

*Writing Across the  
Pharmacy  
Curriculum*

*Drug Problem Evaluation*

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## **PLAN**

### **A. Before you begin**

#### **What is the purpose of the “planning” section of this tutorial?**

The first stage of the writing process involves planning and goal setting. In this first stage of the process, you will be presented with a systematic method of finding relevant information to use in your evaluation and then organizing it in a way that will be useful to your readers. You will be taught a method of reading the articles you have been assigned in a purposive way and a method of audience analysis.

After carefully planning your evaluation and reading the articles, you will then be ready to write your evaluation and revise it, stages two and three in the writing process. Finally, you will want to layout and design the final paper to make it look professional and to make the information accessible to your readers. We call this last stage of the process “packaging.”

### **B. Definition**

#### **What is a drug problem evaluation?**

A drug problem evaluation is a short analytical essay comparing either a group of research articles dealing with the same drug or a group of articles relating to a specific pharmacotherapeutic problem. Generally, these essays are 2-3 pages typed. They include the following parts:

1. Statement of the problem
2. Table: comparing and contrasting the relevant criteria, research designs, and results of the articles
3. Evaluation of the effectiveness of the studies
4. Summary of your findings
5. Recommendations for clinical application
6. Annotated bibliography

For example, you might be asked to compare four research articles on digoxin-quinidine interaction to determine how effective the studies were, whether the

researchers answered the questions they posed, and what recommendations you would make for clinical applications based on your evaluation of the articles.

You may also be asked to compare the research articles on an aspect of one drug, such as the role of prophylactic lidocaine in acute myocardial infarction. In this case, you will be expected to compare the research questions asked, the experimental design, the sample population, and the results to determine whether the research yielded consistent and comparable results or whether the results of one study contradict the results of another.

## C. Audience

### Who are the audiences for the drug problem evaluation?

You have two major audiences for the drug problem evaluation:

1. Your **primary audience** (decision-maker) – the instructor
2. Your **secondary audiences** – your peers and other pharmacy professionals who can use the evaluation to update their knowledge of the research in the problem area and to make decisions about clinical applications.

Your **primary audience** is your instructor. He or she will be reading the evaluation to determine how well you understood the primary research articles you were asked to read and whether you can critically evaluate the significance of the research results. Moreover, your instructor will evaluate your recommendations for clinical application of the research.

Your **secondary audiences** – your peers and other pharmacy professionals – will read your evaluation because they need to continually update their knowledge of the field and will act on your recommendations for clinical application.

Since you have two distinct audiences who will read the information for different purposes, you will want to design your evaluation in a way that enhances rather than inhibits the flow of information. As a result, you will want to define the problem and any terms your audiences may not be familiar with. You will also want to use headings, boldface, bulleted lists, tables and white space effectively to make the most important information stand out.

## D. Purpose

### What is your purpose in writing the drug problem evaluation?

You have **two purposes** in writing the drug problem evaluation: a rhetorical purpose and an instrumental purpose.

Your **rhetorical purpose** is to persuade the readers of your evaluation that you have understood the problem, the research questions and research designs, and the relevance of the results, and that you are in a position to critically evaluate the significance of the research and its implications for clinical practice.

To achieve your rhetorical purpose, you will have to gain your audience's trust by establishing your own credibility. You will have to present the information in a way that illustrates that you have "done your homework." Moreover, you will want to write clearly and concisely to motivate them to read your evaluation.

Your **instrumental purpose** in writing the evaluation is to disseminate the most recent and relevant research in the field to people who need to apply the information. In many cases your peers and other pharmacy professionals do not have the time to find the articles, read them themselves, compare the different studies done, and form an informed professional opinion about the problem. You can provide them with timely, concise summary evaluations which will enable them to keep abreast of the field.

Therefore, your **purpose is both informative and persuasive**. You will inform by comparing and summarizing the research results in the articles you read. You will persuade by presenting your opinion about the significance of the research and its clinical applications.

## E. Getting Started

### How should I begin gathering information to write the evaluation?

You should begin gathering information for the evaluation by reading the assigned articles **purposively**. By "purposively," we mean that you should read with a strategy in mind. To evaluate the effectiveness of the research that has been done on your problem or drug, you will have to be able to compare and contrast the various studies. Since you cannot compare apples and oranges, you will have to determine **the bases for comparison**. In other words, you will want to look for specific items in articles. These items will often include the following:

- the study purpose
- the study design
- the sample size
- the patient population of criteria for selection
- the treatment regimens
- the outcome variables
- the analytical methods
- the statistical analysis
- the risks and benefits of the drug therapy

This is not an all inclusive list, but it gives you an idea of the kinds of things you will want to look for in reading the articles. As you gather this information, you will want to **construct a table** so that you and your readers can see at a glance how the studies you reviewed compare and contrast with each other.

A **table template** with the typical categories of information that you will want to find for each article is available elsewhere as handout and in your WAC folder. We suggest that you print out a copy of this table template and use it to guide your reading of the articles. You can make notations in the table template and add new columns if the articles you are reading require additional comparative information. The already designated columns are ones your instructors feel are important for all the articles you read, but you may want to add to the list. Any proposed additions would make a good discussion for members of your collaborative team.

If you prefer, make a copy of the table template, rename it using the topic or drug in your assigned readings, and begin entering the information into it online as you read the articles. Then you can edit the table and save yourself the trouble of writing and then keystroking the information.

Sample tables and instructions on how to fill in the template, change the columns, or add new columns are in your course handout materials.

## 1. Table for Comparing

### Why should I create a table for comparing the studies I read?

If you are comparing only two studies, the bases for comparison between them will be easy to remember; however, if you compare three or more studies, your readers will have quite a bit of difficulty keeping all the important information in mind. You can make it easy for your readers to quickly gather and process this information by presenting it in tabular form.

A table template has been prepared for you in Microsoft Word. Instructions on how to access the table and examples are in your handout materials (**Using a Table for Problem Evaluation**). You can fill in the authors and years in the first column on the left (the vertical axis) and then select the elements you want to compare and fill them in along the top (the horizontal axis). The typical bases of comparison for most articles are already entered in the table template. We suggest that you begin by filling in the information called for. Begin filling in the cells on the table as you begin reading your first article. You may find it necessary to add columns as you go depending on the content of the articles.

This table will save you time later because after you have read all the articles and filled in the table, you will be able to see at a glance the similarities and differences between the studies. You will also notice the holes or gaps and where the clusters are. All of this information will help you to analyze the data. You want to get beyond describing what the researchers did and found to comparing and contrasting their questions, designs and results. Your comparison and contrast will help you to analyze their findings and to determine their significance.

After you have drafted the table, edit it and save it because you will be using it as part of your evaluation.

# CLINICAL HIGHLIGHTS

## THE CAST STUDY AND ITS IMPLICATIONS

Author(s), date (or Ref. #)	Treatment Regimens Evaluated	Outcome Variables Measured & Method of Measurement	Major Findings (Results)
CAPS <sup>4</sup>	<p>1) Patients were randomized into one of five treatment arms: Encainide, Flecainide, imipramine, Moricizine, or Placebo.</p> <p>2) If the first drug was unsatisfactory, it was changed according to the following:</p> <ul style="list-style-type: none"> <li>• encainide and flecainide switched to imipramine or moricizine</li> <li>• placebo switched to placebo</li> <li>• imipramine and moricizine switched to encainide or flecainide</li> </ul>	<p>Drug efficacy was defined as:</p> <ol style="list-style-type: none"> <li>1) &gt;70% reduction in PVCs and</li> <li>2) &gt; 90% reduction in unsustained VT</li> </ol> <p>Patients were monitored in hospital for 48hours after beginning drug therapy.</p> <p>Patients were evaluated by physical exam and 24 hour ECG at 3, 6, 9, and 12 months.</p>	<ol style="list-style-type: none"> <li>1) 64% of patients stayed on the first drug 42% withdrew and 1.2% died 31 % switched to second drug due to lack of efficacy or side effects</li> <li>2) Of the 31% that switched (153) 112 continued with the second drug 16 returned to the first drug 24 withdrew and 1 died</li> </ol>
CAST <sup>3</sup>	<ol style="list-style-type: none"> <li>1) Open label titration phase (15 days) Up to 3 drugs at two different dosages were evaluated: <ul style="list-style-type: none"> <li>• encainide 35 mg tid, 50 mg tid</li> <li>• flecainide 100 mg bid, 150 mg bid</li> <li>• moricizine 200 mg tid, 250 mg tid</li> </ul> </li> <li>2) Randomization phase Patients whose arrhythmias were successfully suppressed were randomized to receive active drug or matching placebo. Patients were stratified according to the following: <ul style="list-style-type: none"> <li>• LVEF <math>\geq</math> 0.3 or LVEF <math>&lt;</math> 0.3</li> <li>• Time between qualifying Holter readings and MI <math>\geq</math> 90 or <math>&lt;</math> 90 days</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1) Titration phase Titration was stopped as soon as the drug and dose were found that suppressed arrhythmias according to the following: <ul style="list-style-type: none"> <li><math>\geq</math> 80% reduction of PVCs and, <math>\geq</math> 90% reduction of unsustained VT runs</li> </ul>                     Measurement was done by 24 hr Holter monitor 4-10 days after dose was begun.                 </li> <li>2) Randomization phase Primary endpoint is death from arrhythmia which was categorized as follows: <ul style="list-style-type: none"> <li>• witnessed instantaneous death in absence of severe CHF or shock</li> <li>• unwitnessed death with no preceding change in symptoms and for which no other cause can be attributed</li> <li>• cardiac arrest</li> </ul>                     Data was collected on the following second endpoints: <ul style="list-style-type: none"> <li>• new or worsened CHF</li> <li>• sustained VT</li> <li>• recurred MI</li> <li>• various cardiac procedures</li> <li>• quality of life</li> </ul>                     Patients returned for follow up at 4 month intervals.                 </li> </ol>	<p>Total number of deaths from arrhythmias or cardiac events and non-cardiac deaths were higher in patients assigned encainide or flecainide therapy vs. placebo (56 of 730 patients = 7.7% mortality vs. 22 of 725 patients = 3.0% mortality, respectively.)</p>

## THE CAST STUDY AND ITS IMPLICATIONS

Author(s), date (or Ref. #)	Study Designs	Demographics			Study Location	Study Duration
		Number	Inclusion Criteria	Exclusion Criteria		
CAPS <sup>4</sup>	Blind, Placebo controlled, Randomized	n=502	1) Acute myocardial infarction between 6 and 60 days before enrollment 2) Less than 75 years old 3) Average of $\geq 10$ PVCs/hour or $\geq 5$ episodes of unsustained VT in a 24 hr ECG.	1) Left ventricular ejection fraction (LVEF) $< 20\%$ 2) Contraindications to any of the study medications 3) $\geq 10$ PVCs at a rate of $\geq 100$ bpm	National, Multicenter	1 year
CAST <sup>3</sup>	Random assignment of subjects to receive active drug or placebo	n = 1455	Patients were screened by ambulatory ECG between 6 days and 2 years post MI 1) LVEF $\leq 0.55$ if recording done within 90 days of MI 2) $\geq 6$ PVCs/hour 3) LVEF $\leq 0.4$ if recording done 90 days to 2 years of MI	1) Ventricular arrhythmias causing syncope or presyncope 2) Unsustained VT with 15 or more successive beats at $\geq 120$ bpm 3) Potentially poor compliance 4) Contraindication to any of the drugs being used 5) Other life-threatening conditions 6) ECG abnormalities that would make interpretation of rhythm difficult	National, Multicenter	10 months

## F. **Analyzing the Articles**

### **What kind of information should I include in the analysis?**

You can use the table you have created for comparing the articles and the information in the annotated bibliography as the basis of your analysis. Notice that the tabular information and the abstracts you have written from that information are descriptive in nature. They simply relate the facts presented in the articles. Now you have to interpret the significance of the findings. In your analysis, you want to answer the question: “So what?”

In writing your analysis, look at the table to determine what parameters or findings are the same in two or more articles and which are different.

- Are there any trends?
- Do all of the articles have certain elements in common?
- Are the research questions or assumptions of the researchers the same?
- Are there any obvious gaps in the studies?
- Are there any approaches or findings that are mentioned by only one group of authors?
- Do the results reported by the researchers answer the research questions they pose?
- How conclusive are their results?
- Are there major flaws in the studies which invalidate the investigators findings?
- Is there corroborating evidence from more than one study?

These are just some of the questions you want to ask yourself as you review and think about the articles.

You can use the results of your comparison and contrast of the articles to explain the significance of the authors’ findings. At this time, you want to draw on what you know about effective research design and effective practice to analyze the effectiveness of the studies and their findings. Marshal evidence from the articles to support your points and develop well reasoned arguments. You will use this

information in section B of your evaluation, the evaluation of the studies. Here is where you give your opinion about the significance of the studies and their findings. You will want to evaluate the individual articles for internal consistency and integrity and then compare them as a group and make judgments about the importance of one in comparison to the others. Be specific in your comments and criticisms. You will want to give reasons for the conclusions you have reached.

You will be ready to do your analysis after creating the table and writing the abstracts for the annotated bibliography. The purpose of the analysis section is to go beyond relating what the researchers did and said to interpret it for your readers in the light of common sense and what you know about effective research design and clinical practice.

## **DRAFT**

### **A. Before you begin**

#### **What is the purpose of the “drafting” section of the tutorial?**

In the drafting section, you will be given suggestions and outlines of what to include in the major sections of the body of the drug problem evaluation.

The organization of the drug problem evaluation has been given to you, so you will not have to “re-invent the wheel.” The drug problem evaluation consists of six parts:

- A. Statement of the problem
- B. Evaluation of the studies
- C. Summary of your findings
- D. Recommendations for clinical application
- E. Comparative table
- F. Annotated bibliography

The entire evaluation should be between 2-4 pages typed.

Using this outline, you will want to organize the information you have already gathered to write the evaluation. After you have completed the planning section, you will already have a draft of section E, the comparative table, and section F, the annotated bibliography. If you have begun answering the questions in the “Analyzing the articles” section of planning, you will already have notes and ideas about what to include in section B (Evaluation of the Studies). So by now you will already have between 25-40% of your first draft done!

Don't feel compelled to begin at the beginning in drafting the evaluation paper. You may want to continue to flesh out your ideas in section B and work your way through C (Summary of Applications) before going back to A, (Statement of the Problem). There is no right way to proceed here. Begin writing whichever sections seem easiest to you . You can always arrange them later.

## B. Statement of the Problem

### What should I include in the statement of the problem?

A good **problem statement** has three elements:

1. statement of the problem
2. what you did to solve the problem
3. the purpose of the paper

Now let's look at each of these elements in turn.

1. A **statement of the problem** that you have been asked to review. This problem statement is generally 2-4 sentences long. It includes a short explanation, the context of the problem and a justification or rationale for why this is important. Sometimes the justification really is a statement of the scope of the problem to indicate how large or pervasive the problem is so that your readers understand its significance. The context and scope are followed by a statement of the aspect of the problem you (or the researchers) are actually examining.
2. **What you did to solve the problem.** This section provides a short statement of your tasks, objectives or assignment. It might even provide us with an outline of how the rest of the paper will be organized and thereby function as a forecast of the structure.
3. The **purpose of the paper** is a statement telling the readers what they will find in this evaluation and giving them an idea of how they should respond to it or use the information.

Your problem statement, sometimes called a problem-purpose statement or just a purpose statement, will serve as an introduction to the drug problem evaluation.

The following are two **examples** of effective **problem statements**:

“Significant and sustained elevations from serum digoxin concentration in the presence of quinidine was first noted by Leahey et al. (1). Further studies have demonstrated that 90% of patients treated with

this drug combination exhibit a 2-3 fold increase in serum digoxin concentration. The purpose of this paper is to review selected studies of the digoxin-quinidine interaction, to state various mechanisms by which this interaction occurs, and to provide guidelines for monitoring therapy and dosage adjustment in patients at risk for this interaction.”

AND

“Hydroxyzine is an antihistamine currently indicated for use as an anxiolytic, antiemetic and antispasmodic agent. Hydroxyzine is combined with the narcotic for its proposed analgesic activity and/or its ability to potentiate the analgesic effects of narcotics without causing respiratory depression. However, antihistamines are not without potentially serious side effects. Therefore, a review of the literature has been conducted to ascertain whether or not hydroxyzine has analgesic activity and/or the ability to potentiate the analgesic effects or narcotic agonists.”

In some cases, you may need to include pertinent background information prior to your problem statement. For **example**, the following **background information** may precede the above problem statement example on hydroxyzine.

“In today’s hospital wards, analgesic agents play an important role in patient recovery. For instance, cancer patients or patients undergoing surgery typically experience moderate to severe pain which can prolong their hospital stay. Patients commonly receive a narcotic combined with an antihistamine for analgesia. Frequently prescribed combinations include morphine sulfate with hydroxyzine and meperidine with hydroxyzine.”

### **C. Table: comparing and contrasting**

#### **What do I put in the table?**

Examples of the table are found in your handout folder. Also, instructions on how to fill in the table and add new columns are also located in your handout folder.

We are not including specific instructions on how to create the table here because you will want to call up the table template and have the instructions in front of you on how to enter information into it. The current WAC program does not have graphic capabilities, so you cannot have both the table and instructions in front of you at the same time using WAC.

## D. Evaluation of the studies

### What goes into the Evaluation section?

The following is an **example** of an **evaluation section**. Notice that it summarizes the important information from your table by comparing the most important aspects of the studies.

Example from Hydroxyzine as an Analgesic:

“Several investigators (Table 1) have reported analgesic activity with hydroxyzine (Vistaril). However, in each of these studies, significant biases were present. In the study conducted by Beaver et al., the selection of patients was non-randomized and highly biased. The selection process involved a nurse deciding which patients to include based on perception of the patient’s ability to participate in the recording of data. Hubert et al. noted in their study a statistically significant difference ( $p < 0.04$ ) in pain intensity difference with 10 mg of morphine plus 100 mg hydroxyzine as compared to the other three treatments, but no significant difference was noted in pain relief scores between these groups. In addition, there was no placebo control in this study. In Stambaugh and Lane’s study, all of the participants were cancer patients with chronic, moderate to severe pain. Since patients with chronic diseases perceive pain differently than patients with acute pain, changes in pain may also be interpreted differently. No comparisons can be made between this study and the others because the other three studies evaluated pain relief in patients with acute surgical pain.”

In this example, the author is pointing out the researchers’ biases, flaws or oversights in the study design, and problems with patients’ self-reporting techniques. The author indicates how these problems affect the usefulness and credibility of the studies. In this section, the author helps the reader to decide what to take “with a grain of salt.” This kind of evaluation also keeps practitioners from making hasty generalizations without enough evidence or with flawed evidence.

In this section, you begin to go beyond what the researchers did and said to answer the larger questions of how valid and important their studies are and whether one study corroborates another. You can begin answering the question “So what?” and get at the significance of the studies here.

## **E. Summary of your findings**

### **What goes into the Summary section?**

In the summary section, you will want to choose the most important conclusions you have reached after analyzing the articles and summarize them here. It is important for you to differentiate your conclusions from the researchers' conclusions. You are presenting the researchers' conclusions in both the table and the annotated bibliography. In this section, you should present the conclusions you reach after writing the Evaluation of the Studies section (B). You are summarizing the most significant conclusions you have drawn after comparing these studies.

The following is an **example summary section** from Hydroxyzine as an Analgesic:

In all of the studies, sedation played a major role. Sedation was reported most frequently with the use of hydroxyzine. Whether or not sedation altered the patients' perception of pain was not addressed. In addition, hydroxyzine has an anxiolytic effect which may also bias the patients' perception of pain. Finally, studies assessing the relief pain following the administration of an analgesic agent rely heavily on subjective data. The perception, severity and relief of pain can vary widely between individuals. Although these studies have attempted to control as many of these variables as possible, biases are present.”

## **F. Clinical Recommendations**

### **What goes into the Recommendations section?**

In this section, you will want to go beyond your conclusions about the effectiveness of the studies you read to make specific recommendations for clinical practice. In other words, you will want to tell your instructor and your peers how much faith they should put in the researchers' findings and how much of what the researchers found should actually be put into practice. This information will help clinical pharmacists make informed judgments and offer informed opinions to physicians.

The following **example of recommendations** is from Hydroxyzine as an Analgesic:

“The data presented does not substantiate the claim that hydroxyzine has analgesic activity or that it potentiates the analgesic activity of narcotic agonists. However, hydroxyzine does help to relieve anxiety and induce sleep, thereby enabling the patient to relax and feel comfortable. Since hydroxyzine is not without potentially serious side effects, this agent should be used only when indicated, for instance, in a postoperative patient with anxiety necessitating the use of an antianxiety agent.”



## Title

Author(s), date (or Ref. #)	Study Design	Demographics				
		Number	Inclusion Criteria	Exclusion Criteria		
1.						
2.						
3.						
4.						
5.						

<b>Author(s), date (or Ref. #)</b>	<b>Treatment Regimens Evaluated</b>	<b>Outcome Variables Measured &amp; Method of Measurement</b>	<b>Major Findings (Results)</b>
1.			
2.			
3.			
4.			
5.			