

## Pharmacoeconomics: Cost Effectiveness of Lipid Management

**C**holesterol lowering in patients with symptomatic coronary heart disease (CHD) is clearly beneficial. However, in our current cost-restrictive healthcare environment, interventions must be both clinically effective and cost effective.

"The data regarding the cost effectiveness of lipid lowering with simvastatin in post-MI or angina patients with elevated serum cholesterol is overwhelmingly convincing, even to a skeptic like me," J. Sanford Schwartz, MD, told listeners. Dr. Schwartz is Executive Director of the Leonard Davis Institute of Health Economics and Robert D. Eilers Professor of Medicine and Health Management & Economics at the School of Medicine and The Wharton School at the University of Pennsylvania.

Dr. Schwartz provided an overview of the current healthcare environment and its impact on physician adoption of medical innovations. He then reviewed the basic principles of health economics as applied to the allocation of scarce medical resources and the challenge of providing high-quality medical care in a cost-constrained environment. He concluded by applying these principles to estimate the cost effectiveness of cholesterol lowering therapy in patients with elevated cholesterol and symptomatic CHD.

### Causes of Healthcare Inflation

The rate of healthcare expenditure growth has been rising for more than 4 decades. Several factors have contributed to this upward spiral, including inefficiency, population growth, aging, defensive medicine, inflation, and increased service intensity.

"Approximately 25% of the increase in healthcare expenditures can be attrib-

uted to increased service intensity, which is a function of both technological innovation and patient demand," Dr. Schwartz told listeners. Technological advances have produced more effective drugs, devices, and procedures. Until recently, health insurance coverage grew both in terms of the number of people covered and the extent of coverage, stimulated in part by favorable tax treatment of medical insurance fringe benefits. This expanded coverage, coupled with more medically aware and assertive patients, increased patient demand for effective medical interventions.

The resulting increased intensity of care led to the rapid growth of managed care organizations (MCOs) in an attempt to control healthcare costs. MCO penetration, however, has been uneven in the United States with the most rapid growth occurring in the Western states, the upper Midwest, and scattered areas of the Northeast. To date, managed care has managed costs primarily by reducing provider payment and shifting care from hospitals to less expensive ambulatory sites. The resulting cost pressures on providers is stimulating service consolidation and integration, including hospital mergers and formation of integrated service provider organizations.

"Although managed care has the potential to improve quality of care and contain cost, currently much of what passes for managed care is really *managed cost*," Dr. Schwartz noted. At times, costs are constrained at the patient's expense, denying treatment that may be clinically warranted because of cost considerations. Improved cost-effectiveness assessment of medical interventions is needed to optimally allocate inherently limited medical resources while effec-

tively addressing legitimate concerns about quality of care.

While many current efforts focus on the process of care and on acute and preventive interventions that offer relatively rapid return on resources, increasing attention is being focused on outcomes of care and on chronic conditions.

### Cost Effectiveness: Principles and Applications

Traditionally, medical interventions were adopted once safety (acceptable side effects) and efficacy (net benefit under *ideal* conditions—such as those observed in rigorous clinical trials) were demonstrated. While these criteria are still necessary, they are no longer sufficient. In addition to safety and efficacy, medical interventions must also demonstrate effectiveness (net benefit under *routine* conditions—such as those observed in daily practice) and efficiency (benefit and value provided commensurate with risks and costs).

It is important for physicians to understand basic health economic principles because of the increased impact of economic considerations on healthcare delivery and policy. When interpreting the health economics information in literature, Dr. Schwartz said, it is important to consider the perspective from which a study is conducted. Many current studies are conducted from a narrow perspective, such as that of the payer, hospital, or MCO. Physicians, other medical professionals and providers, and policy makers have a responsibility to assess the impact of medical interventions from a broad societal perspective, incorporating all costs accrued and incurred. Cost-effectiveness analyses conducted from a narrower perspective are of limited value and may be misleading, as they fail to consider all relevant costs, risks, and benefits.

Appropriate interpretation of medical interventions also requires consideration of the types of costs and benefits assessed. Direct medical costs include hospital and physician services, home care and other healthcare services, and

acquisition and administration costs of drugs, devices, tests, and procedures. It also is important to factor in the costs of disease sequelae averted and adverse events caused by the intervention. Estimates of actual resources consumed and costs incurred or reimbursements received should be used when estimating direct medical costs, rather than charges that inappropriately inflate economic estimates. Indirect costs, which refer to productivity losses due to illness, and intangible costs such as pain and suffering are important but difficult to quantify. These are often excluded.

### Types of Analyses

Dr. Schwartz provided an overview of the types of economic analyses performed. Cost-identification and cost-minimization studies that assess only acquisition and administration costs are of limited value, useful only for rare situations where interventions are of equal benefit and risk. As an example, Dr. Schwartz noted that in order to make an informed prescribing decision for statin drugs, one must consider many other aspects in addition to the price of the drug. These include the differential effectiveness of available agents in lowering total and LDL cholesterol, and the clinical impact of resulting lipid reductions on morbidity, mortality, quality of life, and healthcare expenditures.

Occasionally, an intervention is both more effective and less expensive and thus clearly superior. “Unfortunately,” Dr. Schwartz noted, “the more common situation is for the more effective intervention also to be more expensive. In such cases, cost-effectiveness is a relative rather than absolute concept. Cost effectiveness is best determined by comparing the *incremental* costs and benefits of the more expensive but more effective intervention with the next best alternative. The relevant question is whether the additional benefit provided warrants the additional cost.”

An intervention does not have to be cost saving to be cost effective, observed Dr. Schwartz. An intervention that im-

proves survival and reduces morbidity may be cost effective even if the benefits provided are worth any additional costs incurred. While there are no explicit criteria, "we usually consider an intervention to be cost effective if its incremental cost-per-year-of-life-saved is less than \$60,000 or so," explained Dr. Schwartz.

Coronary heart disease is the nation's number one killer,<sup>1</sup> incurring tremendous cost burden in terms of hospitalizations for acute MI, unstable angina, and revascularization procedures (CABG and PTCA) and by virtue of resultant lost productivity and premature death. An intervention that improves outcomes at reasonable cost may be cost effective, even if it does not reduce expenditures. Such is the case with effective lipid-lowering therapy in patients with symptomatic CHD and elevated serum cholesterol. The Scandinavian Simvastatin Survival Study (4S) clearly demonstrates that simvastatin therapy saves lives, prevents acute MI, and reduces hospitalizations for CHD-related events by 20% to 40% in men and women with elevated serum cholesterol who had angina pectoris or who had survived an acute MI.<sup>2</sup>

As demonstrated in an article published in *Circulation* in May 1996,<sup>3</sup> extrapolation of these results to a US population indicates that these results can be achieved at a net cost of approximately \$0.28 per day, since 88% of drug costs were offset by reductions in hospitalization costs, noted Dr. Schwartz. Moreover, integrating the 4S findings with simulation modeling indicates such treatment result in continued additional survival benefits for approximately 20 years and residual though reduced survival benefit for almost 40 years. Thus, lifetime therapy of such patients is extremely cost effective, more so than other worthwhile, widely adopted interventions, such as screening mammograms, hypertension treatment, and renal dialysis. "Cholesterol reduction in patients with elevated cholesterol and symptomatic CHD is one of the more cost effective interventions physicians can provide," Dr. Schwartz said.

### Clear Evidence

The evidence is clear that patients with symptomatic CHD and elevated cholesterol will benefit from simvastatin therapy. Cholesterol lowering therapy also is likely to be cost effective (though somewhat less so) in patients who have symptomatic CHD but low levels of LDL cholesterol such as 125 mg/dL to 130 mg/dL. This was demonstrated recently in the Cholesterol and Recurrent Events (CARE) trial.<sup>4</sup>

The results of both the large recent trials of statin-based cholesterol-lowering therapy in patients with symptomatic CHD (4S and CARE) are consistent with the National Cholesterol Education Program (NCEP) guidelines.<sup>5</sup> These guidelines clearly identify those patients likely to benefit from effective cholesterol lowering drug therapy and, based on current data, appear to provide both clinical and cost-effective guidelines for management of patients with elevated cholesterol.

### ... REFERENCES ...

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