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IRRATIONAL USE OF ANTIBIOTICS IN CHILDREN UNDER FIVE IN COMMUNITY PHARMACIES IN THE ACCRA METROPOLIS DISTRICT

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DECLARATION

I, Kate Damaris Coleman, hereby declare that, with the exception of cited literature, this dissertation is the result of my own original research and this has not been presented elsewhere either in part or in whole for purposes of the award of another degree.

……...	……..
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……..	……..
DATE	**DATE**

DEDICATION

I humbly dedicate this work to my Mother, Grandmother and Brother, Madam Patience Adoley Brown, Madam Henrietta Odofoley Malm and Carl Hugh Coleman.

ACKNOWLEDGEMENT

I am eternally grateful to the Almighty father for the gift of life and strength to complete this program successfully.

I would like to thank my supervisor Dr Ernest Maya for his guidance, support and constructive criticism to make this work a success. I am really grateful. My sincere gratitude goes to my family especially my mother and brother for their immense consideration, support, prayers and thoughtfulness during this period. May God bless you.

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ABSTRACT

Introduction: Antibiotics are by far the most common drugs administered to children. They account for about one-fourth of all medications administered to children, with a third of its use in children considered unnecessary. Due to the lack of education of both healthcare professionals and the general population, antibiotics are commonly used to treat a variety of viral infections including: the common cold, cough, sore throat and acute watery diarrhoea in children. Irrational use of antibiotics has long term consequences for children‟s health and could predispose them to early onset diabetes, hypertension and obesity. This study therefore seeks to examine factors associated with the community pharmacist‟s role in the irrational use of antibiotics in children under five in the Accra Metropolis.

Objective: To examine factors associated with the community pharmacist‟s role in the irrational use of antibiotics in children under five.

Method: A cross sectional study using a quantitative approach. It was conducted by administering questionnaires to pharmacists and pharmacy assistants at community pharmacies. Mystery clients were trained and sent to randomly selected community pharmacies. Bivariate analysis using chi-square test was used to assess the association between different characteristics of the respondents and antibiotic use in children. Logistics regression was done to determine strengths of association between the variables. The findings were reported with a 95% confidence interval and with a level of statistical significance set at $p<0.05$ for all tests.

Results: Findings suggest that 66.0% of pharmacy workers dispense antibiotics without prescription to parents/guardians in community pharmacies. Differences between professional categories and dispensing of antibiotics without a prescription were not statistically significant

(p=0.863). The most common antibiotics used irrationally in the treatment of self-limiting conditions were amoxicillin clavulanic acid and amoxicillin which are penicillin antibiotics. However, knowledge of classification of drugs (p=0.007) according to the FDA‟s reviewed drug classification list and demand for antibiotics by parents/guardians (p= 0.013) showed a significant association with respect to whether a pharmacist will dispense antibiotics without a prescription to parents/guardians of children under five years.

It was found out that about 39% of pharmacy workers in the mystery client survey who dispensed antibiotics without prescription to clients declined to dispensing antibiotics without prescription in the questionnaire.

Conclusion: Dispensing antibiotics for the treatment of self-limiting conditions in children under five is a common practice by pharmacy workers in the community pharmacies. Lack of knowledge that antibiotics are not part of prescription only medications and the demand for antibiotics from parents/guardians are the driving forces for people dispensing antibiotics irrationally in children under five.

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LIST OF ABBREVIATIONS

WHO – World Health Organisation

STG – Standard Treatment Guidelines

OTC – Over the counter

AMA – Accra Metropolitan Area

FDA – Food and Drugs Authority

POM – Prescription Only Medication

MCA – Medical Counter Assistant

LIST OF DEFINITIONS

"Antibiotics" means drugs used to treat bacterial infections.

"**Antimicrobial agents"** means an agent that kills or inhibits the growth of microorganisms.

"**Gut microbiota**" also known as gut flora refers to the microbe population living in the intestine.

"Dysbiosis" means the condition of having imbalances in the microbial communities either in or on the body.

CHAPTER ONE

INTRODUCTION

1.1 Background

The discovery of naturally occurring antimicrobial agents was the major breakthrough in the treatment of infectious diseases. Antibiotics are among medicine"s most powerful tools and have revolutionized the treatment of common bacterial infections (Adedeji, 2016). Antibiotics play a crucial role in reducing child mortality in low- and middle-income countries and they now constitute the single largest group of drugs purchased (Larsson et al., 2000). The more frequently antibiotics are used, the more they promote bacterial resistance that undercuts their effectiveness (Steinman, Gonzales, Linder, & Landefeld, 2003).

Over several decades and to varying degrees, bacteria which cause common infections have developed resistance to many new antibiotics, representing a worldwide health threat (Prestinaci, Pezzotti, & Pantosti, 2015). In recent studies conducted by the World Health Organization (WHO), it was discovered that few antibiotics are under development to combat the threat of multi-drug resistant infections and the speed of increasing resistance will gradually outpace the slow drug development process (WHO, 2017). Even though the judicious use of antibiotics can still result in the emergence of antibiotic-resistant bacteria, inappropriate use greatly accelerates this process (Bahnassi, 2016).

Rational use of antibiotics requires that "patients receive antibiotics appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community" (Chambers, 2011). Irrational use of antibiotics refers to dispensing antibiotics in disease conditions where they may not be deemed necessary

such as in common ailments like the common cold and watery diarrhoea of viral aetiology. The Standard treatment guidelines (STG) in Ghana states that antibiotics are not required in the treatment of diarrhoea that is of viral etiology: when diarrhoea is present with vomiting, low grade fever and with no mucus in stools. The STG further states that oral rehydration therapy with zinc tablets should be used in the management of acute diarrhoea of viral etiology in children under five (STG, 2010). In the treatment of acute diarrhoea in children, antibiotics may be more profitable than more rational treatment such as zinc or oral rehydration solution, hence community pharmacists tend to give out antibiotics, not following the recommended guidelines (Löfgren, Tao, Larsson, Kyakulaga, & Forsberg, 2012). The common cold is a common viral infection of the nasopharyngeal mucosa and is contagious and is spread by airborne droplets. The symptoms resolve without antibiotic treatment within a week. The STG recommends oral paracetamol 10-15 mg/kg/dose 6-8 hourly and Sodium Chloride 0.9%, nasal, 2 drops, into each nostril, to relieve congestion as required for the management of common cold in children(STG, 2010). However, antibiotics are usually used in the management of common cold in children under five (Togoobaatar et al., 2010).

The repeated use of antibiotics in children in the treatment of self-limiting conditions in children leads to the emergence of more resistant bacteria as a result of continuous exposure to antibiotics (Bahnassi, 2016). Children are at a higher risk as compared to adults by the threat posed by antibiotic resistance. This is due to the high vulnerability of children to bacterial illness than are adults and is evident in their higher disease rates (Shea, Florin, & Barlam, 2001) which can be attributed to their high tendency to be exposed to more disease-causing bacteria through day-to-day activities such as childcare and mouthing behaviours (Guest & President, 2009). There has been a decrease in infant mortality over the years due to the availability of effective antibiotics

but then many therapeutic medications have not been approved for use in children, in part because metabolic differences between children and adults can make use of certain drugs impractical or unsafe for children. For example, tetracycline binds to immature calcium structures and it permanently disfigures enamel in the teeth of children. Similarly, fluoroquinolones, a powerful class of Cipro-related drugs used to treat serious infections, can damage immature cartilage in bones and joints (Guest & President, 2009). If antibiotic resistance further depletes the number of effective drugs available, sick infants and children will have even fewer treatment options. The vital organs of children such as the liver and kidney which are responsible for drug metabolism are not well developed and a high rate of antibiotic use might impede their development and prompt significant issues for clinical treatment (Bi, Tong, & Parton, 2000).

Community pharmacies are usually the first point of call for many individuals seeking primary health care services for common ailments in Ghana (Buabeng, 2010). Studies from Peru suggest that irrational use of antibiotics in children in community pharmacies could be attributed to a number of factors such as inadequate regulation of the distribution and sale of antibiotics in community pharmacies, commercial interest of pharmacists, educational level and tendency to demand antibiotics on the part of patients, inadequate knowledge of antibiotics as well as over stock and near expiry of antibiotics promoted antibiotic misuse (Salim & Elgizoli, 2017).

Sustainable intervention programmes must be developed to promote rational use of antibiotics in the country.

1.2 Problem statement

Antibiotic misuse leading to antibiotic resistance is a major public health concern in most parts of the sub-Saharan Africa including Ghana (Asante et al., 2017). Findings suggest that about half (50%) of antibiotics purchased worldwide are dispensed without a valid prescription from community pharmacies (WHO, 2011). Studies from Vietnam, China and Mongolia indicate that between 12% - 42% of antibiotics used in children under five are obtained without a prescription from community pharmacies (WHO, 2011).

Studies conducted among tertiary students in the Accra metropolis showed that, about 30% of tertiary students in Accra take an antibiotic within a month and 70% of the respondents in the study obtained the antibiotics without a prescription from community pharmacies (Donkor, Tetteh-Quarcoo, Nartey, & Agyeman, 2012). No previous studies in Ghana have investigated the irrational use of antibiotics in children under five in community pharmacies in the Accra metropolis district.

Due to poor drug regulation, data on antibiotic consumption patterns in Ghana is limited although antibiotics remain readily available in pharmacies across the country and can easily be obtained without authorization from a qualified prescriber (Mensah & Ansah, 2016).

Frequent use of antibiotics with or without a valid prescription could lead to resistance but then the frequent use of antibiotics without a prescription is often associated with insufficient treatment durations and inappropriate drug and dose selections (Bahnassi, 2015). Children are particularly prone to high rates of antibiotic use as many parents‟ demand antibiotics for conditions of viral aetiologies (WHO, 2012). Majority of antibiotics given out to children in community pharmacies are for self-limiting conditions such as upper respiratory tract infections

and acute diarrhoea which have viral aetiologies (Lucie Ecker, Ochoa, Vargas, Valle, et al., 2013).

Irrational use of antibiotics has long term consequences for children‟s health such as early childhood obesity when repeatedly exposed to broad-spectrum antibiotics at ages 0 to 23 months due to changes to the gut microbiota (Bailey et al., 2014). Antibiotic-induced gut microbiota dysbiosis dramatically modifies the development of the immune system as well as glucose and lipid metabolism which could predispose children to early onset diabetes, hypertension and obesity (Principi & Esposito, 2016). Studies also show that antibiotic use in the first year of life is associated with an increased risk of early-onset childhood asthma and allergies (Risnes, Belanger, Murk, & Bracken, 2011).

This research seeks to provide data on the factors associated with the irrational use of antibiotics in children under five in community pharmacies in the Accra metropolis.

1.3 Conceptual Framework

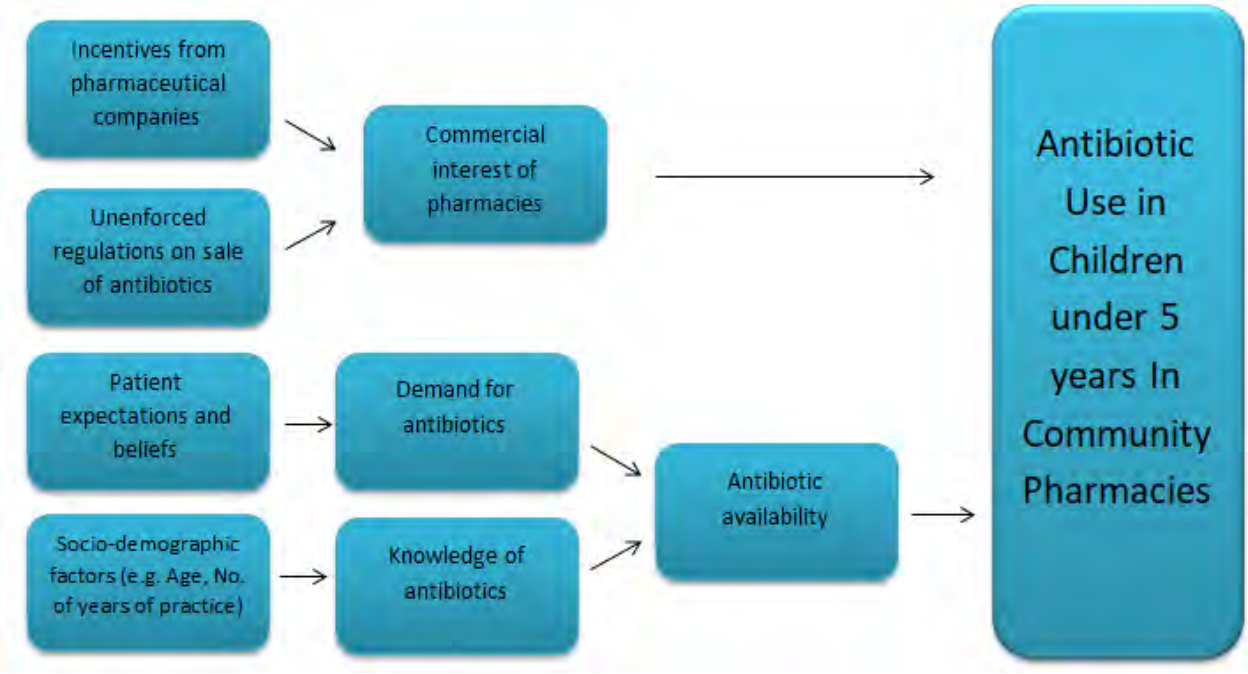

Figure 1.1: Conceptual framework depicting potential factors that may influence irrational use of antibiotics in children under 5 years in community pharmacies.

The conceptual framework aims to explore factors that may influence the rational use of antibiotics in children under 5 years in community pharmacies.

Antibiotics should not be readily accessible over the counter and must be dispensed to patients with a prescription. However a number of possible factors influence the pharmacist‟s decision to give out antibiotics over the counter without a valid prescription from a prescriber. Socio-demographic characteristics such as age, educational background and qualification, number of years of practice and knowledge of antibiotics are very likely to affect the Pharmacist‟s or Pharmacy assistant‟s decision towards the use of antibiotics in children under five (Hadi et al., 2016) .

Studies from American, Asian and European countries indicate that between 22% and 70% of parents tend to have expectations and beliefs towards the use of antibiotics in the treatment of minor ailments in their children due to misconceptions about appropriate applications and efficacy of antibiotics hence tend to demand for them in community pharmacies (WHO, 2011). Unenforced regulations on the sale of antibiotics and incentives from the pharmaceutical company play a role in the misuse of antibiotics in children by influencing the commercial interest of the pharmacies (Salim & Elgizoli, 2017).

In Ghana, regulations on the sale of antibiotics are not strictly enforced hence community pharmacists and assistants tend to give out antibiotics to parents without a prescription for the financial benefit of the pharmacy. Studies from countries like Ethiopia and Bangladesh show that pharmaceutical companies influence prescribing patterns (Workneh et al., 2016). Incentives are given to community pharmacists by these pharmaceutical companies to influence them to sell more of their branded drugs (Biswas & Ferdousy, 2016). This is a probable factor which may influence the pharmacist‟s decision in the misuse of antibiotics in children under five as they tend to sell more of the branded antibiotics as a result of incentives received.

1.4 Justification

Pharmacies serve as a first source of healthcare for people throughout the world, particularly in low income and rural area. Data available from previous research shows that community pharmacists and pharmacy assistants sell antibiotics readily over the counter (L. Ecker, Ochoa, Vargas, Del Valle, & Ruiz, 2013). The frequent use of antibiotics in children under five comes along with many health consequences as well as antibiotic resistance.

Dispensing antibiotics depends on the attitude of each pharmacist. This study aims at investigating the factors associated with the irrational use of antibiotics in children under five in community pharmacies in the Accra metropolis. The findings of this study will be useful to the Accra metropolis, Greater Accra and the country as a whole. The results generated will also inform policy makers and health educators to implement, monitor and evaluate relevant policies that further improve the rational use of antibiotics. This might further prevent or reduce the irrational use of antibiotics in children in community pharmacies which will in turn prevent antibiotic resistance and the associated health consequences of antibiotic misuse in children like the early development of obesity which leads to chronic conditions like diabetes and hypertension in children. Pharmacists and pharmacy assistants would also benefit from the research as they would be given a clear picture of the current situation.

1.5 Research Questions

1. What are the factors that influence pharmacist‟s decision in prescribing antibiotics in children under 5years?
2. What types of antibiotics are used in the management of self-limiting conditions in children under 5 years in community Pharmacies?

1.5.1 General Objectives

To examine factors associated with the community pharmacist‟s role in the irrational use of antibiotics in children under five.

1.5.2 Specific Objectives

1. To determine the proportion of pharmacists who dispense antibiotics for children under five without prescription
2. To describe the types of antibiotics which are commonly used in the management of self-limiting conditions in children under five.
3. To determine factors that influence pharmacist‟s decision in prescribing antibiotics in children under five in community pharmacies.

CHAPTER TWO

LITERATURE REVIEW

2.0 Introduction

This chapter reviews relevant literature appropriate to the study topic. Major areas to be covered include: Irrational use of antibiotics in children and Community Pharmacy practices.

2.1 Irrational use of antibiotics in children

Antibiotics are by far the most common drugs administered to children (Chai et al., 2012) and they account for about one-fourth of all medications administered to children, with a third of its use in children considered unnecessary (Prestinaci et al., 2015). During the last few decades, irrational use of antibiotics has become an emerging high priority global health topic, affecting high, middle and low-income countries (Prestinaci et al., 2015).

Due to the lack of education of both healthcare professionals and the general population, antibiotics are commonly used to treat a variety of conditions including: viral infections, the common cold, and acute watery diarrhoea in children. Antibiotic resistance due to irrational use of antibiotics in most community pharmacies is a major public health challenge (Zapata-Cachafeiro et al., 2014). There has been documentation in relation to irrational use of antibiotics worldwide. World Health Organization (WHO) estimates that about 50% of all medications are inappropriately prescribed, dispensed or sold. More than half of patients fail to take their prescribed antibiotics correctly and many fail to complete the course of antibiotics. Incorrect use may take the form of overuse, underuse and misuse of prescription or non-prescription medicines. Rational use of medicines means that "*patients receive medication appropriate to*

their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community". Access to affordable health care is limited in many low and middle income countries; hence people rely, to a large extent, on self-medication and buying antibiotics directly from pharmacies, street vendors or markets (Gwimile, Shekalaghe, Kapanda, & Kisanga, 2012). Dispensing antibiotics without prescription is a major contributing factor in the irrational use of antibiotics in children leading to the development of antimicrobial resistance. It leads to treatment failures causing deaths and an increase in use of more costly antibiotics (Santa-Ana-Tellez, Mantel-Teeuwisse, Dreser, Leufkens, & Wirtz, 2013).

Studies show that antibiotics are prescribed to 76% children, although many children have no need of it(Hameed & Naveed, 2016). As is the case for most diseases, children under five are considered one of the major risk groups for antibiotic resistance, because of their underdeveloped immune system, great exposure to disease-causing bacteria and being subject to age-inappropriate medication(Lucie Ecker, Ochoa, Vargas, Del Valle, & Ruiz, 2013).

In an attempt to manage antibiotic resistance at the national level, countries are implementing different policy approaches and guidelines to combat the spread of resistant bacteria. A commonly used strategy is control through restricted market access for medications such as antibiotics, meaning that citizens are not able to purchase antibiotics over the counter (OTC) without prescription. Nonetheless, many countries, in particular low- and middle-income countries like Ghana are not following this trend (Mohrs, 2015).

Infants and young children are at increased risk for adverse effect from bacterial infections for three reasons. First, their immune systems are not yet fully functional; second, they are exposed to numerous pathogens because of their behaviour patterns and third, some antibiotics that have

been approved for use in adults are not appropriate for use in children(Shea, Florin, & Barlam, 2001).

Antibiotics alter the gut microbiota and since the gut microbiota is important in host immune development, nutrient absorption, and protection from pathogens, changes in the community composition could have deleterious effects on the host (Schulfer & Blaser, 2015). The spectrum of diseases for which an altered gut microbiota has been implicated is quite broad. The imbalances in gut microbes, called dysbiosis, have been tied to infectious diseases, allergies, asthma and other autoimmune disorders, and even obesity (Vangay, Ward, Gerber, & Knights, 2015).

2.1.1 Antibiotic use and childhood asthma

Asthma is a chronic disease characterized by recurrent attacks of breathlessness and wheezing, which vary in severity and frequency from person to person (WHO, 2013). Asthma is one of the most common chronic diseases of childhood, affecting an estimated 1 in 4 urban children in the developed world (Risnes, Belanger, Murk, & Bracken, 2011). Several environmental and genetic factors have been identified as risk factors for asthma and asthma exacerbations, including early life risk factors such as antibiotic exposure (Ahmadizar et al., 2017).

Over 80% of asthma deaths occurs in low and lower-middle income countries (WHO, 2013). The WHO estimates an asthma country incidence rate of 1.5/1000 per year for Ghana compared to rates as low as 0.3/1000 per year for countries such as Greece and 2.8/1000 per year for Wales and New Zealand (Who, 2009).

The prevalence of asthma has doubled in developed countries over the last 30 years and the concurrent increase in children‟s antibiotic use led to speculation of a possible causal relationship (Freels, Chavez, & Hernandez, 2015). Although a number of published studies have tested this hypothesis, the results have been conflicting. Several factors might have accounted for contradictory findings, including study design, the definition of asthma, and the age at which asthma was assessed (Semic-Jusufagic et al., 2014).

Studies conducted by Ortqvist et al., 2014, dismissed previous claims that there is a link between the increased use of antibiotics in society and a coinciding rise in childhood asthma. The study proposed a causal link to respiratory infections increasing the risk of asthma, regardless of whether or not they are treated with antibiotics as well as other factors like genetics, home environment and lifestyle (Ortqvist et al., 2014).

Recent studies reported that antibiotic use is associated with an increased risk of childhood asthma. However, asthmatic children who were exposed to antibiotic early in life did not have a higher risk of asthma exacerbations (Ahmadizar et al., 2017). The adverse effect of antibiotics on asthma risk was particularly strong in children with no parental history of asthma (Risnes, Belanger, Murk, & Bracken, 2011). A broader understanding is that microflora, especially gastrointestinal flora, are important for developing a healthy immune system with resistance to allergic sensitization, therefore antibiotic exposure in early life could increase the risk of atopic diseases through altered microbial exposure (Teo et al., 2015). Increased antibiotic use in infancy has been suggested to limit exposure to gastrointestinal microbes, hence causes a response that leads to an increase in inflammatory markers, which then leads to asthma and allergies in later life (Ong, Umetsu, & Mandl, 2014).

Children with asthma are more likely to develop a range of health and social problems as they enter into adulthood. Studies from Canada found that children with asthma have a 12 percentage point higher risk of adult obesity and this may be due to certain lifestyle choices adopted in childhood such as avoiding routine or vigorous exercise in order to avoid triggering asthma attacks (Marra et al., 2009).

2.1.2 Antibiotic use and childhood obesity

The incidence of childhood obesity is rising across the globe, and obesity related co-morbidities are increasing concomitantly in the paediatric population and irrational antibiotic has been discovered to be strongly associated with increased risk of early development of obesity in children(Lee, 2009). Obesity may be described as a physical condition characterised by excessive deposition or storage of fats in adipose tissues. Obesity usually results from consumption of foods in excess of physiological needs(Mohammed & Vuvor, 2012).

In 2010, 43 million children (35 million in developing countries) were estimated to be overweight and obese with 92 million at risk of becoming overweight. The worldwide prevalence of childhood overweight and obesity increased from 4.2% in 1990 to 6.7% in 2010 and this is expected to reach 9.1% or 60 million, in 2020. The estimated prevalence of childhood overweight and obesity in Africa in 2010 was 8.5% and is expected to reach 12.7% in 2020 (WHO ,2011). In 2016, an estimated 41 million children under the age of 5 years were overweight or obese. In Africa, the number of overweight children under 5 has increased by nearly 50 per cent since 2000 (WHO, 2017).

This problem is particularly relevant in children because they are frequently treated with antibiotics. Exposure to antibiotics during the first 6 months of life is associated with increase in body mass and an increased risk of being overweight (Mensah & Ansah, 2016). Repeated use of antibiotics may have an impact on the intestine and may cause antibiotic-induced gut microbiota dysbiosis which dramatically modifies the development of the immune system as well as glucose and lipid metabolism which predisposes children to early onset obesity (Prestinaci et al., 2015). Childhood obesity is associated with a higher chance of obesity, premature death and disability in adulthood. In addition to increased future risks, obese children experience breathing difficulties, increased risk of fractures and psychological effects (WHO, 2017). Obesity is also associated with cardio metabolic outcomes such as type 2 diabetes mellitus, hyperlipidemia, hypertension, and other long-term consequences. No age group is spared, with 10% of children obese by 24 months of age (Bailey et al., 2014). Comorbidities often affect children before they reach adulthood, requiring increased diligence in evaluating and treating these conditions and leading to increased healthcare expenditures. The personal and emotional face of childhood obesity is also serious: daily quality of life can be significantly worsened by obesity. The psychosocial complications of obesity include depression, body dissatisfaction, unhealthy weight control behaviours, stigmatization, and poor self-esteem (Brown, Halvorson, Cohen, Lazorick, & Skelton, 2015).

2.2 Community pharmacy practices

The mission of pharmacy practice is to contribute to health improvement and to help patients with health problems to make the best use of their medicines (WHO, 2014). One of the main aims of the pharmacy profession is promoting safe and rational use of drugs. In many developing

countries, retail pharmacies serve as a vital primary source of medical advice. Community pharmacies are often the most accessible and available healthcare outlets in many communities(Smith, 2015). Retail pharmacy practice is poorly developed in most developing countries and the practice of prescribing and dispensing is not distinct and clearly separated. This breeds conflict of interest and promotes irrational antibiotic prescribing and usage (Agarwal, Yewale, & Dharmapalan, 2015).

Research has shown that irrespective of the fact that a prescription from a qualified physician is prerequisite for the dispensing of certain medicines, pharmacists and other pharmacy assistants are increasingly selling these drugs over the counter(Lexchin, 2010). Pharmaceutical marketing can substantially influence attitudes, beliefs, and behaviours of community pharmacists towards the irrational use of antibiotics. Such marketing promotes the use of patented, and thus lucrative, medications(WHO, 2014). There are many factors that may contribute to the wide spreading of this practice including, lack of pharmacist‟s knowledge, poor legislations enforcement on community pharmacy practice, demand of antibiotics by patient, financial incentives from the pharmaceutical industry and the business nature of the pharmacy (Bahnassi, 2015).

2.2.1 Knowledge and attitudes of dispensing antibiotics without prescription

It has been estimated that more than 50% of the antibiotics worldwide are sold without a medical prescription (Goossens, Ferech, Vander Stichele, & Elseviers, 2005). The phenomenon of dispensing antibiotics to children without a prescription is not only common in low-income countries, but is also common in the developed world. Studies from several European and South

American countries, including Spain, Greece, Portugal, Mexico, and Brazil, have reported this malpractice (Hadi et al., 2016).

A study conducted in Saudi Arabia showed that more than two-thirds (70.5%) of the pharmacists who participated in the study were not aware of the fact that dispensing antibiotics without prescription was illegal and this could be linked to the poor understanding of the regulations prohibiting the over the counter sale of antibiotic by community pharmacists in the country (Bahnassi, 2015).

It is common practice in many community pharmacies to dispense antibiotics on demand from the patient or customer even though a valid prescription from a registered medical provider is not available (Rathnakar, Sharma, Garg, Unnikrishnan, & Gopalakrishna, 2012). Medical prescribing is influenced by patients' expectations and a similar pattern of behaviour could well arise in the dispensing process in community pharmacies, where patients are more prone to use antibiotics even for treating minor complaints and/or viral illnesses(Zapata-Cachafeiro et al., 2014). The most common reason cited by the community pharmacists for this malpractice was fear of losing a customer, as the customer would have obtained antibiotics from any other pharmacy(Al-Mohamadi, Badr, Bin Mahfouz, Samargandi, & Al Ahdal, 2013).

A community-based survey from Mongolia revealed that self-medication of antibiotics was common, particularly for childhood illnesses, and was driven by widespread misperceptions that antibiotics can „cure“ viral illnesses (WHO, 2011).

2.2.2 Poor legislation enforcement on the sale of antibiotics

In many African, Asian and Latin American countries, antibiotics are readily available on demand from pharmacies, drug stores, roadside stalls and hawkers (Rathnakar et al., 2012).

The sale of antimicrobials is largely unregulated, without involvement of a licensed trained pharmacist, and is often without prescription(Morgan, Okeke, Laxminarayan, Perencevich, & Weisenberg, 2011). Several other simulation studies conducted in Spain and Brazil have shown that antimicrobial agents could be easily obtained in spite of regulations prohibiting such practice (Al-Faham, Habboub, & Takriti, 2011).

One of the reasons for antibiotic misuse may be its widespread availability and poor oversight by community pharmacies(Togoobaatar et al., 2010).

2.2.3 Commercial interests of pharmacies

A study conducted in Spain showed that pharmacists who believe that patient would find the antibiotic at some other pharmacy increase the probability of dispensing antibiotics without prescription, probably to foster customer loyalty or for fear of losing the sale (Zapata-Cachafeiro et al., 2014). Personnel in charge of most pharmacies and drug stores are predominantly businessmen rather than professionally trained healthcare providers (Shet, Sundaresan, & Forsberg, 2015).

A focus group discussion study among retail pharmacists in Delhi showed that commercial interests including the pressure to sell antimicrobials nearing their expiry date constitute a major force in driving sales of inappropriate antibiotics (Kotwani, Wattal, Joshi, & Holloway, 2012).

In the treatment of acute diarrhoea in children, antibiotics may be more profitable than more rational treatment such as zinc or oral rehydration solution and this may be another reason for widespread antibiotic dispensing(Löfgren et al., 2012).

According to Salim & Elgizoli 2017, commercial interest of pharmacists has been playing an important role behind dispensing of antibiotics without prescriptions. Pharmacists are looking to increase their pharmacies‟ revenues regardless of the appropriateness of dispensing practices. This attitude might be associated with pharmacists who own pharmacies or have sales incentives (Salim & Elgizoli, 2017).

CHAPTER THREE

METHODOLOGY

This chapter outlines the various methods used for the study; giving detailed descriptions of the study design, study location, data collection techniques, data collection tools, data processing and analysis, quality control measures employed and ethical issues.

3.1 Study Area

This study was conducted in Accra Metropolitan Area (AMA) which can be found in the Greater Accra region of Ghana. The Greater Accra Region is the smallest of the ten administrative regions in terms of area in Ghana. It is further divided into sixteen (16) districts with the Accra Metropolis being the most populated district in the region with a population of 1,665,086. This comprises of 51.9% females and 48.1% males representing 42% of the region‟s total population (Ghana Statistical Service, 2014).

The Metropolis has a household population of 1,599,914 with a total number of 450,748 households. The average household size is 3.7 persons per household. Children constitute the largest proportion of the household composition of 35.5% (Ghana Statistical Service, 2014).

The study was conducted in selected pharmacies across the Accra metropolis. According to the Pharmacy Council of Ghana, the total number of pharmacies in the Greater Accra region is 1713 with 1122 registered retail pharmacies in good standing (this refers to facilities that have renewed their yearly license and therefore are eligible to conduct business) (Gazette of Pharmacies,2017). Out of this number, 917 can be found in the Accra Metropolis. This forms

approximately 53.5% of the total population of community pharmacies in the region. Figure 3.1 (below) shows a map of Accra Metropolis and some of the areas located within the Metropolis.

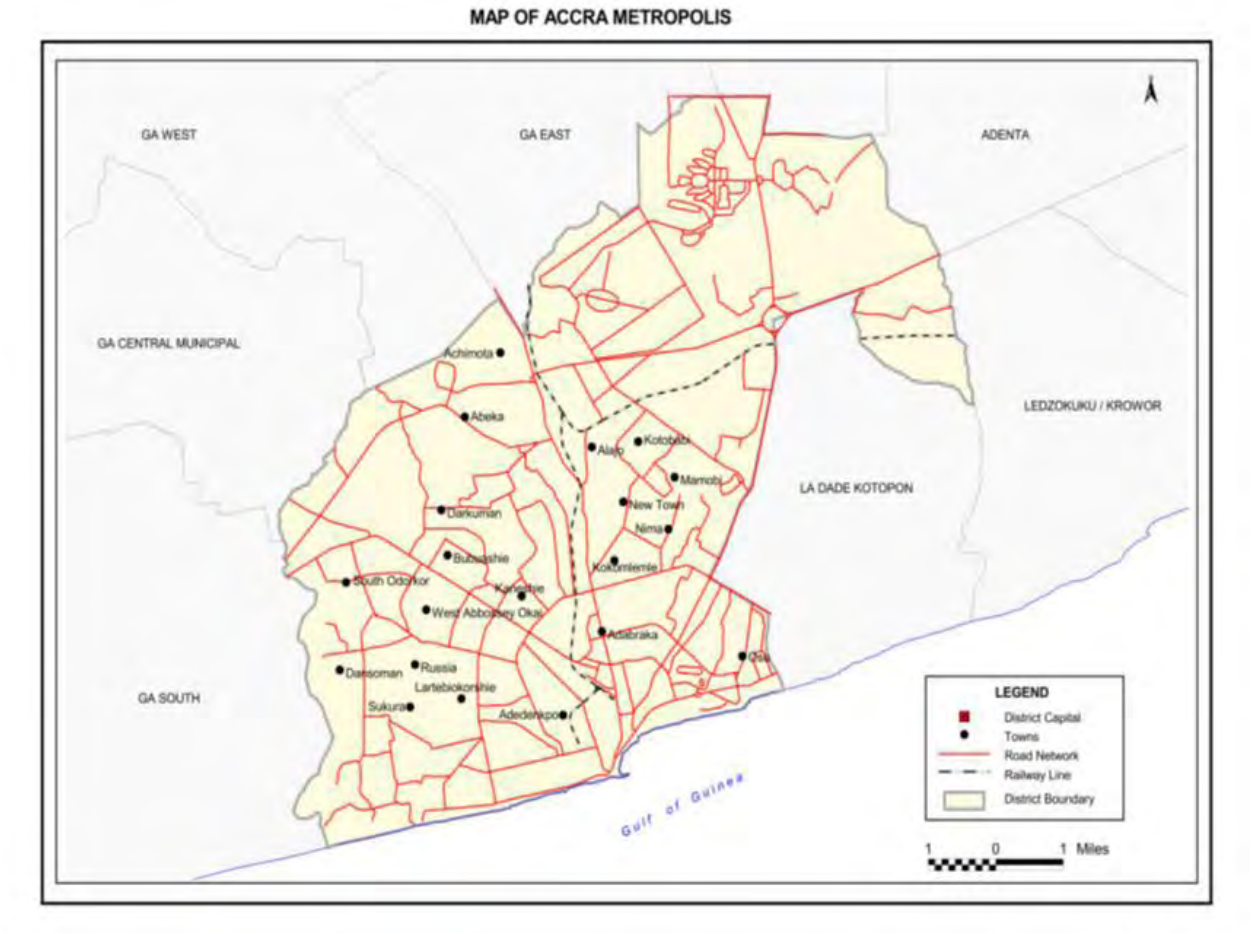

Figure 3.1: Map of Accra Metropolis. Source: Ghana Statistical Service (2012).

3.2 Study Design

The study was a cross sectional community based survey amongst community pharmacists and pharmacy assistants within the Accra metropolis. The list of pharmacies in the Accra Metropolis was obtained from Pharmacy Council. The pharmacies were arranged alphabetically and

numbers were assigned to these pharmacies. The pharmacies were then randomly selected using a random number generator. Questionnaires were prepared and sent to the various pharmacies randomly selected. Mystery clients were trained and sent to randomly selected community pharmacies out of the initial selected pharmacies.

3.3 Study Variables

The variables for this study were:

3.3.1 Dependent variable

- Antibiotic use without prescription in children

3.3.2 Independent variables

- Pharmacist‟s Knowledge on antibiotics
- Antibiotic availability
- Demand for antibiotics by parents/guardians
- Business nature of the pharmacy
- Financial incentives from pharmaceutical companies

3.4 Study population

The study population covered primarily all community pharmacists in retail pharmacies within the Accra metropolis. The regular absence of pharmacists in community pharmacies is generally recognized and professional activities in the pharmacy are often carried out by personnel who may have no formal education or training (Smith, 2004). Hence, in the absence of a community

pharmacist, the pharmacy assistants were required to participate in the survey because they manage the pharmacy and dispense drugs to patients in the absence of the community pharmacist.

3.5 Sample size determination

The formula below proposed by Glenn et al, (1992) was used to calculate the sample size from a finite population

$$n = \frac{\frac{P[1-P]}{\frac{e^2}{Z^2} + \frac{P[1-P]}{N}}}{R}$$

Where:

n = Based sample size required

N = Total number of pharmacies (917) (Gazette, 2017)

P = estimated prevalence of inappropriate antibiotic use in children in community pharmacies = 42% (Togoobaatar et al., 2010)

e = Precision desired, expressed as a decimal (ie. 0.05 or 5%)

Z = Based on confidence level: 1.96 for 95% confidence,

R = Estimated Response rate (80%)

The sample size was:

$$n = \frac{\frac{0.42[1-0.42]}{\frac{0.05^2}{1.96} + \frac{0.42[1-0.42]}{917}}}{0.8}$$

This gave a sample size of approximately 198.

For the mystery clients approach, the guidelines for implementing the mystery client surveys for Marie Stopes International Partners was used.

Number of facility in country	Total number of facilities to sample
< 10	ALL
10 - 39	Minimum of 20
40 - 99	Minimum of 30
≥ 100	Minimum of 40

(Marie Stopes Int., 2012)

Nb. These are minimum numbers and the greater number of facilities included in the sample the more representative this will be of the programmes service delivery.

Hence since there are more than 100 pharmacies in the Accra Metropolis, 103 pharmacies which is 60% which represents more than half of the 198 facilities sampled were selected for the mystery client survey.

3.6 Sampling Approach

Sampling of community pharmacies was done by obtaining a list of all retail pharmacies in the Accra Metropolis from Pharmacy Council. Out of the list, 198 pharmacies were selected through random sampling approach. All retail facilities within the study area were arranged alphabetically and numbered. Using a simple random number generator, all chosen numbers were separated to get the 198 pharmacies. The pharmacist on duty in the pharmacy was the preferable respondent to fill the questionnaire. In the situation where there was more than one pharmacist on duty, the superintendent pharmacist was selected to participate in the study. In the absence of a pharmacist after two consecutive visits to the pharmacy shop, the pharmacy assistant was required to fill the questionnaire.

3.6.1 Inclusion Criteria

All Pharmacists and Pharmacy assistants in community retail pharmacies.

3.6.2 Exclusion Criteria

Those excluded were Pharmacists and Pharmacy assistants who did not give voluntary consent to be part of the study.

3.7 Data Collection Technique

Two main methods of data collection were employed in this study. First, structured questionnaires were designed and administered to pharmacists or pharmacy assistants. The respondents were required to read and fill the questionnaires.

Secondly, a mystery client scenario survey was also conducted in about 103 pharmacies to collect data on what pharmacists or pharmacy workers actually do when approached by a client demanding antibiotics for their children who are under five. The mystery client scenario is useful in evaluating already existing practice, or to aid in developing outcome measures for pharmacy practice research (Boyce & Neale, 2006). The assumption that a pharmacist or pharmacy assistant would be more likely to provide truthful information about a sensitive issue when approached by a client rather than an interviewer forms the underlying principle behind this method.

In this approach the mystery clients posed as parents needed to purchase medications for their ill children under five at home. Three mystery clients were used for the survey, two were female and One was male aged 27 to 32. These mystery clients were trained to go to pharmacies describing ailments which depicted self-limiting conditions. Two scenarios were adopted for this method; One approach was conducted by the mystery client visiting pharmacies and demanding to buy either Amoxiclav 228 suspension, Amoxicillin suspension, Cefuroxime suspension or Azithromycin suspension for the treatment of cough, cold and sore throat without stating the duration at which the child was ill. This was to verify whether they would ask further questions as to the duration of the ailment and presence of other symptoms or whether they would just hand over the antibiotics without further questions. In the second scenario, the mystery clients were trained to present their complains to the pharmacy worker, they complained of their young

children suffering of diarrhoea with low grade fever with vomiting and no mucus and also of mild symptoms of cold, cough and sore throat that had lasted for 1 – 2 days. The mystery clients were trained to request for antibiotics if the pharmacy worker provided them with OTC medications and attempt to walk out of the pharmacy if the pharmacy workers refuse to give them the antibiotics. This was to verify if they were more interested in keeping their customers than following the recommended protocols and being ethically professional.

3.8 Data Collection Tools

A well-structured questionnaire on irrational use of antibiotics in children was the main instrument for collection of primary data. The main themes covered by the questionnaire were inclusive of:

- Socio demographic factors
- Availability of antibiotics to parents/guardians to be administered to children under 5 years
- Types of antibiotics used in the management of acute upper respiratory infections, acute diarrhoea, fever and sore throat in children under 5 years.
- Appropriateness of antibiotics given to children under 5years in community pharmacies
- Provision of adequate counseling for antibiotic use.
- Factors that influence pharmacist‟s decision in prescribing antibiotics in children under 5years

3.9 Data Processing and Analysis

Data entered on the questionnaires was checked for completeness and consistency. Data obtained from respondents was coded and entered into Stata I/C version 15.0 for processing. Univariate and Bivariate analysis using chi-square test were used to assess the association between different characteristics of the respondents and antibiotic use in children. Logistics regression was done to determine strengths of association between the variables. The findings were reported with a 95% confidence intervals (C.I.'s) and with the level of statistical significance set at $p<0.05$ for all tests.

3.10 Quality Control

Questionnaires were pre-tested and the necessary corrections made before commencement of the study. Mystery clients and field assistants were trained in order to ensure they appreciate the background of the study, the objectives, the delicate nature of the topic and need for confidentiality. They were also taken through the questionnaire to make sure that they were well informed to provide further explanation to the respondents where necessary. Daily meetings were held with the field assistants and mystery clients after data collection to identify any challenges. Solutions to all identified challenges were offered by the team.

3.11 Ethical Issues

Ethical approval was sought from the Ghana Health Service Ethical Review Committee (GHSERC063/01/18).

Approval was also sought from the owners of the community pharmacies in which the research will be undertaken. Prior to data collection, adequate information about the study was provided to each potential respondent to enable him/her decide whether to take part in the study or not. Participation in this study was voluntary and participants could choose not to partake. Participants were at liberty to withdraw from the study at any time. Respondents who agreed to participate in the study were required to sign an informed written consent form**.** Each respondent was assured of safety, anonymity and confidentiality. Highest form of confidentiality concerning any information given towards this study was maintained at all times. The identities of all those involved in the study were kept confidential and were not mentioned in the write-up or under any other circumstance when the results were presented or published. The filled questionnaires have been kept safely in a cabinet under lock and key. All analysed data have been transferred to a laptop and protected by password. Another copy has been kept on an external hard drive which would be securely kept in a cabinet, with access limited to the researcher. After a year, the data would be deleted. The data collected was used for only academic and research purpose. Snacks were provided to each respondent at the end of the study. There were no monetary rewards for participants participating in the study.

CHAPTER FOUR

RESULTS

4.0 Introduction

This chapter provides details of the results of the study. It covers background characteristics of pharmacy staff, antibiotic dispensing practices of pharmacists and other pharmacy staff, demand for antibiotics and factors that affect dispensing of antibiotics by pharmacy staff in community pharmacies.

4.1 Socio-Demographic Characteristics of Respondents

An expected population of one hundred and ninety-eight pharmacy employees were to be recruited. However, one hundred and eighty-seven (187) pharmacy employees consented to partake in the study, with one hundred and seventy-three (173) providing completely filled questionnaires. Out of the 187 self-administered questionnaires, about 14 of the questionnaires which were filled by medical counter assistants left some very important questions unanswered hence had to be taken out. Table 4.1 summarises the socio-demographic characteristics of the respondents interviewed during the survey.

Table 4.1: Socio-Demographic Characteristics of Respondents

Characteristics	Frequency (n=173)	Percentage (%)
Sex	71	41.0
Male	102	59.0
Female		
Age		
15 – 24	15	8.7
25 – 34	80	46.2
34 – 44	44	25.4
45+	34	19.7
Marital Status		
Single	101	58.4
Married	69	39.9
Other	3	1.7
Level of Education		
Secondary	44	25.4
Tertiary	129	74.6
Professional Category		
Pharmacist	83	48.0
Pharmacy Technician	31	17.9
Medical Counter Assistant	59	34.1

Other- divorced, separated, widowed

Complete responses were obtained from 173 pharmacy employees with a majority of the respondents being females. Females were 102 (58.96%) and males represented 71 (41.04%) of

the population. Majority of the respondents 129 (74.6%) had tertiary education. The professional categories of pharmacy staff ranged from pharmacists, pharmacy technicians and Medical Counter Assistants (MCA). Majority of the respondents were pharmacists; 83 (48.0%) were pharmacists, 59 (34.1%) were medical counter assistants and the remaining 31 (17.9%) were pharmacy technicians.

4.2. Dispensing of Antibiotics without Prescription in Community Pharmacies

With reference to dispensing antibiotics without a prescription as shown in Table 4.2, 114 (65.9%) of the pharmacy workers dispensed antibiotics without prescription to parents/guardians. Out of the 114 pharmacy workers that gave out antibiotics without prescription 53 (46.5%) were pharmacists, 40 (35.1%) were MCA"s, 21 (18.4%) were pharmacy technicians. A chi square test of significance however shows that the differences between professional categories and dispensing of antibiotics without a prescription were not statistically significant, p = 0.863.

Table 4.2: Dispensing Patterns of Antibiotics by Qualification of Pharmacy Staff

	Dispensing antibiotics without a prescription		
	Yes	**No**	
	N (%)	**N (%)**	**p-value**
Professional categories			0.863
Pharmacist	53 (46.5)	30 (50.9)	
Pharmacy Technician	21 (35.1)	10 (16.9)	
Medical Counter Assistant	40 (18.4)	19 (32.2)	

From the responses obtained from the survey, majority of the pharmacy workers 141 (81.5%) dispense antibiotics for the treatment of cough while common cold was the least 37 (21.4%) condition treated with antibiotics in the community pharmacies. About 71 (41.0%) dispense antibiotics for the treatment of acute watery diarrhoea and 40 (23.12%) dispense antibiotics for the treatment of sore throat.

4.3 Irrational use of antibiotics in community pharmacies

Amoxicillin clavulanic acid was the most common drug used in the treatment of the listed self-limiting conditions (i.e. Cough, common cold and sore throat) whiles azithromycin was the least used. Among the respondents who dispense antibiotics without prescription for the treatment of cough (Table 4.3), 75 dispense amoxicillin clavulanic acid, 23 dispense cefuroxime, while 17 dispense azithromycin which were all classified under prescription only medications and 26 dispensed amoxicillin which was part of the pharmacy‟s list of medication.

Table 4.3 Irrational use of antibiotics in community pharmacies

	Frequently dispensed antibiotics					
	Amoxicillin clavulanic acid	**Cefuroxime**	**Amoxicillin**	**Azithromycin**	**Other**	**Total**
Do you give out antibiotics for the following conditions?						
Common Cold						
Yes	19	2	7	9	0	37
Acute Watery Diarrhoea						
Yes	38	13	14	6	0	71
Cough						
Yes	75	23	26	17	0	141
Sore throat						
Yes	21	6	5	8	0	40

The pie chart (Fig. 4.1) below shows the distribution of antibiotics frequently dispensed in the treatment of self-limiting conditions in community pharmacies.

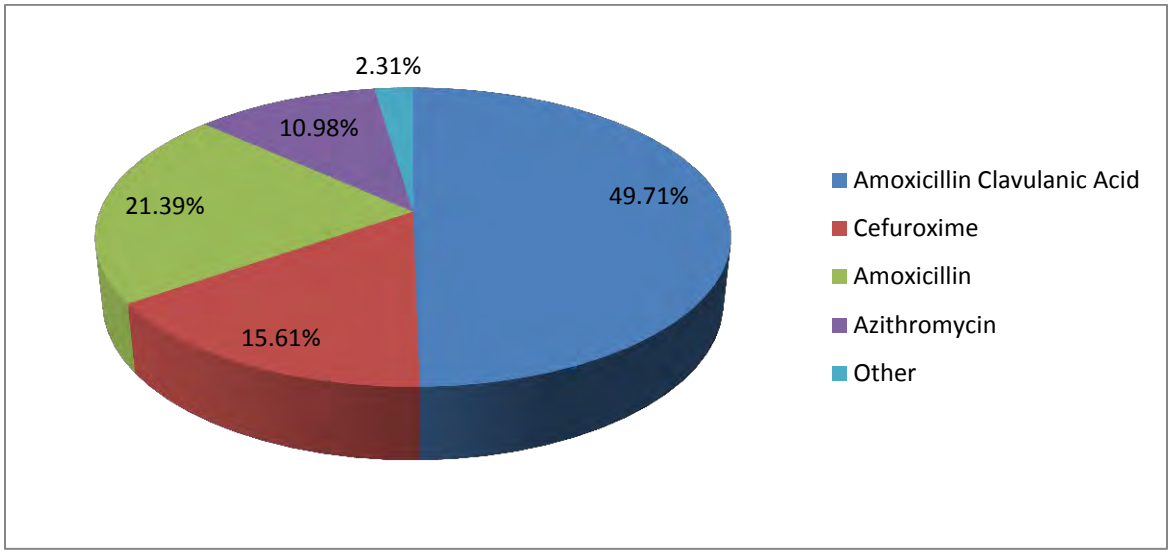

Fig.4.1. Frequently dispensed antibiotics used in the treatment of self-limiting conditions in children under five

When asked for the duration of disease condition at which antibiotics will be recommended to a parent/guardian to treat a child under five years suffering from common cold, cough, sore throat or acute watery diarrhoea, 8 (4.62%) said they dispense antibiotics within 2 days of occurrence, 93 (53.76%) dispense within 3-5 days of the disease condition and 72 (41.62%) said they dispense after one week after symptoms persist. In terms of appropriateness of the dosage of the antibiotics to children under five, 163 (94.22) of pharmacy workers interviewed dispensed the antibiotics per kg body weight of the children.

With respect to giving out antibiotics to a parent/guardian who is asking for a second pack of previously prescribed antibiotics for a child under five, majority 154 (89.02%) of the respondents did not give out antibiotics to clients requesting for a second pack of previously prescribed

antibiotics with some of their reasons being; disease condition may be caused by a virus, antibiotic may not be indicated for the current diagnosis, current condition might not be the same as first even though symptoms may be similar, recurrent condition requires the attention of a physician, to prevent the abuse of antibiotics which may lead to resistance. Among the 19 (10.98%) pharmacy workers that give out antibiotics to parents/guardians requesting for a second pack of previously prescribed antibiotics 13(61.9%) assume that the parents/guardians have enough education and counselling regarding the use of the antibiotic and amongst this 13 pharmacy workers 12 are MCA"s.

From the findings obtained from the survey with reference to knowledge of the consequences of irrational use of antibiotics in children under 5 years, 168 ((97.1%) of pharmacy workers had the knowledge that irrational use of antibiotics causes antibiotic resistance, 84(48.6%) knew about allergies being a consequence of irrational use while only 16 (9.2%) were aware about childhood obesity being a consequence of irrational antibiotics use in children under five. None of the respondents had the knowledge that antibiotic misuse in children could lead to asthma and also in the long run lead to hypertension and diabetes.

4.4 Findings from Mystery Client Survey

In order to minimise the problems of bias that are encountered in direct observation, a mystery client survey was conducted as a verification tool to investigate what pharmacy staff do when approached by parents/guardians demanding antibiotics for their children under five years for the treatment of self-limiting conditions to enable the researcher check for consistency with the information provided on the questionnaire and the actual practice on the field. The mystery client

approach (Table 4.4) was conducted in 103 of the pharmacies initially sampled which is more than half of the sample size (173) at which the study was conducted.

Majority of the respondents 94 (91.3%) out of the 103 pharmacies visited dispensed antibiotics without prescription while 9 (8.7%) recommended OTC medications for the self-limiting conditions presented. Out of the 94 pharmacy workers that did not ask for a prescription, 16 (17.0%) readily dispensed antibiotics to the mystery client upon the client‟s request without asking any further questions, 5 (5.3%) recommended alternate antibiotics when the mystery clients requested for a specific antibiotic for treatment and 22 (23.4%) dispensed antibiotics to the clients after enquiring about the symptoms and condition of the child , 26 (27.7%) of the pharmacy workers dispensed antibiotics to the clients based on their own discretion of the condition and 23 (24.5%) of the respondents who said they do not dispense antibiotics to parents or guardians without prescription eventually dispensed antibiotics without prescription upon the client‟s demand for antibiotics drugs.

The pharmacy workers‟ response to the questionnaire was matched against the response given to the mystery client and majority of the pharmacy workers‟ 80 (77.7%) responses to the mystery client survey were consistent with the responses provided on the questionnaire however 23 (22.3%) of the responses obtained from the mystery client survey was inconsistent with the data obtained from the questionnaires.

Table 4.4 Comparison of mystery client and questionnaire responses

Do you dispense antibiotics without prescription?			
	Response from Pharmacy		
	No	**Yes**	
	N (%)	**N(%)**	**Total**
Response from mystery client			
No	9 (28.1)	0	9
Yes	**23 (71.9)**	71 (100)	94
Total	32	71	103

The bivariate analysis shows that, the difference between the responses from the questionnaire and the responses from the mystery client approach was highly significant ($p<0.001$ i.e. very unlikely to have occurred by chance alone).

4.5. Factors Influencing the Decision of Pharmacists When Dispensing Antibiotics without a Prescription

Determining the factors influencing the decision of pharmacists to dispense antibiotics without a prescription was also one of the objectives of this study. Table 4.5 presents the results of chi square tests done to determine association between certain factors and whether a community pharmacy employee dispenses antibiotics without prescription.

Table 4.5 Factors Influencing the Decision of Pharmacy Workers When Dispensing Antibiotics without a Prescription

Characteristics	Do you give out antibiotics without prescription, N (%)				
	No N (%)	Yes N (%)	Total N (%)	$\chi 2$	p-value
Age				1.460	0.691
15-24	5 (33.3)	10 (66.7)	15(8.7)		
25-34	24 (30.0)	56 (70.0)	80 (46.2)		
35-44	16 (36.4)	28 (63.6)	44 (25.4)		
45+	14 (41.2)	20 (58.8)	34 (19.7)		
Sex				1.524	0.217
Male	28 (39.4)	43 (60.6)	71 (41.0)		
Female	31 (31.1)	71 (68.9)	102 (59.0)		
Level of Education				2.164	0.141
Secondary	19 (43.2)	25 (56.8)	44 (25.4)		
Tertiary	40 (31.0)	89 (69.0)	129 (74.6)		
Qualification				0.297	0.863
Pharmacist	30 (36.1)	53 (63.9)	83 (48.0)		
Medical Counter Assistant	19 (32.2)	40 (67.8)	59 (34.1)		
Pharmacy Technician	10 (32.3)	21 (67.7)	31 (17.9)		
Classification of Drugs				7.328	**0.007***
Prescription only medication	35 (44.8)	43 (55.2)	78 (45.1)		
Pharmacist list of medication	24 (25.3)	71 (74.7)	95 (54.9)		
Knowledge of law				4.658	0.097
No	4 (66.7)	2 (33.3)	6 (3.5)		
Yes	33 (37.5)	55 (62.5)	88 (50.9)		
Depends	22 (27.8)	57 (72.2)	79 (45.6)		
Profit made from selling antibiotics				0.483	0.487
No	33 (32.0)	70 (68.0)	103 (59.5)		
Yes	26 (37.1)	44 (62.9)	70 (40.5)		
Incentives from pharmaceutical companies				0.202	0.654
No	47 (33.3)	94 (66.7)	141 (81.5)		
Yes	12 (37.5)	20 (62.5)	32 (18.5)		
Demand by parents /guardians for antibiotics				6.175	**0.013**
No	9 (64.3)	5 (35.7)	14 (8.1)		
Yes	50 (31.5)	109 (68.5)	159 (91.9)		
Near expiry date of certain antibiotics on the shelf				1.542	0.214
No	32 (29.9)	75 (70.1)	107 (61.8)		
Yes	26 (39.4)	40 (60.6)	66 (38.2)		

Depends – not for all disease conditions but can be used for the treatment of diseases of common occurrence**

Variables like age, sex, level of education, qualification and knowledge of law concerning dispensing antibiotics did not show any significant association with respect to whether pharmacy staff dispenses antibiotics to parents/guardians without a valid prescription. However, factors like knowledge of classification of antibiotics ($p< 0.007$) according to the FDA‟s reviewed drug classification list and demand by parents/guardians for antibiotics ($p< 0.013$) influencing the decision of pharmacists to dispense antibiotics showed a significant association with respect to whether a pharmacist will dispense antibiotics without a prescription to parents/guardians of children under five years.

Table 4.6 Logistic regression of factors associated with dispensing of antibiotics without Prescription

Characteristics	Crude OR (95% CI)	p-value	Adjusted OR (95% CI)	p-value
Classification of Drugs				
Prescription Only Medication *(ref)*	1.0		1.0	
Pharmacist's List of Medication	2.41 (1.27 - 4.58)	**0.007***	2.34 (1.22 - 4.50)	**0.011***
Demand for antibiotics by parents/guardians				
No *(ref)*	1.0		1.0	
Yes	3.92 (1.25 -12.31)	**0.019***	3.71 (1.16 - 11.93)	**0.028***

A logistic regression model was then run in order to determine the strength of association of the factors that were shown to be significant in the bivariate analysis; Crude as well as the Adjusted Odds Ratios were found and are shown in table 4.6 above.

Crude analysis of the association between the outcome variable (antibiotic use without prescription) and predictor variables showed that classification of drugs according to the FDA and demand for antibiotics by parents/guardians were associated with antibiotic use in children without prescription. In the presence of other factors, the odds of a pharmacy staff dispensing antibiotics based on the knowledge of the class of antibiotics as Pharmacist‟s list of medications was 2.41 and when controlled for factors like demand and unethical practices the odds ratio was 2.34. This means that pharmacy workers who believed that antibiotics were pharmacy medicines had 2.41 times the odds of dispensing antibiotics without prescription relative to those who believed that antibiotics were prescription only medication.

Demand for antibiotic from parents/guardians was found to be significant and the odds of a pharmacist dispensing antibiotics without prescription by demand from parents was 3.92 times as compared to pharmacists who dispense antibiotics without demand from parents.

4.6 Conclusion

This chapter presented the results obtained from the field survey. The chapter revealed a number of interesting findings. The next chapter deals with a thorough discussion of these findings and their implications for policy and further research

CHAPTER FIVE

DISCUSSION

This chapter presents a detailed discussion of the study findings presented in the previous chapter with respect to the key objectives of the study and also discusses with the implications of the findings.

5.1 Summary of findings

More than half of the pharmacy workers recruited dispense antibiotics to parents/guardians for the treatment of self-limiting conditions like acute watery diarrhoea and acute respiratory tract infections in children under five. Amoxicillin Clavulanic acid was the most common drug dispensed without prescription. Lack of knowledge of the classification of drugs by the FDA in Ghana and demand for antibiotics by parents/guardians were the key influencing factors significantly affecting the dispensing practices of pharmacists.

It is widely believed that pharmacists could make a greater contribution to the provision of primary health care, especially in developing countries (WHO, 1998). Pharmacy is concerned with promoting the safe and appropriate use of drugs and they are viewed as being well placed to advise on the management of common symptoms and long-term conditions, and to participate in health education and promotion. However, the practices of pharmacy retailers, which are conducted in the context of wider structures and processes of health care provision, have also been questioned (Smith, 2015) especially with respect to the inappropriate dispensing of antibiotics in community pharmacies.

From the study, almost 7 out of 10 (66.0%) of pharmacy workers dispense antibiotics without prescription in community pharmacies. The high percentage of pharmacy workers dispensing antibiotics without prescription could be attributed to that fact that the law makes provision for pharmacists to dispense specific antibiotics for diseases of common occurrence but not for self-limiting conditions (cough, common cold, acute watery diarrhoea). According to the Pharmacy act of 1994, "No person shall open or permit any other person to open any premises to the public under the description of „pharmacy", „dispensary", „chemist", „drug store" or any other similar description unless a registered pharmacist is on the premises to supervise the dispensing of drugs or medication"(Pharmacy Act, 1994). This study was meant to be conducted amongst community pharmacists but despite the many attempts to recruit more pharmacists, less than half of the facilities visited had pharmacists (46%) on post and the rest were managed by MCA"s (35%) and pharmacy technicians (18%). However, there was no significant difference between professional categories and dispensing of antibiotics without prescription (p=0.863).

The mystery client survey revealed that about almost 4 out of 10 (39%) of pharmacy workers from the 59 respondents who denied giving out antibiotics to parents /guardians for the treatment of self-limiting conditions of children gave out antibiotics in the mystery client survey and these antibiotics were dispensed on request by the mystery client hence the actual proportion of pharmacists who dispense antibiotics is likely higher that predicted as stated initially. This can be attributed to keenness of pharmacy workers to keep their clientele happy at the expense of refraining from dispensing antibiotics without a prescription. Out of this 38.9% of the respondents, 65% were MCA"s, 26% were pharmacy technicians and 9% were pharmacists. This is consistent with another study conducted in Syria where 8 out of 10 (89.3%) of antibiotics are sold without prescription in community pharmacies (Bahnassi, 2015) and another survey in

Pakistan where antibiotics are prescribed to 7 out of 10 (76%) children, although many children have no need of it (Hameed & Naveed, 2016).

According to the reviewed drug classification by FDA, antibiotics are classified under pharmacist‟s list of medicines and prescription only medications (FDA, 2010). MCA‟s are limited to dispensing only OTC drugs in the absence of a pharmacist and are allowed to dispense antibiotics with a valid prescription only under the supervision of a qualified pharmacist. However as indicated in the findings from the survey conducted, MCA‟s dispense antibiotics without prescription. Although this practice is unlawful, it is favored by the fact that it is not clearly punishable by law. A similar study conducted in Saudi Arabia attributed this practice of irrational dispensing of medications by pharmacy support staff to the continuous absence of pharmacists from their post (Al-Mohamadi, Badr, Bin Mahfouz, Samargandi, & Al Ahdal, 2013).

According to the reviewed drug classification by FDA, most antibiotics inclusive of amoxicillin clavulanic acid, cefuroxime and azithromycin are strictly prescription only medication unlike amoxicillin which is part of pharmacy only medicines (FDA, 2010). From this study, antibiotics commonly used in the treatment of cold, cough, acute watery diarrhoea and sore throat were amoxicillin clavulanic acid (49.71%), cefuroxime (15.61%), Azithromycin (10.98%) which were all prescription only medicines and 1 out of 5 (21.39%) pharmacy workers dispensed amoxicillin which is part of pharmacist‟s list of medicines but still not indicated for the treatment of self-limiting conditions hence was dispensed inappropriately. Acute watery diarrhoea and upper respiratory tract infections like the common cold, cough and sore throat have viral etiologies and antibiotics are not indicated for the treatment of these self-limiting conditions. With reference to acute upper respiratory tract infections, 81% of pharmacy workers dispense antibiotics for the

treatment of cough which was found to be the most common condition in which antibiotics are dispensed to parents/guardian for treatment in community pharmacies while 21.4% dispense antibiotics for the treatment of common cold in children under five. According to the STG, symptoms of acute upper respiratory tract infections resolve without antibiotic treatment usually within a week (STG, 2010). However, 53.76% of the pharmacy workers who prescribed antibiotics for these self-limiting conditions gave out antibiotics within 3-5days of occurrence of the disease condition.

The Standard treatment guidelines (STG) in Ghana also states that antibiotics are not required in the treatment of diarrhoea that is of viral etiology: when diarrhoea is present with vomiting, low grade fever with no mucus in stools. The STG further states that oral rehydration therapy with zinc tablets should be used in the management of acute diarrhoea of viral etiology in children under five (STG, 2010). However, from the study conducted about 4 out of 10 (41%) of pharmacy workers admitted to dispensing antibiotics for the treatment of acute watery diarrhoea. Studies in suggest that this could be due to the fact that in the treatment of acute diarrhoea in children, antibiotics may be more profitable than more rational treatment such as zinc or oral rehydration solution, hence community pharmacists tend to give out antibiotics, not following the recommended guidelines (Löfgren et al., 2012). Almost all (97.1%) pharmacy workers knew that antibiotic misuse leads to antibiotic resistance, 4 out of 10 (48.6%) had the knowledge about allergies being a consequence of irrational use of antibiotics in children while about 1 out of 10 (9.2%) knew that antibiotics can lead to childhood obesity.

Knowledge on the classification of drugs according the reviewed drug list by the FDA ($p=0.007$) and factors like demand for antibiotics by parents/guardians ($p=0.013$) had a significant association with dispensing antibiotics without prescription in children under five. In the presence of other factors, the odds of a pharmacy staff dispensing antibiotics based on the knowledge of the

classification of antibiotics per the FDA‟s reviewed classification of drug list as Pharmacist‟s list of medications was 2.41 and when controlled for factors like demand and unethical practices the odds ratio was 2.34. This means that the odds of a pharmacy worker with the knowledge that antibiotics are classified as pharmacists list of medicines to dispense antibiotics without a prescription is 2 times as compared to pharmacy workers with the knowledge that antibiotics are prescription only medication.

Demand for antibiotic from parents/guardians was found to be significant and the odds of a pharmacist dispensing antibiotics without prescription by demand from parents was 3 times as compared to pharmacists who dispense antibiotics without demand from parents. About 4 out of 10 (41%) of the pharmacy workers acknowledge that profit made from selling antibiotics, 2 out of 10 (18.5%) admitted to incentives from pharmaceutical companies and 3 out of 10 (38.2%) also admitted to near expiry dates of certain antibiotics on the shelf being an influencing factor in dispensing antibiotics without prescription. Though factors like near expiry date of certain antibiotics on the shelf, incentives from pharmaceutical companies and profit gained from the sale of antibiotics contribute to the wide spreading of irrational used of antibiotics in children, no significant association was found between the dispensing antibiotics without prescription in children for self-limiting conditions and these factors. This does not entirely eliminate the chances of these factors being an influencing factor of irrational use of antibiotics but could rather be due to the sample size and the type of study population recruited for the study. This unethical practice of misappropriate dispensing of antibiotics by pharmacy workers due to these influencing factors could lead to the emergence of many resistant bacterial strains. This could lead to a high incidence of antibiotic treatment failure and fewer treatment options available in the country which could lead to delirious repercussions such as an a high rate morbidity and

mortality in children under five since they are more at risk bacterial infections as compared to adults.

5.2 Strengths of the study

The data collection tools in this study was a combination of self-administered questionnaires and the mystery client approach in order to minimize levels of bias in the study. Also the self- administered questionnaires assure of anonymity and privacy, and the respondents can therefore feel comfortable to provide honest responses.

5.3 Limitations of the study

This was a cross-sectional study. The results also only represent the current situation hence might not be a true reflection of what pertains. This means that different results may be obtained if the study is conducted at a different time in the same facility due to the fact that respondents may differ. Also this study was done in a urban set up hence findings may not apply to communities outside Accra.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The practice of pharmacy workers dispensing antibiotics without prescription is very common in Accra. Most self-limiting conditions in children under five are irrationally treated with antibiotics. The most common antibiotics irrationally used in the management of self-limiting conditions in community pharmacies were Amoxicillin clavulanic acid which is a prescription only drug and amoxicillin which is part of pharmacy only medicine but still used inappropriately. Lack of knowledge that antibiotics are not part of prescription only medications and the demand for antibiotics from parents/guardians are the driving forces for people dispensing antibiotics irrationally in children under five.

6.2 Recommendations

The findings of this study have important implications for the Pharmaceutical Society of Ghana and Pharmacy Council and the FDA:

- The pervasive nature of the absence of pharmacists suggests that the pharmacy council needs to implement and enforce laws regarding ethics of the profession.
- Training and supervisory visits should be intensified to ensure promotion of appropriate dispensing practices.
- Mystery client survey should be used as a monitoring tool and carried out frequently to assess the dispensing practices of pharmacy workers and to ensure no pharmacy operates without a pharmacist.
- Sanctions should be put in place and should be strictly adhered to all pharmacies that operate without the presence of pharmacists

REFERENCES

Adedeji, W. A. (2016). THE TREASURE CALLED ANTIBIOTICS. Annals of Ibadan Postgraduate Medicine, 14(2), 56–57. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/28337088

Agarwal, S., Yewale, V. N., & Dharmapalan, D. (2015). Antibiotics Use and Misuse in Children: A Knowledge, Attitude and Practice Survey of Parents in India. Journal of Clinical and Diagnostic Research : JCDR, 9(11), SC21-4. https://doi.org/10.7860/JCDR/2015/14933.6819

Ahmadizar, F., Vijverberg, S. J. H., Arets, H. G. M., Boer, A. De, Turner, S., Devereux, G., … Zee, A. H. M. Der. (2017). Early life antibiotic use and the risk of asthma and asthma exacerbations in children, (April), 430–437. https://doi.org/10.1111/pai.12725

Al-Faham, Z., Habboub, G., & Takriti, F. (2011). The sale of antibiotics without prescription in pharmacies in Damascus, Syria. Journal of Infection in Developing Countries, 5(5), 396–399. https://doi.org/10.1086/598183

Al-Mohamadi, A., Badr, A., Bin Mahfouz, L., Samargandi, D., & Al Ahdal, A. (2013). Dispensing medications without prescription at Saudi community pharmacy: Extent and perception. Saudi Pharmaceutical Journal : SPJ : The Official Publication of the Saudi Pharmaceutical Society, 21(1), 13–8. https://doi.org/10.1016/j.jsps.2011.11.003

Asante, K. P., Boamah, E. A., Abdulai, M. A., Buabeng, K. O., Mahama, E., Dzabeng, F., … Gyansa-Lutterodt, M. (2017). Knowledge of antibiotic resistance and antibiotic prescription practices among prescribers in the Brong Ahafo Region of Ghana; a cross-sectional study. BMC Health Services Research, 17(1), 422. https://doi.org/10.1186/s12913-017-2365-2

Bahnassi, A. (2015). A qualitative analysis of pharmacists‟ attitudes and practices regarding the sale of antibiotics without prescription in Syria. Journal of Taibah University Medical Sciences, 10(2), 227–233. https://doi.org/10.1016/j.jtumed.2014.09.001

Bahnassi, A. (2016). Pharmacists Views and Practices in Regard to Sales of Antibiotics Without a Prescription in Madinah, Saudi Arabia. Journal of Patient Safety, 12(3), 159–64. https://doi.org/10.1097/PTS.0000000000000087

Bailey, L. C., Forrest, C. B., Zhang, P., Richards, T. M., Livshits, A., & DeRusso, P. A. (2014). Association of Antibiotics in Infancy With Early Childhood Obesity. JAMA Pediatrics, 168(11), 1063. https://doi.org/10.1001/jamapediatrics.2014.1539

Biswas, K., & Ferdousy, U. (2016). Influence of Pharmaceutical Marketing on Prescription Behavior of Physicians: A Cross-sectional Study in Bangladesh. Journal of Accounting & Marketing, 5(2), 1–4. https://doi.org/10.4172/2168-9601.1000160

Boyce, C., & Neale, P. (2006). USING MYSTERY CLIENTS : A Guide to Using Mystery Clients. Pathfinder International Tool Series, (May), 1–20.

Brown, C. L., Halvorson, E. E., Cohen, G. M., Lazorick, S., & Skelton, J. A. (2015). Addressing Childhood Obesity: Opportunities for Prevention. Pediatric Clinics of North America, 62(5), 1241–61. https://doi.org/10.1016/j.pcl.2015.05.013

Buabeng, K. O. (2010). The Role of the Pharmaceutical Sector in Mlalaria Control in Ghana.

Chambers, P. (2011). Rational use of medicines. Veterinary Record, 169(9), 226–227. https://doi.org/10.1136/vr.d5420

Donkor, E. S., Tetteh-Quarcoo, P. B., Nartey, P., & Agyeman, I. O. (2012). Self-medication practices with antibiotics among tertiary level students in Accra, Ghana: a cross-sectional study. International Journal of Environmental Research and Public Health, 9(10), 3519–29. https://doi.org/10.3390/ijerph9103519

Ecker, L., Ochoa, T. J., Vargas, M., Del Valle, L. J., & Ruiz, J. (2013). [Preferences of antibiotic use in children less than five in physicians working health centers of primary level in peri-urban areas of Lima, Peru]. Revista Peruana de Medicina Experimental y Salud Pública, 30(2), 181–9. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/23949500

Ecker, L., Ochoa, T. J., Vargas, M., Del Valle, L. J., & Ruiz, J. (2013). Factors Affecting Caregivers‟ Use of Antibiotics Available Without a Prescription in Peru. PEDIATRICS, 131(6), e1771–e1779. https://doi.org/10.1542/peds.2012-1970

Ecker, L., Ochoa, T. J., Vargas, M., Valle, L. J. Del, Ruiz, J., Rossignoli, A., … Bauchner, H. (2013). Factors Affecting Caregivers‟ Use of Antibiotics Available Without a Prescription in Peru. Pediatrics, 131(6), 1099–1106. https://doi.org/10.1542/peds.2012-1970

FDA. (2010). Downloads - FDA GHANA. Retrieved July 26, 2018, from https://fdaghana.gov.gh/index.php/downloads/

Freels, S., Chavez, N., & Hernandez, E. (2015). NIH Public Access, 134(3), 728–729. https://doi.org/10.1016/j.jaci.2014.05.006.The

Ghana Statistical Service. (2014). 2010 Population & Housing Census: Accra Metropolitan District Analytical Report, 78.

Goossens, H., Ferech, M., Vander Stichele, R., & Elseviers, M. (2005). Outpatient antibiotic use in Europe and association with resistance: A cross-national database study. Lancet, 365(9459), 579–587. https://doi.org/10.1016/S0140-6736(05)17907-0

Guest, K., & President, E. V. (2009). Antibiotics research supplement, 1–52. Retrieved from http://www.myhealthyhome.com/wp-content/uploads/2011/02/ANTIBOTICS_RESEARCH_PART2.pdf

Gwimile, J. J., Shekalaghe, S. A., Kapanda, G. N., & Kisanga, E. R. (2012). Antibiotic prescribing practice in management of cough and/or diarrhoea in Moshi Municipality, Northern Tanzania: cross-sectional descriptive study. The Pan African Medical Journal, 12, 103.

Hadi, M. A., Karami, N. A., Al-Muwalid, A. S., Al-Otabi, A., Al-Subahi, E., Bamomen, A., … Elrggal, M. E. (2016). Community pharmacists‟ knowledge, attitude, and practices towards dispensing antibiotics without prescription (DAwP): a cross-sectional survey in Makkah Province, Saudi Arabia. International Journal of Infectious Diseases : IJID : Official Publication of the International Society for Infectious Diseases, 47, 95–100. https://doi.org/10.1016/j.ijid.2016.06.003

Hameed, A., & Naveed, S. (2016). Irrational Use of Antibiotics, in Different Age Groups of Karachi: A Wakeup Call for Antibiotic Resistance and Future Infections. Journal of Bioequivalence & Bioavailability, 8(5), 242–245. https://doi.org/10.4172/jbb.1000302

Kotwani, A., Wattal, C., Joshi, P. C., & Holloway, K. (2012). Irrational use of antibiotics and role of the pharmacist: An insight from a qualitative study in New Delhi, India. Journal of Clinical Pharmacy and Therapeutics, 37(3), 308–312. https://doi.org/10.1111/j.1365-2710.2011.01293.x

Larsson, M., Kronvall, G., Chuc, N. T. K., Karlsson, I., Lager, F., Hanh, H. D., … Falkenberg, T. (2000). Antibiotic medication and bacterial resistance to antibiotics: A survey of children in a Vietnamese community. Tropical Medicine and International Health, 5(10), 711–721. https://doi.org/10.1046/j.1365-3156.2000.00630.x

Lee, Y. S. (2009). Consequences of childhood obesity. Annals of the Academy of Medicine Singapore, 38(1), 75–81. https://doi.org/10.1007/s12098-011-0489-7

Lexchin, J. (2010, June 16). Statistics in drug advertising: What they reveal is suggestive what they hide is vital. International Journal of Clinical Practice. BioMed Central. https://doi.org/10.1111/j.1742-1241.2010.02398.x

Löfgren, J., Tao, W., Larsson, E., Kyakulaga, F., & Forsberg, B. C. (2012). Treatment patterns of childhood diarrhoea in rural Uganda: a cross-sectional survey. BMC International Health and Human Rights, 12, 19. https://doi.org/10.1186/1472-698X-12-19

Marra, F., Marra, C. A., Richardson, K., Lynd, L. D., Kozyrskyj, A., Patrick, D. M., … Fitzgerald, J. M. (2009). Antibiotic use in children is associated with increased risk of asthma. Pediatrics, 123(3), 1003–10. https://doi.org/10.1542/peds.2008-1146

Mensah, K. B., & Ansah, C. (2016). Irrational use of antibiotics and the risk of diabetes in Ghana. Ghana Medical Journal, 50(2), 107–14. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/27635099

Mohammed, H., & Vuvor, F. (2012). Prevalence of childhood overweight/obesity in basic school in Accra. Ghana Medical Journal, 46(3), 124–7. Retrieved from http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3645158&tool=pmcentrez&rendertype=abstract

Mohrs, S. (2015). Factors influencing the use of antibiotics and knowledge about antibiotic resistance in Jakarta A qualitative study on the perceptions of stakeholders involved in Yayasan Orangtua Peduli"s Smart Use of Antibiotics campaign in Indonesia Factors influencing. Retrieved from https://www.diva-portal.org/smash/get/diva2:971676/FULLTEXT01.pdf

Morgan, D. J., Okeke, I. N., Laxminarayan, R., Perencevich, E. N., & Weisenberg, S. (2011, September). Non-prescription antimicrobial use worldwide: A systematic review. The Lancet Infectious Diseases. https://doi.org/10.1016/S1473-3099(11)70054-8

Ortqvist, A. K., Lundholm, C., Kieler, H., Ludvigsson, J. F., Fall, T., Ye, W., & Almqvist, C. (2014). Antibiotics in fetal and early life and subsequent childhood asthma: nationwide population based study with sibling analysis. BMJ, 349(nov28 3), g6979–g6979. https://doi.org/10.1136/bmj.g6979

Pharmacy Act. (1994). Pharmacy Act, 1994.

Prestinaci, F., Pezzotti, P., & Pantosti, A. (2015). Antimicrobial resistance: a global multifaceted phenomenon. Pathogens and Global Health, 109(7), 309–18. https://doi.org/10.1179/2047773215Y.0000000030

Rathnakar, U. P., Sharma, N. K., Garg, R., Unnikrishnan, B., & Gopalakrishna, H. N. (2012). A study on the sale of antimicrobial agents without prescriptions in pharmacies in an urban area in south India. Journal of Clinical and Diagnostic Research, 6(6), 951–954. Retrieved from http://www.jcdr.net/articles/pdf/2308/7 - 4511_E(C)_PF1(R)_F(P)_PF(V)_PFA(P)_PF(R)_U(P).pdf

Risnes, K. R., Belanger, K., Murk, W., & Bracken, M. B. (2011). Antibiotic Exposure by 6 Months and Asthma and Allergy at 6 Years: Findings in a Cohort of 1,401 US Children. American Journal of Epidemiology, 173(3), 2226–2235. https://doi.org/10.1093/aje/kwq400

Salim, A. M. A., & Elgizoli, B. (2017). Exploring the reasons why pharmacists dispense antibiotics without prescriptions in Khartoum state, Sudan. International Journal of Pharmacy Practice, 25(1), 59–65. https://doi.org/10.1111/ijpp.12317

Schulfer, A., & Blaser, M. J. (2015). Risks of Antibiotic Exposures Early in Life on the Developing Microbiome. PLoS Pathogens, 11(7), e1004903. https://doi.org/10.1371/journal.ppat.1004903

Semic-Jusufagic, A., Belgrave, D., Pickles, A., Telcian, A. G., Bakhsoliani, E., Sykes, A., … Custovic, A. (2014). Assessing the association of early life antibiotic prescription with asthma exacerbations, impaired antiviral immunity, and genetic variants in 17q21: A population-based birth cohort study. The Lancet Respiratory Medicine, 2(8), 621–630. https://doi.org/10.1016/S2213-2600(14)70096-7

Shea, K., Florin, K., & Barlam, T. (2001). When Wonder Drugs Don't Work: How Antibiotic Resistence Threatens Childen, Senior, and Medically Vurnrable. Retrieved from http://www.edf.org/sites/default/files/162_abrreport.pdf

Shet, A., Sundaresan, S., & Forsberg, B. C. (2015). Pharmacy-based dispensing of antimicrobial agents without prescription in India: appropriateness and cost burden in the private sector. Antimicrobial Resistance and Infection Control, 4(1), 55. https://doi.org/10.1186/s13756-015-0098-8

Smith, F. (2015). Community Pharmacy in Ghana : enhancing the contribution to primary health care Community pharmacy in Ghana : enhancing the contribution to primary health care, (AUGUST 2004). https://doi.org/10.1093/heapol/czh028

Steinman, M. A., Gonzales, R., Linder, J. A., & Landefeld, C. S. (2003). Changing Use of Antibiotics in Community-Based Outpatient Practice, 1991-1999. Annals of Internal Medicine, 138(7), 525–533+I24. https://doi.org/200304010-00008 [pii]

STG. (2010). Stg. Standard Treatment Guidelines. Retrieved from www.ghndp.org

Stopes, M., & International. (n.d.). Monitoring-Quality-of-Care-Through-Mystery-Client-Surveys_MSIGlobal (1).

Teo, S. M., Mok, D., Pham, K., Kusel, M., Serralha, M., Troy, N., … Inouye, M. (2015). The Infant Nasopharyngeal Microbiome Impacts Severity of Lower Respiratory Infection and Risk of Asthma Development. Cell Host & Microbe, 17(5), 704–715. https://doi.org/10.1016/j.chom.2015.03.008

Togoobaatar, G., Ikeda, N., Ali, M., Sonomjamts, M., Dashdemberel, S., Mori, R., & Shibuya, K. (2010). A survey of non-prescribed use of antibiotics for children in an urban community in Mongolia. Bulletin of the World Health Organization, 88(12), 930–936. https://doi.org/10.2471/BLT.10.079004

Vangay, P., Ward, T., Gerber, J. S., & Knights, D. (2015). Antibiotics, Pediatric Dysbiosis, and Disease. Cell Host & Microbe, 17(5), 553–564. https://doi.org/10.1016/j.chom.2015.04.006

Who. (2009). "Country Profile of Environmental Burden of Disease-Ghana," (2008), 1.

WHO. (2011). WHO | Survey of non-prescribed use of antibiotics for children in an urban community in Mongolia. WHO.

WHO. (2017). Who | Antibacterial Agents in Clinical Development. Who. Retrieved from http://www.who.int/medicines/areas/rational_use/antibacterial_agents_clinical_development/en/

WHO | Asthma. (2013). Retrieved November 11, 2017, from http://www.who.int/respiratory/asthma/en/

WHO | Global prevalence and trends of overweight and obesity among preschool children. (2011). WHO. Retrieved from http://www.who.int/nutgrowthdb/publications/overweight_obesity/en/

WHO | Obesity and overweight. (2017). WHO. Retrieved from http://www.who.int/mediacentre/factsheets/fs311/en/

WHO Regional Office for Europe. (2014). The role of pharmacist in encouraging prudent use of antibiotics and averting antimicrobial resistance: a review of policy and experience. World Health Organisation, 57. Retrieved from http://www.euro.who.int/en/health-topics/disease-prevention/antimicrobial-resistance/publications/2014/the-role-of-pharmacist-in-encouraging-prudent-use-of-antibiotic-medicines-and-averting-antimicrobial-resistance-a-review-of-current-policies-and-experie

Workneh, B. D., Gebrehiwot, M. G., Bayo, T. A., Gidey, M. T., Belay, Y. B., Tesfaye, D. M., & Kassa, T. T. (2016). Influence of Medical Representatives on Prescribing Practices in Mekelle, Northern Ethiopia. PloS One, 11(6), e0156795. https://doi.org/10.1371/journal.pone.0156795

Zapata-Cachafeiro, M., González-González, C., Váquez-Lago, J. M., López-Vázquez, P., López-Durán, A., Smyth, E., & Figueiras, A. (2014). Determinants of antibiotic dispensing without a medical prescription: a cross-sectional study in the north of Spain. Journal of Antimicrobial Chemotherapy, 69(11), 3156–3160. https://doi.org/10.1093/jac/dku229

APPENDICES

Appendix A: Participant Consent Form

School of Public Health

College of Health Science

University of Ghana

Project Topic

Irrational Use of Antibiotics in Children under Five in Community Pharmacies

Introduction

My name is Kate Damaris Coleman, a student of the School of Public Health, University of Ghana. I am conducting a research in this community to assess the irrational use of antibiotics in children under five in community pharmacies. I would like you to participate in this study. Kindly read the consent before deciding to whether or not to be part of the study.

Description of Procedure

You are being invited to participate because the location of your pharmacy falls within randomly selected retail pharmacies.

Risks and Benefit

There is no risk in participating in this survey. You may feel a little uncomfortable with some of the questions and also take a little more of your time. However, well trained field assistants will carry out the interview in order to minimize time spent or any other discomfort. There is no direct benefit. However, information obtained will be useful in providing some recommendations to improve upon the laws concerning availability of antibiotics.

Participant Rights

Your participation in the study is voluntary and you may choose to skip any of the questions you feel uncomfortable with or end your participation at any time.

Confidentiality

This study is purely for academic purposes. Information divulged would in no way be used against the pharmacy. The facilities would be given unique codes and as such no names would be mentioned in any part of the study.

Subject's permission

The informed consent has been read to me and I understand all the conditions of this project. All my questions have been answered and so I agree to take part in the study

Name of participant…….

Signature/thumbprint……

Date ……..……...

Researcher,s signature……. Date……

Contacts for additional information

If you have any further questions regarding clarification of the study, you can contact Kate Damaris Coleman on 0245078412

Appendix 2: Questionnaire

Project Title: Irrational use of antibiotics in children under five in community pharmacies

A. SOCIO DEMOGRAPHIC BACKGROUND

1. Date of interview (dd/mm/yy): DATE __ __/__ __/__ __

2. Age (at last birthday) …….
   Sex: a. Male b. Female

3. Marital status:
   a. Single b. Married c. Separated/Divorced d. Widow/Widower

4. What is your highest educational level?
   a. None b. Primary/Elementary c. Secondary d. Tertiary e. Others

   If other please specify……

5. Professional Category
   - ☐ Pharmacist
   - ☐ Medicine Counter Assistant (MCA)
   - ☐ Pharmacy Technician
   - ☐ Nurse
   - ☐ Physician Assistant
   - ☐ Other

   If other please specify……

6. Duration of practice
   a. Less than 1 year b. 1-2 years c. 3 – 5 years d. more than 5 years

B. AVAILABILITY OF ANTIBIOTICS

7. Do you stock antibiotics in this facility?
   a. Yes b. No
8. Do you give out antibiotics to parents/guardians to be administered to children under five without prescription?
   a. Yes b. No
9. What class of medications do antibiotics fall?
   a. Prescription only medication
   b. Pharmacist‟s list of medications
   c. Over the counter medications

d. I don‟t know

C. COMMUNITY PHARMACIST'S DISPENSING PRACTICES

10. Do you give out antibiotics for the following conditions in children under five without a prescription? Select all that apply

- ☐ Common Cold
- ☐ Acute watery diarrhoea
- ☐ Cough
- ☐ Sore throat
- ☐ None

11. Which of the following antibiotics do you frequently use in the treatment of the above conditions in Q10?
    a. Amoxicillin/ Clavulanic acid
    b. Cefuroxime
    c. Amoxicillin
    d. Azithromycin
    e. Other (please specify)…….
12. In terms of duration of disease conditions, at which point will you recommend antibiotics to a parent to treat a child under 5 years suffering from any of the above stated disease conditions?
    a. 1-2 days b. 3 days c. 4 to 5 days d. one week e. more than one week

13. What are some of the reasons why you will dispense or not dispense antibiotics without a prescription for the above conditions?

    ……

    ……

14. Was the dosage of the antibiotic given per mg/kg body weight of the child?
    a. Yes b. No

15. What advice/additional information will you give when dispensing the drug?

.....

.....

D. FACTORS THAT INFLUENCE PHARMACIST CHOICE IN GIVING OUT ANTBIOTICS

16. What are the common indications that parents/guardians describe when they demand for antibiotics for their children without a prescription?
    - ☐ Cough
    - ☐ Diarrhoea
    - ☐ Common cold
    - ☐ Sore throat
    - ☐ Others (please specify) …….

17. Will you give out antibiotics to a parent/guardian who is asking for a second pack of previously prescribed antibiotics for a child under five?
    a. Yes b. No

18. If yes, do you assume that the parent/guardian of the child has had enough education and counselling regarding the use of the antibiotic?
    a. Yes b. No

19. If no, explain your reason for not supplying antibiotics in the above scenario in Q17.
    - ☐ Disease condition may be caused by a virus
    - ☐ Antibiotic may not be indicated for the current diagnosis
    - ☐ Current condition might not necessarily be the same as the first even though the symptoms might be similar
    - ☐ I will not supply because a recurrent condition requires the attention of a physician
    - ☐ I do not supply to prevent the abuse of the antibiotic which may lead to resistance

20. Which antibiotic is mostly dispensed on demand by parents/guardians in your pharmacy for children under five without a prescription?
    a. Cefuroxime
    b. Amoxicillin
    c. Metronidazole

d. Amoxicillin/Clavulanic acid

21. When dispensing antibiotics do you ask parents/guardians about any drug allergies the child may have?
    a. Yes b. No

22. What are the major points that you cover when you counsel parents about antibiotics sold without a prescription to children under 5 years? Select all that apply
    - ☐ Storage of antibiotic
    - ☐ Dosage - how it should be taken, any specific dosage timing issues, and what to do if the patient misses a dose.
    - ☐ Completing the course of antibiotics
    - ☐ Consequences of non-adherence
    - ☐ Side effects

23. When dispensing antibiotics without prescription, do you warn parents/guardians about the potential side effects the antibiotics may have on the child?
    a. Yes b. No

24. When dispensing antibiotics without prescription, do you ask parents/guardians if the child is taking any other medication for the same complaint?
    a. Yes b. No

25. When parents demand to buy antibiotics for their children under 5, do you recommend alternative equally effective methods (exclusive of antibiotics) of treating the condition without using antibiotics?
    a. Yes, all the time b. Yes, but not all the time c. Never

26. Do the following factors influence your decision when giving out antibiotics in the community pharmacy?

Select all that apply

- ☐ Profit made from selling antibiotics)
- ☐ Incentives from pharmaceutical companies
- ☐ Demand by parents/guardians for antibiotics
- ☐ Near expiry date of certain antibiotics on the shelf

27. Do Patients return to the pharmacy complaining of antibiotic treatment failure?

    a. Yes, quite often
    b. Yes, but not frequent
    c. Never.

28. What measures do you take when a patient reports antibiotic treatment failure for their children?

    a. Treat patient with an alternate antibiotic
    b. Ask patient to conduct lab investigations
    c. Refer patient to hospital

29. What are the consequences of irrational use of antibiotics in children under 5years? Select all that apply

    - ☐ Antibiotic resistance
    - ☐ Childhood Obesity
    - ☐ Asthma
    - ☐ Allergies
    - ☐ Hypertension
    - ☐ Diabetes

30. Does the law permit pharmacists to dispense antibiotics over the counter without a prescription?

    a. Yes b. No c. Depends