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# Pharmacovigilance in South Africa: Undocumented undergraduate training and practice

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## ABSTRACT

Pharmacovigilance is a clinical discipline that is gaining more and more attention worldwide and in Africa. The rolling out of large scale programs on HIV/AIDS, tuberculosis and malaria has heightened the need to step up efforts to have pharmacovigilance concepts to be operationalized in clinical practice. A quick search in PubMed and Google Scholar and a review of available literature was conducted in order to establish whether medical, nursing and pharmacy undergraduate students are taught pharmacovigilance concepts and skills for effective practice. It seems that there is a paucity of data on the undergraduate training in pharmacovigilance in South Africa. It may be that there might be inadequate training on pharmacovigilance during undergraduate training of medical, nursing and pharmacy students in South Africa. More studies are needed to document the views and experiences of South African students and healthcare professionals on training and practice of pharmacovigilance.

Key Words: pharmacovigilance, training, South Africa

## INTRODUCTION

Pharmacovigilance is a clinical discipline that is gaining more and more attention worldwide and in Africa. The rolling out of large scale programs on HIV/AIDS. tuberculosis and malaria has heightened the need to step up efforts to have pharmacovigilance concepts to be operationalized in clinical practice. Yet, to date little is known about what is being taught to future healthcare professionals who have the duty to practice pharmacovigilance in South Africa. The perspective discussed here aimed at was investigating whether medical, nursing and pharmacy undergraduate students are taught pharmacovigilance concepts and skills for effective practice.

## METHODS

A quick search in PubMed and Google Scholar using the key words "undergraduate", "training", "pharmacovigilance" and "South Africa" was conducted. In addition, available syllabi on pharmacology of some pharmacy, nursing and medical schools were reviewed to ascertain whether pharmacovigilance appeared thereon as a subject. Several other literatures in the forms of documents from the Ministry of Health, books and dissertations were also consulted.

## RESULTS

Although over 200 publications were retrieved from the search, none reported specifically on undergraduate training in pharmacovigilance concepts in South Africa. Data from other sources suggest that all eight pharmacy schools in South Africa offer a lecture or a tutorial on pharmacovigilance to their students. During this lecture, students are taught the importance of pharmacovigilance and what is expected of them. It is unclear whether the skill on reporting could be possibly taught during a lecture. With regard to nursing schools, it is clear they are taught to record patients' complaints including potential and known side effects; and implicitly report these to the attending medical officers. Yet again, it is unclear whether the skill of reporting of side effects to the national pharmacovigilance centre is also taught. With regard to medical students, it seems from the curricula reviewed topic that the of

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#### Malangu *et al.*, World J Pharm Sci 2014; 2(3): 210-212 roduced during the **DISCUSSION**

pharmacovigilance might be introduced during the clinical pharmacology course. Similarly, it is not clearly whether reporting is taught. It is also noted that there is no specific undergraduate program leading to a qualification in pharmacovigilance. On the contrary, several postgraduate programs at both pharmacy and medical schools mentioned pharmacovigilance as one of the subjects.

These included programs in clinical pharmacy, clinical pharmacology, and other medical sciences. What is undeniable is that the books that medical, nursing and pharmacy students use during their training and as references for clinical practice. namelv the National Standard Treatment Guidelines, the Treatment Guidelines for specific diseases such as for HIV/AIDS, and the National Medicines Formulary altogether have in their annexures the reporting form and the contact details of where the reports of adverse effects should be directed to [1-4]. With regard to pharmacovigilance practice, there is a national pharmacovigilance committee and a national pharmacovigilance program coordinator at the national ministry of health, but there are no corresponding posts at provincial, district and institutional levels of healthcare. The National pharmacovigilance programme is part of the Medicines Control Council (MCC), the regulatory body responsible for the administration of the legislation about medicines in the country [5].

The pharmacovigilance programme has two units for the monitoring of the safety of medicines: the National Adverse Drug Event Monitoring Centre (NADMEC) based at the University of Cape Town which monitors the safety of all registered medicines and a focused surveillance unit based in Pretoria at Medunsa, the "Medunsa National Antiretroviral Pharmacovigilance Centre (MNPAC)". This centre is responsible for the monitoring the safety of antiretroviral (ARV) complementary medicines. medicines and unregistered medicines. The NADMEC has been established in 1987, while the MNAPC was established in 2004 [6].

The lack of published papers on undergraduate training in pharmacovigilance in South Africa is deplorable since the country is one of the few countries in Africa with well-established pharmacovigilance programs [7]. There is a need for national surveys of institutions, students and healthcare professionals in order to document their views and experiences on the training and on the practice of pharmacovigilance. Elsewhere, several investigators have reported on the experiences of their students and health care workers [8-15]. The lack of positions of pharmacovigilance officers at various levels of the South African healthcare system constitutes a serious impediment for the training of healthcare professionals wishing to specialise in a field in which job opportunities are not guaranteed in the public healthcare system. Almost all of those trained in some aspects of pharmacovigilance at postgraduate level, are employed mainly by the pharmaceutical industry and academia.

Given the need to encourage young graduates to start their careers with good habits, it is important that pharmacovigilance be taught as a topic not only as a lecture but also as a workshop or a seminar during which students should be given practical exercises that would allow them to practice the skill of reporting. This is important because reporting adverse effects is the cornerstone of pharmacovigilance practice. Unless this skill is gained and widely practiced by a substantial number of healthcare professionals, underreporting of adverse effects will continue unabated [16].

## CONCLUSION

There is a paucity of data on the undergraduate training in pharmacovigilance in South Africa. It may be that there might be inadequate training on pharmacovigilance during undergraduate training of medical, nursing and pharmacy students in South Africa. More studies are needed to document the views and experiences of South African students and healthcare professionals on training and practice of pharmacovigilance.

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#### **Conflict of interests**

The author declares no conflict of interest in relation to this paper.