DARWIN EU® - Coverage of meningococcal vaccines in the target population in Europe

First published: 15/07/2025

Last updated: 23/01/2026

Study Finalised

Administrative details

EU PAS number

EUPAS1000000675

Study ID

1000000675

DARWIN EU® study

Yes

Study countries

- [ ] Croatia
- [ ] Denmark
- [ ] Finland
- [ ] Germany
- [ ] Spain
- [ ] United Kingdom

Study description

Vaccine exposure data supports readiness for safety signal management and can inform the feasibility of vaccine effectiveness or safety studies. However, coverage data is often mostly available from MAH sales/distribution data, which does not accurately reflect actual use. Coverage data for meningococcal vaccines, which are recommended to prevent invasive meningococcal disease in children and adolescents, is scarce and of limited granularity.
This population-level drug utilisation study generated evidence on temporal trends in the coverage of meningococcal vaccines, by brand and/or vaccine composition (as available in the data sources), and by age group and dose, in 6 data sources in 5 countries (Croatia, Spain, UK, Denmark, Finland). Exposure included: MenB vaccines (Bexsero® and Trumenba®); MenC and Haemophilus influenzae type b (Hib)/MenC conjugate vaccines; MCV4 vaccines (serogroups A, C, W-135, and Y: Menveo® and Nimenrix®). As expected, countries with universal meningococcal vaccination in childhood (ES, UK) showed higher and more consistent coverage than those without this recommendation (DK, FI, HR), reflecting the different immunisation policies across Europe. Recent decrease in coverage observed in some countries may be related to the impact of the COVID-19 pandemic on vaccine availability and access to vaccination, and increased recent increasing public vaccine hesitancy.

Study status

Finalised

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

- [ ] Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | Educational Institution | ENCePP partner

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

- [ ] Belgium
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal

- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

First published: 01/02/2024

Last updated: 30/04/2025

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ivan Lam

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/03/2025

Actual: 27/03/2025

Study start date

Planned: 30/06/2025

Actual: 30/06/2025

Date of final study report
Planned: 15/11/2025

Actual: 10/12/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C1-006_Utilisation of Meningococcal Vaccines in Europe_V3.0.pdf (1.02 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

A drug utilisation cohort study will be conducted, using routinely collected health data from seven nationwide or regional databases in six European countries

Main study objective:

1. To examine the coverage of MenB vaccines in children at age one and two years by dose received (≥1 dose, ≥2 doses, ≥3 doses, =1 dose, =2 doses, =3 doses)
2. To examine the coverage of MenC or Hib/MenC conjugate vaccines in children at age two years (≥1 dose, =1 dose)
3. To examine the coverage of MCV4 vaccines in individuals at age 18 years (≥1 dose, =1 dose)
4. To estimate the coverage of specific brand of MenB vaccines (Bexsero® and Trumemba®) in individuals aged two years and MCV4 vaccines (Menveo® and Nimenrix®) in individuals aged 18 years =
5. To characterise the age distribution of receival of MenB, MenC, and MCV4 vaccines

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Monovalent Meningococcal group B surface protein vaccine, Monovalent Meningococcal group B surface protein vaccine, Quadrivalent Meningococcal conjugate vaccine (groups A, C, W-135, and Y)

Population studied

Short description of the study population

This study will include all individuals present in their respective database who reach two years of age for examining the coverage of MenB or Hib/MenC vaccines, and 18 years of age for examining the coverage of MCV4 vaccines

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Age groups

- **In utero**
- **Paediatric Population (< 18 years)**
  - Neonate
    - Preterm newborn infants (0 – 27 days)
    - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)

        - Adults (46 to < 65 years)
    - Elderly (≥ 65 years)
        - Adults (65 to < 75 years)
        - Adults (75 to < 85 years)
        - Adults (85 years and over)

Study design details

Data analysis plan

The point prevalence of recipients of vaccine coverage at quarterly and yearly time interval were estimated
using the IncidencePrevalence package. The age distribution of vaccine recipients was characterised using
the CohortCharacteristics package in R. Missing records for a given variable or outcome were assumed to indicate that the information was not present, or that a given individual was unvaccinated. Sensitivity analyses were conducted by 1) defining the study population as the target population for specific meningococcal vaccines without the requirement for complete follow-up and 2) defining the study population for the coverage of MCV4 as all individuals aged between 12 and 18 to test for the robustness of the findings and to examine the coverage of MCV4 in a broader population. A minimum cell count of 5 will be used when reporting results, with any smaller count reported as “<5” and zero counts as “0”.

Documents

Abstract of study report

DARWIN EU_Report_P4-C1-006_Uptake of meningococcal vaccines_V3.0.pdf
(2.25 MB)

Shiny App

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)
The Information System for Research in Primary Care (SIDIAP)
Danish Health Data Registries
Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)
BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)
Clinical Practice Research Datalink (CPRD) GOLD

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown