



Department
of Health



NHS public health functions agreement 2015-16

Core service specification

National immunisation programme

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NHS public health functions agreement 2015-16

Core service specification

National immunisation programme

Prepared by Public Health England

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Core service specification

This is a service specification within Annex C of the 'NHS public health functions agreement 2015-16 (the '2015-16 agreement') published in December 2014.

This service specification is to be applied by NHS England in accordance with the 2015-16 agreement. This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

Where a specification refers to any other published document or standard, it refers to the document or standard as it existed at the date when the 2015-16 agreement was made between the Secretary of State and NHS England Board. Any changes in other published documents or standards may have effect for the purposes of the 2015-16 agreement in accordance with the procedures described in Chapter 3 of the 2015-16 agreement

Service specifications should be downloaded in order to ensure that commissioners and providers refer to the latest document that is in effect.

The 2015-16 agreement including all service specifications within Annex C is available at www.gov.uk (search for 'commissioning public health').

This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply. It must always be read in conjunction with the vaccine specific service specifications <https://www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2015-to-2016> and the online version of the Green

Book: <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

1. Purpose of the national immunisation programme

- 1.1. This document relates to the core elements of the national immunisation programme.
- 1.2. The purpose of the service specification is to enable the NHS Commissioning Board (NHS England) to commission national immunisation services to a standard that will continue to minimise the infections and outbreaks caused by vaccine preventable diseases. The aim is to achieve 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. 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 to protecting the population's health through both individual and herd immunity.
- 1.4. This core specification underpins national and local commissioning practices and service delivery. The providers referenced in the document can be within primary care or community settings. The existing, successful national immunisation 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 national programme across England. However, it is important to note that immunisation schedules 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 and within the financial constraints and processes as set out in Chapter 3 of the S7A agreement and as directed by the national schedule.
- 1.5. [Immunisation against infectious disease](#) (known as 'the Green Book'), issued by Public Health England (PHE) provides guidance and has the latest information on vaccines and immunisation procedures for all the vaccine preventable diseases that may occur in the UK. This service specification must be read in conjunction with the vaccine-specific service specification, the online version of the Green Book and all relevant guidance from PHE, NHS England and the Department of Health. This specification must also be read in conjunction with additional evidence, guidance and literature issued by the [Joint Committee on Vaccination and Immunisation](#) (JCVI).
- 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. Scope

Aims

- 2.1. The overall aim of the national immunisation programme is to protect the population from vaccine preventable diseases and reduce the associated morbidity and mortality.

Objectives

- 2.2. 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
 - is safe, effective, of a high quality and is independently monitored
 - is delivered and supported by suitably trained, competent and qualified clinical and non-clinical staff who participate in recognised ongoing training and development
 - delivers, manages and stores vaccine in accordance with national guidance e.g [Chapter 3](#) of the Green Book.
 - is supported by regular and accurate data collection using the appropriate returns. E.g Cover, Immform which provides information at a local, regional and national level.

Direct health outcomes

- 2.3. In the context of health outcomes the national immunisation 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 in the target cohorts and
 - minimise adverse physical/psychological/clinical aspects of immunisation (e.g. anxiety, adverse reactions).
 - Reduce hospital admissions
 - Reduce the use of antimicrobials.

Baseline vaccine coverage

- 2.4. Local services must aim to offer immunisation to 100% of eligible individuals in accordance with the Green Book and other guidance from PHE, NHS England or the Department of Health (DH).

Wider health outcomes

- 2.5. The national immunisation programme supports the right in the *NHS Constitution* for everyone in England has ‘... to receive the vaccinations that the JCVI recommends that you should receive under an NHS provided national immunisation programme’.
- 2.6. This right is set out in the *NHS Constitution* that was originally published in 2009, and updated most recently in 2013. The right is underpinned by law. This places a statutory duty on the Secretary of State for Health to make arrangements to ensure, so far as is reasonably practicable, that any recommendation from JCVI for a new or changed national immunisation programme is implemented, where the Secretary of State has asked JCVI for a recommendation and cost-effectiveness has been demonstrated. Where JCVI makes a recommendation that the vaccine should be offered as part of a national immunisation programme, DH will fund and PHE, in collaboration with NHS England, will implement the programme as soon as practicably possible and in accordance with the procedures set out in Chapter 3 of the S7A agreement.
- 2.7. To balance this right, the *NHS Constitution* introduced a new responsibility for patients that states ‘You should participate in important public health programmes such as vaccination’. However, this does not mean that vaccination is compulsory.
- 2.8. The 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.
- 2.9. Many vaccinations form 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.
- 2.10. The national 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.

3. Service description / care pathway

Roles

- 3.1. NHS England is responsible for commissioning the local provision of immunisation services and the implementation of new programmes through general practitioners and 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 have key roles to play and are vital in ensuring strong working relationships.
- 3.2. Public Health England (PHE) is responsible for providing expert advice and guidance to commissioners and providers about the national immunisation schedule, including the national communication strategy, setting standards and following recommendations as advised by JCVI and other relevant organisations.
- 3.3. PHE also undertakes the purchase, storage and distribution of most vaccines at a national level. It collates and holds the coverage and surveillance data and has the public health expertise for analysing the coverage of, and other aspects of, immunisation services. Annual vaccine uptake data are published by the Health and Social Care Information Centre (HSCIC): www.hscic.gov.uk/searchcatalogue?q=title%3A%22NHS+Immunisation+Statistics%2C+England%22&area=&size=10&sort=Relevance
- 3.4. The Director of Public Health (DPH), based in local authorities (LAs), would be expected to provide appropriate support and also to advocate within the LA and with key stakeholders to improve access and uptake to immunisation programmes. NHS England, PHE and DPH's need to work together to understand and address poor uptake, for example vaccine coverage within underserved communities, this may include sharing knowledge and information and best practice. For more information see the [national delivery framework](#).

Local service delivery

- 3.5. 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 national 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 local service aspirations that may include increasing local innovation in service delivery. It is essential, in order to promote a nationally aligned, high-quality programme focusing on improved outcomes, increasing coverage and local take-up that all the following core elements are included in contracts and specifications.

3.6. The following elements must be covered:

- target population
- reducing variation across communities and population groups
- vaccine schedule
- consent
- requirements prior to immunisation
- vaccine administration
- vaccine storage and wastage
- vaccine ordering
- documentation
- reporting requirements
(including adverse events, untoward incidents and vaccine preventable diseases where applicable)
- staffing and training
- premises and equipment
- patient involvement
- governance
- service improvement
- disposal of clinical waste
- interdependencies
- local communication strategies.

3.7. Most of these elements are covered in the [Green Book](#), which must be read in conjunction with this service specification.

3.8. Every appropriate opportunity should be taken to check vaccination status and offer immunisation to individuals who may have missed or not fully completed the national routine schedule. If the status of that person is incomplete then any necessary doses of vaccine should be offered as outlined in the Green Book. Timely vaccination for each individual is important to ensure the best protection.

Consent

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

Requirements prior to immunisation

- 3.10. As part of the commissioning arrangements, NHS England is required to ensure that providers have:
- systems in place to assess eligible individuals for suitability by a competent individual prior to each 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 offered immunisation in a timely manner
 - systems in place to identify those in clinical risk groups and to optimise access for those in underserved groups (e.g. travellers and looked after children)
 - arrangements in place to access specialist clinical advice so that immunisation is only withheld or deferred where a valid contraindication exists.
 - address poor uptake for the services set out in the S7A agreement, where local delivery is lower than the key deliverables set out in the S7A agreement and in accordance with the objective to reduce the variation in local levels of performance.
 - Arrangements in place to report and co-ordinate responses to outbreaks of diseases, for the immunisation programme set out in the S7A agreement. Where serious outbreaks or incidents occur providers will be expected to work with key partners, including NHS England and PHE to support the assessment of risk and consider the case of new provision or changes to existing provision as set out in the [*Immunisation and Screening National Delivery Framework and Local Operating Model*](#).
 - health professionals must take all opportunities, particularly those contacts during the early years and during the pre-school and teenage booster visits, to check vaccination status and remind parents and carers of the importance of immunisations and the need to have them at the appropriate times. Every contact should be used to promote immunisation, as set out in the [*Healthy Child Programme*](#). Any missing doses should be offered as appropriate to ensure that everyone has completed an age-appropriate course. The link below provides guidance on the vaccination of individuals with uncertain or incomplete immunisation status:
<https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status>

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

Vaccine administration

- 3.12. As part of the commissioning arrangements, NHS England is required to ensure that 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. The provider has a duty to ensure it has, or will have, trained and competent staff to deliver (any) given immunisation programme they agree a contract for.
 - regular training and development (taking account of national standards) should be routinely available. Training is likely to include diseases, vaccines, delivery issues, consent, cold chain, vaccine management and anaphylaxis. See section 4 of this document for reference to training standards
 - the professional lead in the provider organisation 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 an appropriate prescriber.

Vaccine storage and wastage

- 3.13. Effective management of vaccines is essential to ensure patient safety and reduce vaccine wastage. NHS England must ensure that providers will:
- have effective cold chain and administrative protocols that reduce vaccine wastage to a minimum and reflect 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
 - how to reset fridge thermometers
 - what to do if the temperature falls outside the recommended range
 - See further information:
 - www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digital_asset/dh_130276.pdf
 - The ImmForm helpsheet <https://www.gov.uk/government/collections/immform>

Vaccine ordering

- 3.14. All centrally procured vaccines must be ordered via the ImmForm online ordering system. You can register to order vaccine via ImmForm:
- online: <https://www.immform.dh.gov.uk/SignIn.aspx?ReturnUrl=%2f>
 - via email: Send your request to helpdesk@immform.org.uk
- 3.15. Further help is available at:
- <https://www.gov.uk/government/organisations/public-health-england/series/immform>
 - ImmForm Helpdesk 0844 376 0040.
- 3.16. Where organisations are required to purchase vaccines advice should be sought from the relevant chapter of the Green Book, and ordered directly from manufacturers.

Documentation

- 3.17. Accurate recording of all vaccines given and good management of all associated documentation is essential. Providers must ensure that:
- the patient's medical records and Child Health Information Systems (CHIS) 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, product name and expiry date
 - the date of administration of the vaccine
 - the site and route of administration
 - any adverse reactions to the vaccine
 - name of immuniser.
- 3.18. Where the parent held child record is available it should be updated in line with the requirements for the red book.

Reporting requirements

- 3.19. 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 to 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. Exceptions to these reporting requirements are set out in individual service specifications and providers must check the detail within service specifications for those requirements.

- The provider must ensure that information on vaccines administered is documented and that this information is transferred to the general practice record.
- 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 onto 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.
- Any reported adverse incidents, errors or events during or post vaccination must follow determined procedures.
- Practices are encouraged to report incidents on the National Reporting and Learning System (NRLS) and to the Area Team.
- 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.
- Providers are required to report cases of suspected vaccine preventable notifiable diseases to the local PHE centre.
- Any cold chain failures must be documented and reported to the screening and immunisation team and PHE and registered on ImmForm as appropriate.
- The provider must to 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.

Staffing including training

3.20. The provider has a duty to ensure that it has, or will have, trained and competent staff to delivery (any) given immunisation programmes which they contract for. 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 (eg measles, flu and hepatitis B)
- meet the [National minimum standards in immunisation training](#) 2005 either through training or professional competence ensuring that annual update trainings 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
- encourage all staff to register to receive [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 any new programmes and additional guidance on the (PHE) website.

Premises and equipment

3.21. 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 (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

3.22. 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 require that:

- there is a clear line of accountability from local providers to NHS England
- clear incident reporting mechanisms are in place so that any learning can be shared
- providers should be able to demonstrate that there is appropriate internal clinical oversight of the programme's management and must have a nominated lead for immunisation
- evidence of provider governance should be available, if requested, to a clinical lead (for example a member of the screening and immunisation team) and immunisation system leader
- there is regular monitoring and audit of the immunisation programme, including the establishment and review of a risk register by the provider 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 investigation
- the provision of high quality, accurate and timely data to relevant parties including PHE and NHS England 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
- screening and immunisation teams 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
- NHS England press office will liaise closely with DH, PHE and MHRA press offices on the management of press enquiries as necessary.

Service improvement

- 3.23. 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 underserved groups.
- 3.24. NICE guidelines ([Reducing differences in the uptake of vaccines](#)) highlight evidence to show that there are particular interventions, which can increase immunisation rates and reduce inequalities. Providers must also consider the following suggestions:
- up-to-date patient reminder and recall systems
 - 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
 - check the Green Book for specific clinical queries or where appropriate refer to local screening and immunisation team or experts based in the national PHE team
 - for NHS England and providers to have clear expectations to improve and build upon existing immunisation rates.

Interdependencies

- 3.25. The immunisation programme is dependent upon systematic relationships between stakeholders, which include vaccine suppliers, primary care providers, NHS England, etc. The PHE Screening and Immunisation team (SIT) that is embedded within the NHS Area Team is 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 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
 - working with providers to ensure robust electronic links with IT systems and relevant organisations along the pathway are maintained
 - 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

- 3.26. 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.

4. Service standards and guidance

4.1. 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* (Health Protection Agency (HPA), 2012) <http://legacytools.hpa.org.uk/Publications/InfectiousDiseases/Immunisation/1207Qualitycriteriaforimmprogramme/>
- *National minimum standards for immunisation training* (HPA June 2005) <https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards>
- *Protocol for ordering, storing and handling vaccines* (DH Sept 2010) www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_120010
- National Patient Safety Agency – *Advice on vaccine cold storage* (January 2010) 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 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. www.nice.org.uk/PH21
- Resuscitation Council – *UK guidelines* www.resus.org.uk/pages/guide.htm
- World Health Organization – *Immunisations* www.who.int/topics/immunization/en/
- NICE – Shared learning resources www.nice.org.uk/usingguidance/sharedlearningimplementingniceguidance/examplesofimplementation/eximpresults.jsp?o=575