FOUNDATIONS OF PRACTICE
ADVANCED PHARMACOTHERAPEUTICS
LECTURE NOTES

FOUNDATIONS OF PRACTICE

1. Roles of registered nurses in medication management
    a. Often RN's find themselves offering the best drug a patient should receive with a physician and other prescribing/providers
    b. The RN is an advocate for the patient and his or her input should be sought and highly valued in the prescribing process
    c. Collaboration is key and that between the nurse and the prescriber often involves patient safety quality of care but…..
        i. **** ultimately the final responsibility is that of the providers

2. Role of the Practitioner
    a. Collecting a thorough history and physical examination (data)
    b. Formulating a diagnosis
    c. Create and implement a treatment plan
    d. Understanding the risk & benefit principles of the chosen medications
    e. Consider ethical and practical issues when prescribing
    f. Educating the patient on the medications, ADRS and MOA

3. Effective Drug Therapy Factors
    a. Step-by-step process of prescribing –
    b. Practitioner's role and responsibilities-
    c. Drug safety/product safeguards-
    d. Follow-up measures/goals of therapy (GOT)-
    e. Promoting adherence to therapeutic regimen-
    f. Keeping up to date with latest developments-

4. Advanced Knowledge
    a. NPs blend medicine and nursing knowledge.
    b. Understanding of disease process, pharmacology, and nursing
    c. Knowledge required to be a safe prescriber
    d. Pathophysiology and disease process
    e. Pharmacology
    f. Rational drug selection

5. Benefits of NP as Prescriber
    a. Nursing is foundational to NP practice
    b. Communication

c. Education
d. Lifestyle management
e. Nutrition
f. Holistic approach to care
g. Culturally specific and sensitive
h. Education is tailored to patient

6. Clinical Judgment in Prescribing (define and give examples of each)

    a. Is a prescription the right treatment?

    b. What are the effective drugs for the disease?

    c. What are the goals of therapy?

    d. Monitoring to see if drug is meeting goals?

    e. Duplications in medications

    f. Over the counter vs. prescription drugs

    g. Cost?

    h. Sources of information

7. Collaborating with Other Providers

    a. Collaboration is critical for quality patient care
    b. Physicians
        i. Historical issues in NP-medical doctor relationships
        ii. Different perspective on prescribing
    c. Pharmacist
        i. PharmD is a clinical practice doctorate.
        ii. Expert in pharmacokinetics and pharmacotherapeutics
    d. Other APRN's
        i. Share pearls for practicing, collaboration on scope of practice
    e. Other non-prescribing nurses
        i. CDE's; WOCN are specialized nurses with extra certification, assist with ordering

8. Process for Prescribing Medications

    a. Medication prescribing variables

b. Age, sex, race, culture

c. Weight

d. Allergies

e. Other diseases or conditions, other therapies, and previous therapies

f. Socioeconomic issues

g. Health beliefs

h. Pharmacogenomics

9. FDA
   a. Food and Drug Administration
   b. U.S. Food and Drug Administration (FDA)

   c. Role of the FDA IN DRUG THERAPY is to:

   d. clinical trials- conducting and monitoring through the process

   e. Approving new drugs for market and manufacture

   f. Ensuring safe drugs for public consumption

10. New Drug Approval Process

    a. Preclinical research

    b. Phases of drug testing before approval

    c. Phase I

    d. Phase II

    e. Phase III

    f. New drug application

    g. Post-marketing research

11. Official Labeling
    a. The FDA regulates what goes on a label.
    b. Labeling on over the counter (OTC) drugs
    c. Insert in prescription drugs
    d. Off-label prescribing
        i. Prescribing for a use not indicated on the official FDA label

12. Legal
    a. Decision is based on _____
    b. Understanding the medication being prescribed
    c. Rational scientific principles
    d. Expert medical opinion (the literature)
    e. Controlled clinical trials

13. OTHER CONCERNS OF DRUG THERAPY

    a. Prescription vs. nonprescription drugs

    b. Generic drugs vs. brand name drugs

    c. CAM

    d. Use of foreign medications

    e. Proper medication disposal

14. Writing a Prescription must include
    a. Prescribing date
    b. Patient name, address, date of birth
    c. Prescriber's name, address, and phone number
    d. Name of drug
    e. Dose, dosage regimen, route of administration
    f. Allowable substitutions
    g. Prescriber's signature and license number

15. Other "need to know" of Writing a Prescription
    a. Avoid the use of "as directed" or "as needed."
    b. Include the general indication, such as "for infection."
    c. Write "Dispense as Written" if generic substitution is not desired.

d. Include the patient weight, especially if pediatric or elderly.
e. Indicate if a safety cap is not required, as medications will be dispensed with them by default
f. Use metric units of measure, such as milligrams and milliliters
g. avoid apothecary units of measure
h. Avoid abbreviations

16. E-Prescribing Advantages
    a. Improved legibility of prescriptions
    b. Completed prescriptions INCREASES
    c. Greater convenience
    d. Increased compliance with formulary requirements
    e. Decreased drug–drug interactions
    f. Reduced medication errors with use of drug-checking software

17. Errors in Drug Prescribing
    a. Lack of drug knowledge
    b. Lack of patient information
    c. Poor communication

DRUG THERAPY OUTCOMES

18. Expected outcomes

    a. Improvement in clinical symptoms or pathologic signs

    b. Changes in biochemistry as determined by lab tests

    c. Undesirable outcomes

    d. Side effects

    e. Drug or food interactions

    f. Toxicity

19. Monitoring Effectiveness

    a. Passive monitoring:
        i. Patient is educated on expected outcome and instructed to contact provider

b. Active monitoring:
    i. follow-up laboratory tests or monitoring to measure therapeutic effectiveness

20. Medication Adherence Factors

a. Approachability of the health care provider

b. Perception by patient of respect with which he or she is treated by the practitioner

c. Belief the therapy is beneficial

d. the benefits of therapy outweigh the risks or side effects

e. Individualized treatment

f. Degree to which the patient participates in developing the treatment regimen

g. $$$ of the regimen

h. Intentional vs Nonintentional Adherence

21. Methods of Updating Drug Information
a. Reference books
b. Internet resources
c. Pharmacists
d. Easy-to-carry drug handbooks
e. Pocket guides

22. Legal issues in Advanced Prescribing

a. Collaborative Agreement:

b. Prescriptive Authority:

    i. Full to restricted practice

23. Prescriptive ability incorporates
    a. National Provider Identifier (NPI)
        i. Identify all health care providers by a unique number in standard transactions
        ii. Identify health care providers on prescriptions
        iii. Link provider in internal files
        iv. Coordinate between health plans
        v. Update patient EMR
        vi. Use in program integrity files

    b. Prescriptive Authority
        i. Regulated by the state in which the practitioner practices
        ii. State board of nursing, board of medicine, or board of pharmacy
        iii. Practitioner must be aware of procedures required when using drug samples
        iv. Practitioner must monitor for adverse drug events

24. Healthcare Literacy and Use of Medications
    a. For all patient interactions limited health literacy MUST be assumed
    b. NAAL (national Assessment of Adult Literacy)
    c. 36% of Americans function at the 2 lowest health literacy (levels out of 4)
    d. Below basic, basic, intermediate and proficient

25. Healthcare literacy
    a. https://health.gov/communication/HLActionPlan/pdf/Health_Literacy_Action_Plan.pdf

    b. Healthcare literacy and Cultural Influences and its effects on pharmacotherapeutics

26. Cultural & Ethnic Influences
    a. Religious and Cultural Competency
    b. Culture, Language, and Health Literacy Web site
    c. Resources for Translated Materials
    d. CDC.gov in Spanish
    e. Easy to Understand Medicine Instructions in 6 Language
    f. HealthReach from the National Library of Medicine is a resource of quality multilingual, multicultural public health information for those working with or providing care to individuals with limited English proficiency.

27. Ethical Issues
    a. Informed consent
    b. Prescribing for family or friends
    c. Sale of pharmaceuticals and supplements
    d. “disclosure”

PHARMACOGENOMICS

28. The study of the effects of genetic differences among people and the impact these differences have on the uptake, effectiveness, toxicity, and metabolism of drugs
    a. Humans share 99.9.% of DNA sequence
    b. less than 0.1% difference is about 3 million nucleotides
    c. Of the 0.1% difference, over 80% will be single nucleotide polymorphisms (SNPs).
    d. SNP is a single base substitution of one nucleotide by another
    e. An example: individual “A” has a sequence GAACCT, whereas individual “B” has a sequence GAGCCT; the polymorphism is a A/G.

29. Heterogeneity in genetic makeup
    a. This aspect contributes to many variations in pharmacokinetics
    b. Various factors contribute to specific observable pharmacodynamic differences.
    c. cytochrome P450 (CYP450) enzyme system is the MAIN drug metabolism pathway
    d. What are poor metabolizers and extensive metabolizers? How does that impact provider management?

30. Applying pharmacogenomics to clinical practice
    a. Genetic polymorphism
        i. Difference in the allele(s) responsible for the variation
        ii. Phase I and phase II metabolism
        iii. CYP450 enzymes account for ~75% of drug metabolism and bioactivation in the liver.
        iv. Certain CYP metabolize only one (or a very few) drug(s)
        v. others may metabolize multiple drugs
        vi. P-gp: membrane-bound transport system responsible for drug transport across cell membranes
        vii. drugs inhibit or activate both CYP450 and P-gp at the same time (grapefruit juice).
    b. Use in practice:
        i. Warfarin and testing for VKORC1

ii. Carbamazepine and HLA-B1502 in patients with Asian Ancestry
iii. Dapsone and G-6-PD deficiency

INFORMATION TECHNOLOGY IN PHARMACOTHERAPEUTICS

31. American Recovery and Reinvestment Act
    a. Doctors of nurse practice (DNP) must be meaningful users of health information tools.
    b. Enacted to increase patient safety and reduce cost.
    c. Reimbursement connected to use of electronic health record (EHR), computerized provider order entry (CPOE), and clinical decision support systems (CDSSs).
    d. Changes in patient privacy

32. Meaningful Use
    a. Meaningful use and need to use technology with pharmacotherapeutics
    b. EHR, CPOE, CDSSs: function together to increase patient safety
    c. Medication reconciliation using technology and PHR
    d. Patient privacy includes provisions, including their EHRs

33. Electronic Health Record
    a. Most practice areas can improve care by using EHRs.
    b. Cost is a determinant for most practices: upfront and recoup.
    c. Goal: exchange of patient information between practice sites and hospitals and across regions

34. Clinical Decision Support Systems
    a. CDSS alerts to guide the provider in decision making
    b. Alerts require two patient data points from vital signs to laboratory data and medication history
    c. CDSSs use elements of artificial intelligence and machine learning to function
    d. Risk “alert fatigue” by having too many alerts for workflow

35. Medication Reconciliation
    a. Required as part of meaningful use and to be done at each encounter
    b. Technology using EHR and personal health record (PHR) can help meet this requirement
    c. Reduces the risk of error with poor historians or when medications are not with the patient

36. Patient Education
    a. Materials can be standardized and printed off the EHR or kept in electronic format.

b. Electronic versions can also be edited for specific patient issues.
c. Applications for smart phones can be recommended by providers for patient education.
d. Internet with screening can be a good source of information.

37. Personal Health Record (PHR)
    a. Patient-owned and maintained health record
    b. Commercial products available or simple spreadsheet
    c. PHRs can be connected to EHRs and include inpatient data.
    d. Encouraged to prevent health information being lost during national disasters

38. Computerized Provider Order Entry (CPOE)
    a. Embedded within the EHR for order entry
    b. Increases safety by reducing the medication errors that occur with paper-based systems
    c. Implementation and adoption slow in the United States because of cost and changes in workflow
    d. Based on the formulary of the organization

PHARMACOECONOMICS $$ MONEY MONEY MONEY $$

39. Starting Points Pharmacoeconomics
    a. Defined= Provides a framework for evaluating drug treatments in terms of comparing one treatment with another

40. Pharmacoeconomics studies

41. Generic drugs

42. Applying Pharmacoeconomics to practice

43. Impact
    a. Designed to only look at economic impact of therapy

    b. Need to think of clinical impact

    c. Components of well-designed studies

    d. Point of view

44. Types of costs
    a. Direct

b. Indirect

c. Intangible

45. Cost-Effectiveness Analysis
    a. Two or more treatments/programs that are not necessarily therapeutically equivalent
    b. Measures effectiveness in therapeutic outcomes vs dollars saved

46. Cost-Benefit Analysis
    a. The costs of a specific treatment or intervention are calculated and then compared with the dollar value of the benefit received.
    b. Compares and determines the greatest benefit for the dollar spent.
    c. Cost–benefit ratio
    d. Difference between two therapies

47. What is the Cost??

48. Cost of Illness Analysis
    a. The costs of a specific disease in each population
    b. Costs of resources needed to treat illness
    c. Costs of nonmedical resources
    d. Loss of productivity

49. Cost-Minimalization Analysis
    a. Compares the costs of two or more treatment alternatives that are considered equal in efficacy
    b. Compares cost of drugs within a class
    c. Cost of drug
    d. Total cost, including monitoring and administration

50. Cost Utility Analysis
    a. Costs of the treatment choice are in dollars $$$
    b. the outcomes are expressed in terms of patient preference
    c. This =quality-adjusted life years
    d. Used when quality of life is a factor

51. Generic Drugs
    a. Generic drugs may or may not be less expensive.
    b. Pharmacy coverage may determine whether a generic drug is used.
    c. Tiered benefit
    d. Lower co-pay for generic drugs

e. Retail prescription drug programs.

52. Generic substitution
    a. 69% of prescriptions filled with generic drugs
    b. Prescriber influenced by:
    c. Innovator company
    d. Payer
    e. Patient
    f. Innovator companies support for health care

53. Bioequivalence
    a. The U.S. Food and Drug Administration (FDA) regulates and sets standards for bioequivalence.
    b. FDA Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations is:
    c. Available online
    d. Searched by active ingredient
    e. Searched by proprietary name
    f. Updated daily

54. Medicare Part D
    a. Covers 75% of drug costs once the patient pays a deductible of $250/year
    b. In 2018, the gap is $3,750 to $5,000, and Medicare enrollees get a 65% discount on costs of brand-name drugs and 56% on generic drug
    c. Prescriptions covered 95% after $5,000/year

55. Pharmacoeconomics in Practice
    a. Prescribing generic vs brand-name drugs
    b. Pharmacist may substitute a less expensive drug that is therapeutic equivalent
    c. “Dispense as written”
    d. Patients may switch due to costs and prescription benefit.
    e. Retail drug programs
    f. Walmart, Target, Kroger, Sam’s Club
    g. $4 for a 30-day supply of common generic drugs

56. Take Home Points
    a. Pharmacoeconomics influence every prescription
    b. Understand your generic equivalents.
    c. Consult with pharmacist
    d. Use Orange Book
    e. Collaborate with the patient regarding costs.
    f. Generic vs brand-name drugs
    g. Ask about prescription coverage.