UK Health Security Agency

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

This PGD is for the administration of Respiratory Syncytial Virus (RSV) vaccine to individuals eligible for the national vaccination programme aged 75 years and over and for individuals who are pregnant, from week 28 of pregnancy.

This PGD is for the administration of RSV vaccine 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:	v1.00
Valid from:	1 September 2024
Review date:	1 October 2026
Expiry date:	1 April 2027

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 organisation using the PGD. The fields in section 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.**

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, under the current version of this PGD before working according to it.

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

[1] This includes any relevant amendments to legislation.

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

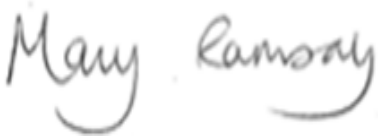
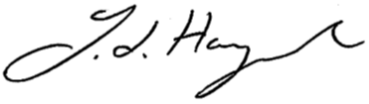
Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: [Contacts listed on page 6 & 7 of this PGD

Change history

Version number	Change details	Date
V1.00	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

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 and Vaccine Preventable Diseases Division, UKHSA		18 July 2024
Doctor	Dr Mary Ramsay CBE Director of Public Health Programmes and Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		18 July 2024
Registered Nurse and Midwife (Chair of Expert Panel)	Greta Hayward Consultant Midwife– Immunisation and Vaccine Preventable Diseases Division, UKHSA		18 July 2024

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 members

Dr Conall Watson	Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Dr Tami Benzaken	Clinical Fellow and Specialist Registrar in Paediatrics, UKHSA
Dr Jonathan Broad	Clinical Fellow and Specialist Registrar in Paediatrics, UKHSA

Expert Panel (continued overleaf)

Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy, NHSE
Rosie Furner	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
Gemma Hudspeth	Senior Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board
Jacqueline Lamberty	Medicines Governance Consultant Lead Pharmacist, UKHSA
Elizabeth Luckett	Senior Screening & Immunisation Manager, NHSE South West

Dr Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Nikki Philbin	Screening and Immunisation Manager, Vaccination and Screening Programmes, NHSE Midlands
Tushar Shah	Lead Pharmacy Adviser, NHSE London

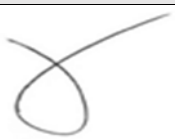
2. Organisational authorisations

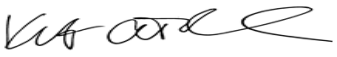
The PGD is not legally valid until it has had the relevant organisational authorisation.

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.

NHSE North East and Yorkshire authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
NHS England (NHSE) commissioned immunisation services or NHS Trust providing immunisation services
Limitations to authorisation
Authorisation is limited to those registered practitioners listed in Section 3 who are employed by organisations/providers commissioned by NHSE North East and Yorkshire (NEY) to deliver immunisation programmes within the whole of the NHSE region of North East and Yorkshire

Organisational Approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Deputy Medical Director: System Improvement and Professional Standards NHS England - North East and Yorkshire	**DrJames Gossow**		**25th July 2024**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Medicines Optimisation Pharmacist Lead, NHS NECS NHS England – North East and Yorkshire	**Kurt Ramsden**		**25th July 2024**
Screening and Immunisation Place Lead Public Health Programme Team – Yorkshire and the Humber NHS England (NE and Yorkshire)	**Laura Brown**		**25th July 2024**

Local enquiries regarding the use of this PGD may be directed to to your local screening and immunisation teams. See area-specific contacts below:

For North East and North Cumbria Area (i.e. Northumberland, Tyne & Wear, Durham Darlington and Tees and North Cumbria) use the following:

NHS England Screening and Immunisation Team:

email england.cane.screeningimms@nhs.net

or NECS Medicine Optimisation Pharmacists: Kurt Ramsden: kurtramsden@nhs.net

or Sue White: sue.white14@nhs.net

Please note - All North East and North Cumbria PGDs can be found at:

https://medicines.necsu.nhs.uk/resources/patient-group-directions/

For Yorkshire and Humber Area use the following:

West Yorkshire - england.wysit@nhs.net

South Yorkshire and Bassetlaw - england.sybsit@nhs.net

North Yorkshire and Humber ENGLAND.NYAHSIT@nhs.net

or the Health Protection Team Acute Response Centre (ARC): Contact Number: 0113 3860 300.

Please note - All Yorkshire and Humber PGDs can be found at: https://www.england.nhs.uk/north-east-yorkshire/our-work/information-for-professionals/pgds /.

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) • paramedics, physiotherapists 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 products 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 Immunisation Training for Registered Healthcare Practitioners • 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 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). Practitioners should be constantly alert to any subsequent recommendations from UKHSA, NHS England (NHSE) and other sources of medicines information.

Continued training requirements (continued)	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 immunisation of individuals, as detailed in the inclusion criteria, against RSV. Immunisation is indicated in accordance with the recommendations given in Chapter 27a of Immunisation Against Infectious Disease: the Green Book, the JCVI statement and the RSV letter.
Criteria for inclusion	**1. Pregnant individuals:** • from week 28 of pregnancy (see dose and frequency of administration section for operational recommendations) **2. Older adults:** **(i) Prospective programme** • aged 75 years of age on or after 1 September 2024 (that is, with a date of birth (DOB) on or after 1 September 1949). These individuals should be vaccinated on or after (**but not before**) their 75th birthday **(ii) Catch-up campaign** • adults who are aged between 75 and 79 years of age on or before 1 September 2024 (DOB between 1 September 1945 and 31 August 1949). Such individuals remain eligible up to the age of 79 years and 364 days (in other words, up to and including the day before the individual's 80th birthday) • adults who turn 80 years of age between 2 September 2024 and 31 August 2025 (DOB between 2 September 1944 and 31 August 1945) remain eligible up to and including **31 August 2025**
Criteria for exclusion[2] (continued over page)	Individuals who have not given valid consent (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 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) • 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 dose during the current pregnancy **Exclusion criteria for adults aged 75 years and over**: • have not yet reached their 75th birthday

[2] 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 (continued)	• are 80 years of age or over. With the exception of individuals turning 80 years of age during the first year of the programme (as outlined above in the catch-up campaign), individuals are no longer eligible from their 80th birthday
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. 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	In cases where there is confirmed prior anaphylaxis to the vaccine or to any of its excipients, seek the advice of an allergy specialist. In case of postponement due to acute severe febrile illness, advise when the individual may be vaccinated and ensure another appointment is arranged. Pregnant individuals who have not yet reached week 28 of pregnancy should be advised that 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. Individuals who are not of eligible age for the RSV vaccination programme should be advised when they will become eligible or why they are no longer eligible for immunisation. 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 or carer declines treatment	Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained for each administration. 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®** (respiratory syncytial virus bivalent, recombinant), comprising: RSV subgroup A stabilised prefusion F antigen 60 micrograms RSV subgroup B stabilised prefusion F antigen 60 micrograms
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. Vaccines 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 consider, as part of the consent process informing the individual, parent or carer that the vaccine is being offered outside of product licence but in accordance with national guidance. **Older adults** Abrysvo® is licenced for use in adults aged 60 years and older. The advice to administer to adults from the age of 75 years of age is in accordance with the national programme. **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 also 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

(continued over page)

Off-label use (continued)	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. Individuals with bleeding disorders may be vaccinated intramuscularly if in the opinion of a doctor 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 receive intramuscular vaccination. 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 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. 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. 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 inconsistent with the SPC description 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 vaccine solvent to the powder vial, the vial should be gently swirled. The product 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.

Dose and frequency of administration (continued)	Individuals remain eligible up to birth. A dose of RSV vaccination is indicated for each pregnancy, irrespective of the interval between successive pregnancies. **Adults aged 75 years and over** Single 0.5ml dose, administered before the individual reaches 80 years of age, except for those who turn 80 years of age as outlined in the catch up campaign.
Duration of treatment	**Pregnant individuals** A dose of Abrysvo® is indicated for each pregnancy. **Adults aged 75 years and over** A single dose of Abrysvo® should be given.
Quantity to be supplied and administered	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 Green Book Chapter 3).
Storage	Store between +2°C to +8°C. Store in original packaging in order 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 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. For specific advice on management of temperature excursions, contact the manufacturer.
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 NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste. Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste disposal.

Drug interactions	**Interactions in older adults** Influenza and COVID-19 vaccines should not be routinely co-administered on the same day as RSV vaccines in individuals aged 75 years and over. Studies suggest a lowered immune response to both RSV and influenza components when co-administered with aQIV. Data also suggests a lowered immune response to RSV vaccination when given with COVID-19 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 either the COVID-19 vaccine, the influenza vaccine or both. Abrysvo® may be given with other vaccines routinely administered in older individuals eligible for the RSV vaccination programme, such as shingles and PPV23. **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, COVID-19 and influenza vaccines may be safely co-administered to pregnant individuals. Pregnant individuals requiring treatment with Anti-D immunoglobulin at 28 to 30 weeks gestation may have their RSV vaccine administered at the same appointment.
Identification and management of adverse reactions	Very common reactions include vaccination site pain. Other commonly reported reactions include injection site redness and swelling. In pregnant women 49 years and under, headache and myalgia are also very commonly reported. Hypersensitivity reactions can occur but are very rare. A detailed list of adverse reactions associated with the vaccine is available from the product's SPC.
Reporting procedure of adverse reactions	Healthcare professionals and 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 or carer (continued over page)	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the medicine.

Written information to be given to individual or carer (continued)	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 Home- Health Publications. Where applicable, inform the individual or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SPC.
Advice and follow up treatment	Inform the individual or carer of possible side effects and their management. Give advice regarding normal reaction to the injection, for example redness and pain at the injection site. The individual 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 or carer when to return for vaccination.
Special considerations and additional information (continued over page)	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1,000 injection and access to a telephone at the time of vaccination. As with any vaccine, a protective immune response may not be elicited after vaccination, particularly in individuals with known immunosuppression. Vaccination should be postponed in individuals suffering from an acute febrile illness. However, vaccination should not be deferred in the presence of a minor infection, such as a cold. **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. A repeat dose of Abrysvo® should be given from 28 weeks, where a dose has been inadvertently administered before week 16 of pregnancy. In both situations, local procedures for medicines error reporting should be followed. The mother 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.

Special considerations and additional information (continued)	**Timing of doses** **(i) in individuals aged 75 years and over** Administering Abrysvo® to eligible individuals before cases of RSV infection reach their seasonal peak maximises the efficacy of the vaccine. Individuals who become eligible between November to February should be encouraged to take up the offer of vaccination as soon as reasonably possible, to reduce their chance of contracting the virus. The timing of vaccination for other individuals who become eligible between March and October should be completed before RSV activity increases in the approaching season and taking into account the individual's ongoing eligibility. This timing is especially important for individuals who turn 80 years of age in the first year of the programme (catch-up campaign), who have both a narrow window to maximise benefit from vaccination and where they retain eligibility. **(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	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 • name of the immuniser • 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 declines immunisation • details of any adverse drug reactions and actions taken • the vaccine was 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 and the individual's GP informed. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	**Respiratory syncytial virus** • Abrysvo® powder and solvent for solution for injection. Summary of Product Characteristics, last updated 3 July 2024 https://www.medicines.org.uk/emc/product/15309/smpc • Immunisation Against Infectious Disease: The Green Book, Chapter 27a, updated 11 July 2024 https://www.gov.uk/government/publications/respiratory-syncytial-virus-the-green-book-chapter-27a • Respiratory syncytial virus vaccination programme collection https://www.gov.uk/government/collections/respiratory-syncytial-virus-rsv-vaccination-programme • Respiratory syncytial virus (RSV) vaccination programmes letter, published 24 June 2024 https://www.gov.uk/government/publications/respiratory-syncytial-virus-rsv-vaccination-programmes-letter **General** • NHSE 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 Immunisation Training, published 7 February 2018 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 • UK Statutory Instruments 2024, Number 729. The Human Medicines (Amendments relating to Registered Dental Hygienists, Registered Dental Therapists and Registered Pharmacy Technicians) Regulations 2024, published 29 May 2024 https://www.legislation.gov.uk/uksi/2024/729/introduction/made

7. Practitioner authorisation sheet

RSV vaccine PGD v1.00 Valid from: 1 September 2024 Expiry: 1 April 2027

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.