

PHAR 671 – Applied Pharmacoeconomics and Outcomes Research Spring Semester - 2004

Course Faculty:

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Course Purpose:

Pharmacoeconomics is the study of the costs and consequences (outcomes) associated with the use of pharmaceutical services and drugs. It is closely related to outcomes research which is the scientific measurement of the impact of antecedent health care. The current job market requires pharmacists who understand basic and pharmacoeconomic research design. Pharmaceutical companies, universities, governmental agencies, and managed care organizations are demanding increasing numbers of health professionals with these skills. This course is designed to give students at VCU an opportunity to compete for those positions.

Description:

Course Objectives:

1. To understand and apply the principles of pharmacoeconomics and outcomes research through lectures, readings, class participation, and individual projects.
2. To critically appraise pharmacoeconomic and health outcomes research.
3. To plan and initiate an outcomes research project with a focus on data collection issues, study assumptions, and limitations of various approaches to outcomes evaluations.
4. To discuss the role of pharmacoeconomics in the decision-making process.
5. To identify the role of pharmacists in pharmacoeconomics research.
6. To appropriately use the vocabulary of pharmacoeconomics.

Applications to clinical and managerial problems will be emphasized. The three credit hour course will consist of lectures, participatory discussions, and projects. Class size will be limited to 20 students to permit more extensive faculty contact.

Most course work will be conducted by pharmacy administration and clinical faculty in the pharmacy school. Case materials and projects will consist of real problems seen in practice such as drug formulary decision making and pharmacy service program development. Problems will be solicited from practitioners and providers in the community and adapted for classroom exercises.

Required Text: Data 4.0 Student Version – Decision Analysis Software by TreeAge Software, Inc., Williamstown MA.
Handouts will be given to supplement lectures.

Course Time and Place: Fridays 8-10 am Location: Room 466

Special Needs of Disabled Students

The Americans with Disabilities Act of 1990 requires Virginia Commonwealth University to provide a "reasonable accommodation" to any individual who advises us of a physical or mental disability. If you have a physical or mental limitation that requires an accommodation or an academic adjustment, please arrange a meeting with Dr. Carroll or Dr. Holdford at your earliest convenience.

Course Structure:

The course will consist of one 2-hour lecture period per week. One credit hour per week will be committed to work on the pharmacoeconomics project.

Grading:

Grades will be calculated based on performance on article reviews, class participation, tests, and the pharmacoeconomics project. The quality of learning will be primarily dependent on the students. Therefore, students will have significant autonomy in setting class goals. The grading distribution will be as follows:

Class Participation	25%
Exam (To Be Announced)	25%
Pharmacoeconomics Project Paper	25%
Pharmacoeconomics Project Presentation	25%

To receive 90% of the full class participation grade, students must complete all readings and assignments before class and verbally respond in class discussions. Students who are qualitatively assessed by both Drs. Holdford and Carroll to consistently excel in class participation and assignments can receive a class participation score above 90%. The Exam will be a short answer test designed to assess student’s understanding of major concepts and vocabulary. The pharmacoeconomics project paper and presentation will be graded on the appropriateness of pharmacoeconomics methods used and the quality of presentation. Forms used by faculty in the grading of the written and oral portions of the project are included at the end of this syllabus to assist students with their projects.

To keep on schedule with the pharmacoeconomics project, **each student will be asked to hand in a weekly progress report (two or three sentences long in an e-mail to Dr. Holdford) that describes steps taken toward completion of the project. You will be expected to complete a progress report even if you have accomplished nothing in the last week (i.e., say you have accomplished nothing). THIS IS A GRADED ASSIGNMENT!!!!!!**

Methods of Instruction:

- C Lectures will be used to explain complex topics.
- C Readings are provided to supplement lectures.
- C Recall and comprehension will be checked through class discussion and the test.
- C Students will learn the application of pharmacoeconomics principles through independent research associated with their pharmacoeconomic project.
- C Instructors will facilitate independent learning with class explanations and helpful tips.

Formal lectures will be used sparingly in this class. The primary approach used in this course is LEARNING BY DOING. Students will actually conduct a cost-effectiveness study and present the results in written and verbal form. This is the only way in which students can gain the knowledge and confidence necessary to apply pharmacoeconomic concepts. The secondary approach used in this class is LEARNING FROM MISTAKES AND OTHERS. The instructors in this class realize that students will make mistakes. Mistakes are OK because they are part of the learning process. The instructors also encourage students to consult with clinical faculty on their projects. Clinical faculty are experts in the “pharmaco” part of pharmacoeconomics and can provide significant insight into therapy issues.

Educational Outcomes

It is hoped that at the end of this course, both course instructors will be able to recommend each student for residencies, pharmacoeconomic fellowships, pharmaceutical industry positions, managed care positions, or any other type of advanced practice opportunity available to pharmacy graduates. Both instructors should be able to accurately evaluate each student’s writing, presentation skills, and problem solving and analytical capabilities. In addition, students will develop skills of interest to employers such as a working familiarity with the DATA decision analysis software package, the ability to conduct a cost-effectiveness study from conceptualization to completion, and an expertise in a disease state of interest. Some students may even be able to present their project at state & national conventions.

The course is designed to provide students with skills and knowledge that can be applied to pharmacy practice. Skills can

be used to accomplish tasks. Knowledge can assist decision making. The following are expected skills and knowledge to be gained in the class.

Skills

Decision Analysis Software Program
Decision Analysis Project
Literature Review
Writing
Formal Presentation

Knowledge

Terminology
Basic Concepts
Common Applications in Practice
Career Options

The Cost Effectiveness Project

A major component of the course is the cost effectiveness exercise. Each student or group of students will select a therapeutic class of products and will perform a cost effectiveness analysis on the primary agents within the class. The didactic portion of the class is designed to provide economic analysis skills for this project. The project will also require students to use their literature retrieval and analysis skills. The analysis will be summarized in a written report and will be presented to the class in a 30 minute Powerpoint presentation.

Examples of previous therapeutic areas/classes include:

- Birth Control Options: Birth control pill v. the patch
- Coronary Revascularization: Sirolimus-eluting stents v. traditional bare stents.
- Endometriosis therapy: danocrine v. luprolide
- Anticlotting Therapy: Aspirin v. Clopidogrel.
- Osteoporosis Therapy: Alendronate v. Raloxifene.

The topics selected for the project must be approved by the instructors. A suggested guideline will be provided for your use in writing up the CEA project. Cost-effectiveness projects from prior years are available for your use. When using these, please pay particular attention to the evaluation of these projects - these point out their strengths and weaknesses. The DATA software should be used to complete the project.

Identifying a Pharmacoeconomic Topic – Some students have difficulty identifying a pharmacoeconomic research topic. There are numerous ways to choose a topic for research. Here are some suggestions on how to get started.

- C Choose a disease state or drug of personal interest to you.
- C Conduct a MEDLINE literature search about the drug or disease state to identify clinical studies and review articles that describe the issues involved in selecting between therapies.
- C When choosing drugs therapies for your analysis, remember the following criteria.
 - C The drugs that are to be compared must have different clinical outcomes -- either in effectiveness or through side effects. If the clinical outcome of each alternative is exactly the same, then they are therapeutically equivalent and a poor choice for this project. For example, comparing the cost effectiveness of ibuprofen and naproxen would be a poor topic because the drugs are therapeutically equivalent. A better choice would be to compare either with a COX-2 inhibitor.
 - C The different clinical outcomes must result in a significant difference in resource use. (i.e., if there are no differences in cost of drugs, hospitalizations, MD visits, etc. then a pharmacoeconomics analysis is not necessary). For example: Zolpidem and Zaleplon have only slight clinical differences between the two drugs and the differences do not result in significant differences in resource use. They would therefore be a bad choice for a project. In addition, they are poor choices because it is difficult to measure differences in resource use (e.g., how do you measure lost sleep?)
- C Talk with the instructors about your project ideas. They can ask questions and provide feedback to guide your

choice.

- C Do not procrastinate!!! Start to research your topic today. The research itself is part of the learning process so get started now.

Class Objectives

<u>Date</u>	<u>Objective</u>
Week 1: Holdford	Establish expectations for class. Review syllabus and pharmacoeconomic project. Assignment: weekly progress reports. C Define and contrast pharmacoeconomics, outcomes research, and pharmacoepidemiology. C Identify the characteristics of pharmacoeconomic analyses that differentiate them from cost analyses and cost descriptions. C Discuss the importance of pharmacoeconomics to pharmacists and the health care system. C Identify the key audiences for pharmacoeconomics research and their information needs. C Describe how pharmacoeconomics research can be conducted in a manner to maximize the utility for society. C List several ways that pharmacists might utilize pharmacoeconomics training.
Week 2: Holdford	Review major pharmacoeconomic ideas and terminology. Discuss how pharmacoeconomics fits into the overall big picture. Be able to describe and differentiate terms. C Compare and contrast CEA's with Cost-Utility, Cost-Benefit, Cost-Minimization, and Cost-of-illness (i.e., burden of disease) analyses. C Discuss the importance of perspective in CEA's. C Contrast efficacy and effectiveness. C Define each of the following costs and give examples of each. 1. Direct costs 2. Medical costs 3. Non-medical costs 4. Indirect costs 5. Intangible costs 6. Opportunity costs C Given a CEA topic, identify which costs would be relevant from the perspective of: 1. Private insurers 2. Patients 3. University hospitals 4. Society 5. Medicare 6. Medicaid C Describe the difference between average and incremental cost effectiveness ratios. Identify which is preferred in economic analyses and discuss why. C Discuss the purposes of discounting and sensitivity analyses.
Week 3: Holdford	Discuss the process of conducting a pharmacoeconomic decision analysis. In class, build a decision tree modeling the choice between COX-2's and NSAIDs. Assignment: Select a Topic for a Cost-Effectiveness Project. C Define the purpose of conducting a cost-effectiveness analysis. C List the conditions under which a cost-effectiveness analysis should be conducted. C List the benefits of conducting DA C Describe the steps in the DA process C Discuss critical issues associated with the:

1. framing the decision of interest.
2. audience.
3. population to be studied.
4. time period of the analysis.
5. outcome. (I.e., effect of cost-effectiveness)
6. decision model to be used.(e.g., Markov)
7. method of analysis (e.g., cost-benefit)
8. drawing the decision tree
9. choosing probabilities.
10. assigning Costs.
11. choosing the preferred course of action.
12. Sensitivity Analyses (SA)
13. Limitations

Week 4: Modeling CEAs Using DATA Decision Analysis Software. **Assignment: Compete and interpret a cost-effectiveness example.**

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- C Construct and interpret a cost-effectiveness analysis example with Decision Analysis Software.
- C Assess expected and marginal cost effectiveness.
- C Conduct a sensitivity analysis of the decision analysis.

Week 5: Probability and Effectiveness Estimates in CEAs. **Assignment: Complete an effectiveness analysis tree.**

Holdford

- C Describe how outcomes data is used in constructing CEAs.
- C List various sources of outcomes data and the advantages/disadvantages of each.
- C Identify the conditions in which outcomes data should be included in CEAs.

Week 6: Costs and Discounting in CEAs. **Assignment: Complete a cost analysis tree.**

Carroll

- C Differentiate costs from charges and prices
- C Compare and contrast the economic and accounting definitions of cost.
- C Identify sources of cost information for
 1. Hospitals
 2. Physicians
 3. Diagnostic tests.
 4. Drugs
- C Discuss when it is appropriate to discount costs and benefits
- C Describe the present value approach to discounting.
- C Identify what discount factor should be used in studies.

Week 7: Evaluating Pharmacoeconomic literature. **Assignment: Complete a written analysis of a cost-effectiveness study.**

Holdford

- C Understand what to look for in pharmacoeconomic studies.
- C List and discuss criteria for evaluating a pharmacoeconomic study
- C Critically analyze a cost-effectiveness study.

Week 8: Cost of Illness studies.

Carroll

- C Describe the purpose of COI studies
- C Differentiate prevalence- & incidence-based COI studies.
- C List and discuss characteristics of good COI research.
- C Recognize and discuss reasons for variability in COI studies.

Week 9: Uncertainty and Limitations in CEAs. **Assignment: Hand in one- and two-way sensitivity analyses of the project.**

Holdford

Discuss the purpose of sensitivity analyses (SA)

- C List variables most often assessed in SA's.
- C Describe sources of uncertainty in data in pharmacoeconomic analyses.
 1. variability in data.
 2. generalizability of results.
 3. extrapolation of results.
- C Describe the following types of SA's.
 1. Simple one-way and multiple way SA's.
 2. Threshold analysis.
 3. Analysis of extremes.
 4. Probabilistic e.g., Monte Carlo simulations
- C Discuss the purpose of presenting limitations in DA's.

Week 10: Markov analysis. **Assignment: Complete a written review of a cost-utility paper.**

Carroll

- C Compare and contrast Markov analyses and Decision Analyses.
- C Conduct a simple Markov analysis
- C Describe how Markov models differ from traditional decision analyses.
- C Discuss the role of Markov modeling.
- C List the steps involved in developing a Markov model.
- C Describe the limitations of Markov models.

Week 11: **Final Exam**

Holdford

Week 12: Presenting pharmacoeconomic data.

Holdford

- C List the criteria that make a good written CEA paper.
- C List the criteria that make a good verbal CEA presentation.

Week 13: **Hand in pharmacoeconomic paper.**

Week 14 & 15: **Presentation of projects**

Pharmacoeconomics Presentation Form

Student's Name: _____

Please rate each presentation for all of the criteria listed below. Bear in mind that the presentation time is limited and may force the student to leave out important details (i.e., 15 minutes for presentation and 5 minutes for Q & A). Feel free to question students about these details in the question and answer period.

1. Definition of the problem clearly stated? Purpose for conducting the analysis given? (20 points)

2. Outline? (5 points)

3. Methods clearly described and appropriate?
 - A. Decision analysis (5 points)
 - B. Sources of data (5 points)
 - C. Sources of costs. (5 points)

4. Analysis and results described and appropriate? (10 points)

5. Appropriate sensitivity analysis conducted (i.e., variables with greatest uncertainty)? (10 points)

6. Conclusions provided and supported by the data & information presented? (10 points)

7. Organization and clarity of presentation and audiovisuals. (15 points)

8. Did the student demonstrate a depth of knowledge about the subject? (15 points)

Score Sheet for Written Presentation of the CEA Project

It is critical that you are thorough, yet concise. A poorly written CEA project will be neither persuasive or comprehensible. On the other hand, a well written paper can be used to demonstrate not only your arguments, but also your mastery of pharmacoeconomics to faculty and employers.

	Possible Pts	Score
Introduction	15	_____
C Clear statement of Pharmacoeconomic problem. Purpose of study		
C Perspective of analysis .		
C Description of alternatives evaluated. Compare with current standards of treatment.		
C Description of population studied.		
C Time period of study.		
C Specify the primary outcome measure to be used in the study and why this was selected over other outcome measures. If intermediate outcomes are chosen, provide evidence that links them with final outcomes.		
Methods	20	_____
C Clear construct and explanation of decision tree.		
C Describe steps in treating disease.		
C Explain assumptions in model.		
C Defensibility of assumptions.		
C Appropriate methods if applicable – e.g., discounting.		
Sources of Clinical Data	10	_____
C Describe sources of clinical data.		
C Provide clear documentation of sources.		
C Justification for omitted data.		
Cost and Resource Data	10	_____
C Describe sources of data.		
C Provide clear documentation of sources.		
C Justification for omitted data.		
Sensitivity Analysis	20	_____
C Describe sensitivity analyses and their implications.		
C Variables used and the ranges over which they were varied.		
C Justification of why these particular variables were included and why these particular ranges were used.		
C Incremental analysis used appropriately if applicable.		
Discussion	20	_____
C Clear explanation of the results and significance of findings. Explained in a manner accessible to a manager who has little clinical experience.		
C Conclusions match the methods and results.		
C Limitations and assumptions discussed. Their effects on results and conclusions given.		
C Selection an alternative made and justification given.		
References	5	_____
C Appropriate referencing.		