Facilitating the Understanding of the Formulary Decision Making Process Using Group Project.s[1]

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Pharmacy graduates must have knowledge and skills allowing them to participate in the management of medication therapies for populations of patients. Outcomes Assessment in Pharmacy was a required course designed to introduce students to the methods and tools used within the managed care environment to document and evaluate therapeutic alternatives. Third professional-year students completed group projects where they were provided a "real life" decision-making situation where they chose among several therapeutic alternatives (including both drug and non-drug therapies) for a specific condition or disease by employing the principles of decision analysis. Each group was required to provide an executive summary describing final recommendations to a hypothetical Pharmacy and Therapeutics Committee. The results of student evaluations were very favorable toward the group project over the four-year period.

INTRODUCTION

Traditionally, efficacy and safety have been the primary indicators for assessing medication therapy. Since the mid-1980s interest in the economic value and total costs associated with medication therapies and availability of limited resources in the United States has increased due to many factors. Such factors include escalating health care costs, competitive technology and products, influence of managed health care organizations (MCOs) and integrated health care delivery systems, growing expectations of third party reimbursement plans, increased reimbursement of prescriptions by third parties increased availability of medical and prescription data, and quality-of-life issues. Pharmacy graduates need additional knowledge and skills in order to participate in the management of medication therapies for populations of patients in the managed health care environment into the next millenium. Graduates must be able to both manage individual patients in one setting (*i.e.*, pharmaceutical care), but also be able to oversee the care delivered to a specified population of patients in diverse settings (*i.e.*, disease state management).

In the business world, the techniques of decision analysis have been used for sometime(1). In simplistic terms, decision analysis allows for systematic analysis of various options and their associated outcomes, given certain variables leading to the generation of results that can be quantified(2). This quantification may result in economic information or criterion ratings. As increased pressure to quantify and justify the value of pharmaceutical products and services continues, future pharmacists must understand the various pharmacoeconomic principles and methods used to describe the outcomes (both health related and economic) associated with the provision of health care services and products.

COURSE OVERVIEW

Outcomes Assessment in Pharmacy was a required three-quarter credit course taught to pharmacy students in their third professional year. The course was designed to introduce students to the methods and tools used within the managed care environment to document and evaluate therapeutic alternatives given limited resources within a specific population of patients. The course was built upon previous coursework taught in the basic and clinical sciences while exposing students to new areas such as decision analysis and pharmacoeconomics.

Topics covered within the course included: formulary management, drug usage evaluation, adverse drug events, pharmaceutical care, disease management, critical pathways, decision analysis, pharmacoeconomics, methods of reimbursement, and health care reform. Guest lecturers and panel discussions consisting of individuals working directly in managed care settings were used to bring a "real-life" feel to the class. Guests represented the pharmaceutical industry, pharmacy benefit management companies, health insurers, health care institutions, software manufacturers and health care providers.

Course requirements over the four years and their percent contribution to the final course grade are seen in Table I. The first two years a group project was required of all students. For the last two years, students desiring to earn a letter grade of "A" or those wishing to earn extra points were required to contract as individuals with the course coordinator to complete a group project. Others have described similar assignments to achieve ability-based outcomes in the classroom(3).

Description of the Course Project

The course project requirement was modified over the four-year period in which it was used in the class. In 1994 and 1995 all enrolled students completed the required projects in pre-assigned groups. In 1996 and 1997 students were allowed

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Table I. Course requirements and grading in outcomes assessment

Year	Percent Project	Exams	Assignments	Paper	Pre-post assess
1994[a]	24	76	n/a	n/a	required
1995[a]	21	69	10	n/a	required
1996[b]	n/a	73	15	12	required
1997[b]	n/a	80	10	10	required

[a]Projects were required in 1994 and 1995.

[b]Projects were elective in 1996 and 1997, completion of the group project would add 30 points to individual's cumulative total of 300 points or 10 percent.

Table II. Projects completed over the four-year period of 1994-1997

Year	Number of Students	Percent of class participation	Number of projects
1994	88	100[a]	15
1995	108	100[a]	18
1996	60	58.8[b]	20
1997	86	78.2[b]	18

[a]Projects were required in 1994 and 1995.

[b]Projects were elective in 1996 and 1997.

to self-select their groups if they desired to complete the project. Based on student feedback from the first two years, the project was changed from being required for all students to optional in 1996/97. The students in these following years suggested that the project be required for all students once again. Table II, provides the number of students and projects completed over the four-year period.

Course projects were completed by groups of students and consisted of "real life" decision-making situations where they selected several therapeutic interventions (including both drug and non-drug therapies) for a specific condition or disease and provided a final recommendation to a Pharmacy and Therapeutics Committee. The course coordinator predetermined project topics, though some student groups suggested topics for consideration. Specific projects assigned in 1997 can be seen in the Appendix. For example, a group may have been assigned the evaluation of benign prostatic hyperplasia and its various treatment options, including alpha blockers, androgen hormone inhibitors, natural products, and surgical intervention. Students had approximately six weeks to complete the project requirements.

Student were required to complete both mid and final student-peer evaluations of the group project. The course coordinator reviewed all evaluations and scheduled group meetings when evaluations indicated that one or more group members were not contributing to the project. The course coordinator reserved the right to make a student complete the project by themselves or not be awarded any points for the project. Over the four years in which the projects were assigned, the course coordinator made three students complete the project alone. Because all students signed a contract to complete the project, anyone not doing so would receive a penalty on their final grade.

Project Requirements

Students were required to employ the techniques of decision analysis and pharmacoeconomics as explained in class when assessing various therapeutic options. Projects required the assessment of epidemiologic, financial, and clinical data in the overall analysis. The overall recommendation(s) was to be based upon the data generated from the project that was

obtained from primary and secondary literature sources. A typical project in the first three years was about 20 typed-pages in length and consisted of monographs, decisions tables, pharmacoeconomic analyses, and an executive summary describing final recommendations to a hypothetical Pharmacy and Therapeutics Committee.

In the last year, a poster session was instituted in lieu of the comprehensive 20-page write-up, though the executive summary report was still required. Posters have been used as effective alternatives to traditional classroom instruction in both nursing and pharmacy education(4-6). A total of 18 posters were presented in conjunction with the annual career fair in late-October. Students were encouraged to use Powerpoint™ software to produce their posters, as it was available in the university library. Each poster display consisted of the following:

1. Title of project with authors' names;
2. Abstract of approximately 500-600 words describing the project and its conclusions;
3. Panel displays depicting the following;
   a. study objectives
   b. background of the disease/condition (epidemiology)
   c. methodology (including assumptions used)
   d. results describing the following:
   • A decision tree with assigned probabilities depicting a treatment "strategy" and the costs associated with the various paths/options. Assumptions used in the construction of the decision tree and expected value calculations were included as well.
   • A decision table depicting the criterion, values, assigned weights, and criterion rating and sum of criteria ratings.
   Calculated cost effectiveness ratios and expected values (costs), and a sensitivity analysis (pharmacoeconomics).
   e. limitations of the analysis
   f. conclusions

Decision Analysis Techniques Employed

The following were presented in the course to students before they started their projects.

Decision Tables. Decision tables require the identification of several alternatives for a stated problem/situation. Each alternative in the decision table is then evaluated against various criteria that have been identified as being important to various stakeholders. The foundation of this approach is the multi-attribute utility (MAU) model(2). Each criterion receives an assigned weight, which is consistent among all similar criterions of the different alternatives. The total sum of the assigned weights among the criteria must add up to 1.0. The assigned

Table III. Example decision table

| | Value | | Assigned weight | | Criterion rating | |
| | Drugs | | | | | |
	A	B	A	B	A	B
Criterion 1 (safety)	75	100	0.40	0.40	30	40
Criterion 2 (efficacy)	75	75	0.30	0.30	22.5	22.5
Criterion 3 (dosing convenience)	75	25	0.20	0.20	15	5
Criterion 4 (product acquisition cost)	40	100	0.10	0.10	4	10
Totals	n/a	n/a	1.00	1.00	71.5	77.5

Table IV. Steps involved in decision tree analysis

1. Define the objectives (state the problem)
2. Identify alternatives to attain desired outcomes
3. Structure the decision problem as a logical sequence of events (include choice nodes)
4. Characterize known and uncertain events then establish probabilities of events occurring (include chance nodes)
5. Place values on the resource consumed and calculate expected costs
6. Perform appropriate calculations
7. Make a selection based on the results
8. Conduct a sensitivity analysis (alter various probabilities and/or assumptions to see if the calculated results change)

weights essentially prioritize the various criteria to be evaluated, in a numerical manner. A criterion that has a greater utility would have a larger numerical value.

Additionally each individual criterion specific to each alternative is given a value rating. This value rating is specific to the alternative and can not exceed 100 for each criterion being assessed. An alternative that is exceptional may have several scores of 100 for individual criteria. A final criterion rating is then determined for each criterion by multiplying the assigned weight by the value rating. Each criterion is then added together to determine the overall criteria rating.

For example, a comparison is made between products A and B for a given disease or condition. Product A is dosed once daily but costs significantly greater than product B which is dosed three times daily. The four criteria evaluated for these products are: Criterion 1 (safety); Criterion 2 (efficacy); Criterion 3 (dosing convenience); and Criterion 4 (product acquisition cost). Table III provides an example decision table based on the previously listed conditions. Overall product B scores higher (77.5) than A (71.5) given the assigned values and weights. Thus B is the preferred agent.

Decision Trees. Decision trees provide a graphic representation of each course of therapy from beginning to end., depicting the multiple events and sequelae that can result from one or more courses of action. Decision trees represented graphically usually contain choice and chance nodes. Choice nodes typically depict a point at which a decision needs to be made for the user to progress forward in trying to achieve a desired outcome. Chance nodes have a likely probability of taking place and may or may not be favorable (*e.g.*, adverse medication events). Each event in the decision tree can be assigned a probability of occurrence. The sum of the probability values associated with each branch of the tree must equal 1.0 or 100 percent.

The primary literature usually serves as a source for the probabilities, but they can also be derived from consensus panels. Databases offer more promising sources for the future, allowing the use of accumulated clinical data or records and outcomes from actual practice to determine predictable scenarios for similar clinical situations. Once probabilities are

assigned to all likely discrete events, the sum probabilities of outcomes must be calculated.

Some disease states such as infectious processes lend themselves to defined clinical endpoints, such a clinical resolution or microbiological cure. Yet some diseases such as hypertension typically use surrogate endpoints. In the treatment of hypertension, the desired outcome may be a reduction in the incidence of myocardial infarction; however the surrogate endpoint assessed is normalized blood pressure in the patient. Utilization of decision trees usually requires several steps, as seen in Table IV.

An example best illustrates this process. As seen in Figure 1, drug regimen 1 has the following probabilities: treatment success of 60 percent and treatment failure of 40 percent. Treatment success has associated with it, no adverse effects 80 percent of the time and adverse effects 20 percent resulting in dosing adjustments 50 percent and switching drugs 50 percent. Regimen 1 also has treatment failure of 40 percent resulting in switching drugs 50 percent, and adding an additional agent 50 percent of the time. Knowing this, the overall probability of an outcome and expected values can be determined and compared to other drug regimens.

In regimen 1 the following probabilities can be determined for successful outcomes: (*i*) without adverse effects occurs 48 percent of the time [(0.6) x (0.8) = (0.48)]; (*ii*) with adverse effects that results in switching to another agent occurs six percent of the time [(0.6) x (0.2) x (0.5) = (0.06)]; and (*iii*) a successful outcome with adverse effects that results in adjusting the dose of the current agent occurs six percent of the time [(0.6) x (0.2) x (0.5) = (0.06)]. Probabilities associated with treatment failures can also be calculated, each being 20 percent respectively: (*i*) failures resulting in switching therapy [(0.40) x (0.50) = (0.20)]; and (*ii*) failures resulting in additional agents being added [(0.40) x (0.50) = (0.20)].

Expected values can then be calculated based on the costs associated with each event in the decision tree. If the occurrence of a successful outcome without adverse effects occurs 48 percent of the time with regimen 1, and the sole costs at this point are related to drug acquisition costs of the agent in this regimen (*i.e.*, $50), then the expected value associated with this outcome is $24 [(0.6) x (0.8) x $50 = ($24)]. Likewise, the

Table V. Student comments related to what they learned most from the project and course

"How to organize and evaluate a disease state and its' therapies."
"I learned to effectively evaluate an outcomes study."
"I never realized the different types of outcomes and how decisions were made as to which drugs can be used on a formulary."
"How to do decision analysis."
"Cost-effectiveness and decision trees and tables."
"Importance of being familiar with outcomes assessment."
"Analyzing data and comparing drug treatments."
"How to read decision tables and trees."
"The process of evaluating outcomes and making decision trees."
"How to compare products and choose one based on more than just cost. Also how many factors can influence an outcome."
"Patient outcomes along with assessing quality-of-life in determining patient outcomes."
"I learned how drug formularies impact prescription use and patient outcomes."
"Pharmacy has to change to an active role if we want to survive in this changing health care system."
"Overall it was a lot of work."
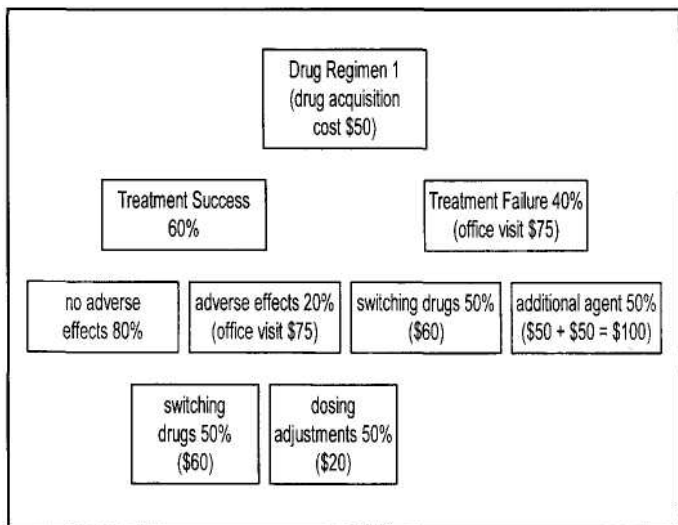"I learned how to work with others."

Fig. 1. Example decision tree with associated outcomes and costs.

expected value for a successful outcome with adverse effects that results in switching to another agent would be $11.10 based on the following costs: drug acquisition cost of $50, $75 for the second physician office visit due to the adverse event, and $60 for the new agent switched to [(0.6) x (0.2) x (0.5) x ($50 + $75 + $60) = ($11.10)]. In the final scenario for successful outcomes of regimen 1, the expected value for a successful outcome with adverse effects that results in adjusting the dose of the current agent would be $8.70 based on the following costs: drug acquisition cost of $50, $75 for the second physician office visit due to the adverse event, and $20 for costs associated with a dosing adjustment [(0.6) x (0.2) x (0.5) x ($50 + $75 + $20) = ($8.70)]. Treatment failure costs would be $37.00 [(0.4) x (0.5) x ($50 + $75 + $60) = ($37.00)] and $45.00 [(0.4) x (0.5) x ($50 + $75 + $100) = ($45.00)] respectively.

Once all expected values are calculated for each possible path in the decision tree, an overall sum of costs associated with the decision tree can be attained. Thus the overall expected value for successful outcomes in regimen 1 are $43.80 based on the following calculations [($24.10) + ($11.10) + ($8.70)] and overall treatment failure costs would be $82.00 [($37.00) + ($45.00)]. Therefore, the average cost a patient could incur in this model is the sum of $43.80 and $82.00, equaling $125.80, not simply the drug acquisition cost of $50.00. This is because when therapy is initiated, it is difficult to predict which patients will have 60 percent successful out-

comes as opposed to 40 percent treatment failures. The same process described above would be repeated for drug regimen 2 and the lowest overall expected value between drug regimen 1 and 2 would be selected as providing least overall cost of therapy including successes and failures.

EVALUATION

A significant amount of time was required by the instructor to evaluate and provide comment on the aforementioned projects, which on average was four to five hours per project. All projects were reviewed and graded solely by the course coordinator. Overall, student evaluations with respect to the course project were very favorable. For the first two years (1994-95) some students commented that the project should be elective in nature and that groups should be able to self-select, as opposed to using the groups that were pre-assigned by the coordinator. During years three and four (1996-97), students commented that they liked self-selecting their group but felt the project should be required of all the class and not elective. Many felt that those who elected not to participate in the project were being cheated as well as not having to work as hard in the course.

At the 1997 poster display, prospective employers, students, faculty, and administration commented that the posters were professionally done and very enlightening. Students were able to showcase their work to not only faculty and peers, but also to future employers. All students, faculty, and employers were asked to provide comments related to the project and poster session. Student comments can be seen in table V. Employers were very supportive of the concept and hoped it would be carried on.

DISCUSSION

Future pharmacists must have the ability to critically review and evaluate the growing amount of health and pharmacoeconomic literature. They must also be able to determine if economic evaluations use appropriate methods, have valid results and conclusions, and if such results are applicable to their practice environment. Through this course and the project, students were exposed to the fact that drug acquisition costs should not be the only factor considered when selecting medication therapies for either individual patients or populations of patients. The full-economic impact of an intervention must be determined and examined. In the future, some of the graduates may be asked to apply similar tools employed in this course to evaluate and conduct studies in their own environments. It was hoped that through this course and assigned projects, students

as future pharmacists are able to understand and possibly apply these important principles. As two students commented in the final course evaluation in 1997,

> *"Much more is involved in outcomes assessment than simply monitoring a patient's therapy. The pharmacist has to be aware of all roles a pharmacist plays in outcomes assessment in order to provide the best care for the patient."*

> *"Pharmaceutical care doesn't end with the patient taking his/her last pill. It is an ongoing process we must become an integrated part of. Simply dispensing meds will limit our existence as a profession."*

References
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APPENDIX A. GROUP PROJECTS COMPLETED IN 1997

Disease or Condition	Interventional Therapies
Migraine	Imitrex (injection), Imitrex S(oral), Imitrex (nasal spray), Maxalt (rizatriptan), Excedrin Extra Strength (OTC)
Vaginal Candidiasis	Clotrimazole (intravaginal) 3 day Rx, Diflucan (oral) 1x Rx, Terconazole 0.8% (Terazol 3) 3 day Rx, Butoconazole (Femstat 3) 3 day OTC, Tioconazole 6.5% (Vagistat-1) 1xOTC
Hypertension	Lisinopril, Enalapril, Diovan, Cozaar
Hypercholesterolemia	Zocor, Pravachol, Lescol, Lipitor, Baycol, Cholestin
Alzheimer's Disease	Cognex, Aricept, Ginko biloba (natural product)
LV Heart Failure w/no volume overload	Digoxin, Vasotec, Corge, Isosorbide dinitrate
Otitis Media (peds)	Bactrim, Ceclor, Augmentin, Biaxin, Amoxicillin
Hypertension	Posicor, Sular, Procardia XL, Norvasc
Benign Prostatic Hyperplasia	Proscar, Flomax, Cardura, Hytrin, TURP (surgery)
Chemotherapy Nausea and Vomiting – from high to moderate emetogenicity	Kytril, Zofran, Dexamethasone
Peptic Ulcer Disease (H. Pylori)	Metronidazole/Amoxicillin/H2 Antagonist, Helidac, Tritec/Clarithromycin, Omeprazole/Clarithromycin
Allergic Rhinitis	Chlorpheniramine, Claritin, Allegra, Zyrtec
Depression	Amitriptyline, Paxil, Zoloft, Prozac
Smoking Cessation	Nicotrol NS (spray), Nicorette gum-OTC, Zyban, Nicotrol patch-OTC
HIV	Ritonavir (Norvir), Saquinavir (Invirase), Indinavir sulfate (Crixivan), Lamivudine (Epivir), Stavudine (Zerit)
Diabetes (NIDDM, Type II)	Glucophage, Precose, Rezulin, Glucotrol
Uncomplicated UTI	Maxaquin, TMP/SMZ, Macrodantin, Floxin