Real-world data availability in Latin America: Assessment and implications for research and health care decision-making

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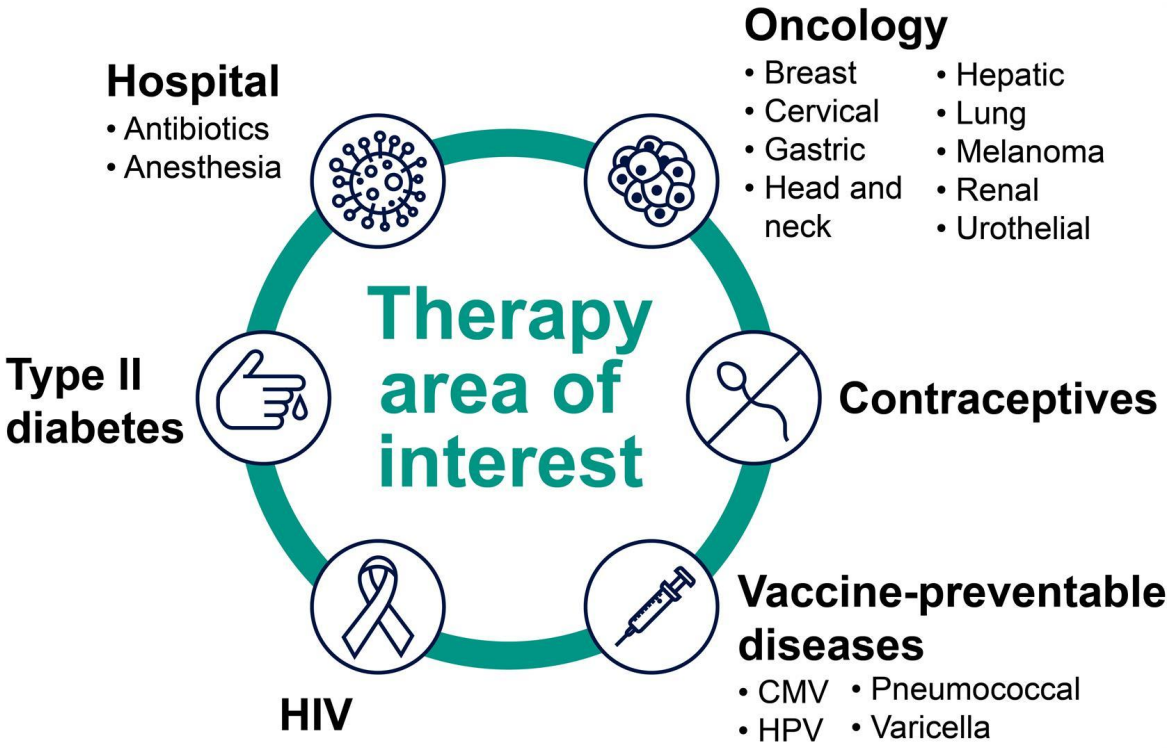
OBJECTIVES

To gain a deep understanding of the real-world data (RWD) landscape through:

- Characterizing and describing existing health care databases in 9 countries prioritized for RWE studies (Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, México, Panamá, Perú) and 18 therapy areas
- Identifying whether RWE is accepted for health care decision-making in Latin America (LA)

Figure 1. Therapy area of interest

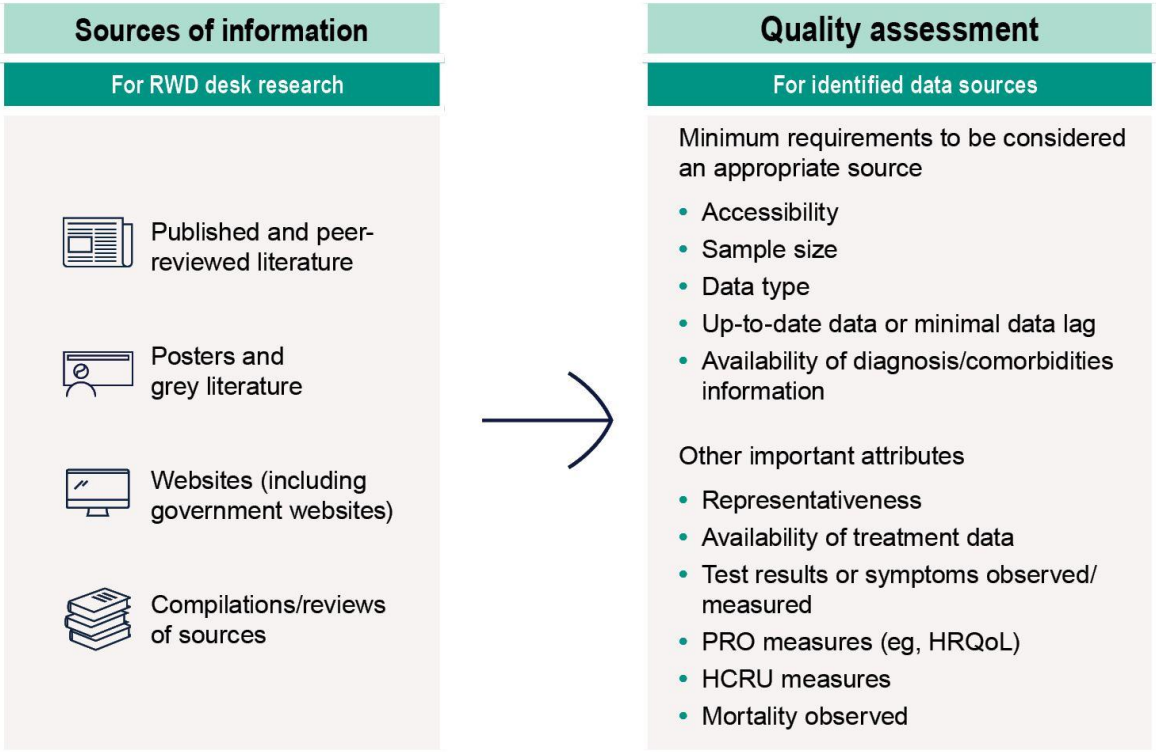


METHODS

Table 1. Methodology

Identification of RWD sources	Triage and extraction	RWD utility assessment	Qualitative assessment of RWD landscape
• Prespecified list of search terms were defined and used as part of an agreed search protocol • Desk research was performed to identify a comprehensive list of RWD sources PubMed BRIDGE TO DATA Google Scholar U.S. National Library of Medicine ClinicalTrials.gov	• Initially identified RWD sources were reviewed and triaged based on RWE needs • Shortlisted sources were further investigated for full evaluation – Accessibility – Most up-to-date – Representative – Treatment data – PRO – HCRU • Definitive source of value to extract • Valuable source but with less priority • Exclude (relatively poorer quality source)	• Prespecified decision criteria agreed to assess utility • Utility of individual RWD sources are mapped out BoI (health care system perspective) BoI (patient perspective) Clinical characteristics Disease history HCRU/cost Quality of life Survival Treatment patterns	• Interviews conducted with payers to ascertain a broad range of insights including: – Current and future perceptions of RWE in payer decisions **Examples of participant profiles:** • Data providers • Users of RWD: Academics, KOLs • Decision-makers • Payers

Figure 1. Sources of information and quality assessment



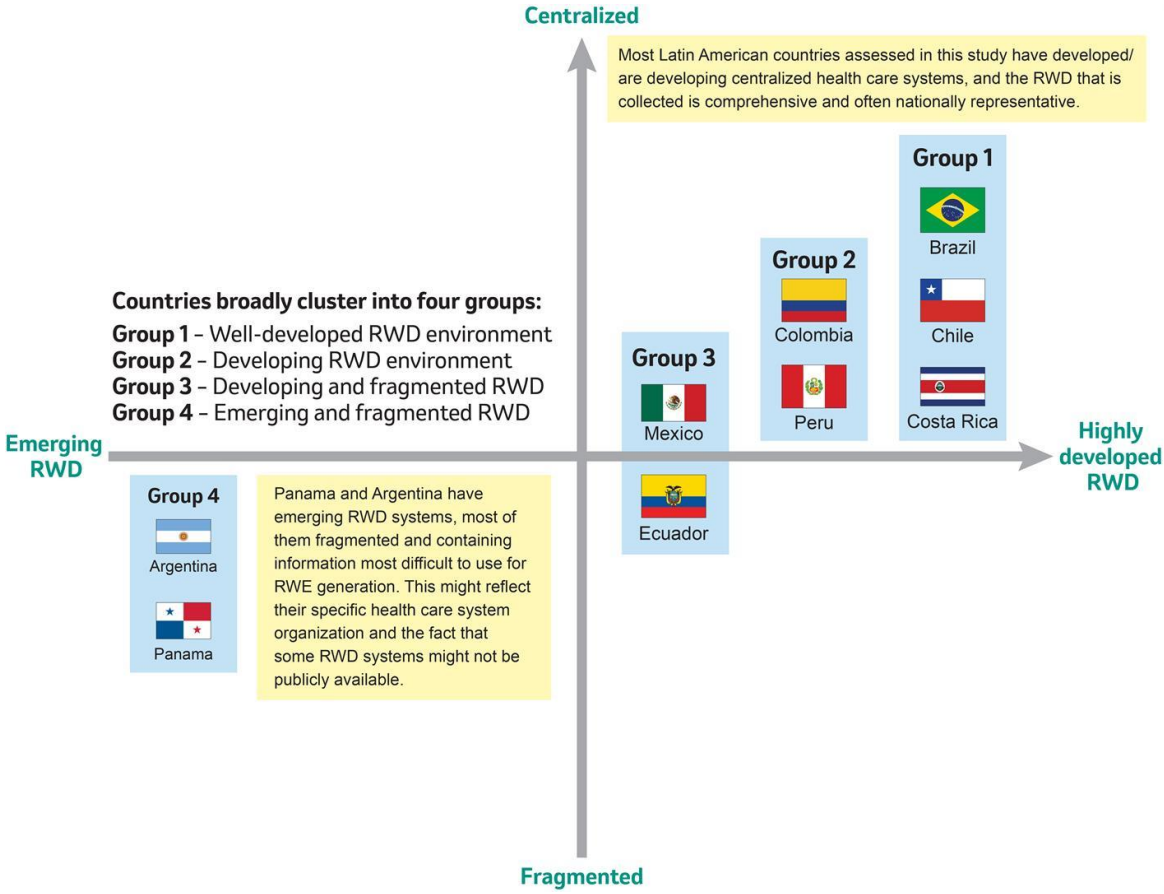
RESULTS

- **98** data sources meeting the quality assessment were identified, including disease-specific registries (26%), public surveys (16%), and electronic medical records (EMR, 16%)
- 25 data sources cover **all targeted therapeutic areas,** while 15 are oncology-specific, 7 are HIV-specific, 7 are specific to vaccine-preventable diseases
- **Brazil** (17%), **Chile** (17%), **Peru** (13%), **Colombia** (12%), and **Mexico** (10%) accounted for most of these RWD sources

Figure 3. Latin America

- In general, **LA countries have a fragmented RWD landscape** due to different levels of health care systems governing RWD collection
- However, there is an **emergence of nationwide health care data management** to collect and use RWD

Figure 4. RWD landscape

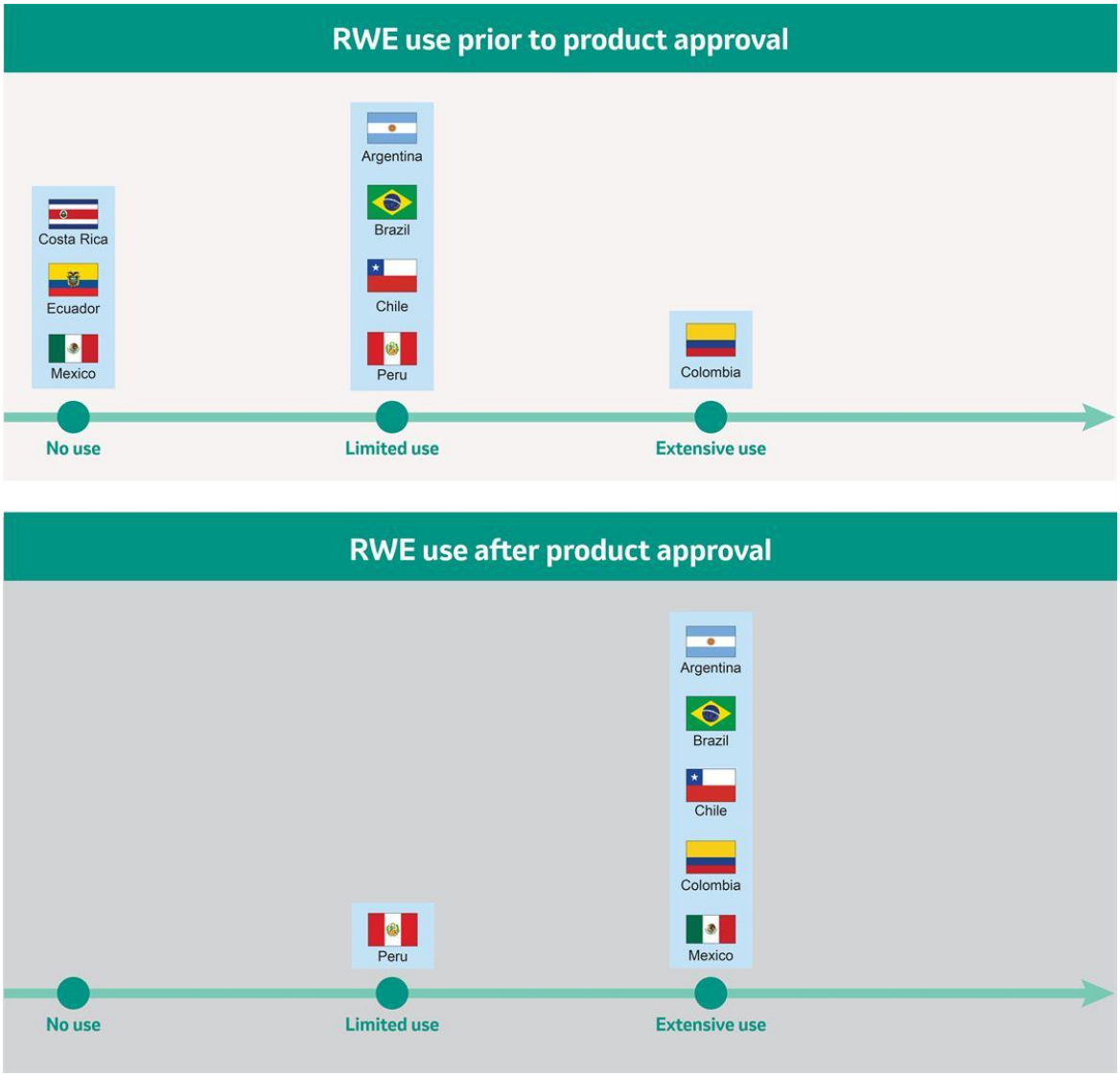


RWD gaps and use of RWE for health care decision-making

- Despite the existence of public surveys and disease-specific registries across the region, the absence of sources with detailed information on **patient-reported outcomes** is the **biggest RWD gap observed**
- Survey respondents[a] across most markets indicated that **RWE is used in decision-making** both prior to approval of health care products, to a limited degree, and following market approval

[a]One participant was recruited from each market matching one of the following profiles: (1) Individual currently directly involved in pricing and reimbursement decision-making (or previously involved no more than 5 years ago) or (2) Individual currently indirectly involved in pricing and reimbursement decision-making (or previously involved no more than 5 years ago) through provision of scientific or medical advice or expertise to decision-making stakeholders.

Figure 5. RWE use


RWE use prior to product approval
Costa Rica
Ecuador
Mexico
Argentina
Brazil
Chile
Peru
Colombia
No use
Limited use
Extensive use
RWE use after product approval
Peru
Argentina
Brazil
Chile
Colombia
Mexico
No use
Limited use
Extensive use

LIMITATIONS

- Sources of data were derived from desk research based on published literature and documents. Hence, there may be data sources that may not have been identified as part of this project
- The feasibility of using the data source for RWE research was not assessed. Some data sources may not be widely accessible to researchers, which may hinder their use in RWE studies
- Although there was a process to assess the relative quality of the data source, this merits further investigation by the end-user to identify potential limitations to answer specific research questions

CONCLUSIONS

- The Latin American RWD landscape is evolving. There is an increased drive to collect RWD nationally, leading to greater availability of general population data sources for RWE research and to inform health care decision-making
- This project enhances the understanding of RWD sources across the Latin America region and will help drive the discussion and potential opportunities to strengthen the RWD landscape in the region
- Recent events, like the COVID-19 pandemic, may heighten the need for governments, health care organizations, and academic/research institutions to develop information system infrastructure to improve the quantity and quality of data to support RWE research

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ABSTRACT

OBJECTIVES: To gain a deep understanding of the Real-World Data (RWD) landscape through characterizing and describing existing healthcare databases and identifying whether RWE is accepted for healthcare decision making in Latin America (LA).

METHODS: To identify and characterize RWD sources in nine countries targeting 18 therapy areas, three consecutive steps were undertaken: 1) comprehensive desk research using a variety of published sources and websites, 2) established and applied criteria to assess data quality, and 3) assessed the ability to address various research questions for data sources meeting pre-specified quality standards. Qualitative, in-depth interviews were conducted with payers and experts in RWD to determine ways that RWE is utilized in each country.

RESULTS: Ninety-eight high quality data sources were identified in total, including disease specific registries (26%), public surveys (16%), and electronic medical records (EMR- 16%). Brazil (17%), Chile (17%), Peru (13%), Colombia (12%), and Mexico (10%) accounted for most of these RWD sources. In general, LA countries have a fragmented RWD landscape due to different levels of healthcare systems governing RWD collection. However, there is an emergence of nationwide healthcare data management to collect and use RWD. Despite the existence of public surveys and disease specific registries across the region, the absence of sources with detailed information on patient reported outcomes is the biggest RWD gap observed. Survey respondents across most markets, indicated that RWE is used in decision-making both prior to approval of health care products, to a limited degree, and following market approval.

CONCLUSIONS: The Latin American RWD landscape is evolving. There is an increased drive to collect RWD nationally leading to greater availability of general population data sources for RWE research and to inform healthcare decision making.

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