Editorials

Cholesterol reduction: What can we afford?

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In this issue van Hout and Simoons describe a cost-effectiveness analysis of cardiovascular disease risk reduction by HMG coenzyme reductase inhibitors (statins)[1]. This exercise stems from the recommendations of the Netherlands Consensus Committee on Lipid Lowering. Costs of prescriptions and of major medical events (death, acute myocardial infarction, stroke, PTCA and CABG surgery) are considered. At an estimated cost of Euro 18 000 per year of life gained, the authors suggest that statin treatment be considered for secondary prevention in most patients with known cardiovascular disease, and for primary prevention among a limited group of patients. They estimate that 1.8% to 3.4% of the Netherlands population would be eligible for treatment under these guidelines. This thorough analysis provides more data to inform the debate on the treatment and prevention of cardiovascular diseases.

As the authors recognize, cost analyses, in general, and the analyses in this study, have limitations. Generalizing from clinical trials to a national population requires assumptions that may not be well founded. Trials may be limited in gender, race and age distributions, requiring extrapolation and imputation from known information. In this study, the authors limit the cost data to medications and hospital charges. This ignores both individual and societal costs of illness. For an individual, the pain, emotional anguish and disability associated with a chronic disease is crucial but difficult to quantify in monetary terms. For society, the loss of a productive member due to chronic illness and the associated economic costs of care outside of the hospital should also be considered. Including these considerations would add to the ‘effectiveness’ side of the equation.

The advent of the statin drugs for lipid lowering contributes a new dimension to the treatment and prevention of cardiovascular diseases. Statins have been extensively evaluated in large clinical trials and shown to be highly beneficial in lowering coronary heart disease, stroke and overall mortality associated with the lowering of LDL cholesterol[2–6]. This benefit accrues with very few side effects. The condition for which they are indicated, LDL cholesterol elevation, is extremely common, and includes up to 50% of some adult populations in industrialized countries. Likewise, coronary heart disease and stroke associated with LDL cholesterol elevations are epidemic in industrialized countries and rising in developing nations. The confluence of these observations — common treatable risk factors, common disease, effective treatment and expensive medication — has prompted intense scrutiny of costs, effectiveness and benefits of the widespread application of this therapy[7–10].

While some might argue that other very costly and common medical therapies (for example cancer chemotherapy, lumbar disc surgery) are rarely subject to cost-effectiveness study, the potential magnitude of costs for statin therapy suggests such analyses are important. In this article, von Hout and Simoons observe that lipid lowering drugs consumed 3.64% of the total medication budget and 0.36% of the total health care budget for the Netherlands in 1997[1]. In 1995–97 in Minnesota, 6% of the adult population aged 25–74 years were taking lipid-lowering drugs, primarily statins[11]. There is great potential for wider use of lipid-lowering therapy to place additional burdens on financially stressed health insurance plans. Some even talk of bankruptcy as pharmaceutical costs become the driving force of the growing financial crisis in health care.

What are the options for an effective and safe therapy when we are uncertain we can afford the costs?

The analysis of van Hout and Simoons implies rationing. They suggest that all patients with established cardiovascular disease be treated, which is both effective and cost-effective. They limit preventive treatment, however, to very-high-risk adults, that is, those with a 25% 10-year event rate at age 40 and a 40% event rate in the elderly. While this strategy may reduce costs of lipid lowering, it ignores the heavy burden of sudden out-of-hospital death in those without known disease. It ignores the large part of the population with elevated LDL cholesterol who will benefit from therapy. Can we ‘afford’ not to treat this group?
The main cost of statin treatment is the drug itself. Those who do cost-effectiveness studies assume these drug costs are fixed, an immutable factor. But this is changing. In the United States, where drug costs are high, statins cost 26–41% more than in Canada[12]. Politicians have organized trips to Mexico or Canada to purchase medications at lower prices. The VA-HIT trial, using generic gemfibrozil, demonstrated rates of disease reduction similar to those observed in the statin trials, while the annual cost of treatment was $39 (Euro 43)[13] (Rubins H. Personal communication). Significant price reductions for statins should be anticipated as generic equivalent statins become available. If the annual medical charges in the Netherlands fell 50% (Euro 550 to Euro 275), the number of treatable people would double at little increase in costs. Clinicians can actively seek price reductions from the manufacturers and prescribe lower-cost statins.

Diet is the other effective therapy not discussed in the rush to a statin prescription. The origin of mass hyperlipidaemia is the population-wide high intake of saturated fats and cholesterol[14]. The preventive strategy is a healthy eating pattern, which is inexpensive and safe. Dietary strategies will also help to control hypertension, diabetes and obesity and may have beneficial effects on cancer risk. Dietary intervention may eliminate the need or the dosage of drugs, which would result in cost savings[15].

We need to understand both the costs and benefits of the treatments we prescribe. We need to provide the best treatment available that is supported by scientific evidence. The literature suggests that lipid-lowering therapy will provide health benefits for many not currently recommended for treatment by the Netherlands Consensus Panel. One solution is to reject the idea that drug costs are fixed and to work for lower prices for effective agents. Another is to remember that there were effective therapies before statins arrived; diet still works for many patients.

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**References**