

Original Article

# Inadequate Knowledge and Practice of Pharmacovigilance affecting Adverse Drug Reaction Reporting by Health Professionals in Private Healthcare Facilities in Lusaka, Zambia

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## ABSTRACT

**Background:** There is currently insufficient information regarding the levels of knowledge and practice of Adverse Drug Reactions (ADRs) reporting among healthcare professionals in Zambia.

**Aim:** The study examined knowledge, attitude and reporting practices among medical doctors, pharmacists and nurses in private healthcare facilities in Lusaka, Zambia.

**Methods:** A descriptive cross-sectional study was undertaken. Data was collected using a self-administered questionnaire assessing general knowledge, attitudes and practice of ADR reporting. A rated score was used to categorize knowledge as poor, average, or good. A Kruskal-Wallis H test followed by Bonferroni test was used to compare knowledge levels among medical doctors, pharmacists and nurses, respectively. To assess practice and attitude towards the ADR reporting, proportions were used to analyze responses to items in each of the respective domain.

**Results:** General knowledge of ADR reporting among the medical doctors, pharmacists and nurses in the private sector was relatively low. A Kruskal-

Wallis H test showed that there was a statistically significant difference in total score between the different occupations,  $\chi^2(2) = 10.839$ ,  $p = 0.004$ , with a mean rank score of 34.08 for pharmacists ( $n = 18$ ), 22.17 for doctors ( $n = 24$ ) and 16.19 for nurses ( $n = 8$ ). Low knowledge levels of ADR reporting were attributed to lack of pharmacovigilance training, with thirty nine (78%) of the participants indicating that they had never received any training on ADR reporting and thirty seven participants (74%) indicated that they had never reported an ADR. Factors that discouraged ADR reporting included: practitioner concern that the information reported may be wrong (46.8%); the level of clinical knowledge to decide whether an ADR had occurred (46.8%); lack of time to complete the ADR report forms (36.2%); reporting generating extra work load (25.5%); and the perceived unimportance of reporting a recognized ADR believing it would make little difference to knowledge and practice (19.1%). The major factors that encouraged ADR reporting included: seriousness of the ADR (98%); unusual reactions (77.6%); adverse reaction to a new product (83.7%); confidence in diagnosis of an ADR (73.5%), and if the reaction was well recognized for a particular drug (67.3%). The training of personnel in private practice was major indicator for improvement of ADR reporting.

**Conclusion:** Despite the relative positive attitudes indicated, low levels of knowledge due to lack of

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training was the main driver of ADR under-reporting practice among private health practitioners that participated in this study. Addressing the knowledge and practice gaps identified will go a long way to further improve ADR reporting rates and medication safety in private healthcare practice settings.

## INTRODUCTION

Efficacy and safety are the two major concerns about medicines. While efficacy can be quantified with relative ease, the same cannot be said about safety.<sup>1</sup> Adverse drug reactions (ADRs) are the fourth to sixth leading cause of death in the USA.<sup>2</sup> ADRs are also associated with a high prevalence of hospital admissions and economic burden; around £466 million is reported as an annual total cost for drug-related admissions in the United Kingdom.<sup>3</sup> McDonnell and Jacobs revealed that 25% of these events were life threatening and 6.3% were considered potentially preventable.<sup>4</sup>

The need to promote medication safety and improve health care has given prominence to the concept of Pharmacovigilance as a practice in country health systems. In Zambia, 2,600 ADR reports were received by Zambia Medicines Regulatory Authority (ZAMRA) between 2008 and 2016. Of these, 312 ADRs were entered in the UMC-WHO Vigiflow for further analysis.<sup>5</sup> Despite the progress that has been made in implementing pharmacovigilance systems in Zambia, the burden of ADRs on public health remains significant. This information on ADRs is required not only to promote medicine safety but also to strengthen the pharmacovigilance mechanisms that exist.<sup>6</sup>

Few studies have assessed healthcare professionals' knowledge, attitude and practice towards ADR reporting in both public and private setting in Zambia. A preliminary study of knowledge, attitude and practice of ADR reporting conducted among healthcare professionals at Zambia's highest public referral hospitals, the University Teaching Hospitals (UTHs), found that knowledge of ADR reporting was very low among healthcare professionals with over half (52%) of the participants indicating they were ignorant about ADR reporting procedures.<sup>7</sup>

Existing evidence suggests that health care professionals, in developing countries have a poor to moderate knowledge, a positive attitude and poor practice of ADR reporting, which can be improved with continuing professional education.<sup>8,9,10</sup> The present study explored the knowledge, attitude and practice of pharmacovigilance among healthcare professionals in the private sector in Lusaka, Zambia. This study was important because local evidence of what health care professionals' know and whether they practice pharmacovigilance has been lacking.

## METHODOLOGY

### Study Design

This was a descriptive cross-sectional survey conducted in Lusaka district, Zambia.

### Study Population

The study population consisted of Medical Doctors, Pharmacists and Nurses working full-time in private healthcare facilities in Lusaka.

### Sampling Technique

A census method of recruiting participants was used. This method was chosen due to the limited numbers of health professionals practicing full-time in private healthcare facilities in Lusaka district. Contact numbers and email addresses of registered medical doctors, pharmacists, and nurses who practice in the private health sector were obtained from their respective professional associations and respective private healthcare facilities. The compiled list of medical doctors, pharmacists and nurses that were practicing full-time in private hospitals and clinics in Lusaka district at the time of the study was 189. This was considered the target sample size for the study.

### Inclusion and Exclusion Criteria

Medical doctors, pharmacists and nurses working full-time in private healthcare facilities in Lusaka district were included in this study. Medical doctors, pharmacists and nurses working on part-time or locum basis while serving full-time in public healthcare facilities were excluded.

### Data Collection Tools and Procedures

Quantitative data was collected using a self-administered questionnaire on an online survey development cloud based software (Survey Monkey<sup>®</sup>) and using hard copies. The questionnaire was adapted from a similar study with minor modifications made to the terminologies to suit private practice facility.<sup>7</sup> A total of 189 questionnaires were distributed.

The questionnaire was accompanied with instructions on how to complete the survey. A reminder was sent via email every two weeks from date of distribution of the tool to the participants, for a follow-up period of 9 months. The online survey tool was designed to only permit one anonymized online submission per respondent. Similarly, the contact persons (i.e. directors/human resource managers of the facilities) were reminded via telephonic calls every two weeks to assist receive the completed paper-based questionnaires on behalf of the researchers to enable ease of collection from a central point. Responses to online questionnaires were captured as they were submitted, while completed hard-copy questionnaires were collected by the investigators from a contact person identified within each private hospital and clinic. Field data collection was undertaken from February to November 2018.

### Data Analysis

All categorical variables were analyzed using frequencies and proportions. In order to determine the levels of knowledge about ADR reporting, the participants were asked to answer 18 questions assessing knowledge of ADR reporting. The scores varied from 1 to 6 with a total score of 33. Scores were tested to establish whether they were normally distributed using Shapiro-Wilk test at a significance level of 0.05. A Kruskal-Wallis H test followed by Bonferroni test was conducted to compare knowledge levels among medical doctors, pharmacists and nurses, respectively. Proportions were used to analyze responses to items in each attitude and practice domain.

### Ethical Considerations

Ethics approval to undertake this study was granted

by the University of Zambia Biomedical Research Ethics Committee (Approval Ref# 022-05-17).

## RESULTS

### Demographic characteristics for the participants

Fifty questionnaires were successfully completed and returned after 9 months follow-up, giving a response rate of 27%.

**Table 1: Demographic distribution of participants**

	n	%
<b>Gender</b>		
Male	34	68
Female	16	32
<b>Age in Years</b>		
20-29	5	10
29-39	19	38
40-49	13	26
≥ 50	13	26
<b>Profession</b>		
Medical Doctor	24	48
Pharmacist	18	36
Nurse	8	16
<b>Work Experience in Years</b>		
1 - 10	14	28
11 - 20	22	44
20 - 30	7	14
≥ 30	6	12

### Knowledge of ADR reporting

Of the total obtainable score of 33 in knowledge assessment, the mean score was  $21.86 \pm 4.7$ . The lowest score was 9, and the highest score obtained was 29. Twenty percent of the participants scored less than 19. Table 2 shows the distribution of correct and incorrect responses to the knowledge related questions. The total scores were tested using Shapiro-Wilk test at a significance level of 0.05, to establish whether they were normally distributed. The results were significant  $t(50) = 0.949$ ,  $p = 0.030$ . A Kruskal-Wallis H test showed that there was a statistically significant difference in total score between the different occupations,  $\chi^2(2) = 10.839$ ,  $p$

= 0.004, with a mean rank score of 34.08 for pharmacists (n = 18), 22.17 for doctors (n =24) and 16.19 for nurses ( n = 8). Post-hoc comparisons using the Bonferroni test indicated that pharmacists were significantly more knowledgeable than medical doctors ( $\chi^2 = 11.917, p = 0.026$ ); or nurses ( $\chi^2 = 17.896, p = 0.011$ ), scores obtained by medical doctors were not significantly different from nurses ( $\chi^2 = 5.979, p = 0.940$ ). These results about ADR reporting suggest that pharmacists were more knowledgeable than doctors and nurses.

**Table 2: Correct and incorrect responses to knowledge related questions**

Knowledge-related questions	Correct response (%)	Incorrect response (%)
The most important purpose of pharmacovigilance is	68.0	32.0
Can serious ADRs to a drug be identified after it has been marketed ?	42.0	58.0
Should all ADRs be reported for newly marketed drugs ?	88.0	12.0
Should serious reactions be reported for established products ?	98.0	2.0
Are you aware of any drug that has been banned due to ADRs ?	72.0	28.0
Which of the following ADR should be reported ?	88.0	12.0
Should a medical error be reported as a part of ADR reporting?	50.0	50.0
Should an adverse event that occurred due to product quality issues be reported as a part of ADR reporting?	74.0	26.0
Should a suspected treatment failure be reported as a part of ADR reporting?	50.0	50.0
Which is the 'WHO online database' for reporting ADRs?	38.0	62.0
Which is the regulatory body in Zambia for receiving and monitoring of ADRs	92.0	8.0
Whom do you report the ADRs to	42.0	58.0

**Attitudes towards ADR reporting**

The majority (98%) of the participants felt that an ADR should be reported if it is serious. Level of clinical knowledge making it difficult to diagnose ADR and fear of wrong report were the major factors indicated as discouraging ADR reporting (46.8%). One of the participants indicated that they did not

report ADRs because the patients' do not complain of ADRs.

**Table 3: Attitude towards ADR reporting**

Attitude -related questions	Agree (%)	Disagree (%)
<b>Factors that encourage reporting an ADR</b>		
1. If the reaction is serious	98.0	2.0
2. If the reaction is unusual	77.6	22.4
3. If the reaction is to a new product	83.7	16.3
4. If the reaction is certainly an ADR	73.5	26.5
5. If the reaction is well recognized for a particular drug	67.3	32.7
<b>Factors that discourage reporting an ADR</b>		
1. Concern that report may be wrong	46.8	53.2
2. Lack of time to fill in a report and single Unreported case may not affect ADR database	36.2	63.8
3. Non-remuneration for reporting	12.8	87.2
4. Concern that reporting may generate extra work	25.5	74.5
5. Lack of time to actively look for an ADRs while at work	17.0	83.0
6. Difficult to decide whether or not an ADR has occurred	46.8	53.2
7. Lack of confidence to discuss the ADR with other colleagues	12.8	12.8
8. Do not feel the need to report a recognised ADR	19.1	80.9
9. Fear that it may have a negative impact on the company that produced or marketed it	12.8	87.2
10. Fear of incrimination	17.0	83.0
<b>ADR Reporting Form:</b>		
1. Have you ever filled an ADR reporting form	42.0	58.0
2. The information on the form was clear	28.0	12.0
3. The adverse drug reaction reporting form too complex to fill	12.0	68.0
<b>Reporting of ADRs is a professional obligation</b>	82.0	8.0

**Practice of ADR reporting**

The most common source for ADR information was 'Internet' followed by 'Journals'. Thirteen participants (26%) acknowledged that they never tried to access information on ADRs.

**Table 4: Major Sources of ADR information**

Source	Frequency	Percentage
Internet	39	78.0%
Journals	33	66.0%
Text books	31	62.0%
Drug advertisements & product catalogues	28	56.0%
Seminars/conferences	25	50.0%
Medical representatives	20	40.0%
Direct mail brochures/letters relating to medicine safety	15	30.0%
Hospital medicine safety bulletins	14	28.0%

Seventeen (34%) participants reported that they had easy access to the official ADR reporting forms distributed by ZAMRA, twenty eight (56%) did not have access to ADR reporting forms and five (10%) did not respond. Ten (20%) of the participants indicated that the forms were available at the Pharmacy in the facilities they work for, four (8%) said that they could download the ADR reporting forms from the ZAMRA website. Thirty six (72%) of participants did not respond.

The majority of the participants (78%, n = 39) had never been trained on how to report ADRs. Seven participants (14%) confirmed having received training on ADR reporting, but only four mentioned the place where they had received it from. Nineteen (38%) of the participants were not aware that they could receive training on ADR reporting and eighteen participants (36%) did not respond.

**Table 5 below shows the distribution based on the number of ADR reports submitted.**

Number of Reports	Frequency	Percentage
0	37	74%
15	2	4%
10	1	2%
2	2	4%
1	6	12%
No response	2	4%

The preferred methods of reporting were as indicated in Table 6

**Table 6: Summary of preferable methods of reporting**

Methods of Reporting	Frequency	Percentage
Email/on Website	24	48%
Direct Contact	15	30%
Telephone	5	10%
Other	3	6%
No Response	3	6%

Training was the main suggested possible ways of improving ADR reporting:

**Table 7: Suggestions of Possible ways of Improving ADR Reporting in Private Practice**

	Frequency
Train personnel in ADR reporting	16
Create a local database on ADR	3
Conduct regular inspections to check if facilities are reporting ADR	2
Ease access to ADR forms	2
Involvement of the private sector practitioners	2
Place ADR forms in each department	2
ZAMRA should provide ADR reporting tools	2
Acknowledge receipt of ADR report	1
Award institutions that are regularly reporting ADR	1
Decentralize ZAMRA offices	1
Encourage patients to report ADR	1
Establish an easier & concise reporting system	1
Establish an online reporting system	1
Establish channels of ADR reporting	1
Establish good communication between healthcare providers and patients	1
Health professionals should feel free to discuss ADR	1
Link common portal	1
Online/email reporting	1
Promote free discussions of ADR among health professionals	1
Provide readily available simplified ADR forms	1
Provide ZAMRA email/website for ADR reporting	1
Quarterly ADR reporting to ZAMRA	1
Sensitize ADR of new drugs	1
Sensitization and awareness of ADRs	1
<b>Total</b>	<b>46</b>

## DISCUSSION

This study assessed the knowledge, attitude and practice of health professionals in private practice in Lusaka, Zambia as regards reporting ADRs. The findings are important because the practice of pharmacovigilance by healthcare professionals in Zambia is still very primitive. To date only two studies on ADR reporting have been published in Zambia.<sup>5,7</sup> This study followed a similar study done on health professional working at the largest public referral hospital in Zambia.<sup>7</sup> The response rate at 27% of the current study, was relatively very low compared to other similar studies involving health professionals working in private practice in Malaysia and Kuwait where the response rate was respectively, 83% and 61%.<sup>11,12</sup> In the local setting, this indirectly reflected unwillingness on the part of the private sector health professionals to provide information related to their practice. It was encouraging however to note the positive attitude (82%) of the participants that felt that the ADR reporting is a professional obligation, a finding similar to a study done in Malaysia where 80.6% of the participants acknowledged ADR reporting to be a professional obligation.<sup>11</sup> Authors argue that such positive attitude towards ADR reporting be complimented with educational interventions.

Knowledge of ADR reporting was generally low, pharmacists had relatively higher knowledge levels on ADR reporting compared to medical doctors and nurses. This was not a surprising finding as pharmacists, by virtue and nature of their practice and training, are expected to be more knowledgeable about medicines and their effects. Since ADR reporting is a practice and responsibility of all healthcare workers involved in patient care, the ideal situation should be to have all relevant health professionals knowledgeable about pharmacovigilance and its practice. Whereas a number of related studies elsewhere have been conducted to assess knowledge, attitude and practice on ADR reporting, such studies were largely conducted in a homogenous population of either medical doctors or pharmacists or in health professionals working at public facilities.<sup>8,12,13</sup> The authors found very few such studies conducted

among private practitioners.<sup>11,12,14</sup> Prashar and Musoke in their study of knowledge, attitude and practice of pharmacovigilance in public healthcare facilities in Lusaka also found that knowledge levels on ADR reporting were relatively higher among pharmacists than other health professionals assessed.<sup>7</sup>

Findings of this study collaborate with those by Bugolubova, who investigated the knowledge, attitudes and practices of nurses and pharmacists towards ADR reporting in the private sector in Gauteng, South Africa and found that although three quarters of nurses and pharmacists believed ADR reporting to be important, most had received no previous pharmacovigilance training and did not know how to report an ADR. In their study, the majority (87%) of participants believed that all ADRs should be reported, with a third (75.5%) of the participants believing they would report all ADRs they encountered in the future provided they had sufficient training and knowledge. The major factors they found that discouraged ADR reporting were; lack of awareness with respect to the process of ADR reporting and lack of access to the ADR reporting forms.<sup>14</sup> These are similar findings to this study where more than half (58%) of the participants had never filled out an ADR report form and submitted the same to ZAMRA. Clearly, challenges of ADR reporting in the private health sector are commonly shared across African countries.

This study did not investigate the awareness of the participants regarding other ADR reporting platforms such as the mobile app that ZAMRA launched in Zambia in June, 2017. Nevertheless about two- third (72%) of the participants were not aware of where to report the ADRs.<sup>15</sup> The majority (78%) of the participants had not received any pharmacovigilance training. This finding in Zambia was similar to the situation in Ghana where lack of pharmacovigilance training was a contributing factor to the poor practice of ADR reporting.<sup>13</sup>

### Implications of the findings

Training of pharmacovigilance and spreading awareness of ADR reporting among health

professionals in the various private healthcare facilities needs to be scaled up. The ADR reporting forms and platforms should be made readily available in private facilities.

### Limitations of the study

The study relied on self-reported data which may be prone to recall bias on the part of the participants<sup>10</sup>, however, the findings were indicative of the nature of current practice. Investigators were confident that findings were trustworthy and reliable. The low response rate may have been influenced by Managers of private healthcare facilities expressing insecurities about their personnel being interviewed or administered questionnaires. This led to some facilities outrightly declining or refusing to grant permission to the collect data from their personnel. This was an external threat to validity beyond the investigators' control. Since participation was entirely voluntary and not incentivized, some practitioners declined to participate on account of having no time, busy work schedules, and lack of interest. It was highly unlikely that extending the study duration further than twelve months for more participation would have yielded any increasing returns in terms of response rates. Despite the challenges to attaining the target sample, coupled by limitations with resources to extend or modify the protocol, the investigators proceeded to report findings attained. The investigators remained confident that the findings reported in this study reflected the state of knowledge, attitude and practice of ADR reporting among medical doctors, pharmacists and nurses in the private clinics and hospitals in Lusaka, Zambia.

### CONCLUSION

This study found that, despite positive attitudes, the practice of under-reporting of ADRs by practitioners in private healthcare facilities in Lusaka was mainly driven by inadequate knowledge of pharmacovigilance and unavailability of ADR reporting tools at the facilities. The knowledge gaps and capacity to report ADRs among health professionals in the private healthcare sector will need to be addressed if improving practice of pharmacovigilance is to be realized in Zambia.

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