



Medication Use Process: A System's Approach to Improve Patient Safety

U.S. Army

Manager, Army Patient Safety Program

U.S. Army Medical Command

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CPE Information and Disclosures

- Dr. Jorge D. Carrillo declares no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

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Learning Objectives

- Outline the history of the Patient Safety Program
- Describe the medication use process as a system
- List risk points in the medication use process
- Identify mitigating strategies to prevent medication errors





Self-Assessment Questions

1. True or False. Patient Safety only addresses medication-related adverse events.
2. Since the release of the Institute of Medicine (IOM) Report “To Err is Human”, the rate of harmful adverse events in the U.S. has:
 - a) Dramatically decreased
 - b) Dramatically increased
 - c) Remained the same
 - d) I do not know





Self-Assessment Questions

3. Which of the following is (are) risk points in the Planning phase of the Medication Use Process?
 - a) Patient-specific information
 - b) High alert medications
 - c) Look-alike/Sound-alike medications
 - d) All of the above

4. Which of the following is (are) best practice recommendations to mitigate nursing medication errors?
 - a) Protocol checklists
 - b) Do Not Disturb signs
 - c) Cover windows of the medication room
 - d) All of the above





What is Patient Safety?

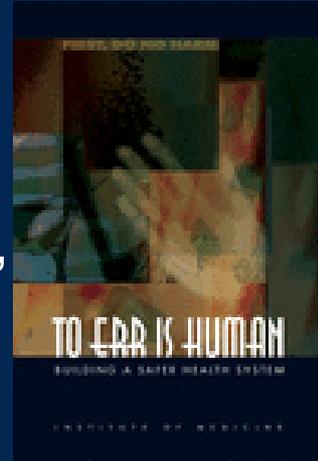
- Patient Safety is the:
 - identification and control of hazards that could cause harm to patients
 - prevention of harm or injury to patients
- Patient Safety includes actions undertaken by patients and staff to protect patients from being harmed by the effects of health care services





Patient Safety – Past

- 1999 - IOM Report “To Err is Human”
 - 98,000 preventable deaths yearly
 - National cost per year \$17-29 billion
 - 10-35% of the patients suffer from preventable adverse drug events
 - Nosocomial infections results in \$2 million and 90,000 deaths per year
- 2001 National Patient Safety Act mandated:
 - Event Reporting and Analysis
 - Culture Change Program
 - Teamwork





Patient Safety – Present

- “Despite best efforts, serious quality and safety problems persist”
- “Routine safety processes break down”
- “Bad things still happen in good hospitals”

Dr. Mark R. Chassin, MD, MPP, MPH
President, The Joint Commission





Patient Safety – Present

- “There is little evidence to suggest that the number of people dying from medical harm has dropped since the IOM first warned about these deadly mistakes a decade ago”

Lisa McGiffert

Director , Consumers Union’s Safe
Patient Project

www.SafePatientProject.org





Patient Safety – Present

- Army Patient Safety Program
 - Mission
 - Establish an environment of trust, transparency, teamwork and communication to facilitate an interdisciplinary proactive approach to improving safety and preventing adverse events.
 - Vision
 - An integrated, responsive and proactive Patient Safety Program that facilitates the critical concepts of a Patient Safety culture.





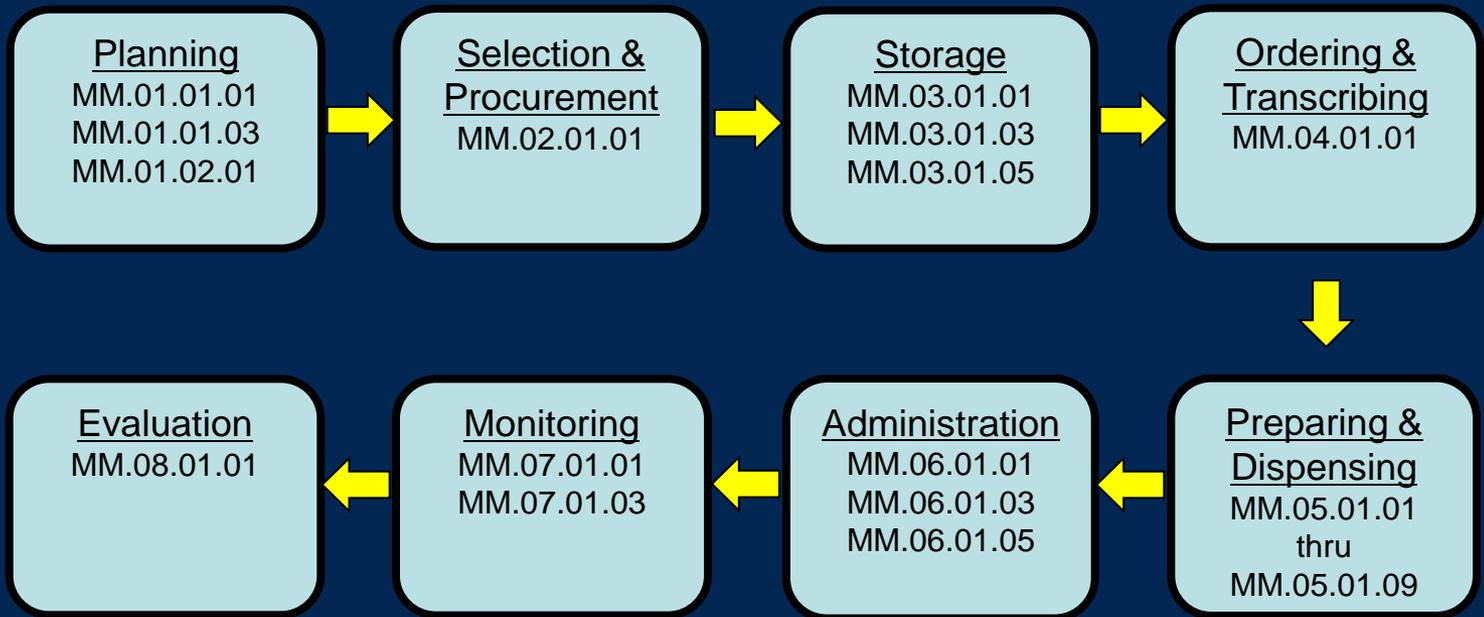
Patient Safety – Present

- Army Patient Safety Program
 - Goals:
 - **Engage leadership** at all levels to foster a culture of Patient Safety
 - Analyze AMEDD **Patient Safety cultural** elements to drive program initiatives
 - Integrate **teamwork concepts**, knowledge, skills and attitudes to improve the quality of Patient Safety
 - Provide facilities with **meaningful and useful data** to identify safe practices, to mitigate potential risks and hazards and to improve clinical outcomes





Medication Use Process: System's Approach





Medication Use Process: System's Approach

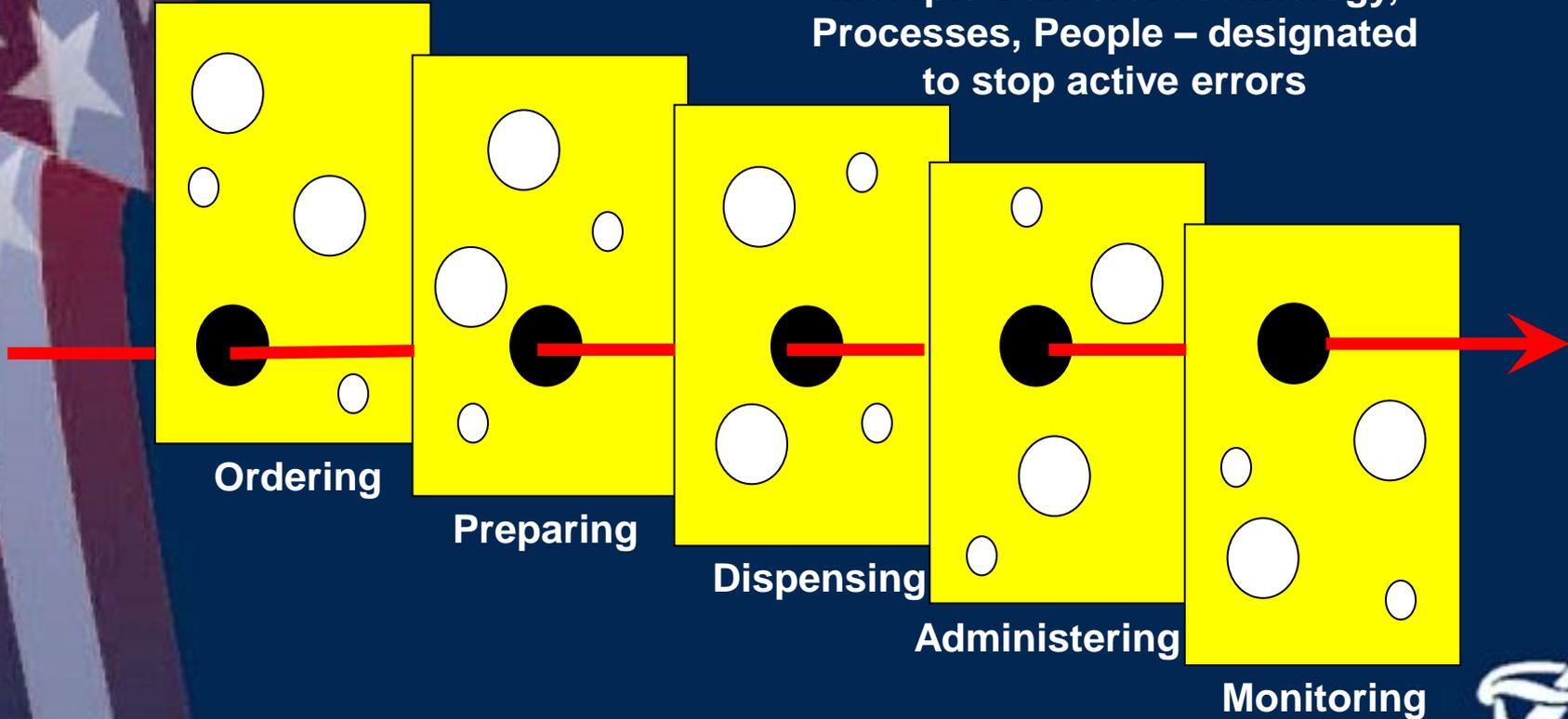
- Institute for Safe Medication Practices (ISMP)
 - Ten Key Elements of Medication Use System
 - Patient information
 - Drug information
 - Communication of drug information
 - Drug labeling, packaging and nomenclature
 - Drug storage, stock and standardization
 - Drug device acquisition, use and monitoring
 - Environmental factors
 - Competency and staff education
 - Patient education
 - Quality processes and risk management





Medication Use Process: System's Approach

Multiple Barriers: Technology,
Processes, People – designated
to stop active errors



Adaptation of James Reason's Swiss Cheese Model





Medication Use Process: System's Approach

- Why are Medication Errors still occurring?
 - Complexity of the medication management system
 - Ineffective use of performance measurement
 - Ineffective use of improvement strategies
 - Leadership & Safety Culture
 - Communication





Risk Points Planning

- Availability of Patient-Specific Information
- High Alert Medications Strategies
 - Identify high alert meds
 - Standardize processes
 - Limit access
 - Use automated alerts
 - Implement redundancies
 - Automated and independent double checks
 - Use auxiliary labels and different color labels
- Look-alike/Sound-alike (LASA) Medications
 - Identify LASA meds
 - Annual review





Risk Points Selection & Procurement

- Formulary decision and management
 - Critically consider medication safety
 - Potential for medication errors
 - Emerging safety information
 - Medication use evaluations
 - Clinical substitution during shortages
- Standardize and limit number of drug concentrations
- Minimize use of multi-dose vials (MDV)





Risk Points Storage

- Automated Dispensing Cabinets (ADC)
 - Most hospitals have ADCs, but not all
 - ADCs safety features are not maximized
 - Single pocket vs. matrix drawers
 - Minimize Overrides
 - Maximize the use of:
 - Ready-to-Administer products/medications
 - Ready-to-Use pre-mixed IV products
 - Pediatric specific products
- Proper Storage Conditions
 - Refrigerators and Freezers
- Beyond Use Date (MDV and others)





Risk Points

Ordering and Transcribing

- Computerized Physician Order Entry
 - Available in outpatient, but not in inpatient
 - Assessment of Clinical Screening Alerts
 - Utilize dose-range check feature
- Develop and formally approve clinical practice guidelines and protocols
- Standardization of Medication Orders
 - PRN Orders
 - Range Orders
- Order Sets and Pre-Printed Forms
- Medication Reconciliation
- Effective strategy for LASA medications





Risk Points Preparation and Dispensing

- Pharmacy Review of Medication Orders
 - Emergency Room
 - Radiology
 - The Joint Commission/DoD Waiver
- Review of orders when pharmacy is closed
 - No 24-hour inpatient pharmacy services
 - Competency of qualified healthcare professional to review order in the absence of a pharmacist
 - Technology
 - Telepharmacy
 - Remote Medication Order Entry and Review Services





Risk Points Preparation and Dispensing

- Preparation
 - USP Chapter 797
 - Compounding medications for immediate-use
 - Maximize ready-to-administer products
- Dispensing
 - Dispense within acceptable delivery times
 - Bar-Coded Medication Dispensing-Outpatient
 - Will-call medication pick-up system
 - Medication dispensing from the ED when pharmacy is closed





Risk Points Administration

- Nursing – last stop before administration
 - Adequate references available
 - Distractions – most common contributing factor
 - Protocol checklists
 - Do Not Disturb signs
 - Brightly colored vests
 - Cover windows of medication room
 - High alert medications – Independent double check
- Availability of oral syringes
- Standardize administration times





Risk Points Administration

- Bar-Code Medication Administration
 - Multi-discipline system
- IV Smart Pumps
 - Safety features are not being maximized
 - i.e. drug library, out of range dose alerts
 - Pump alerts are overridden
 - Nurses find work-arounds
 - Lack of pharmacy involvement





Risk Points Monitoring

- Monitor Effect of Medications
- Monitor Actual and Potential Adverse Drug Events
 - Non-punitive approach ??
 - Poor reporting of events
 - Data integrity issues
 - Lack of data analysis and actions
 - Lack of proactive identification of risk factors
 - Implement process improvement based on data





Risk Points Monitoring

- Inconsistent use or lack of Triggers Tool to identify ADEs
 - Naloxone – Opiate over-sedation
 - Flumazenil – Benzodiazepine over-sedation
 - Glucagon – Insulin-related hypoglycemia
 - Dextrose Bolus – Insulin-related hypoglycemia
 - Vitamin K – Warfarin misuse
 - Protamine – Heparin misuse
 - Diphenhydramine – Allergic reaction
 - Kayexalate – Hyperkalemia
 - Diazepam/Phenytoin – Seizure
 - INR more than 6
 - PTT greater than 100 seconds
 - Blood glucose more than 300
 - Blood glucose less than 50
 - STAT medications or laboratory tests
 - Oversedation
 - Patient Falls
 - Events leading to Rapid Response Team





Risk Points Evaluation

- Poor data collection and analysis of data
 - Analyze available medication safety data
 - Medication Errors
 - RCAs and FMEAs
- Poor review of literature and external sources
- Real Life Case Scenario:
 - May 2008 – ISMP published safety alert on the use of insulin pen injectors on multiple patients
 - Jan 2009 – Army MTF reported improper use of insulin pen injectors on multiple patients





Risk Points Evaluation

U.S. Department of Health & Human Services | www.hhs.gov

FDA U.S. Food and Drug Administration

FDA Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products

Drugs | Email this page | Print this page | Change Font Size

Drug Safety and Availability

Postmarket Drug Safety Information for Patients and Providers

Drug Safety Information for Healthcare Professionals

Communications about Ongoing Safety Reviews

Early Communications About Ongoing Safety Reviews

Healthcare Professional Sheets

Risk of Transmission of Blood-borne Pathogens from Shared Use of Insulin Pens

Information for Healthcare Professionals

FDA ALERT [03/19/2009]: The FDA is issuing this alert to remind healthcare providers and patients that insulin pens and insulin cartridges* (see description below) are never to be shared among patients. Sharing of insulin pens may result in transmission of hepatitis viruses, HIV, or other blood-borne pathogens.

The FDA has received information that insulin pens may have been shared among numerous patients (two thousand or more) in one hospital in the United States from 2007-2009 (<http://www.wbamc.amedd.army.mil/>), and in a smaller number of patients in at least one other hospital. Although the disposable needles in the insulin pens were reportedly changed for each patient, there is still a risk of blood contamination of the pen reservoir or cartridge. Patients who were treated with insulin pens at the hospitals in question are being contacted by the hospitals, and are being offered testing for hepatitis and HIV hepatitis sharing. The pens are shared and patient insulin pens are designed to have a reservoir.

Drug Topics

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Drug Topics

Shared insulin pens can transmit blood-borne pathogens

Jun 1, 2009
By: Scott Dallas, RPh, USPHS, Carol Holquist, RPh, USPHS
Drug Topics

Insulin pens are pen-shaped injector devices designed for patient self-administration of insulin. The pens are intended for use by a single patient only. The pens have a reservoir or cartridge that can deliver multiple doses of insulin; however, a new needle must be used with each injection. Patients should never share insulin pens, cartridges, or needles. If the insulin pens, cartridges, or needles are shared, there is a risk of transmission of blood-borne pathogens, such as hepatitis B (HBV), hepatitis C (HCV), and human immunodeficiency virus (HIV).

The FDA has received information that insulin pens may have been shared among many patients in one hospital and among a smaller number of patients in another hospital.

A press release from the William Beaumont Army Medical Center, El Paso, Texas, announced that 2,114 diabetic patients admitted to the medical center between August 2007 and January 2009 may be at risk for developing a blood-borne disease as a result of incorrect procedures employed during the administration of insulin through insulin pens.

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ISMP Medication Error Report Analysis

Revatio = Sildenafil = Viagra

Vital Initiative by the Institute for Safe Medication Practices Can Keep Patients Safe

Lyrca-Lopressor Mix-up

Cell Phones and E-mail Could Prevent Harm

Reuse of Insulin Pen for Multiple Patients Risks Transmission of Blood-Borne Disease

Michael R. Cohen, RPh, MS, ScD, FASHP*

These medication errors have occurred in health care facilities at least once. They will happen again—perhaps where you work. Through education and alertness, they can be avoided. You should

know your chest pain and elevated troponin T.

The use of organic nitrates in the emergency department while a patient

line. Nevertheless, it is rarely asked that patients specifically provide their cell phone numbers or e-mail addresses. Asking for this information up front makes sense to communicate better with patients in a timely manner and to prevent situations like the one described here.

REUSE OF INSULIN PEN FOR MULTIPLE PATIENTS RISKS TRANSMISSION OF BLOOD-BORNE DISEASE

ISMP recently alerted hospitals to a media release from a US Army hospital. The release, published in February, announced that 2,114 patients with diabetes who were insulin dependent and who were admitted between August 2007 and January 2009 might be at risk for developing a blood borne disease because of incorrect procedures used during the administration of insulin using pen devices.¹ Insulin pens are intended for use by a single patient. However, according to the announcement, although staff changed the pen's needle for use with different patients, they reused the pen for more than 1 patient. In addition, an army-wide investigation

found that patients could enter the cartridge after injection while the needle is still attached to the pen. Thus, pens are not suitable for use with multiple patients without risking cross-contamination. Facilities using insulin pens should act immediately and provide education and continuous monitoring to prohibit situations in which an individual patient's pen might be reused for another patient.

It should not be assumed that all health care professionals know not to do this. In one report a nurse told ISMP that, rather than waiting for dispensing of a patient's pen by the pharmacy, nurses at her hospital often borrowed a pen from another patient, attached a new disposable needle, and injected a dose of insulin into a second patient using the first patient's pen. These nurses were anxious to meet patients' needs for timely insulin administration and did not perceive the risks associated with this practice. Labeling each dispensed pen with the patient's name may help reinforce that the product is intended for that patient alone. ISMP has asked that insulin pen





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Closing Remarks

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