Pharmacotherapy Review and Recertification Course: Medication Safety

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Medication Safety Learning Objectives:

At the conclusion of this session, the participant should be able to discuss national regulations and local (but universally adopted) practices related to

- Adverse drug reaction reporting
- Medication safety
- Formulary management
- Drug development and approval processes
- Ethical issues, such as appropriate interactions with industry and conflict of interest disclosures

Format: This session will use a series of scenarios and audience response questions to engage the audience and prepare participants to answer similar questions on a board certification examination. The facilitator will discuss national regulatory and population health issues pertinent to pharmacy practice. Local practices will also be discussed that have been universally adopted.

Premise: Participants in this course are pharmacists who practice in a health system. This session will serve as a review and help you identify areas you may want to study more in preparation for the board exam.

Presentation Questions

1. Which of the following organizations develops consensus-based safety recommendations that are surveyed by regulatory and accreditation organization as if they are requirements?
    a. ISMP
    b. TJC
    c. CDC
    d. IOM/NAM

2. Buddy Ebsen was the original Tin Man in the Wizard of Oz. He was replaced following hospitalization for toxicity from the aluminum powder used for his costume. Replacement Jack Haley's costume was changed to aluminum paste. Buddy's situation was:
    a. A medication error
    b. An adverse drug reaction
    c. An incompatibility
    d. An unknown toxicity

3. A patient taking 120 units of insulin was switched from U-100 to U-500 concentration. Nobody adequately explained how he would measure and administer the new concentration. He had only U-100 1-mL syringes, so he filled each of two syringes with insulin to the 60-unit mark and gave himself two injections. His wife found him unresponsive. He was taken to the hospital, successfully treated, and discharged the following day.

    In which of the following NCC MERP categories is this medication error classified?

NCC MERP Category	
A	Capacity to cause harm
B	Error occurred but didn't reach the patient
C	Error occurred, reached the patient, but didn't cause harm
D	Error occurred, reached the patient, and required monitoring to confirm that there was no harm and/or required intervention to preclude harm
E	Error occurred, resulted in temporary harm, and required intervention
F	Error occurred, resulted in temporary harm, and resulted in initial or prolonged hospitalization
G	Error occurred, resulted in permanent harm
H	Error occurred, resulted in intervention to sustain life
I	Error occurred, resulted in patient death

    a. Category A – capacity to cause harm
    b. Category C – error reached patient; no harm
    c. Category E – error; temporary harm that required intervention
    d. Category F – error; temporary harm that required initial or prolonged hospitalization

4. The pharmacist and a nurse in the emergency department were setting up a nitroglycerin drip. An IV pump was not available, so they set up the drip with the flow rate controlled only by the roller clamp on the IV tubing, although this violated hospital policy. The clamp didn't hold, and most of the contents of the IV bag were infused into the patient.

   Which of the following is the most appropriate action for the managers of these employees to take?

   a. Console them– errors happen
   b. Coach them– it was the wrong decision to violate policy and not use an IV pump
   c. Punish them– remediate using the hospital policy
   d. Punish them– suspend based on hospital policy

5. Intravenous immunoglobulin (IVIG) is difficult to obtain because of a shortage, and the situation is projected to continue for months. You have one elderly patient who is receiving IVIG for a labeled indication, but he is not responding well. You have a request from your Chief of Staff to start IVIG on his niece as a treatment for autism.

   Which of the following is the best way to avoid this dilemma?

   a. Use formulary agents only for approved indications
   b. Approve usage criteria for every drug added to the formulary
   c. Proactively develop medication use evaluations (MUEs) for drugs prone to shortage and implement the MUE criteria only if a shortage occurs
   d. Ask the Ethics Committee to make the decision on a case-by-case basis if a shortage occurs

6. The Drug Quality and Security Act (DQSA) separated §503 of the Food Drug & Cosmetic Act (FD&C Act) into two sections: 503A and 503B. Which of the following types of entity can compound sterile preparations for office use (not patient-specific preparations)?
   a. 503A compounding pharmacy
   b. 503B outsourcing facility
   c. Either 503A compounding pharmacy or 503B outsourcing facility if they are registered with the FDA
   d. Any state-licensed organization

References and Recommended Readings

Medication Safety

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Medication Safety

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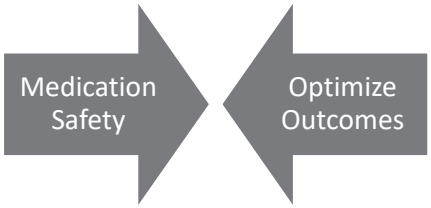
Disclosure

- Patricia Kienle: Employee and stockholder, Cardinal Health
- Patricia Kienle is a member of the U.S. Pharmacopeia (USP) Compounding Expert Committee but this talk is not endorsed by or affiliated with USP.
- All other planners, presenters, and reviewers of this session report no financial relationships relevant to this activity.

Learning Objectives

- At the conclusion of this session, the participant should be able to discuss national regulations and local (but universally adopted) practices related to
  - Adverse drug reaction reporting
  - Medication safety
  - Formulary management
  - Drug development and approval process
  - Ethical issues, such as appropriate interaction with industry and conflict of interest disclosures

Our Primary Job



To Err Is Human

- 1999 Institute of Medicine (IOM) report
  - IOM → National Academy of Medicine (NAM)
- Building a safer health system
- "… perhaps as many as 98,000 people die in hospitals each year as a result of medical errors that could have been prevented …"

Kohn LT, Corrigan JM, Donaldson MS, ed. Committee on Quality of Health Care in America. To Err is Human – Building a Safer Health System. Washington, DC: National Academy Press; 2000.

Safety Organizations …

- International
  - World Health Organization (WHO)
- Federal governmental
  - Food and Drug Administration (FDA)
  - Occupational Safety and Health Administration (OSHA)
  - Drug Enforcement Administration (DEA)
  - Centers for Disease Control and Prevention (CDC)
    - National Institute for Occupational Safety and Health (NIOSH)
  - Centers for Medicare and Medicaid Services (CMS)
  - Agency for Healthcare Research and Quality (AHRQ)

… Safety Organizations

- Quasi-governmental
  - United States Pharmacopeia (USP)
- Professional
  - Institute for Safe Medication Practices (ISMP)
  - Institute for Healthcare Improvement (IHI)
  - American Society of Health-System Pharmacists (ASHP)
  - Medical and nursing organizations

Accreditation Organizations - Hospital

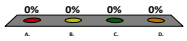
- The Joint Commission (TJC)
- DNV-GL Healthcare
- Healthcare Facilities Accreditation Program (HFAP)
  - Converting to → Accreditation Association for Hospitals/Health Systems (AAHHS)
- Center for Improvement in Healthcare Quality (CIHQ)

Accreditation Organizations - Ambulatory

- URAC
- Accreditation Association for Ambulatory Health Care (AAAHC)
- Accreditation Commission for Health Care (ACHC)
  - Pharmacy Compounding Accreditation Board (PCAB)
- Others

Question 1:
Which of the following organizations develops consensus-based safety recommendations that are surveyed by regulatory and accreditation organizations as if they are requirements?

A. ISMP
B. TJC
C. CDC
D. IOM/NAM



CDC Documents

- Guidelines for hand hygiene
- Infection prevention guidelines
- Vaccine schedules
- Antibiotic stewardship
- NIOSH guidance documents
  - Hazardous Drug Alert and List
- CDC Category 1A recommendations = best practice → surveyed by regulatory agencies and accreditation organizations as if they are requirements

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FDA

- Approvals
  - Drugs
  - Biologics
  - Devices
- Warnings
  - Black box warnings
- Recalls
  - Rare: to patient level

Center for Drug Evaluation and Research (CDER)

- New Drug Application (NDA)
  - Drug sponsor formally proposes that the FDA approve a new pharmaceutical for sale and marketing
- Abbreviated New Drug Application (ANDA)
  - Contains data for the review and approval of a generic drug product
- Investigational New Drug (IND)
  - Investigator
  - Emergency use
  - Treatment

U.S. Food and Drug Administration. Drugs. http://www.fda.gov/Drugs/default.htm (accessed 2018 Sept 6).

What Aren't Drugs?

- Biologics
  - Approved
  - Biosimilars
- Devices
  - Cleared

U.S. Food and Drug Administration. Drugs. Purple book: lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations. https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm (accessed 2018 Sept 6).

FDA Labeling

- Approval
- Labeling vs. label
- Off-label usage
- Safety issues
  - Black box warnings
  - Risk Evaluation and Mitigation Strategies (REMS)

U.S. Food and Drug Administration. Approved risk evaluation and mitigation strategies (REMS). http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm (accessed 2018 Sept 6).

Question 2:
Buddy Ebsen was the original Tin Man in the Wizard of Oz. He was replaced following hospitalization for toxicity from the aluminum powder used for his costume. Replacement Jack Haley's costume was changed to aluminum paste. Buddy's situation was:

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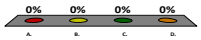
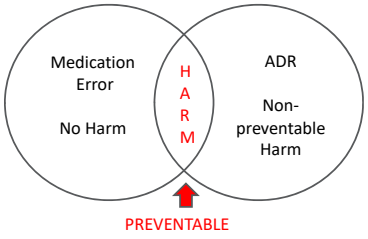


Adverse Drug Events (ADEs)

- ADE is an injury resulting from a medical intervention related to a drug
  - Medication errors
  - Adverse drug reactions (ADR)
  - Incompatibilities

Relationship Among ADEs



Medication Error

- Any preventable event 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

National Coordinating Council for Medication Error Reporting and Prevention. About medication errors. http://www.nccmerp.org/about-medication-errors (accessed 2018 Sept 6).

NCC MERP Index for Categorizing Medication Errors

Scenario

- A patient taking 120 units of insulin was switched from U-100 to U-500 concentration
- No one adequately explained how he would measure and administer the new concentration
- He had only U-100 1-mL syringes, so he filled each of two syringes with insulin to the 60-unit mark and gave himself two injections
- His wife found him unresponsive. He was taken to the hospital, successfully treated, and discharged the following day

Question 3:
In which of the following NCC MERP categories is this medication error classified?

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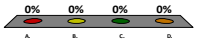
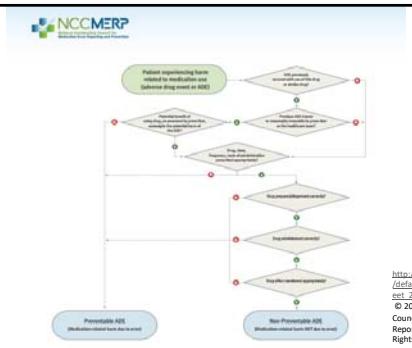




http://www.nccmerp.org/sites/default/files/nccmerp_fact_sheet_2015-02-v91.pdf

Detection of ADEs

- Institute for Healthcare Improvement (IHI) Global Trigger Tool
  - Detects up to 50 times more ADEs than other processes
- Rapid chart review for detection of certain triggers to identify
  - *Clostridium difficile*-positive stool
  - PTT > 100 seconds
  - INR > 6
  - Glucose < 50 mg/dL
  - Rising BUN or SCr 2x baseline
  - Administration of
    - Vitamin K, diphenhydramine, flumazenil, naloxone

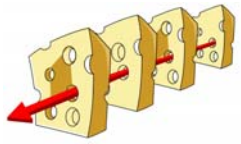
Institute for Healthcare Improvement. Using the IHI global trigger tool. http://www.ihi.org/education/WebTraining/Webinars/Web_Action/TriggerTool/Pages/default.aspx (accessed 2018 Sept 6).

Notification About an ADE

- Internal
  - Per policy
  - Sentinel event
- External
  - Vaccine Adverse Event Reporting System (VAERS)
  - Medication errors → ISMP
  - ADRs → MedWatch

Swiss Cheese Model

- Active errors
- Latent errors
- Skill-based
- Rule-based
- Knowledge-based



Reason J. Human error. Cambridge, MA: Cambridge University Press; 1990.

Analysis of ADEs

- Retrospective
  - Root cause analysis
- Prospective
  - Failure mode and effects analysis
- Continuous Quality Improvement Processes
  - LEAN
  - Six Sigma

Evolution of Patient Safety

- Punitive Culture (Person approach)
  - Places blame on person and ignores the system
  - Discourages reporting
- Non-punitive Culture (System approach)
  - Perceived as too lax
  - Inconsistent or lack of consequences
  - Often misunderstood
- Just Culture (Combined, balanced approach)
  - Includes a focus on behavioral choices
  - Now considered best practice
  - Challenging to implement and maintain

Just Culture Definition

- 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

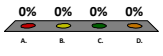
ASHP. Medication misadventures - positions. https://www.ashp.org/-/media/assets/policy-guidelines/docs/policy-positions/policy-positions-medication-misadventures.ashx?la=en&hash=FF75E85D57E12450C13DFA4F22C2E7A1A1ASFA4D (accessed 2018 Sept 6).

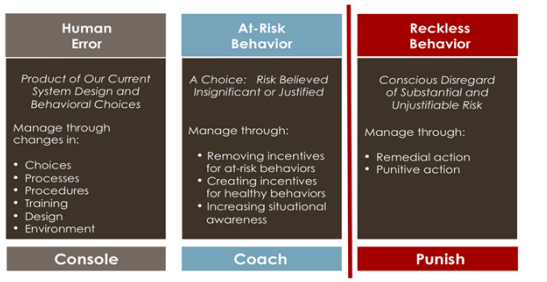
Question 4

The pharmacist and a nurse in the emergency department were setting up a nitroglycerin drip. An IV pump was not available, so they set up the drip with the flow rate controlled only by the roller clamp on the IV tubing, although this violated hospital policy. The clamp didn't hold, and most of the contents of the IV bag were infused into the patient.

Which of the following is the most appropriate action for the managers of these employees to take?

A. Console them– errors happen
B. Coach them– it was the wrong decision to violate policy and not use an IV pump
C. Punish them– remediate using the hospital policy
D. Punish them– suspend based on hospital policy





Outcome Engenuity, LLC. Introduction to the just culture. https://www.outcome-eng.com/david-marx-introduces-just-culture/

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Optimizing Outcomes

- Drug delivery and distribution
- Electronic health records
- Compatibility
- Administration technology
  - Smart pumps
- Shortages

Recurrent Medication Error Issues

- Prohibited abbreviations
  - U, IU, QD, QOD, MS, MSO_4, $MgSO_4$
- Proper use of decimal points
  - 5 mg, not 5.0 mg
  - 0.5 mg, not .5 mg
- High-alert medications
- Look- and sound-alike medications

High-Alert Drugs

- Generally chosen from ISMP list of High-alert Medications
  - Acute Care
  - Community and Ambulatory Care
- Those medications that cause significant patient harm when used in error, such as
  - Insulin
  - Opioids
  - Anticoagulants
  - Hypoglycemics

Institute for Safe Medication Practices. ISMP high-alert medications in acute care settings. https://www.ismp.org/recommendations/high-alert-medications-acute-list (accessed 2018 Sept 6).

Access Issues

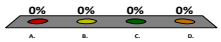
- Prior authorization
- Investigational use
  - Institutional Review Board (IRB)
- Patient assistance programs
- 340B drug discount program

Scenario

- Intravenous immunoglobulin (IVIG) is difficult to obtain because of a shortage, and the situation is projected to continue for months
- You have one elderly patient who is receiving IVIG for a labeled indication, but he is not responding well
- You have a request from your Chief of Staff to start IVIG on his niece as a treatment for autism

Question 5:
Which of the following is the best way to avoid this dilemma?

A. Use formulary agents only for approved indications
B. Approve usage criteria for every drug added to formulary
C. Proactively develop Medication Use Evaluations (MUEs) for drugs prone to shortage and implement the MUE criteria only if a shortage occurs
D. Ask the Ethics Committee to make the decision on a case-by-case basis if a shortage occurs



Formulary Management

Formulary Definition

- Continually updated list of medications and related information, representing the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and treatment of disease and promotion of health
  - Medication-use policies
  - Ancillary drug information
  - Decision-support tools
  - Organizational guidelines

ASHP. ASHP statement on the pharmacy and therapeutics committee and the formulary system. https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/pharmacy-and-therapeutics-committee-and-formulary-system.ashx (accessed 2018 Jul 19).

Formulary: CMS Hospital Conditions of Participation (CoPs)

- Medical staff must establish a formulary
- List of medications available
- Written criteria include at least
  - Indication for use
  - Effectiveness
  - Risks (including propensity for medication errors, abuse potential, and sentinel events)
  - Cost
- Periodic review for safety issues

Centers for Medicare and Medicaid Services. CMS hospital conditions for participation (CoPs). https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf (accessed 2018 Sept 6).

Your Analysis

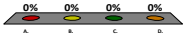
- Cost-minimization
  - Compares treatment alternatives with equivalent efficacy, safety, or both
- Cost-benefit
  - Monetary analysis
- Cost-effectiveness
  - Monetary and effectiveness analysis
- Cost-utility
  - Includes quality of life issues

Drug Shortages: CMS Hospital CoPs

- Processes to address medication shortages and outages, including the following
  - Communicating with appropriate prescribers and staff
  - Developing approved substitution protocols
  - Educating appropriate Licensed Independent Professionals (LIPs), health care professionals, and staff about these protocols
  - Obtaining medications in the event of a disaster

Question 6:
The Drug Quality and Security Act separated §503 of the FD&C Act into two sections: 503A and 503B. Which type of entity can compound sterile preparations for office use (not patient-specific)?

A. 503A compounding pharmacy
B. 503B outsourcing facility
C. Either 503A compounding pharmacy or 503B outsourcing facility if they are registered with the FDA
D. Any state-licensed healthcare organization for use within their state

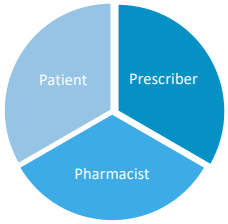


Medication Safety Standards

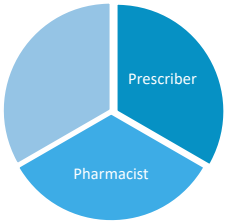
- Drug Quality and Security Act
  - Title I – Compounding Quality Act
    - 503A Traditional pharmacy compounding
    - 503B Outsourcing facilities
  - Title II – Drug Supply Chain Security
    - Pedigree: ability to trace drug from manufacturer to pharmacy

U.S. Congress.gov. H.R.3204 - Drug Quality and Security Act. https://www.congress.gov/bill/113th-congress/house-bill/3204 (accessed 2018 Sept 6).

Traditional Compounding



Outsourcing Facilities



USP Compounding Chapters

- <795> Pharmaceutical Compounding – Nonsterile Preparations
- <797> - Pharmaceutical Compounding – Sterile Preparations
- <800> - Hazardous Drugs – Handling in Healthcare Settings

- Apply to all healthcare settings
- Apply to all disciplines
- Are federally-enforceable
  - Chapters numbered under <1000> are enforceable
  - Chapters numbered over <1000> are informational

U.S. Pharmacopeia National Formulary 2016: USP 39/NF34. Rockville, MD: United States Pharmacopeial Convention, 2016.

USP Compounding Chapters

- <795> Nonsterile compounding
- <797> Sterile compounding
- <800> Handling hazardous drugs
  - NIOSH List of drugs that are hazardous to personnel

FDA Guidance Documents

- Final and draft
- Various topics
  - What can be compounded from bulk substances
  - What cannot be compounded because of safety or complexity
  - Repackaging
  - Insanitary conditions

U.S. Food and Drug Administration. Regulatory policy information. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm166743.htm (accessed 2018 Sept 6).

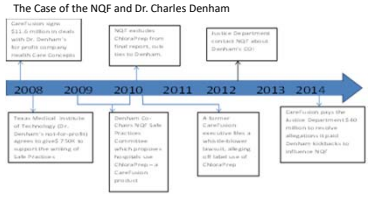
Conflict of Interest (COI)

- IOM/NAM
  - *A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest*
- In general, COI exists when outside financial or other interests may inappropriately influence the way in which an individual carries out his or her responsibilities
  - The PERCEPTION of COI is just as significant

National Academy of Sciences. Conflict of interest in medical research, education, and practice. http://iom.nationalacademies.org/reports/2009/conflict-of-interest-in-medical-research-education-and-practice.aspx (accessed 2018 Sept 6).

Conflict of Interest (COI)

The Case of the NQF and Dr. Charles Denham



- Incorporate policies for COI into your processes for all meetings where decisions are being made
  - Ask for potential COI at the beginning of every meeting
  - Annual signature to acknowledge acceptance of policy

Wu AW, Kavanagh KT, Pronovost PJ, Bates DW. Conflict of interest, Dr Charles Denham and the Journal of Patient Safety. *J Patient Saf.* 2014; 10:181-5. http://journals.lww.com/journalpatientsafety/Fulltext/2014/12000/Conflict_of_Interest,_Dr_Charles_Denham_and_the.1.aspx (accessed 2018 Sept 6).

Physician Payments Sunshine Act

- Open payment provision designed to bring transparency to financial relationships between physicians, teaching hospitals, and the pharmaceutical industry
- Requires manufacturers of pharmaceutical drugs and devices, as well as Group Purchasing Organizations (GPOs), to report payments or transfers of value (such as meals, honoraria, or travel reimbursements) made to U.S. physicians and teaching hospitals
- Reports are made to CMS

Centers for Medicare & Medicaid Services. Open payments. https://www.cms.gov/openpayments/ (accessed 2018 Sept 6).

Topics of Growing Interest

- Electronic health record
- Population health
- Health literacy
- Metrics for safety
- Opioid use

Keeping Current