Study Report

P4-C1-006

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

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Version 3.0

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Public

CONTENTS

Study title	DARWIN EU® - Coverage of meningococcal vaccines in the target population in Europe
Study report version	V3.0
Date	10/12/2025
EUPAS number	EUPAS1000000675
Active substance	Meningococcal vaccines: • Monovalent Meningococcal serogroup B surface protein vaccine • Meningococcal serogroup C conjugate vaccines or Meningococcal serogroup C /Haemophilus influenzae B (Hib) combination vaccine • Quadrivalent Meningococcal conjugate vaccine (serogroups A, C, W-135, and Y)
Medicinal product	Licensed meningococcal vaccines: • Menveo® (meningococcal serogroups A, C, W-135, and Y conjugate; MCV4 vaccine) • Nimenrix® (meningococcal serogroups A, C, W-135, and Y conjugate; MCV4 vaccine) • Bexsero® (meningococcal serogroup B surface protein vaccine) • Trumenba® (meningococcal serogroup B surface protein vaccine)
Objectives	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 Trumenba®) in individuals aged two years and MCV4 vaccines (Menveo® and Nimenrix®) in individuals aged 18 years 5. To characterise the age distribution of recipients of MenB, MenC, and MCV4 vaccines Objective 4 of this study was examined on the Clinical Practice Research Datalink GOLD, UK only due to the potential unavailability of specific data in the other data source.
Countries of study	Croatia, Denmark, Finland, Spain, United Kingdom
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LIST OF ABBREVIATIONS

Acronyms/term	Description
BIFAP	Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público
CDM	Common Data Model
CPRD	Clinical Practice Research Datalink
DARWIN EU®	Data Analysis and Real-World Interrogation Network
DK-DHR	Danish Data Health Registries
ECDC	European Centre for Disease Prevention and Control
FinOMOP-THL	Finnish Care Register for Health Care
Hib/MenC	Haemophilus influenzae type b/Meningococcal serogroup C
InGef	InGef Research Data source
IMD	Invasive Meningococcal Disease
MenB	*Neisseria Meningitidis* serogroup B
MenC	*Neisseria Meningitidis* serogroup C
MCV4	Meningococcal serogroup ACWY vaccines
NAJS	Croatian National Public Health Information System
NHS	National Health Services, UK
OHDSI	Observational Health Data Sciences and Informatics
OMOP	Observational Medical Outcomes Partnership
UK	United Kingdom
SIDIAP	Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària
SNOMED	Systematized Nomenclature of Medicine

1. TITLE

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

2. DESCRIPTION OF THE STUDY TEAM

Study team role	Names	Organisation
Principal Investigators	Ivan Lam Albert Prats-Uribe	University of Oxford
Data Scientists	Xihang Chen Edward Burn	University of Oxford
Clinical Domain Experts	Albert Prats-Uribe Daniel Prieto-Alhambra	University of Oxford University of Oxford and Erasmus MC
Statistician	Anna Saura-Lazaro	University of Oxford
Study Manager	Natasha Yefimenko	Erasmus MC
Data source	**Names**	**Data Partner Organisation***
NAJS	Anamaria Jurčević Jakov Vuković Marko Čavlina Ivan Pristaš, Antea Jezidžić Karlo Pintarić	Croatian Institute of Public Health
DK-DHR	Claus Møldrup Elvira Bräuner Susanne Bruun	Danish Medicines Agency
FinOMOP-THL	Gustav Klingstedt Tiina Wahlfors Toni Lehtonen	Finnish Care Register for Health Care
BIFAP	Elisa Martin-Merino Belén Castillo-Cano Cristina Justo-Astorgano Ana Llorente-Garcia Miguel-Angel Macia-Martinez	Spanish Agency of Medicines and Medical Products
SIDIAP	Elena Roel Herranz Laura Granés González Augustina Giuliodori Picco	IDIAPJGol
CPRD GOLD	Antonella Delmestri	University of Oxford

*Data partners do not have an investigator role. Data partners execute code at their data source, review, and approve their results.

3. ABSTRACT

Title

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

Rationale and background

Meningococcal vaccines are recommended for children and adolescents to prevent Invasive Meningococcal Disease (IMD). Various Meningococcal vaccines have been developed to protect against distinct serogroups of the bacteria *Neisseria Meningitidis* including serogroups A, B, C, W, and Y responsible for IMD. The current vaccination schedules in certain European countries recommend three doses of Meningococcal serogroup B (MenB) vaccines for children at age 2, 4 months, and a booster dose at 12 months, whilst a single dose of MenC or Haemophilus influenzae type b/Meningococcal serogroup C (Hib/MenC) vaccines is recommended at age 12 months. A single dose of quadrivalent Meningococcal ACWY vaccine (MCV4) is also scheduled as part of the routine vaccination schedule in certain European countries for adolescents between 14 and 18 years of age but may be given as early as age 11 in some countries, for the prevention of severe meningococcal infection. Nonetheless, meningococcal vaccines are not implemented in the routine vaccination schedule for children and adolescents in countries including Croatia, Denmark, and Finland. This study aims to generate comprehensive evidence on the coverage of these separate types of meningococcal vaccines within the target population across six European countries.

Research question and objectives

Research questions

The general objective of this study was to examine the coverage of meningococcal vaccines routinely administered in countries across Europe.

Objectives

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 Trumenba®) in individuals aged two years and MCV4 vaccines (Menveo® and Nimenrix®) in individuals aged 18 years
5. To characterise the age distribution of recipients of MenB, MenC, and MCV4 vaccines

Objective 4 of this study was examined on the Clinical Practice Research Datalink GOLD, UK only due to the low exposure counts in the other data sources.

Methods

Study design

Population-level drug utilisation study (DUS) and patient-level characterisation

Population

Eligible individuals reaching the age of one year and two years for assessing the coverage of MenB vaccines, and individuals reaching the age of 18 for assessing the coverage of MCV4 vaccines.

Variables

Outcome:

MenB, MenC, and MCV4 Vaccination

Relevant covariates:

Age and sex (male or female) of individuals

Data sources

The data sources selected for this study include:

1. Croatian National Public Health Information System (NAJS), Croatia
2. Danish Data Health Registries (DK-DHR), Denmark
3. Finnish Care Register for Health Care (FinOMOP-THL), Finland
4. Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (BIFAP), Spain
5. Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària (SIDIAP), Spain
6. Clinical Practice Research Datalink (CPRD) GOLD, United Kingdom (UK)

Study size

This study identified over 2.46M, 2.22M, and 3.74M individuals receiving at least one dose of MenB, MenC, and MCV4 vaccination across all the data sources.

Statistical analysis

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".

Results

CPRD GOLD, BIFAP, and SIDIAP reported considerably higher coverage for MenB compared to NAJS, DK-DHR, and FinOMOP-THL. A considerably higher prevalence of individuals receiving three or more doses of vaccines was observed amongst individuals aged two years with the highest coverage of 85.2% (95% CI: 84.8–85.6) coverage observed in 2019 compared to individuals aged one years with 68.7% (95% CI: 68.2–69.1) in 2018 in CPRD GOLD. A reduction in the coverage of MenB vaccination, particularly on the coverage of the third dose, was observed from 2020 to 2024. Meanwhile, the coverage of MenB vaccination increased steadily in BIFAP and SIDIAP over the study period.

A consistently high coverage of MenC vaccination was observed in CPRD GOLD, BIFAP and SIDIAP. This was followed by a marginal reduction in coverage across the aforementioned data source, with the most profound difference was observed in CPRD GOLD with a reduction from 98.3% (95% CI: 98.2–98.4) in 2017 to 89.6% (95% CI: 89.2–90.0) in 2024.

A gradual increase in coverage of MCV4 vaccines was observed between 2017 and 2020 from 36.2% (95% CI: 35.7–36.6) to 64.6% (95% CI: 64.0–65.1) followed by a reduction in coverage to 51.6% (95% CI: 51.0–

52.2) from 2022 to 2024 in CPRD GOLD. In contrast, a considerable increase from 34.3% (95% CI: 34.0–34.6) in 2020 to 70.1% (95% CI: 69.9–70.4) in 2024 and from 0.9% (95% CI: 0.8–0.9) to 38.9% (95% CI: 38.5–39.3) in 2023 was observed in BIFAP and SIDIAP, respectively.

Discussion

Our findings highlighted substantial differences in vaccine coverage, which may stem from the differences in vaccine schedules and in reimbursement policies. Recent reductions in meningococcal vaccine coverage across parts of Europe highlighted the potential impact of the COVID-19 pandemic on vaccine availability and access and increased public hesitancy toward vaccination. Given the high case fatality associated with invasive meningococcal disease (IMD), coordinated vaccination campaigns and broader reimbursement policies are essential to improve coverage and equity across Europe.

4. AMENDMENTS AND UPDATES

None.

5. MILESTONES

Study deliverable	Timelines (planned)	Timelines (actual)
Final Study Protocol	July 2025	July 2025
Creation of Analytical code	July 2025	July 2025
Execution of Analytical Code on the data	August 2025	August 2025
Draft Study Report	September 2025	September 2025
Final Study Report	October 2025	November 2025

6. RATIONALE AND BACKGROUND

Background of meningococcal infection

Meningococcal infection, caused by the bacteria *Neisseria meningitidis*, is known to cause invasive meningococcal disease (IMD). IMD is a major contributor to severe adverse clinical conditions, including bacterial meningitis and septicaemia, resulting in high case fatality of up to 80% in untreated cases worldwide. Furthermore, IMD is associated with significant life-long complications among survivors.[1] IMD may affect individuals of all ages, however, infants and young children are among the patient group with the highest incidence of case fatality rates globally.[2] In addition, many countries have observed elevated incidence of IMD in late adolescence and early adulthood.[3] Twelve serogroups are recognised, of which six (A, B, C, W, X, and Y) are responsible for the vast majority of cases of IMD.

Epidemiology of invasive meningococcal disease in Europe

The incidence of IMD and responsible serogroups vary widely both geographically within Europe and over time. The reported incidence of IMD in cases per a population of 100,000 across Europe ranges from 0.45 in Northern and Southern Europe to 1.33 in the UK and Ireland. In 2017, a total of 282 fatal cases were reported across the EU and the European Economic Area (EEA), of which 10% were of unknown cause, accounting to a case fatality of 9.7%. The reported incidence of IMD was highest amongst infants aged <1 year (8.2/100,000) followed by toddlers aged 1–4 years (2.5/100,000) and with a second peak in 15–24 year-olds (1.0/100,000). [3, 4] Meningococcal serogroup B bacteria is currently the predominating serogroup in the majority of countries across Europe, including Spain and the UK. Nonetheless, MenW and MenY were also identified as predominate serogroups in several countries in Europe, including Denmark and Finland.

Meningococcal vaccines

Meningococcal vaccination has been a major public health measure in preventing IMD. Various meningococcal vaccines targeting different serogroups of *Neisseria Meningitidis* are currently offered as part of routine vaccination schedules for children and adolescents aged 25 or below in certain countries across Europe.[5]

The current meningococcal vaccines against Meningococcal serogroup C (MenC) and quadrivalent meningococcal conjugate vaccines (MCV4) are conjugate vaccines consisting of capsular polysaccharides from one or more meningococcal serogroups. These vaccines have been shown to be immunogenic and safe in older children and adults. The later generation polysaccharide-protein conjugate vaccines provide additional benefits in inducing immunity in infants from two months of age, conferring longer lasting

protection, and providing a booster response with subsequent doses. In addition, the direct protection against acquisition of carriage from protein-conjugate vaccines disrupts the transmission to others, thus providing indirect herd protection across the population.

Meningococcal vaccines are administered following different regimens in different parts of Europe. A single dose of MenC vaccination has been recommended as a routine schedule for children at one year of age which are typically offered with combined *Haemophilus influenzae* type b/Meningococcal serogroup C (Hib/MenC) vaccines in the UK. In Spain, children are advised to receive two doses of MenC vaccine at 4 months and one year of age. The MCV4 vaccines, including Menveo® and Nimenrix®, protect against four serogroups of meningococcal disease—A, C, W-135, and Y. These are part of the routine vaccination programmes for children with a single dose of vaccination typically given at ages 12–18 in the UK and Spain. (**Table 1 and Figure 1**)

More recently, multi-component protein-based vaccine has been developed with the aim of providing broad protection of various strains of *Neisseria Meningitidis* serogroup B with diverse immunodominant Porin A antigen. Three doses of the Meningococcal, serogroup B (MenB) vaccine have been introduced in the immunisation programme in several countries across Europe, including Germany, Spain, and the UK for children at 2 months, 4 months, and at one year. The novel multi-component protein-based vaccine, Bexsero®, was licensed for use in Europe in 2013 for children aged 2 months or above.[6] This vaccine consisted of multiple subcapsular recombinant protein antigens providing protection against most MenB strains of up to 91% across the globe. Another subcapsular meningococcal antigen vaccine, Trumenba®, was later licensed in Europe in 2017 for children from 10 years of age. (**Table 1**) Despite only being licensed to protect against MenB responsible meningococcal disease, both vaccines have the potential to protect against any meningococcal serogroup possessing a vaccine-related surface antigen. However, meningococcal vaccines are not implemented in the routine vaccination schedule for children and adolescents in countries including Croatia, Denmark, and Finland. (**Figure 1**)

Table 1. Types, serogroups covered, doses recommended, and brands of meningococcal vaccines.

Meningococcal vaccines	Serogroup covered	Doses recommended	Brands
MenB	B	Three	Bexsero® and Trumenba®
MenC	C	One (Two in Spain)	Menjugate® and Meningitec®
MCV4	A, C, W-135, and Y	One	Menveo® and Nimenrix®

Note: Coverage of specific brands of MenC vaccines is out of scope of this study

Countries	Age																	
	Months						Year											
	2	4	6	8	10	12	2	4	6	8	10	12	13	14	16	17	18	
UK	MenB (Dose 1)	MenB (Dose 2)				MenB (Dose 3) and MenC							MCV4					
Spain	MenB (Dose 1)	MenB (Dose 2) and MenC				MenB (Dose 3) and MenC						MCV4						
Croatia	MenB, MenC and MCV4 not included in immunisation schedule																	
Denmark	MenB, MenC and MCV4 not included in immunisation schedule																	
Finland	MenB, MenC and MCV4 not included in immunisation schedule																	

Note: Although not included in the immunisation schedule, meningococcal vaccines are administered to individuals with specific medical need, including those with increased risk of meningococcal disease due to underlying health conditions or medication use in Croatia, Denmark, and Finland.

Figure 1. Meningococcal vaccination schedules in the UK, Spain, Croatia, Denmark, and Finland.

Justification for this study

Immunisation against meningococcal disease forms a crucial public health measure in preventing IMD, especially amongst vulnerable populations. Nevertheless, the coverage of meningococcal vaccines within Europe remains largely unclear due to the variation in vaccination schedules recommended within Europe. This study aimed to generate comprehensive evidence on the coverage of MenB, MenC, and MCV4 meningococcal vaccines amongst eligible individuals across six European countries as illustrated in **Figure 1**. The coverage of meningococcal vaccines was examined, not only in countries where these vaccines are included in the routine vaccination schedule including Spain and UK, but also in countries such as Croatia, Denmark, and Finland, where meningococcal vaccines are only administered to selected individuals with specific medical need and those with increased risk of meningococcal disease due to underlying health conditions or medications rather than as part of the routine vaccination schedule. Given the administration of meningococcal vaccines provided to individuals outside the standard age-based immunisation schedule in certain countries, this study additionally investigated the age distribution of vaccine recipients to identify patterns of off-schedule administration in separate countries across Europe.

7. RESEARCH QUESTION AND OBJECTIVES

Research question

The general objective of this study was to characterise vaccine coverage for MenB, MenC, and MCV4 vaccines in their respective target populations across six healthcare data source and five European countries.

Objectives

The specific objectives are:

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 Trumenba®) in individuals aged two years and MCV4 vaccines (Menveo® and Nimenrix®) in individuals aged 18 years
5. To characterise the age distribution of recipients of MenB, MenC, and MCV4 vaccines.

Objective 4 of this study was examined on the Clinical Practice Research Datalink GOLD, UK only due to the potential unavailability of specific data in the other data source. The detailed definition of the study objectives were listed in **Table 2** below.

Table 2. Primary and secondary objectives.

Objective	1. To examine the coverage of MenB vaccine 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 Trumenba®) in individuals aged two years and MCV4 vaccines (Menveo® and Nimenrix®) in individuals aged 18 years 5. To characterise the age distribution of recipients of MenB, MenC, and MCV4 vaccines Objective 4 of this study was examined on the Clinical Practice Research Datalink GOLD, UK only due to the potential unavailability of specific data in the other data source.
Hypothesis	N/A
Population *(mention key inclusion-exclusion criteria)*	Study population for the coverage of Men B vaccination included all individuals aged 1 and 2 with continuous enrolment since birth. The coverage of Bexsero® and Trumenba® included all individuals aged 2 with continuous enrolment since birth. Study population for the coverage of Men C and Hib/MenC vaccination included all individuals aged 2 with continuous enrolment since birth. Study population for the coverage of MCV4 (including Menveo® and Nimenrix®) vaccination included all individuals aged 18 with continuous enrolment between age 12 and 18 years. Children born on or after 01/01/2015 with two years of enrolment from birth were eligible for inclusion for the examination of coverage of MenB (including Bexsero® and Trumenba®) and MenC (and Hib/MenC) vaccines. Individuals reaching 12 years of age on or after 01/01/2011 with six years of enrolment after reaching 12 years of age were eligible for inclusion for the examination of coverage of MCV4 (including Menveo® and Nimenrix®) vaccines.
Exposure	N/A
Comparator	N/A
Outcome	Records of MenB, MenC, or MCV4 vaccinations
Time *(when follow up begins and ends)*	Study period started on 01/01/2017 and ends on the last quarterly and yearly sampling window prior to the data lock for the last update of each corresponding data source.
Setting	The study utilised routinely collected health data from six nationwide or regional data source in six European countries (Croatia, Denmark, Finland, Spain, United Kingdom). Inpatient, outpatient hospital setting, and primary care setting were used for the study.
Main measure of effect	Meningococcal vaccine coverage

8. RESEARCH METHOD

8.1. Study design

A cohort study was conducted using routinely collected health data from 6 data sources from 5 countries across Europe.

The study comprised of:

- Population Level DUS to address objective 1–4, assessing the coverage of cumulative doses of MenB vaccine in children aged one and two years, MenC vaccines in children aged two years ,MCV4 vaccines in adolescents aged 18 years, and specific brand of MenB vaccines (Bexsero® and

Trumenba®) in individuals aged two years and MCV4 vaccines (Menveo® and Nimenrix®) in individuals aged 18 years at quarterly and yearly time interval.

- Patient-level characterisation to address objective 5, assessing the age distribution of MenB, MenC, and MCV4 recipients.

8.2. Follow-up

The index date was defined as the date of birth for the examination of the coverage of MenB, MenC, or Hib/MenC vaccines and when individuals turn 12 years of age for the examination of the coverage of MCV4 vaccines. Each individual was followed for records of MenB, MenC vaccines, or when individuals reach the age of two. Individuals reaching the age of 12 were followed for records of MCV4 vaccination until reaching 18 years of age. The index date for characterising the age distributions for separate meningococcal vaccines was defined as the date of complete vaccination of separate meningococcal vaccines by type (MenB, MenC, and MCV4). Individuals included for analysis of the coverage of MenB and MenC vaccines were required to be continuously enrolled in their respective data source from up to eight weeks after birth to two years of age (674 days), and individuals analysed at 1 year of age were required to be continuously enrolled from up to eight weeks after birth to one years of age (309 days). Individuals included for the analysis of the coverage of MCV4 vaccines were required to be continuously enrolled for 6 years (2,190 days) from reaching 12 years of age (based on the eligibility of MCV4 in children between age 12 and 18). The index date and requirement for continuous enrolment for each cohort of study populations are illustrated in **Table 3**, **Figure 2,** and **Figure 3** below.

Table 3. Operational definition of time 0 (index date) and other primary time anchors.

Study population names	Time Anchor Description	Number of entries	Type of entry	Washout window	Care Setting[1]	Measurement characteristics/validation
Coverage of MenB vaccines at in individuals aged one year old	Date of birth	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as the date of birth record of individuals
Coverage of MenB vaccines at in individuals aged two years old	Date of birth	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as the date of birth record of individuals
Coverage of MenC vaccines at in individuals aged two years old	Date of birth	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as the date of birth record of individuals
Coverage of MCV4 vaccines at in individuals aged 18 years old	Date of reaching 12 years of age	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as 12 years after the date of birth of individuals
Age distribution of individuals receiving one dose of MenB vaccines	Date of receiving the first dose of MenB vaccine	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as date of first vaccination record of MenB vaccination
Age distribution of individuals receiving two doses of MenB	Date of receiving the second dose of MenB	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as date of second vaccination record of MenB vaccination

Study population names	Time Anchor Description	Number of entries	Type of entry	Washout window	Care Setting[1]	Measurement characteristics/validation
vaccines	vaccine					
Age distribution of individuals receiving full schedule of MenB vaccines	Date of receiving the third dose of MenB vaccine	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as date of third vaccination record of MenB vaccination
Age distribution of individuals receiving full schedule of MenC vaccines	Date of receiving the first dose of MenC vaccine	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as date of first vaccination record of MenC vaccination
Age distribution of individuals receiving full schedule of MCV4 vaccines	Date of receiving the first dose of MCV4 vaccine	Single entry	Prevalent	(0,0)	IP, OP, OT	Defined as date of first vaccination record of MCV4 vaccination

[1] IP = inpatient, OP = outpatient, ED = emergency department, OT = other, n/a = not applicable

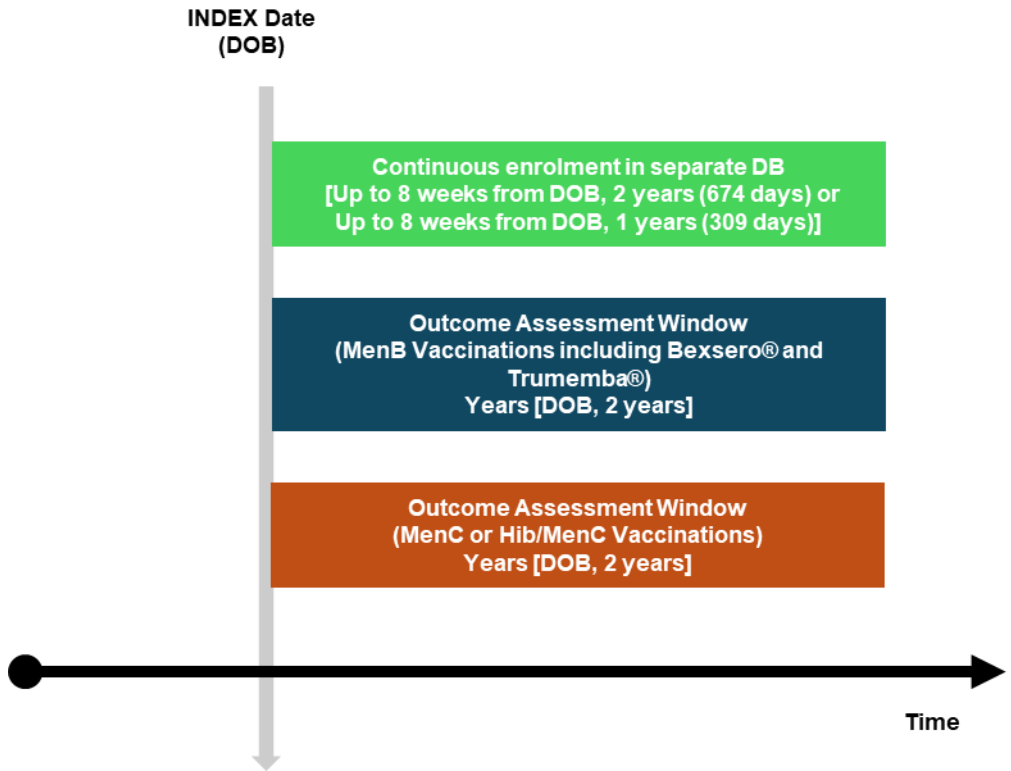

Figure 2. Study design diagram illustrating the index date and follow-up period of study participants for meningococcal serogroup B (MenB) and Meningococcal serogroup C (MenC) vaccination.

Note: MenB: Meningococcal serogroup B; MenC: Meningococcal serogroup C; Hib/MenC: Combined Haemophilus influenzae type b/Meningococcal serogroup C; DOB: Date of birth

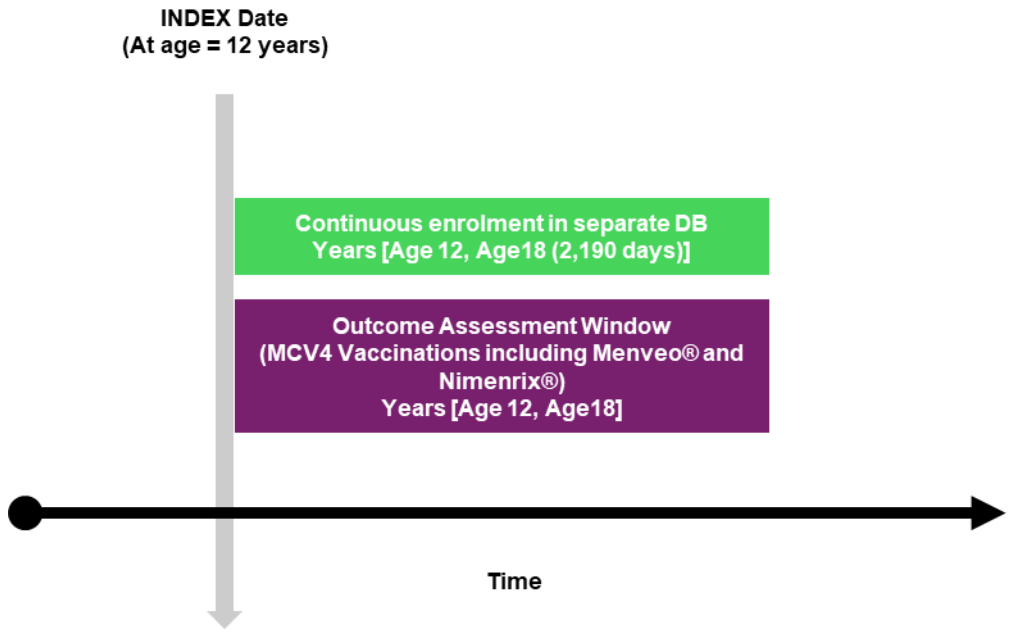

Figure 3. Study design diagram illustrating the index date and follow-up period of study participants for quadrivalent meningococcal conjugate (MCV4) vaccination.

Note: MCV4: Quadrivalent meningococcal conjugate vaccines

8.3. Study population with inclusion and exclusion criteria

This study included all individuals present in their respective data source who reach two years of age for examining the coverage of MenB or MenC or Hib/MenC vaccines, and 18 years of age for examining the coverage of MCV4 vaccines. The coverage of separate meningococcal vaccines were evaluated at each quarterly and/or yearly sampling window. The study population for the analysis of age distribution among recipients of MenB, MenC, and MCV4 vaccines included all individuals with documented records of receiving any of these specific meningococcal vaccine types. The operational definitions of the inclusion criteria were presented by in **Table 4** below.

Table 4. Operational definitions of inclusion criteria.

Criterion	Details	Order of application	Assessment window	Care Settings[1]	Applied to study populations:
Aged =1 years	Study participants include eligible individuals for MenB vaccines based on the ECDC and NHS vaccine schedule.	After index date is determined	[0,0]	IP, OP, OT	All individuals within selected data source
Aged =2 years	Study participants include eligible individuals for MenB, and MenC or Hib/MenC vaccines based on the ECDC and NHS vaccine schedule.	After index date is determined	[0,0]	IP, OP, OT	All individuals within selected data source
Aged =18 years	Study participants include eligible individuals for MCV4 vaccines based on the ECDC and NHS vaccine schedule	After index date is determined	[0,0]	IP, OP, OT	All individuals within selected data source

Criterion	Details	Order of application	Assessment window	Care Settings[1]	Applied to study populations:
Continuous enrolment from up to eight weeks after birth until reaching two years of age	Study participants for assessing the coverage of MenB and MenC were required to have a full continuous history observed from the start of assessment windows before contributing to the study population	After index date is determined	[Up to 8 weeks from date of birth, Age 2 years] for MenB and MenC vaccination;	IP, OP, OT	All study participants included for assessing the coverage of MenB and Men C vaccination aged 2 years
Continuous enrolment from age 12 until age 18	Study participants for assessing the coverage of MCV4 were required to have a full continuous history observed from the start of assessment windows before contributing to the study population	After index date is determined	[Age 12 years, Age 18 years] for MCV4 vaccination	IP, OP, OT	All study participants included for assessing the coverage of MCV4 vaccination aged 18 years
Receiving MenB vaccination	Study participants for assessing the age distribution of recipients of MenB vaccines (≥1 dose, ≥2 doses, ≥3 doses, =1 dose, =2 doses, =3 doses)	After index date is determined	[0,0]	IP, OP, OT	All individuals within selected data source
Receiving MenC vaccination	Study participants for assessing the age distribution of recipients of MenC vaccines (≥1 dose, =1 dose)	After index date is determined	[0,0]	IP, OP, OT	All individuals within selected data source
Receiving MCV4 vaccination	Study participants for assessing the age distribution of recipient of MCV4 vaccines (≥1 dose, =1 dose)	After index date is determined	[0,0]	IP, OP, OT	All individuals within selected data source

[1] IP = inpatient, OP = outpatient, ED = emergency department, OT = other, n/a = not applicable
Note: ECDC = European Centre for Disease Prevention and Control

8.4. Study setting and data sources

This study was conducted using routinely collected data from six primary care and secondary care data sources in the DARWIN EU® network of data partners from five European countries, of which four EU member states. All data were a priori mapped to the OMOP CDM.

Data sources

1. Croatian National Public Health Information System (NAJS), Croatia
2. Danish Data Health Registries (DK-DHR), Denmark
3. Finnish Care Register for Health Care (FinOMOP-THL), Finland
4. Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (BIFAP), Spain
5. Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària (SIDIAP), Spain
6. Clinical Practice Research Datalink (CPRD) GOLD, United Kingdom (UK)

Data sources selection

We selected six out of the 30 data sources onboarded in DARWIN EU® in 2025. The selection of data source for this study was performed based on data reliability and relevance for the proposed research question.[7] The selected data source fulfilled the criteria required for a population-level DUS, while covering different settings and regions of Europe. Two separate data sources from Spain, including BIFAP, representing the national population excluding Catalonia, and SIDIAP, covering the specific regional population from Catalonia, were included to ensure a comprehensive assessment of Meningococcal vaccine coverage across the country. (**Annex II**) Institute for Applied Health Research Berlin GmbH (InGef) was initially selected as a data source for this study but subsequently excluded due to the insufficient record on separate types of meningococcal vaccines required to fulfil the study objectives specified. Detailed information on the selected data sources and their ability to answer the study research questions are described in **Table 5 and Annex I**.

Table 5. Description of the selected data sources.

Country	Name of Data source	Justification for Inclusion	Health Care setting	Type of Data	Number of active subjects	Feasibility counts of meningococcal vaccination record	Data lock for the last update
HR	NAJS	The data source has information on meningococcal vaccination record from primary care or hospital. The denominator is suitable for population rates as it includes population insured.	Primary care, secondary care specialists, hospital inpatient care	Claims	2.68 million	6.59 million	07/08/2024
DK	DK-DHR	The data source has information on meningococcal vaccination record from hospitals, specialist offices, and community pharmacies and treatments administered in hospital. The denominator is suitable for population rates as it includes the entire population.	Community pharmacies, secondary care – specialists, hospital inpatient care	Registries	5.96 million	1.01 million	19/02/2025
FL	FinOMOP-THL	The data source has information on meningococcal vaccination record from hospitals and specialist offices, GPs, and primary care specialist and treatments administered in hospital. The denominator is suitable for population rates as it includes the entire population.	Primary care, secondary care – specialists (ambulatory or hospital OP care), hospital IP care	HER, Registries	7.3 million	0.50 million	24/06/2024

Country	Name of Data source	Justification for Inclusion	Health Care setting	Type of Data	Number of active subjects	Feasibility counts of meningococcal vaccination record	Data lock for the last update
ES	BIFAP	The data source has information on meningococcal vaccination record from primary care or hospital. The denominator is suitable for population rates as it includes the entire population.	Primary care – GPs, community pharmacies, hospital inpatient care, primary care specialists	EHR	22.58 million	5.41 million	01/10/2024
ES	SIDIAP	The data source has information on meningococcal vaccination record from primary care treatments. Denominator is suitable for population rates as it includes all people registered in the GP practice.	Primary care	EHR	5.95 million	6.07 million	30/06/2023
UK	CPRD GOLD	The data source has information on meningococcal vaccination record from primary care or feedbacked to the GP from the specialists. The denominator is suitable for population rates as it includes all people registered in the GP practice.	Primary care	EHR	2.92 million	4.54 million	12/12/2024

CR = Croatia, DK = Denmark, ES = Spain, UK = United Kingdom, FL = Finland, BIFAP = Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público, CPRD GOLD = Clinical Practice Research Datalink, DK-DHR = Danish Data Health Registries, FinOMOP-THL = Finnish Care Register for Health Care, NAJS = Croatian National Public Health Information System, SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària

8.5. Study period

The study period ran from 01/01/2017 until the end of available data in each of the data sources. (**Table 6**) The study start date chosen covers the period during which MenB and MCV4 meningococcal vaccines were introduced as part of the routine childhood immunisation program in countries across Europe and allowed for the examination of potential disruptions in routine vaccinations over the COVID-19 pandemic. Of note, MenC vaccines had been introduced before the start of the study period.

Table 6. Study period by data source.

Data source	Start date	End date
NAJS	01/01/2017	07/08/2024
DK-DHR	01/01/2017	19/02/2025
FinOMOP-THL	01/01/2017	24/06/2024
BIFAP	01/01/2017	01/10/2024
SIDIAP	01/01/2017	30/06/2023
CPRD GOLD	01/01/2017	12/12/2024

BIFAP = Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público, CPRD GOLD = Clinical Practice Research Datalink, DK-DHR = Danish Data Health Registries, FinOMOP-THL = Finnish Care Register for Health Care, NAJS = Croatian National Public Health Information System, SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària

8.6. Variables

8.6.1. Exposure

The exposure in this study was defined as the record of birth for the examination of coverage of MenB and MenC vaccination and reaching 12 years of age for the examination of coverage of MCV4 vaccination from separate data source.

8.6.2. Outcome

- The outcomes of interest for objective 1 were defined as 1) At least one dose, 2) At least two doses, 3) Complete vaccination (at least three doses), 4) exactly one dose, 5) exactly two doses, 6) exactly three doses of MenB vaccination (**Annex III Table S1**). Analysis for this objective was stratified by age in individuals aged one year and aged two years.
- The outcomes for objective 2 were defined as the uptake of 1) at least one dose, 2) exactly one dose of either MenC or Hib/MenC vaccine. (**Annex III Table S2**).
- The outcome for objective 3 was defined as the uptake of MCV4 meningococcal vaccines (**Annex III Table S3**). MCV4 uptake was defined 1) as at least one record and 2) exactly one record of MCV4 vaccines or separate exposure records of meningococcal serogroups A, C, W-135, and Y vaccination on the same date given the possibility where the records of MCV4 vaccination are captured separately by the distinct meningococcal serogroups in certain data source, including FinOMOP-THL.
- The outcome for objective 4 was defined as the uptake of MenB and MCV4 meningococcal vaccines by brand (Menveo®, Nimenrix®, Bexsero®, Trumenba®) in CPRD GOLD, UK due to the potential limitation on the availability of data on brand in other data source. The definition of vaccine brand can be found in **Annex III Tables S4–7**.
- The outcome for objective 5 was defined as the age of recipients of MenB (≥1 dose, ≥2 doses, ≥3 doses, =1 dose, =2 doses, =3 doses), MenC (≥1 dose, =1 dose), and MCV4 vaccination (≥1 dose, =1 dose).

The definitions of outcomes are illustrated in **Table 7**.

Table 7. Operational definitions of outcomes.

Outcome name	Details	Primary outcome?	Type of outcome	Washout window	Care Settings[1]	Code Type	Diagnosis Position[2]	Applied to study populations
MenB vaccination	Coverage of specific type (MenB) of Meningococcal vaccines and age distribution of MenB recipients	Y	Cumulative number of records or dose received (≥1 dose, ≥2 doses, ≥3 doses, =1 dose, =2 doses, =3 doses)	N/A	IP, OP, OT	RxNorm, SNOMED	N/A	All individuals aged 2 years and aged 1 years included in the study population (objective 1) All vaccinated individuals from their respective data source (objective 5)
MenC or Hib/MenC vaccination	Coverage of specific type (MenC) of Meningococcal vaccines and age distribution of MenC recipients	Y	≥1 dose or =1 dose	N/A	IP, OP, OT	RxNorm, SNOMED	N/A	All individuals aged 2 years included in the study population (objective 2) All vaccinated individuals from their respective data source (objective 5)
MCV4 vaccination	Coverage of specific type (MCV4) of Meningococcal vaccines and age distribution of MCV4 recipients	Y	≥1 dose or =1 dose	N/A	IP, OP, OT	RxNorm, SNOMED	N/A	All individuals aged 18 years included in the study population (objective 3) All vaccinated individuals from their respective data source (objective 5)
Bexsero® vaccination	Coverage of specific brand (Bexsero®) of Meningococcal vaccines	Y	Binary	N/A	IP, OP, OT	RxNorm	N/A	All individuals aged 2 years included in the study population (objective 4)
Trumenba® vaccination	Coverage of specific brand (Trumenba®) of Meningococcal vaccines	Y	Binary	N/A	IP, OP, OT	RxNorm	N/A	All individuals aged 2 years included in the study population (objective 4)
Menveo® vaccination	Coverage of specific brand (Menveo®) of Meningococcal vaccines	Y	Binary	N/A	IP, OP, OT	RxNorm	N/A	All individuals aged 18 years included in the study population (objective 4)

Outcome name	Details	Primary outcome?	Type of outcome	Washout window	Care Settings[1]	Code Type	Diagnosis Position[2]	Applied to study populations
Nimenrix® vaccination	Coverage of specific brand (Nimenrix®) of Meningococcal vaccines	Y	Binary	N/A	IP, OP, OT	RxNorm	N/A	All individuals aged 18 years included in the study population (objective 4)

[1] IP = inpatient, OP = outpatient, ED = emergency department, OT = other, n/a = not applicable
[2] Specify whether a diagnosis code is required to be in the primary position (main reason for encounter

8.7. Study size

This population-level DUS and patient-level characterisation study reports descriptive coverage of meningococcal vaccines and the age distribution of vaccines recipients at each quarterly and yearly sampling window. Sample size calculation was therefore not required for this study.

8.8. Data transformation

Analyses were conducted separately for each data source. Before study initiation, test runs of the analyses were performed on a subset of the data sources and quality control checks were performed. Once all the tests passed (see **Annex III**), the final study codes package was released in the version-controlled Study Repository for execution against all the participating data sources.

The data partners locally executed the analytics against the OMOP CDM in R Studio and reviewed and approved the, by default, aggregated results.

The study results of all data sources were checked, after which they were made available to the team, and the dissemination phase started. All results were locked and timestamped for reproducibility and transparency

8.9. Statistical methods

8.9.1. Main summary measures

Population-level DUS

Objective 1 of this study examines the point prevalence of individuals who have received different numbers of doses of MenB vaccines (≥1 dose, ≥2 doses and ≥3 doses, =1 dose, =2 doses, =3 doses) in separate age groups (age 1 year and 2 years of age). Individuals included for this analysis were required to have a continuous enrolment from up to 8 weeks after date of birth.

Objective 2 of this study examines the point prevalence of MenC or Hib/MenC vaccination (≥1 dose, =1 dose) in individuals at two years of age. Individuals included for this analysis were required to have a continuous enrolment from 8 weeks after date of birth.

Objective 3 examines the point prevalence of MCV4 vaccination (≥1 dose, =1 dose) in individuals at 18 years of age. Individuals included for this analysis were required to have at continuous enrolment from the date of turning age 12.

Objective 4 examined the point prevalence of MenB and MCV4 vaccines by brand (MenB: Bexsero®, Trumenba®; MCV4: Menveo®, Nimenrix®). Individuals included for the analyses of separate brands of MenB vaccines were defined as individuals at two years of age with continuous enrolment from up to 8 weeks after the date of birth. Individuals included for the analyses of separate brands of MCV4 vaccines were defined as individuals at 18 years of age with continuous enrolment from the date of turning age 12.

The point prevalence of vaccines recipients was estimated by dividing the numerator defined as the number of vaccinated individuals divided from the target population by the denominators defined as the total number of target population eligible for vaccination. All estimates were provided overall and stratified by sex (male and female).

Patient-level Characterisation

Objective 5 of this study examined the age distribution of cohorts of individuals who received three or more doses of a MenB vaccine, one dose of a MenC vaccine, and one dose of a MCV4 vaccine. The age distributions of vaccinated individuals were examined in the last observation window of each data sources.

The age distribution illustrated were presented in overall and stratified by sex (male and female).

8.9.2. Main statistical methods

The statistical methods adopted included Population Level DUS to estimate the point prevalence of vaccines coverage at quarterly and yearly time interval. The point prevalence is estimated by dividing the number of vaccinated individuals by the number of target population identified from separate databases.

Patient-level characterisation was also conducted to characterise the age distribution of vaccines recipients. The age of each individuals measured was defined as the age of which the cumulative dose of separate types of meningococcal vaccines were observed.

Software

All analyses were performed with R. We used the following R packages:

- *IncidencePrevalence* (v1.0.0) (https://github.com/darwin-eu/IncidencePrevalence) for the estimation of point prevalence.[8]

- *CohortCharacteristics* (v0.4.0) (CRAN: Package CohortCharacteristics) for the patient-level characterisation of age distribution of vaccines recipients.

- *visOmopResults* (v1.0.0) (https://darwin-eu.github.io/visOmopResults/) for computing tables and figures.

8.9.3. Missing values

All variables used in the study were based on the recorded medications, and procedures, codes available in the data. We assumed that missing vaccination records indicated that the individual had not been vaccinated.

8.9.4. Sensitivity analysis

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.

8.10. Deviations from the protocol

Deviation number	Protocol version	Date	Section of study protocol	Deviation	Reason
1	V3.0	09/09/2025	8.4 Study setting and data sources	Excluded InGef as a data source	Information on specific type of Meningococcal vaccines is limited from this data source
2	V3.0	04/08/2025	8.5 Study period	Requirement for continuous follow-up amended from continuous enrolment since birth to from 8 weeks of age for the coverage of MenB and MenC	The constraint of continuous follow-up from birth have led to insufficient sample size for analysis
3	V3.0	04/08/2025	8.9.4 Sensitivity analysis	Additional sensitivity analysis by defining the study population for the coverage of MCV4 as all individuals aged between 12 and 18 was conducted	To examine the coverage of MCV4 in a broader population given the considerable variations in the target population for this vaccine across different European countries

9. RESULTS

The full set of results are available in an interactive web application ("shiny app") at EUPAS1000000675. The shiny app consists of four main tabs as illustrated below:

1. Background – Provides a brief description of the study, including the rationale, background, and objectives.
2. Data source details – Includes a Snapshot subtab with a table summarising metadata for each study data source.
3. Patient characteristics – Displays selected patient-level variables vaccination, available in table format.
4. Vaccine coverage – Displays population-level prevalence rates in both table (raw data) and plot formats. The coverage of separate type of vaccines can be viewed by selecting the vaccines type of interest along with the corresponding target population by age group and time of prior observation.

9.1. Participants

This study identified over 2.46M, 2.22M, and 3.74M individuals receiving at least one dose of MenB, MenC, and MCV4 vaccination across all the data sources, respectively. BIFAP reported the highest number of vaccine recipients, with 1.48 million for MenB, 1.48 million for MenC, and 2.89 million for MCV4. In contrast, NAJS recorded the lowest counts, with 1,216 individuals for MenB, 1,197 for MenC, and 1,197 for MCV4. (**Table 8**)

9.2. Descriptive data

Without applying the operational inclusion criteria for study participants by age, the median age of vaccine recipients of at least one dose of MenB was below one year of age in CPRD GOLD [0 years (IQR: 0–0)], BIFAP [0 (0–3)], and SIDIAP [0 (0–4)], whilst a substantially higher median age was observed in DK-DHR [15 years (2 – 20)], FinOMOP-THL [51 (23 – 67)], and NAJS [46 (19 – 63)]. The median age for MenC recipients was one year or below in CPRD GOLD [1 (1 – 1)], BIFAP [0 (0–1)], and SIDIAP [0 (0–7)], whereas older median age was observed in DK-DHR [23 (16 – 42)], FinOMOP-THL [19 (19 – 21)], and NAJS [45 (26 – 62)]. Recipients for MCV4 were mostly among adolescents and young adults with a median age ranging between [11 (11 – 14)] in SIDIAP and [45 (26 – 62)] in NAJS. The proportion of male of MenB vaccine recipients ranged from 44.9% in FinOMOP-THL to 56.3% in NAJS. Notably, a markedly higher proportion of male recipients was observed for MenC (74.3%) and MCV4 (79.8%) in FinOMOP-THL. Detailed baseline demographics of the study population stratified by vaccine type are summarised in **Table 8** below.

Table 8. Baseline demographics of Meningococcal vaccines recipients across separate data source.

Vaccination cohort	BIFAP			DK-DHR			FinOMOP-THL			NAJS			SIDIAP			CPRD GOLD		
	MCV4	Men C	Men B	MCV4	Men C	Men B	MCV4	Men C	Men B	MCV4	Men C	Men B	MCV4	Men C	Men B	MCV4	Men C	Men B
Number subjects (N)	2,889,398	1,478,040	1,479,680	52,707	53,346	3,304	56,897	49,560	2,470	1,197	1,197	1,216	542,133	407,658	309,337	205,217	236,034	264,082
Median age in years (IQR)	12 (10 – 15)	0 (0 – 1)	0 (0 – 3)	23 (16 – 42)	23 (16 – 42)	15 (2 – 20)	19 (19 – 23)	19 (19 – 21)	51 (23 – 67)	45 (26 – 62)	45 (26 – 62)	46 (19 – 63)	11 (11 – 14)	0 (0 – 7)	0 (0 – 4)	15 (14 – 16)	1 (1 – 1)	0 (0 – 0)
Age range (Year)	0 to 100	0 to 107	0 to 108	0 to 95	0 to 95	0 to 88	0 to 92	0 to 92	0 to 95	0 to 87	0 to 87	0 to 87	0 to 98	0 to 100	0 to 100	0 to 95	0 to 103	0 to 101
Male sex; N (%)	1,472,321 (50.96%)	760,306 (51.44%)	760,626 (51.40%)	26,376 (47.83%)	26,647 (47.75%)	1,861 (54.99%)	42,561 (74.30%)	39,740 (79.78%)	1,112 (44.86%)	715 (59.73%)	715 (59.73%)	684 (56.25%)	277,708 (51.23%)	210,974 (51.75%)	158,772 (51.33%)	101,512 (49.47%)	120,905 (51.22%)	135,628 (51.36%)

BIFAP = Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público, CPRD GOLD = Clinical Practice Research Datalink, DK-DHR = Danish Data Health Registries, FinOMOP-THL = Finnish Care Register for Health Care, NAJS = Croatian National Public Health Information System, SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària

9.3. Main results

The main results are structured according to the study objectives: i) coverage for MenB in individuals (objective 1), ii) coverage of MenC (objectives 2), iii) coverage of MCV4 (objective 3), iv) coverage of vaccine type by brand (objective 4), and v) age distribution of vaccines recipients. Results are presented overall and stratified by sex and age groups. Key stratified findings are presented in this report for clarity. Sex stratified results are available in the shiny app EUPAS1000000675.

9.3.1. Coverage for Meningococcal serogroup B vaccines

Individuals aged one year

MenB vaccination coverage showed an increasing trend over time in both BIFAP and SIDIAP. Despite the highest coverage observed in the CPRD GOLD, a minor reduction in prevalence of vaccine recipients were observed from 2020, especially for the third dose of MenB vaccines (**Figure 4**, **Table S8**).

The prevalence of individuals from the target population at age one receiving at least one dose of vaccine was shown to be the highest in CPRD GOLD, with a coverage of over 95% from 2018 onwards. The highest coverage was observed in 2018 at 97.8% (95% CI: 97.7–98.0). The prevalence of individuals with at least one dose of vaccines increased steadily from 28.2% (95% CI: 28.0–28.5) in 2017 to 78.9% (95% CI: 78.7–79.1) in 2024 in BIFAP, and from 21.7% (95% CI: 21.3–22.0) in 2017 to 65.9% (95% CI: 65.5–66.4) in SIDIAP in 2023. The prevalence of individuals who received at least two doses of MenB vaccine was highest in CPRD GOLD, with 93.0% (95% CI: 92.7–93.2) in 2018, followed by BIFAP with 74.6% (95% CI: 74.3–74.8) and SIDIAP with 62.9% (95% CI: 62.4–63.3) in 2024 and 2023, respectively. The maximum coverage of at least three doses of MenB vaccine within this age group ranged from 68.7% (95% CI: 68.2–69.1) in CPRD GOLD in 2018 to 31.6% (95% CI: 31.1–32.0) in SIDIAP in 2023. (**Figure 6**)

Individuals aged two years

A reduction in coverage of the MenB vaccine of all doses was observed for CPRD GOLD from 84.3% (95%CI: 83.9 – 84.7) in 2020 with the most profound reduction observed in the coverage for the third dose of vaccination to 77.2% (95% CI: 76.67–77.7) in 2023. In contrast, the coverage for individuals aged two years receiving at least one dose of MenB showed an increasing trend from 25.9% (95%CI: 25.6– 26) in 2017 to 75.9% (95%CI: 75.76–76.1) in 2024 in BIFAP, and from 18.7% (95%CI: 18.4–19.1) in 2017 to 61.9% (95%CI: 61.4–62.4) in 2023 in SIDIAP, with a steep increase in prevalence between 2021 and 2022. (**Table S9**)

Compared to individuals aged one year, a similar level of coverage for at least one and two doses of MenB vaccine was observed among those aged two years. Nevertheless, a considerably higher prevalence of individuals receiving three or more doses of vaccines was observed amongst individuals of this age group, with the highest coverage of 85.2% (95% CI: 84.8–85.6) in CPRD GOLD in 2019, followed by 62.5% (95% CI: 62.3–62.8) in BIFAP in 2024, and 50.1% (95% CI: 49.6–50.6) in SIDIAP in 2023. (**Figure 7**, **Table S9**)

DK-DHR, FinOMOP-THL, and NAJS, data source representing countries not recommending universal MenB vaccination, showed negligible coverage within the target population throughout the study period.

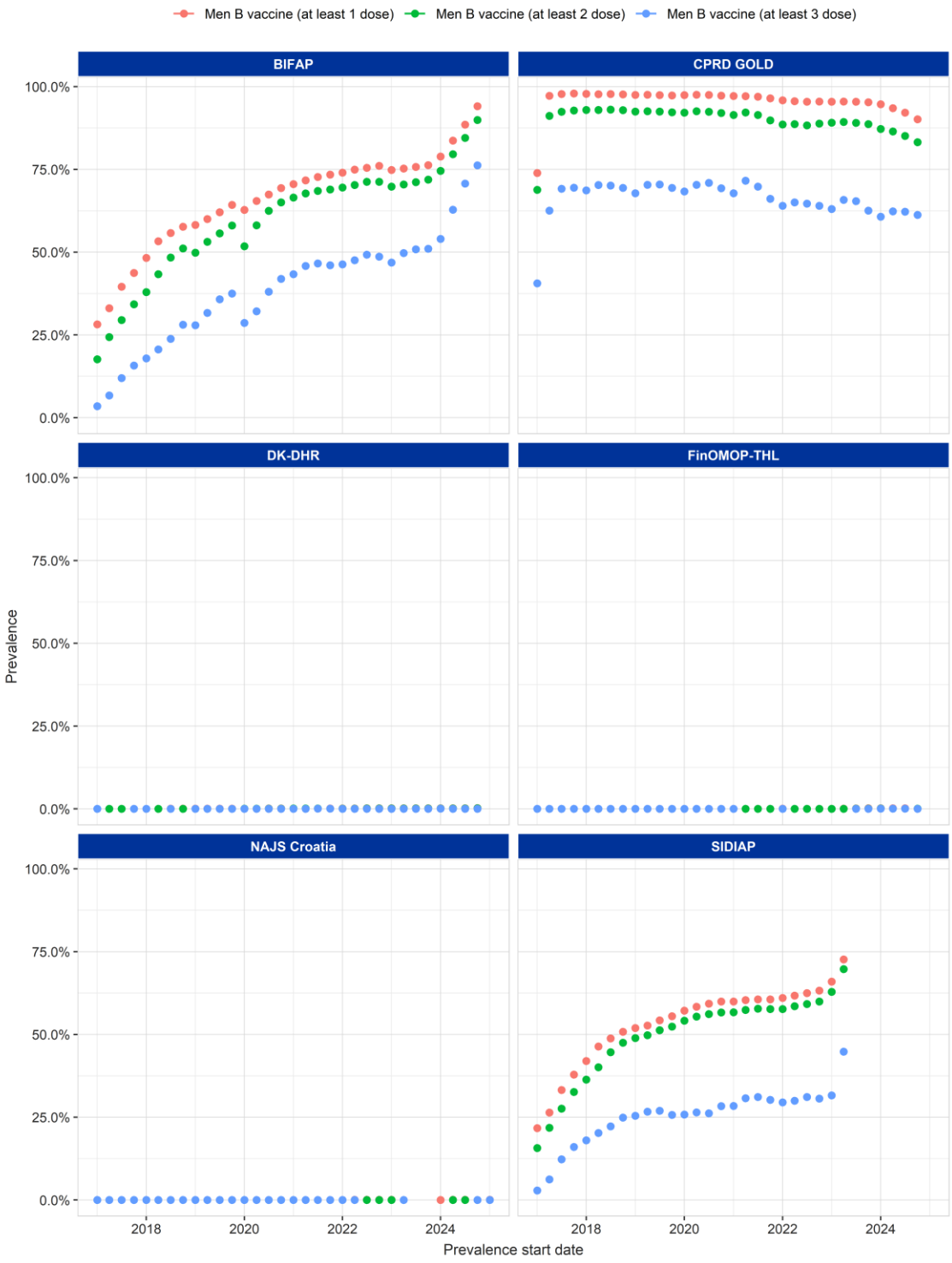

Figure 4. Point prevalence of at least one dose, at least two doses and at least three doses of meningococcal serogroup B vaccines in individuals aged one year.

BIFAP = Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público, CPRD GOLD = Clinical Practice Research Datalink, DK-DHR = Danish Data Health Registries, FinOMOP-THL = Finnish Care Register for Health Care, NAJS = Croatian National Public Health Information System, SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària

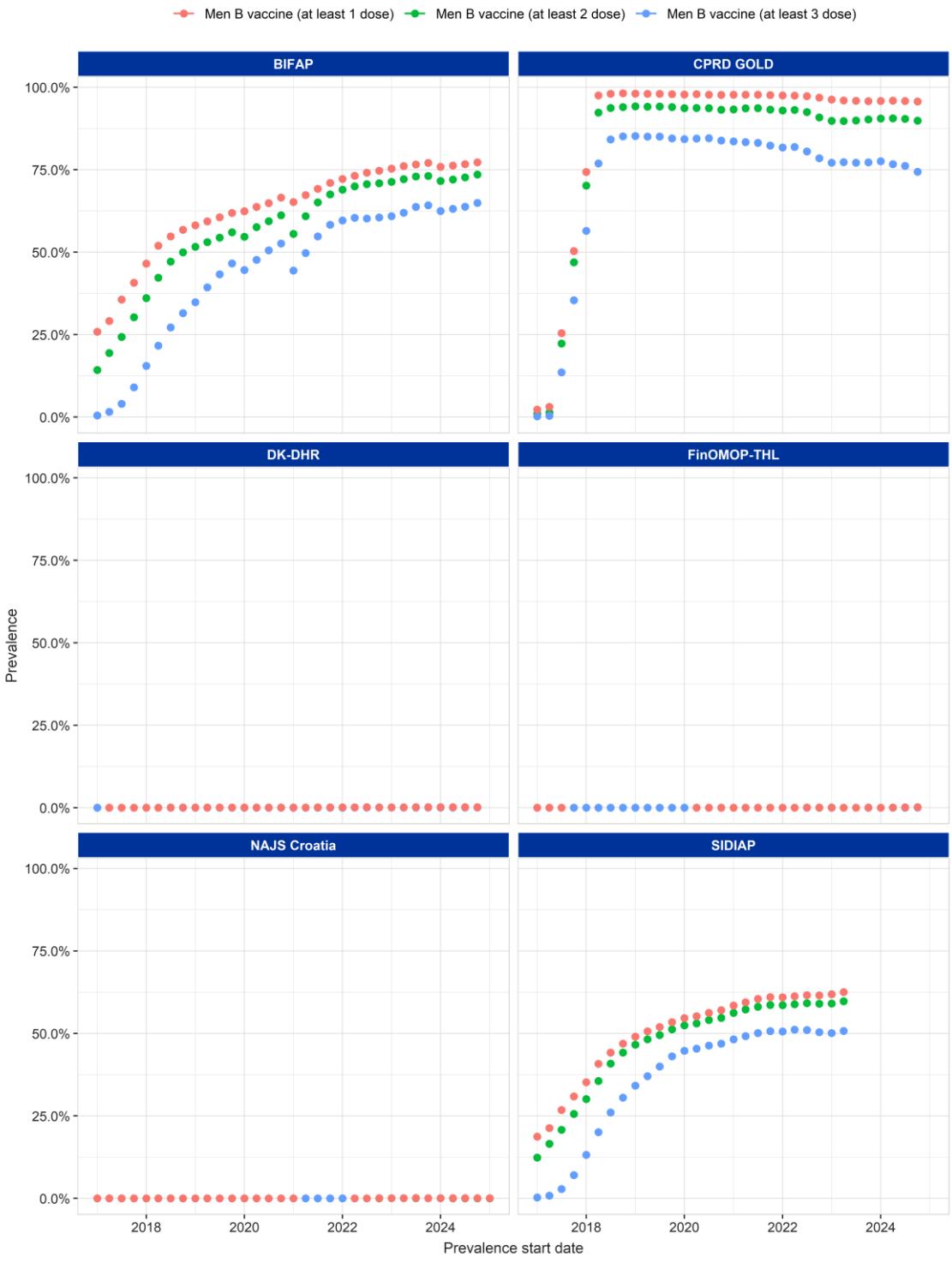

Figure 5. Point prevalence of at least one dose, at least two doses and at least three doses of meningococcal serogroup B vaccines in individuals aged two years.

BIFAP = Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público, CPRD GOLD = Clinical Practice Research Datalink, DK-DHR = Danish Data Health Registries, FinOMOP-THL = Finnish Care Register for Health Care, NAJS = Croatian National Public Health Information System, SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària

9.3.2. Coverage for Meningococcal serogroup C vaccines

The prevalence showed in **Figure 6** illustrates the high coverage of MenC vaccines in CPRD GOLD, BIFAP, and SIDIAP compared to the other data sources with a coverage of 98.3% (95% CI: 98.2–98.4), 97.6% (95% CI: 97.5–97.7), and 97.0% (95% CI: 96.9–97.2) observed in 2017, respectively. However, a consistent reduction in the coverage of MenC vaccines was observed across these data source. The reduction in vaccine coverage was marginal, with the most profound difference observed in CPRD GOLD, where a reduction in coverage to 89.6% (95% CI: 89.2–90.0) was observed in 2024. The coverage of MenC in DK-DHR, FinOMOP-THL, and NAJS were comparably lower amongst the same target population of individuals (**Figure 6**, **Table S10**).

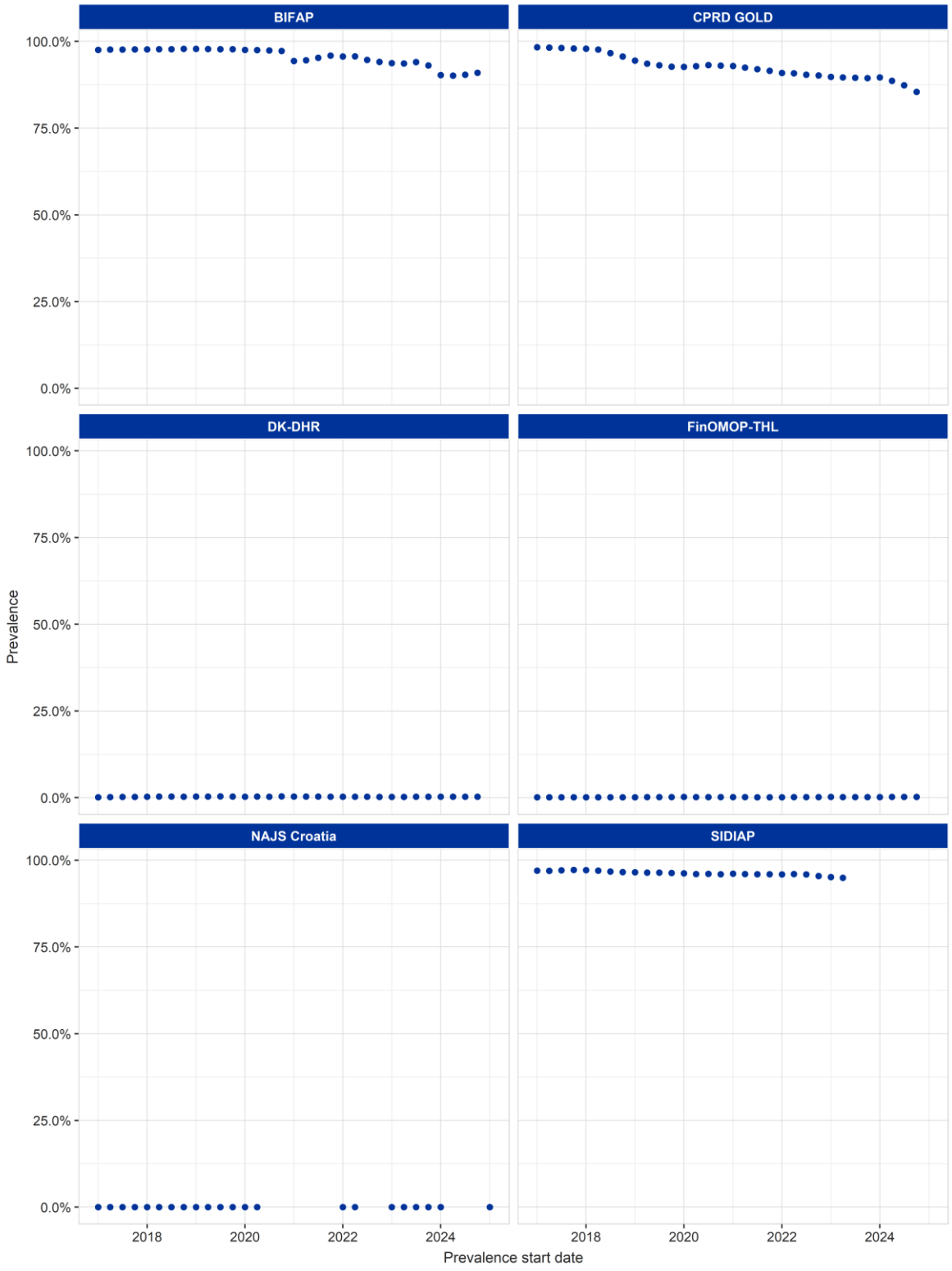

Figure 6. Point prevalence of at least one dose of MenC vaccines in individuals aged two years.

BIFAP = Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público, CPRD GOLD = Clinical Practice Research Datalink, DK-DHR = Danish Data Health Registries, FinOMOP-THL = Finnish Care Register for Health Care, NAJS = Croatian National Public Health Information System, SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària

9.3.3. Coverage for Meningococcal serogroup ACWY (MCV4) vaccines

A gradual increase in coverage in MCV4 vaccines was observed from 36.2% (95% CI: 35.7–36.6) in 2017 to 64.6% (95% CI: 64.0–65.1) in 2020, followed by a reduction in coverage to 51.6% (95% CI: 51.0–52.2) from 2022 to 2024 in CPRD GOLD. In contrast, a considerable increase from 34.3% (95% CI: 34.0–34.6) in 2020 to 70.1% (95% CI: 69.9–70.4) in 2024, and from 0.9% (95% CI: 0.8–0.9) in 2020 to 38.9% (95% CI: 38.5–39.3) in 2023 was observed in BIFAP and SIDIAP, respectively. In contrast, the coverage of MCV4 vaccines in DK-DHR, FinOMOP-THL, and NAJS remained comparatively low, with an observed prevalence of 2–3% in DK-DHR and 1% and 0% observed in FinOMOP-THL and NAJS across the study period, respectively (**Figure 7** and **Table S11**).

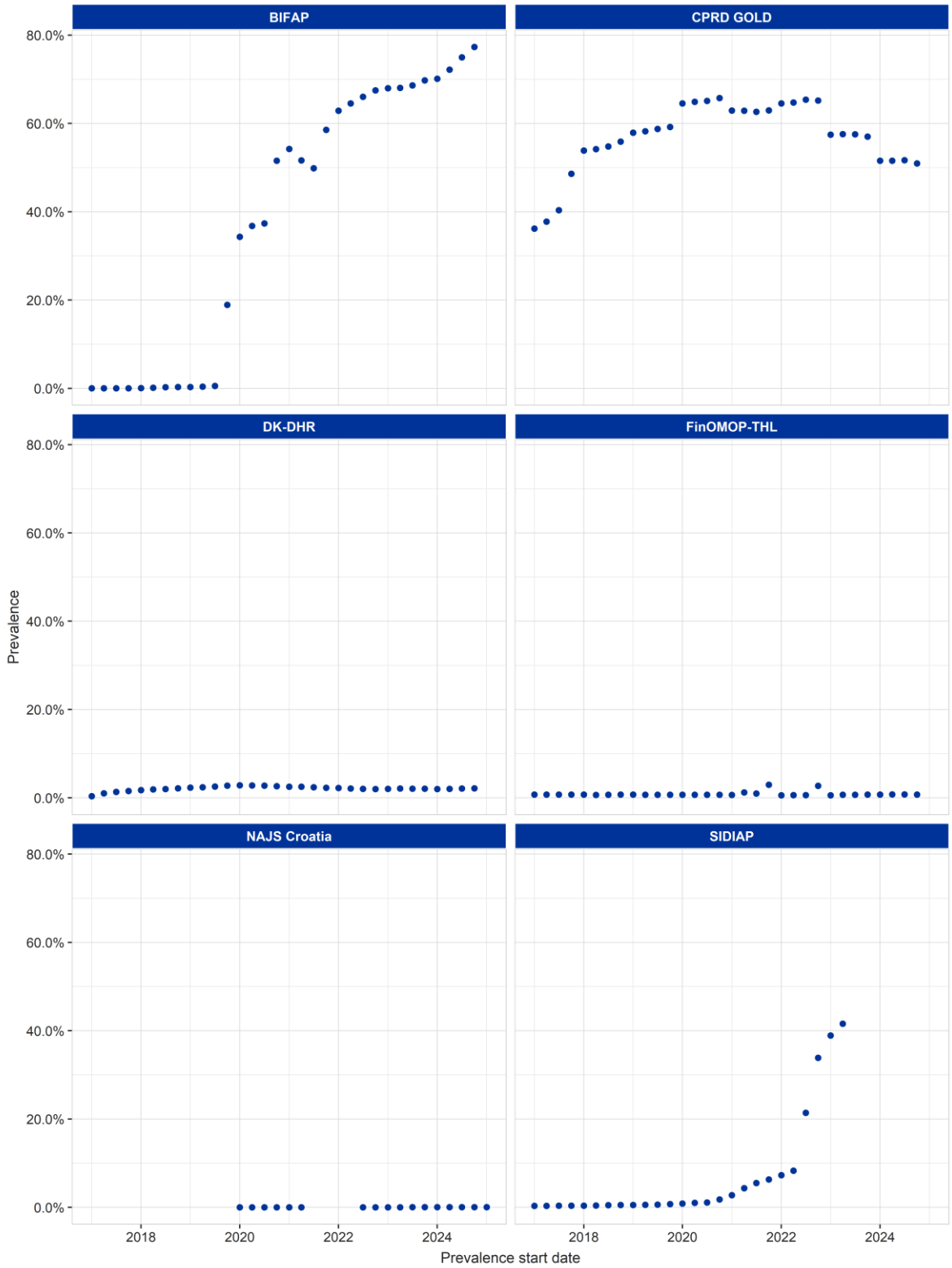

Figure 7. Point prevalence of at least one dose of MCV4 vaccines in individuals aged 18 years.

BIFAP = Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público, CPRD GOLD = Clinical Practice Research Datalink, DK-DHR = Danish Data Health Registries, FinOMOP-THL = Finnish Care Register for Health Care, NAJS = Croatian National Public Health Information System, SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària

9.3.4. Coverage of vaccine type by brand

A low coverage and vaccination record counts was observed in CPRD GOLD for Bexsero® and Trumenba®, Meningococcal serogroup B vaccines, and Menveo® and Nimenrix®, MCV4 vaccines (**Table 8**). The detailed findings on the coverage of separate brands of vaccines were included in the Shiny app (EUPAS1000000675).

Table 9. Yearly Point prevalence of recipients of Bexsero® amongst individuals aged one year of age and Menveo® and Nimenrix® amongst individuals aged 18 years of age.

	Bexsero®			Menveo®			Nimenrix®		
Prevalence start date	Denominator (N)	Outcome (N)	Prevalence (95% CI)	Denominator (N)	Outcome (N)	Prevalence (95% CI)	Denominator (N)	Outcome (N)	Prevalence (95% CI)
2017-01-01	40,273	69	0.17 (0.14 - 0.22)	40,506	75	0.18 (0.15 - 0.23)	40,506	57	0.14 (0.11 - 0.18)
2018-01-01	36,489	111	0.30 (0.25 - 0.37)	36,585	38	0.10 (0.08 - 0.14)	36,585	48	0.13 (0.10 - 0.17)
2019-01-01	35,077	57	0.16 (0.12 - 0.21)	34,308	17	0.05 (0.03 - 0.08)	34,308	39	0.11 (0.08 - 0.16)
2020-01-01	31,552	38	0.12 (0.09 - 0.16)	31,859	19	0.06 (0.04 - 0.09)	31,859	60	0.19 (0.15 - 0.24)
2021-01-01	27,881	32	0.12 (0.08 - 0.16)	30,432	14	0.05 (0.03 - 0.08)	30,432	44	0.14 (0.11 - 0.19)
2022-01-01	24,400	8	0.03 (0.02 - 0.06)	28,115	18	0.06 (0.04 - 0.10)	28,115	53	0.19 (0.14 - 0.25)
2023-01-01	20,836	15	0.07 (0.04 - 0.12)	26,683	11	0.04 (0.02 - 0.07)	26,683	59	0.22 (0.17 - 0.28)
2024-01-01	21,096	15	0.07 (0.04 - 0.12)	26,401	11	0.04 (0.02 - 0.07)	26,401	27	0.10 (0.07 - 0.15)

Note: The record count and prevalence of Trumenba® is not presented due to the absence of recorded vaccinations observed in the study population

9.3.5. Age distribution of recipients of MenB, MenC, and MCV4 vaccines

The sex-stratified age distribution for separate vaccination with MenB, MenC, and MCV4 vaccines are presented in **Figure 8–12**. The age distribution of vaccines recipients was largely consistent between males and females, with the exception of MenC and MCV4 recipients in FinOMOP-THL. The majority of recipients of the first two doses of MenB vaccines were aged 1 year or less in all data source apart from NAJS, whilst the majority of recipients receiving at least three doses of MenB were aged between one to two years of age. Nonetheless, data source representing countries without the recommendation of meningococcal vaccines showed a broader age distribution of vaccines recipients, with distinct peaks of vaccines recipients observed between individuals aged 13–20 in DK-DHR and elder population aged 55–75 in FinOMOP-THL and NAJS (**Figure 8–10**).

The vast majority of MenC vaccines recipients were aged 2 years or below in CPRD GOLD, BIFAP, and SIDIAP. Meanwhile, the majority of recipients for MenC in DK-DHR and FinOMOP-THL were among elder population aged between 18 and 22, with the recipients in FinOMOP-THL among this population observed to be mostly male. The distribution of recipients of MenC in NAJS were distributed among adolescents and adults aged between 15 and 75 (**Figure 11**).

The distribution of MCV4 vaccines recipients in CPRD GOLD, BIFAP, SIDIAP, DK-DHR, and Fin-OMOP showed the majority of vaccines recipients to be among adolescent population aged between 13–20, whilst the distribution in NAJS were among adolescents and adults (**Figure 12**).

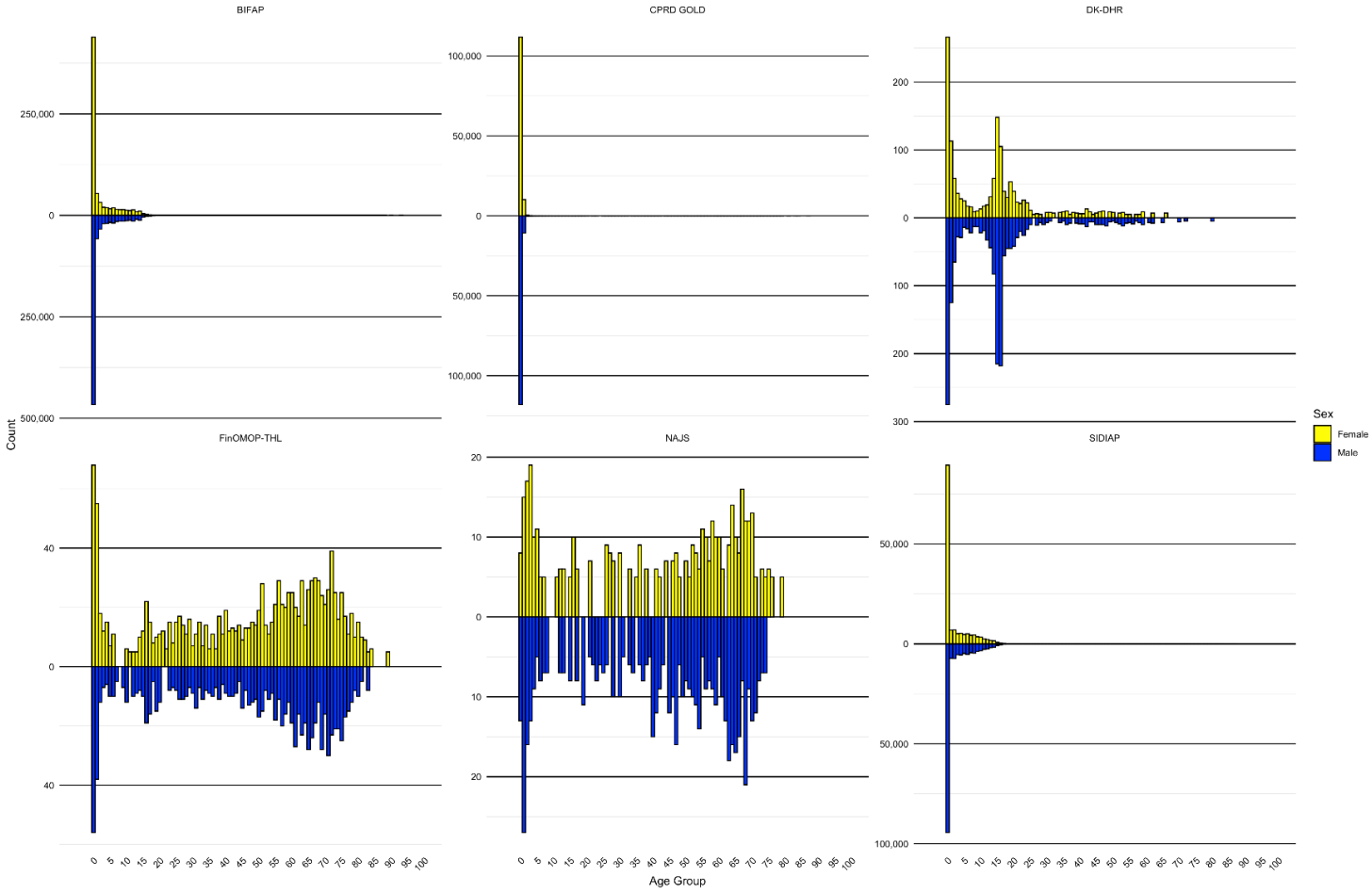

Figure 8. Age distribution of recipients of at least one dose of Meningococcal serogroup B vaccines stratified by sex.

BIFAP = Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público, CPRD GOLD = Clinical Practice Research Datalink, DK-DHR = Danish Data Health Registries, FinOMOP-THL = Finnish Care Register for Health Care, NAJS = Croatian National Public Health Information System, SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària

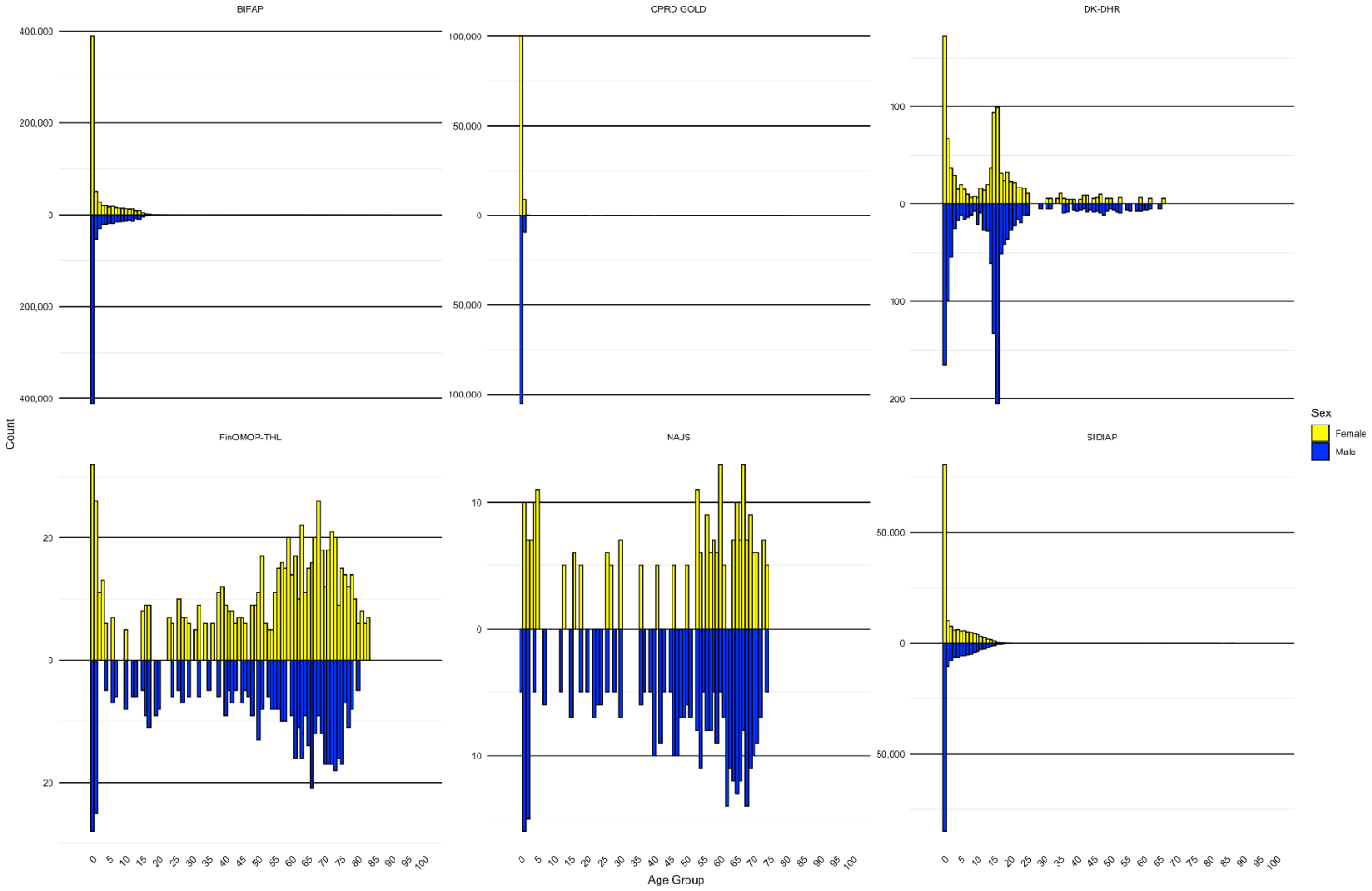

Figure 9. Age distribution of recipients of at least two doses of Meningococcal serogroup B vaccines stratified by sex.

BIFAP = Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público, CPRD GOLD = Clinical Practice Research Datalink, DK-DHR = Danish Data Health Registries, FinOMOP-THL = Finnish Care Register for Health Care, NAJS = Croatian National Public Health Information System, SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària

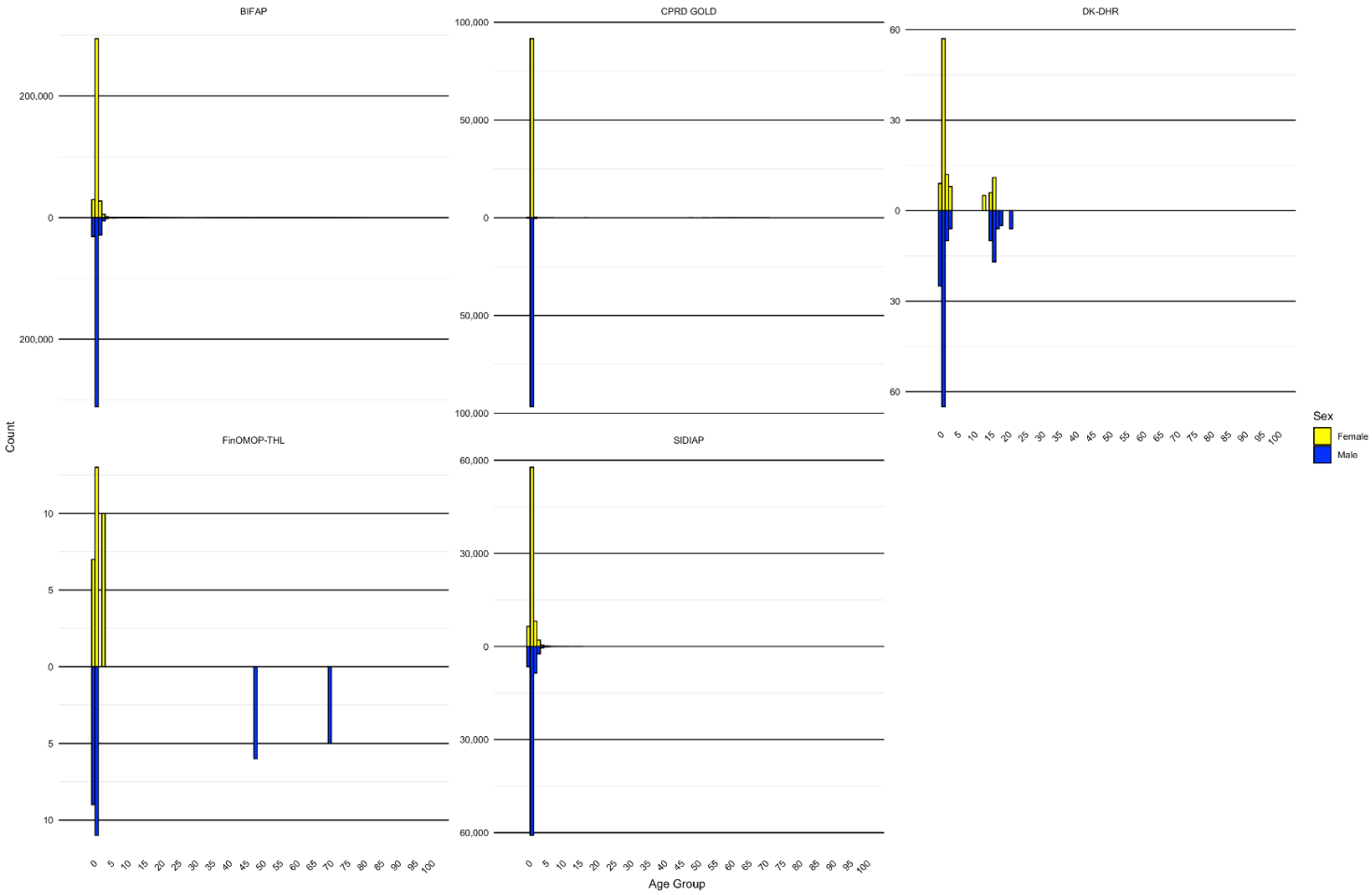

Figure 10. Age distribution of recipients of at least three doses of Meningococcal serogroup B vaccines stratified by sex.

Note: The age distribution of vaccine of recipients from NAJS is not presented due to the absence of recorded vaccine administrations within this dataset, BIFAP = Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público, CPRD GOLD = Clinical Practice Research Datalink, DK-DHR = Danish Data Health Registries, FinOMOP-THL = Finnish Care Register for Health Care, NAJS = Croatian National Public Health Information System, SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària

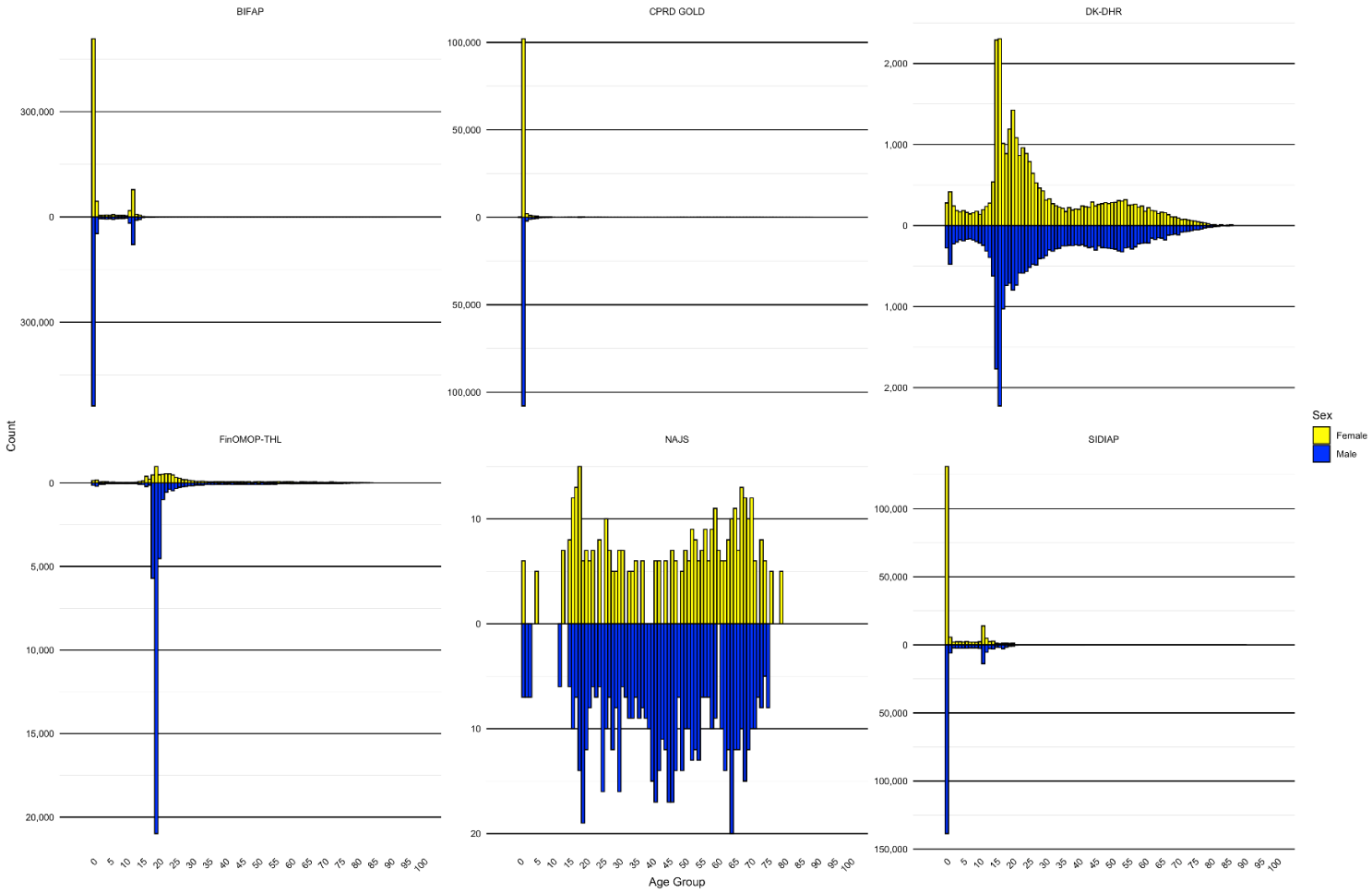

Figure 11. Age distribution of recipients of at least one dose of Meningococcal serogroup C vaccines stratified by sex.

BIFAP = Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público, CPRD GOLD = Clinical Practice Research Datalink, DK-DHR = Danish Data Health Registries, FinOMOP-THL = Finnish Care Register for Health Care, NAJS = Croatian National Public Health Information System, SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària

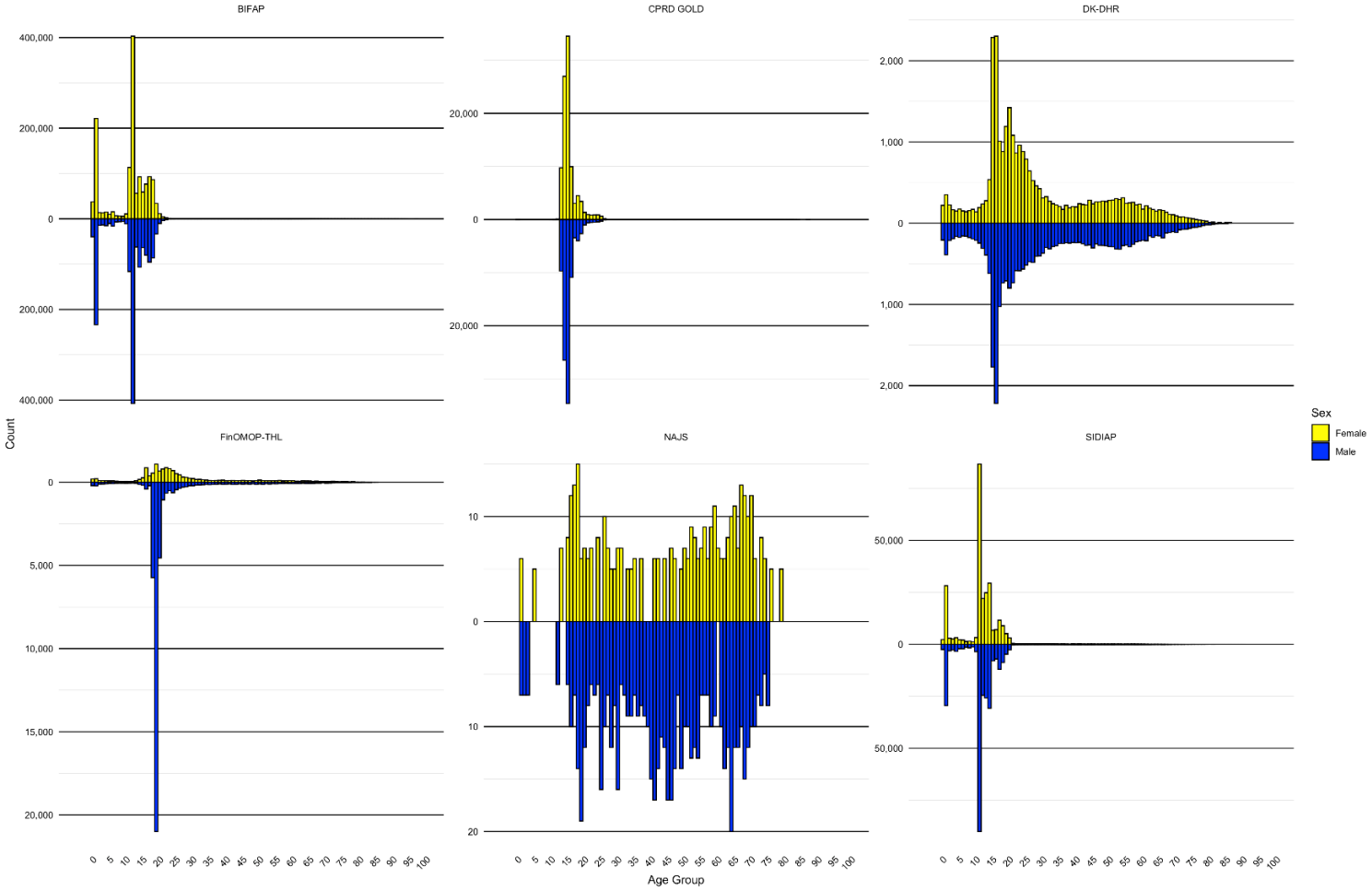

Figure 12. Age distribution of recipients of at least one dose of Meningococcal serogroup ACWY vaccines stratified by sex.

BIFAP = Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público, CPRD GOLD = Clinical Practice Research Datalink, DK-DHR = Danish Data Health Registries, FinOMOP-THL = Finnish Care Register for Health Care, NAJS = Croatian National Public Health Information System, SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària

9.4. Other analysis

Sensitivity analyses based on individuals without a complete history of follow-up showed a broadly lower coverage of distinct types of meningococcal vaccines. Nonetheless, vaccination coverage over time was consistent with trend reported in the main analysis in each of the data sources.

Separate sensitivity analyses on the coverage of MCV4 vaccines amongst individuals aged between 12 and 18 showed a higher coverage of MCV4, reaching 76.6% (95%CI: 76.5–76.7) in BIFAP in 2024 and 75.2% (95%CI: 75.0–75.2) in SIDIAP in 2023, suggesting the higher coverage of MCV4 when considering the younger cohort who are yet to reach 18 years of age.

The detailed results for all sensitivity analyses and analyses on the coverage of exact number of dose of separate type of meningococcal vaccines can be accessed through the Shiny app (EUPAS1000000675).

10. DISCUSSION

10.1. Key results

This study examined the temporal trend of coverage of separate types of meningococcal vaccines amongst the target population defined at country level. Countries with recommendations for separate types of meningococcal vaccines, including Spain and the UK, exhibited greater coverage amongst the target population compared to countries where meningococcal vaccines were not implemented as part of the routine immunisation schedule, including Croatia, Denmark, and Norway.

Regarding MenB vaccines, CPRD GOLD reported the highest overall coverage, with 98% in 2018 and 86% in 2019 of the target population receiving at least one and three doses of MenB vaccines, respectively. This was followed by a subsequent reduction in coverage in CPRD GOLD. In contrast, the coverage of MenB in BIFAP and SIDIAP showed an increasing trend over the course of the study period.

A high coverage for MenC was observed in CPRD GOLD, BIFAP, and SIDIAP in 2017, followed by a reduction in coverage over time, with a more substantial decrease observed in CPRD GOLD: from 98% in 2017 to 90% in 2024.

A gradual increase in MCV4 vaccines coverage from 36% to 65% was observed between 2017 and 2020, followed by a marginal reduction in coverage to 52% from 2022 to 2024 in CPRD GOLD. Conversely, a continuous increasing trend in vaccine coverage of 34% to 70% and 0.9% to 39% was observed in BIFAP and SIDIAP, respectively, from 2020 onward.

The vaccination record counts of MenB (Bexsero® and Trumenba®) and MCV4 (Menveo® and Nimenrix®) were lower compared to the record count of the non-brand specific form of these vaccines (i.e., serogroup composition but no brand name) examined within the same data source in CPRD GOLD, suggesting limited recording of vaccine brand. Therefore, findings on the coverage of specific vaccine brands should be interpreted with caution.

In addition, the majority of vaccine doses were administered within the recommended age range specific to each type of vaccine in UK and ES data sources: CPRD GOLD, BIFAP, and SIDIAP, with comparable distribution by sex. Conversely, the age of administration of meningococcal vaccines showed a broader range of age groups, including adults and older individuals, in countries with no universal administration: Denmark (DK-DHR), Finland (FinOMOP-THL), and Croatia (NAJS). In addition, recipients of MenC and MCV4 vaccines in FinOMOP-THL were predominantly male adults aged between 18 and 22.

10.2. Strengths and limitations of the research methods

The design of this study generated robust real-world evidence on the coverage of different meningococcal vaccines within their respective age-defined target populations. In contrast to available evidence that primarily reports vaccine coverage at national level, this study generates representative EU-wide findings which provide valuable insights into the implementation of national vaccination policies. Additionally, the study assessed changes in vaccine coverage potentially attributable to disruptions in healthcare services during the COVID-19 pandemic. Lastly, by providing data on exposure for meningococcal vaccines in DARWIN EU®, the results contribute valuable information to inform future studies on the effectiveness of meningococcal vaccines and the impact of meningococcal vaccination strategies.

The limited brand information for MenB (Bexsero® and Trumenba®) and MCV4 (Menveo® and Nimenrix®) in the included data sources likely results in the underestimation of coverage due to exposure misclassification related to missing records.

Furthermore, this study focused on the estimation of coverage amongst the target population in infants and adolescents as shown in the European Centre for Disease Prevention and Control (ECDC) vaccine scheduler. Therefore, coverage estimated in this study may not truly represent coverage across the entire data source or country. Vaccination coverage among at-risk populations specifically recommended in the vaccination policies in Finland, Denmark, and Croatia, where universal meningococcal vaccination is not implemented, was not examined. Lastly, vaccines administered outside of the settings recorded by the data sources in this study, for example private clinics, vaccination centres, and in schools, may not be readily captured by the data sources, resulting in the potential under-estimation of vaccination coverage.

10.3. Interpretation

The findings on MenB vaccine coverage from this study were largely consistent with the national statistics in the UK reporting a coverage for the initial dose of vaccine reaching over 90% of the target population at one year of age and the coverage for the booster dose reaching over 87% for the booster dose of MenB.[9] In line with the national statistics, a reduction in MenB vaccines coverage in the UK was observed over the coronavirus disease 2019 (COVID-19) pandemic period between 2019 and 2024. [9] The COVID-19 pandemic has resulted in social disruptions to routine immunisation across Europe, particularly in childhood immunisation, due to interruptions in vaccine supply chains, school closures, and the reallocation of healthcare personnel, thereby reducing opportunities for vaccine administration during the early phase of the pandemic.[10, 11] In addition, the increased vaccine hesitancy within the general public during and following the pandemic could have further contributed to the continuous reduction in coverage observed.[12, 13] As countries globally continue to transition to the endemic phase of COVID-19, the findings of this study emphasise the need for comprehensive catch-up vaccination strategies and strengthened immunisation infrastructure to mitigate the long-term public health impact of pandemic-related disruptions in childhood vaccination programmes. Vaccination campaigns aimed to increase vaccine confidence may also be considered to enhance the coverage of meningococcal vaccines within the community.

In contrast, our findings observe an increasing trend in MenB vaccines coverage in Spain. Such finding was largely consistent with a previous study reporting an increase in coverage in Madrid, with receipt of at least two doses increasing from 44% in 2016 to 68% in 2019. Meanwhile, the coverage of subsequent booster doses increased from 25% to 56% over the same period, demonstrating the increase in public acceptance of these vaccines in Spain.[14] Notably, the marked increase in coverage of separate doses of MenB observed in BIFAP in 2021 could be attributed to

increasing vaccination recording in the data source in a specific region rather than reflecting a surge in uptake of vaccines within the community.

Regional variation in MenB vaccine coverage between BIFAP and SIDIAP could reflect disparities in coverage across different areas of Spain, likely influenced by the availability of funding schemes for meningococcal vaccination across regions. It is noted that MenB vaccination has been funded publicly in certain regions encompassed by BIFAP since 2019, whereas such funding was not implemented in Catalonia, covered by SIDIAP, until 2022. In certain regions, families may be required to pay out-of-pocket for meningococcal vaccines that are not included in the regional immunisation calendar. Such differences in funding and implementation across countries may contribute to variability in vaccine uptake and coverage. In contrast, both MenB and MCV4 vaccines are fully funded and integrated into the routine immunisation schedule provided by the National Health Service (NHS) in the United Kingdom, which may explain the substantially higher coverage observed for these vaccines. Evidence from previous studies has consistently identified lower MenB coverage in socioeconomically deprived areas, reinforcing concerns on the inequity in vaccine access that may be influenced by the cost of vaccination. [1, 15]Going forward, countries across Europe may consider expanding subsidised programmes to reduce out-of-pocket costs of vaccination with coverage beyond infancy to allow catch-up opportunities for older children. Tailored health-promotion campaigns may also encourage vaccines uptake amongst the target children and adolescent population. These strategies have proven effective, as shown by significant increases in vaccine coverage following the introduction of regional funding schemes.[16]

Historically, MenC vaccine coverage has remained consistently high in countries with universal vaccination campaigns. Our data suggest coverage rates of 97–98% in both the UK and Spain. However, a decline in coverage has been observed in recent years. The national immunisation data from the UK have indicated a decrease in Hib/MenC vaccine coverage from over 92% in 2015 to 89% in 2024, consistent with the trends identified in our study.[9] In many European countries, including the UK and Spain, the monovalent MenC vaccine is being phased out gradually in favour of combination vaccines such as MCV4, with broader coverage against multiple disease-causing serogroups including A, C, W, and Y. [3, 17] This transition may have contributed to temporary gaps in coverage of both types of meningococcal vaccines. Accordingly, our study observed an increase in coverage of MCV4 in both BIFAP and SIDIAP data source from 2019, coinciding with the reduction in MenC coverage. Furthermore, the introduction of MCV4 into the routine immunisation schedule at 4 and 12 months of age, as well as in adolescents, prompted by rising incidence of serogroups W and Y in Spain following the COVID-19 pandemic could have further contributed to the reducing trend in coverage in MenC vaccination in the younger targeted age groups, as well as the increasing trend in MCV4 in Spain.[18] Despite the rising trend in MCV4 coverage, the level observed in this study remains below the national average in Spain, likely due to a considerable number of vaccinated individuals still at the “younger end” of the target age range hence not contributing to the analysis set of this study.[19] This is evident from the high distribution of MCV4 recipients and greater coverage observed in younger children and adolescent populations in SIDIAP and BIFAP. However, the variations in the timeline rollout and target populations for MCV4 across different regions in Spain could contribute to the differences in coverage and the trend in uptake between BIFAP and SIDIAP. This factor may also shed light on inter-country differences, including the higher coverage observed in the UK, where MenB and MCV4 were introduced earlier into the routine immunisation programme. [17] In Finland, military service is compulsory for men but voluntary for women, resulting in a markedly skewed gender distribution among conscripts. This population represents the largest single group eligible for free meningococcal vaccination under the Finnish National Vaccine Programme. Vaccines are administered within the conscription setting to mitigate the risk of IMD transmission, particularly given the heightened exposure associated with close living quarters. The

observed vaccination patterns among young adults, especially for MenC and MCV4, reflect this targeted approach and align with national programme guidelines. [20]

The findings of this study highlight the differences in trends in vaccination coverage across countries with different national vaccination programmes for meningococcal vaccines. From a global health standpoint, the epidemiology of dominant IMD-causing serogroups continues to evolve, with patterns varying across age groups and countries. This has led to the licensing and availability of vaccines targeting specific serogroups. Decisions to introduce or expand these vaccines should be taken with consideration of multiple factors, including population-level effectiveness, anticipated coverage and timeliness, local serogroup burden and outbreak risk, cost-effectiveness, and programme feasibility. Given the dynamic epidemiology of IMD across Europe, including rising trends in selected serogroups and the rapid expansion of hypervirulent clones, the implementation of primary immunisation and booster of MenB vaccination concomitantly with MCV4 early in life (i.e., in infancy) may offer a diverse coverage of IMD causing serogroups, serving as an effective strategy in reducing the incidence of IMD, as demonstrated by the effectiveness in the reduction of IMD cases through providing herd immunity modelled based on real-world evidence.[21]

10.4. Generalisability

This study examined the coverage of separate types of meningococcal vaccines across six European data sources and five countries. These data sourced from primary care records and linked health registries, representing diverse healthcare setting across countries with different recommendations for meningococcal vaccination. Findings generated from these data sources highlight the difference in vaccination coverage related to local/national campaigns and reimbursement policies across Europe. These findings also provide reliable evidence amongst the target population in children and adolescent in the countries examined and may serve as a basis for estimating coverage in countries with comparable vaccination policies and economic status.

Furthermore, vaccination coverage amongst the target paediatric and adolescent population may not accurately represent overall coverage within each country, due to differences in catch-up vaccination schedules and vaccination schemes for specific at-risk groups, which were not captured in this study.

11. CONCLUSION

This study examined the temporal trend in coverage of different meningococcal vaccines across five European countries. The data showed marked variations across countries with different immunisation recommendations. As expected, countries with universal vaccination during childhood (ES, UK) showed much higher and more consistent coverage than those without (DK, FI, HR).

Additionally, the results suggest an overall reduction in coverage of the different types of meningococcal vaccines in recent years in the UK, notably after the COVID-19 pandemic. Meanwhile, coverage with meningococcal vaccines continued to increase in Spain in the same period. More work is needed to fully understand the reasons for and the impact of the observed reduction in coverage in the UK.

By providing an overview of meningococcal vaccine exposure data in DARWIN EU®, these findings can inform future vaccine effectiveness studies and studies on the impact of meningococcal vaccination strategies, as specified in the research agenda of the EU vaccine monitoring platform.[22]

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13. ANNEXES

ANNEX I. Description of data sources

Croatian National Public Health Information System (NAJS)

#	Section	Description
1	Database Identification and country	NAJS (Croatian National Public Health Information System) Croatia
2	Data partner information section	Croatian Institute of Public Health Department of Data Science and Analytics
3	Coverage and timespan	Data collection since: 1998 Extent: Nation-wide. Geographic coverage covers whole Croatia, with various levels of resolution for different registries. Current estimates for the population in Croatia will be available at: https://podaci.dzs.hr/hr/podaci/stanovnistvo/procjena-stanovnistva/ for each year.
4	Healthcare setting / type of data	Primary care – gps, and secondary care – specialists (ambulatory or hospital outpatient care), and hospital inpatient care. For both inpatient and outpatient setting diagnoses, medication, procedures, and measurements are captured. Since 2025, also family relationshiops from the birth registry, histopathological data from the cancer registry, and vital signs from health risk assessment have been added. The year of availability of information depends on the setting: • 2014 for lab tests • 2015 for general practitioners • 2016 for secondary conciliatory care • 2017 for hospital records • 2020 for vaccination records
5	Data collection process	Inpatient hospital billing systems, and Other. Data is entered by clinicians at healthcare contact, then combined by CIPH into the NAJS database.
6	General representativeness	The data is collected from public health records, as the majority of health care in Croatia is public. Personal details are collected to a better extent for insured individuals compared to uninsured patients.
7	Data content /source coding	Medication prescriptions are recorded with ATC codes, and diagnoses with ICD10 codes.
8	Data Harmonization	The data has been mapped to the OMOP CDM v5.4 and the OMOP standard vocabularies (SNOMED, RxNorm, LOINC). The format, structural and semantic conformance has been verified upon onboarding into the DARWIN EU® data network. Records from 2017 include insured patients with reliable IDs. Uninsured patients do not have reliable IDs. For example, if a patient changed her status from insured to uninsured, or vice versa, she could be counted several times, as could tracking records from before 2017 and after. By using the unique personal identifier for Croatian citizens, it can be checked and verified.
9	Quality control (database specific)	There is a network of registry personnel (leaders, administrators, coders, sources) working on data coverage and other quality dimensions. An analytical team routinely checks for erroneous entries in hospital records, removing double entries, false dates, and overlapping stays. Entries without enough data or with obviously erroneous dates from primary care analysis are being excluded.
10	Linkage	The national death registry is updated monthly, and primary care is updated weekly. Specific registries are included in NAJS (e.g. diabetes registry), where inclusion criteria vary across these registries.

#	Section	Description
11	Vital status	NAJS is linked to the national death registry.
12	Limitations	Hospital data is available from 2017 onwards. This is often used as start of data collection, while laboratory and GP data is captured before that (since 2014 and 2015 respectively). The total and active person count in the NAJS data is larger than the current population of Croatia. This explained by a) the person table included deceased and all previously insured people and b) there is no information about insurance ending. It is known that a lot of people migrated (300k–400k) and weren't included in the last population census but still are in the NAJS database. In-hospital administrations are managed via paper drug charts and hospital discharge summaries are currently not captured into NAJS.
13	Main references	No main reference provided.
14	Link to HMA-EMA catalogue and database webpage	HMA-EMA Catalogue entry: https://catalogues.ema.europa.eu/data-source/1111155 Website: https://www.hzjz.hr/nacionalni-javnozdravstveni-informacijski-sustav-najs/

Danish Data Health Registries (DK-DHR)

#	Section	Description
1	Database Identification and country	DK-DHR (Danish Data Health Registries) Denmark
2	Data partner information section	Danish Medicines Agency (DKMA) Data Analytics Centre (DAC)
3	Coverage and timespan	Data collection since: 1995 Extent: Nation-wide. The data is representative of the entire Danish population.
4	Healthcare setting / type of data	Community pharmacists, and secondary care – specialists (ambulatory or hospital outpatient care), and hospital inpatient care. The following data elements are collected: diagnosis (including rare diseases and pregnancy data), hospital admissions, discharge and ICU data, Cause of death, Drug prescriptions, dispensing, vaccination and contraception, Procedures, Devices, and Sociodemographic information.
5	Data collection process	Outpatient electronic health records, and Inpatient hospital electronic health records, and Registries, and Other. All causes of deaths, all retrieved drug prescriptions, all records of vaccinations, all hospital inpatient and outpatients contacts including disease diagnoses and hospital surgical and non-surgical procedures, cancers, laboratory test results for the entire Danish population from 1/1/1995 onwards.
6	General representativeness	The data is representative of the entire Danish population. Healthcare is free in Denmark, so we do not expect any bias in data collection based on socio-economic status.
7	Data content /source coding	Diagnoses and causes of death are collected using the ICD-10 vocabulary. ATC and RxNorm are used for Drugs. SNOMED codes are used for Procedures.
8	Data Harmonization	The data has been mapped to the OMOP CDM v5.4 and the OMOP standard vocabularies (SNOMED, RxNorm, LOINC). The format, structural and semantic conformance has been verified upon onboarding into the DARWIN EU® data network. No.
9	Quality control (database specific)	The data we have received relating to nationwide Danish Health Data registries offer an opportunity for large-scale, population-based studies with several advantages 1) Their large size improves the precision of estimates and enables the study of rare exposures and

#	Section	Description
		outcomes with long-term latency, 2) Inclusion of nearly all individuals in the target population ensures that the data reflect routine clinical care and all clinical segments of the source population, 3) Data are collected independently of each research study, thus minimising certain types of bias, e.g., non-response, and the influence from attention to the research question on the diagnostic process. Before the source data is sent to us, the Danish Health Data Authority runs and does comprehensive checks of the registry table data validity of the variables, breaks in data, changes in variable coding, missingness, etc. We perform checks of missingness/completeness in relation to requested variables. In essence, we are receiving a dump of a mirror of the data that is controlled by the SDS. The documentation performed by SDS is available online, in Danish primarily https://www.esundhed.dk/Dokumentation (all variables), but also in English https://sundhedsdatastyrelsen.dk/da/english/health_data_and_registers/national_health_registers
10	Linkage	There is no linkage in this data source.
11	Vital status	The Cause of Death registry (DAR) is used, the cause of death is collected using ICD-10 codes.
12	Limitations	No database-specific limitations documented. General limitations for the data type applicable.
13	Main references	Schmidt M, Schmidt SAJ,Adelborg K,Sundbøll J,Laugesen K,Ehrenstein V,Sørensen HT "The Danish health care system and epidemiological research: from health care contacts to database records." Clinical epidemiology (2019): 31372058
14	Link to HMA-EMA catalogue and database webpage	HMA-EMA Catalogue entry: https://catalogues.ema.europa.eu/data-source/1111217 Website: https://sundhedsdatastyrelsen.dk/da/english/health_data_and_registers/healthdatadenmark

Finnish Care Register for Health Care (FinOMOP-THL)

#	Section	Description
1	Database Identification and country	FinOMOP-THL (Finnish Care Register for Health Care) Finland
2	Data partner information section	Finnish Institute for Health and Welfare (THL) Department of Knowledge Brokers
3	Coverage and timespan	Data collection since: 1998 Extent: Nation-wide. The current CDM population comprises all persons having been alive and residing in Finland since the beginning of 2011.
4	Healthcare setting / type of data	Primary care – gps, and primary care specialists (e.g. paediatricians), and secondary care – specialists (ambulatory or hospital outpatient care), and hospital inpatient care. The THL database covers both public and private, primary, and specialised inpatient and outpatient health care encounters in Finland, starting from 2011. The entire public sector and private inpatient encounters have been included since 2011, while private outpatient encounters, including occupational care, are included since 2020. Since 1998, the register has covered both public outpatient and inpatient specialized care and private inpatient care (TerveysHilmo). Since 2009, the Finnish National Vaccination Register is covered (complete since 2020). The vaccination register covers all vaccinations from the public sector and from a large part of private vaccination providers, with the data coverage from both sections being very good from 2020 onwards. Since 2011, the register has covered public primary care (AvoHilmo).

#	Section	Description
		Since 2020, the register has covered private outpatient care and occupational care. In addition, the CDM also contains positive COVID-19 test results from the Finnish National Infectious Diseases Register, which is maintained by THL.
5	Data collection process	Outpatient electronic health records, and Inpatient hospital electronic health records, and Registries. Data is entered by clinicians upon healthcare contact and processed by THL.
6	General representativeness	The THL data has national coverage and is therefore well representative of the Finnish population. Using the complete population as a basis for the person table also serves to facilitate calculations on a population level, e.g. incidence rates.
7	Data content /source coding	The following coding systems have been OMOP-mapped, typically to a good level of completeness: ICD10fi Finnish Extension, ATC, Toimenpideluokitus (procedure classification adapted from the Nordic Classification of Surgical Procedures (NCSP)), Terveydenhuollon erikoisalat (Hilmo specific provider speciality), Rokotustapa (AR/YDIN National classification for vaccine administration), Tupakointistatus (AR/YDIN National classification for smoking status). Vaccinations are identified on product level based on batch number, trade name, vaccine title, and ATC-code. This is mapped on brand and type in the OMOP CDM.
8	Data Harmonization	The data has been mapped to the OMOP CDM v5.4 and the OMOP standard vocabularies (SNOMED, RxNorm, LOINC). The format, structural and semantic conformance has been verified upon onboarding into the DARWIN EU® data network. Each patient in THL has a unique identifier.
9	Quality control (database specific)	The source data collection undergoes a structural and semantic validation before entry into the source database. Additionally, some coded variables undergo quality assessment against the respective code systems post entry into the database. The source registers are also assessed for completeness and coverage, with the aim of improving future collection in the areas where data is lacking.
10	Linkage	THL is already a linkage of multiple Finnish registries (see above).
11	Vital status	The National Population registry data forms the basis for forming the patient population. This ensures an up-to-date location (municipality of residence) of patients, as well as complete death occurrences (although not the cause of death).
12	Limitations	No database-specific limitations documented. General limitations for the data type applicable.
13	Main references	Häkkinen, Pirjo; Mölläri, Kaisa; Saukkonen, Sanna-Mari; Väyrynen, Riikka; Mielikäinen, Lasse; Järvelin, Jutta "Hilmo - Sosiaali- ja terveydenhuollon hoitoilmoitus 2020 : Määrittelyt ja ohjeistus : Voimassa 1.1.2020 alkaen" Terveyden ja hyvinvoinnin laitos (2019):
14	Link to HMA-EMA catalogue and database webpage	HMA-EMA Catalogue entry: https://catalogues.ema.europa.eu/data-source/1111187 Website: https://thl.fi/fi/tilastot-ja-data/ohjeet-tietojen-toimittamiseen/hoitoilmoitusjarjestelma-hilmo

Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (BIFAP)

#	Section	Description
1	Database Identification and country	BIFAP (Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)) Spain
2	Data partner information section	AEMPS Pharmacoepidemiology and Pharmacovigilance Division - Medicines for human use Department

#	Section	Description
3	Coverage and timespan	Data collection since: 2001 Extent: Regional. Spanish National Health Service (SNS) from 9 of the 17 regions in Spain. The population currently included represents 36% of the total Spanish population.
4	Healthcare setting / type of data	Primary care – gps, and community pharmacists, and primary care specialists (e.g. paediatricians), and hospital inpatient care. BIFAP includes a collection of databases linked at individual patient level. The main one is the Primary care Database, given the central role of PCPs in the SNS. Linked, there are additional important structural databases, like the medicines dispensed at community pharmacies and the patients' hospital diagnosis at discharge. 7 out of the 9 regions have linkage to hospital data. However, hospital data is available for different time periods for each region. From 2014 onwards, linkage to hospital data is available for >68% of patients.
5	Data collection process	Insurance/administrative claims, and Outpatient electronic health records, and Inpatient hospital electronic health records, and Registries. Data in BIFAP is collected from Primary Care and Hospital EHR.
6	General representativeness	Spain has a SNS that provides universal access to health services through the Regional Healthcare Services. Primary care physicians (PCPs), both general practitioners and paediatricians, have a central role. They act as gatekeepers of the system and exchange information with other levels of care to ensure the continuity of care. Most of the population (98.9%) is registered with a PCP and, in addition, most drug prescriptions are written at the primary care level.
7	Data content /source coding	The BIFAP source data is coded in SNOMED, ICD, ICPC-2 (diagnoses), AEMPS (drugs), and local lab codes.
8	Data Harmonization	The data has been mapped to the OMOP CDM v5.4 and the OMOP standard vocabularies (SNOMED, RxNorm, LOINC). The format, structural and semantic conformance has been verified upon onboarding into the DARWIN EU® data network. Pseudonymized ID numbers are generated at regional level. The Personal Identification Code for the Autonomous Community (CIPA) is used to perform the pseudonymisation procedure. Therefore, upon changing practice or de- and re-registration within the same region, (Autonomous Community) the patient in BIFAP is correctly identified as the same person with the same ID number. However, the same patient would obtain different ID numbers if the patient moves to a different region and is registered in a primary care practice in the new region. The percentage of people who are de-registered due to moving to other region in relation to the BIFAP population is, for example, 5% in Madrid and 4% Castilla y Leon. This situation would have a very limited impact on the data analysis due to the following: - The proportion is low (less than 5%) in relation to the overall population in BIFAP. - In BIFAP, only stable residents are included. This means that patients living in another region for a foreseen short time period and are provisionally assigned to a primary care practice are not included in BIFAP. - Medical events of those patients who have more than one ID do not overlap in time, since dates of events correspond to different periods. This means that counts of these events are never duplicated. - A number of study designs allows the same patient to be part of different cohorts or to be selected both as case and as control, provided that their person-time experience correspond to a different period of time. In all these cases, the impact in study analysis of duplicated IDs would be negligible.
9	Quality control (database specific)	Patients who meet any of the following disability criteria are discarded: - Non-owners of the individual health card - Date of birth before 01/01/1801 - Active patients over 115 years of age - Patients without clinical records (only contains administrative information) - Patients marked as "fictitious" in the clinical history - Badly coded sex

#	Section	Description
		- Inactive without termination date - Start date = End date - Clinical records prior to date of birth
10	Linkage	The following data are also linked at individual patient level and available. For a subset of the BIFAP population (regions and/or periods of time): • Information on dispensation of medicines at hospital pharmacies from outpatients and inpatients. • Registration of Causes of Death by the National Institute for Statistics. From the start of the COVID-19 pandemic: • Vaccines COVID-19 Administration Registry linked to patients included in BIFAP. • Diagnosis Tests of COVID-19 linked to patients included in BIFAP, for some regions.
11	Vital status	Source for vital status unknown.
12	Limitations	Primary care is available from 2001, but is considered complete since 2005. Hospital discharge has different coverage periods per region Spain, with most starting between 2014–2016. This means that for different regions and different time periods there is a different coverage of healthcare events. In the release of July 2025, the laboratory results are not covered. These will be added again at the next release, expected at the end of 2025.
13	Main references	Maciá-Martínez MA, Gil M,Huerta C,Martín-Merino E,Álvarez A,Bryant V,Montero D "Base de Datos para la Investigación Farmacoepidemiológica en Atención Primaria (BIFAP): A data resource for pharmacoepidemiology in Spain." Pharmacoepidemiology and drug safety (2020): 32337840
14	Link to HMA-EMA catalogue and database webpage	HMA-EMA Catalogue entry: https://catalogues.ema.europa.eu/data-source/21501 Website: http://www.bifap.org/index_EN.html

The Information System for the Development of Research in Primary Care (SIDIAP)

#	Section	Description
1	Database Identification and country	SIDIAP (The Information System for the Development of Research in Primary Care) Catalunya, Spain
2	Data partner information section	IDIAPJGol
3	Coverage and timespan	Data collection since: 2006 Extent: Regional. The SIDIAP database contains records of around 6 million people residing in Catalonia, estimated to be representing around 76% of the Catalan population.
4	Healthcare setting / type of data	Primary care – gps, and hospital inpatient care. SIDIAP captured data includes routine visits, demographics, diagnoses, laboratory tests, drugs (prescribed and dispensed), referrals, and lifestyle information.
5	Data collection process	Outpatient electronic health records, and Inpatient hospital electronic health records, and Other. Data is entered by primary care physicians upon healthcare contact, supplemented with hospital discharge records. The Institut Catala de la Salut is the owner of the data and acts as the data controller.
6	General representativeness	It was previously shown that the captured SIDIAP population is highly representative of the entire Catalan region in terms of geographic, age, and sex distributions.
7	Data content /source coding	SIDIAP data covers all services that occur at the Primary Care Centres, as well as support services, such as sexual and reproductive health or home end-of-life care.

#	Section	Description
		Drugs are coded in ATC-WHO terminology in the source data. Health outcomes are captured in ICD-10CM codes. The SIDIAP contains all laboratory tests and results performed in primary health centres. Demographics, geographical, as well as socio-economic factors are recorded for each patient.
8	Data Harmonization	The data has been mapped to the OMOP CDM v5.4 and the OMOP standard vocabularies (SNOMED, RxNorm, LOINC). The format, structural and semantic conformance has been verified upon onboarding into the DARWIN EU® data network. No.
9	Quality control (database specific)	Internal and external validation processes are carried out to determine the data quality of the SIDIAP information at each data update. These include stratifying the data by geographical regions and year in order to identify differences in data collection that need to be harmonized (e.g. recording of specific information under different codes). The measurement units of variables measuring one characteristic are also homogenized (e.g. transformation of the data from every laboratory that measures haemoglobin to grams per decilitre). Visual inspection of all data included in the database by week is also conducted, allowing one to see temporal patterns in the registry of a certain variable. With this information, the SIDIAP team can issue recommendations to researchers about the most common variable(s) where certain information is recorded (e.g., there are several variables with information concerning the women's menopausal status and with these visual inspection tools the SIDIAP team can inform the researchers about which related variables have the largest number of records and could be more helpful to capture menopause). Data availability (longitudinally and reliability), plausibility (range checks and unusual values), and consistency are inspected through visualisation tools. In addition, before accessing the data for a requested project, research teams have access to a quality-control report. This document contains counts, years, percentiles, maximums and minimums, incidences, and prevalence of the data requested for the project, allowing detection of inconsistencies in the data extraction prior to data delivery. External validation processes of the SIDIAP database mainly include assessing the data recorded in SIDIAP through linkage to external gold standard data sources, by analysing free text, or by sending questionnaires to health professionals.
10	Linkage	SIDIAP is linked to a hospital discharge database, pharmacy dispensation, and primary care laboratories. It can also be linked to other registries in Catalonia on a project by project basis.
11	Vital status	Mortality is fully captured in SIDIAP. The cause of death is not available, but can be linked to the Spanish death registry on a project by project basis.
12	Limitations	The SIDIAP data is not representative of individuals not using public primary care, and conditions that are usually followed by specialist care might not be properly captured. In addition, there is limited information on lifestyle variables. Patients are followed until Death or when transferring to another primary health care centre that does not contribute to SIDIAP.
13	Main references	Recalde M, Rodríguez C,Burn E,Far M,García D,Carrere-Molina J,Benítez M,Moleras A,Pistillo A,Bolíbar B,Aragón M,Duarte-Salles T "Data Resource Profile: The Information System for Research in Primary Care (SIDIAP)." International journal of epidemiology (2022): 35415748
14	Link to HMA-EMA catalogue and database webpage	HMA-EMA Catalogue entry: https://catalogues.ema.europa.eu/data-source/50190 Website: https://www.sidiap.org/index.php/en

CPRD GOLD(Clinical Practice Research Datalink GOLD)

#	Section	Description
1	Database Identification and country	CPRD GOLD (Clinical Practice Research Datalink GOLD) United Kingdom
2	Data partner information section	University of Oxford NDORMS
3	Coverage and timespan	Data collection since: 1987 Extent: Nation-wide. CPRD GOLD consists of patients in contributing practices using Vision software. Historically this covered the whole of the UK, but the number of contributing practices in the England is dropping. In January 2025 only 3 practices from England were a part of CPRD GOLD, while historical patient data were from the whole of the UK, and will continue to be so. In the future, no practices from England will be present, only practices from Scotland, Wales, and Northern Ireland.
4	Healthcare setting / type of data	Primary care – gps, and primary care specialists (e.g. paediatricians), and secondary care – specialists (ambulatory or hospital outpatient care), and hospital inpatient care. CPRD GOLD data include patient demographics, biological measurements, clinical symptoms and diagnoses, referrals to specialist/hospital and their outcome, laboratory tests/results, and prescribed medications.
5	Data collection process	Outpatient electronic health records. Data is entered by clinicians into the EHR. Data is processed by CPRD and provides data releases for research.
6	General representativeness	CPRD GOLD has been assessed and found to be broadly representative of the UK general population in terms of age, gender, and ethnicity. In CPRD GOLD in January 2025 there were 2,730,707 current acceptable patients (i.e. registered at currently contributing practices that use Vision software, excluding transferred out, deceased patients, and those flagged by CPRD as not acceptable for clinical research for data quality issues). This equals to 4.07%, based on the UK population estimates of 67,026,300 from the Office of National Statistics (mid-2023). Current patients are only from Scotland, Wales, and Northern Ireland. Historically, GOLD does contain data from England as well.
7	Data content /source coding	Gemscript, Read, dm+d
8	Data Harmonization	The data has been mapped to the OMOP CDM v5.4 and the OMOP standard vocabularies (SNOMED, RxNorm, LOINC). The format, structural and semantic conformance has been verified upon onboarding into the DARWIN EU® data network. In GOLD, a patient can be registered under different ID numbers upon changing practice or re-registration. Researchers are not able to identify these patients, as the data are anonymised. However, GOLD covers less than 5% of the current UK GP practices and it is unlikely that an individual who does change GP practice ends up in another GP practice which uses the Vision software and accepts the CPRD data collection agreement. The very small number of duplicated IDs will have different observation periods and should not have an impact on the data analyses.
9	Quality control (database specific)	CPRD GOLD only includes practices whose data quality is assessed to be up-to-standard (uts). Each practice is associated to an uts date set when the data quality standards become satisfactory, and CPRD recommend using only longitudinal data starting from this uts date. Every time CPRD collect the EHR from a practice, checks are run for the data quality standards and if they are not adequate, the EHR is not accepted. When the data quality becomes acceptable again, CPRD updates the practice uts date. CPRD also check data quality standards at the patient level and associate each patient to a flag, reporting if its data is acceptable for clinical research. Only patients with acceptable data quality are included in the population to be mapped to CDM.

#	Section	Description
10	Linkage	CPRD GOLD can be linked to several sources, however our Oxford OMOP CDM is only linked to the CPRD GOLD Ethnicity Record and to the CPRD Townsend Deprivation Index at Practice Level
11	Vital status	Vital status is retrieved from the GP records. Population registry (ONS) data can be requested on a study-by-study basis and linked. This data only covers England and is planned to be mapped to OMOP in the future. The cause of death is not captured.
12	Limitations	The main limitation is due to the fact that CPRD GOLD is limited to GP records, and although it contains information on referrals and discharge letters, it may not fully capture specific hospital information. Events from hospital and specialist care are not covered.
13	Main references	Sanchez-Santos MT, Axson EL,Dedman D,Delmestri A "Data Resource Profile Update: CPRD GOLD." International journal of epidemiology (2025): 40499193
14	Link to HMA-EMA catalogue and database webpage	HMA-EMA Catalogue entry: https://catalogues.ema.europa.eu/data-source/1111113 Website: https://cprd.com

ANNEX II. Fitness for use assessment

Data source justification for inclusion and key characteristics

A formal fitness for use assessment for individual data source was not conducted as part of the implementation stage of this study, as the study protocol was prepared and approved prior to the implementation of this procedure. Consequently, detailed documentation of the fitness assessment for separate data source were unavailable. Nonetheless, a brief discussion outlining the rationale behind the selection of each data source included in this study has been provided below.

Croatian National Public Health Information System (NAJS)

NAJS will be included in this study because it is a claims data source that provides relevant information on meningococcal vaccination record in the general population.

Based on a preliminary feasibility assessment, the expected number of person counts for meningococcal vaccination record (All objectives) in NAJS will be 244,200.

Moreover, data availability and follow-up in NAJS is sufficient, as data availability starts in 1998 (2020 for vaccination records), and the date of most recent data extraction is 07/08/2024, which aligns with the study period. The median follow-up of the first observation period in NAJS is 3.84k (3.31k-3.93k) days.

There are some study specific limitations present in NAJS, namely due to the potential unavailability of data on the specific brand of meningococcal vaccines from the data source, objective 4 of this study will not be conducted on this data source.

Lastly, NAJS has blanket approval, which makes the execution of this study feasible within the current study timelines.

Danish Data Health Registries (DK-DHR)

DK-DHR will be included in this study because it is a registries data source that provides relevant information on meningococcal vaccination record in the general population.

Based on a preliminary feasibility assessment, the expected number of person counts for meningococcal vaccination record (All objectives) in DK-DHR will be 26,100.

Moreover, data availability and follow-up in DK-DHR is sufficient, as data availability starts in 1995, and the date of most recent data extraction is 19/02/2025, which aligns with the study period. The median follow-up of the first observation period in DK-DHR is 7.92k (2.61k-10.9k) days.

There are some study specific limitations present in DK-DHR, namely due to the potential unavailability of data on the specific brand of meningococcal vaccines from the data source, objective 4 of this study will not be conducted on this data source.

Lastly, DK-DHR has blanket approval, which makes the execution of this study feasible within the current study timelines.

Finnish Care Register for Health Care (FinOMOP-THL)

FinOMOP-THL will be included in this study because it is a primary, secondary care electronic health records and registries data source that provides relevant information on meningococcal vaccination record in the general population.

Based on a preliminary feasibility assessment, the expected number of person counts for meningococcal vaccination record (All objectives) in FinOMOP-THL will be 4,200.

Moreover, data availability and follow-up in FinOMOP-THL is sufficient, as data availability starts in 2011, and the date of most recent data extraction is 24/06/2024, which aligns with the study period. The median follow-up of the first observation period in FinOMOP-THL is 5.02k (4.03k-5.02k) days.

There are some study specific limitations present in FinOMOP-THL, namely due to the potential unavailability of data on the specific brand of meningococcal vaccines from the data source, objective 4 of this study will not be conducted on this data source.

Lastly, FinOMOP-THL has blanket approval which makes the execution of this study feasible within the current study timelines.

Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (BIFAP)

BIFAP will be included in this study because it is a primary care electronic health records data source that provides relevant information on meningococcal vaccination record in the general population.

Based on a preliminary feasibility assessment, the expected number of person counts for meningococcal vaccination record (All objectives) in BIFAP will be 2.64M.

Moreover, data availability and follow-up in BIFAP is sufficient, as data availability starts in 2001, and the date of most recent data extraction is 01/10/2024, which aligns with the study period. The median follow-up of the first observation period in BIFAP is 2.55k (2.05k–5.43k) days.

There are some study specific limitations present in BIFAP, namely due to the potential unavailability of data on the specific brand of meningococcal vaccines from the data source, objective 4 of this study will not be conducted on this data source.

Lastly, IRB approval for BIFAP is estimated to take 1–3 months, which makes the execution of this study feasible within the current study timelines.

The Information System for the Development of Research in Primary Care (SIDIAP)

SIDIAP will be included in this study because it is a primary care electronic health records and registries data source that provides relevant information on meningococcal vaccination record in the general population.

Based on a preliminary feasibility assessment, the expected number of person counts for meningococcal vaccination record (All objectives) in SIDIAP will be 2.30M.

Moreover, data availability and follow-up in SIDIAP is sufficient, as data availability starts in 2005, and the date of most recent data extraction is 30/06/2023, which aligns with the study period. The median follow-up of the first observation period in SIDIAP is 5.67k (2.22k–6.39k) days.

There are some study specific limitations present in SIDIAP, namely due to the potential unavailability of data on the specific brand of meningococcal vaccines from the data source, objective 4 of this study will not be conducted on this data source.

Lastly, IRB approval for SIDIAP is estimated to take 1–3 months, which makes the execution of this study feasible within the current study timelines.

Clinical Practice Research Datalink GOLD (CPRD GOLD)

CPRD GOLD will be included in this study because it is a primary care electronic health records data source that provides relevant information on meningococcal vaccination record in the general population.

Based on a preliminary feasibility assessment, the expected number of person counts for meningococcal vaccination record (All objectives) in CPRD GOLD will be 2.59M.

Moreover, data availability and follow-up in CPRD GOLDis sufficient, as data availability CPRD GOLD starts in 1987, and the date of most recent data extraction is 12/12/2024, which aligns with the study period. The median follow-up of the first observation period in CPRD GOLDis 2.15k (727–4.93k) days.

There are no study specific limitations present in CPRD GOLD.

Lastly, IRB approval for CPRD GOLDis estimated to take 1–3 months, which makes the execution of this study feasible within the current study timelines.

ANNEX III. Operational and reporting considerations

DATA MANAGEMENT

Data management

All data sources have previously mapped their data to the OMOP common data model. This enabled the use of standardised analytics and using DARWIN EU® tools across the network since the structure of the data and the terminology system was harmonised. The OMOP CDM was developed and maintained by the Observational Health Data Sciences and Informatics (OHDSI) initiative and is described in detail on the wiki page of the CDM: https://ohdsi.github.io/CommonDataModel and in The Book of OHDSI: http://book.ohdsi.org

The analytic code for this study was written in R and used standardized analytics wherever possible. Each data partner executed the study code against their data source containing individual data and then returned the results (csv files) which only contained aggregated data. The results from each of the contributing data sites were then combined in tables and figures for the study report.

Data storage and protection

For this study, personal data from individuals in various EU member states were processed, using information collected from national/regional electronic health record data sources. Due to the sensitive nature of this personal medical data, it is important to be fully aware of ethical and regulatory aspects and to strive to take all reasonable measures to ensure compliance with ethical and regulatory issues on privacy.

All data sources used in this study were already used for pharmaco-epidemiological research and have a well-developed mechanism to ensure that European and local regulations dealing with ethical use of the data and adequate privacy control were adhered to. In agreement with these regulations, rather than combining person level data and performing only a central analysis, local analyses were run, which generate non-identifiable aggregate summary results.

QUALITY CONTROL

Data source quality control

When defining drug cohorts, non-systemic products will be excluded from the list of included codes summarised on the ingredient level.

When defining cohorts for indications, a systematic search of possible codes for inclusion will be identified using the *CodelistGenerator* R package (https://github.com/darwin-eu/CodelistGenerator). This package allows the user to define a search strategy and will use this to query the vocabulary tables of the OMOP common data model so as to find potentially relevant codes. In addition, the *CohortDiagnostics* (https://github.com/OHDSI/CohortDiagnostics) R packages will be run, if needed, to assess the use of different codes across the data sources contributing to the study and identify any codes potentially omitted in error.

The study code will be based on DARWIN EU® R packages: *IncidencePrevalence* to estimate Incidence and Prevalence, and *CohortCharacteristics* to characterise the cohort by indication. These packages will include numerous automated unit tests to ensure the validity of the codes, alongside software peer review and user testing. The R package will be made publicly available via GitHub.

ANNEX IV: List of stand-alone documents

Table S1. Preliminary code list for Meningococcal serogroup B vaccines (MenB).

Concept name	Concept ID	Domain	Vocabulary
meningococcal group B vaccine Injectable Suspension	36272005	Drug Exposure	RxNorm Extension
meningococcal group B vaccine Injectable Suspension [Bexsero]	36277147	Drug Exposure	RxNorm Extension
meningococcal group B vaccine Injectable Solution [Bexsero]	36405016	Drug Exposure	RxNorm Extension
meningococcal group B vaccine Injectable Suspension [Trumenba]	36810838	Drug Exposure	RxNorm Extension
meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine Injectable Suspension	40745348	Drug Exposure	RxNorm Extension
meningococcal group B vaccine / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) Injectable Suspension	44055776	Drug Exposure	RxNorm Extension
0.1 ML Influenza A virus vaccine, A-Texas-50-2012 (H3N2)-like virus 0.15 MG/ML / influenza A-California-7-2009-(H1N1)v-like virus vaccine 0.15 MG/ML / meningococcal group B vaccine 0.15 MG/ML Injectable Suspension	44132429	Drug Exposure	RxNorm Extension
meningococcal group B vaccine	45775636	Drug Exposure	RxNorm
meningococcal group B vaccine Prefilled Syringe	45775639	Drug Exposure	RxNorm
meningococcal group B vaccine Prefilled Syringe [Trumenba]	45775643	Drug Exposure	RxNorm
0.5 ML Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01	45775644	Drug Exposure	RxNorm

Concept name	Concept ID	Domain	Vocabulary
protein variant antigen 0.12 MG/ML Prefilled Syringe [Trumenba]			
meningococcal group B vaccine Prefilled Syringe [Bexsero]	45892098	Drug Exposure	RxNorm
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant FHBP fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant NHBA fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogr...	45892099	Drug Exposure	RxNorm
Administration of meningitis B vaccine	36715063	Procedure	SNOMED
Booster meningitis B vaccination	37394691	Procedure	SNOMED
First meningitis B vaccination	46284905	Procedure	SNOMED
Second meningitis B vaccination	46287032	Procedure	SNOMED
Third meningitis B vaccination	46284906	Procedure	SNOMED
Fourth meningitis B vaccination	46284907	Procedure	SNOMED
0.5 ML meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension [Bexsero]	35414612	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [Boostrix]	36281011	Drug	RxNorm Extension
meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML [Bexsero]	44067190	Drug	RxNorm Extension
meningococcal group B vaccine 0.03 MG/ML	44091734	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension [Bexsero]	35406900	Drug	RxNorm Extension
meningococcal group B vaccine 0.2 MG/ML	35411056	Drug	RxNorm Extension
meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [Boostrix]	36267567	Drug	RxNorm Extension
meningococcal group B vaccine / Neisseria meningitidis Group B Membrane vesicles External Omv / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B Injectable Suspension	43189720	Drug	RxNorm Extension
meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML [Bexsero]	35408055	Drug	RxNorm Extension
meningococcal group B vaccine 0.15 MG/ML	44117588	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension [Bexsero] Box of 1	35414625	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1 by Orifarm Leverkus	44197172	Drug	RxNorm Extension
meningococcal group B vaccine 0.3 MG/ML Injectable Suspension	36277400	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant FHBP fusion protein antigen 0.1 M	45892095	Drug	RxNorm

Concept name	Concept ID	Domain	Vocabulary
G/ML / Neisseria meningitidis serogroup B recombinant NHBA fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogr...			
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant FHBP fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant NHBA fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogr...	45892095	Drug	RxNorm
meningococcal group B vaccine / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) Injectable Suspension [Bexsero]	44108372	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML Injectable Suspension [Bexsero]	44132794	Drug	RxNorm Extension
meningococcal group B vaccine / Neisseria meningitidis Group B Membrane vesicles External Omv / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B Injectable Suspension [Bexsero]	35411236	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension Box of 1	35414559	Drug	RxNorm Extension
meningococcal group B vaccine Injectable Solution	36405729	Drug	RxNorm Extension
meningococcal group B vaccine Injectable Suspension	36272005	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML Injectable Suspension	44123073	Drug	RxNorm Extension
meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension Box of 1	35411322	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension	35414651	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.3 MG/ML Injectable Suspension	36281092	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [Boostrix] by GSK	36281200	Drug	RxNorm Extension
meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension	35409014	Drug	RxNorm Extension
meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension [Bexsero] Box of 1	35409987	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
0.5 ML meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / ... Injectable Suspension [Bexsero] Box of 1 by Novartis	35414646	Drug	RxNorm Extension
meningococcal group B vaccine 0.3 MG/ML	36264077	Drug	RxNorm Extension
meningococcal group B vaccine 0.3 MG/ML [Boostrix]	36274314	Drug	RxNorm Extension
meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [Bexsero]	36275190	Drug	RxNorm Extension
meningococcal group B vaccine 0.1 MG/ML	45892091	Drug	RxNorm
meningococcal group B vaccine Prefilled Syringe [Bexsero]	45892098	Drug	RxNorm
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant FHBP fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant NHBA fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogr...	45892099	Drug	RxNorm
meningococcal group B vaccine 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant FHBP fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant NHBA fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B s...	45892100	Drug	RxNorm
meningococcal group B vaccine 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant FHBP fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant	45892101	Drug	RxNorm

Concept name	Concept ID	Domain	Vocabulary
NHBA fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B s...			
meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine Injectable Suspension [Bexsero]	40745347	Drug	RxNorm Extension
meningococcal group B vaccine Injectable Suspension [Trumenba]	36810838	Drug	RxNorm Extension
meningococcal group B vaccine 0.09 MG/ML	44078776	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML Injectable Suspension	44132650	Drug	RxNorm Extension
meningococcal group B vaccine 0.3 MG/ML [Bexsero]	36271732	Drug	RxNorm Extension
meningococcal group B vaccine Prefilled Syringe	45775639	Drug	RxNorm
meningococcal group B vaccine 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant FHBP fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B recombinant NHBA fusion protein antigen 0.1 MG/ML / Neisseria meningitidis serogroup B s...	45892097	Drug	RxNorm
meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine Injectable Suspension	40745348	Drug	RxNorm Extension
meningococcal group B vaccine / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) Injectable Suspension [Trumenba]	40745346	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
meningococcal group B vaccine / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) Injectable Suspension	44055776	Drug	RxNorm Extension
meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML Injectable Suspension [Bexsero]	44111622	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML Injectable Suspension [Bexsero] by Glaxosmithkline	44132814	Drug	RxNorm Extension
meningococcal group B vaccine Injectable Suspension [Boostrix]	36274617	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [Bexsero] by GSK	36281177	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [Bexsero]	36281212	Drug	RxNorm Extension
Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML Prefilled Syringe	45775645	Drug	RxNorm
Neisseria meningitidis serogroup B recombinant NHBA fusion protein antigen 0.1 MG/ML	45892093	Drug	RxNorm
Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML	45775637	Drug	RxNorm
Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML	45775638	Drug	RxNorm

Concept name	Concept ID	Domain	Vocabulary
Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML Prefilled Syringe [Trumenba]	45775646	Drug	RxNorm
meningococcal group B vaccine Injectable Product	36248612	Drug	RxNorm
0.5 ML Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML Prefilled Syringe	45775640	Drug	RxNorm
0.5 ML Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML Prefilled Syringe [Trumenba]	45775644	Drug	RxNorm
Neisseria meningitidis serogroup B strain NZ98/254 outer membrane vesicle 0.05 MG/ML	45892094	Drug	RxNorm
Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML [Trumenba]	45775642	Drug	RxNorm
Neisseria meningitidis serogroup B recombinant FHBP fusion protein antigen 0.1 MG/ML	45892092	Drug	RxNorm
Bexsero Injectable Product	36248757	Drug	RxNorm
Trumenba Injectable Product	36248645	Drug	RxNorm
meningococcal B, unspecified formulation	40213175	Drug	CVX

Concept name	Concept ID	Domain	Vocabulary
meningococcal B vaccine, recombinant, OMV, adjuvanted	40213173	Drug	CVX
meningococcal B vaccine, fully recombinant	40213174	Drug	CVX
meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine Injectable Suspension	40745348	Drug	RxNorm Extension

Table S2. Preliminary code list for Meningococcal serogroup C vaccines (MenC) or combined Haemophilus influenzae type b/Meningococcal serogroup C (Hib/MenC).

Concept name	Concept ID	Domain	Vocabulary
Meningococcal group C polysaccharide	509081	Drug Exposure	RxNorm
Haemophilus B Conjugate Vaccine / meningococcal group C polysaccharide Injectable Solution	40731787	Drug Exposure	RxNorm Extension
meningococcal group C polysaccharide Injectable Solution [Meningitec]	40987113	Drug Exposure	RxNorm Extension
meningococcal group C polysaccharide Injectable Suspension [Neisvac C]	41018101	Drug Exposure	RxNorm Extension
meningococcal group C polysaccharide Injectable Solution	41079916	Drug Exposure	RxNorm Extension
meningococcal group C polysaccharide Injectable Suspension [Menjugate]	43643018	Drug Exposure	RxNorm Extension
meningococcal group C polysaccharide Injectable Suspension [Meningitec]	43768802	Drug Exposure	RxNorm Extension
meningococcal group C polysaccharide Injectable Suspension	43840964	Drug Exposure	RxNorm Extension
Administration of first dose of meningitis C vaccine	4197151	Procedure	SNOMED
Administration of meningitis C vaccine	36714392	Procedure	SNOMED
Administration of single dose of meningitis C vaccine	4199650	Procedure	SNOMED
meningococcal group C polysaccharide / tetanus toxoid vaccine, inactivated Injectable Suspension [Neisvac C]	44056939	Drug Exposure	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1 by Kohlpharma	44197087	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 10 by European	44197088	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menj	44197229	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
ugate] Box of 1 by Emra-Med			
meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension	43714860	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension Box of 5	43612171	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate] by Glaxosmithkline	43594210	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate] Box of 5	43791957	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution [Menjugate] Box of 10 by Novartis	41407699	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe [Meningitec] Box of 1	41408975	Drug	RxNorm Extension
0.5 ML Meningitis vaccine 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1	41409709	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 10	40839323	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe Box of 1	40864902	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution [Menjugate] Box of 10	40932623	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution Box of 1	40958354	Drug	RxNorm Extension
Haemophilus B Conjugate Vaccine / meningococcal group C polysaccharide Injectable Solution [Menitorix]	40731786	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.07 MG/ML In	43804769	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
jectable Suspension Box of 10			
meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate]	43679124	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate]	43714859	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension Box of 10	43840965	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] by Nuron Biotech	43791851	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] Box of 10	43594089	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension	43720048	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate] Box of 10 by Glaxosmithkline	43612172	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] Box of 20	41408246	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe [Meningitec] Box of 1 by Orifarm Leverkus	41408318	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution	41409870	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution	40989640	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution [Menjugate] Box of 1	41120141	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
0.5 ML meningococcal group C polysaccharide 0.04 MG /ML Injectable Suspension [Neisvac C] by Pfizer	36281080	Drug	RxNorm Extension
meningococcal group C polysaccharide Injectable Suspension	43840964	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG /ML Injectable Suspension	36281147	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension Box of 5	43750812	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] Box of 2 by Nuron Biotech	43846133	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] Box of 10 by Nuron Biotech	43666359	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension Box of 10	43648340	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 10 by European	41407909	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe Box of 1	41408203	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe Box of 20	41409129	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe Box of 1 by Gerke	41409421	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1 by Eurim-Pharm	44197228	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide	44197086	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
0.02 MG/ML Prefilled Syringe [Menjugate] Box of 10 by Eurim-Pharm			
meningococcal group C polysaccharide 0.02 MG/ML Injectable Suspension [Meningitec]	36264987	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Injectable Suspension	36267195	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.04 MG/ML Injectable Suspension	36281204	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] Box of 10	43661175	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension	43828192	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate] Box of 5 by Glaxosmithkline	43648339	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution [Menjugate] Box of 10	41407826	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution Box of 1	41407586	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 10	41408785	Drug	RxNorm Extension
meningococcal group C polysaccharide Injectable Suspension [Neisvac C]	41018101	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.04 MG/ML Injectable Suspension	36274839	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide	36281198	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
0.02 MG/ML Injectable Suspension [Meningitec] by Nuron Biotech			
meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate] Box of 10	43606890	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] Box of 2	43661174	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension	43732882	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate] Box of 5	43859089	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate] Box of 10	43588843	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec]	43630178	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate]	43756130	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate] Box of 5 by Glaxosmithkline	43702342	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution [Menjugate]	41407420	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1	41407623	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide	41407789	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
0.02 MG/ML Prefilled Syringe Box of 1			
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution [Menjugate] Box of 1 by Novartis	41409031	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe Box of 10	41409325	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution Box of 10	41409667	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1	40901528	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML / tetanus toxoid vaccine, inactivated 0.04 MG/ML Injectable Suspension [Neisvac C]	44132620	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe [Meningitec] Box of 1	41182795	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML / tetanus toxoid vaccine, inactivated 0.04 MG/ML Injectable Suspension	44025498	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec]	43643019	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension Box of 5	43696938	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension Box of 10	43594087	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension	43719955	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
0.6 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension Box of 10	43702341	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate] Box of 10	43684333	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe [Meningitec] Box of 20	41407421	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1 by European	41409991	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe Box of 1	40989642	Drug	RxNorm Extension
meningococcal group C polysaccharide Injectable Solution	41079916	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1 by European	44197015	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Prefilled Syringe Box of 10	41208649	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution Box of 10	41239588	Drug	RxNorm Extension
meningococcal group C polysaccharide Injectable Suspension [Meningitec]	43768802	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate] Box of 5	43859087	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension Box of 10	43750813	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension Box of 2	43679125	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate] by Glaxosmithkline	43756040	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] Box of 2	43594088	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension Box of 2	43810019	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension Box of 5	43756131	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution [Menjugate]	41307103	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.02 MG/ML Injectable Solution [Menjugate] Box of 1	41407419	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension Box of 20	41409668	Drug	RxNorm Extension
meningococcal group C polysaccharide Injectable Solution [Menjugate]	40955877	Drug	RxNorm Extension
meningococcal group C polysaccharide Injectable Solution [Neisvac C]	35745357	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe Box of 20	41114614	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension [Meningitec] Box of 20	41151732	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide	36281126	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
0.02 MG/ML Injectable Suspension [Meningitec]			
0.5 ML meningococcal group C polysaccharide 0.04 MG/ML Injectable Suspension [Neisvac C]	36281185	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Prefilled Syringe [Meningitec] Box of 20	41276009	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension	43624782	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension	43864393	Drug	RxNorm Extension
0.5 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate]	43810018	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.07 MG/ML Injectable Suspension [Menjugate] Box of 5	43810115	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate]	43666462	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate] by Glaxosmithkline	43846229	Drug	RxNorm Extension
0.6 ML meningococcal group C polysaccharide 0.0583 MG/ML Injectable Suspension [Menjugate] Box of 10 by Glaxosmithkline	43594211	Drug	RxNorm Extension
meningococcal group C polysaccharide 0.05 MG/ML Injectable Suspension Box of 20	40864903	Drug	RxNorm Extension
meningococcal group C polysaccharide Injectable Solution [Meningitec]	40987113	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
Meningitis vaccine 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 10	41182793	Drug	RxNorm Extension
Meningitis vaccine Prefilled Syringe [Menjugate]	41049406	Drug	RxNorm Extension
Meningitis vaccine 0.02 MG/ML [Menjugate]	40827669	Drug	RxNorm Extension
0.5 ML Meningitis vaccine 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 10	41408245	Drug	RxNorm Extension
Meningitis vaccine 0.02 MG/ML Prefilled Syringe [Menjugate] Box of 1	40932622	Drug	RxNorm Extension
meningococcal C conjugate	40213176	Drug	CVX
meningococcal group C polysaccharide Injectable Suspension [Neisvac C]	41018101	Drug	Drug Exposure
Haemophilus influenzae type b, capsular polysaccharide inactivated tetanus toxoid conjugate vaccine / meningococcal group C polysaccharide Injectable Solution [Menitorix]	36066373	Drug	RxNorm Extension
influenza B virus antigen, Hong Kong 330-2001 / meningococcal group C polysaccharide Injectable Solution [Menitorix]	36407337	Drug	RxNorm Extension
influenza B virus antigen, Hong Kong 330-2001 / meningococcal group C polysaccharide Injection [Menitorix]	21129872	Drug	RxNorm Extension
Haemophilus B Conjugate Vaccine / meningococcal group C polysaccharide Injectable Solution [Menitorix]	40731786	Drug	RxNorm Extension
meningococcal group C polysaccharide Injection	21046234	Drug	RxNorm Extension
meningococcal group C polysaccharide Prefilled Syringe [Neisvac C]	40893613	Drug	RxNorm Extension

Table S3. Preliminary code list for Meningococcal serogroup A,C,W,Y vaccines (MCV4).

Concept name	Concept ID	Domain	Vocabulary
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injection [ACWY Vax]	21031231	Drug Exposure	RxNorm Extension
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Nimenrix]	35753882	Drug Exposure	RxNorm Extension
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Menveo]	35766293	Drug Exposure	RxNorm Extension
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [ACWY Vax]	35766294	Drug Exposure	RxNorm Extension
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE	36788305	Drug Exposure	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
GROUP Y Prefilled Syringe [Mencevax Acwy]			
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Prefilled Syringe	36788306	Drug Exposure	RxNorm Extension
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Mencevax Acwy]	36788307	Drug Exposure	RxNorm Extension
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / meningococcal polysaccharide vaccine group W-135 / meningococcal polysaccharide vaccine group Y Injectable Solution	40055280	Drug Exposure	RxNorm
Administration of meningitis A, C, W135 and Y vaccine	3656246	Procedure	SNOMED
Meningococcal group A polysaccharide	509079	Drug Exposure	RxNorm
Meningococcal group C polysaccharide	509081	Drug Exposure	RxNorm
Meningococcal polysaccharide vaccine group W-135	514012	Drug Exposure	RxNorm
Meningococcal polysaccharide vaccine group Y	514015	Drug Exposure	RxNorm
Meningitis vaccine 0.02 MG I ntramuscular Solution [Nime nrix] by Pfizer	36261151	Drug	RxNorm Extension
Meningitis vaccine 0.025 MG Intramuscular Solution [Menv eo] by GSK	36276392	Drug	RxNorm Extension
meningococcal group A polys accharide 2.5 MG / meningoc	44036973	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
occal group C polysaccharide 2.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 2.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 2.5 MG Injectable Solution by Aventis			
meningococcal group A polysaccharide 0.5 MG / meningococcal group C polysaccharide 0.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 0.5 MG Injectable Solution	44032490	Drug	RxNorm Extension
0.5 ML meningococcal group A polysaccharide 0.1 MG/ML / meningococcal group C polysaccharide 0.1 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.1 MG/ML / ... Injectable Solution by Sanofi	44132815	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / meningococcal polysaccharide vaccine group W-135 / meningococcal polysaccharide vaccine group Y Injectable Solution [Menomune A/C/Y/W-135]	40055281	Drug	RxNorm
meningococcal group A polysaccharide 0.01 MG/ML / meningococcal group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / ... Injectable Solution [Nimenrix]	44124986	Drug	RxNorm Extension
0.5 ML meningococcal group A polysaccharide 0.01 MG/ML / meningococcal group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE	44132839	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
GROUP Y 0.01 MG/ML / ... Injectable Solution			
meningococcal group A polysaccharide 0.01 MG/ML / meningococcal group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 0.01 MG/ML / ... Injectable Solution	44058468	Drug	RxNorm Extension
0.5 ML meningococcal group A polysaccharide 0.01 MG/ML / meningococcal group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / ... Injectable Solution [Nimenrix]	44132854	Drug	RxNorm Extension
meningococcal group A polysaccharide 0.5 MG / meningococcal group C polysaccharide 0.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 0.5 MG Injectable Solution	44032490	Drug	RxNorm Extension
meningococcal group A polysaccharide 2.5 MG / meningococcal group C polysaccharide 2.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 2.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 2.5 MG Injectable Solution by Aventis	44036973	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / meningococcal polysaccharide vaccine group W-135 / meningococcal polysaccharide vaccine group Y Injectable Solution [Menquadfi]	36923646	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
meningococcal group A polysaccharide 0.5 MG / meningococcal group C polysaccharide 0.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 0.5 MG Injectable Solution by Sanofi	44050095	Drug	RxNorm Extension
0.5 ML meningococcal group A polysaccharide 0.008 MG/ML / meningococcal group C polysaccharide 0.008 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.008 MG/ML / ... Intramuscular Solution [Menactra] by Sanofi	44132687	Drug	RxNorm Extension
meningococcal group A polysaccharide 0.1 MG/ML / meningococcal group C polysaccharide 0.1 MG/ML / meningococcal polysaccharide vaccine group W-135 0.1 MG/ML / meningococcal polysaccharide vaccine group Y 0.1 MG/ML Injectable Solution [Menomune A/C/Y/W-...	19035048	Drug	RxNorm
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Menactra]	35146370	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y / tetanus toxoid vaccine, inactivated Injectable Solution	44055806	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y / tetanus toxoid vaccine, inactivated Injectable Solution [Nimenrix]	44056941	Drug	RxNorm Extension
meningococcal group A polysaccharide 2.5 MG / meningococcal group C polysaccharide 2.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 2.5 MG / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 2.5 MG Injectable Solution	44058469	Drug	RxNorm Extension
hyaluronate 5 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 20 MG/ML Ophthalmic Solution [Hylo-Dual] by Scope Ophthalmics	40746599	Drug	RxNorm Extension
meningococcal group A polysaccharide 0.1 MG/ML / meningococcal group C polysaccharide 0.1 MG/ML / meningococcal polysaccharide vaccine group W-135 0.1 MG/ML / meningococcal polysaccharide vaccine group Y 0.1 MG/ML Injectable Solution	509104	Drug	RxNorm
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Nimenrix]	35753882	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL	35766293	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Menveo]			
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Mencevax Acwy]	36788307	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [ACWY Vax]	35766294	Drug	RxNorm Extension
10 ML hyaluronate 5 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 20 MG/ML Ophthalmic Solution [Hylo-Dual] by Scope Ophthalmics	40715959	Drug	RxNorm Extension
0.5 ML meningococcal group A polysaccharide 0.1 MG/ML / meningococcal group C polysaccharide 0.1 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.1 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 0.1 MG/ML Injectable Solution	44132517	Drug	RxNorm Extension
0.5 ML meningococcal group A polysaccharide 0.01 MG/ML / meningococcal group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / ... Injectable Solution [Nimenrix] by Pfizer	44132631	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
Meningitis vaccine 0.025 MG Intramuscular Solution [Menveo] by GSK	36276392	Drug	RxNorm Extension
Meningitis vaccine Intramuscular Solution [Menveo]	36264497	Drug	RxNorm Extension
Meningitis vaccine 0.025 MG Intramuscular Solution [Menveo]	36267930	Drug	RxNorm Extension
Meningitis vaccine 0.025 MG [Menveo]	36269304	Drug	RxNorm Extension
Meningitis vaccine Injectable Solution [Menveo]	41112106	Drug	RxNorm Extension
Meningitis vaccine Prefilled Syringe [Menveo]	40955876	Drug	RxNorm Extension
Meningitis vaccine 0.02 MG Intramuscular Solution [Nimenrix]	36259812	Drug	RxNorm Extension
Meningitis vaccine 0.02 MG Intramuscular Solution [Nimenrix] by Pfizer	36261151	Drug	RxNorm Extension
Meningitis vaccine Intramuscular Solution [Nimenrix]	36269516	Drug	RxNorm Extension
Meningitis vaccine Injectable Solution [Nimenrix]	41112105	Drug	RxNorm Extension
Meningitis vaccine 0.02 MG [Nimenrix]	36264116	Drug	RxNorm Extension
Meningococcal, MCV4, unspecified conjugate formulation (groups A, C, Y and W-135)	40213178	Drug	CVX
meningococcal ACWY vaccine, unspecified formulation	40213172	Drug	CVX
meningococcal group A polysaccharide / meningococcal group C polysaccharide / meningococcal polysaccharide vaccine group W-135 / meningococcal polysaccharide vaccine group Y Injection	46275260	Drug	RxNorm
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 /	21021512	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injection [Nimenrix]			

Table S4. Preliminary code list for Bexsero®.

Concept name	Concept ID	Domain	Vocabulary
meningococcal group B vaccine Injectable Suspension [Bexsero]	36277147	Drug Exposure	RxNorm Extension
meningococcal group B vaccine Injectable Solution [Bexsero]	36405016	Drug Exposure	RxNorm Extension
meningococcal group B vaccine Prefilled Syringe [Bexsero]	45892098	Drug Exposure	RxNorm
0.5 ML meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension [Bexsero]	35414612	Drug	RxNorm Extension
meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML [Bexsero]	35408055	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension [Bexsero] Box of 1	35414625	Drug	RxNorm Extension
meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML [Bexsero]	44067190	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension [Bexsero]	35406900	Drug	RxNorm Extension
meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B 0.1 MG/ML Injectable Suspension [Bexsero] Box of 1	35409987	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.2 MG/ML / Neisseria meningitidis Group B Membrane vesicles External Omv 0.05 MG/ML / ... Injectable Suspension [Bexsero] Box of 1 by Novartis	35414646	Drug	RxNorm Extension
meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [Bexsero]	36275190	Drug	RxNorm Extension
meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine / meningococcal group B vaccine Injectable Suspension [Bexsero]	40745347	Drug	RxNorm Extension
meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML Injectable Suspension [Bexsero]	44111622	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML Injectable Suspension [Bexsero] by Glaxosmithkline	44132814	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
0.5 ML meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [Bexsero] by GSK	36281177	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.3 MG/ML Injectable Suspension [Bexsero]	36281212	Drug	RxNorm Extension
meningococcal group B vaccine / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) Injectable Suspension [Bexsero]	44108372	Drug	RxNorm Extension
0.5 ML meningococcal group B vaccine 0.1 MG/ML / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) 0.05 MG/ML Injectable Suspension [Bexsero]	44132794	Drug	RxNorm Extension
meningococcal group B vaccine / Neisseria meningitidis Group B Membrane vesicles External Omv / Neisseria meningitidis Recombinant Fusion Protein Fhbp Group B Injectable Suspension [Bexsero]	35411236	Drug	RxNorm Extension
meningococcal group B vaccine 0.3 MG/ML [Bexsero]	36271732	Drug	RxNorm Extension
Bexsero Injectable Product	36248757	Drug	RxNorm

Table S5. Preliminary code list for Trumenba®.

Concept name	Concept ID	Domain	Vocabulary
meningococcal group B vaccine Injectable Suspension [Trumenba]	36810838	Drug Exposure	RxNorm Extension
meningococcal group B vaccine Prefilled Syringe [Trumenba]	45775643	Drug Exposure	RxNorm
meningococcal group B vaccine Prefilled Syringe [Trumenba]	45775643	Drug	RxNorm
meningococcal group B vaccine Injectable Suspension [Trumenba]	36810838	Drug	RxNorm Extension
meningococcal group B vaccine / Outer Membrane Vesicles (Neisseria Meningitidis Group B Nz98/254 Strain) Injectable Suspension [Trumenba]	40745346	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML Prefilled Syringe [Trumenba]	45775646	Drug	RxNorm
Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML [Trumenba]	45775642	Drug	RxNorm
Trumenba Injectable Product	36248645	Drug	RxNorm
0.5 ML Neisseria meningitidis serogroup B recombinant LP2086 A05 protein variant antigen 0.12 MG/ML / Neisseria meningitidis serogroup B recombinant LP2086 B01 protein variant antigen 0.12 MG/ML Prefilled Syringe [Trumenba]	45775644	Drug	RxNorm

Table S6. Preliminary code list for Menveo®.

Concept name	Concept ID	Domain	Vocabulary
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Menveo]	35766293	Drug Exposure	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injection [Menveo]	21100028	Drug	RxNorm Extension
Meningitis vaccine 0.025 MG Intramuscular Solution [Menveo] by GSK	36276392	Drug	RxNorm Extension
Meningitis vaccine Intramuscular Solution [Menveo]	36264497	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 /	35766293	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Menveo]			
Meningitis vaccine 0.025 MG Intramuscular Solution [Menveo]	36267930	Drug	RxNorm Extension
Meningitis vaccine 0.025 MG [Menveo]	36269304	Drug	RxNorm Extension
Meningitis vaccine Injectable Solution [Menveo]	41112106	Drug	RxNorm Extension
Meningitis vaccine Prefilled Syringe [Menveo]	40955876	Drug	RxNorm Extension

Table S7. Preliminary code list for Nimenrix®.

Concept name	Concept ID	Domain	Vocabulary
Meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Nimenrix]	35753882	Drug Exposure	RxNorm Extension
Meningitis vaccine 0.02 MG Intramuscular Solution [Nimenrix]	36259812	Drug	RxNorm Extension
Meningitis vaccine 0.02 MG Intramuscular Solution [Nimenrix] by Pfizer	36261151	Drug	RxNorm Extension
Meningitis vaccine Intramuscular Solution [Nimenrix]	36269516	Drug	RxNorm Extension
0.5 ML meningococcal group A polysaccharide 0.01 MG/ML / meningococcal group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / ... Injectable Solution [Nimenrix]	44132854	Drug	RxNorm Extension
meningococcal group A polysaccharide 0.01 MG/ML / meningococcal	44041273	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y 0.01 MG/ML / ... [Nimenrix]			
Meningitis vaccine Injectable Solution [Nimenrix]	41112105	Drug	RxNorm Extension
meningococcal group A polysaccharide 0.01 MG/ML / meningococcal group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / ... Injectable Solution [Nimenrix]	44124986	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y / tetanus toxoid vaccine, inactivated Injectable Solution [Nimenrix]	44056941	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP Y Injectable Solution [Nimenrix]	35753882	Drug	RxNorm Extension
meningococcal group A polysaccharide / meningococcal group C polysaccharide / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 / MENINGOCOCCAL POLYSACCHARIDE VACCINE	21021512	Drug	RxNorm Extension

Concept name	Concept ID	Domain	Vocabulary
GROUP Y Injection [Nimenrix]			
0.5 ML meningococcal group A polysaccharide 0.01 MG/ML / meningococcal group C polysaccharide 0.01 MG/ML / MENINGOCOCCAL POLYSACCHARIDE VACCINE GROUP W-135 0.01 MG/ML / ... Injectable Solution [Nimenrix] by Pfizer	44132631	Drug	RxNorm Extension
Meningitis vaccine 0.02 MG [Nimenrix]	36264116	Drug	RxNorm Extension

Table S8. Yearly Point prevalence of recipients of least one dose, at least two doses and at least three doses Meningococcal serogroup B vaccines amongst individual aged one years of age.

	BIFAP			CPRD GOLD			DK-DHR			FinOMOP-THL			NAJS			SIDIAP		
Prevalence start date	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]
Meningococcal vaccines serogroup B vaccine (at least 1 dose)																		
2017-01-01	113,548	32,032	28.21 (27.95 - 28.47)	42,530	31,441	73.93 (73.51 - 74.34)	58,121	7	0.01 (0.01 - 0.03)	56,608	-	-	37,503	0	-	50,012	10,842	21.68 (21.32 - 22.04)
2018-01-01	111,288	53,732	48.28 (47.99 - 48.58)	39,740	38,872	97.82 (97.67 - 97.96)	61,587	22	0.04 (0.02 - 0.05)	54,094	0	-	37,479	0	-	49,288	20,680	41.96 (41.52 - 42.39)
2019-01-01	130,205	75,800	58.22 (57.95 - 58.48)	36,246	35,343	97.51 (97.34 - 97.66)	61,160	31	0.05 (0.04 - 0.07)	51,486	-	-	36,482	0	-	47,728	24,796	51.95 (51.50 - 52.40)
2020-01-01	175,836	110,323	62.74 (62.52 - 62.97)	32,645	31,801	97.42 (97.24 - 97.58)	61,145	40	0.06 (0.05 - 0.09)	48,467	6	0.01 (0.01 - 0.03)	37,147	0	-	45,862	26,221	57.17 (56.72 - 57.63)
2021-01-01	170,361	120,239	70.58 (70.36 - 70.80)	29,103	28,278	97.17 (96.97 - 97.35)	60,986	75	0.12 (0.10 - 0.15)	46,468	10	0.02 (0.01 - 0.04)	36,345	-	-	44,424	26,629	59.94 (59.49 - 60.40)
2022-01-01	153,480	113,625	74.03 (73.81 - 74.25)	23,454	22,484	95.86 (95.60 - 96.11)	60,732	72	0.12 (0.09 - 0.15)	47,116	21	0.04 (0.03 - 0.07)	36,082	8	0.02 (0.01 - 0.04)	39,776	24,260	60.99 (60.51 - 61.47)
2023-01-01	159,236	119,170	74.84 (74.62 - 75.05)	23,349	22,279	95.42 (95.14 - 95.68)	63,133	109	0.17 (0.14 - 0.21)	50,145	11	0.02 (0.01 - 0.04)	36,843	12	0.03 (0.02 - 0.06)	41,084	27,099	65.96 (65.50 - 66.42)

	BIFAP			CPRD GOLD			DK-DHR			FinOMOP-THL			NAJS			SIDIAP		
Prevalence start date	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]
2024-01-01	147,111	116,079	78.91 (78.70 - 79.11)	21,813	20,653	94.68 (94.38 - 94.97)	58,321	97	0.17 (0.14 - 0.20)	45,283	84	0.19 (0.15 - 0.23)	34,171	5	0.01 (0.01 - 0.03)	-	-	-
2025-01-01	-	-	-	-	-	-	-	-	-	-	-	-	32,524	11	0.03 (0.02 - 0.06)	-	-	-
Meningococcal vaccines serogroup B vaccine (at least 2 dose)																		
2017-01-01	113,548	20,074	17.68 (17.46 - 17.90)	42,530	29,275	68.83 (68.39 - 69.27)	58,121	-	-	56,608	0	-	37,503	0	-	50,012	7,837	15.67 (15.35 - 15.99)
2018-01-01	111,288	42,231	37.95 (37.66 - 38.23)	39,740	36,945	92.97 (92.71 - 93.21)	61,587	14	0.02 (0.01 - 0.04)	54,094	0	-	37,479	0	-	49,288	17,911	36.34 (35.92 - 36.76)
2019-01-01	130,205	64,867	49.82 (49.55 - 50.09)	36,246	33,520	92.48 (92.20 - 92.75)	61,160	16	0.03 (0.02 - 0.04)	51,486	0	-	36,482	0	-	47,728	23,335	48.89 (48.44 - 49.34)
2020-01-01	175,836	91,038	51.77 (51.54 - 52.01)	32,645	30,082	92.15 (91.85 - 92.44)	61,145	27	0.04 (0.03 - 0.06)	48,467	-	-	37,147	0	-	45,862	24,842	54.17 (53.71 - 54.62)
2021-01-01	170,361	113,253	66.48 (66.25 - 66.70)	29,103	26,616	91.45 (91.13 - 91.77)	60,986	58	0.10 (0.07 - 0.12)	46,468	-	-	36,345	0	-	44,424	25,185	56.69 (56.23 - 57.15)
2022-01-01	153,480	106,669	69.50 (69.27 - 69.73)	23,454	20,770	88.56 (88.14 - 88.96)	60,732	52	0.09 (0.06 - 0.11)	47,116	12	0.03 (0.01 - 0.04)	36,082	-	-	39,776	22,931	57.65 (57.16 - 58.13)

	BIFAP			CPRD GOLD			DK-DHR			FinOMOP-THL			NAJS			SIDIAP		
Prevalence start date	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]
2023-01-01	159,236	111,166	69.81 (69.59 - 70.04)	23,349	20,807	89.11 (88.71 - 89.51)	63,133	72	0.11 (0.09 - 0.14)	50,145	7	0.01 (0.01 - 0.03)	36,843	7	0.02 (0.01 - 0.04)	41,084	25,826	62.86 (62.39 - 63.33)
2024-01-01	147,111	109,671	74.55 (74.33 - 74.77)	21,813	19,024	87.21 (86.76 - 87.65)	58,321	72	0.12 (0.10 - 0.16)	45,283	47	0.10 (0.08 - 0.14)	34,171	-	-	-	-	-
2025-01-01	-	-	-	-	-	-	-	-	-	-	-	-	32,524	6	0.02 (0.01 - 0.04)	-	-	-
Meningococcal vaccines serogroup B vaccine (at least 3 dose)																		
2017-01-01	113,548	3,936	3.47 (3.36 - 3.57)	42,530	17,273	40.61 (40.15 - 41.08)	58,121	0	-	56,608	0	-	37,503	0	-	50,012	1,436	2.87 (2.73 - 3.02)
2018-01-01	111,288	19,966	17.94 (17.72 - 18.17)	39,740	27,288	68.67 (68.21 - 69.12)	61,587	5	0.01 (0.00 - 0.02)	54,094	0	-	37,479	0	-	49,288	8,873	18.00 (17.67 - 18.34)
2019-01-01	130,205	36,333	27.90 (27.66 - 28.15)	36,246	24,576	67.80 (67.32 - 68.28)	61,160	5	0.01 (0.00 - 0.02)	51,486	0	-	36,482	0	-	47,728	12,135	25.42 (25.04 - 25.82)
2020-01-01	175,836	50,306	28.61 (28.40 - 28.82)	32,645	22,315	68.36 (67.85 - 68.86)	61,145	7	0.01 (0.01 - 0.02)	48,467	0	-	37,147	0	-	45,862	11,828	25.79 (25.39 - 26.19)
2021-01-01	170,361	73,865	43.36 (43.12 - 43.59)	29,103	19,737	67.82 (67.28 - 68.35)	60,986	18	0.03 (0.02 - 0.05)	46,468	0	-	36,345	0	-	44,424	12,622	28.41 (28.00 - 28.83)

	BIFAP			CPRD GOLD			DK-DHR			FinOMOP-THL			NAJS			SIDIAP		
Prevalence start date	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]
2022-01-01	153,480	71,067	46.30 (46.05 - 46.55)	23,454	15,011	64.00 (63.38 - 64.61)	60,732	22	0.04 (0.02 - 0.06)	47,116	6	0.01 (0.01 - 0.03)	36,082	0	-	39,776	11,738	29.51 (29.06 - 29.96)
2023-01-01	159,236	74,579	46.84 (46.59 - 47.08)	23,349	14,722	63.05 (62.43 - 63.67)	63,133	19	0.03 (0.02 - 0.05)	50,145	-	-	36,843	-	-	41,084	12,974	31.58 (31.13 - 32.03)
2024-01-01	147,111	79,444	54.00 (53.75 - 54.26)	21,813	13,247	60.73 (60.08 - 61.38)	58,321	23	0.04 (0.03 - 0.06)	45,283	20	0.04 (0.03 - 0.07)	34,171	-	-	-	-	-
2025-01-01	-	-	-	-	-	-	-	-	-	-	-	-	32,524	0	-	-	-	-

BIFAP = Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público, CPRD GOLD = Clinical Practice Research Datalink, DK-DHR = Danish Data Health Registries, FinOMOP-THL = Finnish Care Register for Health Care, NAJS = Croatian National Public Health Information System, SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària

Table S9. Yearly Point prevalence of recipients of least one dose, at least two doses and at least three doses Meningococcal serogroup B vaccines amongst individual aged two years of age.

	BIFAP			CPRD GOLD			DK-DHR			FinOMOP-THL			NAJS			SIDIAP		
Prevalence start date	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]
Men B vaccine (at least 1 dose)																		
2017-01-01	110,141	28,505	25.88 (25.62 - 26.14)	40,080	922	2.30 (2.16 - 2.45)	56,223	-	-	58,438	0	-	37,314	0	-	49,385	9,243	18.72 (18.38 - 19.06)
2018-01-01	112,723	52,466	46.54 (46.25 - 46.84)	36,271	26,946	74.29 (73.84 - 74.74)	57,577	11	0.02 (0.01 - 0.03)	56,227	-	-	37,496	0	-	49,584	17,440	35.17 (34.75 - 35.59)
2019-01-01	109,943	63,927	58.15 (57.85 - 58.44)	34,900	34,223	98.06 (97.91 - 98.20)	61,005	27	0.04 (0.03 - 0.06)	53,736	-	-	37,473	0	-	48,747	23,900	49.03 (48.58 - 49.47)
2020-01-01	128,771	80,420	62.45 (62.19 - 62.72)	31,380	30,684	97.78 (97.61 - 97.94)	60,628	47	0.08 (0.06 - 0.10)	51,132	-	-	36,478	0	-	47,179	25,792	54.67 (54.22 - 55.12)

	BIFAP			CPRD GOLD			DK-DHR			FinOMOP-THL			NAJS			SIDIAP		
Prevalence start date	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]
2021-01-01	174,401	113,741	65.22 (64.99 - 65.44)	27,691	27,060	97.72 (97.54 - 97.89)	60,685	43	0.07 (0.05 - 0.10)	48,206	9	0.02 (0.01 - 0.04)	37,142	0	-	45,448	26,580	58.48 (58.03 - 58.94)
2022-01-01	168,523	121,670	72.20 (71.98 - 72.41)	24,216	23,617	97.53 (97.32 - 97.72)	60,513	83	0.14 (0.11 - 0.17)	46,184	11	0.02 (0.01 - 0.04)	36,335	-	-	43,909	26,770	60.97 (60.51 - 61.42)
2023-01-01	150,030	113,021	75.33 (75.11 - 75.55)	20,662	19,897	96.30 (96.03 - 96.55)	60,254	79	0.13 (0.10 - 0.16)	46,806	23	0.05 (0.03 - 0.07)	36,076	20	0.06 (0.04 - 0.09)	39,235	24,275	61.87 (61.39 - 62.35)
2024-01-01	155,096	117,718	75.90 (75.69 - 76.11)	21,015	20,138	95.83 (95.55 - 96.09)	62,691	116	0.18 (0.15 - 0.22)	49,833	18	0.04 (0.02 - 0.06)	36,833	21	0.06 (0.04 - 0.09)	-	-	-
2025-01-01	-	-	-	-	-	-	-	-	-	-	-	-	34,169	21	0.06 (0.04 - 0.09)	-	-	-
Men B vaccine (at least 2 dose)																		

	BIFAP			CPRD GOLD			DK-DHR			FinOMOP-THL			NAJS			SIDIAP		
Prevalence start date	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]
2017-01-01	110,141	15,759	14.31 (14.10 - 14.52)	40,080	394	0.98 (0.89 - 1.08)	56,223	-	-	58,438	0	-	37,314	0	-	49,385	6,109	12.37 (12.08 - 12.66)
2018-01-01	112,723	40,694	36.10 (35.82 - 36.38)	36,271	25,453	70.17 (69.70 - 70.64)	57,577	8	0.01 (0.01 - 0.03)	56,227	0	-	37,496	0	-	49,584	14,931	30.11 (29.71 - 30.52)
2019-01-01	109,943	56,799	51.66 (51.37 - 51.96)	34,900	32,882	94.22 (93.97 - 94.46)	61,005	17	0.03 (0.02 - 0.04)	53,736	0	-	37,473	0	-	48,747	22,716	46.60 (46.16 - 47.04)
2020-01-01	128,771	70,411	54.68 (54.41 - 54.95)	31,380	29,398	93.68 (93.41 - 93.95)	60,628	31	0.05 (0.04 - 0.07)	51,132	-	-	36,478	0	-	47,179	24,750	52.46 (52.01 - 52.91)

	BIFAP			CPRD GOLD			DK-DHR			FinOMOP-THL			NAJS			SIDIAP		
Prevalence start date	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]
2021-01-01	174,401	96,891	55.56 (55.32 - 55.79)	27,691	25,833	93.29 (92.99 - 93.58)	60,685	35	0.06 (0.04 - 0.08)	48,206	-	-	37,142	0	-	45,448	25,556	56.23 (55.77 - 56.69)
2022-01-01	168,523	116,174	68.94 (68.72 - 69.16)	24,216	22,506	92.94 (92.61 - 93.25)	60,513	66	0.11 (0.09 - 0.14)	46,184	5	0.01 (0.00 - 0.03)	36,335	-	-	43,909	25,709	58.55 (58.09 - 59.01)
2023-01-01	150,030	107,009	71.33 (71.10 - 71.55)	20,662	18,564	89.85 (89.43 - 90.25)	60,254	64	0.11 (0.08 - 0.14)	46,806	13	0.03 (0.02 - 0.05)	36,076	12	0.03 (0.02 - 0.06)	39,235	23,167	59.05 (58.56 - 59.53)
2024-01-01	155,096	111,027	71.59 (71.36 - 71.81)	21,015	19,027	90.54 (90.14 - 90.93)	62,691	94	0.15 (0.12 - 0.18)	49,833	11	0.02 (0.01 - 0.04)	36,833	16	0.04 (0.03 - 0.07)	-	-	-
2025-01-01	-	-	-	-	-	-	-	-	-	-	-	-	34,169	10	0.03 (0.02 - 0.05)	-	-	-
Men B vaccine (at least 3 dose)																		

	BIFAP			CPRD GOLD			DK-DHR			FinOMOP-THL			NAJS			SIDIAP		
Prevalence start date	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]
2017-01-01	110,141	562	0.51 (0.47 - 0.55)	40,080	87	0.22 (0.18 - 0.27)	56,223	0	-	58,438	0	-	37,314	0	-	49,385	139	0.28 (0.24 - 0.33)
2018-01-01	112,723	17,495	15.52 (15.31 - 15.73)	36,271	20,484	56.48 (55.96 - 56.98)	57,577	-	-	56,227	0	-	37,496	0	-	49,584	6,524	13.16 (12.86 - 13.46)
2019-01-01	109,943	38,283	34.82 (34.54 - 35.10)	34,900	29,735	85.20 (84.82 - 85.57)	61,005	6	0.01 (0.00 - 0.02)	53,736	0	-	37,473	0	-	48,747	16,646	34.15 (33.73 - 34.57)
2020-01-01	128,771	57,405	44.58 (44.31 - 44.85)	31,380	26,451	84.29 (83.89 - 84.69)	60,628	11	0.02 (0.01 - 0.03)	51,132	0	-	36,478	0	-	47,179	21,120	44.77 (44.32 - 45.22)
2021-01-01	174,401	77,485	44.43 (44.20 - 44.66)	27,691	23,150	83.60 (83.16 - 84.03)	60,685	14	0.02 (0.01 - 0.04)	48,206	0	-	37,142	0	-	45,448	21,910	48.21 (47.75 - 48.67)

	BIFAP			CPRD GOLD			DK-DHR			FinOMOP-THL			NAJS			SIDIAP		
Prevalence start date	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]
2022-01-01	168,523	100,431	59.59 (59.36 - 59.83)	24,216	19,799	81.76 (81.27 - 82.24)	60,513	22	0.04 (0.02 - 0.06)	46,184	-	-	36,335	0	-	43,909	22,215	50.59 (50.13 - 51.06)
2023-01-01	150,030	91,370	60.90 (60.65 - 61.15)	20,662	15,942	77.16 (76.58 - 77.72)	60,254	30	0.05 (0.04 - 0.07)	46,806	7	0.01 (0.01 - 0.03)	36,076	-	-	39,235	19,659	50.11 (49.61 - 50.60)
2024-01-01	155,096	96,957	62.51 (62.27 - 62.76)	21,015	16,296	77.54 (76.97 - 78.10)	62,691	28	0.04 (0.03 - 0.06)	49,833	5	0.01 (0.00 - 0.02)	36,833	-	-	-	-	-
2025-01-01	-	-	-	-	-	-	-	-	-	-	-	-	34,169	-	-	-	-	-

BIFAP = Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público, CPRD GOLD = Clinical Practice Research Datalink, DK-DHR = Danish Data Health Registries, FinOMOP-THL = Finnish Care Register for Health Care, NAJS = Croatian National Public Health Information System, SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària

Table S10. Yearly point prevalence of recipients of least one dose of Meningococcal serogroup C vaccines amongst individual aged two years of age.

	BIFAP			CPRD GOLD			DK-DHR			FinOMOP-THL			NAJS			SIDIAP		
Prevalence start date	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]
Meningococcal serogroup C vaccine (at least 1 dose)																		
2017-01-01	110,141	107,460	97.57 (97.47 - 97.66)	40,080	39,405	98.32 (98.18 - 98.44)	56,223	75	0.13 (0.11 - 0.17)	58,438	73	0.12 (0.10 - 0.16)	37,314	0	-	49,385	47,913	97.02 (96.87 - 97.17)
2018-01-01	112,723	110,147	97.72 (97.63 - 97.80)	36,271	35,506	97.89 (97.74 - 98.03)	57,577	152	0.26 (0.22 - 0.31)	56,227	82	0.15 (0.12 - 0.18)	37,496	0	-	49,584	48,189	97.19 (97.04 - 97.33)
2019-01-01	109,943	107,596	97.86 (97.78 - 97.95)	34,900	32,962	94.45 (94.20 - 94.68)	61,005	193	0.32 (0.28 - 0.36)	53,736	74	0.14 (0.11 - 0.17)	37,473	0	-	48,747	47,056	96.53 (96.36 - 96.69)
2020-01-01	128,771	125,606	97.54 (97.46 - 97.62)	31,380	29,073	92.65 (92.35 - 92.93)	60,628	183	0.30 (0.26 - 0.35)	51,132	103	0.20 (0.17 - 0.24)	36,478	0	-	47,179	45,401	96.23 (96.06 - 96.40)
2021-01-01	174,401	164,601	94.38 (94.27 - 94.49)	27,691	25,736	92.94 (92.63 - 93.24)	60,685	204	0.34 (0.29 - 0.38)	48,206	83	0.17 (0.14 - 0.21)	37,142	-	-	45,448	43,684	96.12 (95.94 - 96.29)
2022-01-01	168,523	161,224	95.67 (95.57 - 95.76)	24,216	22,009	90.89 (90.52 - 91.24)	60,513	166	0.27 (0.24 - 0.32)	46,184	61	0.13 (0.10 - 0.17)	36,335	0	-	43,909	42,113	95.91 (95.72 - 96.09)
2023-01-01	150,030	140,645	93.75 (93.62 - 93.87)	20,662	18,549	89.77 (89.35 - 90.18)	60,254	147	0.24 (0.21 - 0.29)	46,806	97	0.21 (0.17 - 0.25)	36,076	6	0.02 (0.01 - 0.04)	39,235	37,339	95.17 (94.95 - 95.38)
2024-01-01	155,096	140,034	90.29 (90.14 - 90.44)	21,015	18,829	89.60 (89.18 - 90.00)	62,691	171	0.27 (0.23 - 0.32)	49,833	91	0.18 (0.15 - 0.22)	36,833	7	0.02 (0.01 - 0.04)	-	-	-

	BIFAP			CPRD GOLD			DK-DHR			FinOMOP-THL			NAJS			SIDIAP		
Prevalence start date	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]
2025-01-01	-	-	-	-	-	-	-	-	-	-	-	-	34,169	5	0.01 (0.01 - 0.03)	-	-	-

BIFAP = Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público, CPRD GOLD = Clinical Practice Research Datalink, DK-DHR = Danish Data Health Registries, FinOMOP-THL = Finnish Care Register for Health Care, NAJS = Croatian National Public Health Information System, SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària

Table S11. Yearly point prevalence of at least one dose of MCV4 vaccines in individuals aged 18 years of age.

	BIFAP			CPRD GOLD			DK-DHR			FinOMOP-THL			NAJS			SIDIAP		
Prevalence start date	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]
MCV4																		
2017-01-01	88,514	23	0.03 (0.02 - 0.04)	40,209	14,545	36.17 (35.70 - 36.64)	66,545	256	0.38 (0.34 - 0.44)	59,781	441	0.74 (0.67 - 0.81)	-	-	-	48,884	165	0.34 (0.29 - 0.39)
2018-01-01	100,282	54	0.05 (0.04 - 0.07)	36,331	19,573	53.87 (53.36 - 54.39)	66,335	1,153	1.74 (1.64 - 1.84)	60,204	438	0.73 (0.66 - 0.80)	-	-	-	51,820	198	0.38 (0.33 - 0.44)
2019-01-01	110,786	363	0.33 (0.30 - 0.36)	34,111	19,751	57.90 (57.38 - 58.42)	67,162	1,559	2.32 (2.21 - 2.44)	59,461	435	0.73 (0.67 - 0.80)	-	-	-	53,203	288	0.54 (0.48 - 0.61)
2020-01-01	113,875	39,072	34.31 (34.04 - 34.59)	31,627	20,415	64.55 (64.02 - 65.08)	65,336	1,859	2.85 (2.72 - 2.98)	58,554	413	0.70 (0.64 - 0.78)	19	0	0.00 (0.00 - 16.82)	52,429	452	0.86 (0.79 - 0.94)

	BIFAP			CPRD GOLD			DK-DHR			FinOMOP-THL			NAJS			SIDIAP		
Prevalence start date	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]	Denominator (N)	Outcome (N)	Prevalence [95% CI]
2021-01-01	117,125	63,498	54.21 (53.93 - 54.50)	30,253	19,031	62.91 (62.36 - 63.45)	64,434	1,638	2.54 (2.42 - 2.67)	57,963	394	0.68 (0.62 - 0.75)	10,037	0	0.00 (0.00 - 0.04)	53,961	1,482	2.75 (2.61 - 2.89)
2022-01-01	126,171	79,335	62.88 (62.61 - 63.15)	27,902	18,014	64.56 (64.00 - 65.12)	65,541	1,476	2.25 (2.14 - 2.37)	58,940	344	0.58 (0.52 - 0.65)	39,497	-	-	56,458	4,105	7.27 (7.06 - 7.49)
2023-01-01	123,552	83,993	67.98 (67.72 - 68.24)	26,476	15,216	57.47 (56.87 - 58.06)	66,104	1,354	2.05 (1.94 - 2.16)	60,007	353	0.59 (0.53 - 0.65)	40,154	5	0.01 (0.00 - 0.03)	57,649	22,436	38.92 (38.52 - 39.32)
2024-01-01	132,348	92,808	70.12 (69.88 - 70.37)	26,248	13,534	51.56 (50.96 - 52.17)	66,224	1,327	2.00 (1.90 - 2.11)	60,063	451	0.75 (0.69 - 0.82)	42,253	20	0.05 (0.03 - 0.07)	-	-	-
2025-01-01	-	-	-	-	-	-	-	-	-	-	-	-	41,295	20	0.05 (0.03 - 0.07)	-	-	-

BIFAP = Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público, CPRD GOLD = Clinical Practice Research Datalink, DK-DHR = Danish Data Health Registries, FinOMOP-THL = Finnish Care Register for Health Care, NAJS = Croatian National Public Health Information System, SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària

ANNEX V: Glossary

Additional definitions are available in the EMA Glossary of terms https://www.ema.europa.eu/en/about-us/glossaries.

Aggregated Data

Data collected and combined from multiple sources to generate summary information, typically anonymised.

Benefit-Risk Assessment

Evaluation of the positive therapeutic effects of a medicine compared to its risks (e.g., side effects).

Common Data Model (CDM)

A standardized data structure that enables data from multiple sources to be harmonized, making analysis consistent and reproducible. DARWIN EU® utilises the OMOP CDM maintained by the OHDSI community.

Complex Studies (C3)

Studies requiring the development or customisation of specific study designs, protocols, and Statistical Analysis Plans (SAPs), with extensive collection or extraction of data. Examples include etiological studies measuring the strength and determinants of an association between an exposure and the occurrence of a health outcome in a defined population considering sources of bias, potential confounding factors, and effect modifiers.

Coordination Centre (CC)

The central hub responsible for managing and overseeing the activities within DARWIN EU®. It is based at Erasmus University Medical Centre in Rotterdam, the Netherlands.

Data Access

The process of obtaining permission to use specific datasets for regulatory or scientific studies.

Data Quality Framework

A set of standards and procedures to ensure accuracy, completeness, timeliness, and consistency of data used in DARWIN EU®.

Data Source

A database or repository of structured health-related data, such as electronic health records (EHRs), insurance claims, or registries.

DARWIN EU®

The European Medicines Agency's (EMA) federated network of real-world data sources designed to generate evidence to support regulatory decision-making.

EMA (European Medicines Agency)

The regulatory body responsible for the evaluation and supervision of medicinal products in the EU, overseeing DARWIN EU®.

Evidence Generation

The process of analysing real-world data to produce scientific information that can inform healthcare or regulatory decisions.

Federated Network

A data infrastructure where data remain at their original location but can be analysed in a harmonised way across multiple partners using a common model and tools.

GDPR (General Data Protection Regulation)

The EU regulation governing the protection of personal data and privacy, crucial to how DARWIN EU® handles health data.

Health Technology Assessment (HTA)

A systematic evaluation of properties and impacts of health technology, often using DARWIN EU® data to support assessments.

Metadata

Descriptive information about a data source (e.g., its content, quality, and structure), essential for identifying relevant databases in DARWIN EU® studies.

Off-the-Shelf Studies (OTS)

Studies for which a standard protocol per study/analysis type and standardised analytics may be developed and applied or adapted, typically relating to a descriptive research question. This includes studies on disease epidemiology, for example, the estimation of the prevalence or incidence of health outcomes in defined time periods and population groups, or drug utilisation studies at the population or patient level.

OHDSI (Observational Health Data Sciences and Informatics)

An open-science collaborative community that develops tools and standards (including the OMOP CDM) to enable large-scale analytics of observational health data. OHDSI provides the technical and scientific foundation for DARWIN EU®'s analytical ecosystem.

Patient-Level Data

Data related to individuals, de-identified, used for longitudinal or detailed analyses.

OMOP (Observational Medical Outcomes Partnership)

A common data model (CDM) that standardises the structure and content of observational healthcare data, enabling systematic analysis across disparate datasets. DARWIN EU® uses the OMOP CDM to ensure interoperability and consistency in real-world evidence generation.

Real-World Data (RWD)

Data relating to individual health status or healthcare delivery that is collected from routine clinical practice rather than from randomised controlled trials.

Real-World Evidence (RWE)

Clinical evidence derived from the analysis of RWD, used to inform decisions by regulators, payers, or clinicians.

Regulatory Decision-Making

The process by which authorities like EMA assess data to authorise, monitor, or modify the use of medicines in the EU.

Routine Repeated Studies (RR)

Studies that are either Off-the-Shelf or Complex studies repeated on a regular basis, following the same protocol and study code, but with updated data and/or different data partners.

Study Protocol

A detailed plan describing how a specific real-world study will be conducted, including objectives, design, data sources, and analyses.

Very Complex Studies (C4)

Studies which cannot rely only on electronic health care databases, or which would require complex methodological work, for example, due to the occurrence of events that cannot be defined by existing diagnosis codes, including events that do not yet have a diagnosis code, where it may be necessary to combine a diagnosis code with other data such as results of laboratory investigations. These studies might require the collection of data prospectively, or the inclusion of new (not previously onboarded) data sources.