

Leveraging the OMOP Common Data Model to Monitor WHO AWaRe Access Antibiotic Use Across Europe: A Multi-Database DARWIN EU® Study

Marzyeh Amini¹, Ger Inberg¹, Melissa Leung¹, Elvira Bräuner², Susanne Bruun², Toni Lehtonen³, Laura Salonen³, Dina Vojinovic⁴, Akram Sharim Mendez Rangel⁵, Ellen Gerritsen⁴, Gargi Jadhav⁵, Hugo Vernooij⁵, Isabella Kaczmarczyk⁵, Antea Jezidžić⁶, Marko Čavlina⁶, Karlo Pintaric⁶, Anamaria Jurcevic⁶, Jakov Vukovic⁶, Agustina Giuliodori Picco⁷, Irene López Sánchez⁷, Elena Roel Herranz⁷, Talita Duarte Salles⁷, Katia Verhamme¹

¹ EMC Department of Medical Informatics, Erasmus University Medical Center, The Netherlands.

² Data & Data Analysis, Danish Medicines Agency (DKMA), Denmark.

³ Data and Analytics, Finnish Institute for Health and Welfare (THL), Finland.

⁴ IQVIA, Real World Solutions, Amsterdam, The Netherlands.

⁵ IQVIA, Real World Solutions, Brighton, United Kingdom.

⁶ Division for Health Informatics and Biostatistics, Croatian Institute of Public Health, Croatia.

⁷ Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAPJGol), Barcelona, Spain.

Background

The WHO 2023 AWaRe classification groups antibiotics into Access, Watch and Reserve categories to support monitoring and antimicrobial stewardship. WHO AWaRe Access antibiotics are recommended as first- or second-line treatments for common infections, including pneumonia and urinary tract infections^{1,2}, and play a central role in antimicrobial stewardship. Monitoring their use is essential to evaluate prescribing practices and support efforts to limit antimicrobial resistance. In this study, we aimed to estimate incidence rates and temporal trends of WHO AWaRe Access antibiotics dispensations or prescriptions across multiple European healthcare databases from the Darwin EU® network.

Methods

We conducted a multi-country, population-level drug utilization study within the DARWIN EU® network of healthcare data mapped to the OMOP Common Data Model. The study used data from six European healthcare databases representing national healthcare registries, administrative healthcare databases, and primary care electronic health record systems: National Public Health Information System (NAJS), Croatia; Danish Data Health Registries (DK-DHR), Denmark; Finnish Care Register for Health Care (FinOMOP-THL), Finland; IQVIA Disease Analyser Germany (IQVIA-DA), Germany; The Integrated Primary Care Information (IPCI), The Netherlands; and Information System for Research in Primary Care (SIDAP), Spain. Eligible individuals were observed during 2012–2024 and generally required 365 days of prior observation; exceptions applied to children under one year and hospital data sources. For each antibiotic agent or class, a use was counted as incident after at least 30 days without use of that same agent or class. We described the age and sex distribution of users of each Access antibiotic class, separately by data source. Annual and monthly rates were also calculated as incident uses per 100,000 person-years, separately by data source, class, and agent. The statistical analyses were performed using the Darwin EU® *IncidencePrevalence* R package. Further details on the study design, eligibility criteria, and analysis methods are provided in the study protocol ([EUPAS1000000663](https://doi.org/10.1186/1745-6215-1000000663)).

Results

Main findings: The demographic characteristics of Access antibiotic users varied by class and data source (Figures 1 and 2). Adults accounted for most users in the majority of sources, while the proportions of children and older adults differed across classes. Female users generally represented a higher proportion than male users, although this pattern was not consistent for every class and source.

Across all six countries, penicillin was the most frequently prescribed class, with substantial geographic variation. Overall IRs ranged from approximately 2,140 per 100,000 person-years in IQVIA DA Germany to 24,543 in DK-DHR Denmark. Other commonly used classes included β -lactam/ β -lactamase inhibitors, 1st-generation cephalosporins, and nitrofurantoin derivatives (Figure 3). Among individual agents, amoxicillin-clavulanic acid demonstrated the highest IRs (21,533 in Croatia), followed by amoxicillin (9,565 in Spain) and nitrofurantoin (4,642 in the Netherlands). Temporal trend analyses showed declining Access antibiotic prescribing, with penicillin IRs decreasing by ~20–35%, notably in Croatia (9,920 in 2017 to 6,407 in 2024) and Spain (11,951 in 2017 to 7,752 in 2022), alongside reductions in 1st-generation cephalosporins and tetracyclines. In contrast, trimethoprim-related agents and sulfonamides increased, particularly in Finland (11 to 169 from 2012 to 2023). Strong seasonal patterns were observed, with winter peaks for respiratory antibiotics and summer peaks for urinary tract infection treatments.

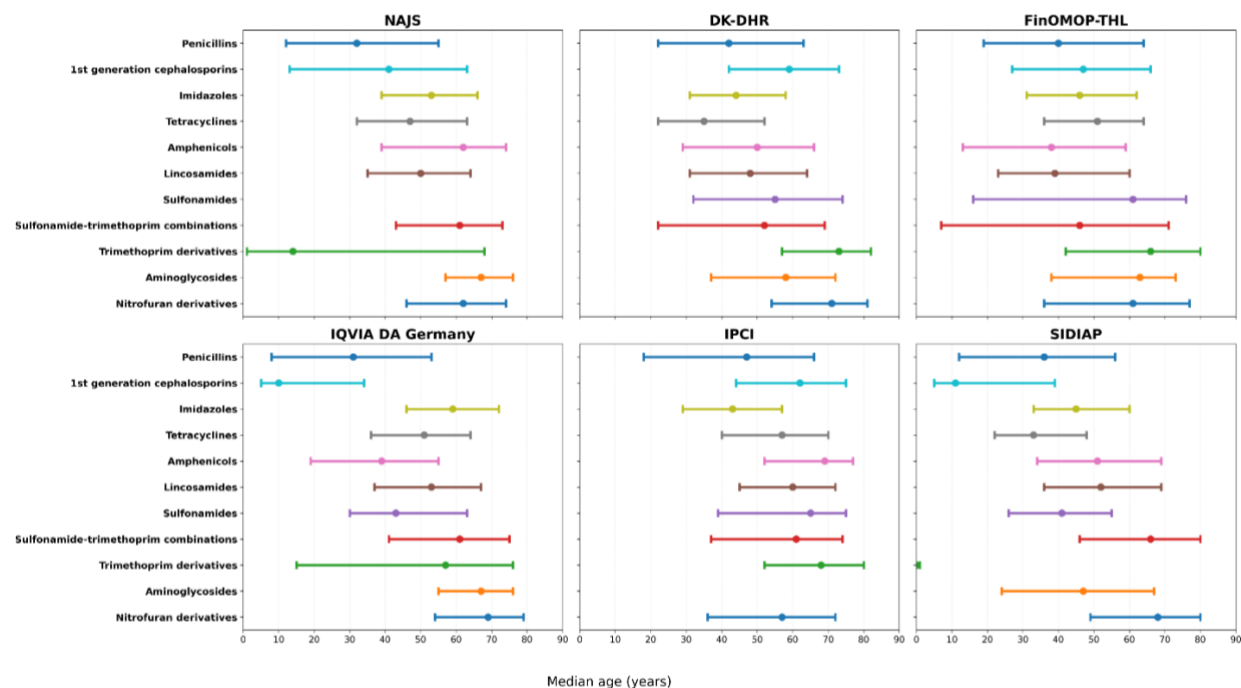


Figure 1. Median age of users of WHO AWaRe Access antibiotics, by antibiotic class and data source.

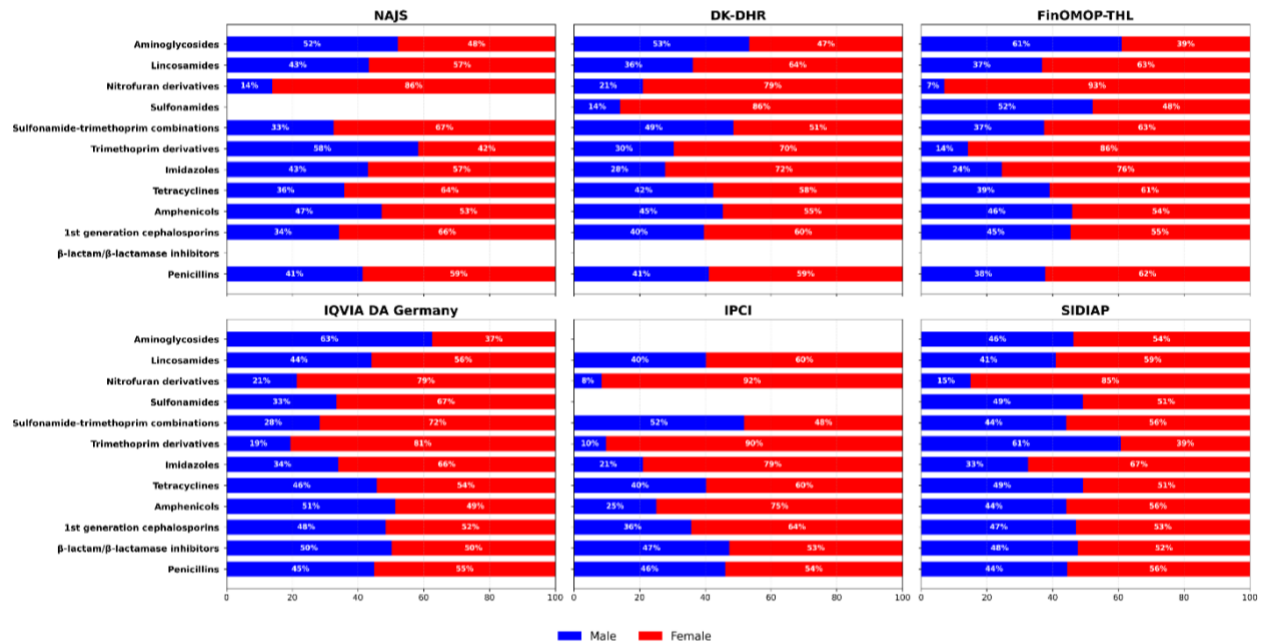


Figure 2. Proportion of female and male users of WHO AWaRe Access antibiotics, by antibiotic class and data source.

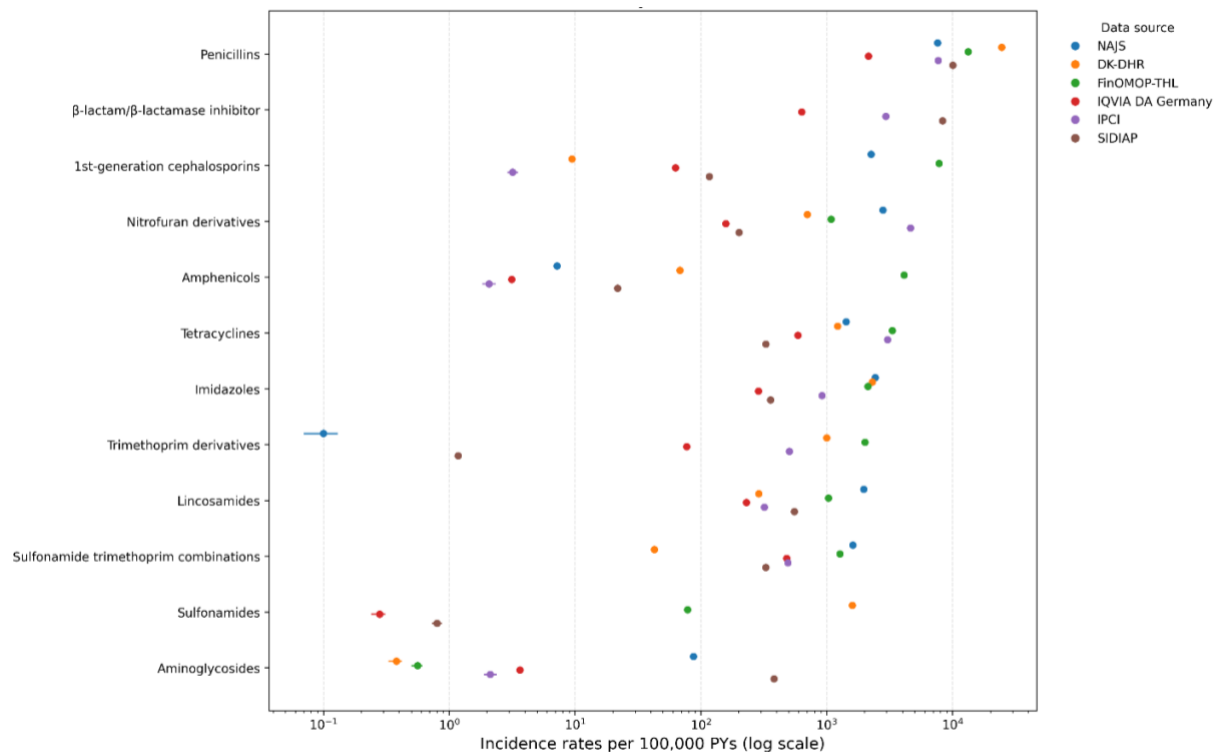


Figure 3. Overall incidence rates of WHO AWaRe Access antibiotic classes by data source, per 100,000 person-years. The horizontal axis uses a logarithmic scale.

Impact and interpretation: This study shows how the OMOP Common Data Model and shared OHDSI analytical tools can support the same antibiotic-use analysis across multiple data sources. Reusing the study definitions and code could speed up future updates and allow the analysis to scale to additional data partners. These estimates provide a baseline for monitoring Access antibiotic use within each data source. Changes over time and differences between antibiotic classes can help identify prescribing patterns that warrant further investigation and inform local antimicrobial stewardship efforts.

Limitations: First, rates should not be used to rank countries. They are crude rather than age- and sex-standardized, and the data sources differ in population coverage, care settings, and how prescriptions or dispensations are captured. Second, the analysis includes Access antibiotics only, so it cannot assess the proportion of total antibiotic use that meets the WHO Access target. Third, recorded prescriptions or dispensations may not reflect actual use, while incomplete capture and coding or mapping differences may affect the estimates. Finally, findings are limited to the populations represented in the six data sources.

Conclusions

WHO AWaRe Access antibiotic use varied across the six data sources and over time, reflecting differences in prescribing practices, infection epidemiology, local treatment guidelines, and antimicrobial stewardship implementation. Applying shared definitions and analytical code to OMOP-mapped data enabled consistent monitoring, while differences in source populations and data capture limit direct country comparisons. These findings provide a baseline for source-specific surveillance and further stewardship investigation.

References

1. World Health Organization (WHO). WHO List of Medically Important Antimicrobials. <https://www.paho.org/en/documents/who-list-medically-important-antimicrobials>. 2024.
2. World Health Organization (WHO). AWaRe classification of antibiotics for evaluation and monitoring of use, 2023. <https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.04>. 2023.

Funding

This study was funded by EMA and performed via DARWIN EU® (EUPAS1000000663). The study funder was involved in revising the study protocol and the objectives and reviewing the study report including the results. Data partners' role is only to execute code at their data source. They do not have an investigator role. This communication represents the views of the DARWIN EU® Coordination Centre only and cannot be interpreted as reflecting those of the EMA or the European Medicines Regulatory Network.