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## EVALUATION OF EXPIRED DRUGS AND MANAGEMENT: ASSESSING THE DISPOSAL PRACTICES AMONG PUBLIC

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**Abstract:** India faces continuous environmental and health oriented concerns from expired, unwanted or unused drugs. It remains as a persistent issue with no proper studies carried to evaluate expired drugs and to the managerial repercussions, therefore, are not hitherto known fully. There are numerous loopholes within the laws governing the expiry of drug. The municipal corporations handling the waste have not been sensitized to it. There is a grave necessitation for the expired/ unused medicines to be managed in a much more effective manner, as the drugs could pose accumulation of potentially toxic substances in the environment. In India, there is currently limited literature on the methods and protocols that are applied by community pharmacists in the disposal of expired drugs. This study assessed disposal practices of expired and unused medications by pharmacists which was determined via carrying a cross-sectional survey, conducted via face-to-face interviews using pre-validated and structured questionnaire. The returned questionnaires were subjected to statistical analysis using Statistical Package for Social Science (SPSS) version 23. From the observed findings it was concluded from the questionnaires were returned showcasing response rate of 100% with majority of the respondents were male compared to female in participation. Over half of the respondents' educational qualification reported as graduates. Interestingly, 84.4% of respondents admitted that they purchased medicines on the prescription of which 47.2% were university graduates, while 14.6% purchased medicine over the counter.

**Index Terms** - Drug, Pharmaceutical products, Pharmaceutical wastes, Medicine disposal

### I. INTRODUCTION

Over the years, there is a growing need for pharmaceutical medications for treatment of several ailments. These pharmaceutical drugs could pose as a preventive and curative agent. Pharmaceutical products are essential in maintaining human health, but many pharmaceuticals contain hazardous chemicals that can contaminate the environment if they are not properly managed or discarded [1]. Due to improper disposal of Pharmaceutical wastes, they can lead to contamination and a wide range of toxicities in man and animals. People are susceptible to exposure of these accumulated pharmaceutical traces/ residues from the environment by drinking contaminated water [2]. This is as a result of general practice observed in households where the drugs which are procured quite frequently turn out unused, or expired which eventually resulted in discarding them indefinitely through general municipal waste bins, sinks, or flush them down their toilets. This practice of disposing unused or expired medications through these unauthorized channels tends to predispose environment and its inhabitants to experience serious health related complications [3]. Through wrong disposal of expired pharmaceuticals result in medication poisoning among adults and children [4]. Dumping sleep aids and Narcotic pain relievers in garbage might have a serious effect of getting abused. With growing concern about safety of urban water supply being the major source for disposal, supported from recent reports indicating traces of antibiotics, antidepressants, and hormone replacement medications in waterways nationwide [4]. Also reports suggesting trace amounts of pharmaceuticals and metabolites identified with some drinking water supplies [5]. The presence of expired pharmaceuticals in the sewage can lead to increased antibiotic resistance to the numerous strains of microorganisms found in sewage which can mutate to deadly and resistant pathogens from harmless microbes [6]. Non-biodegradable anti-infective drugs, cytotoxics, and disinfectants cause the destruction of bacteria necessary for sewage treatment [7]. Recently, antibiotics resistance in humans has been traced to the injection of trace quantities of antibiotics in the surrounding waters due to the poor disposal of expired and unused pharmaceuticals [8–10]. Environmental contamination with non-steroidal anti-inflammatory drugs (NSAID) especially diclofenac which has been shown to cause renal failure in vultures following the ingestion of carrion from cattle treated with the drug [11]. Estrogenic compounds used in oral contraceptives like 17- $\alpha$ -ethinylestradiol feminize fishes in minute concentrations leading to infertility [12]. Proper disposal handling and management of drugs prevent avoidable toxicities and promote the safe and friendly environment. The most commonly returned or expired medications are those used in chronic conditions like antihypertensives and anti-diabetes medications usually associated with non-adherence [13]. Unused pharmaceuticals could arise from alterations to the prescribed treatment. Such practices ultimately lead to the expiration of medications which are eventually stored or disposed of by households into the sewerage system, garbage, and refuse dumps or returned and accumulated in community pharmacies [14].

## MATERIALS AND METHODS

### Study design

This was a descriptive, cross-sectional survey, conducted through face-to-face interviews using pre-validated structured questionnaire. The study was conducted in Delhi between November 2019 to February 2020.

### Study population

The study population was of either gender, which included students, public and private sector employees, storekeepers and population above the age of 18 years, who were local residents of Delhi, regardless of ethnicity or employment status.

### Sampling/sample size

The study employed non-probability sampling technique (convenience method) to reach its representative population easily within the districts of India.

### Study instrument

Literature was reviewed to develop the questionnaire. The questionnaire framework comprised of two major sections. Section one comprised majorly on respondent's demographics (gender, age, the level of education, marital status) and questions that emphasises on procurement approaches for medicines, classes of medicine used and checking the expiry date of medicine before procurement. In case of section two, it comprised of questionnaire that are inclusive of respondents' practices and attitudes concerning with unused and expired medication disposal. The respondents were required to choose from the given descriptions in the questionnaire that best illustrated their usual practices.

The questionnaire was adapted in accordance to local context and translated to local language for their understanding and was then translated into English for avoidance of any misinterpretation. Following the pilot testing, minor changes were made based on respondents' recommendations. For the internal consistency (reliability) assessment, Cronbach's alpha test was performed.

### Data collection method

The data collectors were trained and prevailed upon to explain the purpose of the study to their potential respondents prior to administering the survey questionnaire. Participation in survey was voluntary Face-to-face interview method was used by filling up questionnaires.

### Data analysis

All returned questionnaires were double-checked for accuracy and then the collected data were feed into an Excel spreadsheet Dataset. Then the cleaned data was transferred to Statistical Package for Social Science (SPSS) version 20 for analysis. Descriptive statistics (descriptive, crosstab and chi-square) were used. Ethical considerations, written informed consent was obtained from all the respondents before the start of the survey. Participation in this research was voluntary. Participant identity was kept confidential.

## RESULTS

### Respondent's Demographics

All the approached 50 individuals agreed to participate as respondents for the study and none declined. From the observed participant, the overall response rate exhibited was 100%. Of the 50 respondents, 36 (72%) were male and 14 (28%) were female. Maximum (16; 32%) respondents were within the age group of 31 years and above. 9 (18%) respondents reported with an educational qualification of up to secondary education, 27 (54%) were university graduates, 9 (18%) and 5(10%) were illiterate [Table 1]. The Cronbach's alpha defined from the items was 0.70.

**Table 1. Demographic variables**

Variable	Frequency n	Percent (%)
Age of respondents		
20 year and below	2	4
21–30 years	15	30
31–40 years	9	18
41–50 years	12	24
51–60 years	9	18
≥ 61 years	3	6
Gender of respondents		
Male	36.0	72
Female	14.0	31.2

### Knowledge association with procurement of drugs/ medication

With regards to knowledge on “ways of drug procurement”, 41 (82%) respondents admitted that they purchased drugs from prescribed medical practitioner and the remaining 9 (18%) purchased drugs OTC. Also from the observed data governing with general procurement of drugs based on their application it was observed that almost 44 % (n= 22) of them purchase antibiotics, followed by anti-hypertensive (n = 21; 42%), NSAIDS (n=4; 8%), and anti-diabetic (n = 3, 6%). From the observed data concerning with respondent’s practice on checking drug’s expiry data prior to their buying showed that the majority of respondents (n = 47; 94%) checked the expiry date of medicines, prior to purchase. In addition, it was determined that 21 university graduates procured medicines on prescription. Similarly, 100% Of the respondents who are graduates checked medicine expiry date prior to purchase [Fig. 1].

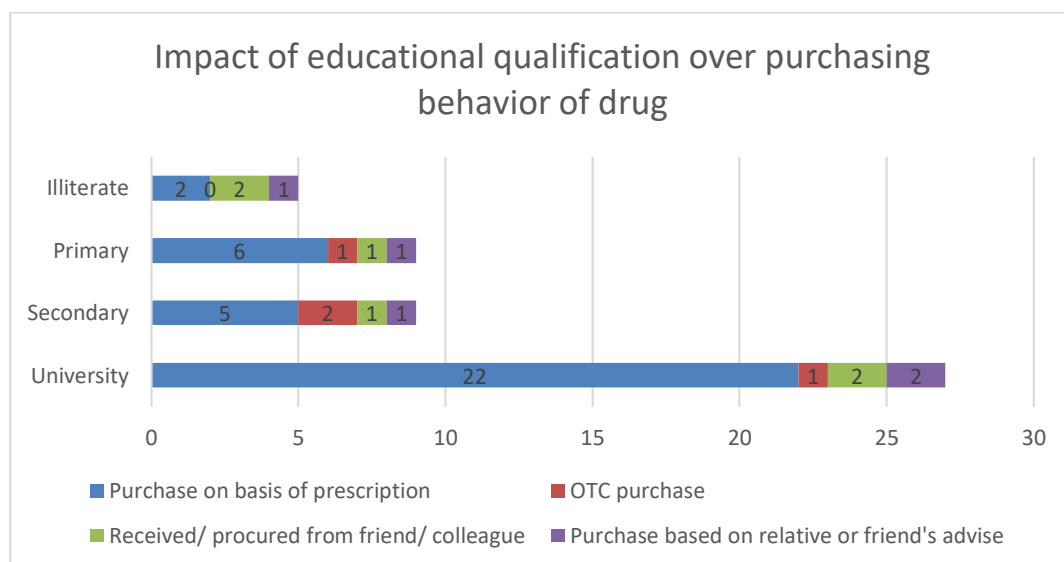


Fig 1. Effect of education on ways of procuring medicine

Table 2 shows that among all respondent the majority 25 (92%) of university graduates checked the expiry date of any medicine prior to its procurement.

**Table 2. Representation of respondents activity/ checking on expiry date while procuring drugs**

	RESPONDENT'S CHECK ON EXPIRY DATE OF PROCURING MEDICINES		
	YES	No	DON'T KNOW
ILLITERATE	2	2	1
PRIMARY	7	2	0
SECONDARY	8	0	1
UNIVERSITY	25	1	1
TOTAL	44	4	2

The results of the disposal pattern of various dosage forms in Table 3 showed inconsistency in the disposal practices across the various drugs dosage forms. This was in line with another study on knowledge, attitude, and practice (KAP) towards disposal of medicines among public, which revealed that participants were very confused about the proper way of drug disposal, as many countries do not have standard drug disposal protocols

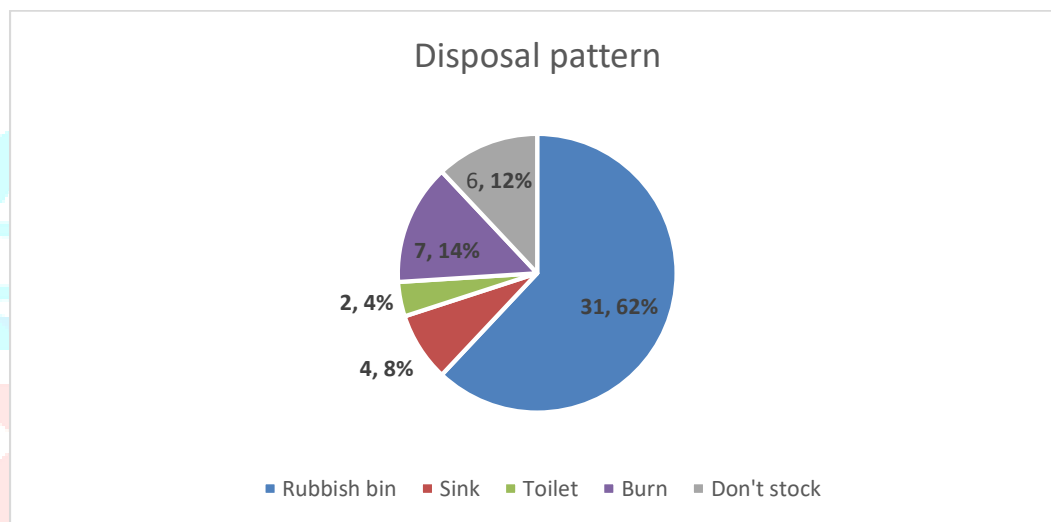
**Fig 2. Disposal pattern observed among the respondents**

Table 3 shows responses to the items intended to measure public practices and attitudes towards unused and expired medication disposal and its environmental impact. When asked, did any quantity of purchase medicine remain unused at their home, majority of the respondents (n = 48; 96 %) replied positively. A slim majority (52%) of the interviewed respondents kept the unused medicines at home until expired. It was reported that 64% of the respondents said that government was responsible to create awareness for proper disposal of unused and expired medicines, whilst a large majority of the sample (n = 49; 98%) reported that improper disposal of unused and expired medicines can affect the environment and health. More than 95% of the respondents had unused medicine stored at home, and most of these were antibiotics.

**Table 3. Public practices and attitudes towards unused and expired medication disposal and its environmental impact**

MAJOR ATTRIBUTES		N	%
DID ANY QUANTITY OF PURCHASE MEDICINE REMAIN UNUSED AT YOUR HOME?	YES	26	52
	NO	24	48
WHO IS RESPONSIBLE TO CREATE AWARENESS FOR PROPER DISPOSAL OF UNUSED AND EXPIRED MEDICINES?	GOVERNMENT	32	64
	PHARMACEUTICAL INDUSTRIES	8	16
	PUBLIC	8	16
	PHARMACIST	2	4
DUMPING MEDICINE IN SOIL OR MEDICINE DISTRIBUTING TO NGO DISPENSARY BEFORE EXPIRY FOR THE USE OF POOR CHILDREN.	YES	28	56
	NO	22	44
IMPROPER DISPOSAL OF UNUSED AND EXPIRED MEDICINES CAN AFFECT THE ENVIRONMENT AND HEALTH.	YES	42	26
	DON'T KNOW	8	4

## CONCLUSION

This study provides a detailed insights governing with the need for strengthening on-going debate over safer disposal practices and approaches on unused and expired pharmaceuticals among the general public. This survey from Delhi in India suggests that, there is a grave need for government as well as pharmaceutical companies to extend their efforts in delivering a robust safe and cost effective pharmaceutical waste management program and to make the people aware of hazardous effects of expired and unused medications through comprehensive media campaign. Moreover, like other healthcare practitioners, and community pharmacists are in an excellent position to educate patients on medicine disposal, therefore leveraging their knowledge through training programs and continuous education is of importance.

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