2016 Pharmacotherapy Specialty Examination Review Course:
Regulatory and Quality Issues

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Regulatory and Quality Learning Objectives:

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

- Quality metrics
- Agencies that oversee quality (governmental and non-governmental)
- Major public health initiatives (e.g., REMS programs, Health People 2020, Core Measures)
- Prescribing and monitoring specific drugs (e.g., methadone, isotretinoin, REMS programs)
- Federal regulations related to patient’s rights and protection (e.g., privacy, child/adult protective services, advance directives, living will, power of attorney, do not resuscitate)

Format: This session will use a series of scenarios and audience response questions to engage the audience and to 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. HIPAA generally requires explicit written authorization when the subject’s data is used for research. Which of the following scenarios allows for the bypassing of such authorization?
   a. The information pertains solely to deceased persons
   b. Information is removed from data collection forms
   c. Information is stored in a secure location
   d. Information is used for quality improvement processes

2. The Tuskegee Syphilis Study used disadvantaged, rural African-American men to study the untreated course of a disease even though the disease was not confined to that population. Based on the patient population served, which ethical research principal was violated?
   a. Beneficence
   b. Justice
   c. Respect for persons
   d. Non-malfeasance

3. You are a hospital employee. A community-based physician asked you to write orders for her inpatients. What approval do you need?
   a. Medication Therapy Management (MTM) agreement between MD and you
   b. Approval of Chief of Service
   c. Credentialing process used for medical staff members
   d. State registration allows this practice without further documentation

4. An ICU set of orders say “titrate to blood pressure” for one of the cardiovascular infusions. This is:
   a. Acceptable, since it is for a monitored patient
   b. Acceptable, since the hospital policy allows certified RNs to handle such orders
   c. Not acceptable, since there is no specific BP range
   d. Not acceptable, since it is not associated with a particular licensed independent professional (LIP)

5. For which of the following patients would the REMS requirements for erythropoiesis-stimulating agents (ESAs) apply?
   a. Orthopedic surgery patient receiving the drug perioperatively to reduce the need for transfusion
   b. Jehovah’s Witness receiving the drug as an adjunct treatment for an upper GI bleed
   c. Chronic renal failure patient receiving the drug for treatment of anemia
   d. Lung cancer patient with anemia receiving the second of four planned cycles of immunosuppressive chemotherapy

6. You are the pharmacist on the medicine service and have been invited to the Quality Committee meeting to present a plan to improve HCAHPS scores. Which of the following programs would meet this goal?
   a. Medication education program
   b. Early urinary catheter removal protocol
   c. Pharmacist-driven venous thromboembolism risk assessment and prophylaxis initiation
   d. Implementation of an antimicrobial stewardship program
7. Which of the following is an example of a hospital-acquired condition as defined by CMS?
   a. Postoperative pulmonary embolism
   b. Stage II pressure ulcer
   c. Medication error
   d. Guillain-Barre syndrome
References and Recommended Readings

Laws and Regulations


License, Registration, Certification


Scope of Practice


Accreditation Organizations

National Patient Safety Goals


National Quality Forum Safe Practices


Health Insurance Portability and Accountability Act (HIPAA), Advance Directives, Living Wills, Do Not Resuscitate

5. National Hospice and Palliative Care Organization http://www.nhpco.org/templates/1/homepage.cfm

Institutional Review Boards and Ethics

REMS Programs

1. FDA Postmarket Drug Safety Information for Patients and Providers

2. ASHP REMS Resource Center http://www.ashp.org/REMS


Quality

1. ASHP Quality and Compliance Resource Center.

2. Centers for Medicare and Medicaid Services (CMS) website that houses the specification manuals for national inpatient and outpatient quality reporting programs and other resources on CMS quality initiatives (e.g., acute myocardial infarction [AMI], pneumonia [PN], Surgical Care Improvement Program [SCIP])
   www.qualitynet.org

3. Centers for Medicare and Medicaid Services website that houses presentations and frequently asked questions regarding the inpatient Hospital Value-Based Purchasing Program
   www.cms.gov/hospital-value-based-purchasing/

4. Overview of key milestones in history of The Joint Commission
   http://www.jointcommission.org/assets/1/18/SIWG_Vision_paper_web_version.pdf

5. Institute of Medicine. To err is human: building a safer health system (1999)


7. Hospital Consumer Assessment of Healthcare Providers and Systems hospital survey
   http://www.hcahpsonline.org/home.aspx

   http://www.ahrq.gov/research/findings/evidence-based-reports/makinghcsafer.html

9. Agency for Healthcare Research and Quality Pharmacy Health Literacy Center


Major Public Health Initiatives


4. Institute for Healthcare Improvement 5 Million Lives campaign www.ihi.org/ihi/programs/campaign

Regulatory and Quality Issues

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Disclosure
• Patricia Kienle is an employee and stockholder of 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

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• At the conclusion of this session, the participant should be able to discuss national regulations and local (but universally adopted) practices related to
  – Quality metrics
  – Agencies that oversee quality (governmental and non-governmental)
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  – Prescribing and monitoring specific drugs (e.g., methadone, isotretinoin, REMS programs)
  – Federal regulations related to patient’s rights and protection (e.g., privacy, child/adult protective services, advance directives, living will, power of attorney, do not resuscitate)

The Continuum

Who Tells Us What To Do?

Regulators
Accreditation Organizations
Best Practices

Laws and Regulations
• Federal regulations related to pharmacy
  – Food and Drug Administration (FDA)
  – Drug Enforcement Administration (DEA)
  – Centers for Medicare and Medicaid Services (CMS)
    – Conditions of Participation
    – Conditions for Coverage
  – United States Pharmacopeia (USP)
Laws and Regulations

• Other federal regulations
  – Occupational Safety and Health Administration
  – Affordable Care Act
  – Health Insurance Portability and Accountability Act (HIPAA)
  – Patient Rights and Protection
    – Institutional Review Boards
    – Conflict of Interest

Accreditation Organizations

• CMS (a regulator) “deems” four hospital accreditation organizations to provide surveys that meet CMS requirements
  – The Joint Commission (TJC)
  – DNV Healthcare
  – Healthcare Facilities Accreditation Program (HFAP)
  – Center for Improvement in Healthcare Quality (CIHQ)
• Ambulatory accreditation organizations survey a variety of sites

Best Practices

• ACCP – American College of Clinical Pharmacy
• ADA – American Diabetes Association
• AHA – American Heart Association
• APIC – Associations for Professionals in Infection Control and Epidemiology
• ASCO – American Society for Clinical Oncology
• ASHP – American Society of Health-System Pharmacists
• ASPEN – American Society for Parenteral and Enteral Nutrition
• CDC – Centers for Disease Control and Prevention
• NIOSH – National Institute for Occupational Safety and Health
• ONS – Oncology Nursing Society

Best Practices

• Guidance documents provided by many professional organizations
  • May be administrative, clinical, specific focus, or a combination of issues
  – ACCP – ASHP
  – ADA – ASPEN
  – AHA – CDC
  – APIC – NIOSH
  – ASCO – ONS

QUESTION #1
HIPAA generally requires explicit written authorization when the subject’s data are used for research. Which of the following scenarios allows for the bypassing of such authorization?

A. The information pertains solely to deceased persons
B. Information is removed from data collection forms
C. Information is stored in a secure location
D. Information is used for quality improvement processes
HIPAA

- Health Insurance Portability and Accountability Act
- Protected health information (PHI)
  - Anything that could identify a particular patient
- Privacy Rule
  - Individual’s privacy must be properly protected
- Covered entities
- Business associates

HIPAA Uses and Disclosures

- Research
  - Needs waiver or altered authorization
- Quality Improvement
- Population Health

QUESTION #2
The Tuskegee Syphilis Study used disadvantaged, rural African-American men to study the untreated course of a disease even though the disease was not confined to that population. Based on the patient population served, which ethical research principal was violated?

A. Beneficence
B. Justice
C. Respect for persons
D. Non-malfeasance

Belmont Report

- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- Subpart A: Federal Policy for the Protection of Human Subjects (“Common rule”)
- Subpart B: Additional protection for pregnant women, human fetuses, and neonates
- Subpart C: Additional protection for prisoners
- Subpart D: Additional protection for children

http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Ethical Principles

- Respect for persons
- Beneficence
  - Do no harm
- Justice
- Informed consent
- Assessment of risks and benefits

Institutional Review Board (IRB)

- Institutional Review Board
  - Registration
  - Clinical investigators
  - Approval process

http://www.hhs.gov/ohrp/assurances/irb/
IRB Definitions

• Research
  — “a systematic investigation... designed to develop or contribute to generalizable knowledge”

• Human Subjects
  — a living individual about whom an investigator (whether professional or student) conducting research obtains:
    — Data through intervention or interaction with the individual
    — Identifiable private information

• Minimal Risk
  — probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons

QUESTION #3
You are a hospital employee. A community-based physician asked you to write orders for her inpatients. What approval do you need?

A. Medication Therapy Management (MTM) agreement between MD and you
B. Approval of Chief of Service
C. Credentialing process used for medical staff members
D. State registration allowing this practice without further documentation

Licensure

• Registration
• Certification
• Licensure
• Primary Source Verification

Scope of Practice

• CMS requirements
• State regulations
• National board certification
• Health-system approval

QUESTION #4
An ICU set of orders say “titrate to blood pressure” for one of the cardiovascular infusions. This is:

A. Acceptable, since it is for a monitored patient
B. Acceptable, since the hospital policy allows certified RNs to handle such orders
C. Not acceptable, since there is no specific BP range
D. Not acceptable, since it is not associated with a particular licensed independent professional (LIP)

Protocols and Standing Orders

• Standing orders
  — Set of orders ordered by an LIP prior to use

• Protocols
  — Orders based on objective criteria that may be implemented prior to LIP orders if certain criteria are met

• Evidence-based
• Nationally accepted therapy
Prescribing Restrictions

- Drug-specific
  - Methadone
- Risk Evaluation and Mitigation Strategies (REMS)
- Specialty pharmacy distribution
- Related to insurance
  - Pre-authorization

QUESTION #5
For which of the following patients would the REMS requirements for erythropoiesis-stimulating agents (ESAs) apply?

A. Orthopedic surgery patient receiving the drug perioperatively to reduce the need for transfusion
B. Jehovah’s Witness receiving the drug as an adjunctive treatment for an upper GI bleed
C. Chronic renal failure patient receiving the drug for treatment of anemia
D. Lung cancer patient with anemia receiving the second of four planned cycles of immunosuppressive chemotherapy

Risk Evaluation and Mitigation Strategies

- Impetus for Food and Drug Administration Amendments Act of 2007 (PDUFA IV)
- Authorizes FDA to require if risk >> benefit
  - Lack of transparency with regard to clinical trials
  - Inadequate postmarketing surveillance tools and information resources
  - Limited post-approval authority of FDA and insufficient emphasis on patient safety
  - Between 2000 and 2007
    - Twelve prescription drugs withdrawn from market due to safety concerns identified post-approval

Elements to Assure Safe Use (ETASU)

- Health care providers who prescribe the drug have specialized training or experience or are specially certified
- Pharmacies, practitioners, or health care settings that dispense drug are specially certified
- Drug dispensed to patients only in certain health care settings, such as hospitals
- Drug dispensed to patients with evidence or other documentation of safe use conditions, such as laboratory test results
- Each patient using drug enrolled in registry
- Each patient using drug subject to specialized monitoring

Erythropoiesis-Stimulating Agents REMS

- Special certification for:
  - Health care providers (HCPs) who both prescribe and dispense ESAs for patients with cancer in private practice settings
  - HCPs who prescribe ESAs for patients with cancer in hospitals are specially certified
- Includes a patient acknowledgment form that must be easily retrievable for audit
  - Hospital designee responsible for maintaining and storing the forms on-site and/or archiving them in a retrievable manner.


Hospital Designee Responsibilities

- Complete ESA APPRISE Oncology Program
- Ensure ESAs are dispensed to patients with cancer after verifying:
  - HCP who prescribed the ESA for patients with cancer is certified
  - The discussion between the patient and certified provider on the risks of ESA therapy is documented by patient and provider signatures on the Acknowledgment Form prior to initiation of each new course of Aranesp/EpoGen/Procrit therapy

Hospital Designee Responsibilities

- Oversee compliance with program
- Maintain evidence of compliance with the ESA APPRISE Oncology Program
  - Each HCP in the hospital who prescribes ESAs is certified
  - Risk:benefit discussion between certified provider and patient documented on the Acknowledgment Form for each patient with
    - Acknowledgment Forms stored on-site and/or archived in a retrievable manner.


Long-Acting Opioid REMS

- Medication Guide
- Elements to ensure safe use
  - “REMS-compliant training” for prescribers consistent with the FDA blueprint
  - Manufacturers responsible for ensuring training is available
  - Focus on the safe prescribing of ER/LA opioids with a core content of about three hours
  - ER-LA opioid REMS
    - Website developed by manufacturers provides access to accredited programming

Emergency Preparedness

- Disaster planning
- Weather issues
- Availability of critical medications
- Development of guidelines and protocols
- Infectious Diseases
  - Ebola
  - Zika

Triad of Medication Use

Quality

Cost

Efficiency

Quality Terms

- Quality control
  - Things you can objectively check
- Quality assessment
  - Evaluating the system
- Quality improvement
  - Making change for the better

Quality Analysis & Improvement

- Retrospective
  - Root cause analysis (RCA)
- Prospective
  - Plan-Do-Check-Act
  - Failure Mode and Effects Analysis (FMEA)
- On-Going
  - Lean
  - Six Sigma
IOM: Crossing the Quality Chasm

- Elements of improvement
- Change the environment
  - Evidence-based healthcare
  - Use of information technology
  - Align payment with quality
  - Prepare the workforce

Quality Elements

- Safe
  - Avoid injuries
- Effective
  - Evidence-based
- Patient-centered
  - Respectful of and responsive to individual patient needs
- Timely
  - Minimize delays
- Efficient
  - Avoid waste
- Equitable
  - Does not vary based on personal characteristics

Quality Efforts of Accreditation Organizations (AOs)

<table>
<thead>
<tr>
<th>Accreditation Organization</th>
<th>Safety &amp; Quality System Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Joint Commission</td>
<td>National Patient Safety Goals</td>
</tr>
<tr>
<td>HFAP</td>
<td>National Quality Forum Endorsed Set of Safe Practices</td>
</tr>
<tr>
<td>DNV Healthcare</td>
<td>ISO Quality Standards</td>
</tr>
<tr>
<td>CIHQ</td>
<td>ISO = International Organization for Standardization</td>
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</tbody>
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2016 National Patient Safety Goals...

- 1: Improve accuracy of patient identification
  - Use two patient identifiers
- 2: Improve caregiver communication
  - Report critical test results in a timely manner
- 3: Improve medication safety
  - Improve anticoagulant safety
  - Reconcile medications

...2016 National Patient Safety Goals

- 6: Reduce harm with clinical alarms
- 7: Reduce incidence of healthcare-acquired infections (HAIs)
  - Prevent HAIs due to multidrug-resistant organisms
  - Prevent surgical site infections

National Quality Forum (NQF) Safe Practices

- 13: Order read-back and abbreviations
- 17: Medication reconciliation
- 22: Surgical site infection prevention
- 24: Multidrug-resistant organism prevention
- 32: Glycemic control
QUESTION #6
You are the pharmacist on the medicine service and have been invited to the Quality Committee meeting to present a plan to improve Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) scores. Which of the following programs would meet this goal?

A. Medication education program
B. Early urinary catheter removal protocol
C. Pharmacist-driven venous thromboembolism risk assessment and prophylaxis initiation
D. Implementation of an antimicrobial stewardship program

Value-Based Purchasing
- Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)
- Core Measures
  - Acute myocardial infarction
  - Heart failure
  - Pneumonia
  - Surgical Care Improvement Project (SCIP)

HCAHPS Survey
- 32 question survey
  - Communication with doctors and nurses
  - Responsiveness of hospital staff
  - Cleanliness and quietness of environment
  - Pain management
  - Communication about medicines
  - Care transitions and discharge
  - Overall rating of hospital

Hospital Compare

ORYX® Measures
- The Joint Commission
- Performance measures
  - Hospital’s performance in important care, services, and treatment areas
  - Hospital’s ability to effect change in clinical processes

http://www.jointcommission.org/facts_about_oryx_for_hospitals/
HEDIS®
• Healthcare Effectiveness Data and Information Set
• National Committee for Quality Assurance
• 80 measures across 5 domains of care
  – Childhood immunizations
  – Pharmacotherapy management of COPD exacerbation
  – Medication management of people with asthma
  – Controlling high blood pressure

QUESTION #7
Which of the following is an example of a hospital-acquired condition as defined by CMS?

A. Postoperative pulmonary embolism
B. Stage II pressure ulcer
C. Medication error
D. Guillain-Barre syndrome

Hospital-Acquired Conditions
• Foreign Object Retained After Surgery
• Air Embolism
• Blood Incompatibility
• Stage III and IV Pressure Ulcers
• Falls and Trauma
• Manifestations of poor glycemic control
• Catheter-associated UTI
• Vascular catheter-associated infection
  • SSI, mediastinitis, following CABG
  • Surgical Site Infection following bariatric surgery
  • SSI following certain orthopedic procedures
  • SSI following CIED
  • DVT/PE following certain orthopedic procedures
  • Iatrogenic pneumothorax with venous catheterization

Meaningful Use
• Use of electronic health record (EHR)
• Compliance to improve
  – Better clinical outcomes
  – Improve population health
  – Increase transparency
  – Improve research data

Organizational Efforts
• Reduce readmissions
• Hospital Engagement Networks (HENs)
• Care models
  – Medical home
  – Federally qualified health centers

Accountable Care Organizations (ACOs)
• Accountable Care Organizations
• Population Health
  – Treating populations of patients
Script Your Future Campaign

- National Consumers League
- Focuses primarily on improving medication adherence
- Tools
  - 12 questions to ask your doctor or pharmacist about your medicine
  - Pocket medicine list
  - Tips for taking medicines safely
  - Caregiver’s medicine toolkit