

cline proved cost-saving or cost effective in relation to the alternatives studied. Overall, a gain of about 78–200 thousand life years (LYG) or 88–226 thousand quality-adjusted life years (QALYs) can be obtained in a long-term. The incremental cost-effectiveness ratio (ICER) is 2.330 EUR per LYG (2.073 per QALY) and 1.781 EUR per LYG (1584 per QALY) compared to unaided cessation or bupropion, respectively. Varenicline is a dominant strategy compared to NRT. Even if the savings from avoided smoking-related diseases are ignored and the time horizon will be reduced to 20 years, varenicline remains cost-effective with ICER under 18.000 EUR per LYG and QALY compared to all other alternatives. **CONCLUSION:** The results corroborate the findings of health benefits and favourable cost-effectiveness of smoking cessation pharmacotherapy from former studies.

## PSM5

**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.

## PSM6

**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.

## SURGERY—Cost Studies

## PSUI

**COST-EFFECTIVENESS OF STAPLED HAEMORRHOIDOPEXY (PPH) COMPARED WITH MILLIGAN-MORGAN TECHNIQUE MM IN PATIENTS IN WHOM SURGICAL INTERVENTION IS CONSIDERED APPROPRIATE FOR THE TREATMENT OF PROLAPSED INTERNAL HAEMORRHOIDS IN UNITED KINGDOM**

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**OBJECTIVES:** To evaluate the cost-effectiveness of PPH compared to MM for treating prolapsed internal haemorrhoids from the NHS's perspective. **METHODS:** A cohort-based model with a decision tree structure was developed to investigate the cost effectiveness of PPH in the treatment of haemorrhoids; the primary outcome was total direct NHS cost and QALYs. Patients in whom surgical intervention is considered appropriate enter the model having undergone either a PPH or MM procedure. The patient then goes through a recovery period during which a proportion of the patients may suffer a recurrent prolapse. The severity of the recurrent prolapse determines whether the patient is able to self-treat or requires further surgery. Those who require re-surgery are readmitted to hospital and undergo the same procedure they had on entry to the model. Resource utilisation associated with procedure cost and post operative complication was estimated by NHS reference costs 2006. **RESULTS:** Cost drivers were identified as the cost of the stapling device and reductions in length of stay in the PPH group. QALYs were driven by reductions in post-operative pain from PPH. Total direct NHS costs per were  $\leq 972.66$  and  $\leq 928.66$  for PPH and MM, respectively. PPH vs. MM offers a cost saving of  $\leq 10.74$ /patient due to less length of stay and OR time considering the