Characteristics of Real-World Data (RWD) in Spain: A Systematic Review

RWD128

Nilixa Raval[1], MDS, MPH; Nency Joshipura[1], MD

[1] Nyra Health, Piscataway, NJ

BACKGROUND

- Real-world databases (RWDs) are important sources for regulatory, clinical, and reimbursement decision-making for novel medical/health technologies1.
- Spain is the fifth-most populated country in the European Union, with 48.4 million people in 2023. Its health system is largely universal, with 99% covered through public insurance administered through 17 autonomous communities.2
- Limited information on the volume and richness of available RWDs within Spain, given the initiative of the European regulatory agency on the use of RWDs in decision-making

STUDY OBJECTIVES

To summarize characteristics of RWDs pertaining to RWE generation within Spain using a systematic literature review (SLR)

METHODS

- **Study Design:** SLR of Published RWD studies
- **Criteria for Selection of Studies:**
  - An observational study utilizing at least one real-world data source, including claims, EMRs, registry, wearables, and web application, and excluding single centers studies or no specific source data published in the past 5 years
- **Electronic Database Search:**
  - PubMed search (Feb 2024) using search terms related to RWDs
- **Data Screening :**
  - First-pass titles and abstracts were screened to identify studies with specific RWDs, followed by full-text screening of full-text for inclusion
- **Data Extraction & Evaluation**

Table 1. Elements of Data Extraction

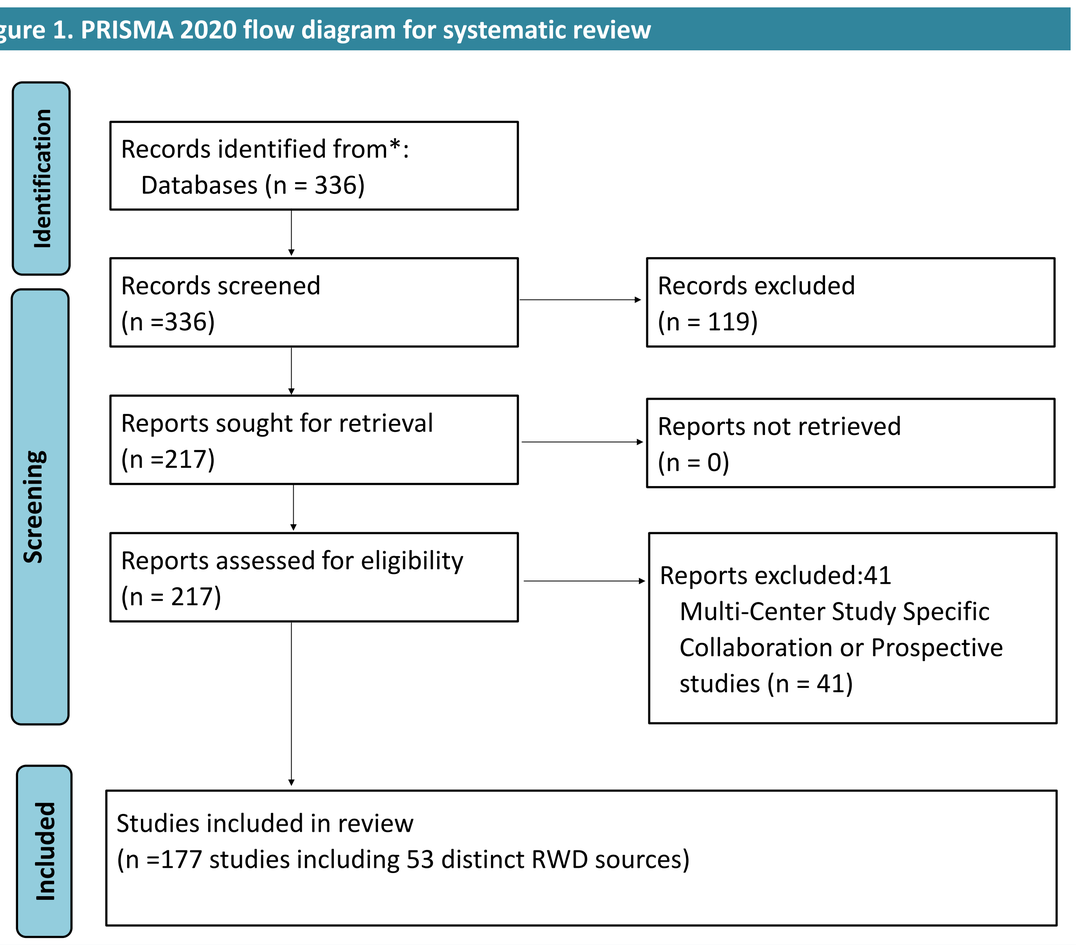
Characteristic	Extracted/Evaluated Information
RWD Types	Claims, EMRs, Registry, Consortium, Wearable/App-based, Survey
Purpose	Transactional; Purpose Driven
Provenance/ Representation	Regionals, Multi-Regional, National
Data Elements with coding semantics	Medical condition, procedure, medications, laboratory, and genomics, imaging and their respective coding semantics
Missingness	Missing constructs/phenotypes within data or entire data
Data Access	Time and resource requirements to data acquisition/access
Data Lag	Data refresh time period

- **Statistical Analysis**
  - Narrative synthesis to describe the characteristics pertaining to quality of RWDs

RESULTS

- Of 336 retrieved citations, 177 studies with 53 distinct sources met the study inclusion criteria (**Figure 1**)

Figure 1. PRISMA 2020 flow diagram for systematic review



RESULTS (Cont.)

- Most common data sources were EMRs and Registry, followed by disease-specific programs, including physician-chart reviewed data, network, surveillance, and other data sources (see Fig.2)
- Given the universal public health system, claims data was generally available through the National Spanish Health System

Figure 2. Types of Distinct RWD Sources in Spain

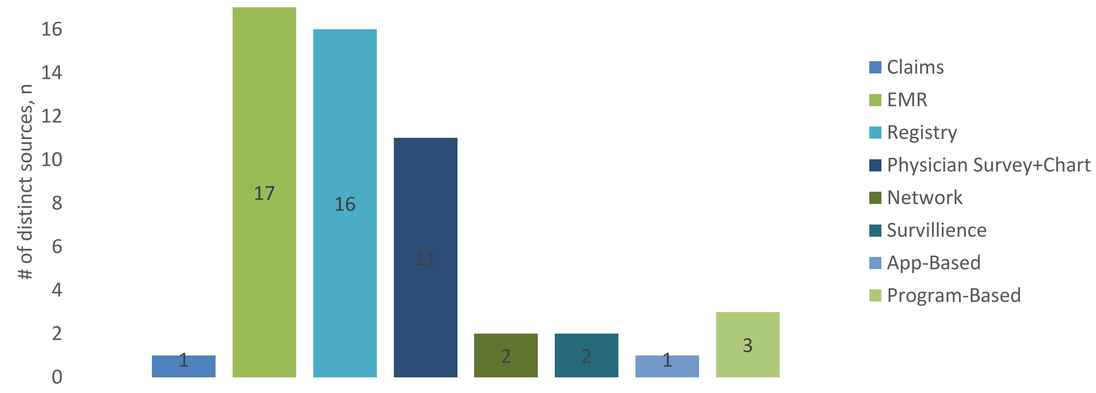


Table 2. Characteristics of EMR and Claims Database in Spain

Type	Database	Representation	Population
Claims	Spanish Health System-National Hospitalization Database	40 M+	All Spain Regions
EMR	BIFAP	26 M; 55% of Spain Pop	9 Regions (92% of Pop)
EMR	BIG-PAC	12 M; 25% of Spain Pop	7 Regions
EMR	Andalusian Population Health Database	8.4 M; 18% Spain Pop	1 Region; Andalusia
EMR	Aragon Health System	2.1 M; 3% Spain Pop	1 Region; Aragon
EMR	EpiChron Cohort	1.3 M; 2% Spain Pop	1 Region; Aragon
EMR	Castilla-La Mancha Regional Healthcare Service (SESCAM)	2.3 M; 5% of Spain Pop	1 Region; Castilla-La Mancha
EMR	Catalan Health Service (CHS)	7.5 M; 16% of Spain Pop	1 Region; Catalonia
EMR	SIDIAP	5.5 M; 16% of Spain Pop	1 Region (75% of Catalan)
EMR	The Valencia Health System Integrated Database	5.5 M; 12% of Spain Pop	1 Region; Valencia
EMR	Canary Islands	2.1 M; 4% Spain Pop	1 Region; Canary Islands
EMR	Galician Healthcare Service (SERGAS)	2.7 M; 6% of Spain Pop	1 Region; Galicia
EMR	Navarra Health Service (BAse Resultados DE Navarra)	118K	1 Region; Navarra
EMR	Health Area V of Murcia (Spain)	1.5 M; 3% of Spain Pop	1 Region; Murcia
EMR	Ribera Saludâs proprietary (Florence) database	25 K	Alicante; 2 Hospital
EMR	IQVIA Cegedim/clinical practice RWD	192 K	3% of Spain Pop
EMR	Madrid-AP	6.7 M	1 Region (12% of Spain Pop)
EMR	Parc de Salut Mar Information System-IMASIS	51 K	1 City; Barcelona

Abbreviations: BIFAP; Base de Datos para la Investigación Farmacoepidemiológica en Atención Primaria; EMR: electronic medical records; SIDIAP: Information System for the Development of Research in Primary Care

- Only two EMR data sources were multi-regionals, whereas the rest of the data were specific to regions or a part of a region (Table 1)
- Primary care served as gatekeeper for advanced outpatient or inpatient use except emergency services. Therefore, the completeness of care was impacted only by immigration to other countries. Almost all data sources had a median data of above 3 years and up to 40 years of duration in some databases.
- Semantics for medications and medical conditions had multiple vocabularies; however, most of the databases, primarily regional EMRs, were available within a common-data model with harmonized coding semantics
- Registry and physician chart reviews were specific to oncology, COVID-19, or rare diseases with rich clinical information in a longitudinal manner
- Data access was subjected to a lengthy review and approval process; whereas, data recency was around 1 to 6 month(s) for EMR/claims

CONCLUSION

- To our knowledge, this is the most up-to-date and comprehensive review summarizing available RWDs in Spain with their characteristics for RWE generation in general
- This review highlights the availability of rich clinical data through regional EMRs, which have almost identical coding semantics and a few variations in the ability to capture disease, medications, and laboratory-related characteristics

References: 1. Ramsey et al. Journal of Clinical Oncology. 2024;42: 977-980; 2. Spain: health system review 2024. HealthSystem in Transition.

Poster Presentation at ISPOR EU 2024, Nov 17- 20, 2024, Barcelona, Spain