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TOWARDS ACTUALIZATION OF PHARMACOVIGILANCE IN ERITREA

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ABSTRACT

An adverse drug reaction is a noxious and unintended response to a drug. It occurs at doses normally used in human for the prophylaxis, diagnosis or therapy of a disease, or for modification of physiological function. ADRS are a major cause of morbidity and mortality worldwide. They are responsible for complicating 5%-15% of therapeutic drug courses. The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem is called "Pharmacovigilance". The Objectives of the present work includes: elucidating the historical and scientific necessity of International and National Pharmacovigilance Centers, assessing awareness of health Practitioners in the different hospitals in Asmara towards ADRs reporting and monitoring, and assessing the current situation of Eritrean Pharmacovigilance Center. Methodologically, the study comprises reviewing international and national experiences for building up pharmacovigilance systems, as well as a cross sectional study, designed to assess current situation of Eritrean National Pharmacovigilance Center. The data was collected by employing pre-coded questionnaire and interviewing an ENPC representative. Results showed that only 38.7% of the respondents were aware of existence of the ENPC and that 29% of the respondents were not aware of the possible incidence of adverse drug reactions. The study also showed that while only 9.7% of the respondents had reported suspected ADR to the ENPC, no one of them did receive any feedback from the center. In conclusion, the performed survey showed under reporting of ADRs, the matter which may be attributed to not knowing the process of reporting, not knowing the ENPC as a center, lack of knowledge about ADRs…etc. Accordingly, actualizing Pharmacovigilance activity in Eritrea is representing an urgent need.

KEYWORDS

Physiological function, Pharmacovigilance and Adverse drug reaction.

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INTRODUCTION

While all medications provide tremendous benefits to the society, yet they also have the potential of producing unwanted or adverse effect. (Adverse drug reaction)[1].

An adverse drug reaction is a noxious and unintended response to a drug. It occurs at doses normally used in human for the prophylaxis,

diagnosis or therapy of disease, or for modification of a physiological function[2].

The most predisposing factors for adverse drug reactions are age, concurrent medicines, duration of therapy, gender, genetics, comorbide conditions, narrowness of therapeutic index of some drugs and pharmaceutical factors[3].

Adverse drug reactions are a major cause of morbidity and mortality worldwide. They are responsible for complicating five to fifteen percent of therapeutic drug courses[4]. The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem is called "Pharmacovigilance".

Adverse Drug Reactions monitoring is a process that facilitates collection of unbiased safety data observed during clinical practice in 'real life' circumstances.

The main objectives of adverse drug reactions monitoring are[5]:-

- To detect the nature and frequency of ADRs, including periodic re-evaluation of the benefit-risk ratio of medicinal products in order to assist the drug regulatory authority, public health programs, scientists and consumer societies to take appropriate action to minimize risks of ADRs to consumers.
- To identify risk factors that may predispose, induce or influence the development, severity and incidence of adverse reactions in the population.

The WHO program for International Drug Monitoring was set up in 1968 as a consequence of the so-called thalidomide tragedy. The WHO Program for International Drug Monitoring has grown to become a global network of pharmacovigilance centers. As of January 2011 report, 104 countries had joined the WHO Drug Monitoring Program, and in addition, 30 associate members including Eritrea were awaiting compatibility between the national and international reporting formats[6].

The network of national centers is coordinated by a WHO Collaborating Centre for International Drug Monitoring in Uppsala in Sweden. This centre is usually called the Uppsala Monitoring Centre or the UMC. The UMC is a foundation created by the Swedish government on the basis of an agreement between Sweden and WHO. According to that agreement WHO headquarters is responsible for all policy issues relating to the WHO Program.

The UMC manages a database of Individual Case Safety Reports (ICSRs) (Figure No.1) received from the national centers in the WHO network. The database, called VigiBase, currently contains over four million descriptions of individual cases in which medicines, including vaccines and biologicals, have been suspected of contributing to an adverse reaction in the exposed patient [6]. Functions of the WHO (Uppsala's Monitoring Center (UMC)) concerning International drug monitoring are illustrated in the associated figure. The functions include providing the following:

- Access to VigiBase using the VigiSearch tool (N.B VigiBase is global individual case safety report (ICSR) database).
- Information about potential safety hazards: Signal document and VigiMine (VigiMine is a searching tool).
- Terminologies and software: WHO Drug Dictionary, WHO-Adverse Reaction Terminology and VigiFlow (see figure below).
- Access to the international network: Vigimed (Vigimed is an e-mail distribution list set up by the UMC to stimulate discussions, meetings and courses)[5,6].

Countries that are members of the UMC should fulfill the following requirements[6]:

- Reporting format compatibility and report quality; ICSRs submitted to the UMC should comply with the ICH-E2B format.
- Frequent submission of ICSRs; Member countries are expected to submit ICSRs to the UMC on a regular basis; at least every quarter.
- Drug formulary of each membership as a reliable reference of drug information.
- Active participation; Member countries should also send at least one delegate to the National Centers Annual Meeting.

As regarding the situation in Eritrea, the department of Regulatory Service created the development of an adverse drug reaction monitoring (Pharmacovigilance) system as one of its key activities and started planning for it in 2001. According to the manual of Eritrean Pharmacovigilance, the Eritrean National Pharmacovigilance Center (ENPC) is located at the Pharmaceutical Information Unit, Division of Medicines Control, Department of Regulatory Services at Ministry of Health, Asmara, Eritrea. However, this center is not settled till now as a unique center, it is currently under the supervision of the Drug information unit[7]. The activity of the Pharmacovigilance work is done up till now by one person, however information has been given to us that the pharmacovigilance activity will be more vitalized in the very near future.

Accordingly, the objectives of the present study include

Elucidating the historical and scientific necessity of International and National Pharmacovigilance Centers, as has been shown in the introductory part. In addition, the study aims at assessing awareness of health practitioners found in five selected hospitals in Asmara, towards Adverse Drug Reaction (ADR) reporting and monitoring, as well as assessing the current situation of Eritrean Pharmacovigilance center.

METHODOLOGY

Study Design

This study was performed as a cross sectional assessment by employing close-ended questionnaire and interviewing ENPC representative. The questionnaire was entitled ‘‘Assessing Conditions of Reporting Adverse Drug Reactions (ADRs) by Heath Practitioners ’’. It consisted of two parts; the first part is information about demographic data (sex, profession, years of experience and working place) of the respondents, and the second part contains questions about reporting condition of ADRs by the health professionals. These questions were designed to get information about knowing the existence of ENPC, suspicion of incidence of ADRs, reporting of ADRs, factors which discourage from reporting, conditions of feedback from ENPC, and others. The collected data was analyzed using SPSS and Microsoft Excel software.

Study Population

The population in this study includes Physicians, Pharmacists, Pharmacy technicians, Nurses (BSN and Registered Nurses), Health assistants (H.A), Anesthetists and Ophthalmic officers, who were currently working in the selected hospitals in Asmara.

Study sites

Five hospitals were selected to perform the present study, namely Halibet, Saint Mary (Psychiatric), Birhan Aeyni (Ophthalmic), Orotta (pediatric) and Mekanehiwet (Maternity) hospitals.

Sample Size

In the present study, 177 health practitioners were selected from the total 661 health practitioners found in those five selected hospitals using stratified random sampling method, according to the following formula.

$$N = \frac{Z^2_{\alpha/2}\, P\,(1-P)}{E^2}$$

Where, N is sample size, while $Z^2_{\alpha/2}$ (i.e. value of the significance level) = 1.96, as it is taken to be 95% significance level, while P (i.e. expected proportion) = 0.08% and E (i.e. precision) = 0.0286.

Ethical Considerations

This research was approved by the ethical committee of the Asmara College of Health Sciences (ACHS). In addition to this, consent was asked to every subject participated in the questioner in a written form.

Frequency of the selected samples and frequency of the samples who respond to the questionnaire in each hospital is shown in Table No.1, and frequency of the different professionals, who respond to the questionnaire, from the five hospitals, is shown in Table No.2.

RESULTS

The obtained results concerning awareness of the existence of ENPC, suspicion in existence of ADRs, frequency of reporting as well as the frequency of

feedback from the ENPC are illustrated in Table No.3, 4, 5 and 6 respectively.

DISCUSSION

Only 38.7% of the respondents were aware of existence of the ENPC. On the other hand, 29% of the respondents were not aware of the possible incidence of adverse drug reactions. Although only 9.7% of the respondents had reported suspected ADR to the ENPC, none of them did receive feedback from ENPC.

The factors which discourage the practitioners from reporting include not knowing the process of reporting, not knowing the ENPC as a center, lack of knowledge about ADRs…etc. It is a satisfactory experience in the present work that, 91.4% of the responders agreed that ADRs reporting is a professional obligation**.** Results of overall evaluation of ADR monitoring and reporting in Eritrea by the practitioners showed 3.2% of the respondents evaluate it as very good, 11.8% evaluate it as good, 18.3% evaluate it as poor and 11.8% evaluate it as very poor, while the remaining 54% of the respondents said, ‘‘we do not know that ENPC exists.

Table No.1: Frequency of the selected samples and frequency of the samples who respond

S.No	Hospital Name	Number of Samples of Health practitioners	Number of respondents
1	Saint Mary Psychiatric hospital	10	6
2	Orotta Pediatric Hospital	43	16
3	Birhan Aeyni Ophthalmic Hospital	23	13
4	Mekane Hiwet-Maternity Hospital	13	13
5	Halibet Hospital	88	45
Total		177	93 (52.54 %)

Table No.2: Frequency of the different health professionals who respond, from the five hospitals

S.No	Profession of the health practitioners	Frequency
1	Physicians	12
2	Pharmacists	4
3	BSN Nurses	15
4	Others (Pharmacy tech, Registered Nurses, H.A, Ophthalmic officers)	62
Total		93

Table No.3: Frequency of the health practitioners in awareness of the existence of ENPC

S.No	Profession of the health practitioner	Awareness of the existence of the ENPC		Total
		Yes	No	
1	Physician	3	9	12
2	Pharmacist	4	0	4
3	Nurse (BSN)	5	10	15
4	Other	24	38	62
Total		36	57	93

Table No.4: Frequency of health practitioners in suspecting incidence of ADRs

S.No	Profession of the health practitioner	Suspecting ADR		Total
		Yes	No	
1	Physician	10	2	12
2	Pharmacist	2	2	4
3	Nurse (BSN)	13	2	15
4	Other	41	21	62
Total		66	27	93

Table No.5: Frequency of the health practitioners on reporting ADRs

S.No	Report ADR	Frequency	Percent (%)
1	Yes	9	9.7%
2	No	84	90.3%
Total		93	100%

Table No.6: Frequency of feedback from ENPC to the reported ADRs

S.No	Health practitioners Receiving feedback	Frequency	Percent (%)
1	Yes	0	0 %
2	No	9	100 %
3	Total	9	100 %

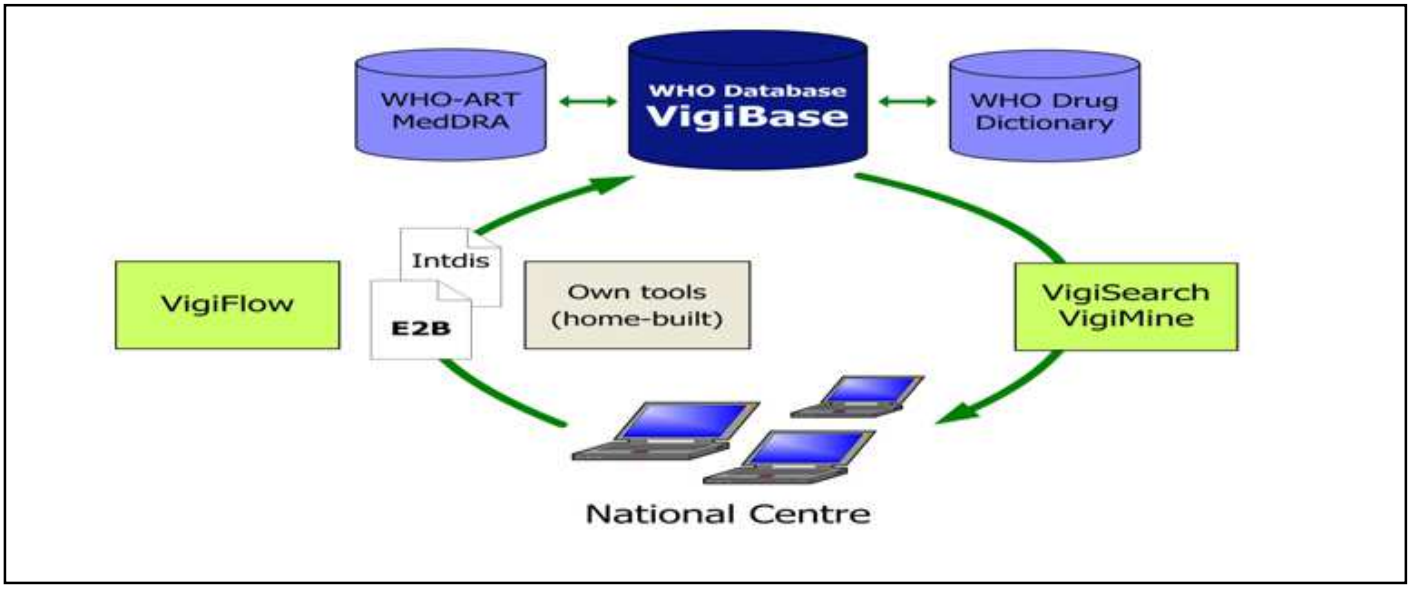

Figure No.1: UMC manages a database of Individual Case Safety Reports (ICSRs)

CONCLUSION

The performed study showed under reporting of ADRs, the matter which may be attributed to not knowing the process of reporting, not knowing the ENPC as a center, lack of knowledge about ADRs…etc. It is expected that the pharmacovigilance activity in Eritrea will be much more developed when the predicted vitalization of the pharmacovigilance center in the ministry of health will be completed. Accordingly, based on the obtained results from the present study, the issue of the national pharmacovigilance center in Eritrea requires urgent analysis and reorganization.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

BIBLIOGRAPHY

1. Remington: The Science and Practice of Pharmacy, *Lippincott Williams and Wilkins*, 21st edition, 2005, 1220-1222.
2. Edwards R I, Aronson J K, Pearson T F *et al*. Adverse Drug reactions: definitions, diagnosis, and management, *The Lancet,* 356, 2000, 255-59.
3. Pirmohamed M, James S, Meakin S *et al*. A Spoonful of Sugar: Medicines Management in NHS Hospitals, HNR2623 Audit Commission Publications, December 2001. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients, *BMJ*, 329, 2004, 15-9.
4. Marc A. Riedl and Adrian M. Casillas. Adverse Drug Reactions: Types and Treatment Options, University of California, Los Angeles, David Geffen School of Medicine, Los Angeles.
5. TFDA January 2006. Guideline for Monitoring and Reporting Adverse Drug Reactions (ADRs) Tanzania Food, Drugs and Cosmetics Act, 2003.
6. Uppsala Monitoring Centre WHO Collaborating Centre for International Drug Monitoring. Uppsala Monitoring Centre, February 2009, http://www.who- umc.org/graphics/22202.
7. Eritrean Manual of pharmacovigilance, 1st Edition, Ministry of Health, January 2004/10.