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Research Article

Diffusion of Pharmacovigilance in the Eritrean Healthcare System: A Cross-sectional Study

Araya N[1], Yemane D[2], Andegiorgish AK[3], Bahta I[4] and Russom M[5]*

[1]Product Evaluation and Registration Unit, Asmara, Eritrea; [2]Traditional Medicine Control Unit, National Medicines and Food Administration, Asmara, Eritrea; [3]School of Public Health, Asmara College of Health Sciences, Asmara, Eritrea; [4]National Medicines and Food Administration, Asmara, Eritrea; [5]Eritrean Pharmacovigilance Centre, National Medicines and Food Administration, Asmara, Eritrea

ABSTRACT

Background: Taking the overstretched healthcare system, inappropriate prescribing, self-medication seeking behavior, infiltration of substandard and counterfeit medicines in the resource-constrained countries into, having a well-functioning Pharmacovigilance system has paramount importance to ensure patient safety. The aim of this study is therefore to assess the degree and pattern of Pharmacovigilance system diffusion and its barriers in Eritrean healthcare system.

Methods: This is an exploratory cross-sectional study among healthcare professionals from representative health facilities in all administrative regions in Eritrea. Participants were selected using systematic random sampling method. Assisted self-administered questionnaire was used for data collection between June 27 and September 8, 2017. Association among demographic variables, knowledge, attitude and practice of Pharmacovigilance were analyzed. Two-tailed p-value <0.05 was considered statistically significant.

Results: A total of 390 healthcare professionals from 141 health facilities across the country were enrolled in the study. Of the respondents, 90% know what Pharmacovigilance is about and 89% know how to report adverse drug reactions (ADRs). There was a significant difference in knowledge among the professional categories (p<0.001) and their level of education (p=0.002). As the level of education increases, so does the positive attitude towards reporting ADRs in professional practice (p=0.009). About three-fourth (73%) reported that they transfer Pharmacovigilance knowledge to their colleagues. Physicians and Pharmacists were found to be the main players in diffusing the system. Majority of the respondents (72%) encountered patients with ADRs and 64% of them claimed they have reported ADRs. Inadequate knowledge, unavailability of suitable reporting channels and inadequate motivation were the main barriers for those unable to report adverse drugs reactions.

Conclusion: Pharmacovigilance as innovation is highly adopted and diffused in Eritrea with an impressive Knowledge, attitude and practice of healthcare professionals in reporting adverse drug reactions and other related problems. Limited knowledge on how to report ADRs, unavailability of suitable reporting channels and inadequate motivation were, however, the top three ADR reporting barriers identified which could negatively impact the progress of the diffusion process.

Keywords: Pharmacovigilance; Diffusion; Health facilities; Eritrea

Correspondence to: Russom M, Eritrean Pharmacovigilance Centre, National Medicines and Food Administration, Asmara, Eritrea, Tel: +2917197450; E-mail: satiswt@gmail.com

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INTRODUCTION

In many resource-constrained countries, medicines that should be prescribed by physicians and/or other specialists are available without prescriptions [1]. Furthermore, due to shortage of physicians, lower health cadres are also authorized to prescribe medicines that would expose consumers to serious medication errors and other medication related harm. With the support of developmental/funding agencies, new medicines aimed at fighting HIV/AIDS, malaria and multidrug resistant tuberculosis have been used without appropriate safety monitoring [2]. Although this has increased access to life-saving drugs, it has left a huge gap in post-market surveillance [3]. With shortage of essential medicines in these setting, infiltration of substandard and falsified medicines is also very common [4]. This along with the fragmented healthcare system, poor legislation and regulation in many of the resource-constrained countries made post-marketing surveillance a challenge [5,6]. As part of strengthening the regulatory capacity of African countries, the World Health Organization (WHO) established two collaborating centers in Ghana and Morocco in 2009 to provide consultancy and training services in Pharmacovigilance [7]; which is defined as a science and activities related to collection, detection, assessment, understanding and prevention of adverse drug reactions and other drug related problems [8]. With this, many of the African countries joined the WHO program for international drug monitoring in the last decade [9]. For different reasons, the performance of many of the established national centers, however, is inconsistent. As a result, despite the huge African population and inappropriate use of medicines, Africa's contribution on the global adverse drug reaction database is only 1% of the over 18 million reports submitted by all member states [10]. As a relatively new science, Pharmacovigilance might be considered as a new innovation that needs to be adopted or diffused in the healthcare system of a respective country. Thus, the adoption of Pharmacovigilance will not be an easy process, requiring non-stop advocacy programs, sensitization workshops, trainings and systematic approaches. Innovation is an idea, practice, or object that is perceived as new by an individual or other decision-making unit in a social system. Pattern and level of diffusion in a social system is a crucial variable to study, so as to fully understand whether an innovation is a success in a system. The innovation diffusion process normally is a complex chain of processes through which an individual passes from a first knowledge of an innovation, to persuasion in forming an attitude toward the innovation, followed by a decision to adopt or reject, then accordingly implement the new idea once accepted by the individual and finally confirming the implementation of the decision [11]. Eritrea, like many nations, established a Pharmacovigilance Centre to monitor adverse events of healthcare products in the Eritrean market. The Centre since its establishment, in 2012, has been working hard primarily focusing on diffusing the knowledge of Pharmacovigilance to all healthcare professionals in the country. As a result, the Centre has been receiving enormous reports of adverse effects/events and is able to generate several safety signals. Despite all the efforts, the level of diffusion of Pharmacovigilance system in the country is unknown. The aim of this work is therefore to assess the degree and pattern of Pharmacovigilance diffusion process in Eritrea and to assess the knowledge, attitude and practice of healthcare professionals on Pharmacovigilance and identify factors that influence the process.

METHODS

Study design and setting

This was a cross-sectional study that involved healthcare professionals from all hospitals available in all administrative regions of the country and representative samples from Health Centers, Health Stations and community Pharmacies. All health facilities and community pharmacies open to the general public during the study period were considered as sampling frame in this study. The study was conducted between June 27 and September 8, 2017.

Study population

All healthcare professionals in the country excluding administrative and laboratory personnel had equal chance to participate in the study. Thus, healthcare professionals working at all levels of health facilities, regardless of their educational level, were randomly selected and enrolled into the study.

Sampling design and sample size determination

A two-stage sampling was used to calculate the sample size that represents health facilities and healthcare professionals in Eritrea. Initially, total numbers of health facilities which are open to the general public and healthcare professionals in all administrative zones were identified from the national Health Management Information System (HMIS), Ministry of Health (2016) with their distribution across the country. According to the HMIS report, there were a total of 45 community Pharmacies and 276 health facilities that comprise: referral hospitals (n=9), intermediate hospitals (n=8), community hospitals (n=14), health centres (n=55) and health stations (n=190). Sampling of health facilities was done in a systematic way to ensure that the findings would be representative of the country. Sample of health facilities was determined using the formula. $n=z^2$ (deff) $(q)/v^2p$ [12], where n is sample size of health facilities, p is proportion of facilities with the attribute of interest q is 1-p, deff is design effect, v^2 is the relative variance (square of the relative error) and Z^2 is the square of the normal deviate (1.96). Assuming deff=1.5, v=0.2, and p=0.5 gives 144 health facilities. At the second stage, 390 representatives of all categories of health professionals were selected using a systematic random sampling proportional to the size of professional category.

Data collection approach

At every health facility, a representative sample of all the selected professional categories was randomly selected. Assisted self-administered questionnaire was provided to all healthcare professionals consented to participate in the study. Professionals' background characteristics, knowledge, attitude and practice on Pharmacovigilance including its definition, scope, what to report, how to report, where to report, reporting practices, importance of safety monitoring, habits on transfer of knowledge to consumers and colleagues, barriers for reporting and so on were included in the questionnaire. Assistance was also provided for those requiring clarifications on some questions.

Statistical analysis

Data input was performed using CSPro Version 7 software and was exported to SPSS statistical package version 20 (SPSS Inc., Chicago, IL, USA) for analysis. Descriptive background characteristics of study participants and their knowledge, attitude and practices on

Pharmacovigilance were presented using proportions and tables. The relationship between each factor of interest and the knowledge of participants on ADR reporting was explored by percent (%) or χ^2 tests (for categorical variables) using SPSS. Two-tailed p-value (<0.05) was considered statistically significant.

Ethical considerations

Ethical approval was obtained from the Health Research Ethics and Protocol Review Committee of the Ministry of Health, Asmara, Eritrea. Approval letter was obtained from the Zonal Medical Officers of the respective Administrative Zones. Medical Directors of selected health facilities were also briefed on the objectives of the study and written consent was obtained from each of the interviewed healthcare professional.

RESULTS

A total of 390 healthcare professionals from 141 health facilities (208 from hospitals, 102 from health centers, 56 from health stations and the rest from Pharmacy retail outlets) across the country were enrolled in the study. The respondents were slightly dominated by males (64.1%). The overall median work experience of the study participants was five years (IQR: 6). Majority of the respondents were nurse practitioners (55.4%) followed by Pharmacy professionals (24.9%) and Medical Doctors (16.9%). Of which, 43.6% were first degree holders and above (Table 1).

Of the respondents, 89.5% know the scope, goals and objectives of Pharmacovigilance and of whom, 89.1% know how to report adverse effects/events related to medicines and other related products (Table 2). Knowledge of Pharmacovigilance was positively associated with respondents' professional categories (p<0.001) and higher level of education (p=0.002) (Tables 2 and 3). Moreover, a significant association (p<0.001) on knowledge of ADR reporting was noted among professional categories with higher level of education compared to those with lower educational level (Table 2).

The main source of Pharmacovigilance knowledge was found to be from the basic Pharmacovigilance training organized by the Eritrean Pharmacovigilance Centre (66.8%) and followed by colleagues (36.4%) and academic classes (29.8%). Almost all of the respondents (98%) believe that Pharmacovigilance is relevant to their professional practice and 91% believe that reporting ADRs do not negatively affect their professional practice. It was observed that, as the level of education increases so does the positive attitude towards the effect of reporting ADRs in professional practice (p=0.009) (Table 3).

However, there was no statistically significant difference among the professional categories (p=0.054). Almost all the respondents (99.7%) believe that reporting ADRs contribute to patients' safety. Analysis has shown that, overall knowledge and attitude of participants on Pharmacovigilance were not associated with sex and years of work experience. More than two-third (71.8%) of the respondents reported that they have encountered consumers with ADRs. Medical Doctors encountered ADRs more frequently compared to other professional categories, and the difference was statistically significant (p<0.001). Similarly, a significant difference (p<0.001) was noted in the level of education, with the degree holders having the highest encounter (87.6%) followed by Diploma (67%) and Certificates (44.6%). Sixty-four percent of the respondents claimed to have reported ADRs to the National Pharmacovigilance Centre, and there was no statistically significant difference in practice of ADR reporting among all educational levels (p=0.59) (Table 3).

Around three-fourth of the respondents (72.9%) reported that they transfer their Pharmacovigilance knowledge to their colleagues. Whereas, 81.2% of the respondents claimed that they transfer

Table 1: Background characteristics of study participants

Sl. No.	Identifiers			Questionnaire Distribution	
				n=390	%
1.	Gender		Male	250	64.1
			Female	140	35.9
2.	Type of Health Facility		Referral Hospital	95	24.4
			Intermediate Hospital	56	14.4
			Community Hospital	58	14.9
			Health Center	102	26.2
			Health Station	56	14.4
			Pharmacy	23	5.9
3.	Professional Category		Medical Doctors	66	16.9
		Pharmacy Professionals	Pharmacists	39	10
			Pharmacy Technicians	58	14.9
		Nurse Practitioners	BSN	56	14.4
			Midwife	51	13.1
			Registered Nurse	16	4.1
			Associate Nurse	93	23.8
			Nurse Anesthesia	6	1.5
		Others	Ophthalmic officer	3	0.8
4.	Level of Education		First Degree and above	170	43.6
			Diploma	130	33.3
			Certificate	90	23.1

Table 2: Summary of associations of knowledge, attitude and practice of healthcare professionals and their professional category

Sl. No.	Indicators	Mean (%)	Medical Doctors (%)	Pharmacy Professionals (%)	Nurse Practitioners (%)	χ^2-value (%)	*p*-value (%)
1	Know about Pharmacovigilance	89.5	100	98.9	82.9	21.43	0.001
2	Know how to report ADRs	89.1	97	95.6	83.6	13.71	0.001
3	Claimed to report ADRs	63.3	70.8	67.2	58.6	3.03	0.22
4	Transfer Pv knowledge to colleagues	72.9	76.9	71.6	73.4	0.55	0.758
5	Transfer Pv knowledge to consumers	76.5	68.2	80.9	89.1	14.49	0.001
6	Had a belief that reporting negatively influence their practice	8.6	1.5	8.7	11.3	5.82	0.054

Pharmacy professionals-includes Pharmacists and Pharmacy Technicians
Nurse practitioners-includes Nursing degree, Registered Nurses, Midwifes and Health Assistants
ADRs: adverse drug reaction; Pv: Pharmacovigilance

Table 3: Summary of associations of knowledge, attitude and practice of healthcare professionals and their level of education.

	Indicators	Mean (%)	Degree & above (%)	Diploma (%)	Certificate (%)	χ^2-value	*p*-value
1	Know about Pharmacovigilance	89.5	95.3	86.9	82.2	12.05	0.002
2	Know how to report ADRs	89.1	93.2	87.7	82.5	5.85	0.054
3	Claimed to report ADRs	63.3	67.4	65.3	45.5	5.67	0.59
4	Transfer Pv knowledge to colleagues	72.9	73.4	75	68.2	0.99	0.606
5	Transfer Pv knowledge to consumers	76.5	70.9	91.4	89.4	21.07	0.001
6	Had a believe that reporting negatively influence their practice	8.6	4.3	9.9	16.2	9.34	0.009

ADRs: Adverse drug reactions; Pv: Pharmacovigilance

their Pharmacovigilance knowledge to consumers. Higher level of transferring Pharmacovigilance knowledge to consumers was obtained from lower health cadres compared to other professional categories (p=0.001) (Table 2).

About one-third of the respondents were not reporting ADRs they encountered. Limited knowledge on how to report ADRs followed by unavailability of suitable reporting channels and inadequate motivation were the top three ADR reporting barriers identified in this study. Neither sex or educational level nor years of working experience were found to have association with the barriers. Compared to other professional categories, majority of those who did not know how to report ADRs were nurse practitioners (p=0.015) and those with lower educational levels (p=0.054) (Tables 2 and 3).

DISCUSSION

In this study, the knowledge and practice of Pharmacovigilance was found to be highly diffused in the Eritrean healthcare system. This finding is however inconsistent with the findings of similar studies conducted elsewhere which reported poor knowledge [13-17] and practice [18] of Pharmacovigilance among healthcare professionals. The high level of knowledge and practice of Pharmacovigilance among healthcare professionals in Eritrea can be learned from the theory of innovation diffusion process [11]. Pharmacovigilance, as a new idea to the healthcare system, can be regarded as an innovation; hence, the process in the theory can be applicable to explain the diffusion process.

The training offered by the Eritrean Pharmacovigilance Centre was found to be the main and most effective source of Pharmacovigilance knowledge. Besides, the contribution of healthcare professionals in transferring their knowledge to colleagues and academic classes were also found to be commendable. In diffusion of an innovation, developing a positive attitude is the key step in persuasion [11]; not only to an individual but also to an institution and ultimately to the whole system. The high level of positive attitude towards Pharmacovigilance reflected in most of the study participants showed that the persuasion stage was successful. The high transfer of knowledge among colleagues reported in this study played a substantial role in diffusing Pharmacovigilance knowledge in Eritrea and maximizing the reporting rate of ADRs; indicating their commitment towards patient safety. This also shows that Pharmacovigilance is highly accepted as innovation in Eritrea. As high level of Pharmacovigilance knowledge and practice (reporting ADRs and transfer of knowledge to colleagues) was reported in those with higher education, especially Physicians and Pharmacists, they are considered as the main catalysts to speed up the Pharmacovigilance innovation process in the Eritrean healthcare system. This could help the Pharmacovigilance activities to be a norm and be accepted by the lower level health cadres in health facilities.

It is however imperative to ask why such significant difference

in Pharmacovigilance knowledge and practice is documented among professional categories and level of education. This might be explained by the fact that Pharmacovigilance is integrated into the undergraduate curriculum of the school of Pharmacy and all medical doctors have been trained for four days right after completion of their studies by the Eritrean Pharmacovigilance Centre. Similar initiatives have been done to the other healthcare professionals but it was not inclusive due to their large number. Thus, some of them have been trained by their colleagues which might not be as equally significant as that of the training offered by the Centre. The difference in educational level and capacity might also have had an impact in understanding and practicing Pharmacovigilance. For instance, the rate of ADR encounter was higher within medical doctors and degree holders compared to the lower level health cadres which are likely due to their inadequate ability in diagnosing or recognizing patients with ADRs, The substantial number of healthcare professionals involved in reporting ADRs, the positive attitude reflected by almost all the study participants and the huge knowledge transfer to colleagues and consumers showed their decision to adopt and implement the Pharmacovigilance system as innovation.

Considering the short years of experience of the program, the rate of Pharmacovigilance system adoption in Eritrea was found to be remarkable. The annual 'Pharmacovigilante award' for best reporters, the quick feedback to reporters, availability of focal persons in health facilities, integration of Pharmacovigilance in public health programs and academia (school of Pharmacy) could be the possible factors that speed up the rate of diffusion of Pharmacovigilance in Eritrea. Moreover, the impact of safety signals detected by the Centre, the extensive and well-organized basic and advanced Pharmacovigilance courses that have been offered as well as the intensive Pharmacovigilance advocacy programs might also have positively affected the rate of diffusion. This however, requires further studies to exactly identify the factors that positively influence the diffusion process.

However, there were some factors like limited knowledge on how to report ADRs (especially in nurse practitioners), unavailability of suitable reporting channels and inadequate motivation that are found to negatively impact the diffusion process of Pharmacovigilance in the Eritrean Healthcare system. This is more or less consistent with findings reported elsewhere [18,19]; while Barbara 2010 [20] reported entirely different barriers for ADR reporting in the South East European region. During the study period, adverse effects/events related to medicines, vaccines and other xenobiotics are being submitted to the Eritrean Pharmacovigilance Centre *via* Pharmacovigilance focal points in health facilities, postage (usually free of charge), Zonal Pharmacy services and/or directly (in person) to the Eritrean Pharmacovigilance Centre. Such reporting systems create inconvenience the reporters, affect the reporting timelines and sometimes cause reports to be lost on the way.

CONCLUSION

This study concluded that Pharmacovigilance as innovation is well adopted and highly diffused in the Eritrean healthcare system. Physicians and Pharmacists are found to be the drivers in transferring the knowledge and practice of Pharmacovigilance to their colleagues. Limited knowledge on how to report ADRs (especially in nurse practitioners), unavailability of suitable reporting channels and inadequate motivation were, however, identified as barriers for the diffusion process. This urges the National Medicines and Food Administration to introduce a digitalized reporting system (preferably free SMS) in Eritrea to ease and speed up the communication process. Moreover, efforts should be made to train the unreached nurse practitioners and other paramedics to augment the existing good Pharmacovigilance practice in Eritrea

AVAILABILITY OF DATA AND MATERIAL

Data used for this study can be available from the corresponding author on official reasonable request

COMPETING INTERESTS

The authors declare that they have no competing interests.

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AUTHORS CONTRIBUTION

The study was conceived by NA and DY. All the authors then designed the study and data was collected by all authors and other research assistants and analyzed by AKA. MR, NA, DY and AKA drafted the manuscript and edited by IB. All authors then proof read and gave their consent for publication.

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REFERENCES

1. Cockburn R, Newton PN, Agyarko EK, Akunyili D, White NJ. The global threat of counterfeit drugs: why industry and governments must communicate the dangers. Plos Med. 2005;2:100.
2. Olsson S, Pal SN, Dodoo A. Pharmacovigilance in resource-limited countries. Expert Rev Clin Phar. 2015;8:449-460.
3. Pirmohamed M, Atuah KN, Dodoo AN, Winstanley P. Pharmacovigilance in developing countries. BMJ 2007;335:462.
4. World Health Organization. A study on the public health and socioeconomic impact of substandard and falsified medical products. 2017.
5. Isah AO, Pal SN, Olsson S, Dodoo A, Bencheikh RS. Specific features of medicines safety and pharmacovigilance in Africa. Ther Adv Drug Saf. 2012;3(1):25-34.
6. Smith F. Drug use in sub-Saharan Africa: quality in processes—safety in use. BMJ Quality & Safety. 2003;12:164.
7. Dodoo AN, Ampadu HH. Pharmacovigilance in Africa. Mann's Pharmacovigilance. 2014:299-301.
8. World Health Organization. International drug monitoring: the role of national centres, report of a WHO meeting. Geneva, 1972.
9. Ampadu HH, Hoekman J, de Bruin ML, Pal SN, Olsson S, Sartori D, et al. Adverse drug reaction reporting in Africa and a comparison of individual case safety report characteristics between Africa and the rest of the world: analyses of spontaneous reports in VigiBase®. Drug Saf. 2016;39:335-45
10. Uppsala Monitoring Centre. WHO global individual case safety reports database.

11. James W. Dearing. Applying Diffusion of Innovation Theory to Intervention Development (2009). Res Soc Work Pract. 19(5): 503–518.

12. Daniel W. Biostatistics: A Foundation for Analysis in the Health Sciences, 7th (edn) R Wiley, New York, 1999.

13. Abubakar AR, Simbak NB, Haque M. A systematic review of knowledge, attitude and practice on adverse drug reactions and pharmacovigilance among doctors. J Appl Pharm Sci. 2014;4:117-127.

14. Mulatu WN, Worku A. Assessment of knowledge, attitude and practice of health professionals towards adverse drug reaction reporting and factors associated with reporting. J Pharmacovigil. 2014.

15. Alsaleh FM, Alzaid SW, Abahussain EA, Bayoud T, Lemay J. Knowledge, attitude and practices of pharmacovigilance and adverse drug reaction reporting among pharmacists working in secondary and tertiary governmental hospitals in Kuwait. Saudi Pharm J. 2017;25:830-7

16. Datta S, Sengupta S. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting in a tertiary care teaching hospital of Sikkim. Perspect Clin Res. 2015;6:200.

17. Saleh HA, Figueras A, Fourrier-Réglat A. Knowledge, attitude and practice of health professionals towards adverse drug reactions reporting. 2016.

18. Ganesan S, Vikneswaran G, Reddy KC, Subrahmanyam D, Adithan C. A Survey on Knowledge, Attitude and Practice of Pharmacovigilance towards Adverse drug reactions reporting among Doctors and Nurses in a Tertiary Care Hospital in South India. J Young Pharm. 2016;8:471-6.

19. Vallano A, Cereza G, Pedròs C, Agustí A, Danés I, Aguilera C, et al. Obstacles and solutions for spontaneous reporting of adverse drug reactions in the hospital. Brit J Clin Pharmaco. 2005;60:653-658.

20. Kozamernik B. Spontaneous adverse drug reaction reporting: attitudes and practice of health care professionals and distributors in South East European region. Farm Vestn. 2010;61:271-281.