SCHOOL OF PUBLIC HEALTH
COLLEGE OF HEALTH SCIENCES
UNIVERSITY OF GHANA, LEGON

RATIONAL PRESCRIBING OF ANTIBIOTICS IN CHILDREN UNDER 5 YEARS WITH UPPER RESPIRATORY TRACT INFECTIONS IN KINTAMPO MUNICIPAL HOSPITAL

BY

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THIS DISSERTATION IS SUBMITTED TO THE UNIVERSITY OF GHANA IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF A MASTER OF PUBLIC HEALTH DEGREE

July, 2015

DECLARATION

This dissertation is the result of my own independent work under the supervision of Dr. Anthony Danso-Appiah with due acknowledgement paid to all reference sources. I declare that this work either in whole or in part has not been presented for the award of any degree nor is currently being submitted in candidature elsewhere for another degree.

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ACADEMIC SUPERVISOR

DEDICATION

This work is dedicated my lovely wife and son, Sherika and Azmat Baahenere.

ACKNOWLEDGEMENT

I am eternally grateful to the Almighty Allah for my life and all I have achieved to date.

My profound gratitude goes to my supervisor, Dr. Anthony Danso-Appiah for all the support and guidance to make this work a success. My sincerest appreciation goes to Mr. Philip Tabong for the insights, scrutiny of the manuscripts and encouragement in carrying out this work. To Dr. Priscilla Nortey, I am grateful for all the useful comments. To Dr. Patricia Akweongo and the entire staff of the Epidemiology and Disease Control Department, I say thank you for all the support.

To my family, especially my wife and siblings, Mahama and Hakeem and Balkiisu, thank you for all the sacrifice and support. I am grateful to the management and staff of the biostatistics department of the Kintampo Municipal Hospital for permitting me and assisting me to carry out the research in their facility. To my research assistants, I appreciate your collective efforts and say thank you.

ABSTRACT

Background: Upper respiratory tract infections are the most frequently occurring illness of children due to their low immunity and are of high cost to society, being responsible for children absenteeism from school and parents from work. Despite their predominant viral aetiology and self-limiting nature, they continue to be treated with antibiotics. The inappropriate use of these antibiotics in children is accompanied by serious adverse effects. When antibiotics are indicated, there is the need to choose the appropriate effective agent and dose, frequency of intake, duration with the narrowest spectrum, fewest side effects and lowest cost. This study sought to find out how rationally, antibiotics are prescribed in children under five years with upper respiratory tract infections in Kintampo Municipal Hospital.

Methods: A review of records was carried out using the medical records of children under five years who attended the out-patient department of Kintampo Municipal Hospital from 1st January, 2009 to 31st December, 2014 and were managed for upper respiratory tract infections. A total of 270 patients' cards/folders were selected through systematic random sampling and information on age, sex, diagnosis and medication with dose, frequency and duration of therapy extracted. Five prescribers were also interviewed through structured questionnaires. The data were analyzed using Microsoft Excel 2013 and STATA SE Version 13 (College of Texas, USA) at 95% Confidence Interval and statistical significance set at $p<0.05$.

Results: There were 270 prescriptions obtained from 140 (51.8%) male children and 130 (48.2%) female children. A total of 839 medicines were prescribed, made up of 237 antibiotics and other medicines such as antipyretics, antihistamines, nasal decongestants and cough mixtures. The prescribers interviewed were 3 males and 2 females. The mean number of medicines prescribed per patient encounter was 3.1.The percentage of patient encounters with antibiotics was 28.2% and with injections 0.4%. The percentage of medicines prescribed generically was 93.8% and from the Essential Medicines List 94.9%. The most diagnosed upper respiratory tract infections were common cold 142 of 270 (52.6%) and otitis media, a complication of URTI with high antibiotic use accounted for 69 (25.6%). The most prescribed antibiotic was amoxicillin 92 (38.8%) belonging to the penicillin class of antibiotics. The category of prescriptions with 5 to 6 medicines prescribed per patient encounter was significantly associated with rational prescribing [AOR 0.17 (95%, C.I; 0.03-0.87), p-value=0.033].The average consulting time was 12 minutes.

Conclusion: There was good adherence to rational prescribing as most of the prescribing indicators fell within the WHO/INRUD standards. Out of five prescribing indicators, only the mean number of medicines prescribed per patient encounter was higher than the required WHO Standard. Common cold and otitis media are the common upper respiratory tract infections and related infections managed in the institution. The penicillins and cephalosporins are the most preferred antibiotics prescribed for the management of upper respiratory tract infections in children under five years.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ACRONYMS

CSF	Cerebrospinal Fluid
DIU	Drug Information Unit
DTC	Drug and Therapeutic Committee
EML	Essential Medicine List
GDHS	Ghana Demographic and Health Survey
GHS	Ghana Health Service
INRUD	International Network for Rational Use of Drugs
KMH	Kintampo Municipal Hospital
NHIS	National Health Insurance Scheme
RUM	Rational Use of Medicines
SES	Socio-economic Status
USA	United States of America
URTI	Upper Respiratory Tract Infection
WHO	World Health Organization
MOH	Ministry of Health

OPERATIONAL DEFINITIONS

Term	Definition
Age	Age in months at the time of attending hospital and ranges from 0-59 months
Antibiotic	A substance or compound that kills bacteria or inhibits their growth. Antibiotics are produced by various species of microorganisms such as bacteria, fungi and actinomycetes and also includes synthetic antimicrobial agents, such as sulphonamides and quinolones (Laurence L. Brunton, Bruce A. Chabner, 2011)
Diagnosis	The disease or condition arrived at ,based on the symptoms and signs manifested
Medicine	A substance or agent used for the prevention, treatment or diagnosis of a disease or modification of a physiological function.
Rational use of medicines (RUM)	Rational use of medicines requires that patients receive medicines 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 (WHO,1985)
Rational Prescribing	Prescription of medicines that meets the clinical needs of a patient and having the correct dose, frequency of intake and duration of therapy
Sex	Being a male or female
Polypharmacy	Prescribing too many medicines per a patient than is clinical necessary (Mahalli, 2012)

CHAPTER ONE

1.0 INTRODUCTION

1.1 BACKGROUND

Upper respiratory tract infections (URTIs) are any infectious disease of the upper respiratory tract. These infections include; common cold, influenza, pharyngitis, tonsillitis and sinusitis. Although otitis media is not an URTI, it has a direct link with the upper respiratory tract and often results, as a complication of URTIs hence tends to be identified with URTIs in some studies (Skolnik, 2008). Common cold is caused by viruses with the rhinovirus and coronavirus accounting for about 80% of infections (Cotton, Innes, Jaspan, Madide, & Rabie, 2014). Pharyngitis is mostly caused by viruses but may be caused by the diphtheria and streptococcus pyogenes bacteria, where appropriate antibiotics are used in their management. Otitis media is caused by viruses such as the rhinovirus, influenza virus, coronavirus and the bacteria *S. pneumoniae, H. influenzae, S. aureus* and *M. catarhalis* (Johnston, 2012). Tonsillitis though mostly viral, may also be caused by the bacteria streptococcus pyogenes which may require the use of antibiotics. The URTI sinusitis may however be caused by a bacteria, fungi or a virus.

The URTIs are often acquired through direct contact with airborne viruses or respiratory droplets of infected persons when they sneeze or cough. The onset of the signs and symptoms of URTIs are often preceded by nasal stuffiness and throat irritation, usually accompanied by low-grade fever, loss of appetite and pains in the muscles. There is often sneezing, watery nasal discharge, which if not resolved after one to three days becomes mucopurulent and can persist for up to ten days in some patients. Though the URTIs are

often regarded as mild illness and therefore not often given serious attention, occasionally, they can have serious sequelae.

Upper respiratory tract infections in general, are mostly managed symptomatically with basic analgesics to relief fever, increased fluid intake and with nasal decongestants. Antibiotic use in childhood URTIs remains contentious since more than 90% of the infections are of viral aetiology and self-limiting (Cotton et al., 2014). However, as symptoms of URTIs such as pharyngitis, sinusitis and tonsillitis persist beyond a period of observation, they are managed judiciously with antibiotics.

Respiratory tract infections account for almost 10% of worldwide morbidity and mortality (Johnston, 2012). The WHO ranks respiratory tract infections as the second leading cause of deaths worldwide for children under five years of age (Yang, Liu, Wang, Yin, & Zhang, 2014). URTIs are also the leading cause of morbidity and mortality in developing countries, especially in Africa (Cotton et al., 2014). URTIs in acute states often lead to hospitalization and mortality in children worldwide and low-income countries in particular (Rajatonirina et al., 2013).

The intervention of antibiotics in the 1940's, have led to a significant reduction in needlessly deaths from infectious diseases including URTIs worldwide (Davies & Davies, 2010). Most people now live longer and healthier lives, partly because of the availability of antibiotics to manage such infections. According to the Ghana National Drug Policy (GNDP, 2004), drugs are estimated to constitute 60-80% of cost of healthcare in Ghana. Nonetheless, the inappropriate use of these medicines has become an issue of global concern. Some reports have shown that more than 50% of all medicines are prescribed, dispensed or sold inappropriately and 50% of all patients also fail to take medicines

correctly globally (Bbosa, Wong, Kyegombe, & Ogwal-okeng, 2014). For the world to continue to derive maximum benefit from these medicines depends on how they are rationally used so as to minimize microbial resistance.

The conference of Experts on the Rational Use of Medicines, convened by the World Health Organization (WHO) in Nairobi in 1985 defined the Rational Use of Medicines as follows: "rational use of medicines requires that patients receive medicines 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". In view of this, the use of medicines that do not meet the needs of patients in terms of disease condition, dose, frequency and duration of therapy is described as irrational or non-rational or inappropriate use of medicines. Common types of irrational use include:

- When too many medicines are prescribed for a patient ('Poly pharmacy')
- Inappropriate use of antibacterial, often inadequate dosage or when used for non-bacterial infections
- Over-use of injections when oral formulations would be more appropriate
- Failure to prescribe in accordance with clinical guidelines such as the Standard Treatment Guideline of Ghana
- Inappropriate self-medication, often using "prescriptions only" medicines.

The irrational use of medicines especially antibiotics is a global problem, more especially in developing countries. The irrational use of antibiotics have several implications including; increased emergence of resistance to these antibiotics by bacteria, higher cost of

treatment, prolonged hospitalization and adverse drug reactions (Bbosa, Wong, Kyegombe, & Ogwal-Okeng, 2014).

Antibiotic comes from the Ancient Greek words; *vri-anti* meaning "against" and *Biog-bios*, meaning "life" which is a substance or compound that kills bacteria or inhibits their growth. Antibiotics are produced by various species of microorganisms such as bacteria, fungi and actinomycetes and are commonly extended to include synthetic antimicrobial agents, such as sulphonamides and quinolones (Laurence L. Brunton, Bruce A. Chabner, 2011).

The Ghana Health Facility survey (2008), revealed a high level of injection use (13.3%) and excessive levels of antibiotic (43.3%) prescribing across health facilities in Ghana. Many countries also fail to implement basic policies to promote the rational use of medicines and less than 40% of patients with infections are treated according to clinical guidelines (Nordberg, Monnet, Cars, Lodato, & Kaplan, 2013).

The world is on the brink of losing this precious arsenal of medicines and it is in line with this that, the WHO in the year 2011 selected antimicrobial resistance (AMR) as the theme for World Health Day with the slogan "Combat Drug Resistance. No action today, no cure tomorrow" (WHO, 2011). Though prescribing patterns generally differ between countries, very little is known about paediatric prescribing practices in Africa. Nonetheless, a study in Gambia had reported the frequency of antibiotic use to be as high as 63.4% in children with cough and coryzal symptoms (Risk et al., 2013).

Approximately three-fourth of all out patient prescriptions given, are for upper respiratory tract infection (viral bronchitis and pharyngitis) and related complications such as otitis

media (Nash, Harman, Wald, & Kelleher, 2002). Where there is the need to prescribe antibiotics, it is essential to use them rationally to minimize antibiotic resistance, adverse effects and higher health costs.

To address the issue of irrational use of antibiotics, requires that strategies to be geared towards initially identifying the types of irrational use, the extent and impact, and the reasons for its occurrence. In view of this, the WHO/INRUD (WHO, 1993) as cited in (Akl, El Mahalli, Elkahky, & Salem, 2014), developed Indicators for assessing the rational use of medicines in primary health care facilities based on the following perspectives;

Prescribing Indicators

- ✓ Average number of medicines prescribed per patient encounter
- ✓ % medicines prescribed by generic name
- ✓ % encounters with an antibiotic prescribed
- ✓ % encounters with an injection prescribed
- ✓ % medicines prescribed from essential medicines list or formulary

Patient Care Indicators:

- ✓ Average consultation time
- ✓ Average dispensing time
- ✓ % medicines actually dispensed
- ✓ % medicines adequately labelled
- ✓ % patients with knowledge of doses

Facility Indicators:

- ✓ Availability of essential medicines list or formulary to practitioners
- ✓ Availability of clinical guidelines
- ✓ % key medicines available

Complementary Drug Use Indicators:

- ✓ Average medicine cost per encounter
- ✓ % prescriptions in accordance with clinical guidelines

1.2 STATEMENT OF THE PROBLEM

In the last decades, medicines have had an unprecedented positive effect on health, leading to reduced mortality and disease burden and consequently to an improved quality of life (WHO, 2012).However, the high occurrence of upper respiratory tract infections in children and the indiscriminate use of antibiotics in their management is of global concern. In the Brong Ahafo region of Ghana, URTIs have ranked second to malaria among the top ten diseases in the years 2012, 2013 and 2014 and also among the top ten diseases in the Kintampo municipality. Upper respiratory tract infections affect both adults and children, however children are the most vulnerable due to their low immunity. Most children tend to suffer 3 to 8 bouts of colds per year with the incidence much reduced in adult life (Woods, 2006).

In spite of the effectiveness of antibiotics to treat many bacterial infections, they are frequently used inappropriately to treat viral infections as in many cases of URTIs (Al-Niemat, Aljbouri, Goussous, Efaishat, & Salah, 2014). Though awareness of the consequences of antibiotic misuse is increasing, overprescribing remains widespread,

driven largely by patient demand, time pressure on clinicians and diagnostic uncertainty (Laurence L. Brunton, Bruce A. Chabner, 2011). In view of this, rational use of antibiotics is extremely important as any injudicious use can adversely affect the patient, initiate emergence of antibiotic resistance and thus increase cost of healthcare.

A major step towards the rational use of medicines was taken in 1977, when WHO established the 1st Model List of Essential Medicines to assist communities in formulating their own rational lists (WHO, 2002). The Ghana National Drug Programme, as part of its mandate, has ensured the publication and distribution of Essential Medicines Lists and Standard Treatment Guidelines to all public health institutions over the years (GNDP, 2004). Data has revealed that, in spite of various measures put in place by countries worldwide to promote the judicious use of medicines, health budgets spent on medicines continue to rise. This ranges between 10% and 20% for developed countries and 20% to 40% in developing countries (Reddenna, 2014).

There is the need for rational prescribing of antibiotics, so as to minimize the risk of adverse drug effects, the extent and rate of antibiotic use especially in children under five years who are the most vulnerable group. Neonates, for example, have immature liver and renal functions which affect their ability to metabolize and excrete antibiotics (Green & Gammouh, 2012).

1.3 CONCEPTUAL FRAMEWORK

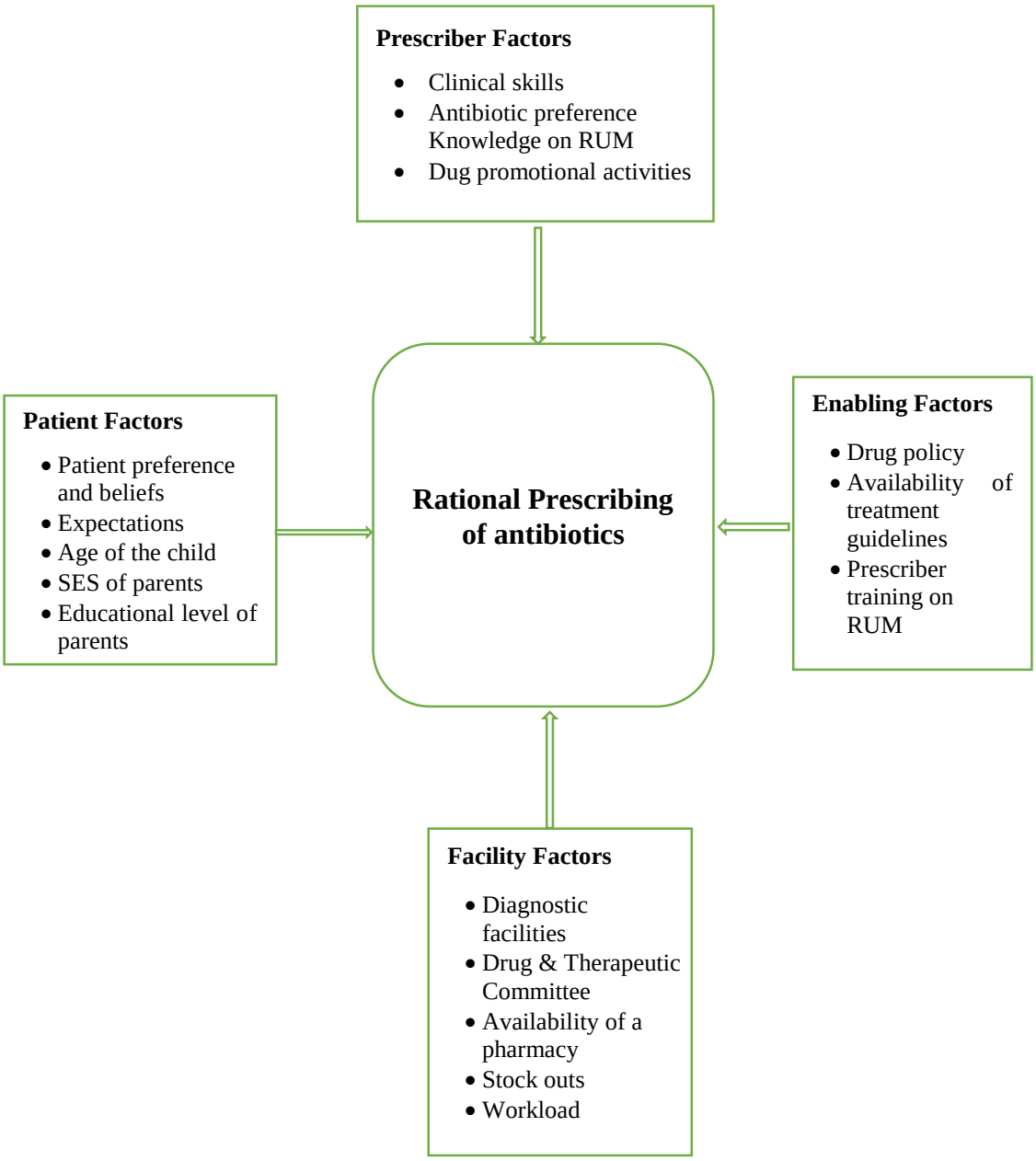

Figure 1: Conceptual Framework of Rational Prescribing of Antibiotics.

Once a child under five years of age develops any URTI and taken to the hospital a diagnosis should be made by either a medical officer or a physician assistant. The appropriateness of the diagnosis made is influenced by the clinical skills of the prescriber, knowledge on RUM and the promotional activities of pharmaceutical companies

attempting to increase patronage of their antibiotics. The rational prescribing of antibiotic is influenced by the patient's factors such as the socio-economic and educational status of the parents of the patient as their preference for certain antibiotics when they are needed. Factors within the health facility such as the presence of requisite diagnostic tools, functioning DTC to advice and formulate medicine formulary, a pharmacy with minimal stock outs affect the rational prescribing of antibiotics. The workload of prescribers also influence the rational prescribing. The appropriateness of the choice of antibiotics the dosage and duration of therapy is further influenced by the drug policy and treatment guidelines of the nation (Figure 1).

1.4 JUSTIFICATION

According to a WHO study of antibiotic use in thirteen low, middle and high countries from 1992 to 1996, it was revealed that antibiotics were wrongly prescribed for approximately 30% of cases of URTI. According to the Ghana Health Facilities Survey (2008) "excessive levels of antibiotic prescribing (43.3%) were observed in 2008. Similar findings were also found in 2002. Prescribing patterns differ between countries, little is known about pediatric prescribing practices in Africa. However there is evidence of high antibiotic prescription in children with cough and coryzal symptoms (Risk et al., 2013). This practice of excessive and inappropriate use of antibiotics poses a great danger to children under 5 years, as this may lead to serious adverse effects such as hepatotoxicity and other complications since their livers and renal systems are less matured.

In the last decade, some studies have been conducted on the use of antibiotics in adults in developing countries including Ghana, however very little has been done on children. The

rationale of this study was to explore the pattern of antibiotics prescribing in children under 5 years of age and whether the requisite indicators for rational prescribing of medicines are followed. This study further sought to generate data on the desired and actual prescribing of antibiotics to guide policy and practice and the development of appropriate framework to address the shortfalls and improve on good practices.

1.5 OBJECTIVES

General objective

To assess rational prescribing of antibiotics in children under 5 years with upper respiratory tract infection in Kintampo Municipal Hospital.

Specific objectives

1. To determine the common types of upper respiratory tract infections in children under 5 years attending to the Kintampo Municipal Hospital.
2. To identify types of antibiotics used in the management of upper respiratory tract infections in children under 5.
3. To assess the appropriateness of antibiotics prescribed for children <5 years managed for URTIs (dose, frequency of dosing and the duration of therapy).

CHAPTER TWO

1.0 LITERATURE REVIEW

2.1 Upper Respiratory Tract Infections and Their Management

Children form a large proportion of the populations of many developing countries hence the importance of their health status (Joseph, Oladele, Oludare, & Olatunde, 2015). Upper respiratory tract infections are the common causes of morbidity in children and the most frequently occurring illness of childhood , one of the most common reasons for mothers' visit to the hospital (Nandimath & Ahuja, 2012).The common URTIs include; common cold,pharyngitis,tonsillitis, and sinusitis. The inclusion of otitis media to the URTIs though a disease of the middle ear is due to its link to the upper respiratory tract and most occurrence as a complication of URTIs with high antibiotic use in children. This has led to its classification as an URTI in some studies.To ensure an efficient management of URTIs requires prudent diagnosis and rational prescribing based on Standard Treatment Guidelines.

COMMON COLD:-This includes a common viral infection of the nasopharyngeal mucosa. Common cold may be caused by more than 200 viruses and many people suffering from cold symptoms are found to be infected with several viruses at the same time. The rhinovirus and the coronavirus tend to account for about 60% of the infections (Nandimath & Ahuja, 2012). Annual epidemics occur within the colder months in temperate climates and during the rainy season in the tropics. It is contagious and spread by airborne droplets but in most cases is self-limiting and symptoms may resolve within a week. Where the cold fails to resolve after one week and is accompanied with persistent fever and cough,

increased phlegm or offensive nasal discharge, it is an indication of secondary bacterial infection or influenza or a complication of otitis media in children (Woods, 2006). No antibiotic is required for common cold, but secondary infection needs to be confirmed and treatment with the appropriate antibiotic.

PHARYNGITIS:-This is an infection of the throat often resulting in sore throats. These are mostly due to viral infections and should not be treated with antibiotics as they resolve within 35 days. However there are two important pharyngitis that are caused by diphtheria and streptococcus pyogenes, hence require antibiotic treatment. Though diphtheria has become a rare occurrence due to various immunization programmes, streptococcal pharyngitis still persists especially among poor economic settings. Streptococcal pharyngitis often manifests as febrile, purulent pharyngitis without cough and may result in rheumatic fever if not treated. Is very important to diagnose streptococcal pharyngitis since it may give rise to abscesses in the throat (retropharyngeal) as well as complications involving the kidneys and the heart (STG, 2010). Pharyngitis is uncommon in children under three years (Woods, 2006). To reduce the complications above, requires the appropriate antibiotics use.

TONSILLITIS:-This is an infection of the tonsils. Though mostly viral and self-limiting, may also be due to *Streptococcus* resulting in peritonsillar abscess. Hence requires antibiotic treatment.

Recommended antibiotics for Pharyngitis and Tonsillitis (STG, 2010)

- Amoxicillin (oral suspension): Dose-< 1 year: 62.5mg 6 hourly for 10 days and 1-5 years: 125mg 6 hourly for 10 days.

- Amoxicillin +Clavulanic acid: Dose- Neonate: 0.25 ml /kg of 125/31 suspension 8 hourly for 7days; 1month-1year: 0.25ml/kg of 125/31 suspension 8 hourly for 7 days; (Should be doubled in severe infection) 1-5 years: 5 ml of 125/31 suspension 8 hourly for 7 days (doubled in severe infection) OR 0.25 ml of 400/57 suspension 12 hourly for 7 days.
- Benzyl penicillin (IV): Dose: 0.5 MU/kg (25 mg/kg) 6 hourly.
- Amoxicillin+clavulanic acid (IV) Dose: 30mg/kg. Where patient is allergic to penicillin.
- Erythromycin; Dose: 0-2 years: 125 mg 6 hourly for 10 days; Dose: 2-5 years: 250 mg 6 hourly for 10 days or Azithromycin (oral suspension): Dose: 10mg/kg daily for 3 days.

ACUTE OTITIS MEDIA: This is an inflammatory disease of the middle ear, which communicates with the throat and especially in children it may come after a common cold or sore throat or measles infection. Untreated or poorly managed cases may lead to complications such as mastoiditis, chronic otitis, deafness, meningitis and brain abscess. It is therefore important in every febrile child to look for otitis media and treat (STG, 2010). However, according to Glasziouu (2002), most episodes of acute otitis media settle spontaneously without ongoing problems. Antibiotics have limited benefit; about 17 children with acute otitis media need to be treated with a broad spectrum antibiotic for one child to benefit, and their use is associated with a near doubling of the risk of vomiting, diarrhoea or rashes (File Jr. & Hadley, 2002).

Recommended antibiotics (STG, 2010)

- Amoxicillin (oral suspension): Dose :< 1 year: 62.5 mg 8 hourly for 10 days; 1-5 years: 125 mg 8 hourly for 10 days.
- Amoxicillin+Clavulanic acid**:** Neonates: 0.25ml/kg of 125/31 suspension, 8 hourly for 10 days; 1month-1year: 0.25ml/kg of 125/31.8 hourly 10 days; 1-5 years: 2.5ml of 400/57 suspension 8 hourly for 10 days**.** (Doses to be doubled in severe cases).

Where patient is allergic to penicillin

- Erythromycin: Dose: 0-2 years: 125mg 6 hourly for 10 days; 2-5 years: 250mg 6 hourly for 10 days.
- Co-trimoxazole: Dose: 6 weeks-5months: 120mg 12 hourly for 7 days; 6 months-5 years: 240mg 12 hourly for 7 day.

Alternative Treatment

- Cefuroxime (oral suspension) Children: 125mg 12 hourly for 5 days or Azithromycin (oral suspension) Children: 125mg once daily for 3 days

2.2 Irrational Use of Antibiotics

Antimicrobials are said to be the greatest discovery of the twentieth century. In the pre-antibiotic era, infectious diseases accounted for significant global morbidity and mortality, and evasive medical procedures were fraught with the risk of infection. However, the irresponsible and erratic use of these life-saving agents has resulted in the development of drug resistance in many organisms. Deaths due to hospital- acquired infections is on the rise, with greater suffering and disability, and higher health care costs.This inappropriate use of medicines and related illness and deaths, are not restricted to low-income countries

(Joda & Aderemi-williams, 2013). Irrational use of antibiotics continues to occur in spite of available tools, information and various interventions and strategies.

Categories of irrational use of antibiotics (WHO, 2002)

- The use of too many medicines per patient.(Polypharmacy)
- Inappropriate use of anti-microbial often in inadequate dosage, for non-bacterial infections
- Over-use of injections when oral formulations would be more appropriate.
- Failure to prescribe in accordance with clinical guidelines.
- Inappropriate self-medication, often of prescription-only medicines

Causes of Irrational Uses of Antibiotics (Brahma & Marak, 2012)

There are several causes of irrational use of antibiotics. Some of these causes include;

Lack of knowledge or skills on the part of prescribers on the rational use of medicines. For instance the prescriber may have received inadequate training either pre-service or in-service or the prescribing practices of the prescriber may have become outdated because of lack of continuing education and a poor supervisory system (WHO, 2002)

The lack of facilities such as Drug Information Unit and Drugs and Therapeutic Committee to provide regular up to date independent information on medicines to enable prescribers update their knowledge on current practices have also been reported to affect the appropriate use of medicines (Desalegn, 2013).

In addition, workload of prescribers do not permit them to carry thorough laboratory investigations. Furthermore, in an attempt to satisfy patients' expectations and demand of

quick relief, clinicians tend to prescribe medicines for every single complaint (polypharmacy). Furthermore, promotional activities of Pharmaceutical companies may influence the prescribing pattern of clinicians as they lack the time to cross check therapeutics claims. An earlier study among prescribers in Malaysia showed that 93 (52.5%), prescriptions were influenced by advertisement/marketing by the drug companies (Hassali et al., 2014).

The non-adherence to good antibiotic prescribing as a result of the aforementioned factors can result in antibiotic resistance.Antibiotic resistance is a serious and growing phenomenon in contemporary medicine and has emerged as one of the pre-eminent health concerns of the 21st century in particular, as it pertains to pathogenic organisms (WHO, 2014).A WHO study of antibiotic use in 13 low-, middle-and high income countries from 1992 to 1996 revealed that, antibiotics were wrongly prescribed approximately in 30% of cases of upper respiratory tract infections .According to the Ghana Health Facilities Survey, (Survey, 2008)" excessive levels of antibiotic prescribing (43.3%) were observed in 2008 as it were the situation in the 2002 survey". In developing and transitional countries, in primary care, less than 40% of patients in the public sector and 30% of patients in the private sector are treated in accordance with standard treatment guidelines.(Holloway, 2011).

A survey done in the U.S reported that, antibiotic agents or drugs were prescribed to 44% of patients with common cold, 46% with upper respiratory infections and 75% of patients with bronchitis and the children aged 0 to 4 years received 55% antibiotics in their prescriptions (Huttner, Goossens, Verheij, & Harbarth, 2010). It is also reported that, up to 75% of antibiotic drugs are prescribed inappropriately in teaching hospitals in developing

countries (Al-Niemat et al., 2014). An overview of Cochrane reviews on the use of antibiotics for upper respiratory tract infections reveals a limited role of antibiotics in acute otitis media, sore throat and streptococcal tonsillitis, common cold and acute purulent sinusitis (Arrol.2005).

2.3 Promotion of Rational Use of Medicines

As part of measures to ensure RUM, the Ghana National Drug Programme (GNDP, 2004) has over the years promoted the establishment of Drug and therapeutic committees in health institutions to oversee the use of medicines. Furthermore, workshops on rational use of medicines for prescribers, pharmacists and other stakeholders are organized routinely.

2.3.1 Drugs and Therapeutics Committees

Drugs and therapeutic committees (DTC) also known as pharmacy and therapeutic committee are established in district and tertiary hospitals to ensure the rational and cost-effective use of medicines (WHO, 2002).The membership of DTC consist of representatives of all major specialties and the administration. A senior medical officer is usually the chairperson and a pharmacist the secretary. An effective and successful DTC has a firm mandate and clear objectives supported by the hospital management and working in transparency with requisite technical competences and sufficient resources.

Responsibilities of a DTC (WHO, 2002)

- Developing, adapting or adopting clinical guidelines for the institution.
- Selecting cost-effective and safe medicines (hospital/district medicine formulary)
- Implementing and evaluating strategies to improve medicine use (including drug use evaluation and liaison with antibiotic and infection control committees)

- Providing on-going staff education(training and printed materials)
- Controlling access to staff by the pharmaceutical industry with its promotional activities.
- Monitoring and taking action to prevent adverse drug reactions and medication errors
- Providing advice about other drug management issues, such as quality and expenditure.

2.4 Choice of Appropriate Antibiotic

Optimal and judicious selection of antibiotic agent for the therapy of infectious diseases requires clinical judgement and detailed knowledge of the pharmacology and microbiological factors (Adorka, Allen, Lubbe, & Serfontein, 2013). It is first required of the prescriber to confirm the presence of an infection through careful history and physical signs and symptoms, predisposing factors including relevant laboratory data. Secondly, the causative pathogen needs to be identified. Examination of infected body materials such as blood, sputum, wound drainage need to be carried out if possible and practical before the initiation of antimicrobial therapy. The pharmacokinetics of the drugs and host allergy to previous medications may also be considered. Antibiotic therapy is therefore more complicated than just matching an antibiotic to a known or suspected pathogen (Mailard, 2002).

In practice, antibiotics may be used in three main ways; empirically, where antibiotic therapy is initiated bearing in mind that, the infecting organism(s) has not been defined therefore a single broad spectrum agent to cover all the likely pathogens or a combination therapy is used. Prophylactic or preventive therapy is often the attempt to prevent an

infection or its reoccurrence and is restricted mainly to patients undergoing some types of surgery or immune-compromised patients (Brayfield, 2014). Definitive therapy on the other hand is required once the infecting organism has been identified, then a definitive antibiotic with a narrow spectrum and low-toxicity which specifically targets the microorganism is selected to complete the course of treatment.

2.5 Types of Antibiotics Used In the Management of Upper Respiratory Infections

2.5.1 PENICILLINS

In 1928, while studying staphylococcus variants in the laboratory at St Mary's hospital in London, Alexander Fleming observed that a mould containing one of his cultures caused the bacteria in the vicinity to undergo lysis (disintegration). Broth in which the fungus was grown was markedly inhibited for many microorganisms and because the mould belonged to genius *penicillium notatum*, he named the antibiotic penicillin (Brayfield, 2014). Four different fractions of penicillin were identified from the *penicillium notatum* namely penicillins F, G, K and X. The first Penicillin to be used therapeutically as an antibacterial was a mixture of the four fractions (Laurence L. Brunton, Bruce A. Chabner, 2011). Better yields were later achieved using *P. chrysogenum* and benzyl penicillin (penicillin G) was selectively produced by adding the precursor phenyl acetic acid to the fermentation medium. Benzyl penicillin is now used generically for the entire group of natural and semisynthetic penicillins. It is inactivated by penicillinase-producing bacteria. Benzyl penicillin is usually given by injection due to its instability in gastric acid. Phenoxymethylpenicillin (Penicillin V), ampicillin and amoxicillin are acid stable and are given orally, though inactivated by the enzyme penicillinase. The long acting penicillins include; procaine benzyl penicillin and benzathine benzyl penicillin.

Antimicrobial Activity

Benzyl penicillin is a beta-lactam antibiotic with bactericidal effect on susceptible microorganisms of both gram positive and gram negative origin.

Mechanism of Action

It kills bacteria by inhibiting the synthesis of bacteria cell wall

Adverse Effects

The most common adverse effects of benzyl penicillin are hypersensitivity reactions, especially skin rashes; anaphylaxis occasionally occurs and has sometimes been fatal. Gastrointestinal effects such as diarrhoea and nausea are the most common adverse effects after oral use of penicillin; Pseudomembranous colitis has been associated with the use of most antibiotics; ampicillin and amoxicillin are the most frequently implicated penicillins.

Hypersensitivity to penicillin gives rise to immediate reactions including anaphylaxis, angioedema, urticarial, and some maculopapular rashes. Late reactions may include, serum sickness-like reactions and haemolytic anaemia.

Precautions

Patients known to be hypersensitive to penicillins should be given an antibacterial of another class. However, sensitized patients may also react to the cephalosporins and other beta lactams. Penicillins should be given with caution to patients with a history of allergy, especially allergy due to drugs. Renal, hepatic, and hematological status should be monitored during prolonged and high-dose therapy. Penicillin therapy changes the normal bacterial flora and can lead to superinfection with penicillin-resistant organisms including *Clostridium difficile* or *Candida,* particularly with prolonged use.

Amoxicillin

Amoxicillin is a penicillinase susceptible semisynthetic penicillin with a D (-)-α-amino hydroxyphenyl acetamido side chain only differs from ampicillin by the addition of hydroxyl group which allows rapid and complete absorption from the gastrointestinal tract. It is acid stable and designed for oral administration, absorption not interfered by food administration (Laurence L. Brunton, Bruce A. Chabner, 2011).

Therapeutic Indications

Effective therapy for sinusitis, otitis media, acute exacerbations of chronic bronchitis and epiglottitis is Amoxicillin. Amoxicillin is the most active of all oral beta-lactam antibiotics against both penicillin-sensitive and penicillin-resistant *S.pneumoniae* (Friedland and MacCraken, 1994).

2.5.2 CEPHALOSPORINS

Cephalosporins or cephem antibacterials are semi synthetic antibacterials derived from cephalosporins C, a natural antibacterial produced by the mould *Cephalosporium acremonium* in 1948 by Brostzu from the sea near sewer outlet off the Sardian Coast. They have an active nucleus, 7-aminocephalosporanic acid, which is very closely related to the penicillin nucleus, consisting of a beta-lactam ring and having an acetoxymethyl group at position 3. Substitutions at the 7-amino group tends to affect antibacterial action whereas at position 3, it may have more of an effect on pharmacokinetic properties.

Classification

They are classified by generations based on their antibacterial activity and to some extent when they were produced. In general, progression from first generation to higher

generations exhibit broadening Gram negative coverage, decreasing efficacy against Gram positive and greater efficacy against resistant strains and higher cost. Some of the first generation cephalosporins include cephalexin and cephazotin.(Brayfield, 2014). The second generation cephalosporins have an enhanced stability to hydrolysis by beta lactamases produced by Gram negative bacteria, hence better activity against *Enterobacterioceae* and *Haemophilus influenza* and members include; cefaclor, cefuroxime and cefoxitin (Powers, 1964).The third generations have broader activity against Gram negative organisms including many of the significant *Enterobacteriaceae* and *Streptococci.* A member of this group is ceftriaxone.

Mechanism of action

The cephalosporins are bactericidal in action and they inhibit bacterial cell wall synthesis.

Therapeutic uses

They are used for the management of conditions such as otitis media, sinusitis, urinary tract infections, and meningitis.

Adverse reactions

Common side effects include hypersensitivity reactions identical to those caused by the penicillins, which may be related to the shared beta-lactam structure of both groups of antibiotics. Anaphylaxis, bronchospasm and urticaria are observed more commonly. Maculopapular rash develops, usually after several days of therapy; this may or may not be accompanied by fever and eosinophilia.

2.5.3 MACROLIDES

The macrolides form a large group of antibiotics isolated from *Streptomyces erythreus* in 1952. They possess a common lactone ring to which one or more sugars are attached. They are weak bases and only slightly soluble in water and exhibit similar properties. Destroyed by gastric acid and therefore always given as enteric-coated formulations as adults or as one of its more stable salts or esters such as the stearate or ethyl succinate in paediatric preparations.

Members of this group include: Erythromycin, azithromycin, clarithromycin, dirithromycin roxithromycin and flurithromycin.

Mechanism of Action

They are bacteriostatic agents which inhibit protein synthesis by binding irreversibly to 50s ribosomal subunits of sensitive microorganisms at or very near the site that binds to chloramphenicol. Active against organisms such as Legionella pneumophila and mycoplasma pneumonia. However they have a post antibiotic effect where their antibacterial activity persist after concentrations have dropped below the minimum inhibitory concentrations (Laurence L. Brunton, Bruce A. Chabner, 2011)

Adverse reactions

Generally, well tolerated, though gastrointestinal disturbances such as abdominal discomfort, cramps, nausea, vomiting and diarrhea may occur probably due to stimulant activity on the gut and this is more associated with ethyl succinate. The adverse effects are however dose related and more common in children and the elderly. Hypersensitivity

reactions are rare, about 0.5% of pruritis, urticaria and skin rash. Infantile hypertrophic pyloric stenosis is also associated with the macrolides.

Precautions

The macrolides should be avoided where there is evidence of existing liver disease and hepatic impairment especially with estolate salt which increases the risk of hepatotoxicity. The lactobionate salts should also be avoided in severe renal impairment.

Pharmacokinetics

Azithromycin given orally is rapidly absorbed and about 40% bioavailable. Absorption from capsular forms unlike the tablets or suspension, is reduced by food. Peak plasma concentrations occur 2 to 3 hours after an oral dose and 1 to 2 hours after intravenous dosage. High concentrations of erythromycin is used as an alternative to penicillin in many infections, especially in patients who are allergic to penicillin. Erythromycin has similar uses to tetracycline in the treatment of infections due to *Mycoplasma pneumoniae* and *Chlamydia trachomatis*, and in acne vulgaris. It is also used in the treatment of infections caused by *Legionella pneumophila.*

These drugs all appear to have similar properties to erythromycin although they may differ in their pharmacokinetics.

Gastrointestinal disturbances are the most frequent adverse effects of azithromycin but are usually mild and less frequent than with erythromycin. Headache, somnolence, and taste disturbances may occur. Severe hypersensitivity reactions occur rarely but may be prolonged. Thrombocytopenia and mild transient neutropenia have been rarely reported in

patients receiving azithromycin. Pain and inflammation may occur at the site of intravenous infusions particularly at high concentrations.

Antimicrobial Action

Azithromycin is less active than erythromycin against *streptococci* and *staphylococci*, but has greater activity than erythromycin in vitro against some Gram-negative organisms such as *Haemophilus influenzae* and *Moraxella catarrhalis*, as well as having activity against some of the *Enterobacteriaceae* such as *Escherichia coli* and *Salmonella* and *Shigella spp* (Brayfield, 2014) Azithromycin is also more active than erythromycin against *Chlamydia trachomatis* and *Urea plasma urealyticum*, and some opportunistic mycobacteria, including *Mycobacterium avium* complex. It has activity against the protozoa *Toxoplasma gondii* and *Plasmodium Falciparum* are taken up into white blood cells.

Uses and Administration

Azithromycin is a nitrogen-containing macrolide with actions and uses similar to those of erythromycin. It is given in the treatment of respiratory tract infections (including otitis media), in skin and soft-tissue infections, and in uncomplicated genital infections. It is also used in the management of trachoma and typhoid. Azithromycin and its salts and esters are generally well tolerated and serious adverse effects are rare. Gastrointestinal disturbances such as abdominal discomfort and cramp, nausea, vomiting, and diarrhoea are fairly common after both oral and parenteral use.

Interactions

Erythromycin and other macrolides have the potential to interact with a large number of drugs through their action on hepatic cytochrome P450 isoenzymes, particularly CYP1A2

and CYP3A4. Macrolides inhibit drug metabolism by microsomal cytochromes by competitive inhibition and by the formation of inactive complexes

CHAPTER THREE

3.0 METHODS

3.1 Study Design

A review of medical records of children under five years who attended the out-patient department of Kintampo Municipal Hospital and were managed for upper respiratory tract infections, between the 1st of January, 2009 and 31st December, 2014.

3.2 Study Area

3.2.1 Profile of study area

The Kintampo Municipality is one of 22 districts in the Brong Ahafo region of Ghana. Administratively, it has 4 sub-districts and shares boundaries with Atebubu district to the East, Wenchi district to the west, Techiman and Nkoranza to the South and South-East respectively. To the North of Kintampo are Bole and central Gonja districts. The municipality has a population of 111,263 (Ghana Statistical Service, 2012) with a total land area of 5,108 km^2 (1,972 sq.m). Kintampo is located at the central point of Ghana and lies within latitudes 8^0 45N" and 7^0 45N and longitudes 1^0 20 W and 2^0 1'E. The main indigenous ethnic groups are of the Bono and Mo origin. However, there are large permanent immigrant population from the North consisting, the Daagabas, Dagomba, Sissalas, kokomba, Grushies and Ewes .Major socio-economic activities of the Municipality are farming and trading. The Kintampo Municipality has one District hospital, two Health centres, two Rural clinics, one CHIPS compound and one Maternity home.

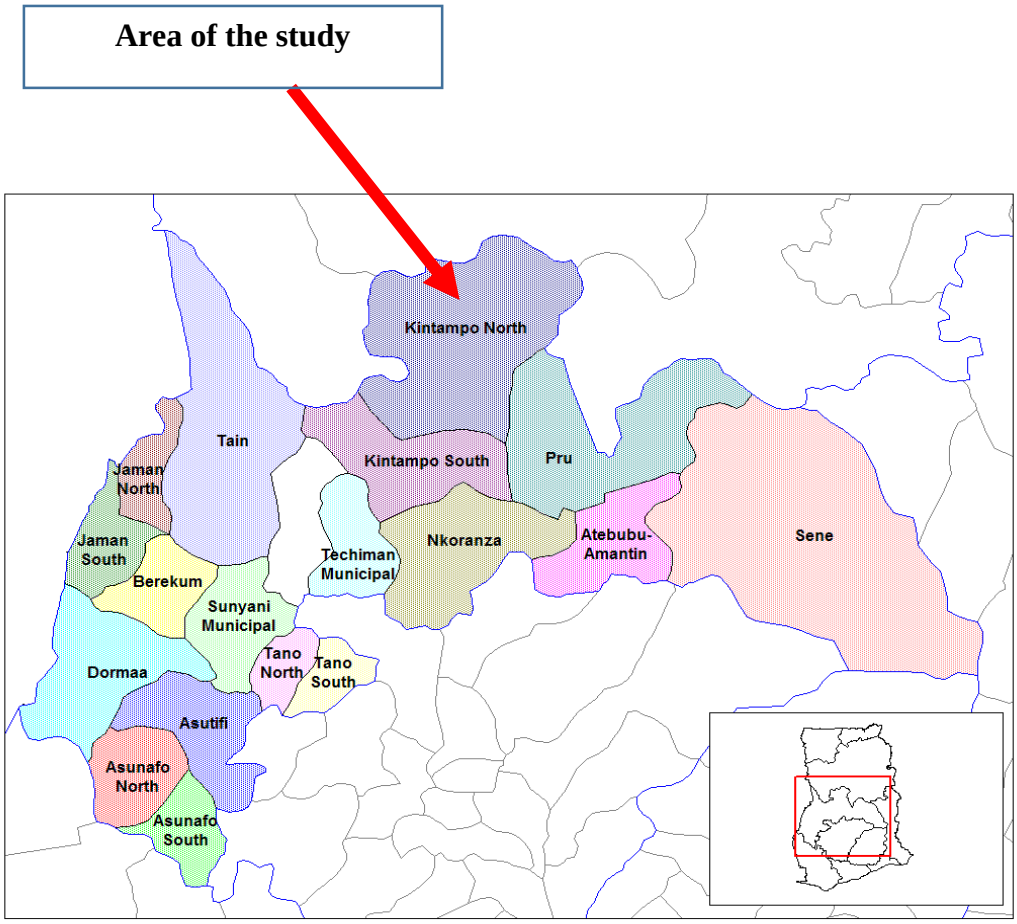

Figure 2: (Map of Brong Ahafo Region Showing Kintampo Municipality)

(Source: En.wikipedia.org)

3.2.2 The Kintampo Municipal Hospital

The Kintampo municipal hospital (KMH) is strategically located in Kintampo which is the most densely populated town of the municipality to effectively serve the entire municipality. Kintampo municipal hospital was built during World War II by the British Colonial Government for their military personnel stationed in Kintampo. It is a 125 bed

capacity hospital, which provides general health care service .The hospital has an average daily out-patient attendance of 250 patients.

3.3 VARIABLES

The outcome variable is the rational prescribing of antibiotics in children under 5 years.

The Independent Variables include:

- Demographic Characteristics (age and sex)
- Types of upper respiratory tract infections
- Types of antibiotics prescribed
- Doses, frequency and duration of antibiotics prescribed

3.4 STUDY POPULATION

The study population included children under 5 years who attended the out-patient department of the Kintampo Municipal Hospital between the period of 1st January, 2009 and 31st December, 2014 and were managed for upper respiratory tract infections. All five prescribers who were at post during the study period were interviewed.

Table 1: Description of Study Variables

Category	Variable	Operational Definition	Scale of Measurement
Outcome	Rational prescribing of antibiotics in children under 5 years with URTIs	Prescription of antibiotic that meets the clinical needs of a patient and having the correct dose, frequency of intake and duration of therapy	Binary
Independent	Age	Age at the time of attending hospital and is 0-59 months	Categorical
	Types of URTIs	Includes; common cold, influenza, otitis media, pharyngitis, tonsillitis, sinusitis and non-specific URTI	Categorical
	Types of Antibiotics prescribed	Antibiotics used in the management of URTIs in KMH	Categorical
	Appropriate Dose, Frequency and Duration of antibiotics prescribed	• Dose = ml/mg per body weight of antibiotic to be taken at a time • Frequency = time interval antibiotic is to be taken within 24 hours • Duration of therapy = For how many days antibiotic is to be taken	Binary
	Diagnosis		Categorical
	Number of antibiotics	The number of antibiotics prescribed for a patient with a single URTI per single visit to the hospital	Categorical
	Number of antibiotic Injections	The number of antibiotic injections prescribed for a patient with a single URTI per single visit to the hospital	Categorical
	Number of medicines	The number of medicines prescribed for a patient with a single URTI per single visit to the hospital	Categorical
	Sex	Being a male or female	Binary

3.4.1 Inclusion Criteria

Records of all children under 5 years of age who attended the outpatient department of the Kintampo Municipal Hospital with URTIs from 1st January, 2009 to 31st December, 2014 were included in the study.

3.4.2 Exclusion Criteria

Patients' medical records with multiple diagnoses were excluded as it would have been difficult to determine which medicines were being prescribed for which diagnosis and also prescribing patterns may differ with such cases. In-patient medical records were also excluded.

3.5 SAMPLING

3.5.1 Sample Size Determination

For a drug utilization studies in a single health facility, WHO (1993) recommends the use of at least 100 patient records. Data from Kintampo Municipal Hospital indicates an average of 9 upper respiratory tract infections cases of children < 5 years per month.

For the period of 6 years, N= 9 x 6 x 12 =648. Using Yamane's formula (1967) for Population Proportion (Oakland, 2009)

$$n = \frac{N}{1+N(e^2)}$$

Where n = sample size

N = population size

e = level of precision,

Using a significance level of 5% and a confidence interval of 95%

N= 648

n = 648/1+648(0.05)2 =247.3 = 248

Assuming a non-response rate of 10%=10/100 x 248=24.8=25

n = 248+25 =273 =270

3.5.2 Sampling Procedure

A systematic random sampling procedure was used. The sampling interval was obtained by dividing the study population (N) by the sample size (n). The sampling Interval (S.I) was given by;

S.I =N/n =648/270=2.4 = 2

A Sampling Register (Appendix 8.1) was initially used to obtain the OPD/FOLDER numbers of all children <5 years who were managed for upper respiratory tract infections from 1st January, 2009 to 31st December, 2014. The first case recorded in January, 2009 was given sequence number one and this data was obtained from the records department and consulting room patients' attendance books. Based on the sampling interval of two obtained, the first sample was randomly picked by simple ballot of sequence numbers 1 and 2 and the subsequent ones were then picked at intervals of two. All five prescribers were interviewed.

3.6 ETHICAL CONSIDERATIONS

Ethical Clearance

The proposal for this study was reviewed and approved by the Ethics and Review Committee of the Ghana Health Service. All participants of this study were provided with names and telephone numbers of the principal researcher, academic supervisor and the secretary to the Ethics Committee of Ghana Health Service to contact us with issues related to the study (Appendix 8.4).

Informed Consent

At the time of data collection, participation in the study was based on willingness of the respondents as none was coerced into participating in the study. Informed consents were obtained from participants before interviews were conducted (Appendix 8.5).

Privacy and confidentiality

Information collected were treated as confidential and the identities of the respondents were not disclosed during analysis or writing of the report.

Risks and Benefits

The objectives, potential risks and benefits of the study were explained to the participants in the language they understood. All questions asked were addressed appropriately after which they were made to sign the consent form as an indication of their acceptance to take part in the study.

Data safety and Storage

The data collected were initially entered into excel sheet in a password protected computer. The dataset will be kept and destroyed two years after the award of the degree.

Dissemination of Results

The results of this study will be disseminated through seminar presentations, dissertation and peer reviewed publications. However, the identities of respondents will not be disclosed during such dissemination platforms.

3.7 DATA COLLECTION TECHNIQUES AND TOOLS

3.7.1 Training of Research assistants

Three research assistants including a Pharmacy technician, two Pharmacy assistants and a records officer from Kintampo hospital and a sister institution were engaged. They were trained on ethical considerations, questionnaire administration and extraction of information on demographic data, diagnosis and treatment from patients' medical records.

3.7.2 Data Collection

The principal researcher together with the trained research assistants collected the data. A Sampling Register (Appendix 8.1) and Prescribing Indicator Forms (Appendix 8.2) were used. Medical records/history of patients were extracted from patient cards/folders and these included; demographic characteristics such as age and sex, diagnosis, antibiotics used, dosages, frequency and duration of therapy and questionnaires (Appendix 8.6) were administered to prescribers to assess their knowledge on rational prescribing and prescribing practices.

3.8 QUALITY CONTROL

The research assistants were selected based on their exposure to hospital environment, names of medicines, medical abbreviations and medical diagnosis. They were trained for one day on the use of the data collecting tools, what information to look for and how to handle ethical considerations and security of data. The prescribing indicator forms were checked daily for completeness and errors and where necessary such data were repeated. As part of data validation, double entries were made where required and the resulting data sets matched for differences

3.9 DATA PROCESSING AND ANALYSIS

Data collected with the Prescribing Indicator Forms (Appendix 8.2) were screened for errors and completeness. The data were entered into a Microsoft excel spreadsheet. Descriptive statistical analysis were carried out to obtain summary tables and graphs containing age groups, sex, frequencies of individual diseases, percentage of antibiotics prescribed within the EML, by generic and percentage with injections using Microsoft Excel Version 2013. Soft copies of all dataset and work done, were sent to my e-mail, and an external drive and all completed individual Indicator forms kept under lock and key.

3.10 STATISTICAL ANALYSIS

All statistical analysis were performed in this study using Microsoft Excel 2013 and STATA SE Version 13 (College Station Texas, USA) and measures of association, mostly ORs, reported with their at 95% confidence intervals (C.Is) with the level of statistical significance set at $p<0.05$ for all tests. Results were expressed as means, frequencies, and percentages and in graphs. A measure of association between the outcome variable and predictive variables was determined using Chi squared test and Fisher's Exact Test. A measure of strength of association between the outcome variable and the predictor variables were obtained by calculating the crude odds ratio using the Simple Logistic Regression Model. All confounding variables were catered for and the effect of prominent predictor variables evaluated using the multivariate Logistic Regression Model obtaining the adjusted odds ratios.

CHAPTER FOUR

4.0 RESULTS

4.1 Patients' Medical Records

A total of 270 prescriptions of children aged less than 5 years (0-59 months) with URTIs from 1st January, 2009 to 31st December, 2014 were retrieved from the medical records available in the Kintampo Municipal Hospital for review and abstraction. All the prescriptions had complete documentation of information, including patients' demographic characteristics, final diagnosis, medicine names, dose, route of administration, frequency of intake and the duration.

The minimum age of the children was 0.5 months (15 days), the maximum age was 57 months and the mean age was 18.3±13 months. Children aged 1-5 years (12-59 months) accounted for majority of patients 169 of 270 (62.6%).Only 3 patients were less than 1 month (1.1%) Table 2.

Table 2 Age Distribution of Medical Records in Kintampo Municipal Hospital

Age (In Months)	Number of Patient Records	Percentage
< 1	3	1.1
1-11	98	36.3
12-59	169	62.6
Total	270	100

Out of the 270 patients, 140 (52.0%) were males and 130 (48.0%) females (Table 3).

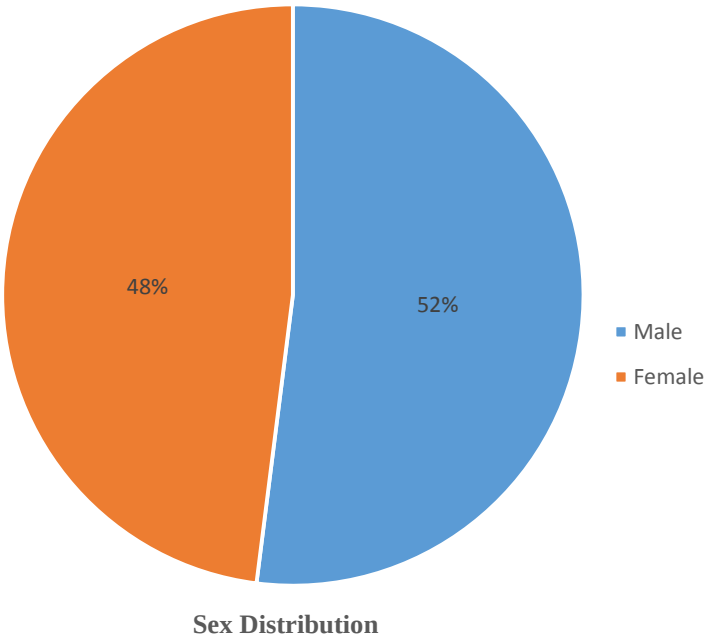

Figure 3: Distribution of Patients According to Sex

Among the 270 prescriptions, the most common URTI was common cold accounting for 142 of 270 (52.6%).There were 69 children with otitis media and with the least being Sinusitis 8 of 270 (3.0%).The distribution of patients according to diagnosis is shown in Table 3.

Table 3: Types of Upper Respiratory Tract Infections over the 6 years period

Disease	Number	Percentage (%)
Common Cold	142	52.6
Otitis media	69	25.6
Pharyngitis	23	8.5
Tonsillitis	11	4.1
Sinusitis	8	3.0
Non-specific URTI	17	6.3
Total	270	100

Out of the 839 medicines prescribed for the 270 prescriptions reviewed, 237 were antibiotics. The penicillin class of antibiotics accounted for about 58% of antibiotics prescribed. The cephalosporins formed 19% and the macrolides about 10% of antibiotics prescribed respectively.

The findings showed that, Amoxicillin was the most commonly prescribed 92 of 237 (38.8%) followed by cefuroxime and amoxicillin+clavulanic acid 44 of 237 (18.6%) and 41 of 237 (17.3%) respectively. The least prescribed antibiotic was flucloxacillin 4 of 237 (1.7%). The distribution of antibiotics prescribed is shown in Table 4.

Table 4: Antibiotics Prescribed For the Management of Upper Respiratory Tract Infections in Kintampo Municipal Hospital

Antibiotic (n=237)	**Frequency F**	**Percentage (%) (F x 100/n)**
Penicillins		
Amoxicillin Suspension	92	38.8
Amoxicillin+Clavulanic acid Suspension	41	17.3
Flucloxacillin Suspension	4	1.7
Cephalosporins		
Cefuroxime Suspension	44	18.6
Ceftriaxone Injection	1	0.4
Macrolides		
Azithromycin Suspension	17	7.2
Erythromycin Suspension	7	3.0
Sulphonamides		
Cotrimoxazole Suspension	21	8.9
Others	10	4.2
* No Antibiotic	33	12.2

*n = 270

Table 5 shows that 77.4% of URTIs for which common cold was diagnosed were prescribed antibiotics, whiles a case of pharyngitis was not managed with an antibiotic. The most prescribed antibiotics for common cold were Amoxicillin and Cotrimoxazole suspensions accounting for 83 of 142 (58.5%). The only antibiotic injection was prescribed for pharyngitis. About 64 % of the otitis media cases were managed with Amoxicillin and Amoxicillin+Clavulanic acid suspensions. Cefuroxime suspension was the most prescribed antibiotic for tonsillitis 6 of 11 (54.6%).

Table 5: Upper Respiratory Tract Infections and the Antibiotics Used in their management

Antibiotic	**Common Cold n (%)**	**Otitis Media n (%)**	**Pharyngitis n (%)**	**Tonsilitis n (%)**	**Sinusitis n (%)**	**Non-Specific URTI n (%)**	**Total**
*Amoxicillin	62 (43.7)	21(30.4)	2 (8.7)	2 (18.2)	1 (12.5)	4 (23.5)	92 (34.1)
*Amoxicillin+ Clavulanic acid	5 (3.5)	23 (33.3)	11 (47.8)	0 (0.0)	1 (12.5)	1 (5.9)	41(15.2)
*Azithromycin	6(4.2)	5 (7.3)	3 (13.0)	1 (9.1)	0 (0.0)	2 (11.8)	17 (6.3)
*Cefuroxime	6 (4.2)	16 (23.2)	4 (17.3)	6 (54.6)	4 (50.0)	8 (47.0)	44 (16.3)
Ceftriaxone Inj	0 (0.0)	0 (0.0)	1 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
*Cotrimoxazole	21 (14.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	21 (7.8)
* Erythromycin	5 (3.5)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (2.6)
*Flucloxacillin	3 (2.1)	0 (0.0)	1 (4.4)	1 (9.1)	0 (0.0)	0 (0.0)	4 (1.5)
Other	2 (1.4)	3 (4.3)	0 (0.0)	1 (9.1)	2 (25.0)	2 (11.8)	10 (3.7)
*No Antibiotic	32 (22.6)	0 (0.0)	1 (4.4)	0 (0)	0(0.0)	0 (0.0)	33 (12.2)
Total	142 (100.0)	69 (100.0)	23 (100.0)	11 (100.0)	8 (100.0)	17 (100.0)	270 (100.0)

*Suspension Inj =Injection

Assessment of Rational Prescribing

The rational use of medicines was assessed using the WHO Prescribing Indicators. The prescribing indicators included, the average number of medicines per patient encounter, medicines prescribed by generic, percentage of patients given antibiotics, percentage prescribed from the EML and the percentage given injections.

The total number of medicines prescribed in the 270 prescriptions was 839.The mean number of medicines per patient encounter was 3.1. Out of the 839 medicines prescribed, 28.6% were antibiotics. Apart from the antibiotics prescribed for the URTIs, other medicines were given which were rational in the management of URTIs. They included antihistamines, antipyretics, nasal decongestants and cough mixtures (Appendix 8.3). The percentage of medicines prescribed in generic and from the Essential Medicines List were 93.8% and 94.9%, respectively. The prescribing indicators are shown in Table 6.

Table 6: Prescribing Pattern of Antibiotics in Kintampo Municipal Hospital

Prescribing Indicator	**Value Obtained**	**WHO Standard**
Total number of patients prescriptions analysed	270	≥100
Total number of medicines prescribed	839	-
Average number of medicines prescribed per encounter	3.1	≤ 2
% Medicines prescribed by generic	93.8	100
% Patient encounters with antibiotics prescribed	28.2	≤ 30
% of patient encounters with injections prescribed	0.4	≤10
% of medicines prescribed from Essential Medicines List or Formulary	94.9	100

The status of all 270 prescriptions reviewed were assessed using the Standard Treatment Guidelines of Ghana (STG, 2010). The severely ill patients and patients diagnosed with more than one URTIs were excluded. Out of the 270 prescriptions reviewed, 248 (91.9%) were rational (Figure 4).

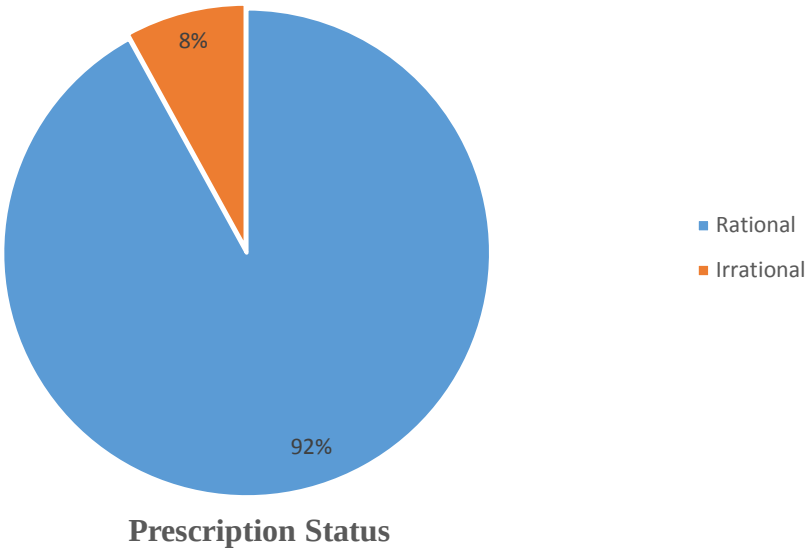

Figure 4: Distribution of Patients According to Prescription Status

Using the Standard Treatment Guidelines of Ghana (STG, 2010), the appropriateness of the doses, frequencies of intake of medicines and the duration of treatment of all 270 prescriptions reviewed were assessed .This did not include severely ill patients. (Table 7).This study showed that, 251 of 270 (93.0%) prescriptions had appropriate doses, 258 (95.6%) were appropriate in frequency and 261 of 270 (96.7%) had appropriate duration of treatment.

Table 7: Distribution of Prescriptions according to Appropriateness

	Prescriptions (N =270)			
Parameter	**No. Appropriate**	**% Appropriate**	**No. Inappropriate**	**% Inappropriate**
Dose	251	93.0	19	7.0
Frequency	258	95.6	12	4.4
Duration	261	96.7	9	3.3

Table 8 shows results of the measure of association between the independent variables and the outcome variables; age, sex, number of antibiotics and the outcome variable (rational prescribing) using Pearson's chi squared test and Fisher's Exact test. Among the 3 patients below one month (neonates) all prescriptions were rational 3 (100%).Rational prescribing was 89 of 98 (90.8%) among 1-11 months (infants) and 156 of 169 (92.3% (p-value=0.797) among 12-59 months (children) Out of the 130 prescriptions for female patients, 118 (90.8%) were rational and 12 (9.2%) were irrational. Prescribing in the male patients on the other hand were 130 (92.9%), p-value=0.531 and 10 (7.14%) rational and irrational respectively. The trend showed a decrease in rational prescribing as the number of medicines per patient encounter increased. Prescribing 1 or 2 medicines per patient encounter was most associated with rational prescribing 73 (96.1%), p-value=0.0.060 followed by 3 to 4 medicines per patient encounter 159 of 174 (91.4%) which formed the majority of prescriptions and 5-6 medicines per patient encounter was the least 16 of 20 (80.0%), p-value=0.058. Prescribing only one antibiotic per patient encounter accounted for the highest number of prescriptions which were considered rational, 236 (92.1%) p-value=0.031 while 2 antibiotics per encounter accounted for 12 (75.0%) of rationally prescribed medicines. The only antibiotic injection was prescribed rationally. Where the

condition diagnosed was as tonsillitis, all the medicines were prescribed rationally, 11 (100%).

Table 8: Measure of association between prescribing indicators and rational prescribing

Indicator	Rational Prescribing N (%)	Irrational Prescribing N (%)	p-value
*Age (In Months)			
< 1	3 (100.0)	0 (0)	
1-11	89 (90.8)	9 (9.2)	0.731
12-59	156 (92.3)	13 (7.7)	
Sex			
Female	118 (90.8)	12 (9.2)	0.531
Male	130 (92.9)	10 (7.1)	
*Number of Medicines			
1-2	73 (96.0)	3 (4.0)	
3-4	159 (91.4)	15 (8.6)	0.058
5-6	16 (80.0)	4 (20.0)	
*Number of Antibiotics			
1	236 (92.9)	18 (7.1)	
2	12 (75.0%)	4 (25.0)	0.031
*Number of Antibiotic Injections			
0	246 (91.8)	22 (8.2)	
1	1 (100.0)	0 (0.0)	1.00
2	1 (100.0)	0 (0.0)	
*Diagnosis			
Common Cold	130 (91.6)	12 (8.4)	
Otitis Media	65 (94.2)	4 (5.8)	
Pharyngitis	22 (95.7)	1 (4.3)	0.022
Tonsillitis	11 (100.0)	0 (0.0)	
Sinusitis	4 (50.0)	4 (50.0)	
Non-Specific URTI	16 (94.1)	1 (5.9)	
*Antibiotic			
Penicillins	126 (92.0)	11 (8.0)	
Cephalosporins	40 (88.9)	5 (11.1)	0.819
Macrolides	22 (91.7)	2 (8.3)	
Others	60 (93.8)	4 (6.2)	

*Fisher's Exact Test Used

Common cold was the most diagnosed illness and accounted for130 of 142 (91.9%) of prescriptions being rational and 12 (8.5%) irrational. Out of 69 prescriptions diagnosed with otitis media, 65 were prescribed rationally and the diagnosis with the least was sinusitis 4 (50.0%). The p-value of 0.022 obtained indicated a strong association between the diagnosis and rational prescribing. The penicillin group of antibiotics were the most

prescribed antibiotics 126 of 137 (92.0%) and together with the macrolides 22 of 24 (92.0%) the most rationally prescribed. The least rationally prescribed antibiotics were the cephalosporins 40 of 45 (88.9%), p-value=0.819.

Prescribing Indicators Influencing Rational Prescribing

The number of medicines, number of antibiotics and diagnosis which were found to be significantly associated with rational prescribing through the Pearson's chi-squared test and Fisher's Exact test where appropriate, were used to determine the strength of association using the univariate logistic models (Table 9). The diagnosis and the number of antibiotics were strongly associated with rational prescribing. The odds of prescribing rationally decreased by about 77% with an increase in number of antibiotics from 1 to 2, [OR 0.23 (95%, C.I; 0.07-0.78), p-value=0.019]. The odds of prescribing rationally decreased with increasing number of medicines with the category 0-2 medicines as the referent. Prescribing 3 to 4 medicines per patient encounter decreased the odds of prescribing rationally by 67%; [OR 0.43 (95%, C.I; 0.12-1.55), p-value=0.200] and 84% for 5 to 6 medicines; [OR 0.16 (95%, C.I; 0.03-0.81), p-value=0.026]. Prescribing 5 or more medicines per patient encounter is significantly associated with rational prescribing. Though the odds of prescribing rationally with a diagnosis of otitis media is 1.5 times compared to common cold as the referent, the association is not significant; [OR 1.5 (95%.C.I; 0.47-4.83), p-value=0.497]. The odds of prescribing rationally when pharyngitis is diagnosed is 2 times and 1.47 times with non-specific URTI, however they are not significantly associated with rational prescribing. The odds of prescribing rationally when diagnosed with sinusitis is decreased by about 91% and is significantly associated; [OR 0.09 (95%, C.I; 0.02-0.42), p-value=0.002].

Table 9: Univariate analysis of potential prescribing indicators influencing rational prescribing

Indicator	Crude OR	95%C.I	p-value
Number of Medicines			
1-2	1		
3-4	0.43	0.12-1.55	0.200
5-6	0.16	0.03-0.81	0.026
Number of Antibiotics			
1	1		
2	0.23	0.07-0.78	0.019
Diagnosis			
Common Cold	1		
Otitis Media	1.5	0.47-4.83	0.497
Pharyngitis	2.03	0.25-16.41	0.506
Tonsillitis	1		
Sinusitis	0.09	0.02-0.42	0.002
Non-specific URTI	1.47	0.18-12.12	0.717

A multivariate logistic regression analysis which adjusted for the effects of all prescribing indicators shown to be significantly associated with rational prescribing in the univariate logistic models showed that the number of medicines, number of antibiotics and diagnosis were independently associated with rational prescribing (Table 10).

Table 10: Multivariate Analysis of Prescribing indicators influencing rational prescribing in children under 5 in Kintampo Municipal Hospital**.**

Indicator	Adjusted OR	95%C.I	p-value
Number of Antibiotics			
1	1.00		
2	0.27	0.06-1.21	0.086
Diagnosis			
Common Cold	1.00		
Otitis Media	1.82	0.54-6.09	0.333
Pharyngitis	1		
Sinusitis	0.13	0.24-0.65	0.013
Non-specific URTI	1.75	0.19-15.83	0.619
Number of Medicines			
1-2	1.00		
3-4	0.46	0.12-1.77	0.260
5-6	0.17	0.03-0.87	0.033

*Odds ratio (OR) were adjusted for number of medicines, number of antibiotics, diagnosis and antibiotics which were found to be significant univariate analysis using logistic regression

The diagnosis sinusitis was significantly associated with rational prescribing. The odds of prescribing rationally in a patient with sinusitis was decreased by 87%; [OR 0.13 (95%, C.I; 0.24-0.65), p-value=0.013].Whilst the multivariate association between otitis media and rational prescribing was 1.8 times the referent diagnosis common cold, the association was not significant; [OR 1.82 (95%,C.I;0.54-6.09),p-value=0.333]. Non-specific URTI though also about 1.8 times the reference, was not significantly associated; [OR 1.75 (0.19-15.83), p-value=0.619]. The number of medicines was significantly associated with rational prescribing as the odds of rational prescribing decreased with increasing number of medicines per patient encounter. The odds decreased by 54.0% in prescriptions with 3-4

medicines; [OR 0.46 (95%, C.I; 0.12-1.77), p-value=0.260] and by 83.0% where 5-6 number of medicines compared to 0-2 number of medicines as a referent; [OR 0.17 (95%, C.I; 0.03-0.87), p-value=0.033].

4.2 Interview of Prescribers

The respondents were 5 prescribers comprising a medical officer, 3 physician assistants and 1 nurse practitioner. The respondents had an average of 2.5 years work experience with the minimum being 1 year and the maximum 10 years (Table 11).

Table 11: Background Information of Prescribers

Parameter	Frequency	Percentage (%)
Sex		
Female	3	60.0
Male	2	40.0
Profession		
Medical Officer	1	20.0
Physician Assistant	3	60.0
Nurse Practitioner	1	20.0
Period of Practice (Years)		
1	1	20.0
2	2	40.0
5	1	20.0
10	1	20.0

Table 12 shows the level of knowledge and awareness of rational use of medicines and standards. The assessment of the knowledge and awareness of Rational Use of Medicines (RUM) showed that all respondents were conversant with the definition of RUM and 3 were able to state the Standards of the RUM. Four of the respondents prescribed in generic .One respondent was highly satisfied with the RUM standard set, 2 were okay and only one was highly dissatisfied.

Table 12: Distribution of prescribers according to knowledge and awareness on rational use of medicines and standards.

Indicator	Yes Number (%)	No Number (%)
Knowledge and awareness of respondent on RUM		
Definition of RUM	5 (100.0)	0 (0.0)
Knowledge of RUM Standards	3 (60.0)	2 (40.0)
Not more than 2 medicines per patient encounter	3 (60.0)	2 (40.0)
Generic prescribing	4 (80.0)	1 (20.0)
Not more than 2 antibiotics per patient encounter	4 (80.0)	1 (20.0)
Whether use of antibiotics in URTIs management is a must	3 (60.0)	2 (40.0)
Satisfaction with RUM Standard set		
Highly satisfied	1 (20.0)	4 (80.0)
Satisfied	1 (20.0)	4 (80.0)
Okay	2 (40.0)	3 (60.0)
Dissatisfied	0 (0.0)	5 (100.0)
Highly dissatisfied	1 (20.0)	4 (80.0)
Training on RUM and its Evaluation		
Having received training on RUM while in school	3 (60.0)	2 (40.0)
Has training being beneficial in practice?	2 (40.0)	3 (60.0)
Having received training on RUM in practice	2 (40.0)	3 (60.0)
The RUM training received		
Excellent	1 (20.0)	4 (80.0)
Good	1 (20.0)	4 (80.0)
Satisfactory	1 (20.0)	4 (80.0)
Poor	0 (0.0)	5 (100.0)
How often should RUM training be conducted in practice?		
3 Months	2 (40.0)	3 (60.0)
6 Months	3 (60.0)	2 (40.0)
1 Year	0 (0.0)	5 (100.0)
Participation in RUM activities	3 (60.0)	2 (40.0)
Knowledge of availability of DIU in facility	4 (80.0)	1 (20.0)
Knowledge of availability of DTC facility	4 (80.0)	1 (20.0)
Source of information on medicines		
Standard Treatment Guidelines (STG)	5 (100.0)	0 (0.0)
British National Formulary (BNF)	4 (80.0)	1 (20.0)
Journals	1 (20.0)	4 (80.0)
Patient Information Leaflet	3 (60.0)	2 (40.0)
Media	2 (40.0)	3 (60.0)
Medical Representatives	2 (40.0)	3 (60.0)
Internet	4 (80.0)	1 (20.0)
Colleagues	2 (40.0)	3 (60.0)

While 3 prescribers received training on RUM while in school, 2 received training during practice. One prescriber each evaluated the training on RUM as excellent, good and

satisfactory respectively. Two prescribers suggested that, the RUM training be organized every three months with the other 3 prescribers suggesting every 6 months. Four out of the five prescribers acknowledged the presence of a Drug Information Unit and Drug and Therapeutic Committee in the hospital. All the 5 prescribers used the Standard Treatment Guideline as a reference source in prescribing and in addition, 4 of them used the British National Formulary. Four and three prescribers respectively used the internet and the patient information leaflets as sources of information. However, 2 prescribers each also considered their colleagues, the media and the medical representatives as sources of information.

Figure 5 shows the time a prescriber spent with a patient. Forty percentage of prescribers indicated they spent averagely 5 minutes with each patient and another 40% said 15 minutes and 20% said 20 minutes. The average consulting time used by all the prescribers was 12 minutes.

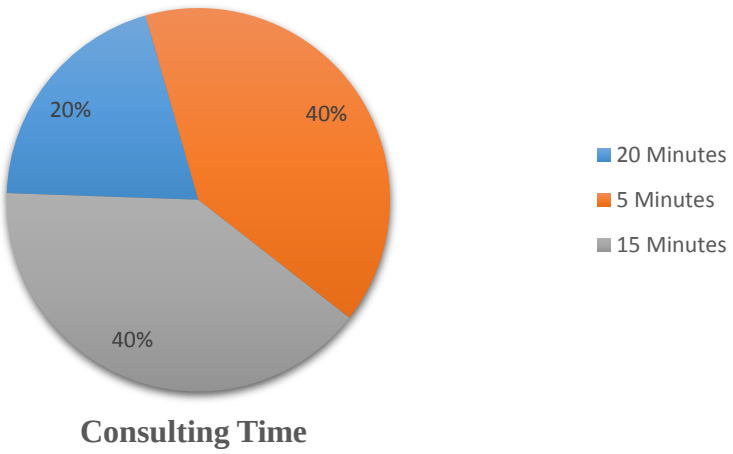

Figure 5: Distribution of Prescribers by Consulting Time

Factors Affecting Rational Prescribing

In respect of clients 'demand and medication preferences, 4 (80%) of respondents considered haematinics as the medicine clients often demanded for and 3 (60%) each for antibiotics and injections respectively,(Table 10).All the prescribers 5 (100%) indicated that, they counselled their patients on the type of condition, type of medication and the expected outcome. Four out of the five prescribers attributed their reasons to not fully adhering to RUM Standards to complexities of disease and late presentation of laboratory results. Two prescribers however attributed the non-adherence to RUM Standards to workload, patient demand, patient satisfaction and frequent visits by medical representatives.

Table 1: Factors Affecting Rational Prescribing

	Affects Rational Prescribing	
	Yes	**No**
Indicator	**N (%)**	**N (%)**
Clients Demand and Preference for medicines		
Antibiotics	3 (60.0)	2 (40.0)
Injections	3 (60.0)	2 (40.0)
Branded products	0 (0.0)	5 (100.0)
Haematinics	4 (80.0)	1 (20.0)
Reasons for not fully Adhering to RUM Standards		
Complexities of Disease	4 (80.0)	1 (20.0)
Patient demand	2 (40.0)	3 (60.0)
Workload	2 (40.0)	3 (60.0)
Late presentation of laboratory results	4 (80.0)	1 (20.0)
Patient Satisfaction	2 (40.0)	3 (60.0)
Frequent visits by medical representatives	2 (40.0)	3 (60.0)
Peer influence	1 (20.0)	4 (80.0)
Desire to try/experiment new drugs	1 (20.0)	4 (80.0)
Patients' belief	1 (20.0)	4 (80.0)

CHAPTER FIVE

5.0 DISCUSSION

This was a review of medical records which sampled health facility records 42% of children aged 0-59 months seen with upper respiratory tract infections during the period of 1st January, 2009 to 31st December, 2014 at the Kintampo Municipal Hospital.

The sex distribution of children with URTIs of 52% males and 48% females which showed a slight preponderance for males. This compares favorably with the results of similar studies carried out in India and Southeast Nigeria, where the male children were 4% more than the females (Nandimath & Ahuja, 2012; Ujunwa & Ezeonu, 2014) (Joseph et al., 2015; Nandimath & Ahuja, 2012). Majority of the children were aged 12-59 months accounting for 169 (62.6%).From literature, children within this age group are either in the crèche, day care/pre-school where the risk of acquiring URTI from another child is high (Woods, 2006). This was followed by 1-11 months which was 98 (1.1%) and the least was less than 1 month among the age distribution.

Types of Upper Respiratory Tract Infections Diagnosed

A total of five common URTIs were identified in this study, with the remaining which did not have definite diagnosis being classified as non-specific upper respiratory tract infections. This study revealed that, common cold was the most diagnosed URTI, followed by otitis media. Common cold accounted for more than half of the diagnoses of the total prescriptions. This is not surprising, since it is known from literature that, children tend to develop 3 to 8 bouts of common cold in a year and this even tends to increase for children who attend daycare or preschool (Woods, 2006). However the frequency with which

children develop common cold decreases after attaining the age of six. This finding compares favorably to the findings of a similar study in Gambia (Risk et al., 2013).Out of the 142 URTIs diagnosed with common cold,110 (77.4%) were given antibiotics. This figure is higher than the finding of 68.9% of a similar study carried out in Northern Tanzania (Gwimile, Shekalaghe, Kapanda, & Kisanga, 2012). This is worrying, since common colds are mostly viral and self-limiting and normally would not require antibiotics.

The second most diagnosed URTIs was otitis media, a condition involving both the ears and throat, which may also occur after an episode of common cold. The diagnoses of pharyngitis, tonsillitis and sinusitis however accounted for lower number of prescriptions as such illnesses rather occur more among adults. Streptococcal pharyngitis which is due to diphtheria was of common occurrence in children less than three years some decades ago has become rare as a result of various immunization programmes put in place by various governments. Based on the conceptual framework, the type of URTI diagnosed was expected to influence rational prescribing, however the study showed that, the type of URTI had very little effect on rational prescribing. The odds of prescribing rationally was however decreased by 91% with a diagnosis of sinusitis.

Antibiotics Prescribed

The study revealed three main classes of antibiotics which were commonly used to manage URTIs in children in the hospital. These classes were the penicillins, cephalosporins and the macrolides in descending order of patronage and this sequence can be likened to the findings of a similar study in South Western Nigeria (Joseph et al., 2015). The most prescribed class was the penicillins involving amoxicillin and amoxicillin+clavulanic acid.

About 64% of all otitis media cases were managed with amoxicillin and amoxicillin+clavulanic acid.

Amoxicillin accounted for a third of the total prescriptions reviewed and this may be due to easy access to and low cost on the market. Amoxicillin is also the first line antibiotic in the management of URTIs according to the Standard Treatment Guideline of Ghana (STG, 2010).The fact that, the second most prescribed penicillin was amoxicillin+clavulanic acid, could be attributed to loss of trust by most prescribers in the efficacy and effectiveness of amoxicillin as a first line medication. This perception is based on the abuse and misuse of amoxicillin.

Cefuroxime belonging to the cephalosporin class, was the second most prescribed antibiotic. The most prescribed antibiotic for the management of tonsillitis was cefuroxime accounting for 6 of 11 (54.6%). Cefuroxime was also very much prescribed because of prescribers' trust in its efficacy and effectiveness as it is more expensive and hardly abused. The only antibiotic injection prescribed; ceftriaxone also belonged to this group. The third class of antibiotics patronized was the macrolides, which mostly served as alternatives for clients allergic to the penicillins. Members of this class were azithromycin and erythromycin and formed the least prescribed. The findings of this study showed that, rational prescribing was not influenced by the type of antibiotic prescribed as expected in the conceptual framework.

Prescribing Indicators

Rational prescribing of medicines is advocated to avoid wastage of medicines and reduce possible adverse effects to patients. Moreover prescribing unnecessary medications to patients comes with cost implications to the health systems.

The study revealed a 3.1 average number of medicines prescribed per patient encounter, implying that, patients were likely to receive 3 medicines per visit. The WHO indicator tools for rational prescribing however requires that only one or two medicines are prescribed per patient encounter (WHO, 1993).This finding suggests the presence of poly pharmacy. A study carried out at the Ghana Police Hospital revealed a similar finding of 3.7 (Afriyie, 2014).Other comparable findings were 2.63 from a study in Uganda (Mcgaughey.N, 2010) and Jordan,(2.4) (Al-Niemat et al., 2014). This finding of 3.1 for average number of medicines prescribed per patient encounter is supported by results obtained from the assessment of prescribers' knowledge on RUM standards, where two-thirds of the prescribers asserted to three or four medicines per encounter. Prescribing many medicines per patient may lead to non-adherence and exposure to the risk of drug-drug interactions. Promotion of rational use of medicines through generic prescribing makes information exchange and communication between healthcare providers easier and serves as a safety precaution for patients.

The percentage of medicines prescribed by generic of 93.8% obtained does not meet the WHO/INRUD standard of 100%.The figure is further supported in the study by 80% of the prescribers interviewed, who indicated they prescribed by generic and all of them also attested to the use of the STG as the primary source of drug information. This however almost conforms to that of a study in South Ethiopia of 98.7% (Desalegn, 2013). The high

level of generic prescribing could also be partly due to the National Health Insurance Schemes' (NHIS) rule on the reimbursement of only prescriptions written in generic. The non-optimal prescribing by generic however could be attributed partly to the promotional activities of pharmaceutical companies and the perceived high efficacy of certain branded medicines by some prescribers.

The percentage of patient encounters with antibiotics prescribed was 28.6%. This is within the range of ≤ 30% optimal, WHO standards and therefore tends to suggest a prudent use of antibiotics in Kintampo Municipal Hospital. Such a judicious use of antibiotics will go a long way to minimize antibiotic resistance and serious adverse effects.

A percentage of 0.4% obtained for patient encounters with injections falls well within the required WHO/INRUD Standard of ≤ 10%.This is however higher than the findings of a study carried out in Ethiopia (0.04%) (Sebsibie & Gultie, 2014). This serves to further discourage the use of injections which come with the concomitant risk of transmission of HIV, hepatitis and other blood related diseases. The low rate of injection use is also likely to reduce the risk of anaphylactic shock, tissue necrosis and sepsis in patients. This study finding of 94.9% for medicines prescribed from the Essential Medicines List falls short of the optimal WHO/INRUD standard of 100%.This is however higher than the figure of 53.6% obtained in a similar study at the Ghana Police Hospital (Afriyie, 2014).

This study revealed that, most of the prescriptions reviewed using the Standard Treatment Guidelines of Ghana (STG, 2010) ,were appropriate in terms of the doses, frequency of intake and the duration of therapy, in more than 90% of prescriptions collected. In addition, taking into consideration all other components of rational prescribing, the study showed that, rational prescribing was achieved in more than 90% of the prescriptions collected.

Majority of prescribers interviewed did not have any training on RUM either in school or in practice. This could have accounted for the 8% of prescriptions irrationally prescribed irrationally, as the effective application of a policy depends on the knowledge one has on that policy.

Most prescribers indicated that there was the need to organize RUM training for prescribers and all stakeholders every six months as this will go a long way to enhance adherence to the RUM standards. Despite the role, Drug Information Unit (DIU) and Drug and Therapeutic Committee play in assisting prescribers to make choices in their prescribing practices, only 4 out 5 prescribers admitted to being aware of the presence of a Drug Information Unit (DIU) and DTC in the hospital. Both units were however not functional. There is the need for the management of the hospital to ensure that both the DIU and DTC are equipped with the requisite professionals and resources to function. This will help ensure the rational use of medicines. In addition to the use of the STG by all prescribers as the primary source of medicine information, most prescribers also used the BNF, the internet and information from medical representatives.

The interview with prescribers revealed an average consulting time of 12 minutes, however an observation of their practice revealed an average of 5 minutes. This current finding is however lower than the recommended 15 minutes (Santos & Nitrini, 2004). The finding however compares favourably with the findings of a similar study from India (12.5 minutes), (Mathew, Gadde, Nutakki, & Doddayya, 2013) but higher than that from Ghana (8 minutes), (Afriyie, 2014). Most prescribers attributed the non-adherence to the RUM to reasons of complexities of diseases and late presentation of laboratory results. Eighty percent of prescribers said their patients demanded for haematinics (blood tonics) and 60%

admitted patients demanded for antibiotics and injections. This finding tends to demonstrate the perception of the most rural folk that, only antibiotics and injections can perform the magic healing.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

This study showed that, common cold and otitis media were the most common upper respiratory tract infections in children under 5 years managed in the institution from 1st January, 2009 to 31st December, 2014. There was good adherence to rational prescribing of antibiotics as most of the prescribing indicators fell within the WHO/INRUD Standards for rational prescribing. Out of five prescribing indicators, only the mean number of medicines prescribed per patient encounter is not within the range of the WHO Standards, hence there is the tendency for polypharmacy. The average consulting time was 12 minutes. The penicillins and cephalosporins were the most preferred antibiotics prescribed for the management of upper respiratory tract infections in children under 5 years. There was non-optimal adherence to the RUM due to the lack of continuing education on Rational Use of Medicines and non-functional DIU and DTC.

6.2 Limitations

- The study was carried out in only one health facility within the municipality and region, hence findings cannot be generalized.
- The sample size of prescribers interviewed was small, hence the inability to apply appropriate analytical statistics. It is recommended that further research be conducted using larger sample size.

6.2 Recommendations

Clinical Practice

- The institution's good adherence to rational prescribing is commendable, however, continuing education on rational use of medicines and prescription audit meetings will to be needed to achieve the optimal results in clinical practice

Public Health and Policymakers

- Considering the low level of awareness on rational use of medicine standards among prescribers, it is recommended that, the Ghana Health Service and Ministry of Health will collaborate with the Ministry of Education to introduce a course on RUM into the curricula of all health programs where it is absent and as a continuing education for those in practice.
- In addition, there will be the need to institutionalize the establishment and resourcing of DIUs and DTCs in all primary healthcare institutions within the country. This will serve as a neutral source of regular information on medicines to prescribers to help make unbiased choices of medicine to prescribe.

Research

- More studies with focus on rational prescribing in paediatrics in low-income settings are required to fill the gap in current knowledge.
- The study looked at the prescribers' perspective on rational use of antibiotics, there will be the need for further studies to be carried out, in respect of other users such as the Patients and the Health facilities.

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APPENDICES

8.1 SAMPLING REGISTER

SEQUENCE NUMBER	FOLDER/CARD NUMBER	SELECTION (0/1)
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2		
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8.2 PRESCRIPTION INDICATOR FORM

PRESCRIBING INDICATOR FORM

LOCATION……DATE……...

INVESTIGATOR …….SIGNATURE……

SECTION A

SEQ No.	DATE OF Rx	DATE OF BIRTH	SEX F/M	WEIGHT (KG)	DIAGNOSIS	NO. OF MEDICINES	NO. OF GENERICS	NO. OF EML	NO. OF ANTIBIOTIC

SECTION B

NUMBER	ANTIBIOTIC	DOSE	FREQUENCY	DURATION OF THERAPY
1				
2				
3				
4				

Seq= Sequence Rx=Prescription

8.3 OTHER MEDICINES

Other Medicines Prescribed for Children under 5 years with Upper Respiratory Tract Infections in Kintampo Municipal Hospital

Group	**Medicines**
1	Antipyretics
	• Syrup Paracetamol
2	Antihistamines
	• Syrup Chlorpheramine maleate
	• Syrup Promethazine Hydrochloride
3	Nasal Decongestants
	• Sodium chloride 0.9% nasal drops
	• Ephedrine 0.5% nasal drops
4	Cough mixtures

GHANA HEALTH SERVICE ETHICAL REVIEW COMMITTEE

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

My Ref. :GHS-ERC: 3
Your Ref. No.

Research & Development Division
Ghana Health Service
P. O. Box MB 190
Accra
Tel: +233-302-681109
Fax + 233-302-685424
Email: Hannah. Frimpong@ghsmail.org

23rd March, 2015

Sumaila Abdul-Nasiru
School of Public Health
University of Ghana
Legon, Accra

ETHICAL APPROVAL - ID NO: GHS-ERC: 104/02/15

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of your Study Protocol titled:

"Rational Prescribing of Antibiotics in Children under 5 with Upper Respiratory Tract Infections in Kintampo Municipal Hospital"

This approval requires that you inform the Ethical Review Committee (ERC) when the study begins and provide Mid-term reports of the study to the Ethical Review Committee (ERC) for continuous review. The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Please note that any modification without ERC approval is rendered invalid.

You are also required to report all serious adverse events related to this study to the ERC within seven days verbally and fourteen days in writing.

You are requested to submit a final report on the study to assure the ERC that the project was implemented as per approved protocol. You are also to inform the ERC and your sponsor before any publication of the research findings.

Please note that this approval is given for a period of 12 months, beginning March 23rd 2015 to March 22nd 2016.

However, you are required to request for renewal of your study if it lasts for more than 12 months.

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

SIGNED.....

DR. CYNTHIA BANNERMAN
(GHS-ERC CHAIRPERSON)

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

8.5 INFORMED CONSENT FORM

Purpose

My name is Sumaila Abdul-Nasiru and I am from School of Public Health, University of Ghana, Legon. I am conducting a study on the Rational Prescribing of Antibiotics in children under five with upper respiratory tract infections in Kintampo Municipal Hospital. The purpose of the study is to find out the various upper respiratory tract infections that affect children under five, the types of antibiotics prescribed and whether they are prescribed rationally. I will be reviewing patient cards/ folders of children under five years. I hope that the information I will obtain from this study will help identify the prescribing pattern of antibiotics and improve upon the rational use of antibiotics in under five who are the most vulnerable of the nation.

Procedure

I am seeking to use the cards/folders of children under-five years who have been managed by your institution. I will be reviewing the demographic data, prescriptions and the types of upper respiratory tract infections for which prescriptions were made.

Allowing your institution to be used for this study is solely voluntary. During the period of study you can decide to withdraw your consent if for any reason you do not want the study to be continued in your institution.

Risks and Discomforts

The risks involved in this study being carried out in your institution are minimal. These include the inconvenience that the search for folders will cause your staff and space. The study will be undertaken at times, patient folders will not be in use and the staff involved will not be engaged.

Benefits

There are no direct benefits to the institution in the study. However, the information that will be obtained from this study will be made available to the hospital which will help you improve health care delivery in the municipality and the nation as a whole.

Confidentiality

Any information obtained from the patient's record will be treated strictly confidential and no personal identifying information concerning any person or patient will be presented in the analysis or publications of this study. The information would not be shared with anyone except your institution and authorities from the University of Ghana.

Right to refuse or withdraw

The decision to allow the study to be carried out in your hospital is voluntary. You will also not lose any benefits if you refuse grant of permission or decide to withdraw the permission.

For further clarification, you may contact the Administrator of the Ethical Review Committee (ERC) of Ghana Health Service: HANNAH FRIMPONG – 0243235225 or 0507041223

Researcher: SUMAILA ABDUL-NASIRU -0208196683 or 0246640666.

I have read the entire information given above and has agreed to allow the study to be carried out in the hospital.

NAME OF OFFICR:……
DESIGNATION:……..
SIGNATURE:.....DATE……..
NAME OF RESEARCHER:……
SIGNATURE……..DATE……

8.6 STRUCTURED QUESTIONNAIRE

QUESTIONARE FOR PRESCRIBERS

My name is Sumaila Abdul-Nasiru from the School of Public Health, University of Ghana, Legon. I am conducting a study on the 'Rational prescribing of antibiotics in children under five with upper respiratory tract infections in Kintampo Municipal Hospital'. The purpose of the study is to find out the various upper respiratory tract infections that affect children under five, the types of antibiotics prescribed and whether they are prescribed rationally. I hope that the information I obtain from this study will help identify the prescribing pattern of antibiotics in children which could be used to improve the care given to these vulnerable children who need to be prescribed antibiotics.

SECTION A:-IDENTIFICATION

NAME OF HEALTH FACILITY……..……

LOCATION OF HEALTH FACILITY …….

DATE OF INTERVIEW.....……

NAME OF INTERVIEWER……

SECTION B:-SOCIO DEMOGRAPHIC INFORMATION OF PRESCRIBER

1. NAME OF PRESCRIBER…….
2. Gender Male [ ] Female [ ]
3. What is your profession? Doctor [ ] Physician Assistant [ ] other specify……..
4. For how many years have you been practicing as a prescriber?.....
5. How many patients do you see on average per day at this facility?.....patients.

6. How long does it take to see a patient on the average?.....

SECTION C:

KNOWLEDE AND AWARENESS OF PRESCRIBER ON RATIONAL USE OF MEDICINES (RUM) STANDARDS

7. Have you heard of RUM standards Yes [ ] No [ ]
8. If yes, which of the following meets the definition of RUM

   a) Appropriate medication, right dosage, adequate period [ ]

   b) Medication, right dosage, adequate period [ ]

   c) None [ ]
9. Among the following parameters which **ones** meet the RUM standards?

   a) Not more than 4 medicines per patient encounter [ ]

   b) Not more than 3 medicines per patient encounter [ ]

   c) Not more than 2 medicines per patient encounter [ ]

   d) Generic prescribing [ ]

   e) Brand prescribing [ ]

   f) Not more than 3 antibiotics per patient encounter [ ]

   g) Not more than 2 antibiotics per patient encounter [ ]

   h) Not more than 4 antibiotics per patient encounter [ ]

   i) Any other (please specify)
10. Are antibiotics always required in the management of upper respiratory tract infections?

    a) Yes [ ] b) No [ ]
11. If yes, what are your reasons……

12. What are some are some of the common upper respiratory tract infections in children under five that you often encounter of ……..
13. Would you please rate your satisfaction or dissatisfaction with the RUM standard set?
    a) Highly satisfied [ ]
    b) Satisfied [ ]
    c) Okay [ ]
    d) Dissatisfied [ ]
    e) Highly dissatisfied [ ]

If dissatisfied, please any reasons for your dissatisfaction?

Reasons:-

1)……

2)……

TRAINING ON RATIONAL USE OF MEDICINES (RUM)

14. Have you received training on RUM standards? Yes [ ] No [ ]
15. If yes to (14), date last training was received…….
16. How will you evaluate the training?:Excellent [ ] Good [ ] Satisfactory [ ] Poor[ ]
17. Have you undergone training in RUM while in school? Yes [ ], No [ ]
18. If yes, has the training been beneficial to you in your practice? Yes [ ] No [ ] Somehow[ ]
19. If yes, how often must training be conducted? a) Once every 3 months b) Once every 6 months c) Once every year, d) Other please state……

RUM ACTIVITIES IN THE FACILITY

b) Have you participated in RUM activities? a) Yes, as a facilitator b) Yes as a participant c) No, I haven't d) No, I haven't heard of RUM

DRUG INFORMATION

20. Do you have a drug information unit (DIN) in this facility? Yes [ ] No [ ]
21. Do you have a Drug and Therapeutic Committee (DTC) in this facility? Yes [ ]No []
22. Do you have a Drug and Therapeutic Committee (DTC) in this facility? Yes [ ]No []
23. What are your sources of information on medicines:
    I. Reference books on medicines
        a) Standard Treatment Guidelines (STG)
        b) British National Formulary (BNF)
        c) Other (please specify) ……
    II. Journals, please name them……
    III. Patient Information Leaflet [ ] Media (TV, Radio, News Paper) [ ] Medical Representatives [ ] Internet [ ] Colleague [ ]

SOCIO-CULTURAL FACTORS

DEMAND AND PREFERENCE FOR MEDICINES

24. Have you had an encounter with clients who demanded/preferred the following, even though they were not needed:
    a) Antibiotics [ ] b) Injections [ ] c) Branded products [ ] d) Haematinics

Other (please specify) …….

If yes, did you find out/explore their reasons for their demand? ……

PATIENT COUNSELING

Do you usually counsel patients who come to you?

25. If yes what information do you usually counsel them on their medications?

a) Type/name of condition Yes [ ] No [ ] c) Name/type of medication Yes [ ] No [ ]

b) Expected outcome Yes [ ] No [ ] Other please specify?.....

26. Could you please tick from the list below the reasons why prescribers may not be fully adhering to RUM standards?

1. Complexities of disease	Yes [ ] No [ ]
2. Patient demand	Yes [ ] No [ ]
3. Workload	Yes [ ] No [ ]
4. Late presentation of laboratory results	Yes [ ] No [ ]
5. Patient satisfaction	Yes [ ] No [ ]
6. Frequent visits by medical representatives	Yes [ ] No [ ]
7. Peer influence	Yes [ ] No [ ]
8. Desire to try/experiment new drugs	Yes [ ] No [ ]
9. Patients' belief	Yes [ ] No [ ]