Estimating the Potential Population Health Impact of Authorizing the Marketing of E-cigarettes in the US

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Abstract

Computational models can be used to assess the likely impact of introducing a new tobacco product on the U.S. population. We have developed and validated an Agent-Based model using best modeling practices, as recommended by the International Society for Pharmacoeconomics and Outcomes Research and the Society for Medical Decision Making. Our model quantitatively integrates an estimate of the relative risk of e-cigarettes (compared to conventional cigarette) and a range of potential changes in behavioral patterns to assess different scenarios to estimate the likely impact of introducing a new tobacco product on the population as a whole. The results are presented as estimated changes in tobacco use prevalence and all-cause mortality by assessing the difference in number of survivors comparing a Base Case (the current market, where cigarettes are the predominately used tobacco product) and a Modified Case (a new market where cigarettes and e-cigarettes are both available). Statistical models combined with likely excess relative risks (ERRs) were used to determine survival probabilities of current and former e-cigarette users. Nationally representative transition probabilities were obtained for the Base Case. The Modified Case transitions probabilities were estimated from a case study based on Wave 1 and Wave 2 data from the Population Assessment of Tobacco and Health (PATH) study which was designed to assess tobacco use transitions of non-users and established tobacco users. Employing these transition probabilities and an ERR value of 0.05 for e-cigarette use, we demonstrate a net benefit to the population through a reduction in mortality of ~ 600,000 lives , along with a reduction in cigarette smoking prevalence over a follow-up period of 60 years. Sensitivity analysis, varying the risk of e-cigarettes, a key input parameter, showed a decrease in the reduction in mortality as the ERR of e-cigarettes increased (i.e. ERRs (0.025 to 0.4) resulted in ~650,000 to 270,000 lives respectively). Population models are tools that can be used to predict the public health impact of changes in use of tobacco products with varying level of inherent risk on the population as a whole.

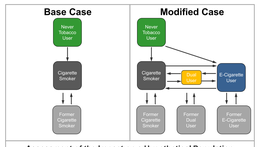
Introduction

- Computational models can be used to predict the likely impact of introducing a new tobacco product on the U.S. population.
- We have developed and validated a population model using best modeling practices to assess the overall population effects following a market authorization of an E-cigarette.
- In our model, agents form a hypothetical population in which they transit between different tobacco use states using defined transition probabilities. The set of attributes associated with each agent (e.g., age, gender, current use status, and tobacco use history) determines the path an agent may consider. Statistical mortality models combined with excess relative risks are used to determine the survival probabilities of an agent at each time step.

Table 1: Input Parameters, Source and Assumptions in the Modified Case Scenario

Parameter	Transition	Source	Assumptions
Proportion of never tobacco user who initiate cigarette smoking	NT → CS	PATH Analysis	
Proportion of never tobacco user who initiate Ecig use	NT→ ECIG	PATH Analysis	
Proportion of cigarette smokers who cessate (quit smoking) on an annual basis	CS → FS	CISNET	Represents long term cessation with no relapse
Proportion of cigarette smokers who initiate Ecig use and quit smoking on an annual basis	CS → ECIG-FS	PATH Analysis	
Proportion of cigarette users who transition to dual product use on an annual basis	CS → DU	PATH Analysis	
Proportion of Ecig users who cessate (quit Ecig use) on an annual basis	ECIG→ FECIG	CISNET	Long-term e-cigarette cessation would be similar to cigarette cessation
Proportion of Ecig users who initiate cigarette smoking and quit Ecig use on an annual basis	ECIG→ CS-FECIG	PATH Analysis	
Proportion of Ecig users who transition to dual product use on an annual basis	ECIG → DU	PATH Analysis	
Proportion of former cigarette smokers who initiate Ecig use on an annual basis	FS→ ECIG-FS	PATH Analysis	
Proportion of Dual users who quit smoking cigarettes and remain Ecig users	DU→ ECIG-FS	CISNET	Cessation of cigarettes when dual using occurs at the same rate as exclusive cigarette cessation
Proportion of Dual users who quit Ecig use and remain cigarette smokers	DU → CS-FECIG	CISNET	Cessation of Ecig when dual using occurs at the same rate as exclusive cigarette cessation
Proportion of Ecig users former cigarette smokers who quit all tobacco use.	ECIG-FS → FDU	CISNET	Cessation of the Ecig with former use of cigarettes occurs at the same rate as exclusive cigarette cessation
Proportion of cigarette smokers former Ecig users who quit all tobacco use.	CS-FECIG →FDU	CISNET	Cessation of cigarettes with former use of the Ecig occurs at the same rate as exclusive cigarette cessation
E-cigarette ERR is set to 5% , E-cigarette are introduced into the model in 2009, Long term cessation with no relapse- reflect successful smoking cessation for at least two years			

Methods



Outputs

Difference in tobacco use prevalence & all-cause mortality:

- Base Case (status quo; the current market, where cigarettes are the predominately used tobacco product) &
- Modified Case (where cigarettes and E-cigarettes are both available on the market)

Inputs

- **Mortality:**
  - Tobacco-related mortality was estimated from a Kaiser Permanente Medical Care Program Cohort study and adjusted for U.S. mortality rates in the year 2000 using data from the Human Mortality Database (HMDB).
  - Excess relative risk (ERR) of E-cigarettes use compared to smoking was 0.05 (i.e. a 95% reduction in risk compared to mortality risk of cigarettes) as determined by Nutt et al.
- **Base Case Transitions:** Reflects the 2000 US population in terms of age, gender, and smoking status and age & gender specific cigarette transition probabilities (i.e. Initiation & Cessation) (NHIS & CISNET).
- **Modified Case Transitions:** Transitions were estimated from a case study based on Wave 1 and Wave 2 data from the Population Assessment of Tobacco and Health (PATH) study which was designed to assess tobacco use transitions of non-users and established tobacco users (i.e. cigarette & E-cigarette users).
- The population is updated on a yearly basis over a 60 year time frame through birth and immigration (US Census).

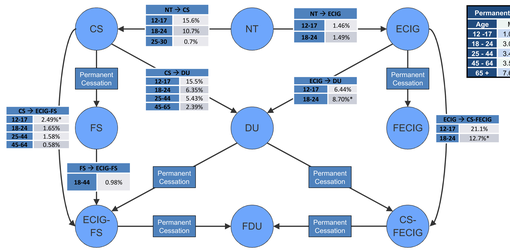
Assumptions

- Dual use (cigarette & E-cigarette use) were assigned the same mortality risk of exclusive cigarette use
- Transition probabilities for relapse behaviors are set to zero in the Base case, since cessation rates reflect successful smoking cessation for at least two years (CISNET)

Analyses

- **Modified Case Scenario:** the effect of all the most-likely changes in tobacco use patterns occur simultaneously (Table 1)
- **Sensitivity Analyses:** evaluating the effects of varying input parameters on the net population

Figure 1: Transition Probabilities Value Under the Modified Case Scenario



Statistical Suppression Rule

*Estimates are reported as statistical unreliable if the estimates have coefficient of variation greater than or equal to 30 but less than 50. Estimates are suppressed if the estimates are based on a sample size of less than 50, or coefficient of variation >=50.

Permanent Cessation= Long term cessation without relapse (i.e. reflects successful smoking cessation for at least two years)

NT = Never-Use of Tobacco *ECIG= E-cigarette User* *DU = Dual User*
CS = Current Cigarette Smoker *FECIG = Former E-cigarette User* *FDU = Former Dual User*
FS = Former Cigarette Smoker *CS-FECIG = Current Cigarette Smoker Former E-cigarette User* *ECIG-FS = E-cigarette User Former Smoker*

Results

Figure 2: Impact of Introducing E-cigarettes on All-cause Mortality between the Base case and Modified case under the defined scenario

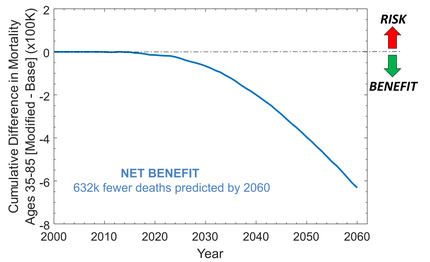


Figure 3: Impact of Introducing E-cigarettes on Product Prevalence under the defined scenario

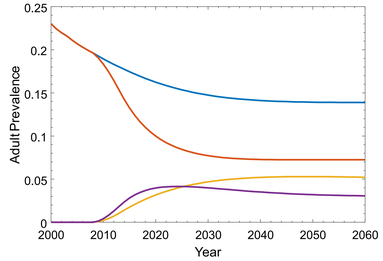


Table 2 : Product Prevalence

Product Use	2060 Prevalence
Base: Cigarettes	13.9%
Modified: Cigarettes*	7.2%
Modified: E-cigarettes*	5.2%
Modified: Dual Use	3.1%

*Exclusive cigarette and E-cigarette prevalence.

Figure 4: Cumulative Difference in All-cause Mortality between the Base case and Modified case under the defined scenario varying the ERR value

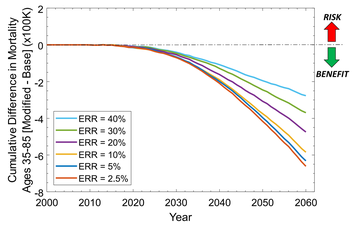
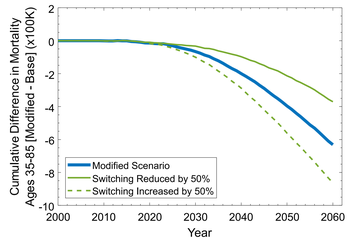


Table 3: Impact of varying the Excess Relative Risk (ERR) of E-cigarettes

Line Color	ERR	Total Reduced Mortality
	40%	277,000
	30%	369,000
	20%	475,000
	10%	584,000
	5.0%	632,000
	2.5%	611,000

Under the defined scenario a net benefit to the population can be observed even for an ERR of 40% for E-cigarettes.

Figure 5: Cumulative Difference in All-cause Mortality between the Base case and Modified case under the defined scenario varying the Cigarette to E-cigarette transition rate



Line Color	Varying Switching Rate	Total Reduced Mortality
	Increase by 50%	862,000
	Modified Case	632,000
	Increased by 50%	371,000

Conclusions

- Our model suggests overall net benefit of introducing E-cigarette into the US market, as indicated by likely reduction in smoking prevalence and a decreased mortality (632,000 deaths prevented) in the US population compared to the status quo.
- The sensitivity analysis indicates that relatively large changes to the ERR of an E-cigarette and cigarette smokers switching to E-cigarette predict a net benefit to the population under our defined scenario.
- As more real-world data on smoking/E-cigarette transition, initiation and cessation rates become available, we will further refine our assumptions to confirm a net impact of E-cigarette on the population as a whole.

References

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No conflict of interest