Public health functions to be exercised by NHS England

Service specification No.1A
Pertussis pregnant women immunisation programme
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Prepared by –
Immunisation Implementation & Planning, Public Health England
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Service specification No.1A

This is a service specification within Part C of the agreement ‘Public health functions to be exercised by the NHS Commissioning Board’ dated November 2012 and amended by variation dated April 2013 (the ‘2013-14 agreement’).

The 2013-14 agreement is made between the Secretary of State for Health and the National Health Service Commissioning Board (“NHS CB” or “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. The 2013-14 agreement may refer interchangeably to NHS CB or NHS England.

This service specification is to be applied by the NHS CB in accordance with the 2013-14 agreement. An update to this service specification may take effect on an agreed date as a variation made in accordance with the 2013-14 agreement.

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

The 2013-14 agreement including all service specifications within Part C is available at www.gov.uk (search for “commissioning public health”).
1. Purpose of the pertussis pregnant women immunisation programme

1.1 This document relates to the pertussis (whooping cough) vaccine for pregnant women that is given to help protect their newborn infants against serious complications from the infection until they receive their routine immunisations from two months of age.

1.2 The purpose of the service specification is to enable the NHS Commissioning Board (‘NHS CB’) to commission pertussis for pregnant women immunisation services of sufficient quantity and quality to prevent the infections and outbreaks caused by this organism. This means achieving high levels of coverage across England as well as within upper tier local government areas and within the context of populations with characteristics as defined by the Equality and Diversity Act.

1.3 This specification forms two distinct parts. Part one (sections 1 and 2) provides a brief overview of the vaccines including the disease they protect against, the context, evidence base, and wider health outcomes.

1.4 Part 2 (sections 3, 4 and 5) sets out the arrangements for:

* front-line delivery
* the expected service and quality indicators, and
* the standards associated with the programme.

1.5 These arrangements underpin national and local commissioning practices and service delivery.

1.6 This is a temporary programme in response to a current outbreak. Independent experts on immunisation – the Joint Committee on Vaccination and Immunisation (JCVI) - have advised that pregnant women between 28 and 38 weeks pregnancy should be offered immunisation against pertussis to help protect their newborn infants before they can receive their routine immunisations. JCVI’s advice can be found by accessing the following link:

(http://transparency.dh.gov.uk/2012/09/28/jcvi-pertussis/)

1.7 Approximately 650,000 women a year are eligible to receive the pertussis vaccination in this temporary programme. This specification is intended to inform a consistent and equitable approach to the commissioning and delivery of the temporary programme across England. However, it is important to note that this programme, although temporary, can change and evolve in light of emerging best practice and scientific evidence. NHSCB and providers will be
required to reflect these changes accordingly in a timely way as directed by the national schedule. In particular NHS CB should make arrangements to enable the termination of this temporary programme in a timely way.

1.8 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 including a chapter on the routine pertussis programme given to children as part of the childhood immunisation programme.

1.9 A range of publications has been produced to support this temporary programme, including information for parents and professionals. This service specification must be read in conjunction with these materials in addition to letters issued by Chief Medical Officer (CMO), Director of Immunisation letters, and any guidance issued by PHE 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 (www.dh.gov.uk/greenbook).

1.10 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. Before the introduction of routine immunisation against pertussis in the 1950s large epidemics occurred every three to five years that affected up to 150,000 people and contributed to about 300 deaths a year. In comparison, over the last ten years (2002 – 2011) there have been on average 800 cases of pertussis with over 300 babies needing admission to hospital and four babies dying each year in England.

2.2 However, there has been a considerable increase in pertussis activity across the UK starting in mid-2011. The current outbreak is the largest seen in the UK for over a decade. Almost 5000 cases of pertussis have been confirmed so far in 2012 in England and Wales. Although most cases are in adolescents and young adults, the highest rates are in infants of less than three months of age, who are at the highest risk of complications and death, and too young to be protected. Between January and October 2012, there were nine deaths - all in unimmunised infants under the age of three months.

2.3 Young infants are particularly vulnerable to complications, hospitalisation and death from pertussis. Immunising pregnant women against pertussis may help provide their newborn infants with protection against serious complications from the infection until they receive their first routine immunisation at two months of age. Therefore, this temporary programme has been introduced to offer pregnant women immunisation against pertussis in response to the current outbreak. While providing vital protection for infants, this programme will not have any effects on the transmission of pertussis across the population.

2.4 PHE will continue to monitor the levels of pertussis and JCVI will keep this temporary programme under review.

2.5 Key details

- JCVI has recommended a single dose of the dTaP/IPV (Repevax®) vaccine to pregnant women in the period weeks 28 to 38 (inclusive) of pregnancy. This dose should be given irrespective of the number of foetuses in pregnancy. Repevax® also provides protection against tetanus, diphtheria and polio.
- JCVI has stated although they have no concerns about the safety of use at any stage of pregnancy; the Repevax® patient information leaflet (PIL) states it is not recommended during pregnancy. This PIL statement relates to the routine exclusion of pregnant women from clinical trials, and not because of any specific safety concerns or evidence of harm in pregnancy.

- The vaccine should be given to pregnant women, ideally at a routine antenatal visit, which is likely to be provided by GPs and midwives in various community settings and in hospitals.

- Vaccine uptake will be monitored with a monthly data collection through Immform (See para 4.21).
3. Scope

Aims

3.1 The aim of the temporary vaccination programme for pregnant women is to provide indirect protection against pertussis to infants by offering immunisation to their pregnant mothers to boost antibody levels such that they pass pertussis-specific antibodies through their placenta.

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 optimal coverage based on the target population set out in paragraph 4.7
- is safe, effective, of a high quality and is independently monitored
- is delivered and supported by suitably trained, competent healthcare professionals who participate in recognised ongoing training and development
- delivers, manages and stores vaccine in accordance with national guidance, and
- is supported by regular and accurate data collection using the appropriate returns.

Direct health outcomes

3.3 In the context of health outcomes the temporary pertussis vaccine programme aims to:

- provide indirect protection against pertussis to infants
- achieve high coverage across all groups identified, and
- minimise adverse physical/psychological/clinical aspects of immunisation (e.g. anxiety, adverse reactions).
Baseline vaccine coverage

3.4 Local services should 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 the Green Book and other official DH/PHE guidance.

Wider health outcomes

3.5 The national immunisation programme supports the right made in the NHS Constitution that everyone in England has ‘the right to receive the vaccinations that the Joint Committee on Vaccination and Immunisation recommends that you should receive under an NHS provided national immunisation programme.’

3.6 This right is set out in the NHS Constitution that was originally published in 2009, and renewed in 2012. The right is underpinned by law (regulations and directions), the regulations require the Secretary of State for Health to fund and implement any cost-effective recommendation made by JCVI where the Secretary of State has asked JCVI to look at a vaccine. Where JCVI makes a recommendation that the vaccine should be offered as part of a national immunisation programme, the Department of Health will fund and implement the programme.

3.7 The programme can be universal, like MenC 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 your own health, as well as that of your 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 the NHS CB and Clinical Commissioning Groups (CCGs) to actively promote it.

3.9 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 The NHS CB will be responsible for commissioning the local provision of immunisation services and the implementation of new programmes through general practice and all other providers. It will be accountable to the Secretary of State for Health for delivery of those services. Other bodies in the new comprehensive health system will also have key roles to play and it will be vital to ensure strong working relationships.

4.2 PHE will undertake the purchase, storage and distribution of vaccines at a national level. It will, together with the HSCIS hold surveillance and coverage data and have the public health expertise for analysing the coverage of, and other aspects of, immunisation services. It will also be 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 may as part of this role annually publish a public health report which could include information on local immunisation services including views on how local services might be improved. To support the development of such reports they will expect the NHS CB to provide analysis including vaccine coverage amongst their communities (in particular social, geographical, and equality and diversity characteristics.) To achieve this, the NHS CB and the provider will need to work closely with their local DPH.

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 temporary pertussis vaccine programme, based on that best practice that the NHS CB must use to inform local commissioning, contracts and service delivery. There is also scope to enable NHS CB and providers to enhance and build on specifications to incorporate national or local service aspirations that may include increasing local innovation in service delivery. However, it is essential, in order to promote a nationally aligned high-quality programme focusing on improved outcomes, increasing coverage and local take-up, that all the core elements listed in 4.5 are included in contracts and specifications.

4.5 The following elements must be covered:
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- 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, and
- 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 (http://immunisation.dh.gov.uk/category/the-green-book/).

Target population

4.7 Providers will be required to make the dTap/IPV vaccine available to:

- pregnant women in the period weeks 28 to 38 (inclusive) of pregnancy: the optimal time for immunisation is in weeks 28 to 32 (inclusive)
Vaccine schedule

4.8 Immunisation during or after the 28th week of pregnancy is likely to maximise levels of anti-pertussis antibodies in the pregnant women in time for optimal transplacental transfer to the unborn child. A locally commissioned service should immunise the target population in the period weeks 28 to 38 of pregnancy (inclusive); the optimal time is in the period weeks 28 to 32 (inclusive).

- In order to provide protection, providers should aim to administer the vaccine as near as possible to the recommended times. Sufficient immunisation appointments must be available so that individuals can receive vaccinations on time – waiting lists are not acceptable.
- Pregnant women who miss vaccination and are beyond week 38 of pregnancy should be offered immunisation up to the onset of labour so that some direct protection may still be provided to the infant.

Vaccination of pregnant women, even after 38 weeks, will reduce the risk of the mother contracting pertussis in the post-partum period and therefore prevent her from infecting her infant. Vaccination may be offered to new mothers who have never previously been vaccinated against pertussis, up to when their child receives their first vaccination.

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 should 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) are used as part of the consent process to ensure that all parties pregnant women have all the available information about the vaccine and the protection it offers
- professionals should be sufficiently knowledgeable about the disease and vaccine and to be able to answer any questions with confidence
- the patient has access to the vaccine’s patient information leaflet (PIL).
Requirements prior to immunisation

4.11 As part of the commissioning arrangements, NHS CB is required to ensure that providers adhere to the following. That providers have:

- systems in place to assess each pregnant woman for suitability by a competent individual prior to each immunisation
- systems in place to invite each suitable pregnant woman for a vaccination
- assessed the immunisation record of each pregnant women to ensure that all vaccinations are up to date
- arrangements in place that enable them to identify and recall under or un-immunised individuals and to ensure that such individuals are immunised in a timely manner
- systems in place to optimise access for those in hard to reach groups
- arrangements in place to access specialist clinical advice so that immunisation is only withheld or deferred where a valid contraindication exists.
- arrangements should be in place to ensure that vaccine can be administered promptly to the target population.
- local arrangements should be in place to target pregnant women in areas with poor uptake.

4.12 Practices that do their own scheduling should ensure their systems allow them to fulfil the actions outlined above.

Vaccine administration

4.13 As part of the commissioning arrangements, NHS CB 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 should ensure that all staff are legally able to supply and/or administer the vaccine by:
  • working under an appropriate patient group direction (PGD), or
  • 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 ensure patient safety and reduce vaccine wastage. NHS CB should ensure that providers will:

• have effective cold chain and administrative protocols that reduce vaccine wastage to a minimum which reflect DH national protocols (Ch 3 of the Green Book and the Guidelines for maintaining the vaccine cold chain) and includes:
  • how to maintain accurate records of vaccine stock
  • how to record of vaccine fridge temperatures
  • what to do if the temperature falls outside the recommended range

• ensure all vaccines are delivered to an appointed place
• ensure that at least one named individual is responsible for the receipt and safe storage of vaccines in each general practice or other appropriate location
• ensure that an approved vaccine fridge is available for the storage of all vaccines
• ensure that approved pharmaceutical grade cold boxes are used for transporting vaccines
• ensure that only minimum stock levels (2 to 4 weeks maximum) of vaccine will be held in local fridges, to reduce the risk of wastage caused by power cuts or inadvertent disconnection of fridges from power supplies
• report any cold chain failures to the local coordinator and PHE and NHS CB.

4.15 Vaccine supply will be controlled by the PHE vaccine supply department.
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Vaccine ordering

4.16 All centrally procured vaccines must be ordered via the online ordering system - the ImmForm service.

4.17 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.

4.18 Further information:

- Providers can register to order vaccine via ImmForm:
  - online: http://www.immform.dh.org.uk/registration
  - via email: send your request to immform@dh.gsi.gov.uk

- Additional help is available at:
  - http://immunisation.dh.gov.uk/immform-helpsheets/
  - ImmForm help desk 0844 376 0040

Documentation

4.19 Accurate recording of all vaccines given and good management of all associated documentation is essential. Providers should ensure that:

- the patient’s medical records are updated with key information that includes:
  - any contra-indications to the vaccine and any alternative offered
  - any refusal of an offer of vaccination
  - details of consent and the person who gave the consent
  - the batch number, expiry date and the title of the vaccination
  - the date of administration of the vaccine
  - the site and route of administration
  - any adverse reactions to the vaccine
  - name of immuniser.
the patient held record should be updated or the patient should be given a personal record that should include:

- the batch number, expiry date and the title of the vaccination
- the date of administration of the vaccine
- the site and route of administration
- any adverse reactions to the vaccine
- name of immuniser.

**Recording and reporting requirements**

4.20 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.

- Monthly surveys will run from the start of the programme (1st October 2012) so that data from the survey month will be collected in the following month. PHE will ensure that data on uptake from areas is collated and manually entered onto ImmForm. This should not cause great disruption to new organisational structures that formally come into place in April 2013 as this data should be recorded by GP practices which can then be submitted and collated. This data requirement will be reviewed on a continuing basis. The collection allows the quick and timely review of uptake figures on a monthly basis with minimal burden to the NHS. The Provider must ensure that information on vaccines administered is documented and that this information is transferred to the general practice record.

- Following an immunisation session/clinic or individual immunisation, local arrangements should be made for the transfer of the appropriate data, including those required for central data collections on to a relevant data collection system. Where possible, this should aim to be within two working days.

- 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 www.mhra.gov.uk/yellow card, including the brand number and batch number in addition to following local and nationally determined procedures.
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- 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-ordinator and PHE/ImmForm as appropriate.

Staffing including training

4.21 To deliver a national immunisation programme it is essential that all staff are appropriately trained. NHS CB 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 Health Protection Agency’s National minimum standards in immunisation training 2005 either through training or professional competence ensuring that annual training is offered to all staff
- have had training (and annual updates) with regard to the recognition and initial treatment of anaphylaxis
- ensure that all staff are familiar with and have online access to the latest edition of the Green Book, noting the clinical guidance may change and 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 (http://immunisation.dh.gov.uk/vu-190-jun-12/);
- ensure that all staff are aware of the importance of and can access the CMO/CNO/CPhO letters that announce changes to or new programmes, the Director of Immunisation letters, and additional guidance on the (PHE) website.

Premises and equipment

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

- suitable premises and equipment provided for the immunisation programme
- disposable equipment meeting approved quality standards
• appropriate 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 should have appropriate training in resuscitation
• premises that are suitable and welcoming for young children, and their carers and all individuals coming for immunisation including those for whom access may be difficult.

Governance

4.23 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 CB
• at the provider level there is appropriate internal clinical oversight of the programme’s management and a nominated lead for immunisation
• provider governance is overseen by a clinical lead (for example, the local immunisation coordinator) and immunisation system leader
• there is regular monitoring and audit of the immunisation programme, including the establishment and review of a risk register as a routine part of clinical governance arrangements, in order to assure the NHS CB of the quality and integrity of the service
• providers supply evidence of clinical governance and effectiveness arrangements on request for the NHS CB or its local offices
• PHE will alert NHS CB to any issues that need further investigations
• the provision of high quality, accurate and timely data to relevant parties including PHE, NHS CB and local authorities (LAs) is a requirement for payment
• data will be analysed and interpreted by PHE and any issues that arise will be shared quickly with NHS CB and others
• local co-ordinators will document, manage and report on programmatic or vaccine administration errors, including serious untoward incidents (SUIs), and escalate as needed. This may include involving the NHS CB and relevant partners and where appropriate for the NHS CB to inform DH
• NHS CB press office will liaise closely with DH, PHE, and MHRA press offices regarding the management of all press enquiries
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- have a sound governance framework in place covering the following:
  - information governance/records management
  - equality and diversity
  - user involvement, experience and complaints
  - fail-safe procedures
  - communications
  - ongoing risk management
  - health and safety
  - insurance and liability.

Service improvement

4.24 NHS CB and providers will wish to identify areas of challenge within local vaccination programmes and develop comprehensive, workable and measurable plans for improvement. These may be locally or nationally driven and are likely to be directed around increased coverage and may well be focused on particular hard to reach groups. Suggestions for improving service and uptake include:

4.25 NICE guidelines (NICE 2009 Reducing differences in the uptake of vaccines) - highlights evidence to show that there are particular interventions that can increase immunisation rates and reduce inequalities. Providers should also consider the following suggestions:

- up-to-date patient reminder and recall systems in addition to appropriate systems that allow electronic automated data transfer and reporting
- well-informed healthcare professionals who can provide accurate and consistent advice
- high quality patient education and information resources in a variety of formats (leaflets, internet forums and discussion groups)
- effective performance management of the commissioned service to ensure it meets requirements
- local coordinators or experts based in PHE to provide expert advice and information for specific clinical queries
- for NHS CB and providers to have clear expectations to improve and build upon existing immunisation rates.
Interdependencies

4.26 The immunisation programme is dependent upon systematic relationships between stakeholders, which include vaccine suppliers, primary care providers, NHS CB etc. The immunisation coordinator, based in the area team (AT) of the NHS CB, will be expected to take the lead in ensuring that inter-organisational systems are in place to maintain the quality and the immunisation pathway. This will include, but is not limited to:

- ensuring all those involved in pathways are sure of their roles and responsibilities
- developing joint audit and monitoring processes
- agreeing joint failsafe mechanisms, where required, to ensure safe and timely processes along the whole pathway
- contributing to any initiatives led by the NHS CB/PHE to develop/improve the childhood immunisation programme
- maintaining an up-to-date population-based immunisation register to provide accurate and timely coverage data and for outbreak investigation and response
- maintaining robust electronic links with IT systems and relevant organisations along the pathway
- local feedback and review of coverage and disease surveillance data
- clear description of and access to advice on the arrangements for provision of and reimbursement for immunisation services
- communication strategies.

Communication strategies

4.27 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 CB and providers must refer to and make comprehensive use of the following key resources: [provide hyperlinks]

- Green Book – *Immunisation against infectious disease* (DH 2006)

- *Quality criteria for an effective immunisation programme* (HPA, 2012)

- *National minimum standards for immunisation training* (HPA June 2005)

- Protocol for ordering, storing and handling vaccines (DH Sept 2010)

- National Patient Safety Agency – Advice on vaccine cold storage

- Official immunisation letters (DH)

- ImmForm information

- British National Formulary
  [http://www.bnf.org/bnf/index.htm](http://www.bnf.org/bnf/index.htm)
- Joint Committee on Vaccination and Immunisation
  http://www.dh.gov.uk/ab/JCVI/index.htm?ssSourceSiteId=en

  http://www.nice.org.uk/PH21