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Knowledge, Attitudes and Practices on Pharmacovigilance among Healthcare Professionals in the North-Eastern Region of Kenya

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ABSTRACT

Background: Some healthcare facilities in Kenya demonstrate low engagement in pharmacovigilance activities, contributing to gaps in knowledge, attitudes, and practices among healthcare professionals in the reporting of adverse drug reactions.

Aim: This study assessed the gaps in the knowledge, attitude and practices of pharmacovigilance among healthcare professionals that existed within the Pharmacovigilance System of the North Eastern Region of Kenya and possible areas of intervention by various stakeholders.

Methodology: A cross-sectional study design recruited 306 Healthcare Professionals from health facilities in the North Eastern Region of Kenya. A convenient sampling method was used to recruit healthcare professionals working in private, public and faith-based health facilities. Data was collected using a pre-designed questionnaire. Descriptive and linear regression analyses of the data were done using STATA Version 13 software. The level of significance was set at 5%.

Results: The majority scored between 60–80% (45.8%) in the knowledge assessment test, while (71.2%) scored 100% in the attitude assessment. Statistically significant differences in knowledge scores were observed among professional groups (χ^2 = 36.91, df = 5, P<.01) and across educational qualifications (χ^2 = 102.3, df = 5, P<.01). Specialists, who also had the highest educational qualifications, achieved the highest median knowledge score, while clinical officers had the lowest.

Conclusion: Healthcare professionals in the North Eastern Region of Kenya demonstrated highly positive attitudes toward pharmacovigilance, with most participants recognizing adverse drug reaction reporting as a professional responsibility and expressing strong willingness to engage in reporting. However, this positive attitude was not fully matched by knowledge and practice levels, as moderate knowledge gaps and weak reporting practices were observed across key pharmacovigilance domains. In addition, pharmacovigilance reporting was hindered by several barriers, particularly lack of motivation (93.3%), limited supportive environments for discussing adverse drug reactions, and fear of legal liability.

BACKGROUND

Under-reporting of Adverse Drug Reactions (ADRs) limits and delays regulatory initiatives that could prevent harm from medications or medical products. [1] Additionally, it creates room for an unnecessary economic burden on an already strained healthcare system. Healthcare professionals have an ethical obligation to report any medication-related harm, which could expose patients to harm arising from the principle of non-maleficence. Some of the barriers to pharmacovigilance (PV) reporting among Healthcare Professionals (HCPs) include limited pharmacovigilance knowledge, lack of awareness on how to report, lack of communication between the patients and HCPs, inadequate time, lack of motivation, complexity of reporting forms, and lack of feedback among others.[1,2]

Several factors contribute to under-reporting of ADRs, including inadequate knowledge about pharmacovigilance, lack of awareness regarding the reporting process, time constraints, and a lack of motivation among healthcare professionals. Studies have shown that education and training can significantly improve the reporting rate. For example, one interventional study demonstrated that educating healthcare professionals could increase ADR reporting by up to four-fold. Furthermore, a collaborative approach involving pharmacists and physicians has also been shown to enhance reporting rates. Despite these improvements, some barriers, such as

lack of administrative support and motivation, continue to hinder effective pharmacovigilance reporting.

Pharmacovigilance

Pharmacovigilance (PV) is defined as the science and activities related to the detection, assessment, understanding and prevention of adverse drug reactions (ADRs) or any other possible drug-related problems.[3] The success of the national PV system depends on the spontaneous reporting of adverse drug reactions (ADRs) by healthcare professionals (HCPs) and patients. An adverse drug reaction is defined as any unintended and harmful response to a drug at normal dosages used for disease prevention, diagnosis, therapy, or modifying physiological disorder or function.[4]

Global and Local Trends in Pharmacovigilance Reporting

This finding suggests there is a strong relationship between the knowledge, attitudes and practices (KAP) among the HCPs and the reporting rate. One interventional study done over 17 months among nurses and physicians reported that educating HCPs through lectures could increase the reporting rate by up to four-fold. [5] The involvement of pharmacists and improved collaboration with physicians has also been reported to increase the reporting rate. Education improves the HCP's perception of the importance of pharmacovigilance activities and their confidence in detecting and reporting occurrences.[6] Additionally, education increases awareness about the available reporting tools, how to report, and what information is required.[6] However, as much as PV knowledge could be improved through educational interventions, under-reporting could still remain an issue due to a lack of motivation and lack of administrative support.[6,7]

Pharmacovigilance Reporting System in Kenya

Across diverse geographical locations, studies on PV reporting among HCPs have revealed both commonalities and variations in KAP. A study by Alshabi et al. [8] highlighted positive trends in pharmacovigilance reporting with increasing awareness and better attitudes among pharmacists, emphasizing the importance of initiatives by regulatory authorities. Both studies underscored the need for ongoing education to address knowledge gaps and enhance pharmacovigilance-reporting practices. A study in India, revealed a positive correlation between PV training and ADR reporting by HCPs, identifying common barriers such as lack of time and knowledge.[9] Hussain et al. [10] provided a comprehensive overview, emphasizing positive attitudes but variations in knowledge and practices among physicians, pharmacists, and nurses.

A study conducted in in Kenya revealed significant associations between ADR reporting and factors such as age, profession and level of education.[11] Particularly, older HCPs and those with higher educational levels reported ADRs more frequently, underscoring the influence of these demographic variables on reporting practices. [12] The study shed light on factors influencing ADR reporting, indicating that HCPs were more likely to report if they were aware of the existence of the role of the drug regulatory authority, knowledgeable about reporting guidelines, or had received training. Barriers to reporting included a lack of knowledge regarding where and how to report, inadequate access to ADR reporting forms and concerns about the perceived futility of reporting. [13] Training emerged as a significant factor, with trained HCPs demonstrating a higher likelihood of reporting ADRs.[14] It underscored the need for continuous education, streamlined reporting processes and enhanced communication to address barriers and promote effective ADR reporting in Kenya's healthcare system.

Pharmacovigilance System in NERK

The pharmacovigilance reporting rate in the NERK has consistently remained low. Data from the Pharmacy and Poisons Board of Kenya (PPB) database has shown a consistently low reporting rate from this region. For instance, in the period between August 2022 and August 2023, the NERK filed only 11 pharmacovigilance reports from the three counties of Garissa, Mandera and Wajir. [15] In contrast, Nairobi County encompassing the capital city reported 481 serious Adverse Drug Reactions (ADRs).[10] Out of the total 1624 ADR reports received at the national level in this period, the NERK region contributed a mere 0.01% of the overall reports.[15] Therefore, this study sought to unveil the status of knowledge, attitudes and practices among the HCPs in this region and factors that hinder PV reporting. It is hoped that the findings of this study may be used to identify interventions to promote reporting of adverse events in this region.

METHODOLOGY

Study Design

This study employed a multisite cross-sectional design, aimed at assessing the KAP of HCPs in the North Eastern Region of Kenya (NERK). The cross-sectional design was chosen because it allows for the collection of data at a single point in time, providing a snapshot of the existing conditions in the region's healthcare system.

Study Area

The study was conducted across three counties in the North Eastern Region of Kenya: Garissa, Mandera, and Wajir. These counties were selected due to their historical low reporting rates for adverse drug reactions (ADRs) in Kenya, making them ideal for exploring the gaps in pharmacovigilance among HCPs.

Study Variables

The primary study variables focused on assessing the KAP of HCPs regarding PV. Attitudes captured the perceptions and beliefs of HCPs toward PV, particularly their willingness and motivation to engage in ADR reporting. This aspect also encompassed how HCPs viewed the importance of reporting ADRs, their confidence in the reporting process, and any concerns or misconceptions they may have had. The study also explored barriers to ADR reporting, such as lack of time, inadequate knowledge, perceived inefficacy of reporting, and administrative challenges, which could hinder the consistent and effective reporting of ADRs.

Sample Size

The sample size was determined using Yamane's formula, which provided a total of 304 participants. The allocation of participants was done equally across the three counties, with 102 HCPs selected from each county. Proportional allocation was based on the level of the healthcare

facility (primary, secondary, and tertiary), ensuring that a representative sample of healthcare professionals from various facility levels was included.

Sampling Method and Procedure

A multistage sampling approach was used in this study. First, stratified sampling was applied to ensure proportional representation of healthcare professional cadres (nurses, clinicians, and pharmaceutical personnel) within each selected health facility. Within each stratum, participants were recruited using convenience sampling based on availability during data collection periods. This approach was used due to operational constraints and the need to access respondents within their work schedules. The combination of stratification and convenience sampling ensured representation across professional groups while maintaining feasibility in the field setting.

Data Collection Methods and Tools

Data on KAP among HCPs were collected using a self-administered questionnaire. The questionnaire was adapted from previous studies that had been tested for conciseness, comprehensiveness, validity, and consistency. Modifications were made to reflect the Kenyan healthcare context, specifically addressing local reporting systems and the operational structure of healthcare facilities in the region. To ensure the instrument's reliability and clarity, a pre-test was conducted with a sample of 10% of the study population. This helped assess the appropriateness and effectiveness of the questions, ensuring that the questionnaire was well-suited for the study's objectives and context.

In addition to the quantitative survey, a supplementary key informant component was conducted among 30 healthcare professionals selected purposively from the participating health facilities. These participants were drawn from nurses, clinicians, and pharmaceutical personnel with experience in PV reporting. The purpose of this component was to obtain contextual information on barriers affecting adverse drug reaction reporting at facility level. The key informant data were analyzed descriptively and used to complement and interpret findings from the main quantitative survey (n = 306).

Data Collection Procedure

Data was collected by the researcher who approached nurses, clinicians, and pharmacists at selected health facilities during their working hours. The questionnaire was administered at a time convenient for the participants. Prior to participation, informed consent was obtained from each HCP. The researcher ensured that participants understood the purpose of the study and the confidentiality of their responses.

Quality Control

To ensure data quality and reliability, the questionnaire was pre-tested on a sample of 10% of the study population to check for consistency and clarity. The research team ensured the correct administration of the questionnaires and provided assistance to any participants who had difficulty understanding the questions. The responses were monitored for completeness, and any incomplete or ambiguous responses were followed up.

Data Presentation and Analysis

Descriptive statistics, such as frequencies, percentages, and means, were used to summarize the demographic characteristics of the participants and their responses on knowledge, attitudes, and practices regarding PV. Linear regression analyses were conducted to assess the relationships between different variables (knowledge level and ADR reporting practices). The data was analyzed using STATA Version 13 software, and the level of significance was set at 5%.

Ethical Approval

The study received ethical approval from the Kenyatta National Hospital/University of Nairobi (KNH/UoN) Ethics and Research Committee (ERC) under the approval number KNH-ERC/A/268. Additionally, approval was obtained from the National Commission for Science, Technology and Innovation (NACOSTI) through the license number NACOSTI/P/23/28576. Each health facility involved in the study was informed about the research via a formal introduction letter sent to the officer in charge of the facility.

RESULTS

The study achieved a response rate of 100%, with all 306 of the targeted participants completing the questionnaire. This was achieved due to on-site recruitment during working hours and immediate questionnaire completion.

Sociodemographic Characteristics of the Healthcare Professionals

In this study, the age distribution was normal, with most HCPs falling in the age range of 26 to 38 years (n=127, 42.5%) (Table 1). Table 1 provides an overview of the sociodemographic characteristics of HCPs in health facilities within the NERK. The age distribution of the HCPs shows that most are between 26 to 38 years old (42.5%), with a mean age of 32.1 years (SD=5.9). The gender distribution indicates a higher proportion of male HCPs (61.4%) compared to females (38.6%). In terms of professional cadre, nurses represented the largest group (59.8%), followed by clinical officers (24.5%), pharmaceutical technologists (7.2%), pharmacists (6.2%), and specialists (1.3%). Regarding educational qualifications, the majority of HCPs held diplomas (79.4%), with smaller percentages having certificates (3.9%), degrees (15.4%), or postgraduate qualifications (1.3%).

Knowledge of Pharmacovigilance among Healthcare Professionals

The knowledge assessment scores of the participants are presented in Figure 1. Most of the HCPs scored between 60% and 80% on the 10 questions (n = 139, 45.8%) (Figure 1). The majority of the participants 184 (60.0%) were aware of the definition of PV. Most participants (57.5%) knew the purpose of carrying out PV activities. The majority of the HCPs (215, 70%) rightly defined an ADR. More than 205 (67%) of the participants also correctly highlighted that all HCPs are responsible for reporting an ADR. Nearly all (268, 87.6%) of the HCPs agreed that even non-HCPs could report an ADR. The majority of the HCPs (258, 84.3%) were aware of the PV reporting system in Kenya and 90.9% identified the

Pharmacy and Poisons Board (PPB) as the responsible body. The majority of the HCPs (233, 76.1%) correctly identified ranitidine as one of the drugs that was withdrawn from the Kenyan market based on ADR reports. However, less than half of the participants 149 (48.6%) were able to define a serious ADR. Similarly, only 136 (44.4%) of the HCPs could tell which adverse reactions should be reported.

Although all participants reported having received training in PV, the observed moderate knowledge levels suggest that this training may largely consist of brief sensitization sessions rather than structured, competency-based PV education. The disparity between universal self-reported training (100%) and limited understanding of key concepts such as serious ADRs (48.6%) indicates that current training approaches may not be sufficiently intensive or standardized to ensure long-term knowledge retention and practical application. This highlights the need for more structured and continuous PV capacity-building programs within healthcare facilities.

TABLE 1: Sociodemographic Characteristics of the Healthcare Professionals in Health Facilities in North Eastern Region of Kenya (N = 306)

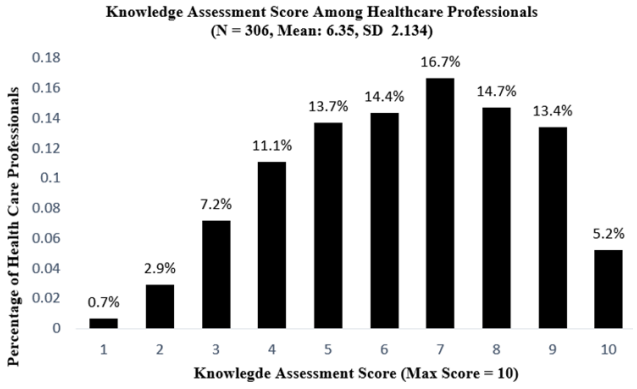
Characteristic	Frequency, n (%)
Age	
≤25 years	31 (10.1)
26–32 years	127 (41.5)
33–38 years	105 (34.3)
≥39 years	43 (14.1)
Mean (SD)	32.1 ± 5.916
Gender	
Male	188 (61.4)
Female	118 (38.6)
Cadre	
Nurses	183 (59.8)
Clinical officers	75 (24.5)
Pharmaceutical technologists	22 (7.2)
Pharmacists	19 (6.2)
Specialists	4 (1.3)
Highest Qualification	
Certificate	12 (3.9)
Diploma	243 (79.4)
Degree	47 (15.4)
Postgraduate	4 (1.3)

Assessment of Attitude of Pharmacovigilance among Healthcare Professionals

The attitude assessment scores of the participants are presented in Figure 2. Most of the HCPs (n= 218, 71.2%) had a score of 100% on the attitude assessment test (Figure 2). All the HCPs reported that they had been trained in PV reporting. A significant majority (304, 99.3%) of participants agreed with the necessity of reporting ADRs, emphasizing its crucial role in enhancing drug and medical product safety. Similarly, an equally high percentage, 304 (99.3%), acknowledged that reporting ADRs is an integral part of HCP obligations, underlining a strong sense of responsibility among the respondents. The survey also established that the majority of the HCPs, 72.8%, support the need for an ADR reporting centre in the health facilities.

The willingness of HCPs to implement ADR reporting in practice was assessed. There was a positive stance, with 304 (99.3%) agreeing, indicating a high level of readiness among participants to actively engage in pharmacovigilance reporting. The participants also demonstrated a unanimous belief in the need for comprehensive education in PV, with 99.0% agreeing that it should be taught in detail to all HCPs. Lastly, the survey explored attitudes towards collaboration in PV matters. The majority of the HCPs, 335 (99.7%) agreed with the idea of collaboration between pharmacists and other HCPs in strengthening PV.

FIGURE 1: Knowledge of Pharmacovigilance among the Health Care Professionals in the North Eastern Region of Kenya



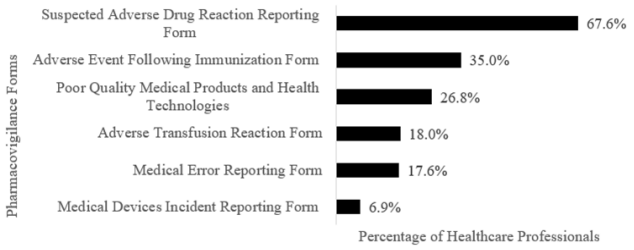
Pharmacovigilance Practices among Healthcare Professionals

The majority of respondents (n=174, 56.9%) reported having experienced a single reportable PV incident within the past 12 months (Table 2).

TABLE 2: Frequency of Reportable Pharmacovigilance Incidents Experienced by Healthcare Professionals in the Past Year in Health Facilities in North Eastern Region of Kenya

Number of Reportable Pharmacovigilance Incidents Experienced in the Last 12 Months	Frequency n (%)
1	174 (56.9)
2	70 (22.9)
3	29 (9.5)
4	20 (6.5)
5	7 (2.3)
6	6 (2.0)

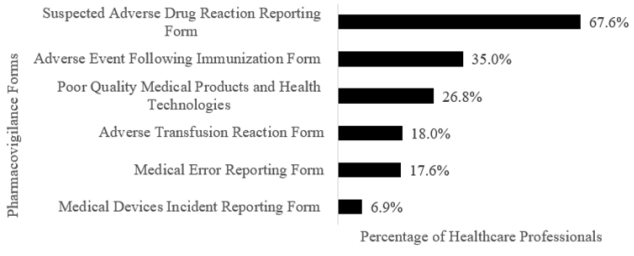
FIGURE 2: Attitude on Pharmacovigilance among Health Care Professionals in the North Eastern Region of Kenya



Interaction with Forms for Reporting Adverse Events

The majority of the HCPs had interacted with the suspected ADR reporting form (n=207, 67.6%) and more than a third (n=107, 35.0%) had also interacted with the adverse event following immunization (AEFI) form immunization form (Figure 3). Healthcare professionals hardly interacted with the Medical Device Incident Reporting Form (6.9%), Medical Errors Reporting Form (17.6%) and the Adverse Transfusion Reporting Form (18.0%), pointing to the need for more sensitization on their use (Figure 3).

FIGURE 3: Healthcare Professionals' Interaction with Pharmacovigilance Reporting Forms



Healthcare Professionals' Interaction with Pharmacovigilance Reporting Forms, Including Adverse Drug Reaction (ADR), Adverse Events Following Immunization (AEFI), Medical Device Incident, Medication Error, and Transfusion Reaction Reporting Forms in the North Eastern Region of Kenya

Participant Reported Factors that Hinder Reporting Adverse Events

In the supplementary key informant component (n = 30), HCPs reported that the main factors hindering PV activities were lack of motivation (93.3%), absence of a professional environment for discussing adverse drug reactions (86.7%), fear of legal liability (63.3%), and difficulty in determining whether an ADR had occurred (53.3%) (Figure 4).

Determinants of Knowledge and Attitude among Healthcare Professionals

There was a statistically significant difference in the knowledge assessment score across the professional cadres ($\chi^2 = 36.91$, df = 5, $P < .01$) (Table 3). Specialists had the highest median score while clinical officers had the lowest median score in the knowledge assessment. There was a statistically significant difference in the knowledge assessment score across the academic qualifications ($\chi^2 = 102.3$, df = 5, $P < .01$). While the HCPs with postgraduate qualifications had a median score of nine, those with certificates had a median score of three (Table 3).

Regression analysis included β coefficients and 95% confidence intervals to improve interpretation of effect sizes. However, due to study design limitations, adjustment for all potential confounders was not fully possible. On, linear regression, healthcare professionals with higher educational qualifications had significantly more knowledge (b = 3.02, $P < .001$) regarding PV reporting (Table 4). These findings suggest that educational qualifications positively influence knowledge among healthcare professionals.

FIGURE 4: Reported Barriers Affecting Pharmacovigilance and Adverse Drug Reaction Reporting among Healthcare Professionals in the North Eastern Region of Kenya

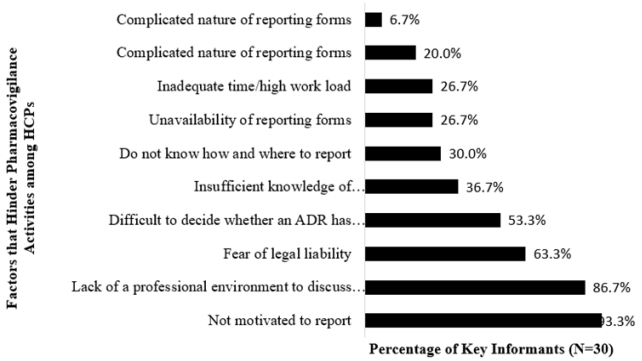


TABLE 3: Determinants of Knowledge on Pharmacovigilance among Healthcare Providers in North Eastern Kenya

Variable	Categories	N	Median	*p-value*
Knowledge assessment score: Gender	Female	118	6	.762
	Male	188	7	
Knowledge assessment score: Professional categories	Clinical officer	75	5	<.001
	Medical officer	3	8	
	Nurse	183	6	
	Pharmacist	19	9	
	Pharmaceutical technologist	22	7	
	Specialists	4	10	
Knowledge assessment score: Highest qualification	Certificate	12	3	<.001
	Diploma	243	6	
	Degree	47	9	
	Postgraduate	4	9	
Knowledge assessment score: Level of facility	Level 5 (3)	126	6	.076
	Level 4 (10)	126	7	
	Level 3 (9)	36	6	
	Level 2 (8)	18	5	
Knowledge assessment score: Ownership	Public	291	7	.979
	Private	15	6	

TABLE 4: Linear Regression Predicting Knowledge Score Activities among Healthcare Professionals Working in the North Eastern Region of Kenya

Predictor	Coefficient (b), 95% CI	Standard Error (SE)	*p-value*
Hospital Ownership	-0.43 (-1.33, 0.48)	0.46	.543
Hospital-Level	0.02 (-0.21, 0.22)	0.12	.896
Gender	-0.20 (-0.20, 0.21)	0.21	.348
Highest Qualification	3.02 (3.02, 0.29)	0.29	.000
Age Categories	-0.11 (-0.11, 0.13)	0.13	.368

DISCUSSION

The age groups 26 to 32 years and 33 to 38 years formed 75.8% of the HCPs proportion. This is slightly above the Kenyan health professional demographic of 2020, where those aged 25-44 years formed 67.5% of the HCPs population. One factor contributing to the observation is the substantial growth in the total number of HCPs, which surged from 77,417 in 2010 to 162,233 in 2020 [16]. There was a remarkable 110% increase in the overall workforce over the decade or an average annual growth rate of around 10%, with an apparent influx of younger individuals into the healthcare sector. [17]

In this study, the majority were male at 61.4%, which contrasts a survey that showed 58% of HCPs in Kenya were females. The disparity could be because of the lack of empowerment of women where education in NERK is still a work in progress, with about 62% of pupils in schools being male. [18] Being a hardship area with a high preference for employees from the local community, the males are still predominant among the HCPs. In contrast, this hinders healthcare delivery to a great extent since female patients in this region are culturally driven toward receiving care from female HCPs. [19] The male-dominated healthcare workforce in the region may indirectly affect PV reporting, particularly in culturally sensitive contexts where female patients prefer female healthcare providers. This may result in reduced patient disclosure of adverse drug reactions and under-detection of gender-specific drug safety issues.

The study noted low educational attainment, with a diploma being the highest qualification amongst most nurses and clinical officers. Some studies have shown a link between education level and pharmacovigilance reporting. For instance, in Lithuania, individuals with higher education demonstrated "good" knowledge of pharmacovigilance and ADRs. [20] Similarly, a study in Portugal found that age and education significantly influenced knowledge of pharmacovigilance and ADRs [21]. Additionally, individuals with lower education levels tended to have a poorer understanding of these concepts and often lacked sufficient knowledge about PV. Higher educational attainment was significantly associated with improved PV knowledge, suggesting that advanced

academic training enhances clinical reasoning, awareness of drug safety systems, and competence in identifying and reporting ADRs.

The findings from this study reveal a mixed level of knowledge among HCPS regarding PV activities. While a considerable portion of HCPs demonstrated a moderate to high understanding, with a substantial number scoring between 60 and 80%, certain areas of knowledge appear to be lacking. One important aspect is that the majority of participants were aware of the definition of PV, which was a relatively higher percentage compared to other studies. A similar study in Saudi Arabia found that 58% of the participants lacked knowledge of the correct definition of PV. [21] Other studies also showed that only 40% [22], 44.3% [23] and 43.4% [24] Of the study participants correctly defined PV. Therefore, there is a significant knowledge gap among HCPs on PV matters.

Moreover, despite a substantial number of HCPs (57.5%) recognizing the purpose of conducting PV activities, there remains room for improvement in ensuring this knowledge translates to daily practice. Other studies have identified a higher score among HCPs in understanding the need for PV. One study reported that 66.3% [25], 74.8% [25] and 91.8% [26] Of HCPs understood the purpose of PV. Encouragingly, a majority of HCPs exhibited a sound understanding of specific aspects of PV, such as correctly defining an ADR and recognizing the shared responsibility among all HCPs for reporting ADRs. There were similar findings from other studies that recognized the definition of ADRs as any harmful or unintended effect of medication at standard doses, aligning with findings from other research studies. [27] The high level of awareness (87.6%) that non-healthcare workers can also report ADRs reflects a positive trend in acknowledging the inclusivity of the reporting process.

On the other hand, challenges persist in certain critical areas, as evidenced by less than half of the participants (48.6%) being able to define a serious ADR, and only 44.4% correctly identifying which ADR should be reported. In contrast, other studies done on HCPs who were predominantly pharmacists reported a significant majority of participants, 75%, accurately identified the criteria for an ADR.[28] Additionally, 66.7% of pharmacists correctly identified the ADR categories to report, a result consistent with findings from other studies, such as those conducted in Kuwait (66.3%) [29] and Al-Khobar (71.6%). [29] This highlights specific areas for targeted educational interventions to enhance the depth of understanding among HCPs, ultimately strengthening the PVS. These findings align with existing literature that emphasizes the need for continuous education and training programs to bolster HCP's knowledge and engagement in PV activities. Addressing these knowledge gaps is crucial for optimizing the reporting system's effectiveness and promoting a culture of vigilant monitoring and reporting within the healthcare community.

Although the study captured healthcare professionals from multiple facility levels, it did not categorize facilities based on their PV reporting performance (reporting versus non-reporting facilities). This limits the ability to directly correlate institutional reporting behaviour with knowledge, attitudes, and practices. Future studies should incorporate facility-level reporting stratification using national PV database records to strengthen this linkage. The positive disposition towards ADR reporting, with 97% acknowledging its necessity and contribution to drug safety, resonates with findings from various studies involving pharmacists in Kuwait (98.8%), [25] Majmaah (100%), [26] and another Kuwaiti study. [25] The consensus among participants from Kuwait (97.1%) [25] that reporting positively affects healthcare and contributes to drug safety further aligns with the current study's observations. Similarly, the recognition of ADR reporting as a professional obligation by 90% of the participants reflects agreement with studies conducted in Oman (90.6%), [27] Kuwait (85.6%) and a multi-centric study from Saudi Arabia (86%).[28] However, contrasting perspectives were observed in studies from Syria (37.6%) and Pakistan (75.7%),[29] where a lower proportion considered ADR reporting an obligation.

Regarding the establishment of ADR reporting centres in health facilities, 66.3% of participants in the current study advocated for such centres, akin to findings from Majmaah (68.9%) and South India (74.3%). [29] However, the willingness to implement ADR reporting into practice was relatively lower at 67.3%, suggesting a potential lack of commitment compared to the greater-willingness from Kuwait (81.3% and 88.6%).[29] Participants' endorsement (87.1%) of teaching HCPS about pharmacovigilance aligns with similar sentiments among pharmacists in Kuwait (92.2% and 93.3%) and a higher percentage (96%) from Majmaah. [30] This underscores a positive perception of the importance of PV and its impact on patient safety.

An important finding is an affirmative response from 94% of participants regarding collaboration between HCPs and pharmacists in the context of ADR reporting and PV. This collaborative approach echoes findings from a study in Pakistan and highlights the potential benefits of an inter-professional team approach in enhancing clinical knowledge transfer and improving the quality of ADR reports. In conclusion, the participants' attitudes align with and contribute to the broader discourse on ADR reporting and PV activities, emphasizing the importance of collaboration and education in ensuring patient safety.

The finding that less than half of participants could correctly define a serious adverse drug reaction highlights a critical gap in PV competence. Addressing this requires structured, competency-based educational interventions, including case-based learning, simulation exercises, and continuous professional development programs focused specifically on ADR severity classification and reporting thresholds.

The marked discrepancy between the proportion of healthcare professionals encountering reportable events (56.9%) and the extremely low national reporting contribution (0.01%) from the region suggests substantial under-reporting. This gap is likely driven by weak reporting culture, lack of institutional feedback mechanisms, and limited integration of PV into routine clinical workflows. A significant number of healthcare professionals faced numerous reportable PV incidents, highlighting the continuous requirement for attentive monitoring and reporting systems. Nevertheless, in stark disparity, only 13 PV reports were submitted during the

same timeframe, indicating a substantial gap, either in PV knowledge or in its practical implementation.

The most substantial reported hindrance to PV activities among HCPs in the NERK was a lack of motivation, which was reported by 93.3% of participants. This lack of motivation is intertwined with various factors, including work processes, design and their impact on processing PV reports. Other significant barriers identified in this study include the lack of a professional environment to discuss adverse reactions, fear of legal liability, difficulty in deciding whether an ADR has occurred, insufficient knowledge of pharmacotherapy, uncertainty about how and where to report, unavailability of reporting forms, high workload, and the complicated nature of reporting forms. Among these barriers, the absence of a professional environment to discuss ADRs (90.9%) and insufficient knowledge of pharmacotherapy/clinical knowledge (78.2%) were cited as the primary reasons discouraging participants from reporting. This aligns with findings from other studies in Alahsa (86%) and Bangladesh (95.5%), where the lack of a conducive professional environment was reported as a significant barrier.[30] Additionally, the unavailability of reporting forms (77.2%) and uncertainty about how and where to report (72.3%) emerged as crucial barriers, resonating with studies from Syria, Jordan, and Jizan, where similar obstacles were reported.[31] Fear of legal liability (69.3%) was another significant barrier, with variations in proportions reported in different regions.

The time factor and the complex nature of reporting forms were also identified as barriers in this study. While time constraints were reported to a smaller extent in other studies the complex nature of reporting forms showed varying degrees of significance across different regions. In addition, addressing these barriers is crucial for effective PV implementation, as indicated by studies from various regions, including Kuwait, Jordan, and Saudi Arabia. The results of this study emphasize the need to address motivational, knowledge-related and logistical barriers to enhance PV reporting among HCPs. Strategies such as organizational redesign, frequent training or mentorship and streamlining of reporting processes could contribute to overcoming these challenges, ultimately improving patient outcomes and the quality of PV practices.

Within the East African region, similar challenges in pharmacovigilance reporting have been documented. Studies from Uganda have reported low ADR reporting rates among healthcare professionals, largely attributed to inadequate training and weak feedback mechanisms from national regulatory authorities. In Tanzania, limited awareness of pharmacovigilance reporting systems and poor integration into routine clinical workflows have been identified as key barriers. Similarly, findings from Ethiopia highlight that although healthcare professionals demonstrate positive attitudes toward ADR reporting, actual reporting practices remain low due to workload constraints and insufficient institutional support. These regional findings closely align with the present study, suggesting that PV challenges in Kenya are part of a broader systemic issue across East Africa rather than an isolated phenomenon.

The diverse sample size across various cadres, qualification levels, facility tiers, and ownership types provided a representative sample of the HCPs across NERK. The stratification of health facilities based on levels and ownership, along with systematic sampling techniques, added validity to the selection process. One potential weakness of this study was the reliance on self-administered questionnaires for data collection, which may have introduced response bias or recall bias.

This study contributes novel evidence from a resource-limited and historically underreported region of Kenya, highlighting unique structural, cultural, and regulatory barriers influencing pharmacovigilance practice. Unlike prior studies conducted in more resourced settings, the findings reflect challenges related to workforce shortages, limited specialist availability, and weak feedback mechanisms from national regulatory systems, which collectively shape ADR reporting behaviour in North Eastern Kenya.

The COVID-19 pandemic may have also influenced pharmacovigilance reporting patterns in the study setting. During the pandemic period, healthcare systems experienced increased workload, reallocation of staff, and disruptions in routine surveillance activities, which likely contributed to reduced attention to ADR reporting. Additionally, heightened focus on pandemic response may have temporarily shifted priorities away from PV activities.

CONCLUSION

To enhance PV practices among healthcare professionals in the North Eastern Region of Kenya, targeted and practical interventions are required at facility, county, and national levels. First, motivational barriers should be addressed by integrating adverse drug reaction (ADR) reporting into routine clinical workflows, including outpatient registers and ward rounds, and by assigning designated PV focal persons in each facility to coordinate reporting and follow-up. Second, Medicines and Therapeutics Committees (MTCs) should be formally activated in all hospitals, with clearly defined roles that include monthly review of ADR reports, dissemination of feedback to reporters, and incorporation of PV indicators into routine quality improvement meetings. Medicines and Therapeutics Committees (MTCs) can significantly strengthen PV systems by providing structured platforms for reviewing ADR reports, ensuring feedback to reporters, and integrating pharmacovigilance indicators into routine clinical governance meetings. This fosters accountability and improves reporting consistency.

At county level, health management teams should ensure quarterly supervision visits specifically assessing pharmacovigilance performance. Third, reporting processes should be simplified through the introduction of user-friendly reporting tools, including mobile-based or WhatsApp-enabled ADR reporting systems linked to the Pharmacy and Poisons Board. Standard reporting forms should be made readily available in all clinical departments, with visual job aids displayed in staff areas.

Fourth, fear of legal liability should be addressed through formal dissemination of national PV guidelines, supported by continuous professional education sessions emphasizing confidentiality protections and non-punitive reporting principles. Finally, structured, competency-

based PV training programs should be institutionalized, with mandatory induction training for new staff and annual refresher courses, rather than ad hoc sensitization sessions. These combined interventions would strengthen reporting culture, reduce barriers to ADR reporting, and improve the effectiveness of the PV system in the region.

Limitations of the Study

One potential weakness of this study was the reliance on self-administered questionnaires for data collection, which may introduce response bias or recall bias. Additionally, the use of a cross-sectional design limits the ability to establish causal relationships or capture temporal changes in pharmacovigilance practices over time. The study's focus on the North Eastern region of Kenya may restrict the generalizability of findings to other geographic areas or healthcare settings. The study may also be subject to social desirability bias, particularly given the high self-reported training and positive attitudes among participants. In addition, although a high response rate was achieved (100%), non-response bias cannot be fully excluded in relation to availability during data collection periods.

In addition, the use of convenience sampling within strata may introduce selection bias, as participation depended on the availability of healthcare professionals during data collection periods. This may limit the representativeness of the sample and reduce the generalizability of the findings to all healthcare professionals in the North Eastern Region of Kenya. However, the use of stratification helped to improve representation across key professional cadres.

In addition, the low proportion of specialists (1.3%) and pharmacists (6.2%) reflects the actual workforce composition in the region but limits the statistical power for subgroup comparisons across professional cadres. As a result, comparisons involving these smaller groups should be interpreted cautiously, and findings may not fully represent variability within these professional categories.

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