Course
Practicum in Health Science - Pharmacology

Unit I
Preparation for Practicum

Essential Question
Why is safety in the pharmacy important not only to the patient, but the pharmacy staff as well?

TEKS
130.205 (c) 6A, 6B, 6C, 6D

Prior Student Learning
Understanding of proper safety practices in the workplace or lab.

Estimated time
1 to 2 hours

Rationale
Safety in dispensing and administrating pharmaceutical agents is important to prevent personal and client illness or injury.

Objectives
Upon completion of this lesson, the student will be able to:
- Know safety standards and rules associated with the pharmacy and identify unsafe practices
- Observe safe procedures in the administration of client care
- Demonstrate these safe procedures in the clinical setting

Engage
Ask students if they can identify the 6th leading cause of death.
(Drug error)

In small groups have students:
- Try to come up with celebrities who have been killed by pharmaceutical mistakes, overdoses, etc.
  (HINT: Michael Jackson, Brittany Murphy, Heath Ledger, Anna Nicole Smith)
- Discuss how human error can lead to pharmacy mistakes
- Discuss how pharmacy drugs come about and who they are tested on for efficacy and who monitors the distribution

Key Points
I. Safety in the Pharmacy
   A. Personal safety
      1. Safety from physical harm
         a. substances
         b. supplies (chemicals, poisons, etc.)
         c. equipment
         d. improper body mechanics
      2. Employee responsibilities
         a. maintain a safe work place
         b. apply principles of proper body mechanics
         c. wear appropriate PPE (Personal Protection Equipment) when indicated
         d. follow proper procedures in handling pharmaceutical agents that may pose a hazard to the practitioner
         e. know where to locate the material safety data sheets (MSDS)
         f. know and apply policies and procedures in case of emergency
i. fire safety  
ii. chemical spills and other hazardous materials  
iii. body fluids  
iv. standard precautions  
v. equipment maintenance and failure  
vi. internal disasters (fire, robbery, bomb threat, etc.)  
vii. external disaster (weather related, traffic disaster, etc.)

B. Environmental Safety  
1. Clean work place  
2. Proper ventilation  
3. Proper lighting  
4. Adequate set-up and layout of work place  
5. Properly functioning equipment  
6. Well trained employees aware of potential hazards

II. Rules and Regulations of Regulatory Agencies  
A. Occupational Safety and Health Administration (OSHA)  
1. Workplaces may be inspected by OSHA officers without prior announcement in order to accomplish intent to decrease hazards in the workplace and maintain a reporting system for monitoring job-related injuries and illness  
2. They develop mandatory job safety and health standards

B. Drug Enforcement Agency (DEA)  
1. Established in 1970 when the Controlled Substances Act replaced the Harrison Narcotics Act of 1914; intended to regulate the manufacturing and dispensing of dangerous and potentially abused drugs  
2. Divided potentially addictive drugs into six categories or schedules based on potential for physical or psychological dependence; these drugs are known as schedule drugs or controlled substances  
3. Regulates handling, storage and disposal of controlled substances  
4. Issues DEA numbers to individuals who are authorized to prescribe medications as part of their professional practice  
5. Sets standards on special prescription forms for controlled substances  
6. Establishes record keeping requirements for the distribution of controlled substances

C. U.S. Food and Drug Administration (FDA)  
1. Established in 1930s in order for the government to review data submitted by drug manufacturers and evaluate the safety of drugs  
2. Authorized to approve or disapprove drugs submitted by manufacturers for marketing  
3. Outlines specific information required in order to make decision on approval or disapproval
4. Can remove any drug from the market even after it has been approved if unforeseen side effects become apparent
5. Has prevented many unsafe drugs from reaching consumers
6. Has removed many dangerous and worthless drugs from the market
7. Lately frequently criticized to be responsible for time lag in approving important new drugs
8. In recent years made concerted effort to streamline approval process, especially in regards to drugs used to treat life-threatening diseases; since then number of drugs that needed to be recalled has increased!
9. FDA Modernization Act of 1977 gave authority to quickly approve life-saving drugs
10. Interested in collecting data to prevent or limit the occurrence of
   a. adverse drug reactions
   b. unexpected obvious change in patient's condition which can reasonably be suspected as due to drug
11. may request drug recalls if not voluntarily initiated by manufacturer; FDA will not initiate recall

D. Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
   1. Pharmacy standards of JCAHO provide quasi-legal standard of practice for the profession
   2. In court of law practice standards define accepted professional practice and assume quasi-legal status
   3. Pharmacies must meet strict standards in order to be accredited by JCAHO
   4. Accreditation is voluntary but important if business is interested in dealing with third party payers who require certification through accreditation process, e.g. Medicaid, etc.

E. Pharmacy Boards regulate who is allowed to dispense medicine

III. Safe Practices
A. Patients trust pharmacy personnel to
   1. Provide accurate and competent service
   2. Safe and effective medications
   3. Dispense according to prescribers directions

B. Pharmacy must ensure
   1. Right drug – always double check the label on bulk bottle for strength and correctness
   2. Right patient
   3. Right dosage
   4. Right route
   5. Right time
   6. Right attitude
C. Practitioner must be familiar with
   1. Common side effects
   2. Contraindications
   3. Drug or food reactions with medications
   4. Generic drugs that may be substituted

D. Practitioner should know at minimum the following information for the
drugs most used in individual practice setting or geographical
location
   1. Adverse drug reactions
   2. Side effects
   3. Contraindications
   4. Drug/food interactions
   5. Safe/effective dosage range
   6. Common dosage regimens
   7. Dosage forms
   8. Route of administration

E. Reviewing Refills
   1. Number of refills
   2. Correct drug selection
   3. Significantly early or late requests for refills may indicate
      medication misuse

F. Beware of dispensing errors

G. Proper storage of pharmaceuticals
   1. Store in original container until dispensed
   2. Follow manufacturer's directions for proper storage
   3. Follow proper disposal of expired drugs
      a. deteriorated drugs are ineffective
      b. deteriorated drugs may be a hazard if a condition not treated
         appropriately
      c. deterioration may cause chemical changes leading to
         dangerous reactions

IV. All schedule II drugs must be kept under lock and key. With schedule III,
IV, and V drugs, lock and key storage is optional but suggested.

Activity
I. Formulate a list of potential hazardous materials to be encountered in a
pharmacy, how to properly store and handle them, and how to intervene
in case of accidental spill or exposure.

II. Research and identify the roles of OSHA, DEA, FDA, and JCAHO as
they apply to the pharmacy as well as at least three Drug and Safety
Laws (Ex. Childproofing the containers, DEA #, etc.). Document
consequences of non-compliances.
III. Invite the Risk Management representative or a Pharmacy Tech/Pharmacist to discuss safety in a pharmacy.

IV. Complete the Case Studies.

V. If funding allows OSHA certification is available with CareerSafe Online at www.careersafeonline.com

Assessment
Safety in the Pharmacy Quiz

Materials
MSDS samples
Fire evacuation map of your facility
Fire safety policy of your facility, possibly from student or employee handbook
Samples of PPE (gowns, gloves, masks, goggles, foot covers, etc.)
KEY – SAFETY IN THE PHARMACY

Occupational Safety and Health Administration (OSHA) http://www.osha.gov/

Drug Enforcement Agency (DEA)

U.S. Food and Drug Administration (FDA)
http://www.fda.gov/

Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
http://www.jointcommission.org/

Accommodations for Learning Differences
For reinforcement, the student will design and create an educational poster display identifying potentially hazardous materials to be found in a pharmacy and describing proper ways of handling in efforts to prevent contamination, injury, or further dangers.

For enrichment, the student will develop a policy and procedure manual covering personal and environmental safety for a new pharmacy about to be opened for business.

National and State Education Standards
National Health Science Cluster Standards
HLC06.01 Health care workers will understand the existing and potential hazards to clients, co-workers, and self. They will prevent injury or illness through safe work practices and follow health and safety policies and
procedures.

TEKS
130.205(c)(6)(A) integrate regulatory standards such as standard precautions and safe patient handling;
130.205 (c)(6)(B) respond to emergencies consistent with the student's level of training such as fire and disaster drills;
130.205 (c)(6)(C) evaluate hazardous materials according to the material safety data sheets; and
130.205 (c)(6)(D) apply principles of infection control and body mechanics in all aspects of the health science industry.

Texas College and Career Readiness Standards
Language Arts
I. A. 2. Generate ideas and gather information relevant to the topic and purpose, keeping careful records of outside sources.
II. A. 4. Draw and support complex inferences from text to summarize, draw conclusions, and distinguish facts from simple assertions and opinions.
Case Studies

Discuss the following case studies.

A woman presents a prescription to the pharmacist. The Rx is written for Norinyl for birth control. The pharmacy technician filled the prescription with Nardil, a mild antidepressant. The pharmacist quickly checked the prescription but did not pick up the medication, and the error was not discovered until after the patient became pregnant. She delivered a healthy baby girl.

A pharmacist received a prescription for Tamoxifen, an oral drug used for certain types of breast cancer. The prescription was filled with Tambocor, an antiarrhythmic drug used by cardiologists to treat arrhythmias and other serious heart disorders. The prescription was refilled incorrectly on two other occasions before the error was corrected.
SAFETY IN THE PHARMACY

1. Who is responsible for the employees’ personal safety?

2. What does the acronym PPE stand for?

3. Give 5 (five) examples of PPE
   ___________________________
   ___________________________
   ___________________________
   ___________________________
   ___________________________

4. List 5 (five) examples for which employees are to be expected to know the policies and procedures in case of emergency:
   ___________________________________________________________________
   ___________________________________________________________________
   ___________________________________________________________________
   ___________________________________________________________________
   ___________________________________________________________________

5. Who may inspect workplaces without prior announcement in order to accomplish intent to decrease hazards in the workplace? (give the complete name)
   ___________________________________________________________________

6. Which agency was established in 1970 when the Controlled Substance Act replaced the Harrison Narcotics Act of 1914?
   ___________________________________________________________________

7. Which agency was established in 1930 in order for the government to review data submitted by drug manufacturers and evaluate the safety of drugs?
   ___________________________________________________________________

8. How do pharmacies qualify for accreditation by JCAHO?
   ___________________________________________________________________
KEY – SAFETY IN THE PHARMACY

1. it is a shared responsibility between then employer and the employee.

2. Personal Protection Equipment


4. (any five): chemical spills and other hazardous materials
   body fluid exposure
   standard precautions
   equipment maintenance and failure
   external disasters (weather, traffic, etc.)
   internal disasters (fire, robbery, bomb threat, etc.)

5. Occupational Safety and Health Administration (OSHA)

6. Drug Enforcement Agency (DEA)

7. Food and Drug Administration (FDA)

8. By meeting strict standards