



Department  
of Health

**NHS**  
*England*

# Public health functions to be exercised by NHS England

Service specification No.12

Td/IPV (teenage booster) 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/](http://www.nationalarchives.gov.uk/doc/open-government-licence/)

© Crown copyright 2013

Published to gov.uk, in PDF format only.

[www.gov.uk/dh](http://www.gov.uk/dh)

**NHS England INFORMATION READER BOX****Directorate**

|         |                   |                           |
|---------|-------------------|---------------------------|
| Medical | <b>Operations</b> | Patients and Information  |
| Nursing | Policy            | Commissioning Development |
| Finance | Human Resources   |                           |

**Publications Gateway Reference:****00717**

|  |  |
|--|--|
| <b>Document Purpose</b>                        | Resources  |
| <b>Document Name</b>                           | Public health functions to be exercised by NHS England service specification no 12: Td/IPV (teenage booster)   |
| <b>Author</b>                                  | NHS England  |
| <b>Publication Date</b>                        | 11 November 2013   |
| <b>Target Audience</b>                         | NHS England Regional Directors, NHS England Area Directors   |
| <b>Additional Circulation List</b>             | CCG Clinical Leaders, Directors of PH  |
| <b>Description</b>                             | 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 |
| <b>Cross Reference</b>                         |  |
| <b>Superseded Docs</b><br>(if applicable)      | 18355  |
| <b>Action Required</b>                         | N/A  |
| <b>Timing / Deadlines</b><br>(if applicable)   | <b>N/A</b>   |
| <b>Contact Details for further information</b> | Direct Commissioning<br>NHS England<br>4-8 Maple Street<br>London<br>W1T5HD<br>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.12

Td/IPV (teenage booster) immunisation programme

**Prepared by Public Health England**

# Contents

|   |    |
|---|----|
| Contents.....                                     | 4  |
| Service specification No.12.....                  | 6  |
| 1. Purpose of Td/IPV immunisation programme ..... | 7  |
| 2. Population needs .....                         | 9  |
| Background .....                                  | 9  |
| Diphtheria .....                                  | 9  |
| Tetanus.....                                      | 9  |
| Poliomyelitis (polio).....                        | 9  |
| Td/IPV – key details.....                         | 10 |
| 3. Scope.....                                     | 11 |
| Aims.....   | 11 |
| Objectives.....                                   | 11 |
| Direct health outcomes .....                      | 11 |
| Baseline vaccine coverage .....                   | 11 |
| Wider health outcomes .....                       | 12 |
| 4. Service description / care pathway .....       | 13 |
| Roles .....                                       | 13 |
| Local service delivery .....                      | 13 |
| Target population.....                            | 14 |
| Vaccine schedule .....                            | 15 |
| Consent .....                                     | 15 |
| Requirements prior to immunisation .....          | 16 |
| Vaccine administration.....                       | 17 |
| Vaccine storage and wastage.....                  | 17 |
| Vaccine ordering.....                             | 18 |
| Documentation .....                               | 18 |
| Recording and reporting requirements .....        | 19 |
| Staffing including training.....                  | 20 |
| Premises and equipment .....                      | 20 |
| Governance .....                                  | 21 |
| Service improvement.....                          | 22 |
| Interdependencies .....                           | 22 |
| Communication strategies .....                    | 23 |
| 5. Service standards and guidance.....            | 24 |



# Service specification No.12

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](http://www.gov.uk) (search for 'commissioning public health').

# 1. Purpose of Td/IPV immunisation programme

- 1.1. This document relates to the Td/IPV (teenage booster) vaccine that protects individuals from developing diphtheria, tetanus and poliomyelitis (polio). This vaccine is the final dose in the routine national childhood immunisation programme which aims to prevent individuals from catching vaccine preventable diseases that are associated with significant mortality and morbidity. The purpose of the service specification is to enable NHS England to commission Td/IPV immunisation services of sufficient quantity and quality to prevent the infections and outbreaks caused by these organisms. This means 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.
- 1.2. 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. 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, 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 Td/IPV vaccines across England. However, it is important to note that this programme can change and evolve in the light of emerging best practice and scientific evidence. NHS England and providers will be required to reflect these changes accordingly in a timely way as directed by the national schedule.
- 1.6. *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, and any official Public Health Letter 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 Joint Committee on Vaccination and Immunisation (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>

- 1.7. 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.

## 2. Population needs

### Background

- 2.1. Immunisation is one of the most successful and cost effective health protection interventions and is 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 Td/IPV teenage booster vaccine is routinely used to boost immunity against tetanus, diphtheria and polio infections.
- 2.2. Coverage of the teenage Td/IPV booster is not routinely measured, and HPA estimate that coverage is only around 70% based on KC50 returns (HPA). Coverage is reported to be higher when delivered in a school setting – this is probably due to easier access for the teenager and the ease of implementing call and recall systems in the school setting.

### Diphtheria

- 2.3. Diphtheria is a serious disease that usually starts with infection of the upper respiratory tract or the skin. The organism releases diphtheria toxin which can quickly cause cardiac, respiratory and neurological complications. In severe cases, it can be fatal and the case-fatality ratio remains high despite modern treatments. Prior to the 1940s, diphtheria was a common disease in the UK with more than 61,000 cases notified in 1940. The introduction of immunisation in the 1940s resulted in a dramatic fall in incidence and fewer than 30 cases have been reported in the last ten years. Most recently reported cases have been imported from the Indian subcontinent or Africa, where diphtheria remains endemic, emphasising the importance of the vaccination.

### Tetanus

- 2.4. Tetanus is a painful disease that causes muscle spasm and respiratory paralysis. It is caused when tetanus spores that are found in soil and manure get into the body through open cuts or burns. Tetanus affects the nervous system and can be fatal. The vaccine was nationally introduced in 1961 and the disease had almost disappeared in children under the age of 15 by the 1970s. Between 1984 and 2004, there were around 200 reported cases of tetanus, largely in the over 45 population, with the highest incidence in adults over 65. There have also been reported cases of tetanus in injecting drug users. Tetanus can never be eradicated because the spores are commonly present in the environment, including soil. Tetanus is not spread from person to person.

### Poliomyelitis (polio)

- 2.5. Polio is a virus that attacks the nervous system and can lead to permanent paralysis, usually of the lower limbs. If the respiratory muscles are affected then it can be fatal.

Before the polio vaccine was introduced, as many as 8000 cases of polio occurred in the UK in epidemic years (the early 1950s). The last case of natural polio acquired in the UK was in 1984. By 2004, polio remained endemic in only a small number of developing countries. Although the risk of importation to the UK is low vaccination continues to be important.

## Td/IPV – key details

2.6. The key details are that:

- Td/IPV was introduced nationally in 1961
- Td/IPV – the teenage booster, is the final dose of the routine childhood immunisation schedule.
- in total five doses of tetanus, diphtheria and polio are required to provide long-term protection
- it has a strong evidence base, an excellent safety profile and is highly effective
- it is given either in a school (often in year 10, sometimes in year 9) or primary care setting; local areas determine which approach is most appropriate
- due to the lack of reliable data, it is not possible to establish accurate coverage rates, however, it is estimated to be around 70% (HPA)
- continued high vaccine coverage is required in order to provide both individual and herd immunity.

## 3. Scope

### Aims

- 3.1. The aim of the Td/IPV booster vaccination programme is to maintain immunity against tetanus, diphtheria and polio, which are associated with significant mortality and morbidity.

### 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 externally and 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 Td/IPV booster 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 that 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 accordance with the Green Book and other official DH/PHE guidance.

## Wider health outcomes

- 3.5. 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’.
- 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 Department of Health (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 which 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 their own health, as well as that of their family and community.
- 3.8. The Td/IPV booster 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 all 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 of which are services that families need to receive if they are able to achieve their optimal health and wellbeing. NHS England should therefore cross-reference to the provisions of the HCP.
- 3.9. 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.
- 3.10. The 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. The WHO has a strategy to eradicate poliomyelitis globally.

## 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. 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 to ensuring strong working relationships.
- 4.2. Public Health England (PHE) undertakes the purchase, storage and distribution of vaccines at a national level. It together with the HSCIS 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 (LAs) 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 will support DsPH in their role as far as practicable with detailed local information, such as analysis including vaccine coverage amongst their communities (in particular social, geographical, equality and diversity characteristics).

### 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 Td/IPV booster, 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. 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 Td/IPV booster vaccine available to:
- all young people both registered and unregistered with a GP, as the final dose of the childhood immunisation programme
  - adults and children who have no history of Td/IPV, 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
  - there is no upper age limit for vaccination, and those at particular risk may require vaccination, even if above the age of the current national programme. Protection against diphtheria, tetanus and polio should be offered at any age

## Public health functions to be exercised by NHS England

- every appropriate opportunity should be taken to offer immunisation to individuals who have missed the routine schedule
- young people from hard to reach groups, for example gypsy traveller children or looked after young people who may require special and specific arrangements.

### 4.8. In addition:

- arrangements should be put in place to ensure that Td/IPV booster vaccine can be administered promptly as directed by PHE for susceptible contacts of cases or for outbreak control
- local 'catch-up' arrangements should be available to prevent outbreaks in areas with poor uptake
- health professionals must take all opportunities, to check vaccination status and remind parents, carers and young people of the importance of immunisations and the need to have them at the appropriate times
- the vaccination status of every young person must be assessed at every contact and if incomplete or missed then any necessary doses of vaccine should be offered (as outlined in the Green Book).

## Vaccine schedule

### 4.9. A locally commissioned service should immunise the target population following the national vaccination schedule.

- One dose, ideally between ages of 13 and 15 years, in school years 9 or 10. This recognises that currently most areas give the booster in year 10. Further information on scheduling is available in the relevant chapters of the Green Book <https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>
- In order to provide early protection, providers must aim to complete the schedule at near as possible to the recommended ages. Sufficient immunisation appointments must be available so that individuals can receive vaccinations on time – waiting lists are not acceptable.

## Consent

### 4.10. Chapter 2 in the Green Book provides up-to-date and comprehensive guidance on consent, which relates to adults and the immunisation of young people. 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 vaccination
- consent is given voluntarily and freely

- individuals giving consent on behalf of a young person must be capable of consenting to the immunisation in question
- relevant resources (leaflets/factsheets, etc.) should be available in an appropriate format and are used as part of the consent process to ensure that all parties (both parents/and where appropriate young people) have all the available information about the vaccine and the protection it offers. In some cases this may involve the use of 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 relevant patient information leaflet (PIL)
- for young people 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.
- Where there is no parental consent it is possible for the provider to administer the vaccine to a Gillick/Fraser<sup>1</sup> competent child.

## Requirements prior to immunisation

4.12. As part of the commissioning arrangements NHS England is required to ensure that 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 young people 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 actively identify those in clinical risk groups and to optimise access for those in hard to reach groups (e.g. gypsy travellers, looked after children)

---

<sup>1</sup> Gillick v West Norfolk & Wisbech AHA (1986)

## Public health functions to be exercised by NHS England

- arrangements in place to inform neighbouring areas when young people 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.

4.13. Practices that do their own scheduling must ensure their systems allow them to fulfil the actions outlined above.

## Vaccine administration

4.14. As part of the commissioning arrangements, NHS England are required to ensure 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 HPA 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

4.15. 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 which reflect 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  
[http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/documents/digitalasset/dh\\_130276.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_130276.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 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 co-ordinator, PHE and NHS England.

4.16. Vaccine supply will be controlled by the PHE vaccine supply department.

## Vaccine ordering

4.17. All centrally procured vaccines must be ordered via the online ordering system – ImmForm service.

4.18. 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.

4.19. Further information:

- providers can register to order vaccine via ImmForm:
  - online: <https://www.immform.dh.gov.uk>
  - via email: Send your request to [helpdesk@immform.org.uk](mailto:helpdesk@immform.org.uk)

4.20. Further help is available at:

- <https://www.gov.uk/government/organisations/public-health-england/series/immform>
- ImmForm HelpDesk 0844 376 0040.

## Documentation

4.21. Accurate recording of all vaccines given and good management of all associated documentation is essential. Providers must 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 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

## Public health functions to be exercised by NHS England

- any adverse reactions to the vaccine
- name of immuniser.
- the young person should be given an individual record which should 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

4.22. 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. 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 and records the vaccination details of each resident in the local area from birth.
- The provider must ensure that information on vaccines administered is submitted directly to any relevant population immunisation registers, in most areas the CHIS and is included in 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 patient's GP held record. Where possible this should aim to be within two working days.
- For age groups not covered by a population based register, then providers must be able to provide and/or allow access to their systems to determine both the denominator eligible population and the numerator of that eligible population who have received vaccination.
- Arrangements will also be required to inform neighbouring areas when young people resident in their area are immunised outside their local area through the CHIS system.
- Any reported adverse incidents, errors or events during or post vaccination must follow the determined procedures. In addition, teams must keep a log of reports to discuss such events with the local immunisation co-ordinator.
- Suspected adverse reactions must be reported to the MHRA via the Yellow Card Scheme card, including brand and batch number 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 co-ordinator and PHE/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

4.23. 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 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 clinical guidance may change and that the Green Book is updated frequently.
- ensure that all staff are registered to receive *Vaccine Update*  
<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 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

4.24. 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

## Public health functions to be exercised by NHS England

- 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

4.25. 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 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 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

4.26. 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 include NICE guidelines (NICE 2009 *Reducing differences in the uptake of vaccines*) highlights 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 who have not been vaccinated in the school setting) 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

4.27. The immunisation programme is dependent upon systematic relationships between stakeholders, which include vaccine suppliers, primary care providers, NHS England, etc. The NHS England Area Screening and Immunisations 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 pathways are sure of their roles and responsibilities
- developing joint audit and monitoring processes

## Public health functions to be exercised by NHS England

- 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.

## 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/1207Qualitycriteriaforimmprogramme>
- *National minimum standards for immunisation training* (HPA June 2005)  
[http://www.hpa.org.uk/webc/HPAwebFile/HPAweb\\_C/1196942164323](http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1196942164323)
- *Protocol for ordering, storing and handling vaccines* (DH Sept 2010)  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_120010](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-helpsheets/>
- 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>
- 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/sharedlearningimplementingniceguidance/examplesofimplementation/eximpresults.jsp?o=575>