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Reasons why medicines are returned to Swedish pharmacies unused.

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Abstract

Objective: To identify the reasons and their relative importance why medicines are returned to Swedish pharmacies unused.

Setting: A random sample of the pharmacies in Sweden.

Method: Interviews using a semi-structured interview form with pharmacy customers returning unused medicines to the pharmacy.

Main outcome measure: Reasons given by patients/relatives/carers for returning unused medicines to the pharmacy.

Results: The four main reasons for returning unused medicines to the pharmacy were: (1) the medicines were too old, (2) the user had died; (3) there was no need for the medicine anymore; and (4) therapy changes. These reasons made up 75% of all reported reasons.

Conclusion: Hoarding or over-supply of prescribed medicines may explain a large part of the volume of medicines that remain unused. Actions aiming to reduce waste of prescribed medicines ought to focus on those patients who contribute to a substantial part of all unused medicines.

Key words Medicines - Drug waste – Medicines – Pharmaceuticals – Pharmacies – Sweden - Unused medicines;

Reasons why medicines are returned to Swedish pharmacies unused.

Introduction

Unused medicines are regarded as a problem in many countries because of the economic value they represent as well as the consequences of non-adherence to prescribed treatment and environmental hazards.

In Sweden, the public is advised to return unused medicines to the pharmacy for incineration. The proportion of dispensed medicines that are returned to Swedish pharmacies has been found to be about 2.3-4.6% of the volume dispensed (1, 2). However, the distribution of returned packs per patient is skewed, with 10% of patients returning about half of all packs (3, 4). Most returned packs have passed the expiry date and less than one-third of all returned packs are purchased during the year before they are returned (1).

Pharmacy in Sweden

All Swedish pharmacies are owned and run by the National Corporation of Swedish Pharmacies. The present drug benefit scheme in Sweden is a co-payment model with a high-cost insurance. During a 12-month period the patient pays a maximum of 1,800 SEK (approx. €200) for prescribed and reimbursed medicines. The first 900 SEK come out of the patient's own pocket and thereafter the reimbursement increases stepwise to 50%, 75%, 90% and finally 100% of the amount. Within the drug benefit scheme, the maximum dispensed volume for each prescription at a time is the number of doses closest to ascertain treatment for 90 days (or 13 weeks) and the next refill is not allowed until two-thirds of the anticipated treatment period has passed, i.e. 2 months.

Studies on the reasons why medicines are returned to pharmacies unused have been performed in different countries including the UK (3, 5, 6, 7, 8), Canada (9), Norway (10) and Sweden (11). However, in some studies only the main reason for each patient has been recorded (3, 8, 11), while other studies do not give details on the methods of data collection (5, 6, 10, 12). When a patient returns more than one drug, there may be a different reason for returning each drug. However, even where the main reasons may be known, their relative importance is not. Actions aimed to reduce waste of prescribed medicines should focus on the quantitative important reasons.

Aim of the study

To identify the reasons and their relative importance why medicines are returned unused to Swedish pharmacies.

Method

Semi-structured one-to-one interviews were conducted with customers who returned unused medicines in a random sample of pharmacies.

The 776 community pharmacies in Sweden were stratified according to pharmacy size (<25; 25-49; 50-74; 75-99; 100-149 and >150 thousand processed prescription items a year). A random sample of twelve pharmacies in each stratum, in total 60 pharmacies, of the 640 pharmacies processing >25 thousand prescription items a year (82% of all pharmacies, 95.5% of the prescription volume) were invited to participate in the study. If a pharmacy declined to take part in the study, a substitute pharmacy was randomly chosen from the same stratum and invited to participate.

Interviewers

One pharmacist at each pharmacy was selected to conduct the interviews. All interviewers participated in a day's training including a thorough presentation of the project focusing on how to perform the interviews and record them on the interview form.

Time setting

The participating pharmacies were randomised to enter the study on different days, 12 per weekday, starting the week of 30 September – 4 October 2003, and continue until the predetermined number of interviews had been completed. For practical reasons, only customers returning unused medicines on weekdays were interviewed. The number of interviews was reported to the project leader (AE) day by day and the interviewers received daily feedback on the progress of the study.

Inclusion criteria

Interviewees

Patients who gave written, informed consent to be interviewed. Where a patient was unable to respond to the questions, (for example due to dementia or because the patient themselves had deceased), a relative or health care professional was interviewed. Where the patient was <18 years of age, the parent was interviewed.

Medicines

Unused medicines for human use, purchased in Sweden, and returned to Swedish pharmacies.

Operational definitions

The packs were divided into two categories, viz. “ongoing medication” and “former treatment”. “Ongoing medication” was defined as (1) medicines the patient was intended to use on the day the medicines were returned or (2) medicines a deceased patient was prescribed to take at the time of his or her death. All other medicines were classified as “former treatment”.

Exclusion criteria

Medicines purchased outside Sweden were excluded.

Data collection

The interviews were conducted at the pharmacy using the returned packs. Each patient was given a study code. The study code, year of birth, gender, returned medicines (trade name, preparation, strength) and the reason for each returned drug were recorded on the interview form by the pharmacist doing the interview. All returned medicines were packed individually for each patient together with a copy of the interview form and sent to a central location where data were recorded using the same protocol as used in a previous study [1]. All data in the interview form plus data on all returned packs (name, preparation, strength, package size, amount remaining in the pack, bar code on the pack, purchase date, expiry date) were entered into a database.

Calculations

“Hoarding” of medicines was defined as having packs of “ongoing medication” that have passed the expiry date or returning packs exceeding 90 days’ treatment.

Study size

Between 10 and 25 interviews per pharmacy were conducted depending on size of the pharmacy, with a total of 960 interviews. Based on previous studies, it was estimated that one-third of patients do not agree to be interviewed. In order to obtain 960 interviews, it was estimated that about 1,500 patients, returning about 10,000 packs of medicines, needed to be asked for informed consent to an interview.

Research ethics

To secure anonymity no data that may be traceable to an individual patient were recorded, as required by legislation. The study has been approved by the Research Ethics Committee, Lund University.

Results

Fifty-six of the invited sixty community pharmacies agreed to participate. For three pharmacies declining participation, a substitute pharmacy was invited. The fourth pharmacy declined participation only a few days before the start of the study, which is why the study consists of interviews performed at 59 pharmacies. Altogether, 9,077 packs were returned. Of these, 282 packs did not meet the inclusion criteria (not for human use; purchased outside Sweden; not licensed medicines). Of the remaining 8,795 packs from 1,557 patients, 109 were “14-day-packs” with dose-dispensed medicines from the pharmacies.

Age of the returned packs

Fifty-six percent of the packs had a pharmacy label including the date of purchase. Of these, 27% had been purchased during the previous 12 months and 57% had been

purchased more than 2 years before, while 26% had been bought more than 5 years being returned (see Table 1).

The expiry date was identified on 91% of the packs and 61% of those had passed the expiry date. Fifty-two percent of the packs classified as “ongoing medication” and 64% of the packs of “former treatment” had passed the expiry date.

Distribution of returned packs per patient

The distribution of returned packs per patient was skewed (median 3; lower quartile 1; upper quartile 6; range 1; 140 packs). Most patients (57%) returned between one and three packs, constituting 17% of all returned packs. Ten percent (90th percentile; 156/1,557) of the patients returned more than 12 packs each (range 13; 140) constituting 45% of all returned packs and 3.4% (47/1,557) of the patients returned more than 23 packs each (range 24; 140) constituting 24% of all returned packs (Table 2).

Patients

Altogether 1,022 (65.6%) patients were interviewed. Fifty-three percent returned their own medicines, while a relative returned them for 34% and health care professionals for 6% of the patients. There were no significant differences with respect to patient age or gender, number of returned medicines or type of drug between those giving informed consent to be interviewed and those not agreeing to the interview (Table 3).

Returned medicines

Multi-dose vials of eye drops/ointment must be used within a maximum period of 1 month after opening/breaking the seal (1 month's use) and the residual (due to over-

filling) is then to be discarded. In total 321 packs with the remains of eye drops/ointment from 24 patients were excluded from the calculations. The total material therefore constitutes 5,414 packs from 1,001 patients, 607 women, 372 men and 22 of unknown gender. Altogether 522 (51.7%) of the patients were 65 years old or older Thirty percent of the packs (1,620) were returned from 136 (13.5%) deceased patients (Table 4).

Reasons why the medicines were unused

Thirty-seven per cent of the returned packs from 408 patients constituted “ongoing medication” while 63% (3,418/5,414) were “former treatment”. The reported reasons for the unused medications are presented in Table 5.

The four main reasons making up >75% of all reported reasons were (1) that the medicines were too old, i.e. they had passed the expiry date; (2) that the patient had died; (3) that the treated condition had improved/there was no need for the drug anymore; and (4) that there had been therapy changes due to adverse drug reactions, lack of effect and/or deterioration of the medical condition. However, for packs purchased during the previous 12 months, two reasons explained >70% of the waste, namely the patient had died (45%) and there had been therapy changes (26%). With regard to “ongoing medication”, 50% of the packs had passed the expiry date indicating that the purchased volume was larger than was needed/used.

New medications

Of the returned packs, 3.1% (167/5,414) were reported to be new medications, i.e. a treatment initiated during the month before interrupting it and for 66 packs the condition had resolved or improved or that the medication was no longer needed. Of

944 packs returned by live patients, 64 packs were “new treatments” purchased during the previous 2 years. Of these, 21 packs were apparently for short-term treatment (antibiotics, anti-tussives etc). Therefore 43 of the “new treatments”, anticipated for long-term use, had been terminated within a month constituting 4.6% of the returned packs. The reasons for interrupting the therapy were adverse drug reaction (n=18); change to other treatment (n=4); or the drug was not efficient in treating the condition/deterioration of the condition (n=4).

Discussion

In the present study, four reasons made up >75% of all reasons for the medicines being returned unused. They were that the medicines were too old/ had expired; the patient had died; the condition had improved or there was no need to take the drug any more and that there had been therapy changes due to adverse drug reactions or lack of effect or deterioration of the condition. Few of the packs returned because of change in therapy concerned a new treatment or new prescription. Deceased patients constituted 14% of the patients and accounted for 30% of all returned packs. One-third of the medicines returned after the patients had died were from “former treatment” which had been terminated previously. Medicines that were returned unused owing to the death of the patient therefore constituted about 20% of all returned packs. The proportion of medicines being returned because of the death of patients may have been overestimated in previous studies, which established only one reason per patient (3, 6, 10). However, in the present study, of packs purchased during the 12 months preceding their return almost half were unused owing to the death of the patient.

The distribution of returned items per patient is skewed, with 3% of patients returning one-quarter of all returned items and 10% returning almost 50% of the packs. This is concordant with previous studies presenting data on the distribution per patient (3, 4), and the trend has been indicated in other studies (5, 6, 9, 10, 13, 14, 15). The findings correspond to another well-reported finding, that a few percent of all patients/the population who are frequent attendees, constitute one-quarter of all general practitioner (GP)-visits as well as prescriptions (16, 17, 18, 19, 20, 21). “Frequent attendees” may have renewals of a prescription long before the expiry of the previous ones, resulting in two or more simultaneous prescriptions for the same treatment. In a pilot study at one health care centre, about 25% of patients had received two or more prescriptions for the same item (M Lundberg, personal communication).

It has been suggested that one way to decrease the volume of unused medicines is that a small “starter-pack” be prescribed whenever a new treatment is initiated. If the treatment has to be withdrawn early, this would render only small volumes of unused medicines to be abandoned and discarded. However, only in a few cases did the interviewees state that the unused drug was a new treatment that had been withdrawn. The results would therefore suggest that prescribing “starter-packs” will only insignificantly influence the volume of unused medicines.

However, there are certain limitations to the present study. Recall bias poses a problem to the validity of the answers as most of the unused medicines had been purchased long before they were returned. Relatives may have limited knowledge on the reasons as to why the medicines that had been dispensed for the deceased had not been used. Non-adherence was only reported in a few cases, and therapy changes of new treatments due to adverse drug reactions or inefficiency were only reported for a few of the deceased patients. Another limitation was that the study included only

returns during weekdays. However, many pharmacies in Sweden are closed on Saturdays and Sundays. The experience from previous studies is that returns on Saturdays and Sundays constitute only a small proportion of all returned medicines. The impact of day of return on the reported reasons is therefore limited.

When a patient returns several different medicines, there may obviously be different reasons for the different medicines being unused. When medicines are returned after a patient has died, only medicines used by the patient at the time of death are considered unused because of the death. Consequently, to have a quantitative estimate of the relative importance of the reasons for medicines being returned unused, the reason for each drug/pack must be recorded along with a note of how old the returned drug is. Previous studies often only recorded one reason per patient irrespective of how many packs/medicines were returned (3, 8, 11); also they failed to present details on data collection (5, 6, 10, 12). Differences in the relative importance of reasons between studies may also depend on the age of the returned medicines.

The volume of medicines in people's homes depends on two factors, namely how much is purchased; and how much is consumed. How much is purchased depends on the number of doses purchased at each fill of continuous treatment and the number of fills. In Sweden a prescription on drug treatment for chronic diseases is usually for a period of 1 year. A maximum of 3 months' supply at a time is dispensed by the pharmacy. A refill of a prescription within the reimbursement scheme is not allowed until after two-thirds of the anticipated treatment period has passed. However, if the patient has two or more prescriptions on each item, each prescription may be filled within the reimbursement scheme. Subsequently, it is possible for patients to hoard medicines far beyond of 3 months' treatment. How much is consumed depends on a patient's adherence to prescribed therapy; on whether the medicines expire/get too

old during the treatment period; on the volume of medicines that are left when there is a change in treatment; on the patient's behaviour to save medicines no longer needed; and on whether the patient dies. When patients die, the stock of medicines for continuous treatment should not exceed 13 weeks' treatment (on average 7 weeks). The results of the present study suggest that more than 50% of the returned medicines were wasted, due to over-supply and hoarding among a minority of patients. The economic value of returned, unused medicines in Sweden has been estimated to be about €80-100 million per year (Dag Malgeryd, personal communication). The cost of hoarding and/or over-supply of prescription medicines may therefore correspond to about €40-50 million per year in Sweden.

In order to assess the relative importance of the reasons why prescription medicines are unused, the reason for each drug should be established. This has obviously been overlooked in previous studies. A small group of patients in Sweden, about 3% of men and 6% of women, are treated with ten or more medicines on prescription (The Swedish Prescription Register; Björn Wettermark, personal communication). In the present study, 3% of the patients returned about 25% of all returned medicines. Pharmaceutical care initiatives and/or managed care initiatives to this group of patients may also reduce waste of medicines. This remains to be studied.

Conclusion

The four reasons that made up >75% of all stated reasons why medicines were returned to pharmacies in Sweden unused were (1) that the medicines were too old; (2) that the patient had died; (3) that the condition had improved or there was no need for the treatment any more; and (4) that therapy changes due to adverse drug reactions, lack of effect and/or deterioration of the medical condition had been implemented. Hoarding or over-supply of prescribed medicines explained a large part

of the medicines that were unused, and 3% of the patients returned 23 or more different packs, constituting 24% of all returned medicines. Actions aimed to reduce waste of prescribed medicines ought to focus on this small group of patients who are on treatment with many different medicines and who are responsible for a very substantial part of all unused medicines.

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Table 1 Age of the returned packs (between purchase and returning); n = 4,958

Age	Number of packs	Percent
<6 months	773	15.9
6-12 months	555	11.1
1-2 years	819	16.5
2-5 years	1,537	31.0
5-10 years	891	18.0
>10 years	383	7.7

Table 2 Numbers of returned packs per patient.

Returned packs/patient	Interviewed		Total	
	Patients (%)	Returned packs (%)	Patients (%)	Returned packs (%)
1	309 (30.2)	309 (5.3)	453 (28.4)	453 (5.2)
2-3	294 (28.8)	721 (12.5)	436 (26.6)	1,057 (12.0)
4-5	134 (13.1)	597 (10.6)	217 (14.4)	963 (11.0)
6-8	113 (11.1)	776 (13.5)	187 (12.0)	1,275 (14.5)
9-12	70 (4.7)	721 (12.4)	108 (8.1)	1,113 (12.7)
13-23	75 (7.3)	1,225 (21.4)	109 (7.1)	1,794 (20.4)
>23	27 (2.6)	1,387 (24.2)	47 (3.4)	2,140 (24.3)
Total	1,022 (100.0)	5,736 (100.0)	1,557 (100.0)	8,795 (100.0)

Interviewed - 1,022 patients, 5,759 packs; Total - 1,557 patients, 8,795 packs.

Table 3 Age distribution of all patients and those giving informed consent to interview.

	Women		Men		Total*	
Age/ Gender	All patients	Inter- viewed (%)	All patients	Inter- viewed (%)	All patients	Inter- viewed (%)
0-9	25	18 (72.0)	43	36 (83.7)	79	54 (68.4)
10-19	19	17 (89.5)	20	20 (100.0)	48	39 (81.3)
20-29	27	19 (70.4)	22	10 (45.5)	57	30 (52.6)
30-39	65	46 (70.8)	20	13 (65.0)	96	59 (61.5)
40-49	65	52 (80.0)	31	16 (51.6)	113	69 (61.1)
50-59	105	91 (86.7)	66	46 (69.7)	195	139 (71.3)
60-69	129	103 (79.8)	70	58 (82.9)	234	165 (70.5)
70-79	154	124 (80.5)	103	88 (85.4)	290	212 (73.1)
80-89	123	108 (87.8)	80	72 (90.0)	237	182 (76.8)
90-99	37	34 (91.9)	22	20 (90.9)	76	54 (71.1)
100+	1	1 (100.0)	1	1 (100.0)	2	2 (100.0)
Unknown age	27	6 (22.2)	7	1 (14.3)	130*	17 (13.1)
Total	777	619 (79.7)	485	381 (78.6)	1,557	1,022 (65.2)

* The totals are different from the sum of men and women due to missing data on gender for 295 patients. Interviewed patients/relatives/carers(%)

Table 4 Age distribution for 1,001 patients returning 5,414 packs with unused medicine

Age	Deceased		Alive		Total			
	Patients	Packs	Patients	Packs	Patients	%	Packs	%
0-6	1	5	37	92	38	3.8	97	1.8
7-14	0	0	33	95	33	3.3	95	1.8
15-24	0	0	29	76	29	2.9	76	1.4
25-44	0	0	107	512	107	10.7	512	9.5
45-64	13	268	247	1,078	260	26.0	1,346	24.9
65-74	25	333	164	764	189	18.9	1,097	20.3
75-84	45	573	157	764	202	20.2	1,337	24.7
85-109	47	398	78	369	125	12.5	767	14.2
Unknown	5	43	13	44	18	1.8	87	1.6
Total	136	1,620	865	3,794	1,001	100.0	5,414	100.0

Table 5 Reasons why medicines remained unused (n=5,414)

Reason	Deceased patients	Live Patients	Total	%
<i>Ongoing medication</i>	1,035*	961*	1,996*	
Death of the patient	1,023		1,023	18.9
Expiry date passed/Drugs too old	37	672	709	13.1
Change in care and/or drug handling	38	246	284	
Non-compliance	-	70	70	
New treatment	1	3	4	
<i>Old treatment</i>	585	2,833	3,418	
No need anymore/ Condition improved	28	964	992	18.3
Expiry date passed/Drugs too old	39	428	467	8.6
Short term treatment	10	57	67	
Adverse Drug Reaction	8	361	369	
Unefficient	9	267	276	
Deterioration of condition	21	34	55	
Difficulties to take the drug	19	38	57	
Sub total - therapy changes	81	857	938	17.3
Non-compliance	4	103	107	
New treatment	7	156	163	
Total numbers of packs	1,620	3,794	5,414	100.0

321 packs with the remains after eyedrops/ointments are excluded.

* The sum of the reasons exceeds the figures for the headings, as more than one reason may be stated.