Respiratory Syncytial Virus (RSV) immunisation programme for older adults

Public Health Agency

Factsheet for healthcare practitioners

This information for healthcare practitioners is about the respiratory syncytial virus (RSV) vaccination programme for older adults. There is separate guidance for the RSV maternal immunisation programme for infant protection. Ensure you are using the correct guidance for the programme you are delivering.

Background

There is a significant burden of respiratory syncytial virus (RSV) illness in the population of the United Kingdom (UK), which leads to substantial impacts on NHS/HSC services, especially during the winter months. RSV infection can occur throughout the year, but the typical RSV season in the UK starts in October, peaks in December and declines by March

Since 2023, the Joint Committee on Vaccination and Immunisation (JCVI) has been actively reviewing the latest evidence on immunisation products which can protect both infants or older adults against RSV infection and disease. RSV infection can occur at any age, however the risks of severe illness and complications from RSV are increased in older adults and in neonates and young infants.

The JCVI considered a range of issues including disease epidemiology, vaccine efficacy, vaccine safety and the cost effectiveness of introducing a routine RSV vaccination programme in the UK. The JCVI recommended that a programme that is cost effective should be developed for both children and older adults.

In Northern Ireland from 1 September 2024, an RSV vaccine should be offered to:

- adults turning 75 years old on or after 1 September 2024, who remain eligible until their 80th birthday
- adults already aged 75 to 79 years on 1st September 2024 as a one-off catch-up cohort throughout the first year of the programme
- all pregnant women from 28 weeks' gestation to provide infant protection.

The RSV vaccine should be offered throughout the year as this is a year-round programme.

What is RSV?

Respiratory syncytial virus is a common cause of acute respiratory tract infections which are usually mild and self-limiting. The virus is transmitted via respiratory droplets (coughing, sneezing), through close contact with an infected person or contact with contaminated surfaces. Symptoms usually include runny nose, cough and fever. For infants, and older adults, the virus can lead to more severe illness and hospitalisation.

As previous infection at any age may only confer partial immunity to RSV, individuals may become repeatedly infected with the same or different strains of RSV.

RSV is considered to contribute significantly to GP consultations, hospital admissions and mortality amongst the elderly. There is a significant burden of RSV illness in the UK

population which has a considerable impact on HSC services, commonly leading to pressure on paediatric intensive care units and cancelled operations during the winter months. A typical RSV season in the UK starts in October, peaks in December, and de-clines by March.

The Green Book RSV Chapter 27a

The **Green Book Respiratory syncytial virus Chapter 27a** includes detailed information about RSV and RSV vaccination.

Healthcare practitioners should familiarise themselves with the information in the Green Book chapter before offering RSV vaccination.

Aim of the RSV vaccination programme for older adults

The aim of the adult RSV programme is to reduce the incidence and severity of RSV disease and hospitalisation as a result of RSV disease in eligible older adults.

Eligibility

From 1 September 2024, the RSV vaccine should be offered to the following routine and catch-up cohorts.

Routine cohort

All adults turning 75 years of age on or after 1 September 2024 (born on or after 1 September 1949) should be offered RSV vaccination on or shortly after their 75th birthday. This is a year-round, ongoing programme.

Catch-up cohort

Individuals aged 75 years old to 79 years old on 1 September are eligible as part of the catch-up campaign. These individuals remain eligible until the day before turning 80 years of age with the exception of those who turn 80 within the first year of the programme, who are eligible until 31 August 2025.

The dates of birth ranges are as follows:

1 September 1945 to 31 August 1949

Individuals with a date of birth from 1 September 1945 to 31 August 1949 are eligible until and including the day before their 80th birthday. To give them the earliest protection against RSV disease, they should be vaccinated as soon as possible and preferably within the first year of the programme.

2 September 1944 to 31 August 1945

Individuals with a date of birth range 2 September 1944 to 31 August 1945 inclusive, who are aged 79 years on 1st September 2024 and will have their 80th birthday within the first year after the catch-up campaign commences are eligible.

They remain eligible up until and including 31 August 2025 to ensure that they have sufficient opportunity to be vaccinated.

To give them the earliest protection against RSV disease they should be vaccinated as soon as possible after the catch-up campaign commences.

Further information can be found in the Department of Health's **policy letter**.

Optimal timing of vaccination

Although vaccination can be given all year round, vaccinating as many eligible individuals as possible before the onset of the main RSV season in the winter will have the greatest impact. This will provide individuals with protection and could reduce transmission of the virus.

For those eligible for the catch-up campaign, as many as possible should be vaccinated during September and October 2024 prior to the expected RSV season.

For those turning 75 years of age between March and October each year, the vaccine should ideally be given by the end of October before RSV activity increases, otherwise soon after turning 75 if this occurs during the RSV season (November to February).

What vaccine will be used in the programme?

Abrysvo® Pre-F RSV vaccine (manufactured by Pfizer Limited) is the vaccine that will be used for the adult national RSV programme. The vaccine's full name is Abrysvo® powder and solvent for solution for injection Respiratory syncytial virus vaccine (bivalent, recombinant).

Abrysvo® was licensed in the UK by the Medicines and Healthcare Products Regulatory Agency (MHRA) in November 2023 following clinical trials.

How the vaccine works

The RSV vaccine Abrysvo® is a non-live bivalent recombinant vaccine. This means a small piece of the genetic material (DNA) from the protein of the virus is taken and inserted into a manufactured cell. As these cells grow, the protein is made too. This protein is then purified and put into the vaccine, which, when introduced into the body via intramuscular injection, activates the immune system to produce antibodies against RSV.

It is referred to as bivalent because Abrysvo® contains versions of two proteins found on the surface of the virus, one from a virus in RSV subgroup A and one from subgroup B. The vaccine is sometimes called pre-F because it is based on the prefusion form of the fusion (F) protein which the virus uses to invade human cells.

The vaccine also contains very small amounts of other ingredients, such as stabilisers (which preserve vaccine potency) and emulsifiers (which help the vaccine powder mix with the solvent (which is water for injection). For the full list of vaccine components and excipients, vaccinators should see below and refer to the Abrysvo® **Summary of product characteristics (SPC)**.

Vaccine safety and effectiveness

Abrysvo® was licensed in the UK by the MHRA in November 2023 following clinical trials which showed it to be effective and have a good safety profile.

The vaccine was trialled against a placebo in over 17,000 immunocompetent adults aged 60 years and above, 52% of whom had at least one stable chronic underlying condition. At the end of the first RSV season (after vaccination) analysis demonstrated statistically significant vaccine efficacy (VE) for Abrysvo® for reduction of RSV-associated lower respiratory tract illness with 2 or more symptoms of 65.1% and 3 or more symptoms of 88.9%. In the second season, the efficacy against 2 or more symptoms was 55.7% and against 3 or more symptoms was 77.8%.

Abrysvo® is also licensed for use in Europe, the USA and in many other parts of the world. Over 3 million doses were administered to adults in the USA during winter 2023 to 2024.

RSV vaccine composition

The RSV vaccine Abrysvo® contains:

- trometamol
- trometamol hydrochloride

- sucrose
- mannitol
- polysorbate 80
- sodium chloride
- hydrochloric acid (for pH adjustment)
- the solvent is water for injection

There is no animal content in the vaccine. Abrysvo® vaccine has been certified Halal by the Islamic Food and Nutrition Council of America (IFANCA).

The Abrysvo® vaccine contains polysorbate 80. Rarely, people may be allergic to polysorbate 80. However, polysorbate 80 is widely used in medicines and foods and is present in many medicines including some vaccines such as the main injected influenza vaccine for individuals aged 65 years and above. Some individuals may be allergic to polysorbate 80 but as it is present in many foods such as ice-cream and other frozen desserts, it is likely that people will know if they are allergic to it and individuals who have tolerated injections that contain polysorbate 80 are likely to tolerate the Abrysvo® vaccine.

Vaccine ordering

In Northern Ireland, supplies should be obtained from local childhood vaccine holding centres. Details of these are available from the Regional Pharmaceutical Procurement Service (Tel: 028 9442 4089).

The same Abrysvo® vaccine will be used for both the older adult programme and the pregnancy programme for infant protection, but will be separate items on ordering platforms for each programme. The product should be managed independently where possible. GP practices ordering stock should only use the vaccine for older adults. Eligible pregnant women enquiring about how to access RSV vaccine should be directed to their local HSC Trust.

Vaccine storage

Abrysvo® should be stored in a vaccine refrigerator between 2°C and 8°C. The vaccine must not be frozen. The vaccines should be stored in the original packaging to protect them from light.

Heat speeds up the decline in potency of most vaccines, thus reducing their shelf life, and storage below 2°C may cause loss of potency and freezing, which can lead to hairline cracks in the container and subsequent contamination of the contents.

Further information on vaccine storage and stability is available in the **Abrysvo® SPC**, the Public Health Agency (PHA) slide set and the PGD.

Vaccine fridge capacity

Service providers should ensure sufficient refrigeration space is available for the vaccine. A review of available fridge space will be necessary to ensure adequate storage capacity at the start of the programme. It should be noted that the Abrysvo® vaccine pack is larger than other vaccine packs: A single dose pack of Abrysvo® measures 73 mm x 35 mm x 116 mm (H x D x W).

No more than two weeks of stock should be ordered.

Contraindications and precautions

The only contraindication to Abrysvo® vaccine is a confirmed anaphylactic reaction to a previous dose or any component of the vaccine.

Immunisation of individuals who are acutely unwell with a fever should be postponed until they have recovered fully. This is to avoid confusing the diagnosis of any acute illness by wrongly attributing any sign or symptoms to the adverse effects of the vaccine. The presence of a minor illness, such as the common cold, is not a contraindication to immunisation.

There are very few individuals who cannot receive Abrysvo®. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team.

For individuals with thrombocytopenia or other bleeding disorders please see the administration advice.

For full details refer to the **Green Book RSV Chapter 27a** and the **Patient Group Direction** (PGD).

Vaccine presentation and preparation

Each box of Abrysvo® vaccine contains one vial of powder, one pre-filled syringe of solvent, and one vial adaptor with one needle for administration. The vaccine must be reconstituted with the solvent provided. The prepared vaccine is a clear and colourless solution.

Clear instructions on how to prepare the vaccine for administration can be found in the SPC and **manufacturer's video**. Immunisers are strongly encouraged to look at the SPC and watch the video in its entirety before preparing the vaccine for the first time.

Vaccine administration

Abrysvo® should be reconstituted according to the manufacturer's instructions. Once reconstituted, the vaccine should be administered immediately.

Abrysvo® is licensed to be given via the intramuscular (IM) route, preferably into the deltoid muscle in the upper arm.

The needle for administration included in the pack is a 25 gauge, 25mm ('long orange') needle. Suitable alternatives can be used if required. For IM injections, the needle needs to be sufficiently long enough to ensure that the vaccine is injected into the muscle. For most adults, the 25mm needle length will be sufficient. In larger adults, a longer length (such as a 38mm) may be required, and an individual assessment should be made. For more information on immunisation procedures, including needle length, please see the Green Book, **Chapter 4**.

Vaccine dosage and schedule

Abrysvo® should be administered as a 0.5mL dose after reconstitution using the full volume of the reconstituted vaccine, drawn up into the syringe.

The schedule for Abrysvo® is a single dose of vaccine.

There are no current data to support revaccination of older adults after a first dose.

Individuals who have received a bone marrow transplant

For individuals eligible for the RSV vaccine who receive a bone marrow transplant, any protective antibodies from exposure or vaccination prior to transplantation are likely to be lost and it is unclear whether the recipient acquires the donor's immunity. All such individuals should be considered for re-immunisation after treatment is

finished. Specialist advice may be required and should be sought from the treating clinician.

Vaccination for individuals with bleeding disorders

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 IM injections can be administered with reasonable safety by this route. If the individual receives medication or treatment to reduce bleeding, for example treatment for haemophilia, IM vaccination can be scheduled shortly after such medication or treatment is administered.

Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled international normalised ratio (INR) blood testing and whose latest INR was below the upper threshold of their therapeutic range, can receive IM vaccination. 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.

If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. On occasion the treating clinician may conclude, in discussion with the individual, that the benefit of protection against RSV disease could outweigh the increased risk of a transient local reaction with intramuscular immunisation. Subcutaneous administration is off-label, and a PSD would be required.

The individual or their carer should be informed about the risk of haematoma from the injection.

Adverse reactions

The adverse reactions reported by Abrysvo® clinical trial participants were the expected side-effects commonly reported after any vaccination, reflecting the initiation of the inflammatory and immune responses that lead to vaccine-induced protection against disease.

For individuals aged 60 years and above, only vaccination site pain was very commonly reported (reported by 11% of those who received the vaccine) following vaccination with Abrysvo®. Commonly reported reactions (affecting more than 1 in 100 but not as many as 1 in 10 of those receiving the vaccine) were vaccination site redness and swelling.

Although headache and myalgia were commonly reported adverse reactions from the clinical trial of younger adults (aged 49 years or below), these were not reported by the 60 years and above age group.

Guillain-Barré syndrome

A small number of cases of Guillain-Barré syndrome (GBS) have been reported in older adults following vaccination with Abrysvo® in the trials and in post-marketing surveillance in the USA. GBS is a rare and serious condition that affects the nerves. It mainly affects the feet, hands and limbs, causing problems such as numbness, weakness and pain. In severe cases, GBS can cause difficulty moving, walking, breathing or swallowing. GBS is most common following infection, including campylobacter and influenza.

Around 5 cases of GBS were reported for every million doses of Abryvso® given to recipients in the USA (against a background rate of 0.5 per million people vaccinated with vaccines

considered not to have association with GBS). Overall, the benefits of RSV protection in the eligible group are highly favourable relative to the risks of serious adverse reactions.

Healthcare professionals should be alert to the signs and symptoms of GBS, to ensure correct diagnosis in order to initiate adequate supportive care and treatment and to rule out other causes.

Individuals who have a history of GBS should be vaccinated if they are in an eligible group. There is evidence from other vaccines to suggest that having had a prior diagnosis of GBS does not predispose an individual to further episodes of GBS following immunisation. Cases of GBS that occur following vaccination may occur by chance (the background rate of GBS is 20 per million people per year in the population). GBS is more common in males and older adults.

Reporting adverse reactions

Abrysvo® is a newly licensed vaccine and is subject to additional monitoring under the black triangle (▼) labelling scheme by the MHRA.

All suspected adverse reactions should be reported to the MHRA via the Yellow Card scheme:

- online at Yellow Card Scheme
- by downloading and using the Yellow Card app for Apple devices or Android devices
- by calling the Yellow Card scheme on 0800 731 6789 (9am to 5pm).

Recommendations for the use of Abrysvo® vaccine

Individuals who present early and before they become eligible for RSV vaccine

Individuals who present early and outside the eligible age for the RSV vaccine national immunisation programme should be advised when they will become eligible. It should be explained to them that the JCVI have advised the vaccine should be offered only to those who are 75 years of age and older, as the evidence shows that the greatest risk from RSV is in those in this age group. These decisions are based on a combination of factors including the risk of the disease and the effectiveness of the vaccine in different age groups, vaccine supply and the capacity of the NHS to deliver the programme alongside other important healthcare priorities. They should be encouraged to attend for vaccination on or shortly after their 75th birthday.

Vaccination of individuals who have previously received RSV vaccine

The RSV vaccine programme offer is a single, one-off dose of vaccine from the 75th birthday, to be given before the 80th birthday.

Both Arexvy® (manufactured by GSK) and Abrysvo® vaccines are approved for use in individuals over the age of 60 in the UK, Europe and the USA. Moderna's mRESVIA® (mRNA-1345) RSV vaccine is approved from 60 years in the USA. Therefore, some individuals may have received an RSV vaccine privately or in another country prior to becoming eligible in the UK national programme.

Current trial data shows protection from Abrysvo® and Arexvy® lasts for at least 24 months. There is some evidence for Arexvy®

that revaccination of older adults at 12 months following the first dose does not confer additional protection. Therefore, revaccination may result in typical vaccine side effects for no clinical benefit. Individuals who received the RSV vaccine in clinical trials will continue to be followed up to establish how long protection lasts. The protective effect for mRESVIA appears to wane more quickly.

Eligible NHS/HSC patients do not lose their eligibility for RSV vaccination if they have received an RSV vaccine outside of the national programme. However, the need for revaccination and the appropriate timing of any revaccination is not established. Until further data emerges, it is recommended that the minimum acceptable interval for older adults is 24 months from a non-NHS/HSC dose of Abrysvo® or Arexvy® and 12 months from a dose of mRESVIA® following a discussion of the risks and benefits with the patient.

Individuals diagnosed with confirmed or suspected RSV

Vaccination of individuals who may be infected or asymptomatic or incubating RSV infection is unlikely to have a detrimental effect on the illness but individuals currently unwell with a febrile illness should not attend for vaccination until they have recovered to avoid confusing disease symptoms with vaccine side effects. Eligible individuals should be vaccinated as soon as they are clinically recovered. Previous infection with RSV at any age will only confer partial immunity to RSV and individuals may therefore be infected repeatedly with RSV. It is very rare for anyone to reach adulthood without having had multiple RSV infections. There are no safety concerns from vaccinating individuals with any past history of RSV infection (recent or historic), or with detectable RSV antibody.

Vaccination offers the best protection against RSV infection.

Vaccination of individuals not included in the eligible cohorts

When providing advice to government, the JCVI reviews the current evidence with regard to benefit and cost-effectiveness. On the rare occasion when a clinician, following an assessment, determines that an individual who is not eligible for the national RSV vaccination programme should receive an NHS/HSC RSV vaccination, the vaccine should be procured from the manufacturer. GP surgeries can reclaim the cost of the vaccine from the HSC.

Administering Abrysvo® at the same time as other vaccines

Advice for co-administration is different for different vaccines. Read the following sections for specific scenarios. This information applies to older adults only. For advice on co-administration of vaccines of pregnant women, *see* ***RSV maternal immunisation programme for infant protection: information for healthcare practitioners***.

Where more than one vaccine can be administered at the same time, the vaccines should be given at a separate site, preferably in a different limb. If more than one vaccine is given in the same limb, they should be given at least 2.5cm apart. The sites at which each vaccine is given should be noted in the individual's health records.

When co-administered, any reactions experienced are expected to be the same as those experienced when receiving the vaccines separately.

Influenza vaccine and RSV vaccines

There is some data which shows that in older adults, administering Abrysvo® at the same time as seasonal influenza vaccine may reduce the immune response to the RSV vaccine. There is also data that suggests that the response to the influenza A(H3N2) component of seasonal influenza vaccine (the influenza subtype which most severely affects older adults) may be diminished when RSV and seasonal influenza vaccine are co-administered to older adults.

The clinical significance of any reduced response is unknown, but influenza immune response is known to correlate with protection against infection, and there is emerging data that RSV immune response also correlates with clinical protection. It is therefore recommended that these vaccines should not routinely be scheduled to be given at the same appointment or on the same day. No specific interval is required between administering the vaccines.

If it is thought that the individual is unlikely to return for a second appointment or immediate protection is necessary, Abrysvo® can be administered at the same time as the influenza vaccine.

COVID-19 vaccine and RSV vaccines

There is some data which shows co-administration with COVID-19 vaccination and RSV vaccination may reduce the immune response to the RSV vaccine. The clinical significance of any reduced response is unknown, but there is emerging data that RSV immune response also correlates with clinical protection. It is therefore recommended that these vaccines should not routinely be scheduled to be given on the same day. No specific interval is required between administering the vaccines.

If it is thought that the individual is unlikely to return for a second appointment or immediate protection is necessary, Abrysvo® can be administered at the same time as the COVID-19 vaccine.

Pneumococcal (PPV) vaccine, shingles vaccine and RSV vaccines

Abrysvo® can be safely given with other vaccines routinely administered to older individuals eligible for the RSV programme, such as the Shingrix shingles vaccine and the pneumococcal (PPV) vaccine.

Administering Abrysvo® at the same time as a live vaccine

While is it not common that live vaccines are indicated in older adults, Abrysvo® is a non-live vaccine and can be given at the same time as any live vaccines that may be required.

Inadvertent vaccine administration errors

Healthcare practitioners should report all inadvertent vaccine administration errors via their local governance systems so that appropriate action can be taken, lessons can be learnt and the risk of future errors minimised.

Inadvertent administration to someone aged less than 75 years

If an individual has received a dose of RSV vaccine before the age of 75 in error, they should be offered a dose when they reach eligible age. It is recommended this is given with an interval of not less than 24 months since their previous dose to maximise any potential benefit from receiving a second dose as current trial data shows protection from these vaccines lasts for at least 24 months.

Abrysvo® vaccines were trialled in individuals younger than 75 years and are being offered to pregnant women of any age. Individuals who inadvertently receive RSV vaccination before they become eligible at age 75 years should be reassured and advised of the possible adverse reactions see **Adverse reactions**.

Inadvertent administration to someone aged 80 years or older

A number of individuals already aged 79 years (but not yet 80 years of age) on 1 September 2024 (date of birth range 2 September 1944 to 31 August 1945) will have their 80th birthday before they are vaccinated. This is acceptable as they are eligible until 31st August 2025, although they should be vaccinated at the earliest opportunity after the programme commences, to ensure their protection.

If the vaccine is administered inadvertently to someone aged 80 years or older who is not eligible, they should be reassured that the vaccine is licensed from 60 years of age, with no upper age limit, and advised of the possible adverse reactions (see 'Adverse reactions' above).

Additional dose given in error

In the event of an additional dose being inadvertently administered, the individual should be monitored and advised an extra dose is expected to have adverse reactions consistent with those of having a single dose. Symptomatic treatment such as paracetamol can be taken if required. A study in which a second dose of vaccine was administered to participants aged 65 to 85 years showed that the percentage of participants reporting local and systemic reactions after revaccination was similar to the number following initial vaccination and no new safety concerns were identified.

Incomplete dose given

If an incomplete dose of Abrysvo® has been given inadvertently, this dose should be discounted. If the individual is still in the clinic, administer a replacement full dose immediately. If the replacement dose cannot be given on the same day, administer it as soon as possible after the invalid (incomplete or partial) dose was given in order to provide protection at the earliest opportunity.

Reconstitution errors

Inadvertent administration of solvent only

Where individuals have inadvertently received the solvent only, they should be revaccinated with the correctly reconstituted vaccine. If the individual is still in the clinic, administer a replacement dose immediately. If the replacement dose cannot be given on the same day (for example because the individual has left before the error has been realised), they should be recalled and the dose administered as soon as possible. The solvent is water for injection and contains no active ingredient, meaning that the individual would not receive any protection.

If only the solvent is injected without reconstituting it with the powder containing the active ingredients, the individual should be reassured that it is not harmful but will not offer them any protection. They should be offered a correctly reconstituted vaccine as soon as possible after the error is realised.

What to do if the vaccine has been shaken

The SPC recommends that the vaccine is swirled and not shaken during reconstitution. If it is shaken in error, this is not expected to affect the potency or effectiveness of the vaccine. If

the vaccine has already been given, it does not need to be repeated. If the vaccine has not yet been given, it can still be used and should not be discarded.

What to do if the luer lock adaptor has not been used

The technique for preparing the vaccine, as set out in the manufacturer's video and SPC, should be followed.

If the luer lock adaptor has been detached following reconstitution, or was not used in the preparation of the vaccine, providing the preparation technique has not introduced microbial contamination (that is, appropriate infection control procedures have been followed) and the syringe contains a full reconstituted dose, it is possible to attach a needle to the luer slip tip and safely administer a full dose of the vaccine.

Resources

Healthcare practitioner resources to support the RSV programme including the **Green Book RSV chapter**, Information for Healthcare Practitioners document and a training slide set for both programmes are available on the **RSV immunisation collection** site. The PGD is also available on the UKHSA **PGD templates collection page** ready for local authorisation.

Pfizer (the product manufacturer) has a preparation video and resources about the Abrysvo® vaccine available on the Pfizer **health professionals website**.

For additional information about RSV disease, see **Respiratory Syncytial Virus (RSV) vaccine for older adults | nidirect**

References

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