health and economic consequences of smoking cessation therapies. The transition probabilities of morbidity and mortality and the efficacy were taken from published studies. The model allows for cost-effectiveness analyses for different time frames (10 years, 20 years and life time). Outcomes are measured in terms of incremental life years gained (LYG) and QALYs. Pharmacological costs and costs of medical visits for the treatment with varenicline and bupropion were considered. Treatment costs of smoking associated morbidity were taken from Spanish studies. Results were expressed in terms of incremental cost per life year gained and incremental cost per QALY of varenicline versus comparators. The analyses were done under the perspective of the National Health System, discounting costs and health benefits at 3 percent. RESULTS: The life time cost-effectiveness analysis shows that varenicline dominates all other smoking cessation interventions (more effective at a lower cost). This is due to the higher efficacy of varenicline associated with a reduction in smoking related morbimortality, which, in the long term, accounts for health care cost savings that overcome the extra cost of varenicline. When shorter timeframes are considered, varenicline presents values under 9,000 €/QALY and 50,000 €/QALY (analyses at 20 and 10 years respectively). CONCLUSION: Varenicline is a dominant option (more effective at a lower cost) compared with all other smoking cessation treatments when the timeframe is the life span of the patient. Varenicline is cost-effective even when shorter timeframes are considered (20 years or more), with an estimated incremental cost per QALY well below the threshold commonly accepted in our environment: 30,000 €/QALY.

SMOKING—Patient Reported Outcomes

AN EVALUATION OF THE COST-EFFECTIVENESS OF AN EXTENDED COURSE OF VARENICLINE IN PREVENTING SMOKERS WHO HAVE QUIT FROM RELAPSING

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OBJECTIVES: Varenicline α4β2 nicotinic acetylcholine receptor partial agonist has been shown to be effective and cost-effective as a smoking cessation aid when given as a 12-week treatment course. Recent data suggests incremental quit rates are seen if further 12 weeks of varenicline treatment are given. This study was designed to model the cost-effectiveness of this additional 12 weeks of varenicline treatment compared with other available courses of existing smoking cessation drug interventions. METHODS: The authors have previously developed a Markov model, the Benefits of Smoking Cessation on Outcomes (BENESCO), which estimates the outcomes and costs of a hypothetical population cohort of current US smokers who make a single attempt to quit smoking. This is a dynamic micro-simulation model which models the cost-effectiveness of all the currently available drug-based smoking cessation modalities (NRT/bupropion/varenicline) and unaided cessation. In the original version of the BENESCO model, subjects were only allowed to make a one-off attempt to quit. In this updated version of the model subjects who have successfully quit following an initial 12 weeks of treatment were permitted a second 12-week treatment course. Results for maintenance therapy with Varenicline were incorporated into the BENESCO model using a mixed treatment comparison. RESULTS: Varenicline, 24 weeks, was found to dominate bupropion, NRT and unaided smoking cessation strategies over the lifetime of the model. CONCLUSION: Varenicline when given for 12 or 24 weeks is a highly cost effective smoking cessation aid. The additional 12 weeks of therapy in initial quitters represents excellent value for money for health services wishing to reduce the numbers of smokers, smoking-related morbidities and deaths in their populations.

HEALTH ECONOMIC MODEL OF SMOKING CESSATION TREATMENT WITH VARENICLINE IN GERMANY

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OBJECTIVES: To evaluate the effects of smoking cessation treatment with varenicline in Germany. METHODS: The health-economic model follows a hypothetical cohort of smokers in Germany who make a single attempt to quit smoking. The Markov model considers the possibility of the following smoking-related diseases: chronic obstructive pulmonary disease (COPD), coronary heart disease (CHD), stroke and lung cancer. The time horizon of the model covers the whole lifespan of the initial cohort with a discount rate of 5% for costs and health effects. Smoking cessation with varenicline will be compared with bupropion, nicotine replacement therapy (NRT) and unaided cessation (status quo) from the health care system perspective. RESULTS: Based on the demographic data used, the model baseline cohort consists of 5.18 million smokers. On the basis of the results of this study, smoking cessation with vareni-
USE OF THE INSULIN TREATMENT SATISFACTION QUESTIONNAIRE (ITSQ) AND THE ENVIRONMENTAL TOBACCO SMOKE QUESTIONNAIRE (ETS-Q) IN AN INTERNATIONAL STUDY
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OBJECTIVES: Prior to use in an international study, the Insulin Treatment Satisfaction Questionnaire (ITSQ) and the Environmental Tobacco Smoke Questionnaire (ETS-Q) underwent linguistic validation in 10 and 6 languages respectively. The original scales containing 22 and 3 items were developed in US and UK English respectively. Rigorous methodology was required to ensure conceptual equivalence and cultural relevance across different languages. METHODS: The translation process was conducted by a specialist in each target country using the following standardized methodology: 1) two forward translations by professional translators; 2) comparison and reconciliation of the translations by the specialist in the target country; 3) backward translation; 4) comparison of source and backward version; 5) review by a clinician (for the ITSQ only); and 6) comprehension test on a small sample of the target population diagnosed with diabetes and undergoing insulin treatment (for the ITSQ only).

RESULTS: Linguistic and conceptual issues emerged during the translation process. Firstly, when an original item used two adjectives to cover one concept some languages only had one term to express this. Secondly, some concepts, in particular in relation to meals, do not exist in certain Indian languages and paraphrases had to be found to ensure conceptual equivalence with the original and appropriateness in the target language. CONCLUSION: The language versions of the ITSQ and the ETS-Q were established according to rigorous translation methodology. The process aims to ensure conceptual equivalence across different language versions to facilitate international comparison and pooling of data. Thus, the result is linguistically validated questionnaires. The linguistic validation process as a whole supports the advantage of integrating international feedback on concepts and wording before a questionnaire is finalized.

REAL WORLD USAGE PATTERNS OF OVER-THE-COUNTER NICOTINE PATCHES
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OBJECTIVES: Little is known about how the public uses the nicotine patch after it was reclassified from prescription to over-the-counter (OTC) status. This observational study describes the characteristics of consumers who purchase OTC nicotine patches from pharmacies and to determine factors associated with off-label use of nicotine patch. METHODS: Prospective, longitudinal study of N = 600 OTC nicotine patch consumers from a random sample of 30 retail pharmacies throughout San Diego County. Each subject completed a self-administered, anonymous questionnaire at the time of purchase and at 2-weeks after using the patch. Off-label use was defined as intention to smoke while on the patch or using the patch for harm reduction rather than quitting. Logistic regression was performed to determine the factors associated with off-label use. RESULTS: The cohort had low Fagerstrom nicotine dependence score (mean = 3.58). Sixty-four percent stated that their physicians were not aware of them using the patch. Main reasons prompting purchase included self-initiative (54%), family/friends (20%), physician advice (15%), and pharmacist’s advice (3%). Eight percent intend to use the patch for harm reduction rather than quitting. Minorities and individuals with high income were more likely to engage in off-label use. Of those who returned the second questionnaire (N = 155), 78% did not review the self-aid counseling materials enclosed in the product package. Forty-five percent reported smoking cigarettes at 2 weeks, and 8% admitted to using more than one patch per day. CONCLUSION: A substantial number of the consumers had low Fagerstrom nicotine dependence scores and would not have qualified as for the patch under the prescription setting. Most consumers did not review the self-aid materials even though it was included in the package, and some consumers intentionally engaged in off-label use of the product. Further research is needed to devise interventions to ensure proper usage of OTC nicotine patch by the public.