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OPTIMIZING AND STRENGTHENING PHARMACOVIGILANCE TO ENSURE DRUG SAFETY IN PATIENTS' CARE AT BAPTIST HOSPITAL MUTENGENE.

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Abstract.

In effective drug regulation systems, clinical practice, and public health programs, pharmacovigilance practice is of utmost importance (WHO, 2004). WHO defines Pharmacovigilance (PV) as "the science and activities related to the detection, assessment, understanding, and prevention of adverse drug effects or any other possible drug-related problems" (Beri et al., 2019; Hadi et al., 2017). Pharmacovigilance ensures the safety and efficacy of drugs throughout their life cycle.

Following the evidence-based needs assessment (EBNA) of October 2022, high incidences of medication errors and adverse drug reactions were identified as the major concerns of pharmacovigilance in BHM, but recording was not done. Thus, a need for pharmacovigilance.

This project aims to prevent or reduce the harm caused to patients by medication errors and ADRs by improving the knowledge of healthcare workers and the provision of a policy to enforce the practice of pharmacovigilance. Factors influencing the management of change are explored. They are divided into patient-related factors and health system-related factors. The change management models used to implement the change project are Lewin's change theory, the I provisional change model, and the ADKAR Model. Influential persons were contacted and departments that use drugs for patient care were selected, and the change project was implemented. An evaluation of the level of implementation was done.

The results of the evaluation were different for different PV activities in the different departments. There was a positive change in some activities; meanwhile, there was no improvement in some activities. Successful implementation of this project will go a long way to reduce or prevent some drug-related problems that cause treatment failure, harm, long hospitalization, increased cost of care, and death.

Keywords: *Pharmacovigilance, Drug Safety, Patient care, Adverse drug reactions (ADRs), Medication monitoring, Baptist Hospital Mutengene.*
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Background

In effective drug regulation systems, clinical practice, and public health programs, pharmacovigilance practice is of utmost importance (WHO, 2004). The use of drugs and vaccines forms part of the core activities of healthcare practice. These drugs and vaccines must be used with care to maximize their health benefits and mitigate or prevent their adverse effects. Charles et al. (2017) define pharmacovigilance as scientific and data-gathering activities relating to the detection, assessment, and understanding of adverse events. Similarly, WHO defines Pharmacovigilance (PV) as "the science and activities related to the detection, assessment, understanding, and prevention of adverse drug effects or any other possible drug-related problems" (Beri et al., 2019; Hadi et al., 2017). This definition was the standard at the time. Fokunang et al. (2020) went further to add the aspect of long-term and short-term side effects of medicines to the definition by WHO. Therefore, pharmacovigilance involves monitoring the use of medicines to ensure treatment safety.

Adverse drug reaction reporting is one of the main activities of pharmacovigilance (WHO, 2004). Pharmacovigilance, which was traditionally limited to the spontaneous reporting of ADRs, now involves quantitative and qualitative methods, an integral part of the registration of medicines and monitoring and evaluation of public health programs and medical institutions (Mehta, Blockman, and Maartens, 2014). Pharmacovigilance activities have expanded to cover other parts of healthcare. Similarly, Joubert and Naidoo (2016) identified spontaneous reporting as the world's most common method of medicine surveillance. On the other hand, some ADRs result from medication errors (MEs) (Kiguba et al., 2015). Therefore, the identification and reporting of ADRs and MEs are vital parts of pharmacovigilance.

Baptist Hospital Mutengene (BHM) is one of the main hospitals of the CBCHS. It is located in the Mutengene

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health area in the Tiko district in the Fako division of the South West region of the Republic of Cameroon. Following the evidence-based needs assessment (EBNA) of October 2022, high incidences of medication errors and adverse drug reactions were identified as the major concerns of pharmacovigilance in BHM. A patient sustained a wound in the ear due to Acetic Acid 99.85% dispensed in place of diluted Acetic Acid 2% used as an ear drop. A patient has paid a huge hospitalization bill due to failure to end treatment with an expensive antibiotic when due. A patient almost went home without discharge medications due to a failure to transcribe discharge medications from the patient's chart to the patient's consultation card. Three staff members came back with serious body rashes after treatment with a particular batch of Cefixime 200mg. Taking measures to improve pharmacovigilance activities will go a long way to reducing high costs, prolonged hospitalization, and harm to patients caused by MEs and ADRs.

This project of improving pharmacovigilance in BHM is still running and will cover project design and implementation, change management, and management of resistance to change. It will dwell more on measures taken to improve pharmacovigilance activities to reduce or prevent harm to patients by drugs during treatment.

Project Design

Background to the project design

Pharmacovigilance is a liability shared with the medicine regulatory authority, public health programs, the pharmaceutical industry, and the Essential Drugs Programme (EDP) (Mehta, Blockman, and Maartens, 2014). According to Hadi et al. (2017), as long as drugs are being used for treatment, adverse drug reactions (ADRs) being one of the leading causes of morbidity and mortality, will continue to pose a threat to public health. Similarly, WHO (2004) ranks adverse drug reactions (ADRs) among the top 10 leading causes of mortality in some countries. Furthermore, the EU legislation empowered Eudravigilance to receive information on ADRs resulting from MEs since 2012 (Kiguba, Waako, Ndagije, and Karamagi, 2015). This makes prompt ADR reporting essential in ensuring drug safety (Hadi et al., 2017).

Pharmacovigilance was introduced in the CBCHS in 2016. Baptist Hospital Mutengene is one of the CBCHS hospitals in which the pilot phase of the introduction of pharmacovigilance in the CBCHS was carried out. Medication error forms and adverse drug reaction (ADR) forms were designed and provided to the pilot centers for reporting. Medication errors and adverse drug reactions were filed in the respective forms by the pharmacy personnel and forwarded to the CBCHS pharmacovigilance center for decision-making. At the end of the pilot phase, the practice gradually died down in BHM.

From observation, an average of over 10 prescribing and 20 dispensing errors were detected and corrected daily in the outpatient department of BHM. An average of 2 ADRs is identified and handled in a week. Only 10 medication errors were recorded in the pharmacy medication error register from January to September 2022, and no ADR was registered. Medication errors are easier to identify, while adverse drug reactions are more difficult to identify. MEs occur more frequently than ADRs, and some ADRs occur as a result of MEs. It is necessary to record MEs to serve as a reference for HCPs to prevent similar errors in the future. Recording ADRs can help the HCPs to identify and be able to manage similar ADRs if they occur in the future.

Underreporting of MEs and ADRs led to the conduction of an EBNA in October 2022. The results of the EBNA showed that 90% of HCPs were not aware of the presence of the pharmacovigilance system in the CBCHS and the presence of ME and ADR reporting forms in BHM. 80% of HCPs were ignorant of the importance of pharmacovigilance. 70% of HCPs gave workload and lack of time as the reason for underreporting. 60% saw a lack of feedback as the reason for under-reporting as they considered that the information was not useful. Fear of being punished was one of the reasons for under-reporting. 80% considered the filling of information in the reporting form to be very bulky, making the reporting system difficult. The results of the EBNA necessitated a project to optimize and strengthen pharmacovigilance practices to improve patient care at Baptist Hospital Mutengene.

Goal of the project

The main goal of this project is to improve the knowledge, attitude, awareness, and practices (KAAP) of healthcare workers on detection, recording, and reporting of MEs and ADRs and other drug related problems to optimize the benefit/risk ratio in the utilization of drugs for patient care in Baptist Hospital Mutengene.

Objectives of the project

To increase the knowledge and awareness of healthcare workers and patients on pharmacovigilance practice from 10% to 60% by February 2024.

To increase clinical pharmacy ward rounds by pharmacy technicians from 10% to 80% by January 2024.

To increase the recording and reporting of medication errors and suspected adverse drug reactions from 5% to 60% by February 2024.

To include pharmacovigilance practice in the training programs of the Baptist School of Public Health to enable all newly employed healthcare workers to know pharmacovigilance practice by October 2024.

Intensify continuous education in the pharmacy department to improve the staff's knowledge to track prescription and

dispensing medication errors from 5% to 60% by February 2024.

The project was implemented in March 2023 in Baptist Hospital Mutengene following the results of the EBNA of August to October 2022, which revealed a gap in pharmacovigilance activities. There was especially a very low rate of recording and reporting of MEs and ADRs of about 10%. This project design was adapted from the pharmacovigilance pilot phase that was carried out in Baptist Hospital Mutengene from 2016 to 2020 under the first hospital pharmacist in which the recording and reporting rate increased to about 80%. This practice was strengthened by the decision of the Director of Health Services (DHS) of the CBC to introduce incidence registers in all departments of the hospital in 2021. The practice continued through 2021 and dropped drastically in 2022. Thus, there's a need to optimize and strengthen Pharmacovigilance.

This project was established both in the pharmacy and the wards of the hospital, as compared to the pilot phase that was established only in the pharmacy department. The following implementation strategy was established for the project.

Desired Outcome	Action	Evidence-based Rationale	Timescale	Evaluation
Knowledge and awareness of healthcare workers and patients on pharmacovigilance practice increased from 10% to 60% by February 2024	Talk with the SNS about the intention to increase the knowledge and awareness of nurses through the head nurses.	Change agent to go to the nursing office and talk with the SNS	December 20th 2023	The intention discussed with the SNS
	Talk with the head nurses to help them work to increase the knowledge and awareness of nurses under them.	Change agent to go to the wards and talk with the head nurses	December 21st 2023 to January 20th 2024	Knowledge and awareness of nurses in the wards increased
	Increase knowledge and awareness of patients through weekly health talks at OPD.	A pharmacy staff member assigned to give health talks at OPD every Wednesday	November 2023 to February 2024	Health talk given at OPD every Wednesday
	Train the pharmacy staff to counsel patients when dispensing on the importance of reporting ADRs	Change agent to remind pharmacy staff during morning briefing to counsel patients when dispensing	November 2023 to February 2024	Patients are being counselled to report ADRs if they experience
Clinical pharmacy ward rounds by pharmacy technicians increase from 10% to 80% by January 2024	Talk with the hospital pharmacist to work on establishing a monthly schedule for clinical pharmacy ward rounds.	Change agent to go to the pharmacist's office and discuss with him	December 20th 2023	Schedule for clinical pharmacy ward rounds drawn and implemented
	Have a meeting with the hospital pharmacist and pharmacy technicians to discuss ways to intensify clinical pharmacy ward rounds.	Change agent to schedule for a meeting with the hospital pharmacist and pharmacy technicians		Meeting held and ways to intensify clinical pharmacy ward rounds discussed
	Discuss with the hospital pharmacist to intensify supervision of clinical pharmacy ward rounds.	Change agent to go to the pharmacist's office and discuss with him	December 20th 2023	Supervision of clinical pharmacy ward rounds by the pharmacist and

				head of the pharmacy department has been stepped up.
Recording and reporting of medication errors and suspected adverse drug reactions increased from 5% to 60% by February 2024	Encourage pharmacy staff through education and reminders to increase the rate at which they record MEs and ADRs.	The Chang agent to encourage and remind pharmacy staff during morning briefing.	November 2023 to February 2024	Recording of MEs and ADRs stepped up
	Discuss with the SNS to encourage the implementation of the incidence register and the use in registering and reporting MEs and ADRs.	Change agent to go to the nursing office and talk with the SNS	December 20th 2023	Discussion with the SNS being done
	Talk with the head nurses to take advantage of the incidence register to record MEs and ADRs and encourage the nurses to do so	SNS and change agent to talk with the head nurses	November 2023 to February 2024	Incidence registers re-established and MEs and ADRs being recorded in it
Pharmacovigilance practice is included in the training programs of the Baptist School of Public Health to enable all newly employed healthcare workers to know pharmacovigilance practice by October 2024.	Propose inclusion of pharmacovigilance in health training programs to the administration of the Baptist School of Public Health through the Dean of Studies.	Change agent to go to Baptist School of Public Health and propose to the dean of studies	January 10th 2024	The proposal made and pharmacovigilance practice included in the training program.
Continuously education intensified in the pharmacy department to improve staff knowledge to track prescription and dispensing medication errors by February 2024	Discuss with the hospital pharmacist to draw a schedule for continuous education and intensify supervision to ensure the schedule is followed.	Change agent to go to the pharmacist's office and discuss with him	December 20th 2023	Schedule for continuous education established and supervision stepped up.
	Encourage pharmacy technicians to present challenging cases from clinical wards rounds to improve the knowledge of the pharmacy staff.	Change agent to encourage and remind pharmacy staff during morning briefing	December 2023 to February 2024	Pharmacy technicians presenting challenging cases they encounter during their clinical wards rounds.
Strategies employed to manage resistance	Identify key people to work with	Change agent to brainstorm on who are the key people to work with	December 2023	Working with key people
	Use group meetings to effectively communicate a clear vision of the change and stimulate group	Change agent to take advantage of morning briefing meetings to communicate information	December 2023 to February 2024	Group participation in planning the changes

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	participation in planning the changes.			
	Determine the obstacles to achieving each milestone	Change agent to brainstorm on what the obstacles are	December 2023 to January 2024	Obstacles identified
	Develop a plan to overcome each obstacle	Change agent to brainstorm on a plan to combat the identified obstacles	December 2023 to January 2024	Obstacles overcome
Staff managed to take ownership of the change	Communicate the need for change and encourage participation of the staff	Change agents work with the staff and encourage them	December 2023 to January 2024	Staff willingly participating in the change.
Change is managed using change models.	Employ Lewin's change theory.	Change agent to work with the staff to manage change using Lewin's change theory	December 2023 to January 2024	Change managed with Lewin's change theory
	Employ the ADKAR Model	Change agent to work with the staff to manage change using ADKAR Model	December 2023 to January 2024	Change managed with the ADKAR Model
	Employ an improvisional change model.	Change agent to work with the staff to manage change using an improvisional change model	December 2023 to January 2024	Change managed with an improvisional change model
Change evaluated	Assess if there is a positive change in staff attitudes towards Pharmacovigilance and ADR reporting.	Change agent to work with HODs to evaluate staff attitudes	February 2024	Positive attitudes found in staff
	Assess if there is improvement in the identification and management of MEs and ADRs by staff.	Change agent to work with HODs to evaluate change in identification and management of MEs and ADRs	February 2024	Improvement in identification and management of MEs and ADRs by staff
	Assess if there is a positive behaviour on ADR reporting in patients	Change agent to work with pharmacy staff to evaluate patients' behaviour on ADR reporting	February 2024	A positive behaviour observed in patients
	Assess if clinical pharmacy ward rounds by pharmacy technicians have improved.	Change agent to work with the pharmacist to evaluate clinical pharmacy ward rounds	February 2024	Clinical pharmacy ward rounds regular
	Assess if MEs that reach the patients are reduced	Change agent to work with pharmacy staff to evaluate MEs that reach the patients	February 2024	Reduction in the number of MEs that reach the patients

Project implementation plan

Change Management Models.

Change management models can help manage change in an organization. The following models apply to this project:

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Lewin's change theory, the Improvisational change model, and the ADKAR Model. These three models are chosen because they can be applied in different areas of the management of the change of improving pharmacovigilance.

Lewin's change theory

The need for the change was discussed with the hospital pharmacist and the supervisor of nursing service as the authorities. They accepted the need for change and acted. The pharmacist convened a meeting with pharmacy technicians and worked with them to plan the way clinical pharmacy ward rounds should be implemented. He started working on the schedule for clinical pharmacy ward rounds for pharmacy technicians. He also planned to intensify continuous professional development to improve the pharmacy staff's knowledge in identifying and tracking MEs and ADRs. The SNS gave the go-ahead to work with the infection prevention nurse to contact the head nurses to pass the knowledge about the change to the nurses. This was unfreezing the old way and effecting the change. Continuous working with the pharmacist, SNS, infection control nurse, and head nurses on supervising the new way is refreezing or sustaining the change.

Improvisational change model.

The improvisational change model consists of three different types of change: anticipated, emergent, and opportunity-based (Orlikowski and Hofman, 1997). Furthermore, both anticipated and opportunity-based changes involve deliberate action, contrary to emergent changes, which arise spontaneously and usually inexplicitly out of people's practices with the technology over time (Orlikowski, 1996 cited by Orlikowski and Hofman, 1997). The anticipated change of implementing identification and recording of MEs and ADRs was done through discussion with the SNS, the pharmacist, the infection control nurse, the head nurses, the nurses, and the pharmacy staff. The idea and knowledge of the change were shared following top-down higher authorities beginning with the SNS and the pharmacist down to the nurses and pharmacy staff. In the process of the change, it emerged that the operating theatre, the intensive care unit, and the observation ward, which were not planned for change, were three critical departments where drugs are used. These three departments were immediately considered for the change. The opportunity was to use the incidence register introduced in the departments by the DHS to record MEs and ADRs.

ADKAR Model

The conclusion from Studies have shown that success in an organizational change results only when individuals are successful in implementing that change (Goyal and Patwardhan, 2018). Similarly, it was explained that managing five key goals that form the basis of the awareness, desire, knowledge, ability, and reinforcement (ADKAR) model is the requirement for effective management of the people dimension of change (Prosci, 2008 cited by Goyal and Patwardhan, 2018).

The awareness of the need to change was created through discussion with the SNS and the pharmacist down to the staff. This raised the desire to participate in and support the change. The knowledge about the change was disseminated to the nursing staff, pharmacy staff, and patients. The knowledge and training provided the staff and patients with the ability to implement the change on a day-to-day basis. Continuous working with the hospital administration and reminders to the staff and patients reinforced the change in place. There is a need to continue to use measures to sustain the change that has been implemented.

Project Implementation design

In this project, influential people and people who were to effect the change were identified. The hospital Pharmacist and the SNS were identified as influential people in the administration to discuss the change with to obtain authorization to go on with the change process. The head nurses were identified as influential people to pass the knowledge and idea of the change to the nurses and to supervise the implementation of the change. The SNS also identified the infection prevention nurse as the influential person to work with the change agent to pass the knowledge and idea of the change to the nurses through the head nurses. These set of people were to serve as the authority, educators, and supervisors.

The pharmacy staff, the nursing staff, the patients, and the caregivers were identified as the people responsible for effecting the change. The pharmacy staff were to serve as the people to participate in effecting the change as well as educators to the new pharmacy staff, patients, and caregivers. The pharmacy technicians, in addition to effecting the change of improving clinical pharmacy in the wards, also serve as supervisors for the change of improving pharmacovigilance in the wards. The nursing staff were to serve as the people to participate in effecting the change of improving pharmacovigilance in the wards as well as educators to the new nursing staff, inpatients, and caregivers. This set of people are the core people responsible for the change.

The hospital pharmacist who doubles as the pharmacist in charge of pharmacy personnel and training was responsible for introducing pharmacovigilance in training in the Baptist Training School for Health personnel. The dean of studies was identified as the person responsible for introducing pharmacovigilance in training at the Baptist School of Public Health. These two schools are the main training centers for health personnel in the CBCHS at the moment. They can participate to a great extent in preparing health

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personnel who will practice pharmacovigilance while working in Baptist Hospital Mutengene as well as the entire CBCHS institutions. The lesson learned was that the production pharmacist is the course coordinator for pharmacy courses in both BTSHP and BSPH and can easily effect the change.

Project description.

The change agent plays the role of a project manager to oversee all the activities of the project. The head nurses and heads of departments oversee the project activities in their various departments. They work hard to promote change by doing on-the-job education for the staff under them and supervising their activities. They work with their staff to educate inpatients and caregivers on the importance of reporting ADRs or any doubt about the medication given to them. They play an active role in change management.

The pharmacy staff, as the custodians of the use of medication in the hospital, play the role of educators to themselves, other healthcare personnel, outpatients, and caregivers. They do research and present in continuous professional development sessions in the morning, following the schedule. This helps them to educate themselves and improve their knowledge in identifying MEs, ADRs, and combinations of drugs in a prescription that can bring about ADRs. They go as far as reviewing patient history and laboratory results to compare with the medication prescription for appropriateness. They contact the prescribers in case of any concern for rectification or clarification. This plays a great role in preventing MEs from reaching the patients and avoiding potentially identifiable ADRs.

Pharmacy technicians go a long way to review inpatient charts for potential concerns with drug treatment. They supervise the use and management of drugs in the wards. This helps to intensify the tracking of MEs, potential drug interactions, and ADRs. Collaboration from the departments using drugs provides a conducive environment that favours the change.

The hospital authorities set an enabling environment for the change to take place. The hospital pharmacist and the SNS accepted the idea of the change and gave the go-ahead for the change to be implemented. The SNS asked the change agent to work with the infection control nurse to educate the nursing staff through the head nurses. The pharmacist drew up a schedule for continuous professional development and clinical pharmacy ward rounds by pharmacy technicians. This was a strong force field that favored the change.

Project sustainability

"Sustainability is one of the most important challenges of our time" (Silvius and Schipper, 2014). Sustainability can be defined as the ability of a system to maintain productivity despite a major disturbance such as that caused by rigorous (maintained) stresses or large anxiety (Bamberger and Cheema, 1990). Similarly, Wimberley (1993, p. 1), cited in Aarseth et al. (2017), defines sustainability as the provision of resources needed for the survival of a group in a manner that maintains the essential resources for present and future generations. On the other hand, the International Institute for Sustainable Development and Deloitte & Touche (1992) cited in Silvius, Schipper, and Planko (2012) look at it as adopting business strategies and activities that meet the present and future needs of the enterprise and its stakeholders. Meanwhile, Bruntland (1987), cited in Silvius and Schipper (2014) and Khalifeh, Farrell, and Al-event (2020), defines sustainability in terms of change development that meets the needs of the present and the future. There is a need for the sustainability of the project after implementation.

The involvement of the hospital administration, which is in support of the change project, is a guarantee that they will ensure the sustainability of the project. The SNS assigned the infection control nurse, whose work is primarily supervision, to work with the change agent. This will ensure there will be sustainable supervision, thus sustaining the project.

The availability of highly qualified staff in the pharmacy department is an applause to this change project. The presence of the pharmacist in the hospital who is in support of the change proves assurance of supervision and thus the sustainability of PV activities. The availability of 8 pharmacy technicians with knowledge of clinical pharmacy practice is an assurance of the sustainability of clinical pharmacy ward rounds and supervision of drug management in the wards. Drawing the monthly schedule for clinical pharmacy ward rounds by the pharmacist is an additional strength. These two qualities of staff are good in ensuring and supervising PV activities.

Continuous education can ensure the sustainability of change. Continuous professional development in the pharmacy department in the mornings on Tuesdays and Thursdays and on-the-job training of pharmacy auxiliaries and pharmacy assistants by the pharmacist and pharmacy technicians have imparted them with much-improved knowledge on identifying prescription errors and other drug-related problems. The staff also have a habit of sharing knowledge. The drawing of a monthly schedule for Continuous professional development by the pharmacist is an assurance of continuity. The above activities can ensure the sustainability of the change project.

Project implementation

The decision to carry on this change project was arrived at following the EBNA of October 2022. The planning of the change project was done. In the planning, key persons to contact were identified. The departments of the hospital to be involved in the project were identified. The strategy to

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contact the persons concerned was developed. The activities to be carried out in the various departments involved in the project were identified. The people who can resist the change were identified. The strategies to overcome the resistance were identified. This planning phase was pivotal to the project as it gave a guide to step-by-step execution of the various stages of the project implementation.

Some key persons need to be contacted and worked with to succeed. The hospital pharmacist was contacted as the technical supervisor of the pharmacy department and the management and use of drugs in the whole hospital. The pharmacist embraced the idea and gave the go-ahead to the project. The SNS was identified and contacted as the administrative supervisor of the nursing and paramedical departments of the hospital. After explanation, the SNS, on behalf of the administration, authorized the project to be carried out. With the instruction from the SNS, the infection control nurse worked with the change agent and gave a presentation to the head nurses. These key people were vital to the implementation of this project.

The hospital is very big, containing many departments, both medical and non-medical. The departments to work with were identified and selected. The selection was focused on departments that use drugs in patient care. The pharmacy department, the wards, and the operating theatre were selected. The heads of these departments were empowered to implement and supervise the project in their departments. They gave knowledge to their staff and created awareness to improve their attitude and practice towards pharmacovigilance. These departments are the key areas where pharmacovigilance activities should be taken seriously.

There is a need to know the PV activities to be carried out to improve PV. The activities were identified for each area of practice. The presentation included the activities that should be practiced in the departments concerned. After each presentation, time was given for the participants to identify more activities that should be practiced and to ask questions. This helped as a guide to the implementation and practice of PV and also to help them feel ownership of the project.

Resistance is one of the challenges faced by many organizations when a change is to take place. There is a need to identify and overcome resistance if a change project is to take place. The potential people to resist the change were identified. Strategies were used to overcome the resistance. The strategies taken were based on following the line of authority from top to bottom and the way of approach. If resistance is not overcome, the implementation of a change project cannot be successful.

The change process/how change management was done.

Understanding and selecting the best approach to the change process is vital. In this project, the planning was done on how to manage the transition from a current state to a desired future state. The pharmacist was the first person contacted for advice and support. The SNS was the second person contacted for administrative authorization. The next person contacted was the infection control nurse. Then, heads of departments were contacted for the creation of awareness and implementation of change in the departments. The heads of departments worked with their staff to implement the change in their departments. The dean of BSPH, the course coordinator for nursing and midwifery training, and the course coordinator for pharmacy training were contacted. This systematically followed the line of authority from the administration down to the staff who implemented the change.

The project was presented and discussed with the SNS on 20/12/2023. The intention of the change project was presented. The departments of the hospital to be involved and the PV activities to be carried out in each department were discussed. The SNS bought the idea and authorized the project to be carried out in the hospital. The SNS then asked the change agent to contact the Infection Prevention and Control/Water, sanitation, and Hygiene (IPC/WASH) nurse to work with her to contact the head nurses. This was the administrative authorization.

The project was presented and discussed with the hospital pharmacist on 20/12/2023. The intention of the change project was presented. The departments of the hospital to be involved and the PV activities to be carried out in each department were discussed. The pharmacist accepted the idea and approved it. This was also an administrative approval as the pharmacist oversees the management and use of drugs in the whole hospital. He promised to do his part to support the change project. The pharmacist convened a meeting with all the pharmacy technicians on 21/12/2023 to discuss the reimplementation of clinical pharmacy ward rounds. He encouraged pharmacy technicians to spend some time in the wards to screen patient charts for medication issues, contribute to patient care during doctors' ward rounds, and oversee drug management and use in the wards. He had talked with the associate chief medical officer and identified the best time that favors the clinical pharmacy in the two surgical wards. Monday and Friday in the general surgical ward and Monday, Tuesday, and Thursday in the orthopedic surgical ward. He programmed each pharmacy technician to spend one month in a ward and present interesting cases for the benefit of the entire pharmacy staff. He encouraged them to spend at least three days in a ward each week, two with the doctor and one by themselves, and end rounds at 11:00 am. The Pharmacist promised to

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develop activities to work on in the wards. The move taken by the pharmacist was very encouraging.

The dean of the Baptist School of Public Health (BSPH) was contacted on 12/01/2024. He was presented with the idea of including PV in the training programs of BSPH. He directed to the CP production pharmacist who is the course coordinator for pharmacy training in both BSPH and Baptist Training School for Health Personnel (BTSHP) and also to the course coordinator for nursing and midwifery in BSPH. The course coordinator for pharmacy training was contacted on 12/01/2024, and he promised to see how to intensify PV in the pharmacy training curriculum and include it in pharmacy courses for nurses and midwives in the planning of the next training programs. He also promised to contact the change agent in the designing of the PV curriculum. The course coordinator for nursing and midwifery was contacted on 15/01/2024 and appreciated the idea and promised to implement PV during clinical practice with nursing and midwifery students. There was a positive response from the side of training.

The IPC/WASH nurse was contacted on 12/01/2024. She advised me to talk with the second assistant SNS (ASNS2) to call for a meeting of head nurses for the project to be presented. The ASNS2 was immediately contacted, and she agreed to call for a meeting with the head nurses on 15/01/2024 after morning devotion. The ASNS2 was advised to talk with the head of the operating theatre separately as they plan their work schedule in the department. The head of the operating theatre was contacted the same day and programmed the change agent to come and present to the staff of the department on 17/01/2024. Contributions and proposals from others are very helpful in accomplishing the change.

The ASNS called for a meeting with the head nurses on 15/01/2024 immediately after morning devotion. In this meeting, a presentation was done on the change project. This presentation included the definition of PV, the history of PV development and PV in the present days, the place of CBCHS and BHM in particular in PV, the need to optimize and strengthen PV, the importance of their participation, the PV activities to be carried out in the departments and the importance of keeping records of PV activities. The use of suspected ADR, ME, and CP complaint forms was explained, and samples were given to each department. At the end of the presentation, time was given for contributions, questions, and discussion. The participants gave their input for the success of the project. This showed their willingness to participate in the change project.

The participants carried the information to their departments and implemented it. Due to a great difference in the PV activities, a separate presentation was done in the pharmacy department on 16/01/2024. Some head nurses requested a presentation to their staff in the department. A presentation was done at the operating theatre on 17/01/2024 in their morning departmental meeting and at the general surgical ward on 01/02/2024 at 2:30 pm during their departmental meeting. It was a lesson to be flexible to take to new ideas that arise during the implementation and effect changes necessary for the success of the project. Some departments that were not originally included in the project plan were identified and included. The ICU and the Observation ward were included during the implementation phase. The Head of the Outpatient Department (OPD) was contacted on 29/01/2024 and directed me to the nurse in charge of the observation ward. The nurse in charge was contacted on 30/01/2024, and information was given to her to pass on to the staff of the department and implement. A presentation was done at ICU on 31/01/2024 in the afternoon during their shift handover meeting. It is a lesson that there is usually a need for amendments in the course of implementing the project.

The heads of departments were in charge of implementation and monitoring in their various departments. They passed the information to staff, encouraged them, and worked with them to implement the change. Departments that did not have an adverse event register created one and started recording adverse drug events. Heads of departments kept on encouraging their staff to carry out the PV activities. The IPC/WASH nurse and the change agent visited the departments from time to time to see what they were doing and to encourage them. The visit serves as a monitoring tool as any doubt is clarified.

Follow-up is important for the success of the project. Follow-up was done in the operating theatre, children's ward, Male medical ward, Female medical ward, orthopedic surgical ward, and Maternity ward on 30/01/2024 and in the Medical surgical ward on 01/02/2024. There was a discussion with the representatives of these departments on what they have done so far. Some of them gave very good proposals. Some of them are as follows: a nurse should not carry out an order when in doubt and should consult the staff of another ward or the pharmacy staff or doctor in case of a challenge in the use of a drug or administration. There was a proposal for the introduction of a PV meeting. The female medical ward has appointed a PV nurse for the department. These were very good contributions to the success of the project.

Project results

This change project is being carried out in 10 departments of the hospital. The departments were selected based on the use of drugs in patient care. The departments concerned are CMW, MMW, FMW, MAT, MSW, SW, OR, OW, ICU, and the pharmacy. The project is ongoing, but evaluation of the level of implementation was done on the 9th and 10th of February, 2024. This evaluation shows the level of success of the project. This evaluation exercise produced project results.

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The evaluation exercise witnessed some positive results. The knowledge and awareness of healthcare workers on PV increased in the departments concerned from 10% to 80%. Clinical pharmacy ward rounds by pharmacy technicians increased from 10% to 20%. The availability of the adverse event register in the departments increased from 30% to 80%. Recording of medication errors and suspected adverse drug reactions increased from 5% to 70%. There was a promise from the pharmacy course coordinator to pay more attention to PV lessons for pharmacy, nursing, and midwifery students both in BSPH and BTSHP in the planning of the next academic year. The course coordinator for nursing and midwifery in BSPH also promised to ensure PV practice during practical experience. The rate of continuous education in the pharmacy department increased from 5% to 20%. These are successes of the change project. There was no change in some of the PV activities. Double reading of drug labels remained at 70%, while 10% do it sometimes. Confirmation of drug and drug calculations remained at 40%, while 20% do it sometimes and 20% only when in doubt. Crosschecking of all orders carried in the ward remained at 44%, while 22% do it sometimes. The second check of each prescription filled in the pharmacy is not being done. Assigning at least two nurse anesthetists in the OR is not being done for the Afternoon and night shifts due to staff shortage in the department. The discussion during the evaluation may bring change in these areas as monitoring and evaluation will continue.

Project monitoring and evaluation

Monitoring progress and evaluating impacts have long been regarded as important to make sure that objectives are met (Guijt, Arevalo, and Saladores, 1998). Therefore, there is growing recognition among practitioners and scholars that a well-designed monitoring and evaluation system is an integral part of good project management, and it should be participatory. (Stem, Margoluis, Salafsky and Brown, 2005; Estrella and Gaventa, 1998). The participation of all involved in monitoring and evaluation is mandatory for project management. Furthermore, according to Crawford and Bryce (2003), one type of management information system (MIS) designed to mitigate poor project performance, demonstrate accountability, and promote organizational learning for the benefit of future projects is the project monitoring and evaluation information system (MEIS). Monitoring and evaluation a vital tools for project implementation.

Monitoring and evaluation were done at irregular intervals as the need arose and as the opportunity came up. The IPC/WASH nurse visited some wards and discussed with the staff. She appreciated those who have implemented it and encouraged those who have not implemented it to do so. She handed books to those who had not established the adverse event register to do so. The change agent planned and visited the departments concerned to see what they were doing. Discussed with the representatives, appreciated and encouraged them, clarified doubts, received their proposals, and gave presentations to the entire staff of the department where necessary. This was external monitoring and evaluation. Monitoring and evaluation were also done at regular intervals. Heads of departments also monitored and evaluated the implementation daily as they worked with the staff. They guided and encouraged the staff on PV activities. They served as exemplary because they carried out PV activities together with the staff. This was internal monitoring and evaluation.

With the above activities, some of the PV activities were assessed and corrected. Some adjustments were made following better alternative ways. This occurred through verbal communication in small, brief meetings in the departments where PV issues were discussed and agreed upon. Some proposals from the departments were put into action and used in the implementation. This made the staff in the departments take ownership of the implementation, especially the heads of departments. This was a positive force field that supported the implementation. Meanwhile, in one ward, one staff argued strongly that due to the nature of work, recording of drug adverse events cannot work. This was a negative force field that hindered implementation. Monitoring and evaluation in this project were participatory.

Management of Resistance

Resistance to change is inevitable. It is necessary to understand health workers' reactions to change, identify those who may resist the change, and choose better ways to manage resistance.

Health workers' reaction to change

Studies on change recipient obvious reactions considered characteristics of the recipient that foretell and help explain their reactions (Oreg, Vakola, and Armenakis, 2011). Employees differ in their way of reactions to organizational change depending on their age, culture, and attitudinal differences (McElroy & Morrow, 2010 cited by Khaw et al., 2023). Similarly, studies focus on the fact that individuals are persuaded to respond in certain ways when experiencing change across different change situations (Oreg, Vakola, and Armenakis, 2011). On the other hand, a study by Oreg and Berson (2011) assessed the role of leaders' personal qualities and inspirational leadership behaviors in explaining employees' intentions to resist a large-scale organizational change. Furthermore, studies affirmed that employees' previous experiences are important in determining employees' reactions to organizational change (Alas, 2007 cited by Khaw et al., 2023). The attributes of the employee, employer, and organization affect the employee's reaction to organizational change.

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In the context of BHM, health workers reacted in different ways to the change. Some workers received the change happily and participated fully in the implementation. Others received it reluctantly while others complained that due to workload, the change would not work. Others received the change quietly without showing signs of acceptance or rejection. In this last group of workers, some participated in the implementation while others remained indifferent. Those in administrative positions like the SNS, the pharmacist, and the heads of departments accepted the change and gave their full support. More than 70% of the health workers in the departments involved showed signs of acceptance of the change.

Management of resistance to change

Resistance to change is a barrier to implementation. Therefore, management of resistance to change is a necessity. Increasing change recipient involvement in the change and putting change recipients at greater ease by allowing participation and ensuring just procedures have been shown to go a long way in reducing resistance (Oreg, Vakola, and Armenakis, 2011). Similarly, increases in managers' self-awareness have been shown to improve performance (Church, 1997 cited by Oreg and Berson, 2011). Furthermore, leaders can identify followers who cheerfully accept and conform to change and encourage them to support their peers who find the change more difficult to adjust to (Oreg and Berson, 2011). Different ways are used to combat resistance following various situations encountered.

In this change project, resistance was managed in different ways. The idea of the change project was first shared with the hospital pharmacist and then the SNS and the IPC/WASH nurse. Contacting these members of the administration reduced resistance from the authorities of the hospital. The head nurses and heads of departments were identified and encouraged to support staff who find it difficult to adjust to the change. This lessened resistance to change recipients. Presentations were given to heads of departments to pass to their staff and the staff of some departments to improve knowledge and awareness and then receive their contributions. This also reduces resistance. Regular visits to departments by the change agent and the IPC/WASH nurses to monitor, evaluate, and discuss the progress with the staff give them a sense of ownership and reduce resistance. Overcoming resistance is the key to success.

Evaluation of change

The evaluation of change was done on the 9th and 10th of February, 2024. A template for evaluation was designed to document the PV activities being implemented in the departments. The change agent moved into the departments concerned and had evaluation meetings with the staff of each department or representatives for some departments. In this meeting, the change agent and the staff went through the activities in the evaluation template one after another and evaluated the level of implementation of each activity. The outcome of the evaluation meeting was analyzed into results. The IPC/WASH nurse was to be part of the evaluation team but was involved in a meeting.

Conclusion.

Pharmacovigilance practice is a necessity in the healthcare system. The practice of PV is worldwide, but under-reporting is common globally, in Africa, Cameroon, and BHM in particular. There is a need for rational and careful use of drugs to maximize the benefits and minimize the risks associated with drug treatment. This can be done through careful detection, recording, and reporting of drug-related problems. Healthcare workers need knowledge, awareness, and a positive attitude and practice in order to achieve this. A PV change project can suffice.

The PV change project in BHM is witnessing progress. The support of the BHM administration and the commitment of the staff will record a great improvement and sustain the project. Successful implementation of this project will go a long way to reduce or prevent some drug-related problems that cause treatment failure, harm, long hospitalization, increased cost of care, and death.

Recommendation

The hospital pharmacist should work with the administration to develop internal policies to enforce the practice of pharmacovigilance.

The administration should request for more nurse anaesthetists to make it possible for the OR to assign two nurse anaesthetists for afternoon and night duty.

The administration and heads of departments should continue to supervise this change project and encourage staff so that PV practice in BHM will be sustainable.

The pharmacy department should intentionally implement a second check of prescriptions and increase the rate of clinical pharmacy visits to the wards.

The administration should be intentional not to punish any staff who is sincere to report an incident. Fear of punishment will scare staff from recording and reporting ADRs, MEs, and other medical errors.

The administration can devise a way of motivating the departments that show proof of high performance in carrying out PV activities.

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List of abbreviations.

ADKAR: awareness, desire, knowledge, ability, and reinforcement
ADRs: Adverse Drug Reactions
ASNS2: Second Assistant Supervisor of Nursing Services
BHM: Baptist Hospital Mutengene
BSPH: Baptist School of Public Health
BTSHP: Baptist Training School for Health Personnel
CBC: Cameroon Baptist Convention
CBCHS: Cameroon Baptist Convention Health Services
CMW: Children's Medical Ward
CPR: Change process research
CP: Central Pharmacy
DHS: Director of Health Services
EBNA: Evidence-based needs assessment
EDP: Essential Drugs Programme
EU: European Union
FMW: Female Medical Ward
HCPs: Health Care Providers
HRM: Human Resource Management
ICSRs: Individual Case Safety Reports
ICU: Intensive care unit
IPC/WASH: Infection Prevention and Control/Water, sanitation, and Hygiene
KAP: Knowledge, attitudes, and practices
KAAP: Knowledge, awareness, attitudes, and practice
MAT: Maternity Ward
MEs: medication errors
MEIS: monitoring and evaluation information system
MIS: management information system
MMW: Male Medical Ward
MSW: Medico-surgical Ward or General surgical ward
NMRAs: National Medicines Regulatory Authorities
OPD: Outpatient Department
OR: Operating Room or Operating Theatre
OW: Observation Ward for emergency cases
PV: Pharmacovigilance
SNS: Supervisor of Nursing Services
SSA: Sub-Saharan Africa
SW: Surgical Ward for orthopedics
UMC: Uppsala Monitoring Centre
WHO: World Health Organization

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Conflict of interest.

No conflict of interest was declared.

Availability of data.

Data used in this study is available upon request from the corresponding author.

Authors contribution.

EK designed the study, reviewed literature, cleaned and analyzed data, and drafted the manuscript; JFN supervised all stages of the study from conceptualization of the topic to manuscript writing and submission; and DK & EO supported study conceptualization, general supervision, and mentorship.

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