The cost-effectiveness of an extended course (12 + 12 weeks) of varenicline compared with other available smoking cessation strategies in the United States: an extension and update to the BENESCO model
Knight C, Howard P, Baker CL, Marton JP

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 an extended (12 plus 12 weeks) course of varenicline in comparison with the available smoking cessation aids, using recent evidence to update a previous decision model. The authors concluded that the extended varenicline treatment was highly cost-effective. The previous model’s methods and data sources were not fully reported, but the analysis was very well conducted and the authors’ conclusions are robust.

Type of economic evaluation
Cost-utility analysis

Study objective
This study examined the cost-effectiveness of an extended (12 plus 12 weeks) course of varenicline, in comparison with other available smoking cessation aids, using recent evidence to update a previous decision model.

Interventions
Extended varenicline (24 weeks) was compared against 12 weeks of varenicline, bupropion, nicotine-replacement therapy, and unaided cessation. Varenicline was given at 1mg per day, for both the 12-week and the extended treatments.

Location/setting
USA/primary care.

Methods
Analytical approach:
The analysis was based on the Benefits of Smoking Cessation on Outcomes (BENESCO) model, which simulated the outcomes associated with the smoking cessation strategies, in a Markov model with a lifetime horizon. The authors did not state the perspective of the study.

Effectiveness data:
The bulk of the clinical evidence was already in the BENESCO model and included data from published censuses, clinical trials, a meta-analysis, and other studies. The details of these sources were published with the original analysis. New evidence on the efficacy of extended varenicline was derived from a randomised, double-blind trial, published in 2006, and the methods of this trial were reported (603 patients were randomised to varenicline and 607 to placebo, after 12 weeks of varenicline). Other efficacy data were also from randomised controlled trials (RCTs). The cessation rates were the key clinical outcome. The efficacy data from various sources were combined, using a mixed-treatment comparison.

Monetary benefit and utility valuations:
The utility values were derived from the literature and were already included in the BENESCO model, so no details were given.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary benefit measure and were discounted at an annual rate of 3%.
Other lifetime benefits, such as the reduction in smoking-related morbidity, were reported, but were not combined with costs.

Cost data:
The economic analysis included two cost categories: smoking cessation interventions and smoking-related morbidities, which were chronic obstructive pulmonary disease, lung cancer, coronary heart disease, stroke, and asthma exacerbations. As these costs were already in the model, no information on their derivation was provided, except for the smoking cessation interventions, which were based on average wholesale prices. The price year appears to have been 2005. All costs were in US dollars ($) and a 3% annual discount rate was applied.

Analysis of uncertainty:
One-way deterministic and probabilistic sensitivity analyses were carried out in the original BENESCO report, but only a probabilistic analysis was used for the current data.

Results
The lifetime costs, in the eligible population of 11.9 million patients, were $328,279 million with 12-week varenicline, $328,528 million with extended varenicline, $330,689 million with bupropion, $332,622 million with nicotine replacement, and $333,283 million with unaided cessation. The QALYs were 174,373,000 with 12-week varenicline, 174,630,000 with extended varenicline, 173,999,000 with bupropion, 173,970,000 with nicotine replacement, and 173,416,000 with unaided cessation.

Extended varenicline dominated all the other options, except 12-week varenicline, which means that it was more effective and cheaper. Compared with 12 weeks, 24 weeks of varenicline had an incremental cost per QALY gained of $972.

The probabilistic analysis showed that the base-case findings were stable. At a willingness-to-pay threshold of $30,000 per QALY, extended varenicline was the most cost-effective strategy in 73% of simulations. The next most cost-effective strategy was unaided cessation (19%), followed by 12 weeks of varenicline (9%).

Authors' conclusions
The authors concluded that the extended varenicline treatment was a highly cost-effective alternative to the available smoking cessation aids.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear in that many of the available smoking cessation aids were considered, but they were not extensively described.

Effectiveness/benefits:
Most of the details on the clinical sources were presented in the original BENESCO report and only the key information was provided in this paper. The efficacy for each strategy was from RCTs, including a recent trial of the efficacy of the extended varenicline regimen. RCTs are generally considered to be a valid source of evidence given the strengths of their design. A mixed-treatment comparison was used to pool the data from different sources and this was valid and reduced the risk of bias due to differences in the original trials. Other epidemiological data were appropriately from US sources. No information on the derivation of the utility values was given, and it is not possible to judge the quality of these data. QALYs were an appropriate benefit measure, given the impact of smoking-related diseases on both quality of life and survival.

Costs:
The analysis of costs was only partially reported. The viewpoint of the study was not stated and the costs were not broken down into individual items. A list of cost items, the quantities of resources used, the price year, and the data sources were not presented, which limits the transparency of the analysis. The authors stated that these data were available in the original BENESCO report.
Analysis and results:
The analytic approach was valid and the findings were clearly presented. Conventional discounting was applied to both the costs and benefits. The issue of uncertainty was appropriately investigated using probabilistic analysis, but the details were not reported. The best feature of the study was the accurate analysis of the efficacy data, while fewer details were given for the costs, due to the use of published information.

Concluding remarks:
This study was an update of a previous model and its methods and data sources were not fully reported, but the analysis was very well conducted and the authors’ conclusions are robust.

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