Journal of Primary Care & Community Health
2(1) 26–32

DOI: 10.1177/2150131910385843
http://jpc.sagepub.com
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Classifying Medication Use in Clinical Research

Dorrie Rizzo, BSc[1,2], Laura Creti, PhD[1], Sally Bailes, PhD[1,3], Marcel Baltzan, MD, FRCPC[1,4], Roland Grad, MD, PhD[1], Rhonda Amsel, MSc[3], Catherine S. Fichten, PhD[1,3,5], and Eva Libman, PhD[1]

Abstract

Background: Medication use data are usually collected in clinical research. Yet no standardized method for categorizing these exists, either for sample description or for the study of medication use as a variable. **Objective:** The present investigation was designed to develop a simple, empirically based classification scheme for medication use categorization. **Method:** The authors used factor analysis to reduce the number of possible medication groupings. This permitted a pattern of medication usage to emerge that appeared to characterize specific clinical constellations. To illustrate the technique's potential, the authors applied this classification system to samples where sleep disorders are prominent: chronic fatigue syndrome and sleep apnea. **Results:** The authors' classification approach resulted in 5 factors that appear to cohere in a logical fashion. These were labeled Cardiovascular or Metabolic Syndrome Medication, Symptom Relief Medication, Psychotropic Medication, Preventative Medication, and Hormonal Medication. **Conclusions:** The findings show that medication profile varies according to clinical sample. The medication profile for participants with sleep apnea reflects known comorbid conditions; the medication profile associated with chronic fatigue syndrome appears to reflect the common perception of this condition as a psychogenic disorder.

Keywords

medication classification, medication grouping, factor analysis, principal components analysis, method

When describing clinical samples, it is important to provide information about the medications taken by participants when they enter a study. Such data are frequently collected in clinical research but seldom reported. This occurs, in part (a) because the number of different medications consumed by participants is often large and varied and (b) because available classificatory systems group medications based on a priori clinical criteria rather than on an empirical basis, which may better serve the needs of the research in question. In our research area, which broadly deals with sleep, insomnia, and daytime functioning, knowing which medications individuals take is vital because of their effects and side effects on the variables of interest.[1] Excluding individuals who take medication reduces ecological validity. Ignoring medication effects can confound the results.

The potential usefulness of a research focus on medications has already been illustrated in such medical epidemiological studies as evaluation of the impact of prescription cost on population health,[2] the use of pharmaceutical data in the identification of patterns of chronic disease status,[3] and prediction of 1-year mortality rates.[4] One study even investigated exposure to various prescription drugs as a proxy measure of disease.[5]

It has been suggested that it is potentially important to take participants' medications into account in terms of their stimulant and sedative effects in psychobehavioral clinical studies related to our research area as well.[6] We implemented this suggestion in a previous study by demonstrating that a sample with chronic fatigue syndrome (CFS) could be distinguished from a sample with sleep apnea/hypopnea syndrome (SAHS) on the basis of the sedative or stimulant properties of their medication profile.[7,8] Clearly, rich details may be lost when there is no empirically sound way of grouping extensive lists of medications used by different clinical samples into a manageable number of categories.

[1]Jewish General Hospital, Montreal, Canada
[2]Université de Montréal, Montreal, Canada
[3]McGill University, Montreal, Canada
[4]Mount-Sinai Hospital, Montreal, Canada
[5]Dawson College, Montreal, Canada

Corresponding Author:
Dorrie Rizzo, Jewish General Hospital, 4333 ch. de la Côte-Ste-Catherine, Montreal, H3T 1E4, Canada
Email: dorrie.rizzo@mail.mcgill.ca

Table 1. Sample Characteristics for the Medication Profile of Comparison Groups

Sample	Chronic fatigue syndrome		Older primary care		Older community		Sleep clinic		Control group	
n										
Males	22		24		77		46		15	
Females	75		23		126		26		39	
Age (*M*, *SD*)										
Males	44.4	8.7	70.9	10.4	64.8	11.4	54.0	11.4	45.9	11.2
Females	46.5	11.2	66.4	11.1	65.7	10.7	54.4	11.2	45.3	10.3

Our ongoing research required that we incorporate medication use into the analyses. This forced us to examine how medications could be combined into meaningful groupings for use in our project. Because this led us to a novel way of conceptualizing medication use in clinical research, in the present article our goal is to share the results of our experience by demonstrating how researchers can develop a simple, empirically based classification system for the diverse medications that their research participants may be using. Thus, here we describe and illustrate a procedure that represents a standardized method to code drug use data in clinical research. The aim is to help with sample descriptions and to enable researchers to use medication as a variable in clinical research.

What distinguishes this approach from the various existing systems is that it groups medications on an empirical basis, given the attributes of the samples in question, rather than on the basis of clinical criteria, as do most conventional systems (eg, the U.S. National Drug Code Directory updated by the Food and Drug Administration, Center for Drug Evaluation and Research,[9] the American Hospital Formulary Service Drug Information from the American Society of Health-System Pharmacists, and the WHO's Anatomical Therapeutic Chemical Classification System). Thus, our technique both allows for the reduction of the number of medication groupings and permits the researchers to see the pattern of medication usage in specific clinical constellations.

Phase 1 Method—Development of the Classification System

Participants

To develop the classification system, we used 473 respondents from our database of participants who had been recruited for a series of sleep- and fatigue-related studies carried out in our laboratory. Overall sample characteristics are presented in Table 1.

CFS sample.[10] A total of 97 participants with CFS were part of a larger study of sleep disorders in this population.[11,12]

Older primary care sample.[13] A total of 47 participants were older adults (ages 55 and older) recruited from primary care waiting rooms at 3 family practice centers in Montreal for a study of sleep disorders.

Older community sample.[14] A total of 203 participants were recruited from the community through media publicity consisting of press releases, presentations, and mailings to seniors' groups and notices in community clinics and residences for older adults. Individuals with daytime fatigue and/or sleepiness and/or insomnia were sought for a study of sleep disorders.

Sleep clinic sample.[15] A total of 72 participants were consecutive new patients referred for evaluation of possible sleep disorder at 2 hospital-based sleep clinics in Montreal. They were recruited from sleep clinic waiting rooms.

Control sample.[16] A total of 54 control group respondents were individuals with no diagnosed medical or psychiatric condition. They were recruited from the community through posters, announcements, and personal contacts.

The research ethics committee of the Jewish General Hospital approved the research protocol. Participants signed an information and consent form prior to data gathering.

Procedure

Data on medication use were collected as a routine part of our research protocol. These were grouped into the 43 specific therapeutic classes provided in the Canadian Compendium of Pharmaceuticals and Specialties (CPS; 2004 electronic version). There are other systems derived for different purposes and used in different countries. We used the CPS for its convenience, availability, ease of use, and relevance to the Canadian health care system. The method we propose may be used with any recognized classification system of choice.

Medications were classified into one of the 43 specific CPS therapeutic classes. Unused therapeutic classes (ie, if no participants took any medication in this class) were excluded, leaving 27 therapeutic classes (see Table 2). Medication use was coded by indicating the number of different drugs used in each CPS therapeutic class for each participant. If the participant did not take a medication in a certain class, this was scored as 0. A 1 was scored when a

Table 2. Number of Medications Taken in Each Compendium of Pharmaceuticals and Specialties (CPS) Therapeutic Class Ranked by Popularity

CPS therapeutic classes	Number of participants taking medications within a class		Maximum number of different medications taken by a participant within a class	Total number of medications taken in each class
	n	%		
Cardiovascular drugs	116	24.3	5	199
Analgesics	71	14.9	3	79
Lipid-lowering agents	61	12.8	2	63
Thyroid hormones	61	12.8	1	61
Antidepressants	58	12.1	2	64
Hypnotics and sedatives	40	8.4	3	52
Gastrointestinal agents	36	7.5	2	37
Sex hormones	34	7.1	3	42
Vitamins and minerals	33	6.9	4	57
Anticonvulsants	30	6.3	2	32
Diabetes therapy	28	5.9	3	37
Diuretics	23	4.8	1	23
Anticoagulants	18	3.8	2	19
Corticosteroids, inhaled (including asthma therapy)	16	3.4	2	18
Osteoporosis therapy	16	3.4	1	16
Prostatic hyperplasia therapy	15	3.1	2	19
Respiratory system agents	12	2.5	2	15
Antihistamines	11	2.3	1	11
Antispasmodics	6	1.3	1	6
Anemia therapy and hematopoietics	3	0.6	1	3
Antipsychotics	3	0.6	1	3
Antiparkinsonian agents	2	0.4	1	2
Corticosteroids, systemic	2	0.4	2	3
Ophthalmologicals	2	0.4	1	2
Immunosuppressive agents	1	0.2	2	2
Mania therapy	1	0.2	1	1
Rheumatic disease therapy	1	0.2	1	1

participant took one medication in a particular class. A score of 4 indicated that a participant took 4 different medications within the class. For example, if a participant took separate vitamin A, C, D, and calcium pills, he or she obtained a score of 4 in the "vitamins" class. Data from all participants were combined for this study and are presented in Table 2, which presents the number of medications taken in each CPS therapeutic class, including multiple medications taken by individual participants.

To organize the data into more manageable classes for further analysis, we first reassigned medications taken 3 or fewer times into an "other" class and then carried out a principal components factor analysis with varimax rotation on the remaining classes. This converged in 5 iterations and resulted in 5 factors. Examination of the scree plot, scree elbow curves, and eigenvalues (see Figure 1) indicated that a 5-factor solution was the most parsimonious. Factor loadings of magnitude less than .4, with the eigenvalue greater than 1 criterion, were suppressed simply because we applied a general and rigorous cutoff rule for factor analysis. These can be seen in Table 3. A guideline for identifying significant (based on a .05 significance level) factor loadings based on sample size is as follows: .30 (n = 350), .35 (n = 250), .40 (n = 200), .45 (n = 150), .50 (n = 120), .55 (n = 100), .60 (n = 85), .65 (n = 70), .70 (n = 60), .75 (n = 50).[17]

Published guidelines for sample size in factor analysis include 2 options: (a) absolute N and (b) N (number of participants):p (observed variables) ratio. In both cases, higher is better. When adopting the absolute N approach, the literature recommends several minimum sample sizes: N = 400 or a sample size evaluated with a suggested scale (50 = *very poor*, 100 = *poor*, 200 = *fair*, 300 = *good*, 500 = *very good*, 1,000 or more = *excellent*).[18] Generally, larger samples minimize the probability of error as in other statistical analysis but other rules about good statistical analyses may not apply to this method (eg, increasing generalizability of the results). The second approach, N:p, suggests a that increasing the ratio also increases the quality of the

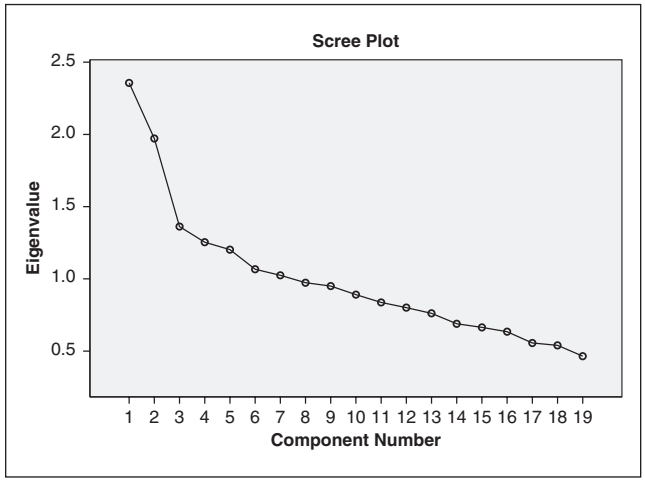

Figure 1. Scree test graph for medication factor loadings

analysis. A recommendation of a minimum ratio of 5:1 to 10:1 has been recommended.[19,20] In this study, we used a sample size of $N = 473$ and a total of 20 variables, translating to a ratio of 23.7:1.

Results and Discussion

The 5 factors, labeled Cardiovascular or Metabolic Syndrome Medication, Symptom Relief Medication, Psychotropic Medication, Preventative Medication, and Hormonal Medication, appear to cohere in a logical fashion (see Table 3) and account for 42.88% of the variance. For example, osteoporosis therapy and vitamins and minerals loaded on Factor 4; this indicates that when participants use a medication for bone loss, for example, they are likely to take calcium or glucosamine as well. Thus, the findings suggest that this method resulted in a series of medication groupings that cluster in a meaningful, valid way.

Phase 2 Method—How Might This Classification System Be Used: An Illustrative Example

To explore some applications of our classification system, we examined how meaningful these groupings are in a research context.

Respondents were a subset of those participating in Study 1. We selected those 107 individuals from our data set who, after the initial assessment, were sent for a polysomnographic evaluation at a sleep laboratory to determine their sleep disorder status. Participants' diagnoses fell into 3 groups: CFS with no SAHS ($n = 23$) aged 42.2 ± 10.3, SAHS with no CFS ($n = 50$) aged 59.7 ± 11.6, and a healthy comparison sample (controls, $n = 34$) aged 51.3 ± 8.6.

The ratio of male to female participants was 2.3:1 in the SAHS group, 0.05:1 in the CFS group, and 0.31:1 in the control group, $\chi^2 = 34.42$, $P = .000$, indicating sex differences among the samples. Similarly, the comparison on age was significant, $F(2, 104) = 25.21$, $P < 001$. In spite of these findings, we decided not to covary sex or age because this example is presented for illustrative purposes only. A series of one-way analysis of variance (ANOVA) comparisons was performed to compare the scores of the 3 groups on the 5 medication factors.

Table 4 shows significant differences among the 3 samples on medication factors: ANOVA and post hoc results show that, as expected, the CFS group had significantly higher scores on the Psychotropic Medication factor and the SAHS group had significantly higher scores on the Cardiovascular or Metabolic Disorder Medication factor than the other 2 groups. In addition, the SAHS group had higher scores than the control group on the Preventative as well as on the Symptom Relief Medication factors.

General Discussion

Our study outlines a procedure for dealing with medication data that are routinely collected in many clinical research studies and that largely go unreported. We found that coding a wide array of medications based on a well-known classification system (in this case, the Canadian CPS) into therapeutic classes was a useful first approach to bring order to the chaos.

Our findings show that in a single day, our participants generally consumed a combination of medications. The use of factor analysis allowed us to reduce medications in the various CPS therapeutic classes into 5 coherent groupings. Notably, the system allows one to include multiple anxiolytics, antidepressives, and over-the-counter medications, for example, and to see the *pattern* of medication usage in any particular clinical constellation. With respect to the present samples, the literature shows that use of cardiovascular, diabetic, and lipid-lowering medications tends to be associated statistically and is characteristic of people at elevated risk for developing cardiovascular or metabolic disorders.[21,22] Similarly, antidepressants, hypnotics, and sedatives are associated statistically and are characteristic of treatment for individuals with CFS.[23] What is of particular interest here is that not only do the constellations of medications describe the 2 samples in a meaningful way but also, in the case of SAHS, medication usage reflects known comorbid conditions, which might be useful to assist in the diagnosis of this condition. On the other hand, the medication profile characteristic of CFS appears to reflect the common perception of this condition as a psychogenic disorder.

The factors derived likely reflect medication use patterns only in clinical samples characterized by disrupted sleep or

Table 3. Medication Factor Loadings Based on Compendium of Pharmaceuticals and Specialties (CPS) Therapeutic Class Frequencies

CPS Medication Classes	Factor 1: Cardiovascular or Metabolic Disorder Medication	Factor 2: Symptom Relief Medication	Factor 3: Psychotropic Medication	Factor 4: Preventative Medication	Factor 5: Hormonal Medication
Cardiovascular drugs	0.75				
Lipid-lowering agents	0.74				
Anticoagulants	0.66				
Diabetes therapy	0.64				
Diuretics	0.42				
Gastrointestinal agents		0.63			
Respiratory system agents		0.58			
Corticosteroids, inhaled (including asthma therapy)		0.56			
Antihistamines		0.54			
Antispasmodics		0.47			
Analgesics					
Anticonvulsants			0.74		
Hypnotics and sedatives			0.65		
Antidepressants			0.41		
Vitamins and minerals				0.70	
Osteoporosis therapy				0.63	
Thyroid hormones					0.68
Sex hormones					0.60
Prostatic hyperplasia therapy					

Table 4. Factor Mean Scores and Test Results for the Chronic Fatigue Syndrome (CFS), Sleep Apnea/Hypopnea Syndrome (SAHS), and Control Groups

Medication factors	Group	*M*	*SD*	*n*	*df*	*F*	Sig. *p* =	Post hoc
Cardiovascular or Metabolic Disorder Medication								
	SAHS	1.20	1.25	50	2	23.23	.000	SAHS > CFS, C
	CFS	0.00	0.00	23				
	Control	0.09	0.29	34				
Symptom Relief Medication								
	SAHS	0.54	0.61	50	2	3.33	.040	SAHS > C
	CFS	0.52	1.16	23				
	Control	0.15	0.44	34				
Psychotropic Medication								
	SAHS	0.38	0.75	50	2	9.67	.000	CFS > SAHS, C
	CFS	0.87	0.81	23				
	Control	0.09	0.29	34				
Preventative Medication								
	SAHS	0.18	0.44	50	2	3.67	.029	SAHS > C
	CFS	0.04	0.21	23				
	Control	0.00	0.00	34				
Hormonal Medication								
	SAHS	0.10	0.30	50	2	1.30	.276	
	CFS	0.13	0.34	23				
	Control	0.24	0.50	34				

chronic fatigue. Most likely, other clinical samples will have very different medication profiles. Alternately, the same medications may group into different factors for different samples. Although this may be considered a limitation of the present investigation, we believe that the benefits of this technique, which allows us to discover, in an empirical manner, the constellation of medications that group together in various clinical categories, outweigh the

disadvantages. As is the case in our own samples, in other disorders, as well, the procedure may enhance the diagnostic process or, as in the case of CFS, reflect a possible distortion by the medical community in prematurely labeling the illness as psychogenic.

A definite limitation is that the technique itself is not fully descriptive. For example, medications that were popular in all samples, such as analgesics, did not load on any of the derived factors and therefore did not differentiate groups. Therefore, such medications must be noted and handled separately in statistical procedures. Another limitation is that most of the frequencies in our samples were low, and thus extreme scores may have had undue influence on the results.

In summary, our findings are illustrative of an easy way to implement a 3-step method to derive empirically based medication classification categories for use in clinical research rather than as a conclusive classificatory system:

1. Identify which therapeutic class each medication belongs to
2. Discard low-frequency therapeutic classes
3. Carry out principal components factor analysis

Deriving factors permitted us to study medication use as a variable in clinical research. Group comparisons yielded differences using the medication factors that would not have been discernable had we attempted to look at medications on a drug-by-drug basis. For example, we found that participants diagnosed with SAHS took significantly more medications in the Cardiovascular or Metabolic Disorder Medication factor than either those with CFS or the healthy controls. The literature shows that untreated SAHS is strongly associated with cardiovascular medication use,[24] as well as with hypertension, insulin resistance, and cardiovascular events, including stroke and arterial fibrillation.[25,26] Because our data reflect medication use prior to the SAHS sleep disorder diagnosis, we are now able to evaluate whether treatment of the SAHS might result in a diminished need for medication. Of course such diagnostic and treatment implications need to be verified for samples with other medical conditions.

In conclusion, the findings of this study add to the meager literature on medication profiles and their relationship to clinical disorders. Our method of drug classification suggests that factor analysis (a) affords an empirical means of deriving medication profiles for clinical samples in health-related research and (b) offers a useful and simple method for handling medication data in an intuitively appealing way.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interests with respect to the authorship and/or publication of this article.

Financial Disclosure/Funding

The author(s) received no financial support for the research and/or authorship of this article. This research was supported by Canadian Institutes of Health Research (CIHR) grant MOP-77816.

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Bios

Dorrie Rizzo, BSc, is senior research assistant with the Sleep Project in the Behavioural Psychotherapy and Research Unit, Department of Psychiatry, Jewish General Hospital, Montreal. She is a graduate student at University of Montreal, Psychology Department, and her principal area of interest is psychometrics and statistical analyses.

Laura Creti, PhD, is a senior researcher and project coordinator and clinical psychologist in the Behavioural Psychotherapy and Research Unit, Department of Psychiatry, Jewish General Hospital, Montreal. Her research expertise is in the area of the evaluation and treatment of sleep disorder and daytime fatigue in individuals with chronic fatigue syndrome.

Sally Bailes, PhD, is a senior researcher, project coordinator, and clinical psychologist in the Behavioural Psychotherapy and Research Unit, Department of Psychiatry, Jewish General Hospital, Montreal. Her research interests and are in the areas sleep disorder and daytime fatigue, with particular expertise in the development and validation of assessment techniques.

Marcel Baltzan, MD, FRCPC, is a medical doctor at the Mount Sinai Hospital in Montreal and Adjunct Professor in the Department of Medicine & Epidemiology & Biostatistics at McGill University, with specialties in epidemiology, biostatistics, respiratory medicine and sleep medicine. He has expertise and research interest in the areas of sleep, sleep apnea, excessive daytime sleepiness and outcome assessment.

Roland Grad, MD, PhD, is a Primary Care Physician for family practice at Herzl Clinic, Jewish General Hospital, an Associate Member of the Centre for Clinical Epidemiology and Community Studies, an Associate Professor, McGill University and Attending Staff, Jewish General Hospital, Department of Family Medicine & Division of Geriatrics, Montreal. His research expertise is in Electronic Knowledge Resources in everyday practice and sleep disorders.

Catherine S. Fichten, PhD, is Professor of Psychology at Dawson College and Associate Professor of Psychiatry at McGill University. She is a clinical psychologist at the Behavioral Psychotherapy and Research Unit of the Jewish General Hospital in Montreal and she co-directs the Adaptech Research Network.

Rhonda Amsel received her BSc degree in mathematics and MSc in computer science from McGill University. She serves as consulting statistician in the Department of Psychology at McGill University, where she teaches statistics. Her research on experimental methodology is done in the context of collaborative work in the areas of health science, neuropsychology, and education.

Eva Libman, PhD, is a Project Director at the Lady Davis Institute for Medical Research at the Jewish General Hospital and specializes in sleep disorders. She has investigated the manifestation, experience and implications of daytime fatigue and sleepiness. More specifically, her research explores insomnia, sleep apnea and chronic fatigue syndrome, which are three disorders predominately associated with daytime fatigue.