

Protecting and improving the nation's health

Extension of the Influenza immunisation programme to children in England

Experiences of using live attenuated influenza vaccine (LAIV) in school age children 2013-16

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

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Published August 2016

PHE publications gateway number: 2016182

This document is available in other formats on request.

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Executive summary

Background

In July 2012, the Joint Committee on Vaccination and Immunisation (JCVI) recommended that the national flu programme should be extended to include vaccination of healthy children aged 2 to less than 17 years with live attenuated influenza vaccine (LAIV) nasal spray ¹.

Due to the scale of the programme it is being phased in over a number of years. National rollout commenced in 2013/14 with the introduction to two and three year old children. In the same year pilots for primary school aged children commenced.

Pilots were set up for school age delivery to assess implementation issues such as workload, uptake and logistics of delivery. To date uptake has generally been good in the primary school aged pilots and early surveillance data is encouraging, showing a positive impact on a number of influenza indicators. The experience from the pilot areas is being used to inform the national roll-out of the programme.

Overview of Pilots

During the 2013/14 flu season vaccination was offered for the first time to all two- and three-year-olds through primary care general practices. In addition, a pilot programme in primary school-aged children (aged 4- to 11 years) was run in seven geographical areas. Six of the pilot areas delivered the programme using a school-based programme. The first year of the pilot programme achieved an overall uptake of 53% (ranging from 36 to 72% in individual pilot areas) in primary school-age children. The lowest uptake was in areas where pharmacy/General Practice delivery models were used.

Although the results were not statistically significant, the cumulative disease incidence was lower in pilot relative to non-pilot areas in both targeted and non-targeted age groups for a range of influenza indicators.

In 2014/15 the national programme was extended to include four year olds through General Practice. Six of the aprimary school-age pilot areas continued to vaccinate children aged 4 to 11 years, including the one non-school-based programme. In addition the pilot was further extended to include children in secondary schools aged 11 to 13 years in 12 geographical areas.

Uptake ranged from 21.2% to 62.0% at pilot level⁴. In both the primary and secondary age pilots, the areas of lowest uptake had used the pharmacy/General Practice models of delivery.

During the 2014/15 season drifted A(H3N2) and B influenza strains circulated leading to poorly matched vaccine strains and a reduced vaccine effectiveness, of around 34%⁵.

However despite these sub-optimally matched strains also being present in the LAIV, vaccinating children of primary school age in pilot areas resulted in a significant reduction in incidence for a range of surveillance indicators in the targeted age groups, with non-significant reductions in influenza swabbing positivity and ICU/HDUrespiratory admission rates in both targeted and non-targeted age groups.

Due to the considerably lower uptake in models where school aged children did not receive the vaccine in school, the preferred model is school based delivery. This document therefore concentrates on the experiences of school based delivery.

Contracting

• To ensure an effective process within procurement legislation the contracting and procurement processes should start a year prior to delivery.

Governance

- There is a programme requirement of a 100% offer to eligible children.
 Commissioners should ensure that there are plans in place to include children not in the traditional school setting e.g. home schooled, travelling communities or where schools refuse access.
- Children in at-risk groups are eligible for vaccination via their general practice but most school based providers also offer vaccination to such children alongside their peers to maximise the opportunities to protect this vulnerable group.

Prescribing arrangements

- All the school based provider teams used a model where the immunisation was supplied and administered by qualified nurses under a patient group direction (PGD).
- A patient specific direction (PSD) proforma and protocol were also produced so that Healthcare support workers (HCSWs) could immunise.
- PSDs were resource intensive and there were some difficulties finding willing prescribers.
- A model using HCSWs to administer the vaccine following supply under PGD by a qualified nurse was tested in the 2014/15 and 2015/16 seasons

Workforce

 Most providers were made up of specific immunisation teams supplemented where necessary by staff employed on short-term contracts and bank staff.
 Other areas used school nurse/health adviser teams.

- In the first year, due to the tight timeframe for set-up, some staff were 'borrowed' from other teams but more sustainable solutions were sought in subsequent seasons.
- One area realigned their other school age immunisation programmes to enable
 the development of a 'whole year' immunisation service, so that additional staff
 members could be employed for the duration of the academic year, reducing
 short-term posts, HR support and increasing retention of experienced
 immunisation staff.
- Where school nursing/health adviser teams were used to deliver this work, care had to be taken to ensure enough staff were available to prevent conflict between delivering the immunisation programme and other aspects of their role.
- HCSWs have been included in some teams to supply and administer vaccine under PSD and in subsequent years to administer the vaccine following supply by a qualified nurse under a PGD (designated for supply).
- Including HCSW as members of delivery teams was regarded as advantageous and provided a flexible resource.

Administration of paperwork and the consent process

- The administrative support required for setting up and delivering the programme was significantly underestimated by all providers.
- The administrative role included: obtaining school and pupil lists; preparation of
 invitation and consent forms; liaising with schools; scheduling sessions; ordering
 supplies; distribution and collection of consent forms, leaflets and vaccine to
 schools; preparation for sessions; supporting immunisers at sessions; data entry
 and data transfer to other healthcare providers and child health records.
- The programme also had an impact on other stakeholder organisations, for example, local authorities were requested to provide school lists, and Child Health Information Departments and General Practice teams had to update children's immunisation records.

Engagement with schools

- All areas felt that visiting schools to plan delivery arrangements was preferable, although probably only necessary the first time a school participated in the programme. It gave the teams an opportunity to conduct a risk assessment and assess facilities for the vaccination session.
- As the programme extends through the age cohorts it will become more challenging to offer schools a choice of dates for the immunisation sessions hence giving the schools plenty of notice of the proposed immunisation session dates will become even more important.

 A small number of schools refused to host immunisation sessions. Where the local teams are unable to access schools, children must be offered the vaccination in an alternative venue.

Impact on schools

Commissioning and provider teams worked very hard to keep additional
workload on schools to a minimum. The vast majority of schools were satisfied
with how the programme was delivered and many headteachers were interested
in the potential of the immunisations to reduce sickness absence among staff
and children in the busy winter and early spring term.

Immunisation invitation

- Parents and children were generally sent an introductory invitation letter, the
 national information leaflet and a consent form via their school. This process
 was administratively time consuming and very resource intensive for the provider
 and school staff.
- One area sent invitations directly to parents via the post but this resulted in a lower uptake than using the school to parent system and was considerably more expensive.
- Completed consent forms were primarily returned to schools and collected prior to the sessions for clinical triage, instead of parents mailing consent from directly back to a provider.

Clinical triage

- Triage of consent forms, to identify children in at-risk groups and those with contraindications to vaccination with LAIV was also very time consuming. A high proportion of consent forms were completed incorrectly, needing parental contact for further clarification or clinical follow-up.
- To begin with triage was undertaken by nursing staff. However in the second season some areas used the administration team to do a first level triage, chasing up missing information and referring forms with any clinical issues to the nursing team for review.
- There were a significant number of consent forms returned after the deadline set by the provider including on the day of the immunisation session. This could be disruptive to the running of the session especially where parental contact was required. One area did not triage forms returned on the day but offered vaccination at community clinics at a later date. Providers are urged to make every effort to immunise children when consent forms are returned on the day.

Immunisation sessions

- Immunisation teams typically contained one or two admin staff and two to four immunisers.
- All areas found that the immunisation process was quicker than expected. The timing was approximately two minutes per child.
- Most areas had more than one team of immunisers working on the programme each day.
- In the first season, one area made parental attendance at the immunisation session mandatory. This model meant that child identification was not an issue but had a number of significant disadvantages including increased disruption within the school setting and a negative impact on uptake. This model was not recommended by the area and has not been taken forward in subsequent seasons.

Session management

- Generally consented children were identified from pre-prepared class-lists and collected from classes in groups by school or provider staff. The completed consent forms were given to the correct child who was then directed to the next available immuniser to confirm eligibility and vaccinate as appropriate.
 Vaccination details were added to the consent form and local data collection process completed.
- In most of the pilot areas, at-risk children were vaccinated as part of the school programme. In some areas they were referred to their general practice although it was recognised that this could be creating barriers for those children who needed the vaccination most.
- It is best practice that at-risk children are included in the school programme.
 However since these children are particularly vulnerable to the effects of flu it is
 important that parents retain the option of taking their child to their General
 Practice to ensure timely immunisation. This is particularly important if their
 school session was scheduled for later in the delivery period.
- In some areas inactivated injectable vaccine was provided as part of the school based delivery, for the small numbers of children with contraindications to LAIV who were also in an 'at risk' category. In the others areas these children were referred to their General Practice.
- HCSWs immunising under PSD alongside qualified nurses immunised a similar number of children during a session as qualified nurses.
- Generating PSDs was time consuming and where the prescriber was not based within the provider team there was some difficulty in getting the PSDs signed off in time.
- A model using HCSWs to administer the vaccine following supply under PGD by a qualified nurse was tested. The qualified nurse confirmed the children's

- identity and eligibility. The children were then supplied with the nasal vaccine and directed to a HCSW for administration of the vaccine. A ratio of 2:3 qualified nurses to HCSWs ensured a steady flow of children without them having to wait too long.
- Self-administration of LAIV was tested in Year 6 (aged 10-11 year olds) pupils in several pilot areas in the first two seasons. Both group and 1:1 models were tested. Self-administration was well accepted by pupils but the process was slower than nurse administration with an estimate of an additional two minutes per child. It was generally felt that whilst self-administration was a useful tool it was likely to be inefficient on a large scale.
- A couple of areas set up a system to monitor the children for 10-15 minutes post vaccination. This created additional disruption for schools, utilised valuable time and resource and is not necessary under the product licence.

Mop-up sessions

- 'Mop-up' or 'catch-up' sessions held in the schools were provided in most areas
 in the first year of the pilot for children who were absent on the day, late returned
 consents or where parents had changed their minds after positive feedback.
 They were time consuming, resource intensive and significantly increased the
 burden on schools for a modest increase in uptake.
- Most areas did not provide mop-up in the second pilot season but rather provided a few follow-up opportunities in community clinics for children who missed vaccination on the day but whose parents requested it.

Vaccine supply and distribution

- LAIV is scheduled to be available from the end of September but like many flu
 vaccine products time lines can slip. Hence, to avoid having booked session but
 no vaccine, providers should plan to start the 1st full week of October at the
 earliest.
- The vaccine comes in packs of 10 pre-filled nasal applicators and has a short shelf life of approximately 12-14 weeks from distribution so stock has to be managed carefully to avoid wastage.

Data management

 The administrative burden of the programme was greatly underestimated across all the sites. Data collection and sharing of information was a major component of this work. This included compiling accurate cohort lists sorted by school and academic year, collecting process data at the sessions, providing uptake data to commissioners and the national team, entering information from consent forms

- and sharing details of children vaccinated with general practices and Child Health Information Systems (CHIS).
- There was no national requirement to update CHIS records after school based immunisation as local administration resource and system flexibility varied substantially. However it is good practice and recommended that for completeness the records should be updated where possible.
- Children's immunisation records have to be stored until their 25th birthday or 26th if the young person was 17yrs at the conclusion of their treatment.
 Arrangements for storage of hard copies or electronic records should be made as per local policies.

National rollout

The pilot areas have been delivering this programme for 3 years now with many refining their delivery each year. Sharing their experiences of what worked and what did not informed the national roll-out.

In 2016/17 children of age appropriate for school Year 3 will be eligible for vaccination. Year 3 is defined as seven- rising to eight-year-olds (i.e. date of birth between 1 September 2008 and on or before 31 August 2009. The intent is that the programme will gradually extend over future years to all primary school aged children. Once extended to all primary school age children the roll-out will pause to assess the epidemiological data and enable the JCVI to further consider whether extension to senior school age children is necessary.

Main report Programme overview

Background

In England, the right to receive relevant vaccinations is set out in the *NHS Constitution* originally published in 2009, and updated most recently in 2013. This places a statutory duty on the Secretary of State for Health to ensure, that any recommendation from the Joint Committee on Vaccination and Immunisation (JCVI) for a new or changed national immunisation programme is implemented. In such cases, DH is responsible for policy and funding and PHE, in collaboration with NHS England, implements the programme.

NHS England is responsible for commissioning the local provision of immunisation services and the delivery of programmes. General Medical Practices deliver the majority of the infant immunisation programme but increasingly other providers have been commissioned to deliver immunisation services for older children including specific immunisation teams and school nursing services.

In July 2012, the Joint Committee on Vaccination and Immunisation (JCVI) recommended that the national flu programme should be extended to include vaccination of healthy children aged 2 to less than 17 years with live attenuated influenza vaccine (LAIV) nasal spray ¹. The JCVI recommendation is based upon analysis suggesting that, when the direct and indirect benefits are taken into account, vaccinating school aged children with LAIV is highly likely reduce the burden of influenza in the community and be cost effective particularly over the longer-term. LAIV has several advantages over inactivated flu vaccine²:

- higher efficacy in children, particularly after a single dose
- potential to provide coverage against circulating strains that have drifted from those contained in the vaccine
- higher acceptability of intranasal administration with parents and carers
- it may offer important longer-term immunological advantages to children by replicating natural exposure/infection and thus inducing better immune memory than inactivated flu vaccines.

Although the patient information leaflet provided with LAIV suggests full vaccine naïve children should be given two doses of this vaccine, JCVI considered that a second dose would only provide modest additional protection. Therefore, JCVI recommended that most children should be offered a single dose except for those children in clinical risk groups aged two to less than nine years old who have not received flu vaccine before who should be offered two doses of LAIV (given at least four weeks apart).

JCVI recognised that implementation of this programme would be challenging and advised that its introduction would require careful planning. Due to the scale of the programme it is being phased in over a number of years. National rollout commenced in 2013/14 with the

introduction to two and three year old children. In the same year pilots for primary school aged children commenced.

Pilots were set up for school age delivery to assess implementation issues such as workload, uptake and logistics of delivery in a variety of settings that will reflect full-scale roll-out as closely as possible. The experience from the pilot areas is being used to inform the national roll-out of the programme.

This report gives an overview of the experiences from the pilot years 2013/14 and 2014/15 seasons and also includes information from the national roll out to all children of appropriate age for school years 1 (aged 5 rising to 6 yrs) and 2 (aged 6 rising to 7 yrs) age in all schools where appropriate.

Overview of Pilots

2013/14

During the 2013/14 flu season vaccination was offered for the first time to all two- and three-year-olds through primary care general medical practices (GMPs). In addition, a pilot programme in primary school-aged children (aged 4- to 11 years)was run in seven geographical areas: Bury, Cumbria, Gateshead, Leicester City, East Leicestershire & Rutland (LLR), London (Newham and Havering), South East Essex

These areas covered a wide range of geography, ethnic diversity and deprivation enabling delivery to be tested across a variety of different settings. The pilot cohorts ranged from just under 15,000 children in Gateshead to almost 55,000 in LLR.

Six of the pilot areas delivered the programme using a school-based programme. Of these, four areas used NHS immunisation teams to deliver, one used the school nursing service and one used a private provider. The seventh area, Cumbria, delivered the programme via pharmacies and General Practice

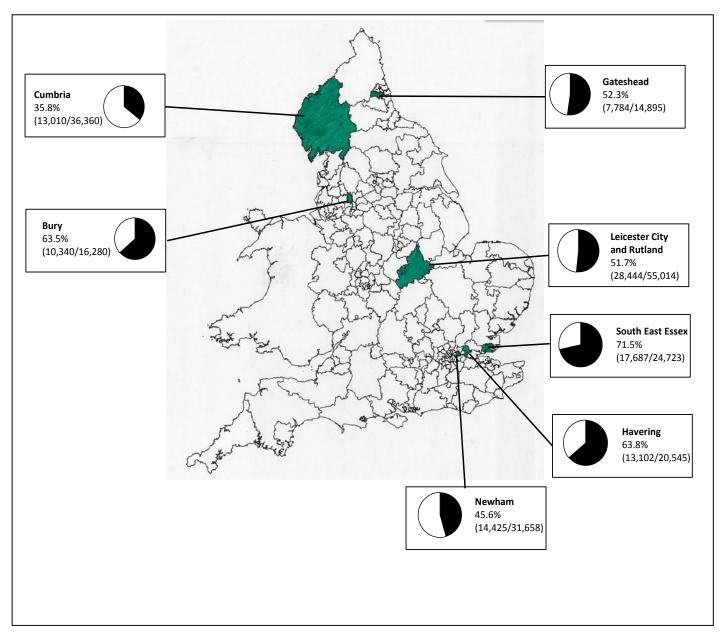


Figure 1: Cummulative uptake of LAIV in pilot sites (black area of pie chart indicates % vaccinated) 2013/14, England³

Uptake and surveillance

This first year of the pilot programme achieved an overall uptake of 53% (ranging from 36 to 72% in individual pilot areas) in primary school-age children. The lowest uptake was in areas where pharmacy/General Practice delivery models were used.

Although the results were not statistically significant, the cumulative disease incidence was lower in pilot relative to non-pilot areas in both targeted and non-targeted age groups for a range of influenza indicators – both laboratory-confirmed and syndromic. These observed differences were smaller for more severe disease end-points³.

2014/15

In 2014/15 the national programme was extended to include four year olds through General Practice. Six of the primary school-age pilot areas continued to vaccinate children aged 4 to 11 years including the one non-school-based model. Some of the areas expanded their geographical size thus increasing their target population.

In addition the pilot was further extended to include children in secondary schools aged 11 to13 years in 12 geographical areas, four of which also ran the primary school age pilots. London with the exception of Havering ran the pilot in special schools only. The pilots were predominately school based with the exceptions of Cumbria and Arden, Hereford & Worcester who ran pharmacy based models and Leeds local authority (LA) where the school aged service ran through General Practice.

The total target population for the pilots was estimated to be 346,962 primary school children and 371,109 for secondary school children aged 11 to13 years. The primary school aged pilot area cohorts varyied in size between 148,383 (Essex) and 15,584 (Gr Manchester). The secondary school aged pilots varied between 60,024 (Birmingham and the Black Country) and 3,115 (Havering).

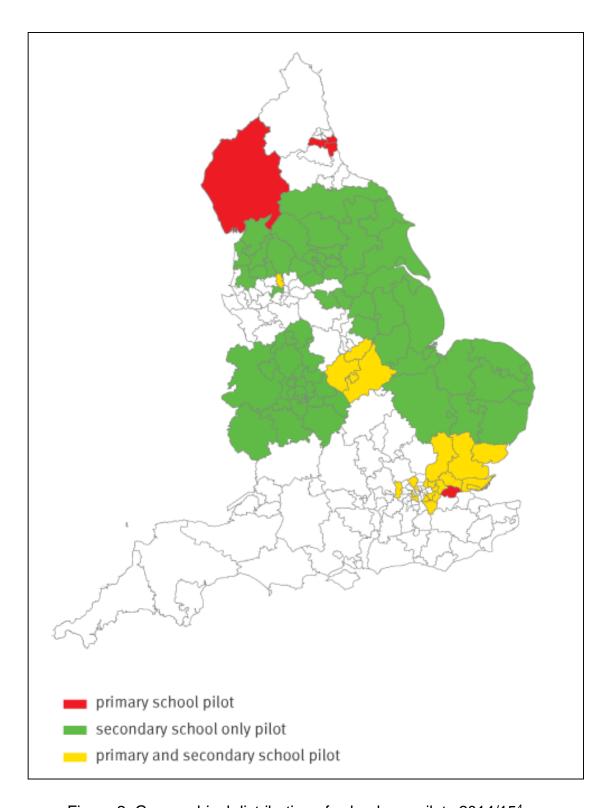


Figure 2: Geographical distribution of school-age pilots 2014/15⁴

Uptake and surveillance

An estimated 196,994 primary school age children received at least one dose of influenza vaccine resulting in an overall uptake of 56.8%. This ranged from 32.3% to 63.1% at pilot-site level. An estimated 184,975 secondary school age children received at least one dose of influenza vaccine, an overall uptake of 49.8%. Uptake ranged from 21.2% to 62.0% at pilot level⁴. In both the primary and secondary age pilots, the areas of lowest uptake had used the pharmacy/General Practice models of delivery.

During the 2014/15 season drifted A(H3N2) and B influenza strains circulated leading to poorly matched vaccine strains and a reduced vaccine effectiveness, of around 34%⁵. However despite these sub-optimally matched strains also being present in the LAIV, vaccinating children of primary school age in the pilot areas resulted in a significant reduction in incidence for a range of surveillance indicators in the targeted age groups including cumulative GP ILI consultation rate emergency department respiratory attendances, and cumulative hospitalisation incidence rate, with non-significant reductions in influenza swabbing positivity, and ICU/HDU respiratory admission rates in both targeted and non-targeted age groups. The size of the effect was less for more severe endpoints, in particular excess mortality. Vaccination of secondary school age children alone (aged 11-13 years) failed to show conclusive evidence of such reductions in disease incidence in either targeted or non-targeted age-groups³

Due to the considerably lower uptake in models where school aged children did not receive the vaccine in school, the preferred model is school based delivery. This document therefore concentrates on the experiences of school based delivery.

Local planning and set-up

Contracting

Timescales for commissioning providers for participation in the pilot were short especially during preparation for the 2013/14 season. In nearly all areas local NHS England commissioners used a contract variation with an existing provider to deliver the programme. Similar contract variations were again used for the 2014/15 season.

For 2015/16 which was the first season the programme was extended nationally to children of age appropriate for school years 1 and 2 age there was a need to establish a safe procurement process within procurement legislation and a national framework of approved providers was set up to assist local commissioners to identify and 'call off' suitable providers. The contracting and procurement processes should start a year prior to delivery.

Governance

During their first year of delivery, pilot areas set up steering/management and implementation groups to develop and to oversee delivery of the programme. All groups included key individuals from the local NHS England commissining teams and provider organisation(s). These groups also had members from other key stakeholders including, for example, representation from local authorities, childrens' and school nursing services, communications and lead pharmacists. In general, the steering/management groups initially met weekly/fortnightly at the beginning of the season then less frequently once delivery was underway. Implementation groups tended to meet weekly for the duration of the season to discuss progress and ensure a prompt response to any issues or problems. These meetings were a mixture of face to face meetings and teleconferences.

In 2015/16, the third year of delivery in pilot areas, as the programme became increasingly part of 'business as usual' these steering/management groups were subsumed into the usual immunisation governance structures.

From 2015/16 when national rollout commenced there was a programme requirement of a 100% offer to eligible children. Commissioners had to ensure that there were plans in place to include children not in the traditional school setting e.g. home schooled, travelling communities or where schools refused access. Schools for children with special educational needs and those ouside the local government control such as academies (publicly funded independent schools) and private schools were also included. Children in at risk groups are eligible for vaccination via their GPs but most school based providers also offered vaccination to such children alongside their peers to maximise the opportunities to protect this vulnerable group.

Prescribing arrangements

In the first year all the school based provider teams used a model where the immunisation was supplied and administered by qualified nurses under a patient group direction (PGD). Some sites used the national PGD template and others produced their own. In one area a patient specific direction (PSD) proforma and protocol were also produced so that Healthcare support workers (HCSWs) could immunise. Children were initially sorted into those potentially eligible for PSD by members of the admin staff. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147823/ Green-Book-Chapter-5.pdf

The consent forms were then clinically triaged for inclusion on the PSD by clinically qualified staff and signed off by a nurse prescriber following assessment of the child's clinical records through a centrally hosted clinical computer system and the clinical information provided on the consent form.

The time taken preparing a PSD per school varied depending on the size of the school. One estimate was approximately five hours to prepare a school of 420 pupils (combined admin and clinical time). A limitation of the PSD system was that if a number of consent forms were returned on the day, HCSWs were unable to assist with

the additional workload as children could not be added to the PSD on the day; unless the prescriber was present.

In the second season several areas included HCSWs vaccinating under PSD. Again it was reported that PSDs were resource intensive and there were some difficulties finding willing prescribers.

One area tested a model using HCSWs to administer the vaccine following supply under PGD by a qualified nurse.

More information about the models used is provided in the 'Immunisation Session' section below. A national LAIV PGD template is available at

https://www.gov.uk/government/publications/influenza-vaccine-fluenz-tetra-patient-group-direction-pgd-template

Workforce

Qualified nurses

All school based providers used qualified nurses vaccinating under PGD to deliver the programme. The majority of these were made up of specific immunisation teams supplemented where necessary by staff employed on short-term contracts and bank staff. Other areas used school health adviser teams (who have a wide public health remit). In the first year, due to the tight timeframe for set-up, some staff were 'borrowed' from other teams but more sustainable solutions were sought in subsequent seasons. Recruitment to short-term posts and use of temporary bank staff was time consuming and HR delays meant that some teams didn't have their full complement of staff for a significant proportion of the programme. This also led to increased 1:1 training requirements as temporary staff had to be trained before joining the teams. Additionally some bank staff were unavailable or reduced their commitment once the programme was underway due to other pressures within their organisations.

One area realigned their other school age immunisation programmes to enable the development of a 'whole year' immunisation service, so that additional staff members could be employed for the duration of the academic year, reducing short-term posts, HR support and increasing retention of experienced immunisation staff. Where school nursing/health adviser teams were used to deliver this work, care had to be taken to ensure enough staff were available to prevent conflict between delivering the immunisation programme and other aspects of the role. Where PSDs were being used to enable healthcare support workers (HCSWs) to vaccinate it was preferable to have a nurse prescriber within the provider team rather than having a prescriber outside the team produce them.

Healthcare support workers (HCSWs)

HCSWs were included in some teams in the first season to supply and administer vaccine under PSD and in subsequent years to administer the vaccine once it had been supplied by a qualified nurse under PGD (designated for supply). Including HCSW as members of delivery teams was regarded as advantageous. The staff integrated well and were considered a flexible resource. It is anticipated that they will become an important addition to all provider teams as the roll-out progresses. More information about the models used is provided in the 'Immunisation Session' section below

Administrative Staff

All new providers each year reported that despite warnings from the pilot areas already running the programme that they had underestimated the administrative support required for setting up and delivering the programme. The administrative roles included; obtaining school and pupil lists; preparation of invitation and consent forms; liaising with schools; scheduling sessions; ordering supplies; distribution and collection of; consent forms, leaflets and vaccine to schools; preparation for sessions; supporting immunisers at sessions; data entry and data transfer to other healthcare providers and child health records. The administrative support staff were seen as being key to the successful running of the programme.

Some areas employed drivers to distribute invitation packs to schools, collect returned consents for triage, deliver consumables and vaccine to and from school sessions. This freed time for the healthcare teams and where drivers were part of the wider team their use was well evaluated. The area with the largest cohort in year one set up a dedicated administrative support team covering 12-hour shifts to support the programme. The programme also had an impact on other stakeholder organisations, for example, local authorities were requested to provide school lists, and Child Health Information Departments and General Practice teams had to update children's immunisation records.

Training

Clinical staff

All pilot areas provided LAIV-specific education and training for immunisers. For staff already involved in other immunisation programmes this training was added on to their annual update where possible.

All areas used a mixture of face to face group and 1:1 education and training. Some used a 'train the trainer' approach to cascade the training to all staff involved in the programme. Training was a significant burden on senior staff, particularly for sites that

had a high proportion of temporary and bank staff or a high staff turnover. eLearning was found to be a useful add-on to face to face training meaning that staff could work through modules at their own pace whilst reducing the time required for face to face training. National training materials were produced including a training slide set https://www.gov.uk/government/publications/childhood-flu-programme-training-slide-set-for-healthcare-professionals and an interactive flu immunisation e-learning package containing a LAIV session. http://www.e-lfh.org.uk/programmes/flu-immunisation/open-access-sessions/

HCSWs

Areas using HCSWs provided face to face education and training in administering LAIV under PSDs and following supply by qualified nurse under PGD. Following training HCSWs initially observed sessions and were then supervised immunising until the required competencies had been achieved. Depending on where the HCSW had worked previously other training such as safeguarding, basic life support or anaphylaxis management was in some cases also necessary. A national guidance document was updated to include training requirements and considerations for HCSWs involved in the LAIV programme.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/464033/HCSW_Training_Standards_September_2015.pdf

Administrative staff

These teams received education and training on the childhood flu programme and the processes that they were involved in. This tended to be more 'on the job' training but again could be time consuming if there were a lot of temporary or part-time staff.

Communications

Engagement with schools

Throughout the pilots effective engagement with schools was highlighted as crucial to the smooth running of the programme. Due to the tight timeframe to set up the pilots in the first year, most areas were not able to carry out as much engagement activity as they considered ideal. In all areas the initial contact with schools was by letter. This was sent out directly by the teams or through a Local Authority email distribution list. The general view was that the ideal time for this initial contact would be in the spring or summer term so that immunisation sessions could be factored into the planning for the following autumn term. Independent schools and special schools were also included in the pilots.

School visits

Some areas routinely carried out an introductory visit with schools, others visited only if specifically requested and a few areas only carried out phone discussions. All areas felt that visiting schools to plan delivery arrangements was preferable, although probably only necessary the first time a school participated in the programme. All pilot areas reported that fewer face to face visits were required in second and subsequent years.

Visits gave the teams a valuable opportunity to engage with the school staff, inform them about the programme, discuss requirements such as agreeing processes for managing consent forms, school support required on the day, and vaccine supply arrangements. It also gave the teams an opportunity to conduct a risk assessment, assess facilities for the vaccination session including size of room, hand washing facilities, availability of refreshments, parking, WiFi, whether mobile phones were permitted and other safeguarding requirements.

Some teams produced documents in conjunction with schools which detailed each teams' responsibilities, the facilities agreed and input required from the school staff. School visits were time consuming and some areas managed with phone discussions although this meant that sometimes (particularly in the 1st year of the pilot) the facilities provided for the immunisation sessions were not ideal. Whatever form of discussions were held with schools, it was important to identify a key individual at the school who would take responsibility for liaising between the healthcare team and the school. Some areas also recommended allocating a named healthcare team member to each school so that the school had a specific contact in case of queries. In some areas the pre-delivery visits were carried out by administrative support team members with nurses contacting schools to respond to specific clinical queries.

Scheduling sessions

Most areas scheduled vaccination sessions by mutual agreement with schools, contacting the school as early as possible in the spring or summer term with potential dates. Sometimes offering the school a choice of dates was more difficult particularly where there were a large number of schools or if there were a group of smaller schools in the same area where it would be advantageous to hold their sessions on the same day so that staff could move easily between the schools if necessary. As the programme extends through the age cohorts it will become more challenging to offer a choice of dates hence giving the schools plenty of notice of the proposed session dates will become even more important.

A small number of schools refused to be venues for immunisation. Reasons for refusal included already crowded timetables, late engagement, a perceived burden of work for the school and reasons of faith or philosophy (particularly in Muslim schools due to the porcine gelatin content of the LAIV). Where the local teams are unable to access schools, the expectation now that there is full rollout to all schools is that the children will be offered the vaccination in an alternative venue eg community clinics.

All areas reported that school engagement was considerably easier in subsequent years. Over the first three years the number of schools refusing to engage has decreased due to the careful and timely engagement with all stakeholders.

Impact on Schools

The pilot commissioning and provider teams worked very hard to keep additional workload on schools to a minimum including providing prepared invitation packs and ensuring a system in palace to deal with parental enquiries directly. However support with sending out invitation packs via 'satchel post', collecting and collating returned consent forms and providing supervision and confirmation of identity for younger children on the day of immunisation was particularly valued by the teams. These are covered in more detail in specific sections below. The vast majority of schools were satisfied with how the programme was delivered and many headteachers were interested in the potential of the immunisations to reduce sickness absence among staff and children in the busy winter and early spring term.

https://www.gov.uk/government/case-studies/flu-vaccination-at-hemington-primary-school

At a national level, there was significant engagement with the department for education (DfE) and national teacher forums. An information leaflet for schools was also produced. https://www.gov.uk/government/publications/flu-immunisation-for-primary-school-children-advice-for-headteachers

Engagement with parents and children

Some teams also attended assemblies and parents' meetings at the schools request. These were felt to be beneficial but are resource intensive and are probably not scalable given the size and timeframe of the programme. Some areas developed powerpoint presentations or video clips

https://www.youtube.com/watch?v=1jHWwm8NQUw so that teachers could share with children. Some schools incorporated the information about the programme into the curriculum eg science, history or Personal, Social, Health and Economic Education (PSHE). One school focused on the citizenship element of the programme with vaccinated children being credited for providing additional protection to more vulnerable members of the community.

Immunisation invitation

The primary school-based pilots communicated with the parents and children by sending out an introductory invitation letter, the national information leaflet and a consent form via the schools. There was a national template invitation letter and consent form which could be modified to suit local circumstances eg include local

contact details and add immunisation dates. These documents can be accessed at https://www.gov.uk/government/publications/childhood-flu-programme-2015-to-2016-extension-advice-for-parents-and-schools.

Several sites translated material into other languages prevalent in their locality and others provided contact details of 'LanguageLine' or other interpretation services. One area did produce the consent form in other languages but found these were difficult to interpret particularly when it was returned with additional handwritten comments.

It was recommended that the letter contained a healthcare provider team number and/or email address for parental queries, to discourage these being asked of school staff. This reduced school workload and minimised the risk of messages being answered incorrectly or going astray. Some areas provided programme specific email addresses or answerphones so that messages from parents could be tracked and responded to in a timely manner.

Additional communications

Most areas sent information about the programme to local health professionals including school nurses, GPs, paediatricians, health visitors etc. Some areas also informed the school nursing service about the dates of the school sessions to minimise any impact on their primary school- based programmes, e.g. National Child Management Programme (NCMP).

All areas had some local media involvement. In some areas, this was in the form of a press release or a local newspaper article and in others it included both local and national radio and television interviews. There was a lot of interest in the programme and the coverage was generally very positive.

Preparing information and approaching parents

Information on school size and pupil details was obtained from local authorities (LA) and/or directly from the schools. Producing, collating and providing the invitation packs to schools for onward distribution to pupils was administratively time consuming and very resource intensive for providers and school staff. Most providers used their own staff to do this work although others found outsourcing the printing, collating and packaging, ready for delivery to the schools, efficient and cost effective. The delivery of the packs to schools and pick up of returned consents for triage were generally undertaken by the teams but this became increasingly difficult once the programme was under way particularly if a driver was not part of the team.

It was also identified as important to give the schools enough time to distribute and collect in the paperwork with clear deadlines for return. The teams usually sent the invite packs to the school 3-4 weeks prior to the planned session. A few areas sent the

packs to schools prior to the summer holidays but this created storage problems for the schools and some materials went missing. Additionally since LAIV is not recommended for children with active wheeze it was recommended that the consent forms were sent to parents as close to the session as possible. Most teams gave parents approximately two weeks to return completed forms. Written reminders were not generally sent although some schools reminded parents through their routine email systems and newsletters. In the first season, one area sent written reminders to non-responders due to low response rates but the timeframe and scale of the programme when rolled out nationally would make written reminders impractical. One area sent invitations directly to parents via the post but this resulted in a lower uptake than using the school to parent system and was considerably more expensive.

Completed consent forms were primarily returned to schools, instead of parents mailing consent from directly back to a provider. Organising and triaging returned consents was much easier for teams if school staff were happy to sort returns into school years. Some areas asked parents to write the child's name and form group on the outside of a return envelope, in order to maintain confidentiality of the completed consent form. Another area didn't provide envelopes but gave parents the option to return the form directly to the team if there was information that they did not want to share with the school. Other areas provided boxes into which schools could 'post' returned consent forms. These were then collected and sorted into school year by the healthcare team. A high number of forms were returned late, meaning that several trips were made to a number of schools. Several areas recommended that the initial delivery to and pick up from schools could be done more efficiently by a team driver or courier company.

Home-schooled children were sent their invitations via local home learning networks

Clinical triage

Triage of consent forms, to identify children in at-risk groups and those with contraindications to vaccination with LAIV was very time consuming. There was a high proportion of consent forms completed incorrectly, needing parental contact for further clarification or clinical follow-up. Often multiple attempts at contact had to be made. One area initially tried to triage forms on the day at the start of the session but soon realised that this was not feasible. Generally, forms were picked up approximately one week prior to the session to triage in advance. Initially triage was undertaken by nursing staff. However in the second season some areas used the administration team to do a first level triage, chasing up missing information and referring forms with any clinical issues to the nursing team for review.

All areas identified the importance of a simple, clear consent form and factoring enough time for triaging and contacting parents.

There were a significant number of consent forms returned after the deadline set by the provider including on the day of the immunisation session. This could be disruptive to the running of the session especially where parental contact was required. One area did not triage forms returned on the day but offered vaccination at community clinics at a later date. Providers are urged to make every effort to immunise children when consent forms are returned on the day.

Immunisation sessions

Staffing

The number of staff sent to each school was dependent to some extent on the size of the school and the skill mix of the team but typically contained one or two admin staff and two to four immunisers. Up to six immunisers were used in larger schools but if there were too many nurses the sessions could become disorganised and less efficient. One area recommended two admin staff and two nurses per 100 pupils with another nurse for each additional 100 pupils. Another area estimated that each nurse was able to immunise about 50 children per session (approximately 2.5 hours). Sometimes an additional nurse was taken to triage if they were aware of a lot of late returned consent forms waiting for them at the school. Most areas recommended two admin staff at the session with one leading the collection of data and distributing consent forms and one to coordinate the collection of children from classes and helping with supervision of the children whilst waiting to see the nurse.

All areas found that the immunisation process was quicker than expected, the timing was approximately two minutes per child which meant that a team could potentially get through two or three schools a day. Most areas had more than one team of immunisers working on the programme each day. Scheduling rotas can be challenging especially where teams were visiting more than two schools a day or in more rural locations when travel time had to be factored in.

Teams usually arrived about 30 minutes before the session started to set up and deal with any queries. The teams tended to work with one desk and two chairs for each immuniser and an additional desk for the administrative support, space where pupils could wait before and after immunisation (if have to wait on their classmates) was also required. All areas recommended a generous supply of tissues for children and anti-bacterial hand gel for healthcare staff use. There were issues with space in a small number of schools with nurses having to vacate the room for assemblies or over lunch and break time. Most teams had to stop immunising over break and lunchtimes which needs to be factored into the scheduling of sessions. Some schools were happy to stagger break and lunchtimes for pupils so sessions could continue.

Most of the schools were happy to provide office support if parental contact was required (mobile phone use was not always permitted in schools) and free up staff to act as a 'runner' to bring children from class, help supervise whilst waiting and to help with identification of younger children. This was often a teaching assistant. Identification of the youngest children was particularly challenging, some were nervous and shy and refused to say or confirm their names. A couple of the sites suggested name badges for the younger children, however teachers had concerns that children might swap or share badges.

Parental attendance

In the first season, one area made parental attendance at the immunisation session mandatory. This model meant that child identification was not an issue but had a number of significant disadvantages. A considerable additional burden was placed on the school, arranging and coordinating appointments for parents. If the session was running early or late it became very challenging to manage. There were some safeguarding concerns due to having numbers of adults without disclosure and barring service (DBS) checks in the school. There was also a negative impact on uptake with a number of parents not being available at the time of the session due to work commitments or returning a completed consent form but not turning up on the day. Additionally some parents were unhappy with having taken time away from work or other commitments for a simple procedure taking a few minutes. This model was not recommended by the area and has not been taken forward in subsequent seasons.

Session management

Processes varied by site but generally consented children were identified from preprepared class-lists and collected from classes in groups. Usually, it was only consented children who were brought down to the session but occasionally, due to staff resources, the whole class had to attend and wait whilst those consented were immunised. Pupils were brought to the session by teachers or teaching assistants or, if not available, occasionally by the admin staff from the provider team or Year 6 pupils (aged 10-11 year olds). Whilst waiting to be immunised, children were supervised by the team administrative support staff or school staff. The completed consent forms were given to the correct child who was then directed to the next available immuniser to confirm eligibility and vaccinate as appropriate. Vaccination details were added to the consent form and local data collection process completed. There were both paper and electronic systems used at school level with some areas having pre-populated electronic spreadsheets prior to the session. Children were usually provided with a certificate of immunisation, summary of product information for parents, and stickers/immunisation certificates (where provided).

In most of the pilot areas, at-risk children were vaccinated as part of the school programme. In some areas they were referred to their GP although it was recognised that this could be creating barriers for those children who needed the vaccination most and it is therefore best practice that at-risk children are included in the school programme. However since at-risk children are particularly vulnerable to the effects of flu it is important that parents retain the option of taking their child to the GP so that these children can be immunised in a timely way This is particularly important if their school session was scheduled for later in the delivery period.

In some areas inactivated injectable vaccine was provided as part of the school based delivery, for the small numbers of children with contraindications to LAIV who were also in an 'at risk' category. In the others areas these children were referred to their GP

Healthcare support workers vaccinating under PSD

In the first season one area piloted the use of HCSWs vaccinating under PSD. The HCSWs worked as part of the immunisation team immunising similar numbers of children during a session as qualified nurses.

In the second season several other areas also tried using HCSWs vaccinating under PSD and whilst they were considered a valuable addition to the team, generating PSDs was time consuming and where the prescriber was not based within the provider team there was some difficulty in getting the PSDs signed off in time.

HCSWs administering vaccine after supply by a qualified nurse

In the second season a model using HCSWs to administer the vaccine following supply under PGD by a qualified nurse was used. The qualified nurse checked the information on the form with the child and confirmed their identity and eligibility. The children were then supplied with the nasal vaccine in a suitable receptacle and directed to a HCSW at a nearby immunisation station for administration of the vaccine. In cases where the child was very nervous, the qualified nurse would both supply and administer the vaccine. This model has been tested further in the 2015-16 season and successfully used in children from 5 years of age

A ratio of 2:3 qualified nurses to HCSWs ensured a steady flow of children without them having to wait too long.

Self-administration

In the first year of the pilots, self-administration of LAIV was tested in Year 6 (aged 10-11 year olds) pupils. Parents were given the option to consent to their children giving their own vaccine following supply by qualified nurse under PGD. Both group and 1:1 explanation and supervision were tested. Children distracting each other was found to be an issue requiring groups to be small, with approximately three children being the maximum the nurses felt was manageable. Self-administration was well accepted by pupils with around 65% choosing to give their own vaccine. The process was slower than nurse administration with an estimate of an additional two minutes per child. Further piloting was carried out in the 2014/15 season and it was generally felt that whilst self-administration was a useful tool it was likely to be

inefficient on a large scale. However, it was felt that there may be some benefit to 'training' a child to self-administer which may engage a child with the programme and potentially speed things up should the programme include teenage children in the future

Mop-up sessions

'Mop-up' or 'catch-up' sessions held in the schools were provided in four areas in the first year of the pilot. These were carried out mostly within the school setting but three of the areas also provided community clinics. The sessions were provided for children who were absent on the day, late returned consents or where parents had changed their minds after positive feedback (from other parents and children) following a school session. These sessions were seen as being more inclusive than a one-off opportunity. However, they were time consuming and resource intensive and significantly increased the burden on schools for a modest increase in uptake.

The value of 'mop up' in healthy children may be limited for two reasons; firstly if the initial uptake of the vaccine is high enough then that child is likely to be protected through the interruption of transmission and secondly because of the resource intensive nature of the 'mop- up'. Most areas did not provide mop-up in the second pilot season but rather provided a few follow-up opportunities in community clinics for children who missed vaccination on the day but whose parents requested it. It is important that unimmunised 'at risk' children are actively encouraged to access immunisation and school providers have to liaise with General Practices to ensure that as many as possible are vaccinated and that second doses are administered where necessary. Mop up sessions and community clinics may also be of value in areas where overall uptake is lower than expected or where schools have refused access. Many providers run community clinics to provide all missed immunisations and are using these during flu season too.

Post vaccination

A couple of areas set up a system to monitor the children for 10-15 minutes post vaccination. This created additional disruption for schools, utilised valuable time and resource and is not necessary under the product licence.

Teams ensured that the premises were left tidy, that any spare vaccine and clinical waste were removed or left securely for collection at an arranged time.

Commissioners should ensure that providers have systems in place for schools or parents to report adverse reactions. These should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) through the yellow card scheme (https://yellowcard.mhra.gov.uk/)

Special schools

Schools for children with special educational needs were included in all the pilot areas. The immunisation time per child was longer and often additional assistance was required from school staff, school nurses or support workers. The first season in particular was challenging as the nasal spray was completely new to the children and teams had to work really hard to

build relationships with the schools, parents and children. Subsequent years were reported as easier. Since nearly all children attending these schools were in at risk groups providers scheduled these schools early in their delivery. Parents with children in 'at risk' categories could choose to have the children immunised at their General Practice if they preferred.

Vaccine supply and distribution

LAIV is scheduled to be available from the end of September but like many flu vaccine products time lines can slip. Hence, to avoid having booked session but no vaccine providers should plan to start the 1st full week of October at the earliest. Provider teams ordered vaccine through ImmForm (https://www.gov.uk/government/collections/immform) generally on a fortnightly basis. The vaccine comes in packs of 10 pre-filled nasal applicators and has a short shelf life of approximately 12-14 weeks from distribution so stock has to be managed carefully to avoid wastage. Most teams used the vaccine storage facilities they already had, one area bought additional fridges due to the size of their cohort and another contracted the management of the vaccine for the programme to the local hospital pharmacy which although expensive was considered to have worked well. It was important that at every delivery venue recipients of the vaccine knew the importance of checking the order and maintaining the cold chain.

At local level vaccine was stored and distributed according to local cold chain maintenance policies. In some areas the healthcare teams picked up their vaccine prior to the sessions, usually based on the number of positive consent forms plus approximately 10% extra to allow for late returned consent forms. Other areas relied on a driver to drop off and pick up supplies at the schools. Drivers were generally considered to be an efficient and cost effective option freeing up the immunisation teams to concentrate on sessions. The drivers dropped the vaccine off in secure cool bags in a safe place pre-arranged with the schools. There was little vaccine wastage at sessions, a few vaccines being wasted due to children moving away at the last moment or dropped applicators. LAIV can be kept at room temperature for up to 12 hours. Any vaccine left after the sessions, which had been kept between 2-8 degrees centigrade was dated and returned to the fridge to be used first at the next session. However, due to the relatively short shelf-life of LAIV, most areas had vaccine left after the expiry date.

Porcine gelatine

LAIV contains hydrolysed gelatine derived from pork as an excipient. Gelatine is commonly used in a range of pharmaceutical products, including many capsules and some vaccines. The gelatine used in LAIV is a highly purified product used to stabilise live viral vaccines.

Public Health England and the Department of Health have indicated (based on the JCVI recommendation) there is no suitable alternative to LAIV for the universal vaccination of healthy individuals. By protecting individual children transmission of influenza can be

interrupted and therefore indirectly protect the whole population – including the elderly, adults and children in clinical risk groups.

Although some sections of the Muslim community consider that the porcine gelatine component has been transformed (conversion of one substance into another) and is therefore purified and permissible (or halal), other sections of the community still consider the product to be forbidden.

Several areas had significant numbers of Muslim children in their schools and additional information on porcine gelatine was produced for to schools and parents.

https://www.gov.uk/government/publications/childrens-flu-vaccination-programme-nasal-flu-vaccine-and-porcine-gelatine

Early indications suggest that vaccine uptake was lower in areas with a high proportion of Muslim children. There is on-going monitoring and assessment of the impact of this reduced uptake and revision of the equality impact assessment each year (insert link if possible.

The Jewish Kashrus has declared that the vaccine is permissible in their community

https://www.gov.uk/government/news/vaccines-and-gelatine-phe-response

The porcine gelatine content may also affect other sectors of the population (for example vegetarians) who are opposed to the consumption of animal products.

Data management

The administrative burden of the programme was greatly underestimated across all the sites. Data collection and sharing of information was a major component of this work. This included compiling accurate cohort lists sorted by school and academic year, collecting process data at the sessions, providing uptake data to commissioners and the national team, entering information from consent forms and sharing details of children vaccinated with GPs and Child Health Information Systems (CHIS). Some areas pre-populated spreadsheets with data from returned consent forms so they could update with the immunisation details at the session and others entered all the data from the consent forms after the session back at their bases.

Depending on the systems used, in some areas, the data only had to be entered once by the immunisation team which then could be accessed by GPs and CHIS teams. In other areas, there was some duplication with data having to be entered by the immunisation team, separately by CHIS teams and also sent by email to GPs for entry onto practice systems by their own staff. Updating clinical records with information about vaccinations given outside of General Practice is a condition of GPs' contracts. Setting up a system to send GPs details of all children vaccinated in a timely way was challenging and a number of sites set up email or fax based systems to inform GPs quickly about at-risk children vaccinated to minimise the risk of children being unnecessarily vaccinated twice. This meant that the rest of the information could be batched and sent less frequently. There was no national requirement to update CHIS records after school based immunisation as local administration resource and system flexibility

varied substantially. However it is good practice and recommended that for completeness the records should be updated where possible.

Children's immunisation records have to be stored until their 25th birthday or 26th if the young person was 17yrs at the conclusion of their treatment

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/200139/Records _Management_-_NHS_Code_of_Practice_Part_2_second_edition.pdf

Arrangements for storage of hard copies or electronic records should be made as per local policies.

National rollout

The pilot areas have been delivering this programme for 3 years now with many refining their delivery each year. Sharing their experiences of what worked and what did not informed the national roll-out. In 2015/16 the national programme was extended to children of age appropriate for school years 1 and 2. Year 1 was defined as five- rising to six-year-olds (i.e. date of birth between 1 September 2009 and on or before 31 August 2010). Year 2 was defined as six- rising to seven-years-olds (i.e. date of birth between 1 September 2008 and on or before 31 August 2009). No new major experiences or issues came to light during the national roll out but delivery to all children aged 5-6 and 6-7 years reinforced many of the lessons learned during piloting.

In 2016/17 children of age appropriate for school Year 3 will be eligible for vaccinaion. Year 3 is defined as seven- rising to eight-year-olds (i.e. date of birth between 1 September 2008 and on or before 31 August 2009) .The intent is that the programme will gradually extend over future years to all primary school aged children.

Once extended to all primary school age children the roll-out will pause to assess the epidemiological data and enable the JCVI to further consider whether extension to senior school age children is necessary.

Acknowledgements

PHE, DH and NHS England wish to thank all the participating pilot teams, schools, parents and children

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