Projecting the Maternal and Infant Health Impact of a Federal Nicotine Product Standard

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Introduction

Background

Prenatal smoking still affects **~3%[1] of U.S. pregnancies** and drives miscarriage, ectopic pregnancy, placental complications, eclampsia, and infant mortality; e-cigarette use during pregnancy has risen to **~5%[2].**

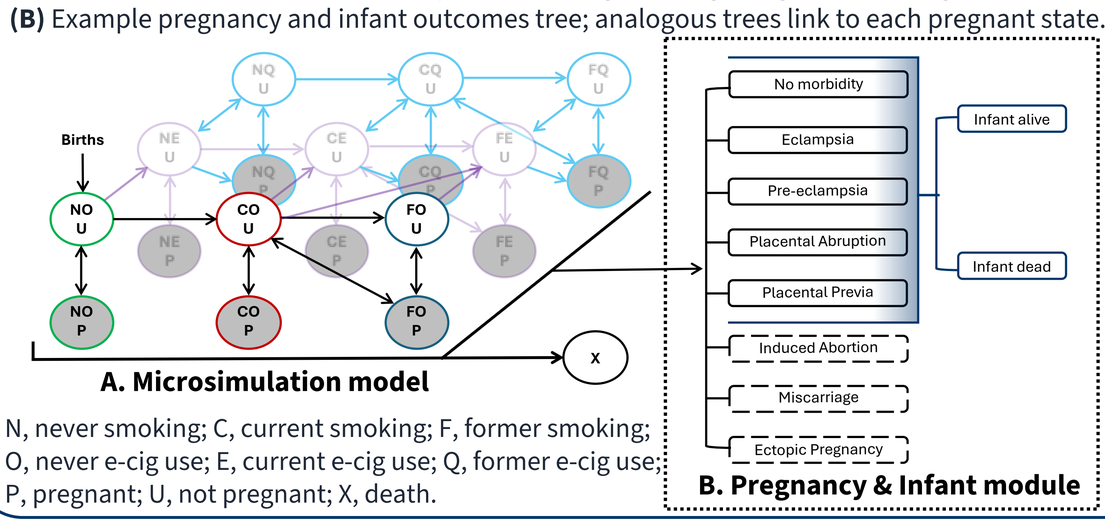
The FDA's proposed nicotine product standard has been modeled only for adult mortality, which leaves pregnant women, **an FDA-designated priority population,** outside the policy evidence base.

Research Objective

How much **maternal morbidity** and how many **infant deaths** would a federal nicotine product standard avert in the United States through 2100, and is the direction of impact robust to the **wide expert-elicitation uncertainty around policy response?**

Exhibit 1. SEP Model Structure

(A) State-transition microsimulation jointly tracking smoking, e-cig use, and pregnancy (SEP).
(B) Example pregnancy and infant outcomes tree; analogous trees link to each pregnant state.



N, never smoking; C, current smoking; F, former smoking; O, never e-cig use; E, current e-cig use; Q, former e-cig use; P, pregnant; U, not pregnant; X, death.

Between 2027 and 2100, a federal nicotine product standard is projected to avert ~60,000 infant deaths (~800/yr), ~1 million miscarriages (~13,500/yr), ~180,000 ectopic pregnancies (~2,400/yr), gain ~37,000 maternal QALYs (~500/yr), and save ~$4.7 billion in pregnancy-related medical costs.

Methods

Population & Study Design

- **U.S. females aged 15 to 49,** individual-based, annual-cycle microsimulation
- Simulation horizon: **2016 to 2100**
- **Policy implemented in 2027**
- **States:** Smoking (N / C / F) × E-cigarette use (O / E / Q) × Pregnancy (U / P).

Data Sources & Calibration

- **Transition probabilities:** CISNET[3] (smoking); PATH Study[4] (e-cigarettes)
- **Calibration:** NHIS 2014–2024 (general population); BRFSS 2016–2023 (pregnant women)
- **Maternal & Infant Outcomes:** NVSS Natality + Linked Birth–Infant Death files; NSFG + Vital Statistics

Policy Intervention

- Federal nicotine product standard capping combustible cigarette nicotine at minimally addictive levels
- Effect sizes anchored in **FDA expert elicitation[5,6]**
- Three scenarios bound expert-elicitation and structural uncertainty: Main, Pessimistic (worst-case), Optimistic (best-case). Comparator: Status quo (no-policy)

Outcomes *(cumulative from 2027 to 2100; healthcare-sector perspective; 2024 USD; 3% annual discount)*

- Smoking prevalence trajectories among pregnant women
- Averted cases: ectopic pregnancy, miscarriage, placenta previa, placental abruption, hypertensive disorders of pregnancy, eclampsia, infant deaths
- Maternal pregnancy QALYs gained and pregnancy-related medical costs avoided

Limitations

- Former smoking as a single state without stratification by time since cessation.
- Acute perinatal outcomes only: infants are not followed beyond the first year of life, and preterm birth, low birth weight, and longer-term child outcomes are not modeled.
- E-cigarette use was modeled indirectly through its effects on smoking transitions rather than as an independent risk modifier of pregnancy outcomes.

Results

Exhibit 2. Tobacco-use trajectories under a nicotine product standard

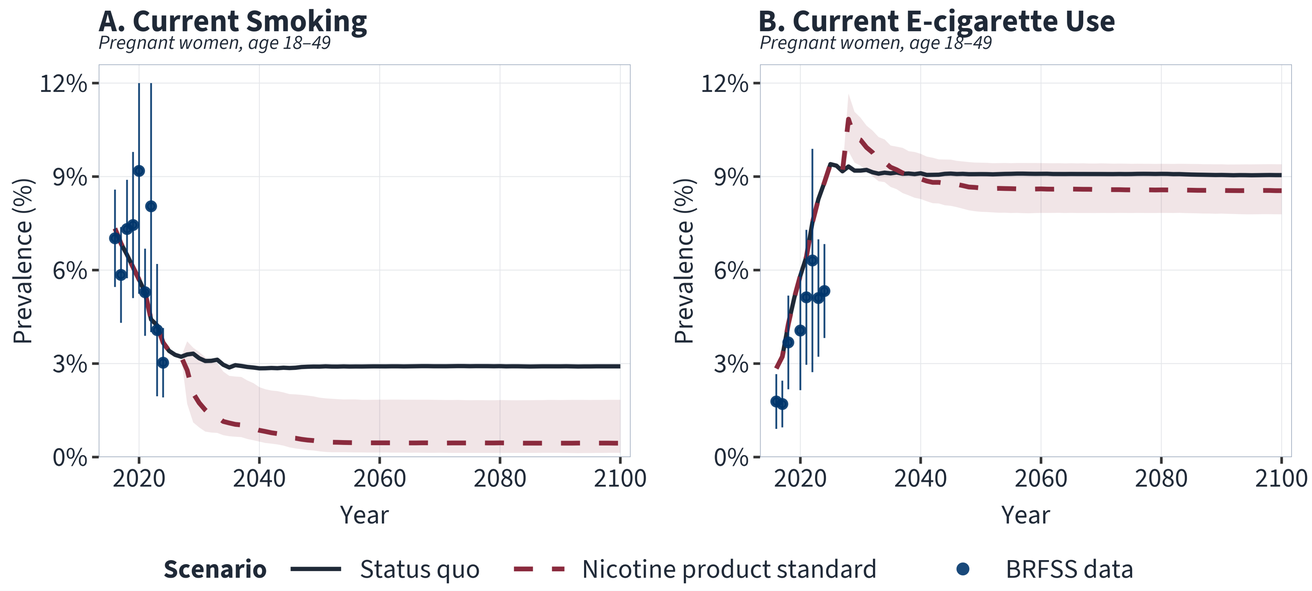


Exhibit 3. Averted maternal and infant outcomes vs. status quo

Main scenario; values in parentheses are pessimistic and optimistic scenario bounds

	By 2060	By 2100	Annual average
Infant deaths	**22,000** (9,000 – 28,000)	**60,000** (28,000 – 73,000)	**800** (400 – 1,000)
Miscarriages	**312,000** (153,000 – 419,000)	**997,000** (534,000 – 1,298,000)	**13,500** (7,200 – 17,500)
Ectopic pregnancies	**60,000** (33,000 – 78,000)	**180,000** (102,000 – 228,000)	**2,400** (1,400 – 3,100)
Hypertensive disorders of pregnancy	**52,000** (30,000 – 83,000)	**219,000** (126,000 – 317,000)	**3,000** (1,700 – 4,300)
Eclampsia	**3,000** (1,000 – 4,000)	**11,000** (6,000 – 14,000)	**150** (80 – 190)
Placental abruption	**19,000** (4,000 – 24,000)	**46,000** (15,000 – 54,000)	**600** (200 – 700)
Placenta previa	**4,000** (0 – 6,000)	**11,000** (3,000 – 13,000)	**150** (40 – 180)
Maternal pregnancy QALYs gained	**19,000** (9,000 – 26,000)	**37,000** (19,000 – 49,000)	**500** (280 – 660)
Pregnancy–related medical costs avoided	**$2.58 B** ($0.97 – 3.49 B)	**$4.73 B** ($2.12 – 6.21 B)	**$64 M** ($29 – 84 M)

Conclusion & Policy Implications

A federal nicotine product standard could avert ~60,000 infant deaths, ~1 million miscarriages, and ~219,000 hypertensive disorders by 2100, with ~$4.7B in pregnancy-related medical costs avoided. The direction of impact is **robust across every expert-elicitation scenario.**

SEP is the **first U.S. tobacco-policy microsimulation** to jointly model smoking, e-cigarette use, and pregnancy, closing the evidence gap for pregnant women, an FDA priority population.

It delivers a **decision-analytic platform** for evaluating current and future nicotine regulations against maternal-fetal endpoints under uncertainty. Future work will extend SEP to **education-level equity analyses** and refine e-cigarette-specific maternal outcomes.

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