

Analyzing the State of Pharmacovigilance in the Health Facilities of Kafue District

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Abstract: Pharmacovigilance has grown significantly in recent years and its importance in the healthcare system has been recognized worldwide. However, there are considerable issues which need to be addressed to ensure the safety of medicines. WHO pharmacovigilance indicators have been endorsed as a suitable tool regarding refining pharmacovigilance activities. Zambia with numerous challenges of medicines related issues is supporting the growth of pharmacovigilance in the public health facilities. The study assessed the status of pharmacovigilance in the public health facilities (health Centres) of Kafue District with a vision of improving the pharmacovigilance system in the district.

The researcher was guided by the objectives of the study which included: To identify the existence of pharmacovigilance committees in the public health facilities of Kafue district; to assess the status of pharmacovigilance reports in the public health facilities of Kafue district and to determine the impact of poor pharmacovigilance in the public health facilities of Kafue district. The significance of adverse drug reaction reporting was noted as it had a critical role in pharmacovigilance.

The study adopted a cross-sectional descriptive study design in the Six (6) selected health centres in Kafue District. The data was collected using prescribed pharmacovigilance indicators. Data was displayed qualitatively and quantitatively. A statistical Software (SPSS version 21.0 used to analyze quantitative data and the results were presented using graphs and frequency tables. Out of a total of six (6) health facilities sampled in Kafue district, Five (5) had showed availability of a pharmacovigilance focal point person.

Standardized functional accommodation was a challenged in all the six facilities. Additionally, only one (1) facility (The District Hospital) had shown availability a financial provision for pharmacovigilance activities in the district. Another common parameter noted was the absence of the adverse drug reaction reports in the four (4) facilities. The number of adverse drug reaction reports found in the system ranged from 0 to 7 and only 2 health facilities had fully submitted their reports to the National Pharmacovigilance Centre.

Limited documented medicines related admissions were noted, ranging from 0.0874/1000 to 0.0532/1000. Additionally, poor documentation of pharmacovigilance services was a common variable observed in all the six (6) selected facilities in the district. The study findings call for an urgent need to develop and improve pharmacovigilance in health facilities of Kafue District.

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I. INTRODUCTION

➤ Background

Medicines safety is now becoming a focus area in the field of pharmacovigilance. The thalidomide tragedy that happened in the 1960's acted as an eye opener for medicines regulatory bodies to put up measures of ensuring medicines

safety. It is against this background that pharmacovigilance systems were put in place in most of the nations. This is because the tragedy posed a great disaster causing children to be born with a condition called phocomelia (shortening or absence of limbs). According to Kim and Sciali, the disaster necessitated the establishment of pharmacovigilance systems

in all countries because it was a major public health concern (Kim and Scialli, 2011).

Pharmacovigilance does not only focus on adverse drug reactions but also other dimensions that includes medication errors, lack of efficacy, counterfeit drugs, drug interaction, rational unauthorized medicines and prescription of medicines. According to WHO, pharmacovigilance is the science and activity relating to the detection, assessment and prevention of adverse drug effects (WHO, 2002).

Lalvani and Milstein stressed that World health organization through its regional has a critical function, which is to promote, spearhead the formulation and building of sustainable pharmacovigilance monitoring system. The world health organization has a collaborating centre for international drug monitoring (Uppsala Monitoring Centre), which is in Sweden (Lalvani and Milstein, 2013).

Adverse drug reactions are a major public health concern globally. An adverse drug reaction is defined by the world health organization as “a noxious, unintended effect of a drug that occurs in doses normally used in humans for the diagnosis, prophylaxis and treatment of disease” (The Ellen MacArthur foundation ,2017). Health workers should always stay alert and able to report any suspected adverse drug reaction when prescribing or administering drugs. This is because when medicines are new, or start to be used in new populations, knowledge on adverse drug reactions is limited (Duijnhoven et al.,2013). The purpose of Pharmacovigilance is based on assessing, monitoring and preventing undesirable drug effects. The impacts of adverse drug reactions include a high clinical, social and economic cost as thus resulting in risk to life and having to stop taking an effective drug therapy, long hospitalizations and use of health services (Thiesen et al.,2013). Most of the health facilities in Kafue district lack resources to run a pharmacovigilance system effectively. Therefore, this call for attention because pharmacovigilance plays a greater role in medicine safety. Kafue district should development a comprehensive pharmacovigilance system that promotes public health.

The conceptualization of the pharmacovigilance indicators followed a meeting of pharmacovigilance experts held in Accra, Ghana in 2007. The first set of potential indicators were developed with pharmacovigilance significance. The two suggested categories of indicators were Core and Complementary indicators. Each of the categories include three types of indicators structural, process and outcome or impact. Core indicators are highly important and valuable in describing pharmacovigilance. They serve to further characterize the pharmacovigilance situation in the stated setting but need not be used in all instances (WHO, 2008). Therefore, the study assessed the status of pharmacovigilance in the public health facilities of Kafue district using WHO pharmacovigilance indicators.

II. MATERIAL AND METHODS

➤ *Study Setting and Design*

The study was conducted in Kafue District, which is situated 45Km South of the capital city Lusaka. It has a total population of 176926, which is served by 23 public health facilities. These include 22 health centres and one general hospital. This study aimed at seeking an understanding on the status of pharmacovigilance in Kafue District. The study adopted a Cross-Sectional design, which is descriptive in nature. Data was collected using WHO pharmacovigilance indicators and this helped to have an in-depth understanding of the status of pharmacovigilance in public health facilities (health centres).

➤ *Sampling*

Six (6) Public Health Facilities were selected. This was done through stratified and random sampling methods. The public health facilities were categorized into rural and urban. The study was subsequently carried out in six (6) public health facilities selected through simple random sampling namely:

- Kafue General Hospital (KGH)
- Nangongwe OPD Clinic (NOPD)
- Estates Urban Clinic
- Railway Urban Clinic
- Shikoswe Urban Clinic
- Chanyanya Rural Health Centre

Ethical approval granted by the University of Lusaka Ethics Committee and permission for data collection obtain from Kafue District Office and selected facilities. Besides, the health centre in-charges were reached for approval and access to collect data. The responsible facility staff persons spearheading pharmacovigilance in the facilities provided responses for the indicator assessments.

➤ *Data Collection and Techniques Data*

The research information was obtained through the use of the world health organization (WHO) core pharmacovigilance indicator by interviewing pharmacovigilance focal point persons or the committee. The data collecting tool was divided into parts that includes structural, process, outcome or impact indicators and background information. The background information captured description of the facilities and staffing in different categories.

The structural metrics assessed the availability of core pharmacovigilance system, mechanism and structures (environments needed for pharmacovigilance activities to facilitate pharmacovigilance activities). Process metrics or indicators assessed levels or status of pharmacovigilance activities in the health facilities. Focus was on the surveillance system of adverse drug reactions. Outcome indicators helped in measuring the benefits or changes that has result because of pharmacovigilance.

➤ *Data Analysis*

Data was analysed quantitatively and qualitatively. This is because the WHO core pharmacovigilance indicators are both quantitative and qualitative in nature. The facilities were exposed to the WHO core pharmacovigilance indicators. The research data collected was analysed using Statistical Package for Social sciences (SPSS, version 20.1) and Excel 2013.

III. RESULTS /FINDING

The targeted facilities were visited and key focal point person, pharmacovigilance committees were exposed to interviews. Targeted facilities were all government owned and provided primary health and curative care. The public health facilities differed in terms of size, bed capacity and human resource. Table 1 shows the characteristics of the assessed six (6) public health facilities in Kafue district.

Table 1 Characteristics of Public Health

Facilities in Kafue District						
	Estates	Railway	NOPD	KGH	Shikoswe	Chanyanya
Number of beds	8	7	10	82	6	6
Number of health workers	33	20	38	85	11	8
Clinical Officers	9	4	7	18	3	3
Doctors	0	0	0	12	0	0
Nurses	18	13	25	34	5	4
Pharmacists	0	0	0	3	0	0
Pharmacy technologists	4	1	4	6	1	0
EHTs	2	2	2	3	2	1
OPD attendances (2019)	16324	12897	18764	22876	9965	9878

Table 2 The Analysis of WHO Pharmacovigilance Structural Indicators of the Six Targeted Public Health Facilities in Kafue District

Assessment	KGH	Nopd	Chanyanya	Railway	Shikoswe	Estates	Positive responses
Presence of pharmacovigilance centre	No	No	No	No	No	No	0
Availability of a Copy of the Zambian Pharmacovigilance policy	Yes	No	No	No	No	No	1
The Presence of Institutional Drug Therapeutic Committee	Yes	Yes	Yes	Yes	No	Yes	5
! Availability of regular Financial Provision for Pharmacovigilance	Yes	No	No	No	No	No	1
! Availability of staff to carry to conduct functions of pharmacovilance	Yes	Yes	No	Yes	Yes	Yes	5
! Availability of standard ADR reporting	Yes	Yes	Yes	Yes	Yes	Yes	6
! Medication error, counterfeit	Yes	No	No	No	No	No	1
! A process is in place for recording of ADR reports.	Yes	Yes	No	Yes	No	Yes	4
! Incorporation of Pharmacovigilance into training programme curriculum	No	No	No	No	No	No	0
! Existence of a newsletter for pharmacovigilance information dissemination	No	No	No	No	No	No	0

The responses were obtained from the interviews conducted based on the questions of the ten (10) structural prescribed indicators for the six (6) facilities. It was noted that all the selected facilities (100%) lacked standardized functional infrastructure for pharmacovigilance services and the pharmacovigilance was not incorporated into training

program curriculum. The findings showed that the 5 selected facilities had a staff assigned to conduct pharmacovigilance activities at facility level. Additionally, the pharmacovigilance committees were presented in the sampled facilities.

Table 3 The Analysis of the WHO Core Pharmacovigilance Process Indicators of the Six Public Health Facilities in Kafue District.

Assessment	KGH	Nopd	Chanyanya	Railway	Shikoswe	Estates
The Total number of ADR reports received in the previous year Reports in the local database (Current number)	6	0	0	0	0	1
! Percentage of total annual reports	4	1	0	0	0	2

acknowledged/issued feedback	0	0	0	0	0	0
! Percentage of total reports subjected to causality assessment in 2019	0	0	0	0	0	0
! Percentage of annual report-satisfactorily completed and send in 2019	66.6	0	0	0	0	0
! Percentage of reports of therapeutic-ineffectiveness received in 2019	0	0	0	0	0	0
! Percentage of reports on medication errors reported in the previous year	0	0	0	0	0	0
! Number of active surveillance activities initiated, ongoing or completed	3	1	0	2	0	3
! Percentage of registered pharmaceutical having pharmacovigilance system	0	0	0	0	0	0

The finding indicated the number of adverse drug reaction reports from the sis selected health facilities in the year (2019) was from 0 to 6 reports. 4 facilities were recorded not have submitted reports. Additionally, the number of reports available in the local database ranged from 0 to 7. Notably, there were limited numbers of reports on adverse drug reactions s, lack of therapeutic effectiveness and medication errors in most of the facilities. Documentation of

feedback and causality assessment carried out on reports in the facilities was similarly poor at the time of the study. Four facilities (Kafue General Hospital, Nangongwe OPD, Railway and Estates clinic had a few active surveillances activates initiated, ongoing and completed. The general hospital had 3 active surveillance activities, Estates clinic also had 3, Railway 2, Nangongwe OPD had 1, Shikoswe and Chanyanya had no active surveillance activities initiated.

Table 4 The Analysis of WHO Analysis of WHO Core Outcome Pharmacovigilance Indicators in Six Public Health Facilities in Kafue District

Assessment	KGH	Nopd	Chanyanya	Railway	Shikoswe	Estates
Number of signals generated in the last 5 years	0	0	0	0	0	0
Number of regulatory notifications issued in the last year 2019.	3	0	0	0	0	0
Number of medicine related hospital admissions per 1000 admissions.	2	1	no data	no data	0	0
Number of medicine-related deaths per 1000 persons per year	no data	no data	no data	no data	0	no data
Number of medicine related mortalities per 100,000 persons in the population	N/A	N/A	N/A	N/A	N/A	N/A
Average cost (ZMK) of treatment of medicine related illness	no data	no data	no data	no data	no data	no data
Average duration of medicines related extension of hospital stay	3	2	no data	1	no data	3
Average Cost (ZMK) of medicine- related hospitalization.	no data	no data	no data	no data	no data	no data

Medicine related facility admissions per 1000 admissions were from 0.0874/1000 to 0.0532/1000 and facilities had no records of medicine related deaths in the death registers in. The! documentation of relevant data was inadequate, rendering calculation of other outcome or impact pharmacovigilance indicators in facilities difficult. The average duration of medicine -related extension of hospital stay! ranged from 1 to 3 days. This indicated that poor pharmacovigilance systems can result to long hospital stay and death.

IV. DISCUSSION OF THE FINDING

This study was conducted to assess the state of pharmacovigilance in the public health facilities in Kafue district, using prescribed World Health Pharmacovigilance indicators. The study pointed out key strengths and weaknesses of the pharmacovigilance system in general.

Additionally, the findings showed that structures were gradually being put in place and noted a general acceptance of the need for! pharmacovigilance in all the selected health facilities despite recording institutional challenges.

Availability of pharmacovigilance staff in the public health facilities is an indication that Kafue district intends strengthen patient safety through quality pharmacovigilance practices. It was noted that the General Hospital and Estates Urban Clinic performed much better than the other sampled facilities within Kafue district, this was attributed to the activities of the pharmacovigilance team and system that was in place and has been followed by the commitment of the pharmacovigilance committee, staff and management of the facility.

The most interesting thing is that the adverse drug reaction reporting tool was available in all the six facilities.

This indicated the commitment of the health facilities to improve patient safety. The findings revealed poor budgeting for pharmacovigilance as only one (1) facility -Kafue General Hospital had financial provision for pharmacovigilance. This was contrary from the findings in Rwanda using the indicator-based pharmacovigilance assessment tool, where the hospitals studied had budgetary allocation for pharmacovigilance.

The availability of important staff and committees are crucial to the development of pharmacovigilance and the facilities with developed committees and personal disposition had slightly better reports. Funding of pharmacovigilance is critical as development of active pharmacovigilance programs, provision of training, feedback, information dissemination are useful tools in pharmacovigilance that require adequate finances.

This is not different from a study conducted by Olsson and Couper, who suggested that pharmacovigilance required greater attention, in terms of governance, training, adequate human resource, innovation and sustainable methodologies (Olsson and Couper, 2010). Additionally, the world health organization also in 2002 observed that due to lack of technical, human resources and financial support, national pharmacovigilance and adverse drug reporting systems for example in Uganda was still in infancy stage. As a result, in many developing countries patients are not protected from accessing harmful and ineffective medicines due to poor pharmacovigilance systems (WHO, 2002).

Mentorship is needed for the improvement and growth of pharmacovigilance. Low facility staff levels contribute to poor development of pharmacovigilance. The processes and outcomes were however poor in the six selected and assessed facilities due to lack of awareness of measuring specific indicators to assess pharmacovigilance. The pharmacovigilance system in the health facilities of Kafue district is still in the infancy stage.

Poor record keeping in all the health facilities posed a challenge to capture data on the process and outcomes. Documentation of medicine related events especially adverse drug reactions was equally poor, contributing to lack of data even in high volume health facilities such as (Nangongwe-OPD and Estates Urban Clinic).

This is in line with Bouvy and Koopmanschap, who stressed that medical cases and mortalities are due to negative drug reactions and when left unattended can lead to major public health impacts because of under recognition of adverse drug reactions and drug related events (Bouvy and Koopmanschap, 2015). It is paramount to introduce a more user friendly approach to routine data gathering and documentation to enable evaluation of the outcomes and impact of Pharmacovigilance Activities in Kafue district.

V. LIMITATIONS

The WHO indicators have proved to be, on the other hand, the non-availability of trained staff disturbed the

provision of results for the pharmacovigilance process indicators and the structural pharmacovigilance indicators posed a challenge to capture the functionality of the pharmacovigilance system in the sampled health facilities, in some facilities. Poor documentation hindered the achievement of the indicator assessment process.

VI. CONCLUSION

The findings of the study have shown a great need to improve the pharmacovigilance system in Kafue district. The World Health Organization Pharmacovigilance indicators have indicated a significant role in assessing the pharmacovigilance system in Kafue District. The critical steps could be improving medical documentation as well as institutionalization of health facilities in the district. Capacity development for facility staff is crucial in setting up and improving pharmacovigilance systems in the district. Therefore, the district needs to take this into account to successfully promote early detection, management and reporting of medicines safety issues among facility staff and provide finances for these activities.

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