RSV Vaccination in Older Adults: Scotland-wide study to assess vaccine safety



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# Overview

This document outlines the technical specification for vaccine safety surveillance of clinical adverse events in older adults following the introduction of the new Respiratory Syncytial Virus (RSV) vaccine in Scotland. This will involve the development of a rapid surveillance system to identify and monitor health conditions potentially associated with the RSV vaccine, defined as Adverse Events of Special Interest (AESI). Planned steps to investigate any detected safety signals will be outlined.

The purpose of this work is to provide additional evidence on the safety of the vaccination programme, aiming to provide reassurance beyond the scope of clinical trials. These are often limited in sample size and heterogeneity.

Safety surveillance will differ for the populations eligible for vaccination, currently older adults and pregnant women. This document will outline the safety surveillance for older adults. Vaccine safety in pregnant women will be outlined in a separate protocol. Where possible, previous analyses used by Public Health Scotland (PHS) for monitoring the safety of COVID-19 and influenza vaccinations will be adapted to avoid duplication of effort.

# Background

Respiratory Syncytial Virus (RSV) is a common infection that usually causes mild respiratory infection in adults and children but can cause severe lower respiratory infection in infants and older adults, accounting for significant morbidity and mortality.1, 2 In particular, older adults with comorbidities are especially vulnerable to severe outcomes of infection.3 Following the development of a new vaccine, an immunisation programme commenced in Scotland in August 2024 to protect against those at highest risk of serious illness from RSV infection:

* Older Adult Programme: A routine programme for those aged 75 years and over, and a one-off offer for 75–79-year-olds. In Scotland, this was offered in late summer / early autumn to accommodate the winter vaccination programme, with some opportunistic vaccination ongoing, and potential for mop-ups outwith the winter programme.
* Maternal Programme: Offered to pregnant women from 28 weeks gestation to help provide protection to newborns. Vaccination is currently offered year-round.

The new Abrysvo® (RSVpreF) vaccine (a bivalent, recombinant vaccine developed by Pfizer) was licensed in the UK in November 20234 and is the only vaccine approved for use in both older adults and pregnant women. For both programmes, the vaccine schedule comprises one dose of Abrysvo®. Further information on the dosing programme is available in Chapter 27a of the [Green Book](https://www.gov.uk/government/publications/respiratory-syncytial-virus-the-green-book-chapter-27a).2

Clinical trials found the Abrysvo® vaccine to be safe and effective overall at preventing RSV-associated lower respiratory tract infections in older adult populations.5-7 However, a higher number of Guillain-Barre Syndrome (GBS) cases were reported among those vaccinated than placebo groups.7 Clinical trials are often limited in size and heterogeneity so may be too small to assess rare outcomes and may not reflect the general population. Surveillance of vaccine safety following the commencement of the programme is necessary to monitor the incidence of clinical adverse outcomes and ensure the safety of the vaccine in the population beyond the scope of clinical trials. Furthermore, the elevated risk of GBS has also been shown in unadjusted results from observed versus expected (OE) and self-controlled case series (SCCS) studies of post-vaccination GBS in older adults aged 65 years and over in the United States (US) (but noting that the eligible cohort in Scotland is older than the eligible group in the US).8

## Aim

The main aim of this work is to assess the safety of the RSV Abrysvo® vaccination among the eligible older adult population.

## Purpose

Monitoring the safety of a new vaccine in real-world settings offers additional and ongoing reassurance together with safety results from clinical trials, which are often limited by sample size and exclusion of individuals with pre-existing health conditions. This ensures the credibility of the programme and maintains public confidence.

## Objectives

1. To estimate whether the incidence of adverse events of special interest (AESI) in older adults is higher following vaccination than expected, based on background incidence rates from a pre-RSV-vaccination period (observed versus expected (OE) study design).
2. To investigate whether there is an increased incidence of AESI in older adults following RSV vaccination, compared to a pre-RSV-vaccination control period (self-controlled case series (SCCS) study design).

# Surveillance Design

## Primary analysis - observed versus expected

Observed versus expected (OE) analysis retrospectively compares background (pre-RSV-vaccination implementation) incidence rates (IRs) with post-RSV-vaccination implementation IRs of AESI. Background IRs of AESI events will be calculated using the same methodology outlined in “COVID-19 vaccine safety in Scotland – background rates of adverse events of special interest".9 Background rate estimates should reflect the RSV vaccination period as closely as possible. However, many of the IRs of AESI were affected by the COVID-19 pandemic in recent years.9 To determine the most suitable background rate period for each AESI, comparisons of IRs will be made between pre-COVID-19-pandemic (01 January 2015 to 31 December 2019), early COVID-19 pandemic (01 January to 31 December 2020), and COVID-19 vaccination (01 January 2021 to 31 December 2023) periods. For each AESI, IRs will be defined as different in one period compared to another (outlier) where the IR and 95% confidence intervals are higher or lower than the comparison period with no overlap. Where all the IRs overlap with the COVID-19 vaccination period, the IRs for the total period 01 January 2015 to 31 December 2023 will be used as the background rate period. If the IRs in the early COVID-19 pandemic period are the only outlier, the early COVID-19 pandemic period will be removed from the total background rate period. Where the pre-COVID-19 pandemic period differs from the most recent period (COVID-19 vaccination), the assumption will be made that the COVID-19 pandemic had an impact on AESI rates and only the most recent COVID-19 vaccination period will be used. Figure 1 illustrates the three proposed background rate periods to be used based on these scenarios.

Figure 1: Illustration of the background rate periods to be used for each AESI based on changes to estimates of incidence rates (IRs) and 95% confidence intervals (CIs) during the COVID-19 pre-pandemic, early COVID-19 pandemic and COVID-19 vaccination periods, from 01 January 2015 to 31 December 2023.

A screenshot of a calendar

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A clean window will be used for each AESI based on their aetiology to identify only those adverse events that are new incidents rather than reoccurring health outcomes. The clean window will be 365 days for the majority of AESI. Exceptions will include facial palsy including Bell’s Palsy (183 days), encephalitis including Acute Disseminated Encephalomyelitis (ADEM;183 days), and seizures (28 days), as multiple hospital admissions for new onset cases of these conditions are more likely to occur within shorter time frames. See the section [Outcomes of Interest](#_Outcomes_of_interest) for further details of the AESI and their definitions. OE ratios will be reported with 95% confidence intervals (CIs). Possible safety signals will be identified where the lower CI is greater than 1.0 (i.e. the observed rate is significantly higher than expected)10 and there are three or more observed incident events in a post-vaccination risk period, out of all those vaccinated. Further details of the methods used are available in Table 2 in the [Appendix](#_Appendix).

## Secondary analysis - self-controlled case series

Self-controlled case series (SCCS) will retrospectively compare the rate of hospitalisations containing a recorded AESI in post-vaccination risk period(s) with the rates during unexposed pre-vaccination control periods for the same individuals using conditional logistic regression. SCCS analysis is conducted within-person and therefore controls for time-invariant confounders. The baseline control period will be from 75 to 15 days prior to vaccination for each individual (consistent with previous analysis for COVID-19 vaccine safety).11 This will give an indication of each individual's incidence rate of AESI from a time period immediately before the vaccination period, whilst allowing for a clearance period from days -14 to 0 prior to vaccination (with day 0 representing the day of vaccination) to be excluded when individuals are likely to be healthy due to the healthy vaccinee effect. This is the period where individuals are less likely to be vaccinated while unwell, creating a healthier bias among vaccinated populations. Exceptions to the clearance period will be made for seizures and anaphylactic shock, which are likely to occur soon or immediately after vaccination and will therefore use a clearance period of -14 to -1 days prior to vaccination. Pre-defined post-vaccination risk periods will be the same as those used previously for COVID-19 vaccine safety11 or else based on literature and verified with clinicians, and are specific to each AESI. If no literature is available, risk periods will be advised by clinicians. See [Outcomes of Interest](#_Outcomes_of_interest) below for further information.

Previously, we determined in the whole population that vasculitis and respiratory failure are seasonal conditions with higher IRs in winter compared with summer months. A temporal stratification of calendar time periods (28 or 56 days) will be used to adjust for any potential trends in these AESI over time / seasonality. The incidence of AESI in the older adult population may have changed or show different patterns to the overall population studied previously. Where seasonal trends in AESI are identified in this proposed study, temporal stratification will also therefore be added to the SCCS analyses as required for these conditions. An incident rate ratio (IRR) of greater than 1 will indicate an increased rate of hospitalisation following vaccination. IRRs will be deemed significant where p < .01, prompting further investigation of a potential safety signal. A p-value of < .01 is likely to identify more signals than other approaches used to adjust significance for multiple testing (e.g. Bonferroni method or False Discovery Rate Method) but has been chosen for pragmatic purposes and to increase the sensitivity of the surveillance conducted. Where potential signals are identified, we will therefore take a stringent approach to investigating these through characterisation of the cases. The purpose of this is to identify any patterns or frequencies in hospitalisations to provide insight into their association with RSV vaccination that may warrant further investigation, and to aid our understanding of the likelihood of their being flagged as a signal by chance.

All hospital stays throughout the baseline control and risk periods will be included to identify new onset cases and exacerbation of existing conditions. Individuals will be censored on the earliest of the following: date of death, study end date, date of leaving the country. Age will be defined as the age on admission to hospital.

See Table 3 in the [Appendix](#_Appendix) for a detailed description of the step-by-step methods, datasets and procedure planned to explore RSV vaccine safety using SCCS in older adults in Scotland.

## Study Periods

Vaccination period: The study period will include all vaccinations from 01 August 2024 when the RSV vaccination programme commenced in Scotland. The study period end will be based on the latest SMR01 hospitalisation data available at the time of running the analyses up until 01 August 2025 (one year after the initiation of the vaccination programme), or until such time as it is no longer deemed necessary.

## Data Sources

The following national health datasets will be used for this study:

* Patient-level RSV vaccination data are recorded using the Turas Vaccine Management Tool (VMT),12 a web-based tool for Healthcare staff in Scotland to record real-time patient vaccination data at the point of care. These data are then stored in the National Clinical Data Store (NCDS) developed by NHS Education for Scotland.
* Inpatient general/acute hospitalisation data from Scottish Morbidity Records 01 (SMR01).13 Data will be extracted from at least one year prior to the study period start date to capture hospital stays in their entirety. SMR data has an approximate 6-week lag in submissions.
* National Records Scotland (NRS) mortality data.
* NRS mid-year population estimates for Scotland from 2015 to 2023 for the 75–79-year-old age group, by sex.

The SMR01 dataset includes data on discharge diagnoses for all inpatient and day patient episodes from acute specialties in hospitals in Scotland, excluding obstetric and psychiatric specialties. Episode-level hospital data will be extracted from SMR01 for the period 01 July 2013 to the most recent date available (refer to Tables 2 and 3 in the [Appendix](#_Appendix) for further details). An episode is a period of hospital care initiated by a referral (including re-referral) or admission and ended by a discharge.14

## Exposure of interest

Receipt of one dose of Abrysvo® RSVpreF vaccine in Scotland, as entered in the VMT and identified through the NCDS.

## Outcomes of interest

The outcome of interest will be hospitalisation with an AESI. AESI that were monitored in previous vaccine safety surveillance for COVID-19 and influenza will be included in this study (See Supplemental Table 19 available at [COVID-19 vaccine safety in Scotland – background rates of adverse events of special interest](https://www.sciencedirect.com/science/article/pii/S0033350623002895?via%3Dihub#mmc1)), with the exception of Kawasaki disease which occurs in children.9 Additional AESI reported through the Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card scheme, from RSV vaccine clinical trials or in literature from countries where RSV has already been administered will also be considered for inclusion. At the time of writing, we have identified an additional four AESI (anaphylactic shock, atrial fibrillation, bulbar palsy and lymphadenopathy) for inclusion in the surveillance of the RSV vaccine.

AESI will be identified from SMR01 hospitalisation records using International Classification of Diseases-10th Revision codes15 in any “main\_condition” or “other\_condition” of an episode. These have been reviewed by the PHS terminology team and clinicians to ensure their suitability. The date of the event will be the first date of hospital admission, regardless of the episode an AESI condition is recorded in.

A list of the 39 AESI along with their ICD-10 code definitions, pre-defined post-vaccination risk periods and clean windows are available alongside this study protocol in "Table 1. AESI Definitions.xlsx".

# Limitations and Caveats

* Timely access to SMR hospitalisation data (approximately 6-week delay).
* Depending on vaccine uptake, sample sizes may not be large enough to provide enough power for analysis, especially for rarer outcomes or if vaccine uptake is low.
* Analysis will provide estimates of potential AESI, however we cannot assume causality.
* Influenza, COVID-19, or other vaccinations may confound results (either coadministration or received later). (Influenza and COVID-19 vaccine coadministration with RSV is not routinely recommended due to evidence of a reduction in vaccine effectiveness in older adults, but may still occur).2 Operationally in Scotland, the RSV vaccination was offered from August to September to accommodate for the winter vaccinations delivery from 16 September, however, RSV vaccinations were still being offered opportunistically. This will be explored through characterisation of any cases contributing to conditions that signal.
* OE analysis assumes that the background rates used to calculate observed rates are reflective of the rates that would occur going forward in the absence of vaccination.
* Depending on the severity of AESI, individuals may only present to primary care facilities or not at all and therefore will not be identified using hospitalisation data. In the future, GP data for this purpose may become available enabling safety analyses of a wider range of AESI.
* SCCS analysis adjusts for all time-invariant confounders. Seasonal changes in the incidence of AESI (unrelated to vaccination) may impact our findings, such that we over or under-estimate the association of an AESI with vaccination, even when including temporal adjustments.

# Use and Dissemination of Findings

Initially, this analysis is designed to be run for internal monitoring purposes, with a view to running a final analysis once sufficient data are available in terms of sample size, post-vaccination follow-up times, and inpatient hospitalisation and mortality data.

Detection of safety signals (defined in the [primary analysis](#_Primary__) and [secondary analysis](#_Secondary_analysis) sections) will be raised with clinical colleagues within the Vaccination and Immunisations Division (VAID) at PHS in the first instance. If appropriate, signals will also then be shared through the PHS clinical governance group and externally with MHRA and UK Health Security Agency (UKHSA) colleagues. To assist with interpretation of results, characterisation of post-vaccination cases will also be completed. If there is sufficient data available, we propose to submit the final results of the analyses for peer-review journal publication. There is also potential for these analyses to be rerun following the completion of the second season of the programme to confirm the robustness of findings.

# Contact information

To get in contact about this study protocol, please email [phs.immunisation@phs.scot](mailto:phs.immunisation@phs.scot)

# Appendix

Table 2: Observed versus expected analysis - step-by-step methods, datasets and procedures planned to explore RSV vaccine safety in older adults in Scotland.

|  |  |
| --- | --- |
| STEP | Procedure |
| 1. Identification of patients aged 75 to 79 years-old with a hospital stay containing a diagnosis for an AESI  using the Scottish Morbidity Record 01 (SMR01) national dataset. | The SMR01 dataset includes data on discharge diagnoses for all inpatient and day patient episodes from acute specialties from hospitals in Scotland, excluding obstetric and psychiatric specialties. Episode level hospital data will be extracted from SMR01 from 01 July 2013 to capture hospital stays in their entirety and include a one-year lookback period to apply the clean window to all hospital admissions (described in Step 2) prior to the background rate periods. An episode is a period of hospital care initiated by a referral (including re-referral) or admission and ended by a discharge.14  AESI events are identified based on the presence of any relevant ICD-10 diagnostic code within any episode. SMR01 data will be aggregated from episodes to hospital stay level for each individual based on their unique Community Health Index (CHI) number, counting multiple events within a hospital stay once for each AESI. Age is defined as the age at the date of hospital admission. |
| 2. Application of a clean window to all hospital stays for each AESI. | For each individual AESI, the time between hospital admissions is calculated. Only those admissions that occur at least a clean window later than the previous admission is included as an event in the incidence rates for each AESI. This limits the incidence rates being inflated by repeat admissions for exacerbations of the same AESI occurrence. |
| 3. Calculation of mean background incidence rates (IRs) by age group (75-79 years) and sex, by month. | The mean monthly incidence rate of hospital admissions per 100,000 PYRS (person-years) for each AESI is calculated by age and sex for background rate time periods of interest. One of the following background rate periods will be chosen following the scenarios outlined in Figure 1:  a) 01 January 2015 to 31 December 2023  b) 01 January 2015 to 31 December 2023, excluding 01 January 2020 to 31 December 2020.  c) 01 January 2021 to 31 December 2023.  The denominator is the NRS mid-year population estimate for ages 75 to79 years-old for each respective year. Where estimates are not yet published for recent year(s), the latest population estimate is used. |
| 5. Calculation of observed events: Identification of vaccinations delivered to 75 to 79-year-olds and linkage with AESI related hospital stays. | Data on RSV vaccinations administered to 75- to 79-year-olds in Scotland will be extracted from the National Clinical Data Store from 01 August 2024 onwards. These data are recorded using the VMT, a web-based tool for healthcare staff in Scotland to record real-time patient vaccination data at the point of care.12  AESI-related hospital stays with an admission date from 01 August 2024 onwards will be linked to RSV vaccination records using the CHI number to calculate the observed number of AESI cases. |
| 6. Methods for Observed Expected Analysis. | The vaccinated population is multiplied by the IRs for each background rate period in turn to calculate the expected rate of events for each AESI in the post-vaccination risk period (0-6 days for seizures and 1-28 days for all other AESI). These are compared to the observed number of events in the post-vaccination risk period using the observed expected (OE) ratio, by dividing the observed value by the expected value. OE ratios will be calculated with 95% confidence intervals. Lower confidence interval (CI) bounds > 1.0 suggest an increase in the AESI events above the expected rate. Lower CI > 1.0 and three or more events in the post-vaccination risk period define a signal for further investigation. |
| 7. Statistical packages used. | All analyses will be conducted in R within the Posit environment using the tidyverse, survival and lubridate packages. |

Table 3: Self-controlled case series analysis - step-by-step methods, datasets and procedures planned to explore RSV vaccine safety in older adults in Scotland.

|  |  |
| --- | --- |
| STEP | Procedure |
| 1. Identification of patients aged 74-80 years with a hospital stay containing a diagnosis for an AESI  using the Scottish Morbidity Record 01 (SMR01) national dataset. | The SMR01 dataset includes data on discharge diagnoses for all inpatient and day patient episodes from acute specialties from hospitals in Scotland, excluding obstetric and psychiatric specialties. Episode level hospital data will be extracted from SMR01 for the period 01 November 2023 onwards to capture hospital stays in their entirety prior to the baseline period starting on 18 May 2024 (75 days prior to the programme start on 01 August). An episode is a period of hospital care initiated by a referral (including re-referral) or admission and ended by a discharge.14  AESI events are identified based on the presence of a relevant ICD-10 code within any episode. SMR01 data will be aggregated from episodes to hospital stay level for each individual based on their unique CHI number, counting multiple events within a hospital stay once for each AESI. Age is defined as the age at the date of hospital admission. |
| 2. Identification of vaccinations delivered to 74 to 80-year-olds and linkage with AESI related hospital stays. | Data on RSV vaccinations administered to 74 to 80-year-olds in Scotland will be extracted from the NCDS from 01 August 2024 onwards. (Note that individuals are eligible for RSV vaccination if they turned 75 on or after the 1 August 2024, up to and including 31 July 2025. Therefore some 74-year-olds will be eligible during the programme. Similarly, individuals aged 79 years old on 01 August 2024 will remain eligible even after they turn 80 years old). These data are recorded using the VMT, a web-based tool for healthcare staff in Scotland to record real-time patient vaccination data at the point of care.12  AESI-related hospital stays with an admission date from 18 May 2024 (75 days prior to the vaccine programme start on 01 August 2024) onwards will be linked to RSV vaccination records using the CHI number. |
| 3. Methods for SCSS. | Conditional logistic regression models will compare rates of hospital admissions in the post-vaccination risk periods with the baseline period, stratified by individual and calendar time (either 28 or 56 days). Incidence rate ratios (IRRs) will be estimated to quantify the rate of hospital stays in the risk period relative to the baseline period. Individuals will be censored on the earliest of the following: date of death, study end, date of leaving Scotland. A p-value of <.01 will be used as the threshold of significance, indicating there is a significant increase in post-vaccination hospitalisations for the AESI and thus indicating a signal for further investigation. |
| 4. Statistical packages used. | All analyses will be conducted in R within the Posit environment using the tidyverse, survival and lubridate packages. |

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