



**EFFICACY, SAFETY CONCERN AND DISPOSAL PRACTICES
FOLLOWED FOR EXPIRED DRUG PREPARATIONS AMONG
MEDICAL PERSONNEL**

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Article Received on 25/12/2014

Article Revised on 15/01/2015

Article Accepted on 06/02/2015

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ABSTRACT

Objectives: The expiry date of pharmaceutical specifies the date that manufacturer guarantees the full potency and safety of a drug. This study was designed/undertaken to assess the knowledge, importance and practices concerning expiry date among medical professionals and to create awareness about toxic potential and methods of disposal of expired medicine. **Method:** This cross sectional study was conducted

in Govt. Medical College, Haldwani associated Dr. Sushila Tiwari Hospital in the Month of Feb March 2014; on 100 medical professionals Doctors, Nurse and Pharmacist. A Questionnaire comprising of 17 well-structured multiple choice questions, regarding knowledge, importance and methods of disposal of expired medicines were framed distributed to 70 Doctor, 24 Nurse, 6 Pharmacist, then collected on the same day. The single most appropriate answer was assessed and data represented as percentage and analysed through Microsoft Excel 2007. **Result:** We observed that 53.33% subjects had knowledge that expiry date of drug indicate loss of efficacy and 33.33% knows it is actually the loss of potency and 6.06% believe that Drug become toxic after expiry date and 6.06% believe nothing happen with drug, 36.36% subjects had knowledge that the expiry date of drug is decided only by pharmaceutical manufactures 56.06% had misconception that it is decided by both manufactures and pharmacologist. We observed that majority (54.54%) prefer to dispose expired medicine by putting them into trash, and 66.66% consider it as most ideal method of disposal of expired medicine. **Conclusion:** The study concludes that significant number of medical professionals lacked proper knowledge and proper practices of safe disposal method.

Health professionals are in an excellent position to educate patient on drug disposal. By getting updated and promoting safe medication disposal, Health professional can make a difference regarding an issue that affect both public health and environment.

KEYWORDS: Expiry date, Medical Personnel, Disposal methods.

INTRODUCTION

Medications are not immortal. Drug expiration dates are meant to indicate the date at which the drug potency begins to diminish. It is legal requirement, that all pharmaceutical products must carry the date of manufacture and date of expiry on their label which is called life period or shelf life of Drug^[1]. The expiry date of a pharmaceutical specifies the date that manufacturer guarantees the full potency and safety of a drug. Toil Davis, a former FDA expiration date compliance chief said that most expired drugs are probably effective except nitroglycerin, Insulin and some liquid antibiotic.^[2] In India the schedule P (Rule 96) drugs and cosmetics Act (1940) specifies the life period (mostly 1-5 yrs.) of drug and conditions of storage.^[3]

The shelf life of medicine is determined by real time stability study or by extrapolation from degradation studies by the pharmaceutical manufactures several factors can influence these dates, including type of active ingredients, storage condition preservations and the kind of container the drug is stored.^[4] Each state has different requirements but all pharmacists must give the consumer some sort of expiration date, sometimes called a 'beyond use date'. It is important to note that once the original container is opened either by patient or by health care provider, who will dispense the drug, that original expiration date on the container can no longer be relied upon.^[5] Patients may not use all the medications dispensed to them due to side effects, intolerance, dosage change, discontinuation of medication or medication reaching expiration date, therefore, it is not uncommon for patients to be in possession of unused or expired medications when this happens, patient need clear guidance on how to dispose of these medications.^[6] Therefore it is crucial for front line health care professionals who already counsel and field medication related questions to educate their patient on the importance of proper medication disposal and correct way to dispose of medications and to encourage patients to be proactive with this process, for that medical professional need to be updated about guideline of Expired Drugs. There are many myths and fear regarding use of expired date drugs. There is dearth of studies done regarding these issues among medical practitioners. So this study was designed to assess the knowledge, importance and practices

concerning expiry date among medical professionals and to create, awareness about toxic potential and methods of disposal of expired medicine.

METHOD AND MATERIAL

This cross sectional study was conducted in Govt. Medical College, Haldwani associated Dr. Sushila Tiwari Hospital. The questionnaire based study was conducted in the Month of Feb March 2014; on 100 medical professionals Doctors, Nurse and Pharmacist. Ethical approval was obtained from Institutional Ethical Committee. A Questionnaire comprising of 17 well-structured multiple choice questions, regarding knowledge, importance and methods of disposal of expired medicines were framed distributed to Doctor, Nurse, Pharmacist, then collected on the same day. The single most appropriate answer was assessed and data represented as percentage and analyzed through Microsoft Excel sheet 2007.

RESULT

In our study 70 doctors, 24 nurses and 6 pharmacist participated. We observed in that 53.33% subjects had knowledge that expiry date of drug indicate loss of efficacy and 33.33% knows it is actually the loss of potency and 6.06% believe that Drug become toxic after expiry date and 6.06% believe nothing happen with Drug (Table I, Fig. 1) 36.36% subjects had knowledge that the expiry date of drug is decided only by pharmaceutical manufactures, 56.06% had misconception that it is decided by both manufactures and pharmacologist.

We found that 89.39% had knowledge that expiry date depends on both Manufacturing and storing condition (Fig. 2), 90.90% subject responded correctly that drug should be best stored in cool dry and dark places (Fig 3). During study we found that majority 65.15% consider expired drug use is not safe but 89.39% (Fig. 4) subject were aware about not using Insulin, Liquid antibiotic, Nitroglycerin after expiry (Fig. 5).

We observed that majority (54.54%) (Table 2, Fig. 6) prefer to dispose expired medicine by putting them into trash, and 66.66% consider it as most ideal method of disposal of expired medicine (Fig. 7) It is observed from the study that 74.24% respondents were aware about environmental concern of improper disposal of left over medicine.

Table- I Knowledge about Expired drug

Question		Percentage
Expiry Date Means		
A)	Drug loses its efficacy	53.03%
B)	Drug loses its potency	33.33%
C)	Drug becomes toxic after expiry date	6.06%
D)	None	6.06%
After Expiry date		
A)	Drug is totally efficacious	3.03%
B)	Drug is partially efficacies	71.21%
C)	Drug is not efficacies	18.18%
D)	None	7.57%
Is it Safe to take expired medicine ?		
A)	No	65.15%
B)	Yes	6.06%
C)	May be	19.69%
D)	May not be	10.60%
Expiry Date depends on		
A)	Manufacturing condition	6.06%
B)	Storing condition	3.03%
C)	Both	89.39%
D)	None	-----
Drug should be best stored in		
A)	Dry, Dark places	7.57%
B)	Cool Dry, Dark places	90.90%
C)	Cool Dark Damp places	-----
D)	Cool Dark lighted places	1.15%
Expiry date should be put on drug strip/container with color of		
A)	Black	25.75%
B)	Blue	15.15%
C)	Yellow	1.5%
D)	Red	53.03%
E)	Non-Responders	4.5%
Expiry date Ranges From		
A)	12-24 month	12.12%
B)	12-36 month	39.39%
C)	12-48 month	22.72%
D)	12-60 month	22.72%
E)	Non-Responders	3.03%
Insulin, liquid Antibiotic, Nitroglycerins can be given up to		
A)	1 month post expiry date	6.06%
B)	1 week post expiry date	15.15%
C)	1 year post expiry date	1.515%
D)	Cannot be given post expiry dates	89.39%
E)	Non-Responders	3.03%

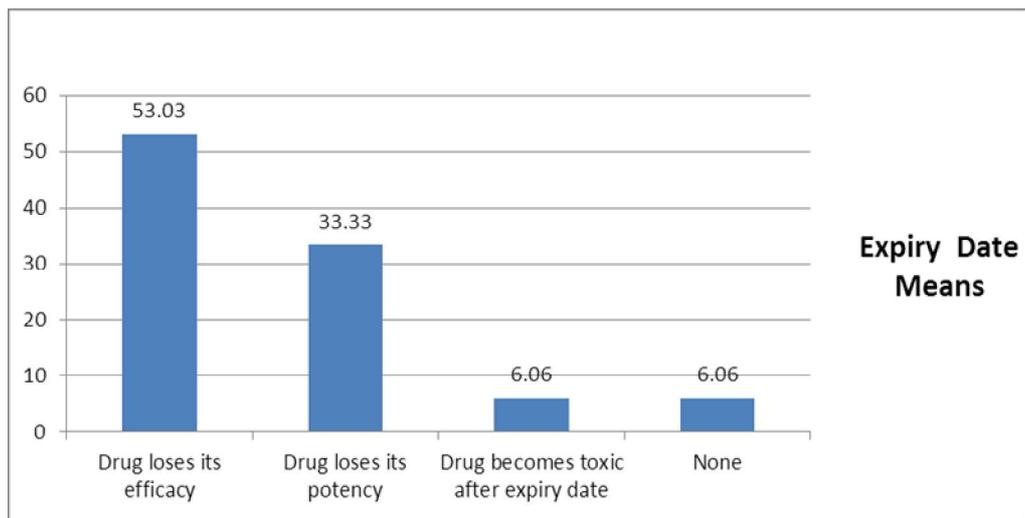


Fig.-1

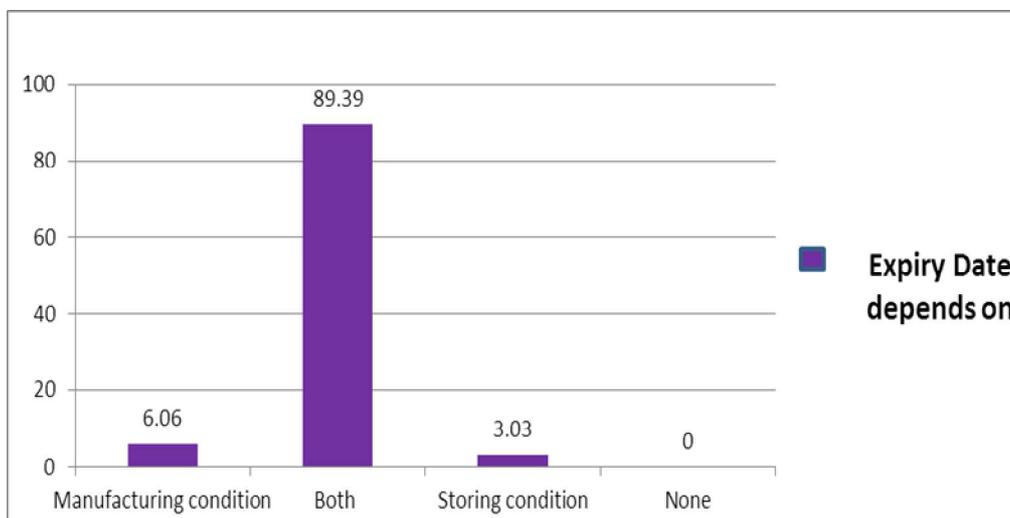


Fig.-2

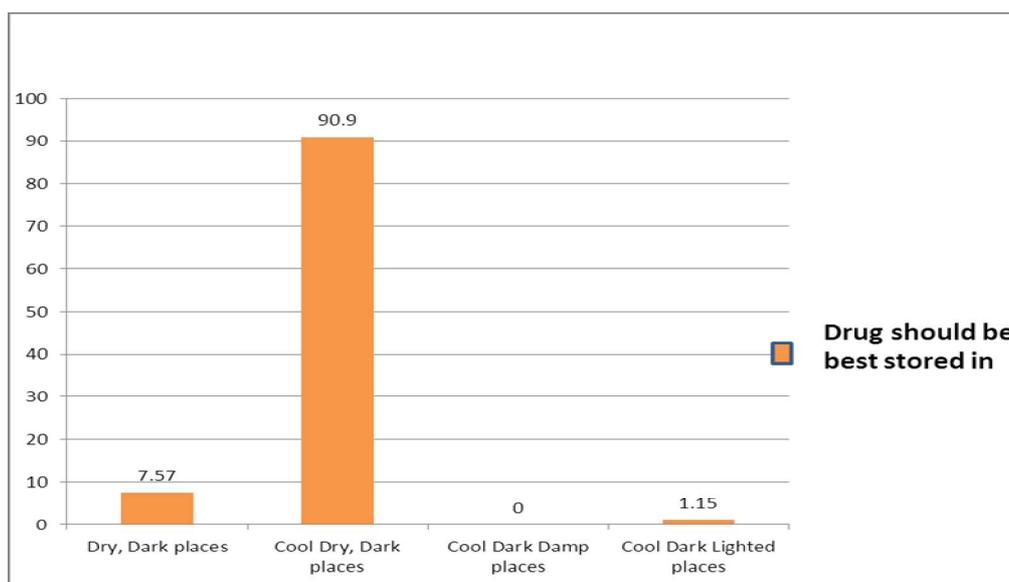


Fig.-3

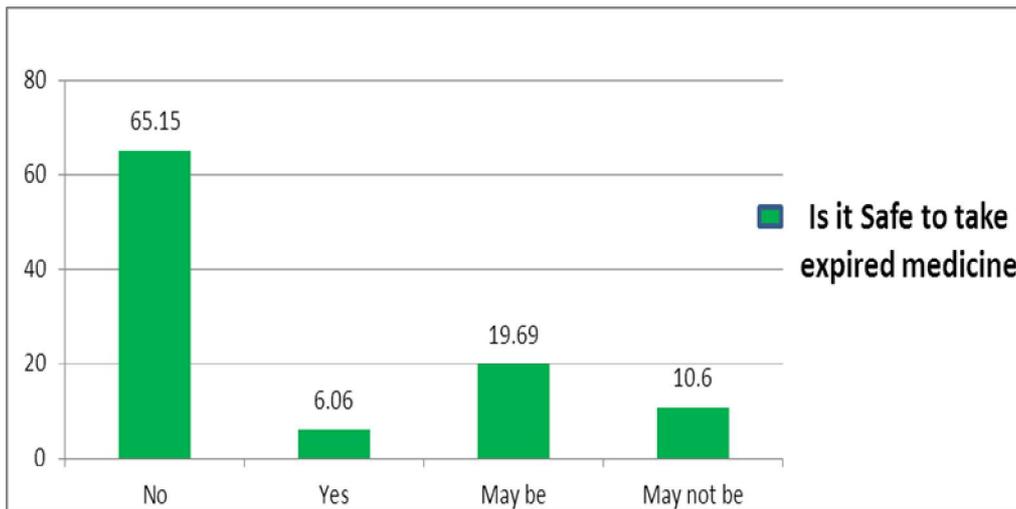


Fig.- 4

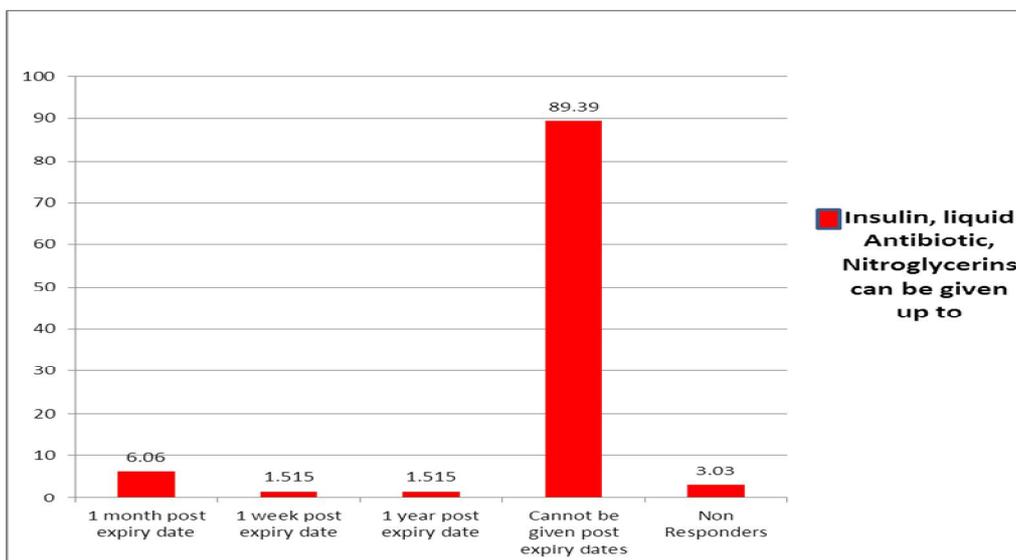


Fig.- 5

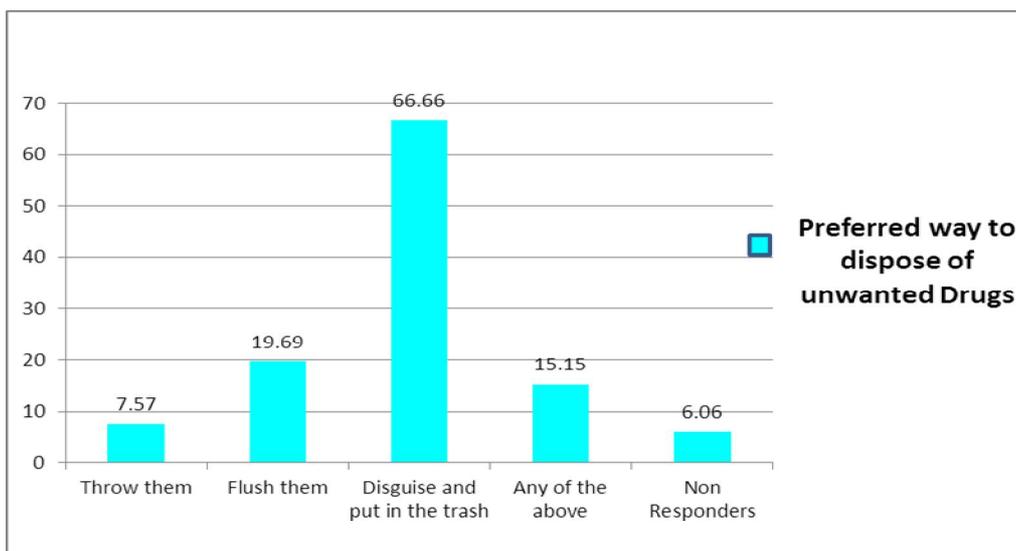


Fig-6

Table II- Disposal of Expired drug

Question	Percentage
The preferred way to dispose of unwanted Drugs	
A) Throw them	18.18%
B) Flush them	10.60%
C) Disguise and put in the trash	54.54%
D) Any of the above	10.6%
E) Non-Responders	6.06%
The Most ideal way to dispose of unwanted Drugs	
A) Throw them	7.57%
B) Flush them	19.69%
C) Disguise and put in the trash	66.66%
D) Any of the above	1.515%
E) Non-Responders	4.5%
Incineration as a disposal method is used for which formulation	
A) Tablets & Capsules	37.87%
B) Liquid formulation	3.03%
C) Transdermal patches	45.45%
D) Inhaler	7.57%
E) Non-Responders	6.06%
Do you know about National take-back programme in other countries for return of unused medicine ?	
A) Yes	34.84%
B) No	62.12%
C) Non-Responders	3.03%
Do you want Take-back programme for return of unused medicine in your country also ?	
A) Yes	77.27%
B) No	15.15%
C) Non-Responders	7.5%

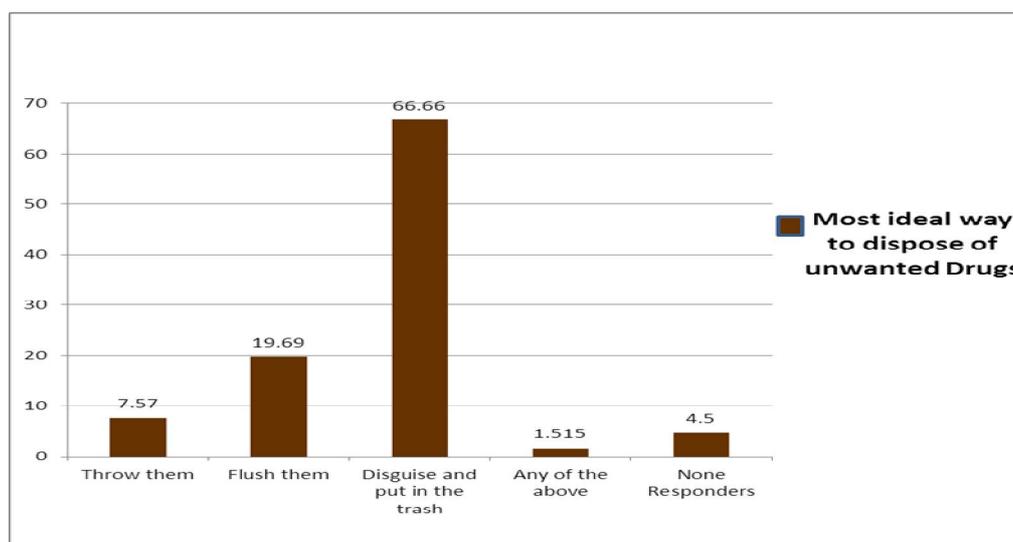


Fig.- 7

DISCUSSION

Since 1979, FDA has passed a law, that drug manufactures are required to stamp an expiration date on their products. This is the date at which the manufactures can still guarantee the full potency and safety of drug.^[8] According to FDA drug 'expire' on the date they are projected to have lost 10% of their potency, which means they are still 90% effective.^[2]

We observed in study that 53.33% subjects had knowledge that expiry date of drug indicates loss of efficacy and 33.33% believes its actually the loss of potency and 6.06% believe that Drug become toxic after expiry date and 6.06% believe nothing happen with drug and only 36.36% subjects are aware that it is decided only by pharmaceutical manufactures 56.06% had misconception that it is decided by both manufactures and pharmacologist.

Environmental condition can impact the chemical and physical properties of medications and shorten the shelf-life. Improper storage can shorten the expiry date of the medication for most medications, storing in a cool, dry and dark place will maximize the life span of your medication.^[2]

We found that 89.39% had knowledge that expiry date depends on both Manufacturing and storing condition, 90.90% subject responded correctly that drug should be best stored in cool dry and dark places.

Pharmaceutical manufacturer determines a drug's shelf-life of expiration date, through stability testing, these date ranges from 12 to 60 month from the date they are manufactured.^[12] In our study we observed only 22.72% knows that expiry date range from 12-60 month. The testing conducted by the US FDA ultimately covered more than 100 drugs prescription and OTC drugs. The result showed that about 90% of them were safe and effective as long as 15 years past their original expiration date. Loel Dawis, expiration date chief said that with a handful of exception notably nitroglycerin, Insulin and Liquid antibiotic most drugs are probably as durable as the agency tested.^[13]

During study we found that majority (65.15%) consider expired drug use is not safe 89.39% subject were aware of about not using Insulin, Liquid antibiotics, Nitroglycerin after expiry. We observed that majority (54.54%) prefer to dispose expired medicine by putting them into trash and 66.66% consider it as most ideal method of disposal of expired medicine.

It was previously believed that the best way to present accidental consumption of unused medicine was to dispose medication in the toilet or down the drain, as opposed to discarding them in the trash^[14] but the white House office of National Drug Control Policy (ONDCP) released an official guidance in 2007 (update in 2009) for proper medication disposal that advises people not to flush their medication because of environmental concern and provide explicit direction of disposal.^[15] Some countries like US have pharmaceutical take back programme or community solid waste programs that allow the public to bring unused drugs to a central location for proper disposal where these exist they are a good way to dispose of unused pharmaceuticals.^[16] We found that 62.12% subject do not know anything about take back program, although 72.27% want take back program for return of unused medicine in our country to be implemented.

It is observed from the study that 74.24% respondents were aware about environmental concern of improper disposal of left over medicine. Exposure of human being and animals to drugs through environment affect them directly or indirectly.^[17] A study from Pakistan revealed that due to the use of diclofenac in treatment of livestock and consumption of their dead bodies by vultures led to the kidney failures of these vultures.^[18] Consequently over a period of time population of vultures declined so drastically that they were declared endangered species. Various Government and non Government organization became active to save these most efficient scavengers of nature, similarly Government of India also banned diclofenac in India for veterinary use.^[19] Not only the drugs but also the excipients used in the formulation may pose a threat to environment.^[20]

CONCLUSION

The study concludes that significant number of medical professionals lacked proper knowledge and proper practices of safe disposal method. These practices need to be inculcated in them. Health professionals are in an excellent position to educate patient on drug disposal. Counseling patient by medical professionals on the correct way to dispose of their unused medication can make a difference in their belief and behaviors. By getting updated and promoting safe medication disposal, Health professional can make a difference regarding an issue that affect both public health and environment.

ACKNOWLEDGEMENT

I would like to acknowledge incomparable understanding and cooperation of all the faculty members of Government Medical College, Haldwani and especially Dr Bhavana Srivastava, Head of the department of Pharmacology.

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