



A STUDY TO ASSESS THE IMPACT OF EDUCATIONAL INTERVENTION ON CONSUMER'S KNOWLEDGE AND PRACTICE REGARDING DISPOSAL OF UNUSED AND EXPIRED DRUGS IN PUDUCHERRY.

Pharmacology

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ABSTRACT

Background: World Health Organization reported that unused and expired drugs are unsuitable for drug donations as these medications and their metabolites have been recognized as harmful substances to environment. A safe and cost-effective pharmaceutical waste management program to educate customers on standard medicine disposal practices is imperative now.

Objective: To evaluate the current method of disposal of unused and expired drugs among the consumers and provide education on safe, easy and costless disposal of them.

Material and Methods: Cross sectional education interventional, Questionnaire-based study conducted among 300 patients/consumers attending different outpatient departments in a tertiary care teaching hospital. The responses were expressed in descriptive statistics using SPSS 20.0 software.

Results: The types of unused and expired drugs stocked commonly were NSAIDs, cardiovascular, antiasthma, antidiabetic drugs etc., and 49% of them stocked more than one group of drugs. Majority of them revealed throwing the drugs in dust bins (82.3%) as a method of drug disposal. Others were flushing in toilets(6.7%), piling at home (3.3%), pouring in sinks (3%), throw in bins and sinks(2.7%), return to pharmacy (0.3%) etc., The educational intervention based on National formulary of India & WHO pharmaceutical waste management effectively increased the knowledge and practice regarding the disposal of unused / expired drugs and dangerous hazards of poisoning in children.

Conclusion: Knowledge and practice of drug disposal was inappropriate among the consumers and education intervention considerably improved the techniques to be followed. Regular public education by healthcare workers with the help of government and other stakeholders could reduce the quantity of unused/expired drugs entering the environment.

KEYWORDS

National formulary, Expired drugs, unused drugs, Disposal methods, Pharmacy.

INTRODUCTION

World Health Organization reported that unused and expired drugs are unsuitable for drug donations. These unused and expired medications and their metabolites have been recognized as harmful substances to environment.¹ Cumulation of these drugs at households is usually due to excessive prescribing by doctors, poor patients' adherence to the prescribed drugs.^{2,3} The causes of wastage of drugs also could be due to change of prescription by prescribers, adverse effects of the drug, unclear instruction, resolution of condition/clinical symptoms, over-the-counter medications (OTC) and medicines reaching the expiry date.⁴ This unused and expired drugs disposed inappropriately may further increase the threat to the environment and may have different safety profile. Disposal of them to dustbins ends up in landfills can cause poisoning or might get redistributed or misused and when poured into water sources, results in contamination thereby affecting the human and animal life.⁵ Studies have shown that unintended exposure to Diclofenac affected vultures thereby declined their numbers, feminization of male fish was attributed to chemicals as by products in industries, development of antibiotic resistance and virulence among micro organisms due to improper drug disposal.⁶⁻⁸ Non biodegradable antibiotics, antineoplastics and disinfectants disposed in sewage may kill the bacteria necessary for sewage treatment.¹ Among the pharmaceutical agents detected antibiotics, estrogens, and antidepressants caused hazardous effects and have been linked to abnormalities in aquatic life.⁹

FDA recommended three acceptable ways of drug disposal: take-back program, return to nearby pharmacy and appropriate household disposal methods. The appropriate household disposal methods like throwing into the trash by take them out of their original containers and seal it in a bag or mix them with an undesirable substance, such as used coffee grounds or kitty litter, the medication will be less appealing to children, pets and unrecognizable to people who may intentionally go through the trash.¹⁰ One study conducted in South India reported that 52% of respondents disposed of pharmaceuticals in the trash, 20%

flushed down to the toilet or sink, and only 1% returned them to pharmacy or doctor.⁶ Previous studies stated that most consumers dispose medicines in garbage and sink in India.^{11,12} Since there is no study done on disposal of unused/expired drugs in Puducherry and a gap exists in practice of safe disposal methods needs to be addressed. Hence a safe and cost-effective pharmaceutical waste management program based on The National Formulary of India, 2011 to educate customers on standard medicine disposal practices should be done.¹³ Keeping in view these facts, this study was carried out to evaluate the knowledge and practices of consumers regarding the disposal of unused medicines and provide education on safe, easy and costless disposal of them using The National Formulary of India, 2011 & WHO pharmaceutical waste management.

MATERIALS & METHODS

This was a cross sectional education interventional, Questionnaire-based study conducted among 300 consumers attending different outpatient departments (OPD) in a tertiary care teaching hospital in Puducherry, between May 2017 to June 2017. The sample size of 300 consumers was selected based on convenient sampling method.^{4,14} Consumers of both genders, attending Medicine, Surgery, Obstetrics & Gynaecology and other special clinics Outpatient Department were included for the study. Patients with acute co-morbid conditions, patients in emergency department and those who did not provide informed consent were excluded. The study was approved by the scientific research committee & Institutional Ethics Committee of our Institute (IEC No: IEC/2017/12). The study was commenced after getting the written informed consent from all the consumers and the purpose of the study was explained to them. Each consumer's personal information was confidential, and participation in the study was voluntary. The Pre-validated questionnaire with case study form was adapted from expert opinion and used in previous studies among different population consisting of both open ended and close ended questions was used in our study.^{4,14}

Educational intervention:

The educational intervention consisted of a short education campaign group lecture, demonstration imparted with audio visual method in the mode of interactive session. Images in the form of flip cart display, handouts were liberally used to convey the intended messages. Questions were written in English and vernacular language in simple terms appropriate for the level of education of the consumers as previously validated. Participants were encouraged to complete the questionnaire independently and also were helped appropriately. The same questionnaire was re administered following the educational intervention to assess the differences in disposal knowledge and practices of unused and expired drugs and the data were compared with the baseline. The questionnaire consisted of two sections (Section A & B). Section A had Demographic data and section B questionnaire dealt with consumer's knowledge (Q1-5) and practices (Q 6 - 10) of unused and expired drugs. (Annexure 1)

STATISTICAL ANALYSIS

Data were entered and analysis was performed using SPSS software version 20.0. Descriptive statistics, Chi-square and Fisher's exact test was used for demographic characteristics of participants such as age, gender, education and for the questionnaire. Statistical significance was set at $p < 0.05$

RESULTS

Among the 300 consumers included in the present study from various outpatient departments of our hospital, all of them attended the post intervention questionnaire out of which 55% were males and 45% were females. The Consumers response rate was 100%. The demographic data of the study population is given in Table.1 Majority of drugs procured by the consumers was by both prescription and over the counter (58%), through prescription (35.6%) and over the counter (6.3%).

Table :1. Demographic data of the study population

Demographic data		Number of responses (Percentage)
Age (years)	1-20	6 (2)
	21-40	122 (40.6)
	41-60	110 (36.6)
	61-80	59 (19.6)
	81-100	3 (1)
Gender	Male	166 (55.4)
	Female	134 (44.6)
Educational qualification	Primary	74 (24.6)
	Secondary	77 (25.6)
	Graduate	84 (28)
	None	65 (21.6)
Marital status	Married	277 (92.4)
	Single	33 (11)
Residency	Urban	187 (62.4)
	Rural	113 (37.6)
Mode of procuring drugs	Prescription	107 (35.6)
	Over the counter	19 (6.4)
	Both	174 (58)

Evaluation of knowledge

The types of unused and expired drugs stocked commonly was observed to be NSAIDs, cardiovascular drugs, antiasthma drugs, antidiabetic drugs etc., as shown in the Figure.1. It was observed that 49% of the consumers have stocked more than one group of drugs and among the combination drugs NSAIDs with antihistaminics(27), antidiabetics, cardiovascular(25) and asthma(19) drugs were common.

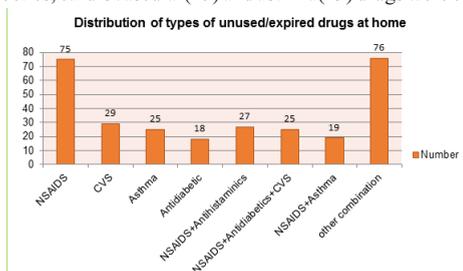
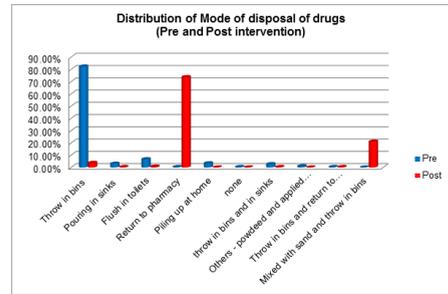


Figure: 1. Distribution of types of unused/expired drugs at home

Majority of the consumers revealed that throwing the drugs in dust bins (82.3%) as a method of drug disposal. Other techniques adopted are flushing in toilets (6.7%); piling at home (3.3%); pouring in sinks (3%); throw in bins and sinks (2.7%); return to pharmacy (0.3%); throw in bins and also return to pharmacy (0.3%) and powdering the drugs for topical application (1%). After brief educational narrative, their knowledge about disposal increased to return to pharmacy (70%), mixed with sand and then thrown in bins (20%) as shown in Figure: 2.

The consumers had lack of knowledge on hazardous impact of improper disposal of medicines into environment (pre intervention) and gained knowledge post interventionally on proper and safe disposal methods of medicines and hazardous impact of improper disposal of them (Table 2). Chi square analysis showed the improvement in their knowledge after educational intervention. ($p < 0.0001$)

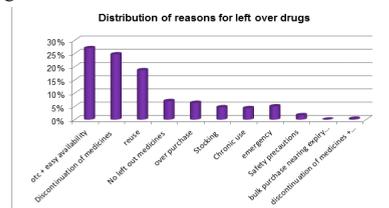


Values are expressed in Percentage

Figure: 2. Distribution of Mode of disposal of drugs (Pre and Post intervention)

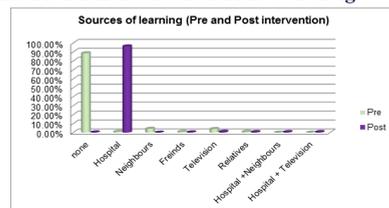
Evaluation of practice

The methods adopted for the left over drugs by the consumers is as shown in the Figure 2. 27% of the consumers opined that easy availability and purchase of medicines over the counter were the reasons for left out drugs. Other reasons for left over medicines are discontinuation of medicines (24.7%), for reuse (18.7%), over purchase (6.3%), emergency(5%), stocking (4.7%), chronic use (4.3%), safety precautions(1.7%), bulk purchase of medicines nearing expiry date (0.3%), discontinuation of medicines + over the counter use (otc) + reuse (0.3%) . Surprisingly 7% of consumers had no left over medicines at home with the usage of all prescribed medications as shown in Figure:3.



Values are expressed in Percentage

Figure: 3. Distribution of reasons for left over drugs



Values are expressed in Percentage

Figure: 4. Distribution of Sources of learning (Pre and Post intervention)

Table: 2. Distribution of Mode of disposal of drugs & Sources of Learning

Sl. No	Responses	Pre intervention	Post intervention	Chi-square, df	P value
1.	Throw in bins	247	11	522.8, 4	< 0.0001*
	Pouring in sinks/Toilets	29	3		
	Return to pharmacy	2	222		

	Piling up at home/ thrown in bins	18	1		
	Others - powdered, mixed with sand and thrown in bins	3	63		
2.	None	266	1	740.6, 4	< 0.0001 *
	Hospital	3	289		
	Neighbours, Friends & relatives	199	3		
	Television	12	3		
	Hospital +Neighbours & Television	0	4		

Data was analysed using Chi-square test. P value $* < 0.0001$ compared with pre and post educational intervention.

Prior to educational intervention, majority of the consumers didn't learn the mode of drug disposal techniques (88.6%). Few consumers learnt the safe disposal of medicines from neighbours (4.3%), television (4%), hospital (1%), friends (1%) and relatives (1%). Figure:4 shows that after educational intervention, majority of the consumers gained knowledge and awareness for proper disposal of unused and expired medicines(96.3%). Table 2.

Out of 300 consumers 41.3% had heard about poisoning cases in children due to accidental intake of left out medicines and 58.7% had no idea on poisoning cases in children due to accidental intake of medicines. All the consumers learned about poisoning and its dangerous hazards in children due to accidental intake of leftover/unused medicines after educational intervention in our study. (Table 2 & 3) Chi square analysis and Fisher exact test showed the improvement in their sources of learning and also hazards effects of poisoning in children respectively after educational intervention. ($p < 0.0001$)

Table: 3. Poisoning in children due to accidental intake of drugs

Sl. No	Responses	Pre intervention	Post intervention	Total	Fisher's exact test, df	P value
1.	Yes	124	300	424	740.6, 4	< 0.0001*
2.	No	176	0	176		

Data was analysed using Fisher's exact test. P value $* < 0.0001$ compared with pre and post educational intervention.

DISCUSSION

The rapid development of the pharmaceutical industry and its products with their increased consumption and availability in the environment might have different biological effects. The improper disposal of these medical wastes often causes contamination of air, water, agricultural products thereby causing harmful to mankind making it health and environmental hazard. So in order to avoid adverse impact of these pharmaceutical compounds on the environment the consumers' knowledge and awareness regarding their improper disposal of expired/unused drugs needs to be addressed. Our study is the first study conducted from Puducherry and this was an observational cross sectional questionnaire based, involving 300 consumers attending various outpatient departments of a tertiary care hospital. This present study evaluated the knowledge and practice of disposal of unused/expired drugs among the drug consumers followed by education about the drug disposal. The brief educational intervention effectively increased the knowledge and practice of the consumers in view of disposal of unused/expired drugs. Majority of the consumers revealed that they procure the drugs from both through prescription as well as over the counter method (OTC). This could be due to easy availability of drugs through OTC in our country and this can lead adverse effects and therapeutic failure which should be discouraged. Similar recommendations were put forth by Mohammad et al in Kabul showed that 80% of the drugs were procured from pharmacy than from OTC.¹⁴ Our study showed that the unused drugs stocked in home were NSAIDs, cardiovascular drugs, antiasthma, antidiabetic drugs etc., and Stocking of these types of drugs could be responsible for their low self life when proper temperature is not maintained. Many consumers had more than one group of drugs stored in the home similar to Mohammed et al. The common disposal technique adopted by the consumers were throwing in bins (80%) and flush in toilet similar to other studies.^{15,16} Study done by Sonowal S et al also showed that majority of the study participants were not aware of safe disposal

techniques.⁴ One study analyzed by Uddin, et al. showed that unused medications were thrown in the trash (57.1%) and 55% of the patients have no knowledge about the harmful effects of unused medication in India.¹⁷

Consumer's knowledge considerably improved after educational advice and replied that they return the unused medicines to pharmacy or mixed with sand, coffee grounds and throw in bins. Common reasons for the left over medicines were OTC availability, discontinuation, reuse and over purchase etc., similar to Sonowal S et al.⁴ In addition almost all the consumers were not aware about the learning of disposal techniques and with education they were aware of take – back programme, return to nearby pharmacy and appropriate household methods like mix them with coffee grounds or kitty litter and disposing the drugs in sealed bags, empty container to prevent them from leaking. Environmental practices like incineration and disposing in impermeable containers with refuse solids like coffee grounds must be implemented for the inappropriately disposed pharmaceuticals like analgesics, antibiotics and opioids which have addictive potential. Implementation of drug- back programme should be strengthened in developing countries like India. Following the drug-take-back system is not popular even in Malaysia and New Zealand as indicated by 8% and 13 – 24% respectively of the respondents return the drugs back to pharmacy, and the percentage depends upon the type of formulation.^{18,19} Developed countries, like USA, has well maintained drug 'take-back' systems which plays a major role in disposing drugs correctly.²⁰ This should be implemented and practiced in all regions of our country. Consumers' awareness regarding poisoning due to improper disposal of drugs also improved after educational intervention. Most consumers also felt the need of increased awareness and education from the pharmacist and doctors regarding hazardous impact such as illegal/unintended use of medicines, adverse reactions and environmental pollution. Some of the suggestions revealed by the consumers were to organize programme to collect the expired and unused drugs from households periodically as similar to previous study.⁴

In addition some of the consumers raised the question on safe disposal of medicines – return to the pharmacy is “What if the pharmacist redistributes the left over drugs or expired drugs”. We have assured them that the pharmacist will dispose the unused and expired drugs properly and recirculation will not happen. One precaution which the consumers can follow is to buy the medicines only if they are sealed, and the straps of medicines are sealed properly. They were also advised that before getting medicines their expiry date should be checked. Despite of the benefits, the adverse reactions of medicines were very common if a consumer did not check the date of expiry or buy the short or expired date products.²¹

There is a need to design and strengthen the innovative policy, namely the drug take-back program, and to motivate the health regulators to strengthen and implement the existing drug disposal policies more effectively. Teaching undergraduate and postgraduate medical, nursing and pharmacy students and conducting continuous medical education training for health care professionals on the use, collection, and disposal of expired and unwanted drugs were recommended. Such endeavours may safeguard the ecosystem and the mankind. Our study was conducted in a small sample of consumers who visited our hospital and wide range for future studies in varied samples in the hospital and community is warranted.

CONCLUSION

Our study provided that the knowledge and practice of drug disposal was inappropriate among the consumers and educational intervention considerably improved the techniques to be followed. Regular public education by healthcare workers with the help of government and other stakeholders could reduce the quantity of unused/expired drugs entering the environment. National guidelines on the appropriate disposal of unused medications need to be disseminated to the public periodically.

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(Annexure -1 : Questionnaire)**A STUDY TO ASSESS THE IMPACT OF EDUCATIONAL INTERVENTION ON****Consumer's Knowledge And Practice Regarding Disposal Of Unused And Expired Drugs In Puducherry.****Section A: DEMOGRAPHIC DATA**

1. Age
2. Gender: Male / Female
3. Education: Primary school/ high school/ graduate
4. Marital status: Single / Married
5. Residency:-urban / rural
6. Drug class used:
7. Modes of procuring the drugs : Prescription / over the counter / both

Section B: CONSUMER'S KNOWLEDGE AND PRACTICE REGARDING UNUSED AND EXPIRED DRUGS

1. What are the types of unused/expired medications at home: Analgesics, CVS drugs, asthma, anti diabetics etc.,
2. What are the disposal techniques adopted by you to dispose solid, liquid and semi-solid medications?
3. Have you heard about safe disposal of medicines?: Yes/No
4. Do you know what are proper disposal methods for medicines? Return to pharmacy / land fill / flushing in sewage / any other
5. Do you aware of hazardous impact of improper disposal of medicines into the environment?: Yes/No
6. What you do with left out medicines in home?
 - a) Throw in bins b) Return to pharmacy
 - c) Flush in toilets d) Pilling up at home
7. What are the reasons for left out medicines in home?
8. Where did you learn the disposing procedures for medicines?
9. Did you ever heard about poisoning cases in children due to accidental intake of left out medicines?: Yes/No
10. What are your suggestions about management of safe disposal of medicines?

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