



# Protocol for the evaluation of Minimum Unit Pricing for alcohol

Monitoring and Evaluating Scotland's Alcohol Strategy (MESAS)

June 2019

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## 1. Introduction

## Purpose of this paper

This evaluation protocol describes plans for the NHS Health Scotland evaluation of minimum unit pricing for alcohol in Scotland. The purpose is to provide the reader with a broader understanding of the approach to the evaluation, the studies within it and when they will report, and the governance processes in place. It covers both the studies funded through and managed by NHS Health Scotland, through the Monitoring and Evaluating Scotland's Alcohol Strategy (MESAS) programme, and the studies funded separately, led by various academic institutions.

## Minimum unit pricing for alcohol in Scotland

The Alcohol (Minimum Pricing) (Scotland) Act<sup>1</sup> was passed by the Scottish Government in June 2012. This provided the legislation required for the introduction of minimum unit pricing (MUP), an important component of the Scottish Government's alcohol strategy: A Framework for Action<sup>2</sup>. This strategy was developed in recognition of the well-documented harm alcohol was causing to individuals, families, communities and society in Scotland.<sup>3</sup> It contained a comprehensive package 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.

The minimum pricing legislation provides provision for Scottish Ministers to set a strength-based floor price below which alcohol cannot be sold in licensed premises in Scotland. The legislation was subject to a legal challenge which ended when the UK Supreme Court ruled in November 2017 that MUP in Scotland was legal.<sup>4</sup>

The legislation requires that MUP expires at the end of the sixth year of implementation unless the Scottish Parliament votes for it to continue. This is referred to as the sunset clause. There is also a requirement for Ministers to lay before the Scottish Parliament a report on the operation and effects of MUP as soon as possible after the end of the fifth

year of implementation. This is referred to as the review clause. The report must review the impact of MUP on:

- producers of alcoholic drinks and licence holders
- the five licensing objectives (preventing crime and disorder, securing public safety, preventing public nuisance, protecting and improving public health, and protecting children and young people from harm)
- different groups (defined by age, gender, social and economic deprivation and levels of alcohol consumption), where possible.

The Act requires that in the preparation of the report the following are consulted:

- a) Representatives of producers of alcoholic drinks and licence holders.
- b) Persons with functions relating to health, prevention of crime, education, social work, children and young people, and others deemed appropriate.

In their ruling, the Supreme Court recognised the experimental nature of MUP and judged the inclusion of the sunset and review clauses to be important in reaching their decision.<sup>4</sup>

NHS Health Scotland has been tasked by the Scottish Government to deliver the evaluation that will form the basis of the review report. As such, the purpose and scope of this evaluation are driven by the requirements set in the legislation.

Secondary legislation setting the level of MUP at 50 pence per unit (ppu) of alcohol was passed in April 2018 and MUP was implemented in Scotland on 1 May 2018.<sup>5</sup>

#### **Existing research**

MUP in the form it takes in Scotland has not been implemented elsewhere. This is why this evaluation is so important. The evidence base underpinning the rationale for MUP, along with the theory of change (see later), can help to identify the potential effects that the evaluation should seek to measure.

#### Price, consumption and harm

There is strong and consistent international evidence that:

- alcohol consumption is associated with substantially increased risks of all-cause mortality.<sup>6</sup>
- price has a significant effect on consumption, especially of binge drinkers, and of younger and older drinkers.<sup>7 8</sup> Policies that increase alcohol price can delay the start of drinking, slow young people's progression towards drinking large amounts, reduce the number of young people drinking heavily, reduce the volume of alcohol consumed per occasion, and reduce the harms caused by alcohol and alcohol dependence.<sup>7</sup>
- increasing alcohol tax is associated with a decrease in harm.<sup>9</sup> Conversely, when alcohol taxes and prices have been lowered, alcohol consumption and alcoholrelated harm have increased.<sup>7</sup>

Estimates of alcohol price elasticity provided by two different reviews suggest that a 10% rise in price might be expected to reduce demand for alcohol by about 5%.<sup>8</sup> <sup>10</sup> A further study found that price elasticity varies by levels of consumption, such that if the price of alcohol increases by 10%, the quarter of drinkers drinking the least alcohol reduce their consumption by 7.1% compared to 3.5% for the quarter of drinkers that consume the most.<sup>11</sup> These estimates suggest heavier drinkers are less responsive to price. Nevertheless, these price elasticities suggest that the effects of a price rise in terms of the reduction in units of alcohol consumed would still be greater in heavier drinkers. The weekly consumption figures reported in this study (47.2 units per week for the heaviest drinkers, 1.9 units per week for the lightest drinkers), suggest that in response to a 10% increase in price, the heaviest drinkers would reduce their consumption by 86 units a year, compared to 7 units for the lightest drinkers. This research found heavier drinkers more likely to mitigate the effects of price increases by consuming lower-quality products, although it notes that in the case of MUP the setting of a floor price may limit the opportunities to mitigate the impacts of MUP in this way.

Because the evidence suggests that an increase in price results in a smaller reduction in consumption in proportionate terms than the price increase, increasing alcohol prices using MUP is likely to reduce alcohol consumption without reducing revenue to the industry as a whole, although the effects may vary across sub-sectors within the industry.

A study with homeless drinkers in Canada found that re-budgeting (e.g. forgoing essentials such as food so as to afford alcohol), waiting for money and going without alcohol were the strategies most commonly reported when alcohol became less affordable (53%, 49% and 48% of the sample, respectively). A number of other negative consequences were reported, such as illicit drug use (41%), drinking non-beverage alcohol (41%) and stealing from liquor stores (32%). Seeking help or treatment was reported by 31% of the sample.<sup>12</sup>

In a study of dependent drinkers in Edinburgh, there was little evidence of acquisitive crime or substituting other harmful substances (such as non-beverage alcohol or illicit drugs) for alcohol during a period when the affordability of alcohol was falling. <sup>13</sup> This study found that these dependent drinkers switched to cheaper products (usually strong white cider), although it is important to note that this research was undertaken before MUP when 'trading down' to high-strength, low-cost alcohol was still an option.

#### Minimum pricing in Canada

Empirical evidence on the impacts of minimum pricing for alcohol comes from Canada where a form of minimum pricing applies in each of the 10 provinces. There is variation in the extent and frequency to which different drink types and outlets are affected by different forms of minimum pricing.<sup>14</sup>

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. These findings are summarised below.

In British Columbia, a 10% increase in the average minimum price across all drinks types led to:

- a 3% decrease in overall alcohol consumption, as measured by alcohol sales.<sup>15</sup>
   The size of the effect differed across drink types.
- an immediate 9% decrease in acute alcohol-attributable\* hospital admissions (i.e. resulting from intoxication) was detected. A 9% decrease in chronic alcohol-attributable hospital admissions (resulting from long-term alcohol use) was detected 2 years later. 16
- an immediate 32% decrease in wholly alcohol-attributable deaths and evidence
  of effects continuing up to 12 months after the price change.<sup>17</sup> Reductions in
  chronic and total alcohol-attributable deaths were detected 2–3 years after the
  price change.
- a 19% reduction in alcohol-attributable traffic violations, a 9% reduction in crimes against persons, and a 9% reduction in total crime rates for all the crime outcomes examined.<sup>18</sup>

In Saskatchewan, which has the form of minimum pricing most like MUP, a 10% increase in the average minimum price across all drinks types led to:

 an 8% decrease in overall alcohol consumption.<sup>19</sup> Effects were most pronounced in the off-trade (i.e. places that sell alcohol for consumption off the premises) and there was evidence of a shift in sales from higher-strength to lower-strength products. The effects observed resulted from 11% of products being affected by the price change.

#### Modelled impacts of MUP in Scotland

We have previously estimated that 47% of the volume of pure alcohol sold off-trade in Scotland was sold below 50ppu in 2016.<sup>20</sup> The Institute of Fiscal Studies, using a

<sup>\*</sup> Alcohol deaths and hospital admissions as a result of causes both wholly and partially due to alcohol.

different data source based on the whole of Great Britain, produced an estimate of 68%.<sup>21</sup>

The minimum pricing model in Canada and those in other countries differ from the MUP model being implemented in Scotland. The Sheffield Alcohol Policy Model has estimated that a 50ppu minimum unit price will reduce alcohol consumption in Scotland by 3.5% per year, 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. <sup>22</sup> It estimated that effects will be most pronounced among those drinking at harmful levels, particularly those on lower incomes.

### Our prior work

This evaluation builds on NHS Health Scotland's Monitoring and Evaluating Scotland's Alcohol Strategy (MESAS) programme of work. MESAS was established in 2009 to evaluate the Framework for Action.<sup>2</sup> It was as part of this programme of work that we first used alcohol sales data to report population alcohol consumption and monitor trends in key indicators of alcohol-related health and social harms.<sup>23</sup> Since then, we have reported these trends annually.<sup>20</sup>

When MUP was first proposed we commissioned a study to scope the feasibility of undertaking a robust evaluation of the economic impact of MUP on the alcohol industry.<sup>24</sup> This study concluded that a mixed-method approach using a combination of descriptive quantitative analyses of routine data, modelling methods and/or case studies would be the strongest option and was used to inform the Economic Impact study described later.

## 2. Evaluation design

The primary purpose of the MESAS evaluation of MUP is to meet the legislative requirement for a review of the operation and impact of MUP. The range of outcomes assessed has been determined by the requirements of the legislation, taking into account the existing evidence to identify expected impacts. The evaluation also identifies other outcomes that it will be important to measure to meet the needs of the legislation.

## **Evaluation questions**

The overarching evaluation questions for the evaluation of MUP are:

- 1 To what extent has implementing MUP in Scotland contributed to reducing alcohol-related health and social harms?
- **2** Are some people and businesses more affected (positively or negatively) than others?

## Theory-based evaluation

We are taking a theory-based approach to the evaluation of MUP, similar to the approach we took during the first phase of monitoring and evaluating Scotland's alcohol strategy (MESAS). Theory-based evaluation is used in the evaluation of social or public health policy interventions where it is difficult or impossible to use traditional experimental methods to establish whether the outcomes observed were caused by the policy being evaluated and where there are many potential outcomes across a range of domains.

In a theory-based evaluation, the conclusion that MUP has contributed to the desired outcomes would be drawn if:

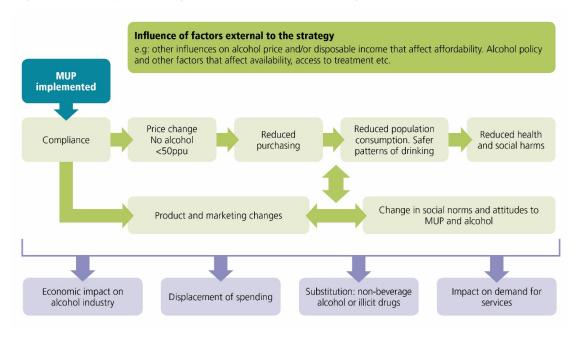
 there is a plausible, evidence-based 'theory of change' that shows the chain of outcomes linking MUP with reduced alcohol-related health and social harms

- it can be demonstrated that MUP was implemented in a way likely to achieve the outcomes
- evidence is gathered which supports the theory of change, i.e. demonstrates that the sequence of expected outcomes is being realised
- external factors influencing outcomes have been assessed and accounted for.<sup>25</sup> <sup>26</sup>

#### The theory of change for MUP

We have developed a theory of change for the evaluation (see Figure 1). The theory of change shows the main expected chain of outcomes whereby implementation of MUP increases the price of low-cost, high-strength alcohol, reducing alcohol consumption and in turn reducing alcohol-related health and social harms.

Figure 1: Theory of change for minimum unit pricing for alcohol



MUP may also stimulate the alcohol industry to make changes to pack sizes, alcohol strength, or product range, with new products introduced while others are discontinued. The price of alcoholic products not affected by MUP may change, either increasing to maintain the price differential that signals their status as a premium product or

decreasing to compete at what is now the lower end of the price range. New marketing strategies may be introduced to replace competition based on low price and/or take advantage of any increase in revenue.

These product and marketing changes may in turn impact on alcohol consumption by changing attitudes to MUP and social norms around drinking, and vice versa (i.e. changes in social norms may stimulate consumption and/or product change). MUP may also result in other changes, such as: substitution to non-beverage alcohol or other drugs; displacement of spending previously used for other goods or services; an increase or decrease in demand for services; and a variable economic impact on organisations that are part of the beverage alcohol production, distribution and retail chain.

The effects of MUP will be mitigated by its interaction with factors external to MUP. These include factors that influence the price of alcohol (e.g. changes in alcohol duty or currency exchange rates, or inflation in the price of raw materials, packaging or distribution costs). Also important are factors that influence the disposable income available to purchase alcohol (e.g. wages, welfare reform, inflation in the prices of other goods and services). There are also other factors that may affect people's drinking. These may be related to attitudes to drinking, alcohol policy that changes alcohol availability or marketing, the provision of treatment and care services, or changes in the broader social and economic determinants of health.

The effects of MUP may change over time. For example, any immediate impact of reduced availability of strong, low-cost alcohol, particularly among those drinking at harmful levels, may differ from longer-term effects of any change in the amount or pattern of drinking.

#### Main outcome areas

We have simplified the theory of change (ToC) into four main outcome areas:

- **Compliance**: This includes the following ToC outcomes: compliance; changes in social norms and attitudes to alcohol and MUP.\*
- Alcohol market. This includes the following ToC outcomes: price change; no alcohol <50ppu; reduced purchasing; product and marketing changes; and economic impact on the alcohol industry.
- **Consumption**. This includes the following ToC outcomes: reduced population consumption; safer patterns of drinking.
- Health and social harms. This includes the following ToC outcomes: reduced harm; displacement of spending; substitution to non-beverage alcohol or drugs; understanding the impact on demand for services.

## **Mixed-method portfolio**

Within the evaluation we are using a variety of quantitative and qualitative study designs to generate robust evidence on the outcomes in the theory of change. These designs have different relative strengths and serve different purposes. The studies within the MUP evaluation have one or more of the following purposes:

- To provide quantitative estimates of change.
- To provide qualitative understanding of mechanisms that underpin (MESAS or other) quantitative estimates of change.
- To provide qualitative understanding where quantitative study is not appropriate, for methodological, ethical or practical reasons.
- To provide qualitative understanding of people's lived experience of MUP in Scotland.

<sup>\*</sup> Change in social norms and attitudes may result from many of the outcomes in the ToC. We have placed it in the Compliance outcome area for purely organisational reasons.

Studies intended to provide evidence of impact require a control or comparison group to understand whether observed changes in outcomes are likely to have occurred due to MUP rather than other potential causal factors. Controls can be similar geographic areas, the same area compared before and after a policy is introduced, or a combination of the two. Where robust and consistent data on exposures, outcomes and potential confounders are available we will compare outcomes in Scotland with those in a control area. Where possible, statistical analysis will be undertaken to evidence the scale of change in outcomes in Scotland compared to the control area and to assess whether any differences are due to MUP. Other studies will provide quantitative evidence on the extent to which outcomes have changed in Scotland after MUP even if comparison with a control area is not possible.

However, quantitative studies are not always appropriate or feasible and, importantly, will not provide the depth of understanding on the mechanisms underpinning observed changes in outcomes. Qualitative evidence helps in understanding the ways individuals or organisations have responded or adapted to MUP and the mechanisms through which change (or no change) has occurred, including the influence of the wider context in which MUP took place. This understanding is essential to improve interpretation of quantitative findings. Taken together, all these types of evidence are necessary to provide a strong assessment on the contribution of MUP to the five licensing objectives (concerned with alcohol-related health and social harms) and its impact on producers of alcoholic drinks and licence holders in Scotland, as required by the legislation.

## Setting

The setting for the study is Scotland, where MUP applies, and comparisons are made with outcomes in England and Wales where possible. The study is a national evaluation. However, some effects may differ in different parts of the country, for example, in areas close to the border with England where MUP does not apply. Therefore, where possible, we will seek to understand how impacts vary geographically within Scotland.

## 3. The portfolio of evaluation studies

We have developed a portfolio of studies to evidence the main outcome areas. Each outcome area will be evidenced by a number of studies from the portfolio, and many studies will contribute evidence on more than one outcome area. The final report will include robust data from all sources to evidence the outcomes and where appropriate will include routine statistics to provide context.

The portfolio consists of a mix of studies funded and managed through the Monitoring and Evaluating Scotland's Alcohol Strategy (MESAS) programme of work, led by NHS Health Scotland, and studies funded and managed separately through other funding sources.

#### **MESAS-funded studies**

At the time of writing (April 2019) the NHS Health Scotland MESAS-funded evaluation of MUP consists of 12 individual studies, either undertaken in-house by NHS Health Scotland or commissioned by NHS Health Scotland from other research teams. These studies are funded by Scottish Government and NHS Health Scotland. Table 1 provides a brief description of these studies and when they will report. More detail (where available) is provided in Appendix 1. Full individual study protocols and analytical plans (where appropriate) will be published on our website. We will update this evaluation protocol if and when further MESAS-funded studies are added to the portfolio.

## Separately funded studies

In addition to the MESAS-funded portfolio of studies, we will draw on relevant, critically appraised studies funded by other sources in preparing the final report. At the time of writing (April 2019) we are aware of six confirmed separately funded studies. Table 2 provides a brief description of these studies and expected reporting dates. More information, including funding source, host institution and contact details for obtaining

more information, is provided in Appendix 2. We will update this evaluation protocol if and when additional separately funded studies are confirmed.

Accompanying this publication is a separate table that summarises all the studies in the MUP portfolio, both MESAS and separately funded studies.

## **Annual monitoring**

During the course of the evaluation we will continue to publish the annual MESAS Monitoring Report.

This brings together the latest data on:

- alcohol sales
- alcohol price
- self-reported consumption
- alcohol-specific deaths
- alcohol-related hospitalisations
- social harms.

## Table 1: Brief description of MESAS-funded studies, outcome areas and reporting

Key: I+C: Implementation and Compliance

AM: Alcohol market

C: Consumption

H+SH: Health and social harms

Study	Brief description	I+C	AM	С	H+SH	Reporting
1. Compliance	National licensing statistics and evidence from licensing practitioners to explore compliance with MUP and related issues.	<b>*</b>				Mid 2019
2. Economic impact on the alcohol industry	Case studies and industry data to assess the economic impact of MUP on producers of alcoholic drinks and licence holders in Scotland.		<b>*</b>			Late 2019 and late 2022
3. Small convenience stores	Store audit with retailers, analysis of price data and review of the trade press to explore how alcohol price, product range and promotions change in small retailers, and how small retailers experience MUP.		<b>✓</b>			Early 2020
4. Alcohol price distribution	Retail sales data to evaluate the impact of MUP on the volume of off-trade alcohol sold at different prices in Scotland.	<b>~</b>	✓			Late 2020
5. Alcohol products and prices	Retailer and wholesaler data to assess the impact of MUP on the price, product range and strength of alcohol products sold in Scotland.		<b>✓</b>			Late 2021
6. Sales-based consumption	Retail sales data to evaluate the impact of MUP on the amount of alcohol sold in Scotland (overall, by trade sector, by drink type).			✓		Late 2019 and mid 2022

Study	Brief description	I+C	AM	С	H+SH	Reporting
7. Drinking at harmful levels	Survey and in-depth interviews with participants drinking at harmful levels recruited through treatment services and in the community, looking at changes in drinking behaviour and substitution to other sources and/or substances, their experience of crime, and the impact on their families. Also uses market research data to assess the impact of MUP on drinking behaviour in the general population.	<b>V</b>		<b>*</b>	✓	Mid 2020 and mid 2021
8. Children and young people: Own drinking and related behaviour	Qualitative interviews with young people under 18 years and key informants to explore the impact of MUP on their drinking and related behaviour.	<b>√</b>		<b>√</b>	<b>V</b>	Late 2019
9. Hospital admissions and deaths	Administrative data to evaluate the impact of MUP on hospitalisations and deaths caused by alcohol in Scotland.				<b>√</b>	Early 2023
10. Crime, public safety and public nuisance	This study will be commissioned in 2019. An overview of data sources and information on lead organisation and reporting dates will be added to a subsequent version of this document				<b>✓</b>	TBC
11. Children and young people: Harm from others	Qualitative interviews with practitioners working with children and young people affected by harmful parental/carer alcohol consumption to explore the impact of MUP on protecting children and young people from harms associated with others drinking.				<b>✓</b>	Late 2019
12. Public attitudes to MUP	National survey data to explore whether public attitudes towards MUP change following implementation.	<b>√</b>				Mid 2020

## Table 2: Brief description of separately funded studies, outcome areas and reporting

**Key**: I+C: Implementation and Compliance

AM : Alcohol market

C : Consumption

H+SH: Health and social harms

Study	Brief description	I+C	AM	С	H+SH	Expected final reporting
S1. Consumption and health service impacts of MUP	Survey data collected with repeated cross-sectional samples (in emergency department (ED) and sexual health clinics (SHC)) to assess the impact of MUP on the prevalence of hazardous and harmful drinking, emergency department attendance (ED only) and changes in other drug use and/or source of alcohol (SHC only). Qualitative interviews with at-risk drinkers and key informants in three communities in Scotland to explore implementation of MUP, responses and attitudes.	<b>√</b>		<b>✓</b>	✓	Late 2020
S2. Self-reported consumption	Analysis of national population survey data to assess the impact of MUP on self-reported consumption.			1	<b>V</b>	Late 2021
S3. Daily survey (N of 1)	Daily data collection using a smartphone survey and qualitative interviews conducted by peer researchers to assess the impact of MUP on drinkers recruited through addiction services.	<b>√</b>		<b>√</b>	<b>√</b>	Mid 2020
S4. Homeless drinkers	Qualitative interviews with homeless drinkers and service providers to explore the impact and experiences of MUP among homeless drinkers and street drinkers, and implications for those providing services to these groups.	✓		<b>V</b>	<b>√</b>	Late 2020

Study	Brief description	I+C	AM	С	H+SH	Expected final reporting
S5. Ambulance call-outs	Ambulance call out data and qualitative interviews with staff to explore the impact of alcohol and MUP on ambulance call-outs, and the management of alcohol-related call-outs by the Scottish Ambulance Service.				<b>*</b>	Late 2021
S6. Prescribing	Prescribing data to assess the short-term impact of MUP on prescribing for alcohol dependence.				<b>✓</b>	Mid 2020

## 4. Synthesis of findings

Given the breadth of outcomes and populations of interest, the impact of MUP will not be determined by a single study. Findings from across the portfolio of studies, and other appropriately critically appraised studies, will be synthesised to generate conclusions about the impact of MUP in Scotland for the final report, due late 2023. This will form the basis of the review report as required by the legislation.

Given the range and variety of outcomes likely to be affected by MUP, it is important to be clear in advance of the final report which of these outcomes we plan to use to judge whether MUP has been effective. Reducing health harms is the main aim of policy. Reduced consumption, in particular in those drinking at hazardous and harmful levels, is the mechanism by which MUP is expected to achieve this outcome. Price is the main mechanism we expect to reduce consumption. This constitutes the main pathway in the theory of change. Further work is required to define more specifically which indicators we will use to measure these outcomes.

We will use the programme theory to ensure we have identified the key outcomes of interest, to establish whether MUP was implemented as intended and to assess whether the sequence of expected outcomes is being realised. We will use the other outcomes on which we are gathering data to help enhance our interpretation about how plausible it is that the observed trends in these outcomes are due to MUP.

Evidence on all outcomes will be interpreted taking account of the purpose of each study and robustness of the evidence produced. This involves considering the sensitivity and specificity of the outcome indicator(s) in each study, the expected time for change to occur, and the consistency of the narrative established by triangulating the findings across the studies in the portfolio. For example, changes in long-term outcomes (such as falls in harms) without changes in the short-term outcomes (such as a fall in consumption) thought to drive the longer-term outcomes, would be considered inconsistent with the anticipated impacts of MUP. We will also describe changes in other outcomes required to meet the legislative requirements

that are not on the causal pathway to the intended outcomes, for example, impacts on beverage alcohol producers and licence holders in Scotland.

We are committed to reviewing established and innovative methods for synthesis across studies. We will draw on best practice and synthesis frameworks from elsewhere. We will continue to engage with our research partners and key stakeholders to ensure that our approach to synthesis is considered robust, appropriate and reasonable and that the conclusions are credible. We will provide more detail on our approach to synthesising findings as we prepare for the development of the final report.

## 5. Strengths of the evaluation approach

There were a number of important considerations when planning the approach to the evaluation of MUP.

Using a theory-based approach to design the evaluation framework provides a robust and accepted approach to national policy evaluation where it is not possible to randomly allocate the study population to an intervention or non-intervention (control) group as required in an experiment. By collecting evidence on the expected outcomes, intermediate links in the causal chain and on external factors that might affect the same outcomes, we can be more confident in drawing conclusions on whether any changes in outcomes are due to the policy or not.

To gather the evidence required, this evaluation will use the most appropriate, feasible and proportionate study designs to meet the aims of each of the component studies. For example, to isolate the specific impacts of MUP on health outcomes, we plan to use a quasi-experiment, comparing health outcomes in Scotland, where MUP applies, to England, where it doesn't. A quasi-experiment is still based on the assumption that the main difference between the two populations is the presence or not of MUP. While another part of the UK (such as England) offers the most similar comparator population, in practice, other factors affecting outcomes, such as alcohol policy or disposable incomes, may change in different ways in different countries at the same time as MUP. Furthermore, MUP may stimulate changes in the comparator population – for example, an MUP-driven product or price change may be rolled out in other countries of the UK. By taking a theory-based approach, with a portfolio of studies collecting evidence on a number of outcomes and other factors thought to influence those outcomes, in Scotland and other parts of the UK, the evaluation will help to understand whether the intended outcomes have occurred and whether this is likely to be due to MUP rather than other confounding factors.

MUP is taking place within a complex system which means there will be a wide range of potential outcomes (positive and negative) in different population groups. Indeed, the MUP legislation requires that the evaluation assesses the impact of MUP

across a number of domains (health, justice, social and economic), and where possible to assess differential impact (by age, gender, socioeconomic and alcohol consumption status).

The effects of MUP will be influenced by interactions with other elements of the system, adaptations by individuals or organisations and feedback loops between impacts. Theory-based evaluation aims to identify what these might be and measure the most important ones.

## 6. Governance and delivery structures

The development and delivery of the MESAS-funded evaluation is overseen by the MESAS Governance Board (MGB) to ensure that the evaluation meets the review requirements of the legislation and adheres to principles of scientific good practice. The MGB provided advice on the importance of studies in terms of evidencing the theory of change and on the overall allocation of funding. An important function of the MGB at the planning stage was to advise on the feasibility of conducting robust studies capable of attributing any observed changes in outcomes to the implementation of MUP, within a budget proportional to the value of the information. Triangulation of importance, feasibility of a robust study, and proportionality of cost were central to agreeing the final portfolio of studies.

Biannual meetings of the MGB review progress and provide advice on issues as required, with advice by email in between. The MGB is chaired by NHS Health Scotland (currently Dr Andrew Fraser, Director of Public Health Science), with members bringing research and/or strategic delivery and contextual expertise.

Evaluation Advisory Groups (EAGs) have been established to provide advice to and oversee the delivery of individual or groups of MESAS-funded studies. EAGs that oversee at least one study delivered by NHS Health Scotland are chaired by an external member. Members of EAGs were identified and invited according to their skills in research and/or understanding of context. There is broad and appropriate representation across the relevant EAGs including, but not limited to, stakeholders from public services, nationally commissioned organisations, Scottish Government, the alcohol industry, and academia.

The overarching purpose of this governance structure is to ensure that the scientific rigor, impartiality and integrity of the individual studies and the evaluation as a whole are maintained, and that the resulting evaluation is transparent and credible to stakeholders. The MGB and EAGs, individually and collectively, form a key role in quality control and assurance for the MESAS-funded evaluation of MUP. Further

details on membership and terms of references for the MGB and EAGs can be found on our website. More detail on the approach to governance is detailed in Appendix 3.

The separately funded studies are responsible for their own governance.

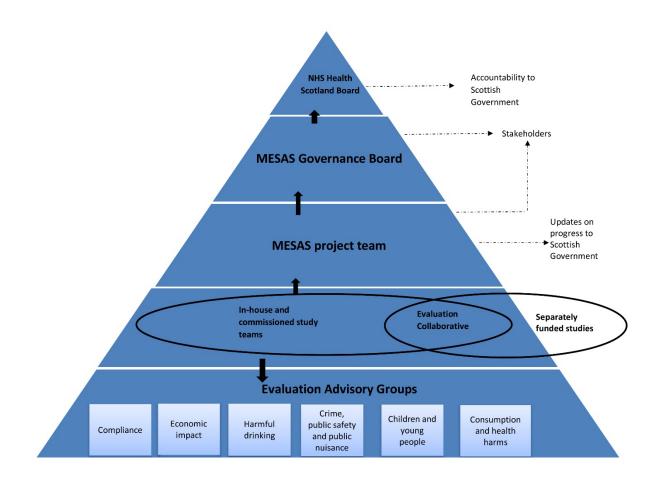
The MESAS project team is responsible for delivery of the MUP evaluation, working with the commissioned research teams and the EAGs, and reporting to the MGB and ultimately, through the Chair of the MGB, to the NHS Health Scotland Board. Responsibility and decision making for the MUP evaluation rests with NHS Health Scotland, and will transfer to its successor organisation, Public Health Scotland.

#### **MUP Evaluation Collaborative**

The MESAS project team, the commissioned research teams and researchers on the separately funded studies meet bi-annually to ensure studies are coordinated and to share learning from across the studies in the portfolio. This group is called the MUP Evaluation Collaborative.

The governance and delivery structure for the evaluation of MUP is illustrated in Figure 2 below.

Figure 2: Governance and delivery structure for the evaluation of MUP



# **Appendix 1: Descriptions of the MESAS-funded studies**

## **Study 1: Compliance**

Research team: NHS Health Scotland.

#### Research questions

- What are the perspectives and experiences of those working in inspection and enforcement of implementing MUP?
- What are the barriers to and facilitators of MUP compliance and implementation?
- What is the extent of non-compliance with MUP for alcohol by licensed premises in the study areas?
- What are the perspectives and experiences of those working in inspection and enforcement of any change in the sale of unlicensed alcohol in Scotland and the introduction of MUP?

## Study description

We will use mixed methods to explore MUP compliance and related issues post implementation.

Qualitative interviews will be conducted with Licensing Standards Officers (LSOs), Trading Standards Officers (TSOs) and Police Officers. Recruitment will ensure breadth of job role (with LSOs the primary target group) and geography (urban, rural and border area). A minimum of 15 interviews will be conducted between August and October 2018. We will analyse interview data thematically using the Framework method.<sup>27</sup> We will utilise member checking of initial findings with the National LSO Network to explore the face validity of initial findings.<sup>28</sup>

Data from interviews will be supplemented with descriptive analysis of any data on MUP compliance published by councils or Alcohol and Drug Partnerships in the first

6 months (corresponding with interview period). Where appropriate data are available, we will analyse descriptively.

National licensing statistics for 2018/19 data will be published after the study's reporting period, and so their findings will be added as a supplement later.

#### **Outcome measures**

Qualitative understanding of licensing practitioner experience of inspection and enforcement of the implementation of MUP in Scotland.

Quantitative measures (if possible) of:

- **1** the extent of MUP non-compliance, disaggregated over time, by trade, and by area of deprivation
- 2 patterns of MUP compliance within premises i.e. always compliant; one-time non-compliant; multiple visits with non-compliance
- 3 changes in the number of applications for review of premises licenses.

## Reporting

This study is expected to report in mid-2019.

# Study 2: Economic impact on the alcohol industry in Scotland

Research team: Frontier Economics.

#### **Research questions**

- What has been the economic impact of MUP on producers and licence holders of alcoholic drinks?
- How has MUP affected the number of such business, employment, turnover, gross value added and value of output?
- Has MUP had any impact on licence holders close to the border with England?

#### Study description

The research team will undertake a mixed-method theory-based evaluation to assess the impact of MUP on the alcohol industry in Scotland, as a whole and on key sub-sectors. They will use four methods:

- analysis of quantitative data,
- case studies
- stakeholder engagement
- qualitative interviews with small retailers in the border area.

The research team will collate and carry out descriptive analysis of routine and unpublished business statistics and industry data on trends in the measures below. The analyses will include data from Scotland and England (or English regions) as a 'control'. Wave 1 data gathered in 2019 will cover the period 2016/17 before MUP was introduced. Wave 2 data gathered in 2022 will cover the period 2019/20.

Eight case study organisations will be selected across all major parts of the alcohol industry in Scotland and different alcohol types. The research team will develop criteria, including likelihood of impact, to guide the selection of organisations for inclusion. The identity of the specific organisations included will remain confidential to encourage respondents to give full accounts of the impact of MUP. Two waves of

quantitative and qualitative data will be collected from each case study organisation in 2019 and 2021. Case studies will explore the relative importance of MUP compared to other factors influencing the outcomes of interest, and the mechanisms by which these outcomes occur.

Two waves of stakeholder engagement will take place involving interviews and round-table discussions with industry representatives covering: off-trade retail, ontrade retail, wholesale and supply chain, and manufacturers across different sectors. The first wave, in 2018, will inform the theory of change, setting out ways in which MUP could affect the alcohol industry in Scotland. The second wave, in 2022, will generate qualitative data on stakeholders' understanding of the impacts of MUP to assess the validity and consistency of initial findings from the quantitative data and case studies.

The team will also conduct interviews with owners or nominated representatives from eight small retailers around the Scotland–England border area to assess whether there are particular economic impacts for this group. Changes in cross-border purchasing will also be explored in the case studies.

#### **Outcome measures**

Quantitative measures of impact of MUP on:

- 1 Number of businesses
- **2** Employment (headcount and/or full-time equivalent)
- **3** Turnover
- 4 Gross Value Added (GVA)
- **5** Value of output.

Qualitative understanding of the impacts of MUP on industry behaviours identified in the theory of change.

Qualitative understanding of the experience of small retailers in the border area after the implementation of MUP in Scotland.

## Reporting

Findings on the Wave 1 baseline (pre-MUP) quantitative indicators, Wave 1 case study findings on short-term economic impacts and results from the interviews with small retailers in the border area will be reported in late 2019. The final Economic Impact study is expected to report in late 2022.

## **Study 3: Small convenience stores**

**Research team**: Institute of Social Marketing at the University of Stirling.

#### **Research questions**

- What happens to the price of alcohol products sold below and above 50 pence per unit (ppu) prior to, and following, the implementation of MUP?
- What happens to the price differential between alcohol products at different points in the price distribution?
- What happens to the alcohol product range offered to consumers?
- What happens to 'cheap' alcohol once it becomes significantly more expensive, for example is it re-branded (in glass bottles) or is it removed from shelves altogether?
- What happens to the ways in which previously 'cheap' alcohol is marketed?

#### Study description

This is a mixed-method study that aims to understand small convenience store retailers' experiences of MUP, how alcohol price, products and promotions change in these retailers after MUP is introduced, and whether there is any difference between small retailers located in more and less affluent areas.

There are three work packages, described below. Although each work package uses varied methods of study design, sampling and analysis, the findings will be synthesised to provide a comprehensive summary of small retailers' experience before and after MUP. To facilitate comparison across the study, each work package will also provide an in-depth case study of five brands that are important to the alcohol market in small retailers. These brands will be selected based on a combination of sales value, sales volume, numbers of retailers selling, and total volume of alcohol units sold.

#### Work package 1: Retailer audit

#### Work package description

The Retailer Audit combines semi-structured observations and interviews with a sample (minimum n=20) of small independent retailers\* at two time points, Oct–Nov 2017 and Oct–Nov 2018. The observations will document changes in alcohol marketing and promotions and the range of alcohol products stocked. Qualitative interviews with store owners or nominated staff will collect data on retailers' views on, and understanding of, the value and purpose of MUP; expectations and experiences of the implementation process; the impact of MUP on business performance; any changes in alcohol products, prices and promotions; and perceptions of customer response. A semi-structured audit tool and photographs will be used to record information on what alcohol is sold, alcohol pricing and how alcohol is displayed and promoted in stores. Data will be collected both on the five case study brands (see below) and across different alcohol categories (for example, beer, wine, cider).

Interview and observational data will be triangulated to describe changes in retail practice. It is anticipated that the findings will be structured around research themes, supplemented by site and product-specific case material.

#### **Outcome measures**

Qualitative understanding of small retailers' experiences of MUP.

Qualitative understanding of changes in alcohol pricing, products and promotion post MUP.

\* These are defined as small ow

<sup>\*</sup> These are defined as small owner-operated businesses, usually comprising a single store or small number of stores owned by an individual or family. They can be either affiliated to a symbol group or non-affiliated. A symbol group is a group of independent retailers trading under a common customer-facing brand – familiar symbol groups include brands such as Spar, Nisa Local, Premier, Best-One and Simply Fresh.

#### Work package 2: Price data

#### Work package description

The researchers will use electronic point of sale (EPoS) data from small retailers in Scotland to monitor trends in product characteristics, availability, and pricing before and after MUP is introduced. The data are provided by the Retail Data Partnership, a supplier of EPoS (electronic till) systems to small independent retailers across the UK. The study will use data supplied by 200 small stores on the data supplier's database. These stores are broadly representative in terms of area deprivation. The data collection is split into two nine-month periods: pre-implementation (August 2017–April 2018) and post-implementation (May 2018–January 2019).

All alcohol products will be monitored through Universal Product Codes (UPCs) (e.g. barcodes). A sample of 1,500 alcohol UPCs will be selected for monitoring from August 2017, based on sales data for June 2016–August 2017. Up to 500 new UPCs (i.e. new products entering the market) will be selected for inclusion over the course of the study, resulting in a total sample of 2,000 UPCs by the end of the study.

Monthly data will be supplied for each UPC. Data will include information on the UPC (e.g. product name, alcohol by volume (ABV) %, product size), number of retailers that sold the UPC, average sales price, and recommended retail price (RRP). Monthly data will be provided across all retailers and segmented by socioeconomic deprivation based on retailer postcode. Three levels of data will be used:

- **1** Product category level, i.e. beer, cider, fortified wine, perry, ready-to-drink (RTDs), spirits, wine, and unclassified UPCs.
- 2 A sub-sample of 50 products will provide more detailed insight into changes beyond the category level. These 50 products will be selected based on sales value, sales volume, average number of retailers selling the product and volume of pure alcohol (units) sold in the pre-data period.
- **3** The top five ranked products (of the 50) will be selected to be case study products, analysed across all three work packages.

The analysis will use descriptive quantitative analysis. Trends will be compared over the study period, between the pre- and post-implementation periods, and across SIMD categories.

#### **Outcome measures**

- 1 Product availability: Trends in UPCs sold, UPCs not sold, UPCs sold in multipacks, and multipacks UPCs split and sold as individual products.
- **2** Product characteristics: Trends in product ABV (%), size (ml), multipack size, number of units, and packaging type.
- **3** Pricing: Trends in sales price, sales-price-per-unit, RRPs, RRP-per-unit, proportion of products sold above/below £0.50-per-unit, and difference between sales price and expected sales price.

#### Work package 3: Retail trade press

#### Work package description

The researchers will review the content of five UK retail trade press publications preand post-MUP to explore what happens to low-cost, high-strength alcohol, including how products are marketed, after MUP. All issues of five publications\* over an 18month period August 2017–January 2019 will be included for analysis of content and themes, and comparison across the five case study brands.

#### **Outcome measures**

Qualitative understanding of changes in how products are marketed and promoted in the retail press post-MUP.

#### Reporting

The study (all work packages) is expected to report early 2020.

<sup>\*</sup> RN: Retail Newsagent (weekly); The Grocer (weekly); Convenience Store (fortnightly); Forecourt Trader (monthly); and Off Licence News (monthly).

Study 4: Alcohol price distribution

Research team: NHS Health Scotland.

Research questions

What is the effect of minimum unit pricing on the volume and proportion of off-

trade alcohol sold at different prices in Scotland, overall and by drink type?

Study description

We will use commercial data on alcohol retail sales to assess whether the

introduction of MUP is associated with changes in the distribution of the volume of

off-trade alcohol sold at different prices in Scotland. Data for England and Wales

(combined) will be used as the geographical control group.

We will obtain weekly alcohol price distribution data from market research company,

Nielsen. Nielsen estimates retail sales in Great Britain using electronic sales records

from all large multiple retailers and a weighted stratified random sample of smaller

'impulse' retailers. More detail on the Nielsen methods can be found in an earlier

report.29

Nielsen data does not include data from the discount stores Aldi and Lidl. We will

obtain data on the retail sales price of products sold within Aldi and Lidl, where

available. The data will not include volumes sold and will therefore not be included

within the planned analysis but will provide an important narrative of changes in

prices charged in this part of the market.

Data covering April 2015 to May 2019 (37 months pre-MUP and 12 months post-

MUP) will be available. We will use descriptive analysis as our primary analytical

approach. Specifically, we will examine how both the volume and proportion of pure

alcohol per adult sold at different price points has changed over time, pre- and post-

implementation. Population estimates will be used to express per-adult volumes per

week. We will explore the use of other statistical methods to further examine the

change in the price distribution of off-trade alcohol sales over time.

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#### **Outcome measures**

Quantitative measures:

- 1 The volume (litres per adult) of pure alcohol sold in each price band.
- 2 The proportion (litres per adult) of pure alcohol sold in each price band.

The outcome measures will be assessed overall and by drink type (beer, wine, spirits, cider, perry, ready-to-drink beverages (RTDs) and fortified wine).

#### Reporting

This study is expected to report in late 2020.

Study 5: Alcohol products and prices

Research team: NHS Health Scotland.

**Research questions** 

1 What is the effect of MUP on the weighted average sales price of alcohol

products sold in Scotland after the implementation of MUP?

2 How does the range of alcohol products change (strength measured by

alcohol by volume (ABV), volume, multipack size, packaging,

discontinuation/introduction of products) following the implementation of

MUP?

3 Do the total volume and value of sales of selected products change following

MUP implementation?

Study description

We will use commercial data on alcohol sales to assess changes in the price, range

and strength of alcohol products sold in the off-trade retail and wholesale sectors in

Scotland following the implementation of MUP. Data for England and Wales

(combined) will be used as the geographical control group.

There are two related work packages, described below.

We will use descriptive analysis to assess the outcome measures for total alcohol

and by drink category as appropriate. In addition, where appropriate, we will focus on

tracking a sample of key products over the course of the study time period. These

products will be chosen based on a combined ranked score calculated from the

following three measures, based on data from a defined pre-MUP period:

1 Total sales value

2 Total sales volume

3 Volume of pure alcohol sold

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All variants across a brand will be included when selecting the tracked products. This approach is similar to the Small Retailer study (Study 3) and taken together will provide an understanding of the impact of MUP on prices and products in different sectors of the market.

#### Work package 1: Off-trade retail sector

We will use off-trade product level retail sales data obtained from market research company, Nielsen. Nielsen estimates retail sales in Great Britain using electronic sales records from most large multiple retailers and a weighted stratified random sample of smaller 'impulse' retailers. More detail on the Nielsen methods can be found in an earlier report.<sup>32</sup>

The data include: brand name; drink category (beer, wine, spirits, cider, perry, RTDs, fortified wine, other); product characteristics (volume, pack size and packaging variant); total units sold; total volume sold and total value sold. We will obtain the data in weekly time periods for the period April 2015 to May 2019 (37 months preand 12 months post-MUP). This dataset will be supplemented with additional ABV data so as to allow accurate analysis of the strength of products and any associated changes.

Nielsen data do not include sales from discount retailers Aldi and Lidl. We will obtain data on the retail sales price of products sold within Aldi and Lidl, where available. The data will not include volumes sold and will therefore not be included within the planned analysis but will provide an important narrative of changes in prices charged in this part of the market.

#### Work package 2: Wholesale sector

We will use product level wholesale data obtained from SalesOut. SalesOut is a consumer market intelligence and analysis company, specialising in the manufacturing and wholesale sector. SalesOut will provide data on all alcohol sales made through wholesalers to registered retailers. The data include: brand name; drink category (beer, wine, spirits, cider, perry, RTDs, fortified wine, other); product characteristics (volume, pack size and packaging variant); ABV; total units sold; total

volume sold and total value sold. We will obtain the data in weekly time periods for the period May 2017 to April 2019.

Currently SalesOut is not able to provide data from one of the major wholesalers. This may change in the future and, if so, SalesOut will provide us with data retrospectively.

We anticipate we will use descriptive analysis of data from Scotland and England and Wales as our primary analytical approach in both work packages to provide an overview of changes in the average price, availability of products, and volume (tracked products only). The tracking of the loss or introduction of brand variants and changes to ABV will enable an assessment of changes to market diversity. Annual population estimates will be interpolated to obtain weekly population estimates, used to express per adult volumes. We will assess the impact of MUP on all alcohol products, by drink category and for a selected group of products (described above).

We will explore the feasibility for further statistical analysis using interrupted time series methods.

#### Outcome measures

Quantitative measures:

- **1** Average price per unit
- 2 Weighted average sales price
- 3 Total number of products sold per week
- 4 Introduction/loss of brand variant
- 5 ABV
- **6** Volume and multipack size
- 7 Total volume (pure alcohol) sales, expressed per adult

In work package 1 (Off-trade retail sector) we anticipate outcome measures will be analysed by market sector: grocery multiples, impulse stores and combined.

#### Reporting

This study is expected to report in late 2021.

#### Study 6: Sales-based consumption

Research team: NHS Health Scotland.

#### **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?

#### Study description

We will use commercial data on alcohol retail sales to assess whether the introduction of MUP is associated with changes in the level or trend of the volume of pure alcohol sold through the off-trade 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. The appropriateness of the primary control group will be reviewed in light of the timing of the implementation of MUP in Wales with changes made if necessary.

Off-trade alcohol retail sales data will be provided by the market research company, Nielsen (see Study 5 for further information). Weekly data on the volume of alcohol sold (in litres of natural volume and pure volume), by drink type, are available.

On-trade alcohol retail sales data will be provided by the market research company CGA Strategy. Estimates of on-trade sales are based on a combination of delivery, sales, and survey data from a stratified sample of on-trade retailers. A more detailed description of the CGA methods is provided in a previous MESAS report.<sup>20</sup> Data on the volume of alcohol sold (in litres of natural volume) for four-weekly periods, by drink type, are available.

We will include data (off-trade, on-trade and combined) 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.

We will use comparative interrupted time-series methods to assess the impact of MUP on the volume of pure alcohol sold per adult in Scotland. Analysis will be undertaken for 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).

#### **Outcome measures**

We will have three main outcome measures in this study:

- 1 Volume (litres) of pure alcohol sold per adult.
- **2** Volume (litres) of pure alcohol sold per adult in the off-trade.
- 3 Volume (litres) of pure alcohol sold per adult in the on-trade.

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

#### Reporting

It is expected this study will report in mid-2022.

#### Study 7: Drinking at harmful levels

**Research team**: University of Sheffield and Figure 8 Consultancy.

#### **Study description**

This is a mixed-methods study comprising three work packages to assess the impact of MUP on those drinking at harmful levels in treatment services, in the community and in the general population.

#### Work package 1: Treatment population

#### **Research questions**

- In what ways does self-reported alcohol consumption by people with alcohol dependence entering specialist treatment services or liver clinics change post-MUP, including level, products drunk and prices paid?
- What strategies do these service users employ to deal with the reduced availability of cheap alcohol?
- How does the level and nature of demand for treatment services change post-MUP?
- What strategies have been or could be put in place to minimise unintended harms arising from increased alcohol prices for people who are alcohol dependent?

#### Work package description

This work package aims to assess how, for those drinking at harmful levels, self-reported alcohol consumption changes following the introduction of MUP, and the strategies employed to deal with the reduced availability of high-strength, low-cost alcohol. Surveys and qualitative interviews will be conducted with participants (hereafter referred to as service users) recruited when entering statutory or third sector specialist treatment services or liver clinics in six areas in Scotland and three areas in north England. Service users with an Alcohol Use Disorders Identification Test (AUDIT score of 16+ (indicating harmful alcohol consumption and probable

dependence)) or who score similarly on an alternative measure will be eligible to take part. Data will be collected in three waves:

- Baseline (November 2017 to March 2018).
- 3–6 month post-MUP implementation (August to November 2018).
- 18–22 month post-MUP implementation (November 2019 to March 2020).

The research team will conduct 200 survey interviews per wave in Scotland and 80 per wave in north England. Survey interviews will collect data on participant demographic and socioeconomic characteristics; alcohol consumption and related behaviour, including volume, brand, price paid, purchase location/source (e.g. given, stolen, traded for other goods or sex) and consumption of non-beverage alcohol or other drugs. The survey interviews will explore anticipated and actual impacts of reduced availability of cheap alcohol on participants' health and social experiences and service users' reflections on impact upon their families and children.

Additional in-depth qualitative interviews with a sub-sample (n≈20/wave per country) of the survey participants will explore some of the strategies used to deal with reduced availability of cheap alcohol, and the service users' experiences post-MUP.

Longitudinal semi-structured interviews with service providers (n≈15–20 per country) will also be conducted at each wave. These will assess: whether the level and nature of demand for treatment change post-MUP; what strategies were or could have been put in place to minimise unintended harms arising from increased alcohol prices for people who are alcohol dependent; and perceived societal-level factors such as policy interventions or macroeconomic changes that potentially affect alcohol use by their clients alongside MUP.

Analysis will examine changes in primary outcomes and examination of subgroup differences. Differences between the Scotland and England samples will also be explored. Qualitative data will be coded thematically. Further details of the analysis plan for this work programme are available on the MUP page of the Health Scotland website.

#### **Outcome measures**

Quantitative measures of change in:

**1** Self-reported alcohol consumption, including level, products drunk and prices paid.

Qualitative understanding of strategies (positive and negative) employed to deal with the reduced availability of cheap alcohol, and of the impact of MUP on demand for treatment services.

#### Work package 2: Non-treatment population

#### Research questions

- How does self-reported alcohol consumption by harmful drinkers change, including level, products drunk and prices paid?
- Do harmful drinkers in remote and rural areas face additional challenges post-MUP and employ alternative strategies to those seen in other areas to deal with the reduced availability of cheap alcohol?
- Do harmful drinkers living close to the border with England engage in crossborder purchasing and is this direct (e.g. purchasing alcohol in England themselves) or indirect (e.g. obtaining alcohol bought in England by others)?
- How are the lives of family members or carers of harmful drinkers affected by this drinking, how does this change post-MUP and what impact does any observed behaviour change have on the lives of family members or carers?
- What strategies have been or could be used by policy makers to minimise the unintended harms of MUP for drinkers, their families or their carers in both remote and rural populations and the general population?

#### Work package description

Qualitative interviews with those drinking at harmful levels will be conducted by Privileged Access Interviewers (PAI) recruited through active recovery communities. Interviews will assess changes in self-reported consumption and strategies used following the introduction of MUP. PAIs will be primarily those in recovery, with some family members of, or carers for, those drinking at harmful levels. Interviews will take

place in three areas (urban, rural and border) in Scotland. Up to six PAIs will be recruited in November 2017 in each area and will undergo training and will receive ongoing supervision. Each PAI will identify potential respondents and carry out the interviews. PAIs will be encouraged to recruit three respondents (harmful drinkers or family members) and interview them several times throughout the follow-up period, until April 2020. Where PAIs or respondents drop out, further cross-sectional recruitment will take place.

Interviews will be structured around key areas of interest. For alcohol users this will include:

- changes in alcohol consumption and acquisition behaviour
- experiences of the removal of cheap alcohol and strategies adopted
- substitution for other drugs or non-beverage alcohol
- support received or required from services or their social networks during the transition period
- experience of crime (either as perpetrator or victim), and reflections on the impact upon their families and children.

Interviews with family members/carers will cover:

- changes in drinkers' typical drinking behaviour
- impact on the family's day-to-day life
- positive and negative strategies adopted by the drinker in response to MUP (including substitution behaviour, criminality or reduced spending on household essentials)
- support received or required by the family from services or social networks.

#### **Outcome measures**

Qualitative understanding of strategies (positive and negative) employed to deal with the reduced availability of cheap alcohol, and of the impact of MUP on those drinking at harmful levels and their families.

#### Work package 3: General population

#### **Research questions**

- Do fewer drinkers consume alcohol at harmful levels?
- Is this reduction seen in key population groups of interest, namely those living with a partner, living with children or in lower socioeconomic groups?
- Do the drinking practices of harmful drinkers change, including the alcoholic products that they drink, the location, days and timing of drinking, and the type of occasion?

#### Work package description

This work package will use market research data collected as part of Kantar World Panel's Alcovision survey (2001–2019). Alcovision is a continuous cross-sectional survey of demographically representative samples of respondents aged 18+ years in Great Britain.

Alcovision contains a behavioural questionnaire and a seven-day retrospective diary of respondents' drinking occasions. Difference-in-difference and/or interrupted time series analysis will be used to assess change in the number of drinkers in the general population that consume alcohol at harmful levels and whether there were changes in the drinking practices of harmful drinkers, including the alcoholic products that they drink, the location, days and timing of drinking, and the type of occasion. The study will explore key population groups of interest: those living with a partner, living with children or in lower socioeconomic groups.

Change in outcome measures in Scotland compared to changes in northern England will be explored. The primary outcome measure will be the proportion of respondents who are harmful drinkers. Further analyses will explore the drinking patterns of hazardous and moderate drinking to understand whether there is differential effect of MUP across the consumption distribution.

Changes in Scotland and Northern England in the proportion of harmful drinkers' consumption accounted for by the following will be explored: (i) different beverage

categories, such as strong beer, strong cider or vodka; (ii) drinking in different locations such as the home, different types of pub or restaurants; (iii) drinking on different days of the week and times of day and (iv) different reasons people drink.

#### **Outcome measures**

- **1** Frequency of consumption stratified by individual-level sociodemographics, household characteristics, geographic location and frequency of consuming different on-trade and off-trade beverage types.
- **2** Change in when, where, why, with whom and alongside what other activities drinking took place.
- 3 Change in amount consumed (including weekly alcohol consumption for the specific population groups (moderate, hazardous and harmful drinkers, by age, sex and sociodemographic characteristics) and the types of beverage drunk.

#### Reporting

This study is expected to report in mid-2021.

Study 8: Children and young people - own drinking and related behaviour

Research team: Iconic Consulting.

**Research questions** 

Have children and young people observed any changes in product availability

or price recently?

Has MUP influenced children and young people's consumption and

acquisition decisions? If so, how?

• What are children and young people's strategies with dealing with any price

increases observed in their favoured drink?

• Is there evidence that harms from children and young people's own

consumption have changed following MUP?

• What factors other than the introduction of MUP might be influencing children

and young people's alcohol use (e.g. external factors, cultural changes or

changes in consumption of significant others (e.g. parental, peers))?

Study description

This study aims to understand how changes in the price of alcohol have impacted

children and young people's own drinking and related behaviour.

Children and young people will be involved in developing age-appropriate

information sheets and a semi-structured discussion guide.

Qualitative interviews will be conducted with children and young people in Scotland

aged between 13 and 17 years who drink alcohol. The study aims to interview up to

45 children and young people, recruited through youth and other relevant

organisations. Sampling will be guided by the following characteristics: age, gender,

socioeconomic position, and location.

Interviews with children and young people will be supplemented by qualitative

interviews with 20 key informants. This will include staff from the organisations

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assisting with the recruitment of children and young people as well as others such as youth workers, project workers and residential staff. This will provide a well-informed, alternative perspective of children and young people's responses to MUP, covering availability, marketing and price of alcohol; acquisition and purchasing decisions; consumption; harms; and external factors affecting alcohol-related decisions.

Data collection will take place between November 2018 and March 2019.

#### **Outcome measures**

Qualitative understanding of how children and young people respond to MUP in terms of drinking and related behaviour such as acquisition.

#### Reporting

This study is expected to report in late 2019.

Study 9: Hospital admissions and deaths

Research team: NHS Health Scotland.

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?

Study description

Using routine administrative time-series data, we 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. We plan to use data for England as the

primary geographical control group. Data for subnational English regions may be

used in supplementary analyses.

Data on deaths will be obtained from National Records for Scotland (NRS) and the

Office for National Statistics (for data from England). To assess the impact of MUP

on alcohol-attributable hospital admissions in Scotland we will use the Scottish

Morbidity Record that records comprehensive information relating to all inpatients

and day cases admitted to either general acute or psychiatric hospitals in Scotland.

Equivalent data for England (including subnational regions) will be obtained from

NHS Digital. We will include monthly 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.

We will estimate alcohol-attributable hospital admissions and deaths by drawing on

the condition-specific estimates of alcohol attributable fractions (AAFs) previously

produced for Scotland<sup>30</sup> and England<sup>31</sup>, as well as the recent update to the list of

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conditions caused by alcohol<sup>32</sup>. Conditions will be categorised as either wholly or partially caused by alcohol, and as either acute or chronic.<sup>32</sup>

Data will be analysed descriptively to present trends and other key information. For statistical analysis of the impact of MUP, a comparative interrupted time-series design will be used. We will assess both immediate and lagged effects and perform a number of additional sensitivity analyses to test the robustness of our results. We will adjust statistical models for sociodemographic characteristics, seasonality and underlying trend.

#### **Outcome measures**

Quantitative assessment of changes in:

- 1 all wholly alcohol-attributable deaths/admissions
- 2 acute wholly alcohol-attributable deaths/admissions
- 3 chronic wholly alcohol-attributable deaths/admissions
- 4 all alcohol-attributable deaths/admissions (those wholly and partially caused by alcohol)
- 5 all acute alcohol-attributable deaths/admissions
- 6 all chronic alcohol-attributable deaths/admissions
- 7 a selection of condition-specific outcomes (these will be specified in the analysis plan and will likely include alcoholic liver disease and acute withdrawal).

#### Reporting

This study is expected to report in early 2023.

#### Study 10: Crime, public safety and public nuisance

The aim of this study is to evaluate the impact of MUP on crime and disorder, public safety and public nuisance in Scotland. This study has not yet been commissioned so it is not possible to detail the research team or describe this study, outcome measures or reporting timescale at the time of writing (April 2019).

#### Study 11. Children and young people - harm from others

Research team: NHS Health Scotland.

#### Research questions

- What are the perceptions and understanding of participants on:
  - the extent to which parental/carer/sibling drinking impacts on children and young people?
  - o the role of alcohol and children's experiences of harms from others?
  - the potential role of alcohol price in mitigating harms to children associated with parental/carers/sibling drinking?
- Have participants observed any changes in alcohol consumption and related behaviour in their work with families post-MUP?
- Have participants observed any recent changes in parental/carer/sibling alcohol consumption and related behaviour post-MUP expressed by the children and young people they work with or observed by participants in their work with families?
- What are the perceptions of participants of the main factors that may have contributed to any changes observed across their existing caseload?
- Have there been any observed changes in participating organisations of their alcohol-related service provision for parents/carers/sibling and families post-MUP (e.g. any changes in the care of children and young people by families or changes in family relationships, and how this potentially impacts on what participants do as practitioners in response to these families)?

#### **Study description**

The primary aim of this study is to contribute to an understanding of the potential role of MUP in protecting children and young people from harms caused by others' alcohol consumption, in the context of family lives. The study will provide an understanding of some of the intended and unintended consequences of MUP on children and young people experiencing harm from others' drinking.

We plan to undertake around 10 focus groups with participants recruited from organisations that work with families and children and young people affected by parental or direct family member alcohol misuse. We will include a mixture of participants to provide perspectives from different practitioner groups and types of organisation. Sampling will be guided by geographical location and will consider levels of deprivation of areas served by participating organisations and teams. It is anticipated that most participants will be working with families from more disadvantaged circumstances due to the nature of their work. Data collection will take place between January 2019 and March 2019.

We will seek to gather data on participants' perceptions and understanding of any general changes or trends they have observed across their existing caseload post-MUP, for instance any changes in alcohol consumption and related behaviour that they have observed in their work with families post-MUP; any recent changes in parental/carer/sibling alcohol consumption and related behaviour post-MUP expressed by the children and young people they work with or observed by participants in their work with families; perceptions of the main factors that may have contributed to any changes observed across their existing caseload; and any observed changes in participating organisations of their alcohol-related service provision for parents/carers/sibling and families post-MUP.

We will analyse the data collected thematically using the Framework method.<sup>27</sup>

#### **Outcome measures**

Qualitative understanding on the potential role of MUP in protecting children and young people from harms from others' alcohol consumption, in the context of family lives.

#### Reporting

This study is expected to report in late 2019.

#### Study 12: Public attitudes to MUP

**Research team**: NHS Health Scotland using data collected by ScotCen.

#### **Research questions**

- To what extent does the public support the policy of MUP?
- What are the reasons for agreement/disagreement?
- How has agreement/disagreement changed over time?

#### **Study description**

We will use data collected through the Scottish Social Attitudes Survey (SSAS) to monitor changes in the Scottish public's attitudes towards MUP before and after MUP has been introduced.

Three questions on MUP have been asked in the SSAS in 2013 and 2015. The questions aim to gauge the extent of and reasons for agreement/disagreement with MUP. We will repeat these questions in the SSAS in 2019.\*

SSAS uses a cross-sectional sample of 1,200 adults in Scotland, selected via random probability sampling. If sufficient modules to make the survey financially viable are commissioned in any given year, data collection takes place between July and December.

Data will be analysed descriptively, with significance testing as appropriate. Where possible, differential analysis by age, gender, household income, and highest educational qualification will be undertaken.

#### **Outcome measures**

- 1 The percentage of the population who agree/disagree with MUP.
- 2 The reasons for agreement/disagreement with MUP.

<sup>\*</sup> The original proposal was to ask the questions in the 2018 SSAS but the survey did not take place that year.

#### Reporting

This study is expected to report in mid-2020.

### **Appendix 2: Descriptions of the separately funded studies**

#### Study S1: Consumption and health service impacts of MUP

Research team: The Medical Research Council/Chief Scientist Office (MRC/CSO) Social and Public Health Sciences Unit (SPHSU) at the University of Glasgow (leading on components 1 and 2) and the Institute of Social Marketing, University of Stirling (leading on component 3). The wider research team includes Kings College London, University of Aberdeen, University of Victoria (Canada), ISD and NHS Health Scotland.

The study is funded by the National Institute for Health Research (NIHR).

Further information and protocols are available on the MUP study webpage: http://mup.sphsu.gla.ac.uk

#### **Study description**

This is a mixed-method study with three work packages.

#### **Work package 1: Emergency departments (EDs)**

#### Research questions

- What are the impacts of MUP for alcohol on alcohol-related harms and drinking patterns (using the Fast Alcohol Screening Test (FAST) for Emergency Department (ED) attendees and by subgroups of interest (age, sex and deprivation)?
- Does the effect of MUP vary dependent on the type of alcohol-related harm:
  - Acute alcohol-related harms vs chronic alcohol-related harms?
  - Broad diagnostic groups (based on coding systems used in EDs?

- Does MUP affect alcohol consumption (on the basis of the FAST score) and alcohol misuse over the reporting period among people attending EDs (FAST >3)?
- Does the MUP intervention effect size (assessed on a variety of measures including FAST) vary at the second and third time points?

#### Work package description

This work package aims to assess the impact of MUP on alcohol-related harms and drinking patterns overall and by subgroups of interest (age, sex and deprivation) among those attending emergency departments. Three waves of interviews (one pre-MUP, in Feb 2018 and two post-MUP, in Oct 2018 and Feb 2019) will be conducted with attendees at sample emergency departments in Scotland and north England. Surveys will collect basic demographic data and details of alcohol consumption using the Fast Alcohol Screening Test (FAST). Additional details of attendance will be collected for interviewees, and anonymised age-band, gender, and diagnostic details for all attendees.

#### Outcome measures

Quantitative changes in:

- Absolute numbers of alcohol-related attendances as defined by any one of:
  - o patient self-reports attendance is alcohol-related
  - patient reports alcohol consumption in past 24 hours of >=8units in men or
     >=6 units in women
  - o patient not approached because too intoxicated with alcohol.
- Absolute number of alcohol-related attendances by age/sex/deprivation.
- Problematic alcohol use (as defined by the Fast Alcohol Screening Test (FAST)).
- Mean FAST score.
- Prevalence of binge drinking in the past week.
- Reason for attendance (coded by ICD10).

#### Work package 2: Sexual health clinics (SHCs)

#### **Research questions**

Among a population at high risk of alcohol and drug-related problems:

- Does alcohol misuse change among people attending SHCs following MUP (on the basis of the FAST score) (FAST ≥3)?
- Does source of alcohol change following MUP?
- Does MUP impact on the use of psychoactive substances apart from alcohol?
- Does effect differ across age group, gender, highest educational attainment, and employment status?
- Do any observed intervention effects vary at the second and third time points?

#### Work package description

This work package aims to assess unintended impacts of MUP on alcohol sources, alcohol spend, and the use of psychoactive substances other than alcohol. Three waves of self-complete questionnaire interviews (one pre-MUP, in Feb 2018 and two post-MUP, in Oct 2018 and Feb 2019) will be conducted with attendees at sample sexual health clinics in Scotland and north England. The questionnaire will collect data on basic demographics and details of alcohol and drug use.

#### Outcome measures

Quantitative changes in:

- 1 Proportion of patients self-reporting recent use of illicit psychoactive substances other than alcohol (i.e. within the last month).
- 2 Source of alcohol for consumption.
- **3** Recent use of all psychoactive substances other than alcohol, including novel psychoactive substances.
- **4** Problematic alcohol use (as defined by the Fast Alcohol Screening Test (FAST)).
- 5 Mean FAST score.
- **6** Prevalence of binge drinking in the past week.
- **7** Differential trends in the above outcomes by age group, gender and socioeconomic position.

#### Work package 3: Communities

#### **Research questions**

- How is MUP affecting key subgroups within the Scottish population?
- What are participants' expectations and experiences of MUP's impact, including unintended consequences, both personally and on family, friends and wider community?
- How do narratives compare between the different sample groups: age, gender and socioeconomic position?
- From different professional perspectives, was the implementation process adequate? Were any difficulties experienced?

#### Work package description

This work package aims to explore participants' expectations, experiences and understanding of the policy and its impacts, including any unintended consequences. It will use qualitative focus groups with young people aged 18–25 years and older heavy drinkers aged 30+ years in three communities in Scotland, an affluent urban community, and two deprived urban communities. It will also use interviews with professional stakeholders in these communities. Data collection will take place in two waves, one before MUP implementation (Jan–April 2018) and the other after (Sep–Nov 2018).

#### **Outcome measures**

Qualitative understanding of the lived experience of those exposed to MUP in relation to social norms, attitudes and any perceived changes in drinking patterns and purchasing habits.

Qualitative understanding of the implementation process within each study community, perceived impacts and any difficulties in implementation.

#### Reporting

This study is expected to report late 2020.

# Study S2: Self-reported consumption – correcting estimates of alcohol consumption in the Scottish Health Survey for non-response

**Research team:** MRC/CSO Social and Public Health Sciences Unit (SPHSU) at the University of Glasgow.

The study is funded by the SPHSU's core funding from the MRC and the CSO.

#### **Research questions**

- How do bias-corrected estimates compare with uncorrected estimates?
- Using the corrected data, how does the social pattern of consumption change following the introduction of MUP?
- How do alternative methods of bias correction compare?

#### Study description

Alcohol consumption is underestimated in social surveys. Researchers at the MRC SPHSU, led by Dr Linsay Gray, have worked with colleagues at NHS Health Scotland to develop a way of correcting estimates of consumption from the SHeS for non-response, using linkage to NHS records. 33 Previous work has produced corrected estimates with data from 1995–2010. The aim of the new study is to produce similarly corrected estimates for later waves of the survey, including at least 20 months post-MUP data, to use the corrected data to evaluate the impact of MUP on self-reported alcohol consumption and to compare alternative methods of correcting for non-response bias.

#### **Outcome measures**

Distribution of per capita consumption for all consumption and health service impacts of MUP for adults, and for subgroups defined by sex and deprivation.

#### Reporting

The study is expected to report late 2021.

# Study S3: Daily survey (N-of-1) study – the psychosocial determinants of 'stopping', 'switching' and 'seeking treatment' behaviour following Minimum Unit Pricing implementation

**Research team:** Led by the MRC/CSO Social and Public Health Sciences Unit (SPHSU) at the University of Glasgow in collaboration with others.

The study is funded by Alcohol Change UK (formerly Alcohol Research UK).

#### **Research questions**

- What are the individual and social determinants of within-person change in:
  - o alcohol use
  - o other drug use
  - o contacting treatment and support services?
- What contextual and environmental factors are related to Q1 outcomes:
  - Minimum Unit Pricing implementation
  - Social networks and social support?
- How feasible is an N of 1 study design to conduct research with heavy alcohol using populations?

#### **Study description**

This project aims to find out: what are the psychosocial determinants: reduced drinking; substance switching and safe/risky drug use behaviour; maintaining 'recovery' or seeking treatment among drinking or recently stopped dependent drinkers; and the extent to which MUP influences these psychosocial determinants.

Daily smartphone surveys will be conduct over a 12-week period and follow-up qualitative interviews incorporating social network data collection with a sample of dependent drinkers, or recently stopped drinkers in three waves: before, during and after MUP implementation. Recruitment and interviews undertaken by peer researchers working with the Scottish Drugs Forum, and the peer team recruited from the community.

Social network analysis and qualitative analysis of interviews will assess the extent to which friends, family and professional social contact influence behaviour change, or the influence of psychosocial predictors of drinking, other drug use, or seeking professional support.

#### **Outcome measures**

Quantitative changes in:

- 1 Number and type of drinks (reported daily).
- **2** Type and self-rated intensity of other drug use.
- 3 Contact with alcohol and drug treatment service.

Qualitative understanding of social networks and support during the study, attitudes, opinions and experience of purchasing alcohol during study participation.

#### Reporting

This study is expected to report mid-2020.

# Study S4: Homeless drinkers – assessing the impact of Minimum Unit Pricing on homeless and street drinkers: a qualitative study

**Research team:** This study is led by Glasgow Caledonian University in collaboration with Queen Margaret University, NHS Greater Glasgow and Clyde, University of Victoria (Canada), University of Stirling and Herriot Watt University.

The study is funded by the Chief Scientist Office (CSO).

#### **Research questions**

- How does MUP affect the health of homeless and street drinkers including their mental health, physical health, and alcohol and drug use?
- What, if any, are the social, financial and legal consequences of MUP for homeless and street drinkers?
- How are health and social services for homeless and street drinkers affected by MUP?

#### Study description

To assess the impact and experiences of MUP among homeless drinkers and street drinkers, and implications for those providing services to these groups.

A qualitative study involving semi-structured interviews with homeless and street drinkers (n=40) and focus groups with service providers (n=40). Qualitative methods were chosen because they provide insight into the experiences and perspectives of those who may be deeply affected by MUP and they offer the most appropriate methods of accessing marginalised groups. Focus groups among service providers provide an opportunity for in-depth discussion and debate.

#### **Outcomes**

Qualitative understanding of both positive and negative responses to MUP, and any unintended consequences in homeless drinkers. Key topics include: change or stasis in alcohol consumption, type of alcohol consumed, substitution e.g. drug use or

industrial/bootleg alcohol products; antisocial behaviour or crime (as perpetrator or victim), involvement in begging or change in housing; daily/weekly expenditure e.g. on alcohol and essential items such as food, electricity, gas and transport; and impact on and from social networks.

Qualitative understanding of stakeholders' views and experiences of the impact of MUP on the homeless/street drinker population, and the extent to which MUP has had an impact on services and/or clinical practice.

#### Reporting

This study is expected to report in late 2020.

# Study S5: Ambulance call outs – the impact of Minimum Pricing of Alcohol on ambulance call-outs in Scotland (IMPAACT)

**Research team:** Led by the Institute for Social Marketing, University of Stirling, in collaboration with others.

The study is funded by the Chief Scientist Office (CSO).

#### **Research questions**

- Did MUP in Scotland lead to changes in: the number of alcohol-related ambulance call-outs; alcohol-related ambulance call-outs in patients of different sex, age or socioeconomic status (SES); overall ambulance callouts?
- What are the direct costs or cost-savings arising from changes in numbers of call-outs found to be due to MUP?
- How are alcohol-related ambulance call-outs identified, experienced, recorded and managed by ambulance service staff?

#### Study description

A mixed-method study. It will include two novel aspects: quantitative examination of the impact of Minimum Unit Pricing on ambulance call-outs in Scotland; and an indepth qualitative exploration of the impact of alcohol on, and management of alcohol-related call-outs by, the Scottish Ambulance Service.

A detailed dataset of all ambulance call-outs in Scotland covering the period April 2015–October 2020 inclusive will be obtained to calculate total daily alcohol-related call-outs by combining calls identified as alcohol-related using a system 'flag', and an algorithm to search free text clinical notes. The impact of MUP on alcohol-related ambulance call-outs will be assessed using interrupted time series analysis.

Ambulance call-outs for under-13 year olds excluding any identified as alcohol-related will be modelled as a counter-factual. The differential impact across

population subgroups will be assessed by repeating the primary analysis after stratifying the data.

Data from ISD on average cost per incident will be used to estimate the annual change in NHS ambulance costs arising from MUP. If the data allow, the average cost per alcohol-related call-out will be calculated from the resource data recorded by SAS for each call-out to improve these estimates.

Up to 60 in-depth semi-structured interviews will be conducted with paramedics and senior managers. Interviews will be analysed thematically, and used to inform the quantitative evaluation and future paramedic practice.

#### **Outcome measures**

- Novel, more complete estimates of alcohol-related ambulance call-outs in Scotland and related costs.
- Number of alcohol-related ambulance call-outs, and overall ambulance-callouts prior to and after the introduction of MUP, and related trends, with alcohol-related call-outs also analysed for population subgroups.
- Qualitative accounts of how alcohol-related ambulance call-outs are identified,
   experienced, recorded and managed by ambulance service staff.

#### Reporting

The study is expected to report late 2021.

Study S6: Prescribing – evaluating the impact of Minimum Unit Pricing for alcohol in Scotland on prescribing levels for alcohol dependence and management of harmful drinking (MUPPEL)

Research team: Led by the University of Glasgow with others.

The study is funded by Alcohol Change UK (formerly Alcohol Research UK).

#### Research questions

- Has MUP led to an increase in prescribing levels for alcohol dependence?
- Has MUP led to an increase in prescribing levels for management of harmful drinking?
- Are any intervention effects in 1) and 2) modified by socioeconomic deprivation?

#### Study description

The aim of this research is to quantify any changes in alcohol prescribing levels that happen in the short term (first six months of law change) that are attributable to MUP, to both contribute to the evaluation and inform the planning and resourcing of alcohol treatment services in Scotland. This research will cover both prescribing for acute episodes (i.e. withdrawal/detox) and in the medium/long-term (i.e. maintaining withdrawal).

The research team will use data covering a one-year period, six months before and after the introduction of MUP from the Scottish National Prescribing Information System. The impact of MUP on prescribing for alcohol dependence will be assessed using interrupted time series analysis adjusted for seasonality and underlying trend. Appropriate counter-factuals will be explored.

#### **Outcome measures**

Weekly counts of prescriptions.

#### Reporting

This study is expected to report mid-2020.

### Appendix 3: Research ethics, governance and commissioning processes

Research governance aims to ensure that all studies are of high quality, meet research ethical standards, and have the capacity to inform our understanding and knowledge in ways that can contribute to the evaluation. Within NHS Health Scotland, research governance is the responsibility of the Director of Public Health Science and the Head of Knowledge and Research Services. The Research and Evaluation Governance Framework (REGF) provides the framework for research governance in NHS Health Scotland.

All MUP evaluation studies will be carried out to the highest ethical and research governance standards, complying with national guidance and legislation such as the Research Governance Framework for Health and Social Care, NHS Research Ethics Service, and data protection legislation including the General Data Protection Regulation. All researchers are responsible for ensuring the protection of people participating in research studies.

All studies involving primary data collection, whether commissioned or undertaken internally, have been or will be subject to an ethical review process as required. Primary data collection will be completed with informed, written consent where participants involved in the research are fully and adequately informed. Responses will be non-attributable in the research outputs and participants have the right to withdraw from studies at any time without giving a reason. All plans for data collection, storage, management and transfer comply with the General Data Protection Act (2018).

Separately funded studies are covered by the same legislation and regulation. Compliance is the responsibility of the host institution.

MESAS-funded studies which raise particular ethical issues or sensitivities and are beyond the remit of the NHS Research Ethics Service are subject to internal ethical review by the NHS Health Scotland Research Development Group (RDG).\*

Formal contracts mutually agreed between parties are in place for the delivery of commissioned studies and supply of commercial data. Suppliers are procured by competition wherever possible, in line with government policy and the relevant procurement legislation. As a public sector organisation, we are required to adhere to a framework of legislation including EU Directives on public procurement, the Procurement Reform (Scotland) Act 2014, and other related policies and our own internal governance. We seek to achieve best value for the services or goods that most closely meet our requirements as described in the specification. Contracts are awarded on the basis of scientific quality and value.

Use of data from other public sector organisations (by ourselves or a commissioned organisation) will be subject to a Memorandum of Agreement to agree the provision, sharing and use of these data.

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<sup>\*</sup> The commission of Sheffield University to undertake the study on harmful drinking preceded the establishment of the RDG and therefore was not reviewed by this group.

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