Knowledge And Practice Of Healthcare Workers Regarding The Use Of Medicine Safety Surveillance Tools In A Primary Healthcare Setting

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ABSTRACT

Despite the implementation of pharmacovigilance centers in developing countries and the institution of Therapeutic Committees at different healthcare delivery levels, the use of official medicine safety surveillance tools among healthcare workers is not widespread. In order to provide evidence on the knowledge and practice of healthcare professionals in the public sector on the use of medicine safety reporting tools, a cross-sectional survey using a self-administered questionnaire to assess the use of medicine safety surveillance tools amongst healthcare workers in Eenhana State Hospital was carried out. Data from the questionnaires were entered into the statistical package Epi Info® version 7 for analysis. About fifty percent of the healthcare workers in this study have identified at least one adverse drug reaction (ADR) in their professional practice. In contrast, only 29% reported ADR using at least one officially prescribed medicine safety reporting tool. The nursing cadre seems to have the least knowledge of medicine safety surveillance tools and pharmacovigilance practice. Pre-registration healthcare workers and continuing professional training for registered healthcare workers must be strengthened to encourage the use of medicines safety surveillance tools, in particular, and pharmacovigilance, in general.

KEYWORDS: Healthcare Workers, Medicines Safety Surveillance Tools, Namibia, Pharmacovigilance.

1. INTRODUCTION

Pharmacovigilance (PV) is defined as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects of drugs or any other drug-related problem” [1]. In 1968, the 16th World Health Assembly resolution called for “a systematic collection of information on serious adverse drug reactions during the development, particularly after medicines have been made available for public use”, which led to the formation of the WHO Program for International Drug Monitoring after which WHO-Uppsala Monitoring Centre (UMC) was established in Sweden in 1978 [2].

In order to achieve the goals of pharmacovigilance, different tools were developed by pharmacovigilance centers to capture reported or identified medicine safety issues such as adverse drugs reactions (ADR); in Namibia, the Ministry of Health and Social Services (MoHSS) through Therapeutic Information and Pharmacovigilance Centre has made available tools for medicine safety reporting by healthcare professionals, which include Individual Case Safety Reporting (ICSR) form also referred to as Yellow form, medication error reporting form, and product quality reporting form [3]. These tools have been designed in compliance with World Health Organisation Uppsala Monitoring Centre (WHO-UMC) guidance.

Under-reporting adverse drug events (ADE) is a major global public health problem. Some ADEs have alluded to the periodic introduction of new medicines or drug molecules [4–6]. ADEs are medication use issues, including abnormal laboratory results, ADR, medication errors etc. [7]. Over the last two decades, there has been enhanced local and international funding for expanded antiretroviral (ARV) and tuberculosis (TB) treatment programs in Namibia, resulting in a better understanding of the burden of ADRs developed by patients. As new essential medicines are registered by Namibia Medicines Regulatory Council (NMRC), particularly life-saving medicines such as antiretrovirals and antituberculotics, spontaneous reporting becomes important for ADR signal generation.

Post-marketing surveillance assists in generating a safety profile of medicine during its life cycle since it is not possible to identify all adverse drug reactions of medicine before regulatory approval [8]. Data gathered through such surveillance systems are aggregated by national pharmacovigilance centers (NPC) into a national medicine safety database and analyzed

periodically before being entered into the VigiBase, a pharmacovigilance database at WHO-UMC in Sweden. Based on information generated through pharmacovigilance, appropriate action can be taken when enough safety signal has been developed with respect to the suspected medicine by regulatory bodies, which may take the form of an educational intervention or regulatory actions, including a product recall or revision of safety information on the package insert and label [9].

This study aims to understand the use of medicine safety reporting tools in the public sector amongst healthcare professionals. This study will also provide evidence of the knowledge of medicine safety reporting tools among healthcare workers (HCWs) in the public sector. It might improve understanding of possible barriers to the use of medicine safety surveillance tools by HCWs at the point of service.

2. METHOD(S)

2.1. DESIGN AND SETTING

Between October and November 2020, a cross-sectional survey was carried out among healthcare workers working in public healthcare facilities in Namibia. A self-administered questionnaire was adapted from previous studies that assessed healthcare workers' knowledge, attitude and practices. Namibia has a total of 14 regions consisting of various districts. Ohangwena region, a region in north-western Namibia, has an estimated population of 281,358, which comprise Engela district (62.3%), Eenhana district (26.5%) and Okongo districts (11.2%). Healthcare workers at Eenhana Regional Hospital were included in the study.

2.2. POPULATION AND SAMPLING

The study population included all current healthcare professionals at Eenhana State Hospital. The sample size for the study was determined using the Epi info 7 sample size calculator. The estimated population of healthcare professionals was entered into the sample size calculator at a 95% confidence level and a 5% margin of error, yielding a sample size of approximately 137 HCWs. The target population was medical doctors, pharmacists, pharmacist assistants and registered and enrolled nurses in Eenhana District Hospital, and the study's convenience sampling method was employed. However, due to the ongoing COVID-19 pandemic, only 62 HCWs participated in the study.

2.3. PROCEDURE

The research instrument comprised 3 sections: (1) demographics of the respondents; (2) knowledge of healthcare workers about pharmacovigilance/ADR reporting and the use of medicines safety surveillance tools (3) practice of ADE reporting by using designated medicines safety surveillance tools.

2.4. DATA COLLECTION

The questionnaire was pretested amongst ten (10) healthcare professionals at Eenhana State Hospital. Healthcare workers who met the inclusion criteria that verbally consented were administered the questionnaire during a pre-arranged appointment with the HCW. A final pretested questionnaire was administered to consented respondents.

2.5. DATA ANALYSIS

Epi-Info® version 7 software was used for data analyses; paper-based questionnaire data were entered manually. Descriptive analyses such as percentages were performed on responses to the questionnaire, including sample characteristics and questionnaire items.

2.6. ETHICAL CONSIDERATION

The Namibian Ministry of Health Ethics Committee approved the study before data collection commenced. Participants' consent was sought after the purpose of the research was explained to them and that participation is voluntary. No personal information of the participants linking them to the questionnaire was collected.

3. RESULTS

The questionnaire was administered to seventy-five (75) healthcare professionals, and sixty-two (62) completed the questionnaire giving a response rate of 82.7%. The nursing cadre made up a majority of the participants (71.0%) (Table 1).

3.1. KNOWLEDGE OF HEALTHCARE WORKERS REGARDING IDENTIFICATION, RECORDING, AND REPORTING OF ADEs WITH MEDICINE SAFETY REPORTING TOOLS

Less than 40% of the healthcare workers in this study believed all categories should report ADEs identified during their daily routines. About 80% of the pharmacy cadre were able to identify TIPC, compared to only 9.1% of the participants from the nursing cadre.

Table 1: Demographic characteristics of healthcare workers.

Demographic variables	Categories	N = 62 (%)
Age, years categorized	20 - 29	25 (40.3)
	30 - 39	21 (33.9)
	40 - 49	10 (16.1)
	50 - 59	6 (9.7)
Years of practice	1 - 9	18 (29.0)
	10 - 19	37 (59.7)
	> 20	7 (11.3)
Gender	Female	39 (62.9)
	Male	23 (37.1)
Professional status	Medical	7 (11.3)
	Pharmacy	11 (17.7)
	Nursing	44 (71.0)

Pharmacy cadre – Pharmacists and Pharmacists' Assistants
Nursing cadre – Registered Nurses and Enrolled Nurses

The majority of HCWs (51.6%) do not know the official medicine safety reporting tools, which are adverse medicine reaction form (yellow form), product quality reporting form and medication error; about 11.0% have knowledge of the unofficial reporting tools, such as case notes and ward book (Table 2).

Table 2: Knowledge of healthcare workers regarding identification, recording, and reporting of ADEs with Medicine safety reporting tools.

	Frequency n (%)
Which healthcare professionals should report ADEs?	
Medical doctors	9 (14.5%)
Pharmacists	6 (9.7%)
Nurses	21 (33.9%)
All HCPs	23 (37.1%)
Other HCPs	3 (4.8%)
Do you know the Therapeutics Information and Pharmacovigilance Centre in Namibia?	
Medical	3 (42.9%)
Pharmacy	9 (81.8%)
Nursing	5 (9.1%)
Can you identify the medicine safety reporting tools?	
Official tools only	21 (33.9%)
Unofficial tools only	7 (11.3%)
Official tools and Unofficial tools	2 (3.2%)
None	32 (51.6%)

3.2. PRACTICE OF HEALTHCARE WORKERS REGARDING USE OF MEDICINES SAFETY REPORTING TOOLS IN IDENTIFICATION, RECORDING, AND REPORTING OF ADEs

Of the participants, more than 50% in the medical cadre have undergone adverse drug events/pharmacovigilance training, while only 9% among both pharmacy and nursing cadres have been trained. More than 50% of the medical cadre have identified an ADE before, compared to 45% of the pharmacy cadre. About 45% of the pharmacy had used any of the prescribed reporting

forms to report adverse drug events, and less than 30% of medical and nursing cadres had used the forms prior to this study. More than 40% of the medical cadre were afraid to report identified ADE due to perceived risk. However, only 9% of the pharmacy cadre felt this way (Table 3).

Table 3: Practice of healthcare workers regarding identification, recording, and reporting of ADEs.

	Frequency n (%)
Have you ever been trained in adverse medicine events reporting?	
Medical	4 (57.1%)
Pharmacy	1 (9.1%)
Nursing	4 (9.1%)
Have you ever identified an ADE in your practice before?	
Medical	4 (57.1%)
Pharmacy	5 (45.5%)
Nursing	22 (50.0%)
Have you ever reported an adverse medicine event using any prescribed forms in your professional practice?	
Medical	2 (28.6%)
Pharmacy	5 (45.5%)
Nursing	11 (25.0%)
Are you afraid that adverse medicine events reporting put your career at risk?	
Medical	3 (42.9%)
Pharmacy	1 (9.1%)
Nursing	14 (31.8%)

4. DISCUSSION

It is the first study that sought to investigate the knowledge and practices of healthcare workers concerning the use of medicine safety surveillance tools in Namibia. Medicine safety reporting tools are the core components of post-marketing medicine surveillance used by regulatory authorities to gather information on medicine safety [3,10]. Healthcare workers should report ADEs associated with the use of medicines to regulatory bodies with prescribed medicine safety reporting tools. These tools are the vehicle of spontaneous reporting. Therefore, healthcare workers' knowledge of obtaining and using these reporting tools will determine the quality and completeness of ADE reports submitted to national pharmacovigilance centers.

When healthcare professional suspects a serious clinical event to be an ADE, they are encouraged to complete a medicine reporting tool and notify the country's drug regulatory agency about the suspected ADE by fax, email, or post. A copy of the report can be kept at the health facility for review by the Therapeutic Committee or equivalent body in private healthcare facilities. The notification system encourages healthcare workers to immediately report any ADE reported by patients or suspected/identified by healthcare workers through a paper-based reporting modality transmitted to TIPC by fax or electronic means. An adverse event is serious when it results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect [11–13], such events require immediate notification and determination of causality by the pharmacovigilance center in conjunction with relevant government agencies.

Although spontaneous ADR reporting tools may differ from country to country, on the whole, the information collected includes patient details (age, sex, weight), details on the suspected drug (dose, duration of treatment), details on the suspected reaction(s) (description of the event, seriousness, outcome), medical history of the patient, and other concomitant medication that the patient might be taking at the time of ADR occurrence. ADRs from the mainstream of events are reported to pharmacovigilance centers. However, product quality issues, medication errors and undesirable laboratory results are infrequently reported. It might be due to lack of training, non-involvement of laboratory personnel and other allied healthcare workers in pharmacovigilance availability and invariably, limited exposure to medicine safety surveillance tools.

This study revealed the nursing cadre as the professional group with the lowest percentage of individuals who have used any reporting tools to report an ADE. It showed a possible lack of awareness amongst these healthcare workers about the different medicine safety surveillance tools available in Namibia. Noteworthy is that the pharmacy cadre's use of the reporting tools is higher than other healthcare workers, which may be due to their exposure to pharmacovigilance content during their pre-

registration training. Furthermore, only about half of healthcare workers know the appropriate reporting tools to transmit a completed report to the TIPC, implying the underreporting of ADEs.

The role of Therapeutic Committees in helping healthcare workers achieve an acceptable level of knowledge on medicine safety reporting tools for pharmacovigilance cannot be overstated. The majority of the nursing cadre staff had no knowledge of the Therapeutics Information and Pharmacovigilance Center in Namibia, similar to what was reported in Namibia among public healthcare workers [14].

A study carried out among healthcare workers in Namibia within the public healthcare setting showed the need for advocacy and workforce strengthening for ADR reporting in the public health sector, with emphasis on the nursing cadre, who are the first contacts for patients within the primary healthcare setting [15]. In another study conducted in Nigeria, among healthcare workers and patients in selected primary healthcare centers, it was observed that more than 70% of healthcare workers had heard of pharmacovigilance. However, only about 5% correctly understood the pharmacovigilance concept [16]. Although these studies focussed on the knowledge, awareness and practices of pharmacovigilance by healthcare workers, it should be noted that knowledge about the tools necessary to convey identified events is integral to achieving the goals of pharmacovigilance by healthcare delivery systems.

In this study, healthcare workers acknowledged using case notes and ward books for documenting ADEs. It should be noted that whatever is recorded remains in these clinical files until they are destroyed according to legal requirements. Without proper communication and documentation of the identified ADE, the history and nature of the suspected ADEs would be lost, and review or acknowledgment by TIPC will not be achieved. On-the-job training can be used to educate healthcare workers, with a special focus on nursing cadre, to improve the identification and documentation of ADEs by using the prescribed tools. However, there remains a gap in the knowledge about how healthcare professionals report using this tool, evident by the low level of spontaneous reporting to TIPC, considering that this should be a vital part of healthcare professionals 'routine.

This study implies that knowing what to use to report ADEs is as important as what is to be reported and where to report such events. Furthermore, the knowledge gap identified amongst healthcare workers on the officially prescribed medicine safety reporting tools is a major contributor to underreporting of ADEs in Namibia.

5. CONCLUSION

The study showed that most healthcare workers who participated in this study do not know the medicine safety reporting tools available in Namibia. Therefore, they may not be reporting the medicine safety issues they encounter daily. Comprehensive training is recommended to bridge this gap in knowledge and practice on medicine safety reporting tools within nursing cadre, in particular and healthcare workers in general, to improve the current state and quality of spontaneous ADE reporting in Namibia.

5.1. LIMITATION

The study was carried out at a single public hospital, covering only available HCPs in the facility. The result might not be generalizable to the Namibian HCPs in private and public healthcare settings. Most healthcare was not available due to the COVID-19 pandemic.

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AUTHOR CONTRIBUTIONS

AA conceptualized, developed and wrote the initial manuscript. AA and BAA conducted data analyses. BAA reviewed the manuscript before finalizing it. Both authors agreed on the final manuscript prior to submission for publication.

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CONFLICT OF INTEREST

None of the authors has any conflicting interests directly related to this project.

REFERENCES

1. Salehi T, Seyedfatemi N, Mirzaee MS, Maleki M, Mardani A. Nurses' Knowledge, Attitudes, and Practice in Relation to Pharmacovigilance and Adverse Drug Reaction Reporting: A Systematic Review. Biomed Res Int. 2021 Apr 9;2021:6630404. doi: 10.1155/2021/6630404. PMID: 33937402; PMCID: PMC8062168.
2. Jeetu G, Anusha G. Pharmacovigilance: a worldwide master key for drug safety monitoring. J Young Pharm. 2010 Jul;2(3):315-20. doi: 10.4103/0975-1483.66802. PMID: 21042493; PMCID: PMC2964775.

3. Mann M. Evaluation and Potential Cost-Effectiveness of Active Surveillance Pharmacovigilance for First-Line HAART in Namibia. PhD Thesis, University of Washington, Department of Pharmacy, 2016.
4. Moride Y, Haramburu F, Requejo AA, Bégaud B. Under-reporting of adverse drug reactions in general practice. Br J Clin Pharmacol. 1997 Feb;43(2):177-81. doi: 10.1046/j.1365-2125.1997.05417.x. PMID: 9131950; PMCID: PMC2042725.
5. Tandon VR, Mahajan V, Khajuria V, Gillani Z. Under-reporting of adverse drug reactions: A challenge for pharmacovigilance in India. Indian J Pharmacol. 2015. doi:10.4103/0253-7613.150344.
6. Aziz Z, Siang TC, Badarudin NS. Reporting of adverse drug reactions: predictors of under-reporting in Malaysia. Pharmacoepidemiol Drug Saf. 2007 Feb;16(2):223-8. doi: 10.1002/pds.1313. PMID: 16947117.
7. Hohl CM, Small SS, Peddie D, Badke K, Bailey C, Balka E. Why Clinicians Don't Report Adverse Drug Events: Qualitative Study. JMIR Public Health Surveill. 2018 Feb 27;4(1):e21. doi: 10.2196/publichealth.9282. PMID: 29487041; PMCID: PMC5849794.
8. Isah AO, Pal SN, Olsson S, Dodoo A, Bencheikh RS. Specific features of medicines safety and pharmacovigilance in Africa. Ther Adv Drug Saf. 2012 Feb;3(1):25-34. doi: 10.1177/2042098611425695. PMID: 25083223; PMCID: PMC4110828.
9. Katusiime B, Semakula D, Lubinga SJ. Adverse drug reaction reporting among health care workers at Mulago National Referral and Teaching hospital in Uganda. Afr Health Sci. 2015 Dec;15(4):1308-17. doi: 10.4314/ahs.v15i4.34. PMID: 26958036; PMCID: PMC4765406.
10. Adenuga BA, Kibuule D, Rennie TW. Optimizing spontaneous adverse drug reaction reporting in public healthcare setting in Namibia. Basic Clin Pharmacol Toxicol. 2020 Mar;126(3):247-253. doi: 10.1111/bcpt.13325. Epub 2019 Oct 23. PMID: 31520574.
11. Gosselin A, Chabut C, Duhamel A, Desjardins I, Lebel D, Bussières JF. Detection of serious adverse drug reactions using diagnostic codes in the International Statistical Classification of Diseases and Related Health Problems. J Popul Ther Clin Pharmacol. 2020 Jul 23;27(3):e35-e48. doi: 10.15586/jptcp.v27i3.705. PMID: 32757540.
12. Mouton JP, Fortuin-de Smidt MC, Jobanputra N, Mehta U, Stewart A, de Waal R, *et al.* Serious adverse drug reactions at two children's hospitals in South Africa. BMC Pediatr. 2020 Jan 4;20(1):3. doi: 10.1186/s12887-019-1892-x. PMID: 31901244; PMCID: PMC6942333.
13. Gautron S, Wentzell J, Kanji S, Nguyen T, Kobewka DM, MacDonald E. Characterization of Serious Adverse Drug Reactions in Hospital to Determine Potential Implications of Mandatory Reporting. Can J Hosp Pharm. 2018 Sep-Oct;71(5):316-323. Epub 2018 Oct 31. PMID: 30401998; PMCID: PMC6209500.
14. Adenuga BA, Kibuule D, Bamitale KDS, Rennie TW. Effective integration of pharmacovigilance systems at public health facilities in resource-limited settings: A qualitative study. Res Social Adm Pharm. 2020 Aug;16(8):1111-1116. doi: 10.1016/j.sapharm.2019.11.010. Epub 2019 Nov 18. PMID: 31812500.
15. Adenuga BA, Rennie TW. A Profile of Adverse Drug Reactions of Atazanavir- and Lopinavir-Based Antiretroviral Regimens in Namibia. Drug Saf. 2019 Jul;42(7):915-917. doi: 10.1007/s40264-019-00832-3. PMID: 31069704.
16. Adisa R, Omitogun TI. Awareness, knowledge, attitude and practice of adverse drug reaction reporting among health workers and patients in selected primary healthcare centres in Ibadan, southwestern Nigeria. BMC Health Serv Res. 2019 Dec 3;19(1):926. doi: 10.1186/s12913-019-4775-9. PMID: 31796034; PMCID: PMC6889459.