Pharmacology learning objectives chapters 1-9

Describe history of pharmacologyModern pharmacology is thought to have begun in the early 1800's, when chemists were making remarkable progress in isolating specific substances (morphine, cocaine, etc) from their natural product sources. Describe history of pharmacology, 2In the 20th century, pharmacologists no longer needed to rely on the slow, laborious process of isolating active agents from scarce natural products; they could synthesize drugs in the laboratory. ONPHARMACOLOGY LEARNING OBJECTIVES CHAPTERS 1-9 SPECIFICALLY FOR YOUFOR ONLY$13. 90/PAGEOrder NowIdentify sources of drugs and drug informationDrug Regulations & Standards:

-Formulary, the 1st standard commonly used by pharmacists; a list of drugs & drug recipes.

-US Pharmacopoeia (USP), 1st comprehensive publication of drug standards (est. 1820)

-US Pharmacopoeia-National Formulary (USP-NF), (est 1975) USP label can be found on many meds verifying purity and exact amounts of ingredients found within the container.

-Food, Drug, & Cosmetic Act, passed by congress (1938) 1st law preventing the sale of drugs that had not been thorughly tested before marketing.

-Food & Drug Administration(FDA), (est 1988), as an agency of the US Dept of Health & Human Services; Responsibilities include: 10 Ensure safe & effective use of prescription and OTC drugs, 2) Regulated use of serums, vaccines, and blood products (biologic drugs); 3)Oversees administration of herbal products and dietary supplements. Define Legal & Ethical Issues in Pharmacology• Legal issues in pharmacology - State & federal legislation dictate the boundaries within which professional nurses practice: Standards

of Care & Practice - hospital licensing laws; Professional & specialty organization standard, American Nurses Association (ANA); Written policies & procedures of the employing institution - Joint Commission

• Ethical issues in pharmacology - The American Nurses Association Code of Ethics for Nurses ICN Code of Ethics for Nurses should be familiar frameworks of practice for all nurses and serve as ethical guidelines for nursing care: -Ensures that nurse is acting on behalf of patient and with patient's best interests at heart - Non-judgmental nursing care from start of patient's treatment until the time of patient's discharge; -Nurse has the right to refuse to participate in any treatment or aspect of a patient's care that violated the nurse's personal ethical principles, but his should be done without deserting the patient. Identify the advantages and disadvantages of prescription drugs-To obtain prescription drugs, a patient must receive a written order from a health care practitioner with legal authority

-Patient must be examined by a physician NP or PA

-Be given a specific diagnosis

-Practitioner can maximize therapy by ordering the correct for the pt's condition and by conveying the amount and frequency of drug to be dispensed.

The practitioner has the opportunity to teach the pt the proper use of Rx drugs and what adverse effects to watch for. Identify the advantages and disadvantages of Over-the-Counter (OTC) drugs+OTC's do NOT require a Rx +Pt preference because the drugs are more easily obtained and less expensive.

+ Since to physician appt is required, the pt saves time and money.

-W/O assistance of a health care provider, choosing the proper OTC drug for

a specific problem can be challenging for a pt.

-OTC can react with food, herbal products, prescription meds, or other OTCs.

-Self treatment is sometime ineffective, and the potential for harm may increase if symptoms are allowed to progress. Explain the Controlled Substance Act•Also called the Comprehensive Drug Abuse Prevention and Control Act. Hospitals and pharmacies must register with the Drug Enforcement Administration (DEA) and then use their assigned registration numbers to purchase scheduled drugs. Hospitals and pharmacies must maintain complete records of all quantities purchased and sold. Physicians, nurse practitioners, and others with prescriptive authority must also register with the DEA and receive an assigned number before prescribing these drugs. Drugs with higher abuse potential have more restrictions. A special order form must be used to obtain Schedule II drugs, and orders must be written and signed by the health care provider. Telephone orders to a pharmacy are not permitted; patients must visit their health care provider first. Those convicted of unlawful manufacturing, distributing, or dispensing of controlled substances face severe penalties. Explain Schedule CategoriesClassified according to their potential for abuse.

Potential Risk//Abuse--Physical--Psychologic-TherapeuticUse

Schedule I---highest---high--------high-----------limited or none

Schedule II ---high------high--------high----------Used with Rx

Schedule III ---mod-----mod--------high---------Used with Rx

Schedule IV---lower---lower--------lower-------Used with Rx

Schedule V---lowest--lowest-------lowest-----Used w/o RxExplain Dispensing Restrictions-Hospitals & pharmacies must register with the DEA and then use their assigned registration numbers to purchase scheduled drugs.

-Hospitals & pharmacies must maintain complete records of all quantities of these drugs purchased and sold.

-Health care providers with prescriptive authority must also register with the DEA and receive an assigned number before prescribing these drugs.

-Drugs with higher abuse potential have more restrictions. Telephone orders to a pharmacy aren't permitted. Refills for Schedule II drugs are not permitted; pts must visit their health care provider. Those convicted of unlawful manufacturing, distributing, or dispensing of controlled substance face sever penalties. Examples of Controlled SubstanceSchedule I - heroin, lysergic acid diethylamide (LSD), marijuana, and methaqualone

Schedule II - morphine, phencyclidine (PCP), cocaine, methadone, and methamphetamine

Schedule III - anabolic steroids, codeine and hydrocodone with aspirin, Tylenol, and some barbiturates

Schedule IV - dextropropoxyphene, pentazocine, meprobamate, diazepam, alprazolam

Schedule V - OTC cough medicines with codeine, diphenoxylate with atropineExplain the process involved in the development of new drugs•Stages of Drug Approval

-Stage 1 - Preclinical Investigation - involves extensive laboratory research. Scientists perform many tests on human and microbial cells cultured in the laboratory. Studies are performed in several species of animals to examine the drug's effectiveness at different doses, and to look for adverse effects.

Phase I - Purpose is to determine the optimal dosage range and pharmacokinetics of the drug and to ascertain if further testing is needed. Specific monitoring tests are performed during this phase.

-Stage 2 - Clinical Investigation - the second stage of drug testing, takes place in three different stages termed clinical phase trials. Clinical phase trials are the logest part of the drug approval process. Clinical pharmacologists first perform tests on healthy volunteers to determine proper dosage and to assess for adverse effects. Large groups of selected patients with the particular disease are then given the medication. Clinical investigators from different medical specialties address concerns such as whether the drug is effective, worsens other medical conditions, interacts unsafely with existing medications, or affects one type of patient more than others. Phase II - Participants are closely monitored to determine the drug's effectiveness and identify any adverse effects. Therapeutic dosage rages are refined in this phase.

-Stage 3 - NDA Review - is the third stage of the drug approval process. During this stage, the drug's brand name is finalized, Clinical phase III trials and animal testing may continue depending on the results obtained from preclinical testing. The average NDA review time for new drugs is approximately 17-24 months. Phase III - Info obtained during this phase helps identify any risks associated with the new drug. To enhance objectivity, many studies are designed to incorporate a placebo.

-Stage 4 - Postmarketing studies - the final stage of the drug approval process, begins after clinical trials and the NDA review have been completed. The purpose of this stage is to survey for harmful drug effects in a larger population. Some adverse effects take longer to appear and are not identified until a drug is circulated to large numbers of people. Discuss how the US Food and Drug Administration (FDA) has increased the speed with which new drugs reach consumers• Prescription Drug user Fee Act - est.

1992, FDA official, members of Congress, and representatives from pharmaceutical companies negotiated this act on a 5-year trial basis. This act required drug and biologic manufacturers to provide yearly product user fees. This added income allowed the FDA to hire more employees and to restructure its organization to more efficiently handle the processing of a greater number of drug applications. The result of this was successful; from '92 to '96, the FDA approved double the number of drugs while cutting some review times by as much as half. In '97, the FDA Modernization Act re-authorizes the Prescription Drug User Fee Act. Nearly 700 employees were added to the FDA's drug and biologics program, and more than $300 million was collected in user fees. Identify the nurse's role in the drug approval processDuring the post-marketing surveillance period of Phase IV that nurses have the most frequent opportunities to participate in the drug approval process. While nurses working at larger, urban medical centers may participate in administering medications during Phase II & III trials, all nurses administering medication monitor for therapeutic effects and adverse reactions from the drugs they give their patients. Whenever a possible drug reaction is noted, nurses are responsible for reporting the reaction to the prescriber and appropriate health care agency personnel. By monitoring for and reporting adverse effects, nurses can ensure that better post-marketing surveillance is achieved. Explain pharmacokinetics across the life spanAbsorption, distribution, metabolism, & excretionDescribe how various drug dosage forms affect absorptionTablets for oral, most common, must be dissolved by the stomach before it can diffuse across intestinal mucosa; Liquid oral meds faster than tabs; drug that is injected intramuscularly will be absorbed faster than the tablet or liquid because it will not require

interaction with the gastrointestinal tract. Also, dosage formulation & chemical properties of the drug will influence the rate of absorption. Since the membranes lining the gastrointestinal tract are composed primarily of lipids, a drug that is lipid soluble will be able to cross the membrane and enter the circulation better than a non-lipid soluble drug. Explain pharmacodynamics across the lifespan...