E: immunisationpolicy@gov.scot



Dear Colleague,

RESPIRATORY SYNCYTIAL VIRUS (RSV) VACCINATION PROGRAMME

- This letter provides information on a new vaccination programme in Scotland which aims to protect vulnerable groups against Respiratory Syncytial Virus (RSV) and its complications.
- 2. RSV Vaccination will be offered to protect infants, through maternal vaccination, and older adults from August 2024.

Background

- 3. RSV is a common respiratory virus that usually causes mild, cold-like symptoms in adults and children, however the severity of illness developed can vary. RSV follows a seasonal pattern of community transmission, typically starting in October, peaking in December and declining by March.
- 4. For infants, RSV can cause bronchiolitis (inflammation of the small airways of the lung) which can be serious and cause death. RSV carries a significant burden across our population, representing one of the leading causes of hospitalisation in the first year of life. RSV is a major cause of infant mortality globally, and results in 20 to 30 deaths per year in the UK.
- 5. After infants, older adults are most likely to experience severe complications from RSV that may require hospitalisation. Older adults are more likely to have underlying chronic health conditions such as lung and heart disorders that increase the likelihood of severe RSV complications.
- 6. A passive RSV immunisation programme already exists for atrisk infants in specified groups, as detailed in the <u>Green Book</u>, and this will also continue.

Joint Committee on Vaccination and Immunisation (JCVI) Considerations

7. The Joint Committee on Vaccination and Immunisation (JCVI) reviewed evidence from manufacturers on the efficacy, safety and duration of protection of RSV immunisation products alongside clinical and epidemiological data on the burden of RSV in infants and older adults.

From the Chief Medical Officer

Professor Sir Gregor Smith Interim Chief Nursing Officer Anne Armstrong Chief Pharmaceutical Officer Professor Alison Strath

24 June 2024

SGHD/CMO(2022)12

Addresses

For action

Chief Executives, NHS Boards
Medical Directors, NHS Boards
Nurse Directors, NHS Boards
Directors of Midwifery, NHS Boards
Primary Care Leads, NHS Boards
Chief Officers of Integration
Authorities
Chief Executives, Local Authorities
Directors of Pharmacy
Directors of Public Health
Midwives
General Practitioners
Immunisation Co-ordinators
CPHMs

For information

Chairs, NHS Boards
Consultant Physicians and
Paediatricians
Chief Executive, NHS National
Services Scotland
Public Health Scotland
Scottish General Practitioners
Committee

Further Enquiries to:

Policy Issues Vaccination Policy Team immunisationpolicy@gov.scot

Medical Issues
Dr Lorna Willocks
St Andrew's House
Iorna.willocks@gov.scot







8. In June 2023, the JCVI issued a <u>short statement of advice that</u> stated that a universal programme to protect infants and a programme to protect older adults against RSV should be developed, provided they can be demonstrated to be cost-effective. A <u>full statement</u> providing further detail on the JCVI advice was published in September 2023.

2024/25 Programme Eligibility

- 9. For older adults, vaccination will be offered to those aged 74 up to 80 (i.e. 79+364 days) on 01 August 2024. This represents:
 - a) A primary offer for those turning 75 within the 12 months from 01 August 2024 on a rolling basis, and
 - b) A catch-up programme in 2024/25 for those aged 75 up to 80 (i.e. 79+364 days) as of 01 August 2024.
- 10. For the protecting infants (maternal) programme, vaccination will be offered from August 2024 to pregnant women or birthing people reaching 28 weeks (+0 days) gestation up to delivery on or after 01 August 2024, as a year-round continuous offer. This does not replace the existing atrisk infants programme which will continue for those who are eligible.
- 11. All vaccination programmes must include an element of proactive inclusion work in an effort to reduce health inequalities, with a particular focus on areas of highest deprivation and certain ethnicities who may have lower uptake.

Vaccination Programme

12. Further information on the older adult programme is included in **Annex A**, with detail on the protecting infants (maternal) programme in **Annex B**.

Action

- 13. Health Boards are requested to action this letter and ensure that their vaccination teams and primary and secondary care colleagues are aware of it.
- 14. We are very grateful for your continued support and hard work in delivering the Scottish Vaccination and Immunisation Programme to the people of Scotland.

Yours sincerely

Professor Sir Gregor Anne Armstrong Professor Alison Strath Smith

Chief Medical Interim Chief Nursing Chief Pharmaceutical

Officer Officer Officer







Eligibility

- 1. For 2024/25, vaccination will be offered to those aged 74 years up to 80 years (i.e. 79+364 days) on 01 August 2024. This represents:
 - a. A primary offer for those turning 75 years within the 12 months from 01 August 2024 on a rolling basis, and
 - b. A catch-up programme in 2024/25 for those aged 75 years up to 80 years (i.e. 79+364 days) as of 01 August 2024. In line with JCVI guidance, individuals will remain eligible until the day before their 80th birthday, with the exception of people who turn 80 in the first year who have until 31 July 2025 to get vaccinated.
- 2. For 2025/26, the primary offer will continue with eligibility for those turning 75 years within the 12 months from 01 August 2025 (i.e. those aged 74+1 days on 01 August 2025).

Vaccine Product and Dosage

3. The older adult programme including catch up will be implemented with Abrysvo® supplied by Pfizer as a one-dose schedule.

Vaccine Delivery

4. The delivery of the RSV programme will be the responsibility of Health Boards / Health and Social Care Partnerships (HSCPs) utilising appropriate local managed and/or commissioned services.

Vaccine Supply

- 5. Abrysvo® will be available to order through vaccine holding centres from August 2024. The vaccine is the same for both the older adult and protecting infants (maternal) programmes.
- 6. The vaccine is supplied in single dose packs and the presentation is a vial (containing active product) and a pre-filled syringe (containing sterile water solvent) for reconstitution.

Vaccine Storage and Disposal

- 7. Vaccines should be stored in their original packaging at +2°C to +8°C and protected from light. At these conditions, the shelf life of Abrysvo® is 30 months. Do not freeze as freezing may cause increased reactogenicity and loss of potency for some vaccines. It can also cause hairline cracks in the container, leading to contamination of the contents.
- 8. Abrysvo® should be administered immediately after reconstitution or within 4 hours if stored between 15°C and 30°C.
- 9. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Vaccine Stock Management

- 10. Please ensure sufficient fridge space is available for the vaccine. No more than two weeks of stock is recommended, and higher stock levels should be reduced to this level. A review of available fridge space will be necessary to ensure adequate storage capacity at the start of the programme.
- 11. Effective management of vaccines throughout the supply chain is essential to reduce vaccine wastage, including the use of appropriate cool boxes/bags for transporting the vaccine during







home/care home visits. Local protocols should be in place to minimise vaccine wastage, as even small percentage reductions in waste have a major impact on the financing of vaccine supplies.

Patient Group Directions (PGD)

12. A national specimen Patient Group Direction (PGD) for administration of Abrysvo® for older adults will be produced by Public Health Scotland (PHS) in time for programme implementation.

Communications Materials for Patients

13. PHS, in partnership with stakeholders, are developing communications materials and a marketing campaign for patients in relation to the introduction of an RSV vaccination programme. An information leaflet to support informed consent will be available for older adults, for enclosure with invitation letters. This information will also be available on NHS inform at www.nhsinform.scot/rsv-adult.

Workforce Education Resources for Healthcare practitioners

- 14. Information on consent for vaccination can be found in chapter two of the Green Book.
- 15. NHS Education for Scotland (NES), in partnership with PHS and stakeholders, are developing educational resources for healthcare practitioners in relation to the introduction of an RSV vaccination programme. These will include a vaccine specific slide set and a webinar and will be available on Turas Learn. Immunisation | Turas | Learn (nhs.scot)

The Green Book

16. Full details on use, dosage, administration, concomitant administration with other vaccines, contraindications, consent and reporting of adverse reactions with Abrysvo® will be included in the Green Book chapter once published.

Vaccine Safety and Adverse Reactions

- 17. The <u>most common adverse events following immunisation (AEFI)</u> observed are injection-site reactions. These include pain, localised itching, redness and swelling at the injection site. Other reactions commonly reported are headache, aching muscles, tiredness and feeling sick. These adverse reactions are usually mild or moderate in intensity.
- 18. Suspected vaccine-induced adverse drug reactions (ADR) should be reported via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard).

Vaccination Adverse Events

19. Vaccination adverse events should continue to be managed in accordance with current local and national protocols and standards and escalated as appropriate. Further details can be found in the existing publication *PHS Vaccination Adverse Event Management Protocol*, version 2.0, published 04 March 2024.

Vaccine Uptake

- 20. Vaccination events should be recorded on the Vaccination Management Tool (VMT). Training on use of the VMT is available here.
- 21. Health Boards are expected to participate in quality improvement activity led by PHS, with an inclusion and equity lens applied to the programme. All programmes must include an element of proactive inclusion work in an effort to reduce health inequalities, with a particular focus on areas of highest deprivation and certain ethnicities who may have lower uptake.







Funding Arrangements

- 22. Scottish Government will provide funding for the full costs of the RSV vaccines that have been administered to patients. This will be provided as an allocation at the end of the financial year.
- 23. Delivery costs are to be covered within the FVCV allocation (£76m) and supported through Health Board baseline budgets.







Eligibility

- 1. For the protecting infants (maternal) programme, vaccination will be offered to pregnant women or birthing people reaching 28 weeks (+0 days) gestation up to delivery on or after 01 August 2024, as a year-round continuous offer.
- 2. This does not replace the existing high-risk infants programme which continues for those eligible. Further detail is provided in the <u>Green Book chapter</u>.

Vaccine Product and Dosage

3. The maternal vaccination programme will be implemented with Abrysvo® supplied by Pfizer as a one-dose schedule. A single dose will be required in each pregnancy.

Vaccine Delivery

4. The delivery of the RSV protecting infants (maternal) programme will be integrated as closely as possibly within routine antenatal care. Vaccination should be accessible and offered appropriately at every opportunity during the period of eligibility within pregnancy.

Vaccine Supply

- 1. Abrysvo® will be available to order through vaccine holding centres from August 2024. The vaccine is the same for both the older adult and protecting infants (maternal) programmes.
- 5. The vaccine is supplied in single dose packs and the presentation is a vial (containing active product) and a pre-filled syringe (containing sterile water solvent) for reconstitution.

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