


# Clinical Compounding Service: New Initiative in the Kingdom of Saudi Arabia

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## ABSTRACT

**Objective:** To declare the clinical compounding service as new initiatives in Saudi Arabia. **Methods:** It is a new initiative project of clinical compounding service. The projects drove the international clinical compounding service guidelines, the global business model, and pharmacy project guidelines a new project. The initial project is written through project management professionals and contained several parts, including the initial phase, the planning phase, the execution phase, the monitoring and controlling phase. **Results:** The clinical compounding service defined vision, mission, and goals. The services had multiple benefits, including clinical and economical, on the healthcare system, as described in the review. The continuation of the services assured by risk management elements description. Moreover, the monitoring and controlling of the projects as illustrated. The transition to operation project though the closing project stage explored in the analysis. **Conclusion:** The clinical compounding service program is a new initiative project in pharmacy practice. The new project is part of innovative pharmacy practice and projecting of new extemporaneous preparations, and it is highly suggested in the Kingdom of Saudi Arabia.

**Key words:** Clinical, Compounding, Formulation, Extemporaneous, Preparations, Saudi Arabia.

## INTRODUCTION

One of the previous significant jobs of a pharmacist was to prepare or manufacture customized medication for a specific patient, which would otherwise not be commercially available. In the early 2000s, the role of a pharmacist started to change which expanded from being product-selling to patient-serving.<sup>1,2</sup> The majority of healthcare organizations accepted this change in clinical pharmacy services.<sup>3-5</sup> However, pharmacy knowledge of a pharmacist should not be forgotten, for instance the knowledge of pharmaceuticals, which is very useful during the preparation of extemporaneous drug formulations for pediatric or geriatric patients and the knowledge of their stability in various drug formulations.<sup>6-9</sup> Several studies have discussed about the pharmacy practice in general and other investigations have discussed about extemporaneous preparation.<sup>10-17</sup> However, the combined clinical pharmacy services with extemporaneous preparation or clinical compounding have seldom been studied.<sup>18,19</sup> To the best of our knowledge, there are no studies discussing on the clinical compounding as an initiative project inside Saudi Arabia, Gulf, or in the Middle Eastern countries. Therefore, in this study, we aimed to prepare a project review to state the clinical compounding services as a new initiative project in the kingdom of Saudi Arabia (KSA).

## Method of the project

This is a new initiative project driven by the national clinical compounding programs. The task force committee of clinical compounding project was formulated, which consisted of experts in the

field of clinical compounding services. The committee unitized and drove the guidelines related to the mass gathering pharmaceutical care. The guidelines were derived from various textbooks and international literature with regard to clinical compounding services by utilizing the international business model, pharmacy project guidelines and project management institution guidelines of a new project.<sup>20-23</sup> The project on clinical compounding services was written by the project management professionals. It consists of four parts: the initial phase, planning phase, execution phase and monitoring and controlling phase.

## Assessment of needs

All professionals in pharmacy implement the pharmaceutical care concept and clinical pharmacy and forget about the fundamentals of clinical compounding. However, the demand for compounding medications for pediatric or geriatric patients is currently in demand.<sup>9</sup> Moreover, compounding medications is needed for some dermatological diseases. However, compounding of medications has some problems; for example, some pediatric formulations lack stability and have off taste.<sup>9</sup> Some compounded preparations for skin problems may not be suitable for some patient with very dry skin; such preparations need moisturizer. While some patient's skin might be very sweaty; their skin needs different type of preparation. Therefore, the combination of clinical pharmacy with clinical compounding is the best solution for some cases.<sup>18,19</sup>

## Market Analysis

The extemporaneous preparation or compounding of pediatric and geriatric formulation is com-

monly followed in most of the government and private healthcare organizations.<sup>9</sup> The extemporaneous units have been established to prepare unmanufactured dosage form oral or skin or ophthalmic preparations. Each pharmacy has a unique formulation and book for different extemporaneous formulation for geriatrics and pediatrics patients. However, both clinical pharmacy services and extemporaneous preparation did not exist together at most hospitals or at primary healthcare centers. Clinical compounding is a new concept of combining clinical pharmacy activities and basic pharmaceuticals to produce the appropriate dosage with content based on the specific disease and recent information.<sup>18,19</sup>

### SWOT analysis

One of the conventional methods of new project assessment is SWOT analysis. The term means strengths, weaknesses, opportunities and threats of the project. The strengths of this project are new pharmacy services, pharmacists involved in actual and appropriate activities, prevent compounding-related mistakes and prevent an additional unnecessary economic burden on the healthcare system. The weaknesses of this project are few pharmacists in the clinical compounding service, no education or training on clinical compounding, few resources of compounding and difficulties in the combination of clinical pharmacy and pharmaceuticals specialty. The opportunities in this project are the implementation of accreditation standards and availability of pharmacists specialized in pharmaceuticals. The threats to this project are there is not pharmacists interested in this field and the plan of pharmacy practice has changed.

### Planning phase

#### Scope of the project

Clinical compounding services cover any non-sterile or sterile preparation or extemporaneous compounding prepared by clinical pharmacists based on the patient's condition. The clinical pharmacist can choose the approach based on the medications for skin disease. If the patient's skin is very dry, then the pharmacist would include a moisturizer in the preparation of the ointment. In the case of pediatric extemporaneous formulation, the tablet or capsule may be converted to syrup or a suspension with the most prolonged half-life with the use of an appropriate vehicle.

### Vision, Missions and Goals

The vision of the clinical compounding program is to provide best extemporaneous and compounded medications using cost-effective materials and methods. While the message of the program is to offer cost-effectiveness, the objectives of the program are to prepare dosage forms that are not regularly available in the market which is appropriate to pediatric and geriatric patients; to use the cost-effective material and methodology for clinical compounding; to measure the stability of extemporaneous oral and non-oral medications; and to innovate the appropriate method of compounding new medications for particular dosage forms based on the patient's condition.

### Project description

The following should be followed by the clinical pharmacist during the preparation of extemporaneous preparations intended for pediatric or geriatric formulation use for topical application:

- ✓ Review the patient's condition and medications history and allergy-related issue(s) if any.
- ✓ Review the patient's medication administration type either topical or oral to make the appropriate formulation dosage form and basic content formulation.
- ✓ Review the stability of the formulation or extemporaneous medication as well as the dosage to be administered.
- ✓ Make the formulation or preparation and dispense to the patients.

- ✓ The pharmacist instructs the nurse if inpatient or to the outpatients during ambulatory care setting about the procedure to administer the medications and storage condition.
- ✓ The pharmacist monitors the patient's condition for drug therapy and allergic reaction.
- ✓ The pharmacist may document any adverse reactions due to the application of formulation.<sup>24</sup>
- ✓ The pharmacist may document any medication errors that might have happened at any stage of the preparation.<sup>25</sup>
- ✓ The pharmacist should standardize all pediatric or geriatric formulations.
- ✓ The pharmacist should investigate the stability of any new drug formulation.
- ✓ The pharmacist should update the formulation, that is, new formulation should be prepared and any newly prepared old formulation should be excluded.

### Cost management plan

One of the essential things to implement in a clinical compounding project is the financial budget. The budget should consider cost-related issues including education and training of clinical compounding; the salary of all pharmacy staff, clinical pharmacists and pharmacists with pharmacy technicians; and compounding solid material sold. Besides, The cost of Equipment that are needed for the preparation and the management team meetings. The defined budget should be monitored throughout the project period implementation.

### Execution phase

#### Management team

The experts in the team should organize the clinical compounding services; the team consists of clinical pharmacists, expert pharmacists and pharmacy technicians expert in pharmaceuticals and extemporaneous preparations and pharmacy total quality management. The team should educate and train the pharmacists and pharmacy technicians in compounding and clinical pharmacy-related issues. The team should setup up new policies and procedures related to the compounding services and monitor the implementation of the program and measure the outcome with the economic impact of the new services.

### Education and training

The clinical pharmacist needs to attend several courses of clinical compounding program with updated information of drug therapy for some diseases and basic pharmaceuticals. However, distributive pharmacists or pharmacy technicians need educational courses about pharmaceuticals. Another part of education on clinical compounding is stability research. This education is very important for clinical pharmacists and healthcare providers, including physicians and nurses. Another educational course for administrative officers, include the management of team and higher administration, as well as coverage of health insurance.

### Monitoring and controlling phase

#### Total quality management of the project

Quality management has elements used in the implementation process. The new concept currently uses balanced scored cards consisting of five categories: customer, finance, internal process, education and innovation. The assessments of clinical compounding services are an example of key performance indicators of the internal process, whereas the outcomes of clinical compounding are measurements are an example of education and competency reflections. The third type of balanced score card is the finance, for instance, the measurement of cost efficiency of clinical compounding services and the fourth type of balanced score card is the

customer, for instance, the patients satisfaction of clinical compounding service or pharmacy staff and healthcare providers satisfaction of clinical compounding services in the KSA.<sup>3,26</sup>

### Risk Management

There are six types of risks in the current project: budget, scope, personnel, scheduled, technical and quality risks. This project might be exposed to personnel risk due to the shortage of expert pharmacists and it might also be exposed to budget risk due to shortage of budget for education and training of the pharmacy staff with multiple experiences. This project might also be exposed to technical risks such as material or equipment not being available. Quality risks are encountered due to the untrained pharmacists being available.

### Closing of the project

The clinical compounding services are vital for any healthcare organization; therefore, we recommend all healthcare organizations to start providing this services in the KSA. This service can be practiced to provide clinical pharmacy services with a new model or basic pharmaceuticals and innovative pharmacy services at all healthcare hospitals and primary healthcare centers. The services need to be continuously provided at each pharmacy department with updates extemporaneous preparations. The clinical compounding education and training should be provided to short- and long-term resident programs. Furthermore, clinical compounding should measure the stability of each extemporaneous formulation before providing it to the patient. Moreover, a new formulation of skin preparation might be provided for multiple diseases for different patients conditions. We suggest an annual celebration of all clinical compounding pharmacists or clinical compounding centers in the KSA.

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None.

### CONFLICT OF INTEREST

The authors declare no conflict of interest.

### ABBREVIATIONS

**MOH:** Ministry of Health; **KSA:** Kingdom of Saudi Arabia; **SWOT:** Strengths, Weaknesses, Opportunities and Threats.

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