MESAS

NHS Health Scotland

Evaluating the impact of Minimum Unit Pricing (MUP) on population alcohol consumption and alcohol-attributable health harms

Study protocol

August 2019

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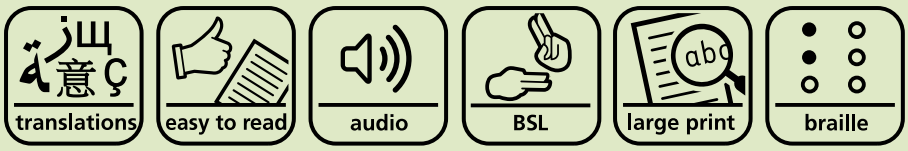

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Contents

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1.3	01/03/2019	Mark Robinson	Reframed from being a PID (to inform discussion at the initial EAG) to a Study Protocol. Removal of self-reported consumption study now being taken forward by MRC SPHSU.
1.4	22/03/2019	Mark Robinson	Changes made in response to comments from Lucie Giles.
1.5	06/08/2019	Mark Robinson	Changes made after internal review and in light of EAG comments on the calculation of AAFs. Timetable updated after progress review.

1 Introduction and background

1.1 Purpose of this paper

The purpose of this study protocol is to provide an overview of our intended approach to evaluating the impact of Minimum Unit Pricing (MUP) on population alcohol consumption and alcohol-attributable health harms in Scotland.

1.2 Policy context

The scale of Scotland's damaging relationship with alcohol is well documented. The rate of deaths related to alcohol is among the highest in Western and Central Europe[1] and, despite falling from a peak in 2003, rates remain twice as high as those seen in England & Wales.[2] Recent estimates using Scotland-level data suggest that alcohol was a causal factor in over 3,700 deaths and 41,000 hospital admissions, and contributed to 8% of the overall disease burden.[3] This is driven by high levels of population consumption levels relative to neighbouring GB countries.[4] Alcohol-related heath harms are experienced most by those living in areas of high deprivation, with stark inequalities in both mortality and hospital admissions caused by alcohol.[2]

In recognition of the harm alcohol was causing to individuals, families, communities, and society at large, the Scottish Government introduced a comprehensive package of measures through its 2009 Framework for Action.[5] The strategy contained a range of policy and legislative actions which, collectively, aimed to reduce population levels of alcohol consumption and, in turn, associated levels of health and social harms. This included the Alcohol (Minimum Pricing) (Scotland) Act (hereafter 'MUP Act'), which was passed in June 2012. Following a lengthy legal challenge, which ended after the judgement of the Supreme Court in December 2017, the Scottish Government implemented MUP on 1 May 2018 setting a minimum price of 50 pence per unit (ppu), below which alcohol cannot be sold in Scotland.

1.3 Evaluation of MUP

The MUP Act includes a sunset clause, which requires that the legislation will expire at the end of the sixth year of implementation unless the Scottish Parliament votes for it to continue. To inform this decision there is a review clause, requiring the Minister to put a review report before Parliament as soon as possible after the end of the fifth year of implementation. The review report is required to assess the impact of MUP on the five licensing objectives (concerned with crime, public safety, public nuisance, public health and protecting children from harm) and on alcohol producers and licence holders. Differential impact (by age, sex, deprivation and drinking status) should be assessed where possible. Representatives of alcohol producers and licence holders and those with a function related to health, prevention of crime, education, social work, and children and young people must be consulted in the preparation of the report for Parliament.

NHS Health Scotland has been commissioned by the Scottish Government to lead this evaluation. We have therefore developed a portfolio of studies to evaluate MUP (see our website for more details).[*] The evaluation is to be completed by 1 November 2023 at the latest and will form the basis of the review report.

Part of the evaluation is a package of studies concerned with the impact of MUP on population alcohol consumption and alcohol-attributable health harms. Although the portfolio of studies set up to evaluate the impact of MUP will assess outcomes across the MUP Theory of Change (Appendix 1), the importance of a robust and credible evaluation of its impact on health outcomes has been emphasised by senior government officials and members of the MUP Governance Board overseeing the overall evaluation. Indeed, much of the evidence that informed the legislation was focused on the potential impacts on hospital admissions and deaths caused by alcohol.[6,7]

[*] See www.healthscotland.scot/health-topics/alcohol/evaluation-of-minimum-unit-pricing

1.4 Existing research

There is strong and consistent evidence to show that increasing the price of alcohol, thereby reducing its affordability, is an effective approach in reducing population levels of alcohol consumption and related harms.[8] Increasing the level of tax applied to alcohol is the most common approach to achieve such effects. However, other fiscal policies can be used. In Canada, for example, a form of minimum pricing applies across all ten provinces, though there is variation in the extent and frequency to which different drink types and outlets are affected.[9] Evaluation of the impact of minimum pricing in Canada has shown consistently that as alcohol prices increase, there is an associated decrease in population consumption, hospital admissions and deaths. **Based on a 10% increase in the average minimum price across all drink types**, these findings are summarised below:

Consumption

- In British Columbia, a 3.4% decrease in overall alcohol consumption (as measured by alcohol sales).[10] The size of the effect differed across drink types.
- In Saskatchewan, which has the form of minimum pricing most like MUP, an 8.4% decrease in overall alcohol consumption.[11] Effects were most pronounced in the off-trade and there was evidence of a shift in sales from higher-strength to lower-strength products.
- It is worth noting that, in Saskatchewan, the effects observed resulted from 11% of products being affected by the price change. We have estimated that 47% of the volume of alcohol sold off-trade in Scotland was sold below 50ppu in 2017.[2]

Hospital admissions

- In British Columbia, an immediate 9% decrease in acute alcohol-attributable hospital admissions; a 9% decrease in chronic alcohol-attributable hospital admissions was detected two years later.[10*]

Deaths

- In British Columbia, an immediate 32% decrease in wholly alcohol-attributable deaths and evidence of effects continuing up to 12 months after the price change.[12] Reductions in chronic and total alcohol-attributable deaths were detected two–three years after the price change.

The minimum pricing model in Canada, as well as those that exist in other countries, differ from the MUP legislation being implemented in Scotland, which will be the first country in the world to introduce such an approach. The Sheffield Alcohol Policy Model has estimated that a 50ppu will reduce alcohol consumption by 3% in Scotland, leading to 121 fewer alcohol-attributable deaths and over 2,042 fewer alcohol-attributable hospital admissions per year when the policy reaches its full effect.[13] It is estimated that effects will be most pronounced among those drinking at harmful levels, particularly those on lower incomes. However, as Scotland is the first country to have introduced MUP, there have been no direct observations of its impact on consumption and harm.

1.5 Research objectives

The overarching aim of this package of studies is to evaluate the impact of the introduction of MUP on population levels of alcohol consumption and alcohol-attributable health harms in Scotland. We propose that this component of the MUP evaluation will be divided into separate work packages (WPs), each with distinct aims and research questions. These are listed below with a more detailed description of the proposed approach for each WP provided in **Section 2**.

[*] Acute conditions refer to those caused by intoxication; chronic conditions are those caused by sustained alcohol consumption over longer time periods.

Throughout, we will follow MRC guidelines on best practice for conducting evaluations of natural experiments.[14]

1.5.1 WP1: Sales-based consumption

Aim

- To evaluate the impact of MUP on the volume of pure alcohol sold in Scotland using alcohol retail sales data.

Research questions

- What is the impact of the introduction of MUP on the volume of pure alcohol sold in Scotland?
- What is the impact of the introduction of MUP on the volume of pure alcohol sold by off-trade retailers in Scotland?
- What is the impact of the introduction of MUP on the volume of pure alcohol sold by on-trade retailers in Scotland?
- To what extent does any impact of the introduction of MUP on the volume of pure alcohol sold in Scotland vary by drink type?

1.5.2 WP2: Hospital admissions and deaths

Aim

- To evaluate the impact of MUP on alcohol-attributable hospital admissions and deaths in Scotland using administrative data.

Research questions

- What is the impact of the introduction of MUP on alcohol-attributable hospital admissions in Scotland?
- What is the impact of the introduction of MUP on alcohol-attributable deaths in Scotland?
- To what extent does any impact of the introduction of MUP on alcohol-attributable hospital admissions and deaths vary by sex, age group and socioeconomic deprivation?

1.5.3 WP3: Economic evaluation

The feasibility of conducting an economic evaluation of the impact of MUP will be undertaken by NHS Health Scotland. This will inform a decision about whether to carry out an economic evaluation.

2 Work packages

2.1 Work package 1: Sales-based consumption

2.1.1 Study design

Alcohol sales data provide the most accurate means of estimating population consumption levels.[15] Using commercial data on alcohol retail sales, WP1 will use a natural experimental design with interrupted time series analytical methods to assess whether the introduction of MUP is associated with changes in the level or trend of the volume of pure alcohol sold in Scotland. Data for England and Wales (combined) (hereafter England/Wales) will be used as the primary geographical control group; subnational English regions will be used in supplementary analyses. We will assess the impact of MUP on overall alcohol retail sales and for different trade sectors and drink types separately. We will adjust statistical models to account for seasonal and secular trends, as well as other important confounders (e.g. disposable income).

2.1.2 Outcome measures

We will have three main outcome measures in WP1:

- Volume (Litres) of pure alcohol sold per adult in the off-trade (primary outcome measure)
- Volume (Litres) of pure alcohol sold per adult (primary outcome measure)
- Volume (Litres) of pure alcohol sold per adult in the on-trade (secondary outcome measure)

These will be considered overall and for individual drink categories (i.e. beer, spirits, wine, cider, perry, fortified wine, and RTDs).

2.1.3 Data

Off-trade alcohol sales data

We will use off-trade alcohol retail sales data obtained from market research company, Nielsen. Nielsen is a global information and measurement company with a leading position for the collation, analysis and provision of alcohol sales data. Nielsen estimates retail sales in Great Britain using electronic sales records from large retailers (retailers with ten or more retail shops operating under common ownership) and a weighted stratified random sample of smaller 'impulse' retailers (retailers in which the consumer mainly uses the store for impulse or top-up purchases i.e. not the main grocery shop). It is estimated that large, multiple retailers account for approximately 80% of total off-trade alcohol sales in Scotland.

As part of the MESAS work programme, Nielsen has provided NHS Health Scotland with off-trade alcohol sales data since 2010. Weekly data on the volume of alcohol sold (in litres of natural volume), by drink type, are available for Scotland and England/Wales from January 2009 and for north-west (NW) and north-east (NE) England from January 2012. Nielsen is currently contracted by NHS Health Scotland to continue to provide these data until 2021/22 meaning data will be available up until the end of calendar year 2021.

On-trade alcohol sales data

We will use on-trade alcohol retail sales data obtained from market research company, CGA Strategy. CGA is a market measurement, data and research consultancy company specialising in the out-of-home food and drink market. CGA estimate on-trade alcohol sales in Great Britain using a combination of delivery, sales, and survey data.

As part of the MESAS work programme, CGA has provided NHS Health Scotland with on-trade alcohol sales data since 2010. Data on the volume of alcohol sold (in litres of natural volume) for four-weekly periods, by drink type, are available for Scotland, England/Wales and English regions from January 2008. CGA is currently

contracted by NHS Health Scotland to continue to provide these data until 2021/22 meaning data will be available up until the end of calendar year 2021.

Data robustness

We have previously performed detailed critiques of the validity and reliability of alcohol retail sales data for monitoring population levels of alcohol consumption in Scotland,[16,17] including a comprehensive description of the sampling methods used by Nielsen/CGA to collect alcohol sales data.[16] Although concluding that alcohol retail sales data provide a robust source of data for estimating population consumption, the work identified a number of important biases that can lead to either under or over-estimation of population consumption levels in Scotland. Using data for 2013, we estimated that the net effect of these biases was to underestimate population consumption by 7%, which represented an increase from 3% in 2010.[17] Over time, unrecorded alcohol and wastage remained the largest sources of bias. However, the research illustrated how biases can change over time and how new data sources can improve the accuracy of bias estimates. We therefore plan to update our estimates of the size of these biases as part of this work package and to draw on the results from other studies as part of the overall MUP evaluation that may help in this regard.

From September 2011, Nielsen was no longer able to estimate off-trade sales by discount retailers, Aldi and Lidl. In order to enable NHS Health Scotland to present trends in population alcohol consumption levels established prior to 2011, we have adjusted the data we receive using estimates of the alcohol market share of Aldi/Lidl obtained from consumer panel data. In 2016, we estimated that the alcohol market share of Aldi/Lidl in Scotland was 12%, increasing from 8% in 2011. We are currently exploring the strengths and limitations of different consumer panel datasets for estimating the market share of Aldi/Lidl as part of our ongoing monitoring of alcohol sales in Scotland. As Aldi/Lidl sell a range of alcohol products at the lower end of the price distribution, which will be most affected by MUP, it will be important to consider adjustment of the off-trade sales data as part of WP1.

2.1.4 Confounders

We intend to adjust our statistical models for the potentially confounding effects of income as this interacts with alcohol prices to determine alcohol affordability. Other covariates, such as overall consumer spending, will also be considered. Quarterly gross disposable household income data will be obtained for Scotland and England/Wales and expressed per adult.

In our study that evaluated the impact of the Alcohol Act on off-trade alcohol sales, we also adjusted our models for alcohol prices. Such adjustment was also done by Stockwell and colleagues[10,11,18] when they evaluated the impact of minimum pricing (not MUP) in Canada. In consultation with the Consumption and Health Harm EAG, we have decided not to include price as a covariate. As shown in the Theory of Change (**Appendix 1**), this is because the purpose of MUP is to increase alcohol prices; adjusting for changes in prices would therefore represent over-adjustment.

2.1.5 Study period

In WP1, we will include data from January 2013 to April 2021. This provides us with data for over five full years before, and three full years after, the implementation of MUP.

When using interrupted time series analysis to evaluate natural experimental designs, longer pre-intervention time periods can strengthen causal inferences by enabling better control of secular trends. As noted above, we have access to weekly off-trade alcohol sales data from 2009 (for Scotland and England/Wales only) and four-weekly on-trade alcohol sales data from 2008. However, for the purposes of this study we will use data for both sectors from January 2013 only for three main reasons:

1. It enables consistency in the time periods used for each sector.
2. It provides us with the option of using data for subnational English regions if necessary (e.g. sensitivity/supplementary analysis).

3 The Alcohol Act in Scotland was introduced in October 2011 and we have previously demonstrated that it was associated with a reduction in the volume of pure alcohol sold off-trade in Scotland in the 12-month period after it was introduced, particularly off-trade wine.[19]

2.1.6 Analysis

The analytical approach described below is largely based on the approach we took when evaluating the impact of the Alcohol Act on off-trade alcohol sales.[19] We will publish a separate, more detailed analysis plan for this WP.

Conversion of natural volumes to pure alcohol volumes

Natural volume sales will be converted into pure alcohol volumes using alcohol-by-volume (ABV) percentages for each drink type. The ABV used will be based on the typical strength of drinks sold in that category as provided by the data suppliers. As part of the MESAS monitoring programme we have sourced more detailed ABV data at product level. We will explore whether these data can be used to refine our estimates of category-level ABV, though this will only be possible for more recent data (i.e. not as far back as 2013).

Expressing alcohol sales per adult

The volume of pure alcohol sold per adult (≥16 years) will be calculated using official mid-year population estimates available from National Records Scotland and the Office for National Statistics. Weekly and four-weekly population estimates (for off-trade sales and on-trade/total sales, respectively) will be interpolated.

We have previously been challenged on using ‘alcohol sales per adult’ as our key outcome measure, rather than ‘alcohol sales per adult drinker’. The latter would take into account differences in the prevalence of non-drinkers between Scotland and England/Wales. While the MUP Act is a targeted measure aimed at reducing consumption among the heaviest drinkers, Scotland’s overall alcohol strategy is aimed at reducing average population levels of consumption. For the purposes of this WP, we propose to use the population that includes non-drinkers in the denominator. This is consistent with previous studies on the impacts of minimum

pricing on population alcohol consumption in Canada.[10,11,18] We will, however, express alcohol sales per adult drinker in sensitivity analysis.

Aligning time periods with the MUP implementation date

MUP was implemented on Tuesday 1 May 2018. Both Nielsen and CGA report data in time periods that end on a Saturday meaning that the MUP implementation date will fall in the middle of their reporting periods. This will be a particular problem for the four-weekly on-trade data as the MUP implementation date falls in the middle of the four-weekly reporting period. The best approach to address this will be discussed among the project team and EAG.

Descriptive analysis

Data for our outcome measures will be initially analysed descriptively to enable trends and other key information to be presented in tables and figures. In addition, to ease visual interpretation of trends, the time series for each primary outcome will be decomposed into trend and seasonal components. We used this approach to present trends in alcohol-related mortality rates in an earlier paper[20] (see Appendix 2). This will also be important for ensuring that the pre-implementation trends in Scotland and control groups are similar, a pre-requisite when using interrupted time series analysis for evaluating natural experiments.[21]

Statistical analysis

We will use controlled interrupted time-series methods to assess the impact of MUP on the volume of pure alcohol sold per adult in Scotland. Interrupted time series methods provide one of the most robust quasi-experimental study designs, enabling underlying temporal and seasonal trends to be accounted for.[22] It is expected that Seasonal Autoregressive Integrated Moving Average (SARIMA) techniques will be employed, consistent with how we evaluated the Alcohol Act.[19] The analyses will be stratified by trade sector to preserve statistical power for the off-trade outcome measure, which is determined by the number of temporal data points. We will also run separate models by drink type.

Our analytical strategy will consist of initially modelling the alcohol sales data time-series to obtain an adequate preliminary model and then modelling and testing the effect of the intervention. Several candidate models will be investigated using graphs and autocorrelation plots of the stationary time-series and its errors with the most appropriate and parsimonious model selected using the Akaike Information Criterion (AIC).

To analyse the magnitude and statistical significance of the effect that the intervention had on alcohol sales in Scotland, we will include a binary explanatory variable, with the value of zero for the time before MUP is introduced (January 2013 to April 2018) and the value of one after the introduction of MUP (May 2018 to April 2021).

There may be an anticipatory effect before MUP is introduced. In addition, there may be differences in the immediate to short-term (i.e. within 6 months) and medium-term impact (6 months to 3 years) post-implementation or there may be lagged effects.[23] We will explore how to incorporate such time factors into the analysis, drawing on intelligence from other MUP evaluation studies if necessary.

Analyses will be performed with and without adjustment for potential confounders. Covariates entered into adjusted models will include:

- Disposable income (in all models)
- On-trade sales (for off-trade models to account for substitution)
- Sales of other alcoholic drink types (in models of specific drink types to account for substitution)

To enable comparison with a control group in our Alcohol Act study,[19] we entered the time-series of corresponding alcohol sales in England/Wales as a covariate in the ARIMA models for Scotland.

In line with STROBE guidance,[24] we will present results from both unadjusted and adjusted models.

Sensitivity and supplementary analyses

We plan to perform a number of additional analysis to test the robustness of our results:

- We will assess the impact of applying adjustment factors to off-trade alcohol sales data to account for the exclusion of sales by Aldi and Lidl.
- We will test the robustness of the timing of any effect (if an effect is detected) by varying the date of implementation (i.e. false legislation dates). Such falsification tests are useful for assessing the plausibility of attribution of effects by checking effect specificity.[21] The analysis plan, which will be published ahead of analysing the post-implementation data, will specify falsification dates.
- We will repeat our analyses using NW and NE England as geographical controls. This is because it has been suggested that Northern England is a more appropriate control group for Scotland than England/Wales due to a more similar socio-demographic make-up and alcohol culture (perhaps reflecting a similar industrial history).[25]

2.2 Work package 2: Hospital admissions and deaths

2.2.1 Study design

Using routine administrative time-series data, WP2 will use a natural experimental design to assess the impact of MUP on hospital admissions and deaths caused wholly or partially by alcohol in Scotland. Data for England will be explored as the primary geographical control group; data for subnational English regions may be used in supplementary analyses. If a geographical control with a similar pre-intervention trend is not available, we will use deaths and admissions not caused by alcohol as a non-equivalent control group. We will assess the impact of MUP on overall deaths and admissions and also stratify our analysis by sex.[26] Other subgroup effects may be explored based on evidence-informed expectations of differential impacts, or if there is evidence of an interaction with the intervention (this

will depend on the specific analytical approach). We will adjust statistical models for sociodemographic characteristics, seasonality and underlying trend.

2.2.2 Outcome measures

The main outcome measures in WP2 will be:

- All wholly alcohol-attributable deaths/admissions
- Acute wholly alcohol-attributable deaths/admissions
- Chronic wholly alcohol-attributable deaths/admissions
- All alcohol-attributable deaths/admissions (those wholly and partially caused by alcohol)
- All acute alcohol-attributable deaths/admissions
- All chronic alcohol-attributable deaths/admissions
- A selection of condition-specific outcomes (these will be specified in the analysis plan and will likely include alcoholic liver disease and acute withdrawal).

To estimate alcohol-attributable hospital admissions and deaths we will consider the condition specific estimates of alcohol attributable fractions (AAFs) previously produced for Scotland[3] and England,[27,28] as well as the recent update to the list of conditions caused by alcohol produced by Angus et al.[29] We will also consider use of the International Model of Alcohol Harms and Policies (InterMAHP). The final approach will be specified in the analysis plan. Conditions will be categorised as either wholly or partially caused by alcohol, and as either acute or chronic, in accordance with Angus et al.[29]

These outcome measures will be expressed as rates as detailed in **Section 2.2.6**. We will specify which of these measures are primary and secondary outcomes in our analysis plan. Wholly alcohol-attributable outcomes are likely to be the primary outcome measures.

2.2.3 Data

Deaths data

National Records for Scotland (NRS) maintain a record of all deaths that occur in Scotland and these individual level data are provided to NHS Health Scotland under a data sharing agreement. These data provide the cause of death as classified by the International Classification of Diseases (ICD) and include details of sociodemographic characteristics. We will use these data to determine the number of deaths occurring monthly for each outcome measure across the study time period and by sex, age group, and socioeconomic deprivation. Equivalent data for England (including subnational regions) will be obtained by submitting a request to the Office for National Statistics.

Hospital admissions data

To assess the impact of MUP on alcohol-attributable hospital admissions in Scotland, we will use the Scottish Morbidity Record, a national data scheme that records comprehensive information relating to all inpatients and day cases admitted to either general acute or psychiatric hospitals in Scotland. We will obtain monthly data on the number of admissions by sex, age group, socioeconomic deprivation and condition. Data on hospitalisations for England (including subnational regions) will be obtained by submitting a request to NHS Digital.

Data robustness

The data on deaths and admissions used in WP2 have complete national coverage and are likely to accurately estimate the true number of alcohol-related deaths and hospital admissions in Scotland and comparator areas.[30]

We do not propose to include alcohol-attributable emergency department attendances that do not result in a hospital admission, mainly because of concerns over reliability, completeness and comparability with other countries. In addition, alcohol-attributable emergency department attendances will be assessed in another MUP evaluation study (see **Section 2.2.7**).

Data comparability

Data on deaths are collected using similar methods and standards across the UK;[31] however, hospital admissions are defined differently. In Scotland, hospital records can include up to six diagnostic codes whereas in England there can be up to 20. There are also differences related to coding practices and coverage (e.g. private patients treated in NHS hospitals), which can change differently over time. Exploratory work by ISD Scotland has investigated options for more comparable measures between Scotland and England (unpublished).

In our previous work assessing the impact of the Alcohol Act on hospital admissions in Scotland,[19] we used data at the individual patient level, counting each person only once in each time period even if they had multiple admissions. We also included only ICD-10 codes that were wholly attributable to alcohol in the primary diagnostic position. While these steps helped to make data more comparable between Scotland and England, they also considerably reduced the number of events in our analysis and meant that it was not possible to assess the impact of the legislation on the wider range of deaths and hospital admissions that are partially attributable to alcohol as has been done in other studies (e.g. Kisely et al,[32] Stockwell et al,[9] Zhao et al[12]).

Clearly there are pros and cons of the different options to expressing and analysing hospital admission data. If we use data at the hospital admission level rather than the patient level then we increase the number of events in our analyses and account for the fact that patients may experience multiple admissions attributable to alcohol in any given period. Similarly, if we include ICD-10 codes in all diagnostic positions, the approach taken for national reporting in Scotland,[30] we are more likely to capture the true extent of alcohol-attributable hospital admissions. However, with each of these options, comparability with our geographical control group may be compromised.

Another important issue in this WP is the application of AAFs to calculate partially and wholly alcohol-attributable admissions. It could be argued that totalling the number of admissions attributable to alcohol in the population would provide

misleading results as people would be counted multiple times for the same conditions and for different conditions (i.e. it would take no account of comorbidity). This is particularly the case for chronic conditions. The counterargument to this is that continued drinking is more likely when alcohol affordability is high and this is more likely to exacerbate conditions, resulting in multiple presentations and impeded recovery (Stockwell, personal communication).

These options will be considered further by the project team in consultation with the EAG, with final decisions detailed in the analysis plan.

2.2.4 Confounders

Confounding will occur if any variable has a differential effect on outcome measures between Scotland and the geographic control. In our previous study, we adjusted regression models for age group, sex and socioeconomic deprivation. We will explore the potential inclusion of other confounding variables in consultation with the EAG.

2.2.5 Study time period

In WP2, we will include data from January 2012 to April 2021. This provides us with data for over six years before, and three full years after, the implementation of MUP.

When using interrupted time series analysis to evaluate natural experimental designs, longer pre-intervention time periods can strengthen causal inference by enabling better control of secular trends.[14] Although data are available from 2001 (using ICD-10), based on our experience of evaluating the impact of the Alcohol Act on admissions and deaths, we propose that the length of the pre-intervention period is curtailed because:

1. This will reduce the number of inflection points in the time series of the outcome measures, which can make fitting models challenging.
2. This marks the end of the steep downward trend in deaths caused by alcohol in Scotland which, in turn, may help to make the pre-intervention trends more similar between Scotland and England.

2.2.6 Analysis

Descriptive analysis

We will calculate the rate of each of our outcome measures during each calendar month in each population subgroup. Monthly population counts for each subgroup will be estimated using interpolation of mid-year estimates. Data for the outcome measures will first be analysed descriptively to enable trends and other key information to be presented in tables and charts. In addition, as described in WP1, the time series for each outcome will be decomposed into trend and seasonal components to ease visual interpretation of trends.

Statistical analysis

There a number of different analytical approaches that could be taken in WP2. When we used a similar study design to evaluate the impact of the Alcohol Act on alcohol-related (i.e. wholly attributable) hospital admissions and deaths in Scotland, we modelled the data using Negative Binomial General Linear Methods.[20] The key covariates in the model were: a dummy variable to indicate whether the outcome was for the intervention or control group; and a dummy variable to indicate whether the event occurred in the pre- or post-intervention period. The interaction between these two variables was the Difference in Difference (DiD) estimate of percentage change in outcome measures attributable to the Alcohol Act. Interactions between the intervention variable and population subgroups were used to explore differential impacts.

Other approaches to our analysis for WP2 might include:

- ARIMA models, as used in WP1. These offer a powerful and flexible approach, particularly in terms of accounting for secular and seasonal trends in the data series and examining lagged effects of the intervention. However, adjustment could not be made for sociodemographic characteristics (though rates in the outcome series could be age/sex standardised). Thus, to explore any differential impact of MUP by sociodemographic characteristics, numerous separate models would be required.

- A synthetic control approach where a synthetic control area is created based on the weighted composite of real areas (e.g. admissions and deaths in subnational regions of England) to provide a more closely matched control. However, this approach is less useful when the exposed population is an outlier in the outcome variable of interest,[21] which is the case in terms of deaths in Scotland compared with rest of the UK.[2]
- A 'mixed model' approach as used by Stockwell and colleagues[10] when assessing the relationship between minimum alcohol prices and health harm outcomes in Canada. This combines cross-sectional estimates of a range of variables (e.g. outlet density), which are adjusted for when analysing the time series data. The extent to which this approach is relevant in the Scottish context would need to be explored.

Irrespective of the analytical approach taken, we will aim to assess both immediate and lagged effects. This is consistent with the work of Stockwell and colleagues who have found both immediate and lagged effects of changes in minimum alcohol prices depending on the outcome assessed (i.e. acute versus chronic alcohol-attributable admissions and deaths).[10,12] Throughout WP2, final models will be used to estimate absolute and relative effects of the implementation of MUP in Scotland.

There is an argument that more than one analytical method should be used. The recent renewed focus on scientific replication has highlighted the need to strengthen the reliability of research findings.[33] This is particularly salient in the field of public health where the use of ecological, observational studies can make results uncertain and attributing causality challenging. A previous study that assessed the impact of minimum pricing in Canada[12] tested the robustness of their key findings by applying a different analytical method to the same data. We therefore propose that the results from the main analytical method chosen for WP2 (e.g. Negative Binomial GLM) are validated using a different method (e.g. ARIMA). This will be described in more detail in the analysis plan.

Sensitivity and supplementary analyses

We plan to perform a number of additional analyses to test the robustness of our results:

- We will test the robustness of the timing of any effect (if an effect is detected) by varying the date of implementation (i.e. false legislation dates). Such falsification tests are useful for assessing the plausibility of attribution of effects by checking effect specificity.[21]
- We will repeat our analyses using NW and NE England as geographical controls. This is because it has been suggested that Northern England is a more appropriate control group for Scotland than England or England/Wales due to a more similar socio-demographic make-up and alcohol culture (perhaps reflecting a similar industrial history).[4]
- We will test the robustness of any key results from the main analytical approach using an alternative analytical method.

2.2.7 Other studies assessing WP2 outcomes

Other studies that form part of the MUP evaluation will assess its impact on health harms caused by alcohol:

University of Glasgow NIHR funded study: Consumption and health service impacts of MUP

- This study includes an audit of alcohol-related emergency department attendances in a sample of hospitals in Scotland and England.

University of Stirling CSO funded study: Impact of Minimum Pricing of Alcohol on Ambulance Call-outs in Scotland (IMPAACT)

- This study will assess the impact of MUP on alcohol-related ambulance call-outs.

2.3 Work package 3: Economic evaluation of the impact of MUP

2.3.1 Study design

A feasibility assessment will consider whether and what kind of economic evaluation would be possible, taking into account data availability and timescales.

A range of approaches to economic evaluation are potentially possible. Cost-benefit or cost-consequence approaches would use data from other studies in the portfolio on a range of health benefits such as reductions in alcohol-attributable deaths or reduced incidence of other alcohol-attributable conditions. These approaches could also include data on non-health benefits such as reduced crime or reduced harms to children. Cost-benefit analysis would seek to value these changes in monetary terms. This is methodologically challenging and time consuming, but enables the benefits of the policy (net of any outcomes that are worse as a result of MUP) to be compared directly to the costs. Cost-consequence analysis would simply present data on an array of impacts from studies across the portfolio. This is easier to do but provides a less clear overall assessment of whether the policy is, on balance, worthwhile in the sense that the benefits outweigh the costs.

A narrower approach would be to carry out cost-utility analysis using health outcome measures such as quality adjusted life years. These would need to be estimated from changes in mortality observed in the harms study adjusted for changes in quality of life. This would involve methodological challenges that will be explored further.

All types of evaluation would require data on costs. Thought will be given to the perspective relevant to costing in each of the types of economic evaluation. A broader perspective would include changes in economic costs to society as a whole (e.g. due to impacts on industry or reduced costs of alcohol-related harms). A narrower perspective might just include direct policy costs.

We will scope the feasibility of each of these options and update the evaluation portfolio as appropriate. Scoping will take place in 2019.

3 Timetable and milestones

An indicative timetable for the WPs included in the Consumption and Health Harm evaluation is provided in the GANNT chart on page 28. The timings are driven by data availability, the proposed study time period, and the deadline for publishing the final MESAS MUP Evaluation report (1 November 2023).

The key milestones for WP1 and WP2 are noted below:

WP1 Sales-based consumption

- Baseline data obtained and prepared by September 2019.
- Modelling approach agreed and analysis plan published by December 2019.
- Report summarising descriptive analysis of sales data in 12 month post-MUP period published by November 2019.
- Final data for study time period received in June 2021.
- Final data analysis and reporting by March 2022.

WP2 Hospital admissions and deaths

- Pre-MUP data (but not full baseline period) obtained and prepared by December 2019.
- Modelling approach agreed and analysis plan published by June 2020.
- Final data for study time period received in January 2022.
- Final data analysis and reporting by December 2022.

4 Outputs and dissemination

The ultimate aim of this package of studies is to produce findings that will inform the MUP Evaluation Final Report. The primary audience for the evaluation of MUP is Scottish Ministers and the Scottish Parliament. However, the findings will be high profile and of interest to a much wider range of stakeholders.

Consistent with the approach we have taken as part of the wider MESAS programme, we are committed to publishing our work as open access academic papers in high-impact, peer-reviewed journals. This will help to increase the critical appraisal, reach and credibility of our work. We will attempt to do this alongside the reporting required to inform the MUP Evaluation Final Report being published in November 2023 to allow submission as soon as possible after our findings are finalised.

The key outputs from this component of the MUP evaluation are listed below:

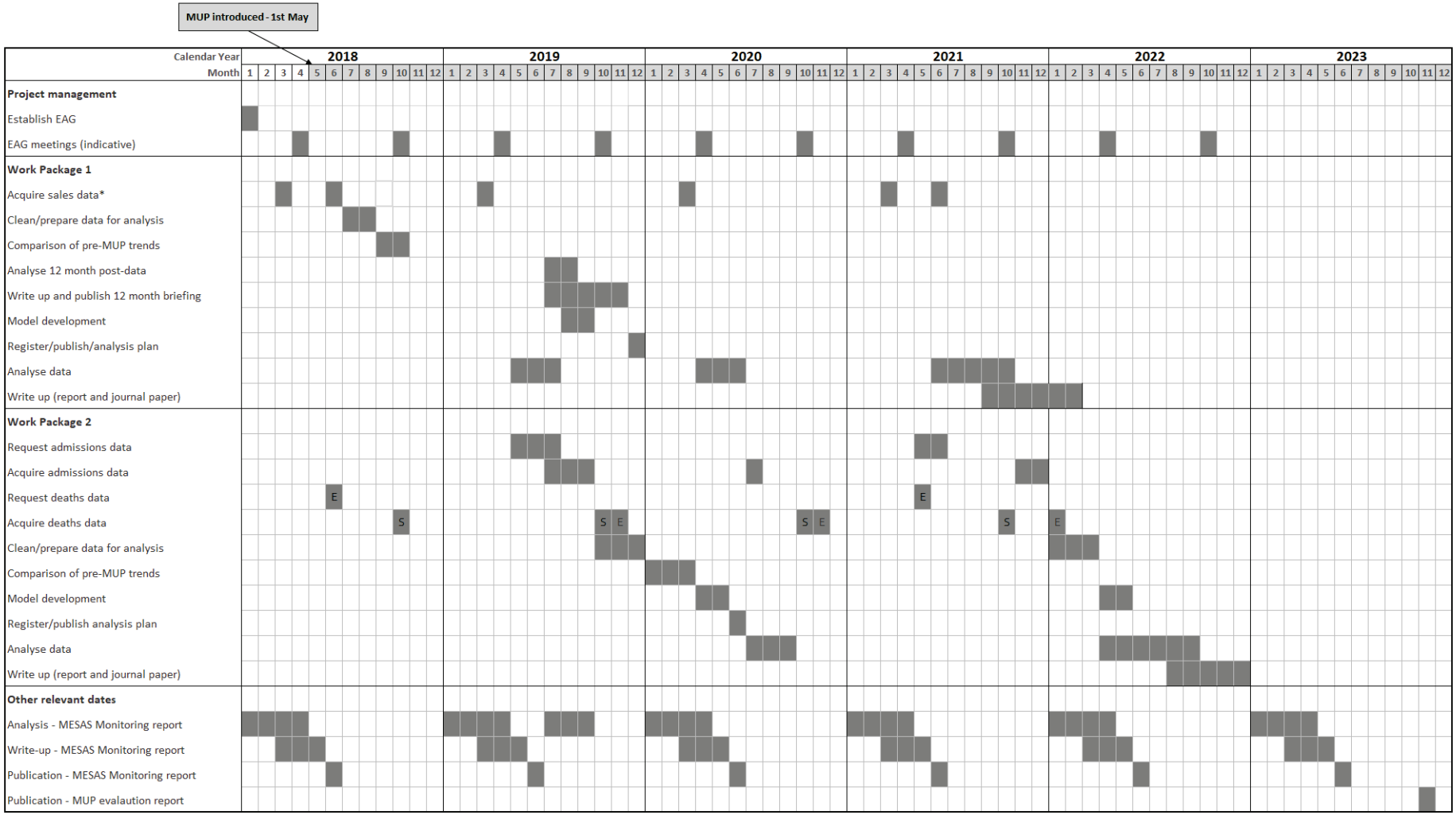
- **Analysis plans for WP1 and WP2**. These will be published on the NHS Health Scotland website and may be pre-registered elsewhere (e.g. on the Open Science Framework). This represents good practice in public health research as analytical decisions are made transparent prior to observing the final data.[33] In addition, journals are increasingly requesting pre-registered analysis plans as part of the submission process.
- **Descriptive analysis of 12-month post-MUP sales data**. This will be published on the NHS Health Scotland website.
- **WP1 final report**. This will be a detailed report that is used to inform the MUP Evaluation Final Report. We will be required to publish this either prior to, or alongside, the MUP Evaluation Final report
- **WP1 journal paper**. This will be largely based on the WP1 final report and will be submitted as soon as possible after the findings are finalised.

- **WP2 final report**. This will be a detailed report that is used to inform the MUP Evaluation Final Report. We will be required to publish this either prior to, or alongside, the MUP Evaluation Final report
- **WP2 journal paper**. This will be largely based on the WP2 final report and will be submitted as soon as possible after the findings are finalised.

Throughout the course of the study, we will also take the opportunity to disseminate other aspects of the work as stand-alone reports, academic papers, or conference presentations if felt worthwhile by the EAG and on the basis we have sufficient staff capacity.

In our written reports and papers, we will use appropriate checklists to improve the quality and transparency of our reporting (e.g. STROBE[24]).

MUP Consumption and Health Harm Timetable



*It is assumed that it will be possible to acquire sales data in June 2018 and June 2021 in addition to our usual March delivery date

S = Scotland, E = England

5 Project management

5.1 Governance

Good governance is required to ensure:

- the evaluation is, and is perceived to be, impartial, robust, useful and credible by stakeholders, Scottish Ministers and ultimately by the Scottish Parliament
- the portfolio of studies in the evaluation is necessary and sufficient
- the evaluation is delivered on time, scope and budget.

The governance structure for the overall MUP Evaluation is presented in **Appendix 3**.

5.2 Project management

The project will be managed by a Project Lead who will be responsible for:

- overseeing project progress
- leading the development of the study protocol and analysis plan
- supporting WP leads to identify, analyse and resolve risks and issues
- reporting progress to the Consumption and Health Harm EAG, the MESAS Governance Board and the Scottish Government, as appropriate
- supporting the Chair of the Consumption and Health Harm EAG in planning and preparing meetings
- chairing regular project team meetings.

WP leads will be responsible for:

- leading specific work packages
- supervising project team staff
- undertaking detailed planning

- delivering specific activities in line with the project plan
- maintaining detailed documentation
- reporting progress to the Project Lead during regular meetings.

Regular Project Team meetings will be scheduled to assess project progress, the status of project risks, and any issues that have arisen. A Decision Log and Issues Log will be developed and maintained. This will be shared with the EAG who will meet two–three times per year.

All Project Team members will attend the wider MUP Evaluation Project Team at NHS Health Scotland who meet on a regular basis.

5.3 Risk management

An initial high-level risk register for the package of studies included in this project is provided in **Table 1** below. This will be maintained and refined as the project progresses.

5.4 Quality assurance (QA)

A number of processes are in place to ensure that our work is sufficiently quality assured:

In addition to the QA processes applied by the data providers, we will apply further data quality checks to identify potentially erroneous data.

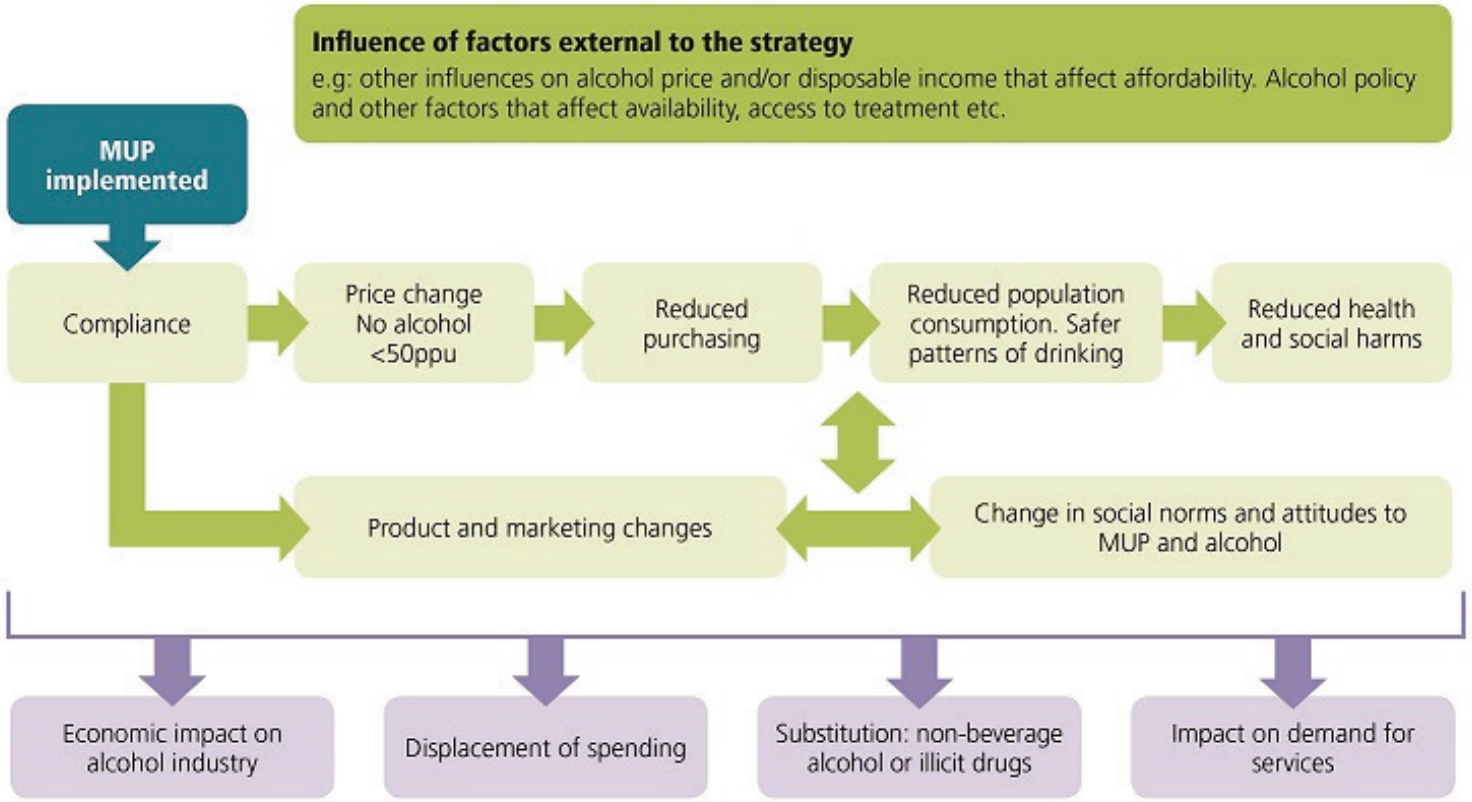
- We will maintain Issues and Decision Logs, which will be shared with the EAG at meetings.
- The EAG will advise on and quality assure the methods and approaches we have proposed, and help with problem solving throughout the project.
- The Project Lead and MUP Evaluation Lead will review all key outputs.
- Draft reports will be peer-reviewed by experts in the field, including members of the EAG as appropriate.

Table 1: High-level risk register

Risk descriptor	Likelihood	Impact	Mitigating action
As a result of poor project management we fail to deliver robust findings that can be used in the sunset process on time, scope and budget, thereby damaging our reputation and limiting our scope to influence evidence-informed decision making.	Low/medium	High	We have developed a detailed study protocol, specifying key tasks, milestones and deadlines; we will use project management tools and approaches throughout the project; the project will be adequately resourced to meet demands on time; progress reporting to EAG, SG and Governance Board
As a result of inadequate governance we fail to deliver an evaluation that is recognised to be robust, credible and independent, thereby damaging our reputation and limiting our scope to influence evidence-informed decision making.	Low	High	We have in place an EAG, independently chaired; the overall MUP Evaluation is overseen by a Governance Board; we have a Memorandum of Agreement with the Scottish Government detailing expectations around reporting; the MUP Evaluation comms and engagement plan promotes transparency.
Team illness or absence results in delays to the project.	Low	Medium	The evaluation is a priority for Health Scotland and is well resourced; additional resource could be added at short notice if required.
There is an insufficient level of data management and statistical analysis expertise within the Project Team to fully deliver the tasks required.	High	Medium	We have a Service Level Agreement with the University of Glasgow for the provision of specialist statistical support and the manager of this service is a member of the EAG;
The expiration in March 2019 of the SLA between Health Scotland and the University of Glasgow for the provision of specialist statistical support results in discontinuity.	High	Medium	tbc
Delays in obtaining the required data impact on study time periods.	Low/medium	High	We have worked with Nielsen/CGA for many years and they have consistently delivered data on time and on scope; we have agreed dates for delivery of future alcohol sales data; we will submit our requests for deaths and admissions data

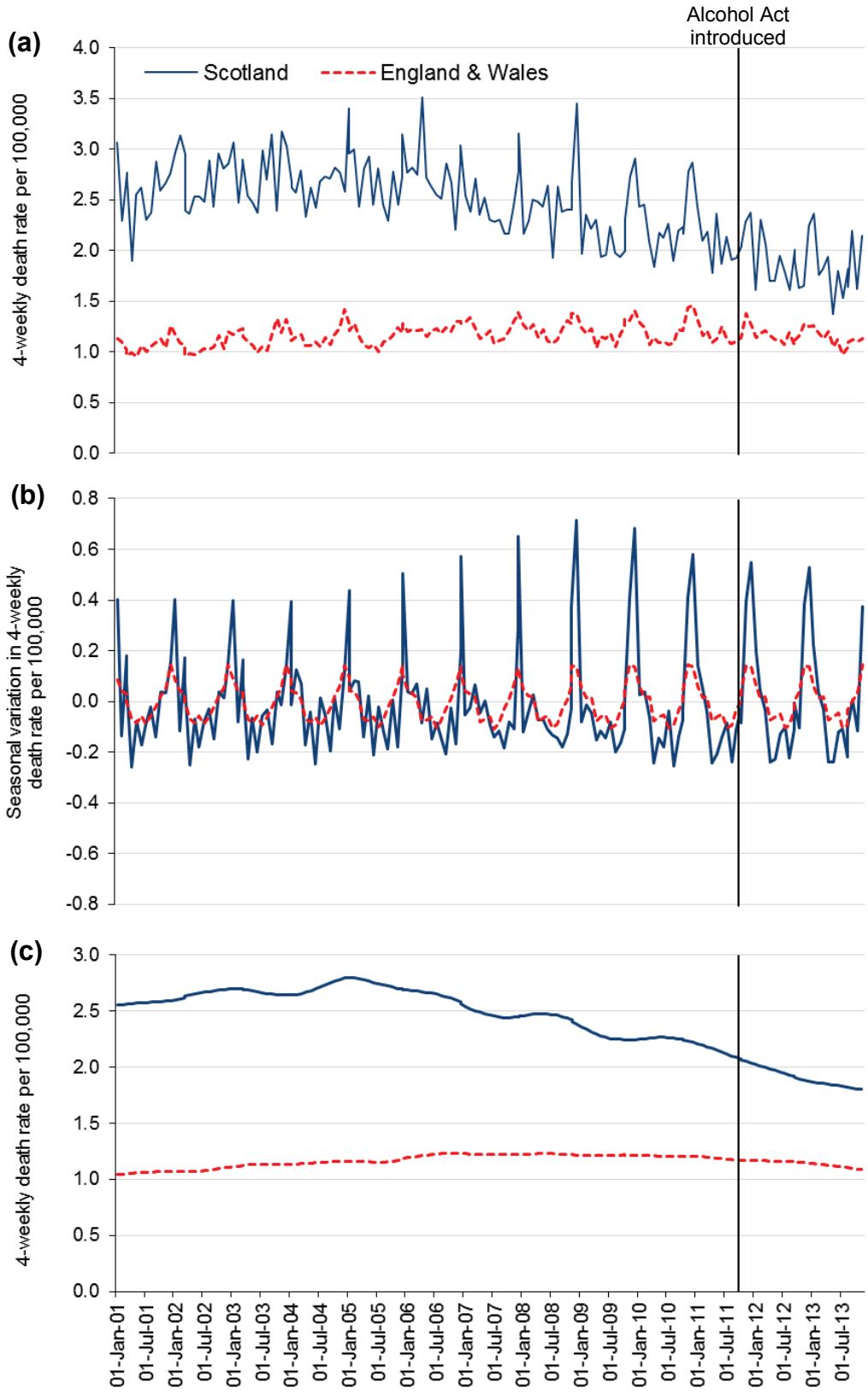
Risk descriptor	Likelihood	Impact	Mitigating action
			as early as possible and seek agreement for timing of delivery (this will be particularly important for the post-implementation data); we will explore the potential to set up a Memorandum of Agreement with ISD Scotland for the delivery of Scottish admissions data as this worked well in the first phase of MESAS; if necessary, Health Scotland employees will request honorary contracts with ISD to access their datasets.
Problems with the quality of the data supplied.	Low	Medium	We have worked with Nielsen/CGA for many years and have developed a good understanding of their methods and QA processes; hospital admissions and deaths data are National Statistics and, as such, are subject to intensive QA processes; we will apply our own QA processes and sense checks to data we receive.
As a result of failure to use appropriate research methods and analytical techniques, our project produces findings that will be questioned on their robustness.	Low	High	We have established an EAG that includes academic experts across a number of relevant fields; our proposed methods and draft outputs will peer-reviewed; we will seek specific advice from experts if deemed necessary.

Appendix 1: Theory of change for MUP

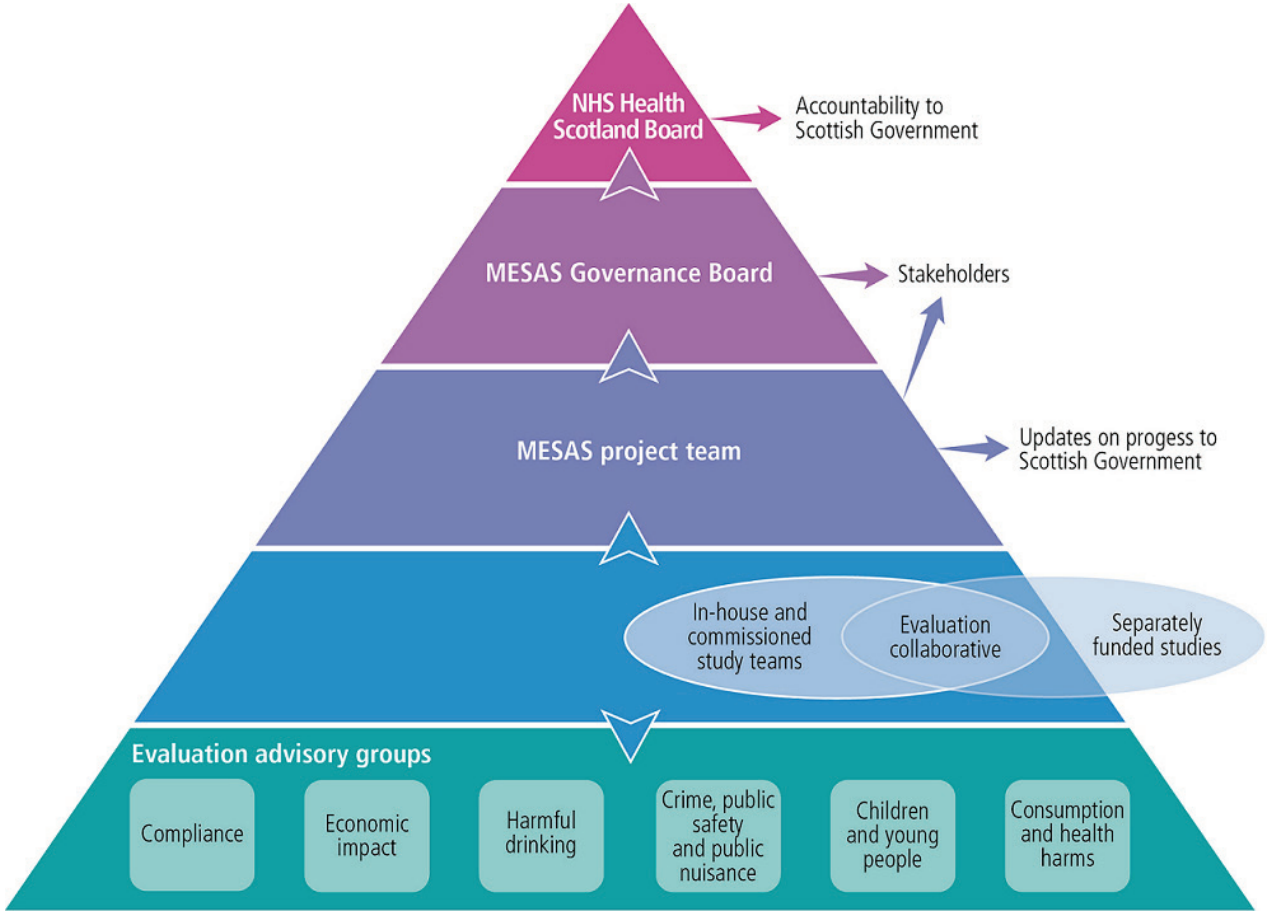


Appendix 2: Example of decomposition of trends to ease visual interpretation

Figure 1: Trends in crude alcohol-related death rates in Scotland and England & Wales (a) and the decomposed seasonal (b) and trend (c) components, January 2001 and December 2013



Appendix 3: MESAS governance structure



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