DRUG INFORMATICS

FACULTY OF PHARMACEUTICAL SCIENCES

LECTURE 3 AND 4

STRUCTURE APPROACH FOR EFFECTIVE SYSTEMATIC RESPONSE (1,2)

Objectives

1. Define the functions of a drug information specialist.
2. Describe how to ask well focus question and background questions.
3. Identify how to build a focused question.
4. Identify the functions of a pharmacist as an information source.
5. Describe the systematic approach to answer drug questions.

(Please return to Chapter 2, Reference 1 of the course outline)

FUNCTIONS OF A DRUG INFORMATION SPECIALIST (PHARMACIST)

- Pharmacists must know how to:

1. Provide drug information
   - Simple professional level (based on well focus question).
   - Advance professional level (based on advance data collection).
2. Provide drug evaluations.
3. Develop policies.

ASKING WELL FOCUS QUESTION

- **Asking (good) questions is critical.**
- You need to develop and write **a well focused question** to help answer your question.

- Focused clinical question questions can help you.

a) Organize a search of the clinical literature for answer for your question.

b) Choose the best article from among those you find.

A GOOD QUESTION

- Is focused and relevant.
- Provides clear communication (good communication skills; both listening and questioning are essential for gathering relevant information for the question).
- Clarifies your goal or need.
- Will reduce the amount of time needed to obtain the answer.

BACKGROUND QUESTIONS

- **Question:** Who, What, When, Where, Why and How.
- **Specific terms:** treatment, reduction, cure, prevention and causes.
- **General knowledge about disorder:** Clinical manifestations of disease, patient findings, differential diagnosis, etiology, patient experience, comorbid condition, screening and diagnostic tests, prognosis, therapy, risk factors … etc.

BUILDING A FOCUSED QUESTION

- **A well-formulated question includes the following elements:**

1. The patient or problem being addressed.
2. The intervention being considered.
3. The comparison intervention.
4. The outcome(s) of interest.

BUILDING A FOCUSED QUESTION

- The **acronym PICO** can be helpful to remember the elements of a well-balanced question:

1. **P = Patient**
2. **I = Intervention**
3. **C = comparison**
4. **O = Outcome**

CATEGORY OF THE QUESTION

- **Therapy/treatment: PICO**
  - Patient and/or problem.
  - Intervention.
  - Comparison.
  - Outcome.
- **Harm: PEO**
  - Patient.
  - Exposure.
  - Outcome.

PATIENT AND/OR PROBLEM

- Type of patient or population: the population, comorbid conditions, patient's prior experience.
- Shall be specific and relevant.
- Prompt: How would I describe a group of patients similar to mine?

- **Examples:**

➢ Patient with unstable angina.

➢ 47 yr male with type 2 Diabetes Mellitus and cellulitis toe.

➢ 25 yr female with deep venous thrombosis and chest pain.

INTERVENTION

- Clinical intervention: **Specific treatment (intervention) of interest, patient perception (patients' view of services received and the results of the treatment).**
- It shall be specific that can help in search.
- Prompt: What main action I am considering?
- **Examples:**

➢ Medication/Drug: clopidogrel in addition to aspirin.

➢ Procedure.

➢ Surgery.

➢ Radiation.

➢ Vaccine.

EXPOSURE

- **Environmental, personal, biological (i.e. chemical exposures in the workplace).**
- Exposure / prognostic factor (measurements available at the time of diagnosis)
- **Examples:**

✓ TB

✓ Tobacco.

✓ Drug.

✓ Diet.

✓ Pregnancy or menopause.

✓ MRSA (methicillin resistant Staph. aureus).

✓ Allergy.

COMPARISON

- **Compare alternative treatment.**
- Prompt: What is/are the other options?
- the specific alternative of interest that can help in search,

➢ Other prior, new or existing therapy (Medication/Drug: aspirin, Procedure, Surgery, Radiation, Vaccine).

OUTCOME

- Clinical outcome of interest
- Shall be objective and meaningful to patient that can help in search
- What do I (or the patient) want to happen (or not happen)?

- **Examples:**
  - Reduced death rate in 5 years.
  - Decreased coronary events.
  - Decreased infections.
  - Fewer hospitalizations.

EXAMPLE 1

- **General question:** Should clopidogrel be prescribed to this 65-year-old man with unstable angina?

- **Well focused question:** Well clopidogrel in addition to aspirin (intervention) prevent death or coronary events (clinically relevant outcome) in this patient with unstable angina (patient with a problem) who is currently on aspirin alone (comparison intervention)?

EXAMPLE 1

➢ Patient	Patient with unstable angina
➢ Intervention	Clopidogrel in addition to aspirin
➢ Comparison intervention	Aspirin alone
➢ Clinically relevant outcome	Prevent death and coronary events

EXAMPLE 2

General question: Is it safe to switch carvedilol to metoprolol in this patient with heart failure?

Well focused question: Is metoprolol (intervention) as effective as carvedilol (comparison intervention) to prevent cardiovascular events (clinically relevant outcome) in a patient with low ejection fraction heart failure (patient with a problem)?

EXAMPLE 2

✓ Patient	
✓ Intervention	
✓ Comparison intervention	
✓ Clinically relevant outcome	

EXAMPLE 3

- Is sildenafil safe in this patient with diabetes mellitus type 2?

- If sildenafil is begun **(Intervention/exposure),** what is the risk of myocardial ischemia **(clinically relevant outcome)** in this asymptomatic patient with known coronary artery disease (CAD) and newly diagnosed with diabetes mellitus type 2 **(patient with a problem)?**

EXAMPLE 3

✓ Patient	
✓ Intervention / Exposure	
✓ Clinically relevant outcome	

FUNCTIONS OF A PHARMACIST AS AN INFORMATION SOURCE

❖ **Advance professional level**

1. **Provide drug information by:**

- Answering information requests.
- Writing patient specific consultations.
- Communicating information that wasn't requested, but is necessary.
- Developing criteria/guidelines for drug use.

FUNCTIONS OF A PHARMACIST AS AN INFORMATION SOURCE

2. Provide drug evaluations.

3. Develop policies for departments & community, Bulletins, newsletters, journal columns, education for practitioners.

4. Be involved with: adverse drug reactions (ADR) reporting, publishing, developing protocols, institutional review board (IRB) (is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities), poison control center information.

SYSTEMATIC APPROACH TO ANSWER DRUG QUESTIONS

1. Secure demographics of requestor.
2. Obtain background information.
3. Determine and categorize ultimate question.
4. Develop strategy and conduct search.
5. Perform evaluation, analysis, and synthesis.
6. Formulate and provide response.
7. Conduct follow-up and documentation.

1. REQUEST DEMOGRAPHICS

1. The requestor's "profession" (e.g., physician, pharmacist, nurse, lay person) should indicate **educational experience and knowledge base**; therefore, the individual receiving the query can use this information to determine the appropriate mannerism (in terms of educational level) to formulate and deliver the response.

1. REQUEST DEMOGRAPHICS

2. **Obtain telephone #, address, fax, etc for follow-up later.**

3. **Determine approximate age** (elderly, adolescent, etc.) (usually no need to directly ask).

4. **Communication skills**.

EXAMPLE

If a patient and a physician inquired about how the new medication Prandin® works (i.e., pharmacology), the depth of the response would differ for each individual.

- For example, a pharmacist should not inform a lay person that the new medication is the first agent approved in the meglitinide class and is a nonsulfonylurea insulin releasing oral hypoglycemic agent for type 2 diabetes mellitus.

CONTINUE OF THE EXAMPLE

- This would not be an appropriate response because the lay person would be unfamiliar with this terminology. Similarly, the pharmacist would not communicate to the physician that the new medication "acts by improving the way your body processes sugar." The physician would require a more scientific description of the product.
- Determine **a method for delivery** of the response.
- **Gather information** from the requestor that will allow you to reply to the request.

2. BACKGROUND INFORMATION

- Think, “Why is requestor asking for this information?”.
- Weigh time involved to get background info.
- Use tact, politeness and assertiveness.
- Background questions should be specific for the nature of the request.
- Ask, “What sources have already been used?”.
- Useful info: age, gender, weight, allergies, other disease states, other meds, lab values, etc.

WHY ??

- Background information aids in clarifying the question and is a critical step in the process.
- The question may not be stated concisely or the requestor may not know how to ask the question.
- To formulate an acceptable response, both the caller and researcher must have a clear understanding of the ultimate question.

EXAMPLE

A pharmacist is asked, "what is the dose of amoxicillin (Amoxil®)?“

- This question could be answered quickly (and potentially inaccurately) by stating that the normal dosage as 500 mg every eight hours.
- The question also could be answered by gathering background information concerning the origin of the question.

- A pharmacist would not provide the most commonly dispensed dose of amoxicillin as the dose for all individuals and conditions.

- The dose of this antibiotic depends upon a number of factors. Determine if the question is in regard to a specific patient or general research in the treatment of a disease state.

ANOTHER EXAMPLE

- If the question is **patient specific**, important information to acquire would include the patient's age, weight, allergies, type of infection, concurrent disease states, other medications, and preferred dosage form (e.g., oral suspension, capsules, or chewable tablets). For example, amoxicillin may not be for a severe infection or 2 grams as a single dose one hour prior to dental procedures for bacterial endocarditis prophylaxis.

DETERMINE AND CATEGORIZE ULTIMATE QUESTION

- Find _____
- How _____
- Use _____
- Determine_____

EXAMPLES OF QUESTION CLASSIFICATIONS

1. Adverse Drug Reaction
2. Contraindication
3. Availability
4. Dose
5. Drug compatibility/stability
6. Drug interaction
7. Drug therapy
8. Identification
9. Pharmacy practice
10. Pharmacology

EXAMPLES OF QUESTION CLASSIFICATIONS

11. Tablet identification.
12. General product information.
13. Laws/policies/procedures, Cost, Foreign products.
14. Pharmaceutics (compounding, formulations).
15. Pharmacokinetics (ADME "absorption, distribution, metabolism, and excretion"/levels).
16. Nutrition support.
17. Adverse effects.
18. Poisoning, toxicology.
19. Pregnancy, Teratogenicity.
20. Lactation/ infant risks.

EXAMPLE

Information gathered from the background questions concerning the request for the dose of amoxicillin (Amoxil®) allowed the actual question to be revealed as the dose and frequency of amoxicillin before a dental procedure for bacterial endocarditis prophylaxis in an 18 year old male.

DEVELOP A TIME LINE FOR RESPONSE

Completely understanding the scope of the "true" question also aids in developing a realistic estimate of the time required to compose a response.

CATEGORIZE THE QUESTION

- **A vital step in the systematic approach.**
- Allows for efficient use of the resources by providing the foundation of a logical progression process.
- An all-inclusive resource with data to answer every drug information question does not exist (References contain specific types of information).
- **Numerous topic specific resources are available** (e.g, drug interactions, infectious disease, internal medicine).

CATEGORIZE THE QUESTION

- **Classification of a request aids in developing a more effective search strategy.**
- **Selecting the resource with the highest probability of containing the desired information can decrease the time requirement and increase the accuracy of the response.**
- **Otherwise, unnecessary time and energy may be expended on searching references unable to produce the needed facts.**

CATEGORIZE THE QUESTION

In the previous example above, the amoxicillin request pertains to a dose.

Therefore, this question would be classified as Dose.

- **The following are examples of references that provide this information:** American Hospital Formulary Service (AHFS), Facts and Comparisons, and USP Drug Information (USPDI) for the Health Care Professional.

- **Textbooks specific for drug interactions:** Drug Interaction Facts and Hansten and Horn's Drug Interactions Analysis and Management.

- **Therefore, if the inquiry concerned the potential of concomitant administration of warfarin (Coumadin®) and aspirin to increase the International Normalized Ratio (INR), the question would be classified as a Drug Interaction and a logical starting point would be these two references.**

4. DEVELOP STRATEGY AND CONDUCT RESEARCH

1. **Select and prioritize resources based on the probability of locating the desired information.**

- Without prioritization, resources may be used based on ease of access or degree of comfort instead of probable efficiency.

4. DEVELOP STRATEGY AND CONDUCT RESEARCH

2. Conduct a systematic search

- Be familiar with the three types of information sources in the literature hierarchy.

- Begin with the established knowledge located within the tertiary literature (e.g., textbooks) due to the condensed, easy-to-use format of the information presented.

4. DEVELOP STRATEGY AND CONDUCT RESEARCH

2. Conduct a systematic search

- Progress through the secondary literature (e.g., MEDLINE, International Pharmaceutical Abstracts [IPA]) to the primary literature (e.g., controlled clinical trails, letters to the editor).

❖ Example:

Continuing with the dose of amoxicillin prior to dental procedures for bacterial endocarditis prophylaxis, the question was classified as a Dose question. Therefore, references most likely to contain the dose of amoxicillin (e.g., American Hospital Formulary Service [AHFS], Facts and Comparisons, and USP Drug Information [USPDI] for the Health Care Professional) were consulted first. However, after reviewing these references a discrepancy in the recommended dose was identified in the references. Two of the references reported the amoxicillin dose as 2 grams orally one hour prior to the dental procedure and the other reference reported the dose as 3 grams one hour prior to the procedure and 1.5 grams 6 hours after the first dose.

- Due to this discrepancy, internal medicine and infections disease textbooks were consulted; these texts further supported the dose of amoxicillin as 3 grams one hour prior to the procedure and 1.5 grams 6 hours after the first dose.

- To insure that the most up-to-date information was obtained, a secondary literature search was conducted (e.g., MEDLINE, Iowa Drug Information Service [IDIS], and International Pharmaceutical Abstracts [IPA]) and an article with updated guidelines for bacterial endocarditis prophylaxis was located.

- **The new guidelines recommend amoxicillin 2 grams orally one hour prior to the dental procedure for bacterial endocarditis prophylaxis; a second dose is not required.**

- **As mentioned previously, if the question is classified as a Drug Interaction, then a logical and efficient search would begin with a text specific for drug interactions (e.g., Hansten and Horn's Drug Interactions Analysis and Management, Drug Interaction Facts and Comparisons).**

- If a text specific for drug interaction is not available, other references likely to contain the desired information (e.g., Drug Facts and Comparisons, American Hospital Formulary Service, Micromedex) should be selected as opposed to references with a decreased probability of containing the information (e.g., Drug Topics Red Book, American Drug Index).

5. DATA EVALUATION, ANALYSIS, SYNTHESIS

Confirm information with other references to assure consistency between various resources while authors, editors, and publishers attempt to assure the reliability of the information published, most resources include a disclaimer statement since errors do occur occasionally.

6. FORMULATE AND PROVIDE RESPONSE

1. Restate the question and any pertinent background information.

2. This allows the requestor to be informed of the question and focused on the impending response.

3. Provide the information and recommendation (if applicable).

- **In addition, a brief review of the search strategy and references reviewed may be included in the response as a confirmation to the comprehensive search conducted.**

- **Compose the response at the requestor's comprehension level.**

7. FOLLOW UP AND FOLLOW THROUGH

- **Verify the appropriateness, correctness, and completeness of a response.**
- **Essential when judgement calls used.**
- **Essential when new data found or circumstances changed from original request.**
- **Document everything!**

ETHICAL AND MORAL RESPONSIBILITY

- How will they use your information?
- Are they asking for lethal dose of drug?
- Are they suicidal or homicidal?
- Are they seeking information for making illicit drugs?
- Are they trying to forge a prescription?
- Are they in serious need of an ER?

METHODS OF DOCUMENTATION

- Paper form
- Logbook
- Computer database

REASONS FOR DOCUMENTATIONS

1. Justification of pharmacist's professional value to the institution.
2. Future reference for repetitive drug information requests.
3. Protective measure against legal liability.

METHODS OF FOLLOW-UP

- Mail survey
- Phone call
- Written communication

REASONS FOR FOLLOW-UP

1. Provide the requestor with additional information that supports or changes a prior recommendation.

2. Obtain feedback concerning the quality of the service.

EXAMPLE

A prescriber inquires about the relationship between elevated homocysteine levels and coronary heart disease (CHD). Furthermore, the caller requests information concerning prescribing folic acid to decrease homocysteine levels. After following the modified systematic approach, evidence that documented a relationship between elevated homocysteine levels and CHD was located. In addition, preliminary therapeutic trial information supported daily supplementation of folic acid to lower homocysteine levels. A few weeks later, additional information that further established the efficacy of folic acid in lowering homocysteine levels was published. Follow-up should be provided to the prescriber due to the recent information affirming the prior response.

THANK YOU