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Original Research Article

Determinants of adverse drug reactions reporting in retail chemists in Nairobi County, Kenya

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ABSTRACT

Background: Reporting of adverse drug reactions remains the mainstay of a vibrant pharmacovigilance system that seeks to safeguard medicines in a health system. This study sought to establish the impact of the national medicines regulatory body, The Pharmacy and Poisons Board (PPB), the operationalization of pharmacovigilance implementation strategies in the retail chemists, the effect of the capacity and that of underlying motivation factors of the retail chemist personnel on reporting of adverse drug reactions.
Methods: This was a descriptive cross-sectional study design conducted between May 2018 to June 2018.
Results: 149 (60%) of the respondents stated that PPB did not engage retail chemists as stakeholders in pharmacovigilance, 127 (51%) said they had never read any PPB publication on pharmacovigilance, 151 (61%) said they had general knowledge on pharmacovigilance, receiving feedback from PPB was considered a major motivational factor towards ADR reporting by 237 (96%). Multivariate analysis of the determinants of ADR reporting in retail chemists established that the pharmacovigilance implementation strategies ($p<0.026$), retail chemist personnel ($p<0.001$) and underlying motivational factors ($p<0.05$) had significant influence on ADR reporting in retail chemists in Nairobi County.
Conclusions: PPB has not engaged retail chemists on pharmacovigilance matters as key stakeholders and this has impacted the quality of the pharmacovigilance implementation strategies in the chemists as well as the capacity and motivation of the retail chemist personnel to report ADRs.

Keywords: Pharmacovigilance, Adverse drug reactions, Reporting, Retail chemist personnel, Regulatory body, Kenya

INTRODUCTION

Access to safe essential medicines is a key success indicator of a functional health system of which the private sector such as retail chemists plays a critical role. Despite their obvious benefits, all medicines are chemical in nature and therefore have an intrinsic risk of causing harm to the patient in the form of expected side-effects or unexpected side-effects referred to as adverse drug reaction (ADR). An ADR has been defined as a noxious and unintended reaction that may arise from use of the product within or outside the terms of the marketing authorization or from occupational exposure.[1] Despite the fact that the safety profile of new medicines is assessed during clinical trials, the process is limited in its scope of population exposure, duration and perspective.[2] ADR monitoring is the mainstay of a larger discipline referred to as pharmacovigilance which has been defined by the WHO as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.[3]

In Kenya, the National pharmacovigilance system was officially launched in June 2009 and the department has since evolved to a centre of excellence in the region. The department of pharmacovigilance has been active in training and sensitizing healthcare workers on pharmacovigilance and as a result, there has been a general upward trend in the number of reports submitted since the inception of the department in 2010. Fifteen ADR reports per million population was submitted in 2010.[4] This was against an estimated population of 40 million people.[5] However, the reports were mainly from hospital settings thus indicating that there is still a gap in detection and collection of data on ADRs from the retail chemists despite its significant contribution to the health system. Due to weak regulatory and supervisory systems, the retail chemists also bear the greater burden of counterfeit products which have an added risk of unprecedented risk of ADRs.[6] The National pharmacovigilance guidelines were issued in 2009 and are conspicuously ambiguous on the ADR reporting channels for the retail chemists.[7] A comprehensive pharmacovigilance policy is also lacking and instead medicine safety is only implied in the national pharmaceutical policy.[8]

According to a survey carried out by the government, Kenya continues to suffer chronic drug stock outs in the public hospitals.[9] Inhibitive consultation costs charged by clinicians often force the public to buy prescription medicines directly from the retail chemists through a practice commonly referred to as self-medication.[10] As a result of this growing demand, retail chemists have over the years evolved to jointly form the largest component of pharmaceutical supplies in Kenya in terms of quantity and variety. Numerous media reports have repeatedly raised concern over the professionalism of the personnel working in these retail chemists with many claims of unethical practices fuelled by commercial gain. One particular article notes that the sheer number of untrained and unregulated medicines dispensers is troubling.[11] This further exposes the public to adverse drug reactions due to medication errors or lack of proper medicine use counselling.

Another factor that predisposes to ADRs is the concomitant use of conventional medicines with herbal medications. WHO estimates that 80 per cent of people in Africa have used traditional medicines at some point in their lives, to meet their health care needs.[12] In spite of this obvious need for active monitoring of medicine safety in the retail chemists, the focus of the pharmacovigilance activities in the country has remained in the public hospitals. The related studies carried out on the area have solely been focused on knowledge and attitudes of healthcare workers in hospital settings. There are no published studies or official reports on the status of pharmacovigilance activities in retail chemists in Nairobi and the factors contributing to this have not been identified.

METHODS

Research design

This was a descriptive cross-sectional study design with both qualitative and quantitative approaches. The qualitative aspect of the study targeted the key informants at the Pharmacy and Poisons Board (PPB) working in the department of medicine information and pharmaco-vigilance. Quantitative data was collected using a structured questionnaire with a 5-point Likert scale administered to the retail chemist personnel.

Sampling procedures and sample size

The study was conducted in Nairobi County which is also the capital city of the Republic. This county was selected due to the high concentration of retail chemists. Records provided by PPB indicated that there were 895 registered chemists within Nairobi County of which a single respondent from each chemist was targeted therefore a sample of 268 respondents was selected.[13]

Data analysis

Out of 268 targeted questionnaires, 250 were returned but only 248 were good for analysis. Both qualitative and quantitative data were analyzed using Statistical Package for Social Scientists (SPSS) Version 23. Descriptive analysis was undertaken for the demographic data and the five study variables. Mean and standard deviation were obtained for the 5- point Likert scale (1-5): strongly disagree=1, disagree=2, not sure=3, agree=4, strongly agree=5. The descriptive statistics were further combined from a five-point Likert scale (strongly agree, agree, not sure, disagree and strongly disagree) to a two-point Likert scale of (agree and disagree). It was assumed that those not sure were more likely not to undertake ADR reporting, this was done to allow for understanding of the study variables. The strongly agree and agree were combined into agree and the not sure, disagree and strongly disagree were combined into disagree. Bivariate analysis was undertaken using Spearman's' Rho product method based on 0.05 (5%) level of significance, to compare each independent variable with dependent variable. The coefficient of correlation (r), determined the degree of the relationship. Multiple regression was undertaken to estimate a model that explained the influence that the independent variables has on the dependent variable in a combined relationship. The regression analysis was based on 5% level of significance (p=0.05).

Ethical approval

Ethical approval and clearance was sought from the Kenya Methodist University scientific, ethics and review committee and from National Commission for Science, Technology and Innovation (NACOSTI). Approval to interview the personnel at the department of medicine

information and pharmaco-vigilance was sought from the registrar to the pharmacy and poisons board. Informed consent was sought from the retail chemist personnel.

RESULTS

Demographic characteristics of respondents

Out of 268 targeted questionnaires, 250 were returned but only 248 were good for analysis. The response rate was then (248/268)*100=92.5%. The specific characteristics are shown in Table 1.

Table 1: Demographic characteristics of respondents.

Characteristics	Respondents N (%)
Gender	
Female	137 (55)
Male	111 (45)
Total	248 (100)
Age category of respondents in years	
20-29	143 (58)
30-39	88 (36)
40-49	17 (7)
Total	248 (100)
Cadre of respondents	
Clinical officer	22 (9)
Nursing officer	5 (2)
Pharmaceutical technologist	204 (82)
Pharmacist	14 (6)
Any other	3 (1)
Total	248 (100)
Education level	
Secondary school	1 (1)
Certificate	5 (2)
Diploma	198 (80)
Graduate	41 (17)
Masters and above	3 (1)
Total	248 (100)

Regulatory body related factors

The study sought to establish the respondents' perception of the role played by PPB in facilitating ADR reporting. Majority of the respondents 161 (65%) felt that PPB lacks adequate funds to coordinate pharmacovigilance activities such as ADR reporting in the chemists. Many of the respondents also felt that PPB did not often engage the chemists as stakeholders in pharmacovigilance activities 149 (60%). Many respondents had not read a single publication of the PPB newsletter on ADR reporting, the lifesaver 127 (51%). The feedback from the key informants from the department of medicines information and pharmacovigilance indicated inadequate pharmaco-vigilance funding, lack of engagement and minimal dissemination of information to retail chemists on pharmacovigilance.

Pharmacovigilance implementation strategies

The study assessed the operationalization of recommended strategies that enhance reporting of adverse drug reactions in retail chemists. These strategies are: presence and use of standard operating procedures, on-the -job training and utilization of data collection tools. Majority of the respondents 175 (71%) agreed with the statements on availability of standard operating procedures in the chemists and that most of them had been trained on them. However, a majority refuted the fact these SOPs were reviewed regularly 128 (52%). Most of the respondents confirmed to have attended a formal training outside the chemist on reporting of ADRs 170 (69%). 71% of the respondents agreed to have received on job training at the chemists on ADR reporting in form of regular updates. According to many of the respondents, manual ADR reporting tools were available at the chemist 137 (55%) A good number were also aware of the online of the online ADR reporting tool on the PPB official website, 140 (56%).

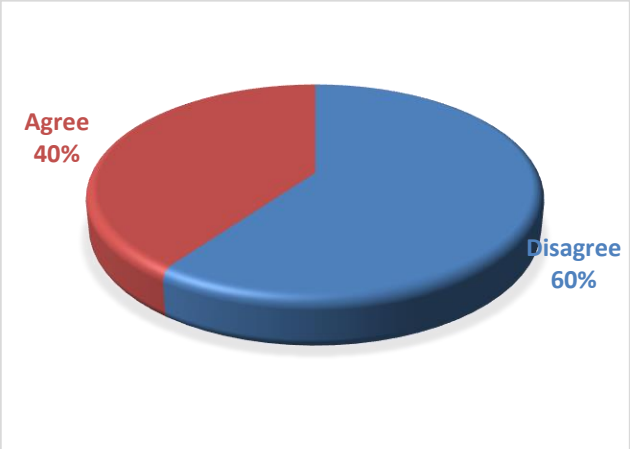

Figure 1: Engagement of PPB with retail chemists on pharmacovigilance.

Retail chemist personnel capacity

The study sought to establish the capability of retail chemist personnel to report ADRs based on their knowledge level and attitude towards ADR reporting. Majority of the retail chemist employees have general knowledge of pharmacovigilance 151 (61%) and an almost equal majority have undergone formal pre-service training in pharmacovigilance, 163 (66%). This was further evidenced by the fact that a majority of the respondents were familiar with the national pharmacovigilance system 176 (71%) and were conversant with the pharmacovigilance ADR reporting tool 155 (63%). Majority of the respondents indicated they were motivated to report ADRs 190 (77%) which was consistent with the finding that 83% of the respondents stated that their workload allowed them to report ADRs.

Underlying motivation factors

This variable was assessing perception of the effect of receiving feedback from PPB on motivation to report ADRs and the social economic aspects at the workplace related to one's gender that may impact motivation to report an ADR. These gender related factors were equal pay across genders, equal working hours and equal access to training on pharmacovigilance. As a demographic characteristic, gender was not considered a significant determining factor for reporting ADRs. Majority of the respondents stated that both male and females worked similar hours 165 (67%) and were paid equally 157 (63%). Receiving feedback from PPB was considered by an overwhelming majority 237 (96%) a major motivational factor towards ADR reporting as shown in Figure 2.

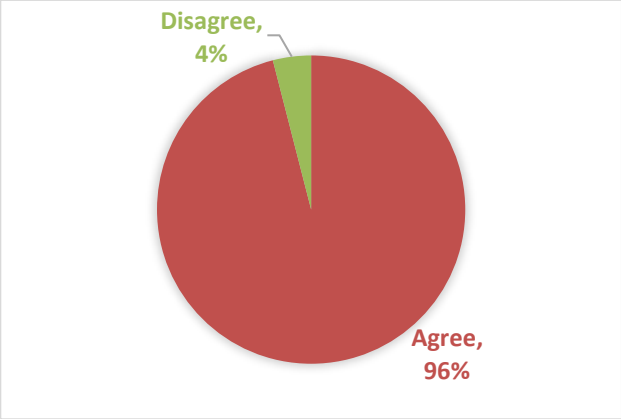

Figure 2: Effect of receiving feedback from PPB on ADR reporting.

Adverse drug reactions reporting

Majority of the respondents confirmed that indeed there was a system to report ADRs, 220 (89%). Presence of a system of reporting is a confirmation that patients do present at the chemists with ADRs and some action is taken. Further to this, most of the respondents confirmed the ability to detect an ADR 177 (71%). Most of the respondents felt that they had a professional responsibility to report adverse drug reactions 227 (92%) and that reporting ADR was important in promoting medicine safety in a health system 229 (92%).

Bivariate analysis

Bivariate analysis was undertaken using Spearman's' Rho product method based on 0.05 (5%) level of significance, to compare each independent variable with dependent variable. The coefficient of correlation (r), determined the degree of the relationship. The study found a coefficient of correlation of Regulatory body/PPB factors and ADR reporting was ($r=0.275$, $p<0.001$), pharmacovigilance implementation strategies was $r=0.374$, $p<0.001$, retail chemist personnel capacity ($r=0.466$, $p<0.001$) and underlying motivation factors ($r=0.416$, $p<0.001$). This indicates there was a positive relationship with ADR reporting. Worth noting is that though the relationship was significant it was below $r=0.5$, thus implying.

Multivariate analysis

Multiple regression was undertaken to estimate a model that explained the influence that the independent variables has on the dependent variable in a combined relationship. The regression analysis was based on 5% level of significance ($p=0.05$). The variance inflation factor (VIF) index for the study was below 10 for all the variables indicating that there was no multicollinearity. From Table 2, the constant was significant with $p<0.05$. This infers that even without the study variables in this study, ADR reporting would still be ongoing. In a combined relationship, pharmaco-vigilance strategies ($p<0.05$), retail chemist personnel capacity ($p<0.05$) and underlying motivation factors ($p<0.05$), had a significant influence on ADR reporting among retail chemist personnel chemist in Nairobi County.

Table 2: Regression weights of the independent variables.

Model	Unstandardized coefficients		Standardized coefficients	T	Significance	Collinearity statistics	
	B	Std. error	Beta			Tolerance	VIF
Constant	8.609	0.829		10.387	0.000		
PPB	0.052	0.067	0.049	0.775	0.439	0.760	1.315
Pharmacovigilance strategy	0.057	0.025	0.149	2.236	0.026	0.685	1.459
Health worker capacity	0.101	0.028	0.262	3.626	0.000	0.583	1.716
Underlying motivational factors	0.101	0.028	0.262	3.626	0.000	0.583	1.716
	0.162	0 .046	0.213	3.502	0.001	0.819	1.221
Dependent variable: ADR reporting							

Further, from the findings on regulatory body factors (X_1, $B_1=0.052$, $p=0.439$) implies that a unit change in regulatory body factors will improve ADR Reporting by 5.2%, however the improvement is not statistically significant at 5% level of significance. On pharmacovigilance implementation strategies (X_2, $B_2=$

0.057, p=0.026) implies that a unit change of X_2, will improve ADR reporting by 5.7%, and the improvement is statistically significant at p<0.05. The interpretation of this is that these strategies that have been proposed by WHO to improve ADR reporting WHO have an effect on the capacity and the motivation of the personnel.[14]

The quality of the SOPs, the training content and availability of ADR reporting tools is determined by the extent to which the national pharmacovigilance centre has disseminated best practices. Further, retail chemist personnel capacity, (X_3, B_3=0.101, p<0.001) implies that a unit change of X_3, retail chemist personnel capacity will improve ADR reporting by 10.1%, and the improvement is statistically significant at p<0.05. Finally, from the findings, on effect of underlying motivation factors on ADR reporting, (X_4, B_4=0.162, p=0.001) shows that a unit change of underlying motivational factors considered in this study X_4, will improve ADR Reporting by 16.2%, and the improvement is statistically significant at p<0.05.

DISCUSSION

These demographic findings revealed cadres that are not legally mandated to carry out the business of pharmacy which is in contravention of the Kenyan law that governs pharmacy practice and regulation of medicines. The pharmacy and poisons Act, CAP 244, defines two healthcare cadres that can legally carry out the business of pharmacy. The two cadres consist of the diploma level of pharmaceutical technologist and the degree level of pharmacist.[15] In their assessment of the Kenyan healthcare system, Abuga et al, depict a sad state of affairs in the retail chemists which are not explicitly forbidden to employ other healthcare cadres as long as there is a pharmacist or pharmaceutical technologist superintending the premises.[16] The consequence of this has been an infiltration of untrained persons who after gradually attaining some skill level to enable them carry out dispensing of medicines. The impact of this task shifting on quality of healthcare has not been adequately evaluated. Majority of the respondents felt that PPB did not have the funds to coordinate pharmacovigilance activities in retail chemists and as such did not engage them as key stakeholders in pharmacovigilance. The statistical significance of this finding indicates that the regulatory body which serves at the national pharmacovigilance centre determines the success of ADR reporting by actively engaging health care providing institutions such as retail chemists to disseminate guidelines, offer technical support and provide feedback whenever ADRs are reported. Similarly, Kabore et al. in Burkina Faso revealed gaps in specific regulations and guidelines required to coordinate the roles of stakeholders in pharmacovigilance activities.[17] The weak correlation between PPB factors and ADR reporting in retail chemists points out the disconnect between the two entities as established from the key informants who stated that lack of sufficient funding and capacity prevents meaningful engagement between PPB and the retail chemists on pharmacovigilance activities. In 2011, the European commission highlighted lack of sufficient funding for PV activities as one of the challenges facing the Kenyan pharmacovigilance centre.[18] This would explain why majority of the respondents were not sure if there was a pharmacovigilance policy in the country. This implies that until the retail chemists are fully aware of and appreciate the role of the PPB in pharmacovigilance, any interventions PPB launches towards ADR reporting may not have significant success. That said, in the quest to formulate guidelines and a policy of ADR reporting, PPB should be guided by studies such as one by Roy & Ma in 2018[12] who established that a policy change in Canada to a new more comprehensive ADR reporting policy was not associated with increased ADR reporting by pharmacists in the study setting.

The study found that many retail chemists had operationalized the recommended strategies that enhance reporting of adverse drug reactions. These findings were contrary to the survey done by SPS in the Sub-Saharan African countries that indicated most health facilities had no written SOPs as well as a study in Ghana that revealed only 25% of facilities had any SOPs.[2,19] The weak correlation in the findings suggests that while there are SOPs, on the job training and data collection tools in place, they have not been fully exploited towards ADR reporting in the retail chemists and further research would be required to interrogate the barriers to the contextual applicability of these strategies. It is easy to have SOPs in place but having personnel use them consistently is a difficult feat to achieve. The standard operating procedures in particular may not have been adequately implemented in the retail chemists. In addition, the quality of the SOPs, the training content and availability of ADR reporting tools is determined by the extent to which the national pharmacovigilance centre has disseminated best practices. A study in Spain showed that extensive and tedious information required on the ADR forms and malfunctioning of the automated reporting tools were the main reason for low rates of reporting ADRs.[8] The training methods may also not be suitable for ADR reporting as was the case in the Netherlands where it was only after a skill-oriented, practice-based pharmacovigilance training of general practitioner trainees was there a significant improvement in number of ADR reports than a more traditional, lecture-based pharmacovigilance training method.[20]

The study established that a majority of the retail chemist employees had general knowledge of pharmacovigilance having undergone formal pre-service training in pharmacovigilance and therefore familiar with the national pharmacovigilance system. Obonyo in her study carried out in a multi-cadre environment in 2014, revealed that pharmacists and pharmaceutical technologists were more likely to report ADRs than other cadres.[21] The correlation was <0.5 suggesting that personnel in the retail chemists may still not have sufficient knowledge on ADR reporting. The study also

established that unit change in retail chemist capacity would improve ADR reporting significantly. Lack of adequate knowledge on a suspected ADR will determine the attitude towards either reporting or not reporting the ADR. This is supported by findings established in a study setting in the Kingdom of Saudi Arabia that majority of the pharmacists would only report if they felt they had sufficient knowledge to establish causality between the suspected culprit drug and the resulting ADR.[22] Inadequate knowledge on pharmacovigilance would inform attitudes towards ADR reporting such as complacency whereby the personnel feel the ADR is already documented therefore no need to report it to the relevant body.[23] The positive effect in a combined model with the other variables shows that the capacity of the personnel is interrelated with the other variables. Knowledge levels on pharmacovigilance after pre-service training largely depend on the extent of information dissemination by the national pharmacovigilance centre. Knowledge and attitude will affect the motivation to report ADRs and vice versa.

The underlying motivational factors of gender and receiving feedback were found to have a positive but weak correlation with ADR reporting. This suggests that motivation is a determinant of ADR reporting but the retail chemist personnel are not adequately motivated towards ADR reporting as part of their scope of work. A study in India identified lack of remuneration as one of the reasons for not reporting ADRs.[24] Other possible contributing factors that have been identified by other researchers include lack of time for performing functions other than medicine dispensing in daily practice and general apathy towards ADR reporting.[25,26] From definition, motivation refers to the internal and external factors that stimulate desire in people to be continually interested and committed to a job or role. This therefore implies that motivation to report ADRs is influenced by and itself influences other factors such one's capacity to recognize, establish causality and report an ADR as per the available implementation strategies. As a healthcare worker, having one's contribution recognized especially in a technical area such as ADR reporting, can be a great motivating factor to not only report future incidences but to also influence colleagues to report. This shows how motivation is affected by PPB factors. These results are consistent with the findings of a study done in Holland that established that receiving feedback after reporting an ADR was the prime motivation for community pharmacists to report ADRs.[27] The effect of motivation in a combined model such as this is adequately summed up by a statement from a respondent in a study targeting community pharmacists in Portugal, who was quoted as saying "pharmacovigilance in the end is made by motivation or consideration".[25]

Limitation of the study

The research depended on information voluntarily given by the personnel in the retail chemists and at the Pharmacy and Poisons Board therefore the answers may have been subjective based on the attitudes of the individuals towards the research. It was also not possible to verify the professional qualifications of the respondents as well as the registration validity of the premises due to lack of the legal mandate to do so. Pharmacovigilance in general is not well established in the sense that it has only recently started being taught in pre-service training. The study was carried out only in Nairobi County which is of an urban setting therefore generalizations drawn from the study can only be done with caution.

CONCLUSION

In conclusion, the study established that pharmacovigilance strategies, retail chemist personnel capacity and underlying motivation factors had an impact on ADR reporting in retail chemists in Nairobi County. Despite its criticality in pharmacovigilance, Pharmacy and Poisons Board was found to not have an influence on ADR reporting in retail chemists due to lack of meaningful engagement with the retail chemists on pharmacovigilance resulting from inadequate funding and capacity. Pharmacovigilance implementation strategies affect ADR reporting to a significant extent by having relevant on-job training, standard operating procedures and ADR reporting tools in place. However, these strategies have not been adequately operationalized to suit context of different retail chemist setups. Knowledge and attitude determine whether the personnel can correctly identify an ADR, establish causality between the ADR and suspected drug and go ahead to utilize the reporting tools in place to report an ADR correctly to the PPB. Finally, this study concludes that underlying motivation factors related to equal pay, equal workload and equal opportunity between male and females as well receiving feedback from PPB were key to the success of consistent ADR reporting in retail chemists. Despite having all the tools and knowledge on pharmacovigilance, motivation to carry out a task that is widely viewed as additional work is in the end what determines if the personnel will report an ADR or not.

Recommendations

PPB is required to play a more active role in promoting adverse drug reaction reporting in the retail chemists through active information dissemination and engaging the retail chemists as key stakeholders in pharmacovigilance. On pharmacovigilance implement-tation strategies, PPB should review the usability of available reporting tools and the potential of the electronic tools in light of available technology. To enhance retail chemist personnel capacity, PPB should facilitate continuous skills-based training on pharmacovigilance through existing platforms such as professional association bodies for retail chemist personnel. PPB should establish a robust feedback sharing mechanism to retail chemist employees for reported adverse drug reactions.

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