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Drug data coding and analysis in epidemiologic studies

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Abstract. In epidemiologic studies that collect comprehensive information on medication use, the complexity of dealing with a large number of trade and generic names may limit the utilization of these data bases. This paper shows the specific advantage of using two coding systems, one to maximize efficiency of data entry, and the other to facilitate analysis by organizing the drug ingredients into hierarchical categories. The approach used by two large surveys, one in the USA and one in Italy, is described: the Established Populations for Epidemiologic Studies of the Elderly (EPESE) and the 'Gruppo Italiano di Farmacovigilanza nell' Anziano' (GIFA). To enter the medications into a computerized database, codes matching the drug product names are needed. In the EPESE the prescription and over the counter drug products are coded with the Drug Products Information Coding System (DPICS) and the Iowa Nonprescription Drug Products Information Coding System (INDPICS), respectively. The GIFA study uses the coding system of the Italian Ministry of Health (MINSAN), with a unique numeric code for each drug product available in Italy. To simplify the analytical process the drug entry codes are converted into hierarchical coding systems with unique codes for specific drug ingredients, chemical and therapeutic categories. The EPESE and GIFA drug data are coded with the Iowa Drug Information System (IDIS) ingredient codes, and the Anatomical Therapeutic and chemical (ATC) codes, respectively. Examples are provided that show coding of diuretics in these two studies and demonstrate the analytic advantages of these systems.

Key words: Classification, Clinical pharmacology, Data bases, Drugs, Epidemiology

Introduction

Drug data coding for research in epidemiologic studies is a complex task. The source information collected in the field includes disparate trade and generic names of drug products which need to be coded for entering the information into a computerized database for future analysis. For combination drugs, the drug product contains more than one drug ingredient, and a decision must be made whether a database is needed that will employ codes for drug products or individual drug ingredients.

The coding system to be utilized depends on the objective of the study. Analyses focusing on beneficial or adverse effects of medications have to consider drug ingredients. Therefore, the coding system must allow for easy identification of the ingredients or combinations of ingredients contained in the drug products. In other potential studies involving the costs of drugs, it is essential to identify with a unique code the manufacturer and the dosage form of each single drug product. Such codes are also useful for data entry in order to recognize single drug products taken by the study participants.

Little has been published on drug coding systems and, surprisingly, there are very few systems that work well for both initial coding and analytic purposes. Recent reports describing drug data collection methods designed for research purposes do not provide adequate information on drug coding systems or do not use a systematic drug classification system that can be easily used for analytical purposes [1, 2].

Although manual assignment of drug category codes may be suitable for studies with limited number of participants, for large studies dealing with thousands of individuals, comprehensive automated drug coding and classification is necessary. The aim of the present paper is to describe and compare two drug data collection and classification systems that have been developed and utilized in two large epidemiologic studies in the USA and Italy, and have proven practical and analytically useful. These studies both use an approach to managing drug data

in an epidemiologic study that maximizes efficiency by utilizing two data bases, one for data collection and one for data analysis. The value of this approach has not been generally appreciated and will be demonstrated here. For illustration purposes, we will show the frequencies of diuretics taken by the participants of one site of the Established Populations for Epidemiologic Studies in the Elderly (EPESE) [3], and of the Gruppo Italiano di Farmacovigilanza nell' Anziano (Italian group of pharmacosurveillance in the elderly, GIFA) study [4, 5]. We will discuss the two coding systems used by these studies for data entry purposes and for analytic drug investigations: the Anatomical Therapeutic and Chemical (ATC) codes [6], and the Iowa Drug Information System (IDIS) codes. The IDIS produces Drug Literature Microfilm File and its online version, IDIS Drug File, which is the drug therapy-specific database used in more drug information centers in both the United States and Europe than any other medical search system [7].

Materials and methods

EPESE and IDIS codes. This report uses information from the Iowa site of the EPESE, a prospective collaborative study supported by the US National Institute on Aging. Drug data were collected in each of the four in-home interviews, the first three spaced three years apart and the fourth at the ten year follow-up. The baseline community survey was conducted between 1 December 1981 and 15 October 1982, 3673 people age 65 years and older, representing 80 percent of all individuals of this age group living in Iowa and Washington counties, IA.

The methods for drug data collection have been reported in detail elsewhere [8, 9]. Briefly, the participants were asked to show the interviewer all medications taken in the preceding two weeks. The drug product name was recorded from the label. If the label was not seen, the participant was asked the name of the product. For data entry, prescription drug products were coded according to the Drug Products Information Coding System (DPICS) [10], and the over the counter drug products were coded using the Iowa Nonprescription Drug Products Information Coding System (INDPICS) [9]. A total number of 9,324 drug products in various dosage forms had DPICS or INDPICS numeric codes. This included all prescription drugs marketed in the USA in 1979 and was updated to include all prescription and non prescription drugs encountered throughout this study. Coders were able to select the appropriate code for each drug product by referring to a coding manual ordered alphabetically by both trade and generic name (e.g. Polymox® or amoxicillin). For analytical purposes, all drug data were re-coded according to IDIS codes. A file matching DPICS and INDPICS with IDIS codes has been recently created by one of the authors (EAC) and allowed computerized automatic re-coding of all drugs to link each drug product, as coded in the DPICS and INDPICS to specific ingredients, as coded by IDIS.

The IDIS codes are a 4 level hierarchical coding system based on the American Hospital Formulary Society (AHFS) drug categories [11], with 3 levels of therapeutic categories and one level of ingredient category. A full IDIS code has 8 numeric digits and represents a single drug ingredient. The first 2 digits identify the main therapeutic category (for example 08: antiinfectives, 10: antineoplastic agents). The next 2 digits identify a therapeutic subcategory (for example 0812: antibiotics, 0818: antivirals, 0836: urinary germicides). The 5th and the 6th digit identify an even more homogeneous subcategory (for example 081202: antibiotics aminoglycosides, 081206: antibiotics cephalosporins). Finally, the last 2 digits identify specific chemical ingredients (for example 08120626: antiinfectives-antibiotics-cephalosporins-cefotaxime, 08121690: antiinfectives-antibiotics-penicillins-amoxicillin).

GIFA study and ATC codes. The GIFA study is a collaborative pharmacosurveillance study on adverse drug reactions observed in hospitalized patients (n = 9148) in 41 clinical centers throughout Italy. The study design has been previously described in detail [4, 5]. Briefly, all patients admitted to the 22 internal medicine and 19 geriatric wards during two surveillance periods (May–June 1988 and November–December 1988) were enrolled. For each patient, a questionnaire was completed at admission and updated daily until discharge. Data recorded included patients' demographic characteristics, diagnoses, routine laboratory blood examinations and adverse drug reactions. The names and dosages of drugs taken prior to admission, taken during hospitalization and prescribed at discharge were entered into a microcomputer at the peripheral clinical centers by means of a dedicated software system. This software, developed in DBase III (TM Ashton-Tate) and compiled with Clipper (TM Nantucket), allowed automated coding of the drug products by typing the first few letters of the drug on the keyboard. All matching drug names appeared on the screen and the drug was recorded and automatically coded simply by choosing with the cursor the appropriate drug product and dosage form. The mass storage of the microcomputer contained all 14,931 drug products in various dosage forms available in Italy [12], and was updated monthly during the study. At the end of the survey period, the data were copied onto floppy disks and mailed to the coordinating center for analysis.

The drugs were coded according to two coding systems. A commercially oriented coding system of the Italian Ministry of Health (MINSAN), with a unique numeric code identifier for each manufacturer,

drug product and dosage form, was used for data entry. For analysis, the drugs were classified according to a modified version of the ATC coding. The ATC classification system has been developed by the Nordic Council on Medicines in collaboration with the World Health Organization (WHO) Collaborating Center for Drug Statistics Methodology and is recommended by WHO for scientific drug analysis. The ATC codes are described in detail in the European Drug Index [6]. Briefly, this is a 5 level hierarchical classification system. Drugs are divided into main anatomical groups (1st level, 1 alphanumeric digit) with 2 therapeutic subgroups (2nd and 3rd levels, 2 numeric digits and 1 alphanumeric digit respectively). The 4th level (1 alphanumeric digit) consists of a chemical/therapeutic subgroup, and the code concludes with a chemical ingredient or a combination of ingredients within a drug product at level 5 (2 numeric digits). For example, the ATC code for amoxicillin is J01CA04; J: general antiinfectives for systemic use, J01: antibiotics for general use, J01C: broad spectrum penicillins, J01CA: ampicillin and similar antibiotics, J01CA04: amoxicillin. In Italy, the 5th level of the ATC code is replaced by a 4 digit unique numeric identifier for the chemical ingredient or combination of ingredients. Thus, the ATC code for amoxicillin in the GIFA study would be J01CA.0283. The files containing the Italian drug products descriptions, and MINSAN and ATC classification codes were purchased from Organizzazione Editoriale Medico Farmaceutica, L'Informatore Farmaceutico s.p.a., Milan, Italy.

Data analysis. As shown in Figure 1, panel B, the EPESE drug data analytic file has been structured on a one record per ingredient basis, as identified by the IDIS code. Thus, a participant has as many records as the number of drug ingredients he or she is taking. A flag was added to indicate whether the ingredient was the single component of the drug product or it was combined with other ingredients. A similar file structure, with one record per ATC code, was created for the GIFA study. When the frequencies of IDIS and ATC codes were tabulated, a descriptive label corresponding to each code was automatically merged from a computerized file containing the code dictionary. Thus, it was possible to obtain fully annotated listings of all drug ingredients. All file structure modifications were made on microcomputers by utilizing DBase III or SPSS (SPSS Inc., Chicago, IL) programming. The frequency tables were obtained by means of SPSS.

Results

EPESE study. At baseline interview, drug data information was obtained from 3467 participants of the Iowa EPESE site for whom face-to-face interviews were conducted [8, 9]. Overall, 11,750 ingredients of 9,955 drug products were taken by the study participants. The first 2 hierarchical levels of IDIS code (first 4 digits) allowed us to identify all diuretics (code: 4028, electrolyte solutions-diuretics, n = 1447 ingredients) (Table 1). According to the IDIS classification there were 15 different diuretic ingredients divided in 3 categories taken by the study population. The first category (3rd hierarchical level of IDIS code: 402800) contained 3 potassium-sparing diuretics (n = 213): spironolactone, triamterene and amiloride. Low-ceiling diuretics were included in the second category (3rd hierarchical level of IDIS code: 402801): 8 thiazide diuretic ingredients (n = 941) (bendroflumethiazide, chlorothiazide, hydrochlorothiazide, benzthiazide, hydroflumethiazide, methyclothiazide, polythiazide, and trichlomethiazide) and 3 sulfonamide derivatives (chlorthalidone, metolazone and quinethazone). The loop-diuretics category (n = 214) (3rd hierarchical level of IDIS code: 402804) contained only 1 ingredient: furosemide (bumetanide was not marketed in the USA in 1980). In the last column of Table 1 are shown the frequencies of diuretic ingredients combined with other drug ingredients within the same drug product. Table 2 describes in detail those combinations and their frequencies.

File A
1 record per participant

ID 1	Drug X	Drug Y	Drug Z	
ID 2				
ID 3				
ID 4	Drug W			

File B
1 record per ingredient

			C *
ID 1	Drug X	Ingredient A	1
ID 1	Drug X	Ingredient B	1
ID 1	Drug Y	Ingredient K	0
ID 1	Drug Z	Ingredient M	0
ID 4	Drug W	Ingredient R	1
ID 4	Drug W	Ingredient S	1
ID 4	Drug W	Ingredient T	1

Figure 1. Comparison of two file structures for drug data bases. In panel A each record contains drug information for one participant (ID). Each variable represents one drug product. In panel B each record represents one drug ingredient. The number of records for each participant is equal to the number of drug ingredients he is taking. The participants taking no drugs (ID2 and ID3) have no records in this file. * = Combination: the ingredient is combined with other ingredients; 1 = Yes; 0 = No.

Table 1. Frequencies (N) of diuretics taken at baseline by the participants from Iowa in the EPESE study. The drugs are classified according to the IDIS coding system

Hierarchical level				Description	N total	N as combination
1	2	3	4			
40				Electrolyte solutions		
	28			Diuretics		
		00		Other diuretics		
			40280013	– Spironolactone	38	29
			40280016	– Triamterene	161	160
			40280062	– Amiloride	14	14
		01		Low-ceiling diuretics, including thiazides		
			40280101	– Chlorthalidone	70	7
			40280104	– Bendroflumethiazide	13	13
			40280106	– Chlorothiazide	162	26
			40280108	– Hydrochlorothiazide	702	394
			40280110	– Metolazone	7	0
			40280111	– Quinethazone	2	0
			40280172	– Benzthiazide	1	0
			40280178	– Hydroflumethiazide	2	2
			40280184	– Methyclothiazide	35	35
			40280186	– Polythiazide	16	1
			40280199	– Trichlormethiazide	10	1
		04		Loop-diuretics		
			40280401	– Furosemide	214	0

EPESE = Established populations for epidemiologic studies in the elderly.
IDIS = Iowa drug information system.

Table 2. Frequencies (N) of diuretics combined with other ingredients taken at baseline by the participants from Iowa in the EPESE. The diuretic ingredients listed in the present table are also included in Table 1.

Diuretic ingredients		Ingredients combined with diuretics		N
IDIS code	Description	IDIS code	Description	
40280101	Chlorthalidone	24080010	Reserpine	7
40280104	Bendroflumethiazide	24080009	Rauwolfia serpentina	12
		40120003	Potassium chloride	1
40280106	Chlorothiazide	24080006	Methyldopa	2
		24080010	Reserpine	24
40280108	Hydrochlorothiazide	12160150	Propranolol	1
		24080003	Guanethidine	2
		24080006	Methyldopa	105
		24080010	Reserpine	52
		24120094	Hydralazine	6
		24080010 + 24120094	Reserpine + Hydralazine	25
		40280013	Spironolactone	29
		40280016	Triamterene	160
		40280062	Amiloride	14
40280178	Hydroflumethiazide	24080010	Reserpine	2
40280179	Methyclothiazide	24080079	Cryptenamine	1
		24080081	Deserpidine	33
40280186	Polythiazide	24080010	Reserpine	1
40280199	Trichlormethiazide	24080010	Reserpine	1

EPESE = Established populations for epidemiologic studies in the elderly.
IDIS = Iowa drug information system.

GIFA study. During their hospital stays, 49,248 drug ingredients or combinations of ingredients were prescribed to 9,148 patients enrolled in the study. The most frequently taken drugs have been described elsewhere [4, 5]. Diuretics taken by the study population were classified into two separate main ATC categories using the first three categories of the system: diuretics (C03) and diuretics combined with antihypertensives (CO2L) (Tables 3 and 4). Distinct ATC code allowed us to discriminate thiazides (code: C03AA) (hydrochlorothiazide), low-ceiling sulfonamides (code: C03BA) (acetazolamide, chlorthalidone, metolazone and xipamide), high-ceiling sulfonamides (code: C03CA) (bumetanide and furosemide), high-ceiling aryloxyacetic acid derivatives (code: C03CC) (ethacrinic acid), and potassium-sparing aldosterone antagonists (code: C03DA) (canrenone, potassium canrenoate and spironolactone). Combinations of diuretic ingredients were coded separately into 2 main categories: low-ceiling diuretics combined with potassium sparing agents (code: C03EA), and high-ceiling diuretics combined with spironolactone (C03EB) (Table 3). Antihypertensive drugs combined with diuretics resulted in 3 categories: rauwolfia alkaloids combined with diuretics (code: C02LA), clonidine and analogues combined with diuretics (code: C02LC), and converting enzyme blockers combined with diuretics (code: C02LM). The specific ingredient combinations and all frequencies are presented in Tables 3 and 4.

Discussion

This paper shows the drug coding procedures utilized in two large epidemiologic studies and demonstrates the specific advantage of utilizing two data bases, the first to maximize efficiency of drug product coding and entry, and the second to facilitate the analysis.

Table 3. Frequencies (N) of diuretics taken during hospital stay in the GIFA study classified by drug categories according to ATC coding system

Hierarchical level					Description	N
1	2	3	4	5		
C					Cardiovascular system	
	03				Diuretics	
		A			Low-ceiling diuretics, thiazides	
			A		Thiazides, plain	
				C03AA 1820	– Hydrochlorothiazide	15
		B			Low-ceiling diuretics excluding thiazides	
			A		Sulfonamides, plain	
				C03BA 0035	– Acetazolamide	6
				C03BA 2444	– Metolazone	8
				C03BA 4000	– Xipamide	2
		C			High-ceiling diuretics	
			A		Sulfonamides, plain	
				C03CA 0551	– Bumetanide	9
				C03CA 1600	– Furosemide	1695
			C		Aryloxyacetic acid derivatives	
				C03CC 0085	– Ethacrynic acid	79
		D			Potassium-sparing agents	
			A		Aldosterone antagonists	
				C03DA 0627	– Canrenone	57
				C03DA 2052	– Potassium canrenoate	221
				C03DA 3435	– Spironolactone	241
		E			Diuretics and potassium sparing agents	
			A		Low-ceiling diuretics and potassium-sparing agents	
				C03EA 5247	– Hydrochlorothiazide and amiloride	604
				C03EA 7051	– Buthiazide and potassium canrenoate	31
				C03EA 8436	– Hydrochlorothiazide and spironolactone	40
			B		High-ceiling diuretics and spironolactone	
				C03EB 8435	– Furosemide and spironolactone	184

GIFA = Gruppo Italiano di Farmacovigilanza nell'Anziano.
ATC = Anatomical, therapeutic and chemical.

Table 4. Frequencies (N) of antihypertensive drugs combined with diuretics taken during hospital stay in the GIFA study classified by drug categories according to ATC coding system

Hierarchical level					Description	N
1	2	3	4	5		
C					Cardiovascular system	
	02				Antihypertensives	
		L			Diuretics and antihypertensives in combination	
			A		Rauwolfia alkaloids and diuretics in combination	
				C02LA 6600	– Reserpine and furosemide	3
				C02LA 6697	– Reserpine, dihydroergocristine and clopamide	2
			C		Clonidine and analogues in combination with diuretics	
				C02LC 5900	– Clonidine and chlorthalidone	1
			M		Converting enzyme blockers and diuretics	
				C02LM 5611	– Captopril and hydrochlorothiazide	159

GIFA = Gruppo Italiano di Farmacovigilanza nell'Anziano.
ATC = Anatomical, therapeutic and chemical.

It was not the intention of the authors to provide an encyclopedic review of all drug coding systems available. The results describe the frequencies and the classification of diuretics taken by participants in the EPESE and the GIFA studies. To code the medications at data entry, we utilized systems that coded trade and generic names of drug products (DPICS and INDPICS, and MINSAN respectively). To identify drug ingredients used, as is necessary for pharmacoepidemiologic studies, the DPICS and INDPICS, and MINSAN product codes were converted into the IDIS and ATC ingredient classification systems, respectively. This conversion was accomplished by running the product codes through a computerized look-up table to create the ingredient code database. These systems were found to be quite valuable. Codes for all drug products taken by participants were available, including prescriptions and over the counter medications, and assignment of product codes and conversion to ingredient codes were relatively easy. Diuretics were chosen to compare these drug classification systems because for this drug category a limited number of ingredients is available for each hierarchical classification level, many combination products exist, and IDIS and ATC have analogous classification criteria. The hierarchical structure of the coding systems allows for the grouping of diuretics into therapeutic and chemical categories. The structure of ATC codes is more complex and has more specific therapeutic and chemical categories. For example, in IDIS all low-ceiling diuretics belong to the same category (Table 1), while in ATC distinct codes identify low-ceiling sulfonamide diuretics and thiazides (Table 3). This feature is particularly useful in large pharmacoepidemiologic studies where an adequate number of drug ingredients might be represented in each category. The main difference between ATC and IDIS systems is that ATC has specific codes for combinations of ingredients, while IDIS codes each ingredient separately (examples are provided in Tables 2, 3 and 4). However, for those DPICS and INDPICS drug codes created to date, a database links each product code to all ingredient codes (IDIS) and indicates whether an ingredient is the sole component of a product or is combined with other ingredients. Hence it is possible to specify a single IDIS code and generate a list of all products containing that ingredient (for example all products containing hydrochlorothiazide).

Within the DPICS and INDPICS codes a 4 digit numeric field identifies the strength of the drug. The same information is available in the MINSAN coding system. By matching the strength with the frequency of drug intake it is possible to easily calculate the actual amount of drug ingredient taken during an interval of time.

The file structure of one record per ingredient basis (Figure 1, panel B), rather than one record per participant (Figure 1, panel A), allowed us to directly assess frequencies of diuretic ingredients taken by the participants of the EPESE and GIFA studies (Tables 1, 2, 3 and 4). The frequency tables are useful for research planning and for creating analytical variables. For example, Table 1 shows that it would not be worth planning an analysis on amiloride because of the very low number of participants taking this drug (n = 14). Analytical variables can be created very easily by taking advantage of the hierarchical structure of both coding systems. An analytical variable can include a whole drug category (for example, all diuretics), a specific therapeutic category (for example, loop-diuretics), or a single ingredient (for example, furosemide), by selecting the appropriate number of significant digits of IDIS or ATC codes. With other drug classification systems

not using hierarchical codes for drug ingredients, analyses may be complex and require time consuming programming [2].

The crucial issue for use of ATC or IDIS systems is to have a file that matches those classification systems with codes used for drug product data entry, DPICS and INDPICS used by the EPESE, or MINSAN used by the GIFA study. Most pharmacies in the U.S. use computer systems that automatically convert alphabetically entered drug product names into corresponding National Drug Code (NDC) numbers. The NDC is a commercially oriented coding system identifying the company, the drug trade name, strength and dosage form. It does not contain unique codes for ingredients or categories of ingredients. For analytic purposes it is usually important to link drug products to specific ingredients and it would be valuable to develop a file matching the NDC codes to IDIS or ATC codes. We are not aware of any data base holding both U.S. trade name or generic name codes and ATC codes. In Europe ATC drug product coding is presently available in 7 countries: Czechoslovakia, Denmark, Finland, Italy, the Netherlands, Norway and Spain [6]. A uniform drug coding system, equally applicable in different countries would simplify the accomplishment of cross-national pharmacoepidemiologic studies.

Automated drug data entry and coding is important for obtaining accurate information in epidemiologic studies. The conversion of information obtained at the time of data entry into a file that is analytically useful is a second and equally as important step.

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