Smoking-cessation therapy using varenicline: the cost-utility of an additional 12-week course of varenicline for the maintenance of smoking abstinence

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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
The objective was to determine whether varenicline, a pharmaceutical aid to smoking cessation, helped to maintain smoking abstinence in a Swedish cohort of male and female smokers, who had been successfully treated for 12 weeks. The authors concluded that maintaining varenicline treatment for up to 24 weeks was justifiable at a willingness-to-pay threshold of between 13,000 and 35,000 Euros. The study was generally satisfactory and the results reflect the scope of the analysis.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective was to determine whether varenicline, a pharmaceutical aid to smoking cessation, helped to maintain smoking abstinence in a Swedish cohort of male and female smokers, who had been successfully treated for 12 weeks.

Interventions
The recommended duration of treatment with varenicline for smoking cessation was 12 weeks. This study looked at maintenance therapy with varenicline, where the initial 12 weeks of varenicline was followed by an additional 12 weeks. This was compared with 12 weeks of placebo following the initial 12 weeks of varenicline. Patients had abstained from smoking for the last seven days of the initial treatment.

Location/setting
Sweden/primary care.

Methods
Analytical approach:
This study used the Benefits of Smoking Cessation on Outcomes (BENESCO) model for the analyses. Bolin, et al. and Hoogendoorn, et al. (2008, see ’Other Publications of Related Interest’ below for bibliographic details) reported detailed descriptions of the BENESCO model, which simulated the consequences of smoking-cessation therapy in Sweden. This model was extended to include the indirect effects of smoking cessation on production and consumption and on the economy. The study had a 50-year time horizon and the authors did not report the perspective.

Effectiveness data:
The main effectiveness parameters were the former smoking prevalence, quit rates, and indirect effects, such as the value of consumption and production. These effectiveness data were from published studies. The treatment effectiveness for a 24-week course of varenicline was from a randomised controlled trial, performed by Tonstad, et al. (2006, see ’Other Publications of Related Interest’ below for bibliographic details). The individual estimates on in-patient care and the causes of death were from the Swedish National Board of Health and Welfare administrative registers. Mortality was based on life tables from Statistics Sweden.

Monetary benefit and utility valuations:
The utility weights for smoking cessation were those already in the BENESCO model. These utilities were supplemented with morbidity-specific utility weights, for chronic obstructive pulmonary disease (COPD), lung cancer, myocardial infarction, coronary heart disease (CHD), and stroke, and these were derived from published literature.
Measure of benefit:
The measure of benefit was the quality-adjusted life-year (QALY) and these effects were discounted at an annual rate of 3%.

Cost data:
The main cost categories were the drugs, general practitioner visits, and motivational support from a nurse. The BENESCO model included information that was collected from a sample of doctors in Sweden, for the prescription costs; the health care consumption of those diagnosed with COPD, CHD, stroke, or lung cancer, for a period of three years; and the morbidity-related health care costs. Published literature was used for the intervention cost of the additional 12-week treatment and was calculated to be 62.8% of the total cost of the initial 12-week treatment. The costs for stroke patient rehabilitation were also from published literature. Prices were reported in Euros (EUR) and the price year was 2003. All costs were discounted at a rate of 3% per annum.

Analysis of uncertainty:
Univariate and bivariate sensitivity analyses were performed on the study parameters. Probabilistic sensitivity analysis was also performed, with Monte Carlo simulations, and the results were presented in two cost-effectiveness acceptability curves, one for men and one for women.

Results
For men, the incremental intervention cost was EUR 42,733,723 and for women it was EUR 52,830,477. The health care costs averted, with varenicline for 24 weeks as opposed to 12 weeks, were EUR 13,162,508 for men and EUR 18,996,258 for women. The QALYs gained for men were 4,185 and for women they were 4,760, over a 50-year time period.

Considering the direct health costs only, the incremental cost per QALY gained was EUR 7,066 for men and EUR 7,108 for women. When indirect costs were also included, the incremental cost per QALY gained was EUR 24,149 for men and EUR 24,436 for women.

The extensive sensitivity analysis demonstrated that the results were robust to changes in the assumptions and input parameters. The cost-effectiveness acceptability curves showed the probability that the intervention was cost-effective over a range of willingness-to-pay thresholds.

Authors’ conclusions
The authors concluded that maintaining varenicline treatment for up to 24 weeks was justifiable at a willingness-to-pay threshold of between EUR 13,000 and EUR 35,000.

CRD commentary
Interventions:
Appropriate information on the comparators was given, but it was unclear if all the relevant comparators were included. Bupropion was mentioned as another smoking cessation treatment, but no reason was given for not including it.

Effectiveness/benefits:
There was no description of the search strategy used for the effectiveness data, but these were mainly from the BENESCO trial, which was explained in some detail. The authors also provided the details of the main treatment effectiveness data that were obtained from this trial. It does not appear that a systematic review was not undertaken but a good overview of the model inputs was provided. The sources used to calculate the QALYs were provided, but the authors did not report the elicitation methods and it was not clear if they were from the Swedish population. This makes it difficult to assess if they were appropriate.

Costs:
The authors presented two scenarios for the costs; one with and one without the indirect costs, which implies that both a payer and a societal perspective were taken, but this was not explicitly reported, which makes it difficult to assess if all the relevant costs were included. The sources, from which the unit costs and resource use were derived, were adequately reported, as were the price year, time horizon, and discount rate.
Analysis and results:
The model was appropriately described and the results were reported both including and excluding the indirect costs. The sensitivity analysis was difficult to interpret as there was no discussion of the results and the increments in costs were reported in Swedish kronor rather than Euros, which was confusing. The tables of results were fairly extensive for the sensitivity analysis and cost-effectiveness acceptability curves were reported for both men and women.

Concluding remarks:
The study was generally satisfactory, but there were some limitations. The data were mainly specific to Sweden and the results reflect the scope of the analysis.

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