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Public health functions to be exercised by NHS England

Service specification No.3
Respiratory syncytial virus (RSV) programme
Public health functions to be exercised by NHS England service specification no 03: Respiratory syncytial virus

This specification is part of an agreement made under the section 7A of the National Health Service Act 2006. It sets out requirements for an evidence underpinning a service to be commissioned by NHS England for 2014-15. It may be updated in accordance with this agreement

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Public health functions to be exercised by NHS England

Service specification No.3
Respiratory syncytial virus (RSV) programme

Prepared by Public Health England
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Service specification No.3

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 RSV immunisation programme

1.1. This document relates to the respiratory syncytial virus (RSV) vaccine, which protects high risk babies from catching respiratory syncytial virus which can cause serious illness and death. Those most at risk of developing severe, and occasionally fatal, RSV infection are very young infants born prematurely who have predisposing conditions such as chronic lung disease (CLD), congenital heart disease (CHD) or children who are immunodeficient. This vaccine is usually delivered in a secondary care maternity setting. The purpose of the service specification is to enable NHS England to commission RSV immunisation services of sufficient quantity and quality. This means achieving high coverage in high risk groups as outlined in *Immunisation against infectious disease* (known as ‘The Green Book’).

1.2. 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.

1.3. 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 RSV vaccine across England. It is important to note that this programme can change and evolve in 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.

1.4. *Immunisation against infectious disease* the ‘Green Book’, a UK document, 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, all official public health letters and reflected in the commissioning of immunisation programmes. This specification must also be read in conjunction with additional evidence, advice and recommendations issued by the JCVI (Joint Committee on Vaccination and Immunisation).


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

Background

2.1. Immunisation is one of the most successful and cost effective public health interventions and a cornerstone of public health. High immunisation rates are key to preventing the spread of infectious disease, complications and possible early death among individuals and protecting the population’s health through both individual and herd immunity.

2.2. The RSV vaccine is routinely used to protect babies who are at high risk from developing the virus. RSV infection is a clearly identified winter virus, usually occurring in the UK within the period October to March with most infections occurring in a relatively short epidemic of about six weeks. Therefore the vaccine is offered during the winter season. Since the introduction of the RSV vaccine, levels of neonatal RSV in the UK are very low (Green Book – Ch 27a).

RSV

2.3. RSV is a common cause of respiratory tract infections. It usually causes a mild self-limiting respiratory infection in adults and children, but it can be severe in infants who are at increased risk of acute lower respiratory tract infection. RSV is best known for causing bronchiolitis in infants.

2.4. RSV is highly communicable. The incubation period varies from two to eight days. The virus is spread from respiratory secretions through close contact with infected persons via respiratory droplets or contact with contaminated surfaces or objects. By two years of age, nearly all children have been infected by RSV at least once (Henderson et al., 1979). Previous infection by RSV may only confer partial immunity to RSV and so individuals may be infected repeatedly with the same or different strains of RSV (Oshansky et al., 2009).

2.5. Predisposing factors for RSV infection include prematurity, cardiopulmonary disease, immunodeficiency, and may also include other factors such as tobacco exposure, day care attendance, overcrowding, lack of breastfeeding, and admission to hospital during the RSV season. Those infected by RSV experience a range of symptoms such as rhinitis (runny nose, sneezing or nasal congestion), cough, shortness of breath, fever, lethargy and decreased appetite. Symptoms can progress to croup, bronchiolitis and acute lower respiratory tract infection. Ear infections may also occur in children (Black, 2003).

2.6. The RSV vaccination is recommended for use in all infants in the following groups:
   - pre-term infants who have chronic lung disease (CLD) at the chronological ages at the start of the RSV season and gestational ages at birth covered within the shaded area of Table 1, Figure 5. The definition of CLD is oxygen dependency from at least 28 days from birth. Therefore, infants under one month of chronological are excluded.
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- pre-term infants who have haemodynamically significant, acyanotic congenital heart disease (CHD) at the chronological ages at the start of the RSV season and gestational ages covered within the shaded area in Table 1, Figure 5 featured in the Green Book

2.7. RSV vaccination should be considered during the RSV season for the following groups of infants:

- all children under the age of 24 months who have severe combined immunodeficiency syndrome (SCID), until immune reconstituted;
- all children who are on long term ventilation (LTV) aged under 12 months at the start of the RSV season and,
- all children who are on LTV aged under 24 months at the start of the RSV season with additional co-pathology (heart disease/pulmonary hypertension, intrinsic lung disease (as reflected by oxygen dependency).

2.8. A tool to assess when the use of the RSV neonatal vaccine is recommended in the groups of infants identified above is available on the Department of Health website at http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publichealth/Immunisation/Keyvaccineinformation/DH_120246

RSV – key details

2.9. The key details are that:

- RSV is a common cause of respiratory tract infections which can cause serious illness or death to premature babies the risk of acquiring RSV while in a neonatal unit is low, those babies at risk should be given the vaccine 24 to 48 hours before being discharged from hospital
- it should only be administered to at risk babies during the start of the RSV season (calendar week 40)
- a maximum of five doses should be given one month apart from the beginning of the RSV season. Chapter 27a of the Green Book provides key details on when the vaccine is recommended and scheduling.
3. Scope

Aims
3.1. The aim of the neonatal RSV vaccine programme is to protect at risk babies from developing RSV which can cause serious illness and death.

Objectives
3.2. The aim will be achieved by delivering a targeted 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 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 RSV vaccine programme aims to:

- protect the health of at risk babies
- reduce the number of preventable infections
- achieve high coverage across the indicated high risk groups
- 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 the aspiration of offering RSV vaccine to all at risk babies in accordance with the Green Book and other official DH/PHE guidance

Wider health outcomes
3.5. The national immunisation programme supports the commitment made in the *NHS Constitution* that everyone in England has ‘the right to receive the vaccinations that the Joint Committee on Vaccination and Immunisation [JCVI] recommends that you should receive under an NHS provided national immunisation programme.’
3.6. This right is set out in the *NHS Constitution* 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 their own health, as well as that of their family and community.

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

3.9. The immunisation programme also works towards achieving The World Health Organization’s (WHO) *Global immunisation vision and strategy* (2006) which is a ten-year framework aimed at controlling morbidity and mortality from vaccine preventable diseases.
4. Service description / care pathway

Roles

4.1. NHS England is responsible for the commissioning of local provision of immunisation services and the implementation of new programmes though general practice and all other providers. It is accountable to the Secretary of State for Health for delivery of those services. Other bodies in the new comprehensive health system also have key roles to play and are vital in ensuring strong working relationships.

4.2. Public Health England (PHE) undertakes the purchase, storage and distribution of vaccines on a national level. It, together with the HSCIS, holds surveillance and coverage data and has the public health expertise for analysing the coverage of, and other aspects of, immunisation services. It is also responsible for the implementation of the national immunisation schedule, including the national communication strategy, setting standards and following recommendations as advised by JCVI and other relevant organisations.

4.3. Directors of public health (DsPH) based in local authorities play a key role in providing independent scrutiny and challenge and publish reports on the health of the population in their areas, which could include information on local immunisation services and views on how immunisation services might be improved. NHS England should expect to support 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 RSV vaccine programme, which can be delivered in a variety of healthcare settings, based on that best practice that NHS England must use to inform local commissioning, contracts and service delivery. There is also scope to enable NHS England and providers to enhance and build on specifications to incorporate national or local service aspirations that may include increasing local innovation in service delivery. It is essential, in order to promote a nationally aligned, high-quality programme focusing on improved outcomes, increasing coverage and local take-up that all the following core elements are included in contracts and specifications.

4.5. The following elements must be covered:
   • target population
   • vaccine schedule
   • consent
   • assessment prior to immunisation
   • vaccine administration
   • vaccine storage and wastage
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- 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.


Target population

4.7. Providers will be required to make the RSV vaccine available during the RSV season to:

- pre-term infants who have chronic lung disease (CLD) at the chronological ages at the start of the RSV season and gestational ages at birth as detailed within Green Book. The definition of CLD is oxygen dependency from at least 28 days from birth. Therefore, infants under one month of chronological are excluded

- pre-term infants who have haemodynamically significant, acyanotic congenital heart disease (CHD) at the chronological ages at the start of the RSV season and gestational ages covered within the shaded area in Table featured in the Green Book

4.8. RSV vaccination should also be considered during the RSV season for the following groups of infants:

- all children under the age of 24 months who have severe combined immunodeficiency syndrome (SCID), until immune reconstituted

- all children who are on long term ventilation (LTV) aged under 12 months at the start of the RSV season, and

- all children who are on LTV aged under 24 months at the start of the RSV season with additional co-pathology (heart disease/pulmonary hypertension, intrinsic lung disease (as reflected by oxygen dependency).
Vaccine schedule


Consent

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

4.11. Therefore providers are required to ensure that:

- consent is obtained prior to starting any treatment
- consent is given voluntarily and freely
- individuals giving consent on behalf of young children must be capable of consenting to the immunisation in question
- for 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
- relevant resources (leaflets/factsheets etc.) in an appropriate format are be 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. In some cases this may involve the use of a trained interpreter. Professionals must be sufficiently knowledgeable about the disease and vaccine and to be able to answer any questions with confidence
- The patient has access to the patient information leaflet (PIL).

Requirements prior to immunisation

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

- systems in place to assess eligible individuals for suitability by a competent individual prior to each immunisation
- 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
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- systems in place to identify, follow-up and offer immunisation to eligible at risk babies, this is particularly important as a series of the RSV vaccine is given during the RSV season
- 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 England is required to ensure the provider adheres to the following:

- professionals involved in administering the vaccine, have the necessary skills, competencies and annually updated training with regard to vaccine administration and the recognition and initial treatment of anaphylaxis
- regular training and development (taking account of national standards) is routinely available. Training is likely to include diseases, vaccines, delivery issues, consent, cold chain, vaccine management and anaphylaxis
- the professional lead must ensure that all staff are legally able to supply and/or administer the vaccine by either:
  - working under an appropriate patient group direction (PGD)
  - working from a patient specific direction (PSD)/prescriptions
  - working as a nurse prescriber (if appropriate).

Vaccine storage and wastage

4.14. 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 reflecting DH national protocols (Chapter 3 of the Green Book and the ‘Guidelines for maintaining the vaccine cold chain’) and includes:
  - how to maintain accurate records of vaccine stock
  - how to record vaccine fridge temperatures
  - what to do if the temperature falls outside the recommended range
    
    

- ensure that all vaccines are delivered to an appointed place
- ensure that at least two named individuals are responsible for the receipt and safe storage of vaccines in each general practice/premise
• ensure that approved pharmaceutical grade cold boxes are used for transporting vaccines

• 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 local coordinators, PHE Screening and Immunisation Area Team and NHS England.

Vaccine Ordering

4.15. Providers must ensure an adequate supply of vaccine from nationally approved pharmaceutical wholesalers who will have local arrangements for the delivery of these vaccines. Synagis® (the RSV vaccine) is manufactured by Abbott SRL, Italy, and supplies can be obtained in England, Wales and Scotland from Abbott UK (Tel: 01795 580303).

Documentation

4.16. Accurate recoding 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.

• regardless of the setting of where the vaccine is administered, the parent-held record must be updated. The 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

4.17. Reporting requirements are as follows:

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

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

- providers are required to report cases of suspected vaccine preventable diseases to the local PHE centre.

- 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.

- Any cold chain failures must be documented as an incident and reported to the local immunisation co-ordinator, and registered on Immform as appropriate.

Staffing including training

4.18. To deliver a national immunisation programme it is essential that all staff are appropriately trained. NHS England must ensure that providers:

- have an adequate number of trained, qualified and competent staff to deliver a high quality immunisation programme in line with best practice and national policy.

- are covered by appropriate occupational health policies to ensure adequate protection against vaccine preventable diseases (e.g. measles, flu and hepatitis B);

- have had training (and annual updates) for all staff with regard to the recognition and initial treatment of anaphylaxis.

- ensure that all staff are familiar with and have online access to the latest edition of the Green Book.

- ensure that all staff are registered to receive Vaccine Update which includes notifications of updates to the Green Book. [https://www.gov.uk/government/organisations/public-health-england/series/vaccine-update](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: https://www.gov.uk/government/organisations/public-health-england/series/immunisation

Premises and equipment
4.19. Appropriate equipment and 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 and their carers.

Governance
4.20. It will be essential to ensure that there are clear lines of accountability and reporting to assure the ongoing quality and success of the national programme. Commissioning arrangements will ensure that:

- there is a clear line of accountability from local providers to NHS England
- at the provider level there is appropriate internal clinical oversight of the programme’s management and a nominated lead for immunisation
- provider governance is overseen by a clinical lead (for example, the local immunisation coordinator) and immunisation system leader
- there is regular monitoring and audit of the immunisation programme, including the establishment of a risk register as a routine part of clinical governance arrangements, in order to assure NHS England of the quality and integrity of the service
- for providers to supply evidence of clinical governance and effectiveness arrangements on request for NHS England or its local offices
- PHE will alert NHS England to any issues that need further investigations
- the provision of high quality, accurate and timely data to relevant parties including PHE, NHS England and local authorities (LAs) is a requirement for payment
- data will be analysed and interpreted by PHE and any issues that arise to be shared quickly with NHS England and others
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- local co-ordinators will document, manage and report on programmatic or vaccine administration errors, including serious untoward incidents (SUJs), 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
  - fail-safe procedures
  - communications
  - ongoing risk management
  - health and safety
  - insurance and liability.

Service improvement

4.21. 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.

4.22. NICE guidelines (NICE 2009 Reducing differences in the uptake of vaccines) highlight evidence to show that there are particular interventions, which can increase immunisation rates and reduce inequalities. Providers must also consider the following suggestions:

- up-to-date patient reminder and recall systems (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 coordinators 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

4.23. The immunisation programme is dependent upon systematic relationships between stakeholders, which include vaccine suppliers, primary care providers, NHS England as well as secondary care neonatal settings. The NHS England Area Screening and Immunisation Team (SIT) Area Team will be expected to take the lead in ensuring that inter-organisational systems are in place to maintain the quality of the immunisation pathway. This will include, but is not limited to:

- ensuring all those involved in the pathway are sure of their roles and responsibilities
- developing joint audit and monitoring processes
- agreeing joint failsafe mechanisms, where required, to ensure safe and timely processes along the whole pathway
- contributing to any initiatives led by NHS England/PHE to develop/improve 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

4.24. It will be important to develop and implement communication strategies to support both the introduction of new vaccines and the maintenance of existing programmes. Such strategies may be developed on a national basis, local strategies may also be further developed to support national programmes or address specific issues.
5. Service standards and guidance

5.1. To support the delivery of an effective and high quality childhood immunisation programme NHS England and providers must refer to and make comprehensive use of the following key resources:


- **Quality criteria for an effective immunisation programme** (HPA, 2012) [http://www.hpa.org.uk/Publications/InfectiousDiseases/Immunisation/1207Qualitycriteriaforimmprogramme/](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/Immunisation/1207Qualitycriteriaforimmprogramme](http://www.hpa.org.uk/Publications/InfectiousDiseases/Immunisation/1207Qualitycriteriaforimmprogramme)


- **British National Formulary** [http://www.bnf.org/bnf/index.htm](http://www.bnf.org/bnf/index.htm)

- **JCVI (Joint Committee on Vaccination and Immunisation)** [https://www.gov.uk/government/policy-advisory-groups/joint-committee-on-vaccination-and-immunisation](https://www.gov.uk/government/policy-advisory-groups/joint-committee-on-vaccination-and-immunisation)


