

# Medication Safety Spontaneous Reporting System: The Lebanese Order of Pharmacists Initiative

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## Original Article

### ABSTRACT

**Background:** The increase in medication use and expansion of the pharmaceutical industry has led to an increase in hazards, errors and adverse events associated with medication use. In Lebanon, medication safety reporting by pharmacists is lacking due to the absence of an official reporting system.

**Objective:** The objective of the Order of Pharmacists of Lebanon (OPL) was to engage pharmacists in reporting the adverse drug reactions by creating an efficient tool for this purpose.

**Methods:** The scientific committee at the OPL worked on designing a reporting tool for adverse drug reactions (ADRs).

**Results:** An electronic platform was created, and several training sessions were conducted for professionals who would be involved in helping community or hospital pharmacists in launching the platform. The form was tuned based on the findings of the Community pharmacists, hospital pharmacists and the general population questionnaires about medication safety culture, to fit the needs of the practice and to be comprehensive and aligned with international validated standards.

**Conclusion:** Pilot testing is ongoing and regular continuing education sessions and sensitization campaigns are planned, in parallel to the official launching of the project in collaboration with the MOPH. This program has important implications in terms of public health, since knowledge and attitudes are viewed as potentially modifiable factors and their improvement is expected to decrease underreporting; the OPL is also hoping to improve the patient safety culture in Lebanon.

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**Key Words:** Community pharmacists; continuing education; electronic platform; general population; hospital pharmacists; KAP study; medication safety; pharmacovigilance.

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## 1. INTRODUCTION

Adverse drug reactions (ADRs) are inevitable harmful consequences of pharmacotherapy, and are considered a leading cause of hospital admissions and deaths<sup>[1-3]</sup>. ADRs impact significantly healthcare costs, as well. Voluntary reporting by health professionals is currently considered the cornerstone for the detection and management of ADRs and makes a valuable contribution to the safe use of medicines. Pharmacovigilance activities are essential for detecting rare but potentially dangerous ADRs, those occurring after prolonged exposure, and drug–drug and drug–disease interactions that may not have been observed in randomized trials conducted prior to drug licensing<sup>[4-8]</sup>. ADR reporting systems are managed by national ADR or pharmacovigilance reporting centers, and differ internationally<sup>[9]</sup>.

Since the early 1960s, many countries have adopted voluntary ADR reporting schemes. In Australia, New Zealand, Belgium, France, Germany, Canada, Singapore, Malaysia, South Africa, the UK and the US, there have been formal reporting systems developed by which health professionals and, in some countries, consumers can report ADRs<sup>[10]</sup>.

In Saudi Arabia, pharmacovigilance is a new concept. However, there are good initiatives being conducted by some stakeholders, including the Saudi Food and Drug Authority (SFDA), some pharmaceutical companies and hospitals<sup>[11]</sup>. Nevertheless, some further actions are suggested such as having a gateway to facilitate the transmission of ADR reports and to increase the number and quality of partnerships between all stakeholders<sup>[11]</sup>.

On another hand, the Egyptian Drug Authority (EDA) established the Egyptian Pharmacovigilance Center in December 2009 (EPVC)<sup>[12]</sup>. EPVC is taking all appropriate measures to encourage physicians and other healthcare professionals to report the suspected adverse reactions to EPVC and obligate marketing authorization holders to systematically collect information on risks related to their medical products and to transmit them to EPVC<sup>[12]</sup>. EPVC Provides information to end-users through adverse drug reaction news bulletins, drug alerts and seminars<sup>[12]</sup>.

Similar to EPVC, the Jordanian Ministry of Health established in 2001 the Jordan Pharmacovigilance Center (JPC) within the drug directorate department which is responsible for the collection and evaluation of information on pharmaceutical products marketed in Jordan with particular reference to adverse reactions<sup>[13]</sup>.

A few years later, in 2008, the UAE launched its National Pharmacovigilance Program<sup>[14]</sup>. It joined the WHO International Drug Monitoring Program in collaboration with the Uppsala Monitoring Centre in 2013<sup>[15]</sup>. The Health Authority of Abu Dhabi (HAAD) took initiatives to encourage pharmacovigilance through greater provision of drug information, the development of a Unified Prescription Form, and formalization of a "Generic Policy"

to enhance pharmaceutical care and reduce medication errors in practice<sup>[16]</sup>.

Unfortunately, in Lebanon no ADR reporting system is established yet as compared to other counties in the MENA region. This system is extremely important to reduce health costs, unplanned hospital admissions and mortalities associated with ADRs. Hence, the Order of Pharmacists of Lebanon (OPL) took the initiative of developing and launching an online platform to be integrated in a national pharmacovigilance program.

## 2. METHODS

### 2.1. *The Order of Pharmacists Initiative: Procedures and Steps*

The OPL is the official pharmacists' association in Lebanon and the legal partner of the Ministry of Public Health to organize and supervise the pharmacy profession. It was established by law in 1950. The governing body of the OPL is elected every 3 years by all registered pharmacists in Lebanon, i.e., total of 8121 active members in 2018. Its main goal is to advance pharmacy practice and support pharmacists. Within the OPL, a nominated Scientific Committee has the role of an executive authority to organize educational activities including conferences, educational sessions and certifications. In 2015, the OPL Scientific Committee took the decision to implement the safety culture and take ownership of the ADR reporting among pharmacists.

The project consisted of multiple steps including creating the Medication Safety Subcommittee, designing the reporting tool and the method of report analysis, assessing the filed medication safety culture, and organizing training and continuing education sessions on medication safety.

### 2.2. *Creating the Medication Safety Subcommittee*

A call for volunteer service on the Medication Safety Subcommittee has been out at the beginning of 2016. Invited pharmacists were pharmacy practitioners in the community and hospital settings, academic pharmacists, as well as pharmacists working in pharmaceutical companies in regulatory, quality and sales/marketing departments. The final structure of the subcommittee included a total of 12 pharmacists from several fields of practice, including academia, regulatory, community and hospital pharmacy practice and medical department officers. Its set objective was evaluating a process to create a just safety culture among pharmacists in Lebanon, and identifying the required roadmap to report ADEs related to any drug or product administered to a patient in a community or hospital setting. Two parallel major endeavors were planned: medication safety reporting tool implementation and culture field assessment.

### 2.3. *Designing The Medication Safety Reporting Tool*

In order to create a standardized reporting and assessment system that allows reporting and objective

evaluation of any reaction based on a reliable and reproducible measurements of causality, there was a need to use an adverse reaction reporting form. After reviewing the causality assessment system proposed by the World Health Organization Collaborating Centre for International Drug Monitoring, the Uppsala Monitoring Centre (WHO-UMC), and the Naranjo Probability Scale<sup>[17]</sup>, the subcommittee created an online form adapted to the Lebanese context and needs that handles 4 pillars: patient, reporter, medication and event details. (Appendix A). A similar downloadable PDF form was also made available online for non-members of the OPL and for those who would like to report anonymously.

The form collects information related to: a) Name and the type of the reporting institution; b) demographics about the patient and the list of medication and supplements being taken; c) information about the suspected drug and the prescriber; d) details about the adverse reaction or product problem including subjective description, picture or documents attachments, questions related to Naranjo Scale (for the popularity and simplicity of the scale among practitioners), laboratories values results if available, outcome of the reaction, action taken, current status of the patient and e) reporter's contact information and details.

The form was then introduced to the OPL Website ([www.opl.org.lb/medicationsafety](http://www.opl.org.lb/medicationsafety)) with a login information section, which provides access to the following sets of expandable headings: a) information on Adverse Reaction Reporting, b) a summary of what to report, c) Purpose and scope, d) confidentiality and protection, e) Instruction to complete the adverse reaction reporting form and f) the references used. The user will have to acknowledge understanding prior to being able to report.

The form and its preambles has been placed on the OPL website in 3 languages: Arabic (native), French, and English. A manual for filling the form has been created and uploaded online in the preamble section (<http://opl.org.lb/oplwebguide>). Finally, a medication safety email has been created in case pharmacists had any questions, or problem to report. ([medication.safety@opl.org.lb](mailto:medication.safety@opl.org.lb)) (Appendix B)

#### **2.4. Analyzing Reported Submissions**

The OPL has also designed an electronic system to analyze the reported events. This system enables dual screen viewing of the report by administrators. One screen will enable reading the submitted report (no edition allowed), and the other split screen will give access to the complete Naranjo Scale Electronic Form. This latter will enable a professional objective evaluation to determine the likelihood of whether an ADE is actually due to the drug rather than the result of other factors. Causality is assessed via a score that leads to classifying the ADE into definite, probable, possible or doubtful. A follow-up message appears on the screen of the reporter that the submission has been evaluated, under progress or completed with the probability results. Furthermore, the system allows searching the reporting database by drug, reaction severity,

or submission date. It allows the transfer of data to a Microsoft Excel sheet for analysis. The end outcome is to report to concerned authorities to optimize patient safety.

#### **2.5. Assessing the Field Medication Safety Culture**

The medication safety subcommittee designed 3 surveys intended to assess the medication safety knowledge and practice among community pharmacists, hospital pharmacists and outpatients before the implementation of the notification tool. A cross-sectional study was thus carried out between March and July 2016, using a proportionate random sample of community and hospital pharmacies from all districts of Lebanon (Beirut, Mount Lebanon, North, South and Bekaa). A complete list of community and hospital pharmacists was provided by the OPL<sup>[18]</sup>. All pharmacists were targeted by the survey. For the outpatients' survey, in every selected community pharmacy, 2 randomly selected patients were approached to fill out their addressed survey.

The detailed questionnaire was distributed to community and hospital pharmacists randomly by interviewers. The interviewers were well trained before the start of the data collection process. The interviewers explained the study objectives to participants; obtained their informed written consents, and informed them that their participation is completely voluntary. The questionnaire was mainly self-administered and was completed by participants within approximately 15-20 minutes. During the data collection process, the anonymity of the pharmacists was guaranteed by putting filled out questionnaires into closed boxes. At the end of the process, the completed questionnaires were collected by the interviewers and sent for data entry.

The anonymous questionnaire addressed to pharmacists was in French or English language. It was composed of different sections: 1. Socio-demographic and practice characteristics: age, gender, level of education, location of the pharmacy, surface of the pharmacy, demographic area, approximate number of patients per day, years of practice, working hours per week, position in the pharmacy; 2. Questions related to the definition and recognition of ADE and pharmacovigilance; 3. Questions related to reporting; 4. Questions related to patient safety and response to mistakes. The questionnaire was translated into French or English by a translator and then translated back by another translator to ensure translation accuracy.

The patient questionnaire addressed the following areas: (1) patients' sociodemographic characteristics and medical condition; (2) elements of medication knowledge; and (3) medication-related practices and experience, directed to depict risk-prone behaviors and interest in medication use and risks. Throughout the questionnaire, frequency was measured using a five-point Likert scale with answer categories ranging from always (5) to never (0). To assess medication-related knowledge, patients were asked to cite the name, strength and dosage regimen of each medication they were taking at the time of the interview, along with the indication, and any potential ADR they

know may be caused by these medications. The answers, provided by each patient, were analyzed according to each of the following 5 elements: name (brand or generic), strength, dosage regimen, indication, and potential ADRs (at least one ADR per drug). For each element, patients' answers were analyzed as follows: patients who knew the answer for <50% of their medications scored 0, patients who knew the answer for  $\geq 50\%$  of their medications, but not 100% scored 1, and patients who knew the answer for all of their medications scored 2. An index for total medication knowledge (additive score) was then created, with a minimum score of zero and a maximum score of 10 (patients who knew all the answers for all the 5 elements of their medications). Accordingly, the patient's "total medication knowledge" was classified as follows: sub-optimal medication knowledge (Index score of 0–7); and optimal medication knowledge (Index score of 8–10).

As for data management and statistical analysis, data entry was performed by a pharmacist who was not involved in the data collection process. Statistical analysis was performed using SPSS software, version 22. Descriptive statistics were calculated for all study variables; this includes the counts and percentages for all variables.

### 3. RESULTS

#### 3.1. Medication Safety reporting tool

The reporting form developed by the medication safety sub-committee is the product of the work (Appendix A) that was based on the findings of previous projects run by the OPL, the results of which are presented in the next sections.

#### 3.2. Community Pharmacists' survey results:

The results from surveying 1857 community pharmacists showed that pharmacists had good knowledge concerning the concept and purpose of pharmacovigilance as well as adverse drug reactions and events (how to report, importance of reporting, definition of an ADE and pharmacovigilance). The majority of community-pharmacists admitted having a positive attitude towards their role in adverse drug reaction reporting and this activity was even seen as one of their core duties. The questionnaire revealed a lack of practice and training regarding pharmacovigilance. Nonetheless, the pharmacists agreed on the role of the OPL and the Ministry of Health in promoting this practice and helping them be more involved in reporting ADEs. The pharmacists thought they are well positioned regarding patient-safety practice in their pharmacies and the results were not statistically different between pharmacy employers and employees. This survey was published in 2017<sup>[18]</sup>.

#### 3.3. Hospital pharmacists' survey results:

The results of the hospital pharmacists' surveys showed that the majority of respondents (N= 187) do not have adequate knowledge about the concept and process of pharmacovigilance and spontaneous ADE reporting

system. Around 84.5% of participants highlighted that the pharmacist is responsible for ADE reporting in their respective hospital while 61% said they do not support direct ADE reporting by the patient. Only 64% were trained to report ADE. The study highlighted the need of educational programs to emphasize the role and responsibility of pharmacists in pharmacovigilance practices, and to raise awareness toward ADE reporting process. This survey is submitted for publication<sup>[19]</sup>.

#### 3.4. Outpatients' survey results:

The study included 921 patients, with around 16% taking  $\geq 5$  medications/day. Around 56% of the patients showed sub-optimal medication knowledge. Patients' higher educational level, number of chronic diseases, and patient-physician interaction were mainly associated with higher medication knowledge. Many patients admitted not discussing the medications they take each time they visit their doctors (38.7%), not reading the leaflet of each medication they take (61.2%), and not asking about the interactions between the over-the-counter drugs they are buying and the medications they already take (53.9%). Higher educational level, younger age, and patient-physician interaction were significantly associated with a higher interest in medication use and safety. Around 40% of patients reported experiencing ADE. Female gender and increased number of medications were significantly associated with a higher frequency of self-reported ADE. The study showed suboptimal total medication knowledge and practices, with a particular deficiency in knowledge of potential ADEs of their medications. The findings were published in 2017<sup>[20]</sup>.

### 4. ORGANIZING TRAINING AND CONTINUING EDUCATION SESSIONS ON MEDICATION SAFETY

Prior to launching the online forms, a series of educational activities were delivered in an intent to increase the pharmacists' awareness to medication safety, spread the safety culture, and arm the attendees with the minimum medication safety terminologies and background to be able to support and take part of this initiative. The educational activities delivered were part of:

#### 4.1. National Pharmacist Day Organized by the OPL (2016)

A review of the different aforementioned assessment studies was presented to the attending pharmacists. The presenters highlighted the suboptimal medication safety knowledge among community pharmacists, hospital pharmacists and patients; and emphasized on the need for patients and healthcare professionals to be vigilant regarding the potential ADRs of their medications.

#### 4.2. Annual OPL Congress (2016)

The OPL introduced the Medication Safety Initiative, and the new "Adverse Reaction Reporting form" in three different languages (Arabic, English and French). The

presentation guided the attending pharmacists through the form, and highlighted the need to report any suspected adverse event to a drug or product used by their patients<sup>[21]</sup>.

#### **4.3. Continuing Education (CE) Program**

Medication safety sessions were organized in all governorates of Lebanon (North, South, Beirut, Bekaa and Mount Lebanon) and mandated for all licensed pharmacists. They mainly focused on the recognition of medication errors and ADEs, on the different classifications and reporting systems and on stimulating the attending pharmacists to report suspected ADEs through the online form launched by the OPL<sup>[22]</sup>.

#### **4.4. Training/Workshop for pharmacists**

The medication safety subcommittee organized a set of advanced training geared to OPL inspectors to provide them with the necessary medication safety background knowledge to support the pharmacists in ADE reporting during their inspection rounds, and guide them through the adverse reaction reporting form if needed. The training focused on the classification, assessment, and reporting of ADEs and briefly reviewed the causality assessments.

In addition, a full-day workshop was organized at the OPL premises for a small of volunteer pharmacists willing to participate in the pilot period that is now ongoing.

### **5. PROVIDING INCENTIVES TO MEDICATION SAFETY CULTURE**

The effectiveness of a national surveillance program is highly dependent on the active participation of health professionals.

As drug experts, and as part of their professional responsibility, pharmacists are urged to report ADEs when suspected. The most significant incentive would be to optimize patient care, reduce patient suffering, and save patients' lives by increasing the body of data and preventing potentially serious ADEs<sup>[23]</sup>.

Other potential incentives that are under consideration by the OPL include allocating CE credits to the pharmacists for each submission of a truthful adverse reaction report, and developing a "good catch" award in recognition of pharmacists who submit adverse event reports that can lead to the identification or prevention of serious patient harm.

### **6. PROSPECTIVE STEPS**

Pilot testing is ongoing and regular CE sessions and sensitization campaigns are planned, in parallel to the official launching of the project in collaboration with the MOPH. Once the memorandum of understanding signed with the MOPH, we will urge pharmacists to start reporting and the first 20 reports will allow us to connect with Uppsala Monitoring Centre and collaboration with other stakeholders will be implemented in an integrated national pharmacovigilance system.

A detailed list of steps of the whole project is presented in Appendix C.

### **7. LIMITATIONS TO ADR REPORTING**

A voluntary reporting system of adverse drug events is fundamental to drug safety surveillance; it represents the cornerstone of pharmacovigilance. However, all over the world, spontaneous reporting system shows several limitations. In this section we will dive deeper to try to unveil the various restrictions and reasons behind reporting issues, taking into account the different stakeholders at play. Other limitations that may arise are: delays in reporting, difficulties detecting common ADRs, lack of denominator data, bias, and quality of reports.

#### **7.1. Underreporting in Lebanon**

In Lebanon, as in other countries, under-reporting is expected to be a major issue, hindering proper pharmacovigilance practices. Pharmacists and physicians claim that it results from a lack of trust in the effectiveness of the pharmacovigilance reporting centers, a lack of awareness about existing reporting systems, and the absence of a clear legal frame resulting in the worry of being chased legally, being blamed or having a bad reputation. That reporting is limited only to the medical or sales representatives of pharmaceutical companies. They also mention having other interests than reporting.

Another contributor is the lack of awareness about the medication safety concept among health professionals and the general population. All pharmacists may not consider counseling as an essential duty, but that it is the physician's role. Patients on the other hand, attribute this to a lack of awareness about a reporting system, lack of trust in the medical and official parties, carelessness and a lack of awareness about the medication safety concept [Unpublished data]. This data is not different from what was reported in other countries.

#### **7.2. Underreporting in other countries: Physician-related barriers**

In a systematic review<sup>[24]</sup> conducted by Gonzalez et.al, authors concluded that under-reporting was associated with ignorance (only severe ADRs need to be reported) in 95% of studies; diffidence (fear of appearing ridiculous for reporting merely suspected ADRs) in 72%; lethargy (an amalgam of procrastination, lack of interest or time to find a report card, and other excuses) in 77%; indifference (the one case that an individual doctor might see could not contribute to medical knowledge) and insecurity (it is nearly impossible to determine whether or not a drug is responsible for a particular adverse reaction) in 67%; and complacency (only safe drugs are allowed on the market) in 47% of studies<sup>[25]</sup>.

Another study conducted by Figueiras et. al [25] with the objectives of identifying 1) the practitioner's demographic and professional characteristics associated with ADE reporting; and 2) knowledge, attitudes, and opinions associated with ADE reporting. Results revealed that the probability of reporting ADEs increases with increasing volume of prescriptions and decreases with

increasing patient load. The following attitudes were identified to be associated with a smaller probability of reporting: 1) belief that really serious adverse drug events are well documented by the time a drug is marketed; 2) belief that it is nearly impossible to determine if a drug is responsible for a particular adverse event; 3) only reporting an adverse drug reaction if one is sure that it is related to the use of a particular drug; and 4) belief that the one case an individual physician might see cannot contribute to medical knowledge<sup>[25]</sup>. In the article “Spontaneous Reporting Systems: Achieving Less Spontaneity and More Reporting”<sup>[25]</sup>, time constraint was identified as one major reason, as the doctors prioritised spending more time in actual contact with the patients then spending time on reporting. Liability factor may play a role in stifling reporting as well. And there is also a preference in the medical community to publish adverse reactions rather than to report them.

### 7.3. Underreporting in other countries: Patient-related barriers

In a systematic review, identified barriers to patient reporting of ADEs include poor awareness, confusion about who should report the ADE, difficulties with reporting procedures as well as not being aware of reporting systems, lack of feedback on submitted reports, mailing costs, ADRs resolved and prior negative reporting experiences. Other articles highlight patients’ fear to ask their physicians or suggest that the doctor had erred contributes to their conservative behavior as well<sup>[26]</sup>.

Finally, while personal and professional factors display a weak influence, the knowledge and attitudes of health professionals appear to be strongly related with reporting in a high proportion of studies. Altogether under-reporting is clearly multifactorial and remains a major obstacle to overcome until this day. However, many opportunities for improvement to spontaneous reporting systems exist and must be put in place for the overall benefit of patient safety. This result may have important implications in terms of public health, if knowledge and attitudes are viewed as potentially modifiable factors.

## 8. RECOMMENDATIONS

The initiative of the OPL will succeed when the pharmacists will be more involved in the educational activities offered by the Medication safety sub-committee. Increasing the awareness about the importance of a medication safety culture among pharmacists, will motivate them to encourage the patients to report the ADEs.

## 9. CONCLUSION

In conclusion, the Order of Pharmacists of Lebanon was able to implement a medication safety notification system in Lebanon, a developing country with many constraints. The starting project will need to be consolidated by raising awareness and changing the perception in the general population and among some health professionals, to overcome the problem of underreporting that may arise.

## CONFLICTS OF INTEREST

The authors have nothing to disclose.

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## Appendix A



If you equally suspect more than one drug, please fill out one form for every suspected drug

### Adverse Reactions Reporting Form

*Fields marked with an \* are required*

Health care institution\*: \_\_\_\_\_

Institution type

- Community Pharmacy   
  Public Hospital   
  Private Hospital  
 University Medical Center/University-Affiliated Hospital   
  Other: \_\_\_\_\_

#### A. Patient Information

Name\* \_\_\_\_\_ Medical Record Number (E-health number) \_\_\_\_\_

Date of birth\* \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ Gender\*:  Male     Female    Weight\* \_\_\_\_\_ Kg    Height\* \_\_\_\_\_ cm  
(DD/MM/YYYY)

Mohafazat\* \_\_\_\_\_ Caza\* \_\_\_\_\_ Nationality \_\_\_\_\_  
 Area \_\_\_\_\_ Street \_\_\_\_\_ Building \_\_\_\_\_  
 Mobile\* \_\_\_\_\_ Telephone \_\_\_\_\_ Email address \_\_\_\_\_

Patient consents for follow-up\*     Yes     No

- List medications and supplements that the patient is currently taking\*

	Brand Name	Active Ingredient	Manufacturer	Strength or Concentration	Dosage Form	Indication	Dose	Frequency	Route	Start Date	Stop Date	Lot Number	Expiry Date	Reference Code Number
Most Suspected Drug	▼								▼					
Least Suspected	▼								▼					





- Physician
- Dentist
- Midwife
- Pharmacist suggestion
- Self-medication
- Other \_\_\_\_\_

### C. Adverse Reaction or Product Problem

1. Date reaction started\*: \_\_\_\_\_ Date: \_\_\_\_\_ Time: : : - - -

Did the Reaction stop\* ?  Yes  
 No, is still on-going

2. Describe the reaction\*

Please upload any photo, document(tests,etc...) that you think are appropriate to the reporting form

Add file (please note that the combined file size should be less than 2 megabytes)

3. Reaction appeared after initiating the drug/product\*?  Yes  No  Don't know
4. Reaction stopped after discontinuing the drug/product\*?  Yes  No  Don't know
5. Reaction reappeared after restarting/reintroducing the drug/product\*?  Yes  No  Don't know  
 Did not retake/reintroduce the drug/product
6. What was the outcome of the reaction\*? (please select all that applies)

- Requiring no interventions
- Discontinuing the drug/product
- Changing the therapy
- Administration of an antidote
- Requiring supportive treatment
- Hospitalization (Emergency Room or less than 24 hours)
- Hospitalization (for more than 24 hours)
- Prolonged hospitalization in case of in-patients
- Interventions to prevent permanent impairment or damage
- Transfer to an intensive care unit
- Disability
- Life-threatening
- Death
- Unknown
- Congenital anomaly
- Other: \_\_\_\_\_

Additional comment

**7. Relevant laboratory data including dates**

Other relevant history including preexisting medical conditions: (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, drug-drug interactions, drug-food interactions, drug-disease interactions, drug-laboratory interactions, substance abuse, etc...)

Please answer the following questions concerning the most suspected drug

**8. Further action taken\***

- No further action taken
- Prescriber was notified
- Medical record documentation was written
- Patient was counseled

**9. How is the patient doing now?**

- Recovering                       Unknown  
 Recovered                         Fatal  
 No improvement                 Fatal

10. Is the adverse reaction related to a medication error\*?  
 Yes  No

11. Are there alternative causes (other than the drug) that could have on their own caused the reaction \*?  
 Yes  No  Do Not Know

12. Did the reaction reappear when a placebo was given \*?  
 Yes  No  Do Not Know

13. Was the reaction more severe when the dose was increased or less severe when the dose was decreased \*?  
 Yes  No  Do Not Know

14. Did the patient have a similar reaction to the same or similar drugs in any previous exposure \*?  
 Yes  No  Do Not Know



#### D. Reporter details

Physician     Pharmacist     Nurse     Public-Patient     Other \_\_\_\_\_  
 Name\* :    rony zeenny    Speciality: \_\_\_\_\_    OPL Registration Number:    4530  
 Address: \_\_\_\_\_    Email:    rony.zeenny@opl.org.lb    Phone Number: \_\_\_\_\_

Submit

Date of report: Monday 21/08/17

## Appendix B

Adverse Reaction (Drug/Product)  
Reporting Form Logoutcharacter size  

Eng ▼

A. Information on Adverse Reaction Reporting 

- Adverse events include both adverse reactions and medication errors.
- An adverse reaction is a harmful and unintended response to a health product. This includes any undesirable patient effect suspected to be associated with health product use. Unintended effect, health product abuse, overdose, interaction, and unusual lack of therapeutic efficacy are all considered to be reportable adverse reactions.
- A medication error is any preventable event that may (but not necessarily) cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer.
- Medication errors are not reported using this form, but they may be the cause of adverse reactions as mentioned in section B of that form.

B. What to Report ? 

- All suspected adverse reactions should be reported, especially those that are:
  - *Unexpected*, regardless of their severity
  - *Serious*, whether expected or not
  - Reactions to *recently marketed health products (≤ 3 years on the market)*, regardless of their nature or severity.
- A serious adverse reaction is one that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability, is life-threatening or results in death. Adverse reactions that require significant medical intervention to prevent one of these listed outcomes are also considered to be serious.

C. Purpose and Scope 

In the perspective of medication safety, the Lebanese Order of Pharmacists (OPL) elaborated an "Adverse reaction (drug/product) reporting form" in order to report adverse reactions related to any drug or product administered to a patient in a community or hospital setting

and has led to an adverse reaction. The aim is to create a standardized assessment system, reporting objectively any reaction based on a reliable and reproducible measurement of causality. The present form has been developed based on the causality assessment system proposed by the World Health Organization Collaborating Centre for International Drug Monitoring, the Uppsala Monitoring Centre (WHO-UMC), and the Naranjo Probability Scale [1 2]. This tool will allow us to screen, detect, investigate, analyze and establish any causal relationship between the drug/product and the adverse event/reaction. Furthermore, evaluated data will enable us to classify the adverse event/reaction according to its severity, its probability, and the pharmaceutical category of drug/product behind its occurrence, creating a national adverse reaction database of health products, which will be forwarded, at a later stage, to the Global Pharmacovigilance Database managed by WHO-UMC. Our ultimate purpose is to support good decision-making regarding the benefits and risks of treatment options for patients taking medicines and thus enhancing the key role of the pharmacist in the practice of medication safety. We appreciate the time allocated to complete the form. If you have any questions or concerns, send them to the following email: [medication.safety@opl.org.lb](mailto:medication.safety@opl.org.lb)

#### D. Confidentiality and Protection

- Submission of a report does not imply that the reporter, the institution or the product caused or contributed to the adverse reaction. Adverse reaction reports are only suspected associations; [4] they do not imply a definitive causal link.
- All obtained data will stay *confidential and anonymous*; they will be protected and handled in strict confidence, and will be used for medication safety reporting and follow up only.

#### E. Instructions to complete the Adverse Reaction Reporting Form

- Use the form to report adverse reactions to Lebanese marketed health products, including prescription and non-prescription medications, vitamins and herbal products, electrolytes and serums, biologically derived products such as vaccines and fractionated blood products, radiopharmaceuticals and diagnostics, and cosmetics.
- All sections of the form should be filled in as completely as possible. Each reported adverse reaction requires a separate form for every patient.
- Any follow-up information for an adverse reaction that has already been reported can be submitted by accessing "review previous submissions". Selecting the corresponding submission, and adding a note at the end of the page where indicated. Once done, press submit.

## F. References

I have read and understood all the above terms & conditions.



I agree

[Submit a new form](#)

[Review previous submissions](#)

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## Appendix C

### Appendix C - Medication Safety Plan – Phases

#### **Phase I**

*Completion End of July 2016*

- Field assessment of Medication Safety Culture among pharmacists and the population
- Pharmacist Form Completed from IT perspective in English
- Administrator Completed from IT perspective in English
- Manual for Pharmacist Users – Completed In English
- Post Manual on the website
- Complete the training of 2 DIC pharmacists
- Announce Launch by message to pharmacists

#### **Phase II**

*Completion End of August 2017*

- Pharmacist Form Completed from IT perspective in French
- Administrator Completed from IT perspective in French
- Pharmacist Form Completed from IT perspective in Arabic
- Administrator Completed from IT perspective in Arabic
- Manual for Pharmacist Users – Completed In French
- Manual for Pharmacist Users – Completed In Arabic
- Post Manual in French and Arabic on the Website
- Announce Launch by message to pharmacists

#### **Phase III**

*Estimated Completion End of December 2017*

- Collect Data Entry – Pilot cases
- Analyze the data received – Generate first level recommendation
- Correct the bugs of the reporting system in all three languages

#### **Phase IV**

- Establish regular CE sessions related to medication safety (once / 3months – In regions).

#### **Phase IV**

*Estimated Completion January 2018*

- Reset Data
- Start Effective Data Collection with at last 20 reports to submit to UPPSALA
- Initiate Collaboration with Pharmaceutical companies.

#### **Phase V**

- Generate Quarterly Report starting June 2018