

IMPROVING STERILE COMPOUNDING OF PARENTERAL PREPARATIONS BY PHARMACY TECHNICIANS IN MBINGO BAPTIST HOSPITAL PHARMACY.

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Abstract

Breaching the required standards for sterile compounding results in patient harm and death. Three deaths have been recorded in Mbingo Baptist Hospital resulting from contaminated sterile preparations compounded by the pharmacy. This is due to a lack of training, policy and procedures, a proper compounding facility and equipment, and poor aseptic techniques. To address these problems, a project was initiated and is ongoing.

The goal of the project is to contribute to the improvement of the quality of compounded sterile parenteral preparations and ensure they are free from contamination and safe for inpatients in Mbingo Baptist Hospital from May 10th, 2023, to November 12th, 2024. The objectives are to improve the facility and equipment for sterile compounding by the 12th of November 2023, enhance personnel knowledge and skills by the 30th of December 2023, and institute a policy and standard operating procedures for sterile compounding by the 15th of April 2024. The project implementation strategy is through training, construction, and equipment purchase.

The expected outcome of this project is six pharmacy technicians trained in sterile compounding, a separate facility and laminar air flow hood for sterile compounding, and a policy and standard operating procedures for sterile compounding. The acquired knowledge and skills will be sustained by assessing the aseptic technique skills of trained personnel every 6 months through media field and glove finger tests.

Keywords: Sterile, Compounding, Parenteral Preparations, Pharmacy, Technicians, Mbingo Baptist Hospital.

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Background.

Compounding is the preparation, mixing, assembling, or altering of ingredients of a drug to create a medication that meets the needs of an individual patient (Kairuz et al., 2007; Qureshi et al., 2014; Gudeman, 2013). Compounding is carried out due to the unavailability of commercial forms or when commercial forms are not suitable for the patient (Gudeman, 2013; Myers, 2013). Sterile compounding involves manipulating sterile ingredients to achieve a sterile end product and to achieve sterility when using non-sterile ingredients (Borgonje et al., 2002; Myers, 2013).

Compounded sterile preparations are parenteral products that are administered as infusions, injections, or eye drops and are commonly used in hospitalized patients (Scheepers et al., 2016; Kairuz et al., 2007). Breaching required standards for sterile compounding results in patient harm, such as bloodstream infections, sepsis, meningitis, and death (Virtanen et al., 2021; Genatrika et al., 2022; Myers, 2013). The American Food and Drug Administration (FDA) has reported more than 200 problems with compounded sterile preparations since the early 1990s, leading to patient injury and death (Kastango and Bradshaw, 2004; D'Arrigo, 2011;

Gudeman et al., 2013). Furthermore, in the United States of America, there have been 27 incidents due to contaminated sterile preparations between 1990 and 2020, resulting in harm to 1119 patients (Lomis et al., 2019; Watson et al., 2021). Similarly, in Indonesia, a 3% error has been reported by Genatrika et al. (2022). However, there are no reports for Cameroon.

In Mbingo Baptist Hospital in Cameroon, there have been patient harm and three deaths due to contaminated sterile preparations resulting from poor compounding practices. To prevent patient harm, guidelines have been provided by the United States Pharmacopeia (USP) chapter 797 on sterile compounding and similarly, Cameroon also has guidelines published in December 2011 (USP, 2019; Genatrika et al., 2022; Kastango, 2004).

To improve sterile compounding in the Mbingo Baptist Hospital pharmacy, an evidence-based needs assessment was carried out in November 2022, and gaps were identified. They include a lack of proper infrastructure and equipment for sterile compounding, a lack of training on sterile compounding, and inadequate aseptic techniques. A project was initiated to run from 10th January 2023 to the 12th of

November 2024 and is ongoing to meet these identified needs. Therefore, this write-up includes a literature review on sterile compounding, project design, implementation, monitoring and evaluation, theories and models of change management, the process of change, people's reactions to change, and managing resistance to change.

Project design background.

Mbingo Baptist Hospital is owned by the Cameroon Baptist Convention and is found in the Northwest Region of Cameroon. It was founded in 1954 as a leprosy treatment center, and today, it is a referral hospital offering many different services. In addition, it is also a teaching hospital with two specialization programs for general practitioners. It is a non-profit making faith-based hospital with a bed capacity of 310 beds. The personnel in the pharmacy include a pharmacist, 6 pharmacy technicians, 4 pharmacy assistants, and 12 pharmacy auxiliaries. The expansion of the hospital has resulted in the need for compounded sterile preparations for inpatients.

The pharmacy compounds parenteral preparations for inpatients like neonates, children, patients with intestinal sectioning, and severely ill patients who cannot take anything by mouth. These preparations are parenteral infusions that have to be administered intravenously. In addition, the preparations compounded by the pharmacy are risk level one and two preparations (Kastango, 2004).

In Hospital X, there have been reports of patient harm and three deaths due to contaminated sterile preparations. Following these incidents, an evidence-based needs assessment was conducted. The Cameroon guidelines on sterile compounding and the USP 797 guidelines for sterile compounding were reviewed. Then, the sterile compounding practice was assessed following what the guidelines stated, which resulted in the identification of some gaps.

The USP guidelines and the Cameroon policy on sterile compounding are not being implemented. The personnel compounding sterile preparations have not been trained in sterile compounding. Also, they perform inadequate aseptic techniques during compounding. In addition, the facility and equipment required for sterile compounding are not available. A report of the needs assessment was presented to the head of the pharmacy department. It was decided that a project would be carried out to address the identified needs.

Situational Analysis

In the United States of America, there have been 27 incidents due to contaminated sterile preparations between 1990 and 2020, resulting in harm to 1119 patients, including deaths (Malviya et al., 2019; Lomis et al., 2019; Watson et

al., 2021). Also, in Germany and the United Kingdom, the compounding error is estimated between 34- 48%, and in Indonesia, 3%. These patient harms are due to poor compounding practices such as inadequate aseptic techniques, inadequate training or untrained personnel, improper environment for compounding, and poor-quality assurance practices (Virtanen et al., 2021; Gupta et al., 2014; Gudeman, 2014).

In Mbingo Baptist Hospital, there has been patient harm resulting in three deaths due to contaminated sterile preparations resulting from poor compounding practices. These poor compounding practices are due to the lack of a policy and standard operating procedures for sterile compounding. In addition, the personnel have not been trained on sterile compounding and carry out poor aseptic techniques. Furthermore, the facility and equipment required for sterile compounding are not available.

To address this issue requirement specified by the USP chapter 797 has to be implemented. This includes training all pharmacy personnel involved in sterile compounding, adopting the Cameroon policy for sterile compounding and writing standard operating procedures, and providing the correct facility and equipment for sterile compounding.

Aim of the project.

To contribute to the improvement of the quality of compounded sterile parenteral preparations and ensure they are free from contamination and safe for inpatients in Mbingo Baptist Hospital.

Target group

Pharmacy technicians

Location

This project is being carried out in the Mbingo Baptist Hospital Pharmacy.

Time frame

This project will run from May 10th, 2023, to November 12th, 2024.

Project objectives

- Improve the facility and equipment for sterile compounding by 12th November 2023.
- Enhance personnel knowledge and skills on sterile compounding by the 30th of December 2023.
- Institute a policy and standard operating procedures for sterile compounding by the 15th of April 2024.

Logical Framework Strategy

Table 1: showing Logical Framework for sterile compounding project in Mbingo Baptist Hospital Pharmacy.

	Project structure	Indicator	Means of verification	Assumptions
Goal	Contribute to the improvement of the quality of compounded parenteral preparations to ensure they are free from contamination and safe for inpatients within 1 year and 6 months.	Percentage reduction of inpatient harm and death due to contaminated parenteral preparations.	Pharmacovigilance record in the health facility.	
Objectives(outcomes)	-Improve the facility and equipment for sterile compounding by the 12 th of November 2024. - Enhance personnel knowledge and skills in sterile compounding by the 30 th of December 2023. -Institute a policy and standard operating procedures for sterile compounding by the 15th of April 2024.	The rate of inpatient harm due to contaminated compounded parenteral preparations.	Pharmacy Pharmacovigilance record of the facility.	
Outputs	-A constructed sterile compounding room.	-The number of rooms constructed. -Number of laminar	-View the building and Laminar air flow hood physically.	

	<ul style="list-style-type: none"> -One laminar air flow hood purchased. -Three trainers identified -Six pharmacy technicians trained in sterile compounding . -One policy and three standard operating procedures written. -Two stakeholder meetings were held. -Three presentations made 	<ul style="list-style-type: none"> airflow hoods bought. -Number of trainers involved in the training. -Number of pharmacy technicians trained. -The number of policies and SOPs written. -Number of stakeholder meetings held. -Number of presentations made 	<ul style="list-style-type: none"> -Trainers attendance log book. -Training results and attendance sheet. -A printed copy of the policy and SOPs. -Meeting minutes. Continuous education record. 	
Activities	<ul style="list-style-type: none"> - Stakeholder meeting. -Supervise and monitor the construction of the sterile compounding room. -Procure and transport Laminar air flow hood. -Source training classroom -Identify trainers -Train six pharmacy technicians on sterile 	Budget 60000frs 1000000frs 6000000frs 30000frs 2000frs 200000frs Voluntary presentations	Person incharge Pharmacist -Supervisor of technical services The procurement officer Pharmacy supervisor Pharmacist Pharmacist Pharmacy technicians	Inputs Trainers Training material Stakeholders. A Computer Typing sheets Building material and equipment Building engineer

	compounding . -Do quarterly presentations on sterile compounding during continuous education. - Write a policy document and SOPs on hand hygiene, gowning, and compounding in the laminar airflow hood.	5000frs	Pharmacy technicians.	
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This logical framework targets the project proposed in Mbingo Baptist Hospital pharmacy on improving sterile compounding of parenteral preparations by pharmacy technicians. The focus of the logical framework is on interventions that will create an impact on the problem statement. The objectives are targeted at improving the quality of compounded parenteral preparations, which will result in improved treatment outcomes. They have been developed based on USP Chapter 797 and Cameroon guidelines for sterile compounding and the study by Genatrika et al. (2022). In addition, the result of the study of sterile compounding in three clinical environments (the ward, pharmacy, and Laminar air flow hood in an isolated room) by Virtanen et al. (2021) has also been taken into account

Project SWOT analysis

Strength

The pharmacy department has the following strengths. The Cameroon Baptist Convention Central pharmacy manufactures infusion fluids and carries out training on sterile work practices. Therefore, facilitators for the course will be obtained from the Central Pharmacy. Also, there are adequate human resources. Furthermore, there is a technical service department in the hospital made up of the biomedical, electrical, construction, and carpentry departments. Therefore, the skills required for the construction work are already available.

Weaknesses

Personnel have not been trained on sterile compounding. Appropriate facilities and equipment are not available for sterile compounding. There is also frequent stock out of

medication and inadequate space to expand pharmacy services. Additionally, there is poor governance, a lack of policy and standard operating procedures for sterile compounding. Furthermore, there is poor data collection.

Opportunities

There is an ongoing project to improve cancer treatment, and it covers chemotherapy compounding by pharmacy technicians. Likewise, there is another project to renovate the entire block where the compounding room is located. This project will cover the cost of the renovation of the compounding room to provide a room for sterile compounding.

Threats

There is a threat to the achievement of the project, which is the socio-political crisis going on in the region of the country where the hospital is located. There is the challenge of road blockages, which go on for months at times. This makes traveling in and out of the region difficult. Also, there is insecurity with kidnapping and demands for ransom. Furthermore, there is an economic factor, like the devaluation of the currency, which has led to inflation, resulting in very high prices.

Project implementation

The following strategy will be used in implementing the project. A three-month training will be conducted to train pharmacy technicians on sterile compounding practices. The purpose of the training is to equip pharmacy technicians with the knowledge and aseptic techniques and skills required for sterile compounding. This will promote safety and prevent harm to patients by ensuring that all

compounded sterile preparations are free from contamination and are accurate. The training will include compounding procedures, aseptic work practices, cleaning, and garbing (Allen, 2009; Kastango, 2005; Banu et al., 2022). At the end of the training, media fill assessment and competency-based skill assessment of sterile compounding activities such as accurate garbing and aseptic techniques will be done (Kastango, 2005; Banu et al., 2022).

In addition, the Cameroon policy on sterile compounding will be instituted, and standard operating procedures will be written. Furthermore, construction work will be done in the old compounding room. The room will be partitioned and renovated to provide a separate room for sterile compounding, and a laminar air flow hood will be purchased.

The strategy to carry out this project was chosen based on the USP chapter 797 and Cameroon guidelines for sterile compounding, the study by Genatrika et al. (2022), and the study on sterile compounding in the ward, pharmacy, and Laminar air flow hood in an isolated room. According to the guidelines, all personnel involved in sterile compounding must be adequately trained and skilled. According to the studies, sterile compounding carried out by trained and skilled personnel in a biological safety cabinet inside a clean room significantly prevents microbial contamination (Banu et al., 2022; Kastango, 2005; Masupye, 2015).

Project implementation action plan.

Table 2: A project action plan for the sterile compounding project going on in the Mbingo Baptist Hospital pharmacy.

Desired outcome	Action	Evidence-based rationale	Time scale	Evaluation
Construct ed facility for sterile compound ing.	Partition and renovate the general compounding room.	USP <797> guideline (Kastango, 2005).	10 th May 2023 to 30 th September 2023.	View completed structure.
Six trained pharmacy technician s on sterile compound ing.	-Carry out a three-month training on sterile compounding. -Quarterly presentations on sterile compounding	USP <797> guideline (Shephard, 2014).	2 nd October 2023 to 30 th December 2023.	Examination results.
Purchased and installed laminar airflow hood.	The procurement officer is to source and purchase laminar air flow hoods.	USP<797> guidelines (Kastango, 2005).	5 th April 2024 to 9 th November 2024.	View installed laminar airflow hood.
A written policy and three SOPs for sterile compound ing	Pharmacists to write the policy. Trained pharmacy technicians to write standard operating procedures	USP <797> guideline (Shephard, 2014).	15 th January 2024 to 15 th April 2024.	View the written documents .

Project Description

The project activities will be implemented as follows. There will be quarterly presentations on sterile compounding in the

pharmacy department throughout the project period. The first presentation will take place on the 10th of May, 2023. The other presentations will be on the following dates: 10th

of September 2023, 10th of January 2024, 10th of May 2024, and 10th of September 2024. The old compounding room will be repartitioned and renovated. Work will begin in the old compounding room from the 10th of May 2023 to the 30th of September 2023 and will be done by the hospital technical services department. The pharmacy staff will remove all items in the compounding room from the 10th to the 20th of May 2023 for renovation to start in the room.

This will be coordinated by the pharmacy technician assisting the pharmacist. From the 21st of May, the builders will start work in the compounding room. The old general compounding room will be repartitioned and renovated to provide a separate room for sterile compounding and another room for general compounding. When the builders are through, carpenters will do the work surfaces and wall cupboards. After the carpenters are through, plumbers and electricians will do their work in the rooms, and by the 30th of September 2023, the work will be completed.

Furthermore, a three-month training will be carried out on sterile compounding. The training participants will be six pharmacy technicians from the hospital pharmacy, and the training will take place in the Mbingo Baptist Hospital pharmacy. The teaching methods will include lectures, videos demonstrating sterile compounding, and practical sessions. The lectures will run from the 2nd of October to the 2nd of December, 2023.

Practical sessions will run from the 3rd of December to the 15th of December 2023, with the pharmacy technicians doing sterile compounding and the facilitators overseeing it. The training will cover infection control and quality assurance, aseptic work practices, hand hygiene and garbing, cleaning, and disinfection of the compounding area, and how to use a biological safety cabinet. During the training, there will be three facilitators: two from the CBC central pharmacy sterile production unit and the hospital pharmacist.

At the end of the training, there will be written and practical examinations from the 15th of December to the 23rd of December, 2023. Trainees will also be assessed on psychomotor skills, which include the use of a biological safety cabinet, cleaning and disinfection, hand hygiene, and garbing. Furthermore, aseptic technique skills will be assessed through the media fill test and glove finger test. On the 30th of December 2023, the results of the training will be released. This training program was chosen to make use of the skills already available in the Cameroon Baptist Convention health board.

The pharmacist will work on the policy to be used in sterile compounding. The trained Pharmacy technicians will write standard operating procedures for garbing, hand washing, and how to compound in the Laminar air flow hood. These activities will run from the 15th of January to the 15th of April, 2024.

The procurement officer will source for and purchase a class two laminar airflow hood and purchase. This activity will run from the 5th of April 2024 to the 9th of November 2024. On the 10th of November 2024, the project will be evaluated to see if the aims and objectives have been achieved. On the 12th of November, 2024, the completed project will be presented to the hospital administration, and on the 13th of November, sterile compounding will commence in the new sterile compounding room.

Project Outcomes

It is expected that by the end of the project, the following will be achieved.

- A separate room for sterile compounding.
- A new laminar air flow hood was installed for the sterile compounding room.
- Six Pharmacy technicians trained in sterile compounding.
- A policy and three SOPs were written for sterile compounding.

Overall outcome

Improved treatment outcomes for admitted patients receiving compounded parenteral preparations

Project monitoring and evaluation

Monitoring and evaluation are very important aspects of a project. It tracks the objectives, strategies, activities, and indicators of the logical framework. This enables the project team to know if the project is on track or not. In addition, it is also the basis for which information is used for timely decision-making (Kissi et al., 2019; Crawford and Bryce, 2003).

Project monitoring is defined as a process of gathering information to compare the actual use of project inputs and completed outputs with the planned use of inputs and completed outputs (Kissi et al., 2019; Crawford and Bryce, 2003). Monitoring aims to determine if the intended objectives are being met. Monitoring involves the continuous assessment of the project regarding the implementation schedule agreed upon. Monitoring is a good management tool that, when properly used, provides continuous feedback on how the project is being implemented. Also, it assists in identifying potential success and constraints, which facilitates timely decision-making (Kissi et al., 2019; Crawford and Bryce, 2003).

In this project, monitoring will be done continuously in several ways as the project is going on to ensure the project is achieving its set objectives. Physical monitoring will be done to measure the progress of the project activities against the established schedules and success indicators. In addition, processes will also be monitored to identify factors accounting for the progress of activities or drawbacks.

The activities to be monitored are sterile compounding training, quarterly presentations on sterile compounding, partitioning and renovating the general compounding room, and sourcing and purchasing the laminar air flow hood. Furthermore, impact monitoring will be done to assess how the stakeholders have understood the project, to minimize the risk of the project failing, and to assess how the implementation of the project is progressing. The tools to be used in monitoring are verbal communication, quarterly meetings, reports, and diary notes. Monitoring will be done to assess if there is an improvement in behavior change when carrying out aseptic techniques.

Evaluation of the ongoing project

Project evaluation is defined as the process whereby information is gathered to assess the effects and impacts of a project. Evaluation is made using data and information generated through project monitoring to analyze the effects and impact of the project (Frechtling, 2002; Kissi et al., 2019). Project evaluation has several purposes. It helps in determining the degree to which objectives have been achieved. It also determines and identifies problems associated with project planning and implementation. In addition, it assists in the reformulation of objectives, strategies, and policies in projects. Evaluation can be done in three ways: interim evaluation, terminal evaluation, and ex-post evaluation (Kissi et al., 2019; Dias et al., 1996).

In the ongoing project, interim evaluation will be done when the project has gone midway, and at the end of the project, another evaluation will be done. The evaluation will be done by looking at the indicators for the outcomes to see if the outcomes have been achieved.

Achievements and challenges

The project is ongoing, and the renovation work to be done in the old compounding room has been completed. The room has been partitioned and renovated to provide a separate room for sterile compounding and another for nonsterile compounding. Now, there is a separate room where sterile compounding is carried out.

Challenges

The project is also facing some challenges. The socio-political crises have brought the project to a standstill, and other objectives have not yet been met.

The pharmacy technicians to be trained have not started training yet. When the training was about to start, the crisis escalated, and there was a roadblock for over 5 months, with no traveling in and out of the area where the hospital is located. This made it impossible for trainers to come for the training. As a result of the crisis, the project was halted to

continue as of the 5th of January 2024 with the training of the pharmacy technicians.

Sustainability

To ensure sustainability, the competency of the trained pharmacy technicians will be assessed every six months on gloved fingertip sampling and growth media transfer. Gloved fingertip sampling is performed after the hand hygiene and garbing procedure. This is to show that the operator can successfully don a pair of sterile gloves without contaminating the fingertips (Kastango, 2005; Loomis et al., 2018). The media fill test is used to evaluate aseptic techniques. The test is customized to mimic the preparation that is most challenging and frequently prepared in a facility, under similar conditions (Kastango, 2005; Loomis et al., 2018).

Change Management Models.

This chapter covers the models that have been used in carrying out this project. These models are Lewin's three-step model, social cognitive theory, the theory of reasoned action and planned behaviour, and Prochaska and DiClemente's change theory. It has been expanded in the chapter on how these models and theories have been applied in the project, and the leader's role in change management has also been covered in this chapter.

Lewin's three-step model

Kurt Lewin is the founding father of change management, and he initiated the planned approach to change in 1946. He was a theorist, researcher, and practitioner in interpersonal, group, intergroup, and relationships in community relationships (Cameron and Green 2009; Tondem, 2005). Lewin's three-step change model consists of unfreezing the present level, moving to the new level, and refreezing the new level. This model is considered a fundamental approach to managing organizational change (Burnes, 2004; Tondem, 2005).

This model is based on the premise that before the change is introduced into an organization, employees in the organization have to be prepared for the change. Also, they should be motivated to change. In addition, there should be in place an established and integrated mechanism to bring about change in the behavior of all organizational members (Odor, 2018; Burnes, 2004). For change and new behavior to be successfully acquired, the previous behavior is to be discarded. This requires that the old behavior, structures, processes, and culture have to be discarded before new approaches can be successfully adopted (Cameron and Green, 2009; Burnes, 2004).

Unfreezing the present level involves recognizing the need for change and improvement. In this stage, change agents

and everyone involved in leading the change process source the information needed to solve the identified problem (Odor,2018; Mullins,2007). This is a very important stage requiring leaders and managers to educate and motivate employees to buy the idea of change. In addition, any change initiative involves two types of divergent forces. Therefore, at this stage, it is important to identify the driving forces for the change and those against the change (Odor,2018; Cameron and Green,2009).

The principle of the force field analysis is that driving forces must outweigh resisting forces in any circumstance for change to occur (Cameron and Green, 2009; Odor,2018). The force field analysis enables a management team to discuss and agree on the driving and resisting forces existing in any change situation. Using this analysis, together with a collaborative definition of the current state versus the desired end state, a team easily defines the next step in the change process (Mullins,2007; Burnes,2004).

Step two is moving to the desired position, dealing with the development of new behavior and attitudes, and executing the change program (Burnes,2004; Todnem,2005). This stage is critical, and the following should be done to ensure success. Continuous education must be provided on the need for the change to take place. Also, extensive support must be provided to employees, especially those resistant. In addition, an undiluted flow of communication should be maintained with subordinates regarding the change process, especially the benefits to be derived (Odor,2018; Cameron and Green,2009).

Step three is the refreezing stage. It involves stabilizing the change intervention by striking a balance between the driving forces of change and restraining forces. This is done through policies, procedures, structures, and cultural norms (Odor,2018; Burn,2004). To achieve success in this stage, employees must not be rushed. They should be given enough time to get used to the change, and the benefits of the change initiative should be emphasized (Cameron and Green, 2019; Burn,2004).

However, this model has some shortcomings. It has been suggested that this approach is for small-scale and incremental change and is not applicable in situations where rapid and transformational change is required (Burnes, 2004; Todnem,2005). Also, in the planned approach to change, it is assumed that organizations operate under constant conditions and can move in a pre-planned manner from one stable state to another (Burnes, 2004; Todnem,2005).

However, these assumptions have been questioned by several authors. They argue that the present fast-changing environment is increasingly weakening this model (Higgs and Roland, 2005; Tonden,2005). In addition, this model ignores situations requiring more directive approaches.

Therefore, many authors have developed Lewin's work to make it more practical (Mullins,2007; Todnem,2005).

These include communicating the gap between the current state and the expected results to key players in the change process (Burnes,2004; Higgs and Roland,2005). In addition, working to reduce resisting forces and to maximize the driving forces. Also, they must agree on a change plan and a timeline in which to achieve the end state (Burnes, 2004; Todnem,2005).

Social Cognitive Theory

Humans learn through human dialogue and interactions, direct experiences, and observation. According to this theory, behavior change is affected by environmental influence, personal factors, and attributes of behavior itself (Schunk,2012; Kritsonis et al., 2005). For change to occur, an individual must possess self-efficacy. The individual must believe they can perform the behavior and also perceive there is an incentive to do so. Therefore, for learning to take place, the individual's positive expectation of the behavior has to outweigh their negative expectations (Luszczynska and Schwarzer,2015; Kritsonis et al., 2005).

Self-efficacy can be increased by providing clear instructions, providing an opportunity for the development of skills or training, and modeling the desired behavior (Schunk,2012; Kritsonis et al., 2005). The success of employee training programs can be increased by exercising the following processes. Attentional processes, motor reproduction processes, retention processes, and reinforcement processes (Schunk, 2012; Kritsonis et al., 2005)

The theory of reasoned action and planned behavior

The theory of reasoned action postulates that an individual's performance of a given behavior is determined primarily by a person's intention to perform the behavior. An individual's attention is shaped by two major factors (Madden and Ajzen, 1992; Luszczynka and Schwarzar,1992). The individual must have a positive attitude towards the desired behavior for change to occur. Secondly, the influence of the person's social environment or subjective norms. This includes peer beliefs and what is believed the individual should do, likewise how motivated the individual is to comply with peer opinions (Madden and Ajzen, 1992; Luszczynka and Schwarzar,1992).

The theory of planned behavior includes the concept of perceived control over resources, opportunities, and skills required to do the desired behavior (Kritsonis et al 2005; Madden and Ajzen,1992). The concept of perceived behavior is the same as the concept of self-efficacy. An

important aspect of the behavioral change process is perceived behavioral control over opportunities, resources, and the required skills to perform a behavior (Kritsonis et al., 2005; Madden and Ajzen,1992).

Prochaska and DiClemente's Change Theory.

This model defines a more general change process. Following this model, people go through a series of stages when change occurs. These stages are: the pre-contemplation stage, the contemplation stage, the preparation stage, action and maintenance stage (Prochaska and DiClemente, 1986; Freeman,2001). Progression through this stage is not linear, it is cyclical. This is because many individuals will initially relapse in their change efforts and will not successfully maintain their gains the first time (Freeman,2001; Kristonis,2005).

In the pre-contemplation stage, an individual is unaware or fails to acknowledge the problems without engaging in any processes of change (Norcross,2013; Freeman,2001). At this stage, an individual does not want to change their behavior and may insist that their behavior is normal. In the contemplation stage, individuals raise consciousness of the issue. Here, individuals are thinking of changing their behavior but are not ready to commit to the change process yet (Norcross,2013; Freeman,2001).

In the preparation stage, the individual is ready to change their behavior and plans to do so within the next two weeks (Kristonis,2005; Freeman,2001). At this stage, individuals need counseling, social support, and assistance in problem-solving. At the action stage, there is an increase in coping with behavior change, and the individual starts engaging in change actions. The last stage is the maintenance stage, where actions are taken to reinforce the change, coupled with establishing the new behavior to an individual's lifestyle and norms. This stage may last six months or throughout an individual's lifespan (Prochaska and DiClemente,1983; Freeman,2001).

Change Management Process to improve the quality of compounded parenteral preparations.

Change management is the process of continuous renewal of an organization's direction, structure, and capabilities to meet the changing needs of internal and external customers (Cameron and Green,2019; Hayes, 2002). The quality of compounded parenteral preparations can be improved by developing skills and behavior change in aseptic technique, using the right facility and equipment. Also, enforcing the Cameroon guidelines on sterile compounding (Kastango, 2004; Genatrika et al.,2022).

For this change to occur, old cultural practices have to be unfrozen and evidence-based practices acquired. These evidence-based practices include acquiring knowledge and aseptic technique skills in sterile compounding and using the right facility and equipment for sterile compounding

(Leueck,2003; Burnes,2004). Change models have been used to effectively carry out the change. These include Lewin's three-step model, social cognitive learning theory, the theory of reasoned action, and planned behavior (Leueck,2003; Burnes,2004).

Application of the Change models in the ongoing project

Lewin's three-step model of change

In the ongoing project, Lewin's three-step model is being used to implement the change. Step one is unfreezing the present level, which involves recognizing the need for change and improvement. In this stage, change agents and everyone involved in leading the change process source the information needed to solve the identified problem (Odor,2018; Mullins,2007).

In this project, a needs assessment was carried out and gaps were identified, and recommendations were made. The results of the needs assessment revealed a need for change and improvement. In addition, a presentation was also made in the pharmacy department on safe practices for sterile compounding. From the presentations, pharmacy personnel identified the need for change and improvement in the sterile compounding practice in the pharmacy. That is to stop inaccurate old practices and embrace accurate practices.

From the recommendations of the needs assessment, the pharmacy personnel saw ways through which sterile compounding could be improved in the pharmacy. Doing a force field analysis, there were driving and restraining forces for the change. The driving forces for the change included: improving personnel knowledge of sterile compounding and aseptic techniques, the need for a laminar air flow hood, and the need for a facility for sterile compounding. The forces against the change were inadequate trainers, inadequate finances, and no appropriate land to construct a facility.

The following was arrived at to combat the forces against the change. The old compounding will be repartitioned and renovated to provide a separate room for sterile compounding since it is very large. Also, to get trainers from the CBC Central Pharmacy for the training. In addition, work with the hospital administration to purchase a laminar airflow hood. Step two in Lewin's model is moving to the desired position, dealing with the development of new behavior and attitudes, and executing the change program (Odor,2018; Burnes,2004; Todnem,2005). This stage is critical, and the following should be done to ensure success. Continuous education must be provided on the need for the change to take place. Also, extensive support must be provided to employees, especially those resistant. In addition, an undiluted flow of communication should be maintained with subordinates regarding the change process,

especially the benefits to be derived (Odor,2018; Cameron and Green,2009).

Step two in the ongoing project is executing the project activities. This involves training six pharmacy technicians on sterile compounding practice for three months. In addition, the repartitioning and renovating of the old compounding room to provide a separate room for sterile compounding and to purchase a new lamina airflow hood. Also, write a policy and SOPs for sterile compounding. There will also be quarterly presentations on sterile compounding practices during the period of the project. In stage two, the social cognitive theory, the theory of reasoned action, and planned behavior will be used during the training.

Step three is the refreezing stage. It involves stabilizing the change intervention by striking a balance between driving forces of change and restraining forces. This is done through policies, procedures, structures, and cultural norms (Odor,2018; Cameron and Green,2019). To achieve success in this stage, employees must not be rushed. They should be given enough time to get used to the change, and the benefits of the change initiative should be emphasized (Odor,2018; Burn,2004).

At stage three of the ongoing project, the new knowledge acquired from the training will be maintained. This will be done through sterile compounding policies and standard operating procedures. All pharmacy technicians compounding sterile preparations must follow the policy and carry out all the steps as detailed in the standard operating procedures. In addition, culture media and glove fingertip tests will be done every six months to test aseptic techniques.

The Social Cognitive Theory

According to this theory, humans learn through dialogue, direct experiences, and observations (Kritsonis et al., 2005; Schunk,2012). Self-efficacy can be increased through providing clear instructions, providing opportunities for the development of skills or training, and modeling the desired behavior. The success of employee training programs can be increased by exercising the following processes. Attentional processes, motor reproduction processes, retention processes, and reinforcement processes (Kritsonis et al., 2005; Schunk,2012).

This theory will be applied during training in the ongoing project. To enable personnel to acquire the required knowledge and skills, learning will be through lectures, videos on sterile compounding, and practical sessions on sterile compounding for personnel to develop aseptic technique skills. At the end of the training, there will be a written examination and a practical session on aseptic technique skills. In addition, personnel will be financially motivated after the training.

The theory of reasoned action and Planned behavior

This theory will be used to enhance personnel behavior change in aseptic techniques. For behavior change to occur, an individual must believe they can perform the behavior. Therefore, the self-efficacy of personnel will be increased through training so that they can acquire the knowledge and skills required for proper aseptic techniques. This will result in behavior change.

The role of leaders in change management.

Leadership plays a key role in setting direction, inspiring change throughout an organization, and making sure the change is implemented. Also, leaders have to identify and define the change that is required (Peng et al., 2021; Alqatawenh,2018). It has been shown that the beliefs and mindset of leaders influence their orientation of choices and approaches to solving problems. Therefore, a leader's behavior influences their approach to change and its implementation (Higgs and Rowland,2005; Oakland and Tanner, 2007).

The transformational leadership behaviour is a useful strategy that can be applied to create workplace conditions that promote better outcomes. According to Conger (2002), transformational leadership is leadership that goes beyond incentives for performance to develop and encourage workers intellectually, creatively and also transform their concerns into an important part of the organisational mission. Change is the fundamental trait of transformational leadership (Bass and Avolio,1999; Alqatawenah and Sulieman,2018).

Transformational change is based on a change that will be made in the behavior and attitudes of followers (Bass,1985; Tanner, 2007). Transformational leadership can inspire subordinates to do their best, develop their skills, and deliver subordinates to advanced intellectual levels. The transformational leader enables his followers to achieve more than expected (Alqatawenah and Sulieman,2018; Conger,2002).

In this ongoing project, the transformational leadership style is being used. This leadership style will enhance employee knowledge, behaviour, and attitude in sterile compounding. It will enable employees to apply the knowledge and skills acquired during sterile compounding training effectively. Therefore, through this leadership style, the pharmacy personnel will be transformed to function appropriately in sterile compounding.

People's reaction to change.

The reaction towards change is a cognitive and behavioral response. According to Prochaska and DiClemente's change

theory, people go through a series of stages when change occurs. People react differently towards organizational change, and their reactions depend on how they perceive the change (Khaw et al.,2022; AL-Abrow et al.,2019; Peng et al., 2020). A reaction towards change is developed through interaction between attitudes, beliefs, and individual feelings toward change. This greatly depends on how the change is introduced by the manager and the extent to which others respond (Khaw et al., 2022; Oreg et al., 2011).

Following Prochaska and DiClemente's change theory, people go through a series of stages when change occurs (Prochaska and DiClemente,1983; Kristonis,2005). These stages are: the precontemplation stage, the contemplation stage, the preparation stage, the action and the maintenance stage. Progression through this stage is not linear, it is cyclical. This is because many individuals will initially relapse on their change efforts and will not successfully maintain their gains the first time (Prochaska and DiClemente,1983; Kristonis,2005). In the pre-contemplation stage, an individual is unaware or fails to acknowledge the problems without engaging in any processes of change (Prochaska and DiClemente,1983; Kristonis,2005). At this stage, an individual does not want to change their behavior and may insist that their behavior is normal. In the contemplation stage, individuals raise consciousness of the issue. Here, individuals are thinking of changing their behaviour but are not ready to commit to the change process yet. In the preparation stage, the individual is ready to change their behavior and plans to do so within the next two weeks (Prochaska and DiClemente,1983; Kristonis,2005).

At this stage, individuals need counseling, social support, and assistance in problem-solving (Kristonis,2005; Freeman,2001). At the action stage, there is an increase in coping with behavior change, and the individual starts engaging in change actions. The last stage is the maintenance stage, where actions are taken to reinforce the change, coupled with establishing the new behavior to an individual's lifestyle and norms. This stage may last six months or throughout an individual's lifespan (Prochaska and DiClemente,1983; Freeman,2001).

Success in change implementation depends on how individuals interact with organizational change. People commit more to change when they perceive the change aligns with their expectations, and this results in less resistance (Khaw et al., 2022; Helpap,2016). When there is a positive reaction to change, individuals are job-focused, which results in less resistance to change than expected. Similarly, a negative reaction to change generates strong resistance to change. A negative reaction to change occurs when the expected results of the change will lead to more workload, uncertainty, and fatigue, or are perceived to be harmful (Khaw et al.,2022; Michela and Vena 2012)

Managing resistance to change.

According to Block (1989), resistance in an organizational setting is expressing reservation that normally arises as a response or reaction to change. Management witnesses this as any employee action perceived as attempting to stop, delay, or alter change. Commonly, resistance is linked to negative attitudes or behaviors that are counterproductive (Waddel and Sohal,1998). Resistance to change is a critically important factor that can influence how successful an organizational change effort will be (Waddel and Sohal,1998; Georgalis et al., 2014).

The change process can be severely obstructed by resistance to organizational change. This can result in negative outcomes like decreased employee satisfaction, productivity, and well-being (Maurer,1996; Georgalis et al., 2014). Maurer (1996) argues that one-half to two-thirds of all major corporate change efforts fail, and resistance is a contributing factor. Several factors can cause employee resistance (Waddel and Sohal,1998; Maurer,1996).

Causes of employee resistance to change

Rational factors

Resistance can occur when the employees' rational assessment of the outcomes of the change proposal differs from the outcome that the management envisages (Waddel and Sohal,1998; Block,1989). The differences in opinion cast doubts in the employees' minds as to the worth of the change. As a result, the employee can oppose or voice concerns (Waddel and Sohal,1998; Kotter et al.,1986).

Non-rational factors

An employee's reaction to a proposed change is a function of predisposition and preferences not necessarily based on an economic-rational assessment of a change. These include situations where an employee does not want to change an office, likes working closer to a particular friend, or is not sure of the outcome of implementing the new technology (Conner, 1992; Waddel and Sohal,1998).

Political factors

Factors like favoritism against those implementing the change can cause resistance (Conner,1992; Judson,1966).

Management factors

The role of leaders in the change process significantly impacts the success of change. It has been shown that the beliefs and mindset of leaders influence their orientation of choices and approaches to solving problems. Poor management or inappropriate management styles contribute to resistance (Judson,1966; Waddel and Sohal,1998). Resistance is a symptom of a more basic problem underlying a particular situation. It can serve as a warning signal

directing the timing of technological changes. Therefore, resistance plays a vital role by drawing attention to aspects of change that are inappropriate or incorrect. Also, resistance contributes to an influx of energy (Waddel and Sohal,1998; Higgs,2003)

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Handling resistance

Resistance to change is best handled through participative techniques. Employer involvement in the learning, planning, and implementation stages of the change process significantly influences commitment to change and lowers resistance (Higgs, 2003; Conner,1992). According to the participative management technique, through two-way communication, information sharing, and consultation, employees become more committed to the change effort rather than complaining about it. This technique is advocated where resistance is expected to be high, with the goal being to reduce the level of resistance (Waddel and Sohal,1998; Higgs,2003).

To prevent resistance to change in this project, the pharmacy personnel have been involved in the planning and implementation of the change project. Before the start of the project, a presentation was made in the pharmacy department on safe practices for compounding sterile preparations, and the results of the needs assessment were also presented. From the presentation, the pharmacy personnel identified that sterile compounding practice needed improvement. The personnel have been assigned to carry out tasks in the project. In addition, information is being shared with personnel on the progress of the project.

Students learn through this process.

The following has been acquired through this learning process. For a change project to be successfully carried out, first of all, a problem has to be identified that requires a solution. A literature review has to be conducted to search for solutions and the best solution is chosen. Strategies have to be chosen on how to apply the solution, and objectives have to be written. To effectively do this, a change management model must be used to guide the process. As the change is being implemented, there has to be monitoring and evaluation to ensure that what was planned is being achieved. When the change has been acquired, it has to be maintained through enforcing policies.

Action Learning.

Action learning is a process that supports problem-solving by applying a questioning formula to challenge issues and prompt actions. It is self-directed learning by handling work and business problems with support from colleagues and peers (Pedler,2011; Leonard and Marquardt,2010). The problems being handled are real-life problems for which the

solutions are not known. Learning from observation and practice is the central approach to action learning. It was initially developed to support organizational change but is now recognized as a motivating and influencing process for team development. In addition, individual goal setting, change initiatives, quality improvement, and leadership development (Marquardt,2000; Leonard and Marquardt,2010).

Changing organizational culture, management style, and organizational structures takes time. Through action learning, these can be achieved faster and more effectively than with other forms of organisational change (Pedler,2011; James and Stacy,2019). Therefore, action learning is very useful to managers who want to implement change, enhance change, and promote teamwork in multidisciplinary settings (Pedler, 2011; James and Stacy,2019).

In action learning, participants work together in action learning sets of about four to eight members. Members should be chosen from different departments or have different levels of experience (Pedler, 2011; James and Stacy,2019). Also, an action learning coach has to be chosen to motivate the team and keep members focused on learning goals. The coach encourages communication and reflection from each team member. The first step in action learning is identifying a challenge. Team members then ask questions to understand what the problem is. Once the problem has been identified, the team starts looking for a solution to the problem (Marquardt, 2000; Pedler, 2011).

Once the team determines the most effective solution to the problem, steps should be taken to implement the change following the proposed action steps (Marquardt,2000; Leonard and Marquardt,2010). In action learning sets, members may all be working on the same problem or have their problems and meet to work as a set to resolve them. The set meets regularly for several months. During set meetings, members take turns to give an update on their work, and they are questioned on it by set members. In addition, members act as mentors to each other (Pedler,2011; Leonard and Marquardt,2010).

Furthermore, reflection should occur in each step of the action learning, and questions should be asked. Once a problem has been solved, time should be allowed for team members to reflect on the overall process to improve the action team's results in the future (Pedler,2011; James and Stacey,2019).

Benefits of action learning.

Action learning increases awareness and enables individuals to identify their personal development challenges. It also helps in the development of self-confidence and the readiness to take responsibility and initiative (James and Stacey,2019; Leonard and Marquardt,2010). It enables

people to relate, communicate, and network with others effectively. In addition, it provides structured peer support and enables more disciplined ways of working in powerful teams. In action learning, individuals and teams also learn while working. It develops system thinking, creativity, flexibility, and problem-solving skills. Furthermore, it builds leadership competencies and supports innovations (Pedler, 2011; Marquardt, 2000).

During this course, unit action learning was used, and students met as a group to discuss how they going on with their respective assignments and the challenges they were facing. It has helped the students to develop problem-solving skills and self-confidence.

Conclusion.

Breaching required standards for sterile compounding results in patient harm, such as bloodstream infections, sepsis, meningitis, and death (Genatrika et al., 2022; Myers, 2013). A lot of patient harm and death has been recorded due to contaminated compounded sterile preparations resulting from poor sterile compounding practices. Similarly, patient harm and three deaths have been recorded in Mbingo Baptist Hospital. The cause of these problems is poor employee training, lack of policy and procedures, poor aseptic techniques, lack of validated sterility methods, and lack of properly designed and operating compounding facilities (Gupta et al., 2014; Myers, 2013).

The USP <797> is the primary standard for sterile compounding, specifying conditions and practices to be used. These guidelines are intended to prevent patient harm (USP, 2019; Gudeman et al., 2013). To prevent patient harm in Mbingo Baptist Hospital due to contaminated compounded parenteral preparations, a project was initiated and is being implemented. The project aims to improve the quality of compounded parenteral preparations to ensure they are free from contamination and safe for inpatients. The objectives are to train 6 pharmacy technicians on sterile compounding, provide a facility and laminar airflow hood, and write a policy and SOPs for sterile compounding. It is expected that at the end of the project, the USP requirements will be met. Which will result in improved patient outcomes.

Recommendations.

To ensure sustainability, the following should be done.

- The pharmacist should monitor the implementation of the policy.
- The competency of the trained pharmacy technicians should be assessed every six months through a gloved finger test and growth media transfer test.

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CBC: Cameroon Baptist Convention

CSP: Compounded Sterile Product

USP: United State Pharmacopeia

ISO: International Standardization Organization

ASHP: American Society of Health-System Pharmacy

FDA: Food and Drug Administration

PEC: Primary Engineering Control

PPE: Personal Protective Equipment

SOP: Standard Operating Procedures

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Availability of data.

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

Authors contribution.

EK designed the study, reviewed the 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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