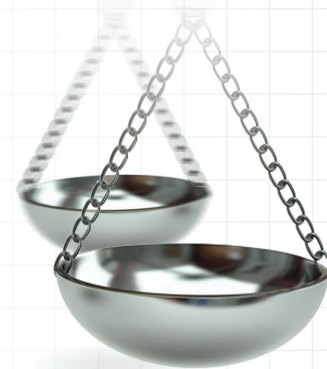




Availability of secondary healthcare data for conducting pharmacoepidemiology studies in Mexico: a systematic review

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Aim: To investigate the data sources available in Mexico for real-world research. **Materials & methods:** A systematic literature review on PubMed, EMBASE and VHL using a combination of controlled vocabulary and keywords for the concepts of electronic health records, epidemiologic studies and Mexico was performed. **Results:** A total of 331 articles and 89 conference abstracts reporting real-world studies were identified. These included 320 data sources: 142 unique named databases, 172 unnamed databases from specified providers, and 26 electronic medical record datasets. The main data sources came from healthcare institutions (35%), followed by government agencies (26%). The most frequent database design corresponded to surveys (34%) and disease registries (20%). Most databases included cohort studies (43%), population-based (25%) and cross-sectional studies (18%). Specific diagnostic tests (28%), access (22%) and pharmacological treatment (21%) were the most common issues analyzed in databases at patient-level data. Neoplasms, cardiac disorders and infections/infestations were the most common therapeutic areas analyzed in databases. **Conclusion:** In Mexico, the use of databases has increased, driven by governmental and nongovernmental organisations and companies. However, further efforts are still needed to improve the quality and knowledge of real-world evidence.

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Keywords: drug utilization • electronic health records • Mexico • pharmacoepidemiology • secondary source

Clinical trials currently represent the gold standard for analyzing the efficacy and safety of a new drug or strategy in a controlled environment, with a well-defined population, with specific inclusion and exclusion criteria and strict follow-up [1]. However, as the population included in clinical trials is somewhat selected in experimental conditions, the information provided by these studies cannot always be extended to patients daily attended in clinical practice. For example, real-world pharmacoepidemiology studies include people who are often excluded from clinical trials, such as those with multiple chronic conditions or disabilities that may limit them. Furthermore, the extensive monitoring that takes place during clinical trials is not representative of routine clinical practice, nor would its implementation be practical due to the associated costs. This statement highlights that, in certain cases, variations in the effectiveness and safety of specific medications among individual patients may not be identified during clinical trials. There are other reasons why clinical trials may not be feasible. For example, it is unethical to randomly assign participants to a drug with a poor safety profile when comparing medicines. In summary, real-world evidence (RWE) may provide complementary information that is important to determine which treatment is more suitable for certain subgroups of patients not well-represented in clinical trials [2,3].

In this context, drug makers, regulatory agencies, healthcare professionals and payers are progressively turning to real-world data to response questions that cannot be evaluated in clinical trials, such as everyday safety, effectiveness and cost-effectiveness of the different therapeutic approaches [4–6]. RWE research using secondary data sources, including electronic health records, pharmacy or insurance claims, among others is useful to better understand how a drug is being used in clinical practice [7,8], the safety profile across all subpopulations [9], comparative effectiveness [10,11] and intervention related healthcare costs [12,13].

The majority of healthcare-related data sources of RWE comes from United States and Europe [14–16]. Although this information is relevant, it cannot necessarily be translated into Latin America population. Despite in Latin America a continuous evaluation of safety and effectiveness of new treatments is required, there is a great variability in the amount, quality and standardization of patient-level data resources [17–19]. In this context, it is important to generate local data on disease epidemiology, drug utilization, effectiveness, safety and/or customers preferences.

Although hospitals and healthcare centers in Mexico are adopting electronic medical record systems that may facilitate the collection of patient data, diagnoses, treatments and outcomes, it is still unknown the data sources available in Mexico for real-world research. Recognizing these data sources would facilitate tailoring the medical strategy based on local evidence and building strong relationships with stakeholders based on collaborative initiatives. The objective of this study was to investigate the data sources available in Mexico for real-world research by conducting a literature review of real-world studies and extracting the details of the data sources (registries and databases) utilized in these studies.

Materials & methods

To address the primary objective of the study, the methodology for all literature reviews involved conducting comprehensive literature searches, systematically screening publications to identify those relevant, and subsequently extracting data regarding the information sources used in real-world research.

Search strategy

A systematic literature review was conducted following PRISMA guidelines [20,21]. A comprehensive search strategy for peer-reviewed articles was conducted to identify literature published prior to the start of 2020 in the following bibliographic databases: PubMed, Embase and Virtual Health Library (VHS, *Biblioteca Virtual en Salud* [BVS] in Spanish), which includes Latin American sources. A combination of controlled vocabulary and keywords was used to perform the search strategy and included electronic health records (EHR), databases, epidemiologic studies (with different designs) and Mexico. The operators “AND” and “OR” were used to combine these concepts ([Supplementary Material](#) Search strategy). English and Spanish manuscripts, from journal articles and congress materials were included in the search without any other limits. All citations were introduced into a citation management system and duplicates were eliminated.

Eligibility criteria

Analytical studies performed on secondary data sources originating from Mexico were considered for inclusion into the study. These involved publications reporting real-world studies (observational studies, including database studies, cross-sectional studies, registry studies, pharmacoepidemiologic studies, pharmaco-economic studies, population-based studies and safety studies, among others). Secondary data sources were considered as articles that analyzed data already collected for other purposes (e.g., EHR, administrative and commercial databases, insurance records, disease and drug registries). If the database covered different countries, this was considered if information from Mexican patients was available. The reported data sources should meet one of the following criteria: EHR plus named hospital/institute source, unnamed ‘database’ or ‘registry’ plus named hospital/institute source, named database or registry (e.g., ‘GARFIELD-AF registry’) and/or a database or registry, as part of the study reported in the publication.

By contrast, studies performed under a ‘primary data collection’ approach [22], case reports, case series, pharmaco-economic models, review articles, editorials, policy-related articles and studies not involving Mexican data were excluded from the search.

An external qualified organization (PGA Farma) performed an initial screening of titles to select the eligible articles for abstract review and full-text data extraction by the authors. After exclusion of articles based on information in the title and abstract, full text screening was performed by the authors to determine the final inclusion.

Data extraction & analysis

For each publication, data were extracted into prespecified extraction tables using a standardized collection form. Two independent reviewers performed the search strategy and extracted each study. In case of disparities, consensus was reached after discussion. Key data for extraction included the following: publication metrics (e.g., full citation, authors, and article type), details of the real-world study reported in the article (e.g., study design, study aim, and types of data gathered from databases), and details of the real-world data sources described in the study

methods (e.g., database name, size, description, data contents, and hyperlinks to the database online). For articles that reported multiple data sources of interest, each database was extracted as a separate row in the spreadsheet. Each publication reporting on the same data source was compared side-by-side to cross-check the database-specific information. All information was harmonized between such publications. For each identified database, the data extraction was supplemented by searches online. The authors performed the data extraction on Microsoft Excel. Subsequent quality assurance was performed in order to verify data quality.

Results

The PubMed, EMBASE and VHL searches yielded a total of 3617 publications. Of these, 399 corresponded to duplicates, and thus, the titles/abstracts of 3218 articles were screened. Among these, 2486 articles were excluded, and 595 articles were fully text screened, of which 20 were related to congress material, 198 were excluded and 46 articles were not available. As a result, 331 full text references were included. Additionally, 157 congress abstracts were considered, but after exclusion of 68, 89 were finally included. Therefore, overall, 331 articles and 89 conference abstracts reporting real-world studies were identified (231 articles were reported in English and 100 articles were reported in Spanish), had interpretable data, fulfilled the eligibility criteria and were used for data extraction (Figure 1).

Regarding secondary healthcare databases in Mexico, 518 data sources were reported. Across the database descriptions extracted, 137/518 were supplemented with online information and 81/518 were supplemented with information from other publications extracted in the review. Among the 518 data sources extracted, there were numerous duplicates; for example, 27/518 of the extracted sources corresponded to the ENSANUT – Mexican National Survey of Health and Nutrition ('Encuesta Nacional de Salud y Nutrición Cuernavaca, México: Instituto Nacional de Salud Pública), 320 data sources, covered 142 distinct named databases, there were 172 unnamed databases from specified providers and 26 electronic medical record datasets from specified providers. Patient-level information was available in 110 databases and were used by in the 420 articles as the data source. The most frequently-reported data source types were unnamed databases followed by ENSANUT, MHAS/ENASEM - Mexican Health and Aging Study (Estudio Nacional de Salud y Envejecimiento), CONAPO – database of population projections – (Datos de Proyecciones de la población) and ENIGH – National Survey of Household Income and Expenditures – (Encuesta Nacional de Ingresos y Gastos de los Hogares) (Supplementary Table 1). Additionally, the most frequently reported data source types at specified hospitals or institutions were unnamed database, followed by IMSS – Mexican Social Security Institute (Instituto Mexicano del Seguro Social) and INCMNSZ – Salvador Zubirán National Institute of Health Sciences and Nutrition, Mexico City (Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán) (Supplementary Table 2). Electronic medical records were the most common databases used for pharmacoepidemiology studies (Figure 2).

The number of publications using secondary data sources has progressively increased every year, from 1 to 2 per year in the early 90s to 40 per year in 2018 (Figure 3). The main characteristics of the databases identified are presented in Table 1. The main data sources came from healthcare institutions (35%), followed by government agencies (26%). The most frequent database design corresponded to surveys (34%) and disease registries (20%). Most of databases included cohort studies (43%), population-based (25%) and cross-sectional studies (18%). Specific diagnostic tests (28%), access (22%) and pharmacological treatment (21%) were the most common issues analyzed in the databases at patient-level data. Benign and malignant neoplasms, cardiac disorders and infections/infestations were the most common therapeutic areas analysed in databases (Supplementary Table 3 & Figure 4).

The description of global and regional data sources is reported in Supplementary Table 4, with 38 articles, 61% reporting data only from Mexico and the remaining 39% not only from Mexico, but also from other countries. They were focused on disease epidemiology (82%), effectiveness (11%) and drug utilization (7%) [23–60]. The description of local disease and drug registries is reported in Supplementary Table 5, with 89 articles, 75% reporting data only from Mexico and the remaining 25% data not only from Mexico, but also from other countries. They were focused on disease epidemiology (65%), drug utilization (15%), effectiveness (8%) and drug safety (2%) (in 10% this information was not available) [23–111].

Discussion

This study was aimed to build and expand the capabilities to identify, acquire, maintain and use RWE in-house in Latin America with a particular focus on Mexico and to demonstrate the importance and impact of generating and

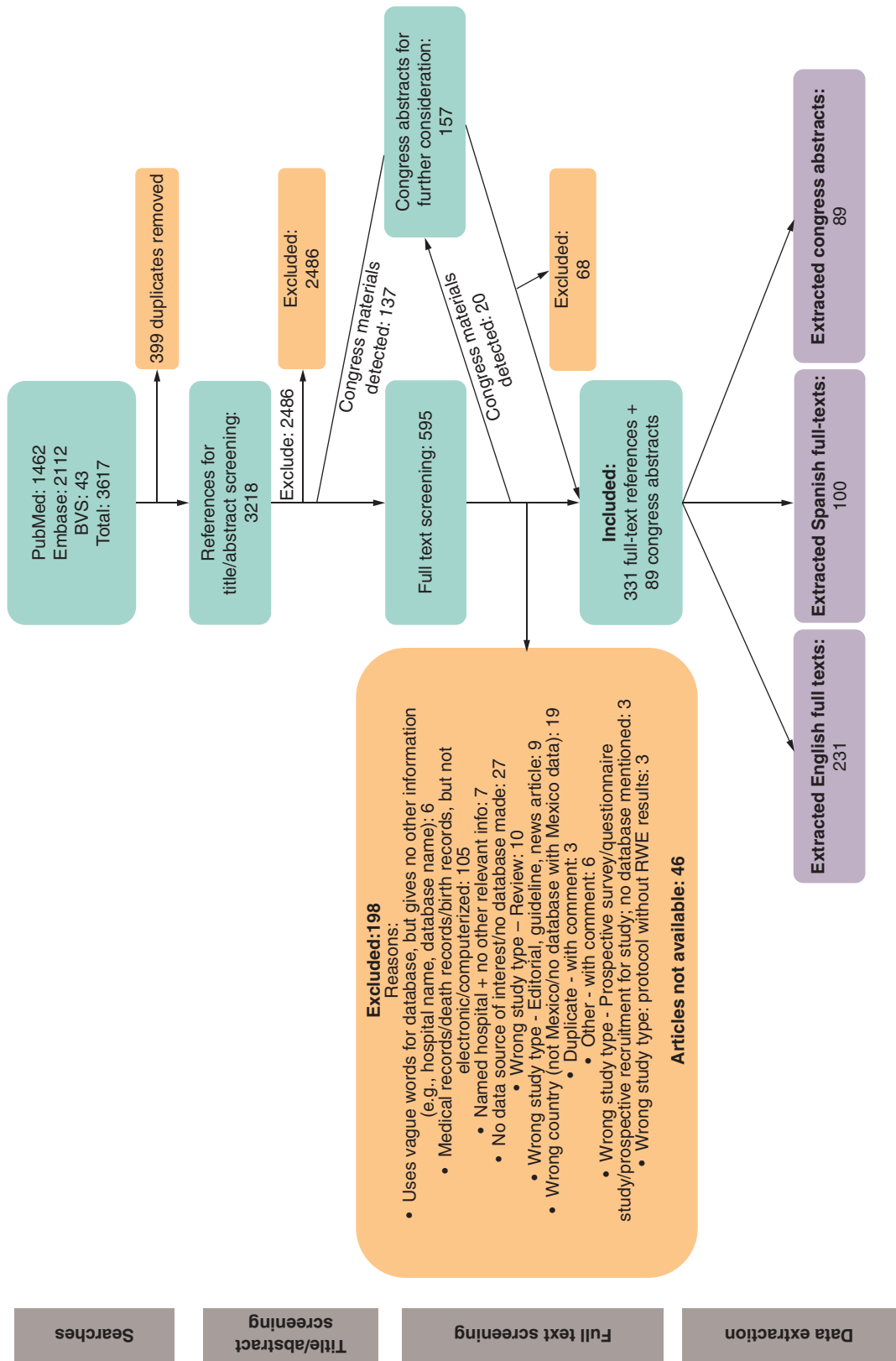


Figure 1. Flowchart of article selection.
BVS = VHL: Virtual Health Library.

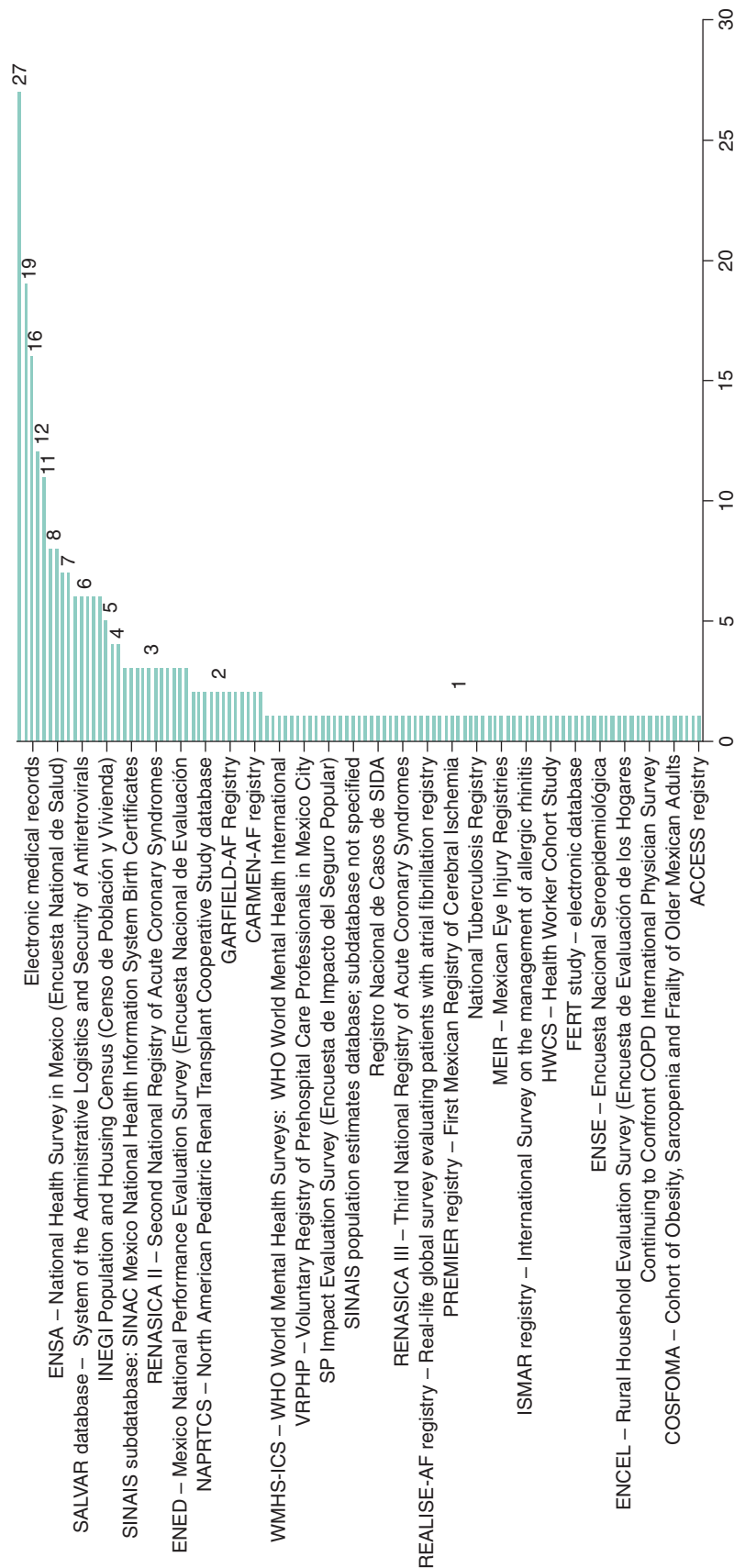


Figure 2. Databases used for pharmacoepidemiology studies.

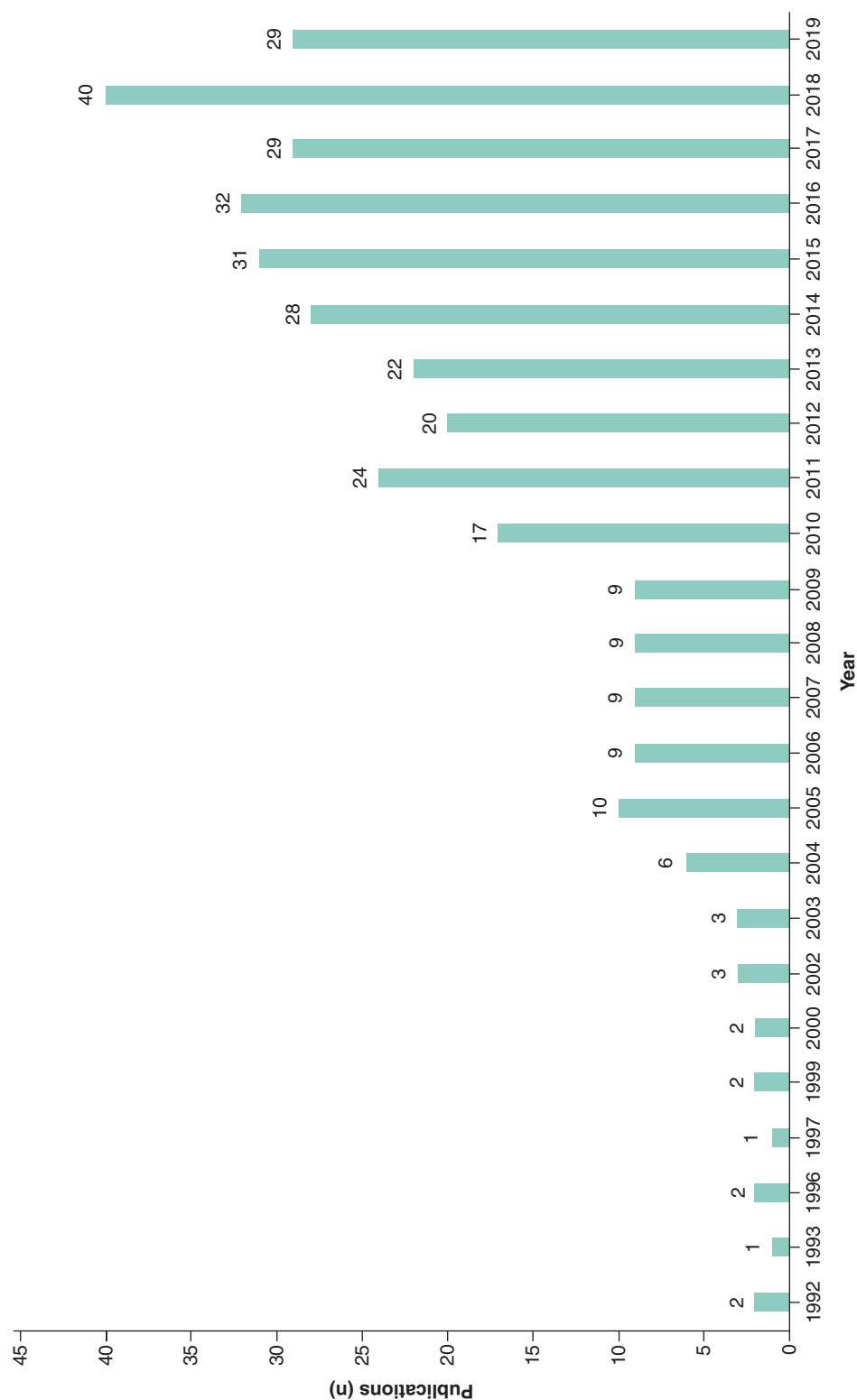


Figure 3. Number of publications using secondary data sources per year.

Table 1. Main characteristics of the databases identified.

Classification of data sources	Frequency
Healthcare institution	35%
Government agency	26%
Nongovernment agency	9%
Health insurance company	8%
Other	18%
NA	4%
Database design	Frequency
Survey	34%
Disease registry	20%
Administrative	11%
Electronic health records	8%
Drug registry	2%
Others	11%
NA	14%
Study designs	Frequency
Cohort study	43%
Population-based	25%
Cross-sectional study	18%
Pharmacoeconomic study	6%
Drug utilization study	5%
Case-control study	3%
Patient-level data available	Frequency
Specific diagnostic tests	28%
Access	22%
Pharmacological treatment	21%
Disease diagnosis codification by ICD-10	11%
Disease/Drug costs	9%
Adverse event information	6%
Quality of Life (QoL)	2%
Drug codification by ATC	1%

ATC: Anatomical Therapeutic Chemical Classification System; ICD: International Classification of Diseases; NA: Not available.

disseminating local data on disease and product related access to medical care and treatment results for our internal and external stakeholders. Furthermore, our study may aid in developing a search strategy that other researchers can use as a template, and it offers a repository of data sources for generating RWE in Mexico that could benefit fellow researchers.

In order to reach these objectives, special care was taken in the methodology and data extraction. Thus, regarding the screening of the literature, since there was heterogeneity across publications in the level of methodological detail reported in the title and abstract, rules were developed to define the minimum requirements for inclusion of an abstract. Data sources were often described as named studies/surveys or acronyms. It was not always clear if there was an associated database for a named study. To ensure there was no associated database, research was conducted online prior to exclusion of any named studies/acronyms. In cases where it was not possible to verify if a database source was used, the study was excluded. Although some publications used the word 'database' as a general term to describe the results of a study, whether it was not possible to determine if a database of interest had been made as part of the study (and would be usable as a source for future work), the study was excluded. There were inconsistencies in the use of the term 'registry' across the literature. For instance, in some cases, the term 'registry' referred to a database source of interest, but in others 'registry' was used as a synonym for 'registration' and did not refer to a data source (this was very common in Spanish articles). Cases where it was not possible to verify if a database source was used, the study was excluded. To maintain the consistency for screening English and Spanish articles, because of differences in the terminology and key words, Spanish articles were screened using the same criteria as

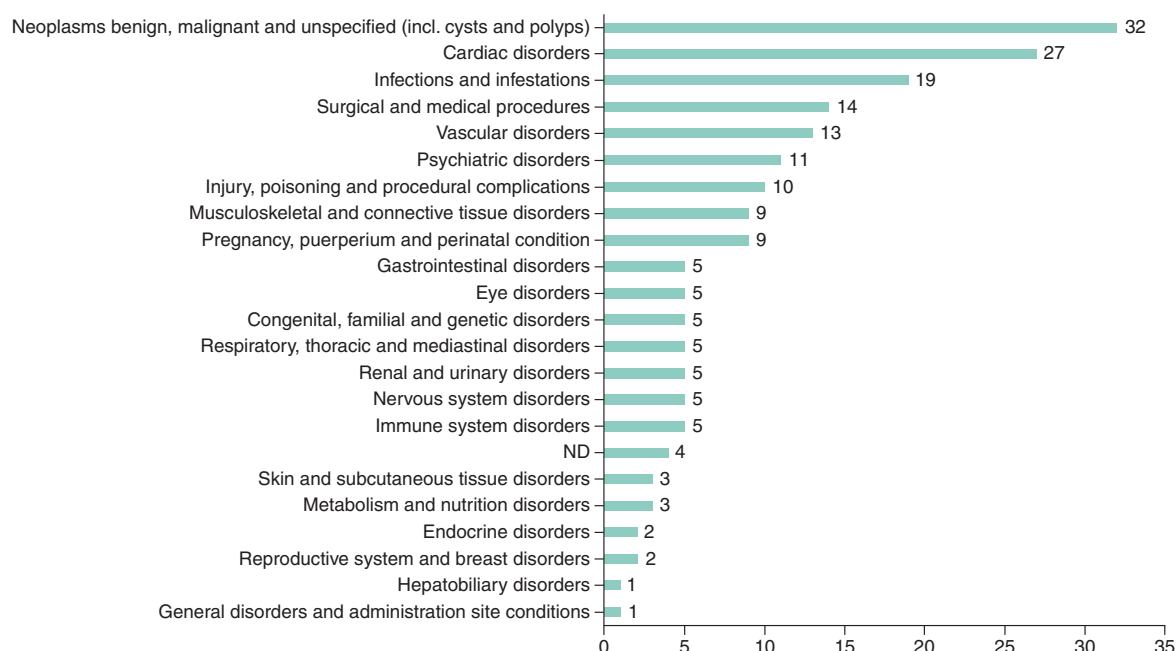


Figure 4. Therapeutic areas of databases.

for English articles. In those cases, in which it was difficult to ascertain whether two publications were using the same database, cross-checks were performed to identify evidence for alternative names online or hyperlinks that led to the same database webpage. As some publications reported numerous database sources, the number of data sources associated with each publication was recorded in separate rows.

In our study, after an extensive search, a total of 331 articles (70% in English and 30% in Spanish) and 89 conference abstracts reporting real-world studies were identified. About secondary healthcare databases in Mexico, 518 data sources were initially reported, but after eliminating duplicities, 320 data sources, covered 142 distinct named databases, there were 172 unnamed databases from specified providers and 26 electronic medical record datasets from specified providers. Our study also showed that the number of publications using secondary data sources has progressively increased in the last decades. This does not only occur in Mexico, but also in other countries from Latin America [17–19]. In fact, secondary data sources provide important and extensive information that have become extensively used over the recent years worldwide [112–115].

In Mexico, the databases sources came from administrative data, electronic medical records and registries originating from government agencies, healthcare institutions and pharmacy dispensing companies, being surveys (34%) and disease registries (20%) the most frequent database designs. One of the main problems with secondary data sources is that the information from different sources is heterogeneous, without linkage between them. This occurs not only because of technical difficulties, but also due to privacy/property concerns [113,116]. This makes more difficult the interpretation of the data, as the differences in the results between sources may not be real, but the consequence of disparities in quality recording, confounding control, missing data or misclassification [113,117]. As a result, extensive quality control measures are required and interpretation of the data from different databases sources should be performed after an extensive analysis of the quality of the information.

The majority of data provided from Mexico sources and only a small amount as part of international data. Data sources mainly focused on disease epidemiology, drug utilization, drug effectiveness and drug safety and also covered the most relevant diseases, particularly cancer, cardiac disorders and infections. Therefore, these results emphasize the role of Mexico in collecting data from different sources and the use of this information to develop epidemiologic research with important impact on clinical practice. A recent analysis has shown that there are relevant differences in the quality of RWE in Latin America and that this RWE is not consistently used in healthcare decision making [17]. Our study showed that in Mexico, important efforts are being made to improve the quality of data sources in order to increase their application on healthcare decision making. In this setting, this research could assist in developing a database repository for RWE reporting in Mexico and help identify RWE studies within pharmacoepidemiology.

In Mexico, the most frequently reported data source types were unnamed databases followed by ENSANUT, MHAS/ENASEM, CONAPO and ENIGH. In addition, government main data sources provided from healthcare institutions (35%), and government agencies (26%). Therefore, government databases were commonly used as secondary data sources. RWE is important for physicians and payers to assess clinically relevant end points and estimate the impact of interventions on the quality of healthcare after the analysis of comparative effectiveness and safety of different approaches across therapeutic areas [118]. In this context, in Mexico the government is performing marked efforts to implement information systems that allows the capture of diverse health-related data at a population level [119,120]. In addition to government databases, disease registries actively enroll cases of disease from a well-defined demographic and therapeutic areas, and this could improve the data consistency [25,30–35,37–40,44,46–48,53,56–59]. Both, government and nongovernment databases, offer complementary information that may be very useful for decision making in clinical practice. In response to these efforts, we have shown an increase in the number of publications using secondary data sources in Mexico, which reached 40 per year in 2018, highlighting RWE growth.

This study has some limitations. Although our research employed stringent inclusion criteria, there remains a possibility that certain articles lacking methodological clarity may have been overlooked during the initial title and abstract screening process. Thus, as the search was performed at the article-level, rather than the database-level, only the data sources that were used for publication purposes were included in analysis, but not other data sources. Owing to the volume of literature, it was necessary to initially filter publications according to the information in the title/abstract. It is possible that some relevant articles were excluded owing to lack of methodological detail reported in the title/abstract. In addition, in cases where the location of the study (Mexico) was not specified in the title/abstract/index terms, (e.g., international studies) publications were not captured. Every effort was made to capture all named database or registries that were not clearly described in the publications. However, owing to inconsistencies in the descriptions and, in some cases, lack of information online, some relevant data sets may have been excluded.

Conclusions

Generating and disseminating local data through the access to secondary data sources to validate and contrast local research findings is mandatory to improve healthcare decision making for patients, healthcare professionals, regulatory agencies and internal and external stakeholders. In Mexico, in recent years there has been an increase in the use of these databases, promoted by government and nongovernment agencies/companies. Despite that, more efforts are required to expand the quality and knowledge of RWE. For instance, incorporating updated MeSH or lay terms to reflect the growth of RWE studies could improve the identification of relevant RWE.

Summary points

- Real-world evidence (RWE) provides clinical and health information collected outside of controlled clinical trials.
- In a real-world healthcare setting is a key component of post marketing drug evaluation, and plays a fundamental role in the access of drugs to health systems. Despite that, the availability of secondary data sources in Mexico is not well known.
- In this study we investigated the data sources available in Mexico for real-world research by conducting a literature review of real-world studies and extracting the details of the data sources (registries and databases) used in these studies.
- For this purpose, a systematic literature review on PubMed, EMBASE and VHL using a combination of controlled vocabulary and keywords for the concepts of electronic health records, epidemiologic studies and Mexico was performed.
- A total of 331 articles and 89 conference abstracts reporting real-world studies were identified. These comprised 320 data sources, covered 142 distinct named databases, 172 unnamed databases from specified providers and 26 electronic medical record datasets from specified providers.
- The main data sources came from healthcare institutions (35%), followed by government agencies (26%). The most frequent database design corresponded to surveys (34%) and disease registries (20%). Specific diagnostic tests (28%), access (22%) and pharmacological treatment (21%) were the most common issues analyzed in databases at patient-level data.

Supplementary data

To view the supplementary data that accompany this paper please visit the journal website at: <https://becarispublishing.com/doi/epdf/10.57264/cer-2025-0160>

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Competing interests disclosure

The authors are employees of Bayer Mexico. The authors have no other competing interests or relevant affiliations with any organization or entity with the subject matter or materials discussed in the manuscript apart from those disclosed.

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- **A higher use of research in real-world policymaking is desirable, to better fit to the complex adaptive nature of health systems.**