UK Health Security Agency

NHS

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Respiratory Syncytial Virus (RSV) vaccine Patient Group Direction (PGD)

This PGD is for the administration of RSV vaccine to individuals eligible for the national vaccination programme aged 65 to 74 years with a qualifying health condition, 75 years and over or resident in a care home for older adults and for pregnant individuals from week 28 of pregnancy.

This PGD is for use by registered healthcare practitioners identified in section 3, subject to any limitations to authorisation detailed in section 2.

Reference no:	RSV vaccine PGD
Version no:	v3.0
Valid from:	1 September 2026
Review date:	28 February 2029
Expiry date:	31 August 2029

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2**.

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 (characteristics of staff). **Sections 2 and 7 can be amended within the designated editable fields provided, but only for the purposes for which these sections are provided, namely the responsibilities and governance arrangements of the NHS commissioned organisation using the PGD. The fields in sections 2 and 7 cannot be used to alter, amend or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations. The legal validity of this PGD is contingent on those authorising sections 2 and 7 complying with the above.**

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

Individual practitioners must be authorised by name, to work according to the current version of this PGD by signing section 7. A manager with the relevant level of authority should also provide a countersignature unless by exception there are arrangements for self-declaration. Providers are also reminded to ensure vaccination is in line with the contractual arrangements and limitations of service provision agreed with the service commissioner as well as the criteria for inclusion.

[1] This includes any relevant amendments to legislation.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of the UKHSA PGD templates for authorisation can be found from:
Immunisation patient group direction (PGD) templates

Any concerns regarding the content of this PGD should be addressed to:
immunisation@ukhsa.gov.uk.

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to:
For East Anglia email: England.eaimms@nhs.net
For Essex email: England.essexatimms@nhs.net
For Bedfordshire, Hertfordshire, Luton and Milton Keynes email: England.immsqa@nhs.net

Change history

Version number	Change details	Date
v1.0	New UKHSA PGD for the vaccination of adults over 75 and under 80 years of age (including those turning 80 years of age in the catch-up campaign) and for pregnant individuals from week 28 of pregnancy, against respiratory syncytial virus (RSV)	24 July 2024
v2.0	UKHSA RSV PGD updated as follows: • inclusion criteria extended for the older adults' programme to include immunisation of individuals aged over 80 years and residents of older adult care homes, as recommended by JCVI • removal of the exclusion criteria for adults who have reached 80 years of age • reinforcing that the vaccine may be given to pregnant individuals of any age, including those aged under 18 years • adjustment of the dose and frequency of administration advice for older adults, to include residents in older adult care homes • inclusion of the MHRA Drug Safety Update from July 2025, advising of a small increased risk of Guillain Barré syndrome in older adults aged over 60 years. Adverse drug reactions updated in line with the Abrysvo® summary of product characteristics • advice that COVID-19 vaccine may be safely co-administered with RSV vaccine in line with the update to the RSV chapter of the Green Book • clarification that older adults immunised before the age of 75 years under the private market remain eligible for an NHS dose of vaccine.	16 February 2026
v3.0	UKHSA RSV PGD updated as follows: • inclusion criteria extended in the older adults' programme to incorporate updated JCVI recommendations for those with underlying health conditions, aged 65 to 74 years of age	28 July 2026

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Christina Wilson Lead Pharmacist - Immunisation Programmes Division, UKHSA		20 July 2026
Doctor	Dr Mary Ramsay CBE Director of Public Health Programmes and Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		20 July 2026
Registered Nurse (Chair of Expert Panel)	Helen Eley Lead Immunisation Nurse Specialist, Immunisation Programmes, UKHSA		20 July 2026

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD and Protocol Policy. It has been ratified by the UKHSA Medicines Governance Committee.

Working Group advisory member

Dr Conall Watson	Consultant Epidemiologist and RSV programme lead, Immunisation and Vaccine Preventable Diseases Division, UKHSA

Expert Panel (continued overleaf)

Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Helen Beynon	Clinical Advisor, Immunisation Clinical Advice Response Service (ICARS), NHS England (London)
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHS England (Midlands)
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy, NHS England (national team)
Rosie Furner	Advanced Specialist Pharmacist - Medicines Governance (Patient Group Directions and Medicines Mechanisms), NHS Specialist Pharmacy Service
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Primary Care Based, Southbourne Surgery
Shilan Ghafoor	Lead Pharmacist Medicines Governance, Medicines Governance, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board
Gemma Hudspeth	Senior Health Protection Practitioner, North East Health Protection Team, UKHSA
Elizabeth Luckett	Senior Screening & Immunisation Manager, Screening and Immunisation Team – Kent and Medway, NHS England (South East)
Dr Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation Programmes Division, UKHSA
Briony Mason	Vaccination Manager and Professional Midwifery Advocate, Vaccination and Screening, NHS England (West Midlands)

Tushar Shah	Lead Pharmacy Adviser, NHS England (London)

2. Organisational authorisations

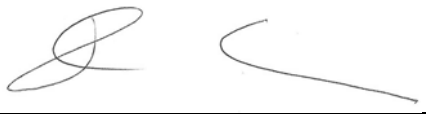
The PGD is not legally valid until it has had the relevant organisational authorisation.

The fields in this section cannot be used to alter, amend or add to the clinical or other PGD content (sections 3 to 6 inclusive). Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations. See page one for full details.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England East of England authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
NHS England East of England commissioned immunisation services or NHS Trust providing immunisation services covering Norfolk, Suffolk, Cambridgeshire, Peterborough, Essex, Southend-on-Sea, Thurrock, Bedfordshire, Hertfordshire, Luton and Milton Keynes local authorities, and Health and Justice facilities where NHS England East of England is the commissioner.
Limitations to authorisation
None.

Organisational Approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director	**Dr Ian Gibson**		**07/08/2026**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Screening and Immunisation Lead	**Dr Eleanor Powers**		**7 August 2026**
Pharmacist	**Sarah Cavanagh**		**7 August 2026**
Screening and Immunisation Coordinator	**Melanie Vincent**		**3 August 2026**

Local enquiries regarding the use of this PGD may be directed to

For East Anglia email: England.eaimms@nhs.net
For Essex email: England.essexatimms@nhs.net

For Bedfordshire, Hertfordshire, Luton and Milton Keynes email: England.immsqa@nhs.net

For the Health Protection Team email EastofEnglandhpt@ukhsa.gov.uk .

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration required	**All practitioners should only administer vaccinations where it is within their clinical scope of practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the sections below.** Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) (Note: this PGD is not relevant to privately provided community pharmacy services) • dieticians, occupational therapists, paramedics, physiotherapists, podiatrists and radiographers currently registered with the Health and Care Professions Council (HCPC) Check section 2 (Limitations to authorisation) to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply and administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the Green Book) and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the national minimum standards and core curriculum for vaccination training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines and management of the cold chain • must be competent in the appropriate administration method for the vaccine listed in this PGD • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements (continued over page)	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).

Continued training requirements (continued)	Practitioners should be constantly alert to any subsequent recommendations from UKHSA, NHS England and other sources of medicines information. Note: the most current national recommendations should be followed, but a patient specific direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals as detailed in the inclusion criteria, against RSV. Immunisation is indicated in accordance with the recommendations given in the RSV chapter of Immunisation Against Infectious Disease: the Green Book and the RSV letter.
Criteria for inclusion	**1. Pregnant individuals of any age:** • from week 28 of pregnancy (see dose and frequency of administration section for operational recommendations) **2. Older adults' programme:** • **individuals aged 65 to 74 years of age with the following underlying health conditions:** **(i) chronic respiratory disease including:** - poorly controlled asthma[2] (as defined in Table 1 of the RSV chapter of the Green Book) - chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema - bronchiectasis - cystic fibrosis - interstitial lung fibrosis - pneumoconiosis - bronchopulmonary dysplasia **(ii) immunosuppression – either due to disease or treatment, as defined in Table 1 of the RSV chapter of the Green Book** • **all residents in a care home for older adults including** those under 75 years of age • **all individuals 75 years of age and over** These individuals should be vaccinated on or after (but not before) their 75th birthday. **There is no upper age limit to the offer of vaccination.**
Criteria for exclusion[3] (continued over page)	Individuals for whom no valid consent has been received (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained). For further information on consent, see chapter 2 of the Green Book. Several resources are available to inform consent (see written information to be given to individual, parent or carer section). **Exclusion criteria for all individuals:** • have had a confirmed anaphylactic reaction to Abrysvo® or to any of its active ingredients or excipients (see product SPC)

[2] Poorly controlled asthma is defined as 2 or more courses of oral corticosteroids in the preceding 2 years, or prescribed maintenance oral corticosteroids or one or more admissions to hospital for asthma in the preceding 2 years.

[3] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required.

Criteria for exclusion[4] (continued)	• are suffering from acute severe febrile illness (the presence of a minor illness without fever or systemic upset is not a contraindication for immunisation) **Exclusion criteria for pregnant individuals:** • are less than 28 weeks pregnant • have already given birth, such that passive immunity is not possible • have already received a valid dose of RSV under the NHS programme during the current pregnancy **Exclusion criteria for older adults aged 65 to 74 years of age with eligible underlying health conditions:** • have not yet reached their 65th birthday • have already received a dose of RSV vaccine under the NHS programme **Exclusion criteria for older adults aged 75 years and over:** • have not yet reached their 75th birthday • have already received a dose of RSV vaccine under the NHS programme **Exclusion criteria for residents of care homes for older adults:** • have already received a dose of RSV vaccine under the NHS programme
Cautions including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all RSV clinics (see chapter 8 of the Green Book and advice issued by the Resuscitation Council UK). The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. However, vaccination should proceed in accordance with national recommendations. Additional dose(s) are not currently recommended in individuals with immunosuppression. Syncope (fainting) can occur following, or even before, any vaccination, especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.
Action to be taken if the individual is excluded (continued over page)	Individuals who have had a confirmed anaphylactic reaction to a previous dose of RSV vaccine or to any components of the vaccine should be referred to a clinician for specialist advice and appropriate management. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged at the earliest opportunity. However, vaccination should not be deferred in the presence of a minor infection, such as a cold. Pregnant individuals who have not yet reached week 28 of pregnancy should be advised that current evidence suggests protection for their baby is most effective when the RSV vaccine is given at week 28 of pregnancy (or as soon as possible after) and should be offered an appointment. The vaccine may be given up to birth.

[4] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required.

Action to be taken if the individual is excluded (continued)	Individuals who are not of eligible age for the RSV vaccination programme should be advised when they will become eligible. In the older adult programme, there is no current evidence to support revaccination. If a dose of vaccine has been previously administered under the NHS older adult programme to an individual, they should be reassured that no further protection against RSV is currently advised (see special considerations and additional information - repeating doses). Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Inform or refer to the individual's GP or a prescriber as appropriate.
Action to be taken if the individual, parent or carer declines treatment	Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications of the disease. Document advice given and the decision reached. Inform or refer to the individual's GP or a prescriber as appropriate.
Arrangements for referral for medical advice	As per local policy.

5. Description of treatment

Name, strength and formulation of drug	**Abrysvo®** powder and solvent for solution for injection: respiratory syncytial virus vaccine (bivalent, recombinant).
Legal category	Prescription Only Medicine (POM).
Black triangle▼	Yes. As a new vaccine product, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of associated adverse drug reactions. All suspected adverse drug reactions should be reported using the MHRA Yellow Card Scheme.
Off-label use	Administration of Abrysvo® by deep subcutaneous injection to individuals with a bleeding disorder is off-label, but appropriate where the intramuscular route is unsuitable and is in line with advice in chapter 4 of the Green Book. See route and method of administration section below. The vaccine should be stored according to the conditions detailed in the storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to Vaccine Incident Guidance. Where vaccines are assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD. Where a vaccine is recommended off-label, as part of the consent process consider informing the individual, parent or carer that the vaccine is being offered outside of product licence but in accordance with national guidance. **Pregnant individuals** Abrysvo® is licensed for administration to pregnant individuals between weeks 28 and 36 of gestation. Offering Abrysvo® beyond 36 weeks gestation and up to birth, is off-label but in line with national guidance. For pregnant individuals, the Abrysvo® SPC advises a 2 week minimum interval between administration of Abrysvo® and pertussis-containing vaccines, due to some evidence that co-administration of both vaccines may weaken the response to one of the pertussis components, although the clinical significance of this response is unclear. As the pertussis and RSV vaccines are recommended at different stages of pregnancy, RSV and pertussis vaccines should not be routinely scheduled for co-administration. However, where an individual becomes eligible for the RSV vaccine but has not yet had the pertussis-containing vaccine, it is recommended that the pertussis-containing vaccine should be given at the same time as the RSV vaccine to avoid further delay in conferring passive protection to the infant. Please also refer to the drug interactions section. The advice to repeat the dose of Abrysvo® where it has been inadvertently administered to individuals who are less than 16 weeks pregnant is off-label but in line with recommendations in the relevant information for healthcare practitioners document. See special considerations and additional information section.

Route and method of administration	The vaccine must be prepared in accordance with the manufacturer's instructions prior to administration. Following reconstitution, Abrysvo® should be given as a single dose by intramuscular (IM) injection, preferably into the deltoid muscle of the upper arm. When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. Other vaccines should be given at separate sites, preferably into different limbs. If given into the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. Individuals with bleeding disorders may be vaccinated intramuscularly if in the opinion of a clinician familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can be vaccinated via the intramuscular route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or other treatment is administered. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual, parent or carer should be informed about the risk of haematoma from the injection. For individuals with an unstable bleeding disorder or where the intramuscular route is otherwise deemed unsuitable, vaccines normally given by the intramuscular route may be given by deep subcutaneous injection to reduce the risk of bleeding (see the Green Book chapter 4). The vaccine must not be given via the intradermal or intravascular route. Abrysvo® forms a clear and colourless solution upon reconstitution. The vaccine components should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, do not administer the dose and discard the vaccine in accordance with local procedures. Do not mix the vaccine with other vaccines or other medicinal products. When adding the diluent to the powder, the vial should be gently swirled until the powder has completely dissolved. The vaccine SPC provides further guidance on preparation and administration.
Dose and frequency of administration (continued over page)	**Single 0.5ml dose per administration.** **Pregnant individuals** Single 0.5ml dose of Abrysvo®, from week 28 of pregnancy. For clinical reasons, vaccination is best offered at the time of the antenatal appointment at week 28 of pregnancy. Individuals remain eligible up to birth.

Dose and frequency of administration (continued)	A dose of RSV vaccination is indicated for each pregnancy, irrespective of the interval between successive pregnancies. **Adults eligible for the older adults' programme** Single 0.5ml dose of Abrysvo®.
Duration of treatment	**Pregnant individuals** A dose of Abrysvo® is indicated for each pregnancy. **Adults eligible for the older adults' programme** A single dose of Abrysvo® should be given.
Quantity to be supplied and administered	A single dose of 0.5ml.
Supplies	Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book chapter 3).
Storage	Store between +2°C to +8°C. Store in original packaging to protect from light. Do not freeze. Within the context of a temperature excursion, the unopened, unpunctured Abrysvo® vial is stable for 5 days when stored at temperatures between +8°C and +30°C. At the end of this period, the vial should be used or discarded. After reconstitution, chemical and physical in-use stability for Abrysvo® has been demonstrated for 4 hours between +15°C and +30°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the user's responsibility. In the event of an inadvertent or unavoidable deviation of these conditions, vaccines that have been stored outside the conditions stated above should be quarantined and risk assessed on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance. Contact the manufacturer where more specific advice is required about managing a temperature excursion.
Disposal	Follow local clinical waste policy and operating procedures to ensure safe and secure waste disposal. Equipment used for immunisation, including used vials, ampoules, or syringes, should be disposed of safely in a UN-approved puncture-resistant sharps box, according to local authority arrangements and NHS England guidance (HTM 07-01): safe and sustainable management of healthcare waste.

Drug interactions	The immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. **Interactions in older adults** Influenza vaccines should not be routinely co-administered on the same day as RSV vaccines in individuals receiving the vaccine under the older adults' programme. Studies suggest a lowered immune response to both RSV and influenza components when co-administered with adjuvanted influenza vaccines. No specific minimum interval is advised. If immediate protection is necessary or there are concerns the individual will not return for a second appointment, then Abrysvo® may be given at the same time as the influenza vaccine. Abrysvo® may be given with other vaccines routinely administered in older individuals eligible for the RSV vaccination programme, such as shingles, COVID-19 and pneumococcal vaccines. **Interactions in pregnant individuals** Abrysvo® should not be routinely scheduled for co-administration with the pertussis vaccine. However, if a pregnant individual presents from week 28 of pregnancy or beyond and has not received either Abrysvo® or Tdap (or dTaP/IPV), the benefit of offering both due vaccines at the same appointment outweighs the risk of not protecting the unborn infant against pertussis and RSV infection via passive immunity and avoids the risk of the individual not returning for a later appointment. This advice is outside the 2 week interval recommended between the vaccines in the Abrysvo® SPC and as outlined in the off-label section. RSV and influenza vaccines may be safely co-administered to pregnant individuals. Pregnant individuals eligible to receive the COVID-19 vaccine may also have this safely co-administered with the RSV vaccine. Pregnant individuals requiring treatment with Anti-D immunoglobulin at 28 to 30 weeks gestation may have their RSV vaccine administered at the same appointment. A detailed list of drug interactions associated with Abrysvo® is available from the product's SPC.
Identification and management of adverse reactions (continued over page)	Very common reactions include vaccination site pain, headache and myalgia. Fatigue is reported in individuals aged 18 years and over. Other commonly reported reactions include injection site redness and swelling. Hypersensitivity reactions can occur but are very rare. **Small increased risk of Guillan-Barre syndrome in older adults (over 60 years)** In July 2025, the Medicines and Healthcare products Regulatory Agency (MHRA) advised of a small increase in the risk of Guillain-Barré syndrome (GBS) following immunisation with RSV vaccines (including Abrysvo®) in adults aged 60 years and older. Healthcare practitioners are advised to be attentive to signs and symptoms of GBS in individuals who have been immunised with Abrysvo® to ensure early and correct diagnosis, rule out other causes and initiate adequate supportive care and treatment, as early

Identification and management of adverse reactions (continued)	medical care can reduce severity and improve outcomes. Individuals receiving the vaccine should be advised to seek immediate medical attention if they have symptoms such as tingling, numbness, weakness, sharp pain or pins and needles in their hands, feet, arms or legs. An MHRA Yellow Card should also be completed (see reporting procedure of adverse reactions). Individuals should continue to be reassured that the benefits of vaccination against RSV outweigh the risk of developing GBS in older adults and that the incidence of occurrence is still very rare – the incidence of excess GBS cases is estimated to be one case for every 40,000 to 100,000 administered doses. No such effect has been seen in pregnant women. A detailed list of adverse reactions associated with the vaccine is available from the product's SPC.
Reporting procedure of adverse reactions	Healthcare professionals, individuals, parents and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme, or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to the vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to individual, parent or carer	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the medicine. Recommended patient information materials to accompany the RSV vaccination programmes are outlined on the RSV vaccination programme website, including: • your guide to the RSV vaccine for older adults • a guide to RSV vaccination for pregnant women For resources in accessible formats and alternative languages, please visit Find public health resources. Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility by providing the medicine name and product code number, as listed on the product SPC.
Advice and follow up treatment	Inform the individual, parent or carer of side effects and their management. Give advice regarding normal reaction to the injection, for example redness and pain at the injection site. Individuals receiving vaccines should be advised to seek immediate medical attention if they have symptoms such as tingling, numbness, weakness, sharp pain or pins and needles in their hands, feet, arms or legs, as this may be suggestive of GBS (see also identification and management of adverse reactions, above). The individual, parent or carer should be advised to seek medical advice in the event of a severe adverse reaction and report this via the Yellow Card reporting scheme. When administration is postponed, advise the individual, parent or carer when to return for vaccination.

Special considerations and additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1,000 injection and access to a telephone at the time of vaccination. **Repeating doses** There is no data on the effectiveness of Abrysvo® before week 24 of pregnancy, as outlined in the SPC. However, if a dose has been inadvertently administered between week 16 and week 27+6 of pregnancy, the dose does not need to be repeated, as based on first principles, maternal antibodies should start to cross the placenta and confer passive immunity from a gestational age of 16 weeks. See the relevant information for healthcare professionals document for further information. When a dose of Abrysvo® has been inadvertently administered before week 16 of pregnancy, a repeat dose should be given from 28 weeks gestation. In both situations, local procedures for medicines error reporting should be followed. Pregnant individuals should be offered a repeat dose of RSV vaccine for any subsequent pregnancies, regardless of the interval between pregnancies. **Note**: administration of a dose of Abrysvo® before week 28 of pregnancy is outside the scope of this PGD and therefore must be administered under a different legal mechanism, such as a PSD. Presently, there is no data to support revaccination of older adults following their first dose. Individuals who have received a dose of RSV vaccine on the private market are still eligible to receive a dose under the routine NHS programme and so there is no requirement to exclude them from invitations for vaccination at the appropriate time. See also criteria for exclusion. **Timing of doses** **(i) in individuals eligible under the older adults' programme** Administering Abrysvo® to eligible individuals before cases of RSV infection reach their seasonal peak maximises the efficacy of the vaccine. Individuals should be encouraged to take up the offer of vaccination as soon as reasonably possible, to reduce their chance of contracting the virus. **(ii) in pregnant individuals** When RSV vaccine is given late in pregnancy, whilst the potential for passive immunity is greatly reduced, the dose will help protect the mother from contracting RSV infection and thereby passing RSV infection onto the infant. Pregnant individuals should be encouraged to take up the offer of vaccination at week 28 of their pregnancy (or as soon as possible after) to maximise production and transplacental transfer of maternal antibodies to their baby.
Records (continued over page)	The practitioner must ensure the following is recorded: • that valid informed consent was given (or a decision to vaccinate was made in the individual's best interests, in accordance with the Mental Capacity Act 2005) • name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) • name of the immuniser

Records (continued)	• name and brand of vaccine • date of administration • dose, form and route of administration of the vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if the individual is excluded or the individual (or parent or carer) declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or password-controlled on e-records). All records should be clear, legible and contemporaneous. This information should be recorded in the individual's GP record. Where vaccination occurs outside the GP setting, appropriate health records should be kept (including on RAVs or other NHS assured point of care systems) and the individual's GP informed. For pregnant women, immunisation should also be documented in the hand-held maternity record. When administered to individuals under 19 years of age, notify the local Child Health Information Service (CHIS) using the appropriate documentation or pathway as required by any local or contractual arrangement. PGDs should be audited as part of an organisation's medicines audit programme. An audit tool is available from NHS Specialist Pharmacy Service (SPS).

6. Key references

Key references	**Respiratory syncytial virus** • Abrysvo® powder and solvent for solution for injection. Summary of Product Characteristics, last updated 4 June 2026 https://www.medicines.org.uk/emc/product/15309/smpc • Immunisation Against Infectious Disease: The Green Book, RSV chapter, last updated 3 June 2026 https://www.gov.uk/government/publications/respiratory-syncytial-virus-the-green-book • Expansion of eligibility to adults aged 65 to 74 years in certain clinical at-risk groups letter, published 1 July 2026 https://www.gov.uk/government/publications/rsv-vaccination-expansion-of-eligibility-to-older-adults-in-certain-clinical-risk-groups/expansion-of-eligibility-to-adults-aged-65-to-74-years-in-certain-clinical-at-risk-groups-letter **General** • NHS England Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Vaccination Training, updated 31 July 2025 https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions, updated 27 March 2017 https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated 4 January 2018 https://www.nice.org.uk/guidance/mpg2/resources • Vaccine Incident Guidance: responding to errors in vaccine storage, handling and administration, updated 7 July 2022 https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

RSV vaccine PGD v3.0 Valid from: 1 September 2026 Expiry: 31 August 2029

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Practitioner

By signing this PGD, you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of [**Insert name of organisation]** for the above named healthcare professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.