EVALUATING LATER OR EXPANDED PREMISES HOURS FOR ALCOHOL IN THE NIGHT-TIME ECONOMY (ELEPHANT): A MIXED-METHODS, NATURAL EXPERIMENT EVALUATION (Revised 03.02.21)

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Changes since last version: Addition of adaptations to focus and methods of study due to COVID-19.

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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 noncommunicable 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 latenight 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 <u>actors</u> and their <u>environments</u> [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 callouts 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 alcoholrelated ambulance call-outs (primary outcome), drug-related ambulance call-outs, 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 will interview venue staff and review venue's social media feeds [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 discussd 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:
 - 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)
 - RQC2: How have closures, curfews and other restrictions during COVID-19 been associated with alcohol-related harms (ambulance call-outs & police-recorded assaults)? (Quantitative)
- We will consider RQC1 in all of our qualitative work; and will add an additional descriptive analysis to WP3 for RQC2. If possible, we will carry through the findings of RQC2 into WP4 and 5.
- **WP1:** We will include a broader range of national stakeholders in our interviews in WP1 to better consider RQC1.
- **WP2:** We will add a new strand of data collection to WP2, focusing on public consultation on RQC1 and on opening hours and trading conditions and behavioural intentions in relation to licensed premises post-COVID-19. We will postpone venue observations until 2022, and at that time review the likely value of and capacity for additional staff interviews.
- **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 but with additional analysis related to RQC2 if appropriate and feasible. WP5 will include additional questions relating to RQC1 in the local authority survey.

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

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 le	vel (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 lev	el (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 and the nature of local authority level COVID-19 restrictions at in Scotland to support RQC2. 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 ~20 venues by trained sessional fieldworkers working in pairs using validated instruments. Postponed until 2022, review late 2021 to see if still feasible.	16-28
To explore public views. Replace for now with 'To explore public views on the role of the licensed premises in the NTE post-COVID-19'.	Recruit interviewees (bar/ club staff) during observations of venues. Semi-structured individual interviews with ~30 frontline bar and security staff in Glasgow and Aberdeen. Conduct fieldwork (i.e. deliberative focus groups or citizens' juries) with members of the public in 2021. Sample etc. TBC.	12-19
To analyse for RQs 1-3 & RCQ1 and synthesise data to feed into WP3 and 4.	Collation of aggregate later opening hours and local authority level COVID-19 restrictions for WP3 exposure measure. Descriptive analysis of observation data. Thematic analysis of interview data using framework approach including business practices and consumer profiles for WP4 and 5. Comparison & triangulation with WP1.	8-30
WP3: Evaluating Impact on Harms (JL, IHC (na	med 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 (including algorithm development to identify drug-related call-outs). Data manipulation using statistics software. Close working with WP1 & 2 to define policy change variables i.e. exposure in each city and nationally for RQC2	1-16
To identify if the extended opening hours led to changes in primary and secondary outcomes.	ARIMA and Poisson / negative binomial models (including subgroup analyses and sensitivity analyses).	11-26
To describe patterns in primary and secondary outcomes associated with changes in trading	Descriptive time series analysis. ARIMA and other models if data allows.	6-16

conditions for licensed premises during the COVID-19 pandemic (RQC2)		
To assess whether the extended opening hours (or COVID-19 restrictions where feasible) 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, Glasge	ow 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 (and if feasible, COVID-19 related) policy changes.	Use existing published sources of reference costs. Using unscheduled care datamart, calculate costs of alcohol-related ambulance call-outs based on outcome of call, and average 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	Development, piloting and distribution online survey of local authority areas (via Public Health Teams and local authority licensing authorities). Analyse findings to identify cities most likely to benefit from prospective modelling (Section 4.5.3) and to contribute to answering RQC2.	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 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	30-36
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.	32-36

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, rationale and arguments relating to the policy changes will be analysed using the <u>Framework</u> 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; 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. We will also explore RQC1 with all stakeholders including national stakeholders added above and local authority staff with an interest in community development, planning and health;

- Local authority licensing stakeholders (convenors, clerks, forum chairs, LSOs, see Box 1 above) and night-time economy managers; the rationale for the change, how it came about, and views on success/challenges and mechanisms of impact (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.

• 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.

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, alcohol promotions, 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 examine the implementation of any changes in venue operation, directly observe clientele and staff behaviour, and explore the experiences of bar and security staff of the change in opening hours. 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.

COVID-19 restrictions on licensed premises at local authority level: With the support of WP3/4 team, we will map the restrictions on licensed premises at local authority area over the full pandemic period (March 2020 to June 2021, and further if possible/appropriate) to establish an exposure measure around licensed premises trading hours for each local authority over time. If possible we will also establish the extent to which by-laws preventing drinking in public applied within local authorities over the same time period.

4.2.2 REPEATED VENUE OBSERVATIONS (POSTPONED, TO BE REVIEWED LATE 2021)

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]. Access to venues will be facilitated through the Licensing Forum in both cities, drawing on our experience in previous projects, e.g. [50]. Our intention is to seek permission from venues to carry out observations, and then for our fieldworkers to covertly 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 venues via licensing forums and our ethics committee.

Recruitment & Training of Field Staff: We will recruit 8 field researchers from existing pools of sessional staff (who have collected data from injecting drug users on a national study or have worked on the Scottish Gay Men's Sexual Health Bar Survey which has successfully maintained the safety of fieldworkers in bars and clubs over seven sweeps). 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 mixed gender pairs, have costed for taxis for fieldworkers' travel and will provide a clothing budget to ensure fieldworkers 'blend in' as much as possible in each venue (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 approximately half (n~20) of the relevant venues in both Glasgow and Aberdeen, selected for variety. Observations will be recorded on mini tablet devices/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 up to ~24 months after the policy change. The final observation items will be decided in consultation with the study advisory group, the PPI groups and the licensing forum in each city, and initial visits without formal observation. 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). For quantitative items, we will conduct inter-rater reliability tests between fieldworkers, produce frequency counts, and use descriptive statistics to assess differences (e.g. between different venue types). 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 INTERVIEWS WITH BAR/CLUB STAFF (POSTPONED, TO BE REVIEWED LATE 2021)

Sampling and Recruitment: We will conduct confidential face to face semi-structured interviews with frontline serving and security staff (in post prior to the changes) from observed venues (as above) to explore their experiences of the trading hours changes (n-30, \sim 30mins). We will use convenience sampling but seek to include staff in different roles from a variety of venues in the two cities. We will speak with potential interviewees during venue observations, but will follow up by telephone to explain the study, seek informed consent and arrange a convenient location and time to conduct the interview. Interviewees will be given a £30 voucher to thank them for participating.

Interview Topics: We will explore how bar / club staff view and manage any changes in venues, and their perceptions of any change in patrons' behaviours. Following similar studies [61], we will begin with a general discussion about the change in opening hours and then ask participants to describe their observations and experiences from the period before, immediately after, and longer term after the change. Follow up questions will include views on any changes in their own working hours and conditions, effect on business, monitoring and managing patrons, patron safety and perceptions of any changes in consumption of alcohol and other drugs.

Analysis: Interview data will be handled as for WP1. Findings about impact on business operation will feed into WP4.

RQC1: CONSULTATION WITH THE GENERAL PUBLIC (ADDED IN FOR 2021)

Sampling and Recruitment: We are currently working on a sampling strategy for public consultation and further detail will be added here in due course. We are considering deliberatiave focus groups or citizens' juries and will make a final decision on which to take forward in summer 2021 when the WP2 RA is in post and we have attended online training on citizens' juries. **Discussion topics**: public views on licensed premises opening hours, impacts on consumer behaviour, health and communities, the local economy and services, and potential policies that might apply to licensed premises post-COVID-19.

Analysis: Data will be handled as for WP1.

4.3 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 a) later opening hours and b) closures, curfews and other restrictions during COVID-19. 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 (or COVID-19 restrictions where feasible) 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: Data will be obtained for the local authority areas Aberdeen City, Glasgow City and Edinburgh City. Edinburgh will be used as a control city because it is also a Scottish city with a population size between that of Aberdeen and Glasgow, and our pilot work has shown there were no policy changes in late night trading hours in Edinburgh over the study period. National data will also be needed for two purposes. Firstly, in response to peer-reviews, we will need national data on (1) exposure (broad licensing-board level data on changes to opening hours outside of the three above cities) 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). Secondly, we will require national data to describe and if possible analyse any possible association between COVID-19 restrictions on licensed premises trading at local authority level in Scotland and outcomes at local authority level.

Ambulance Call-Outs: electronic records of all ambulance call-outs in Scotland (~500,000 per year) are available from Scottish Ambulance Service (SAS) and ISD Scotland unscheduled care datamart (UCD) [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 CI 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.

For the secondary outcome of drug-related call-outs, we will also not rely on the available drug 'flags' but develop a simple algorithm using the most common terms that identify the call-out as being drug-related. Variables in the ambulance call-out data set include call date, call time, patient age, patient sex, patient postcode district¹, alcohol flag, drug flag and crew count.

We have costed for the extraction of the data by SAS (who will apply the algorithm to the free text data to identify alcohol-related ambulance call-outs) and for ISD to match the identified alcohol-related call-outs to records in the Unscheduled Care Datamart (UCD) to enable more accurate and complete cost analysis for WP4.

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).

<u>All Police-Recorded Assaults:</u> 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 on all police-recorded assaults, from the three separate Police Scotland IT systems for the cities of Aberdeen, Glasgow and Edinburgh and nationally as described above to facilitate our synthetic control-based analyses and RQC2. 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 crime reference number, type of crime, age, sex and 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 last month available with complete data. For later opening hours exposure analyses, the data coverage will end in March 2020. As the research progresses, we will have a more accurate measure of a) when the additional hours were used by the premises and b) the dates of closures / restrictions due to COVID-19 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.

<u>Unit of analysis</u>: 4-weekly totals of weekend night-time events (or night-time events for other days of the week in line with when premises are using their additional permitted hours / COVID-19 closures and restrictions if they can be reliably identified) providing 13 'monthly' observations per year. 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).

<u>Primary outcome</u>: 4-weekly totals of weekend night-time alcohol-related ambulance call-outs (or night-time alcohol-related ambulance call-outs for other days of the week in line with when premises are using their additional permitted hours / COVID-19 closures and restrictions). <u>Secondary outcomes</u>: 4-weekly totals of weekend night-time alcohol-related ambulance call-outs (fatal): note: available by UCD linkage to death records and defined as deaths within one week of call-out; 4-weekly totals of weekend night-time ambulance call-outs (all); 4-weekly totals of weekend night-time drug-related ambulance call-outs; 4-weekly totals of weekend night-time police recorded-assaults. In all cases we will analyse outcomes for other nights of the week in line with when premises are using their additional permitted hours and to reflect COVID-19 closures and restrictions, where feasible and appropriate.

Later opening hours intervention exposure variables: (we refer to the policy change as an 'intervention' here to keep in line with the methodological literature, even though we are evaluating whether this change in policy is detrimental to public health); 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 December 2018 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 open. For example, in any given 4weekly period the total amount of extra time available is 480 hours in 30 premises if WPs 1&2 reveal that additional hours are only utilised on Friday and Saturday nights in Aberdeen (~30 premises x 4 weeks x 2 nights x 2 additional hours). If we find in 4-weekly periods that an additional 160, 240, 320 hours of opening occurred then the covariate would take the values of 0.33, 0.5, 0.66, respectively. 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. Following the same approach, a Glasgow covariate will be constructed. Further, an Aberdeen + Glasgow covariate will be constructed to facilitate modelling where Aberdeen and Glasgow data are combined. The information on the actual 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) but lagged effects are possible (e.g. sexual assault reporting). We will test for interventions at lag 1

(e.g. outcomes occurring after 'exposure' in the previous 4-weekly period). 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.

National synthetic control: We will examine exposure to changes in relevant opening hours in local authorities outside of the above three 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.

National COVID-19 policy exposure: We will assess opening hours and alcohol availability across Scotland during the pandemic using government announcements regarding COVID-19 restrictions to examine local authority-level changes in opening hours/curfews for licensed premises, alcohol sales on premises (e.g. bans on indoor alcohol sales), and closures of premises (such as local closures in Aberdeen City in August).

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 (Edinburgh), 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. drink promotions, 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]. 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 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 AND TO ANSWER RQC2)

1) synthetic control based analysis of original outcomes; 2) descriptive and if possible statistical analysis of associations between local authority level restrictions on trading during the pandemic and our outcome measures to answer the new RQC2 above.

ARIMA (later opening hours): we will fit autoregressive integrated moving average (ARIMA) models with the 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 6 modelling approaches in total: model 1: Aberdeen covariate fitted to Aberdeen time series; model 2: Glasgow covariate fitted to Glasgow time series; model 3: Aberdeen + Glasgow covariate fitted to combined Aberdeen and Glasgow time series: model 4: Aberdeen covariate fitted to Edinburgh time series; model 5: Glasgow covariate fitted to Edinburgh time series; model 6: Aberdeen + Glasgow covariate fitted to Edinburgh time series. Models 1-6 will be fitted to both alcohol-related ambulance call-outs (primary outcome), and all secondary outcomes (fatal alcohol-related call-outs, all call-outs, drug-related call-outs and assaults). Models 4-6 will provide estimates of the counterfactual to bolster the causal inference, i.e. if we observe effect sizes of similar magnitude in Edinburgh compared to Aberdeen and Glasgow then we cannot say the intervention has a causal effect on outcomes. Further, a different type of counterfactual will be provided by modelling all outcomes for days where it is known the additional hours were not used (models 1-3 will be run with these response variables). 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. 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. Although formal statistical inference cannot be performed with synthetic controls, falsification tests (placebo analysis) can accompany graphical presentation of results.

ARIMA (COVID-19 closures/restrictions): this will proceed as the ARIMA described above with these differences: a) the time series will be for whole of Scotland, b) only one modelling approach with one covariate to reflect the national COVID-19 policy exposure.

Poisson/negative binomial (later opening hours): panel data sets will be created by splitting each 4-weekly count into strata formed by combinations of agegroups, sex and socio-economic deprivation quintiles. Poisson models will be fitted with a variable representing time period (to adjust for temporal trend), and the intervention variables described above. Any confounding effect will be assessed by comparing these models to models additionally adjusted for age, sex and socio-economic deprivation. We will test for over-dispersion in the Poisson models and fit negative binomial models if appropriate.

Poisson/negative binomial (COVID-19 closures/restrictions): this will proceed as the Poisson/negative binomial described above with this difference: another strata will be formed based on local authority area. This will allow variations in closures/restrictions in terms of what was done and the timing to be reflected in the modelling.

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. In addition, the Poisson / negative binomial models fitted to the panel data sets will allow the inclusion of interactions between the intervention variables and age/sex/socio-economic deprivation and so obtain p-values associated with null hypotheses of no effect modification. 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 statistical model:* test sensitivity of findings if use ARIMA or Poisson / negative binomial modelling – already described above; *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 (Edinburgh) or control outcome (weekday events) [67]; *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 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.

Additional data source - Innkeeper: Through Police Scotland, we will also have access to data from the 'Innkeeper' national licensing system [69] which contains data on every bar/club licensed to sell alcohol in Scotland. This data provides extra contextual information for crimes (already recorded in the police-data) which are linked to licensed premises. Innkeeper records crimes if they occur inside premises, including if they continued outside, or if crimes happened directly outside premises. Variables included are date and time of crime, whether or not door staff were on duty, and crime reference number (allowing linkage back to main crime records – see above). Further, the walking distance between premises and crimes (e.g., sometimes a crime at some distance away has been explicitly connected to events at a premise) will be calculated using routing algorithms. We will further explore the utility of these data, particularly for triangulating data from venue observations, for spatio-temporal patterning (see 5.3.3) and economic analysis (WP4).

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 different policy changes have changed this distribution in each city or across each local authority area during the COVID-19 pandemic. 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 nonlinear 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 (both the original opening hours and changes, and subject to capacity and data, the COVID-19 level restrictions at local authority level, RQC2) by conducting a cost consequence analysis from a broad societal perspective. The feasibility of national analysis relating to RQC2 will be reviewed in late 2021.

4.4.1 COST-CONSEQUENCES ANALYSIS OF 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/drug 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, linked and anonymised via a safe haven with the ISD Scotland Unscheduled Care Datamart (UCD). The UCD was set up in Scotland to gain more of an understanding of the interaction between unscheduled care services and the patient journey. UCD data provides 'bottom up' resource use information on A&E attendances, acute Emergency, inpatient admissions, NHS 24 calls, primary Care Out of Hours Services, SAS incidents and deaths. Accessing these data provides a valuable opportunity to triangulate our other resource use data sources whilst providing additional detail on other NHS services and mortality. 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]. The linked UCD data will be used to calculate the total cost of each alcohol-related ambulance call-out in the dataset including the cost of any follow-on health service usage. This will be used to calculate the most robust estimate to date of the average cost to the NHS of care relating to an alcohol-related ambulance call-out, before and after the policy changes in each city. The findings of WP3 will then be used to calculate the total cost differences arising for the NHS as a result of the policy changes in each city.

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, and data on 'assault type' will also be available to allow more precise estimation of costs. These specific 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]. In addition, existing published cost sources on fees and chargeable rates will be combined with crime classification data to generate precise costs [81]. Finally, we will have access to 'Innkeeper' data, a national licensing dataset (an expanded subset of Police Scotland data) including records of almost 100% of incidents/crimes occurring inside, outside, or originating from a licensed premises. If funded, we will further explore the utility of this dataset for economic evaluation.

Synthesis and Reporting: 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 development and implementation of a survey of local authorities (LAs) across the UK. 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 (both the original opening hours and changes, and subject to capacity and data, the COVID-19 level restrictions at local authority level) 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. The feasibility of modelling relating to the national analysis for RQC2 will be reviewed in late 2021. Finally, the survey findings 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 SURVEY

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. In consultation with LAs with whom we are working closely on the ExILEnS study [45] and our advisory group, we will develop and pilot an online survey of local approaches to licensing hours. The survey will be straightforward to complete, including simple multiple choice response options on if, how and why licensing hours are changing locally, how the effects of these changes are perceived, the impact of COVID-19 on local licensing policies and policymaking, local visions for the future of alcohol licensing in the NTE post-COVID-19, and evidence needs for local policymaking and optional free text response items. We will work closely with our partner organisations Public Health England, Alcohol Focus Scotland, Public Health Wales to distribute the survey to public health and licensing teams for all local licensing authorities. PHE, PHW and AFS hold contact details for each area and have agreed to support the study (see letters attached). We will further publicise the survey through the UK-wide Public Health and Licensing Network (PHLN) of which Fitzgerald and Angus are members. Results will be analysed descriptively and through thematic analysis of any free text responses, including stratification by UK nation and whether the LA is primarily rural or urban.

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, informed by the results of the above survey, based on their interest in implementing potential restrictions on late-night licensing hours. 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

<u>Public involvement</u>: 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 stakeholder involvement groups, one for each city, to consult with public sector stakeholders and 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.

<u>Impact:</u> 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) <u>generating new knowledge, (ii) informing local</u> 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. An additional novel output will emerge from WP4 which will generate the most detailed and accurate estimate to date of the cost of alcohol-related ambulance call-outs. We will develop a 'testable' theory of change on the system-wide effects of the opening-hours changes, and provide a template for future studies taking a systems perspective.

The findings of our study will be immediately relevant to (ii) <u>informing local licensing practice &</u> <u>policy</u>, 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 nonacademic 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 enewsletter. 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 <u>relevant to local policy and practice in England and Wales</u>. 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 PHE-led National Public Health and Licensing Network. Both organisations will disseminate study news/requests through established mechanisms.

Our findings will also inform (iii) <u>licensing legislation and related guidance</u>. 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. STUDY STEERING COMMITTEE

An advisory group has been assembled, consisting of individuals from academia, policy and NGOs and will provide support throughout the study. This committee reviewed and approved the adaptations to the study outlined above related to COVID-19.

- 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;
- Dr. Zara Quigg, Reader in Behavioural Epidemiology, Public Health Institute, Liverpool John Moores University;
- Professor Jon Bannister, Director, Crime and Well-Being Big Data Centre, Manchester Metropolitan University;
- 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;
- Supt Tim Ross, Police Scotland

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 may not be required, but NHS R&D approval from the local health board and/or Scottish Ambulance Service will be sought where needed. 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.

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