Structure approach for effective Systematic response

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Functions of a Drug Information Specialist_ Pharmacist

- Pharmacists must know how to:

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

a) Asking well focus questions

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
  - Organize a search of the clinical literature for answer for your question
  - Choose the best article from among those you find

(مواصفات ال advance → documentation اخطا)

[*] Profissional advance ⇐ بيعطيك معلومة اضافية حتى لو هو ما ساأل عنها

A good question

- Is focused and relevant
- Provides clear communication
- Clarifies your goal or need
- Will reduce the amount of time needed to obtain the answer

(2) who system

(3) de bisson calculation → معادلة الحسابية

عندي ٣ أنواع لقياسها

[*] ⇐ Pharmacovigilance → risk of side effect

(1) Naranjo algorithm score ⇐ خ المنكي ⇐ ماك

(scale) تقيس عليه Pharmacovigilance

أي علة بجيبها لك ماكانة منها تاخير جوابه لحاجي
والأسئلة بتكون زجلة تاعنيه أكثر ...

Background questions

- Question: Who, What, When, Where, Why and How (wh-question s)
- 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:
  - The patient or problem being addressed
  - The intervention being considered
  - The comparison intervention
  - The outcome(s) of interest
- The acronym PICO can be helpful to remember the elements of a well-balanced question
  - P = Patient
  - I = Intervention
  - C = comparison
  - O = Outcome

هاي هي المنظومة تامة
(Professional response)

سؤال بالامتحان (أكثر عليها)

* هاي منظومتنة باعدواعلى إني أحدد إذا السؤال ناقص ولا لاء
- كل ماكانة السؤال منه تحديد أكثر كانة ناقص أكثر ...

[Patient (or Problem) Being adressed clearly]

Category of the question

(Proffissional term to answer question)

Therapy/treatment: PICO

- Patient and/or problem — Being adressed clearly
- Intervention — Being considerd
- 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
- 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
- Exposure / prognostic factor
- 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

* هاد السؤال بالنسبة للأسئلة الي بتنطرح بالأردن هاد السؤال ناجح بسبه

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

بالنسبة للعلم لا غشه ناجح

- 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)?

بعطيني معلومات عند المريض وأدويته والهدف منه

في أدوية داخل Black Box ⇐ الهم معلومة مهمة لازم احكيها عند المريض

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

* جواب السؤال بطريقة (Profissional) انه اضيف معلومة مهمة حتى لو ما سأل عنها السائل

مثال ⇐ هدا سأل عن سعر سيارات الهونداي ⇐ جاوبه انه سعرها كذا [وهي أرخص من سيارات الجيب] ⇓ هاي معلومة اضافية ما هدا سأل عنها

* مثال → هدا سأل عن المضاد الحيوي ها بحكي ال مثلا منع هاي الحالة [وبحكي انه بعمل (diarrhea)] عشان هاي معلومة اضافية 90٪ يرجع يسأل عنها المريض

Scanned by CamScanner

على ذلك
بجوابه Profissional
فيها معلومة اضافية

إما لانك بتوقع المريض يرجع يسأل فيها
أو لانه هاي المعلومة مهم
يعرفه عنها المريض

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

* هو بيوخذه من أول ولا بده يوخذه ؟

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

عدد نوع ischemia عدد نوع (safety)

⇒ sildenafil ⇐ ما في أي interaction مع DH

⇒ بس في interaction with HF و HTN

سؤال خبر ناجح = جواب خبر ناجح ← بسبب مشاكل للمريض

Example 3

Patient	
Intervention / Exposure	
Clinically relevant outcome	

⇒ فيها خاصية. تجميع أسئلة ⇐ * advance

المرض لغاية التقدم المستمر

والبحث العلمي

Functions of a Pharmacist as an Information Source

Advance professional level

- 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

THANK YOU

Functions...

- Provide drug evaluations
- Develop policies for departments & community, Bulletins, newsletters, journal columns, education for practitioners.
- Be involved with:
  - ADR reporting, publishing, developing protocols, IRB, Poison Control Center information.

THANK YOU

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**

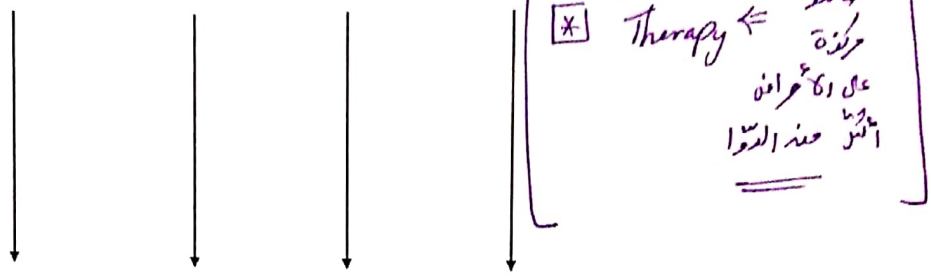
THANK YOU

1. Request Demographics

- 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.

THANK YOU

- Obtain telephone #, address, fax, etc for follow-up later.
- Determine approximate age (elderly, adolescent, etc.) (usually no need to directly ask)



Communication skills

THANK YOU

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.
- 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.

THANK YOU

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.

Exampel

- 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.
- Other issues to consider with the antibiotic are dose adjustment for renal impairment and interactions with concomitant medications. e the best agent to select for the infection. In addition, the dose of amoxicillin can be 500 mg every eight hours

3. 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

11. Tablet identification
12. general product information
13. Laws/policies/procedures, Cost, Foreign products
14. Pharmaceutics (compounding, formulations)
15. Pharmacokinetics (ADME/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

- **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

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.
- 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

- Restate the question and any pertinent background information
- This allows the requestor to be informed of the question and focused on the impending response
- 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 (examples)

1. Paper form
2. Logbook
3. Computer database

- Reasons for documentations (examples)

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

1. Mail survey
2. Phone call
3. 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.

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Case Study 2–3

INITIAL QUESTION

Are there any drug interactions between labetalol, clonidine, amlodipine, lorazepam, and minoxidil?

POTENTIAL RESPONSE IN THE ABSENCE OF RELEVANT BACKGROUND INFORMATION

An extensive search of tertiary[4,9,12] and secondary literature sources did not reveal any significant drug–drug interactions between labetalol, clonidine, amlodipine, lorazepam, and minoxidil. However, concomitant therapy with a β-adrenergic antagonist, an α-adrenergic antagonist, a calcium channel antagonist, and a peripheral vasodilator may increase the potential for additive hypotension.

PERTINENT BACKGROUND INFORMATION

The requestor is a physician who is caring for a patient with severe hypertension. The physician plans to add minoxidil to the antihypertensive regimen because the patient's morning blood pressure is not optimally controlled. He would like to make sure that there are no drug interactions between minoxidil and the patient's other medications.

PERTINENT PATIENT FACTORS

S.L. is a 40-year-old man with severe hypertension and renal insufficiency.

Past Medical History

- HIV infection × 5 years
- Hepatitis C × 8 years
- Hypertension × 4 years
- Renal dysfunction

Social History

- [illegible] pints of vodka daily × 12 years
- [illegible]k per day (PPD) of cigarettes × 25 years
- [illegible]ory of intravenous drug abuse

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Current Medications

- Labetalol 400 mg orally daily (@9 AM)
- Clonidine transdermal patch 0.3 mg/day
- Amlodipine 10 mg orally daily (@9 AM)
- Lorazepam 1 mg orally as needed for anxiety
- Multiple vitamin orally daily
- 0 complementary/alternative or other nonprescription medications

Allergies/Intolerances

- Lisinopril (angioedema)

Laboratory Results

- Sodium 136 mmol/L, potassium 4.7 mmol/L, chloride 102 mmol/L, CO_2 24 mmol/L, creatinine 2.9 mg/dL, glucose 98 mg/dL, BUN 14 mg/dL
- Viral DNA <100 copies/mL
- Cluster designation 4 (CD4) count 900 cells/mm^3

Blood Pressure Measurements

4/15		4/16		4/17	
@6 AM	172/116	@6 AM	168/110	@6 AM	178/114
@noon	121/81	@noon	116/86	@noon	119/84
@8 PM	158/100	@8 PM	150/104	@8 PM	166/100

PERTINENT DISEASE FACTORS

It is not known whether patients with HIV infection respond differently to antihypertensive medications.

PERTINENT MEDICATION FACTORS

There are no primary or tertiary literature reports describing drug interactions between minoxidil and any of S.L.'s current medications.[4,9-12] A review of the patient's current antihypertensive medications suggests that the dose of each agent is appropriate for achieving adequate blood pressure control in the face of significant renal compromise.[13] However, the duration of action of labetalol is 8 to 12 hours, and this agent is typically dosed twice daily. S.L. is receiving 400 mg of labetalol daily at 9 AM.

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ANALYSIS AND SYNTHESIS

S.L.'s blood pressure appears to be highest in the morning, just before the daily doses of labetalol and amlodipine are administered. He is receiving 400 mg of labetalol daily at 9 AM. Because the duration of action of labetalol is 8 to 12 hours, and the usual maintenance dose is 200 to 400 mg twice daily, the increase in blood pressure observed in the morning could be due, at least in part, to inappropriate dosing of labetalol. This medication should generally be administered twice daily to achieve maximal benefit. Adjustment of the labetalol dose should precede the addition of other antihypertensive agents to this patient's medication regimen. Although long-term cigarette smoking can increase the cardiovascular risk associated with hypertension, there is no indication that smoking or alcohol ingestion are contributing to this patient's present problem.

RESPONSE AND RECOMMENDATIONS

There do not appear to be any significant drug interactions between any of S.L.'s current medications and minoxidil.[4,9-12] Additionally, after considering the pharmacokinetics, pharmacodynamics, adverse effect profiles, and pharmaceutical properties of the patient's medications, the potential for a clinically significant drug interaction appears low. However, a review of the patient's current antihypertensive regimen suggests that the dosing of labetalol is inappropriate. The duration of action of labetalol is 8 to 12 hours, and the usual maintenance dose is 200 to 400 mg twice daily. Because S.L. is receiving 400 mg of labetalol once daily at 9 AM, the increase in blood pressure observed in the morning could be due to inappropriate labetalol dosing. The physician was directed to optimize labetalol therapy before the addition of another antihypertensive agent. If the patient's blood pressure is not controlled with proper dosing of labetalol and minoxidil therapy is required, the physician should be advised that minoxidil is usually administered with a diuretic to prevent fluid retention.

CASE MESSAGE

This is another example emphasizing the importance of the proper context of the question. In this case, the pharmacist was able to recommend appropriate drug therapy management, even though the initial question posed by the physician was not related to the dosage and administration of labetalol.

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