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ORIGINAL ARTICLE

Analysis of the database quality of the National Controlled Products Management System (SNGPC)

Análise da qualidade da base de dados do Sistema Nacional de Gerenciamento de Produtos Controlados (SNGPC)

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ABSTRACT The study aimed to analyze the quality of the database regarding antimicrobials from the Brazilian National Controlled Products Management System (SNGPC) available in the public domain and propose improvements. This was an exploratory and descriptive study of antimicrobial sales records from Brazilian private pharmacies, conducted from June 2017 to 2020. Three quality dimensions were considered: completeness, methodological clarity, and validity. Data was analyzed using descriptive statistics. Although the database offers valuable information on antimicrobial consumption, it also poses several challenges that hinder or complicate the analysis. The main obstacles found were: a lack of standardization of the name and description of antimicrobials, the presence of different information in the presentation description field, and the absence of anonymized individualized data. The SNGPC is a key data source on antimicrobial consumption in Brazil, as private pharmacies and drugstores are the population's primary sources of access to these medications. However, the SNGPC requires improvements to facilitate its use by researchers, policymakers, and healthcare professionals. These improvements would enable more comprehensive studies and support the systematic monitoring of antimicrobial consumption, contributing to strategies to tackle antimicrobial resistance (AMR).

KEYWORDS Health Information Systems. Database. Public health surveillance. Drug utilization. Anti-infective agents.

RESUMO *O objetivo do estudo foi analisar a qualidade dos dados do Sistema Nacional de Gerenciamento de Produtos Controlados (SNGPC), disponíveis em acesso aberto, quanto aos antimicrobianos (ATM) e propor melhorias. Trata-se de estudo exploratório e descritivo dos registros das vendas de ATM das farmácias e drogarias privadas brasileiras, realizadas nos meses de junho de 2017 a 2020. Foram consideradas três dimensões da qualidade: completude, clareza metodológica e validade. Análise dos dados realizada utilizando-se estatística descritiva. A despeito de o banco fornecer dados relevantes sobre o consumo de ATM, este apresenta problemas que limitam ou dificultam sua análise. Os principais entraves encontrados foram: falta de padronização do nome e descrição dos ATM, presença de informações diversas no campo de descrição da apresentação e ausência de dados individualizados anonimizados. O SNGPC é uma importante fonte de dados do consumo de ATM no Brasil, tendo em vista que farmácias e drogarias privadas são as principais fontes de acesso da população a esses medicamentos. No entanto, o SNGPC necessita de melhorias que facilitem sua utilização por pesquisadores, gestores e profissionais de saúde, possibilitando a realização de estudos mais robustos e o monitoramento sistemático do consumo de ATM para subsidiar estratégias de combate à resistência microbiana.*

PALAVRAS-CHAVE *Sistemas de Informação em Saúde. Base de dados. Vigilância em saúde pública. Uso de medicamentos. Anti-infecciosos.*

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Introduction

Health Information Systems (HIS) are important sources of secondary data that can portray the health situation of a population, and aspects involving the functioning of the health system. This requires valid and reliable databases that can guide and support decision-making and the planning of health actions based on evidence[1].

Following the creation of the Unified Health System (SUS) and the decentralization of health services to local levels, the demand for information to support SUS managers increased. In this context, the SUS Information Technology Department (DATASUS) and the Interagency Health Information Network (RIPSA) were established to improve the quality of HIS in Brazil.

Brazil has a vast nationwide HIS network that continuously generates a great volume of data, most of which is accessible online. This broad availability of HIS makes it easier for managers, health professionals, and researchers to access data, which can be used to support their practices, while also enabling civil society empowerment for social participation[2,3].

Despite the progress that has been made, there is still fragmentation among existing systems, which leads to the underutilization of the available data for decision-making. The main users of SIS, therefore, are researchers. While the role of academia in producing scientific knowledge in the health field is crucial, it should be emphasized that the main purpose of HIS is to generate the necessary and timely information to support the management of healthcare services[4].

Quality is essential if HIS is to be fully utilized and provide truly useful information for solving public health problems. Therefore, understanding the strengths and limitations of the data made available through systematic evaluations is fundamental if HIS is to be continually improved[1,3].

One of the most important public health concerns in the world today is the growing risk of deaths associated with antimicrobial resistance (AMR). AMR is a complex and multifactorial problem associated with the use of antimicrobials in humans and animals, as well as their presence in the environment[5].

Although AMR is expected and occurs naturally from the exposure of microorganisms to antimicrobial drugs, their indiscriminate use has led to an accelerated advance of AMR, placing it in the ranking of the top 10 threats to global public health, according to the World Health Organization (WHO)[6]. Considering the pillar of antimicrobial use in humans, the consumption pattern of these drugs by outpatients represents an important area for analysis and intervention, since the vast majority of antimicrobial prescriptions are aimed at this public, with a significant portion deemed inappropriate[7-10].

In Brazil, the population predominantly accesses antimicrobials through private pharmacies and drugstores, through direct disbursement[11]. Until 2021, those establishments were obliged to submit monthly antimicrobial sales data to the National Health Surveillance Agency (ANVISA) via the National System of Controlled Products Management (SNGPC)[12]. This makes the SNGPC an important data source for monitoring outpatient antimicrobial consumption in the country.

The SNGPC has been recently the subject of scientific literature[13]; however, it is relevant to consider this database through quality dimensions focused on the managerial use of such data. As highlighted by Feliciano et al.[14], Health Information Systems (HIS) play a crucial role in decision-making processes, where ensuring data quality is fundamental. Furthermore, since the National Action Plan for the Prevention and Control of Antimicrobial Resistance within the One Health framework (PAN-BR) expired in 2022 and the updated plan had not yet been published as of the closing date of this text, we believe that this discussion is highly opportune.

As such, this study aimed to describe aspects of the quality of SNGPC data available

in open access, focusing on antimicrobials. It is an extension of a broader study, conducted in 2021, which analyzed outpatient consumption of antimicrobials in Brazil's private sector and identified several issues in the use of the SNGPC.

To improve the effective use of this database for both regulation and research, it is necessary to identify its obstacles. Thus, this study also set out to identify the main challenges in using the SNGPC and as opportunities for improvement to support managers in constantly refining this important national database on medication consumption.

Material and methods

An exploratory and descriptive study was carried out on the quality of SNGPC data from June 2017 to 2020, focusing on antimicrobials, considering three dimensions of quality: completeness, methodological clarity, and validity. These dimensions were selected because they are part of the list of quality dimensions of a Health Information System (HIS) described by Lima et al.[3] The completeness and validity dimensions are among the most addressed in HIS evaluation studies, along with the coverage and reliability, although variations occur depending on the HIS being evaluated[15], based on the information made available by ANVISA on the Brazilian Open Data Portal (PBDA)[16]. As for the period covered, the last full year of data availability from the database was used.

SNGPC data is available in files for download on the PBDA website. The files are organized in such a way that each one refers to a month of sales of industrialized medicines subject to record-keeping in private pharmacies and drugstores. On the web portal, you can find records of sales made from January 2014 to November 2021. After that date, there was a temporary suspension on the use of the SNGPC as a way of recording transactions of drugs under special control[17].

The completeness dimension is understood as the degree to which a variable is filled out in the database, i.e. the proportion of non-null records for a given variable. Methodological clarity refers to the extent to which the instructions for using and filling out the HIS describe the necessary data in a clear and accessible way. Finally, the validity dimension deals with the degree to which the data is capable of measuring what it is intended to measure, i.e. it refers to the internal validity of the data within the variable itself[3].

A series of steps were taken to process the data before analysis. Initially, the medicines were classified as: antimicrobials; controlled; and not applicable to the SNGPC. The latter refers to medication mistakenly included in the system, as they are not part of the medication list under special control by ANVISA.

Next, only the antimicrobials were filtered, which were classified into systemic use of antimicrobials (ATC group J01) and topical use of them (not J01). The data selected for the quality study were only those relating to sales of systemic-use antimicrobials.

Descriptive statistics were used to analyze the data quality, which allowed for the definition of exclusion criteria for the study titled 'Antimicrobial consumption in Brazilian private pharmacies and drugstores in the light of the PAN-BR and the COVID-19 pandemic'. The objective was to analyze the antimicrobial consumption in the private pharmacy network in Brazil, from 2017 to 2020[18]. In addition, the analysis of data quality enabled the identification of cut-off points for case exclusions to reduce information bias due to loss of internal validity.

THE SNGPC

The National System of Controlled Products Management (SNGPC) was developed and implemented in 2007 by ANVISA, to electronically manage and monitor the movement of medications subject to compulsory record-keeping in private pharmacies and drugstores in Brazil[19-20]. The submission of data was the

responsibility of the pharmacist in charge or their legal substitute[12].

The SNGPC gradually replaced physical record-keeping with electronic record-keeping, allowing data to be transmitted directly to ANVISA, making this process more efficient and secure for pharmacies[12]. Among the list of drugs subject to SNGPC recording are: psychotropic drugs, narcotics, and other products regulated in the same ordinance[21]; antimicrobial, included in 2013[22]; and drugs containing chloroquine, hydroxychloroquine, nitazoxanide, and ivermectin, included in 2020, after the onset of the COVID-19 pandemic[23-24]. The latter two were excluded from the list of controlled substances in September 2020[23].

The SNGPC enables the identification of patterns and deviations in the prescription and consumption of medications as well as potential health risks to the population[25-26]. This system has already been used to analyze the consumption and prescription of appetite suppressants[26]; identify deviations in the use of fluoxetine[27]; and explore the consumption of benzodiazepines, including their relation with users' sociodemographic and social characteristics[28,29].

Therefore, the information generated by the SNGPC has effectively supported health surveillance agencies in inspection and control actions. It has also provided data to assist managers in developing strategic policies to curb the abusive use of this group of medications, including antimicrobials[28,29].

The sale of antimicrobials in Brazil was regulated in 2010[19] and updated in 2011[22] and 2021[23], requiring the presentation and retention of a prescription at the time of purchase to prevent indiscriminate access to antimicrobials by the population, minimizing self-medication and the consequent risk of inducing antimicrobial resistance (AMR). The list of substances classified as antimicrobial subject to control is published in specific legislation[23].

In 2020, ANVISA provided open access to data on sales of industrialized medicines subject to record-keeping in the SNGPC, from 2014 onwards, in private pharmacies and drugstores throughout the country. This expands the possibilities for conducting studies in the field of drug use.

The SNGPC database includes the following variables (*table 1*): year of sale, month of sale, State of the sale, municipality where the sale was made, active ingredient of the antimicrobial sold, product presentation description, quantity of units sold, unit of measurement of the product, prescribing council of the professional who prescribed the antimicrobial, State of the prescribing professional's council, type of prescription, ICD-10, sex and age of the patient and unit of age (months or years). It should be noted that the variables ICD-10, sex, age, and age unit are only applicable to antimicrobial sales.

Quality and challenges in using SNGPC data

The SNGPC provides several variables of interest to analyze antimicrobial consumption in Brazil. Its data allows for the generation of information on the profile and trends of antimicrobial use over time by the Brazilian population. It also enables to understanding of antimicrobial users' characteristics, such as gender, age, and consumption patterns according to municipal size, regions of the country, and prescribing professionals (physician, dentist, and veterinarian).

Nevertheless, a set of problems related to filling out and systematizing the data in the SNGPC were identified, with some examples of inconsistencies found during the exploratory analysis shown in *table 1*.

Regarding the completeness dimension, it was observed that the field referring to the patient's age was not filled out for around 2% of the analyzed sales (206,871 records). The ICD-10 field was not filled out in any of the antimicrobials sales records until June 2019 and was present in less than 1% of sales by

June 2020. This incompleteness concerning ICD-10 is likely related to the absence of this information on the prescription presented by patients at the time of purchase.

Table 1. Description of SNGPC variables available in open access. Brazil, 2017 to 2020

Variables	Description of variable	Texts/Codes	Examples of inconsistencies
YEAR_ SALE	Year the medicine was sold	Numbers from 2014 to 2020	-
MONTH_ SALE	Month the medicine was sold.	Numbers frm 1 to 12	-
STATE_ SALE	State of the pharmacy or drug-store where the sale took place.	State acronyms	-
MUNICIPALITY_ SALE	Municipality of the pharmacy or drugstore where the sale took place.	Names of municipali-ties	-
ACTIVE_PRINCIPLE	Active ingredient name of the sold medication	Name of medicines by DCB (Brazilian Non-proprietary Name), but with variations	Notations for amoxicillin: amoxicillin; amoxicillin base; amoxicillin tri-hydrate; amoxicillin trihydrate.
DESCRIPTION_ PRESENTATION	Description of the medication's presentation sold.	Dose, pharmaceutical form, type of packag-ing, number of units per package	Example: 500 MG COM REV CT BL AL PLAS INC X 20. Meaning: Each pack contains 20 coated tablets of 500mg each.
QTY_SOLD	Number of packages sold in the same purchase.	Number of boxes or bottles sold	-
MEASURE_UNIT	Defines the unit sold.	Box or bottle	Oral solutions have sometimes been classified as boxes, and tablets as bottles.
PRESCRIBER_ COUN-CIL	Professional Council of the pre-scriber of the medication sold.	CRM, RMS, CRO, and CRMV	CRM-physicians; RMS-physicians from the 'Mais Médicos' Program; CRO-dentists; and CRMV-veteri-narians.
STATE_ PRESCRIBER_ COUNCIL	State of the prescriber's profes-sional council.	State acronyms	-
PRESCRIPTION_TYPE	Type of prescription form used for the medication sold.	Codes from 1 to 5	Unknown code description.
ICD10	International Classification of Diseases (ICD) for which the antimicrobial was prescribed.	ICD-10 code	Field applicable only for sales of antimicrobials.
SEX	Sex of the patient for whom the antimicrobial was prescribed.	Code 1 for male and 2 for female	Field applicable only for sales of antimicrobials.
AGE	Age of the patient for whom the antimicrobial was prescribed.	Number referring to age in months or years	Field applicable only for sales of antimicrobials.
UNIT_ AGE	Unit of age of the patient for whom the antimicrobial was prescribed.	Code 1 for years and 2 for months	Field applicable only for sales of antimicrobials.

Source: Own elaboration.

i) CRM = Regional Council of Medicine; ii) RMS = Ministry of Health registration for physicians in the Mais Médicos program (More Physicians program); iii) CRO = Regional Council of Dentistry and iv) CRMV = Regional Council of Veterinary Medicine.

As for the methodological clarity dimension, we observed that the codes for the variables 'SEX', 'RECEIPT_TYPE', and 'AGE_UNIT' were not described in the dictionary of SNGPC variables, which is available on the PBDA website. The lack of code descriptions for these variables makes it impossible to translate the meaning of the record in the database and therefore prevents these variables from being used in any kind of analysis.

In the case of the variable 'AGE_UNIT', it was possible to deduce which code corresponded to months and years units, based on the number of records and the corresponding values in the 'AGE' variable. Regarding the 'SEX' variable, it was only possible to identify its codes through direct contact with the ANVISA professional responsible for the system at the time.

The field relating to the unit of packaging sold ('UNIT_MEASURE'), described as a box or bottle, showed inconsistencies in its entries. Sometimes oral solutions or suspensions were classified as boxes, while oral solids were determined as bottles in some records. In addition, topical formulations, such as dermatological creams, were also defined as boxes. Methodological clarity was thus compromised, making it impossible to use this variable. If better classified and filled out correctly, it could serve as a useful filter between liquid, solid, and topical antimicrobials.

The alternative for obtaining information on the unit of packaging sold was to use the 'PRESENTATION_DESCRIPTION' field. The use of this variable is complex and labor-intensive as it is an open-text field with no standardized format for data entry. The same is true of the 'ACTIVE_INGREDIENT' field, which represents the main challenge in analyzing SNGPC data, also related to the methodological clarity dimension.

Considering that the analyzed sample contained only systemic-use antimicrobials, 58 active ingredients were selected, for which 108 different descriptions were used. In other words, 46.2% of the names did not correspond to actual variations of active ingredients. Amoxicillin was chosen as an example to illustrate the challenge encountered. For this drug, four different forms of notation were identified: 'amoxicillin', 'amoxicillin base', 'amoxicillin trihydrate', and 'amoxicillin trihydrate'. The antimicrobials with the highest number of variations in this variable were: amoxicillin/clavulanate (9), ciprofloxacin (6), amoxicillin (4), ampicillin/sulbactam (4), and ampicillin (4)).

In the presentation description field, the variability of description types was much more significant. Of the total of 1,370 presentations of systemic-use antimicrobials registered in the SNGPC, only 30% (411) corresponded to different products. This means that the number of variations identified in the database is incompatible with the variety of antimicrobial presentations available on the pharmaceutical market and sold by Brazilian pharmacies and drugstores.

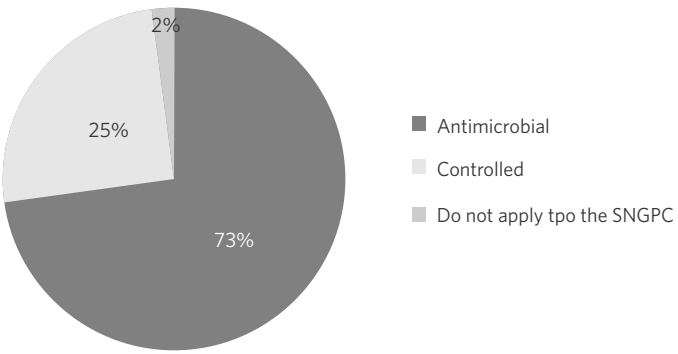
Using amoxicillin as an example, sales were recorded for 39 different presentations of this antimicrobial, 24 of which corresponded to tablets or capsules, and 15 to oral suspensions. However, 227 different descriptions for amoxicillin were registered in the database, which means that 82.8% of the description type variations for this antimicrobial were unnecessary - 75.2% (97) for solid presentations and 88.5% (130) for oral suspensions. This indicates that standardizing the drug description would represent a significant improvement in the clarity of the variable and, consequently, of the database.

Regarding the validity dimension, three issues were identified. The first concerns the presence of records for medication sales that are not subject to record-keeping in the SNGPC (2%) (*graph 1*). These included corticosteroids, non-steroidal anti-inflammatory drugs, vitamins, antihypertensives, and muscle relaxants, among others. Although the percentage found was small, only 2%, this suggests a need for periodic training of the professionals involved in using the system or validations to prevent incorrect recording.

Another finding was the presence of records for patients over 120 years of age in 13,723 sales (0.11%), indicating data entry errors in these cases. This resulted in the exclusion of these records from the database used for research purposes, as they were inconsistent data.

The same occurred with sales records that contained quantities far exceeding the maximum expected for the treatment of infections for an individua. This suggests that these sales were made to healthcare facilities rather than to specific patients. Some presentations even contained the term 'hospital packaging' in the product description. It is noteworthy that the legislation does not mention the possibility of selling antimicrobials to healthcare facilities or other types of healthcare establishments by pharmacies and drugstores, nor does it specify the need for or method of recording such cases in the SNGPC[20].

Graph 1. Sales distribution of antimicrobial, controlled, and medicines that do not apply to the SNGPC, in June. Brazil, 2017 to 2020



Source: Own elaboration.

Finally, the SNGPC data available through open access is only presented in an aggregate form, which imposed limitations on conducting a more in-depth analysis of outpatient antimicrobial consumption in Brazil.

Opportunities to improve the SNGPC

Given the challenges encountered when using the SNGPC, as previously outlined, some improvement suggestions for improvements are proposed to enhance the speed and efficiency of using this database to produce information on the outpatient consumption of antimicrobials by the Brazilian population. It is important to stress the need to test any suggested changes before widespread implementation, including analyzing the operationality of the information recording procedures and the impact on user service times, considering the workflow of pharmacies and drugstores.

The first and most important suggestion for providing a faster and more accurate analysis of SNGPC data is to include a set of variables that make it possible to identify and standardize the different medications included in the database. This information could be linked to the product registry of pharmacies and drugstores.

Table 2 shows the variables suggested for inclusion in the SNGPC, based on the original variables 'ACTIVE_INGREDIENT' and 'DESCRIPTION_PRESENTATION', and provides some examples based on antimicrobial sales records in the database. It is suggested to include the variables: Brazilian Common Denomination (DCB), 5th level ATC

classification, AWaRe classification, pharmaceutical form, route of administration, dose, dosage unit, and the total number of units in the package. Additionally, it is also recommended to include an identification code for each medication.

The DCB is the nomenclature system adopted in Brazil for standardizing the names of the active ingredients of medications[30], avoiding duplication of equivalent items. The classifications of antimicrobials into groups – AWaRe and 5th level ATC – aim to facilitate the data analysis by strategic therapeutic groups from the point of view of managing the use of antimicrobial[31].

The other suggested variables refer to the stratification of the information set provided in the presentation description field (dose, pharmaceutical form, unit, and number of units per package). The fact that the description field contains multiple pieces of information about the product makes standardization difficult across the various pharmacies linked to the SNGPC.

Table 2. Original variables and variables suggested for inclusion in the SNGPC, with examples of extracted data. Brazil, 2024

BANK'S ORIGINAL VARIABLES		VARIABLES SUGGESTED FOR INCLUSION IN THE SNGPC							
ACTIVE INGREDIENT	DESCRIPTION PRESENTATION	GENERIC NAME	CTA 5th LEVEL	AWaRe	18 / 5.000 PHARMACEUTICAL FORM	ADM. WAY.	DOSAGE	PODIATRY UNIT	TOTAL NUMBER OF UNITS
AZITHROMYCIN	500 MG WITH REV CT BL AL PLAS TRANS X 5	AZITHROMYCIN	J01FA10	Watch	TABLET	ORAL USE	500 MG	TABLET	5
AMOXICILLIN TRIHYDRATE	500 MG HARD CAP CT BL AL PLAS TRANS X 21	AMOXICILLIN	J01CA04	Access	CAPSULE	ORAL USE	500 MG	CAPSULE	21
AMOXICILLIN TRIHYDRATE	50 MG/ML PO OR USE CT FR VD AMB X 150 ML + COP	AMOXICILLIN	J01CA04	Access	ORAL SOLUTION/SUSPENSION	ORAL USE	50 MG	MILLILITER	150
GENTAMICIN SULPHATE	280 MG/2 ML INJ SOL CT CAMA AMP VD INC X 2 ML + SER	GENTAMICIN	J01GB03	Access	INJECTABLE SOLUTION/SUSPENSION	IV	140 MG	MILLILITER	2
BACITRACIN + NEOMYCIN	5 MG + 250 UI/G DERM OIN CT BG AL X 15 G	BACITRACIN + NEOMYCIN	D06AX04	-	"DERMATOLOGICAL CREAM / OINTMENT / GEL"	TO	"5 MG + 250 UI"	GRAM	15
RIFAMYCIN SV SODIUM	10 MG/ML TOP SOL SPRAY CT FR VD AMB X 20 ML	RIFAMYCIN	D06AX15	Watch	TOPICAL SOLUTION	TO	10 MG	MILLILITER	20
TOBRAMYCIN	3 MG/ML OPH SOL CT FR PLAS OPC GOT X 5 ML	TOBRAMYCIN	S01AA12	-	"OPHTHALMIC SOLUTION / OINTMENT "	TO	3 MG	MILLILITER	5
CIPROFLOXACIN HYDROCHLORIDE MONOHYDRATE	3,0 MG/ML SOL OTO CT FR PLAS OPC GOT X 5 ML	CIPROFLOXACIN	J01MA02	Watch	OTOLOGICAL SOLUTION	TO	3 MG	MILLILITER	5
NYSTATIN	25.000 UI/G VAG CRE CT BG AL X 60 G + 14 APPLICATIONS	NYSTATIN	G01AA01	-	VAGINAL CREAM/ OVUM	TO	25.000 UI	GRAM	60

Source: Own elaboration.

It is suggested to break down this information into the following variables, as shown in *table 2*.

- Pharmaceutical form: tablet; capsule; oral solution or suspension; injectable solution or suspension, cream, ointment or gel; topical solution; ophthalmic solution or ointment; otologic solution; vaginal cream or ovule; capsule or inhalation powder or solution;

- Route of administration: PO (oral), IV (intravenous), IM (intramuscular), TD (transdermal);

- Dose (per dosage unit);

- Dosage unit: tablet, capsule, milliliter, milligram, gram;

- Total number of units (per package).

Creating these variables in the SNGPC would contribute to faster and more effective data analysis, especially for calculating the Defined Daily Dose (DDD), the primary method for measuring medication consumption. In addition, these fields would simplify the database's use for analyzing the consumption data of controlled medications, encouraging the systematic use of this database by researchers and healthcare managers.

Table 3 encloses the description of all the systemic-use antimicrobials selected in this study, with their respective AWaRe and ATC classifications, which may help researchers or managers when using this data source.

The second proposed improvement is the provision of individualized and anonymized data from SNGPC medication sales records. This would allow an analysis of the number of antibiotic treatments administered to each individual over a given period. The number of times an individual is exposed to antibiotics at short intervals increases the risk of AMR[32] and is therefore also an important indicator of antimicrobial consumption.

The inclusion of a field to distinguish the origin of drug prescriptions – private sector or SUS (Unified Health System) – is another suggested proposal. This would allow for the analysis and comparison of the main sources of antimicrobial prescriptions, as well as the different prescribing patterns in the public and private sectors nationwide.

Table 3. ATC level 5 classification and AWaRe of systemic antimicrobials present in the SNGPC in June. Brazil, 2017 to 2020

ANTIMICROBIAL	ATC	AWARE	ANTIMICROBIAL	ATC	AWARE
NALIDIXIC ACID	J01MB02	-	ERTAPENEM	J01DH03	WATCH
AMIKACIN	J01GB06	ACCESS	SPIRAMYCIN	J01FA02	WATCH
AMOXYCILLIN	J01CA04	ACCESS	PHENOXYMETHYLPENICILLIN	J01CE02	ACCESS
AMOXICILLIN/CLAVULANATE	J01CR04	ACCESS	GEMIFLOXACIN	J01MA15	WATCH
AMOXICILLIN/SULBACTAM	J01CR02	ACCESS	GENTAMICIN	J01GB03	ACCESS
AMPICILLIN	J01CA01	ACCESS	IMIPENEM	J01DH51	WATCH
AZITHROMYCIN	J01FA10	WATCH	LEVOFLOXACIN	J01MA12	WATCH
AZTREONAM	J01DF01	RESERVE	LIMECYCLINE	J01AA04	WATCH
BENZYLPENICILLIN BENZATINE	J01CE08	ACCESS	LINCOMYCIN	J01FF02	WATCH
BENZYLPENICILLIN POTASSIUM	J01CE08	ACCESS	LINEZOLID	J01XX08	RESERVE
BENZYLPENICILLIN POTASSIUM/ PROCAINE BENZYLPENICILLIN	J01CE09	ACCESS	MEROPENEM	J01DH02	WATCH
CEFACLOR	J01DC04	WATCH	METRONIDAZOLE	J01XD01	ACCESS

Table 3. ATC level 5 classification and AWaRe of systemic antimicrobials present in the SNGPC in June. Brazil, 2017 to 2020

ANTIMICROBIAL	ATC	AWARE	ANTIMICROBIAL	ATC	AWARE
CEFADROXIL	J01DB05	ACCESS	MINOCYCLINE	J01AA08	RESERVE
CEPHALEXIN	J01DB01	ACCESS	MOXIFLOXACIN	J01MA14	WATCH
CEPHALOTHIN	J01DB03	ACCESS	NITROFURANTOIN	J01XE01	ACCESS
CEFAZOLIN	J01DB04	ACCESS	NORFLOXACIN	J01MA06	WATCH
CEFEPIME	J01DE01	WATCH	OXACILLIN	J01CF04	ACCESS
CEFOTAXIME	J01DD01	WATCH	OXYTETRACYCLINE	J01AA06	WATCH
CEFOXITIN	J01DC01	WATCH	PIPERACILIN / TAZOBACTAM	J01CR05	WATCH
CEFTAZIDIME	J01DD01	WATCH	ROXITHROMYCIN	J01FA06	WATCH
CEFTRIAXONE	J01DD04	WATCH	SULFADIAZINE	J04AB02	.
CEFUROXIME	J01DC02	WATCH	TRIMETHOPRIM/SULFA-METHOXAZOLE	J01EE01	ACCESS
CIPROFLOXACIN	J01MA02	WATCH	TEICOPLANIN	J01XA02	WATCH
CLARITHROMYCIN	J01FA09	WATCH	TETRACYCLINE	J01AA07	ACCESS
CLINDAMYCIN	J01FF01	ACCESS	TIANPHENICOL	J01BA02	ACCESS
CHLORAMPHENICOL	J01BA01	ACCESS	TIGECYCLINE	J01AA12	RESERVE
DAPTOMYCIN	J01XX09	RESERVE	TOBRAMYCIN	J01GB01	WATCH
DOXYCYCLINE	J01AA02	ACCESS	VANCOMYCIN	J01XA01	WATCH
ERYTHROMYCIN	J01FA01	WATCH	-	-	-

Source: Own elaboration.

There is also a need to improve the SNGPC data dictionary by defining the codes for missing variables. Furthermore, this document could include suggestions for data cleaning resources.

The final suggestion for refining the SNGPC is to create a specific prescription model for antimicrobial prescriptions in Brazil, preferably in electronic format. This measure would allow for the definition of mandatory fields and the electronic recording of prescriptions, facilitating qualitative analysis of antimicrobial use in outpatient settings.

Discussion

The SNGPC is a valuable source of research on the outpatient consumption of antimicrobials in Brazil since private pharmacies and drugstores are the primary means for the population to access these drugs[11]. However, this study identified a series of obstacles that hinder the use of this database to produce information on antimicrobial consumption.

The performance of a Health Information System is measured by the quality of its data and its use in decision-making[33]. The quality of information sources depends primarily on the presence of reliable, valid, and properly compiled data[34]. According to Carvalho and Mota[15], the factors determining the quality of HIS data can be related to technical, behavioral, and organizational aspects.

Technical factors are those associated with data collection tools and the available technological resources. Behavioral ones are related to the knowledge, skills, motivation, commitment, and confidence of the professionals who feed the database. Organizational factors refer to the management of information culture and healthcare service operations[15].

Considering all the obstacles faced in using SNGPC data, it can be said that the majority

were related to technical factors, involving structural limitations of the system and incomplete information for its adequate use. Behavioral factors also compromised the quality of SNGPC data, as mistakes were made in the inclusion of various medications that are not under special control as well as the failure to fill out user characterization fields, such as gender and age in some of the records.

Gaps in knowledge and lack of motivation among professionals are some of the behavioral factors that can lead to data entry errors in the HIS[15]. Periodic and systematic training for the professionals who manage SNGPC data is essential to ensure its proper use. It is also essential to raise their awareness of the epidemiological importance of accurate and timely data recording. Lemma et al.[35] demonstrated that combined interventions targeting both technical and behavioral factors improved the quality and use of HIS data.

The quality of HIS data has improved globally[36,37], but low- and middle-income countries still face a range of issues such as incomplete records, inconsistent data, and low levels of accuracy[38,39]. Moreover, despite the growing availability of health information, its use in decision-making remains limited in many of these countries[40]. Healthcare professionals report low use of data for planning purposes, often due to a lack of confidence in its quality[41].

In the case of high-income countries, major investments have been made in the development of health information technologies. However, they also face challenges, especially in terms of interoperability between different systems[42].

Regarding data quality, the SNGPC presented greater challenges in terms of methodological clarity and validity. Completeness, validity, and timeliness were the most frequently assessed attributes in studies involving the quality of Health Information Systems, according to a review conducted by Chen et al.[43].

Finally, it is worth highlighting that since December 2021, due to the significant instability of the SNGPC, ANVISA has temporarily and indefinitely suspended the mandatory submission of electronic files. During the suspension, private pharmacies and drugstores began to keep their records in specific physical or computerized logbooks, which must remain available to the inspection authorities[24].

Failure to submit the sales records of prescription medications through the SNGPC will result in a large gap in this database during the suspension period. It will lead to an unparalleled loss in the ability to analyze the long-term trends in the consumption of these drugs. This is even more critical for antimicrobials, considering that monitoring has become an urgent global priority in the fight against the spread of antimicrobial resistance (AMR).

Final considerations

The SNGPC data available in open access is presented in such a way as to enable the extraction of various relevant information for analyzing the consumption pattern of antimicrobials in private pharmacies and drugstores in Brazil.

However, some limitations of this database have been identified, such as the absence of individualized data and the lack of completion of the ICD-10 field. These issues hinder a qualitative analysis of the outpatient use of antimicrobials, including the indications for their use and the number of antibiotic courses taken by each patient in a given period. This information is relevant for managers, healthcare professionals, and researchers committed to controlling AMR in the country.

Moreover, some challenges were faced when using this database, such as the lack of standardization of antimicrobial names and descriptions, the presence of different types of information in the presentation description field, data entry errors, and the presence of null values. There was a considerable increase in the time required to process the data and the need to exclude some of it.

Incorporating variables that can help standardize and classify antimicrobials is crucial for enabling more comprehensive, faster, and

efficient analyses of SNGPC data. One way in which ANVISA could improve the database is through a partnership with the DATASUS, from the Ministry of Health, which has expertise in developing systems that support SUS management.

In summary, the SNGPC offers open access to valuable data for analyzing outpatient consumption of antimicrobials. It also serves as a key resource for generating knowledge in this field, given that private pharmacies and drugstores are the primary access to these drugs for the Brazilian population. However, the system's quality can and should be improved to make it more user-friendly for researchers, healthcare professionals, and managers, thereby increasing the potential for conducting more robust analyses and studies. Thus, the SNGPC could significantly enhance the monitoring of outpatient antimicrobial use in Brazil and support the development of actions and health policies aimed at tackling the advance of microbial resistance in the country.

Collaborators

Caetano MC (0000-0001-5696-8916)* contributed to the conception, design, collection, analysis, interpretation of data, writing of the manuscript and approval of the final version. Campos MR (0000-0002-7443-5977)*, Emmerick ICM (0000-0002-0383-2465)* and Luiza VL (0000-0001-6245-7522)* also contributed to the conception, design, data interpretation, critical revision and approval of the final version. ■

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