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Cost-Effectiveness of the US Food and Drug Administration Added Sugar Labeling Policy for Improving Diet and Health

Editorial, see p 2625

Yue Huang, MS*
Chris Kypridemos, MD, PhD*
Junxiu Liu, PhD
Yujin Lee, PhD
Jonathan Pearson-Stuttard, BMBCh
Brendan Collins, PhD
Piotr Bandosz, MD, PhD
Simon Capewell, MD, DSc
Laurie Whitsel, PhD
Parke Wilde, PhD
Dariush Mozaffarian, MD, DrPh
Martin O'Flaherty, MD, PhD†
Renata Micha, RD, PhD†
Food-PRICE (Policy Review and Intervention Cost-Effectiveness) Project

BACKGROUND: Excess added sugars, particularly from sugar-sweetened beverages, are a major risk factor for cardiometabolic diseases including cardiovascular disease and type 2 diabetes mellitus. In 2016, the US Food and Drug Administration mandated the labeling of added sugar content on all packaged foods and beverages. Yet, the potential health impacts and cost-effectiveness of this policy remain unclear.

METHODS: A validated microsimulation model (US IMPACT Food Policy model) was used to estimate cardiovascular disease and type 2 diabetes mellitus cases averted, quality-adjusted life-years, policy costs, health care, informal care, and lost productivity (health-related) savings and cost-effectiveness of 2 policy scenarios: (1) implementation of the US Food and Drug Administration added sugar labeling policy (sugar label), and (2) further accounting for corresponding industry reformulation (sugar label+reformulation). The model used nationally representative demographic and dietary intake data from the National Health and Nutrition Examination Survey, disease data from the Centers for Disease Control and Prevention Wonder Database, policy effects and diet-disease effects from meta-analyses, and policy and health-related costs from established sources. Probabilistic sensitivity analysis accounted for model parameter uncertainties and population heterogeneity.

RESULTS: Between 2018 and 2037, the sugar label would prevent 354 400 cardiovascular disease (95% uncertainty interval, 167 000–673 500) and 599 300 (302 400–957 400) diabetes mellitus cases, gain 727 000 (401 300–1 138 000) quality-adjusted life-years, and save $31 billion (15.7–54.5) in net healthcare costs or $61.9 billion (33.1–103.3) societal costs (incorporating reduced lost productivity and informal care costs). For the sugar label+reformulation scenario, corresponding gains were 708 800 (369 200–1 252 000) cardiovascular disease cases, 1.2 million (0.7–1.7) diabetes mellitus cases, 1.3 million (0.8–1.9) quality-adjusted life-years, and $57.6 billion (31.9–92.4) and $113.2 billion (67.3–175.2), respectively. Both scenarios were estimated with >80% probability to be cost saving by 2023.

CONCLUSIONS: Implementing the US Food and Drug Administration added sugar labeling policy could generate substantial health gains and cost savings for the US population.

*Y. Huang and Dr Kypridemos are equal first authors.

†Drs O'Flaherty and Micha are equal senior authors.

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Clinical Perspective

What Is New?

- Using nationally representative data and a validated microsimulation model, we found that implementation of the Food and Drug Administration added sugar label would prevent 354 400 cardiovascular disease and 599 300 diabetes mellitus cases over 20 years, gaining 727 000 quality-adjusted life-years.
- Healthcare savings were $31 billion and societal savings $61.9 billion.
- The Food and Drug Administration policy was cost saving from both a healthcare and societal perspective.
- Potential health gains and cost savings would be twice as large accounting for corresponding industry reformulation, highlighting industry's critical role in maximizing the health and economic benefits of the Food and Drug Administration policy.

What Are the Clinical Implications?

- Food and Drug Administration's added sugar labeling policy could generate substantial health gains and cost savings for the US population, particularly if the new label stimulates industry reformulation.
- Compliance date for updating the Nutrition Facts label, including the added sugar provision, has been continuously delayed. Our findings highlight the need for timely implementation to maximize health and economic gains.

In May 2016, in the first major revision to the Nutrition Facts label since 1993, the US Food and Drug Administration (FDA) announced mandatory labeling of added sugar content as a strategy to reduce the intake of added sugars from packaged foods and beverages.[1] Overconsumption of added sugars, particularly from sugar-sweetened beverages (SSBs), is a risk factor for cardiometabolic diseases including obesity,[2,3] type 2 diabetes mellitus,[4,5] and cardiovascular disease (CVD).[4,6] These conditions pose substantial economic burdens, with total US direct and indirect costs of obesity-related diseases exceeding $1.4 trillion/y and expected to escalate.[7] Despite recent declines in added sugar intake in the United States, largely because of reduced SSB consumption,[8] current added sugar intake from SSBs and foods remains high: Americans still consume >300 kcal/day (>15% of total energy),[8] exceeding US guidelines of <10% of total energy.[9] The single largest source in the United States is SSBs, followed by grain desserts (eg, cookies, cakes, and pastries), fruit drinks, candy, and dairy desserts (eg, ice cream).[10] Considering that 52 000 annual US cardiometabolic deaths are attributed to SSB consumption alone,[4] cost-effective approaches to reduce added sugar consumption are a public health priority.

Food labeling supports informed consumer choice, and can effectively change consumer behavior and stimulate industry reformulation,[11] for example, as supported by recent experience with trans-fat labeling.[12] Yet, the health and economic impacts of the FDA's added sugar labeling policy have not been estimated. Even though some companies have already opted to implement the new label on their products,[13] the FDA recently announced another delay in mandatory implementation of the updated Nutrition Facts label until 2020.[14]

To elucidate the effects of implementing the added sugar label in the United States, a validated microsimulation model was used to estimate the potential cardiometabolic impact, costs, and cost-effectiveness of the FDA's added sugar labeling policy based on (1) expected changes in consumer behavior and (2) potential additional impact of the corresponding industry reformulation. This investigation was performed as part of the Food-PRICE Project (Policy Review and Intervention Cost-Effectiveness) (https://www.food-price.org).

METHODS

Study Overview

We extended the previously validated US IMPACT Food Policy model[15,16] to estimate the cost-effectiveness of the FDA's added sugar labeling mandate over a 20-year period (2018–2037), from both healthcare and societal perspectives. The model used nationally representative data on population demographics, risk factors, dietary habits, and diseases to assess cumulative cardiometabolic health outcomes and costs based on current trends. At each stage of the logic pathway, the best available sources (Table I in the online-only Data Supplement), supplemented with reasoned assumptions (Table II in the online-only Data Supplement), were used to estimate the potential health and economic consequences of the federal added sugar labeling policy. Data from the National Health and Nutrition Examination Survey (NHANES) were used to generate the simulated population and are publicly available.[17] The analytic methods, including elements of the model inputs, structure, and outputs are each described in further detail below and in Text I in the online-only Data Supplement, which includes Figures I through XIII in the online-only Data Supplement. The source code of the model is not publicly available. This modeling investigation was exempt from institutional review board review because it was based on public data and nationally representative, deidentified data sets that included no personally identifiable information.

FDA Added Sugar Labeling Policy Scenarios

We modeled 2 scenarios including (1) implementation of the FDA added sugar label on all packaged foods and beverages with no change in industry formulations (sugar label), and (2) implementation of the added sugar label plus further

accounting for corresponding industry reformulation (sugar label+reformulation). We compared these 2 scenarios with a counterfactual usual-care base-case scenario. In all scenarios, we assumed that the recently observed declining trends in added sugar consumption, particularly from SSBs, would continue in the future, providing a conservative estimate of the additional impact of sugar labeling.

Simulated US Population

To generate a US representative synthetic population of adults aged 30 to 84 years at baseline, the model used demographic information, body mass index (BMI) data, and added sugar intakes from the 2 most recent NHANES cycles (2011–2014).[17] Demographic information included age, sex, race/ethnicity (race), income, and education. Dietary intake included added sugar from SSBs and other foods, estimated based on two 24-hour dietary recalls per person as previously described (further details on dietary intakes are available in Text I in the online-only Data Supplement).[4,18] Population size by age, sex, and race and future population projections were derived from the Centers for Disease Control and Prevention Wonder Database (2014). To first create a static synthetic population, the model drew the traits of the synthetic individuals from conditional distributions that were estimated from multinomial models fitted in the NHANES data. The statistical framework of this method and its extension to epidemiological modeling have been described.[19,20] The model further projected recent trends in BMI and added sugar intake (from SSBs and other foods), as observed from NHANES 2003 to 2014, to evolve the traits of the model population individuals over time to create a dynamic synthetic population. For these projections we fitted generalized linear models to NHANES data by using inverse-probability weighting and design-based standard errors to account for the complex survey design and methods. A detailed description of the method and validation can be found in Text I in the online-only Data Supplement.

Policy Effects on Added Sugar Intake

A recent systematic review and meta-analysis of labeling interventions was identified as the best available evidence to estimate the effects of the FDA's labeling policy on added sugar intake.[11] Because no interventional studies on added sugar labels were identified, we extended the modest effect of labeling interventions on reducing calorie intake by 6.8% (95% CI, 4.5%–9.0%), with no heterogeneity identified by labeling type (eg, package labeling, menu labeling, and other point-of-purchase labeling) or population characteristics (eg, age, sex, race, and socioeconomic status).[11] This proportional effect on calories and its uncertainty were extended to the plausible percentage change in added sugar consumption, because this provided a more conservative effect size than the larger pooled effects of labeling on other additives such as sodium and trans fat. Consistent with the time period of interventional studies, we assumed the time lag between policy implementation and change in added sugar intake was less than a year, with the intervention effect sustained throughout the 20-year simulated period.

The potential for industry reformulation to reduce added sugars in foods, and subsequently population intake, were based on the FDA's regulatory impact analysis.[21] We assumed no reformulation in the first year of labeling implementation, with 7.5% to 9% of sugar-containing products being reformulated to achieve 25% reduction in added sugar content in these products each of years 2 to 5 of the intervention, and no additional reformulation thereafter. In sum, this represents an 8.25% net reduction in added sugar contents of US products over the 20-year intervention period (see Text I in the online-only Data Supplement for details on assumptions and calculations).

For both consumer effects and industry reformulations, we evaluated only the subset of added sugar in NHANES from packaged products that would carry a Nutrition Facts label, ie, sugars from supermarkets, convenience stores, and vending machines. We excluded added sugar consumed from other sources, eg, in restaurants and as sugar added by consumers.

Effects of Added Sugar Changes on Cardiometabolic Risk

Our detailed methods for reviewing and synthesizing evidence to estimate effect sizes for associations between dietary factors and cardiometabolic end points have been reported.[4,22] Considering harms linked to SSB consumption, in part, because of their liquid form, large dose, and rapid digestion in comparison with solid foods,[4,22] we separately evaluated the evidence from meta-analyses of long-term prospective cohorts or randomized clinical trials for associations of added sugars in SSBs versus other foods with cardiometabolic end points, including coronary heart disease (CHD), stroke, and diabetes mellitus (Figure 1).[4] The final model incorporated (1) associations of added sugars from SSBs and from other foods with BMI; (2) subsequent BMI-mediated effects on CHD, stroke, and diabetes mellitus; and (3) separate BMI-independent associations of added sugars from SSBs (but not from other foods) with CHD and diabetes mellitus (Table III in the online-only Data Supplement). These observed etiologic effects on how changes in added sugars influence BMI (and subsequent disease risk) also inherently account for the average dietary substitutes and complements in the population, and are more conservative than simply translating an observed caloric decrease to a reduction in BMI, as further described in Text I in the online-only Data Supplement.

We have published detailed validity analyses comparing the estimated etiologic effects of individual dietary factors on disease risk with findings from prospective studies of diet patterns and randomized control trials of diet patterns.[4,22] These analyses demonstrated that estimated etiologic effects for individual dietary components were very similar to what would be expected based on these other lines of evidence.[4,22] We assumed a median 1-year time lag from change in sugar intake to BMI and a median 1-year time lag from change in BMI to change in disease risk.

US IMPACT Food Policy Model Structure and Outputs

The extended US IMPACT Food Policy model is a stochastic dynamic microsimulation model that simulates the life course

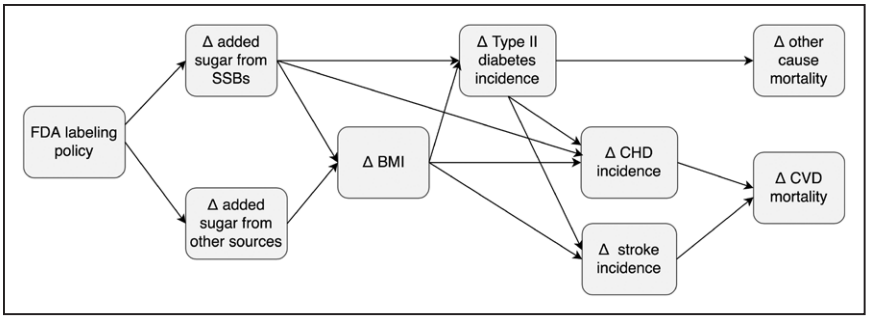

Figure 1. Etiologic pathway through which the US FDA added sugar labeling policy is translated into changes in disease burden. Considering harms linked to SSB consumption, in part, because of their liquid form, large dose, and rapid digestion in comparison with solid foods, etiologic effects on cardiometabolic outcomes were evaluated separately for added sugars in SSBs vs other foods.[6] BMI indicates body mass index; CVD, cardiovascular disease; FDA, Food and Drug Administration; and SSB, sugar-sweetened beverage.

of synthetic individuals under different policy scenarios.[23] In comparison with previous versions of the model,[15] it allows for more detailed and flexible simulation of food policies in a competing risk framework, taking into account individual heterogeneity and lag times between exposures and outcomes. The model first simulated the life courses of synthetic individuals aged 30 to 84 years under the base-case scenario and estimated their added sugar intake, BMI, incidence of type 2 diabetes mellitus, first episode of CHD or stroke, quality-adjusted life-years (QALYs), costs, and death from these diseases or any other cause on an annual basis. Then, it calculated the life courses of the same synthetic individuals under both labeling scenarios and generated annual estimated changes in each health outcome at the individual level (Figure 2).

CVD and type 2 diabetes mellitus outcomes were modeled as previously reported[23] and are fully described in Text I in the online-only Data Supplement. In brief, using a population-attributable risk approach, the model estimated the annual risks of the synthetic individuals aged 30 to 84 years to develop CHD and stroke based on their BMI, type 2 diabetes mellitus status, incidence rate forecasts, and etiologic effects of added sugar intake (Figure 2). Furthermore, the model calibrated the annual case fatality for CHD, stroke, and any other cause to the forecasted mortality rates, in a competing risk framework. Specifically, for any-other-cause mortality, we assumed that synthetic individuals with type 2 diabetes mellitus have higher mortality rates, to account for diseases other than CHD and stroke that were not explicitly modeled and are causally related to type 2 diabetes mellitus.[24]

Model outputs included the total numbers of relevant outcomes for the simulated population over the 20-year open cohort analytic period and estimated cases and deaths prevented or postponed (CHD, stroke [CVD], type 2 diabetes mellitus, or other), QALYs, life-years gained, and disaggregated costs. We calculated the health state utility values (preference weights) using published equations, which used EQ-5D-3L data from the Medical Expenditure Panel Survey 2000 to 2002.[25] Outputs were further stratified by age (30–49, 50–69, 70–84), sex (male, female), and race (non-Hispanic white, non-Hispanic black, Hispanic, and other).

Policy Costs

Policy costs included government administration and industry compliance/reformulation costs (Text I in the online-only Data Supplement). Government costs to administer, enforce, and evaluate the policy were estimated using FDA budget reports.[26] Industry costs to redesign and reprint the labels to comply with the labeling requirement and (for the sugar label+reformulation scenario) reformulation costs, including uncertainty, were derived from the FDA's regulatory impact analysis.[21] The FDA estimated industry reformulation costs by using a reformulation cost model developed by the Research Triangle Institute. This reformulation model accounted for variations in product formula complexity, company size, reformulation type, compliance period, and other factors, thereby producing a more accurate cost estimate than a standard per-product cost approach.

Health-Related Costs

The model evaluated formal health care (medical), informal care, and productivity costs for CVD (CHD and stroke) and type 2 diabetes mellitus, referred to collectively as health-related costs (Text I in the online-only Data Supplement). CVD medical and productivity costs per person per year were derived from an Research Triangle Institute report,[27] and CVD informal care (ie, unpaid caregiving) costs were estimated by using published data.[28,29] CVD productivity costs, which included workplace, home, and leisure time productivity losses, were divided into morbidity (living with diseases) and mortality costs (premature deaths). Medical and productivity costs for diagnosed and undiagnosed type 2 diabetes mellitus, and informal care costs for diagnosed type 2 diabetes mellitus, were derived from published sources.[30–32] All cost inputs were stratified by age and sex, with the exception of informal care costs. CVD costs were additionally stratified by race (Table IV in the online-only Data Supplement).

Statistical Analyses

Cost-Effectiveness Analyses

In accordance with recommendations from the US Second Panel on Cost-Effectiveness in Health and Medicine,[33] we conducted analyses from 2 perspectives. This included a (1) healthcare perspective incorporating policy costs and medical costs and (2) societal perspective further incorporating informal care costs and productivity costs. All costs were inflated to 2017 US dollars using the Consumer Price Index, and all costs and QALYs were discounted at 3% annually. Net costs were calculated as policy costs minus health-related costs from cardiometabolic diseases. Incremental cost-effectiveness ratios were calculated as the net change in costs divided by the net change in QALYs. Net monetary benefit was calculated by summing net costs (or savings, if negative), and further adding a monetary value of QALYs gained based on a willingness-to-pay threshold per QALY. For this calculation, we assumed a willingness-to-pay threshold of $100 000 per QALY and allowed it to vary in sensitivity analysis, consistent with

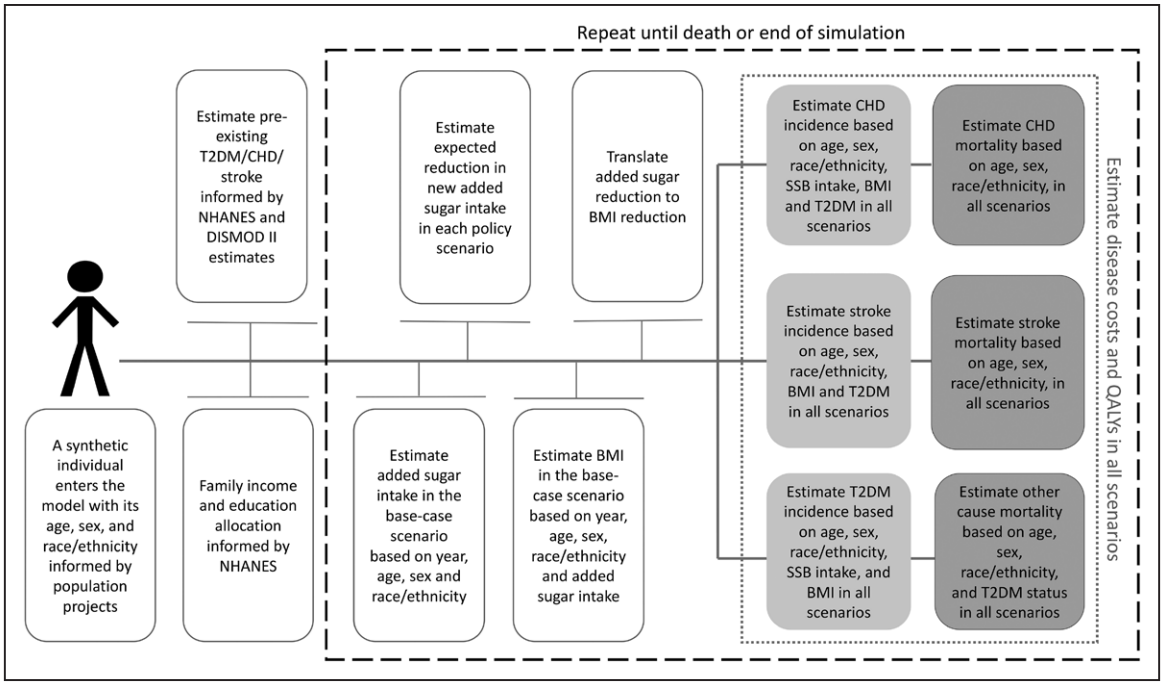

Figure 2. Simplified IMPACT model structure for estimating the cost-effectiveness of the US FDA added sugar labeling policy.
To generate a US representative synthetic population of adults aged 30 to 84 years at baseline, the model used demographic information, body mass index (BMI) data, and added sugar intakes from the 2 most recent NHANES cycles (2011–2014). Demographic information included age, sex, race, income, and education, and dietary intake included added sugar from SSBs and other foods, estimated based on two 24-hour dietary recalls per person. Population size by age, sex, and race and future population projections were derived from the CDC Wonder Database (2014). The model simulates first the life courses of synthetic individuals under the base-case scenario and estimates their added sugar consumption, BMI, incidence of type 2 diabetes mellitus (T2DM), the first episode of coronary heart disease (CHD) or stroke, quality-adjusted life-years (QALYs), costs, and death from these diseases or any other cause on an annual basis. Then, it calculates the life courses of the same synthetic individuals under both labeling scenarios and generates annual estimated changes in each health outcome at the individual level. CDC indicates Centers for Disease Control and Prevention; FDA, Food and Drug Administration; NHANES, National Health and Nutrition Examination Survey; and SSB, sugar-sweetened beverage.

American Heart Association/American College of Cardiology and Second US Panel recommendations.[33,34]

Sensitivity and Uncertainty Analyses

We used probabilistic sensitivity analysis via a second-order Monte Carlo approach that allowed the individual heterogeneity and estimated uncertainty of model parameters to be propagated to the outputs.[35] The sources of uncertainty considered included the NHANES sampling design (sampling error of baseline added sugar intake, BMI, and prevalent type 2 diabetes mellitus), the sampling error of the relative risks; the time lag between dietary intake change and change in disease risks; the uncertainty of mortality forecasts; the uncertainty around the true incidence of CHD and stroke; the uncertainty of policy effects; and the uncertainty of costs (Text I in the online-only Data Supplement). We summarized the output distributions by reporting the medians and 95% uncertainty intervals. We also plotted the annual probability that a scenario is cost saving over the simulation period. Discount rate and willingness-to-pay values were included in one-way sensitivity analyses and allowed to vary in steps between 0% and 9% and $50 000 and $150 000, respectively. To identify the threshold percentage change in added sugar intake that would render the policy cost-effective and cost saving, we performed additional one-way sensitivity analyses on the overall policy effect size of the sugar label+reformulation scenario, and allowed it to vary in steps between 0.5% and 6%.

RESULTS

Population Characteristics and Added Sugar Intake

Among packaged products, baseline mean added sugar intake was 60.6 g/day (59.9–61.2) and corresponding median intake was 37.3 g/day (36.7–37.8; Figure III in the online-only Data Supplement). Over 20 years without any new intervention, median added sugar intake was projected to decrease by 5.8 g/day (5.3–6.2; Figure III in the online-only Data Supplement). Conservatively accounting for those declining underlying trends, the sugar label scenario would reduce median added sugar intake by an additional 2.1 g/day (1.4–2.9), whereas the sugar label+reformulation scenario would reduce median added sugar intake by an additional 4.8 g/day (3.9–5.6).

Health Outcomes

Over 20 years, the sugar label scenario was estimated to prevent or postpone 354 400 new CVD cases (167 000–673 500), including 27 830 CVD deaths (9277–51 950); and 599 300 new type 2 diabetes mellitus cases (302 400–957 400) and 16 700 type

Table. Estimated Health Gains, Costs, and Cost-Effectiveness of the US FDA Added Sugar Labeling Policy Over 20 Years From 2018 to 2037

Health Outcomes and Cost-Effectiveness	Sugar Label (95% UIs)	Sugar Label+Reformulation (95% UIs)
Population in 2037 (million)	219.41 (216.43 to 221.97)	219.44 (216.46 to 222.00)
Health outcomes		
BMI in 2037, kg/m^2	28.58 (28.51 to 28.66)	28.53 (28.45 to 28.60)
CVD cases prevented/postponed	354 400 (167 000 to 673 500)	708 800 (369 200 to 1 252 000)
CHD cases prevented/postponed	330 300 (150 300 to 647 600)	666 100 (324 600 to 119 800)
Stroke cases prevented/postponed	24 120 (5566 to 57 520)	46 390 (14 840 to 102 100)
CVD deaths prevented/postponed	27 830 (9277 to 51 950)	50 100 (24 030 to 87 300)
CHD deaths prevented/postponed	25 980 (9277 to 50 100)	48 240 (22 270 to 85 350)
Stroke deaths prevented/postponed	1855 (–1855* to 5566)	1855 (–1855* to 7422)
T2DM cases prevented/postponed	599 300 (302 400 to 957 400)	1 184 000 (666 000 to 1 703 000)
T2DM-related deaths prevented/postponed	16 700 (3711 to 37 110)	31 540 (9277 to 61 230)
Life-years gained	298 700 (124 300 to 539 900)	532 500 (276 400 to 849 900)
QALYs gained	727 000 (401 300 to 1 138 000)	1 337 000 (847 900 to 1 905 000)
Change in health-related costs† ($ billion)	–63.69 (–104.91 to –34.36)	–117.63 (–179.87 to –72.44)
CHD medical costs	–11.74 (–24.76 to –4.73)	–22.21 (–44.05 to –9.67)
CHD mortality productivity costs	–10.89 (–24.80 to –3.38)	–20.84 (–41.22 to –8.02)
CHD morbidity productivity costs	–3.93 (–9.24 to –1.53)	–7.38 (–16.24 to –3.27)
CHD informal care costs‡	–3.10 (–7.19 to –1.30)	–5.81 (–12.64 to –2.58)
Stroke medical costs	–0.63 (–1.79 to –0.05)	–1.17 (–3.00 to –0.27)
Stroke mortality productivity costs	0 (–2.38 to 0.40)	–0.49 (–3.27 to 0.51)
Stroke morbidity productivity costs	–0.18 (–0.52 to –0.02)	–0.33 (–0.86 to –0.08)
Stroke informal care costs‡	–11.74 (–24.76 to –4.73)	–22.21 (–44.05 to –9.67)
T2DM medical costs	–18.14 (–33.00 to –8.28)	–33.05 (–55.37 to –16.61)
T2DM productivity costs	–11.71 (–21.02 to –5.40)	–21.44 (–35.66 to –10.71)
T2DM informal care costs‖	–0.36 (–0.74 to –0.12)	–0.62 (–1.17 to –0.26)
Change in policy costs† ($ billion)	1.68 (0.67 to 3.79)	4.32 (2.26 to 7.60)
Government administrative costs	0.02 (0.01 to 0.02)	0.02 (0.01 to 0.02)
Industry compliance costs	1.66 (0.64 to 3.78)	1.66 (0.64 to 3.78)
Industry reformulation costs	0	2.46 (0.93 to 5.35)
Total net cost from healthcare perspective§ ($ billion)	–31.01 (–54.53 to –15.74)	–57.62 (–92.42 to –31.89)
Total net cost from societal perspective§ ($ billion)	–61.92 (–103.26 to –33.07)	–113.25 (–175.21 to –67.33)
Net monetary benefit‖ (valuing QALYs at $100,000)	134.78 (74.96 to 217.27)	247.03 (155.96 to 363.94)
Incremental cost-effectiveness ratio¶ (2017 USD per QALY)	Dominant; (dominant to dominant)	Dominant; (dominant to dominant)

Health outcomes and costs were evaluated among US adults aged 30 to 84 years over a 20-year simulation period (2018–2037). Values are median estimates of each of 2000 Monte-Carlo distributions (95% UIs). Costs and QALYs were discounted at 3% annually. BMI indicates body mass index; CHD, coronary heart disease; CVD, cardiovascular disease; QALY, quality-adjusted life-years; T2DM, type 2 diabetes mellitus; UIs, uncertainty intervals; and USD, US dollars.

*Impacts on stroke may be negative in a competing risk framework, with the prevention of other diseases leading to more stroke deaths.

†Costs are median from 2000 Monte Carlo iterations so may not add up to totals. Negative costs represent savings. Costs are inflated to 2017 USD using the Consumer Price Index. Detailed health-related costs are available in Table IV in the online-only Data Supplement.

‡Informal care costs refer to unpaid caregiving costs. We conservatively excluded other informal healthcare costs such as transportation costs and patient time costs.

§Net costs were calculated as policy costs minus health-related costs from reduced cardiometabolic diseases. Healthcare perspective included policy costs and medical costs; societal perspective further incorporated informal healthcare costs and productivity costs.

‖Net monetary benefit was calculated by summing net savings and adding a monetary value of QALYs based on a $100 000 willingness-to-pay threshold per QALY.

¶Incremental cost-effectiveness ratios were calculated as the net change in costs divided by the net change in QALYs. Dominant = cost saving and more effective than the base-case scenario.

2 diabetes mellitus–related deaths (3711–37 110); overall gaining 727 000 discounted QALYs (401 300–1 138 000; Table, Figure IV in the online-only Data Supplement). Adding industry reformulation, health gains would be twice as large, preventing 708 800 CVD cases (369 200–1 252 000), 50 100 CVD deaths (24 030–87 300), 1 184 000 type 2 diabetes mellitus cases (666 000–1 703 000), and 31 540 type 2 diabetes

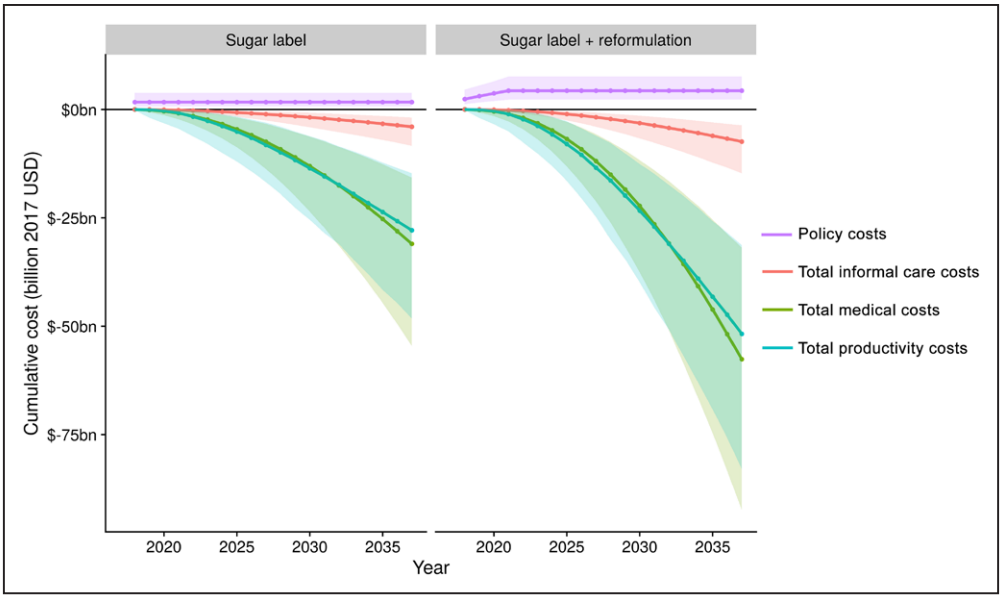

Figure 3. Projected policy and health-related costs for the US FDA added sugar labeling policy over the 20-year simulated period (2018–2037). Probabilistic sensitivity analysis via a second-order Monte Carlo approach estimated the uncertainty of model parameters and individual heterogeneity to be propagated to the outputs. Output distributions are summarized by medians (lines) and 95% uncertainty intervals (shaded areas). Policy costs included government administration and industry compliance/reformulation costs. Health-related costs included medical care, informal care, and productivity costs related to coronary heart disease, stroke, and type 2 diabetes mellitus (Table IV in the online-only Data Supplement). The shaded purple area depicts the uncertainty intervals for policy costs; the red area, for informal care costs; the dark green area, for the overlap between medical costs and productivity costs; the light blue area, for productivity costs alone; and the light green area, for medical costs alone. Negative costs represent savings. Costs were inflated to 2017 USD and discounted at 3% annually. FDA indicates Food and Drug Administration; and USD, US dollars.

mellitus–related deaths (9277–61 230); overall, gaining 1.3 million QALYs (0.8–1.9).

In both scenarios, absolute health benefits were larger in men than in women, reflecting both higher added sugar intakes (mainly from SSBs) and CVD burdens in men (Table V in the online-only Data Supplement). Estimated CVD and type 2 diabetes mellitus benefits were also higher among younger adults (30–49 years), reflecting their higher added sugar intakes (particularly from SSBs), whereas middle-aged adults (50–69 years) gained the most net QALYs (Table VI in the online-only Data Supplement). Although absolute health benefits were larger in whites (Table VII in the online-only Data Supplement), health benefits accounting for population size were greater among blacks, consistent with their higher added sugar intakes and higher baseline BMI.

Cost-Effectiveness

From a healthcare perspective, considering policy costs and medical costs, the sugar label scenario was estimated to save $31 billion (15.7–54.5) in total net costs from 2018 to 2037 (Table, Figure 3). The sugar label+reformulation scenario would generate substantially larger healthcare savings, at $57.6 billion (31.9–92.4). The majority (nearly 60%) of healthcare savings for both scenarios was driven by reduced type 2 diabetes mellitus medical costs. From a societal perspective, incorporating informal care and productivity costs, total net savings generated by the policies were about twice as large, $61.9 billion (33.1–103.2) for the sugar label scenario and $113.2 billion (67.3–175.2) for the sugar label+reformulation scenario. Policy costs were estimated at $1.7 billion (0.7–3.8) for the sugar label scenario (99% industry compliance, 1% government costs) and $4.3 billion (2.3–7.6) for the sugar label+reformulation scenario (40% industry compliance, 1% government costs, 59% industry reformulation). Despite substantially higher policy costs when industry reformulation costs were included, scenarios from both healthcare and societal perspectives were dominant (ie, both cost saving and gaining health in comparison with the base-case; Figure 4). Valuing each QALY at $100 000, the sugar label would generate $134.8 billion (75–217.3) in net monetary benefit, and the sugar label+reformulation, $247 billion (156–363.9). When assessed in the short term (5 years) and medium term (10 years), both scenarios were cost saving (Tables VIII and IX in the online-only Data Supplement).

Consistent with health gains, larger net savings would accrue in men than in women (Table V in the online-only Data Supplement), in middle-aged adults (50–69 years) versus other ages (Table VI in the online-only Data Supplement), and among whites versus blacks and Hispanics/others (Table VII in the online-only Data Supplement). Accounting for population size, estimated proportional savings were larger among men, middle-aged adults, and blacks.

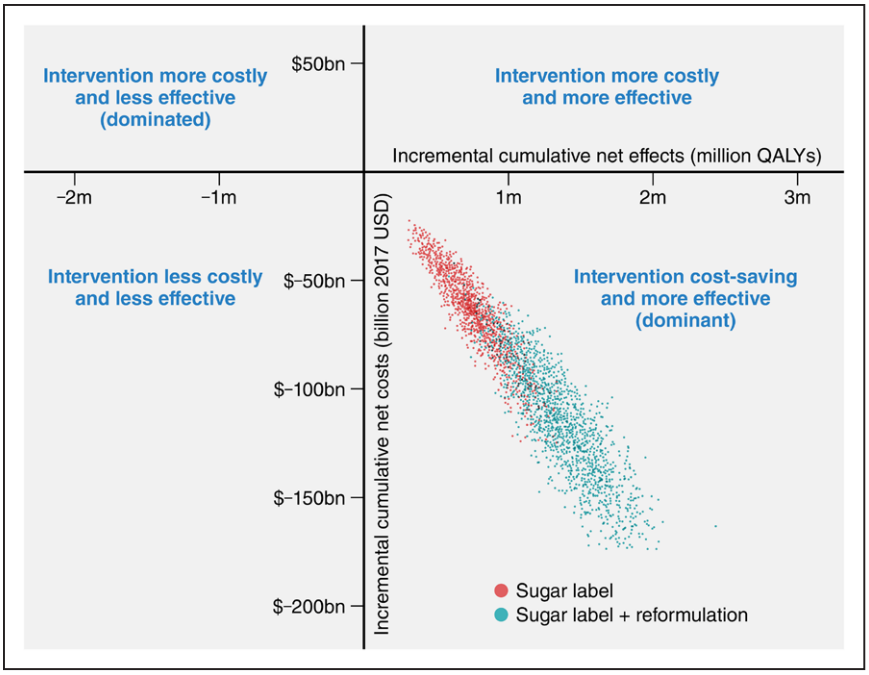

Figure 4. Cost-effectiveness plane for the US FDA added sugar labeling policy by the end of the 20-year simulated period (year 2037).
Each colored dot is the result of each of 2000 Monte Carlo iterations. Large dots are median combinations of cumulative discounted net costs (2017 USD) and discounted net QALYs for each simulated scenario, and ellipses depict 95% uncertainty intervals. Negative costs represent savings. bn indicates billion; FDA, Food and Drug Administration; m, million; QALYs, quality-adjusted life-years; and USD, US dollars.

Probabilistic and Sensitivity Analyses

We estimated a probability of near 100% that the policy would become cost-effective within 5 years (by 2023) for both scenarios, and cost saving within 7 years (by 2025). In addition, both scenarios would have >80% probability of being cost-effective within 4 years (by 2022), and cost saving within 5 years (by 2023; Figure 5). In one-way sensitivity analyses, net monetary benefit remained positive when willingness-to-pay was varied down from $100 000 to $50 000 per QALY, and when annual discount rates were varied up from 3% to 9% (Tables X and XI in the online-only Data Supplement). In one-way sensitivity analyses of the policy effect in the sugar label+reformulation scenario, as low as a 1% reduction in added sugar intake could be cost saving over the 20-year simulation period, whereas a 0.5% reduction could be cost-effective, but not cost saving over the same period (Figures V and VI in the online-only Data Supplement). Table XII in the online-only Data Supplement presents model estimates for the base-case scenario.

DISCUSSION

Using nationally representative data, our microsimulation study suggests that implementing the FDA added sugar labeling policy would generate substantial health gains and produce net cost savings for both the healthcare system and society overall. Over 20 years, the model predicted that the effects of the added sugar label on consumer behaviors could gain >700 000 QALYs, whereas further accounting for anticipated modest ef-

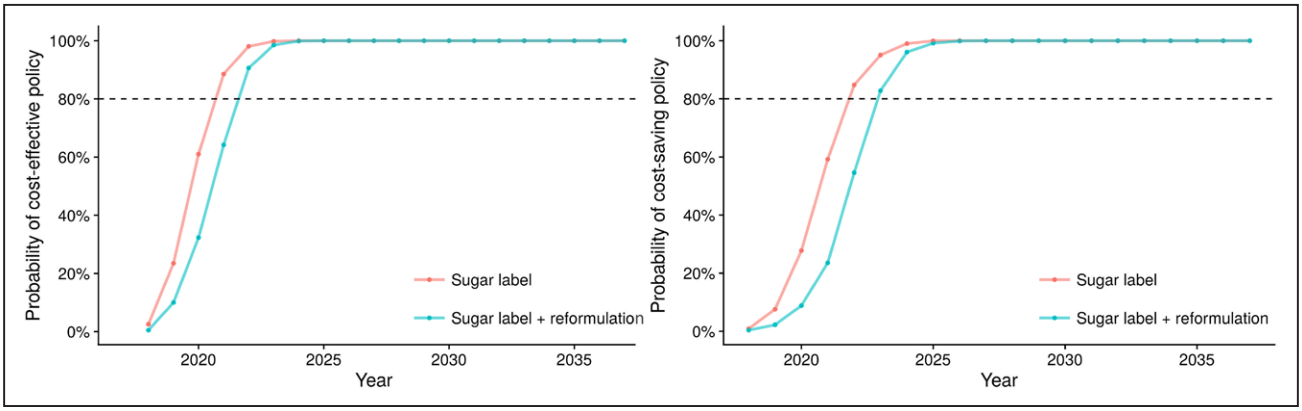

Figure 5. Estimated probability of cost-effective and cost saving of the US FDA added sugar labeling policy over the 20-year simulated period (2018–2037).
Probabilities for cost-effectiveness and cost saving of the FDA added sugar labeling policy in comparison with the base-case scenario were estimated via a second-order Monte Carlo approach, with willingness-to-pay threshold being valued at $100 000 per quality-adjusted life-year (QALY). FDA indicates Food and Drug Administration.

fects on industry reformulation could gain a total of 1.3 million QALYs. Both scenarios were cost saving, with the label on consumer effects alone generating >$30 billion in healthcare savings and >$60 billion in societal savings. Cost savings would be twice as large when accounting for potential modest industry reformulation, highlighting industry's critical role in maximizing the health and economic benefits of the FDA policy.

The economic burdens of cardiometabolic diseases are staggering, with direct and indirect diabetes mellitus costs estimated at $245 billion/y[30] and corresponding CVD costs at $555 billion/y.[36] Suboptimal diet is a leading and preventable cause for cardiometabolic mortality and morbidity, with overconsumption of added sugars being a significant risk factor.[4] Our results indicate that the implementation of the FDA's added sugar labeling policy to the Nutrition Facts label could substantially reduce US cardiometabolic disease and economic burdens, mainly through reductions in type 2 diabetes mellitus incidence and related deaths.

Of all sources of added sugar in the US diet, SSBs are the largest contributor and most consistently linked to cardiometabolic risk.[22] Several population-based strategies have been proposed or implemented to target SSBs, including taxation,[37] health warning labels,[38] and restriction of SSB purchases within food assistance programs such as SNAP (Supplemental Nutrition Assistance Program).[39] Previous studies have modeled the health and economic impacts of these strategies,[37,40,41] including our own work demonstrating the cost saving potential of a nationwide tax on SSBs[42] and of restricting or disincentivizing SSB purchases within SNAP.[39] Despite these ongoing efforts, added sugar intake in the United States remains high.[8] Declaring added sugar content on the Nutrition Facts label, together with the percentage of Daily Value to help consumers contextualize such information, is a key policy opportunity to target not only SSBs, but all added sugar from all packaged products.

Combined approaches to target added sugar appear especially promising. Added sugar labeling can be complemented by government-led reformulation strategies and consumer education, which together can help to level the playing field for industry and to gradually change public taste preference.[43] For example, the United Kingdom has introduced a front-of-package labeling scheme that includes sugar content[43] in combination with nationwide SSB taxes and voluntary industry sugar reformulation targets.[44] Nonetheless, targeting added sugar alone will not prevent all obesity and cardiometabolic diseases, and there is a need for complementary policies to improve overall dietary patterns. Such multicomponent policies targeting sugar, and other dietary factors, as well (eg, fruit and vegetables, sodium), have been implemented in countries such as France[45] and Chile.[46] Our recent study modeling several policy changes within SNAP found that combining incentives for purchasing healthier foods (fruits, vegetables, nuts, whole grains, and seafood) with disincentives for purchasing unhealthy foods (SSBs, junk food, and processed meats) produced the largest health gains and cost savings.[39]

In comparison with some other types of dietary policies, labeling policies can have the added advantage of stimulating industry reformulation,[11] the potential effects of which our investigation quantifies. Prior cost-effectiveness analyses of food labeling strategies have considered a general traffic light front-of-pack label in Australia[47] or calorie menu labeling in the United States.[48] Our investigation builds on and extends previous studies by using a microsimulation model to assess the impact of added sugar labeling in the United States, including potential additional effects of industry reformulation. Our results are consistent with prior labeling studies in finding that these policies are generally dominant because of their relatively low implementation costs and high cost savings. Even when considering only healthcare savings, such approaches promoting healthy eating were estimated to be far more cost-effective than many federally approved medical interventions, such as drug treatment of hypertension ($20 000/QALY),[49] or the use of statins for primary CVD prevention ($37 000/QALY).[50]

To our knowledge this is the first study to assess the health impacts, costs, and cost-effectiveness of implementing the FDA's added sugar labeling policy. The FDA has recently announced delays to the new label implementation from 2018 to 2020 for large manufacturers, and from 2019 to 2021 for small manufacturers, to provide industry more time for compliance and to decrease costs.[14] Our findings support more proximal implementation of the FDA's policy, considering the opportunity costs in preventable cardiometabolic events not prevented. In addition, we demonstrate that the healthcare and societal savings as a result of the added sugar label significantly outweigh policy costs, even when an estimated $2.5 billion of industry reformulation costs were considered.

Our investigation has several strengths. We used a validated microsimulation model and national data with probabilistic sensitivity analyses, increasing confidence in the validity of our findings. Potential effects on consumer behavior and industry reformulation were separately evaluated, providing a range of plausible findings. We assumed that recent large observed declines in added sugar intake in the United States would continue into the future, moderating the benefits in the policy scenarios and providing more realistic and conservative estimates of potential impact. We separately evaluated added sugar from SSBs and other foods to incorporate distinct trends in intake, and to apply the etiologic effects for BMI-independent effects of SSBs on cardiometabolic outcomes. Instead of directly translating caloric decrease to BMI reduction, the etiologic effects of changes in add-

ed sugar on changes in BMI were based on long-term prospective cohort studies, which were more conservative and inherently incorporate additional health effects of the average dietary substitutes and complements across the population. We accounted for the proportions of added sugar from packaged products that would be affected by the labeling policy, excluding, for example, added sugars from restaurants. We assumed conservative consumer effects and industry reformulation effects, for example, in comparison with past experience with trans-fat labeling.[12] Yet, in one-way sensitivity analyses, we showed that the policy remains cost saving even if the reduction in added sugar consumption is as low as 1%. Finally, we assessed both short- and long-term health impacts, costs, and cost-effectiveness, providing a range of results across different potential time periods of interest and from distinct relevant perspectives.

Potential limitations should be considered. Modeling approaches cannot prove the health and cost impacts of implementing the FDA added sugar labeling policy. Rather, these estimates provide evidence supporting timely implementation and additional considerations for the monitoring and evaluation of added sugar labeling. As with any medical or public health intervention, our findings should be considered as estimates of the average population effects, and not the effect on any individual person, in whom there may be larger or smaller changes depending on individual variation (eg, based on age, sex, activity, adiposity, genetics, and other risks). Our estimates may be conservative and underestimate the full health and economic impacts, because we included declining added sugar consumption trends and conservative assumptions about industry reformulation. We only evaluated health benefits and cost savings from cardiometabolic health outcomes; inclusion of increased healthcare costs from competing disease could reduce cost-effectiveness, whereas other health benefits such as on obesity-related cancers or dental caries would further augment the health gains and cost savings of added sugar labeling.

In conclusion, our investigation suggests that timely implementation of the FDA's added sugar labeling policy would generate significant health gains and both healthcare and societal cost savings. Industry reformulation motivated by this policy could provide substantial additional benefits.

ARTICLE INFORMATION

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Correspondence

Renata Micha, RD, PhD, Friedman School of Nutrition Science and Policy, Tufts University, 150 Harrison Ave, Boston, MA 02111. Email renata.micha@tufts.edu

Affiliations

Friedman School of Nutrition Science and Policy, Tufts University, Boston, MA (Y.H., J.L., Y.L., P.W., D.M., R.M.). Department of Public Health and Policy, University of Liverpool, UK (C.K., J.P.-S., B.C., P.B., S.C., M.O.). School of Public Health, Imperial College London, UK (J.P.-S.). Department of Preventive Medicine and Education, Medical University of Gdansk, Poland (P.B.). American Heart Association, Washington DC (L.W.).

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