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Data sources for drug utilization research in Latin American countries—A cross-national study: DASDUR-LATAM study

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Abstract

Purpose: Drug utilization research (DUR) contributes to inform policymaking and to strengthen health systems. The availability of data sources is the first step for conducting DUR. However, documents that systematize these data sources in Latin American (LatAm) countries are not known. We compiled the potential data sources for DUR in the LatAm region.

Methods: A network of DUR experts from nine LatAm countries was assembled and experts conducted: (i) a website search of the government, academic, and private health institutions; (ii) screening of eligible data sources, and (iii) liaising with national experts in pharmacoepidemiology (via an online survey). The data sources were characterized by accessibility, geographic granularity, setting, sector of the data, sources and type of the data. Descriptive analyses were performed.

Results: We identified 125 data sources for DUR in nine LatAm countries. Thirty-eight (30%) of them were publicly and conveniently available; 89 (71%) were accessible with limitations, and 18 (14%) were not accessible or lacked clear rules for data access. From the 125 data sources, 76 (61%) were from the public sector only; 46 (37%) were from pharmacy records; 43 (34%) came from ambulatory settings and; 85 (68%) gave access to individual patient-level data.

Conclusions: Although multiple sources for DUR are available in LatAm countries, the accessibility is a major challenge. The procedures for accessing DUR data should be transparent, feasible, affordable, and protocol-driven. This inventory could permit a comparison of drug utilization between countries identifying potential medication-related problems that need further exploration.

KEYWORDS
cross-national, drug utilization research, Latin America, pharmacoepidemiology

Key Points

- There is an urgent need to identify and compile an inventory of data sources for drug utilization research (DUR) in Latin American (LatAm) countries.
- The 125 data sources for DUR were identified from nine LatAm countries.
- From nine LatAm countries (Argentina, Brazil, Chile, Colombia, Ecuador, Mexico, Nicaragua, Peru, Uruguay), two (Ecuador and Nicaragua) did not have any publicly available information.
- Disproportionalities concerning the number of publications on DUR in the nine LatAm countries was found.

1 | INTRODUCTION

Knowledge about drug use patterns is crucial in the assessment of the risk–benefit and the decision-making process when selecting appropriate medications and their reimbursement.[1] Drug utilization research (DUR) is a multidisciplinary science that aims to describe and provide understanding on the use of medications in society, using descriptive and analytical methods. One of DUR's basic requirements is the availability of reliable and representative data sources, including primary sources containing data collected prospectively for a specific research objective and secondary sources collected for nonresearch purposes.[2]

An important type of DUR is the Cross-National Comparison (CNC), measuring the patterns, extent, and determinants of drug exposure between countries and between regions within countries.[2–4] An essential requirement to perform a CNC study is the availability of reliable and valid data sources with transparent and clear regulations to access the data.[4]

In Europe, the first initiatives for CNC studies were developed more than 20 years ago. All early CNC initiatives (e.g., EuroMEDSTAT,[5] EuroDURG,[6] and PROTECT) started with the identification of publicly available data sources for use in subsequent studies.[7,8] The first important attempt to conduct a CNC of drug use was focused on differences in the utilization of antibiotics among European countries in the ESAC project.[9]

In contrast with Europe, North America, and Asia, only a few CNC studies on DUR have been carried out across Latin American (LatAm) countries.[10–13] The lack of comparable data sources might be a possible explanation for the gap in DUR among these countries. The socioeconomic and political environment in LatAm countries, and particularly, health systems fragmentation and infrastructure (e.g., lack of well-structured electronic databases, human resources, linkage with several sources, easy communication, etc.) limit the availability of patient-level DUR data.[13,14]

The CNC studies are needed in the LatAm region to inform stakeholders about the patterns and inequalities in drug use, drug-related expenditures and adverse events to improve the health care of these countries' populations. However, CNC studies can only be performed if data sources are available to provide relevant and valid data. Therefore, there is an urgent need to identify and compile an inventory of publicly available data sources useful for DUR in these countries.

The aim of this study was to compile an inventory of available national drug utilization data sources and to characterize these sources, by building network capacity, involving collaboration to improve pharmacoepidemiological research in the LatAm region.

2 | METHODS

2.1 | Design

This is a cross-national comparison study conducted by a network of DUR experts from nine LatAm countries. The approach was to build a network of national teams who were responsible for screening and extracting the data sources by country.

2.2 | Building a network of national teams

Five researchers who are experts in pharmacoepidemiology from Brazil ($n = 2$), United States - US ($n = 1$) and Europe ($n = 2$) designed the study and constituted the coordinating team. Two of these experts participated in previous CNC studies in Europe.[15,16]

The coordinating team invited researchers (suggested by the ISPE Brazilian International Regional Interest Group [BRAZINT – RIG], and DUR Group Latinamerica-DURG LA) that worked in the government sector of 12 LatAm countries (Argentina, Brazil, Bolivia, Chile, Colombia, Equator, Guatemala, Honduras, Mexico, Nicaragua, Peru, Uruguay). A first sample of experts was approached. After their initial contributions, they were asked to identify an additional number of experts. This was repeated until all aspects of information pertaining to data sources for DUR were covered.[17,18]

A multidisciplinary network of national DUR experts involving researchers and data custodians was established. The objective of this network was to investigate the available data sources in each country, in cooperation with the interested parties at the national level.

2.3 | Type of data sources (eligibility criteria)

Data sources for DUR were defined as anyone with information on medicines utilization, including volume and price, supported by governmental organizations (or public agency created by either a national government or a state government within a federal system).

We included routinely gathered administrative and non-administrative drug-related data sources of public or private health organizations that covered jurisdictions (regional or national) or multi-site organizations serving large populations (e.g., a population not

restricted to one hospital, or a specific small setting), which necessarily portrayed data from the public sector.

We excluded data from health insurance companies, sickness funds, and individual healthcare facilities (hospitals, primary care, or specialized clinics).

2.4 | Search strategy and screening process

In the first step, the coordinating team conducted a structured systematic internet searching in the health-related institutional and governmental LatAm countries websites to identify potential data sources for DUR. To optimize this process, the coordinating team identified national DUR experts, or teams and invited them to participate in the study.

In the second step, the national experts in each country contacted other DUR researchers to identify additional potential data sources.

The third step involved searching in bibliographic data sources. The experts searched for studies or documents published between each database inception to October 31, 2020 without any limit regarding publication type or status, in the following web-sources: MEDLINE/PubMed, LILACS (Health information from Latin America and the Caribbean countries), and Scopus. In addition, the experts searched the gray literature such as the CAPES THESES DATABASE (Brazil), national health institutes, bulletins, or other documents of the Ministry of Health and other healthcare providers and health-related institutions in each country. In addition, we performed a manual search (through medical journals or conference publications for reports, which were not indexed in the major electronic databases) and perusing reference lists based on citations of selected documents (Figure 1).

The following keywords were used: "pharmacoepidemiology," "drug utilization," "Latin America," the names of each LatAm country and acronym of data sources. These concept terms were combined with Boolean operators and used along with their English, Spanish, and Portuguese translations.

Experts from each country, working in pairs and independently, conducted an in-depth screening and review of potentially eligible data sources. The divergences about the usefulness of each database for DUR were discussed during the monthly meeting of the coordinating team with the national teams until consensus was achieved.

2.5 | Data extraction and analysis

Once available data sources were identified, we described the characteristics of each database using the Checklist shown in Box 1.

A database was defined as publicly accessible when it was available on websites free of charge and without requiring registration to browse for information. Granularity was defined as the level of geographic area at which data was collected and stored. The information on the data sources (e.g., surveys, pharmacy records, patient records, notifications of suspicious adverse drug reactions) helps identify if the database contains information on the specific DUR topics. For instance, the information on dispensed prescriptions is available in the pharmacy records, while the information on the indication for prescribing is available in the patient records. The national DUR expert teams described the data sources available in their countries.

3 | RESULTS

DUR experts from 12 countries were contacted. Three of them were not able to participate in the study activities and provide the requested information (Bolivia, Guatemala and Honduras). The National teams of nine countries (Argentina, Brazil, Chile, Colombia, Ecuador, Mexico, Nicaragua and Peru) participated. These teams included 44 experts from 32 organizations, Table S1 (supplementary material).

A total of 125 data sources for DUR met the inclusion criteria, while 60 data sources did not, and were excluded from the inventory (Figure 2).

We did not find any published studies that use the DUR data sources from Uruguay, Peru and Nicaragua. Brazil was the country with the highest number of published DUR studies from its data sources.

Table 1 summarizes all information about data sources for DUR in LatAm countries, presenting their main characteristics.

3.1 | Accessibility of data sources

Data sources could be classified into multiple categories specified by the accessibility criteria (Box 1). Overall, thirty-eight data sources were publicly accessible and 89 (71.2%) had access restrictions. Nine data sources had unclear rules for data access and nine were unavailable for public use. Ecuador and Nicaragua did not have publicly accessible data sources; fewer than four publicly available databases were identified in Peru, Chile, Uruguay and Mexico (one, two, two, and three, respectively). Most of the data sources ($n = 44$, 35.2%) were available only to people working at the institutions that that generated the data therein.

3.2 | Type of healthcare provider and sector

Seventy-six data sources provided only public sector data, 46 (36.8%) contained data from both sectors (public and private) and three included data from the private sector but controlled by the government.

Forty-six data sources originated from pharmacy records, 18 (14.4%) came from patient clinical records, nine data sources derived from both pharmacy and patient records, nine from wholesalers, eight were survey data (data sources with information from surveys), and 34 (27.2%)were another type of data (e.g., patient reports, notifications of suspicious adverse drug reaction, lawsuit for medicines etc.).

Chile and Colombia did not have data sources generated by pharmacy records. Nicaragua, Peru, and Uruguay did not have data sources originated solely from patient clinical records.

The majority of data sources ($n = 43$, 34.4%) contained data from ambulatory care, three data sources were based on data from hospitals only, and 64 (51.2%) provided data from both settings

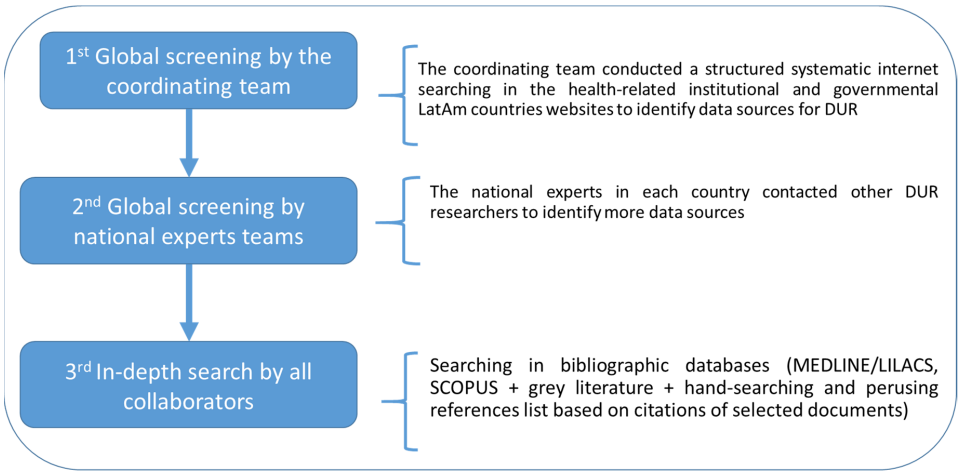

FIGURE 1 Searching strategies to identify Data Sources in LatAm for drug utilization research (DUR)

BOX 1 Checklist of data source

1. Data provider custodian, steward.
2. Type of data source (public, private or both).
3. Health care setting of data sources (hospital, ambulatory care, both).
4. Years of coverage.
5. Accessibility (publicly and convenient; restricted pre-authorized research protocol only access; access limited to or dependent on country-specific legislation; available only to researchers working in the institution; the process for obtaining data is not clear or lacking specific regulation; Not accessible any way/ data not available for public use.
6. Sources of the data (wholesalers, pharmacy/retail outlet, physician, others).
7. Geographic granularity of data (national, regional, municipality, multisited organization, other).
8. Type of data (aggregate or individual-level).

(ambulatory and hospital). Thirty-nine (31.2%) of these databases was classified as able to provide separated information and 25 (20%) without this possibility.

In most countries data generators were the Ministry of Health and Social Security Institutions, regulatory authorities and research institutions.

3.3 | Further characteristics of the data sources, including years of coverage, level of aggregation and geographic granularity

The majority ($n = 85$, 68%) of the data sources provided individual-level data. The level of data aggregation in Argentina and in Brazil depended on the type of accessibility, in which a given publicly accessible data source provided only aggregate-level data while individual-level data could be available only upon request (details on supplementary table). Nicaragua (4/4), Uruguay (8/9), Argentina (28/31), and Mexico (8/11) where most data sources provided patient-level data.

Regarding the geographic granularity of the data, 75 (60%) data sources provided national data with further granularity, 19 national data without further granularity, and 31 (24.8%) provided regional data with or without further granularity.

Twenty-one data sources had 20 (16%) or more years of data coverage, and 45 (36%) were created in the last 10 years. For 44 (35.2%) data sources the year of coverage or creation were not known.

Detailed information on the data sources per country are presented in the supplemental materials Table S2.

4 | DISCUSSION

4.1 | Main findings

The present study compiled an inventory of 125 potential data sources for DUR from nine out of the 12 invited LatAm countries. Bolivia, Guatemala and Honduras did not participate. The majority of data sources for DUR came from the Ministries of Health or other governmental health institutions such as social security and regional or municipal organizations. Most of the data sources were created for administrative purposes in the last 10 years to register and inform on public health sector data. The most frequent sources were those that originated from pharmacy records, which mostly contained individual-level data.

Despite the large number of data sources identified in this inventory, their accessibility was a major concern. In most of cases, data sources were only available to researchers working in the institution in which the data were generated. Frequently, only aggregate-level data were accessible, despite the great number of publicly and conveniently available data sources. In addition, in LatAm countries, 17 data sources were either not accessible in any way or for which the process for obtaining data was not

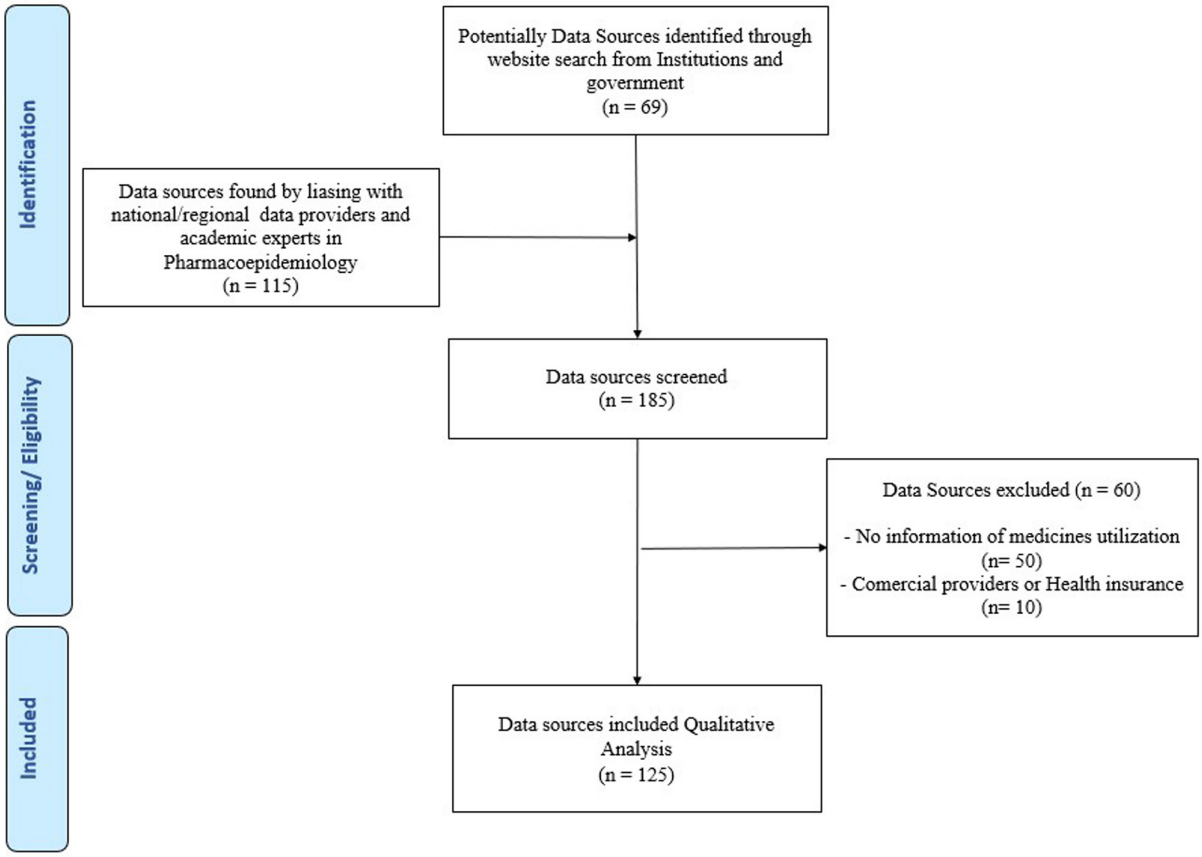

FIGURE 2 Flowchart of data sources for drug utilization research (DUR)

transparent or lacking regulation. Additionally, in two countries (Ecuador and Nicaragua), there were no publicly available data.

Data accessibility is critical for DUR researchers, to inform the decision-making process. DUR information is necessary for strategic planning and priority setting; for assurance of healthcare quality and design of quality improvement strategies; for management of diseases and injuries; and for implementing policies and programs focusing on the acquisition, reimbursement, pricing, and use of cost-effective medicines in clinical settings. These strategies are especially important in settings with scarce healthcare resources and high disease burden, as in many LatAm countries..[19,20] Previous studies have identified that the available DUR data sources in LatAm countries were not used for decision-making purposes,[12,13,21] and this reality must be changed.

The healthcare providers´ and patients´ choices on the use of medicines should be based on the evidence-based information that comes from the rigors systematic research and formal reports of healthcare providers. In addition, DUR information can help citizens to demand effective policies and services and to hold their governments accountable for the allocation and use of resources for health. This is the recurrent context in LatAm and Asian countries, where despite the existence of universal healthcare, no standardized sources for provision of longitudinal data are in-place. We found not only limited access to the DUR data sources, but also lack of transparency in releasing data for national research, considering most of data sources are restricted to certain institutions.

There is a remarkable mismatch between the need for DUR-related information in LatAm countries and the ability of researchers and decision-makers to respond to this need; and this is a lost opportunity for the Region. In contrast, European and North American countries have been successfully using health care data sources to determine the coverage of recently licensed therapies while diminishing price/payment terms based on the actual performance of these medicines.[6,22] In addition, countries where healthcare-related information is routinely collected have used this information to compare use of medicines and their health and economic impact, both within and across nations.[20]

Positive changes in drug licensing, regulation and pricing practices in Europe, and North America have resulted from data gathering and analyzes from multiple data sources or for large populations.[22] In the USA, the Food and Drug Administration constructed a large database of more than 100 million subjects to address the safety and effectiveness of novel medicines. In Canada, the Canadian Network for Observational Drug Effect Studies has similar goals. The European Union has recently launched a Big Data taskforce to address this issue.[22–24]

Although the purpose of the literature search was to detect data sources for DUR and not to make an exhaustive inventory of the publications generated from them, important inequalities in the DUR

TABLE 1 Data sources within Latin American countries meeting the specified characteristics for DUR

Countries	Argentina	Brazil	Chile	Colombia	Ecuador	Mexico	Nicaragua	Peru	Uruguay	TOTAL
Number of data sources by country	31	38	9	12	4	11	4	7	9	125
Characteristics of the data sources										
Acessibility[a] (data source)										144
Publicly and conveniently accessible	4	18	2	8	0	3	0	1	2	37
Restricted pre-authorized protocol-only access	0	1	4	3	3	3	2	0	0	16
Access limited to or dependent on country-specific legislation	1	19	6	0	0	0	0	0	4	30
Available only researchers working in the institution (It is only people that is from the institution that provide the database)	29	6	1	1	0	5	2	0	0	44
The process for obtaining data is not clear, without general regulation	0	0	2	0	1	0	0	6	0	9
Not accessible any way/ Data not available for public use	0	6	0	0	0	0	0	0	2	8
Geographic granularity (data)										124
National data without further granularity	1	1	1	6	0	1	1	4	4	19
National data with further granulatiry	6	29	8	6	4	10	3	3	5	74
Regional data (with or without) further granularity	24	7	0	0	0	0	0	0	0	31
Sector of data source (data source)										124
Public health system	29	20	4	1	3	9	2	5	3	76
Private sector	0	1	0	2	0	0	0	0	0	3
Both	2	16	5	9	1	2	2	2	6	45
Data source generate by (data source)										124
Wholesaler	2	0	3	2	0	0	0	0	2	9
Pharmacy records	27	10	0	0	1	1	1	2	4	46
Patient records	2	5	6	1	1	3	0	0	0	18
Pharmacy and Patients records	0	6	0	0	1	1	1	0	0	9
Survey data	0	3	0	2	0	1	0	2	0	8
Other (administrative records, lawsuit, spenditure, notifications, prices, etc.)	0	13	0	7	1	5	2	3	3	34
Setting of data source (data source)										124
Ambulatorial	28	12	1	0	0	1	0	1	0	43
Hospital	0	1	0	0	0	1	0	1	0	3
Both (possible to separate)	2	10	4	4	2	7	3	5	1	38
Both (not possible to separate)	1	7	4	4	2	0	0	0	7	25
Not applicable	0	7	0	4	0	2	1	0	1	15
Type of data[a]										135
Individual-level data	28	23	3	8	2	8	4	4	8	88
Aggregated-level data	6	22	6	4	2	3	0	3	1	47

[a]The sum might be more than the number of the data sources, considering there were data sources providing more than one type of accessibility and type of aggregate data.

publications in the nine LatAm countries exist. Uruguay, Peru, and Nicaragua do not have published studies that use the DUR data sources in these countries.

To achieve dissemination and use of DUR results, policymakers need to be involved in the research process from the setting of the research objectives. Moreover, data should be open to other institutions other than data owners. Even though most data sources in the studied countries belonged to the ministries of health and other government organizations, they were not publicly available and there was no clear process for accessing these data for decision-making purposes. We believe that government data should be freely available for DUR and for dissemination of results for accountability, administrative and clinical reasons. Multiple studies[22,24] demonstrated that DUR is important to strengthen the countries' health systems' capacities to develop national medicine policies that support equitable access and quality in the use of medicines.[15]

4.2 | Strengths, challenges, and limitation of this study

This is the first study that compiles and describes the inventory of data sources for DUR in nine LatAm countries. The study aimed at facilitating the progress of DUR studies and cross-national comparison of drug-related issues and improving drug-related policies in these countries. The creation of a DUR sources inventory was possible due to the voluntary cooperation of the DUR experts and the support of the International Society of Pharmacoepidemiology, showing that cooperative work can overcome country boundaries and advance knowledge.

The strengths of this study include the comprehensive search strategy, the use of the predefined checklist to describe characteristics of the databases for DUR and the inclusion of nine LatAm countries.

This study represents an important step forward to develop pharmacoepidemiologic research in the LatAm region. It aligns with the PROTECT EU[7,8] and The European Surveillance of Antimicrobial Consumption (ESAC)[9] cross-national comparative studies. The PROTECT EU started by building an inventory of drug consumption databases across Europe useful for DUR purposes, while the ESAC project mapped available data sources on the use of antimicrobial drugs.

The present study compiled inventory is useful to identify the opportunities for future DUR within and among countries, promoting networking of LatAm researchers. For instance, within countries, the databases that have a unique identifier (e.g., databases of patient records in family medicine clinics and hospitals, such as SIMF–IMSS and SICEH–IMSS) might be linked with each other, as well as with other databases that have such identifier (e.g., mortality database). Additionally, among countries, the databases with similar sources (e.g., patient records), similar granularity, and similar type (e.g., individual level) might be compared after unifying the names of the variables and their categories. The comparisons within and among countries are crucial for evaluating drug safety and effectiveness and of value to regulatory and health policymaking.

Our research has some limitations and challenges. First, some data sources could have been missed because of the difficulty of accessing the websites of the healthcare institutions in LatAm countries, or because there are still health institutions with only paper-based data sources. Second, we did not perform a systematic review, but a comprehensive broad exploration of the current DUR data sources in the studied nine LatAm countries. Third, this study only intended to identify and characterize the available and accessible data sources in the LatAm countries. We investigated the characteristics and the content of the DUR useful data sources. As suggested by the PROTECT EU[7,8] and the ESAC[9] projects, before focusing on the quality of the information in the databases, the researchers have to know the available data sources and type of information they provide.

Further research is needed to evaluate the completeness and accuracy of each data source. However, we do not expect identified data sources to be complete and accurate in the sense of having linkage with patient demographics and health status. Even in Europe, 20 years after establishing their first inventories of DUR data sources, most countries do not have comparative national data available for all medications, with complete information accessible for research purposes and ready for data linkage. Fourth, there is a possibility that other suitable databases exist whose information is not publicly available. For instance, private data sources were not included. Also, some sources of information are only available after paying for the access, while it is a common circumstance that LatAm researchers have funding constraints for conducting research. Fifth, publication bias might have occurred due to the using sources available on websites or those only reported in publications.

5 | CONCLUSION

The present study identified a large number of the DUR-relevant data sources in nine LatAm countries. The compiled inventory has a great potential for DUR. Validation of these data sources, however, should be a topic of further studies.

The accessibility to these databases represents an important challenge. The national health information systems with clearly defined access rules for DUR should be promoted to overcome the current data fragmentation and accessibility problems in LatAm countries. The access to DUR data sources should be transparent, feasible, affordable, and research-protocol-driven.

The DUR sources inventory might be of value for researchers, health and other regulatory authorities, and pharmaceutical companies conducting DUR. Latin America and member states' health authorities should encourage and support national DUR and LatAm collaboration in this field.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

Luciane C Lopes is the principal investigator and led the writing of the manuscript. Luciane C Lopes, Monique Elseviers, Claudia Garcia Serpa Osorio-de-Castro, Lisiane Freitas Leal, and Maribel Salas are the project managers, co-investigators and contributed to the writing and revision of the manuscript. All co-investigators contributed to the data collection, writing, and revision of the manuscript. All authors read and approved the final manuscript.

ETHICS STATEMENT

The authors state that no ethical approval was needed.

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