Evaluating graduated progress towards, and impacts of, the implementation of indoor smokefree prison facilities in Scotland

The Tobacco in Prisons (TIPs) study. Version 1.4

Kate Hunt, Helen Sweeting, Sean Semple, on behalf of the TIPs research team

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Principal Investigator: Professor Kate Hunt, Associate Director, MRC/CSO Social and Public Health Sciences Unit, Institute of Health and Wellbeing, University of Glasgow

Co-Investigators: Dr Helen Sweeting[1], Dr Sean Semple[2], Professor Linda Bauld[3], Douglas Eadie[3], Professor Jill Pell[1], Professor Alastair Leyland[1], Dr Peter Craig[1], Dr Kathleen Boyd[1], Dr Evangelia Demou[1], Dr Phillip Conaglen

Researchers: Dr Greig Logan[1]; TBA[1]; Dr Richard Purves[3]

[1]University of Glasgow; [2]University of Aberdeen; [3]University of Stirling; [4]NHS Lothian

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1. Background

Smoking bans in public places decrease exposure to SHS (Semple, Maccalman et al. 2007) with direct health benefit (Pell, Haw et al. 2008), but national smoking bans are very heterogeneous, especially in custodial settings (Hartwig, Stover et al. 2008). In the UK, prisons (as both staff's workplace and prisoners' 'home') have had partial exemption from smokefree legislation, and are one of the few institutions in which smoking is still normative. Whilst rates have fallen markedly in the general population, except in the most deprived(Hiscock, Bauld et al. 2012, Scottish Government 2013), across Europe 64-88% of prisoners are smokers(Hartwig, Stover et al. 2008). Internationally, smoking in prison staff is also thought to be high but evidence is sparse, with only one study (Carpenter, Hughes et al. 2001) identified in a recent review.

Prisoners' high levels of smoking can lead to high levels of second-hand smoke within prisons (Semple, Ibrahim et al. 2015), despite the fact that smoking is already subject to some restrictions in these settings. (In Scotland, prisoners are only permitted to smoke in their cells or during outdoor recreation.) As a result, prisoners' smoking poses a threat to the health of both smoking and non-smoking prisoners and staff, particularly those entering or opening up prisoners' cells. Exposure to second-hand smoke in prisons is attracting increasing concern both internationally and within the UK. Several countries have implemented total smoke-free policies (i.e. all indoor and outdoor areas) across their prison estate. In the UK, comprehensive smoke-free policies were adopted by Broadmoor Secure Hospital in 2007 and by the State Hospital in Scotland in 2011. In October 2015, following five years of preparation, it was announced that a comprehensive smoke-free policy would be implemented in all Welsh prisons from January 2016 and at four early adopter sites in England from March 2016.

The Scottish Government's current Tobacco Strategy states that "[C]reating a smoke-free prison service should be seen as a key step on our journey to creating a smoke-free Scotland" (Scottish Government 2013) , p26). The Scottish Government, NHS Boards and the Scottish Prison Service (SPS) are considering options on how best to proceed towards a smoke-free prison service, as the issues around implementing/delaying the introduction of such a policy are increasingly debated in the public domain. Following a recommendation from the Ministerial Group on Offender Reintegration, a NHS specification was launched in June 2015 to harmonise smoking cessation services across Scottish prisons (NHS Health Scotland 2015), and a joint action plan concerning smoking in prisons was submitted to ministers in early 2016. Although the exact timing of any policy change in Scotland has yet to be decided, those concerned about second-hand smoke exposures will press for the shortest feasible timescale, whilst acknowledging the need for sufficient time and resources to make any change in policy effective, supported and enforceable. Best evidence to date, following New Zealand's experience (Gautam, Glover et al. 2011, Collinson, Wilson et al. 2012) suggests that a minimum period of around one year is needed, but some countries may require longer to mobilise resources for adequate smoking cessation and support.

1.1. Existing research

Description of the problem: high smoking rates in prisoners and exposure of prisoners and prison workers to secondhand smoke

The high prevalence of smoking in prisons has been described as "one of the most pernicious public health problems affecting prisons .. all too often .. ignored [in] community based tobacco control policies" (Binswanger, Carson et al. 2014) (p291). A European Commission (EC) report cites the prevalence of smoking in prisoners as "64 to 88%" (Hartwig, Stover et al. 2008), and identified only one study (Carpenter, Hughes et al. 2001) of smoking prevalence among prison staff. Public Health England suggest smoking rates in prisoners are approximately four times higher than in the general population (Public Health England 2015). The national biannual survey of prisoners in Scotland conducted in 2013 reported that 74% smoke[1], three times the national average, with little evidence of reductions in smoking as seen in the general population. These

[1] The equivalent figure from the 2015 Prisoner Survey is 72%

"staggeringly high" (Binswanger, Carson et al. 2014) rates partially reflect the fact that prisoners are disproportionately drawn from deprived and socially excluded communities which have high smoking rates (Hiscock, Bauld et al. 2012). However, imprisonment can also lead to uptake of, or increased, smoking (Donahue 2009, Globalsmokefree Partnership 2009, MacDonald, Angus et al. 2010, Baybutt, Ritter et al. 2014, Australian Institute of Health and Welfare 2015, Public Health England 2015), but it can present the opportunity for interventions to improve health too.

The persistence of high levels of smoking poses a threat to prisoner health and a challenge to aspirations to achieve smoke-free societies and decrease inequalities in health (Scottish Government 2013). Prisoners' high levels of smoking can lead to high levels of secondhand smoke (SHS) within prisons (Semple, Ibrahim et al. 2015), despite existing restrictions on smoking in prisons. (In Scotland, for example, Prison Rule 36 was amended in 2006 so that prisoners are only permitted to smoke in their cells or during outdoor recreation.) WHO considers that "there is no safe level of exposure to second-hand tobacco smoke", citing evidence that SHS increases the risk of CHD, lung cancer, breast cancer, and respiratory symptoms and illnesses in adults, and, for those exposed during pregnancy, of low birth weight and preterm delivery (World Health Organisation 2007). Both prisoners and staff (particularly those entering or opening up prisoners' cells) are potentially at risk. Binswanger et al note that "People in prisons live and work in confined indoor spaces that can be crowded and poorly ventilated .. [with] limited movement options and restricted opportunities for outside air to avoid smoke exposure even if they do not smoke" (Public Health England 2015) (p2). Prisons' dual status as 'workplace' for staff and 'home' for prisoners was noted when indoor smoke-free legislation was introduced in the UK and elsewhere, and national smoking bans have been described as "very heterogeneous, especially when it comes to the custodial settings" (Hartwig, Stover et al. 2008) (p9).

Exposure to SHS in prisons is attracting increasing concern. A report published in October 2015 (Semple, Ibrahim et al. 2015), based on data from six prisons in England provides major new evidence. It showed that peaks in SHS in cells where smoking takes place can be considerable; measurements over 24h periods suggested average levels in smokers' cells that are frequently in the range of 100-200 $\mu g/m^3$ of fine Particulate Matter less than 2.5 microns in size ($PM_{2.5}$[2]) (consistent with the upper 10% of levels measured in smokers' homes). Prison staff reported that about half their time involves exposure to SHS (Semple, Ibrahim et al. 2015). Objective measurement of personal exposures indicated that staff spent about one-sixth of their shift in areas where SHS-derived $PM_{2.5}$ concentrations exceed $25\mu g/m^3$ (the 24h guidance level from the WHO for indoor $PM_{2.5}$ levels) and biological markers (salivary cotinine) validated SHS exposure (Semple, Ibrahim et al. 2015). The report concludes that "There is no safe level of exposure to SHS ..[and] it is now widely considered prudent that workers' exposure to SHS .. should be limited as far as reasonably practicable .. [T]he National Offender and Management Service (NOMS) should consider implementing measures to further reduce or eliminate SHS within the prison estate" (p38). Others have highlighted an "urgent need to ensure the same protection [from SHS] for offenders, [prison] staff and visitors as afforded to the general population" (Public Health England 2015) (p8).

Thus momentum is building throughout the UK, as elsewhere (e.g. Australia (Australian Institute of Health and Welfare 2015)), to increase tobacco control in prisons, both to improve the health of staff and prisoners and as a means of addressing inequalities in health (Butler, Richmond et al. 2007, Scottish Government 2013). The Scottish Government's Tobacco Strategy states that "consideration should be given to ensuring all prisoners and staff are protected from the harms caused by second-hand smoke .. [C]reating a smoke-free prison service should be seen as a key step on our journey to creating a smoke-free Scotland" (Scottish Government 2013) (p26). The strategy set an action to "work in partnership with the Scottish Prison Service and local NHS Boards to have plans in place by 2015 that set out how indoor smoke-free prison facilities will be delivered" (p26). The English Government's *Healthy Lives, Healthy People, A Tobacco Control Plan for England* similarly includes an action to "continue progress to reduce secondhand smoke in prisons" and Public Health England argued in 2015 that, "reducing smoking should be given the highest priority across the CJS [Criminal Justice System] and comprehensive nicotine dependence treatment (cessation and/or harm reduction) should be delivered to all smokers in the CJS" (Public Health England 2015) (p4).

[2] $PM_{2.5}$ is an internationally recognised marker of SHS concentrations that has been previously used to quantify SHS concentrations in workplace, domestic and car settings [Hyland, A., M. Travers, C. Dresler, C. Higbee and K. Cummings (2008). "A 32 country comparison of tobacco smoke derived particle levels in indoor public places." Tobacco Control **17**(3): 159-165.]

However, it is widely recognised, given high smoking amongst prisoners (Hartwig, Stover et al. 2008, Australian Institute of Health and Welfare 2015), that introducing smoke-free legislation in this setting presents particular and considerable challenges, including concerns about prisoner unrest (McInerney 2015, Shaw 2015). In media coverage of the announcement that a smoke-free policy would be implemented in all four prisons in Wales from January 2016 and piloted in four prisons in England in March 2016 as part of a "phased roll out that will eventually see all jails in England and Wales go smoke-free", Prisons Minister Andrew Selous is quoted as saying this is a "necessary" but "difficult thing to do" given the "unique environment". The "operational safety and security of our prisons", he continues, will "always be our top priority .. We have no plans to move to smoke-free prisons overnight and will only do so in a phased way that takes into account operational resilience and readiness of each prison". Similar concerns are shared by the Scottish Government and Prison Service.

Tobacco and smoking within prison culture

The challenges underlying the introduction of smoke-free prisons are underpinned by: the social and cultural meanings of tobacco products and smoking in day-to-day prison life; and the complexities of the management of nicotine addiction and the regulation and delivery of nicotine replacement, as with other medications, within the prison environment (Lankenau 2001, de Viggiani 2007, Richmond, Butler et al. 2009, Richmond, Butler et al. 2012). Butler described tobacco smoking as "an integral part of prison life and an established part of the prison culture". He notes that it serves a range of functions in prison "as a surrogate currency, a means of social control, as a symbol of freedom in a group with few rights and privileges, a stress reliever and as a social lubricant" (Butler, Richmond et al. 2007) (p291). In addition, prisoners frequently cite boredom and coping with stress to explain a stronger felt need to smoke while in prison (Enggist, Moller et al. 2014). Cigarettes can thus represent a means of dealing with the challenge of 'killing time' as well as representing "both property and privilege" (Taylor, Ogden et al. 2012). Tobacco-based products offer prisoners "cultural capital to buy and exchange items; favours and protection" (Taylor, Ogden et al. 2012), as a *de facto* (Beck 1995) or alternative (Richmond, Butler et al. 2009) currency. Cigarettes can also give "inmates the opportunity to construct their own identity through material possessions available to them…Perhaps the decision to smoke (or not to smoke) is indicative of one of the last functions that the inmate has control over" (Taylor, Ogden et al. 2012). Ireland notes how, in the context of racketeering, extortion, bullying and 'baroning', tobacco can be used to "alleviate immediate danger" and "as a measure of self-protection, insulating against physical attacks of acts of violence"; without nicotine, he suggests, some other "substance or artefact is likely to act as the currency of power and influence".

Hence, for the implementation of any smoke-free prison policy to be successful and enforceable, it is crucial to understand the social and cultural value of tobacco and smoking that prevails in prisons prior to, and following, any change in legislation, and whether other harmful substances or practices replace the use of tobacco. To date, however, qualitative research on the meaning of smoking in prisons, and particularly on how this changes in the context of increased restrictions, is sparse.

Evidence and evidence gaps in introducing smoke-free prison policies

Although restrictions on smoking in many parts of UK prisons have been in place for some time, there are precedents for 'total' smoking bans. New Zealand introduced the first country-wide ban on smoking within prisons and outside areas in 2011 (Gautam, Glover et al. 2011, Collinson, Wilson et al. 2012). It was recognised there that a ban would need to be supported by "comprehensive cessation support for all inmates" to maximise health gain and the likelihood that abstinence is maintained post-release, and to mitigate negative unintended consequences of imposing a ban (Gautam, Glover et al. 2011). Preparatory work included: a detailed communications strategy; offers of psychological and pharmacological support for prisoners and staff; and the establishment of voluntary smoke-free units prior to the ban. Following the ban, negative incidents included: increases in contraband tobacco and a doubling of the black-market price; smoking of alternative substances (e.g. nicotine patches); and increased reported violence between prisoners in one prison. However, no major incidents were reported, and SHS ($PM_{2.5}$) reduced by 63% and arson-related incidents decreased. By contrast, research in Switzerland, the first to measure exposure to SHS in Europe before and after introduction of a partial smoking ban in prisons, did not show a reduction in particulate matter (PM_{10}[3]), although a reduction in nicotine in the ambient air was detected (from 7.0μg/m^3 2 months before tobacco restrictions

[3] As noted earlier, it is more usual to measure $PM_{2.5}$

were enacted in 2009 to 2.1µg/m^3 11 months after the ban was introduced). The authors concluded that communication and movement between cells and shared rooms leads to "inevitable" air contamination and that the "suboptimal decline in particulate matter" and the residual nicotine indicated that the ban may not have been "fully respected or enforced" (Ritter, Huynh et al. 2012). This again emphasises the need to understand how increased restrictions can be introduced in the most acceptable, enforceable and therefore effective ways. A further gap in the evidence, given the recent rapid increase in the use of electronic cigarettes (e-cigarettes) in the general population, is whether (and if so how) e-cigarettes may either facilitate the introduction of smoke-free policies in prisons or pose particular risks in this environment.

Evidence from jurisdictions which have adopted total smoke-free policies suggests that the factors required for success include: "comprehensive levels of planning; a long lead-in period; clear communication and consultation with both staff and prisoners; clear instruction and guidance from management; holistic cessation support for staff and prisoners; the provision of alternative activities; and comprehensive staff training and support" (Offender Health Research Network 2014), p28). However, there is little published research in this area.

This context provides a unique opportunity to conduct research which will: inform policy-makers' detailed planning and communication strategies nationally and internationally; address the scarcity of robust evidence on the *impacts* of the implementation of smoke-free policies in prisons; and allow evaluation of the *process of implementing policies* during the preparatory period.

We have worked in close collaboration with the SPS and their Tobacco Strategy Group to develop a comprehensive research programme to fully understand: (1) the place and prevalence of smoking in Scottish prisons prior to the introduction of any new policies on smoking in prison; and (2) the impact of the implementation of any policy change.

This research comprises six workpackages (see Figure 1): WP1 - scoping the international landscape; WP2 - (changes in) health, smoking and exposures to SHS; WP3 - staff attitudes and experiences of smoking-related issues in the prison context; WP4 - prisoners' attitudes and experiences of smoking-related issues in the prison context; WP5 - provision and impact of smoking cessation services across Scottish prisons; WP6 - stakeholder partnership working to integrate evidence from WPs1-5 to inform decision-making and communication strategies in relation to Scotland's implementation of indoor smoke-free prison facilities.

1.2 Risks and benefits

Reductions in SHS are highly likely to lead to health benefits for staff and prisoners. A World Health Organisation study (World Health Organisation 2007) estimated that SHS exposure led to 603,000 deaths in 2004. The smoking ban introduced in Scotland in 2006, and similar legislation in England in 2007, led to significant reductions in SHS in public places and positive impacts on health outcomes and public health. In Scotland, a 17% decrease in admissions for heart attack was observed following the smoking ban (Pell, Haw et al. 2008). An American study demonstrated that smoke-free rules in homes increase the likelihood of low income smokers quitting (Vijayaraghavan, Messer et al. 2013). There is evidence too of a reduction in occupational SHS exposures in those previously at high risk. A study of bar workers, for example, reported an 89% reduction in SHS exposure (as measured by salivary cotinine levels) in non-smokers after the ban (Semple, Maccalman et al. 2007) and a reduction in respiratory and sensory symptoms in smoking and non-smoking staff (Ayres, Semple et al. 2009). We are not aware of any research to date that has conducted a similar evaluation of the implementation of prison smoke-free policies on the health of workers in the prison environment (Sweeting and Hunt 2015).

In the US, half of state prisons had some sort of smoking ban by 2001, increasing to 48 states in 2011 (when 44 states banned tobacco indoors and 39 states banned tobacco or smoking indoors or outdoors). In 2014, research on the impact of these US bans on prisoner health was reported for the first time, using self-reported smoking data from a cross-sectional nationally representative survey of 14,499 individuals in state prisons in 2004, mortality data from all US state prisons for 2001-11, and data on tobacco control policies in 50 states for each of these years. This demonstrated that smoking contributed to substantial excess mortality in prisoners, and that smoking bans reduced this excess. States with the most restrictive bans had the lowest mortality rates, and where bans had been in place for longer (9+ years compared with no ban) there were significant

reductions in all smoking-related deaths (adjusted incidence rate ratio 0.89, 95% confidence interval 0.85 to 0.94), cancer deaths (0.81, 0.74 to 0.82) and deaths from pulmonary disease (0.66, 0.54 to 0.80) but no reduction in mortality from causes other than tobacco for 2001-11 (Binswanger, Carson et al. 2014). However, there is little evidence on *process* - what facilitates or militates against the timely introduction of smoke-free prison policies (Sweeting and Hunt 2015).

The introduction of smoke-free prisons therefore has great potential benefits to protect and improve the health of prison staff and prisoners. If prisoners can be supported to become life-long non-smokers, these benefits may extend into the community after their release, potentially extending their impact on health inequalities. However, there could be risks to staff and prisoner safety and well-being if prison smoking 'bans' do not attract sufficient support from staff and prisoners to be enforceable, or if increased tobacco control measures threaten security at the institutional or individual level. Awofeso argues that "sustainable, humane and cost effective" approaches, including providing good smoking cessation programmes in prisons, are essential to the goal of improving the health of prisoners and staff long-term rather than a more limited goal to achieve smoke-free prisons (Awofeso 1999). Such programmes, he suggests, will also undermine the growth of a black market in tobacco and the perception of tobacco control policies as primarily punitive.

1.3 Rationale for current study

Momentum is building in many countries to increase tobacco control in prison (Offender Health Research Network 2014); Public Health England, 2015 #2933; Scottish Government, 2013 #2921}. This is high on media, and policy agendas (Baybutt, Ritter et al. 2014, McInerney 2015, Shaw 2015), driven by concerns to protect staff and prisoners from SHS, support health improvement in prisoners and tackle a key driver of inequalities. Prison is one of the only environments in which people are exposed to SHS in an indoor workplace or large communal living space, a cause of concern amongst staff and their unions. Whilst the UK governments are committed to immediate progress toward smokefree prisons, the timing of policy implementation is uncertain. This research forms a key part of Scotland's strategy to make and evaluate "graduated progress towards smokefree prisons"[4]. The research proposed will provide data to inform this process, and will collect baseline, process and outcome data for robust evaluation of the impact of increased tobacco control in prisons/introduction of smokefree prisons. A European Commission report notes "Hardly any smoking prevention programme has been evaluated and integrated in a prison setting .. Studies addressing the effectiveness .. are few, methodologically weak, and do not provide a comprehensive overview about effects and side effects of a smoking ban in prisons." (Hartwig, Stover et al. 2008) (p6). In addition to the pressing concerns about exposure to SHS, issues around tobacco control and smoking have unique features in prisons (Richmond, Butler et al. 2006, de Viggiani 2007), both in socio-cultural meanings and the management of nicotine addiction and regulation and delivery of nicotine replacement (Eadie, MacAskill et al. 2012). For increasing restriction, or smokefree prisons, to be successful, it is important to understand the cultural value of tobacco in prisons prior to, during and following changes in legislation.

2. Research Objectives

Overall aims:

a) To evaluate the process of implementing enhanced tobacco control in Scottish prisons to: i) strengthen the evidence-base on what is likely to facilitate successful implementation of smokefree prison policies for other jurisdictions; and ii) feed into planning and communication strategies.
b) To evaluate: (i) changes in smoking status and exposure to second-hand smoke; and (ii) changes in related health indicators among prisoners and staff; and iii) organisational/cultural impacts in Scottish prisons, following the implementation of an indoor smokefree prison service.

Objectives:

i. To understand barriers and facilitators to implementation of smoke-free policies, via a scoping of evidence and experiences internationally within other jurisdictions (WP1).
ii. To evaluate changes in smoking and exposures to SHS following the implementation of a smoke-free policy in Scotland's prison service, and associated health-related indicators and costs, and other intended and unintended consequences (e.g. predictors of compliance and enforceability, incidences of unrest) (WP2).

[4] See section 4.7, Scotland's Journey towards Smokefree Prisons, published 13th September 2016, available at http://www.sps.gov.uk/Corporate/Publications/Publication-4405.aspx

iii. To understand staff attitudes to and experiences of smoking-related issues in the prison context, including access to/restriction on tobacco and tobacco-related products (including e-cigarettes) in the prison environment; if/how these vary between prisons; and how these change leading up to and following the implementation of smoke-free policies (WP3).
iv. To understand prisoners' attitudes and experiences of smoking-related issues in the prison context, including access to/restriction on tobacco/tobacco-related products (including e-cigarettes) in the prison environment; if/how these vary between prisons; and how these change leading up to and following the implementation of smoke-free policies (WP4).
v. To evaluate provision and impact of smoking cessation services across Scottish prisons, and experiences of providers, users and potential users of these services in the lead up to implementation of indoor smoke-free prisons; and to evaluate efforts to harmonise smoking cessation services from 2016 (WP5).
vi. To synthesise this evidence to inform decision-making and communication strategies in relation to Scotland's implementation of indoor smoke-free prison facilities through stakeholder partnership working, and address international evidence gaps (WP6)

3. Research design

The study will take place in three phases (see Figure 1).

- **Phase 1** will establish baseline values (for smoking, SHS and relevant health indicators) and cultural/social norms against which to assess the impact on health, economic, cultural and organisational outcomes of the implementation of smokefree prison policies. This will also be informed by scoping the international landscape.
- **Phase 2** entails a process evaluation of initiatives within Scottish prisons and events outwith the Scottish Prison Service in the period leading up to the implementation of indoor smokefree prison facilities in Scotland.
- **Phase 3** entails an evaluation of the impact of the implementation of smokefree policies on health, economic, cultural and organisational outcomes, and predictors of success or difficulties.

As the exact timing of implementation of a smoke-free prison policy in Scotland is unknown, the study may be stopped/ 'hibernated' after Phase 2; a key role of the independent Study Steering Committee (SSC) will be to review progress towards the implementation of indoor smokefree prison policies in the second half of 2017, and to advise then whether this should occur. If any announcement indicates that implementation will be earlier than mid-2018, the SSC will advise on adjustments required to the research to take account of Phases 1 and/or 2 being concatenated.

Phases 1 and 3 and some Phase 2 work will take place in all Scottish prisons (n=15). Data obtained in phase 1 will inform the selection, in consultation with the SPS, of about 4 case-study prisons for more detailed qualitative work, to be conducted in Phase 2.

3.1 WP1 – Scoping the international landscape (Phase 1)

In order to understand barriers and facilitators to implementation of smokefree policies within other jurisdictions we will conduct telephone interviews (n=c15-20) with key personnel (including health workers) in prisons which have introduced bans to elicit their views on key challenges, successes, pitfalls and advice. We aim to include prison personnel from: New Zealand; Isle of Man; Canada; California, US; and Victoria, Australia. We may also include a small number of interviews with policy-makers and/or academics from these jurisdictions. We will also interview key personnel in pilot prisons introducing smokefree policies in England and Wales in 2016 (n=c.8). Interviews will be semi-structured, based on a topic guide. Participants will be encouraged to express themselves freely and to raise any additional issues which they believe are important. We anticipate that interviews will last around 30 minutes and potential participants will be made aware of this before deciding to take part.

Interviews will be audio recorded with participants' permission. Brief notes will also be taken during the interviews and may be used for reference during analysis; if any interviews take place within the prison setting rather than by telephone (e.g. in England and/or Wales), brief field notes summarising any pertinent observations or comments will be taken and may also be used during analysis. All data will be transcribed either by a member of the MRC/CSO Social & Public Health Sciences Unit, University of Glasgow (SPHSU)

administrative support staff or an external transcribing service which has signed a confidentiality agreement with SPHSU and been vetted for security.

All data will be treated confidentially and participants' anonymity will be maintained by de-identifying the data, unless an interviewee agrees to or wishes to be named. All identifiable data will be kept securely in a locked cabinet or in a password-protected computer at the University of Glasgow. Only the researchers will have access to any identifiable data.

3.2 WP2- Evaluating exposures and outcomes (Phases 1 and 3)

In this section (4.2), we describe how we will conduct the measurements of exposures to SHS. In the next section (4.3) we describe how we will obtain data on health and smoking outcomes via questionnaires administered to staff and prisoners. We will also explore with SPS the feasibility of obtaining suitably anonymised routinely-collected health data, e.g on sickness absence, among ***prison staff***, in the form of a monthly series of data for each prison; we will seek to obtain only anonymised, aggregate data (i.e.no individual level or identifiable data). In respect of ***prisoners***, we will also explore whether we can obtain suitably anonymised routinely-collected health care and medication data and/or use anonymised linkage to deaths and Scottish Morbidity Record (SMR) hospitalisation data that would enable us to model long term changes pre- and post-implementation on smoking related disease outcomes. We will also review routine data available from ISD Scotland (WP5 lead (LB) sits on their advisory board) on quit dates set and cessation outcomes in the 12 months prior to the interviews.

Air Quality Monitoring

Instrument: Recently developed, low-cost, simple to use laser particle counters (Dylos DC1700) will measure and log minute-by-minute concentrations of second-hand smoke (Semple, Ibrahim et al. 2015). The Dylos DC1700 counts particle numbers using a low-powered laser; measures particle numbers in two size ranges (>0.5 microns and >2.5 microns) every second; and logs the average each minute. The output can be converted to provide a Particulate Matter ($PM_{2.5}$) concentration, a commonly used marker for SHS. Instruments have an internal memory enabling data to be collected for 6 days and 6 hours (which, within prisons, provides detail on changes in SHS levels over the course of the week to identify the impact of visiting days, weekends, and/or provision of tobacco). They require mains electricity to run for periods beyond the 4-5 hour internal battery life.

A Health & Safety (H&S) Co-ordinator and/or his/her designated representative for each prison will be trained in the use of the Dylos device at a half-day training session. Each H&S Co-ordinator will install the Dylos device in the main hall/atrium area of a residential hall within their prison to gather data on $PM_{2.5}$ concentrations during a 6 day period. Data collection forms will be completed to indicate that the machine has been checked each day. The 6-day main hall/atrium data will be downloaded at the end of the week by connecting the device to a laptop during a visit by a member of the research team. The Dylos will then be returned to the staff member so that further 'task-based' data collection can be carried out by the H&S Co-ordinator as soon as possible afterwards to gather a series of short-term (30-min) measurements at a variety of strategic locations where staff and prisoners spend time (e.g. other residential halls/floors, canteen, games room, library) to check on exposures and compliance with existing policies. Since the devices are small enough to carry on a strap, data will also be gathered on particular tasks carried out by staff, including unlocking and entering cells where smoking is permitted. A data collection form will record the time/location for these short/mobile sampling tasks. On completion of this 'task-based' sampling, the Dylos device and the data collection sheet will be returned by the H&S Co-ordinator to one of the research staff, or by prior arrangement by courier to the University of Aberdeen.

In addition to the Dylos, a small 'nicotine badge' will be used to gather information on airborne nicotine levels over the 6 day measurement period. This 'badge' will provide an overall average of the airborne nicotine concentration at the location used. It will assist in determining the relationship between airborne nicotine and airborne $PM_{2.5}$ concentrations and will thus help quantify how much $PM_{2.5}$ is from tobacco sources compared to non-tobacco sources. The 'badges' (Hargreaves, Lewis et al. 2003) will be supplied by John Hopkins University and will be removed by the H&S Co-ordinator from the supplied container, positioned alongside the Dylos instrument and left exposed to the air throughout the 6-day sampling period in the main hall or atrium. At the end of the 6-day sampling prior to the researcher's visit to the prison, the 'badge' will be placed in a

sealed container and collected from the prison for return to the University of Aberdeen or the University of Glasgow, together with the air quality monitoring data collection form. Training in the handling and positioning of the nicotine badge will be included in the half-day training for each H&S Coordinator or his/her nominated designate(s).

Datafiles downloaded from the Dylos device will be forwarded to the research team at the University of Aberdeen as soon as possible after being downloaded. Should any issues arise, full technical support will be provided by the University of Aberdeen by telephone and email during data collection. The H&S Coordinator or his/her nominated designate(s) will also have access to a FAQ guide and an abbreviated manual from their training session.

In order to provide comparison with outdoor $PM_{2.5}$ concentrations (from non-tobacco, generally vehicle and industrial combustion emissions), publically available data from the Scottish Government/Local Authority Air Quality Network (http://www.scottishairquality.co.uk/) will be acquired from the nearest fixed monitoring site to each prison for the main 6-day monitoring period. The median distance between prisons and these outdoor $PM_{2.5}$ monitors is 16km with only one prison located >50km from a monitoring station. The average outdoor $PM_{2.5}$ concentration during the measurement period will then be subtracted from the indoor Dylos results to provide an estimate of SHS-derived $PM_{2.5}$. Results will be available with and without this adjustment.

Salivary cotinine measurement

Non-smoking staff (who do not live with a smoker nor travel to work in a vehicle where smoking occurs) will be invited to participate in a study of salivary cotinine concentration changes over a typical work-shift in each of the Scottish prisons. Recruitment procedures may vary across prisons and will be discussed with Governors/senior staff. Our preferred method of invitation will be via an e-mail from the research team, to be forwarded by individual Governors/nominated prison staff representative. This will give brief information about the procedure, detail who would be eligible (see below), and ask those interested in participating to contact us. In addition, it may also be possible for researchers to approach and recruit staff during fieldwork visits to the prisons. We envisage high awareness of the study because of its topicality, our publicity materials and communications from the SPS, and the ongoing research activity around air quality monitoring and online staff survey (see below). Interested staff will be provided with further information. Staff volunteering to take part will be asked to complete a consent form and confirm that they understand the purpose and process of sampling and satisfy the inclusion/exclusion criteria. We aim to gather paired samples of saliva from the start and end of shifts from approximately 10% of staff from each prison (c. 400 staff in total). Inclusion criteria are that they are: (1) prison staff (preferably operational staff or staff who are likely to have some exposure to SHS during their working day); and (2) available and willing to provide a saliva sample at the start and end of their working day on the days that our fieldwork team is in attendance at their prison. Exclusion criteria are that they: (1) smoke or use any form of nicotine containing product (electronic cigarettes, patches, gums); (2) live in a home where someone smokes; or (3) travel to work in a vehicle where someone smokes.

The saliva collection protocol is based on that used for the Bar Workers' Health and Exposure to Environmental Tobacco Smoke (BHETSE) study (Semple, Maccalman et al. 2007). Participants will be asked to provide a saliva sample in a salivette tube (plastic test-tube like receptacles with a cotton wool roll inside). The salivettes have three parts: an inner tube with stopper; an outer tube (marked with a bar code and ID number); and a cotton wool roll. A member of the research team will guide the prison staff member through collecting a sample of saliva at the start and end of their working shift. The researcher will complete a data collection sheet; and will ensure the participant provides a completed log of activities they have undertaken over the course of the sampling day (using a standard proforma). The collected saliva samples will initially be temporarily stored at the University of Glasgow before being sent by the research team to the University of Aberdeen for storage and batching before analysis by ABS Laboratories Ltd. Saliva samples will be analysed for the presence of cotinine, a marker of how much nicotine a person has breathed in. By comparing the levels at the start of the shift with those at the end of the shift it is possible to estimate the amount of cigarette smoke inhaled using previously published methods (Repace, Al-Delaimy et al. 2006). Any before-shift samples that are not paired with an after-shift sample will be destroyed.

Staff will also be asked about their perceived exposure to SHS in the online staff questionnaire (see below).

Prison staff SHS exposure estimates
By combining the air monitoring data gathered over 6 days from the main atrium area of one residential hall and the shorter task-based measurements from each prison with details of the typical work-shift patterns of operational staff estimates of full-shift SHS-$PM_{2.5}$ exposure will be generated. These will be produced for a range of specific job titles and for each prison. Where possible and where sufficient samples are available, these estimates of airborne exposure will be validated by comparison with the data gathered from the salivary cotinine measurements.

3.3 WP3 – staff survey/staff focus groups in all prisons; staff telephone interviews in c.4 case-study prisons; WP4 – prisoner survey in all prisons and interviews in c.4 case-study prisons (Phases 1, 2 and 3)

Staff and prisoner questionnaires – Phases 1, 2 and 3
Questionnaires will be administered to staff and prisoners during each study phase, covering similar, but not identical topics. Both include items on: basic demographics; physical, respiratory and mental health; smoking history and behaviour, including quit attempts and use of electronic cigarettes; second-hand smoke exposure; opinions on smoking and smoking restrictions, both generally and in prisons. A Research Advisory Group (RAG), constituted and convened by the SPS, will ensure consultation with relevant parties (e.g. trade union representatives, SPS Research Access and Ethics Committee).

Staff questionnaires will be administered online, to all prison staff via an email link, forwarded by a nominated representative in each prison (see WP2 SHS measures above). The online survey will be generated and housed by IT staff at SPHSU, ensuring highest standards of security. Given that both we as researchers and SPS management believe it is important that the research is, and is seen to be, independent of SPS management, the questionnaire link will be forwarded directly by us as researchers to the nominated staff member, for him/her to forward to all staff in their prison. We believe the alternative, an email forwarded by SPS Headquarters staff, would not be satisfactory in this respect.

We consulted widely on whether: staff should be asked to enter their unique SPS employee ID, in order to ensure that we could send reminders to those who had not yet completed a questionnaire and remove any duplicate responses from any member of staff who completes the survey more than once, with assurances that staff IDs would be immediately removed; or be completely anonymous. The most widely expressed view was that staff would not wish to divulge their staff ID or other potentially identifying information; hence all staff questionnaires are entirely anonymous and untraceable back to individual staff members by any means. Union representatives of prison staff have indicated that we should anticipate a high response rate from both smoking and non-smoking staff, at least in Phase 1, given the concern expressed by some prison staff about exposure to second-hand smoke during the course of their work.

Prisoner questionnaires will be administered as paper copies. Our target is to achieve a 20% randomly selected sample from all prisons; we will be advised on how best to achieve this and how best to invite prisoners to take part by each Governor-in-Charge, or his/her appointed representative. Some prisons have indicated that, on equality and pragmatic grounds, they may ask for questionnaires to be available for a greater proportion of their prisoner population. On the basis of the SPS biannual prisoner survey, we might anticipate a response of 50-60% of those approached, but response levels may be higher if prisoners view this as an opportunity to express their views on a potentially highly emotive topic. Prisoners will be provided with information about the questionnaire beforehand. In ideal circumstances, they will be: given the opportunity to discuss this and ask questions with research staff before deciding whether to participate; able to complete their questionnaires without disturbance from other prisoners, given the role of smoking and tobacco-products in prison life, including in relation to bullying and intimidation; and given the opportunity to have impartial (researcher) assistance if they have literacy or other learning difficulties. When SPS conduct their biannual prisoner survey, prisoners with literacy/learning difficulties are offered help with questionnaire completion by other prisoners; ideally we wish to avoid this in this context, and we will offer to make trained field-workers available to assist prisoners who require help (ideally checking whether prisoners have a preference for being supported by a research staff or SPS staff member). However, operational considerations will determine the preferred means of administration of the prisoner survey in each prison. We anticipate fieldwork administering the prisoner questionnaires will be completed over a short time period (c1-3 days, depending on operational considerations and the size of the prison) in each prison, going into each prison with enough field-workers to ensure sufficient help is available given local guidance about the means of

administration of the survey. Since prisons vary in both their size and individual prisoner characteristics (e.g. literacy levels), we will liaise closely with Governors/their appointed representative over the best way to achieve our aims in respect of prisoner questionnaire administration in their prison (e.g. numbers of field-workers required).

Staff focus groups – Phase 1 only

Staff in each of the Scottish prisons will also be invited to attend focus groups (maximum participants per group=c.8, including both smokers and non-smokers) conducted around the time of the saliva collection/survey administration. Recruitment procedures may vary across prisons and will be discussed with Governors/senior staff. Our suggested method will be an e-mail/letter from us as researchers, to be forwarded by individual Governors/appointed representative (i.e. the same as the anticipated method for the online staff questionnaire link). This would give brief information about the focus groups and ask those interested in participating to contact us by email. Interested staff will be provided with further information. Participants in each focus group will complete a consent form before participating. SPS have suggested that focus groups should be conducted during work-time on prison premises where possible and at a time which suits participants, taking account of operational constraints in each prison and fieldwork constraints. The focus groups will cover experiences of smoking and exposures to second-hand smoke, particularly within prisons; smoking norms and perceived prevalence within the prison; the 'culture' of smoking within prisons; restrictions on smoking and opinions on these; and views of prisoners who smoke.

Staff and prisoner face-to-face / telephone interviews – Phases 1, 2 and 3

Individual interviews will be conducted with staff (face-to-face or by telephone) and prisoners (face-to-face) in c. four case-study prisons, selected, in consultation with SPS, for more detailed qualitative work (e.g. based on more/less positive attitudes towards smoking restrictions). As with the questionnaires, staff and prisoner interviews will cover similar topics, but are not identical. We anticipate similar content in phases 2 and 3, allowing us to compare responses over time. Both staff and prisoner topic guides will aim to cover: time in prison (current and other prisons – as staff or prisoner); experience of smoking and use of e-cigarettes; changes over time (particularly, for prisoners, associated with coming into prison); experiences of the working environment as a smoker/non-smoker; smoking norms and perceived prevalence within the prison; tobacco availability, trading and as 'currency'; locations of prisoner smoking; restrictions on smoking and opinions on these; views of prisoners who smoke. All interviews will be semi-structured and participants will be encouraged to express themselves freely and to raise any additional issues which they believe are important. We anticipate that interviews will last around 45 minutes and potential participants will be made aware of this before deciding to take part.

In each case-study prison, face-to-face / telephone interviews will be conducted with 6-8 ***staff*** (3-4 smoking, 3-4 non-smoking). In order to recruit them, as with the staff focus groups, staff will be invited to participate and will complete a consent form before participating (for those participating via telephone, agreement to each item of the consent form will be recorded prior to the interview). Again, as with the staff focus groups, recruitment procedures may vary across prisons and will be discussed with Governors/senior staff, but we hope to send an initial email invite with further information for those who show interest by providing contact details.

In each case-study prison, individual face-to-face interviews will be conducted with 15 ***prisoners*** (approximate ratio of 8:4:3 for current, ex- and never smokers). We will discuss precise details on exactly how this can be done within the operational/physical constraints of each prison with Governors/senior staff from each prison. Potential participants will be provided with an invitation to participate and will complete a consent form before participating, should they indicate that they wish to take part. Individual interviews will be conducted in interview rooms in the residential halls, or other suitable facilities as advised by those in charge of local prison operating facilities. Detailed practical arrangements (e.g. interview location) will be discussed with individual prison Governors/senior staff; safety and operational concerns will be paramount.

Focus groups and interviews will be audio recorded with participants' permission. Brief field-notes will also be taken and may be used for reference during analysis and reporting of findings. All data will be transcribed either by a member of SPHSU administrative support staff or an external transcribing service which has signed a confidentiality agreement with SPHSU and been vetted for security.

All data will be treated confidentially and participants' anonymity will be maintained by de-identifying the data. All identifiable data will be kept securely in a locked cabinet or in a password-protected computer within the SPHSU, University of Glasgow. Only the researchers will have access to any identifiable data.

*3.4 WP5 –**Cessation services: experiences, provision and outcomes (Phases 1 and 2)***

Individual interviews with cessation service leads in all prisons and associated Health Boards -Phase 1
Members of staff with lead responsibility for cessation support in each prison and in those health boards where prisons are located will be invited to take part in a telephone interview. These staff will be identified via the health boards, SPS, individual prison Governors/senior staff and through established NHS smoking cessation networks. Identified staff will be provided with further information (via email/post to work addresses) and asked for opt-in consent (scanned and returned via email/post or recorded prior to the interview). Interviews will be semi-structured, last up to one hour and be undertaken during work time. Topics covered will include: time (working) in prison (current and other prisons – as staff or prisoner); experience of smoking within prisons; awareness and understanding of smoking restrictions, compliance with these provisions; norms and attitudes to quitting and remaining abstinent while in prison; expectancies post-release (prisoners only); attitudes and experience of smoking cessation support within and between prisons (and for prison staff within the wider community); attitudes towards smokefree policy within prisons; views on factors likely to influence effective implementation of smokefree policy; and views on the value of e-cigarettes as a cessation and abstinence aid. Participants will be encouraged to express themselves freely and to raise any additional issues which they believe are important.

Individual interviews with cessation service providers in prisons in c.4 case-study prisons – Phase 2
Members of staff responsible for delivering and supporting cessation support in the selected case study prisons (including a mix of professionals such as staff dedicated to providing cessation support and staff responsible for general prisoner health who have smoking as part of their remit) will be invited to take part in an interview. It is anticipated that most of these interviews will be conducted face-to-face and will include service leads, trainers and frontline healthcare staff. Telephone interviews may be offered in some instances where there are significant organisational barriers to arranging direct access. These participants will be identified from the Phase 1 interviews with prison and Health Board leads. In some cases it may be appropriate to interview participants together, for example if they assume similar or joint roles. In order to assess progress towards implementation of a smokefree policy, approximately two-thirds of participants will be interviewed on two occasions; the first to assess existing smoking cessation services and development needs and the second to assess preparations and progress towards implementation. We anticipate the timing between these interviews will be in the region of 6-8 months but this will be informed by government decisions and announcements regarding implementation of smokefree policy in Scottish prisons. As with Phase 1, all interviews will be semi-structured, will last up to one hour and will be undertaken in work-time and at a time suitable to participants. The issues covered will be similar to those described above (individual interviews with cessation service leads in all prisons and associated Health Boards), although the emphasis given to different topic areas will vary as the policy develops. Staff who have been identified to take part will be provided with further information and asked to complete a consent form before participating. For those participating via telephone, and where the respondent chooses not to provide a scanned version of the consent form, oral consent will be recorded prior to the interview.

Staff and prisoner focus groups (smokers and former smokers) in c.4 case-study prisons – Phase 2
Focus groups will be conducted (separately) with staff and with prisoners who smoke or who are ex-smokers in the case study prisons on two occasions, the first to assess development needs and the second to examine progress towards implementation of smokefree policy. One focus group will be conducted with staff and one with prisoners in each of the case study prisons at each stage, although where difficulties in recruitment are encountered we would retain the option of conducting individual or paired interviews. Precise details on recruitment for and conduct of the prisoner focus groups/interviews will be discussed with Governors/senior staff from each prison.

Staff and prisoner focus groups will cover similar topics to those described above (individual interviews with cessation service leads in all prisons and associated Health Boards), with slight modifications to allow us to compare responses over time, in relation to assessment of need and progress towards meeting need.

Participants who have been identified to take part will be provided with further information and asked to complete a consent form before participating.

All identifiable data from WP5 will be kept securely in a locked cabinet or in a password-protected computer within the University of Stirling. Copies of all research data will also be archived by the University of Glasgow. Only the researchers will have access to any identifiable data.

4. Study population

WP1: representatives from prisons internationally with experience of implementing partial/total smoking bans within prisons
WP2-4: Prisoners and prison staff within all 15 prisons in Scotland. This includes a female-only prison, two private prisons, one open prison, and a Young Offenders Institution (16-21 years) that operates a smokefree policy for its under 18 population. For the qualitative work, participants will be purposively sampled on the basis of their smoking status.
WP5: users and providers of smoking cessation services within the 15 prisons in Scotland, including SPS and NHS staff, and prisoners.

Participants will be excluded from WP2-5 if we are advised by SPS that specific potential participants raise health/safety issues for either researchers/field staff, or the prisoner him/herself, or if they have communication/health issues which preclude participation. It is anticipated that interviews will be conducted in English, unless arrangements can be made for staff/volunteers to be present to translate.

5. Socio-economic position and inequalities

Around half of those who smoke will die from tobacco-related illnesses, and tobacco-attributable deaths are estimated to be 6.4 million globally in 2015. In Scotland, tobacco use was estimated to be associated with a quarter of deaths (approximately 13,000 per annum) and 56,000 hospital admissions in 2013, with an annual cost to the Scottish health service of £300-500m (Scottish Government 2013). A particular challenge for ambitions to achieve smokefree societies is that tobacco and poverty have become "inextricably linked" (Hartwig, Stover et al. 2008) (p5). In Scotland in 2011, more than three times as many (38%) of those living in areas classified as in the most deprived quintile were current smokers compared with the most affluent quintile (12%) and estimates for 2016 suggest little erosion of this disparity (27% vs 10% respectively) (Scottish Government 2013). Health Survey for England data show that 80% of smokers are deprived on at least one of seven commonly used indicators of deprivation (NS-Socio-economic classification, neighbourhood index of deprivation, lone parent, car access, housing tenure, income and unemployment), and the prevalence of smoking rises from 15% in those with no indicators of low SES to 61% of those with all seven (Hiscock, Bauld et al. 2012). In his foreword to Scotland's recent smoking strategy, the Minister for Public Health observed that "perhaps the most troubling aspect of current smoking patterns is the hugely disproportionate impact on Scotland's most deprived [and]...effective action to reduce smoking prevalence demands a focus on those communities at greatest risk of unequal health outcomes" (Scottish Government 2013) (piii). The Report states "We will not achieve our ambition of a tobacco-free Scotland without addressing the stark socio-economic inequalities in smoking prevalence rates" (p2). When considering 'Inequalities-Targeted Services', prisoners are highlighted: "We recognise the real need to work towards protection of offenders from second-hand smoke and in the provision of effective smoking cessation services" (p41). These statements reflect a growing recognition that if inequalities in the harms of smoking are to be reduced, prisoners are an important target population (Public Health England 2015): as well as having disproportionately high substance abuse and mental health problems which are associated with high smoking rates, they are also at increased risk of factors associated with smoking, including having low/no educational qualifications, having experienced poverty, unemployment[5], homelessness, exclusion from school, adverse family and social experiences such as domestic and/or sexual abuse and time in local authority care (World Health Organization Regional Office for Europe 2013).

[5] Recent research also suggests that smokers remain unemployed longer than non-smokers: Prochaska JJ et al. Likelihood of unemployed smokers vs nonsmokers attaining reemployment in a one-year observational study [published online April 11, 2016]. *JAMA Intern Med*. doi:10.1001/jamainternmed.2016.0772.

6. Planned interventions

a) Harmonisation and increased provision of smoking cessation services for prisoners (including health service provision as provided by Health Boards and other smoking cessation support) across Scottish prisons. It is anticipated that this will increasingly occur during Phases 1-2 of the study.
b) Implementation of indoor smokefree prison policy.

7. Proposed outcome measures

Primary outcomes: Current smoking in prisoners; objective indicators of SHS (before-after shift salivary cotinine in sub-sample of staff; air quality within prisons [$PM_{2.5}$, nicotine]).

Secondary outcomes:
Staff: smoking status; general health and well-being; respiratory symptoms; use of primary health care; self-reported and/or aggregated sickness absence data;
Prisoners: self-perceived smoking status (i.e. extent to which they see themselves as lifelong quitters to estimate impacts post-release); general health and wellbeing; use of primary care; (if available) aggregate medication and health data; acceptance of and compliance with current tobacco control policy.

8. Assessment and follow-up

Measurement of all primary and secondary outcomes (including measurement of indicators of SHS exposures) will be repeated post-implementation of indoor smokefree policies/smokefree prisons (Phase 3), following the same protocols as at baseline (Phase 1). Interim data (in anticipation of implementation of policy change) will be collected, via process data from c. four case study prisons, and repeat staff and prisoner surveys in Phase 2, as described above. Anticipated timings are shown in Figure 1, and in the project timeline and milestones, subject to decisions re policy changes nationally or locally.

9. Proposed sample size:

WP1: We propose 15 telephone interviews with key personnel in countries which have introduced smokefree prison policies, and face-to-face/telephone interviews (n=c.8) with key staff in prisons introducing smokefree in early 2016 in England and Wales.

WP2. Survey data will be gathered from c.2700 prison workers (estimated 60% response rate from staff within Scottish prisons of 4500 invited).
Staff salivary cotinine measures: We anticipate that c30% will be smokers, and perhaps a further 25% live with or travel with a smoker or spend significant non-occupational time in 'smoky' environments (e.g. travel to work with smoking colleagues). Of the remaining 1100 (non-smoking workers with minimal non-occupational exposure to SHS), we anticipate that 50% will agree to providing two saliva samples on a given work day; an 80% return rate of valid samples would give a total sample size of c440 (average 29 per prison). We assume an ICC of 0.15; we can find no reported ICCs for salivary cotinine in prisons but believe this to be conservative as it is much larger than the ICCs of 0.047 and 0.022 reported for two studies of smoking cessation in Finnish workplaces (Kouvonen, Kivimaki et al. 2012). Then we would have power of 0.8 to detect a difference of 0.56 ng/ml (an effect size of 0.43 based on SD=1.29). This compares to a reduction of 1.1 ng/ml (from 1.6 to 0.5) found among hotel workers following the Irish smoking ban (Mulcahy, Evans et al. 2005).

Air quality measures: Six-day air quality measurements will be made in each of Scotland's 15 prisons. These will provide an average $PM_{2.5}$ concentration together with the percent of time above specific thresholds such as the WHO guidance limit of 25 $\mu g/m^3$ and other comparative markers (e.g. average levels measured in pubs prior to implementation of smokefree legislation in Scotland in 2006). Around six 30-minute 'task-based' measurements will also be made in each prison. For comparison, mean $PM_{2.5}$ over a 24 hour period was found to be 33.3 and 4.4 in smoking and non-smoking homes respectively (Semple, Ibrahim et al. 2015).

WP3. *Staff survey*: as above, we will invite all staff to participate in the online staff survey (n=c4500 staff) and aim to gather data from 60%. A 50% response with a true prevalence of smoking of 30% would mean a tolerance of + 1.5%, giving a 95% confidence interval for the estimate of prevalence of 28.5%-31.5%.
Qualitative: Year one, 1 FG in each of 15 prisons with a mixture of smoking and non-smoking staff (15 FGs, total n=90 staff, assuming 3 smoking and 3 non-smoking staff members in each group).

In years 1, 2 and 3 semi-structured telephone interviews with 10 staff (5 smokers, 5 non-smokers) in each of c.4 case-study prisons (total n per annum=40 staff).

WP4 *Prisoner survey with c20% subsample of prisoners.* We assume a sample size of n=1480 prisoners and a true prevalence of smoking of 70%. In the absence of a known figure we again assume a conservative ICC of 0.15. This would provide power of 0.8 to detect a fall in prevalence in male prisoners from 70% to 48%.

Qualitative: 15 45 minute face-to-face semi-structure individual interviews (with representation of smokers, ex-smokers and never smokers reflecting proportions from survey data) in each of c.4 'case-study' prisons in years 1, 2 and 3 (total n=60 in each year).

WP5 Cessation service (CS): experiences/provision.
Phase 1: Mapping of prison estate and cessation service links - assessment of preparedness and proposed plans for harmonisation - 15 telephone interviews with prison smoking cessation service leads; up to 15 telephone interviews with Health Board smoking cessation service leads.
Phase 2: Formative and process evaluation in four case study prisons - development and preparation for implementation of smokefree.
Stage 1: Assessment of existing smoking cessation service and development needs
- Interviews with key stakeholders (prison leads, health staff, trainers): up to 3 per site, option of telephone interviews (n=12)
- Interviews/focus groups with staff who smoke/recent ex-smokers: up to 5 participants per site, mix of cessation service users and non-users as appropriate, option of telephone (n=20)
- Interviews/focus groups with prisoners who are smokers/recent ex-smokers: up to 5 participants per site, mix of cessation service users and non-users as appropriate (n=20)

Stage 2: Response to preparations made in the lead up to implementation
- Follow-up interviews with key stakeholders up to 2 per site, option of telephone interviews (n=8)
- Interviews/focus groups with staff as per Stage 1
- Interviews/focus groups with prisoners as per Stage 1

10. Analysis

10.1 Statistical analysis: Analysis of objective measures of SHS will follow previously published methods (Feyeraband and Russell 1990, Repace, Al-Delaimy et al. 2006, Semple, Ibrahim et al. 2015). SHS levels in the prisons will be assessed using air quality monitors. We will compare mean $PM_{2.5}$ concentrations before and after the implementation of a smokefree policy within each prison over a 6 day period. We will compare each site individually using paired sample t-tests and collectively using a multilevel model including the levels of prison, site, measurement occasion (day and hour) and wave (pre- and post-intervention). Making the conservative assumption that we will not be able to include the same staff at both waves (e.g. because staff have changed location or type of job, were not on shift on Phase 1 and Phase 3 saliva measurement days in their prison, have left the prison service), the change in exposure of non-smoking staff to SHS through salivary cotinine will be assessed treating the two as separate samples. Multilevel regression analysis will adjust for socio-demographic characteristics and job type with the levels of prison, wave and individual.

Subject to the anonymised, aggregate data being made available, we will calculate sickness absence rates as the number of hours lost due to sickness absence as a proportion of the total number of hours that could have been worked by prison officers in each prison for each month. We will identify the impact of the smokefree prison policy on sickness absence among prison officers by fitting interrupted time series models to the monthly data. The models will take account of pre-implementation trends, seasonality and the way in which any new policy is introduced (i.e. whether the transition to smokefree is abrupt or gradual). Data permitting, we shall also analyse sickness absence rates by cause, distinguishing smoking-related absences from all other absences.

Analyses of quantitative questionnaire data will include: basic descriptive statistics (e.g. proportions agreeing with particular attitudinal items); and examination of change in prisoner/staff smoking prevalence, health and attitudes over time via multilevel logistic regression with the levels of prisons, study phases and prisoners, treating the samples at different waves as independent (repeat cross sections) since there will be considerable movement of prisoners and adjusting for socio-demographic characteristics. Analyses will assess missing data

patterns and use multiple imputation[6] to create multiple datasets with as many relevant predictor variables as possible included in the imputation models. Questionnaire data will also be utilised in health economic modelling.

Any change in the prevalence of smoking among prisoners will be assessed using multilevel logistic regression, treating the samples at different waves as independent since there will be considerable movement of prisoners, with the levels of prisons, waves and prisoners. We will adjust for socio-demographic characteristics.

Secondary outcomes collected by survey will be analysed by multilevel linear, logistic or multinomial regression depending on the outcome. In all analyses we will assess missing data patterns and use multiple imputation to create multiple datasets for analysis with as many relevant predictor variables as possible included in the imputation models.

10.2 Qualitative data analysis: Interview and focus group transcripts will be checked for accuracy against the digital recordings, suitably anonymised, and analysed using a structured thematic approach (Ritchie and Lewis 2003) to explore our research questions and any emerging themes. Several members of the research team with qualitative expertise will read anonymised transcripts to support the development of robust analytical frameworks for each of the embedded qualitative studies. Coding frames and codebooks will be developed through discussion and close reading of transcripts, and will be tested and discussed to ensure common understandings of key themes before coding to broad themes is undertaken. The content of the themes relevant to the key research questions will be examined in detail by at least two researchers, who will read coded extracts line by line to identify all sub-themes, using suitable methods to enable systematic comparison of data from different participants/groups, noting anticipated and unanticipated themes. Attention will be paid to 'deviant cases' to ensure all perspectives are captured. Nvivo software will be used to assist in the organisation and analysis of the qualitative data.

11. Ethical arrangements

Ethical approval for WPs1-5 will obtained from Glasgow University College of Social Sciences Ethics Committee. All elements of the study will also be separately approved by the Scottish Prison Service Research Access and Ethics Committee, who were asked to advise whether research within any of the work packages also required approval from an NHS Research Ethics Committee. Given WP5 involves interviews with Health Board smoking cessation managers, advice has been sought from the South East Scotland Research Ethics Service. We have been advised that the research does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees.

Research involving prisoners, as with other potentially vulnerable groups, raises many issues (Schlosser 2008) and requires particularly careful attention to ethics. Prison governors, prison staff and prisoners will be informed about the study via in-person visits by the PI (Kate Hunt) and/or Helen Sweeting, together with a representative of the Health and Wellbeing at SPS (Sarah Corbett and/or Ruth Parker), in advance of any data collection. These will be arranged via SPS, and a key point of contact within each prison will be agreed. Permission for the participation of each prison will be required from the SPS and prison governor. Following these in-person visits, general information leaflets and posters alerting staff and prisoners to the research will be distributed and displayed within each of the prisons by prison staff in advance of data collection, so that staff and prisoners are aware that they may be approached about the study.

Participants in any element of the research will receive an information sheet explaining the aims and objectives of the research that they are being asked to contribute to. This will clearly indicate: why they have been approached; that their participation is voluntary and they are free to withdraw at any time and have no obligation to answer any questions they do not wish to; that all data will be anonymised and stored securely, and only be reported in anonymised form to any parties. They will be given assurances that their answers will be treated in the strictest confidence, explaining the independence of the research team from Scottish Government and the Scottish Prison Service. Only aggregate and anonymised data will appear in any Reports,

[6] We will investigate whether it is possible to use relevant data from the SPS biannual prisoner questionnaire to inform imputation of missing data on smoking

publication or presentations. In particular, prisoners will be reassured that their participation (or lack of participation) will not in any way influence their care or treatment in prison. Written opt-in consent will be obtained for all qualitative interviews and measures of personal exposure to SHS. As the online staff survey and prisoner survey have no identifying information, it will be explained that completion of the online survey by staff and the paper questionnaire survey by prisoners is deemed to constitute consent, unless other requirements are detailed during ethical review. We will consult with SPS and unions before finalising the content of the questionnaires.

Prisoner questionnaire data will be entered in-house at SPHSU and transcription of qualitative data will be undertaken by a specialist transcription service bound by confidentiality guidelines. Data from questionnaires will be stored in an anonymised format, using questionnaire identification numbers (IDs).

For focus groups and individual qualitative interviews, participant ID numbers and corresponding names will be held in separate files and all will be stored in password protected folders. Individual names will be replaced with pseudonyms in transcribed interview materials; we will follow SPS advice and guidance on anonymisation of prisons. Digital recordings of interviews (made with written participant permission) will be stored securely, and held separately from transcripts and information on participant identity. Care will be taken to prevent deductive disclosure of identities in the use of selected extracts from interviews/focus groups in all project outputs. All quotations will be anonymised, except where there is an explicit request and permission for an attributed quote. We will follow data service requirements for recording and management of data (hhtp://ukdataservice). SPHSU is bound by the MRC's and Glasgow University's rigorous research governance policies. Research data will be destroyed according to MRC research guidelines. In line with this, the research data will be kept for ten years after the study has been completed, and then destroyed in accordance with MRC and University of Glasgow policy (audio and electronic documents will be deleted and paper copies will be shredded).

Any member of the research team visiting a prison will be required to undergo appropriate security checks, and any member who is expected to have one-to-one encounters with prisoners will be required to complete any safety and security training as recommended by SPS, in addition to training in SPHSU's standard fieldwork safety procedures for research team members in community settings. All research will be carried out in accordance with MRC best practice guidelines (http://www.mrc.ac.uk/publications/browse/good-research-practice-principles-and-guidelines/), the ESRC Framework for research ethics (http://www.esrc.ac.uk/files/funding/guidance-for-applicants/esrc-framework-for-research-ethics-2015/), and any relevant guidance on research practice from SPS and Health Boards. At all times, safety and prison operational considerations, and any impacts on the delivery of health care in the prisons, will dictate the day-to-day conduct of the research within each prison.

12. Research Governance: University of Glasgow will be the nominated sponsor of the research.

An **Operational Research Management Group** will meet fortnightly (chaired by Kate Hunt, with Helen Sweeting and other SPHSU research/support staff involved in other aspects of the overall study).

Project Research Team meetings (all co-Investigators on the NIHR proposal) will occur face-to-face or by teleconferencing at least quarterly.

SPS Research Advisory Group: A Research Advisory Group will be convened by SPS, comprising representatives of the key stakeholders they identify. This will include representatives from stakeholder partners who contributed to SPS' 2015 Tobacco Strategy group (SPS Health and Wellbeing team; Scottish Government Tobacco Control Team; NHS Health Scotland; SPS trade union representatives or similar representative of prison staff) and representatives of SPS Communications branch and Research Ethics Committee. It is anticipated that the RAG will meet at least bi-annually during most phases of the overall study, and more often as deemed necessary. This group will ensure that proposed activities are achievable and realistic within the resources available and any operational constraints within the day-to-day good governance of prisons, and to ensure a focus is maintained on achieving the outputs SPS considers a priority.

Study Steering Committee (SSC): The SSC will meet face-to-face at least annually, with additional teleconferences/ meetings as required, chaired by Dr Andrew Fraser, NHS Health Scotland.

13. Project timetable and milestones:

All timings beyond the early stages of Phase 1 may be subject to change, depending on the timing of any Government or prison service announcements about the implementation of new policies on smoking in prisons in Scotland. The project timetable and milestones will be reviewed with NIHR, the SPS-convened Research Advisory Group, the Study Steering Committee, and with the Research team in the event of the announcement of a timeframe for the implementation of new policies on smoking in prisons.

Dates	**Milestone**	**Workpackage**
Feb-Jul 2016	Obtain ethical approval from SPS Research Access and Ethics Committee; check whether NHS ethical permission needed for WP5	All
Jul-Oct 2016	Obtain local Glasgow University ethics for WP1-5	All
1st Sept 2016	*Project starts*	
Apr-Sept 2016	Initial consultations with SPS Research Advisory Group. In-person visits to all prisons to meet senior staff to discuss research and establish key point of contact in each prison. Finalisation of staff survey questionnaire and topic guides; drafting of prisoner questionnaires.	All
Sept 2016-May 2017	Collect and analyse interviews for WP1; update literature scoping review	WP1
Sep-Dec 2016	Phase 1 measurement of SHS exposures	WP2
Oct-Dec 2016	Phase 1 staff survey and staff focus groups	WP3
Nov 2016-Mar 2017	Phase 1 prisoner survey	WP4
Oct 2016-Feb 2017	Scoping of smoking cessation provision; Phase 1 interviews with smoking cessation staff	WP5
Dec 2016-Jan 2017	Analysis of Phase 1 staff survey. Prepare summary of Phase 1 staff survey and present to RAG	WP3; WP6
Dec 2016-May 2017	Analysis of SHS exposure data; analysis of prisoner survey; analysis of staff focus groups; analysis of scoping of smoking cessation provision. Prepare summaries and present to RAG, prepare papers and dissemination materials for prison staff and prisoners	WP2-5; WP6
Jan-Feb 2017	Selection of case study prisons	WP3-5; WP6
Feb-Apr 2017	Phase 1 interviews with prisoners - data collection and analysis. Prepare summaries and present to RAG	WP4
May 2017	*Phase 1 complete; Phase 2 commences*	
Jun-Dec 2017	Staff and prisoner follow-up interviews and analysis	WP3-4
Jun 2017	Phase 2 Interviews with providers/users of smoking cessation services (WP5)	Mar 2018
Oct 2017	Phase 2 staff survey (WP3)	Dec 2017
Nov 2017	Phase 2 prisoner survey (WP4)	Feb 2018
Jan-May 2018	Review policy development; analysis of Phase 2 data; prepare summaries and present to RAG	All
Jun 2018	*Meetings with RAG; Study Steering Committee meeting to review need for hibernation/suspension of study if no further policy announcements/changes implemented*	*WP6*
Jun-Oct 2018	Analysis, write up and dissemination of Phase 1 and Phase 2 data	All
?Sept 2018	*Phase 3 commences*	
?Sept-Dec 2018	Phase 3 (post-implementation) measurement of SHS exposures	WP2
?Oct-Dec 2018	Phase 3 (post-implementation) staff survey	WP3
?Nov-Feb 2018	Phase 3 (post-implementation) prisoner survey	WP4
?Dec 2018-Aug 2019	Analysis; modelling of impacts	WP1-5; WP6
?September 2019	Project ends; outcomes paper submitted for publication	
?Dec 2019	Project report submitted	

14. Expertise.

- Service and academic public health; social scientific, epidemiological and biomedical research on smoking and smoking cessation (Kate Hunt, Helen Sweeting, Sean Semple, Linda Bauld, Douglas Eadie, Jill Pell, Alastair Leyland, Philip Conaglen)
- Measurement of indoor air pollution including exposure to SHS and other occupational exposures, in prisons and other settings (Sean Semple, Evangelia Demou)
- Evaluating smoking cessation services and the implementation of smokefree policies (Sean Semple, Linda Bauld, Douglas Eadie, Jill Pell, Kathleen Boyd)
- Evaluating complex public health interventions (Kate Hunt, Linda Bauld, Peter Craig, Alastair Leyland, Jill Pell, Kathleen Boyd) and natural experiments (Peter Craig, Alastair Leyland, Jill Pell, Kathleen Boyd)
- Improving health and wellbeing in those with contact with the criminal justice system (Philip Conaglen)
- Design, conduct and analysis of health surveys (Kate Hunt, Helen Sweeting, Jill Pell, Alastair Leyland, Kathleen Boyd, Evangelia Demou, Philip Conaglen); use of routine health data through linkage (Jill Pell, Alastair Leyland); advanced statistics and health and economic modelling (Alastair Leyland, Kathleen Boyd); inequalities in health and health behaviour (Kate Hunt, Helen Sweeting, Jill Pell, Alastair Leyland, Philip Conaglen); conducting qualitative research in prison settings (Kate Hunt, Douglas Eadie) and qualitative data analysis (Kate Hunt, Helen Sweeting, Linda Bauld, Douglas Eadie); and masculinities, health and health behaviour (Kate Hunt, Helen Sweeting), including in a prison setting.

In addition, research team members have served on relevant national bodies or have direct experience of policy-making and research, including: LB is CRUK's Cancer Prevention champion, with expertise in smoking cessation services and use of evidence to inform policy and was UK government's scientific adviser on tobacco control (2006-10); HS is Chair of the Scottish Tobacco-free Alliance Research Group and a member of ASH Scotland Policy and Development sub-committee; JP is a member of the CLEAN collaboration, a pan-Scotland group evaluating impacts of Scottish smokefree legislation; PCr has policy experience within central government, previously managing research on health services and public health research; PCo represents Scottish Directors of Public Health on the Scottish National Prison Healthcare Network Advisory Board and has responsibility for improving health and being in those in contact with the CJS for NHS Lothian.

15. Partner Collaboration

We will continue to work in close collaboration with representatives from key partner organisations, including the SPS (through Ruth Parker (Head, Health and Wellbeing), Sarah Corbett and Tina Everington (Health Improvement Manager)); Scottish Government (Fiona Dunlop, National Tobacco Control Advisor); NHS Health Scotland (Celia Gardiner, Tobacco Programme Manager); and Health Boards. SPS will facilitate access to prisons and resources, subject to approval by their Research and Ethics Committee, to cover any operational implications of the conduct of the research (e.g. escorting researchers/field staff through prison facilities and grounds, distributing study information sheets to appropriate parties, facilitating support for prisoner survey). We will ensure rapid dissemination of all phases of the research to prison management, prison staff and prisoner populations.

16. Funding

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Figure 1: Overview of workpackages