Drug Information Paper

You will need to prepare a written drug information consult for a question of interest to you. This web page will give you information about the process and expectations of your paper.

Writing Level

You will write this at a level appropriate to give to a physician requesting the information. Therefore, for the purposes of this exercise, assume that a physician has asked you the question and requested a written reply, i.e., you will write at a level appropriate for a health care professional.

Choosing a Topic

Your topic will be written in the form of a question that the physician has asked you. This question should be one sentence long, and should appear at the top of your paper. The question must be related to a medication of some type (this includes prescription, over-the-counter, and herbal products). It also must include the disease state or condition for which the drug is being used. One type of question that makes an excellent topic for this kind of paper is asking about the effectiveness of a specific agent when used for a specific medical condition. There are many studies examining effectiveness of medications. There are not as many studies examining adverse reactions to medications, drug interactions, or drug mechanisms, so these topics may not be ideal for this type of paper.

Reference Sources

You will need to use at a minimum three sources from the primary literature and three sources from the tertiary literature. It is traditional and logical to use the tertiary literature when preparing your introduction, and primary literature when writing the body of your reply. In order to locate both primary and tertiary literature you will need to use PubMed and at least one other indexing (secondary) source (EMBASE, IPA, Current Contents, BIOSIS, or Science Citation Index) and you must indicate at the end of each reference which secondary source you used to locate the reference.

Length and Style

The finished consult should be 5-6 pages in length and typed double-spaced in 12-point font. It should contain an introduction that is at least a paragraph in length, the body of the paper (including one paragraph for each study you consulted), and a summary or conclusion paragraph (where you summarize the evidence, answer the question, and provide appropriate and specific recommendations).

Your paper should be written in third person language only. Avoid using emotion-evoking words. Keep your wording objective. Your conclusion should be evidence-based and should clearly answer the question.

One publication which contains articles very similar in format to the paper you will write is *The Annals of Pharmacotherapy*. There are some copies of this journal in the student lounge. Every edition of this pharmacy journal contains 1-3 articles in a section called **Drug Information Rounds**. These articles are written in roughly the same format as you are expected to use. Please

look over the format and content (as well as type of question) used in these articles, if you would like to see an example.

Please do not use a cover sheet. Place your name at the top of the first sheet of your paper. Format your question as a sentence, not as a title (i.e., do not capitalize each important word in the question).

Rough Drafts

You will complete two rough semi-drafts.

- The first draft will be of the introduction alone. You will need to include references for the information - remember that these will be primarily tertiary sources. Your introduction will be evaluated for how well it introduces the topic, how well it prepares your reader for the body of your paper, whether at least 3 tertiary references are used (along with the proper citation format for those references), and whether your writing mechanics are acceptable.
- The second rough draft will be a one-paragraph outline of the methods and the results in one of the studies you will include in the body of your paper. Please reference the paper after the paragraph. You will also need to turn in with the paragraph a paper copy of the study you outlined. This study will be returned to you when your paragraph is handed back. You will be graded on your ability to clearly and accurately convey the study methods and results *in your own words*, the use of the proper citation format, and writing mechanics.

Grading for Overall Paper

Papers will be graded on both content and mechanics, as follows:

4.0	Exemplary work. The introduction clearly presents the important issues involved in answering the drug information question. The response is complete as written and requires almost no revision. Citations exceed the minimum number. There are no major misspellings or grammar errors. The style is appropriately written for a reader who is a trained health care professional.
3.0	Expected work. The introduction clearly presents the important issues involved in answering the drug information question. The response is complete as written and requires only minimal revision. Citations meet the minimum number. There are some misspellings or grammar errors. The style is appropriately written for a reader who is a trained health care professional.
2.0	Deficient work. The introduction presents at least one of the important issues involved in answering the drug information question, but not in a concise and clear manner. There are major format or content issues. The response is incomplete as written and requires a fairly extensive revision. Citations do not meet the minimum number. There are many misspellings and/or grammar errors. The style is inappropriately written for a reader who is a trained health care professional.
1.0	Unacceptable work. The paper will have to be redone. A 3.0 is the maximum grade that can be earned.

Remember that the whole purpose of the rough drafts is to help you get a grade of 3.0 or higher on this assignment!

The Introduction

The purpose of your introduction is to explain to your reader why the question you have asked is important and why the answer is not universally already known. You will need to present the

issues which led you to the primary literature to seek an answer to the question.

Your introduction will generally be two paragraphs in length. It should provide information about the disease state or condition for which the drug is used; your introduction should also include a description of the pharmacology of a drug, where appropriate. For example, if you were trying to answer the question, "Does the maternal use of caffeine during pregnancy adversely affect the child?" you might want to outline in the first paragraph information about the ubiquity of caffeine use and why pregnant women might consume caffeine. In the next paragraph you will outline how the pharmacologic effects of caffeine could decrease placental blood flow, leading to a relative hypoxemia and thus decreased fetal growth and/or development, or even cause fetal demise.

You will find that it is usually most logical to introduce the disease or condition first. Make good use of numbers to explain to your reader how prevalent the condition is - remember that you can get information about disease epidemiology from good review articles and also through the statistics links you can find on Healthlink's red "references" tab. It will then be logical in the next paragraph to introduce the treatments for the condition, focusing your reader on the specific treatment about which you will be providing evidence.

The last sentence will be a transition sentence. It should make your reader want to read on to examine the evidence regarding the question. Please do not phrase this last sentence as a question. Avoid the awkward, "This paper will examine..." transition style. Most importantly, do not answer your question in your transition sentence, in effect summarizing what your reader is about to read (why should the reader read any further if you have answered the question?).

Plan to reference at least one common medicine resource (such as Harrison's, UpToDate, or the Merck Manual) and one common drug resource (such as Drugdex, Facts and Comparisons, or Natural Medicine Comprehensive Database) in your introduction.

One thing you may be unsure of is where, when, and how to use citations. Please read the information on the citations and references web page.

The Body

The body of your paper should contain a series of paragraphs outlining studies from the primary literature. A reasonable subtitle for the body of your paper would be "Published Literature."

How do you summarize a study in one paragraph?

- The **first sentence** should include such information as the **year the study was published**, the **type of study**, the **geographical setting**, the **number of subjects**, and the **study objective**. It is unnecessary to use the first author's name followed by "et al;" use of the first author's name to describe a study is currently discouraged by medical writing experts. This first sentence should be followed by the citation number in superscript (*after* the period at the end of the sentence).
- After the first sentence should come **two to three** (2 -3) **sentences** summarizing the study **methods**. Note which drugs were compared and for how long (if the study is comparative). Also emphasize any notable methodologic aspects of the study that were particularly well done or that may have biased the results. Consider subject selection and measurement methods.
- The **results** should then be summarized in **two to four** (2-4) **sentences** that report **raw numbers** as well as **statistical significance**. Try to limit your result information to the most important (as you see it) 2-3 pieces of information found in the results. Be sure that your summary contains the most interesting point that you gained from reviewing the journal

article. This point may not be an important part of the results, but it should be something about the study that you felt was very educational, either in a positive or negative way.
- In **one sentence** summarize the **conclusion** of the study investigators.
- If you feel comfortable doing so, then you can follow with a few evaluative comments. *Evaluative comments are optional at this point in your education*. Be certain that any evaluative comments are supported by information in your study summary. In general, you should try to make at least one positive and one negative comment about each study you review in order to give your reader the feeling that you are objective. Occasionally, you will review a study that was exceptionally well done or particularly heinous. In these cases you may not be able to think of any notable study weaknesses or strengths (respectively). In this case it is okay to be one-sided in your evaluation, but be sure you provide balanced commentary for the other studies you review or else your reader will suspect you of author bias!
- The final statement in your paragraph should give your reader an idea of how the study fits into the answer to the drug information question.

This should give you a paragraph for each study that contains approximately 6-13 sentences.

Example paragraph for a study examining rheumatoid arthritis treatments:

A blinded, randomized, comparative, controlled trial published in 1996 examined the efficacy of three second-line drug regimens in 102 moderately severe rheumatoid arthritis patients at Omaha, Nebraska rheumatology clinics.[1] Patients who had failed at least one of the single-drug, second-line antirheumatic agents were randomized to methotrexate alone, hydroxychloroquine plus sulfasalazine, or methotrexate plus hydroxychloroquine plus sulfasalazine. Patients were titrated to maximum methotrexate therapy (17.5mg/week) over nine months and then were only allowed to remain in the trial over the remaining 15 months if they consistently displayed a 50% reduction in baseline symptoms. Survival analysis was used to compare between-group dropout rates. The three-drug group had a statistically-significantly higher number of patients (24 of the original 31 patients: 77%) left in the trial at the end of the second year when compared to the two-drug group (14 of the original 35: 40%), and the one-drug group (12 of the 36 patients: 33%). The investigators concluded that the three-drug regimen had greater efficacy than the other regimens. Since there is a paucity of studies examining the efficacy of multi-drug therapy in the treatment of moderately severe arthritis, this study was a laudable attempt to further define the answer to the regimen-of-choice question. Additionally, although it was not the primary study objective, the value of dose escalation (i.e. dosing up to 17.5mg weekly) for methotrexate patients who are non-toxic at lower doses (e.g. 7.5mg weekly) and not achieving acceptable efficacy, was well-illustrated. That said, the investigators may have biased the results slightly away from the methotrexate group because their inclusion criteria included failure to respond to single-drug treatment 9which is often methotrexate) and toward the 3-drug group since patients who had previously used (and failed?) 2- or 3-drug therapy were excluded. This trial, then, does not yet answer the question of the initial treatment of choice for rheumatoid arthritis patients not responding adequately to NSAID therapy.

The conclusion

In your conclusion you will need to summarize the evidence you have reviewed and use it to form an evidence-based answer to the question posed at the start of your paper. Your recommendation should be practical, clear, and specific. If you are going to recommend the use of a drug in a particular disease state, it is best to also provide the dose, route, frequency, duration of therapy, and monitoring parameters, if appropriate. Remember not to say, "I recommend..." Instead, you will want to say what the evidence appears to support. Your conclusion will be judged on whether or not you answered the question, and whether or not your answer was evidence-based.

Reference list

Links to expected formats for references are on the main PHARM 309 web page. Please do not use Endnote style or function for your references. Your style should look like the following:

References

1. Sobel JD, Kaye D. Urinary tract infections. In: Mandel: Principles and Practice of Infectious Diseases [Internet]. New York (NY): Churchill Livingston; c2000 [cited 2005 Sep 26]. Available from: http://www.mdconsult.com/
2. Hooton TM, Stamm WE. Recurrent urinary tract infection in women. In: UpToDate [Internet]. Wellesley (MA): UpToDate, Inc; c2005 [updated 2005 Feb 14; cited 2005 Sep 26]. Available from: www.uptodateonline.com
3. Gingrich CL. Bacterial infections of the urinary tract in women. In: Rakel RE, Bope ET, eds. Conn's Current Therapy. [Internet] Philadelphia (PA): W.B. Saunders; c2005 [cited 2005 Sep 26]. Available from: http://home.mdconsult.com/
4. Cranberry. In: Review of Natural Products. [Internet] St. Louis (MO): Facts and Comparisons; c2005 [updated 2005 Jul; cited 2005 Sep 26] Available from:http://online.factsandcomparisons.com/
5. Cranberry. In: Natural Medicines Comprehensive Database [Internet]. Stockton (CA):Therapeutic Research Faculty; c1995-2005 [cited 2005 Sep 26].Available from: http://www.therapeuticresearch.net/
6. Briggs S, Rouse JE: Cranberry- Alternative Medicine Evaluation. In: Klasco RK (Ed): AltMedDex® System (electronic version). Thomson MICROMEDEX, Greenwood Village, Colorado, USA. Available at: http://www.thomsonhc.com (cited: 9/26/2005).
7. Cranberry (Vaccinium macrocarpon) and Urinary Tract Infection. [Internet] Bethesda (MD): National Institutes of Health (US); c2003 [modified 2004 Feb 5; cited 2005 Sep 26]. Available at: http://nccam.nih.gov/research/concepts/consider/cranberry.htm
8. Can your diet prevent a urinary tract infection? [Internet] Santa Fe (NM): Web-based Health Education Foundation; c2005. [upated 2003 Apr 17; cited 2005 Sep 26]. http://www.healthandage.com/
9. Lowe FC, Fagleman E. Cranberry juice and urinary tract infections: what is the evidence? Urology 2001; 57:407-13. (PubMed)
10. Kontiokari T, Sundqvist K, Nuutinen M, Pokka T, Koskela M, Uhari M. Randomised trial of cranberry-lingonberry juice and Lactobacillus GG drink for the prevention of urinary tract infections in women. BMJ 2001;322:1571-5. (Current Contents)
11. Schlager TA, Anderson S, Trudell J, Hendley JO. Effect of cranberry juice on bacteriuria in children with neurogenic bladder receiving intermittent catheterization. J Pediatr 1999;135:698-702. (PubMed)
12. Reid G, Hsiehl J, Potter P, Mighton J, Lam D, Warren D, Stephenson J. Cranberry juice consumption may reduce biofilms on uroepithelial cells: pilot study in spinal cord injured patients. Spinal Cord 2001;39: 26-30. (Current Contents)
13. Avorn J, Monane M, Gurwitz JH, Glynn RJ, Choodnovskiy I, Lipsitz LA. Reduction of bacteriuria and pyuria after ingestion of cranberry juice. JAMA 1994;27:751-4. (PubMed)
14. Terris MK, Issa MM, Tacker JR.Dietary supplementation with cranberry concentrate tablets may increase the risk of nephrolithiasis. Urology 2001;57:26-9. (EMBASE)

The first nine references provide general background information and were cited in the introduction. References 7 and 8 are internet sites and are given as examples of the correct format for citing something located on the web. Reference 9 is a review article. The remaining five articles were studies and were outlined in the body of the paper.

Note that for the journal articles, the title of the journal article is abbreviated. If you are unsure of the correct journal title abbreviation, you can find it via the journals database on PubMed. Type in the full name of the journal: the correct abbreviation is on the MEDLINE abbr: line.