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 compared varenicline combined with counselling versus counselling alone for smoking cessation in Japan. The authors concluded that despite some uncertainty surrounding the results, varenicline in addition to counselling appeared to be cost-effective for smoking cessation. The methods were valid, but there were several limitations that mainly related to the validity of the effectiveness data. The authors’ conclusions should be considered with these limitations in mind.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective was to compare the cost-effectiveness of two smoking cessation interventions in Japan. It was assumed that smokers had started smoking at the age of 20 years and the interventions were provided to cohorts at different ages, which were 30, 40, 50, 60, or 70 years.

Interventions
The interventions were the drug varenicline in addition to smoking cessation counselling (performed by a physician) compared with the same smoking cessation counselling alone. Both interventions were administered for 12 weeks.

Location/setting
Japan/primary care.

Methods
Analytical approach:
A Markov model was used to assess the impact of the interventions on the tobacco-associated deaths, disease, and treatment costs over a patient's lifetime. The impact of the two interventions on the quit rate and 19 smoking-associated diseases was evaluated. The authors reported that the health care payer’s perspective was adopted.

Effectiveness data:
A committee of expert physicians was used to derive the standard treatment for each state, to identify the smoking-related diseases for inclusion, and to identify the Markov transition probabilities between the health states. The methods used to calculate the incidence rate for each disease, with each smoking status, were presented. The varenicline success rate was from a randomised placebo-controlled dose-response trial. The primary clinical outcomes were the success rates (stopping smoking with or without tobacco-associated disease) for each intervention. These were derived from appropriate Japanese randomised controlled trials. The relative risks for smokers and the five-year survival rates were presented for the 19 tobacco-associated diseases. Japanese data were used wherever possible.

Monetary benefit and utility valuations:
The utility values for tobacco-associated diseases were from the literature or based on authors’ assumptions; all 19 values were reported.

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

Cost data:
The economic analysis included the treatment costs for tobacco-associated diseases (oropharyngeal cancer, oesophageal cancer, hepatic cancer, lung cancer, etc.), varenicline costs, and the smoking cessation intervention costs, such as out-of-hospital prescriptions, in-hospital prescriptions, clinic visits, and counselling meetings. The costs and quantities were reported separately for the smoking cessation intervention and varenicline. They were from official national sources and were reported in Japanese yen (JPY). The price year was 2007, and no adjustments for inflation were necessary as Japan had an inflation rate of less than 1% over previous years. The currency conversion rate for October 2007 was one US dollar equalled JPY 115. The costs were discounted at an annual rate of 3%. A budget impact analysis was performed to estimate the overall savings by calculating the difference between the initial investment for the intervention and the treatment costs for tobacco-related diseases.

Analysis of uncertainty:
The parameter uncertainty was investigated using one-way sensitivity analysis on the relapse rate and the success rate of varenicline, the discount rate, and the utility scores for those who quit smoking without tobacco-related disease. The assumption that people who survived tobacco-related disease would quit smoking was removed and a scenario where survivors did not quit smoking was tested. A probabilistic sensitivity analysis was conducted on five model parameters; the success rate for each intervention, and the relative risks of gastric, lung, and rectal cancers. The pre-assigned distributions were reported.

Results
Men and women were analysed separately. These results are the weighted means of the separate age group analyses. For men, varenicline plus counselling resulted in mean lifetime medical costs of JPY 1,763,042 while counselling alone resulted in JPY 1,806,888. Varenicline resulted in a mean of 18.741 QALYs while counselling alone resulted in a mean of 18.647 QALYs. Varenicline was dominant as it was more effective and less costly than counselling alone.

For women, the mean lifetime costs were JPY 1,213,151 with counselling and JPY 1,225,266 with varenicline. The expected mean QALYs were 20.633 with counselling and 20.699 with varenicline. When varenicline plus counselling was compared with counselling alone it resulted in an incremental cost of JPY 346,143 per QALY gained.

For the whole population, varenicline plus counselling was dominant. The budget impact analysis for the smoking population in Japan revealed that varenicline resulted in cost savings of JPY 9.5 billion.

The sensitivity analysis demonstrated that these results were most sensitive to variation in the relapse rate. At a willingness-to-pay threshold of JPY 5,000,000 per QALY gained, varenicline had a probability 0.951 of being cost-effective for men, 0.652 for women, and 0.873 for the whole population.

Authors' conclusions
The authors concluded that, despite some uncertainty around the results, varenicline in addition to counselling appeared to be cost-effective for smoking cessation.

CRD commentary
Interventions:
The rationale for the choice of intervention was clearly reported. The authors appear to have compared the usual care with an approved pharmacological treatment in their setting. Alternative drugs, such as bupropion, were not included as they had not been approved in Japan.

Effectiveness/benefits:
An expert committee appears to have identified and verified all the aspects of the model, but the limited reporting makes it difficult assess exactly what was done. Some of the clinical and epidemiological data and the assumptions on which they were based were presented, but many of the parameters were not, making it impossible to assess their validity. The utilities were one of the few parameters that were from outside the Japanese setting. The values for 19 diseases were presented, but the details of how they were measured and selected were not. This is understandable due to space constraints, but the lack of detail makes it difficult to objectively assess the validity of these data.

Costs:
The cost categories appear to have reflected the perspective adopted. The treatment costs for tobacco-related diseases were reported as totals, which limits the transparency of the analysis. The intervention costs were reported in great detail, with the costs and quantities reported separately, making it possible to reproduce the analysis. The conversion rates, discounting, and the price year were reported, facilitating future reflation exercises. Overall the cost data were fairly well reported.

Analysis and results:
The model structure and the modelling assumptions were reported in detail, with a diagram. The generalisability was partly assessed in deterministic and probabilistic analyses on specific model parameters, but variations in the cost estimates were not investigated. The authors compared their results with those of previous studies and discussed the differences. Several limitations that mainly related to the unavailability of data were also reported.

Concluding remarks:
The methods were valid, but there were several limitations that mainly related to the validity of the effectiveness data. The authors’ conclusions should be considered with these limitations in mind.

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