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NHS public health functions agreement 2014-15

Service specification no.11

Human papillomavirus (HPV) programme

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Human papillomavirus (HPV) programme

Prepared by Public Health England

Contents

Contents.....	Error! Bookmark not defined.
Service specification No.11	Error! Bookmark not defined.
1. Purpose of the HPV immunisation programme	6
2. Population needs.....	8
Background	8
The HPV immunisation programme – key details.....	9
3. Scope	10
Aims.....	10
Objectives.....	10
Direct health outcomes	10
Baseline vaccine coverage	10
Wider health outcomes	11
4. Service description / care pathway	12
Roles	12
Local service delivery	12
Target population.....	13
Vaccine schedule	14
Consent	14
Requirements prior to immunisation	15
Vaccine administration.....	15
Vaccine storage and wastage.....	16
Vaccine ordering.....	17
Documentation	17
Reporting requirements	17
Staffing including training.....	19
Premises and equipment.....	19
Governance	20
Service improvement.....	21
Interdependencies	21
Communication strategies	22
5. Service standards and guidance	23

Service specification No.11

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 HPV immunisation programme

- 1.1. This document relates to the human papillomavirus (HPV) immunisation programme, a national programme delivered with the aim of reducing the incidence of cervical cancer. This vaccine forms part of the national childhood immunisation programme, which aims to prevent children from developing vaccine preventable diseases that are associated with significant mortality and morbidity. The purpose of the service specification is to enable NHS England to commission HPV immunisation services of sufficient quantity and quality to prevent women from developing cervical cancer. This means maintaining high coverage rates in England as well as within upper tier local government areas and within the context of populations with protected characteristics as defined by the Equality Act 2010.
- 1.2. This specification forms two distinct parts. Part 1 (sections 2 and 3) 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 arrangements underpin national and local commissioning practices and service delivery.

- 1.4. The existing, highly successful programme provides a firm platform on which local services can develop and innovate to better meet the needs of their local population and work towards improving outcomes. This specification will promote a consistent and equitable approach to the provision of the commissioning and delivery of the HPV 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 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>

- 1.6. This service specification is not designed to replicate, duplicate or supersede any relevant legislative provisions that may apply, e.g. the Health and Social Care Act 2012. The specification will be reviewed and amended in line with any new recommendations or guidance, and in line with reviews of the Section 7A agreement.

2. Population needs

Background

- 2.1. 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 HPV vaccines are highly effective at preventing the infection of susceptible women with the HPV types covered by the vaccine.
- 2.2. The UK has successfully implemented an HPV immunisation programme. This programme is achieving coverage that is amongst the highest in the world. It has been estimated that this will save 400 women each year from developing cervical cancer. The third annual report on HPV immunisation coverage reports 86.8% of the target population, 12- to 13-year-old females, completed the three-dose course in 2011/12.
- 2.3. The UK has a population of 25.51 million women aged 15 years and older who are at risk of developing cervical cancer. Cancer registration data show that around 3000 women are diagnosed with cervical cancer and more than 1000 die from the disease every year. Cervical cancer ranks as the eleventh most frequent cancer among women in the UK, and the second most frequent cancer among women between 15 and 44 years of age worldwide. (World Health Organization (WHO)/Institut Catala d'Oncologica (ICO) Human Papillomavirus Information Centre – HPV Summary 2010).
- 2.4. Persistent infection by high-risk HPV types is detectable in more than 99% of cervical cancers (Munoz *et al.*, 2006). Of these high-risk types, HPV16 is responsible for more than 50% and HPV18 for more than 15% of all cervical cancers in Europe (Smith *et al.*, 2007). A further 11 high-risk types have been described (WHO IARC, 2007). Two vaccines against HPV16 and HPV18 have been found to be highly efficacious in preventing disease due to these HPV types, and to have a limited effect on disease associated with other, non-vaccine, high-risk types (Lu *et al.*, 2011).
- 2.5. The introduction of an organised national cervical screening programme in the UK in the late 1980s made major contributions to the fall in the incidence and death rates from cervical cancer: mortality rates fell approximately 60% between 1974 and 2004 and is estimated to save around 5000 lives a year (Peto *et al.*, 2004). The HPV immunisation programme builds on this and will help to further safeguard women by preventing the development of cervical cancer. It is therefore necessary to build on and improve this programme, under the auspices of PHE along with NHS England and local authorities (LAs).

The HPV immunisation programme – key details

2.6. The key details are that:

- in October 2007, the Department of Health (DH) announced the introduction of the HPV vaccine into the routine national immunisation schedule, and a catch-up programme to offer immunisation to girls above the age of routine immunisation. The routine national programme commenced in September/October 2008 and will continue annually for all 12- to 13-year-old (i.e. year 8) girls. School-based delivery of the programme was recommended.
- the catch-up programme, originally planned to run over two years (2009/10 and 2010/11) targeted girls up to age 18 in September 2008. In December 2008, DH announced the acceleration of the HPV catch-up programme for these older girls. This acceleration enabled all girls identified for the catch-up programme (girls born between 1 September 1991 and 31 August 1995) to be offered protection in the academic year 2009/10.
- there are currently two different HPV vaccine products, Cervarix and Gardasil. HPV vaccines are highly effective at preventing the infection of susceptible women with the HPV types included in the vaccine. Current studies show that protection is maintained for over seven years, and suggest that protection is likely to last for 20 years or more.
- vaccine choice for the national immunisation programme is determined by competitive tender; the programme started in 2008 using Cervarix supplied by GSK. Following a second competitive tendering for the supply of HPV vaccine, a three-year contract has been awarded to Sanofi Pasteur MSD for supply of Gardasil to the programme that started in September 2012.
- in March 2014, the Joint Committee on Vaccination and Immunisation (JCVI) revised its existing recommendation on the HPV vaccination programme for adolescent girls to change from a three-dose to a two-dose schedule. The change to the programme took effect from September 2014.

3. Scope

Aims

- 3.1. The aim of the HPV immunisation programme is to reduce morbidity and mortality from cervical cancer by routinely offering the vaccination to 12- to 13-year-old girls.

Objectives

- 3.2. The aim will be achieved by delivering a population-wide, evidence-based immunisation programme that:
- identifies the eligible population and ensures effective, timely delivery with high coverage (see eligible population set out in paragraph 4.6).
 - is safe, effective, of a high quality and is externally and 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
 - is supported by regular and accurate data collection using the appropriate returns.

Direct health outcomes

- 3.3. In the context of health outcomes, the HPV immunisation programme aims to:
- reduce the number of preventable infections and their onward transmission
 - reduce HPV-related disease
 - achieve high coverage across all groups identified
 - minimise adverse physical/psychological/clinical aspects of immunisation (e.g. anxiety, adverse reactions).

Baseline vaccine coverage

- 3.4. Local services must ensure they maintain and improve current immunisation coverage (with reference to vaccine coverage public health outcomes framework indicators) with the aspiration of 100% of relevant individuals being offered immunisation in accordance with *Immunisations against infectious disease* (the Green Book) and other official DH/PHE guidance.

Wider health outcomes

- 3.5. Everyone in England has ‘the right to receive the vaccinations that the Joint Committee on Vaccination and Immunisation (JCVI) recommends that you should receive under an NHS provided national immunisation programme’.
- 3.6. This right is set out in the *NHS Constitution* that was originally published in 2009, and renewed in 2012. The right is underpinned by law (regulations and directions), the regulations require the Secretary of State for Health to fund and implement any cost-effective recommendation made by JCVI where the Secretary of State has asked JCVI to look at a vaccine. Where JCVI makes a recommendation that the vaccine should be offered as part of a national immunisation programme, the DH will fund and implement the programme.
- 3.7. The programme can be universal 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 getting 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. HPV immunisation 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 of which are services that families need to receive if they are to achieve their optimal health and wellbeing. NHS England should therefore cross-reference to the provisions of the HCP.
- 3.10. The programme also works towards achieving the World Health Organization’s (WHO) Global immunisation vision and strategy (2006), which is a ten-year framework aimed at controlling morbidity and mortality from vaccine preventable diseases.

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 in ensuring strong working relationships.
- 4.2. Public Health England (PHE) undertakes the purchase, storage and distribution of vaccines on a national level. It collects and analyses data on the surveillance of vaccine preventable diseases and has the public health expertise for analysing the coverage of, and other aspects of, immunisation services. It is also responsible for the implementation of the national immunisation schedule, including the national communication strategy, and setting standards as advised by JCVI and other relevant organisations.
- 4.3. Directors of public health (DsPH) based in LAs 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 DsPH in their role by sharing information as appropriate and according to need, for example vaccine coverage within communities (such as, among populations with protected characteristics as defined by the Equalities Act).

Local service delivery

- 4.4. The delivery of immunisation services at the local level is based on evolving best practice that has been built since vaccinations were first introduced more than a hundred years ago. This section of the document specifies the high-level operational elements of the HPV vaccine programme, based on that best practice that NHS England must use to inform local commissioning, contracts and service delivery. There is also scope to enable NHS England and providers to enhance and build on specifications to incorporate national or local service aspirations that may include increasing locally competition and 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 and communications
 - 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 – patients
- 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 HPV vaccine available to:
- all 12- to 13-year-old girls (school year 8)
 - any girl in school years 8, 9, 10 and 11 regardless of date of birth who has not had HPV immunisation. This may include girls who are resident in neighbouring CCGs but are attending school in a different CCG. This will include girls in eligible age groups who move into the area, school or who newly register with a general practice after the invitations have been issued.
- 4.8. Additionally the NHS England will wish to ensure that providers:
- offer immunisation to girls who are in special schools, pupil referral units and independent schools. Immunisation should also be offered to girls who are educated at home
 - ensure that any girl who misses a routine visit is automatically invited to the next planned sessions, or given a suitable, locally agreed alternative
 - ensure efforts are made to include as part of the programme girls from communities with objections on family or religious beliefs and hard to reach groups, which may include looked after children and girls from traveller communities. Health professionals must take all opportunities, particularly those contacts during the early years to remind parents and carers of the importance of immunisations and the need to have them at the appropriate times.

- As good practice GPs should offer a course of vaccinations to any girl, under the age of 18 who has not received the vaccinations.

Vaccine schedule

- 4.9. A locally commissioned HPV service should immunise the eligible population using the two-dose vaccination schedule as set out in the HPV chapter of the Green Book: <https://www.gov.uk/government/publications/human-papillomavirus-hpv-the-green-book-chapter-18a>
- 4.10. In addition:
- local 'catch-up' arrangements must be considered
 - health professionals must take all opportunities to remind the eligible population of the importance of HPV immunisation, and of cervical screening when eligible/invited
 - the HPV immunisation status of a young person must actively be considered at the time of the teenage booster, and if incomplete or missed the vaccine should be offered.

Consent

- 4.11. 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 although many local services send consent forms to parents via the school service. Sufficient information must be available to make an informed decision. Local providers must:
- write to all parents/carers of all girls identified in the routine and catch-up cohorts asking for consent for the full two-dose course. To make clear, when asking parents to give their consent for immunisation to take place, that they are giving consent for all two vaccines and that their child will receive all two vaccines unless a letter is received withdrawing consent.
 - ensure DH guidance detailed in Chapter 2 of the Green Book for obtaining informed consent from the girls in this group is followed, including properly obtained checks made to see whether the girl remained happy to receive the vaccine. There is no legal requirement for consent to be in writing but sufficient information must be available to make an informed decision
 - consider when it is possible for the provider to administer the vaccine to a (Gillick¹)/Fraser competent child who requests it where there is no signed parental consent. The decision to vaccinate will be at the individual practitioner's discretion and must be re-assessed at each visit. It must be clearly documented that the girl

¹ Gillick v West Norfolk & Wisbech AHA (1986)

has been deemed Fraser competent when she receives each vaccination.
The girl's confidentiality must be maintained

- ensure resources (leaflets/factsheets, etc.) are used as part of the consent process to ensure that all parties (both parents/children) have all of the available information on 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.
<https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>

Requirements prior to immunisation

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

- systems in place to assess eligible individuals for suitability by a competent individual prior to each immunisation
- assessed each individual to ensure they are suitable for immunisation
- assessed the immunisation record of each individual to ensure that all vaccinations are up to date
- systems in place to identify, follow-up and offer immunisation to eligible individuals. In some areas, contracts may be in place for Child Health Information Systems (CHIS) to invite children 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. In some areas, the CHIS will supply practices with lists of unimmunised children
- systems in place to actively identify those in clinical risk groups and to optimise access for those in hard to reach groups (e.g. gypsy travellers, looked after children)
- arrangements in place to inform neighbouring areas when children move into their area
- arrangements in place to access specialist clinical advice so that immunisation is only withheld or deferred where a valid contraindication exists
- practices that do their own scheduling must ensure their systems allow them to fulfil the actions outlined above.

Vaccine administration

4.13. As part of the commissioning arrangements, NHS England are 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) is routinely available. Training is likely to include the subjects of disease, vaccines, delivery issues, consent, cold chain, vaccine management and anaphylaxis. See section 5 of this document for reference to the HPA training standards
- the professional lead must ensure that all staff are legally able to supply and/or administer the vaccine by:
 - working under an appropriate patient group direction (PGD)
 - working from a patient specific direction (PSD)/prescriptions, or
 - working as a nurse prescriber (if appropriate).

Vaccine storage and wastage

4.14. Effective management of vaccines is essential to reduce vaccine wastage. NHS England must ensure that providers will:

- have effective cold chain and administrative protocols that reduce vaccines wastage to a minimum which reflect DH national protocols (chapter 3 of the Green Book and the 'Guidelines for maintaining the vaccine cold chain') and includes:
 - how to maintain accurate records of vaccine stock
 - how to record vaccine fridge temperatures
 - what to do if the temperature falls outside the recommended range
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digital_asset/dh_130276.pdf
 - and the ImmForm helpsheet
<https://www.gov.uk/government/organisations/public-health-england/series/immform>
- ensure all vaccines are delivered to an appointed place
- ensure that at least two named individuals are responsible for the receipt and safe storage of vaccines in each general practice/premise
- ensure that approved pharmaceutical grade cold boxes are used for transporting vaccines
- ensure that only minimum stock levels (two to four weeks maximum) of vaccine will be held in local fridges, to reduce the risk of wastage caused by power cuts or inadvertent disconnection of fridges from power supplies
- vaccine supply will be controlled by the PHE vaccine supply department.
- report any cold chain failures to the local co-ordinators, PHE the Screening and Immunisation Area Team and NHS England.

Vaccine ordering

- 4.15. All centrally procured vaccines to be ordered via the ImmForm Service. Vaccines can be ordered by:
- appropriate providers (with a wholesale dealers licence) for delivery to their location
 - GP practices / hospital pharmacies for delivery to their location.
- 4.16. Further information:
- 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
- 4.17. Further help is available at:
- <https://www.gov.uk/government/organisations/public-health-england/series/immform>
 - ImmForm Helpdesk 0844 376 0040.

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.
 - the individual must be given an individual record which must include:
 - the batch number, expiry date and the title of the vaccination
 - the date of administration of the vaccine
 - the site and route of administration
 - any adverse reactions to the vaccine
 - name of immuniser.

Reporting requirements

- 4.19. 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 for ministers and the public. In-depth analysis underpins any necessary changes to the programme, which might include the development of targeted programmes or campaigns to improve general coverage of the vaccination.

- The provider must ensure that information on vaccines administered is documented in the general practice record (if not given in general practice). In most areas, the CHIS will inform GPs that a patient on their list has been immunised via the current vaccination history printout. 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.
- Data management must ensure that vaccine uptake, supply and wastage data are provided to the DH (via the ImmForm website) in order to ensure the programme is managed effectively. Current guidance and instructions for data management must be consulted and complied with.
- It is crucial the HPV vaccine status of girls and young women is recorded on the NHAIS (Exeter System), in addition to the local recording on CHIS and GP clinical records. This information will be essential when the women are first invited for cervical screening at age 25, as by the time they become eligible, the evidence may point to different screening management regimens based on HPV vaccination status. Data can be uploaded manually or by electronic transfer from CHIS to NHAIS: current instructions should be consulted and complied with.
- The provider must ensure that information on vaccines administered is submitted directly to any relevant population immunisation registers, in most areas the CHIS.
- Following an immunisation session/clinic or individual immunisation, local arrangements 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.
- Any reported adverse events or reactions post vaccination must follow determined procedures and be reported to the MHRA via the Yellow Card Scheme - NHS England. In addition, teams must keep a local log of reports and discuss such events with the local immunisation co-ordinator.
<http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/TheYellowCardScheme>

- The provider must report any significant concerns it has in relation to the delivery of services, including reports of serious failings, incidents or major risks to enable NHS England to inform the DH. This is in line with Part A of the Section 7A agreement.

Staffing including training

4.20. 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 and hepatitis B)
- meet the HPA *National minimum standards in immunisation training 2005* either through training or professional competence.
- have had training (and annual updates) with regard to the recognition and initial treatment of anaphylaxis
- ensure that all staff are familiar with and have online access to the latest edition of the Green Book
- ensure that all staff are registered to receive *Vaccine Update* <https://www.gov.uk/government/organisations/public-health-england/series/vaccine-update>
- ensure that all staff are aware of the importance of and can access the official public health letters that announce changes to or new programmes, the Director of Immunisation letters, and additional guidance on the (PHE) website.

Premises and equipment

4.21. 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 for young children, their carers and 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 on-going 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 that internal 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 as a routine part of clinical governance arrangements, in order to assure NHS England of the quality and integrity of the service
- for providers to supply evidence of clinical governance and effectiveness arrangements on request for NHS England or its local offices
- PHE will alert NHS England to any issues that need further investigations
- the provision of high quality, accurate and timely data to relevant parties including PHE, NHS England and LAs is a requirement for payment.
- data will be analysed and interpreted by PHE and any issues that arise will be shared quickly with NHS England and others.
- local co-ordinators will document, manage and report on programmatic or vaccine administration errors, including serious untoward incidents (SUIs), and escalate as needed, 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.
- 4.24. NICE guidelines (NICE 2009 *Reducing differences in the uptake of vaccines*) highlights evidence to show that there are particular interventions, which can increase immunisation rates and reduce inequalities. Providers must also consider the following suggestions:
- up-to-date patient reminder and recall systems (particularly for those being vaccinated in a non-school setting)
 - well-informed healthcare professionals who can provide accurate and consistent advice
 - high-quality patient education and information resources in a variety of formats (leaflets, internet forums and discussion groups)
 - effective performance management of the commissioned service to ensure it meets requirements
 - local co-ordinators or experts based in PHE to provide expert advice and information for specific clinical queries
 - for NHS England and providers to have clear expectations to improve and build upon existing immunisation rates.

Interdependencies

- 4.25. The immunisation programme is dependent upon systematic relationships between stakeholders, which may include vaccine suppliers, primary care providers, NHS England, etc. The NHS England Screening and Immunisation Area 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 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 the childhood immunisation programme
 - maintaining an up-to-date population based immunisation register to provide coverage data and for outbreak investigation and response
 - maintaining robust electronic links with IT systems and relevant organisations along the pathway

- local feedback and review of coverage and disease surveillance data
- clear description of and access to advice on the arrangements for provision of and reimbursement for immunisation services.

Communication strategies

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 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)
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- *Protocol for ordering, storing and handling vaccines* (DH Sept 2010)
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_120010
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