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A system dynamics modelling approach to assess the impact of launching a new nicotine product on population health outcomes

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ABSTRACT

In 2012 the US FDA suggested the use of mathematical models to assess the impact of releasing new nicotine or tobacco products on population health outcomes. A model based on system dynamics methodology was developed to project the potential effects of a new nicotine product at a population level. A model representing traditional smoking populations (never, current and former smokers) and calibrated using historical data was extended to a two-product model by including electronic cigarettes use statuses. Smoking mechanisms, such as product initiation, switching, transition to dual use, and cessation, were represented as flows between smoking statuses (stocks) and the potential effect of smoking renormalisation through a feedback system. Mortality over a 50-year period (2000–2050) was the health outcome of interest, and was compared between two scenarios, with and without e-cigarettes being introduced. The results suggest that by 2050, smoking prevalence in adults was 12.4% in the core model and 9.7% (including dual users) in the counterfactual. Smoking-related mortality was 8.4% and 8.1%, respectively. The results suggested an overall beneficial effect from launching e-cigarettes and that system dynamics could be a useful approach to assess the potential population health effects of nicotine products when epidemiological data are not available.

1. Introduction

Smoking-related mortality affects approximately 6 million people per year worldwide (World Health Organization, 2016a). Despite public health campaigns and tobacco control policies, tobacco use remains a major public health concern in Europe (Organisation for Economic Co-operation and Development, 2014), as well as in emerging countries (World Health Organization, 2016b). Policy makers and regulators have considered new nicotine products as potential alternatives to complement cessation within their tobacco harm reduction strategies. The US Food and Drug Administration released guidance for 'modified-risk tobacco products' (MRTPs) in 2012, describing the requirements for products that wish to claim reduced harm (Food and Drug Administration, 2012). Being granted permission to claim a reduced risk with respect to conventional cigarettes could become a valuable marketing tool attracting an important segment of current smokers. New nicotine products that potentially offer reduced exposure to toxicants, reduced toxicity and a reduced health risk to consumers compared with conventional cigarettes, are being developed and introduced in markets worldwide. These next generation products (NGPs), include tobacco heated products, smokeless tobacco and other nicotine products, such as e-cigarettes.

The tobacco industry is developing methodologies to characterise nicotine products within a risk spectrum (Lowe et al., 2015). However, factors beyond nicotine product chemistry and its direct biological effect are likely to have an impact on the potential risk/benefit of launching a product in terms of population health effects. For example, if the introduction of a new product with lower health risks than smoking but with risk higher than complete nicotine cessation leads to prolongation of exposure to harmful constituents, especially if used in conjunction with traditional tobacco products, as the smoker may have quit smoking altogether had the new product not been available then, the overall effect could be harmful even when the intrinsic risk of the product is lower than cigarettes. Literature has also pointed to the possibility that some of these products could be attractive to non-tobacco users (De

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Abbreviations

CI	confidence interval
CS	current smoker
FS	former smoker
MRTPs	modified-risk tobacco products
NGP	next-generation product
NS	never smoker
ONS	UK Office for National Statistics
PAF	population attributable fraction
RR	relative risk
SAM	smoking attributed mortality

Andrade et al., 2013) and used as gateway products leading to more harmful products, especially those aged <20 years. Another potential scenario that authorities have expressed concern is over the possibility that even if new nicotine product users do not progress to cigarettes, the use of the new products could re-normalise the social perception of smoking (Fairchild et al., 2014), and reverse the recent decline in smoking prevalence. In this context, mathematical models can be valuable tools for assessing different scenarios by providing simplified representations of these behaviours and mechanisms. Then different parameters and assumptions are introduced in comparative scenarios to help identify tipping points between benefit and burden for a set of parameters of interest.

Simulation models have an established and effective record when studying the potential health impacts of smoking. Models have been used to assess the impact of regulatory policies (Levy et al., 2006), such as a simulation model to assess the ban on menthol cigarettes (Levy et al., 2011), and to assess investment in smoking cessation services (Tobias et al., 2010). More recently, in response to changes in the nicotine product landscape, simulation models for product assessment have been suggested using different methodologies (Bachand and Sulsky, 2013; Vugrin et al., 2015; Weitkunat et al., 2015).

In this study, we built on previous system models used by regulators for policy assessment to describe a compartmental model developed using system dynamics and aimed to investigate the potential health effects of launching an NGP, while maintaining model simplicity and transparency. This multiproduct model incorporated feedback mechanisms to assess the potential renormalisation of smoking as a result of launching a new product. We illustrate our approach with the introduction of e-cigarettes in the UK as e-cigarettes are still a relatively novel product but for which some information is available. In this case-study, we assessed the effect on mortality and smoking prevalence of launching e-cigarettes in the UK and what could be the effect of a potential renormalisation of smoking. Although there are a wide range of e-cigarettes in the UK market with potentially different toxicant emissions, for this case study, we are considering them as a category with a nominal intrinsic risk. This simplification will facilitate the study of the effect of using different estimates for the intrinsic risk of e-cigarette use on all-cause mortality.

2. Methods

We used a system dynamics approach to model the potential health impacts of an NGP in the tobacco market place. The quantified system dynamics model was constructed using Vensim® DSS version 6.3c (Ventana Systems Inc., MA, USA) and the packaged interfaced version Sable Developer v5.1.492 (Ventana Systems UK Ltd, UK) was used to visualise results.

Model development was conducted over two phases. In phase one, the Core Model was defined to represent the structure of traditional smoking populations (never smoker, current smoker and former smoker) and calibrated with historical data. During phase two, the Core Model was extended to a two product model (the NGP Conceptual Model), in which both cigarettes and a single NGP exist, and included subpopulations of current and former NGP users.

System dynamics models describing tobacco-use behaviour mechanisms represent a population as a system, with separate groups of people with similar smoking behaviour characteristics (stocks). As a stock is required for each population group with similar characteristics, system dynamics models can become structurally complex, limiting their ability to represent demographically diverse population groups. We required the model to represent population groups characterised by smoking status categorised by gender and age cohorts within a single stock, as transition rates between smoking status and relative risk (RR) for all-cause mortality are influenced by these parameters. The model also considers time since quitting as this parameter is directly linked to relative risks after smoking cessation and product switching. We strived to maintain the overall transparency of the model structure and flexibility, whilst modelling at a greater level of complexity, to provide an appropriate representation of smoking behaviours and mechanisms. Age cohorts rather than individual ages were used due to a lack of available data to inform the model at the single year age cohort level.

2.1. Core model

The Core Model used individual stocks to represent the traditional smoking populations of 'never smoker', 'current smoker' and 'former smoker' (Fig. 1). Never smokers were defined as individuals having smoked <100 cigarettes in their lifetime; current smokers, as those having smoked >100 cigarettes in their lifetime and still smoking, this definition of smokers includes hand-rolled cigarette smokers but excludes smokers of any other tobacco product such as pipes and cigars; and former smokers, as individuals that used to smoke but that no longer smoke.

An overview of the Core Model is shown in Fig. 1 with stocks representing smoking status and flows the transition rates between these stocks. The model used birth and migration rates (net migration) to present a more realistic portrait of the population. All-cause mortality was measured by applying mortality rates to stocks based on smoking status, age, gender and time since quitting smoking. In the diagram, inflows correspond to the projected population birth rate going into the stock of never smokers and migration flows into each stock proportional to the number of people in each stock. Migrant smoking status was assumed to be proportional to UK stocks because we did not have information regarding their smoking status. Model outflows were determined by the mortality rates associated with each stock. Flows within the model represent classic smoking behaviour, people remaining as a never smoker unless they initiated cigarette smoking. Those that initiated smoking transitioned to the stock of current smokers, where they remained until they quit (or die). Those that quit smoking transferred to the stock of former smokers that had been abstinent from smoking for <1 year. Former smokers were subdivided into separate stocks based on the period of abstinence, gender and age cohorts. As the period of abstinence increased, the former smoker transferred through stocks of quit periods. At each abstinence period, smokers could relapse back to smoking with different relapse rates. Additionally, within each stock, an automated mechanism was employed to simulate aging along age