

The Distributional and Financial Impacts of the Soft Drinks Industry Levy on Childhood Dental Caries in England - Research Protocol

Authors: E Bernabe, V Toffolutti, J Wu

Host Institution: Queen Mary University of London

Version	Date	Description	Author
1.0	17/07/2024	Protocol as approved by funder (grant number: NIHR159649)	EB
2.0	26/07/2024	Addition of disclaimer on front page	EB

Disclaimer:

This study/project is funded by the NIHR Public Health Research programme (NIHR159649). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

PLAIN ENGLISH SUMMARY OF RESEARCH

What is the problem being addressed?

Many young children in England suffer from tooth decay (holes in teeth). The disease leads to pain and trouble chewing. Many of these children will end up in hospitals to have their teeth pulled out. Tooth decay is common among children in poor and rural areas. It is also common among ethnic groups.

Soft drinks play a major role in this problem. They are a main source of sugars in children's diets. They are also a major cause of tooth decay. Reducing the intake of soft drinks through health policies could reduce the high rates of tooth decay. Groups at risk of tooth decay will benefit more.

What is the research about?

The UK government enforced a tax on soft drinks in April 2018. A recent study showed a promising 12% decline in tooth extractions done in hospitals following the tax. Yet, it is still unclear whether the tax helped reduce the gap in tooth decay rates between social groups. Some people argue that the tax unfairly affects the poor. They will pay more taxes, as a share of their income, to consume soft drinks.

This proposed study aims to address two questions:

- (1) How does the sugar tax impact the distribution of severe tooth decay across social groups, ethnic backgrounds, and living areas?
- (2) What are the economic benefits of the sugar tax?

How will the research be done?

The study will use existing data on tooth extractions in hospitals among children under 18 years in England. It will cover the time between 2008 and 2024. The study will check for changes in tooth extractions in hospitals before, during, and after the sugar tax was enforced. These checks will be done across social groups, ethnic groups and areas. The second part of the project will calculate public savings due to the sugar tax.

How will the findings be shared?

We will share the findings of the study through various ways. These include workshops, lay sum-ups, and press releases. Website content will be created for the public, health authorities, consultants, and service managers. Also, the results will be presented in papers and oral reports.

SCIENTIFIC ABSTRACT

Background

Untreated dental caries is the most prevalent condition worldwide, affecting 2.3 billion people across all ages (26.2%) and 250 million children under 5 years (37.6%). In England, 10.7% of 3-year-olds and 23.7% of 5-year-olds have the condition. Childhood caries is more common in low-income families, deprived areas and ethnic minority groups. It is also the most common reason for children to be admitted to hospitals in England, mostly for dental extractions under general anaesthesia.

Sugar-sweetened beverages (SSBs) are one of the largest sources of sugars in the diet and a major risk factor for childhood caries. Policies to curb the intake of SSBs can help reduce the high prevalence of untreated caries, especially among socially disadvantaged groups. The UK government announced a soft drinks industry levy (SDIL) in March 2016, which came into effect in April 2018.

Aim and objectives

The aim of this proposal is to evaluate the impact of the SDIL on social inequalities in severe dental caries among children in England and resulting financial outcomes. This is an important question as opponents of the tax argue it is regressive (i.e., poor people will pay more taxes as a proportion of their income) and could therefore affect the poor more. Such an evaluation can provide valuable information to other governments considering a new tax or revising an existing one.

The objectives of this project are:

- 1) To evaluate the impact of the SDIL on absolute and relative inequalities in hospital admissions for caries-related extractions according to deprivation, ethnicity and urbanicity.
- 2) To evaluate the distributional consequences of the SDIL in terms of both financial and health outcomes through an extended cost-effectiveness analysis (ECEA).

Methods

This proposal will use routine administrative data on hospital admissions for caries-related extractions among children under 18 years in England. Admissions for dental extractions are a robust indicator that captures the most severe end of the distribution of dental caries in the population.

Monthly data from January 2008 to June 2024 will be used, including over 10 years before the SDIL was announced, around 2 years between the date the SDIL was announced and enforced (implementation period) and over 6 years after it was enforced. Data on hospital admissions will be requested from NHS Digital for a fee. We will compare socioeconomic, ethnic and geographical differences in admissions for dental extractions before, during and after the implementation periods for all child patients and for different age groups (0-4, 5-9, 10-14 and 15-17 years).

The ECEA will evaluate both the health and financial consequences of the SDIL on three domains: health gains (reductions in childhood obesity and dental caries rates), financial benefits and the distributional impact across social groups. The findings of this proposal and those from published studies will inform the economic evaluation.

Timeline for delivery

The project will be completed in 15 months.

Anticipated impact and dissemination

Findings will be disseminated via multiple strategies, such as commentaries and viewpoints in media outlets and Queen Mary's website, established professional networks, and engaging with WHO Collaborating Centres internationally. We anticipate that the findings will inform updates of the government's obesity strategy and reaching target 2.1 of the WHO global oral health action plan.

BACKGROUND AND RATIONALE

Dental caries is the most prevalent condition worldwide, affecting 2.3 billion people across all ages (26.2%) and 250 million children under 5 years (37.6%).¹ In England, 10.7% of 3-year-olds² and 23.7% of 5-year-olds³ have dental caries requiring fillings or extractions. The disease is overrepresented among low income families, deprived areas and ethnic minority groups.^{2,3} Free sugars are the essential dietary factor in the development of dental caries.⁴ Sugar-sweetened beverages (SSBs) are one of the largest dietary sources of free sugars and their habitual consumption increases the risk of dental caries.⁵ The substantial role of SSBs as a common risk factor for many non-communicable diseases (NCDs), including dental caries, necessitates the consideration of upstream approaches, such as taxing unhealthy foods.

Evidence on the impact of SSB taxes on oral health outcomes is growing, although slowly moving from simulation models to primary studies.^{6,7} An evaluation of the effects of joint taxes on SSBs and energy-dense foods implemented in Mexico from January 2014 found immediate post-tax reductions followed by decreasing trends for the number of outpatient caries-related visits and the number of individuals having experienced dental caries.⁸ In addition, an evaluation of the Philadelphia beverage tax, implemented in January 2017, found that it was not associated with reduced dental caries in the general population, but it was associated with reduced dental caries in low-income groups (i.e. those on Medicaid).⁹

The soft drinks industry levy (SDIL) came into effect in England on 6th April 2018. In April 2023, the SDIL was extended to include packaged concentrates which are mixed with sugar and diluted by a fountain machine to dispense a drink containing a total sugar content of 5+ g per 100 ml. There is evidence that the SDIL led to product reformulation (i.e. reduction of the sugar content of drinks to move them from the higher to the lower levy tier),¹⁰ but did not affect market availability or the volume of soft drinks purchased.¹¹ The SDIL was also associated with reductions in obesity prevalence among year-6 girls, but not among year-6 boys or children in reception year. For year-6 girls, the largest reductions in prevalence of obesity were found in the two most deprived quintiles.¹² A recently published evaluation found a relative reduction of 12.1% (95%CI: 7.2-17.0) in hospital admissions for carious tooth extractions in 0-18-year-olds, 22 months after the SDIL was implemented. Reductions were seen in 0-4- and 5-9-year-olds but not in older children. Reductions were also seen in all five deprivation quintiles but the middle one.¹³

Given the current available evidence and after our early PPI work, the present proposal will further our knowledge on the impact of the SDIL by (i) conducting a health equity impact assessment and (ii) extending the time series to evaluate post-pandemic effects. Our health equity impact assessment will focus on the distributional and financial impacts of the SDIL. In terms of distributional impacts, we will move beyond the simple stratification of caries-related outcomes by deprivation quintiles to capturing other important social dimensions (such as ethnicity and urbanicity) and using measures of absolute and relative inequalities as our primary outcomes. Understanding the role of policies to reduce health inequalities is essential to prioritise those with larger benefits on socially disadvantaged groups (or conversely, to ensure they do not disproportionately burden already disadvantaged communities). Opponents of SSB taxes argue they are regressive (tax paid as share of income decreases as income increases), and thus, they disproportionately impact the poor. A systematic review found that SSB taxes were regressive but benefits on childhood weight were progressive.¹⁴ A comprehensive evaluation of the impact of the SDIL on inequalities in caries-related outcomes across multiple social dimensions and averted healthcare costs would provide valuable information to promote equity through health policy. An economic evaluation incorporating equity concerns will highlight the impacts of the SDIL on different population groups,¹⁵ ensuring that the intended tax is equitable and accessible to all segments of society. Finally, we will extend our assessment beyond the first two years post-implementation of the SDIL. All previous primary studies excluded outcome data from 2020 and later because of COVID-related changes in dental care utilization.^{8,9,13} Therefore, there is a need for further research on the post-pandemic effects of SSBs taxes. We will estimate the mid-term effect of the SDIL

(at 6.25 years by June 2024), under the assumption that hospital admissions are slowly going back to normal (see more details on section 3.1.5.3).

RESEARCH QUESTIONS

The aim of this proposal is to evaluate the impact of the SDIL on social inequalities in severe dental caries among children in England and resulting financial outcomes for the government. Hospital admissions for caries-related extractions are a robust population-level marker that captures the most severe end of the caries distribution among children.¹⁶ Given its whole population and regressive nature, it is anticipated that the SDIL has reduced inequalities in severe caries prevalence across different social dimensions.

The objectives of this project are:

- 3) To evaluate the impact of the SDIL on absolute and relative inequalities in hospital admissions for caries-related extractions according to area deprivation, ethnicity and urbanicity.
- 4) To evaluate the distributional consequences of the SDIL in terms of both financial and health outcomes through an extended cost-effectiveness analysis (ECEA).

While objective 1 will focus on dental caries, our ECEA will incorporate two health outcomes (childhood obesity and dental caries) to provide a comprehensive and realistic health equity assessment. Findings from objective 1 will inform the ECEA. Information on the impact of the SDIL on rates and social inequalities in childhood obesity will be extracted from available resources to inform the ECEA.

RESEARCH PLAN/METHODS

The proposal will be completed over 15 months as detailed in the research timetable.

3.1. Interrupted time series (ITS) analysis – objective 1

We will use a natural experiment design with a controlled ITS analysis to compare observed changes associated with the implementation of the SDIL to the counterfactual scenario of no implementation. The proposal adheres to recent recommendations for the design and analysis of ITS,^{17,18} and the Reporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement.¹⁹

3.1.1 Study period and population

We will obtain monthly data on all hospital admissions in NHS hospitals in England between January 2008 and June 2024 (10.2 years before and 6.2 years after the implementation period of the SDIL) for 0-17-years-olds, from the Hospital Episode Statistics (HES) Admitted Patient Care database.²⁰ Anonymised data will be accessed via the NHS Digital Data Access Request Service for a fee.

The time series will contain 122 months before announcement, 26 months between announcement and enforcement (implementation period) and 75 months after enforcement of the SDIL. For the primary analysis, the post-intervention period will be stopped in January 2020 (22 months only) to avoid conflating the impact of the COVID pandemic on hospital admissions. The full post-intervention period will be used in sensitivity analysis that excludes the COVID lockdown period (see section 3.1.5.3). A time series with a minimum of 72 data points, one-third of which represent the post-intervention period, is required to detect a small effect size (0.5) for the change in level or slope for the outcome, assuming a statistical power of 0.80 and autocorrelation between -0.40 and -0.90.²¹

3.1.2. Outcome measures

The population-based hospital admission rate for extractions due to dental caries, per 100,000 person-months, among 0-17-year-old children, will be first estimated. The numerator data will be all finished consultant episodes (FCE) with a primary procedure code for surgical removal of tooth (OPSC-4 code: F09) or simple extraction of tooth (F10) and a primary diagnosis code

for dental caries (ICD-10 codes K02.1, K02.5, K02.8 and K02.9) or diseases of pulp and periapical tissues (K04.0, K04.5, K04.6 and K04.7). The denominator data will be the mid-year population estimates for 0-17-year-olds, derived from census data published by the Office for National Statistics (ONS).

Inequalities in admission rates for caries-related extractions according to area deprivation, ethnicity and urbanicity will be measured using complex measures that take the whole population distribution into account, rather than only comparing the most extreme social groups.^{22,23} The World Health Organization (WHO) recommends using the slope and relative index of inequality to quantify absolute and relative inequalities when working with ordered groups (such as area deprivation) and the weighted absolute mean difference from the overall mean and the Theil index to quantify absolute and relative inequalities when working with non-ordered groups (such as ethnicity and urbanicity).²² Area deprivation will be measured using the 2015 English Index of Multiple Deprivation (IMD) quintiles at Lower Super Output Area (LSOA) level. The largest minority ethnic groups in England as per the UK census (Indian=3.4%, Pakistani=4.3%, Bangladeshi=1.8%, Black African=3.7%, Black Caribbean=1.0%, Mixed=6.1% and Other white=5.5%) will be compared separately against the white British group. Some groups may need to be combined into broader categories (Asians, Blacks, Mixed and other ethnicities) depending on size. As for urbanicity, LSOAs will be grouped using the ONS Rural-Urban classification.

We will use inequalities in negative control outcomes to account for confounding events and co-interventions.^{17,18} They are hospital admissions with a primary procedure and diagnosis codes for (1) bilateral tonsillectomies (F34.1-4) and tonsillitis (J03.0 and J03.8), (2) ventilation support (E85) and asthma (J45); (3) appendicectomy (H01-H03) and acute appendicitis (K35); and (4) removal of a foreign body from the nose or ear (D07.3, E08.5) and foreign body in ear or respiratory tract (T16-T17). These control outcomes are common reasons for hospitalization among children that were affected by the lockdowns during the pandemic but are unlikely to be affected by the SDIL.

3.1.3. The intervention

The SDIL is a two-tiered levy: drinks with ≥ 8 g of sugar per 100 ml are taxed at 24 pence per litre (higher levy tier) while drinks with 5 to < 8 g of sugar per 100 ml are taxed at 18 pence per litre (lower levy tier). Drinks with < 5 g of sugar per 100 ml are not levied.²⁴ Milk-based drinks, 100% fruit juices, drinks sold as powder, and drinks with $> 1.2\%$ alcohol by volume are exempt. Unlike most SSB taxes that aim to increase price for the end consumer (excise tax) to reduce demand,²⁵ the SDIL aims to incentivise manufacturers to reformulate soft drinks to move them from the higher to the lower levy tier. The implementation period (also known as a transition period in the ITS literature) includes the 26 months between the announcement (March 2016) and enforcement of the SDIL (April 2018).

3.1.4. Time-varying confounders

Inequalities in admission rates for caries-related extractions could be affected by changes in population characteristics and access to caries preventive measures during the ITS period. We will divide records into age bands (0-4, 5-9, 10-14 and 15-17 years) to reflect their different levels of lifetime exposure to the SDIL and admission rates. As hospital admissions require a referral from primary dental care services, they can vary by the number of children seen and preventive services offered in primary care. The number of children seen by a primary care dentist and who received fissure sealants and fluoride varnish (as proportion of the child population) will be extracted from the quarterly online reports by the NHS Business Service Authority. Community water fluoridation will not be included as the number of LSOAs with such schemes has remained relatively stable, at around 10%, since 1995.²⁶

3.1.5. Statistical analysis

All analysis will be carried in Stata. Descriptive analysis will include a plot of monthly outcome data, and by age and social groups, to identify the underlying trend, seasonal patterns and outliers, and to compare outcome data and time-varying confounders before, during and after

the implementation period. In addition, the presence of serial correlation (autocorrelation) will be formally assessed using the plot of residuals and the partial autocorrelation function.

3.1.5.1. Counterfactual scenario and the impact model

The counterfactual is the hypothetical scenario under which the intervention would have not taken place and the trend continues unchanged. It provides a comparator to evaluate the impact of the intervention by examining any change occurring post-intervention. In our case, this is the trend that would have been expected based on the regression line derived from data before the SDIL was announced.

For the impact model, we hypothesise a gradual decline in measures of inequalities after enforcement of the SDIL (temporary slope change) leading to level changes in outcomes (sustained shift in intercept) 3 years after enforcement. We anticipate: (i) an immediate slope change after enforcement because many manufacturers reduced the sugar content of drinks since the SDIL was announced,¹¹ and (ii) a delayed (lagged) effect of the SDIL because dental caries takes, on average, 2-3 years to progress from enamel to dentine (cavitation stage)¹ and longer to reach a severe stage requiring extractions.

3.1.5.2. Regression modelling

We will use the ITS to examine whether the implementation of the SDIL is associated with changes in health inequality measures. A segmented regression will be fitted to detect a change in the level (intercept) or trend (slope) between the regression lines derived from three consecutive periods: pre-enforcement, enforcement till 3 years after enforcement, and 3 years post-enforcement.^{27,28} Therefore, two changes in trend and level will be estimated to evaluate the impact of the SDIL, reporting absolute and relative effects with 95% confidence intervals on outcomes at 22 months (primary analysis).

Regression analysis of health inequality measures will be conducted according to deprivation quintiles, ethnic groups and urban/rural status for all children and separately by age groups as the largest impact of the SDIL was observed in younger children.¹³ All health inequality measures will be modelled using linear regression. Alternatively, we will use an autoregressive integrated moving average (ARIMA) model to account for any serial autocorrelation structures in the data (including seasonality) that remain after adjustment for time-varying confounders.²⁹

3.1.5.3. Sensitivity analysis

One particular concern is the impact of the COVID pandemic on admission rates, especially between March 2020 and July 2021 when lockdowns were introduced. Hospital admissions, including those for caries-related procedures, decreased during this period.^{30,31} To avoid this potential contamination, the ITS for the primary analysis will stop in February 2020 (before the first national lockdown) to estimate effects at 22 months after enforcement of the SDIL. As an alternative, we will extend the ITS to June 2024 but excluding the period between March 2020 and July 2021 to estimate the effect of the SDIL at 75 months, under the assumption that admissions are slowly going back to normal. There were 26741 episodes of carious tooth extractions in NHS hospitals for 0-to-19-year-olds in 2021/22, which is 24% lower than pre-pandemic.³² Figures for the 2022/23 have not been published yet but are expected to be higher. We will use a two-step approach. First, we will single out the period between March 2020 and July 2022 to model how inequalities in the primary and negative control outcomes varied with each separate lockdown. We anticipate drops in hospital admissions immediately after each lockdown that are followed by a gradual recovery (upward slope) after the lockdown ends. Our plan is to identify the best specification for time in the ITS model to account for these non-linear trends. Negative control outcomes will be used to evaluate whether trends were affected disproportionately (i.e. recovery was faster for certain outcomes). Once the best shape for the trend of each outcome is identified, we will create a common (weighted average) trend across all negative control outcomes, which will be used as a comparator for the trend in inequalities in caries-related extractions. A formal test will be carried out using the common trend model, which eliminates the effect of potential confounders by subtracting the control outcome series from the intervention series.

We will also evaluate any inflection points in the trends in April 2023 when the SDIL was expanded to include further drinks taxed at the highest rate. Furthermore, the robustness of the study findings will be checked using a control outcome not causally related to SSBs to account for secular trends in the data, and falsification tests.^{33,34}

3.2. Extended cost-effectiveness analysis (ECEA) – Objective 2

Our ECEA will take a societal perspective relating the cost associated to the implementation of the SDIL to the cumulative impacts on three major outcomes: health gains, financial benefits and the distributional impact across social groups (measured as described below).³⁵⁻³⁷ Unlike other approaches for economic evaluation (equity-based weighting methods and distributional CEA),¹⁵ ECEA has been successfully used in the past to evaluate the impact of health policies,^{15,35} including taxes on SSBs.^{38,39}

3.2.1. Time horizon

The time horizon for our ECEA will be 75 months (6.25 years) post-implementation of the SDIL to yield a robust assessment of the intermediate (mid-term) impacts of the policy using existing data. In the analysis, cost and outcomes will be evaluated at yearly bases applying a 3.5% discount rate for costs in year>1.⁴⁰

We will not estimate long-term impacts as they would involve extrapolating cohort experience into the future and making strong assumptions about the effectiveness of the SDIL. In modelling terms, a lifetime horizon would require projection forward of current health states (childhood caries and obesity) and costs of care, estimating transitions between health states and associated health outcomes (morbidity and mortality due to diabetes, ischaemic heart disease and stroke [common obesity-related disorders]) and costs at time points over the lifespan, as well as discounting of future costs and health outcomes.

3.2.2. Outcomes

Health gains will be indicated by reductions in (i) child obesity and (ii) dental caries. **Financial benefits** (also known as non-health benefits) will be measured by improvements in (iii) financial risk protection (FRP), (iv) out-of-pocket payments (OPP) for dental care (including savings in indirect costs), (v) government health expenditure (subsidies) associated with foregone healthcare and (vi) tax revenues. Reducing FRP associated with OPP for dental care (averted cases of catastrophic health expenditure) is a target of the WHO Global Oral Health Action Plan.⁴¹ Even in England where child dental care is fully funded by the NHS, OOP is common and could lead to catastrophic health expenditure.^{42,43} **Distributional impacts** will be indicated by differences in health and financial benefits according to social groups.

3.2.3. Resources

We will use published and unpublished data as inputs for the ECEA, disaggregated across social groups (area deprivation, ethnicity and urbanicity). Data on the pass-through effect, elasticity, and changes in SSB prices, purchases and consumption will be retrieved from previous evaluations of the SDIL.^{10,11} Data on treatment costs for dental caries in primary and secondary care, indirect costs (transportation, parental productivity loss due to children health, impacts of school absence related to child ill-health), tax revenues and population estimates will be obtained from official government websites. The quantities of healthcare resources utilization will be identified and estimated using secondary sources of data, namely HES. Annual treatment costs for obesity among adolescents in the UK will be extracted from a recent analysis.⁴⁴ In addition, we will use official statistics at regional level to compute the number of days off taken by parents due to child ill-health. To estimate the cost of days out of work due to the child's illness, we will use the national median 2022 hourly earnings of the relevant occupational group using data from the Annual Survey of Hours and Earnings (ASHE).⁴⁵ We will apply similar procedures to compute the cost related to children's school days lost. Additional data will be generated from analysis of national surveys carried out before and after the SDIL, such as the National Diet and Nutrition Survey (SSB intake), the Health Survey for England and National Child Measurement Programme (obesity), the National Dental Epidemiology Programme and Children's Dental Health Survey (dental caries and OPP

for dental care) and the Living Costs and Food Survey (OPP for dental care and catastrophic health expenditure).

3.2.4. Model estimation

All ECEA parameters will be estimated by area deprivation, ethnicity and urbanicity, separately, to evaluate the share of health and financial benefits of each population subgroup. We will calculate the number of prevented cases of childhood obesity and dental caries by comparing disease burden before and after SDIL implementation. FRP will be estimated as the difference in catastrophic health expenditure due to OPP for dental care as a result of the policy. OOP related to medications, private dental and healthcare will be derived from the literature. A societal perspective will be taken to estimate the averted direct and indirect costs and the additional tax revenue collected from the SDIL (discounting implementation and monitoring/auditing costs). Healthcare costs and tax revenues will be adjusted for inflation.

The total SDIL net cost will be calculated, from the perspective of the policy maker,^{36,37} as implementation-and-monitoring costs per child minus cost savings (OPP and government expenditure) from prevented cases. Incremental cost-effectiveness ratios (ICER) will be estimated for health (averted cases of childhood obesity and dental caries, separately) and non-health benefits (FRP: averted cases of catastrophic health expenditure). By doing so, ECEA estimates the “efficient purchase” of health and non-health benefits. The 95% uncertainty limits will be estimated from Monte Carlo simulations, by modifying key parameters and assumptions such as price elasticities, pass-through rates, estimation of indirect costs, changes in outcomes, etc. All the analysis will be run in Stata.

To quantify distributional impacts, we will disaggregate the three dimensions of our analysis (health benefits, FRP and the net cost of the policy per child) by population subgroups defined by area deprivation, ethnicity and urbanicity. The SDIL will be deemed equity enhancing if it provides more benefits to the most disadvantaged than to the least disadvantaged group of the population.^{36,37}