

# Pharmacovigilance Training of BPharm Undergraduates by Self-Directed Learning: A Report

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## Abstract

Pharmacovigilance (PhV) was initiated to prevent adverse drug reactions and other adverse drug events, in response to drug use tragedies such as phocomelia. As such, PhV has been long in existence in North America and Europe. However, in some countries the practice of PhV is relatively new. For example: In Namibia the Therapeutics Information and PhV Centre (TIPC) was established in 2008 by the Ministry of Health and Social Services (MoHSS), with technical support from Management Sciences for Health. Following the establishment of TIPC the MoHSS embarked on training in-service health care workers as a strategy to promote PhV. Training in-service HCW is a costly venture, and its continuous implementation may be interrupted. The training of medical, pharmacy, and nursing students is a more sustainable strategy for promoting PhV, by virtue of its long-term nature. In cognizance of the importance of PhV and the need to promote it, the School of Pharmacy (SoP), Faculty of Health Sciences at the University of Namibia included a module on PhV as part of the curriculum to train Bachelor of Pharmacy students. While didactic face to face training has been used to train PhV, the SoP utilised Self-Directed Learning. This report contains the aims of pharmacovigilance training at the SoP; how the module was structured; how the sessions were conducted; recommendations on how to make PhV training practical; and how to broaden student coverage on PhV training.

**Keywords:** Pharmacoepidemiology; Pharmacovigilance; Adverse drug reactions; Self-directed learning

## Background

Pharmacovigilance (PhV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem [1]. It is through pharmacovigilance, during clinical trials and during the post marketing period, that previously unknown adverse drug reactions (ADR) [1]; increasing incidences and severities of known ADR [2]; and risk factors are identified. From these, further ADR's are mitigated. Therefore, the World Health Organisation (WHO) recommends that each country should establish a pharmacovigilance (PhV) centre to coordinate drug safety monitoring, and thereby promote public health.

The institution of drug safety monitoring systems was mainly driven by serious ADR. The tragedy of phocomelia, which was observed in thousands of neonates born to mothers who received thalidomide for the treatment of nausea and vomiting during pregnancy, was the major reason

for the birth of pharmacovigilance [1]. Phocomelia led to the development of the spontaneous reporting of adverse effects in the United Kingdom via the Yellow Card in 1964 [3]; and to the establishment of The World Health Organisation Programme for International Drug Monitoring in 1972 [4]. The need to protect patients led to the development of The World Medical Association (WMA) Declaration of Helsinki. This declaration states that, "Medical research involving human subjects must conform to generally accepted scientific principles..." [5]. As a result, a new medicine will have gone through a set of rigorously designed clinical studies before its approval for clinical use. However, due to budget constraints these clinical studies utilise small numbers of patients, and their implementation time is short. Worse still, these studies only recruit patients who meet certain criteria. As such, results emanating from these studies do not represent the full safety profile of a drug. This is one of the reasons as to why post-marketing surveillance (PMS) was introduced [6].

In the developed regions of the world PMS is well established. This is evidenced by the frequent safety alerts published by the United States' Food and Drug Administration (FDA), and the European Medicines Agency (EMA), which are responsible for PhV in their respective regions [7]. The practice of pharmacovigilance – particularly the PMS type – was introduced 2008, in Namibia, when the Ministry of Health and Social Services (MoHSS) set-up the Therapeutics Information and Pharmacovigilance Centre (TIPC), with support from Management Sciences for Health (MSH) [8]. Since PhV was generally a new practice in Namibia, the MoHSS invested in activities to promote the reporting of ADR. Many PhV training workshops for in-service health workers have been conducted. Furthermore, MSH has supported the production of materials such as flyers, pens, clinical coats, and bulletins towards promotion of PhV. Nevertheless, the number of spontaneous reports dwindles, and only picks-up following a visit from the centre or training (**Unpublished information**). At the moment, boosting the promotion activities is what sustains the influx of ADR reports into the PhV centre in Namibia.

While the scope of activities implemented in support of PhV is justifiable, they constitute a costly venture, whose uninterrupted sustainability may not be guaranteed. There is therefore need to exert effort on a more sustainable and cost-effective mechanism to support PhV, which includes training of medical, pharmacy, and nursing students on PhV. In cognizance of this, the University of Namibia's (UNAM) School of Pharmacy, with technical support from the University of Washington, included a module on PhV in

the curriculum of the Bachelor of Pharmacy (**Unpublished information**). (The title of the module is Pharmacoeconomics and Pharmacoeconomics. Pharmacoeconomics is the study of effects of drugs on large populations, which adopts the principles of PhV. In this paper we refer to the classroom based training of pharmacoeconomics as PhV training).

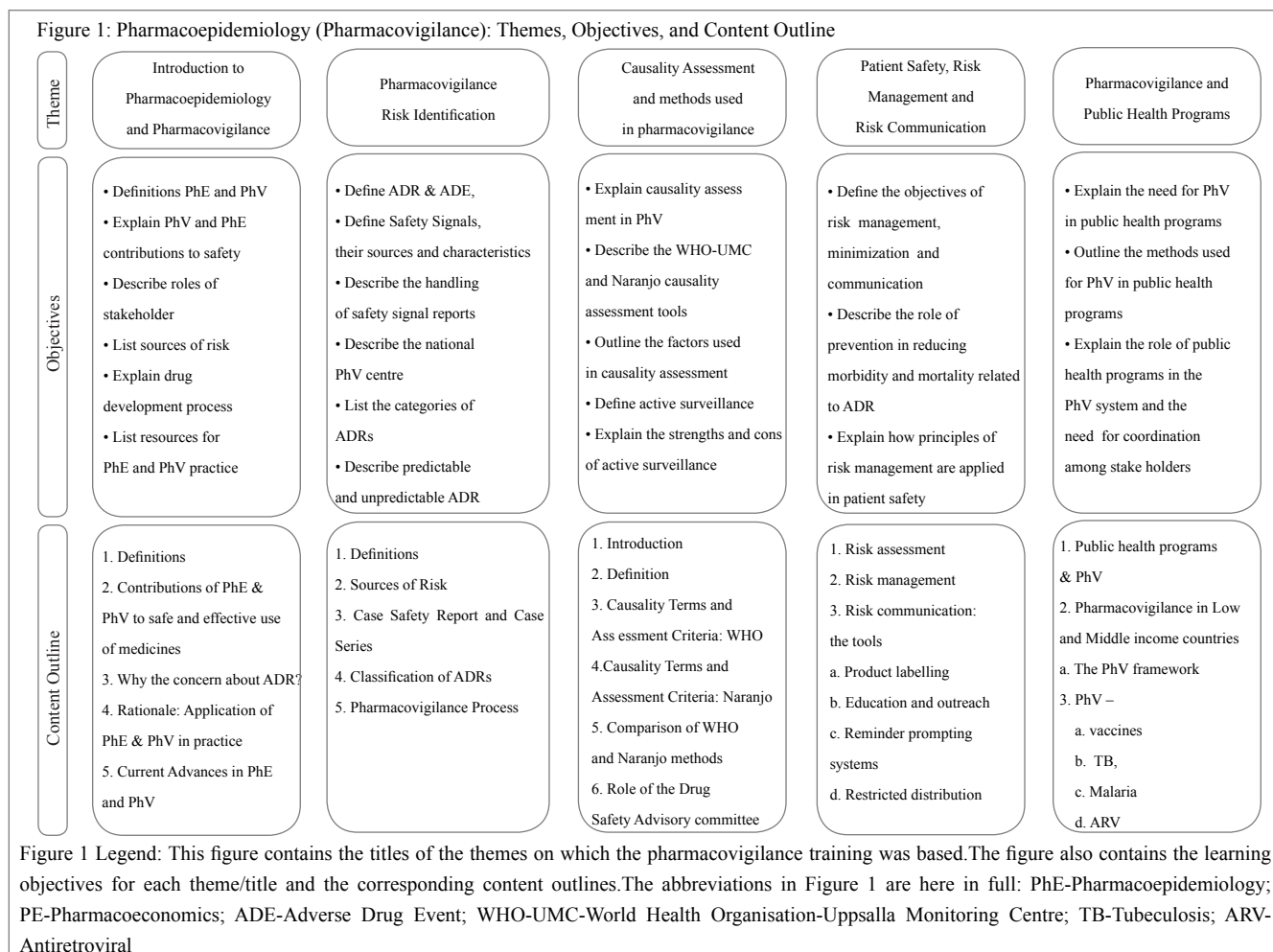
While conventional methods such as didactic face-to-face sessions can be used in the training of PhV, as observed with the trainings by the MoHSS, the School of Pharmacy embarked on Self-Directed Learning (SDL). This is a report on the aims of pharmacovigilance training at the School of Pharmacy; how the module was structured; how the sessions were conducted; recommendations on how to make PhV training practical; and how to broaden student coverage.

### Aims of Pharmacovigilance Training

The pharmacovigilance module aims to give knowledge to the students on the mechanisms and benefits of drug safety surveillance; to equip the students with the skills to identify ADR and populate the adverse medicine reaction reporting tools; and to help students to recognise that sending filled reports to the pharmacovigilance centre is critical for assuring patient safety and public health.

### How the Module was Structured

The module was made up of five themes, each with learning objectives and a content outline (Figure 1).



## How the Module was Implemented

The students received the module guide from the lecturer, and a presentation of the key aspects of the module. (NB: These were the first Bachelor of Pharmacy students of the School of Pharmacy.) The class of 14 students was divided into two groups. The classroom session, on day one of the week, always started with an introduction to the theme, during which the learning objectives and content outlines were presented and discussed to ensure that each one perceived what the theme was about. After that, class room tasks were given to the students (Figure 2).

Figure 2: Knowledge Acquisition and Sharing Processes

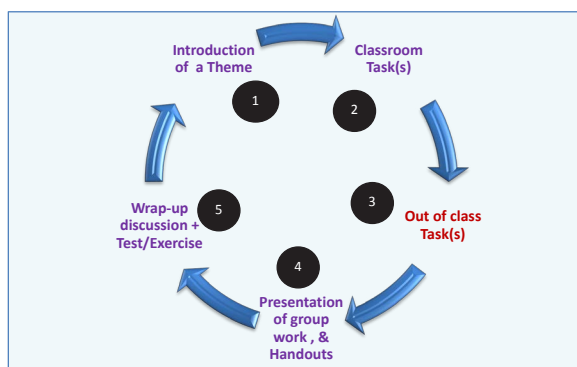


Figure 2 Legend: This figure depicts how the pharmacovigilance training was implemented, each session starting with an introduction and ending with a Wrap-up discussion.

The classroom tasks consisted of group discussions. The discussions were guided by questions derived from hypothetical and real scenarios. During the discussions, the lecturer provided guidance or interjected when required. After completion of the classroom task, the out of class tasks were introduced to the class. The students were given at least one reference that they could use to complete the out of class task, and they had three solid days to complete the tasks. Each group was required to submit a written report, and to prepare a power point presentation of their findings. The presenter was always selected randomly by the lecturer at the time of presentation –that is, on the last day of the week. Sometimes a presenter was stopped in the middle of the presentation and another student was selected by the lecturer to continue the presentation from where the last presenter had stopped. This was done to ensure that each student was well versed with the subject matter. On some occasions, one of the group members interjected the presentation to add information that the presenter had left out. The presentation was followed by questions from the other group and from the lecturer. The presentations were assessed for content, correctness of information, and appearance of the slides. Also, responses to questions were included in the assessment, and scores were given. At the end of the presentations, the students were given notes on the very theme/title that they had studied. They had the weekend to peruse through the notes. On Monday, the students were given the opportunity to share any new knowledge they acquired from the notes, and to ask questions for clarity. Before the introduction of the next theme, time was given to wrap up the theme.

## Conclusion and Recommendations

The written reports on the tasks that were given were comprehensive and so were the presentations the students made. However, there were a few instances of inclusion of unnecessary information in the reports. The assessment included tests, quizzes, and exams in addition to the presentations. Since, there was no comparison; the results have not been included in this report. Nevertheless, it is worth mentioning that the performance was satisfactory. Self-Directed Learning is an effective method for training undergraduate pharmacy students on Pharmacovigilance, and is likely to be a mechanism to sustain PhV services in Namibia. The PhV training can be made practical by directing the BPharm students who undergo clinical rotation during their fourth year, to suspect occurrence of an ADR in patients who come to the health facility for medical attention. The students should be encouraged to exercise their knowledge of causality assessment, and if there is a relationship between the ADR and the drug, to fill the ADR tool and send the report to TIPIC. This should be followed with a visit to TIPIC to track their reports. Lastly, the PhV module should be embedded in the MBChB and the Nursing students' curricula too.

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