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Optimizing spontaneous adverse drug reaction reporting in public healthcare setting in Namibia

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Abstract

Despite the universal scale-up of pharmacovigilance systems globally, adverse drug reaction (ADR) reporting remains suboptimal among resource-limited countries. Few studies in sub-Saharan Africa evaluate the effectiveness of adverse drug reaction (ADR) reporting programmes. A cross-sectional survey using a self-administered questionnaire to assess ADR reporting knowledge, attitude and practices among healthcare workers in Namibia's public sector was conducted between September and December 2018. The primary outcome were practices, knowledge and attitude of the respondents towards ADR reporting. Quantitative and qualitative data were analysed using descriptive statistics and thematic analysis, respectively. Of the 197 healthcare workers surveyed, 43.1% were nurses, 63.4% of the respondents knew about the ADR reporting system in Namibia, 76.7% knew the pharmacovigilance/ADR reporting centre in Namibia, while 37.3% had reported an ADR before. Nurses were less likely to be knowledgeable and report ADRs. The independent predictor of ADR reporting was the nursing cadre; adjusted odds ratio (aOR) = 0.17 (95% CI: 0.07, 0.401, $P < .01$). Pre- and in-service trainings including introduction of electronic reporting platforms were some of the identified ways of optimizing the pharmacovigilance and ADR reporting systems by the respondents. As pharmacovigilance in Namibia relies on spontaneous reporting of ADRs, there is a need for advocacy and workforce strengthening for ADR reporting in the public health sector.

KEYWORDS

adverse drugs reactions, namibia, public health care, reporting

1 | INTRODUCTION

The HIV/AIDS epidemic among other communicable and non-communicable diseases has devastated public health in sub-Saharan Africa (SSA), necessitating the scale-up of pharmacovigilance systems for surveillance of safety of standard treatment, which change frequently.[1] For instance, the retrospective study among patients on second-line antiretroviral therapy in South Africa underscored the importance of optimal pharmacovigilance systems.[2]

Adverse drug reactions (ADRs) are a public health challenge associated with high morbidity and mortality.[3] ADRs are a major cause of hospital admissions and treatment interruptions; it was estimated that approximately 6.5% of hospital admissions were due to ADRs in the United Kingdom.[4] As sub-Saharan Africa (SSA) is worst hit by the HIV epidemic, it is important that systems are in place to monitor new and ongoing antiretroviral therapies (ART).[5] As newer medicines are increasingly integrated into standard treatment guidelines for public health care in SSA, the strengthening of adverse drug reaction reporting becomes critical to improve quality of care.[6,7]

In addition, this integration of new essential medicines into standard treatment guidelines not only demands improved

pharmacovigilance but also raises the need for training and awareness of healthcare workers concerning ADRs and ADR reporting. Dealing with ADRs requires a multi-professional approach by healthcare workers—including medical practitioners, pharmacists and nurses—both in public and in private healthcare settings to safeguard population health.[8]

Namibia, a country in southern Africa with a population of about 2.5 million people, has a high burden of infectious diseases such as HIV, tuberculosis and malaria as well as a growing burden of non-communicable diseases. The HIV prevalence in Namibia was estimated at 12.6% in 2017 among adults aged 15-64;[9] the burden of the disease has reduced dramatically in the last two decades largely as a result of effective roll-out of efficacious ARVs and other essential medicines. Nevertheless, the establishment of the Therapeutics Information and Pharmacovigilance Centre (TIPC) in 2007, in the Ministry of Health and Social Services (MoHSS), has improved the access to pharmacovigilance services in public health care in Namibia.[10] Most healthcare workers at public health facilities mainly report ADRs by use of a paper-based spontaneous reporting system (ie voluntary adverse drug reaction reporting by healthcare workers or patients on suspected improper effect of a medicine). The reports can be faxed, scanned and emailed or hand-delivered to the TIPC office, depending on the proximity of the facility and resources available at the reporting facility.

In a recent audit carried out between August 2017 and August 2018, using the Individual Case Safety Report (ICSR) submitted by healthcare workers to TIPC, it was found that, although patients may be experiencing ADRs due to atazanavir- and lopinavir-containing regimens, cases were under-reported.[11]

Studies have elsewhere been carried out to assess the knowledge, attitudes, awareness, practices and perceptions of healthcare workers in different settings in Africa. In Nigeria, for example, the knowledge and perception of pharmacy students of pharmacovigilance activities in three Nigerian universities were assessed.[12] It was found that the knowledge of pharmacovigilance activities was low among students. In another study in Nigeria among healthcare workers, factors associated with under-reporting of ADRs included the lack of availability of reporting forms and lack of awareness of how to report ADRs.[13] Introduction of an electronic reporting platform was suggested to improve and encourage ADR reporting. Furthermore, in western Ethiopia, a lack of awareness and knowledge of pharmacovigilance and pharmacovigilance systems were reported to contribute to under-reporting of ADRs among healthcare professionals.[1]

The current study aimed to better understand the reasons for under-reporting of ADRs in the Namibian context and from the perspective of the healthcare workers empowered to report through the existing pharmacovigilance system.

2 | METHODS

2.1 | Design and settings

Between September and December 2018, a cross-sectional survey was carried out among healthcare workers working in the public healthcare facilities in Namibia. A self-administered questionnaire was adapted from previous studies that assessed the knowledge, attitude and practices of healthcare workers in Nigeria.[11,12] There are 14 geographical regions in Namibia. The study respondents were stratified by 7 regions; the 7 regions were purposively selected with varying settings and populations, that is 2 coastal towns (Karas and Erongo regions), 2 border towns (Caprivi and Omaheke regions), 1 centrally located town (Otjozondjupa region) and 2 central business districts (Khomas and Oshana regions). Healthcare workers at the respective state/regional referral hospital were included in the study.

2.1.1 | Population

Public healthcare workers from different cadres (medical doctors, nurses, midwives, pharmacists, dentists, radiographers, etc) participated in the study. They were invited by the researcher to voluntarily complete an anonymous questionnaire (online or paper-based). Target number of respondents was estimated at 200 respondents using the Kish Leslie method for a one-sample cross-sectional study with the power set at 80% and level of significance at 0.05; 197 respondents participated in the study; thus, the response rate was 98.5%.

2.1.2 | Pharmacovigilance programme in Namibia

TIPC co-ordinates pharmacovigilance activities in Namibia. Namibia is a full member of the World Health Organization Programme for International Drug Monitoring. ICSR from healthcare facilities submitted to the TIPC is collated, aggregated and sent to the WHO-UMC through VigiBase, a database for reporting ADRs.

2.2 | Procedure

The research instrument comprised of 5 sections: (1) demographics of the respondents; (2) knowledge of health workers about pharmacovigilance/ADR reporting, attitude of health workers to pharmacovigilance and ADR reporting measuring separately (3) positive and (4) negative attitudes; and (5) practice of pharmacovigilance and ADR reporting among healthcare workers. To measure knowledge, four multiple-choice question responses were used and scored; a summed

score was generated for analyses. A Likert scale rating system was used to measure the negative and positive attitudinal item responses (strongly agree = 5, agree = 4, neutral = 3, disagree = 2 and strongly disagree = 1); negatively worded items were reverse coded so that higher scores represented more negative attitudes. Respondents were asked to report on their actual pharmacovigilance practice in response to two questions relating to whether they had reported ADRs to the centralized pharmacovigilance reporting system or within their practice setting. Finally, participants were asked to use an open-response question about possible ways of improving the current pharmacovigilance systems in Namibia.

The questionnaire was disseminated using an online platform (ie Google Forms®) as well as paper format. A network sampling method was used in the online questionnaire administration. Index healthcare professionals were identified and asked to request their fellow professionals to complete the questionnaire. A purposive sampling method was used in the paper questionnaire administration, whereby a focal person was identified for seven different health facilities around the country with a high patient turnover. The focal person was sent questionnaires to distribute locally and collect responses to be couriered or hand-delivered back to the main investigator. For responses to the attitudinal scales in the questionnaire, reliability analysis was determined using Cronbach's alpha. Cronbach's alpha for positive and negative intentions was 0.839 and 0.811, respectively, showing acceptable reliability for both scales (Table S1).

The questionnaire was validated through face validity and pilot study. Face validity was carried out by one of the faculty members at the School of Pharmacy, University of Namibia, prior to the pilot phase. Five (5) respondents working with the MoHSS were selected; these completed the paper-based questionnaire in July 2018, and also three (3) academic respondents from the staff of the Faculty of Health Sciences, University of Namibia, completed the online format in August 2018. Feedback was received and incorporated to improve the questionnaire tool.

2.2.1 | Factor analysis

Factor analysis was conducted to determine the construct validity of the questionnaire items for the three domains, knowledge, attitude and practice of ADR reporting. Most questionnaire items loaded onto the common scales that were included in the questionnaire tool (Table S2). The question loading was between 0.42 and 0.89. Three items did not load onto pre-existing scale but did not appear to show any rational commonality. From this analysis, we were reasonably satisfied that the survey tool—including those scales within—was valid for the measurement of perceptions towards pharmacovigilance in Namibia. However, further work can explore why the three items did not load as anticipated including whether this was related to insufficient sample size or whether they were measuring a distinct theme not captured adequately by the questionnaire. A qualitative approach may help in this.

2.3 | Data collection and analysis

SPSS (ver. 25) software was used for data analyses; electronic survey response data were imported, and paper-based questionnaire data were entered manually. Descriptive analyses were performed on responses to the questionnaire including sample characteristics and questionnaire items. Bivariate analysis was conducted to examine the relationships between ADR reporting and willingness or ability to report suspected ADRs and other variables. A multivariate logistic regression model was constructed to explore the independent associations with under-reporting of ADRs. The following variables were entered for regression analysis: professional group, negative intention to report, knowledge of pharmacovigilance and number of years of experience (Table 1).

3 | RESULTS

3.1 | Population characteristics

A total of 197 health workers completed the survey. Of the 145 questionnaires distributed physically, 88.3% (n = 128) were completed. Of the 70 questionnaires completed online, one was a duplicate response which was excluded from the analysis. The majority of the respondents were nursing (43.2%) or pharmaceutical personnel (31.5%). The mean age and years of experience of the respondents were 35.4 (SD 9.1) years and 10.1 (SD 8.3) years, respectively. The majority of the respondents were female (60.9%; Table 2) and worked at either a district hospital (31.5%) or a clinic setting (27.4%) (Table 1).

3.2 | Knowledge, attitude and practice of adverse drug reaction reporting

The majority of respondents (63.4%) knew about the ADR reporting and monitoring system in Namibia, and even more (76.7%) were able to identify the centre responsible for pharmacovigilance activities. Although most respondents (75.1%) acknowledged that every healthcare worker is responsible for ADR reporting, only 64.4% disclosed knowing how to report ADRs. Of the respondents, only 16.5% had attended a pharmacovigilance training while just over one third (37.3%) had reported an ADR before.

Different levels of knowledge were observed among the three professional groups reporting most frequently (Kruskal-Wallis test: $\chi^2 = 11.087$, $P = .004$); about 33% of the nursing

TABLE 1 Demographics of respondents

Demographic variables	Categories	N = 197 (%)
Age, years (mean, SD)		35.38 (9.1)
Age, categorized (n, %)	20-29	60 (30.5)
	30-39	82 (41.5)
	40-49	34 (17.3)
	50-59	19 (9.6)
	60-69	2 (1.0)
Years of experience (mean, SD)		10.11 (8.3)
Years of experience categorized (n, %)	0-9	111 (56.3)
	10-19	55 (27.9)
	20-29	24 (12.2)
	30-39	7 (3.6)
Gender (n, %)	Female	120 (60.9)
	Male	77 (39.1)
Type of facility (n, %)	District Hospital	62 (31.5)
	Clinic	54 (27.4)
	Intermediate Hospital	32 (16.2)
	Health Centre	19 (9.7)
	NMRC	9 (4.6)
	National Referral Hospital	8 (4.1)
	Others	12 (6.0)
	TIPC	1 (0.5)
Professional group (n, %)	Nursing	85 (43.1)
	Medical	31 (15.7)
	Pharmacy	62 (31.5)
	Dental	5 (2.5)
	Allied	5 (2.5)
	Others	9 (4.6)

Abbreviations: NMRC, Namibia Medicines Regulatory Council; TIPC, Therapeutic Information and Pharmacovigilance Centre; Allied, Radiographer.

TABLE 2 Correlations for training and willingness/ability to report ADRs

	ADRs reported ever		ADRs reports in respondent's setting	
Variables (N = 197)	*r*	*P*	*r*	*P*
Negative intention to report (n = 184)	−0.115	.060	−0.202	.003
Positive intention to report (n = 187)	−0.028	.703	0.086	.245
Age of respondents (n = 197)	0.118	.099	0.084	.244
Number of years of experience (n = 184)	0.168	.011	0.135	.034
Ever attended PV training (n = 194)	0.178*	.013	0.274**	.000
Knowledge of pharmacovigilance (n = 185)	0.229	.001	0.189	.005
Professional group (n = 197)	−0.065	.365	0.023	.752
ADRs reported ever	–	–	0.401**	.000

Abbreviations: ADR, adverse drug reaction; *r*, Pearson's coefficient
$P < .05$ level was set to infer statistical significance.
*Number of respondents varies as per the answered paper questionnaire items.
Correlation is significant at the .05 level (2-tailed).
**Correlation is significant at the .01 level (2-tailed).

TABLE 3 Predictors of adverse drug reaction under-reporting based on multivariate logistic regression model

			95% CI for OR	
Variables	*P*	OR	Lower	Upper
Profession (reference: Pharmacy)				
Medical	.288	0.595	0.229	1.549
Nursing	.000	0.168	0.070	0.401
Number of years of experience	.248	1.028	0.981	1.078
Ever attended PV training	.997	0.998	0.379	2.629
Negative intention to report	.092	0.659	0.406	1.071
Knowledge of pharmacovigilance	.451	1.804	0.389	8.369

Note: $P < .05$ level was set to infer statistical significance. Odds ratio (OR) and 95% confidence interval (CI) were calculated using multivariate logistic regression, and all variables were entered by forward stepwise method. Wald's test statistic shows the variables that contribute to the logistic regression model (Wald's test statistic was 5.361, $P = .021$), Nagelkerke R square for the model was 0.251.

professionals gave incorrect responses to knowledge of pharmacovigilance questions compared to 31% and 25% of the medical professionals and pharmacy professionals, respectively. Different levels of reporting ADRs between the health professions were also observed with pharmaceutical cadres reporting most frequently, followed by medical personnel and then nursing (Kruskal-Wallis test: $\chi^2 = 19.494$, $P < .001$).

A positive association was observed between training received and ADR reporting ($r = 0.178$, $P = .013$), and negative intention to report ADRs was negatively associated with ADR reporting ($r = -0.202$ $P = .003$) (Table 3).

In logistic regression analysis, only the nursing profession emerged as a potential predictor of ADR reporting such that respondents from the nursing profession were about six times less likely to report ADRs compared with the reference group, pharmacy profession respondents (Table 4: CI 0.070-0.401, $P < .001$).

TABLE 4 Thematic summary of responses for improvement of Pharmacovigilance and ADR reporting system in Namibia

Theme	Subtheme	Respondents' quotes
Training gaps	Training on pharmacovigilance Training on how to complete ADR report forms Training on how to detect ADRs in practice	"Continuous professional development on pharmacovigilance should be strengthened in all state hospitals. District hospital's therapeutic committee meetings should be educative and it should motivates all health care providers to report any adverse drug effects. This will help most health care providers to differentiate between side effects and adverse effects (it is a responsibility for Pharmacists to educate or motivate other health care providers)" "Create awareness about pharmacovigilance and provide relevant information in regard to the centers where adverse reactions can be reported to and the necessary steps that one will need to follow to report adverse drug reactions." "Educate all pharmacists and other healthcare workers on the importance of drug safety and post marketing surveillance" "Health workers and health care providers should be regularly trained and appraised on the importance of Adverse Drug Reactions reporting" "Continuous professional development on pharmacovigilance should be strengthened in all state hospitals. District hospital's therapeutic committee meetings should be educative and it should motivate all health care providers to report any adverse drug effects. This will help most health care providers to differentiate between side effects and adverse effects Continuous professional development on pharmacovigilance should be strengthened in all state hospitals. District hospital's therapeutic committee meetings should be educative and it should motivate all health care providers to report any adverse drug effects. This will help most health care providers to differentiate between side effects and adverse effects." "Training of all healthcare workers, especially nurse, on ADR reporting and pharmacovigilance because they are the first to be seen by the patients. In-service training on what should be reported."
Electronic ADR reporting system	Use of a mobile or cell phone application Digital reporting system	"Electronic/online options eg TIPC mobile application" "electronically reporting, like data base" "Digitalization of the ADR reporting and pharmacy vigilance system"
Decentralization of pharmacovigilance/ADR reporting system	Creation of reporting hubs at district/facility level	"Each hospital must have a specific staff responsible giving awareness assessing, detecting and receiving and reporting to TIPC." "Get a focal person to deal with ADR reporting"
Community engagement	Awareness creation in the community	"Encourage patient/user of medicine to report directly all the adverse reactions in writing to the pharmacy/clinic near him/her"
Feedback	Communication between TIPC and ADR reporters	"Feedbacks and should come back to the person or the organization who report the ADR report" "Provision of feedback on reports and regular feedback to stakeholders on the TIPCs ADR related activities and country status. Pre and post training field visits to health facilities to maximize impacts of trainings and to motivate reporting by professionals - raising public/patients awareness on ADR identification and reporting using various platforms including TV, MOHSS website, social media platforms, etc (I wonder if there exist any report from patients so far)."

3.3 | Responses to open-ended question

Out of 197 respondents who participated in the survey, 168 (85.3%) respondents answered the open-ended question "What other ways would you propose/suggest to improve adverse drug reactions reporting and pharmacovigilance system in Namibia?" Five (5) themes were identified such as training gaps, electronic reporting, Feedback from TIPC and community engagement; subthemes identified included training on pharmacovigilance, awareness creation in the community and digital/electronic reporting (Table 4).

5 | DISCUSSION

This is the first study in Namibia to explore knowledge, attitudes and practices of healthcare workers concerning ADR reporting. Findings suggest that pharmacovigilance practice among healthcare workers in Namibia could be substantially improved, given that a minority have undergone pharmacovigilance training before. Training also appeared to be an important factor that may be related to ADR reporting practices.[13] In a recent audit carried out between August 2017 and August 2018, using the Individual Case Safety Report (ICSR) submitted by healthcare workers to TIPC, it was

found that, although patients may be experiencing ADRs due to atazanavir- and lopinavir-containing regimens, cases were under-reported,[14] though; the under-reporting may not be limited to these regimens.

Respondents themselves suggested that training and education around pharmacovigilance could empower current systems of reporting. Strengthening the communication channel between TIPC and healthcare workers through Therapeutics Committees at the facility level as well as the provision of analytical feedback on TIPC reports could serve as an incentive for the reporters.

Studies have elsewhere been carried out to assess the knowledge, attitudes, awareness, practices and perceptions of healthcare workers in different settings in Africa. In Nigeria, for example, the knowledge and perception of pharmacy students of pharmacovigilance activities in three Nigerian universities were assessed.[15] It was found that the knowledge of pharmacovigilance activities was low among the students. In another study in Nigeria among healthcare workers, factors associated with under-reporting of ADRs included the lack of availability of reporting forms and lack of awareness of how to report ADRs.[16] Other studies have reported that not knowing how to report can be a barrier to ADR report among clinicians.[11,17] Introduction of an electronic reporting platform was suggested by the respondents as a way to improve and encourage ADR reporting in Namibia. Furthermore, in western Ethiopia, a lack of awareness and knowledge of pharmacovigilance and pharmacovigilance systems was reported to contribute to under-reporting of ADRs among healthcare professionals.[16]

The level of awareness of ADR reporting among the respondents was found to be 37.1%. The result is similar to other studies conducted in Nigeria and India which estimated the awareness of the Yellow Card ADR reporting scheme and/or had reported an ADR at 32% and 37%, respectively.[18,19]

More reports were received from the nursing cadre, these are more in number within the health system and the pharmacy cadre which is more involved with pharmacovigilance activities, and this raises questions relating to representation of the sample. However, in general, the survey was inclusive and able to distinguish subtle differences between the professional groups, for example, knowledge levels. Indeed, the only emerging variable that may serve to predict ADR reporting through regression analysis was found to be respondents belonging to the nursing profession.

Further research in this area needs to focus on how to strengthen the pharmacovigilance systems through engagement with stakeholders and development of innovative ways of reporting ADRs in Namibia. Specifically, a better focus on the nursing profession—who are often at the frontline of patient care where they will be administering medicines and observing the effects—in terms of improving competence in recognizing and reporting ADRs may be necessary. As the largest health profession worldwide and in Namibia, this also stands to have significant public health impact especially following any introduction of new standard treatment guidelines incorporating new treatment regimens such as the antimalarials, antituberculosis drugs or antiretroviral medicines or other drug classes.[9]

This study relied on voluntary participation and purposive sampling of healthcare workers. This type of study has the potential of selection bias and limited generalizability. However, the survey of healthcare workers in Namibia was regionally stratified focussing on locations with high number of healthcare workers or locus of activity. The current study did not focus on independent patient-reported ADRs which remains a limitation of the study but can be further investigated through future research.

Depending on the setting, centralized, national reporting systems may not always be the solution to pharmacovigilance but if they are adopted—as is the case in Namibia—there is a need to continually support their function and improvement. This may include ongoing training and education at pre-service and in-service levels, involvement of Therapeutic Committees at facility and regional levels and introduction, for example, of innovative electronic reporting to improve efficiency and boost the response rate among healthcare workers.[19-22]

In conclusion, the study revealed a high level of knowledge of pharmacovigilance and ADR reporting system among the healthcare workers, though this has informed neither their attitude nor their practice of ADR reporting as seen in their reported attitude and practice. In other to optimize the current system, there is a need for effective communications between TIPC and the healthcare workers; this may be in the form of feedback, continuing professional development (CPD) lectures, advocacy within the health sector and community engagement.

CONFLICT OF INTEREST

The three authors, Babafunso Aderemi Adenuga, Dan Kibuule and Timothy William Rennie, have no conflict of interests that are directly relevant to the content of this study.

ETHICAL APPROVAL

Research ethics approvals were obtained from the Research and Ethics Division of the MoHSS (Reference No. 17/3/3) and Ethics Committee of the University of Namibia (Reference No. SOPHA/209/2017).

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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