National Immunisation Advisory Committee
An Coiste Comhairleach Náisiúnta um Imdhíonadh

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Vaccination against respiratory syncytial virus in older adults: Protocol for an evidence summary to inform updated recommendations

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About the National Immunisation Advisory Committee

The National Immunisation Advisory Committee (NIAC) is Ireland's National Immunisation Technical Advisory Group (NITAG). NIAC provides independent evidence-based recommendations and advice to the Minister for Health on immunisation and related health matters to inform health policy in Ireland.

First established in 1998, NIAC has been hosted by HIQA as a statutory function under Section 8(1)(g) of the Health Act 2007 (as amended) since 31 March 2025.

NIAC membership is voluntary, and includes nominees from the Royal College of Physicians of Ireland, its Faculties and Institutes, the Royal College of Surgeons in Ireland, the Irish College of General Practitioners, the Nursing and Midwifery Board of Ireland, the Infectious Diseases Society of Ireland, the Travel Medicine Society, the National Virus Reference Laboratory, as well as members with expertise in gerontology and inclusion health, and lay members. Meetings are attended by representatives from the Department of Health and the Health Service Executive (HSE), including the HSE's National Immunisation Office. Representatives of the Health Products Regulatory Authority attend to provide regulatory advice in relation to vaccines.

The NIAC Secretariat team, situated within the HTA Directorate in HIQA, provides clinical, evidence synthesis, and administrative support to NIAC.

Visit www.hiqa.ie for more information.

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1 Purpose and aim

In October 2023, the National Immunisation Advisory Committee (NIAC) published recommendations for passive immunisation and vaccination against respiratory syncytial virus (RSV) in infants, children, and older adults.[1] At the time the recommendations were made, two vaccines were authorised in the European Union (EU) for the prevention of lower respiratory tract disease (LRTD) caused by RSV in adults aged 60 years and older. Each of these authorised vaccines, RSVPreF3 (Arexvy®, GSK)[2, 3] and RSVpreF (Abrysvo®, Pfizer) was supported by a published study reporting on a phase 3 clinical trial.[4, 5]

From late 2023 to 2025, there were a number of developments relating to vaccination of adults against RSV. A third RSV vaccine was authorised in the EU for the prevention of RSV-related LRTD in adults aged 60 years and older, RSV mRNA vaccine (mRESVIA®, Moderna),[6] with supporting phase 3 clinical trial data published.[7] In addition, further data regarding the safety, efficacy and effectiveness of RSVPreF3 and RSVPreF were published. Given these developments, National Immunisation Technical Advisory Groups (NITAGs) in several countries made and or updated their recommendations with respect to RSV. In this context, NIAC has also decided to revisit its recommendations regarding RSV vaccines for older adults issued in October 2023.

This protocol outlines the methods by which the NIAC Secretariat will identify and summarise updated evidence in relation to vaccination against RSV among older adults in Ireland. The evidence summary will support the development of updated recommendations by NIAC.

2 Policy questions and evidence summary outline

The evidence summary will address the following policy questions (PQs):

PQ1. What is the best use of RSV vaccines for adults aged 60 years and older?

PQ2. What is the best use of RSV vaccines for adults aged 60 years and older considered to be at increased risk of severe RSV infection?

These policy questions will be considered by NIAC according to the adapted Evidence to Recommendation (EtR) framework[8] used to develop its recommendations to the Minister for Health. Information relating to the following EtR domains will be obtained and summarised:

1. Problem
2. Benefits and harms

3. Values and preferences
4. Resource use
5. Equity
6. Acceptability
7. Feasibility.

This evidence summary will primarily focus on the first two domains — the problem, and the benefits and harms of the interventions. A standardised approach to the evidence summary process has been developed and documented in this protocol to allow for transparency, to aid project management, and to mitigate risks.

3 Problem

To describe the public health importance of RSV, an overview of the epidemiology of RSV and burden of disease associated with RSV in the general population of adults aged 60 years and older in Ireland will be provided. This overview will include up-to-date data on notified cases and outbreaks of RSV, as well as hospitalisations, intensive care unit (ICU) admissions and mortality associated with RSV, obtained from the Health Protection Surveillance Centre.

To identify risk factors for severe RSV disease in adults, scoping searches of online databases will be conducted in consultation with a librarian (see Appendix 1). These searches will aim to identify systematic reviews of studies that report on risk factors and their associations with incidence of severe disease related to RSV infection. For the purposes of this scoping work, severe disease will be defined as disease that results in emergency department visit, hospital admission, use of mechanical ventilation, ICU admission, or death.

4 Benefits and harms

A high-level description of the RSV vaccines currently authorised for use in the target populations in Ireland, either by the European Medicines Agency or the Health Products Regulatory Authority, will be provided.

Up-to-date evidence regarding the efficacy, effectiveness and safety of RSV vaccines in older adults will be summarised based on the findings of an existing systematic review, supplemented by rapid scoping of immunogenicity and co-administration studies. To guide this work, the policy questions of interest are outlined according to the PICOS (population, intervention, comparator, outcome and study designs) framework, as detailed in Table 1.

Table 1. Population, intervention, comparator, outcomes, study designs (PICOS) and language for the efficacy, effectiveness, safety and immunogenicity of RSV vaccines in older adults

Population	▪ Adults aged ≥60 years in the general population ▪ Adults aged ≥60 years considered to be at increased risk* of severe RSV disease†.
Intervention	Primary: ▪ A single dose of any one of the following RSV vaccines: – RSVpreF (Abrysvo®) – RSVPreF3 (Arexvy®) – RSV mRNA vaccine (mRESVIA®). Secondary: ▪ Co-administration of an RSV vaccine with any other vaccine. ▪ Revaccination with a second or subsequent dose of an RSV vaccine.
Comparator	▪ No vaccine ▪ Placebo ▪ Co-administration with another vaccine ▪ Another authorised RSV vaccine.
Outcomes	▪ Vaccine efficacy and or effectiveness — main outcomes – Hospitalisation due to RSV disease – Length of hospital stay – Use of supplemental oxygen – ICU admission – Use of invasive ventilation – Mortality (due to RSV and all-cause mortality) – Long-term outcomes, for example reduced functional capacity. ▪ Vaccine efficacy and or effectiveness — additional outcomes – Laboratory-confirmed RSV infection – Medically attended RSV infection (including ED presentations) – Measures of the severity and or duration of symptoms of RSV infection among those not hospitalised – Antibiotic usage – Duration of protection from any main outcome. ▪ Safety – Serious adverse events related to vaccination, including Guillan-Barré syndrome – Solicited adverse events

	– Unsolicited adverse events. ▪ Measures of immunogenicity (for vaccines for which effectiveness data are not available).
Study designs	Vaccine efficacy, effectiveness and safety: ▪ Randomised controlled trials ▪ Observational studies with at least one valid comparator group (for example, cohort studies with vaccinated and unvaccinated groups, case-control studies in which differences in vaccination status between groups were assessed). Immunogenicity: ▪ Clinical trials (any design).
Language	English only.

Key: ED – emergency department; ICU – intensive care unit; mRNA – messenger ribonucleic acid; RSV – respiratory syncytial virus.

* For the purposes of this review, adults at increased risk of severe infection include, but are not limited to, those with chronic lung disease, chronic conditions affecting the circulatory system, and those who are immunocompromised.

† For the purposes of this review, severe RSV disease is defined as disease that results in emergency department visit, hospital admission, use of mechanical ventilation, ICU admission, or death.

To address the efficacy, effectiveness and safety of RSV vaccines, the findings of an update to a relevant systematic review commissioned by the European Centre for Disease Prevention and Control will be used.[9] The update to this review was carried out by HIQA as part of a health technology assessment (HTA) of immunisation against RSV in Ireland.[10] The HIQA update included updated searches, based on the search strategy of the original review, conducted in January and April 2025 in consultation with a librarian. Forward and backward citation chasing was also conducted in May 2025. Findings will be summarised narratively, with consideration of assessments of the risk of bias of included studies and the overall certainty of the evidence reported by the authors of the original systematic review and the HIQA update.

To identify available evidence regarding the immunogenicity of RSV vaccines for which effectiveness data are not available, as well as evidence regarding co-administration of RSV vaccines with other adult vaccines, and revaccination, supplementary scoping searches will be conducted. Online databases will be searched in May 2025 to identify records as per the PICOS outlined in Table 1. Search strategies will be developed in consultation with a librarian (see Appendix 1).

For supplementary scoping searches, results will be exported to Covidence (www.covidence.org). Single screening of records retrieved will be conducted by two reviewers. For both title and abstract screening, and full text review, a minimum of 10% of records will be dual screened to ensure agreement between reviewers. For each included study, data extraction will be carried out by one reviewer using a standard electronic template. Cross-checking by a second reviewer will be conducted for any critical data that may affect the results or conclusions (for example, definitions and or outcomes data). Any disagreements regarding eligibility for inclusion or data extraction will be resolved through discussion, and using a third reviewer where necessary.

5 Other domains

The following domains will be primarily informed by the shared expertise and experiences of NIAC members: values and preferences, resource use, equity, acceptability, and feasibility. Where relevant information regarding these domains is identified through the evidence syntheses relating to the problem, and benefits and harms domains, it will be summarised narratively.

In addition, targeted online searches will be conducted to identify relevant recommendations issued by selected international NITAGs, including a combination of EU and non-EU countries. Countries will be selected on the basis of having established NITAGs that meet all six WHO criteria,[11] combined with other factors such as geographical proximity to Ireland, similarity of healthcare systems and or immunisation programmes to Ireland, and availability of relevant recommendations and or supporting documents. An overview of these recommendations will be provided for NITAGs in countries including, but not limited to:

- Australia
- Canada
- France
- Germany
- New Zealand
- UK
- US.

6 Quality assurance processes

The review will be undertaken in accordance with HIQA's HTA Directorate Quality Assurance Framework and led by an experienced member of the NIAC Secretariat team. The outputs will be reviewed by at least two senior members of the team to ensure processes are followed and quality is maintained. To further ensure quality,

accurate interpretation of the evidence, and accurate representation of their considerations, feedback on draft outputs will be sought from the Working Group and Committee.

7 Recommendations and publication

The evidence gathered, as outlined above, will be compiled for presentation at a meeting of the NIAC RSV Working Group, and at a full NIAC meeting. The evidence summary will be presented in accordance with the adapted EtR framework[8] used by NIAC to develop its recommendations to the Minister for Health. The evidence summary findings will then be synthesised, together with the opinion, discussion points and recommendations of NIAC, in a report for submission to the Minister for Health and publication on the HIQA website.

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Appendix 1. Outline of planned search strategies

Topics for which supplementary scoping searches will be conducted:

- risk factors for severe RSV disease in adults
- immunogenicity of RSV vaccines
- co-administration of RSV vaccines with other vaccines in adults
- revaccination of adults with RSV vaccines.

Databases to be searched:

- Embase via Ovid
- Medline via Ebsco
- The Cochrane Library.

Searches will be conducted in May 2025. The search periods will be from database inception to the date on which the search is run. Sample search strategies for each topic for a single database (Embase via Ovid) are shown in Tables A1.1 to A1.4. Full line-by-line search strategies are available on request to info@hiqa.ie.

Table A1.1 Sample search strategy in relation to risk factors for severe RSV disease in adults, to be run in Embase via Ovid

#	Searches
1	Human respiratory syncytial virus/ or respiratory syncytial virus infection/
2	('respiratory syncytial virus*' or rsv).ab,ti.
3	1 or 2
4	exp Systematic Review/ or exp Meta Analysis/ or ((systematic* adj2 (review* or overview*)) or (meta analys* or meta analyz*) or (literature adj3 (review* or overview*))).ti,ab.
5	3 and 4
6	exp hospitalization/
7	emergency care/ or exp emergency health service/
8	(severe or severity or critical or hospital* or intensive or emergency or ICU or ED or ventilat* or burden or mortality or death).ab,ti.
9	6 or 7 or 8
10	5 and 9
11	limit 10 to yr="2020 -Current"
12	limit 11 to (conference abstract or conference paper or "conference review" or editorial)

Table A1.2 Sample search strategy in relation to immunogenicity of RSV vaccines, to be run in Embase via Ovid

#	Searches
1	Human respiratory syncytial virus/ or respiratory syncytial virus infection/
2	(respiratory syncytial virus* or RSV).ab,ti.
3	1 or 2
4	exp vaccine/
5	immunization/
6	exp respiratory syncytial virus vaccine/
7	(vaccin* or immuni*).ab,ti.
8	(Abrysvo or "pf 6928316" or "pf06928316" or "pf6928316" or "pf 06928316" or Arexvy or "gsk 3844766a" or gsk3844766a or mRESVIA or mRNA-1345 or mRNA1345).ab,ti.
9	4 or 5 or 6 or 7 or 8
10	3 and 9
11	exp Systematic Review/ or exp Meta Analysis/ or ((systematic* adj2 (review* or overview*)) or (meta analys* or meta analyz*) or (literature adj3 (review* or overview*))).ti,ab.
12	exp Randomized Controlled Trial/ or randomized controlled trial.pt. or ((random* adj3 trial) or (placebo* or single blind* or double blind* or triple blind*)).ti,ab.
13	11 or 12
14	10 and 13
15	limit 14 to dc=20230601-20251231
16	limit 15 to (conference abstract or conference paper or "conference review")
17	15 not 16
18	limit 17 to english language

Table A1.3 Sample search strategy in relation to co-administration of RSV vaccines with other vaccines in adults, to be run in Embase via Ovid

#	Searches
1	Human respiratory syncytial virus/ or respiratory syncytial virus infection/
2	(respiratory syncytial virus* or RSV).ab,ti.
3	1 or 2
4	exp vaccine/
5	immunization/
6	exp respiratory syncytial virus vaccine/
7	(vaccin* or immuni*).ab,ti.
8	(Abrysvo or "pf 6928316" or "pf06928316" or "pf6928316" or "pf 06928316" or Arexvy or "gsk 3844766a" or gsk3844766a or mRESVIA or mRNA-1345 or mRNA1345).ab,ti.
9	4 or 5 or 6 or 7 or 8
10	3 and 9
11	(coadminist* or concurrent* or combin* or simultaneous* or concomitant).ab,ti.

12	10 and 11
13	limit 12 to dc=20230601-20251231
14	limit 13 to (conference abstract or conference paper or "conference review" or editorial)
15	13 not 14
16	limit 15 to english language

Table A1.4 Sample search strategy in relation to revaccination with RSV vaccines, to be run in Embase via Ovid

#	Searches
1	Human respiratory syncytial virus/ or respiratory syncytial virus infection/
2	(respiratory syncytial virus* or RSV).ab,ti.
3	1 or 2
4	exp vaccine/
5	immunization/
6	exp respiratory syncytial virus vaccine/
7	(vaccin* or immuni*).ab,ti.
8	(Abrysvo or "pf 6928316" or "pf06928316" or "pf6928316" or "pf 06928316" or Arexvy or "gsk 3844766a" or gsk3844766a or mRESVIA or mRNA-1345 or mRNA1345).ab,ti.
9	4 or 5 or 6 or 7 or 8
10	3 and 9
11	exp revaccination/
12	(re-vaccination or revaccination).ab,ti.
13	((boost* or repeat*) adj3 (vaccin* or immun*)).ab,ti.
14	11 or 12 or 13
15	10 and 14
16	limit 15 to dc=20250401-20251231

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