ORIGINAL RESEARCH

Impact of in-service training on the knowledge, attitude, and practice of pharmacovigilance in Malawi: a cross-sectional mixed methods study

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Abstract

Background

Spontaneous reporting of adverse drug reaction (ADRs) is low in Malawi. We assessed the impact of training intervention on knowledge, attitudes, and practices of health care professionals (HCPs) in pharmacovigilance (PV).

Methods

We employed a mixed-methods study design. A questionnaire was administered among HCPs who were trained in PV, followed by face-face interviews. We further extracted individual case safety reports which were submitted to the local databasewithin a period of six months prior and after the PV training. Quantitative data was analyzed using STATA 14.1. Paired t-test was used to assess the differences in PV knowledge among HCPs before and after the training. For qualitative data, we manually derived key themes from the participant's responses.

Results

Overall, the mean knowledge score was significantly improved across all the participants from a mean of 56% (95% CI 53% to 58%) to 66% (95% CI 64% to 69%) after the training, p< 0.001. There was a 2.8-fold increase in the number of participants who were able to detect an ADR after the training and a 1.8-fold increase in the percentage of reporting the detected ADRs after the training. Participants expressed preference of a paper-based reporting system to other reporting tools. However, they outlined several challenges to the system which discourages HCPs from reporting ADRs, such as lack of feedback, unavailability of reporting forms and delay to transmit data to the national centre.

Conclusion

The survey found that in-service training for HCPs improves KAP of PV and reporting rates of ADRs. We recommend widening of the training and introducing PV courses in undergraduate programs for health care workers in Malawi.

Keywords: Pharmacovigilance, Adverse drug reactions (ADRs), ADR reporting tools, Knowledge, Attitudes and Practices (KAP)

Introduction

The World Health Organization (WHO) defines *pharmacovigilance (PV) as the 'science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems'*[1]. A strong and effective PV system is essential for ongoing monitoring of the safety of medicines. Safety surveillance starts from the early stages of drug development. However, clinical trials are not adequate to detect all possible harm from medication as they are conducted on a small group of less diverse and closely monitored subjects for a short duration[2]. Adverse drug effects have a negative impact on the patients as they contribute to patient morbidity and mortality, loss of confidence in Health Care Professionals (HCPs), and increased health costs[3]. Efforts to increase access to medicines in low- and middle-income countries and the development of new medicines and vaccines such as the COVID-19 vaccine require that sufficient measures are put in place to ensure systematic safety monitoring of the products. Even though medicine safety data may be available from other developed countries, it is essential for every country to have its own functional and reliable PV system as there is a significant variation in the occurrence of ADRs due to differences such as among others, disease burden, health care practices and genetics[4,5].

Spontaneous reporting of ADRs is a key strategy for national PV centres by providing real-life safety information about locally used medicines[6]. However, lack of awareness and knowledge on what and how to report, remains one of the important problems leading to under-reporting of suspected ADRs globally[7,8]. Raising awareness among health care professionals (HCPs) is therefore a key to the success of any spontaneous reporting scheme[9]. Alongside the training, it is also important to improve the reporting systems by using appropriate and readily accessible tools that enable HCPs to submit reports in a manner which is easier and more convenient to them can help to address some of the challenges of ADR under-reporting[8,10].

In Malawi, PV is a relatively new and still developing. Located in central Africa, Malawi is one of the low- income countries with high burden of infectious diseases such as Malaria and

Table 1 Characteristics of survey participants

Variable	Characteristic	Frequency	Percentage (%)
Gender	Male	45	50.56
	Female	44	49.44
Age (years)	19 to 30	29	32.95
	31 to 45	43	48.86
	46 and above	16	18.18
Profession	Pharmacy personnel	5	5.62
	Clinicians	23	25.84
	Nurses	39	43.82
	Laboratory personnel	3	3.37
	Health surveillance assistants	1	1.12
	Others	18	20.22
Qualification	MSCE	3	3.37
	Certificate	15	16.85
	Diploma	44	49.44
	Degree	22	24.72
	Specialized degree	5	5.62
Years of experience	1 year or less	3	3.37
	2 to 5 years	42	47.19
	6 to 10 years	3	3.37
	11 to 20 years	18	20.22
	21 years and more	23	25.84

HIV/AIDS and critical shortage of healthcare professionals. As of 2019, the physicians and nursing personnel density was at 0.019 and 0.283 (per 1000 population) respectively[11,12]. Basic PV activities in Malawi started in 2015 which included setting up of the PV center at Kamuzu University of Health Sciences (formerly College of Medicine of the University of Malawi) with support from GIZ, CDC and GSK. Through the support from these partners, awareness campaigns among HCPs were done in some parts of the country and by the year 2018, the number of reports significantly increased to up to more than 200 reports being entered into the VigiFlow, thereby enabling the country to attain full membership of the WHO- PIDM in 2019[13]. Despite such a tremendous achievement, PV activities are still facing challenges as evidenced by the low rates of ADR detection and reporting. Among these challenges, are lack of trained personnel in PV especially in hospitals, heavy work burden due to high patient to health care personnel ratio, which renders most health care providers consider PV as not essential part for daily practice, insufficient funding to promote PV activities and lack of modern, effective and convenient methods or technologies for reporting adverse events[4,14].

As pharmacovigilance is not yet incorporated into the curricula of most of healthcare professional training in Malawi, the Pharmacy and Medicines Regulatory Authority (PMRA) conducted in-service pharmacovigilance training to healthcare workers in district hospitals. A total of 391 healthcare workers were trained in 27 districts. The training was both theory and practical-based and focused on equipping the HCPs including pharmacists, doctors, nurses, laboratory scientists and Health Surveillance Assistants (HSAs) with knowledge and skills for the detection and reporting of

suspected (ADRs) and Adverse Events Following Immunization (AEFIs). HSAs in Malawi are semi-skilled community health care workers who provide primary health services such as vaccination, HIV testing and counselling in remote areas where there is critical shortage of well-trained health professionals[15,16]. Participants were also oriented to the history of pharmacovigilance and the National Pharmacovigilance System in Malawi. This survey was therefore conducted to assess the impact of the training programs on the knowledge, attitude and practice (KAP) of health care professions and ADR reporting rates, to inform future trainings and other strategies for improving PV outcomes.

Methodology

Study design and setting

We employed a mixed-methods cross sectional study design. The study was conducted in August 2021 in Rumphi, Mzimba, Lilongwe, Ntcheu, Zomba, Mangochi, Blantyre and Nsanje districts.. The study districts represented two districts from each region (North, Central, South and Eastern) and were randomly selected using the RAND function in Microsoft Excel 2019 version. This represented 30% (8/27) of the districts where the PV training was conducted.

Study Population and sample size

We targeted health care professionals who participated in the PV trainings that were conducted by PMRA in December 2020. A total of 120 health professionals were trained in the eight study districts (15 per district). As the number of eligible participants was small, we targeted to collect quantitative data from all the training participants who were available during data collection. The total number of participants included in the qualitative interviews was based on data saturation.

Data Collection

Prior to the training in December 2020, facilitators administered a questionnaire to all training attendees. The questionnaire was systematically designed to assess baseline KAP for the HCPs before the training. In the reported survey, we administered a similar questionnaire to assess KAP of PV among the participants in August 2021, which was about eight months after the training. Individual case safety reports submitted to the local database for a period of six months prior and after the trainings were extracted from the PMRA local database. Furthermore, a semi-structured face-face interview was conducted to explore the usability and preferences of ADR reporting tools among participants. We firstly pre-tested the interview guide in four participants before reaching out to the rest of the participants.

Data analysis

Quantitative data was entered in Microsoft Excel version 2019 and analyzed using STATA version 14.1.

We used frequencies and percentages to describe participant's demographics and responses to the questionnaire.

Paired t-test was applied to assess for improvement in PV knowledge after the training. A significant improvement in knowledge was determined if p value was < 0.05. Qualitative data was transcribed soon after conducting interviews. To minimize bias, two investigators independently read the transcripts repeatedly for familiarization and analyzed the data. Key themes were derived manually from the participant's responses.

Results

Characteristics of study participants

A total of 120 HCPs attended the PV training. Among them 74% (n=89) of which 51 % were male and 49% were female, participated in this survey (Table 1). The number of participants per district ranged from 8 to 14. The majority were nurses by profession (43.8%, n=39), followed by clinicians (25.8%, n= 23), and pharmacy personnel (5.6%, n=5). In terms of qualification, most of the participants were diploma holders (49.4%, n=44), followed by degree holders (24.7%, n=22), and certificate holders (16.9%, n=15). Most of these participants had 2- 5 years of experience (47.2%, n= 42) and were aged between 31 and 45 years (48.9%, n=43).

PV Knowledge

A set of 20 key questions was used to assess participants' knowledge in different PV areas including basic definitions, key stakeholders in PV, ADR classifications, what and how to report ADRs. Participants' knowledge was evaluated using percentage scores of the correct answers provided by the participants. Overall, the knowledge score was significantly improved across the participants from a mean of 56% (95% CI 53% to 58%) to 66% (95% CI 64% to 69%), p< 0.001. As shown in Table 2, the improvement in PV knowledge after the training was affected by age and level of education. Participants' age groups below 45 years old showed a significant improvement in PV knowledge after the training, p<0.001 while those above 45 years old did not show significant knowledge improvement, p < 0.152. In terms of level of education, those with lower qualifications (MSCE and professional certificates) had poor PV knowledge improvement (p<0.096 and 0.135 respectively), while those with at least a diploma (p<0.001), first degree (p<0.006) or specialized degree (p<0.001) showed significant improvements in the PV knowledge.

Attitude towards PV

Health care professionals' attitudes towards ADR reporting was assessed by asking their views about the characteristics of ADRs which they deem as reportable and their perception on the usefulness of the available tools for ADR reporting. Less than 50% of the participants responded to questions for this section. Before the training, 23 participants were of the view that a case should be reported when it is new or serious ADR while one indicated that they would be motivated to report if the reporting tool was easy. After the training, we noted an increase in the number of those who responded that they would report a new and serious ADR by 3.7-fold (n=85) while those who said that they would report an ADR if the reporting tool was easy increased to 25 (Figure 1).

Table 2 Mean knowledge scores for various characteristics of study participants before and after PV training

| Variable	Characteristic	Pre-training knowledge		Post training Knowledge		
		Mean score	Std. Dev	Mean score	Std. Dev.	P Value
Age	19 to 30	0.5448	0.1339	0.7107	0.1244	<0.000
	31 to 45	0.5674	0.1154	0.6723	0.1161	0.001
	46 and above	0.5438	0.1276	0.5813	0.1504	0.152
Gender	Male	0.5478	0.1082	0.684	0.1008	<0.000
	Female	0.5682	0.139	0.6441	0.1646	0.007
Education	High School Certificate	0.5667	0.0764	0.6833	0.0577	0.096
	Professional Certificate	0.5333	0.1175	0.5887	0.1907	0.135
	Diploma	0.5409	0.1226	0.6589	0.1157	<0.001
	Bachelor's degree	0.5864	0.1416	0.6977	0.1324	0.006
	Specialized degree	0.65	0	0.78	0.0447	0.001
Profession	Pharmacy	0.58	0.1151	0.75	0.0866	0.024
	Clinicians	0.5674	0.1221	0.6674	0.1416	0.010
	Nurses	0.5679	0.134	0.6572	0.1402	<0.001
	Laboratory	0.5667	0.0764	0.65	0.1	0.099
	Others	0.525	0.111	0.6541	0.1354	0.002
Years of experience	≤1	0.4833	0.1258	0.6867	0.1097	0.092
	2 to 5	0.5452	0.1324	0.6721	0.1259	<0.001
	6 to 10	0.5667	0.0289	0.6667	0.1041	0.092
	11 to 20	0.5639	0.1359	0.695	0.1461	0.001
	≥20	0.5848	0.106	0.6226	0.1549	0.147
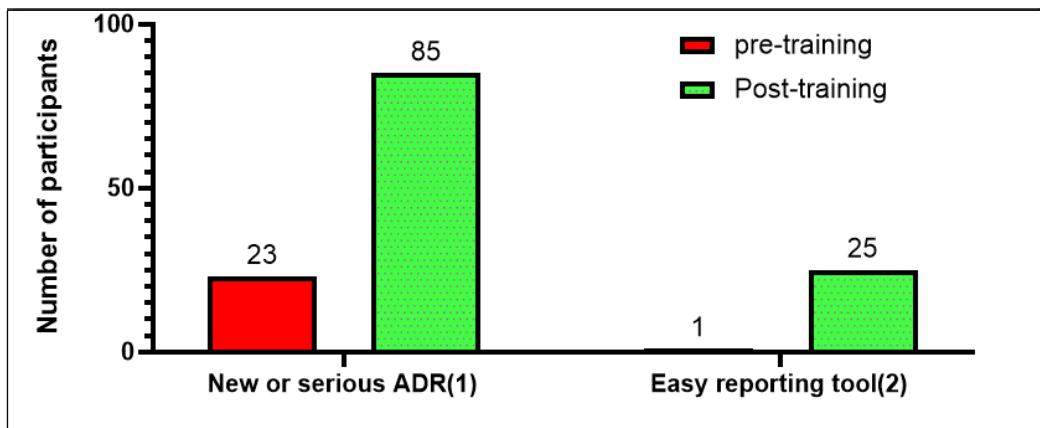
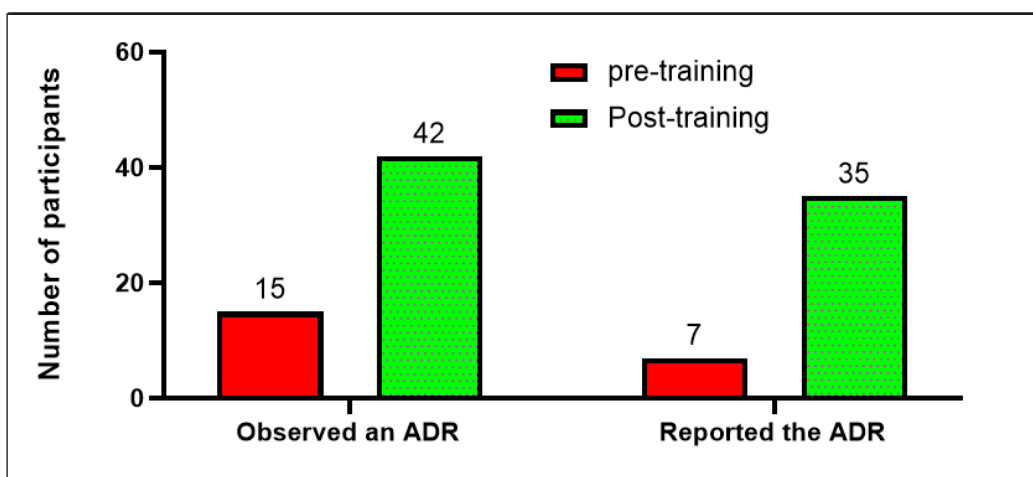**Fig 1: Circumstances that participants are mostly likely to report an ADR**

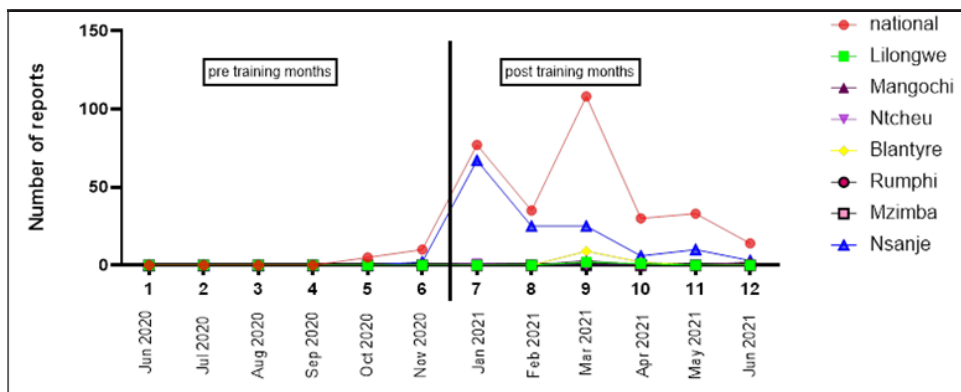**Fig 2: Ability to detect and report to ADRs**

Fig 3: ADR reporting rates before and after training

Practice

Figure 2 shows the Participants' ability to detect and report an ADR to PMRA. Before the PV trainings, 15 HCPs were able to detect ADR in clinical practice and seven of them reported the ADR representing a reporting rate of 47% of the detected ADRs. After the training, 42 participants were able to detect an ADR and 35 of them (83%) reported the ADR to the national centre. Thus, we found a 2.8-fold increase in the number of participants who were able to detect an ADR and 1.8-fold increase in the percentage of reporting the detected ADRs after the training.

ADR reporting rates

ADR reports were quantified for the period of June 2020 to June 2021. The reports for December 2020 were not included in the analysis as these were done while the training was still

being conducted. Before the training, the number of reports were as low as zero for the months of June to September 2020. There was a dramatic increase in the number of ADR reports from January 2021(Figure 3). Highest number of reports was achieved in the months of March in which up to 108 ADR cases were reported national wide. However, this increase was not stable over the whole six-month post training duration as there were fluctuations in the number of reports between January and march (77 reports in January, 35 in February and 108 in March), followed by a gradual decrease in the reporting rate after April (from 30 to14 reports as of June 2021). Amongst the study districts, Nsanje reported the highest number of reports, contributing to more than 50% of the national reports.

Participants' opinion on PV reporting systems

All the 89 training participants were eligible for the semi-structured face-face interviews. However, due to data saturation, only 72 participants were interviewed. Key themes were summarized based on the preferences on reporting tools, suggested measures for improving PV systems and preferred motivational strategies to encourage reporting of ADRs by HCPs. Most HCPs expressed preference of paper reporting system to other tools. This was based on the opinion that the tool was the easiest to fill out the required information and sending the report to the national PV centre. Furthermore, some participants felt that it was more secure.

"The [paper-based] form is very easy for me. It's very easy to fill because they included all the important sections on the form and it doesn't need much [resources]" Participant #4

Challenges faced during ADR reporting

However, they also highlighted several challenges faced by the paper-based system. These included lack of reporting forms in some facilities, delays in sending the forms to the national PV center and lack of feedback. Some participants who had reported before expressed no further interest in reporting another ADR in future as they felt like they were not appreciated for their efforts or were not sure if their previous reports had reached the national PV center.

"I have no interest in sending another ADR report because nothing is done after receiving the report. I am not even sure what happens if the report reached the National PV centre." Participants # 11

On the measures that can be used to improve PV, the key suggestions from the participants included introduction of focal persons and task force PV committees at facility level, engagement of more stakeholders and staff, ensuring that there is continuous professional development (CPDs) for the trained staff and improving on the logistical problems being faced by the paper-based reporting systems. In order to motivate HCPs to report ADRs, the participants were of the view that provision of opportunities such as further training or refresher courses, supportive supervisions and other incentives such as mobile devices for reporting would make them very active in reporting of ADRs.

"We need a committee at hospital level. One person alone cannot handle ADR issues without support from the in-charge and DHO [District Health Officer]" Participant #1

"Follow up visits encourage participants to keep on reporting. Sometimes there are challenges and people can give feedback during the refresher trainings" Participant #4

Discussion

This survey was conducted in eight districts out of the 27 districts in which PMRA conducted the PV training, representing a 30% coverage by districts. Our target was to include all the 120 participants (15 per district) who participated in the training. However, this cross-sectional survey reached out to only 74% (n=89) of the participants as some of the participants were not reachable during data collection for due to other reasons such as transferring to a different facility. The participants were a mixture of various health care professionals including the Health Surveillance Assistants (HSAs). Due to shortage of HCPs, there has been task shifting and the HSAs, who are semi-skilled are involved in patient care tasks such as dispensing of medicines and vaccination[15,16]. Several studies have shown that generally PV knowledge is low among HCPs worldwide[17,18]. However,

comparison among various professional cadres indicate that pharmacy personnel usually have better knowledge in PV as compared to other professionals since they have a basic background from their undergraduate studies[19,20]. In our study we found out that the baseline knowledge of PV was not associated with the profession of the participants. This might be because in Malawi, PV was previously not part of the curriculum of any of the health care professionals including pharmacists. Hence, there were no differences among the professionals before training.

Recently, PV has just been introduced in the pharmacy curriculum in Malawi and there are also initiatives aiming to incorporate it in the undergraduate curricula for the other health professions. However, among the participants of this study, none was a recent graduate who could have had a chance to undergo pre-service PV training. The survey found out that knowledge of participants was significantly better after training despite that more than six months had passed from the time of training to the time the survey was conducted. This therefore suggests that the retention of the PV knowledge was good among the participants. The results are consistent with a similar study which was conducted in South India which found a PV knowledge increase by about 20% on average, among nurses and doctors following an educational intervention[21].

The qualitative approach in the survey helped to further explore the challenges in PV and possible solutions. As suggested by the participants, refresher trainings and follow up site visits would lead to even better outcomes in terms of knowledge retention and translation into practice.

Most of the participants (>50%), particularly before the training did not respond to questions which were assessing their attitude on PV. This might be because they had very little knowledge about PV and thereby could not be able to have a clear opinion on what needs to be reported to the National PV centre. This is evident as the participants were able to express their thoughts in the face-face interviews which were conducted after they were trained in PV. In terms of the practice, it was found that the detection and reporting rate of PV was significantly improved following the training. The exponential increase, which was then followed by gradual decline in the rate of ADR reporting is consistent with what Aylin and others found in their study which was assessing the short- and long-term impact of PV training. In this study, they found out that the PV knowledge was decreasing with time among the participants, thereby further validating our presumption that that refresher PV activities would be necessary to keep the trainees up to date in terms of knowledge and practical skills[22].

A similar study done in Germany, found out that training of in-service doctors working in primary level health facilities improved the ADR reporting rate by 148%[23]. This is similar to what we found in this study. However, we observed a decline in the number of reported cases after the third month of post-training. Moreover, there was a great variation of number of reports among the participating districts. Only Nsanje district was able to reach the WHO recommended number of reports of at least 200 individual case safety reports (ICSRs) per 1,000,000 population[6] in the month of January 2021 when they reported 67 ICSRs which represents 343 reports per 1,000,000 population. The reports for Nsanje district alone contributed to more than 50% of the national reports.

At the time of conducting this survey, there was no any alternative ADR reporting tool in Malawi as electronic methods such as mobile applications had not yet been launched. Thus, there was no comparator tool such that the participants expressed absolute preference for the paper-based reporting method[24]. Our findings, however, revealed that the HCPs desire to have a reporting tool that is easy and fast to fill in the required information, such as the current paper-based form. This is because, there is a critical shortage HCPs in Malawi, and the HCPs are already overburdened with their clinical tasks. For instance, as of 2019 the healthcare to patient densities were estimated at 0.019 and 0.283 doctors and nurses respectively, per 1000 population[11]. This is far below the minimum ratio of 4.45 for each cadre per 1000 patients that is recommended by WHO[25]. It is therefore very essential to establish a reporting system that is very flexible and convenient to integrate with the routine tasks that the HCPs perform.

As outlined by participants, the HCPs still face several other challenges that are associated with the paper-based tool such as lack of reporting forms, delays in data transmission and feedback. The new and innovative digital platforms such as the use of the unstructured supplementary service data (USSD) system, mobile phone applications and web-based reporting can therefore offer best solutions to these logistical problems as long they are designed to have a user-friendly interface that is flexible and therefore suitable for the Malawian setting. The USSD is a global system for mobile communication which is initiated by dialing a specific code. A menu is provided to select the required services by pressing appropriate buttons and interactive responses are provided in form of a text message[26]. Digital tools are not only simple to use but are also easily accessible since can be operated on mobile phones, and transmit data in a very fast and reliable way. In addition the digital tools provide immediate feedback to the sender and thereby providing motivation to the reporters[24,27]. Considering the associated costs and connectivity challenges that can be associated with tools that require internet access such as the mobile phone application, USSD system offers relatively more convenient and reliable way for both rural and urban areas across the country as it can be able to be used on any type of phone and does not require any internet connectivity[28].

Recommendations

To achieve continuous improvement in the PV system in Malawi, we recommend to further widen the coverage of in-service PV trainings for HCPs in Malawi, supplemented with supportive supervisions and mentorship in health facilities. With the shortage of personnel who have technical expertise at national level, there is also a need to identify and adequately equip district and institutional PV champions who can be trained as PV trainers. There is a further need to assess these trainers to ensure consistency which will reflect on the knowledge retention and reporting rates of different districts. The assessment of trainers is also a quality assurance and benchmarking tool. Furthermore, introducing PV in the undergraduate curricula for all health professional training program would not only help to widen the coverage in terms of PV awareness but also help to improve competency in the PV skills among HCPs as the in-service trainings face limitations in terms of depth of the content covered due to the heterogeneity of participants and short duration for the trainings.

The current system challenges are addressable at the central level. There is a need to ensure that adequate resources and personnel are assigned to ensure availability of reporting forms in all the facilities across the nation. In addition, we also recommend an improved notification system to provide feedback to reporters about the receipt, and the action taken on the reported cases. Supplementing the available tools with digital report methods such as USSD and mobile applications would also help to improve flexibility in the choice of reporting methods according to individual preferences. This might lead to an increase in ADR reporting rates.

There is also a need to conduct further investigations on the factors that have helped to achieve high ADR reporting rates in Nsanje districts. This can be used as a model that can be extended to the other districts to achieve the desirable outcomes from the PV activities across the nation.

Strength and Limitations

The mixed design study approach provides a better understanding of the PV KAP among the healthcare workers and the associated challenges. Further, the independent analysis of qualitative data by more than one investigator helped to reduce bias. The major limitation of the study is the poor response rate among participants. During data collection, we failed to reach out to some participants as they were on holiday or were transferred to another facility. This further affected the already small sample size, as only 15 participants were trained in PV per district. In addition, there was low response rate in some of the questions that were provided to the participants.

Conclusion

The survey found out that in-service PV trainings are significantly making a positive impact to improve the KAP of HCPs and helping to improve ADR reporting rates in Malawi. However, the total number of Malawian HCPs trained in PV is still too low to sustain a strong PV system at all levels and achieve the WHO recommended ADR reporting rate. As the efforts to train more in-service HCPs continues, it is also important to assess the feasibility and subsequent implementation of including PV in the undergraduate curricula of all health training institutions in Malawi and addressing the current system challenges at all levels.

Declarations

Ethical considerations

This survey was approved by the College of Medicine Research and Ethics Committee (COMREC) under study number P.04/21/3304. Written informed consent was sought from all study participants and permission was also granted by the management of their respective health facilities.

Consent for Publication

Not applicable

Availability of data and materials

All data for the survey has been provided in the manuscript and supplementary materials

Competing interests

The authors declare no any competing interests for this work

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Authors Contribution

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