The value of atorvastatin over the product life cycle in the United States

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
This study examined the cost-effectiveness of atorvastatin for the primary and secondary prevention of cardiovascular events, during its production, from 1997 to 2030. This period covered the development of generic forms of atorvastatin and of another statin. The cost-effectiveness varied over the period, increasing between the introduction of generic simvastatin and generic atorvastatin, but remaining cost-effective. A valid framework was used and, despite limited reporting of some data sources, these conclusions appear to be robust.

Type of economic evaluation
Cost-utility analysis

Study objective
This study examined the cost-effectiveness of atorvastatin for the primary and secondary prevention of cardiovascular events, during its production, from 1997 to 2030. This period covered the development of generic forms of atorvastatin and of a comparable medication.

Interventions
Atorvastatin was compared with simvastatin. Various dosages of these statins were considered.

Location/setting
USA/primary and secondary care.

Methods
Analytical approach:
A dynamic model, with a 33-year time horizon, was used. The authors stated that the perspective of the third-party payer was adopted.

Effectiveness data:
The clinical data were from published sources, including two cost-effectiveness analyses using clinical trial data (one for primary and one for secondary prevention). Official national databases, such as the National Health and Nutrition Examination Survey, were used mainly for the epidemiology and clinical patterns. The efficacy of treatment was the primary endpoint of the analysis and was from two randomised trials that included both atorvastatin and simvastatin. Full compliance with medication was assumed.

Monetary benefit and utility valuations:
The utility values were from published studies.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary benefit measure and they were discounted at an annual rate of 3%.

Cost data:
The economic analysis included the costs of drugs and cardiovascular events. Event costs were from published studies of the costs in clinical trials and were assumed to remain constant over time. Drug costs were based on their average wholesale prices for both branded and generic forms. All costs were in US $ and were discounted at an annual rate of 3%. The price year was 2008.
Analysis of uncertainty:
One-way sensitivity analyses were carried out on the incremental costs, incremental benefits, discount rates, indication weights, and other selected inputs. Published or assumed ranges of values were used.

Results
Compared with simvastatin, atorvastatin had an additional cost of $30.54 billion and produced a gain of 1.50 million QALYs. Over 33 years, the incremental cost per QALY gained with atorvastatin was $20,331. This ranged from cost-saving when atorvastatin was released to a maximum of $45,066 in 2012 with branded atorvastatin after six years availability of generic simvastatin.

The sensitivity analysis showed that these findings were robust to variations in the selected inputs. At a threshold of $50,000 per QALY, atorvastatin was good value for money and produced benefits for the US health care system.

Authors' conclusions
The authors concluded that the cost-effectiveness of atorvastatin varied over its production period, increasing when generic simvastatin was introduced until generic atorvastatin became available. Over the whole period it remained cost-effective.

CRD commentary
Interventions:
The comparators were the two most commonly prescribed statins, as shown by their official market shares from 1997 to 2010 (70% of the market). They are likely to be relevant comparators in other settings.

Effectiveness/benefits:
The clinical data were from two published cost-effectiveness analyses, which obtained treatment effect data from two head-to-head randomised clinical trials. These trials should have had high internal validity, but they could have been described in more detail. The authors acknowledged that they assumed perfect compliance, and it was unclear whether this could have favoured either drug. Extensive sensitivity analysis was conducted on some clinical parameters. QALYs were an appropriate benefit measure, as they capture the effect of the treatments on survival and quality of life, which are both affected in patients on statins. The sources for the utility weights were not reported.

Costs:
The economic analysis included all those costs relevant to the perspective of the payer. The authors stated that a broader perspective, such as that of society, would have improved the cost-effectiveness of atorvastatin due to the greater reduction in cardiovascular events compared with simvastatin. The unit costs and quantities of resources were not reported, except for the unit costs of drugs, which changed over time with generic or branded prices. Some sources for the costs of cardiovascular events were described and these appear to have been cost-effectiveness analyses. The impact of alternative costs was assessed in the sensitivity analysis. Reflation exercises are feasible as the price year was explicitly stated.

Analysis and results:
The model outcomes were clearly presented. The costs and benefits were appropriately synthesised, using an incremental approach. A deterministic approach was used to assess uncertainty, and the findings were clearly reported. The model used to estimate the long-term costs and benefits was not described; a published model might have been used. The authors stated that other economic evaluations had shown the cost-effectiveness of atorvastatin, but these usually used placebo as a comparator and its branded price. These results were specific to the US setting.

Concluding remarks:
A valid cost-effectiveness framework was used and, despite limited reporting of some data sources, the authors’ conclusions appear to be robust.

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