Development and evaluation of a novel intervention providing insight into the tobacco industry to prevent the uptake of smoking in school-aged children

Background:

Rationale for the proposed study: the benefits of preventing smoking uptake in young people

Cigarette smoking is the biggest preventable cause of morbidity and mortality in the UK. Smoking caused 81,700 deaths in adults in England in 2009[1] and, of the 10 million current smokers in the UK, 5 million will die prematurely as a consequence of smoking unless they quit[2]. Smoking cost the NHS an estimated £5.2 billion in 2005-6[3] with wider societal costs of a further £9 billion[4]. Most smokers become addicted to smoking before they reach the age of 18, with nearly 40% before the age of 16[5], predominantly during their years in secondary education[6]. Smokers who start at an early age tend to smoke more cigarettes per day in adulthood[7], smoke for longer[8], are less likely to quit[9] and are more likely to die from a smoking-attributable cause[8]. Smoking in adolescence impedes lung growth and causes a premature decline in lung function[10], is linked to early signs of heart disease and stroke[10], and is a major driver of inequalities in health; children in lower socio-economic groups are more likely to start smoking and to do so at a younger age[5]. Intervening with young people to prevent them smoking is thus a crucial public health priority[11].

What are the implications of existing research evaluating approaches to preventing adolescent smoking uptake?

Systematic reviews of studies of the design, implementation and effect of interventions to reduce uptake of smoking in young people conclude that whilst there is some (though by no means conclusive) evidence that school-based interventions may have short-term positive effects, there is little robust evidence that these interventions prevent young people from taking up smoking in the longer term[12-14]. However, as noted by NICE, since very little of this work has been carried out in the UK, these findings may not be applicable in the context of the UK education and healthcare systems[14]. Also, much of this evidence dates from the 1980s and 1990s, when the tobacco control environment and public attitudes towards smoking were very different to the present day. However, in the absence of relevant and recent UK data, evidence from older studies and those conducted elsewhere is useful in informing key questions surrounding the design and implementation of a successful intervention to prevent smoking uptake in young people in the UK today.

What does an effective intervention look like?

Existing studies have tested a variety of interventions, differing in theoretical approach, design, intensity and mode of delivery and utilising different outcome measures and follow-up periods in evaluation. Therefore, given the substantial heterogeneity between studies, evidence from systematic review and meta-analysis of this literature is difficult to interpret. Whilst there is no definitive evidence regarding interventions that do not work and should thus be avoided, there is also no clear evidence for what may be effective.

There is no conclusive evidence that any one theoretical approach or conceptual framework is superior to others in preventing smoking uptake[14]. Interventions that involve providing young people with information about the prevalence and consequences of smoking, enhancing their social competence (e.g. teaching skills to increase self-esteem and cope with stress) and addressing social influences (e.g. increasing awareness of peer and media influence and teaching refusal skills) have all been tested with inconsistent results in terms of their effects on uptake[15]. Recent evidence from the USA suggests that a focus on the ethics and exploitative tactics of the tobacco industry may be effective in encouraging young people not to smoke[16, 17]. Through mass media campaigns and additional online content, the 'Truth campaign'[18] has been credited with producing declines in youth smoking prevalence by countering the tobacco industry's deceptive marketing strategies and denial of the addictive nature and health effects of cigarettes and focussing attention on the negative effects of the industry on the environment and society. Though not specifically a school-based intervention, the relevance of the approach of the Truth campaign to the UK has been identified by NICE as an area for further research[14] and will be addressed in the proposed study. The emphasis of the Truth campaign has been adopted by Kick It, the Hammersmith and Fulham Stop Smoking Service, in designing '*Operation Smoke Storm*', a novel educational package for use in schools to increase awareness of the tobacco industry. In this package, students act as secret agents to uncover the tactics of the tobacco industry through a combination of

videos, quizzes, discussions and presentations spread over three hour-long classroom-based sessions. Additionally, the package covers the health effects of tobacco, passive smoking, nicotine addiction and tobacco cost. To date, Operation Smoke Storm has not been formally evaluated; we plan to use this existing resource as the basis of our intervention and provide evidence for its effectiveness and cost effectiveness.

Existing interventions have taken a number of different forms, though again heterogeneity between studies makes comparison of their effectiveness difficult. In the UK in 2002 the ASSIST trial trained students in Year 8 (aged 12-13) as peer supporters able to intervene with their friendship groups to encourage non-smoking[19]. This study found a significant reduction in reported recent smoking (in the last two weeks) up to two years later. However, this intervention requires the provision of two-day training events for peer supporters, held outside of school, with follow-up visits by trainers to schools to trouble shoot any problems. In the only other UK study, in the late 1990s a randomised controlled trial in 52 schools in the English West Midlands tested the effectiveness of a year-long programme in which students in Year 9 (aged 13-14) received three classroom-based sessions and three sessions using an expert computer system to encourage them to refrain from or stop smoking[20]. This study found no significant effect of the intervention on the proportion of adolescents smoking one or more cigarettes per week 12 months later.

There is good evidence that 'booster' sessions are useful in the months and years after the delivery of a main intervention to strengthen and maintain its effectiveness and NICE recommend their use[14]. Booster components which have been trialled have included both classroom-based sessions[21] as well as the delivery of tailored letters[22] to students, phone calls[23], videos[24] and magazines[25]. Some of these approaches are less resource-intensive than others and thus may be more appropriate and acceptable, particularly given the many competing demands on schools' time.

Young people may experiment with smoking intermittently over many years before they identify and report themselves as a smoker, whereas others show signs of dependence very early in their smoking career[26]. For this reason the evidence as summarised by NICE suggests that school-based interventions contain elements of both smoking prevention and cessation and that a school smokefree policy should include efforts to promote local NHS stop smoking services to both students and staff[14]. We will heed these recommendations.

What constitutes a cost-effective intervention?
There is limited evidence for the cost effectiveness of smoking prevention interventions in UK schools; studies carried out elsewhere are also of limited relevance here given differences in their populations and health care and education systems[27]. In the only UK study of which we are aware, the ASSIST trial was judged to reduce adolescent smoking at a modest cost; the incremental cost of the intervention per student not smoking at two year follow-up was £1500 (95% CI £669–£9,947)[28]. Given the limited existing evidence, the study proposed here will provide further useful information to quantify the cost effectiveness of UK school-based smoking prevention interventions, informing future discussions about the provision and funding of such programmes.

Who should deliver the intervention?
Existing studies have utilised a range of people to deliver anti-smoking interventions to young people, including teachers, school nurses, project staff external to the school and students themselves. However, there is no consistent evidence regarding which of these providers gives the best results and it is impossible to compare across studies given the likely confounding by other factors such as the content of the intervention itself. A Canadian study carried out in the 1990s found that teachers and school nurses were equally effective in delivering a classroom-based intervention to students in grades 6 to 8 (ages 11-14) and there was no differential effect according to whether staff were formally trained in organised workshops or were provided with self-preparation materials[29]. The ASSIST study trained students themselves as peer supporters and, as noted earlier, found a significant impact on student smoking up to two years later[19]. This positive effect was not restricted to the students trained as peer educators, as has been reported in other studies, but also extended to the non-trained students with whom the supporters were intervening. The ASSIST intervention was most effective in schools in the Welsh valleys and the authors attribute this to the existence here of clearly defined, close-knit communities in which trained students are able to diffuse new behavioural norms. Therefore, the use of peer educators may be less effective in more poorly defined communities. Peer educators may also be counter-productive amongst students who already smoke. Studies have identified a 'boomerang effect',

whereby over the course of a study smoking prevalence amongst baseline smokers increased more in those exposed to anti-smoking interventions compared to controls who did not receive the intervention[21, 30].

At what age should you intervene with young people to prevent smoking uptake?
Age is a strong predictor of smoking behaviour and existing studies have intervened across the age spectrum from the earliest years of primary school[31, 32] to the later years of secondary school[33]. The majority of interventions have been aimed at young people between the ages of 11 and 14; the ASSIST trial intervened with students in Year 8 (aged 12-13)[19]. There is no conclusive evidence on the age at which is it best to start delivering school-based interventions to prevent young people smoking, but Years 7 and 8, the years when smoking experimentation and the prevalence of regular smoking begin to increase dramatically[6], are arguably a logical point at which to intervene.

How do other student and school characteristics influence the effectiveness of an intervention?
There is conflicting evidence as to whether school-based interventions have a differential impact according to sex and indeed the direction in which this effect might operate[14]. Similarly, students' ethnicity and social group may or may not influence the effectiveness of an intervention. The ASSIST intervention was most effective in the Welsh Valleys, a deprived area, and in particular was only effective in reducing smoking amongst girls[11]. In contrast, an intervention with 13-year olds in the Netherlands was only significant among young people whose parents had high education levels and who worked full time, particularly amongst boys with high levels of parental education[24]. Previous work by the co-applicants[34, 35] has shown that young people are more likely to begin smoking if they attend a school where smoking prevalence among senior students is high; therefore, school smoking prevalence may influence the effectiveness of an intervention. Students who are smokers are also more likely to be absent from school, and less likely to engage fully with an intervention, than non-smokers[20]. Given these findings, the proposed study will develop and refine the intervention in schools with contrasting socio-demographic profiles and will carry out subgroup analyses to understand any differential impact of the intervention according to student and school characteristics.

What do schools and teachers want?
An intervention must be acceptable to teachers if it is to be delivered as intended and have the hoped-for consequences. At present, the National Curriculum for PSHE in England, though non-statutory, suggests that schools teach facts and laws about tobacco use and misuse, and the personal and social consequences for students themselves and others[36, 37]. However, a wide variety of approaches to teaching this material are seen across schools and, although Ofsted conclude that the quality of PSHE delivery is generally improving, there exist variations in coverage and quality[38]. In many secondary schools PSHE is taught by form tutors, though many of these may lack the training, skills and experience to deliver content effectively; only 22% of PSHE teachers have any relevant training and half of secondary schools have no staff with Continuing Professional Development accreditation in the subject[39]. The intervention proposed here is therefore designed to be taught as part of PSHE and to be accessible to teaching staff with no subject-specific training. Additionally, schools face an increasing number of demands on their time and thus any intervention must be suitable for implementation with little preparation. A process evaluation of the ASSIST trial suggested that teachers are receptive to new ideas and ways of teaching the difficult topic of smoking prevention and cessation, but that this must fit in with a school's existing ethos and organisation[40]. The inevitable added workload for teachers involved in trialling a new intervention means it should arguably be delivered before students reach Year 9 when they have often begun work towards external GCSE examinations and when teachers may be occupied with SAT teacher assessments[40].

How can young peoples' families be engaged to help prevent young people from smoking?
NICE recognise that no one intervention will succeed in preventing young people from taking up smoking, but that a wider approach tackling individual as well as family, community and societal influences is needed[14]. There is no good evidence available to support and inform the development of a community intervention[41]. Given the strong association between parental and child smoking[6], the addition of a family component to the planned school-based intervention may help to both encourage young people not to smoke but also to encourage cessation amongst any parents who smoke themselves.

A recent Cochrane review showed there to be no conclusive trial evidence for the effectiveness of family interventions implemented as an add-on to school-based components[15]; of the seven studies analysed,

none showed any additional benefit of the family intervention, though only one of these[42] was of good quality. This study demonstrated that the provision of evening classes for parents to provide training in parenting skills was not effective as only 20% of invited parents turned up[42]. The family component proposed for the current study must be carefully designed so as to ensure a high degree of participation and up-take by parents. Evidence for the effectiveness and acceptability of family-based components can be gleaned from multi-component interventions, though with these it is difficult to isolate and assess the effectiveness of individual components, or, indeed, to know whether it is the components acting synergistically in the package as a whole which has positive effects.

A promising literature is developing around the effectiveness of interventions to encourage parents to talk with their adolescent children about smoking[43]. Various approaches to prompt discussions between parents and children have been trialled, including the provision of pamphlets and quizzes[44], booklets[45], newsletters[46] and postcards[47] mailed to parents, homework activities for the child to complete with their parents[47], videos[46] and financial incentives[46]. These have demonstrated some positive effects on the degree to which children report talking to their families about smoking, though their effectiveness in reducing smoking uptake remains unclear. As expected, interventions prompting communication may be most effective when the parent is a non-smoker[43]. Most of these studies were carried out in rural, middle-class areas of the United States and their relevance to the UK is not clear.

To our knowledge, no work has been undertaken with secondary school-aged children themselves to understand their views on whether and how their families should and could be engaged to support them to remain non-smokers. Focus groups with primary-aged children after they had received a smoke-free homes intervention suggested they were confident in talking to their parents about the issue, though the children themselves were not involved in designing the intervention[48]. We will address this gap in the literature in the proposed study - our planned work with young people to understand their views about whether and how to engage with their parents will provide needed evidence on the nature of a family-based intervention which is likely to be effective and acceptable.

What are the risks and benefits for study participants and society?
Given the health and economic consequences of smoking for both individuals and society, an intervention to prevent youth smoking uptake is likely to be highly beneficial; providing signposts to sources of cessation support for students and their family members, as well as school staff who smoke but who wish to quit, will extend these benefits. No studies of school-based interventions have specifically examined any unintended consequences of the intervention or research process[49]. However, in one study in the Netherlands, students who were exposed to a programme of individual, school and family-level smoking prevention interventions reported lower situational self-efficacy and were less likely to report not intending to smoke than students in control schools[30]. We will monitor these potential negative outcomes in our proposed study.

Summary
Our literature review has highlighted a lack of recent, UK-specific evidence regarding how best to design and implement interventions to prevent youth smoking uptake. However, we do know that a successful intervention will likely involve a booster component, should make few demands on busy teachers with little subject-specific knowledge, and should be evaluated for both short and long term effectiveness. We also know that an approach similar to that of the US 'Truth campaign' is yet to be tested in the UK and has been highlighted by NICE as an area for further investigation.

Research objectives: The overall purpose of this research is to assess whether a multi-component intervention involving educational resources for use in schools, alongside family components, is effective and cost-effective in preventing the uptake of smoking in school-aged children. Specific objectives are to:

1) Pilot a new smoking cessation resource (Operation Smoke Storm[50]) designed for use in the early years of secondary school by *Kick It* (the Hammersmith and Fulham NHS Stop Smoking Service) to gain preliminary evidence for its acceptability and effectiveness.

   Operation Smoke Storm will be trialled with Year 7 students (aged 11-12) in two contrasting schools in Nottingham and Nottinghamshire in the first year of our study. Quantitative evaluation will provide preliminary evidence for its effect on the prevalence of current smoking and non-smokers' susceptibility to smoking, and qualitative work with students and teachers will evaluate the intervention's acceptability.

2) Develop an effective and acceptable 'booster' intervention for use with students in Year 8 to maintain and strengthen the effects of Operation Smoke Storm.

   Qualitative work with Year 7 students and teachers will be used to explore views of what the booster element should include, whether the booster intervention should be classroom-based or less intensive requiring no teacher input, as well as likely uptake by students.

3) Identify and develop acceptable and effective intervention components for use by families which build on Operation Smoke Storm to prevent the uptake of smoking in young people and promote and signpost support for cessation to students, their family members and school staff who smoke.

   We will explore with Year 7 students whether and how their families could be engaged to help them not to start smoking, or to quit if they already smoke, mapping their opinions on the variety of family interventions that have been used previously so as to design a family-based intervention for use here which is both acceptable and likely to be effective.

4) During the first two years of the study, provide preliminary evidence for the effectiveness of the combined school (Operation Smoke Storm plus boosters) and family intervention on which to base a decision whether to continue to a full trial.

   We will assess the change between Year 7 and Year 8 in the proportion of students reporting smoking or susceptibility to smoking, comparing this to control data from our existing Nottingham School Smoking Survey (further details provided later). An independent trial steering committee will make the decision whether to proceed to full trial, based on this evidence of effectiveness, alongside: evidence of the acceptability of the intervention to schools, teachers, students and parents, derived from our qualitative work; the readiness of the intervention for immediate implementation; an indication of willingness to take part in the trial from a sufficient number of schools.

5) Initiate and complete the first year of a cluster-randomised controlled trial to test the effectiveness and cost-effectiveness of the combined school and family intervention.

   This trial will initially provide definitive evidence for the short-term effectiveness of the intervention in preventing smoking uptake and susceptibility to smoking, as well as evidence for cost-effectiveness (further details on planned analyses are provided later).

Research design: As illustrated in the accompanying flow diagram, this study comprises an initial phase of developmental work to design, pilot, evaluate and refine a multi-component intervention to prevent smoking uptake in young people, including elements based in schools and with families. This work will be followed by the first year of a cluster-randomised controlled trial of the intervention, with the intention to apply for additional funds for longer-term follow up should initial results look promising.

In the first phase, Operation Smoke Storm will be delivered to all Year 7 students in two schools, with questionnaires administered before and immediately after to assess changes in students' smoking behaviour and susceptibility to smoking. Up to four focus groups will then be carried out in each school (2 groups of boys, 2 groups of girls, with 8-12 students in each group) to explore views on the perceived effectiveness and acceptability of the intervention and to inform any necessary improvements. Using examples of existing resources to facilitate discussion, students' views on the design of a booster component for use in Year 8, and a family-based component to engage their parents, will also be sought. Depth interviews will be used to elicit teachers' views of the acceptability of the intervention, covering aspects such as how easy it was to take the package and deliver as an 'off-the-shelf' resource, how it fits in with the ethos of the school (e.g. does it support their current approach to PSHE, the school smoking policy and how that can be enhanced) and whether it fits in with timetabling and the existing curriculum. One year later, when students are in Year 8, all those who previously received Operation Smoke Storm in Year 7 will receive the booster intervention designed to strengthen and maintain its effectiveness, followed by a questionnaire to assess changes in smoking behaviour and susceptibility. Qualitative work comprised again of up to four focus groups in each school will be carried out with Year 8 students to assess the effectiveness, appropriateness and acceptability of the booster component. At the same time, the improved Operation Smoke Storm will be trialled with the new cohort of Year 7 students in the same two schools, and these students' families will also be offered the family-based component. This new

cohort of Year 7 students will only complete a post intervention questionnaire to assess their views about Operation Smoke Storm as no follow-up data will be collected from this group a year later. Qualitative work with students (up to four focus groups in each school) and a sub-sample of paired student and family (e.g. parents/caregivers) depth interviews will be conducted to assess the reach, acceptability and perceived impact of this component, in combination with the others, and to identify any aspects that could be improved. Families who participate in the paired student/family interviews will receive a £15 inconvenience allowance in the form of a high-street voucher.

At this point we will judge the effectiveness of the intervention based on the evidence available so far. Our current Nottingham School Smoking Survey is collecting data from students in Years 7 to 10 in 11 local schools, with the aim of evaluating students' responses to tobacco point-of-sale display legislation. By mid-2013 the Nottingham Survey will have collected three years' data and will have estimates of current smoking and susceptibility to smoking in Year 7 and Year 8 for two successive cohorts of students. We will compare the combined proportion of Year 8 students in our two schools reporting current smoking or susceptibility after receiving the full intervention with the proportion of Year 8 students from the same two schools reporting these behaviours in our Nottingham School Smoking Survey carried out before our research started. We will adjust our analyses for smoking behaviour at baseline in Year 7 if this differs between the two groups. We will judge the intervention to be effective if the confidence interval for the difference in prevalence between the two groups excludes the possibility of no change (i.e. a true reduction above zero). The estimate of effect obtained from two schools will obviously not provide statistically significant evidence of effectiveness (hence the need for the trial). However, we would expect to obtain an estimate that is consistent with the intervention having some benefit (i.e. an estimate that is consistent with a prevalence reduction greater than 0). We will therefore calculate an estimate of the difference in smoking prevalence pre- and post-intervention for the two schools combined, and provide a guide to the precision of this estimate by giving 95% confidence intervals. With 300 Year 8 students in the two schools, and assuming a prevalence of 35% current smoking or susceptibility to smoking in the years before the introduction of the intervention, our estimate of the difference in prevalence pre- and post-intervention will be calculated to within 6.6% i.e. if the observed effect is 6.7 or greater the confidence intervals will preclude the possibility of no effect or a negative effect of the intervention. Therefore, the point estimate will need to be approximately 6.7% or more lower following the introduction of the intervention (having adjusted for any baseline differences in prevalence in Year 7). This is consistent with the size of effect that we are aiming to detect in the subsequent clinical trial.

Should we satisfy our criteria for progression we will continue to the first year of a cluster-randomised controlled trial of our intervention. 20 schools will receive the school and family-based components in Year 7 and the booster in Year 8 and 20 schools will continue to receive the usual anti-tobacco education, with quantitative evaluation of changes in students' smoking behaviour and susceptibility to smoking, a cost effectiveness analysis and a qualitative process evaluation of intervention delivery. Schools will be stratified by the proportion of students eligible for free school meals and the number of Year 7 students, and will be randomly allocated to either the control or treatment arm by an independent statistician.

Study population: Initial developmental work will be undertaken in two schools in Nottingham City and Nottinghamshire. We have established contacts in several schools in this area through our existing Nottingham School Smoking Survey, and several teachers have expressed an interest in being involved in further research. The two schools we intend to recruit are very different in nature: one serves an estate in the city suburbs with a large proportion of social housing; the second is located in a market town in Nottinghamshire and serves a generally more affluent catchment area in the town and surrounding villages. Smoking behaviour amongst students in the two schools is very different: in the city school, 30% of students in Years 7-10 completing our recent survey reported ever smoking compared to 16% in the county school. Students in Year 7 in both schools had a similar prevalence of ever smoking (~8%) but in the city school 'take-off' occurred by Year 8 when 29% reported ever smoking, rising to 42% in Year 10; in the county school take off occurred later – 9% of Year 8 students had ever smoked, rising to 24% in Year 9 and 26% in Year 10. Susceptibility to smoking was also higher amongst never-smokers in the city school. Given the contrasting nature of these schools, which capture a range of smoking behaviours and socio-economic profiles, we have restricted our initial developmental work to two schools rather than the three stated in our outline bid; this will also help to contain research costs. All students in Year 7 during the development phase will be eligible for inclusion (n=~300). Opt-out consent will be sought from parents and full consent from students before completion of

s or participation in focus groups (see discussion of ethical arrangements below). Teachers and parents taking part in qualitative work will also be asked to give their informed consent.

For the cluster-randomised controlled trial we aim to recruit 40 schools in the East Midlands, with 20 receiving the intervention and 20 acting as controls (who will be offered the intervention at the end of the trial if its effectiveness is proven). All mainstream secondary schools (both private and non-private) with students in at least Years 7 to 11 will be eligible for recruitment. In Leicestershire many areas have linked middle (aged 10-14) and high schools (14-18) with students progressing automatically from one to the other. In these areas, schools will only be recruited in linked pairs to ensure longer-term follow up of students is possible. All students in Year 7 at the start of the trial will be eligible for inclusion and again we will gain consent as detailed later.

Socioeconomic position and inequalities: The data collected as part of our existing Nottingham School Smoking Survey has highlighted the socioeconomic distribution of students in each school. Approximately half of the students in the county school we intend to recruit for our initial development work are in the least deprived quintile nationally of the 2010 Index of Multiple Deprivation, whereas approximately half of the students in the city school are in the most deprived quintile. In our questionnaires we will seek non-identifiable information to classify students according to their socioeconomic status. The spread across deprivation quintiles in our two proposed development schools gives us the opportunity to explore variations in the outcomes of our quantitative evaluation according to students' socioeconomic position, and to tailor our intervention appropriately to ensure its acceptability to different groups. In both the development phase and the cluster-randomised controlled trial we will use subgroup analyses to assess whether the intervention is effective in all socioeconomic groups or just some, and thus whether it might widen, maintain or reduce inequalities.

Planned interventions: This project will develop and test a new intervention comprising materials for schools and families. We plan to pilot, evaluate and refine Operation Smoke Storm[50] for use with Year 7 students. This package is strongly evidence-based and draws heavily on the ideas of the US Truth Campaign[16, 17], with students acting as secret agents to uncover the tactics of the tobacco industry through a combination of videos, quizzes, discussions and presentations spread over three hour-long classroom-based sessions. Additionally, the package covers the health effects of tobacco, passive smoking, nicotine addiction and tobacco cost. In a small-scale evaluation in two London schools of changes in awareness and attitudes, as well as acceptability and ease of use, Operation Smoke Storm has been very positively evaluated[51]. Though no formal statistical analyses were carried out, students who received Operation Smoke Storm reported increased knowledge of smoking and the tobacco industry, 89% liked the resource, 98% thought it was easy or very easy to understand, and 72% went on to tell their friends and/or parents about their lessons[51]. Teachers also gave very positive feedback; Operation Smoke Storm comes with detailed lesson plans and thus requires minimal teacher preparation, making it suitable for use by busy staff with many competing demands on their time and who may have little or no subject-specific knowledge or training[39]. Accompanying Operation Smoke Storm is a template to help schools develop a smoke-free policy if they do not have one already, and we will explore the need for this in our qualitative work with teachers[52]. At present, schools who wish to use Operation Smoke Storm must pay an annual license fee of £150 to cover administrative costs. During our study period, this intervention cost will be met by Kick It and the University of Nottingham; after the research has ended schools will need to meet this cost themselves. Operation Smoke Storm was not designed to prevent or reduce smoking per se, but instead to increase young people's awareness of, and change attitudes towards, the tobacco industry. However, evidence from the US showed the Truth campaign to be effective in preventing smoking uptake, and thus there is precedent here to suggest that Operation Smoke Storm might have a similar effect in the UK. We will use our qualitative work to refine Operation Smoke Storm and develop additional components to maximise the potential for the intervention to be effective in reducing smoking in young people.

Qualitative work will inform the development of booster materials for use in Year 8 to strengthen and maintain the effects of Operation Smoke Storm. The exact nature of these materials will be finalised by the end of the first year of the study, and ethical approval sought for their use. These materials will be based upon booster resources proven effective in earlier studies, with consideration of the acceptability and practicality of their use in the UK. We propose to explore initially the use of printed materials, videos and online resources which, after development costs have been met, could be provided to students at little or no additional cost. The aim of the family-based component will be to promote communication

about smoking between children and their parents in line with the promising developing literature[43], as well as to signpost smokers who wish to quit to local cessation services. Again the exact nature of the intervention will only be finalised after qualitative work with students, teachers and families. The materials will similarly be based around resources with some evidence of effectiveness in earlier studies, with printed materials, videos and online resources again initially seeming potentially useful; qualitative work will help us ensure they are acceptable and appropriate to the socio-demographic characteristics of the students and their families. At the end of the research period we propose that, whilst the Intellectual Property rights for new resources developed during the project remain with the University of Nottingham, Kick It are granted a non-executive license to market and distribute these in the not-for-profit market, alongside Operation Smoke Storm. Kick It have proven experience and capacity to support the marketing, distribution and on-going technical support required to ensure a successful intervention reaches a wider audience. We know from our previous work in schools, as well as Dr Szatkowski's teaching experience, that there are few good quality resources for aiding the delivery of the smoking component of the National Curriculum; in our dealings with PSHE teachers regarding smoking we invariably encounter a desire for more effective and interesting approaches. We therefore expect that our intervention will complement or replace existing teaching on smoking. Given National Curriculum requirements, it is highly unlikely that the interventions developed in this project will replace teaching on other topics.

During the research, Operation Smoke Storm will be delivered to students during school hours and thus all students present should receive the intervention. Our quantitative and qualitative work will measure the extent to which students engaged with the intervention and whether the intervention was delivered as intended. All students will be given access to the booster and family components, and we will again measure uptake of these interventions. In the cluster-randomised controlled trial, schools receiving the intervention described above will be compared with control schools where usual anti-smoking education is delivered, governed by National Curriculum requirements. The manner in which PSHE is delivered is not prescribed and each school will have a different approach, using different resources. We will use short questionnaires or brief teacher interviews in these control schools to ascertain the nature of this usual practice, which will be described fully when we write up our results for publication.

Proposed outcome measures: As our primary outcome in both the developmental phase and cluster-randomised controlled trial we will measure and compare differences in the proportion of students who are current smokers (smoking one or more cigarettes per week now) combined with the proportion of non-current smokers who are susceptible to smoking uptake before and after the delivery of the intervention. We do not intend to biochemically validate students' self-reported smoking behaviour; most students of this age will not be daily smokers and so cotinine analysis is unsuitable[24], and assuring participants of the anonymity and confidentiality of their data (see discussion of ethical arrangements) is known to improve the validity of self-reported smoking behaviour[53]. Our measure of susceptibility will combine students' responses to three questions: Do you think that you will try a cigarette soon?; If one of your best friends were to offer you a cigarette would you smoke it?; Do you think you will be smoking cigarettes one year from now?[54]. This measure has been shown to identify a higher proportion of young people who will eventually smoke than asking whether they have smoked in the last month[54], and in addition the higher prevalence of susceptibility compared to current smoking gives greater power to detect small post-intervention changes. Whilst it is inevitable that some students will be absent from school on the day the questionnaires are completed we expect this proportion to be small and thus there will be negligible losses to follow-up. Secondary outcomes assessed quantitatively will include: attitudes to smoking including situational self-efficacy; smoking experimentation and uptake; cessation attempts; smoking in students' homes; exposure to second hand smoke; perceived acceptability of the intervention; cost-effectiveness.

Qualitative work in the developmental phase of our study will explore and map a range of topics including: perceived acceptability and effectiveness of Operation Smoke Storm; students' awareness of, and attitudes towards, the tobacco industry; opinions on whether and how their families can be engaged to help them to remain smoke-free or to quit if they already smoke; views of teachers on the design, suitability and ease of use of the school-based component and suggestions about ways to engage families.

Assessment and follow up: As illustrated in the accompanying flow diagram, our initial developmental phase will provide evidence of effectiveness of Operation Smoke Storm immediately after students receive the intervention and up to one year after its delivery to the first cohort of students. Given the

limited time and funding, in our developmental work we will only be able to gain evidence for the effectiveness of the booster and family components immediately after students receive these elements.

The cluster-randomised controlled trial will deliver Operation Smoke Storm and the family component to students in the summer term of Year 7, followed by the booster component between seven and ten months later in the spring term of Year 8. Baseline assessment will occur immediately before the delivery of the first part of the intervention, with intermediate follow-up as close to the end of Year 7 as possible. Final follow-up will then occur at the end of the spring term of Year 8, approaching 12 months after the start of the research. The majority of earlier studies have evaluated only the short-term effectiveness of interventions, considering outcomes up to two years after intervention delivery. Whilst some of these studies show a significant short-term benefit of the intervention, they lacked the funding to undertake long-term evaluation. Should our one-year follow up prove our intervention to be effective in the short term we will seek funding to extend follow up to the end of Year 11 giving four years' follow-up in total (estimated cost £750,000).

Our intervention and research are not likely to result in any substantial harm to participants. However, students who are concerned about their friends and family members smoking may become distressed and tensions about smoking may follow. Nottingham's links to the tobacco industry (Imperial Tobacco employs several hundred people in its local manufacturing plant) may also cause friction if students who receive the intervention have family connections to the industry. To address these harms we will address these issues in the family component and school smoking policy, and ensure that students, families and teachers are provided with information signposting them to the local smoking cessation services available to support smokers to quit (the local NHS Stop Smoking Service, GP surgeries, or, if available, school nurses).

Statistical analysis and proposed sample size: Our primary outcome will compare the combined prevalence of self-reported smoking and susceptibility to smoking in intervention and control schools after the delivery of the booster intervention in Year 8. We will use a multi-level model to take into account the clustering of students within form groups and schools, including as covariates baseline smoking behaviour, school stratifying variables, and other demographic variables that are predictors of the smoking outcome to adjust for any baseline differences and to improve power. In our recent Nottingham School Smoking Survey, 26% of Year 7 students across 11 schools reported they were either ever smokers or were susceptible to smoking (range between schools 8-40%). In Year 8 this figure increased to 35% (range 24-47%). Assuming an intraclass correlation coefficient of 0.017 (in line with our recent survey), and assuming that 35% of students smoke or are susceptible in the control schools (also in line with our recent survey), the cluster-randomised controlled trial with 20 schools in each arm (and 150 pupils in Year 7 in each school, the average in our recent survey) will provide just over 80% power to detect a 7% absolute difference in combined current smoking and susceptibility to smoking in Year 8 between intervention and control schools. Therefore we will be able to detect as significant a prevalence of 28% in students who receive the intervention. This 7% change is equivalent to the size of effect used to power the ASSIST study[19]. Analyses of interactions will be carried out to determine the effectiveness of the intervention in students according to sex, baseline smoking status and socio-economic group.

The study will estimate the cost-effectiveness of the intervention in line with previous work[55]. The costs of the programme (materials and staff time) will be estimated using local costs. Potential health care cost savings will also be estimated from the reductions in current smoking and susceptibility to smoking. The reduction in current smoking and susceptibility will be used to model QALY gains and combined with the costs to estimate cost per QALY. Longer term health care cost savings can be estimated using recently published models to demonstrate savings in NHS resources as a consequence of reductions in smoking rates[56].

During the development phase, focus groups with students will be used to explore the acceptability of Operation Smoke Storm and to provide feedback to inform refinements. Data from these focus groups will also help to inform the design of the booster and family-based components. In each of our two pilot schools we will carry out up to two focus groups with Year 7 boys and two with Year 7 girls. Boys and girls will participate separately as research suggests that smoking has become increasingly gendered, with the UK having one of the most pronounced gender differences in regular smoking in Europe (with girls having the higher prevalence)[57]. Qualitative research with 15 and 16 year old smokers in Scotland concluded that these gender differences could be attributed to individuals' social worlds and

relationships, interests, meanings attached to smoking and the role smoking played in dealing with everyday experiences of being a girl or boy in their teens[58]. We will aim to recruit between 8 and 12 students into each gender-specific focus group, in line with recommendations for group size[59, 60]. All students who have received Operation Smoke Storm will be eligible and therefore invited to take part, and we will randomly sample 12 students to participate. This proposed sampling technique will ensure that adequate numbers are interviewed even if some individuals choose to withdraw, and will help to ensure individuals feel comfortable enough to contribute equally[61]. Recruitment will however remain flexible and will continue or cease according to when data saturation is reached. Ideally, we would have liked to purposively sample focus group participants based not only on gender, but also on children's smoking status (smokers and susceptible and non-susceptible never smokers), as well as children from other 'at risk' groups such as those exposed to familial and peer smoking. However, the Data Protection Act prevents schools from passing on non-anonymised information about their pupils without having the active consent of parents. As active consent will not be gained from parents in this study (due to the likely resulting decimation of participation rates), pupils completing questionnaires will not be required to give any personal identifiers and we will not use ID codes linked to names. Therefore, we will not be able to purposively sample focus group participants and thus as we will only know their gender and which school they attend. Given these data protection issues, it therefore appears appropriate to invite all pupils (who have not opted out of the survey) to participate in a focus group and sample randomly from the group who accept this invitation. The researchers will provide refreshments for students participating in the focus groups. To explore the acceptability and effectiveness of Operation Smoke Storm, teachers delivering the intervention will be invited to take part in semi-structured depth interviews. We aim to recruit all of the teachers who deliver the package in each school, with the hope of interviewing at least half; however, this will remain flexible and will continue or cease according to when saturation of key themes is attained. The researchers will strive to conduct face-to-face (or telephone) interviews at a time convenient for the teachers.

Data generated from the student focus groups and teachers' depth interviews will be analysed using the framework approach[62] to examine emergent themes. Recordings will be transcribed verbatim by an external specialist transcription company. Following receipt of the focus group transcripts, the researchers will ensure all personal identifiers are removed and that transcripts are accurate. Data will be double coded by two researchers and analysed using the framework approach. This approach will allow the research team to understand differences in views of the intervention according to gender and school. As an initial step and to aid familiarisation, data for each focus group will be summarised into a framework matrix (using NVivo 10) which will provide a visual representation of the dataset. Transcripts will be read several times and will be annotated where emerging themes and sub-themes will be identified, resulting in an analytical framework of key themes and sub-themes. Themes and sub-themes will then be discussed between the research team which will allow clarification of the final framework. Data will then be charted according to each theme to synthesise the data and aid interpretation, where particular attention will be given to highlighting the similarities and differences according to gender and school. Extracts from focus group transcripts will be included in the charts.

Qualitative work will also be conducted during the second year of the project. Focus groups will be conducted with Year 8 students who receive the booster component. Again, up to four focus groups will be conducted in each school to explore views about the effectiveness and acceptability of the booster component, and whether it needs to be refined. In addition, following implementation of Operation Smoke Storm and the family component with the new cohort of Year 7 students, the researchers will carry out focus groups with students and paired student-family depth interviews to evaluate the intervention components in terms of their appropriateness, acceptability and effectiveness. Through our procedures for gaining consent families will already be aware that their children are receiving the intervention and that they will be receiving the family component. At this time, families will be invited to express an interest in taking part in a depth interview along with their child. The researchers will randomly sample families and attempt to contact each one to arrange a time for the interview, aiming to conduct approximately ten paired student and family interviews from each school. Recruitment of families will remain flexible and depend upon whether saturation of themes is reached. Families who participate in the paired student/family interviews will receive a £15 inconvenience allowance in the form of a high-street voucher. Finally, to evaluate the design, implementation, delivery and effectiveness of the booster and family components, all teachers will be invited to take part in a depth interview, where preference will be to purposively sample those that participated in depth interviews in the first year; these individuals would have helped to inform the design of these components and therefore exploring their views on the implementation and effectiveness of these aspects would be invaluable. Again, the

researchers will strive to interview at least half of the teachers from each school. These data will also be analysed using the framework approach described earlier.

We acknowledge the potential conflict of interest created by the involvement of *Kick It*, the developers of *Operation Smoke Storm*, in this programme of research. During the development phase, *Kick It's* expertise in designing multimedia resources and bringing them to fruition will be invaluable as we seek to develop the proposed booster intervention and materials for use with parents. However, they will have no access to any raw data (either qualitative or quantitative) collected during the development phase or any input into data analysis or interpretation of results. All qualitative analysis will be undertaken by Dr Jones, Dr Bains and Professor McNeill, and all quantitative evaluation will be completed by Dr Szatkowski and Professor Lewis. *Kick It's* involvement will end at the end of the development phase; they will play no role in the cluster randomised trial. They will not be involved in the recruitment of schools, delivery of the intervention, collection, analysis and interpretation of results, or preparation of manuscripts for publication.

Ethical arrangements: This project will be reviewed by the University of Nottingham Medical School Research Ethics Committee, to ensure the work is conducted in accordance to the highest standards of ethics. This committee is compliant with the ESRC's research ethics framework and with substantial experience of reviewing research to be undertaken in schools is regarded by the applicants as the most appropriate review body.

Ethical issues pertaining to gaining informed consent and data protection are relevant to the proposed study. In line with procedures used in the national Smoking, Drinking and Drug Use in Young People survey[6], and our own Nottingham School Smoking Survey, we intend to give pupils letters to take home to give to their parents or guardians detailing information about the study. Parents will be asked to reply only if they wish to withdraw consent for their child to complete the questionnaires or take part in a focus group. In addition, the students themselves will be asked to give their own active consent before completing a questionnaire or taking part in a focus group. Given the age of the children involved in the study (11-13) we feel these arrangements are appropriate. In addition, requiring active consent from parents is likely to decimate participation rates, not because parents do not wish their child to take part but because the consent form may not complete the journey from school to home and back again, and will also increase workload for schools which we aim to keep to a minimum.

The Data Protection Act prevents schools from passing on (for example, to researchers) non-anonymised information about their pupils without having the active consent of parents, and this will include questionnaires filled in by pupils which contain any personal identifiers or unique identification codes which can later be linked back to students' names. Given that we feel it is impractical to gain active parental consent we will not collect any personal information so as to ensure students' anonymity and confidentiality. Pupils completing questionnaires will not be required to give any personal identifiers and we will not use ID codes linked to names. Instead, at the beginning of the study, students will be given a cardboard folder on which they will be asked to write their name. The folder will contain copies of the questionnaires to be completed at baseline, immediately after receiving the Year 7 intervention, and after receiving the booster intervention. So that responses can be linked for analysis, these three questionnaires will have a unique code per student (e.g. 1a, 1b and 1c to indicate the three responses for student 1). After completing a questionnaire the student will be asked to seal it in an unmarked envelope to prevent other pupils or teachers identifying their responses and then to place it in a box which will be returned to the researchers.

Focus group and interview audio recordings and transcripts will be anonymised and identifiable only by a unique study code assigned to each participant, which will only identify the school the student attends, their gender and year group; this will allow the researchers to unpick and explore differences according to school and gender. Teachers will be assigned a code that identifies the school they are from and their gender. Paired student and family depth interviews will be assigned a unique code identifying the school their child attends. Audio files will then be sent via a secure server for transcription by an external University-approved supplier, who will highlight any identifiers, such as names which will subsequently be anonymised by the researchers following receipt of the transcripts. We intend to work with both the University of Nottingham's legal representatives, as well as the NIHR, in establishing the legality of our proposed arrangements, and will ensure that the research is covered by the appropriate indemnity.

Study documents, including information sheets, consent forms and logbooks will be produced in accordance with requirements stipulated by the University of Nottingham's Medical School Research Ethics Committee. The lead applicant will be the custodian of the data collected, with management and storage of data conducted in accordance with University requirements. Data will be kept confidential, accessible to the research team only. Hard copies of questionnaires will be stored securely in locked filing cabinets within the University of Nottingham's Division of Epidemiology & Public Health, along with a hard copy of data from the focus groups and interviews with students, teachers and families. Audio recordings will be anonymised, with any identifiable data removed and replaced with a code. Electronic files will be held securely on password-protected computers within the Division of Epidemiology and Public Health, accessible only to the research team. On completion of the study, research data will be archived for seven years, in accordance with the sponsor requirements, in a facility within the King's Meadow campus of the University of Nottingham.

For those students, teachers and family members who express a desire to stop smoking and would like further help to do so the researchers will refer them to appropriate sources of support, namely the local NHS Stop Smoking Service (New Leaf in Nottingham and Nottinghamshire) and family GP.

Research Governance: The University of Nottingham will act as research sponsor for all research in the programme. A Management Group will meet monthly to discuss on-going issues with managing the work. This will consist of LS, LJ, SL, AM and JB. In addition we will set up a Study Steering Committee (SSC). This will be chaired by an independent expert in research involving schools, with an independent qualitative researcher, the lay members and members of the Management Group. This will meet at the start of the project and then annually thereafter. A Data Monitoring and Ethics Committee (DMEC) will also be established. This will have three independent members including a statistician and will meet annually. The programme will be conducted as far as possible in accordance with the sponsor's requirements and where applicable, the Research Governance framework for Health and Social Care.

Project timetable and milestones:
End 2012 (pre-funding): Recruit and train research assistant; confirm two schools recruited for development work; begin process of seeking ethical and research governance approval.
2013 Months 1-3: Develop questionnaires to assess students' smoking behaviour, compile examples of resources for booster and family components to facilitate discussion in focus groups; finalise ethical and research governance approval.
2013 Months 4-7: Gain parents' opt out consent; administer baseline questionnaire and deliver Operation Smoke Storm to Year 7 students in two schools; administer follow-up questionnaire to assess immediate changes in smoking behaviour and attitudes towards the intervention; recruit students and carry out focus groups to assess acceptability of Operation Smoke Storm and to gain views on the design of the booster and family components; semi-structured interviews with teachers.
2013 Months 8-12: Analyse quantitative and qualitative feedback from students and teachers; make any necessary changes to Operation Smoke Storm; finalise design of booster and family components.
2014 Months 13-15: Continue to analyse quantitative and qualitative data and produce booster and family components; seek ethical approval for the use of the booster and family components.
2014 Months 16-19: Deliver booster component to students in Year 8 who received Operation Smoke Storm the previous year; administer questionnaire to these Year 8 students to assess changes in smoking behaviour and attitudes towards the booster intervention; trial improved Operation Smoke Storm with new cohort of Year 7 students having gained parents' opt out consent, with questionnaires ~~before and~~ after to assess ~~smoking behaviour and~~ attitudes towards the intervention; Deliver family component to Year 7 students alongside Operation Smoke Storm; carry out paired student-family interviews to evaluate effectiveness of family component.
2014 Months 20-24: Analyse quantitative and qualitative feedback from students and their families; assess likely effectiveness based on evidence collected so far in line with criteria described above; improve the school and family components as necessary; approach schools to take part in trial.
2015 Months 25-27: Seek ethical and research governance approval for cluster randomised controlled trial; recruit 40 schools to take part in trial; randomly allocate schools to intervention or control arm.
2015 Months 28-31: Gain parents' opt-out consent; administer baseline questionnaire to all Year 7 students in all 40 schools; deliver Operation Smoke Storm and family component to Year 7 students in 20 schools; administer immediate follow-up questionnaire to students in all schools at the end of Year 7.
2015 Months 32-36: Questionnaire data entered into dataset by external company using optical mark recognition technology; data checking, cleaning and analysis.

2016 Months 37-40: Delivery of booster component to students who will now be in Year 8; administer post-intervention questionnaire; questionnaire data scanned and compiled into dataset.
2016 Months 41-43: Analysis of results; feedback results to participants; write report; write and submit articles to peer-reviewed journals.

Expertise: The study will be led by members of the UK Centre for Tobacco Control Studies (UKCTCS), a UKCRC-funded UK Public Health Research Centre of Excellence which provides all of the expertise in tobacco control necessary to lead and deliver the project. Specific details of roles and skills are provided in the accompanying application form, but in summary the team includes expertise in: secondary education including teaching PSHE; undertaking surveys in schools; the design, implementation and analysis of clinical trials; analysing quantitative data; qualitative research methods; designing, implementing and evaluating smoking cessation and abstinence interventions for families; health policy and promotion; smoking cessation services for young people; economic evaluation of tobacco control interventions; user involvement in research; designing and developing multi-media interventions for young people; research coordination, financial and ethical processes.

Members of the Public: The involvement of users is very important to this proposal. Through the qualitative research with students, teachers and parents we will get feedback to further develop and refine the interventions. However, we are also proposing two other pathways to enable relevant lay people to contribute to the research. The UKCTCS smokers' panel was formed in 2009 and consists of active smokers who are recruited from the Bath and North East Somerset area. The panel meets face to face every six months to discuss tobacco control research and policy and currently there are 26 members including a few panellists who have stopped smoking since recruitment. Between meetings they also contribute to the centre's work by commenting on research proposals and in some cases getting involved in specific projects. We will devote one of these panel meetings in 2013 to discussing the interventions and two members of the panel (a mother and daughter) have agreed to be lay collaborators. If the proposal is successful, we will also build on existing links with the National Children's Bureau who have a diverse group of 17 11-18 year old NCB Research Advisors. The NCB is already working with the University of Stirling (where one of the coapplicants to this proposal, Linda Bauld, is based) through the Public Health Research Consortium, and we will be able to draw on their expertise and make links with their youth research advisors to inform this study. We would plan to utilise two existing meetings if possible during the first and second years of project implementation to enable further contributions to be made from young people to the intervention components.

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