A cost-effectiveness model of smoking cessation based on a randomised controlled trial of varenicline versus placebo in patients with chronic obstructive pulmonary disease

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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 of the study was to assess the cost-effectiveness of varenicline as a smoking cessation aid in smokers with chronic obstructive pulmonary disease (COPD). The authors concluded that varenicline was expected to be cost-effective as an aid to smoking cessation in COPD patients. Overall the quality of the study methodology was good with methods and results reported appropriately. The authors’ conclusions appear valid within the scope of the analysis.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
To assess the cost-effectiveness of varenicline as an aid to smoking cessation in smokers with chronic obstructive pulmonary disease (COPD).

Interventions
The study compared use of varenicline or placebo for a period of 12 weeks as an aid to smoking cessation in smokers with COPD.

Location/setting
Spain/primary care.

Methods
Analytical approach:
A Markov cohort simulation model was used to assess the costs and outcomes of the two interventions under study. The authors reported that the structure of the model was derived from a previously published Swedish study by Borg et al. (see Other Publications of Related Interest). The time horizon was the lifetime of the patient. The perspective of the Spanish National Health System was adopted.

Effectiveness data:
Clinical and effectiveness data were derived from previously published studies. The main effectiveness parameter was the one-year smoking cessation efficacy of varenicline and placebo. This information was derived from a multicentre double-blind randomised controlled trial in 504 patients with mild to moderate COPD. Efficacy in the trial was measured using carbon monoxide-confirmed continuous abstinence rates at 52 weeks from Tashkin et al. (see Other Publications of Related Interest). Relapse rates after quitting at one year came from a longitudinal study of former smokers after sustained abstinence.

Monetary benefit and utility valuations:
Utility estimates for COPD severity states were based on a previous study using the EQ-5D (Borg et al.) in which responses to the EQ-5D were valued using the UK EQ-5D tariff.

Measure of benefit:
Life years gained and Quality-Adjusted Life-Years (QALYs) gained were the summary measures of benefit. Future benefits were discounted using an annual rate of 3%.
Cost data:
Direct costs included hospitalisation, oxygen therapy, general practitioner visits, pharmacy and the cessation programme. Most costs were derived from a survey of Spanish COPD patients. Other costs were derived from previously published studies. All costs were reported in Euros (EUR) and inflated to 2010 prices using the index of consumer prices. Future costs were discounted using an annual rate of 3%.

Analysis of uncertainty:
A series of one-way sensitivity analyses were conducted to assess the impact of changing model parameter inputs. A probabilistic sensitivity analysis was undertaken by assigning probability distributions to all model parameters. A series of 10,000 Monte Carlo simulations were performed by drawing parameter values at random from each distribution. The authors repeated the cost-effectiveness analysis for five other European countries (France, Germany, Greece, Italy and UK) by varying the country-specific unit costs. Results were presented using a tornado diagram, a cost-effectiveness acceptability curve and cost-effectiveness plane.

Results
Average cost per patient was EUR 20,169 for varenicline and EUR 19,249 for placebo. The average life years per patient were 7.98 for varenicline and 7.74 for placebo. The average QALYs per patient were 5.78 for varenicline and 5.62 for placebo.

Costs and benefits were combined using an incremental cost-effectiveness ratio (additional cost per life year gained) and an incremental cost-utility ratio (additional cost per QALY gained). When compared to placebo, the incremental cost-effectiveness ratio of varenicline was EUR 3,850 per life year gained and the incremental cost-utility ratio was EUR 5,566 per QALY gained.

Results of the probabilistic sensitivity analysis showed that at a willingness to pay threshold of EUR 30,000 per QALY gained, the probability that varenicline was cost-effective was over 95%.

The authors reported that varenicline would also be cost-effective for the five other European countries assessed at a willingness to pay threshold of EUR 30,000 per QALY gained.

Authors' conclusions
The authors concluded that varenicline was expected to be cost-effective as an aid to smoking cessation in patients with COPD.

CRD commentary
Interventions:
The interventions were reported adequately and their selection was appropriate. Other potentially relevant pharmacological alternatives were considered as part of the sensitivity analyses.

Effectiveness/benefits:
The authors did not report the methods they used to identify the relevant published studies that supplied the clinical and effectiveness estimates (such as a systematic review of the literature), so it was not possible to determine whether all the major relevant data were included in the analysis. The main effectiveness estimate was derived from one large recently published study that evaluated varenicline with placebo and so was likely to be internally valid. The analysis assumed a one-time quit attempt and did not allow for subsequent attempts (this limitation was acknowledged by the authors). The sources of other data used were reported clearly. The instrument and study that provided the utility values was reported, but these estimates appeared to be UK-specific may not have been representative for all populations/countries investigated. Life years and QALYs appeared to be valid benefit measures as they not only captured the impact of the disease on patients' health but also allowed cross-disease comparisons to be made.

Costs:
It appeared that all relevant major costs for the healthcare system perspective were included in the analysis. Sources from which costs were derived were reported and appeared to be from appropriate Spanish published studies (where these were available). Costs were generally presented as category totals and were not broken down into individual items and the resource quantities and unit costs were not given separately, which reduced the transparency of the analysis.
Price year, time horizon, discount rate and currency details were all reported. The authors reported brief details of the results of an additional analysis that assessed costs associated with the intervention in other European countries.

**Analysis and results:**
The analysis was based on a published Markov Model. Full details of the model methods, structure (including a diagram) and parameter assumptions were provided. An incremental approach was used appropriately to synthesise the costs and benefits of the two strategies and the results were presented comprehensively. The impact of uncertainty was fully assessed using a series of one-way and probabilistic sensitivity analyses. The authors reported as a main limitation to their study that they did not include costs to patients, carers and society in general in the analysis.

**Concluding remarks:**
Overall the quality of the study methodology was good with methods and results reported appropriately. The authors’ conclusions appear valid within the scope of the analysis.

**Bibliographic details**

**PubMedID**
22017336

**DOI**
10.1517/14656566.2011.628935

**Original Paper URL**

**Other publications of related interest**


**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Benzazepines /economics /therapeutic use; Cost-Benefit Analysis; Europe; Female; Humans; Male; Markov Chains; Middle Aged; Models, Economic; Nicotinic Agonists /economics /therapeutic use; Pulmonary Disease, Chronic Obstructive /drug therapy /economics; Quinoxalines /economics /therapeutic use; Randomized Controlled Trials as Topic; Smoking Cessation /economics; Varenicline

**AccessionNumber**
22011002026

**Date bibliographic record published**
15/02/2012

**Date abstract record published**
15/05/2012