Research Article Int J Pharmacol. Clin. Sci

# **Cost Analysis of Clinical Compounding in Saudi Arabia: Antibiotic Pediatrics Formulations**

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Received: 14-10-2018; Accepted: 03-02-2019

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www.ijpcs.net

DOI: 10.5530/ijpcs.2019.8.37

#### **ABSTRACT**

Objectives: The aim of this study to explore the cost analysis of selected pediatrics antibiotics formularies in the Kingdom of Saudi Arabia. Methods: It is a retrospective cost analysis of pediatrics formulations at 300-beds pediatrics and maternity hospital in Riyadh city, Saudi Arabia. The pharmacy section received the specific formulation from physician then the expert pharmacist applied the international standard of clinical compounding through providing to healthcare staff over eight hours per days for five days per a week. The pediatrics formulations consisted of selected four antibiotics (Nitrofurantoin, Oseltamivir, Chloroquine and Clindamycin). The analysis of the cost included the variable expenses included personal cost, material and supply cost, Costs fixed including direct cost, non-salary cost and overhead cost. The cost was derived from the Ministry of Health information database. All cost used US dollar currency. The study analyzed the cost of anti-hypertension pediatrics formulations through the Microsoft Excel sheet version 10th. Results: The estimated average total standard cost of pediatrics formulations per hour was (53.82 USD). The average estimated cost of Nitrofurantoin per each preparation was (14.13 USD) which consisted of standard cost (0.31 USD) and the direct cost was (13.82 USD). The average estimated cost of Oseltamivir per each preparation was (16.95 USD) which consisted of standard cost (0.33 USD) and the direct cost was (16.62 USD). The average estimated cost of Chloroquine per each preparation was (6.645 USD) which consisted of standard cost (4.36 USD) and the direct cost was (6.645 USD). The average estimated cost of Clindamycin per each preparation was (14.478 USD) which consisted of standard cost (2.018 USD) and the direct cost was (12.46 USD). Conclusion: There are varieties in the cost analysis between selected pediatric formulation and manufactured ready-made products. The pharmacist should select the cheapest one among them. The cost analysis of pediatrics formulation was used for health insurance coverage and to meet the updated pharmacy strategic plan and Saudi vision 2030 in the Kingdom of Saudi Arabia.

Keywords: Cost, Clinical, Compounding, Antibiotic, Pediatrics, Formulations, Ministry of Health, Saudi Arabia.

#### INTRODUCTION

In the late year 2012, the general administration of pharmaceutical care released the pharmacy strategic plan of the Ministry of Health institutions.[1] In 2017, the updated Pharmacy strategic plan with new Saudi idiom 2030 had been released.[2] In both strategies, the common goal included was the pharmacoeconomic and healthrelated cost. Both concepts consisted of several aspects, for instance; health insurance, cost analysis of pharmacy services, medications prices and impact of cost avoidance of pharmacist and pharmacy-related services.<sup>[2]</sup> The cost analysis of medications is demandable to calculate the economic income and experience with net results of profit in the budget. Most of the medications, including antibiotics for pediatrics or geriatrics dosage forms prices organized locally through the Saudi Food and Drug Authority.[3] Some of the antibiotic pediatrics dosage form may rarely be used or the company may not manufacture them anymore or some of the antibiotics not even got registered in the Kingdom of Saudi Arabia. Some examples of pediatrics or geriatrics antibiotics formulations were clindamycin syrup

and Nitrofurantoin syrup, not used much and not manufactured frequently and may be called orphan drugs.[4,5] Thus, some hospital pharmacies prepare those medications in case of any circumstances occurred. Besides, they need to develop their prices based on the cost analysis. The authors are not familiar with any publications locally about cost analysis of previous antibiotics pediatrics formulations in Saudi Arabia or Gulf and Middle East countries. The aim of this study is to explore the cost analysis of some pediatrics antibiotics formularies in the Kingdom of Saudi Arabia.

## **METHODS**

It is a retrospective cost analysis of drug information services past one year at 300-beds pediatrics and maternity hospital in Riyadh city, Saudi Arabia. It had inpatient admission and ambulatory care clinics and emergency departments. The hospital had a different specialty for women adults and pediatrics. The hospital treats the common neonatal, pediatrics and women health disease. The hospital had pharmacy serve the patient including inpatient pharmacy with unit dose drug distribution system, outpatient pharmacy and extensive extemporaneous pediatrics section and drug information center. The pharmacy computerized physician order entry with an electronic prescription in addition to the pharmacy had medications safety program. The pharmacy has trained clinical and pharmacy student training programs. The extemporaneous section had very evidence-based comprehensive pediatrics formulations for neonates and pediatrics in the central region of Ministry of Health hospitals. The section received the specific formulation from physician then the expert pharmacist applied the international standard of clinical compounding through providing to healthcare staff over eight hours per days for five days per a week. The pediatrics formulations consisted of antibiotics, anti-tuberculosis (TB) medications, anticonvulsant medications, Gastrointestinal (GI) drugs, anti-hypertension medications, Electrolyte supplements, Renal preparations, Diuretics formulation, Steroid perorations and other supportive substances formulation. The analysis of the cost included the variable expenses included personal cost, material and supply cost. Costs were fixed including direct cost, non-salary cost and overhead cost. [6,7] In addition, there were the cost of compounding substances, number of preparations and time of preparations. The price was derived from the Ministry of Health information database. All cost was used as US dollar currency. The study analyzed antibiotics pediatrics formulations through the Microsoft Excel sheet version 10th.

## **RESULTS**

The estimated average total standard cost of pediatrics formulations per hour was (53.82 USD and consisted of 58.58% (31.53 USD) for personal cost, 25.14% (13.53 USD) for overhead cost, 3.34% (1.8 USD) for material and supply cost, 12.93% (6.96 USD) for non-salary cost (Table 1). The average estimated cost of Nitrofurantoin per each preparation was (14.13 USD) which consisted of standard cost (0.31 USD) and the direct cost was (13.82 USD). The total annual cost of Nitrofurantoin was (1836.9 USD) (Table 2). The average estimated cost of Oseltamivir per each preparation was (16.95 USD) which consisted of standard cost (0.33 USD) and the direct cost was (16.62 USD). The total annual cost of Oseltamivir was (4,068 USD) (Table 3). The average estimated cost of Chloroquine per each preparation was (6.645 USD) which consisted of standard cost (4.36 USD) and the direct cost was (6.645 USD). The total annual cost of Chloroquine was (66.45 USD) (Table 4). The average estimated cost of Clindamycin per each preparation was (14.478

USD) which consisted of standard cost (2.018 USD) and the direct cost was (12.46 USD). The total annual cost of Clindamycin was (144.78 USD) (Table 5).

#### **DISCUSSION**

Several antibiotics registered in the MOH drug formulary. It included several dosage forms,[8] for adults and pediatrics. Various antibiotics came as ready-made pediatrics formulations in the MOH drug formulary. For instance; Amoxicillin, Erythromycin, Azithromycin and Amoxicillin-Clavulanic Acid. However, some pediatrics formulations of antibiotics were not continuously available in the current site pharmacy. As a result, for the patients who needed those products, the medications were prepared at extemporaneous unit in the inpatient pharmacy as a part of the new pharmacy strategic plan with new Saudi vision 2030.[2] It recommended determining the cost analysis of the pharmacy services and pharmacy produce. The current study showed the cost calculation for the four selected pediatrics formulations. All the pediatrics formulations shared with the same indirect and different direct cost. The majority of the direct cost came from personal cost and overhead cost. That is related to pharmacist commonly prepare the medications through using a few types of equipment. The cost of Nitrofurantoin had cost less than registered in the USA and UK market while it was not registered in KSA (Table 6).[3,9-11] That related seldom to using in the pediatrics due to adverse reaction to the pediatrics population. The pediatrics formulation of Nitrofurantoin should continue to prepare it because it is cheaper than ready made in the market and currently not registered in the KSA. Oseltamivir syrup had cost less than registered in the market of KSA and UK while not available in USA (Table 6).[3,9-11] The readily available product with good manufactured practice factories locally or internationally. Oseltamivir was the highest consumed from pharmacy budget among the four antibiotics pediatrics formulations discussed in the results above. It suggested to discuss with local manufactures to reduce the price of the ready-made Oseltamivir syrup because of high utilization and consumption of high workload of preparations. If the manufacture refuse to decrease the price, may be better to continue prepare Oseltamivir as extemporaneous product in the pharmacy. The ready-made chloroquine syrup available in the market of KSA and UK while it is not available in the USA (Table 6).  $^{[3,9-11]}$  The cost of readymade antibiotic in KSA less expensive than what prepared in the pharmacy. The chloroquine syrup was more expensive than being marketed in KSA because of seldom use

Table 1: Standard cost analysis of pediatrics formulations (USD).			
	Cost per hour		
Personal			
Head compounding pharmacist	27.27		
staff compounding pharmacist	4.26		
Total	31.53		
Over Head cost			
Rent	0		
Bed	0		
Offices	0.46		
Chairs	1.54		
Computer	0.68		
Printer	1.43		
Zebra label printer (Direct Thermal)	3.08		
Refrigerator	1.66		
Balance	0.17		
Beakers	0.14		
Stainless steel spoon	0.21		
Measuring cup	0.25		
Measuring Cylinder	0.15		
Silicone spoon	0.05		
cooker	0.03		
Funnel	0.04		
Bunchner	0.05		
Test tube brush	0.04		
Kettle	0.15		
Mortar and Pestle	0.11		
Glass rode	0.02		
Shelf	3.23		
Pen/pencils	0.04		
scissors	0.02		
Total	13.53		
Material and supply			
Large	0.65		
Amber bottle	0.21		
Syringe	0.12		
gloves	0.49		
Blue sheet	0.31		
Face mask	0.02		
Total	1.8		
Non Salary cost			
Education and Training head	6.61		
Education and Training staff	0.34		
Total	6.96		

Table 2: Cost of Nitrofurantoin 10mg/1ml (USD).				
Personal	31.53			
Over Head cost	13.53			
Material and supply	1.8			
Non Salary cost	6.96			
Total	53.82			
Preparation time 45 min per one bottle	40.365			
Total of preparation 130 per year, the cost per one 100 ml	0.31			
Direct cost				
Nitrofurantoin100mg = 10 tab	2.08			
Oral Plus 50 ml	5.87			
Oral Sweet to 100 ml	5.87			
Total	13.82			
Grand Total 100 ml per bottle	14.13			
Annual Grand Total cost	1,836.90			

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Table 4: Cost of Chloroquine 25mg/1ml (USD).			
Personal	31.53		
Over Head cost	13.53		
Material and supply	1.8		
Non Salary cost	6.96		
Total	53.82		
Preparation time 45 min per one bottle	40.365		
Total of preparation when needed per year (around 10), the cost per one 100 ml $$	4.365		
Direct cost			
Chloroquine 250mg= 10 tablet	1.36		
Universal vehicle to 100 ml	0.88		
Total	2.28		
Grand Total 100 ml per bottle	6.645		
Annual Grand Total cost	66.45		

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Table 3: Cost of Oseltamivir 15mg/1ml (USD).			
Personal	31.53		
Over Head cost	13.53		
Material and supply	1.8		
Non Salary cost	6.96		
Total	53.82		
Preparation time 90 min per one bottle	80.73		
Total of preparation 240 per year, the cost per one 100 ml	0.33		
Direct cost			
Oseltamivir 75mg = 20 cap	13.95		
Simple syrup to 100 ml	2.67		
Total	16.62		
Grand Total 100 ml per bottle	16.95		
Annual Grand Total cost	4,068.00		
D. C			

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Table 5: Cost of Clindamycin 10mg/1ml (USD).			
Personal	31.53		
Over Head cost	13.53		
Material and supply	1.8		
Non Salary cost	6.96		
Total	53.82		
Preparation time 22.5 min per one bottle	20.18		
Total of preparation when needed per year ( around 10), the cost per one 120 ml $$	2.018		
Direct cost			
Clindamycin 150mg vial= 8 ml	11.4		
Universal vehicle to 120 ml	1.06		
Total	12.46		
Grand Total 120 ml per bottle	14.478		
Annual Grand Total cost	144.78		
D.C.			

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Medications	Cost of Current study		Cost in KSA (USD) [3]		Cost in US (USD)[9]		Cost in UK (USD) [10,11]	
name	Conc. mg/ml	Volume	Conc. mg/ml	Volume	Conc. mg/ml	Volume	Conc. mg/ml	Volume
Nitrofurantoin 10mg/1ml	1mg/ml= 0.0141 \$	100 ml =14.13 \$	Not available	Not available	1mg/ml= 0.399 \$	5 mg/ml 140ml = 279.53 \$ (100 ml=199.66 \$)	1mg/ml= 0.3752\$	5 mg/ml 300ml = 562.86 \$ (100 ml=187.62 \$)
Oseltamivir 15mg/1ml	1mg/ml= 0.0113\$	100 ml = 16.95 \$	1mg/ml= 0.0249 \$	12 mg/ml 100 ml=29.88\$	Not available	Not available	1mg/ml= 0.033\$	6 mg/ml 65 ml=12.929 \$ (100 ml=19.89 \$)
Chloroquine 25mg/1ml	1mg/ml= 0.002658 \$	100ml= 6.645\$	1mg/ml= 0.00108\$ 1mg/ ml=0.00192\$ 1mg/ ml=0.00161\$	16 mg/ml 60 ml= 1.04\$ (100 ml=1.733\$) 10 mg/ml 100ml= 1.92 \$ 24 mg/ml 60 ml= 2.33 \$ (100 ml=3.88\$)	Not available	Not available	1mg/ml= 0.0314\$	16 mg/ml 75 ml=37.78 \$ (100 ml=50.37\$)
Clindamycin 10mg/1ml	1mg/ml= 1.2065 \$	120ml= 14.478\$ (100ml=12.065\$)	Not available	Not available	Not available	Not available	Not available	Not available

in the local market and few preparations annually. It suggested to hold prepare the product as extemporaneous preparation and buy the product from KSA market. The pharmacy can prepare the product during shortage of stock only. The clindamycin syrup not registered in the local market, USA or UK and it was hard to compare cost with them (Table 6).[3,9-11] The product is seldom used in the hospital as inpatient drug, not outpatient medications and not frequently used in the OPD hospitals because of the presenting of safe alternative medications. The pharmacy may prepare during high demand and when there are no alternatives in the pharmacy. The study explored the cost analysis of some selected antibiotics pediatrics formulations with considerable variation from the market. The policy of orphan, including the cost analysis of drug and that, is should establish and implement in the Kingdom of Saudi Arabia.

#### **CONCLUSION**

The antibiotics commonly prescribed for adults and pediatrics in over the world. Antibiotics adults' oral dosage form is mostly available in the local or international market. However, antibiotics oral pediatrics formulation is available for most used medications except orphan drugs or not commonly used for neonates or

pediatrics. Besides, the cost of antibiotics oral pediatric formulation is unknown. The cost analysis of the orphan drug is a crucial element of the pharmacy budget. The determination of cost analysis of antibiotics orphan medications is highly recommended regularly in the kingdom of Saudi Arabia.

## **ACKNOWLEDGEMENT**

None.

## **CONFLICT OF INTEREST**

The authors declare no conflict of interest

#### **ABBREVIATIONS**

KSA: Kingdom of Saudi Arabia; USD: United State Dollars; GI: gastrointestinal; GERD: Gastroesophageal reflex diseases; MOH: Ministry of Health; TB: tuber-culosis; SFDA: Saudi Food and Drug Authority; USA: United States of America; UK: United Kingdom; OPD: Outpatient Department.

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