

National Pharmacy Research and Development (R&D) Program: New Initiatives in Saudi Arabia

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ABSTRACT

Objective: To declare the national pharmacy research and development program as new initiatives in Saudi Arabia. **Methods:** It is a new initiative project of pharmacy research and development. The projects drove the international research and development guidelines, and pharmacy project guidelines of a new project and the global business model. The initial project is written through project management professionals and included several parts, including the initial phase, the planning phase, the execution phase, the monitoring and controlling phase. **Results:** The pharmacy research and development services that 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. Furthermore, the monitoring and controlling of the projects as illustrated. The transition to operation project through the closing project stage explored in the analysis. **Conclusion:** The pharmacy research and development program is a new initiative project in clinical pharmacy and pharmacy administration tools. The new project is useful to measure the clinical and economic of pharmacy practice and forecasting of new pharmacy programs, and it is highly recommended in the Kingdom of Saudi Arabia.

Key words: National, Pharmacy, Research, Development, Initiatives, Saudi Arabia.

INTRODUCTION

In the early 1960s, research and development was started in the College of Pharmacy on various pharmacy subspecialties.¹ Research in the field of hospital pharmacy and clinical pharmacy increased after the establishment of the Clinical Pharmacy Department at the College of Pharmacy in the late 1970s.¹ Several studies have been conducted through the King Khalid University Hospital. In the late 1980s, King Faisal Specialist Hospital and Research Center started to provide pharmacy services at their hospital including pharmacy researches.^{2,3} The MOH founded the research pharmacy services in the late 1980s and 1990s after the clinical pharmacy services was started at the main hospital in the central area in Riyadh.² The research activities were started in parallel with the new regulation of medications registration in the kingdom of Saudi Arabia (KSA) and MOH through the department of medical and pharmacy licensing. All bioequivalent studies of any new products should be registered at the MOH's biggest hospital. Several types of research had been conducted at that is times. In the late 1990s, pharmacy practice changed drastically.⁴⁻⁶ Most of the investigations have been shared through Saudi Pharmaceutical Society. In the late 2000s, the drug information center at the same hospital participated in international conferences with American College of Clinical Pharmacy.⁷ The big revolution in the pharmacy research was started by the general administration of pharmaceutical care by founding the national pharmacy research and development services in 2013-2014.^{2,8} Massive amounts of research ac-

tivities are being conducted at Ministry of Health (MOH) institutions in the KSA.^{3,9-15}

METHOD OF THE PROJECT

This is a new initiative project driven by the international pharmacy research and development programs. The task force team of pharmacy research and development projects formulated and consisted of authors of this article, who are experts in the pharmacy research and development. The committee unitized and drove the guidelines on research and development, international literature about pharmacy research and development. The guidelines were written by utilizing the international business model, pharmacy project guidelines, and project management institution guidelines of a new project.¹⁶⁻¹⁹ The pharmacy research and development was written by the project management professionals and consisted of the following parts: the initial phase, the planning phase, the execution phase, and the monitoring and controlling phase.

Initiative phase

Assessment needs

Over the past few years, multiple programs and projects have been released and implemented on the pharmacy practice at MOH institutions. The pharmacy programs belonged to the pharmacy strategic plan and were recently updated with New Saudi Vision 2030.^{20,21} The programs need to be written as projects, which includes the importance of the project, how to implement it and how to monitor the successful indicators. After

applications, the implant and outcome of the program should be measured through the scientific pharmacy practice studies. Thus, several publications discussed on the clinical and economic outcome of the programs and the projects.²²⁻²⁴ The only method to document the pharmacy performances or new initiative pharmacy practice programs and related impact of the services was the scientific researches and scientific publish it in the international conferences or biomedical journal. Several studies have discussed the impact of pharmacy services on pharmacy practice in the KSA.²²⁻²⁴ However, various programs need to be written as a project and measure the outcomes of the programs.

Market Analysis

Healthcare institutions at MOH, MOH hospitals and specialized centers conduct several R&D activities. Moreover, the GAPC at MOH also conducts R&D activities. All these organizations have policies and procedures and IRB with the ethical committee. However, at King Faisal Research Center, King Abdulaziz Medical city and Ministry hospitals, pharmacy research is rarely conducted. Some new and big hospitals including medical cities at MOH have policies and procedures for research on investigational new drugs, but the complete R&D activities do not exist.

SWOT analysis

SWOT analysis is being used for most of the new projects even before starting the practice. The primary strengths of the project is the new strategic plan in the pharmacy practice, which is part of the New Saudi Vision 2030, the documentation system of the pharmacy services in relation to clinical and economic outcomes, is tool used for student and younger pharmacist for research practice; these strengths are a part of pharmacy investments. There are several weaknesses in this project, for instance, pharmacy staff needs education and training, absent of pharmacy research leaders and the project needs financial support. The opportunities in this project are a part of New Saudi Vision 2030²⁵ and the growing demand for pharmacy investments and privatization. The threats to this project includes the articles submitted through this project being rejected for publications, expert professionals moving to another institution and change in the pharmacy strategic plan in the KSA.

Planning phase

Scope of the project

This project will cover the research topics related to the pharmacy practice and to the pharmacy-based human clinical trial in addition to innovations in pharmacy, usage of electronic tools for pharmacy research and grant research.

Vision, missions, and goals

The vision of the project is to reach best with high-quality pharmacy research and development at all healthcare institutions, while the message to provide large advance and evidence of pharmacy research and development services with different kinds of researches. The project aims to implement the pharmacy research and development at healthcare organizations, educate and training the pharmacist on pharmacy research, to develop pharmacy research culture for resident and pharmacy students, to evaluate the clinical and economic outcomes of pharmacy programs, to analyze the pharmacy performance pattern and forecasting of new pharmacy projects and development, and to implement the clinical trials system for new medications.

Project description

The following steps should be taken care when conducting a pharmacy R&D activity at various medical institutions in the KSA:

- ✓ The pharmacy practitioner should familiarize with the research before

obtaining the approval from the IRB.²⁶

- ✓ The pharmacy practitioner should follow the international guidelines of requirements of IRB approval.
- ✓ The pharmacy practitioner should follow the international and national guidelines of clinical trials through the Saudi Food and Drug Authority.
- ✓ The pharmacy practitioner should have complete authority to publish his/her research at any national or international journal with ISSN for the journal and provide DOI for the article.
- ✓ It is highly recommended to write the report of research according to the guidelines of Enhancing the Quality and Transparency of health Research (EQUATOR).²⁷
- ✓ The pharmacy practitioner should choose any national or international journal index without promoting any publishers.
- ✓ If the author has any comments about any scientific research, then he or she should write a letter to the editor with his/her comments.
- ✓ The pharmacy staff practitioner should not state any comments about any biomedical journal with ISSN number.
- ✓ The author should send a copy of the publications.

Planning schedule management

The project should be started with the R&D team for 2-3 months. The director of the new services should be founded within 3-4 months. The pharmacy research strategic plan should be implemented within 4-6 months. After 12 months, the team of the new project should review the performance of the new services and correct accordingly. The team should be finished and director of the new services should continue the work of the units.

Planning cost management

At the beginning of providing new services, the project should obtain some financial aid for education and training for all healthcare providers. In addition, some grant is required for various new research projects. Further support may be obtained from government organizations such as King Abdulaziz City for Science and Technology (KACST). Then, they should start a new clinical trial for self-support and obtain investments with pharmaceutical research on new product from pharmaceutical companies.

Execution phase

Management team

The project initially needs a task force team to arrange and implement the project. The team should consist of the director of pharmacy assigned by the director. He should be the representative from inpatient pharmacy, outpatient pharmacy, IV admixture, pharmacy quality management and clinical pharmacy departments. The team establishes policies and procedures and selects the new services and their quality indicators. After finding the new department, the director of pharmacy assigns the director of pharmacy R&D to continue the work.

Education and training

The project should deliver a short course on research annually with basic and advance research course. Moreover, scientific medical writing either basic and advance course. These types of educational courses should involve all young pharmacists. The long courses on research should be delivered to the pharmacy and health leaders in the future.

Monitoring and controlling phase

Total quality management of the project

The standard tools used for quality management during the implementation of the project pharmacy research and development services were the Balanced Score Card. It consisted of four types that are including

the customer, finance, internal process, education, and innovation. The internal processes type contained the assessment of healthcare services of pharmacy research and development services. On the other hand, the education and innovation types had an example of the measures of clinical outcome of pharmacy research and development services that are declared the education and competency of pharmacists and clinical pharmacists. Furthermore, The financial elements had an example of the measurement of the cost-saving impact of pharmacy research and development services. The fourth types involved the customer types that measure the patient's satisfaction or pharmacists and healthcare providers toward pharmacy research and development services in the kingdom of Saudi Arabia.

Risk management

There are six types of risks to the project: budget risks, scope risks, personnel risks, schedule risk, technical risks and quality risks. This project might be exposed to risks such as budget risks, personnel risks and quality risks. This project might have a budget risk due to nonavailability of the budget for education and training for the healthcare staff, including young pharmacists and grant support for researches. This project may be exposed to personnel risks such as shortage of expert staff. This project might be exposed to quality risks such as availability of nonqualified pharmacists and no training on quality pharmacy tools, or KPIs not being implemented. The project might experience technical risks such as nonavailability of the electronic resources of pharmacy research with friendly use.

Closing of the project

After 1 year of the new service implementation, the task force team should review the project with their outcomes. The pharmacy research and development services at hospitals and primary healthcare centers of governmental and private sectors are highly suggested to implement the pharmacy research and measure the clinical and economic outcome of pharmacy programs and part of the pharmaceutical investment in the healthcare system in the Kingdom of Saudi Arabia. The project should continue as a section in each pharmacy department and membership of related committees. The pharmacy research and development services Education and training should be performed periodically. Pharmacy research and development services should be expanded the number of research and clinical trials in the future. The pharmacy research and development services teams should conduct the Annual celebrate is highly suggested in Saudi Arabia. The director of the new services should continue to work and track forces should be finished.

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CONFLICT OF INTEREST

The authors declare conflict of interest.

ABBREVIATIONS

KSA: Kingdom of Saudi Arabia; **MOH:** Ministry of Health; **GAPC:** General Administration of Pharmaceutical Care; **R&D:** Research and Development; **IV:** Intravenous; **KACST:** King Abdulaziz City for Science and Technology; **KPIs:** Key performance indicators; **IRB:** Institutional Review Board; **ISSN:** International Standard Serial Number; **DOI:** digital object identifier; **EQUATOR:** Enhancing the Quality and Transparency of health Research.

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