OTC statins – an ethical test case

Statins are currently provided at NHS expense for patients with coronary heart disease (CHD), diabetes and those whose coronary risk is greater than 3% per year. This is enshrined in numerous government documents, notably the two National Service Frameworks for Coronary Heart Disease and Diabetes.

Statins, however, have a protective effect where risk of CHD is much lower – as low as 0.6% per year in the Texas study.[1] Age is the most important determinant of coronary risk.[2,3] Nevertheless, treating younger people may be reasonable if they have other strong risk factors.[4] Statins are essentially very safe therapies, and probably cause less harm than aspirin. Liver failure and rhabdomyolysis are extremely rare and raised liver enzymes are usually reversible. Long-term concerns about conditions such as cancer, however, remain unanswered.[4]

The main reason for the NHS not treating people with a risk lower than 3% per year is cost. At a risk of 3% per year, the cost-efficacy of statins is £4,500 per life year gained. At 1.5% risk it is £6,100. This puts the net discounted NHS price at £7,500 and £11,800 per life saved respectively[5] – well within the usual cost-efficacy benchmark of the National Institute for Clinical Excellence of £30,000 per life year gained. The British Hypertension Society[6] has recently updated its statin guidance to include anyone with a risk greater than 2% per annum, which means virtually every man over 60 being prescribed a statin. This is formal recognition that more people would benefit from statins than are currently eligible on the NHS.

The medical profession does not have a monopoly on this information. Many people understand the data and want the benefits. They are mostly people with small but multiple risks – men over 45 years with minor elevations of cholesterol; smokers; people who are overweight or obese; those with a family history of CHD and diabetes; and those with early metabolic syndrome. These people have a right to make an informed choice and the medical profession should help them do this.

It seems logical, therefore, that if a well-informed patient with a level of coronary risk which does not make him eligible for free NHS care, wishes to exert personal choice and to purchase a relatively safe therapy which the NHS has chosen not to provide, then doctors should respect that decision.

There are questions: clinical questions such as the correct level of supervision and ongoing monitoring; and the need for therapy to be modified according to biochemical response. These can be answered. More important questions are organisational and ethical. If the treatment is non-NHS, what is the position of the general practitioner who is not remunerated for non-NHS work? Who should foot the bill for supervision, remembering that NHS general practitioners cannot charge their own patients for private medical services?

Ethical considerations

Then there are the ethical problems. Patient choice is necessary and desirable but the proposal to sell statins over the counter opens up major debates: debate about the distinction between NHS and private care; about responding to want rather than need; about freedom of information; and about the state's right to ration care. The list of therapies not provided on the NHS is growing; allowing patients to choose what they want in this way goes against one of the founding principles of the NHS – that of equity. If the government intends to proceed much further down this path, then it will require major discussion with the public and with the profession. It may also require the formalisation of a system of healthcare in which state provision based upon need is complemented by personal choice and ability to pay.

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