

TCORS 2.0 CAsToR Summer 2023 Symposium

Modeling the Potential Impact of Instantaneous versus Gradual Nicotine Policy Regulation on Smoking Associated Mortality

David Mendez, PhD

Thuy TT Le, PhD

Acknowledgments

- CAsToR support is provided by grant U54CA229974 from the National Institutes of Health, National Cancer Institute, and the Food and Drug Administration (FDA)
- Many thanks to the whole CAsToR team of investigators
- Nothing to disclose

Introduction

- The 2009 Family Smoking Prevention and Tobacco Control Act gave the Food and Drug Administration (FDA) the authority to regulate the amount of nicotine in combustible tobacco products to any level other than zero.
- In 2017, the FDA announced a plan to explore reducing nicotine in combustible tobacco to non-addictive levels.
- More recently, in 2022, the agency issued a public announcement renewing its intention to reduce nicotine in combustibles to non-addictive levels.

Introduction

- In a 2018 *NEJM* article, Apelberg et al. estimated that an instantaneous reduction in nicotine to non-addictive levels in 2020 would prevent 8.5 million smoking-related premature deaths, totaling 134.4 million life-years-saved by 2100.
- The article employed initiation and cessation rates estimated up to 2015.
- Since then, the background smoking initiation rate has continued to fall, and the cessation rate has increased.

Introduction

- Additionally, the FDA must evaluate several implementation timelines for potential regulatory action.
- While a published study (Hatsukami et al., JAMA 2018) found that immediate nicotine reduction in cigarettes produced a larger decline of biomarkers of smoke exposure compared to a gradual reduction, the implications of these findings at the population level have not yet been studied.

Study Objectives

- Develop estimates of the public health effect of a policy to reduce the nicotine levels in combustible to non-addictive levels using more current initiation and cessation rates.
- Evaluate the difference in effectiveness between an instantaneous and a gradual nicotine reduction policy.
- Evaluate the public health cost of delaying the reduction of nicotine in combustibles to non-addictive levels.

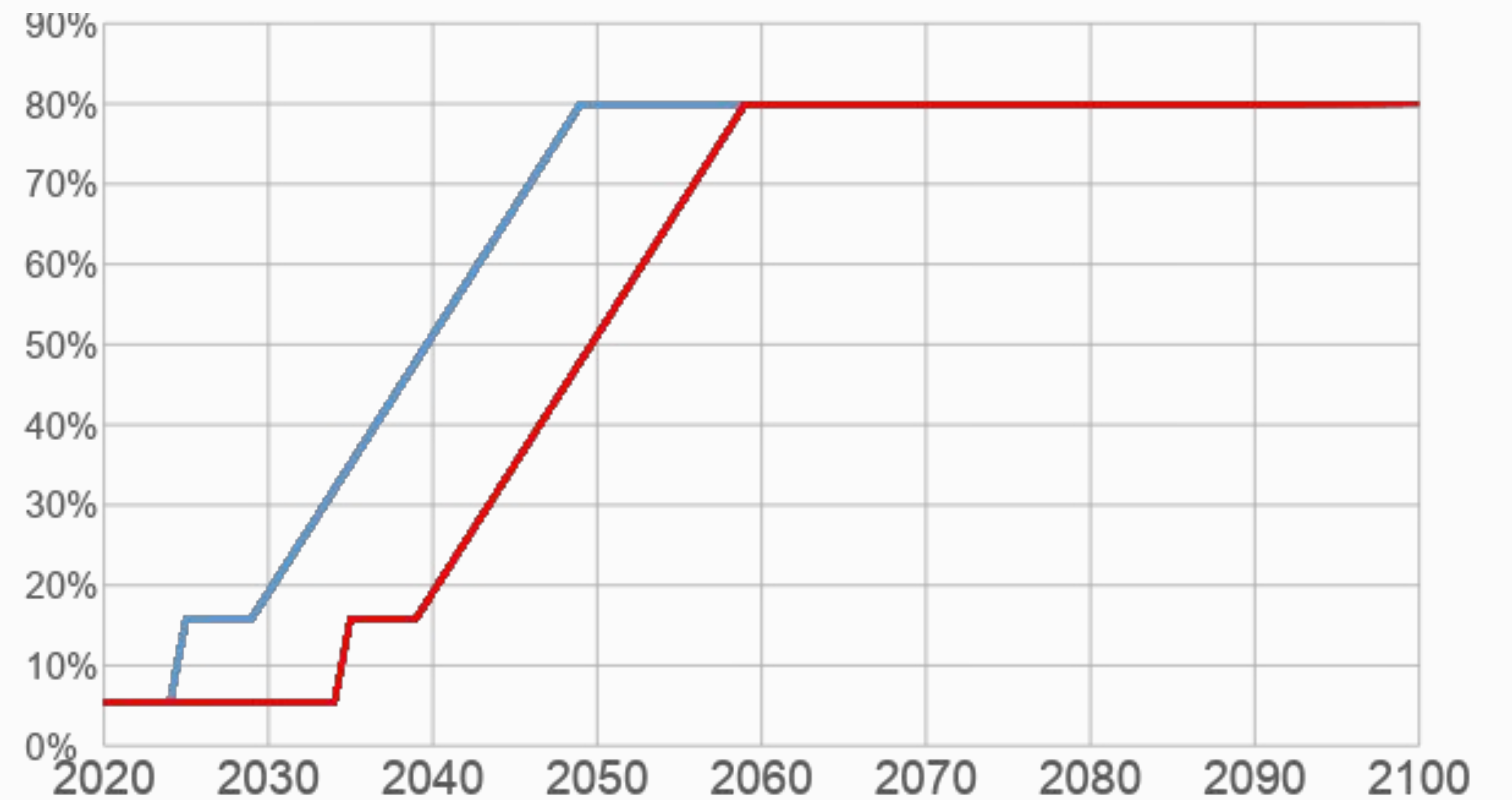
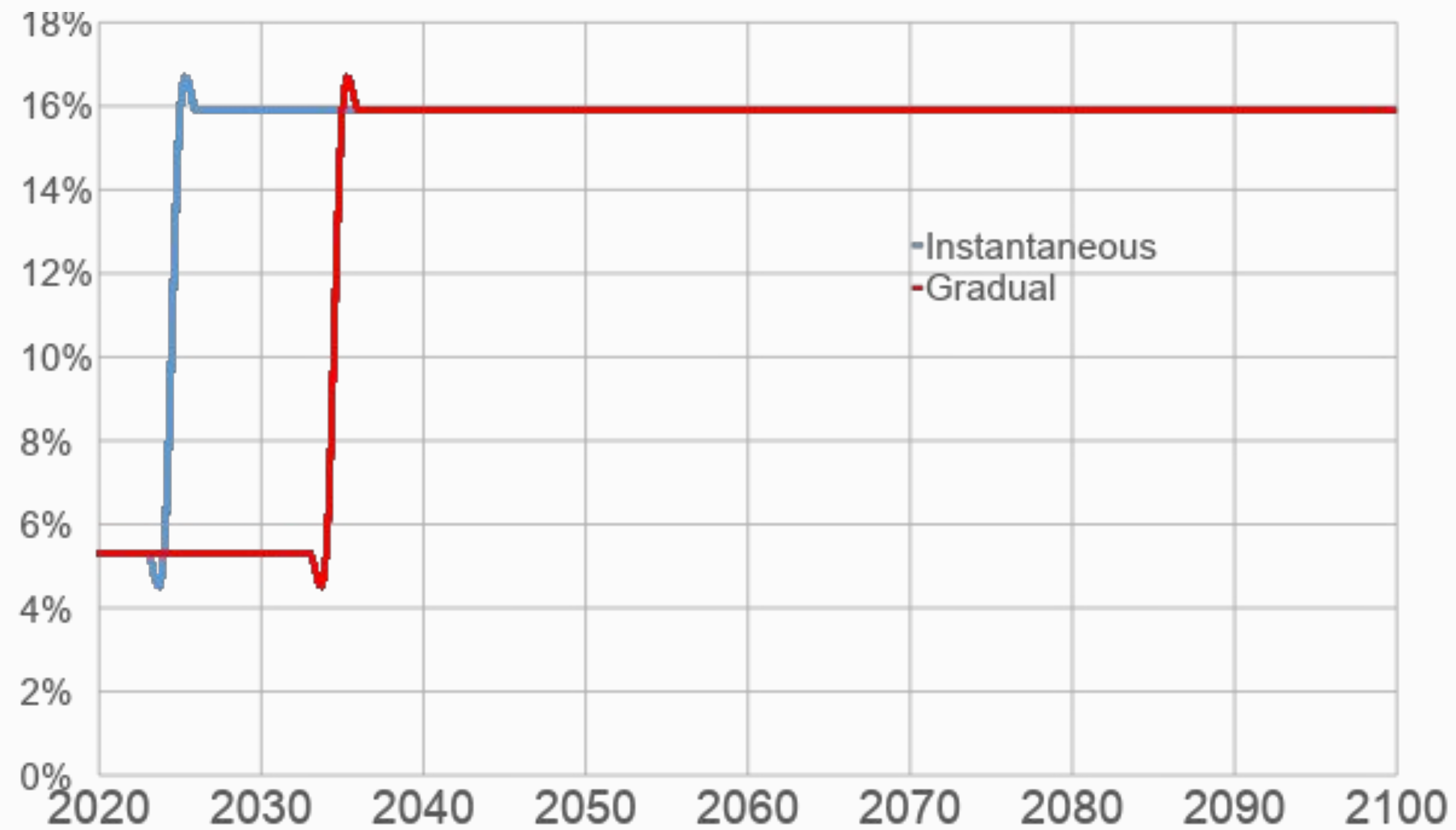
Methods

- We used a population-dynamics simulation model of smoking prevalence and health effects (the Mendez-Warner model) to calculate and contrast the cumulative mortality over 2025 – 2100 between an immediate and a gradual (over ten years) nicotine reduction regime.
- We parameterized the model with NHIS data and published results of RCTs of nicotine reduction and recommendations from an expert panel.

Methods

- We then performed a sensitivity analysis by simulating 40 different scenarios varying the effects of nicotine reduction in the smoking cessation rate (100%, 133%, 163%, 200% increase) and the persistence of those effects indefinitely, increasing to 80% cessation after 15 years, under five different background initiation rates (13%, 7.8%, 5%, 3%, and 0%).
- Each of the simulated scenarios consisted of two runs, depicting an immediate and gradual reduction of nicotine in cigarettes. We then reported the difference in cumulative mortality between the immediate and gradual runs for each scenario.

Cessation Rate Increases from 5.35% to 16.05% (3x) following Nicotine Reduction Implementation starting in 2025

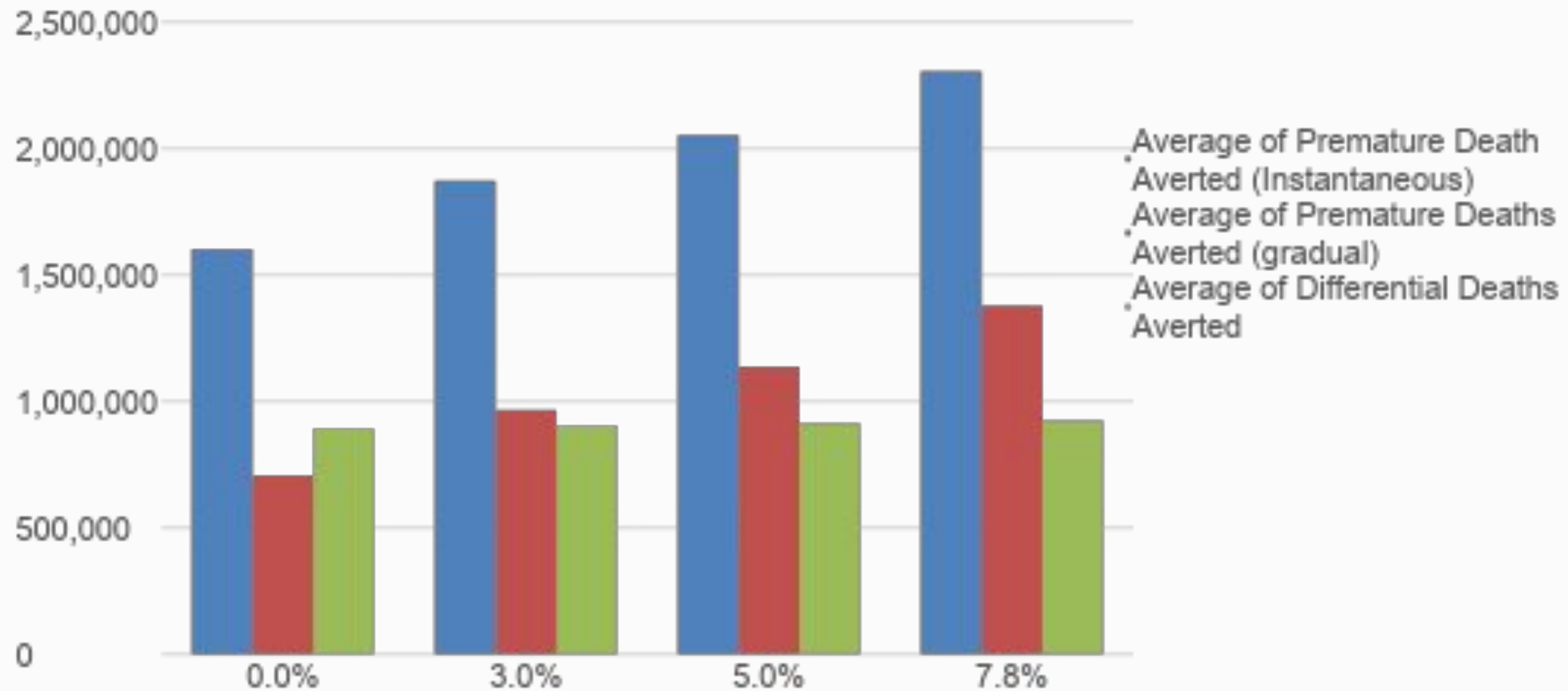


Results

Cessation Rates Double and Triple due to Nicotine Reduction

Initiation Rate	Cessation Rate	Life-years Saved (Instantaneous)	Life-years Saved (Gradual)	Difference in LYS	Premature Deaths Averted (Instantaneous)	Premature Deaths Averted (Gradual)	Difference in PDA
7.8%	5.35%-10.7%	28,688,573	15,771,880	12,916,693	1,748,550	1,042,409	706,140
7.8%	5.35%-10.7%-80%	40,910,571	22,748,496	18,162,076	2,432,058	1,465,937	966,121
7.8%	5.35%-16.1%	40,658,608	22,401,968	18,256,639	2,412,724	1,436,503	976,221
7.8%	5.35%-16.1%-80%	45,670,471	25,299,163	20,371,307	2,679,537	1,604,413	1,075,123

Results by Initiation Rate



Conclusions

- A nicotine reduction policy enacted in 2025 will prevent between 1.7 and 2.7 million premature deaths and 30-45M LYS by 2100 if current conditions persist.
- As cessation rates increase and initiation rates decrease, the policy will be less effective. If the adult initiation rate decreases from 7.8% to 5% by 2025, the policy will prevent around 2M premature deaths by 2100. This is, actually, a good outcome.
- A delay of 10 years in implementing the policy in 2025 will cost 700K-1M premature deaths and 12-20M LY by 2100.

Conclusions

- Time is of the essence. Only 37% of the smoking-related premature deaths between 2020 and 2100 can be prevented. Of those, our result shows that around 50% could be prevented by a nicotine reduction policy implemented in 2025.

THANK YOU

