

# Drug Evaluation Steps of Ministry of Health Drug Formulary in Saudi Arabia

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## ABSTRACT

**Objective:** To illustrate the Drug Evaluation Steps of Ministry of Health Drug Formulary at Health care institutions in the Kingdom of Saudi Arabia. **Method:** It is description analysis of Drug Evaluation Steps of drug information service at the Ministry of Health of Health institutions. The modified pharmacy business model system and Project Management Procedure used in the report. **Results:** The Drug Evaluation Steps established with a defined vision, mission and goals. The system human or economic and other resources described in the review. The risk management was discussed to assure the continuation of the system. Besides, the monitoring and controlling of the system as illustrated. The closing stage with convention to operation project demonstrated in the analysis. **Conclusion:** The drug evaluation steps system implemented and it is considered as part of the health care system and drug information centers regulations. The drug evaluation Steps needs the continuous updating accordingly at all Ministry of Health strategic planning in the Kingdom of Saudi Arabia.

**Key words:** Drug Evaluation, Steps, Ministry of Health, Drug Formulary, Saudi Arabia.

## INTRODUCTION

All medications show both benefits for management of the patients and associate with problems related.<sup>1,2</sup> Recently, drug-related problems and mortality have become extremely dangerous to the public.<sup>3-8</sup> It is affecting patient safety and causes more economic burden on the healthcare system.<sup>9-12</sup> In order to prevent drug-related problems, the healthcare team, including the pharmacist, should choose the best medications for patient which might show greater efficacy and safety.<sup>1,2</sup> The medications are chosen through PTC,<sup>13</sup> which is the official committee to regulate the addition or deletion of medications from hospital's drug formulary. The PTC is responsible for setting up guidelines or procedures for selecting the appropriate medications for inclusion in drug formulary.<sup>13</sup> The corporate PTC establishes steps for selecting medications through best practice. Several pharmaceutical associations have established the regulations and guidelines for the same.<sup>14-18</sup> Each method of selecting medications is based on previous guidelines or practices. The GAPC with drug information teams tried to include international guidelines and scoring system for the drug evaluation.<sup>19</sup> To the best of our knowledge, there are no studies conducted in the KSA, Gulf and Middle Eastern countries. Therefore, in this study, we aimed to explore the steps of drug evaluation for addition or deletion from MOH drug formulary in the KSA.

## MATERIALS AND METHODS

### Method of development of the project

The drug formulary task force committee consisted of expert people from the pharmacies of the MOH hospital, primary healthcare centers

and dental centers to perform drug evaluation for addition or deletion from the MOH drug formulary. The first author of this article headed the taskforce committee; he conducted regular periodical meetings. The committee utilized the pharmacy procedures of addition or deletion of medication to MOH drug formulary made some evidence based management guidelines of the diseases in MOH hospitals. In this study, we collaborated with the College of Pharmacy, Purdue University, USA, to obtain procedures and drug information. In addition, we used the international business model, pharmacy guidelines and project management institution guidelines of a new project.<sup>20-23</sup> The prepared draft was sent to several reviewers, who corrected and updated it. Then, the second draft was submitted to the reviewers again for their final comments and approval. This took around 3 months to complete the task. The GAPC at the MOH sent the final document to all the hospitals for implementation. The drug formulary consisted of several parts including the initial phase, planning phase, execution phase and monitoring and controlling phase.

### Initial phase

#### Assessment needs

In order to avoid low effectiveness of medications, all drugs must be evaluated for addition or deletion in the drug formulary. Each healthcare institution has a different method of evaluation. There are unified steps for drug evaluation at MOH institutions. In addition, it is tool of an educational or training program delivered to the pharmacist about this issue.

## SWOT analysis

In this project, we performed SWOT analysis. The strengths of this project were unified effective steps for addition or deletion of medications to the drug formulary at all MOH institutions; furthermore, scientific process of addition or deletion medications used in the healthcare institutions prevent the additional cost of ineffective medications. The weak points of this project were long time taken for the addition or deletion of medications and for education and training required in this process. The opportunities of this project were the implementation of healthcare and Saudi New Vision 2030, local and international accreditation standards, monitoring of cost management and management of control in the health insurance. The threat to this project will be privatized healthcare institutions without drug formulary.

## Market Analysis

Several governmental and private hospitals developed their drug evaluation steps for addition or deletion medications from hospital formulary. Most of the healthcare institutions implemented drug evaluation steps based on the American Society of Health-System Pharmacist (ASHP).<sup>24</sup> All of those experiences not published yet except from King Abdulaziz medical city.<sup>25</sup> All those formats were manual written documentation. The practice demand to unified steps of drug evaluation steps for MOH drug formulary. The electronic format should be designed to make the life easy and better for documentation system in the Ministry of Health institutions.

## Planning phase

### Scope of the project

The steps of drug evaluation of addition or deletion from MOH drug formulary consisted of a general review of new medication, its clinical efficacy and safety, medications safety process and pharmacoeconomic aspect of the new drugs. Furthermore, the comparison between the new drugs with the previous drugs in the formulary or new drugs resembling a previous one indicates that the drug is marketed in Saudi Arabia or in rest of the world.

## Vision, Mission and Goals of the project

Vision of this project is drug evaluation of addition or deletion of new medications to the MOH drug formulary at MOH. The mission of this project is to provide the evidence based steps for the drug evaluation system at MOH institution in the Kingdom of Saudi Arabia. The goals

of this project are to unify the steps of drug evaluation process at MOH institution and provide the evidence based procedures of drug evaluation analysis, provide cost-effective medications to the MOH formulary and prevent any additional unnecessary of medications related addition to the MOH formulary.

## Project description

All the drug information pharmacists or clinical pharmacists should be aware of following policies:

1. If the PTC needs to add or delete any medication or nutrition support products, then the concerned pharmacist should fill the drug evaluation form for addition or deletion.
2. The drug information pharmacist or clinical pharmacist should utilize drug evaluation formulary addition or deletion form (appendix 1) and complete the following information:
  - General information
  - Drug information
  - Comparative with previous medications
  - Medication safety

- Summary of published evidence (efficacy and safety)
  - Summary of pharmacoeconomic studies
  - Summary of cost analysis
  - Summary of pharmacoeconomic drug-related problem analysis
  - Utility rank
  - Conclusion
3. The caregiver should take approval and signature from the hospital and regional PTC
  4. The form should be sent to the corporate PTC for final approval
  5. If the drug has been approved for addition into the MOH drug formulary, then the medicine should be ranked based on its therapeutic and economic value.

## Planning cost management

This project required finance for the education and training of pharmacy staff and clinical pharmacist, to maintain electronic library, electronic documentation of drug evaluation through any database system and for the annual celebration of the best drug evaluation among pharmacist and clinical pharmacist.

## Execution phase

### Management team

The management team responsible for the follow-up of drug evaluation and documentation is the drug information services committee. The central committee designed through the GAPC at MOH; The committee consisted of representatives from each region specialized in medications safety. Another regional committee established for each part included representatives from each hospital and primary healthcare center. All committees have a monthly meeting to discuss the drug evaluation status of new medications and update the MOH drug formulary. These activities should be reported to the corporate PTC at MOH for the final decision.

### Education and training

The project needs educational courses on a regular basis on the steps involved in the process of drug evaluation for addition and deletion from MOH drug formulary; these courses have to be conducted through the GAPC at MOH and RAPC and involve drug information pharmacist, staff pharmacist and clinical pharmacist at MOH hospitals.

## Risk Management

The risk management is divided into six parts: scope risks, personal risks, technical risks, budget risks, quality risks and schedule risks. Scope risks involve the pharmacist not being able to follow exact steps of drug evaluation; the pharmacist may take action by accepting and rejecting medications without final approval. The pharmacist should follow all steps and regulations of the drug evaluation process. The personal risks included the required workforce to implement the project which a high-risk impact and high priority and the team should send a member to analyze the number of pharmacy staff required based on the demand of the workforce. All concerned committees should send members to their related departments and human resources to request the number of pharmacy staff required based on the demand for the project. All personnel pertaining to this project need education and training, which is a high-impact and medium-priority requirement. All management teams should collaborate with human resources to set up an education plan with cost coverage. Technical risks in this project includes designing of the electronic system of the drug evaluation system. This risk is a high-impact and high-priority risk. The information technology personnel in all the concerned committees should set up an action plan for all the per-

sonnel who are related to the project and propose the necessary budget and obtain approval from all the related departments. This might help to overcome the risk. Moreover, the education and training of the new computer system is another risk, which is a high-impact and high-priority risk. The concerned committee should collaborate with the information technology department and human resources department to avoid this risk. Budget risks includes the educational and training courses of the project, which is a high-impact and high-priority risk. The team should cover all topics that are needed to prevent this risk. The second type of budget risk is travel and accommodation, which is again a high-impact and high-priority risk. The team should obtain permission from the higher committee to avoid this risk. Both these risks are acceptable. Quality risks includes the KPIs not reaching the optimal levels. This risk is very high-impact and high-priority risk. All committees and management teams should review all the process of the project implementation and discuss with all staff members about the results of the KPIs and set up a solution for that the risks. Schedule risks includes the delay in the implementation of an action plan from management teams or pharmacy staff. This is a high-impact and high-priority risk. The central committee of the project should closely monitor all project-related activities and visit all regions periodically to take care of the implementation.

## Monitoring and controlling phase

### Project Quality management

The following KPIs of drug evaluation system were established to monitor the implementation at MOH institution. The adherence documentation of drug evaluation process; literature comparisons of safety, efficacy and economy; drug evaluation analysis with detailed information; the reporting rate of acceptance or rejection; and the number of medications added without registration in SFDA, US FDA or UK.<sup>26,27</sup>

## The closing of the project

The steps of addition or deletion of drug from drug formulary at MOH institution is very crucial to control cost-effective medications in the KSA. The annual report of new drugs added to the MOH drug formulary should be prepared. Education and training courses should be provided to the healthcare providers on a regular basis regarding updating of new medications and drug regulation. In the future, further project needed to expand and include cost avoidance impact of adding new drugs and nutrition support medicines in the future. Annual celebration with the involving members of the project should also be conducted.

## ACKNOWLEDGEMENT

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## CONFLICT OF INTEREST

None.

## ABBREVIATIONS

**KPIs:** Key performance indicators; **KSA:** Kingdom of Saudi Arabia; **MOH:** Ministry of Health; **PTC:** Pharmacy and therapeutic committee; **RAPC:** Regional administration of pharmaceutical care; **GAPC:** General administration of pharmaceutical care; **SFDA:** Saudi Food and Drug Authority; **US FDA:** United States Food and Drug Administration; **UK:** United Kingdom.

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**APPENDIX:1**

<b>Ministry of Health</b>			
<b>Drug Evaluation and Economic Analysis Summary</b>			
<b>Prepared by:</b>		<b>Date:</b>	
<b>Requester:</b>		<b>Date of Request:</b>	
<b>Hospital:</b>		<b>Department:</b>	
<b>Drug Name:</b>		<b>Trade Name:</b>	
<b>Therapeutic Classification:</b> [Disease State(s) or Clinical Use(s)]		<b>Manufacturer:</b>	
<b>Similar Drugs:</b> [List all applicable]			
<b>Formulary</b>		<b>Non-Formulary</b>	
<b>Approved status</b>			
USA	UK	EMEA	Canada KSA
<b>General Drug Information</b>			
Manufacturers			
Generic Available.	Yes	No	Locations
Mechanism of Action			
Indication (approved/unapproved)			
Route of Administration			
Dosage Forms			
Dose	Adults:	Pediatrics:	
Adjustment required in Specific population	Liver	Renal	Not studied
	Others, specify: .....		
Indicated for pediatrics	Yes	No	Not studied
Pharmacokinetics	-Absorption -Time to peak -Excretion -Others	-Distribution -Metabolism -Half life	
<b>Safety</b>			
Common Adverse Reactions (%)			
Rare/serious adverse Reactions (%)			
Drug Interactions			
Contraindications / Precautions			
Monitoring Requirements			
Sound-Alikes/ Look-Alikes			
Boxed warning or alerts issued			
Toxicity if antidote required	Yes	No	
High Alert as per MOH policy	Yes	No	
Handling	Hazardous/Antineoplastic Precaution		None
	Others		
Storage if there is special condition	Yes	No	

**Table 1: Summary of Published Evidence (Efficacy and Safety).**

Ref.	Design*	Drug Regimens	n.	Duration	End Points	Demog.	Results/Comments	NNT
1		1.			1.			
		2.			2.			
2		1.			1.			
		2.			2.			
3		1.			1.			
		2.			2.			
4		1.			1.			
		2.			2.			
5		1.			1.			
		2.			2.			

Study design abbreviations: DB= Double Blind, RCT= Randomized Control Trial, PC= Placebo Controlled, PG= Parallel-Group, XO= Crossover, Mc= Multi-center

Number needed to treat; only calculated if P value <0.05; i.e., statistically significant NNT= 1/Absolute risk reduction

Evidence grades:

*I*- from meta-analysis or systematic review of randomized controlled trials (RCT's)/ large multicenter RCT's;

*II*- from one or more RCT;

*III*- from controlled trials without randomization; cohort, case control, analytic studies, multiple time series, before and after studies (preferably from more than one center or research group);

*IV*- from other observational studies;

*V*- from opinions of respected authorities based on clinical experience, descriptive studies or reports of expert committees.

**Table 2: Summary of Pharmacoeconomic Studies.**

Ref.	Drug/Treatment Arms	n/D*	Method*	Outcome Measures	Cost Measures	Results/Comments
1	1.			1.		
	2.			2.		
2	1.			1.		
	2.			2.		
3	1.			1.		
	2.			2.		

\*n/D\*: Number of patients/ Duration of the study

\*Method abbreviations: CEA= cost- effective analysis, CUA= cost-utility analysis, CBA= cost- benefit analysis, CCA= cost-consequence analysis.

**Table 2a: Summary of Pharmacoeconomic Studies (CMA=cost-minimization analysis).**

Ref.	Drug/Treatment Arms	n/D*	Method*	Outcome Measures	Comparison of both total cost A and B	Results/Comments
1	1.			1.		
	2.			2.		
2	1.			1.		
	2.			2.		
3	1.			1.		
	2.			2.		

\*n/D\*: Number of patients/ Duration of the study

\*Method abbreviations: mainly evaluation of two different medication with same efficacy and different cost

Discount rate (5-20%), measuring direct and indirect cost

**Table 2b: Summary of Pharmacoeconomic Studies (CBA=cost-benefit analysis).**

Ref.	Drug/Treatment Arms	n/D*	Method*	Outcome Measures	Net Benefit= Total Benefit- Total Cost	Cost Benefit Ratio= Total Benefit/Total Costs
1	1. 2.			1. 2.		
2	1. 2.			1. 2.		
3	1. 2.			1. 2.		

\*n/D\*: Number of patients/ Duration of the study

\*Method abbreviations: mainly evaluation of programs in medical or pharmacy (vaccines, pharmacokinetics, ADIS,...) either one or two comparable program

Discount rate (5-20%), if the ratio more 2:1 that main more saving money

**Table 2c: Summary of Pharmacoeconomic Studies (CEA= cost-effective analysis).**

Ref.	Drug/Treatment Arms	n/D*	Method*	Outcome Measures	Average Cost per cure for each medications	Incremental C/E ratio
1	1. 2.			1. 2.	1. 2.	
2	1. 2.			1. 2.	1. 2.	
3	1. 2.			1. 2.	1. 2.	

\*n/D\*: Number of patients/ Duration of the study

\*Method abbreviations: mainly evaluation of two medication with different cost and efficacy

Discount rate (5-20%),

Average Cost per cure = Total Cost to treat Number of patients/effective rate percentages

Incremental C/E ratio= Total Cost to treat Number of patients between medications (A-B)/ effective rate percentages between medications (A-B).

**Table 2d: Summary of Pharmacoeconomic Studies (CUA=cost-utility analysis).**

Ref.	Drug/Treatment Arms	n/D*	Method*	Outcome Measures	QALYs	Results/Comments
1	1. 2.			1. 2.		
2	1. 2.			1. 2.		
3	1. 2.			1. 2.		

\*n/D\*: Number of patients/ Duration of the study

\*Method abbreviations:, mainly evaluation of two medication with different Length of Life and Health Quality of that Life

Discount rate (5-20%),

Quality Adjusted Life-years (QALYs), one full healthy year of life is scored as 1.0, the sum are additive years

QALYs measured by completion rating scales (Standard Gamble, Trade-OFFS).

**Table 3: Summary of Cost Analysis.**

Ref	Generic Name (Manufacturer)	Dose	Cost/ Unit SFDA	Cost/ Unit GCC	Cost/ Unit USA	Cost/ Unit UK	Cost/ Unit Canada
1	<i>Requested drug</i>						
2	<i>Comparator drug # 1</i>						
3	<i>Comparator drug # 2</i>						
4	<i>Comparator drug # 3</i>						
5	<i>Comparator drug # 4</i>						

**Table 4: Type of Pharmacoeconomic Evaluation.**

<input type="checkbox"/> Clinical outcomes studies	<input type="checkbox"/> Patient-reported outcomes studies
<input type="checkbox"/> Compliance/adherence studies	<input type="checkbox"/> Quality of life studies
<input type="checkbox"/> Cost studies	<input type="checkbox"/> Utility studies
<input type="checkbox"/> Health policy studies	<input type="checkbox"/> Using real-world data studies
<input type="checkbox"/> Health technology assessment(HTA)	<input type="checkbox"/> Health care decisions studies
<input type="checkbox"/> Outcomes research issues	<input type="checkbox"/> Others _____
<input type="checkbox"/> Patient-preferences studies	

**Table 5: Summary of Pharmacoeconomic Analysis.**

Ref	Generic Name (Manufacturer)	Dose	Cost/ Unit	Support Therapy	Inpatient + Outpatient Cost	Cost Drug Related Problems	Total number of patients	Total Cost
1	<i>Requested drug</i>							
2	<i>Comparator drug # 1</i>							
3	<i>Comparator drug # 2</i>							
4	<i>Comparator drug # 3</i>							
5	<i>Comparator drug # 4</i>							

**Table 6: Summary of Pharmacoeconomic Drug Related Problem Analysis.**

Ref	Generic Name (Manufacturer)	Dose	Cost/ Unit	Cost ADR	Cost Medication Errors	Cost other Drug Related Problems	Total number of patients	Total Cost
1	<i>Requested drug</i>							
2	<i>Comparator drug # 1</i>							
3	<i>Comparator drug # 2</i>							
4	<i>Comparator drug # 3</i>							
5	<i>Comparator drug # 4</i>							

**Table 7: Utility Rank.**

Ref	Generic Name (Manufacturer)	Cost/ Unit	Total number of patients	Total Cost	Budget impact	Comments
1	<i>Requested drug</i>					
2	Comparator drug # 1					
3	<i>Comparator drug # 2</i>					
4	<i>Comparator drug # 3</i>					

Therapeutic:

Rank= 1 if large randomized clinical trials demonstrate clear –cut therapeutic advantage (enhanced efficacy and /or reduced toxicity ) over available modalities and use of drug will lead to clinically significant improvement in patient mortality, morbidity or quality of life.

Rank= 2 if clinical studies indicate therapeutic advantage over available modalities but there is questionable / marginal improvement in patient outcome and /or efficacy advantage is somewhat offset by toxicity disadvantage.

Rank= 3 if no therapeutic advantage but secondary chrematistics confer some advantage (e.g dosage form, route / frequency of administration, pharmacokinetics, convenience).

Rank =4 if no demonstrated advantage over currently available modalities.

Cost :

Rank= A if addition of drug will significantly reduce direct cost to hospital.

Rank= B if addition of drug will modestly reduce direct costs to hospital.

Rank= C if addition of drug will have minimal direct cost impact (i.e., less than 20,000 per year.

Rank= D if addition of drug will modestly increase direct costs to hospital (i.e., 20,000 SR to 60,000 SR per year).

Rank= if addition of drug will significantly increase direct cost to hospital (i.e., more than 60.000 SR per year).

**Conclusions:****References:**

1	
2	
3	
4	
5	
6	