NIHR PHR 14/186/58 Evaluation of legislation to reduce the drink drive limit in Scotland: a natural experiment

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1. Introduction

1.1. Background

It is well recognised that drink driving is a leading cause of road traffic accidents (RTAs). In 2000, the European Commission estimated that one-quarter of road accident fatalities were due to alcohol [1]. Although there have been large reductions in accidents involving drink driving in Great Britain (GB) over recent decades (deaths and serious injuries related to drink driving have fallen by three-quarters between 1980 and 2010 [2]), drink drive accidents still accounted for 13% of all road deaths in 2012 [3]. It has been estimated that drink driver injury accidents cost the Scottish economy £80m per year [4]. There is evidence that accident risk increases with blood alcohol concentration (BAC) such that the relative risk of being involved in a fatal crash as a driver is 4 to 10 times greater for BACs in the range 0.05-0.07 g/dL than a zero BAC [5].

The first country to introduce a legal BAC limit to combat drink driving was Norway in 1936, where it became illegal to drive with a BAC level of 0.05 g/dL or above. Since then many other countries and jurisdictions have followed this 'Scandinavian model' to deter drink driving, and legal BAC limits are in place in countries and regions across Europe, North America, Japan and Australasia, with most having BAC limits of 0.05 or 0.08 g/dL [6]. The British Road Safety Act (BRSA) introduced a legal limit of 0.08 g/dL in 1967 [7] which is still in place today, with the exception of Scotland where the BAC limit was reduced to 0.05 g/dL on 5th December 2014.

The desired effect of a legal BAC limit, or reduction of legal BAC limit, is to deter people from drink driving. However, in an early study assessing the impact of the BRSA, it was found that single vehicle nighttime collisions returned to prelaw levels after an initial marked and statistically significant decline [7]. It has been suggested that the reason for this observation is that initially drivers have a heightened perception of risk of being caught drink driving, followed by a realisation that the actual risk is lower than initially thought [6]. Hence, it has been argued that for a law, or a change in law to be successful, publicity and public education has to be maintained, and that random breath testing measures are required in conjunction with other efforts [8].

1.2. Association between BAC and population drinking

In a NICE review of effectiveness of laws to limit BAC, a conceptual framework was developed to set out the rationale why a reduction of BAC from 0.08 to 0.05 g/dL could work. A logic model was developed, based on a set of assumptions about the links between the BAC intervention, change in drink driving behaviours, and risk of RTAs [9]. Interestingly, this work not only emphasised the importance of the perception of risk of being detected and punished, but also the potential of a BAC intervention to reduce overall alcohol consumption.

It has been shown that population drinking (i.e. alcohol consumption per capita) is positively associated with a large number of outcomes (e.g. liver cirrhosis, suicide, violence [10]). A recent study hypothesised that population drinking would also be associated with drinking while under the influence of alcohol. Their ecological analyses, using Norwegian and Swedish data, demonstrated a strong and statistically significant association – as alcohol consumption per capita increases or decreases so does the incidence of driving under the influence of alcohol [11]. We are not aware of any studies that have evaluated whether a legal reduction in BAC limit (for a whole country) has led to a reduction in that country's population drinking. This could be a wider, perhaps unintended, outcome that can be attributed to change in BAC legislation. This would be beneficial to public health because alcohol consumption per capita is positively associated with alcohol related harms [12].

1.3. Risks and benefits

The intervention to be evaluated has already been implemented in Scotland (from 5th December 2014), so all our proposed analyses are retrospective and use secondary data sources; therefore there are no specific risks to study participants. The benefit of our evaluation is that we will significantly enrich the evidence base as to whether a change in BAC limit from 0.08 to 0.05 g/dL improves public health (both by reducing levels of RTAs and population drinking), can impact on inequalities associated with socio-economic deprivation and offers good value for money. If our evaluation concludes that such a change in legislation works, other governments may follow suit leading to wider improvements in public health.

2.3. Rationale for current study

Although there is an evidence base that establishing a 0.05 g/dL BAC limit, and changing the limit from 0.08 to 0.05 g/dL, is effective in reducing RTAs there is still a strong rationale for evaluating the change in legislation in Scotland. The scientific quality of the studies in the existing evidence base is poor. Our proposed study will directly address these shortcomings by using weekly rates of RTAs, allowing for adjustment for seasonal and temporal factors, and including all RTAs in our outcome measure (not just RTA fatalities) which is more appropriate for assessing the full impact of the law change.

No previous study has investigated whether the effectiveness of a change in BAC legislation varies by levels of socio-economic deprivation. Reducing health inequalities is a Scottish Government priority and is a theme of this funding call. If, as the evidence suggests, that any intervention effect is observed across the entire population of drink drivers, then we can expect absolute levels of socio-economic deprivation inequality to reduce due to different RTA prevalence across socio-economic deprivation groups. In our study we will measure socio-economic deprivation using the Carstairs index [13] which will be obtained from postcode of driver. We will measure the slope index of inequality (SII) and relative index of inequality (RII) based on rates of RTAs in the before and after intervention periods, and in both the intervention and control groups, and test for change in SII and RII using our statistical models.

No previous study has evaluated whether a legal reduction in BAC limit has led to a reduction in that country's population drinking. In early 2015, a Scottish newspaper in separate articles has reported that pub operators were indicating that overall sales had been "hit" by the change in drink driving legislation [14], representatives of the Scottish Licensed Trade Association saying that the change will be worse for business than the smoking ban [15], and the Bank of Scotland's chief economist saying that the change has stunted the growth of the licensed trade [16]. We also hear anecdotally of individuals stating they have reduced their alcohol drinking consumption in evenings before driving the next morning. In our study we will measure the intervention effect for a population drinking outcome measure using high quality market research off- and on-sales data with coverage across GB, used in past evaluations of Scotland's alcohol strategy. These evaluations are carried out by the Monitoring and Evaluating Scotland's Alcohol Strategy (MESAS) team in NHS Health Scotland, and two members of our research team collaborate with this team and provide statistical expertise.

There is a lack of economic evaluation studies in the BAC literature. The cost-effectiveness analysis that we propose allows the joint distribution of costs and effects to be consistently measured as we are drawing on the same data sources for measures of effectiveness and cost.

2. Research objectives

The proposed research will answer four primary questions:

1. Has the change in drink driving legislation in Scotland been effective (reduction in RTAs)?
2. Has the change in drink driving legislation in Scotland led to changes in relative and absolute RTA rates that differ by levels of socio-economic deprivation?
3. Has the change in drink driving legislation in Scotland led to a reduction in population alcohol consumption?
4. Has the change in drink driving legislation in Scotland provided good value for money (been cost-effective)?

3. Research design

In our proposed research, we will employ a natural experimental design and difference in differences (DiD) analytical approaches to measure the causal effect of the change in BAC legislation in Scotland. Our control group will be England and Wales, the other countries in GB that still have a 0.08 g/dL BAC law. The data for the intervention and control groups used to measure effectiveness comes from the same data source and covers the same study period (four years in duration, two years pre- and post-legislation change - 5th December 2012 to 5th December 2016). We will follow MRC guidelines on best practice for conducting natural experiments [17].

The statistical analyses planned for research objectives 1-3 below are detailed in section 9.

<u>Research objective 1 (RO1) – measure the percentage change in the weekly RTA rate attributable to BAC8to5 by quantifying the change observed in pre- and post-intervention periods and contrasting between intervention and control groups</u>

Outcome measure: The outcome measure for measuring effectiveness will be weekly rates of all RTAs, not just fatalities and not just those that involved illegal BAC levels (see section 6).

Data source: Data on RTAs reported to the police are recorded in the STATS19 database. STATS19 holds individual level data on RTAs for the whole of GB. This data set is used by the Department for Transport (DfT) to populate their annual reports on road casualties [2-3]. The data set contains the following variables that are required to address this research objective: age and sex (both of driver(s) involved in accident and casualties), postcode of driver(s), accident severity (slight, serious or fatal), casualty severity (slight, serious or fatal), number of casualties, location of accident (eastings and northings), date of accident. The definitions of slight and serious severity class are shown below [18]:

‘Slight injury’ - an injury of a minor character such as a sprain (including neck whiplash injury), bruise or cut which are not judged to be severe, or slight shock requiring roadside attention. This definition includes injuries not requiring medical treatment.

‘Serious injury’ - An injury for which a person is detained in hospital as an “in-patient”, or any of the following injuries whether or not they are detained in hospital: fractures, concussion, internal injuries, crushings, burns (excluding friction burns), severe cuts, severe general shock requiring medical treatment and injuries causing death 30 or more days after the accident. An injured casualty is recorded as seriously or slightly injured by the police on the basis of information available within a short time of the accident. This generally will not reflect the results of a medical examination, but may be influenced according to whether the casualty is hospitalised or not. Hospitalisation procedures will vary regionally.

An accident is classified as slight if at least one person is slightly injured but no person is killed or seriously injured, as serious if at least one person is seriously injured but no person is killed, and fatal when at least one person is killed.

Data coverage: It is well known that not all RTAs will become known to the police [19], and many casualties of RTAs who attend hospital will not be captured in STATS19 - a study that linked STATS19 with the Scottish Morbidity Records - General / Acute and Inpatient Day Case dataset (SMR01) [20], showed that 45% of hospital admissions due to road casualties were not reported to (or recorded by) the police. Reassuringly, research by DfT that linked STATS19 with Hospital Episode Statistics (HES) [19], showed that both data sources cover a representative (though different) population of the more seriously injured casualties in England. We are therefore confident that any percentage change intervention effect we observe in the STATS19 data will be generalisable and also fit for purpose to address research objectives 2 and 4 (see below).

Denominators for rates: In order to compare outcomes between the intervention and control group (which are vastly different sizes), weekly rates of RTAs will be used as the outcome measure and therefore denominators are required. The ideal denominator for this study is the number of miles driven by each person at risk of having a RTA. Clearly this data does not exist, but traffic counts are a useful proxy. The DfT have temporal street-level traffic data for every junction-to-junction link on the 'A' road and motorway network in GB [21]. We will use these data to provide weekly estimates of overall traffic flow in the intervention and control groups in the study period. We acknowledge that absolute estimates of traffic flow will not be perfect using this method but what really matters is that it will provide us with good estimates of how traffic flows vary on a temporal basis (both in the intervention and control groups). Furthermore, it will not be possible to split this denominator by subgroups which we will include in our statistical models (i.e. age, sex, socio-economic deprivation). However, this would only be a concern if at different levels within these subgroups there were different temporal trends in traffic counts observed, and there is no reason (or evidence) to support this.

<u>Research objective 2 (RO2) – assess whether the relative and absolute change in the weekly RTA rate attributable to BAC8to5 is different between socio-economic deprivation groups</u>

The research design is the same as that for RO1 with the following extra considerations.

Measuring socio-economic deprivation: Socio-economic deprivation, measured at the area-level, will be captured by the Carstairs index. A difficulty is that postcode sectors and electoral wards, traditionally the levels at which Carstairs is measured, markedly differ in size when comparing Scotland to the rest of GB. However, work has been carried out for another research project to calculate Carstairs scores for new levels of geography that are more comparable across GB. The postcodes of drivers in STATS19 can be mapped to these new levels of geography and assigned a Carstairs score. An important step is to standardise the Carstairs score for the entire GB distribution before creating Carstairs deciles for statistical analysis purposes.

Missing data: STATS19 data sets with postcode were made available to the research team, with no charge, after an end user agreement form between DfT and the University of Glasgow was completed. Postcode of driver is recorded in just over 80% of cases in the 2012 and 2013 STATS19 data sets. Ideally, these postcodes would be missing completely at random (MCAR) so that the distributions of Carstairs would be the same for observed and unobserved postcode data. However, even if there is some mechanism influencing the probability of postcode being missing, the estimates of the relative and absolute change in the weekly RTA rate for each socio-economic deprivation group will be unbiased if the mechanism behind the missingness is the same for the intervention and control arms, and this seems a reasonable assumption to make. In our analyses, we will compare the characteristics of RTAs (e.g. age, sex, severity of accident, date of accident) for those with observed and unobserved postcode data to assess bias.

<u>Research objective 3 (RO3) – measure the percentage change in alcohol consumption per capita attributable to BAC8to5 by quantifying the change observed in pre- and post-intervention periods and contrasting between intervention and control groups</u>

Data source: Alcohol consumption per capita, for the intervention and control groups, will be measured using off- and on-trade alcohol retail sales data from market research specialists, Nielsen [22]. These data provide population level estimates based on electronic sales records from large retailers and a weighted stratified sample of smaller retailers. MESAS have reviewed the validity and reliability of this data source for evaluation purposes and identified the main potential sources of bias as underestimation due to unrecorded alcohol (e.g. home brewing, illicit alcohol, cross-border purchases) and overestimation due to wastage/spillage [22]. However, in the absence of a true gold standard, alcohol retail sales data is a high quality measure of per capita alcohol consumption, and superior to relying on self-reports of alcohol drinking from surveys which vastly underestimates total consumption [23]. Regardless, using the DiD approach, the main concern is if there is a differential temporal impact in terms of bias caused by data quality between the intervention and control group and this seems unlikely.

It should be noted that sales from discount stores Aldi and Lidl are not included in the Nielsen data. However, as MESAS have done previously in their evaluations, we can uplift sales to account for this by applying country-specific estimates from shopping scan surveys. We will check the sensitivity of our results to whether or not this uplift is applied.

Off-trade alcohol sales are available in weekly units but on-trade alcohol sales are only available in 4-weekly units. To preserve statistical power for the off-trade sales outcome, which is driven by the number of temporal data points, the off-and on trade alcohol sales will be analysed separately.

<u>Research objective 4 (RO4) – carry out an economic evaluation to assess whether change in drink driving legislation in Scotland provided good value for money</u>

The economic evaluation will run in parallel to the effectiveness analyses. Three frameworks for economic evaluation (cost-effectiveness, cost-utility and CBA) will be used to reflect different outcomes as detailed below.

Costs: In line with guidance from a recent DfT economic valuation study of road accidents in the UK [24], the costs associated with prevention of accidents will be categorized into ‘Casualty related costs’ and ‘Accident related costs’. Using this distinction, casualty related costs will comprise human costs, medical and ambulance costs and lost output. Accident related costs will comprise police costs, insurance and admin costs and costs of damaged property. The methodology used to value the cost of accidents/casualties has been updated and is published in UK Government's Transport Analysis Guidance [25]. In order for this economic evaluation to be comparable with DfT estimates this methodology will be mirrored for these costing elements. Estimates of the average value of prevention per reported road accident casualty and per reported road accident will be reported. Direct costs associated with hospitalisations will be estimated using SMR01 data. The cost of the hospitalisation due to RTA will be estimated as well as costs of related readmissions (we will request SMR01 data going back to December 2012, to allow a maximum of 24 months follow-up in the pre-change of legislation period to assess type and rates of readmission). Additional associated costs related to deaths will be estimated (Ambulance, A&E admissions, coroner and legal costs) based on Scottish data sources and estimates from the literature. Costs will also include the implementation costs of the law change and associated campaign to advertise the reduced limit as well as the associated surveillance and monitoring costs.

Outcomes: Outcome measures included in the economic evaluation will include: weekly rate of RTAs (for the cost-effectiveness analysis); years of life lost (YLL), Quality Adjusted Life Years (QALYs) (for the cost-utility analysis) and contingent valuation values related to prevented fatalities as well as human injuries (for the CBA).

YLL are calculated from the number of deaths multiplied by a standard life expectancy at the age at which death occurs. YLL take into account the age at which deaths occur by giving greater weight to deaths at younger age and lower weight to deaths at older age. The standard life expectancy used for YLL at each age is the same for deaths in all regions of the world and is the same as that used for the calculation of DALYs. By incorporating the population size, YLL provides a summary measure of premature mortality and can be thought of as a population health tool to compare the relative importance of different causes of premature deaths within a given population, to set priorities for prevention, and to compare the premature mortality experience between populations. Additional calculation of Years lost due to Disability (YLD) for people living in a given health state would facilitate the estimation of DALYs.

The estimation of QALYs gained though the prevention of RTAs will be informed by a literature review. The purpose of this review will be to extract utility values associated with relevant common health states arising due to motor vehicle related injuries. Previous research has compiled health states and QALYs associated with RTAs including crash survivor utility values [26]. These values can be broken down in relation to health state utility associated with, presence of a fracture/dislocation, body region injured (e.g. head, neck, thorax, spinal cord, pelvis, lower extremity, upper extremity) and hospitalised versus non-hospitalised injuries. By utilising such data, estimates of QALYs lost per injured survivor can be included in the evaluation to generate any resulting QALY impacts associated with the change in drink driving legislation.

Contingent valuation estimates for injuries and death prevented will be identified and combined with costs within a CBA framework. Key to this process will be the identification of monetary valuation estimates for avoided death and injury in addition to identifying standard values for lost productivity due to absenteeism. The DfT report such values [27], and since 1993 the valuation of both fatal and non-fatal casualties has been based on a willingness to pay (WTP) approach. This approach encompasses all aspects of the valuation of casualties, including the human costs, which reflect pain, grief, suffering; the direct economic costs of lost output and the medical costs associated with RTAs.

The cost and outcome results from the within-natural experiment analyses will be extrapolated within a lifetime cohort model to identify the likely longer term impacts of the change in Scottish drink driving legislation.

Perspective, discounting and sensitivity analysis: The perspective of the economic evaluation will be the societal perspective to allow health sector and broader judiciary costs to be included. The time horizon will be lifetime costs and outcomes with a population health economics discount rate of 1.5% applied (www.nice.org). Detailed sensitivity analysis will be undertaken to identify thresholds of cost-utility (when using QALYs as the outcome measure) and cost-benefit (when using contingent valuation for prevented injuries). Results will be reported and presented with associated uncertainty around the costs, outcomes and net benefit.

4. Study population

We are studying the entire population of Scotland (intervention) and England and Wales (control).

5. Socioeconomic position and inequalities

As detailed above, socio-economic deprivation will be measured using the Carstairs index. We did consider using the Index of Multiple Deprivation (IMD) but we discovered the domains used to construct the indices differ between constituent GB countries, as well as other methodological differences [28], making IMD scores not directly comparable between our intervention and control arms. To measure inequalities associated with socio-economic deprivation, we will calculate SII and RII based on weekly RTA rates in the before and after intervention periods, and in both the intervention and control groups (more detail is provided on the statistical analyses used to analyse SII and RII in section 12).

6. Proposed outcome measures

The primary outcome measure for our proposed effectiveness study is weekly rates of all RTAs. Although much of the evidence on the effectiveness of BAC limits has used RTA rates where individuals are above legal limits, there are good reasons why all RTA rates are preferable. Most importantly, like others [29], we would argue that all RTA rates is the true outcome of interest when evaluating BAC policy. Looking at only RTA rates where individuals are above legal limits would provide only a partial assessment of effectiveness. Moreover, in many research settings it is not possible to obtain BAC levels for fatal accidents, or at the least there is a long delay in getting BAC from coroner's reports. Finally, if BAC is not measured within 12 hours of a person dying, the BAC level would have naturally worn off. Our secondary outcome measure is alcohol consumption per capita. We are using this to assess whether a legal reduction in BAC limit has led to a reduction in Scotland's drinking at the population level.

The outcome measures in our economic evaluation are weekly rate of RTAs (for the cost-effectiveness analysis); YLL and QALYs (for the cost-utility analysis); and contingent valuation values related to prevented fatalities as well as human injuries (for the CBA).

7. Assessment and follow up

We are proposing a follow up period of 2 years in our study. Although 1 year of follow up is sufficient in terms of providing enough statistical power to detect a range of plausible effect sizes (see next section), it is important to determine whether any effect is maintained in the medium to long term. It is expected that any effect would be more or less immediate as the multi-media advertising campaign regarding the change in legislation was far reaching and continued to be reported in the Scottish press soon after the change with articles appearing in the press reporting the impact the new legislation was having on pubs and alcohol retailers.

8. Proposed sample size

The STATS19 data on effectiveness is available at the individual level but will be analysed as RTA counts (with traffic flow as on offset) for strata formed by covariate patterns. If we use 4 age categories (x4), sex (x2), Carstairs decile (x10), intervention group (x2) and weekly periods (x104), the number of unique covariate patterns is 16,640. From our review of the literature, we can expect intervention effect sizes (ES) to be in the range 7% to 14%. As there is no recognized formula for calculating power (or sample size) associated with any given effect size for our proposed analysis, we have used simulation methods based on Poisson-type GLM models for count data [30] to estimate the statistical power associated with a 'sample size' of 16,440 and the results are shown in the table below. As can be seen, our study will have sufficient statistical power, even for small ESs.

Table: Statistical power estimates for a range of expected ESs

ES (%)	-7	-8	-9	-10	-11	-12	-13	-14
Power	87.0%	94.4%	98.6%	99.2%	99.4%	99.8%	100%	100%

We also anticipate that an abundance of zero counts will not be a concern for our analyses. Concentrating on the intervention group (Scotland) as zero counts will certainly not be an issue for England and Wales, there were, for example, approximately 11,500 casualties from RTAs in 2013 [31]. A total count of that magnitude will be dispersed between 4,160 cells (4 (age) x 2 (sex) x 10 (Carstairs decile) x 52 (weeks)), so a large percentage of zero counts should not occur.

9. Statistical analysis

RO1: Separately for the intervention and control groups, we will calculate weekly total counts of RTAs split by age, sex and Carstairs using the STATS19 data set. We will also calculate weekly total counts of traffic flow, again separately for the intervention and control groups, by adding up all the traffic flow counts from roads and motorways across Scotland and England and Wales. We will model the data using a Poisson or Negative Binomial GLM (log link function) with the weekly RTA counts as the outcome and the weekly traffic flow counts as an offset in the model. The key covariates in the model are a dummy variable to indicate whether intervention or control group (*Interv*), a dummy variable to indicate whether in the pre- or post-intervention period (*Post*), and the interaction term between these two variables (*Interv***Post*). The exponential of the coefficient associated with this interaction term is the DiD estimate of percentage change in the weekly RTA rate attributable to BAC8to5. Other covariates for risk adjustment purposes will include a time variable(s) to adjust for overall temporal trend (we will consider using restricted cubic spline variables if time does not have a linear association with the log RTA rate); variables to account for seasonality (possibly 4-weekly dummy variables or sine/cosine terms in a Fourier analysis); and other time-dependent covariates to reflect potential confounding variables (see sub-section below).

An important assumption we make in this DiD approach is that the RTA rates in the intervention and control groups would follow the same temporal trend in the absence of the intervention. Following common practice, we will use the pre-intervention period to test whether the trends are the same in the two arms. If this assumption is not met, we will instead develop time series models to estimate percentage change in the weekly RTA rate attributable to BAC8to5.

RO2: The modelling strategy outlined for RO1 will be extended into a DiDiD model to test whether the intervention effect is modified by Carstairs decile. This will be tested by doing a likelihood ratio test on the three-way interaction which will manifest itself as nine variables (*Interv*Post*Car2 - Interv*Post*Car10*). By specifying a log link function for the GLM and running this three way interaction model will result in a test for inequality on the relative scale. Whereas, when we specify the identity link function, a test for inequality on the absolute scale will be provided [32]. We will also adapt these strategies to present inequalities in the RII and SII measures by replacing the Carstairs decile dummy variables with a continuous Carstairs covariate. This covariate represents the midpoint of the range in the cumulative distribution of the population of Carstairs ranks [32]. Again, the choice of link function described above will determine if the model tests the three-way interaction between RII or SII and *Interv*Post*.

RO3: A similar DiD modelling strategy to RO1 will be used. We will use a Normal GLM (log link function) with the weekly per capita alcohol consumption as the outcome variable. However, from a previous collaboration with MESAS on assessing the impact of the Scottish Alcohol Act on per capita alcohol consumption, we know that this variable has very strong seasonal patterning, with very large spikes in the Christmas period, and lesser spikes in the summer. If our GLM does not fit the data well, we will use a seasonal autoregressive integrated moving average time series model fitted to the intervention, with the time series of per capita alcohol consumption for the control group fitted as a covariate.

Potential confounding variables: confounding will occur if any variable has a differential temporal effect on outcome between the intervention and control groups. Potential confounding variables in this study include concurrent drink driving campaigns, urban/rural population density and environmental factors that impact driving conditions (e.g. weather). We will be thorough in identifying potential confounding variables, determining if they can be reliably measured in both the intervention and control groups, and adjusting for them in our statistical models.

Sensitivity analyses: as well as determining whether results are sensitive to adjustment for potential confounding variables, we will also explore whether results are sensitive to choice of control group. In a natural experiment, the characteristics of the control group should closely match those of the intervention group and we will use a subset of England and Wales based on measured potential confounding variables to act as a secondary control group. If possible, this last part of the sensitivity analysis will use a synthetic control methodology [33].

10. Ethical arrangement

This is a secondary analysis project without any new data linkages. No ethical concerns.

11. Research Governance

The University of Glasgow will act as sponsor (contact: Dr Debra Stuart, Research Governance Manager, Clinical Trials Unit, Glasgow G11 6NT). For the economic evaluation analyses, the linked Scottish hospital and death data set will be analysed on the NHS Scotland National Safe Haven.

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