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Cost-effectiveness of retreatment with varenicline after failure with or relapse after initial treatment for smoking cessation

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ABSTRACT

Objectives. A recent trial showed the clinical benefit of retreatment with varenicline in subjects failing on the initial treatment, or relapsing after initial success. The objective of this study was to evaluate the cost-effectiveness of retreatment with varenicline compared with other smoking cessation interventions.

Methods. A published Markov model was adapted to compare one quit attempt of varenicline followed by retreatment to treatment/retreatment with nicotine replacement therapy (NRT), bupropion or placebo, and with only 1 quit attempt of varenicline. Efficacy was obtained from clinical trials. Incidence of smoking-related diseases was based on published data. Cost of therapies and complications was obtained from databases and literature.

Results. For 1000 smokers willing to quit, varenicline retreatment saves 275,000€, 118,000€, 316,000€ and 237,000€ compared to NRT, bupropion, placebo, or one single varenicline quit attempt respectively at lifetime and from the healthcare payer perspective. The number of quality adjusted life years gained is 74, 63, 193 and 111 respectively. Sensitivity analyses showed the robustness of these findings.

Conclusion. This analysis suggests that in the long term, varenicline retreatment is a dominant intervention, meaning both greater health gains and greater costs saved, over other possible interventions and therefore should be considered as a standard option.

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Introduction

Smoking cessation (SC) therapies are widely available in Europe and many are reimbursed by public health care payers (Aubin et al., 2014).

Smoking cessation is aimed at preventing severe complications associated with smoking, including COPD, lung cancer, coronary heart diseases (CHD), stroke and asthma exacerbations. It is well established that the lifespan of a smoker is shorter than that of a non-smoker, with a difference of 6 to 10 years, on average, depending on the number of cigarettes smoked (Van den Bruel et al., 2004).

Varenicline, nicotine replacement therapy (NRT) and bupropion are the current standard pharmacological interventions to aid in smoking cessation. In motivated subjects, starting a treatment with one of these therapies is justified in association with behavioral counseling. However, smoking cessation is difficult and relapse is common among individuals attempting to quit (Fiore et al., 2000).

A recent trial assessing the efficacy of varenicline retreatment in subjects unsuccessful after a first attempt showed a success rate (defined as continuous abstinence from 9–52 weeks) of 20.1% (Gonzales et al., 2014).

In the current health care environment, the need to allocate public finances has increased the interest in cost-effectiveness research (Annemans et al., 2011) and reimbursement of medicines does not only require clinical effectiveness but also cost-effectiveness.

The objective of this study was to estimate the cost-effectiveness of varenicline in retreatment compared to other possible retreatment options including no treatment, and retreatment with bupropion or NRT.

Methods

General aspects

The perspective of this analysis is the healthcare payer perspective: the public health care payer (Rijksinstituut voor ziekte — en invaliditeitsverzekering/Institut National d'Assurance Maladie-Invalidité — RIZIV/INAMI) and the patient. This combined perspective follows the recommendations of the Belgian Health Technology Assessment (HTA) body KCE (Kenniscentrum—Centre d'expertise) (Cleemput et al., 2012) and gives a complete picture of smoking cessation since

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NRT is not reimbursed by the public health insurance. Given this chosen perspective only direct health care costs are included.

Decision model

The Two-quit BENESCO (Benefit of Smoking Cessation on Outcomes) model is based on an adaptation of the original BENESCO model, a Markov model that was developed to assess the cost-effectiveness of one quit attempt with smoking cessation interventions (Howard et al., 2008). The BENESCO model simulates the incidence of smoking-related morbidity and mortality over time and is an extension of the HECOS (Health Economic Consequences of Smoking) model that was used by the World Health Organization European Partnership Project to reduce tobacco dependence (Orme et al., 2001). BENESCO model has also been reviewed in various health technology assessments. This model has been customized for various countries, including Belgium, and the results have been widely published (Hoogendoorn et al., 2008; Fernández de Bobadilla Osorio et al., 2008; Bolin et al., 2008; Annemans et al., 2009; Igarashi et al., 2009; Bae et al., 2009; Linden et al., 2010; Athanasakis et al., 2012; Lutz et al., 2012). These analyses were also included in systematic reviews about the cost-effectiveness of varenicline (Keating and Lyseng-Williamson, 2010; Zimovetz et al., 2011; Mahmoudi et al., 2012).

The Two-quit BENESCO model follows a simulated cohort of 1000 Belgian smokers from first quit attempt through retreatment among those who were initially not successful or who relapsed, until all members of the cohort have either died or reached the age of 100 (Fig. 1). Lifetime clinical and economic outcomes of an initial quit attempt with varenicline followed by retreatment with varenicline, if the patient fails with or relapses after initial treatment (=2QA varenicline) are simulated and compared with the alternative interventions:

- 1 quit attempt with nicotine replacement therapy (NRT) followed by NRT retreatment in case of failure or relapse (=2QA NRT)
- 1 quit attempt with bupropion followed by bupropion retreatment in case of failure or relapse (=2QA bupropion)
- 1 quit attempt with placebo followed by placebo retreatment in case of failure or relapse (=2QA placebo)
- Only 1 quit attempt with varenicline followed by 1 quit attempt with placebo (1QA varenicline).

As in the initial BENESCO model, this model allows transitions to the smoking-related diseases as described in Fig. 2. A cycle length of one year was chosen because the abstinence rate is measured at 1 year in the clinical trials. Moreover, the benefits of smoking cessation interventions are apparent only up to several years after cessation, which makes a shorter cycle length not useful. All subjects entering the model are smokers, with co-morbidities according to their baseline prevalence among smokers. In the first year, subjects in the cohort receive initial smoking cessation treatment. At the end of each year, subjects transition between 3 smoking states (smoker, recent quitter, long term quitter), each of which can be further defined in terms of the presence or absence of the mentioned smoking-related diseases.

Subjects are considered recent quitters if abstinent for 2–5 years after successful quit attempt and long term quitters after more than 5 years of abstinence. Health benefits of cessation are applied to all quitters, although risk of relapse remains (Feenstra et al., 2005; van Genugten et al., 2003). Furthermore all subjects who fail during first quit attempt or relapse after first quit attempt will attempt a second quit. The evaluation of treatment failure or relapse occurs at the end of each cycle.

Fig. 2 illustrates the order of the smoking-related diseases in the BENESCO model. By modeling the morbidities in this way, a patient can have, for example, one or more asthma exacerbations, followed by CHD or stroke with one or more acute events, followed by lung cancer or COPD. Death can occur at any time, and its cause is specified. If subjects have one of the two acute morbidities (CHD or stroke) they cannot develop the other. Similarly if subjects develop one of the two chronic complications (lung cancer or COPD) they cannot develop the other. Subjects can progress from an acute disease to chronic, but not the other way. If subjects progress from an acute disease to a chronic one, their acute disease is ignored from that point forward.

Health data input

The abstinence rates of the various smoking cessation interventions were derived from a recent Cochrane systematic review (Cahill et al., 2013) as well as from the results of the randomized clinical trial on varenicline treatment/retreatment. In the absence of efficacy data of NRT and bupropion at 52 weeks in retreatment trials, we have conservatively used the same value in the retreatment as in the first treatment for these 2 interventions. As in the initial BENESCO model, the current model does not consider the adverse events related to the SC interventions because clinical trial data do not indicate sustained comparative difference between interventions that would impact on outcomes.

The clinical data are shown in Table 1.

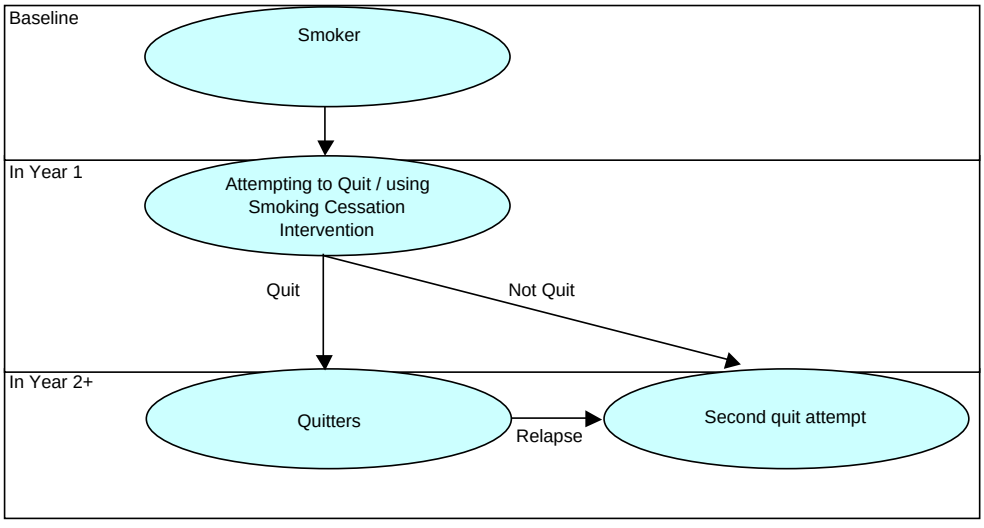

Fig. 1. Schematic diagram of three-stage process of quitting and relapsing to smoking.

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