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ORIGINAL ARTICLE

Bridging the Knowledge Gap: Educating Novice Nurses on Pharmacovigilance

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ABSTRACT

Pharmacovigilance plays a crucial role in assessing the risk-benefit ratio of medications, promoting their safe, rational, and effective use, and ultimately improving patient safety and care. Nurses play a fundamental role in drug administration and monitoring the therapeutic and non-therapeutic effects of drugs. The study aimed to assess knowledge, attitudes, and practices regarding pharmacovigilance among newly graduated registered nurses in Lesotho, both before and after an educational intervention. This study utilized a questionnaire-based educational intervention with a pre- and post-test design, involving newly graduated registered nurses. A link to a 15-item pre-validated electronic questionnaire assessing knowledge, attitudes, and practices related to pharmacovigilance was distributed to newly graduated registered nurses before and after an educational intervention. Ethical clearance and consent from the respondents were secured prior to the start of the study. A total of 197 newly graduated registered nurses from 6 nurse training institutions participated in this pre- and post-KAP questionnaire study. When comparing the KAP of pharmacovigilance before and after the educational intervention, the increase in correct response rates was statistically significant ($P < 0.001$). The training evaluation received positive feedback from the participants. Incorporating a pharmacovigilance module into pre-service nurse training is essential. Additionally, continuing in-service and hands-on nurse training on adverse drug reaction reporting can enhance the KAP of pharmacovigilance and improve adverse drug reaction reporting in nursing practice. The concepts of pharmacovigilance and adverse drug reaction reporting should be further reinforced, as there is significant potential for growth in this area.

Keywords: Adverse drug reaction; Novice nurse; Pharmacovigilance; Reporting

INTRODUCTION

The World Health Organization [1] defines Pharmacovigilance (PV) as the science and activities focused on detecting, assessing, understanding, and preventing adverse effects or any other problems related to medicine use. Adverse drug reactions (ADRs) are significant contributors to both morbidity and mortality worldwide and are also known to lead to longer hospital stays and increased treatment costs [2,3]. The primary goal of pharmacovigilance is to minimize the risk of drug-related harm to patients. Since all medications have the potential to cause adverse effects, administering a drug inherently involves some level of risk [4]. Health care professionals play an important role in reporting and monitoring of adverse reactions. Medication safety is a shared responsibility among physicians, nurses, pharmacists, and other healthcare workers. Knowledge, Attitude, and Practice (KAP) studies are effective tools for evaluating ADR reporting among healthcare professionals in relation to pharmacovigilance.

In 17 studies conducted in Europe, the proportion of adverse drug reactions leading to acute hospital admissions varied between 0.5% and 12.8% [3]. Furthermore, in 10 studies, the percentage of hospital patients experiencing an ADR ranged from 1.7% to 50.9% [5,6]. In the United States, adverse drug reactions are responsible for 100,000 to 218,000 deaths each year, making them the third leading cause of death after heart disease and cancer [7]. Stausberg [8] reports that the rate of in-hospital adverse drug reactions is 5.6% in the United States and 3.2% in the United Kingdom. In the United Kingdom, the total annual expenditure for admissions linked to adverse drug reactions was approximately £466 million,

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whereas in the USA, the estimated cost for ADR-related admissions in ambulatory care settings was expected to exceed $177 billion[7,9]. In Saudi Arabia, Khan et al.[10] conducted a study at King Abdulaziz University Hospital in Jeddah and found an incidence rate of adverse drug reactions of 3.1% in a retrospective study and 5.5% in a prospective study involving hospitalized internal medicine patients. Another study conducted at the same hospital among hospitalized pediatric patients found an incidence rate of adverse drug reactions of 4.5% in a retrospective analysis and 8.2% in a prospective study[10]. In Asia, a recent study from South Korea found that consumers are more likely than healthcare workers to report therapeutic ineffectiveness[11].

Low-and middle-income countries (LMICs), like Lesotho, face specific challenges in pharmacovigilance, including the limited integration of pharmacovigilance systems despite recent efforts to harmonize regulations within regional economic communities[12]. There is a need to translate reporting tools into numerous local languages and address the high patient-to-healthcare worker ratios with very short consultation times[13]. Moreover, there is a scarcity of well-trained pharmacovigilance personnel, coupled with minimal budgetary support from national governments. High staff turnover, which requires substantial training resources, and low awareness of pharmacovigilance among healthcare workers, decision makers, and consumers further complicate the issue[14]. The very low reporting rates and poor-quality spontaneous reports hinder robust signal detection analyses. There is also a lack of collaboration between public health programs and national medicines regulatory authorities, limited investment in pharmacovigilance activities during mass drug administration for neglected tropical diseases, and high use of herbal and traditional medications, often through self-medication. Furthermore, regions affected by disruptive conflicts face jeopardized systems, and limited access to drug utilization data makes it difficult to reliably estimate the true safety risks of medication use[15]. In Lesotho, the pharmacovigilance program is still in the infancy stage, having just started in the year 2018. The national pharmacovigilance centre is located at the Ministry of Health of Lesotho. According to the Uppsala Monitoring Centre (UMC), Lesotho became an Associate Member of the WHO Programme for International Drug Monitoring (PIDM) in 2020[16].

There is a strong correlation between ADR reporting and the knowledge, attitudes, and practices of healthcare professionals[17]. Studies[18–20] from various settings reveal that inadequate knowledge and understanding of pharmacovigilance among healthcare professionals contribute to a high rate of underreporting of adverse drug reactions. Data on KAP studies related to pharmacovigilance among newly graduated nursing staff are limited in the literature. Therefore, a questionnaire-based comparative study was designed to assess KAP regarding PV among newly graduated nursing staff before and after an educational intervention, specifically a pharmacovigilance training workshop.

MATERIALS AND METHODS

A pre–post interventional, questionnaire-based study was conducted to evaluate the impact of an educational intervention on newly graduated nurses' knowledge and awareness of pharmacovigilance and adverse drug reaction reporting. A total of 197 newly graduated registered nurses from six nurse training institutions in Lesotho participated in the study. The participants were provided with an electronic informed consent form, an electronic questionnaire and guaranteed the confidentiality of the collected information. Questions that could reveal personal details, such as the participant's name, contact information, and the name of their organization, were avoided. The participants were assured that the study's results would be published anonymously. The intervention involved a sensitization workshop designed to enhance newly graduated registered nurses' understanding of pharmacovigilance and adverse drug reaction reporting.

The authors then conducted a 5 day blended educational intervention via a face-to-face lecture and Zoom meetings, using a PowerPoint presentation to assist with the educational guide. Each session lasted between 40 and 60 minutes. The educational guide was created by the authors, drawing on literature, educational materials from the CDC website[21,22] and pharmacovigilance training material from the Ministry of Health in Lesotho. The guide covered key topics, including an overview of pharmacoepidemiology (PE) and its relationship with PV, basic PV concepts, components of adverse drug events (ADEs), investigations and causality assessment of ADRs, diagnosis, management, and prevention of ADRs, monitoring and ensuring medication safety, the national PV system, and the role of PV in public health programs (PHPs). It was presented and assessed by the second author who is an expert in the field of clinical pharmacy. The presentation was followed by hands-on training on filling out the ADR reporting forms as per the case history provided. Prior to the workshop, participants were emailed a link to an electronic questionnaire, referred to as the pre-test, following a brief description of the study. On average, it took participants about 30 minutes to complete the pre-test. At the end of the training session, the posttest was conducted with the same questionnaire and was collected after 30 minutes. The pre-test and posttest were analyzed using statistical methods.

The collected data were entered into a Microsoft Excel spreadsheet for evaluation. A paired t-test was used to assess the pretest and posttest scores of newly graduated nursing staff. All results were recorded in Excel, and the statistical calculations were performed using GraphPad InStat. A P-value of less than 0.05 was considered statistically significant.

RESULTS

Demographic Data

The study questionnaire was emailed to a total of 197 newly graduated registered nurses. All the questionnaires were completed and returned, resulting a response rate of 100%. The demographic details of the participants, along with baseline characteristics are summarized in Table 1. The majority (82%) of the participants were female, while the remaining (18%) were males. More than half of the participants (87%) were in the age group of 20 to 25 years, followed by 26% in the age group of 26 to 30 years with the age group of 31 to 35 years being the lowest at 4%. Additionally, 56% were degree nurse-midwives and the remaining 44% were diploma nurse-midwives.

Table 1: Biographical data of participants

Serial #	Characteristics		Frequency	Percentage
1.	Gender	Male	36	18
		Female	161	82
2.	Age	20-25yrs	171	87
		26-30yrs	23	12
		31-35yrs	3	1
3.	Qualification	Diploma in general nursing and midwifery	86	44
		Bachelor's degree in nursing and midwifery	111	56

Knowledge, attitudes and practice analysis before and after an educational intervention

Table 2 illustrates the results of knowledge, attitudes and practices assessment before and after an educational intervention.

Knowledge analysis before and after an educational intervention

The first question aimed to assess awareness of the existence of the ADR monitoring unit in Lesotho. The results showed statistically significant differences ($P < 0.0001$) in responses between the pre-KAP and post-KAP assessments following the educational intervention.

The second question evaluated knowledge of the year in which the pharmacovigilance unit was established. The correct response rate increased significantly from 20.8% to 93.3% after the educational intervention ($P < 0.0001$).

The third question focused on reporting drug-related issues to the ADR monitoring unit, with the percentage of correct responses rising from 44.1% to 92.5% ($P < 0.0001$).

The fourth question assessed the knowledge of pharmacovigilance. According to the data, 8.33% of newly graduated registered nurses answered correctly in the pre-test, which increased to 100% in the post-test ($P < 0.0001$).

The fifth question assessed the knowledge of the health care professional responsible for reporting ADRs. The number of correct responses increased significantly ($P < 0.0001$) after the intervention.

The sixth question focused on the benefits of reporting ADRs to medicine regulatory authorities. In the pre-test, only 8.3% of newly graduated registered nurses provided the correct answer. After the educational intervention, the percentage of correct responses increased significantly to 96.6% ($P < 0.0001$).

The seventh question addressed the definition of ADRs. A total of 66.6% of newly graduated registered nurses answered correctly in the pre-test, and after the session, correct responses significantly increased to 98.3% ($P < 0.0001$).

The eighth question evaluated knowledge of detecting rare ADRs in phase 4 clinical trials. Statistically significant differences ($P < 0.0001$) were observed between the pre-test and post-test responses after the educational session.

The ninth question assessed knowledge of the regulatory body overseeing the pharmacovigilance (PV) system in Lesotho. The percentage of correct responses significantly increased from 28.3% to 86.6% ($P < 0.0001$) after the intervention.

The tenth question evaluated knowledge of serious adverse events. Among newly graduated registered nurses, only 8.3% initially selected the correct answer. However, this percentage increased significantly to 100% following the intervention.

Question 11 was designed to assess awareness of the existence of the PV committee in Lesotho. The percentage of newly graduated registered nurses who responded 'yes' increased significantly from 37.5% to 100% ($P < 0.0001$) after the intervention.

Attitude analysis before and after an educational intervention

In question twelve, participants were asked if reporting an ADR is necessary. The percentage of respondents who answered "yes" increased from 90% in the pre-test to 100% in the post-test ($P<0.0007$).

Question thirteen focused on participants' overall perception of pharmacovigilance. Before the intervention, 73.3% of newly graduated registered nurses believed that pharmacovigilance improves public health. This perception increased to 96.6% after the training session.

Table 2: Knowledge, attitudes and practices of newly graduated registered nurses towards pharmacovigilance

Variable	#	KAP Questions	Answers	Pretest score, n (%)	Posttest score, n (%)	P-value
knowledge	1.	Are you aware of ADR reporting to Pharmacovigilance Centre?	A. Yes p B. No	10 (5)	197 (100)	0.0001
	2.	The Ministry of Health Lesotho, established the National Pharmacovigilance Unit in:	A. 2015 B. 2018 p C. 2008 D. 2022	0	184 (93.3)	0.0001
	3.	Which of the following drug-related issues are to be reported?	A. Adverse Reactions B. Drug interactions C. Medication errors D. All p	67 (34.1)	182 (92.5)	0.0001
	4.	Which of the following best defines Pharmacovigilance?	A. The science of monitoring ADRs occurring in a hospital B. The process of improving of safety of drugs C. The detection, assessment, understanding and prevention of adverse effects p D. Continuous drug use	16 (8.3)	197 (100)	0.0001
	5.	The health care professional responsible for reporting ADRs is/are:	A. Physician B. Pharmacist C. Nurse D. All of the above p	41 (20,8)	197 (100)	0.0001
	6.	Benefits of reporting ADRs to medicine regulatory authorities include all the following except:	A. Exposure of health workers with poor prescribing/dispensing skills p B. Exposure of counterfeit and substandard medicines C. Improvement in labeling of medicines D. Helps identify rare ADRs.	16 (8.3)	190 (96.6)	0.0001
	7.	ADRs are	A. Only side effects B. Noxious and unintended response of drug at normal therapeutic dose p C. 1st leading cause of death D. Pharmacogenomic effect	131 (66.6)	193 (98.3)	0.0001
	8.	Rare ADRs can be identified in the following phase of a clinical trial?	A. Phase-1 B. Phase-2 C. Phase-3 D. Phase-4 p	49 (66.6)	158 (80)	0.0001
	9.	In Lesotho Pharmacovigilance system is regulated by	A. LNC B. MoH-NPU p C. LNA D. LMDPC	49 (66.6)	197 (100)	0.0001

Continued on next page

Table 2 continued

	10.	Serious adverse event in Pharmacovigilance is?	A. Results in death B. Is life threatening C. Requires in patient hospitalization or prolongation of existing hospitalization D. Results in persistent or significant disability/incapacity E. Is a congenital anomaly/birth defect F. All p	16 (8.3)	197 (100)	0.0001
	11.	Is there any Pharmacovigilance Committee that you are aware of?	A. Don't know B. Yes p C. No D. Not yet formed	10 (5)	197 (100)	0.0001
Attitudes	12.	Do you think reporting of adverse drug reaction (ADR) is necessary?	A. May be B. Can't say C. Yes p D. No	177 (90)	197 (100)	0.0007
	13.	What do you think about Pharmacovigilance?	A. Increase economic burden on healthcare system B. Improve public health p C. Neglects patient safety D. D. Discourage effective drug use	144 (73.3)	184 (93.3)	0.0001
Practices	14.	Are you trained for ADR reporting including filling of ADR form?	A. Yes p B. No	0	197 (100)	0.0001
	15.	Which of the following factor can prevent you from reporting ADRs? Mark all that apply	A. Unable to decide whether ADR occurred or not B. Lack of time to report ADR C. No remuneration D. Reporting a single case may not affect ADR database	26 (13.3) 41 (20.8) 15 (7.5) 114 (58.3)	16 (8.3) 62 (31.6) 105 (53.3) 13 (6.6)	0.0137 0.0002 0.0001 0.0001

Practice analysis before and after an educational intervention

The fourteenth question focused on training in ADR reporting, including the completion of ADR forms. None of the newly graduated registered nurses had received training in ADR reporting.

The fifteenth question asked about the factors preventing them from reporting ADRs. A total of 13.3% of newly graduated registered nurses stated that they were unable to determine whether an ADR had occurred. Lack of time to report ADRs was cited by 20.8%, while 7.5% indicated that the absence of remuneration discouraged them from reporting. Moreover, 58.3% believed that reporting a single ADR would not impact the database; however, this percentage dropped to 6.6% after an educational session ($P<0.0007$).

DISCUSSION

Pharmacovigilance has grown in importance recently as a key element of effective drug regulation systems, clinical practice and public health programs[23]. Health care professionals play an important role in reporting ADRs, with spontaneous reporting remaining an essential tool in detecting and reporting ADRs to avoid harm as much as possible. A total of eleven questions were used to evaluate a newly graduated registered nurse's knowledge and awareness of PV and ADRs, two questions assessed attitudes, and two other questions assessed the practices. Details of the responses to the knowledge-related, attitude-related and practice-related questions are presented in Table 2.

The results indicated that newly graduated registered nurses generally lacked knowledge of pharmacovigilance, adverse drug reactions, and the existence of the National Pharmacovigilance Unit before the intervention. However, after receiving educational intervention, their post-test scores significantly improved, highlighting the importance of education in the success of the PV program. A study conducted by Gupta et al.[24] assessed the knowledge, attitude, and practices (KAP) of doctors, nurses, and pharmacists but did not include an educational intervention. Their findings suggested that while awareness and attitudes toward PV were gradually improving among healthcare professionals, the actual practice of ADR reporting remained inadequate. Similarly, a study by[25] found that only 39.6% of healthcare professionals were aware of the National Pharmacovigilance Centre, with nurses accounting for 27.2%, physicians 39.2%, and pharmacists 70.27%. However, these results contradicted the findings of Suyagh et al.[26], which indicated that pharmacists also had poor knowledge of the pharmacovigilance system.

Knowledge of the criteria for identifying serious ADRs in the nursing pretest group was found to be poor, with only 8.3% demonstrating awareness. This may be attributed to the fact that newly graduated registered nurses have had limited exposure to ADRs, making them less familiar with the criteria. Overall, there was a significant increase in knowledge scores after the intervention, particularly regarding the definition and types of ADRs, serious ADRs, and the benefits of reporting ADRs to medicine regulatory authorities. These findings highlight the importance of incorporating PV and ADR education into pre-service training, as well as the need for ongoing educational sessions for healthcare workers. The results of this study suggest that newly graduated registered nurses were strongly influenced by the educational sessions on PV, including hands-on training in ADR reporting. These findings align with previous studies by Bagewadi et al.[27], Augustine et al.[28], and Suveges[29].

In this study, the total pre-intervention knowledge-attitude (KA) score (mean $\pm$ standard deviation) for knowledge was 27.63 ± 21.62, while the attitude score was 98 ± 14.14. Following the intervention, the mean knowledge score significantly increased to 113.81 ± 7.38, and the attitude score rose to 114.5 ± 6.36. A statistically significant improvement in the correct response rate ($P < 0.0001$) was observed in the knowledge domain after the educational intervention. In the analysis of attitudes and practices, most newly graduated registered nurses agreed that ADR reporting is necessary and contributes to public health improvement. However, none of the participants had received prior training on completing ADR forms. Three primary reasons were identified as barriers to ADR reporting: uncertainty about whether an ADR had occurred, lack of time to report ADRs, and the belief that a single ADR report is insignificant. Medications are the most commonly used therapeutic interventions, and their rational use is essential. Failure to ensure drug safety can lead to severe consequences, ranging from lifelong disability to mortality. Conversely, consistent ADR reporting enhances drug safety[30]. Many low- and middle-income countries struggle with low ADR reporting rates, which limits the generation of pharmacovigilance signals and data[31]. The participants in this study demonstrated similar challenges in ADR reporting. The failure to document ADR reports reflects poor reporting practices among healthcare professionals, potentially leading to drug safety issues[32]. Several studies have reported similar findings, showing that despite encountering ADRs in their practice, most healthcare professionals do not report them[33–36].

Various technical terms related to pharmacovigilance, such as ADR, reporter, reportee, causality, and outcome, were explained using non-medical examples, drawing parallels with burglary. This novel approach was found to be highly engaging and made the session easier to understand.

Bagewadi et al.[27] and Augustine et al.[28] evaluated the effectiveness of educational interventions on PV among undergraduate medical students and medical interns,

respectively. Both studies concluded that enhancing knowledge of PV and ADR reporting plays a crucial role in promoting drug safety and ensuring the rational use of medicines in the future.

Limitations

The major limitation of this study is that it was conducted among newly graduated registered nurses from six nurse training institutions in Lesotho, and there are likely to be variations between nurse training institutions in different countries. In addition, other factors associated with questionnaire-based studies, such as accuracy of recall and leading language bias, could have also affected the results of this study. Another important limitation of this questionnaire-based study is that while improvement in knowledge and/or attitude is easily seen in a short time, a change in practice requires long-term follow-up.

Recommendations

The findings of this study suggest that knowledge of medicine safety and ADR reporting should be included in pre-service education. Additionally, an institutional level hands-on training system for managing ADR events should be established. Due to lack of awareness about PV and inadequate training on ADR reporting among newly graduated registered nurses, the authors recommend that both only newly graduated and practicing nurses undergo educational hands-on training to address the issue of underreporting of ADR. Furthermore, collaboration among academic institutions, drug manufacturers, regulatory authorities, and healthcare professionals should be enhanced to promote awareness and best practices in ADR reporting.

CONCLUSIONS

The comparison of the pretest score and posttest core is definitive proof that educational intervention is very helpful in improving knowledge, attitudes, and practices of pharmacovigilance among newly graduated registered nurses. This study suggests that including a pharmacovigilance module in nursing curricula and providing educational interventions on PV are necessary to increase awareness and reporting of adverse drug reactions by newly graduated registered nurses and practicing nurses who are at the forefront of health care delivery.

DECLARATION

Data availability

The datasets used and/or analysed during the current study are available from the corresponding author upon request.

Ethics approval and consent to participate

This study confirms compliance with the Declaration of Helsinki and has received ethical approval from the Health Research Ethics Committee at the National University of Lesotho, Maseru, Lesotho (NUL/NUR/2023/28). The researchers conducted the study competently, following rigorous and methodologically sound procedures. Ethical considerations were adhered to throughout all stages of the study and dissemination. Each author contributed to writing this manuscript in various capacities, as outlined in the authors' contribution section. All sources cited in this paper have been properly referenced and acknowledged and are accessible online and through the corresponding author.

Consent for publication

The participants gave consent for the study's results to be published anonymously.

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Competing interests

The authors confirm that they do not have any known financial conflicts of interest or personal relationships that could have influenced the research presented in this paper.

Authors' contributions

MZS worked on the initial draft of the manuscript, while PRP reviewed and edited it. As a result, all authors contributed to drafting the manuscript and revising it for important intellectual content. All authors have read and approved the final version of the manuscript.

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