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FACILITY-LEVEL FACTORS AND BARRIERS TOWARDS ADVERSE DRUG REACTION MONITORING AMONG HEALTHCARE PROVIDERS IN KIRINYAGA COUNTY, KENYA: A QUALITATIVE STUDY

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ABSTRACT:

Background: Under reporting of adverse drug reactions (ADR) has serious ramifications on the treatment outcomes and quality of healthcare for patients. Lack of reporting tools, guidelines, training and feedback have contributed significantly to under reporting. Objective: To explore facility-level factors and barriers associated with ADR monitoring among healthcare providers in Kirinyaga County, Kenya. Methods: A qualitative study utilising in-depth interviews was conducted among 12 departmental heads in 1 level 5 and 3 level 4public hospitals in Kirinyaga County, Kenya. A pre-tested interview guide was utilised to collect data. Audio taped interview transcripts were coded using NVivo version 12 software. Data were analysed using deductive thematic analysis. Findings from the study were presented using verbatim quotes and tables. Results: Deductive thematic analysis resulted in 5 themes, namely (1) Capacity to monitor ADRs; (2) Training; (3) Feedback; (4) Barriers of ADR reporting;(5) Perceived solutions for improved ADR reporting. Overall, all hospitals lacked pharmacovigilance (PV) centers. Additionally, frequency of feedback from the Pharmacy and Poisons Board (PPB) was low. Barriers of ADR reporting that were identified included: not knowing where to report, inability to access healthcare providers, unfriendly healthcare personnel and lack of training. Conclusion: The study noted that selected hospitals had limited capacity to monitor ADRs. Additionally, lack of training and feedback were major hindrances to ADR reporting at facility-level. Continuous training, providing prompt feedback in addition to developing a PV centre are highly recommended in order to promote ADR reporting and rational use of medicine in Kirinyaga County.

KEYWORDS: Adverse drug reaction; pharmacovigilance; healthcare provider; barriers; facility-level factors.

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INTRODUCTION

World Health Organization (WHO) has defined pharmacovigilance (PV) as the science and activities relating to the detection, assessment, understanding and prevention of adverse events or any other possible drug related problems.[1]The Pharmacy and Poisons Board (PPB) defines adverse drug reaction (ADR) as a response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.[2] ADRs occur via two mechanisms; direct toxicity and hypersensitivity. Direct toxicity occurs when a drug or its metabolites cause alteration to physiological processes. A hypersensitivity reaction occurs when thebody responds to a drug or its metabolites in an exaggerated manner. [3]

Spontaneous reporting is a PV approach in which ADR reporting is voluntary and lies on the hands of health care providers. [1]In the United Kingdom(UK), ADR reporting is facilitated by the yellow card scheme. The United States of America (USA), depends on spontaneous reporting to monitor ADRs. The Food and Drug Administration (FDA) launched Adverse Event Reporting System (AERS) in 1969; a database that employs data mining to capture signals. [4] In Kenya, ADRsare reported to the PPB through post or online or through departmental heads of healthcare settings.[2]

The capacity to monitor ADRs is assessed 5 WHO least prerequisites: a PV center, a spontaneous method of reporting that uses a standard ADR reporting form, a database that analyzes ADR reports, a committee that conducts risk-benefit analysis of drugs and a clear channel for feedback.[5] Previous studies have attributed underreporting to lack of training on how to identify and report ADRs, minimal feedback, lack of PV center, busy schedules, legal liability and unawareness of ADR reporting scheme. [6,7,8] Trained healthcare practitioners were inclined to report ADRs more than healthcare workers who were not sensitized. [9]

MATERIALS AND METHODS:

This was a cross-sectional study that utilized a qualitative approach to data collection. The approach was adopted as it's flexible, it stimulates an in-depth exploration of the problem and allows generation of ideas in line with how participants perceive the issue. The study was conducted in Kirinyaga County, Kenya in 1 level 5 hospital and 3 level 4 hospitals namely: Kerugoya Referral hospital, Kimbimbi, Kianyaga and Sagana Sub-County hospitals between May and August 2019. Departmental heads working as full-time employees in the selected hospitals were eligible.Key informants (KI) who did not consent were excluded from the study.A pre-tested interview guide was used to collect data. The tool was adopted with modifications from comparable studies.[7,10]It was validated by co-authors at the Jomo Kenyatta University of Agriculture and Technology, Kenya. The guide was pre-tested at ACK Mt. Kenya hospital on 2 departmental heads to ensure applicability. It was modified based on pretest results.Purposive sampling was used to recruit respondents. A total of 12 departmental heads were selected. They comprised of 2 Consultants, 3 Medical Officers, 3 Pharmacists, 2 Clinical Officers and 2 Nursing Officers. Prior to the interviews, informed consent was sought from respondents.A self-administered questionnaire attached to the consent form was used to collect respondent's demographic data. The principal author presided over the interviews. Face to face interviews were conducted in the afternoon at a convenient place for the respondents. Respondents were asked probing questions to obtain necessary information.Interviews were audio recorded and notes were hand-written. Each session lasted between 30 - 40 minutes. Responses were transferred into Microsoft Word 2016 within 72 hours. Data saturation was achieved after 10th interview however 2 more interviews were carried out to capture any emerging themes. NVivo version 12 software was used to code data. Data was analyzed using deductive thematic analysis. Results were presented usingverbatim quotes and tables. Ethical clearance was obtained from Kenyatta University-Ethical Review Committee (Ref. NO: KU/ERC/APPROVAL/VOL.1/250). Permission to execute the study was obtained from the County Director of Health, Kirinyaga County (CDH/RES/VOL.11/79).

RESULTS:

Demographic characteristics of departmental heads in selected hospitals, Kirinyaga County, Kenya

A total of 12 departmental heads aged 36 and 49 years were successfully interviewed. They consisted of 2 male and 10 female respondents. Four of the respondents had Master of Medicine-level training while the rest had undergraduate training. Majority of respondents had a working experience of 5-10 years. Additionally, health cadres comprised of 2 Consultants, 3 Medical Officers, 3 Pharmacists, 2 Clinical Officers and 2 Nursing OfficersThe results are presented in Table 1.

Table 1: Demographic characteristics of departmental heads in selected hospitals, Kirinyaga County, Kenya, 2019 (n=12)

Characteristics		Frequency
Gender	Male	2
	Female	10
Age group (Years)	30 - 45	7
	36 - 40	2
	> 40	3
Duration of Practice (Years)	5 -10	6
	10-15	4
	> 15	2
Highest level of education	Bachelor's degree	8
	Master of Medicine	4
Professional cadre	Consultant	2
	Medical officer	3
	Pharmacist	3
	Nursing Officer	2
	Clinical Officer	2
Training on ADR reporting	Trained	4
	Not trained	8

THEMES:

Deductive thematic analysis identified 5 major themes namely: (1) Capacity to monitor ADRs, (2) Training, (3) Feedback, (4) Barriers of ADR reporting and (5) Perceived solutions for improved ADR reporting.

Theme 1: Capacity to monitor ADRs

All departmental heads were asked if their individual facilities had adequate capacity to monitor ADRs. A WHO checklist containing 5 prerequisites was used assess the capacity to monitor ADRs. Majority of respondents opined that the selected hospitals had conformed to 1 WHO prerequisite. The facilities lacked adequate capacity to monitor ADRs effectively.

> "*From the WHO least prerequisites, this health facility has a spontaneous reporting method that uses a yellow form.*" (KI7, Pharmacist).

All selected hospitals lacked a PV center. PV activities were facilitated by the District Health Management team that lacked resources to undertake this role.

> "*There is no PV center to manage drug safety concerns but a committee that's scarcely financed and has unsatisfactory human capital.*" (KI4, Pharmacist).

Theme 2: Training on ADR reporting

Majority of health professionals had not acquired training on ADR reporting. Pharmacists had been trained locally on commodity management, reporting tools and guidelines, how to capture ADRs and reporting procedure. Although Pharmacists organized continuous medical training to sensitize other health cadres, training was not routine. Training was not prioritized by hospital managers.

> "*We lack training on ADR reporting simply becausetraining all healthcare workers is challenging as hospital managers view buying of drugs and therapeutic devices as a more imperative role.*" (KI8, Nurse).

Theme 3: Feedback after ADR reporting

When asked whether they obtained feedback from the PPB after reporting ADRs, majority of respondents concurred that they rarely obtained feedback from the national PV center after reporting. In other instances, feedback was obtained after a long time. This was perceived as a demotivator of regular ADR reporting.

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> "*Feedback from the PPB after reporting ADRs is obtained after a long time; this discourages healthcare professionals from reporting as*

they feel that no action will be taken." (KI12, Clinical Officer).

Theme 4: Barriers of ADR reporting

Respondents were probed about the factors that discouraged them from reporting ADRs. Analysis showed that barriers of ADR reporting were categorized into 3 domains: health staff related, patient related and health system related barriers.One participant identified lack of access to the ADR forms and inadequate PV knowledge as a barrier to reporting ADRs.

"*I have come across numerous ADRs in my department but the main challenges that have discouraged me from reporting are lack of access to ADR report forms and not knowing where to report due to inadequate PV knowledge*." (KI2, Medical Officer).

The barriers of ADR reporting are described in Table 2.

Table 2: Barriers of ADR reporting among healthcare providers in selected hospitals, Kirinyaga County, Kenya, 2019

Category	Barrier
Healthcare provider related	Not knowing where to report
	Lack of access to ADR report forms
	Lack of time to report
	Not sure what caused the ADR
	Belief that managing the patient is more important
	Knowledge that no action will be taken
Patient related	Fear due to unfriendly healthcare personnel
	Healthcare personnel not accessible
	Lack of feedback
	Long-distance covered to report ADRs
	Unawareness of ADR reporting scheme
Health system related	Lack of ADR reporting tools and guidelines
	Under staffing
	Lack of a PV center
	Lack of training
	Delayed/no feedback

Theme 5: Perceived solutions for improved ADR reporting.

After probing the key informants on ways to reduce under reporting, several comparable themes emerged.Participants suggested the need for focal PV persons to whom drug safety issues would be reported and addressed.

"*The County needs focal individualsto champions PV activities. They should be responsible for addressing drug security issues in the County*." (KI4, Pharmacist).

Some key informants felt that a PV center equipped with ample funds and human resource should be developed in Kirinyaga County to coordinate PV activities.

"*Developing a PV center in the County will promote reporting, follow up and prompt feedback*." (KI9, Clinical Officer).

Moreover, the need to deploy Pharmacists to the wards to assist in capturing, reporting and managing ADRs was also suggested. One of the interviewees said:

"*The administration should permit Pharmacists to take part in ward rounds and deploy others to the wards to help in ADR identification and documentation*." (KI3, Nurse).

Finally, key informants felt that instantaneous feedback from the PPB would simplify patient follow up and motivate healthcare workers to report ADRs.

"*If the PPB provide prompt feedback on the action to be taken against reported drugs along with sending its representatives to the ground then ADR reporting rates will surge*." (KI1, Consultant).

DISCUSSION:

The present study revealed that the selected hospitals lacked capacity to monitor ADRs as they conformed to one WHO prerequisite for a functional PV system. A study conducted in India, Uganda and South Africa to assess practice of PV in relation to WHO's minimum prerequisites found similar findings. [5] Although the countries had a spontaneous reporting scheme it was frail as ADR forms and reporting guidelines were not available. This finding could be ascribed to inadequate funding or poor coordination of PV activities in Kirinyaga County. A competent PV system is imperative in ensuring safety and rational use of medicine.

The findings from the study found that feedback from the PPB was never given or was not timely. A consistent finding was reported by a Malaysian study where majority of respondents opined to receive minimal feedback after reporting.[6]This could be attributed to poor relationship and communication gap between the PPB and health facilities. Lack of feedback influences under reporting and healthcare workers feel less motivated to report as they feel that no action will be taken. Strengthening communication between the national PV center and health facilities is necessary to improve ADR reporting.

The results demonstrated that majority of health professionals had no formal training on ADR reporting. Similar findings were reported by a qualitative study conducted among healthcare providers in Pakistan.[7] Lack of training on ADR reporting is a fundamental cause of under reporting and has been listed as the 8th sin in under reporting. [11] The hospitals should take interest in training healthcare providers and patients routinely in order to improve ADR reporting. Furthermore, [9] revealed a significant relationship (P = 0.010) between training and ADR reporting.

Comparable studies in Malaysia and Kenya identified lack of awareness on the existence of ADR reporting scheme, not knowing where to report, failure of patients to disclose ADRs, high workload, lack of ADR reporting tools, lack of training and feedback as major barriers of ADR reporting. [6,10] The resultsare consistent with findings of this study that revealed barriers of ADR reporting as lack of training and feedback, lack of ADR reporting tools, healthcare workers not knowing where to report and poor patient-doctor relationship. Similar barriers have been reported by other studies across the globe. [5,7,8]

Having a focal PV person to supervise ADR, developing a PV center, deploying Pharmacist towards and lobbying for prompt feedback from the national PV centerwere the main interventions suggested to improve reporting in this study. This seems to be the foundation of measures to enhance ADR reporting as similar suggestions have been proposed and proven by various studies across the globe.[5,6,7,8,10]

CONCLUSION:

The findings of this study demonstrated that the selected hospitals lacked adequate capacity to monitor ADRs as they conformed to only one WHO prerequisite for a functional pharmacovigilance system. Developing a PV center in the County is imperative to boost ADR reporting. Majority of departmental health professionals had no formal training on ADR reporting. Regular education workshops and training are mandatory to encourage ADR reportingamong healthcare workers. The PPB did not give prompt feedback after reporting; a factor that promoted under reporting. Prompt feedback in addition to filling the communication gap between the PPB and stakeholders would enhance ADR reporting rates. Further research is necessary to determine other health provider factors especially inter-provider specialty factors influencing ADR reporting nationally.

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ABBREVIATIONS:

ACK: Anglican Church of Kenya
ADRs: Adverse drug reaction
AERS: Adverse Event Reporting System
FDA: Food and Drug Administration
KI: Key Informant
PPB: Pharmacy and Poisons Board
PV: Pharmacovigilance
UK: United Kingdom
USA: United States of America
WHO: World Health Organization

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