

# Evaluating possible intended and unintended consequences of the implementation of Minimum Unit Pricing of Alcohol in Scotland: a natural experiment

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| <b>Submission date</b><br>24/04/2018   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>16/05/2018 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>31/10/2022       | <b>Condition category</b><br>Other                | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Minimum unit pricing of alcohol is a new public health policy that aims to reduce alcohol-related harms and health inequalities. It sets a minimum price (based on alcohol content) below which alcohol cannot be sold and it is designed to impact those at greatest risk of experiencing alcohol-related harms. A comprehensive set of evaluations is being coordinated by NHS Health Scotland, which this study contributes to. This study aims to investigate the impact of the introduction of minimum unit pricing of alcohol in Scotland on alcohol-related attendances to Emergency Departments and sexual health clinics.

### Who can participate?

Patients over 16 years of age who attend the participating Emergency Departments or sexual health clinics

### What does the study involve?

Data is collected from four Emergency Departments in Scotland and North England to see if there is a difference in the rates of alcohol attendees before and after the legislation is in place. Data is also collected from six sexual health clinics in Scotland and North England. Questionnaires are provided to all attendees at the clinics for self-completion, seeking information on alcohol consumption, drug use and the source of any alcohol consumed. Differences in the outcomes between Scotland and North England are measured to see if there have been any potential negative effects caused by the introduction of the legislation.

### What are the possible benefits and risks of participating?

Participants have the opportunity to contribute to the evaluation of a national health policy. Risks are negligible.

### Where is the study run from?

1. Glasgow Royal Infirmary (UK)

2. Sheffield Teaching Hospital (UK)
3. Royal Liverpool University Hospital (UK)
4. Royal Infirmary of Edinburgh (UK)
5. Sandyford Clinic (UK)
6. Sexual Health Lothian (UK)
7. Sexual Health Manchester (UK)
8. The Centre for Sexual Health - Leeds (UK)
9. Royal Hallamshire Hospital (UK)
10. Sexual Health Tayside (UK)

When is the study starting and how long is it expected to run for?  
September 2017 to September 2020

Who is funding the study?  
National Institute for Health Research (UK)

Who is the main contact?  
Ross Forsyth

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Ross Forsyth

**Contact details**  
MRC/CSO Social and Public Health Sciences Unit  
University of Glasgow  
Top floor  
200 Renfield Street  
Glasgow  
United Kingdom  
G2 3QB

## Additional identifiers

**Protocol serial number**  
11/3005/40

## Study information

**Scientific Title**  
Evaluating possible intended and unintended consequences of the implementation of Minimum Unit Pricing of Alcohol in Scotland: a natural experiment

**Study objectives**  
This study aims to investigate the impact of the introduction of minimum unit pricing (MUP) of alcohol in Scotland on alcohol-related attendances to Emergency Departments and potentially

unanticipated negative impacts of the introduction of minimum unit pricing (MUP) of alcohol in Scotland.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Scotland A Research Ethics Committee, original approval 14/08/2012, latest ethical review 17/01/2018, REC ref: 12/SS/0120 for the Emergency Dept arm and 12/SS/0121 for the Sexual Health arm

### **Study design**

Observational cross sectional study

### **Primary study design**

Observational

### **Study type(s)**

Prevention

### **Health condition(s) or problem(s) studied**

Alcohol-related A&E attendances, and Sexual Health Clinic attendances

### **Interventions**

This research is a natural experiment study of the impact of introducing MUP in Scotland. The methods involve a repeated cross-sectional audit of all alcohol-related attendances at EDs in two Scottish hospitals and two North England geographical control hospitals at three timepoints. On each occasion, data collection will involve a face-to-face survey administered by research nurses to ED patients over selected times during a three week time period.

The sexual health arm of the 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 approximately 6 months after and 12 months after.

### **Intervention Type**

Other

### **Primary outcome(s)**

The primary outcome for the ED arm:

Absolute numbers of alcohol-related attendances as defined by any one of:

1. Patient self-reports attendance is alcohol-related
2. Patient reports alcohol consumption in past 24 hours  $\geq 8$  units in men,  $\geq 6$  units in women
3. Patient not approached because too intoxicated with alcohol

Compared between intervention and control areas, adjusted for baseline attendances

Measured by questionnaire administered by research nurses at the Emergency Departments:

Wave 1 – February 2018, Wave 2 - October 2018 and Wave 3 – February 2019

The primary outcome for the sexual health arm:

Rates of higher/lower risk drinking, as measured by FAST score, compared between intervention and control areas, adjusted for baseline attendances. Data will be collected at baseline (February 18), 6 month follow up (October 18) and 1 year follow up (February 19)

### **Key secondary outcome(s)**

Secondary outcomes for the ED arm:

1. Changes in absolute number of alcohol-related attendances by age/sex/deprivation
2. Changes in problematic alcohol use, as defined by the Fast Alcohol Screening Test (FAST)
3. Changes in mean FAST score
4. Changes in prevalence of binge drinking in the past week
5. Changes in reason for attendance, coded by ICD-10

Measured by questionnaire administered by research nurses at the Emergency Departments:  
Wave 1 – February 2018, Wave 2 - October 2018 and Wave 3 – February 2019

The secondary outcome for the sexual health arm:

Self-reported binge-drinking with analyses for differential impact by age/sex/deprivation. Data will be collected at baseline (February 18), 6 month follow up (October 18) and 1 year follow up (February 19)

### **Completion date**

30/09/2020

## **Eligibility**

### **Key inclusion criteria**

For the Emergency Department arm of the study, the target population for the study is all patients over 16 years age who attend EDs to receive acute treatment for a health condition. For those who are approached, the inclusion criteria are:

1.  $\geq$  age 16
2. able to speak English and no interpreter available
3. Is a new ED presentation
4. The patient is conscious
5. The patient is physically well enough
6. The patient is mentally well enough
7. The patient is sober enough (alcohol)
8. The patient is sober enough (drugs)
9. The patient is still in the department
10. The patient is safe for staff to approach

For the sexual health arm of the study the target population for the study is all patients of any age attending participating sexual health clinics during data collection periods. The inclusion criteria are:

1. People able to complete the questionnaire
2. People who are deemed by the clinical staff as appropriate to approach

### **Participant type(s)**

Other

### **Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Key exclusion criteria**

For the ED sites:

1. Patient too unwell
2. Too distressed
3. Grossly intoxicated (alcohol)
4. Grossly intoxicated (drugs)
5. Cognitive impairment
6. Police in attendance
7. Clear language barrier, and no interpreter available
8. Patient already participating
9. Routine follow-up that has been instigated by ED staff
10. Patient left dept
11. Patient admitted
12. Staff safety issue
13. End of shift
14. Dead on arrival
15. Other

For the Sexual Health sites:

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

**Date of first enrolment**

22/11/2017

**Date of final enrolment**

28/03/2019

**Locations****Countries of recruitment**

United Kingdom

England

Scotland

**Study participating centre**

Glasgow Royal Infirmary

United Kingdom

G4 0SF

**Study participating centre**  
**Sheffield Teaching Hospital**  
United Kingdom  
S10 2JF

**Study participating centre**  
**Royal Liverpool University Hospital**  
United Kingdom  
L7 8XP

**Study participating centre**  
**Royal Infirmary of Edinburgh**  
United Kingdom  
EH16 4SA

**Study participating centre**  
**Sandyford Clinic**  
United Kingdom  
G3 7NB

**Study participating centre**  
**Sexual Health Lothian**  
United Kingdom  
EH3 9HQ

**Study participating centre**  
**Sexual Health Manchester**  
United Kingdom  
M13 9WU

**Study participating centre**  
**The Centre for Sexual Health - Leeds**  
United Kingdom  
LS2 8NG

**Study participating centre**  
**Royal Hallamshire Hospital**  
United Kingdom  
S10 2JF

**Study participating centre**  
**Sexual Health Tayside**  
United Kingdom  
DD1 9SY

## **Sponsor information**

**Organisation**  
NHS Greater Glasgow & Clyde

**ROR**  
<https://ror.org/05kdz4d87>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
National Institute for Health Research

**Alternative Name(s)**  
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

## **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as although not personal data the data are potentially sensitive. Electronically entered data will be held on a secure computer drive at SPHSU and paper versions shelved in a locked storage room.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               |                               | 01/10/2021   | 31/10/2022 | Yes            | No              |
| <a href="#">Protocol article</a>              | protocol                      | 20/06/2019   | 17/06/2020 | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |