



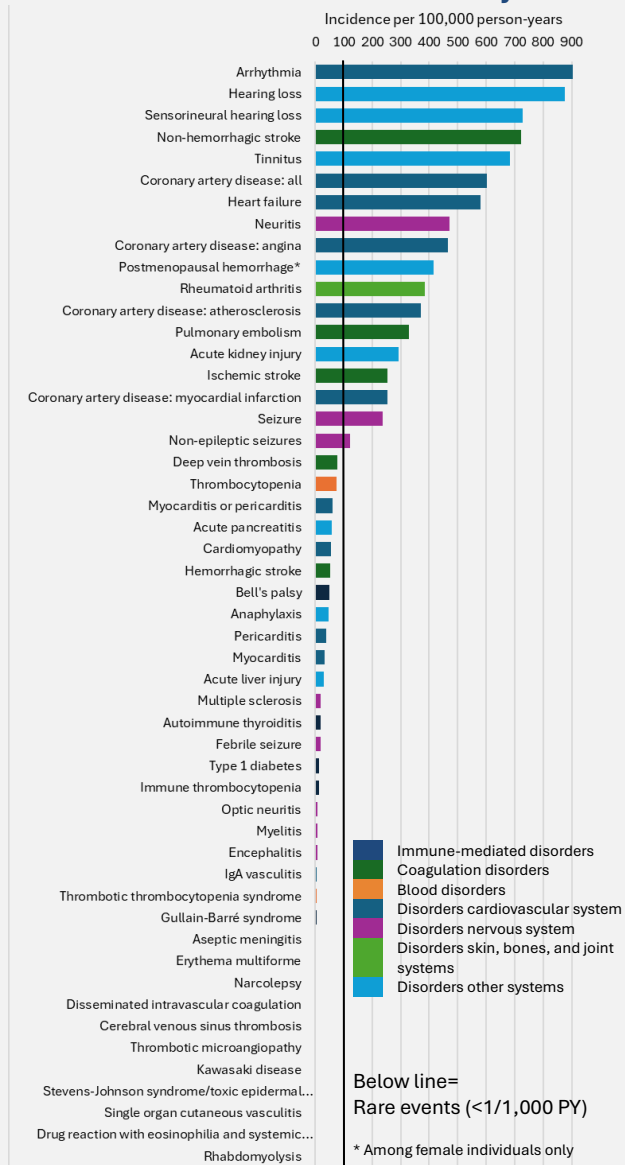
Baseline incidence rates of Adverse Events of Special Interest in Norway before, during, and after the COVID-19 pandemic

Background incidence rates of Adverse Events of Special Interests (AESIs) may support rapid regulatory responses to vaccine safety concerns. This study estimated the background incidence rates of selected AESIs, and described the demographic and clinical characteristics of patients affected in Norway.

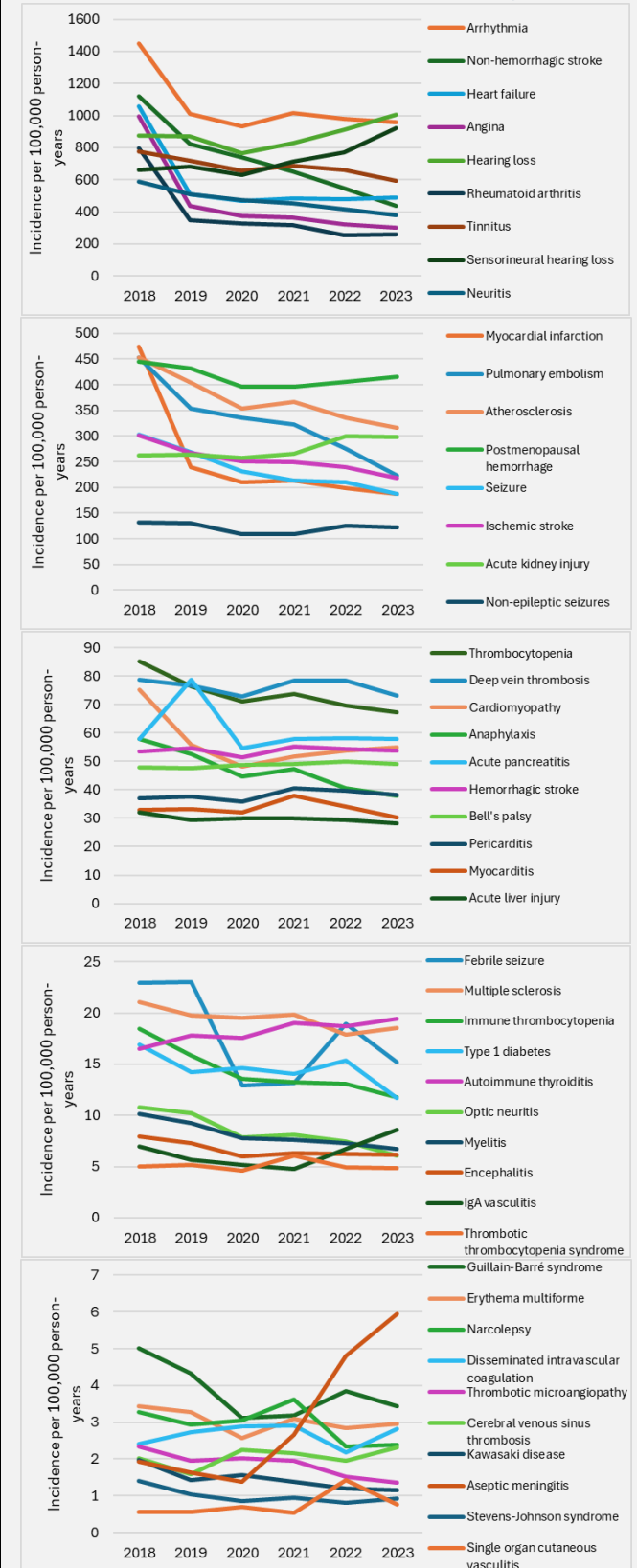
Study overview

- Design: Population-level cohort study in the UK, Germany, The Netherlands, Norway, and Spain.
- Population: 6.11 million individuals from Norway, 2018-2023.
- Outcome: **51 AESIs** most representative for vaccine safety assessment: immune-mediated diseases (7), blood disorders (2), cardiovascular disorders (13), nervous system disorders (9), coagulation disorders (7), skin/bones/joint disorders (4), and other AESIs (9).
- Comparison of characteristics of individuals with and without AESIs.

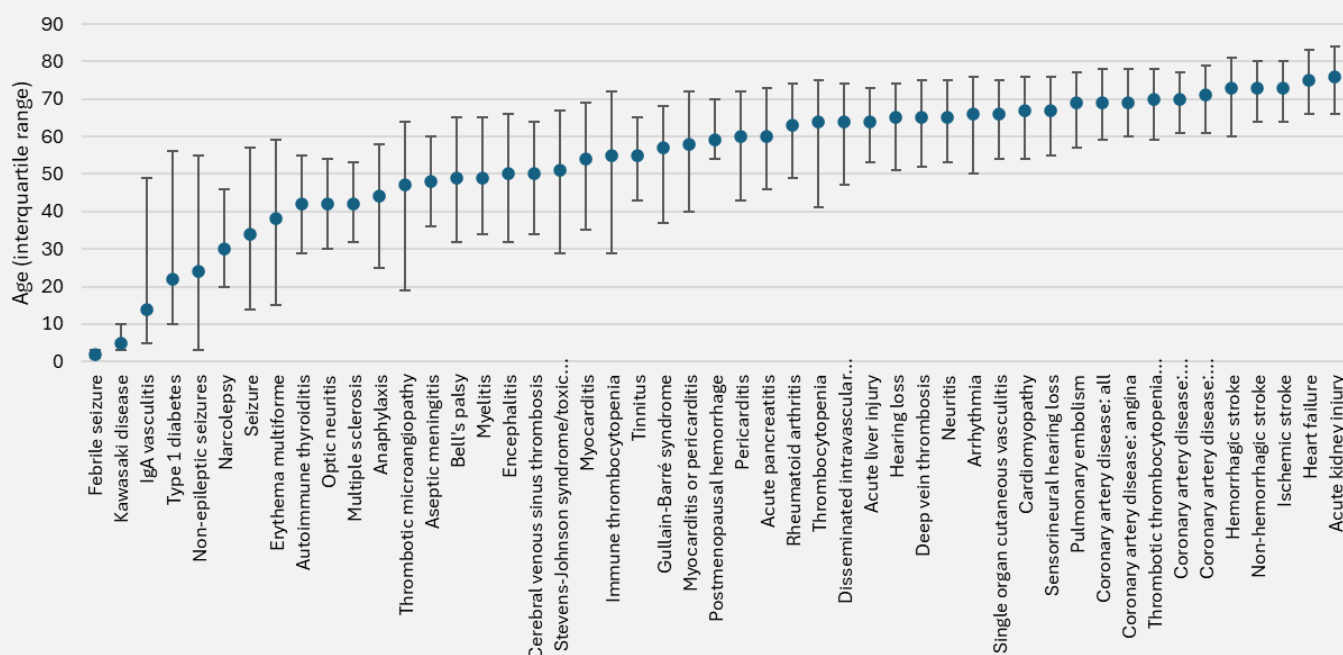
Baseline incidence of AESIs in Norway



Time trends in AESI incidence in Norway



Age at diagnosis of Norwegian patients with AESIs



Characteristics of Norwegian AESI patients

- For most AESIs, there were no substantial differences when stratifying for sex.

More common among women (≥60% female):



Aseptic meningitis, autoimmune thyroiditis, multiple sclerosis, and optic neuritis.

More common among men (≥60% male):



Atherosclerosis, Kawasaki disease, myocardial infarction, and myocarditis.

- Individuals with AESIs had more comorbidities and medication use than their age- and sex-matched peers.
- Observed incidence rates and characteristics generally align with literature.

Data & Methods notes

- For some AESIs, particularly chronic conditions or with extended progression over time such as arrhythmia, heart failure, and rheumatoid arthritis, there was evidence of index date misclassification (i.e. we may not capture true incidence time due to delayed records).
- A washout period (in which there was no record of the same AESI) was set for each AESI (30-90 days for acute/recurrent AESIs and lifetime for chronic AESIs), though its ideal length is unknown. As a result, some rates reflect a combination of prevalent and incident cases.
- Changes in clinical guidelines or practice could affect estimation of incidence rates over time.

How was this useful?

The COVID-19 pandemic did not impact AESI incidence rates for most AESIs.

Most common AESIs (>400/100,000 person-years): arrhythmia, hearing loss, non-hemorrhagic stroke, tinnitus, coronary artery disease, heart failure, neuritis, and postmenopausal hemorrhage. **Very rare AESI (<2/100,000 person-years):** single organ cutaneous vasculitis, Stevens-Johnson syndrome/toxic epidermal necrolysis, Kawasaki disease, and thrombotic microangiopathy.

Impact of age: Incidence rates for most AESIs increase with age. **U-shaped relationship with age:** Immune thrombocytopenia and thrombotic microangiopathy.

Most common in children: Kawasaki disease, type 1 diabetes, and seizures.

This work established a framework for future studies. For any new studies aiming at using background rates for an emerging signal evaluation, it will be important to first assess if the phenotypes are fully aligned with the outcome(s) to be assessed, run diagnostics in the databases, and tailor as needed.

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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