STUDY PROTOCOL

ExILEnS: EXPLORING THE IMPACT OF ALCOHOL LICENSING IN ENGLAND AND SCOTLAND: A mixed methods natural experiment evaluation of local alcohol harm outcomes.

Protocol Version 1.1: 29th June 2017

IRAS Number: 224965

National Institute for Health Research [Public Health Research programme] project number: 15/129/11

Key Study Contacts:

Chief Investigator: Niamh Fitzgerald, Lecturer in Alcohol Studies, Institute for Social Marketing (ISM), UK Centre for Tobacco & Alcohol Studies, Faculty of Health Sciences & Sport, University of Stirling

Co-Investigators: Frank de Vocht, University of Bristol; Colin Angus, University of Sheffield; James Nicholls, Alcohol Research UK; Matt Egan, London School of Hygiene and Tropical Medicine (LSHTM); Niamh Shortt, University of Edinburgh; Tim Nichols (formerly Brighton & Hove City Council) and Linda Bauld, University of Stirling.

Researchers: Richard Purves, Nathan Critchlow, University of Stirling; Nason Maani Hessari, Courtney Scott, LSHTM.

Collaborators: Aidan Collins/Jennifer Ruddick, Alcohol Focus Scotland.

Independent Advisory Group: Prof. Eileen Kaner, Newcastle University (Chair); Maria Smolar, Public Health England; Jon Foster, Institute for Alcohol Studies; Alison Douglas, Alcohol Focus Scotland; Colin Sumpter, NHS Forth Valley, formerly of Islington Council; Vittal Katikireddi, Glasgow University; Kypros Kypri, Newcastle University, Australia; Jamie Pearce, Edinburgh University; Clare Flach, King's College London; Eva Batistatou, University of Manchester.

Public Advisors: Morgan McDonald; Margaret Ogden.

Study Summary

In England and Scotland, local councils have power over alcohol licensing – that is the system by which certain premises are allowed to sell alcohol. In recent years, professionals who work on ways to improve health across the population ('PUBLIC HEALTH TEAMS' or 'PHT's) have been trying to influence this licensing system. They do this by getting involved in licensing processes and encouraging licensing authorities and licence-holders to act in ways they hope will ultimately improve the health of the local population.

Our AIM is to find out what PHTs have been doing and whether their actions have had any impact on these alcohol-related harms, and if this activity is worth the cost and effort.

OUR PLAN OF WORK: To answer these questions we will divide our work into four packages:

1) CURRENT ACTIVITY: Identify and engage the most active PHTs by speaking to national organisations who help them – these are 'intervention areas'.
    a) Gather a wide range of information about what PHTs are doing (or not doing) to engage with alcohol licensing authorities, as well as records of licences applied for, granted, refused etc. and any other activity aiming to reduce harms from alcohol from 2012 to 2018.
    b) Ask public health and licensing practitioners about how acceptable these activities are, how they make a difference, what are the challenges? (By visiting, interviewing them and looking at paperwork)
2) CHANGES IN HARMS: Match intervention areas with teams from similar areas where nothing or very little has been done in relation to these activities – these are 'comparison' areas. Gather existing information on alcohol-related harms and crime rates from 2009 to 2018 in both the 'intervention' and 'comparison' areas. Analyse whether any changes in harms or crime rates are related to the level of activity of PHTs, specific aspects of the local licensing system, and any differences between Scotland and England.
3) COSTS & BENEFITS: Estimate the value of this kind of PHT activity by comparing the costs of the activities with the savings from any health harms or crimes avoided, and the impact on inequalities between different groups in society. Estimate whether or not this kind of activity may have other impacts, such as on alcohol consumption or deaths in the longer term.
4) IMPACT: Pull together all the information, in consultation with local areas, to examine the ways in which the PHT's licensing activity might have an effect, and to make recommendations about future activity, policy, and research on this topic.

Key Words: alcohol, licensing, availability, outlet density, public health, local alcohol policy, natural experiment.

1. BACKGROUND

The purpose of the ExILEnS (Exploring the Impact of alcohol Licensing in England and Scotland) study is to examine the impact of public health stakeholders' engagement in alcohol premises licensing on alcohol-related harms in England and Scotland. Since legislative changes in both nations in the early 2000s, local health stakeholders have sought to influence licensing policies and decisions to varying degrees. This study will contribute to understanding the potential mechanisms of effect of such activity, and whether alcohol-related health and crime outcomes are reduced in localities with high intensity public health activity on licensing, compared with areas with little or no such activity. In so doing, we aim to generate detailed, policy-relevant evidence that can be acted on locally, and inform potential national legislative changes and international licensing regimes.

1.1. ALCOHOL HARMS & PROBLEMS

Alcohol consumption is the leading cause of death amongst 15-49 year-olds worldwide [1]. There are over 1 million alcohol related hospital admissions a year in England, and in 2013 there were 6,592 alcohol related deaths, a 10% increase from 2003[2]. Alcohol harms are socially patterned making alcohol a key driver of health inequalities. Lower socioeconomic status (SES) is associated with higher mortality for alcohol-attributable causes, despite lower socioeconomic groups often reporting lower than average levels of consumption. One study found lower SES groups to have a 1.5 – 2 fold higher alcohol related mortality [3], whereas another found the most deprived quintile of local authorities in England to have alcohol specific mortality rates 5.5 times the rate of the least deprived [4]. Research has shown that the density of alcohol outlets is higher in deprived areas [5], thus alcohol premises licensing policy has the potential to have a greater positive impact on health harms in these areas, and may reduce alcohol-related health inequalities [5,6].

1.2. ALCOHOL AVAILABILITY, PUBLIC HEALTH & KNOWLEDGE GAPS

Systematic reviews, and reviews of reviews, have concluded that legislative measures, including control of the availability of alcohol, are consistently more effective than education or individual interventions in reducing alcohol-related harms [7,8]. Strong review-level evidence identifies control of the availability of alcohol as a key approach for reducing alcohol-related harm [9–11], an approach supported by a broad consensus of scientists and health organisations [8,12].

The evidence suggests an association between increased availability of alcohol, including the number and proximity and opening hours of alcohol outlets in an area, with higher rates of consumption and associated alcohol-related harms [10,13–15] and includes some UK studies [5,16–18]. However, the extent to which this association reflects a causal relationship, and if so, the mechanisms by which effects are exerted remains the subject of study, since much of the research is cross-sectional and the validity of availability measures uncertain [15,19–22]. A recent review of 160 studies found that the relationship between public health activities, specific local licensing controls, indicators and types of availability and alcohol-related harms is not clear or consistently examined in the literature [19]. The same study noted the difficulty of translating the research into practice, due both to these limitations and the lack of clear theories of change [19]. Examining the relationship between these three sets of variables – public health team activity, the licensing regime, and local level health/crime outcomes – is the core focus of this study as summarised in Figure 1 below.

Figure 1: Key areas under study

2.3 THE UK ALCOHOL LICENSING SYSTEM, PRACTICE, & IMPACT ON HARMS

In the UK, the sale of alcohol requires a licence issued by local authorities (or local legislators in Northern Ireland) [6,15,22,23]. Historically, UK licensing has had a primary focus on limiting public disorder, though health considerations have played a limited part in motivating legislative change [24,25]. Under reforms to the licensing systems in England and Wales (2003) and Scotland (2005) many discretionary aspects of licensing were formalised. The essential principle of current licensing law is that alcohol licence applications can only be refused if a) there is a formal representation from a 'responsible authority' (e.g. the local PHT, police or fire service), and b) that representation shows that the application threatens to undermine one or more of the statutory 'licensing objectives'. These are to promote the prevention of: crime and disorder, public safety, the prevention of public nuisance, the protection of children from harm and, in Scotland only, to protect and improve public health. This fifth licensing objective in Scotland is unique globally, although some jurisdictions (including some Australian states and territories) have a requirement to consider 'harm minimisation' in licensing decision-making [26]. The 2012 Government Alcohol Strategy proposed the introduction of a public health licensing objective for England and Wales, however the policy was put on hold following a public consultation.

Under current legislation, licensing authorities in England and Scotland are required to produce a 'statement of licensing policy', every 4-5 years, outlining their approach to achieving the licensing objectives. Scottish licensing authorities are required to include a policy on 'overprovision' in their policy statements. In an area declared 'overprovided' with alcohol outlets, the assumption that an application will be approved is reversed and applicants need to demonstrate that they have made provisions not to undermine the licensing objectives. In England and Wales, local authorities have the option of declaring specified zones to be 'cumulative impact areas' (CIAs), this similarly reverses the assumption that an application will be approved. These provisions have been identified as an important lever for the application of PH knowledge to licensing, as mechanisms that allow licensing authorities to consider area-wide or population-level effects. The impact of such policies in England may be through discouraging particular types of outlet, rather than a blanket reduction in availability per se [27,28].

Local Licensing activity/regime e.g.

- Licence application levels, types
- Licence approval levels & conditions attached
- Cumulative impact policies & policy scale
- Statements of licensing policy.

Two recent studies found that local authorities in England with a more intensive licensing regime experienced an additional 5% reduction in alcohol related hospital admissions rates from 2009 to 2015 (or 2% annually) [29] as well as an additional 4-6% reduction in public nuisance and alcohol-related crime rates [30], compared with what would have been expected had these local areas had no active licensing policy in place.

2.4 PUBLIC HEALTH TEAM ENGAGEMENT IN ALCOHOL LICENSING

Since becoming responsible authorities, many public health stakeholders have increased their engagement with licensing [27,28,31–35]. In so doing, they have developed an innovative range of activities including processes for reviewing and responding to licence applications; collation of local datasets on outlet density and alcohol-related harms; representations to licensing boards; supporting the development of licensing policy, including cumulative impact/ overprovision areas; involving local communities; and direct engagement with licence-holders [32–34,36]. These approaches are utilised to varying degrees of intensity and in varying combinations in local areas across the UK and have yet to be robustly evaluated.

Local Public Health Team activity e.g.

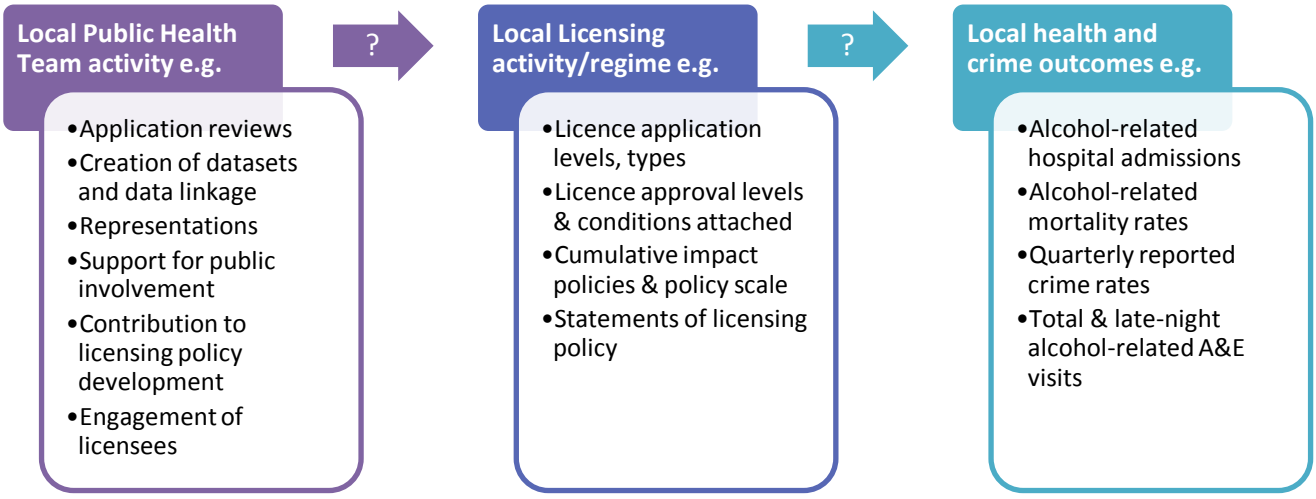
- Application reviews
- Creation of datasets & data linkage
- Representations
- Supporting public involvement
- Contribution to licensing policy development
- Engagement of licensees

Research in Scotland found that early public health involvement achieved mixed results, with some areas introducing large-scale overprovision policies, and others strongly resisting public health engagement [31,32,37]. In England and Wales, public health activities also vary significantly by area and PHTs have often faced challenges in adapting to the licensing environment [6,25,38,39]. PH engagement in licensing forms part

of a wider, interactional system involving 'responsible authorities' (such as fire, police and child protection authorities as well as health bodies), licensing committees, the alcohol trade and, in some cases, the general public. PHTs may, for instance, provide data in support of a representation by the local police or Trading Standards; they may respond to consultations on cumulative impact policy or, as has been more common in Scotland, take the lead in developing the case for the establishment of overprovision areas[27,31,37]. While previous research has demonstrated a relationship between licensing policy and health and crime outcomes [29,30], it has not measured the effect, or mechanism of effect, of public health stakeholder involvement.

While there have been several studies [27,28,31,32,40,41], there has been no broad, systematic study with those working in the field, to identify and examine theories of change and to support future implementation. The wide range of current public health practice gives rise to an opportunity to generate qualitative contextualised data on the challenges and mechanisms for PHTs seeking to affect alcohol-related harms through engaging with local premises licensing.

Figure 1: Simplified theory of change



2.5 RATIONALE AND AIMS FOR THIS STUDY

This study will examine whether and how local public health stakeholder engagement in alcohol licensing, operates through the local licensing regime, to affect alcohol-related harms.

Public health engagement is potentially resource-intensive, and evidence is needed to establish the level at which this activity represents the best use of capacity within public health teams. If it is shown that there are measurable benefits, this will help to make the case for greater investment, and by extension, greater legislative support through the introduction of a public health objective. If, however, the evidence suggests limited effects or little potential for legislative change to materially affect licensing, then this will also be very important. Currently, there is widespread support for greater public health team involvement in licensing (both in the UK and elsewhere); however, there is an urgent need for the potential value of that activity to be examined. This study will significantly contribute to this, such that null findings would be as significant in policy terms as a demonstration of positive effects.

This natural experiment builds on the methodology and findings of recent work demonstrating an impact of licensing on health and crime outcomes [15,29,30], takes account of the complexity of the relationship between public health activity, licensing decisions, and these outcomes, as recommended in recent reviews [19–21]; and enables in-depth examination of practice, acceptability and feasibility across two jurisdictions (England and Scotland) to build on earlier work [25,31,32].

AIM: To critically assess the impact and mechanisms of impact of public health stakeholders' engagement in alcohol premises licensing on alcohol-related harms in England and Scotland from 2012 to 2018 by comparing areas with differing types and intensities of engagement.

3. RESEARCH DESIGN OVERVIEW, OBJECTIVES & TIMESCALES

PUBLIC HEALTH ENGAGEMENT IN LICENSING is a multicomponent intervention defined as proactive involvement of PHTs in engaging with, and seeking to influence alcohol premises licensing processes, decisions or actions at a local level to reduce alcohol-related harms.

Four work packages (WPs) will be delivered over 3 years, with WPs 1, 2 & 4 running in parallel throughout and WP 3 running in Years 2 and 3 as described in the Gantt chart (uploaded separately). Table 1 below summarises our Research Objectives with timescales.

- **Work Package 1** led by NF and ME includes the primary data collection necessary to establish public health activity, the licensing regime and confounding activity in each area, as well as the study of the experiences of stakeholders and theories of change.
- **Work Package 2** led by FdV includes the collation of secondary harms data in each area and analysis of the impact of public health activity on harms.
- **Work Package 3** led by CA will calculate the potential impact of this activity on consumption, in the longer term beyond the study, and on different population groups, including on inequalities.
- **Work Package 4** led by LB will focus on the overall analysis, finalising an overall theory of change, reporting, dissemination and the impact of the research.

Table 1: Research Objectives, Milestones & Timescales

Work Package 1: LOCAL PUBLIC HEALTH AND LICENSING ACTIVITY: To describe and explore public health team engagement in licensing, the local licensing regime, and related processes in 20 high activity and 20 low activity public health team (PHT) areas over the period 2012 to 2018.		**Continues throughout project.**
Objective	**Methods**	**Timescale**
a. To identify and recruit 40 local PHTs in England and Scotland that vary demographically and in the timing and intensity of their efforts to engage alcohol licensing/licensees since 2012.	Email and other outreach to inform local areas; Select and recruit 20 intervention areas with informed consent. Recruit 20 low activity control areas identified by WP2.	By October 2017 (already underway)
b. To establish a clear picture of activity within intervention and control PHTs in relation to local alcohol licensing, the local licensing regime, and any confounding activity, from 2012 – 2018.	Desk-based investigations, site visits, documentation analysis and structured telephone interviews to complete data collection protocol in each area (40).	In three phases: Aug 2017 to Jan 2018; Oct 2018-Jan 2019; Jul to Oct 2019.
c. To establish measurable indicators of the intensity and costs of these activities, local licensing activity and confounding activities in each area.	Expert consultation to develop indicators and intensity measure. Apply to completed dataset to quantify intensity in each area (40).	By March 2018 Following each data collection phase.
d. To explore perceived mechanisms of change and real and perceived barriers to PHT engagement in licensing, from the perspectives of public health, licensing, police and other stakeholders.	80 in-depth interviews (face to face and/or by telephone) i.e. 1 interview each with public health, licensing, police, other in 20 intervention areas.	Phase 1: with Public health, Aug 2017 to Jan 2018; Phase 2: with others: Oct 18 – Feb 2019.

2. Work Package 2: ALCOHOL HARMS EVALUATION: To quantitatively evaluate whether public health engagement in licensing has a measureable impact on health harms and crime rates using routine data from 2009 to 2018.	**Continues throughout project.**

Objective	Methods	Timescale
a. To match the selected intervention local areas to 20 best possible control areas.	Collate data for LAs and fit propensity score models to match each intervention area to a unique control area.	By Sep 2017
b. To collect quantitative data on a set of key alcohol harm outcome indicators on which subsequent evaluation will be based.	Identify data sources, collate and clean data. Import activity data from WP1. Link datasets for each area.	By Jun 2018
c. To evaluate if, and to what extent, the breadth, components and intensity of the intervention is associated with subsequent measureable changes in the key outcome indicators.	Develop analysis plan; set up and run hierarchical growth models and time series analyses.	By Sep 2019

3. Work Package 3: WIDER IMPACTS, COSTS AND DISTRIBUTION OF EFFECTS: To examine implementation costs, estimate the short-term impact of PHT engagement in licensing on alcohol consumption and the longer-term impact of the intervention on health and healthcare costs, and explore the likely distribution of effects across the population.		**April 2018 to end of project.**
Objective	**Methods**	**Timescale**
a. To estimate and compare the costs to PHTs of implementation activity	Import and harmonise WP1 costs data to estimate costs.	By Aug 2018
b. To develop locally-specific policy models	Use WP2 baseline data to adapt the Sheffield Alcohol Policy Model to 20 intervention and 2 control areas.	By March 2019
c. To use these models to estimate the wider impacts of the intervention in terms of long-term health benefits, NHS cost savings and how these impacts may impact on health inequalities	Use SAPM results from 3b and WP2 results stratified by age, gender, deprivation to estimate population distribution of effects. Estimate impact on consumption and on all outcomes in longer term.	By November 2019
d. To estimate the potential impact of high intensity PHT activity in areas which are not currently active.	Use local alcohol policy models to estimate in 2 exemplar control areas.	By December 2019

4. Work Package 4: IMPACT OF FINDINGS		**Throughout project.**
Objective	**Methods**	**Timescale**
a. Revise and refine hypothesised theories of change to qualitatively examine how PHT activities and key aspects of the licensing system, may lead to changes in licensing outcomes and related harms.	Draft and disseminate theory of change. Revise as data emerges. Host stakeholder workshop to discuss and finalise, and agree dissemination plans.	Throughout project. By Jul 2019
b. To synthesise all findings, identify recommendations for practice, policy and future research and disseminate.	Analysis within each work package. Overall analysis and reporting. Dissemination.	Throughout project. By March 2020 2019 onwards

4. RESEARCH PLAN

4.1 WORK PACKAGE 1

4.1.1. RECRUITMENT OF PUBLIC HEALTH TEAMS (PHTS)

To identify and recruit 40 local PHTs in England and Scotland that vary demographically and in the timing and intensity of their efforts to engage alcohol licensing/licensees since 2012.	Email and other outreach to inform local areas; Select and recruit 20 intervention areas with informed consent. Recruit 20 low activity control areas from WP2.	By Oct 2017

We will recruit **20 intervention PHTs** who are actively seeking to influence alcohol licensing in at least one local authority under their remit. Our sample size calculations are outlined in Section 4.2.1 below.

Eligible intervention teams will have been active in that particular area across multiple aspects of the intervention (public health engagement in alcohol premises licensing) commencing as early as possible since 2012. The unit of analysis for each selected area will be a lower-tier local authority area (in England) or a single licensing board area (in Scotland); the focus of data collection will be on activities within that area, even if the public health stakeholders are also active elsewhere.

We will recruit 6 intervention (and control) area in Scotland and 14 in England to facilitate meaningful comparison between the nations.

In England, selection of the 14 intervention areas will be guided by existing intelligence (survey and case study data) from Public Health England, expressions of interest received from local areas interested in taking part in the study, our prior research, and scoping telephone calls to clarify the extent of public health stakeholder activity where necessary. Selection will aim for a spread of areas in terms of geographic location (across 6 English regions – NE, NW, Midlands, London, SE, SW); rurality (to include cities, more rural, and mixed urban-rural areas); and baseline alcohol-related harms and outlet density.

In Scotland, the selection of the 6 intervention areas will be guided by existing intelligence from Alcohol Focus Scotland, expressions of interest received from local areas interested in taking part in the study, our prior research and scoping telephone calls to clarify the extent of public health stakeholder activity, and the availability of good quality information on such activity since 2012. There are 40 licensing board areas in which various public health stakeholders can intervene to address alcohol-related harm; those public health stakeholders may (typically) be professionals within the public health department of one of 14 local NHS boards and/or the staff of one of 30 local Alcohol and Drug Partnerships. Selection will aim for variety in terms of rurality, region, and size. The Scottish islands will be excluded due to the low level of licence applications under consideration in those areas.

We will also recruit 5 reserve local authorities in both the intervention and control groups to allow for drop-out/lack of engagement amongst the chosen areas at a later stage.

Local public health stakeholders have been informed about the study by email from Public Health England and Alcohol Focus Scotland, at several events in Scotland and England, through a wide range of existing networks (such as the Association of Directors of Public Health and the Public Health and Licensing network) and by direct email contact. To date 19 Scottish teams and 69 English teams have expressed interest in taking part in the research. Basic demographic information will be compiled for interested areas to facilitate selection of intervention areas (and the control areas, see Work Package 2 - Section 4.2.2 below). Control areas will be recruited by direct contact, aiming for the best possible match, emphasising the low level of time commitment involved, and benefits including the opportunity to learn from other areas and a free stakeholder event in Year 3.

4.1.2. DATA COLLECTION - PHT INTERVENTION ACTIVITY, LOCAL LICENSING REGIME, COUNFOUNDING ACTIVITY

To establish a clear picture of activity within intervention and control PHTs in relation to local alcohol licensing, the local licensing regime, and any confounding activity, from 2012 – 2018.	Desk-based investigations, site visits, documentation analysis and structured telephone interviews to complete data collection protocol in each area (40).	In three phases: Aug 2017-Jan18; Oct 2018 Jan 19; Aug to Nov 2019..

We will develop a detailed data collection protocol for use in each intervention and control area. This will be completed in the 20 intervention areas via an initial site visit, sourcing and analysis of relevant documentation by email, and structured telephone interviews with public health and licensing practitioners in year 1 to gather information on activity from 2012-2016 and will be updated for 2017 and 2018 activity in years 2 and 3. In control areas, the data will be completed by sourcing relevant documentation by email and structured telephone interviews in each of the three years.

The protocol will collect information on intervention components (i.e. PHT engagement in licensing), the licensing activity/the local regime, and confounding activities as shown in Table 2. This will be further developed following the initial scoping calls with potential intervention areas and consultation with the study advisory group; informed by prior research.

Table 2 Local Data Collection

Intervention Components (Indicators)	Licensing activity/regime	Confounding activity
a. A systematic process for review of new licensing applications & variations (known point of contact, clear criteria, use of routine data) b. Active response to applications (liaison with responsible authorities, licensing reps, applicants; representations) c. Development of bespoke datasets (robust/ systematised local data collection on harms etc.) d. Engagement with licensing authorities (meetings, awareness raising, licensing policy input) e. Activity towards development of cumulative impact/overprovision areas (submissions, representations, consultation) f. Public health-led activity to involve the public/local communities (depth, breadth of involvement, activity of local licensing fora) g. Public health-led engagement with licensees ('Reducing the Strength' schemes; advertising/ promotion bans) h. Any other public health led activity to influence licensing/licensees.	i. Licence application levels, types, conditions j. Licence decisions k. Cumulative impact/overprovision policies/areas l. Outlet density by type. m. Late night levies n. Health commitment in licensing policies o. Reducing the strength scheme sign up p. Local advertising/promotion ban q. Health as a licensing objective (if introduced locally in England) r. Any other relevant elements	s. Local initiatives around alcohol screening/brief advice t. Public information & education initiatives u. Policing activity in the night time economy v. Specific industry activities w. Any other major relevant confounding activity

Most of these indicators and interim licensing outcomes leave a documentary trail (e.g. databases, policy statements, records of meetings) which we will identify with assistance from local contacts and supplement with further information obtained from interviews. This will enable us to accurately map activities and locate them temporally within the six monthly timeline used in the study's quantitative analysis of engagement intensity in Work Package 2.

4.1.3. ASSESSING INTERVENTION INTENSITY

To establish measurable indicators of the intensity and costs of the three elements of public health team activities, local licensing regime and confounding activities in each area.	Expert consultation to develop indicators and intensity measure(s). Apply to completed dataset to quantify intensity in each area taking into account the three elements (40).	By March 2018 Following each of the 3 data collection phases.

We will conduct preliminary analysis of the data collected to develop measures of the (1) the intensity of public health stakeholder activity, (2) the strength of the licensing regime, and (3) the

scale and nature of any confounding activity. The development process will be defined following discussion with the lead authors of studies which developed three other alcohol policy measures in the literature [42–44].

The content (categories of activity and indicators) of the three intensity measures will be devised in collaboration with small working groups of public health and licensing experts including co-applicants, the study advisory group and other relevant experts. The development process will be broadly include sharing of drafts with the groups e.g. for comment on the categories and indicators of activity items included, any missing items, how each item will be scored, the relative weighting applied to each item, and how best to combine items, to generate an overall intensity score for each six month period. The draft measures will be applied independently by at least two researchers to a subset of intervention and control areas and the scores compared in discussion, checking for consistency and face validity. The measures will then be further refined as needed for reliability and ease of use.

Once the measures have been finalised, they will be reapplied to the data for all intervention and control areas to calculate intensity scores for each 6 month period 2012-2018. All scoring will be conducted independently by two researchers and the final scores for each area agreed by consensus, drawing in a third researcher where necessary to resolve any disagreement. The intensity scores will be used in Work Package 2 to examine the relationship between intervention intensity, licensing regime activity and alcohol-harm outcomes.

4.1.4. MECHANISMS OF CHANGE, ACCEPTABILITY, PROCESSES

To explore perceived mechanisms of change and real and perceived barriers to PHT engagement in licensing, from the perspectives of public health and others (licensing, police and others).	80 in-depth interviews (face to face and/or by telephone) i.e. 1 interview each with public health, licensing, police, other in 20 intervention areas.	Phase 1: with Public health, Aug 2017 – Jan18; Phase 2: with others: Oct18 - Feb 2019.

The final element of Work Package 1 will involve in-depth qualitative interviews in each intervention area. We anticipate conducting detailed interviews with public health practitioners in each area during the site visits in Year 1 (20 x 90minute interviews) and slightly shorter interviews with three other stakeholders in each area to be conducted by telephone in Year 2 (3 x 20 x 60 minute interviews). These other stakeholders may include local authority licensing practitioners, police, and others such as trading standards or licensing board members. These interviews will focus on:

- Acceptability of public health team engagement in licensing
- Resource/capacity implications of PHT engagement
- Contextual factors influencing PHT engagement
- Other barriers to and facilitators of PHT engagement
- Barriers to and facilitators of strengthening licensing activity
- Perceived mechanisms by which PHT activity may influence licensing
- Perceived mechanisms by which licensing regimes may influence harms
- Any unintended consequences of PHT engagement

Semi-structured topic guides will be developed in consultation with our practitioner representative (TN) and advisory group in line with our research questions, informed by relevant literature. All interviews will be audio-recorded (with permission, see Section 5 Ethics). Audio-recordings will be transcribed verbatim by experienced transcribers, transcripts checked for accuracy, and anonymised.

Detailed fieldnotes will supplement interviews conducted during site visits to intervention areas and will inform later analysis. Transcripts and recordings will be stored securely and destroyed in line with University procedures. Analysis will use a collaborative, qualitative framework approach [45,46] to identify the themes arising and to compare between England and Scotland, different stakeholders and public health teams (PHTs).

4.2 WORK PACKAGE 2

4.2.1. SAMPLE SIZE CALCULATION

Data on the effectiveness of local alcohol licensing policies is limited, but two recent studies led by De Vocht have evaluated its effect on lower tier local authority (LTLA) level alcohol-related hospital admissions [29] and alcohol-related reported crime rates [30]. In the former, the effect size was an average additional 2% (95%CI -3%:-2%) reduction in alcohol-related hospital admissions annually in the period up to and including 2013 in the LTLAs with active alcohol licensing policies compared to those with no specific policies [29]. Similarly in the latter, for the period up to 2013, an additional 4-6% annual decrease was seen in alcohol-related violent crimes, sexual crimes and public order offences in areas with active licensing policies compared to those with none [30].

This study will be the first to consider the impact of local licensing on A&E attendances. Injuries and accidents are the largest single driver of A&E attendances [47] and are strongly linked to acute alcohol consumption and intoxication [48]. Therefore we expect an effect size in or around the range found for crimes as these are also strongly linked to acute alcohol consumption [49].

We used the methodology developed by [50] for power calculations of linear mixed effects models with random slope to mimic the growth models used in previous work on population health impact of alcohol licensing [29]. Based on the previous studies, we conducted separate sample size calculations for hospital admissions and for reported crime rates. For both analyses we assumed a standard level of statistical significance α (5%) and statistical power β (80%), and further assumed a 9-year follow-up (2009-2018) and a two-sided alternative.

Table 3: Sample size data

	Expected average effect size %/year (slope)	Between-slope variance	Residual variance model	Number of areas in each group
From previous study of impact of licensing on alcohol-related crime [30]				
Crime rates *(Effect size is a range between 4-6% as estimated using quadratic trends)*	-4.00% (-0.04)	0.003	0.03	**29**
	-5.00% (-0.04)	0.003	0.03	**19**
	-6.00% (-0.06)	0.003	0.03	**13**
From previous study of impact of licensing on alcohol-related hospital admissions [29]				
Rates	-2.31% (-0.229)	0.110	0.011	**34**
Current study - minimum detectable effect size with proposed sample size				
20 areas per group	**-3.00% (-0.296)**	0.110	0.011	20

Based on Table 3, we expect the study to be able to detect effects within the range found in previous observational studies for our outcomes with 20 intervention and 20 control areas. We have also taken into account the following in choosing our sample size:

- Improved intervention measurement: The measure of licensing intensity in the previous studies [29,30] was based solely on the self-reported presence of cumulative impact policies and the number of licence applications being declined over the 2009-2015 period. These studies may therefore have underestimated the effect of PH engagement in licensing as highly active areas will have been assessed as lower activity areas. For example, strong PHT engagement in licensing may reduce the number of licence applications being made (and therefore no need to decline), alter the type of premises which seek licences (also then not declined), or result in the introduction of voluntary licensing conditions on premises including on the price of alcohol (again not declined) [27]. The previous studies did not measure these aspects, whereas the current study will collect detailed and longitudinal information on these and other aspects of PHT engagement in licensing and the local licensing regime to avoid such measurement error.

- Use of a continuous measure: The previous research in this area has used categorical measures of licensing intensity whereas we will use a continuous measure. Using a finer 'exposure' scale

and enabling the investigation of exposure-response associations, will allow detection of smaller effect sizes (or conversely require a smaller sample size) than could be achieved otherwise.

- Accounting for confounding PHT activity: Previous studies were unable to consider the potential confounding effect of non-licensing activities led by PHTs including those which have chosen to focus instead on initiatives such as alcohol brief advice. Previous studies have not accounted for this, potentially underestimating any effect of engagement in licensing. This study will collect detailed information on confounding activity in both intervention and control areas and account for it.

In summary, the proposed project specifically aims to collect detailed and longitudinal information on public health team, licensing and confounding activity in WP1, which will considerably reduce measurement error from that in [29,30] to more accurately estimate effect size, and improve our signal-to-noise ratio to enable the detection of smaller effect sizes.

4.2.2. SELECT CONTROL AREAS

To match the selected intervention local areas to 20 best possible control areas.	Collate data for LAs and fit propensity score models to match each intervention area to a unique control area.	By Sept 2017

For each of the 20 selected intervention areas, one lower-tier local authority area (LTLA in England) or licensing board area (in Scotland) will be matched with a suitable control area. In England, an initial matching round in year 1 will select the 10 best potential control areas (from 326 LTLAs) for each intervention area using propensity score matching (PSM). PSM is increasingly used in observational epidemiological studies to improve causal inference [51]. Members of this study team have previously extended its methodology to study area-level local alcohol policy interventions in the UK [52].

The selection of control areas in Scotland will be guided by pragmatism, given the relatively narrow choice of matched areas due to the lower numbers of overall areas. Existing intelligence from Alcohol Focus Scotland and our prior research will be used to identify potential high activity areas and potential low activity control areas with which to match them. However, as there are only 40 local licensing board areas available including the proposed 6 intervention areas, it may be that after evaluation of actual matching (based on PSM), there is evidence that matching is not satisfactory. In this case, a pragmatic way forward will be discussed with the advisory group.

Following the methodology outlined in our previous study [52], we will match areas on important covariates *a priori* including rurality, baseline (2009) alcohol-related harms, and alcohol outlet density. This list can be modified or expanded as WP1 data emerges. Most of these data are routinely collected quarterly (or monthly) and publicly available via Local Alcohol Profiles for England (LAPE), UK Office of National Statistics, National Records of Scotland, NHS Scotland Information and Statistics Division, NHS England and National Archives from 2009. The alcohol outlet density data are already held by our team.

Once potential control areas have been identified for each intervention area, the WP1 team will identify and recruit a unique, best available control area by taking account of best match (propensity distance), low level of activity in terms of the intervention components being evaluated (by further liaison with AFS/PHE and direct contact as needed), and willingness to participate in the study.

As a result of this process, and the qualitative data collection in WP1, we will identify twenty matched pairs of intervention and control areas with detailed information on the intensity of intervention delivery, the local licensing regime, and potential confounding activity.

4.2.3. HARMS OUTCOME DATA COLLECTION

To collect quantitative data on a set of key alcohol harm outcome indicators on which subsequent evaluation will be based.	Identify data sources, collate and clean data. Import activity data from WP1. Link datasets for each area.	By June 2018

Longitudinal data on a set of 'key alcohol harm outcome indicators' will be collected for each intervention and control area from 2009 to 2018 as shown in Table 4. Some alcohol-related harms take time to develop so there will be some lag. Implementation of these lags will be specified prior to the analyses being undertaken by reference to relevant literature and in consultation with our advisory group.

Table 4: Outcome data sources

Outcome indicator	Source
Quarterly alcohol-related hospital admissions	Obtained either as freely downloadable data from the Public Health England (PHE) Local Alcohol Profiles for England (LAPE) website, or through a LAPE data request. Comparable data for Scotland from NHS ISD Scotland).
Weekly A&E attendance rates for weekdays/weekends, both daytime and night-time [54]	NHS Hospital Episode Statistics (HES) through their Data Access Request Service (DARS). Comparable data for Scotland from NHS ISD Scotland).
Quarterly alcohol-related deaths	Obtained through a LAPE data request. Comparable data for Scotland from NHS ISD Scotland).
Quarterly reported crime rates with significant attribution of alcohol abuse (violent, sexual, and public order offences)	Crime outcomes in England and Wales from the Home Office. Available through Office for National Statistics Gov.UK website or through a request. Comparable data will be gathered for Scotland from the Scottish Government's Justice Analytical Services.

4.2.3. HARMS OUTCOME EVALUATION

To evaluate if, and to what extent, the breadth, components and intensity of the intervention is associated with subsequent measureable changes in the key outcome indicators.	Develop analysis plan; set up and run hierarchical growth models and time series analyses.	By Sept 2019

We will evaluate temporal trends in all key outcomes from 2009-2018 and compare these in intervention and control areas using hierarchical log-rate growth models. We previously used this methodology to identify a positive association between a metric of 'licensing activity' and alcohol related hospital admissions [29] and crime rates [30] in England.

Unlike those studies, here we will know the period (within 6-month intervals) when interventions (or components thereof) are introduced. This enables more specific exploration of causal effects through inclusion of pre/post indicators and interactions in the growth models as well as the use of 'Differences-in-Differences' statistical methods [55]. Inferences about causality can be made through quantitatively evaluating, using a pre-specified plan based on the emergent theory of change, whether there is statistical evidence of changes in longitudinal trends in outcome measures that coincide with the expected effect of the intervention (and is not present in the corresponding control area). Where data is available we will analyse outcomes by socioeconomic status and gender.

4.3 WORK PACKAGE 3

4.3.1. IMPLEMENTATION COSTS [WP3 - OBJECTIVE 3A]

To estimate and compare the costs to PHTs of implementation activity	Import and harmonise WP1 costs data to estimate costs.	By July 2018

Within WP1 data collection, estimates of staff time and resource use involved in public health team's intervention activity will be obtained for each intervention area. We will use this data to estimate the cost of PHT engagement in licensing (both overall and in terms of individual components of activity).

4.3.2. DEVELOPMENT OF LOCAL MODELS [WP3 - OBJECTIVE 3B]

To develop locally-specific policy models	Use WP2 baseline data to adapt the Sheffield Alcohol Policy Model to 20 intervention and 2 control areas.	By March 2019

The Sheffield Alcohol Policy Model (SAPM) is an advanced epidemiological simulation model which has previously been used to estimate the impacts on alcohol consumption and related harms of a wide range of alcohol policies, including those affecting price, outlet density and licensing hours in both England and Scotland at the national level [56–58].

Through the NIHR School for Public Health Research (which includes CIs on this bid), we are developing a Local Authority version of SAPM which will produce estimates of the changes in alcohol consumption, alcohol-related harm and associated healthcare costs, and the distribution of these changes across the local population, resulting from the implementation of local policies and interventions. We will update and adapt this model using local data on alcohol consumption, demography and alcohol-related harms to create tailored models for each of the 20 intervention areas (for Objective 3c). We will also create models for 2 exemplar control areas, selected from the control areas identified in WP1, based on data availability and the extent to which the PHT is interested in increasing the intensity of their activity (for Objective 3d). These models will produce estimates of the long-term impact of changing alcohol consumption on hospital admissions, NHS costs, alcohol-related mortality and crime.

4.3.4. THE WIDER IMPACT OF THE INTERVENTION [WP3 - OBJECTIVE 3C]

To use these models to estimate the wider impacts of the intervention in terms of long-term health benefits, NHS cost savings and how these impacts may impact on health inequalities	Use SAPM results from 3b and WP2 results stratified by age, gender, and deprivation to estimate population distribution of effects. Estimate impact on consumption and long-term.	By November 2019

As described above, PHT engagement in licensing is intended to result in changes to the local alcohol licensing system, and therefore to affect key outcomes measured in the general public, as licensing policy affects alcohol consumption and drinking behaviour, and thus their health and propensity to commit crime. Alcohol consumption and harms are not evenly distributed across the population, with wide variation in drinking patterns and harm and, further, intervention activity may have different impacts on different population groups. Considering this variation is key to understanding both the true impact of an intervention and also the potential for the intervention to alter these distributions and narrow or widen existing socioeconomic and gender inequalities in health [59,60]. SAPM addresses this need by modelling baseline consumption and harm, policy effects, and all outcomes fully stratified by sociodemographic level as well as age, gender and drinking level.

We will explore these issues and the potential for licensing engagement and policy to affect these socioeconomic gradients through: a) using the Local Authority versions of SAPM and b) exploring the differential impact of the intervention on health outcomes by gender and socioeconomic group (defined by quintiles of the Index of Multiple Deprivation or other relevant markers)) to establish the potential of intervention activity to reduce (or exacerbate) the substantial existing inequalities in alcohol-related harms [61].

WP2 will produce estimates of the short-term effect (<2 years) of the intervention on a range of outcome harm measures. We will use the local versions of SAPM to estimate the reduction in alcohol consumption which would be required to achieve these harm reductions. This will be

further informed, where possible, by identifying additional data which stratifies outcome measures by sociodemographic characteristics to estimate where effectiveness may vary within the population.

We will use these consumption changes to estimate, for each intervention area, the long-term impacts (20 years) on health and costs to the NHS. These will be compared to the intervention costs to consider the relative cost-effectiveness of intervention activity across the intervention areas.

4.3.4. THE IMPACT OF INTERVENTION ACTIVITY IN NEW AREAS [WP3 - OBJECTIVE 3D]

To estimate the potential impact of high intensity PHT activity in areas which are not currently active.	Use local alcohol policy models to estimate in 2 exemplar control areas.	By December 2019

The estimates of the relationship between intervention activity and alcohol consumption will be incorporated into new SAPM versions for 2 control areas to produce estimates of the likely impacts on health, NHS costs and crime from licensing activity should the public health teams in these areas increase their involvement in the licensing process.

4.4 WORK PACKAGE 4

4.4.1 USE LITERATURE & FINDINGS TO DEVELOP THEORY OF CHANGE FOR INTERVENTION

Revise and refine hypothesised theories of change to qualitatively examine whether key aspects of the licensing system, such as a public health objective, are associated with changes in local public health practice or licensing processes.	Draft and disseminate theory of change. Revise as data emerges. Host stakeholder workshop to discuss and finalise, and agree dissemination plans.	Throughout project. By July 2019

Systematic reviews e.g. [11,62,63] and a reviews of reviews [64] have concluded that there is evidence to support interventions based on restricting the availability of alcohol including hours/days of sale and outlet density. However, there is a need for greater clarity in relation to the assumed mechanisms through which such interventions exert effects on alcohol-related harms [19–21] and it can be challenging to apply the evidence in a local policy context [6,31,32,34,38,65,66].

We will therefore develop a THEORY OF CHANGE to support better understanding of the findings of the study and to facilitate further analysis. In developing the theory, we will consider both indirect mechanisms of action (discouraging licence applications or influencing the nature and type of applications accepted e.g. arts venues but not nightclubs [27]) and more direct action through licensing policies and decisions. We will also examine the contribution of individual or groups of intervention components or confounding activities to outcomes.

The final theory of change will be informed by practitioners' views (from WP1), interim outcome data (from WP2) and also information gathered on the licensing outcomes gathered in WP1.

The final theory will be developed by the WP leads, in discussion with the full study team, the study advisory group and our public engagement panel.

This will be further developed in consultation with practitioners at a STAKEHOLDER WORKSHOP. We will consult with practitioners from the intervention and control areas on emerging findings and the draft theory of change at this event in Year 3 which will inform the final analysis and overall SYNTHESIS OF FINDINGS [WP4 - OBJECTIVE 4B]

4.4.2 DISSEMINATION & IMPACT

To synthesise all findings, identify recommendations for practice, policy and future research and disseminate.	Analysis within each work package. Overall analysis and reporting. Dissemination.	Throughout project. By March 2020 2019 onwards

We will continue to work closely with Public Health England (PHE), Alcohol Focus Scotland (AFS) and the Institute for Alcohol Studies (all on advisory group) who are leading UK organisations supporting local public health teams on alcohol issues. Jointly with JN (CI), PHE run a National Public Health and Licensing Network. AFS hosts regular knowledge exchange events in Scotland for local teams, runs annual licensing conferences, and publishes a monthly e-newsletter. Both organisations will disseminate study information and findings through these established mechanisms.

NF, LB, CA (CIs) are part of the 13 University UK Centre for Tobacco and Alcohol Studies where LB is Deputy Director responsible for alcohol research. Through UKCTAS, NF co-ordinates 2 training courses on alcohol policy for local policy practitioners. UKCTAS is a member of the Alcohol Health Alliance, which brings together more than 40 organisations that have a shared interest in reducing the damage caused to health by alcohol. LB is also Cancer Prevention Champion at Cancer Research UK. These links will help us to both disseminate the study and achieve impact. In terms of dissemination we will aim to reach practitioners, the public and research audiences.

For practitioners and the public, with the input of our practitioner co-applicant TN, we will create a section for the study on the UKCTAS website and prepare an interim and final summary of findings in plain English, and if appropriate a findings infographic, for dissemination through all channels. For public audiences in particular this will involve press releases of publications and dissemination through UKCTAS social media feeds.

In terms of academic outputs, we expect to publish several peer-reviewed journal papers from each WP. We will disseminate findings at two UK and two international conferences.

<u>In terms of impact, the proposed research will produce outputs and impact in 3 categories: generating new knowledge; informing practice and policy; and informing future research.</u>

First, this study will produce NEW KNOWLEDGE to inform local and national approaches to alcohol licensing in the UK. Evidence from other countries shows that local approaches to tackling alcohol harms including changing licensing provisions, can make a difference. Recent work in Australia successfully translated published findings of a study in Newcastle, Australia to Sydney, in which changed licensing provisions led to substantial reductions in alcohol-related violence and health harms [15,67]. This study will aim to generate similar new knowledge through peer reviewed publications and policy briefings to improve alcohol licensing in the UK.

Secondly, we expect our results to be directly RELEVANT TO LOCAL LICENSING PRACTICE, including ongoing public health team decisions on whether and how to invest in engaging with local alcohol premises licensing, in a context of diminishing overall resources. We will work with Public Health England, Alcohol Focus Scotland and the Local Government Association to incorporate the findings into user-friendly guidance for local areas e.g. adapting existing licensing 'toolkits'[35] and infographics.

Our results could also influence NATIONAL LICENSING POLICY. Opportunities will arise in the future for the study to influence national alcohol strategies in both England and Scotland and revised or new legislation should this arise, particularly in the context of the public health licensing objective being in place in Scotland but still under consideration in England . The UK Centre for Tobacco and Alcohol Studies (involving 3 CIs) is a member of the Alcohol Health Alliance (AHA). The AHA is an alliance of more than 40 organisations – including royal colleges, universities and professional organisations – that works with policy-makers to promote evidence-based alcohol policies. We also have excellent links with Scottish Health Action on Alcohol Problems (SHAAP) who work in a similar way in Scotland, as with Eurocare in Europe.

Finally, the study will aim to inform FUTURE RESEARCH. We will develop a 'testable' theory of change on alcohol licensing and public health that could inform the design and conduct of future studies in this field including in Australia (where some jurisdictions have a requirement to consider 'harm minimisation' in alcohol premises licensing), and provide a template for future studies focusing on complex systems. We will also establish a cohort of local authorities that can be followed up in future at minimal cost to explore the impact of other policy changes, such as the introduction of health as a licensing objective in England.

5. ETHICS

Ethical approval for this study has been granted by the University of Stirling's "NHS, Invasive or Clinical Research" ethics committee (NICR 16/17 – Paper no 64).

NHS Research and Development Management Approval will be required for any NHS-based sites participating in the study. This applies to Scotland only as public health teams in England are not based within the NHS. At the time of writing, approval had been granted in advance of recruitment for 10 of the 14 Scottish NHS Board areas, although not all of these will actually be recruited to the study. The research in Scotland will be conducted by researchers at the University of Stirling. Letters of access are required prior to any research being conducted by these researchers on NHS sites. Some NHS areas in Scotland have already issued letters of access; others will do so following the issuing of 'Research Passports' for the university researchers.

6. REFERENCES

1. Lim SS, Vos T, Flaxman AD, et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet*. 2012;380(9859):2224-2260. doi:10.1016/S0140-6736(12)61766-8.
2. Health and Social Care Information Centre. Statistics on Alcohol, England 2015. 2015;38(June):e103. doi:http://www.ic.nhs.uk/pubs/alcohol09.
3. Probst C, Roerecke M, Behrendt S, Rehm J. Socioeconomic differences in alcohol-attributable mortality compared with all-cause mortality: a systematic review and meta-analysis. *Int J Epidemiol*. 2014;43(4):1314-1327. doi:10.1093/ije/dyu043.
4. Department of Health (UK). Written evidence from the Department of Health (GAS 01). 2012. http://www.parliament.uk/documents/commons-committees/Health/Writtenevidencebyoralwitnesses.pdf.
5. Shortt NK, Tisch C, Pearce J, et al. A cross-sectional analysis of the relationship between tobacco and alcohol outlet density and neighbourhood deprivation. *BMC Public Health*. 2015;15:1014. doi:10.1186/s12889-015-2321-1.
6. Foster J, Charalambides L. *The Licensing Act (2003): Its Uses and Abuses 10 Years On.* London; 2016. doi:10.1017/CBO9781107415324.004.
7. Martineau F, Tyner E, Lorenc T, Petticrew M, Lock K. Population-level interventions to reduce alcohol-related harm: an overview of systematic reviewsp. *Prev Med (Baltim)*. 2013;57(4):278-296. doi:10.1016/j.ypmed.2013.06.019.
8. Babor TF, Caetano R, Casswell S, et al. *Alcohol: No Ordinary Commodity: Research and Public Policy*. 2nd ed. OUP Oxford; 2010. http://www.amazon.co.uk/Alcohol-Ordinary-Commodity-Research-Public/dp/0199551146. Accessed November 17, 2013.
9. Popova S, Giesbrecht N, Bekmuradov D, Patra J. Hours and days of sale and density of alcohol outlets: impacts on alcohol consumption and damage: a systematic review. *Alcohol Alcohol*. 2009;44(5):500-516. doi:10.1093/alcalc/agp054.
10. Campbell CA, Hahn RA, Elder R, et al. The effectiveness of limiting alcohol outlet density as a means of reducing excessive alcohol consumption and alcohol-related harms. *Am J Prev Med*. 2009;37(6):556-569. doi:10.1016/j.amepre.2009.09.028.
11. Middleton JC, Hahn R a, Kuzara JL, et al. Effectiveness of policies maintaining or restricting days of alcohol sales on excessive alcohol consumption and related harms. *Am J Prev Med*. 2010;39(6):575-589. doi:10.1016/j.amepre.2010.09.015.
12. University of Stirling, Alcohol Health Alliance UK, British Liver Trust. *Health First. An Evidence-Based Alcohol Strategy for the UK*. Stirling; 2013.
13. Hahn R a, Middleton JC, Elder R, et al. Effects of alcohol retail privatization on excessive alcohol consumption and related harms: a community guide systematic review. *Am J Prev Med*. 2012;42(4):418-427. doi:10.1016/j.amepre.2012.01.002.
14. Popova S, Giesbrecht N, Bekmuradov D, Patra J. Hours and days of sale and density of alcohol outlets: impacts on alcohol consumption and damage: a systematic review. *Alcohol Alcohol*. 2009;44(5):500-516. doi:10.1093/alcalc/agp054.
15. Miller P, Curtis A, Palmer D, et al. Changes in injury-related hospital emergency department presentations associated with the imposition of regulatory versus voluntary licensing conditions on licensed venues in two cities. *Drug Alcohol Rev*. 2014;33(3):314-322. doi:10.1111/dar.12118.
16. Young R, Macdonald L, Ellaway A. Associations between proximity and density of local alcohol outlets and alcohol use among Scottish adolescents. *Heal {&} place*. 2013;19:124-130. doi:10.1016/j.healthplace.2012.10.004.
17. Fone D, Morgan J, Fry R, et al. *Change in Alcohol Outlet Density and Alcohol-Related Harm to Population Health (CHALICE): A Comprehensive Record-Linked Database Study in Wales*. NIHR Journals Library; 2016.

http://www.ncbi.nlm.nih.gov/pubmed/27054222. Accessed July 28, 2016.

18. Knight I, Wilson P. *Scottish Licensing Laws*. London; 1980.

19. Holmes J, Guo Y, Maheswaran R, Nicholls J, Meier PS, Brennan A. The impact of spatial and temporal availability of alcohol on its consumption and related harms: a critical review in the context of UK licensing policies. *Drug Alcohol Rev*. 2014;33(5):515-525. doi:10.1111/dar.12191.

20. Gmel G, Holmes J, Studer J. Are alcohol outlet densities strongly associated with alcohol-related outcomes? A critical review of recent evidence. *Drug Alcohol Rev*. June 2015. doi:10.1111/dar.12304.

21. Gmel G, Holmes J, Studer J. We have to become more specific: A reply to Morrison et al. *Drug Alcohol Rev*. December 2015. doi:10.1111/dar.12365.

22. Maclennan B, Kypri K, Connor J, Potiki T, Room R. New Zealand's new alcohol laws: protocol for a mixed-methods evaluation. *BMC Public Health*. 2016;16(1):29. doi:10.1186/s12889-015-2638-9.

23. Fitzgerald N, Angus C. Four Nations: How Evidence-based are Alcohol Policies and Programmes Across the UK? 2015.

24. Nicholls J. Alcohol licensing in Scotland: a historical overview. *Addiction*. 2012;107(8):1397-1403. doi:10.1111/j.1360-0443.2012.03799.x.

25. Nicholls J. Public Health and Alcohol Licensing in the UK: Challenges, Opportunities, and Implications for Policy and Practice. *Contemp Drug Probl*. 2015;42(2):87-105. doi:10.1177/0091450915579875.

26. Davoren S, O'Brien P. Regulating to reduce alcohol-related harm: Liquor licensing and the harm minimisation test. In: Manton E, Room R, Giorgi C, Thorn M, eds. *Stemming the Tide of Alcohol: Liquor Licensing and the Public Interest.* Canberra: Foundation for Alcohol Research and Education in collaboration with University of Melbourne; 2014.

27. Egan M, Brennan A, Buykx P, et al. Local policies to tackle a national problem: Comparative qualitative case studies of an English local authority alcohol availability intervention. *Health Place*. 2016;41:11-18. doi:10.1016/j.healthplace.2016.06.007.

28. Grace D, Egan M, Lock K. Examining local processes when applying a cumulative impact policy to address harms of alcohol outlet density. *Health Place*. 2016;40:76-82. doi:10.1016/j.healthplace.2016.05.005.

29. de Vocht F, Heron J, Angus C, et al. Measurable effects of local alcohol licensing policies on population health in England. *J Epidemiol Community Health*. 2015;70(3):231-237. doi:10.1136/jech-2015-206040.

30. De Vocht F, Heron J, Campbell R, et al. Testing the impact of local alcohol licencing policies on reported crime rates in England. *J Epidemiol Community Health*. August 2016:jech - 2016-207753. doi:10.1136/jech-2016-207753.

31. Mahon L, Nicholls J. *Using Licensing to Protect Public Health From Evidence to Practice*. London; 2014.

32. Fitzgerald N. *Influencing the Implementation of a Public Health Objective in Scottish Alcohol Licensing: A Qualitative Interview Study - Summary Report*. Vol 1. Stirling; 2015. doi:10.1017/CBO9781107415324.004.

33. Coke C, Murage P, Smolar M, Tong M. *Licensing Information Pack*. London; 2014.

34. Alcohol Focus Scotland. *Review of Statements of Licensing Policy 2013 to 2016*. Edinburgh; 2014.

35. Alcohol Focus Scotland. Licensing resource toolkit. http://www.alcohol-focus-scotland.org.uk/media/59983/Factsheet-3-Overprovision.pdf. Published 2013.

36. Alcohol Focus Scotland. *Alcohol Licensing in Your Community: How You Can Get Involved Toolkit.* Glasgow; 2016.

37. Fitzgerald N, Nicholls J, Winterbottom J, Katikireddi S. Implementing a Public Health Objective for Alcohol Premises Licensing in Scotland: A Qualitative Study of Strategies, Values, and Perceptions of Evidence. *Int J Environ Res Public Health*. 2017;14(3):221. doi:10.3390/ijerph14030221.

38. Martineau FP, Graff H, Mitchell C, Lock K. Responsibility without legal authority? Tackling alcohol-related health harms through licensing and planning policy in local government. *J Public Health (Oxf)*. 2014;36(3):435-442. doi:10.1093/pubmed/fdt079.

39. Local Government Association. *LGA Survey: Public Health in the Licensing Process*. London; 2016. http://www.local.gov.uk/documents/10180/11493/researh+-+health+-+LGA+survey+-+Public+Health+and+the+Licensing+Process+Findings+2+feb+2016/8758dd6d-da38-4221-b23e-b56790fb6e66.

40. Sulkunen P. Commentary on Maclennan et al. (2013): Is local alcohol policy possible? *Addiction*. 2013;108(5):898-899. doi:10.1111/add.12174.

41. Maclennan B, Kypri K, Room R, Langley J. Local government alcohol policy development: case studies in three New Zealand communities. *Addiction*. 2013;108(5):885-895. doi:10.1111/add.12017.

42. Nilsson T, Leifman H, Andréasson S. Monitoring local alcohol prevention in Sweden: Application of Alcohol Prevention Magnitude Measure (APMM). *NAD Nord Stud Alcohol Drugs*. 2015;32(5):479-494. doi:10.1515/nsad-2015-0047.

43. Naimi TS, Blanchette J, Nelson TF, et al. A new scale of the U.S. alcohol policy environment and its relationship to binge drinking. *Am J Prev Med*. 2014;46(1):10-16. doi:10.1016/j.amepre.2013.07.015.

44. Giesbrecht N, Wettlaufer A, Simpson S, et al. *Strategies to Reduce Alcohol-Related Harms and Costs in Canada: A Comparison of Provincial Policies*. Toronto; 2013.

45. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol*. 2013;13(1):117. doi:10.1186/1471-2288-13-117.

46. Ritchie J, Lewis J, Nicholls CM, Ormston R. *Qualitative Research Practice*. London: Sage; 2013.

47. Baker C. *Briefing Paper 6964: Accident and Emergency Statistics*. London; 2015.

48. Cherpitel CJ, Borges G, Giesbrecht N, et al., eds. *Alcohol and Injuries: Emergency Department Studies in an International*

Perspective. Geneva: World Health Organisation; 2009. doi:10.1001/archfami.5.2.67.

49. Greenfeld L. *Alcohol and Crime: An Analysis of National Data on the Prevalence of Alcohol Involvement in Crime*. Washington; 1998. http://www.bjs.gov/content/pub/pdf/ac.pdf.

50. Edland SD. Which MRI measure is best for Alzheimer's disease prevention trials. Statistical considerations of power and sample size. *Jt Stat Meet Proc*. 2009:4996-4999.

51. Stürmer T, Joshi M, Glynn RJ, Avorn J, Rothman KJ, Schneeweiss S. A review of the application of propensity score methods yielded increasing use, advantages in specific settings, but not substantially different estimates compared with conventional multivariable methods. *J Clin Epidemiol*. 2006;59(5):437-447. doi:10.1016/j.jclinepi.2005.07.004.

52. de Vocht F, Campbell R, Brennan A, Mooney J, Angus C, Hickman M. Propensity score matching for selection of local areas as controls for evaluation of effects of alcohol policies in case series and quasi case-control designs. *Public Health*. December 2015. doi:10.1016/j.puhe.2015.10.033.

53. Abadie A, Diamond A, Hainmueller J. Synthetic Control Methods for Comparative Case Studies: Estimating the Effect of California's Tobacco Control Program. *J Am Stat Assoc*. 2010;105(490):493-505. doi:10.1198/jasa.2009.ap08746.

54. Young DJ, Stockwell T, Cherpitel CJ, et al. Emergency room injury presentations as an indicator of alcohol-related problems in the community: a multilevel analysis of an international study. *J Stud Alcohol*. 2004;65(5):605-612. http://www.ncbi.nlm.nih.gov/pubmed/15536770. Accessed April 21, 2016.

55. Abadie A. Semiparametric Difference-in-Differences Estimators. *Rev Econ Stud*. 2005;72(1):1-19. doi:10.1111/0034-6527.00321.

56. Purshouse R, Brennan A, Latimer N, et al. *Modelling to Assess the Effectiveness and Cost-Effectiveness of Public Health Related Strategies and Interventions to Reduce Alcohol Attributable Harm in England Using the Sheffield Alchol Policy Model 2.0. Report to NICE Public Health Programme Developme*. Sheffield; 2009.

57. Holmes J, Meng Y, Meier PS, et al. Effects of minimum unit pricing for alcohol on different income and socioeconomic groups: a modelling study. *Lancet*. 2014;6736(13). doi:10.1016/S0140-6736(13)62417-4.

58. Angus CR, Holmes J, Pryce R, Meier P, Brennan A. *Model-Based Appraisal of the Comparative Impact of Minimum Unit Pricing and Taxation Polciies in Scotland*. Sheffield; 2016.

59. Meier PS, Holmes J, Angus C, Ally AK, Meng Y, Brennan A. Estimated Effects of Different Alcohol Taxation and Price Policies on Health Inequalities: A Mathematical Modelling Study. Basu S, ed. *PLOS Med*. 2016;13(2):e1001963. doi:10.1371/journal.pmed.1001963.

60. Meier PS, Purshouse R, Brennan A. Policy options for alcohol price regulation: the importance of modelling population heterogeneity. *Addiction*. 2010;105(3):383-393. doi:10.1111/j.1360-0443.2009.02721.x.

61. Bellis MA, Hughes K, Nicholls J, Sheron N, Gilmore I, Jones L. The alcohol harm paradox: using a national survey to explore how alcohol may disproportionately impact health in deprived individuals. *BMC Public Health*. 2016;16(1):111. doi:10.1186/s12889-016-2766-x.

62. 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. ScHARR Public Health Evidence Report 2.1*. Sheffield; 2009.

63. Hahn RA, Kuzara JL, Elder R, et al. Effectiveness of policies restricting hours of alcohol sales in preventing excessive alcohol consumption and related harms. *Am J Prev Med*. 2010;39(6):590-604. doi:10.1016/j.amepre.2010.09.016.

64. Martineau F, Tyner E, Lorenc T, Petticrew M, Lock K. Population-level interventions to reduce alcohol-related harm: an overview of systematic reviews. *Prev Med (Baltim)*. 2013;57(4):278-296. doi:10.1016/j.ypmed.2013.06.019.

65. Public Health England. Public health and licensing survey An overview of current engagement. 2015.

66. Nicholls J, Greenaway J. What is the problem?: Evidence, politics and alcohol policy in England and Wales, 2010–2014. *Drugs Educ Prev policy*. 2015;22(2):135-142. doi:10.3109/09687637.2014.993923.

67. Kypri K, Jones C, McElduff P, Barker D. Effects of restricting pub closing times on night-time assaults in an Australian city. *Addiction*. 2011;106(2):303-310. doi:10.1111/j.1360-0443.2010.03125.x.

68. Beeston C, McAdams R, Craig N, et al. *Monitoring and Evaluating Scotland's Alcohol Strategy - Final Annual Report*. Edinburgh; 2016. http://www.healthscotland.com/uploads/documents/26884-MESAS__Final annual report.pdf.