Adverse drug reaction reporting among health care workers at Mulago National Referral and Teaching hospital in Uganda

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Abstract

Background: Adverse Drug Reactions (ADRs) are an important contributor to patient morbidity and hospitalisation in Uganda. Under-reporting of ADRs may increase medicine-induced morbidity and mortality among patients. This study determined the extent of ADR reporting, and associated factors, among healthcare workers in Uganda.

Methods: A quantitative, cross-sectional, study was conducted. Pretested, semi-structured questionnaires were administered to 289 randomly sampled healthcare workers over a three-month period in Mulago National Referral Hospital, Uganda. The primary outcome was the proportion of healthcare workers who had ever reported an ADR. Data was double-entered in Epidata version 3.0, cleaned and exported to STATA version 10.1 for analysis.

Results: The overall response rate was 77.2% (n=223). The majority of the respondents were females (139, 62.3%). The median age of all respondents was 32.6 years (min-23; max-65). Only about 16.6% (n=37) of healthcare workers had ever reported an ADR. Very few (n=84, 37.7%) healthcare workers knew the tools used in ADR reporting. Less than a quarter (n=41, 18.4%) of the healthcare workers knew where to report ADRs. Lack of training was reported as the major (56.5%, 126) deterrent to reporting ADRs by healthcare workers.

Conclusion: Adverse drug reactions are under-reported in Uganda, and healthcare workers have insufficient knowledge of existing pharmacovigilance systems, including ADR reporting systems. To address these challenges, there is need to sensitize and train healthcare workers in patient-centred aspects of medicine surveillance, so as to provide appropriate care while optimising patient safety.

Keywords: Adverse drug reaction, ADR, adverse effects, reporting, healthcare worker, pharmacovigilance, Uganda **DOI:** http://dx.doi.org/10.4314/ahs.v15i4.34

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Introduction

The World Health Organisation1 defines an adverse drug reaction (ADR) as 'a response to a medicinal product which is noxious and unintended, and occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for modification of physiological function.' From the patient perspective, ADRs vary in severity and duration, and can be, ap-

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preciably, unpleasant and harmful.² They usually require dose alteration, halting of treatment, or monitoring future drug administration.² Six categories of ADRs are cited alphabetically: augmented (dose-related), bizarre (non-dose related), chronic (dose- and time- related), delayed (time-related), end of use (withdrawal), and failure (failure of therapy).² Unlike ADRs, side effects are often related to the medicine's pharmacological properties1, and may be beneficial.² For instance, the beta-blockade side effect of some antihypertensive medicines may benefit patients with angina.² Irrespective, this study focuses on ADRs, and not side effects.

ADR reporting involves voluntary submission of patient-specific information on a suspected ADR, to a drug regulatory agency, following administration of at least one medicinal product¹. It remains the foundation of pharmacovigilance and patient safety^{2,3}. Almost half

(49.5%) of all hospitalised patients in Uganda are prone to experiencing an ADR⁴. Despite this, under-reporting of ADRs frustrates efforts in identifying, evaluating and preventing several unusual, serious, hazardous and novel ADRs, and thus under estimating their burden in populations^{3,5}. This may consequently lead to increased medicine-induced morbidity and mortality. Additionally, ADRs impart economic constraints on public health systems⁶.

Health care professionals are frontline stakeholders in detecting and reporting adverse drug reactions occurring in patients⁵. However, there is limited literature on the magnitude, and factors associated with ADR reporting among healthcare workers in Uganda. Existing pharmacovigilance studies conducted in Uganda⁸⁻⁹, and neighbouring countries¹⁰, focus on ADRs related to antimalarial therapy, in spite of diversities in disease burden and medicines used in Uganda. Nevertheless, one of the studies9 superficially hinted that some of Uganda's healthcare workers were unfamiliar with formal pathways for reporting ADRS. Additionally, a variety of factors are cited to deter healthcare workers from reporting ADRs including inadequate knowledge about the purpose of reporting, fear of extra workload, failure to differentiate clinical symptoms from ADRs, among several other factors^{7,18}.

There are on-going efforts to improve pharmacovigilance systems in Uganda. The National Pharmacovigilance Centre (NPC), under the National Drug Authority, was set up to promote ADR reporting by healthcare workers and the general public 11,24. Reporting of ADRs to the centre is made possible through an installed phone line, text message service, fax and printed ADR reporting forms, with the latter provision commonly encouraged in hospital settings 11,24. More recently, user-friendly reporting forms have been developed to support ADR reporting among all cadres of health care workers and non-clinicians in Uganda 12.

This study therefore sought to determine the extent of ADR reporting, and associated factors, among health-care workers in Mulago National Referral and Teaching hospital, in Uganda. The specific objectives of the study were: to determine the proportion of healthcare workers who had ever reported an ADR, by any means, to a drug regulatory agency in Uganda; to assess healthcare workers' level of knowledge of ADR reporting in

Uganda; and to determine the factors associated with ADR reporting among healthcare workers in Uganda.

Methods

Design and settings

A cross-sectional study was carried out from January to March 2010 (3 months) to determine the extent of ADR reporting by healthcare workers, and the associated factors, at Mulago National Referral and Teaching hospital in Uganda using a pre-tested, semi-structured questionnaire. This hospital is located on Mulago Hill, in the northern part of Kampala city. Being Uganda's largest hospital, with an official bed capacity of about 1790 beds, the hospital has an annual in-patient turnover in excess of 140,000 patients and attends to over 600,000 out-patients annually^{13,26}. The hospital provides specialist services in Surgery, Internal Medicine, Paediatrics and child health, Obstetrics and Gynaecology, Oncology, Radiology, Dentistry, Orthopaedics, and Accident and Emergency²⁶. By the time of conducting the study, the hospital employed about 2300 staff including about 650 doctors, 930 nurses and 53 pharmacists (including intern doctors, pharmacists, and nurses, and residents in training)¹³.

Sample size determination

A 25 % prevalence of ADR reporting¹⁴, a z-value corresponding to 95% level of significance, and an absolute permissible error of 5%, was assumed¹⁵. Using the Kish, L (1965) formula for sample size determination¹⁵, a sample of two hundred eighty nine healthcare workers (289) was required.

Study participants, selection criteria, and sampling strategy

The study sample included 289 healthcare professionals (doctors, nurses and pharmacists) participating directly in patient care during the study period. These are professionals who were thought to have the knowledge and responsibility of reporting suspected ADRs to the hospital and national pharmacovigilance centres. Healthcare professionals who did not consent to participate in the study were excluded. A proportionate (stratified) sampling strategy was adopted. Based on the proportions of each category of healthcare workers employed in the hospital, a random sample of one hundred fifteen (115) doctors, one hundred sixty four (164) nurses and ten (10) pharmacists, was selected using lists from the hospital's human resource department as the sampling frame¹³.

Data collection tool and data collection procedures

The survey instrument of Oshikoya and Awobusuyi (2009) was adapted with minor modifications, where a 38-item questionnaire was utilised to determine ADR reporting practices among doctors in Nigeria⁷. By the time of conducting the study (January to March 2010), this instrument was thought to provide the most suitable basis for assessment of ADR reporting practices among healthcare workers in Africa.

Irrespective, this instrument was slightly modified to suit the Ugandan setting. Of the 16-items which were removed from the original questionnaire, 4 items relating to participants' demographic characteristics (country of undergraduate training, year of qualification, healthcare workers' position in the hospital, and country of any additional qualification) were excluded owing to their irrelevance to the study's objectives.

In the knowledge-domain, two items seeking healthcare workers' understanding of the yellow-card reporting systems (commonly utilised in the UK) were eliminated because of the study's focus on the local ADR reporting systems in Uganda. One item seeking participants' knowledge of drug categories that require ADR reporting, was excluded as the study did not intend to assess reporting of drug-specific ADRs. One repetitive item, assessing participants' knowledge of reporting serious ADRs, was also eliminated. Finally, 8 items, comprising short, hypothetical cases of ADRs were excluded owing to their drug-specificity; some of the drugs included in the hypothetical cases were not in clinical use in Uganda, at the time of conducting the study.

To give rise to the final 31-item questionnaire, utilised in this study, nine additional items were included: 3 items on socio-demographic characteristics (profession, marital status, religious affiliation); 1 item in the knowledge-domain (general understanding of the concept of ADR reporting); and 5 items on the practice of ADR reporting. The practice-domain included: 2 items on submission of ADR reporting forms, 1 item on the circumstance under which ADR reporting was done, 1 item on the frequency of ADR reporting, and 1 item on the drug regulatory centre used to report an ADR. The final questionnaire collected data on participant's socio-demographic characteristics, knowledge, attitudes, practice, and factors associated with ADR reporting (such as seriousness of an ADR, duration of a medicine on the market, and training of healthcare workers).

The final questionnaire was pre-tested on 20 randomly selected healthcare professionals in Mulago Hospital. The 20 health care professionals were not included in the final sample used in the study. The final questionnaire was also peer-reviewed by a senior pharmacist and researcher who recommended its use.

The principal investigator, together with two trained research assistants, sought appointments and informed consent from study participants, delivered the questionnaire, had it filled out and picked it up immediately after completion, up to the end of the day. In case participants needed help with some sections of the questionnaire, the study team were on hand to assist the participants. The same copy was re-administered to those who had misplaced the previous copy administered. All this was done to increase the response rate of the participants.

Study outcomes

The primary outcome of interest was the proportion of health care workers who had ever reported an ADR by any means, to a drug regulatory centre. To assess participants' level of knowledge of ADR reporting, their understanding of ADR reporting and its purpose, awareness of who should report ADRs, awareness of existence of pharmacovigilance centres and awareness of the existence of National ADR reporting forms, was determined. All correct answers were summed up into a percentage score, and finally knowledge levels were rated as poor (0-24%), fair (25-49%), good (50-74%), and very good (75-100%). Factors associated with ADR reporting such as the seriousness of an ADR, duration of the drug on the market, remuneration of ADR reporting, availability of ADR reporting forms on the wards, and training of healthcare workers, were assessed.

Data analysis strategy

The data was coded, double-entered in an electronic form designed using Epidata version 3.0, and exported to STATA version 10.1 (STATA Corp, TX, USA) for analysis. Participant socio-demographic characteristics were summarised as frequencies and percentages for all categorical variables. To evaluate the factors associated with ADR reporting, a bivariate analysis was conducted with the following independent variables: profession of healthcare worker, department of work, duration of service, level of knowledge of ADR reporting. Also, the gender, age, marital status, religious affiliation of health care workers was included in the bivariate analysis.

Ethical considerations

The study was approved by the Research and Ethics Committee of Mulago National Referral and Teaching hospital in Uganda. Participation in the study was voluntary, and informed consent was obtained from all study participants before completing the questionnaires. Data collection forms were anonymous and all information was kept with strict confidentiality.

Results

Out of the 289 questionnaires that were distributed, only 223 respondents returned them giving a response rate of about 77.2%.

Socio-demographic characteristics of respondents

The majority of the respondents were females (62.3%, n=139). The median age of the respondents, in complete years, was 32.5 (minimum=23, maximum=65). Participants had an average work experience of 12.5 years (minimum=0, max=30). Nearly half of all respondents were nurses (53.8%, n=120). A third (30%, n=66) of all respondents were working in the General Medicine department. Other characteristics of study participants are summarized in Table I below.

Table I: Characteristics of healthcare professionals at Mulago National Referral Hospital, January 2010–March 2010 (N=223)

pital, January 2010–March 2010 (N=223)		
Characteristic	Values	
Median age (min-max) in years	32.5(23-65)	
Years of work experience, median (min- max)	12.5(0-30)	
Other characteristics	n (%)	
Gender		
Male	84(37.7)	
Female	139(62.3)	
Healthcare workers at each Hospital department		
General medicine	66 (29.6)	
Surgery	37 (16.6)	
Obstetrics/Gynaecology	36 (16.1)	
Paediatrics and child health	48 (21.5)	
Oncology	7 (3.1)	
Others*	29(13.0)	
Profession		
Doctor	95(42.6)	
Nurse	120(53.8)	
Pharmacist	8(3.6)	
Marital Status		
Single	101(45.3)	
Married	118(52.9)	
Widowed	4 (1.8)	
Religious Affiliation		
Roman Catholic	65(29.1)	
Anglican	78 (35.0)	
Pentecostal	58 (26.0)	
Muslim	17 (7.6)	
Others	5(2.2)	

^{*} includes Accident & Emergency, Family medicine, Nutrition & dietetics, Ophthalmology, Psychiatry and Radiology.

ADR reporting among respondents in the teaching hospital

The overall prevalence of ADR reporting among health-care workers in Mulago National Referral and Teaching hospital was 16.6% (n=37, 95% CI = 11.7-21.5%). Of the respondents who claimed to have ever reported ADRs, thirty one reported to have used National ADR reporting forms. Only seventeen (n=17) respondents had reported ADRs under routine patient care.

Knowledge of the ADR reporting system among respondents

More than half (69.1%, n=154) of the respondents understood, correctly, the concept of ADR reporting. Almost three-quarters (75.3%, n=168) of all respondents correctly knew that all healthcare workers were required to report ADRs. Less than half (41.7%, n=93) of all

respondents were aware of the existence of the Uganda National Pharmacovigilance Centre (NPC). Out of those respondents who were aware of this centre, only 41 could correctly identify the Uganda National Drug Authority (NDA) head offices as the centre's location. Less than a quarter (21.5%, n=48) of all respondents were aware of the existence of the local hospital pharmacovigilance centre (HPC), and only eleven respondents knew its correct location. A few (37.7%, n=84) respondents were aware of the existence of the national ADR reporting forms within the hospital, 62 of whom did not know if these forms were available on their hospital wards. About 60.5% (n=135) of all respondents correctly knew the identification of safety signals of medicines as a purpose of ADR reporting. Overall, the majority (39.9%, n=89) of the respondents had a fair level (25-49%) of knowledge regarding ADR reporting (See Table II).

Table II: Knowledge of ADR reporting among healthcare workers at Mulago National Referral Hospital, January 2010-March 2010 (N=223)

Characteristic	n (%)
Understand the concept of ADR reporting	
Understand	154(69.1)
Don't understand	69(30.9)
Know who should report ADRs	
Know	168(75.3)
Don't know	55(24.7)
Awareness of the existence of the NPC in Uganda	
Aware	93(41.7)
Not aware	130(58.3)
Knowledge of location of Head offices of the NPC	
Know	41(18.4)
Don't know	182(81.6)
Awareness of the existence of the HPC	
Aware	48(21.5)
Not aware	175(78.5)
Knowledge of the location of the HPC	
Know	11(4.9)
Don't know	212(95.1)
General awareness of the existence of national ADR reporting forms	3
Aware	84(37.7)
Not aware	139(62.3)
Awareness of availability of ADR reporting forms on hospital ward	s
Aware	21(25.3)
Not aware	62(74.7)
Knowledge of the purpose of ADR reporting	
Identification of safety signals	135(60.5)
Identify serious and rare ADRs	124 (55.6)
Reveal clinical features of ADRs	98 (44.0)
Identify risk factors for ADRs	76(34.1)
Comparison of ADRs	63(28.3)
Calculate incidence of ADRs	109(48.9)
General level of knowledge of ADR reporting	
Poor (0-24%)	80(35.9)
Fair (25-49%)	89(39.9)
Good (50-74%)	40(17.9)
Very Good (75-100%)	14(6.3)

NPC-National Pharmacovigilance Centre, HPC- Hospital Pharmacovigilance Centre

Factors associated with ADR reporting among respondents

Participants' socio-demographic characteristics (gender, age, profession, department of work, duration of service, marital status and religious affiliation), and knowledge indicators (understanding the concept of ADR reporting, awareness of the purpose of ADR reporting, awareness of who should report ADRs, awareness of the existence of pharmacovigilance centres) were assessed for their association with ever reporting an ADR in a bivariate analysis. All socio-demographic characteristics of participants were associated with ever reporting an ADR. Healthcare workers with 36-65 years of age were three times (OR = 3.068, 95% CI 1.433-6.568) more likely to have ever reported an ADR when compared to younger colleagues in the age bracket 21-35 years. Nurses were less likely (OR= 0.276, 95% CI 0.117-0.650) to have ever reported an ADR when compared to doctors and pharmacists. Healthcare workers with more than 10 years of work experience were four times more likely (OR = 3.919, 95% CI 1.522-10.084) to have ever reported an ADR when compared to those with at most 5 years of work experience (See Table IIIa).

Healthcare workers who did not understand the concept of ADR reporting were less likely (OR=0.160, 95% CI 0.046- 0.561) to have ever reported an ADR when compared to those who understood. Healthcare workers who were not aware of the existence of the local Hospital Pharmacovigilance Centre (HPC) were less likely (OR= 0.095, 95% CI 0.039 – 0.228) to have ever reported an ADR when compared to those who were aware of this centre. Healthcare workers who knew the purpose of ADR reporting were more likely (OR=1.617, 95% CI 1.071- 1.702) to have ever reported an ADR when compared to those who did not know its purpose. Results on the bivariate analysis of factors associated with ADR reporting are summarized in Table IIIa below.

Table IIIa: Factors associated with reporting Adverse Drug Reactions among health professionals at Mulago National Referral Hospital, January 2010- March 2010

Characteristic	Bivariate analysis
	Unadjusted Odds Ratio, OR (95% CI)
Age in years	
21- 35	1.000
36-65	3.068 (1.433-6.568)
Gender	
Male	1.000
Female	0.335 (0.159- 0.706)
Profession	
Doctor	1.000
Pharmacist	0.633 (0.214- 1.874)
Nurse	0.276 (0.117- 0.650)
Hospital department	,
General Medicine	1.000
Obstetrics/Gynaecology/Surgery	0.952 (0. 424-2. 139)
Paediatrics and child health	1.464 (0.371-5.785)
Years of work experience	,
0 - 5	1.000
6 - 10	2.027 (0.808-5.082)
> 10	3.919 (1.522-10.084)
Marital Status	,
Not married	1.000
Married	2.819 (1.273 - 6.242)
Religious Affiliation	,
Roman catholic	1.000
Anglican	0.727 (0. 305 -1. 735)
Pentecostal	0.296 (0.088- 0.994)
Muslim	2.800 (0. 867 -9. 038)
Other	2.000 (0.164- 24.373)
Understanding of the concept of ADR reporting	,
Understand	1.000
Don't understand	0.160 (0.046- 0.561)
Awareness of who should report ADRs	
Don't know	1.000
Know	0.541 (0.213 – 1.376)
Awareness of the existence of the NPC	0.0 - 1 (0.0 - 0)
Aware	1.000
Not aware	
Awareness of the existence of the HPC	0.145 (0.060- 0.352)
	1 000
Aware Not aware	1.000
Not aware	0.095 (0.039 – 0.228)
Awareness of the national ADR reporting forms	1 000
Aware	1.000
Not aware	0.140 (0.048 - 0. 413)
Awareness of purpose of ADR reporting	1 000
Not aware Aware	1.000 1.617 (1.071- 1.702)
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Univariate analysis was also conducted to determine other factors perceived to influence ADR reporting. The majority (91.9%, n=205) of the respondents felt that a serious, unusual ADR would encourage them to report it. About 42.2% (n=94) of the respondents felt that an adverse drug reaction to a new drug would encourage them to report it. Lack of time to actively look out for ADRs and fill in ADR reporting forms

was most frequently (56.5%, n=126) cited to discourage ADR reporting among participants. Lack of training was the other frequently (54.7%, n=122) perceived factor to discourage ADR reporting. Perceived lack of feedback even after ADR reporting was another commonly reported (48%, n=107) factor to discourage ADR reporting. Table IIIb summarises the univariate factors perceived to influence ADR reporting among respondents.

Table IIIb: Factors perceived to influence ADR reporting among health professionals at Mulago National Referral Hospital, January 2010- March 2010

professionals at Mulago National Referral Hospital, January 2010- March 2010		
Factors		n (%)
Factors perceived to encourage	Serious and unusual reaction	205 (91.9)
ADR reporting	ADR to a new medicine	94 (42.2)
	Well recognized ADR	57 (25.6)
	Other*	8 (3.6)
Factors perceived to discourage		, ,
ADR reporting	Lack of time	126 (56.5)
	Lack of training	122 (54.7)
	No feedback even after reporting	107 (48)
	Fear for extra workload	101 (45.3)
	Limited knowledge	99 (44.4)
	No reward for reporting	85 (38.1)
	Fear for wrongly filling in an ADR	64 (28.7)
	single unreported case is insignificant	42 (18.8)
	Lack of confidence in identifying ADRs	43(18)
	Fear for legal implications	40 (17.9)
	Reporting is not compulsory	27 (12.1)
	Irrelevant to report	26 (11.7)
	Design of ADR form	18 (8.1)
	Other**	10 (4.5)

^{*} includes: remuneration of ADR reporting; availability of ADR report forms; training of healthcare workers. ** includes minor and self-limiting reaction; unaware of where to report; lack of ADR forms

Discussion

Adverse drug reactions contribute significantly to patient morbidity and hospitalisation in Uganda⁴. Regardless, this study found that, similar to other studies^{7,14,16-18}, healthcare professionals working in Uganda's National Referral Hospital under-reported adverse drug reactions to the National pharmacovigilance centre. Only a small proportion (16.6%) of health care workers in the present study had ever reported an ADR. This level was substantially lower than that reported elsewhere^{5,7}.

Clearly, substantial effort for improvement, in this area, is necessary.

Similar to other studies^{7,14,16,18}, the under-reporting of ADRs observed in the present study was associated with healthcare workers' insufficient knowledge levels of the existing pharmacovigilance systems and facilities. Only one-third (n= 84) of respondents in the present study were aware of the existence of the national ADR reporting forms within the hospital. This is similar to the findings of one recent study²⁵, con-

ducted in an Ethiopian tertiary hospital, indicating that 36% of health professionals were not aware of existing ADR reporting systems. This could be a result of limited awareness and support for ADR identification and monitoring, competing medical priorities with less emphasis on monitoring the negative outcomes of medicines, or difficulties in differentiating clinical symptoms of disease from ADRs.

Similar to related studies conducted in Africa¹⁴, health-care workers revealed limited training and sensitization in areas of pharmacovigilance and ADR reporting. More sensitization and training regarding identification and managing of ADRs, existing pharmacovigilance systems, the purpose of ADR reporting, and the availability of resources for ADR reporting (such as reporting forms) is necessary for Uganda's healthcare professionals. This will subsequently support the identification of potentially harmful medicines, and prevent medicine-induced burden among patients.

The profession of health care workers may contribute to their knowledge, attitude or practice of ADR reporting¹⁶. In the present study, nurses comprised the vast majority of healthcare workers, and the bivariate analysis indicated that they were less likely to report ADRs when compared to pharmacists and doctors. It is also worth noting that very few pharmacists participated in the present study, and the same is true in actual practice in Uganda²⁰. Irrespective, research has shown that pharmacists are a fundamental cadre of healthcare professionals with relatively better knowledge of medicines, including side effects or adverse reactions, and thus have a more likelihood of reporting ADRs when compared to other health professionals¹⁶. All these factors may explain the very low ADR reporting levels observed in the present findings.

In addition, the existing constraints in Uganda's health workforce, characterised by overstretched health care worker:patient ratios, and excessive workload²⁰, may not allow ample time for ADR monitoring during routine patient care. Similar to findings elsewhere^{16,21-23}, lack of time to actively look out for ADRs and fill in ADR reporting forms, was cited as a deterrent to ADR reporting by healthcare professionals. This suggests that, even though willing to report ADRs, Uganda's healthcare workers face workload demands that may not favour ADR monitoring and reporting, which potentially impacts on patient safety.

Notably, a vast majority of healthcare workers in the present study felt the need to report only serious and unusual ADRs. Evidence suggests that, compared to non-serious drug reactions, serious adverse drug reactions are five-fold more likely to be reported to drug safety committes⁵. Although Uganda's drug regulatory authority encourages reporting of all ADRs, including unserious, unproven reactions^{11,24}, healthcare providers may have had difficulties in differentiating all types of ADRs from disease-related clinical symptoms. More in-depth research needs to explore Ugandan health care providers' knowledge of ADRs (including identification and causality assessment), and their preferred methods for ADR reporting.

In spite of the good response rate, adequate sample size, and randomised selection of study participants and possible generalisability of findings, the present results need to be interpreted with respect to the limitations and the complexities surrounding pharmacovigilance research. Patient safety and ADR monitoring, rely on many other factors beyond ADR reporting in spite of being the study's main concern. Additionally, the present study largely assumes that healthcare providers are primarily responsible for ADR monitoring and reporting in Uganda. Recent trends suggest that patients and non-clinicians, in Uganda, have the potential to directly report ADRs¹², and thus further work is needed to explore other avenues for monitoring adverse effects of medicines and patient safety.

Conclusion

Only about 2 in every 10 healthcare workers in Uganda had ever reported an adverse drug reaction. Several factors were associated with under-reporting of ADRs among health professionals in Uganda. Notably, healthcare workers revealed inadequacies in knowledge of existing local pharmacovigilance systems, and insufficient training and sensitization. Evidently, there is a need for more sensitization and training of Uganda's healthcare workers with respect to drug-related patient safety, including ADR monitoring, so as to support better treatment outcomes. Strengthening pharmacovigilance systems in Uganda's public health sector will go a long way in improving rational medicines use and patient safety.

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Author contributions

BK and DS conceived and designed the study. BK participated in data collection and entry. DS and SJL analysed and interpreted the data. BK, DS and SJL drafted and critically revised the manuscript for intellectual content. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

References

- 1. WHO(2011).Glossary of terms used in Pharmacovigilance [Online] Available at: http://who-umc.org/Graphics/24729.pdf Last accessed: 7 /04/ 2014.
- 2. Edwards, I. R., & Jeffrey K. A. Adverse drug reactions: definitions, diagnosis, and management. *The Lancet* 2000; 356 (9237): 1255-1259.
- 3. Lazarou, J., Pomeranz, B. H., & Corey, P. N. Incidence of adverse drug reactions in hospitalized patients. *IAMA* 1998; 279(15):1200-1205.
- 4. Tumwikirize, W. A., Ogwal-Okeng, J. W., Vernby, A., Anokbonggo, W. W., Gustafsson, L. L., & Lundborg, S. C. Adverse drug reactions in patients admitted on Internal Medicine wards in a district and Regional Hospital in Uganda. *African Health Sciences* 2011; 11(1): 72 -78.
- 5. Heeley, E., Riley, J., Layton, D., Wilton, L. V., & Shakir, S. A. Prescription-event monitoring and reporting of adverse drug reactions. *The Lancet* 2001; 358(9296): 1872-1873.
- 6. Ayani, I., Aguirre, C., Gutierrez, G., Madariaga, A., Rodríguez-Sasiaín, J. M., & Martínez-Bengoechea, M. J. A cost-analysis of suspected adverse drug reactions in a hospital emergency ward. Pharmacoepidemiology and drug safety 1999; 8 (7): 529-534.
- 7. Oshikoya, K. A., & Awobusuyi, J. O. Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. *BMC Pharmacology and Toxicology* 2009; 9(1), 14.
- 8. Willcox, M. L., Burton, S., Oyweka, R., Namyalo, R., Challand, S., & Lindsey, K. Evaluation and pharmacovigilance of projects promoting cultivation and local use of Artemisia annua for malaria. *Malaria Journal* 2011; 10(1): 84.

- 9. Bukirwa, H., Nayiga, S., Lubanga, R., Mwebaza, N., Chandler, C., Hopkins, H. & Staedke, S. G. Pharmacovigilance of antimalarial treatment in Uganda: community perceptions and suggestions for reporting adverse events. Tropical Medicine & International Health 2008; 13(9):1143-1152.
- 10. Kamat, V. R. Cultural interpretations of the efficacy and side effects of antimalarials in Tanzania. Anthropology and Medicine 2009; 16(3): 293-305.
- 11. National Drug Authority. Pharmacovigilance Bulletin 2012; Volume 1. Issue 6.
- 12. Davies, E. C., Chandler, C. I., Innocent, S. H., Kalumuna, C., Terlouw, D. J., Lalloo, D. G., & Haaland, A. Designing Adverse Event Forms for Real-World Reporting: Participatory Research in Uganda. *Plos One* 2012; 7(3): e32704.
- 13. Mulago Hospital Complex. Human Resource Records. Unpublished data 2010.
- 14. Elnour, A. A., Ahmed, A. D., Yousif, M. A. E., & Shehab, A. Awareness and reporting of adverse drug reactions among health care professionals in Sudan. *Journal on Quality and Patient Safety* 2009; 35(6):324-329.
- 15. Kish, L. Survey sampling. New York: J. Wiley & Sons, 643 (1965):16.
- 16. Green, C. F., Mottram, D. R., Rowe, P. H., & Pirmohamed, M. Attitudes and knowledge of hospital pharmacists to adverse drug reaction reporting. *British Journal of Clinical Pharmacology* 2001; 51(1):81-86.
- 17. Vessal, G., Mardani, Z., & Mollai, M. Knowledge, attitudes, and perceptions of pharmacists to adverse drug reaction reporting in Iran. Pharmacy world & science 2009; 31(2):183-187.
- 18. Hazell, L., & Shakir, S. A. Under-reporting of adverse drug reactions. *Drug Safety* 2006; 29(5): 385-396.
- 19. Kuemmerle, A., Dodoo, A. N., Olsson, S., Van Erps, J., Burri, C., & Lalvani, P. S. Assessment of global reporting of adverse drug reactions for anti-malarials, including artemisinin-based combination therapy, to the WHO Programme for International Drug Monitoring. *Malar Journal* 2011; 10:57.
- 20. Africa Health Workforce. Human Resources for Health Country Profile-Uganda; 2009.
- 21. Belton, K. J., Lewis, S. C., Payne, S., Rawlins, M. D., & Wood, S. M. Attitudinal survey of adverse drug reaction reporting by medical practitioners in the United Kingdom. *British Journal of Clinical Pharmacology* 1995; 39(3): 223-226.
- 22. Bateman, D. N., Sanders, G. L., & Rawlins, M. D. Attitudes to adverse drug reaction reporting in the

- Northern Region. British Journal of Clinical Pharmacology 1992; 34(5): 421.
- 23. Belton, K. J. Attitude survey of adverse drug-reaction reporting by health care professionals across the European Union. *European Journal of Clinical Pharmacology* 1997; 52(6), 423-427.
- 24. The National Drug Authority of Uganda. Guide to detecting and reporting Adverse Drug Reactions. May 2009: 1-20.
- 25. Srikanth, B.A., Hailu, W., Admassie, E., & Khan, T.M. Knowledge, attitude and practices of health professional towards adverse drug reactions reporting in Gondar University Hospital, Northwest Ethiopia. *Afr J Health Sci* 2014; 27(1):46-56.
- 26. Mulago Hospital (2014). Services [Online] Available at: http://mulago.or.ug/medical-services Last accessed: 08/06/2014.