MEDICATION SAFETY KNOWLEDGE, ATTITUDE, AND PRACTICE AMONG HOSPITAL PHARMACISTS IN LEBANON

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Short title: Medication safety KAP among Lebanese Hospital Pharmacists

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Abstract

Background: Studies showed that pharmacists have little experience with adverse drug reactions (ADRs) reporting due to insufficient knowledge of the concept of ADR and pharmacovigilance (PV). There is an urge to assess hospital pharmacists' knowledge in medication safety practices.

Objective: To evaluate the knowledge, attitude, and practice, among hospital pharmacists in Lebanon concerning ADRs and PV concepts.

Methods: A cross-sectional study, conducted between March and July 2016, enrolled 187 hospital pharmacists in all Lebanese districts.

Results: Concerning knowledge, 60.8% of the pharmacists said that ADR is an injury caused by appropriate and suboptimal care, while 74.6% of them said it can be preventable and non-preventable. Moreover, 47.5% of them defined PV as being the study that detects, assesses, understands and prevents adverse effects. Furthermore, 55.1% believed that PV concerns drug, herbal, medical devices and vaccines problems.

Concerning attitude, 61% of the pharmacists said they don't support direct ADR reporting by the patient. 78.6% of them confessed that ADR reporting is a professional obligation to them while 88.2% admitted that it is time consuming with no outcome.

When it comes to practice, 64.2% had been trained to report ADRs. Only 20.8% and 24.2% confessed reporting ADRs more than once a week respectively. More than half (54.5%) said they report the ADR to the patient's prescriber.

Conclusion: Lebanese hospital pharmacists have little knowledge about the concept and process of PV and spontaneous ADRs reporting system. However, these pharmacists have positive attitudes, but very little practice with reporting systems. Educational programs are urgently needed to emphasize the role and responsibility of pharmacists in PV practices and to raise awareness toward ADRs reporting process.

Keywords: knowledge; attitude; practice; hospital; pharmacists; pharmacovigilance; Lebanon; Adverse drug reaction.

Introduction

Adverse drug events (ADEs) are a major public health concern associated with patient related morbidity and mortality [1], prolonged length of hospital stay, unnecessary hospital admissions[2-4] and increased economic burden[5]. An adverse drug reaction (ADR) is an injury caused by taking a medication, which may occur following a single dose or prolonged administration of a drug or result from the combination of two or more drugs [6].

To allow healthcare practitioners identifying, reporting and treating ADEs, the Institute of Medicine adopted simplified definitions of ADEs, Adverse Drug Reactions (ADRs), and Medication Errors (ME). Thus, an ADE is "an injury resulting from the use of a drug". It includes harm caused by the drug (adverse drug reactions and overdoses) and harm from the use of the drug (including dose reductions and discontinuations of drug therapy). ADR is a subtype of ADE defined as drug-induced harm occurring with appropriate use of medication and not caused by an error. ME encompass all preventable errors that may occur at any stage of the medication process, with or without patient harm [7].

The earliest record of a medication error dates back to the 17th century BC where patient's harm lead to punitive action [8]. While today, patient safety initiatives are generated by government agencies [9], regulatory and accrediting bodies, professional associations, and healthcare organizations [10,11], medication-related adverse events still occur in the healthcare settings and are expected to increase due to the development of new molecules, the discovery of new indications of already marketed drugs, and the increasing use/misuse of medications, and population aging.

In this context, pharmacovigilance (PV), defined by the World Health Organization (WHO) as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects and any other possible drug-related problem" [12], plays an essential role in minimizing ADRs. Furthermore, among all healthcare professionals, pharmacists are highly recognized for their role in applying PV principles in their day-to-day clinical practice [13-16].

After the thalidomide disaster in the 1960s, most Western countries developed national PV systems [17]. These systems use spontaneous reporting to systematically collect and analyze adverse events associated with the use of drugs, identify the emerging problems, and communicate how to minimize or prevent harm [18]. In fact, less than 27% of lower middle income and low income economies countries have national PV systems registered with the WHO program, compared with 96% of the high income countries in the Organization for Economic Co-operation and

Development [18], mainly due to a lack of resources, infrastructure, and expertise. In Lebanon, the political will of having a PV center is present; in fact, in addition to the National PV Center that was launched in 2004 by the Lebanese University [19], an agreement was signed between representatives of the Ministry of Health and the Lebanese University in February 2016 to establish the National Center for the quality of the medications and monitoring of the bio-integration of genetic medicine "Bioequivalence Center", with the aim of studying and analyzing the side effects of generic drugs [20].

However, some studies showed that pharmacists have little experience with ADRs reporting due to insufficient knowledge of the concept of PV [21,22]. In view of the potentially significant impact of these findings on hospitalized patients, there is an urge to assess hospital pharmacists' knowledge in medication safety practices and a need to define strategies aiming at encouraging all hospital pharmacists in reporting ADRs, thus, to join global efforts trying to solve patient safety issues.

The primary objective of this study is to evaluate the knowledge, attitude, and practice (KAP) of ADR and PV among hospital pharmacists in Lebanon, whereas the secondary objective is to compare the KAP of chief pharmacists (head of the hospital pharmacy department) and that of remaining pharmacists in the department.

Methods

General study design

A cross-sectional study was carried out between March and July 2016, using a proportionate random sample of 75 out of a total 161 hospitals operating in Lebanon from all governorates (Beirut, Mount Lebanon, North, South, and Bekaa). A list of all hospitals in Lebanon was provided by the Order of Pharmacists of Lebanon (OPL). Hospitals were randomized using an online software [23]. A total of 75 hospitals was included; thirteen were public and 122 hospitals were private. All pharmacists within a designated hospital were given the questionnaire to fill, without any obligation to participate in the study. A total of 187 hospital pharmacists accepted to participate out of 200 distributed questionnaires (93.5%); the sample represents 60% of the total number of pharmacists registered in the OPL as working in hospitals of Lebanon.

Minimal sample size calculation

We fixed our expected frequency of good knowledge at a frequency of 50% in the absence of similar studies in the country. Considering a total number of 312 hospital pharmacists registered within the OPL, the Epi-info software version 7.2 (population survey) calculated a minimum sample size of 172 participants to ensure a confidence level of 95%.

Ethical aspect

The Institutional Review Board at the Lebanese University waived the need for an approval based on the fact that it was an observational study, which respected participants' autonomy and confidentiality and induced no harm to them.

Sample size calculation

A minimal sample size of 160 hospital pharmacists was targeted to allow for adequate power for bivariate analyses to be carried out according to the Epi info sample size calculations, out of a total of 312 hospital pharmacists (including chief pharmacists) in Lebanon, based on a 68.7% expected frequency of pharmacists' knowledge in ADR [24] and a 5% confidence limits [25]. A total of 200 questionnaires were distributed.

Data collection process

A self-administered KAP survey questionnaire was inspired and designed based on previous studies [21,26,27] but tailored to the Lebanese sector. A total of 10 pharmacists, with long expertise in the hospital practice added more questions according to their professional experience among Lebanese hospitals. The final survey consisted of 64 questions out of which 19 questions were knowledge-based, 16 were attitude-based, and 29 were practice-based questions. The questions asked in the three parts can be found in Appendix 1 (with the correct answers).

The detailed questionnaire was distributed to all pharmacists working in the hospital pharmacies by one person responsible for the whole data collection. The study objectives were explained to each pharmacist; after obtaining an informed oral consent, the pharmacist was handed the anonymous and self-administered questionnaire. On average, the questionnaire was completed by participants within approximately 15-20 minutes. The pharmacist had the choice to accept or refuse to fill the questionnaire. At the end of the data collection period, all completed questionnaires were put in a sealed box and sent for data entry. Therefore, the anonymity of the pharmacists was guaranteed and respected.

The distributed questionnaire was either in French or English language, since education in Lebanon is based on French and/or English language in addition to native Arabic. The questionnaire was designed in English, translated into French and then back to English by another person to ensure translation accuracy. Translation discrepancies were few but were resolved by investigators, in agreement with the translators. Both versions were tested on a pilot sample of 20 pharmacists, which was not included in the analysis, before the data collection was officially started. This resulted in minor changes in the questions for better understanding.

Statistical analysis

Data entry was performed by one person who was not involved in the data collection process. Statistical analysis was done using SPSS software, version 22. The sample showed a normal distribution, therefore, parametric tests were used for the analysis; the Chi-2 test was used to compare between dichotomous or multinomial qualitative variables. A $p<0.05$ was considered as significant. Finally, to confirm the knowledge, attitude and practice scales construct validity in the Lebanese population, three exploratory factor analyses were launched for all items of the questionnaire, using the principal component analysis technique, with a Promax rotation, since the extracted factors were found to be significantly correlated. The Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy and Bartlett's test of sphericity were ensured to be adequate. The KMO measures sampling adequacy for each variable in the model and for the complete model, whereas Bartlett's test would indicate if the variables are unrelated and therefore unsuitable for structure detection. The retained number of factors corresponded to Eigen values higher than one. Moreover, Cronbach's alpha was recorded for internal consistency for the different scales.

Results

Socio-demographic results

One hundred eighty seven out of 200 distributed questionnaires (93.5%) were collected back from hospital pharmacists. Table 1 summarizes the socio-demographic and socioeconomic factors. The results showed that 41.2% of the pharmacists were aged between 21-30 years; 82.4% were females; 35.8% worked in Beirut and 16.6% in Mount Lebanon. The highest percentage (40.6%) had a bachelor degree in pharmacy whereas 32.1% had a Pharm.D. degree. In addition, 53.3%

were chief pharmacists), 26.6% staff pharmacists and 20.1% clinical pharmacists; 33.2% had less than 5 years of experience while 26.2% had a range of experience between 5 to 10 years. The largest number of the visited hospitals had a number of beds ranging between 101 and 299 beds. More than half of these hospitals were accredited by the Ministry of Public Health (MOPH) while 17.6% had an International Organization for Standardization (ISO) accreditation.

Factor analysis and reliability analysis

The factor analyses for the scales were run (Total n = 187). All items of the knowledge, attitude and practice scales could be extracted from the list, since no items over-correlated to each other ($r > 0.9$), had a low loading on factors (< 0.3) or because of a low communality (< 0.3). The three scales items converged over a solution of two factors for each scale that had an Eigenvalue over 1. A high Kaiser-Meyer-Olkin measure of sampling adequacy of >0.8 was found, with a significant Bartlett's test of sphericity ($p<0.001$) for all three scales. Moreover, high Cronbach's alphas were found for the knowledge scale (0.896), the attitude scale (0.812) and the practice scale (0.839). Thus, the scales used have adequate construct validity and reliability, and can be utilized for the rest of the analysis.

Knowledge of hospital pharmacists concerning pharmacovigilance (Table 2)

The results of the hospital pharmacists' knowledge about PV showed that 79.7% of the pharmacists considered that "a side effect of a drug is an ADR" (right answer), 74.6% of them that "an ADR is preventable and non-preventable" (right answer), and 95.1% of them that "not all drugs on the market are safe" (right answer). In addition, only 52.1% of these pharmacists knew that "the Institute for Safe Medication Practices (ISMP), the Uppsala Monitoring Center (UMC), the European Medicines Agency (EMA) and the Agency for Healthcare Research and Quality (AHRQ)" are Medication Safety Agencies (right answer), 90.9% of them had ever heard about "the concept of PV", whereas only 43.7% of them knew what PV relates to and 79.9% knew what PV's functions are (right answer). Only 55.1% of the pharmacists knew that PV concerns drug-related problems, herbal products, medical devices and vaccines (right answer), whereas 67.0% of them knew that PV consists of ADRs, Adverse Drug Events (ADEs) and ME . Fifty-six percent of the pharmacists knew that "an augmented drug reaction is dose-dependent, common in occurrence and rarely fatal" (right answer). Moreover, 23.1% of the pharmacists knew that "the International

ADR center location is located in Sweden" (right answer), 20.0% knew that "VigiBase is the World Health Organization online database for reporting ADRs" (right answer), and 17.5% knew that "there is a PV center in Lebanon" (right answer). Concerning the definition of a never event, 57.1% of the pharmacists said that it is "a preventable incident", 30.1% of the pharmacists said it "causes serious harm", whereas 30.3% of the pharmacists said it can be "a medication and a non-medication related event" (right answers). When it comes to the definition of a sentinel event, 51.1% of the pharmacists declared that it is "an unexpected incident", 62.4% of them said "it causes death or permanent disability", 49.5% of them said "it needs immediate investigation and attention, whereas 40.3% of the pharmacists said it can be "a medication and a non-medication related event" (right answers). Concerning the definition of the Failure Mode and Effects Analysis (FMEA), 41.2% of the pharmacists said that "it is a prospective risk assessment method", 47.8% of them said "it examines possible process and/or product failures", whereas 16.1% of them confessed that "it provides the anticipated results" (right answers). Concerning the Root Cause Analysis, the pharmacists said that "it is a retrospective risk assessment method" (46.5%), "it examines possible process and system failures" (31.7%), and "provides the underlying cause" (54.3%) (right answers). Concerning the "Just culture", 50.8% of the pharmacists said "it cultivates trust in the workplace", 62% said "it encourages people to speak up about their mistakes", 58.3% confessed "it increases reporting of ME", whereas 38.5% declared "it decreases the incidence of ME" (right answers).

Attitude/Opinion of hospital pharmacists concerning pharmacovigilance (Table 3)

The results of the attitude questions asked to pharmacists showed that 84.5% of the pharmacists agreed that the pharmacist is the health care professional that should be responsible for ADR reporting in the hospital, whereas 39.0% of them supported "direct ADR reporting by the patient instead of healthcare professionals". The majority of the pharmacists (96.8%) agreed that "ADR reporting and monitoring system would benefit the patient" and that "the pharmacist could be the right person to assist physicians in ADR reporting". In addition, 49.2% of the pharmacists confessed "worrying about legal problems while thinking about ADRs"; only 11.8% of the participants felt that "reporting ADR is a time consuming activity with no outcome", whereas 79.0% of them thought that "reporting ADR is a professional obligation" and 75.4% of them believed that "ADR reporting should be mandatory for practicing pharmacists". Moreover, the

majority (88.8%) of the pharmacists were interested "in participating in an ADR reporting system" and 96.3% of them thought that "there should be a national PV program". It is noteworthy that 89.8% of the pharmacists expect "financial compensation for the time and energy spent while reporting an ADR in case a national PV program is instituted".

When asked about why ADR reporting is important, 79.1% of the pharmacists said that "it measures the incidence of ADRs", "it enables the safe use of drugs" (75.4%), and "it identifies factors that might predispose to an ADR" (74.9%). Pharmacists thought that they are encouraged to report ADRs "when the reaction is of serious nature" (83.4%), whereas they might be discouraged to report ADRs when they are uncertain about the association between the drug and the adverse reaction (64.0%). Finally, half of the pharmacists declared that the perception of safety culture revolves around the statement "risk management is an integral part of everything we do" (Table 3).

Practice of hospital pharmacists concerning pharmacovigilance (Table 4)

Concerning the practice of hospital pharmacists in PV, 81.3% of them admitted that "all medication safety related standards are applied in the hospital they work at", and "the hospital has written policies and procedures about medication safety practices" (90%). In addition, 84.5% of the pharmacists confessed that the hospital established a defined system for adverse drug reporting. A total of 82.9% admitted having a medication safety department/committee in their hospital and 68.4% confirmed that "the pharmacist chairs/oversees the latter committee". Moreover, 92.5% of the pharmacists said that "there is a standardized form for reporting ADRs in their hospital" and that "it is available at the pharmacy". Pharmacists confessed that ADRs are reported if "they are serious and life-threatening" (76.5%), "severe and cause disability" (73.8%), with these ADRs reported first to the prescriber (54.5%). When asked about the preferred method to be used to report an ADR to drug companies, the answers varied between formal email/letter (49.7%), and via a national PV center (50.8%). Furthermore, 44.9% attended a congress or seminar about medication safety during the last year; 35.8% had attended a workshop about PV. Only 20.8% and 24.2% declared reporting more than once a week ADRs and MEs respectively. More than half said they report the ADR to the patient's prescriber while 93.0% of them thought that medication safety programs should be implemented in the current pharmacy university curriculum. Finally, 48.6% declared that "Root Cause Analysis (RCA) is the method implemented in the hospital when

reporting ADR". The main causes of medications incidents were high workload (79.1%), followed by insufficient human resources (55.1%) according to these pharmacists (Table 4).

Comparison between chief and staff pharmacists concerning pharmacovigilance

A comparison was done between the chief, staff and clinical pharmacists concerning their knowledge, opinion, and practice concerning PV. A significantly higher percentage of staff pharmacists (75.5%) declared that the "just culture" encourages people to speak up about mistakes compared to chief (54.1%) and clinical pharmacists (64.9%) (p=0.038). A significantly higher percentage of staff and clinical pharmacists said that the physician and the pharmacist are responsible for ADR reporting. A significantly higher percentage of staff pharmacists confessed that "when an ADR is encountered in the hospital, it is reported to the ministry of public health". Finally, a significantly higher percentage of staff (79.6%) and clinical pharmacists (70.3%) have been "trained on how to report an ADR" compared to chief pharmacists (54.1%) (p=0.007) (Table 5).

Discussion

Hospital pharmacists play a key role in PV and ADRs reporting process as they are responsible for the medication use process throughout the hospital. In Lebanon, a comprehensive and well-structured PV program is lacking; the National PV Center still carries out very limited activity in hospitals [19]. We thought that this lack in ADR reporting could be due to issues related to the hospital pharmacists' knowledge, attitude and practice (KAP). We therefore conducted this study to evaluate the KAP towards ADR and PV among a representative sample of hospital pharmacists. It completes the series of surveys initiated by the Order of Pharmacists of Lebanon concerning medication safety among community pharmacists [28] and patients [29] as well.

This study showed that hospital pharmacists in Lebanon have a poor knowledge on the PV concept and the difference between ADRs, whether they are preventable or not. Furthermore, only half of the participants defined PV correctly and stated that it was related to drugs, and to herbal and other medical devices as well. These results are similar to those reported by previous researchers [26,30].

The majority of participating pharmacists have an insufficient knowledge and lack of awareness of ADR reporting systems. Indeed, 60.0% of the pharmacists revealed that there are no staff

educational sessions on medication safety best practices and half of them have never worked on a quality improvement plan. These results corroborate with those of a previous report by Toklu and Uysal, in which authors have shown that the majority of the pharmacists were not aware of the concept of PV and reporting system [31].

Regarding hospital pharmacists' perception and opinion toward ADRs reporting, pharmacists showed a positive opinion toward ADRs reporting process despite the low reporting rate, a pattern similar to other studies [31-33]. Therefore, pharmacists need to take a more proactive role in the assessment and decision-making concerning the safety of patient medications[16]. Despite their positive opinion, the pharmacists considered that the main barriers for reporting are the lack of knowledge about ADR reporting processes and judgment, the need for training to better define ADRs and time constraints as well as workplace pressure. These factors have been already reported in numerous studies that have shown a positive association between reporting manners and the level of knowledge [34-37]. This under-reporting of ADRs is a worldwide phenomenon as demonstrated by previous researches [38-41] and in Lebanon as well, as shown in our results. Many factors may play a role in ADR under-reporting, including the lack of knowledge of the reporting procedures, unfamiliarity with the reporting methods, and unawareness with the type of reactions to be reported. Hence, other studies showed that low rates of ADRs reporting are being noted even if they have a national pharmacovigilance center and authors attributed these low rates not only to the lack of knowledge in PV but also to the poor knowledge of reporting procedures and requirements [31,42]. In Lebanon, we lack of both. It is important to note that 66.0% of the pharmacists are trained to report an ADR. This shows that some of the hospital pharmacists are not well informed about PV practice. Other published reasons for ADRs under-reporting are the lack of time, belief that the ADR is already well known, doubt about the importance of, and fear to report ADRs [26].

The majority of the questioned pharmacists were interested in participating in an ADR reporting system and felt that reporting is a professional obligation to them. Our findings showed however, that Lebanese hospital staff pharmacists are not at ease when it comes to reporting ADRs. In fact, event reporting can only happen in a non-punitive milieu where healthcare professionals can report any incident without having the fear of doing so, an essential step for improving patient safety [43]. This study did not assess the reasons behind this issue, however, we hypothesize that some of the pharmacists may have committed errors in their practice but covered it up to avoid career-

threatening disciplinary actions and possible malpractice litigation and liability. Concerned authorities, including but not limited to the Order of Pharmacists, the Ministry of Public Health and the Syndicate of hospitals, should work together to implement this non-punitive culture and among Lebanese hospitals and encourage health care professionals to admit errors and understand why the errors occurred in order to prevent it in the future.

The majority of participants considered ADR reporting to be the main responsibility of all healthcare providers, but the pharmacist was ranked to be the most important provider in reporting ADRs. Moreover, almost all of them agreed that there should be a national PV program in the country and that the ADR reporting system should be included in the pharmacy curriculum. Therefore, unlike other neighboring countries who seem to have a PV culture problem and lack of understanding their role in the healthcare team because they do not consider ADR reporting as a natural task of their profession [31], Lebanese pharmacists seem enthused. They have the will to have a more active role in the assessment and decision-making regarding patient safety related to medications, results similar to those of van Grootheest [16] and Abdel-Latif [26]. However, and despite this enthusiasm, a large number of pharmacists admitted having insufficient knowledge regarding PV. The majority admitted they never had a course or attended a workshop/congress/seminar concerning PV. Finally, when comparing chief to staff pharmacists (youngest pharmacists), the latter seem to be more trained on reporting ADRs/ME, which explains why they have a higher rate of reporting errors and why they consider that pharmacists should have a central role in reporting ADRs. Such results emphasize the importance of education in PV and implementation of ADR and ME programs in the undergraduate pharmacy curriculum and the postgraduate training sessions [44]. In that context, a study has shown that pharmacy students who attended interactive educational intervention session on PV and ADR reporting were shown to be much satisfied and were considered to be more effective [27].

Based on the aforementioned, and since a comprehensive and well-structured pharmacovigilance program is lacking in Lebanon, the Lebanese Order of Pharmacists (OPL) took the initiative of developing an online reporting system tool to be used by community and hospital pharmacists, enhancing their key role in the practice of medication safety [45]. The starting project will need to be consolidated by raising awareness and changing misconception in the general population and among some health professionals, to overcome the problem of underreporting that may arise.

Different strategies could be implemented as well to help Lebanese hospital pharmacists in reporting. These strategies include written hospital policies, better cooperation with clinicians (especially with the integration of clinical pharmacists within the medical teams in Lebanese hospitals), training, simplifying the system, allocation of time for ADR reporting, promotion, etc. [31,46].

Limitations

There are some methodological weaknesses in this study since the questionnaire relied on pharmacists' self-rated assessment of their own knowledge, attitude and practice towards PV. Moreover, pharmacists might have been unwilling to reveal their practice deficiencies. Thus, this information bias cannot indicate the real knowledge of hospital pharmacists in Lebanon concerning PV. In addition, a selection bias is also possible because of the seven percent refusal rate. The knowledge, attitude and practice of pharmacists working in rural areas was not adequately assessed; this might lead to an even lesser knowledge about medication safety practices among Lebanese hospital pharmacists. The findings obtained cannot be generalized to all pharmacists since some governorates (i.e. South Lebanon) was underreported compared to other governorates (i.e. Beirut). In addition, although we validated the questionnaire by ourselves, we did not have the possibility of performing a test-retest analysis to assess the reliability of the scales we used. Other studies taking into account these weaknesses are necessary to confirm our results; nevertheless, we have no reason to believe that the results will be substantially different from the ones found in this study.

Conclusion

These results suggest that Lebanese hospital pharmacists have little knowledge about the concept and process of PV and spontaneous ADR reporting system. However, they have positive attitudes towards it. Educational and training programs are urgently needed to emphasize on the role and responsibility of hospital pharmacists in PV practices and to raise awareness towards ADR reporting processes, in order to achieve optimal patient care. This research data serves as well as

a trigger for governmental institutions to accelerate the implementation process of a national safety alert notification system.

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Conflict of Interest

The authors have no conflicts of interest to declare.

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Tables

Table 1. Sociodemographic and socioeconomic characteristics of the participants	
Factor	**N (%)**
Gender	
Male	33 (17.6%)
Female	154 (82.4%)
Age (in years)	
21-30	77 (41.2%)
31-40	51 (27.3%)
41-50	42 (22.5%)
> 50	16 (8.6%)
District	
Beirut	67 (35.8%)
Chouf/Aley	14 (7.5%)
Mount Lebanon	31 (16.6%)
Jbeil	14 (7.5%)
Bekaa	21 (11.2%)
North	12 (6.4%)
South	24 (12.8%)
Educational level	
BS Pharmacy	76 (40.6%)
Pharm.D.	60 (32.1%)
University diploma in hospital pharmacy	6 (3.2%)
Fellowship in clinical pharmacy	4 (2.1%)
Masters	34 (18.2%)
PhD	4 (2.1%)
Professional status	
Chief pharmacist	98 (53.3%)
Staff pharmacist	49 (26.6%)
Clinical pharmacist	37 (20.1%)
Experience	
< 5 years	62 (33.2%)
5-10 years	49 (26.2%)
11-20 years	38 (20.3%)
> 20 years	37 (19.8%)
Bed number in the hospital	

< 50	32 (17.1%)
51-100	48 (25.7%)
101-299	83 (44.4%)
> 300	21 (11.2%)
Accreditation	
Ministry of Public Health (MOPH)	99 (52.9%)
Joint Commission International (JCI)	16 (8.6%)
International Organization for Standardization (ISO)	33 (17.6%)
Magnet certified	4 (2.1%)
Not accredited/in process	15 (8.0%)
Multiple answers	8 (4.2%)

Table 2. Knowledge of the hospital pharmacists concerning pharmacovigilance.

A side effect is an adverse drug reaction?	
No	38 (20.3%)
Yes	149 (79.7%)
An adverse drug reaction is:	
Preventable	13 (7.0%)
Non-preventable	34 (18.4%)
Both	138 (74.6%)
All drugs on the market are safe:	
No	176 (95.1%)
Yes	9 (4.9%)
Which of the following is a Medication Safety Agency?	
Institute for Safe Medication Practices (ISMP)	36 (21.8%)
Uppsala Monitoring Center (UMC)	3 (1.8%)
Agency for Healthcare Research and Quality (AHRQ)	5 (3.0%)
European Medicines Agency (EMA)	33 (20.0%)
All of the above	86 (52.1%)
None of the above	2 (1.2%)
Have you ever heard about the concept of Pharmacovigilance?	
No	17 (9.1%)
Yes	169 (90.9%)
Pharmacovigilance is the study that relates to:	
Safe, effective, appropriate and economic use of medicines	7 (3.8%)
Therapeutic drug monitoring	9 (4.9%)
Detection, assessment, understanding & prevention of adverse effects	87 (47.5%)
All of the above	80 (43.7%)
The functions of pharmacovigilance are:	
Detection and study of ADRs	26 (14.1%)
Measurement of risk and effectiveness of drug use	6 (3.3%)

Dissemination of ADR information and education	5 (2.7%)
All of the above	147 (79.9%)
Pharmacovigilance concerns:	
Drug related problems	76 (41.5%)
Herbal products	2 (1.1%)
Medical devices and vaccines	4 (2.2%)
All of the above	101 (55.1%)
Pharmacovigilance consists of:	
ADRs	50 (27.5%)
ADEs	7 (3.8%)
MEs	3 (1.6%)
All of the above	122 (67%)
ADRs which are independent can be treated by:	
Withdrawing the drug	19 (10.5%)
Reducing the dose	3 (1.7%)
Replacing the medication	27 (14.9%)
All of the above	132 (72.9%)
Augmented drug reaction is:	
Dose dependent, common in occurrence, rarely fatal	98 (56.0%)
Dose independent, comparatively rare in occurrence, more fatal	28 (16.0%)
All of the above	35 (20.0%)
None of the above	14 (8.0%)
International ADR center location	
USA	31 (16.6%)
France	19 (10.4%)
Australia	2 (1.1%)
Sweden	42 (23.1%)
Don't know	88 (48.4%)
WHO online database for reporting ADRs	
ADR advisory committee	36 (26.7%)
Medsafe	17 (12.6%)
Eudravigilance	4 (3.0%)
VigiBase	27 (20.0%)
MedWatch	29 (21.5%)
None of the above	22 (16.3%)
Is there a national pharmacovigilance center in Lebanon?	
Yes	32 (17.5%)
No	92 (50.3%)
Don’t know	59 (32.2%)
A never event:	
Is a preventable incident	105 (57.1%)
Causes serious harm	56 (30.1%)
Is a medication and non-medication related-event	56 (30.3%)
Is a medication-related event only	13 (7.0%)
Don’t know	38 (20.5%)
A sentinel event:	
Is an unexpected incident	95 (51.1%)
Causes death or permanent disability	116 (62.4%)
Needs immediate investigation and attention	92 (49.5%)
Is a medication and non-medication related event	75 (40.3%)
Is a medication-related event only	19 (10.2%)
Don’t know	27 (14.4%)
A Failure Mode and Effects Analysis (FMEA):	

Is a prospective risk assessment method	77 (41.2%)
Is a retrospective risk assessment method	47 (25.3%)
Identifies and prevents problems before they occur	63 (33.7%)
Examines possible process and/or product failures	89 (47.8%)
Provides the anticipated result	30 (16.1%)
A Root Cause Analysis (RCA):	
Is a prospective risk assessment method	29 (15.6%)
Is a retrospective risk assessment method	87 (46.5%)
Identifies and prevents problems after they occur	98 (52.7%)
Examines possible process and system failures	59 (31.7%)
Provides the underlying cause	101 (54.3%)
Develops corrective actions and preventive actions	93 (49.7%)
A "Just Culture":	
Non-punitive or blame-free culture	120 (64.2%)
Open and fair culture	75 (40.1%)
Develops accountability towards staff's actions	51 (27.4%)
Cultivates trust in the workplace	95 (50.8%)
Encourages people to speak up about mistakes	116 (62.0%)
Increases reporting of MEs	109 (58.3%)
Decreases the incidence of MEs	72 (38.5%)

Answers in red are the correct answers to the question; some questions have missing values, i.e. valid percentages were put between brackets for all variables.

Table 3. Attitude/Opinion of hospital pharmacists concerning pharmacovigilance.	
Which of the following health care professionals is/are responsible for ADRs reporting in your hospital	
Doctor	128 (68.4%)
Pharmacist	158 (84.5%)
Nurse	152 (81.3%)
Do you support "direct ADR" by the patients instead of healthcare professionals?	
Yes	73 (39.0%)
Do you think that ADR reporting and monitoring system would benefit the patient?	
Yes	181 (96.8%)
Do you think that pharmacists could be the right person to assist physicians in ADR reporting?	
Yes	181 (96.8%)
Do you worry about legal problems while you think of ADR?	
Yes	92 (49.2%)
Do you feel that ADR reporting is time consuming activity with no outcome?	
Yes	22 (11.8%)
Do you think reporting ADR is a professional obligation to you?	
No	18 (9.7%)
Yes	147 (79.0%)
Don't know	2 (1.1%)
Perhaps	19 (10.2%)
Do you believe reporting should be made mandatory for practicing pharmacists?	
Yes	141 (75.4%)

Are you interested in participating in an ADR reporting system?	
Yes	166 (88.8%)
Do you think there should be a National Pharmacovigilance Program?	
Yes	180 (96.3%)
If a National Pharmacovigilance Program is instituted, what is your expectation from it?	
Someone from the center to coordinate with you	18 (9.7%)
Financial compensation for time and energy spent	168 (89.8%)
ADR reporting is important to:	
Enable safe drugs to be used	141 (75.4%)
Measure the incidence of ADRs	148 (79.1%)
Identify factors that might predispose to an ADR	140 (74.9%)
Identify previously unrecognized ADR	123 (65.8%)
Compare ADRs for drugs in similar therapeutic classes	132 (70.6%)
Compare ADRs of the same drug from different drug companies	135 (72.6%)
Pharmacists are encouraged to report ADRs when:	
The reaction is of serious nature	156 (83.4%)
The reaction is unusual	148 (79.1%)
The reaction is to a new product	146 (78.1%)
The reaction is not reported before for a particular drug	130 (69.5%)
The reaction is well organized for a particular drug	62 (33.2%)
Pharmacists may be discouraged to report ADRs when:	
Level of clinical knowledge makes it difficult to decide whether an ADR has occurred or not	89 (47.8%)
Uncertain association between the drug and the adverse reaction	119 (64.0%)
The ADR is too trivial to report	56 (30.3%)
Concern that a report will generate extra work	48 (25.8%)
ADR reporting form is not available when needed	61 (32.8%)
Lack of confidence when discussing the ADRs with the prescriber	59 (31.7%)
No enough information available from the patient	87 (46.8%)
Lack of time to fill in a report	66 (35.5%)
Did not know how to report	41 (22.2%)
Fear of legal liability	51 (27.6%)
Unaware of the need to report an ADR	46 (24.9%)
Consider it the doctors' responsibility	32 (17.3%)
In your hospital, the perception of a safety culture revolves around which of the following statements:	
Why waste our time on safety	3 (1.7%)
We do something when we have an incident	22 (12.2%)
We have systems in place to manage all identified risks	25 (13.9%)
We are always on the alert for risks that might emerge	40 (22.2%)
Risk management is an integral part of everything that we do	90 (50.0%)

Some questions have missing values, i.e. valid percentages were put between brackets for all variables.

Table 4. Practice of hospital pharmacists concerning pharmacovigilance.	
Concerning the national accreditation Pharmacy chapter, are all medication safety related standards applied in your hospital? (yes)	152 (81.3%)
Does your hospital have written policies and procedures on safe medication practice?	170 (90.0%)
Has your hospital established a defined system for adverse events reporting? (yes)	158 (84.5%)
Is there a medication safety department in your hospital? (yes)	155 (82.9%)
If yes, does the pharmacist chair/oversee that committee/department?	128 (68.4%)
In your hospital, is there a standardized form for reporting ADRs?	173 (92.5%)
Is the reporting form available at your Pharmacy?	174 (93.0%)
Does your workplace encourage you to report any ADR?	170 (90.9%)
Have you ever come across with an ADR?	165 (88.2%)
In your hospital, ADRs are reported only when they are:	
Serious and life-threatening	143 (76.5%)
Severe and cause disability	138 (73.8%)
Mild and cause less inconvenience	133 (71.1%)
When an ADR is encountered in your hospital, it is reported to:	
Patient	31 (16.6%)
Prescriber	102 (54.5%)
Drug company	92 (49.2%)
OPL drug information center	10 (5.3%)
Ministry of public health	5 (2.7%)
None of the above	43 (23%)
How do you prefer to report ADRs to drug companies?	
Verbally inform the representative of the drug company on routine visits	33 (17.6%)
Formal e-mail/letter	93 (49.7%)
Phone call	28 (15.0%)
Via a National Pharmacovigilance Center	95 (50.8%)
Have you attended any congress/seminar or CE program on safe medication practice issues in the last year?	
Yes	84 (44.9%)
Have you ever had a course or attended a workshop about pharmacovigilance?	
Yes	67 (35.8%)
Have you anytime read any article on prevention of ADRs? (yes)	**148 (79.1%)**
Have you ever been trained on how to report ADRs? (Yes)	120 (64.2%)
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	177 (94.7%)
Do you think medication safety (ADR) programs should be included in the actual Pharmacy curriculum?	174 (93.0%)
Which of the following medication safety preventive measures are applied in your Pharmacy?	
Unit dose labeling	143 (76.5%)

Unit dose labeling per patient	117 (62.6%)
Look-A-Like/Sound-A-Like labeling	147 (78.6%)
High Alert Medication labeling	151 (80.7%)
"Store in Fridge" labeling	146 (78.1%)
Use of TALLman letters	81 (43.3%)
Avoidance of ambiguous nomenclature (abbreviations, trailing zeros)	105 (56.1%)
Bar-coding	52 (27.8%)
Temperature monitoring	160 (85.6%)
Are there any staff educational sessions in your pharmacy on medication safety best practices?	
Yes	73 (39.2%)
Which of the following assessment methods are implemented in your hospital when reporting ADRs?	
Root Cause Analyses (RCA)	90 (48.6%)
Failure Mode and Effects Analysis (FMEA)	34 (18.4%)
Causality Assessment tools	24 (13.0%)
Severity Assessment tools	34 (18.4%)
Classification tools	29 (15.5%)
All of the above	31 (16.7%)
None of the above	24 (12.9%)
How often are ADRs reported?	
More than once a week	38 (20.8%)
Once a month	60 (32.8%)
A few times a year	79 (43.2%)
Never	6 (3.3%)
Whether electronic and/or paper-based, are ADRs documented in the patient medical record? (yes)	109 (58.3%)
If yes, is there an alerting system, such as pop-up alerts and/or colorful labeling, on the electronic or paper-based patient's medical record, preventing future events from occurring with the same medication? (yes)	84 (44.9%)
Which activities in the field of safe medication practice are implemented in your hospital on regular basis (more than 50%)?	
Unit dose dispensing	158 (84.5%)
Centralized cytotoxic preparation	100 (53.5%)
Centralized intravenous administration service	31 (16.6%)
Therapeutic drug monitoring	106 (56.7%)
Drug information	121 (64.7%)
Pharmacists round with physicians	60 (32.1%)
Pharmacists round independent of physicians	87 (46.5%)
Patient counseling at discharge	61 (32.6%)
Medication reconciliation	60 (32.1%)
ADEs reporting	120 (64.2%)
SBAR communication	14 (7.5%)
None of the above	5 (2.7%)

Some questions have missing values, i.e. valid percentages were put between brackets for all variables.

Table 5. Comparison between chief and staff pharmacist concerning their pharmacovigilance knowledge.				
Factor	**Chief**	**Staff**	**Clinical**	**p-value**
FMEA				
Prospective risk assessment method	39 (39.8%)	21 (42.9%)	16 (56.8%)	0.906
Retrospective risk assessment method	21 (21.4%)	14 (29.2%)	11 (29.7%)	0.462
Identifies and prevents problems after they occur	32 (32.7%)	18 (37.5%)	12 (32.4%)	0.826
Examines possible process and/or product failures	48 (49.0%)	24 (50.0%)	15 (40.5%)	0.630
Provides the anticipated results	11 (11.2%)	12 (25.0%)	6 (16.2%)	0.101
Develops corrective actions and preventive actions	45 (45.9%)	20 (40.8%)	16 (43.2%)	0.837
RCA				
Prospective risk assessment method	15 (15.3%)	8 (16.7%)	6 (16.2%)	0.976
Retrospective risk assessment method	40 (40.8%)	24 (49.0%)	21 (56.8%)	0.228
Identifies and prevents problems after they occur	47 (48.0%)	26 (54.2%)	24 (64.9%)	0.21
Examines possible process and/or product failures	31 (31.6%)	17 (35.4%)	10 (27.0%)	0.712
Provides the anticipated results	47 (48.0%)	30 (62.5%)	22 (59.5%)	0.194
Develops corrective actions and preventive actions	49 (50.0%)	26 (53.1%)	16 (43.2%)	0.658
Just culture:				
Non-punitive or blame-free culture	59 (60.2%)	33 (67.3%)	26 (70.3%)	0.476
Open and fair culture	40 (40.8%)	17 (34.7%)	16 (43.2%)	0.684
Develops accountability towards staff's actions	24 (24.5%)	12 (25.0%)	13 (35.1%)	0.437
Cultivates trust in the workplace	43 (43.9%)	29 (59.2%)	21 (56.8%)	0.151
Encourages people to speak up about mistakes	53 (54.1%)	37 (75.5%)	24 (64.9%)	**0.038**
Increases reporting of MEs	51 (52.0%)	32 (65.3%)	24 (64.9%)	0.200
Decreases the incidence of MEs	32 (32.7%)	23 (46.9%)	15 (40.5%)	0.229
Who is responsible for ADR report?				
Physician	58 (59.2%)	38 (77.6%)	29 (78.4%)	**0.025**
Pharmacist	76 (77.6%)	45 (91.8%)	35 (94.6%)	**0.013**
Nurse	76 (77.6%)	41 (83.7%)	33 (89.2%)	0.270

Worry about legal problems while thinking about ADR reporting?				
Yes	52 (53.1%)	26 (53.1%)	12 (32.4%)	0.081
ADR reporting is time consuming with no outcome				
Yes	15 (15.3%)	3 (6.3%)	4 (10.8%)	0.278
Interested in participating in ADR reporting system				
Yes	87 (88.8%)	44 (89.8%)	33 (89.2%)	0.983
Pharmacist's expectation from PV center				
Someone from the center to coordinate with you	90 (91.8%)	42 (87.5%)	34 (91.9%)	0.672
Financial compensation for time and energy spent	14 (14.3%)	9 (19.1%)	6 (16.2%)	0.754
The perception of a safety culture revolves around which of the following statements:				0.503
Why waste our time on safety	1 (1.1%)	1 (2.1%)	1 (2.7%)	
We do something when we have an incident	11 (11.8%)	7 (14.9%)	4 (10.8%)	
We have systems in place to manage all identified risks	16 (17.2%)	4 (8.5%)	5 (13.5%)	
We are always on the alert for risks that might emerge	23 (24.7%)	11 (23.4%)	5 (13.5%)	
Risk management is an integral part of everything we do	42 (45.2%)	24 (51.1%)	22 (59.5%)	
When an ADR is encountered in the hospital, it is reported to:				
Patient	19 (19.8%)	5 (10.4%)	7 (18.9%)	0.352
Prescriber	58 (59.8%)	27 (55.1%)	17 (45.9%)	0.351
Drug company	52 (54.2%)	22 (44.9%)	17 (45.9%)	0.492
OPL DIC	6 (6.3%)	1 (2.1%)	3 (8.1%)	0.436
MOPH	0 (0.0%)	4 (8.3%)	0 (0.0%)	**0.003**
None of the above	23 (23.7%)	12 (25.0%)	8 (21.6%)	0.936
Staff educational sessions				
Yes	57 (58.2%)	27 (56.3%)	27 (73.0%)	0.223
Have you attended a congress on safe medication practice last year?				
Yes	45 (45.9%)	25 (51.0%)	13 (35.1%)	0.332
Have you attended a course or workshop about PV?				
Yes	42 (42.9%)	14 (28.6%)	11 (29.7%)	0.152
Have you been trained on how to report an ADR?				
Yes	53 (54.1%)	39 (79.6%)	26 (70.3%)	**0.007**
Have you ever worked on a Quality Improvement Plan aiming at reducing the incidence of ADR?				
Yes	48 (49.5%)	25 (51%)	19 (51.4%)	0.974
Do you think medication safety programs should be included in the actual pharmacy curriculum?				
Yes	92 (93.9%)	46 (93.9%)	33 (89.2%)	0.610
Which assessment method(s) is (are) implemented in your hospital to report ADR?				

RCA	50 (51.0%)	20 (42.6%)	18 (48.6%)	0.633
FMEA	23 (23.5%)	6 (12.8%)	4 (10.8%)	0.127
Causality assessment tools	11 (11.2%)	7 (14.9%)	6 (16.2%)	0.689
Severity assessment tools	17 (17.3%)	7 (14.9%)	10 (27.0%)	0.324
Classification tools	14 (14.3%)	6 (12.2%)	9 (24.3%)	0.264
All of the above	15 (15.3%)	11 (22.9%)	5 (13.5%)	0.425
None of the above	16 (16.3%)	3 (6.3%)	5 (13.5%)	0.237
How often are ADR reported?				0.463
More than once a week	15 (15.8%)	11 (22.4%)	11 (29.7%)	
Once a month	30 (31.6%)	16 (32.7%)	14 (37.8%)	
A few times a year	46 (48.4%)	21 (42.9%)	11 (29.7%)	
Never	4 (4.2%)	1 (2.0%)	1 (2.7%)	

* The Chi-square test was used to compare between the chief and the staff groups for all variables.