



Background incidence rates of selected vaccine adverse events of special interest in Norway

Adverse events of special interest (AESIs) are health events monitored because they may be associated with vaccine safety. Since these events also occur naturally in the population background, incidence rates are essential for assessing vaccine safety. The aim of this DARWIN EU® study was to estimate the background incidence rates of thirteen AESIs across eight European countries. Here, we highlight the results for Norway.

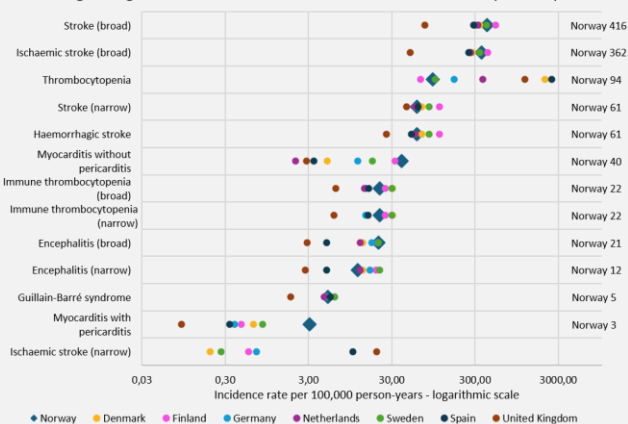
Study overview

- **Design:** Population-level cohort study in databases across Denmark, Finland, Germany, Netherlands, Norway, Spain, Sweden, and UK.
- **Population:** Individuals in Norway (2018–2023) with a 365-day look-back period (N = 5.5 mill).
- **Outcomes:** Thirteen AESIs incl. different phenotype definitions of myocarditis, Guillain–Barré syndrome, thrombocytopenia, encephalitis, and stroke.
- **Measures:** Crude and age-standardized incidence rate (per 100,000 person-years), quarterly and pooled overall, with a 90-day washout period to define recurrent events.

Background incidence rates in Norway

- Most Norwegian AESIs incidence rates were comparable with those reported in other European countries. The main exception was myocarditis, where Norway had the highest incidence rates (Figure 1).

Fig. 1 - Age-standardised incidence rates of selected AESIs by country

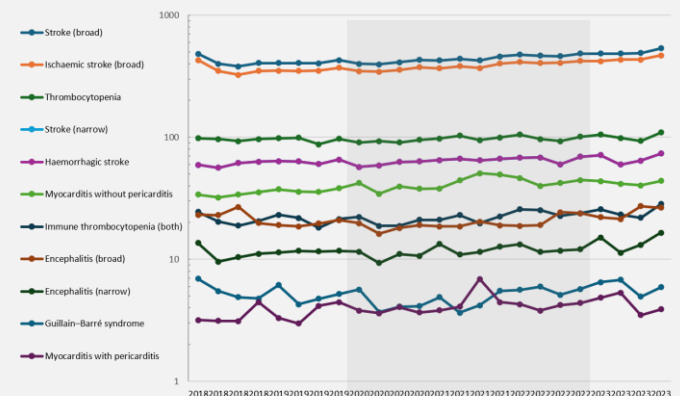


- Incidence increased with age for most AESIs.
- Guillain–Barré syndrome, encephalitis, and immune thrombocytopenia showed higher incidence in early childhood and after age 30.
- Myocarditis with pericarditis was most frequent among individuals aged 20–29 years.

Temporal patterns in incidence rates in Norway

- In Norway, stroke incidence increased towards 2023, while myocarditis peaked in 2021 and subsequently declined (Figure 2).
- Guillain–Barré syndrome incidence was largely stable over time, with a recurring increase during autumn and winter.

Fig. 2 - Quarterly incidence rates of selected AESIs in Norway, 2015–2023



Note. Incidence rates are per 100,000 person-years (log scale). Each marker represents one calendar quarter. Rates for Q1 2018 and Q4 2023 should be interpreted with caution, reflecting data-source onboarding and incomplete end-of-period follow-up respectively. Grey shade: COVID-19 period.

- The COVID-19 pandemic did not impact AESI incidence rates for most AESIs.
- In Norway, ischemic and hemorrhagic stroke showed an increase during and after the COVID-19 pandemic period.

Data & Methods notes

- Norwegian hospital data were only available from 2018; earlier incidence estimates were therefore underestimated.
- Lack of platelet measurements likely resulted in underestimation of thrombocytopenia.
- Limited granularity of some ICD-10 codes may have reduced ascertainment of some AESIs.
- The study differs from DARWIN P3-C3-001 in phenotype definitions and study period.

How was this useful?

This study provides background incidence rates for selected vaccine AESIs in the Norwegian population. For most AESIs, Norwegian rates were within the range of the other data sources. The exception was myocarditis, where Norway reported the highest incidence both with and without pericarditis. Most AESI rates were broadly stable from 2018 onwards with outcome-specific seasonal and pandemic-related variation. These background rates provide an important reference for interpreting vaccine safety signals in Norway. Future work should examine how data availability and coding affect the Norwegian estimates.

Access to the full report

[DARWIN EU - Background incidence rates of selected vaccine adverse events of special interest \(AESIs\) in Europe](#)

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