

A CROSS-SECTIONAL OBSERVATIONAL STUDY ON KNOWLEDGE, ATTITUDE, AND PRACTICE REGARDING HANDLING OF EXPIRED MEDICINES AMONG DOCTORS IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Objectives: The present study was conducted to assess knowledge, attitude, and practice related to use and disposal of expired medicines among doctors working in a tertiary care hospital.

Methods: The study was conducted in the Government Medical College, Nandyal, Andhra Pradesh. After obtaining verbal consent, a pre-validated questionnaire was shared to the participants through Google Forms. It had two parts; part one with participant demographic details and part two comprised structured multiple choice questions, regarding their knowledge, attitude, and practice toward handling of expired medicines. Forms with completed responses were included and analyzed using Microsoft Excel 2007.

Results: A total of 84 responses were analyzed, and it was observed that 88% of the participants knew the definition of expiry date and its calculation. All the participants checked for the expiry date always. About 66% opined that expired drugs should never be used. Only 37% were aware of the color-coded bin used to dispose expired medication. About 33% responded that pharmaceutical waste can be reduced by rational drug use.

Conclusion: The study shows that there is lacuna regarding knowledge, attitude, and practice related to use of expired drugs and their disposal. It is recommended to create awareness regarding the same through workshops and awareness programs.

Keywords: Shelf life, Expiry date, Pharmaceutical waste, Drug disposal.

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INTRODUCTION

Shelf life of a drug is defined as the time interval where it remains physically, chemically, and/or biologically stable and is effective for human consumption when stored under specified conditions beyond which it is labeled as expired. In general, drugs should be used within their shelf life as per the regulations but even after the expiry date, most of the drugs remain in stable condition for at least 5 years [1]. In case of emergencies, regulatory authorities allow the reuse of expired pharmaceutical products for human use after thorough analysis and revalidation. Excluding certain medicines such as insulin, epinephrine, and tetracycline, most medicines stored under reasonable conditions retain nearly 80% of their original potency for at least 1–2 years after the expiration date. Placing medication in a cool dry place will help it remain potent for many years [2]. Some of the various disposal methods recommended by WHO are landfill, encapsulation, sewer, incineration at high temperatures, burning in open containers, and return to manufacturer for safe disposal [3]. However, improper disposal of expired pharmaceutical products can be hazardous as it contaminates the environment and also might result in accidental poisoning. The FDA suggests that the safest and most effective way to dispose of unwanted medications is the medicine take-back system [4]. They are community-based efforts that encourage the general population to surrender unused pharmaceuticals to a specified collection site, where they may then be safely disposed. The present study aims to assess the knowledge and practice regarding the use and proper disposal of expired drugs among doctors as it is important that they are aware of and have good practices toward use and disposal of expired medications [5,6].

METHODS

This was a cross-sectional, questionnaire-based observational study conducted in the Government Medical College, Nandyal, Andhra Pradesh. Institutional Ethics Committee approval was taken. All the doctors working in the tertiary care hospital and willing to participate in the current study were included in the study. The participants included junior residents, senior residents, assistant professors, associate professors, and professors. The importance of the current study was explained to them and consent was obtained. Pre-validated questionnaire was shared to the participants through Google Forms. It had two parts; part one with demographic details of the study participants and part two comprised 15 questions structured in multiple choices, regarding their knowledge, attitude, and practice toward handling of expired medicines. Forms with completely filled responses were collected and analyzed using Microsoft Excel 2007.

RESULTS

Out of 106 doctors of clinical, pre, and para clinical departments working in the tertiary teaching hospital, 94 consented to participate in the current study. Out of the 94 responses, a total of 84 completely filled responses were selected and analyzed. Among them, 28(33%) were male and 56 (67%) were female.

About 67% (56) were in the age group of 20–40, 24% were in the age group of 41–60, and 9% were aged above 60 years. Out of the 84 faculty, six were junior residents, 13 were senior residents, 39 assistant professors, 16 associate professors and 10 were professors as shown in Fig. 1.

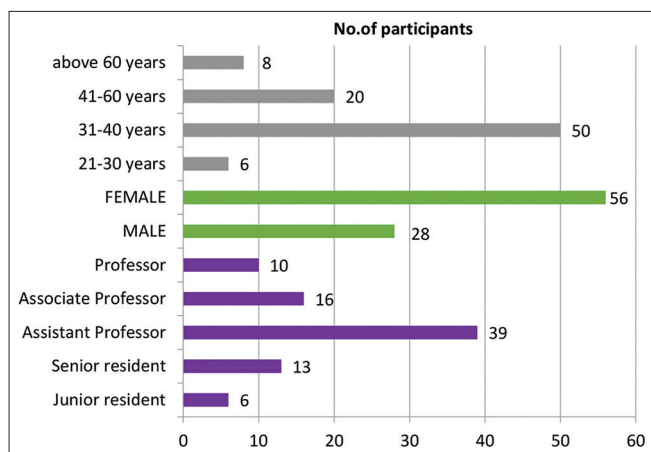


Fig. 1: Demographic details of the participants (n=84)

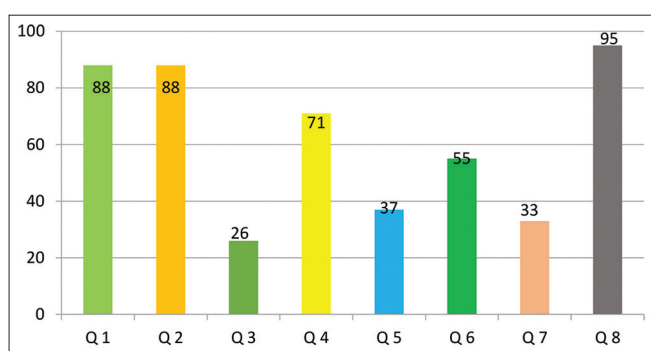


Fig. 2: Correct responses (in percentages) to the questions related to the assessment of knowledge

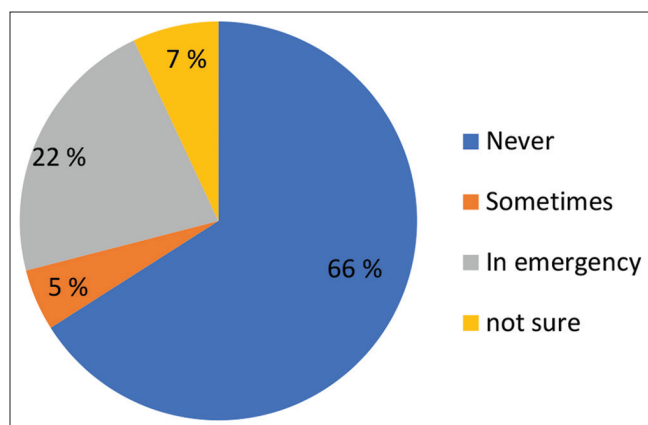


Fig. 3: Should we use drugs after the date of expiry, responses in percentages

Questionnaire to assess knowledge

About 88% (n=74) of the participants knew the definition of the expiry of drugs and the calculation of the expiry date from the month provided on the label printed on the medication strip correctly. Only 26% of the participants had knowledge related to the shelf life of various drugs. About 71% knew about the concept of the medicine take-back system. Only 37% were aware of the color of the bin used to dispose expired medication.

Regarding the nature of drugs beyond their date of expiry, 12 participants (14%) responded that they become toxic, 24 responded that the drug action is lost, and 46 (55%) that depending on the drug it might become toxic or loses its therapeutic effect. Two participants

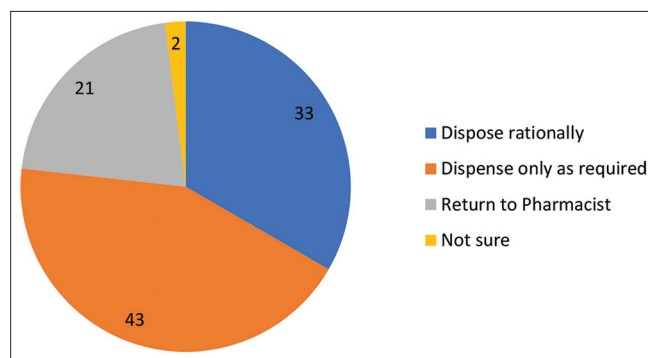


Fig. 4: How to reduce pharmaceutical waste, responses in percentages

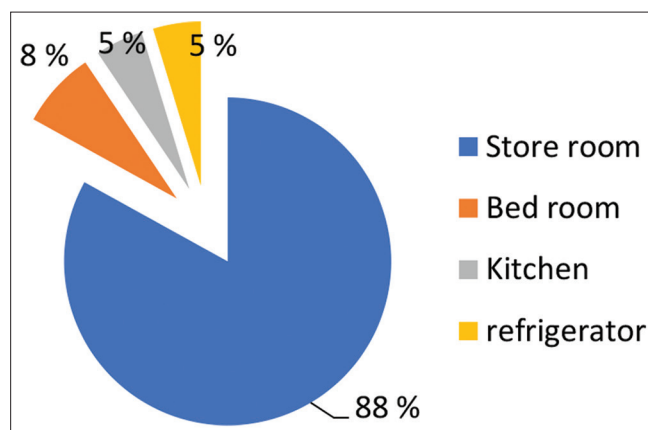


Fig. 5: Places used to keep expired drugs at home, responses in percentages

opted that the effect remains same even after expiry. Only 28 participants knew that extreme age groups were more vulnerable to the risks associated with the expired medications when stored at home. Nearly all the respondents (95%) had knowledge regarding the various pharmaceutical wastes and their sources as shown in Fig. 2.

Questionnaire to assess attitude

About 66% of the doctored opined that drugs should never be used beyond their date of expiry and 22% (n=8) of respondents had the opinion that expired drugs should only be used in case of an emergency. About 7% of the participants were not sure if expired drugs can be used after their expiry date as shown in Fig. 3.

About 43% of the respondents opined that pharmaceutical waste can be reduced by dispensing drugs to the patients only when required and 33% (n=28) opined that medication when rationally disposed reduces pharmaceutical waste. About 21% of the participants responded that returning the unused drugs back to the pharmacist can reduce the pharmaceutical wastes. Only 2% were not sure about the ways to reduce pharmaceutical wastes as shown in Fig. 4.

Questionnaire to assess practice

It is observed that all the participants had the practice of checking for the date of expiry before use. 52% of them had the habit of reading the medication disposal instructions related the drug in use. Most of them (79%) had the practice of educating their patients regarding proper use of the prescribed medications and also their safe handling when expired. About 88% of the doctors had the habit of storing the expired medication in the storeroom out of reach of children and elderly. Few of the doctors (n=6) kept the expired drugs in their bedroom while very few (n=5) stored them in their kitchen or refrigerator as shown in Fig. 5.

Table 1: Questions related to test the knowledge regarding handling of expired drugs

S. No	Question	n	Correct answer in %
1	The medicinal product is known to remain stable until the date of expiry in term of	74	88
2	If expiry of a drug is mentioned as April 2024, the day of expiry would be	74	88
3	What is the average shelf life of over-the-counter drugs?	22	26
4	The term 'Medicine take back system' for medicines is:	60	71
5	Expired medication should be put in which colored waste disposal container.	51	61
6	What will be the effect of drugs beyond its expiry date?	46	55
7	Which age groups are more vulnerable to the risks associated with expired household medications	28	33
8	Which one of the following can be considered as pharmaceutical waste	80	95

Table 2: Questions related to test the attitude toward handling of expired drugs

S. No	Question	Response	n	%
1	In your opinion, can drugs be used in patients even after expiry	Never	54	66
		Sometimes	4	5
		In case of emergency	18	22
		Not sure	6	7
2	In your opinion how can we reduce pharmaceutical waste	Dispose rationally	28	33
		Dispense only as required	36	43
		Return to pharmacist	18	21
		Not sure	2	2

Table 3: Questions to test the practice regarding handling of expired medications

S. No	Question	Response	%
1	Do you check the expiry date of the medications before using them	Yes	100%
2	Do you usually read medication disposal instructions?	yes	52% (n=44)
3	Do you educate and advice the patients regarding handling of expired drugs	yes	79% (n=66)
4	Where do you keep the expired medications at home	Storeroom	88% (n=70)
		Bedroom	8% (n=6)
		refrigerator	5% (n=4)
		kitchen	5% (n=4)
5	In daily practice, in what way do you discard expired medications	Garbage bin	64% (n=54)
		Crushing the medication	29% (n=24)
		Mixing with unwanted substance	7% (n=3)
		Flushing in the toilet	0

About 64% discarded the expired medication directly into the garbage bin while 29% (n=24) crushed the medication before throwing into the bins. Only 7% of the doctors had the habit of mixing the expired medication with unwanted substances before disposing as shown in Table 3

DISCUSSION

Advances in medical research resulted in the tremendous increase in the use of pharmaceutical products. Medication shift, poor patient compliance, early recovery, excess procurement of over-the-counter medicines, and irrational prescription results in the accumulation of unused and expired medications. Most of the time, the healthcare professionals instruct the patients regarding proper use and storage of medications but seldom do they provide proper instructions on appropriate ways to dispose them. Improper disposal of unused and expired medication poses a significant threat to the environment [2,3]. If stored at home in an unsafe condition, they can lead to an increased risk of accidental exposure by children and elderly [7,8].

The period between the date of manufacture and date of expiry is called the shelf-life or life period of the drug. In India, the Schedule P (Rule 96) of the Drugs and Cosmetics Act specifies the shelf life of drugs and the conditions of storage. When stored under these specified conditions, the product remains stable retaining >95% potency. The expiry date can be drastically shortened once the drug container is opened. Various other factors such as contact with water, temperature, air, or

light can also affect the expiry date. Shelf life of drugs depends on the degradation of the active drug and the degree of contamination. Hence, certain basic storage guidelines should be followed while handling the drugs, irrespective of their date of expiry.

The expiry date does not mean that the medicine has lost its potency or it is toxic after it, but simply that its quality is not assured beyond the expiry date, and the manufacturer is not liable if any harm arising from the use of the product. In fact, studies have shown that the majority of solid oral dosage forms (tablets/capsules, etc.) stored under ordinary conditions in unopened containers remained stable for 1-5 years after the expiry date. Liquid formulations are less stable. Suspensions clump by freezing. Injectable solutions may develop precipitates or become discolored on prolonged storage.

In our current study, assessment of knowledge showed that 88% (n=74) of the participants knew about the definition of the expiry date of drugs and the calculation of the same from the month provided on the label printed on the medication strip. Most of the doctors knew about the concept of medicine take-back system. Very few of them were aware of the color of the bin used to dispose expired medication. Almost half of the respondents were aware of the effects of various drugs beyond their date of expiry as shown in Table 1.

Loss of potency beyond the date of expiry depends on the drug as well as the storage conditions. Degradation of drugs is accelerated with

high humidity and temperature. Majority of medicines, especially solid oral dosage forms remain safe years after the expiry date but their use cannot be legally allowed beyond this date. The degradation product of only one drug (tetracycline) has caused toxicity in humans. Outdated tetracycline capsules produced renal tubular damage resembling Fanconi syndrome in the early 1960s [9]. They have been reformulated to minimize degradation now.

In our present study, only 33% knew that the extreme ages were more vulnerable to the risks associated with the expired medications when stored at home. Nearly all the respondents (95%) had knowledge regarding the various pharmaceutical wastes and their sources. About 66% of the doctors opined that drugs should never be used beyond their date of expiry, around 22% (n=8) of respondents had the opinion that expired drugs should only be used in case of emergency as shown in Table 2.

According to a case report published in 2021, a patient was presented to an emergency department with an acute anterior myocardial infarction. Due to the unavailability of percutaneous coronary intervention, standard of care required the use of thrombolytics but the only available thrombolytic, streptokinase, was 2 weeks past expiration date. The physicians faced the ethical dilemma of using the medication violating regulations versus failing to provide the patient with the best available therapy [10].

In the current study, even though all the participants had the practice of checking for the date of expiry before use, only half of them had the habit of reading the medication disposal instructions. Most of them (79%) had the practice of educating their patients regarding the proper use of the prescribed medications and also their safe handling when expired. Most of the respondents (88%) stored the expired medication at home. This was consistent with the practice found in a study conducted by Mohammed and Al-Hamadani [11] and most of the disposal practices followed by the participants were not recommended as observed in a study done by Ayele and Mamu [12].

As shown in Fig. 6, majority (64%) of the doctors discarded the expired drugs directly into the garbage bin. This was lower than those reported in studies done in Jharkhand (75%) [13] Malaysia (94%) [14], and Bangladesh (97%) [15]. This was consistent with the observations found in a study conducted in the general population of northern India by Manocha *et al.* where 93% of general population discarded the expired medication directly in the trash [16]. Very few of the doctors had the habit of mixing the expired medication with unwanted substances before disposing. According to the federal guidelines by the Office of National Drug Control Policy [17], expired drugs should be mixed with undesirable substance such as coffee grounds or cat litter, and putting the mixture into sealable containers. The sealed container with the mixture and empty drug containers are thrown in the trash. Flushing prescription drugs down the toilet can be followed only if instructed so on the label. For example, fentanyl, gatifloxacin, and stavudine should be flushed down instead of throwing in the trash.

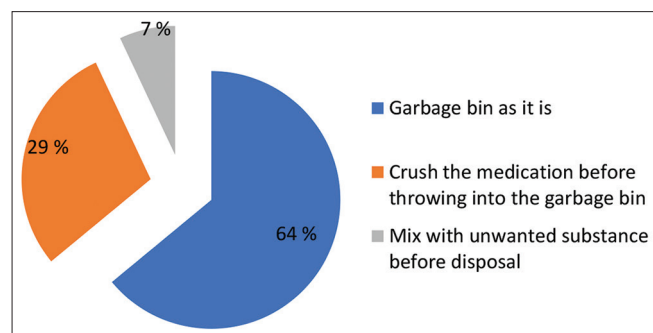


Fig. 6: Ways to discard expired medication, expressed in percentages

CONCLUSION

Two myths about medications pervade both the professional and lay communities that they are uniformly effective and that medications taken past their expiry dates may be ineffective or even harmful. Scientific studies have demonstrated that both are false. Despite having better awareness about the possible effects of expired medicines than the general population, there is an absence of understanding concerning the proper techniques for disposing in health-care providers. A drug bank can be maintained for distribution of medication nearing expiry date to the needy at a subsidized price to reduce the burden of pharmaceutical waste. As the participant number in the current study was small, larger studies are recommended for better conclusions. Furthermore, as improper disposal of expired medications poses a significant threat to the ecosystem; the government should make appropriate policies for implementation of proper drug disposal. Knowledge about the proper disposal of drugs among medical professionals is still lacking, and discussion on this topic can be given priority. Medical professionals should join hands and coordinate with other professionals to overcome the same.

AUTHORS CONTRIBUTION

Study conception and design: D. Jayasree, Sowmya deepthi Chavala, Data collection – V.Naga Jyothi, Sowmya deepthi Chavala, Analysis and Interpretation of results: Dara Aruna Kumari, D. Jayasree, Draft and manuscript preparation: D. Jayasree, V. Naga Jyothi.

CONFLICTS OF INTEREST

None.

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