MRC/CSO Social and Public Health Sciences Unit Study Protocol Template and Guidance

This document should be used for all studies that do not include a trial. If the study is a trial then the "Trial Protocol" document should be used.

This document is a SPHSU study protocol template. It is provided to SPHSU Staff/collaborators for developing SPHSU-led study protocols. Instructions/guidance is highlighted in *italics* and can be deleted from the completed protocol. Sections should not be deleted if not applicable. Instead, a statement recording that the section is not applicable should be used.

Any problems or queries with this form please contact Lisa McDaid.

Template authorised by:

Name:	Laurence Moore	Role:	Director, SPHSU
Signature:		Date:	18 June 2015

Document History

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Version number	Revision date	Previous revision date	Summary of changes	Changes marked
1.0	1/6/2012	N/A	Original protocol approved by NHS REC	
2.1	13/2/2017		Protocols for ED study and Sexual Health study have been separated and entered into the new standard SPHSU template. Mechanism of data collection has been altered from paper and pen data collection, to the use of iPads.	
2.2	1/7/17		Addition of reviewer comments	
2.3	1/8/17		Incorporation of reviewer comments. Update of project timelines.	

Distribution This document has been distributed as follows

Name	Responsibility	Date of issue	Version
Alastair Leyland	Overseeing the document and responsible for final approval	19/2/2017	2.1
Drew Millard, NHS Health Scotland	Reviewing document for potential errors	19/2/2017	2.1

University of Glasgow

CHIEF SCIENTIST OFFICE

Project: **Evaluating the potential unintended impacts of minimum unit pricing of alcohol: A study in sexual health clinics in Scotland and England**

STUDY PROTOCOL

V2.3

Start date: 01 August 2017
End date: 31 July 2020
Duration: 36 months

Purpose

The purpose of the Protocol is to describe the study/project and provide information about the procedures for entering participants into the study/project. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary.

This protocol has been authorised by:			
	SPHSU Director		
Name	**Role**	**Signature**	**Date**
	Chief Investigator		
Name	**Role:**	**Signature**	**Date**

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1. Summary

This study aims to identify potentially unanticipated negative impacts of the introduction of minimum unit pricing (MUP) of alcohol in Scotland. Important negative impacts include: consumers switching to alternative alcohol sources (e.g. internet sales, cross-border purchase and illegal sources); increased alcohol-related harm through substitution (e.g. use of illicitly produced alcohol associated with greater toxicity) or changed drinking patterns (e.g. increased binge drinking); displacement with increased use of illicit substances.

The main study will compare self-completed questionnaires at three sexual health clinics in Scotland with three sexual health clinics in North England at three different time points. Each wave of data collection for the main study will last three weeks. The first wave is planned for prior to the introduction of MUP in Scotland with two follow-up waves of data collection at 6 months after and 12 months after. The main study will be preceded by an initial short pilot phase lasting two days at one sexual health clinic and is intended to be carried out by the end of October 2012. A further pilot during the month before the main baseline wave of data collection is planned across all six sites.

Patients attending sexual health clinics will be handed a short questionnaire by a research assistant and asked to self-complete it while they are awaiting their clinic appointment. The questionnaire will include: basic demographic information; problematic alcohol use in the past year (assessed using a validated tool); illicit substance use and sources of alcohol purchase. The research assistant will emphasise that completion of the questionnaire is entirely voluntary. No identifiable details will be sought and participants will be asked to post their completed responses into sealed boxes.

The study will provide valuable information on the impact of MUP and will form an important component of the planned evaluation portfolio (coordinated by NHS Health Scotland). Potentially negative impacts of the intervention on important population subgroups (including by deprivation, age and sex) will be reported.

2. Introduction

2.1 Background

It has been suggested that alcohol is the most harmful substance to society once all the health, social and economic costs are accounted for [1]. The level of alcohol-related harm in the UK in general, and Scotland in particular, is high and is a major contributor to socio-economic Inequalities [2, 3]. It is also increasingly acknowledged to be a global problem, with alcohol ranked as the ninth most common cause of death **worldwide** [4]. The over-consumption of alcohol is associated with a multitude of health problems including an increased risk of liver disease, heart disease, unintended pregnancy, sexually transmitted infections, some cancers and accidental injuries [5-7]. Its impact extends beyond the individual, with adverse effects on families, communities and the wider economy.

A comprehensive evidence review found evidence that consistently confirms a link between alcohol price, consumption and harm, although the strength of the association varies between studies [8]. From a UK perspective, the cost of alcohol has not risen in line with the rise in disposable income and alcohol was 44% more affordable in 2010 than it was in 1980 [9]. The evidence suggests that price mechanisms, such as taxation or MUP, to restrict affordability offer some of the most effective strategies to reduce alcohol-related harm but there is limited published research to date evaluating the particular strategy of minimum unit pricing [6, 8]. Although some forms of minimum pricing have been in place in some provinces in Canada for a number of years, **MUP represents a somewhat distinct policy since it sets a minimum price based purely on the alcohol content of a beverage, thereby reducing the likelihood of substitution effects.** Econometric modelling suggests that introducing a MUP would have a considerable impact in Scotland and England [10-12].

Minimum unit pricing has widespread support within the Public Health community [5, 13, 14]. The National Institute for Health and Clinical Excellence has published guidelines presenting a clear case for pursuing minimum unit pricing for alcohol, with evidence underpinning the recommendation from a comprehensive systematic review and modelling exercise [15]. NHS Health Scotland **has led** the Scottish Government's evaluation of Scotland's alcohol strategy through the Monitoring and Evaluating Scotland's Alcohol Strategy (MESAS) programme [16]. MESAS focused on evaluating licensing reforms, delivery of alcohol brief interventions and specialist treatment services. **NHS Health Scotland plans to build on MESAS by using routinely collected data to** assess changes in price, consumption and alcohol-related harms at a population level **that occur as a result of MUP**.

The work planned by NHS Health Scotland relies on routinely collected data and hence there are a number of areas of the MUP intervention that they cannot assess, in particular individual level changes in drinking and acute health harms not captured by routine data; and the possible unintended consequences of MUP and the likely differential impact of such consequences on the young and/or disadvantaged populations. Unintended consequences may occur through: increases in the use of illicit or industrial alcohol, use of other substances, and/or reducing the buying of food rather than alcohol to offset increased prices.

This study therefore, aims to build on the planned NHS Health Scotland research programme to assess changes in drinking behaviours and selected acute health harms not captured by routine data. Different mechanisms may cause varied impacts on population sub-groups. As with any pricing policy, MUP is likely to affect drinkers on lower incomes, and those who consume greater quantities, disproportionately. **This research will therefore look at potential disproportionate effects by comparing the impact across different socioeconomic groups.**

Alcohol-related harm in the UK in general, and Scotland in particular, is high and is a major contributor to health inequalities. MUP has been identified as an important potential public health policy intervention to address the burden of alcohol-related health harms and to reduce health inequalities. The Alcohol (Minimum Pricing) (Scotland) Bill was introduced to the Scottish Parliament on 31st October **2011 and passed in May 2012. Following the passage of the legislation into law, MUP has been subject to substantial delays as a consequence of a series of legal challenges. However, in October 2016 the Scottish Court of Session ruled in favour of the legality of MUP [17], raising expectations that the policy may finally be implemented. However, the legal options for the Scotch Whisky Association are not yet exhausted with a final appeal to the UK Supreme Court being pursued at the time of writing [18]. Current information suggests that MUP may be implemented as early as October 2017, although it is possible that implementation could be delayed. As a consequence of the potential implementation of MUP relatively soon, it is important that baseline data be collected as soon as practicably possible**.

Scotland is therefore likely to be the first country to introduce MUP nationally. If so there will be a clear difference in policy between Scotland and England. MUP is expected to have significant health impacts, but with uncertainty about size and adverse consequences. These divergent policy options coupled with uncertainty about effect size, and with the interest in MUP elsewhere in the UK and internationally, provide the opportunity to evaluate MUP as a natural experiment [19]. Evidence from Canada is confined to retrospective analysis of routine data on price, consumption and selected harms [20-23]. **NHS Health Scotland plan** to undertake analysis similar to that in Canada, of routine data to determine the impact of MUP on price, consumption and alcohol-related hospital admissions and deaths in Scotland. **This** will rely on routinely collected data and hence there are a number of areas of the MUP intervention that it cannot assess, in particular changes in drinking and acute health harms not captured by routine data; and the possible unintended consequences of MUP and the likely differential impact of such consequences on the young and/or disadvantaged populations.

<u>Changes in acute health harms:</u>
Alcohol-related attendances to Emergency Departments (EDs) are strongly associated with both levels of population consumption and population harms (Drummond, paper in preparation). Alcohol-related attendances to EDs that do not result in admission are not routinely collected and so will not be included in MESAS. There is a need for robust, prospective evaluation evidence to measure the effectiveness of MUP in changing this important health outcome; to determine if and how it alters alcohol use, and to monitor possible differential impacts and potential adverse consequences. Our proposed assessment of changes in alcohol-related attendances at EDs will help establish the effects of MUP on alcohol-related harms. It will also add to the evidence base on the burden alcohol places on EDs. It will make an important contribution to our understanding of the effects of MUP, which routinely collected data may miss as there is potential for secular trends to occur (for example, related to the economic downturn[24] and hospital admissions data will be subject to time lags that may make establishment of causality based purely on routine data more difficult [25]. Furthermore, primary data collection planned in this study makes use of reliable validated tools (the Fast Alcohol Screening Test (FAST) which is a shortened form of the AUDIT questionnaire designed for use in emergency departments) [26]. This tool not only quantifies levels of harmful alcohol use but allows detection of changes in drinking patterns [27]. Such information is currently not adequately collected within routine health surveys, particularly for young people and deprived populations who are most likely to be affected by the intervention [28]. Assessment of drinking patterns is crucial as different patterns of consumption (for example binge drinking compared with chronic levels of use) are associated with different patterns of health and other social harms [6, 29].

Potential unintended consequences:
A number of potential unintended consequences have been identified that might arise from the introduction of MUP:

1) Consumers may switch to alternative sources of alcohol not subject to MUP so that the price paid does not increase. Such sources include both legal (internet sales from outwith Scotland, legitimate cross-border purchase for own use [30], and home fermentation) and illegal sources (counterfeit, smuggled or stolen alcohol) [31, 32].
2) Increased alcohol-related harm could occur through substitution (e.g. to illicitly produced or industrial alcohol associated with greater toxicity) or changed drinking patterns (e.g. moving from regular drinking to binge drinking).
3) Displacement effects with reductions in alcohol-related harms being accompanied by increases in harms related to other substance use could be observed, and
4) MUP could unfairly penalise deprived populations less able to absorb the additional financial cost [33] and this may adversely affect access to other essentials such as food.

There is a need for robust, prospective evaluation evidence to measure the effectiveness of MUP in changing alcohol-related emergency department attendances; to determine if and how it alters alcohol use, whether it changes public attitudes and norms and perhaps more importantly to monitor possible differential impacts and potential adverse consequences. To the investigators knowledge, no other studies are planned to detect these adverse impacts in a robust way. Investigation of these potential impacts is of major public health importance as it may have important impacts on the overall assessment of health benefits compared to harms, as well as the distribution of those harms.

This proposal is informed by the MRC guidance on using natural experiments to evaluate population health interventions [19] and is based on a similar framework to the portfolio of studies investigating the smoking ban in public places in Scotland [34]. Evidence on the impacts, both positive and negative, will be of interest to the public, politicians and the public health community in Scotland, the rest of the UK and internationally.

2.2 Rationale

The legislation introducing MUP includes a so-called 'sunset clause', formally a provision that the measure will expire at the end of six years, unless an order for continuation is made between the fifth and sixth year [35]. A decision on whether implementation should continue is to be based on findings from a comprehensive evaluation, which this work constitutes an important part. The need for an evaluation is also stipulated within the Alcohol (Minimum Pricing) (Scotland) Bill which states that Scottish Ministers must present to the Scottish Parliament a report on the operation and effect of the minimum pricing provisions. This report must include information about how the policy has affected relevant businesses, different population subgroups and health.

The SPHSU has considerable expertise required to carry out this evaluation. In particular, the Unit's Policy programme focuses on methodology to evaluate natural experiments and led the development of the MRC's guidance in this area. Similarly, the Inequalities programme has a long history in evaluating major public health policies (for example, the National Evaluation of Sure Start) and in particular, assessing their impact on health inequalities.

2.3 Aims/Objectives/Research questions

The overarching NIHR grant includes three related studies that together make an important contribution to the overarching evaluation of the impact of MUP in Scotland. The three research aims and their associated studies are summarised in the Table below. The remainder of this protocol will only focus on the survey of alcohol-related behaviours (based on data collection within sexual health clinics), with a separate protocol available for the Emergency Department (ED) study.

Research aims (RAs)	Study components
RA1: To determine the impact on alcohol-related harms and drinking patterns for the overall population and by subgroups of interest (age, sex and deprivation)	Emergency Department study; Survey of alcohol-related behaviours (C1)
RA2: To determine the impact on non-alcohol substance use for the overall population and by subgroups of interest (age, sex and deprivation).	Survey of alcohol-related behaviours (C2); Qualitative focus group study (C3)
RA3: To describe changes in experiences and norms towards MUP and alcohol use following the introduction of MUP by subgroups of interest (age, sex and deprivation).	Qualitative focus group study (C3)

The more specific research objectives (ROs) of the MUP unintended impacts study are as follows:

1. To investigate whether alcohol consumption (on the basis of the FAST score: sensible, hazardous, harmful, possible dependence) has changed amongst a population at high-risk of alcohol and drug-related problems
2. To investigate how sources of alcohol consumption have changed following MUP
3. To determine whether MUP has impacted on the use of psychoactive substances apart from alcohol
4. **To determine whether any unintended impacts of MUP differ across the following population subgroups**
    a. **Age group**
    b. **Gender**
    c. **Highest educational attainment**
    d. **Employment status**
5. **To investigate whether any observed intervention effects vary over time**

3 Study Design/Methods

3.1 Study Design

This research is a natural experiment study of the impact of introducing MUP in Scotland. The methods involve the completion of a repeated cross-sectional questionnaire by all those attending sexual health services in three Scottish cities and three North England geographical control cities at three time points. On each occasion, data collection will be administered by a research assistant/nurse handing out a questionnaire for self-completion to all patients attending sexual health clinics at selected times during a three week time period. Prior to formal

data collection, the processes for collecting data will be piloted – initially within Glasgow only, followed by pilot data collection at all six sites.

The study has been designed to be robust to potential delays in the timing of the intervention. Since the implementation of MUP is not under the control of the investigators, it is possible that there may be delays in the timing of the intervention. Baseline data collection will occur as soon as is practically possible. The 2nd and 3rd waves of data collection will take place six and 12 months post implementation. If implementation of MUP occurs more than 12 months after baseline the 2nd wave will be conducted shortly before implementation to act as a 2nd baseline. The 3rd wave will remain as close to a 12 month follow-up as feasible. **If this occurs, it will not be possible to investigate whether the intervention effect varies over time (RO5). In general, investigators will attempt to avoid conducting data collection during months that are expected to be atypical in terms of alcohol consumption (i.e. Dec-Jan and Jun-Aug). Furthermore, we will attempt to collect data for one follow-up wave at the same time of year as the baseline data, to control for seasonal variation in consumption.**

Since the design of the study is by necessity non-randomised, there remains potential for confounding. Furthermore, given the need to include high-risk drinkers within the study, previous experience has demonstrated that it is not possible to conduct longitudinal research with satisfactory rates of follow-up. For this reason, repeated cross-sectional samples have been chosen. However, the validity of analysis of repeated cross-sectional samples require high response rates and for participants interviewed to be representative of the population from which they are drawn (i.e. attenders to the sexual health clinic in this study). It is therefore crucial that considerable effort is made to ensure that all eligible patients attending sexual health clinics during data collection periods are invited to participate. The absolute numbers of participants within the study is far less important.

3.2 Settings

The intervention sites and local Principle Investigator are listed in the table below.

Hospital	Principle Investigator	E-mail address
Leeds	Janet Wilson	janet-d.wilson@nhs.net
Glasgow	Pauline McGough	paulinemcgough@nhs.net
Sheffield	Salmon Omokanye	salmon.omokanye@nhs.net
Manchester	Gabriel Schembri	Gabriel.Schembri@cmft.nhs.uk
Dundee	TBC (c/o Liz Coote)	liz.coote@nhs.net
Edinburgh	Duncan McCormick	Duncan.McCormick@nhslothian.scot.nhs.uk

No changes to catchment areas are expected within the six sites during the conduct of the study.

3.3 Participant Selection

The target population for the study is all patients of any age attending participating sexual health clinics during data collection periods.

The exclusion criteria are:

- people unable to complete the questionnaire with assistance from the research assistant
- people who leave the department before an approach can be made
- people who are deemed by the clinical staff as inappropriate to approach.

We intend to obtain a total sample size of at least 5 000 participants across all six sites over each three week period of data collection. This equates to 288 participants per week per site of data collection. No target sample size is required for the pilot phases of the study as these phases are intended to help identify potential practical issues involved in conducting the study. If we are able to recruit 50% of attendees at sexual health clinics at the six sites (three Scotland, three England) then we envisage a total of slightly over 10,000 recruits over the two 3 week periods (an average of 288 per clinic per week). This would give us power of more than 80% to detect an increase in the proportion of people using drugs from 30% to 34%.

3.4 Recruitment

Promotional material to make potential participants aware of the research will be displayed in the waiting areas of the sexual health clinics.

Potential participants will be approached by the research staff, given a brief verbal explanation of the study's purpose, what participation involves and invited to ask any questions they have about the study. Patients will be handed a questionnaire, a pen and invited to self-complete the questionnaire and post the completed form into the box provided.

Sexual health staff will be briefed about the study (including at continuing professional development sessions, team meetings and individually as appropriate). Sexual health clinic staff will be encouraged to mention the existence of the study to patients but given their existing workload, it is envisaged that initial approaching by clinical staff for all potential participants would be impossible. However, we will ask clinical staff to inform research staff if any patients express a desire not to be approached by research staff regarding participation in the study.

Interpreter services will be used to provide information to potential participants who are not able to speak English if available at the time of approach. If it is unclear whether the participant has understood the information provided, the recruitment attempt will be excluded. Similarly, if no suitable interpreters are available, the patient will be excluded from the study. Given the nature of the questions asked, family members will not be used for interpretation purposes. Written translations of the questionnaire for a number of languages (Mandarin, Hindi, Polish) will be available for the main study but not for the pilot phases.

Given that the questionnaire is entirely anonymous, no additional identifiable information (including written consent forms) will be collected. We believe this is most appropriate as it minimises risks of disclosure of sensitive information and self-completion indicates implied consent to participate in the study.

Aggregated data on total numbers of patients (with aggregated demographic characteristics) will be retrieved from each sexual health clinic for data collection periods to allow assessment of the response rate for the questionnaire and extent of bias arising from non-response.

3.5 Withdrawal and loss to follow up

If the participant loses capacity to consent during the process of data collection, their research data would be withdrawn from the study. As active involvement is relatively short, occurrences of this type of event are expected to be very rare.

3.6 Study Procedures

Prior to the main study data collection, two pilot phases of research are planned. Two days of data collection for the first pilot phase will occur to ensure the data collection instruments are appropriate and identify any unexpected barriers to smooth conduct of the research. If following the pilot work, the research methods for further phases of the study require modification, an amendment or further application to the research ethics committee will be made as appropriate.

A second pilot phase is planned in the run-up to the first wave of the main study. This will be conducted across all six sites and will help ensure that the research staff do not interfere with the smooth operation of the sexual health clinics.

Research staff will receive training from the research team and others, to inform them about the purpose of the study and to discuss frequently asked questions. A FAQ resource will be created, based on expected questions and lessons from the above pilots.

3.7 Data Collection

Each wave will collect data over three weeks, ideally with one wave of data collection prior to the implementation of MUP and two post-implementation waves (after six months and 12 months). In general, the times of the day and week which will be chosen for data collection will be kept consistent across the different clinics and across waves. As noted above, periods of the year when alcohol consumption is atypical will be avoided.

Data collection will be facilitated by locally based research assistants/research nurses, on behalf of the study team. Research staff will be able to contact a member of the study team throughout data collection periods in the event of an emergency.

The study will be coordinated by a project coordinator based at the SPHSU who in turn will be supported by a post-doctoral researcher. These individuals will be responsible for ensuring distribution of materials for data collection to the sites and liaising with the sexual health clinics to coordinate the study and in particular, ensure that data collection processes are followed consistently across sites and over time. During each wave of data collection, all paper-based forms should be stored securely within local facilities. The questionnaires should be returned to the SPHSU using secure couriers at the end of each three week data collection period. It is the responsibility of the project coordinator to monitor transfers of the data and consent forms to the SPHSU. Monitoring data on the numbers of people attending the sexual health clinic (by age group and sex) will be sent to the SPHSU using secure file transfer at the end of each three week data collection period.

3.8 Data Analysis

<u>Primary outcome</u>

The primary outcome for this study is the:

- proportion of patients self-reporting recent use of illicit psychoactive substances other than alcohol (i.e. within the last month)

<u>Secondary outcomes</u>

Secondary outcomes will be changes in:

- source of alcohol for consumption
- recent use of all psychoactive substances other than alcohol, including novel psychoactive substances
- problematic alcohol use (as defined by the Fast Alcohol Screening Test (FAST))
- mean FAST score
- prevalence of binge drinking in the past week
- differential trends in the above outcomes by age group, gender and socioeconomic position (educational attainment and employment status)

After the first post-intervention wave, we will test for differences in the outcomes between the intervention and comparison groups using a fixed-effects regression model, with individuals nested within sexual health clinics, before and after adjustment for relevant covariates including baseline levels of the outcome. We will also attempt to determine the nature of the effect more precisely in terms of whether a dose-response effect according to the time since MUP was implemented is present (through a test of the significance of an interaction between time and intervention). We will test for interactions of the intervention with defined important covariates (including age, gender, education and employment status) to investigate the possibility of differential intervention effects and will subsequently stratify the analyses if indicated.

4. Research Governance and Regulatory Issues

4.1 Ethical issues

This study (titled 'Evaluating the potential unintended impacts of Minimum Unit Pricing of Alcohol: A study in sexual health clinics in Scotland and England) has been considered by NHS Research Ethics Committee Scotland A – reference 12/SS/0121 at a meeting held on 9 August 2012. The application received a favourable ethical opinion.

4.2 Data Monitoring

The Principal Investigator will be overall responsible for monitoring the quality of data collected. The postdoctoral researcher will be responsible for day-to-day management of data collection. External monitoring of data collection will be via the Advisory Group (described below).

4.3 Data Management

The original data received in a variety of file formats from the data sources (e.g. Microsoft Excel, SPSS, tab-delimited text) will be imported to new SAS files (.DAT) for data management and the original files backed up unaltered on unit's the network drive only accessible to the project team. Data cleaning, manipulations and analysis will be performed in separate coding/syntax files. We will provide well documented (i.e. with extensive commenting) SAS/R syntax so that all processing of data and results are reproducible. Metadata information on all variables of are already documented by the data sources. Recoded or derived variables necessary for secondary analysis will be documented and original variables retained to enable the data to be used accurately and effectively.

4.4 Data Storage and Retention

The original questionnaire data will initially be stored within the Population Health Research Facility. Questionnaires will be logged on their arrival and held securely using standard SPHSU procedures.

Access to data will be restricted to members of the research team during fieldwork and processing at the MRC/CSO Unit. Where data input occurs outside the Unit, external companies (who have all signed strict confidentiality agreements) are not given access to any identifiable data.

Storage and use of data after the end of the study
Long term storage of data is at Iron Mountain, a commercial data storage facility. All data are held in secure conditions with links to the contents of the sealed boxes held on a database at the MRC/CSO Unit. Access to the data is controlled and permission from the data guardian for the study is required to access long-term archived data.

Strict data protection policies will be followed as outlined in the University of Glasgow's data protection policy (http://www.gla.ac.uk/services/dpfoioffice/policiesandprocedures/dpa-policy/). The data will be worked from and stored upon the unit's secure protected server (only accessible to the project team). Upon completion of the project, the data will then be archived in line with University of Glasgow University guidance on data archiving and the MRC's 'Personal Information in Medical Research' guidance document.

5 Project Management

5.1 Project Manager

The Project Manager with responsibility for the day to day management of the project is:
TO BE CONFIRMED

5.2 Project Management Group

The Project Team for the Sexual Health study consists of the following members:

Name	Division/Organisation
Alastair H Leyland	MRC/CSO Social & Public Health Sciences Unit
S Vittal Katikireddi (SVK)	MRC/CSO Social & Public Health Sciences Unit
Post-doctoral researcher (TBA)	MRC/CSO Social & Public Health Sciences Unit
Ross Forsyth	MRC/CSO Social & Public Health Sciences Unit
Pauline McGough	NHS Greater Glasgow and Clyde
Duncan McCormick	NHS Lothian
Ann Erikson (confirmation pending)	NHS Tayside
Gabriel Schembri	Central Manchester University Hospitals NHS Foundation Trust
Janet Wilson	Leeds Teaching Hospitals NHS Trust

Name	Division/Organisation
Stephen Goodacre	Sheffield
Patient representative	
Clare Beeston (CB)	NHS Health Scotland
Gerry McCartney (GMc)	NHS Health Scotland
Lyndal Bond (LB)	University of Melbourne

The Project Management Group will meet three times per year throughout the project. Initial meetings will focus on planning data collection, followed by monitoring data collection and planning research outputs. All meetings are to be considered strictly confidential.

Minutes of PMG meetings will be taken on the SPHSU template and a Decision Log will be created and maintained by the Project Manager.

In addition to the regular meetings of the PMG for this study, investigators of the NIHR-funded MUP evaluation grant will meet twice per year. SVK, AL the postdoctoral researcher and the project manager will also be involved in the conduct of the study on the impacts of MUP on Emergency Department attendances. Lastly, SVK will also contribute to the conduct of the qualitative focus group study that is led by Stirling University. These joint members will be responsible for ensuring communication is maintained across different studies within the MUP evaluation portfolio.

5.3 Steering Group

A Steering Group will be established with membership drawn from academics not involved in the study. Members of the Steering Group will likely include Professor John Frank (Director of the Scottish Collaboration of Public Health Research and Policy), Prof Tim Stockwell (who has led an evaluation of reference pricing of alcohol in Canada), Scottish Government, third sector alcohol representatives (such as Alcohol Focus Scotland) and members of the public. Meetings will be held six monthly. To enable participation by members not based in Scotland, meetings will use video/teleconference facilities. Involvement of potential end-users of the research (including policymakers, advocacy groups) as well as public representation is intended to ensure the research is carried out in a sensitive and policy-relevant manner.

All discussions of the Steering Group will be considered to be confidential.

5.4 Project Filing Structure

The project files will be kept on a secure drive that are accessible to the SPHSU staff directly involved in the project. Responsibility for managing version control of the project files will rest with the postdoctoral researcher (to be appointed). Sub-folders created include: Grant Application; Closure and Archiving; Correspondence and Reports; Data; Data Collection; Dissemination and Impact; Ethics and Governance; Finance and Legal; Intervention and Process Evaluation; Meetings; Protocol; Risk and SOPs.

The electronic project files will be kept on:

T:\projects\MUP Sexual Health

The paper project files will be kept by the Population Health Research Facility during the study conduct, followed by archiving using University of Glasgow preferred suppliers.

6. Dissemination

6.1 Communication method

The key communications channels are:

- NIHR research report
- Journal Publication (possible targets):
    - *British Medical Journal (BMJ)*
    - *PLoS Medicine*
    - *International Journal of Epidemiology (IJE)*
    - *Addiction*
- Conference presentations (possible targets):
    - Society for Social Medicine
    - Kettil-Bruun Society
    - European Public Health Association conference
    - Scottish Faculty of Public Health conference
- Face-to-face dissemination with Scottish, UK and international policymakers
- Mass media, with issuing of press releases to increase the likelihood of gaining media interest
- Talks aimed at the public with an interest in public health and/or addiction e.g. events run by the Edinburgh Science Festival, local addiction charities

6.2 Publication Policy

All individuals who fulfil the ICMJE criteria for authorship will be invited to be an author of research outputs. It is expected that this is likely to include the study investigators (AHL, SVK, CB, GMc), clinical leads at the six sites and the postdoctoral researcher.

All publications relating to the project will be authorised by the PMG. Furthermore, the Advisory Group will be notified of plans to publish research outputs. Presentations will be authorised by a minimum of the Principal Investigator (AHL), but attempts will be made to gain approval from the overall PMG if time allows.

6.3 Public Engagement and Knowledge Exchange

This study has direct policy relevance and has been developed in close collaboration with policymakers within NHS Health Scotland and the Scottish Government. Ongoing discussion with policymakers is planned for throughout the project, with invited presentations to NHS Health Scotland and Scottish Government expected. The findings of this study will be more formally submitted to the Scottish Government to contribute to their report on the impact of MUP which is to be laid to the Scottish Parliament.

Given the political sensitivity around the project, care will be necessary to ensure interim results are not publicly disclosed. Finalised results will be communicated to the general public by actively engaging the mass media.

7. Project Milestones / Timelines

The following sets out the key project milestones points when key decisions must be taken or key milestones should be reached:

1. Approval of major amendment to NHS REC and approvals for site-specific NHS R&D
2. Recruitment of postdoctoral researcher
3. Agree membership of the Advisory Group and hold first meeting
4. Submit joint protocol paper for publication in an open-access journal (including ED study)
5. Pilot data collection processes within Glasgow
6. Agree timing of baseline data collection across all six sites and pilot data collection processes across all six sites and quality assure collected data
7. Collect baseline data (wave 1) over three weeks and transfer data to SPHSU
8. Conduct analysis of baseline data
9. Collect follow-up data at approximately six months post-implementation of MUP, with transfer of baseline data shortly after
10. Conduct analysis of initial follow-up data
11. Collect follow-up data at approximately twelve months post-implementation of MUP, with transfer of baseline data shortly after
12. Statistical analysis of main results
13. Communicate findings of initial results to key stakeholders
14. Draft and submit first substantive results paper
15. Conduct additional analyses for further results papers
16. Submit further papers
17. Hold dissemination event
18. Submit final report to NIHR

A project timeline is included in Appendix A.

8. Project Risk Assessment

The risks relevant to the project are recorded in the risk assessment form and contained in the initial Project Risk/Issue log on:

T:\projects\MUP UnintendedCons\Risk and SOPs\Risk Assessment Form.xlsx

The Risk Log will be reviewed and updated at Project Management Group meetings.

9. References

1 Nutt DJ, King LA, Phillips LD. Drug harms in the UK: a multicriteria decision analysis. *The Lancet* 2010;376:1558-65.

2 Leon DA, McCambridge J. Liver cirrhosis mortality rates in Britain from 1950 to 2002: an analysis of routine data. *The Lancet* 2006;367:52-6.
3 Jones L, Bates G, McCoy E*, et al.* Relationship between alcohol-attributable disease and socioeconomic status, and the role of alcohol consumption in this relationship: a systematic review and meta-analysis. *BMC public health* 2015;15:400.
4 Forouzanfar MH, Afshin A, Alexander LT*, et al.* Global, regional, and national comparative risk assessment of 79 behavioural, environmental and occupational, and metabolic risks or clusters of risks, 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015. *The Lancet* 2016;388:1659-724.
5 Casswell S, Thamarangsi T. Reducing harm from alcohol: call to action. *The Lancet* 2009;373:2247-57.
6 Babor T, Caetano R, Casswell S*, et al. Alcohol: No ordinary commodity: Research and public policy*. Oxford: Oxford University Press 2010.
7 Room R, Babor T, Rehm J. Alcohol and public health. *The Lancet* 2005;365:519-30.
8 Jackson R, Johnson M, Campbell F*, et al.* Interventions on Control of Alcohol Price, Promotion and Availability for Prevention of Alcohol Use Disorders in Adults and Young People. Sheffield: School of Health and Related Research (ScHARR), University of Sheffield 2010.
9 Lifestyle Statistics HaSCIC. Statistics on Alcohol: England, 2013. London: National Statistics 2013.
10 Holmes J, Meng Y, Meier PS*, et al.* Effects of minimum unit pricing for alcohol on different income and socioeconomic groups: a modelling study. *The Lancet* 2014;383:1655-64.
11 Purshouse RC, Meier PS, Brennan A*, et al.* Estimated effect of alcohol pricing policies on health and health economic outcomes in England: an epidemiological model. *The Lancet* 2010;375:1355-64.
12 Meier PS, Holmes J, Angus C*, et al.* Estimated Effects of Different Alcohol Taxation and Price Policies on Health Inequalities: A Mathematical Modelling Study. *PLoS Med* 2016;13:e1001963.
13 Coltart CEM, Gilmore IT. Minimum alcohol pricing in England. *BMJ*;342.
14 World Health Organization. Global Strategy to Reduce the Harmful Use of Alcohol. Geneva 2010.
15 NICE. Alcohol-use disorders - Preventing the development of hazardous and harmful drinking: Public Health Guidance 24. London: National Institute of Health and Clinical Excellence 2010.
16 Beeston C, McAdams R, Craig N*, et al.* Monitoring and Evaluating Scotland's Alcohol Strategy Final Annual Report. Edinburgh: NHS Health Scotland 2016.
17 Court of Session. Opinion of the Court delivered by Lord Carloway, the Lord President in the reclaiming motion: The Scotch Whisky Association and others Petitioners and Reclaimers; against The Lord Advocate and The Advocate General. Edinburgh 2016.
18 Scotch Whisky Association. The SWA on its decision to appeal minimum unit pricing (MUP) ruling. 2016.
19 Craig P, Cooper C, Gunnell D*, et al.* Using natural experiments to evaluate population health interventions: new Medical Research Council guidance. *JECH* 2012;66:1182-6.
20 Stockwell T, Auld MC, Zhao J*, et al.* Does minimum pricing reduce alcohol consumption? The experience of a Canadian province. *Addiction* 2012;107:912-20.

21 Stockwell T, Zhao J, Giesbrecht N*, et al.* The raising of minimum alcohol prices in Saskatchewan, Canada: impacts on consumption and implications for public health. *Am J Public Health* 2012;102:e103-10.
22 Stockwell T, Zhao J, Martin G*, et al.* Minimum Alcohol Prices and Outlet Densities in British Columbia, Canada: Estimated Impacts on Alcohol-Attributable Hospital Admissions. *Am J Public Health* 2013:e1-e7.
23 Stockwell T, Zhao J, Sherk A*, et al.* Assessing the impacts of Saskatchewan's minimum alcohol pricing regulations on alcohol-related crime. *Drug and Alcohol Review* 2016:n/a-n/a.
24 Kendell RE, de Roumanie M, Ritson EB. Effect of Economic Changes on Scottish Drinking Habits 1978–82. *Br J Addict* 1983;78:365-79.
25 Room R, Rehm J, Ramstedt M*, et al.* Policy changes and effects on individual consumption: Complexities of measurement and of influences. *Addiction Research & Theory* 2009;17:588-90.
26 Hodgson R, Alwyn T, John B*, et al.* THE FAST ALCOHOL SCREENING TEST. *Alcohol Alcohol* 2002;37:61-6.
27 Hodgson R, Alwyn T, John B*, et al.* Manual for the Fast Alcohol Screening Test (FAST): Fast screening for alcohol problems. *Health Development Agency and University of Wales College of Medicine http://tinyurl com/mneu3sz (accessed 9 September 2014)* 2002.
28 Catto S. *How Much are People in Scotland Really Drinking?: A Review of Data from Scotland's Routine National Surveys*: Health Scotland 2008.
29 Bobak M, Room R, Pikhart H*, et al.* Contribution of drinking patterns to differences in rates of alcohol related problems between three urban populations. *J Epidemiol Community Health* 2004;58:238-42.
30 Asplund M, Friberg R, Wilander F. Demand and distance: Evidence on cross-border shopping. *Journal of Public Economics* 2007;91:141-57.
31 Lachenmeier DW, Rehm J. Unrecorded alcohol: a threat to public health? *Addiction* 2009;104:875-7.
32 Paasma R, Hovda KE, Jacobsen D. Methanol poisoning and long term sequelae - a six years follow-up after a large methanol outbreak. *BMC Clinical Pharmacology* 2009;9:5.
33 Decoster A. How progressive are indirect taxes in Russia? *Economics of Transition* 2005;13:705-29.
34 Haw SJ, Gruer L, Amos A*, et al.* Legislation on smoking in enclosed public places in Scotland: how will we evaluate the impact? *J Public Health (Oxf)* 2006;28:24-30.
35 Scottish Parliament. Alcohol (Minimum Pricing) (Scotland) Act 2012 (asp 4). Edinburgh: The Stationary Office Limited 2012.

Appendix A: Project Timeline

Year	2017					2018												2019												2020		
Calendar month	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M
Project month	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
Tasks																																
REC/R&D approval																																
Recruit postdoc																																
Advisory group established																																
Submit protocol paper																																
Pilot data collection																																
Collect baseline data																																
Conduct analysis of baseline data																																
Collect wave 2 data																																
Initial analysis of follow-up data																																
Collect wave 3 data																																
Analysis of main findings																																
Communicate initial findings to stakeholders																																
Submit first results paper																																
Additional statistical analyses																																
Submit further papers																																
Dissemination event																																
Submit NIHR report																																
Project Management Group meetings																																
Advisory Group meetings																																

Potential implementation date