

ANALYSIS OF EXPIRED MEDICATIONS IN SERBIAN HOUSEHOLDS

ANALIZA KOPIČENJA ZDRAVIL S PRETEČENIM ROKOM TRAJANJA V SRBSKIH GOSPODINJSTVIH

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ABSTRACT

Keywords:

drug wastage, households, expired medications, Serbia

Introduction. An ongoing issue of expired medications accumulating in some households is a universal problem around the world. The aim of the study was to investigate the extent and structure of expired medications in Serbian households, and to determine which therapeutic groups generated the most waste.

Methods. This was an observational, cross-sectional study conducted in households in the city of Novi Sad, Serbia. The study had been performed over 8 month period (December 2011 - July 2012) and it consisted of personal insights into the medication inventory in households.

Results. Of 1008 families, 383 agreed to participate and complete the questionnaire (38.3% response rate). In almost a half of households (44.4%), expired medications were maintained. The amount of expired medications was 402 items, corresponding to 9.2% of total medications presented in surveyed households. The majority of expired medications (64.7%) was in solid dosage (tablets, capsules, granules, lozenges), following semisolid (ointments, creams, gel, suppositories) and liquid dosage forms (drops, syrups). Expired medications in the households belonged mostly to 3 categories: antimicrobials for systemic use (16.7%), dermatological preparation (15.9%) and medications for alimentary tract and metabolism (14.2%).

Conclusions. This study revealed that there were relatively large quantities of expired medications in Serbian households, with a high prevalence of antibiotics for systemic use, anti-inflammatory and antirheumatic products, and medications for alimentary tract and metabolism.

IZVLEČEK

Ključne besede:

odpadna zdravila, gospodinjstva, zdravila s pretečenim rokom trajanja, Srbija

Uvod. Težava s kopičenjem zdravil s pretečenim rokom trajanja v gospodinjstvih je velik problem po vsem svetu. Cilj te študije je bil raziskati obseg in sestavo zdravil s pretečenim rokom trajanja v srbskih gospodinjstvih in določiti, katere terapevtske vrste zdravil predstavljajo največji odpad.

Metode. Opazovalna, presečna raziskava je bila izvedena v srbskih gospodinjstvih v Novem Sadu. Trajala je osem mesecev (od decembra 2011 do julija 2012). Sestavljena je bila iz osebnega vpogleda v zalogo zdravil v gospodinjstvih.

Rezultati. Od 1008 družin se jih je 383 odločilo za sodelovanje in izpolnilo vprašalnik (38,3-odstotna odzivnost). V skoraj polovici gospodinjstev (44%) so imeli zdravila s pretečenim rokom trajanja. Skupno sta bili najdeni 402 zdravila s pretečenim rokom trajanja, kar predstavlja 9,2% vseh zdravil v anketiranih gospodinjstvih. Večina zdravil s pretečenim rokom trajanja (64,7%) je bila v trdi obliki (tablete, kapsule, granule, lozenge), sledila so zdravila v poltrdni obliki (masti, kreme, geli, suspenzije) in tekočine (kapljice, sirupi). Večina zdravil s pretečenim rokom trajanja v gospodinjstvih pripada eni od naslednjih treh skupin: antimikrobna zdravila za sistemsko rabo (16,7%), dermatološki preparati (15,9%) in zdravila za bolezni prebavil in presnove (14,2%).

Zaključki. Raziskava je pokazala, da je v srbskih gospodinjstvih shranjenih relativno veliko zdravil s pretečenim rokom trajanja. Najpogosteje se pojavljajo antibiotiki za sistemsko uporabo, protivnetni in antirevmatski pripravki ter zdravila za bolezni prebavil in presnove.

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1 INTRODUCTION

Pharmaceuticals are produced and consumed in increasing volume every year and, as some people tend to accumulate medication, vast quantities go unused or expire. Medications may accumulate in households for a variety of reasons: improvement of the patient's medical condition, oversized medication packages resulting in leftover medications, death of the patient and change in prescription due to side effects or lack of therapeutic effect. Poor adherence, as the result of patients doubting the need for medication, fear of adverse effects or forgetfulness also contribute to the medication wastage (1, 2).

Stockpiling of expired medications in households is a significant and common public health issue worldwide (4). The potential presence of expired medications in households has, in the last 15 years, received attention due to its impact on health outcomes, health care cost, patient and environmental safety. Unsafe storage of expired medications at home leads to increased risk of toxicity, suicide and accidental childhood poisoning (5). Whilst pharmaceuticals can enter the environment during the production, consumption and disposal, incorrect disposal from households is considered the second major pathway into the environment. Recent research has shown that trace levels of ethinyl estradiol, which is an active compound of some contraceptives, have caused impaired sexual development and increased feminization of fish, whilst the presence of antibiotics in water has been associated with development of antibiotic resistance (6, 7). The consequence of improper disposal of household pharmaceutical waste is the presence of pharmaceuticals in groundwater, lakes, rivers, and even drinking water, which is a serious environmental problem that will continue to grow as the population expands and more medications are consumed. The environmental consequences and human health risk that this represents is intensely debated, and the real risk may not be known for years (8-11). Notwithstanding the health and environmental issues, medication wastage has a huge impact in monetary terms and can result in a substantial economic loss (12-14).

Expired medications in households are a fairly new topic analysed in a limited number of studies (2, 5, 16), so the true scope and magnitude of medication wastage in households is largely unknown. In order to collaborate effectively with Serbian health system and to improve medication prescribing, education, and appropriate use as well as disposal, we analysed expired medications in a sample of households in Serbia.

The aim of the study was to get insight into the extent and structure of expired medications in Serbian households and to determine which therapeutic groups and clinical

areas generated the most waste. The attitudes of the population with respect to proper medication disposal practices were also analysed.

2 METHODS

This was an observational, cross-sectional study conducted in households in the city of Novi Sad, Serbia. The study protocol was approved by the Ethical Committee of the Faculty of Medicine in Novi Sad. The study has been performed over an 8-month period (December 2011-July 2012). The sample size was calculated according to the results of the pilot study researching medications in home pharmacies conducted in 2008 on 191 households in Novi Sad, Serbia, where the percentage of expired medications was 11.2%. Based on this result, a sample size necessary to estimate the proportion of expired medications with 95% confidence interval and 5% precision was 153 households. This research was conducted as a part of a larger study that researched the total inventory of medications in households, disposal practices and self-medication. The sample size necessary to estimate the extent of self-medication was 383 households; consequently, the larger sample size was used. Contacting 1,008 households using systematic random sampling of the telephone directory yielded 383 households willing to cooperate (response rate 38.0%). The study was performed by a trained interviewer. During a telephone conversation the interviewer identified the family member most informed about the content of household medication supplies (the respondent). The respondent received an explanation that the survey includes a visit to their home, as well as the inspection of home medicine cabinets. The respondents were Serbian speaking adults (at least 18 years of age) and a written consent was obtained from the respondent prior to the data collection. During the visit to the households that agreed to cooperate, all encountered medications were recorded. The interviewer examined where the medications were being stored, and counted the number of medications, while checking the expiry dates. The accessibility of the medications to children was also checked by an interviewer.

Afterwards, the respondents filled in the questionnaire. The structured questionnaire used in this survey consisted of 3 parts and 13 questions. The first part of the questionnaire (7 questions) was related to the sociodemographic characteristic of the population (the number of household members, age, gender, occupation and education of respondent). In order to investigate the possible associations between the presence of expired medications in households and some of characteristics of households (the presence of persons aged >65 years or children aged <12 years in their households), this information was also recorded. The second part of the

questionnaire focused on questions (3) related to expired medications and their disposal.

Statistical analysis was performed with SPSS software (SPSS 15.0 for Windows, SPSS Inc., Chicago, IL USA). Descriptive statistics on the distribution of the number of packages in the surveyed households was performed. For parametric data of independent samples t-test was used to test differences between groups. For numeric data with non-normal distribution and ordinal data Mann-Whitney U test was used. Chi-square test was used to test differences between nominal data (frequencies). All p values less than 0.05 were considered significant.

3 RESULTS

In almost a half of households (170, 44.4%), expired medications were maintained. The total amount of expired medications was 402 items, corresponding to 9.2% of all medications present in surveyed households. Of the total expired medications, 70.4% were prescription-only and 29.6% were over-the-counter (OTC) medications. The majority of expired medications (260, 64.7%) were in solid dosage forms (tablets, capsules, granules, lozenges), following semisolid (ointments, creams, gels, suppositories) and liquid dosage forms (drops, syrups) (Table 1).

Table 1. Dosage forms of expired medications.

Dosage forms	Items	
	N	%
Tablets, capsules, dragées, lozenges, powders	260	64.7
Ointments, creams, gel, suppositories	88	21.9
Drops, syrups	48	11.9
Inhalers, sprays	6	1.5
Total	402	100.0

Expired medications classified according to ATC classification are presented in Tables 2 and 3. Predominant therapeutic groups among expired medications were anti-infectives for systemic groups (16.7%), dermatologicals (15.9%) and medications for alimentary tract and metabolism (14.2%).

Table 2. Dosage forms of expired medications.

ATC	N	%
J-anti-infectives for systemic use	67	16.7
D-dermatologicals	64	15.9
A-alimentary tract and metabolism	57	14.2
M-musculo-skeletal system	48	11.9
R-respiratory system	46	11.4
N-nervous system	44	10.9
C-cardiovascular system	27	6.7
S-sensory organs	18	4.5
B-blood and blood forming organs	15	3.7
G-genito-urinary system and sex hormones	13	3.2
H-systemic hormonal preparations, excluding sex hormones and insulins	2	0.5
P-anti-parasitic products, insecticides and repellents	1	0.2
L-antineoplastic and immunomodulating agents	0	0
Grand Total	402	100

Table 3. ATC therapeutic categories (level II) of expired medications.

ATC	Therapeutic groups	N	%
J01	Antibacterials for systemic use	66	16.4
M01	Anti-inflammatory and antirheumatic products	35	8.7
N02	Analgesics	31	7.7
D07	Corticosteroids, dermatological preparations	25	6.2
D06	Antibiotics and chemotherapeutics, dermatological	24	6.0
R01	Nasal preparations	22	5.5
A07	Antidiarrheals, intestinal anti-inflammatory/anti-infective agents	17	4.2
R05	Cough and cold preparations	13	3.2
S01	Ophthalmologicals	12	3.0
A03	Drugs for functional gastrointestinal disorders	11	2.7
B03	Antianemic preparations	11	2.7
A02	Drugs for acid related disorders	11	2.7
Other		278	69.0
Total		402	100.0

The opinion of the majority of the respondents was that medications should not be used after the expiration date (75.2%). However, a fifth of the respondents (20.4%) agreed that medications can be used 6 months after the expiration date. Despite the fact that the majority of respondents (66.3%) think throwing medications into the garbage has detrimental effects on the environment, this was the predominant disposal method among the surveyed households (82.8%). Only 4.4% of the respondents reported returning expired medications to a pharmacy (Table 4).

Table 4. Participants' responses to the question related to expired medications and their disposal.

The availability of expired medications to children	N	%
yes	91	69.6
no	41	30.4
total	132	100.0
In your opinion, can medications be used after the expiration date?	N	%
yes	10	2.6
yes, 6 month after the expiration date	78	20.4
no	288	75.2
don't know	7	1.8
Do you think that disposal of expired medication into the garbage has detrimental effects on the environment?	N	%
yes	254	66.3
no	52	13.6
don't know	77	20.1
How do you currently dispose of expired medications?	N	%
into the garbage	317	82.8
flush down the toilet or sink	11	2.9
return to pharmacy	17	4.4
store	3	0.8
burn	7	1.8
always use till the end	28	7.3
total	383	100.0

As presented in Table 5, the number of expired medications in households was significantly associated with the family size, level of respondents' education, presence of children younger than 12 years ($p < 0.05$).

Table 5. Demographic and socioeconomic characteristics associated with expired medications in households.

Variable	Households with no expired medications	Households with expired medications	p
Family size	2.7±1.2	3.0±1.1	0.002
Gender			0.963
male	43 (20.1%)	34 (20.0%)	
female	170 (79.9%)	136 (80%)	
Elderly ≥65 years			0.094
no	183 (85.9%)	156 (91.8%)	
yes	30 (14.1%)	14 (8.2%)	
Education			0.007
elementary school	18 (8.4%)	9 (5.3%)	
secondary school	103 (48.3%)	66 (38.8%)	
junior college degree	15 (7.1%)	10 (5.9%)	
degree	77 (36.3%)	85 (50.0%)	
Occupation			0.088
employed	106 (49.7%)	107 (62.9%)	
unemployed	39 (18.3%)	23 (13.5%)	
student	12 (5.6%)	6 (5.3%)	
retiree	56 (26.3%)	34 (20.0%)	
Children ≤12 years			0.019
yes	64 (30.0%)	71 (41.8%)	
no	149 (70.0%)	99 (58.2%)	

4 DISCUSSION

4.1 The Extent and Type of Expired Medications in Serbian Households

To the best of our knowledge, our study analysed for the first time the contents of a pharmaceutical waste generated in households in Serbia. Although this study collected information on the percentage and types of medications that expired without investigating the underlying reasons for not using them, it provides evidence to an under-researched area.

The findings are mostly consistent with other studies in terms of the percentage of expired medications, but varied in the most common therapeutic groups. The extent of expired medications in Serbian households of 9.2% is comparable to those reported in Croatia, where

expired medication comprised 10.8% of total household medication supplies (17).

More than 70% of expired medications in Serbian households were prescription-only medications. The existence and extent of expired prescription medications could be adopted as a direct measure of non-compliance and poor adherence by the patient population, as demonstrated in many studies. For example, in the United Kingdom, only one third of people surveyed did not complete a course of the prescribed medication. In addition, more than 20% of the prescribed medications in British homes were not being taken, while 14% of prescribed medications were partly used. In an Iranian and the British study, approximately 10% of patients who filled their prescriptions have never taken the prescribed medications (12). Notwithstanding the reasons for leftovers of prescription medications, these medications can definitely lead to unintentional pharmaceutical poisonings of children, facilitate abusive use, and promote emerging social problems, such as teenage "pharming", a recreational use and abuse of prescription medications among teenagers (18).

The structure of expired medication according to the type of formulation was similar to other studies with by far the highest percentage of solid dosage forms, followed by semisolids (e.g. crèmes, ointments) (15). In our study, the expired medications in the households belonged mostly to 3 categories: anti-microbials for systemic use, dermatological preparations, and medications for alimentary tract and metabolism. On the contrary, both Mexican and U.S. studies reported the painkillers and cardiovascular medications as the most common expired medications, while antibiotics occupied the third place (15, 16). In our opinion, as these studies were carried out in different countries, these differences are potentially attributable to the difference in demographic characteristics, health seeking practices or different supply ways of medications in surveyed households. However, the main reason for large quantities of expired antibacterials stored in Serbian households was easy access. This study was conducted just after Serbian authorities enforced stricter law rules regarding antibiotics' acquisition in November 2011. Until then, antibiotics were routinely available without a medical prescription in private pharmacies.

The second possible reason for the levels of storage of antibacterial medications is patients' non-compliance with recommended treatments. The presence of expired antimicrobial agents implicates that the patients did not complete the full dispensed course, and left-over antibiotics might later be used for self-medication without proper indication, in insufficient quantities, or even when contraindicated (7, 19). In contrast to a Mexican study, where dermatological preparations comprised less than

2% of all medications expired, they ranked second in households in Novi Sad, with mostly topical antibiotics and corticosteroids.

Expired medications from alimentary tract category were also commonly encountered in Serbian households. Many of the gastrointestinal tract (GIT) medications are OTC medications (e.g. antacids, laxatives), which could partially explain the high percentage of expired GIT medications. Abushanab et al. also identified medications for alimentary tract and dermatologicals as the medications that commonly go unused and expire (19).

Surprisingly, the expired cardiovascular medications comprised a noticeably lower percentage of expired medication in households than in other studies (15, 16). This discrepancy could be partially attributed to the demographic characteristics of surveyed Serbian households (e. g. low presence of persons older than 65). In addition, Serbian National Health Insurance Fund allows for chronic disease medications, including cardiovascular medications, to be prescribed in maximum two months' course, definitely decreasing the possibility of the medication passing the expiry date. A high percentage of medications belonging to musculoskeletal (mostly anti-inflammatory and antirheumatic products) and nervous system (mostly analgesics) was also demonstrated in other studies (11, 16, 18, 22).

4.2 Expired Medications and their Disposal

The attitude of around a fifth of the Serbian respondents is that medication can be used up to 6 months after the expiration date, while the majority thought that expired medications should not be used. This is in accordance with the general opinion that expiration date is the end of the useful life of the medication. However, this may not be necessarily true, since the labelled expiration date is the final day that the manufacturer guarantees the full potency and safety of a medication, while the actual shelf life of some products is, in fact, longer (15).

Despite the fact that Serbian public was generally concerned on how improper medication disposal detrimentally affects the environment, the behaviour regarding disposal of unused medications did not equate the awareness. A previous study carried out in South Backa District, Serbia, showed that environmental awareness may not necessarily affect how people dispose of their medications, because other factors, such as the availability of formalized disposal protocols, may also play an important part (7, 20). However, according to Food and Drug Administration (FDA) recommendations, where no organized collection system exists, a disposal of medications in domestic garbages destined for landfills is accepted as more environmentally friendly than flushing them down the drain. Actually, in this situation,

medications may be disposed of in the household trash by removing them from their original containers, mixing them with unpalatable substances, such as kitty litter or used coffee grounds, placing the mixture in a sealed plastic container, and putting that sealed container into the household trash (21, 22).

Disposal of expired medications into the garbage, the leading method of disposal in Serbia, has also been identified as the predominant way of disposal in Kuwait, United Kingdom and Lithuania (4). Disposal of medications into the sewage system is still a common practice in New Zealand, USA and Bangladesh, and is mostly reserved for liquid dosage forms (6, 23, 24). In contrast, in Sweden, a country with a long tradition of the reverse distribution network for the collection of unused and unwanted medications, a high percentage of population returns unused medications to pharmacies (43%). Sweden is an excellent example of how the essential part of communicating a message to the public is to postulate a clearly defined mechanism for disposal and an unambiguous obligation on specified agent/agencies to take medications for disposal (25). Also, confusion over the adequate methods of medication disposal still exists in many countries, mostly because of conflicting or incomplete guidelines for disposal of unused medications (4).

4.3 Limitations

Despite the fact that an in-home inventory of medications obtained by direct observation has been shown to be a more reliable measurement tool than self-report recall methods, some weaknesses of our study need to be mentioned. First of all, it may be difficult to extrapolate our study results to the other parts of our country, because Novi Sad, a wealthy university city, might not be representative of Serbia in general. Secondly, answers to the questions regarding disposal habits and attitudes are self-reported in nature, and some respondents may not have been telling the truth. Notwithstanding these limitations, the study adds information to the area of scant knowledge.

4.4 Study Implications

Serbia must seriously consider the issue of medication wastage. A part of this wastage can be prevented and, considering the limited health resources of the country, it is prudent to start taking action. Firstly, like in many countries, Serbian government should limit prescription medication wastage by dispensing medication according to the exact number needed for treatment, rather than by the original pack, and also by increasing compliance through educational campaigns targeting different age groups and using various communication routes. Also, in order to limit environmental effects of improper expired

medication disposal, an established formalized state-run disposal system that is cost-effective and easily accessible is necessary in Serbia.

5 CONCLUSIONS

This study revealed that expired medications were commonly encountered in Serbian households, with a high prevalence of antibiotics for systemic use, anti-inflammatory and antirheumatic products, and medications for alimentary tract and metabolism. Throwing medications into the garbage was the predominant disposal method among the surveyed households, despite the fact that more than a half of the population is aware of the harmful effects of improper medication disposal on the environment.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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ETHICAL APPROVAL

Received from the Ethical Committee of the Faculty of Medicine in Novi Sad.

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