From the Chief Medical Officer
Professor Sir Michael McBride

HSS(MD)24/2024 (Addendum)

FOR ACTION
Chief Executives, Public Health Agency/HSC Trusts/NIAS
Deputy Secretary SPPG
GP Medical Advisers, SPPG
All General Practitioners and GP Locums *(for onward distribution to practice staff)*
OOHs Medical Managers *(for onward distribution to staff)*

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Your Ref:
Our Ref: HSS(MD)24/2024
Date: 2 August 2024

PLEASE SEE ATTACHED FULL CIRCULATION LIST

Dear Colleague

INTRODUCTION OF UNIVERSAL RESPIRATORY SYNCYTIAL VIRUS (RSV) VACCINATION PROGRAMME FOR OLDER ADULTS AND DURING PREGNANCY FOR INFANT PROTECTION

ACTION REQUIRED
Chief Executives must ensure that this information is drawn to the attention of all staff involved in the planned RSV vaccination programme.

The Strategic Planning and Performance Group (SPPG) must ensure this information is cascaded to all General Practitioners and Practice Managers for onward distribution to all staff involved in the planned RSV vaccination programme.

The Regulation and Quality Improvement Authority (RQIA) must ensure this information is cascaded to all Independent Sector Care Homes for onward distribution to all staff involved in the planned RSV vaccination programme.

1. This letter provides information about the forthcoming introduction of the new respiratory syncytial virus (RSV) vaccination programme. This programme will be offered to two cohorts:

a. older adults turning 75 years of age, with a one-off catch-up provided throughout the first year of the programme for those aged 75 to 79 years old, and
b. pregnant women from 28 weeks gestation to provide infant protection.

We encourage you to share this guidance with all those who are and/or will be involved in delivering this important vaccination programme.

2. RSV vaccination will be offered to older adults and during pregnancy for infant protection from **1 September 2024.**

Background

3. RSV is a common respiratory virus that can cause serious lung infections. For most people, RSV infection causes a mild respiratory illness. Globally, RSV infects up to 90% of children within the first 2 years of life and frequently reinfects older children and adults.

4. While RSV infection can occur at any age, the risk and severity of RSV and its complications are increased in older adults and in neonates and small infants. The clinical significance of RSV in infants is that it can cause bronchiolitis which leads to the inflammation of the small airways and significant breathing difficulties. It is a leading cause of infant mortality globally, resulting in 20 to 30 deaths per year in the UK.

5. 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 declines by March.

6. A targeted passive RSV vaccination programme already exists for at-risk infants in specified groups as detailed in The Green Book, and this targeted passive programme will continue as the new programme is introduced.

RSV Vaccine Programme for Older Adults

7. In June 2023, based on impact and cost effectiveness modelling, the JCVI advised that an RSV vaccination programme, that is cost effective, should be developed for older adults aged 75 years and above.

8. A **routine programme for older adults** will be offered as a single dose of RSV vaccine throughout the year to all adults turning 75 years from 1 September 2024. **i.e. all individuals born on or after 1 September 1949.** The programme will continue indefinitely unless JCVI recommend any changes. Individuals remain eligible up to the day before turning 80 years of age.

9. A **one-off catch-up campaign** will also be offered during the programme's first year (until 31 August 2025) for those already aged 75 to 79 years old on 1

September 2024. **i.e. all individuals born between 1 September 1945 and 31 August 1949 up to and including the day before their 80th birthday.** This includes individuals aged 79 years on 1st September 2024 who will have their 80th birthday during the catch-up campaign. They will remain eligible up until, and including 31 August 2025, to ensure that they have sufficient opportunity to be vaccinated.

10. The programme for older adults will be delivered by General Practice as a local enhanced service (LES), starting from 1 September 2024. Practices should identify, call and administer the vaccine to all eligible individuals registered in their practice for the routine and the one-off catch-up campaigns. Referrals for vaccination in those who are housebound should be made to the respective HSC Trust Vaccination Teams.

11. HSC Trust Vaccination Teams will be responsible for vaccinating eligible adults (i.e. those as outlined in para 8 and 9) who live in Nursing and Residential Care Homes or who are housebound. PHA may also ask Trusts to vaccinate other specific patient groups, including where a GP service is not available. They should identify eligible individuals from their caseload, communicate with the registered GP and administer the vaccine. Trust vaccinators should provide a best interest decision for clients registered in a care home who are eligible.

12. RSV infections occur year-round but primarily within the period October to March, with most infections occurring in a relatively short period of about six weeks. The Green Book recommendation is that eligible individuals for the routine RSV vaccine programme (i.e. those turning 75 years of age) should be offered the vaccine as soon as possible after they become eligible so that they are protected at the earliest opportunity. However, this means that individuals that turn 75 years between October and March should receive the vaccine during the time when GP practices are also delivering the Influenza and COVID-19 vaccine programmes. We acknowledge that it is operationally challenging to deliver three vaccines to the same age cohort, especially as expert advice at present is that it is not recommended that the three vaccines be co-administered. The RSV vaccine programme is not a seasonal vaccine programme but a programme that is offered throughout the year. If operationally possible, GP practices should aim to vaccinate eligible individuals in line with Green Book recommendations, but not at the expense of the Influenza and COVID-19 Programmes. If it is thought that the individual is unlikely to return for a second appointment or immediate protection is necessary, the RSV vaccine can be administered at the same time as Influenza and/or COVID-19 vaccination.

13. GP practices may wish to vaccinate individuals that are eligible through the catch-up campaign (i.e. those aged 75-79 years) as soon as possible and as operationally feasible, but otherwise can choose to offer vaccination to this cohort on completion of their Influenza and COVID-19 vaccine programmes.

RSV Vaccine Programme for Pregnant Women for Infant Protection

14. In June 2023, based on impact and cost effectiveness modelling, the JCVI advised that a RSV vaccination programme, that is cost effective,

should be developed for infants. Further details can be found in the JCVI RSV statement.

15. A **routine programme for pregnant women** will be offered as a single dose of RSV vaccine to all women from 28 weeks gestation, from 1 September 2024. Vaccine should be offered in each pregnancy.

16. Whilst the vaccine can be given from 28 weeks gestation, it should ideally be administered in week 28, or soon after, to maximise the likelihood that a baby will be optimally protected from birth although the vaccine can be given up until delivery.

17. Women may still be vaccinated later in pregnancy, including off-label, after week 36 of pregnancy, but this may not offer as high a level of passive protection to the baby. Vaccines given to the mother close to the time of delivery, including soon after delivery, may offer indirect protection by preventing maternal infection/infectiousness and through antibody transfer in breastmilk.

18. The RSV vaccination programme for pregnant women will be administered locally by HSC Trusts. Implementation of the programme will be led by Trust vaccination services in collaboration with Trust maternity services and will include oversight of the programme by respective Trusts. Programme implementation by Trusts will include training considerations for staff, identification of pregnant women, provision of patient information on the vaccine, vaccine administration and vaccine recording. Vaccination clinics should take place alongside antenatal clinics and, at present, should be supported by the existing HSC Trust COVID-19 Vaccination Teams. Eligible pregnant women enquiring about how to access RSV vaccine should be directed to their local HSC Trust.

19. Infants at high risk of RSV disease should also continue to receive passive immunisation against RSV in accordance with criteria in the Green Book, chapter 27a regardless of whether the mother was vaccinated during the pregnancy.

Vaccine Equity

20. The universal RSV programme should aim to maximise uptake across all groups, with a particular focus on ensuring vaccination equity.

21. Regional vaccine uptake monitoring should include uptake according to socioeconomic status, geographical area of residence and any other factors that contribute to vaccine inequity.

22. Providers delivering the vaccine programmes should have access to uptake monitoring, either through arrangements with PHA or through their own monitoring arrangements, so that they can direct programme delivery to ensure maximum uptake.

Surveillance and reporting

23. The Vaccine Management System (VMS) software will be updated to enable appropriate recording of RSV vaccination. Use of the VMS to underpin delivery of this programme is expected to provide accurate and timely data relating to vaccine uptake and programme coverage.

24. **All providers administrating the RSV vaccine should record administration on VMS**. This includes Trusts delivering through maternity services and to care homes and to the housebound, as well as GP practices delivering to older adults. The PHA will support service providers with operational instructions on how to complete this recording.

25. The PHA vaccine surveillance team should monitor and extract data from VMS at regular intervals, to provide regular reports of uptake RSV vaccination programme among pregnant women and older adults.

Vaccine supply/New ordering arrangements for vaccine

26. 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 2089).

27. 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.

28. Abrysvo® is presented as a single dose pack for reconstitution.

Vaccine Dosage

29. Abrysvo® is approved by regulators for pregnant individuals and older adults. A single dose of 0.5 mL should be administered using the full volume of the reconstituted, drawn up syringe.

Vaccine Storage and Disposal

30. RSV vaccines should be stored in their original packaging in a refrigerator at +2°C to +8°C.

31. RSV vaccines should ordinarily be used immediately after being taken from the fridge (and reconstituted if applicable) to reduce the risk of administration errors, minimise waste, and from a microbiological perspective.

32. After reconstitution Abrysvo® (Pfizer Pre-F vaccine) is stable for 4 hours at room temperature between 15°C and 30°C.

33. Service providers should ensure sufficient refrigeration space is available for the vaccine. No more than two weeks of stock is recommended. 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 pack of Abrysvo® vaccine is physically larger than most other vaccines supplied. Pack size information will be provided by PHA.

34. Additional storage and preparation information is available here.

Patient Group Directions (PGD)

35. A single PGD for administration of Abrysvo® for older adults and pregnant women will be published by the SPPG/PHA PGD Development Team and will be available for GP practices and Trusts prior to the launch date of the programme. The PGD will be developed in line with national PGD and The Green Book.

Information and Guidance for Healthcare Practitioners

36. Health professionals responsible for all aspects of programme delivery should follow the advice detailed in chapter 27a of Immunisation Against Infectious Disease (the Green Book) for policy, programme management and clinical guidance.

37. The PHA should ensure that training materials, including educational slides are developed and made available to those delivering the programme in advance of the launch date.

38. Consideration should be given for how training will be distilled to ensure that health professionals, including maternity health professional from all disciplines, are competent and confident to deliver the RSV vaccine.

39. Trust and GP practice providers should ensure that their staff are appropriately trained to deliver RSV vaccine programme under the regional PGD and are aware of the training resources available to them.

Patient Information Materials

40. Communications materials are being developed to support the introduction of RSV vaccination programmes for older adults and during pregnancy for infant protection.

Consent

41. Guidance on informed consent can be found in Chapter 2 of the 2006 edition of *Immunisation against infectious disease* (the ‘Green Book’).

Black Triangle Scheme and reporting suspected adverse reactions

42. Abrysvo® is part of the Medicines and Healthcare products Regulatory Agency's (MHRA) Black Triangle Scheme for new medicines and vaccines to allow rapid identification of new safety information.

43. Health professionals and those vaccinated are asked to report suspected adverse reactions through the online Yellow Card scheme, by downloading the Yellow Card app or by calling the Yellow Card scheme on 0800 731 6789 9am to 5pm Monday to Friday.

Funding and Service Arrangements

44. Additional funding will be provided for commissioning of programme delivery models in HSC Trusts and GP practices for both the older adults and pregnant women. Funding will be transferred to PHA for onward management with HSC Trusts and for GP Practices via SPPG.

45. PHA will be responsible for:

    a. Commissioning, including performance management, assurance, and distribution of funding, of the Trust delivered elements of the programme.
    b. Ensuring the funding for the GP practice delivery is ringfenced for GP costs that SPPG will recharge PHA for in a similar way to the GP costs for other vaccination programmes.
    c. Production and distribution of communication resources for both health professionals and the public.
    d. Oversight and management of required VMS software changes. Development of operational guidance on vaccine recording on VMS for providers.
    e. Regional monitoring and surveillance of vaccine uptake, considering vaccine equity indicators, and production of regular output reports.
    f. Support the development and distribution of the regional RSV vaccine PGD through the SPPG / PHA PGD Development Team.

46. SPPG will be responsible for:

    a. Development and negotiation of the Locally Enhanced Service in line with policy requirements.
    b. Regional oversight of the GP practice delivered element of the programme, including performance management and assurance of delivery by GP Practices in line with the LES.
    c. Timely communication to GP practices at implementation of the programme and as required.
    d. Ensuring funding is recharged to PHA in a timely fashion in a similar way to the GP costs for other vaccination programmes.
    e. Lead development and distribution of the regional RSV vaccine PGD through the SPPG / PHA PGD Development Team.

47. The Regional Pharmaceutical Procurement Service will be responsible for:

    a. Providing support and product technical information to Trust Pharmacy Departments to ensure a smooth uptake.

48. Trusts will be responsible for:

    a. Distribution of the vaccine to GP practices for the older adults' programme.
    b. Overall programme delivery of pregnant women programme, which includes strategic oversight within the Trust, training of staff, identification of eligible women, provision of patient information, administration of the vaccine and recording of administration on VMS.
    c. Supporting GP practices with the older adults' programme, which includes timely communication with GP practices if applicable, identification, administration and recording vaccine on VMS for care home residents aged 75-79 years, the housebound and those patients whose GP does not choose to offer RSV vaccination.

49. GP Practices will be responsible for:

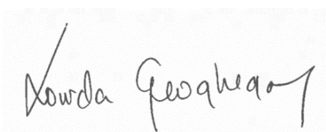
    a. Overall programme delivery of the routine older adult programme for 75 year olds and the one-off catch-up for 75-79 year olds in line with the LES.

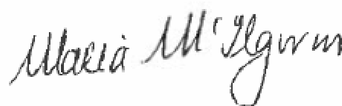
Conclusion

50. We would like to acknowledge that planning for the RSV programmes will be undertaken at pace, and alongside preparations for the 2024 to 2025 winter respiratory vaccination programmes.

51. We are very grateful for your continued support in the delivery of vaccinations to the people of Northern Ireland and your commitment in protecting those most vulnerable to RSV infection.

Yours sincerely





Pp Professor Lourda Geoghegan
Deputy Chief Medical Officer

Professor Sir Michael McBride
Chief Medical Officer

Ms Maria McIlgorm
Chief Nursing Officer

Professor Cathy Harrison
Chief Pharmaceutical Officer

Circulation List

Director of Public Health/Medical Director, Public Health Agency (*for onward distribution to all relevant health protection staff*)
Assistant Director Public Health (Health Protection), Public Health Agency
Director of Nursing, Public Health Agency
Assistant Director of Pharmacy and Medicines Management, SPPG *(for onward distribution to Community Pharmacies)*
Directors of Pharmacy HSC Trusts
Director of Social Care and Children, SPPG
Family Practitioner Service Leads, SPPG *(for cascade to GP Out of Hours services)*
Medical Directors, HSC Trusts *(for onward distribution to all Consultants, Occupational Health Physicians and School Medical Leads)*
Nursing Directors, HSC Trusts *(for onward distribution to all Community Nurses, and Midwives)*
Directors of Children's Services, HSC Trusts
RQIA (*for onward transmission to all independent providers including independent hospitals*)
Joe Brogan, Assistant Director, Head of Pharmacy and Medicines Management, Strategic Planning and Performance Group (SPPG) (*for onward distribution to SPPG Pharmacy and Medicines Management Team and community pharmacists*)
Regional Medicines Information Service, Belfast HSC Trust
Regional Pharmaceutical Procurement Service, Northern HSC Trust
Professor Donna Fitzsimons, Head of School of Nursing and Midwifery QUB
Professor Neal Cook, Head of School of Nursing, University of Ulster
Heather Finlay, CEC
Maurice Devine, Open University
Professor Paul McCarron, Head of School of Pharmacy and Pharmaceutical Sciences, UU
Professor Colin McCoy, Head of School, School of Pharmacy, QUB
Postgraduate Pharmacy Dean, NI Centre for Pharmacy Learning and Development, QUB
Michael Donaldson, Head of Dental Services, SPPG *(for distribution to all General Dental Practitioners)*
Raymond Curran, Head of Ophthalmic Services, SPPG *(for distribution to Community Optometrists)*
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Prof Alan Smyth, QUB
Prof Louise Dubras, University of Ulster

This letter is available on the Department of Health website at

https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications