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ESTIMATED PUBLIC HEALTH IMPACT OF ITALIAN SMOKERS SWITCHING TO SMOKE-FREE PRODUCTS: A POPULATION HEALTH IMPACT MODELING STUDY

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Introduction

We estimated the potential public health impact of switching from cigarette smoking to smoke-free products (SFPs) in Italy, in terms of reductions in smoking-attributable deaths (SADs) from the four below-mentioned diseases over a 30-year period (2010–2040).

Cigarette smoking is associated with several oncological and cardiorespiratory diseases including lung cancer (LC), ischemic heart disease (IHD), chronic obstructive pulmonary disease (COPD), and stroke. SFPs do not combust tobacco and, therefore, substantially reduce user exposure to harmful or potentially harmful constituents compared to cigarettes [1].

A Population Health Impact Model (PHIM) was used. A population of individuals was observed over a follow-up period in a scenario where no SFPs were introduced (NULL scenario) and three alternative scenarios. Two alternative scenarios were designed to describe market penetration of heated tobacco products (HTPs) and e-cigarettes (ECIGs) based on two Italian databases (ISTAT [2] and OssFAD [3,4]), which differed in terms of methodology for collecting data and sample size and were therefore considered separately. We also examined a hypothetical scenario (GRADUAL QUITTING) in which all SFP users from the ISTAT scenario transitioned to complete cessation upon entering the simulation instead of continuing to use SFPs.

Methods

The PHIM was developed by Philip Morris Products S.A. [5] and has previously been applied to assess the potential population health impact of introducing SFPs into the German [6], US [7, 8], and Japanese [9] market.

The basic method used for estimating the population health impact of introducing SFPs into a country involves two components: the Prevalence (P-) component and the Epidemiologic (E-) component (Fig. 1).

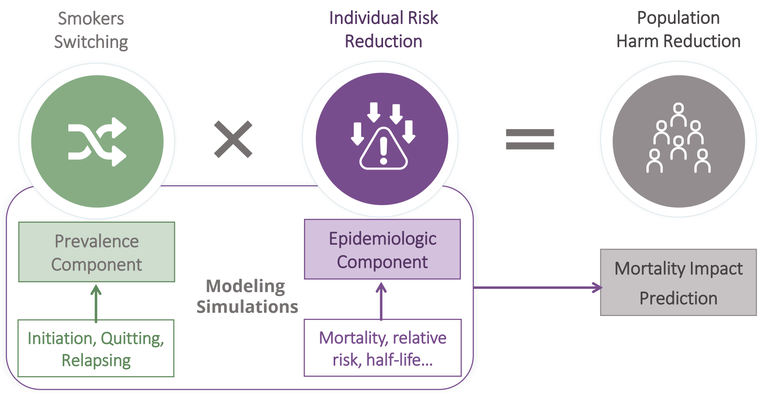


Fig. 1: The PHIM framework.

❑ Prevalence Component

In the P component, the population starts with a defined distribution of tobacco use at the baseline year (2001). This population is then followed over discrete time intervals under a *"NULL Scenario"* and several alternative scenarios, by using different sets of transition probabilities (TPs).

Product use groups:

Null scenario (no SFPs):	**Alternative scenarios (where SFPs are introduced):**
Never users	Never users of any product
Current exclusive cigarette smokers	Current exclusive cigarette smokers
Former cigarette smokers	Current exclusive HTP users
	Current exclusive ECIG users
	Current Dual cigarette and HTP users
	Current Dual cigarette and ECIG users
	Former product users

In the *"NULL Scenario"* (Fig. 2), SFPs are never introduced, and there are only three cigarette smoking statuses which are updated annually. The methodology of how TPs for the Null scenario were developed is fully described in [6]. In each alternative scenario (Fig. 2), where SFPs are introduced during follow-up, the TPs allow for switching between seven groups (see alternative scenarios in the table above).

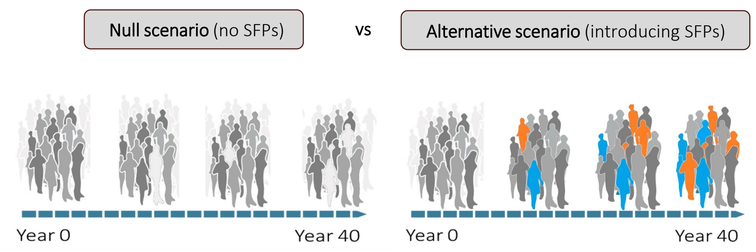


Fig. 2: Schematic representation of a hypothetical population with product use groups under NULL and alternative scenarios over a 40-year simulation period.

❑ Epidemiological Component

The epidemiological (E) component uses the tobacco use histories to estimate each product use group's relative risk of developing LC, IHD, stroke, and COPD compared to never tobacco users at each year of follow-up and for each scenario. The estimation involves an extension of the negative exponential model (NEM), described in detail for LC [10], COPD [11], IHD [12], and stroke [13], which allows for multiple changes in tobacco use habits.

NEM is used to calculate the excess relative risk over time t $(RR_t - 1)$ given the effective doses for HTP use, ECIG use, and Dual use (cigarettes + ECIGs and cigarettes + HTPs) relative to that for current cigarettes smoking, as well as estimates of the excess relative risk for a continuing cigarette smoker $(RR_{cc} - 1)$,and the disease-specific half-life of excess risk (H), with H being the time at which half the excess risk associated with continued cigarette smoking has disappeared [5]:

$$RR_t = 1 + (RR_{cc} - 1)\left(f + (1 - f)exp\left(\frac{-t\ ln(2)}{H}\right)\right)$$

For the alternative scenarios, the effective doses are assumed to be 0.2 for exclusive HTP use and 0.05 for exclusive ECIG use, in contrast to an effective dose of 1 for exclusive cigarette smoking [6]. For Dual use, it is assumed to be the mean of the two effective doses (0.6 and 0.525 for cigarettes + HTPs and cigarettes + ECIGs, respectively) [5, 6].

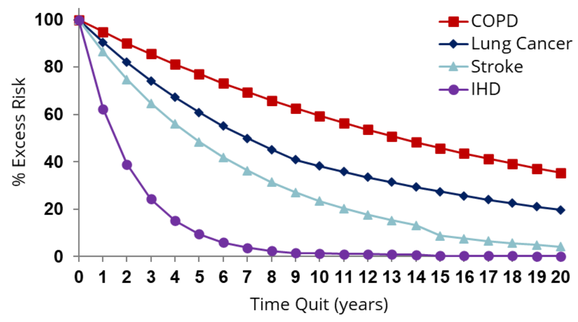


Fig. 3: Reduction in excess risk for four diseases as a function of time after quitting, as described by the NEM.

For each scenario, the average RR_t for each disease is calculated for individuals of a given sex and age group for each follow-up year, from which proportions of smoking-attributed deaths can be derived. These are converted to numbers using national mortality estimates by sex, age group, and year [5].

Model verification

Model is verified using smoking prevalence data collected from the ISTAT database:

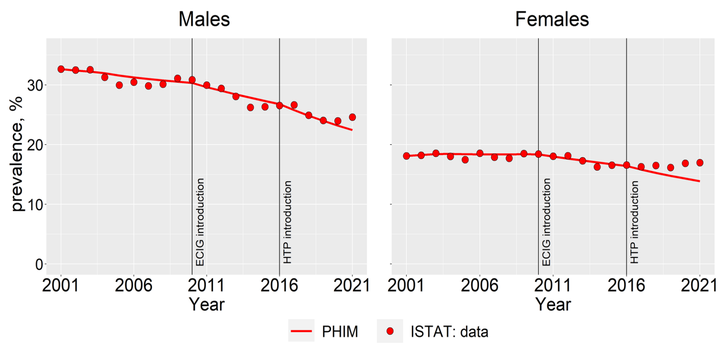


Fig. 4: Cigarette smoking prevalence collected from ISTAT database (red dots) and PHIM simulated results (solid lines). Vertical lines correspond to the years when ECIGs and HTPs were introduced on the Italian market.

Results: P-Component

NULL scenario is the scenario based on the smoking prevalence trend before any SFPs were introduced to the market.

Three simulated alternative scenarios (Figs. 5 & 6):

1. *ISTAT Scenario* was developed to satisfy historical trends of ECIG and HTP usage taken from the ISTAT database [2], where reported prevalences for ECIGs and HTPs in 2021 were 2.8% and 2.1% respectively (exclusive and dual use not distinguished).
2. *OssFAD Scenario* was developed to satisfy historical trends of ECIGs and HTPs usage taken from the OssFAD database [3, 4], where HTP prevalence in 2022 and 2023 were 3.3% and 3.7%, respectively.
3. *GRADUAL QUITTING Scenario* in which all SFP users from the ISTAT scenario transitioned to complete cessation upon entering the simulation, instead of continuing to use SFPs.

In *all* scenarios, ECIGs were introduced in 2010, and HTPs in 2016. For the period from 2021 to 2041, we assumed a continuation of the trends in smoking, HTPs, and ECIGs prevalences seen before 2021, considered in aggregates.

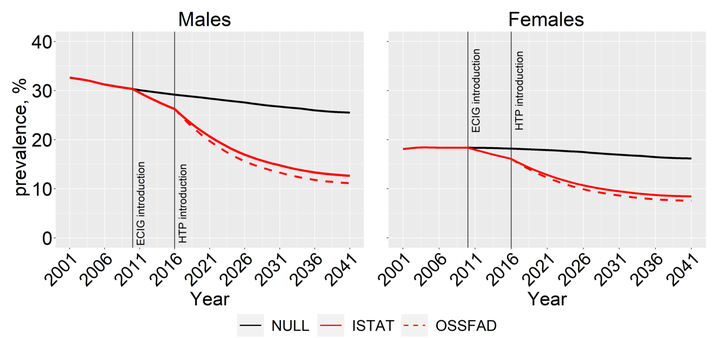
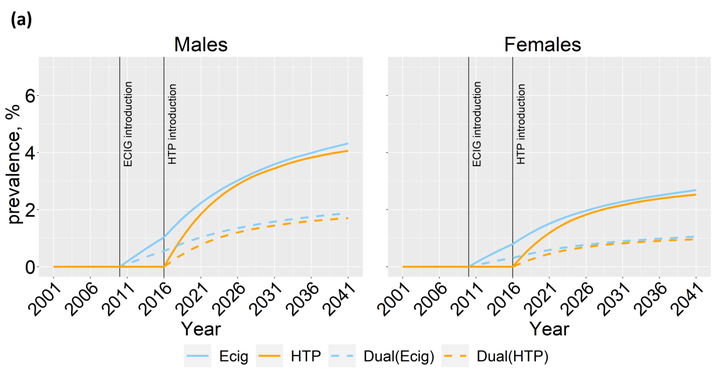


Fig. 5: Estimated cigarette prevalence in the *"NULL Scenario," "ISTAT Scenario,"* and *"OssFAD Scenario"* for males and females. Vertical lines correspond to the years when ECIGs and HTPs were introduced on the Italian market.



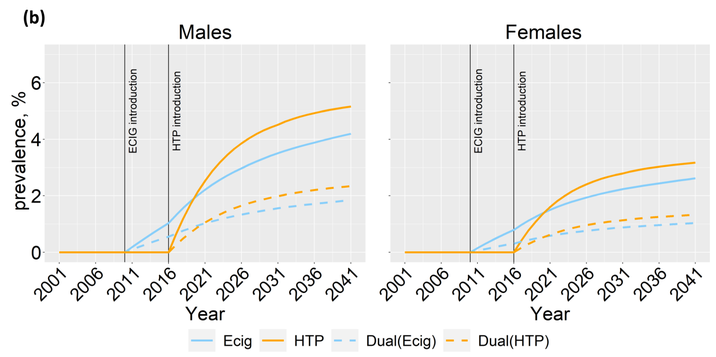


Fig. 6 Estimated prevalence of SFPs use, both exclusive and dual use of ECIGs and HTPs, for males and females, in "*ISTAT Scenario*" (a) and *"OssFAD Scenario"* (b). Vertical lines correspond to the years when ECIGs and HTPs were introduced on the Italian market.

Results: E-Component

Fig. 7: Drop in SADs (in thousands) and life years saved (in millions) for all four diseases and for both sexes, by "*ISTAT*" and "*OssFAD*" scenarios (ECIGs & HTP exclusive use only) compared to the Null. Vertical lines correspond to the years when ECIGs and HTPs were introduced on the Italian market.

Conclusions

The PHIM is used to estimate the long-term population health impact of introducing two SFPs, ECIGs and HTPs, into the Italian market. It provides insights into the level of public health benefits that could be obtained and how their introduction could influence the product use distribution in Italy and the mortality linked to four key smoking-related diseases.

Based on estimates of the rate of SFP uptake from two main Italian databases (ISTAT and OssFAD) and SFPs' effective doses compared with cigarettes, it is estimated that transitioning from cigarettes to ECIGs and HTPs in Italy would result in a substantial reduction in smoking-attributed mortality if the Italian population was to behave similarly to the different scenarios modeled in our study.

According to our findings, the introduction of SFPs— and encouraging smokers who would otherwise continue smoking cigarettes to switch to such products— would translate into a remarkable population health benefit in Italy, at least at the current rate of uptake.

Debates continue on whether existing policies and regulations, including those in Italy, should prioritize risk reduction as a minimum objective to decrease cigarette smoking rates.

Our results could be both informative and help in developing an integrated approach that considers adult smokers who otherwise would continue to smoke.

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