



Department
of Health

NHS
England

Public health functions to be exercised by NHS England

Service specification No.10

Measles, mumps and rubella (MMR)
immunisation programme

November 2013

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NHS England INFORMATION READER BOX**Directorate**

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

Publications Gateway Reference: 00715

Document Purpose	Resources
Document Name	Public health functions to be exercised by NHS England service specification no 10: Measles, mumps and rubella (MMR)
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Superseded Docs (if applicable)	18357
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

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Public health functions to be exercised by NHS England

Service specification No.10

Measles, mumps and rubella (MMR) immunisation programme

Prepared by Public Health England

ContentsContents	4
Service specification No.10.....	5
1. Purpose of measles, mumps and rubella (MMR) immunisation programme.....	6
2. Population needs	8
Background	8
Measles	8
Mumps.....	9
Rubella	9
MMR vaccine – key details	10
3. Scope.....	11
Aims.....	11
Objectives.....	11
Direct health outcomes	11
Baseline vaccine coverage	11
Wider health outcomes	11
4. Service description / care pathway	13
Roles	13
Local service delivery	13
Target population.....	14
Vaccine schedule	15
Consent	16
Requirements prior to immunisation	17
Vaccine administration.....	17
Vaccine storage and wastage.....	18
Vaccine ordering.....	18
Documentation	19
Reporting requirements	19
Staffing including training.....	20
Premises and equipment.....	21
Governance	21
Service improvement	22
Interdependencies	23
Communication strategies	23
5. Service standards and guidance.....	24

Service specification No.10

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 the National Health Service Commissioning Board (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 measles, mumps and rubella (MMR) immunisation programme

- 1.1. This document relates to the MMR vaccine, a combined live attenuated vaccine that protects against measles, mumps and rubella, all highly infectious viral infections. MMR vaccine was introduced as a single dose schedule in 1988 and a two-dose schedule in 1996 with the aim of eliminating measles and rubella (and congenital rubella) from the UK population. The purpose of the service specification is to enable the NHS Commissioning Board ('NHS England') to commission MMR immunisation services of sufficient quantity and quality to prevent the infections and outbreaks caused by these organisms. 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.
- 1.2. 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.

These underpin national and local commissioning practices and service delivery.

- 1.4. The existing, successful 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 for the commissioning and delivery of the MMR vaccination programme across England. It is important to note that this programme can change and evolve in the light of emerging best practice and scientific evidence and changing epidemiology. 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, all 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 (Joint Committee on Vaccination and Immunisation).

<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 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. The MMR vaccine, given as part of the routine childhood vaccination schedule protects against measles, mumps and rubella. Two doses of MMR vaccine are required to provide satisfactory protection against measles, mumps and rubella. This is supported by the low number of cases reported to the HPA during periods of high vaccine coverage. (HPA website) Outbreaks of measles and mumps have continued to occur in recent years reflecting older age groups who missed MMR vaccination as a child.
- 2.2. Figures published by Public Health England (PHE) show high numbers of confirmed cases in England in the first 3 months of 2013, reaching 587 by the end of March, followed by a record annual high of almost 2,000 cases in 2012. Experts believe the rise in measles cases can be mostly attributed to the proportion of unprotected 10-16 year olds who missed out on vaccination in the late 1990's and early 2000s when concern around the discredited link between autism and the vaccine was widespread. Estimates indicate that there are approximately one third of a million 10-16 year olds (around 8%) who are unvaccinated and another third of a million who will at least need 1 further dose of MMR to give them full protection.
- 2.3. In response to this, a national catch-up programme to increase MMR vaccination uptake rates was announced by Public Health England in April 2013. Led by NHS England Teams, working alongside Directors of Public Health in Local Government, supported by PHE Centres – will produce tailored plans to identify and give MMR to unvaccinated and partially vaccinated 10-16 year olds through GPs and/or school programmes. Local intelligence may reveal the need to expand the focus of the catch-up activity beyond the 10-16 age groups and where this is recognised, further local action will be taken.

Measles

- 2.4. A highly infectious viral illness that is characterised by coryza, cough, conjunctivitis and fever. Koplik spots (small bluish white spots on the buccal mucosa) are present about one to three days before the onset of the rash and although characteristic of measles are not found in all cases. After a few days a maculo-papular (red-brown spotty) rash will appear. Measles can be extremely unpleasant and can lead to complications such as meningitis and pneumonia, in rare cases people can die from measles. Statutory reporting of measles began in England and Wales in 1940. Before the introduction of a measles vaccine in 1968, annual notifications varied between 160,000 and 800,000, with peaks every two years, and around 100 deaths from acute measles occurred each year.
- 2.5. Following the introduction of a single dose of MMR vaccine in October 1988 and the achievement of coverage levels in excess of 90% measles transmission was substantially reduced and notifications fell progressively to low levels. The introduction of a second dose of MMR as a pre-school booster dose was included in 1996 to provide a second opportunity for protecting those individuals who did not respond to the first dose of vaccine. Outbreaks of measles and mumps do occur in populations with low vaccine coverage. Current vaccination coverage for MMR in England is 92% (HPA COVER data Jan- Mar 2012)

Mumps

- 2.6. Mumps is a viral infection that causes an acute illness with swelling of the parotid glands. Mumps is spread in the same way as colds and flu, by infected drops of saliva that can be inhaled or picked up from surfaces and passed into the mouth or nose. Serious complications are rare but it can lead to viral meningitis, orchitis and pancreatitis.
- 2.7. Before the introduction of the MMR vaccine, mumps occurred commonly in school-age children. More than 85% of adults had evidence of previous mumps infection. Mumps was the cause of about 1200 hospital admissions each year prior to the introduction of the vaccine and was the commonest cause of viral meningitis. Like measles, since the introduction of the MMR vaccine, there has been a significant fall in the number of reported cases. (Green Book)

Rubella

- 2.8. Rubella (also known as German measles) is a viral infection that was a common childhood infection prior to the introduction of routine immunisation. Rubella is generally a mild infection in children characterised by a maculo-papular rash and lymphadenopathy. Complications can occur and these include thrombocytopenia and rarely, post infectious encephalitis. In adults, rubella infection can (rarely) result in arthralgia.
- 2.9. Although mild in children, rubella infection during pregnancy can have serious consequences for the foetus. Infection in the first eight to ten weeks of pregnancy results in congenital rubella syndrome (CRS) in up to 90% of surviving infants: multiple defects are common. CRS is characterised by a number of features including abnormalities of the heart, growth retardation, vision impairment, sensorineural hearing loss and jaundice. The risk of damage declines to about 10 to 20% when infection occurs between 11 and 16 weeks of gestation (Miller *et al.*, 1982 – cited in Green Book). This is because the rubella virus can disrupt the development of the baby and can cause a wide range of health problems including deafness, heart abnormalities and in some cases brain damage.
- 2.10. Before the introduction of the rubella immunisation, rubella occurred commonly in children, and more than 80% of adults had evidence of previous rubella infection. The two-dose schedule of MMR has been highly successful in achieving elimination of circulating rubella and CRS is now very rare in the UK. There has only been one case recorded since 2007 (Green Book).

MMR vaccine – key details

2.11. The key details are that:

- the MMR vaccine(s) supplied by PHE should be used for this programme
- the MMR vaccine is given as part of the childhood immunisation schedule and the first dose should be given to children between 12 to 13 months of age
- children are given a second dose before they start school at three years and four months of age (or soon after). The second dose can be given sooner when local need dictates. At the time of the teenage booster, the MMR vaccination status should be checked and any missing doses offered where needed to ensure that everyone has received both doses
- between 5 and 10% of children are not fully immune after the first dose. The second dose provides a further opportunity to protect children who did not respond to the first dose of MMR, with less than 1% of children remaining susceptible after receiving the two recommended doses
- There is a national catch-up campaign, via, GPs and School settings, to immunise 10-16 years who have not been immunised or have been partially immunised.
- some adults remain susceptible to one or more of these infections as they may have missed receiving the recommended two doses of MMR vaccine. These individuals should be offered two doses of MMR vaccine at least one month apart
- in the event of a measles outbreak, MMR vaccine can be given to protect susceptible individuals who have been in contact with cases of measles. This is because measles antibodies develop more quickly following vaccination than they do after natural infection. There are no negative effects from vaccinating people who are already immune
- rubella-susceptible women require two doses of MMR one to three months apart. The first dose should be given before the women leave hospital post delivery and the second (or both doses if not given in the maternity unit) should be given by a GP. Vaccine should be purchased by the GP and the cost claimed from the prescription pricing authority. They must not use the vaccine supplied for the childhood immunisation programme.

3. Scope

Aims

- 3.1. The aim of the MMR programme is to protect individuals and the population from measles, mumps and rubella, interrupt the spread of the diseases and reduce the associated morbidity and mortality.

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 MMR vaccination 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 eligible 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 will fund and implement the programme.
- 3.7. The programme can be universal like MMR 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 their own health, as well as that of their family and community.
- 3.8. The NHS 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 MMR 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.
- 3.10. The European Region of the World Health Organization (WHO) has adopted an elimination goal for measles and rubella by 2015. This relies on achieving high coverage (above 95%) of vaccination in all regions and countries.
- 3.11. The programme also works towards achieving the WHO's *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. 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 holds the coverage and surveillance 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, 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 MMR 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. 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 MMR 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 between 12 to 13 months of age and the second dose, before they start school, at three years and four months of age (or soon after). The second dose can be given sooner when local need dictates.
 - adults and children who have no history of MMR vaccination, or incomplete immunisation status, as indicated in the Green Book.
 - as part of a national catch-up campaign, unvaccinated and partially vaccinated 10-16 year olds through the schools/GP programme.
 - rubella-susceptible women.
 - 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. MMR is indicated for unvaccinated and partially vaccinated persons born after 1970, and for healthcare workers and women of childbearing age born before 1970.
 - every appropriate opportunity must be taken to offer immunisation to individuals who have missed the routine schedule.
 - children from hard to reach groups, for example gypsy traveller children or looked after children who may require special and specific arrangements.

4.8. In addition:

- arrangements must be put in place to ensure that the MMR vaccine can be administered promptly as directed by PHE for susceptible contacts of cases or for outbreak control
- local 'catch-up' arrangements must 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 individuals of the importance of immunisations and the need to have them at the appropriate times
- the vaccination status of every individual 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:

- the first dose should be given to children between 12 to 13 months of age
- children are given a second dose before they start school at three years and four months of age (or soon after). The second dose can be given sooner when local need dictates
- rubella-susceptible women: two doses (one to three months apart). First dose delivered immediately post delivery by maternity services (as per the Infectious Disease in Pregnancy Standards)
- the vaccination status of every child or young person should 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>
- there is an opportunity to offer unimmunised/partially immunised individuals MMR vaccine with the school leaver booster (Td/IPV) and this should be considered as routine practice
- there is a national catch-up campaign, to immunise 10-16 year olds who may not have been immunised or who have been partially immunised.
- 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 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 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.
- Where there is no parental consent it is possible for the provider to administer the vaccine to a Gillick/Fraser¹ competent child.

¹ Gillick v West Norfolk & Wisbech AHA (1986)

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 to invite young people for vaccination
 - arrangements in place that enable them to identify and recall under or un-immunised individuals and to ensure that such individuals are immunised in a timely manner
 - systems in place to identify those in clinical risk groups and to optimise access for those in hard to reach groups (e.g. gypsy travellers, looked after children)
 - 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 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 HPA training standards
 - the professional lead must ensure that all staff are legally able to supply and/or administer the vaccine by either:
 - working under an appropriate patient group direction (PGD)
 - working from a patient specific direction (PSD)/prescriptions
 - 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 vaccine 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 of 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_0W.pdf
 - 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, 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 dealer's licence) for delivery to their location.
- 4.19. For 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

4.20. Further help is available at:

- <https://www.gov.uk/government/organisations/public-health-england/series/immform>
- Immform Help Desk 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
 - any adverse reactions to the vaccine
 - name of immuniser.
- the parent/carer or individual should be given a personal 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.

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 national and local level, outbreak investigation and response as well as providing information for ministers and the public. In depth analysis 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 transferred to the general practice record. In most areas, the Child Health Information System (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 vaccines administered is submitted directly to any relevant population immunisation register, in most areas the CHIS.

- Following an immunisation session/clinic or individual immunisation, local arrangements must be made for the transfer of data on to the relevant CHIS. 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 System.
- Vaccine uptake, covering 2-18 year olds, will also be monitored via a monthly automated GP data collection through Immform. This will run in parallel to a CHIS Cover data collection.
- 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 coordinator.
- Suspected adverse reactions must be reported to the MHRA via the Yellow Card Scheme card, 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 coordinator and PHE Screening and Immunisation Team (SIT) and NHS England.
- 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
- ensure that all staff are registered to receive *Vaccine Update* which includes update 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 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
- disposable equipment meeting approved standards
- appropriate waste disposal arrangements in place (eg 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 coordinator) 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 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

- 4.26. 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:
- 4.27. 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
 - 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 coordinators 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

- 4.28. 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 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/PHE to develop/improve the childhood immunisation programme
 - maintaining an up-to-date population based immunisation register to provide 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

- 4.29. 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 diseases* (DH 2006) <https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>
- Details on the MMR catch-up campaign. <https://www.gov.uk/government/organisations/public-health-england/series/mmr-catch-up-programme-2013>
- *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
- *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 (DH) <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/sharedlearningimplementingniceguidance/examplesofimplementation/eximpresults.jsp?o=575>