

DARWIN EU® - A Transportable Framework For Evaluating Pregnancy Episode Algorithms In Heterogeneous Real-World Databases

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Background

Routinely-collected data are commonly used in pregnancy research by applying rule-based algorithms to reliably extract pregnancy episodes. Accurate identification of pregnancy episodes is essential for advancing maternal and child health outcomes and informing regulatory decisions. However, validation is often missing or limited to certain databases, limiting our understanding on the quality of the extracted pregnancy episodes. For pregnancy research at scale, we need a standardised quality assessment framework that can be applied across heterogeneous databases.

Objectives

1. To develop a standardised quality assessment framework for evaluating the accuracy of derived pregnancy episodes.
2. To validate the framework across datasets within the DARWIN EU® network to assess readiness for multi-dataset studies and regulatory use.

Methods

We designed a framework including four quality dimensions of pregnancy episodes:

1. Episode frequency: plausibility and consistency of counted pregnancies within and across databases (e.g. pregnancy incidence rate, maternal age distribution),
2. Episode duration: accuracy of gestational length and alignment with known clinical timelines per pregnancy outcome (e.g. gestational age distribution, temporal patterns),
3. Episode construction: completeness and correctness of the algorithmic output (e.g. overlapping episodes, missing dates),
4. Episode outcomes: capture of key maternal and fetal outcomes linked to each pregnancy episode (e.g. mode of delivery frequency).

Results

The pregnancy episode quality framework was applied across 15 DARWIN EU® databases. Preliminary findings demonstrate substantial heterogeneity in the ability to detect pregnancy episodes across the network. Standardised output across databases allowed to identify and prioritise the most high-

impact issues based on feasibility and impact, supporting algorithm refinements as shown in Figure 1. Episode duration and episode construction were recognized as key areas for refinement, as implausible gestational lengths (> 44 weeks) were observed in at most 20% of episodes across all databases and pregnancy overlap occurred in more than 5% of individuals with multiple pregnancies in nine databases.

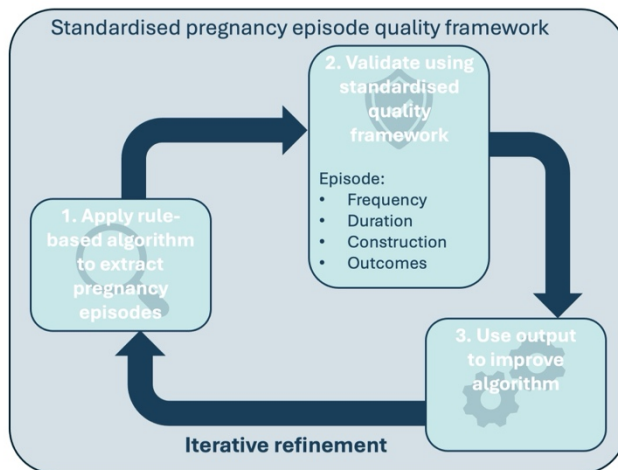


Figure 1. Proposed framework to evaluate and improve the accuracy of derived pregnancy episodes.

Conclusion

The proposed framework enables a standardised, transparent assessment of the performance of pregnancy episode algorithms across heterogeneous real-world data mapped to the OMOP Common Data Model. It supports targeted fixes to improve derived pregnancy episodes across databases by providing insight into differences between health care systems and data granularity. Future work will define minimum quality requirements, assess performance over time, and benchmark the results against national statistics.

Funding

This study (EUPAS1000000812) was funded by EMA and performed via DARWIN EU[®]. The study funder was involved in revising the study protocol and the objectives. 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.