Respiratory syncytial virus (RSV) maternal immunisation programme for infant protection

Public Health Agency

Factsheet for healthcare practitioners

Background

There is a significant burden of respiratory syncytial virus (RSV) illness in the population of the United Kingdom (UK), which leads to a substantial impact 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 for Vaccination and Immunisation (JCVI) have been reviewing the latest evidence on immunisation products which can protect both infants and 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 have considered a range of factors, including disease epidemiology, vaccine efficacy (effectiveness), vaccine safety and the cost effectiveness of introducing a routine RSV vaccination programme in the UK. On 7 June 2023, JCVI recommended that a universal immunisation programme should be developed to protect both infants and older adults.

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

- all pregnant women from 28 weeks' gestation
- adults turning 75 years old
- adults who are already aged 76 to 79, up until the day before their 80th birthday.

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

What is RSV?

Respiratory syncytial virus (RSV) is an RNA virus that is a common cause of acute respiratory tract infections. Infection is usually mild and self-limiting, however for infants and older adults, the virus can lead to more severe illness and can result in hospitalisation. RSV is highly infectious and is transmitted via respiratory droplets (coughing and sneezing) or through close contact with an infected person or with contaminated surfaces.

At least half of children in the UK experience an RSV infection in the first year of life, and almost all will have experienced infection with RSV by the age of two. Previous infection with RSV results in only partial immunity to the virus, therefore individuals can be infected repeatedly throughout their life course.

What are the symptoms of RSV?

Infection with RSV results in a range of acute respiratory symptoms, including: rhinitis (runny nose), cough, shortness of breath, wheeze, lethargy and occasionally fever.

Complications of RSV in infants and children

In infants, RSV can cause bronchiolitis (inflammation and narrowing of the small airways in the lungs), which can lead to significant breathing and feeding difficulties. Other paediatric complications of RSV infection include apnoea (temporary pauses in breathing) and hypoxemia (low oxygen

levels within the bloodstream), cardiovascular abnormalities (such as tricuspid regurgitation and arrythmias) and secondary bacterial infections.

RSV is also associated with croup and otitis media (middle ear infection) in children.

RSV accounts for approximately 33,500 hospitalisations annually in children aged under five years old. It is a leading cause of infant mortality across the world and results in 20 to 30 deaths per year in the UK. RSV infects up to 90% of children within the first two years of life and frequently re-infects older children and adults.

Aim of the maternal RSV vaccination programme

The aim of the RSV vaccination programme for pregnant women is to reduce the incidence and severity of RSV disease in infants. While RSV can occur at any age, infants under one year of age are at the greatest risk of hospitalisation and severe illness.

Although most women will have been exposed to RSV infection as children and in adulthood, the antibodies acquired from natural infection will not provide sufficient protection for their unborn infants. Immunisation with the RSV vaccine from week 28 of every pregnancy will temporarily boost maternal antibody levels, which will enable high levels of antibody transfer across the placenta to the fetus. This will offer passive protection to the infant against RSV in the first few months of life. Ideally the vaccine should be given in week 28 of pregnancy, or soon after, to allow sufficient time for the mother to make high levels of antibodies and transfer these across the placenta.

A targeted (or selective) RSV monoclonal antibody immunisation programme is available for high-risk infants in the UK, and this will continue in addition to the maternal immunisation programme (see page 9).

RSV vaccination in pregnancy

From 1 September 2024, the RSV vaccine has been offered to every pregnant woman from week 28 of their pregnancy.

The maternal immunisation programme is a year-round programme and should routinely be offered as women reach week 28 of pregnancy. Pregnant women will remain eligible up until birth.

RSV vaccination should be offered in each pregnancy.

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

Timing of vaccine administration

Week 28

Ideally, the RSV vaccine should be given in week 28 of pregnancy or soon after so that there is sufficient time for the mother to make high levels of antibodies and for these to transfer across the placenta to provide passive immunity to the unborn child, giving them the best protection during early infancy. Administering the vaccine around week 28 also increases the potential for protection for babies who are born prematurely.

After week 28

For those women who have not been vaccinated in or shortly after week 28 of pregnancy, the vaccine should continue to

be offered up until birth. Immunisation after week 36 of pregnancy may not offer as high a level of passive protection to the baby, as there may be insufficient time for the mother to make a good response and for maternal antibodies to pass across the placenta.

There is some evidence that good transplacental antibody transfer can take place within two weeks of vaccination, so even doses given later in pregnancy may offer some protection to the infant. Vaccination late in pregnancy may also potentially protect the mother from RSV infection and reduce the risk of her becoming a source of infection for her infant, as well as potentially providing antibodies in breastmilk.

In labour or after birth

It is clinically reasonable for women who present in labour, and have not received the RSV vaccine during pregnancy, to be offered the vaccine up until the time of discharge from hospital, or in comparable circumstances for births outside of hospital. However, the emphasis remains on offering vaccination from week 28 of pregnancy.

A vaccine delivered to the mother in labour or after birth would not offer passive protection to the baby through transplacental antibody transfer, but may protect the mother from contracting RSV or make her less infectious and therefore reduce the chance of transmission to her infant. There may also be antibody transfer to the baby through breastmilk.

Before week 28

The vaccine should not routinely be given before week 28 of pregnancy. Where a consultant obstetrician or similar specialist considers that there is a compelling clinical reason for early immunisation the vaccine could be prescribed off-label and the rationale documented.

What vaccine will be used in the programme?

Abrysvo® Pre-F vaccine (manufactured by Pfizer Limited) is the vaccine that will be used in the routine maternal RSV vaccination programme for infant protection. This is the only vaccine currently available for use within the national programme.

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

In Northern Ireland until 31 December 2024, Abrysvo® is licensed for administration to pregnant individuals between weeks 24 and 36 of gestation by the European Medicines Agency (EMA). However, in line with national guidance, Abrysvo® should be administered from week 28 gestation. This is to maximise the likelihood that a baby will be optimally protected from birth.

Is the vaccine effective?

Abrysvo® was trialled in over 17,000 adults over the age of 60 and in over 4,000 pregnant women. In the clinical trial, Abrysvo® was shown to be 70% effective at preventing severe lower respiratory tract disease caused by RSV in infants born to vaccinated mothers for at least the first 6 months of life (which is the period of time when infants are most vulnerable to severe RSV infection). There is also some evidence of protection beyond this age from the same clinical trial.

Is the vaccine safe?

Abrysvo® has been licensed for use as a maternal vaccination in the United States since May 2023. Over 100,000 doses have been administered to pregnant women in the USA since the maternal vaccination programme started in September 2023, where monitoring has shown a good safety profile. It has also been licensed for use in several European countries, Argentina, Australia, Canada and Japan.

In the vaccine trial, a slightly higher number of babies were born prematurely to women who received the vaccine than to women who received the placebo, but this was not statistically significant and there was no temporal relationship between vaccination and premature birth (1). This observation was seen in upper middle-income countries, from where the data are consistent with a chance difference and was not seen in high-income countries of Europe and North America. In the month following immunisation, the period when vaccine-related adverse events are considered to be most plausible, the rate of preterm birth in the vaccine group was 2.1% and, in the control (placebo) group 1.9%, which was statistically equivalent. In the two study groups the median gestational age at birth was equal at 39 weeks, and median birth weight was equal at 3.3kg (1). There was no mortality signal associated with prematurity, and the overall number of deaths by 24 months of age was five in the vaccination group and twelve in the placebo group (1). There are no safety concerns around congenital anomalies, which were less common in the vaccine group (5%) than the placebo group (6%).

The JCVI has advised that it is reassured that the safety data for Abrysvo® does not raise any significant concerns about use in a maternal vaccination programme, and the vaccine is approved by the MHRA on the basis of safety, quality and effectiveness (2).

Abrysvo® is an inactivated vaccine, therefore it cannot cause RSV infection in either the mother or the fetus. The inactivated pertussis-containing vaccine and inactivated influenza vaccine are routinely given to pregnant women with no adverse effects and with proven safety and efficacy.

Composition of the RSV vaccine

Abrysvo® is an inactivated bivalent recombinant protein vaccine. Recombinant vaccines are made using bacterial or yeast cells to manufacture the vaccine. A small piece of the genetic material (DNA) from the protein of the virus (in this case, respiratory syncytial virus) is taken and inserted into a manufactured yeast or bacterial cell. As these cells grow, the protein is made too. This protein is then purified and put into the vaccine as the active ingredient, which, when introduced into the body by intramuscular injection, activates the immune system to produce antibodies against RSV. 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.

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 RSV subgroup B.

How does the vaccine work?

When a pregnant woman is given the vaccine, her immune system recognises the proteins as being foreign and makes antibodies against them. These antibodies pass across the placenta to her unborn baby and provide the baby with protection against RSV disease during infancy.

Are there any other ingredients in the vaccine?

Abrysvo® also contains very small amounts of other ingredients, a full list of ingredients and excipients can be found in the summary of product characteristics (SPC). The additional ingredients and excipients found in the vaccine act as stabilisers (to preserve the vaccine potency) and emulsifiers (to help the vaccine powder mix with the solvent).

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

The RSV vaccine does not contain any live organisms.

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, 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 physically larger than most other vaccines. A single dose pack of Abrysvo® measures 73mm x 35mm x 116mm (height x depth x width).

No more than two weeks of stock should be ordered.

Vaccine presentation and preparation

Abrysvo® (Pfizer RSV pre-F vaccine) is presented as a single dose pack for reconstitution. Each pack contains one vial of powder, one pre-filled syringe of solvent (water for injection), one vial adaptor, and one needle for administration. The vaccine must be reconstituted with the solvent provided. The prepared vaccine should appear as a clear and colourless solution.

Abrysvo® should be reconstituted according to the manufacturer's instructions. Clear instructions on how to prepare the vaccine for administration can be found in the SPC and manufacturer 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.

Once reconstituted, the vaccine should be administered immediately.

Vaccine administration

Abrysvo® should be administered via the intramuscular (IM) route, preferably into the deltoid muscle in the upper arm.

For IM injections, the needle needs to be sufficiently long enough to ensure that the vaccine is injected into the muscle. For most women, the orange 25-gauge 25mm needle supplied with the Abrysvo® vaccine will be suitable and should be used. In larger women, 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, immunisation procedure.

Vaccine dosage and schedule

Each dose of Abrysvo® is 0.5mL. The full volume of the reconstituted vaccine should be drawn up into the syringe and administered.

Abrysvo® is given as a single dose in each pregnancy.

Contraindications

Abrysvo® vaccine should not be given to anyone with a confirmed anaphylactic reaction to a previous dose or any component (excipient or ingredient) of the vaccine.

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. Some women 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.

There are very few individuals who cannot receive an RSV vaccine. Where there is doubt, appropriate advice should be sought from a specialist or the Public Health Agency immunisation team (pha.immunisation@hscni.net).

Precautions

Vaccination of women who are acutely unwell with a fever should be postponed until they have fully recovered. 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 valid reason to postpone immunisation.

For full details refer to the Green Book RSV Chapter 27a and Abrysvo® PGD.

Vaccination of women with bleeding disorders

Women with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the woman's bleeding risk, vaccines or similar small volume IM injections can be administered with reasonable safety by this route. If the woman 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.

Pregnant women on stable anticoagulation therapy, including women taking prophylactic

anticoagulants, can receive IM vaccination. On the rare occasions where warfarin is used in a pregnant woman, IM vaccination can be used if the patient is up to date with scheduled international normalised ratio (INR) testing and the latest INR blood test is below the upper level of the therapeutic range. 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 woman should be informed about the risk of haematoma from the injection.

If in any doubt, consult with the clinician responsible for prescribing or monitoring the woman's anticoagulant therapy.

Adverse reactions (side effects)

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

The most commonly reported adverse reactions (affecting at least 1 in 10 of those receiving the vaccine) were pain at the injection site (41%), headache (31%) and myalgia (muscle pain, 27%). The majority of side effects were mild to moderate and resolved within a few days.

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).

Co-administration of RSV vaccine with other vaccines given to pregnant women

The following advice applies only to pregnant women. Separate advice regarding co-administration is available for the older adult RSV vaccination programme.

Where more than one vaccine is 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 2.5 cm apart. The sites at which each vaccine is given should be noted in the woman'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

Abrysvo® can be co-administered with inactivated influenza vaccine to pregnant women. Similarly, there are no safety or effectiveness concerns around giving Abrysvo® to pregnant women under the

age of eighteen, who are due to have or who have recently had a live attenuated influenza vaccine.

COVID-19 vaccine and RSV vaccines

For pregnant women who are eligible to receive COVID-19 vaccine during a vaccination campaign, this can be given at the same time as the RSV vaccine.

Pertussis-containing vaccine and RSV vaccines

There is some evidence that co-administration of the RSV vaccine with pertussis-containing vaccines may reduce the response made to pertussis components. The clinical significance of this is unclear and any impact on protection is likely to be small, as the key pertussis toxoid component is least affected.

Giving the vaccines separately at the usual scheduled times of around 16 to 20 weeks for pertussis (usually given around time of the fetal anomaly scan at 20 weeks), and from 28 weeks for RSV, will avoid any potential attenuation (weakening) of antibody response to the pertussis containing vaccine.

If a woman has not received a pertussis-containing vaccine by the time she presents for an RSV vaccine, both vaccines can and should be given at the same appointment to provide timely protection against both infections to the infant. If the vaccines are not given at the same time, they can be given at any interval.

Who is responsible for delivering the maternal RSV immunisation programme?

The maternal RSV vaccination programme for infant protection will be delivered by the local Health and Social Care Trust (HSCT) vaccination services in collaboration with HSC maternity services. Vaccination clinics will take place alongside antenatal clinics and will be supported by the existing HSCT COVID-19 Vaccination Teams.

Eligible pregnant women enquiring about how to access RSV vaccine should be directed to their local HSCT or maternity team.

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.

Vaccine inadvertently given before 28 weeks' gestation

If the RSV vaccine was inadvertently given prior to 16 weeks of pregnancy, the dose should be discounted, and a further dose should be given from 28 weeks gestation. To maximise the volume of antibodies generated by the mother to transfer across the placenta to the fetus, the repeated dose should be given in week 28 or as soon as possible after.

If the woman is more than 16 weeks pregnant when she receives the vaccine, this will be counted as a valid dose and does not need to be repeated, as transplacental antibody transfer occurs from 16 weeks gestation.

Additional dose given in error

If a pregnant woman is inadvertently given a second dose of RSV vaccine in pregnancy, she should be reassured that no adverse effects are anticipated other than those that may occur following the first dose of RSV

vaccination (the commonly reported side effects).

Incomplete dose given

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

Reconstitution errors

Inadvertent administration of the Abrysvo® solvent only

Where women have inadvertently received the solvent only, they should be revaccinated with the correctly reconstituted vaccine. If the woman is still in the clinic, administer a replacement dose immediately. If the replacement dose cannot be given on the same day, the woman should be recalled and the dose administered as soon as possible.

The solvent is water for injection and contains no active ingredients, meaning no protection will be generated by its administration. If only the solvent is injected without reconstituting it with the powder containing the active ingredients, the pregnant woman should be reassured that it is not harmful but should be advised it will not offer her baby any protection. She 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. 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 should not be discarded and can still be used.

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

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

If the luer lock adaptor has been detached from the syringe following preparation of the vaccine, or was not used in the preparation, 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.

Monoclonal antibody immunisation for high-risk infants

Predisposing clinical risk factors for severe RSV disease amongst infants include:

- prematurity
- cardiopulmonary disease
- congenital heart disease
- chronic lung disease
- chromosomal abnormalities
- neuromuscular disorders
- large airway abnormalities
- immunodeficiency.

RSV monoclonal antibody immunisation was first approved for use in infants in European countries in 1999. A targeted RSV monoclonal antibody immunisation programme will continue in Northern Ireland for high-risk infants meeting eligibility criteria outlined in the Green Book. RSV monoclonal antibody immunisation for high-risk infants is delivered in secondary care by paediatric services.

All pregnant women should be offered RSV vaccination in every pregnancy. High-risk infants and children who meet the eligibility criteria in the Green Book Chapter 27a, should also be offered a monoclonal antibody immunisation regardless of whether or not their mother received an RSV vaccine in pregnancy.

Frequently asked questions

Can RSV vaccine be administered at the same time as anti-D immunoglobulin?

Yes. The response to RSV vaccination will not be affected by, or interfere with, anti-D immunoglobulin. The administration of RSV vaccine should not be delayed due to the woman receiving anti-D immunoglobulin.

Should RSV vaccine be offered in every pregnancy?

Yes. Pregnant women should be offered an RSV vaccine from week 28 of each pregnancy, regardless of the interval between pregnancies. This is to maximise the antibodies the woman can transfer across the placenta to her unborn baby to offer them protection during infancy.

Can vaccination be given if the woman has a confirmed or suspected RSV infection?

Vaccination of women who may be infected, or incubating RSV infection, is unlikely to have a detrimental effect on the illness, however women currently experiencing symptoms of RSV disease should not attend for vaccination if they are acutely unwell with a fever. They should be vaccinated as soon as they are clinically recovered.

Although it might be expected that a woman diagnosed with RSV infection during pregnancy would transfer antibodies to her unborn baby, there is no assurance that the levels would be high enough to sufficiently protect the infant. As high levels of antibodies are made following vaccination, offering the vaccine in week 28 of pregnancy or as soon as possible after should ensure that optimal antibody levels can be transferred to the baby.

Can the vaccine be given to women who are planning to breastfeed?

Yes. It is likely that antibodies produced following vaccination with Abrysvo® are present in human milk. These antibodies may contribute to further protective effects for breastfed babies.

No adverse effects from receiving RSV vaccine have been shown in breastfed infants of vaccinated mothers. Infants born to women who have received Abrysvo® can be safely breastfed.

Can the RSV vaccine be given to women with a previous diagnosis of Guillain-Barré syndrome?

A small number of cases of Guillain-Barré syndrome were observed following vaccination with Abrysvo® in older adults. Up to 2 June 2025, the MHRA received 21 Yellow Card reports of suspected Guillain-Barré syndrome in older adults (75 to 79 years,

where known) following Abrysvo. This is in the context of over 1.9 million doses of Abrysvo administered in the older adult RSV

vaccination programme up to 26 May 2025. Guillain-Barré syndrome occurs more commonly in males and older adults.

Guillain-Barré syndrome is a very 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, Guillain-Barré syndrome can cause difficulty moving, walking, breathing or swallowing.

A history of Guillain-Barré syndrome is not a contraindication for RSV vaccination and eligible women should continue to be vaccinated as recommended. There is evidence from other vaccines to suggest that having had a prior diagnosis of Guillain-Barré syndrome does not predispose an individual to further episodes following immunisation. Cases of Guillain-Barré syndrome that occur following any vaccination may occur by chance (as the background rate of Guillain-Barré syndrome is 20 per million people per year in the population).

Where can I get more information?

The Green Book Respiratory syncytial virus Chapter 27a includes detailed information about RSV and the RSV vaccination programme. Healthcare practitioners should familiarise themselves with the information in the Green Book chapter before offering RSV vaccination.

The PGD offers detailed information on the Abrysvo® vaccine.

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