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ARTICLE

Adverse drug events identified in hospitalized patients in Brazil by International Classification of Diseases (ICD-10) code listings

Eventos adversos a medicamentos identificados em pacientes hospitalizados no Brasil de acordo com códigos da Classificação Internacional de Doenças (CID-10)

Eventos Adversos por Medicamentos identificados en pacientes hospitalizados en Brasil según los listados de códigos de la Clasificación Internacional de Enfermedades (CIE-10)

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Abstract

Studies of adverse drug events (ADEs) are important in order not to jeopardize the positive impact of pharmacotherapy. These events have substantial impact on the population morbidity profiles, and increasing health system operating costs. Administrative databases are an important source of information for public health purposes and for identifying ADEs. In order to contribute to learning about ADE in hospitalized patients, this study examined the potential of applying ICD-10 (10th revision of the International Classification of Diseases) codes to a national database of the public health care system (SIH-SUS). The study comprised retrospective assessment of ADEs in the SIH-SUS administrative database, from 2008 to 2012. For this, a list of ICD-10 codes relating to ADEs was built. This list was built up by examining lists drawn up by other authors identified by bibliographic search in the MEDLINE and LILACS and consultations with experts. In Brazil, 55,604,537 hospital admissions were recorded in the SIH-SUS, between 2008 and 2012, of which 273,440 (0.49%) were related to at least one ADE. The proportions and rates seem to hold constant over the study period. Fourteen out of 20 most frequent ADEs were identified in codes relating to mental disorders. Intoxications figure as the second most frequently recorded group of ADEs in the SIH-SUS, comprising 76,866 hospitalizations. Monitoring of ADEs in administrative databases using ICD-10 codes is feasible, even in countries with information systems under construction, and can be an innovative tool to complement drug surveillance strategies in place in Brazil, as well as in others countries.

Drug-Related Side Effects and Adverse Reactions; Medication Errors; Hospital Information Systems; International Classification of Diseases

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Introduction

Studies of adverse drug events (ADEs) are important in order not to jeopardize the positive impact of pharmacotherapy. Such events include, in addition to medication errors, those associated with risks intrinsic to the drugs even when used appropriately [1]. Hospital studies have identified high incidence of ADEs, which can affect 1.6 to 28.3% of inpatients [2] and up to 5.8% of admissions [3]. These events have substantial impact on the population morbidity, not only causing deaths, but increasing costs [2,4]. This phenomenon is a conspicuous public health problem, to which responses have been made at the international and national levels [5,6].

The importance of studying ADEs stems from the need to learn their frequency, characteristics and magnitude, identify vulnerable groups and, particularly, take measures to prevent them. Considering only events associated with hospital admissions or those that lead to emergency service care, half the events are regarded as avoidable [7].

Efforts to gauge the magnitude of the risks apply several methodological approaches, singly or in combination, and various different data sources. The scope and accuracy of each approach will affect the estimates of such events [2,8].

In Brazil, data are available from the national health surveillance notification system [9] and also from ad hoc research into ADEs at hospitals with prospective [10,11,12], retrospective [13,14] and cross-sectional [15] monitoring.

Administrative databases are an important source of information for public health purposes and for identifying ADEs. These have permitted low-cost studies with considerable geographical and time coverage, involving large numbers of patients. They enable outcome frequencies to be calculated with reference to populations of local regions, to extract national estimates and to compare countries, because they share the same coding of health disorders and conditions, the International Classification of Diseases, currently in its tenth version (ICD-10) [16,17,18].

In Brazil, today, the scenario for study of adverse events has been favourable since the Ministry of Health introduced the national patient safety programme [5]. In order to contribute to learning about ADE in hospitalized patients, this study examined the potential of applying ICD-10 codes to a national database of the public health care system (Hospital Information Systems of the Brazilian Unified National Health Syustem – SIH-SUS).

Methods

Study design and data sources

The study comprised retrospective assessment of ADEs in the SIH-SUS administrative database, from 2008 to 2012, which were identified by way of a listing of ICD-10 codes. This public-access database covers more than 11 million hospitalizations yearly in a universal system where treatment is free of charge. The data are submitted electronically by hospitals after patient discharge, consolidated at the national level, anonymized and posted on the Ministry of Health website (Brazilian Health Informatics Department. http://www2.datasus.gov.br/DATASUS/index.php, accessed on 04/Nov/2017).

The World Health Organization's (WHO) ICD is a health care classification system used as a standard research tool. Otherwise studies of ADEs have shown differences in regard to: choice of system (code list and ADE-related definitions); mechanisms or processes necessary to build up a study code list; research objectives; criteria for delimiting the research boundaries. A standardized set of codes for all countries would be more useful for international comparisons. Meanwhile, codes were selected following objective criteria, so as to guarantee some comparability with others studies.

The database contains variables relating to the treating facility and patient age and sex, together with fields for recording the principal diagnosis, secondary diagnosis, associated diagnosis and cause of death, by ICD-10 codes. In addition, the database records the procedures performed and amounts paid [19].

The mandatory fields, "principal diagnosis" and "ICD causes of death", were completed in 100% of cases, but the secondary diagnosis and associated causes fields were completed in only 12.6% and 1.1% of instances, respectively.

ADE definition and identification by ICD-10 codes

For this study, ADE was considered to be "*any incident in which the use of a medication (drug or biologic) at any dose, a medical device, or a special nutritional product (e.g., dietary supplement, infant formula, medical food) may have resulted in an adverse outcome in a patient*" [1]. That definition was used to take in events relating to medications and vaccines, as well as intoxications by medicines, although the study did not include medical devices or special nutritional products.

The listing of ADE-related ICD-10 codes was built up by examining lists drawn up by other authors identified by bibliographical search in the MEDLINE and LILACS electronic bases. Selection of the articles considered only those that included a complete, comprehensive listing of ADE-related ICD-10 codes. The information extracted from the articles included: definition of adverse event; procedures for identifying ICD-10 codes; inclusion and exclusion criteria; and code categories, by their sensitivity in indicating an event. As a result, four articles were selected [16,20,21,22].

From those articles, a preliminary list of 860 codes was built up, of which only those appearing in at least two articles were retained, resulting in 465 codes. Another 128 were included as comprising special situations, although cited in only a single article. Codes excluded were those selected in a single article (224 codes), as well as those classified in previous studies as "possible" [16] or in categories C or D [22], because the association between drug and ADEs was regarded as weak. Three additional codes (G21.2; L27.8 and L27.9) were included. The uncertainties regarding the inclusion of 14 codes were discussed with experts and assessed against one recent systematic review [23].

The final list was subjected to preliminary analysis against the database. On the basis of those results, the code D70 (neutropenia) was excluded: although it met the inclusion criteria, having been cited by two authors [16,20], neutropenia was associated with a diagnosis of cancer in more than 70% of cases, thus indicating low specificity in detecting ADEs.

The final list developed for this study thus comprised 595 ICD-10 codes, classified into: "Adverse Effects – Chapter XX" (drugs, medicaments and biological substances in therapeutic use); "Adverse Effects – Other Chapters"; "Vaccines"; and "Intoxications" (Box 1).

Cases of ADEs were considered to be admissions with at least one code on the list, when recorded in one of the four database input fields, viz., principal diagnosis secondary diagnosis, associated causes and cause of death.

Statistical analysis

The indicators of ADE frequency were "proportion of patients with ADEs" (number of patients with at least one ADE per 1,000 admissions) and "ADEs rate" (number of ADE per 1,000 admissions), stratified by year.

The database management system used was PostGreSQL version 9.3.3 (https://www.postgresql.org/). The study was conducted exclusively using secondary data from public-access databases and, was authorized by the Research Ethics Committee of the Sergio Arouca National School of Public Health, Oswaldo Cruz Foundation (Opinion n. 15/2013 – CEP-ENSP).

Results

In Brazil, 55,604,537 hospital admissions were recorded in the SIH-SUS, between 2008 and 2012, of which 273,440 (0.49%) were related to at least one ADE and ranging from 0.47 to 0.53, according to the year studied. Of them, 2,528 (0.92%) died. All of them had an ICD code of ADE as a cause of deaths.

The deaths corresponded to 235 different codes, but about a quarter of the cases were concentrated in the following codes: poisoning by other and unspecified drugs, medicaments and biological substances (T509) – 234 deaths; cardiomyopathy due to drugs and other external agents (I427) – 230 deaths; diseases of liver (K719, K717, K710) – 296 deaths; and poisoning by penicillins (T360) – 77 deaths. The other causes of death are scattered among the remaining codes.

Of total admissions associated with ADEs, 15,475 (5.7%) involved two different events and 62 (0.02%), three, bringing total events to 289,039 and resulting in a rate of 5.20 ADEs per 1,000

Box 1

List of the 10th revision of the International Classification of Diseases (ICD-10) codes related to adverse drug events (ADEs).

Category	Number of codes	ICD-ADEs
Adverse Effects – Chapter XX	185	Y40; Y40.0; Y40.1; Y40.2; Y40.3; Y40.4; Y40.5; Y40.6; Y40.7; Y40.8; Y40.9; Y41; Y41.0; Y41.1; Y41.2; Y41.3; Y41.4; Y41.5; Y41.8; Y41.9; Y42; Y42.0; Y42.1; Y42.2; Y42.3; Y42.4; Y42.5; Y42.6; Y42.7; Y42.8; Y42.9; Y43; Y43.0; Y43.1; Y43.2; Y43.3; Y43.4; Y43.5; Y43.6; Y43.8; Y43.9; Y44; Y44.0; Y44.1; Y44.2; Y44.3; Y44.4; Y44.5; Y44.6; Y44.8; Y44.9; Y45; Y45.0; Y45.1; Y45.2; Y45.3; Y45.4; Y45.5; Y45.8; Y45.9; Y46; Y46.0; Y46.1; Y46.2; Y46.3; Y46.4; Y46.5;Y46.6; Y46.7; Y46.8; Y47; Y47.0; Y47.1; Y47.2; Y47.3; Y47.4; Y47.5; Y47.8; Y47.9; Y48; Y48.0; Y48.1; Y48.2; Y48.3; Y48.4; Y48.5; Y49; Y49.0; Y49.1; Y49.2; Y49.3; Y49.4; Y49.5; Y49.6; Y49.7; Y49.8; Y49.9; Y50; Y50.0; Y50.1; Y50.2; Y50.8; Y50.9; Y51; Y51.0; Y51.1; Y51.2; Y51.3; Y51.4; Y51.5; Y51.6; Y51.7; Y51.8; Y51.9; Y52; Y52.0; Y52.1; Y52.2; Y52.3; Y52.4; Y52.5; Y52.6; Y52.7; Y52.8; Y52.9; Y53; Y53.0; Y53.1; Y53.2; Y53.3; Y53.4; Y53.5; Y53.6;Y53.7; Y53.8; Y53.9; Y54; Y54.0; Y54.1; Y54.2; Y54.3; Y54.4; Y54.5; Y54.6; Y54.7; Y54.8; Y54.9; Y55; Y55.0; Y55.1; Y55.2; Y55.3; Y55.4 ; Y55.5; Y55.6; Y55.9; Y56; Y56.0; Y56.1; Y56.2; Y56.3; Y56.4; Y56.5; Y56.6; Y56.7; Y56.8; Y56.9; Y57; Y57.0; Y57.1; Y57.2; Y57.3; Y57.4; Y57.5; Y57.6; Y57.7; Y57.8; Y57.9; Y63.0; Y63.1; Y63.8; Y63.9; Y65.0; Y65.1; Y88.0
Adverse Effects – Other Chapters	145	A04.7; D52.1; D59.0; D59.2; D61.1; D64.2; D68.3; E03.2; E06.4; E16.0; E23.1; E24.2; E27.3; E66.1; F11; F11.0; F11.1; F11.2; F11.3; F11.4; F11.5; F11.6; F11.7; F11.8; F11.9; F13; F13.0; F13.1; F13.2; F13.3; F13.4; F13.5; F13.6; F13.7; F13.8; F13.9; F15; F15.0; F15.1; F15.2; F15.3; F15.4; F15.5; F15.6; F15.7; F15.8; F15.9; F19; F19.0; F19.1; F19.2; F19.3; F19.4; F19.5; F19.6; F19.7; F19.8; F19.9; F55; G21.0; G21.1; G21.2; G24.0; G25.1; G25.4; G25.6; G44.4; G62.0; G71.1; G72.0; G93.7; H26.3; H40.6; H91.0 ; I42.7; I95.2; J70.2; J70.3; J70.4; K71; K71.0; K71.1; K71.2; K71.3; K71.4; K71.5; K71.6; K71.7; K71.8; K71.9; L10.5; L23.3; L24.4; L25.1; L27.0; L27.1; L27.8; L27.9; L43.2; L51.2; L56.0; L56.1; L64.0; M10.2; M32.0; M34.2; M80.4; M81.4; M83.5; M87.1; N14; N14.0; N14.1; N14.2; N14.3; N14.4; O35.5; O74.2; O74.3; O74.4; O74.6; P04.0; P04.1; P58.4; P93; P96.1; P96.2; Q86.1; Q86.2; R50.2; T80; T80.0; T80.1; T80.2; T80.3; T80.4; T80.5; T80.6; T80.8; T80.9; T88.2; T88.3; T88.5; T88.6; T88.7
Intoxications	245	T36; T36.0; T36.1; T36.2; T36.3; T36.4; T36.5; T36.6 ; T36.7; T36.8; T36.9; T37; T37.0; T37.1; T37.2; T37.3; T37.4; T37.5; T37.8; T37.9; T38; T38.0; T38.1; T38.2; T38.3; T38.4; T38.5; T38.6; T38.7; T38.8; T38.9; T39; T39.0; T39.1; T39.2; T39.3; T39.4; T39.8; T39.9; T40.2; T40.3; T40.4; T40.6; T41; T41.0; T41.1; T41.2; T41.3; T41.4; T41.5; T42; T42.0; T42.1; T42.2; T42.3; T42.4; T42.5; T42.6; T42.7; T42.8;T43; T43.0; T43.1; T43.2; T43.3; T43.4; T43.5; T43.6; T43.8; T43.9; T44; T44.0; T44.1; T44.2; T44.3; T44.4; T44.5; T44.6; T44.7; T44.8; T44.9; T45; T45.0; T45.1; T45.2; T45.3; T45.4; T45.5; T45.6; T45.7; T45.8; T45.9; T46; T46.0; T46.1; T46.2; T46.3; T46.4; T46.5; T46.6; T46.7; T46.8; T46.9; T47; T47.0; T47.1; T47.2; T47.3; T47.4; T47.5; T47.6; T47.7; T47.8; T47.9; T48; T48.0; T48.1; T48.2; T48.3; T48.4; T48.5; T48.6; T48.7; T49; T49.0; T49.1; T49.2; T49.3; T49.4; T49.5; T49.6; T49.7; T49.8; T49.9 ; T50; T50.0; T50.1; T50.2; T50.3; T50.4; T50.5; T50.6; T50.7; T50.8; T50.9; T96; X40; X40.0; X40.1; X40.2; X40.3; X40.4; X40.5; X40.6 ; X40.7; X40.8; X40.9; X41; X41.0; X41.1; X41.2; X41.3; X41.4; X41.5; X41.6; X41.7; X41.8; X41.9; X43; X43.0; X43.1; X43.2; X43.3; X43.4; X43.5; X43.6; X43.7; X43.8; X43.9; X60; X60.0; X60.1; X60.2; X60.3; X60.4; X60.5; X60.6; X60.7; X60.8; X60.9; X61; X61.0; X61.1; X61.2; X61.3; X61.4; X61.5; X61.6; X61.7; X61.8; X61.9; X63; X63.0; X63.1; X63.2; X63.3; X63.4; X63.5; X63.6; X63.7; X63.8; X63.9; Y10; Y10.0; Y10.1; Y10.2; Y10.3; Y10.4; Y10.5; Y10.6; Y10.7; Y10.8; Y10.9; Y11; Y11.0; Y11.1; Y11.2; Y11.3; Y11.4; Y11.5; Y11.6; Y11.7; Y11.8; Y11.9; Y13; Y13.0; Y13.1; Y13.2; Y13.3; Y13.4; Y13.5; Y13.6; Y13.7; Y13.8; Y13.9
Vaccines	20	A80.0; M02.2; T88.0; T88.1; Y58; Y58.0; Y58.1; Y58.2; Y58.3; Y58.4; Y58.5; Y58.6; Y58.8; Y58.9; Y59.0; Y59.1; Y59.2; Y59.3; Y59.8; Y59.9

admissions. In spite of fluctuations, the proportions and rates seem to hold constant over the study period (Table 1). Most of the ADEs identified in the study period were those classified as "Adverse Effects – Other Chapters" and "Intoxications", at rates of 3.56 and 1.38 per 1,000 admissions, respectively. The ADEs identified as in the "Adverse Effects – Chapter XX" and "Vaccines" groups resulted in rates of 0.23 and 0.02 per 1,000 admissions, respectively (Table 2).

Table 1

Number and rate of adverse drug events (ADEs) per year, as recorded in the Hospital Information System of the Brazilian Unified National Health System (SIH-SUS), from 2008 to 2012.

Year	Total admissions	Admissions with ADEs n (%)	ADEs	Rate/1,000 admissions
2008	10,743,603	56,565 (0.53)	59,772	5.56
2009	11,128,809	54,364 (0.49)	57,555	5.17
2010	11,357,965	53,781 (0.47)	56,858	5.01
2011	11,281,571	54,360 (0.48)	57,453	5.09
2012	11,092,589	54,370 (0.49)	57,401	5.17
Total	55,604,537	273,440 (0.49)	289,039	5.20

Source: Brazilian Health Informatics Department (http://www2.datasus.gov.br/DATASUS/index.php, accessed on 04/Nov/2017).

Table 2

Number and rate of adverse drug events (ADEs) by 10th revision of the International Classification of Diseases (ICD-10) code category, per year, as recorded in the Hospital Information System of the Brazilian Unified National Health System (SIH-SUS), from 2008 to 2012.

ICD-10 code category	Number and rate/1,000 admissions					Total
	2008	2009	2010	2011	2012	
Adverse Effects – Other Chapters	39,246 (3.65)	36,604 (3.29)	39,758 (3.50)	41,030 (3.64)	41,425 (3.73)	198,063 (3.56)
Adverse Effects – Chapter XX	1,992 (0.19)	2,460 (0.22)	2,924 (0.26)	2,909 (0.26)	2,776 (0.25)	13,061 (0.23)
Intoxications	18,361 (1.71)	18,276 (1.64)	13,945 (1.23)	13,332 (1.18)	12,952 (1.17)	76,866 (1.38)
Vaccines	173 (0.02)	215 (0.02)	231 (0.02)	182 (0.02)	248 (0.02)	1,049 (0.02)
Total	59,772 (5.56)	57,555 (5.17)	56,858 (5.01)	57,453 (5.09)	57,401 (5.71)	289,039 (5.20)

Source: Brazilian Health Informatics Department (http://www2.datasus.gov.br/DATASUS/index.php, accessed on 04/Nov/2017).

Table 3 shows the 20 most frequent ADEs, which accounted for approximately 70% of the total. Fourteen of them were identified in codes relating to mental disorders. All the 20 most frequent ADEs were identified in codes classified in this study as "Adverse Effects – Other Chapters" and "Intoxications".

Table 4 shows the five most frequent ADEs by category. In addition to the "Adverse Effects – Other Chapters" and "Intoxications", which are among the 20 most frequent ADEs, as described above, also prominent were those classified as "Adverse Effects – Chapter XX", associated with specific drugs such as oestrogens, progestogens and anticoagulants. In the "Vaccines" category, the most frequent events were associated with complications resulting from medical care.

Discussion

The study detected ADEs that had occurred in patients admitted to Brazil's public hospital system between 2008 and 2012. For that purpose, it used the database of the SIH-SUS, to which a list of 595 codes of the ICD-10 was applied in order to identify cases. There were 273,440 hospitalizations associated with at least one ADE. As a frequency, 0.49% of total patients admitted were patients with events. In these, 289,039 events occurred, resulting in an ADE rate of 5.20 per 1,000 admissions. About 1% of the hospitalizations with ADE had an ICD code in the field "cause of death" which has significant impact to public health purpose. Although Chapter XX (drugs, medicaments and biological

Table 3

Twenty most frequent adverse drug events (ADEs) recorded in the Hospital Information System of the Brazilian Unified National Health System (SIH-SUS), from 2008 to 2012.

ICD-10	Description	Category	n	%
F19.2	Mental and behavioral disorders due to multiple drug use and use of other psychoactive substances: dependence syndrome	Adverse Effects – Other Chapters	89,036	30.80
F19.0	Mental and behavioral disorders due to multiple drug use and use of other psychoactive substances: acute intoxication	Adverse Effects – Other Chapters	27,428	9.49
F19.5	Mental and behavioral disorders due to multiple drug use and use of other psychoactive substances: psychotic disorder	Adverse Effects – Other Chapters	16,656	5.76
T50.9	Poisoning: other and unspecified drugs, medicaments and biological substances	Intoxications	15,755	5.45
F19.9	Mental and behavioral disorders due to multiple drug use and use of other psychoactive substances: unspecified mental and behavioral disorder	Adverse Effects – Other Chapters	9,798	3.39
F19.1	Mental and behavioral disorders due to multiple drug use and use of other psychoactive substances: harmful use	Adverse Effects – Other Chapters	5,760	1.99
T36.9	Poisoning: systemic antibiotic, unspecified	Intoxications	4,400	1.52
I42.7	Cardiomyopathy due to drugs and other external agents	Adverse Effects – Other Chapters	4,366	1.51
F19.3	Mental and behavioral disorders due to multiple drug use and use of other psychoactive substances: withdrawal state	Adverse Effects – Other Chapters	4,198	1.45
X61.9	Intentional self-poisoning by and exposure to antiepileptic, sedative-hypnotic, antiparkinsonism and psychotropic drugs, not elsewhere classified – unspecified site	Intoxications	3,769	1.30
T42.4	Poisoning: benzodiazepines	Intoxications	3,416	1.18
F11.1	Mental and behavioral disorders due to use of opioids: harmful use	Adverse Effects – Other Chapters	2,780	0.96
T36.0	Poisoning: penicillins	Intoxications	2,526	0.87
F11.0	Mental and behavioral disorders due to use of opioids: acute intoxication	Adverse Effects – Other Chapters	2,463	0.85
T43.9	Poisoning: psychotropic drug, unspecified	Intoxications	2,462	0.85
T43.2	Poisoning: other and unspecified antidepressants	Intoxications	2,341	0.81
F13.0	Mental and behavioral disorders due to use of sedatives or hypnotics: acute intoxication	Adverse Effects – Other Chapters	2,334	0.81
F19.8	Mental and behavioral disorders due to multiple drug use and use of other psychoactive substances: other mental and behavioral disorders	Adverse Effects – Other Chapters	2,267	0.78
T80.0	Air embolism following infusion, transfusion and therapeutic injection	Adverse Effects – Other Chapters	1,969	0.68
T46.9	Poisoning: other and unspecified agents primarily affecting the cardiovascular system	Intoxications	1,883	0.65
Total			289,039	100.0

ICD-10: 10th revision of the International Classification of Diseases.
Source: Brazilian Health Informatics Department (http://www2.datasus.gov.br/DATASUS/index.php, accessed on 04/Nov/2017).

substances in therapeutic use) relates specifically to the problem studied here, the codes that returned most information were scattered across the various chapters of the ICD-10, mostly as relating to mental disorders.

Similar studies performed with databases in England for the period from 1996 to 2008 resulted in percentages from 0.35% to 0.9% [21,24,25] . Nonetheless, the English data do not include intoxications. Taking the proportion of hospitalizations in the SIH-SUS, less intoxications, 3.8 ADEs were identified per 1,000 hospitalizations, a value similar to the English data for the period 1996 to 2000 [24]. However, estimates by more recent European studies are higher than those for Brazil. One French study, which

Table 4

Most frequent adverse drug events (ADEs) recorded in the Hospital Information System of the Brazilian Unified National Health System (SIH/SUS) by the 10th revision of the International Classification of Diseases (ICD-10) code category, from 2008 to 2012.

Category/ICD-10	Description	n	%
Adverse Effects – Other Chapters			
F19.2	Mental and behavioral disorders due to multiple drug use and use of other psychoactive substances: dependence syndrome	89,036	44.95
F19.0	Mental and behavioral disorders due to multiple drug use and use of other psychoactive substances: acute intoxication	27,428	13.85
F19.5	Mental and behavioral disorders due to multiple drug use and use of other psychoactive substances: psychotic disorder	16,656	8.41
F19.9	Mental and behavioral disorders due to multiple drug use and use of other psychoactive substances: unspecified mental and behavioural disorder	9,798	4.95
F19.1	Mental and behavioral disorders due to multiple drug use and use of other psychoactive substances: harmful use	5,760	2.91
Total		198,063	100.00
Intoxications			
T50.9	Poisoning: other and unspecified drugs, medicaments and biological substances	15,755	20.50
T36.9	Poisoning: systemic antibiotic, unspecified	4,400	5.72
X61.9	Intentional self-poisoning by and exposure to antiepileptic, sedative-hypnotic, antiparkinsonism and psychotropic drugs, not elsewhere classified – unspecified site	3,769	4.90
T42.4	Poisoning: benzodiazepines	3,416	4.44
T36.0	Poisoning: penicillins	2,526	3.29
Total		76,866	100.00
Adverse Effects – Chapter XX			
Y57.9	Drug or medicament, unspecified	1,743	13.35
Y42.5	Other estrogens and progestogens	1,601	12.26
Y57.8	Other drugs and medicaments	1,544	11.82
Y44.2	Anticoagulants	941	7.20
Y88.0	Sequelae of adverse effects caused by drugs, medicaments and biological substances in therapeutic use	532	4.07
Total		13,061	100.00
Vaccines			
T88.1	Other complications following immunization, not elsewhere classified	473	45.09
T88.0	Infection following immunization	221	21.07
Y59.9	Vaccine or biological substance, unspecified	119	11.34
Y59.8	Other specified vaccines and biological substances	60	5.72
Y58.9	Other and unspecified bacterial vaccines	56	5.34
Total		1,049	100.00

Source: Brazilian Health Informatics Department (http://www2.datasus.gov.br/DATASUS/index.php, accessed on 04/Nov/2017).

also excluded intoxications, found a proportion of 0.6% [20]; a German study, which used a listing of codes similar to the one used here, estimated 0.63% of hospitalizations with ADEs [22]. The differences encountered may be explained, not only by characteristics of the health systems, but by other factors, such as the set of codes selected to identify cases and the number of database input fields available for recording secondary diagnoses. However, the strategy used in this study allows us to identify smaller estimates than other methods [2,3], since events are recorded by health professionals during providing health care.

Identification of ADEs by ICD-10 codes in administrative databases can be a complementary drug surveillance tool for monitoring large populations over time. It would be useful to develop a systematic, prospective use of the two systems, in order to compare and integrate their contribution, also in terms of focusing on the differences, if any, of their origin from the different settings of the health system.

In the countries mentioned above, more secondary diagnosis input fields are available than in the SIH-SUS and the mean number of secondary diagnoses entered was greater than 2.7 [26]. In Brazil, only one secondary diagnosis field is available and, even so, completion rates are low. In this study, 87% of secondary diagnosis fields were not completed in the SIH-SUS database. However, in recent years, two additional diagnosis fields ("associated causes" and "cause of death-related ICD code") have been introduced into the database, extending the scope for recording ADEs.

The list of 595 ICD-10 codes drawn up from the literature review and by consulting experts was originally based on four articles that examined only administrative and hospital databases. A recent review of studies that used the ICD-10 [23] was examined with a view to validating the list. No substantial discrepancies were observed.

The intention was to build a comprehensive list, while endeavouring not to include codes that might result in an accumulation of false positives. Accordingly, codes expressing very frequent diagnoses that may or may not be associated with drugs were excluded. Although these may possibly be drug-related, other, highly prevalent causes cannot be discarded. "Gastrointestinal haemorrhage, unspecified" (K92.2) and "Neutropenia" (D70) are examples of this situation. The decision to exclude very frequently used codes is based on clinical and statistical criteria. For instance, gastrointestinal haemorrhage (GIH) (K92.2) is associated with widely used drugs, such as nonsteroidal anti-inflammatories. However, it may also be related to diagnoses such as ulcers, varices, esophagitis, gastritis, tumours, alcohol, vascular disease, infection and so on. The proportion of drug-related cases of GIH is relatively low (about 30%) compared with the proportion of cases of GIH related to other diseases.

Few studies offered validity analyses of the selected codes. Hohl et al. [23], comparing data from a prospective study of ADEs with cases identified in an emergency service database, found sensitivity of 28%. Wu [27], meanwhile, comparing data from emergency electronic patient records with chart review, found sensitivity of 45% and specificity of 100%.

The most frequent ICD-10 codes present in the "Adverse Effects – Other Chapters" group reflect predominantly events relating to mental disorders and to psychotropic drugs. Even though some of these codes are non-specific, these findings are useful in characterizing problems with drugs in the field of psychiatric disorders. The inappropriate use or abuse of psychotropic drugs, together with the reduced use of other therapeutic resources, has been discussed in the Brazilian and international literature [28,29,30]. The use of benzodiazepine drugs for long periods, for non-specific conditions and in populations of older adults, for example, has been associated with several adverse outcomes, including dependence, cognitive decline, falls and even death [31,32]. However, use of this class of drugs is widespread. In Europe, benzodiazepine prescription rates are from 570 to 1,700 per 10,000 person-years [33]. In Brazil, consumption of these drugs has been increasing. In 2012, 45 in every 10,000 residents of Brazil's state capitals used one dose of benzodiazepine drugs every day of the year [34].

In this study, "Intoxications" figure as the second most frequently recorded group of ADEs in the SIH-SUS, comprising 76,866 hospitalizations. These estimates represent a significant portion of notifications of drug-related intoxications compiled by the Brazilian poisoning information system, which recorded 138,376 intoxications over the same period (Sistema Nacional de Informaçãoes Tóxico-Farmacológicas. Estatística anual de casos de intoxicação e envenenamento, Brasil 2008-2012. http://sinitox.icict.fiocruz.br/dados-nacionais, accessed on 04/Nov/2017). Prominent among drug classes related to intoxications are antibiotics (systemic-use and penicillins). Neurotoxic effects from several groups of antibiotics are common among vulnerable individuals [35]. Age extremes, prior neurological disease and renal failure are factors that should be considered in adjusting doses in this population and preventing neurotoxicity associated with these drugs.

Among admissions evaluated in the SIH-SUS, benzodiazepines figured among the five most frequent intoxication-related causes recorded. Although widely prescribed for more than 50 years, the risk-benefit ratio of using benzodiazepines is still being discussed [36]. There is worldwide concern with the risks involved in the use of this drug class, as mentioned earlier, and the findings of this study corroborate the data of international studies [37,38].

Anticoagulants are among the drug classes most involved in ADEs relate to non-specific drugs among inpatients ("Adverse Effects – Chapter XX") [39,40,41]. They are considered high-alert medications, because they entail heightened risk of causing significant patient harm when administration is faulty [42]. In the USA, a large number of hospitalizations are associated with ADEs from the therapeutic use of anticoagulants, many of them regarded as medication errors and thus preventable [43]. Studies in Brazil show that anticoagulants are among the classes most implicated in ADEs detected in inpatients by the trigger method [14,16].

As regards vaccines, of the five most frequent codes, two related to complications from medical care: "Other complications following immunization, not elsewhere classified" (T88.1) and "Infection following immunization" (T88.0). In Northeast Brazil, a descriptive study using data from the National Vaccine Adverse Event Reporting System identified 667 adverse events in 402 records evaluated; adverse events occurred more commonly in bacterial (82.6%) than in viral vaccines [44]. The Institute for Safe Medication Practices alerts to the risk of medication errors involving vaccines, which can precipitate severe events, including reported deaths [45]. One US study, describing errors reported to the Vaccine Adverse Event Reporting System, from 2000 to 2013, received a total of 311,185 reports of adverse events following vaccination, of which 7% were vaccination error reports, and documented 21,843 errors. Reports increased from 10 per year in 2000 to 4,284 in 2013 [46].

The characteristics of the events and of the drugs, as well as the measures necessary to prevent them, may be different depending on whether they originate inside or outside the hospital. The ADE related to mental disorders and those related to complications following immunization illustrate the differences, the first one occurring inside or outside the hospital and the second one only in ambulatory setting, demanding distinct management of intervention and prevention.

Limitations in the reliability of the results presented here can be discussed at several levels. The small number of diagnosis input fields for Brazilian databases is certainly a factor of concern, which may reduce the usefulness of the list of codes for calculating ADE occurrence statistics. The SIH-SUS offers only two such input fields (principal and secondary diagnosis), while low completion rates for secondary diagnosis particularly limit information on events. However, these issues have not prevented the ICD-10 from being used, because they are not problems of Brazilian databases alone [18].

Also in relation to the diagnosis fields, the quality and rules of completion entail important implications for the study of ADEs. In order to monitor, control and reduce the frequency with which adverse reactions and errors occur in drug indication, dispensing and administration processes, it is of interest to know if the event occurred at hospital admission or during the hospital stay. In Stausberg & Hasford [22], the event is considered present at admission if recorded in the principal diagnosis; if in the secondary diagnosis, it may have occurred during the hospital stay. However, that assumption has limitations. In Brazil, the guidelines for completing principal and secondary diagnosis fields are restricted to certain specific pathologies and procedures. Although in some cases, completion of the secondary diagnosis field is mandatory, as in the cases of disorders from external causes [47], it is possible that there is under-reporting.

One important shortcoming in Brazil's national health care system, which compromises service evaluation and the quality of patient care, is the absence of information on drugs prescribed. Brazilian databases offer no information on medications prescribed or used, with the exception of a restricted group of (generally high-cost) drugs, which are reported as procedures in group six of the SIH-SUS schedule of procedures.

Studies using large databases encounter considerable theoretical and operational difficulties, which can affect event frequency statistics. The most prominent difficulties include the concept and diagnosis of ADEs and the identification of events among ICD codes. One pioneering study of methodological standardization, using the same ICD-10 codes and defining variables for adjusting rates, found adjusted prevalences of 5.64%, 4.78% and 3.22% for the USA, Germany and England, respectively. All the same, the comparison is limited, especially by differences in service structure and diagnosis coding processes [48].

As there is no single, internationally-agreed list of codes, the list of codes built up for this study was based on lists provided by a number of authors, consultations with experts, the literature and objective selection criteria. This study points to a need to develop a single list suited to ADE research and monitoring. Efforts to achieve this goal are ongoing. In addition to the ICD-WHO code list there

is the Medical Dictionary for Regulatory Activities (MedDRA) Terminology, an international medical terminology list. Members of the WHO and MedRA have attempted to harmonize these systems [49].

In conclusion, although there is a similar previous study, restricted to the State of Rio de Janeiro [16], the strength and originality of this study is that it analyses 11 million hospitalizations yearly and describes the main causes of adverse drug events.

The ICD-10 code listing proved applicable to Brazilian conditions, in spite of the small number of diagnosis input fields available in SIH-SUS administrative database. In future, validation studies using other databases or hospital patient records will be an important research strategy.

Monitoring of ADEs in administrative databases using ICD-10 codes is feasible and can be an innovative tool to complement drug surveillance strategies in Brazil, as well as in other countries.

Contributors

A. C. Martins participated in the conception and design of the study, analysis and interpretation of data, writing and critical review of the manuscript and approval of the final version. F. Giordani, L. Guaraldo and S. Rozenfeld contributed in the conception and design of the study, analysis and interpretation of the data, critical revision of the manuscript and approval of the final version. G. Tognoni contributed in the interpretation of the results, critical revision of the manuscript and approval of the final version.

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Resumo

Os estudos sobre eventos adversos a medicamentos (EAMs) são importantes para evitar de prejudicar o efeito positivo da farmacoterapia. Os EAMs têm impacto substancial nos perfis de morbidade da população e no aumento dos custos operacionais do sistema de saúde. As bases de dados administrativos representam uma fonte de informação importante para fins de saúde pública em geral e especificamente para identificar os EAMs. No intuito de contribuir para o conhecimento sobre EAMs em pacientes hospitalizados, o estudo examinou a aplicabilidade dos códigos da CID-10 (10ª revisão da Classificação Internacional de Doenças) ao Sistema de Informações Hospitalares do Sistema Único de Saúde (SIH-SUS). O estudo integrou uma avaliação retrospectiva de dados administrativos do SIH-SUS referentes aos anos de 2008 a 2012. Para tanto, foi elaborada uma lista de códigos da CID-10 relacionados a EAMs. A lista foi produzida a partir de uma consulta às listas projetadas por outros autores e identificadas através de uma busca em MEDLINE e LILACS e consultas com especialistas. No Brasil, foram registradas 55.604.537 internações hospitalares no SIH-SUS entre 2008 e 2012, das quais 273.440 (0,49%) estiveram relacionadas a pelo menos um EAM. As proporções e taxas de EAMs permaneceram constantes ao longo do período estudado. Quatorze dos vinte EAMs mais frequentes foram identificados através de códigos relacionados a transtornos psiquiátricos. As intoxicações figuram como o segundo grupo mais frequente de EAMs registrados no SIH-SUS, com 76.866 internações. O monitoramento dos EAMs com o uso dos códigos da CID-10 mostrou ser uma metodologia viável, mesmo em países com sistemas de informação ainda incompletos, e pode ser uma ferramenta inovadora para complementar as estratégias atuais de vigilância farmacológica no Brasil, assim como, em outros países.

Efeitos Colaterais e Reações Adversas Relacionados a Medicamentos; Erros de Medicação; Sistemas de Informação Hospitalar; Classificação Internacional de Doenças

Resumen

Los estudios sobre eventos adversos por medicamentos (EAMs) son importantes, para no comprometer el impacto positivo de la farmacoterapia. Estos eventos tienen un impacto sustancial en los perfiles de morbilidad de la población e incrementan los costes operativos del sistema de salud. Las bases de datos administrativas son una importante fuente de información por motivos de salud pública y para identificar EAMs. Con el fin de contribuir al aprendizaje sobre EAM en pacientes hospitalizados, este estudio examinó el potencial de aplicar códigos CIE-10 (10ª revisión de la Clasificación Internacional de Enfermedades) a una base datos nacional del sistema de salud público (SIH-SUS). Este estudio estuvo constituido por una evaluación retrospectiva de EAMs, en la base de datos administrativa del SIH-SUS, desde 2008 a 2012. Para ello, se desarrolló la lista de la CIE-10 con códigos para EAMs. Esta lista se creó examinando listas diseñadas por otros autores, identificados a través de búsquedas bibliográficas en MEDLINE, LILACS y consultas con expertos. En Brasil, se registraron 55.604.537 admisiones hospitalarias en el SIH-SUS, entre 2008 y 2012, de las cuales 273.440 (0,49%) sufrieron al menos un EAM. Los porcentajes y tasas parecieron mantenerse constantes durante el periodo de estudio. Catorce de los 20 más frecuentes EAMs fueron identificados con códigos relacionados con enfermedades mentales. Las intoxicaciones fueron el segundo grupo registrado más común de EAMs en el SIH-SUS, representando 76.866 hospitalizaciones. La supervisión de EAMs en las bases de datos administrativas, usando los códigos CIE-10, es factible, incluso en países cuyos sistemas de información se encuentran en proceso de construcción, y puede ser un herramienta innovadora como complemento de las actuales estrategias de supervisión sobre medicamentos en Brasil, así como en otros países.

Efectos Colaterales y Reacciones Adversas Relacionados con Medicamentos; Errores de Medicación; Sistemas de Información en Hospital; Clasificación Internacional de Enfermedades

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