Orientation
&
Modified Systematic Approach

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Learning Objectives

The course is designed to:

1-Understand the concept of drug information.

2-Learn the systematic approach to answering a drug related questions and indicate an efficient strategy to locate drug information necessary to answer any drug related.

3-Demonstrate the ability to appropriately comprehend and utilize the primary, secondary or tertiary sources to answer a variety of drug information questions.

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4-Develop critical understanding of the strengths and limitations of these resources (scope, type of information, method of access, structure, and application of frequently used drug information tertiary resources.)

5- Learning how to make informative and indicative abstracts and indexing.

6-Demonistrate writing skills by :

writing a report using a variety of information sources:

a- Searching appropriate primary literature

b- Evaluating the literature

c- Summarizing the findings.

d- Developing conclusions and recommendations.

7- Learning the skills of writing drug evaluation (review) using the variety of information resources (Primary, secondary and tertiary).

8-Demonstrate proficiency in the use of computerized information databases.

9-Understand and differentiate the type of information cited in a biomedical journal (original article, review article, case report, editorial, etc)

10-Evaluate online drug information sites for appropriateness and quality.

11-Develop sufficient communication skills through verbal and written activities.

12-Demonstrate sufficient skills to perform appropriate calculations.

13-List literature resources utilized to manage poison cases.

14-Understand basic principles when managing poison cases.

15-Understand other activities performed by drug information pharmacist (drug evaluation, DUE, ADR reporting, DI newsletter, etc

Textbook(s) / Required Learning Resources

•Required (textbook is available in University bookstore)

1- Malone PM et al. *Drug information: a guide for pharmacists*. 3rd ed. NY: McGraw-Hill, 2008. (http://books.mcgraw-hill.com/medical/druginfo/)

2- Galt KA: Clinical skills program drug information series, module 1. Analyzing and recording a drug information request. Bethesda, MD: American Society of Hospital Pharmacists; 2000. (Copies of the required chapters are available).

Systematic Approach (1975)

Step I.	Classification of the request
Step II.	Obtaining background information
Step III.	Systematic search
Step IV.	Response
Step V.	Reclassification

SOURCES: From Watanabe et al.

Modified Systemic Approach to answering Drug Information questions(1987)

The modified systemic approach to answering drug information questions consists of the following steps:

1- Secure demographic data of the 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.

General Questions for Obtaining Background Information

The requestor's name

The requestor's location and/or pager number

The requestor's affiliation (institution or practice) if a health care professional

The requestor's frame of reference (i.e., title, profession or occupation, and rank)

The resources that the requestor already consulted

Whether the request is patient specific or academic

The patient's diagnosis, other medications, and pertinent medical information

The urgency of the request (i.e., negotiate the time response)

Specific Questions according to the classification of the request

Availability of Dosage Forms

1- What is the dosage form desired?
2- What administration routes are feasible with this patient?
3.-Is this patient alert and oriented?
4- Does the patient have a water or sodium restriction?
5- What other special factors regarding drug administration should be considered?

Identification of Product

1. What is the generic or trade name of the product?
2. Who is the manufacturer? What country of origin?
3. What is the suspected use of this product?
4. Under what circumstances was this product found? Who found the product?
5. What is the dosage form, color markings, size, and so on?
6. What was your source of information? Was it reliable?

General Product Information

1. Why is there a particular concern for this product?
2. Is written patient information required?
3. What type of information do you need?
4. Is this for an inpatient, outpatient, or private patient?

Foreign Drug Identification

1. What is the drug's generic name, trade name, manufacturer, and/or country of origin?
2. What is the dosage form, markings, color, strength, or size?
3. What is the suspected use of the drug? How often is the patient taking it? What is the patient's response to the drug? Is the patient male or female?
4. If the medication was found, what were the circumstances/conditions at the time of discovery?
5. Is the patient just visiting, or planning on staying?

Investigational Drug Information

1. Why do you need this information? Is the patient in need of the drug or currently enrolled in a protocol?
2. If a drug is to be identified, what is the dosage form, markings, color, strength, or size of the product?
3. Why was the patient receiving the drug? What was the response when the patient was on the drug? What are the patient's pathological conditions?
4. If a drug is desired what approved or accepted therapies have been tried? Was therapy maximized before discontinued?

Method and Rate of Administration

1. What dosage form or preparation is being used (if multiple salt forms are available)?
2. What is the dose ordered? Is the drug a one-time dose or standing orders?
3. What is the clinical status of the patients? Could the patients tolerate a fluid push of XX mL? Is the patient fluid or sodium restricted? Does the patient have congestive heart failure (CHF) or edema?
4. What possible delivery routes are available?
5. What other drugs are the patient receiving currently? Are any by the same route?

Incompatibility and Stability

1. What are the routes for the patient's medications?
2. What are the doses (in mg), concentrations, and volumes for all pertinent medications?
3. What are the infusion times/rates expected or desired?
4. What is the base solution or diluent used?
5. Was the product stored in a refrigerator or at room temperature? For how long?
6. Was the product exposed to sunlight? For how long?
7. Was the product frozen? For how long?
8. When was the product compounded/prepared?

Drug Interactions

1. What event(s) suggest that an interaction occurred? Please describe .
2. For the drugs in question, what are the doses, volumes, concentrations, rate of administration, administration schedules, and length of therapies?
3. What is the temporal relationship between the drugs in question?
4. Has the patient received this combination or a similar combination in the past?
5. Other than the drugs in question, what other drugs is the patient receiving? currently? When were these started?

Drug-Laboratory Test Interference

1. What event(s) suggest an interaction occurred? Please describe.
2. For the drug in question, what is the dose, volume, concentration, rate of administration, administration schedule, and length of therapy?
3. What is the temporal relationship between drug administration and laboratory test sampling?
4. What other drugs are the patient receiving?
5. Has clinical chemistry (or the appropriate laboratory) been contacted? Are they aware of any known interference similar to this event?

Pharmacokinetics

1. What is the generic name, dose, and route of the drug?
2. What is the patient's age, gender, height, and weight?
3. What are the diseases being treated and the severity of the illness?
4. What are the patient's hepatic and renal functions?
5. What other medications are the patient receiving?
6. What physiologic conditions exist (e.g., pneumonia, severe burns, or obesity)?
7. What are the patient's dietary?

Serum or Urine Therapeutic Levels

1. Is the patient currently receiving the drug? Have samples already been drawn? At what time?
2. What is the disease or underlying pathology being treated? If infectious in nature, what is the suspected/cultured organism?
3. If not stated in the question, what was the source of the sample (blood, urine, saliva; venous or arterial blood)?
4. What was the timing of the samples relative to drug administration? Over what period of time was the drug administered and by what route?
5. What were the previous concentrations for this patient? Was the patient receiving the same dose then?
6. How long has the patient received the drug? Is the patient at steady state?

Therapy Evaluation/Drug of Choice

1. What medications, including doses and routes of administration, are the patient receiving?
2. What are the patient's pathology(ies) and disease(s) severity?
3. What are the patient's specifics: age, weight, height, gender, organ function/dysfunction?
4. Has the patient received the drug previously? Was response similar?
5. Has the patient been compliant?
6. What alternative therapies has the patient received? Was therapy maximized for each of these before discontinuation? What other therapies are being considered?
7. What monitoring parameters have been followed (serum concentrations/levels, clinical status, other clinical lab results, objective measurements, and subjective assessment)?
8. What is the patient's name and location?

Dosage Recommendations (Normal and Compromised)

1. What disease is being treated? What is the extent/severity of the illness?
2. What are the drugs being prescribed? What drugs have the patient received to date?
3. Does the patient have any insufficiency of the renal, hepatic, or cardiac system?
4. For drugs with renal elimination, what are the serum creatinine/creatinine clearance, blood urea nitrogen (BUN), and/or during output? Is the patient receiving peritoneal dialysis or hemodialysis?
5. For drugs with hepatic elimination, what are the liver function tests (LFTs), bilirubin (direct and indirect), and/or albumin?
6. For drugs with serum level monitoring utility, characterized the most recent levels per timing relative to dose and results.
7. Are these lab values recent? Is the patient's condition stable?
8. Does this patient have a known factor that could affect drug metabolism (ethnic background, such as Japanese or Chinese, or acetylator status)?

Adverse Effects

1. What is the name, dosage, and route for all drugs currently and recently prescribed?
2. What are the patient specifics (age, gender, height, weight, organ dysfunction, and indication for drug use)?
3. What is the temporal relationship with the drug?
4. Has the patient experienced this adverse relationship (or a similar event) with this drug (or similar agent) previously?
5. Was the suspected drug ever administered before? Why was it discontinued then
6. What were the events/findings that characterize this adverse drug reaction (ADR) (include onset and duration)?
7. Has any intervention been initiated at this time?
8. Does the patient have any food intolerance?
9. Is there a family history for this ADR and/or drug allergy?

Toxicology Information

1. What is your name, relationship to the patient, and telephone number?
2. What are the patient specifics (age, gender, height, weight, organ dysfunction, and indication for drug use)?
3. Is this a suspected ingestion or exposure?
4. What is the product suspected to have been ingested? What is the strength of the product and the possible quantity ingested (e.g., how much was in the bottle)?
5. How long ago did the ingestion occur?
6. How much is on the child or surrounding floor?
7. How much was removed from the child's hands and mouth? Was the ingestion in the same room where the product was stored?
8. What has been done for the patient already? Has the poison control center or emergency room (ER) been called?
9. Do you have syrup of ipecac available? Do you know how to give it properly?
10. What is the patient's condition (heart rate, respiratory rate, temperature, skin color, pupils, sweating/salvation, and so on)?
11. Does the patient have any known illnesses or organ dysfunction?

Teratogenicity

1. What was the drug the patient received and what was the dose? What was the duration of therapy?
2. Is the patient pregnant or planning to become pregnant?
3. When during pregnancy was the exposure (trimester or weeks?
4. What are the patient specifics (age, height, weight, gender)?
5. What is the source of the case information?
6. Was the patient compliant?
7. For what indication was the drug being prescribed?

Drugs in Breast Milk

1. What was the drug the patient received and what was the dose? What was the duration of therapy ?
2. How long has the infant been breast-feeding?
3. Has the infant ever received nonmaternal nutrition? Is bottle-feeding an acceptable alternative?
4. What is the frequency of the breast-feeds? What is the milk volume?
5. How old is the infant?
6. Does the mother have hepatic or renal insufficiency?
7. What was the indication for prescribing the drug? Was this initial or alternate therapy?
8. Has the mother breast-fed previously while on the drug?

Drug and Poison Information Request Form

General questions for obtaining background information:-

1- Requestor's name

2-requestor address and Tel, E-mail

3- Requestor's frame reference (e.g. profession)

4- Resources that the requestor already consult.

5- Whether the request is patient specific or Academic or drug oriented.

6- Patient's diagnosis, other medications and pertinent medical information

7- Urgency of the request

Procedure and Documentation

A standard procedure for enquiry processing should be developed.

1- Identification of the enquirer

The pharmacist receiving the query is to obtain the caller's name, address, phone number and profession.

2- Obtain the necessary background information.
If the request is patient specific, obtain the patient's:

i. name, age, weight and sex.

ii. medical history (including allergies).

iii. Major organ function (cardiac, liver, kidney).

iv. Drug history (name, dose, regimen, duration and indication).

3- Establish whether the caller has consulted any references.

4- Assign priority to the request according to the urgency of the problem or query.

Cases may be clinically urgent and the physician may have a patient waiting. To enhance the credibility of the unit, it is essential that the caller be provided with some sort of time frame within which they can expect an answer. It is important to maintain contact with the caller and follow up if agreed upon deadline cannot be met.

5- Clarify the request if not clear. If it is clear go ahead

6- Classification of the request. Notice that there may be more than one classification.

7- Systemic search

Search the available reference. Evaluate and interpret the information that has been sourced.

8- Formulation the appropriate response:

All statements made should be traceable to the literature. Statements where you think the answer is correct (but are not sure) are dangerous and must not be made. Always check with at least two reference sources. Only the information that is pertinent to the request.

Questions to Consider before Formulating a Response

Do I know the requestor's name, profession, and affiliation?
Does the question pertain to a specific patient?
Do I have a clear understanding of the question or problem?
Do I know if the correct question is being asked?
Do I know why the question is being asked?
Do I understand the requestor's expectations?
Do I know pertinent patient history and background information?
Do I know about the unique circumstances that generated the question?
Do I know what information is really needed?
Do I know when the information is needed and in what format?
Do I have insight about how the information I provide will actually be used?
Do I know how the problem or situation has been managed to date?

Desired Characteristics of a Response

Timely.
Current.
Accurate.
Complete.
Concise.
Well referenced.
Clear and logical.
Objective and balanced.
Free of bias or flaws (mistakes).
Applicable and appropriate for specific circumstances.
Answers important related questions.
Addresses specific management of patients or situations.

9- Communication of the response

This must be clearly and concisely given. It must be established that the caller fully understands the answer.

a- Oral response

Most suited to conveying response to a simply uncomplicated query. Can assess whether a written response is required following the verbal reply.

b- Written response

May be more appropriate for a more complex enquiry. The following format may be used as a guideline.

i- Request and background information.

ii- Response: in some cases a brief introductory paragraph is necessary clarification of the terminology and issues at hand. Summarize what the literature says about the problem,

pointing out inadequacies or deficiencies

In the references. Be concise, unbiased and above all accurate.

iii- Conclusion.

Summarize the information together with the appropriate conclusion.

iv- References

The query should be appropriately referenced.

10- Follow-up

This should be done by phone, in person or by mail to ascertain whether the information provided was appropriate.

11- Documentation

All query information should documented on a Query form on the computer for legal purposes and for future enquiries

Case Study

Initial Question

What is the molecular weight of enalapril?

Potential Response in the Absence of Relevant Background Information

Enalapril is an oral angiotensin converting enzyme (ACE) inhibitor that is indicated for the management of hypertension, symptomatic congestive heart failure, and asymptomatic left ventricular dysfunction.[,] The molecular weight of enalapril is 376.45.

Pertinent Background Information

The requestor is a basic scientist who is conducting an *in vitro* experiment to evaluate the pharmacologic effects of enalapril. She would like to know the molecular weight of enalapril so that she can perform appropriate calculations specified for this experiment.

Pertinent Medication Factors

Enalapril is a prodrug that is converted *in vivo* to the pharmacologically active form, enalaprilat.[,] Both enalapril and enalaprilat are commercially available for use.

Analysis and Synthesis

Considering that enalapril is a prodrug that must be converted to a pharmacologically active compound *in vivo*, and given that this researcher wishes to conduct an *in vitro* study, the researcher should use the active form of the drug in her experiment. Therefore, she should have requested the molecular weight of enalaprilat.

Response and Recommendations

Enalapril is an oral angiotensin-converting enzyme inhibitor that is indicated for the management of hypertension, symptomatic congestive heart failure, and asymptomatic left ventricular dysfunction. Because enalapril is a prodrug that requires conversion to the active form, the requestor was advised to consider using enalaprilat in the experiment. The molecular weight of enalaprilat is 384.43.