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# MISUSE AND DEPENDENCE ON NON-PRESCRIPTION CODEINE ANALGESICS OR SEDATIVE H1 ANTIHISTAMINES BY ADULTS

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### **ABSTRACT**

Background: Given the growing worldwide market of non-prescription drugs, monitoring their misuse in the context of self-medication represents a particular challenge in Public Health. The aim of this study was to investigate the prevalence of misuse, abuse, and dependence on non-prescription psychoactive drugs(paracetamol, codeine combined with paracetamol in analgesics, or sedative H1 antihistamines) that lead to the development of tolerance; withdrawal symptoms; frequent use of higher doses than intended; persistent desire or unsuccessful efforts to control drug use; rising costs of health services, development of side effects; and the negative effects of the drug use on health, social, or professional life. **Objectives:** This study will evaluate the pertinent factors contributing to the misuse and dependence on Non-Prescription Codeine Analgesics or Sedative HI Antihistamines by adults worldwide. Methods: A observational study design was adopted using convenient sampling technique, during the period June-2017 to August-2017. A sample size of 100 adults between 18-55 years age, was taken and data was collected from community pharmacies in Lahore Pakistan. A data collection form was designed and was filled during face to face interviews with them. Data was presented in percentage. Results: Number of medicines/prescription used were pulmonol syrup 16%, diphenhydramine 4%, phenergan 4%, hydrallin syrup 26%, avil 20%, and paracetamol 30%. The most commonly adverse effects regarding non-prescribed drugs were sedation, gastrointestinal disturbance, drowsiness and motion sickness. Conclusion: It was concluded that nonprescribed OTC medicines availability from pharmacies can help individuals to self-manage symptoms. Adult used non-prescribed codeine and H1antihistamine to relief pain, insomnia and anxiety. However, they may be abused, dependent or misused due to lack of knowledge & proper guidance. It may results in sedation, drowsiness or other GIT disturbance. The results obtained in the present study on the prevalence of problematic uses of codeine analgesics and H1 blockers in non-prescription drugs requesting that clinical management should be improved.

KEYWORDS: Non-Prescription Codiene analgesics, H1 Anti-histamines Sedatives, Adults, Misuse, Dependence.

## INTRODUCTION

OTC drugs are easily available at community pharmacies without a medical prescription & are considered to be safe enough by following the current knowledge and understanding of medicine. [1] OTC medicine misuse & dependence was identified in many countries with varied products, i.e codeine-based (especially compound analgesic) medicines, cough products (particularly dextromethorphan) or sedative antihistamines.

An analgesic drugs used to relieve pain & act in various ways on the peripheral and central nervous system either by blocking pain signals going to the brain or by interfering with the brain's interpretation of the signals. [2]

Non-Narcotic over-the-counter analgesics include Paracetamol or Acetaminophen; if not used according to the directions, increase the risk of hepatotoxicity. It is found in combination with other active ingredients in many cold, sinus, and cough medications. Narcotic Analgesics are of two types: the opiates and the opioids. Codeine is a narcotic (opium alkaloids) painkiller & is anti-tussive. it is also used in combination medications with the drug acetaminophen or aspirin. [3]

Common adverse effects of opioids are nausea, orthostatic hypotension, urinary retention, vomiting, drowsiness, dry mouth, miosis, sometimes caused tachycardia, raised intracranial pressure, confusion, hallucinations, delirium, hypothermia, muscle rigidity, flushing, respiratory depression.<sup>[4]</sup>

Opioids are only prescribed and administered under medical supervision. Patients also need to be monitored while undergoing withdrawal period once the drug is discontinued. As abrupt discontinuation will cause a palette of withdrawal symptoms and signs that include

restlessness, agitation, irritation, anxiety, insomnia and involuntary leg movement strong craving, sweating, shakes and chills cramps and cold flushes, dilated pupils. [5]

Over the counter (OTC) cough and cold preparations are some of the most widely used medications in Pakistan for treatment of as allergies including urticaria, allergic rhinitis and common cold in adults. They mainly contain combinations of antihistamines, antitussives, decongestants and expectorants, in various proportions.

Antihistamines are a class of agents that block histamine release from histamine-1 receptors and are used to treat the symptoms of an allergic reaction, such as edema (swelling), itch, inflammation (redness), sneezing, or a runny nose or watery eyes, also helpful in reducing anxiety, inducing sleep, or at preventing or treating motion sickness.<sup>[8]</sup>

Several generic OTC drugs preparations which contain more than one active ingredient i.e combination of up to three anti allergic drugs; promethazine, diphenhydramine and ephedrine in various proportions as the main active ingredients, are cheap and readily available. In addition, promethazine and ephedrine have serious toxicity profiles with no warning labels barring their use. [9] Some even contain an antihistamine, chlorpheniramine to prepare antiallergic drugs in one preparation.

Promethazine is a first-generation antihistamine with strong sedative, antiemetic and anticholinergic properties. However serious adverse effects including fatal respiratory depression, sleep apnea, over sedation, agitation, seizures, hallucinations, and dystonic reactions have been reported with its use. [10] It led to withdrawal of its use in children less than 2 years in America in 2004, and strengthened warning (boxed warning) in children over 2 years. [11]

Diphenhydramine is a first-generation antihistamine with anticholinergic, antitussive, antiemetic and sedative properties that is mainly used to treat allergies and common cold. [12] It is also used in the management of drug-induced Parkinsonism and other extrapyramidal symptoms and has been approved as a non-prescription sleep aid. [13]

Case report studies conducted in USA regarding diphenhydramine monotoxicity concluded that the most common symptoms were cardiac dysrhythmias, seizure activity, and/or sympathetic pupil responses, pulmonary congestion. This led to its contraindication in adults. [12]

Ephedrine is a sympathomimetic drug used as a decongestant and bronchodilator in treatment of allergic disorders, asthma and hypotension associated with an overdose include nervousness, insomnia, vertigo, headache, tachycardia, palpitations and convulsions. [6]

The current researches suggested that 1<sup>st</sup> generation antihistamines should no longer be dispensed as OTC medicine because of their adverse effects. [14] the fact is that they are still sold as OTC medicine .the regulation of drugs is still of major concern. In fact, the American College of Chest Physicians (ACCP) and US Food and Drug Administration (FDA) have both recommended that OTC cough and cold products should not be used without consultation. [15,11]

Pharmacoepidemiological research on non-prescription drug use and safety has demonstrated the feasibility and validity of survey relying on an anonymous questionnaire given to patients seen in community pharmacies to investigate problematic use of psychoactive drugs used for self-medication or diversion.

The study helps to report the experiences and views of community pharmacy staff in relation to current practices and concerns, management and support relating to OTC medicine misuse and dependence. A lack of information about customers, easy access to, and poor communication between community pharmacies were emergent barriers to pharmacists providing more support. [16]

In the light of above, the aim and objectives of the present study is to investigate the prevalence of misuse, abuse of, and dependence on codeine analgesics or on sedative H1 antihistamines for non-prescription drugs spontaneously requested by patients in community pharmacies and to identify reasons for persistent use, in comparison with non-prescription paracetamol.

## MATERIALS AND METHODS

A observational study design was adopted using convenient sampling technique, during the period June-2017 to August-2017. 100 sample sizes were taken and study carried out in major community pharmacies of Lahore Pakistan.

**Inclusion and Exclusion Criteria:** Adults using codeine and antihistamines between age 18 to 55 years were included in this research study while neonates, children, admitted patients other OTC's and Rx medicines were excluded from this research study.

Ethical Considerations: The study was conducted after obtaining ethical approval from the Institute of Pharmacy of Lahore College for Women University. The institute provided ethical approval after assessing informed verbal consent submitted with all components of the research protocol. The verbal consent of questionnaire was asked before data filling. The participants for the study were asked whether they were willing or unwilling after hearing about the consent of the study and this was confirmed by their response shown as yes or no. Data collection was carried out after the confirmation of the willingness of the participant. The data was recorded

anonymously in order to ensure confidentiality and privacy of the participant.

#### RESULTS

Table-1 shows about Age and gender distribution. There were 64% of males and 36% of females found with 36%(18-27),58%(28-37),6%(38-46),3%(47-55)of age seen.

Figure -1 shows reasons of self medication were seen due to time saving 10%, emergency 8%, economical factors 2%, confidence 24%, previous expertise 16% and quick relief 40% respectively.

Figure-2 shows form of non-prescription drugs preferred were Generic 48% and brand 52% respectively.

Figure-3 shows Sign and symptoms were seen due to fever & headache 52%, stomach upset 14%, cough & cold 6%, skin problems 0%, diarrhea or constipation 6%, pain 12%, allergies 6%, and motion sickness 4% respectively.

Figure-4 shows number of medicines/prescription used were, pulmonol syrup 16%, diphenhydramine 4%, phenergan 4%, hydrallin syrup 26%, avil 20%, and paracetamol 30%.

Figure-5 shows side effect caused by non-prescribed drug were seen as according; sedation 30%, dry mouth 4%, mydriasis 0%, flushing 2%, motion sickness 4%, GTS 32%, drowsiness 12%, others 16%.

Table-1: Biography.

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Gender Distribution	
Male	64%
Female	36%
Age Distribution	
18-27 yrs	36%
28-37 yrs	58%
38-47 yrs	06%
48-55 yrs	03%

Table. 1: There were 64% of males and 36% of females found & were 36%(18-27),58%(28-37),6%(38-46),3%(47-55)of age seen.

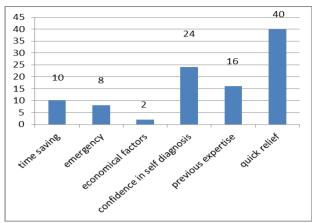


Figure. 1: Reasons of self medication were seen due to time saving 10%, emergency 8%, economical factors 2%, confidence 24%, previous expertise 16% and quick relief 40% respectively.

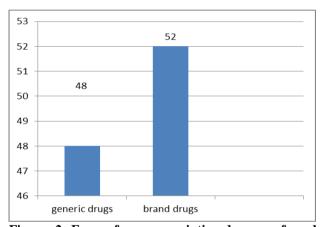


Figure. 2: Form of non-prescription drugs preferred were Generic 48% and brand 52% respectively.

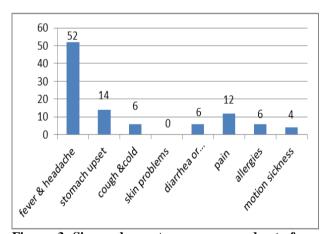


Figure. 3: Sign and symptoms were seen due to fever & headache 52%, stomach upset 14%, cough & cold 6%, skin problems 0%, diarrhea or constipation 6%, pain 12%, allergies 6%, and motion sickness 4% respectively.

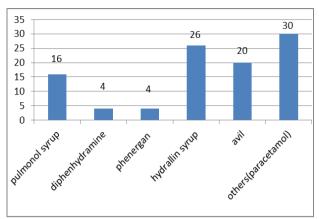


Figure. 4: Number of medicines/prescription used were, pulmonol syrup 16%, diphenhydramine 4%, phenergan 4%, hydrallin syrup 26%, avil 20%, and paracetamol 30%.

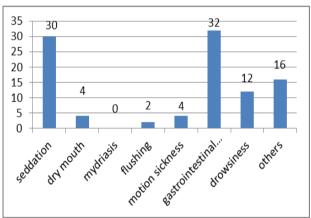


Figure-5 Side effect caused by non-prescribed drug were seen as according; sedation 30%, dry mouth 4%, mydriasis 0%, flushing 2%, motion sickness 4%, GTS 32%, drowsiness 12%, others 16%.

# DISCUSSION

This study was done to observe Over the counter (OTC) analgesics, cough and cold preparations most widely used medications in Pakistan .the non-prescription potent drugs with psychoactive properties should not be OTC because of well-known potential of misuse and dependence (such as codeine) & problematic use of such drugs for self-medication have been recognized as an important issue in community pharmacies, particularly opioids, first generation anti-histamines with sedative properties, and sympathomimetics.

The patients have to request above drugs from the pharmacist. And they must be administered under supervision and in optimal doses. people who are prescribed opioids and take these drugs for an extended period of time eventually develop a physical dependence. Patients also need to be monitored while undergoing withdrawal period once the drug is discontinued.

Non-Narcotic Analgesics used to relieve pain, most commonly include Paracetamol or Acetaminophen & is found in combination with codeine as strong analgesics.

These preparations are quite popular because they are cheap and readily available.

Policy implications include the need for improved knowledge for community pharmacy stuff about signposting to relevant services, increased awareness of who might be affected, and review of how pharmacists can have more information about patients to inform OTC medicine sales.<sup>[16]</sup>

The study helps to report the experiences and views of community pharmacy staff in relation to current practices and concerns, management and support relating to OTC medicine abuse. A surveillance role placed to emphasis on regulations, procedure and monitoring frequency of purchases to manage misuse, with referral on to pharmacists. [17] A lack of information about customers, easy to access to, and poor communication between community pharmacies were emergent barriers to pharmacists providing more support.

#### CONCLUSION

The over-the-counter medicines sale from community pharmacies, medicine advertising with low prices cause public access to medicines and self treat conditions, thus increasingly potential for abuse and harm despite their perceived relative safety.

Pharmacist has to step forward to analyze the root cause of this trend by exploding his position in the community through building trusted relationship with patients and care-takers for discouraging self-medication, dispensing medications rationally, arranging educational programs for general public, communicating physicians about current guidelines for OTC prescribing and thus has to fight the battle for the survival of the most important drugs.

Pharmacist plays an important role in providing information regarding OTC, Promoting Rational Use of Drugs, Evaluation of a national program in order to reduce inappropriate use of drugs. Pharmacist can make strategies to decline the trend of self-medications.

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