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 affects 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.

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 questionnaires (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

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

**Table 3: Level of Familiarity.**

| 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 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.**

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

**Table 7: Summary of Results.**
play in drug safety and thereby potentially help enhance the level of ADR monitoring, reporting, documentation and preventing ADR and ADE.

References

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