

## Take Home Message for Policy Makers: Study on Over-The-Counter Drugs among Puducherry Population

Velvizhy R<sup>1</sup>, Sabari Selvan MR<sup>2</sup>, Shanmugapriya Seshatri<sup>3</sup>, Dhivya R<sup>4</sup><sup>1</sup>Associate Professor, Department of Pharmacology, Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry<sup>2</sup>Senior Assistant Professor, Department of Pharmacology, Government Thiruvavur Medical College, Thiruvavur<sup>3</sup>Assistant Professor, Department of Pharmacology, Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry<sup>4</sup>Senior Resident, Department of Pharmacology, JIPMER, Karaikal

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Corresponding Author: Dr. Velvizhy R

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**Abstract:**

The inappropriate use of non-prescription drugs (NPD), particularly over-the-counter (OTC) medications, poses a significant global health challenge. This cross-sectional study conducted in Puducherry, India, aimed to assess the prevalence of OTC drug use and its adverse effects. The study involved 462 participants, mainly from the 20-40 age group, with a majority having graduate degrees. Private employees were found to use OTC drugs more frequently. Surprisingly, even with medical professionals participating, OTC medications were not replaced by prescribed alternatives. Many participants visited pharmacies without a prescription, relying on expired prescriptions or describing symptoms to pharmacists. Fever was a common symptom leading to OTC purchases, often for chronic conditions requiring proper medical attention. The study identified 26 oral drug groups, 3 topical drugs, and 15 injections purchased as OTC, with some life-saving drugs obtained without prescriptions. Adverse effects were reported by a small percentage of participants, mainly mild hypersensitivity reactions, gastritis, and diarrhea. The findings emphasize the need for stricter regulations and increased awareness about the potential risks associated with OTC drug misuse. While OTC medications offer convenience, affordability, and self-management, their misuse can lead to adverse outcomes, warranting a focus on regulatory measures within pharmacy practices.

**Keywords:** Over-the-counter medications, Non-prescription drugs, Drug abuse, Self-medication, Topical drugs.

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**Introduction**

Non-prescription drugs (NPD) are tightly regulated in many parts of the world. However, inappropriate use of medicines such as over-the-counter (OTC) medicines continues to pose a serious challenge to health authorities in developed and developing countries. Such drug abuse includes purchasing over-the-counter drugs without consulting a doctor, reusing leftover drugs, and sharing drugs with other members[1].

Often, NPDs run the risk of inconsistency in dosage, timing, and frequency of dosing. The main risk factors associated with inappropriate use of over-the-counter medications are excessive waste of purchased medications, serious adverse reactions and prolonged suffering, and worsening of existing medical conditions. The World Health Organization (WHO) reports that approximately 50% of patients take their medications incorrectly and more than 50% of pharmaceutical products supplied or

distributed worldwide increases morbidity and mortality [2]. Selling antibiotics without a prescription can lead to serious consequences such as misdiagnosis, development of drug resistance, inappropriate treatment and increased morbidity. The availability of over-the-counter products beyond registered pharmacies or the open market also contributes significantly to NPD. In developing countries, the proportion of self-medication has been reported to be up to 90%, whereas in India, it varies from 8.3% to 93% [3].

Many factors contribute to self-medication, including peer pressure, illiteracy, marketing in the press and media, overconfidence in one's pharmacological expertise, and advice from friends and family [4]. Overstretched hospitals, crowded clinics, avoiding waiting time at hospitals, non-affordable consultation fee are the key factors that prompt patients to purchase medicines without prescription

in nearby pharmacies [5, 6]. The sale of OTC antibiotics in pharmacies without a valid prescription by registered medical practitioner's prescription appears to be widespread in India, indicating serious problems in controlling the emergence of antimicrobial resistance development [5]. The risk of using NPD in pregnant women remains elusive. Unfortunately, despite significant efforts by medical professionals, widespread self-medication among pregnant women remains common in developing and under developed nations. Therefore, this study aimed to determine the proportion of OTC drugs and their adverse effects among the population of Puducherry.

## Materials and Methods

### Study design

A questionnaire-based cross-sectional study was designed and conducted in 10 pharmacies of Puducherry using convenience sampling method. The selection criterion was registered pharmacists practicing in a retail chain in Puducherry. Pharmacists practicing in settings other than community pharmacy will be excluded from the study. The study was granted approval (IEC/C-P/16/2023) by the Institutional Ethics Committee of Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry. The study was conducted between March 2023 and August 2023. All study participants were notified about the purpose of the study and informed consent was taken prior to administering the questionnaire. Participation was voluntary and their confidentiality was maintained by assigning unique code numbers throughout the study process.

### Data collection

The first page of the online questionnaire included the purpose of the study, OTC medications, and forms of inappropriate drug use. The names, and contact details of the study investigators such as email, contact numbers were also made available to the participants. Before proceeding to the questionnaire, the participants were asked to provide their consent to participate in the study. Questionnaire consists of demographic information and practice of self-medication were circulated to all the participants who were willing to participate and then collected back on the spot. The participants were also requested to record their responses only once. Age, sex, education, occupation and other demographic characteristics are used to divide the population into several groupings. All the data were pooled and results are analyzed using descriptive statistics.

### Statistical analysis

The responses collected through paper-based questionnaire was first entered in Microsoft Excel and coded. Data were then tabulated using pivot table and analyzed by data analysis tool package in Microsoft Excel v2018. The demographic characteris-

tics were analyzed descriptively and expressed as frequencies and percentages. Cross-tabulation was done with Pearson's chi-square and Fisher's exact test (for variables having an expected cell count below 5) was used to test significant association between groups. Significant level was set to be  $P < 0.05$ .

## Results and Discussion

Prevalence of NPDs could not be compared between different studies due to their varying nature of definitions, recall period for definition, region selected and methodology adopted. Studies on the use of OTC was conducted predominantly in the northern region of India [3,7,8]. The demographic characteristics of 462 participants included in the study are summarized [Table/Fig-1]. More men (68.2, 315/462) participated in this study than women. Most respondents were under the age group between 20 and 40 years (37.4, 173/462). Surprisingly, most of them had graduate degree (63, 291/462) of which bachelor's degrees are followed by post graduates. Various studies have concluded that the education of responders was considered as major influencing factor for self-medication [7,9].

Among study population, private employers used OTC drugs more frequently (28.8, 133/462). So, on closer inspection, educated people are more likely to use over-the-counter drugs than illiterate people. Similar observation was documented by earlier study [10]. Although some doctors and medical students have also participated in the study, despite their greater medical expertise, they were not allowed to replace the use of over-the-counter medications. Half of the participants (46.1, 213/462) belonging to Tamilnadu and Pondicherry whereas the other parts of India was 36.1% (167/462). This could be because Pondicherry hires more people from other states. Another reason for this is that Puducherry is one of the famous tourist destinations and parts of Tamil Nadu are surrounded by the Pondicherry region.

The majority of participants visited pharmacies without a prescription, and an almost equal number also have expired prescriptions [Table/Fig-2]. Many people who carry medicines without a prescription know the names of the medicines used to treat diseases. They get this information through the Internet, friends, neighbors and famous doctors. Not knowing the name of the medication, half of the participants simply described their symptoms to the pharmacist before making a purchase. These people may not be aware of the worsening of their condition and the side effects of the medication if they buy the medication by name or symptoms.

Over-the-counter medications are used to treat the complaints listed in the table [Table/Fig-3]. Like previous studies, fever is one of the most common

symptoms[11], followed by many associated symptoms and chronic diseases such as hypertension, diabetes, asthma, epilepsy, cancer, etc. Despite the fact that the majority of these symptoms call for proper medical treatment, these patients approach the pharmacy without prescription or outdated prescription. With these over-the-counter medications, their symptoms may be reduced, but the progression of the disease remains questionable. Hence, it is better to consult a doctor when they need medical attention.

Out of 462 patients, a total of 26 different groups of oral drugs, 3 different topical drugs and 15 different injections were purchased as OTC [Table/Fig-4]. Almost all the patient's purchased combinations of drugs despite their main symptoms were associated to particular disease. Some of the life-saving drugs used in emergency department have also been given as OTC without doctor's prescription. Nearly all the commonly prescribed drugs with severe adverse effects also bought from the pharmacy without prescription. Some pharmacies had restrictions on what medications they may give to patients, but few pharmacies given the drug without any restriction to patients. Antimicrobials, anti-

hypertensive, insulin and drugs with narrow therapeutic range were also given to the patient without any investigations and doctor's consultation. In rural areas of Pune, NSAIDs (33.33%), antibiotics (10.32%), vitamins (14.08%), and Gastro intestinal tract ailment drugs (13.61%) are most used as self-medication [12]. Even though certain drugs are regarded to be safe, the adverse effects caused by few drugs are unimaginable.

#### Adverse effects

Among 462 participants, only few (3.0, 14/462) were experienced with adverse effects due to drugs. Mild hypersensitivity type of reactions was occurred in few and others experienced gastritis and diarrhea. Most of them not presented to pharmacy about any other issues, although it is uncertain whether they have presented to hospitals with any other serious adverse reactions.

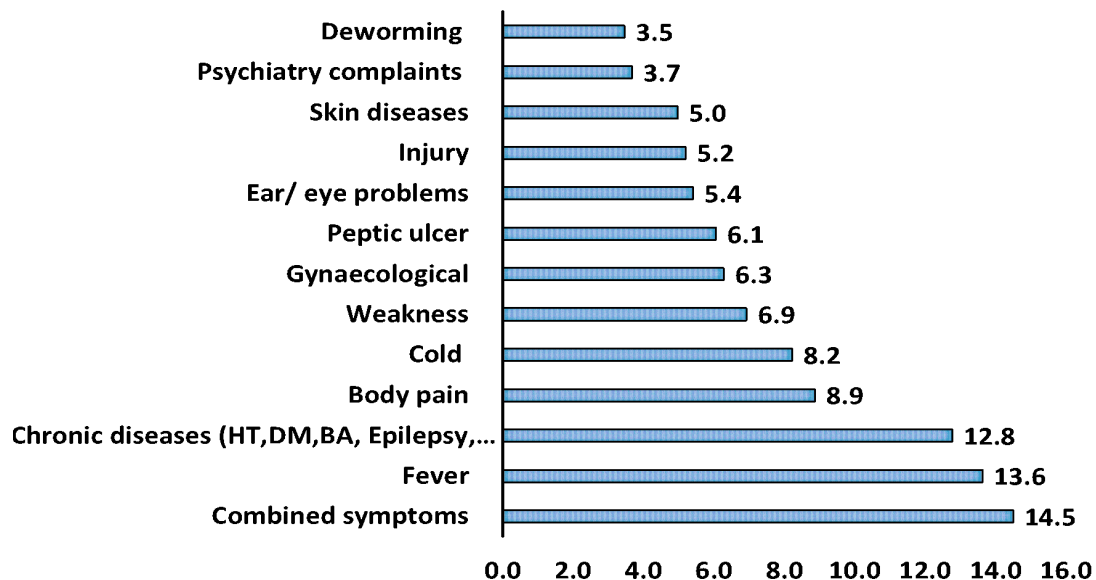
Majority of them purchased drugs for 1 or 2 doses only and few bought drugs for entire course. Even while they do not complained of adverse effects, it is still uncertain whether they had symptomatic relief or were cured of their illness. Few studies in South India had opined the similar features[13].

**Table 1: Demographic characteristics of study participants**

Sample characteristics (n=462)	Frequency	(%)
<b>Age (years)</b>		
<20	68	14.7
20-40	173	37.4
40-60	157	34.0
>60	64	13.9
<b>Gender</b>		
Male	315	68.2
Female	126	27.3
Transgender	21	4.6
<b>Education</b>		
Illiterate	41	8.9
Primary	78	16.8
secondary	52	11.3
Graduate	159	34.4
Postgraduate	132	28.6
<b>Occupation/Profession</b>		
Government employers	96	20.8
Private employers	133	28.8
self-employers	83	18.0
Unemployed	42	9.1
students	59	12.8
Medical and paramedical employers	49	10.6
<b>Demographic distribution</b>		
Western Indians	42	9.1
Eastern Indians	31	6.7
North Indians	94	20.3
Other Southern Indians	82	17.7
Tamilnadu	108	23.4
Pondicherry	105	22.7

**Table 2: Method of procurement of OTC drugs**

OTC purchase	Frequency (n=714)	(%)
Old prescription	210	45.5
Without prescription	252	54.5
(a) Aware of drug name	133	52.8
(b) Without aware of drug name	119	47.2

**Figure 1: Symptoms for which OTC drugs are purchased****Table 4: Suspicious request for prescription and OTC drugs**

S. No	(A) Drugs	Total number of people purchased the drug (n=701)	(%)
1	Tab. Para	72	10.26
2	Tab. Aceclofenac + para	43	6.13
3	Tab. Pantoprazole	32	4.56
4	Tab. Azithromycin	19	2.71
5	Tab. Amoxicillin+clavulanic acid	17	2.42
6	Tab. Junior lanzol	9	1.28
7	Tab. Rantac	58	8.26
8	Tab. Gelusil	42	5.98
9	Tab. Multivitamin	34	4.84
10	Tab. Albendazole	22	3.13
11	Tab. Bisacodyl	11	1.57
12	Tab. Cetrizine, levocetizine& pheniramine maleate	27	3.85
13	Tab. Alprazolam, clonazepam & escitalopram	16	2.28
14	Tab. Losartan	9	1.28
15	Tab. Furosemide	11	1.57
16	Tab. Atenolol	19	2.71
17	Tab. Metformin	26	3.70
18	Tab. Glibenclamide	22	3.13
19	Tab. Salbutamol	23	3.28
20	Tab. Deriphylline	19	2.71
21	Tab. Amlodipine	20	2.85
22	Tab. Aspirin	32	4.56
23	Tab. Sorbitrate	17	2.42
24	Tab. Ondansetron	26	3.70
25	Cough syrup & liquid dosage forms	44	6.27
26	ORS	31	4.42
	<b>(B) Injections</b>	<b>(n=207)</b>	<b>(%)</b>

1	Inj. Para	31	14.98
2	Inj. Diclofenac	27	13.04
3	Inj. Pantoprazole	9	4.35
4	Inj. Multivitamin	18	8.70
5	Inj. Calcium gluconate	5	2.42
6	Inj. Botrophase	3	1.45
7	Inj. TT	19	9.18
8	Inj. Dexamethasone	11	5.31
9	Inj. Deriphylline	15	7.25
10	Inj. Insulin	27	13.04
11	Inj. Furosemide	7	3.38
12	Inj. Hydrocortisone	3	1.45
13	Inj. Ondansetron	13	6.28
14	Iv fluids	17	8.21
15	TPN	2	0.97
	<b>(C) Preparations</b>	<b>Number of person (101)</b>	<b>(%)</b>
1	Ointments/ cream/gel/	35	34.65
2	Eye/ear drops	27	26.73
3	Medicated shampoo, soap	39	38.61

### Conclusion

Pharmacies that sell over-the-counter (OTC) medications can help the customers in managing their symptoms on their own.

Over-the-counter medications may provide advantages such as lower prices, more availability, convenience, and the capacity for self-management of sickness.

However, addiction and risks from using some OTC medications are becoming better acknowledged. When the risks and adverse effects outweigh the benefits, overconsumption is defined as misuse or abuse.

This goes beyond the accepted medical practice or standards. When it comes to administering medications without a prescription, pharmacies should be the major target of rigorous regulations and constant attention.

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