



A discursive presentation of community pharmacies: Premises, storage, staff, documentation and legal compliance

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ABSTRACT

Objectives: This study aimed to assess compliance with legal requirements, safe medication storage and staffing standards in community pharmacies in Punjab, Pakistan.

Method: We conducted a three-step cross-sectional study using observations, questionnaires and face-to-face interviews in 544 systematically-selected community pharmacies. We used descriptive statistic and one-way ANOVA to assess the data.

Results: Only 23 (4.2%) pharmacies had accurate area and only 3.9% had appropriate walls. In total, 23.3% had glass-fronted shelves and 38.2% had a glass door. More than half (53.8%) had separate narcotics shelves and 43.0% a separate shelf of expired medicines. Less than half (47.5%) of the pharmacies were able to maintain hygiene. About 36.2% of the pharmacies segregated different types of product. Drugs were protected from direct sunlight in most (61.3%) pharmacies, but the refrigerator was working properly in less than half (43.4%) and only a very small number (2.4%) had an alternative power supply for the refrigerator. Only 37 (6.8%) were able to maintain an appropriate room temperature. The vast majority (93.0%) displayed a valid drug sale license, but a qualified person/pharmacist was only present in 4.8%. The average number of employees was 4.2, and more than 71.0% of staff had 10–12 years of formal education. Only 0.2% of employees could explain term “PRN”, although 57.3% explained “IV” correctly. About 22.8% replied correctly about the room temperature but the vast majority (97.6%) did not know about cold chain temperature. The location of the pharmacy (p -value = 0.045) affected its performance.

Conclusions: Noncompliance with legal requirements, unsafe drug storage and limited human resources reflect the poor enforcement of drug laws in Pakistan. The findings suggest that there is a need to strengthen inspection and management of community pharmacies.

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1. Introduction

Community pharmacies are an integral part of the global healthcare system. They provide a wide range of healthcare services as well as dispensing medicines and medical devices [1]. Community pharmacies should ideally comply with regulations and provide optimum storage of medicines under the supervision of qualified and skilled staff [2,3]. Compliance with legal requirements ensures the supply of appropriate medication [4]. Proper storage is a vital way to ensure medication safety [5,6]. Staff perform different tasks including dispensing of medicines and counseling of patients [7].

In 2003, the World Health Organization (WHO) developed guidelines with the International Pharmaceutical Federation (FIP) and recommended good storage practices. It emphasized that trained staff should be involved in safe storage and that national regulations should endorse the guidelines [8]. Features of community pharmacies therefore indicate their performance against guidelines [2].

The healthcare system in Pakistan depends mainly on the private sector [9]. There are more than 80,000 community pharmacies [10], in diverse locations. They are operated under specific types of licenses. All pharmacies with licenses need to fulfill some legal requirements [11], set out in the Pharmacy Act 1967, on the establishment of community pharmacies. This law is designed to ensure that community pharmacies have optimal and hygienic premises with good storage facilities under the supervision of trained staff [12]. The Government of Punjab (GOP) has also set out legal requirements in Punjab Drug Rules 2007 (PDR-2007), with a minimum licensing requirement [13]. In 2014, it amended the rules on storage of medicines in pharmacies [14].

In many developing countries, community pharmacies make efforts to comply with legislation [2,15,16–21]. Community pharmacies in many cities of Pakistan, for example, have improper medication storage, poor compliance with legal requirements and unqualified staff [5,11,12]. Very few pharmacies have facilities for proper drug storage [5], and the majority do not comply with the legal requirements of their drug sale license [11]. The qualifications of staff are also unsatisfactory [22], and the knowledge of many staff about dispensing, counseling and storage of medicines is fragmented [12,23]. There is insufficient data to fully understand the status of community pharmacy practices in the Punjab, and none at all about community pharmacy practices in rural or suburban areas. This study therefore aimed to examine compliance with regulatory requirements and legislation, facilities for medication storage, and human resources in community pharmacies across the province of Punjab, Pakistan.

2. Methods

2.1. Study setting

This study was conducted in community pharmacies of Punjab province, Pakistan. The area of this province is 205,344 square kilometers. Its population is estimated at more than 91, 379, 615, or around 56 % of the total national population [24].

2.2. Study design and sampling

We carried out a cross-sectional study, in a stratified selection of pharmacies. Nine strata were formed using local government administrative divisions, and each was divided into four sub-strata: divisional city, district city, tehsil city, and suburban and rural area (Attached file 1).

A list of pharmacies was obtained from the department of health or medicine supply companies. After confirming that each had a suitable license, the list was arranged geographically and each pharmacy given a serial number. The sample size of pharmacies for total 22,319 pharmacies was calculated by keeping response distribution (70 %), confidence interval (99 %), margin of error (5 %). Pharmacies were systematically randomized from the list by number to give a total of 544 pharmacies (Attached file 1). Participation in the study was voluntary. Where a pharmacy did not wish to participate, an alternative was chosen from within 2 km of the original. We therefore ensured that we had a representative sample of pharmacies from all areas of Punjab (Fig. 1).



Fig. 1. Formation of strata and Sub - strata.

2.3. Study tools and validation

Data collection forms and questionnaires were developed from previous studies [11,12,15–23,25], the rules set out by the Punjab government [13,14] and available literature [6,8]. Three experts of social pharmacy research assessed the validity and contents of the data collection form, questionnaires and interview guide.

2.3.1. Pilot study

We used a pilot study in 25 community pharmacies to check reliability of study tools that were not included in the final results of the study. The questionnaire was partially modified as a result, and the modified version was reassessed by applying it to a further 15 pharmacies. Test-retest method was applied.

2.4. Data collection

A three-step study was performed in three intervals (Attached file 2) to assess the community pharmacies with respect to PDR-2007 [13], WHO recommendations [8] and amendments of PDR 2014 [14]. These three steps were completed during a single visit to each community pharmacy. Each pharmacy was given an identification number, and then observed to assess its compliance with legislation, presence of a qualified person, medication storage and documentation.

Step 1 was observational, and used a data collection form (Attached file 3) with 28 items. We assessed inter-rater reliability of the data collectors using the percentage agreement method. The temperature was measured using a suitable scale.

In Step 2, the data collectors administered the validated questionnaire (Attached file 4) to find the pharmacy specification, total number of staff and the educational level and experience of each staff member.

In Step 3, the knowledge of staff about common terminology in medication counseling and safe storage of medicine was explored in a face-to-face interview. A semi-structured questionnaire (Attached file 5) was used, and data collectors completed the form. One employee from each pharmacy was invited to participate.

2.5. Statistical analysis

We used Statistical Package for Social Sciences for Windows, Version 18.0 (SPSS Inc., Chicago, IL, USA) for all analyses. Pharmacy specifications, compliance with regulatory requirements and storage of medicine were calculated as a percentage using descriptive analysis. Hygiene level, protection from sunlight, segregation of particular drugs, and floor condition were measured using a five-point Likert-type scale ranging from 1 (“very bad”) to 5 (“very good”). The average was calculated as a percentile. To understand the impact of demographic characteristics of the pharmacy and staff on variation in measures, we used one-way analysis of variance (ANOVA).

2.6. Ethical approval

The study in accordance with the Declaration of Helsinki. However design and protocol were approved by “The Islamia University, Bahawalpur, Pakistan” (Ref # 67–2015/PREC).

Table 1

Specification of pharmacies (n = 544).

Specification	Categories	Frequency	%
Number of the sale counters	1	327	60.1
	2 to 5	211	38.8
	More than 5	6	1.1
Staff engaged in services	1	124	22.8
	2 to 5	289	53.1
	6 to 10	96	17.6
	11 to 15	28	5.1
	More than 15	7	1.3
Average number of customers dealt in a day	30 to 50	87	15.9
	51 to 100	411	75.6
	More than 100	46	8.5
Location of pharmacy	Near or in-front of hospitals	387	71.1
	General market	124	22.8
	In community or residential area	33	6.1
Nature of business venture	Branch of chain pharmacies	8	1.5
	Individual pharmacy	536	98.5
Years of establishment	Less than 1 year	5	0.9
	1–5 years	105	19.3
	6–10 years	219	40.2
	11–15 years	122	22.4
	More than 15 years	93	17.1

2.7. Patient and public involvement

Written and verbal consent was obtained from pharmacy retailers (Attached file 6). Pharmacy identities were anonymized by using identification numbers in data collection and monitoring. All participants were informed of the study purpose.

3. Results

In total, 1243 community pharmacies were contacted, and 544 agreed to participate in the survey, a response rate of 43.7 %.

3.1. Specification of pharmacies

Pharmacies were open on average 11.1 h/day. Most pharmacies (60.1 %) had one sales counter and the majority (75.6 %) dealt with 50–100 patients per day (see Table 1).

3.2. Compliance with legal requirements

In total, 61.3 % of pharmacies had a suitable arrangement to protect medicines from direct sunlight, 70.6 % had refrigerators and 93.0 % displayed a valid drug sale license (see Table 2).

3.3. Profile of staff

The sample pharmacies employed a total of 2281 members of staff, all male. An average of 4.2 employees were providing services in each one pharmacy (see Table 3).

3.4. Knowledge of staff

Only one employee of pharmacies could explain the term “PRN” or “use as needed”, although 57.3 % explained “IV” appropriately. About 22.8 % replied correctly about room temperature (see Table 4).

Table 2
Compliance to legislation (n = 544).

Domains	Items/Measures	Frequency	%
Premises	Accurate area of pharmacy	23	4.2
	Accurate walls of pharmacy	21	3.9
	Accurate signboard	70	12.8
	Shelves having front glass	127	23.3
	Presence of front glass door	208	38.2
	Present of pest killer	71	13.1
	Presence of separate expiry shelf	234	43.0
	Presence of separate narcotics shelves	293	53.8
	Floor of pharmacy smooth and washable ^{*1}	–	51.8
	Hygienic condition ^{*2}	–	47.5
	Protection from direct sunlight to drug rakes ^{*3}	–	61.3
	Segregation of cosmetics, disinfectants, pharmaceuticals and veterinary product ^{*4}	–	36.2
	Standardized shelves ^{*5}	–	51.0
	Storage	Refrigerator available	384
Refrigerator working properly		236	43.4
Refrigerator having medicines only		176	32.3
Availability of alternative power supply for refrigerator		13	2.4
Presence of refrigerator's temperature-monitoring device		89	16.4
Presence of temperature-monitoring devices for premises		132	24.3
Presence of air conditioner		86	15.8
Documents	Maintenance of room temperature 15–30 °C	37	6.8
	Presence of valid and visible license	506	93.0
	Presence of pharmacist/Qualified person	26	4.8
	Narcotics register available	259	47.6
	Narcotics register maintained	125	22.9
	Record/device have recording option for cold chain 2–8 °C	19	3.5
	Warranties and purchase record maintain	447	82.2
	Inspection book	78	14.3
Expiry record	102	18.7	

*1,2,3,4,5 Results are represented and explained according to Likert scale (Attached file 7).

Table 3
Profile of staff (n = 2281).

Profile	Categories	Frequency	%
Gender of staff	Male	2281	100
	Female	0	0
Age of staff	Below 25	211	9.3
	25–35	587	25.7
	36–45	989	43.3
	46–55	416	18.2
	More than 55	78	3.3
Working experience	Below 1 year	43	1.9
	1–5 years	1113	48.8
	6–10 years	812	35.6
	11–15 years	301	13.2
	More than 15 years	12	0.5
Educational level	Pharm.D/B.Pharmacy	8	0.4
	Dispenser class/Pharmacy technician diploma	311	13.6
	Below Matriculation (Below 10 years schooling)	217	9.5
	Matriculation (10 years schooling)	1183	51.8
	F.A (Faculty of Arts)/F.Sc(Faculty of Sciences)/A Level (12 years schooling)	442	19.4
	B.A (Bachelor of Arts)/B.Sc (Bachelor of Sciences) (14 years schooling)	95	4.2
	M.A (Master of Arts)/M.Sc (Master of Sciences) (16 years schooling)	9	0.4
	Above 16 years schooling	2	0.1
	Other	14	0.6

Table 4
Knowledge of staff (n = 544).

Domains	Indicator	Frequency	%	
Medication counseling and dispensing terms	IM	309	56.8	
	SOS	142	26.1	
	SC	128	23.5	
	IV	312	57.3	
	OTC	33	6.1	
	POM	17	3.1	
	OD	234	43.0	
	BID	144	26.5	
	TID	71	13.1	
	QID	5	0.9	
	HS	3	0.5	
	PRN	1	0.2	
	Storage of medicine and legal terms	Misbranded	65	11.9
		FEFO	47	8.6
Keep cool		119	21.8	
Store at room temperature		124	22.8	
Optimum Humidity		47	8.6	
	Cold chain temperature	13	2.4	

4. Discussion

The community pharmacies sampled showed low compliance with legal requirements. No pharmacy complied with all the requirements. The unsatisfactory level of education of staff was coupled with inadequate knowledge. As in many other developing countries, the community pharmacies often had improper documentation, filthy storage conditions and inappropriate premises [2, 15–18,25]. This study, however, found a few improvements over previous from Pakistan, including the display of a valid license, the presence of air conditioners and record maintenance for medicine purchase [11,12]. The daily average opening time (11.1 h) is aligned to operational hours of community pharmacies in Yemen (8–12 h/day) [25].

Like Karachi, Sri Lanka and the UK, storage facilities for medicines in many community pharmacies in Punjab were inadequate [5, 20,26]. Medicines were not properly protected from extreme temperatures and the majority of pharmacies did not maintain the appropriate room temperature [5,26]. Medicine efficacy is reduced by high temperature storage and transition [26]. The daytime temperature during summer in many cities in Punjab ranges from 45 to 52 °C [27], and more than half of the refrigerators in the community pharmacies did not work properly. The majority also had no alternative power supply for the refrigerator, even though a minimum of 6–8 h scheduled load-shedding per day is routine in Punjab [28]. During this time, vaccines and many other medicines can lose their efficacy [26]. An alternative power supply for refrigerators is compulsory for the safety of medicines, so this study has shown that there are serious deficiencies in vaccine and medicine storage in the Punjab, similar to previous findings in India [29].

The hygiene level was very poor, in contrast to Saudi Arabian pharmacies [21]. Most pharmacies have inappropriate space, walls and signboards. The overall premises of most pharmacies did not meet the legal requirements. As per law premises or space need

minimum covered area for a pharmacy must be 140 square feet, with a front breadth of at least 8 feet and a minimum height of 8 feet. For a medical store, the required covered area is 96 square feet, with a minimum front breadth of 8 feet and a height of 8 feet. Similarly, for a pharmacy, the individual is required to exhibit the term “Pharmacy” in white lettering on a green signboard affixed to the exterior wall of the pharmacy. The signboard must have a minimum length of 5 feet and a width of 2.5 feet. For a medical store, the individual must display the words “Medical Store” in white lettering on a blue signboard with the same minimum dimensions specified for a pharmacy [11,12]. Documentation and records maintenance is designed to ensure the transparency of the supply chain, recording all transactions from manufacturer to customers [30]. In contrast to previous findings, record keeping for warranties and purchase of medicines improved in community pharmacies [11]. But like the Indian drug stores, weak record keeping for narcotics and expiry medication exists yet [29,31].

Like African and European pharmacies [16,17], poor staffing in community pharmacies appears to be a big issue in Pakistan. The average number of employees (4.2) was higher than in Palestinian pharmacies (2.8) [25], but this study exposes the absence of a pharmacist or qualified person in most community pharmacies. This is a big challenge in Pakistan [22,32], as it is elsewhere, including Malaysia [4]. The study also found that staff have little or no pharmaceutical education and training. A large proportion of staff have no more than 10–12 years’ formal education, and most pharmacies are operated by untrained staff [21,32]. The ratio of professional trained staff, including pharmacists (0.4 %) and pharmacy technicians (13.6 %), was comparatively low [12]. The pharmacies only employ male staff because of social expectations on women [33].

Staff knowledge is an important aspect of community pharmacy services and good pharmacy practice [34]. The knowledge of staff about common terminologies used in medication counseling and dispensing was not satisfactory. They also had insufficient awareness of requirements for safe storage of medicines, even though many had considerable experience [22,23]. The employment of under-qualified staff with poor knowledge, and the low level of compliance with legal requirements, indicate that community pharmacies are business ventures rather than healthcare entities [31]. Non qualified staff can’t provide the patients centered services [35,36]. Moreover, policies are not implemented properly, and the accountability and inspection systems are weak [2,12].

5. Conclusions

This study found that the premises of many community pharmacies in Punjab, Pakistan, did not comply with legal requirements. Medicines were not stored safely, and supply chain documentation was poorly maintained. This reflects the poor enforcement of drug laws, because policies and regulations are not implemented properly by health authorities. The findings suggest that there is a need to strengthen inspection and management of community pharmacies. Drug safety during distribution should insure. More training to staff can strengthen the medicine supply system in Pakistan.

6. Limitations

Firstly, this study is conducted in selected pharmacies and shows a limited insight. In addition, due to stumpy response rate; original snapshot may vary. To overcome this issue, we selected a pharmacy within 2 km area to ensure equal participation of pharmacies from every locality. Secondly, the age, number and qualification of staff and area of pharmacy is based on self-reporting of pharmacy owner or manager. Thirdly, this study did not illustrate the reason of pharmacy’s refusal to study participation. Fourthly, although rater reliability of data collectors was analyzed but observations about hygienic condition, smooth and washable floor, direct sunlight, segregation of products and standardized shelves may vary. Therefore, we apply Lickert scale to minimize the biasness. Fifth limitation of this study includes a single representation from a pharmacy in step 3 but it had highest level of education or experience.

Data availability statement

Data included in article/supp. Material of article. Raw or further data will be made available on request.

CRedit authorship contribution statement

Muhammad Majid Aziz: Writing – review & editing, Writing – original draft, Validation, Methodology, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Amany Alboghdady:** Writing – review & editing, Writing – original draft, Data curation, Conceptualization. **Muhammad Fawad Rasool:** Writing – review & editing, Supervision. **Marwa S. Shaalan:** Visualization, Validation, Software, Resources, Funding acquisition. **Hind Khalid Goresh:** Validation, Resources, Funding acquisition, Formal analysis, Data curation. **Muath Fahmi Najjar:** Writing – review & editing, Validation, Software, Resources, Methodology, Funding acquisition. **Samar Zuhair Alshawwa:** Writing – review & editing, Visualization, Validation, Resources, Methodology, Funding acquisition.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.heliyon.2023.e23112>.

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