Establishing a Valid Model to Estimate the Impact of Introducing a Reduced Risk Product on the Population as a Whole

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Introduction

Philip Morris International (PMI) is developing products with the potential to reduce the risks of diseases associated with smoking cigarettes. In order to quantify the effect that marketing these products may have on the health of the population as a whole, PMI has developed a Population Health Impact Model (PHIM)[1]. The model uses publicly available data together with assumptions on product use and relative exposure of a Reduced Risk Product (RRP*) as compared with cigarettes and smoking cessation. The PHIM estimates the impact on smoking-attributable mortality, by calculating the smoking-attributable deaths in both the scenario with and without the introduction of the RRP.

To assess the performance of the PHIM, a verification was performed to test that the assumptions were properly implemented. The model was validated by testing if the assumptions produce reasonable estimates of a real population's smoking prevalence and mortality rates.

Methods

The model simulates the US smoking distribution and smoking attributable deaths during a 20-year period.

The simulated population of age- and sex-specific smoking distributions was based initially on the International Smoking Statistics (ISS)[2] data for 1990. Then the population was followed for 20 annual transitions using a set of "Smoking Transition Probabilities". Diseases-specific relative risk estimates derived from meta-analyses were used to generate the smoking attributable deaths for the age range of 30-79 years.

Data used to inform the simulation

- UN – US population estimates
- WHO – mortality estimates
- National Health Interview Survey – distribution of quit times
- PN Lee meta-analyses – disease-specific relative risk estimates

Data used to assess the results

- International Smoking Statistics[2] – smoking prevalence estimates
- 2014 US Surgeon General Report[3] – mortality estimates

Results

PHIM projections are consistent with the US population data, in terms of the distribution of smoking habits compared to the International Smoking Statistics estimates[2] of current and former smoking prevalence by sex, age and year.

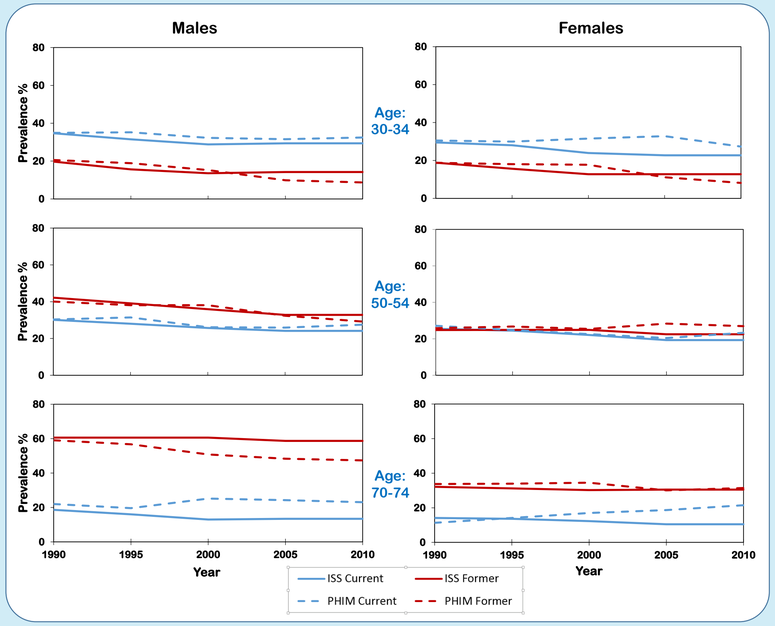

Figure 1. Comparison of Prevalance of Current and Former Smoking as Predicted by the PHIM and as Reported by International Smoking Statistics[2] by Sex and Year for Three Selected Age Groups, 30-34, 50-54 and 70-74

Results

Table 1. Comparison of Simulated 2009 Smoking-Attributable Mortalities with 2014 US Surgeon General Report (Years 2005-2009)[3]

		Proportion of Smoking Attributable Deaths (%)	
Disease	Sex	PHIM 2009	US Surgeon General 2005-2009
LC	M	77.2	83.7
	F	73.2	80.7
COPD	M	55.7	82.0
	F	49.8	75.7
IHD	M	21.6	28.2
	F	15.9	19.4
Stroke	M	14.3	15.3
	F	11.0	8.7

The proportion of deaths due to smoking for lung cancer (LC), ischaemic heart disease (IHD), stroke, and chronic obstructive pulmonary disease (COPD) are in line with the 2014 US Surgeon General Report[3].

Differences from the US Surgeon General Report were due to the fact that the Surgeon General Report includes deaths above the age 80, and different relative risk (RR) estimates.

- PHIM used RR estimates from comprehensive meta-analyses (*e.g.*, COPD RR=4.6)
- Surgeon General Report applied RR estimates from the Cancer Prevention Study II – higher for COPD and LC (*e.g.*, COPD RR=9.7-38.9)

Conclusions

The PHIM estimates are consistent with published data on smoking prevalence and smoking-attributable deaths. Differences from the specific sources of published data are explainable due to differences between the approaches (*e.g.*, high RR estimates for COPD and LC, including deaths above the age of 80).

The PHIM can be applied to a variety of tobacco use behaviors and the risks associated with different patterns of tobacco product use. Therefore it can be used to evaluate the population health impact associated with the introduction of an RRP while considering many different scenarios that may emerge once the product is marketed.

REFERENCES

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*Reduced Risk Products ("RRPs") is the term we use to refer to products with the potential to reduce individual risk and population harm in comparison to smoking cigarettes. PMI's RRPs are in various stages of development, and we are conducting extensive and rigorous scientific studies to determine whether we can support claims for such products of reduced exposure to harmful and potentially harmful constituents in smoke, and ultimately claims of reduced disease risk, when compared to smoking cigarettes. Before making any such claims, we will rigorously evaluate the full set of data from the relevant scientific studies to determine whether they substantiate reduced exposure or risk. Any such claims may also be subject to government review and approval, as is the case in the USA today.

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COMPETING FINANCIAL INTERESTS

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