

OVER-THE-COUNTER DRUG USE, ADVERSE DRUG REACTION AWARENESS, AND PHARMACOVIGILANCE PRACTICES AMONG MIGRANT WORKERS AND COMMUNITY PHARMACISTS: A CROSS-SECTIONAL STUDY

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ABSTRACT

Over-the-counter (OTC) medications are extensively used for self-medication because of their easy accessibility, affordability, and convenience. However, irrational and unsupervised use may result in adverse drug reactions (ADRs), drug interactions, therapeutic failure, and other medication-related complications. Migrant workers constitute a vulnerable population with limited access to healthcare services, making them particularly susceptible to inappropriate OTC drug use. Community pharmacists play a pivotal role in promoting rational drug use and strengthening pharmacovigilance.

This study aimed to evaluate the pattern of OTC drug use and ADR awareness among migrant workers and to assess the knowledge, attitude, and practices (KAP) of community pharmacists regarding pharmacovigilance and ADR reporting.

A descriptive cross-sectional study was conducted using a structured, validated questionnaire among migrant workers and community pharmacists. Information on demographic characteristics, OTC medication use, self-medication practices, ADR awareness, and familiarity with the Pharmacovigilance Programme of India (PvPI) was collected. Community pharmacists were additionally evaluated for their pharmacovigilance-related KAP. Data were analysed using descriptive statistics.

KEYWORDS: bOTC drugs; pharmacovigilance; adverse drug reactions; migrant workers; community pharmacists; self-medication; awareness; reporting; India; safety.

INTRODUCTION

Pharmacovigilance is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly, long term and short-term effects of medicines. Recently, its concerns have been spread to cover herbal products, blood products, traditional and complementary medicines, medical devices and vaccines. Clinical development of a drug is a complex process, but they will only have been tested for short term safety and efficacy on a limited number of individuals. Thus, Pharmacovigilance is required for early detection of new adverse drug reactions or for identification of patients with exceptional sensitivity and measures for management of such risks. Also, Pharmacovigilance should maintain a strong link with the drug regulatory authorities to ensure safety of medicinal products [1, 2]. Pharmacovigilance is essential for the safe, rational, as well as cost-effective utilization of medicines worldwide; it plays an important role in improving the clinical outcomes and also decreasing mortality and morbidity rates. The success of pharmacovigilance centres depend on the rate of effective and spontaneous reporting of suspected adverse drug reactions (ADRs), as is considered the core component of pharmacovigilance activities.[3]

Pharmacovigilance should however not be limited to the reporting of classical adverse effects, it should also be concerned with identification of product defects, unexpected insufficient therapeutic effects, intoxications and misuse – abuse situations.[4]

1.1 Over-The-Counter Drugs

The non-prescriptive drugs or over-the-counter drugs (OTCs) are the drugs that are purchased without prescription. There are currently more than 300000 different OTC drugs available only in US. The list of OTC drugs in the modern society is over expanding with the inclusion of new formulations and prescription to OTC switches. As the general rule OTC drugs have to be primarily used to treat a condition that does not require the direct supervision of a doctor and must be proven to be reasonably safe and well tolerated.

There is no regulation for the use of OTC drugs in India. Further in the absence of strategic consideration for the use of OTC drugs, chaos prevails and the reasons for these alarming situations are manifold. Perhaps, the poor economic status and busy lifestyle of an individual makes him rely on the OTC drugs. In India (1995), it has been shown that literate

people were 76% more likely to self-medicate than illiterate people. It is evident with research that self-care improves the health care awareness and reduces the economy related to health care. Although OTC drugs are believed to be safe and effective, indeed they are not. They mask the underlying disease and may cause several adverse effects.^{8,9} Therefore the study was taken up to analyse the population at risk, rate of self medication, extent of OTC use and awareness of the adverse effects among the participants.^[5]

The class of OTC drugs includes vitamins, tonics, iron preparations, analgesics, nonsteroidal anti-inflammatory drugs (NSAIDs), cough mixtures, skin care products, sore throat products, antipyretics, and laxatives. Despite all their benefits, improper use of medicines can bring potential health hazards and evidence continue to mount that adverse reactions to medicines are common, yet often preventable, cause of illness, and even death is evident.

OTC medicines can be classified into two categories: • First category OTC medicines are those which were non-prescription medicines since the time they were introduced. • The second category OTC medicines are those that had been prescription medicines initially but were later shifted to the OTC category ^[6].

Over-the-counter (OTC) medicines are medicines that may be sold directly to a consumer without a prescription from pharmacy personnel, as compared to prescription drugs, which are dispensed only to consumers possessing a valid prescription. Lack of adequate knowledge about OTC medications may directly lead to bad outcomes, such as overuse or non-compliance to treatment programs. There are several potential risks with the use of inappropriate self-medication such as the risk of adverse drug reactions, risk of wrong use of drugs, risk of missing the diagnosis, risk of drug dependence, risk of drug-drug, drug-food, drug-disease interactions, risk of overuse or toxicity.^[7]

In India, though OTC has no legal recognition, all the drugs that are not included in the list of prescription drugs“ are considered as OTC drugs. Although OTC drugs are of proved efficacy and safety, their improper use due to lack of knowledge regarding their side effects and interactions could have serious implications in general population. Furthermore, the use of such products may delay/mask the diagnosis of serious illness, with increased risks of interactions, adverse reactions, misuse/abuse of such products.^[13]

1.2 Adr (Adverse Drug Reaction)

Adverse drug reaction (ADR) which is defined as ‘response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.^[4]

ADR is defined by WHO as “any noxious, unintended, and undesired effect of drug that occurs as a result of treatment with drug at normal doses used in man for diagnosis, prophylaxis, and treatment”. ADRs are considered a major cause of patients’ morbidity, mortality, hospital admissions, as well as increasing length of hospitalization and cost of treatment. Literature demonstrates the importance of involving pharmacists in ADR reporting and considered pharmacists the most valuable sources of spontaneous reporting of ADRs ^[3]

ADRs are common cause of morbidity and mortality in both hospital and community settings. ADRs are responsible for about 5%-20% of hospital admissions. It has major impact on public health by imposing a considerable economic burden on the society and the already stretched health care systems ^[4]

1.2.1 Adr Related To Misuse Of Otc Medications

OTC drugs are relatively safe, however inappropriate use can lead to complications and adverse events that affect public health. Due to their greater availability and ease of acquisition, these drugs are consumed before or at the onset of symptoms.^[14] There has been an alarming increase in self-medication with these OTC medicines available in pharmacies and in retail outlets.^[13]

Non-steroidal anti-inflammatory drugs (NSAIDs) are mainly used for the management of inflammation and pain. Although several other classes of analgesics are available, most patients are either prescribed NSAIDs or consume NSAIDs without the consent of their physician (OTC route). ^[15] Gastrointestinal injuries, ranging from mild dyspepsia to life-threatening upper gastrointestinal bleeding and perforation, represent some of the most commonly reported adverse drug reactions (ADRs) associated with NSAID use. In addition to gastrointestinal effects, NSAIDs are also known to cause other important ADRs, including cutaneous reactions, renal complications, allergic responses, alterations in hepatic enzyme levels, and, in rare cases, hepatopathies.^[17] Approximately one-third of patients using NSAIDs experience foregut symptoms such as dyspepsia, including epigastric discomfort, bloating, post-prandial nausea, early satiety, and belching, as well as symptoms of gastroesophageal reflux like heartburn and regurgitation.^[18] The duration of NSAID use and the dose administered decide the severity of complications. Lim et al ^[16] in a review showed that the use of NSAIDs increased the risk of GI complications in 55-75% healthy volunteers ^[15]

Gastrointestinal ADRs are important indicators when evaluating the overall risk profile of NSAIDs ^[17]

1.3 Prevalence Of Otc Drug Use Among Migrant Workers

Migrant workers are helpless and exposed to many health issues such as decreased awareness about local health facilities, food insecurity, climate, and environmental hazards. Self-medication and over-the-counter (OTC) drug use are common among migrant workers due to easy availability of medicines, time constraints, and limited access to healthcare services.

A community-based study conducted among interstate migrant workers in Udupi taluk, Karnataka reported that 68.8% i.e., 263 of (382) of migrants practiced self-medication. Most of the participants stated that pharmacy (88.6%) is the primary source of self-medication. The majority of the participants were practicing self-medication for cough (24.7%) followed by fever (20.9%), followed by headache and fever (11.4%), and for fever and cough (17.9%).

A study conducted in Bangalore city by Shwetha et al [19]. reported that the study subjects utilized government health services more frequently than private services, thereby ruling out poor health-seeking behavior due to inadequate knowledge of available services. However, most migrants preferred over-the-counter drugs and home remedies as their first choice, which may be attributed to factors such as long working hours, easier accessibility of these options from their workplace, perceptions toward healthcare, and issues related to affordability.

A study conducted by Pranav et al. [20] among slum dwellers in Udupi Taluk had assessed the knowledge about the expiry date and more than 76% of the participants shown complete ignorance about it.

Most of the migrant workers perceive that they have minor illnesses and it is easily treatable with self-medication and they feel that self-medication saves time and is readily available at the pharmacy [11]

1.4 Pharmacist Role In Otc Medication Dispensing:

OTC product management is one of the central roles of community pharmacists, and one of the critical tasks is to educate and advise patients. Some people in need of over-the-counter drugs will need more information concerning the content of the drugs, the right proportions to take, as well as side effects. In these situations, pharmacists fill the knowledge gap with necessary counselling, which would inform the patient about the various OTC products available in the market and their uses, benefits, and associated risks. Pharmacists advise each customer based on the health condition, medical history, and signs or symptoms presented before being sold an OTC product. This individual approach also allows pharmacists to consult with patients appropriately and at the correct dosage. For example, if the patient is in search of remedies for cold and flu, their pharmacist could recommend a medicine that treats specific symptoms, i.e., a nasal decongestant for a stuffy nose or an expectorant for a persistent cough, and exclude any compounds that are dangerous to take together with other medicines. Furthermore, pharmacists counsel patients on how to properly use Over-the-counter products. They educate patients concerning possible consequences, how to identify complications, and what should be done if a problem occurs. This guidance is essential for patients with chronic diseases or those using prescription drugs because such patients could be more susceptible to bad reactions. Thus, by making sure that patients have a proper amount of data, a pharmacist helps to minimize the risks of dangerous self-treatment with OTC drugs [3].

Besides counselling, pharmacists screen and refer appropriate OTC products every occasion, depending on their health state. During the first pharmacy interview, patients are asked a few questions to gather information about their symptoms, past or present illnesses, or possible allergies. This process enables one to determine other factors that may contradict the use of OTC products, including pregnancy, high blood pressure, diabetes, or asthma. Screening also entails studying likely unwanted effects and interactions of the drug with other drugs.[9]

A drug-related problem (DRP) is an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes. Pharmacists are highly educated and have a professional responsibility for the efficient counselling of patients to ensure safe use of medication . They play a vital and proactive role in preventing and resolving DRPs and thus in preventing adverse events, avoiding extra costs resulting of inappropriate use of medications and adding value to patient safety. Pharmaceutical counselling provided by community pharmacies is particularly crucial when medications are purchased over-the-counter (OTC), without advice given by a physician. Consumers consider easily accessible OTC medications harmless and thus often underestimate the potential risks.

They have an incomplete awareness of several risk areas with regard to OTC medications, such as those relating to drug interactions and misuse/abuse.[10]

2. REVIEW OF LITERATURE

1. Ayenew and Tegegne et al. (2025) conducted a community-based cross-sectional study in Gondar City, Ethiopia, and reported a high prevalence (69.2%) of over-the-counter NSAID self-medication. About 11.2% of users experienced adverse drug reactions, with gastrointestinal complaints such as gastric discomfort, nausea, and heartburn being the most common. The study highlighted that easy OTC availability and reliance on community pharmacies contribute to inappropriate NSAID use and preventable ADRs. These findings emphasize the need for stricter regulation and pharmacist-led counseling to reduce OTC drug-related adverse outcomes.

2.Ochoa Mora et al. (2025) examined over-the-counter (OTC) medication use among Mexican immigrants in Southern Arizona and highlighted extensive self-medication practices, particularly with NSAIDs and acetaminophen. The increased reliance on OTC drugs post-migration raises concerns about adverse drug reactions (ADRs), especially gastrointestinal and drug-interaction-related effects due to unsupervised use. The study emphasized that limited healthcare access and prolonged OTC consumption may heighten the risk of preventable ADRs. These findings underscore the need for pharmacovigilance and patient education to reduce OTC-related adverse outcomes.

3.Chenyang Ma and Hanqing Zhang (2025) reported a high prevalence of over-the-counter drug self-medication among adolescents, particularly with analgesics and cold remedies. The study found poor awareness regarding correct dosing and potential adverse drug reactions, increasing the risk of medication-related harm. Reliance on non-professional sources such as family, peers, and online media further contributed to inappropriate OTC use. The authors emphasized the need for improved medication education, pharmacist involvement, and regulatory control to reduce OTC-related adverse drug reactions.

4.Andy A, Andy D, Tharayil AS et al. (2024) conducted a s comprehensive study on the role of pharmacists in promoting the safe and effective use of over-the-counter (OTC) medications in retail pharmacy settings. The authors highlighted that pharmacists play a crucial role in guiding patients about appropriate product selection, correct dosage,

potential drug interactions, and side effects. The study emphasized the importance of pharmacist-patient communication and continuous professional education to ensure rational use of OTC drugs. It concluded that active pharmacist involvement significantly enhances patient safety and promotes responsible self-medication practices.

5.Kotian SD, Sumit K, et al. (2022) conducted a study on self-medication practices among migrant workers in Udupi district, published in the International Journal of Current Research and Review. The study reported a high prevalence of self-medication, commonly for ailments such as fever, headache, and cough. Convenience, previous experience, and easy access to medicines without prescription were the major contributing factors. The authors also noted poor awareness regarding potential adverse effects and emphasized the need for awareness programs and stricter regulatory measures to promote rational drug use.

6.Owusu et al. (2022) highlighted that inappropriate over-the-counter use of NSAIDs is strongly associated with gastrointestinal adverse drug reactions such as dyspepsia, gastritis, and gastrointestinal bleeding, particularly with prolonged or unsupervised use. Both studies emphasize that irrational OTC NSAID consumption significantly contributes to preventable ADRs and underscore the need for improved patient education, pharmacist involvement, and strengthened pharmacovigilance systems.

7.M. Kumaraswamy, Jithin et al. (2022) investigated over-the-counter drug use in community pharmacies and reported extensive self-medication, with analgesics and NSAIDs being the most commonly dispensed drugs. The study highlighted limited patient awareness regarding potential adverse drug reactions, despite the perception that OTC medicines are safe. Inadequate counselling and weak regulatory control were identified as factors contributing to inappropriate OTC use. The authors emphasized that improving public awareness and strengthening pharmacist-led guidance are essential to reduce OTC-related adverse drug reactions.

8.Gutlapalli and Navitha et al. (2022) highlighted widespread misuse of over-the-counter medicines in India, driven by irrational self-medication and weak regulatory enforcement. The authors reported that inappropriate OTC use of NSAIDs and other prescription-only drugs significantly contributes to adverse drug reactions, including gastrointestinal, renal, and cardiovascular toxicity. The review emphasized that the absence of a clearly defined OTC framework and limited pharmacist supervision increase the risk of preventable ADRs, underscoring the need for stricter regulation and improved patient education.

9.Foong Way David Tai, McAlindon ME et al. (2021) reported that widespread over-the-counter use of NSAIDs is commonly associated with gastrointestinal adverse drug reactions such as gastric irritation, epigastric pain, bloating, acidity, and dyspepsia. The authors highlighted that a substantial proportion of OTC NSAID users exceed recommended doses or fail to disclose use to healthcare professionals, increasing GI risk. Importantly, GI symptoms may occur even in the absence of visible mucosal injury, leading to under-recognition of harm. The study emphasizes rational OTC NSAID use and appropriate gastroprotective strategies to reduce preventable GI-related ADRs

10.Saeed and Umballi et al. (2021) assessed community pharmacists' awareness of adverse drug reactions and pharmacovigilance in Sudan and found substantial gaps in knowledge and ADR reporting practices. Limited training and poor familiarity with ADR reporting systems were identified as major barriers, despite pharmacists frequently encountering drug-related adverse effects. The study highlights that inadequate pharmacist involvement can contribute to under-reporting of ADRs associated with over-the-counter drug use. These findings emphasize the need to strengthen pharmacist education and pharmacovigilance to reduce preventable OTC drug-related adverse drug reactions.

11.Elizabeth T. et al. (2020) highlighted that non-steroidal anti-inflammatory drug, particularly diclofenac, are strongly associated with gastrointestinal adverse drug reactions due to cyclo-oxygenase inhibition and reduced prostaglandin-mediated gastric protection. Pharmacovigilance data from the UK MHRA Yellow Card Scheme showed that gastrointestinal complications were the most frequently reported and clinically serious ADRs, even among children and adolescents. The study underscores that unsupervised or prolonged NSAID use can lead to severe, preventable GI outcomes. These findings reinforce the importance of cautious OTC NSAID use, early recognition of GI symptoms, and strengthened ADR reporting system.

12.Almubark RA, Aljadani RH, et al. (2020) conducted a national cross-sectional, pharmacy-based study in Saudi Arabia to estimate the prevalence of community-reported adverse drug reactions (ADRs). The study reported an annual population-weighted ADR prevalence of 28%, with gastrointestinal disorders being the most common reactions. Nonsteroidal anti-inflammatory drugs (NSAIDs) were the leading drug class associated with ADRs. The authors also found low public awareness and reporting of ADRs, highlighting the need for improved pharmacovigilance systems and patient education in Saudi Arabia

13.Chatterjee S, Dureja GP et al. (2015) conducted a multicentric cross-sectional study across India to assess the prevalence of NSAID-induced gastrointestinal, cardiac, and renal complications. The study reported a high point prevalence of gastrointestinal complications (30.08%) among NSAID users, indicating significant GI toxicity. Prolonged and excessive use of NSAIDs, especially through over-the-counter consumption, was identified as a major contributing factor. Elderly patients and those with existing comorbidities were found to be at higher risk. The authors emphasized the need for rational NSAID use and preventive strategies to reduce adverse drug reactions.

14.Lapeyre-Mestre M, Grolleau S et al. (2011) analyzed spontaneous reports from the French pharmacovigilance database (2002–2006) to evaluate adverse drug reactions associated with commonly used NSAIDs. The study identified gastrointestinal adverse reactions as one of the most frequently reported serious events, following cutaneous reactions. Certain NSAIDs, particularly ketoprofen, piroxicam, and naproxen, were associated with a higher risk of serious gastrointestinal complications. The findings highlight variability in safety profiles among NSAIDs and emphasize the importance of careful drug selection and risk assessment to minimize adverse drug reactions.

15.Horton and Stewart (2011) conducted a study to understand the reasons for self-medication and perceptions of risk among Mexican migrant farm workers. The study revealed that many workers practiced self-medication mainly due to barriers such as limited access to healthcare services, financial difficulties, and language barriers. Despite being aware of possible health risks, the participants considered self-medication as a convenient and necessary option to manage minor illnesses while continuing their work. The authors emphasized the need for improved healthcare accessibility and culturally appropriate health education to minimize unsafe self-medication practices and promote safer health behaviors among migrant populations.

3.AIM AND OBJECTIVE

3.1 AIM

To evaluate the ADR and assess the patterns of over-the-counter (OTC) drug use among migrant workers and to assess the awareness, attitudes, and pharmacovigilance practices of community pharmacists.

3.2 OBJECTIVES:

Primary Objective:

- 1.To assess the prevalence and pattern of over-the-counter (OTC) drug use among migrant workers.
- 2.To identify commonly used OTC drug categories and the self-reported adverse effects experienced by migrant workers.
- 3.To assess the level of awareness regarding adverse drug reactions (ADRs) and safe use of OTC medications among migrant workers.

Secondary Objective :

- 1.To identify factors influencing OTC drug use and occurrence of adverse effects among migrant workers, including age, self-medication practices, literacy level, and language barriers.
- 2.To assess the awareness, attitude, and reporting behavior related to ADRs among community pharmacists.
- 3.To identify barriers to ADR recognition and reporting among migrant workers and community pharmacists.

4.METHODOLOGY

4.1 Study Setting

The study was carried out at selected NHAI (National Highways Authority of India) construction sites and community pharmacies located in the Pilathara region.

4.2 STUDY DURATION

The study duration was 3 months.

4.3 STUDY POPULATION

The study population consisted of migrant workers in NHAI and community pharmacists in the same locality.

4.4 STUDY DESIGN

A cross-sectional, questionnaire-based study was conducted among migrant workers employed in the NHAI (National Highways Authority of India) construction sites and community pharmacists in the Pilathara region, aimed at assessing the prevalence and patterns of OTC drug use and the level of awareness regarding adverse drug reactions. A structured questionnaire was administered for migrant workers and pharmacists to collect the data.

4.5 SAMPLE SIZE

A sample size of 150 migrant workers.

4.6 STUDY PROCEDURE

The study was conducted among migrant workers and community pharmacists by using a structured questionnaire. The study population includes adult migrant workers currently employed in the selected worksite and registered pharmacists working in the community pharmacies in the same geographical area. The data was collected covering socio-demographic characteristics, OTC usage pattern, ADR recognition & awareness and reporting behavior. An informed consent will be secured from all participants with full assurance of confidentiality and voluntary participation. Questions were asked verbally and answers were collected.

4.7 STUDY CRITERIA

Inclusion criteria: MIGRANTS: Age > 20

Residing in the study area for at least 2 years PHARMASCISTS: Registered pharmacist

Exclusion criteria:

Workers who have language difficulty preventing effective communication

Workers who are unwilling to participate.

4.8 Statistical Analysis

The collected data was entered into a spreadsheet format using Microsoft office excel. Percentage and frequency distribution used to present demographic characteristics ,prevalence of otc drug use, knowledge of ADR , commonly used OTC medicines, reporting behaviour and other answers obtained from migrants and community pharmacists from the questionnair ,statistical analysis were done using SPSS software.

5.RESULT

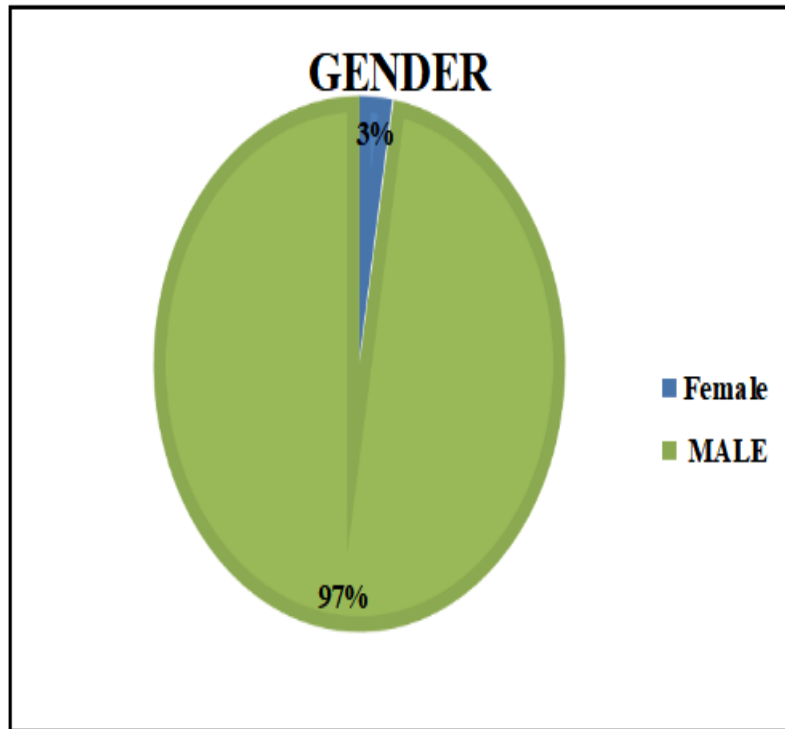
The duration of study was 3 months and the data was collected from NHAI construction site and community pharmacy located in Pilathara region. The study included 150 migrant workers and 33 community pharmacists. They were administered a questionnaire via direct contact and it satisfied all the inclusion and exclusion criteria of the study

5.1 Data Analysis

Demographic Characteristics Of Respondents

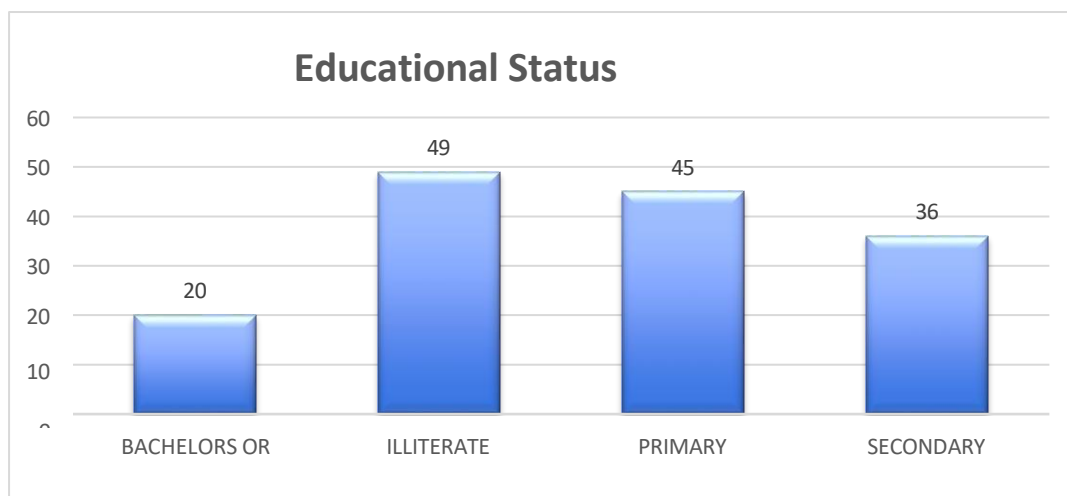
This Table shows the demographic profile of the respondents including age, gender, education and occupation.

Gender:



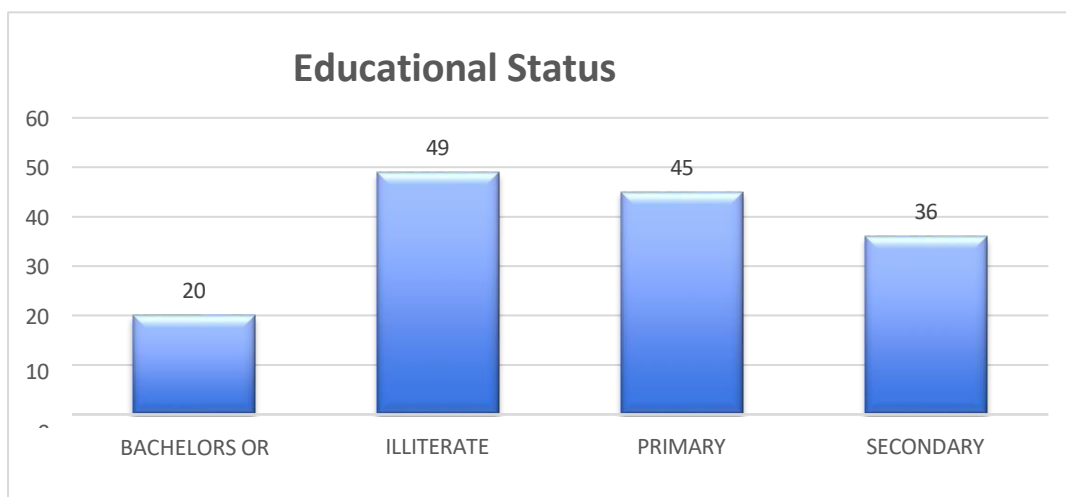
Educational Status:

A significant proportion of participants (32.7%) were illiterate, (30%) were primary, (24%) were secondary, (13.3%) were bachelors or diploma education



Occupation:

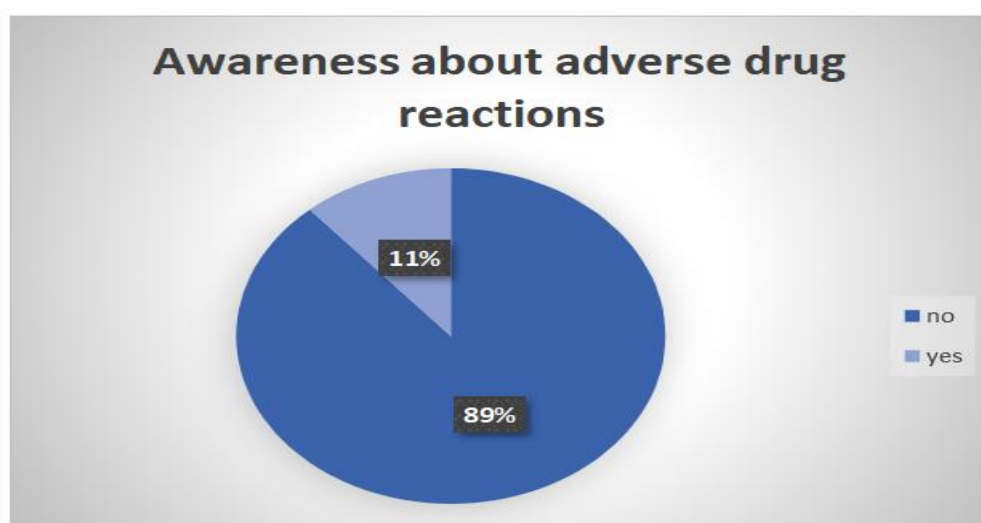
Majority of them were construction workers (45.3%),driver(12.3%),canteen/food related (4.7%),operator (3.3%),skilled workers (7.3%),business(0.7%),security(1.3%),others(24.7%).



AWARENESS ABOUT ADVERSE DRUG REACTIONS (ADRS)

This Table shows the awareness of respondents regarding adverse drug reactions.

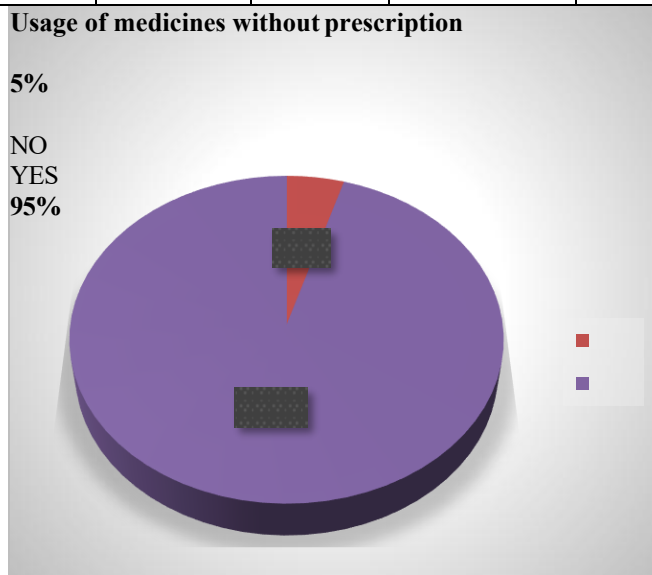
Awareness about adverse drug reactions					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	no	132	88.0	88.6	88.6
	yes	17	11.3	11.4	100.0
	Total	149	99.3	100.0	
Missing	System	1	.7		
Total		150	100.0		



USE OF OVER-THE-COUNTER (OTC) MEDICINES

Usage of medicines without prescription

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	no	7	4.7	4.7	4.7
	yes	143	95.3	95.3	100.0
	Total	150	100.0	100.0	



OPINION ON IMPORTANCE OF REPORTING ADR REACTIONS

5.2 Objective 1

To assess the pattern of OTC drug use and awareness regarding Adverse Drug Reactions (ADR) among migrant workers.

To Analyse the objective, we are using Chi square test for Educational ADR Awareness

ADR Awareness × Importance of ADR Reporting ADR Experience × Reporting ADR

Source of Information × ADR Awareness

5.2.1 Education × ADR Awareness

A statistically significant association was observed between educational status and awareness about adverse drug reactions ($\chi^2 = 23.449$, $df = 3$, $p < 0.05$). This indicates that awareness regarding adverse drug reactions varies significantly with the level of education.

Respondents with higher educational status showed greater awareness about adverse drug reactions compared to those with lower educational levels

Educational status of the respondent * Awareness about adverse drug reactions Crosstabulation					
			Awareness about adverse drug reactions		Total
			no	yes	
Educational status of the respondent	Illiterate	Count	47	1	48
		%within Educational status of the respondent	97.9%	2.1%	100.0%
		% within Awareness about adverse drug reactions	35.6%	5.9%	32.2%
	Primary	Count	43	2	45
		%within Educational status of the respondent	95.6%	4.4%	100.0%

	Secondary	% within Awareness about adverse drug reactions	32.6%	11.8%	30.2%
		Count	30	6	36
		%within Educational status of the respondent	83.3%	16.7%	100.0%
	Graduate & above	% within Awareness about adverse drug reactions	22.7%	35.3%	24.2%
		Count	12	8	20
		%within Educational status of the respondent	60.0%	40.0%	100.0%
		% within Awareness about adverse drug reactions	9.1%	47.1%	13.4%
	Total	Count	132	17	149
		%within Educational status of the respondent	88.6%	11.4%	100.0%
		% within Awareness about adverse drug reactions	100.0%	100.0%	100.0%

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	23.449a	3	0.000
Likelihood Ratio	20.341	3	0.000
Linear-by-Linear Association	19.627	1	0.000
N of Valid Cases	149		
a. 2 cells (25.0%) have expected count less than 5. The minimum expected count is 2.28.			

5.2.2 ADR Awareness × Importance of ADR Reporting

A statistically significant association was observed between awareness about adverse drug reactions and opinion regarding the importance of reporting adverse drug reactions ($\chi^2 = 6.763$, $df = 2$, $p < 0.05$). This indicates that respondents who were aware of ADRs were more likely to consider ADR reporting as important.

Purchase of medicines without prescription * Experience of adverse drug reactions Crosstabulation						
			Experience of adverse drug reactions			Total
			yes	no	not sure	
Purchase of medicines without prescription	no	Count	2	3	2	7
		% within Purchase of medicines without prescription	28.6%	42.9%	28.6%	100.0%
		% within Experience of adverse drug reactions	6.9%	15.0%	2.0%	4.7%
	yes	Count	27	17	99	143

		% within Purchase of medicines without prescription	18.9%	11.9%	69.2%	100.0%
		% within Experience of adverse drug reactions	93.1%	85.0%	98.0%	95.3%
Total	Count		29	20	101	150
	% within Purchase of medicines without prescription		19.3%	13.3%	67.3%	100.0%
	% within Experience of adverse drug reactions		100.0%	100.0%	100.0%	100.0%

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	6.763a	2	0.034
Likelihood Ratio	5.463	2	0.065
Linear-by-Linear Association	2.641	1	0.104
N of Valid Cases	150		
a. 3 cells (50.0%) have expected count less than 5. The minimum expected count is .93.			

5.2.3 ADR Experience × Reporting ADR

No statistically significant association was observed between awareness about adverse drug reactions and the person to whom the adverse drug reaction was reported ($\chi^2 = 2.924$, $df = 2$, $p > 0.05$). This indicates that being aware of ADRs did not meaningfully influence whether respondents reported the reaction to a pharmacist, doctor, or did not report it at all.

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	6.763a	2	0.034
Likelihood Ratio	5.463	2	0.065
Linear-by-Linear Association	2.641	1	0.104
N of Valid Cases	150		
a. 3 cells (50.0%) have expected count less than 5. The minimum expected count is .93.			

5.2.4 Source of Information × ADR Awareness

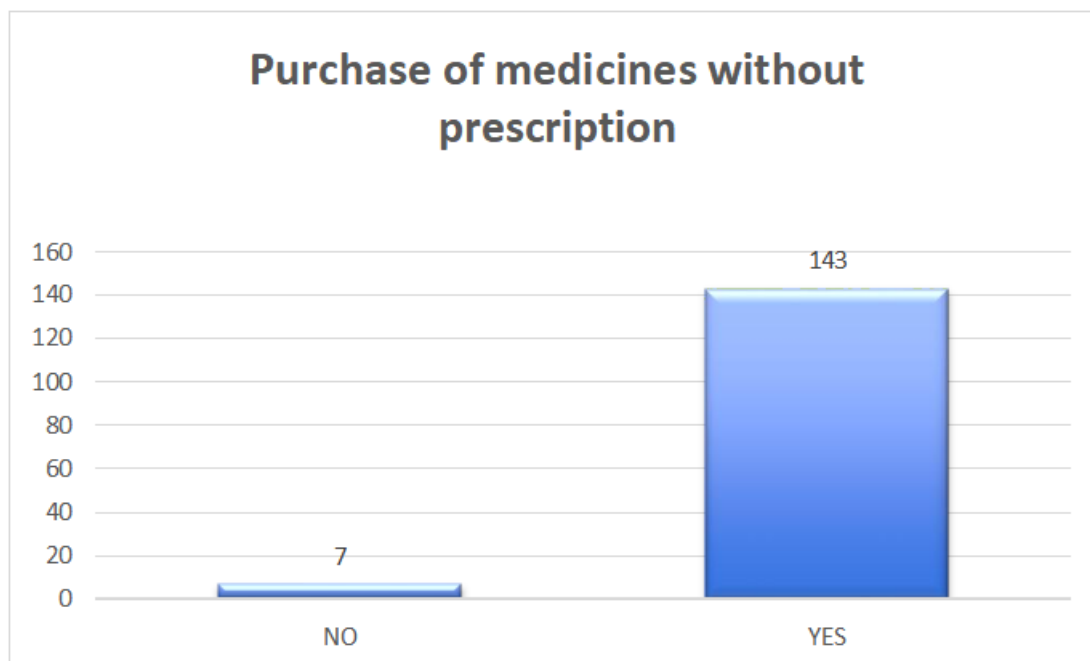
A statistically significant association was observed between educational status of the respondent and opinion on the importance of reporting adverse drug reactions based on the Likelihood Ratio test ($\chi^2 = 14.152$, $df = 6$, $p < 0.05$). This indicates that respondents with higher educational levels, particularly graduates and above, were more likely to consider ADR reporting as important compared to illiterate, primary, and secondary educated participants.

Educational status of the respondent * Opinion on importance of reporting adverse drug reactions
Crosstabulation

			Opinion on importance of reporting adverse drug reactions			Total
			Yes	no	not sure	
Educational status of the respondent	Illiterate	Count	14	3	32	49
		% within Educational status of the respondent	28.6%	6.1%	65.3%	100.0%
		%within Opinion on importance of reporting adverse drug reactions	22.2%	60.0%	39.0%	32.7%
	Primary	Count	20	2	23	45
		% within Educational status of the respondent	44.4%	4.4%	51.1%	100.0%
		%within Opinion on importance of reporting adverse drug reactions	31.7%	40.0%	28.0%	30.0%
	Secondary	Count	15	0	21	36
		% within Educational status of the respondent	41.7%	0.0%	58.3%	100.0%
		%within Opinion on importance of reporting adverse drug reactions	23.8%	0.0%	25.6%	24.0%
	Graduate & above	Count	14	0	6	20
		% within Educational status of the respondent	70.0%	0.0%	30.0%	100.0%
		%within Opinion on importance of reporting adverse drug reactions	22.2%	0.0%	7.3%	13.3%
Total		Count	63	5	82	150

5.3 Objective 2

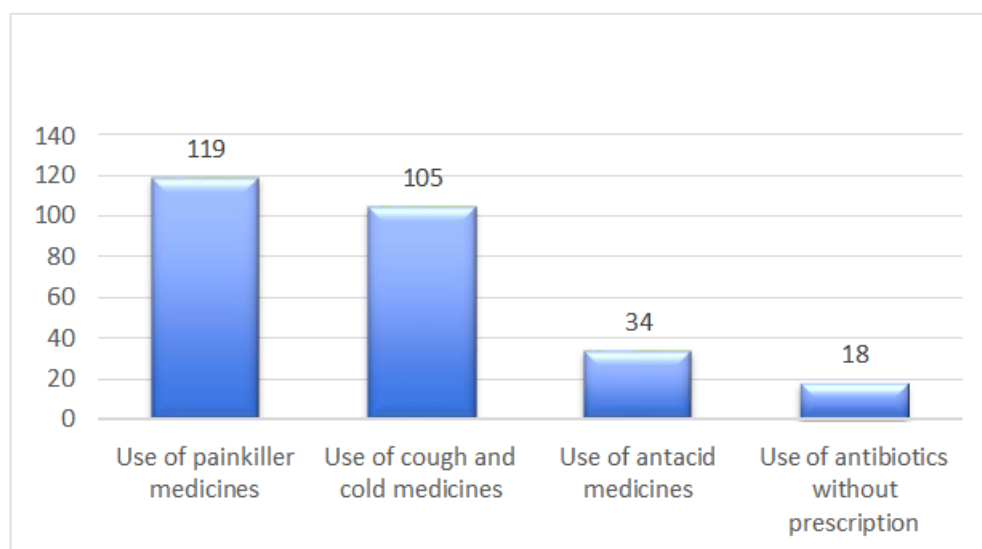
To identify the frequency of OTC drug use without prescription among migrant workers



The frequency analysis showed that a majority of migrant workers purchased medicines without prescription. A considerable proportion also reported the use of antibiotics without prescription.

5.4 Objective 3

To identify the most commonly purchased OTC drug category

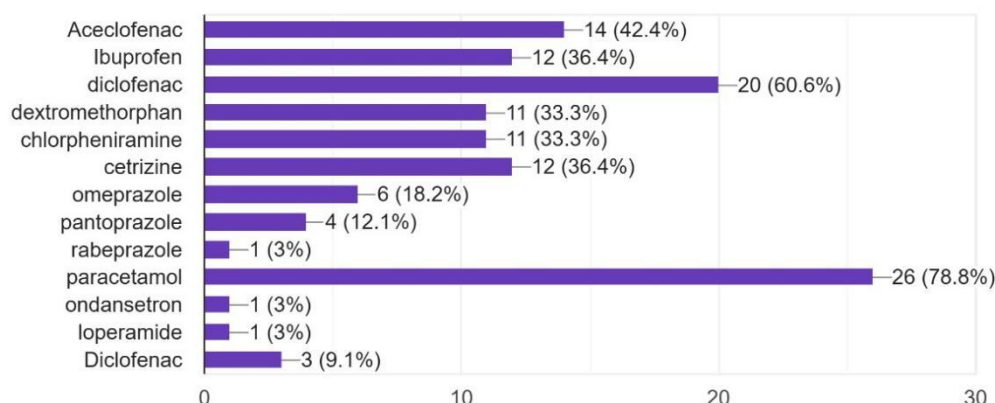


The multiple response analysis revealed that painkillers were the most commonly purchased OTC drug category among migrant workers. This was followed by cough and cold medicines and antacids. Antibiotics were also purchased without prescription by a smaller proportion of respondents.

The frequent purchase of painkillers may be attributed to the physically demanding nature of work among migrant workers. Easy availability and previous experience with these medicines may encourage their repeated use without medical supervision.

5.4.1 Specific Drug From This Categories Which Has Been Dispensed The Most

Which specific medicine from the above category do you dispense most frequently?
33 responses

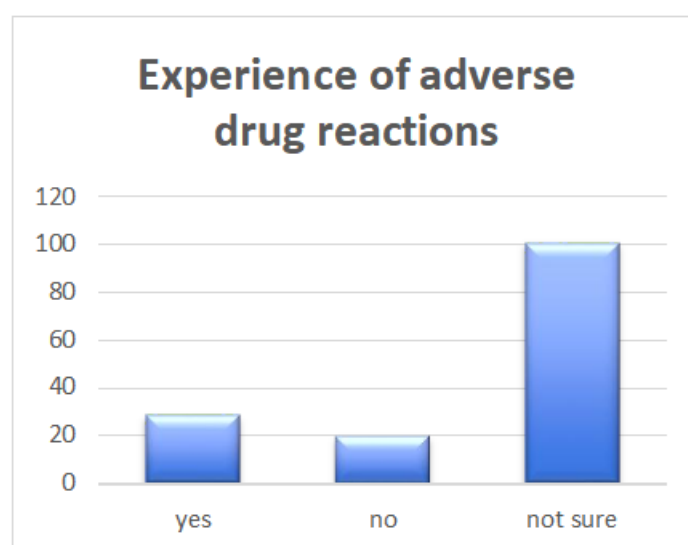


From the data obtained , paracetamol is the drug which is dispensed the most (78.8%),diclofenac (69.7%), acetoclofenac (42.4%), cetirizine (12%), ibuprofen (12%),dextromethorphan , chlorpheniramine (11%), omeprazole (6%),pantoprazole (4%),rabeprazole ,ondansetron,loperamide(1%).etc

5.5 Objective 4

To identify the adverse drug reactions (ADRs) experienced by migrant workers following over-the-counter (OTC) medication us

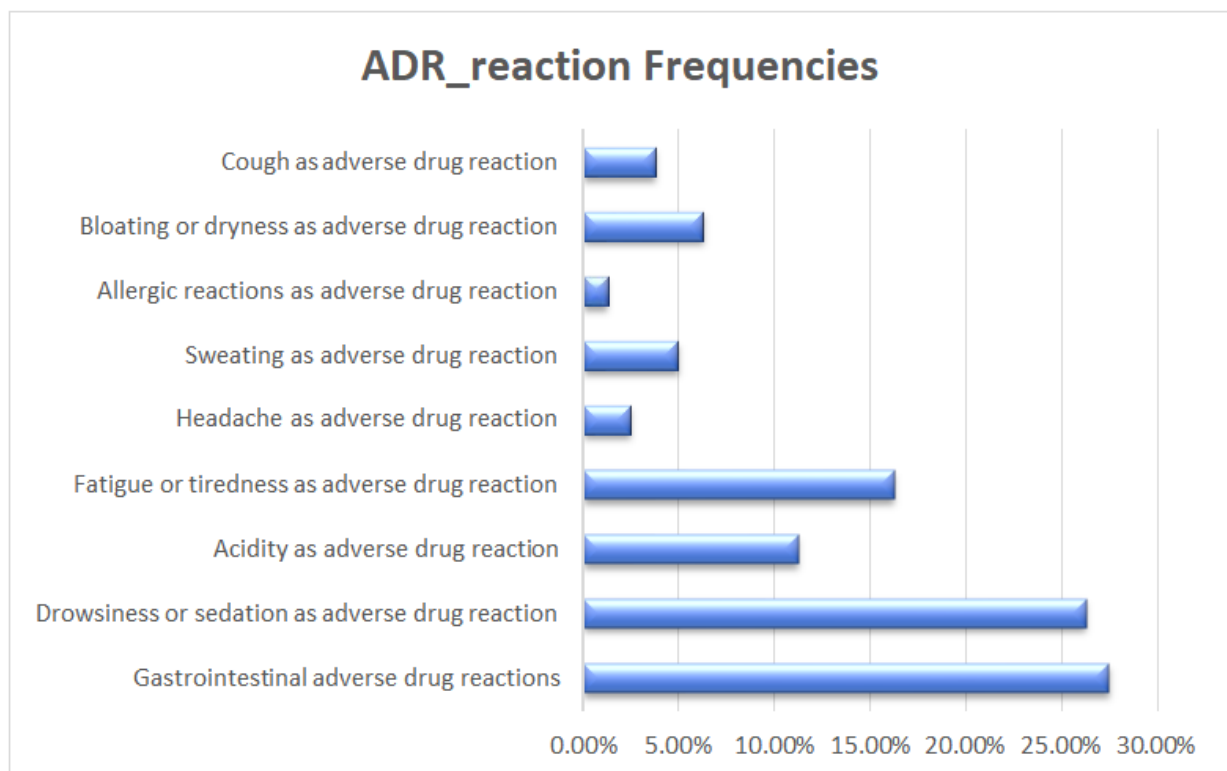
Experience of ADRs among migrant worker



Types of ADRs experienced by migrant workers

ADR_reaction Frequencies				
		Responses		Percent of Cases
		N	Percent	
Most commonly reported ADR reactiona	Gastrointestinal adverse drug reactions	22	27.5%	42.3%

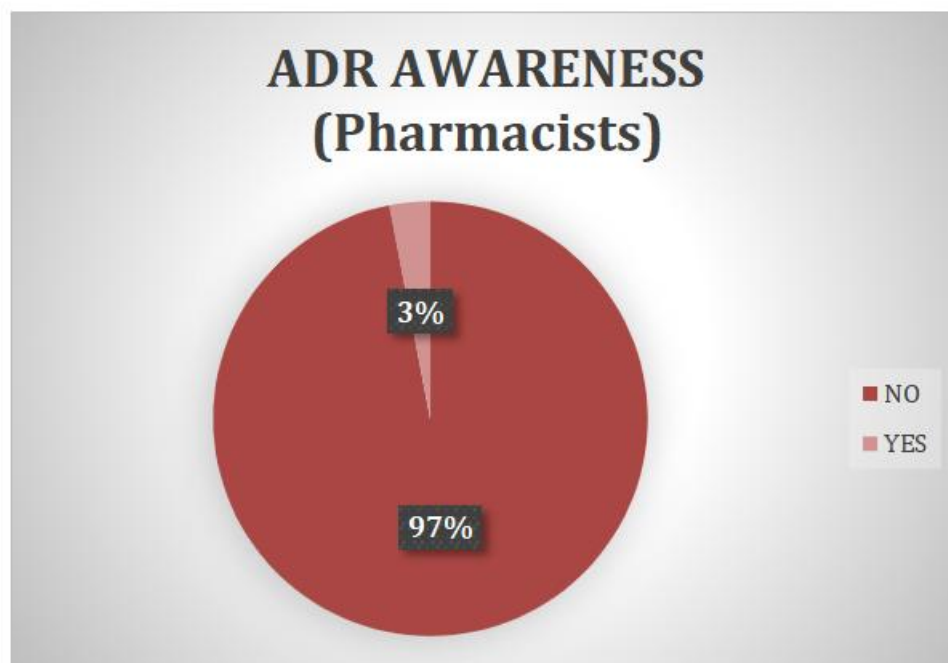
	Drowsiness or sedation as adverse drug reaction	21	26.3%	40.4%
	Acidity as adverse drug reaction	9	11.3%	17.3%
	Fatigue or tiredness as adverse drug reaction	13	16.3%	25.0%
	Headache as adverse drug reaction	2	2.5%	3.8%
	Sweating as adverse drug reaction	4	5.0%	7.7%
	Allergic reactions as adverse drug reaction	1	1.3%	1.9%
	Bloating or dryness as adverse drug reaction	5	6.3%	9.6%
	Cough as adverse drug reaction	3	3.8%	5.8%
Total		80	100.0%	153.8%
a. Dichotomy group tabulated at value 1.				



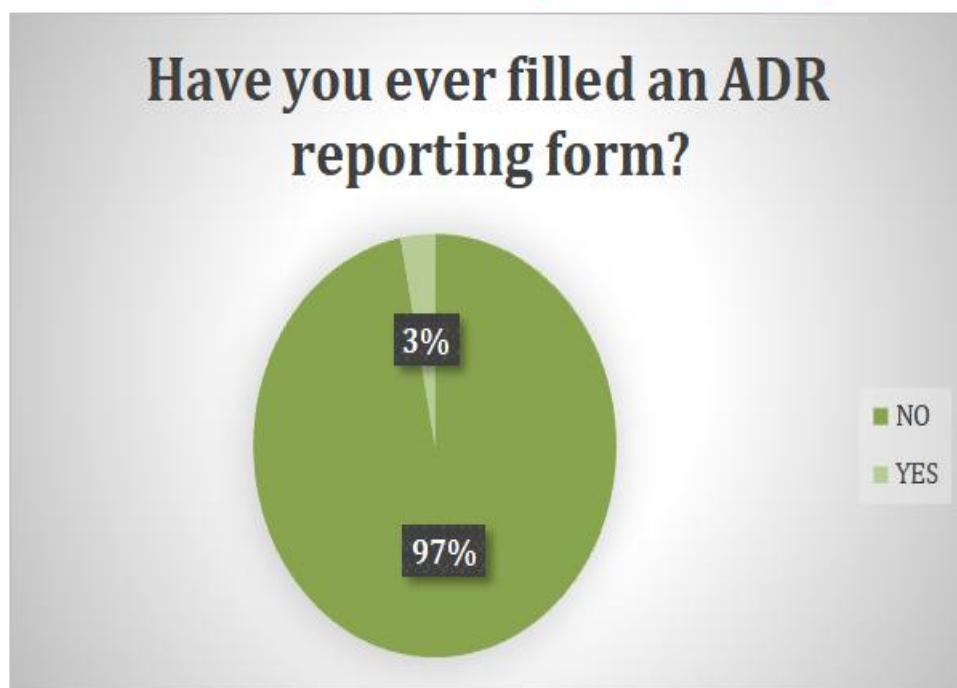
Multiple response analysis revealed that the most commonly reported adverse drug reactions among migrant workers included gastric irritation, acidity, drowsiness, fatigue, and headache. Other reported reactions included sweating, bloating, allergic reactions, and cough. This indicates that gastrointestinal and central nervous system-related adverse effects were predominant among migrant workers using OTC medications.

5.6 Objective 5

To assess pharmacists' awareness and knowledge regarding rational OTC use and ADR reporting



The analysis showed that 3% of pharmacists were aware of the Pharmacovigilance Programme of India (PvPI), whereas 97% reported no awareness. This indicates that nearly half of the pharmacists lack formal awareness of the national pharmacovigilance system.



The results indicate that an overwhelming majority of pharmacists (97%) had never filled an ADR reporting form, while only a very small proportion (2.9%) reported having filled such a form

Training on ADR Reporting:

A majority of pharmacists (76.5%) had not received any formal training related to ADR reporting or pharmacovigilance, while only (20.5%) reported having received such training.

Willingness To Receive Training



Most pharmacists (85.3%) expressed willingness to receive further training or workshops on pharmacovigilance and ADR reporting.

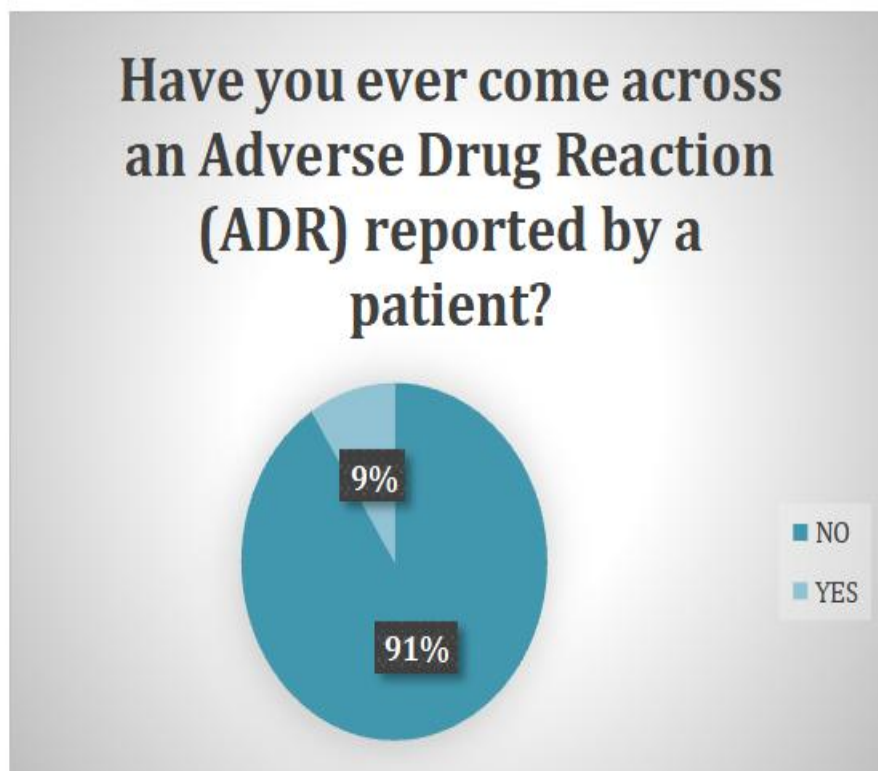
5.7 ADR KNOWLEDGE & ATTITUDE

Attitude towards Public Awareness Programs



The majority of pharmacists (87.9%) believed that pharmacists should be actively involved in ADR reporting, indicating a positive attitude towards their professional responsibility in ensuring drug safety.

5.8 Adr Experience & Practice:



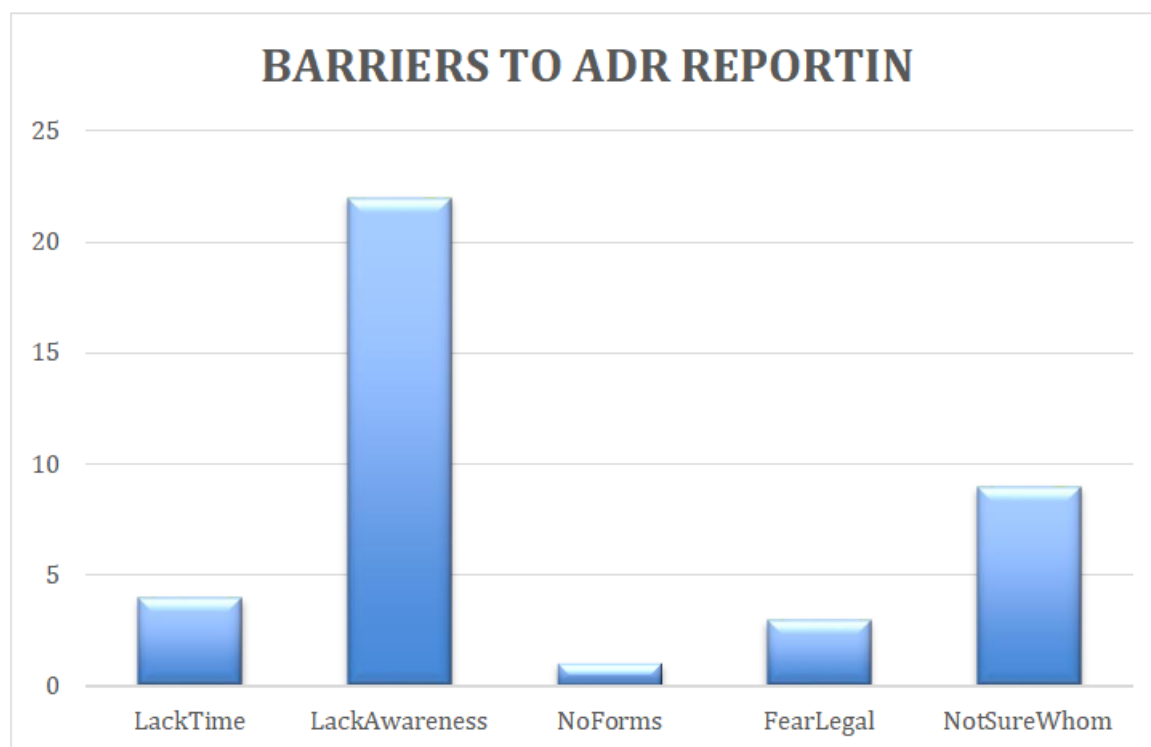
The findings reveal that a large majority of pharmacists (90.9%) had not encountered any adverse drug reactions (ADRs) reported by patients, whereas only a small proportion (9.1%) reported having come across ADRs in their professional practice.

5.9 ADR REPORTING PRACTICES AMONG PHARMACISTS



Among the pharmacists surveyed, only 3.0% reported ADRs to the appropriate authorities.

5.10 BARRIERS TO ADR REPORTING



Multiple response analysis revealed that the most commonly reported barrier to ADR reporting was lack of awareness (73.3%). Other reported barriers included uncertainty about whom to report to (30.0%), lack of time (13.3%), fear of legal issues (10.0%), and non-availability of reporting forms (3.3%).

6. DISCUSSION

The findings of the study reveal that over-the-counter medicine (analgesics, anti-inflammatory agents, and respiratory medications) use without prescription is common among migrant workers, primarily due to ease of access, time-saving, and previous experience with similar medications. This observation aligns with the socio-occupational profile of the study population, which includes prolonged physical labour, environmental exposure, and limited access to formal healthcare services. Such practices may contribute to irrational drug use and increase the risk of adverse drug reactions.

A considerable number of migrant workers reported experiencing adverse drug reactions such as gastric irritation, drowsiness, acidity, fatigue, and headache. These reactions may be attributed to improper dosage, prolonged use, and lack of professional guidance during medication use. The frequent usage of otc medications by the migrant workers were observed and have been answered positively to the structured questionnaire which is administered during the study period. Notably , gastrointestinal adverse drug reactions were the most commonly reported effects and were predominantly associated with OTC NSAID use. The findings of the present study are consistent with those report by Al mubarak RA et al [21] ,who similarly observed a high prevalence of adverse drug reactions among otc medicine users ,with gastro intestinal disorders being the most commonly reported effects .

The most commonly purchased category of otc medines was obtained from the data are According to the Anatomical Therapeutic Chemical (ATC) classification system:

□ **Paracetamol**–ATC Code: N02BE01

(Level 1: Nervous system – N; Level 2: Analgesics – N02)

□ **Diclofenac** – ATC Code: M01AB05

□ **Aceclofenac** – ATC Code: M01AB16

(Level 1: Musculoskeletal system – M; Level 2: Anti-inflammatory and antirheumatic products – M01)

paracetamol was the most frequently dispensed OTC medication (78.8%), followed by diclofenac (69.7%) and aceclofenac (42.4%). These drugs belong to the analgesic and anti-inflammatory category, indicating a high reliance on pain-relieving medications among the study population. This finding correlates with the physically demanding nature of migrant workers' occupations, particularly construction work, which involves prolonged manual labour, exposure to dust, vibration, and repetitive strain. Frequent musculoskeletal pain may drive repeated and unsupervised use of these medicines.

In this study, paracetamol emerged as the most commonly purchased over-the counter analgesics. Taken together ,the present study and the review by Bannwarth [21] , further support the well-established view that paracetamol, when used in therapeutic doses has a more favourable gastrointestinal safety profile than conventional non-steroidal anti-inflammatory drugs.

The predominance of ATC Level 1 groups N (Nervous system) and M (Musculoskeletal system) suggests that pain management is the primary therapeutic need among migrant workers. However, prolonged and frequent use of NSAIDs such as diclofenac and aceclofenac without medical supervision may explain the high prevalence of gastrointestinal adverse drug reactions observed in this study, including gastric irritation and acidity. This is consistent with the findings of Namgay Bhutia et al [23], who reported that gastrointestinal adverse effects constituted 51.37% of the total adverse reactions attributed to diclofenac and aceclofenac. (Highlighting their well-recognized gastrointestinal risk profile.)

[It is therefore reasonable to infer that the gastrointestinal adverse effects observed in the present study are more likely related to NSAID use rather than paracetamol itself.]

Antihistamines and cough suppressants such as cetirizine (12%), chlorpheniramine (11%), and dextromethorphan (11%) were also commonly dispensed. Their ATC classifications include:

- ☐ Cetirizine – R06AE07
- ☐ Chlorpheniramine – R06AB04
- ☐ Dextromethorphan – R05DA09

These drugs fall under ATC Level 1: Respiratory system (R), indicating frequent treatment of cough, cold, and allergic symptoms. The high exposure of migrant workers to dust, smoke, and environmental pollutants at construction sites likely contributes to respiratory complaints, explaining the demand for these medications. The reported ADRs such as drowsiness, sedation, fatigue, and excessive sweating are consistent with the known pharmacological profiles of first-generation antihistamines and centrally acting cough suppressants.

In line with our findings, Shah DK et al. [24] reported that cetirizine is associated with measurable sedative effects, including drowsiness, even at therapeutic doses, highlighting that second-generation antihistamines are not entirely free from central nervous system adverse effects.

Drugs used for gastric symptoms such as omeprazole (6%), pantoprazole (4%), and rabeprazole (1%) belong to:

- ☐ Omeprazole – A02BC01
- ☐ Pantoprazole – A02BC02
- ☐ Rabeprazole – A02BC04

These are classified under ATC Level 1: Alimentary tract and metabolism (A). Their use likely reflects self-treatment of NSAID-induced gastric discomfort, further supporting the association between high NSAID consumption and gastrointestinal adverse effects.

Additionally, medications such as ondansetron (A04AA01) and loperamide (A07DA03), though less frequently dispensed (1%), indicate self-management of nausea and diarrhea. This may be linked to poor sanitation, irregular meals, and occupational stress among migrant workers.

Overall, analysis of the ATC classification reveals that ATC Level 1 groups N (Nervous system), M (Musculoskeletal system), R (Respiratory system), and A (Alimentary tract) were the most commonly utilized. This pattern highlights a symptom-based, short-term, and largely unsupervised approach to medication use, rather than rational, diagnosis-based therapy.

The findings strongly correlate with the reported adverse drug reactions in this study, particularly gastric irritation, drowsiness, fatigue, and sweating, and underline the risks associated with irrational OTC drug use. The absence of prescription oversight, combined with limited awareness of ADRs and rare consultation with healthcare professionals, further exacerbates these risks.

These results emphasize the critical role of community pharmacists in monitoring OTC drug dispensing, providing patient counselling, identifying potential drug-related problems, and promoting ADR awareness. Strengthening pharmacist involvement and implementing targeted educational interventions for migrant workers could significantly improve medication safety and reduce preventable adverse drug reactions.

Among pharmacists, although a positive attitude towards pharmacovigilance and ADR reporting was observed, actual reporting practices were limited. Insufficient awareness, lack of training, and uncertainty regarding reporting procedures were identified as major barriers. These findings highlight the need to strengthen education and training initiatives to bridge the gap between knowledge and practice in ADR reporting.

Although many migrant workers reported experiencing symptoms such as gastric irritation, excessive sweating, and tiredness, most of them did not recognize these symptoms as adverse drug reactions. None of these effects were formally reported to doctors, pharmacists, or any pharmacovigilance authority; instead, they were mentioned only during direct interactions with the researchers. This clearly reflects underreporting of ADRs and a low level of awareness regarding pharmacovigilance. The findings support the study hypothesis that poor ADR reporting among migrant workers is not due to the absence of adverse effects, but rather due to limited awareness, lack of access to healthcare services, and inadequate knowledge about reporting mechanisms.

These observations highlight a significant gap in pharmacovigilance within community settings, especially among vulnerable populations such as migrant workers. The frequent use of over-the-counter medicines from certain ATC categories, along with continuous exposure to environmental hazards and infrequent consultation with healthcare professionals, increases the risk of preventable adverse drug reactions. In this context, community pharmacists play a

crucial role in bridging this gap by identifying drug-related problems, providing appropriate counselling, improving awareness about ADRs, and encouraging safe and rational use of medicines.

7. LIMITATIONS

The present study has certain limitations that should be considered while interpreting the results. The study was conducted over a short duration of three months, which restricted the assessment of long-term patterns of OTC drug use and delayed or cumulative adverse drug reactions.

The findings are primarily based on self-reported information collected through interviews, which may be subject to recall bias. In addition, some reactions may have been underreported due to lack of awareness or the perception that minor symptoms are not drug-related.

Another limitation is the lack of clinical confirmation of the reported adverse drug reactions. The ADRs identified were based solely on participants' experiences and were not validated through medical records or diagnostic investigations, making it difficult to establish a definitive causal relationship.

The study was conducted in a limited geographical area with a specific population group, which may limit the generalizability of the findings to other regions or migrant populations.

Despite these limitations, the study provides meaningful insights into OTC drug use, ADR awareness, and reporting behavior among migrant workers and highlights the need for improved pharmacist-led education and pharmacovigilance activities.

8. FUTURE RECOMMENDATIONS

Future studies should be conducted over a longer duration with a larger and more diverse sample size to better understand long-term patterns of OTC drug use and the progression of adverse drug reactions among migrant workers. Including participants from multiple geographical regions would improve the generalizability of the findings.

Clinical tests such as liver function tests, renal function tests, and gastric assessments could help confirm suspected ADRs related to commonly used drugs like analgesics, NSAIDs, and antibiotics, thereby improving the reliability of ADR identification.

Future research should also focus on structured pharmacist-led interventions, including counselling at the time of OTC dispensing, educational programs on safe medication use, and guidance on recognizing and reporting ADRs. Establishing simple and accessible ADR reporting mechanisms at community pharmacies may encourage better reporting behavior.

In addition, collaboration between community pharmacists, healthcare providers, and public health authorities is recommended to design awareness programs tailored specifically for migrant populations. Educational materials in local and understandable languages can further improve health literacy and promote responsible self-medication practices.

Overall, integrating clinical assessments with educational and pharmacovigilance strategies in future studies can significantly enhance patient safety, reduce preventable adverse drug reactions, and strengthen the role of pharmacists in community health care.

9. CONCLUSION

The present study demonstrates that the use of over-the-counter (OTC) medicines is highly prevalent among migrant workers, with self-medication largely driven by easy accessibility, occupational demands, and limited access to healthcare services. Despite experiencing symptoms suggestive of adverse drug reactions (ADRs), most participants failed to recognize these events or report them, indicating inadequate awareness of medication safety and pharmacovigilance practices. Although community pharmacists exhibited a positive attitude toward ADR monitoring and acknowledged the importance of pharmacovigilance, their actual reporting practices remained suboptimal because of insufficient training, lack of awareness of reporting procedures, and limited institutional support. These findings underscore the need for targeted educational interventions to improve ADR awareness among migrant workers and continuous professional training for community pharmacists. Strengthening pharmacist-led patient counselling, enhancing participation in the Pharmacovigilance Programme of India (PvPI), and establishing effective community-based ADR reporting systems are essential to promote the rational use of OTC medicines, improve pharmacovigilance practices, and ultimately enhance patient safety and public health outcomes.

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11. APPENDICES

11.1 Appendix A: Informed Consent Form:

INFORMED CONSENT FORM

‘A CROSS-SECTIONAL PHARMACOVIGILANCE STUDY ON OTC DRUG USE AND ADR AWARENESS AMONG MIGRANT WORKERS AND COMMUNITY PHARMACISTS’

You are invited to participate in a research study conducted as part of the BPharm project work. If you agree to participate, you will be asked to answer a few questions regarding your medicine usage habits, knowledge about OTC drugs, and awareness of side effects. The questionnaire will take approximately 10–15 minutes to complete. All the information you provide will be kept strictly confidential. Your name or identity will not be disclosed in any report or publication. Data will be used only for research purposes. There are no known risks associated with this study. However, if you feel uncomfortable answering any question, you may skip it.

Name of Investigators:

- 1.Ahalya. K
- 2.Riya C V
- 3.Suvarna TP
- 4.Fathimathul Nadha MP
- 5.Lulu shega

Under the guidance of: Ramya Chandran (Associate professor, department of Pharmacy Practice, MGM college of pharmacy, Kannur)

I have read (or been explained) the information provided above. I voluntarily agree to participate in this study. I understand that my identity will be kept confidential and that I may withdraw from the study at any time.

Participant's Name:

Signature / Thumb Impression:

Date:

Place:

Investigator's Signature:

Date:

सहमति पत्र

‘प्रवासी श्रमिकों’ और सामुदायिक फार्मासिस्टों में ओटीसी दवाओं के उपयोग और एडीआर (दवा के प्रतिकूल प्रभावों) के प्रतिकूल जागरूकता के लिए एक क्रॉस-सेक्शनल फार्माक त्वतजर्लेस अध्ययन’

आज इस शोध अभियान में भाग लेने के लिए आमंत्रित किया गया है, जो बी.फार्मके प्रजेक्ट कायमका एक लक्ष्य है। आंकी जानकारी केवल शैक्षणिक और अनुसंधान प्रयोजन के लिए उपयोग की जाएगी। यद्यपि इस अभियान में भाग लेने के लिए सहमत हैं, तो आपसे तो वाओ के उपयोग, ओटीसी तो वाओ की जानकारी और साइड इफेक्ट्स के बारे में कुछ प्रश्नों को पूछा जाएगा। पूरी प्रश्नावली को पूरा करने में लगभग 10 से 15 मिनट का समय लगेगा। इस अभियान से कोई भी जानें कि यह शोध नहीं है। यद्यपि आज लक्ष्य प्रश्न का उत्तर तभी तब तक समय असुलवधा महसूस नहीं है, तो आप उस प्रश्न को छोड़ सकते हैं।

शोधकर्ताओं के नाम:

- 1.Ahalya. K
- 2.Riya C V
- 3.Suvarna TP
- 4.Fathimathul Nadha MP
- 5.Lulu shega

माध्यमशमन में: Ramya Chandran (Associate professor, department of Pharmacy Practice, MGM college of pharmacy, Kannur)

मैंने पढ़ी तभी गई जानकारी ली है (या मुझे समझाई गई है)। मैं स्वेच्छा से इस अभियान में भाग लेने के लिए सहमत हूँ। मुझे समझ है कि मेरी पहचान गोपनीय रखी जाएगी और मेरी लक्ष्य भी समय लक्ष्य लक्ष्य कारण बताए अभियान से हट सकता/सकती हूँ।

प्रतिक्रिया का नाम:

हस्ताक्षर / ओओ गूठका तनशान:

तततत:

स्थान:

शोधकर्ताका हस्ताक्षर:

2. Would you like to receive more information about safe medicine use and ADRs?

1. क्या आक क ई िरानी बीमारी है(जैसे मधुमेह, उच्च रक्तचाि, अस्थमा आतद)?

यतद हा०ँ, कृ िया बताणीः

☐ कभी-कभी ☐ कभी नहीं।

4. यतद् हाँ, त आ आमतौर िर तोवा कहाँसे िरीतोतेहैं?

☐ અન્ય:

d.અન્ય

☐ एी 'टादसड ☐ एलजी ☐ एी ' टीबाय दटक ☐ अन्य:

☐ અન્ય:

□ हाँ □ नहीं □ • दनतदत नहीं •

☐ हाँ ☐ नहीं

11.3 Appendix C: Questionnaire For Community Pharmacists

Questionnaire for Community Pharmacists

Section A: Demographic Details

1.Name (optional):

2.Age:

3.Gender: ☐ Male ☐ Female ☐ Other

4.Qualification: ☐ D.Pharm ☐ B.Pharm ☐ M.Pharm ☐ Pharm.D ☐ Others:

5.Years of professional experience:

6.Type of pharmacy: ☐ Independent ☐ Hospital-based ☐ Chain pharmacy ☐ Others:

Section B: OTC Drug Dispensing Practices

7.Do you dispense medicines without a doctor's prescription? നിങ്ങൾ ഡോക്ടറുടെ പ്രസ്ക്രിപ്ഷൻ ഇല്ലാതെ മരുന്നുകൾ നൽകാറുണ്ടോ?

☐ Yes ☐ No

8.How frequently do you dispense OTC medicines? ഒട്ടിസ് മരുന്നുകൾ എപ്രാവശ്യം നൽകാറുണ്ടാകും?

☐ Always ☐ Often ☐ Sometimes ☐ Rarely

☐ എല്ലായ്പ്പോഴും ☐ രാവിലെ ☐ ചിലപ്പോൾ ☐ അപൂർവ്വമായി

9.What are the most commonly sold OTC drugs in your pharmacy? നിങ്ങളുടെ ഫോർമസ്കിയിൽ ഏറ്റവും കൂടുതൽ വിറ്റഴിക്കപ്പെടുന്ന ഒട്ടിസ് മരുന്നുകൾ ഏവയെന്ന്?

☐ Analgesics (painkillers) ☐ Antibiotics

☐ Cough and cold medicines ☐ Others:

☐ Antacids

☐ Vitamins / Supplements

10.What are the common reasons patients give for requesting OTC medicines? ഡോക്ടർ ഒട്ടിസ് മരുന്നുകൾ ഡിമാന്റുന്ന സാധാരണ കാരണങ്ങൾ എന്തെല്ലാമെന്ന്?

☐ Minor illness

☐ Time-saving

☐ Previous experience

☐ Cost-saving

☐ Advertisement influence

☐ Others:

11.Do you provide any counselling to patients while dispensing OTC drugs? നിങ്ങൾ OTC (ഓവർ ദി കൗണ്ട്) മരുന്നുകൾ നൽകുമ്പോൾ ഡോക്ടർമാർക്ക് എടുക്കേണ്ട കാര്യങ്ങൾ രൂപം നൽകാറുണ്ടോ?

☐ Always ☐ Sometimes ☐ Rarely ☐ Never

12.Do you think patients understand the correct dosage and side effects of OTC drugs? ഡോക്ടർമാർക്ക് OTC (ഓവർ ദി കൗണ്ട്) മരുന്നുകളുടെ ശരിയായ അളവും കാര്യക്ഷമതകളും മനസ്സിലാക്കാനാകുന്നുണ്ടെന്നു നിങ്ങളോട് പറയുന്നുണ്ടോ?

☐ Yes ☐ No ☐ Not sure

Section C: Awareness and Attitude towards ADRs

13.Have you ever come across an Adverse Drug Reaction (ADR) reported by a patient? ഡോക്ടർ റിപ്പോർട്ട് ചെയ്ത ഒരു അനിഷ്ട മരുന്നുകൾ പ്രതിരോധം (ADR) നിങ്ങൾ ഒരിക്കലും രജിസ്റ്ററുണ്ടോ?

☐ Yes ☐ No

14.If yes, what was the type of ADR observed? ഒന്നാകെ, ഉടക്കിൽ, എത്ര കഠിനമായ (ADR) ആണു പരിശോധിച്ചത്?

15.Did you report that ADR to any authority? നിങ്ങൾ ആ (ADR) എടുക്കേണ്ട അധികാരിയോട് റിപ്പോർട്ട് ചെയ്തിട്ടുണ്ടോ?

☐ Yes ☐ No

If yes, to whom? ☐ Doctor ☐ Pharmacovigilance centre ☐ Regulatory authority ☐

Others:

16.Are you aware of the Pharmacovigilance Programme of India (PvPI)? നിങ്ങൾക്ക് ഇന്ത്യയിലെ ഫോർമക്കോവിജിലൻസ് ഡ്രഗ് പ്രോഗ്രാം (PvPI) സംബന്ധിച്ച അറിവുണ്ടോ?

☐ Yes ☐ No

17.Have you ever filled an ADR reporting form? നിങ്ങൾ ഒരിക്കലും ADR റിപ്പോർട്ട് ഡ്രഗ് റിപ്പോർട്ടിംഗ് ഫോർമ് രജിസ്റ്ററുണ്ടോ?

☐ Yes ☐ No

18. Do you think pharmacists should be actively involved in ADR reporting? നിങ്ങളുടെ അഭിപ്രായത്തിൽ ഫോർമസ്റ്റുറൽ സജീവമായി ADR റിപ്പോർട്ടിംഗിൽ രംഗത്തുവരിക എന്നതിനെക്കുറിച്ച് നിങ്ങളുടെ അഭിപ്രായം എന്താണ്?

☐ Yes ☐ No ☐ Not sure

Section D: Knowledge and Training

19. Have you received any training related to ADR reporting or pharmacovigilance? നിങ്ങൾക്ക് ADR റിപ്പോർട്ടിംഗ് അല്ലെങ്കിൽ ഫാർമക്കോവൈജിലൻസ് നൽകിയ ഏതെങ്കിലും തരം പരിശീലനം ലഭിച്ചിട്ടുണ്ടോ?

☐ Yes ☐ No

20. Would you like to receive more training or workshops on pharmacovigilance and ADR reporting? നിങ്ങൾക്ക് ഫാർമക്കോവൈജിലൻസ് (ADR) റിപ്പോർട്ടിംഗ് സംബന്ധിച്ച കൂടുതൽ പരിശീലനം അല്ലെങ്കിൽ വർക്കുഷോപ്പുകൾ ലഭിക്കാൻ ആഗ്രഹമുണ്ടോ?

☐ Yes ☐ No

21. In your opinion, what are the main barriers to ADR reporting? (Tick all that apply)

നിങ്ങളുടെ അഭിപ്രായത്തിൽ, ADR റിപ്പോർട്ടിംഗിന് പ്രധാനമായ തടസ്സങ്ങൾ എന്തെല്ലാം ഉണ്ടെന്നതിനെക്കുറിച്ച് നിങ്ങളുടെ അഭിപ്രായം എന്താണ്?

☐ Lack of time

☐ Lack of awareness

☐ No reporting forms available

☐ Fear of legal issues

☐ Not sure whom to report

☐ Others:

22. Do you think awareness programs on safe OTC use should be conducted for the public? നിങ്ങളുടെ അഭിപ്രായത്തിൽ ഓവർ ദി കൗണ്ടർ (OTC)

ഉപയോഗത്തെക്കുറിച്ചുള്ള സുരക്ഷിതമായ ഉപയോഗത്തെക്കുറിച്ച്

പൊതുജനങ്ങൾക്ക് നൽകേണ്ടതെന്ന് നിങ്ങളുടെ അഭിപ്രായം എന്താണ്?

☐ Yes ☐ No

11.4 APPENDIX D: VALIDATION CERTIFICATE

To:

Dr. Anvin Joseph Sebastian

MBBS, MD

St. Joseph Mission Hospital, Mananthavady, Wayanad

Subject: **Request for Expert Validation of Research Questionnaire**

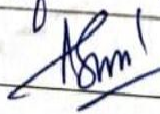
Sir,

We are currently conducting a research study titled "A CROSS-SECTIONAL PHARMACOVIGILANCE STUDY ON OTC DRUG USE AND AWARENESS AMONG MIGRANT WORKERS AND COMMUNITY PHARMACISTS" as part of our Bpharm final year project under Kerala university of health sciences.

We have developed a structured questionnaire to collect data for this study. I kindly request your expert review and validation of the questionnaire to ensure its relevance, clarity, and appropriateness in addressing the study objectives. Your valuable feedback and suggestions will be incorporated to improve the quality of the instrument.

Overall Comments:

The questionnaire is well-structured
Comprehensive and covers all necessary
aspect of study topic

Signature of Expert: 

Date: _____

Dr. ANVIN JOSEPH SEBASTIAN
Consultant General Medicine
MBBS, MD(Gen. Med)
Reg.No: 29157