



Department
of Health

NHS
England

Public health functions to be exercised by NHS England

Service specification No.5

Rotavirus immunisation programme

November 2013

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Public health functions to be exercised by NHS England

Service specification No.5

Rotavirus immunisation programme

Prepared by Immunisation Implementation & Planning, Public Health England

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Service specification No.5

This is a service specification within Part C of the agreement 'Public health functions to be exercised by NHS England' dated October 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 Rotavirus immunisation programme

- 1.1. This document relates to the rotavirus vaccine given to infants to help protect them from developing rotavirus infection. Rotavirus can cause gastroenteritis which may lead to severe diarrhoea, vomiting, stomach cramps, dehydration and mild fever. If unvaccinated, nearly all children would have at least one episode of rotavirus gastroenteritis before reaching five years of age. Rotavirus vaccination was added to the routine childhood schedule in England in July 2013. The vaccine, given orally, is over 85% effective at protecting against severe rotavirus gastroenteritis. An estimated 130,000 children with rotavirus gastroenteritis would have visited their GP and approximately 12,700 of these children would have been hospitalised in England and Wales each year if there was no vaccination programme. The vaccination programme is significantly reducing these numbers. In the UK, deaths caused by rotavirus are extremely rare and difficult to quantify accurately, but in England and Wales there are approximately three to four a year prior to the vaccination programme commencing.
- 1.2. The purpose of the service specification is to enable NHS England to commission a rotavirus immunisation programme of sufficient quantity and quality to prevent the infections caused by rotavirus. 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.
- 1.3. This specification forms two distinct parts. Part 1 (sections 1 and 2) provides a brief overview of the vaccine including the diseases they protect against, the context, evidence base, and wider health outcomes.
- 1.4. 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.
- 1.5. The on going rotavirus immunisation programme was introduced in response to seasonal rotavirus infection in the UK, occurring mostly in winter and early spring (January to March). People of any age can be infected by rotavirus but most infections occur in children between one month and four years of age. This is still a new programme, introduced on the advice of the Joint Committee on Vaccination and Immunisation (JCVI) who have recommended that the health benefit of vaccination means it is a cost effective way of protecting children against rotavirus.
- 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 all official 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 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 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. The rotavirus immunisation programme, which commenced in July 2013 is playing a key role in preventing young infants from developing this highly contagious infection.
- 2.2. Prior to the start of the programme, an estimated 130,000 episodes of rotavirus induced gastroenteritis occurred each year in children of less than five years in England and Wales and approximately 12,700 of these children were hospitalised. Although deaths from rotavirus in the UK are rare and are difficult to quantify accurately, there may have been approximately three to four a year, prior to vaccination. Rotavirus infections in children and adults leads to severe diarrhoea, vomiting, stomach cramps, dehydration and mild fever and is likely to last approximately three to eight days.
- 2.3. In the UK, there are several different circulating strains of rotavirus with the strain G1P[8] the most abundant, although distribution of strains change over time. Rotavirus is highly contagious and transmission by the faecal-oral route is the most frequent route, although respiratory transmission may also occur. Although good hygiene measures can help prevent spread of the disease, the robustness of rotavirus and the low minimal infectious dose of 10 – 100 virus particles, renders rotavirus readily transmissible and makes standard sanitary measures to halt transmission of the virus relatively ineffective.
- 2.4. Rotavirus infection in the UK is seasonal occurring mostly in winter and early spring (January to March). People of any age can be infected by rotavirus but most infections occur in children between one month and four years of age. Infections are often recurrent, and many children experience infection on one or more occasions by three years of age. Symptomatic infections are usually associated with another genotype, although asymptomatic infections can be the result of infection with a strain not previously encountered. Infection in newborns is common but tends to be either mild or asymptomatic because of protection by circulating maternal antibodies. Once someone has had a rotavirus infection they usually develop immunity although it may be short lived.
- 2.5. Public Health England (PHE) is monitoring the levels of rotavirus caused disease with regular updates demonstrating the impact the vaccination has had on the recorded number of cases.

Rotavirus – key details

- 2.6. The key details are that:
 - JCVI has recommended that the health benefit of vaccination means it is a cost effective way of protecting children against rotavirus.

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- Rotarix®, a live attenuated vaccine licensed for use in the UK and administered orally, is being supplied centrally for this programme
- the vaccine is over 85% effective at protecting against severe rotavirus gastroenteritis
- anyone can report a suspected adverse reaction to the Commission on Human Medicines (CHM) using the Yellow Card reporting scheme
<http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/TheYellowCardScheme>
- Rotarix® vaccine should not be given to an infant who is older than 24 weeks of age. A two course dose of the vaccine should be offered at the existing two and three month immunisation appointments.
- Rotarix® can be given at the same time as other vaccines administered as part of the routine childhood immunisation programme such as DTap/IPV/Hib, PCV and Men C.
- vaccine uptake is being monitored with a monthly automated GP data collection through Immform (See para 4.38) Additionally a quarterly COVER data extraction from Child Health Information Systems (CHIS) will be undertaken, possibly by the Health and Social Care Information Centre (HSCIS), for children at one year of age to assess population coverage and reviewed by PHE.

3. Scope

Aims

- 3.1. The aim of the rotavirus vaccination programme is to prevent young infants from developing rotavirus induced gastroenteritis.

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 on going training and development
 - 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 rotavirus vaccination programme aims to:
- provide protection to infants against rotavirus infection.
 - 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 should ensure they establish high 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. Initial coverage rates for rotavirus vaccination should be at least as high as other infant vaccinations such as DTaP/IPV/Hib. A rotavirus vaccination coverage indicator is planned to be added to the panel of sub-indicators as part of the Public Health Outcomes Framework.

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'.

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- 3.6. A rotavirus vaccination coverage indicator is planned to be added to the panel of sub-indicators in the Public Health Outcome Framework indicator on population vaccination coverage.
- 3.7. 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.
- 3.8. The programme can be universal like MenC vaccination, or a targeted programme like hep B vaccination, 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.
- 3.9. 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 rotavirus vaccination also forms part of the childhood immunisation programme – 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 that 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.
- 3.11. The programme also works towards achieving the World Health Organisation'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. 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 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 support DsPH in their role by sharing information as appropriate and according to need, for example vaccine coverage within communities (such as populations with protected characteristics as defined by the 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 rotavirus vaccination 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

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- 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 are required to make the rotavirus vaccine available to:
- Infants aged over six weeks and less than 24 weeks as part of the childhood immunisation programme, noting the restrictions in scheduling described in 4.9.
- 4.8. In addition:
- 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 must be checked at any opportunity and missing doses offered as appropriate to ensure that everyone has completed an age-appropriate course
- http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1194947406156

Vaccine schedule

- 4.9. A locally commissioned service should immunise the target population of infants aged over six weeks and less than 24 weeks:

Schedule for Rotarix®

- First dose of 1.5 ml of Rotarix® vaccine at two months (approximately eight weeks) of age.
- Second dose of 1.5 ml at least four weeks after the first dose.

- A full course of Rotarix® should preferably be completed before 16 weeks of age. Infants older than 15 weeks of age who have not received a first dose of vaccine should not be offered the immunisation, those who have received the first dose before week 15 should complete the course by 24 weeks of age, allowing four weeks between each dose. If the course is interrupted, it should be resumed but not repeated, again allowing at least four weeks between the first and second dose.
 - Rotarix® is given orally – it must not be injected.
- 4.10. Rotarix® can be given at the same time as other vaccines administered as part of the routine childhood immunisation programme such as DTaP/IPV/Hib, PCV and Men C. It can also be given at the same time as BCG vaccination.
- 4.11. If the infant spits out or regurgitates most of the vaccine, a single replacement dose may be given at the same vaccination visit.

Infants aged over six months

- 4.12. Rotarix® vaccine is not licensed for children over 24 weeks of age and should not be given to an infant who is older than 24 weeks.

Vaccination of infants with unknown or incomplete immunisation status

- 4.13. Where an infant in the target cohort aged over six weeks and less than 25 weeks presents with an inadequate vaccination history, every effort must be made to clarify what doses they have had. An infant who has not completed the schedule should complete the vaccination course at the minimum intervals (see above) where possible. Infants coming to the UK from overseas may not have been offered protection against rotavirus in their country of origin and should be offered vaccination where appropriate.

Contraindications

- 4.14. There are very few infants who cannot receive rotavirus vaccine. Where there is doubt, appropriate advice should be sought from an immunisation coordinator or consultant in health protection rather than withholding vaccination.
- 4.15. Rotarix® should not be given to:
- infants with a confirmed anaphylactic reaction to a previous dose of rotavirus vaccine,
 - infants with a confirmed anaphylactic reaction to any components of the vaccine,
 - infants with a previous history of intussusception,
 - infants over 24 weeks of age
 - infants with Severe Combined Immunodeficiency Disorder (SCID).
 - infants who have a malformation of the gastrointestinal tract that could predispose them to intussusception
 - infants with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency

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- 4.16. Administration of rotavirus vaccine should be postponed in infants:
- suffering from acute severe febrile illness
 - suffering from acute diarrhoea or vomiting. This is to make sure that the vaccine is not regurgitated or passed through the intestines too quickly, which could reduce the effectiveness of the vaccine.
- 4.17. Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine.

Premature Infants

- 4.18. It is important that premature infants have their immunisations at the appropriate chronological age, according to the schedule.
- 4.19. The occurrence of apnoea following vaccination is especially increased in infants who were born very prematurely. Very premature infants (born ≤ 28 weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 hours when given their first immunisations, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48-72 hours. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

Immunosuppression and HIV infection

- 4.20. Rotavirus vaccine should not be administered to infants known to have severe combined immunodeficiency disorder (SCID). There is a lack of safety and efficacy data on the administration of rotavirus vaccine to infants with other immuno-suppressive disorders. Administration in these cases should be considered in relation to the risks and benefits of vaccination.
- 4.21. However, in a clinical study, 100 infants with HIV infection were administered Rotarix® lyophilised formulation or placebo. The safety profile was similar between Rotarix® and placebo recipients (Steele et al, 2011). Therefore vaccination is supported in HIV infected infants. Additionally infants with unknown HIV status, but born to HIV positive mothers should be offered vaccination.
- 4.22. There is a potential for transmission of the live attenuated vaccine virus in Rotarix® from the infant to severely immunocompromised contacts through faecal material. Therefore, severely immunocompromised individuals should avoid close contact with infants who have had the rotavirus vaccine for at least 14 days (Anderson, 2008). Additionally, those in close contact with recently vaccinated infants should observe good personal hygiene

Adverse reactions

- 4.23. Anyone can report a suspected adverse reaction to the Commission on Human Medicines (CHM) using the Yellow Card reporting scheme <http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/TheYellowCardScheme>

- 4.24. The most common adverse reactions observed after administration of Rotarix® vaccine administration are diarrhoea and irritability. Other reactions commonly reported are vomiting, abdominal pain, flatulence, skin inflammation, regurgitation of food, fever, loss of appetite and fatigue. A detailed list of adverse reactions associated with Rotarix® is available in the Summary of Product Characteristics for this vaccine, which is available from the European Medicines Agency website: <http://www.ema.europa.eu/ema>
- 4.25. Intussusception is a naturally-occurring condition, with a background annual incidence of around 120 cases per 100,000 children aged under one year (ref:). Research from some countries suggests that Rotarix may be associated with a very small increased risk of intussusception within seven days of vaccination, possibly 2 cases per 100,000 first doses given, and the Rotarix prescribing information includes this as a possible side effect. Even with this small potential risk, the benefits of vaccination in preventing the consequences of rotavirus infection outweigh any possible side effects.
- 4.26. There is no evidence that Rotarix® has a causal association with the development of Kawasaki disease.
- 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 further information on scheduling is available in the relevant chapters or *Immunisation against infectious disease*.
<https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>

Consent

- 4.27. 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.
- 4.28. 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)

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- for infants and young children not competent to give or withhold consent, such consent can be given by a person with parental responsibility, provided that person is capable of consenting to the immunisation in question and is able to communicate their decision. Although a person may not abdicate or transfer parental responsibility, they may arrange for some or all of it to be met by one or more persons acting on their behalf.

Requirements prior to immunisation

- 4.29. 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 child to ensure they are suitable for immunisation
 - assessed the immunisation record of each child 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 optimise access for those in hard to reach groups (e.g. gypsy travellers, looked after children)
 - arrangements in place to access specialist clinical advice so that immunisation is only withheld or deferred where a valid contraindication exists.
- 4.30. Practices that do their own scheduling must ensure their systems allow them to fulfil the actions outlined above.

Vaccine administration

- 4.31. As part of the commissioning arrangements, NHS England is required to ensure the provider adheres to the following:
- professionals involved in administering the vaccine, have the necessary skills, competencies and annually updated training with regard to vaccine administration and the recognition and initial treatment of anaphylaxis
 - regular training and development (taking account of national standards – see section 5) is routinely available. Training is likely to include diseases, vaccines, delivery issues, consent, cold chain, vaccine management and anaphylaxis
 - the professional lead must ensure that all staff are legally able to supply and/or administer the vaccine by:

- working under an appropriate patient group direction (PGD)
- working from a patient specific direction (PSD)/prescription, or
- working as a nurse prescriber (if appropriate).

Vaccine storage and wastage

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

- have effective cold chain and administrative protocols that reduce vaccine wastage to a minimum which reflect DH national protocols (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

See further information

at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_130276.pdf

The ImmForm helpsheet <https://www.gov.uk/government/organisations/public-health-england/series/immform>

- ensure all vaccines are delivered to an appointed location
- 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 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 Screening and Immunisation Area Team and NHS England, and complete an ImmForm stock incident report form online

Vaccine ordering

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

4.34. Vaccines can be ordered by:

- GP practices/hospital pharmacies for delivery to their designated location
- appropriate providers (with a wholesale dealers licence) for delivery to their designated location.

4.35. Further information:

Providers can register to order vaccine online via ImmForm:

- online: <https://www.immform.dh.gov.uk/SignIn.aspx?ReturnUrl=%2f>
- via email: Send your request to helpdesk@immform.org.uk

4.36. Further help is available at:

- <http://immunisation.dh.gov.uk/immform-helpsheets/>
- ImmForm Help Desk 0844 376 0040.

Documentation

4.37. 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 contra- indications 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 held record must be updated or the parent/carer must 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.

Recording and reporting requirements

4.38. 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.

4.39. Monthly automated surveys from GP systems have run from the start of the programme (1st July 2013) so that July data (1/7/13 to 31/7/13 inclusive) was collected in early August 2013. A review will be conducted in March 2015 on continuing the sentinel collection. The automated collection allows the collection of monthly data with minimal or no burden to the NHS and also gives quick and timely uptake figures. This ImmForm data collection will run in parallel to a proposed COVER data collection.

- NHS England needs to ensure Child Health Information Systems (CHIS) are in place to ensure children are called for vaccination and also that vaccinations are recorded.

- 4.40. The provider must ensure that information on the vaccines administered is documented and that this information is 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 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 the patients GP held record. Where possible this should aim to be within two working days.
 - Arrangements are also required to inform neighbouring areas when children 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 determined procedures in addition teams must keep a local log of reports and discuss such events with the local immunisation co-ordinator.
 - Scheme, including the brand number and batch number in addition to following local and nationally determined procedures.
<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 as an incident and reported to the local immunisation coordinator and registered on Immform as appropriate.
 - Suspected adverse reactions must be reported to the MHRA via the Yellow Card co-ordinator and PHE/ImmForm as appropriate.

Staffing including training

- 4.41. 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

Public health functions to be exercised by NHS England

- have had training (and annual updates) with regard to the recognition and initial treatment of anaphylaxis
- ensure that all staff are familiar with and have online access to the latest edition of the Green Book, noting the clinical guidance may change and that the Green Book is 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 official public health letters that announce changes to or new programmes, the Director of Immunisation letters, and additional guidance on the (PHE) website:
<https://www.gov.uk/government/organisations/public-health-england/series/immunisation>

Premises and equipment

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

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

Governance

4.43. It is 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 must 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 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

- 4.44. 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.
- 4.45. 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 in addition to appropriate systems that allow electronic automated data transfer and reporting
 - well-informed healthcare professionals who can provide accurate and consistent advice

Public health functions to be exercised by NHS England

- 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 CB and providers to have clear expectations to improve and build upon existing immunisation rates.

Interdependencies

4.46. 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 Immunisation (SIT) will be expected to take the lead in ensuring that inter-organisational systems are in place to maintain the quality of the immunisation pathway. This will include, but is not limited to:

- ensuring all those involved in pathways have a clear understanding 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.

Communication strategies

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

5. Service standards and guidance

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

- Green Book – *Immunisation against infectious disease* (DH 2006)
<https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>
- *Quality criteria for an effective immunisation programme* (HPA, 2012)
<http://www.hpa.org.uk/Publications/InfectiousDiseases/Immunisation/1207Qualitycriteriaforimmprogramme>
- National minimum standards for immunisation training (HPA June 2005)
http://www.hpa.org.uk/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
- Official immunisation letters (DH)
<https://www.gov.uk/government/organisations/public-health-england/series/immunisation#publications>
- National Patient Safety Agency – *Advice on vaccine cold storage*
<http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=66112&type=full&servicetype>
- 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)
<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>