

A Basic Course in Pharmaceutical Economics: Background, Rationale, and Suggested Syllabus

E. M. Kolassa

ABSTRACT. Pharmaceutical economic research is growing as a field of study and as a tool for health-care decision-making. Pharmacists, especially those in administrative and managerial positions in hospitals and large health-care systems, are expected to incorporate the results of these studies into their recommendations and daily routines. Past research has shown that pharmacy curricula do not adequately prepare students for performing or using pharmaceutical economic research studies. This paper offers a rationale for the inclusion of a basic course in pharmaceutical economics into the curriculum and provides a syllabus for such a course.

INTRODUCTION

The field of pharmaceutical economic research, while widespread and growing, is still in its relative infancy (1). In theory, the study of the economic and other nonclinical effects of medications should be relatively straightforward, using the techniques and methods favored by such leading authorities as Eisenberg, Drummond, and Feeney. Unfortunately, despite the person-years of work put into the field, and the study of the field, we are left with at least

E. M. Kolassa, M.B.A., is a research associate at the Research Institute of Pharmaceutical Sciences who has worked in the field of pharmaceutical pricing and economics for over 12 years and a doctoral candidate in Pharmacy Administration at the School of Pharmacy, University of Mississippi, University, MS 38677.

three basic problems when attempting to perform, evaluate, or use pharmaceutical economics research.

Health-Care Systems Differences: Problem of Applying Results

Among the most noticeable flaws in pharmaceutical economic studies is the inconsistency of endpoints measured in the reported literature. While consensus might be reached on the most appropriate endpoints for a single health-care system, international comparisons are made very difficult because of cultural, demographic, and administrative differences in health-care delivery systems (2).

A common resource measurement in studies performed in the United States is hospital length of stay (3). This measure has become more important with the advent of Diagnostic Related Groups (DRGs), a system of health-care financing used for hospital treatment for Medicare patients that bases reimbursement on a predetermined set of payments, based on average costs and other capitated payment schemes. These cost-containment methods, instituted initially by the U.S. Health Care Financing Administration, sought to control costs by forcing providers to manage health care within the constraints of a budget. The length of hospital stay is a key element in DRG case management, and provides a fairly good surrogate for total hospital costs or charges. Some European nations, on the other hand, do not feel this measure to be as relevant, due to cultural expectations of long stays and the fact that hospitals are owned and managed by central authorities, who view hospital days as fixed costs and not subject to greater efficiencies.

Work days lost or saved should be vital statistics in nations where national health-care systems rely upon productive workers. In the United States, however, the majority of Medicare patients are no longer employed, and private health insurers and many other payers are not directly affected by this measure—the number of work days lost or saved have no direct affect on the payers. This lack of attention to work days lost should be changing, as more employers are taking an active role in health-care decision-making.

The Academic versus the Practitioner's Perspective

As in many fields of study, pharmaceutical economic studies have yet to be diffused into the general population of practitioners.

Some of the more common measures used in pharmaceutical economic research, such as the Quality-Adjusted Life Year (QALY), are difficult for novices to interpret (4). While these measures are commonly used, their validity and utility are constantly called into question. Several authors have called for agreement that such research must take the broadest view possible, that of society (5), while the decision-makers, those who select and administer pharmaceutical therapy, cannot relate the societal effect to the individual patient's immediate needs or to those of the institution in which they are practicing (6).

Combined with the difficulty in interpreting and using the result of many of these studies, practitioners, who have not been trained in the field of economic analysis or the several of the social sciences used in pharmaceutical economics (7), must choose between simply accepting that the published studies are factual or ignoring the results of the studies and determining appropriate use of new agents based either on their cost or their effectiveness, but not a combination of the two.

A Business-Policy Necessity: Is It Science, Art, or Marketing?

Confounding the issues already addressed is the problem that the environment for health care has changed significantly in recent years and the economic consequences of health-care interventions are now of paramount importance. Pharmaceutical manufacturers, along with other providers, payers, and consumers of health care, must concern themselves with these consequences. The lack of agreement on methodologies and research endpoints, or even a commonly accepted definition and purpose for the research, has resulted in an environment with more questions than answers.

The lack of hard and fast rules for economic analysis, and no consensus on the use of the studies, renders the field susceptible to the very real problems of charlatans providing spurious study results; moreover, because study design and data interpretation are not well-established, those with a preconceived idea or a biased agenda may generate studies that are misleading. The lack of background in economic analysis among those who need and/or commission these studies, commonly either pharmaceutical marketers or government policy makers, and even some performing the stud-

ies, makes it easy for improper conclusions to be drawn from good and bad studies alike (8).

DEALING WITH THE PROBLEMS

Many of these problems cannot be dealt with in a simple manner. The lack of consensus on the most appropriate measures and methodologies is likely to remain, as those who champion one approach argue with those who favor another. The lack of comparable results between different nations is likely to remain, since it would require significant cultural shifts to align these systems.

Nevertheless, two approaches, one scientific and already loosely followed and the other the application of basic marketing theory, could go a long way toward dealing with the problems. The first is to collect and report the data from economic studies in terms of resource consumption, as opposed to reporting these results exclusively in currency-based units. Provision of a model that allows practitioners and others to apply the costs within their own systems would allow for some translation between studies and transferability of the results. This has been done, to some extent, by a few pharmaceutical companies, such as Roche and Amgen, who provide hospitals with computer-based models of the use of their products, and allows the users to provide their own unique cost and protocol information for the model. The end result is relevant information.

The second approach is to educate practitioners, to develop in them the ability to interpret and utilize the studies, and to demand from those producing the studies the information that is needed by them. Inclusion of pharmaceutical economics courses and materials in Pharm.D. programs and continuing education programs is a start, but these must be based not on how to conduct the studies as currently practiced, but how to incorporate economic information into clinical and administrative decisions. With that accomplished, the studies will be performed to meet the needs of the market.

AN INTRODUCTORY COURSE IN PHARMACEUTICAL ECONOMICS

To prepare future pharmacy practitioners and health economists for their eventual responsibilities, an introductory course in phar-

maceutical economics that focuses on learning the basic techniques of the area and the development of the ability to critically evaluate health-related economic studies has been developed. This course will provide practitioners with the knowledge and skills needed to incorporate the results of economic studies into their roles as decision-makers, and supply students of health and pharmaceutical economics with the background necessary for more advanced studies in the field. The syllabus for this course is presented here.

Pharmaceutical Economics

The terms *pharmacoeconomics* and *pharmaceutical economics* will be used interchangeably in this document. *Pharmaceutical economics* is the preferred term of the author, because it is felt to more broadly encompass the areas including and surrounding the use of pharmaceutical agents.

Definition

Pharmacoeconomics is the description and analysis of the costs of drug therapy to health-care systems and society. Pharmacoeconomic research identifies, measures, and compares the costs (i.e., resources consumed) and consequences of pharmaceutical products and services. (9)

The definition provided here encompasses more than the study of the financial effect of medication use—it also includes the study of the effects of interventions by pharmacists and others in the drug distribution system.

Course Objective

To provide students with as broad an understanding of the area as possible, since many may not pursue further study in the area, this course should provide:

1. An overview of the need for and use of pharmaceutical economic research
2. An introduction to commonly used methods of pharmaceutical economic research

3. A history of the use and misuse of health economics studies
4. Exposure to the sometimes conflicting views and philosophies of the area
5. An understanding of the difficulties in performing and using these studies
6. An understanding of the potential new uses of this information

The student, upon completion of this course, will have the ability to:

1. interpret and critically analyze published pharmaceutical economic studies
2. design a valid pharmaceutical economics study protocol
3. integrate the results of pharmaceutical economics studies into the decision making processes of pharmacy directors, physicians, and other decision makers in the health-care system.

Text

J. Lyle Bootman, Raymond J. Townsend, and William F. McGhan, *Principles of Pharmacoeconomics* (Cincinnati, Ohio: Harvey Whitney Books Company, 1991).

This book has been selected as the primary text because it provides a general overview of the many uses of pharmaceutical economics, as well as providing a comprehensive bibliography of pharmaceutical economics literature.

Supplementary Materials

To accompany the text, supplemental reading and exercises will be used extensively. Additionally, students will be exposed to and use the MUST database and other literature search sources. These will be used regularly in exercises for the class.

Course Process

The course is divided in five sections, each building upon those previously covered. Each of these sections will require two to three weeks (six to nine contact hours) of classroom time. The remaining three weeks of the semester will be devoted to review and testing.

**SECTION 1:
INTRODUCTION TO PHARMACEUTICAL ECONOMICS**

ECONOMIC ANALYSIS

- Marginal Analysis
- The Measurement of Costs
- Total vs. Compartmentalized Costs

USES OF PHARMACEUTICAL ECONOMICS

- Pharmacy Budgeting Uses
- Outcomes Analysis
- Public Health-Care Policy

Book Chapters

1. Introduction to Pharmacoeconomics
2. Drug Use Economics: Prescription and Nonprescription Drug Use
3. Cost Determination and Analysis

Readings

- Freund DA, Dittus RS. Principles of pharmacoeconomic analysis of drug therapy. *PharmacoEcon.* 1992; 1(1):20-29.
- Hall J, Mooney G. What every doctor should know about economics: part 2. The benefits of economic appraisal. *Med J Aust.* 1990; 152(2):80-82.
- Wilensky GA, Blumberg LJ, Neumann PJ. Pharmaceuticals and decision-making in the United States: Cost-consciousness and the changing locus of control. In: van Eimeren W, Horisberger B, eds. *Socioeconomic evaluation of drug therapy.* Berlin and New York: Springer Verlag; 1988:32-45.
- Drummond MF. The economic evaluation of pharmaceuticals: Science or marketing? *PharmacoEcon.* 1992; 1(1):8-13.
- Dao, TD. Cost-benefit and cost-effectiveness analysis of drug therapy. *Am J Hosp Pharm.* 1985; 42(4):791-802.
- Williams A. The role of health economics in clinical decision-making: Is it ethical? *Respir Med.* 1991; 85(Supp B, Sept):3-5.

- Berk A, Paringer L, Mushkin SJ. The economic cost of illness, fiscal 1975. *Med Care*. 1978; 16(9):785-90.
- Scitovsky AA, McCall N. Changes in the costs of treatment of selected illnesses, 1951-1964-1971. San Francisco: School of Medicine, University of California; 1975.
- Simpson CA, Sournay PF. Calculating the costs of drug therapy: A review of a decade of literature (1977-1987). *Clin Ther*. 1988; 10(6):616-50.

SECTION 2: OVERVIEW OF METHODOLOGIES AND EXERCISES

METHODOLOGIES

- Cost Minimization
- Cost Effectiveness
- Cost Benefit
- Cost Utility
- Quality of Life Measurements

Book Chapters

4. Health Status Indices and Quality of Life Assessment
5. Cost Effectiveness Analysis
6. Cost-Benefit Analysis

Readings

- Hurley S. Indices of therapeutic outcome in pharmaco-economic evaluation of drug therapy. *PharmacoEcon*. 1992; 1(3):155-60.
- Drummond MF. Resource allocation decisions in health-care: A role for quality of life assessments? *J Chron Dis*. 1987; 40(6):605-16.
- Sonnenberg A. Costs of medical and surgical treatment of duodenal ulcer. *Gastroenterology*. 1989; 96(6):1445-52.
- Weiss JC, Shoshana TM. Cost effectiveness in the choice of antibiotics for the initial treatment of otitis media in children, a decision analysis approach. *Pediatr Infect Dis J*. 1988; 7(1):23-26.
- Kemp BA, Moyer PR. Equivalent therapy at lower cost: The oral penicillins. *JAMA*. 1974; 228(8):1009-14.

Exercises

Using the MUST data base, locate and critically evaluate two studies that compare:

Two Medications (Drug/Drug)

A Medication with Surgery (Drug/Non-Drug)

The evaluation must include:

1. Identification of the type of study and the professional background of the researchers.
2. Evaluation of the appropriateness of the endpoints measured.
3. An assessment of the adequacy of the scientific rigor used in the performance of the studies.
4. The usefulness of each study in the practice setting.
5. A comparison of the two studies in terms of balance, rigor, and usefulness.

Student papers for this assignment should be no fewer than five typewritten, single-spaced pages, and no longer than ten pages.

**SECTION 3:
PHARMACEUTICAL ECONOMIC RESEARCH DESIGN**

MAJOR COMPONENTS OF RESEARCH DESIGN

RESEARCH OBJECTIVES

STUDY TYPES

Retrospective vs. Prospective

Active vs. Literature Review

ISSUES IN RESEARCH DESIGN

Statement of Hypotheses

Inclusion in Clinical Trials—Pros and Cons

Readings

Adams ME, McCall NT, Gray DT et al. Economic analysis in randomized clinical trials. *Med Care.* 1992; 30(3):231-43.

- Simes RJ, Glasziou PP. Meta-analysis and quality of evidence in the economic evaluation of drug trials. *PharmacoEcon.* 1992; 1(4):282-92.
- Jolicouer LM, Jones-Grizzle AJ, Boyer JG. Guidelines for performing a pharmacoeconomic analysis. *Am J Hosp Pharm.* 1992; 49(7):1741-47.

Study Evaluations—Assignment

- Lezaun R, Brugada P, Smeets J et al. Cost-benefit analysis of medical vs. surgical treatment of symptomatic patients with accessory atrioventricular pathways. *Eur Heart J.* 1989; 10(12):1105-9.
- Pashko S, Johnson DH. Potential cost savings of oral versus intravenous etoposide in the treatment of small cell lung cancer. *PharmacoEcon.* 1992; 1(4):293-97.

Students will evaluate these two studies using the guidelines provided by the readings assigned for this section. They will:

1. Identify the type of study
2. Evaluate the studies using the guidelines provided by Adams et al.
3. Using the approach outlined by Jolicouer et al., recommend improvements in the studies.
4. Assess the usefulness of the studies and estimate change in utility by applying the guidelines.

SECTION 4: QUALITY OF LIFE AND RELATED ISSUES

OVERVIEW OF MEASURES: QOL, QALY, HYE

USES OF TABLES AND INDICES FOR QUALITY DETERMINATION

Life Tables, Standard Gambles, Rosser and Watt's Classifications

Readings

- Kaplan RM, Atkins CJ. The well-year of life as a basis for patient decision making. *Patient Educ Couns.* 1989; 13:281-95.
- Siegrist J, Junge S. Conceptual and methodological problems in research on the quality of life in clinical medicine. *Soc Sci Med.* 1989; 29(3):463-68.
- Smith A. Qualms about QALYs. *Lancet.* 1987; 1(May 16):1134-36.
- Donaldson C, Atkinson A, Bond J. Should QALYs be programme-specific? *J Health Econ.* 1988; 7(3):239-57.
- Pearlman RA, Joneson AJ. The use of quality of life considerations in medical decision making. *J Am Geriatr Soc.* 1985; 33(5):344-52.
- Gafni A. Measuring the adverse effect of unnecessary hypertension drug therapy: QALY vs HYE. *Clin Invest Med.* 1991; 14(3):266-70.

**SECTION 5:
USES OF PHARMACEUTICAL ECONOMIC
RESEARCH INFORMATION**

INTERNAL DECISION MAKING

- Formulary Management
- Clinical Pharmacy Interventions
- Budgetary Control and Analysis

OUTPATIENT BENEFIT DESIGN

- Restriction, Co-Payments, and Outpatient Formularies

AFFECTING DECISION MAKING

- Prescriber Education

PUBLIC POLICY PERSPECTIVES**Readings**

- Schumacher GE. Multiattribute evaluation in formulary decision making as applied to calcium-channel blockers. *Am J Hosp Pharm.* 1991; 48(2):301-8.

- Segal R, Pathak DS. Formulary decision making: Identifying Factors that influence P & T Committee drug evaluations. *Hosp Form.* 1988; 23(2):174-78.
- Kirking DM, Svinte MK, Berardi RR et al. Evaluation of direct pharmacist intervention on conversion from parenteral to oral histamine H₂-receptor antagonist therapy. *DICP Ann Pharmacother.* 1991; 25(1):80-84.
- Chrischilles EA, Helling DK, Aschoff CR. Effect of clinical pharmacy services on the quality of family practice physician prescribing and medication costs. *DICP Ann Pharmacother.* 1989; 23(5):417-21.
- Nagumey JT, Braham RL, Reader GC. Physician awareness of economic factors in clinical decision-making. *Med Care.* 1979; 17(7):727-36.
- McGhan WF, Wertheimer AI, Rowland CR. Using Medicaid data to identify patients with drug therapy problems. *Inquiry.* 1982; 19:79-88.
- Goldberg T, DeVito CA, Smith D et al. Evaluation of economic effects of drug product selection legislation. *Med Care.* 1979; 17(4):411-19.
- Schweitzwe SO, Salehi H, Boling N. The social drug lag: an examination of pharmaceutical approval delays in medicaid formularies. *Soc Sci Med.* 1985; 21(10):1077-82.
- Hadsall RS, Lipson DP, Norwood GJ. The effect of Medicaid on the quantity of drugs dispensed per prescription. *Contemp Pharm Pract.* 1982; (5)1:45-49.
- Soumerai SB, Ross-Degnan G, Avorn J, McLaughlin TJ. The effect of Medicaid drug-payment limits of admission to hospitals and nursing homes. *N Engl J Med.* 1991; 325(15):1072-77.

Study Evaluations—Assignment

Students will critically evaluate two of the following:

- Ray WA, Schaffner W, Federspiel CF. Improving antibiotic prescribing in outpatient practice. *Med Care.* 1985; 23(11):1307-13.
- Nelson AA, Reeder DE, Dickson WM. The effect of a Medicaid drug copayment program on the utilization and cost of prescription services. *Med Care.* 1984; 22(8):724-36.

- Bloom BS, Jacobs J. The cost effects of restricting cost-effective therapy. *Med Care*. 1985; 23(7):872-80.
- Hefner DL. Cost effectiveness of a restrictive drug formulary: Louisiana vs Texas. Washington, DC: National Pharmaceutical Council; 1980.

REFERENCES

1. Drummond MF. Economic evaluation of pharmaceuticals, science or marketing? *Pharmacoecon*. 1992 1(1):8-13.
2. Pearlman RA, Jonsen A. The use of quality-of-life considerations in medical decision making. *J Am Geriatr Soc*. 1985; 33(5):344-52.
3. Larson L. Cost determination and analysis. In: Bootman JL, Townsend RJ, McGhan WF, eds. *Principles of pharmacoeconomics*. Cincinnati, OH: Harvey Whitney Books Company; 1991:34-49.
4. Smith A. Qualms about QALYs. *Lancet*. 1987; 1(May 16):1134-36.
5. Drummond M. Australian guidelines for cost-effectiveness studies of pharmaceuticals: The thin edge of the boomerang? *Pharmacoecon*. 1982 (Supp. 1):61-69.
6. Kolassa EM, Smith MC. Hospital pharmacy directors' use and understanding of economic outcomes studies. Paper presented at 8th annual meeting of the American Association of Pharmaceutical Scientists. Lake Buena Vista, FL:1993 Nov 16.
7. Juergens JP, Szeinbach SL, Smith MC. Will future pharmacists understand pharmacoeconomic research? *Am J Pharm Educ*. 1992; 56(2):135-40.
8. Adams ME, McCall NT, Gray DT, Orza MJ, Chalmers TC. Economic analysis in randomized control trials. *Med Care*. 1992; 30(3):231-43.
9. Townsend RJ. Postmarketing drug research and development. *Drug Intell Clin Pharm*. 1987; 21(1):134-36.