



Department
of Health

NHS
England

Public health functions to be exercised by NHS England

Service specification No.6

Meningitis C immunisation programme

November 2013

You may re-use the text of this document (not including logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view this licence, visit www.nationalarchives.gov.uk/doc/open-government-licence/

© Crown copyright 2013

Published to gov.uk, in PDF format only.

www.gov.uk/dh

NHS England INFORMATION READER BOX**Directorate**

Medical	Operations	Patients and Information
Nursing	Policy	Commissioning Development
Finance	Human Resources	

Publications Gateway Reference:**00706**

Document Purpose	Resources
Document Name	Public health functions to be exercised by NHS England service specification no 01A: Pertussis for pregnant women
Author	NHS England
Publication Date	11 November 2013
Target Audience	NHS England Regional Directors, NHS England Area Directors
Additional Circulation List	CCG Clinical Leaders, Directors of PH
Description	This specification is part of an agreement made under the section 7A of the National Health Service Act 2006. It sets out requirements for an evidence underpinning a service to be commissioned by NHS England for 2014-15. It may be updated in accordance with this agreement
Cross Reference	
Superseded Docs (if applicable)	
Action Required	N/A
Timing / Deadlines (if applicable)	N/A
Contact Details for further information	Direct Commissioning NHS England 4-8 Maple Street London W1T5HD 0113 8250550
Document Status	This is a controlled document. Whilst this document may be printed, the electronic version posted on the intranet is the controlled copy. Any printed copies of this document are not controlled. As a controlled document, this document should not be saved onto local or network drives but should always be accessed from the intranet

Public health functions to be exercised by NHS England

Service specification No.6

Meningitis C immunisation programme

Prepared by Immunisation Implementation & Planning, Public Health England

Contents

1.	Purpose of MenC immunisation programme (new schedule)	6
2.	Population needs.....	8
	Background	8
	MenC.....	8
	Men C – key details	9
3.	Scope	10
	Aims.....	10
	Objectives.....	10
	Direct health outcomes	10
	Baseline vaccine coverage	10
	Wider health outcomes	10
4.	Service description / care pathway	12
	Roles	12
	Local service delivery	12
	Target population.....	13
	Vaccine schedule	14
	Consent	14
	Requirements prior to immunisation	15
	Vaccine administration.....	16
	Vaccine storage and wastage.....	17
	Vaccine ordering.....	17
	Documentation	18
	Recording and Reporting requirements.....	18
	Staffing including training.....	19
	Premises and equipment.....	20
	Governance	20
	Service improvement.....	21
	Interdependencies	22
	Communication strategies	22
5.	Service standards and guidance	23

Service specification No.6

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 MenC immunisation programme (new schedule)

- 1.1. This document relates to the meningitis C (MenC) vaccine, which protects children from developing meningococcal disease resulting from meningococcal C bacterial infections. This vaccine forms part of the national childhood immunisation programme, which aims to prevent children from developing vaccine preventable childhood diseases that are associated with significant mortality and morbidity. The purpose of the service specification is to enable NHS England to commission MenC immunisation services of sufficient quantity and quality to prevent the infections and outbreaks caused by these organisms. This means achieving high levels of coverage 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.
- 1.2. This specification forms two distinct parts. Part 1 (sections 1 and 2) provides a brief overview of the vaccines including the diseases they protect against, the context, evidence base, and wider health outcomes.
- 1.3. 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.
- 1.4. These arrangements underpin national and local commissioning practices and service delivery.
- 1.5. The existing, highly successful programme provides a firm platform on which local services 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 MenC vaccine across England. It is important to note that this programme can change and evolve in the light of emerging best practice and scientific evidence. NHE England and providers will be required to reflect these changes accordingly in a timely way as directed by the national schedule.
- 1.6. This specification relates to the revised Men C schedule which the Joint Committee on Vaccination and Immunisation (JCVI) have recommended in light of evidence that shows that Men C vaccination protection wanes significantly in infants and younger children. The revised schedule removes a dose at 4 months and introduces a booster which is recommended to be given at the same time as the (Td/IPV) teenage booster vaccination is given. It also recommends a time-limited catch-up programme for several academic cohorts to be given to young people on first entering university. This element of the programme will commence in 2014/15.
- 1.7. *Immunisation against infectious disease* (known as 'the Green Book'), a UK document, issued by Public Health England (PHE) 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, allofficial public health letters, and reflected in the commissioning of immunisation programmes. This specification must

also be read in conjunction with additional evidence, advice and recommendations issued by the JCVI.

<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>

- 1.8. 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 annually and amended in line with any new recommendations or guidance, and in line with reviews of the Section 7A agreement.

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. High immunisation rates are key to preventing the spread of infectious disease, complications and possible early death among individuals and protecting the population's health through both individual and herd immunity. The MenC vaccine is routinely used to protect against infections with serogroup C *Neisseria meningitidis* (meningococcal) infections. This vaccine is given to babies initially at 12 weeks, a booster in the second year of life and a final adolescent booster around school year nine (aged 13-14) . There is also a time limited catch-up programme for young people entering university for the first time. Since the introduction of the MenC vaccine, levels of MenC in the UK are very low (Green Book, Chapter 22).
- 2.2. A number of studies have shown that Men C vaccination wanes significantly in infants and younger children. For those under six years old, only twelve per cent were found to have protective levels four years after vaccination. If children are immunised at age six then around fifty per cent still had protective levels of antibodies in early adolescence. In contrast, those vaccinated from the age of 10 years had antibody levels that were markedly higher and considered to be protective. This protection persists until at least early adulthood and possibly longer. Based on these findings JCVI recommended in 2012:
 - The dose previously given at 16 weeks (four months) to be discontinued.
 - A booster dose is introduced during adolescence (ideally to be given during school age year 9 (age 13-14) at the same time as the Td/IPV.
 - The implementation of a time-limited catch-up programme, for a number of academic cohorts, to be given to young people on first entering university.

MenC

- 2.3. Meningococcal disease results from bacterial infection, the route of transmission is through droplets or respiratory secretions (e.g. coughing and sneezing). There is a marked seasonal variation in meningococcal disease rates, with peak levels in the winter months, usually declining to low levels by late summer. There are at least 13 known serogroups of meningococcal disease. Of these, prior to the introduction of the vaccine, only two – serogroups B and C – were of major importance to the UK.
- 2.4. Meningococcal infection can cause meningitis (inflammation of the membranes surrounding the brain) and septicaemia (blood poisoning). Septicaemia may occur alone or as part of an attack of meningitis. Meningococcal infection is relatively rare affecting 5 in 100,000 people a year in the UK. Approximately one in ten people who develop meningococcal disease will die. The highest risk of meningococcal disease is in the under one-year-old group, with the one to five age group following closely. The next highest risk group is young people aged 15 to 19 years.
- 2.5. Since the introduction of Men C vaccine the number of laboratory confirmed group C cases has fallen by over 90% in those age groups immunised and in other age groups

as a result of herd immunity (Green Book, Chapter 22). In 1998/9 – the year before vaccine was introduced – there were 955 serogroup C cases reported. There are now around 20 cases per year.

Men C – key details

2.6. The key details are that:

- Men C vaccine is given to babies at three months of age, with a booster at 13 months (using combined with Hib-MenC vaccine)
- A booster is introduced during adolescence in school year 10. It is recognised that currently many areas give the Td/IPV vaccine in school year 10. Our intention is that in the future there will be a planned approach to enable areas to move towards giving Td/IPV and MenC vaccines in year 9 to align both the programmes across the country.
- The programme includes the implementation of a time-limited catch-up programme, for several academic cohorts, to be given to young people on first entering university.
- it has a strong evidence base and is highly effective
- Men C vaccine should be offered to anyone under 25 who has not already received the vaccine routinely.

3. Scope

Aims

- 3.1. The aim of the Men C vaccine programme is to protect the population against meningococcal disease resulting from bacterial infection, which includes meningitis and septicaemia.

Objectives

- 3.2. The aim will be achieved by delivering an evidence-based, population-wide 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

- 3.3. In the context of health outcomes, the Men C vaccine programme aims to:
- protect the health of individuals and the wider population
 - reduce the number of preventable infections and their onward transmission
 - achieve high coverage across all groups identified
 - minimise adverse physical/psychological/clinical aspects of immunisation (e.g. anxiety, adverse reactions).

Baseline vaccine coverage

- 3.4. Local services must ensure they maintain and improve current immunisation coverage (with reference to vaccine coverage public health outcomes framework indicators) with the aspiration of 100% of relevant individuals being offered immunisation in concordance with the Green Book and other official DH/PHE guidance.

Wider health outcomes

- 3.5. The national immunisation programme supports the right 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'.

- 3.6. 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.
- 3.7. The programme can be universal like Men C or a targeted programme like hep B, and those who fit the JCVI criteria (for example, HPV criteria include age and gender) will have a right to receive the vaccine. 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 your own health, as well as that of your family and community.
- 3.8. 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.
- 3.9. The Men C vaccination, as part of the childhood immunisation programme, forms a key part of the Healthy Child Programme (HCP). The HCP is an early intervention and prevention public health programme that lies at the heart of universal services for children and families. The HCP offers all families a programme of screening tests, immunisations, developmental reviews, information and guidance to support parenting and healthy choices – all services families need to receive if they are able to achieve their optimal health and wellbeing. NHS England must therefore cross-reference to the provisions of the HCP.
- 3.10. The immunisation programme also works towards achieving the World Health Organization's (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. The NHS England is responsible for the commissioning of local provision of immunisation services and the implementation of new programmes through general practice and all other providers. It 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 are vital in ensuring strong working relationships.
- 4.2. Public Health England (PHE) undertakes the purchase, storage and distribution of vaccines on a national level. It also, together with the Health and Social Care Information Centre (HSCIC) holds surveillance and coverage data and has the public health expertise for analysing the coverage of, and other aspects of, immunisation services. It is also responsible for the implementation of the national immunisation schedule, clinical guidance via the Green Book, including the national communication strategy, setting standards and following recommendations as advised by JCVI and other relevant organisations.
- 4.3. Directors of public health (DsPH) based in local authorities play a key role in providing independent scrutiny and challenge and will 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 expect to support DsPH in their role by sharing information as appropriate and according to need, for example vaccine coverage within communities (such as, among populations with protected characteristics as defined by the Equalities Act).

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 Men C vaccine programme, based on that best practice that 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. 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/policy-advisory-groups/joint-committee-on-vaccination-and-immunisation>).

Target population

- 4.7. Providers will be required to make the Men C vaccine available to:
- all children both registered and unregistered with a GP, as part of the childhood immunisation programme's primary immunisation course. The first dose should be given to children at three months of age, the second dose at the same time as the of the MMR & PCV vaccine at 12/13 months
 - a third adolescent dose ideally at the same time as the Td/IPV booster.
 - both adults under 25 years of age and children, who have no history of MenC, or incomplete immunisation status, as indicated in the Green Book. This will include those in eligible age groups who move into the area, school or are newly registered with general practice after the initial invitations have been issued
 - children from hard to reach groups, for example gypsy traveller children or looked after children who may require special and specific arrangements
 - children and young people, over the age of 12 months and younger than 25 years, moving in from abroad, should have their vaccination status checked to ensure that they have received one dose of Meningitis C containing vaccine
 - As part of a time limited catch-up campaign, those entering university for the first time, who have not been provided with the opportunity to have an adolescent dose, will require a booster.

4.8. In addition:

- any individual who has never received MenC vaccine and is attending university for the first time, irrespective of age, should be immunised before they enrol or as soon as possible thereafter
- arrangements must be in place to ensure that MenC can be administered promptly for contacts of cases or for outbreak control, on the advice of PHE
- local 'catch-up' arrangements must be available to prevent outbreaks in areas with poor uptake
- health professionals must take all opportunities, particularly those contacts during the early years to check vaccination status and remind parents and carers of the importance of immunisations and the need to have them at the appropriate times
- the vaccination status of every child or young person must be checked and missing doses offered as appropriate to ensure that everyone has completed an age-appropriate course
(<http://www.hpa.org.uk/webc/HPAwebFile/HPAwebC/1194947406156>).

Vaccine schedule

4.9. A locally commissioned service should immunise the target population following the proposed vaccination schedule:

First dose	3 months
Second dose	12/13 months as part of Hib-MenC vaccination
Third dose	Adolescent booster (ideally at the same time as the Td/IPV)

- As part of a time limited catch-up campaign, those entering university for the first time, who have not been provided with the opportunity to have an adolescent dose, will require a booster.
- in order to provide early protection, providers must aim to complete the schedule as near as possible to the recommended ages
- further information on scheduling is available in the relevant chapters or *Immunisation against infectious disease 2006*
(<https://www.gov.uk/government/policy-advisory-groups/joint-committee-on-vaccination-and-immunisation>).

Consent

4.10. 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.

- 4.11. 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 young children must be capable of consenting to the immunisation in question
 - for 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
 - Where there is no parental consent it is possible for the provider to administer the vaccine to a Gillick/Fraser¹ competent child.
 - relevant resources (leaflets/factsheets, etc.) in an appropriate format are to be 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, or patient's representative has access to the patient information leaflet (PIL). <https://www.gov.uk/government/policy-advisory-groups/joint-committee-on-vaccination-and-immunisation>

Requirements prior to immunisation

- 4.12. As part of the commissioning arrangements NHS England is required to ensure that the providers adhere to the following. That providers have:
- systems in place to assess eligible individuals for suitability by a competent individual prior to each immunisation
 - assessed each individual to ensure they are suitable for immunisation
 - assessed the immunisation record of each individual to ensure that all 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. For further information on CHIS see service specification 28 in Part C

¹ Gillick v West Norfolk & Wisbech AHA (1986)

- 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. In some areas, the CHIS will supply practices with lists of unimmunised children
- systems in place to actively identify those in clinical risk groups and to optimise access for those in hard to reach groups (e.g. traveller communities, looked after children)
- arrangements in place to inform neighbouring areas when children move into their area
- arrangements in place to access specialist clinical advice so that immunisation is only withheld or deferred where a valid contraindication exists
- practices that do their own scheduling must ensure their systems allow them to fulfil the actions outlined above.

Vaccine administration

4.13. As part of the commissioning arrangements, NHS England is required to ensure that providers adhere 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) is routinely available. Training is likely to include diseases, vaccines, delivery issues, consent, cold chain, vaccine management and anaphylaxis. See section 5 of this document for reference to the PHE training standards
- 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

- 4.14. Effective management of vaccines is essential to reduce vaccine wastage. NHS England must ensure that providers will:
- have effective cold chain and administrative protocols that reduce vaccines wastage to a minimum reflecting DH national protocols (Chapter 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
 - https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/223753/Green_Book_Chapter_3_v3_OW.pdf and the ImmForm helpsheet <https://www.gov.uk/government/organisations/public-health-england/series/immform>
 - ensure that 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/premise
 - 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 co-ordinator, PHE and NHS England.
- 4.15. Vaccine supply will be controlled by the PHE vaccine supply department.

Vaccine ordering

- 4.16. All centrally procured vaccines must be ordered via the online ordering system – ImmForm service.
- 4.17. Vaccines can be ordered by:
- GP practices/hospital pharmacies for delivery to their location
 - appropriate providers (with a wholesale dealers licence) for delivery to their location.
- 4.18. Further information:
- you can register to order vaccine via ImmForm:
 - online: <https://www.immform.dh.gov.uk>
 - via email: Send your request to helpdesk@immform.org.uk
- 4.19. Further help is available:
- <https://www.gov.uk/government/organisations/public-health-england/series/immform>

- ImmForm HelpDesk 0844 376 0040

Documentation

4.20. Accurate recoding of all vaccines given and good management of all associated documentation is essential. Providers should ensure that:

- the patient'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 relationship of 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
- the parent-held record must be updated or the patient must be given an individual record which must include:
 - 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

4.21. 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

- The provider must ensure that information on vaccines administered is documented and that this information is also transferred to the general practice record. In most areas, the CHIS will inform GPs that a patient on their list has been immunised via the current vaccination history printout. The CHIS is a patient administration system that provides a clinical record for individual children, it records the vaccination details of each individual child resident in the local area from birth.
- The provider must ensure that information on the vaccines administered is submitted directly to any relevant population immunisation register, in most areas, the CHIS and is included on the patient's GP held record.
- Following an immunisation session/clinic or individual immunisation, local arrangements must be made for the transfer of data onto the relevant CHIS, and is included on the patient's GP held record. Where possible this should aim to be within two working days.

- Arrangements will also be required to inform neighbouring areas when children resident in their area are immunised outside their local area through the CHIS.
- Any reported adverse incidents, errors or events during or post vaccination must follow determined procedures, in addition teams must keep a local log of reports and discuss such events with the local immunisation co-ordinator.
- Suspected adverse reactions must be reported to the MHRA via the Yellow Card Scheme, including the brand number and batch number in addition to following local and nationally determined procedures, including reporting through the NHS. <http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/TheYellowCardScheme>
- Providers are required to report cases of suspected vaccine preventable diseases to the local PHE centre.
- Any cold chain failures must be documented and reported to the local Immunisation co-ordinator and ImmForm as appropriate.
- 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

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

- 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 and to ensure that annual training is offered to all staff
- have had training (and annual updates) for all staff 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 the Green Book is updated frequently;
- 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 the CMO official public health letters that announce changes to or new programmes, the Director of Immunisation letters, and additional guidance on the (PHE) website.

Premises and equipment

4.23. 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, their carers and all individuals coming for immunisation including those for whom access may be difficult.

Governance

4.24. 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 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 local 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 LAs is a requirement for payment
- data will be analysed and interpreted by PHE and any issues that arise to 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 which 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

- 4.25. NHS England and providers will wish to identify areas of challenge within local vaccination programmes and develop comprehensive, workable and measurable plans for improvement. These may be locally or nationally driven and are likely to be directed around increased coverage and may well be focused on particular hard to reach groups. Suggestions for improving service and uptake:
- 4.26. 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 and reduce inequalities. Providers must also consider the following suggestions:
- up-to-date patient reminder and recall systems (particularly for those being vaccinated in a non- school setting) in addition to appropriate systems that allow electronic and automated data transfer.
 - 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

- 4.27. The immunisation programme is dependent upon systematic relationships between stakeholders, which include vaccine suppliers, primary care providers, NHS England, etc. The NHS England Area and Screening Immunisation Team (SIT) 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 the pathway 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/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
 - clear description of and access to advice on the arrangements for provision of and reimbursement for immunisation services

Communication strategies

- 4.28. 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 further developed to 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/1207/Qualitycriteriaforimmprogramme/>
- *National minimum standards for immunisation training* (HPA June 2005) http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1196942164323
- *Protocol for ordering, storing and handling vaccines* (DH Sept 2010) <https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines>
- 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 <https://www.gov.uk/government/organisations/public-health-england/series/immunisation#publications>
- Immform information <https://www.gov.uk/government/organisations/public-health-england/series/immform>
- British National Formulary <http://www.bnf.org/bnf/index.htm>
- JCVI (Joint Committee on Vaccination and Immunisation) <https://www.gov.uk/government/policy-advisory-groups/joint-committee-on-vaccination-and-immunisation>
- 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>
- Resuscitation Council – *UK guidelines* <http://www.resus.org.uk/pages/guide.htm>
- 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>