Non-Prescription Dispensing of Controlled Medicines at Drug Outlets in Pakistan: Findings and Implications to Improve Future Health Care

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Abstract

Introduction: Non-prescription sale of controlled medicines is a growing public health problem, especially amongst low-middle-income countries, not helped by weak regulatory enforcement. Consequently, controlled medicines continue to be purchased without a prescription, exacerbating misuse and increasing morbidity and mortality. Currently, little is known about this in Pakistan. Therefore, this study aimed to evaluate the prevalence of non-prescription dispensing of controlled medicines in Pakistan. **Materials and Methods:** A multicentre, cross-sectional study using simulated clients (SC) was conducted in Lahore, Pakistan. SC visited 378 drug outlets (285 pharmacies and 93 medical stores) to purchase controlled medicines without providing a prescription. Data about dispensing, interactions and grounds for refusal were acquired. **Results:** About 61.9% of outlets dispensed controlled medicines without a prescription. The most commonly dispensed controlled medicines were tramadol (29.5%), followed by codeine (26.1%) and alprazolam (23.1%). There was no significant difference in non-prescription dispensing between pharmacies and medical stores. However, outlets lacking licenced personnel were significantly more likely to dispense controlled drugs without a prescription ($P = 0.049$). Refusals were mainly due to prescription requirements (55.6%) or product unavailability (44.4%). **Conclusions:** There was appreciable dispensing of controlled medicines without a prescription, greater when licenced personnel were not present. Enhanced regulatory enforcement and increased presence of certified personnel are necessary going forward.

Keywords: Controlled medicines, health policy, Pakistan, pharmacy, simulated client

INTRODUCTION

Controlled medicines or substances are medicines that are primarily active in the central nervous system and have the potential to cause physical and mental dependence, which leads to addiction.[1,2] Inappropriate use of these agents can have serious adverse health consequences, which include fatal overdoses, memory loss, violence, severe mental disorders and suicides.[3-7] There can also be considerable emotional strain on parents when adolescents abuse controlled medicines.[8,9] These combined issues are a public health concern, with an estimated 61 million people globally in 2020 taking opioids,[10] with half

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of these people residing in South Asia.[10] Overall, substance use, or misuse, has become a major global public health concern. According to the recent World Drug Report of the United Nations Office on Drugs and Crime, 296 million people aged 15–64 years used addictive substances in 2021, a 23% increase over the last decade.[11] Furthermore, non-medical use of prescription drugs has been ranked second in prevalence after cannabis.[12]

Controlled items are medically indicated for a wide array of medical conditions, which include insomnia, anxiety, severe pain and attention-deficient hyperactive disorder.[13] These agents are not over-the-counter medications, and their availability to the public should be prohibited without a prescription to help control and optimise their use.[14,15] Despite this, the non-medical use of these controlled medicines is common, especially in low- and middle-income countries (LMICs),[4,11,15,16] often propagated by weak or non-existent implementation of laws banning such practices.[17] Their growing use has resulted in significant morbidity and mortality,[5,11] exacerbated by concerns with the current training of healthcare professionals (HCPs) in LMICs surrounding pain management, which includes opioid use.[18] There are also concerns amongst LMICs regarding the current lack of palliative care professionals, as well as other professionals, to manage pain, including cancer pain, increasing the self-purchasing of opioids, especially where access to appropriate HCPs is challenging.[17,19]

Alongside this, religion may also play a part in influencing socio-cultural norms, including current practices regarding controlled medicines. Amongst Muslims, Islam affects all aspects of life, including alcohol prohibition. As a result, Muslims who use controlled substances such as opioids without a prescription for recreational use do so typically clandestinely to avoid exclusion from the community.[10,17] Coupled with this, there are concerns that people with addiction problems may avoid accessing healthcare services due to issues of denial, lack of trust with HCPs and accompanying breach of confidentiality, as well as fears of being reported to the authorities.[10,20] Such issues may be exacerbated in Pakistan with a growing prevalence of opioid use in recent years.[21,22] Opioid addiction is exacerbated in Pakistan by the illicit sales of controlled medicines.[15] According to a recent national survey, over 4 million people in Pakistan are reported to be drug addicts, including 1.6 million people admitting to opioid abuse.[21] As a result, recreational drug overdosing has surpassed motor accidents as the leading source of unintentional fatalities in Pakistan, with opioids now accounting for more fatalities than cocaine and heroin.[21,23] In a recent study, Ochani *et al*. documented that approximately 700 people die of drug-related complications and overdose in Pakistan every day, equating to 250,000 deaths annually, arising from an estimated 7 million citizens taking drugs regularly.[21] Amongst these, approximately 4 million regularly use cannabis, and 2.7 million use opiates, enhanced by the lack of regulations surrounding the sales of medicines without a prescription in the country, as well as peer pressure.[7,21]

Overall, the purchasing of prescription medicines without a prescription, including controlled medicines, is common in Pakistan, with easy access to these medicines from drug outlets.[15,21,24,25] The purchasing of antibiotics without a prescription is common amongst LMICs, even for self-limiting conditions, exacerbated by issues of affordability where there are high co-payments, clinic over-crowding leading to long waiting times, the convenience of community pharmacies and drug stores, as well as pressure from patients to prescribe or dispense antibiotics.[26-30] These insights reinforce the relevance of assessing medicine-seeking behaviour and non-prescription sales within broader health system contexts, including Pakistan, where controlled medicines are increasingly misused under similar circumstances. This is particularly important in Pakistan, with currently high prevalence rates of opioid addiction.[21,23]

Drug sale outlets in Pakistan are divided into two categories. These include community pharmacies and medical stores. Community pharmacies are operated under the supervision of registered pharmacists, while medical stores are supervised by registered dispensers.[29] According to the current drug regulations, a licencee of a medical store is not allowed to store or sell drugs included in the Schedule G list, i.e. anti-leprosy medicines, immunologicals, vaccines, chemotherapeutic agents, anaesthetic agents, a number of antibiotics including vancomycin and colistin, antivirals, narcotics, anti-psychotics and tricyclic anti-depressants, antivirals and hormones.[31,32] Furthermore, Schedule B and D drugs must only be sold when presented with a valid prescription at both pharmacies and medical stores.[31] However, prescription medicines can be easily obtained from drug outlets in Pakistan without a prescription.[15,29,33]

Consequently, there is an urgent need to understand the extent of current dispensing of controlled medicines without a prescription in Pakistan, building on the findings of Bashir *et al*.[15] This is especially important in drug outlets where no registered community pharmacist is present and where the sales of controlled medicines without a prescription can be higher, mirroring the situation in other LMICs.[6] We are aware that there can also be concerns with trainee pharmacists' knowledge of opioid dispensing practices.[34] In addition, concerns with HCPs' knowledge and competencies regarding opioids and their dispensing amongst LMICs, including Pakistan.[35] This is reflected by a lack of screening of patients for possible addiction issues before prescribing opioids and a phobia towards opioids, as well as a lack of HCPs in the first place to effectively manage patients experiencing pain.[23,36,37] However, the number of tests detecting drug abuse in Pakistan is increasing, albeit from a low base.[38] Consequently, the objective of this study was to evaluate the dispensing practices and rationale regarding controlled medicines amongst the different types of medicine outlets in Pakistan. As a result, providing an up-to-date picture of the extent of non-prescription dispensing of controlled medicines in Pakistan, the possible rationale and future direction. This could include instigating opioid stewardship

initiatives amongst community pharmacists in Pakistan. We are seeing a growing role for community pharmacists across LMICs to improve the care of patients, which includes improving the management of patients with both infectious and non-infectious diseases, which this potential initiative will build upon.[39-43]

Materials and Methods

Study design including scenarios

A multicentre, cross-sectional study was conducted using the simulated client (SC) technique between November 2023 and January 2024, covering medicine outlets in Punjab province. Medicine outlets include community pharmacies, which are under the supervision of registered pharmacists. Alongside this, medical stores are typically supervised by registered dispensers. Punjab province was chosen for this research as it is the most populous province in Pakistan, currently containing more than half of the population in the country.[44,45] The SC technique was used for this study as this technique typically leads to a more reliable representation of actual practices or interactions between medicine providers and their patients compared with medicine providers completing anonymised questionnaires.[46-49]

Four scenarios were designed to assess the response of medical store and community pharmacy personnel to a request for a controlled medicine without a prescription. Of these, three were for specific product requests using common brand names, whereas the fourth scenario was a request for a controlled item by showing an empty alprazolam blister pack. The study questionnaire was developed based on earlier studies using a SC methodology[29,33,50,51] and subsequently piloted at 10 medicine outlets, including both types of outlets. These medicine outlets were not part of the main study. The final questionnaire was subsequently used to record information following the visit of the SC to the various types of medicine outlets in Punjab province.

The study questionnaire had the following two sections:
*   Section A contained 5-items to record observations made by the SCs while visiting a medicine outlet, including the medicine outlet category (pharmacy or medical store),
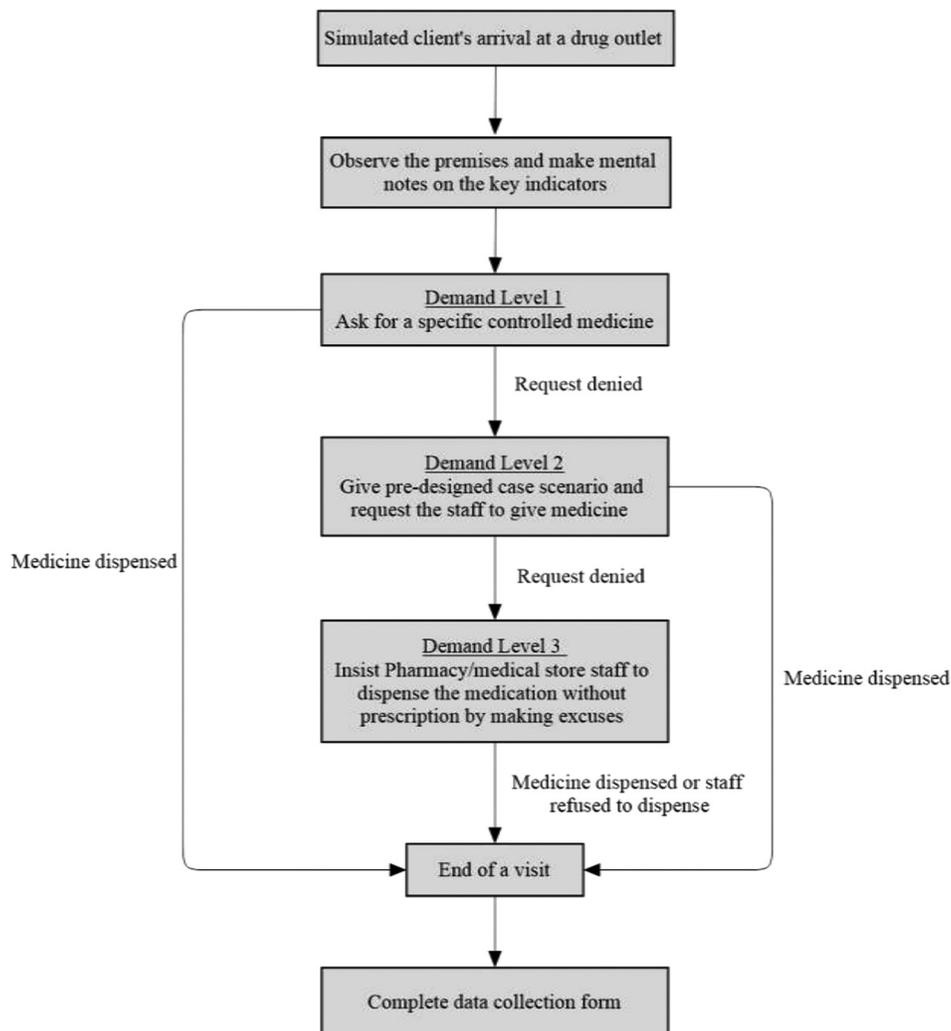

Figure 1: Flowchart of the simulated client visit process.

the type (independent or a chain outlet), the presence of licenced personnel (yes or no), as well as the age and gender of the attending staff
• Section B contained 8 items to record data regarding the controlled medicines dispensing practices without presenting a prescription, for example, the medicine dispensed (yes or no), under which demand level the medicine was dispensed [Figure 1], reasons for refusal, prescription request, referral advice, medicine counselling or advise and the interaction time.

Sample size estimation

The Raosoft® sample size calculator was used to compute the sample size for the present study. By setting a 95% confidence interval, 5% margin of error and 50% response distribution, a sample of 377 drug outlets was needed for this study.

Procedures

Medicine outlets were chosen to cover all major areas in Lahore city in Punjab province using a purposive sampling approach. Each medicine outlet was visited once, with five final year pharmacy students serving as SCs. These students received comprehensive training for 2 days on all four scenarios of data collection, including how to behave in a pharmacy/medical store as a typical consumer, observe and record the key indicators, how to respond to questions posed by the staff, and the use of simple lay language.

All SC visits were conducted during the opening hours of the medicine outlet. During each visit, a randomly selected scenario was used to request a controlled item from the attending staff. The random selection was achieved by arranging each of the four different data collection sheets for the respective scenarios sequentially so that every fifth data collection sheet represented the same scenario.

During the visits, the SCs observed the environment and made mental notes on the key indicators. The SCs also observed the licence displayed in the outlet with a photograph of the licenced personnel. If the attending staff did not match the photo on the licence or there was no photo displayed, the SC subsequently asked, 'Can I talk to your pharmacist/dispenser, please?'

The availability of the licenced personnel was then based on the response to this question.

The SCs subsequently used three degrees of product request until the requested item was dispensed or refused [Figure 1]. At first, the SC directly asked for a specific item without presenting a prescription (Demand Level 1). If refused or asked further questions, the SC presented a pre-designed case scenario to convince the pharmacy/medical store staff to dispense the requested item (Demand Level 2). If the staff still refused to dispense the requested item, the SC tried insisting to the staff to give them the requested medicine by making excuses, e.g. forgetting to bring the prescription with them, i.e. leaving it at home, or they cannot visit a doctor right now (Demand Level 3). Interaction time between the SC and the staff was also noted. The SC subsequently completed the data collection form soon after leaving the drug outlet.

Data analysis

All data were entered and analysed using SPSS version 25 (IBM, Armonk, NY, USA) for Microsoft Windows®. Continuous data were presented as mean ± standard deviation (SD), whereas categorical data were presented as frequency and percentage. The Chi-square test was used to compare the differences in characteristics and dispensing practices of controlled items between pharmacies and medical stores. $P < 0.05$ was considered statistically significant.

Ethical approval

The study protocol was reviewed and approved by the Research Ethics Review Board, Office of Research, Innovation and Commercialisation (ORIC), Lahore College for Women University (Ref. No. ORIC/LCWU/54). Written informed consent was obtained from all SCs prior to their recruitment and training. The Review Board granted a waiver of prior consent for drug outlet personnel in recognition of the study design. Anonymity of the providers (drug outlet personnel) was ensured, and study findings were reported exclusively at the aggregate level.

RESULTS

Three hundred and seventy-eight medicine outlets were visited by the SCs, with the characteristics as shown in Table 1. The frequency of pharmacies and medical stores was 285 (75.4%) and 93 (24.6%), respectively. The majority of the attending staff were males (99.2%) and typically aged 30–50 years (50.5% of the total). 48.4% of medicine outlets had licenced personnel on duty, with the majority present within community pharmacies as compared to medical stores ($P < 0.001$). The mean interaction time was 2.78 min (SD = 0.99).

Regarding the sale of controlled medicines without a prescription, 38.1% of medicine outlet personnel visited refused to dispense the requested medicine to the SCs, with 61.9% dispensing the requested item. 83.8% of these
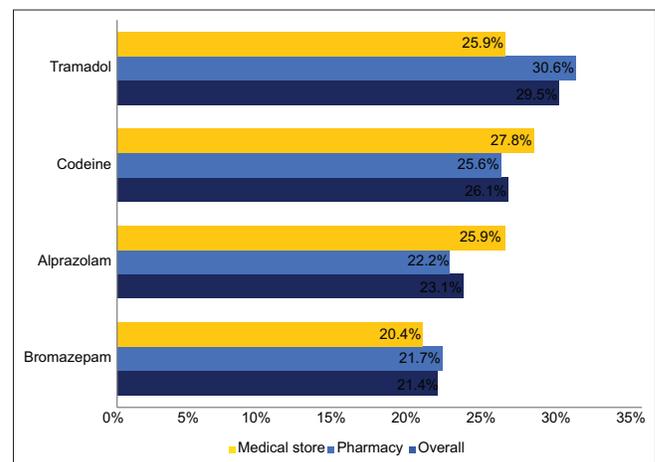

Figure 2: Frequency of non-prescription dispensing of controlled items (*N* = 234).

Table 1: Characteristics of the medicine outlets visited by simulated clients

Characteristics	Overall (*n*=378), *n* (%)	Pharmacy (*n*=285), *n* (%)	Medical store (*n*=93), *n* (%)	*P*
Type of outlet				
Independent*	276 (73.0)	188 (66.0)	88 (94.6)	<0.001
Chain**	102 (27.0)	97 (34.0)	5 (5.4)	
Gender of the attending staff				
Male	375 (99.2)	282 (98.9)	93 (100.0)	1.000
Female	3 (0.8)	3 (1.1)	-	
Age of the attending staff				
Below 30 years	185 (48.9)	138 (48.4)	47 (50.5)	0.679
30–50 years	191 (50.5)	146 (51.2)	45 (48.4)	
Above 50	2 (5)	1 (0.4)	1 (1.1)	
Licenced personnel on duty				
Yes	183 (48.4)	165 (57.9)	18 (19.4)	<0.001
No	195 (51.6)	120 (42.1)	75 (80.6)	
Interaction time (mean±SD)	2.78±0.99	2.75±0.98	2.85±1.04	0.423

*Medicine outlets owned and operated by an individual or a small group of partners, functioning autonomously and are not affiliated with a large brand, **Medicine outlets that are part of a larger company or retail chain that operate several pharmacy/medical store locations under a single brand.
SD: Standard deviation

Table 2: Comparison of non-prescription dispensing practices between pharmacies and medical stores

Variable	Non-prescription dispensing of controlled items		Significant
	Yes, *n* (%)	No, *n* (%)	
Type of drug outlet			
Pharmacy	180 (76.9)	105 (72.9)	0.392
Medical store	54 (23.1)	39 (27.1)	
Licenced personnel on duty			
Yes	104 (44.4)	79 (54.9)	0.049
No	130 (55.6)	65 (45.1)	

items were dispensed at Demand Level 1, i.e. asking for a specific controlled medicine, and 16.2% at Demand Level 2, i.e. presenting a pre-defined scenario. No requested medicine was dispensed at Demand Level 3, i.e. insisting that the controlled medicine is dispensed without a prescription using pre-arranged excuses.

The frequency of controlled medicines purchased without a prescription is shown in Figure 2. From the 234 pharmacies and medical stores that dispensed these medicines without a prescription, the principal medicines dispensed were tramadol (29.5%) and codeine (26.1%). There was no significant difference in dispensing practices between pharmacy and medical stores [Table 2; *P* = 0.392]. However, the frequency of non-prescription sales of controlled medicines was significantly higher at medicine outlets where a licenced individual was not present (*P* = 0.049).

Of those SCs that were denied a controlled medicine (*n* = 144), 55.6% of drug store personnel stated they would require a prescription, with 44.4% stating that the product was not available. The primary reasons for refusal varied significantly between community pharmacies and medical stores (*P* = 0.039). The majority of pharmacies (*n* = 64, 61%) refused dispensing controlled medicines on request, citing that they would require a prescription, and 41 (39%) stated that the requested items were not available. This contrasted with medical stores, where 23 personnel present (59%) stated to the SCs that the items were not available, with only 16 (41%) stating that they could not dispense a controlled medicine without a prescription. Overall, in only eight encounters, five pharmacies and three medical stores, were the SCs advised to visit/consult a doctor, with none dispensing the requested item. Furthermore, medication counselling/advice was only given to 9 SCs during their visits.

DISCUSSION

While various studies previously conducted in Pakistan have found that antibiotics are the most frequently sold prescription-only medicines in Pakistan,[29,33,52-54] there continues to be widespread dispensing of controlled substances without a prescription, even at Demand Level 1, i.e. just asking for a controlled medicine. This is a concern given increasing opioid abuse in Pakistan,[21] with the overdosing of recreational drugs in Pakistan now surpassing motor accidents as the leading source of unintentional fatalities in the country.[21,23] Consistent with findings of earlier studies,[15,21-23] opioid analgesics was found to be the most widely sold controlled medicines without prescription. Furthermore, unauthorized sale of benzodiazepines was also high in our study, indicating widespread use of benzodiazepines amongst the general public. These findings are consistent with previously conducted studies in Pakistan, where the illicit sale and use of controlled medicines were reported.[15,55] Iqbal *et al.* reported that around 14% of adults in urban settlements were using benzodiazepines, with the majority of users acquiring these medicines without a prescription or professional guidance.[55] The regular use of such medications was reported to be for insomnia and anxiety,

which further raises concerns about the potential likelihood of developing dependency, cognitive impairment and long-term health consequences amongst long-term users.[55]

Interestingly, in our study, there was no significant difference between the two types of medicine outlets, as both the types were selling controlled medicines without a prescription. This is in line with other studies conducted in Pakistan, where poor dispensing practices have been widely reported.[15,29] Having said this, the sale of Schedule G medicines at medical stores is a matter of serious concern in Pakistan since, as mentioned, legally they cannot be stored or sold at a medical store.[31] However, in our study, two of the four requested controlled medicines (codeine and alprazolam) belonged to the Schedule G category, and both medicines were available at medical stores and dispensed to the SCs (codeine 27.8% and alprazolam 25.9%). This raises concerns regarding the current inadequate enforcement of the drug regulations in Pakistan. Another notable observation was that medical stores generally did not have licensed individuals present at the time of dispensing. This is important as the rate of unauthorised sales appeared to be higher in pharmacies where no licenced pharmacist was available on-site, emphasising the need for a professional to be present to enhance the safer use of these medicines.

Another noteworthy finding from our study was that 38% of requests for controlled medicines without a prescription were denied. At first glance, this may appear to reflect responsible dispensing practices. However, closer inspection reveals a more complex picture that needs further examination. Of the SCs denied requests, approximately 39% were turned down simply because the requested medication was not in stock and not because of any legal or ethical concerns, with only 61% denied controlled medicines despite Demand Level 3 on the grounds that a valid prescription was required. This raises the possibility that if the requested items had been in stock, they might have been dispensed regardless of the lack of a prescription. As a result, further raising concerns about the enforcement of medicine and pharmacy regulations and the actual role of professional oversight in controlling the dispensing of controlled medicines in Pakistan. This highlights the need for better enforcement of existing laws and greater accountability for pharmacies and medical stores. Alongside this, greater discussions between patients and community pharmacists regarding the rationale for their current condition and potential ways forward, building on their increasing role across LMICs.[39,40] This is particularly the case if personnel in community pharmacies or medical outlets just comply with patient requests without a comprehensive discussion about their condition, due to now normalised behaviour amongst both patients and personnel in the medical outlets, as seen with continued high rates of dispensing of antibiotics without a prescription across LMICs.[30,56-60] Such behaviour may also be driven by a profit motive amongst the various dispensers and sellers of medicines.[27,59,60]

Further analysis of our results also showed that the pharmacist/customer interaction time was similar and shorter than expected, regardless of whether patients were visiting pharmacies or medical stores. This is a concern as pharmacists being HCPs are expected to have the necessary knowledge and skills regarding drug dispensing and medication counselling and are expected to fulfil their obligations by giving customers detailed information regarding medication use and its consequences. Alongside this, making efforts to ensure the key messages are understood and adhered to by the patients/clients, which has worked well in patients with both infectious and non-infectious diseases, including amongst LMICs.[39-43] Counselling patients before dispensing any medicine is an essential part of their role that helps to prevent drug misuse, improve medication adherence and treatment outcomes, as well as ensure patient safety.

Our findings highlight a need to emphasise the professional duties that community pharmacists, as well as dispensers in medical stores, must undertake in their everyday practice to reduce the dispensing of controlled medicines without a prescription. This starts with their training in universities and continues post-qualification in view of concerns regarding the knowledge of HCPs in Pakistan regarding opioids.[23,34] University training must emphasise that enablers and determinants of good pharmacy practices are diverse and multilevel. Community pharmacists on qualification must have the necessary knowledge, competencies and skills to deal with requests from patients for controlled medicines without a prescription, which includes offering alternative treatments or approaches. As part of this, being able to discuss with patients the potential impact on their health following the abuse of these medicines. Suitable training of personnel operating in medical stores is also essential to reduce current high levels of dispensing of controlled medicines without a prescription on request. This is similar to concerns regarding the knowledge of pharmacists and dispensers regarding antibiotics and antimicrobial resistance in Pakistan.[61-63] These findings are supported by other studies conducted globally, with community pharmacists helping to improve the outcomes of patients with non-communicable diseases.[40-43,64,65] According to recent studies, patients' quality of life and medication adherence were considerably improved by pharmacist-led counselling.[40-43,66] Pharmacists' interventions during dispensing also enhanced prescription adherence and shielded patients from drug-related issues.[66]

Our findings also underscore the urgent need for stricter enforcement of pharmacy laws, mandatory presence of qualified personnel and regular monitoring of medical outlets to ensure responsible dispensing practices that safeguard public health. These strategies necessitate greater regulatory supervision of pharmacies in addition to ensuring adequate knowledge and training of pharmacists and other medicine dispensers during university and post-qualification. Alongside this, gaining with the help of universities, a greater understanding of the incentives and disincentives associated with dispensing controlled medicines without a prescription. A greater understanding of these key issues will necessitate further research amongst compliant pharmacies on the rationale behind their compliance,

or lack of it amongst others, to current regulations. In addition, potential ways forward to improve overall compliance rates with current regulations where there are concerns.

Other potential activities include greater regulation of the professional activities of pharmacists and other medicine sellers, which could include fines or potential closure of their pharmacies or medicine outlets, with evidence of abusing current regulations. This has worked amongst LMICs to reduce the extent of inappropriate dispensing of antibiotics without a prescription; however, less effective when the fines are seen as comparatively small.[63,67-69] Alongside this, increased patient education regarding the potential harms with controlled medicines, along with alternative ways forward, which has also helped reduce inappropriate dispensing of antibiotics.[39,56,63,69-71] In addition, encouraging patients with addiction problems to seek professional help despite their possible concerns with issues such as trust and potential breaches of confidentiality.[10,23] These are all possibilities for the future to reduce inappropriate dispensing of controlled medicines and improve public health.

We believe that the strengths of this study include its use of SCs, which allows for direct observation of real-world dispensing practices in a natural setting. As a result, minimising reporting bias and providing a more accurate assessment of non-prescription sales. The multicentre design and purposive sampling across diverse geographic areas also enhance the generalisability of the findings.

We are aware, though, of a number of limitations with this study. First, the study was limited to Lahore; however, this is the capital of Punjab province and the second-largest metropolis of Pakistan. We acknowledge, though, that this may affect the applicability of our findings to other regions of Pakistan. Second, the SC approach, while robust, may still be subject to detection by staff, potentially influencing their behaviour, especially if they are aware that such activities are illegal. Third, the study itself relied on a limited number of scenarios and did not explore the motivations or attitudes of pharmacy staff towards the dispensing of controlled medicines without a prescription, nor did it assess patient outcomes following non-prescription dispensing. Despite these limitations, we believe that our findings are robust, providing direction to all key stakeholder groups in Pakistan to address rising morbidity and mortality from the abuse of controlled medicines. Future research should address the identified gaps by including qualitative methods to better understand the underlying factors associated with such practices, including the influence of patients, as well as expanding the research to other regions. In addition, evaluating the impact of potential interventions to improve regulatory compliance and pharmacy practice. We will be following this up in the future.

Conclusions

There is continued concern with the high rates of dispensing of controlled medicines without a prescription amongst community pharmacies and medical stores. There is an urgent need to address this, given the impact of controlled medicine abuse and addiction on morbidity and mortality. Pharmacy professionals must rigorously comply with legal and ethical norms, ensuring that controlled substances are supplied solely with a valid prescription. In addition, speak appropriately with patients and offer counselling as well as other approaches to avert misuse. Health authorities must also enhance regulatory enforcement, mandate the increasing presence of qualified personnel at all pharmaceutical establishments and perform routine inspections to protect public health. Future research should examine the fundamental factors influencing non-prescription dispensing of controlled medicines in Pakistan and assess the effectiveness of targeted regulatory and educational initiatives to reduce patient harm.

Authors' contributions

All authors contributed equally in the current study. Furthermore, all authors read and approved the final manuscript.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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