Data transparency for building a stronger healthcare system: A case study from Argentinean administrative drug utilization data sources

Transparencia de datos para construir un sistema de salud más sólido: estudio de caso de bases de datos administrativas argentinas sobre utilización de medicamentos

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ABSTRACT In order to compile an inventory of national data sources for drug utilization research (DUR) in Argentina and to verify publicly available data sources, we performed a cross-sectional study that sought to identify national and provincial databases of drug use. In July 2020, we searched the websites of government institutions, carried out a systematic query of bibliographic databases for “drug utilization research” conducted in Argentina, and conducted a survey with local experts. Data collected included: the institution responsible for the database, population covered, accessibility, source of the data, healthcare setting, geographic information, and whether data were individual or aggregated. Descriptive analyses were then performed. We identified 31 data sources for DUR; only one was publicly and conveniently accessible. Five published aggregated data and provide more detailed access by formal request. Only seven sources (23%) reported national data, and most (n=29) included only data from the public healthcare sector. Although data sources for DUR have been found in Argentina, limited access by researchers and policymakers is still an significant obstacle. Increasing health data transparency by making data sources publicly available for the purpose of analyzing public health information is crucial for building a stronger health system.

KEY WORDS Drug Utilization Evaluation; Pharmacoepidemiology; Drug Databases; Argentina.

RESUMEN Para realizar un inventario de fuentes de datos nacionales sobre utilización de medicamentos en Argentina y verificar las fuentes de datos disponibles públicamente, llevamos a cabo un estudio transversal que investiga la existencia de bases de datos nacionales y provinciales sobre utilización de medicamentos. En julio de 2020, realizamos una búsqueda en sitios web de instituciones gubernamentales, una búsqueda sistemática en bases de datos bibliográficas sobre “drug utilization research” en Argentina y una encuesta de expertos. Se identificaron 31 fuentes de datos de utilización de medicamentos, solo una era de acceso público y conveniente, cinco publicaban datos agregados y proporcionaban un acceso más detallado mediante solicitud formal, solo siete fuentes (23%) informaban datos nacionales, y la mayoría de ellas (n=29) incluían solo datos del sector público de salud. Aunque se han encontrado fuentes de datos de utilización de medicamentos en Argentina, el acceso a investigadores y legisladores sigue siendo una barrera importante. Aumentar la transparencia de los datos de salud a través de fuentes disponibles públicamente para analizar la información de salud pública es crucial para construir un sistema de salud más sólido.

PALABRAS CLAVES Evaluación de Utilización de Medicamentos; Farmacoepidemiología; Bases de Datos Farmacéuticas; Argentina.
BACKGROUND

The need for data-driven decisions and research-based knowledge to plan and implement health policies is essential. Although health data is generated and compiled consistently, its evaluation is limited.

Drug Utilization Research (DUR) has been defined by the World Health Organization (WHO) as “the marketing, distribution, prescription and use of drugs by society to determine the resulting medical, social and economic consequences,” and more recently, as an “eclectic collection of descriptive and analytical methods for the quantification, the understanding and the evaluation of the processes of prescribing, dispensing and consumption of medicines, and for the testing of interventions to enhance the quality of these processes.”

DUR is important to identify potential problems associated with drug use and to quantify them, as well as to design and evaluate drug policies. It may allow the identification and quantification of the divergence between data from clinical trials in experimental conditions, daily clinical practice, and the health needs of the population, which are consolidated to design and implement best prescribing and dispensing practices. It is also useful to explore differences in drug exposure relative to specific outcomes and to optimize policies for promoting appropriate drug use.

Argentina has 45 million inhabitants and its health system consists of three subsectors: 57% of people have health coverage through the “social security” subsector, which is a system of mandatory insurance linked to employment sector; 5% is covered through voluntary private insurance; and the remaining 38% relies upon the public subsector. Due to its size, Argentina ranks fourth in Latin American pharmaceutical markets, with nearly 65% of drugs currently being supplied by locally-manufactured industries.

As Argentina has a federal system of government, each of the 23 provinces and the Autonomous City of Buenos Aires has its own healthcare system. The national Ministry of Health fulfills regulatory and stewardship functions. National drug regulations cover everything from research to aspects related to the access, quality, and rational use of medicines. The national regulatory agency is known as the Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), and it is considered a regional reference regulatory agency by the Pan American Health Organization (PAHO).

Concerning the use and access to medicines, the fragmentation of the healthcare system and the existence of different lists of essential medicines for each subsector implies many challenges to providing equitable access to medicines. The Remediar Program is a program implemented in the public subsector of the health system aimed at providing free access to essential medicines for 15 million people, which has a positive redistributive impact. Other measures taken by Argentina to promote the rational use of drugs are the adoption of a list of essential drugs, mandatory for the public sector, the approval of a law on prescription and dispensing of drugs by their generic names, and the confection of medical practice guidelines for prevalent diseases.

In 1992, during the foundational meeting of the Argentine Group for the Rational Use of Medicines (Grupo Argentino para el Uso Racional de Medicamentos, or GAPURMED, for its Spanish acronym), the need to carry out pharmacoepidemiological studies was highlighted. Since then, the group has produced countless field studies that have been presented at national meetings, many of them aimed at sensitizing involved health professionals, planning interventions to solve problems, and evaluating their impact. Unfortunately, most of these studies were not published nor did they become part of the gray literature, with little access to them. Over the years, only a small percentage of these studies have been published, mainly by universities or national journals. A few studies have been carried out using data sources from institutions that provide medicines with coverage at the national or provincial level.
Access to standardized and validated information on drug use is essential for evaluating drug use patterns, problem identification, educational interventions, and monitoring the results of access and rational use programs. DUR is important for policy formulation at the national level, as well as for individual patient management. But in Argentina, as in most Latin American countries, the availability of information on drug consumption and spending is scarce. Furthermore, it is expected that at least the information on drug utilization from public entities be freely available, with the appropriate safeguards, to carry out DUR.

Therefore, this study aimed to identify data sources on drug use from public agencies and to verify their accessibility for DUR in Argentina. This study is part of the ongoing “Data Sources for Drug Utilization Research in Latin American Countries: Cross-National Comparison” (DASDUR-LATAM) Study, which intends to take an inventory of available national drug utilization data in the Latin American region as potential data sources for DUR.

METHODS

Design

This is a cross-sectional study that investigates the existence of national and provincial data sources on drug utilization.

Search Strategy

We combed through the websites of national and provincial government authorities that implement programs involving the use of medications, as well as those that provide information from the pharmaceutical industry, through July of 2020.

We searched bibliographic databases (Medline/PubMed and LILACS) for studies or documents published from the inception of the database up to and including July 2020, with no limits regarding publication date, publication type, or status. We also looked for examples of DUR that have been conducted in Argentina or that involve the use of Argentinean data sources.

The search strategy was based on thesaurus terms and free-text keywords to combine the concepts DUR and Argentina. Additionally, we did a free-text search in Google Scholar and Google using the following keywords both in English and in Spanish: drug use, drug utilization, DUR, Argentina, pharmacoepidemiology, and database.

We conducted a brief online survey to complement information about the characterization of data sources, and to investigate the availability of databases at the provincial level (not accessible through their websites or from the bibliographic search). The survey was administered to the members of three drug networks: the aforementioned GAPURMED, the Argentine Network of Drug Information Centers (RACIM), and a national network of experts in health technology assessment. The questionnaire asked them about their knowledge and/or use of publicly accessible databases suitable for conducting DUR. If necessary, affirmative responses were confirmed via e-mail exchange with respondents.

Type of data sources (eligibility criteria)

We defined a data source for DUR as any data source with information about the use of medications including volume and price supported by governmental organizations.

We included public data sources at the national or provincial level, and/or data sources containing a mix of data from the public and private sectors. We excluded data from private organizations, individual hospitals, or individual primary care or specialized clinics, and data sources from health insurance companies or sickness funds. We also excluded data sources from commercial data providers, such as IQVIA.
The screening process

Two researchers (MC and MAU) independently assessed data sources to decide whether they met the eligibility criteria. Possible divergences were resolved by a third researcher (GHM).

Data extraction and analysis

Once eligible data sources were identified, a checklist was used to extract the following information: 1) institution responsible for the database; 2) covered population; 3) accessibility (publicly and convenient; restricted pre-authorized protocol only access; available only to researchers working in the institution; unclear process for obtaining data, lack of general regulation; and other); 4) source of the data (wholesalers, pharmacy, physician, others); 5) healthcare setting (hospital, ambulatory care, both); 6) geographic scale (national, regional, provincial, other); 7) type of data (aggregated or individual level). Data were analyzed descriptively.

RESULTS

A total of 35 publicly available data sources were identified. Seven databases derived from official websites on drug use, 10 data sources found through bibliographic searches, and an additional 18 data sources at the provincial level identified through the online survey that included responses from 30 drug experts.

Once the duplicated data sources were excluded, 31 different sources of information for DUR remained: seven (23%) reported national data and the other 24 provincial-level data (Figure 1).

Our query of the Argentine Ministry of Health’s website identified the Argentine Integrated Health Information System (SISA, for Sistema Integrado de Información Sanitaria Argentino), which was developed to serve as the basis for harmonizing data from different registries and programs with national reach, seeking to articulate pre-existing information sources in an integrated framework. Some of the national drug data sources identified were already included in SISA (Remediar Program and SUMAR). The other two were INDEC and PAMI (Table 1).

The Remediar Program is a national government program that provides free access to essential medications to the population covered exclusively by the public sector and is implemented through the provincial health services. The program has been used to perform several DUR. Data generated by the program are obtained from the prescription forms that include patient data (name, age, sex, etc.), coded diagnosis, and drug name. The program has a complementary data source called “transferencias monetarias por medicamentos” (cash transfers for medications) that offers an overview of transfers (drug, number of packages by province, ATC code in the first level, and year) made by the Remediar Program. Information can be visualized at the national and provincial levels.

SUMAR is a national program that provides basic effective coverage for people without other forms of health insurance. Although common ambulatory drugs are provided through the Remediar Program, treatment for specific diseases and high-cost medicines might be supplied by SUMAR. Data from SUMAR contains information about beneficiaries, services, benefits, and medications provided by the program. Access to data is available only to researchers working in the institution.

INDEC is the Instituto Nacional de Estadística y Censos (National Institute of Statistics and Census). The Institute provides quarterly data on sales revenues of pharmaceutical products for human use, classified by the first level of the Anatomical Therapeutic Classification (ATC) of the World Health Organization, and provides information on production at the national level, resale of imports, country of origin of basic drugs, among other data. Furthermore, INDEC conducts periodic surveys of household consumption and surveys of risk factors for chronic diseases in the general population, in cooperation with
the National Ministry of Health. These surveys have been used to report specific aspects of drug use, such as the family spending on drugs, or the prevalence of drug use for diabetes or hypertension.\(^{18,19}\)

PAMI is the National Institute of Social Services for Retirees and Pensioners, providing medical assistance to 76% of people in the country over 65 years of age.\(^{20}\) The database contains individualized information on outpatient drug dispensations, including generic and brand name, pharmaceutical product, total price, and out-of-pocket expense. This database has been used for studies of psychotropic and hypertension drugs, among others.\(^{19,21,22,23}\)

The other three national data sources focused on specific issues. They are: the National Pharmacovigilance System (SNFV, for its Spanish acronym); the National Program for HIV Care; and the National Bank of Special Drugs, dedicated mainly to the provision of cancer drugs.

The National Pharmacovigilance System – operating within the ANMAT – is in charge of detecting, evaluating, understanding, and preventing adverse effects derived from the use of medications and vaccines. The database of the Pharmacovigilance Department contains the necessary information for monitoring and control actions. In addition to annual reports, some DUR has been published.\(^{24,25}\)

The Drug Bank at the National Ministry of Health provides essential cancer drugs to patients who only have public health coverage and receive care in public hospitals.\(^{26}\) Similarly, the National Program for the Prevention and Control of HIV/AIDS provides antiretroviral drugs to the same population. Aggregated reports of the Program are regularly updated.\(^{27,28}\)

The coverage of uninsured people by the public sector is provided by 24 provincial healthcare systems; outpatient medications are supplied by the Remediar Program, which is described above. In addition, the provinces have their own social security systems (Obra Social Provincial, or OSP) for public employees and their families. Therefore, there are 24 OSPs, each one with its own administrative
Table 1. Characteristics of the administrative databases on drug use, Argentina, 2020.

<table>
<thead>
<tr>
<th>Data source acronym</th>
<th>Data source full name</th>
<th>Accessibility</th>
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<th>Type of data</th>
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<td>PAMII</td>
<td>Programa de Atención Médica Integral</td>
<td>Publicly and conveniently accessible online. Detailed data available to institution researchers or by special request. PAMII also has a data request form available on its website</td>
<td>National and provincial</td>
<td>Individual level data</td>
<td>Decentralized autonomous organization that depends directly on the national government. However formally depends on the Ministry of Health</td>
<td>Website</td>
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<td>Pharmacy records</td>
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data, which would be a potential data source for DUR. The IOMA, the Province of Buenos Aires’ OSP – which covers about 2,000,000 people – is presented as case in point. It has an administrative database that contains information about dispensed medications, but access is limited to internal users. A small number of studies using this data have been published.  

Only INDEC and National Pharmacovigilance System data include information about both the public and private sectors; all other sources cover public institutions.

In terms of the accessibility of data sources, INDEC data are publicly and conveniently accessible online. SUMAR, the Remediario Program, PAMI, the National Pharmacovigilance System, and the HIV/AIDS Program regularly publish aggregated data on their websites. Studies that go into greater detail are available only to researchers working in the institution, or via formal requests for research purposes. This is also the case of the 24 OSPs. PAMI and the National Pharmacovigilance System have data request forms on their websites. The other data sources lack a clear process for obtaining data.

The INDEC database provides wholesaler information while the Remediario Program offers information on wholesale transfers from the program to the Provinces, patient record data, and individual dispensation data. The SUMAR database contains patient records and drug dispensation data. All other data sources

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**Table 1. Continued.**

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<td>Remediar</td>
<td>Programa Remediario</td>
<td>Publicly and conveniently accessible on line</td>
<td>National and provincial</td>
<td>Aggregate level data</td>
<td>Ministry of Modernization and National Secretary of Health</td>
<td>Website</td>
<td>Public</td>
<td>Wholesalers</td>
<td>Ambulatory only</td>
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<td>SEMPRE</td>
<td>Servicios Médicos Previsional</td>
<td>Restricted Access to Program Managers, (however some limited data could be available). Online data sources no available</td>
<td>Provincial</td>
<td>Individual level data</td>
<td>Ministry of Health, Province of La Pampa</td>
<td>Website</td>
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<td>Individual level data</td>
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<td>Public</td>
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<td>Ambulatory only</td>
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<td>SHFV</td>
<td>Sistema Nacional de Farmacovigilancia</td>
<td>Publicly and conveniently accessible on line. Detailed data available to institution researchers or by special request</td>
<td>National and provincial</td>
<td>Aggregate and individual level data</td>
<td>ANMAT (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica)</td>
<td>Website</td>
<td>Public and private</td>
<td>Patient records</td>
<td>Ambulatory and hospital (possible to separate)</td>
<td>Available online since 2007</td>
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<td>National Secretary of Health. Sub-Secretariat of Public Health Coverage</td>
<td>Website</td>
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<td>Patient records</td>
<td>Ambulatory only</td>
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<tr>
<td>SVIH</td>
<td>Sistema de Administración de Pacientes VIH</td>
<td>Publicly and conveniently accessible on line. Detailed data available to institution researchers or by special request</td>
<td>National and provincial</td>
<td>Aggregate and individual level data</td>
<td>Ministry of Health of the Nation</td>
<td>Website</td>
<td>Public</td>
<td>Pharmacy records</td>
<td>Ambulatory only</td>
<td>Unknown</td>
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</table>

Source: Own elaboration.
provide individual dispensation information through pharmacy records, except for the National Pharmacovigilance System, which registers individual adverse effects reports. The data from SUMAR, the Remediare Program, PAMI, the HIV/AIDS Program, and the 24 OSPs refer to outpatient settings. INDEC, the Drug Bank for cancer medicines and the National Pharmacovigilance System contain both outpatient and inpatient data, although only the last allows us to separate them.

Regarding geographic information, national data from SUMAR, the Remediare Program, PAMI, National Pharmacovigilance System, and the HIV/AIDS Program are disaggregated at the Province level.

DISCUSSION

There are multiple data sources for DUR in Argentina, at both the national and provincial levels. However, the lack of public availability and accessibility for DUR are important barriers for researchers and policymakers.

Few data sources offered access to data through the website (Table 1). The authors of most published studies that we reviewed belonged to the institution in which the study was carried out.\(^{12,30}\)

Our study only considered data sources from the public sector, but excluded those that provide healthcare coverage for employees of national universities, the Armed Forces, and the Judiciary and Legislative systems, due to their restricted scope. Nonetheless, the set of national and provincial data sources identified are responsible for covering more than 60% of the country’s population. The rest of the population is covered by autonomous health insurance institutions in the social security subsector – which are regulated by the Superintendence of Health Services – and private insurance providers.\(^{31}\)

A recent study that evaluated data sources for conducting “real-world evidence” research identified 44 data sources in Argentina. This study was driven by the possibility of carrying out health technology assessment studies in the broadest sense, which far exceeds the objective of our study, which was limited to DUR. However, the details of all analyzed databases were not provided, so it is not possible to establish direct comparisons.\(^{32}\)

The value of clinical information stored in electronic medical records and administrative databases has been well established for a long time. As early as the late 1980s, the first primary care research databases were created in the United Kingdom; today there are numerous examples in many countries.\(^{33}\)

More recently, the metaphor of a “health ecosystem” has gained traction, to emphasize the multiplicity of actors in the healthcare sector and the dynamic nature of their interactions.\(^{34}\) Data transparency, defined as the open access to information generated by public institutions, would make a significant contribution to better understanding their operation.\(^{35}\)

Obstacles to DUR in Latin American countries have recently been pointed out, and include factors such as the fragmentation of health systems, the inexistence of databases at the national level, and the lack of knowledge on the part of decision-makers regarding this type of study.\(^{36}\)

Comparisons between Latin American countries have been poorly documented. Also, the validity of comparisons is hampered by the potential risk of extrapolation bias, considering the availability of data on the use of medications in the public health sector.\(^{37}\)

Health systems, funders, and providers must permanently record data to correct, adapt, or control healthcare claims. In pharmacoepidemiology, drug databases are necessary to monitor the prescription, dispensing, or consumption of drugs in a given population. However, the information generated by different actors in the healthcare system is reserved mainly for internal use in many countries and rarely shared with other institutions in the network.

As a result, even when drug databases are becoming more and more numerous, very few of them are freely and transparently accessible. Furthermore, many drug utilization data sources were identified through a
survey because they were not openly published. Obtaining data from public entities is discretionary as explicit requirements for accessing data are not stated.

Another source of drug use data is private companies, such as IQVIA, which collect retail sales information. However, these data correspond to the consumption of drugs in the private sector, and should not be extrapolated to the total national population.

Thus, there is a growing need for researchers and policymakers to work together to establish nationally validated data collection systems to accurately describe drug use in the country. Priority should be given to data from the public sector.

This study has shown that access to data sources for DUR from public entities in Argentina is limited. Although there is legislation in effect that guarantees access to public information (Law 27275) and requires public agencies to provide essential data to the public regarding their activities, not all institutions have complied with these regulations. This situation is similar to other countries in the region.

Increasing health data transparency by making data sources publicly available for the purpose of analyzing public health information is crucial for structuring a stronger healthcare system and making data-driven decisions.

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