1. Project title

The effectiveness of promotional campaigns associated with revised UK drinking guidelines: An evaluation of a prospective natural experiment.

2. Background

2.1. Context for the study

In 2012, the UK Government's Alcohol Strategy placed a strong emphasis on supporting drinkers to make healthier choices. A key mechanism for achieving this was for the Chief Medical Officer to lead a review of the country's lower risk drinking guidelines (DG).[1] Following that review, proposals for revised drinking guidelines were published in January 2016; however, the publication of new DG is not, on its own, a public health intervention; it is the **promotional activity** that disseminates these guidelines and encourages engagement with them which the project will seek to evaluate.

The promotion of public health guidance is a major strand of UK public health policy. Public Health England's (PHE) marketing plan has a stated aim of "motivating and supporting more people than ever before to improve their health".[2 p.3] Crucially, PHE have identified a "relentless focus on behaviour" (p.6) as a guiding principle for that plan, noting that previous campaigns have often succeeded in raising awareness of and motivation for healthy behaviour, but have failed to translate that into behavioural change. Therefore, the study focuses on evaluating the impact of promoting DG on alcohol consumption behaviour (primary outcome) using an interrupted time series design. Alcohol consumption is difficult to measure, so a triangulation approach will be used to assess whether an extensive series of secondary analyses using alternative outcome measures (e.g. alcohol-related hospital admissions, alcohol taxation data) and analytical approaches will provide validation of the primary analysis and aid its interpretation. Health economic outcomes will also be modelled using the Sheffield Alcohol Policy Model. [3,4]

Promoting DG is a complex intervention as it is delivered in diverse forms by diverse bodies with an extended causal chain from implementation to outcome. For example, DG are not promoted by a single organisation but by a range of governmental and non-governmental bodies including PHE, the NHS, Drinkaware (an alcohol industry-funded charity), public health charities, and the news media. These bodies are likely to engage in a range of promotional activity including use of mass media campaigns, interactive social media, consultations with health professionals, product labels and point of sale advertising. Behaviour change theory suggests any resulting impacts on alcohol consumption will not be direct but mediated through changes in factors including individuals' knowledge, motivations and social context.[5] Therefore, the triangulation approach will be extended to elicit evidence on each stage of this causal chain and assess whether that evidence tells a consistent story. A logic model of the causal is provided in Appendix B and this accounts for additional complexities such as a public consultation on draft guidelines and that stigmatisation and improved knowledge may alter self-reporting biases for alcohol consumption.

2.2. Existing research

***Lack of evidence**:* DGs are promoted in most developed nations and many emerging economies but are often viewed by public health stakeholders as an ineffective distraction from more meaningful interventions.[6-9] Scientific evidence to support this perspective is lacking and reviews have repeatedly noted that there have been no rigorous evaluations of the impact of producing, revising or promoting DG on alcohol consumption or other factors linked to behaviour change.[9-12] However, guidance on health behaviours including smoking, drink-driving, physical activity, nutrition and cancer risk awareness has been shown to produce small to moderate effects on knowledge, attitudes and behaviour.[12-16] The likelihood of positive effects is increased when attention is paid to good intervention design, including drawing on theories of behaviour change.[14,15]

***Previous studies**:* The small literature examining effects of promoting DG relies on weak research designs and generally contains little engagement with the promotional activity itself (e.g. with the media and content through which DG are promoted, demographic targeting of promotional activities and theory-based mechanisms for behaviour change). Cross-sectional analyses of public knowledge of guidelines have been undertaken in several countries. These generally conclude that large minorities of the population are aware of DG and can correctly identify guideline consumption levels, but there is little evidence that this influences drinking behaviour.[17-19] The impact of promoting guidelines on related knowledge and perceptions has been examined in Australia[20] and Denmark[21,22] via retrospective analysis of varying numbers of repeat cross-sectional surveys. Similarly, the UK ONS included occasional DG-related questions within its monthly Omnibus survey until 2009. In each country, it was concluded that promotional activity improved knowledge of guidelines and in Australia there was evidence that beliefs regarding what constituted safe drinking also changed.[20] In the UK, ONS found awareness of DG had increased from 54% in 1997 to 75% in 2009 with little variation by gender and with greater awareness among heavier drinkers.[23] However, just 33% of all men and 39% of all women were able to correctly identify the guideline for their gender (37% and 57% among heavier drinkers) with only modest increases in this proportion over time. Further, in 2009 just 13% of all drinkers and 16% of those exceeding the UK guidelines reported using units to monitor their drinking.[23] The most detailed study to date of promoting DG evaluates an Australian campaign aiming to raise awareness of DG and alcohol-related cancer risks.[24] This prospective evaluation used three small sample (N≈150-200) repeat cross-sectional surveys of women over a 15 month period. The results suggested that multiple waves of advertising led to good recognition and recollection of campaign content which, in turn, impacted on cancer awareness, DG-related knowledge and behavioural intentions among heavier drinking women in particular. However, no impacts were seen on behaviour and the authors attributed this to competition from commercial pro-alcohol marketing and pro-drinking social norms; a barrier also noted by in a major review of alcohol policy effectiveness.[9]

***Recommendations for future research**:* Several studies have made research recommendations which emphasise the need for rigorous prospective evaluations of the impact of producing, revising and promoting guidelines.[11,25] Specific recommendations have highlighted the need for evaluations with control arms where feasible, examination of the effects of different campaign messages and studies which are theory-driven and evaluate impacts on both behaviour and factors influencing behaviour change.[11,17,25]

As described in the sections below, the project is designed to meet these recommendations and provide the most authoritative analysis to date of the effectiveness and cost-effectiveness of promoting DG. This is facilitated by unique features of the project including the research team being embedded in the UK guideline review process, advanced knowledge of publication and promotional timeframes which permits robust baseline data collection, a powerful existing evaluation tool (the Alcohol Toolkit Study), robust primary analyses supported by multiple detailed secondary analyses and an interdisciplinary team of world-leaders in alcohol policy analysis, behaviour change theory and evaluation of health promotion campaigns who have worked together over several years within the NIHR School for Public Health Research and UK Centre for Tobacco and Alcohol Studies.

2.3. Rationale for the current study

***A rare evaluation opportunity**:* Promoting DG is a key feature of alcohol policy debate in the UK and internationally. Successive UK governments have been reluctant to increase regulation of the alcohol market and have instead focused on promoting 'responsible' drinking with the support of vested interests within the alcohol production and retail industries.[26] Evaluating the public health consequences of such decisions is challenging as research possibilities are limited by the often small-scale nature and unpredictable timing of promotional activity. Revision of the DG presents a rare and valuable opportunity as promotional activity is likely to be at its peak and its timing can be anticipated. It is unlikely similar circumstances will arise for many years given the forthcoming revisions are the first since 1995 and a significant investment is required to update and communicate DG. The situation is comparable

internationally and recent revisions to DG in Canada and Australia were implemented without rigorous evaluation of their impacts on public health. The research team are well-placed to take this once-in-a-generation opportunity as the PI is an advisory member of the Chief Medical Officers' Guideline Development Group and has detailed knowledge of the likely revisions to the DG and the planned promotional activity.

***Evaluating the Government's Alcohol Strategy**:* In addition to providing the most robust evaluation to date of promoting DG, the project will evaluate the effectiveness of the Government's Alcohol Strategy (published in 2012). The strategy initially included many evidence-based measures (e.g. minimum unit pricing, restrictions on price-based promotions, a public health licensing objective) which were later withdrawn following a public consultation.[27] However, emphasis on the need to "support individuals to make informed choices about healthier and responsible drinking";[1 p.4] was retained, with the main mechanism for achieving that aim being to review and promote the DG. Therefore, this project will evaluate the public health impact of a central element of current Government alcohol policy.

***Value to policy stakeholders**:* UK Department of Health have voiced a strong interest in the project and its outputs, while PHE have agreed in principle to stagger of rollout their campaign across the country to facilitate more robust evaluation (e.g. by using a step-wedge design). **NICE have also provided a letter of support** (see attached uploads) highlighting areas of interest to them. The monthly survey data generated by the project will be available within one month of collection, allowing for rapid provision of feedback to stakeholders on trends in outcome measures while promotional activities are on-going. International stakeholders are also likely to benefit as DG are promoted in most developed nations[28] and international convergence in guideline consumption levels has been noted,[29] meaning evidence on the effectiveness of promoting UK guidelines will have increased international relevance. In general, the evaluation will make a key contribution to international policy debate on reducing alcohol-related harm commercial actors have successfully exploited the lack of effectiveness evidence to argue education and persuasion approaches should be preferred to regulatory interventions for which the evidence-base is stronger (e.g. tax increases, restricted advertising).[9] Robust evaluation of the impacts of promoting DG will better allow policy makers to compare the effectiveness of these different approaches and respond accordingly.

***Contribution to behaviour change science**:* We have designed questions to reflect a well-supported integrative model of behaviour change (COM-B[30]) which will allow us to identify mechanisms of effect (i.e. capability, opportunity and motivations for behaviour). This will advance our understanding of how promotional activities such as mass media campaigns and product labelling impact on outcomes. It will also provide data on inequalities in effects across society and the variations in impact for different promotional activities. This, in turn, can inform the development and design of future health promotion activities.

Added value to NIHR: The project will add DG-related questions to the ongoing NIHR-funded Alcohol Toolkit Study (ATS).[31] The ATS started in March 2014 and was designed to facilitate evaluation research. It comprises a monthly survey of adults living in private households in England and is modelled on the Smoking Toolkit Study (STS) which began in 2006 and sits within the same Ipsos Mori Omnibus survey. The STS has achieved high impact through successful evaluation and monitoring of a range of smoking interventions and developments leading to over 50 scientific journal articles.[32-37] Additional ATS data collected within this project will be subsequently available for analysis by other ATS users and facilitates further high value analyses related to alcohol and smoking behaviour and behavioural trends (e.g. planned evaluation of the Dry January initiative, the reasons for long-term declines in per capita alcohol consumption).

3. Research objectives

The study aims to conduct a detailed prospective evaluation of the impact of promoting revised DG on alcohol consumption behaviour. It will elicit evidence on the complex causal chain from implementation to effect including what promotional activity occurs, who is exposed to it, how it affects factors theorised to influence behaviour

change and the relationship between those factors and behaviour itself. The evaluation will utilise data collected both pre- and post-publication and promotion of the revised DG.

The project aims will be achieved through meeting the following research objectives:

(1) Documenting the timing, audience and content for major promotional activity following the publication of revised DG.

(2) Using interrupted time series analysis to assess whether trends in alcohol consumption behaviour (primary outcome) alter following publication and promotion of revised DG. Trends will be measured using monthly repeat cross-sectional survey data. A series of secondary analyses will use alternative outcome measures (e.g. additional individual and aggregate-level measures of alcohol consumption, alcohol-related hospital admissions, factors theorised to influence behaviour change) and alternative analytical approaches.

(3) Undertaking subgroup analyses to examine whether there are variations in intervention effects across groups of the population defined by age, sex and socioeconomic status.

(4) Using difference-in-difference methods to examine whether direct and frequent exposure to promotion of DG increases effectiveness. Intervention effects will be compared between those reporting recent and frequent exposure and those reporting infrequent or no recent exposure.

(5) Undertaking pathway analyses to validate theorised relationships between capability, opportunity and motivation to change behaviour and behaviour itself.

(6) Assessing cost-effectiveness of any identified effects on alcohol consumption using the published Sheffield Alcohol Policy Model framework.[38]

4. Research design

Overall design*:* The starting point for designing the study is that promotion of DG is a complex intervention as it is delivered in diverse forms by diverse bodies with a complex causal chain from intervention to outcome. A further challenge is that no robust control population is available. MRC best practice guidelines for evaluating complex interventions and natural experiments acknowledge that in such cases an optimal methodology is unlikely to be feasible but stress that application of best available methodologies can still deliver useful results. [39,40] Therefore, the study applies a triangulation approach to assess whether evidence obtained using a variety of methods tells a consistent story. In practice this means that we aim to validate results of the primary analysis by undertaking a series of secondary analyses using alternative outcomes, research designs and analytical techniques. Similarly, we aim to elicit evidence on the progression of intervention effects through the causal chain and assess whether this evidence is consistent with the intervention causing observed changes in the outcome measures. This triangulation approach permits stronger conclusions to be drawn and enhances understanding of intervention effectiveness

The primary analysis applies an **interrupted time series design** to test for changes in alcohol consumption trends within repeat cross-sectional individual-level survey data. One set of secondary analyses will apply the same design to a series of secondary outcomes including measures of capability, opportunity and motivation to change behaviour, alcohol-related hospital admissions and a series of alternative alcohol consumption measures in recognition of challenges in measuring consumption. A further set of secondary analyses will (a) attempt to evaluate the impact of specific promotional campaigns; (b) apply a **difference-in-difference design** to compare intervention effects between those reporting and not reporting exposure to DG and (c) using pathway analysis to test theorised relationships between capability, opportunity and motivation to change behaviour and behaviour itself. Finally, a cost-effectiveness analysis will be conducted using the Sheffield Alcohol Policy Model framework.[4,38]

PHE have committed in principle to staggering roll-out of their promotional campaign across English regions or groups of regions to enable the creation of a stepped wedge design. At the time of writing, PHE have not sufficiently progressed in planning their campaign to allow us to commit to treating this design as our primary evaluation approach; however, as more detail is agreed, this may become feasible.

Promotional activity timeline: As the promotion of DG is the active component which is being evaluated, a timeline of promotional activities will be constructed and used to understand the timing and nature of the intervention. The timeline will be created using a structured tool adapted from a previous study by co-investigator Lewis.[41] Where data are available, this will document the activity timing, content (e.g. theme, style, emotional content, suggested action) and audience size and demographic. Secondary analyses will use the timeline to explore whether effects of specific large-scale promotional campaigns can be detected on primary and secondary outcome measures.

The Alcohol Toolkit Study: Time series data will be collected via the Alcohol Toolkit Study (ATS). The ATS is a monthly repeat cross-sectional survey of new nationally-representative samples of approximately 1,800 adults each month living in private households in England. Data collection for the existing ATS began in March 2014 and includes the validated screening instrument AUDIT (Alcohol Use Disorders Identification Test).[42] However, detailed alcohol consumption questions and questions on exposure to DG or wider factors theorised to influence behaviour change are not included. Therefore, this project will add questions addressing these topics to the ATS for 24 consecutive months including approximately six months before publication of revised guidelines (Nov 2015 – Mar/Apr 2016) and 18 months post-publication (Apr/May 2016 – Oct 2017).

Strengths of the Alcohol Toolkit Study*:* The ATS has considerable strengths as a policy evaluation tool. The collection of monthly data provides multiple pre- and post-intervention time points within a relatively short timeframe, particularly for the primary outcome where data collection began in March 2014. This increases statistical power within population-level analyses, permits more robust subgroup analysis and allows for examination of temporal effects (e.g. how the development and decay of intervention effects aligns with the timing of specific promotional activities). The latter is particularly important for the project where timing of promotional activity is unknown in advance and any effects on outcome measures may be time-limited. ATS also represents excellent value for money as collection of sociodemographic and primary outcome data are already funded by NIHR and additional data on smoking behaviour for sample members is available via the Smoking Toolkit. The budget allocated to purchase of additional ATS questions will add further value to NIHR's existing investment as data will be available for analysis by other researchers and will greatly enhance the study by strengthening the causal inferences and conclusions which can be made. Neither the existing nor the additional ATS questions are present within any comparable UK dataset, nor could they be incorporated in an existing dataset to permit a comparably robust or timely evaluation.

Control population: Selecting an interrupted time series design for the primary analysis is appropriate as a robust contemporaneous control population cannot be identified given data from a comparable control country are unavailable, DG are promoted to the UK as a whole and exposure to this promotional activity is not distributed across the population in a random manner or in a way which can be predicted in advance. As a secondary analysis, a difference-in-difference approach will compare change in outcome measures between those reporting and not reporting exposure to DG.

5. Study population and sampling

Study population: The study population are respondents to 43 monthly samples within the ATS between March 2014 and October 2017. A subsample of 24 monthly samples between November 2015 and October 2017 will be used in some secondary analysis. Each monthly sample is collected by the research agency Ipsos Mori using in-home computer-assisted interviews and contains approximately 1,800 adults aged 16+ in England. All sampled individuals are included in the study assuming they respond to the ATS section of the Omnibus survey within which it sits.

Sampling: The baseline survey uses a form of random location sampling which is a hybrid between random location sampling and simple quota sampling. England is first split into 171,356 'Output Areas', each comprising approximately 300 households. These areas are then stratified according to ACORN characteristics and geographic region. ACORN is a socioeconomic profiling tool developed by CACI (http://www.caci.co.uk/acorn), which segments postcodes into five categories (wealthy achievers, urban prosperity, comfortably off, moderate means and hard-pressed). These categories are subdivided into 17 groups and 56 types using government and consumer research data (e.g. census data and lifestyle records). Areas are then randomly allocated to interviewers who travel to their selected areas and conduct the electronic interviews with one member of the household. Interviews are conducted until quotas based upon factors influencing the probability of being at home (i.e. employment status, age, gender) are fulfilled. Morning interviews are avoided to maximise participant availability. This method of sampling is often seen as superior to conventional quota sampling as the choice of properties approached is significantly reduced by random allocation of small output areas to interviewers. However, no response rate can be calculated as interviewers still choose houses within allocated areas.

6. Socioeconomic position and inequalities

Public and policy debate has given particular attention to alcohol consumption patterns among certain age and gender groups (e.g. middle-aged female daily drinkers, young binge drinkers). Recent research by the applicants has also identified sharp distinctions in the nature of heavy drinking occasions across age and sex groups and these findings are being used to inform design of health promotion campaigns.[43] It is therefore likely that promotion of revised DG will involve campaigns targeted toward particular drinking patterns and demographics.

There are also concerns regarding large and paradoxical inequalities in alcohol-related mortality and morbidity risks across socioeconomic groups. In general, lower socioeconomic groups have higher rates of harm despite being less likely to drink and more likely to drink at low levels if they do so.[44] Well-evidenced policies which may address these inequalities (e.g. minimum unit pricing) have been criticised for financially penalising already disadvantaged drinkers[3] and such criticism has contributed to public and Government reluctance to support these policies.[27] Therefore, evidence on whether alternative interventions offer similar potential for reducing inequalities would be valuable for informing policy debate and decision making.

The ATS provides a wide range of sociodemographic data on all respondents including age, gender and socioeconomic grade which is based on the occupation of the main earner. Additional indicators which are being used as a composite index of socioeconomic status in on-going ATS analyses include car and home ownership, employment status, educational achievement and income.[45] Subgroup analysis will examine inequalities in intervention effects and exposure to DG in different media by age, sex and socioeconomic status.

7. Planned interventions

Nature of revisions to the DG: In January 2016, the Department of Health published draft revisions to the UK's lower risk drinking guidelines. These recommended that men and women are 'safest not to drink regularly more than 14 units per week, to keep health risks from alcohol to a low level'. It was also recommended that 'if you drink as much as 14 units per week, it is best to spread this evenly over 3 days or more'. The previous guidance stated that men should not regularly consume more than 3-4 units on a single day and women should not regularly consume more than 2-3 units on a single day.

Nature of promotional activities: The scale, nature and content of promotional activity are also unknown at this stage. It is likely that they will be promoted by governmental and non-governmental organisations including the NHS, Public Health England, public health charities, Drinkaware, the alcohol industry and the news media. The project will define promotional activity broadly as: any activity that increases public awareness of the DG even if this is not its main aim. Therefore, relevant activities are likely to include mass media campaigns, interactive social

media applications, point of sale advertising, dissemination to the public during medical and pharmacy consultations, changes to product labels and news coverage. The latter may be particularly relevant if a consultation on draft guidelines is published as this will likely attract substantial reporting and comment within our pre-intervention period. As a likely source of large-scale campaigns, the project team has met with PHE and Department of Health and received updates on their planned activities.

Monitoring timescales: An important challenge for the evaluation will be monitoring and managing shifting timescales for publishing final revisions to the guidelines and launching any major government public information campaign. This problem is inherent to prospectively evaluating a politically sensitive intervention. The alternative of retrospective evaluation was used recently when evaluating the Scottish Alcohol Strategy and, although the project achieved some success, the strength of conclusions was limited as routinely collected alcohol data lack sufficient detail or focus to evidence clear policy effects or causal processes.

The proposed project will have robust processes to manage uncertainty. First, the research team have access to timely information due to the PI's advisory role on the Guideline Development Group and the applicant institutions' strong working relationships with Department of Health and Public Health England who are supporters of the ATS (e.g. they provide co-authorship on the ATS protocol paper [31]). Second, at the time of writing draft guidelines have been published in January 2016 and non-governmental bodies have already started to promote these meaning effects of the intervention should already be emerging. Third, stopping rules were written into the original proposal such that discontinuation of data collection would be discussed with the funder in November 2016 if: (a) Department of Health cannot confirm DG publication will occur by end of 2016 (this test has already been met); (b) No meaningful revisions to DG are agreed (this test has already been met); (c) No change in promotional activity by PHE is planned (this test has not yet been met). Allowing 12 months of data collection means a large dataset can be collected for non-evaluation analyses can be collected ensuring funds are not wasted.

8. Methods

An overview of the ATS is provided in the Research Design section of this proposal and sampling is provided in the Study Population and Sampling section. Here we focus on outcome measures and statistical analysis with the latter detailing how hypotheses derived from the timeline of promotional activity will be tested using ATS data.

8.1. Analysis of Alcohol Toolkit Study data

8.1.1. Outcome measures

The effects of promoting DG on alcohol consumption behaviour are the focus of this evaluation. Alcohol consumption is challenging to measure and survey-based studies consistently and substantially underestimate per capita consumption relative to sales or taxation data for reasons which are well-documented.[46] Of particular relevance here is that promoting DG may alter stigmatisation of heavy drinking and change knowledge so as to affect self-reporting biases related to alcohol consumption. However, UK taxation data are also problematic as (a) they do not account for the approximately 10% of alcohol consumed which is untaxed; (b) are difficult to model due to highly inconsistent seasonality (e.g. due to producers warehousing or pre-releasing alcohol ahead of duty cuts or rises); (c) may misrepresent short-term changes in consumption due to stockpiling by retailers or purchasers and (d) have been found to be subject to inconsistent coding practices.[46,47] Alcohol-related harm metrics, such as hospital admissions, offer an alternative proxy for consumption but also have limitations. These include time lags between changes in consumption and changes in harm, unobserved trends in attributable fractions (i.e. the proportion of cases attributable to alcohol) and, for many alcohol-specific conditions which are associated with very heavy drinking (e.g. liver cirrhosis), low likelihood that promoting DG will impact short-term trends to a detectable extent.

Given these challenges, analysis of the primary outcome measure will be validated via analysis of a carefully selected set of secondary outcomes. This approach reflects best practice as set out in MRC guidance on evaluating complex interventions[40] and the combined results will strengthen confidence in our findings and conclusions.

Primary outcome measure: The primary outcome measure will be AUDIT-C score. AUDIT-C is the short-form of the AUDIT (Alcohol Use Disorders Identification Test); a validated screening test for heavy drinking and/or active alcohol abuse or dependence.[42] It has demonstrated excellent reliability and responsiveness to short-term change.[48] The questions focus on alcohol consumption and combine measures of drinking frequency, typical quantity per occasion and frequency of drinking heavily on a single occasion and has been found to be sensitive to short-term changes in behaviour. AUDIT-C has been included within the ATS since March 2014 and thus sufficient pre-intervention data are available to detect modest effects (see Section 8.1.2. below). AUDIT-C is preferred to full AUDIT as the latter (a) includes questions with 12 month reference periods (e.g. in the last year have you…) which may prove insensitive to short-term intervention effects and (b) contains several items addressing alcohol dependence which promoting DG would not be expected to affect directly. A further advantage of AUDIT-C is it is widely used internationally and will thus offer comparability with future studies.

Secondary outcome measures*:* Three sets of secondary outcomes measures will be used:

1. Alternative alcohol consumption measures: The project will fund adding **Graduated frequency** (GF) questions on alcohol consumption to the ATS for 24 months from November 2015.[49] GF questions ask (a) on how many days participants drank during the last four weeks; (b) how many units they consumed on their heaviest drinking day; (c) on how many days they drank at that level and (d) on how many days they drank at progressively decreasing levels (e.g. if the maximum was 20 units, they would then be asked on how many days they drank 15-19 units, 10-14 units, 5-9 units etc.). GF measures are a recent development and have rarely been used in the UK. However, they are used extensively in the US, within the international GENACIS project and have been recommended for use by WHO.[50] Relative to other common measures, GF performs comparably in estimation of consumption volume and in ranking drinkers by consumption level.[51-53] The greatest strength of GF is detailed measurement of drinking patterns; a property of interest in this evaluation where changing patterns may be an aim of promotional activity. A potential weakness of GF is that respondents sometimes record more drinking days across consumption categories than the total number of days provided at the outset; however this has been mainly seen with 12 month reference periods and should be a lesser problem with the four week period used here. As no other large-sample UK survey uses GF, data collection will provide opportunities to compare its performance against AUDIT-C and other measures used within UK surveys which are generally weak. **Alcohol duty data** taken from HRMC's monthly duty bulletins record alcohol released for sale in the UK and provide an aggregate-level measure of consumption not subject to self-report biases. Finally, we highly recommend analyses using **full AUDIT score.** This would provide a test of the impact of promoting DG on a broader measure of hazardous drinking which, unlike the above measures, explicitly incorporates questions on harmful outcomes and dependence symptoms. By using standard cut-off AUDIT scores, further added value can be gained by examining change in the proportion of the population within different categories, including those at highest risk of dependence who may be of special interest to policy makers. Full AUDIT is funded within the ATS from March 2014 to March 2016; therefore **additional funds of £110,754 are required** to fund full AUDIT questions to October 2017. This would also allow an existing time series to continue providing benefit to wider research. We would welcome the NIHR PHR committee's advice on inclusion of this funding.

2. Behavioural antecedents: To strengthen causal inference analyses will examine change in factors which are theorised to influence behaviour. **Questions informed by the COM-B model of behaviour change will be used** and design of these has been guided by questions found to have predictive validity in the Smoking Toolkit Study. A literature review of behaviour change theories found 83 different theories, each with a different combination of constructs playing meditational and moderating roles within the theory.[5] Many of these theories are overlapping and there is a need to develop core integrative constructs that are evident across theories. One such integrative

model is COM-B which identifies Capability, Opportunity and Motivation as necessary for Behaviour to occur and also identifies the ways in which these constructs reciprocally influence each other.[54] A COM-B oriented questionnaire has been developed by the research team (Appendix A) and covers guidelines-related knowledge, perceived capability and skills required to drink within DG, social opportunity to do so and automatic and reflective motivations. These questions have been piloted internally by Ipsos Mori and will be commented on by PPI representatives ahead of a funding decision to avoid delays to starting data collection.

3. Alcohol-related harm: Trends in acute alcohol-related hospital admissions will be examined to detect short-term effects of alcohol-related harm resulting from modest consumption change. Data on **monthly admissions for alcohol poisoning (ICD-10: T51.0,T51.1,T51.9) and assaults (ICD-10: X85-Y09)** will be requested from Hospital Episode Statistics. The former proxies change in heavy episodic drinking, while the latter proxies alcohol-related violence, a key outcome for policy makers.

8.1.2. Primary evaluation analysis

The interrupted time series will be analysed using segmented regression through the application of Generalized Additive Mixed Models (GAMM). These can account for complex autocorrelation structures and seasonality. Although to our knowledge not previously used in alcohol policy analysis, segmented regression approaches have been used within a diverse set of tobacco studies; for example to evaluate smoke-free legislation, the cessation of UK mass media campaigns, changes to licensing arranges for nicotine replacement therapy and the partial tobacco point of sale display ban, as well as to analyse whether the growth in the use of e-cigarettes was responsible for the decline in the use of licensed nicotine products.[37,55-58]

In the research, three variables will be derived to model the trend in the outcome variable in the pre-intervention period, any immediate step change in the dependent variable following the intervention, and any change in the trend in the post-intervention period relative to the pre-intervention period. The first variable, time, will be measured in months from the start of the observation period to the last time point in the series. The second variable, level, will be a dummy variable taking the values 0 before the intervention and 1 after; while the third variable, slope, will be coded as 0 up to the intervention and record the number of months post-intervention months thereafter. The extent and type of autocorrelation will be assessed using the autocorrelation function and partial autocorrelation, in combination with the Durbin Watson statistic.[59]

Insofar as there is no evidence of effect in the primary analysis, secondary analyses will use linear and polynomial regression models to evaluate different potential accumulations and decays of effects in the population. This will include testing for a pulse effect in which there is short-term (e.g. 2-3 month) decline in AUDIT-C scores before a return to pre-intervention levels. In a final exploratory approach, segmented regressions will be run with unspecified breakpoints to identify points where significant changes in trends occur and the Bayesian Information Criterion will be used to select the optimal number of breakpoints. Causal inferences will be weaker here and will need substantial supporting evidence (e.g. alignment with the timeline of promotional activity or temporal sequencing of changes in COM-B and alcohol consumption measures which correspond with behaviour change theory).

Confounding: Analyses will control for three major sources of confounding. First, major changes in other **policy-related factors**. Price represents a key factor and will be controlled for using the quarterly alcohol affordability index.[60] We will monitor the policy environment to identify additional interventions potentially affecting our outcome measures and control for these using binary control variables indicating pre- and post-intervention periods. Second, alcohol consumption trends display **seasonality** with December and January representing extremes of high and low consumption. We will attempt to directly control for seasonality by (a) simulating seasonal trends in AUDIT-C scores using the available ATS data and (b) Estimating monthly seasonality effects from multiple years of alcohol consumption data within the General Household/Lifestyle Survey and the Health Survey for England. **Hot weather**

and **major events (e.g. sports tournaments)** can also lead to spikes in alcohol consumption and analyses will control for monthly temperature trends. Sensitivity analyses will also test the effect of controlling for the 2016 European football championships which may lead to a spike in alcohol consumption.

Where analyses are weighted, this will use a marginal (rim) weighting technique described in the ATS protocol paper.[31]

Statistical power: As the ATS is an established module of Ipsos Mori's Omnibus survey, we have no control over the sample size of approximately 1,800 per monthly wave. Power simulations were run in R version 3.1.1. Data were simulated using a normal distribution and with 42 months of data collection, implementation of the guidelines during the 24th month, n=1800 participants sampled each month, no underlying trend over time (i.e. assuming stable levels of alcohol consumption), a significance value of $p<0.05$ for the interaction term in the time series model and no step change following the implementation of the guidelines. Simulations were set to n=1000. **Assuming a baseline AUDIT-C score of 2.9 (SD=3.02) (STS, 2014), this study would have 80% power to detect a decline in the post-guideline period of -0.18 points (6% reduction overall).**

8.1.3. Secondary evaluation analyses

A series of secondary analytical approaches will be used to explore and validate results from the primary analysis. These are described below:

Difference-in-difference analysis: A difference-in-difference analysis will be facilitated by collection of a graded measure of self-reported exposure to the DG for 24 months from November 2015. A brief review of the literature suggests graded measures of exposure to health promotion campaigns are uncommon as evaluations typically focus on a single campaign and ask about recollection of that campaign in detail.[24] This is not feasible here as the intervention evaluated here comprises multiple campaigns. Therefore, we will ask participants whether they have been exposed to promotional messages through each of a series of media (e.g. TV, radio, internet or social media, health professional, product label) either 0, 1-2, or 3+ times in the last month.

Subgroup analyses: Additional subgroup analyses will examine effects on sociodemographic groups of interest defined by age, sex and socioeconomic status. Given sharp regional variations in alcohol-related harm, it is possible promotional activity may vary substantially across the UK and, if this is the case, we will examine the feasibility of regional analyses. At the time of writing, PHE are at a very early stage of developing their promotional campaign but have agreed in principle to explore staggered rollout of promotional campaigns by region to permit a stepped wedge analytical design and also strengthen such regional analysis.

Evaluation of specific campaigns: Following Sims et al.[61] we will explore whether data from the timeline of promotional activity can be used to evaluate impacts of specific campaigns. Hypotheses will be generated regarding breakpoints where intervention effects would be expected to begin and, potentially, further breakpoints where an 'effect decay' segment would be expected to begin.

Sensitivity and specificity analyses: Alternative definitions of pre- and post-intervention periods will be tested to assess the sensitivity of the findings. In particular, the effect of defining the post-intervention period as beginning when a consultation on draft guidelines is published will be tested. A specificity analysis will be conducted by repeating the primary analysis using smoking-related outcomes (e.g. quantity smoked, prevalence of quit attempts). These measures are available in the Smoking Toolkit Study which sits within the same survey as the ATS. Although there may be some cross-over effects onto smoking of alcohol health promotion campaigns, these should be markedly smaller and, if absent, confidence in the inference that observed effects are not attributable to general improvements in health behaviour trends would be strengthened.

8.1.4. Consistency of results with behaviour change theory

To enhance understanding of the mechanisms by which promoting DG affects behaviour and inform design of future health promotion activity, exploratory analyses will also be undertaken to assess whether a theory-based structural equation model (SEM) of the relationship behaviour and factors influencing behaviour change can be constructed. This will be based on the COM-B integrative model (see Section 8.1.1. Secondary outcome measures) and will examine the interrelationship between measures of capability, opportunity and motivation to change behaviour and behaviour itself measured by AUDIT-C (and potentially the alternative individual-level consumption measures).

A model will be initially fitted on six months of pre-intervention data using the generalised SEM ordinal regression command in Stata. Accounting for measurement error, the model will be specified to permit testing of whether statistically significant pathways between COM-B variables correspond to those proposed by theory.[30] To assess the stability and sensitivity of identified pathways, the analysis will be repeated using data from the post-intervention period. In the absence of true longitudinal panel data, experimental analyses using pseudo-panel techniques will be used to test pathways through which change in COM-B variables predicts change in alcohol consumption. Pseudo-panel methods assume a longitudinal panel can be created where individuals are aggregated into subgroups based on shared characteristics (e.g. age, gender socioeconomic status), and these subgroups then become the unit of analysis. This approach has previously been used by the applicants to estimate alcohol price elasticities.[62]

8.2. Constructing a timeline of promotional activity

Promotional activity is likely to occur at multiple points and in different forms across the evaluation period. Causal inferences regarding intervention effects can be strengthened if changes in outcome measures can be shown to temporally align with promotional activities plausibly influencing those measures. To facilitate such inferences, a timeline will be constructed of the promotional activity which occurs over the evaluation period. The timeline will focus on large-scale promotional activity which the research team judge could plausibly lead to population-level effects. Cumulative effects of smaller-scale activities will be captured by the primary evaluation analysis.

Promotional activities will be identified primarily by interviews with key organisations from the public, commercial and charity sector (e.g. Public Health England, Department of Health, Drinkaware, Alcohol Concern, The Portman Group) with the research team's social media presence and monitoring of alcohol-related news used to identify further activities. Interviews will be conducted at the time of guideline publication and update interviews will be conducted at six month intervals throughout the evaluation period to confirm activities were undertaken as planned, gather any evaluation data and identify further activities. Interviews are for fact-finding purposes only and therefore, will be recorded for checking information but will not be transcribed. Summaries of the information provided will be sent to interviewees for verification following the interview.

For mass media campaigns, we will seek audience metrics from the body responsible. Following Langley et al.[41] we will attempt to obtain *advertising creatives* specifying the desired content of the campaign and also *Gross Rating Points (GRP)* for TV and radio advertising. GRP measure the number of times an advert is seen or heard taking account of the audience size and number of broadcasts and can also be broken down to indicate audience composition.[63] We will also seek to obtain online- and social media-related data (e.g. unique views, click-through rates, app downloads and registered or active users of services) to assess audience scale and thus potential impact.

Promotional activity will be classified using a tool adapted from one used previously by co-investigator Lewis to classify tobacco mass media campaigns.[41] The tool is informed by COM-B[30] (the same integrative model we apply to examine influences on behaviour change) and focuses particular on motivation through the PRIME theory.[64] It also draws on effectiveness evidence for tobacco mass media campaign content.[65] The smoking tool classifies content by **key themes** (e.g. smoking cessation, preventing uptake), **delivery style** (e.g. acted scenes, testimonials), **call to action** (e.g. prompts for quit attempt or quitline calls) and **positive/negative emotional content**. An initial version of an equivalent alcohol tool has been developed informed by a review of promotional material available on the websites of key organisations (e.g. NHS, Drinkaware, Alcohol Concern). The tool will be iteratively developed as the

guidelines and promotional activity emerge to ensure comprehensive coverage of content. In year 3, following data collection and prior to using the tool within statistical analysis or publications, both the tool and the research team's coding of materials will be validated by PPI representatives (see PPI on application form).

Data will be used to construct a timeline of major promotional activities across the evaluation period allowing for development of testable hypotheses. For example, a period with intense mass media advertising focused on changing motivations would be hypothesised to trigger a change in ATS measures of motivation.

8.3. Cost-effectiveness analysis

The Sheffield Alcohol Policy Model (SAPM) has been developed to provide estimates of the effectiveness and cost-effectiveness of alcohol policies including pricing and screening and brief interventions. For a given policy-induced change in consumption, the outputs of the model provide estimates of changes in the incidence or prevalence of 47 chronic and acute health conditions which are either wholly or partially attributable to alcohol. The full model methodology is published elsewhere.[4] In brief, functions relating risks of each health condition to measures of either mean weekly or single occasion consumption are the key component. Change in consumption, and hence risk, over time is used to adjust observed mortality and morbidity rates by applying the potential impact fraction method.[66] For chronic conditions, debate exists regarding the time lag between population-level changes in exposure and changes in outcome and SAPM uses lag functions posited in a recent systematic review.[67] SAPM also provides estimates of the long-term costs associated with alcohol-related harm including direct costs to the health service as well as a financial valuation of changes in individuals' quality of life. Analyses with the model can be carried out on population subgroups defined by age, sex, consumption level and income or socioeconomic status. This means the model is able to present results describing the impact of alcohol policies on particular subgroups of interest such as young hazardous drinkers, low income moderate drinkers or high income harmful drinking women.

We will incorporate evidence of intervention effectiveness into SAPM in order to evaluate long terms health costs and benefits. To understand the effects of the intervention on long-term outcomes, SAPM needs three pieces of evidence. First, a baseline distribution for mean weekly consumption which will be taken from the Health Survey for England (HSE) 2014. Second, a revised distribution of mean weekly consumption after promotion of DG has completed its effect and this will be simulated based on the results of the evaluation analyses, with simulation methods dependent on the results obtained. Third, an assumption regarding the counterfactual (i.e. the distribution of mean weekly consumption if the intervention had not occurred) and we will assume a steady state (i.e. that consumption remains as it is in the baseline). Our basecase analyses will examine effects in the full population and the resulting analyses will present the expected incremental effects of promoting DG in terms of mortality reductions, disease prevalence, NHS costs and quality-adjusted life years gained. Further scenario analyses will examine the effects of alternative model assumptions which will be selected based on the results of the evaluation analyses. Scenarios may include modelling health and health economic consequences of short-term effects on acute alcohol-related harms. Adaptations to SAPM's annual structure would be required in this instance. Subgroup analyses will also be undertaken for age, sex and socioeconomic groups.

9. Ethical arrangements

Ethical approval for the Alcohol Toolkit Study has been granted by the UCL Ethics Committee. The project was treated as an extension to the Smoking Toolkit Study (ID 0498/001) and the committee judged asking about alcohol consumption in addition to smoking behaviour placed participants at no additional risk of harm. This ethical approval covered issues of informed consent and use of data for research purposes such as the project. For the present study, ethical approval for the additional questions pertaining to DG and stakeholder interviews relating to promotional activity will be sought from the ScHARR Ethics Committee at University of Sheffield. We do not envisage these questions creating substantial additional risks for participants.

10. Research Governance

The nominated sponsor for this work will be the University of Sheffield with JH as the Principal Investigator. The core research team (JH, PM, PB, JB, SM, EB) will make key decisions with routine decisions taken at Sheffield by JH and UCL by JB. Cost-effectiveness modelling will be managed by AB and CA in consultation with the core team.

Subcontracts will be set up between Sheffield, UCL and Nottingham detailing budget allocations, responsibilities and expected contributions. Contracts with Ipsos Mori for the Alcohol Toolkit Study (ATS) will be managed by the University of Sheffield. Risks related to Ipsos Mori are minimal as UCL have a strong working relationship developed across four separate projects. JB at UCL will liaise with Ipsos Mori on delivery and quality control of all ATS data.

A steering group of researchers and stakeholders will be established whose expertise can be drawn on throughout the project and who will also benefit from the project results. Those agreeing to join the steering group at time of application include representatives from the Chief Medical Officers' Guideline Development Group (Prof Mark Petticrew), the Alcohol Health Alliance (Katherine Brown) and researchers with knowledge of this topic (Prof Tim Stockwell). We will discuss with NIHR an appropriate model for engagement with industry bodies (e.g. Drinkaware, The Portman Group) at the start of the project.

PPI will be provided by the UK Centre for Tobacco and Alcohol Studies drinker panel which is made up of members of the general public. Full details of PPI activity are provided on the application form.

11. Project timetable and milestones

The three year project will start November 2015. Preliminary work will begin ahead of award of funding to allow data collection to start immediately on award. The following project milestones are proposed and are highlighted in the timeline below.

1. Obtain ethical approval: September 2015
2. Obtain PPI input on survey: October 2015
3. Finalise steering group: November 2015
4. Start data collection: November 2015
5. Finalise promotional activity data collection tool: February 2016
6. Submit study protocol for journal publication: March 2016
7. Final revised drinking guidelines published: Approximately March/April 2016
8. Interim report to funder (including assessment of likely output of evaluation after full details of revised guidelines are known): December 2016
9. Complete data collection: October 2017
10. Discuss preliminary results with steering group and drinker panel: June 2018
11. Final report to funder: October 2018

Year	2015		2016				2017				2018		
Quarter	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Month	Pre	1-2	3-5	6-8	9-11	12-14	15-17	18-20	21-23	24-26	27-29	30-32	33-36
Obtain ethical approval	M1												
Obtain PPI input on survey	M2												
Finalise steering group		M3											
Develop promotional activity data collection tool			M5										
Survey data collection		M4		M7						M9			
Produce protocol paper			M6										
Baseline data analysis													
Produce interim report						M8							
Collect promotional activity data													
Real-time feedback on outcome trends to stakeholders													
Main data analysis												M10	
Cost-effectiveness analysis													
Dissemination													
Produce final report													M11

12. Expertise and contributions of the research team

University of Sheffield: The Sheffield Alcohol Research Group (SARG) is the UK's largest multidisciplinary alcohol research group and has expertise across a range of health and social sciences and methodological approaches. SARG is a world-leader in modelling the potential effects of policy interventions and has a track record of innovative and internationally impactful applied alcohol policy research with recent projects addressing alcohol pricing, screening and brief interventions, drinking guidelines and specialist treatment provision. The PI for the project, Dr John Holmes, is a senior member of SARG and has developed substantial experience in applied policy research as project manager and lead on external engagement for SARG's highly influential analyses of minimum unit pricing for alcohol.

Dr John Holmes (PI) will have overall responsibility for the project, lead on statistical analyses and collaborate on collection of data on promotional activity. **Dr Penny Buykx (CI)** will lead collection of data on promotional activity and support other aspects of the project. **Prof Petra Meier (CI)** will supervise work at Sheffield and contribute expertise in policy analysis. **Prof Alan Brennan (CI)** will lead the cost-effectiveness modelling. **Colin Angus** will undertake the cost-effectiveness modelling. **Dr Abdallah Ally** will lead on structural equation modelling.

University College London (UCL): UCL's Alcohol and Tobacco Research Group led by Robert West and Health Psychology Research Group, led by Susan Michie produce world-leading research in behaviour change and addiction and work closely with Government policy-makers. Jamie Brown is a member of both and manages the Alcohol Toolkit Study and Smoking Toolkit Study. The latter is used frequently by PHE and its data has been used in more than 50 publications.

Dr Jamie Brown (CI) manages the ATS and STS and will contribute to survey data analysis. **Prof Susan Michie (CI)** is PI for the ATS and will supervise work at UCL as well as providing expertise in behaviour change and health psychology. **Dr Emma Beard (CI)** will provide statistical support in the analysis of ATS data. **Prof Robert West** will provide expertise in using the ATS for evaluation research and in behaviour change and health psychology.

University of Nottingham: **Prof Sarah Lewis (CI)** has expertise in the evaluation of tobacco health promotion campaigns and medical statistics and will provide input into evaluation analyses.

13. Partner collaboration

The key collaborators on this project will be the UK Department of Health and Public Health England. The former has responsibility (through the UK Chief Medical Officers) for the review of the DG and the latter is responsible for government health promotion campaigns. Both have met with the applicants to discuss supporting the study.

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