

1. BACKGROUND

This proposal is for a study that will describe, understand and evaluate the introduction, operation and impact of later trading hours for licensed alcohol premises in two Scottish cities (Glasgow and Aberdeen). This study will provide novel and important evidence on whether and how the new policies are impacting on harms and will inform future decisions and legislation on trading hours locally, nationally and internationally.

Firstly, we set out briefly what we know about harms associated with late-night sales of alcohol in the UK, then the evidence base relating such harms to trading hours for licensed premises internationally and in the UK. We explain how opening hours are managed in the UK and why the existing evidence base is insufficient to guide alcohol premises licensing policy at local or national levels. Finally, we outline why our proposed study will take a systems perspective and draw on a wide range of disciplines to generate policy-relevant findings.

1.1 ALCOHOL HARMS

Alcohol consumption is a major contributor to the burden of both communicable and non-communicable diseases (NCDs) globally [1–4], is the leading cause of preventable death in people aged 15–49 years, underpins increased crime, road traffic accidents and violence [2, 5], and imposes a huge health and economic burden [1, 6]. In 2018, 1,136 people in Scotland died from a cause wholly attributable to alcohol (alcohol-specific); that is an average of 22 people every week [7]. In 2017, rates of alcohol-specific death were more than seven times higher in the 10% most deprived areas in Scotland than in the 10% least deprived areas, and 2.5 times higher than in 1981 [7, 8]. From a peak in 2003/2006 for men/women, a downward trend in deaths was seen, but that since 2012 that downward trend in Scotland has stalled [8]. In 2018, alcohol-specific death rates were more than twice as high in men and 90% higher in women in Scotland compared with England [8].

While alcohol-specific mortality rates are lower in England than Scotland, they are significantly higher than they were in 2001, with rates in Scotland having fallen over the same period [9], and 5,698 people died from alcohol-specific causes in England in 2018. There are also substantial inequalities, with the age-standardised mortality rate from alcohol-specific causes being 4.1 times higher for men in the most deprived quintile of the population compared to the least deprived and 3.5 times higher for women in 2018. The most recent available hospitalisation figures show that there were more than 300,000 hospital admissions from alcohol-specific causes in England in 2017 and an estimated 1.2 million admissions caused by alcohol in total, accounting for all conditions where alcohol is a risk factor [10]. In spite of declining levels of alcohol consumption between 2008/09 and 2017/18 [11], admission rates for alcoholic liver disease have risen steadily from 82 to 121 per 100,000 adults per year [10].

1.2 ALCOHOL-RELATED VIOLENCE AND DISORDER IN THE UK

Late night alcohol sales are associated with increased rates of assaults, injuries, disorder and use of services.

- Alcohol-related ambulance call-outs are estimated by Scottish Ambulance Service (SAS) at ~171,000 annually [12], costing ~£52M [13]. Surveys of SAS staff indicate that 50% of weekend call-outs; 42% of assault-related call-outs; and 62% of cases of physical abuse against staff may be alcohol-related, with a heavy concentration late at night [12].
- In Scotland, an audit of A&E presentations [14] indicated that 70% of assaults presenting were alcohol-related. The busiest time for alcohol-related presentations was between midnight and 4am on a Saturday morning with four and a half times more patients presenting during these 4 hours than at the same time during the rest of the week. The most common presenting complaint was some form of alcohol-related injury (53%) followed by intoxication (23%) [14].
- The annual cost of assaults in Scotland is estimated at >£1.5bn despite progress made in tackling violence [15].

- This audit has not been repeated but in 2018/19, alcohol brief interventions were delivered in A&E settings in Scotland, to 10,598 patients who screened as at risk of alcohol problems [16].
- In 2017/18, of respondents to the Scottish Crime and Justice Survey who reported being the victim of crime, 39% felt that the offender was under the influence of alcohol. For violent crime this rose to nearly half (46%) of offenders [17].
- In England, offenders were believed to be under the influence of alcohol in 40% of all violent incidents and 38% of sexual assaults [18]; as well as in two-thirds of weekend and night-time violent incidents and 91% in or near pubs/clubs [19].

1.3 LATER TRADING HOURS FOR LICENSED PREMISES & WHAT THIS STUDY ADDS

Systematic reviews [20–24] find that extensions in late night opening of alcohol premises are linked to increased intoxication, assaults, injuries, and burden on public services. Recent studies of late-night trading hour changes using robust methods have found significant impacts:

- a 1-hour extension of closing times in the central district of Amsterdam was associated with 34% more alcohol-related ambulance call-outs (from 2-6am) [25];
- in a study across 18 Norwegian cities, each additional 1-hour extension to opening times was associated with a 16% increase in police-reported assaults (10pm to 5am) and the converse was true for each 1 hour reduction in opening [26];
- in Newcastle, Australia, the impact of each additional hour of trading on assaults (10pm to 6am) was 21%, and sustained beyond five years after implementation [27];

The 2003 Licensing Act, which applies only to England and Wales, allowed for 24 hour licensing where agreed locally for both on- and off-licence premises at the same time. Early studies of the changes gave mixed findings in terms of A&E attendances and crimes but were methodologically weaker than the international studies cited above, using only before and after designs (see [28]). Using the more robust time series approach (as we propose here), Humphreys found no evidence of an overall increase in violent crime in the City of Manchester, but found a statistically significant 36% increase in violence between 3am and 6am. This suggested that violence shifted to later time periods. However, Humphreys did not consider wider health outcomes, and pointed to the need for future research such as we propose here *“to move beyond black-box evaluative designs by investigating the impact of policy on exposure (e.g. alcohol availability) as well as the impact of exposure on multiple indicators of physical and social harm”*. A later study of consumption data for England and Wales found the 2003 Act led to a marked increase in net alcohol consumption as on premise expenditure increased without any evidence of a corresponding decrease in off-premise expenditure. In addition, these increases in alcohol consumption were generated by increases in the amount of alcohol people consumed on their heaviest drinking day [29].

No previous study in the UK has considered the impact of later trading hours in alcohol-related ambulance call-outs, and there have been no studies of later trading hours in Scotland. Opening hours changed from 10pm to 11pm in Scotland in the 1970s, and were found (in a before/after survey) to have slightly increased consumption in women, and slightly shifted drinking to later times [30]. This study will provide important and more robust contextualised qualitative and quantitative evidence of the introduction, operation and impact of later trading hours specific to on-licence premises in two cities, and is novel in topic and approach (see Section 1.6 below).

1.4 MANAGEMENT OF OPENING HOURS FOR LICENSED PREMISES IN THE UK

In the UK, alcohol availability, including hours of sale, is regulated through a system of local authority premises licensing which differs slightly across the four nations of the UK [31, 32]. In Scotland, under the 2005 Licensing Act (‘the Act’), licensing boards are the decision-making body on licensing matters, including who can sell alcohol, where it can be sold, the conditions of sale and the hours and days of sale. Opening hours in the off-trade in Scotland are restricted by the Act to 10am till 10pm. For on-trade premises, in terms of section 64 of the Act, there is a presumption against granting 24 hour licences including for one-off events, unless there are exceptional circumstances (defined in guidance as one-off local or national festivals and rarely used).

There are several actors and structures within the Scottish licensing system established under the Act (Box 1). For the first time, the Act created a role in the licensing system for local public health departments based within the National Health Service, who, along with the police and others, became 'statutory consultees' who are informed of all applications for new or changed premises licences (including changes to opening hours). Such applications can only be refused if a) a 'representation' is made against the application by a statutory consultee or other party and b) that 'representation' successfully shows the application is likely to undermine one or more of the statutory 'licensing objectives'. The statutory licensing objectives in Scotland are:

- preventing crime and disorder
- securing public safety
- preventing public nuisance
- protecting children and young people from harm
- protecting and improving public health

The explicit inclusion of public health improvement as a decision criterion in licensing is relatively unique globally – only the first four objectives apply in England. Local licensing boards must produce a regular 'Statement of Licensing Policy' (SLP) (approximately every 4 years) giving due regard to the licensing objectives and normally including details of their standard approach to trading hours. They are required to consult publicly on their proposed policy and a statutory Licensing Forum should exist in each licensing area to advise the Board (see Box). Licensing board decisions to refuse applications are more likely to be upheld where granting the application would contravene their stated policy.

In England and Wales, as noted above, the Licensing Act (2003) removed permitted hours for licensed premises both for on- and off-trade premises.

Box 1: Structures & Actors in Alcohol Premises Licensing in Scotland.

The Licensing Board: Made up of between 5 and 10 local elected councillors who are appointed to the board by the local authority for a term of 4-5 years.

The Convenor: The licensing board elects its own chairperson known as the 'convenor' who has the casting vote in decisions.

The Licensing Clerk: A local authority-employed lawyer who provides legal support to the licensing board.

Licensing standards officers (LSOs): practitioners employed by the local authority to provide guidance to licence-holders, ensure compliance and mediate in disputes.

The Local Licensing Forum: Local licensing Forums were established under the 2005 Act with the purpose of ensuring community stakeholders had an active voice in scrutinising the operation of licensing in their area. Each licensing board should have a Forum to give them advice and recommendations. Forum membership includes an LSO, a health representative, licence-holders, police, education, social work, young people, local residents and licensing board members.

1.5 THE POLICY CHANGES: LATER OPENING HOURS IN GLASGOW & ABERDEEN

Two different processes in recent months have led to later opening hours in Glasgow City and Aberdeen City, which form the basis of our proposed natural experiment.

Policy Change 1: In Glasgow, as of 12th April 2019, under a scheme planned by the Glasgow Licensing Board (GLB), 10 nightclubs were granted a variation in their licence enabling them to open for an extra hour until 4am for at least 12 months. The scheme was described by the Licensing Board as an '*opportunity to reward and continue to encourage great practice in the nightclub trade*' as the extra hour was only granted to premises meeting certain criteria. The licence holder had to demonstrate, to the satisfaction of the GLB, not only that the premises make a positive contribution to the late night economy, but that it invests in safety and security measures for both staff and customers, designed to promote the licensing objectives. These changes followed on from a Glasgow City Night Time Economy Commission looking at future considerations within Glasgow City.

The GLB stated its desire to *‘properly measure and gauge the impact, [of the changes], if any...on the late night dispersal of customers from the city centre, alcohol related crime and disorder, public nuisance and public health’*. When this extension was first proposed via the GLB Statement of Licensing Policy (SLP) Consultation in September 2018, objections to the extended hours were submitted by NHS and local Alcohol and Drug Partnership asking if the policy was consistent with the licensing objectives, highlighting the potential for increased harms and impact on services including NHS, Police and SAS. Police Scotland stated that they had no evidence to show later hours would contribute to violence or disorder but highlighted concerns around the availability of taxis, taxi marshals, street pastors, night-zones and late night catering after 4am. However, the policy was adopted by the GLB in November 2018. At the time when premises applied for the extended licences, police and health board representatives successfully argued for the extension to be dependent on agreement to ten licensing conditions.

Policy Change 2: In Aberdeen City in 2017/18, a potential problem came to light with a clause in the local SLP (from 2013) which permitted later opening hours only in premises which provided ‘significant entertainment’. During 2017/18 the definition of significant entertainment was questioned by the licensed trade and board members in considering several individual applications for premises seeking extended hours, some of which were subsequently granted. A range of different trade groups and Aberdeen Inspired, the city business regeneration coalition then advocated for the “significant entertainment” clause to be removed. After representations from Police Scotland, the new SLP (2018) allowed for this clause to be dropped, providing certain licensing conditions were met. From November 2018, and continuing throughout 2019, bars and pubs (which previously had to close no later than 1am) began to apply to extend their hours - some to 2am and some to 3am and these were granted. To date, approximately 30 bars/pubs have applied for, and been granted, extended hours. The available scientific evidence was again insufficient to enable NHS Grampian to open dialogue with the Licensing Board to explore potential harm that might arise from these changes, or how those harms might be mitigated.

1.6 OUR APPROACH

Our proposed research will be the most methodologically robust and in-depth study of additional late night alcohol availability in the UK to date, informed by systems thinking. We will utilise a robust time series analysis approach in the two cities to quantitatively examine changes in outcomes over time, but will also make use of other quantitative and qualitative methods to better understand and improve the relevance and value of the findings.

Understanding alcohol harms, and the contribution of policies to changes in such harms, can benefit from adopting a complex systems perspective [33]. This perspective allows the impact of later opening hours to be conceived not so much as an aggregation of individual ‘choices’ to drink more or stay out later, and more a result of the interactions between a diverse range of actors and their environments [34]. Their actions and interactions serve to maintain or disrupt consumption behaviours and impacts by reshaping systems to promote or undermine health including via social and commercial determinants. Complex systems thinking has long been recommended as a potentially powerful tool for the analysis of alcohol systems, but has been under-utilized to date [35].

Policy changes like extended opening hours are developed by governments, introduced quickly and challenging to evaluate. Systems-informed natural experiments are often recommended but rarely conducted, in part because they can be more complex and unpredictable than clinical trials, and harder to fund [36]. Following current guidance, we take a complex systems approach to avoid simplistic linear impact assumptions (as in a ‘traditional hypothesis driven’ approach -R4) [34, 37]. Instead we ask what led to the changes, their contribution to a wide range of outcomes, practices and behaviours, and how the changes and their effects evolve and interact over time for all sectors and stakeholders [38]. Our study overcomes several weaknesses of prior research [39] enabling improved theorisation of mechanisms of impact and appraisal of a “‘pattern’ of impacts...to provide the strongest possible basis on which to draw causal inference” R5Q2&3 [36].

In this study, the systems under scrutiny will be the night time economy in the two cities and the legal and political institutions that govern the management of the local night time economy including premises licensing. The actors involved will be: local policymakers, local government staff and professional stakeholders; service providers; owners/staff in bars, nightclubs and other businesses; and the general public. In line with systems thinking, as well as considering the impact on harms and costs arising from the policy changes, we will examine the *antecedents* and *implementation* of the changes, their contribution to *adaptations* or changes in consumers, businesses and services, *intended or unintended ancillary impacts or feedback effects*, and *emergence* of new thinking, ways of working, or behaviour as a result of the changed opening hours. It is challenging to capture this using a 'logic model' which often depicts more linear pathways. We have therefore attached a systems map of a wide range of potential effects of the changes, including feedback effects, based on existing evidence and unknowns identified to date. Systems thinking requires a multidisciplinary approach which we will employ here via five interdependent work packages (WPs), led by Fitzgerald (Policy Studies); Emslie (Sociology); Lewsey (Medical Statistics); McIntosh (Health Economics); and Angus (Policy Modelling). Our WPs are fully described in Sections 3 and 4 below.

1.6 WHAT THIS STUDY ADDS

This study will be important and novel in several respects.

Firstly, this kind of change in on-premises availability at local level is common, but has been little studied, creating an important natural experiment opportunity. The policy changes are notably different from the national legislative changes brought about in England and Wales via the Licensing Act (2003), in that they are city-level, and in on-licence premises only.

Secondly, evidence is needed to enable local stakeholders (e.g. police and NHS) to make representations when such policy changes are proposed locally, to inform whether or not the policy changes in these two cities could or should be reversed. Further, our earlier work and that of others has found that international evidence is often discounted by local decision-makers such as licensing boards [40–43]. We will provide specific evidence not only for Glasgow and Aberdeen, but will model the changes for other UK cities to inform their future decision-making. **The need for specific evidence from this study on the impact of changes in on-licence trading hours at city level is strongly supported by a wide range of partners at local, Scottish and UK level** (see letters of support) and will also be of keen interest internationally.

Thirdly, the **processes that led to these policy changes, implementation of the changes, and their impact have not been studied using a mixed-methods systems approach.** The combination of qualitative and quantitative methods proposed includes several methods not previously applied to this area. These will enable understanding not only of the impact of the changes, but also several other aspects not previously studied in the UK including: (i) qualitative interviews and documentary analysis to explore how the policy decisions arose, framing and evidence in the process, and what evidence is needed by policymakers; (ii) observations of consumer and premises behaviour and practices in the later opening time, which will help to understand quantitative findings; and (iii) spatio-temporal patterning of any harms arising.

Finally, **this will be the first UK study of premises licensing to make use of the rich routine data available** in alcohol-related ambulance call-outs. Ambulance services manage many intoxicated patients in the community who would be missing from A&E and police data, and call-outs have been found to be sensitive to changes in opening hours in the Amsterdam study (as above) [25]. The attributable fraction for alcohol in the violence outcome analysed in Humphreys et al. [28] is 37% whereas for alcohol-related ambulance call-outs, we expect that it will be 100%. We will make full use of the data by using two counterfactuals - control outcomes (non-equivalent dependent variables as recommended by Humphreys) from days when additional hours are not used; and a control city where there is no equivalent change in opening hours during the period of analysis.

2. AIM & RESEARCH QUESTIONS

Aim: To understand and evaluate the contribution of changes in trading hours for bars and clubs in Glasgow and Aberdeen to harms, services and costs in the local night-time economy, and implications for other major UK cities.

This study will address seven **RESEARCH QUESTIONS** in the cities of Glasgow and Aberdeen, which will be answered by drawing on or triangulating data from more than WP in each case as indicated. Edinburgh will be used as a control city for WP3 only, see Section 4.3 below.

- RQ1 What is/was the exact nature of, rationale/explanation for, and intended outcome of the extended opening hours and other related changes in the licensing system? (WP1 and WP2)
- RQ2 How have the changes contributed to the reshaping of business and consumer behaviour and provision of services, and how have they been experienced from the perspective of public services staff and business owners/managers? (WP1 and WP2)
- RQ3 What do the changes mean for venue operation and consumer behaviour before and during the extended hours? (WP1 and WP2)
- RQ4 To what extent, if at all, have the changes affected the volume and patterning of alcohol-related ambulance call-outs (primary outcome), total ambulance call-outs, and police-recorded assaults, including amongst specific subgroups? (WP3 using WP1&2 findings)
- RQ5 What are the effects of the changes, if any, on costs from assaults, health harms and service usage, other public service responses, and if possible, on the local night-time economy? (WP4 using WP1, 2 & 3 findings)
- RQ6 What are the implications of the changes, if any, for longer-term health and associated NHS costs and potential impacts on health inequalities? (WP5 using WP3 & 4 findings)
- RQ7 Given the findings of RQ4, what would be the likely impact, if any, of similar changes in other UK cities? (WP5 using WP3 & 4 findings)

3. RESEARCH DESIGN OVERVIEW & TIMESCALES

Our five WPs are summarised here, and outlined in detail in the following Sections. Table 1 below outlines specific objectives of each WP and timescales. WPs 1-3 will start data collection and access as soon as relevant approvals are secured, and WP4 and 5 will begin preparatory work at the same time, with an increase in work towards the end of the study.

- **WP1: Understanding the Changes at System Level:** will focus on understanding why the changes came about, what effects were expected, and how public services/businesses were affected. We will search licensing meeting notes and media reports, and interview officials, managers and premises owners [Fitzgerald (lead) Mohan, Emslie, Smith].
- **WP2: Understanding the Changes at Venue Level:** will explore changes in bars/clubs including exactly when they are opening later and what happens during the later opening period such as who is in the venue, alcohol and drug use, violence and how the venue operates. Researchers will attend venues to observe the later openings, and review venue's social media feeds. We will also explore public views on later opening hours[Emslie (Lead), Mohan, Fitzgerald, Smith].
- **WP3: Evaluating Impact on Harms:** will evaluate if changes in alcohol-related ambulance call-outs and crimes have resulted from later opening hours, working with Scottish Ambulance Service and Police Scotland data from before and after the changes. We will also look for impact on different groups (men/women, age-groups, residence) and changes in call-out locations [Lewsey (Lead), Fitzpatrick, Angus, with collaborator Henriques-Cadby].
- **WP4: Evaluating Economic Impact:** leading on from WP3 will evaluate any associated costs of the changes especially to NHS and police services and local businesses [McIntosh, Lewsey, Angus, with in-kind contribution from collaborator Deidda].
- **WP5: Evaluating Impact on Inequalities, Long-Term NHS Costs and for other UK Local Authorities:** will identify whether other UK local authorities (LAs) are considering similar changes, and model the likely impact of the changes on inequalities, long-term health and healthcare costs both for Glasgow and Aberdeen, and the potential impact on short- and long-term health outcomes if they were introduced in selected other UK LAs [Angus, Fitzgerald].

COVID-19 CONTEXT & ADAPTATIONS TO STUDY

In March 2020, the UK initiated a national lockdown to control the spread of coronavirus-2019 (COVID-19). The initial lockdown closed all licensed premises in Scotland and was lifted in July 2020, except for nightclubs which have remained closed. In July 2020, other licensed premises were permitted to re-open with a range of restrictions in place and under strong government guidance. As transmission rates have changed locally and nationally, the measures affecting licensed premises have varied from curfews (6pm/10pm/11pm), opening premises with a ban on sales of alcohol for indoor consumption, opening premises outdoors only, or full closures. Different measures have been applied locally or regionally at different times.

The unprecedented changes in licensing create both challenges and opportunities for this study, and we already slowed our start date to allow time to make adjustments. Methodologically, challenges persist in relation to data collection, particularly in nightclubs, until they re-open. There is however an opportunity to supplement our research questions to generate data to inform government policy regarding recovery from COVID-19. Having discussed these issues as a team and with our Study Steering Committee, we will therefore adapt our methods as follows:

- We will add two new research questions (RQs) in light of the pandemic:
 - o **RQC1: What is our vision (as a society) for the future of the night-time economy in terms of the balance between alcohol-related harms and benefits, and impact on services, communities, and the local economy post-Covid? (Qualitative)**
- We will consider RQC1 in all of our qualitative work.
- **WP1:** We will include a broader range of national stakeholders in our interviews in WP1 to better consider RQC1.
- **WP2:** We will consider public views on RQC1 and on opening hours in relation to licensed premises post-COVID-19.
- **WP3:** We will adjust the follow-up period in the time series analysis for WP3 outcomes to stop before the UK lockdown.
- **WP4 and 5** will progress as planned building on the findings of WP3 except that we will examine all GB local authority policies systematically instead of conducting a survey (see below).

These changes are noted below where the work packages are described in more detail.

Table 1: Overview of objectives, methods and timescales

Please also see our Flow Diagram (attached) and new Gantt Chart (attached) which illustrate the interdependent nature of the work packages.

Objectives	Methods	Months
WP1: Understanding the changes at system level (NF, AM, Stirling RF & RA, CE)		
To raise awareness and build relationships with key stakeholders in both cities.	Engagement of stakeholders via the licensing forums, local authority and other partners in each city, via email, telephone and face to face contact building on prior contact.	1-6
To identify, source and analyse relevant documentation/	Outreach to licensing forum members and other stakeholders; searches of local authority websites; FOI requests; Nexis search for relevant media reports.	3-16, 25-26
To recruit interviewees and explore views on the rationale/explanation for, and intended/expected outcomes & explore RQC1	Recruitment using pragmatic range of methods building on earlier outreach. Semi-structured individual interviews with ~60 licensing, business & service staff.	7-20
To thematically analyse the collected data to answer research questions (RQs) 1-3 & RQC1.	Thematic analysis using framework approach. Development of new/adapted theory of change. Comparison & triangulation with data from WP2, including for usage of extra hours. Synthesis of findings on business changes and reported impacts for WP4.	10-32
WP2: Understanding the changes at venue level (CE, GCU RF & Researchers, Stirling RF, Glasgow RF to assist with data for RQC2, NF)		
To establish precise changes in opening hours in Glasgow and Aberdeen pre and post COVID-19.	Identify, source and analyse data on usage of opening hours by reviewing social media feeds for all relevant venues (Supplement with web searches and WP1 findings.	9-13
To describe what happens in relevant venues in the hours before and after the original closing time	Direct, repeated observation of 15 venues by trained sessional fieldworkers working in pairs using validated instruments. .	16-28
To explore public views on later opening hours	Conduct 16 deliberative focus groups with venue goers, city centre residents & mixed population groups in both cities.	12-19
To analyse for RQs 1-3 & RCQ1 and synthesise data to feed into WP3 and 4.	Collation of aggregate later opening hours for WP3 exposure measure. Descriptive analysis of observation data. Thematic analysis of focus group data using framework approach . Comparison & triangulation with WP1.	8-30
WP3: Evaluating Impact on Harms (JL, IHC (named researcher), Glasgow RF, CA, NF)		
To identify study variables and prepare data sets for analysis.	Close working with ambulance & police to understand data systems, define a data dictionary and extract data sets . Data manipulation using statistics software. Close working with WP1 & 2 to define policy change variables i.e. exposure in each city.	1-16
To identify if the extended opening hours led to changes in primary and secondary outcomes.	ARIMA models (including subgroup analyses and sensitivity analyses).	11-36
To assess whether the extended opening hours led to significant changes in the timing and location of outcomes.	Poisson regression. Bayesian space-time models. Conditional autoregressive models.	22-29
WP4: Evaluating Economic Impact (EM, Glasgow RF, Manuela Deidda (in-kind collaborator), JL, CA)		
To develop an economic evaluation logic model	Literature review of economic evaluations of opening hours. Add economic inputs and outcomes to an economic evaluation logic model, drawing on the systems map for the study.	1-16

To develop Health Economics Analysis Plan (HEAP)	Follow methods according to guidance on conducting economic evaluations alongside natural experiments [44].	7-14
To identify key sources of unit costs and calculate any cost differences arising as a result of the opening hours policy changes.	Use existing published sources of reference costs calculate alcohol-related call-out costs differences as a result of the policy changes. Use same method for police-recorded assaults.	13-21
To conduct the economic evaluation	Attach unit costs to identified and measured service use. Use regression methods to estimate cost-effectiveness. Conduct cost-consequences analysis by collating costs and all consequences on a spreadsheet.	22-36
WP5: Evaluating Impact on Inequalities, Long-Term NHS Costs and for other UK Cities (CA, NF, Stirling RF for survey)		
To describe the approach to late night trading in other local authorities (LAs) in Great Britain and identify areas considering changes	Sourcing and analysis of all local authority licensing policies in England, Scotland and Wales to identify innovative approaches to temporal availability. Requests were disseminated through the UK Licensing and Public Health network and Scottish licensing contacts to local authorities to invite expressions of interest in being selected for modelling.	3-15
To estimate the sociodemographic profile of the consumers affected by the interventions	Review of evidence from other WPs and analysis of national individual-level survey data which includes data on individual occasion-level drinking behaviours	18-24
To develop a greater understanding of the role of drinking context on risks of harm	Review of key peer-reviewed international epidemiological studies linking alcohol consumption and drinking setting to acute harm outcomes	21-27
To develop new versions of the Sheffield Alcohol Policy Model (SAPM) for the 2 intervention areas and a selection of LAs considering licensing hours changes.	Adaptation of the existing structure of SAPM based on previous findings from WP5 and relevant outcomes from WPs 3 & 4 and incorporation of the latest available routine data into these models.	24-30
To assess the longer-term impact of the changes in the 2 cities, and the potential impact in other modelled LAs, including Edinburgh.	Analysis using the newly-developed SAPM models	33-39
Synthesis and write up of all findings, dissemination and impact activities	Cross-compare and analyse outcomes and findings from across the WPs. Consider and re-draft systems map to reflect findings; write up main findings papers for peer reviewed publication, report to funder, organise stakeholder workshop and disseminate as per plans in Section 5 below.	32-42

4. RESEARCH PLAN IN DETAIL

4.1 WORK PACKAGE 1: UNDERSTANDING THE CHANGES AT SYSTEM LEVEL

WP1 will seek to understand the local licensing policy ‘subsystem’ which led to the changes including the involvement of individuals and organisations, their belief systems and framing of the nature and causes of alcohol-related harm in the night-time economy, and the role of internal or external events or other factors in shaping the changes. This will be essential for understanding what evidence could influence future decisions in these and other cities, and to use stakeholder beliefs to further develop theories of change to inform the other work packages.

Prior to data collection, we will further establish working relationships with relevant stakeholders, most of whom are represented on the local Licensing Forum in each city (see Box 1 above). Co-Investigator Smith (Health Improvement Lead for Alcohol Licensing and member of Glasgow City Licensing Forum), and Shamini Omnes (Chair of Aberdeen Licensing Forum, see letter of support) have liaised with both forums, which are enthusiastic and supportive. If funded, we will meet with each forum at their next available meeting to further explain the study, data collection and PPI plans, and to answer any questions. We (Fitzgerald, Angus) are currently studying public health involvement in alcohol licensing decisions in Scotland and England [45], also informed by systems thinking, and as a result have excellent links in the cities under study here on which we can build.

Led by Smith, and in collaboration with our advisory group, we will conduct a rapid stakeholder mapping exercise to guide documentation collection and interview sampling, identifying those who have been involved in or directly affected by the policy changes in each city such as:

- Local authority staff involved in licensing or development of the night-time economy or provision of services to the night-time economy (e.g. street cleaning, taxi wardens etc.)
- Local authority staff with an interest in community development, planning and health;
- NHS, police and other public sector representatives at senior and team leader levels in relevant roles;
- Representatives of third sector organisations involved in providing relevant services;
- Representatives of transport providers in the night-time economy;
- All licensing forum members at the time of the changes;
- Representatives of local residents or residents’ groups close to affected venues.
- National representatives (Scotland & UK) with an interest in the future of the night-time economy.

Initial spreadsheets will be created for each city based on information in the public domain or through personal contact; stakeholders will be invited (by email or telephone) to provide relevant documentation, to express interest in the study including taking part in interviews, and, in line with GDPR, to indicate if they wish to be removed from our records and opt out of any further contact.

4.1.1 DOCUMENTARY ANALYSIS & OVERALL APPROACH TO QUALITATIVE ANALYSIS

A detailed data collection protocol will guide the sourcing of relevant documentation, much of which will already be in the public domain. Desk-based web searches and direct stakeholder requests via our advisory group and interviewees will be used, with FOI requests only to access key documents not available by other means.

- Licensing documentation: Local licensing policy statements, draft statements, consultation papers and submissions; Agendas, papers and minutes of licensing board and forum meetings; Applications for extensions of licensed hours for individual premises under the policy changes; Relevant written submissions and court records in any legal challenges.
- Other relevant local authority documents e.g. night time economy strategies, city centre business plans or similar, minutes/papers from meetings discussing the policy changes.
- Documentation from services where relevant: we will ask for relevant documents from police, ambulance, transport or other services relating to staffing patterns, service provision or other issues arising from the changed opening hours.
- Any specific business planning documents relating to the policy changes, where premises are willing to share, on the basis of assurances of anonymity.

- Media reports relating to the changes. We will pilot and finalise a systematic search strategy for the Lexis Nexis database to identify relevant print and online media reports relating to the policy changes in the two cities.

All interviewees in WP1 will be asked if they have relevant documentation they could share to supplement the data gathered by other means, as noted above. This documentation set is likely to be a rich source of data and will be analysed at different levels of depth as appropriate:

Establishing the Details of the Policy Changes: A spreadsheet will record the following information through review of licensing board policies, applications and meeting minutes:

- The timing and nature of the policy changes in each city;
- The specific venues granted additional licensed hours, the nature of the changes granted, and the date on which granted;
- Any venues declined additional hours;
- Any specific licensing conditions under which additional hours were granted;
- Any information on intended or actual usage of the permitted extension in hours.

This spreadsheet will be triangulated with data provided during interviews and in WP2. Any additional licensing decisions reported by interviewees, and any data provided by interviewees that conflicts with the documentation records will be investigated further to verify dates/decisions.

Qualitative Data Analysis for All WPs: The media reports will be analysed using content analysis. The rationale and arguments relating to the policy changes in consultation responses will be analysed using the Framework method [46, 47], as will all interview data from WPs 1 & 2, and observation data from WP2. 'Framework' is a systematic method of analysing qualitative data suited to applied health research with specific questions, a limited time frame, a pre-designed sample, and a priori issues of interest [48]. It generates charts, facilitating analysis within and between cases to seek patterns, connections and explanations, enabling us to answer specific research questions for each WP. This largely inductive, exploratory approach will take account of specific observations in our data before moving to broader themes or theory development including comparisons across the data between stakeholder groups, venues, data sources (within and between work packages) and cities. In conducting framework analysis of the documentation collected, we will search for key themes to fulfil our research questions (particularly 1-3 above) as follows, as well as being alert to additional themes relevant to our overall aim.

4.1.2 IN-DEPTH SEMI-STRUCTURED KEY STAKEHOLDER INTERVIEWS

Sample: We will conduct ~60 in-depth one to one semi-structured interviews; face to face where possible; recorded and fully transcribed. Informed by stakeholder mapping (above), we will sample interviewees for variety in terms of: individual role, experience, seniority; organisation or service type; business/venue size, location, type, clientele, opening hours; local/national remit etc.

Recruitment Strategy: We will maximise the likelihood of successful recruitment through snowball sampling and follow up of individuals who have changed role, providing reassurances about confidentiality, and offering interviewees the option to review/correct transcripts prior to analysis. Any data which might identify an interviewee will be checked with the interviewee after anonymisation. Full informed consent will be secured prior to interview. We have successfully used these approaches to recruit similar stakeholders in previous alcohol policy research, without a need for incentives, [40, 49], including bar/pub/nightclub owners/managers [50], police [45], ambulance service staff [51] and a variety of licensing stakeholders [40, 45, 52].

Topics and Duration: We will explore the following topics with each group in line with our research questions as well as being alert to additional themes raised by the interviewees.

- **Local authority stakeholders** (licensing convenors, clerks, forum chairs, LSOs as per Box 1 above, plus community development, planning and health,) and **night-time economy managers**; the rationale for the change, how it came about, and views on success/challenges and mechanisms of impact and the future of the NTE (n~15, ~40mins);
- **Owners/managers of licensed premises** (n~20 = half of affected premises, selected for location, size, type, clientele etc., ~40mins) and **other late night business owners** – fast food, casinos (n~10, similar variety, ~20mins); views on the changes; business impact

including staffing/venue operation, perceived impact on customer behaviour and the future of the NTE.

- **Service managers/team leaders** – police/third sector/health/transport (n~15, ~40mins); if/how services have adapted; any changes in staffing or resourcing; perceived impact/benefits and mechanisms of any impact.
- **Other relevant national stakeholders** (n~10, if other groups are under-recruited) to discuss the implications of our findings and the future regulation of the NTE.

Interviews will be recorded, anonymised, transcribed, and analysed thematically using a framework approach [53] as outlined above to answer our research questions and inform other WPs.

4.2 WORK PACKAGE 2: UNDERSTANDING THE CHANGES AT VENUE LEVEL

WP2 will develop the complex systems approach by focusing on interactions between actors and their environment in the night time economy. Aspects of the environment which increase risky drinking and associated harms in bars and clubs, and so need to be considered when exploring later trading hours, include clientele mix, levels of intoxication, management of venues and behaviour of security staff [54]. Drawing on Miller et al's [55] similar work in Australia, and the work of Graham and Homel [56], we will directly observe clientele and staff behaviour. We will also explore public views on later opening hours using deliberative focus groups. This WP will provide important insights into clientele behaviour and venue operation which are not apparent from other data sources, and will feed into our theory of change.

4.2.1 DATA ON USE OF OPENING HOURS

Starting by reviewing the social media feeds of all relevant venues (~40 venues) in Glasgow and Aberdeen before and after the changes, we will establish how and when venues are making use of the extension in their permitted hours. Venues build brand loyalty through social media marketing and so use posts to advertise specific events, alcohol promotions and changes in opening hours [57]. For example, in April 2019 the Sub Club in Glasgow tweeted "*Totally buzzing to announce that as of today, the Sub Club will stay open till 4am every Friday and Saturday (plus other nights as and when)!*" (<https://twitter.com/subclub/status/1116728204591546372>)

Data Access: These data are free and publicly available. Previous studies have tracked venue social media feeds to explore alcohol marketing [57, 58]. Our preliminary analysis has confirmed the feasibility and utility of this approach; we manually searched the social media feeds of a sample of relevant venues to record relevant information (e.g. opening hours as advertised on social media, posts per week about opening hours, details of those posts) and checked that posts were available for the time points we require. Where information is missing from social media feeds, we will supplement it with web searches and interview/documentation data from WP1.

Data Collation & Reporting: An Excel spreadsheet will record the additional hours and days each venue has opened each week, with precise changes in opening hours over time feeding into the exposure measure and choice of counterfactual in WP3.

4.2.2 REPEATED VENUE OBSERVATIONS We will **directly observe what happens in venues in the hours** before and after the original closing times following adapted field observation procedures, schedules and analysis techniques from work in Glasgow nightclubs [59], bars in Canada and Australia [56], and studies of opening hours changes in Australia (>1,200 venue observations) [55]. Our intention is for our fieldworkers to discreetly observe whilst in venues, to reduce threats to personal safety and to limit any potential observer effects [60]. Scottish studies have successfully used this approach in bars and clubs [59, 60]. All procedures will be finalised following discussion with our ethics committee.

Recruitment & Training of Field Staff: We will aim to recruit field researchers from existing pools of sessional staff (e.g. who have collected data from injecting drug users on a national study). Drawing on the protocols from these studies, our fieldworkers will be expected to attend a full day of paid training provided by the research team which will include potential risks, coping strategies and emergency procedures. To address threats such as **traveling to venues at night, working in bars/clubs and unpredictable behaviour from participants due to alcohol /drug use**, we will ensure fieldworkers always work in pairs and, have costed for taxis for fieldworkers' travel

(following [59]). Data collection will be closely supervised by the GCU RA, reporting to Emslie, ensuring the quality of the data and supporting the fieldworkers.

Data Collection & Analysis: Field staff will observe 15 of the relevant venues in both Glasgow and Aberdeen, selected for variety. Observations will be recorded on mobile phones via fieldnotes and validated checklists, allowing fieldworkers to record data while blending in with customers (following [55, 59]), and will be repeated three times. The final observation items will be decided in consultation with the study advisory group, the PPI groups and our ethics committee. Observations may include: **venue operation** (e.g. adherence to licensing conditions, responses to disorder, number and behaviour of bar & security staff, venue entry and staff closing procedures), **clientele mix** (gender, age, style), **physical environment** (cleanliness, noise, crowding & flow of people through venue), **social environment** (levels of intoxication, presence of illegal drugs, physical & other arguments). Detailed fieldnotes written up post-observation will be analysed qualitatively to add depth to the data. Venue observations will also provide contextual data on impact on business operation and economic impact for WP4.

4.2.3 PUBLIC VIEWS ON LATER OPENING HOURS

Sampling and Recruitment: We will conduct a total of 16 deliberative focus groups (2 discussions with 8 groups) with venue goers, city centre residents & mixed population groups in Glasgow and Aberdeen to explore public views on later trading hours for licensed premises. We will recruit through community Facebook groups, paid adverts on social media and professional recruitment agencies. Respondents will be given a £40 voucher after the first group, and £60 after the second, to thank them for their time.

Topics and duration: Deliberative focus groups seek to provide information about topics to promote more nuanced discussion and encourage questions from participants and engagement with different opinions. In the first session, we will provide summaries of public health evidence on later trading hours, licensing boards' rationale for licensing changes & qualitative accounts of the harms and pleasures of nightlife. The second session will encourage discussion on the pros and cons of later opening hours, perceptions of impacts on the economy, consumer behaviour, health and communities and views on the future of the night-time economy post COVID-19. Each discussion will last 90 – 120 minutes

ANALYSIS: FOCUS GROUP DATA WILL BE HANDLED AS FOR WP1. R4.3 WORK PACKAGE 3: EVALUATING IMPACT ON HARMS

WP3 will evaluate, using interrupted time series modelling, if changes in alcohol-related ambulance call-outs and crimes have resulted from later opening hours and . Further, we will test for differential impact on specific subgroups (men/women, age-groups, socio-economic deprivation). Finally, we will use Bayesian spatio-temporal models to assess whether the extended opening hours led to significant changes in the timing and location of outcomes. We will make best use of the rich routine data available for these analysis plans by working closely with Scottish Ambulance Service and Police Scotland, with whom we have good working relationships from prior studies [50, 51].

Data Source & Access: Scotland-wide data will be obtained from two separate routinely recorded sources: ambulance call-out data from the Scottish Ambulance Service (SAS) and crimes data from Police Scotland. In response to peer-reviews, we will need national data on (1) exposure (broad licensing-board level data on changes to opening hours) and (2) outcomes (national data on ambulance call-outs and police-recorded assaults) to construct a synthetic control-based analysis of the impact of the opening hours changes (our original research question).

Ambulance Call-Outs: Electronic records of all ambulance call-outs in Scotland (~500,000 per year) are available from Scottish Ambulance Service (SAS) [62]. We have previously sourced this data set for a separate CSO-funded study of minimum unit pricing, and are familiar with the processes involved including the need to put in place an information sharing agreement. For our CSO study, we are collaborating with SAS to develop an algorithm to optimise identification of alcohol-related call-outs using free text entries in call-out records [51]. In pilot work, under an enhanced information sharing agreement with SAS, call-out records were obtained for the first 100

calls after midnight on the first Saturday in May for 2016, 2017 and 2018 where “alcohol” or “drunk” was mentioned in free text records. These records were examined on a case by case basis by Cl Fitzpatrick (a paramedic within SAS) to determine the quality and utility of the free text data for improving identification of alcohol-related call-outs, compared to relying only on the alcohol tick-box or ‘flag’ within each record. This simple strategy (just two words searched for) is our initial algorithm and it performed well - identifying 258 (86%) call-outs which were assessed as being genuinely alcohol-related and 42 (14%) which were not. In comparison, the alcohol ‘flag’ identified only 67 (26%) genuine alcohol-related call-outs and 1 which was not. The initial algorithm identified 191 call-outs (74%) in which the alcohol ‘flag’ was not ticked, and which would have been missed if only the alcohol flag was used. The specificity of the algorithm was improved by excluding records which said ‘not drunk’ or ‘no alcohol’. Our current CSO funded research is further refining this algorithm by identifying an exhaustive list of terms for alcohol, using training and validation data sets and testing performance using sensitivity, specificity, positive predictive value and negative predictive value statistics.

Variables in the ambulance call-out data set include call date, call time, patient age-group, patient sex, patient postcode district¹, alcohol flag, and X/Y location coordinates of incident.

All Police-Recorded Assaults: We held a meeting with Police Scotland’s Violence Prevention and Licensing Co-ordination Unit to discuss the study and have subsequently been in touch with their Academic Research Team. We will obtain anonymised individual crime level data from Police Scotland IT systems for all cities in Scotland to facilitate our synthetic control-based analyses. An information sharing agreement will be put in place to cover a single data request to Police Scotland who will co-ordinate data access for the datasets needed. Available variables include type of crime, postcode of those involved, date and time of crime and X/Y coordinates of crime location.

Data Coverage and Quality: At this stage, we will analyse harms during ‘weekend night-time’ periods, defined as Fridays (after 8pm), Saturdays (before 6am and after 8pm) and Sundays (before 6am) [63], and the time series will run from May 2015 to July 2022. As the research progresses, we will have a more accurate measure of when the additional hours were permitted by the premises and we will change the unit of analysis / outcome measures (see below) accordingly, to cover other days of the week. We will work closely with our contacts in SAS and Police Scotland to understand any data quality concerns and the exact definitions of variables in each dataset. One important consideration for the police data is that information can be added over time as the officer updates an initial report with new information, as it becomes available. If we identify outliers (i.e. time periods with very low or high assault counts) that are due to idiosyncrasies in the data systems, we will use dummy variables in our models to adjust for these at the times they occur. Information for qualitative assessment will include analysis of local licensing board policy statements for 2018-2023 [45].

Unit of analysis: We will consider weekly or 4-weekly totals of weekend night-time events, providing 52 ‘weekly’ or 13 ‘monthly’ observations per year as the unit of analysis. The rationale of this level of aggregation for the analysis is that small/zero counts will be avoided and statistical power is high (see later section).

Primary outcome: Weekly/4-weekly totals of weekend night-time alcohol-related ambulance call-outs.

Secondary outcomes: Weekly/4-weekly totals of weekend night-time ambulance call-outs (all); 4-weekly totals of weekend night-time police recorded-assaults.

Later opening hours intervention exposure variables: different intervention variables are required depending on the statistical model used – see below. Aberdeen covariate will take the value 0 in all time periods before March 2017 and a value between 0 and 1 in all subsequent periods reflecting the proportion of total extra open hours available to the total number of premises with extra hours at the end of follow-up, were they actually permitted. We will calculate the total number of additional person hours available across all premises in a week and take this as a proportion of the maximum number of additional person hours – 127,962, which is the sum of the maximum

¹ Each postcode area is divided into a number of districts which are represented by the numerical portion of each part of the postcode (e.g. postcode district AB10 for the postcode unit AB10 1BF).

additional person hours available per week across all 40 premises. The maximum potential additional person hours for a given venue in a week is calculated by using the formula (additional hours x the number of nights additional hours are permitted to be used in a week x capacity of the venue). For instance, if five premises with capacities of 400, 300, 350, 400, and 260 were permitted to open for two additional hours on both Friday and Saturday in a given week, the maximum potential additional person hours available for that week would be $(1600+1200+1400+1600+1040 = 6840)$. We would then divide this by 127,962 to give an exposure measure of 0.0535 for that week. With this set-up, in the statistical modelling a unit change in the covariate will reflect the change in outcome over time moving towards 'full' exposure to the Aberdeen intervention. Separately, we will conduct a before and after analysis of the adoption of the new policy around later opening hours by using a binary variable for the Aberdeen covariate that takes the value 0 before 21st March 2017 and 1 for all subsequent periods. In Glasgow all 10 nightclubs were permitted to implement extended hours from the same date i.e., 12th April 2019. This will therefore be reflected in our analyses using a dummy variable taking the value 0 for all time periods before 12th April 2019 and 1 in all analyses thereafter.

The information on the opening times in the final group of affected premises will be determined in WP1 and WP2. We expect most effects to be immediate (e.g. ambulance call-outs to acute alcohol intoxication, police records of assaults). Although longer lagged effects are possible we think these are unlikely and, if found, would be harder to attribute to the exposure that occurred a long time ago.

Control selection: We will use a location-based control if we can identify any appropriate control. In a location-based control, different geographical areas with similar features are typically chosen as a control, where the policy or intervention has not been adopted. We will assess the appropriateness of the 30 Scottish councils/cities (except intervention cities, Aberdeen, and Glasgow). The appropriateness of the potential control candidates ($n=30$) will be tested by visually and statistically assessing the assumption of parallel trends. In addition, we will qualitatively assess control cities suitability. For example- we will explore whether other policy changes connected with alcohol premises hours occurred in the control cities, which might limit their suitability. Moreover, we will consider on-premises outlet density, socio-economic, and geographical features to assess control locations/cities' suitability.

National synthetic control: We will examine exposure to changes in relevant opening hours in local authorities to utilise in our synthetic control analyses. This will be done by examination of local licensing policies which state the standard licensing hours in each area and any changes to those over the time period.

Confounding variables: In interrupted time series designs, time-varying confounding is a threat to obtaining a causal estimate of intervention effect [64]. Although we will not know age, sex and socio-economic deprivation distributions for all those at risk of a call-out or assault, it will be important to adjust for these variables if their distributions for call-outs/assaults are different in the pre- and post-intervention periods. We will assess whether any such pre- and post- intervention changes are likely to be caused by the intervention by analysing the data for the control city (if any), and if this is the case, we will be careful not to over-adjust. We will also use a synthetic control approach using Scotland-wide data to support causal attribution. We will also adjust for other interventions identified in WP1 & 2 (e.g. minimum unit pricing albeit the latter affects off-licence prices more than bars/clubs) which we are confident are independent of the policy changes under study. Another potential confounder is disposable income and we will adjust for this using quarterly gross disposable household income data for Scotland [65]. We will also adjust for weather (temperature, and rainfall). Finally, we will adjust for seasonality by testing the model fit of different approaches (e.g. Fourier terms or dummy variables representing the time point of the year each weekly/ 4-weekly period represents).

4.3.1 STATISTICAL MODELLING FOR 3.1 (MAIN ANALYSIS) AND 3.2 (SUBGROUP ANALYSIS) (WILL BE ADAPTED IN LINE WITH SYNTHETIC CONTROL METHOD)

ARIMA (later opening hours): we will fit autoregressive integrated moving average (ARIMA) models with the weekly/4-weekly total counts as the response variables. Such models account for

autocorrelation and underlying temporal trend and we will use AIC/BIC to determine the best fitting ARIMA models. After a best fitting model is determined, we will then add the intervention variables to measure the effect size. There will be **9** modelling approaches in total, summarised in table below. Our primary approach will be discussed and agreed as a team and published in a Statistical Analysis Plan prior to modelling.

Model	Model type	Time series	Policy exposure/ covariate	Type of control
Model 1	Uncontrolled	Aberdeen	Aberdeen (staggered)	None
Model 2		Aberdeen	Aberdeen (binary)	None
Model 3		Glasgow	Glasgow (binary)	None
Model 4	Controlled, Difference in difference (if any suitable control identified)	Differences between Aberdeen and control city	Aberdeen (staggered)	Location-based control
Model 5		Differences between Aberdeen and control city	Aberdeen (binary)	Location-based control
Model 6		Differences between Glasgow and control city	Glasgow (binary)	Location-based control
Model 7		Synthetic Aberdeen (if applicable)	Aberdeen (staggered)	Location-based control
Model 8		Synthetic Aberdeen (if applicable)	Aberdeen (binary)	Location-based control
Model 9		Synthetic Glasgow (if applicable)	Glasgow (binary)	Location-based control

Models 1-9 will be fitted to both alcohol-related ambulance call-outs (primary outcome), and all secondary outcomes. Models 4-9 will utilise a location-based control and will be based on difference in difference technique for generating counterfactuals, while models 7-9 will adopt a synthetic control technique. In accordance with Bernal's recommendation, differences between the primary outcome and location-based control outcomes (i.e., Aberdeen/Glasgow minus (-) control city) will be modelled if any suitable control identified [39]. In order to undertake hypothesis testing on the synthetic control method, non-parametric permutation test will be performed, and 95% confidence intervals will be constructed based on the permutation test's p-values [50,51].

All models will then be further adjusted by adding the confounding variables described above.

Synthetic control (later opening hours): this method will construct a counterfactual by using a weighted average of the outcome variable from a group of control 'units'. The control units will be local authority regions of Scotland (apart from the intervention areas of Aberdeen and Glasgow). Variables that inform the weighted average will be the outcome measured at times before the intervention was in place and other variables (e.g. disposable income, weather (temperature and rainfall) percentage of local authority population residing in highest quintile of socio-economic deprivation, mean age, etc.). An effect is determined by a difference between the post-intervention outcome observed in Aberdeen and Glasgow and the weighted control outcome observed for the same time period. In order to determine more accurate weights for the synthetic control series, we will incorporate population size-adjusted alcohol-related ambulance call-out/crime rates for all regions in Scotland. We anticipate that by utilising population-adjusted rates, the SCM series will yield a closer match to the observed outcomes prior to the intervention.

Subgroup Analyses (later opening hours): In line with previous literature [25, 28], we will also fit models for different strata based on what time of day the outcomes occurred to test for effect modification (e.g., a larger increase in outcome observed between 4am and 6am when premises have closed). The differential impact by age, socio-economic status and sex will be assessed by repeating the primary analysis ARIMA models after stratifying the call-out and assault data, separately, by age, sex and socio-economic deprivation. Subgroup analyses will be conducted for primary and secondary outcomes.

Sensitivity Analyses: A range of pre-specified sensitivity analyses will be conducted. If we deviate from our *a priori* plans we will explain the rationale for doing so in our reporting: *Type of intervention covariate:* the definition above assumes a linear association between exposure to additional hours and outcome. We will test the appropriateness of this assumption by categorisation of the covariate and fitting of restricted cubic splines if appropriate [66]; *Type of counterfactual:* test sensitivity of findings if use location-based control (control city, if any) [67]; *Population size-adjusted rates:* To assess consistency of our findings, we will generate population size-adjusted alcohol-related ambulance call-outs and crimes and then re-run all modelling. *Number of premises exposed in Aberdeen:* we will use the point in time when the policy has implemented at least half 'strengt' (i.e., when the value of the covariate is > 0.5) as the point of policy implementation for the synthetic control series, with a dummy variable taking the value 0 for all time periods prior to this date and 1 for all periods thereafter. We will then re-run models 2, 5, and 8 with this alternative exposure measure. *Level of aggregation:* test the sensitivity of our results if we change the unit of analysis, for example to weekly, fortnightly or 12-weekly counts. A potential benefit of 12-weekly counts is reducing the number of zero / small counts when conducting the subgroup analyses; *Boundary of cities:* test the sensitivity of our results if we narrow the boundaries of the cities. We would expect any intervention effect to be increased if we only include areas in close proximity to where the intervention occurred; *Length of pre-trend series:* test the sensitivity of our results if we bring forward the start of our time series to test how well the underlying trend is being modelled.

Power Calculation: We have obtained a preliminary dataset of ambulance call-outs for May 2016 – April 2018, which confirms the stability and quality of the data. We estimate a pre-intervention mean of 1623 alcohol-related call-outs per 4-weekly intervals, assuming one-third of call-outs at these times are alcohol-related, and 74 and 236 in Aberdeen and Glasgow, respectively. The power estimates below use a power calculator [68] which takes into account autocorrelation in the time series data, where appropriate (our pilot analyses showed that there was no statistical evidence for autocorrelation at 4-weekly and 2-weekly aggregation levels, but an estimate of 0.2 was observed at the weekly level), and are for the weekend night-time period.

We obtained power estimates for combinations of 'intervention' (Aberdeen, Glasgow, and both cities combined) and level of aggregation (4-weekly, 2-weekly and weekly). We present the power results in terms of the minimum effect size (MES) able to be detected at 80% power with (two-tailed) Type 1 error at 5%. In Aberdeen, Glasgow and both cities combined the MESs we are powered to detect are in the ranges 7.0-11.4%, 5.0-7.0% and 4.6-6.6%, respectively (the range reflects the estimates at different levels of aggregation). Comparing these effect sizes to the existing literature [25], it is very likely we have more than sufficient statistical power.

For subgroups, the pilot data we have obtained does not include sex and socio-economic deprivation but does have age recorded. Below we provide MESs for subgroups of age (same categorisation as de Goeij's study from Amsterdam [25]). In Aberdeen, Glasgow and both cities combined the MESs we are powered to detect in under 25 year olds are in the ranges 17.3-19.4%, 13.3-14.0% and 11.1-12.7%, respectively. In Aberdeen, Glasgow and both cities combined the MESs we are powered to detect in 25-34 year olds are in the ranges 19.3-23.0%, 14.2-16.5 and 12.1-15.0%, respectively. In Aberdeen, Glasgow and both cities combined the MESs we are powered to detect in 35-44 year olds are in the ranges 21.4-24.4%, 10.8-18.5% and 10.7-16.6%, respectively. In Aberdeen, Glasgow and both cities combined the MESs we are powered to detect in 45 year olds and above are in the ranges 10.8-15.0%, 8.1-9.3% and 7.7-8.7%, respectively. As for the overall power estimates above, these effect sizes that we are powered to detect at the 80% level compare favourably with the existing literature.

5.3.3 PATTERNING OF HARMS OVER TIME

Assessing changes in spatio-temporal patterns of harms will enable us to establish how the distribution of harms relates to the distribution of venues and the extent to which the interventions in Glasgow and Aberdeen have changed this distribution in each city or across each local authority area. Results from this analysis, taken alongside the results of the time series analysis (section 3.1) will illustrate whether extending opening hours is associated with a change in the spatial distribution of harms over and above any change in their overall level.

- The spatio-temporal distribution of alcohol premises, ambulance call outs and crimes will be assessed by modelling the number of premises/call outs/assaults, in each area and each time period using a Poisson regression with a log link [70]. The geographic units of analysis (e.g. postcodes/data zones) and the time periods (e.g. monthly/quarterly/yearly) will depend on the number of incidents in each unit and period so as to ensure sufficient sample size is available for each outcome.
- In addition, Bayesian space-time models [71–74] will be fitted to model alcohol-related ambulance call outs and police-recorded assaults committed in the study period. In addition to demographic confounding variables, these models will include a variable reflecting the number of additional opening hours for premises within each area at each time point. These models will enable assessment of any significant spatial, temporal, or spatio-temporal (interaction) effects that explain variation in call-outs such as longer term trends and/or intervention effects.
- We will further explore the existence of more complex effects and interactions, such as non-linear temporal effects and interactions between neighbouring geographical units, by fitting BYM (Besag, York & Mollie) [75] and Conditional Autoregressive (CAR) models [76].

All models will be implemented in Winbugs and R, and goodness of fit will be assessed using the Deviance Information Criterion [77].

This analysis will allow us to label areas within the 3 study areas as having increasing, decreasing or stable rates of ambulance callouts and/or recorded assaults. We will also be able to identify hotspots and cold spots for alcohol-related harms and assess whether these have changed following the policy change.

4.4 WORK PACKAGE 4: EVALUATING ECONOMIC IMPACT

WP4 will evaluate the economic impact of the policy changes of the later opening hours by conducting a cost consequence analysis from a broad societal perspective.

4.4.1 ECONOMIC IMPACT ON NHS AND POLICE SCOTLAND

An economic analysis will be designed and conducted building directly onto WP3 in line with our recent guidance “*A Framework for conducting economic evaluations alongside natural experiments*” [44]. Using any measured differences in quantity of resource use from WP3, including alcohol related ambulance call outs, and police recorded assaults, we will attach published unit costs to these resource quantities to value the total cost impacts.

Health Services Economic Impact: We will use the ambulance data from WP3 above.

Ambulance call outs, subsequent A&E visits and related hospital admissions will be valued using existing national reference costs and Scottish Health Service cost data [78, 79]. Scotland Costs Book, NHS Scotland, providing unit cost data for ambulance services according to the ambulance service types (e.g., A&E, patient transport service, ambulance car service, and patient air transport service), A&E attendance, and hospitalization in Scotland.

The findings of WP3 will be used to calculate the total cost differences arising for the NHS as a result of the policy changes in each city (Aberdeen and Glasgow).

Police Economic Impact: A similar approach will cost the impact of the policy changes for our secondary outcome on police-recorded assaults if data on outcomes (no further action, prosecution, conviction, etc.) are available. Data will be available for each city from Police Scotland. Costs associated with police-recorded assaults relate to three main cost areas: costs in anticipation of crime, costs as a consequence of crime, and costs in response to crime [46]. The crime costs will be valued using nationally available sources including ‘New Economy’ including

Home Office/Government costs, estimates of fiscal, social and economic values will also be identified [80].

Synthesis and Reporting: An economic evaluation alongside a natural experiment will be conducted to evaluate the economic impact of two policy changes by conducting a multi-framework economic evaluation including a cost-effectiveness analysis (CEA) framework for the primary outcome (ambulance call-outs) using a health care perspective and a cost consequences analysis (CCA) for the primary and secondary outcomes from health care and criminal justice system perspective. An economic evaluation logic model will be developed, building on the main study systems map. Outcomes will be reported in terms of 'consequences' in line with a cost-consequences analysis (CCA) framework recommended by NICE for reporting public health economic evaluations [82]. CCAs have been recommended for complex interventions that have multiple effects that are difficult to measure in a common unit. In line with a systems approach, the economic evaluation will report from a number of differing perspectives including a broad perspective incorporating societal impacts (crime sector); NHS perspective (hospital and A&E) and will draw on evidence from WPs 1&2 to assess, and if possible estimate, the likely impact on local businesses. The economic evaluation will also describe the opportunity cost of any increased extended hours-related hospital admissions in relation to already-existing increases in admissions due to winter seasonality. This way, the true resource impacts of extended hours and any associated displacement will be explored as they affect the hospital system.

4.5 WORK PACKAGE 5: EVALUATING IMPACT ON INEQUALITIES, LONG-TERM NHS COSTS, AND FOR OTHER UK CITIES

WP5 will provide an overview of the current approaches and developments in relation to late-night trading hours, through the analysis of statements of licensing policy from across England, Scotland and Wales. It will make use of new local Sheffield Alcohol Policy Models (SAPM) for Glasgow and Aberdeen to estimate the longer-term impacts of the policy changes on public health and related costs building on WPs 3 & 4. These analyses will also enable appraisal of the potential impact of the changes on socioeconomic inequalities in health. Finally, an EOI process will be used to select additional LAs for which SAPM models will be created, to model the potential impact of similar changes in late night licensing hours in those LAs and inform their decision-making.

4.5.1 LOCAL AUTHORITY

In order to inform and contextualise the findings from WPs 1-4 and their implications for local policy making, both within Scotland and across the rest of the UK, it is important to understand the extent to which changes in licensing hours feature in current LA decision-making and plans. We will examine all statements of licensing policy across England, Scotland and Wales to identify common practices and innovation in how different local licensing authorities interpret and implement current laws and guidance in relation to opening hours of licensed premises.

4.5.2 LONGER-TERM OUTCOMES MODELLING AND IMPACT ON INEQUALITIES

The focus of the outcomes analysis in WP3 is on the immediate harms of drinking and intoxication, as they impact on alcohol-related ambulance call-outs and assaults, however this represents only a small proportion of the total estimated burden of harm that alcohol places on health [83]. Further, for many chronic alcohol-related health conditions it can take several years for the full impact of a change in alcohol consumption to be realised as a change in harm rates [84]. In order to extend the analyses in WP3 and WP4 to account for these longer term harm outcomes we will develop new versions of SAPM, a highly sophisticated and influential policy appraisal tool [85], for Glasgow and Aberdeen cities.

As part of the ongoing NIHR-funded ExILENS study led by Fitzgerald [45], the University of Sheffield have developed LA-level versions of the latest version of SAPM (v4.0) for LAs in both Scotland and England. These models account for existing local patterns of both alcohol consumption and harm as well as sociodemographic differences between areas. SAPM synthesises this data, alongside evidence on the relationships between alcohol consumption and harm from a wide range of international epidemiological evidence, to estimate the impact of

changes in alcohol consumption on rates of mortality and morbidity for 45 different alcohol-related health conditions [86].

These new models will incorporate the latest available data on alcohol consumption and harm, but will also go beyond existing versions of SAPM in three key ways. Firstly, we will bring together data from WP2 and existing drinking-occasion level surveys such as the National Diet and Nutrition Survey and Kantar Alcovision, a large-scale market research survey, to estimate the characteristics of the individuals drinking in the late-night establishments affected by the interventions. This will allow the development of more refined estimates of the distribution of the intervention's impact on alcohol consumption across the population. Secondly, we will review context-specific evidence from key peer-reviewed studies, about links between occasion-level alcohol consumption and acute harm outcomes, particularly ambulance callouts and assaults to align with the outcomes examined in WP3, to develop new models which account for the setting of a drinking occasion in estimating the associated risks of harm. Thirdly, we will incorporate new evidence from WP4 on the costs associated with these harms in order to produce more comprehensive estimates of the longer-term NHS and societal cost impacts of the interventions. The new models for Glasgow and Aberdeen will be calibrated against the results of the WP3 analyses which stratify outcomes by population subgroups in order to ensure that the short-term estimates from the models align with the observed changes in acute outcomes within each group.

The resulting set of models will enable a detailed appraisal of the impact of the policy changes on alcohol consumption and longer-term health and associated costs and how these impacts vary across population groups. This analysis will also allow an assessment of the potential impacts of late-night licensing hour changes on socioeconomic inequalities in health, arising through differential patterns in exposure to the intervention as well as differential rates of harm outcomes.

4.5.3 PROSPECTIVE MODELLING FOR OTHER UK LOCAL AUTHORITIES

Finally, we will develop additional new SAPM models for a selection of key LAs including the control city (Edinburgh). Other LAs will be selected based on their interest in implementing potential restrictions on late-night licensing hours, and in discussion with the research team. We will disseminate information about our proposed prospective modelling through the UK Licensing and Public Health Network and Scottish licensing contacts and request expressions of interest from local authorities. We will then use these new models to appraise the potential impacts on alcohol consumption, harm, inequalities and associated costs, should these LAs implement similar policies to those in Glasgow and Aberdeen. These results will provide direct, local evidence to support evidence-based policy making in these local authority areas.

5. PUBLIC INVOLVEMENT, IMPACT & DISSEMINATION

Public involvement: NHS licensing leads for Glasgow (Elaina Smith, CI) and Aberdeen (Tara Shivaji) will be co-investigator and advisor on the study respectively. We will meet with Licensing Forums (groups established by statute to advise licensing committees in Scotland - see Box 1 above) at study start and end, and as needed throughout (see letters of support). We will establish two public involvement groups, one for each city, to consult with members of the public (e.g. patrons and local residents) and meet with them bi-annually. These groups should include representatives from the local police, NHS and council.

Impact: Our findings will inform decisions, practices, policies and laws on hours of trading for licensed premises for public health, police, licensing stakeholders, devolved, UK and international governments as well as service planning for areas where a decision is made to extend opening hours. Impact will be generated in three ways: (i) generating new knowledge, (ii) informing local licensing practice and policy; and (iii) informing future licensing legislation in the UK and abroad.

First, this study will produce (i) new knowledge about the impact of late-night alcohol trading on health harms and outputs in the academic literature, which will feed into future synthesis and systematic reviews and form a robust basis for other impact. We will publish peer-reviewed publications of our findings, including papers drawing on data from across WPs to answer our research questions 1-7 above. We will press release papers as appropriate, with accompanying social media dissemination using a custom animation and infographic for our main findings if

appropriate. Our data will inform theory on the system-wide effects of opening-hours changes, and our study will provide a template for future studies taking a systems perspective.

The findings of our study will be immediately relevant to (ii) informing local licensing practice & policy, not least in licensing in Glasgow and Aberdeen and we will have a close working relationship with licensing authorities throughout the study. We will share our findings with the Licensing Board and Forums in both cities in advance of publication to enable them to make an early decision about any expansion or reversal of changes in licensing hours. We will develop policy briefings/an infographic to effectively and succinctly communicate the findings to non-academic audiences. Alcohol Focus Scotland (who are represented on our advisory group) host regular knowledge exchange events in Scotland for local teams, will incorporate findings into their annual licensing conferences, publishing licensing toolkits and resources, and a monthly e-newsletter. They support us to disseminate the findings and incorporate them into ongoing training and resources to reach other licensing authorities and public health stakeholders across Scotland. Our data will also be very relevant to local policy and practice in England and Wales. For example, Home Office data show a 16% increase in premises with a 24-hour licence in England from 2008-2017. WP5 will provide city-specific modelled outcome findings for other cities considering similar changes, directly informing their decision-making. Our links with Public Health England (PHE) and Wales (PHW) are excellent through previous licensing research [45, 87] and we will make use of these to disseminate the study findings to local teams. We are also members (Fitzgerald, Angus) of the National Public Health and Licensing Network, Fitzgerald is on the steering group. Both organisations will disseminate study news/requests through established mechanisms.

Our findings will also inform (iii) licensing legislation and related guidance. Three teams at Scottish Government have expressed support for this study (see letter attached): the Alcohol Policy Team, the Violence Reduction Team and Justice and Analytical Services. We would expect our findings to inform future decision making on amendments to licensing legislation or the guidance accompanying the Licensing Act (Scotland) 2005, as well as national violence prevention strategies. We will send findings directly to MSPs and MPs on relevant committees/cross-party groups in Scotland and other UK administrations. Internationally, several countries have locally-led systems of premises licensing and ongoing debates (Australia, Norway, California) about extensions to hours [27, 88–90]. We will disseminate our findings at the Kettil Bruun Society and the Global Alcohol Policy Conference as well as via the World Health Organization, with whom we (NF, CA) have strong links.

6. MANAGEMENT, GOVERNANCE & ETHICAL APPROVAL

6.1 PROJECT MANAGEMENT

NF will manage the project (15%) and will lead WP1, with support from a Research Fellow (30%) who will oversee the day to day data collection for WP1, support the Stirling RA, oversee the survey for WP5, monitor the day to day progress of all WPs, and plan and prepare with NF for team meetings. NF is an experienced PI and will keep in regular contact with the named research manager from the Public Health Research programme at NIHR. In addition, progress reports will be submitted on the milestones identified in Table 1 above at six monthly intervals. AM will set up and manage the PPI groups for the study and the study steering committee, and will support WP1 and 2. CE will lead WP2, support WP1, and manage a GCU RA. JL and EM will lead WPs 3 and 4, with DF providing expert paramedic input and linking with SAS, Dr. Ines Henriques-Cadby leading on the spatiotemporal analysis, and an RA. Finally, CA will support WP3 and 4, and will lead WP5 with support of NF and an RA. Dr. Manuela Deidda (lead author of relevant guidance [44]) will provide in-kind support to WP4. WP subgroups will meet regularly (at least monthly) to monitor progress and report to NF. The full study team will meet quarterly with Sheffield colleagues joining by video conference for half the meetings (and otherwise in person if possible).

6.2 STUDY STEERING COMMITTEE

An advisory group has been assembled, consisting of individuals from academia, policy and NGOs and will provide support throughout the study: Prof. Linda Bauld [chair], Usher Professor of Public Health, University of Edinburgh; Prof. Niamh Shortt, Professor of Health Geographies, University of

Edinburgh; Dr. Ingeborg Rossow, Senior researcher, Department of Alcohol, Drugs and Tobacco, Norwegian Institute of Public Health; Prof. Peter Miller, Professor of Psychology, Deakin University; Prof. Jennie Connor, Chair in Preventive and Social Medicine, University of Otago; Prof. Kathryn Graham, University of Toronto; Andrew Fraser, Former Licensing Clerk/Head of Democratic Services, North Ayrshire Council; Shamini Omnes, Convener, Aberdeen Local Licensing Forum; Dr. Tara Shivaji, Consultant in Public Health, NHS Grampian; Jim Sherval, Consultant in Public Health, NHS Lothian; Maria Smolar, Programme manager, Health Improvement: Drugs, Alcohol and Tobacco, Public Health England; Dr. James Ward, Medical Director, Scottish Ambulance Service; Laura Mahon, Deputy Chief Executive, Alcohol Focus Scotland; Elaine Gordon, Sergeant, Violence Prevention & Licensing Co-ordination Unit, Police Scotland; Senior data analyst, Police Scotland (see letter); PPI Representative (to be recruited).

We will hold a face to face meeting of the advisory group around month 3, with international colleagues joining by Zoom video conference. Other advisory group meetings will be held every six months in year one and then at the discretion of the advisory group chair (at least annually).

6.3 ETHICS/REGULATORY APPROVALS

Ethical review will be undertaken by the University of Stirling and Glasgow Caledonian University Ethics Committees and approval obtained prior to any fieldwork commencing. The project will comply with the Economic and Social Research Council's (ESRC) research ethics framework. Full informed consent will be obtained separately from participating venues and individual interviewees. Each area will be assigned a code, with identifying data anonymised. NHS REC approval will not be required, but NHS R&D approval from the local health board and/or Scottish Ambulance Service will be needed to interview NHS staff. Outcome data will be obtained from prior data sets which will already be anonymized, aggregated and (where necessary) censored at absolute values lower than 5 to ensure that individuals cannot be identified. All interview data will be recorded, transcribed and then anonymised. Data, recordings and transcripts will be held in confidence, stored securely and destroyed in accordance with GDPR and University procedures.

7. TEAM TRACK RECORD & EXPERTISE

This team has worked closely together on several similar mixed-methods studies: ExILeNS: public health influence on licensing [45] NIHR-funded (NF, CA, AM); Under the Limit: Scotland's lower drink-drive limit [50, 91] NIHR/CSO (NF, AM, JL, EM, CE); IMPAACT: minimum unit pricing impact on ambulance call-outs CSO (NF, CA, AM, JL, DF) and the SPECTRUM Consortium (NF, CA).

FITZGERALD (Stirling, 15%FTE), Prof of Alcohol Policy, PI, WP1 lead. NF leads the ExILeNS, IMPAACT and Under the Limit, is SPECTRUM Deputy Director for Impact, and has an international reputation. An RF (Stirling, 30% FTE) will support NF with reporting/management, conduct of senior interviews for WP1, co-analysis of qual data for WP1&2, and supervision of the Stirling RA. MOHAN (Dundee, 10%FTE) will lead PPI for the study (building on her experience with a long-standing alcohol research PPI group at Stirling), and will manage the study steering group. EMSLIE (GCU, 10%FTE), WP2 Lead, will support WP1, manage the GCU RA and field staff. CE is an internationally recognised experienced social scientist and has a track record in gender & alcohol/qual research. LEWSEY (Glasgow, 5%FTE), Prof. of Medical Statistics, WP3 lead, will manage the Glasgow researcher with EM. JL is a chartered statistician with 20+ years' relevant experience. NF & JL will work closely as on other studies to maximise synergies between the qual & quant WPs. HENRIQUES-CADBY (IHC, Sheffield 50% for 3 months), Research Associate, will lead the Bayesian spatiotemporal analysis in WP3. IHC is an MRC skills development fellow in the spatial epidemiology of alcohol availability, consumption and harms. MCINTOSH (Glasgow, 5% FTE), Prof. of Health Economics, will lead WP4. EM has 25+ years' experience leading the health economics components of clinical trials and natural experiments. ANGUS (Sheffield, 5%FTE for 18 months then 10%), Senior Research Fellow, Senior Modeller for SAPM, will lead WP5 and manage the Sheffield RA. CA has led numerous high profile appraisal studies of alcohol policies in several countries inc. Scotland. FITZPATRICK (Stirling, 3% FTE), Senior Lecturer, practising paramedic, will liaise with SAS, advise on analysis and interpretation of call out data. SMITH (NHS GGC, 10%FTE), health lead for alcohol licensing in Glasgow City and Renfrewshire, will lead stakeholder

mapping, collate licence application documentation and provide expert insight into local licensing processes.

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