices (ISMP)
  - The nation's only nonprofit, independent, watchdog organization
  - Receives no advertising revenue and depends entirely on charitable donations, educational grants, newsletter subscriptions, and volunteer efforts to pursue its lifesaving work
- Devoted entirely to medication error prevention and safe medication use
  - Began in 1975 with a groundbreaking and continuing column in *Hospital Pharmacy* that increases understanding and educates healthcare professionals and others about medication error prevention
- Five key areas: knowledge, analysis, education, cooperation, and communication
- Each year, ISMP's national Medication Errors Reporting Program (MERP), receives hundreds of error reports from healthcare professionals

ISMP

- Other initiatives include
  - Publishing four "ISMP Medication Safety Alert!®" newsletters that reach nearly a million total readers
  - **List of high alert medications**
  - **Do not use list of abbreviations**
  - **Do not use list of abbreviations**

Ten Key Elements of Medication Use Systems

- **Patient information:**
  - Having essential patient information at the time of medication prescribing, dispensing and administration will result in a significant decrease in preventable adverse drug events (ADEs)
- **Drug information:**
  - Providing accurate and usable drug information to all healthcare practitioners involved in the medication-use process reduces the amount of preventable ADEs
- **Communication of drug information:**
  - To minimize the amount of medication errors caused by miscommunication it is always important to verify drug information and eliminate communication barriers.

Key Elements (Cont'd)

- **Drug labeling, packaging and nomenclature:**
  - The incidence of medication errors is reduced with the use of proper labeling and the use of unit dose systems within hospitals.
- **Drug storage, stock, standardization, and distribution:**
  - Standardizing drug administration times, drug concentrations, and limiting the dose concentration of drugs available in patient care areas will reduce the risk of medication errors or minimize their consequences should an error occur
- **Drug device acquisition, use and monitoring:**
  - A system of independent double-checks should be used within the institution to prevent device related errors such as, selecting the wrong drug or drug concentration, setting the rate improperly, or mixing the infusion line up with another.

Key Elements (Cont'd)

- **Environmental factors:**
  - Environmental factors that often contribute to medications errors include poor lighting, noise, interruptions and a significant workload.
- **Staff competency and education:**
  - Staff education can be an important error preventions strategy when combined with the other key elements for medication safety.
- **Patient education:**
  - Patients can play a vital role in preventing medication errors when they have been encouraged to ask questions and seek answers about their medications before drugs are dispensed at a pharmacy or administered in a hospital
- **Quality processes and risk management:**
  - Effective strategies for reducing errors include making it difficult for staff to make an error and promoting the detection and correction of errors before they reach a patient and cause harm.

JCAHO

- The Joint Commission is an independent, not-for-profit organization, that accredits and certifies more than 18,000 health care organizations and programs in the United States.

- Joint Commission accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards

- ***Mission:***
  - To continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.

- ***Vision Statement:***
  - All people always experience the safest, highest quality, best-value health care across all settings.

JCAHO

- The Joint Commission provides accreditation services for the following types of organizations:
  - General, psychiatric, children's and rehabilitation hospitals
  - Critical access hospitals
  - Home care organizations, including medical equipment services, hospice services
  - Nursing homes and other long term care facilities
  - Behavioral health care organizations, addiction services
  - Ambulatory care providers, including group practices, office-based surgery practices
  - Independent or freestanding clinical laboratories

- Benefits of Joint Commission accreditation and certification
  - Strengthens community confidence in the quality and safety of care, treatment and services
  - Provides a competitive edge in the marketplace
  - Improves risk management and risk reduction
  - Provides education on good practices to improve business operations
  - Provides professional advice and counsel, enhancing staff education
  - Enhances staff recruitment and development
  - Recognized by insurers and other third parties
  - May fulfill regulatory requirements in select states

JCAHO

- Standards and performance measurement
  - The Joint Commission develops its standards in consultation with health care experts, providers, measurement experts, purchasers, and consumers.
  - Joint Commission standards address the organization's level of performance in key functional areas, such as patient rights, patient treatment, medication safety and infection control.
  - The standards focus on setting expectations for an organization's actual performance and for assessing its ability to provide safe, high quality care.
  - Standards set forth performance expectations for activities that affect the safety and quality of patient care. If an organization does the right things and does them well, there is a strong likelihood that its patients will experience good outcomes

- The Joint Commission's Quality Check® Web site is a comprehensive guide to health care organizations in the United States. Joint Commission accredited and certified organizations are easily identified by The Joint Commission's Gold Seal of Approval™.

NPSG

- National Patient Safety Goals program established in 2002 and the first set of NPSGs was effective January 1, 2003
- The NPSGs were established to help accredited organizations address specific areas of concern in regards to patient safety
- The development and annual updating of the NPSGs is overseen by an expert panel of widely recognized patient safety experts, as well as nurses, physicians, pharmacists, risk managers, and other professionals who have hands-on experience in addressing patient safety issues in a wide variety of health care settings
- Each year, the Patient Safety Advisory Group works with Joint Commission staff to undertake a systematic review of the literature and available databases to identify potential new NPSGs
- The Patient Safety Advisory Group is charged with reviewing draft patient safety suggested actions for potential publication in The Joint Commission's *Sentinel Event Alert* patient safety advisory.

Conclusions

- It is a virtual certainty that patients admitted to the hospital will receive multiple medications and each administration occurrence carries with it the risk of error or misadventure
- Everyone, from patient to federal agencies, is responsible for patient safety
- FDA seeks to partner and collaborate with relevant stakeholders to measurably reduce preventable harm from medications
- AHRQ is the lead Federal agency charged with improving the quality, safety, efficiency, and effectiveness of health care for all Americans
- ISMP is devoted entirely to medication error prevention and safe medication use
- Joint Commission accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards
- The NPSGs were established to help accredited organizations address specific areas of concern in regards to patient safety

References

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