INTRODUCTORY CLINICAL PHARMACOLOGY

Chapters 1, 2 and 4

General Principles of Pharmacology

Chapter 1

Pharmacology

- The study of drugs and their action on living organisms.
Drugs Development

- 7-12 years
- FDA responsible for approving new drugs and monitoring drugs currently in use for adverse or toxic effects.
- 2 phases
  - Pre-FDA phase
  - FDA phase

Investigational New Drug (IND)

- 3 phases - last from 2 – 10 years
  (5 year average) – Clinical Trials
  - Phase I lasts 4 – 6 weeks involves 20 – 100 individuals
  - Phase II larger subject population
  - Phase III larger subject population offers additional information on dosing and safety.

New Drug Application (NDA)

- Submitted after the investigative phase is completed and the drug is found to be safe and effective.
- All data from clinical trials submitted
- Material is reviewed (~ 2 years)
- Approved or disapproved based on review.
- If approved the drug continues to watched in the market, focus particularly on adverse drug reactions. (Celebrex)
Special FDA Programs

- Orphan Drug Program
  - Orphan Drug Act: Passed to encourage development and marketing of products – rare diseases
  - Rare disorders: Tourette’s syndrome; ovarian cancer; amyotrophic lateral sclerosis
  - Drug approved: Manufacturer gets 7 years of exclusive marketing rights

Special FDA Programs

- Accelerated Programs
  - Accelerated approval / Provisional approval
  - Diseases that are a threat to public health: AIDS – Considered for shorter IND approval process
  - Allows primary care providers to administer medications with positive results in early Phase 1 and 2 clinical trials
  - Waiting until final approval not required: Drug continues to prove beneficial – Process of approval accelerated

Drug Names

- Chemical Name
- Generic Name
- Official Name
- Trade Name (Brand Name)
Drug Categories
- Prescription
- Nonprescription
- Controlled Substance

Controlled Substances
- Most carefully monitored
- High abuse potential
- May cause:
  - Physical Dependency – the body's dependence on repeated administration of a drug
  - Psychological Dependency – the mind's dependency on the repeated administration of a drug.
  - Schedule I (C-I)
  - Schedule II (C-II)
  - Schedule III (C-III)
  - Schedule IV (C-IV)
  - Schedule V (C-V)

Drug Use and Pregnancy
- Teratogen
- 5 Pregnancy Categories
  - Pregnancy Category A
  - Pregnancy Category B
  - Pregnancy Category C
  - Pregnancy Category D
  - Pregnancy Category X
Drug Activity Within the Body

- Drugs act in various ways in the body
- Oral drugs: Three phases
  - Pharmaceutics: Dissolution of drug occurs; drug must be soluble to be absorbed
  - Pharmacokinetics: Absorption; distribution; metabolism; excretion
  - Pharmacodynamics

Pharmaceutic Phase

- Liquid and parenteral drugs: Already dissolved – quickly absorbed
- Solid forms of drugs: Tablets or capsules – Disintegrate into small particles; dissolve into body fluids in GI tract
- Enteric-coating tablets: Disintegrate after reaching alkaline environment of small intestine

Pharmacokinetic Phase

- Pharmacokinetics: Activities within the body after a drug is administered
  - Absorption
  - Distribution
  - Metabolism
  - Excretion
Absorption

- Drug particles within gastrointestinal tract: Move into body fluids
- Factors influencing rate of absorption: Route of administration; solubility of drug
- First-pass effect: Drug absorbed by small intestine; liver first metabolizes drug; remaining drug not sufficient to produce therapeutic effect
  - Patient needs higher dosage for desired effect

Distribution

- Systematic circulation: Drug distributed to various body tissues and target sites – interacts with specific receptors in body
- Factors affecting distribution: Protein binding (free/bound drugs); blood flow; solubility (lipid-soluble drugs/water-soluble drugs)
- Quick distribution: Heart; liver; kidneys
- Slow distribution: Other internal organs; skin; muscle

Metabolism and Excretion

- Metabolism: Body changes drug to a more or less active form for excretion
- Excretion: Elimination of drugs from the body
- Patients with kidney disease: Require dosage reduction and careful monitoring of kidney function
- Older adults: Diminished kidney function – require careful monitoring and lower dosages
Half-life
- Time required for the body to eliminate 50% of the drug
- Drugs with short half-life: Administered frequently
- Drugs with long half-life: Require less frequent dosing
- Difficulty in drug excretion: Increases half-life and risk of toxicity

Onset, Peak, and Duration
- Onset of action: Time between drug administration and beginning of therapeutic effect
- Peak concentration: Absorption rate equals elimination rate
- Duration of action: Time for drug to produce therapeutic effect

Drug Reactions
- Adverse Drug Reactions
- Allergic Drug Reactions
- Drug Idiosyncrasy
- Drug Tolerance
- Cumulative Drug Effect
- Toxic Reactions
- Pharmacogenetic Reactions
Pharmacodynamic Phase

- Pharmacodynamics: Study of drug mechanisms producing biochemical/physiologic changes in body
- Primary effect of drug: Desired or therapeutic effect
- Secondary effect of drug: Other desirable or undesirable effects
- Drugs exert action – two mechanisms: Alteration in 1) cellular form and 2) environment

Receptor-mediated Drug Action

- Drug interacts with receptor; function of a cell alters; drug molecule joins with reactive site (receptor) on surface of cell
- Agonist: Binds with and stimulates receptor – therapeutic response
- Antagonist: Joins with but does not stimulate receptors; prevents drug response; competitive/noncompetitive
- Effects of number of available receptor sites; potent drugs

Alteration in Cellular Environment

- Physical changes: Osmotic pressures; lubrication; absorption; conditions – surface of cell membrane
  - Mannitol; sunscreen; activated charcoal; docusate
- Chemical changes: Inactivation of cellular functions; alteration of chemical components of body fluid – change in the pH
  - Antacids; cancer drugs or some antibiotics
Various Drug Reactions

- Allergic drug reactions
- Drug idiosyncrasy
- Drug tolerance
- Cumulative drug effect
- Toxic reactions
- Pharmacogenetic reactions

Allergic Drug Reactions
(Hypersensitivity Reactions)

- Usually begin after more than one dose of the drug is given; body views drug as antigen
- Signs and symptoms: Itching; skin rashes; hives; wheezing; cyanosis; sudden loss of consciousness; swelling of eyes, lips, or tongue
- Anaphylactic shock; hypotension and shock; angioedema

Anaphylactic Shock Symptoms

- Respiratory
  - Bronchospasm, Dyspnea, SOB, Feeling of fullness in throat, Cough, Wheezing
- Cardiovascular
  - Hypotension, tachycardia (>100), palpations, syncope, loss of consciousness, cardiac arrest
- Integumentary
  - Urticaria, angioedema, pruritus, sweating
- Gastrointestinal
  - Nausea, vomiting, ABD pain
Drug Idiosyncrasy

- Unusual, abnormal reaction to drug; different from expected reaction
- Cause: Believed to be due to genetic deficiency

Drug Tolerance

- Decreased response to a drug: Requires increased dosage for desired effect
- Example: Narcotics or tranquilizers taken for a long time

Cumulative Drug Effect

- Patients with liver and kidney disease: Body is unable to metabolize and excrete one dose of drug before next dose is given
- Dose lowered to prevent toxic drug reaction
Toxic Reactions

- Drug is administered in large dosages; blood concentration levels exceed therapeutic levels
- Reverse drug toxicity: Administer another drug as antidote; monitor drugs with low safety margin

Drug Interactions

- One drug interacts and interferes with the action of another drug
  - Oral anticoagulants; oral hypoglycemics; anti-infectives; antiarrhythmics; cardiac glycosides; alcohol
- Effects: Additive; synergistic; antagonistic

Additive Drug Reaction

- Combined effect of two drugs is equal to sum of each drug given alone ($1 + 1 = 2$)
Synergistic Drug Reaction

- Drug synergism: Drugs interact with each other and produce a sum greater than the sum of their separate actions (1 + 1 = 4)

Antagonistic Drug Reaction

- One drug interferes with action of another: Neutralization/decrease in effect of one drug

Drug–Food Interactions

- Food may impair or enhance its absorption
  - Drug taken on empty stomach (captopril)
  - Drugs that irritate stomach; cause nausea; vomiting; epigastric distress: Given with meals (anti-inflammatory drugs; salicylates)
  - Drug–food mixture: Drugs combine with a drug forming an insoluble food (tetracycline administered with dairy products)
Factors Influencing Drug Response

- Age
- Weight
- Gender
- Disease
- Route of Administration

Herbal Therapy and Dietary Supplements

- Herbal therapy
  - Type of complementary/alternative therapy – using plants or herbs
  - Explain that ‘natural’ is not necessarily safe
- Nutritional or dietary supplements
  - Substances not regulated as drugs by FDA; effective for promoting health

Discussion Question

- A 20-year-old client is admitted to the clinic for a hand injury and is treated with penicillin. The next day, the client reports having nauseous feeling and severe abdominal pain. The client also has a feeling of fullness in the throat.
  - A) What is the possible cause of the client’s symptom(s)?
  - What is the condition known as?
Discussion Question

- A 20-year-old is has been taking penicillin. He is admitted to the hospital with a nausea, severe abdominal pain and a feeling of fullness in the throat.
  - What is the possible cause of the patient's symptoms?
  - What is this condition known as?
  - What should the nurse do to ensure the patient suffers no adverse effects?

Discussion Question

- You are assigned to care for a 28 year old pregnant women. You are to provide patient education on the different categories the FDA has established for drugs. The categories suggest the potential of a drug to cause birth defects. You discuss category D with her.
  - Which points are included in pregnancy category D?
Introduction

- Drug administration
- Understand basic concepts
- Nurse’s role
  - Monitor the therapeutic response
  - Report adverse reactions
  - Teach the patient and family members

Eight Rights of Drug Administration

- Right Patient
- Right Drug
- Right Dose
- Right Route
- Right Time
- Right Documentation
- Right to Know
- Right to Refuse

Considerations in Drug Administration

- National Patient Safety Goals
  - Accrediting body for hospitals: JCAHO
  - Approved the 2008 National Patient Safety Goals
Considerations in Drug Administration

• Drug Errors
• Medication Order
• Once a Week Drugs
• Drug Dispensing Systems
  – Computerized Dispensing System
  – Unit Dose System
  – Floor Stock

Considerations in Drug Administration

Drug errors – patient receives:
– The wrong dose
– The wrong drug
– An incorrect dosage of the drug
– A drug by the wrong route
– A drug given at the incorrect time

• Nurses: Last defense against detecting drug errors; if error occurs, report immediately

Considerations in Drug Administration (cont’d)

• Each time a drug is prepared and administered: Follow the eight rights
• Precautions taken by the nurse:
  Confirm any questionable orders; verify calculations with another nurse; listen to the patient; concentrate on only one task at a time
• Most common occurrence of errors: Insulin and heparin
Considerations in Drug Administration (cont’d)

• The medication order: To administer medication, a physician’s order is essential
  – Common orders: Standing; single; PRN; STAT
• Once-a-week drug: Doses designed to replace daily doses of drugs; beneficial for those experiencing mild adverse reactions
  – Example: Alendronate (Fosamax) – Treat osteoporosis

Considerations in Drug Administration (cont’d)

• Drug dispensing system
  – Computerized dispensing system
  – Unit dose system
  – Floor stock

General Principles of Drug Administration

• Factual knowledge of each drug given
  – Reason given, general action, common adverse reactions, special precautions, & normal dose ranges
• Patient considerations
  – Allergy history, previous adverse reactions, patient comments, & change in patients condition
Situations

- Comments by patient indicating an adverse reaction.
- Comments stating the drug looks different from the one previously received.
- Comments by the patient that the drug had been discontinued.
- A change in one or more vital signs or the appearance of new symptoms.

Preparing a Drug for Administration

- Check written order – Clarify if any questions
- Prepare drugs in a quiet well lit area
- Check each label 3 times
- Never remove a drug from an unlabeled container or a container with an illegible label.
- Wash hands

- Do not touch tablets or capsules directly.
- Observe aseptic technique when handling syringes and needles
- Be alert for drugs with similar or sound alike names.
- Replace caps of containers immediately after med is removed.
- Never give a drug that someone else has prepared.
Preparing a Drug for Administration

- Return drugs to special storage areas after they are prepared.
- Never crush tablets or open capsules without first checking with pharmacist.
- Do not open unit dose packages before reaching the bedside.

Oral Administration

- Upright position
- Full glass of water – few sips before placing tablet in mouth
- Place pill on back of tongue
- Give any special instructions
- Never leave med at bedside unless specific order from doctor received
- Buccal – cheek – given for a local effect - lozenges
- NGT – check for placement before administering meds flush with water after meds
- Sublingual – do not swallow or chew

Parenteral Route

- Subcutaneous (SC), intramuscular (IM), intravenous (IV), or intradermal route
  - Wear gloves
  - Cleanse with alcohol in circular motion
  - Aspirate for IM administration
  - Do not recap
OSHA

- Needle sticks
  - 80% could be prevented
  - Expose you to AIDS, Hepatitis C, Hepatitis B
  - Also exposed to TB, Syphilis, malaria

Subcutaneous Route

- Places the drug into the tissue between the skin and the muscle
- Nursing responsibilities
  - Volume of injection: Generally volume of 0.5 – 1 mL used. Volumes larger than 1 mL should be given in 2 sites with separate needles and syringes
  - SC injection sites: Upper arms; upper abdomen; upper back
  - Needle length and angle of insertion: 45 degree angle, 23 – 25 gauge needle, ½ to 5/8 inches

Intramuscular Route

- Into a muscle
- Absorbed more rapidly than SC
- Larger volume (1-3 mL)
- Volumes > 3 mL divided into 2 injections
- Generally use 3 mL syringe with 22 gauge 1 ½ inch needle
- Needle inserted at 90 degree angle
- Sites: Deltoid (upper arm), ventrogluteal or dorsogluteal (hip) and vastus lateralis (thigh)
**Z-track technique**
- Used when drug is highly irritating to SC tissues or has the ability to permanently stain the skin
- Prevents the backflow of drug into the SC tissue

**Intravenous Route**
- Given directly into vein.
- May be given:
  - Slowly over 1 or more minutes
  - Rapidly (IV Push)
  - Piggyback
  - Saline Lock
- Extravasation – escape of fluid from blood vessels into surrounding tissues while the needle or catheter is in the vein.
- Infiltration – collection of fluid in tissues (usually SC) when the needle or catheter is out of the vein.

**Intradermal**
- Sensitivity tests – Tuberculin; skin allergy
- Nursing responsibilities
  - Injection sites: Inner part of forearm; upper back; hairless; avoid areas near moles, scars, or pigmented skin
  - 1-mL syringe; 25- to 27-gauge needle; 1/4 to 5/8 inch
  - Needle insertion: 15-degree angle; do not aspirate syringe or massage the area
Skin or Mucous Membrane Administration

• Topical - act on the skin but are not absorbed through the skin
• Transdermal – readily absorbed from the skin and provide systemic effects.
• Inhalation
  – Be sure to have patient rinse mouth after treatment

Discussion

• The nurse is caring for a patient scheduled for an operation. The nurse is required to administer drugs to the patient.
  – What should the nurse’s intervention be regarding the primary care provider’s order for this patient?
  – What information should a primary care provider’s order include?
  – Under what circumstances can the nurse question an order?

Discussion

• A nurse is caring for a patient with a nasogastric feeding tube.
  – What procedure should the nurse follow for administration of oral drugs to the patient?
Discussion

- A nurse is caring for a patient with asthma. The nurse is required to administer drugs to the patient through inhalation.
  - What are the responsibilities of the nurse regarding administration of drugs through inhalation?

Nursing Process

Chapter 4

5 Phases
- Assessment
- Nursing Diagnosis
- Planning
- Implementation
- Evaluation
Assessment

• Collecting objective and subjective data
  – Objective data
    • Facts obtained by means of a physical assessment, physical examination
  – Subjective data
    • Facts supplied by patient or patient’s family

Assessment

• Initial assessment
  – Objective and subjective data collected when patient is first seen in a hospital, outpatient clinic, health care provider’s office, or other type of health care facility
  – Objective data
    • Obtained during initial assessment through activities such as examining skin, obtaining vital signs, palpating a lesion, auscultating lungs

Assessment

• Initial assessment (cont’d)
  – Subjective data
    • Acquired during initial assessment by obtaining information from patient, such as family history of disease, allergy history, occupational history, a description of current illness or chief complaint, medical history, and drug history
Assessment

• Ongoing assessment
  – Made at time of each patient contact and may include the collection of objective data, subjective data, or both
  – Objective data
    • Blood pressure; pulse; respiratory rate; temperature; weight; examination of the skin; examination of an intravenous infusion site; auscultation of the lungs

Assessment

• Ongoing assessment (cont’d)
  – Subjective data
    • Any statements made by the patient about relief or non-relief of pain or other symptoms after administration of a drug

Nursing Diagnosis

• Description of patient’s problems and their probable or actual related causes based on subjective, objective data in database
• Provide framework for selection of nursing interventions to achieve expected outcomes
• North American Nursing Diagnosis Association (NANDA): Formed to standardize the terminology used for nursing diagnoses
Nursing Diagnosis

• Effective Therapeutic Regimen Management
• Ineffective Therapeutic Regimen Management
• Deficient Knowledge
• Noncompliance
• Anxiety

Planning

• Nurse develops expected outcomes after nursing diagnoses are formulated
  – Expected outcome: Describes maximum level of wellness that is reasonably attainable for patient
  – Expected patient outcomes related to drug administration
    • Patient will effectively manage the therapeutic regimen

Planning

– Expected patient outcomes related to drug administration (cont’d)
  • Patient will understand the drug regimen
  • Patient will comply with the drug regimen
Planning

• Nurse: Select appropriate interventions on basis of expected outcomes to develop plan of action or patient care plan
• Planning phase: Describes the steps for carrying out nursing activities or interventions that are specific and that will meet the expected outcomes
  – Expected outcomes serve as basis for evaluating the effectiveness of nursing interventions

Implementation

• Carrying out of a plan of action is natural outgrowth of assessment, planning phases of nursing process
• Refers to preparation and administration of one or more drugs to specific patient when related to administration of drugs

Implementation

• Effective therapeutic regimen management
  – Nursing diagnosis: Takes into consideration that patient is willing to regulate, integrate into daily living the treatment regimen
Implementation

– Effective therapeutic regimen management (cont’d)
  • Patient willing and able to manage treatment regimen: He or she may simply need information concerning drug: method of administration; what type of reactions to expect; what to report to primary health care provider

Implementation

– Effective therapeutic regimen management (cont’d)
  • Patient willing to take responsibility: Need to develop teaching plan that gives patient information needed to properly manage therapeutic regimen

Implementation

Ineffective therapeutic regimen management
  • NANDA definition: Pattern of regulating and integrating into daily living program for treatment of illness and sequelae of illness that is unsatisfactory for meeting specific health goals
Implementation

– Ineffective therapeutic regimen management (cont’d)
  • Patient who is not managing the drug regimen correctly: Nurse must ensure that patient understands drug regimen
  • Discuss drug regimen with patient, including reason drug is to be taken, times, amount, adverse reactions to expect, reactions that should be reported

Implementation

– Deficient knowledge
  • Absence or deficiency of cognitive information on a specific subject
  • Determine what information patient is lacking and then plan a teaching session that directly pertains to specific area of need

Implementation

– Noncompliance
  • Behavior of patient or caregiver that fails to coincide with therapeutic plan agreed upon by patient and health care provider
  • Lack of information about the drug, the reason the drug is prescribed, or the expected or therapeutic results; also result of anxiety or bothersome side effects
Implementation

- Anxiety
  - Vague uneasiness or apprehension that manifests itself in varying degrees – from expressions of concern regarding drug regimen to total lack of compliance with the drug regimen; decreases with understanding of therapeutic regimen
  - Critical for nurse: Allow time for a thorough explanation and to answer all questions and concerns in language patient can understand

Evaluation

- Decision-making process that involves determining effectiveness of nursing interventions in meeting expected outcomes
- Used to determine if the patient or family member understands the drug regimen
- Evaluate patient’s response to therapy: Check patient’s blood pressure every hour, inquire whether pain has been relieved, or monitor pulse every 15 minutes

- Evaluate patient’s or family’s understanding of drug regimen, noting if one or both appear to understand the material that has been presented
Discussion

• A nurse is required to administer a drug for a GI condition to an elderly patient. The patient refuses to comply with the treatment, saying that he is scared and apprehensive about the drugs that will be administered to him.
  – How should the nurse help this patient comply with the treatment?
  – What are the factors on which anxiety in a patient depends?

Introductory Clinical Pharmacology

Chapter 5
Patient and Family Teaching

The Teaching/Learning Process

• Teaching: An interactive process that promotes learning
• Learning: Acquiring new knowledge or skills
• Motivate patient
• Encourage patient participation
The Three Domains Of Learning

- Cognitive Domain
- Affective Domain
- Psychomotor Domain

Adult Learning

- Demonstrate technique
- Supervise the practice
- Help patient get ready
- Allow patient to perform the task

The Nursing Process as a Framework for Patient Teaching

- Identify patient health needs
- Devise a plan of care
- Initiate the plan
- Evaluate effectiveness of plan
The Nursing Process as a Framework for Patient Teaching (cont’d)

• Assessment
  - Gather data
  - Develop an effective teaching plan
  - Assess individual’s learning ability
  - Determine purpose of assessment

• Nursing Diagnoses
  - Effective Individual Therapeutic Regimen Management
  - Ineffective Therapeutic Regimen Management
  - Deficient Knowledge

• Planning
  - Actual development: Use strategies
  - Develop individualized teaching plan
  - Select relevant information
The Nursing Process as a Framework for Patient Teaching (cont’d)

• Implementation
  – Actual performance:
    Interventions identified in teaching plan
  – Put the plan into action
  – Begin teaching

The Nursing Process as a Framework for Patient Teaching (cont’d)

• Evaluation
  – Evaluate patient’s knowledge of materials presented
• Factual material: Ask patient to list/repeat information presented

Discussion

• Patient hospitalized with bronchial asthma and breathing problems. She has been prescribed certain drugs for the treatment of asthma. These drugs are administered by means of spray inhalers, the use of which has to be taught and practiced by the patient.
  – What is the responsibility of the nurse in this regard?
  – How should the nurse educate the patient about the use of the prescribed drugs?
  – How should the nurse encourage maximum patient participation in the learning process?
Discussion

- A patient is preparing for discharge from the hospital. The patient has some questions about the medications that need to be administered at home. The patient finds the regimen complex and difficult to remember.
  - Which nursing diagnoses would be most appropriate for the patient?
  - What nursing interventions could the nurse implement?