



Department
of Health

NHS
England

Public health functions to be exercised by NHS England

Service specification No.13A

Seasonal influenza immunisation programme for children (2014-15 programme)

November 2013

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Public health functions to be exercised by NHS England

Service specification No.13A

Seasonal influenza immunisation programme for children (2014-15 programme)

Prepared by Immunisation Implementation & Planning, Public Health England

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Service specification No.13A

This is a service specification within Part C of the agreement 'Public health functions to be exercised by NHS England' dated November 2013 (the '2014-15 agreement').

The 2014-15 agreement is made between the Secretary of State for Health and NHS England under section 7A of the National Health Service Act 2006 ('the 2006 Act') as amended by the Health and Social Care Act 2012.

This service specification is to be applied by NHS England in accordance with the 2014-15 agreement. An update to this service specification may take effect as a variation made under section 7A of the 2006 Act. Guidance agreed under paragraph A38 of the 2014-15 agreement may inform the application of the provisions of this service specification.

This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

The 2014-15 agreement including all service specifications within Part C is available at www.gov.uk (search for 'commissioning public health').

1. Purpose of the seasonal influenza immunisation programme for children

1.1. This document relates to the second stage of the extension of the influenza vaccination programme to children aged 2-16 years. Those to be offered immunisation in 2014-15 include:

- children aged 2 to 4 years inclusive (defined as children aged 2, 3 or 4 years but less than 5 years of age on the 1 September 2014). This includes children aged 2-4 years in clinical risk groups who are already covered by the existing programme.
- the continuation of delivery to primary school-aged children in all areas included in the 2013-14 geographical pilots.
- secondary school children (those children in school years 7 to 12), the extent of the roll-out of this part of the programme will be determined by April 2014 as described in Table 4 of the 2014-15 agreement.

1.2. The vaccine will provide protection against the strains of seasonal influenza that the World Health Organization (WHO) specifies as the most likely to cause disease each year. This vaccination programme extends the existing annual routine immunisation programme against influenza to more age groups of children. The purpose of the service specification is to enable NHS England to commission influenza immunisation services of sufficient quantity and quality to significantly lower the number of infections and outbreaks caused by flu viruses. Since the number of infections will be related inversely to vaccine coverage, this means achieving high coverage rates across England as well as within upper tier local government areas and within the context of populations with protected characteristics as defined by the Equality Act 2010.

1.3. This specification forms two distinct parts. Part one (sections 1 and 2) provides a brief overview of the vaccine including the disease it protects against, the context, evidence base, and wider health outcomes.

Part 2 (sections 3, 4 and 5) sets out the arrangements for:

- front-line delivery
- the expected service and quality indicators, and
- the standards associated with the programme,

These underpin national and local commissioning practices and service delivery.

1.4. The existing programme provides a firm platform on which designated areas can develop and innovate to better meet the needs of their local population and work towards improving outcomes. This specification will also promote a consistent and equitable approach to the provision of the commissioning and delivery of the influenza vaccine across England. It is important to note that this programme will change and evolve in the light of emerging best practice and scientific evidence. Guidance is issued annually through the Flu Plan and related 'flu letter'. NHS England and providers will be

required to reflect these changes accordingly in a timely way as directed by the national schedule.

- 1.5. *Immunisation against infectious disease* (known as 'The Green Book'), a UK document, issued by Public Health England provides guidance and the main evidence base for all immunisation programmes. This service specification must be read in conjunction with the electronic version of the Green Book, in particular the influenza chapter which is updated ahead of the influenza immunisation campaign each year based on advice from JCVI the annual seasonal flu letter and any guidance or information issued by DH, PHE or NHS England, and reflected in the commissioning of immunisation programmes. <https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>
<https://www.gov.uk/government/policy-advisory-groups/joint-committee-on-vaccination-and-immunisation>
- 1.6. This service specification should also be read in conjunction with service specification 13, the seasonal flu immunisation programme.
- 1.7. This service specification is not designed to replicate, duplicate or supersede any relevant legislative provisions that may apply e.g. the Health and Social Care Act 2012. The specification will be reviewed and amended in line with any new recommendations or guidance, and in line with reviews of the Section 7A agreement.
- 1.8. Guidance agreed under the 2013-14 agreement informed the application of the provisions of the 2013-14 service specification. Guidance that covered the partial implementation of flu immunisation for pre-school children for a single birth cohort of 2 year olds (i.e. children who are 2 years old, but less than 3 years old on the 1st September 2013) was agreed on 26 June 2013 by the NHS Public Health Steering Group. This guidance was based on new advice from JCVI that reduced the dosage requirements for Fluenz®, the vaccine used for the children's flu programme. This allowed PHE and NHS England to use the vaccine supply to vaccinate 3 year olds, as well as the 2 year olds included in the original specification. DH, PHE and NHS England are grateful to the General Practitioners Committee of the British Medical Association for agreeing a change of contract at so late a date in the process.

2. Population needs

Background

- 2.1. Immunisation is one of the most successful and cost effective public health interventions and a cornerstone of public health. Maintaining high vaccine coverage is essential to prevent the spread of infectious disease, complications and deaths among individuals to protect the population's health. Influenza vaccine is routinely used to protect those most at risk of serious illness or death should they develop influenza. The Joint Committee on Vaccination and Immunisation (JCVI) has recommended the programme should also be extended to all children aged between 2 years and less than 17 years to lower the impact of influenza on children and lower influenza transmission to other children, adults and those in clinical risk groups at any age.
- 2.2. This service specification relates to the second stage of the extension of the influenza vaccination programme to children aged 2-16 years to include:
- children 2 to 4 years years inclusive (defined as children 2, 3 or 4 years of age but less than 5 years of age on the 1 September 2014). This includes children aged 2-4 years in clinical risk groups who are already covered by the existing programme;
 - continuation of delivery to primary school-aged children in all areas included in the 2013/14 geographical pilots
 - the implementation in secondary schools (to those children in years 7 -12) the extent to which this part of the programme will be rolled out will be determined by April 2014 as described in Table 4 of the 2014-15 agreement
- 2.3. Alongside the first phase of implementation to 2 and 3 year olds in 2013-14 were seven geographical pilots that examine a variety of methods for delivering the immunisation programme to primary school aged children. The majority of these pilots focussed on schools-based programmes, looking at a range of staff mixes and provider types. One pilot area looked at delivery through local pharmacies and GPs. The learning from these pilots will be used to inform planning for the programme in 2014-15 and for longer-term preparedness to implement the programme more widely in the coming years.

Influenza

- 2.4. Influenza is an acute viral infection of the respiratory tract. There are three types of influenza virus: A, B and C. Influenza A and influenza B are responsible for most clinical illness.
- 2.5. The disease is characterised by the sudden onset of fever, chills, headache, myalgia and extreme fatigue. Other common symptoms include a dry cough, sore throat and stuffy nose.
- 2.6. The risk of serious illness from influenza is higher amongst children under six months of age, older people and those with underlying health conditions such as respiratory disease, cardiac disease or immunosuppression, and pregnant women.

Influenza vaccine – key details

2.7. The key details are that:

- the genetic make up of the flu virus is unstable and new variations (strains) often emerge
- vaccination is required annually
- the vaccination recommended by JCVI for the children covered by this service specification is a live attenuated intranasal influenza vaccine (Fluenz® marketed by AstraZeneca). This vaccine has a good safety record profile in children aged two years and older and an established history of use in the United States. However, for some children this vaccine is contraindicated or unsuitable. In these cases, a suitable alternative flu vaccine should be offered.
- influenza vaccines provide protection against strains of two influenza A and B virus with the strains in the vaccine specified in recommendations made annually by the World Health Organisation.
- the genetic make up of the flu virus is unstable and new variations (strains) often emerge
- all authorised influenza vaccines need to meet immunogenicity, safety and quality criteria set by the European Medicines Agency (EMA), with the assessment of efficacy based on meeting or exceeding indicated requirements in serological assessments of immunogenicity.
- influenza vaccine is offered to those in the target population as outlined in section 4.7 and detailed in the Green Book influenza chapter.

3. Scope

Aims

- 3.1. The aim of the routine influenza immunisation programme is to protect those who are most at risk of serious illness or death should they develop influenza. This extension of the programme to healthy children between 2 and less than 17 years is to lower the impact of influenza on children and lower influenza transmission to other children, adults and those in clinical risk groups at any age. This service specification relates to the second stage of the extension of the influenza vaccination programme to children aged 2-16 years to include:
- children 2 to 4 years inclusive (defined as children 2, 3 or 4 years of age but less than 5 years of age on the 1 September 2014). This includes children aged 2-4 years in clinical risk groups who are already covered by the existing programme;
 - continuation of delivery to primary school-aged children in all areas included in the 2013/14 geographical pilots;
 - The implementation in secondary schools (to those children in years 7 -12) the extent of the roll out of this part of the programme will be determined by April 2014 as described in Table 4 of the 2014-15 agreement.
- 3.2. Further implementation to cover all the recommended age groups is planned for the coming years.

Objectives

- 3.3. The aim will be achieved by delivering an evidence-based, targeted immunisation programme that:
- identifies the eligible population and ensures effective timely delivery with optimal coverage based on the target population set out in paragraph 4.7
 - is safe, effective, of a high quality and is independently monitored
 - is delivered and supported by suitably trained, competent healthcare professionals who participate in recognised ongoing training and development in line with national standards
 - delivers, manages and stores vaccine in accordance with national guidance
 - is supported by regular and accurate data collection using the appropriate returns.

Direct health outcomes

- 3.4. In the context of health outcomes, the influenza vaccine programme aims to:
- protect the health of specified groups, individuals and the wider population

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- protect those who are most at risk of serious infection or death should they develop influenza
- reduce the transmission of infection, and thereby contribute to the protection of vulnerable individuals who may have suboptimal response to their own immunisation
- achieve high coverage across all groups identified
- minimise adverse physical/psychological/clinical aspects of immunisation (e.g. anxiety, adverse reactions).

Baseline vaccine coverage

3.5. Local services must aspire to 100% of relevant individuals being offered immunisation in accordance with the Green Book and other official DH/PHE/NHS England guidance.

3.6. In proceeding with the phased implementation of the extension of seasonal influenza vaccination to all children aged 2 to less than 17, NHS England in 2014/15 will seek to achieve the highest practicable national level of performance in relation to each [key deliverable shown below:

- i. Vaccination coverage (2 and 3 year olds) via primary care as delivered in 2013/14;
- ii. Vaccination coverage in primary care extended to include 4 year olds;
- iii. Continued implementation of the programme in the 2013-14 pilot sites; and
- iv. Implementation of the programme to secondary schools in England, (for children in years 7 to 12) the extent of the roll out of this part of the programme will be determined by April 2014 as described in Table 4 of the 2014-15 agreement..

3.7. In 2013/14, the extension of the seasonal flu programme to all children commenced with the offering of vaccination to all 2 and 3 year olds through general practice, and the piloting of a range of delivery methods in a range of settings in seven areas. For the second year of implementation, Table 4 of the 2014-15 agreement describes the circumstances in which full coverage in relation to children of secondary school age may not be achieved within one year.

3.8. Therefore, the key aim for this programme is the eventual successful and sustainable delivery to all children aged 2 to less than 17 on an annual basis.

Wider health outcomes

3.9. The national immunisation programme supports the commitment made in the *NHS Constitution* that everyone in England has ‘the right to receive the vaccinations that the Joint Committee on Vaccination and Immunisation (JCVI) recommends that you should receive under an NHS provided national immunisation programme’. This specification, referring to the partial implementation of a single cohort of two year olds will work towards achieving this constitutional aim.

3.10. This right is set out in the *NHS Constitution* that was originally published in 2009, and renewed in 2012. The right is underpinned by law (regulations and directions), the regulations require the Secretary of State for Health to fund and implement any cost-effective recommendation made by JCVI where the Secretary of State has asked JCVI

to look at a vaccine. Where JCVI makes a recommendation that the vaccine should be offered as part of a national immunisation programme, the DH will fund and implement the programme in partnership with NHS England and PHE.

- 3.11. To balance this right, the *NHS Constitution* introduced a new patient responsibility that states 'You should participate in important public health programmes such as vaccination'. This does not mean that vaccination is compulsory. It simply reminds people that being vaccinated is a responsible way to protect their own health, as well as that of their family and community.
- 3.12. The NHS Health and Social Care Act 2012, is wholly consistent with the principles of the *NHS Constitution* and places new legal duties which require NHS England and clinical commissioning groups (CCGs) to actively promote it.
- 3.13. The programme also works towards achieving the WHO *Global immunisation vision and strategy* (2006) which is a ten-year framework aimed at controlling morbidity and mortality from vaccine preventable diseases.

4. Service description / care pathway

Roles

- 4.1. NHS England is responsible for commissioning the local provision of immunisation services and the implementation of new programmes through general practice and all other providers. PHE, in partnership with NHS England, is responsible for the commissioning of pilots to test the delivery mechanisms for the programme in a variety of settings and geographical locations. NHS England is accountable to the Secretary of State for Health for delivery of those services. Other bodies in the new comprehensive health system also have key roles to play and it is vital to ensure strong working relationships.
- 4.2. Supplies of flu vaccine for the routine programme are procured by primary care or pharmacists. The option of central procurement of flu vaccine, with PHE directly procuring all flu vaccine required by primary care and distributing it free of charge to GPs, will be reviewed, in particular in relation to the extension to healthy children. The main vaccine (since it is predominantly one brand of vaccine - Fluenz®) for the extension of the routine influenza immunisation programme for children is being centrally procured, though decisions will need to be made about the supply of inactivated influenza vaccine for those children who are contraindicated for Fluenz®).
- 4.3. Directors of public health based in local authorities play a key role in providing independent scrutiny and challenge and publish reports on the health of the population in their areas, which could include information on local immunisation services and views on how immunisation services might be improved. NHS England should support Directors of Public Health in their role by sharing information as appropriate and according to need, for example vaccine coverage within communities (such as populations with protected characteristics as defined by the Equality Act 2010).

Local service delivery

- 4.4. The delivery of immunisation services at the local level is based on evolving best practice that has been built since vaccinations were first introduced more than a hundred years ago. This section of the document specifies the high-level operational elements of the seasonal influenza immunisation programme for children is based on this best practice NHS England must use to inform local commissioning, contracts and service delivery. There is also scope to enable NHS England and providers to enhance and build on specifications to incorporate national or local service aspirations that may include increasing local innovation in service delivery. However, it is essential, in order to promote a nationally aligned, high-quality programme focusing on improved outcomes, increasing coverage and local take-up that all the following core elements are included in contracts and specifications.
- 4.5. The following elements must be covered:
 - target population
 - vaccine schedule
 - consent

- assessment prior to immunisation
- vaccine administration
- vaccine storage and wastage
- vaccine ordering
- documentation
- reporting requirements
(including adverse events and vaccine preventable diseases)
- staffing and training
- premises and equipment
- patient involvement
- governance
- service improvement
- interdependencies
- local communication strategies.

4.6. Most of these elements are covered in the Green Book, which must be read in conjunction with this service specification

<https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>

Target population

4.7. Providers will be required to make the seasonal influenza vaccine Fluenz® available to:

- children aged 2 to 4 years but less than 5 years on the 1st September 2013, including those in this age range in the flu clinical risk groups, and ensure that alternative vaccines are made available to children who are not able to have Fluenz®.
- all primary school-aged children in areas included in the 2013/14 pilots
- secondary school aged children (in year 7 to 12), the extent to which this part of the programme will be rolled out will be determined by April 2014 as described in Table 4 of the 2014-15 agreement

All providers must ensure they are familiar with the contra-indications of Fluenz® as detailed in the Green Book.

Vaccine schedule

4.8. A locally commissioned service should immunise the target population following the guidance in the supplement to the Green Book.

- Information on scheduling is available in the Green Book *Immunisation against infectious disease 2006*.

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- In order to provide early protection, providers must aim to complete the vaccination as early as possible in the third quarter of the calendar year.
- Providers to ensure that at least four weeks is given between the two doses
- That vaccinations are given in a timely way to reflect the short shelf life of the product.
- Sufficient immunisation appointments must be available so that children can receive vaccinations on time. Vaccinating children as soon as the vaccine is available will provide them with protection should the flu season prove to be early.

Consent

4.9. Chapter 2 in the Green Book provides up-to-date and comprehensive guidance on consent, which relates to both adults and the immunisation of younger children. There is no legal requirement for consent to be in writing but sufficient information must be available to make an informed decision.

4.10. Therefore, providers will be required to ensure that:

- consent is obtained prior to giving any immunisation
- consent is given voluntarily and freely
- individuals giving consent on behalf of infants and young children must be capable of consenting to the immunisation in question
- relevant resources (leaflets / factsheets, etc.) are used as part of the consent process to ensure that all parties (both parents/and where appropriate individuals) have all the available information about the vaccine and the protection it offers. In some cases this may involve the use of a trained interpreter.
- professionals must be sufficiently knowledgeable about the disease and vaccine and to be able to answer any questions with confidence
- the patient has access to the patient information leaflet (PIL)
- for infants and young children not competent to give or withhold consent, such consent can be given by a person with parental responsibility, provided that person is capable of consenting to the immunisation in question and is able to communicate their decision. Although a person may not abdicate or transfer parental responsibility, they may arrange for some or all of it to be met by one or more persons acting on their behalf.

Requirements prior to immunisation

4.11. As part of the commissioning arrangements, NHS England is required to ensure that providers adhere to the following, i.e. that providers have:

- systems in place to assess eligible individuals for suitability by a competent individual prior to each immunisation
- assessed each child to ensure they are suitable for immunisation

- assessed the immunisation record of each child (including vaccinations given as part of the pilots and the partial implementation programme) to ensure that all other vaccinations are up to date
- systems in place to identify, follow-up and offer immunisation to eligible individuals. In some areas, contracts may be in place for Child Health Information Systems (CHIS) to invite children for vaccination
- arrangements in place that enable them to identify and recall under or unimmunised individuals and to ensure that such individuals are immunised in a timely manner
- systems in place to optimise access for those in hard to reach groups (e.g. traveller communities, / looked after children)
- arrangements in place to access specialist clinical advice so that immunisation is only withheld or deferred where a valid contraindication exists.

Vaccine administration

4.12. As part of the commissioning arrangements, NHS England is required to ensure the provider adheres to the following:

- professionals involved in administering the vaccine, have the necessary skills, competencies and annually updated training with regard to vaccine administration and the recognition and initial treatment of anaphylaxis
- regular training and development (taking account of national standards – see section 5) is routinely available. Training is likely to include diseases, vaccines, delivery issues, consent, cold chain, vaccine management and anaphylaxis.
- the professional lead must ensure that all staff are legally able to supply and/or administer the vaccine by:
 - working under an appropriate patient group direction (PGD)
 - working from a patient specific direction (PSD)/prescriptions, or
 - working as a nurse prescriber (if appropriate).

Vaccine storage and wastage

4.13. Effective management of vaccines is essential to ensure patient safety and reduce vaccine wastage. NHS England must ensure that providers will:

- have effective cold chain and administrative protocols that reduce vaccine wastage to a minimum which reflect DH national protocols (Ch 3 of the Green Book and the *Guidelines for maintaining the vaccine cold chain*) and includes:
 - how to maintain accurate records of vaccine stock
 - how to record vaccine fridge temperatures
 - what to do if the temperature falls outside the recommended range
 - to be aware of the short shelf life of various vaccines and to ensure vaccines are given in a timely way.

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- to have appropriate storage available that will accommodate larger packaging.
- <https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3>
- the ImmForm helpsheet <https://www.gov.uk/government/organisations/public-health-england/series/immform>
- ensure all vaccines are delivered to an appointed place
- ensure that at least two named individuals are responsible for the receipt and safe storage of vaccines in each general practice or other appropriate location
- ensure that an approved vaccine fridge is available for the storage of all vaccines
- ensure that approved pharmaceutical grade cold boxes are used for transporting vaccines
- ensure that only minimum stock levels (two to four weeks maximum) of vaccine will be held in local fridges, to reduce the risk of wastage caused by power cuts or inadvertent disconnection of fridges from power supplies
- report any cold chain failures to the local coordinator and PHE Screening and Immunisation Area Team and NHS England.

Vaccine ordering

4.14. Detailed guidance on vaccine ordering for general practitioners and others will be set out in the Annual Flu letter for 2014/15 which will be published in 2014. NHS England should seek assurance that general practitioners are aware of arrangements for vaccine ordering.

Documentation

- 4.15. Accurate recording of all vaccines given and good management of all associated documentation is essential. Providers must ensure that:
- the child's medical records are updated with key information that includes:
 - any contraindications to the vaccine and any alternative offered
 - any refusal of an offer of vaccination
 - details of consent and the person who gave the consent. The batch number, expiry date and the title of the vaccination
 - the date of administration of the vaccine
 - the site and route of administration
 - any adverse reactions to the vaccine
 - name of immuniser.

Recording and reporting requirements

4.16. The collection of data is essential. It has several key purposes including the local delivery of the programme and the monitoring of coverage at a national and local level, and outbreak investigations and response. In-depth analysis of coverage underpins any necessary changes to the programme, which might include the development of targeted programmes or campaigns to improve general coverage of the vaccination

PHE will monitor and publish:

- i. cumulative national flu vaccine uptake by GP registered patients for the following cohorts from the beginning of October to around the end of January via ImmForm through the automatic extraction of data from a large national sample of GP practices (e.g. 50% of practices):
 - i. children aged 2 to 4 years years (defined as children 2, 3 or 4 years of age but less than 5 years of age on the 1 September 2014). This includes children aged 2-4 years in clinical risk groups who are already covered by the existing programme;
 - ii. secondary school children (those children in years 7 to 12 (where vaccinated)
 - iii. primary school-aged children in all areas included in the 2013/14 pilots
- ii. cumulative flu vaccine uptake at the CCG, Area Team and national levels by GP registered patients from the following cohorts from all GP practices on vaccinations up to the end of October, November, December and January via ImmForm though the automatic extraction and manual submissions of data:
 - iv. children 2 to 4 years years (defined as children 2, 3 or 4 years of age but less than 5 years of age on the 1 September 2014). This includes children aged 2-4 years in clinical risk groups who are already covered by the existing programme;
 - v. secondary school children (those children in years 7 to 12 (where vaccinated)
 - vi. primary school-aged children in all areas included in the 2013/14 pilots
- iii. Administration of the vaccine through other delivery mechanisms, such as nurseries, playgroups and schools will also need to be captured and fed back to the child's health records. Arrangements will need to be made to support this effectively.
- iv. Any reported adverse events or reactions post vaccination must follow determined procedures and be reported to the MHRA via the Yellow Card Scheme - NHS England. In addition, teams must keep a local log of reports and discuss such events with the local immunisation co-ordinator. <http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/TheYellowCardScheme>
- v. The provider must report any significant concerns it has in relation to the delivery of services, including reports of serious failings, incidents or major risks to enable NHS England to inform the DH. This is in line with Part A of the Section 7A agreement.

Staffing including training

- 4.17. To deliver a national immunisation programme it is essential that all staff are appropriately trained. NHS England must ensure that providers:

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- have an adequate number of trained, qualified and competent staff to deliver a high quality immunisation programme in line with best practice and national policy
- are covered by appropriate occupational health policies to ensure adequate protection against vaccine preventable diseases (e.g. measles, flu and hepatitis B)
- meet the HPA *National minimum standards in immunisation training 2005* either through training or professional competence ensuring that annual training is offered to all staff
- have had training (and annual updates) with regard to the recognition and initial treatment of anaphylaxis
- ensure that all staff are familiar with and have online access to the latest edition of the Green Book, noting the clinical guidance may change and that the Green Book is frequently updated.
- ensure that all staff are registered to receive *Vaccine Update* which includes notifications of updates to the Green Book. <https://www.gov.uk/government/organisations/public-health-england/series/vaccine-update>
- ensure that all staff are aware of the importance of and can access official letters and information from DH/PH and NHS England i.e. that announce changes to or new programmes.

Premises and equipment

4.18. Appropriate equipment and suitable premises are needed to deliver a successful immunisation programme. NHS England must ensure that providers have:

- suitable premises and equipment provided for the immunisation programme
- disposable equipment meeting approved quality standards
- appropriate waste disposal arrangements in place (e.g. approved sharps bins, etc.)
- appropriate policies and contracts in place for equipment calibration, maintenance and replacement
- anaphylaxis equipment accessible at all times during an immunisation session and all staff must have appropriate training in resuscitation
- premises that are suitable and welcoming for young children, and their carers and all individuals coming for immunisation including those for whom access may be difficult.

Governance

4.19. It will be essential to ensure that there are clear lines of accountability and reporting to assure the ongoing quality and success of the national programme. Commissioning arrangements will ensure that:

- there is a clear line of accountability from local providers to NHS England
- at the provider level there is appropriate internal clinical oversight of the programme's management and a nominated lead for immunisation
- provider governance is overseen by a clinical lead (for example the local immunisation co-ordinator) and immunisation system leader
- there is regular monitoring and audit of the immunisation programme, including the establishment and review of a risk register as a routine part of clinical governance arrangements, in order to assure NHS England of the quality and integrity of the service
- for providers to supply evidence of clinical governance and effectiveness arrangements on request for NHS England or its area offices
- PHE will alert NHS England to any issues that need further investigations
- the provision of high quality, accurate and timely data to relevant parties including PHE, NHS England and local authorities (LAs) is a requirement for payment
- data will be analysed and interpreted by PHE and any issues that arise will be shared quickly with NHS England and others
- local co-ordinators will document, manage and report on programmatic or vaccine administration errors, including serious untoward incidents (SUIs), and escalate as needed. This may include involving NHS England and relevant partners and where appropriate for NHS England to inform DH
- That NHS England press office will liaise closely with DH, PHE, and MHRA press offices regarding the management of all press enquiries
- have a sound governance framework in place covering the following:
 - information governance/records management
 - equality and diversity
 - user involvement, experience and complaints
 - failsafe procedures
 - communications
 - ongoing risk management
 - health and safety
 - insurance and liability.

Service improvement

4.20. NHS England and providers will wish to as a key part of the partial implementation programme and pilots, identify key learning and best practice that will inform the successful implementation of the full programme at a later date. This learning will further support local areas if they identify areas of challenge, which may be directed around increased coverage and accessing hard to reach groups and enable them to develop comprehensive, workable and measurable improvement plans. More general suggestions for improving service and uptake include:

- NICE guidelines (NICE 2009 *Reducing differences in the uptake of vaccines*) highlight evidence to show that there are particular interventions, which can increase immunisation rates.
- Research funded by the Policy Research Programme in the DH has identified seven key strategies that, if widely implemented by general practice, could increase average vaccination rates by 7-8% (*Strategies to increase influenza vaccination rates: outcomes of a nationwide cross sectional survey of general practice*. Dexter LJ, Teare MD, Dexter M et al. May 2012, BMJ Open) <http://bmjopen.bmj.com/content/2/3/e000851.full>

4.21. Providers must also consider the following suggestions:

- up-to-date patient reminder and recall systems, in addition to appropriate systems that allow electronic automated data transfer and reporting.
- well-informed healthcare professionals who can provide accurate and consistent advice
- high-quality patient education and information resources in a variety of formats (leaflets, internet forums and discussion groups)
- effective performance management of the commissioned service to ensure it meets requirements
- local co-ordinators or experts based in PHE to provide expert advice and information for specific clinical queries
- for NHS England and providers to have clear expectations to improve and build upon existing immunisation rates.

Interdependencies

4.22. The immunisation programme is dependent upon systematic relationships between stakeholders, which include vaccine suppliers, primary care providers, NHS England, etc. The immunisation co-ordinator, based in the Area Team of NHS England, will be expected to take the lead in ensuring that inter-organisational systems are in place to maintain the quality and the immunisation pathway. This will include, but is not limited to:

- ensuring all those involved in pathways are sure of their roles and responsibilities
- developing joint audit and monitoring processes
- agreeing joint failsafe mechanisms, where required, to ensure safe and timely

- processes along the whole pathway
- contributing to any initiatives led by NHS England/DH/PHE to develop/improve the childhood immunisation programme
- maintaining an up-to-date population based immunisation register to provide accurate and timely coverage data and for outbreak investigation and response
- maintaining robust electronic links with IT systems and relevant organisations along the pathway
- local feedback and review of coverage and disease surveillance data.

Communication strategies

4.23. It will be important to develop and implement communication strategies to support both the introduction of new vaccines and the maintenance of existing programmes. Such strategies may be developed on a national basis. Local strategies may also be developed to further support national programmes or address specific issues.

5. Service standards and guidance

5.1. To support the delivery of an effective and high quality childhood immunisation programme, NHS England and providers must refer to and make comprehensive use of the following key resources:

- Green Book – Immunisation against infectious disease (DH 2006) <https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>
- *Quality criteria for an effective immunisation programme* (HPA, 2012) <http://www.hpa.org.uk/Publications/InfectiousDiseases/Immunisation/1207Qualitycriteriaforimmprogramme>
- *National minimum standards for immunisation training* (HPA June 2005) <http://www.hpa.org.uk/Publications/InfectiousDiseases/0506NationalMinimumStandardsforImmunisationTraining>
- *Protocol for ordering, storing and handling vaccines* (DH Sept 2010) http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_120010
- National Patient Safety Agency – *Advice on vaccine cold storage* <http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=66112&type=full&servicetype>
- Official immunisation letters (DH) <https://www.gov.uk/government/organisations/public-health-england/series/immunisation#publications>
- ImmForm information <http://immunisation.dh.gov.uk/immform-helplets/>
- British National Formulary <http://www.bnf.org/bnf/index.htm>
- JCVI (Joint Committee on Vaccinations and Immunisations) <http://www.dh.gov.uk/ab/JCVI/index.htm?ssSourceSiteId=en>
- NICE guidance 21 Sept 2009 – *Reducing differences in the uptake of immunisations (including targeted vaccines) among children and young people aged under 19.* <http://www.nice.org.uk/PH21>
- WHO – World Health Organization – *Immunisations* <http://www.who.int/topics/immunization/en/>
- NICE – Shared learning resources <http://www.nice.org.uk/usingguidance/sharedlearningimplementingnicguidance/examplesofimplementation/eximpresults.jsp?o=575>