

44. Smoking cessation science

187

**Late-breaking abstract: Long-term efficacy of intensive behavior interventions and free medications for smoking cessation in Brazil**  
 Ana Thereza Rocha<sup>1</sup>, Marla Rocha<sup>2</sup>, Marina Cabral<sup>2</sup>, Lucas Macedo<sup>2</sup>, Franklin Pompa-Filho<sup>2</sup>, Manuela de Pinho<sup>1</sup>. <sup>1</sup>NATTAB - Pulmonary Department, Complexo Hospital Universitário Professor Edgard Santos - Universidade Federal da Bahia, Salvador, Bahia, Brazil; <sup>2</sup>Faculdade de Medicina da Bahia, Universidade Federal da Bahia, Salvador, Bahia, Brazil

**Introduction:** Treatment of tobacco dependence is associated with low long-term success rates, particularly in women. Our public clinic (NATTAB) offers intensive behavior interventions (IBI) program combined with free medications in Salvador. **Purpose:** To evaluate the long-term tobacco abstinence rates and gender differences in our IBI program combined with free medications.

**Methods:** We evaluated consecutive smokers, clinical and psychologically, verified the Fagerstrom's test (FT) score and offered IBI by a multidisciplinary team in group sessions (weekly x 4; then biweekly x 4 and monthly x 9). Coping skills and problem solving activities were developed. The rates of reported abstinence were evaluated by telephone contact or review of last visit on clinical charts, and compared by chi-square test.

**Results:** 467 patients were evaluated in 35 months, 350 initiated IBI, 85% of the patients used medications and had follow-up for 14±11 months (67% for 12 months). Mean age was 53±10 yrs, 67% were women and median FT score was 6 (IQR 3). 79% of women and 75% of men quit smoking at some point. The abstinence and relapse rates were respectively: 51% and 31% at 1-3 mo; 50% and 36% at 3-6 mo; 48 and 39% at 6-12 mo; 44% and 41% at 12-24 months and 42% and 42% at 24-35 months. Abstinence rates did not differ for men and women (45% vs. 51%, p=NS, respectively). Among those who relapsed, the mean time of abstinence was 3.6±4.1 months, and they stated that abandoning the IBI sessions contributed to relapse.

**Conclusions:** Programs combining IBI with free medications can be effective for long-term smoking cessation despite moderate to high nicotine-dependence, independently of gender.

188

**Smoking prevalence and willingness to quit in newly screened Danish patients diagnosed with airway obstruction**  
 Jens Døllerup<sup>1</sup>, Peter Bo Poulsen<sup>1</sup>, Charlotte Suppli Ulrik<sup>2</sup>, Anders Løkke<sup>3</sup>, Jens Holt<sup>4</sup>, Jørn Løkke Jensen<sup>4</sup>, Klaus Kaa Andersen<sup>5</sup>, Ronald Dahl<sup>3</sup>. <sup>1</sup>Medical and Access, Pfizer, Ballerup, Denmark; <sup>2</sup>Card. & Pulm. Department, Hvidovre Hospital, Copenhagen, Denmark; <sup>3</sup>Pulm Department, Aarhus University Hospital, Aarhus, Denmark; <sup>4</sup>Boehringer Ingelheim, Med. and Acc., Copenhagen, Denmark; <sup>5</sup>Inst of Mat. & Statistics, DTU of Denmark, Kgs. Lyngby, Denmark

**Background:** 436,000 Danes have chronic obstructive pulmonary disease (COPD) with one third diagnosed. 80-90% is tobacco related. Smoking cessation (SC) initiatives is primary intervention managing COPD. The Danish National Board of Health (NBH) recommends early detection of COPD focusing on: Age above 35 years. At least one pulmonary symptom. Smokers/ex-smokers or occupational exposure.

**Aims and objectives:** To evaluate the smoking prevalence and willingness to quit smoking in a population of newly diagnosed patients with airway obstruction in primary care in Denmark.

**Methods:** Following the recommendations by the NBH, participating GPs (n=335; 10% of Danish GPs) offered consecutively spirometry to patients with no previous diagnosis of obstructivity. Demographic, spirometry, smoking status, smoking history and willingness to quit was recorded. The population indicated having COPD, was assessed as to smoking status and smoking cessation initiatives.

**Results:** 3498 patients had spirometry, 1295 patients (37%, 61 years, 48% females) diagnosed with obstructivity (FEV<sub>1</sub>/FVC < 70%). With more women than men (P=0.03) in total 64%, diagnosed with obstructivity smoked (37 pack years, 17 cigarettes/day). 66% of smokers had a history of cessation attempts and 54% had used medication as part of the SC. 62% of the smokers like to quit, but only 11% intended to start immediately.

Indicated COPD severity and willingness to quit was not correlated.

**Conclusions:** Many patients identified with airway obstruction, indicating COPD, are current smokers. There is willingness to quit smoking, but only a few intend to initiate SC immediately, though guidelines recommend smoking cessation as primary intervention.

189

**Predicted health and economic benefits of smoking cessation incorporating multiple quit attempts over a lifetime**

Jeno P. Marton<sup>1</sup>, Denis Getsios<sup>2</sup>, Richard J. Willke<sup>1</sup>, Nikhil Revankar<sup>2</sup>, Kelly H. Zou<sup>1</sup>, James Xenakis<sup>2</sup>. <sup>1</sup>Global Health Economics and Outcomes Research, Pfizer, Inc., New York, NY, United States; <sup>2</sup>Health Economic Modeling and Simulation, United Biosource Corporation, Lexington, MA, United States

**Objective:** To evaluate the impact of age at start of smoking cessation treatment (SCT) on predicted health benefits and costs over smokers' lifetimes.

**Methods:** A discrete event simulation of SCT allowing multiple quit attempts and estimates of lifetime health and economic outcomes was developed in a U.S. population. SCT types were assigned based on observed use.

**Results:** The predicted life expectancy of the 18 to 74 years old (mean age 42.1 years) reference population was 26.8 years, corresponding to 13.9 discounted quality adjusted life years (QALY). The lifetime cost of SCT averaged \$1,462, with a total direct cost (IDC) of smoking-attributable disease of \$54,550/smoker. Smokers averaged 7.9 QAs; 66.2% were permanent abstainers at the time of death. Smokers who started SCT at 35 to 40 years of age, accrued 15.6 discounted QALYs, and 71% achieved permanent abstinence. Smokers who start SCT between 45 and 50 years of age accrued 11.5 discounted QALYs and 60.2% achieved permanent abstinence at the time of death. Total abstinence times (tAT) were 10.1 vs. 7.2 years in the younger and older age groups, respectively, with corresponding SCT costs of \$1,642 vs. \$1,385 and lifetime tDC of disease of \$43,306 vs. \$72,439/smoker.

**Conclusion:** The number of individuals achieving permanent abstinence at the time of death is greater if smokers make their first quit attempt at age 35-40, rather than later at age 45-50. Despite longer survival times, their costs are lower. The lifetime cost of SCT is negligible compared with the IDC of smoking-attributable diseases. Based on simulations, the timing of SCT initiation is critical to optimize health benefits and to reduce costs of care.

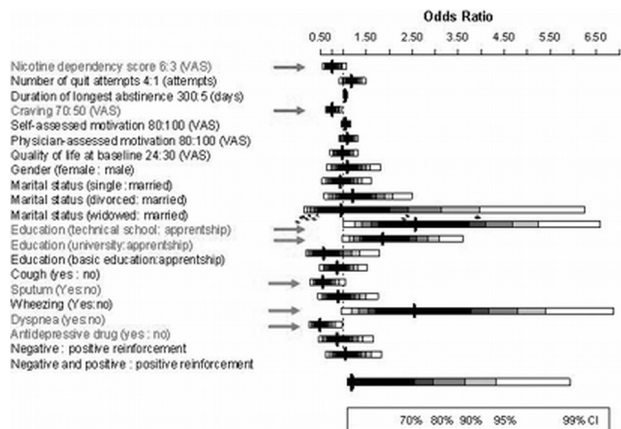
190

**Long term predictors for smoking cessation in a long-term, population study at the workplace**

Daiana Stolz<sup>1</sup>, Andreas Scherr<sup>1</sup>, Bruno Seiffert<sup>2</sup>, Kuster Martin<sup>3</sup>, Meyer Anja<sup>1</sup>, Tamm Michael<sup>1</sup>. <sup>1</sup>Clinic of Pulmonary Medicine and Respiratory Cell Research, University Hospital Basel, Basel, Switzerland; <sup>2</sup>Industrial Health Service, F. Hoffmann-LaRoche AG, Basel, Switzerland; <sup>3</sup>Industrial Health Service, Novartis Pharma AG, Basel, Switzerland

We implemented a voluntary, intensified, structured smoking cessation program with combined medical therapy for health care and health industry employees at workplace.

703 smoking employees from three sites absolved a 2 year program. This consisted of 10 visits with intensified counselling and motivational support. Various modalities of both nicotine replacement therapy and/or bupropion could be prescribed. Primary endpoint was nicotine abstinence at 12 and 24 months, which was defined as self reported abstinence confirmed by exhaled CO < 6ppm. Predictive factors of nicotine abstinence were analyzed by multivariate regression analysis. Smoking abstinence rates reached 38% after 12 months and remained unchanged after 24 months. Predictors of a successful quit attempt were higher education level (1.86 95% CI 1.12-3.07; p=0.016) and breathlessness at baseline (OR 2.53 95% CI 1.18-5.42; p=0.017). More severe nicotine dependency (OR 0.76 95% CI 0.59; 0.97; p=0.003), higher craving scores (OR 0.75 0.64-0.89; p=0.001) sputum at baseline (OR 0.54 95% CI 0.33-0.89; p=0.015) and antidepressive medication (OR 0.48 95% CI 0.28-0.82; p=0.069) were negative predictors for successful quitting.



Our real life smoking cessation intervention achieved high and stable longterm abstinence rates. Predictive factors for smoking cessation could be helpful to increase the effectiveness of smoking cessation programmes.

**191**

**Smoking cessation effectiveness in smokers with obstructive respiratory disease**

Angeliki Florou, Konstantinos Eleftheriou, Georgios Patentlakis, Athanasios Sachlas, Dimitrios Michailidis, Christina Gratziou. *Smoking Cessation Centre, Respiratory and Critical Care Dept., University of Athens, Evgenidion Hospital, Athens, Greece*

Cigarette smoking is the major risk factor for the development of Chronic Obstructive Pulmonary Disease (COPD) and is associated with increased morbidity and reduced sensitivity to medication in asthmatic patients.

The aim of the present study was to evaluate the effectiveness of smoking cessation treatment in a sub-population of smokers with COPD and asthma in real life conditions and to compare the efficacy of three specific pharmacological agents. A total of 2139 adults, current smokers were enrolled in the study. 298 subjects suffered from obstructive respiratory disease (COPD n=175, asthma n=123). After an initial counseling by a respiratory physician smokers were allocated to treatment either with Nicotine Replacement Therapy (NRTs), Bupropion SR or Varenicline. The CO-confirmed continuous abstinence rate (CAR) at the end of treatment (weeks 9-12) and during the follow-up period are shown in table 1. The abstinence rate in respiratory patients was 60.9% at the end of treatment and 39.9% in 12 months.

Table 1. Continuous abstinence rate

	At the end of treatment	6 months	12 months
Control smokers	56.6%	52.4%	39.4%
COPD-Astma	60.9%	55.1%	39.3%

The abstinence rates for the three treatment groups in respiratory patients are shown in table 2.

Table 2. CAR in respiratory patients in different treatment groups

	NRT (n=61)	Bupropion (n=79)	Varenicline (n=117)
At the end on treatment	50.9%	56.2%	75.6%
6 months	55.3%	54%	66.7%
12 months	46.7%	37.7%	47.8%

**Conclusion:** Smoking cessation treatments are highly effective in smokers with respiratory co-morbidity as asthma and COPD and it can be achieved with all approved pharmacological agents through a personal approach, motivation and intensive follow-up program.

**192**

**Smoking cessation treatment for COPD smokers**

Carlos A. Jimenez Ruiz, Ana Maria Cicero Guerrero, Maria Luisa Mayayo Ulibarri, Maria Isabel Cristobal Fernandez, Gema Lopez Gonzalez. *Unidad Especializada Tabaquismo, Salud Madrid, Madrid, Spain*

We reviewed medical histories of all COPD patients who were treated in our Unit between January 2004 and 2010. All patients received both psychological and pharmacological treatment (NRT, varenicline or bupropion). Medical and smoking histories were obtained during the baseline visit. A Quit date was chosen and therapy was begun. In all follow-up visits, patients received treatment, and control of abstinence and monitoring of adverse effects were carried out. The treatment was free of charge. The following aspects were assessed: continuous abstinence rate (CAR) between week 9 and 12 and CAR between week 9 and 24, both defined by not smoking over those periods of time. Levels of CO of 10 ppm or less were required. 472 COPD smokers received treatment, average age 58,3 (9,8), and 65% of them were male. Average number of cigarettes a day, number of smoking years and number of pack-year were 29,7 (13,4), 40,5 (9,9) y 59,1 (30,2), respectively. The average rate on FTND-questionnaire was 7,4 (2,1). NRT was prescribed in 233 (49%), Bupropion in 45 (9,5%), Varenicline in 190 (40%), and 4 (1,5%) of them did not received treatment. Global effectiveness was: CAR from week 9 to 12 was met by 54,3%, and CAR from week 9 to 24 was met by 48,5%. Taking into consideration the kind of treatment used, CAR from week 9 to 24 were 44,1%, 60% y 61% for nicotine patches, bupropion and varenicline respectively. Significant differences were observed between varenicline and nicotine patches. OR: 1,98 (1,25-3,12); p: .003.

Good effectiveness of pharmacological treatments for COPD smokers.

Good safety pattern of smoking cessation pharmacological treatments for COPD smokers.

Varenicline gets better efficacy results than nicotine patches in this group of smokers.

**193**

**A placebo-controlled trial with varenicline for long term nicotine replacement product users**

Philip Tonnesen, Kim Mikkelsen. *Pulm Dept, Gentofte Hospital, Copenhagen, Denmark Pulm Dept, Gentofte Hospital, Copenhagen, Denmark*

In this placebo, controlled trial we enrolled 139 long-term users of nicotine replacement products (NRT) (>1 year) to either varenicline (N=70) or placebo (N=69) for

3 months combined with 9 visits with counselling by nurses. The primary outcome showed that the varenicline group had a higher quit rate with NRT compared with placebo, statistical significant after 12 and 36 weeks but borderline significant on most other measure points. After 1 year the NRT quit rate was 42.9% vs. 36.2%, respectively. A Mantel-Haenszel test over all visits showed significant superiority for active therapy vs. placebo, odds ratio 1.83 (95%CI; 1.43-2.35), P<0.0001. Results for withdrawal symptoms, adverse events from varenicline, and weight changes will be reported. Also, changes in total-cholesterol, LDL, HDL and triglyceride after 3 and 12 months will be reported for NRT quitters and failures as well as changes in p-cotinine for users of NRT.

This is the first study reporting data for varenicline to be used for long-term NRT users. The study seems to be underpowered but overall the findings showed superiority for varenicline vs. placebo.

In conclusion, this study shows that varenicline seems to be an drug that might be effective in getting long-term NRT users to quit.

**194**

**Efficacy and safety of a novel nicotine mouth spray in smoking cessation: A randomized, placebo-controlled, double blind, multicenter study with 52-week follow up**

Philip Tonnesen, Hans Lauri, Roland Perfekt, Anil Batra, Karl Mann. *Pulmonary Dept, Gentofte Hospital, Copenhagen, Denmark Research Dept, McNeil AB, Helsingborg, Sweden Central Institute of Mental Health, University of Heidelberg, Mannheim, Germany Dept. of Psychiatry & Psychotherapy, University Hospital of Tübingen, Tübingen, Germany*

The study was a randomized (2:1) double-blind, placebo-controlled, low-intensity counseling study of the efficacy of a novel nicotine mouth spray (1 mg/spray) as an aid to smoking cessation. The study enrolled daily cigarette smokers, aged 18 years or older, who were motivated to quit and who had a CO level of ≥10 ppm. During Weeks 1-6, they were instructed to use 1-2 sprays whenever they would normally have smoked a cigarette, or whenever they experienced cravings to smoke, up to a maximum dose of 4 sprays per hour, and 64 sprays per day. The dose was tapered down during Weeks 7-12. Low intensity counseling was provided during the study.

Continuous CO-verified abstinence rates (CAR) were measured from Week 2 and were statistically significantly higher with active treatment than placebo. CAR after 6 weeks and 52 weeks were 26.1% vs. 16.1% and 13.8% vs. 5.6% (RR: 2.48, (95% CI; 1.24-4.94)) for active vs. placebo, respectively.

Treatment-related adverse events were common with both active and placebo, and were reported by 87% of subjects who used active spray and 71% of subjects who used placebo spray. Most adverse events reported were mild to moderate, and only 9.1% of participants in the active group and 7.5% in the placebo group withdrew due to adverse events.

In conclusion, these findings show that the nicotine mouth spray is a well-tolerated and effective aid to smoking cessation. At one year, the OR for sustained abstinence with active spray versus placebo was 2.7, and the RR was 2.5. Adverse events were common with both active spray and placebo, but were mostly mild to moderate, and generally tolerated.