Public health functions to be exercised by the NHS Commissioning Board

Service specification No.2

Neonatal BCG immunisation programme

November 2012
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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 (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) 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 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.dh.gov.uk/publications
1. Purpose of neonatal BCG immunisation programme

1.1 This document relates to the neonatal BCG vaccine, which protects newborn babies who are at risk from exposure to, or developing human tuberculosis (TB) which can cause serious illness and premature death.

1.2 The purpose of the service specification is to enable the NHS Commissioning Board (NHS CB) to commission the neonatal BCG vaccine immunisation services of a sufficient quantity and quality. This means achieving high coverage rates in identified at risk groups in appropriate settings across England as well as within upper tier local government areas and within the context of populations with protected characteristics as defined by the Equality Act 2010.

1.3 This specification forms two distinct parts. Part 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.

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, 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 also promote a consistent and equitable approach to the provision of the commissioning and delivery of the neonatal BCG vaccine
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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 CB 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, as issued by Public Health England 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, CMO letters, Director of Immunisation letters and any guidance issued by DH and PHE, and reflected in the commissioning of immunisation programmes. This specification must also be read in conjunction with additional evidence, guidance and literature issued by the Joint Committee on Vaccination and Immunisation (JCVI).

www.dh.gov.uk/greenbook

www.dh.gov.uk/ab/JCVI

1.6 This service specification is not designed to replicate, duplicate or supersede any relevant legislative provisions that may apply e.g. the Health and Social Care Act 2012. The specification will be reviewed and amended in line with any new recommendations or guidance, and in line with reviews of the Section 7A agreement.
2. 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 diseases, complications and possible early death among individuals. The neonatal BCG vaccine is routinely used to protect newborns who are at risk of TB infection, or exposure to it.

2.2 Human tuberculosis (TB) is caused by infection with bacteria of the *Mycobacterium tuberculosis* complex (*M. tuberculosis*, *M. bovis* or *M. africanum*) and may affect almost any part of the body. The most common form is pulmonary TB, which accounts for almost 60% of all cases in the UK. Non-respiratory forms of TB are more common in young children in communities with connections to areas of the world with high prevalence, and in those with impaired immunity.

2.3 The symptoms of TB are varied and depend on the site of infection. General symptoms may include fever, loss of appetite, weight loss, night sweats and lassitude. Pulmonary TB typically causes a persistent productive cough, which may be accompanied by blood-streaked sputum or, more rarely, frank haemoptysis. Untreated, TB in most otherwise healthy adults is a slowly progressive disease that may eventually be fatal.

2.4 Almost all cases of TB in the UK are acquired through the respiratory route, by breathing in infected respiratory droplets from a person with infectious respiratory TB. Transmission is most likely when the index case has sputum that is smear positive for the bacillus on microscopy, and often after prolonged close contact such as living in the same household.

2.5 The initial infection may:

- be eliminated
- remain latent – where the individual has no symptoms but the TB bacteria remain in the body, or
- progress to active TB over the following weeks or months.

2.6 Latent TB infection may reactivate in later life, particularly if an individual’s immune system has become weakened, for example by disease (e.g. HIV), certain medical treatments (e.g. cancer chemotherapy, corticosteroids) or in old age.
BCG immunisation programme

2.7 The BCG immunisation programme was introduced in the UK in 1953 and has undergone several changes since, in response to changing trends in the epidemiology of TB. The programme was initially targeted at children of school-leaving age (then 14 years), as the peak incidence of TB was in young, working-age adults. In the 1960s, TB rates in the indigenous population continued to decline. BCG remained part of the adolescent programme.

2.8 In 2005, following a continued decline in the indigenous population the schools programme was stopped. The BCG programme is now a risk-based programme, the key part being a neonatal programme targeted at those children most at risk of exposure to TB, particularly from the more serious forms of the disease.

2.9 This service specification relates to the selective neonatal immunisation programme.

Neonatal BCG – key details

2.10 The key details are that:

- following a continued decline in TB rates in the indigenous population the schools based BCG programme was stopped in 2005
- it has been replaced with a risk-based programme, the key part being the neonatal programme which targets those children most at risk from or exposure to TB
- it is offered to all infants (0–12 months) living in areas of the UK where annual incidence of TB is 40/100,000 or greater
- it is offered to all infants (0–12 months) where a parent or grandparent was born in a country where the annual incidence of TB is 40/100,000 or greater
- the BCG (Bacillus Calmette-Guerin) vaccine contains a live strain of the TB virus. A single dose is required for infants under 12 months
- analysis shows the vaccine to be 70 to 80% effective against the most severe forms of the disease that includes TB meningitis in children.
3. Scope

Aims

3.1 The aim of the neonatal BCG vaccine programme is to protect those infants, identified in 'at risk' groups being at risk from TB or exposure to it.

Objectives

3.2 The aim will be achieved by delivering an evidence-based, population-wide immunisation programme that:

- identifies the eligible population and ensures effective timely delivery with optimal coverage based on the target population set out in paragraph 4.6
- 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 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 neonatal BCG vaccine programme aims to:
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- reduce the number of newborns at risk from TB or exposure from it
- reduce the number of preventable infections and their onward transmission
- achieve high coverage across the groups identified
- minimise adverse physical/psychological/clinical aspects of immunisation (e.g. anxiety, adverse reactions).

Baseline vaccine coverage

3.4 Local services should ensure they maintain and improve current immunisation coverage with the aspiration of 100% of at risk newborns babies being offered immunisation in accordance with the Green Book.

Wider health outcomes

3.6 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.

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

3.8 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.

3.9 The NHS Health and Social Care Act 2012, is wholly consistent with the principles of the *NHS Constitution* and places new legal duties which require the NHS CB and clinical commissioning groups (CCGs) to actively promote it.

3.10 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 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 Public Health England (PHE) will undertake the purchase, storage and distribution of vaccines on a national level. It will hold the coverage and surveillance 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, including the national communication strategy, setting standards and following recommendations as advised by JCVI and other relevant organisations.

4.3 Directors of public health (DsPH) based in local authorities play a key role in providing independent scrutiny and challenge and will publish reports on the health of the population in their areas, which could include information on local immunisation services and views on how immunisation services might be improved. The NHS CB 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 neonatal BCG vaccine programme, which may be delivered in a variety of health care settings, 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. 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 (http://immunisation.dh.gov.uk/category/the-green-book/)
4.7 More detailed information on at risk groups is available in chapter 19 of the Green Book (www.dh.gov.uk/greenbook).

Target population

4.8 Providers will be required to make the neonatal BCG vaccine available to:

- all infants (aged 0–12 months) living in areas of the UK where annual incidence of TB is 40/100,000 or greater

- all infants (aged 0–12 months) with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater.

Vaccine schedule

4.9 A locally commissioned service should immunise at risk newborns with a single dose. Contraindications as outlined in the Green Book should be observed.

- For further information follow www.dh.gov.uk/greenbook.

Consent

4.10 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.
4.11 Therefore, providers will be required to ensure that:

- consent is obtained prior to giving any immunisation
- consent is given voluntarily and freely
- individuals giving consent on behalf of infants and young children must be capable of consenting to the immunisation in question
- relevant resources (leaflets/factsheets, etc.) are used as part of the consent process to ensure that all parties (both parents and where appropriate individuals) have all the available information about the vaccine and the protection it offers
- 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 patient information leaflet (PIL)
- for infants and young children not competent to give or withhold consent, such consent can be given by a person with parental responsibility, provided that person is capable of consenting to the immunisation in question and is able to communicate their decision. Although a person may not abdicate or transfer parental responsibility, they may arrange for some or all of it to be met by one or more persons acting on their behalf.

Requirements prior to immunisation

4.12 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 eligible individuals for suitability by a competent individual prior to each immunisation
- assessed each child to ensure they are suitable for immunisation
- assessed the immunisation record of each child to ensure that all vaccinations are up to date
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- systems in place to identify, follow-up and offer immunisation to eligible individuals. In some areas, contracts may be in place for Child Health Information Systems (CHIS) to invite young people for vaccination

- arrangements in place that enable them to identify and recall under or unimmunised individuals and to ensure that such individuals are immunised in a timely manner

- systems in place to optimise access for those in hard to reach groups (e.g. gypsy travellers, looked after children)

- arrangements in place to access specialist clinical advice so that immunisation is only withheld or deferred where a valid contraindication exists.

Vaccine administration

4.13 As part of the commissioning arrangements, NHS CB 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 – 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)
  - 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 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 (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
- report any cold chain failures to the local coordinator and PHE and NHS CB.

Vaccine ordering

4.15 All centrally procured vaccines must be ordered via the online ordering system – ImmForm service.
4.16 Vaccines can be ordered by:

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

4.17 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

- Further help is available at:
  - http://immunisation.dh.gov.uk/immform-helpsheets/
  - ImmForm Help Desk 0844 376 0040.

Documentation

4.18 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 contraindications to the vaccine and any alternative offered
  - any refusal of an offer of vaccination
  - details of consent and the person who gave the consent
  - the batch number, expiry date and the title of the vaccination
  - the date of administration of the vaccine
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- the site and route of administration
- any adverse reactions to the vaccine
- name of immuniser.

- regardless of the setting where the vaccine is administered, the parent held record should be updated. The individual record which 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.

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.

4.20 Neonatal BCG uptake data is collected through the KC50 system and is reported annually via the Information Centre reports.

- Any reported adverse incidents, errors or events during or post vaccination must follow determined procedures in addition teams must keep a local log of reports and discuss such events with the local immunisation co-ordinator.

- Suspected adverse reactions must be reported to the MHRA via the Yellow Card Scheme [www.mhra.gov.uk/yellow](http://www.mhra.gov.uk/yellow) card, including the brand number and batch
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number in addition to following local and nationally determined procedures, including reporting through the NHS.

- 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 HPA *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
- ensure that all staff are registered to receive *Vaccine Update* (http://immunisation.dh.gov.uk/vu-190-jun-12/)
- ensure that all staff are aware of the importance of and can access the CMO/Chief Nursing Officer/Chief Pharmaceutical Officer (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 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 co-ordinator) and immunisation system leader
- there is regular monitoring and audit of the immunisation programme, including the establishment and review of a risk register as a routine part of clinical governance arrangements, in order to assure the NHS CB of the quality and integrity of the service
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- for providers to 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
- that NHS CB 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

4.24 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:
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- 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.

4.25 Providers should also consider the following suggestions:

- 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 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 co-ordinator, based in the Local Area Team (LAT) 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
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- 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 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.

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:

- **Green Book – Immunisation against infectious disease** (DH 2006)
  
  www.dh.gov.uk/publichealth.immunisation.greenbook

- **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)
  

- **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)
  
  http://immunisation.dh.gov.uk/category/letters/

- **ImmForm information**
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http://immunisation.dh.gov.uk/immform-helpsheets/

- British National Formulary
  
  http://www.bnf.org/bnf/index.htm

- JCVI (Joint Committee on Vaccinations and Immunisations)
  
  http://www.dh.gov.uk/ab/JCVI/index.htm?ssSourceSiteId=en

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

- Resuscitation Council – UK guidelines
  
  http://www.resus.org.uk/pages/guide.htm

- WHO – World Health Organization – Immunisations
  
  http://www.who.int/topics/immunization/en/

- NICE – Shared learning resources:
  
  http://www.nice.org.uk/usingguidance/sharedlearningimplementingniceguidance/examplesofimplementation/eximpresults.jsp?o=575

- Hepatitis B antenatal screening and newborn immunisation programme/
  