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ASSESSMENT OF METHODS USED BY REGISTERED PHARMACISTS FOR DISPOSING OF THE PHARMACEUTICAL WASTE AND EXPIRED MEDICINES AT COMMUNITY PHARMACIES IN URBAN AREA

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ABSTRACT: Introduction: The use of improper disposal methods for expired medicine is an emerging issue that is affecting the ecosystem, and misuse of expired medicines is potentially hazardous for public safety. Our study was aimed to assess the methods used by the registered pharmacist for disposing of the expired medicines in community pharmacies. Materials and Methods: A questionnaire-based cross-sectional descriptive study was conducted at a community pharmacy from June to September 2020. Pharmacists were asked to answer a questionnaire by interview method, wherein their socio-demographic details were also captured during this study. Data was collected and analyzed by using Microsoft Excel. Results: 133 pharmacists participated in our study with 76% of response rate. In spite of adequate experience in pharmacy majority of pharmacists lacks the knowledge and awareness about the disposal methods. Our study found that 75% of pharmacists were not even aware of guidelines for the disposal of expired medicines. Due to unawareness of guidelines, 92% of the pharmacist thinks that their pharmaceutical waste disposal method is satisfactory and 80 % pharmacist admitted that generic medicines are not that much carefully handled and disposed of as much as other branded medicine. Conclusion: Our study found that there is no adequate knowledge of pharmaceutical waste disposal methods among the pharmacist, which is eventually becoming a major threat to ecosystem and public safety. The unawareness among these pharmacists is improper education about expired medicine disposal in their pharmacy education.

INTRODUCTION: Expiry date specifies the shelf life of the medicines or pharmaceutical product; it is a particular time period in which the medicines are physically and chemically stable as well as safe and effective for human consumption. Expired, unused, contaminated medicines, vaccines, and sera products are included under pharmaceutical waste.



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Due to incorrect choice of medicine or noncompliance by the patient with the therapy leads to increase in the number of unused pharmaceutical products. This type of pharmaceutical waste is generated in bulk quantity, so proper disposal methods are essential in the community pharmacy.

Pharmaceutical waste has been one of the main reasons for increasing pollution in the environment by water, air, and soil medium. Improper disposal of unused and expired medicines leads to environmental pollution and health hazards ^{1, 2}. Adverse effects of this pharmaceutical waste in

humans, animals, and marine species are well documented. Improper drug disposal causes various harmful consequences such as accidental consumption of expired medicines by children or intentional administration of the expired medicine for suicidal use by anyone ³. On consumption of outdated medicines such as nitroglycerin, insulin, and liquid antibiotics may develop serious adverse drug reactions ⁴.

Discontinuation of antibiotics leads to increase in unused medicines and also develops antibiotic resistance in the patient. A study from Chandigarh by Suruchi et al, showed that 80.3% of patients never received advice on medication disposal from a health care provider ⁵. This is because there is no proper education about the procedure used for disposing of expired medicines ^{6, 7}. As per the government gadget of pharmacy council of India dated on 5th Nov 2019 there should be a provision for providing adequate hours of training, including a demonstration on bio-medical waste management in course of pharmacy ⁸. To minimize the adverse effects of pharmaceutical compounds on the environment as well as the humans and animals, the issues related to the improper disposal of unused and expired medicines needs to be addressed. According to the Central Pollution Control Board of India, registered healthcare facilities generate 4,057 tons of waste per day 5.

The World Health Organization (WHO) approved some environment-friendly methods of drug disposal like Encapsulation, Landfilling, Fast Incineration. Inertization, flowing watercourse, and Returning to distributor according to the physical form of the expired product ⁹. A study conducted in Chennai by Umamangeshwari et al. found that approximately 75-80% of the population does not even aware of the approved methods for disposal of expired drug 4. This unawareness among the general public is basically occurred due to improper counseling by the pharmacists, which is the result of not educating the pharmacy graduates about the proper disposal methods of pharmaceutical waste and expired medicines in their pharmacy education. This problem can be overcome by including the proper disposal methods of pharmaceutical waste and expired medicines in pharmacy education. A study conducted in Karnataka by Padmnabha et al.

showed 74.22% of people were aware of the consequences of using improper disposal methods. But still, they are not using proper methods for disposing of expired medicines. This study also stated that Sinks, toilets, and Dustbins are the most commonly used methods for disposal pharmaceutical waste ¹⁰. Eco-pharmacovigilance is an important area in these circumstances. It is defined as "The study associated with detecting and adverse effects waste the of pharmaceuticals in the environment.

These Eco-pharmacovigilance studies detected that waste of pharmaceutical products by humans are increasingly found on water surfaces in the last few years. Adverse effects of these pharmaceuticals waste are well documented about numerous species. Some years ago, it was reported that the number of vultures is substantially decline due to unintended exposure to Diclofenac ^{1, 11}. AS these waste pharmaceutical substances are potentially hazardous, they should be managed and disposed of carefully to avoid the accumulation of them in the environment ⁸. The recommended pharmaceutical waste disposal methods include returning to distributor, encapsulation, incineration, landfilling, and disposing in the drainage line. These methods are categorized according to the physical form of the waste product. Therefore, the appropriate method of disposal should be used according to the physical form of the waste product. As the study is a serious global issue, our study aims to assess the knowledge and practice of pharmacists towards the methods used for disposal of pharmaceutical waste and expired medicines among the community pharmacy.

MATERIALS AND METHODS: The study was a cross-sectional questionnaire-based descriptive study conducted for a period of 4 months from June to September 2020 among the registered pharmacist. A pilot study was conducted during which ¹⁰ registered pharmacists were given the self-administered questionnaire, and they responded to all the questions without any confusion. Complete information regarding the study was provided to 175 pharmacists, out of whom 133 willingly agreed to participate in the study. The questionnaire was divided into two sections. The first section comprised demographic details, and the second section included questions based on the approach

towards the knowledge of methods used for disposal of pharmaceutical waste and expired medicine. Data were collected and analyzed by using Microsoft Excel.

RESULT AND DISCUSSION: The present study was an observational, cross-sectional, questionnaire-based study conducted among the registered community pharmacists in pharmacy. knowledge, awareness, attitude, and practice of registered pharmacists regarding the disposal of expired medicines were evaluated by a prevalidated investigator through a predesigned questionnaire form. 175 pharmacists were provided with a pre-designed questionnaire form, out of which 76% of them filled the questionnaire form. Among all those participants (69.9%) were male and (30.1%) were female from age group 18-45 years. Majority of the pharmacists had qualification of diploma in pharmacy (60.9%), followed by a bachelor of pharmacy (33.9%) experienced in the practice of pharmacy Table 1.

TABLE 1: SOCIO-DEMOGRAPHIC DETAILS

S. no	Parameters	Criteria	Percentage
1	Gender	Male	69.9%
		Female	30.1%
2	Age	18-25 years	60.1%
		26-35 years	33.9%
		36-45 years	5.2%
		46-55 years	0.80%
3	Qualification:	Diploma in	60.9%
		pharmacy	
		Bachelor of	33.9%
		pharmacy	
		Master of	5.2%
		pharmacy	
4	Number of	1 Male	51.8%
	pharmacist	2 Male	28.5%
	working in	1 Female	9.7%
	the pharmacy	1 Male 1 Female	4.5%
		2 Female	3.8%
		2 Male 2 Female	1.5%

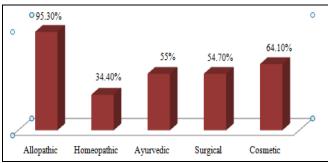


FIG. 1: TYPE OF PRODUCTS ARRIVED IN THE PHARMACY ACCORDING TO PHARMACIST

Among all the pharmacist's majority of them purchased allopathic medicines (95.3%) followed by cosmetics (64.1%), ayurvedic (54.7%), surgical (54.7%) and homeopathic medication (22%) every week **Fig. 1** which shows that the allopathic medicines were majorly sold in pharmacy practices. According to the responders, 5-15% of products get expired per month in the pharmacy. The pharmacists reported that they implemented systematic management at pharmacy that is having a separate stocking section for expired medicines. Even if all of them had a separate section for storing expired medicine, but only a few of them follow the guidelines for disposal of expired medicines.

This study found that even if all the pharmacists were properly educated from the pharmacy colleges, 75% of pharmacists were not even aware of the existence of guidelines for disposal methods of expired medicines **Fig. 2.** which shows poor knowledge of pharmacy practices among them. For this, they gave a reason that they were never taught this in their pharmacy education. A total of 83.65% of pharmacists check expired products after every 3 months, and remaining pharmacists' checks expired products after 4 months **Fig. 3.**

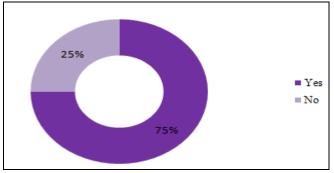


FIG. 2: AWARENESS OF EXISTENCE GUIDELINES FOR DISPOSING METHODS OF EXPIRED MEDICINES

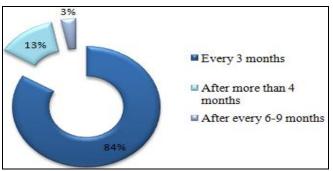


FIG. 3: CHECKING OF EXPIRED MEDICINES IN THE PHARMACY

Most of the expired medicines were returned to the distributor, irrespective of the dosage form. Pharmacist admitted that majority of solid expired medicine were returned to the distributor (75%) similar to this for liquid medicine 73.4 % of pharmacists return it to the distributor but remaining of them uses other methods of disposal like throwing in the dustbin, burning, dumping or disposing of in drainage system. Our study found that most of the leftover and expired medicines were returned to the distributor, irrespective of their dosage form, which promotes a good pharmacy practice. Using other methods of disposal will affect the community's safety and the environment. A survey conducted in Haryana found that 60% of total expired pharmaceuticals are returned to the distributor by the pharmacists. Similar results are found in our study that majorly 65-75% of the pharmacists return the expired pharmaceuticals back to the distributor ¹. In spite of adequate practice in pharmacy majority of pharmacists lacks the knowledge and awareness about expired drug disposal.

On observing the disposal method of expired medicine for a particular category of drug, the majority of the pharmacist returns it to the distributor (81.3%) irrespective of the drug category. The majorly expired category of the drug was found to be antibiotics. Regarding the medicines that get accidentally broken or spoiled in pharmacy, one-fourth of pharmacists admitted that they throw it into the trash without any concern. Eventually, it affects the environment at a great extent by polluting water, soil, and air. Current WHO and FDA guidelines stated pharmaceutical waste should be disposed of by returning to the distributor, encapsulation, incineration, and landfilling. The appropriate type of disposal methods should be used for each type of pharmaceutical. The present study found that 75 % of pharmacists were not even aware of safe disposal guidelines by WHO. This unawareness among the pharmacist may cause violations of guidelines. Therefore, each pharmacist should be updated about the rule and regulations about pharmaceuticals.

Although 62.5% of pharmacists stated that they were sending the expired medicine to the distributor, they were not clear about what happens

to the expired medicines after returning, and 12.50% of them thought that the distributor might reuse the medication, this poor knowledge of pharmacists will result in imperfect pharmacy practice in pharmacy **Fig. 4.** Due to unawareness of guidelines, 92% of the pharmacist thinks that their method of disposal for expired medicine is satisfactory. The reason behind the unawareness among these pharmacists is improper education about expired medicine disposal in their pharmacy education. To resolve this issue, the Government gadget of Pharmacy Council of India published on 5th Nov 2019 stated that there is a nto provideding adequate training for pharmaceutical waste management to all the pharmacy graduates ⁸.

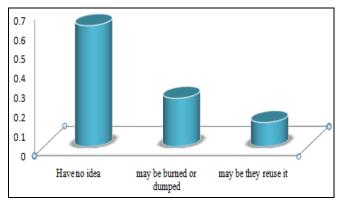


FIG. 4: KNOWLEDGE ABOUT EXPIRED MEDICINES RETURNED TO DISTRIBUTOR

Our study found that 56 % of pharmacists purchase generic medicines regularly. Only 20 % of pharmacists admitted that for generic medicine, they use a similar disposal method as that of branded medicine. But remaining pharmacist admitted that generic medicines are not that carefully handled and disposed of as other branded medicine. But generic medicines should be disposed of with similar concerns as much as the branded medicines. This 56% of pharmacists stated that if the distributors and wholesalers deny taking expired generic medicines back, 13% of them throw it into the trash, 20% dispose of it by burning /dumping, and 34.5% dispose of it with it other domestic waste. Even though India is the biggest country for consuming generic medicines, these medicines are not handled, stored, and disposed of carefully because of their cheaper cost. However, they are equally active pharmaceuticals ingredients that should be disposed of according to guidelines. Improper handling of this drug will affect the environment and the community health to the same

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extent as branded medicines; therefore, these medicines are also being manufactured, dispensed, and disposed of consciously.

After providing them the recommended WHO guideline of safe disposal methods used for expired medicine, pharmacists were asked to answer which disposal method is most appropriate. Majority of the pharmacist chooses the option of returning to distributor followed by landfilling and incineration Fig. 5. If pharmacists are willing to send the expired medicine back to the manufacture, they should be concerned about the further disposal implemented manufacture. method by the Awareness among the pharmacist about proper drug disposal methods will promote a good pharmacy practice and eventually leads to the betterment of public and environmental safety ¹².

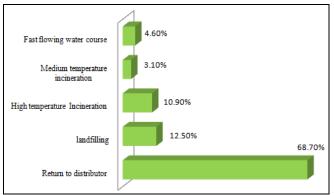


FIG. 5: METHODS USED FOR DISPOSAL OF EXPIRED MEDICINE BY PHARMACIST

Limitations: The study's main limitation is the small sample size; this study could take up a larger extend from the institutional level in the future. The response rate was also low because of unawareness about the importance of the topic. And accurate data collection is difficult in this type of study due to recall bias responses and social desirability responses. However, the study gives an insight into a problem that has not been given the importance it deserves, as proper disposal of expired medications can help to reduce harmful effects on the environment.

CONCLUSION: Improper disposal methods used of expired medicines is a vital emerging threat to the ecosystem. It can be controlled over time, but it will need proper awareness and desirable recognition of this problem in the community. Community pharmacists can play an important role

in this scenario because nowadays a pharmacist is not just about dispensing the medicines. They act as a drug therapy manager in the community. So they must spread awareness about the importance of this topic. Therefore, pharmacists should keep themselves updated about new guidelines stated by the Food and Drug Administration (FDA) and World Health Organization (WHO). Awareness among the pharmacist and eventually in the general public can be achieved by including pharmaceutical waste disposal methods in pharmacy education. The guidelines regarding pharmaceutical waste disposal should be implemented and supervised more strictly by controlling authorities. The use of appropriate disposal methods like returning to the distributor, incineration, landfilling will decrease the load of pharmaceutical waste on the ecosystem.

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Data Availability: We declare that the research data will be available to the public and provided after query.

CONFLICTS OF INTEREST: Nill

Funding Information: Nill

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