

Data source heterogeneity in multi-data base pharmacoepidemiologic studies: an ISPE-sponsored scoping review

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BACKGROUND

Interpreting the findings of multi-data base studies requires a clear understanding of the context and purpose of data collection for each participating data source. There is currently no guidance for how heterogeneity between data sources (HDS) should be reported and leveraged upon. The DIVERSE scoping review on this topic is sponsored by ISPE and is conducted within the Database Special Interest Group.

OBJECTIVES

To identify and report on literature including or suggesting recommendations to describe, report on or leverage HDS for pharmacoepidemiologic research

METHODS

Refinement. In a first phase, the authors were asked to propose key papers which they considered to meet the requirements of the scoping review (core papers). Based on this list, the scope of the review was further refined, a detailed list of exclusion/inclusion criteria was created and embedded in a screening tool, which was used to screen the candidate core papers, and the search strategy was defined.

Search. The search strategy consisted of three steps: 1) a snowball search of the reference lists of the core papers, 2) a PubMed search and 3) a web-based search for grey literature. To ensure sensitivity, the search string was refined to capture at least 80% of the core papers. The search spanned all time up to 2021.

Selection. Documents were reviewed in a standardised process by independent pairs of reviewers; first title and

abstract (TIAB), then full text review if TIAB was of interest. We excluded documents if they met any of the following criteria: 1) described only clinical trials and not observational (or routinely collected) data sources, 2) reported only statistical methods to handle heterogeneity in results (e.g. meta-analysis), 3) applied pharmacoepidemiologic studies that were not focussed on methodology or providing guidance, 4) papers otherwise out of scope (e.g. pre-clinical studies). We included documents if they reported at least one of the following:

- description of HDS (relevant descriptions of multiple data sources, tools to report on HDS, guidance on reporting HDS), or
- strategies to leverage on HDS to improve evidence.

Data extraction. A data extraction tool was designed and

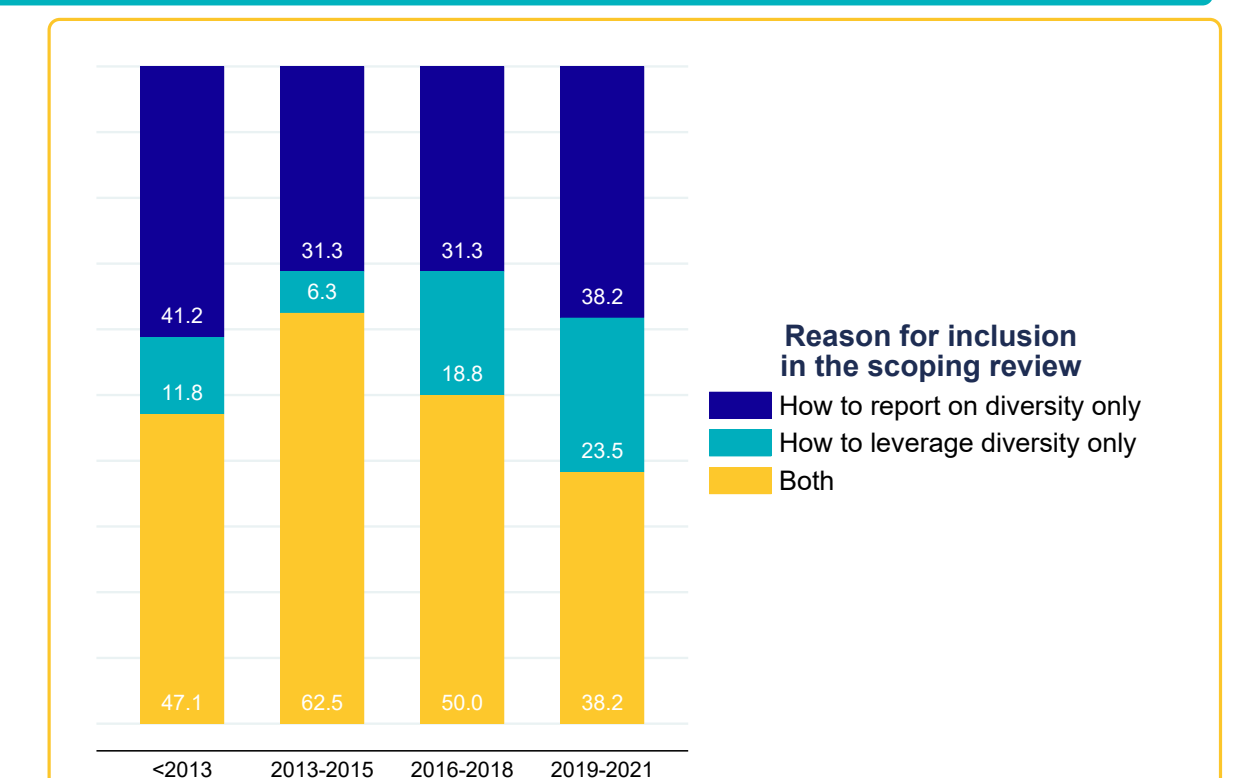
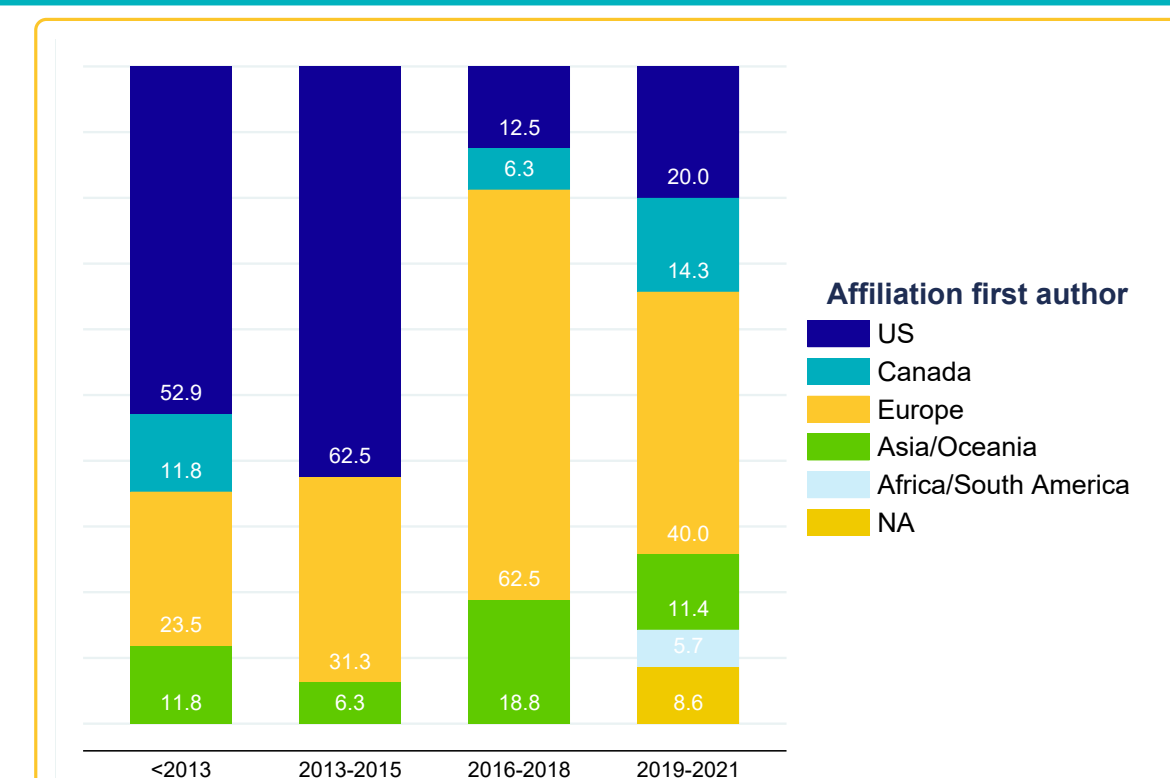
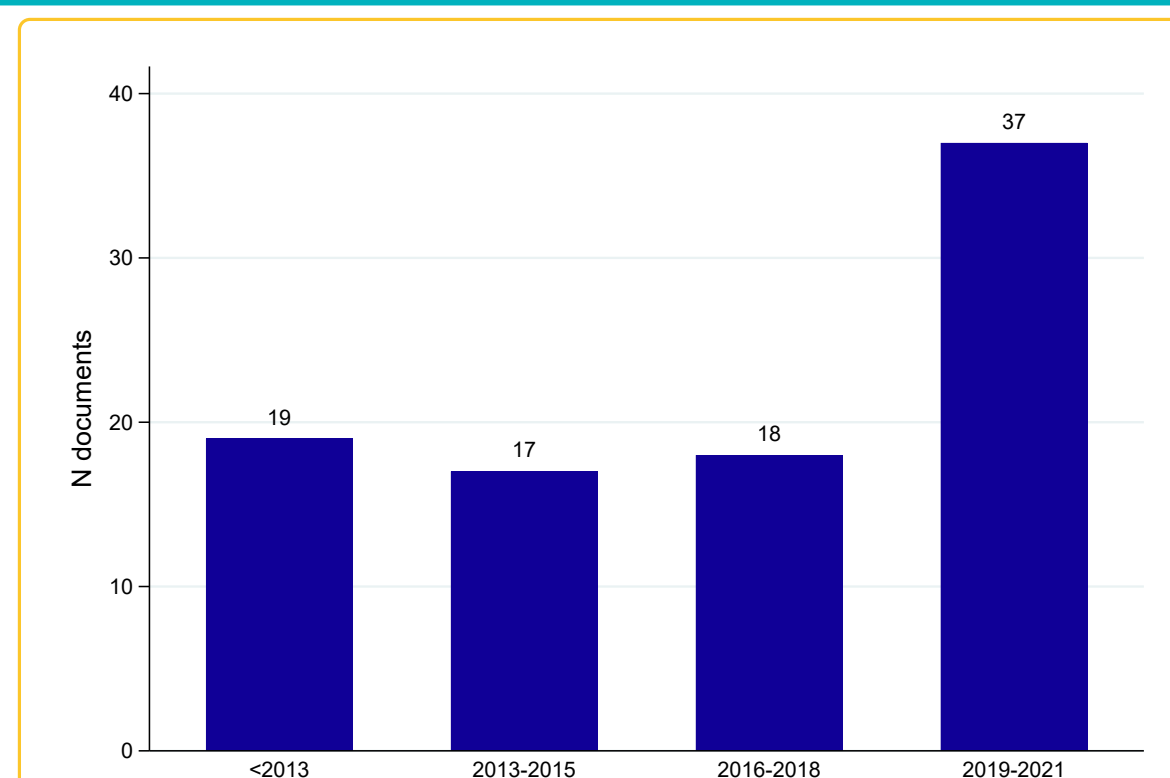
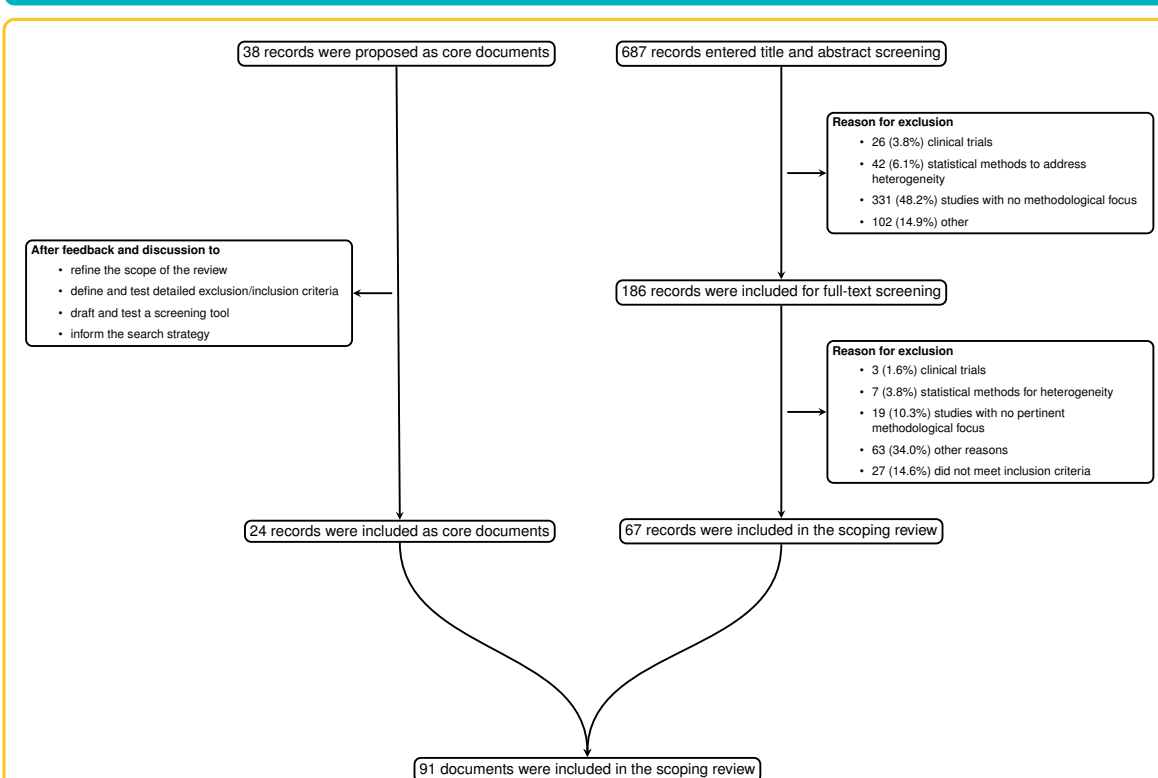
used to extract from the selected documents year of publication, affiliation of the first author and categorical questions on

- which categorical items were used to describe/report on data sources and
- whether heterogeneity was seen as a challenge and/or as an opportunity

Text was extracted alongside each categorical variable. **Data analysis.** A descriptive analysis of the categorical variables was conducted. Extracted text will undergo content analysis.

Transparency. The protocol and reports of the activity are published in the EU PAS Register, EUPAS39757, www.encepp.eu/encepp/viewResource.htm?id=39758.

PRELIMINARY RESULTS

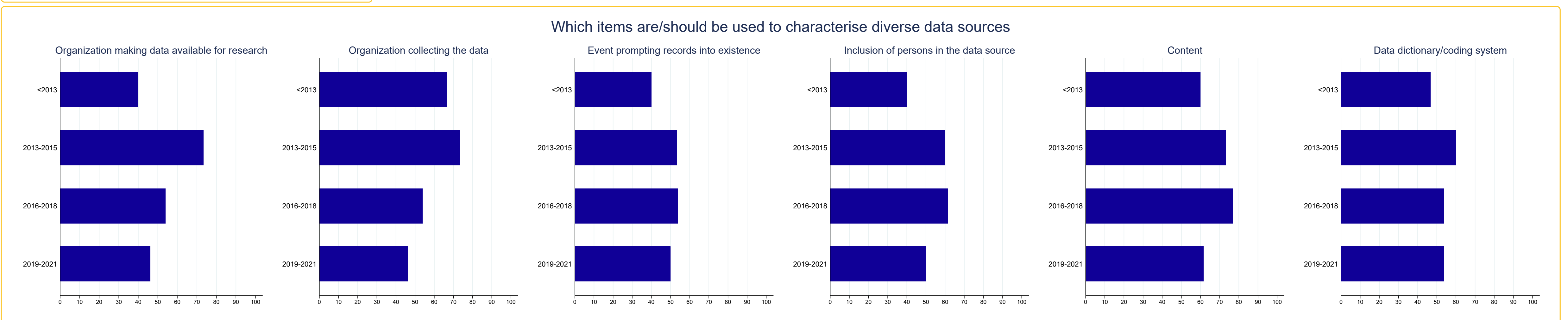


Selection. Screening of 38 candidate core papers led to inclusion of 24 documents. The search strategy produced a list of 687 unique records. After screening, 67 additional documents were included. The total number of documents included in the review was 91.

Characteristics of the documents across time. During the last three years an increase was observed in the number of papers included in the scoping review, up to 37, almost doubling the number observed

in the previous periods. Before 2013 the majority of the papers were authored in the United States, Europe became prevalent in the period 2015-2018, in the last 3 years all continents contributed documents to the

review. Categorical items to describe HDS were indicated/recommended in an inconsistent manner across documents, and no clear trend was observed.



CONCLUSIONS AND NEXT STEPS

- This scoping review identified 91 documents including or suggesting recommendations to describe, report on or leverage HDS for pharmacoepidemiologic research
- 2019 to 2021 saw more publications and first authors from every continent.
- Content analysis will extract which strategies are used or recommended in order to leverage on diversity
- Knowledge gaps will be identified
- This scoping review will eventually inform the development of a guidance paper

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