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of Health

NHS
England

Public health functions to be exercised by NHS England

Service specification No.14

Shingles immunisation programme

November 2013

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Public health functions to be exercised by NHS England

Service specification No.14

Shingles immunisation programme

Prepared by Public Health England

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Service specification No.14

This is a service specification within Part C of the agreement 'Public health functions to be exercised by NHS England' dated November 2013 (the '2014-15 agreement').

The 2014-15 agreement is made between the Secretary of State for Health and NHS England under section 7A of the National Health Service Act 2006 ('the 2006 Act') as amended by the Health and Social Care Act 2012.

This service specification is to be applied by NHS England in accordance with the 2014-15 agreement. An update to this service specification may take effect as a variation made under section 7A of the 2006 Act. Guidance agreed under paragraph A38 of the 2014-15 agreement may inform the application of the provisions of this service specification.

This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

The 2014-15 agreement including all service specifications within Part C is available at www.gov.uk (search for 'commissioning public health').

1. Purpose of the shingles (herpes zoster) immunisation programme

- 1.1. This document relates to the shingles (herpes zoster) vaccine which helps to reduce the number of shingles cases and associated sequelae. The Joint Committee on Vaccination and Immunisation (JCVI) advised that a universal shingles programme should be implemented for people aged 70 years and up to 79 years inclusive. The purpose of this service specification is to enable NHS England to commission shingles vaccine immunisation services of sufficient quantity and quality. This means achieving timely vaccination with high coverage rates in this group in appropriate settings across England as well as within upper tier local government areas. This programme requires evaluation and monitoring 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 programme provides a 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 shingles vaccine across England. It is important to note that this programme can change and evolve in the light of emerging best practice and scientific evidence. 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 (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 JCVI (Joint Committee on Vaccination and Immunisation). Best practice guidance was also issued by Department of Health (DH) in 2012 and is an important reference tool to support the delivery of high quality and robust shingles vaccination services.

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

2. Population needs

Background

- 2.1. Immunisation is one of the most successful and cost effective public health interventions and a cornerstone of public health. High immunisation rates are key to preventing the spread of infectious disease, complications and possible early death among individuals and protecting the population's health through both individual and herd immunity. The shingles vaccine will help to reduce the number of cases of shingles and its associated sequelae including post herpetic neuralgia (PHN). PHN can last up to six months or in some cases years and in the most severe cases is only partially treatable with expensive painkillers. About a quarter of adults will get shingles at some point in their life and in some severe cases people may die from complications arising from shingles.

Shingles

- 2.2. Shingles is caused by the reactivation of the chicken pox virus in a person previously infected with chicken pox. It is not known what causes the virus to reactivate but this is usually associated with conditions that can depress the immune system such as immunosuppressive therapy, HIV infection and old age. Shingles incidence is highest in older people as the incidence of shingles increases with age. In the UK this is estimated to be around 790 to 880 cases per 100,000 people per year for people aged 70 -79.
- 2.3. It is not possible to catch shingles from somebody who has shingles. However an individual who has not previously been infected with chicken pox can catch it from someone with shingles. It is advised for people with shingles to stay away from pregnant women (especially if they have not had chickenpox), babies younger than one year and people with a weakened immune system.
- 2.4. The first sign of shingles is usually pain in the area of the affected nerve – most commonly in the chest. A rash of vesicles (fluid filled blisters) then appears, typically on one side of the body. The affected area is often intensely painful, with tickling, pricking or numbness of the skin, becoming more serious with advancing age.
- 2.5. JCVI reviewed medical, epidemiological and economic evidence as well as vaccine safety and efficacy data relevant to the shingles programme and advised that it would be cost effective to vaccinate people 70 years and older.

Shingles – key details

2.6. The key details are that:

- an estimated 30,000 cases of shingles occurs in older people aged 70-79 in England and Wales each year.
- JCVI recommended that it would be most cost effective to vaccinate those aged 70 years with a catch up programme for those aged up to and including 79 years.
- There is only one vaccine in Europe Zostavax®, marketed by Sanofi Pasteur MSD that is licensed for the prevention of shingles. The vaccine contains a live strain of the virus, and is supplied in a pre-filled syringe and is licensed in use in adults aged 50 years and over.
- Adults should receive a single dose.
- One dose of Zostavax reduced the incidence of shingles by 38% in a group of 17,775 people aged 70 years and older. In the vaccinees that developed shingles, the vaccine significantly reduced the burden of illness by 55%.

3. Scope

Aims

- 3.1. The aim of the shingles vaccine programme is to reduce the number of shingles cases in this age group and its associated sequelae.

Objectives

- 3.2. The aim will be achieved by delivering a targeted evidence-based immunisation programme that:
- identifies the eligible population and ensures effective and 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 health-care 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 shingles vaccine programme aims to:
- reduce the number of cases of shingles and associated sequelae.
 - achieve on time vaccination and high coverage across all groups identified
 - minimise adverse physical/psychological/clinical aspects of immunisation (e.g. anxiety, adverse reactions).

Vaccine coverage

- 3.4. Local services must aim for 100% of the eligible group being offered immunisation in accordance with the Green Book and other official DH/PHE and NHS England 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* 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 Men C or a targeted programme like hep B, and those who fit the JCVI criteria (for example, HPV criteria include age and gender) will have a right to receive the vaccine. To balance this right, the *NHS Constitution* introduced a new patient responsibility that states 'You should participate in important public health programmes such as vaccination'. This does not mean that vaccination is compulsory. It simply reminds people that being vaccinated is a responsible way to protect their own health, as well as that of their family and community.
- 3.8. The NHS Health and Social Care Act 2012, is wholly consistent with the principles of the *NHS Constitution* and places new legal duties which require NHS England and clinical commissioning groups (CCGs) to actively promote it.
- 3.9. The immunisation programme also works towards achieving the World Health Organization's (WHO) *Global immunisation vision and strategy* (2006) which is a ten-year framework aimed at controlling morbidity and mortality from vaccine preventable diseases.

4. Service description / care pathway

Roles

- 4.1. NHS England is responsible for the commissioning of local provision of immunisation services and the implementation of new programmes through general practice and all other providers. It is accountable to the Secretary of State for Health for delivery of those services. Other bodies in the new comprehensive health system also have key roles to play and are vital in ensuring strong working relationships.
- 4.2. Public Health England (PHE) undertakes the purchase, storage and distribution of vaccines on a national level. It together with the HSCIS also 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 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 Directors of Public Health 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 shingles vaccine programme, which can be delivered in a variety of health care settings, based on that best practice that NHS England must use to inform local commissioning, contracts and service delivery. There is also scope to enable NHS England and providers to enhance and build on specifications to incorporate national or local service aspirations that may include increasing local innovation in service delivery. It is essential, in order to promote a nationally aligned, high-quality programme focusing on improved outcomes, increasing coverage and local take-up that all the following core elements are included in contracts and specifications.
- 4.5. The following elements must be covered:
 - target population
 - vaccine schedule
 - consent
 - assessment prior to immunisation
 - vaccine administration
 - vaccine storage and wastage

- vaccine ordering
 - documentation
 - reporting requirements
(including adverse events and vaccine preventable diseases)
 - staffing and training
 - premises and equipment
 - patient involvement
 - governance
 - service improvement
 - interdependencies
 - local communication strategies.
- 4.6. Most of these elements are covered in the Green Book, which must be read in conjunction with this service specification (<https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book> **Target population**).
- 4.7. Providers will be required to make the shingles vaccine available to:
- people aged 70 years on the 1st September 2014.
 - catch-up cohort for those aged 79 and 78 on the 1st September 2014.
- .

Vaccine schedule

- 4.8. A single 0.65ml dose of Zostavax® should be administered.

Consent

- 4.9. 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.
- 4.10. Therefore providers will be required to ensure that:
- consent is obtained prior to giving any immunisation
 - consent is given voluntarily and freely
 - relevant resources (leaflets/factsheets, etc.) in an appropriate format are used as part of the consent process to ensure that all 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).

Requirements prior to immunisation

4.11. As part of the commissioning arrangements NHS England are required to ensure that the providers adhere to the following. That providers have:

- systems in place to assess eligible individuals for suitability by a competent individual prior to each immunisation
- systems in place to identify and offer the shingles vaccine to the appropriate group.
- arrangements in place that enable them to identify and recall unimmunised individuals and to ensure that such individuals are immunised in a timely manner
- arrangements in place to access specialist clinical advice so that immunisation is only withheld or deferred where a valid contraindication exists.

Vaccine administration

4.12. 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 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

4.13. 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 reflecting DH national protocols
- (Chapter 3 of the Green Book and the *Guidelines for maintaining the vaccine cold chain*) and includes:
 - how to maintain accurate records of vaccine stock
 - how to record vaccine fridge temperatures

- what to do if the temperature falls outside the recommended range http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_130276.pdf
- Immform information <https://www.gov.uk/government/organisations/public-health-england/series/immform>
- ensure that all vaccines are delivered to an appointed place
- ensure that at least two named individuals are responsible for the receipt and safe storage of vaccines in each general practice/premise
- ensure that approved pharmaceutical grade cold boxes are used for transporting vaccines.
- report any cold chain failures to the local coordinator and PHE and NHS England.

Vaccine ordering

- 4.14. All centrally procured vaccines must be ordered via the online ordering system – the ImmForm service.
- 4.15. 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.
- 4.16. Further information
- Qualified 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
- 4.17. Further help is available at:
- <https://www.gov.uk/government/organisations/public-health-england/series/immform>

Documentation

- 4.18. 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 relationship of the person who gave the consent
 - the batch number, expiry date and the title of the vaccination
 - the date of administration of the vaccine
 - the site and route of administration
 - any adverse reactions to the vaccine
 - name of immuniser.

Recording and reporting requirements

- 4.19. The collection of data is essential. It has several key purposes including the local delivery of the programme and the monitoring of coverage at 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.
- Providers must be able to provide and/or allow access to their systems to determine BOTH the denominator eligible population AND the numerator of that eligible population who have received vaccination.
 - The provider must ensure that information on vaccines administered is submitted directly to any relevant population immunisation register, and is included on the patient's GP held record.
 - 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 co-ordinators, and the PHE Screening and Immunisation Team and ImmForm as appropriate.

Staffing including training

- 4.20. To deliver a national immunisation programme it is essential that all staff are appropriately trained NHS England must ensure that providers:
- have an adequate number of trained, qualified and competent staff to deliver a high quality immunisation programme in line with best practice and national policy
 - are covered by appropriate occupational health policies to ensure adequate protection against vaccine preventable diseases (e.g. measles, flu and hepatitis B)
 - meet the HPA *National minimum standards in immunisation training 2005* either through training or professional competence and to ensure that annual training is offered to all staff
 - have had training (and annual updates) for all staff with regard to the recognition and initial treatment of anaphylaxis

- ensure that all staff are familiar with and have online access to the latest edition of the Green Book, noting the clinical guidance may change and 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 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

4.21. 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 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 all individuals coming for immunisation including those for whom access may be difficult.

Governance

4.22. 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 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 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 to be shared quickly with NHS England and others
- local co-ordinators will document, manage and report on programmatic or vaccine administration errors, including serious untoward incidents (SUIs), and escalate as needed which may include involving NHS England and relevant partners and where appropriate for NHS England to inform DH.
- That NHS England press office will liaise closely with DH, PHE, and MHRA press offices regarding the management of all press enquiries.
- have a sound governance framework in place covering the following:
 - information governance/records management
 - equality and diversity
 - user involvement, experience and complaints
 - failsafe procedures
 - communications
 - ongoing risk management
 - health and safety
 - insurance and liability.

Service improvement

- 4.23. 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 hard to reach groups. Suggestions for improving service and uptake include NICE guidance (see paragraph 4.24).
- 4.24. NICE guidelines (NICE 2009 *Reducing differences in the uptake of vaccines*) highlight evidence to show that there are particular interventions, which can increase immunisation rates and reduce inequalities. Providers must also consider the following suggestions:
- up-to-date patient reminder and recall systems in addition to appropriate systems that allow electronic automated data transfer and reporting.
 - well-informed health-care professionals who can provide accurate and consistent advice
 - high quality patient education and information resources in a variety of formats (leaflets, internet forums and discussion groups)

- effective performance management of the commissioned service to ensure it meets requirements
- local co-ordinators or experts based in PHE to provide expert advice and information for specific clinical queries
- For NHS England and providers to have clear expectations to improve and build upon existing immunisation rates.

Interdependencies

4.25. The immunisation programme is dependent upon systematic relationships between stakeholders, which include vaccine suppliers, primary care providers NHS England as well as secondary care settings. The NHS England Area Screening and Immunisation Team (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 the pathway are sure of their roles and responsibilities
- developing joint audit and monitoring processes
- agreeing joint failsafe mechanisms, where required, to ensure safe and timely processes along the whole pathway
- contributing to any initiatives led by NHS England/PHE to develop/improve immunisation programmes
- maintaining an up-to-date population based immunisation register to provide accurate and timely coverage data and for outbreak investigation and response
- maintaining robust electronic links with IT systems and relevant organisations along the pathway
- local feedback and review of coverage and disease surveillance data
- clear description of and access to advice on the arrangements for provision of and reimbursement for immunisation services.

Communication strategies

4.26. 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 further developed to support national programmes or address specific issues.

5. Service standards and guidance

5.1. To support the delivery of an effective and high quality 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/Publications/InfectiousDiseases/0506NationalMinimumStandardsforImmunisationTraining>
- *Protocol for ordering, storing and handling vaccines* (DH Sept 2010) http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_120010
- National Patient Safety Agency – *Advice on vaccine cold storage* <http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=66112&type=full&servicetype>
- Official immunisation letters (DH) <https://www.gov.uk/government/organisations/public-health-england/series/immunisation#publications>
- Immform information <http://immunisation.dh.gov.uk/immform-helplets/>
- 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>
- 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>