

Original Research

Good pharmacy practice assessment among community pharmacies in Lebanon

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Abstract

Objective: This study aims to assess good pharmacy practice (GPP) aspects and compare GPP scores among community pharmacies in Lebanon, using a tool developed jointly by the International Pharmaceutical Federation (FIP) and the World Health Organization (WHO) to improve and maintain standards of pharmacy practice.

Methods: Data collection was carried out between July and October 2018 by a team of 10 licensed inspectors who work at the Lebanese Order of Pharmacists (OPL) and visited community pharmacies across Lebanon. The questionnaire was adapted to the Lebanese context and included 109 questions organized under five sections: socio-demographics, Indicator A (data management and data recording), Indicator B (services and health promotion), Indicator C (dispensing, preparation and administration of medicines), and Indicator D (storage and facilities). The value of 75% was considered as the cutoff point for adherence to indicators.

Results: Out of 276 pharmacies visited, a total of 250 (90.58%) pharmacists participated in the study with one pharmacist being interviewed in every pharmacy. Results showed that 18.8% of pharmacists were generally adherents to GPP guidelines (scores above the 75% cutoff): 23.3% were adherent to indicator A, 21.6% to indicator B, 14.8% to indicator C and 13.2% to indicator D. Moreover, comparison of GPP scores across geographical regions revealed a higher adherence among community pharmacists working in the Beirut region compared to the North region, the South region, Mount Lebanon, and the Bekaa.

Conclusions: Our study shows that community pharmacists in Lebanon do not fulfill GPP criteria set by FIP/WHO, and that this poor adherence is a trend across the country's geographical regions. Therefore, efforts should be made to raise awareness among pharmacists about the necessity to adhere to GPP guidelines and standards, and train them and support them appropriately to reach that goal. This is the first indicator-based comprehensive pilot assessment to evaluate GPP adherence in community pharmacies across Lebanon. Working on the optimization of this assessment tool is also warranted.

Keywords

Pharmacies; Professional Practice; Quality of Health Care; Pharmacists; Pharmaceutical Services; Health Promotion; Goals; Management Audit; World Health Organization; Reference Standards; Lebanon

INTRODUCTION

"The mission of pharmacy practice is to contribute to health improvement and to help patients with health problems to make the best use of their medicines".¹ In an effort to standardize pharmacy practice, the International Pharmaceutical Federation (FIP) and the World Health Organization (WHO) published a joint document in 2011 about Good Pharmacy Practice (GPP).¹ The document delineated sets of standards that would guide national pharmacy professional organizations through the establishment of their own national GPP guidelines, and broke down pharmacists' practice under four roles and specified the minimum standards required to meet GPP.¹ Roles included the preparation, storage, distribution, administration and disposal of medications, the provision of effective medication therapy management, the

continuous improvement of professional knowledge and performance, and the contribution to improving effectiveness of community health.

The updated GPP guidelines served as supporting material to community pharmacists practicing in continually changing healthcare systems and increasingly complex standards of practice. Over the past few decades, a number of factors have directly or indirectly contributed to complicating the initially rather streamlined mission of pharmacy practice. Therefore, the monitoring of GPP is crucial, particularly in developing countries such as Lebanon where dispensing antibiotics without prescription is common practice, alongside other public health issues, including high prevalence of smoking, inappropriate disposal of medicines, dispensing of counterfeit medicines, poor generic substitution, readiness for but limited adequate medication therapy management, and lack of reporting of adverse drug reactions (ADRs).²⁻⁹ Moreover, a report published by the WHO in 2014 indicated that non-communicable diseases (NCDs) account for 85% of total deaths in the country, thus emphasizing the importance of the pharmacist's involvement in the prevention of chronic diseases.¹⁰

Pharmacists in Lebanon have become exposed to activities that were not within the primary scope of their practice, leading to a new role for Lebanese pharmacists that goes beyond their regular duties (as per the minimum legal requirement). Indeed, the emergence of local healthcare crises consequent to refugee displacements and the

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resulting spread of communicable diseases are only a few among numerous other critical aspects that have severely impacted community health.¹¹⁻¹³ All these roles have to be practiced within well-managed settings to guarantee quality of medications and pharmaceutical services while minimizing errors and malpractice. In Lebanon, to be allowed to practice, pharmacists must register with the Lebanese Order of Pharmacists (OPL, is the official pharmacists' association), as per the Lebanese law of 1950.¹⁴ To maintain their registration, pharmacists should pay an annual fee and enroll in the mandatory continuing education program.^{14,15} Moreover, pharmacists' practice is overseen by inspectors from the OPL in collaboration with inspectors from the Ministry of Public Health (MOPH); however, a standardized tool for pharmacy practice evaluation is not yet available in the country.

Figures retrieved from the OPL indicate that at the end of 2017, 2,968 pharmacies, harboring 3,762 pharmacists (employers and employees), were distributed across a territory of 10,452 Km² as follows: 232 (7.8%) in Beirut, 431 (14.5%) in the North region, 553 (18.7%) in the South region, 463 (15.6%) in the Bekaa region, and 1,289 (43.4%) in the Mount Lebanon region. The evaluated ratios of pharmacies and community pharmacists were 6.61 and 8.36 per 10,000 inhabitants, respectively.¹⁶ The latter was higher than the mean density of 3.73 pharmacists per 10,000 inhabitants identified within the WHO Eastern Mediterranean region in a study conducted by the FIP in 2016. Moreover, the average density of community pharmacists per 10,000 inhabitants in Lebanon (8.36) was higher than the mean ratio (3.31 per 10,000 inhabitants) across all WHO regions and in the higher range of the ratios (1.92 to 11.82) found in some neighboring WHO countries (United Arab Emirates, Bahrain, Jordan, Egypt, Kuwait).¹⁷ In Lebanon, the easy access to pharmacies and familiarity with pharmacists, the distant location of hospitals, particularly in remote regions, the expensive clinical/medical consultation fees, and the possibility to obtain medication without prescription are all contributing factors that have made pharmacists the first healthcare professionals to be consulted by patients.¹⁸

In this context, the aspects of pharmacy practice that require particular attention or urgent intervention are not clearly identified, in particular the common practice in Lebanon of dispensing medications without prescription or appropriate indications of use. This haphazard practice that started during the Lebanese civil war still prevails, despite efforts of regulatory authorities to enforce article 43 of law 367/94 of 1994, requiring that the dispensing of medications be done upon physician's prescription.¹⁹ In fact, the only two classes of medications strictly regulated in Lebanon are psychotropic agents and narcotics, where the pharmacist is required by law to keep the physician's prescription and record it in specifically designed registers; other medications are not subject to law enforcement. Other practice items are also addressed in the law (such as the prohibition to perform any medical act or injecting medications and vaccines); however, no mention is made about the majority of other practice issues, such as counseling to the patient, medication therapy management, reporting adverse effects, etc. Regarding the technical specifications of the pharmacy, they are featured

in the Decree No. 2622 issued in 1992 that briefly describes the location, inner layout, fixtures, materials, and supplies.²⁰

In Lebanon, as in many developing countries, law enforcement is limited, and the introduction of new laws is slow and thus laws of 1950 are still enforced. Moreover, inspection visits to community pharmacies are sporadic and penalties differ according to the breach of the law identified. Consequently, and to improve the quality of pharmacy practice and practice evaluation, GPP standards were suggested by the OPL and published in 2019. These standards were based on those suggested by the FIP/WHO and those in application in the United States, Europe, and regional countries, and adapted to the Lebanese context. The GPP requirements applicable to Lebanon were defined and categorized into fifteen sections that set standards for various aspects of pharmacy practice, including pharmacy settings, handling of stock, supply of non-prescription medicines, health promotion, and research and professional development.²¹

The leading authority entitled to evaluate GPP is the MOPH in collaboration with the OPL. However, the process of monitoring pharmacists' professional activities is neither standardized nor quantitative and might be subjective due to the lack of a quantitative tool. A pre-requisite for efficient and fair evaluation of GPP in the community is the establishment of an indicator-based tool that can be used reliably for the assessment. Studies conducted among community pharmacists in Lebanon have already reported about GPP performance; however, these studies were limited in number and focused on some but not all aspects of GPP.⁹

To implement the GPP standards already defined by the OPL, and since no validated tool is available in Lebanon, it is essential to start by assessing the current situation using international tools. Thus, the objective of this pilot study was to assess GPP aspects as recommended by the FIP and the WHO, and compare GPP scores among community pharmacists in Lebanon based on pharmacies' geographical distribution and pharmacists' characteristics, using a FIP/WHO-developed tool.¹

METHODS

Data collection

Data collection was carried out between July and October 2018. Data were prospectively collected by a team of 10 licensed OPL inspectors who were designated by the OPL and visited community pharmacies across all Lebanese geographic areas, namely Beirut, Mount Lebanon, North, South, and Bekaa. Based on the list of pharmacies available in the OPL, inspections were scheduled by the OPL administration in regular rounds, following specific routes of visits outside of their district of origin.

In preparation for data collection, OPL inspectors received a one-day training session on the use of the inspection tool. Pharmacies to be visited were randomly selected and were not informed beforehand of the OPL inspector's visit. In every visited pharmacy, only one licensed community pharmacist (employer or employee) was approached; if

more than one was on duty at the time of the visit, then the OPL inspector would choose one of them randomly. Those who refused to participate were excluded from the study. No unlicensed staff were approached. It is noteworthy to highlight that in Lebanon, pharmacists have the legal obligation to comply with OPL inspectors' demands during visits; however, this does not include filling out surveys.

Institutional Review Board (IRB) approval was granted by the American University of Science and Technology to conduct the study (IRB request number AUST-IRB-20180518-01). The study was anonymous and verbal approval of participation was obtained from all participating pharmacists. Anonymity was ensured by analyzing the data after removing any pharmacist related identifier.

Indicators and scale

The FIP/WHO document described four roles in pharmacy services and identified 15 functions under those roles. Using the FIP/WHO document and the questions published by Trap *et al.* (2010), a 109-item questionnaire was designed; it included one section detailing demographics and characteristics of the community pharmacist, and four indicators.²² Indicator A was labeled "Data management and data recording" and was designed to evaluate data management and data recording, such as the systems used to record medications dispensed. Indicator B was labeled "Services and facilities" and measured items related to services and health promotion, including health campaigns and services available to patients such as vaccinations. Indicator C evaluated "Dispensing, preparation, administration and distribution of medicines" by assessing the quality of dispensing, preparation and administration of medicines by pharmacists. Indicator D focused on "Storage" and addressed power supply, contingency plans, and other storage-related aspects. Additional questions about facility details and medication disposal were added to indicator D.

The questionnaire was designed to fit requirements and standards of pharmacy practice in Lebanon. Some of the questions were self-administered by the community pharmacist, while others were answered by the OPL inspector since they required direct observation and visual verification. All of the eight questions under Indicator A were self-administered. Eight of the 20 questions under Indicator B were self-administered, while 12 were answered by the OPL inspector after direct observation. Thirty-two of the 33 questions under Indicator C were self-administered, while one was assessed by the OPL inspector, and 14 of the 36 questions under Indicator D were self-administered, while 22 were answered by the OPL inspector. The maximum possible score is 26, 32, 55 and 16 for indicators A, B, C, and D, respectively. The Cronbach's alpha was 0.833, 0.301, 0.119, and 0.526 for indicators A, B, C and D, respectively. The GPP adherence total score was calculated by summing the scores of the four indicators. In addition, overall adherence to an indicator was assessed using a cut-off value of 75%: for every indicator, the pharmacist had to have appropriate behavior/answer on more than 75% of items to be considered adherent to the FIP/WHO indicator.

All 35 questions administered by OPL inspectors were excluded from their specific indicator section and grouped into an "OPL-administered group" (OAG). Those questions were considered as indicators and taken into account when estimating Cronbach's alpha.

The questionnaire was available in both Arabic and English languages, and participants chose their preferred language. It was initially developed in English, then translated into formal Arabic language and reverse translated into English [See Online appendix 1 for the questionnaire].

Specific items of the FIP/WHO document were purposefully excluded from our questionnaire, such as the role of pharmacists in vaccination campaigns, in the writing of standard operating procedure for referral to appropriate healthcare providers, and in the implementation of new technologies in pharmacy services. Those aspects of pharmacy practice were not used to evaluate GPP scores since they do not rely on the professional capacities of the pharmacist or their standard of practice solely and require support by other healthcare professionals as well as ministries. Therefore, our indicator-based tool specifically focused on the items of the FIP/WHO document that evaluated efficacy and standards of practice for the items that can be managed by the pharmacists unilaterally in the Lebanese context and where no external intervention or support is required or needed.

Statistical analyses

Data entry was performed by two people not involved in the data collection process. Data were analyzed using IBM SPSS Software version 23. After weighting for the community pharmacists' geographical distribution according to the OPL official figures, frequencies were calculated for all categorical variables, while means and standard deviations were calculated for continuous variables.²³ GPP indicators were analyzed as continuous variables and as dichotomous variables, where adherence to an indicator was considered positive in case the score was above the passing grade set at 75%.²⁴

Since our sample included more than 100 participants, the data was considered normally distributed, whereby non-normal distributions have no significant consequences in the case of samples greater than 100.²⁵ The Student's t-test was used to investigate differences between two groups, while ANOVA was used to compare means of adherence scores between three groups or more. A post-hoc analysis using the Bonferroni test was also applied to study differences between variable modalities taken two by two. No multivariable analyses were conducted since the majority of bivariate tests were non-significant. A p-value of 0.05 was considered significant and 95% confidence intervals were used.

RESULTS

A total of 250 pharmacies participated in the study, whereby one pharmacist was surveyed in every pharmacy. Most pharmacies were located in the Mount Lebanon region (44.50%), while Beirut included the lowest percentage (12.60%). Across demographic regions, 138 (57.20%) participating pharmacists were females and most

Table 1. Sociodemographic and other characteristics of the participants.	
Variable	N (%)
Gender	
Male	103 (42.80%)
Female	138 (57.20%)
Level of education	
BS Pharmacy	145 (60.60%)
PharmD	76 (31.60%)
Master's	14 (5.70%)
PhD	5 (2.10%)
Governorate	
Beirut	31 (12.60%)
Mount Lebanon	109 (44.50%)
North	32 (13.20%)
South	41 (16.70%)
Bekaa	32 (13.10%)
Number of patients per day	
<50	106 (45.20%)
50-100	95 (40.30%)
>100	34 (14.50%)
Years of practice	
Less than a year	8 (3.20%)
1 year to less than 3 years	28 (11.20%)
3 years to less than 6 years	37 (14.90%)
6 years to less than 12 years	72 (29.50%)
12 years or more	101 (41.20%)
Hours of work per week	
Less than 31 hours	19 (7.60%)
32-40 hours	31 (12.40%)
>40 hours	199 (79.90%)
Position in the pharmacy	
Owner/Employer	197 (80.50%)
Staff/Employee	48 (19.50%)
Family monthly income *	
<1000 USD	8 (4.20%)
1000-2000 USD	58 (30.20%)
2000-3000 USD	51 (26.60%)
>3000 USD	75 (39.10%)
	Mean (SD)
Age (in years)	39.01 (10.19)
House crowding index	0.94 - 0.47
*The mean family income in Lebanon is 1833 USD	

had at least 12 years of experience in pharmacy practice (41.20%). The mean age of pharmacists was 38.88 years (SD 10.06), with 64.80% having a Bachelor of Science (BS) degree and most (77.30%) working more than 40 hours a week. Additional descriptive results are summarized in Table 1.

Descriptive results related to indicators' items are presented in Online appendix 2 - Tables 1 to 5. Almost all pharmacists made use of a computerized data management system (99%) mainly for stock management (92%), but rarely for clinical services and medication management. Around one-quarter (27%) of the pharmacists interviewed used log books, but only a few used them for clinical services. Three-quarters of pharmacists kept copies of prescriptions for non-controlled medications (76%) (Online appendix 2 - Table 1).

The majority of pharmacies (83%) employed a licensed pharmacist for patient services and health promotion, and offered a suitable place to discuss confidential information (93%). Furthermore, less than a third of pharmacists declared participating in awareness campaigns against most common diseases, and half of them made information of various types and health resources available for patients.

Finally, most pharmacies offered services such as flu vaccination, blood pressure, and glycemia checks (Online appendix 2 - Table 2).

All pharmacists had dispensed more than one prescription per day (Online appendix 2 - Table 3), and almost all of them had encountered prescription errors and provided information regarding adherence to treatment and antibiotic resistance (98%). Less than half of them had to call back patients because of a wrong delivery of medication or wrong dosage prescription after patients had left the pharmacy (41%), while 88% acknowledged dispensing medications without prescription. Those medications included NSAIDs (95%), antibiotics (60%), steroids (27%), benzodiazepines (14%), gastrointestinal drugs (67%), hormones and contraceptives (48%). Moreover, 88% declared explaining to patients the purpose of switching to a generic and less than 40% made extemporaneous preparations in a suitable area using appropriate equipment. The vast majority did not have a clear recall procedure for dealing with products suspected to be adulterated, unlicensed, spurious, falsely labeled, falsified, or counterfeit, while almost all pharmacists declared that patients could consult them for unusual adverse events. Most of the pharmacists interviewed had access to documentary and information resources, mainly through the internet (63%). More than 90% counseled patients and checked medications before dispensing, while one-quarter did not check for contraindications, drug interactions, or prescribed doses (Online appendix 2 - Table 3).

With regard to the management of medication stock (Indicator D), around 7% of pharmacists stated that there was no electric power supply available overnight, 9% indicated that they did not have adequate inventory management and expiration date monitoring systems, 85% did not encourage patients to return expired or unwanted products, and 68% did not have a specific procedure to dispose of expired products (Online appendix 2 - Table 4).

Regarding items that were directly checked by OPL inspectors, the evaluation of Indicator B showed that around 60% of community pharmacies did not have drinking water or toilet facilities available for customers. The evaluation of Indicator D showed that 3% of pharmacists did not protect their stock of medications from direct sunlight. However, most pharmacies were equipped with cooling and heating systems, 88% had a refrigerator where, in 22% of cases, products other than medications were stored. In 52% of pharmacies, pharmacists did not label shelves, and in 58% of the cases medicine bottles/containers were stored on the floor in the storage area (Online appendix 2 - Table 5). Finally, half of the pharmacists surveyed declared that they did not use pest control services at the pharmacy (Online appendix 2 - Table 5).

The mean GPP adherence score was 4.62 (SD 1.36) for indicator A, 9.39 (SD 4.05) for indicator B, 14.02 (SD 2.27) for indicator C, and 9.35 (SD 2.02) for indicator D; for the full scale, the results were 33.90 (SD 3.95) (Figure 1). Moreover, in the absence of a cutoff point for the GPP adherence total scale score, the value of 75% was adopted as the cutoff point.²⁴ Results were presented as percentage

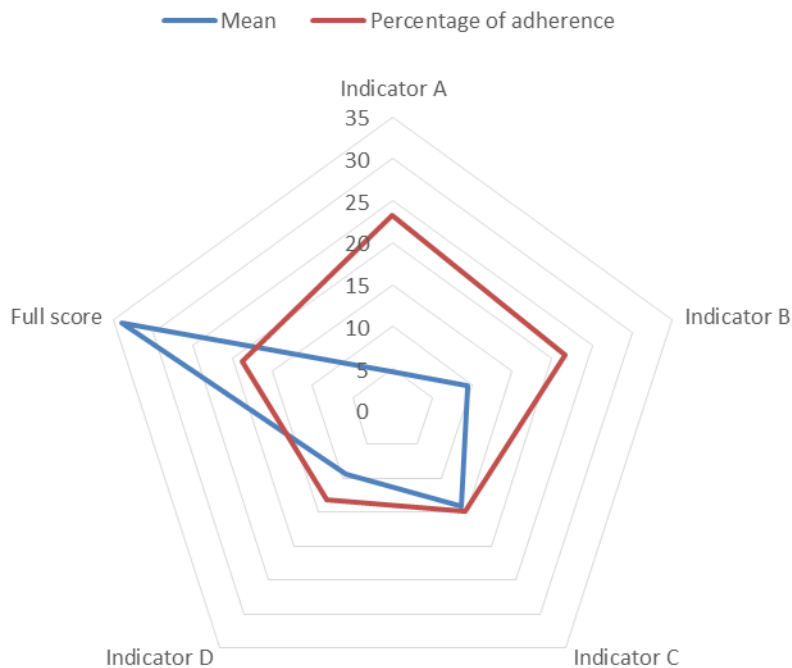


Figure 1. Spidograph depicting mean score and percentage of adherence per indicator and for the full scale

of adherence to GPP; 41 (18.80%) of the pharmacists were considered adherent to GPP guidelines (all scores above 75%), 57 (23.30%) were considered adherent to indicator A, 53 (21.60%) to indicator B, 36 (14.80%) to indicator C, and 32 (13.20%) to indicator D (Figure 1).

The bivariate analysis was used to examine GPP adherence for each of the demographics and characteristics of the pharmacists (Table 2). The results of the ANOVA test showed significantly higher adherence score to indicator D in Beirut (11.25; SD 0.50); also the highest GPP overall adherence score (37.75; SD 0.50) for the four indicators altogether was found in Beirut (Table 2). Post-hoc analysis results identified a significantly higher mean GPP adherence total score in Beirut compared to other regions. Concerning indicator D, a significantly higher mean score was found in Beirut compared to the Bekaa ($p=0.036$), in the Mount Lebanon compared to the Bekaa ($p=0.010$), and in the North compared to the Bekaa ($p=0.024$).

No significant difference was found between the GPP adherence total score and all indicators and gender, years of practice, number of weekly working hours, and total family income per month ($p>0.05$ for all variables). A significantly higher indicator D score was found in employees compared to employers ($p=0.049$), whereas there was no significant difference between the two groups and the GPP total score, indicators A, B, and C. Finally, a significantly higher indicator A mean score was found in pharmacists receiving between 50 and 100 patients per day, whereas significantly higher indicators C and D mean scores were found in pharmacists receiving more than 100 patients per day (Table 2).

In the multivariable analysis, a significantly lower adherence was found in the South as compared to Beirut

and the Bekaa regions. Doctor of Pharmacy (PharmD) holders demonstrated better adherence to GPP guidelines in comparison with BS Pharmacy holders. All other characteristics did not affect the adherence to GPP guidelines (Table 3).

DISCUSSION

This study sought to assess the level of adherence to GPP guidelines of community pharmacists in Lebanon. The results showed that 18.80% of pharmacists were generally adherent to GPP guidelines (scores above the 75% cutoff): 23.30% were adherent to indicator A, 21.60% to indicator B, 14.80% to indicator C, and 13.20% to indicator D. The use of indicators rather than other measurement tools was deemed most appropriate because, despite its limitations, it is a well-accepted “measurable element of practice performance for which there is evidence or consensus that it can be used to assess the quality, and hence change in the quality of care provided”.²⁶⁻²⁸

Moreover, comparison of GPP scores across geographical regions revealed a higher adherence among community pharmacists working in the Beirut region compared to the North region, the South region, Mount Lebanon, and the Bekaa. The data collected can be used as a baseline in future GPP evaluations over the years, across geographical locations, and according to the demographic characteristics of pharmacists, particularly if the assessment tool is improved in future studies.

Furthermore, it is important to point out that FIP encourages national pharmacy professional associations to evaluate pharmacy practice by adapting the FIP/WHO guidelines to the national context. Indeed, they state that

Table 2. Mean scores and standard deviations for all indicators univariate analysis

	GPP adherence total score	Indicator A	Indicator B	Indicator C	Indicator D
Region					
Beirut	37.75 (0.50)	5.50 (0.57)	12.50 (4.36)	14.25 (2.22)	11.25 (0.50)
Mount Lebanon	34.78 (3.07)	4.52 (1.37)	9.51 (3.77)	13.61 (2.25)	9.35 (2.13)
North	30.00 (9.90)	4.71 (0.99)	9.36 (4.84)	14.35 (2.24)	10.07 (1.77)
South	31.00 (3.84)	4.57 (1.29)	8.77 (3.86)	14.57 (2.30)	9.19 (1.82)
Bekaa	34.01 (4.58)	4.70 (1.71)	9.04 (4.21)	14.48 (2.35)	8.37 (1.75)
p-value	<0.001	0.318	0.403	0.076	<0.001
Gender					
Male	33.79 (4.08)	4.67 (1.51)	9.43 (4.20)	14.33 (2.33)	8.99 (2.07)
Female	33.40 (4.22)	4.57 (1.41)	9.14 (3.88)	14.05 (2.33)	9.09 (1.87)
p-value	0.483	0.627	0.575	0.354	0.700
Years of practice					
Less than 6 months	31.16 (3.06)	4.50 (1.73)	10.00 (1.15)	13.25 (1.50)	9.50 (2.38)
6 months to less than a year	33.62 (6.67)	4.25 (1.71)	11.50 (3.42)	15.00 (2.00)	9.50 (1.73)
1 year to less than 3 years	33.09 (4.44)	4.86 (1.24)	9.46 (3.78)	13.75 (2.34)	9.39 (2.02)
3 years to less than 6 years	34.23 (4.36)	4.62 (1.59)	9.70 (3.98)	14.51 (2.43)	9.19 (2.09)
6 years to less than 12 years	34.18 (3.49)	4.64 (1.32)	9.52 (4.34)	14.21 (2.44)	8.98 (2.05)
12 years or more	33.92 (3.95)	4.53 (1.56)	8.74 (4.02)	14.10 (2.25)	9.01 (1.89)
p-value	0.644	0.927	0.569	0.708	0.919
Hours of work/week					
1-16 hours	32.67 (2.59)	5.33 (0.52)	9.00 (1.41)	14.67 (0.82)	9.00 (0.89)
17-31 hours	31.20 (4.88)	5.00 (1.00)	8.92 (3.25)	14.62 (2.10)	10.23 (1.88)
32-40 hours	34.65 (3.25)	4.52 (1.61)	9.10 (4.02)	13.97 (2.85)	9.03 (2.14)
>40 hours	34.01 (3.99)	4.58 (1.47)	9.31 (4.17)	14.13 (2.28)	9.03 (1.97)
p-value	0.052	0.543	0.978	0.799	0.205
Position in pharmacy					
Owner/Employer	33.72 (3.82)	4.64 (1.46)	9.16 (3.93)	14.14 (2.29)	8.98 (1.88)
Staff/Employee	34.61 (4.41)	4.57 (1.39)	9.89 (4.71)	14.19 (2.56)	9.68 (2.40)
p-value	0.186	0.794	0.313	0.892	0.049
Family income/month					
<1000 USD	32.54 (4.46)	4.12 (1.73)	7.75 (2.60)	12.62 (1.51)	9.13 (1.64)
1000-2000 USD	33.46 (4.13)	4.64 (1.45)	9.19 (4.50)	14.14 (2.35)	9.22 (1.99)
2000-3000 USD	34.83 (3.70)	4.59 (1.69)	9.53 (3.91)	14.04 (2.46)	8.78 (1.84)
>3000 USD	34.17 (3.78)	4.60 (1.35)	9.76 (3.96)	14.40 (2.24)	9.48 (1.88)
p-value	0.256	0.839	0.557	0.218	0.254
Number of patients per day					
<50	2.32 (1.14)	1.78 (0.75)	2.26 (1.02)	2.11 (0.99)	2.18 (1.08)
50-100	2.30 (1.13)	2.04 (0.73)	2.48 (1.08)	2.38 (0.94)	2.29 (1.03)
>100	2.76 (1.01)	1.76 (0.77)	2.34 (1.25)	2.60 (1.17)	2.85 (0.85)
p-value	0.106	0.026	0.375	0.027	0.005

“The minimum national standards for each activity are based on processes that need to be relevant and defined appropriately according to the local needs of the pharmacy practice environment and national profession aspirations. All national pharmacy professional associations should also adapt these roles and functions in accordance with their own requirements. The activities listed below can be further defined and measured by setting indicators of good practice within a national context and can be weighted by actual practice-setting priorities”.¹ Accordingly, items of our indicator-based tool were adapted to the Lebanese context. For instance, in the FIP/WHO joint document, under Role 1/Function B/2nd requirement, it is indicated that “Pharmacists who are responsible for procurement should ensure that procurement is supported by strong quality assurance principles to assure that substandard, adulterated, unlicensed and spurious/falsely-labelled/falsified/counterfeit medicines are not procured or allowed into the system”.¹ While we trust in the MOPH and their strict control of the pharmaceutical products imported into the country, we believe that pharmacists, as healthcare providers, do not have any tangible power in assuring that counterfeit medicines are not being “allowed

into” the “system”. Therefore, instead of evaluating them on their ability to control quality of products at the time they are allowed into the system, community pharmacists were evaluated on their readiness to report in case of suspicion over the quality of products beyond the time point when those medications were allowed into the system, which is the time those products are being delivered to patients (see questions C16-C18 in Online appendix 1).

The geographical distribution of pharmacies into Beirut, Mount Lebanon, Bekaa, North, and South was representative of the OPL distribution of pharmacies. Expectedly, pharmacists were predominantly females (57.2%) and overall, degrees earned were BS (60.6%), Pharm.D. (31.6%), Master’s (5.7%), and PhD (2.1%). These findings are contradictory with the data published recently by Bizri *et al.*, possibly due to the slightly varying geographical distribution of the participating pharmacists.²⁹ Nevertheless, our data are in line with the official national figures available in the OPL databases, thus our study sample can be considered representative of Lebanese community pharmacists.²³ However, some confidence intervals are extremely wide, showing that for some

Table 3. Univariate analysis of different factors associated with the adherence vs. non-adherence to the GPP guidelines.				
Variables	p-value	Unadjusted OR	Confidence Interval	
Age	0.310	1.02	0.99	1.04
Gender (males* vs females)	0.063	0.60	0.36	1.03
Education level	0.094			
BS Pharmacy	-	1		
Pharm.D.	0.048	1.89	1.01	3.56
Master's degree	0.274	0.57	0.21	1.56
PhD	0.581	0.60	0.10	3.69
Governorate	<0.001			
Beirut		1		
Mount Lebanon	0.859	1.08	0.46	2.53
North Lebanon	0.492	0.50	0.07	3.61
South Lebanon	<0.001	0.15	0.05	0.43
Bekaa	0.730	0.83	0.30	2.35
Years of experience	0.213			
Less than 6 months	-	1		
6 months to less than a year	0.178	9.00	0.37	220.92
1 year to less than 3 years	0.706	1.59	0.14	17.56
3 years to less than 6 years	0.268	3.80	0.36	40.34
6 years to less than 12 years	0.251	3.87	0.38	39.05
12 years or more	0.197	4.54	0.46	45.22
Number of working hours / week	0.241			
1-16 hours	-	1		
17-31 hours	0.711	0.67	0.08	5.68
32-40 hours	0.278	2.77	0.44	17.46
>40 hours	0.252	2.73	0.49	15.30
Position in the pharmacy (employer* vs employee)	0.791	1.10	0.53	2.28
House crowding index	0.788	0.92	0.51	1.66
Number of patients per day	0.169			
<50	-	1		
50-100	0.802	0.93	0.51	1.69
>100	0.089	2.11	0.89	4.97

*Reference group

analyses, the sample size was small. Studies with larger sample are recommended to overcome this drawback.

Overall, our results showed that pharmacy practice in Lebanon is not compliant with GPP standards, with less than a fifth of pharmacists meeting the requirements of all four indicators. The highest adherence score detected was for indicator A (23.3% of pharmacists). It is noteworthy that indicator A consisted of eight questions in total and that none of those questions were subjected to direct verification by the OPL inspectors, thus possibly allowing the pharmacists to have a better adherence score for that indicator specifically. Pharmacists scored poorly on indicators C and D, with less than 15% of pharmacists properly adhering to GPP standards, respectively. Those indicators are critical in a healthcare context since they relate to the dispensing, preparation, and storage of medications. Importantly, the adherence levels were not related to the pharmacy or the pharmacists' characteristics.

The analysis of Indicator A showed that almost all pharmacists surveyed used a computerized system for data management (99%), mainly for stock management (92%), and rarely for clinical services and medication management. Since the electronic patient profile is not mandatory yet, this result was expected but not in accordance with the suggested Lebanese GPP guidelines.^{8,21} Moreover, only three-quarters of pharmacists kept copies of prescriptions for non-controlled medications, although required by law. Issues concerning the unified prescription – a new prescription system implemented in Lebanon – are still unresolved, and the OPL had already suggested related

solutions yet to be approved and implemented by the MOPH.³⁰

Indicator B served to identify services and facilities available at the pharmacies. A licensed pharmacist was employed at most pharmacies (83%) for patient services and health promotion, which means that 17% are breaching the law by not having a pharmacist on a continuous basis (besides during the interview where the pharmacist was present); thus, it is suggested to enforce the law on the pharmacist's continuous presence in the pharmacy. There was a suitable place to discuss confidential information in almost all pharmacies. However, less than a third of pharmacists declared engaging in awareness campaigns about most common diseases. In fact, the participation of pharmacists in outreach activities organized by the MOPH is still weak, and higher levels of collaboration between the OPL and the MOPH are recommended to improve pharmacists' involvement. Nevertheless, half of the pharmacists had information of various types and sources available to patients, which impact on patients' health needs to be assessed in future studies. The majority of pharmacists offered services such as flu vaccination, blood pressure, and glycemia checking; these activities can be considered as a satisfactory involvement in health promotion and their extension to other preventive measures would be encouraged to optimize pharmacists' implication in health awareness.³¹

Indicator C was of particular importance since it aimed to investigate the dispensing, preparation, and administration of medicines. Our results showed that all pharmacists had

dispensed more than one prescription per day, most of them identified errors in prescriptions, and engaged in awareness by providing information about adherence to treatment and antibiotic resistance. These figures are considered appropriate. Less than half of the pharmacists had to call back patients after leaving the pharmacy, which is relatively low, while almost all pharmacists declared that patients could consult for unusual adverse events. Although more than 90% declared counseling patients and checking medications before dispensing, one-quarter did not check for contraindications, drug interactions, or prescribed doses; more efforts should be deployed by relevant authorities to optimize these practices through continuing professional development.³²

Moreover, although the majority of pharmacists have access to literature and information resources for their own education, mainly through internet, pharmacists should broaden their knowledge and acquire better dispensing practices.³³ They should also be encouraged to maintain effective communication with their patients, and follow up on their treatments to improve health outcomes.³⁴ Indeed, a study in Lebanon had revealed that 40 to 50% of Lebanese patients were asking for better communication with pharmacists, and enhanced pharmacy services. Pharmacists are also encouraged to improve their communication with prescribing physicians in cases of identified unnecessary medical prescriptions.^{18,35,36}

Additional questions within Indicator C showed that almost all pharmacists declared dispensing medications without prescription (NSAIDs [95%], antibiotics [60%], steroids [27%], benzodiazepines [14%], gastrointestinal drugs [67%], hormones and contraceptives [48%]), despite laws prohibiting it. This high rate of dispensing medications without prescription was found across all geographical areas. The undermining reasons found in previous studies were mainly patients' inability to visit a physician due to financial constraints and lack of time.^{2,37} Therefore, it is imperative to strengthen law enforcement through collaborative actions between the OPL and the MOPH, taking appropriate measures to improve the system, protect patients' health, and reduce antibiotic resistance.^{38,39} Furthermore, 88% of pharmacists declared explaining to patients the purpose of switching to a generic, knowing that there are no evidence-based guidelines in Lebanon (similar to the book Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book in the US) to drive the pharmacist's choice and define a clear legal framework; the OPL had already suggested to the MOPH appropriate guidelines for safe substitution of medications, allowing pharmacists to use generic substitution whenever adequate and safe.^{30,40}

Within Indicator D, results showed an obvious problem with the disposal of expired medications and pharmaceutical waste. Moreover, the vast majority of pharmacists did not have a clearly designed recall procedure for products they suspected to be adulterated, unlicensed, spurious, falsely labeled, falsified, or counterfeit. In addition, 9% did not have an adequate stock management and expiry date monitoring system, 85% did not encourage patients to return expired or unwanted products, and 68% did not have a specific procedure to

dispose of expired products. This is another major issue that the competent authorities must address, because of its environmental and health consequences, particularly in Lebanon where pollution of ecosystems linked to the waste crises has been lasting for years.^{41,42}

With regard to the items confirmed by the interviewer, serious hygiene problems were identified, with half of the pharmacists declaring that they do not use pest control services. In addition, 88% had a refrigerator (confirmed by the interviewer), but 22% used it to store products other than medications. Another major issue is that 7% of pharmacists stated that the pharmacy was not supplied with electrical power during the night, while 3% did not store medication stocks away from direct sunlight, which may alter their quality.⁴³ GPP adherence scores by region were low for each of the four indicators except for Indicator D (Storage) in Beirut.

Comparison across regions revealed a higher overall GPP adherence score in Beirut. The underlying explanation is yet to be identified and requires confirmation by larger studies. It is hypothesized that an urban status of Beirut dwellers (and thus pharmacists) would allow pharmacist to have more assets and better apply standards that require resources at the human or financial levels, which may not be the case in other regions. This finding corroborates those of a previous situation analysis of pharmacists in Lebanon conducted recently, showing that a substantial percentage of Lebanese pharmacists have financial difficulties and cannot afford hiring assistant pharmacists.⁴⁴

While pharmacists may proactively and actively work on improving their adherence to GPP guidelines, the quality of pharmacy practice can be affected by involuntary factors unrelated to the pharmacist's skills or standards of practice, such as the patients' load or the educational level of patients in the geographical area of the pharmacy. Indeed, a heavy load of patients means that the pharmacist can only dedicate a limited amount of time explaining to each patient the proper use of medications, or providing health awareness information to patients with a possibly low level of knowledge. Therefore, patient load, patient education level, and the socioeconomic status of the pharmacist must be included in GPP assessment tools to ensure a fair evaluation of pharmacists' adherence to GPP. Our results revealed that most pharmacies were visited daily by 10 to 50 patients (44.66%) and many were visited by 50 to 100 patients (40.30%). Moreover, the majority of pharmacists (79.90%) declared working more than 40 hours per week. Taken altogether, these data indicate that the load of visits does not always provide enough room for the pharmacist to discuss with every patient and abide by the requirements of the FIP/WHO to explain the purpose of use of medication and indications of use, collect information about their medical history and provide health habits tips, especially if the pharmacist is not assisted by an additional staff at the pharmacy. Adherence to GPP requires further study since the multivariable analysis did not demonstrate that the number of weekly working hours and the daily patient load were associated with poor adherence to GPP standards; this could be due to a lack of power in the analysis, or to a real absence of association in the Lebanese context. Since previous studies in both developed and

developing countries had demonstrated the importance of the adequacy of the number of pharmacists compared to the patients load in terms of quality of care, future studies are warranted to further assess this issue.^{28,45,46}

It is suggested that competent authorities, mainly the MOPH and the OPL, discuss solutions to improve the financial situation of community pharmacists by remunerating the services they might provide (particularly the ones that were shown to be cost-effective), such as medication therapy management, medication reconciliation, and others.⁸ Improving the situation of pharmacists might allow them to better adhere to GPP standards, which is expected to improve patients' health as demonstrated in developed countries; additional studies are necessary to confirm these ideas. Furthermore, continuing education related to this topic would also consolidate pharmacists' knowledge, improve their attitude towards the importance of GPP, and motivate them to spend resources towards improving the quality of their services.^{47,48} In addition to education, research has shown that multi-interventions might improve pharmacy practice in developing countries: regulatory enforcement, education, and peer influence were useful in specific aspects of pharmacy practice, when applied together.⁴⁹

Finally, our results and recommendations could be extrapolated to other developing low- and middle-income countries; they can however be also useful for high-income countries in rural areas, where several pharmaceutical services are not available. This point was clearly highlighted by the WHO European region report on legal and regulatory framework for community pharmacy in Europe.⁵⁰

Limitations and strengths of the study

This pilot study has several limitations including a possibility of information bias. Indeed, 80.5% of the pharmacists interviewed owned the pharmacy: they may have feared sanctions or penalties by the visiting OPL inspector and may have altered their answers to meet GPP standards and protect the interests of their businesses. Therefore, we suggest evaluating pharmacists anonymously and have all answers pooled by geographical location. Similarly, items that require direct evaluation by the OPL inspector would be answered electronically on site, which decreases the risk of errors. However, we note that the inspectors involved in this validation study were selected based on their experience; in addition, there was a high number of completed questionnaires that were returned.

Moreover, there is a risk of error during data entry that was done electronically and checked at three different time points by three different individuals. Therefore, we believe that data entry mistakes are minimal if not absent. Also, increasing the population size for the purpose of a cross-

national study will be important for statistical significance and appropriate comparison across geographical regions over time. Finally, the validity was not assessed and reliability results of the standardized tool we used was suboptimal; this may be due to the fact that respondents better understood the question in one indicator than the others. We suggest further studies to better adapt the tool to the Lebanese context and prove its validity and improve its reliability characteristics, particularly in a constantly changing healthcare system.⁵¹ Since the tool we used was not previously validated, using it in a standardized way might still lead to a non-differential information bias, underestimating some associations. Improving the tool may show additional associations and further precise the results, although we do not have reasons to believe that the overall direction (i.e., suboptimal pharmacy practice) would change. Another limitation is related to the assessment of Indicators B, C, and D since those were measured by combining together two distinct measurement methods namely, self-reporting and visual evaluation by OPL inspectors. We suggest that in future studies only one measurement method is used or that self-reported items are evaluated separately from items evaluated by OPL inspectors. Finally, for the accurate assessment of those GPP items that are of critical importance for patients' health, we could envisage using specific measurement models.⁵²

CONCLUSIONS

This study aimed at designing an indicator-based tool to assess the level of adherence to GPP among community pharmacists in Lebanon, and compare scores across geographical regions. To our knowledge, this is the first indicator-based comprehensive pilot assessment study that evaluates GPP adherence in community pharmacies across Lebanon. It showed that community pharmacies in Lebanon do not fulfill GPP criteria. Efforts should be made to support pharmacists with appropriate measures, make them aware of the importance of GPP adherence, and train them on GPP guidelines and standards. Working on the optimization of the assessment tool is also imperative. It must be validated and adapted to the Lebanese context, thus leading to more precise assessment results and better implementation of GPP standards in community practice.

CONFLICT OF INTEREST

Prof. Pascale Salameh was Chair of Scientific Committee at the OPL at the time of this research work.

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