The reporting of adverse drug reactions by healthcare providers in Kenya

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Abstract

Background: Spontaneous and consistent reporting is the cornerstone of adverse drug reaction (ADR) reporting. Under reporting is an enormous obstacle to effective pharmacovigilance (PV).

Objective: To determine factors affecting ADR reporting by healthcare providers in selected hospitals in Kirinyaga County, Kenya.

Methods: A cross-sectional study was conducted in four selected hospitals. A pretested self-administered questionnaire was utilised to collect data. Stratified sampling was used to recruit 224 healthcare providers. Statistical Package for Social Sciences (SPSS) version 23 analysed data. The Chi-squared test was used to determine association. Binary logistic regression assessed strength of association. Outcomes were considered significant at p-values of <0.05.

Results: Of 224 questionnaires distributed 215 were completed, 159 (74%) healthcare providers had not reported ADRs to the Pharmacy and Poisons Board (PPB) within the last 3 months. In total, 92 (42.8%) healthcare providers knew about reporting guidelines; 194 (90.2%) were not trained in ADR reporting. Those aware of the reporting guidelines and those trained were more likely to report ADRs. Continuing medical education was the preferred source of information about ADRs. The main barriers to ADR reporting include inadequate training, delayed feedback, not knowing where or to whom to report, lack of a PV centre in the county and inadequate access to ADR forms and guidelines.

Conclusion: ADR reporting among healthcare providers could be improved. Age, profession, level of education, knowledge and training affected ADR reporting. Healthcare provider centred training and promotion of ADR reporting tools are necessary to boost ADR reporting and increase patient safety.

Keywords: adverse drug reaction; spontaneous reporting; healthcare provider; pharmacovigilance, Kenya.

Introduction

The Pharmacy and Poisons Board (PPB) in Kenya defines an ADR as a response to a drug which is noxious and unintended, that occurs at doses used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.[1] Modern ADR reporting practice began in 1961 when thalidomide caused phocomelia among new-borns.[2] The PPB in Kenya launched the Department of Pharmacovigilance (PV) in 2004 and started the National PV Centre in 2009 to report ADRs and product quality issues.[1]

Since Kenya joined the global drug monitoring programme in 2010, as of June 2019, Kenya had submitted 12,231 ADR reports accounting for 0.06% of global reports.[3] Under reporting remains an issue and has been attributed to: lack of awareness of PV tools and national PV centre, inadequate training, no feedback and non-adherence to the ADR reporting guidelines.[4,5]

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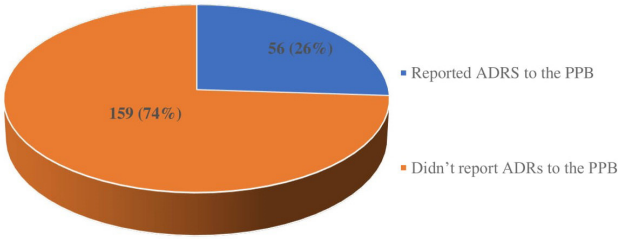

Figure 1. Proportion of healthcare providers who reported ADRs to the PPB

Spontaneous reporting involves identification and reporting of suspected ADRs on standardised report forms to the national PV centre.[6] It is important in identifying risk-benefit profiles of drugs throughout their life cycle, product quality, medication errors, and new, rare and fatal reactions not identified in clinical trials. Clinical trials do not identify all ADR's as they are brief, use a limited number of participants and may exclude some age groups. Assessing drug safety should be incorporated in the daily practice of healthcare providers who should be trained to report ADRs.[7]

The objective of this study was to determine factors affecting ADR reporting by healthcare providers in selected hospitals in Kirinyaga County, Kenya.

Method

A hospital-based cross-sectional study was conducted in Kerugoya Referral Hospital and Kianyaga, Kimbimbi and Sagana Sub-County Hospitals between April and September 2019.

A sample size of 224 healthcare providers was generated using the Cochran formula. A sample size of 383 healthcare providers was calculated using a 5% margin error, standard deviation at 95% confidence interval (CI) and a prevalence of 53.2%. The sample size was adjusted using the finite population correction equation to obtain a minimum sample size of 203. A 10% non-response level was added to obtain the minimum number of participants required.

Stratified sampling was utilised to recruit respondents (Consultants, Medical Officers, Pharmacists, Pharmaceutical Technologists, Nurses and Clinical Officers). The sample size of 224 was proportionately allocated to these cadres and each hospital, using the list of healthcare providers on duty. A random starting point was selected, then every Kth (Population size/Sample size = sampling interval) healthcare provider on the list was selected until the desired sample size was reached. Data were collected using a self-administered pre-tested questionnaire adopted, with revisions, from comparable studies.[5,8,9] Questions exploring drugs withdrawn from the market due to ADRs, reporting guidelines, sources

Table 1. Association between healthcare provider characteristics and ADR reporting

Characteristics		Reported ADRs		Totals n (%)	Chi-squared and p-value
		Yes n (%)	No n (%)		
Sex	Male	27 (30.7)	61 (69.3)	88 (40.9)	$\chi2 = 1.662$
	Female	29 (22.8)	98 (77.2)	127 (59.1)	0.210
Age group (years)	18-25	4 (9.3)	39 (90.7)	43 (20.0)	
	26-35	31 (25.4)	91 (74.6)	122 (56.7)	$\chi2 = 13.130$
	>35	21 (42.0)	29 (58.0)	50 (23.3)	0.001
Professional category	Nurse	25 (19.4)	104 (80.6)	129 (60.0)	
	Clinical Officer	10 (25.6)	29 (74.4)	39 (18.1)	$\chi2 = 16.632$
	Medical Officer/ Consultant	9 (31.0)	20 (69.0)	29 (13.5)	0.001
	Pharmacy staff	12 (66.7)	6 (33.3)	18 (8.4)	
Duration of practice (years)	<1	3 (18.8)	13 (81.3)	16 (7.4)	$\chi2 = 1.043$
	1–10	43 (25.6)	125 (74.4)	168 (78.1)	p=0.608
	>10	10 (32.3)	21 (67.7)	31 (14.4)	
Highest level of education	Graduates	24 (36.4)	42 (63.6)	66 (63.6)	$\chi2 = 5.263$
	Diploma	32 (21.5)	117 (78.5)	149 (69.3)	0.028

Table 2. Association between healthcare providers' knowledge and ADR reporting

Healthcare provider factors		Reported ADRs n (%)	Didn't report ADRs n (%)	Total n (%)	Odds Ratio (95% CI)	p-value
Knowledge of the PPB	No	28 (18.2)	126 (81.8)	154 (71.6)	Ref.	p<0.001
	Yes	28 (45.9)	33 (54.1)	61 (28.4)	3.818 (1.995, 7.307)	
Knowledge of the ADR reporting guidelines	No	25 (20.3)	98 (79.7)	123 (57.2)	Ref.	p=0.028
	Yes	31 (33.7)	61 (66.3)	92 (42.8)	1.992 (1.076, 3.689)	
Training on ADR reporting	No	45 (23.2)	149 (76.8)	194 (90.2)	Ref.	p=0.006
	Yes	11 (52.4)	10 (47.6)	21 (9.8)	3.642 (1.453, 9.130)	

of ADR information and feedback from the PPB were added to verify participants knowledge and practice in ADR reporting. The modifications helped to build on the inconclusive data in the literature.

Socio-demographic characteristics, awareness and training were compared between ADR reporters and non-reporters. Data were analysed using Statistical Package for Social Sciences (SPSS) version 23. The Chi-squared test was used to determine the association between independent and dependent variables and Fisher's exact test to determine significance. P-values of <0.05 were considered statistically significant.

Kenyatta University-Ethical Review Committee granted ethical approval, the National Commission for Science, Technology and Innovation authorized the research, and the County Director of Health, Kirinyaga County gave permission for the study.

Results

Of 224 questionnaires distributed 215 (96.0%) were returned. Socio-demographic characteristics of 215 healthcare providers are shown in Table 1 column 5.

Figure 1 shows the proportion of healthcare providers who reported or did not report ADRs to the PPB within the last three months.

Factors affecting ADR reporting

Chi-squared test compared socio-demographic characteristics between reporters and non-reporters. A significant relationship was reported between age, profession and level of education (Table 1).

Respondents were more likely to report ADRs if they were aware of the existence of the PPB, aware of the reporting guidelines or had been trained (Table 2).

Information concerning ADRs caused by new brands was obtained by 93 (43.3%)from continuing medical education and 57(26.5%) from the internet, 28 (13.0%) from a medical representative, 19 (8.8%) from seminars/ conferences and 18 (8.4%) from textbooks.

Table 3 lists barriers to ADR reporting.

Healthcare providers suggested the following strategies to improve reporting:

- Develop a PV centre in the County.
- Devolve functions of the National PV Centre to County level.
- Routine healthcare provider-centred training on ADR reporting.
- Appoint focal PV persons to coordinate PV activities.
- Lobby for prompt feedback from the PPB by improving the communication gap.
- Make ADR forms and guidelines available in all hospital departments.
- Use ADR reporting to appraise performance of healthcare providers.
- Make ADR reporting part of the prescribing standard operating procedures.
- Deploy pharmacists to the wards to assist in ADR identification and reporting.
- Routine patient follow-up to capture ADRs early.

Discussion

This study shows that in a 3-month period 26.0% of healthcare providers reported ADRs. This is greater than that found in the Philippines where, in a 6-month period, 14.0% reported ADRs.[10] This difference could be attributed to differences in the studies such as inclusion of more cadres and the healthcare setting.

The WHO receives at least 200 reports per million population annually from countries with a functional ADR reporting system.[11] Considering 610,411 population in Kirinyaga County the expected rate would

Table 3. Barriers to ADR reporting

Category	Barriers	n (%)
Healthcare provider factors	Not knowing where or to whom to report	40 (18.6)
	Inadequate accesses to ADR report form and guidelines	26 (12.1)
	Perception that no action will be taken	19 (8.8)
	Insufficient time to report/ busy schedules	19 (8.8)
	Managing the patient is more vital	17 (7.9)
	Not sure what caused the ADR	15 (7.0)
Health-system factors	Inadequate training	66 (30.7)
	Delayed feedback	47 (21.9)
	Lack of a PV centre in the County	23 (10.7)
	Understaffing	15 (7.0)

be 122 reports annually translating to at least 10 reports per month. Assuming the sampled healthcare providers reported once within the 3-month period, 56 reports in three months suggests good reporting rates considering it was only a sample population. However, this could be enhanced by filling gaps in reporting.

In this study age, level of education and profession were significantly associated with ADR reporting. A northeast Ethiopian study also reported a significant relationship between profession and reporting,[12] however a comparable Kenyan study reported that socio-demographic factors did not influence reporting.[5] An Ethiopian study conducted among doctors found that sex, work experience and level of education, but not age, significantly affected ADR reporting.[13]

In our study, older healthcare providers reported ADRs more often. This could be because they have a positive perception towards ADR reporting. Pharmacists reported ADRs more than other cadres. The PPB's quarterly PV report also showed that pharmacists submitted most of the ADR reports.[3] Nurses reported ADRs less frequently than other cadres. An Ethiopian study[14] also reported that nurses registered the lowest knowledge and practice score while pharmacists registered the highest. Another Kenyan study revealed that pharmacists accounted for 85.2% of submitted ADRs, while nurses accounted for 3.7%. [4] Pharmacists are more knowledgeable about the ADR system. Respondents with higher educational levels reported ADRs most frequently; a finding similar to that reported by an Ethiopian study.[13]

In our study, 28.4% of healthcare providers were aware of the national PV centre whereas in India 58.67% were aware of it.[8] Not knowing where ADR report forms are submitted nationally would affect reporting and identify poor communication from the national PV Centre.

In our study, 57.2% of healthcare providers were unaware of the ADR reporting guidelines compared to 59.4% in a Nigerian study.[15] This may be the consequence of insufficient promotion of the ADR reporting guidelines and implies that healthcare providers are not educated on the ADR reporting scheme.

The study noted that healthcare providers with knowledge of the ADR reporting guidelines and national PV Centre were twice as likely to report ADRs, a result also found by Necho and Worku.[9] This implies that knowledge on ADR reporting system is a key determinant of ADR reporting.

The majority of healthcare providers, 90.2%, had not been trained on ADR reporting. An Ethiopian study reported a slightly lower figure at 77.6%.[9] This may be because hospital administrations are not prioritizing training. Trained healthcare providers were more likely to report ADRs. Similar findings were reported by other studies.[5,16]

Healthcare provider barriers to ADR reporting were not knowing how to report, inadequate access to ADR forms, insufficient time and perception that no action will be taken. Chief health system barriers were inadequate training and delayed feedback. These findings are in line with studies from India and Ethiopia.[8,9,10,13] To overcome these obstacles, healthcare providers suggested that there should be ADR forms and guidelines available in all hospital departments; routine healthcare provider-centred training on ADR reporting, a PV Centre in the County and lobbying for prompt feedback from the PPB. These are similar to those proven by studies across the globe.[8,9,13,14,15]

A limitation of this study was that only four public hospitals were included.

Conclusion

ADR reporting should be improved; gaps in reporting can

be bridged by creating routine training programmes for healthcare providers, such as online training courses by the PPB and including PV training at higher institutions. Departmental heads should check healthcare providers ADR reporting practices. The County should employ focal PV persons to co-ordinate PV activities and deploy pharmacists to the wards to assist in identification and reporting ADRs. Promoting reporting forms and guidelines, establishing prompt feedback, decentralising roles of the national PV centre and developing a PV centre in the County would enhance ADR reporting. Further research should be conducted to check PV practices and ADR reporting rates after implementing these suggestions. Baseline studies are recommended across all hospitals to harmonise the practice of ADR reporting in the County. Further research is necessary to determine other health system factors to give a more holistic finding on determinants of ADR reporting nationally.

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