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Original Research Article

Patient safety at risk: non compliance with drug regulations among community pharmacies in Chennai, Tamil Nadu

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ABSTRACT

Background: Over-the-counter (OTC) drugs are available for consumer purchase without prescriptions, whereas Schedule H medications require valid prescriptions from registered medical practitioners. This pilot study assesses the dispensing practices of community pharmacists in Chennai using the simulated client method.
Methods: Two Pharm.D. students, trained to role-play as simulated clients, visited 25 community pharmacies in Chennai to request Tab. Prednisolone 40 mg. Each interaction was documented using a data collection form focusing on control, compliance, and complications. Data were analyzed using descriptive statistics and Chi-square tests.
Results: Out of 25 pharmacies, 52% agreed to dispense the medication without justification, while 44% strongly disagreed even after explanations were provided. Only 36% asked for a prescription, and a concerning 64% did not prioritize its necessity. Only 12% of respondents provided information about the medication, with location statistically significant in relation to prescription requests (p=0.027). Notably, two pharmacies allowed unqualified personnel to dispense medications.
Conclusions: The pilot study reveals inappropriate practices among community pharmacists in Chennai, emphasizing the urgent need for awareness programs and regulatory revisions. The high rates of non-compliance raise concerns about patient safety and highlight the necessity for strategic public health initiatives similar to Kerala's Operation AMRITH. Immediate action is essential to improve pharmacy practice standards and ensure safe dispensing of medications.

Keywords: Community pharmacists, Over-the-counter drugs, Patient safety, Prescribing practices, Regulatory compliance, Simulated client method

INTRODUCTION

Over-the-counter (OTC) drugs, or non-prescription medications, are available for consumer purchase without a prescription, contrasting with prescription medications that require a valid prescription from a registered medical practitioner (RMP) and must be dispensed under pharmacist supervision. The World Health Organization (WHO) defines self-medication as the selection and use of medications by individuals for self-recognized health issues. In India, drugs classified under Schedule H and Schedule H1 require a written prescription from an RMP, who must sign, date, and specify the patient's details along with the medication's dosage.[1] Although India does not officially categorize OTC drugs, medications not listed under Schedules H, G, and X are considered non-prescription.[2,3] Global research indicates a growing trend in self-medication, with pharmacists playing a vital role as the final point of contact in the medication process.[4,5] The International Pharmaceutical Federation has issued guidelines on good pharmacy practice, supported by the

WHO, while the Indian Pharmaceutical Association (IPA) has developed specific guidelines emphasizing the need for pharmacists to provide informed counseling.[6,7] This pilot study utilizes the Simulated Client (SC) method-widely employed since the 1940s for assessing service delivery and performance standards-to evaluate community pharmacists' practices in dispensing Schedule H drugs.[8]

METHODS

Simulated client visit methodology

In this pilot study, two Pharm.D students underwent standardized training to effectively role-play as simulated clients, ensuring consistency in their performance throughout the scenario. They engaged in extensive role play and received constructive feedback to refine their skills. Each simulated client enacted the same scenario during separate visits to community pharmacies, conducted at different times of day across various days of the week.

Scenario description

During the visits, each simulated client approached the pharmacy requesting Prednisolone 40 mg. The scenario was carefully crafted to standardize pharmacist-patient communication. If queried by the pharmacist, the client stated that the medication was intended for his father, who had been using it for arthritis. When asked about the prescription, the client explained that the prescription had been lost a few weeks prior. The expected outcome of this interaction was for the pharmacist to decline the request based on the absence of a prescription and to refer the client back to a physician for proper authorization.

Documentation of the visit

Immediately following each encounter, the simulated client documented details of the interaction using a data collection form. This form included items related to control, compliance, and complications encountered during the visit.

Setting and sampling

This descriptive cross-sectional study was conducted in July 2024. A comprehensive list of registered community pharmacists in Chennai was obtained from the Pharmacist Directory, with assistance from the Tamil Nadu Chemists and Druggist Association. A convenience sampling method was employed to select the sample population, consisting of 25 community pharmacies for this pilot study.

Inclusion criteria

Samples included 25 random registered community pharmacies in Chennai.

Inclusion criteria

Ayurvedic and homeopathic pharmacies, wholesale pharmacies, hospital pharmacies, government-run free drug distribution centers, and those pharmacies attached to clinics were excluded.

Data analysis

All collected data were entered into Microsoft Excel, and descriptive statistics, along with the Chi-square test, were performed using SPSS software to analyze the results. This methodological approach aimed to evaluate the practices of community pharmacists regarding the dispensing of Schedule H medications in a structured and systematic manner.

RESULTS

Location

Out of the 25 community pharmacies visited, 15 were located in urban areas of Chennai, while the remaining 10 were situated in rural regions. The demographic analysis of the respondents revealed that the majority were male (92%), with females constituting 8% of the total. Table 1 provides a detailed breakdown of the frequency of community pharmacies categorized by their location and the gender of the pharmacists.

Table 1: Frequency of community pharmacies based on their location and gender.

Parameters		Frequency (n)	Percentage (%)
Gender	Male	23	92
	Female	2	8
Location	Urban	15	60
	Rural	10	40

Table 2: Overall outcomes of the simulated patient interview.

Response	Frequency (n=25)	Percentage (%)
Acceptance of reasons		
Agree	13	52
Disagrees but easily convinced	1	4
Strongly disagree	11	44
Prescription		
Asks for prescription	9	36
Did not ask for the prescription	16	64

Response to the simulated client visit

Out of the 25 respondents, 13 (52%) agreed to dispense the medication upon request, without requiring any

justification. Conversely, 11 (44%) strongly disagreed the request, even after the simulated clients provided explanations for needing the medication. Additionally, one respondent initially disagreed but was subsequently convinced by the reasons presented.

Notably, two respondents refrained from dispensing the medication, citing it was out of stock, despite their staff being prepared to fulfill the request. Furthermore, two pharmacies were identified where medications were dispensed by individuals who did not possess the necessary pharmacy qualifications. Table 2 presents a comprehensive overview of the outcomes from the simulated patient interviews.

Assessment of findings

Control

Out of the 25 respondents, only 2 (8%) inquired about the necessity of the medication, while the majority did not seek any clarification regarding the reasons for the request.

Compliance

Regarding adherence to prescription requirements, only 9 (36%) of the respondents showed concern for the need for a prescription, even when some were convinced by the reasons provided. Conversely, 16 (64%) did not prioritize the necessity of a prescription.

Complications

Three respondents (12%) provided detailed information about the medication and explained why it could not be dispensed without a prescription.

Statistical significance

The location of the pharmacy was found to be statistically significant in relation to the requisition of a prescription, with a p-value of 0.027. This indicates that the likelihood of requiring a prescription varied significantly between urban and rural pharmacies.

DISCUSSION

A comparable study conducted in Germany found that 98% of participating pharmacies provided advice during pseudo-customer visits, whereas our study revealed that only 12% of the pharmacies offered information regarding the medication, its uses, and potential complications.[9] In our research, the practice of dispensing non-prescription medicines without a prescription was identified in 64% of cases, significantly higher than the 45-55% range reported in Bangalore and the 32.5% observed in Belagavi city.[10-12]

Additionally, a study in urban China reported that pharmacists were available in only 14.8% of pharmacies, with performance regarding the provision of information and advice deemed unsatisfactory.[13]

Qualitative investigations have indicated that many pharmacists lack awareness of the legal implications of their actions and are often motivated by economic factors. This aligns with our findings, where 52% of community pharmacists agreed to dispense medications based on reasons provided by simulated patients, despite regulations prohibiting such practices, and 64% failed to request a prescription for a corticosteroid drug. This highlights a concerning lack of awareness regarding legal implications and suggests motivation driven by economic factors among community pharmacists.[14]

Furthermore, our study reinforces the importance of public health initiatives aimed at educating both pharmacists and consumers about the risks associated with non-prescription sales. Enhanced regulatory oversight and the establishment of clear guidelines are essential to ensure that Schedule H drugs are dispensed safely and appropriately, preserving their intended therapeutic benefits.[15]

Research from Australia demonstrated that clinical and quality of life improvements occur when pharmacists provide regular counseling on the medications they dispense. Our findings echo this sentiment, as 88% of community pharmacists in Chennai did not provide information on the medications dispensed or the reasons for not dispensing certain drugs without a prescription.[16]

Community pharmacists are legally required to be present during the sale and dispensing of medicines according to Rule 65(15) of the Drugs and Cosmetics Act, 1940; however, our study found two community pharmacies where individuals without pharmacy degrees were involved in dispensing medications.[17]

Corticosteroids, which are hormone mediators produced by the adrenal glands, are indicated for serious conditions such as chemotherapy, systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), and osteoarthritis due to their anti-inflammatory and immunosuppressive effects. Despite their efficacy, corticosteroids pose potential adverse effects, including steroid-induced osteoarthritis and the risk of drug dependence.[18] In our study, one community pharmacist suggested a less harmful alternative, paracetamol, after explaining why prednisolone could not be sold without a prescription.

The prevalence of self-medication was reported at 60% in central India, with similarly high rates observed in studies by Shamsudeen et al and Garofalo et al, lower prevalence rates were noted by Hajira et al.[19-22] The high prevalence in our study can be attributed to the adult participants, primarily from the working class, who face increased responsibilities to maintain economic stability. This

reality often drives them to seek quick and cost-effective solutions for family health issues. Variations in self-medication prevalence observed both within and between countries may result from differing definitions of self-medication, variations in health-seeking behavior, sociocultural factors, and seasonal disease fluctuations.[19]

Since it is a pilot study, it may (or may not) differ from the results from main study, was the limitation of this study.

CONCLUSION

The findings from our study indicate that simulated client visits are an effective method for assessing the actual practice patterns of community pharmacists, contrasting with the limitations of other cross-sectional studies. The results reveal a concerning trend of inadequate practices among community pharmacists, highlighting the urgent need for comprehensive awareness programs and a revision of regulations to enforce strict compliance within the healthcare sector.

The recent initiative by the Kerala government, known as Operation AMRITH (Antimicrobial Resistance Intervention to improve Total Health), has demonstrated significant positive outcomes. A similar strategic approach is necessary in Tamil Nadu, especially in light of the unsatisfactory results obtained from this pilot study. If such deficiencies exist within a smaller sample, the implications for larger population studies could be even more alarming. Therefore, immediate action is essential to enhance the standards of pharmacy practice and ensure patient safety across the region.

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