

# The Extent of Pharmacovigilance Awareness among Pharmacy Senior Students of Centro Escolar University, Manila, Philippines

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## Introduction

The Philippine Pharmacists' Association (PPHA) Code of Ethics for Pharmacists defines Pharmacists as Health Professionals who help individuals protect themselves against diseases, maintain good health and make the best use of their medications. They promote rational use of drugs and ensure the provision of safe, effective and quality drugs for improved patient care and quality of life [1]. The Pharmacist roles have truly evolved from their traditional roles of filling prescriptions to the management of medication therapy of their patients through Pharmaceutical Care, a concept introduced by Hepler and Strand [2] in the late 1980s. The Pharmacist, as part of the Healthcare Team is committed to place the well being of the patient at the centre of professional practice. The pharmacist's knowledge and expertise is important to the application of the safety profile of a medicine to the needs of a particular patient. Maintaining and monitoring of drugs safety and efficacy is an integral part of clinical practice. Thus, pharmacovigilance being part of the clinical discipline will play a vital role in assessing clinical practice standards in each country. The World Health Organization (WHO) [3] defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems."

Since, Adverse Drug Reactions (ADR) are common causes of morbidity and mortality in different healthcare settings, Pharmacists are more likely to detect ADRs than other healthcare professionals. According to US Food and Drug Administration [4], a serious Adverse Reaction is one in which the patient outcome is death, life threatening (real risk of dying), hospitalization (initial or prolonged), disability (significant, persistent or permanent), congenital anomaly, or required intervention to prevent permanent impairment or damage. Even if the Practice of Pharmacovigilance varies from country to country, the pharmacists' prime responsibility is the welfare of each individual.

Level of Awareness	Mean	Standard Deviation	Interpretation
PHARMACOVIGILANCE ACTIVITIES	3.72	0.23	High Level of Awareness
Adverse Drug Reaction (ADR) and Adverse Drug Events (ADE)	4.12	0.22	High Level of Awareness
Description of Adverse Drug Reaction (ADR) or a Serious Adverse Drug Event (ADE)	4.19	0.13	High Level of Awareness
OVERALL AWARENESS	4.01	0.25	High Level of Awareness

Table 1: Level of Awareness.

Mean	Interpretation
4.50	Very High Level of Awareness
3.50	High Level of Awareness
2.50	Neither High Nor Low
1.50	Low Level of Awareness
0.00	Very Low Level of Awareness

Table 2: Mean values and Interpretation of Level of Awareness.

The primary objective of this study was to "Determine the Extent of Pharmacovigilance Awareness" among Pharmacy Senior Students of Centro Escolar University, Manila, Philippines.

## Objectives

- To determine the awareness of the Centro Escolar University (CEU), Manila Pharmacy Senior Students' Knowledge about Pharmacovigilance, Adverse Drug Reaction (ADR) and Adverse Drug Events (ADE).
- To assess the respondents' familiarization regarding ADR monitoring, reporting, and documentation.
- To measure the respondents' perception on pharmacovigilance education or training as part of Pharmacy Curriculum and Practice.

## Methods

A Descriptive Type of Research was used to determine the Extent of Pharmacovigilance Awareness among Pharmacy Senior Students of Centro Escolar University, Manila, Philippines between January 2013 to March 2013 (Appendix 1). A validated questionnaire (Appendix 2) was administered to 336 Pharmacy Senior Students using a Five-Point Likert Scale ranging from 1 (not aware/very low level) to 5 (very much aware/very high level) [5].

## Results

### To determine the awareness of the Centro Escolar University (CEU), Manila pharmacy senior students' knowledge about pharmacovigilance, adverse drug reaction (ADR) and adverse drug events (ADE) (Table 1)

The results showed that the respondents have high level of awareness about Pharmacovigilance activities and knowledge on adverse drug reactions and adverse drug events (Table 2).

### To assess the respondents' familiarization regarding ADR monitoring, reporting, and documentation (Table 3)

The computed general weighted mean of 3.52 suggest that respondents have high level of familiarity when it comes to the Existence

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Level of Familiarity	Mean	Standard Deviation	Interpretation
Existence of National Pharmacovigilance Center	3.52	0.53	High level of Familiarity
Aware of the National Policy and Program on Pharmacovigilance	3.27	1.10	Neither High nor Low level of Familiarity
Aware on where to report a suspected ADR/ADE?	3.24	0.63	Neither High nor Low level of Familiarity
Aware on who can report a suspected ADR/ADE	3.93	0.93	High Level of Familiarity
Aware of Adverse Drug On-Line Reporting System	3.53	0.31	High Level of Familiarity
Aware of the existence of an Adverse Reaction Form used in making reports to FDA	3.61	1.13	High Level of Familiarity
Aware of the minimum criteria for a valid ADR report	3.34	1.11	Neither High nor Low level of Familiarity
The minimum criteria	3.76	0.18	High Level of Familiarity
OVERALL FAMILIARITY	3.53	0.24	High Level of Familiarity

Table 3: Level of Familiarity.

Mean	Standard Deviation	Interpretation
4.50	5.00	Very High Level of Familiarity
3.50	4.99	High Level of Familiarity
2.50	3.49	Neither High Nor Low
1.50	2.49	Low Level of Familiarity
0.00	1.49	Very Low Level of Familiarity

Table 4: Mean values and Interpretation of Level of Familiarity.

Level of Perception	Mean	Standard Deviation	Interpretation
Pharmacovigilance should be included as a core topic in a 4-yr BS Pharmacy Curriculum	4.47	0.70	Very Positive Perception
Pharmacovigilance must be discussed in :	4.24	0.24	Very Positive Perception
ADR Monitoring & Reporting should be taught to Pharmacy			
Senior students during their internship	4.56	0.74	Very Positive Perception
Registered pharmacists in all areas of specialization should actively participate in ADR Monitoring , Reporting & Documentation	4.69	0.62	Very Positive Perception
ADR Monitoring , Reporting & Documentation should be made compulsory :	3.84	0.56	Positive Perception
ADR's that are not-life threatening must not be reported anymore	2.15	1.26	Negative Perception
Managing patient & patient confidentiality is more important than ADR Monitoring, Reporting & Documentation	2.83	1.27	Neither Positive nor Negative
It makes no sense at all to report known ADR	1.54	0.99	Negative Perception
It's just a waste of time monitoring ,reporting & documentation the ADR	1.49	0.97	Very Negative Perception
OVERALL PERCEPTION	3.31	1.32	Neither Positive nor Negative

Table 5: Level of Perception.

of National Pharmacovigilance Center. Likewise, with a mean of 3.24, the respondents are undecided on whether they are familiar or not with

regards to where to report a suspected ADR/ADE. On the other hand, 3.93 implied that they have high level of familiarity with regards on who to report a suspected ADR/ADE. Lastly, the respondents have high level of familiarity with regards to the adverse drug online reporting system with a mean of 3.53.

Furthermore, the general weighted average of 3.27 showed that respondents have neither high nor low level of familiarity with regards to the national policy and program on pharmacovigilance [6]. Moreover, the general computed mean of 3.61 means that respondents have high level of familiarity with regards to the existence of an adverse reaction forms used in making reports to FDA [7]. Additionally the general weighted average of 3.34 indicates that respondents have neither high nor low level of familiarity when it comes to the minimum criteria for a valid ADR report (Table 4).

### To measure the respondents' perception on pharmacovigilance education or training as part of pharmacy curriculum and practice (Table 5)

The respondents have a very high level of perception with 4.47 weighted mean with regards to the inclusion of Pharmacovigilance in a 4-year BS Pharmacy Curriculum. The respondents also strongly agree that it should be discussed in different Pharmacy subjects particularly on Internship 2 (Hospital) with a weighted mean of 4.50 (Table 6). Furthermore, a general weighted mean of 4.56 implies that they have a very positive perception with regards to ADR monitoring, reporting, documentation and 4.69 on Pharmacists participation in different areas of specializations regarding the said activities (Table 7 and Figure 1).

### Conclusions

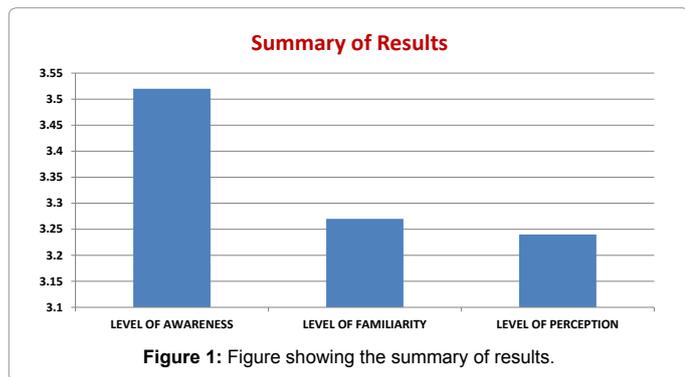
Pharmacy Senior Students of Centro Escolar University, Manila, Philippines have high level of awareness about Pharmacovigilance activities and knowledge on adverse drug reactions (ADR) and adverse drug events. However, even if the respondents have a very high level of perception with regards to the inclusion ADE). Also, a high level of familiarity by the respondents regarding ADR monitoring, reporting and documentation of Pharmacovigilance in a 4-year BS Pharmacy Curriculum, in terms of level of perception, the overall extent obtained from the respondents response resulted to neither positive nor negative perception. Considering the results obtained from this study, Pharmacist Educators should ensure that the curriculum include the pharmacists' importance in pharmacovigilance. By doing so, future pharmacists would be more informed and aware of the vital role they

Mean	Standard Deviation	Interpretation
4.50	5.00	Very Positive Perception
3.50	4.99	Positive Perception
2.50	3.49	Neither Positive nor Negative
1.50	2.49	Negative Perception
0.00	1.49	Very Negative Perception

Table 6: Mean values and Interpretation of Level of Perception.

Criteria	Mean	Standard Deviation	Interpretation
Level of Awareness	3.52	0.53	High level of Awareness
Level of Familiarity	3.27	1.10	High level of Familiarity
Level of Perception	3.24	0.63	Neither Positive nor Negative
Overall Extent of Pharmacovigilance Awareness	3.93	0.93	High Level of Awareness

Table 7: Summary of Results.



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play in drug safety and thereby potentially help enhance the level of ADR monitoring, reporting, documentation and preventing ADR and ADE.