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Impact of educational interventions on knowledge, attitude, practice toward pharmacovigilance and adverse drug reaction reporting among healthcare professionals at the University Teaching Hospital, Rwanda

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ABSTRACT

INTRODUCTION: Pharmacovigilance (PV) is crucial in healthcare for detecting, understanding, and preventing adverse drug reactions (ADRs). Despite its significance, there persists underreporting of ADRs due to gaps in knowledge, attitude, and practice (KAP) among healthcare professionals (HCPs), leading to global impacts on patient safety and healthcare costs. This study aimed to enhance the KAP regarding PV and ADR reporting among HCPs at the University Teaching Hospital of Kigali (CHUK), Rwanda. The study's focus was on implementing an educational intervention (EI) to address these gaps and assess its impact on HCPs' confidence in ADR monitoring and reporting, alongside the actual number of reported drug adverse events in the hospital post-EI.

METHODS: A quasi-experimental study was conducted at CHUK, Rwanda, using a one-group pretest-posttest design. The study involved 217 HCPs, assessing their KAP on PV and ADR reporting before and after an EI. A self-administered questionnaire and data on reported ADRs were used for the evaluation of the EI.

RESULTS: The EI significantly enhanced HCPs' KAP regarding PV and ADR reporting. The proportion of participants understanding the purpose of PV increased from 61.9% to 78.8% (p=0.001), while awareness of the national PV in Rwanda surged from 38.1% to 96.6% (p<0.001). Attitudes among HCPs notably improved, particularly in identifying events as serious, escalating from 59.8% to 79.5% (p < 0.001). The observed improvement in practice was solely in the availability of ADR reporting forms, rising from 58.7% to 82.2% (p < 0.001). However, no significant changes were observed in certain KAP aspects. Participants exhibited increased confidence in monitoring and reporting ADRs post-intervention. Furthermore, a significant increase in reported drug adverse events to the quality assurance office was observed (p<0.001).

CONCLUSION: The study underscores the effectiveness of EI in enhancing HCPs' KAP concerning PV and ADR reporting. While improvements were evident, sustaining education initiatives remain critical for optimal ADR reporting and patient safety.

Keywords: Adverse Drug Reaction Reporting, Educational Intervention, Healthcare Professionals; Pharmacovigilance, Knowledge, Attitude, Practice

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INTRODUCTION

Pharmacovigilance (PV) was defined by the World Health Organization (WHO) as "the science and activities related to the detection, assessment, understanding and prevention of adverse drug effects or any other possible drug-related problems"[1]. The main aim of pharmacovigilance is to enhance the patient's quality of life-related to the healthcare system by reducing and assessing the risk-benefit profile of treatment therapy. The fundamental process of PV is adverse drug reaction (ADR) identification and reporting of the documented record of ADR to the regional, national, and international drug authorities [2]. An ADR is defined as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function" [3, 4]. It was demonstrated that one reason for the underreporting of ADRs is the lack of knowledge, attitude, and practice (KAP) regarding ADR reporting [2, 3]. Adverse drug reactions from medications are a major concern for health policymakers, clinicians, and patients because they impact treatment adherence, and increase healthcare costs, morbidity, and mortality. ADRs may range from mild to life-threatening, with short or long-term effects [6, 7].

The medicines are monitored on the market despite pre-market approvals to ensure their safety in real patients in clinical settings. Research conducted in the US FDA Adverse Event Reporting System revealed that from 2006 to 2014, a total of 902,323 serious outcomes resulted from approved drugs. Those serious outcomes included 244,408 deaths, 72,141 disabilities, and 585,774 other serious outcomes [9]. The adverse drug reactions reporting helps to make the decision to withdraw medication from the market. Health professionals play a significant role in reporting adverse drug reactions, and they also render the national pharmacovigilance system successful [2–4].

The study conducted in India revealed that most of the clinicians (50%) reported lack of training as the cause of the underreporting of ADRs, and 30% were unaware of the reporting process[6]. The adverse drug reactions are underreported in developing countries [10]. Studies in Sub-Saharan Africa identified a lack of reporting knowledge, lack of information about national pharmacovigilance systems, and absence of ADR identification and management knowledge as the leading causes of under-reporting ADRs [7].

It was revealed that the inadequate reporting of adverse drug reactions because of a lack of knowledge on pharmacovigilance was not only observed in developing countries because a study conducted in Turkey on "Healthcare professionals' pharmacovigilance knowledge and adverse drug reaction reporting behavior and factors determining the reporting rates" revealed that the healthcare providers were characterized by limited pharmacovigilance knowledge leading to underreporting [6, 7, 10, 4, 13].

The previous study conducted in Rwanda found that 81 (62.3%) respondents had inadequate practice in monitoring adverse drug reactions. Having heard about pharmacovigilance (p=0.004) and being aware of the ADR reporting system in the hospital had a statistically significant association with the practice of nurses and midwives toward monitoring adverse drug reactions (p=0.005)[14]. Therefore, this study aimed to improve knowledge, attitude, practice, and reporting of adverse drug reactions among healthcare professionals at CHUK.

METHODS

Study design and setting

We used a one-group pretest-posttest design to compare the knowledge, attitude, and practice (KAP) of pharmacovigilance among healthcare professionals before and after an educational intervention (EI). This design represents a quasi-experimental approach where the focus is on measuring the outcome of interest within a single non-random group of participants both before and after the administration of an intervention. In our study, we're particularly focused on KAP as the outcome of interest, with healthcare professionals being the specific group under observation, and the intervention being EI [15].

Figure 1 illustrates the procedural steps followed in conducting this study. Initially, we measured the knowledge, attitudes, and practices (KAP) concerning pharmacovigilance and adverse drug reaction (ADR) reporting among healthcare professionals in January 2022. Subsequently, we developed an educational intervention (EI) and implemented it starting on February 4, 2022. Finally, we assessed the KAP post-intervention in February 2023. The study was conducted at the

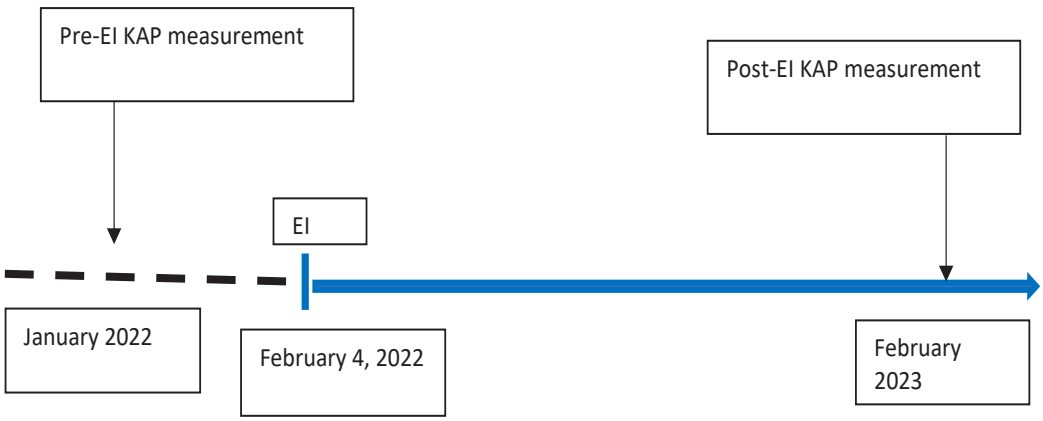

Figure 1: One-group pretest-posttest design used to study the effect of an EI on the KAP concerning PV and ADR reporting among healthcare professionals.

University Teaching Hospital of Kigali, which is popularly known as CHUK, the French acronym of "Centre Hospitalier Universitaire de Kigali." The CHUK was awarded the status of a university teaching hospital on 7/12/2000 by law No: 41/2000, and it has a capacity of 519 beds. CHUK, the largest hospital in Rwanda, is situated at KN 4 Ave, Kigali City. It provides tertiary healthcare to the population, training, clinical research, and technical support to district hospitals. The hospital provides numerous services to diagnose and treat clients without excluding preventive and checkup services. Both inpatient and outpatient services are available.

Study population, sample, and sampling

The study involved the healthcare professionals (HCPs) who provide direct healthcare services to the patients.This study included HCPs involved in the medication administration process: prescribing, dispensing, administering, and monitoring medications or medical products. For this study, HCPs, including physicians, nurses, midwives, and pharmacists, are involved in the medication administration process. We excluded the HCPs who mainly work in administration and have very limited time or no time to care for patients. The sample size for this study was 217 HCPs, calculated using the Yamane formula 1976. The sample size estimated using the Yamane formula 1976 assumed that the confidence level is 95% and the acceptable margin error is 0.05.

$$n = \frac{N}{1 + N(e)^2}$$

n= sample size, e= margin error. N= population

A convenience sampling method was used to get study participants.

Data collection tool and procedure

We collected data using a self-administered questionnaire initially developed by [2] and modified it to fit our context. The questionnaire was used before and after the EI to measure KAP concerning PV and ADR reporting among HCPs.

The questionnaire comprised three sections. Section A was composed of five items that explored demographic and related information of HCPs: professional status, age, gender, working experience, and educational qualifications. Section B comprised sixteen items to evaluate HCPs' KAP regarding PV and ADR reporting. The last section, section C, comprised one question to choose one barrier discouraging the HCPs from reporting ADRs. In addition to these questions, we added three questions to evaluate the confidence of participants in monitoring and reporting ADRs and the availability of ADR reporting forms after the intervention in section C. All questions were in multiple-choice question format, except two questions asking age and years of experience, which were open questions. Each participant was requested to choose the right answer applied to him or her. For knowledge questions, each question had one correct answer. For the attitude questions, each one had one option indicating a positive attitude; for the questions related to practice, each question had one option to indicate good practices. Additionally, to understand the real practices of HCPs, we reviewed the number

of drug adverse events reported to the quality assurance directorate before and after EI. The researchers collected data for themselves. The researchers collected pre-EI data in January 2022 and post-EI data in February 2023.

We utilized a self-administered questionnaire initially developed by [2], which we adapted to suit our specific context. This questionnaire was administered both before and after the EI to assess KAP regarding PV and ADR reporting among HCPs. The questionnaire encompassed three sections. Section A delved into demographic information, exploring five key aspects of HCPs' background: professional status, age, gender, work experience, and educational qualifications. Section B comprised sixteen items aimed at evaluating HCPs' KAP concerning PV and ADR reporting. Section C consisted of a single question prompting HCPs to choose a barrier discouraging them from reporting ADRs. Additionally, we included three supplementary questions in section C post-intervention to gauge participants' confidence levels in monitoring and reporting ADRs, as well as the availability of ADR reporting forms.

All questions were in a multiple-choice format except for two open-ended questions soliciting information about age and years of experience. Participants were requested to select the most applicable answer for each question. Correct answers were provided for knowledge-based questions, while attitude-based questions featured options indicative of a positive attitude. Practice-related questions offered choices reflecting good practices. To gain insights into the actual practices of HCPs, we conducted a review of drug adverse events reported to the quality assurance directorate before and after the EI. The researchers themselves collected data, gathering pre-EI information in January 2022 and post-EI data in February 2023.

The researchers distributed questionnaires to 217 HCPs before the EI. They gave them time to complete the questionnaires, and the researchers were in the unit to collect the completed questionnaires and attend to any questions related to the research. They collected data on weekdays from 7:00 AM to 5:00 PM. The questionnaires completed after the researchers left the unit were kept in the office of the unit managers and collected later by the researchers. The participants were instructed to complete the questionnaires in their free time to avoid compromising patient care. The average time to complete one questionnaire was 15 minutes. After the intervention, we also used the same sampling strategy and included 217 participants. We also used the same method for data collection.

Educational intervention: Training on PV and ADRs

In this study, the EI was a training on PV and ADR reporting. In collaboration with the Rwanda Food and Drugs Authority (Rwanda FDA) team, the researchers developed a training manual for PV and ADRs reporting. This manual served as the instructional material for training HCPs and was crafted in adherence to the Rwanda FDA guidelines. The content of the training manual was developed in accordance with our hospital's objective to identify and report the ADRS early, which is aligned with the guidelines of the Rwanda FDA [16]. We employed various teaching aids such as the training manual, PowerPoint presentations, and ADR reporting forms during the instruction. Our training approach included lectures, small group discussions, and interactive question-and-answer sessions. Following the training on fundamental knowledge and skills pertinent to PV and ADRs, emphasizing their roles in identifying and reporting ADRs, we engaged participants in practical exercises. These exercises involved case scenarios and the completion of ADR reporting forms to simulate the ADR reporting process. The entire training session spanned three hours. This training was provided by the PV team from Rwanda FDA and a senior hospital pharmacist on February 4, 2022.

We purposely selected 40 participants for the initial training due to budget constraints. These individuals were chosen for their potential to impact practice within their respective units. Most of the selected participants held formal leadership roles, while others held informal leadership positions within their departments or at the hospital level. Termed as 'champions,' we entrusted these individuals with the responsibility of training their peers. At the conclusion of the training, we distributed ADR reporting forms to each participant, encouraging them to report any ADRs they encountered. Additionally, we provided them with comprehensive training materials to facilitate in-service training within their units. We also guided them in requesting and obtaining new ADR reporting forms from the hospital for

use in their respective units. We requested that they formulate a plan for in-service training for their colleagues within their departments and committed to following up to monitor the implementation of this training. This implies that the subsequent training was conducted through in-service training sessions led by the appointed champions.

Data analysis

We entered data in Microsoft Excel (Publisher: Microsoft Corporation, Redmond, Washington, USA, 2016), and then we imported the data from Excel to Statistical Package for the Social Sciences Statistics (SPSS) for Windows, Version 25.0. for analysis. We used descriptive statistics for demographic characteristics and KAP variables, employing the Chi-square and Fisher Exact test when appropriate to compare the response before and after the intervention. We compared the proportions of participants who provided favorable responses to each question regarding the KAP of HCPs toward PV and ADR reporting before and after the EI. We utilized the Chi-square and Fisher Exact tests as appropriate to compare before and after the intervention, not the McNamara test, because we did not match the pretest and posttest responses to have paired data. A p-value of less than 0.05 was considered statistically significant. We used the figure in Excel to plot monthly reported ADRS and paired t-tests to compare monthly reported ADRs one year before and after EI.

This study has been approved by the Research Ethics Committee of CHUK (Review Approval Notice Ref. N° EC/CHUK/114/2021. Prior to obtaining the participant's consent, each participant was offered enough explanations about the purpose and process of the study. Moreover, the participant was given time to ask questions of clarification regarding the research and its process in the letter of information; after that, each participant signed a consent form. The researchers have emphasized the participant's right to withdraw from this study without any negative impact on his/her employment at CHUK or elsewhere he/she may want to go. Additionally, the participant has ensured anonymity and confidentiality throughout the study by maintaining anonymity in the questionnaire, storing completed questionnaires and informed consent forms in a locked cupboard accessible only by the research team, securing data files with a computer password, and reporting the results as aggregated data without identifiers.

RESULTS

A total of 217 HCPs were selected to participate in the pre-EI study, of which 189 HCPs completed and returned the filled questionnaire, equivalent to a response rate of 87.1%. After training, we also contacted 217 HCPs, and 146 out of 217 HCPs returned the completed questionnaires, equal to the response rate of 67.3%.

Table 1 shows the demographic characteristics of the participants before and after training. The results show their characteristics are similar before and after training (P>0.05). Most of the respondents in the study were nurses (n=284, 84.8%), aged 30-39 years old (n=150, 44.8%), female (n=285, 85.1%), with bachelor's degree (n=209, 62.4%) and with working experience of 10-14 years (n=164, 49.0).

Table 2 shows the percentage of the participants who responded favorably to questions. The KAP of HCPs toward pharmacovigilance and adverse drug reaction reporting pre- and post-educational intervention. Significant improvements in knowledge about pharmacovigilance and adverse drug reaction reporting were observed before and after the intervention. The percentage of participants who understood the purpose of pharmacovigilance increased from 61.9% to 78.8% (p=0.001), and awareness of the existence of national pharmacovigilance in Rwanda surged from 38.1% to 96.6% (p<0.001). Similarly, the proportion of participants familiar with the clinical trial phase for identifying rare ADRs increased from 41.8% to 75.3% (p<0.001). Additionally, knowledge regarding the most common method used by HCPs to monitor ADRs of new drugs post-launch increased from 60.9% to 79.5% (p<0.001), while awareness of the hospital's ADR reporting system grew from 62.4% to 69.9% (p=0.002).

In terms of the attitudes of HCPs toward pharmacovigilance and adverse drug reaction reporting, significant differences were noted before and after the intervention. The proportion of HCPs capable of categorizing an event as serious increased from 59.8% to 79.5% (p<0.001), and those knowledgeable about what specific aspects

Table 1: Demographic participants' characteristics pre- and post-education intervention

Characteristics	Pre-intervention (n=189)	Post-intervention (n=146)	p-value
Profession, n (%)			
Medical doctor	8(4.2)	5(3.4)	
Nurse	160(84.7)	124(84.9)	0.97
Midwife	17(9)	13(8.9)	
Pharmacist	4(2.1)	4(2.7)	
Age, n (%)			
20-29years	46(24.3)	32(21.9)	
30-39years	85(45)	65(44.5)	
40-49years	43(22.8)	36(24.7)	0.93
50- 59 years	15(7.9)	13(8.9)	
Gender, n (%)			
Male	29(15.3)	21(14.4)	
Female	160(84.7)	125(85.6)	0.81
Education, n (%)			
Advanced diploma	23(14.2)	17(11.6)	
Bachelor	118(62.2)	91(62.3)	
Masters	48(25.4)	38(26)	0.98
Experience, n (%)			
5-9years	70(37)	61(41.8)	
10-14years	96(50.8)	68(46.6)	
15-19years	11(5.8)	13(8.9)	0.25
20 and above	12(6.3)	4(2.7)	

of reporting about ADRs increased from 50.8% to 69.2% (p=0.001). Additionally, a significant change in practice regarding PV and ADR reporting after the educational intervention was primarily observed in the number of participants reporting having free access to the ADR reporting form, which increased from 58.7% to 82.2% (p<0.001).

However, we did not observe significant changes in the knowledge of HCPs, particularly in their awareness of the regulatory body responsible for monitoring ADRs in Rwanda (61.9% vs. 71.2%, p=0.07), the correct time to notify a serious adverse event to the regulatory body in Rwanda (70.9% vs. 80.1%, p=0.05), and their awareness of the pharmacovigilance committee in their hospital remained stable (63.0% vs. 61.0%, p=0.94). Similarly, no significant changes were observed in the attitudes of HCPs before and after the intervention, particularly in their beliefs regarding the consideration of ADR reporting as their professional obligation (60.9% vs. 69.2%, p=0.11), their beliefs about the establishment of an ADR monitoring center in every hospital (91.5% vs. 92.5%, p=0.76), and their beliefs about the importance of pharmacovigilance for in-patient safety (95.8% vs. 94.5%, p=0.60). Furthermore, no significant changes were noted in the practices of HCPs regarding the observation of ADRs in patients during their professional practice before and after the intervention (81.3% vs. 83.6%, p=0.90), as well as in reporting ADRs to the pharmacovigilance center/unit either at the hospital or national level before and after the intervention (45.5% vs. 46.6%, p=0.85).

Table 3 shows the self-reported factors discouraging healthcare professionals from

Table 2: Knowledge, attitude, and practice of health care professionals toward pharmacovigilance and adverse drug reaction reporting pre- and post-educational intervention

	Pre-EI (n=189)	Post-EI (n=146)	p-value
Knowledge (correct response), n (%)			
The most important purpose of pharmacovigilance is:	117(61.9)	115 (78.8)	0.001
Do you know that a National Pharmacovigilance program exists in Rwanda?	72(38.1)	141(96.6)	<0.001
In Rwanda, which regulatory body is responsible for monitoring ADRs?	117 (61.9)	104 (71.2)	0.07
A serious adverse event in Rwanda should be notified to the regulatory body within:	134 (70.9)	117 (80.1)	0.05
Rare ADRs can be identified in which of the following clinical trial phases?	79 (41.8)	110 (75.3)	<0.001
Which of the following methods is commonly employed by HCPs to monitor ADRs of new drugs once launched in the market?	115 (60.9)	116 (79.5)	<0.001
Is there any committee responsible for pharmacovigilance in your hospital?	119 (63.0)	89 (61.0)	0.94
Are you aware of the adverse drug reaction reporting system in your hospital?	118 (62.4)	102 (69.9)	0.002
Attitude (responses indicating positive), n (%)			
Is ADR reporting your professional obligation?	115 (60.9)	101 (69.2)	0.11
When do you consider an event to be serious?	113 (59.8)	116 (79.5)	<0.001
What is your opinion about establishing an ADR monitoring center in every hospital**?**	173 (91.5)	135 (92.5)	0.76
What should a healthcare professional report?	96 (50.8)	101 (69.2)	0.001
Do you think that pharmacovigilance is important for in-patient safety?	181 (95.8)	138 (94.5)	0.60
Practices (yes response), n (%)			
Have you ever observed ADRs in your patient during your professional practice?	157 (83.1)	122 (83.6)	0.90
Have you ever reported ADR to the Pharmacovigilance center or unit at the hospital or the national level?	86 (45.5)	68 (46.6)	0.85
Do you have free access to the ADR reporting form?	111 (58.7)	120 (82.2)	<0.001

Table 3: Self-reported factors discouraging ADR reporting among healthcare professionals

	Pre-intervention (n=189)	Post-intervention (n=146)	p-value
No remuneration	48 (25.4)	25 (17.1)	0.002
Lack of time to report ADRs	77 (40.7)	90 (61.6)	
A single unreported case may not affect the ADR database	17(9.0)	9 (6.2)	
Difficult to decide whether ADR has occurred or not	47(24.9)	22 (15.1)	

reporting ADRs before and after the intervention. Before the intervention, the lack of time to report ADRs and remuneration were the most common barriers to reporting ADRs, with 40.7% and 25.4%, respectively. These barriers continued to be the most prevalent, but the lack of time to report ADRs became the most dominant, with 61.6% of all barriers (p=0.002).

Table 4 shows the evaluation of the impact of educational intervention on participants. After the intervention, participants were asked to assess their overall confidence in monitoring and reporting ADRs, as well as the availability of appropriate reporting forms in the unit compared to before the intervention. Most participants expressed heightened confidence levels, with 80.1% feeling very confident in monitoring adverse drug reactions and 78.8% feeling the same about reporting adverse drug reactions, compared to the pre-intervention phase. Moreover, the availability of appropriate forms for reporting adverse drug reactions also saw improvement, with 38.4% of participants reporting a much better availability post-intervention.

Figure 1 compares the numbers of adverse drug

Table 4: Evaluation of the impact of educational intervention on participants

Question	n(%)
Confidence in monitoring adverse drug reactions compared to prior training about pharmacovigilance	
Not very confident	12(8.2)
Neither	2(1.4)
Fairly confident	15(10.3)
Very confident	117(80.1)
Confidence in reporting adverse drug reactions compared to prior training about pharmacovigilance	
Not very confident	18(12.3)
Fairly confident	13(8.9)
Very confident	115(78.8)
Availability of appropriate forms for reporting adverse drug reactions after training	
About the same	35(24.0)
Somewhat better	55(37.7)
Much better	56(38.4)

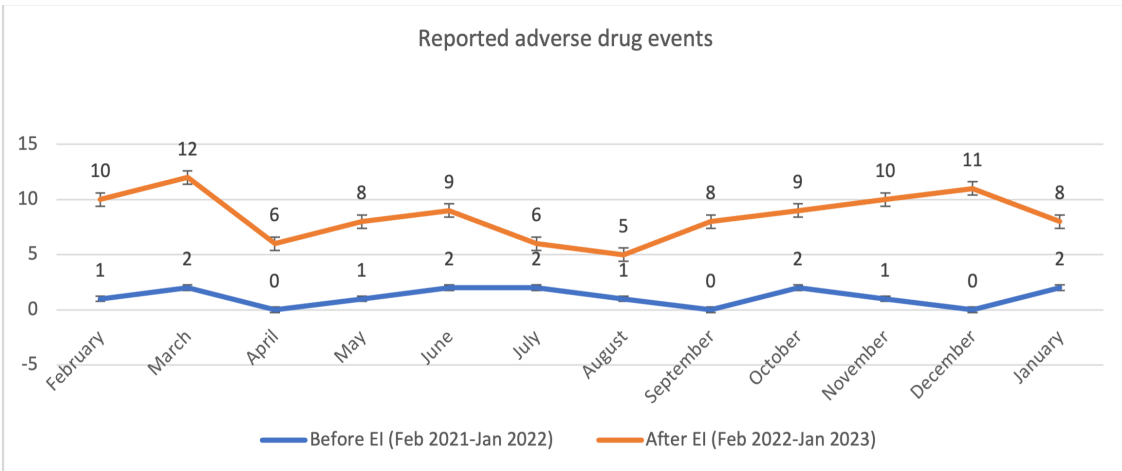

Figure 1. Comparison of adverse drug reactions reported one year before and one year after EI.

events reported one year before and one year after the intervention. Before the intervention (February 2021 to January 2022), the reported number of adverse drug events varied between 0 and 2 events per month. However, after the intervention (February 2022 to January 2023), the reported number of adverse drug events ranged between 5 and 12 events per month. Using the paired t-test to compare the number of adverse drug events reported before and after the intervention, results indicated a significant increase in reported ADRs after the intervention (p<0.001).

DISCUSSION

The present questionnaire-based pre-post intervention cross-sectional study was conducted at CHUK to assess the impact of educational training on HCPs' knowledge, attitude, and practice towards PV and ADRs reporting. Additionally, this study also compared the ADRs reported one year before and after EI. Several studies have been conducted to assess HCPs' knowledge, attitude, and practice towards PV and ADRs reporting [6, 7, 11, 16]. These studies evaluated knowledge and attitude without any kind of educational intervention. However, only very few limited studies [3, 5, 16] have assessed PV knowledge after educational intervention among HCPs. This is the first study to assess the impact of education intervention on PV and ADRs reporting at CHUK.

The current study showed that females participated more than males. These findings were similar to those of studies conducted at different hospitals in Nepal. Most of the participants in this study were nurses and staff nurses. The reason for the increase in female staff nurses and nurses is probably due to the preference of females to choose nursing as their career compared to males [2, 4, 9].

Most participants, 90 (61.6%) of the present study, responded that lack of time is the most important factor discouraging HCPs from reporting ADRs. Other studies conducted in Nepal also reported a similar factor in the present study [6, 7, 11, 16]. In this study, educational intervention was the key component for improving HCPs' knowledge, attitude, practice, and ADRs reporting.

A significant difference (p < 0.001) was found in some knowledge questions between pre- and post-educational intervention. Likewise, a significant difference (p < 0.001) was found in some attitude questions between pre- and post-educational intervention. Similarly, a study conducted in Pokhara, Nepal, demonstrated that knowledge and attitude scores of HCPs increased significantly to 72 (8), 75 (11.5), and 146 (16.5) (p<0.001).[3,17] Another similar study revealed that the knowledge score was significantly increased from [mean ± SD (Ranges)] [6.90 ± 2.527 (1- 12)] to [11.36±1.189 (6-12)] after an intervention. The attitude score was also significantly increased from [5.56±1.616 (4-10)] to a [6.97±1.793 (4-12)]. After an intervention, knowledge, and attitude scores were increased following an educational intervention[19].The results from a study in Saudi Arabia showed a significant improvement in healthcare providers' knowledge scores immediately after conducting an intervention (workshop).

Regarding the HCPs practice, A significant difference (p < 0.001) was found in some practice questions between pre- and post-educational intervention. Previous literature has shown that educational intervention in healthcare professionals significantly increases the KAP of PV [19]. These findings are similar to findings from studies conducted [3, 17,18]. EI also significantly changed the practice of respondents.

Our study findings revealed that there is an improvement in ADRs reporting as 14 ADRs were reported within one year of 2021 before EI, while 104 ADRs were reported to the quality assurance office within one year of 2022 post-EI EI improved ADR reporting by HCPs at CHUK. This was similar to the study conducted and demonstrated an increase in the number of ADRs reports noted in the intervention group (74 times higher than in the control group) during the intervention period, which was gradually decreased as the study progressed (adjusted OR = 74.1, 95% CI = 21.11–260.1, p<0.001)[21]It was also in line with the study conducted in Germany which revealed that an initial 148% increase (P = 0.001) in the number of ADR reports was observed after the educational intervention. Compared to baseline, the postinterventional number of ADR reporting was statistically significantly higher (P < 0.005) through the first 16 months after the intervention but not significant in the last 4-month period (median: 8.00 (IQR [2.75; 8.75]; P = 0.605)[21].

To the best of our knowledge, this is the only study that was carried out in one tertiary hospital in Rwanda to improve HCPs' knowledge, attitude,

practice, and ADR reporting. This study was conducted in a natural working environment without manipulation to accommodate the intervention. Still, some limitations might compromise the study findings' internal and external validity (i.e., generalizability). This study was a quasi-experimental design. We did not use the control group, and we did not control the confounders. Therefore, we cannot conclude that our intervention caused the change observed. We also used a similar questionnaire for self-reporting before and after the intervention, which is associated with self-reporting bias and testing threat to the study's internal validity.

Moreover, the sample size was small, so the findings may only apply to the study setting. We did not also control the intervention fidelity, which may indicate the variability in intervention among the participants because we trained the champions to train the rest of their colleagues, which was our best strategy to reach as many healthcare providers as possible with our constraints of the budget. However, we observed an increase in the number of ADRs reported to the hospital, which indicates an impact of the intervention in our hospital. We must still reach more healthcare professionals in our hospitals to maximize the chance of reporting the ADRs since this study showed that, in general, 83.3% of health professionals had ever observed the ADRs. Still, only 46.0% reported ADRs to the appropriate unit.

CONCLUSION

This study demonstrates the effectiveness of EI in enhancing HCPs' KAPs regarding pharmacovigilance and adverse drug reaction reporting. The intervention notably improved knowledge in crucial areas, leading to increased confidence and more frequent reporting of ADRs. Despite these positive improvements, persistent challenges remain, including time constraints and lack of remuneration, hindering optimal ADR reporting. While attitudes showed improvements in some respects, certain beliefs and practices remained unchanged.

The substantial rise in reported drug adverse events to the quality assurance office post-intervention highlights the tangible impact of education on actual reporting practices. This increase validates the importance of tailored interventions in driving meaningful changes in HCPs' behaviors. Sustained efforts are crucial to address persistent barriers and further enhance HCPs' attitudes and practices toward ADR reporting. Targeted strategies, including incentivization and streamlining reporting processes, could increase the positive changes observed. Moreover, continuous training (CPDs) and support systems should be in place to ensure the longevity of these improvements. These initiatives will ensure patient safety and foster a culture of proactive reporting and continuous improvement within healthcare settings.

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