## SCHOOL OF PUBLIC HEALTH

#### **COLLEGE OF HEALTH SCIENCES**

#### **UNIVERSITY OF GHANA**



# ASSESSING SUSTAINABILITY OF OUTSOURCING MEDICATION SERVICES AT GHANA PORTS AND HARBOURS AUTHORITY CLINIC

BY:

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THIS DISSERTATION IS SUBMITTED TO THE UNIVERSITY OF GHANA, LEGON
IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE AWARD OF
MASTER OF PUBLIC HEALTH DEGREE

## DECLARATION

I, Kofi Frimpong Prempeh, hereby declare that this su	ibmission presented for the award of Masters						
in Public Health degree is my own work and has not	t been presented for any examination in any						
other institution. Where references have been used, these have been cited accordingly.							
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## **DEDICATION**

This work is dedicated to my family, the PREMPEH FAMILY for their support and encouragement throughout the course.

## ACKNOWLEDGEMENTS

I wish to acknowledge the people who assisted me in diverse ways to complete this dissertation.

Firstly, I would like to thank the Director of Port – Tema, the Head of Health Services and the Head of Pharmacy GPHA Clinic, for granting me permission to undertake my research in the organization and accommodating my weekend school schedule.

My deep gratitude goes to my supervisor Dr. SETH KWAKU AFAGBEDZI of the Biostatistics Department, University of Ghana - Legon, whose guidance and constructive criticisms were instrumental in helping me complete this dissertation.

Finally, I wish to express my sincere gratitude to my mother BEATRICE OSEI – ANSONG for her patience and encouragement in all the trying periods of this course.

#### **ABSTRACT**

**Introduction**: Outsourcing of medication services is an alternative form of health financing and an ingenious way of managing medication costs and improving service delivery in most developed countries today. Ghana Ports and Harbors Authority clinic, Tema outsources medication services to Top up pharmacy. However the cost of outsourcing medication services appears to be rising steadily.

**Objective of study**: The aim of this study is to assess the sustainability of outsourcing medication services as a cost minimization intervention.

Methodology: Secondary data from claim invoices and purchase invoices from January to September 2018, were reviewed and a cross-sectional descriptive-comparative analysis of the mean unit costs of all medications based on outsource status (outsourced formulary and matched purchased formulary medications) were used to investigate any difference at a statistically significant level. This comparison was done using a Paired T - test. Also the average cost per medication and frequency of prescription of outsourced medications was used to establish an inclusion criterion for expansion of the local formulary.

**Results**: The cost of purchased medications was found to be statistically significantly less than the cost of outsourced medications, t (92) = -7.55, p $\le$  0.001. Seven (7) medications were identified to meet the inclusion criterion for formulary expansion. It may be sustainable to outsource because to 73% of outsourcing cost is still due to 800 non formulary medication which will be impractical stock immediately, despite the higher comparative cost

Conclusion: The findings indicate that the cost of outsourced medication was higher than purchased medications at GPHA Clinic. However, sustainability of outsourcing medication

services is significantly impacted by the outsourcing of a vital few expensive non formulary and formulary medications. The inclusion criterion is critical to gradually update the local formulary to allow for improving infrastructural capacity to expand the formulary.

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## LIST OF ABBREVIATIONS

GDP - Gross Domestic Product

GPHA - Ghana Ports and Harbours Authority

NHS - National Health Service

OECD - Organization of Economic Cooperation and Development

PNDCL - Provisional National Defense Council Law

#### **CHAPTER ONE**

#### INTRODUCTION

#### 1.1 Background

Ghana Ports and Harbors Authority (GPHA) is a "statutory corporation established under Ghana's Provisional National Defense Council Law (PNDCL 160) of 1986 that is mandated to build, plan, develop, manage, maintain, operate and control ports in Ghana" (Ghana Ports and Harbors Authority, 2018). It has as one of its core values a commitment to employees to provide total healthcare for all of its staff and their registered dependents. The organization values its human resource as its greatest asset and as such has made colossal investments into establishing three health facilities to cater for the health needs of staff and their dependents. It is a fee-free service operating as a private employer health insurance scheme for staff and their dependents, and retired staff, where the authority is the sole financier and a paid service for other companies and registered port users. As a public corporation, GPHA Clinic, Tema is a quasi-state health institution that demands that all forms of procurements are subjected to The Public Procurement Act 2003 (Act 663) and selection of drug products based on the criteria prescribed by the Essential Medicines List. The pharmacy department has a local formulary for general dispensing to clients that patronize its services.

Additionally, there are contractual arrangements with selected retail Pharmacies within the Tema communities to provide non-formulary medication services to its staff and dependents for claimed payment on a monthly basis, after vetting of claims by pharmacy staff and Audit department of GPHA. These retail pharmacies where the medication services are outsourced at are TOP-UP PHARMACY, MANHEAN PHARMACY and KWADYS CHEMISTS. The price rates applied to unit medications are flexibly regulated by the health care facility and are expected to be fair market value. Monthly claim amounts submitted have been on a steady rise in recent years, with

most of the cost attributed to claims from TOP-UP PHARMACY. This has given cause for concern and requiring an assessment of the cost of outsourcing these medication services.

The cost of healthcare is on the rise globally. Direct out-of-pocket payments for consultation, procedures, commodities and medications are among the most prevailing barriers to accessing quality health care in low- and middle-income countries (Global Health Insights, 2012). In the United Kingdom, it is reported that medicines cost the National Health Service (NHS) an approximate amount of £13 billion every year, and accounts for about 10% of the United Kingdom's budget (Hughes, 2010). According to the Organization of Economic Cooperation and Development (OECD, 2017), pharmaceutical spending accounts for 12% of health spending in the United States, compared to about 17.5% in Canada, and 18.8% in Japan. India is reported to spend only 5% of its annual gross domestic product (GDP) on health care (Ministry of Health and Family Welfare, 2005). Of these spending, it is estimated that about 80% is private out-of-pocket. These high costs have resulted in inaccessibility of health services to most households in India. Unfortunately the few with access to health care in the public sector are generally receiving unsatisfactory services (Prinja et al., 2012).

Ghana's health care system, as observed in other African countries, presents with great healthcare inefficiencies (Kaseje, 2006), which do not allow for a robust enough health system to negotiate with multinational drug manufacturing companies to mitigate the rising cost of medication despite the positive rise in the country's gross domestic product (GDP), with the World Bank reporting growth rates around 5-6% per annum (World Bank, 2017).

As an integral part of any healthcare facility, Ghanaian pharmacies are challenged by dynamics of the finance structure of health care, to reduce cost and improve quality of performance. A means of achieving this goal is by the use of outsourcing. By definition, outsourcing is that formal

arrangement between a healthcare organization and an external company to derive certain pharmaceutical services, and by negotiation, given contractual. Access to the expertise, resources and technologies of an outside company, where it would otherwise be impossible, extremely difficult or economically unsound to do so (American Society of Health-System Pharmacists, 1998). Outsourcing of pharmacy services of this nature tends to rely crucially on the tenets of economically sound management of pharmacy services and the principles of pharmacoeconomics - which is a discipline that is concerned with optimal allocation of resources to maximize population health from use of medicines (Hughes, 2012). As more expensive drugs are being produced and licensed, it is imperative for especially, developing nations, where resources are scarce, to apply the principles of pharmacoeconomics for various drugs and treatment options to provide high quality care at low cost (Bhosle et al., 2017). This involves evaluating the cost and effectiveness of a pharmaceutical product (Arnold, 2010). In as much as cost of drugs is being considered, compromise must not be put on quality of drugs as well. The "products and services delivered by today's healthcare professionals should demonstrate pharmacoeconomic value, that is, a balance of economic, humanistic, and clinical outcomes" (Trask, 2011).

The importance of the success of outsourcing medication services in any health care facility cannot be over emphasized. However limited studies on the economic benefits of outsourcing medication services specifically, exist upon extensive literature search. To that effect, this study seeks to assess the sustainability of outsourcing pharmacy services at GPHA clinic.

#### **1.2 Problem Statement**

The pharmaceutical industry, in recent times, has experienced great changes in market situations related to merges, acquisitions, internalization, downsizing and changing regulatory trends which have consequently led to restructuring of the financing of health care services to make it cost

effective; improving overall performance (American Society of Health-System Pharmacists., 1988).

Owing to the aforementioned changes, most pharmacies have to reallocate resources and funds and rely on partnership relations with outside contract organizations (Hassanzadeh, Modarres, Nemati, & Amoako-Gyampah, 2014; Mitchelle, 1997). In the pharmacy industry, low productivity and service delivery as well as less profits and flexibility have triggered the initiatives of most to resort to outsourcing (Gummerus, Airaksinen, Bengtström, & Juppo, 2016).

Though outsourcing offers advantages such as cost-effectiveness and greater flexibility in rendering service, it also has its downsides. These include increased cost of the outsourcing process, problems of monitoring the performance of outside contract organizations and poor quality of work done by these outside contract organizations (Gummerus et al., 2016)

The situation at the GPHA clinic seems to mirror this unfortunate cycle of disadvantageous outsourcing of medication services. It is expensive and unrealistic to stock every possible medication available; as such the GPHA clinic outsources some of its medication services to community retail pharmacies on contractual basis. Generally medication services outsourced at GPHA clinic have been well received due to convenience and professionalism of the outsourcing retail pharmacies. However the cost of outsourcing medication services though, appears to be outweighing the inherent benefits it promises, hence the sustainability of outsourcing pharmacy services as a cost minimization intervention may be under threat. Thus, it is unclear if outsourcing medications at the clinic is entirely meeting the objective it was set for, requiring an assessment of the sustainability of outsourcing medication services at GPHA clinic.

#### 1.3 Justification

Given the inadequate and declining government financial support to healthcare in the country, it has become imperative for other sources of financing for pharmacy services to be implemented. Thus, pharmacies have resorted to outsourcing some medications in order to minimize cost. In the United Kingdom, outsourcing pharmacies have afforded health seekers the opportunity to leave hospitals early as drugs are generally dispensed faster (Pate & Anderson, 2012). It is generally agreed that most people refuse attending to health facilities because of the fear of their time being wasted. Again, it was observed that these outsourced pharmacies provide investment opportunities for community members (Pate & Anderson, 2012). However to simply conclude that outsourcing of medication services is the solution to all the economic woes of the health care system would be a grave misrepresentation.

This research therefore seeks to shed some light on the benefits or otherwise of outsourcing medication services, but most importantly inform other cooperate bodies on the choice to outsource medication services or not. It is expected that such institutions shall benefit from the specific experience of GPHA clinic Tema in outsourcing medication services. It must be iterated that all beneficiaries of the GPHA Health service, namely the workers, their dependents and all port users at GPHA alike stand to profit from this study as the sustainability of outsourcing medications service is assessed and possibly improved. Other community retail pharmacies and outsourcing companies also stand to benefit from the refinement of such contractual relationships with the health facilities, in terms of future revenue generation.

Finally GPHA Clinic, Tema will also boost its customer service experience and stand to encourage more people to access healthcare services. Findings from this study will help determine which medications should be outsourced, which ones should be included to expand the local formulary.

This should help in the sensible expansion of the local formulary with rational utilization of medicines to meet the health care needs of clients without astronomical medication costs to the Authority.

However, in Ghana, there is paucity of studies with regard to the assessment of the sustainability of outsourcing medication services. This therefore presents the need for research on the topic at GPHA clinic in order to obtain up-to-date and reliable information on this study area.

#### 1.4 Aims and objectives

## 1.4.1 Aim of the study

The purpose of the study is to assess the sustainability of outsourcing medication services at GPHA clinic.

## 1.4.2 Specific Objectives of the Study

- To determine the total and mean unit cost of outsourced medications (formulary and non-formulary) and matched purchased formulary medications over the study period.
- To test the hypothesis of equal mean unit costs between outsourced formulary medications and matched purchased formulary medications over the study period through a comparative analysis.
- To establish an inclusion criterion for formulary expansion and determine outsourced nonformulary medications that meet this criterion.

#### 1.5 Research questions

• What is the total and mean unit cost of outsourced medications (formulary and non-formulary) and matched purchased formulary medications over the study period?

- Will a comparative analysis show a difference between mean unit cost of outsourced formulary medications and matched purchased formulary medications over the study period?
- Is there an appropriate inclusion criterion for formulary expansion and what outsourced non-formulary medications meet this criterion?

#### 1.6 Operational definitions

- Medication services as used in the study connote outsourced dispensed drugs and are synonymous to pharmacy services. This may include; patient counselling, requisition and purchase of medications.
- Sustainability of outsourcing medication services implies whether it is economically viable
  to source medication based on costs incurred in outsourcing compared to purchasing
  medications in-house. For this study, continuous outsourcing of a medication will be
  classified as sustainable if;
  - i) Comparative cost analysis reveals a lower mean unit cost of outsourced formulary medications as compared to matched purchased formulary medication to a statistically significant level.
  - ii) The total cost for each outsourced medication over the study period is less than the average cost per medication. Thus, medications which cost more than the average cost per medication over the study period will be recommended to be added to the local formulary and would no longer be outsourced.
  - iii) The frequency of prescription of each outsourced medication is less than 72 or at least 2 prescriptions per week over the 36 week study period, according to practice.

- Cost benefit analysis is a tool used in determining the feasibility of a project. This tool helps to weigh the costs and benefits of a project in order to determine its feasibility or to compare alternatives. Furthermore, this tool is useful for weighing decisions that have computable financial risks and rewards. In this study, same drugs with the same pharmacological activity were compared and as such benefit was assumed to be the same on both sides. As such, the cost benefit analysis depended solely on the comparative costs of the various medications.
- The local formulary is a list of medications that GPHA Pharmacy purchases on a regular basis to serve its clients at the clinic. A Drugs and Therapeutic Committee is responsible for the management of the local formulary, comprising of pharmacists and medical doctors.
- Outsourced medication refers to all medication that were dispensed at TOP-UP
  PHARMACY to GPHA staff and dependents over the study period. TOP UP PHARMACY
  is used as a model because of the quantum of prescriptions it dispenses and also for its
  added advantage of being a wholesale/retail pharmacy and as such less affected by external
  price variations of medication.
- Outsource status refers to the means by which medication is obtained for clients. This could be purchased in-house or outsourced.
- Outsourced formulary medication refers to medications that were dispensed at TOP-UP
   PHARMACY over the period but are also on the local formulary list of GPHA Pharmacy.
- Outsourced non-formulary medications refer to all other medications dispensed at TOP-UP PHARMACY over the period that are not on the local formulary list of GPHA Pharmacy.

 Matched purchased formulary medications refer to medications on the local formulary list that were purchased by the medical store of GPHA pharmacy and were also outsourced over the study period.

#### **CHAPTER TWO**

#### LITERATURE REVIEW

## 2.1 Introduction to Outsourcing

Outsourcing is considered to be one of the tools for developing health care organizations and improving productivity in health care institutions (Kavosi et al., 2018), thereby making it an important instrument necessary to be implemented in health care services. The decision of healthcare institutions to outsource pharmacy services is not autonomous. Several factors are taken into consideration. Health care organizations make outsourcing decisions on pharmacy services by carefully assessing their expertise in providing quality services themselves, especially when they realize, after the assessment that their own resources cannot provide the services they intend to provide (American Society of Health-System Pharmacists, 1998).

### 2.2 Reasons for Outsourcing Services

One of the reasons for outsourcing pharmacy services is that healthcare institutions seek to reduce cost and increase efficiency (Young, 2005). It is believed that obtaining external pharmacy services is less expensive (Macinati, 2008). According to Macinati (2008), in the 1980s, the burden of increased healthcare spending and declining quality of services encouraged healthcare institutions to improve efficiency and lower cost, and thus resorted to contracting out services, including pharmacy services. Another reason for outsourcing pharmacy services is to reduce management-associated problems (Young, 2005). In this regard, the use of outsourcing increases the power of management over the workforce and discourages lackadaisical attitudes. When demands for pharmacy services exceed capacity to provide timely quality care, access becomes a concern, and clients must choose between waiting in long queues and accessing care from a different facility. As a result, strategic outsourcing of pharmacy services provides a feasible solution to the

healthcare institution without costly expansion of infrastructure, whilst maintaining commitment to patient population (Billi et al., 2007). The American Society of Health-System Pharmacists (1998) outlines several reasons for outsourcing pharmacy services, including:

- Resolving operative inadequacies, by improving medication dissemination systems,
   reducing inaccuracies with distribution and administration of medication, and
   technological systems improvement.
- Allowing the healthcare organization to attract expert human resource.
- Giving the healthcare institution a competitive advantage through improved services.
- Increase the health facility's financial operating margin, through wholesale purchases,
   using group purchasing contracts and decreasing drug diversion and pilferage.
- Enable the institution to maintain and/or improve the level of patient care, by obtaining specialized expertise in pharmaceutical care.

#### 2.3 Reasons for Not Outsourcing Services

Although outsourcing pharmacy services have several potential benefits, some studies have reported multiple disadvantages as well (Macinati, 2008). According to Roberts (2001), outsourcing pharmacy services may hinder the healthcare organization from achieving its own goals and objectives. Again, the healthcare institution may lose control over some of its services and become over-dependent on the external pharmacy being outsourced (Billi et al., 2004). This makes the healthcare organization liable for the outsourced pharmacy's actions (Macinati, 2008). Another reason why pharmacy services may not be outsourced is that the healthcare facility's own pharmacy may see the external pharmacy as a competitor (Billi et al., 2007). The American Society

of Health-System Pharmacists (1998) outline several reasons for not outsourcing pharmacy services, including:

- The perception that changes are not needed as current systems meet the healthcare facility's needs, cost-effectively.
- Concerns about isolating the practice of pharmacy from other health disciplines of health care staff.
- Paradoxical increase in cost of outsourcing pharmacy services rather than decreasing.
- Concerns of reducing quality due to inconsistent values and priorities between the outsourcing pharmacy and the healthcare organization.
- Concern that the contract agreement with the outsourced pharmacy service provider will include only low-cost medications.

## 2.4 Criteria for Decision-Making in Outsourcing Services

Quality improvement stands as one decision-making criteria for outsourcing services (Oduk, 2013). In this regard, in healthcare institutions, the main goal for which pharmacy services will be outsourced is to promote the quality and service productivity of the pharmacy services in the healthcare organization (Kavosi et al., 2018). Provision of quality pharmacy services at the healthcare institution can go a long way to increase the trust of clients in the facility, reduce costs, and increase customer satisfaction (Al-Nehmi, 2009). Akbulut et al. (2013) proved that outsourcing services improved quality of services provided by 38.8%, and increased productivity and efficacy by 27.7%. To ensure effective provision of quality services, monitoring and control measures must be instituted by the healthcare facility (Ferdosi et al., 2013).

Kavosi et al. (2018) assert that, several studies have stated that organizations consider costs saving as a criterion that informs their decision-making to outsource services. They further assert that, the key driver to most decisions on outsourcing services is to reduce cost of work force, materials, and resources (Kavosi et al., 2018). Agreeably, there is the need for healthcare institutions to steer decision-making towards cost-effectiveness. Through principled outsourcing, an institution can save many of their financial resources (Al-Nehmi, 2009). In this respect, pharmacy services can be outsourced.

The criterion of management is another factor that influences decision-making in outsourcing services. In assessing this criterion, Kavosi et al. (2013) utilized seven sub-criteria including management pertaining to saving time, reducing workload, increasing speed of implementation, improving safety, improving accountability, specialized management and difficult-to-manage functions. Reducing time spent at a health facility is an essential aspect of healthcare delivery. Outsourcing pharmacy services can be a worthy approach to achieve this objective (Al-Nehmi, 2009). The need for specialized services, including pharmacy services, have been shown to be a decisive factor in outsourcing services (Assaf et al., 2011).

Another criterion that influences the decision to outsource pharmacy services is strategy. Flexibility, an aspect of strategy has been defined as "the ability to respond to changes in the least amount of cost, time, effort and performance" (Kavosi et al., 2013). Customer preferences for medications are variable, and keep changing. Healthcare institutions need to be flexible and responsive to this variability of client needs (Kremic et al., 2006), which can be achieved through outsourcing medication services.

A set of criteria, generated by Billi et al (2007), in considering potential retail pharmacies for outsourcing medication services is listed below:

- Capacity to handle patients referred from healthcare organization
- Reputation in high quality of care
- Shared vision
- Ability to perform services at lower cost than healthcare institution\*
- Ability to perform services at positive margin

#### 2.5 Benefits of Outsourcing Services

Managers of healthcare facilities consider outsourcing as an effective tool for organizations development and enhancing productivity (Kavosi et al., 2018). Outsourcing services improves performance and increases accountability (Macinati, 2008). Another benefit healthcare institutions derive from outsourcing pharmacy services is that they are afforded the opportunity to focus their financial resources to advance distinct specialties to achieve strategic goals (Billi et al., 2007). According to Jennings (1997), with outsourcing, opportunity cost is avoided since resources are released for alternative revenue-generating programs. Again, when pharmacy services are outsourced, costs saving is achieved, especially in the event when the outsourced pharmacy have lower unit costs for their services (Billi et al., 2007). Another benefit of outsourcing pharmacy services is that the healthcare institution learns best practices, for instance patient communication, from the outsourced pharmacy (Billi et al., 2007). Billi et al. (2007) further asserts that, the healthcare facility is most likely to receive specialized and most appropriate referrals from the outsourced pharmacy, since they are well aware of the specific services of the healthcare facility.

A predictable advantage the outsourced pharmacy shall gain from the healthcare institution is increased revenues (Billi et al., 2007). Yigit et al (2007) express advantages of outsourcing pharmacy services to include cost reduction, improvement of services and increasing profits. Yigit et al (2007) further showed that healthcare organizations decided to outsource services to decrease costs (78.8%), increase the quality of services (65.5%), increase flexibility and sharing risk (36.6%), and to increase profits (11.2%). In another study, Mayson & Fleshner (2009) proposed several benefits including patient satisfaction, improved access, health promotion and reduction in wasting time. Mayson & Fleshner (2009) further evince that about 74% of Canadians report reduction in wait times and improved quality of care by 73%. Karimi et al (2009) outline similar advantages of outsourcing pharmacy services: cost reduction, customer satisfaction, and increased productivity in providing quality health care. Moschuris & Kondylis (2007) affirms that economies of scale and the use of the external provider of health services' infrastructure were the main benefits realized by users after outsourcing. In a most recent study, Kavosi et al. (2018) elucidates advantages of outsourcing to include reducing costs, increasing efficiency, reducing service delivery time, improving skills and increasing competitive advantage. Another advantage outsourcing has proven to bring is the use of modern technologies in providing healthcare services (Mehdizadeh et al., 2016).

#### **CHAPTER THREE**

#### **METHODOLOGY**

#### 3.1 Introduction

This chapter looked at the procedures and methods that were employed in this study. The chapter focused on issues such as the type of study design that were employed, study site description, study population as well as the required sample size for this study and sampling techniques. Again, tools for data collection, ethical considerations and data management and analysis were also included in this chapter.

#### 3.2 Study design

A cross-sectional comparative study was used to assess the sustainability of outsourcing medication services at GPHA clinic. This study was conducted in July 2019.

## 3.3 Study site description

This study was conducted at the Ghana Ports and Harbors Authority (GPHA) clinic which is in Tema community 2 in the Greater Accra Region of Ghana. This health facility is among the top health facilities which offers various health services to the people of Tema and its environs. The GPHA clinic started operating in the year 1985 as a cargo clinic to respond to the health needs of workers and their dependents. With time, the clinic was expanded to accommodate staff of other organizations in various departments of the port as well as individuals who could afford services rendered by paying directly. Averagely, daily outpatient attendance ranges from 100-150 patients. The clinic operates a 24 hour service and is equipped with five trained medical doctors as well as a visiting cardiologist and orthopedic surgeon. Services provided by the clinic include; outpatient

services, ultrasound, cardiology, laboratory services, in-patient services, orthopedic services and

antenatal care. Medication services have been outsourced to Top Up pharmacy since 2010. A total of 5,039 prescriptions were outsourced within the study period.



Figure 1 Map of Study site

(Google Maps, 2019)

## 3.4 Study population

The study population was all outsourced (formulary and non-formulary) medications and purchased formulary medications for the study period.

#### 3.5 Inclusion criteria

- All drugs outsourced within the study period of January to September 2018 were included in this study.
- Also, all purchased formulary medications that were outsourced within the study period were eligible for inclusion into this study.

#### 3.6 Exclusion criteria

• For this study, purchased formulary medications which were not outsourced were excluded.

#### 3.7 Study variables

#### 3.7.1 Dependent variable

The dependent variable in this study was the mean unit costs of each medication of the various classes of medication.

#### 3.7.2 Independent variable

For this study, the independent variable was the outsource status of the medications.

#### **3.8 Data**

The data sources for this study were submitted monthly TOP - UP Pharmacy claims, GPHA Pharmacy drug purchase invoices and GPHA Pharmacy Formulary. For this study, TOP - UP Pharmacy claims and GPHA Pharmacy drug purchase invoices from January to September 2018 were reviewed. In doing so, the MEAN UNIT COSTS of drugs and their OUTSOURCE STATUS were extracted from the data sheets. This study involved a review of all the medication that met the inclusion criteria and thus did not require any sample size calculation and employed a record

review of TOP - UP Pharmacy claims and GPHA Pharmacy drug purchase invoices. Data collection was initiated by extracting secondary data from these primary data sources via the use of Microsoft Excel 2010.

#### 3.9 Quality control

Data extracted from the various data sources in this study was kept private during and after the period of data collection. Data would not be kept for more than 2 years. The research assistants that were employed in this study were trained a week prior to the commencement of data collection. Data extractions sheets were validated to correct any errors during the data collection. The extracted data was entered twice using Epi Info version 7.2.2.2. Furthermore, the data and as well as the data entry template were coded to prevent any typographical errors during data entry.

#### 3.10 Data analysis

Quantitative analysis of the mean unit cost of medications supplied based on outsource status was used to determine a difference to a statistically significant level. As such, a comparative cost analysis was conducted between the mean unit cost of outsourced formulary medications and the mean unit cost of matched purchased formulary medications. To do this, the GPHA PRICE (mean unit cost of matched purchased formulary medication) and TOP UP PRICE (mean unit cost of outsourced formulary medication) were determined for each medication using statistical software. The mean unit costs of all matched purchased formulary medications and outsourced formulary medications were compared to see if a statistically significant difference exists. This comparison was done using a Paired T - test using Stata version 15.0.

Descriptive analysis such as frequencies was conducted on the categorical variables of outsource status whiles, mean and standard deviation will be conducted on continuous variable of mean unit costs.

For this study, the inclusion criteria for formulary expansion was any drug with a total cost of at least the average cost per medication and a frequency of prescription of at least 72 prescriptions or 2 prescriptions per week over the study period.

#### 3.11 Ethical consideration

Ethical clearance was sought from the Ghana Health Service (GHS) Ethics Review Committee (ERC), and approval was granted with approval number GHS – ERC022/06/19, please refer to Appendix A.

#### **Approval**

An introductory letter was sought from the University of Ghana, School of Public Health to the Director of Port, Tema (GPHA) and the Director of Health Services, GPHA Clinic Tema to access the secondary data from the outsourced claims and purchase invoices used in this study.

#### Risk

The research posed minimum risk to Ghana Ports and Harbors Authority.

#### Possible benefits

The findings informed Ghana Ports and Harbors Authority Clinic, Tema, on the sustainability of outsourcing medication services. The results influenced policy in determining the size of the local formulary and the criteria for expanding the formulary in the future.

#### **Privacy and confidentiality**

The data received from the outsourced claims and purchase invoices during the study was protected with a two way authentication, that is, a request was sent to the Principal Investigator automatically

anytime an individual involved with the work attempted to access the data. Under no circumstance was information received shared with a third party. Hard copy data was kept in a cabinet under lock and key, accessible to the Principal Investigator only.

Personal data of individual in the extracted outsourced claims was not included. Individual information like name, contact numbers, employers and companies were excluded and deleted from the data set to ensure the identity of any person involved in the data would not be viewed.

#### Data storage and management

Secondary data collected for the study was stored on external hard disk drive, Google drive and Dropbox. Hardcopies and softcopies were burnt and deleted from all devices respectively after data had been analyzed.

#### **Conflict of interest**

The Principal Investigator had no conflict of interest.

#### **Funding**

The entire study was funded by the Principal investigator.

#### **Ownership**

GPHA remains the owner of the secondary data collected through its Outsourced Claims and Purchase Invoices and Receipts and has requested a copy of the study afterwards. Data collected was used solely for this study.

#### **CHAPTER FOUR**

#### **RESULTS AND FINDINGS**

#### Introduction

This chapter presents the analysis of data collected. The aim of this study was to assess the sustainability of outsourcing medication services at GPHA clinic.

## 4.1 Mean Cost of outsourced formulary medications and matched purchased formulary medications

The mean cost of outsourced formulary medications and matched purchased formulary medications is summarized in table 4.1 below. With reference to purchased formulary medications, the most expensive medicine was Nasonex nasal spray (GHS 88.05) and the least expensive was Rhizin tabs (0.04). Similarly, with respect to outsourced medications, the most expensive medications was Symbicort 160/4.5 Adult (GHS 200.5), and the least expensive was Zinc tab 20mg (GHS 0.15).

The mean unit costs of outsourced formulary medication was generally higher than matched purchased formulary medication. However, in the case of Aerius, Para infusion, Para 500mg tabs, Piriton syrup, Neo Hycolex eye drop, Chloramphenicol Eye Drop, Buscopan, Norvasc 10mg, Prednisolone and Wellman capsules purchased formulary prices were higher.

Table 4.1 Mean Cost of outsourced formulary medications (Top Up price) and matched purchased formulary medications (GPHA price)

Drug Name	GPHA	Top Up	Drug Name	GPHA	Top Up	Drug Name	GPHA	Top Up	
	Price	Price		Price	Price		Price	Price	
Advantan Cream	26.45	30	Diamicron 60mg Tab	2.7	3.04	Nucleo-Cmp Forte	1.57	3.48	
Aerius Syrup	53	65	Diclo-Denk 100 Supp	1.44	2.1	Olfen Gel 50g	13.77	13.77 20	
Aerius 5mg Tab	4.8	4.43	Dilatrend 12.5mg tab	1.44	2.1	Orelox 100mg Tab	4.88	6.95	
Aldomet 250mg Tab	1.39	2.71	Doreta tab	2.52	6.29	Otrivin Child	14.14	17	
Amoksiklav 457 Susp	13.5	22	Drez oint 10g	1.53	1.9	Para 500mg Tab	1.4	1	
Arthrosamine Cap	2	2.69	Elocom ointment	9	10	Para Inf Iv 1g	31.9	15.5	
Astymin Syr	16.4	18	Eurax cream 20g	30.02	44	Para-Denk Supp 250mg	1.2	1.8	
Atacand 16mg Tab	3.97	5.2	Evening Primrose 1g	15.55	17.03	Griseofulvin Susp	8.1	13	
Augmentin 1.2g Injection	18.5	23	Flagentyl Tab	4.08	5.75	Piriton Syrup	35	28	
Augmentin 457 Susp	32.87	40.5	Flucloxacillin 500mg U.K	0.65	0.89	Polygynax Pessaries	3.27	4.13	
Augmentin 625mg Tab	3.48	4.5	Furosemide 40mg	0.42	0.25	Prednisolone Tab 5mg	0.8	0.4	
Avamys Nasal Spray	38.88	58.11	Galfer Cap 30's	0.61	0.69	Pregnacare Plus Cap 1.23		2.87	
Benylin Chesty	23.39	29.5	Galfer Syr 100ml	28	46.48	Rhizin Tab 0.04		0.2	
Buscopan Tab 10mg Blist	1.19	0.47	Gastrone Susp 200ml	5.63	7.5	Scheriproct Supp	1.53	2.2	
Caduet 10/10mg Tab	5.21	9	Kombiglyze 2.5/1g	3.57	4.2	Symbicort 160/4.5 Adult	71.41	200.5	
Calci-D Denk	3.5	3.17	Lipitor 10mg Tab	2.91	4.8	Symbicort 80/4.5 Paed	48.23	107.5	
Calcium Vit D3 5000	1.77	3.53	Lyrica 75mg Cap	5.32	6.5	Ventolin Inhaler	24.46	29	
Celebrex 200mg Cap	4.45	6.2	Maalox Susp	29.62	35	Ventolin Nebules 5mg	5	5	
Chloramphenicol Eye Drop	5	4	Menthodex 200ml	15.64	23	Vermox Syrup	10.08	14.61	
Chloramphenicol Oint.	1.49	2	Menthol Crystals	13	17.56	Vermox Tab	5.09	7.25	
Cialis 20mg Tab	56.67	78.81	Metronidazole 200mg Tab	5.5	8.31	Vit B Denk Tab	0.76 1		

Coartem D 12s Tab	1.2	1.75	Nasonex Nasal Spray	88.05	118	Voltfast 50mg Sachet	1.15	2.2
coartem D 6s Tab	1.53	2.28	Neo-Hycolex Drop	15.5	15	Vomi 10 Supp	1.3	2.38
Crepe Bandage	1.3	1.25	Nexium 20mg Tab	3.65	4.6	Vomi 30 Supp	1.5	2.6
Crestor 10mg Tab	2.25	4	Nexium 40mg Inj	42.86	57	Wellman Cap	1.81	1.44
Crestor 20mg Tab	4.1	6.5	Nizoral Cream	16.18	25	Wellwoman 50+ Cap	1.29	2.2
Daktarin Cream	18.6	20.5	Nizoral Shampoo	15.33	24	Wokadine M/W	12	13
Dalacin C 150mg Cap	1.75	2.45	Norvasc 10mg Tab	5.49	5	Zincovit Syr	10.26	12.5
Decatylene Lozenges	0.94	1.4	Norvasc 5mg Tabs	3.38	5	Zinc Tab 20mg	0.18	0.15
Deep Freeze Spray	23.27	32	Nospa 40mg Tab	0.47	1	Zinnat 250mg Tab	3.37	4.8
Depo Medrol Inj	25	36.5	Novomix 30	59.77	89.72	Zyloric 100mg	0.87	1.7

Table 4.2 Comparative analysis between log mean unit cost of outsourced formulary medications and log mean unit cost of matched purchased formulary medications.

Variable	Observations	Mean	Standard error	Standard deviation.	95% CI	T(df)	p-value
Mean Log GPHA Price	93	1.58	0.15	1.49	1.27 - 1.89		
Mean Log Top Up Price	93	1.86	0.16	1.50	1.55 – 2.17	-7.55(92)	<0.0001
Difference	93	-0.28	0.04	0.36	-0.35 – -0.21		

# 4.2 Comparative analysis between log mean unit cost of outsourced formulary medications (Top up Price) and log mean unit cost of matched purchased formulary medications (GPHA Price).

A paired T-test was conducted on the log mean unit costs of outsourced formulary medications and matched purchased formulary medications to test the hypothesis that the mean unit costs of outsourced formulary medications were equal to matched purchased formulary medications. This revealed that the log mean unit cost of outsourced formulary medication (m=1.86, SD=1.50) was higher than that of matched purchased formulary medications (m=1.58, SD=1.49), t (92) =-7.55, p≤0.001, as such the Null hypothesis of equal mean unit costs was rejected. There was a negative value for difference of means;

Mean log GPHA Price – Mean log Top up Price = NEGATIVE VALUE, suggesting that Mean log of Top up Price > Mean log of GPHA price.

Prior to conducting the analysis, the assumption of normal distribution of the mean unit costs was examined. Initially mean unit cost values were not normally distributed as shown in figure 1 below, however transformation of the mean unit cost to log of mean unit cost satisfied the assumption of

normality, producing a skewness and kurtosis level of (0.4214) and (0.9668), respectively which showing normality as seen in Figure 2 below.

Also correlation between the two groups of prices was estimated at r = 0.97, p<0.001 further suggesting that the paired samples T-test is appropriate in this case. The last check for robustness of the Paired T-test for this case also was the sample size of greater than 30 (92).

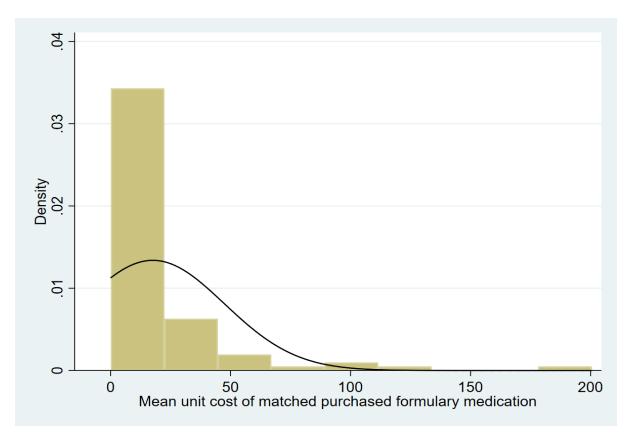


Figure 2 Normality of mean unit cost of matched purchased formulary medication

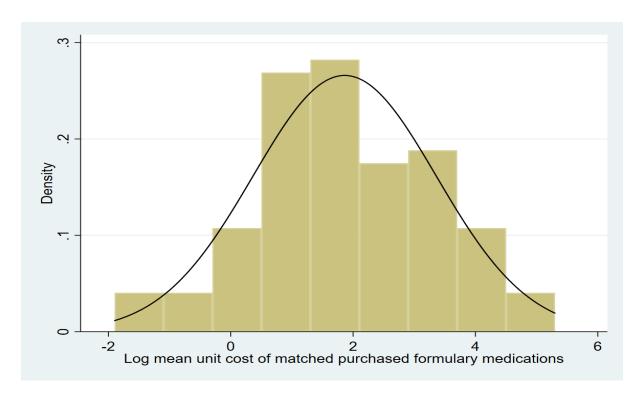


Figure 3 Normality of log mean unit cost of matched purchased formulary medication

### 4.3 Inclusion criterion for formulary expansion

The total cost of all outsourced medications over the study period was GHS 867,466.40, with GHS 237,788.60 (27.4%) and GHS 629,677.80 (72.6%) being the cost of outsourced formulary (outsource stat 1) and outsourced non-formulary (outsource stat 0) medications respectively. The number of outsourced non-formulary medications costing more than GHS 1000 was 137 representing 17.9% of the total number of outsourced non-formulary medications and costing GHS 502,232.70, representing 82.1% of the total cost of outsourced non-formulary medications (GHS 629,677.80) which were numbering 763. The most expensive outsourced non-formulary medication was Cialis 20mg tabs, costing GHS 75,225 (11.9% of the total cost of outsourced non-formulary medications) it was also the most prescribed medication (244 times or 6.8 prescriptions per week).

Table 4.3 Results of Analysis for formulary expansion

TOTAL COST OUTSOURCE STATUS 1 (STAT1)	GHS 237,788.60
TOTAL COST OUTSOURCE STATUS 0 (STAT0)	GHS 629,677.80
TOTAL COST OF OUTSOURCED MEDS	GHS 867,466.40
TOTAL COST OF STAT 0 ABOVE GHS 1000	GHS 502,232.70
TOTAL COST OF STAT 0 BELOW GHS 1000	GHS 127,445.10
NO OF STAT 0 ABOVE GHS 1000	137
NO OF STAT 0 BELOW GHS 1000	626
TOTAL NO OF STAT 0	763
% NO OF STAT 0 ABOVE 1000	17.9%
% COST OF STAT 0 ABOVE GHS 1000	79.8%

In this study, for a drug to meet the criterion for formulary expansion, its total cost should not exceed GHS 1000 (average cost per drug) and have an average of at least two (2) prescriptions per week or at least 72 prescriptions over the study period. With this, 82.1% of outsourced non-formulary medications cost below GHS 1000 while less than a fifth (17.9%) cost above GHS 1000 representing 79.8% of the total cost of outsourced non-formulary medications.

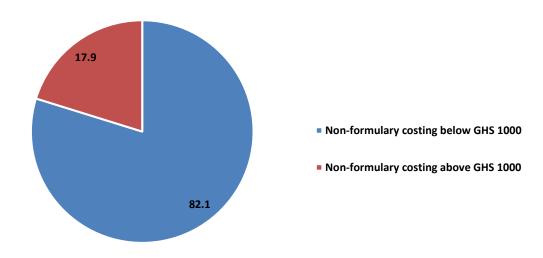


Figure 4 Criterion for formulary expansion

Table 4.4 Results for medications selected by inclusion criterion.

ITEM	NO OF PRESCRIPTIONS	TOTAL COST
BONJELA ADULT GEL	82	GHS 2,997.50
CIALIS	244	GHS 74,225.00
DOXYCYCLINE	107	GHS 1,713.80
OSTEOCARE CALCIUM	89	GHS 8,567.00
SAVLON BATH	83	GHS 2,986.00
TETMOSOL SOAP	106	GHS 1,742.00
WELWOMAN CAP	92	GHS 6,148.50

The above 7 medications in Table 4.4 were prescribed at least 72 times (at least 2 prescriptions per week) and also had a total cost of at least GHS 1000. These were selected from the number of outsourced non-formulary medication for formulary expansion. Of the remaining 130, Xarelto 10mg tabs, in total cost the highest (GHS 37,038) but was excluded because it was prescribed only 21 times over the study period.

#### **CHAPTER FIVE**

#### **DISCUSSION**

#### Introduction

This chapter presents the discussion, conclusion and recommendations of this study. The discussion explains the findings of the study. The conclusion presents a summary of the results obtained in the study. The recommendations provide suggestions derived from the results of the study, and areas around which this study can be improved.

#### **Discussion**

The results of this study show that the mean unit cost of outsourced formulary medications from Top up Pharmacy is relatively high, compared to the mean unit cost of matched purchased formulary medications at GPHA Pharmacy suggesting that the cost of procuring formulary medications is generally lower than the cost of outsourcing same medications to Top Up. Contrary to this finding, Marek et al, discovered up to about 13-17% cost saved due to outsourcing pharmacy services (Marek, Diallo, Ndiaye, & Rakotosalama, 1999). Similarly, Liu and colleagues revealed cost-effectiveness associated with outsourcing pharmacy services (Liu, Hotchkiss, & Bose, 2007). Again, Hodge identified an average of 6-12% cost saved due to outsourcing pharmacy services (Hodge, 2018). Paradoxically, some cost savings were realized compared to outsourcing of medication services at GPHA Clinic. The competitive tender process of procurement, as mandated by law, could have been a factor in bargaining for better prices. Additionally, bulk purchasing of a relatively fewer selection of formulary medications could be an influence on the lower cost of purchased formulary medication. Liu identified that due to National Health Insurance, hospitals in Taiwan incurred lower cost with pharmacy services (Liu et al., 2007).

Of course this perspective of costing is that of the Payer – GPHA, and as such does not take into account direct non-medical and indirect costs that the provider of the outsource service and patient may incur (Meltzer, M., 2001). The retail pharmacies are also conveniently located in key residential areas of clients reducing patient costs to acquire medication through outsourced pharmacies negligibly. It should be noted though, that the increased cost could be attributed to investments made by the outsourcing organization to improve its service to remain competitive such as hiring more staff to improve waiting times, monthly reminder cards for hospital visits and specialized counselling sessions for chronic patients - to mention a few. This notwithstanding, a key driver to most decisions on outsourcing services is to reduce cost of work force, materials, and resources (Kavosi et al., 2018).

Several studies have been conducted that have shown the benefits of outsourcing in the healthcare industry. Contractually, outsourced organizations are required to offer services at a lower price than the outsourcing organization for the service to be feasible (Billi et al 2007). Therefore although Top up may incur other charges in order to remain competitive, the organization is bound to perform the service in a cost effective manner and still at a positive margin.

As such, solely on the basis of a direct medical cost analysis, it is not possible to holistically determine the sustainability of outsourcing medication services at GPHA Clinic Tema. Outsourcing can then be considered as sustainable because 73% of outsourcing cost is still due to 800 non formulary medication which will be impractical to stock immediately.

According to Macinati (2008) healthcare institutions outsource to improve efficiency and lower cost bringing into focus that these benefits are not mutually exclusive. That is, an improvement in patient waiting times should not necessarily translate to higher costs of submitted claims, for

example. This is reiterated by Kavosi et al. (2018) that organizations consider costs saving as a criterion that informs their decision-making to outsource services.

However outsourcing of rarely prescribed medication (less than 2 prescriptions per week), that are impractical to purchase in – house due to low prescription rates as shown by the results, is still logical. Majority (85.4%) of the outsourced medications over the study period were non formulary costing 72.6% of the total cost of outsourced medication roughly confirming that the percentage cost contributed by these medications was significantly lower than their percentage quantity suggesting they are, as a whole, less expensive as the formulary medications that were outsourced. Hence the outsourcing process was beneficial in improving access to these medication services since it would be impossible to stock them at GPHA Clinic over the study period.

Conversely 14.6% of outsourced medication were from the local formulary representing 27.4% of the total cost of outsourced medications. This suggests that, nearly one-third of the total cost of outsourced medications were contributed by only one-sixth of the total number of outsourced medications (outsourced formulary medications). This phenomenon may be due to the outsourcing of medication from a 'vital few' of the local formulary. According to Pareto principle, for many events, roughly 80% of effects come from 20% of the causes (Bookstein, 1990). Applied roughly to the local formulary, it could be that 80% of the total cost can be attributed to 20% of the number of medications on the formulary. Outsourcing of medications from these 'vital few' could be a major contributor to rising cost of outsourcing medication services. Less than efficient inventory management of these 'vital few' medications could lead to stock outs and eventual disproportionately high quota contribution to the total cost of outsourced medication, when outsourced.

We should be mindful of the fact that customer preferences for medications are variable, and keep changing. Healthcare institutions need to be flexible and responsive to this variability of client needs (Kremic et al., 2006). Changes in prescribing patterns and prescriber preferences for certain brands of medication may also be a possible cause of this problem. A non-commensurate increase in procurement volumes to match increasing consumption patterns of such medications could be due to procurement inefficiency and a factor in resolving stock outs of preferred brand medications - which tend to be more costly than generic medications. An ABC analysis of inventory could be applied to enable tighter control of these 'vital few' from the 'trivial many' medications of the formulary to reduce cost of inventory, and prevent unnecessary outsourcing of medications (Gandhi P., 2000). This leads to consideration for generic substitution of prescribed brand medications, where necessary to mitigate the increase in number of outsourced prescriptions. This is critical in ensuring that the limited resources are appropriately utilized so as not to jeopardize the sustainability of outsourcing medication services. Of course a comprehensive review of key cost and performance elements of the outsourcing contract would not be out of place. Further studies could be conducted to investigate these scenarios in the future.

Again an inclusion criterion was established to gradually expand the local formulary to reduce the quantity of outsourced medication and its attendant costs. Parrish (2018), defined a formulary as "the product of an evaluative process of the formulary process conducted by an expert panel that both sanctions and guides the selection, prescription, administration and monitoring of pharmaceuticals". By this definition, a multidisciplinary team of health professionals must comprise the Drugs and Therapeutics committee to manage the local formulary and influence the procurement process to effectively decrease outsourcing of vital medication and propose generic substitutes in the event of stock outs to reduce the number of outsourced formulary medications.

Jelacic and colleagues discovered that hospital pharmacy drugs were relatively cheaper compared to outsourced drugs (Jelacic et al., 2017), supporting the need to include more medications in the procurement process at GPHA Pharmacy through the deliberate expansion of the local formulary.

This study sought to establish an inclusion criterion for formulary expansion and to determine outsourced non-formulary medications that meet this criterion. It was decided that for a drug to meet the criterion for formulary expansion, it had to have been prescribed at least 72 times (at least 2 prescriptions per week according to practice) and cost a total of at least GHS 1000 (approximated average cost per medication outsourced). Hence the criterion for selection was to balance out usage of medication with their inherent costs when outsourced. Again this distribution followed Pareto principle in that, 17.9% of the outsourced non-formulary medication contributed 79.8% of the total cost of outsourced non-formulary medications (Bookstein, 1990).

Of the seven (7) medications that were selected by this criterion, Cialis 20mg tabs was the most frequently outsourced, and contributed the highest total cost of any individual medication. Cialis is used to treat erectile dysfunction and benign prostatic hyperplasia (Joint Formulary Committee, 2016). As such it is critical as an adjunct in order to encourage compliance in the management of hypertension in the predominantly male population of GPHA workers. This explains its frequent prescription further enforcing the need to include it on to the local formulary. Again, there were a number of medication that cost above GHS 1000 like Xarelto 10mg Tabs, but were excluded due to a low prescription rate although it had a high unit cost. It shows the budgetary impact of not just cost but the frequency of prescription of a single medication out of 892.

The results of this study suggests that, although outsourcing of medication services may still be sustainable in the GPHA Clinic setting, it may not necessarily be as cost effective as outsourcing other aspects of healthcare provision. Liu identified 94.6% effectiveness in outsourcing medical

waste services (Liu et al., 2007). Also, this study has suggested that hospitals should be wary of hasty decisions to outsource medication services, according to Guy and Hill, due to some misconceptions that may mislead healthcare facilities in making decisions for outsourcing services (Guy & Hill, 2007). Outsourcing services have proven to cut down cost with human resource management, acquisition of new instruments and improved efficiency (Hsiao et al., 2009). However, the results of this study have shown that hospital-based pharmacies can provide more cost-effective medication services than when outsourced. Other alternatives to outsourcing pharmacy services to cut down cost can be employed, including consolidating pharmacy services provided in healthcare facilities (Douglass & Kastango, 2013).

#### **CHAPTER SIX**

### CONCLUSION AND RECOMMENDATIONS

### **6.1 Conclusion**

The cost of procuring similar medications within the same time period is less expensive than the cost of outsourcing same at Top up Pharmacy. Despite this, sustainability of the outsourcing of medications is not predicated on only cost of medication but ability to procure a wider range of medications to be included on the local formulary. Currently, GPHA pharmacy does not have the infrastructural and administrative capacity to procure the required medication that were outsourced over the study period, although based on the study it can do so at a lower cost. The inclusion criterion for formulary expansion is therefore very much critical to continuously update the local formulary with vital medication to reduce cost of outsourcing thereby making it more sustainable.

#### **6.2 Recommendations**

This study sought to assess the sustainability of outsourcing medication services primarily through comparative cost of medication.

- A review of cost of the outsourcing process could be performed to investigate other elements contributing to the higher outsourced cost of medication at Top Up, such as direct non-medical and indirect costs.
- Administrative and procurement processes should be evaluated by GPHA Clinic to identify
  lapses and reorganized to prevent stock outs, especially of frequently prescribed or 'vital
  few' medications that may incur higher cost if outsourced.
- 3. The process of formulary expansion should be facilitated by the Drugs and therapeutic Committee and the Procurement Department, to timeously add on to the formulary, medications that meet the established inclusion criterion.

4. Further studies to evaluate patient satisfaction, prescriber preference and other causes of changes in prescribing patterns could enrich present knowledge on the outsourcing of medication services.

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#### APPENDIX A

### GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

In case of reply the number and date of this Letter should be quoted.



Research & Development Division Ghana Health Service P. O. Box MB 190 Accra GPS Address: GA-050-3303 Tel: +233-302-681109 Fax + 233-302-685424

Email: ghserc@gmail.com

26<sup>th</sup>July, 2019

MyRef. GHS/RDD/ERC/Admin/App Your Ref. No.

Kofi Frimpong Prempeh P.O Box SR 114 Spintex Road Tema

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of

your study r rotocor.	
GHS-ERC Number	GHS-ERC022/06/19
Project Title	Assessing the Sustainability of Outsourcing Medication Service at Ghana Ports and
	Harbors Authority Clinic, Tema
Approval Date	26 <sup>th</sup> July,2019
Expiry Date	25 <sup>th</sup> July, 2020
GHS-ERC Decision	Approved

#### This approval requires the following from the Principal Investigator

- Submission of yearly progress report of the study to the Ethics Review Committee (ERC)
- Renewal of ethical approval if the study lasts for more than 12 months,
- Reporting of all serious adverse events related to this study to the ERC within three days verbally and seven days in writing.
- Submission of a final report after completion of the study
- Informing ERC if study cannot be implemented or is discontinued and reasons why
- Informing the ERC and your sponsor (where applicable) before any publication of the research findings.
- Please note that any modification of the study without ERC approval of the amendment is invalid.

The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Kindly quote the protocol identification number in all future correspondence in relation to this approved protocol

SIGNED..... DR. CYNTHIA BANNERMAN (GHS-ERCCHAIRPERSON)

Cc: The Director, Research & Development Division, Ghana Health Service, Accra