

Payor vs. Societal Perspective for  
Healthcare Technology Coverage Decisions:  
Effects and Recommendations

by

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Submitted to the Department of Mechanical Engineering  
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Master of Science in Technology and Policy

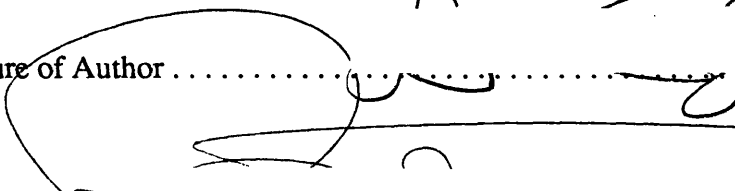
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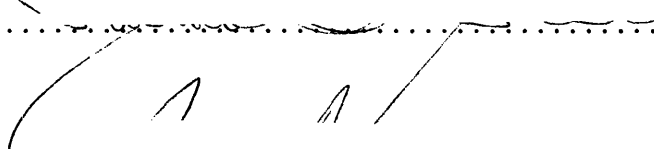
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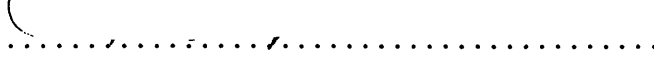
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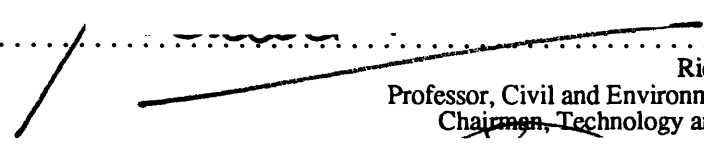
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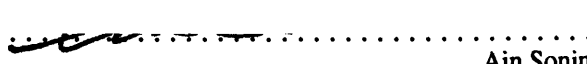
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**ABSTRACT:**

Managed care organizations look to limit the use of healthcare technologies in an effort to control costs. This allocation of healthcare resources from the managed care viewpoint may be in conflict with overall social priorities.

By investigating how the cost-effectiveness of drugs, devices, and medical equipment change when examined from a managed care point-of-view, this thesis shows how differences between a private payor and societal perspective affect health technology coverage decisions. To show this effect, the paper investigates how analytical assumptions used in cost-effectiveness studies that are performed from the managed care perspective change the relative value of certain health technologies. By re-analyzing the epidemiological studies from peer-reviewed journals, conclusions are made and policy alternatives suggested to bring decision-making closer to the social optimum.

Specifically, four examples were studied: pharmaceutical treatments for hypertension, recurrent depression, osteoporosis, and Alzheimer's Disease. In these analyses, the cost structure and time horizons were changed to reflect the operating environment of a managed care organization. Cost were measured in 1996 US dollars; effectiveness was measure in quality-adjusted life years.

The overall effect of the managed care perspective was to undervalue long-term preventative technologies when compared to the societal viewpoint. Pharmacy controls actually made an intervention look cheaper by reducing the effective price that a managed care organization pay for a drug. However, by ignoring certain costs that are irrelevant to an individual health plan (i.e., worker productivity), the treatment strategies appeared more expensive. The shortened time horizon due to disenrollment rates dominated the analysis and severely raised the price per unit of health benefit that is realized by a managed care organizations.

Policy options to help align the societal and managed care perspectives are discussed. These include the use of malpractice suits, patient and employer education strategies, state and federal legislative options, and the use of retrospective risk policies.

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## 1.0 INTRODUCTION

*or*

### Why is this important?

The healthcare industry is in transition. Over the last few decades, healthcare costs have consumed an increasingly greater percentage of this country's financial resources. Currently, spending on health care consumes close to 16% of GDP, compared to just 9.1% in 1980 (OMB, 1996). Health insurance costs have increased at a rate greater than wages, costing the average American worker nearly \$1000 in foregone earning potential over the same period. If the same trends continue, health care expenditures could rise to nearly 19% of GDP and hold down wages by the equivalent of an additional \$650/year by the year 2000 (The White House Domestic Policy Council, 1993). As health

care costs continue to increase faster than the economy, the question must be asked: "What returns can we gain by allocating more dollars toward health care, and what is the opportunity cost of spending our money there?"

**Table 1.1: Health Trends by Decade, 1929-1990**

	Growth in real health spending per person	Growth in real GDP per person	Growth in no. of physicians per person	Health Share of GDP at end of period
1929-1940	1.4%	0.0%	0.6%	4.0%
1940-1950	4.0	3.1	-0.1	4.5
1950-1960	3.6	4.5	-0.1	5.3
1960-1970	6.5	2.5	1.1	7.3
1970-1980	3.8	1.7	2.4	9.1
1980-1990	4.4	1.7	2.0	12.2

Source: J. Newhouse, 1993

### MANAGED CARE

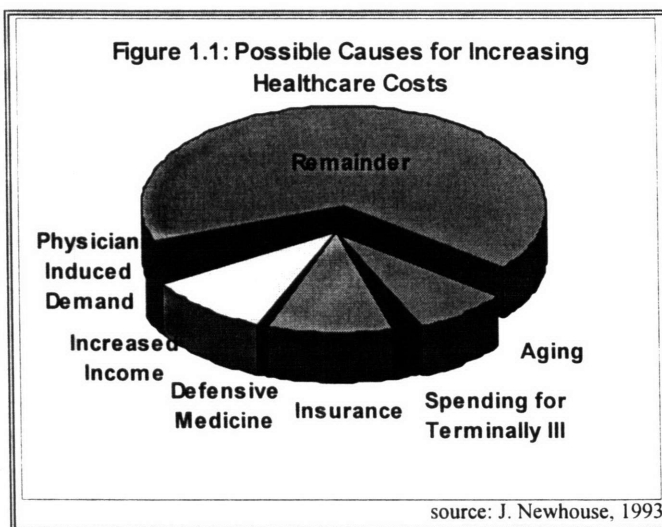
In response to rising costs, federal and industry leaders are looking for ways to better spend our limited dollars to ensure better allocation of our healthcare resources. Indeed, the growth of managed care can be attributed to these efforts. Over one-fifth of all American are now enrolled in managed care plans, nearly double the number just eight years ago (Managed Care Digest, 1995). Managed care, which includes HMOs, PPOs, and point-of-service providers, seeks to reduce costs by controlling the utilization of health services. Typically, this is accomplished by managing physician referrals and prescribing behavior in an attempt to reduce costs while maintaining quality.

By re-aligning financial incentives, managed care seeks to eliminate waste and create greater efficiencies within the health care field. Rather than directly reimbursing the costs for medical services on a fee-for-service (directly reimbursing the total charge of care) basis, managed care seeks to control costs by managing utilization or providing care on a capitated (reimbursing for a pre-set fixed fee per patient) basis.

### **THE “CULPRITS” OF HEALTHCARE COSTS**

But where should managed care plans direct their cost-reducing efforts? The causes of the increase in US healthcare spending are complex and controversial. Among others, Joseph Newhouse has sought to quantify the contribution of each of the most commonly cited causes for rising healthcare expenditures (Newhouse, 1993). Isolating these singular causes, he calculated the individual gain of a) the growing population of elderly citizens (8%); b) the moral hazard of comprehensive insurance (10%); c) physician-induced demand (3%), d) the ability for a wealthier nation to consume more health resources (10%), e) defensive medicine to combat malpractice suits (1%), f) rising administrative costs (3%), and g) efforts to save the terminally ill (2%).

So, what’s left? The total of these causes doesn’t even explain half of the total increase in spending. While many other causes could contribute to the remainder of this increase, the technological component can not be ignored. Without question, the capabilities of medicine have dramatically increased since the turn of the century. New drug therapies,



complex medical procedures, and intensive diagnostic equipment have contributed both health benefits and costs to the US healthcare system. To date, Americans have not seemed to object to

spending more to gain the added capabilities of medicine. But spending levels may now have reached a point where Americans are no longer willing to pay for these extra benefits.

### **MANAGED CARE AND HEALTHCARE TECHNOLOGIES**

Managed care organizations have initiated many programs to evaluate and assess the benefits of medical technology. Defined by the Office of Technology Assessment as “drugs, devices, procedures, and organizational and support systems” (US Congress, Office of Technology Assessment, 1994), these costs are increasing and have become a significant portion of a managed care plan’s budget. For instance, pharmacy benefits alone rose 9% in 1994 and made up over 10% of all HMO operating expenses (Managed Care Digest, 1995). How managed care organizations assess and control medical technology can seriously affect the health of patients, the cost of care, and the profitability of the medical technology industry.

While cost-control mechanisms used by managed care organizations are realized in many different ways, all require objective information about the costs and effectiveness of varying health interventions. Consequently, cost-effective analyses (CEAs) of health care technologies are playing an increasingly important role for resource allocation purposes. Physician groups are looking at the costs (both incurred and avoided) and the health benefits in CEA studies to help inform clinical policies and practice guidelines. Health plans are demanding such information for health coverage reimbursement decisions. For these reasons, the growth in the number of these studies (and of the new scientific field of health- or pharmaco-economics) is astounding. For example, Bradley et al. (1995) documented the growth of cost studies by MEDLINE, a medical journal database. The cumulative number of studies from just a few dozen in the late 1960’s to over 35,000 in 1995.

### **THE ARGUMENT**

But many of these studies investigate a medical intervention from a societal point of view, quantifying all the aggregate health benefits and costs no matter whom they affect. Indeed, expert panels convened for the purpose of establishing guidelines for cost-effectiveness analyses recommend using the societal perspective (US Department of Health and Human Services,

1996). By using a more global public perspective, all the costs and benefits can be addressed and various analyses can be compared to better allocate our limited resources.

But managed care organizations are in business to serve their individual enrollees and may have little interest in the population as a whole. Furthermore, because many patients leave a health plan when they change jobs or enter Medicare, they may have little interest in the long term consequences of their own enrollees. Analyses from a societal perspective may not reflect their own population characteristics, reimbursement policies, or time horizons. Therefore, an economic study performed from a managed care perspective may result in a different conclusion than one performed from a social viewpoint. In essence, what's good for society may not be good for an HMO and vice versa. ***If coverage decisions are being made from an HMO perspective, society may be losing out on valuable technologies.***

But do these perspectives really conflict? and if so, why? If the healthcare market is truly efficient, then the decisions of a managed care entity would directly align with the overall good for society. But the market is not efficient, and policies need to be created to direct us back toward the social optimum.

Assuming that the societal view of CEA studies provides a baseline of maximum societal utility, this thesis will investigate how a managed care perspective leads us away from this ideal. More importantly, however, it will discuss policy alternatives that could change the managed care incentives to bring the market closer to the social optimum.

## **THE ORGANIZATION OF THE THESIS**

This report is organized into eight chapters. The next two sections give the reader some background to the issue at hand. Chapter Two will generally discuss cost-containment strategies in managed care organizations and specifically how healthcare technologies are affected by those strategies. Chapter Three will provide an overview of the techniques employed in cost-effective analyses.

The fourth chapter will discuss the assumptions and methodologies of this paper, specifically documenting what changes when a technology is economically assessed from a managed care perspective. Chapter Five will analyze the cost-effectiveness of four specific medical interventions: pharmaceutical therapies for hypertension, recurrent depression,

osteoporosis, and Alzheimer's disease. These four analyses are based upon previously published cost-effective studies. By varying the assumptions and inputs into those analyses, quantitative comparisons can be made between the cost-effectiveness of socially- vs. privately-adopted therapeutic strategies. Chapter 6 will further analyze these results and discuss the implications of any possible financial disincentives.

Chapter 7 will discuss the implications for health technology manufacturers and society. Specifically, the chapter will suggest policy options to help create more socially-optimal incentives for managed care companies. Finally, in Chapter 8, the paper will conclude, discussing the limitations of this argument and suggesting possibilities for further research.

## 2: Managed Care

*or*

### How does managed care assess health technologies?

This chapter provides the reader with a broad overview of managed care organizations. By discussing the economic foundation of these healthcare insurers, this section outlines the managed care incentive structures to control costs and maintain health. In this context, this chapter will discuss the basis for which drugs, devices, and other medical technologies are assessed. Those familiar with managed care organizations may wish to skim or skip this section altogether.

As competitive pressures rise in the US health care market, many employers are looking toward managed care as a lower-cost alternative to insuring their employees. Fifty-five million Americans, more than half of the employed insured population, are now enrolled in some form of managed care network (Managed Care Digest, 1995). Considering that this percentage has nearly doubled in the last eight years and now encompasses one-fifth of all Americans, the growth of managed care has been called dramatic (Shepherd and Salzman, 1990).

By realigning the incentive structure for the providers of medical services,

#### Glossary of Managed Care Terminology:

- **Indemnity/ Fee-for-service:**  
Traditional insurance that pays physicians, hospitals, and other health providers based directly on submitted claims.
- **Managed Indemnity:**  
Traditional indemnity coverage with utilization controls.
- **Managed Care Organization (MCO):**  
An organization such as a PPO, HMO, or one of many hybrids that manages the utilization of health care services.
- **Preferred Provider Network (PPO):**  
Enrollee choice is limited to a list of "preferred" hospitals, physicians, and other providers; the enrollee pays more out of pocket for using a provider not on the list
- **Health Maintenance Organization (HMO):**  
The enrollee is limited to certain providers and historically could not go out of plan (though see POS definition below). HMO structures include, in order of most to least control over service utilization:
  - Staff Model: Physicians are salaried employees of the HMO
  - Group Model: The HMO contracts with a single group practice, typically at reduced fees.
  - Network Model: The HMO contracts with multiple group practices and/or integrated organization.
  - Independent Practice Association (IPA): The HMO contracts with physicians who are usually not members of groups and whose practices include both fee-for-service and capitated patients.
  - Point of Service (POS): Regardless of the structure of the plan, enrollees may choose to go out of the plan for care, while paying more out of pocket if they do.

Source: adapted from Friedman, 1993

managed care theoretically offers a more efficient and cost-effective system for delivering healthcare. The traditional fee-for-service system typically reimbursed for the direct costs of treatment, providing the healthcare provider compensation only when patients use services. Consequently, if all bills were paid in full by an insurance company, physicians and patients had no cause to control the amount of tests and treatments. Just as a businessman on a company expense account spends little attention to the price of his dinner, healthcare costs under indemnity insurance were often ignored. Critics argued that the system was wasteful and inefficient, citing the lack of responsibility to control costs throughout the industry (The White House Domestic Policy Council, 1993).

Alternatively, by charging a pre-established monthly fee to enrollees, HMOs are forced to provide service to all beneficiaries within a fixed budget. Proponents claim that the economic structure better advances general health. Because sick people tend to use more expensive hospital, pharmaceutical, and physician services, managed care entities have the economic incentive to keep their enrollees healthy. These incentives motivate MCOs to invest in preventative medicine on a scale that fee-for-service insurance never accomplished. On the other hand, since HMOs receive a fixed payment per patient, they also have an economic incentive to ration the number and cost of therapies. This balance between controlling expenditures and maintaining overall quality of care has been the subject of much controversy.

### **TECHNOLOGY ASSESSMENT IN MANAGED CARE**

Managed care has historically focused cost-cutting programs on hospital expenditures. Many claim that admissions and lengths-of-stay have currently been reduced to the lowest efficient level of care without impairing quality (Fraser, 1993). The next wave of cost-cutting measures, then, will be directed at drugs, devices, complex procedures, and other technologically-based services (Lopez, 1991).

MCOs do have a financial incentive to control the use of technology. Pharmaceuticals alone accounted for 10% of all operating expenses for HMOs in 1994 (Managed Care Digest, 1995). In response, these organizations have developed strategies to contain these costs. All strategies have the (sometimes conflicting) objectives to 1) advance the use of cost-effective technologies, 2) limit the use of unnecessary or wasteful treatments and 3) maintain the health of

the enrollees. Fundamental to these goals is the ability to appraise the value of a health technology intervention; does a medical intervention yield a reasonable amount of health benefits for the dollars spent? One method to objectively accomplish this goal is to conduct a rigorous cost-effective analysis. (The methodology of cost-effective analyses will be discussed in detail in the next chapter.) The following is a discussion of ways in which MCOs attempt to control the use of healthcare technology, and how cost-effective analyses can inform those efforts.

### **COST SHARING**

By mandating that a portion of technological costs are borne by the patient, a managed care organization can effectively reduce the amount of use for those services. These strategies typically occur in the form of deductibles, co-insurance, and copayments. A deductible requires that an enrollee pay a fixed amount toward the total cost of the claims before reimbursement will begin. Co-insurance obligates the patient to pay a pre-established percentage of all healthcare costs, while copayments are mandated charges to the patient per unit of service consumed. Health plans may adopt one or all of these strategies. For example, an HMO may stipulate that it will reimburse 80% of all pharmacy benefits with a \$50 yearly deductible. A patient would then be required to purchase the first \$50 worth of prescriptions and then pay one-fifth of the total cost past that point.

Cost sharing places a positive price on consumption so that the consumer must consider the opportunity cost of spending his or her personal income on healthcare (Reeder et al., 1993). While deductibles for pharmacy benefits have not been widely adopted in HMOs (nearly 15%), co-payments are employed by almost all of them (96%) (Managed Care Digest, 1995). The effect of these factors will be addressed later in this paper.

**FORMULARIES:**

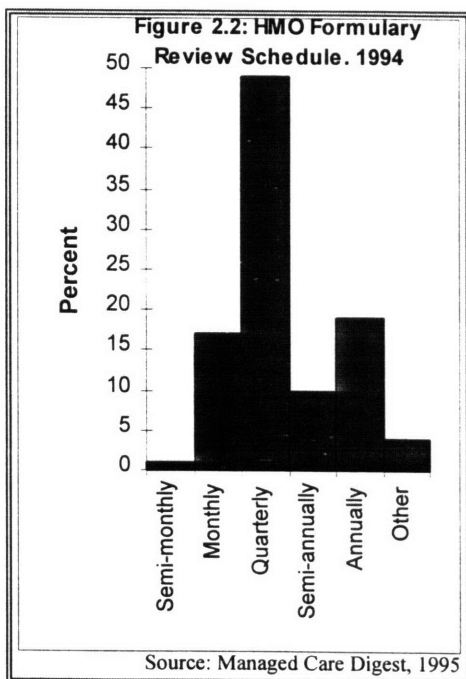
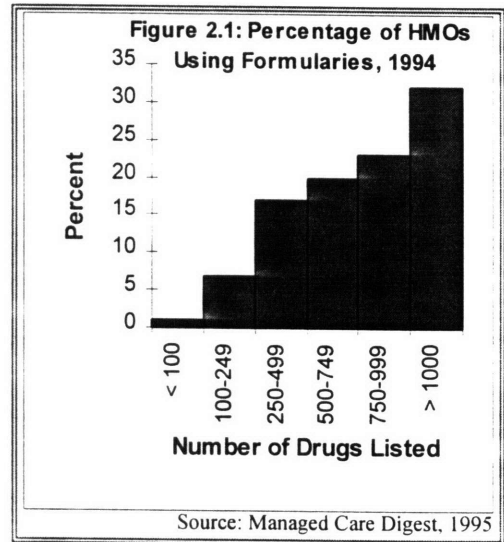
A formulary is a selective list of drug products that have been approved for reimbursement by the pharmacy and therapeutics (P&T) staff. Because a wide choice of drugs can be used to treat a specific disease and condition, the P&T staff compare their many attributes (safety, effectiveness, costs, product quality, ease of administration, etc.) to provide a list of health-promoting, cost-effective pharmaceuticals.

The restrictiveness of formularies also varies across the industry. Most formularies act as guidelines, allowing prescribers to use non-formulary pharmaceutical products without penalty. Just over one quarter of all formularies, however, are restricted (or closed), meaning that HMO enrollees can only be administered drugs off of the pre-approved list. Prescribing a drug that is not included on the formulary usually requires administrative pre-approval and can have financial penalties for the physician, patient, or both.

The use of formularies have been estimated to save 5-15% of annual costs for large pharmaceutical benefit management groups

(Grabowski, 1995). In 1994, more than 81% of HMOs and 37% of PPOs used formularies to control drug utilization, compared to 67% of HMOs in 1992 and 44% in 1990 (Managed Care Digest, 1995). Of those organizations that used these approved lists, over 88% of all prescriptions were filled using formulary drugs.

Products are added to the formulary based upon a variety of criteria. Most importantly, drugs are selected based upon efficacy and safety. Although the US Food and Drug Administration approves products based on this criteria, the FDA does not require



comparisons of the effectiveness or safety between products. For instance, one drug may have more severe side effects or a better success rate for older patients. Further, products are also selected based on convenience factors: ease of use, storage requirements, patient compliance, flavor, etc.

But products are also chosen with the goal of reducing overall pharmaceutical costs without compromising patient care. This includes utilizing cheaper substitutes, switching to equivalent generic products, and finding the most cost-effective alternatives. In determining whether to include a product on the formulary, the P&T committee must consider all the costs associated with using the pharmaceutical product, not just the list price of the drug. Does the product require more physician visits or nursing time? Will the drug reduce expensive hospital episodes? Can the patient return to work faster? It is precisely these questions that a cost-effective analysis helps to answer.

### **DRUG UTILIZATION REVIEW**

Drug Utilization Review can be defined as “an authorised, structured and continuing programme that reviews, analyses and interprets patterns of drug usage in a given healthcare delivery system against predetermined standards and includes efforts to correct patterns of drug use that are not consistent with these standards” (Brodie and Smith, 1976). Many managed care organizations conduct these types of reviews by the P&T committee and use the results to inform formulary considerations and educate providers.

In 1994, over 68% of HMOs had formal drug utilization reviews and the percentage has grown by an average of 12% per year since 1991 (Managed Care Digest, 1995). This strategy has been associated with saving pharmaceutical benefits management groups two to four percent a year (Grabowski, 1995).

A major component of these reviews consists of detailed surveys of claims data. By investigating actual use (and misuse) of drugs and technologically-based therapies, the MCO can infer real-world effectiveness rather than clinical “laboratory” efficacy. In essence, the MCO can conduct a cost-effective analysis based solely on their own population. For instance, Drug A may be half as expensive and just as safe as Drug B, but because it needs to be administered four times a day, patients had a hard time complying to the regimen. Consequently, these patients do

not recover as quickly and required being on the drug longer. A drug utilization review may conclude that Drug B is more cost-effective.

### CAPITATION

Capitation has been defined as “a prospective payment method based on an actuarial projection of utilisation rates and service benefit costs for a determined population of enrollees” (Schondelmeyer, 1986). Capitation rates can be applied to physicians and hospitals to control all healthcare utilization or directly to pharmacies to control prescription rates. An MCO will contract with these groups and pay a fixed sum at the beginning of a specified period of time, based on the number of patients who agree to purchase services solely from that provider. Often, this payment is contracted for an amount Per Member Per Month (PMPM).

The MCO hopes to control the use of expensive technologies by shifting the financial risk of over-utilization to the individual providers of services. Further, a pre-paid contract allows both sides to have better control of their own finances. For instance, an HMO contracting with a large pharmacy chain can budget their prescription benefits for the length of the contract and may also lead to administrative cost savings.

On the other side, the pharmacist knows ahead of time her budget constraints and does not have the cash flow difficulties of waiting for reimbursement. She will get paid whether or not the enrollees actually use her services. Consequently, she has a financial incentive to eliminate unnecessary utilization, encourage preventative care, and attempt to reduce harmful drug interactions and overdoses. Further, she will also attempt to limit her expenditures for each prescription she does fill, often substituting prescriptions with a less expensive therapeutic equivalent or generic product (Kozma et al., 1993).

While the pharmacy and drug utilization was used here as an example, similar contracts can be arranged with other healthcare professionals (e.g. general practitioners, blood laboratories, MRI centers) and have the similar effect of controlling the use of medical technology. Classic capitation puts the provider at risk, potentially losing money in periods of abnormal utilization or when cost increase. In these types of arrangements, the doctor, pharmacist, or lab technicians must assess which technologies offer value for the money. Rather than health plan

administrators, it is the health providers that requires the information determined from cost-effective analyses.

### **PRIOR APPROVAL**

Pre-authorization or prior approval is process by which the level of third party reimbursement is established before the time that the services are rendered (Kozma et al., 1993). Often this cost-containment strategy is used only for expensive or experimental technologies because the cost of obtaining approval may exceed that of the service. Pre-authorization is often used with restrictive formularies, thereby allowing access, albeit very limited, to certain high cost diagnostics, biotechnology treatments, and surgical interventions. The effectiveness of these strategies, however, are suspect since cost savings need to be compared against therapeutic switching and additional administrative costs.

On the other hand, this strategy can also be used with Drug Utilization Review to monitor potentially abused medications. Some MCOs require prior approval after a specified length of treatment has been surpassed. Massachusetts Medicaid patients, for instance, were allowed 60 days of pharmacotherapy after a heart attack, after which they were required to obtain prior approval (Nardi, 1990).

### **DRUG PRODUCT SELECTION**

MCO plans often implement strategies of pharmaceutical switching campaigns, instructing pharmacists to fill prescriptions with generic substitutes or less expensive brand-name alternatives. These strategies vary according to the pharmacist's ability to override the prescription as written by the attending physician. While some plans require the doctor's approval before making a change, others will automatically fill the drug order with a cheaper alternative unless explicit instructions have been given otherwise. Incentive plans can also be directed toward the patient, who may have to pay a higher co-payment or the difference between the generic and brand-name if the more expensive drug is dispensed.

Assuming that generic substitutions will automatically save money for their Medicaid programs, some states have begun writing legislation to change the process by which drugs are administered. In states in which physicians must explicitly state to prescribe as written, the level

of brand-name substitutions is 24%, while the substitution rate is 19% in states that allow a doctor to sign a prescription on one of two lines (McDonough and Neff, 1988). While some success has been reported, drug switching campaigns (particularly those funded by pharmaceutical manufacturers) have been the subject of much public debate.

Most health plans use many of these strategies concurrently. Never-the-less, the need for objective information about the costs and effectiveness of these therapies is essential. But where can this information be obtained and how is it assembled? The methodologies of cost-effectiveness analysis is presented in the next chapter.

### 3: Cost-Effective Analyses

*or*

#### What does it mean to be cost-effective, and how do you prove it?

The dramatic rise in health care expenditures at levels that exceed the growth of the general economy has ignited interest in the economic evaluation of healthcare interventions. Because the pool of available resources is limited, decision makers must prioritize programs and advance those that are more cost-effective. But cost-effectiveness means different things to different people; objectively demonstrating it has become a science unto itself.

Before the re-analyses are presented in Chapter 5, the reader should understand how these studies were performed. This chapter provides a brief review of how cost-effective analyses are being used, as well as an overview of the methodology that support these studies. Those familiar with the techniques of performing economic evaluations for medical technology and healthcare programs may wish to skim this section or directly leap to Chapter 4.

Value does not exist in a vacuum; one must compare the risks and benefits of a new technology to the best alternative treatment currently in practice. The goal of an economic evaluation is to produce a ratio that compares costs and health effects. The cost-effectiveness ratio for comparing two competing alternatives is the difference in their costs divided by the difference in their effectiveness or  $\Delta C/\Delta E$ .

$$\frac{\Delta C}{\Delta E} = \frac{C_{\text{treatment}} - C_{\text{current practice}}}{E_{\text{treatment}} - E_{\text{current practice}}}$$

Interventions that have a relatively low C/E, that is a small incremental price per unit of health effect, are “good buys” and interventions that have a negative C/E ratio are cost-saving.

#### **THE USE OF ECONOMIC EVALUATIONS**

As stated previously, managed care healthcare organizations have a financial incentive to limit access and use of expensive therapies. Consequently, economic evaluations may help tremendously in the decision-making process of healthcare organizations. By comparing the cost-effectiveness ratios across varying programs, the organization can theoretically allocate

resources optimally. While the use of these analyses for coverage and reimbursement decisions was outlined in the previous chapter, CEAs can also be used in alternative settings.

Additionally, economic evaluations can be incorporated into treatment guidelines. Traditionally, these voluntary guidelines, whether created locally within an academic hospital or nationally by the American Cancer Society or a federal health agency, are disseminated in an attempt to advise health care providers on most effective treatment options. For instance, recommendations could be made about who is eligible for liver transplants or which drugs should be administered to hypertensive patients of different ages. Cost-considerations can be incorporated into these guidelines, although physicians have traditionally resisted discussing costs when making treatment decisions.

Often in economic evaluations, drug and medical technology costs represent a critical component to the overall cost-effectiveness. Healthcare plan administrators can reduce their technology expenditures and essentially alter the relative value of an intervention by negotiating down the price of drugs and devices with the manufacturer or supplier. While this is quite common in single payor countries like Canada and Australia that list drugs on a national formulary, it has also been utilized by Medicare, Medicaid (US Congress, Office of Technology Assessment, 1992), and for many 'in-house' pharmacies of large, private health plans with bargaining power. On the other hand, drug and device manufacturers often have the same information. They have the capability to use these analyses to price their products in order to maximize profit while maintaining a reasonable cost-effectiveness ratio.

Lastly, economic evaluations are being used within medical device and pharmaceutical suppliers to assess the marketability and profit potential of technologies currently in research and development. By performing such a study backwards (i.e. beginning with an acceptable C/E ratio), a manufacturer can calculate how effective the technology must be. For instance, a 'pharmaco-economist' could calculate that for a new drug for schizophrenia to be competitive in the market, it must be able to reduce psychotic episodes by 40%. This conclusion can then be compared to initial laboratory results to determine whether to continue funding the project.

## **PERFORMING ECONOMIC EVALUATIONS**

It is not necessary to conduct an economic evaluation on all new medical technologies. Decision-makers must first determine issues of efficacy (can the health program work?), effectiveness (will it work in practice?), and availability (is it reaching the proper beneficiaries?) (Drummond et al., 1987). Further, an economic evaluation should only be performed if there is question of value. Many

	Costs Less	Costs More
Increases Health	Adopt the Technology	<b>Perform Economic Evaluation</b>
Decreases Health	<b>Perform Economic Evaluation</b>	Do Not Adopt the Technology

Figure 3.1: When to Perform a CEA

technologies (like generic drugs) undergo extensive clinical testing to show that they are just as effective and then marketed at a reduced price.

## **THE PROPER COMPARATOR**

Once the necessity of an economic analysis has been shown, the first requirement of a CEA is to choose the proper comparator(s). For new therapies, the proper comparator may be “no treatment” in which case the costs and health effects are matched against those related to the natural course of the disease or affliction. For other technologies (like kidney transplantation), the study should contrast financial and health gains against current therapies (like kidney dialysis). Occasionally, more than one comparator is appropriate, particularly when multiple treatment options are available.

## **THE PROPER METRIC**

While all economic evaluations calculate costs, there are a variety of ways in which to measure effectiveness. Each type of study yields a different denominator to this ratio.

- **Cost-Minimization Studies:** Cost-minimization studies are often used when the intervention is a new technique that produces the same (or extremely similar) health outcomes. In these studies, the effectiveness is assumed to be identical (denominator equal to 1), in which case only the costs matter. Since the two treatments have been previously found to be equally efficacious, comparing health expenditures will yield the cheaper

alternative. For instance, after FDA studies have shown that a new drug is just as effective as one already on the market, an HMO can conduct a cost-minimization to compare overall drug costs for their members.

- **Cost-Benefit Analyses:** Cost-benefit analyses attempt to quantify all health benefits into a dollar value. Here, disability days avoided, life-years gained, and medical complications avoided all must be translated into economic quantities. Often, these effects are valued through wages and productivity by measuring earnings gained or lost (human-capital approach) or what individuals would buy with their own money (willingness-to-pay approach). In these studies, the end product yields a purely economic ratio of dollars invested to dollars returned; a value less than one means that the intervention is cost saving. In practice, relatively few studies have attempted this type of analysis; instead, many in the healthcare field have resisted, citing their distaste for placing an economic value on health.
- **Cost-Effective Analyses:** Cost-effective analyses use a common health endpoint as a metric for measuring effectiveness. These can be an episode of care specific to the indication in question (i.e., cost/childbirth, cost/heart attack avoided, or cost/nursing home resident treated). Alternatively, researchers can select a common metric so that value of many therapies for diverse afflictions can be compared to one another. The most common metrics have been Years of Life Saved and Quality-Adjusted Life Years (QALYs). In these analyses, health benefits are measured by the amount of time a treatment can extend life. Since quantifying the quality of health (discussed in detail below) requires that individual preferences be elicited, these studies are also called cost-utility analyses. Cost-effectiveness analyses, in all its forms, represent the vast majority of studies published today. In fact, a recent panel of experts convened by the Department of Health and Human Services has explicitly recommended that QALYs be used as a common metric to establish a set of comparable cost-effectiveness values (US Department of Health and Human Services, 1996).

Quality of Life:

While measuring the additional years of life gained may suffice in many instances, it does not measure the quality of these years. For example, total hip replacement for elderly women is a very expensive procedure. Alternatively, these women could simply be administered pain killers for their affliction, a much cheaper alternative. Because of their advancing years, neither alternative may yield significant differences in survival rates. But the first therapy would allow the patients to be active and mobile while the second may force many of them to remain bedridden in the last “golden” years. To make a fair comparison between the two, the quality of their remaining lives must be taken into consideration.

<b>Condition:</b>	<b>QoL Weight</b>
Mild chest pain	1.0
Outpatient treatment/ sick at home	0.9
Myocardial Infarction	0.9
Post-hip fracture: recovery	0.9
Children with reading disability	0.77
HIV infection	0.75
Functioning kidney transplant	0.71
Standard chemotherapy	0.7
Severe chest pain	0.7
Home dialysis	0.6
Hospital stay w/ nonfatal illness	0.5
Long-term nursing home placement	0.4
Chronic liver disease on dialysis	0.36
Hospital stay / near-death	0.1

source: Neumann and Zinner, 1996 (forthcoming)

To resolve this, each year of life can be multiplied by a ‘quality of life’ adjustment between 1.0 representing perfect health and zero representing the health state judged equivalent to death. From this foundation, eight years of life at with a quality weight of 0.75 would be equivalent with living six years in perfect health; one a year in a hospital at 0.5 is the same as six months disease free. While the methods for obtaining an individuals personal preferences for different health states are varied and complex, quality weights have been acquired for many conditions and afflictions. A selected subset of quality weights used in published studies are presented in Table 3.1.

**THE PROPER PERSPECTIVE**

Defining the perspective is essential to an economic analysis. The point-of-view being considered will make a tremendous difference on what population to study, the costs accrued by that population, and the relevant benefits. From a patient’s perspective, the study should include such parameters as travel costs, time away from work, and out-of-pocket expenditures for drugs

or tests. From the point-of-view of a health payor (HMO, Medicare, etc.), these values may be meaningless because, aside from overall patient satisfaction, they do not affect their bottom line. Most economic analyses of medical technologies published today take a societal perspective, calculating all the costs and health benefits, no matter whom they affect. In these studies, aggregate costs could include loss of productivity; potential health benefits could encompass effects to individuals not even within the primary population being studied (i.e. second-hand smoke, pre-natal care). The societal perspective is unique in that it is the only viewpoint that does not count a gain as something which is, in reality, someone else's loss. For instance, from an employer's point of view, money can be saved by shifting costs to its workers.

While in practice, the relevant "society" is typically a nation or very large geographic region, the societal perspective should not be confused with the governmental perspective, which only includes a subset of the total costs. Table 3.2 shows how health care costs are divided among different constituencies.

	<b>Table 3.2: Costs and Time Horizons for different Perspectives</b>				
	Societal/ National	Managed Care Organization	Patient	Hospital	Employer
<b>Costs</b>					
Physician Visits	√	√	<i>a</i>	<i>when relevant</i>	<i>b</i>
Hospital Costs	√	√	<i>a</i>	√	<i>b</i>
Drugs and Medical Tech.	√	√	<i>a</i>	<i>when relevant</i>	<i>b</i>
Diagnostic Tests	√	√	<i>a</i>	<i>when relevant</i>	<i>b</i>
Nursing Home/ Ancillary Care	√		√		<i>b</i>
Patient Time & Travel	√		√		√
Friction Costs	√				√
<b>Time Horizon</b>	lifetime	duration of enrollment	life of patient	length of stay & re-admissions	duration of employment (& retirement benefits)
<b>See Text for Definitions/Further Clarification</b>					
<i>a</i> Patient may pay a portion of costs through deductibles, co-insurance, and co-payments					
<i>b</i> Level of expenditures vary with nature of insurance contract					

## COSTS

In the healthcare arena, costs are often realized by many different entities and each is primarily concerned with its own financial obligations. While many of the costs listed in Table 3.1 have a direct impact on the price of healthcare, there are a number of indirect costs associated with medical treatment. The opportunity cost for the patient's time and travel should also be included in the numerator. For instance, instead of surgically treating an abdominal aneurysm, doctors may choose to a strategy of "watchful waiting" to see if the affliction worsens. This latter strategy, however, may require significantly more trips to the doctor. While the physician fees will be included as a direct costs, the extra time and travel expenses should also be counted as an indirect cost.

However, these indirect contributions must be distinguished from the quality adjustments put on health states. When viewed from a societal point of view, researchers must be careful not to "double count" both the utility of work in the denominator and the cost of lost time and wages in the numerator. For example, a chemotherapy patient may be too sick to go into work after an individual treatment regimen. But the lost productivity of that patient should not be included as a cost because the utility for working has already been taken into consideration in the quality of life weight for standard chemotherapy (QoL = 0.7, Table 3.1).

On the other hand, the lost productivity to a business that must find a temporary substitute or permanent replacement for that worker is not reflected in that patient's quality of life weight. This temporary slow down in production is called a "friction cost" (Koopmanschap and Van Ineveld, 1991) and is quite relevant from a societal perspective.

Other indirect costs are also relevant from a societal perspective. The lost time and productivity of family members and other caregivers is important to consider when dealing with long-term, disabling conditions like Down Syndrome or Alzheimer's Disease. Taken from a societal viewpoint, all costs are relevant, including social services and spill-over costs. If a pre-natal health program will reduce children with learning disabilities, the cost-savings to the educational system should also be considered (US Department of Health and Human Services, 1996).

## **TIME HORIZON**

The relevant time horizon is vastly different depending on the perspective of the study. The study should be long enough in duration to observe all the relevant costs and health impacts of the medical intervention. However, since these effects are impacted by the perspective of the study, the proper time horizon will also change. For instance, a hospital under a capitated reimbursement scheme will try to minimize its costs and maintain health for the time when the patient is under the care of the hospital. To reduce costs, the hospital may try to discharge patients sooner. From this perspective, the hospital needs to investigate the cost-savings of early discharge versus the health risks and costs of re-admissions.

For society, all costs and health benefits are included so that a cost-effective analysis should follow the patient for his or her entire lifetime. For some very long-term interventions, like cleaning up hazardous waste, the societal perspective may need to investigate the consequences for the lives of many future generations as well.

This thesis will specifically investigate how the managed care perspective affects the overall results of cost-effectiveness analysis. By modifying the cost inputs and time horizons, quantitative comparisons can be made between the managed care and societal viewpoints. The next chapter outlines exactly why the managed care perspective changes and what modifications to the relevant costs and time-horizons are necessary.

## 4: METHODS

*or*

### **What exactly is different about the managed care perspective?**

Based upon the most current guidelines (US Department of Health and Human Services, 1996), cost-effective analyses should be performed from a societal perspective, thereby analyzing the costs and benefits to all constituencies no matter whom they affect. But these studies incorporate parameters which may mean little to individual HMOs that must assess, for instance, whether a new pharmaceutical therapy should be included on a formulary. By investigating how cost-effective analyses change when examined from a managed care point-of-view, this thesis intends to show how differences between a private payor and a social perspective may affect health technology coverage decisions. Assuming that social point-of-view provides the socially-optimum solution, any differences reflect departures based upon individual agendas.

To show this effect, this paper will investigate how analytical assumptions used in the managed care perspective change the relative value of certain health technologies. By re-analyzing the epidemiological studies from peer-reviewed journals, conclusions can be made and policy alternatives can be suggested to bring decision-making closer to the social optimum.

### **THEORETICAL FOUNDATIONS OF THE SOCIETAL PERSPECTIVE:**

The societal and managed care perspectives differ fundamentally based on philosophical goals. The societal perspective assumes that money spent on health care should be considered with respect to other programs that benefit individuals. Therefore, because there is a limited amount of resources necessary to satisfy all of society's needs, there is an opportunity cost for spending money on health rather than education, the environment, or law enforcement.

Cost-effective analysis from a societal perspective attempts to maximize health within a constrained budget. Through a common metric like cost/QALY, a society (or its agents) can rank the cost-effectiveness of diverse health interventions. By moving up the list until all the money is spent, society can theoretically maximize the health benefits (defined by QALYs) within the budget. Conversely, the resulting health benefit will be achieved for the lowest possible cost.

Because they want to stay in business, managed care organizations have to make money. Even not-for-profit plans need to make decisions that maintain their financial stability. Therefore, whether implicitly or explicitly stated, managed care organizations are attempting maintain a standard level of health for their enrollees, while maximizing profit. Theoretically, increases in the quality of care are only relevant if it can keep subscribers alive longer to pay more premiums or is economically necessary to keep and grow the consumer base.

The conflict can best be seen in new, long term strategies for improving health. These therapies offer an improvement compared to the status-quo, both in terms of costs and health. For society, the budget constraint has not changed; it will investigate the cost-effectiveness of each treatment as it compares on the list. For managed care, the assumption on which their evaluation is based -- maximizing profit given an acceptable level of healthcare -- is in jeopardy. The new technology seeks to advance this foundation, raising what the HMO considers to be an acceptable level of healthcare. If managed care decides that this improvement is not warranted, they may ignore the technological improvement, even though it could be acceptable to society.

## **THE MODELS**

Specifically, the following therapies and analyses will be investigated:

- Hypertension/ Heart Failure  
from B. van Hout, G. Wielink, G. Bonsel, and F. Rutten. "Effects of ACE Inhibitors on Heart Failure in The Netherlands: A Pharmacoeconomic Model," *Pharmacoeconomics* 1193: 3 (5): 387-397.
- Episodic vs. Maintenance Pharmaceutical Therapy for Depression  
from E. Hatzianandreu, R. Brown, D. Revicki, R. Turner, J. Martindale, S. Levine, and J. Siegel. "Cost Utility for Maintenance Treatment of Recurrent Depression with Sertraline Versus Episodic Treatment with Dothiepin," *Pharmacoeconomics* 1994; 5 (3): 249-264.
- Osteoporosis  
from B. Jonsson, C. Christiansen, O. Johnell, and J. Hedbrandt. "Cost- effectiveness of Fracture Prevention in Established Osteoporosis," *Osteoporosis International* 1995; 5: 136-142.

- Alzheimer's Disease  
from D. Lubeck, P. Mazonson. and T. Bowe. "Potential Effect of Tacrine on Expenditures for Alzheimer's Disease," *Medical Interface* 1994; October: 130- 138.

(Note: Every attempt was made to reconstruct these models from the information provided in the public domain. In certain cases, the original authors were contacted to verify assumptions and clarify unclear points. The following analysis should not be used for resource allocation purposes; the numbers presented are only approximations of the original work.)

### **THE MANAGED CARE PERSPECTIVE: NEW INPUTS INTO THE MODELS**

The above models compare the costs and health effects of a given treatment regime over time from a societal or national perspective. When re-analyzing the cost-effectiveness ratios of these interventions from a managed care perspective, certain assumptions were changed. These assumptions reflect the operating environment within which MCOs operate in the United States healthcare system. The effect of each parameter will be investigated individually and, when appropriate, collectively.

### **EFFECT OF COST-CONTAINMENT STRATEGIES**

Managed care entities like HMOs and PPOs often use cost-containment strategies to control expenditures. While many of these strategies are documented in Chapter 2, of particular interest in these scenarios involve pharmacy benefits and restrictions. When assessing the cost-effectiveness of pharmaceutical treatments, the costs of purchasing and administering the drugs is allocated to the managed care organization. While 99% of HMOs offer prescription benefits, many plans invoke co-payments, deductibles, and annual caps to defray some of these costs for pharmaceuticals. Based on data from the 1995 Managed Care Digest Series/ HMO-PPO Edition, the following adjustments have been made:

- Deductibles:

While the average annual individual and family deductible was \$74.71 and \$166.62 respectively, 85% of HMOs imposed no deductible at all. Because the consequence of hurdle requirement on spending may have a significant effect on costs, this

modification will be investigated individually. But since most organizations do not require any deductible, this modification will not be included in the overall results.

- Co -payments:

In 1995, co-payments were required in 96% of HMOs. The average co-pay was \$7.05 per prescription for brand-name drugs and \$5.06 per prescription for generics, both representing approximately a third of the total prescription cost. Since most of the treatments in question involve brand-name pharmaceuticals taken continuously for preventative measures, the analysis will assume that enrollees make co-payments of **\$7.05 monthly** for refills. This effectively reduces the pharmaceutical cost for the managed care organization by \$84.60 per patient per year.

- Pharmacy Caps:

Pharmacy caps limit the annual amount an individual or family may be reimbursed for each year. Once the cap is reached, the managed care organization will refuse to pay for any more claims and the enrollee find other mechanisms for payment (i.e. out-of-pocket or co-insurance).

While the average individual spending cap for drugs in 1995 was **\$3,101**, eighty percent of HMOs imposed no cap on maximum annual pharmacy benefits. Like the case with deductibles, pharmacy caps may have a substantial effect, but only for the relative minority of plans that require spending limits. Therefore the individual consequence will be studied, but not included in the overall findings.

### **OTHER NON-REIMBURSED COSTS (NURSING HOME, HOME CARE, FRICTION COSTS):**

Managed care organizations do not cover all the costs of healthcare. While health plans differ on the extent to which services (i.e. physician visits, hospitalization, pharmacy benefits) are covered, HMOs across the board do not reimburse for certain services. These services include nursing home stays, home-health care, and lost work productivity. Prevention programs often deter or delay the onset of illness which has economic repercussion for these services.

From the general perspective of society, these related costs are every bit as important to measure as drug and hospitalization expenditures. From the managed care point-of-view,

however, these are not as relevant. **The following analyses will show how ignoring this parameter will effect the overall cost-effectiveness of a treatment program.**

#### **DISENROLLMENT TIME HORIZON:**

The social perspective follows patients for their entire life-span until death, measuring all costs and health consequences for the appropriate population. An HMO, however, can expect a portion of enrollees to leave the plan each year for numerous reasons (e.g. moved away, employment changes, dissatisfaction, primary physician moved), thus reducing its effective time horizon. This may have severe consequences when assessing long-term or preventative healthcare interventions because the benefits may be too far in the future for most current subscribers to realize them.

Allen et al. (1994) published the findings of the Employee Health Care Value Survey showing that annual plan disenrollment in 1993 from general managed care entities to be nearly 10% and prepaid HMOs to be just over 6%. Further, Harrington et al. (1993) found that annual HMO disenrollment rates between 1986-89 were consistently near 8.6%.

Assuming a constant 8% annual disenrollment rate, roughly half of an incoming population would have left after **seven years**, 75% after **10 years**, and 95% after **13 years**. With this in mind, all analyses will be viewed at these time intervals.

#### **CROSSING PAYOR LINES:**

In the fragmented marketplace of the US Healthcare system, citizens are eligible for Medicare enrollment at age 65. Knowing this, managed care entities may not have an incentive to provide preventative care for the elderly because they do not continue to cover these patients. Any additional expenditures spent today may yield both financial and health benefits that will not be realized until after the patient has left. In other words, the MCO may never be able to reap the rewards of any long-term therapy and will decide not to pay for it instead.

To demonstrate this, all analyses will follow patients until **age 65** and evaluate the cost-effectiveness until that point. While the growth of Medicare HMO plans has been tremendous in

the past five years (DATA), only 10% (CHECK) of Medicare recipients are currently enrolled. The effect of Medicare HMOs have in tempering this effect will be discussed later.

The next chapter will provide a general description of the ailments and briefly outline the structure of the models involved. The results will also be reported, but a full discussion will be presented in Chapter 6.

## Chapter 5: The Re-Analyses

*or*

### What is the effect of viewing CEAs from a managed care perspective?

By re-analyzing these models using the assumptions for costs and time horizons described in Chapter 4, a comparison can be made between the societal and managed care perspectives. This chapter will present four cost-effective analyses of previously published studies, all of which contain an epidemiological model of a particular disease. While the assumptions that guide each model are informed by longitudinal research, each model follows a hypothetical cohort over time.

This section will give a brief background to the issues that instigated the original study, present the basic structure of the models, and report how the cost-effectiveness ratios change with each parameter.

#### **Glossary of modeling terminology:**

- Longitudinal study: a clinical study that follows patients over time and documents the progression of the disease and treatment in useful terms.
- Cohort model: a hypothetical group of similar patients whose health changes due to statistical probabilities of improvement/deterioration.
- Friction Costs: costs born by society due to productivity losses of sick patients.

### 5a: Heart Failure/ Hypertension

#### **BACKGROUND OF THE DISEASE**

Approximately 50 million Americans have high blood pressure, only half of which are being treated with anti-hypertensive medications (National High Blood Pressure Education Program, 1993). Although changes in lifestyle are recommended as primary prevention, a number of pharmaceutical therapies have been developed to treat hypertension and subsequent heart failure. Current guidelines suggest the use of diuretics,  $\beta$ -blockers, and calcium antagonists as an initial medical intervention, depending largely on the severity of complaints.

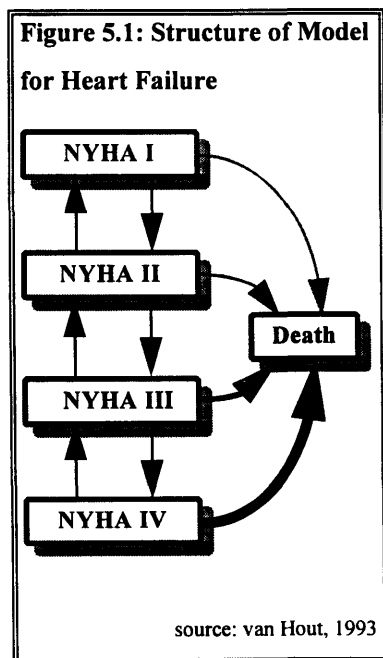
Another therapy, angiotensin converting enzyme (ACE) inhibitors, reduces heart failure by reducing the pressure the heart must pump against. By relaxing the walls of smaller blood vessels called arterioles throughout the body, the drugs allow the blood to flow more smoothly, thereby easing the workload of the heart. Although ACE inhibitors have traditionally been

suggested for patients with severe forms of heart failure, some recent clinical research (Cohn et al., 1991; Captopril Multicenter Research Group, 1983) suggests that the medications can improve health outcomes in patients with less severe conditions. The SOLVD-trial (1991), for instance, found that ACE inhibitors increased 4-year survival by 5%.

From this research, one could argue that ACE inhibitors should be used first, since they are superior in effectiveness to alternatives. Unfortunately, since ACE inhibitors have recently entered the market, they are more expensive than the generic versions of other pharmaceutical therapies (Bucey, 1996; Manolio, 1995). Approximately 75% of the \$7.5 billion (1986) in hypertension-related cost of healthcare in the US was estimated to cover the costs of drugs (Stason, 1989; Malcom et al., 1988) If the medication truly does increase survival and quality of life, then the question of cost-effectiveness must be raised. In other words, how much more health do we buy with the extra expenditures on medication (and cost-savings from reduced heart failures)?

### DESCRIPTION OF THE MODEL

In a study published in 1993, van Hout et al. proceeded to answer just that question. By



creating an epidemiological model of heart failure in men, they traced the progression of the disease with and without a pharmacological intervention. When compared to current treatments, the costs and quality of life of these men could be measured and a cost/QALY ratio could be calculated. This result can then be compared to other therapies to judge whether ACE inhibitors are cost-effective.

The model follows men between the ages of 35 and 85 by classifying them into four stages of heart disease. The four stages, originally established by the New York Heart Association (NYHA), represent slight, mild, moderate, and severe stages of heart disease. Each year, a patient has a probability of improving or deteriorating, depending on his

age and current health stage. These transition probabilities have been developed based upon

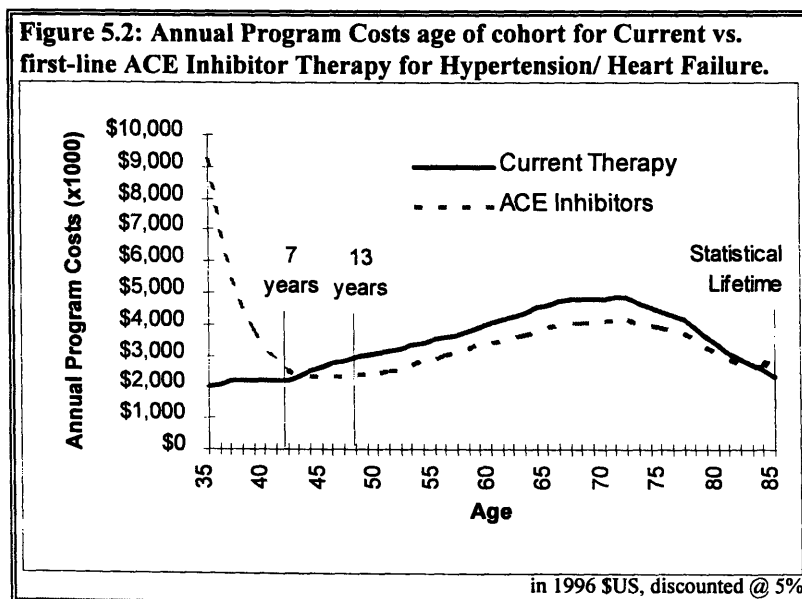
large, longitudinal observation studies that have charted patients for many years (Kannel, 1987; Kannel et al., 1988). When ACE inhibitors are used as a first-line pharmacotherapy, these transition probabilities change: the odds of improvement increase, while the patients have less chance of deteriorating.

Each NYHA stage is associated with a quality of life value and a risk of mortality over normal, with the most severe stage correlated to the greatest death rate. The most mild stage, NYHA I, was assumed to be symptom free and require no treatment. Further, each stage was stratified by age to allocate the costs of hospitals, nursing homes, physician visits, nursing services, as well as other medication costs. Further, friction costs were included to estimate production losses, defined here as “the period that society needs to adapt to the situation in which the production decreases as a result of temporary absence from work, disablement, or premature mortality” (p. 391).

**RESULTS: SOCIETAL PERSPECTIVE**

When comparing the use of ACE inhibitors as a first-line of therapy to current practices, a number of interesting results occur. First, the net program cost over the lifetime of the patient is roughly the same, no matter which strategy is used. *But for this given level of expenditures, treatment with ACE inhibitors yields an additional 6.7 quality-adjusted life years per patient.*

While ACE inhibitors do significantly reduce hospitalization and other medical costs, this benefit is tempered by the increased cost of medications. Because younger men (age 35-40 in the model) are not likely to have expensive treatment for heart failure, drug costs represent over three-fourths of all medical expensed in the initial years of the program. When discounting is considered (Figure 5.2), these extra initial costs take longer to recuperate. It is not



until age 43 that the intervention begins to show some financial benefits.

**RESULTS: MANAGED CARE PERSPECTIVE**

The effect of viewing these costs and health benefits from a managed care perspective is seen in Table 5.1. While the overall effect was to raise the cost-effectiveness ratio, the four variable affected the number in different ways. All of these effects can be explained through the original C/E equation:

$$\frac{\Delta C}{\Delta E} = \frac{C_{\text{treatment}} - C_{\text{current practice}}}{E_{\text{treatment}} - E_{\text{current practice}}}$$

The cost-containment strategies reduced the effective cost the of the drug that the managed care organization sees. In doing so, the deductibles and co-payments reduced the cost of the treatment strategy ( $C_{\text{treatment}}$ ), thereby making the numerator in the  $\Delta C/\Delta E$  ratio negative. Although it may be unrealistic to view these factors separately, the individual effect of deductibles and co-payments was to lower the C/E ratio even further to -\$6102/QALY and -\$7198/QALY, respectively.

**Table 5.1: The Effect of a Managed Care Perspective on the Cost-Effectiveness of Hypertension Agents**

Societal Perspective	\$9/QALY
Managed Care Perspective	
7 years	\$38719/QALY
10 years	28975
13 years	23360
Age 65	7025

note: 1996 \$US, costs and benefits discounted @ 5%

On the other side of the spectrum, not incorporating nursing home and friction costs made the cost/QALY ratio worse. Since these costs are associated with people in the more severe stages of heart disease, improving health correlates to reducing these costs. (However,

some of the net benefit of reduced or delayed admissions into nursing homes is discounted away because these costs occur more than thirty years after the start of the program.) These costs affect both the treatment and non-treatment strategies. Since the drug keeps people healthier, these non-reimbursable costs make-up a smaller portion of  $C_{\text{treatment}}$  and a larger portion of the ‘current practice’ strategy . By not including them, the analysis reduces  $C_{\text{current practice}}$  much more than  $C_{\text{treatment}}$  thereby making the difference between the two larger and producing a higher cost-

effectiveness ratio. The individual effect of this parameter would raise the value to \$4775/QALY. By not including them in the analysis, the managed care has correctly determined that these benefits, although real and important in their own right, are realized by other constituencies.

Of most notice, however, is the effect of time horizons in the cost/QALY ratio. The trends from the time-horizon parameters accurately reflect the fact that this drug therapy becomes more cost-effective as the years progress. Smaller time horizons do not allow for the cost-savings of foregone medical treatment or the improved health in more quality-adjusted life years to be fully realized. As the time horizon lengthens, the effect of the time horizon alone makes the C/E ratio drop from \$50,698 QALY at seven years to \$26,276/QALY at thirteen years. This decrease reflects the fact that the technology is beginning to save money (smaller numerator) and increasing health (larger denominator).

## **5b: Depression**

### **BACKGROUND OF THE DISEASE:**

Nearly one out of every 15 women and one in 40 men will suffer from depression in his or her lifetime (Eaton et al., 1989). Every year, 1.59 million people are diagnosed with depression and experts suggest that two to five times more go undiagnosed, making the disease the one of most common psychiatric disorders in the US (Weissman et al., 1991; West, 1992).

Commonly misperceived as a temporary, passing affliction, depression is a chronic disorder. Between 50 to 85% of all patients who have endured a major depressive episode will experience at least one more, with a significant portion suffering through many more episodes (National Institutes of Mental Health/ National Institute of Health, 1985). Other research has documented that patients who have experienced 2 or more depressive episodes in the past five years have as high as a 75% chance of encountering another in the next half decade (Angst, 1992).

The costs of depression are realized on many levels. Greenberg et al.(1993) estimated that the US spent \$12.4 billion dollars in 1990 in direct medical costs, including general physician and psychiatrist visits, hospitalization, and medications. Additionally, depression results in substantial productivity losses because most patients are of employment age and many are unable to perform daily work routines, costing the US over \$31 billion dollars.

Treatment options include individual and group psychotherapy, electro-convulsant therapy, and pharmaceutical treatments. Because of their costs and ease of administration, patients will typically be prescribed antidepressant drugs as a major part of treatment (Saklad, 1995). Of these, tricyclic antidepressants (TCA) are the most commonly administered, having positive results in nearly three-quarters of patients (Potter et al., 1991). But TCAs are associated with many side-effects, including “sedation, orthostatic hypotension, bodyweight gain, arrhythmias, and anti-cholinergic effects such as dry mouth, blurred vision, and constipation” (Hatziandreu et al., 1994). While living with depression is difficult enough, these side-effects further reduce the quality of life of those in treatment.

These side-effects also lead to poor patient compliance in taking the daily regimen of the drug. Further, overdoses of TCAs are extremely toxic, sometimes resulting in death. Because

many patients with depression have suicidal tendencies, physicians often prescribe subtherapeutic dosages or short courses of treatment (Katon et al, 1992; Thompson & Thompson 1989). Consequently, TCAs are administered only as required, typically on a three month regimen.

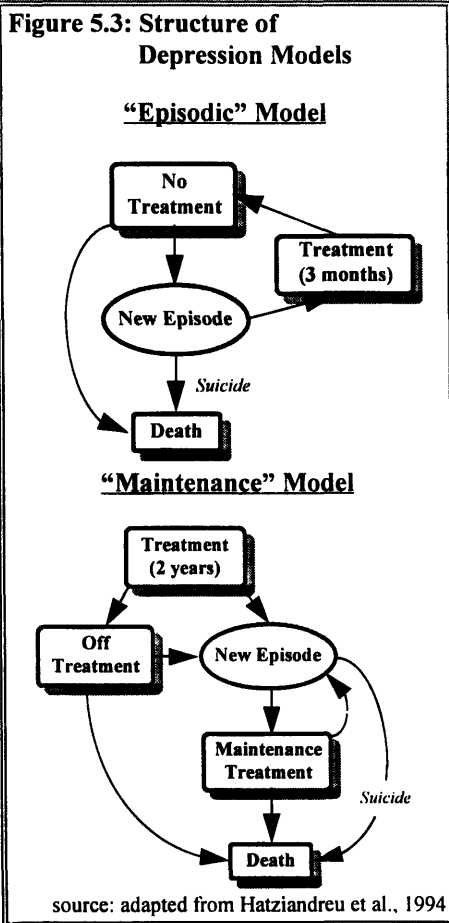
In response, new pharmacological therapies have been developed, including selective serotonin reuptake inhibitors (SSRI). SSRIs make up a class of drugs whose trade names include Prozac and Zoloft. While clinical efficacy has been shown to be equivalent (Song et al., 1993; Potter et al., 1991), these drugs do not have the side-effect profile of TCAs.

With these new antidepressive agents, patients can be treated continuously, thereby preventing some depressive episodes before they occur. While the evidence indicates that SSRI treatment may reduce adverse events and pharmacological side effects, these advantages come at a significant cost. Hatziandreu et al. (1994) cited the daily cost of dothiepin at just over \$0.25, while sertraline treatment was priced at \$1.62/day (1991 dollars). Providing an uninterrupted regimen of pharmacotherapy requires yearly drug costs that may dwarf any potential savings from reduced healthcare service use. Thus, the question is raised: is maintenance therapy for recurrent depression cost-effective when compared to the current strategy of episodic treatment?

### **OVERVIEW OF THE MODEL**

In their 1994 paper, Hatziandreu et. al. investigated these two separate methodologies for treating recurrent depression. Specifically, the researchers sought to compare ‘maintenance’ therapy using the SSRI drug, sertraline, against the standard practice of ‘episodically’ prescribing the TCA, dothiepin.

Two separate models were developed to track a hypothetical cohort of 35-year-old women who have experienced two previous episodes of depression within the past four years. Thus, these individuals are extremely likely to experience additional episodes. The two models are shown in Figure 5.3. Each year a woman could either: 1) remain in remission; 2) develop a recurrence; or 3) die from natural causes.



The ‘episodic’ strategy assumes that pharmacotherapy is prescribed only during a depressive event and no treatment will be given until the beginning of another bout with depression. The “maintenance” strategy provides all patients with the SSRI treatment for two years, at which point everyone who has been unaffected by depression in that time will be taken off the treatment. Any woman who experiences an episode within the first two years or subsequently encounters an additional episode is assumed to need the pharmacotherapy to control her depression and is administered the drug continuously for the rest of her lifetime. Both models assume that 2% of all patients suffering from a depressive episode will commit suicide, and allow for up to five recurrences for each patient.

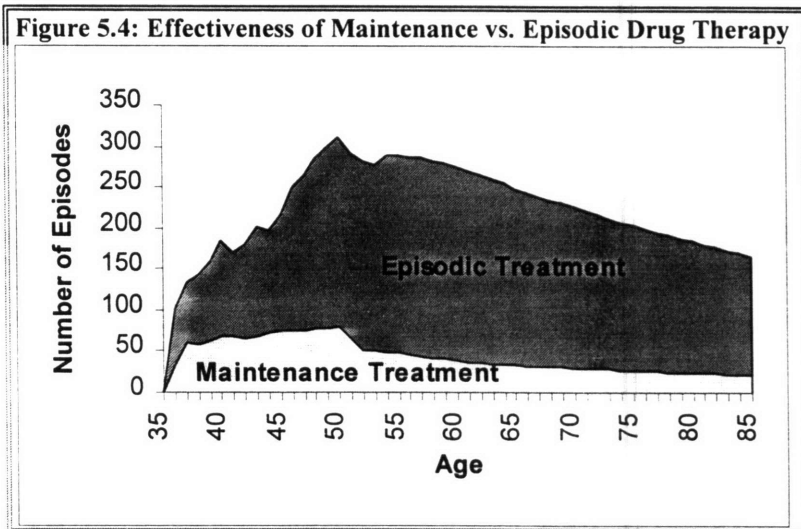
Costs were calculated by summing all the costs within a single depressive episode (\$908 for three months under ‘episodic’ treatment vs. \$2752 over two years on ‘maintenance’ therapy), which included blood tests, physician and psychiatrist visits, hospitalizations, and medication costs. The model also charts non-compliers separately. Due to the side-effects of the medication, patients treated with dothiepin were assumed to have a higher non-compliance rate (33.5% vs. 23.5% for maintenance treatment) and a lower quality of life. These weights are given in Table 5.2.

	<u>QoL Weight</u>
Remission, no drug treatment	0.95
Maintenance treatment, no depressive episode	0.93
Maintenance treatment, depressive episode	0.72
Episodic treatment, depressive episode	0.69

source: Hatziandreu et al., 1994

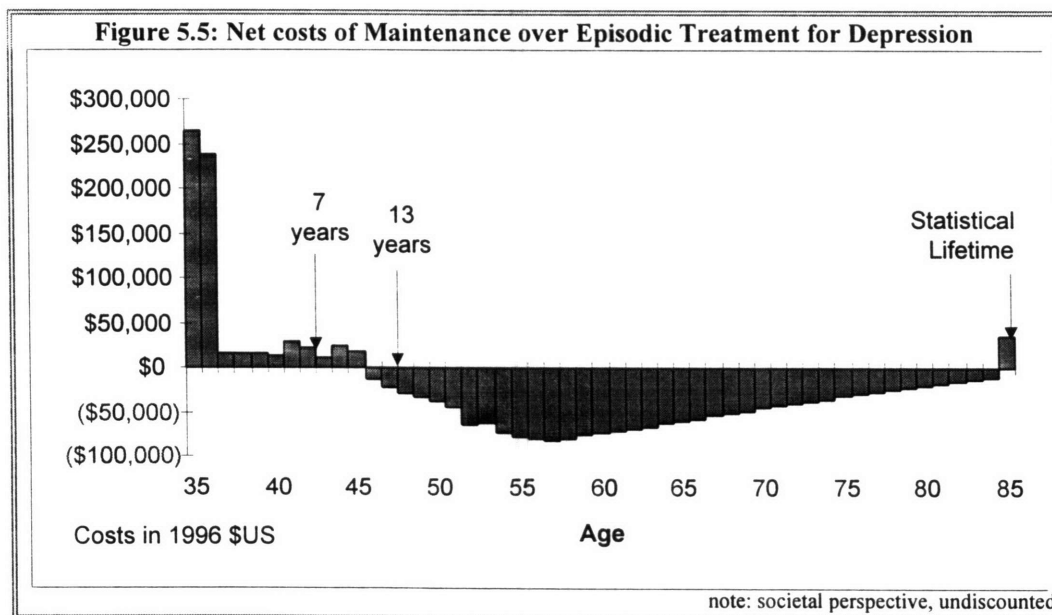
**RESULTS: SOCIETAL PERSPECTIVE**

From the societal perspective, *the maintenance strategy resulted in improved health (.952 QALYs/patient) with slightly higher costs (\$100/patient), yielding a cost-effective ratio of \$105/QALY.* (Although this may be an underestimate since caregiver and friction costs were

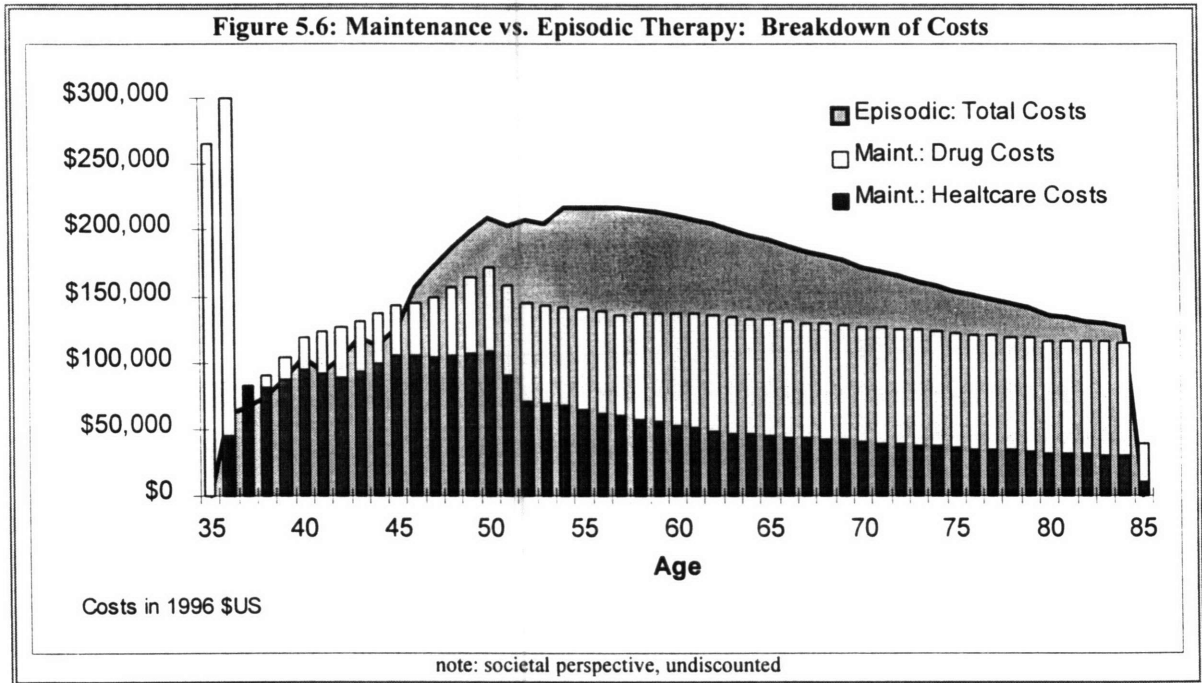


not considered.) As can be seen from Figure 5.4, the maintenance strategy significantly reduces the number of depressive episodes each year. This effect results in cost savings due to decreased healthcare utilization. The undiscounted cost differences between the two strategies can be seen in Figure 5.5.

Giving every subject a daily regimen of drugs for the first two years requires a tremendous financial outlay. But in this process, the strategy can separate out those patients who need the drug continually to maintain the brain's chemical balance. After the tenth year, the reduced number of depressive episodes begins to yield cost savings over the episodic strategy.



Ironically, this reduction leads to increased expenditures much later. The final positive outlay at age 85 represents the costs of treating extra patients who would have otherwise died of suicide (but because this value will be heavily discounted, this is a relatively minor issue).



Also of interest is the role the pharmaceutical price plays in overall expenditures. As can be seen from Figure 5.6, the cost of the drug represents the majority of the financial expenses after age 56. In the analysis, sertraline was over six times more expensive than dothiepin and eventually is administered to over half of all patients in the cohort for their entire lifetime. With only a 7% reduction off the price of sertraline, the costs of both strategies would be equal, but maintenance therapy would still offer more QALYs. In other words, maintenance treatment would ‘dominate’ the episodic therapy. Price negotiations or the introduction of generic equivalents could significantly improve the cost-effectiveness of SSRI treatments.

**RESULTS: MANAGED CARE PERSPECTIVE**

The results of re-analyzing the CEA from a managed care perspective can be seen in Table 5.3. Even though some major components of costs were excluded from the analysis (e.g. friction and caregiving costs), all the remaining expenditures documented in the analysis are covered by managed care through various mechanisms.

(Nursing home costs are not relevant because most patients with a primary diagnosis of depression are generally not elderly and the condition typically does not require admission to a caregiving facility.) Therefore the role of pharmaceutical controls and time horizons are the only suitable comparators.

Societal Perspective	\$105/QALY
Managed Care Perspective	
7 years	\$2257/QALY
10 years	2125
13 years	2267
Age 65	413
note: 1996 \$US. costs and benefits discounted @ 5%	

While the annual spending caps instituted by managed care organizations were not reached in any year, deductibles and co-payments played an interesting role. Because the proportion of drug expenditures for episodic treatment is relatively small (\$300 over the three months, 1996 dollars), the one-time deductible covered over a third of that cost.

$$\frac{\Delta C}{\Delta E} = \frac{C_{\text{maintenance}} - C_{\text{episodic}}}{E_{\text{maintenance}} - E_{\text{episodic}}}$$

Because  $C_{\text{episodic}}$  became smaller and relatively cheaper, the cost/QALY ratio worsened. The individual effect of deductibles was to raise the C/E ratio to \$261/QALY. Co-payments, however, helped the maintenance strategy reduce costs more. Because drugs are purchased all year round, the maintenance strategy required patients to pay \$84.60 each year toward their medication (assuming one refill per month with a \$7.05 co-payment). In contrast a three month drug regimen used in the episodic strategy reduced the effective drug cost by only \$21.15. The net effect of co-payments alone was to lower the cost-effectiveness value to \$83/QALY.

Again, the time horizon plays a critical part. The seven- to thirteen- year time frame represents a period within the model that sees slightly rising costs for both strategies. Further, the increase in QALYs from the reduced number of depressive episodes is offset by the decrease

in quality of life from the side effects of taking the SSRI medication. Therefore, these numbers do not fluctuate much in those years. In this time period, the maintenance strategy is trying to effectively separate the women who need the an uninterrupted regimen of pharmacotherapy to prevent further episodes. Whereas the maintenance costs level out at this point, the episodic strategy continues to increase overall expenditures. The true benefits of maintenance therapy will not be realized for a few more years.

## **5c: Osteoporosis**

### **BACKGROUND OF THE DISEASE:**

Osteoporosis is an age-related disease affecting millions of women around the world. Affecting nearly 25 million individuals in the United States alone, the disease itself creates no external symptoms; the effects are realized through bone fractures, primarily of the hip, wrist, and spine (Daly, 1995). Diagnosed by the progressive loss of bone mineral density (BMD), women become increasingly susceptible to these bone fractures as they age. This increase is due in part to the rapid bone loss after menopause and to the increased risk of falls in the elderly (Schuute, 1995). Just over one-quarter of all women in their 50's have low bone mass, while the proportion over 80 years old rises to nearly 84% (Melton et al, 1992). Since the elderly are the fastest growing segment of our population, the effects of osteoporosis will only become more significant in the coming years. Currently, the illness is estimated to cost the US over 10 billion dollars each year (Consensus Development Conference, 1993).

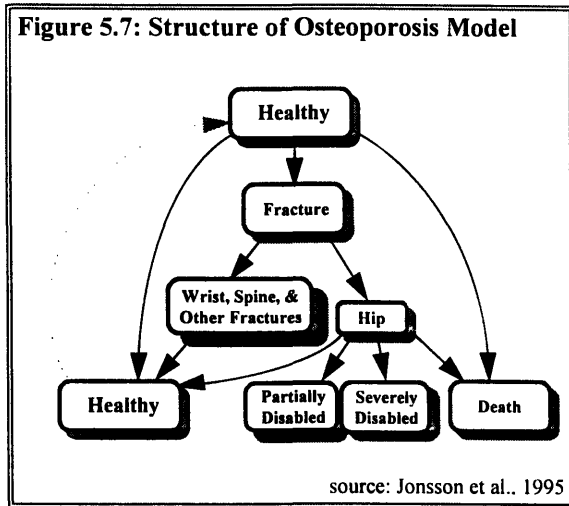
Since there are no effective means for restoring bone loss, early diagnosis and treatment are critical for slowing the progression of the illness. While the affliction has a strong genetically link, other factors such as poor nutrition and childhood illnesses have been found to correlate to bone loss as well.

Non-pharmacological treatment options include dietary or supplemental intake of calcium or vitamin D as well as lifestyle changes that help promote bone retention (i.e., increased exercise, smoking cessation, decreased alcohol consumption). Among the various drug therapies, hormone replacement therapy has been shown to decrease bone loss and is the treatment of choice for postmenopausal osteoporosis (Daly, 1993).

### **OVERVIEW OF THE MODEL**

In their 1995 paper, "Cost-effectiveness of Fracture Prevention in Established Osteoporosis," Jonsson et al. presented a computer model for measuring the costs and health benefits of treating patients with established osteoporosis.

Each year in the model, a woman can remain healthy, experience a bone fracture, or die of natural causes. Since it is a very serious and disabling condition, hip fractures are associated



with a certain level of mortality and long term health consequences. The model as based upon a mathematical algorithm that calculates the probability of four separate types of bone fractures according to certain risk factors. Established from epidemiological study of 1,076 women in Sweden, the model relates this risk based upon sex, age, and bone mineral density.

Two cohorts of 1000 50-year old women are simultaneously followed in the model, one of which is administered a hypothetical pharmacological agent. This therapy is assumed to last for five years, immediately reducing the fracture risk by 50% and maintaining this lower risk status for the remainder of the patients life. (While this therapy may not represent any known, current treatments, the plausibility of these assumptions will be discussed later.)

The year in which a patient experiences a fracture, she accrues healthcare costs and a reduced quality of life. For wrist, vertebrae, or 'other' fractures, the patient returns to a healthy, cost-free state. The second year after a hip fracture, half of the patients are assumed to fully recover, 40% live the rest of their life with slight impairment, while the remainder require institutionalization. The costs and quality of life weights are given in Table 5.4.

**Table 5.4: Costs and QoL Weights used in Osteoporosis Model**

	Costs	QoL	
Health	--	1.0	
Vertebrae	\$16000/	0.9	first year after fractur
Forearm Fracture	400	0.9	"
Other	400	0.9	"
Hip	15600	0.8	"
Slight Disability	--	0.9	lifetime
Institutionalization	20000	0.4	"
Intervention (Drug)	\$6000/y		
Indirect	\$250/y		
Extra Follow-up Visits	\$350/visi		

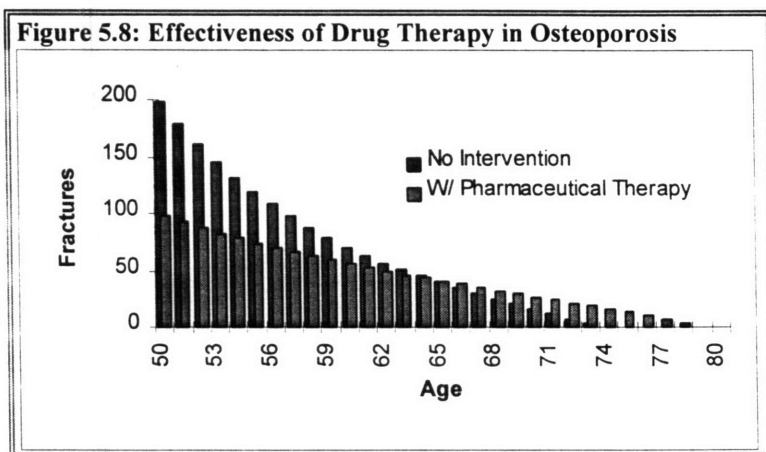
source: Jonsson et al., 1995

In the published paper, costs were collected from a societal perspective. Indirect costs were calculated to compensate for the patients time and travel expenses. No effort was been made to quantify the friction costs of productivity losses, citing that most of the afflicted patients are beyond traditional employment age.

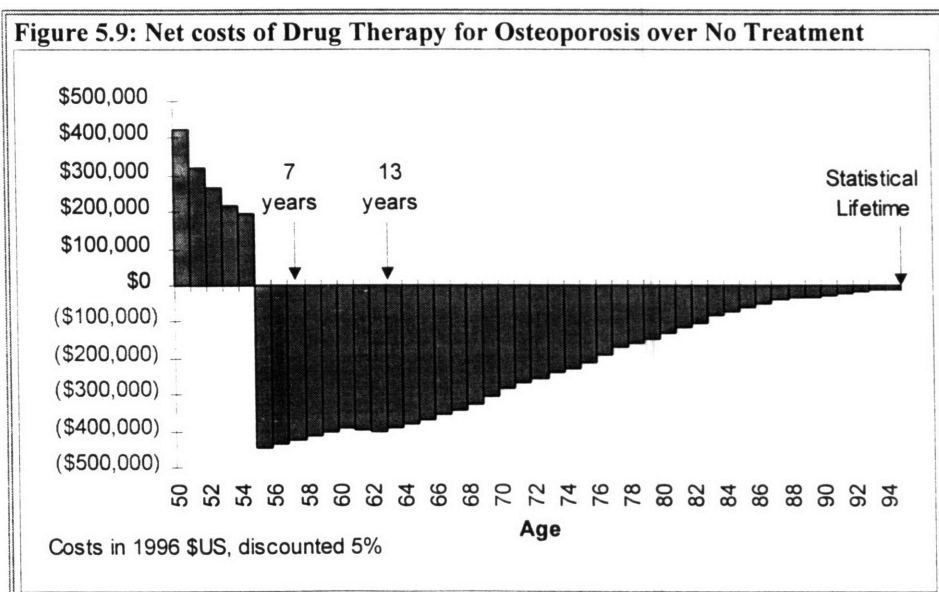
**RESULTS: SOCIETAL PERSPECTIVE**

From Figures 5.8 and 5.9, one can deduce that *the pharmaceutical intervention improves health, but requires more financial outlays up front*. But because the reduced number of bone fractures requires fewer expenditures, the overall cost/QALY ratio is negative, showing that the treatment is **cost-saving**.

(However, the supposition that a five-year course could immediately lower and maintain the reduced fracture risk is not realistic. A more plausible assumption would be to require that the medication be continued for a woman's entire lifetime to maintain her bone density and reduced risk of fractures. With this new hypothesis, the yearly costs shown in Figure 5.9 may never be lower than 'no treatment', but the increased number of quality-adjusted life years may yield a cost/QALY ratio that is reasonable.)



With the model, one can chart the number of episodes and costs over time. Figure 5.8, for instance, properly demonstrates the natural conclusion that a 50% reduction in fracture risk



results in half the fractures over time. Because some patients die from hip fracture complications, the reduction in medical episodes has the effect of extending overall life.

## **RESULTS: MANAGED CARE PERSPECTIVE**

Table 5.5 shows the effect of changing the perspective of the analysis. Like the others, the pharmacy caps were not reached in this analysis. Because the pharmaceutical regimen lasted for only five years, deductibles and co-payments had little effect on the overall expenditures. Using the alternate hypothesis, it can be deduced that the pharmacy control would act in much the same way as they did with hypertension medication in the first example. That is, to reduce the overall price paid for the drug, making the treatment strategy cheaper and lowering the cost/QALY ratio.

Again, like with hypertension, selecting only the costs that affect a managed care entity's bottom line has the effect of masking some of the benefits. Here, since 10% of all hip fractures were assumed to be so severe that

institutionalization would be required, the lower risk of hip fractures translates into reduced admissions. By not including these costs in the CEA, the "no treatment" strategy appears to be cheaper, thereby making the difference in the numerator larger. The resulting C/E ratio from adjusting this parameter alone

(-\$1314/QALY) reflects these relative cost-savings that are not realized by a managed care.

With the time horizons, the shorter periods actually made this drug intervention cost-inducing rather than cost-savings. Again, the changes were dramatic as the seven-year time horizon was just above the break-even point (\$1491/QALY) when considering time effects alone. Interestingly, however, the cost-effectiveness ratio at age 65 (-\$15191/QALY) was actually lower than the societal value which measured events until death. The explanation stems from the structure of the model. As explained earlier, the decrease in severe hip fractures causes more women to be healthier longer; thus there are more women eligible to experience a bone fracture in the later years of life. Therefore, the final years of the model actually require more relative expenditures than the corresponding years of 'no treatment'.

Societal Perspective	-\$12927/QALY
Managed Care Perspective	
7 years	\$8602/QALY
10 years	1122
13 years	-1749
Age 65	-2654

note: 1996 \$US, costs and benefits discounted @ 5%

## **5d: Alzheimer's Disease**

### **BACKGROUND OF THE DISEASE**

Alzheimer's Disease (AD) is a devastating illness characterized by progressive cognitive deterioration. Affecting more than 10% of people over 65 years of age and between 25 and 45% of everyone over 85, the number of cases of AD is expected to rise dramatically as the US population ages (Office of Technology Assessment, 1987). Although it is the leading cause of dementia in the United States and has been the subject of intensive scrutiny by researchers, Alzheimer's Disease remains a mystery in many respects. For example, the cause of the disease remains unknown and a cure is not predicted in the foreseeable future.

Persons afflicted with Alzheimer's Disease gradually find that daily chores become difficult and must rely on others for assistance. Indeed, informal caregivers contribute significant time and money toward the health of the patient. Rice et al. (1993) that caregivers in the community spend 286 hours per month (almost ten hours a day, including weekends) and nearly \$47,000 per year (1990 dollars). Further they documented that around 65 percent of community and institutionally-based care was self paid. Of the remainder, public sector funds accounted for 12.5 and 34% of the costs of care for community and institutional patients, respectively.

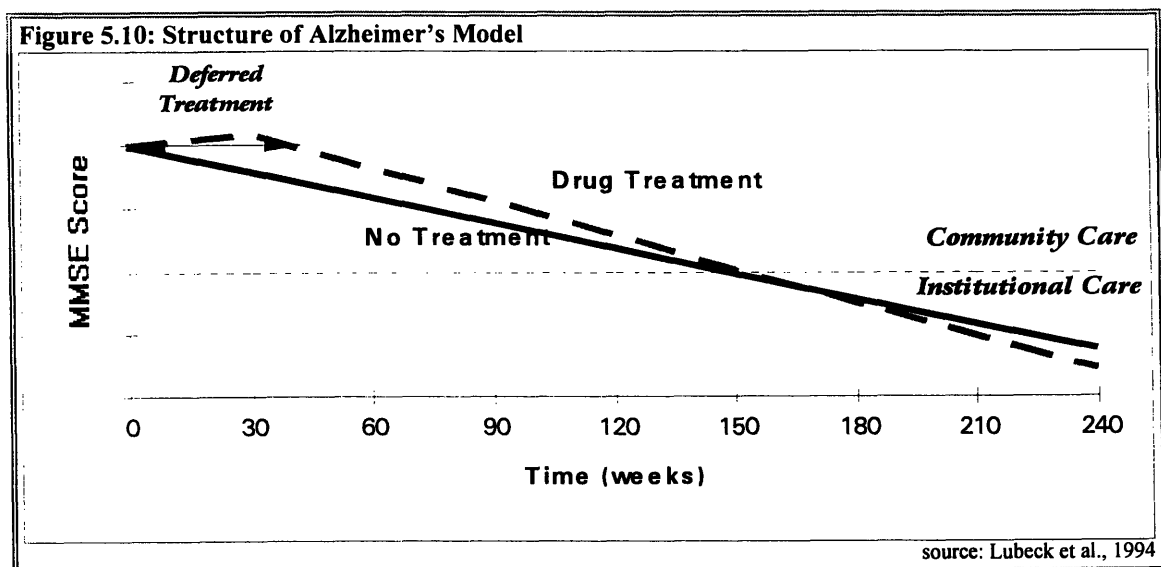
While much of the treatment for AD is directed toward managing behavioral/psychiatric difficulties and providing support and counseling for the caregiver, clinical researchers have begun in earnest to find a suitable pharmaceutical therapy. Tacrine, an acetylcholinesterase inhibitor, is the first drug marketed to alleviate the symptoms of AD. By blocking the destruction of memory-aiding neurotransmitters, tacrine slows the cognitive deterioration and helps individuals regain some of their lost cognitive skills. Unfortunately, the drug does not affect the underlying pathology of the disease and relief is only temporary. Moreover, the drug has some substantial, but non-life threatening side-effects including nausea and liver toxicity. The toxicity requires that specific enzyme levels must be monitored periodically throughout the course of treatment.

## **DESCRIPTION OF THE MODEL**

Lubeck et al. (1994) published an analysis that investigated the economic repercussions of clinical results from a recently completed trial of tacrine. The Lubeck model was produced to estimate whether tacrine would produce cost savings for Alzheimer's patients by temporarily increasing cognitive ability and postponing the progression of the disease. This Alzheimer's model calculates lifetime costs of "no treatment" and then makes assumptions about the potential savings and additional expenditures for patients taking the drug. Specifically, it attempts to answer whether the increased costs of the drug and its side effects counter the savings gained by delaying the use expensive institutional care.

The model assumes a link between cognitive ability and healthcare utilization, wherein the progression of the disease will lead to eventual institutionalization. A patient begins the model just after the time of first diagnosis, so that medical and psychological assessment costs are not included in the calculations. Because so little was known about the long-term health affects of taking the drug, the authors also assumed that tacrine does not extend life. From this assumption, there can be no difference in life years gained, and the only health benefit would be directly related to quality of life. But obtaining QoL weights for demented adults is difficult and poses some challenging methodological problems. So rather than yielding a cost/QALY ratio like the other models, the authors reported results in net costs (or savings) per patient per year.

Based on the clinical trial results, patients will gain one MMSE point after 30 weeks of pharmacotherapy. (The MMSE, or Mini-Mental State Exam, is a brief test that measure cognitive



ability on a 30-point scale through questions such as “What town are we in?” and “Can you spell WORLD backwards?”) Because tacrine does not affect the underlying progression of the disease, patients are assumed to deteriorate faster than normal after this point.

The period of time that it takes a patient to gain and then subsequently lose exactly the same amount of cognitive ability (measure by the MMSE score) is called the 'deferred treatment' period (Figure 5.10). In this analysis, the deferred treatment period was equal to nine and a half months. In essence, this is the amount of time “gained” by the benefits of the drug. At the end of the deferred treatment period, the patient is no worse off than when he or she started. During this period, a patient will spend less on healthcare costs (specifically, 50% less) and defer

entrance into a nursing home.

**Table 5.6: Assumption in Alzheimer's Model**

	Treatment	No Treatment
Life Expectancy	4.4 years	4.4 years
Cognitive Change	+ 1 MMSE pt @ 30 weeks -4.64 MMSE pts/yr	-3.5 MMSE pts/yr
Community Care		
Duration	2.89 years	3.52 years
Costs	\$10,245/yr	\$10,245/yr
Institutional Care		
Duration	.74 years	.88 years
Costs	\$4,4197/yr	\$4,4197/yr
"Deferred Treatment"		
Duration	.79 years	--
Costs	\$5,123/yr	--
Drug Costs	\$4.43/day	--
Monitoring Costs	\$538/year 1 \$109/ years 2+	--
costs in 1996 \$US		

Community care and institutionalization costs were both estimated from longitudinal studies of AD patients. Community care costs included paid home care, physician visits, in-patient hospitalizations, and mental hospital services.

Additionally, the amount of time spend in a nursing home was estimated to be 20% of the patient's remaining lifetime.

Because of side-effects of the drug, the treatment arm also needed to include liver-enzyme monitoring costs. Remaining consistent with the original analysis, drug costs were not discounted in an effort to conservatively estimate drug price increases.

**RESULTS: SOCIETAL PERSPECTIVE**

Since health effects were assumed to be constant in the model, only the costs are relevant for comparison. From the societal perspective, the costs savings of the deferred treatment was offset by the additional expenditures for drugs and monitoring. In the end, the treatment required an additional financial outlay of \$69 per patient per year over ‘no treatment’. The end result was very sensitive to the initial increase caused by the drug. For instance, if the overall effect of Tacrine increased the patient’s cognitive ability by two MMSE points rather than one, the treatment would save money in every year of life.

**RESULTS: MANAGED CARE PERSPECTIVE**

Managed care does not reimburse for much of the costs associated with Alzheimer's Disease. MCOs do not pay for any part of nursing homes, so all institutional costs were taken

Societal Perspective	\$69 per patient per year
Managed Care Perspective	
7 years	\$798 per patient per year
10 years	1222
13 years	1361
1996 \$US, discounted 5%	

out for this parameter. In addition, Rice et al. (1991) documented that paid home care represented \$10,000 of a total of \$12,885 spent per patient in the community (1991 dollars). Ernst and Hay (1994) reported that 62% of the \$5,120 per community-based patient was allocated to paid home

care (1991 dollars). From these numbers, one can estimate that non-reimbursed home care consists of 70% of all community costs.

The pharmaceutical controls acted in the same way as in all the other models. By lowering the cost of the drug, deductibles and co-payments effectively lower  $C_{\text{treatment}}$ , causing the numerator in the C/E ratio to be smaller. The effect of deductibles and co-payments alone made the new ratio equal to -\$12 and -\$26 per patient per year, respectively.

Because of the very high amount of non-reimbursable costs, this parameter had the greatest impact on the overall value. Not apparent in the chart is the magnitude of the difference between total program cost between the societal and managed care perspectives. When nursing home, paid home care, and co-payments were dismissed, total program (discounted) costs for the treatment arm fell almost four fold, from \$64,721 to \$16,610. However, the costs of the non-

treatment arm fell even more, from \$64,420 to \$9810, nearly a six and a half fold difference. Consequently, the net difference in costs ( $C_{\text{treatment}} - C_{\text{no treatment}}$ ) grew from \$301 to \$6800 over the patients lifespan. Isolating this parameter, the net effect of not including non-reimbursable costs was to increase the dollars per patient per year to \$1622.

While the pharmaceutical controls and non-reimbursed costs affected the cost/QALY ratio much like in the other examples, what is most striking here are the results of changing the time horizon. Because Alzheimer's disease affects the elderly, the effects of looking at the cost-effectiveness until age 65 was not explored. Further, since the lifespan was assumed to be 4.4 years after diagnosis, time horizons of one, two, and three years were investigated.

In this model, the deferred treatment period was in the beginning, where cost-savings are barely discounted. After the first 9½ months, the patient accrues costs at the same rate as those in the 'no treatment' arm. Further, the entrance to the nursing home was also deferred by two months until after halfway into the third (of 4.4) years. The last year of life finds patients in both strategies in nursing homes, the only difference in treatment are the extra drug and liver monitoring costs. When investigating the effect of the time horizon alone, the most cost-effective year for this therapy is the first, saving \$1871 in the first year. (However, it can not be concluded that the drug should be discontinued after the first year unless information is known about the health consequences of stopping the medication. Patients may suffer side-effects from withdrawal that reduces quality of life and incurs extra costs, making the decision to terminate treatment to be cost-ineffective.)

The figures show in Table 5.7 are the cumulative effects of all these parameters. While the pharmaceutical and early time horizons pushed to cost-effectiveness ratio lower, the impact of the dismissing nursing home and home care costs overwhelmed these tendencies. The end result indicates that managed care views this intervention as less cost-effective than society does.

## 6: Discussion

or

### How the values from these differing perspectives lead to conflicts in resource allocation

The results presented in the previous chapter indicate that the societal and managed care perspectives for cost-effectiveness analysis are not equal. ***Based on these results, one can conclude that the managed care perspective tends to undervalue long-term, preventative technologies.*** Table 6.1 shows that in each instance, the C/E ratio worsened. The numerical increase means that an MCO realizes a higher price per unit of health benefit than society in general. ***This discrepancy between social and managed care viewpoints can lead to a conflict in how to prioritize our limited healthcare resources.***

	Societal	Managed Care <sup>1</sup>
Hypertension	\$9/QALY	\$28975/QALY
Depression	105	2125
Osteoporosis	-12927	1122
Alzheimer's Disease	69 <sup>2</sup>	1622 <sup>2,3</sup>

1996 \$US, costs and benefits discounted @ 5%  
<sup>1</sup> Cumulative effect of all parameters, 10 year time horizon  
<sup>2</sup> Dollars per patient per year  
<sup>3</sup> Three year time horizon

This chapter will discuss the significance that each of the four parameters contributes toward the discrepancy in cost-effective ratios: cost-control mechanisms, non-reimbursable costs, disenrollment rates, and crossing payor lines. But the decision to adopt or deny reimbursement for a technology is not based solely on

cost/QALY calculations. This chapter will also discuss market externalities that affect this decision-making process. These externalities will both bolster and detract from the above conclusion.

### **COST-CONTROL MECHANISMS**

In Chapter 4, four parameters within the managed care environment were identified that could alter the value of medical technologies. The first of which discussed pharmacy cost-controls. Whether these are accomplished through deductibles, co-payments, or pharmacy caps, such control mechanisms require that the patient contribute financially toward the costs of his or her own care. In doing so, the managed care organization hopes to simultaneously reduce unnecessary utilization while providing the psychological impression that the service has worth.

While these strategies are not ordinarily enacted to generate profit for the plan, they have the effect of lowering the MCO's overall costs. In essence, these patient contributions reduce the effective price paid for the medication. From a societal view, however, deductibles and co-payments only serve to shift the costs from the payor to the patient and do not change the overall value of the technology.

Not one of the strategies came close to reaching the average HMO's maximum allowable pharmaceutical cap. Typically, however, these reimbursement ceilings tend to affect only patients with multiple conditions taking multiple medications. Single-disease epidemiological models (such as the ones presented here) will not, by definition, include these types of patients.

***The general effect of deductibles and co-payments was to improve the cost-effectiveness of the pharmacological intervention from a managed care perspective.*** By lowering the costs of the treatment strategy, these cost-control mechanisms reduced the difference in numerator, thereby lowering the cost-effectiveness ratio:

$$\frac{\Delta C}{\Delta E} = \frac{C_{\text{treatment}} - C_{\text{current practice}}}{E_{\text{treatment}} - E_{\text{current practice}}}$$

From these results, deductibles and co-payments may be worthwhile not only in curbing unnecessary utilization, but in promoting preventative therapies.

The magnitude of this effect varied according to the intervention. When pharmaceutical expenditures represent a major portion of the additional treatment costs, this effect can be significant. In the hypertension example, the C/E ratio changed from near break even to a cost-saving strategy that saved nearly \$7000/QALY. On the other hand, if the comparative strategy also requires a pharmaceutically-based, then the cost reductions from deductibles and co-payments will be realized in both strategies and will have little to no effect on the  $\Delta C$ . In the model for depression, cost-control mechanisms actually made the result worse by eliminating most of the cost of the cheaper drug.

Cost-containment strategies may also have another effect. Many individuals may choose not to refill a prescription and save themselves the \$7.05 co-payment (on average). If a patient does not continue on therapeutically necessary pharmaceutical regimen, bad health outcomes may arise. Proper compliance is critical to the effectiveness of an intervention; non-compliers

require more medical services like physician visits and hospitalizations and decrease the quality of life for the patient. While the effect of co-payments may reduce the numerator, poorer health may require greater healthcare utilization and subsequently counter that reduction by decreasing the denominator. The goal for a managed care plan is to set a co-payment that is large enough to stem over-utilization without being so large that it block access to necessary care.

Large deductibles and co-payments may also have another effect: driving individuals out of the plan. This presents a very interesting paradox. While a large co-payment may help preventative therapies look more cost-effective to MCOs, large disenrollment rates make a managed care entity's time horizon shorter. Though discussed in more detail below, the effect of a short time horizon makes preventative technologies look rather cost-ineffective. Again, the managed care plan must also take into consideration these additional factors when setting cost sharing levels.

### **NON-REIMBURSABLE COSTS**

As opposed to the societal view that incorporates all expenditures no matter whom they affect, a managed care organization needs to care less about costs (or cost-savings) that are not seen in their bottom line. In the four examples presented here, these costs included nursing homes, home care, and productivity costs. In the first two cases, these costs are borne by patients who must pay for them out-of-pocket. As for productivity (or friction) losses, the payment is more diffuse, affecting society primarily through employment costs (i.e. hiring temporary help while the patient is sick or getting a new person up to speed if the worker dies).

In every relevant instance, *the net effect of excluding non-reimbursable costs was to worsen the cost-effectiveness ratio from a managed care perspective.* A clinically superior health technology will yield benefits that are measured in a C/E ratio. The quality of life benefits increase the denominator, while the reduced health utilization lowers the numerator. But if the reduced health utilization is for services not reimbursed by the MCO (like nursing homes), then these benefits are ignored and the numerator remains comparatively large. The end result is to increase the cost-effectiveness ratio, making the technology appear less valuable.

This discrepancy between the societal and managed care perspectives creates “collective good” externalities. Although the rewards of a health technology may be warranted from a

**Figure 6.1: Non-Reimbursable Costs and Market Externalities**

	Costs <u>Incurred</u>	Costs <u>Saved</u>	<u>Net</u>
HMO	\$100/person	\$70/person	-\$30/person
Employer	“	\$50/person	-\$50/person
Patient	“	\$20/person	-\$80/person
Society	\$100/person	\$140/person	+\$40/person

collective, societal perspective, no single group benefits sufficiently to invest in it. Hypothetically, suppose a new vaccine has been developed to cure the common cold, costing \$100 per person. The vaccine will reduce HMO's expenditures by \$70 per enrollee by eliminating many doctor visits.

It will save employers \$50 per worker by reducing sick days and maintaining productivity. It will save patients \$20 each by eliminating the need to buy so many over-the-counter medications. Figure 6.1 demonstrates the problem. No single constituency will individually gain back their investment so no one has the economic incentive to purchase the vaccine. What has been shown in the aggregate to be a beneficial technology will go unused because of the fragmented marketplace.\*

### **TIME HORIZONS**

While the individual parameters affect the final cost/QALY ratio in different ways, *the time horizon issues tend to dominate the cumulative effect, causing a preventative health intervention to look much less cost-effective.* The numbers are dramatic. Reviewing the C/E ratios in the year it takes for half of a given population to statistically disenroll from a managed care plan (seven years), the values are orders of magnitude higher than those calculated from a societal perspective. Not only did the MCO incur the costs of treatment with realizing the economic benefits, but the pharmaceutical therapies did not have enough time to create significantly better health. In other words, using a smaller time horizon causes both the numerator to become larger and the denominator to become smaller. In the depression and heart failure analyses, the cost/QALY ratios increased from \$9 to \$2300/QALY and from \$105 to

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\* To remedy this problem, economics recommend that the government subsidize the cost of this treatment. In this case, the government could contribute \$30 and effectively reduce the price of the vaccine to the point where the HMO would break even. Even with the subsidy, society would still stand to gain \$10 (Pindyck and Rubinfeld, 1995). However, there are many downsides to this solution, including administrative and political factors.

\$50,000/QALY, respectively. In the osteoporosis example, the same time horizon changed what was clearly a cost-saving technology to one that is cost-inducing.

The four technologies presented in this paper affect the time aspects of resource utilization in different ways. The heart failure model shows the results of a clinically superior, but more expensive technology whose benefits increase gradually over the life of the patient. Consequently, since the added drug costs are consistent over time, the cost/QALY ratio from a managed care perspective improves as its time horizon lengthens. The depression and osteoporosis analyses demonstrate technologies that require a significant initial investment, but then yield consistently lower costs through enhanced health outcomes. The depression model generated benefits gradually, while health improvement in the osteoporosis model was immediate and constant. Here again, the cost-effectiveness ratio from a managed care perspective gets progressively better in the later years as that investment is recouped. Lastly, the Alzheimer's Disease study presented the cost/QALY value for a technology that produced a health benefit early and subsequently deteriorated to the equivalent of no treatment. In this instance, the most cost-effective time horizon was in the first year and worsened as the disease progressed.

The examples presented represent an entire class of therapies where up-front costs and long-term benefits make the time horizon especially important. Pharmaceuticals and biotechnology products are particularly affected because of their capabilities to treat preventative or long term conditions, but immunizations and childhood vaccinations should also be included in this class. Typically, children are immunized before the age of five to prevent serious illness and hospitalizations that occur in their adult life. But using a seven- or ten-year time horizon, the immunization would not be cost-effective unless those children develop those afflictions before puberty. Accordingly, immunizations and vaccinations, the gold standard of cost-effective medicine, look downright expensive from a managed care viewpoint.

Understanding the conditions that affect disenrollment over a long period of time are complex. If patients would remain in a single plan, then there would be less discrepancies between the managed care and societal perspectives. But how can disenrollment and patient

turnover be reduced? The answer lies in the reasons for disenrollment: patient dissatisfaction and employment issues.

Health plans go through tremendous efforts to conduct patient satisfaction surveys. Recent findings indicate that much of an enrollee's impression of service is dependent on the primary care physician. Further, patients in managed care organizations indicate that overall cost and choice of physicians as their first and second most important criterion of a health plan (Allen, 1994).

In the US, individuals receive healthcare through their employment. Consequently, when a worker changes jobs, he or she may be required to switch health plans. Further, in an effort to reduce their employee benefit costs, companies are constantly re-negotiating health plan contracts, changing the managed care organizations that serve their workers. Although companies do negotiate on quality issues, these contracts are won and lost based upon premiums.

For these reasons, enrollment is directly related to costs. By keeping costs down, MCOs can keep both patients and employers pleased. To accomplish this, MCOs need to control their expenditures for expensive services. So, rather than putting additional restrictions on physician choice that will only increase the anger of enrollees, administrators will choose to manage the use of healthcare services and technology instead. Consequently, medical interventions that have high initial expenditures and long-term benefits (i.e., preventative therapies) may be denied access or passed over altogether. For instance, an MCO may choose to treat depressed patients episodically with TCAs rather than institute an (initially) expensive strategy of maintenance therapy with SSRIs. An HMO may opt not to give post-menopausal women a drug for osteoporosis in an effort to keep drug costs down.

If these efforts are successful in keeping premiums low, then patients should stay with the health plan longer. With the decrease in disenrollment, a managed care organization may want to reanalyze how long-term ailments are treated. But paradoxically, longer enrollments tend to favor the same preventative therapies that got rejected in order to maintain enrollment. Compared to episodic treatment, maintenance therapy for depression starts to save money after ten years. Osteoporosis patients start to save money after only five years. Thus, short term decisions may significantly effect long-term profitability.

## CROSSING PAYOR LINES/ MEDICARE HMOs

The effect of time horizons were examined through two parameters: 1) disenrollment rates and 2) patients entering other health plans (specifically, Medicare) at age 65. To properly address the latter issue, a discussion of Medicare HMOs is in order. The federal government has been encouraging many of its enrollees to join managed care entities in an effort to control costs. The percentage of the Medicare elderly in these programs has risen rapidly. While only 9% (more than 3 million) of Medicare patients were enrolled in managed care programs in 1994, they represented nearly one fourth of the total growth in HMOs (De Lew, 1995). Many managed care organizations are actively recruiting healthy elderly individuals into their plans. These groups feel that they can manage and provide geriatric health services for less money than the negotiated rates set by the government (typically 95% of the average current rate for fee-for-service Medicare enrollees).

Medicare HMOs may curtail the exodus of patients from HMOs after retirement age. As more and more HMOs offer Medicare health plans, an individual could stay within the same MCO for his or her entire lifetime. While the details of the plan may change, most patients prefer to stay with their primary care physician and would be reluctant to leave the plan. These factors would detract from the conclusion that managed care plans do not have economic incentives to provide long-term care; *while they do not affect other parameters, Medicare HMOs may all but eliminate elderly disenrollment.*

But not all HMOs have an elder-care plan, and those that don't can adjust cost-effective analyses to reflect this. Unlike disenrollment rates that are only statistical guesses of patient departure, an HMO without such a plan automatically knows it will not have responsibility for the care of an enrollee after age 65. Depending on what age a particular medical treatment will commence, this fact could lead to dramatic results. Therapies for younger ailments like childhood immunizations should be unaffected. In the examples presented here, treatments for mid-life afflictions like depression and heart failure showed modest corrections, while more geriatric conditions like osteoporosis model yielded a five-fold difference in cost-effectiveness ratios.

## EXTERNALITIES

The use of cost-effectiveness analyses can be instrumental in informing resource allocation decisions, but they are by no means the final word. Given the fact that the shortened time horizon and non-reimbursable costs lead MCOs to undervalue healthcare technologies, are there other inputs into the decision-making process that would temper these tendencies not to cover preventative therapies?

## Marketing and Competition

When making decisions about adding a drug to the formulary, many competitive and marketing issues must be reviewed. In general, a plan does not want to be too generous nor too stingy with their health benefits package when compared with its competitors. If they are committed to keeping health premiums low, then MCOs have an economic disincentive to expanding their benefits. A plan that is the first to reimburse for a new oncology therapy, for example, may attract sick (and very expensive) cancer patients. Unless the plan raises their insurance premiums to compensate, they will lose money. (In reality, very few patients choose a health plan based on access to one specific drug or technology. Instead, the choice, even among sicker individuals, is associated with personal choice and finances. Primarily, sicker patients choose a plan based on physician choice: either to stay with their primary care physician or to maintain the right to choose their doctor. Secondly, a patient that knows he or she is a heavy user of services will review the plan's requirements for patient contributions in the form of any required co-payments, co-insurance, or spending caps (Steinberg, 1996). )

On the other hand, a plan should not be overly strict. Lagging behind your competition in providing access to health technologies also has its dangers. Recently, some HMOs have been sued for malpractice for not providing commonly accepted treatments (Lopez, 1991).

Rather than deny coverage for expensive technologies, managed care plans often approve it for reimbursement but seriously limit access to it. For instance, while HMOs do cover MRIs, the number of patients who receive them is quite small. Consequently, coverage lists of technology do not adequately reflect actual use or policies. *Since attracting patients has little to do with actual coverage decision, marketing has little effect on the conclusions above.*

## MACRO- AND MICRO-ECONOMIC ARGUMENTS

A patient that leaves one health care plan will inevitably enroll with another. The managed care organizations might lose one patient today and then get two others to join up tomorrow. Why then couldn't all HMOs agree to invest in long-term therapies?

MCOs don't want to invest the money in long-term treatments when the patient will leave before they reap the financial benefit from the improved health. But an agreement with every HMO, PPO, and fee-for-service plan is untenable. First of all, the coordination involved to establish such an agreement is overwhelming. Getting everyone to agree and keeping the list of technologies up to date would be monumental administrative task.

More importantly, any arrangement will probably not hold because there is an economic incentive to ignore the agreement. Consider the extreme case where every HMO but one agrees to the contract for providing drug treatments to prevent a set of illnesses. The one dissenting health plan could now invest the money it did not spend on preventative therapies on reducing premiums, thereby attracting more patients. These patients will be healthier (and consequently use less costly services), since they come predominantly from plans that are parties to the agreement. The outlier has now "cheated" the system and gained a competitive advantage. On the other hand, any enrollee that leaves the one plan and goes to any of the others has not received any preventative treatment and will subsequently cost the new plan more money to treat. The plans that have honored the agreement are now at a competitive disadvantage. Consequently, there is a market inducement to break any agreement.

## Chapter 7: Policy Options

*or*

**What can be done to resolve this conflict?**

If managed care organizations do not have the financial incentive to cover new, socially-beneficial preventative therapies, then public policies may need to be enacted to help resolve this conflict. This chapter will investigate strategies that will help bring the managed care and societal perspectives (and the subsequent health technology coverage decisions) closer together. Specifically, this section will discuss: 1) the existing market mechanism of malpractice legislation; 2) information dissemination strategies to educate patients and employers; 3) the role of the government healthcare programs to lead the industry by example; and 4) the use of retrospective risk.

### **POLICY OPTION 1: Let the Market Work**

The first (and possibly easiest) response to this conflict is to simply do nothing, letting the market take care of itself. In fairness, there is not yet evidence that managed care organizations are not providing these socially-valuable technologies. Simply put, the analyses of the previous chapters may only be useful as a theoretical exercise and may not reflect actual practices. Managed care organizations do have much more incentive than fee-for-service plans in maintaining their enrollees' health. A prepaid premium entices health plan administrators to invest in therapies that keep patients from consuming expensive medicine; fee-for-service groups only get paid when people are sick. Immunizations, for instance, are standard practice for all managed care associations, and no HMO or PPO will refuse to cover their costs. In fact, Medicaid data indicates that more children are being immunized in prepaid plans than under fee-for-service (Wisconsin Department of Health and Social Services, 1995).

But as mentioned earlier, simply approving reimbursement does not necessarily mean that the technology will be adopted. Coverage decisions do not accurately reflect actual reimbursement. Though they are widely available, many children in this country do not get immunized. The same Medicaid study indicated that even in managed care plans, only one in four eligible children were being full immunized (Wisconsin Department of Health and Social

Services, 1995). Even if prepaid plans offer greater motives than fee-for-service medicine to invest in preventative therapies, this paper has shown that these incentives are imperfect. As presented here, ACE inhibitors and maintenance therapy for depression are not being universally adopted. To accurately determine whether technology is being adopted (and promoted), one would need to pour through actual reimbursement claims data. (While this is an interesting and necessary next step, it is beyond the scope of this analysis.) In other words, managed care as it is practiced today may be a good first step, but it does not get us all the way to our goal of allocating resources optimally, as defined by the societal perspective. Conflicts still exist in aligning corporate and societal priorities for health care.

But there are a number of mechanisms within the marketplace now that may correct this problem. If an HMO does not cover a necessary health program or intervention, it can be sued for malpractice. Litigation may be a very powerful weapon in keeping formularies and reimbursement lists up to date. Currently there is considerable debate about coverage for new, expensive technologies. To give just one example, Health Net, an HMO in California, was sued for not reimbursing an enrollee's bone marrow treatment to fight metastatic breast cancer, claiming that the procedure was experimental and therefore not reimbursable. The HMO lost the decision from an independent arbitration panel (Larson, TIME, 1996). Other plaintiff-patients have successfully sued HMOs for denying "unnecessary" medical tests and referrals to specialists which led to the advancement of diseases that should have been caught earlier (e.g. Ching vs. Gaines et al. (Moore, 1996)).

Patient advocacy groups are beginning to form in opposition of managed care (e.g. Consumer for Quality of Care). If preventative therapies truly are being overlooked, these groups could bring malpractice suits against the health plans. In fact, only the threat of a lawsuit may be sufficient to rectify the problem; HMOs do not want to incur the expensive and negative publicity of a public trial.

While patient advocacy groups traditionally do not have money to fight well-endowed managed care corporations, they will have a very powerful (and deep-pocketed) ally in these cases: drug and device manufacturers. Currently, the producers of these products are the real losers; they can not find a market for what has been shown to be a socially beneficial technology. Industry would eagerly sponsor any patient-driven attempt to mandate that their product be

offered to all subscribers. Glaxo-Wellcome, for example, would reap untold fortunes from the increased sale of its new drug for osteoporosis far exceeding any immediate court costs.

Unfortunately, lawsuits may not solve the problem entirely. Relief through legal channels is impeded by a number of factors. First, if health coverage is provided through a self-insured employer, a beneficiary can only sue the plan under the ERISA (Employee Retirement Income Security Act of 1974) statute, which limits many of the patient's rights (Brennan, 1996). Secondly, HMO contracts often require that disputes be settled through arbitration. These resolutions often contain the stipulation that financial settlements and other specifics of the case be kept confidential. Hence, patients, managed care organizations, and the media are less aware of these lawsuits and this market “fix” occurs much more slowly.

Third, and most importantly, these lawsuits require that patients are informed of treatment options that were not given. Physicians on a capitated rate are looking for ways to treat a patient inexpensively and are instructed to follow the company’s guidelines for treatment. Discussing other therapies that are very expensive or not covered by the health plan is not legally required and only opens the doctor to scrutiny. Without a medical degree, it is very difficult for patients to know if they are being treated sub-optimally. In a managed care setting, to get a second opinion, a patient is required to see another of the plan's physicians who is bound by the same financial and contractual agreements. Patients need this kind of information just to know if they have a legitimate claim against the HMO. Adequately informing the ultimate consumers of health care (i.e., employers and patients) will be the focus of the next policy option.

## POLICY OPTION 2: Information Dissemination Strategies

One of the basic foundations of classical economics is the assumption of informed buyers and sellers. The discrepancies between the managed care and societal perspectives may be growing simply because valuable information is not being considered by the interested constituencies. With more information, consumers and insurers could better choose health plans and medical technologies that satisfy their long-term needs.

Managed care organizations may be able to not cover long-term preventative therapies because employers and patients do not know enough to ask about them. The current philosophy of cost-cutting and competitiveness may ignore future health; too much focus on short term

finances may detract from looking at long-term cost-saving strategies. While these trends are valid for businesses and individuals as well, the time horizons of all these parties may differ. Typically, employers are footing the bill for most of their worker's premiums and may be very interested in future savings longer than seven or thirteen years. This financial responsibility carries for the entire employment of the patient, and often through death when retirement benefits and pension plans are included. Similarly, patients also need to balance current expenditures with long-term needs.

Consumers should be aware of what treatments are (and especially are not) covered. They should know when it is appropriate to receive treatment. And they should have data about how often a managed care plan actually approves treatment. The latter is a better indication than a coverage list about whether an MCO really has incorporated the technology into its practice. Without this, employers and patients are left to choose a health plan based solely on price.

To date, certain steps are being taken to provide this information. Recognizing this need, the private, non-profit National Committee for Quality Assurance (NCQA) has undertaken the role of auditing managed care plans to help give consumers better information about quality. These endeavors have the support of HMOs and other health plans who would like to compete on other dimensions besides just cost. The NCQA, in cooperation with employers, federal officials, and private health organizations, has developed a set of performance measures called HEDIS (Health Plan Employer Data Information Set) that value the quality of managed care organizations.

This quantitative rating includes measures of disenrollment rates, patient satisfaction, and quality of care (Table 7.1). The latter category involves measurements for preventative medicine: childhood immunization, cholesterol screening, mammography screening, cervical cancer screening (NCQA Website, April 1996). Starting in the fall of 1996, the NCQA will be publishing "report cards" that will compare almost all of the managed care plans in the nation.

So, is the problem solved? Not entirely. While the report cards will go a long way to educating employers and individual subscribers, there still are shortcomings to this system. First, the quality of care category only measures a subset of conditions as seen in Table 7.1. In order to appear concerned about quality, a managed care organization could concentrate on only that subset. Like a student that only studies what will be on the exam, the MCO would ignore other

**Table 7.1: HEDIS version 2.5 / Major Areas of Health Plan Performance Measured by NCQA**

Quality of Care

**Preventative Medicine**

- Childhood immunizations
- Cholesterol screening
- Mammography screening
- Cervical cancer screening

**Prenatal Care**

- Low birthweight
- Prenatal care in the 1st trimester

**Acute and Chronic Disease**

- Asthma Inpatient Admission Rate
- Diabetic retinal exam

**Mental Health**

Member Access

% of Members with a Plan Visit in Last 3 Years

Num., % of Physicians Accepting New Patients

Member Satisfaction

Membership and Utilization

Enrollment/Disenrollment Rates

High Occurrence/ High Cost Procedures

Frequency and avg. cost of treating 9 conditions

Frequency of 7 selected procedures

Inpatient Utilization

Maternity

Total Deliveries, vaginal and Cesarean Section

Number of well newborns

Mental Health and Chemical Dependency

Type of treatment, readmission rate

Outpatient Drug Utilization

Avg. cost and num. of prescriptions per member

Finance

Premiums

Liquidity

Solvency/Efficiency

Compliance w/ Statutory Requirements

Descriptive Information

Provider

Recredentialing

Utilization Review Activities

Health Plan Management and Activities

Source: NCQA, 1996

aspects of care. Secondly, the data on these prepaid plans are collected by the HMOs and PPOs themselves; NCQA only audits the information. This may bring into question the validity of the results. Finally, the NCQA only gives information only on current practices. Consumers still do not know what could have been offered instead. While the report cards will be beneficial in distinguishing quality of care from amongst the plans, it will not indicate therapies that are ignored by all of them. Since MCOs are instrumental in developing and updating the NCQA criteria, they will try to prevent incorporating categories that make themselves look bad. The technologies that are in conflict between the societal and managed care perspectives are precisely the ones that will never make the HEDIS list.

### POLICY OPTION 3: Federal and State Programs

If managed care organizations are acting in their own best interests, who represents society? Theoretically, that role is best served by the government. Further, the government should also step in when economic markets fail; in this case correct the vast information asymmetries. What then can the government do to help resource allocation toward the societal viewpoint?

First of all, the government is a very large consumer and provider of health care. Not only does the federal and state governments contribute financing for the Medicare and Medicaid programs, but they must also contract out coverage to federal employees. By mandating that all federal formulary and reimbursement decisions need to be based upon the societal perspective, the government could set the example that industry should follow. While not a legislative requirement, federal approval of a new therapy would lead to public acceptance and create pressure on privately-run health organizations to also cover it.

Furthermore, for the government to accurately determine what technologies to reimburse, the Health Care Financing Administration (HCFA) must first perform an economic analysis. These analyses could then be published in the public domain. Rather than sponsor their own time- and resource-consuming studies, individual MCOs could simply defer to the government's results. In this way, HCFA would help standardize and establish the science of economic evaluations.

With the growth of Medicare and Medicaid HMOs, HCFA is in a position to tie federal reimbursement to specific coverage decisions. If, for instance, a societal perspective indicates that a vaccine for chicken pox is cost-effective in the long run, HCFA could require that all managed care companies offer the vaccine to be eligible to contract for federal enrollees. Submitted claims data could verify if children were actually getting the vaccine.

But the essential assumption that the Health Care Financing Administration and state Medicaid programs represent society is tenuous at best. The Medicare and Medicaid programs have disenrollment rates and cost-cutting programs just as unique as managed care organizations. Since Medicaid is based on financial need, many individuals go on and off state support every month. In the age of government downsizing, it may be unrealistic to think that these programs

do not have their own individual agendas that are very different from the societal perspective. Elected officials feel the need to show improvements in these programs in time for their next election. Politics make it difficult to invest large dollars today for financial and health return that won't occur for two more presidential administrations.

#### POLICY OPTION 5: Retrospective Risk

“Sec 1112. Enrollment

c) Additional Periods of Authorized Changes in Enrollment

2) Disenrollment for Cause

B) Additional remedies -- In the case of an individual who changes enrollment from a plan for good cause due to a pattern of underservice under a plan, the Secretary [of Health and Human Services] may provide rules under which the carrier providing the standard health plan is liable, to the subsequent standard healthplan in which the individual is enrolled, for excess costs (as identified in accordance with such rules) during the period for which it may be reasonably anticipated that the individual would (but for such cause) have continued enrollment with the original standard health plan.”

Senate Bill 2357,  
103rd Congress, 2d Session

While this bill was subsequently defeated, it does demonstrate another policy option: allocating financial risk retrospectively. In this strategy, no formal, legislative mandates are need to control which services will be covered. Instead, one health plan could ‘sue’ another plan for services that should have been given.

For instance, suppose an enrollee enters an HMO clinic complaining of migraines. Claiming that it was unnecessary and redundant, the HMO refuses to administer a CT scan or MRI and recommends a therapy of aspirin and blood thinners. The patient, unsatisfied with the diagnosis and course of treatment, gets a second opinion from a doctor within a second health plan who confirms his beliefs that the problem was much more serious. Wanting the best and quickest remedy, the patient changes plans and is treated by the new doctor. Under this policy, the second HMO can sue the first for all the subsequent healthcare costs in treating this patient.

The option is similar to the malpractice litigation presented above, with one major exception: the litigating parties are informed, sophisticated health plans. The problems

concerning uneducated consumers is no longer an issue. These insurer groups know better than anyone what is appropriate, cost-effective medicine. They understand how managed care organizations choose technologies based upon their unique perspective.

The repercussions of such a policy are extremely interesting. Aggressive health plans could actively recruit very sick patients, prove these patients were not getting adequate treatment in their old plan, and then pass the costs of their subsequent therapies on to the former insurer. In essence, these plans are garnishing the premiums of the patients without spending any money on them. While these new lawsuits will probably not be backed by the drug and device industry like in patient-initiated malpractice suits, many of the managed care plans themselves have enough financial reserves to begin litigation.

Without this policy, an HMO without a Medicare option may not offer an expensive osteoporosis-preventing drug, knowing that they will never realize the health and cost benefits. However, with this retrospective-risk allocation, another HMO with such an elder-care plan could try to entice the relevant sub-population of enrollees to switch and then sue former for “underservice”. By showing a judge or jury that this is appropriate and necessary preventative medicine (possibly in terms of cost/QALY), the second HMO would be allowed to treat these patients cost-free and collect their premiums as pure profit.

Forseeably, “second opinion” shops could be created by aggressive health plans to allow patients to test the diagnoses of their own HMO’s doctors. The increased, cut-throat nature of the ensuing competition will cause insurers to be much more cautious in implementing cost-reducing programs and prohibiting access to medical technology. On the other hand, it will undermine the doctor-patient relationship, possibly causing psychological harm and potentially slowing the patient's recovery.

Are any of these policy options the absolute correct answer? Probably not. Each has benefits and drawbacks that affect the healthcare market in unique ways. But these options do not have to be considered individually, nor are they the only options available. Congress can pass legislative mandates that require managed care organizations to use a societal perspective or to offer coverage on specific therapies. But these heavy-handed remedies will be unpopular

politically and difficult to administer. For instance, since cost-effective analyses are only one input into the overall coverage decisions, how can the government know whether the societal perspective was used or not? Secondly, in this age of government down-sizing and reducing its influence in private markets, mandating each specific technology that it deems worthy of coverage based on a societal viewpoint is unrealistic. Not only will managed care companies adamantly protest the interference in their business practices, but manufacturers will object to the government recommending a competitor over their own products (e.g. ACE inhibitors over  $\beta$ -blockers for hypertension). Moreover, new technologies are being developed all the time; keeping up-to-date with governmental coverage mandates may be difficult (if not impossible) to administer. Therefore, these kinds of direct, congressional mandates are not a viable option.

## Conclusions

*or*

### What should be done from here?

The crux of this thesis shows that long-term, preventative technology, when viewed from a managed care perspective, are in danger of being undervalued. Consequently, managed care organizations may choose to not cover these treatments for reimbursement. This indicates that an HMO and society in general disagree on how to allocate resources. Policy options were presented to help re-align these incentives and bring these two viewpoints closer.

### LIMITATIONS

What's next? First, the reader should understand the limitations of this argument. Most importantly, this thesis is a theoretical investigation into how society and managed care views healthcare technologies. "Society" in this paper was assumed to be a theoretical maximum of coverage for a given area and population. But in the real world, properly defining "society" is much more difficult and involves moral choices that are not included in CEAs. For instance, should society include illegal immigrants who are not contributing money to the social pool of funds? Since Medicaid programs are state-run, should each state allow for a different "societal" viewpoint?

From a managed care environment, cost-effective analyses are only one input into the decisions to adopt and reimburse for new drugs, devices, and medical equipment. Even though the results from CEAs taken from this particular viewpoint may indicate that an HMO or PPO would not choose to cover the therapy, the actual decision may be quite different.

Furthermore, only four technologies were re-analyzed from a managed care perspective. Each of these four examples involved a long-term, preventative therapy, many of which containing costs that are not reimbursed by HMOs. These four were specifically chosen because they would yield interesting results. Since the change in the time horizons for managed care was the biggest factor in the difference between C/E ratios, many other drugs and devices that provide faster health benefits may not react in the same manner. The extent of this effect to other

kinds of therapies (e.g. home vs. hospital dialysis, laser surgery to correct near-sightedness) still needs to be evaluated.

### **NEED FOR FURTHER RESEARCH**

While this thesis has provided a theoretical background, it has failed to determine whether the unique environment of managed care organizations is really affecting reimbursement decisions. One method is to correlate the results of CEAs taken from a managed care perspective with coverage lists. By characterizing specific therapies and the cost/QALY ratio, researchers could determine which kinds of technologies are most susceptible to be undervalued by managed care (e.g. long-term, preventative therapies).

Unfortunately, coverage lists do not reflect actual usage. In many instances, an HMO will “officially” sanction the use of a technology, but severely limit access to it. Therefore, a better method for investigating actual utilization would be to analyze claims data. For instance, state auditors are currently reviewing their Medicaid HMOs to determine how many eligible children are actually getting immunized (Wisconsin Department of Health and Social Services, 1995). In this way, researchers could determine if a technology is being adopted nation-wide or only through individual plans or specific doctors.

Alternatively, researchers could investigate the utilization of healthcare technologies from a societal vs. managed care perspective by looking at single-payor countries like Australia and Canada. Since the Australian government has a national formulary list, it provides the best-known example of healthcare coverage decisions from a societal perspective. Is maintenance therapy for depression being adopted in Australia? Will a drug for osteoporosis or Alzheimer’s Disease have a larger market share in these countries? These answers will help to inform whether the theoretical arguments in this thesis have real-world implications. Once the validity of this thesis has been established, more in-depth analysis can be given to policy options to help remedy the conflict between the societal and managed care perspectives.

## References

- Allen HM, Darling H, McNeil DN, and Bastien F. "The Employee Health Care Value Survey: Round One," *Health Affairs* 1994; Fall: 25-41.
- Angst J. "The Epidemiology of Depressions," *Psychopharmacology* 1992; 106 (Suppl.): 71-74.
- Bradley C. "Quality Adjustments in the Medical Literature," *Pharmacotherapy* 1995; Suppl 15 (6): 58S-64S.
- Brennan RF. "Protect Yourself Against Malpractice by Your HMO Doctor," Brennan Website (<http://directnet.com/~rbrennan/hmoartcl.html>), May, 1996.
- Brodie DC and Smith WE. "Constructing a Conceptual Model of Drug Utilization Review," *Hospitals* 1976; 50: 143-150.
- Bucey L. Hospital Pharmacy, Brigham and Women's Hospital. Personal Communication, May 13, 1996.
- Captopril Multicenter Research Group. "A Placebo-controlled Trial of Captopril in Refractory Chronic Congestive Heart Failure," *Journal of the American College of Cardiology* 1983; 63: 755-763.
- Cohn JN, Jonson G, Ziesche S, et al. "A Comparison of Enalapril with Hydralazine-isorbide Dinitrate in the Treatment of Chronic Congestive Heart Failure," *New England Journal of Medicine* 1991; 325: 303-310.
- Consensus Development Conference. "Diagnosis, Prophylaxis, and Treatment of Osteoporosis," *American Journal of Medicine* 1993; 94: 646-650.
- Daly PA. "Office Management of Osteoporosis: A Guide for the Primary Care Provider," *Comprehensive Therapy* 1995; 21 (10): 565-574.
- De Lew. "The First 30 Years of Medicare and Medicaid," *Journal of the American Medical Association* 1995; 274 (3): 262-267.
- Detsky et al. "Prognosis, Survival, and the Expenditure of Hospital Resources for Patients in Intensive Care Unit," *The New England Journal of Medicine* 1981; 305: 667-672.
- Drummond MF, Stoddart GL, and Torrance GW. *Methods for the Economic Evaluation of Health Care Programmes* (Oxford, England, Oxford University Press), 1987

- Eaton WW, Dramer M, Anthony JC, et al. "The Incidence of Specific DIS/DSM-III mental Disorders: Data from the National Institutes of Mental Health Epidemiologic Catchment Area Program," *Acta Psychiatrica Scandinavica* 1989; 79:163-176.
- Ernst RL and Hay JW. "The US Economic and Social Cost of Alzheimer's Disease Revisited," *American Journal of Public Health* 1994;84(8):1261-1264.
- Feegel K "Update on Prior Authorization," *Medicaid Pharmacy Bulletin* 1992, 6 (4): 35-43.
- Fraser, I "Managed Care: Where Will Your Hospital Fit In?" *Hospitals* 1993; April 5: 18-24.
- Friedman E. "The Alphabet Soup of Managed Care," *Hospitals* 1993; April 5: 18-23.
- Gibson JM. "National Health Expenditures, 1978," *Health Care Financing Review* 1979; Summer: 1-36.
- Grabowski H. "Use of Cost-Effectiveness Analysis by Pharmacy Benefit Management Companies," presentation at *Cost-Effectiveness in Decisionmaking Conference*, Duke University Nov 30-Dec 1, 1995.
- Greenberg PE, Stiglin LE, Frankelstein SN, and Berndt ER. "The Economic Burden of Depression in 1990," *Journal of Clinical Psychiatry* 1993; 54: 405-418.
- Harrington C, Newcomer RJ, and Preston S. "A Comparison of S/HMO Disenrollees and Continuing Members," *Inquiry* 1993; 30: 429-440.
- Hatziandreu EJ, Brown RE, Revicki DA et al. "Cost Utility of Maintenance Treatment of Recurrent Depression with Sertraline Versus Episodic Treatment with Dothiepin," *Pharmacoeconomics* 1994; 5 (3): 249-264.
- Jonsson B, Christiansen C, Johnell O, and Hedbrandt J. "Cost-effectiveness of Fracture Prevention in Established Osteoporosis," *Osteoporosis International* 1995; 5: 136-142.
- Kannel WB. "Epidemiology and Prevention of Cardiac Failure: Framingham Study Insights," *European Heart Journal* 1987; 8 (Suppl F): 23-29.
- Kannel WB, Plehn JF, and Cupples LA. "Cardiac Failure and Sudden Death in the Framingham Study," *American Heart Journal* 1988; 115: 869-875.
- Katon W, Vonkorff MM, Lin E, et al. "Adequacy and Duration of Antidepressant Treatment in Primary Care," *Medical Care* 1992; 30: 67-76.
- Koopmanscap MA and Van Ineveld BM. "Towards a New Approach for Estimating Indirect Costs of Disease," *Social Science and Medicine* 1992; 34: 1005-1010.

Kozma CM, Shulz RM, Dickson WM, et al. "Economic Impact of Cost Containment Strategies in Third Party Programmes in the US (Part II)," *PharmacoEconomics* 1993; 4 (3): 187-202.

Larson E. "The Soul of an HMO," *TIME Magazine* Jan 22 1996; 147(4).

Levit KR et al. "National Health Expenditures, 1990," *Health Care Financing Review* 1991; Fall: 29-54.

Lopez L. "Medical Technology Assessment: Who Decides?" *HMO Magazine* 1991; March/April: 20-32.

Lubeck DP, Mazonson PD, and Bowe T. "Potential Effect of Tacrine on Expenditures for Alzheimer's Disease," *Medical Interface* 1994;Oct:130-138.

Malcom LA, Kawachi I, Jackson R, et al. "Is the Pharmacologic Treatment of Mild to Moderate Hypertension Cost Effective in Stroke Prevention?" *New Zealand Medical Journal* 1988; 101: 167-171.

*Managed Care Digest Series/ HMO-PPO Digest* (Kansas City, MO, Hoechst Marion Roussel, Inc.), 1995.

McDonough J and Neff A. "Audit Offers New Insights into Rx Substitution," *Drug Topics* 1988; 132 (3): 16-18.

Melton LJ, Kan Sh, Tyre MA, et al. "Epidemiology of Vertebral Fractures in Women," *American Journal of Epidemiology* 1989; 129: 1000-1011.

Monolia TA, Cutler JA, Furberg CD, et al. "Trends in Pharmacologic Management of Hypertension in the United States," *Archives of Internal Medicine* 1995; 155: 829-837.

Moore DL. "Ethics pinched by the system, lawyer says," *USA Today* Jan 21 1996; D1.

Nardi KM. "Controlling Costs with Prior Authorization," *Medicaid Pharmacy Bulletin* 1990; 4 (3): 28-31.

National Committee for Quality Assurance. *Hedis/Report Cards*, NCQA Website (<http://www.ncqa.org>), April 1996.

National High Blood Pressure Education Program. "The Fifth Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure," *Archives of Internal Medicine* 1993; 153: 154-183.

National Institutes of Mental Health/ National Institutes of Health (NIMH/NIH) Consensus Development Conference Statement. "Mood Disorders: Pharmacological Prevention of Recurrence," *American Journal of Psychiatry* 1985; 142: 4.

Newhouse JP. "An Iconoclastic View of Health Cost Containment," *Health Affairs* 1993; Suppl: 152-172.

Pindyck RS and Rubinfeld DL *Microeconomics*, Third Edition (Prentice Hall, Englewood Cliffs, New Jersey), 1995.

Potter WZ, Rudorfer MV, and Manji H. "The Pharmacologic Treatment of Depression," *New England Journal of Medicine* 1991; 325: 633-642.

Reeder CE, Lingle EW, Schulz RM, et al. "Economic Impact of Cost-Containment Strategies in Third Party Programmes in the US (Part I)," *PharmacoEconomics* 1993; 4 (2): 92-103.

Rice DP, Fox PJ, Max W, et al. "The Economic Burden of Alzheimer's Disease Care," *Health Affairs* 1993; Summer: 164-176.

Saklad S. "Pharmacoeconomic Issues in the Treatment Depression," *Pharmacotherapy* 1995; Suppl 15 (6): 76S-83S.

Schondelmeyer SW. *Pharmacy Compensation and Reimbursement, APHA Pharmacy Commission on Third Party Programs - Final Report* (Washington, American Pharmaceutical Association), 1986.

Schutte HE. "Social and economic impacts of osteoporosis. A review of the literature," *European Journal of Radiology* 1995; 20: 165-169.

SOLVD-investigators. "Effect of Enalapril on Survival in Patients with Reduced Left Ventricular Ejection Fractions and Congestive Heart Failure," *New England Journal of Medicine* 1991; 325: 315-321.

Song P, Freemantle N, Sheldon TA et al. "Selective Serotonin Reuptake Inhibitors: Meta-Analysis of Efficacy and Acceptability," *British Medical Journal* 1993; 306: 683-687.

Stason WB. "Cost and Quality Trade-offs in the Treatment of Hypertension," *Hypertension* 1989; 13 (Suppl 1): I145-I148.

Steinberg R. Director of Managed Care, Department of Psychiatry, Cambridge Hospital: Personal Communication; April 20, 1996.

The White House Domestic Policy Council. *The President's Report to the American People: The Official Text of the Health Security Act* (Simon and Schuster, New York, 1993).

Thompson C and Thompson CM. "The Prescription of Anti-depressants in General Practice I: Critical Review," *Human Pharmacology* 1989; 4: 91-102.

US Congress Office of Technology Assessment, *Losing a Million Minds: Confronting the Tragedy of Alzheimer's Disease and Other Dementias* (Washington: U.S. Government Printing Office), 1987.

US Congress Office of Technology Assessment. *Evaluation of the Oregon Medicaid Proposal*, OTA-H-531 (Washington: U.S. Government Printing Office), 1992.

US Congress Office of Technology Assessment. *Identifying Health Technologies that Work: Searching for Evidence*, OTA-H-608 (Washington: US Government Printing Office), 1994.

US Department of Health and Human Services, Public Health Service, Office of Disease Prevention and Health Promotion. "Panel on Cost-Effectiveness in Health and Medicine," (Forthcoming, 1996).

US Office of Management and Budget. "OMB Documents and Statistics," OMB Website (<http://www.whitehouse.gov/WH/EOP/OMB/html/ombhome.html>), April 1996.

van Hout BA, Wielink G, Bonsel GJ, and Rutten FFH. "Effects of ACE Inhibitors on Heart Failure in the Netherlands: A Pharmacoeconomic Model," *Pharmacoeconomics* 1993; 3 (5): 387-397.

Weinstein M and Stason W. "Foundations of Cost-Effectiveness Analysis for Health and Medical Practice," *The New England Journal of Medicine* 296 (1977):716-721.

Weissman MM, Livingston BM, Leaf PJ, et al. "Affective Disorders," in Robins et al. (Eds.) *Psychiatric Disorders in America: the Epidemiologic Catchment Area Study* (Free Press, New York), 1991: 53-88.

West R. *Depression*. Office of Health Economics, London, 1992.

Wisconsin Department of Health and Social Services. *Wisconsin Medicaid Program - HMO/Fee-for-Service Comparison Report: 1993-1994* (Madison, Wisconsin, Bureau of Health Care Financing), 1995.