

Can we still observe a net health benefit due to the introduction of modified-risk tobacco products (MRTPs) should the illegal trade in counterfeit cigarettes increase? A model perspective

Sylvain Larroque, Maurane Charrière, Michael Meger, JT International SA, Geneva, Switzerland

ABSTRACT

Since 2012 and the publication of the MRTP guidance by the US FDA encouraging the use of computational modelling, many robust dynamic models have been developed that are projecting net health benefits in the whole population after introduction of modified-risk tobacco products.

The purpose of this additional exploratory analysis is to evaluate what could be the computational impact when varying the size of the market in illegal counterfeit cigarettes, given the potential for these products to increase risk of harm versus legal cigarettes.

We developed and ran an average population modelling having the capability to differentiate relative risks between the legal and illegal counterfeit markets in combustible cigarettes, as well as the effect of MRTP availability.

NSDUH smoking prevalence and US census bureau demographics data were combined into the model from 2010 and computed until 2030. Status quo scenario (i.e. without any MRTP) as well as introduction of MRTP scenario from 2020 were tested and compared.

While the wide range of scenarios is still showing a beneficial health impact in the long run after introduction of MRTP, the analysis is showing that there are cut-off points in prevalence and harmful potential of the illegal trade counterfeit cigarettes beyond which no further benefits are observed (e.g., from figure 7 counterfeit cigarettes prevalence of 20% being 20% more harmful on average).

High prevalence of harmful illegal counterfeit cigarettes may have the potential to limit or even lower all foreseen benefits achieved through the introduction of MRTPs.

METHODS

Computational equation & algorithm (first order Markov process using SAS® Proc IML)

$$[\text{Status}_{ij}(y+1)] = [\text{Transition}_{ij}] * [\text{Status}_{ij}(y)] + [\text{Birth}_{ij}(y)] + [\text{Migration}_{ij}(y)]$$

where y: Year, i: Age & j: Sex

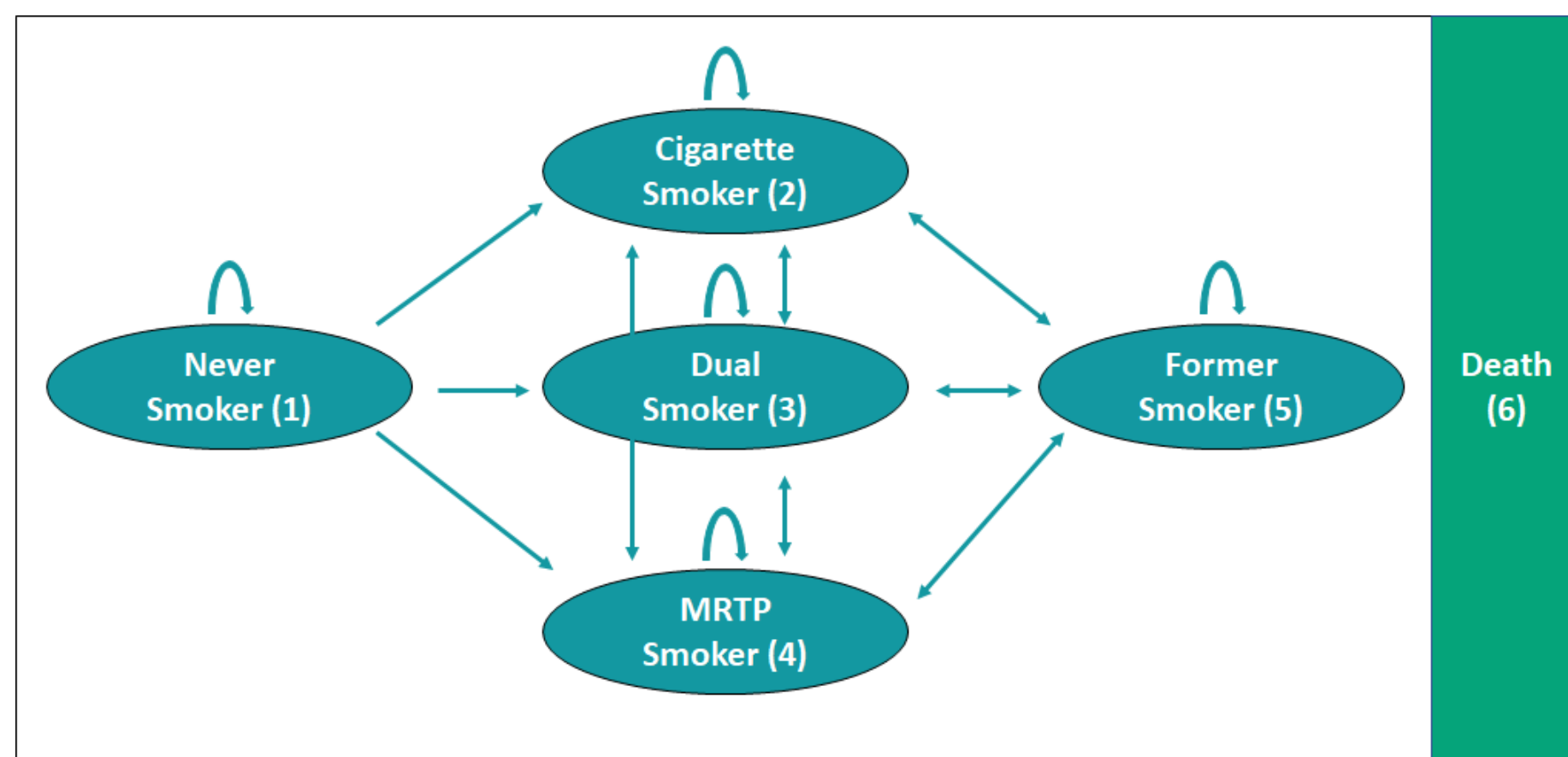


Figure 1: Tobacco use transition diagram. Six annual possible states for every individual are represented as bubbles with one- or two-sided possible transitions.

Transition from	Transition to					
	Never	Cigarette	Dual	MRTP	Former	Death
Never	P_{11}	P_{12}	P_{13}	P_{14}	0	P_{16}
Cigarette	0	P_{22}	P_{23}	P_{24}	P_{25}	P_{26}
Dual	0	P_{32}	P_{33}	P_{34}	P_{35}	P_{36}
MRTP	0	P_{42}	P_{43}	P_{44}	P_{45}	P_{46}
Former	0	P_{52}	P_{53}	P_{54}	P_{55}	P_{56}
Death	0	0	0	0	0	1

Figure 2: Mathematical transition matrix. For each Markov process step at year y, the vector representing the average number of people within the 6 status is multiplied by the transition matrix to form the new status vector at year y+1 before adding births and net migration.

Demographics

The Initial 2010 demographics population by age and sex was extracted from the March 2018 US Census Bureau issue of data. Annual birth and net migration rates were averaged from the total population using the same source. The death rates (status no. 6) by age and sex were modeled and interpolated from NCHS 2016 mortality data. Finally these assumptions data were slightly calibrated to obtain the best goodness of fit between the modeling and the US census bureau historical and projection of data during the 2010 to 2030 period.

Smoking status

The Initial 2010 current cigarette smokers' prevalence was extracted from the 2016 NSDUH retrospective data. Percentage of former smokers was scaled from NHIS available data to fit with NSDUH current smoking prevalence.

Relative Risk (RR) and Excess Relative Risk (ERR)

Current and former cigarettes' relative risks of mortality were averaged and set in the model (NCHS 2016). The relative risk for MRTP smokers which is product-specific, has been set here to reflect an averaged 10% Excess Relative Risk from cessation to cigarette smoker. Relative risk for dual smoker has been equally weighted between MRTP and cigarette smoker relative risks (assuming reduction of cigarettes per day).

Illegal trade of counterfeit cigarettes

In its report, "Preventing and Reducing Illicit Tobacco Trade in the United States" CDC is estimating 7%-21% of cigarettes consumed in US are purchased illicitly with a trend for increase over time. For the purpose of this exercise we did integrate the impact of the extent and harmfulness of illegal trade of counterfeit cigarettes within the global relative risk of cigarette smokers.

For example, the scenario with counterfeit cigarettes prevalence of 20% being 20% more harmful did result in an average relative risk of RR cig. [scenario] = (1 + 0.2*0.2) * RR cig. [base]

RESULTS

Demographics

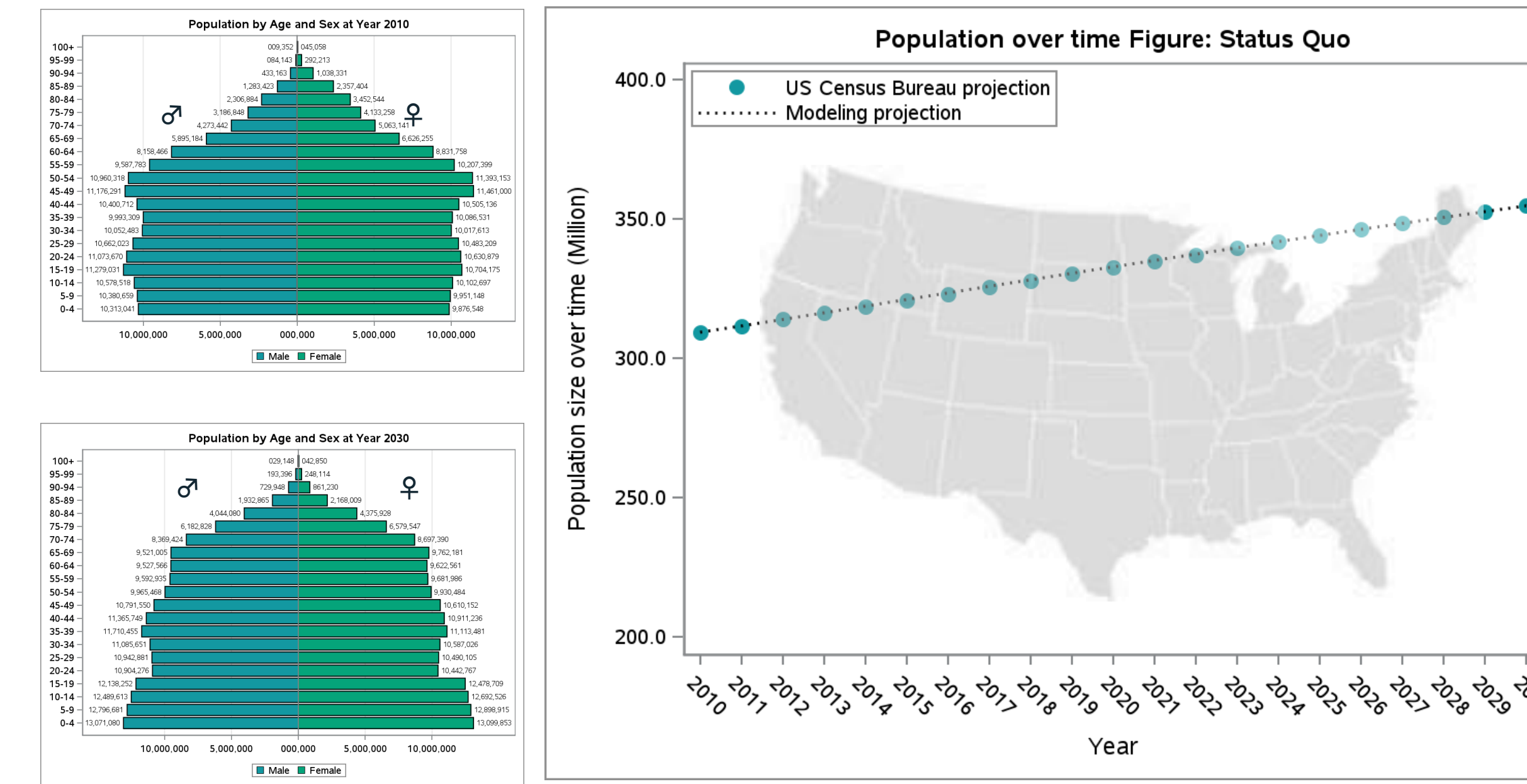


Figure 3: US population age pyramid, 2010 & 2030 for the observed and projected status quo scenario. Figure 4: Observed and projected US population, 2010-2030. From the US census bureau and modeled demographics data, population is ranging from an observed 309 millions in 2010 to a projection of 355 millions in 2030.

Smoking Prevalence

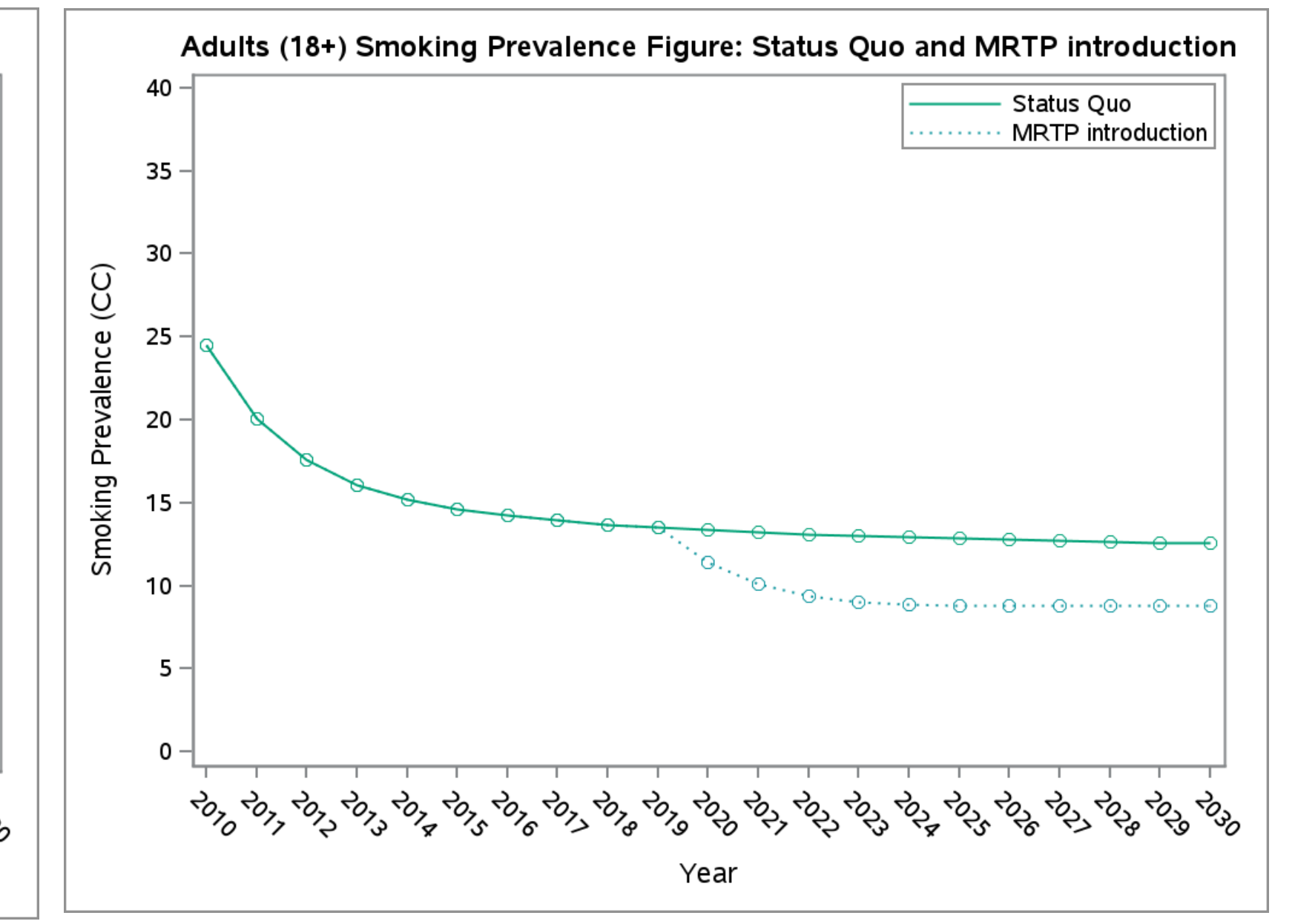


Figure 5: Projected US NSDUH adult cigarette smoking prevalence, 2010-2030. Adult cigarette prevalence is ranging from 24.5% in 2010 to a projection of 12.6% in 2030 for the status Quo scenario versus 8.8% for the scenario with MRTP introduction during 2020.

Cumulative difference in living population

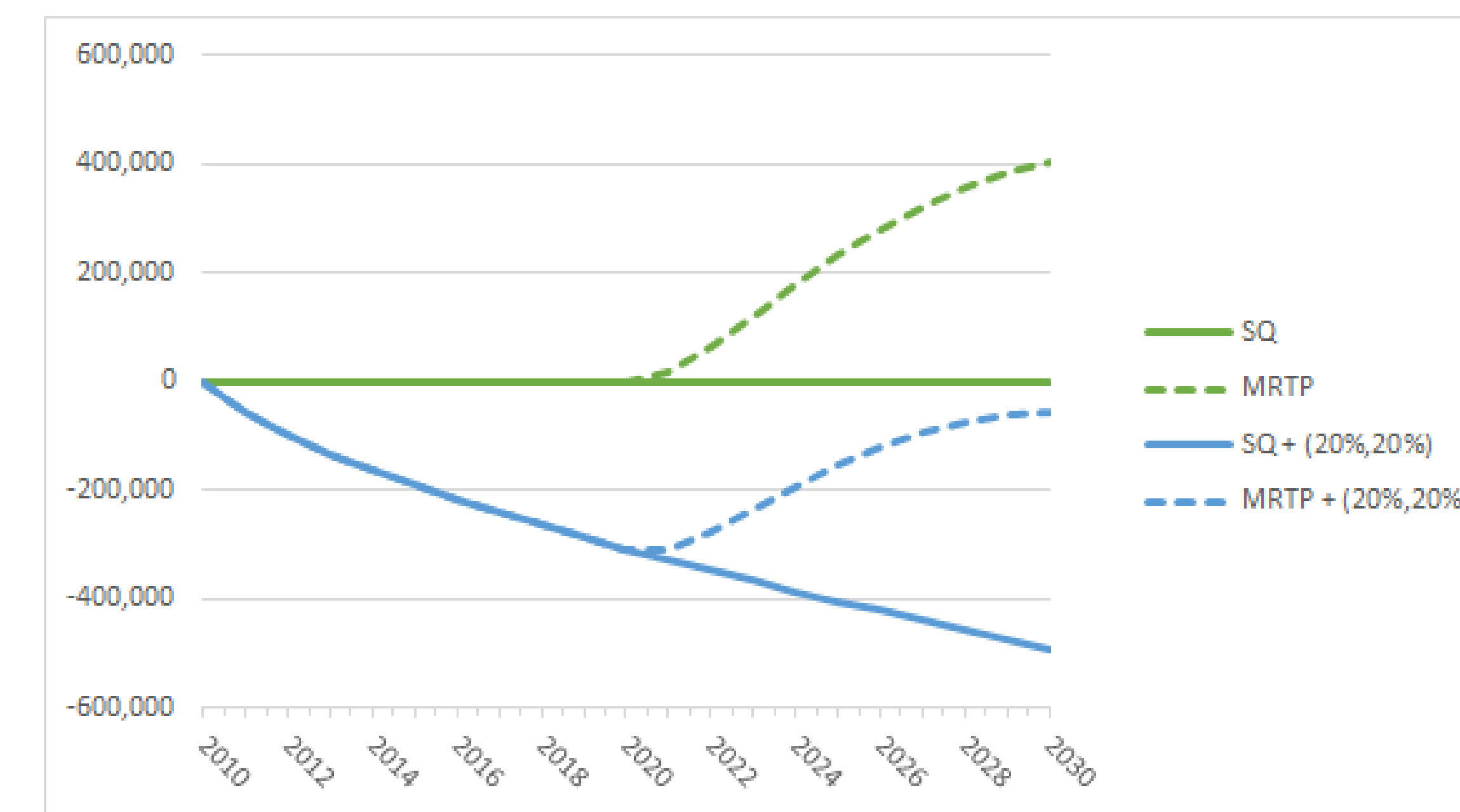


Figure 6: Cumulative difference in living population from the status quo scenario. Introduction of an MRTP in 2020 will lead to an estimated 404,000 life-year saved in 2030. Increase illegal trade prevalence of counterfeit cigarettes of 20% being 20% more harmful may lead to an estimated 492,000 life-year lost in 2030. And introducing MRTP within this scenario will still lead to an estimated 57,000 life-year lost in 2030.

Impact of illegal trade of cigarettes

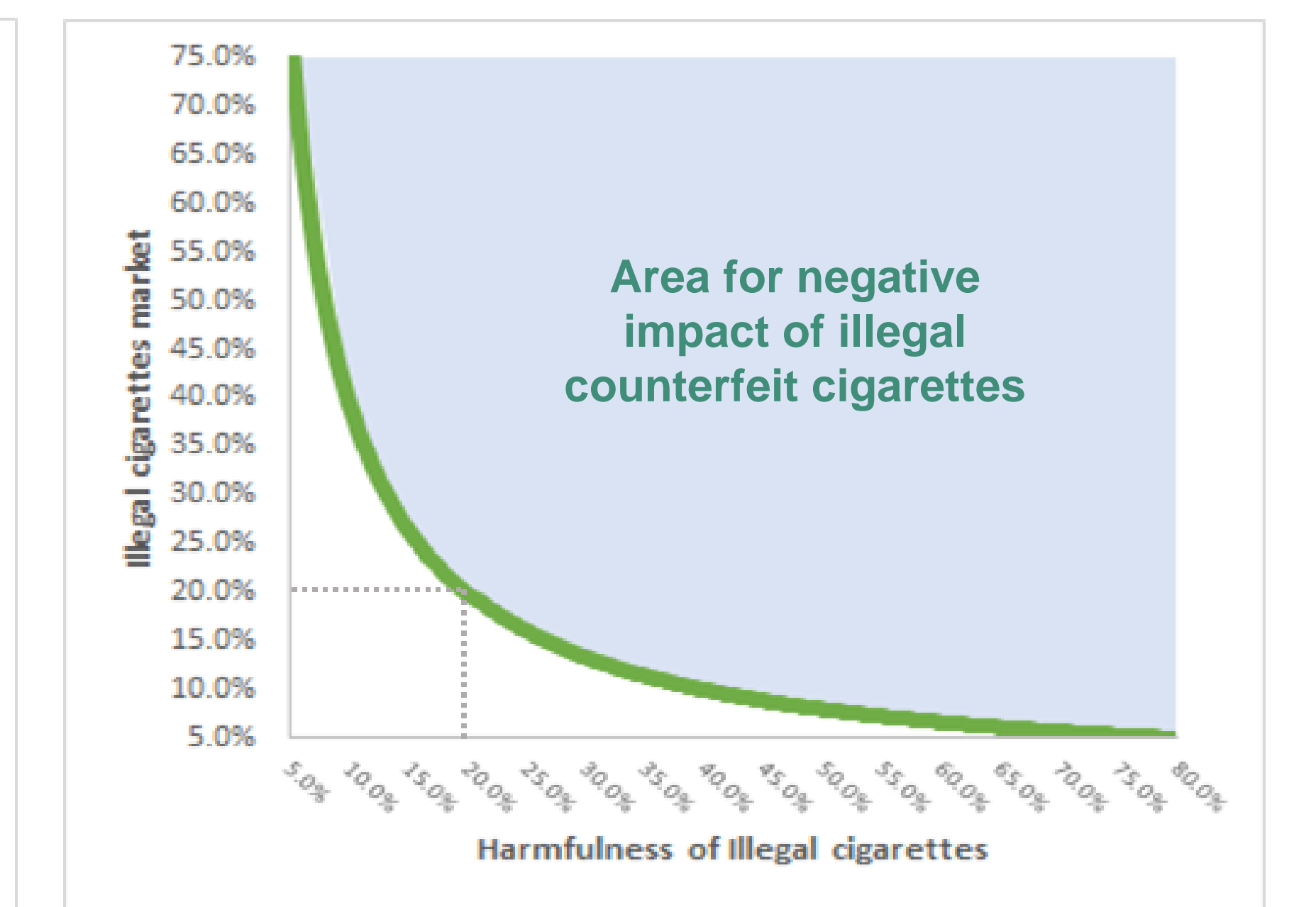


Figure 7: Impact of illegal trade of counterfeit cigarettes. The higher the prevalence of illegal trade and/or harmfulness of counterfeit cigarette the higher the probability to get a negative impact in number of living population.

DISCUSSION

Computational modeling is showing that counterfeit & harmful cigarettes may have the potential to limit all foreseen benefits after the introduction of an MRTP.

The illegal tobacco trade is a serious global problem and global tobacco companies are committed to support governments and law enforcement in their fight against it.

This model is showing good properties in fitting current US demographics and smoking prevalence projections and in being able to differentiate between legal and potential additional harm from illegal cigarettes. Sensitivities analyses by varying assumptions and/or by using Monte-Carlo re-sampling simulations can be run to draw confidence interval and show robustness of estimates.

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