Combining the Principles of Epidemiology and Economics

C. Daniel Mullins
School of Pharmacy, University of North Carolina, Chapel Hill NC 27599-7360

INTRODUCTION
Since the advent of managed care, increased focus on pharmacoeconomic evaluation has penetrated the health care system in general and pharmaceutical reimbursement in particular. The managed care focus has increased the demand for researchers who are trained in both the epidemiology and economics of drug evaluation and treatment. Consequently, the number of employment opportunities for users of such information has expanded. To date, the supply of individuals with appropriate training in both epidemiology and economics has lagged behind the demand. To address this problem, schools of pharmacy, in conjunction with medical schools, schools of public health, and economics departments, are faced with the challenge of redesigning their curricula and teaching methods that will meet this need. This article describes how this newly emerging discipline can respond to the anticipated demand for researchers and users of pharmacoeconomics and pharmacoepidemiology. Certain aspects are based on the model which is currently implemented in the Pharmacy Administration curriculum at the University of North Carolina.

KNOWLEDGE DISCIPLINES
Epidemiology examines the distribution of disease and health in human populations and those factors that have either a positive or adverse effect on health status. In a controlled environment such as a clinical trial, randomization permits quantitative analysis of exposure. The restraints of a controlled clinical trial reduce the likelihood of bias in establishing relationships between exposure and health status in the trial sample. The randomized, controlled trial (RCT) design reduces threats to what has been called internal validity(1) or what Senn(2) has called “proof within the trial.”

In the general population, when exposure may be a natural concomitant of the forces that produce and prevent diseases, there are greater challenges in separating out the relevant factors of causation and those components that can introduce bias into an analysis. The generation of epidemiologic analyses requires careful consideration of

Table I. Research objectives in pharmacoeconomics

<table>
<thead>
<tr>
<th>Cost measured in:</th>
<th>Outcomes measured in:</th>
<th>Evaluative measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost Minimization Analysis (CMA)</td>
<td>Monetary units</td>
<td>Equivalent units of relevant indicators such as efficacy and risk</td>
</tr>
<tr>
<td>Cost Effectiveness Analysis (CEA)</td>
<td>Monetary units</td>
<td>Natural units</td>
</tr>
<tr>
<td>Cost Benefit Analysis (CBA)</td>
<td>Monetary units</td>
<td>Monetary units</td>
</tr>
<tr>
<td>Cost Utility Analysis (CUA)</td>
<td>Monetary units</td>
<td>Nonmonetary units such as quality or patient’s preferences</td>
</tr>
</tbody>
</table>

Fig. 1. Subspecialties created by merging of epidemiology and economics.

study design and methods to evaluate and control for bias and confounding influences(3). There are significant differences in the analysis of outcomes in subjects participating in controlled clinical trials vis-a-vis the general population of patients in the indication area. The distinction is highlighted through the difference between efficacy and effectiveness. Efficacy reflects the extent to which a drug or other intervention has the intended effect in a controlled environment, while effectiveness contemplates the effect of a drug in a natural setting where full compliance is not assured and confounding influences may alter the intended outcomes.

While RCTs offer advantages in reducing threats to internal validity, RCT-based research often does not properly address the issue of external validity(4). This issue is sometimes referred to as generalizability in the epidemiology literature(5). Issues related to both internal and external validity provide the basis for collaborative research between epidemiologists and economists, with each type of researcher bringing a set of methodological tools to these complex issues. For a more detailed discussion of this topic, see the article by Rittenhouse which follows in this issue(6).

A subspecialty within epidemiology is the field of pharmacoepidemiology, which, as its name implies, is the application of epidemiologic knowledge, methods, and reasoning to drug therapy. Pharmacoepidemiology is concerned with the effects of pharmaceutical products in specified human populations during a defined period of time(7). The demographics of the observed population and the timing of medical interventions allow researchers to describe and explain differences among population groups based on age, gender, sociocultural characteristics, and other variables.

Economics examines how individuals use scarce resources for the production and allocation of goods and services. Efficiency considerations dictate that resources should be allocated so that dollars or other inputs obtain the greatest return, measured in monetary units or some notion of worth. It is not sufficient that an investment yield a positive return in the future in order for an economic analysis to support a decision. It must also be the case that there is no other feasible use of a given resource during the period of observation that would yield a higher return. This return may be in the form of output of goods or services, dollar value equivalents, or what economists refer to as utility—a measure of the perceived value to a specified individual or group.

Pharmacoeconomics applies the tools of economics to decisions concerning the use and financing of drugs. There are four basic methods for assessing the economic impact of pharmacotherapy: (i) cost minimization analysis (CMA); (ii) cost effectiveness analysis (CEA); (iii) cost benefit analysis (CBA); and (iv) cost utility analysis (CUA). The proper use of these methods has been discussed and debated in the literature(8,9) with each methodology focusing on a unique research objective, as described in Table I. In addition to providing evaluative analysis of competing drug therapies on a cost basis, pharmacoeconomics allows drug manufacturers to strategically determine prices. Pharmacoeconomic analyses have been used to support marketing efforts in phase III and phase IV clinical trials, but recently there has been a push to incorporate pharmacoeconomics into the earlier drug development phases(10).

A variety of subspecialties that combine the principles of epidemiology and economics are appropriate for Pharmacy Administration curricula. Some of the major topic areas are pharmacoepidemiology, pharmacoeconomics, pharmaceutical outcomes research, and pharmaceutical care decision making. Certain areas utilize epidemiology or economics to a greater extent, as shown in Figure 1. While there has been significant research which combines these two disciplines, and several journals that publish almost exclusively in this area, there are few academic programs that provide students with integrated course work. Part of this
can be attributed to the fact that pharmacy administration departments traditionally do not include professors who received doctoral training in one of these disciplines. Furthermore, faculty who have doctoral training in epidemiology or economics typically do not have training in the other. In addition, the recognized need for researchers who are knowledgeable in both epidemiology and economics is a recent phenomenon. While future generations of educators may be appropriately trained to teach courses that cross both disciplines, currently there is a shortage of individuals who have true expertise in both epidemiology and economics.

**MODULAR APPROACH TO TEACHING**

To address the need for graduates with training in both economics and epidemiology, it is imperative that course instructors from both disciplines be included. Since programs that combine this knowledge are only in the formative stages, faculty for such courses must include both epidemiologists and economists. This necessity lends itself to a modular approach to teaching.

Table II. Syllabi for health care technology assessment

<table>
<thead>
<tr>
<th>Lecture 1</th>
<th>Economics emphasis</th>
<th>Epidemiology emphasis</th>
<th>Sequential</th>
<th>Parallel tracking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lecture 1</td>
<td>Foundations of Economic Analysis</td>
<td>Foundations of Epidemiology</td>
<td>Foundations of Economic Analysis</td>
<td>Economic Evaluation</td>
</tr>
<tr>
<td>Lecture 2</td>
<td>Distinction between Costs and Charges</td>
<td>Clinical Trials</td>
<td>Distinction between Costs and Charges</td>
<td>Clinical Trials</td>
</tr>
<tr>
<td>Lecture 3</td>
<td>Average, Marginal and Incremental Costs</td>
<td>Cohort/Case-control Designs</td>
<td>Average, Marginal and Incremental Costs</td>
<td>Average, Marginal and Incremental Costs</td>
</tr>
<tr>
<td>Lecture 4</td>
<td>Clinical Evaluation</td>
<td>Estimation of Outcome Probabilities</td>
<td>Clinical Trials</td>
<td>Estimation of Outcome Probabilities</td>
</tr>
<tr>
<td>Lecture 5</td>
<td>Pharmacoeconomics</td>
<td>Pharmaceutical Care Decision Making</td>
<td>Estimation of Outcome Probabilities</td>
<td>Pharmacoeconomics</td>
</tr>
</tbody>
</table>

There are several paths that allow faculty in a Division of Pharmacy Administration to introduce a modular approach into their curriculum. When a division’s faculty includes expertise in each subspecialty, a joint teaching endeavor among all relevant faculty provides the most well rounded course for students. This permits students to learn various aspects of integrated disciplines from those faculty who are most proficient in the various subspecialties. Students not only benefit by learning the material from individuals who have professional experience in the topic area, but are also more likely to further explore the topics through in-depth discussions with faculty members who have genuine interest and experience with the issues.

When the number of faculty members is limited outside experts may be used to expand and enhance the course syllabus. In many cases, invited lecturers bring personal experiences that allow students to gain a more accurate sense of how the theories embedded in course readings apply to the “real world”. One advantage of using outside speakers is that they allow students to see the relevance of their studies in potential career opportunities. This should be weighed carefully against the advantages of using full-time faculty who are generally more knowledgeable about the frontiers of their disciplines and who are available outside the classroom for students who wish to clarify concepts or pursue more in-depth learning. In any case, the number of individuals who are involved in instruction should not become so large that the course seems disjointed. The touchstone at the end of any modular course is whether students are able to synthesize the material, not simply understand various concepts in isolation.

There are two paths that can lead to a successful integration of material. The first is a sequential approach whereby one individual does a series of lectures on his/her area of expertise and then the next instructor presents a series of lectures. The alternative is to develop a parallel sequence of topics that span disciplines. Under this approach, one lecturer talks on the first topic from the perspective of his/her discipline and a different lecturer presents the following lecture on the same topic, but from a different academic background. For example, an epidemiologist may provide a lecture about the threats to validity of a particular research study that has been used to evaluate a new drug product. This may be followed by a session in which an economist talks about the resource utilization implications of such endpoints as measured in the study. Together, the two instructors may develop a model (grounded in both epidemiology and economic principles) that can better predict both health and economic outcomes than either stand alone study. Such models can appeal to outside experts in the indicated area, meta-analysis of other evidence(11), or literature reviews to determine frequency of events not actually experienced in the trial(6).

An important consideration in determining which type of modular approach to implement is the potential benefit from the standpoint of student learning. To the extent that students must be familiar with both epidemiology and economics, either the parallel tracking or the sequential approach can be valuable. While faculty may prefer the sequential approach since it allows them to commit to a block of time rather than a sporadic series, students may find it easier to learn under parallel tracking. This is because students are able to fully integrate concepts as they are
presented. There is not an initial presentation of a topic followed by a future "refinement" weeks later at a time when students may not fully recall pertinent information. In addition to the benefit of augmenting material while it is still fresh in students' minds, the parallel tracking method provides value by instilling a sense of accomplishments at regular intervals throughout the semester. Students can become proficient in certain topics without waiting for material to be integrated as a summary at the end of the course.

COURSE IMPLEMENTATION
Courses that integrate the principles and methodologies of economics and epidemiology may focus on a variety of topic areas. Such courses may be more heavily based in economics, as would be the case in a course on “Economic Evaluation of Health Care Technology”, or may have a greater emphasis on epidemiology, as would be found in a course on “Methods in Pharmacy Services Research.” Certain courses, such as “Health and Economic Outcomes Assessment,” may include an equal portion of epidemiology and economics. In all cases, the course coordinator ensures that the major topics are covered and incorporates lectures by colleagues accordingly.

Table II describes four approaches to teaching a section on New Health Care Technology Assessment, depending on whether there is a greater emphasis on economics or epidemiology or an equal emphasis on the two disciplines. The first column represents a series of six lectures that would bring students through the basics of economics reasoning, teach students the tools of economics analysis with an emphasis on cost considerations, introduce pharmacoeconomics as it relates to clinical evaluation, and apply this information to assess new health care technology. The second approach focuses more heavily on research methods from epidemiology, such as clinical trials, cohort trials, case-control design and estimation of outcome probabilities. The role of economics is not incorporated until the fifth lecture.

Two examples of lecture series that contain approximately equal emphasis on economics and epidemiology are contained in columns three and four of Table II. The sequential approach introduces economics methods and cost considerations in the first three lectures and is followed by related epidemiology topics in subsequent sessions. In the parallel tracking series, lectures on related topics alternate between economics and epidemiology. That is, a lecture on evaluation techniques based in economics is followed by one that emphasizes techniques from epidemiology as they relate to clinical evaluation.

SUMMARY
Research that combines the principles of economics and epidemiology has emerged in response to cost-containment efforts. The political environment and managed care market forces will likely generate increased demand for additional research in this area. Furthermore, the necessity for employees who can critically analyze this research will grow as consumers of drugs and health services become more concerned and knowledgeable about cost-effectiveness of medical goods and services. Universities that engage in interdisciplinary teaching in economics and epidemiology will educate students to meet these future needs. Part of the process will include the collaboration of individuals who are trained in very different specialties. The result will be a more integrated curriculum for students.

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References