Public Health England

Trial Protocol:
Can uptake of childhood influenza immunisation through schools be increased through behavioural-insight informed changes to the invitation process?

Short title: Childhood influenza immunisation invitation trial in schools

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Trial Number: *TBC*

Public Health England

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1. Background

In 2012, the Joint Committee on Vaccination and Immunisation (JCVI) recommended a national childhood influenza immunisation programme be rolled out to 2-16 year olds, using a live attenuated influenza vaccine (LAIV) (JCVI, 2012).[1] Roll out of the programme began in 2013 (winter season 2013/14) with immunisation of 2 and 3 year olds through primary care. The following year, 4 year olds were added to this group and in 2015/16 the programme was extended to children in school years 1 and 2 (Table 1). This year (2016/17), all children aged 2-4y and those in years 1 and 2 will continue to be offered flu vaccination and the offer is being extended to all those in year 3. In a number of geographical areas, pilot programmes were established which included a wider age-cohort. The exact cohorts and number of areas participating in the pilot studies varied slightly from year to year (Table 1).

In 2015/16 nationally, uptake in Years 1 and 2 was 53.6%.[2] Areas that participated in the pilot programme vaccinating primary school children (5-11 years) showed both decreasing uptake with increasing age (from 62.6% in Year 1 to 54.7% in Year 6 in 2015/16) and lower uptake last year than the previous year (57.9% compared with 60.4%). Delivery methods (school, GP or pharmacy) had considerable impact on uptake, with higher uptake in those areas that delivered flu immunisation through schools[i]. Analysis has also shown that lower uptake is associated with deprivation and ethnicity.

The majority of areas offer the immunisation through school-based programmes delivered by providers that are commissioned by the NHS. Parents of eligible children are sent a letter informing them about the vaccination programme and inviting them to return the consent form for their child's vaccination. While uptake in schools is higher than GP or pharmacies, there remains approximately 30% of children for who consent is neither given nor actively withheld.[3]

PHE provides template letters that immunisation providers can use. The PHE Behavioural Insights Team has worked with the NHS England and the PHE immunisation team to design the template letter for 2016/17. This letter is informed by behavioural insight theory to encourage parents to return the consent form.

There is evidence from the field of behavioural science to suggest that a low cost intervention, such as the content of an invitation letter or a reminder text message, may be effective in changing behaviour. In a previous trial run by our team, PHE Behavioural Insights Team, a 4% increase in health checks was shown by simplifying invitation letters and adding a tear-off slip where individuals could note the time and

[i] (55.6%, 32.9% and 16.1% uptake school, GP and pharmacy delivery respectively)

date of their first appointment, as a memory aid.[4] Redesigning the invitation letter in combination with primer and reminder text messages increased uptake by 12% compared to the standard letter. Similar effects have been found in other non-health areas, for example, research from the Behavioural Insights Team and the DVLA showed that including an image of a person's car in their car tax collection letter increased tax payments from 40%-49%[5] and an HMRC trial showed that providing a localised social norm message increased tax returns by 5%.[6]

Here we set out our proposal to test whether behaviourally-informed interventions (i.e. the new template letter and SMS/email reminders) increase uptake of childhood influenza vaccination in schools, through increasing response rate. Such evidence would encourage adoption of the national template letter, which we understand many areas do not currently adopt, provide evidence for the provision of reminders and confirm whether the theory-based changes to the invitation letters have the anticipated impact.

Table 1. Target age groups for national and pilot childhood influenza immunisation programmes, by winter season.

Winter season	National programme[a]	Pilot programme[a]
2013/14	2y and 3y olds (in primary care)	4-11 year olds (reception to school year 6) eligible for vaccination in 7 geographically discrete areas.
2014/15	2-4 years of age (in primary care)	Both primary school aged children (5-11y) and secondary school aged children, 11-13y (school years 7 and 8 age) eligible for vaccination in 14 pilot areas (including pilot areas that participated in 2013/14)
2015/16	2-4 years of age (in primary care) and school years one and two (5y and 6y at 31st August)	6 pilot areas that had piloted the school based programme since 2013 to 2014 continued to offer the vaccine to all primary school age children aged 5-11 years (school years 1 to 6 age).
2016/17	2-4 years of age (in primary care) and School years 1, 2 and 3 (5, 6 and 7y at 31st August)	As in 2015/16 primary school children in years 1 to 6 in former school pilot areas will continue to be offered the vaccine.

[a] Ages refer to age on 31st August/1st September of the year

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2. Aims and hypothesis

The aim of this study is to investigate whether behavioural insight-informed changes to the invitation process can improve uptake of childhood flu immunisation. Our specific hypotheses are:

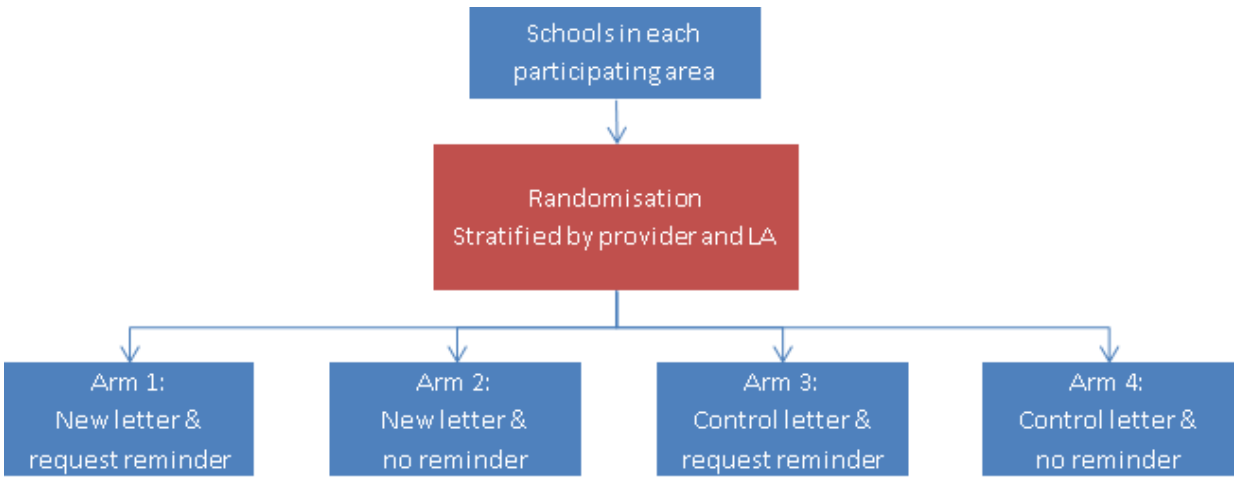
1. Changes to the invitation letter will increase return of consent forms and thereby increase uptake of childhood flu vaccine through schools.
2. Reminders to return the consent form will increase return of consent forms and thereby increase uptake of childhood flu vaccine through schools

3. Trial design

3.1. Design overview

This is a 2x2 factorial design, open-label, randomised (at school level) trial of invitation letters and SMS/email reminders for childhood flu immunisation (Figure 1).

Figure 1. Randomisation and trial arms



3.2. Primary and Secondary outcomes

The primary outcome for this study is the proportion of children in school years 1-3 who receive influenza immunisation as part of the national childhood immunisation programme.

We will also look at a number of secondary outcomes to determine the effect of the interventions on influenza immunisation in different age groups and on consent-giving. The secondary outcomes are:

1) Proportion of children who receive influenza immunisation
   a) in school years 4-6[ii]
   b) in Reception[iii]
   c) in each individual year group
2) Proportion of children for who consent is neither given nor withheld (i.e. non-responders)
   a) in school years 1-3
   b) in school years 4-6
   c) in each individual year group

3.3. Intervention and control

There are four arms to this 2x2 study:

1. New template invitation letter and SMS/email reminder
2. New template invitation letter and no reminder
3. Last year's invitation (control) letter and SMS/email reminder
4. Last year's invitation (control) letter and no reminder

Parents at schools randomised to one of the new template letter intervention arms will receive the behavioural-insight informed invitation letter (Appendix 1), with minimal local adjustments. The behavioural-insight framing for this letter are summarised in Parents at schools randomised to one of the control letter arms will receive the letter used by the immunisation provider last year (with necessary updates). These letters vary from area to area and examples are given in Appendix 2.

Schools randomised to one of the reminder SMS/email arms will be asked to send a reminder message to parents through their usual email/SMS system (e.g. parentmail). Schools will be asked to send a specific message and for this to be sent at a specified time (

[ii] Children in School Years 4-6 (age 8-11y) are included in the immunisation programme in pilot areas including Leicestershire and Lincolnshire Area Team and Essex Area Team

[iii] Reception children (age 4-5y) are being offered immunisation through schools in Essex Area Team.

Table 3). These messages are informed by behavioural insights and are action-orientated with a focus on scarcity in both message (*ensure your child doesn't miss out* and *There will be only one vaccination session at the school*). The email message (with more space) includes other behavioural science informed messages used in the invitation letter. Providers will be given a Standard Operating Procedure detailing how this request to schools is to be made and monitored.

Table 2.

Parents at schools randomised to one of the control letter arms will receive the letter used by the immunisation provider last year (with necessary updates). These letters vary from area to area and examples are given in Appendix 2.

Schools randomised to one of the reminder SMS/email arms will be asked to send a reminder message to parents through their usual email/SMS system (e.g. parentmail). Schools will be asked to send a specific message and for this to be sent at a specified time (

Table 3). These messages are informed by behavioural insights and are action-orientated with a focus on scarcity in both message (*ensure your child doesn't miss out* and *There will be only one vaccination session at the school*). The email message (with more space) includes other behavioural science informed messages used in the invitation letter. Providers will be given a Standard Operating Procedure detailing how this request to schools is to be made and monitored.

Table 2. Behavioural insights informed changes to the flu invitation letter and rationale.

Formatting and phrasing used in new template invitation letter	**Behavioural rationale**
Formatting	
Reduced in length and made **simpler**.	Reduces the cognitive effort required to process the information and identify the action required.
We have formatted text to highlight the key points of note/ actions required.	Reduces cognitive effort to identify action required.
Provider letterhead plus NHS logo	NHS is a trusted brand when it comes to medical/ health issues.
Phrasing	
Your child's annual flu vaccination is now due	Salience of message
This vaccination programme is in place to help protect your child against flu.	Gain-framed message for prevention
Flu can be an unpleasant illness and sometimes causes serious complications.	Loss framed message
Please complete the enclosed consent form (one for each child) and return to the school [by/ within] [**INSERT DATE or TIME FRAME**]	Action orientated
The vaccination is free …	There is anecdotal evidence that parents do not realise it is free or annual. Note: the evidence on use of 'free' is mixed as this can be deemed as less valuable, particularly by some cultures
… and will be given by a quick and simple spray up the nose	Addresses parental concerns of what the vaccination entails
Last year, most children offered the vaccine in schools had the immunisation.	Social norms

Table 3. Proposed text for SMS and email reminder message

Reminder format	Message	Timing
SMS (160 characters limit)	Thank you for returning your child's flu vaccine consent form. If you have not, please return it by xxxxxx to ensure your child doesn't miss out.	Message to be sent two days ahead of deadline for returning forms
Email	Subject: Flu vaccine consent form due xx/xx/xx: make sure your child doesn't miss out Dear Parent/Guardian, Please return your child's flu vaccine consent form by [*insert day and date*] to make sure your child doesn't miss out. Thank you to those parents who have already done so. There will be only one vaccination session at the school. Last year, most children offered the vaccine in schools had the immunisation. [*The consent form is attached for use if you have lost the letter*][a] If you decide you do not want to vaccinate your child against flu, please return the consent form giving the reason. This will help us plan and improve the service Yours sincerely, SIGNED BY PROVIDER	Message to be sent two days ahead of deadline for returning forms

[a]This sentence will only be included if feasible to include the original letter as an attachment

3.4. Setting

This trial will be conducted in state schools in participating areas in England. The trial will be implemented by the immunisation providers for the areas and schools themselves will not be aware that they are taking part in a research study.

3.5. Trial Sites

We are working with providers of childhood flu school vaccination in Wessex, Leicester and Essex NHS England Area Teams. We will randomise schools in each of the trial local authority to one of the four trial arms. Details of the areas and providers which we are working with are given in Table 4.

Table 4. Number of schools by area, provider and target cohort.

Local Area Team	Provider	Local authority	Years in prog	Number of schools				
				Total*	Infant	Junior	Primary	Special
Leicester	Leicestershire Partnership NHS Trust	Leicester	Y1-Y6	91	9	9	66	7
		Rutland	Y1-Y6	19	0	0	17	2
		Leicestershire	Y1-Y6	241	6	6	214	10
Essex	South Essex Partnership University NHS FT	Essex	R-Y6	473	51	48	356	16
		Southend on Sea	R-Y6	37	5	5	25	2
		Thurrock	R-Y6	41	0	0	40	1
Wessex	Southern Healthcare Partnership NHS Trust	Hampshire	Y1-Y3	454	117	104	207	26
	Solent NHS Trust	Portsmouth	Y1-Y3	53	16	12	23	2
		Southampton	Y1-Y3	59	10	8	37	4
	Dorset Healthcare Uni Trust	Dorset	Y1-Y3	150	4	4	124	8
		Poole	Y1-Y3	34	8	6	16	3
		Bournemouth	Y1-Y3	32	2	3	26	1
	Boots UK	Isle of Wight	Y1-Y3	42	0	0	40	2
Total				**1726**	**228**	**205**	**1191**	**84**

*Independent schools are excluded. Data are taken from https://www.compare-school-performance.service.gov.uk/download-data

3.6. Recruitment

Three areas and six providers have agreed to take part in this trial. All schools in their areas will be included in the trial. Due to the nature of the trial and research question, this study will not recruit individual children or individual schools.

3.7. Power calculations

Given that all school-based flu immunisation programmes send invitation letters to parents, even a small increase in uptake from changes to the phrasing of the letter will be worthwhile. Furthermore, given that participating areas will be sending letters to all parents of eligible children it is simpler to include all schools within a participating local authority area. Including a number of providers, which cover 13 local authorities, increases the generalisability of our research findings. We are therefore starting from the position of having potentially ~1700 schools to include in the trial. Sample size calculations are not therefore appropriate as we are not sampling from the participating areas, but rather including the full population. We can however explore the potential power of our study.

Although our allocation will be stratified by local-authority, to explore the potential power of the study we have made the crude assumption that all strata are equal (i.e. that there is no variation between local authorities). We therefore used *sampsi*

followed by the *sampclus* commands in Stata to estimate our study power. We determined the number of schools using data on schools by local authority available from Compare school and college performance website[iv]. We used 2015/16 data provided for Leicester, Leicestershire and Rutland to estimate the average size of each cluster (i.e. average number of children in school years 1-3) (excluding schools with fewer than 20 pupils in years 1-3). The average size of cohort was 110, and we have therefore conservatively used 100 as our estimate. We used an average vaccine uptake of 63.0% (SD 16.2%) in our power calculations.

We do not have a known value for the intra-class correlation (ICC). Shackleton et al[7] estimated that ICC values for health outcomes in adolescent children ranged from ICCs ranged from 0.01 to 0.21 depending on the outcome being measured and the country. Within Britain, ICC ranged from 0.01 to 0.15 depending on health outcome, with the highest correlation for regular smoking. These health outcomes are not directly comparable with vaccine uptake or primary school age children (for which the behaviour is actually one of the parents) but nonetheless provide an anchor point around which to explore in the absence of more relevant estimates. We used 0.025 as our basic estimate.

We have conducted power calculations that indicate with this number of schools we would have 90% power to detect a 1% absolute increase in uptake, from 63% to 64% in children in years 1-3. The large number of schools available to us (~1700 schools), will enable us to have 90% power to detect an absolute change even if ICC is relatively high (

[iv] Available at https://www.compare-school-performance.service.gov.uk/download-data

Table **5**). Furthermore, we will have the power to detect our secondary outcomes e.g. uptake by year group.

It is possible, due to delays getting this project off the ground, that providers areas will need to go ahead with printing their letters before we have the approvals necessary to issue the randomisation. Our power calculations show that despite this we are likely to have sufficient schools to detect, with 90% power an absolute increase of 2% in uptake, with all but the highest estimates of ICC with just one or two providers (e.g South Essex NHS Partnership Trust, who have indicated a slightly later date for printing letters, has 451 schools. Clearly the size of the effect we have the power to detect will also depend on the impact of variation between strata in the trial (which are not accounted for in these power calculations).

Table 5. Power calculations for various scenarios, assuming no variation between strata.

Outcome	Scenario	Absolute % change able to detect	Power	ICC	Number clusters required in each arm	Total number of schools required
Primary outcome	Detecting lowest absolute effect	1%	90%	0.025	187	748
Primary outcome	Estimate of impact of ICC estimates on required minimum sample size	2%	90%	0.025	47	188
		2%	90%	0.05	81	324
		2%	90%	0.15	214	856
		2%	90%	0.25	347	1388
Secondary outcome	Analysis by individual year group (i.e. average size of the cluster 30)	2%	90%	0.025	78	312
		2%	90%	0.05	110	440
		2%	90%	0.15	240	960
		2%	90%	0.25	370	1480

3.8. Randomisation

Randomisation will be undertaken by PHE Behavioural Insights Team. An up-to-date list of schools will be obtained from each area (or obtained from PHE and validated by the local team). Schools will be identified by their Unique Reference Number (School URN) to create the allocation list. Randomisation will be stratified by Provider and local authority. It is unlikely that we will know in advance (i.e. at the time of randomisation) which schools have email/SMS systems. (We anticipate this to be fairly common amongst schools.) We will therefore allocate all schools, irrespective of their available system, to one of the four trial arms. Randomisation will be carried out using a randomisation tool (e.g. ralloc or random number generator with schools ranked for allocation by random number order) in Stata, or other appropriate statistical-package to one of the four arms of the trial.

3.9. Data collection

Data are collected by immunisation providers as part of the routine programme. While data on the number of vaccines administered and denominators (i.e. not including data on consent) will be submitted centrally at the end of November 2016, December 2016, January 2017 and February 2017 only the final data submission in March 2017 will provide school-level data and data on consent as well as uptake.

Many areas use a spreadsheet generated by PHE which records individual level data for local management and enables data to be cumulated to the different levels required (e.g. school, local authority) and includes data on consent. These different

cumulative levels can be submitted as required, without the inclusion of individual-level data.

School-level data by school year are routinely submitted to PHE. We will obtain final school-level data from PHE at the national level in March 2017. These data will then be linked with the allocation list for analysis using the School Unique Reference (Figure 2). We will ask providers to submit an interim school-level data extract (e.g. in November) to enable the analysis to be fully planned (i.e. statistical analysis code written) ahead of the availability of final data. This will be important to enable the timely production of results which can then inform next year's programme, however it will not be compulsory if an area is not able to provide these interim data. This analysis will be seen only by a quorum of the investigators and they will not be results released to the wider study team or beyond so as not to impact on the final uptake data. No individual-level data or Personal Identifiable Information will be collected.

Data on characteristics of the schools will be obtained from publically available sources and linked to the immunisation database. This will include data from gov.uk, Compare school and college performance website[v] on characteristics such as the proportion of children on free school meals, pupils with English not as the first language, religious denomination of the school and type of school. The postcode of schools will be linked to Index of Multiple Deprivation (IMD) data to obtain a deprivation indicator, quintile or decile ranking, for the school location.

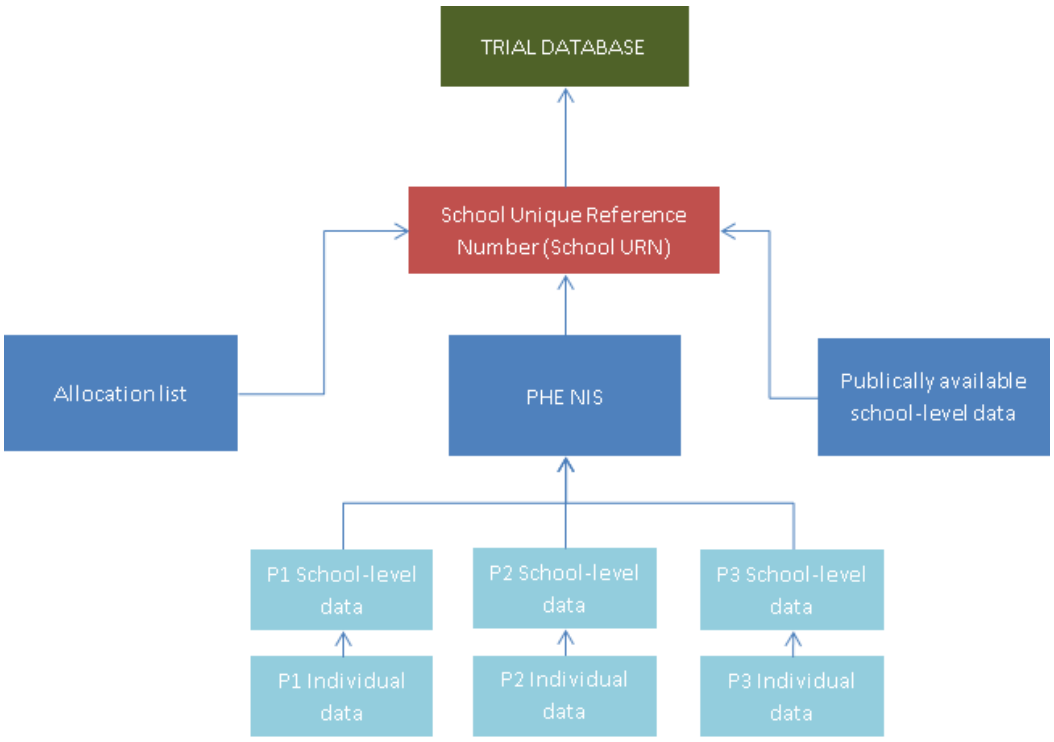
Providers will obtain data on the implementation and fidelity of any reminder message delivered by the school (in line with the Standard Operating Procedure). For schools in trial arms 1 and 3 (who will be asked to send reminder messages to parents) providers will ascertain whether schools implemented the request to send a message to parents and if so, what medium they used (SMS and/or email) and whether they altered the message. For schools in trial arms 2 and 4 (who will not be explicitly asked to contact parents) providers will ascertain whether schools sent a message to parents (before or after the invitation letter but not including mention in newsletters or similar). We anticipate that providers will collect this information during the immunisation session at the school.

Finally, given the geographical and temporal variation in immunisation flu uptake levels and variation in the use of template letters in different areas, we will collect and analyse the letters sent in non-trial areas. This will give us valuable insight into the extent to which national templates are adopted and an understanding of the variation in invitation letters. This information will inform the understanding of the analysis of the trial, with respect to understanding changes in uptake seen from year to year in non-

[v] Available at https://www.compare-school-performance.service.gov.uk/download-data

trial areas. To collect this information we will request that areas send us a copy of their invitation letter for this year's immunisation programme. This request will most likely be sent from NHS England central team (Pauline MacDonald and Sarah Jones – co-investigators on this trial) asking commissioners to obtain invitation letters from their local providers).

Figure 2. Data flow from allocation list, PHE National Infection Service immunisation data and school characteristics data, with linkage through the School Unique Reference Number (URN).



Abbreviations: NIS: National Infection Service; Pn Provider

3.10. Data analysis

Analysis will be undertaken by the PHE Behavioural Insights Team working with the Statistic Unit, PHE National Infection Service. Our main analysis will be by intention to treat allocation for the primary and secondary outcomes. We will use logistic regression to investigate the main effect of the interventions and their interaction. The model also will include provider, local authority and school effect to take into account extra variation that was not explained by intervention and other confounder variables. In the models, we will also investigate the impact of secondary factors such as school-year (to determine if there's any greater impact for those that have not previously

received an invitation letter) and inequalities (e.g. IMD quintile, proportion of children eligible for free school meals, proportion of children not with English as first language).

We will also undertake a per-protocol analysis of the primary and secondary outcomes, including in the analysis only those schools in trial arms 1 and 3 who implemented the request to send a reminder message with high fidelity to the request and those schools in trial arms 2 and 4 who did not send a reminder request. While the intention to treat analysis will be a composite of the effectiveness of reminders and the prevalence of SMS/email systems, the per-protocol analysis will enable these components to be disentangled.

We will analyse the invitation letters used in non-trials areas by coding the letters using the Theoretical Domains Framework (TDF). This will enable us to assess their behavioural-insight framing and fidelity to the new template letter. We will analyse whether those areas that used a letter similar to the new template had i) higher uptake and ii) greater change in uptake from to last year, compared to areas that used a dissimilar letter.

4. Study sponsorship and approvals

This study has been reviewed by the PHE Research Ethics and Governance Group to gain approval for PHE to act as the study sponsor.

Health Research Authority (HRA) approval has been sought, which includes ethical (opinion provided through UK Health Departments' Research Ethics Service), governance and legal review. (HRA/ethics number xxxxxxx).

The trial has been registered on clinicaltrials.gov, trial number xxx.

5. Main risks and mitigation

5.1. Timelines

The main risk to the successful implementation of this trial is meeting the timeline to enable local areas to implement the randomisation of letters component of the trial (mid-July deadline for most areas). The delay in initiating this development of the trial has been due to changes in budgets at PHE which led to a reduction and delay in the resources that could be allocated to this project. Should the trial not gain approvals in time to implement the randomisation of letters in a participating area, we will recommend that the area use the behaviour insights informed template letter for all

schools. Such areas would be invited to trial the effect of the SMS/email reminder on uptake. In the unlikely scenario of all areas being unable to participate in the letter-intervention (due to print-deadlines being ahead of approvals), the evaluation of the new template will rely on the ecological-analysis of fidelity to the new template letter in non-trial areas and uptake. While we are and will actively work with research sites to aim for this approach, if particular areas are unhappy to universally use the new template letter, we will take the above approach using the local letter updated from last year. One of the main reasons for including a large number of research sites at this stage is to give us the greatest possibility of running an effective and sufficiently powered trial, given the practical considerations.

5.2. Ethical issues

This study is using an intervention letter which is the nationally-available template for the childhood schools immunisation programme in the 2016/17 winter season, and by contrast using for the control arm, last year's letters. This potentially raises ethical issues given that we expect the intervention letter (which is in fact the national template) to be more effective than the control letters used last year. In conducting a trial of the letter we are randomising half of the children in participating areas to receive last year's letter. However, there is no direct evidence that the new letter will be more effective and, crucially, **we need to ensure that there is no unintentional decrease in vaccination uptake**.

Furthermore, we understand that there is often reluctance at a local level to change letters substantially from one year to the next, even given changes to the national template. A randomised trial of the new letter is the best way to obtain evidence as to whether the new letter increases uptake of vaccination. If successful, this evidence could help argue for increased fidelity to the national template by local programmes who would otherwise not change their letter.

5.3. Consent

In this trial of invitation letters it is neither desirable nor appropriate to obtain consent from schools or individuals to participate. Doing so would invalidate the validity of the trial and mean that the research questions cannot be answered. This potentially raises ethical concerns but these are mitigated by:

- the minimal harms that could arise through receipt of different letters or SMS/email reminders (there are no invasive or pharmaceutical procedures being tested in this research)
- we will not deviate from current policy or implementation – the vaccine will be offered to all children through a uniform approach and schools will not experience any difference from last year

- the population benefit of having robust evidence to answer the research question
- the individual benefit arising from vaccination and the minimal risks – and the fact that parents are provided with full information in all arms of the trial and have to provide consent to participate in the vaccination programme.

The providers and commissioners of the childhood flu immunisation programmes in participating areas have agreed willingly to take part in the study. The invitation letters are signed by the provider and not from the school.

5.4. Data security

Routine systems for data collection will be used, with data obtained at school level. PHE is the data owner of these information systems. The research team will not have access to any patient identifiable information. As the analysts work for PHE, no data will leave PHE and the research team will maintain data confidentiality of this information, including storage on restricted access PHE drives. School level data are not currently made publically available and the research team will adhere to this such that no school is identifiable in any published reports.

6. Timeline

Ethics approval	Early July 2016
Randomisation of schools	Mid July 2016
Trial implemented (i.e. school letters printed)	Mid July 2016
Invitations sent to schools and on to parents	October to December 2016
Schools requested to send reminders	October to December 2016
Data collection	Nov 2016, Dec 2016, Jan 2017, Feb 2017 and final data (with ability to adjust denominators) March 2017
Preliminary data analysis	Nov/Dec 2016
Final Analysis/Reporting	April/May 2017

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7. References

[1] Joint Committee on Vaccination and Immunisation. JCVI statement on the annual influenza vaccination programme – extension of the programme to children. 25 July 2012. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224775/JCVI-statement-on-the-annual-influenza-vaccination-programme-25-July-2012.pdf

[2] Public Health England. National Childhood Influenza Vaccination Programme 2015 to 2016 Seasonal influenza vaccine uptake for children of primary school age Final data for 1 September 2015 to 31 January 2016. May 2016.

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[4] Sallis, A., Bunten, A., Bonus, A., James, A., Chadborn, T., & Berry, D. (2016). The effectiveness of an enhanced invitation letter on uptake of National Health Service Health Checks in primary care: a pragmatic quasi-randomised controlled trial. *BMC Family Practice, 17*(1), 1.

[5] Behavioural Insights Team (2014). *EAST: Four simple ways to apply behavioural insights.*

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[6] Hallsworth M, List J, Metcalfe R, Vlaev I. The Behavioralist As Tax Collector: Using Natural Field Experiments to Enhance Tax Compliance. NBER Working Paper 2014;20007. doi: 10.3386/w20007

[7] N. Shackleton, D Hale, C Bonell and R M Viner. Intraclass correlation values for adolescent health outcomes in secondary schools in 21 European countries. SSM - PopulationHealth2(2016)217–225

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Appendix 1. Behavioural-insight framed letter

[Provider letterhead plus NHS logo]

TEMPLATE LETTER FOR SCHOOL-AGED CHILDREN

[Date]

Dear Parent/Guardian,

Your child's annual flu vaccination is now due

This vaccination programme is in place to help protect your child against flu. Flu can be an unpleasant illness and sometimes causes serious complications. Vaccinating your child will also help protect more vulnerable friends and family by preventing the spread of flu.

Please complete the enclosed consent form (one for each child) and return to the school [by/ within] **[INSERT DATE or TIME FRAME]** to ensure your child receives their vaccination.

The vaccination is free and recommended for young children, and will be given by a quick and simple spray up the nose.

A leaflet explaining the vaccination programme is enclosed and includes details about the small number of children for whom the nasal vaccine is not appropriate.

Last year, most children offered the vaccine in schools had the immunisation.

If you have any queries please contact the healthcare team on [INSERT NUMBER].

Yours sincerely,

[Signed by Provider]

If your child becomes wheezy or has their asthma medication increased after you return this form, please contact the healthcare team on [phone number].

If you decide you do not want to vaccinate your child against flu, please return the consent form giving the reason. This will help us plan and improve the service.

For further information see: www.nhs.uk/child-flu

Public Health England

Appendix 2.1. Example 1 invitation letter from 2015/16 season

Local Services, Local Solutions

SEPT

Dear Parent/Carer,

Flu vaccination for pupils in years 1-6

Annual influenza immunisation for children is being implemented across England in a staged process. In Essex all children in years 1-6 will be offered this vaccine in school. Reception age children will be offered this vaccine through their GP.

Most children (including those with asthma) can have this vaccine via a nasal spray called Fluenz Tetra. It is quick and painless to give with side effects being rare and generally mild. A very small number of children cannot have Fluenz but may be able to have the injectable vaccine, for instance if they have very unstable asthma. This is unusual and we will contact you if this applies to your child. Answering the questions on the consent form will help the nurse to assess your child's eligibility. A nurse will contact you if we require any additional information to make this assessment.

If your child has increased their asthma medication, or has been wheezy/unwell in the days leading up to their immunisation please contact your immunisation team.

In previous years, children with egg allergy were excluded from receiving Fluenz. However this year following extensive research it has now been established that only children with **anaphylactic reaction to eggs resulting in admission to an intensive care unit in hospital** will not be able to have this vaccine.

Please complete the attached consent form and return it to your child's school within **one week**. Please return your child's consent form in a sealed envelope addressed to the 'Immunisation Team' if you do not want their information to be viewed. We will not vaccinate your child if a valid consent form is not received. The consent form needs to be signed by a person with **parental responsibility** which includes:

- Mother: automatic
- Father: if married to mother either when baby is born or marries subsequently
- Unmarried father: if name appears on birth certificate (since 01.12.03) or legally acquired
- Others: if parental responsibility is legally acquired
- Parental Responsibility Agreement: signed, properly witnessed and sent for registration to Principle Registry or the Family Division (High Court)
- Residence Order: granted by the Court

If you have any questions or would like to discuss the vaccine with a nurse, please do not hesitate to contact your local Immunisation Team on the relevant contact number:

01702 220181 (Southend Locality)

01268 366606 (Castle Point, Rayleigh & Rochford Locality)

07943 533 460 (Basildon, Billericay, Brentwood, Thurrock & Wickford Locality)

Additional information is also available at: http://www.nhs.uk/Conditions/vaccinations/Pages/child-flu-vaccine.aspx

Yours faithfully

Immunisation Team

SEP320s (South)

Positive About Disabled People · Carbon Trust Standard · Personal Fair Diverse Champion · The NHS Constitution · Investors in People Gold · Stonewall

South Essex Partnership University NHS Foundation Trust

www.SEPT.nhs.uk

Public Health England

Appendix 2.2. Example 2 invitation letter from 2015/16 season

0-19 CHILDREN'S SERVICES
Today's health, Tomorrow's future

Southern Health NHS
NHS Foundation Trust

Autumn 2015

Dear Parent/Guardian,

Flu vaccination for children in Years 1 and 2

From October 2015 all children in years 1 and 2 will be offered flu vaccination through a nasal spray. This extension of the national flu immunisation programme to children is part of a phased introduction, based on the advice of independent experts.

Your child will be offered a flu vaccine that is given as a simple spray up the nose. It is painless, very quick, and side effects are uncommon. This vaccination programme is designed to protect your child against flu which can be an unpleasant illness and although rarely, sometimes causes serious complications. By having the flu vaccination, children are also less likely to pass the virus on to friends and family. This will help to protect those who are at greater risk from flu including infants, older people and those with an underlying health condition. The flu vaccine provides protection against the strains that are predicted to circulate in the coming season. These strains may change from year to year which is why we recommend vaccination every year.

A consent form and leaflet explaining the programme is enclosed.

Please complete the consent form (one for each child) and return it to the school within one week, so your child can be given the vaccine in school. Please note if the consent form is not returned your child will not be able to have the vaccine. Please contact your school, or telephone the healthcare team on 02380294424 for the date planned for your school. For more information about the flu vaccine please see the school nurse website at:
http://www.southernhealth.nhs.uk/health-and-wellbeing/childrens-health/flu-immunisation

If your child becomes wheezy or has their asthma medication increased just before or on the day of the vaccination session, please contact the healthcare team on 02380294424

Please remember to return the consent form even if you DO NOT consent to the vaccination for your child, explaining the reason for your decision. This will help us in the development of the flu vaccination programme in the future.

Your child's school will be collecting the completed consent forms. If you would prefer to keep the information confidential please return the form in a sealed envelope addressed for the attention of the School Nurse with your child's name on the back of the envelope.

We look forward to hearing from you.

School Nurse Team,

Southern Health NHS Foundation Trust