

Evaluation of the health impacts of the UK Treasury Soft Drinks Industry Levy (SDIL)

ISRCTN: 18042742

Protocol Version Table:

Version number	Author	Purpose/change	Date
1.0	Martin White	-	11/08/17

Funded by NIHR Public Health Research Programme
Study number: 16/130/01



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1 Protocol contacts and authorisation

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1.4 Steering Committee

An independent international study steering committee will be appointed by NIHR. Details of membership will be added here when available.

1.5 Protocol sign-off

Protocol authorization signatories

Chief Investigator signature:

Martin White

2 Responsibilities

2.1 The Chief Investigator

Prof Martin White, Programme Leader in the Centre for Diet and Activity Research (CEDAR), MRC Epidemiology Unit Cambridge, whose research focuses on the influence of the food system on health. He will provide overall leadership for the study and lead WPs 4 and 5.

2.2 The project co-investigators

Prof Richard Smith, Professor of Health System Economics. Faculty of Public Health & Policy, LSHTM. His expertise lies in macro and health economics, and systems analysis. He will be Lead for WP3.

Prof Steven Cummins, Professor of Population Health. Faculty of Public Health & Policy LSHTM. Evaluation of natural experiments, social, environmental and system determinants of health, and health geography. Co-lead for WP4.

Dr Harry Rutter, Senior Clinical Research Fellow. Faculty of Public Health & Policy LSHTM. Complex adaptive systems, obesity. Co-lead for WP5.

Prof Mike Rayner, Professor of Population Health and Director, BHF Centre on Population Approaches for Non-Communicable Disease Prevention. Nuffield Department of Population Health, University of Oxford. He will provide expertise on food policy, diet and nutrition.

Dr Peter Scarborough Associate Professor, Nuffield Department of Population Health, University of Oxford. Mathematical modelling, sugar taxes. Lead for WP2.

Dr Adam Briggs, Wellcome Trust PhD Fellow & Honorary Specialist Registrar in Public Health, Nuffield Department of Population Health, University of Oxford. Public health impact modelling, sugar taxes. Co-lead for WP2.

Dr Richard Harrington, Data Scientist, Nuffield Department of Population Health, University of Oxford. Lead for development and analysis of FoodDB and social media (WPs 1 and 4).

Dr Jean Adams, Programme Leader, CEDAR, MRC Epidemiology Unit, University of Cambridge. Evaluation of natural experiments, dietary public health, food marketing. Lead for WP1.

Dr Oliver Mytton, Wellcome Trust PhD Fellow & Honorary Specialist Registrar in Public Health, CEDAR, MRC Epidemiology Unit, University of Cambridge. Public health modelling and evaluation, food taxes. Co-lead for WP1.

2.3 The project staff

Dr Tarra L Penney, Research Associate in Dietary Public Health, Centre for Diet and Activity Research (CEDAR), MRC Epidemiology Unit, University of Cambridge. Project management support, qualitative research, evidence synthesis and dissemination.

Dr Laura Cornelsen, Assistant Professor in Health Economics, Faculty of Public Health & Policy,

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3 Protocol summary

3.1 Scientific abstract

We will conduct a natural experimental evaluation of proximal, intermediate & distal outcomes (work package (WP) 1), micro & macro-economic evaluation (WP3), & qualitative process evaluation (WP4) over 3 2-year time periods (2014-20). Simulation modelling of health & economic outcomes will focus on longer time horizons (WP2). In WP5, findings from WP1-4 will be synthesised and interpreted to refine intervention theory, and stakeholders engaged in dissemination.

Work package 1 – will use interrupted time series & regression analyses to evaluate impacts of the SDIL on:

1. Soft drink product diversification, formulation & price by brand, category & product size (volume) using data from 6 leading supermarket chains
2. Purchases of SSBs, all other drinks, confectionary & toiletries overall & by age, sex & socioeconomic position (SEP), using household purchasing data from Kantar World Panel
3. Consumption of SSBs & confectionary overall & by age, sex & SEP using data from the National Diet & Nutrition Survey
4. Prevalence of childhood obesity using data from the National Child Measurement Programme & hospital admissions for severe dental caries using data from Hospital Episode Statistics (HES) overall & by age, sex & SEP.

Work package 2 – will adapt an existing life table model (PRIMEtime) for proportional multistate life table analyses. Data from WP1 will be used to estimate the effect sizes for SSB consumption & free sugars from drinks. We will estimate the impact of these changes on health outcomes over the short (5 years), medium (5-10 years) & long term (>10 years). Disease outcomes of interest will include dental caries, T2DM, cardiovascular & kidney disease, & obesity-related cancers (e.g. colon, kidney, liver, breast & pancreas).

Work package 3 – will involve: (1) a micro-economic evaluation, modelling (using PRIMEtime) the health & social care cost impacts & health outcomes (QALYs gained); & (2) a macro-economic evaluation, to assess the wider impacts of SDIL on industry, households, Treasury and UK economy.

1. NHS costs will be estimated using programme-budgeting & HES data. Social care & wider societal costs will be assessed overall & by age, sex, utility score & ICD10 codes. Data on dental caries & associated health care costs will be incorporated & we will extend the cost estimates to cover children & adolescents.
2. We will use a Computable General Equilibrium (CGE) model of the whole economy that includes the cost minimising & profit maximising behaviour of producers, consumption & saving behaviour of households & government, taxation mechanisms & the use of labour, capital & other factors in order to produce goods & services for investment or consumption, & includes trade across international borders.

Work package 4 – will use qualitative methods to determine the perceived acceptability & impacts of the SDIL. We will conduct thematic Framework analysis of interviews with professionals & focus groups with the public, thematic content analysis of newspapers articles & social media (twitter) output & analysis of survey questions on consumer attitudes to SSBs collected by Kantar in their household purchasing panel.

Work package 5 – will involve synthesis of the findings from WPs1-4 using our systems map & refinement of intervention theory. Triangulation of evidence generated using different methods from WPs1-4 will facilitate corroboration of findings, supported by techniques such as pattern matching. We will engage stakeholders in dissemination.

3.2 Health condition addressed

The main focus of this work is the prevention of obesity and risk of chronic non-communicable diseases through reduction of sugar-sweetened soft drink, and therefore sugar, consumption in the population. Consumption of SSBs is independently associated with total energy intake & risk of dental caries, obesity, type 2 diabetes mellitus (T2DM) & heart. For example, adults who consume one or more sugary drinks per day double their risk of diabetes and raise their risk of CHD by 23% compared to those who consumed one SSB drink or less per month.

4 Background

4.1 The problem and intervention

The public health problem: consumption of sugar sweetened beverages

Sugar-sweetened beverage (SSB) consumption is independently associated with dental caries, total energy intake, obesity, type 2 diabetes (T2DM) and cardiovascular disease (CVD).¹ For example daily consumption of SSBs is associated with a 19% increased risk of T2DM and 17% increased risk of CVD.^{2,3} The economic burden of these conditions is significant. Although not entirely attributable to SSBs, obesity cost the UK an estimated £27 billion in 2015;⁴ with direct cost to the NHS of over £5 billion.⁵

The dietary patterns that contribute to an increased risk of disease are often formed during childhood and adolescence,⁶ with SSBs currently representing the single biggest source of dietary sugar for young people in the UK.⁴ SSBs are thought to contribute to poor health through behavioural (e.g. limited satiation of sugar from liquids) and biological mechanisms (e.g. effect of high glycaemic load on insulin resistance).⁷ In childhood and adolescence, SSB consumption is associated with dental caries (the most common cause of hospital admission for children aged 5-9 years) and obesity.^{8,9} These child and adolescent conditions can track into adulthood; 80% of obese children between the ages of 10-14 become obese adults,¹⁰ increasing their risk of T2DM, cardiovascular and musculoskeletal conditions. SSB consumption, and associated dietary risks, are also strongly socioeconomically patterned,¹¹ contributing to inequalities in health.

The use of fiscal policies to reduce consumption of sugar sweetened beverages

In 2015, the UK Scientific Advisory Committee on Nutrition (SACN), consistent with World Health Organisation guidelines, recommended intake of free sugars should be <5% of daily energy (approximately half the present level of consumption in the UK) and SSB consumption minimised.^{12,13} Furthermore PHE⁴ and WHO¹⁴ have recommended regulatory measures, including a tax on SSBs, to support reduction of population sugar consumption. Globally a number of SSB taxes have been introduced, although few have been evaluated. Mexico introduced a specific excise tax on SSBs in 2014, as part of a wider package of taxes on energy dense foods. The tax has been associated with a reduction in purchases of taxed beverages and increase in purchases of alternative (untaxed) beverages.¹⁵ The tax had a flat rate, regardless of sugar level within products, and thus potentially lacked an incentive for industry reformulation. Impacts on reformulation and consumption have not been studied.

Berkley, CA, introduced a tax on SSBs in 2015, that was associated with an increase in the price of, and marked reduction in consumption of SSBs three months after implementation (even though the tax was not fully passed onto consumers),¹⁶ relative to comparable cities that did not implement the tax.¹⁷ However, this evaluation was conducted in low-income neighbourhoods so may not be generalizable to the whole population, albeit SSB consumption is greater in lower income groups.

In 2016, Portugal announced an excise tax and Ireland an industry levy, both using a threshold approach to taxation based on the sugar content of SSBs. The Irish levy will be implemented to coincide with the UK levy.¹⁸ The UK SDIL provides an important opportunity to conduct a comprehensive evaluation of not only the direct effect of taxation on purchasing and consumption, but also the influence of the announcement of the levy on actions taken by industry (e.g. to reformulate) and the public.

The Soft Drinks Industry Levy

In 2016 the Chancellor announced a tiered soft drinks industry levy (SDIL) on industries importing or selling SSBs in the UK with the explicit intention of reducing consumption of sugar from SSBs. The introduction of the SDIL is punctuated by three events:

- I. the chancellor's announcement (Apr 2016, 2 years ahead of implementing the levy)
- II. the introduction of legislation (anticipated Dec 2016-Apr 2017, which will confirm details of the levy)
- III. the implementation of the Levy (anticipated Apr 2018)

Each of these events aim to prompt changes in industry behaviour (primarily reformulation to lower sugar content but also other changes, e.g. in marketing to persuade consumers to switch to lower sugar alternatives). Reformulation (e.g. by Tesco and Britvic) is already occurring. Moreover, each phase of the introduction of the SDIL is accompanied by media coverage orchestrated by HM Treasury, which may emphasize the health risks of SSB consumption. Introduction in April 2018 is also likely to be associated with a rise in the price of SSBs. All of these changes may impact SSB and total sugar consumption, with potential consequences for diet and health. The effects of these 'perturbations' in highly complex food and health systems are multiple and likely to interact dynamically, as illustrated by our 'systems map' (see Appendix A). The outcome of the levy consultation (undertaken in summer 2016)¹⁹ has been published and the amounts of the levy were included in the Finance Bill 2017, which received Royal Assent in May 2017. The current proposal is to impose the levy in relation to the sugar content of drinks as follows:

- No levy on drinks $\leq 5\text{g}/100\text{ml}$ of added sugar
- 18p/L on drinks $>5\text{g}/100\text{ml}$ and $\leq 8\text{g}/100\text{ml}$ of added sugar
- 24p/L on drinks containing $>8\text{g}/100\text{ml}$ of added sugar

Additional components may be announced, which we will consider including within the evaluation. Levy revenue will be used to promote children's health (funding sport and breakfast clubs in school). As this expenditure is guaranteed (i.e. not contingent on SDIL revenue) it will not be considered in this evaluation.

4.2 Existing research

Soft drink excise tax: reformulation, price, purchasing and consumption

The UK SDIL is different from other SSBs taxes: it is an industry levy rather than an excise tax and has three levels. Our formative research has highlighted several pathways (see systems map in Appendix A) through which the levy could reduce sugar and SSB consumption. Existing research primarily only considers one of these pathways (change in price). Previous studies (of excise taxes) have shown that the tax is passed onto the consumer, although not always fully, and that the taxes/price rises are associated with reduced purchases.^{15 16 20} Economic theory and data strongly suggest that price is an important determinant of SSB purchases.²¹ No study has shown excise taxes are associated with reduced consumption (i.e. drinking of SSB) or changes in health (although modelling studies suggest that such taxes may result in important health gains).

However, the government has made it clear that the SDIL is not a tax on consumers and that companies should seek to reformulate and not pass the levy on to consumers.²² Moreover, the tiered nature of the levy, early signs that industry is reformulating in response to the levy,²³ and

our initial scoping work, all suggest that reformulation may be an important industry response (potentially alongside price rises). No studies have quantified the extent of reformulation in response to levies or taxes.

However, members of our team have recently modelled the potential impacts of the SDIL and have found that price increases, reformulation and other activities (e.g. marketing) that result in consumers switching to low sugar alternatives all have considerable scope to improve health (e.g. 144,000 (95% uncertainty interval: 5,100 to 306,700) fewer adults and children with obesity in the UK, 19,000 (6,900 to 32,700) fewer incident cases of diabetes per year, and 269,000 (82,200 to 470,900) fewer decayed, missing, or filled teeth annually).²⁴ However the study, informed by expert opinion, highlighted considerable uncertainty around the nature and magnitude of the industry response.

Indirect taxes (i.e. taxes levied on goods) are financially regressive, although they may be progressive from a health perspective.²⁵ More disadvantaged individuals suffer from a disproportionate burden of diet-related diseases,²⁶ but are also more sensitive to price changes.²¹ As SSBs are not a dietary requirement, and one alternative (i.e. water) is available at little or no cost, a shift from SSBs toward water among disadvantaged groups could improve health and reduce diet related health inequalities.²⁷ An assessment of population level differential effects has yet to be undertaken.

The soft drinks industry levy as an event within a complex system

The implementation of a fiscal policy is an intervention that is highly context dependent,^{28 29} resulting in reactions by many stakeholders including government, civil society, industry, health sector and consumers, and the potential to affect a range of diet and health outcomes. The complex nature of the SDIL necessitates consideration of the context (i.e. the system(s) of factors) that surrounds the levy to systematically guide empirical work, which is illustrated in our system map (Appendix A). Our evaluation will focus on several aspects of the system, in addition to direct measures of reformulation, price, purchasing, consumption and potential health impacts:

- ***Compensatory industry strategies:*** HM Treasury expectation is that the levy should prompt reformulation by industry. However, opposition to the levy has been voiced in media reports³⁰ and position statements (e.g. the British Soft Drinks Association).³¹ This reaction has been seen elsewhere: for example, PepsiCo threatened to move its corporate headquarters out of New York when the state considered implementing an 18% sales tax on SSBs.³² Industry strategies may include: creating doubt regarding scientific studies, political lobbying, criticising potential policies as negatively impacting on employment, complaining about restrictions on personal choice, or emphasising physical activity.³³
- ***Media and public discourse on sugar and taxation:*** SSBs are covered frequently in mainstream British media (e.g. print newspapers, online news websites). A media analysis (2014) found significant coverage on SSBs related to public health advocacy with messaging from experts, campaign groups and health organisations on the detrimental effects on health. However, only 25% of this coverage included solutions, in particular fiscal policies related to addressing consumption.³⁴ Given the broader context of the UK levy, such as the 2015 WHO sugar guidelines and call for fiscal solutions, the media and public discourse is likely to have shifted with unknown influences on acceptability of the levy, industry reformulation and purchasing or consumption.
- ***Consumer acceptability:*** Public support for food and beverage taxes to address obesity has

been increasing in the US.³⁵ The way in which the issue is framed is considered important for shaping consumer acceptability, with presentation of the tax as a way to promote health and highlighting that revenues are earmarked for promoting child health shaping a more favourable view of taxation.³⁴

4.3 Our preliminary work

With funding from NIHR PHR's Rapid Funding Scheme, we undertook formative work to underpin this evaluation. This work was completed in April 2017. The study developed a platform for this comprehensive evaluation and involved the following components:

1. Developing a 'systems map' to capture the range of potential effects of the SDIL, including distributional impacts. Time horizons for parameters were estimated and direction of likely changes hypothesised. Potential confounders, moderators and mediators were specified. An online stakeholder Delphi survey was undertaken to refine the map and prioritise data acquisition. The system map also serves as our 'theory of change' for the proposed work (See Appendix A).
2. Routine data sources for parameters identified in the systems map have been specified and availability over time identified. Feasibility and cost of new data have been appraised (Appendix B).
3. Time-sensitive data collection has been prioritised including:
 - a. Qualitative data, from documentary sources and stakeholder interviews, to document the immediate impacts of the SDIL announcement (e.g. industry reactions and changes to the levy)
 - b. Enhancement of existing data collection on nutritional composition and portion sizes of SSBs and related food & drink categories, to evaluate impact on reformulation
 - c. Data on shifting public attitudes to the SDIL, and harms of sugar and excess energy intake.

5 Rationale

5.1 Whole system approach

To reduce population consumption of SSBs, a range of interventions have been proposed, including fiscal measures. However, there have been no comprehensive evaluations of SSB taxes that have measured impacts on reformulation or consumption of SSBs. In addition, no evaluations have yet explored impacts on health or broader economic, political, and sociocultural systems.

The SDIL is unique in its construction including a tiered levy directed at industry, and its two-year lead time from date of announcement to implementation. This evaluation seeks to examine each of these phases to improve our understanding of how such interventions evolve over time within complex food systems to influence products and purchasing, consumption and health outcomes.

Evaluation of such a multi-faceted and multiphasic intervention needs to go beyond a narrow focus on a single outcome (e.g. sales of SSBs) to incorporate assessment of a range of theorised intervention effects. The evaluation will thus take a 'systems' perspective, aiming to evaluate a range of outcomes, associated processes and their dynamic interrelationships. The evaluation will be guided by theorised pathways for a range of factors related to the potential impact of the SDIL (Appendix A), each of which will be measured. Relationships between these multiple (proximal, intermediate and distal) outcomes will be explored in WP5.

5.2 Evaluation design

Randomised controlled trials (RCT) are recognised as the strongest method for determining causal effects. However, in the current context where the SDIL is introduced to the whole country at once, randomisation to intervention and control groups is not feasible. An alternative is to use quasi-experimental observational, or 'natural experimental', methods.³⁶ Interrupted Time Series (ITS) methods offer one of the strongest quasi-experimental research designs.^{37,38} By studying outcomes at the population-, rather than individual-level, confounding by individual-level variables is avoided. By including substantial time-series data before and after interventions, underlying secular trends are taken into account. Auto-regressive and moving-average functions in time series regression models are used to adjust for any biases introduced by the serial nature of data (including seasonality). Data requirements for ITS analyses are discussed further below.

Using ITS designs, consideration of a range of outcomes (e.g. SSB consumption declining as consumption of lower sugar alternatives increase) and mechanistic processes (e.g. the relationship between price and purchases) can be explored such that a 'pattern' of impacts is appraised to provide the strongest possible basis on which to draw causal inference. ITS designs will be used for our primary outcome and quantitative process evaluations (WP1), but will sit alongside long term outcome modelling (WP2), macro- and micro-economic evaluation (WP3), and qualitative process evaluation (WP4). This approach will allow us to seek triangulation of findings across these methods (WP5), also strengthening causal inference.³⁶

5.3 Data synthesis

Findings from WPs1-4 will be synthesised in WP5 to generate overall conclusions about the impact of the SDIL at different time points in its evolution and implementation. We will draw on quantitative (e.g. modelling relationships between observed time trends) and qualitative

techniques (e.g. pattern matching) to enhance causal inference, and generate overall conclusions with stakeholder input.

6 Objectives

We propose an evaluation of the SDIL using a systems approach to enable the wide range of possible impacts of the SDIL, identified and prioritised by stakeholders from our systems map (Appendix A), to be measured and their relationships explored. NIHR is interested primarily in health impacts, but these may be influenced by many other proximal, intermediate and distal impacts, which are likely to interact dynamically. These impacts could be considered simplistically, according to a relatively linear theory of change, but because of the likely existence of feedback loops and unpredictable actions and reactions, representing them in this way is potentially unhelpful. The evaluation will therefore be divided into a series of work packages, each focusing on a set of impacts that are related and for which the research methods are similar, in order to generate a range of evidence that can be triangulated and synthesised. We will primarily use routine data to allow retrospective data acquisition and an efficient design, focusing on the whole of the UK where feasible. All outcomes will be assessed comparatively across the three two-year time periods related to hypothesised intervention points where impacts are likely to be observed:

- *Time period 1:* Prior to the announcement of the SDIL (from April 2014 to March 2016)
- *Time period 2:* following the chancellor's announcement of the SDIL in March 2016 up to confirmation of legislation for the SDIL (anticipated April 2017), and following the confirmation of SDIL legislation (anticipated April 2017) up to implementation of the SDIL (anticipated April 2018)
- *Time period 3:* following implementation of the SDIL (anticipated April 2018) up to 24 months later

WP1 will use a natural experimental evaluation design and utilise quantitative analytical methods, including ITS analysis. WP2 and elements of WP3 will employ modelling to simulate longer term health and economic outcomes. WP3 will employ micro- and macro-economic modelling approaches to identify the net costs/benefits of the intervention from perspectives including HM Treasury, industry, society and NHS. WP4 will use qualitative methods to explore perceived impacts and acceptability of the SDIL to stakeholder groups, including the public, politicians and professionals. WP5 will synthesise the findings from WPs1-4, engage stakeholders and disseminate findings. Our objectives for these work packages are:

WP1 – Impacts on diversification, formulation, marketing, prices, purchases and consumption of SSBs, and early health impacts (dental caries, obesity)

To measure the impacts of the SDIL on:

1. Non-alcoholic drink market diversity, sugar content and price
2. Purchases of drinks, a high-sugar potential substitution food category (confectionery) and an unrelated control category (toiletries); overall and by age, sex and socio-economic position (SEP)
3. Consumption of drinks, confectionery and free sugar; overall and by age, sex and SEP
4. The prevalence of childhood obesity (if indicated by effect on purchasing) and hospital admissions for severe dental caries; overall and by age, sex and SEP.

WP2 – Impacts on medium to long term health outcomes

5. To estimate (via simulation) the impacts of the SDIL on medium to long term health outcomes (dental caries, T2DM, cardiovascular diseases, kidney disease and obesity-

related cancers) overall and by age, sex and SEP.

WP3 – Economic impacts on food and other industries, HM Treasury, health and social care

6. To estimate the impacts of the SDIL on costs and revenues to the food and other industries, HM Treasury, and to health and social care sectors, including the extent to which the levy is passed on to consumers (and if not, then to whom).

WP4 – Impacts on key stakeholders: the public, politicians and professionals

7. To determine the perceived acceptability and impacts of the SDIL among key stakeholders, including the public, politicians and professionals in industry and health sectors.

WP5 – Synthesis of findings from WPs1-4, stakeholder engagement and dissemination

8. To synthesise findings from WPs1-4, develop an overarching interpretation, refine our intervention theory, draw conclusions, identify and disseminate implications for policy, practice and research.

7 Work packages

7.1 WP1 – Impact on diversification, formulation, marketing, prices, purchases and consumption of SSBs, and early health impacts

Overall approach

Study design

We will use routine and commercial data to explore the short-term effects of the intervention on levy-eligible drink market diversification, formulation, price, purchases and consumption. We will also explore effects on purchasing and consumption of all drinks (including alcoholic drinks) and confectionery as these are possible substitutes for SSBs. Finally, we will explore effects on inpatient admissions for dental caries – arguably the most proximal health outcome associated with SSB consumption. If results indicate a substantial effect on levy-eligible drinks purchases (defined below), we will conduct exploratory analyses of the effect of this on adiposity at ages 4-5 and 10-11 years. WP1 will use a natural experimental evaluation design and quantitative analytical methods, making use of a range of bespoke, commercial and routine data sources.

Data sources

We will use an in-house, bespoke dataset (FoodDB) to assess soft drink market diversification, formulation and price. We will use four external representative datasets to assess: purchasing of drinks, confectionery and toiletries (Kantar WorldPanel; KWP); consumption of drinks, confectionery and sugar as a whole (the National Diet & Nutrition Survey; NDNS); inpatient admissions for dental caries (Hospital Episode Statistics; HES), and childhood adiposity (the National Child Measurement Programme; NCMP).

There are no perfect data sources for the proposed study. *De novo* collection of consumption data or data on the prevalence of dental caries would be prohibitively costly and the opportunity to collect data for the pre-intervention period has now been lost. In addition to developing a bespoke and novel dataset on soft drink market diversity, formulation and price, we have selected a group of existing datasets that will allow us to conduct a complementary package of analyses across a range of outcomes. This reflects the complexity of our systems map and adds strength to our work by allowing us to triangulate and synthesise findings across a range of outcomes and data sources.³⁶

We have chosen data sources to enable study of differential intervention effects across population groups. This will allow us to determine, for example, whether any overall beneficial effects on purchasing or consumption mask detrimental effects in some population sub-groups and hence whether the intervention has equitable or inequitable impacts. As far as possible, all relevant analyses will be conducted for the population as a whole as well as by gender, age and SEP to determine if effects vary across these population groups.

Outcome measures

The range of outcome measures included in WP1 reflects the complexity of our systems map, and the most important of the proposed short-term impacts of the SDIL, prioritised with stakeholder involvement. For drinks market diversity, formulation, price, purchases and consumption, our outcome measures will relate to drinks in four categories:

- non levy-eligible drinks (i.e. non-alcoholic drinks with <5g total sugars/100ml and drinks excluded from the levy) – these will be disaggregated into further sub-categories including

- bottled waters; pure fruit juices; and entirely artificially sweetened, 'diet', drinks
- lower level levy-eligible drinks (i.e. non-alcoholic drinks with $5 < g < 8$ total sugars/100ml)
- higher level levy-eligible drinks (i.e. non-alcoholic drinks with $> 8g$ total sugars/100ml)
- alcoholic drinks

The SDIL is focused on reducing sugar in soft drinks via reformulation³⁹ and a tax was recommended in Public Health England's Sugar Reduction review.⁴⁰ As such the primary aim is to reduce consumption of sugar, rather than consumption of soft drinks *per se*.⁴¹ Furthermore, we are not aware of other pragmatic evaluations of soda taxes that have studied total sugar consumption from drinks as an outcome, making this a significant evidence gap. Thus, in terms of purchasing and consumption, within the four drinks categories listed and also in the confectionery category, we will explore both volume of drinks and confectionery purchased/consumed and total sugars in those.

Ideally, we would include purchasing and consumption of sugary products across the whole diet to capture all substitution effects. However, the cost of KWP data is directly related to the number of food/drink categories included. In order to balance scientific value against value for money, we will restrict our analysis of KWP to drinks plus confectionery only, assuming that confectionery is an important potential category for sugary substitution. However, we will extend our analysis of (free-to-access) NDNS consumption data to added sugars from all sources.

Many of our analyses in this WP will make use of data that is only available at the group, rather than individual, level. In these cases we will use interrupted time series (ITS) methods. These require that data are expressed as a single metric per unit time (see sample size and analysis sections for details). Specific outcome measures are described below in relation to each study.

Study period and population

Consistent with the rest of the evaluation, as far as possible, we will include as a minimum data from April 2014–March 2020. That is: two full years before intervention announcement to two full years after intervention implementation. In some cases (i.e. study 1a), we have not been able to access retrospective data that extends all the way back to April 2014. In other cases, where comparable pre-intervention data from before April 2014 is readily available at no financial cost (i.e. study 1c and id), we will include all that is available to increase the robustness of our estimates.

In the main, the population of interest is the whole of the UK. Our population of interest for analyses of inpatient treatment for dental caries and childhood adiposity is England only – reflecting data availability and comparability. England accounts for 84% of the UK population, making it a good proxy for the whole of the UK.

Data analysis

For data aggregated per time point (i.e. soft drink market diversification, formulation, price; drinks, confectionery and toiletries purchases; and dental caries), we will conduct ITS analyses – either uncontrolled or controlled depending on the specific analysis and as described below in more detail. ITS models estimate the change in 'level' and 'trend' of the outcome of interest associated with interventions. The change in level is the difference in intercepts between regression lines estimated from observations before and after the intervention. The change in trend is the difference in slopes. In the case of two 'interventions' (as here), two changes in level and trend are estimated. In the case of uncontrolled ITS, the 'comparator' is the counterfactual for

what would have been expected, based on the regression line from data in the previous period. In the case of controlled ITS, the 'comparator' is the counterfactual for what would have been expected, based on the regression line from the data in the previous period, less any effect identified in 'control' group. This allows secular trends to be taken into account.

General linear models will be used allowing for autoregressive and moving average correlation structures as appropriate. These allow any seasonality, or other serial correlation structures, to be taken into account, which we know to be important for soft drink consumption. Throughout, final models will be used to estimate absolute and relative effects of the initial SDIL announcement, and final implementation on each outcome at 12 and 24 months, with 95% confidence intervals calculated as described previously.⁴² All analyses will be conducted in StataSE v14.

Study 1a: the impact of the SDIL on non-alcoholic drinks market diversity, total sugar content and price

Study design

Using an in-house dataset collected from major UK supermarket websites, we will use interrupted time series (ITS) methods to study whether the implementation of the SDIL was associated with changes in level or trend of non-alcoholic drink market diversity, sugar content and price.

Data source

We will use an in-house, bespoke dataset (developed during our formative work) to assess non-alcoholic drink market diversification, formulation and price. We have developed automated data collection techniques (i.e. 'data scraping') and will use these to collect monthly, time-stamped data on all soft drinks available for purchase from six online UK supermarkets (Tesco, Morrison's, Asda, Sainsbury's, Waitrose and Ocado). Together these supermarkets (online and in-store) represent more than 75% of the UK grocery market.⁴³ The resultant database (FoodDB) contains data on the complete product range of soft drinks from each supermarket in each month.

We will add data from any new online supermarkets that open during the project. Maintenance of FoodDB will be conducted monthly to ensure that the source code that supplies the dataset continues to run appropriately (it also will be necessary to adapt this source code when online supermarkets change their appearance, format or layout).

For each drink we will continue to collect: date of data collection; nutritional content; price; pack size; serving size; whether or not the drink is on promotion; and manufacturer. Complete datasets for all drinks were collected in December 2013 and October 2016. Data from 1281 Tesco drinks were collected from 2011 to 2016 using a combination of live and archived websites, 391 of which have more than three time points at which data was available. Full monthly data on all drinks from all six major online supermarkets is available from October 2016.

Outcome measures

We will have three outcome measures, one related to each of market diversity, formulation and price:

- number of products (e.g. Coca-Cola, not Coca-Cola 500ml bottle) available across six online supermarkets per month (market diversity)
- mean total sugar concentration in g/100ml per month (formulation)
- mean price (not sales-weighted) in £/100ml per month (price)

These will be considered overall and in each of the four drinks categories described above separately.

Study period and sample size

As described above we have some FoodDB data from 2013, with full data available from October 2016. This study will, therefore, include data from October 2016 (6 months after intervention announcement) – April 2020 (2 years after intervention implementation).

Data are available per calendar month, thus providing 12 time points/year from full establishment of FoodDB onwards (October 2016), and a total of 42 time points in the study. Currently, we estimate that more than 1000 unique soft drinks products will be included per time point. This dataset therefore substantially exceeds current recommendations for minimum samples sizes for ITS analyses of at least 10 time points before and after the intervention, and at least 100 observations per time point.

Data analysis

We will conduct single time point, ITS analyses for each outcome overall in each of the four drinks categories described above separately. The unit of analysis will be the calendar month. As data is only available from after intervention announcement to after intervention implementation, we will include only one 'intervention' point – intervention implementation.

As FoodDB is a database of products, rather than purchases or consumption, it will not be possible to study any differences by socio-demographic characteristics of purchases or consumers. Additional analyses stratified by supermarket price point may be possible e.g. as a student project add-on.

Study 1b: The impact of the SDIL on purchases of drinks, confectionery and toiletries; overall and by age, sex & SEP

Study design

Using commercial data on household purchasing, we will use ITS methods to study whether the announcement or implementation of the SDIL was associated with changes in level or trend of purchasing of drinks in the four categories described above. Inclusion of all four categories will allow us to explore substitution between drinks categories. We will study changes in confectionery purchases to explore substitution to another high-sugar category. Throughout we will use purchasing of toiletries as a 'non-equivalent' comparator that is likely to be effected by income and spending, but not the SDIL. We will study effects across total volume (l or kg), total value (£) and total sugar content of products. Whilst the SDIL aims to reduce consumption of added sugars, levy bands are expressed in terms of total sugars as this is the data that most producers have available to them and which is also available in the KWP dataset. We will study effects overall, and whether there are any differences in effect by household socio-demographics – householder age, household composition and size, and occupational social class.

Data source

We will use KWP data to measure household purchasing of drinks in each of the four categories described above, as well as confectionery and toiletries. This is a commercial, continuously refreshed, representative panel of UK households (n=30,000) who record all food and beverage purchases brought into the home using a barcode scanner. Using quota sampling, the KWP panel is nationally representative in terms of region, occupational social class, age of main shopper and number of children in households. Most households stay in the panel for 2-3 years. Barcode

scanners capture detailed information on purchases (e.g. product line, package size, and price). This is linked to basic nutritional information, including sugar content. A validation study confirmed that KWP data closely reflected data from the Living Costs and Foods Survey (LCFS; described below), which is a similar government funded household panel.⁴⁴ However KWP may still include some underreporting of total energy consumption.⁴⁵

Until recently, a major limitation of KWP (and source of underreporting) was the exclusion of purchases that did not come into the home. Around one-third of UK soft drink purchases are for immediate consumption (and hence unlikely to come into the home).⁴⁶ To address this, since 2015, a representative sub-sample (n=8,000) of the KWP panel has recorded on-the-go purchases using a mobile phone app. We will include this to test the robustness of findings from the main panel.

We will study effects on purchasing of drinks in all four categories described above and confectionery in order to capture possible substitution effects across drinks, and to one other high sugar category (i.e. confectionery). Identifying decreases in purchases of levy-eligible drinks alongside increases in purchases of other drinks will increase our confidence that the effect on levy-eligible drinks is 'true'. Identifying decreases in purchases of levy-eligible drinks alongside increases in confectionery would alert us to possible unintended consequences of the intervention. Sales of toiletries are included as an unrelated category in order to act as a 'non-equivalent' control³⁸ which should be unaffected by the intervention, but which would be sensitive to wider changes in the grocery market or economy that might impact purchases of all items.

Outcome measures

Outcome measures will be:

- mean 4-weekly purchases of drinks (in litres and £) in each of four drinks categories per household
- mean 4-weekly purchases of confectionery (in kg & £) per household
- mean 4-weekly total sugars (in kg and £) in drinks purchased in each of four categories per household
- mean 4-weekly total sugars (in kg and £) in confectionery purchased per household
- mean 4-weekly purchases of toiletries (in £) – the 'control' condition

We will use product-specific nutritional information within the KWP dataset to determine into which of our four categories drinks fall and to determine total sugar in drinks and confectionery.

Study period and sample size

We will include data from the main household panel from April 2014–March 2020. That is: two full years before intervention announcement to two full years after intervention implementation. Data from the on-the-go panel is only available from September 2015. We will include data from the on-the-go panel from September 2015-March 2020. That is: 7 months before intervention announcement to two full years after intervention implementation.

KWP data is provided aggregated into 4-weekly periods. KWP is unwilling to make more granular data available to us. This will provide 78 time points from the household panel, with 30,000 households per time point; and 60 time points from the on-the-go panel, with 8000 individuals per time point. This dataset therefore substantially exceeds current recommendations for minimum samples sizes for ITS analyses.

Data analysis

We will conduct controlled, multiple time points, ITS analyses for each outcome overall and then (where appropriate), separately for each drinks category. In all cases, purchases of toiletries will be used as a non-equivalent comparator.³⁸ The unit of analysis will be 4-weekly periods. We will include two ‘intervention’ points in each model – intervention announcement and intervention implementation. We will first conduct analyses in the whole sample. We will then disaggregate households by occupational social class of the head of household (assigned using the National Readership Survey (ABC1C2DE) categorisation), age group (in 10 year bands) of the main shopper, household composition and size. Interaction terms will be used to determine whether effects differ between groups. We will plot significant interactions to explore and interpret them.

Study 1c: the impact of the SDIL on consumption of drinks, confectionery and added sugar; overall and by age, sex and SEP

Study design

Using the National Diet and Nutrition Survey (NDNS), we will use standard regression methods to study whether the announcement or implementation of the SDIL was associated with changes in consumption of drinks in four categories, confectionery and added sugars as a whole. We will study effects overall and whether effects differ by individual age, gender and SEP.

Data source

We will use NDNS data to measure consumption of drinks (in the four categories described above) and confectionery. This data is free to access for researchers from the UK Data Service. NDNS is an annual (since 2008), cross-sectional survey of people living in UK private households.⁴⁷ Participants complete a socio-demographic questionnaire and are given a prospective, estimated, 4-day food diary to complete. Diaries are reviewed at a follow-up interview. Parents or carers provide information for children <12 years. Food diaries collect information at the product level and are linked to a nutrient database. To date, 56% of individuals recruited have returned usable food diaries (3 or 4 completed days).⁴⁷ Weighting variables take account of selective non-response. Food diaries are one of the most accurate methods of capturing diet.⁴⁸ However, under-reporting of energy intake and selective under-reporting of less healthy foods (relative to purchase data) occurs.⁴⁴

We include consumption of drinks in each category as a direct measure of exposure to levy-eligible, and other, drinks. We are not aware of other pragmatic evaluations of soda taxes that have measured consumption of eligible drinks. As purchases may not entirely represent consumption (e.g. due to waste), this is an important evidence gap.

Nutritional composition of products consumed is included in NDNS. However, updating of this information can be *ad hoc*. Given we expect reformulation of many drinks during the evaluation, we will link contemporaneous total sugar content data on drinks from KWP to NDNS data. In the great majority of cases, all sugar in drinks (with the exception of fruit juices) is added sugar.

Outcome measures

Outcome measures, at the individual level, will be:

- mean daily consumption (ml) in each of the four categories of drinks
- mean daily consumption (g) of confectionery
- mean daily added sugars (g) consumed in drinks in each of the four categories

- mean daily added sugars (g) consumed in confectionery and from all sources

Study period

In order to maximise study power, we will include all possible data, that is from survey waves 2008-09 to 2019-20. This 12 year period covers from eight years before intervention announcement to two years after intervention implementation.

Sample size

Around 1000 individuals are recruited per survey wave. Thus, by including data from 12 survey waves, we will include information on around 12,000 individuals. We have estimated current consumption of soft drinks from NDNS data as mean(SD)=143(195)ml/day; 52(82)g of total sugar from soft drinks/day. With a sample of 8000 before the first phase of intervention implementation, and 4000 after (from 2016-2020), we estimate that we will have 80% power to detect 7.4% change in volume of soft drinks/day; and 8.5% change in total sugar from soft drinks/day. With a sample of 10,000 before the second phase of intervention implementation (from 2008 when the current NDNS programme started to 2018), and 2000 after (from 2018-2020), we will have 80% power to detect a 9.6% change in volume and 11.0% change in total sugar from current levels.

Data analysis

We will use regression models to explore the effects of the intervention on the outcomes, introducing continuous variables for time at data collection and dummy variables representing each intervention time point. Seasonality will be explored and adjusted for if required.

NDNS includes a wealth of socio-demographic data enabling us to both adjust for and explore interactions by household composition, age, gender, equivalised household income, education and occupational social class of the head of household.⁴⁹ We will use interaction terms to explore any differences in effect across socio-demographic groups. Where these are found, they will be plotted to aid interpretation.

Study 1d: the impact of the SDIL on the prevalence of childhood obesity and hospital admissions for severe dental caries; overall and by age, sex and SEP

Study design

Using English hospital admissions data, we will use ITS methods to study whether the announcement or implementation of the SDIL was associated with changes in the level or trend of hospital admissions for dental caries (perhaps one of the earliest health effects expected). If indicated, we will use routine English national child measurement data and standard regression methods to study whether the announcement or implementation of the SDIL was associated with changes in child adiposity. We will study effects overall and whether effects differ by individual age, gender and SEP.

Data sources

We will use HES data to assess inpatient admissions for dental caries in England. These data are free to access for researchers from the UK Data Service. HES contain information on all admissions to NHS Hospitals in England – including inpatient admissions, outpatient appointments and attendance at Accident & Emergency. Data is submitted by NHS trusts and contracting organisations. Dental caries is socio-economically patterned⁵⁰ and the most common reason for children aged 5-9 years to be admitted to hospital.⁵¹ There is also a dose-response relationship between sugar sweetened beverage (SSB) consumption and dental caries in both children and

adults.⁵²⁻⁵⁴ Thus, reduction in SSB consumption is likely to lead to reductions in dental caries and this may be one of the most proximal health outcomes to be affected by changes in SSB consumption. We are not aware of other pragmatic evaluations of SSB taxes that have included dental caries as an outcome, leaving an important evidence gap.

We focus on admissions for dental caries as this is the only comprehensive English data on dental caries. Inpatient admissions represent the severest end of the scale of dental caries, but a primary diagnosis of dental caries is present in almost half (49%) of dental inpatient admissions.⁵⁰

If our SSB purchasing results indicate an effect size large enough to impact on childhood adiposity we will use data from the English NCMP to measure this. Individual-level data is available to researchers free of charge from NHS Digital. A meta-analysis indicated that 100ml/day change in SSB consumption is associated with a 0.45kg change in body weight in children.⁵⁵ This is equivalent to 0.4 (0.2) BMI units in children aged 4.5 years (10.5 years) with a height on the 50th centile. Thus, if we find an effect of the intervention on purchasing of 50ml/day (equivalent to ~26% of current daily SSB intake in children) by 2 years after implementation, we will explore effects on prevalence of childhood adiposity. As described below, NCMP provides statistical power to detect a much smaller change than this.

The NCMP aims to measure the height and weight of all children at state-maintained schools in England in reception (4-5 years) and year 6 (10-11 years). Participation in 2012-13 was 94% in reception and 93% in year 6 children.⁵⁶ This equates to around 1 million children per year.

Outcome measures

The outcome measure for dental caries will be:

- rate of finished admission episodes for dental procedures (F08-17 & F63) with a primary diagnosis of dental caries (ICD-10 K02) per 100,000 population per calendar month.

A finished admission episode is the first period of inpatient care under a particular consultant with a particular healthcare provider. As such, it is a measure of admissions, not individuals. Procedures F08-17 & F63 identify those admitted primarily for dental care, rather than where dental care is provided to those admitted for other reasons. A primary diagnosis of dental caries (ICD-10 K02) identifies those individuals admitted for dental care for dental caries. Calculating a rate per 100,000 takes any changes in population sizes into account. These will be calculated using annual mid-year population estimates calculated by ONS for gender and 5-year age-specific groups and freely available from them. This outcome will be calculated overall and by age, gender and deprivation decile of household of residence. The outcome measures for childhood adiposity, if indicated for study, will be:

- mean BMI z-score (calculated as previously described⁵⁷)
- risk of being overweight (BMI>85th centile based on UK 1990 reference)
- risk of being obese (BMI>95th centile based on UK 1990 reference)

Data on annual overweight and obesity prevalence are published in NCMP annual reports. However, it is possible that small, but meaningful, changes in mean BMI z-score associated with the intervention will not translate into an identifiable effect on prevalence of overweight or obesity. We will, thus, use anonymised individual level data to study effects on BMI z-score.

Study period

As HES data is free to access, we will include the largest pre-intervention period possible to maximise the robustness of findings. We will include HES data from April 2008–March 2020. That

is: eight full years before intervention announcement to two full years after intervention implementation.

As NCMP data is also free to access, if indicated for study, we will include data from the school year 2006-07 (when NCMP began) to the school year 2019-20. That is: 10 years before intervention announcement to two years after intervention implementation.

Sample size

HES data is available at the calendar month level. Recent data suggests about 100,000 finished admission episodes for dental main operative procedures with a primary diagnosis of dental caries per annum.⁵⁰ HES data collection methods changed in 2008. We will, therefore, include data from April 2008 in the pre-announcement phase. This gives 96 calendar months prior to intervention announcement and 24 in the following two phases. With more than 8000 cases expected per month, this again substantially exceeds the sample size requirements for an ITSA.

NCMP includes about 1 million children annually – that is 250,000 per annum in each of four gender and school year-specific groups. Current mean (SD) BMI z-score in reception children is 0.33 (0.99) for girls and 0.37 (1.07) for boys. Comparable figures for year 6 children are 0.43 (1.21) and 0.57 (1.19). With a sample of 2.5 million children in each gender and school year-specific group before intervention announcement (from 2006 when NCMP began to 2016), and 1 million after (from 2016-2020); or 3 million before intervention implementation (2006 – 2018) and 0.5 million after (2018-2020), we estimate that we will have 80% power to detect changes in BMI z-score of around 0.008 - 0.01 units.

Data analysis

We will conduct controlled, multiple time points, ITS analyses on HES admission data. The units of analysis will be calendar months. Controlled analyses will be conducted with admissions for other conditions (i.e. appendectomy, acute exacerbation of asthma) being used as ‘non-equivalent’ controls that are also common in both adults and children and unlikely to be linked to sugar consumption or effected by the SDIL.³⁸

General linear models will be used allowing for autoregressive and moving average correlation structures as appropriate. These allow any seasonality, or other serial correlation structures, to be taken into account, which we know to be important for soft drink consumption.

We will first conduct analyses in the whole cohorts, then disaggregate by socio-demographic groups and use interaction terms to determine whether effects differ between groups. We will plot significant interactions to explore and interpret them. We will explore differences by age group (in 10 year bands), gender and deprivation decile. Deprivation will be measured using the Index of Multiple Deprivation (IMD)⁵⁸ for home postcode using the most recent iteration of IMD for year of study.

If indicated, we will use standard regression models to explore the effects of the intervention on childhood adiposity outcomes, introducing continuous variables for time at data collection and dummy variables representing each intervention time point. Seasonality will be explored and adjusted for if required.

NCMP includes few details on individuals, but information is available on age (in months), gender and deprivation decile of the location of schools (measured using IMD as per HES data). We will use interaction terms to explore any differences in effect across socio-demographic groups. Where these are found, they will be graphically explored.

7.2 WP2 – Impacts on medium to long term health outcomes

Study design

To estimate the impacts of the SDIL over longer time horizons, we will simulate a range of outcomes using a proportional multistate life table approach, adapting an existing life table model (PRIMEtime).⁵⁹ The results from WP1 will be used to estimate effect sizes in terms of sugary drink consumption and free sugars from drinks. The PRIMEtime model will then estimate the impact of these changes on health outcomes over the medium term (next 10 years), and long term (>10 years).

Proposed methods

The health model will use a proportional multi-state life table approach.⁶⁰ It will be parameterised with data on disease incidence and mortality in the UK taken from the Office for National Statistics, linked datasets of HES and death certificates and disease registries. The diseases in the health model will include dental caries, T2DM, cardiovascular diseases, kidney disease and obesity-related cancers (i.e. cancers of the colon, kidney, liver, breast and pancreas). The results of WP1 will determine the change in mean soft drink consumption (ml/day) and the mean sugar concentration of soft drinks (g/ml). Using a method that we have previously developed to estimate the potential impact of the SDIL under different implementation scenarios⁵⁵, we will convert these outputs into measures of ‘equivalised sugar drink intake’. These changes will be translated into changes in body weight using bespoke meta-analyses of the effect of sugar drink consumption on body weight in both adults and children. For an overview of the trial literature on sugar drink consumption and body weight, see Schillinger et al. (2016).⁶¹ Changes in body weight will be translated into the health outcomes by estimating population impact fractions (PIFs), similar to methods used by the Global Burden of Disease project⁶². The PIFs will be based on hazard ratios linking body weight and the health outcomes, which will be drawn from meta-analyses of prospective cohort studies (e.g. Prospective Studies Collaboration, 2009; WCRF/AICR, 2007). For T2DM, we will model the health impact between soft drinks and disease outcome directly using results from prospective cohort studies.^{59 63} For dental caries we will model the impact between sugar consumption and disease outcome using results from a prospective cohort study.⁶⁴ Work has recently been completed to apply disease utility weights to the PRIMEtime model using a comparable study of population-based EQ-5D scores for the US population adapted for the UK by using UK-based time trade-off tariffs.⁶⁵

For this project, we will further develop the PRIMEtime model in five ways. First, we will build the first part of the model that estimates changes in soft drink risk as a result of the SDIL, based on results drawn from elsewhere in this project. Here, the inputs will be changes in consumption of sugar drinks (from the interrupted time series analysis of the Kantar World Panel dataset) and changes in average sugar levels in sugar drinks (from the interrupted time series analysis of the foodDB dataset), which will provide population-level estimates that can be converted into changes in ‘equivalised sugar drink consumption’.

Second, we will adapt the existing model to incorporate dental caries, using the datasets described above. Third, we will extend the PRIMEtime model to incorporate children and adolescents who are high consumers of soft drinks by using age and sex-specific estimates of soft drink consumption derived from the NDNS. This will require us to make assumptions regarding how overweight and obesity tracks from childhood into adulthood, which will be informed by the literature. We will conduct sensitivity analyses to test how sensitive our results are to these

changes. However, with the exception of T2DM we do not anticipate that these assumptions will have a big influence on the results as the cardiovascular disease and cancer outcomes that are linked to overweight status in the model do not occur until old age, which for children will not occur for many decades when the model results will be heavily discounted.

Fourth, we will explicitly model lag times between changes in soft drink consumption and health outcomes, with reference to models that have explored time lag between dietary change and health.⁶⁶ The assumptions around time lag will be tested in sensitivity analyses. Fifth, we will re-parameterise the model for the whole UK (currently the model is parameterised for England) using data on health statistics from the Office for National Statistics, the General Register Office for Scotland, the Northern Ireland Statistics and Research Agency and UK results from the Global Burden of Disease study.

Study populations & data sources

The results from the health model will compare health outcomes in the UK in a baseline scenario where the three stages of implementation of the SDIL (see above) are introduced with a counterfactual scenario where the SDIL is not introduced. Sensitivity analyses will explore scenarios when the early stages of the implementation are introduced without the final implementation of the levy. The data sources that will be used to parameterise the model are described above.

Proposed outcome measures

We will model key health outcomes over medium and long term time horizons, simulating a cohort representing children, adolescents and adults in the UK. The model will estimate the change in dental caries, obesity and T2DM (and associated long term health conditions including cardiovascular disease and renal disease) as a result of age and sex specific estimates of soft drink consumption and average sugar levels in soft drinks. Modelling results will be stratified by socioeconomic groups, to provide estimates of the impact of the SDIL on health inequalities.

The PRIMETIME model will produce outcomes over the medium term (up to 10 years) and long term (>10 years), explicitly accounting for time lag between implementation of the three phases of the SDIL, system change and subsequent changes in health. Sensitivity analyses will explore the effect of applying discount rates to future events. We will use a discount rate of 1.5% as recommended by NICE for evaluations of public health interventions (NICE, 2012).

The outcomes will be changes in the following:

- Medium and long term change in prevalence of dental caries, overweight and obesity
- Change in incidence of T2DM over the medium and long term
- Change in incidence of cardiovascular and kidney diseases and cancers in the medium and long term
- Change in years of life lost due to early mortality from any condition
- Change in quality adjusted life years (QALYs) lost or gained.

Data analyses

We will estimate 95% uncertainty intervals around all of the outcomes, based on Monte Carlo analyses that will sample from distributions around each of the model parameters included in the analysis (e.g. the relative risk estimates associated with dietary change and health outcomes; the effect size of the intervention etc.) Since the PRIMETIME model only includes risk parameters that are statistically significant at a 5% level, it follows that the uncertainty associated with the diet-

disease risk relationships generate uncertainty intervals that do not cross zero (uncertainty intervals tend to be in the region of 5% to 10% of the outcome measure). This uncertainty will increase with incorporation of uncertainty around the effect size of the intervention, but it is not possible to estimate the final amount of uncertainty before the earlier work packages are completed. We will present the results of the uncertainty analyses in tornado plots, which demonstrate how much of the uncertainty is due to the different model parameters.

We will assess the validity of the model results in a number of ways, following published frameworks for assessing model validity.⁶⁷ We will conduct rigorous unit testing on all model features to ensure internal consistency. We will run the model with extreme values to assess the model logic is appropriate and well-applied in the model framework. Where possible, we will compare the short term results of the model with external datasets collected for this project (e.g. hospital episode statistics for dental caries; national childhood measurement programme results for childhood obesity). And we will compare our model with other models that have assessed the health impact of dietary interventions.

7.3 WP3 – Economic impacts on food and other industries, HM treasury, health and social care

Study design

We will undertake a comprehensive economic assessment of the SDIL that integrates evidence from the other WPs to produce both micro- and macro-economic assessments. As indicated in our earlier work developing a systems map related to the SDIL [NIHR PHR RFS 16-49-01], the implementation and impact of a SDIL may be widespread and diffuse, entailing multiple feedback effects directly from the SDIL, or via impacts on health status, across the health sector, food industry, other government departments, other sectors (such as leisure and retail) and consumer behaviour, with impacts on population health being reinforced or diminished through these broader effects. This requires analysis of both micro-level impacts together with the broader macro-economic context within which these impacts take place.

Micro-economic analysis: will focus upon an assessment of the healthcare cost impacts associated with the SDIL, and in combination with health outcome estimates from WP2, will generate an assessment of cost-effectiveness of the SDIL from the health sector perspective. However, as the direct implementation costs of the SDIL will not fall on the NHS this analysis will also consider cost impacts on the food industry, consumers and other sectors, linking with WP1 and WP4, and feeding in to the macro-economic analysis and a societal perspective.

Macro-economic analysis will encompass these wider impacts of SDIL across industry, households and HM Treasury especially. Through a dynamic assessment of the diffusion of the impact of the SDIL through the broader UK economy, including indirect impacts through changes in health status from WP3, this analysis will identify and quantify the overall macro-economic impact, and disaggregated impacts by sector, socio-economic status and geography, to the UK providing a more holistic assessment of net change and specific areas of economic gain and/or loss.

Proposed methods

Micro-economic analysis: Micro-economic analysis will focus specifically on the health and social care sector, and examine other specific impacts which will provide the wider context of impact across the announcement and implementation phases of the SDIL and be used to feed in to the macro-economic assessment outlined below.

With respect to the health and social care sector, the PRIMETIME model (WP2) will provide predictions of the core medium- and long-term health impact of the SDIL across a number of health conditions (see description of WP2). This model will form the basis for a micro-economic model through adaptation to incorporate key cost nodes specifically for health and social care services. NHS costs will be estimated using programme budgeting data and Hospital Episode Statistics, with adjustments for specialised services and primary care expenditure.⁶⁸ Social care and wider societal costs will be implemented using methods developed by the University of York and the Department of Health,⁶⁹ and are based on a regression analysis estimating the probability of needing residential care by age and quality of life with adjustments for those with dementia and stroke. Analysis will extend the PRIMETIME model to incorporate dental caries and associated health care costs, as well as cost estimates to cover children and adolescents. We will further develop UK-specific cost estimates alongside the model being extended for wider UK health application (the PRIMETIME model is currently parameterised for England only). This model will allow assessment of the costs (or most likely savings) accrued to the NHS and social care from a reduction in SSB consumption and QALY impact from the SDIL. Given that the implementation cost of SDIL do not fall on NHS budgets, it is expected that this will be a dominant intervention – cost saving and outcome enhancing – but we will be able to determine the extent of this and identify where these savings may fall; and if there are any costs accruing elsewhere in the profile of ICD-10 and HES data (e.g. higher level of accidents due to increase physical activity programmes).

With respect to the wider economic impact on specific sectors and population groups, we will work closely with WP1 and WP4. WP1 utilises Interrupted Time Series (ITS) analysis to estimate impacts of the SDIL to estimate causal impact of the SDIL across the system previously specified (Appendix A). The core data is focussed on expenditures on SSB products and the levy/price impact associated with demand changes. The data will provide diverse information on (re)formulation, promotional activities, actual prices, purchases and consumption of SSBs to provide estimates of early health impacts (dental caries, obesity – WP2 will extend this in breadth and depth). Additionally the data allow analysing substitution effects towards confectionery. This considerable depth of analysis of the primary industry will be supplemented through work in WP3 estimating financial impact more broadly across critical sectors of the economy based on corporation financial reports (e.g. on product mix, product pricing, revenues per product stream etc.) and government statistics (e.g. on sector employment, growth and tax receipts, and spending across education). We will work with WP4 in their qualitative interrogation of impacts and responses from groups such as consumers, retail and manufacturing to focus on the economic impacts that have or are likely to result. This information will form a portfolio of observed and likely economic impacts across the range of core areas identified in our systems map (Appendix A). Work with WP4 will also inform the specification of scenarios to model in both micro- and macro-economic analyses of possible future impacts of SDIL under different contexts.

Macro-economic analysis: We will use the Computable General Equilibrium (CGE) approach to build a mathematical model of the UK economy. This approach is based on micro-foundations, specifying all sectors of the economy and incorporating international trading relationships thus linking the UK within the global context. The micro-foundations enable it to indicate impacts across sectoral, demographic and spatial areas of interest. It also enables it to utilise data such as that gathered above to increase sensitivity to critical factors of relevance, but set within the broad macro-economy. Our CGE approach has been developed over several years to uniquely integrate the core economic model with modules that replicate the core demographic and epidemiological variables of concern to ensure that feedback effects between these areas are integrated in a fully

dynamic assessment.^{70 71} Based on this previous work, we will construct a fully integrated dynamic model for a system-wide evaluation of the SDIL.

In brief, a CGE model is a mathematical model of the whole economy that includes the cost minimising and profit maximising behaviour of producers, consumption and saving behaviour of households and government, taxation mechanisms and the use of labour, capital and other factors in order to produce goods and services for investment or consumption, and includes trade across international borders.^{72 73} The model produces a benchmark solution (representing the current economy going forward on its current trajectory), which is then compared with alternatives incorporating policy change or other events/shocks simulated by the model; in this case various scenarios encompassing a SDIL. Counter-factual solutions based on these scenarios are then compared with the original benchmark (and each other) to estimate the economic impact of the simulated event overall (eg on GDP, employment and inflation), specific sectors (eg SSB manufacturers, retail or leisure), and population groups (eg household by SES).

CGE modelling is an established economic analysis tool, including several applications within health (in the UK and beyond) over the last decade for instance where economic impacts are expected to be diffuse;⁷⁴⁻⁷⁸ such as pandemic influenza, anti-microbial resistance and dietary guidelines.⁷⁹ The model proposed here will draw together two developments made in separate projects. First, the core model used thus far for UK-based analysis is a static UK open-economy CGE model.^{75 79} This will be enhanced by development of a recursive dynamic model, where outputs from the current period are used to build the next period, allowing for feedback effects, such as those developed in previous applications, to be incorporated in the model. Second, in a project focused on malaria in sub-Saharan Africa we have produced a fully integrated model combining modules that reflect demographic and epidemiological parameters mathematically with the CGE core model to facilitate automatic and instant feedback effects between these areas.

As it is micro-founded, this building upwards from economic sectors unlike most macro-economic models that deconstruct from the top-down, the model will enable us to disaggregate sectors to a large degree of detail to reflect the core elements of the systems map (see Appendix A), both in terms of sectors and relationships. This will allow us to draw out the impacts of the SDIL across various industrial sectors, households of different SES, and areas of government, especially HM Treasury, and encompass the multiple dynamic feedback effects predicted by the preliminary systems work (Appendix A). The systems map also provides the basis for specifying the impact points in the model. For instance, labour supply will be impacted by changes in health (morbidity and mortality) and changes to industry profits may impact on participation rate within those sectors; health will also be affected by changes in employment, creating a dynamic interaction over time. Similarly, there will be changes in purchases that affect employment, reflected in demand for labour across different sectors, and the feedback effects from this will also be captured. There could be effects on the import and export of goods as inputs (e.g. sugar) and outputs (e.g. SSBs). The multi-sectoral nature of the model will capture these and relationships between them, guided by the systems map.

Other WPs will feed critical information into the CGE model on both demand and supply sides. WP1, looking at the impacts on the food industry, will enable the development of specific impacts around product change; price, diversification and formulation. WP1, looking at the demand response in purchases of SSBs, will also enable fine-tuning of the relevant elasticities contained within the model for price change for SSBs. The health assessments provided in WP2 by PRIMETIME will be embedded within the demographic and epidemiology modules, and drive the

economic-related health impacts of the SDIL. Work on the micro-economic analysis for WP3, as outlined above, will be used to add greater specificity to the main sectoral impacts beyond health, as well as within the health sector itself. This will also enable fine-grained sectoral disaggregation of the health and social care sector. WP4 will provide additional detail concerning likely impacts across sectors and population groups, and also provide the basis for specific counter-factual scenarios, looking at alternative views of possible responses and future developments in policy and response to policy.

Study populations & data sources

As indicated, the micro-economic analysis will draw upon WP2 for health outcomes data, and WP1 for data on price and demand effects for the targeted SSB and related goods (non-levied beverages, confectionary). This will be supplemented with data related to industry and cross-sectoral impact based on responses to qualitative work in WP4 and monitoring and observation of impact to specific organizations reported in annual financial reports, industry press and government statistics. This will enable reporting of ongoing impacts (and initiatives), and be used to populate core nodes within both micro- and macro-economic models.

Both the micro- and macro-economic models will then simulate the UK population and model the health and economic outcomes of the SDIL across the three time periods of the evaluation, such that they can estimate the (additive) effects of the announcement, legislation, introduction and post-introduction phases. Impacts will be estimated through generation of a counterfactual path compared to a baseline trajectory where the SDIL is not introduced, and also compared with different future scenarios for SDIL.

The health impact for both micro- and macro-economic analyses will be based on the PRIMETIME model used in WP2. This is based on an artificial cohort that incorporates children, adolescents and adults and is representative of the UK population in terms of age and sex. This cohort will be built with reference to mid-year population estimates from the Office for National Statistics and the General Register Offices for Scotland and Northern Ireland. Transition matrices that will dictate the progress of the cohort between the states of the model will be parameterised using disease incidence and mortality estimates taken from national mortality statistics, disease registries and linked datasets of HES and mortality.

For the micro-economic analysis this model will be augmented through clear links to cost drivers, for the NHS and wider health service, and beyond (as indicated it is likely that these will be cost savings for the health service), and use standard health service cost (e.g. using programme-budgeting and HES data) supplemented by specific organisation costs from the wider assessment indicated above (corporation financial reports, industry reports and government statistics on aspects such as employment, revenue growth and tax income).

For the macro-economic analysis, PRIMETIME will be translated in to an epidemiological component linked directly to the CGE model through demographic effects, to estimate the economic impact of changes to health status. The direct financial impact of SDIL, to industry, consumers and retail for example, will be gained from the review of wider economic data as indicated above (corporation financial reports, industry reports and government statistics) and these effects combined will then be used to inform model construction, policy scenarios and feedback effects.

The core data for the macro-economic assessment, on which the CGE model is built, is the social accounting matrix (SAM). This is a matrix that represents the balanced income and expenditure flows of a regional, national or global economy aggregated to make them a manageable size for use in a CGE model (the matrix rows represent income to the economy and the columns represent expenditure). We will use the latest available SAM when the model is constructed, and update it as the project continues. A critical part of SAM construction is to aggregate and disaggregate the sectors (from a few to hundreds) that best represent the issue at hand, and this will be informed by the systems map we have produced already (Appendix A). The SAM is complemented by a series of elasticity parameters that govern the relationships between sectors and economic actors. As we have previously specified a model for the UK these are already incorporated in the model, and will be refined through research conducted especially in WP1 (more precise relationship between change in price and demand), but also WP4 (such as industry response) and the micro-economic assessment indicated earlier on wider impacts.

Proposed outcome and impact measures

The micro-economic analysis will produce estimates of the NHS and social care costs and savings accrued from the SDIL over the short-, medium- and long-term. It will also provide information on wider observed and likely economic impacts to other sectors. Health outcomes, expressed as QALYs, will enable cost-effectiveness estimates of the SDIL to be estimated from both health/social care and societal perspective. The macro-economic analysis will indicate economy-wide impacts on macro-economic variables nationally, as well as disaggregated sectoral impacts and population impacts. These broad economic outcome measures will encompass impacts on the economy overall, and specifically on HM Treasury, industry and consumers by SES.

For example:

- Revenue raised by the levy
- Spending on funding for child health promotion in primary schools
- Extent to which the levy is passed on to consumers (i.e. by increases in prices of SSBs)
- Extent to which the costs of the levy to industry are defrayed by industry through price increases across a broader range of products
- Broad macro-level indicators, such as GDP/GNI, inflation, balance-of-payments and employment
- Other sector specific changes in income, profits and costs
- Overall implementation costs, resulting from changes across government, industry and households

7.4 WP4 – Impacts on key stakeholders: the public, politicians and professionals

Study design

We will collect data to develop an understanding of the impacts of the SDIL and responses to it from key stakeholder groups including the public, industry, media and government. Quantitative and qualitative methods will be employed as follows:

- Thematic analysis will be undertaken to identify predominant discourses relating to sugar and the SDIL using documentary sources including: media coverage, political discourse & industry communications
- Analysis of social media (Twitter) to identify predominant discourses relating to sugar and the SDIL, and the spread of discourses over time and between groups.
- Longitudinal qualitative research comprising one-to-one interviews and focus groups will be used to gauge the reactions of the public and key stakeholder groups to the SDIL

Study populations, sampling and recruitment

Study populations for the qualitative components will be sampled as follows:

Food industry reactions to the SDIL will be tracked in two ways:

- *Food industry trade press*, such as The Grocer magazine. The range of relevant trade press media will be identified by iterative searching of the internet and the LexisNexis database. A sampling strategy will be determined, dependent on the volume of material and frequency of publication, aiming to achieve thematic saturation to ensure that changes in discourse can be tracked over time across the implementation phases of the SDIL.
- *In depth telephone interviews* with a purposive sample of professionals representing key sectors of the food industry with interests in SSBs, which will include manufacturers, distributors, retailers, and vendors. Participants will be identified through snowball sampling, starting with the extensive database of contacts we have developed in our formative work (stakeholder consultation on the SDIL systems map). Informed consent will be obtained verbally and documented by the researcher. Interviews in each implementation phase will continue until saturation has been achieved, building on interviews conducted as part of our formative research (current NIHR PHR Rapid Funding Grant). A maximum of 15 interviews per phase will be undertaken. Where they are willing, interviewees will be asked to participate in interviews across each phase of the SDIL evolution and implementation, so as to gain a longitudinal view of discourses on sugar consumption and the SDIL.

Public discourse surrounding the SDIL will be similarly tracked in three ways:

- *News media coverage* will be identified by interrogating the LexisNexis database using a pre-determined search strategy that will be refined following initial scoping, to identify all articles referring to regulation of sugar in food/drinks, or to the SDIL specifically in national newspapers and trade (food industry) press from 2 years before announcement of the levy until 2 years after implementation. It is likely that articles will be clustered sporadically. Searches and screening of articles will therefore take place at the end of time periods 2-3. Depending on the volume of material, we may need to sample articles from each time period to limit workload, while achieving thematic saturation. The majority of national press articles can be accessed online, where public reactions to articles can also be found. This public discourse will also be sampled and analysed iteratively, to saturation.
- *Social media discourse* will be identified via analysis of Tweets, which will be collected using both specific keywords and also by following Twitter accounts of key individuals and bodies, from October 2016 until March 2020. This will include data on public and professional (e.g. public health, industry) discourse, as well as advocacy from civil society organisations and individuals, which will be triangulated with other sources (see below). Relevant tweets from each of the four time periods will be identified using search strategies (determined during our current formative work) to identify discourse on the SDIL. Key sources (twitter accounts) identified as commenting on the SDIL in early searches will be routinely searched in subsequent searches for continuing discourse (e.g. Faculty of Public Health, British Soft Drinks Association, Jamie Oliver). The volume of material is likely to be high. For qualitative analysis, to ensure a manageable quantity of data, we will prioritise 'popular' tweets (e.g. highly retweeted) and those from key stakeholders, as well as sample material for content analysis, which will continue to saturation. We will also undertake network analysis to explore the spread of discourses between groups and over time. Detailed methods are being developed in our formative work.

- *Focus groups with members of the public*, including parents, secondary school children and young adults (16-24 years), will be undertaken to identify degree of consensus on the potential acceptability and impacts of the SDIL. Purposive sampling will aim to achieve maximum variation with regard to geography (UK countries/regions), age (12-15, 16-24, 25-44, 45-74 years), gender (male, female) and socio-economic position (non-manual occupations, manual occupations). We will work with NIHR's People in Research (www.peopleinresearch.co.uk) to recruit adults for focus groups. Secondary school pupils will be identified via their parents and approached with parental consent. We will recruit 10-12 participants per focus group. We will aim to achieve focus groups that are relatively homogeneous within each group, but diverse across groups, with a view to identifying in particular the degree of consensus on issues of interest. A sub-sample of volunteers who agree to take part in multiple focus groups across the phases of SDIL evolution and implementation, will join groups that will act as panels, to gain a longitudinal view of discourses on sugar consumption and the SDIL. We will sample and analyse focus group discussions iteratively, aiming to achieve saturation. We anticipate conducting approximately 5 focus groups in each of time periods 2-4, a total of 15 groups.

Political discourse on the SDIL will be identified from Hansard (official record of Parliamentary sessions), select committee records and published records (e.g. policy documents) of key departments (e.g. HM Treasury, Department of Health). A key analysis will focus on the material submitted to the HM Treasury consultation on the SDIL during summer 2016, when this is made publicly available. We anticipate analysing this data in its entirety, but if the volume is too great, we will determine a sampling strategy to ensure a representative range of views are contained in the data.

Political advocacy arising from public health and other groups (e.g. UK Health Forum, Sustain and Children's Food Campaign), including groups opposed to the SDIL (e.g. Institute of Economic Affairs (IEA), Food and Drink Federation (FDF)) will be tracked by identifying and monitoring relevant media over the course of the study (which may include social media, web sites, press releases and newsletters). These media will first be identified through internet and social media searches and our searches of LexisNexis (see above), and then sampled if necessary to ensure a representative but manageable volume of material is analysed to achieve saturation.

Data collection

- Document analysis: Documents to be analysed will be retrieved electronically where feasible (e.g. from online sources) and saved as digital files. Documents only available in hard copy will be scanned to create digital files. Complete texts will be extracted and entered into NVivo/Atlas.ti for analysis.
- Twitter analysis: Automated methods to harvest relevant tweets using pre-specified search strategies are being developed in our formative work.
- Interviews and focus groups: data collection will be supported by topic guides that will be informed by existing theory and discourses, and developed with stakeholder input (professional or public as appropriate) and piloted prior to formal data collection. Topic guides for interviews and focus groups will ask about participants' perceptions of the potential benefits and harms of the SDIL to any individuals or sectors, as well as attitudes to fiscal food policies and the SDIL in particular. Interviews and focus groups will be digitally recorded with participants' permission and transcribed verbatim. Transcripts will be checked by the interviewer and then entered into NVivo/Atlas.ti for analysis. Interviewers' notes will be transcribed verbatim and entered into NVivo/Atlas.ti for analysis alongside transcripts.

Data analysis

- Documentary sources, including news and social media content: Data from documentary sources will be analysed qualitatively using thematic content or critical discourse analysis, as appropriate, assisted by NVivo software. Rather than a static analysis at a single point in time, sequential analyses will be undertaken using data from key time segments corresponding to the phases of the introduction of the SDIL (i.e. mirroring the quantitative analyses). Using this approach we will be able to explore how prevailing narratives for each group of interest (public, professional, industry, political) develop over time as plans for the SDIL develop and solidify. A dialogue between the qualitative and quantitative analyses will allow us to explore the extent to which the development of narratives appear to be contingent on the emerging processes and outcomes of the SDIL. This approach will be strengthened by longitudinal analysis of data from key sources with ongoing⁸⁰ discourse on the SDIL (e.g. specific newspapers, trade journals or twitter accounts). We will also use network⁸¹ and sentiment analysis⁸² of the accumulated relevant tweets to identify the trends, spread and emergence of discourses, and relationships between key stakeholder discourses.
- Interview and focus group data: Data from face to face dialogues will be analysed thematically,⁸⁰ assisted by NVivo/Atlas.ti software, using the Framework method⁸³ with constant comparison⁸⁴ and deviant case analysis⁸⁵ to enhance validity. Initial frameworks will be developed from interview topic guides and modified iteratively using emergent themes, so that earlier transcripts influence the analysis of subsequent transcripts. As with the analysis of documents, interviews and focus groups will be analysed in time segments corresponding to the implementation phases of the SDIL. The enquiry will be strengthened by longitudinal analysis of data from focus group panels allowing investigation of emerging discourse on the SDIL.

All data will be anonymised following transcription to preserve the anonymity of individual participants or organisations where possible. A sample of all qualitative data will be independently analysed by a second researcher to ensure reliability of the thematic coding frameworks. Data clinics involving WP4 team members will also be held to achieve consensus in data interpretation. Any data that are unavoidably identifiable will only be used with the consent of the relevant participants.

7.5 WP5 – Integrate, synthesis and dissemination of findings from WP 1-4

We will integrate and synthesise the findings from WPs 1-4 in order to develop a coherent overarching interpretation of the findings. To achieve this, we will first map our findings on to our systems diagram (Appendix A), in order to test and refine our underlying intervention theory for the SDIL. As this is an area without established methods, we will conduct a scoping review to identify a range of evidence integration and synthesis methods, develop criteria to assess their appropriateness for use within the context of synthesising data and evidence available as a result of the SDIL evaluation and select a set of appropriate methods. These methods will not be restricted in terms of their disciplinary origin, and will reflect approaches used within epidemiology, systems science, behavioural and social science. Broadly, this could involve further quantitative analysis to explain outcomes, such as mediational analyses or exploration of the relations between time trends in outcome variables (e.g. using Dynamic Regression or ARIMAX modelling).⁸⁶ Findings generated using different methods (qualitative, quantitative) could be triangulated to explore the extent to which they provide a consistent interpretation and conclusions about the impacts of the SDIL using pattern matching⁸⁷ and causal process

observation,⁸⁸ thus strengthening causal inference.³⁶

To gain further validation of our interpretation, findings will be shared with key stakeholders (professional and public) in engagement workshop events, in which we will seek their detailed reactions and reflections on specific analyses, findings and interpretations. These will be formally documented and contribute to our final interpretation and conclusions.

During WP5, we will seek wide dissemination of our findings by a variety of means, including presentation at national and international conferences and publication in high-impact journals, preparation and dissemination of policy briefings and policy briefing events, and use of social media and web sites.

8 Setting

The focus of the research will be the United Kingdom, all of which is covered by the SDIL. There may be differences in impacts across the country by region, and we will explore whether these might be captured using routine data. Where data are not available at UK level, the largest geographical area will be used.

9 Data monitoring, quality control and quality assurance

The MRC Epidemiology Unit, University of Cambridge is the lead institution. Collaborations with LSHTM and University of Oxford will be governed by formal collaboration agreements and financial sub-contracts. The University of Cambridge will act as sponsor.

The PI (White) will have primary responsibility for scientific and strategic oversight, supported by work package (WP) leads and co-leads (listed below). A senior post-doctoral researcher will work on WP4 and act as overall project manager, responsible for day-to-day coordination of the Work Packages (WPs), liaising closely with the WP leads and co-leads.

A Programme Management Group comprising the PI and WP leads will meet monthly face-to-face or by teleconference. All investigators and research staff will attend bi-annual investigator meetings. Additional, regular WP meetings will take place as required by the work schedule. Collaborators, stakeholders and PPI representatives will be invited when appropriate to seek their input. An independent Study Steering Committee (Independent chair, 2 independent scientific members, 2 PPI representatives – appointed by NIHR) will meet annually with the Programme Management Group to provide external oversight.

The research will be undertaken to the highest ethical and research governance standards, complying with current guidelines and legislation, including the Research Governance Framework for Health and Social Care and Data Protection Act.

10 Ethics and regulatory issues

This work will comply with the ESRC research ethics framework and follow the guidance of Ethical Research Involving Children (ERIC) where appropriate. A significant part of the work involves the use of existing routine data sources, where ethical approval was sought and managed by data providers (WP1, WP2 & WP3) or not required (WP5). All research involving primary data collection (interviews and focus groups) will be subject to ethical committee approval. We will apply for approval through the Humanities and Social Sciences Research Ethics Committee at the University of Cambridge, which gave approval for our formative research that included an online survey and telephone interviews.

All interview and focus groups will be completed with informed consent, or assent by parents for secondary school children, with the right to withdraw consent at any time, providing all participants with an opportunity to review the risks and benefits prior to participation either in person or via email (as appropriate), with no details withheld. There are minimal ethical risks to participation in this work given that no sensitive personal questions will be asked. However,

stakeholders in different organisations may feel their personal opinions relating to the levy are counter to the interests of their organisation. In order to reduce any risk of feeling conflicted, we will reinforce the desire to share their perspective from an organisational perspective and also that their participation is non-identifiable (interviews only) and non-attributable in research outputs (interviews/focus groups), and that they are able to withdraw at any time. Similarly, the general public may feel sharing preferences for consuming soft drinks is stigmatising. They will be reassured that their participation will be non-identifiable (interviews only), and are free to withdraw at any time. Questions will be developed to minimise this risk and all quotations in research outputs will be completed anonymised.

The MRC Epidemiology Unit has an over-arching data management plan that includes standards and processes applied to all research and operational activities of the Unit. The PI will ensure that all data generated, stored and shared will be handled in compliance with this plan. Research staff are trained in handling qualitative data, and taking the proper steps regarding data security. All data collected through telephone or in personal interviews or focus groups will be link-anonymised with any personally identifiable information and stored separately. All data, where appropriate, will be held on the Unit's secure network.

11 Study reporting and publication

We will seek wide dissemination of our findings by a variety of means, including presentation at national and international conferences and publication in high-impact journals, preparation and dissemination of policy briefings and policy briefing events, and use of social media and web sites.

12 Study timetable and milestones

The overall timeline for work packages will overlap over the duration of the project (Appendix C). In summary, we have proposed the following timetable and milestones:

- WP1 – Initial data acquisition and preparation completed by December 2017 and after levy implementation by December 2020. Initial analysis of outcomes will be completed by December 2018 and after levy implementation by December 2021.
- WP2 – Data audit and acquisition will be completed by June 2021, model preparation by September 2021 and scenario analysis and papers completed by December 2021.
- WP3 – initial data acquisition and preparation for macro-economic modelling will be completed by March 2018 and after levy implementation by June 2020. Initial model construction will be completed by June 2019 and after levy implementation by September 2021, with analysis and papers completed by June 2019 and December 2021 respectively. Micro-economic modelling will be completed by June 2019 and December 2021 respectively.
- WP4 – Ethical approval will be obtained by January 2018. Participant recruitment, interview and focus group data collection, qualitative analysis and papers will be

completed by April 2019 and February 2021, and content and media analysis and papers completed by March 2018, October 2019 and May 2021.

- WP5 – System map revision and synthesis of findings will be completed by September 2021. Final report to NIHR and other outputs (e.g. policy briefings), and stakeholder impact events by December 2021

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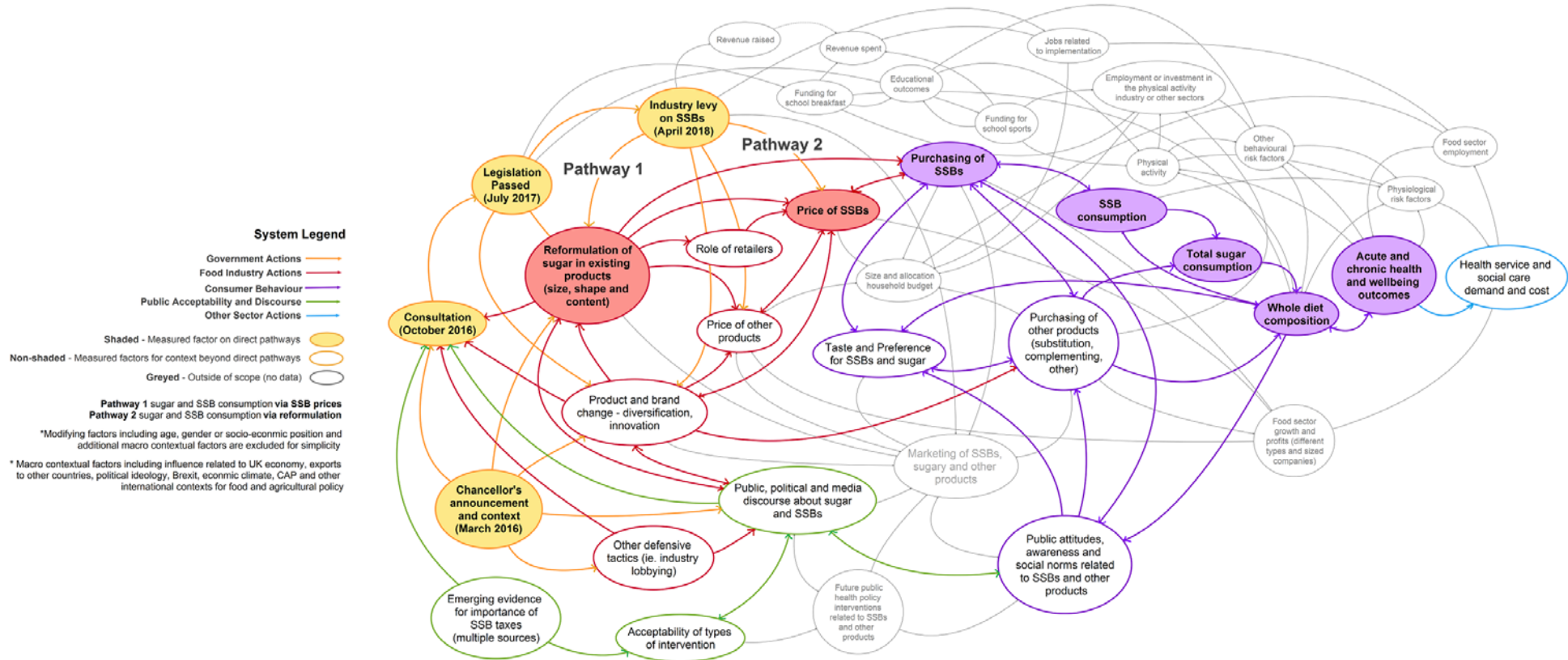
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14 Appendices

14.1 Appendix A: System map



14.2 Appendix B: Data table

	System map factor with measurement available	Data type	Data source	Work Package	Cost for access	Cost for collection
Industry Actions	Reformulation of sugar in existing products and role of retailers	Commercial sales data	Kantar WorldPanel	WP1	Yes	No
	Product and brand change - diversification, innovation	Supermarket inventory data	Online supermarket websites	WP1	No	Yes
	Price of other products	Supermarket inventory data	Online supermarket websites	WP1	No	Yes
	Price of SSBs	Supermarket inventory data	Online supermarket websites	WP1	No	Yes
	Other defensive tactics (i.e. industry lobbying)	Industry communications and interviews	Industry online publications and stakeholders	WP4	No	No
Consumer Behaviour	Purchasing of SSBs	Commercial sales data	Kantar WorldPanel	WP1	Yes	No
	Purchasing of other products (substitution, complementing, other)	Commercial sales data	Kantar WorldPanel	WP1	Yes	No
	Taste and preference and public attitudes for SSBs and sugar	Commercial sales data	Kantar WorldPanel	WP1	Yes	No
	SSB consumption	National Survey	National Diet and Nutrition Survey	WP1	No	No
	Total sugar consumption	National Survey	National Diet and Nutrition Survey	WP1	No	No
	Whole diet composition	National Survey	National Diet and Nutrition Survey	WP1	No	No
	Acute and chronic health and wellbeing outcomes	Administrative data, national study and PRIMETIME model estimates	Hospital Episode Statistics (dental caries); National Child Measurement Programme (childhood adiposity); Office for National Statistics and the General Register Offices for Scotland and Northern Ireland and Hospital Episode Statistics (model)	WP1 & WP2	No	No
Public Acceptability and Discourse	Media, political and public discourse on SSBs and sugar	News media coverage, social media, documentation and online sources	LexisNexis, Twitter, Parliamentary records and documents and online media	WP4	No	No
	Acceptability of types of intervention	Focus groups	General public including parents, children and young adults	WP4	No	Yes
	Emerging evidence for importance of SSB taxes	Interviews	Professional stakeholders	WP4	No	Yes
Government Actions	Chancellor's announcement	Documentation	UK Treasury	WP1-5	No	No
	Consultation	Documentation	UK Treasury	WP1-5	No	No
	Legislation passed	Documentation	UK Treasury	WP1-5	No	No
	Industry levy	Documentation	UK Treasury	WP1-5	No	No
Other Sectoral Actions	Health service and social care demand and cost	Micro (PRIMETIME) and Macro (Computable general Equilibrium) model estimates	Office for National Statistics and the General Register Offices for Scotland and Northern Ireland and Hospital Episode Statistics (micro), Global Trade Analysis Project and UK Treasury (macro)	WP3	No	No

14.3 Appendix C: Timeline and milestones

