



Original Article

A Cross Sectional Study to Evaluate the Storage and Expiry Date of Medicine in Kalanaur Town of Haryana, India

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Objective: The aim of the study was households' survey to evaluate the storage and expiry date of medicines in families in Kalanaur town of Haryana, India. **Methodology:** A cross-sectional, pre and post-study was conducted using a set of household interview questionnaire. **Results:** A total of 500 families' are enrolled, of which 38.4% are male and 61.6% are female. The proportion of respondents having age 15-30 years 59.8%, 30-40 years 22.6%, 40-50 years 8.4%, 50-60 years 6%, and > 60 years 3.2%, 64.6% are married and 35.4% are unmarried respondents. They lives in urban areas, of which respondents having primary to high education level 49.8%, 42% have high to graduation and 8.2% have post graduate, regarding occupation majority are labour 42% and private sector 39% and 15.2 % families have government and 4.2 % has work as farmer, check expiry date of medicine (pre-intervention 90.6%, post-intervention 99.4%), kept left over medicines for reuse (pre-intervention 57%, post-intervention 50%), return-back the unused medicines to pharmacy (pre-intervention-9.6%, post-intervention 17.6%), throw left over medicines (pre-intervention 33.4%, post-intervention 32.4%), stored medicines as per instruction in refrigerator (pre-intervention 43%, post-intervention 54.2%), place where the medicines stored at home are: - wardrobe (pre-intervention 7%, post-intervention 1.8%), medicines box (pre-intervention 43%, post-intervention 54.8%) table drawer (pre-intervention 19.8%, post-intervention 21%), in bag (pre-intervention 17.6%, post-intervention 17.8%), other places (pre-intervention 12.8%, post-intervention 4.6%), **Conclusion** There is a widespread lack of knowledge about dealing with medicines.

Key Words: - Households, Intervention, Storage, Expiry date, Questionnaire.

1. INTRODUCTION

Adherence with drug therapy is necessary for treatment and prevention of disease. Many patients do not complete their medications and stored medicine at home or thrown away. If drugs are not properly stored and disposed, these can have a direct impact on public

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safety, environment, and the health care services. 40% of prescription drugs dispensed each year to consumer in the United States are never actually used, instead drugs are either stored or thrown away.¹ Over the counter and prescription drugs have caused 75% of all unintentional poisonings in North Carolina.² The National Institute on Drug Abuse has estimated that 20% of the population in America will use prescription drugs for nonmedical reasons within their lifetime.³ National Survey on Drug Use and Health (NSDUH) found that over 70% of people who abused prescription pain relievers got them from friends or relatives, while approximately 5% got them from a drug dealer.⁴ DEQ sponsors “community medication” take-back events called “Clean Out Your Medicine Cabinet”. Many community organizations also sponsor medication take back events, but should have approval from Drug Enforcement Agency (DEA). Community based programs have the greatest impact.⁵ In May 2010, the U.S. Attorney General office signed a letter of support for two bills one in the house and the other in senate both of which entitled “Secure and Responsible Drug Disposal” Act 2009.3. These bills would make easier to implement drug take back program.⁶ Active pharmaceutical ingredients are contaminating the environment and finding their way into our drinking water via human excretion and improper drug disposal. Dozens of pharmaceutical drugs including antibiotics, anticonvulsants, mood stabilizers and sex hormones have been found in the drinking water of an estimated 46 million Americans.⁷ Keeping expired medication in the home or giving them to friends and family which may increase the risk of accidental or inappropriate ingestion.⁸ Many Poisoning cases have been reported to Poison Control Centers in the United States in

recent years due to accidental intake of left over medicines in residential areas.⁹

Expiration dates are meant to indicate the date at which the drug's potency begins to diminish. The drug does not usually become harmful after the expiration date listed on the box or bottle, but rapid degradation of certain drugs, such as insulin or liquid antibiotics.¹⁰

Guideline for safe storage of prescribed drug

Always check the expiry date of medicines. Expired date medicines and discolored, dried out, crumbled medicine, if found discard them. Leftover prescription medicines discard, since you should never try to treat yourself with these medicines.

At home where keep the prescribed medicine

Medicines should be kept in medicine box and keep at safe, cool, and dry place. Few medicines require to be kept in refrigerator and should be kept as per instructions.

How to keep the prescribed medicine

Keep your medicines separate especially from children to prevent taking wrong medicine by mistake. Keep medicines in good lighting, so that you can see properly and make sure you are taking the right medicine and always see the instruction on medicines.

Medication Take-Back Programs

There are different modes of take back program.”Permanent collection site” located in the lobby of law enforcement agencies. Each location contains a locked, mounted steel collection bins in the lobby. Unwanted medications are dropped into these bins. Bins are emptied by Law Enforcement officers and ultimately incinerated at Department of Environment quality (DEQ) permitted facilities.

Disposal of unused and expired medicines in household trash

When no medicine take back program is available in your area you can dispose medicines in the household trash but consumers should take certain

precautions before tossing them out. Take unused, unneeded or expired prescription drugs out of their containers and mix them with undesirable substances (like used coffee grounds or kitty litter, spoiled food), put the mixture in an empty can or bag or sealed in an opaque container, before you throw them away.

Proper education to society

It is very necessary to educate the people about proper storage and disposal and expiry date of prescribed medicines.

2. MATERIAL AND METHODS

Kalanaur is a significant town of Rohtak District in State of Haryana situated on Delhi- Rohtak- Bhiwani road. This was a pre and post Interventional study.¹¹ The data collection method was a structured interview of families or household.

Sampling

The baseline data collection research study was documented at 500 families interviewed, including the respondent of either gender and permanent resident of the town who were willing to participate. The study design was a baseline cross sectional study based on the method enclosed in World Health Organization (WHO) manual- How to investigate the use of medicine by consumers.¹² A written questionnaire in Hindi was designed, field, tested, revised and finalized. The pilot study tested the questionnaire for reliability, comprehension, question design and length. According to the result of pilot study the draft protocol was revised and the weaknesses were addressed before the actual study was conducted. The data collected in the pilot study did not form a part of study sample. The questionnaire, composed entirely of closed question, covered the following aspects:-

- a) Socio-Demographic characteristics of interviewed households including- gender, marriage status, age, education, income.

- b) Storage, expiry date and dealing with left over medicines

For collecting data Kalanaur town was selected. One member from each family was interviewed, generally the parents or other member of the family aged around 15 to 60 years old. A total of 500 households were involved in the study. Interviewer introduced themselves to the household respondent and informed them, all the information will be kept confidential. When respondents give their agreement to participate in this study, Interviewer gave them the questionnaire. The answer of the interview and the observation were recorded instantly into the questionnaire form by interviewer. All respondents were assured of anonymity and informed that only aggregate data would be reported that they were free to refuse to participate at any time.

Handouts and interactive lectures session

Printed handouts information and an interactive lecture session intervention during study. Face-to-face communication with the households or respondent could be also achieved. This session aimed with respondents that they must know information how stored and deal with left over medicines.

Press Release

As part of advocacy, liaison was established with local press who were given articles for publication, about rational use of medicines in general and how that affects the people. After completing the triads of intervention a post intervention interview was undertaken using the same instrument and find out the impact of intervention.

Data processing and analysis

Information obtained was checked and verified. Pair-wise comparison of pre and post-intervention groups has been performed by using a normal test. The Chi-Square test for independence of attributes has been

applied. The cut off for statistical significance was set at 5% level. Result was presented in tabular form.

Ethical approval

Ethical approval of the study was approved by the Municipal Committee, Kalanaur town and Department of Pharmaceutical Sciences Maharshi Dayanand University Rohtak, Haryana, India under the guidance of Dr. Neeraj Gilhotra Associate Professor of Pharmacology at MDU Rohtak. A consent form was signed by the respondents and all the collected data have been used only for the purpose of this study.

3. RESULTS

A total of 500 families’ respondents or households participate in this study, of which 38.4% are male and 61.6% are female, the proportion of respondents having age 15-30 years 59.8%, 30-40 years 22.6%, 40-50 years 8.4%, 50-60 years 6%, and > 60 years 3.2% participate in this study. 64.6% are married and 35.4% are unmarried respondents. They lives in urban areas which may reflects high percentage of respondents having primary to high education level 49.8%, 42% have high to graduation level and 8.2% have post graduate. The majority of the families has a source of livelihood; regarding occupation majority are earning being labour 42% and private sector 39% and 15.2 % families have government job as an income source and 4.2 % has work in fields or farmer. In pre-intervention 90.6% and in post-intervention 99.4% families mentioned that they check the medicines expiry date. In pre-intervention 57% and in post-intervention 50% families mention that they do not reuse or given them to relative or neighbor. In pre-intervention 9.6% and in post-intervention 17.6% families’ mention that they were return-back the unused medicines to the pharmacy. In pre-intervention 33.4% and in post-intervention 32.4% said that they dispose medicines properly and not through in streets and any other place. In pre-intervention 43 % and in post-intervention

54.2% families know that medicines stored as per instruction in refrigerator in order to maintain their quality and efficacy. Families store medicines at home following place:- wardrobe (in pre-intervention 7% and in post-intervention 1.8%), medicines box (in pre-intervention 43% and in post-intervention 54.2%), table drawer (in pre-intervention 19.8% and in post-intervention 21%), in bag (pre-intervention 17.6% and in post-intervention 17.8%), other place (in pre-intervention 12.8% and in post-intervention 4.6%). The following findings are statistically significant.

Table 1: Socio-Demographic characteristics of interviewed households include gender, Age, marriage status, occupation, income, education.

Characteristics	Parameter	Households	Percentage
City	Kalanaur	(n=500)	100%
Location	Urban	500	100
Gender	Male	193	38.4
	Female	307	61.6
Age	15-30	299	59.8
	30-40	113	22.6
	40-50	42	8.4
	50-60	30	6
Marriage status	>60	16	3.2
	Married	323	64.6
	Unmarried	177	35.4
Occupation	Government	76	15.2
	Agriculture	21	4.2
	Private	195	39
	Labour	210	42
Income	Unemployed	0	0
	1000-5000	226	45.2
	5000-1000	115	23
	>10000	159	31.8
Education level	5 th to 10 th	249	49.8
	10 th to Graduate	210	42
	Graduate	41	8.2

4. DISCUSSION

IEC (Intervention education communication) implement a positive change in knowledge of consumers. This is a time consuming research study. The Families interviewed are very difficult to conduct in a single town of a city. Family’s respondents were afraid about it and thought what they do after data collection. However, studies carried out in the community are very important as they enable researchers to understand medicine use practice and

related aspects from both the patients as well as consumers point of view, and may encourage the development of adequate medicines policies.¹²

Table 2: Storage and disposal of medicines

Interviewed Households (all figures in percentages)	Intervention			
	Pre (n=500)	Post (n=500)	P value	
Families check expiry date of medication	90.6	99.4	0.596571	
Families dealing with Left over Medicines	Keep it for future use by myself or Other	57	50	0.847296
	Return it to pharmacy	9.6	17.6	0.000000
	Throw it	33.4	32.4	0.873047
Families store medicines as per instruction in fridge	43	54.2	0.767181	
Families Store medicine in which of the following place	Wardrobe	7	1.8	0.010059
	Medicine box	43	54.8	0.027697
	Table drawer	19.8	21	0.124714
	Bag	17.6	17.8	0.980191
	Other place	12.8	4.6	0.000654

The current study had planned on intervention based on families need assessed through first contact. This study evaluates how families deal with storage, disposal and expiry date of medicine. Change in level of knowledge is concerned; it was achieved through face to face intervention with families. The overall result of this study regardless education level, age, occupations and monthly income were calculated.

Expiry date is defined as the period extended from the date of manufacture to the date on which the medicines should not be used by the patients or consumers. Medication expiry date is valid if the medication stored as per instruction given by the manufacturer or on label. During intervention Interviewer gives the information's about expiry date of medicines. It's very important to check the expiry date not only medicines even every product. Consumers should not use the medicines or products after its expiry date or if change in color, taste or appearance of medicines. In post-study 99.4% families mentioned that they check the medicines expiry date. It's very important to check the expiry date when receiving or using medicines.

Left over medicines i.e. medicines left from the past treatment or medicines course no fully consumed or parched medicines over-the-counter. Usually consumers not fully consumed medication prescribed to them because of many reasons: they may avoid unpleasant side effects, the symptoms have been relived, forgetfulness, dosage changes, side effects intolerance and medication reaching the expiration date. In pre-intervention 57% of families report that they are reuse left-over medicines or given them to relative or neighbor who need them and 9.6% said that they were return the unused or left over medicines to pharmacy and 33.4 said they were throw the unused medicines. During intervention interviewer inform the families how to deal with the left-over medicines they should not be taken on the basis of previous experience or according to advice from others than health care professional and should not exchange medicines with others. Many families do not know what to do or how deal with left over medicines. It causes not only an economic burden but also the irrational used and accidental poisoning particularly for children. Left-over medicines previous treatment should not throw out or not kept for future use. It is very important to consult a dispenser how to deal with left-over medicines or return back the unused medicines to pharmacy in order to avoid any health risk and wastage. After intervention this is improve and 17.6% families return the medicines to pharmacy and 50% said that they kept unused medicines and consult with the prescriber or dispenser before reuse and 32.4% said that they throw the unused medicines properly or not in street. Inappropriate medicines disposed is a serious environmental problem so therefore guidelines on safe disposal of unwanted medicines are required and an organized method of collecting unused medication needs to be introduced.

Interview Form

Ref. Document: WHO & HAI

MDU, Rohtak

How to investigate the use of medicines by consumer

Interviewed households No... Address.....
 Community: Urban/Rural Phone No.....
 Interviewers Name Interviewers Profession.....

Family knowledge, attitude and practice towards use of medicines.**Socio-Demographic characters of interviewed households****A Personal data**

1. Sex: Male Female **2. 6. Age:** 15-30 30-40 40-50
 50-60 > 60

3. Married/Unmarried..... **4. No. of children**

5. Occupation: Govt. Job Agriculture Private Sector

Labour Contractor No occupation

6. Income: 1000-5000 5000-10000 >10000

7. Qualification or Level of Education: 5th to 10th 10th to Graduate PG

B Storage and disposal of medicines

1. Do you store medicines in the fridge as per instruction?

a) Yes b) No

2. If no, in which of the following place: a) Wardrobe b) Medicine's box

c) On a shelf d) In a drawer e) In a bag f) Another place.....

3. Do you check the expiry date before using the medicines?

a) Yes b) No c) No response

4. How do you deal with left-over medicine?

a) Keep it for future use by myself or others

b) Return it to Pharmacy c) Throw it

Signature of Interviewed

Signature of Interviewer.....

Supervisor: Dr Neeraj Gilhotra

How to investigate the use of medicines by consumers. (WHO/PSM/PAR/2007.2). Geneva; World Health Organization 2007.

<http://www.who.int/drugresistance/manual.2>

The appropriate place of medicines at home is in a medicines box and this box stored at cool and dry place if medicines box is not available then stored medicines at high place or hung high in a room or in locked cabinet. Medicines storage is very important. Heat, moisture, light and dirt can all harm the medicines and making them unsuitable for use. So there for always asked the prescriber or dispenser where and how to stored medicines at home and always should follow the instruction given on label. Medicines should always store as per instruction that helps to maintain their quality and efficacy. In this study during intervention interviewer give the information how they safely stored there medicines and protect from the accidental poisoning and instruct that stored away from sunlight, moisture and dirt all making the medicines unsuitable for use If medicines are not stored properly may lose their action and become toxic even before expiry date. So it's very important that medicines should be stored out of children to avoid any accidental poisoning.

5. CONCLUSION

India is a developing country and there is poor knowledge of proper storage and disposal of prescribed medicines. Thus, there for more societal awareness and also Government of India should bring awareness program and law enforcements for proper storage and disposal of prescribed medicines. Excess of medication at home creates unintentional poisoning, illegal distribution, substance misuse, and environmental contamination. Pharmacists and Doctors should prevent over prescription, which will help to minimize the problem of left over medicines and its storage and disposal problem. Other social groups along with health-cares should come forward and work on take back program of prescribed medicine, also help to reduce the economical burden and chances of resistance of medicine in the community.

6. REFERENCES

- 1 Avalere Health: Safe disposal of unused controlled substance/ current challenges and opportunity for reform undated. Retrieved February 2010 from: <http://www.takebacknetwork.com/pdf/SafeDisposa>

- 1_of_Unused_Controlled_Substance.pdf. February 2010.
- 2 Sanford C. An unrelenting epidemic of deaths from prescription drugs in North Carolina. NC Medical Board's Forum 2008; 4-7.
 - 3 National Institute on Drug Abuse Research Report Series: Prescription drug abuse and addiction 2005.
 - 4 National survey on Drug Use and Health (NSDUH): National Findings, SAMHSA 2010.
 - 5 Office of National Drug Control Policy: Proper disposal of prescription drugs. October, 2009. Retrieved March 2010 from <http://www.Whitehousedrugpolicy.gov/publications/pdf/prescripdisposal.pdf>
 - 6 National Drug Control Policy: The President's national drug control strategy <http://www.ondcp.gov/publications/policy/ndcs09/chapter1> April 2010.
 - 7 Donn J, Mendoza M, Pritchard J. AP Impact: Health care industry sends tons of drugs into nation's waste water system. April 2010. Retrieved April 2010 from: <http://hosted.ap.org/specials/interactives/pharmawater/site/sept14a.html>
 - 8 World Health Organization: Guidelines for Drug Donations. Geneva, WHO 1999.
 - 9 Bronstein AC, Spyker DA, Cantilena JR, Louis R, Jody LG, Barry HR, Stuart EH. 2007 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 25th Annual Report (Clin Toxicol Phila) 2008; 46: 927-1057
 - 10 Swaroop AP and Varun D. A glimpse on expiry date of pharmaceutical dosage forms 2011; 2: 5-6.
 - 11 Thawani VR, Gharpure KJ, Sontakke SD. Impact of medicine-related information on medicine purchase and use by literate consumers. Indian journal of pharmacology 2014; 46.
 - 12 Hardon A, Hodgkin C, Fresle D. How to investigate the use of medicines by consumers. WHO and University of Amsterdam 2004.