DETERMINANTS OF HEALTH WORKERS' PRESCRIPTION PATTERNS FOR PATIENTS AT PRIMARY HEALTH CARE FACILITIES IN ZAMBIA

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DECLARATION

I, Micky Ndhlovu, hereby declare that this research report is my own work. It is being submitted for the degree of Master of Science in Medicine in Epidemiology and Biostatistics at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

This 25th day of October 2009

DEDICATION

For Eve, Makobani and Tarisai

You give me more than I could ever want!!!

In memory of my father and mother

You taught me to be strong but thankful for all that life offers

ABSTRACT

Introduction

The study aimed at determining health workers' prescription patterns using selected WHO/INRUD core drug-use indicators and investigated determinants of appropriate antibiotic prescribing in public Zambian primary health care facilities.

Methods

The study was a secondary data analysis of a cross sectional survey of health facility data collected in four districts of Zambia. This study extracted patients' diagnoses and treatments and linked them to the health worker demographics and health facility characteristics in order to determine prescription patterns and factors influencing appropriate antibiotic prescribing.

Results

A total of 2206 prescriptions were analysed. An average of 2.5 drugs per encounter was prescribed. Injections were prescribed in 4% of the encounters. While over 95% of drugs were from the essential drug list fewer drugs were prescribed by their generic names. Only 1.5% of encounters did not result in a prescription.

Antimalarial drugs and antipyretics were prescribed in at least 70% of encounters while antibiotics were prescribed in close to 40% of encounters. Of all encounters in which a systemic antibiotic was prescribed, just above a quarter were of appropriate indication and dosage.

Determinants of appropriate antibiotic prescribing included patient's age, presence of clinical wall charts and treatment guidelines; and the health worker cadre. Under-5s were more likely to receive antibiotics when indicated, though at wrong dosages. Health workers with access to guidelines were more likely to prescribe antibiotics only when indicated. Health worker cadre

without pre-service clinical training were more likely to prescribe antibiotics when not indicated and at wrong dosages.

Discussion

This study showed that health workers' performance for most of the WHO drug-use core indicators was similar to findings in other developing countries. The study also revealed overuse of antibiotics for diseases that do not require antibiotics as treatment. Increasing access to guidelines and other clinical job aids, continuous medical education for all health workers and targeted training of health worker cadres without prior medical training will contribute to better prescribing of antibiotics.

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INTRODUCTION

1.1 Background information

More than half of early deaths in the developing world are related to infectious diseases like pneumonia, tuberculosis, diarrhoeal diseases, measles, Acquired Immunodeficiency Syndrome (AIDS) and malaria; death that could be prevented by, among other measures, appropriate use of drugs[1]. The World Health Organisation (WHO) highlights two concomitant problems regarding the drug situation in the developing world: one out of three people living in the developing world are in need of essential drugs although there are concurrent higher rates of inappropriate drug-use and drug resistance[2,3] . The WHO also estimates that 50 percent of all medicines are inappropriately prescribed, dispensed, or sold[4]. According to the 1985 WHO Conference of Experts on drug-use, appropriate, or rational use of medicines is only when drugs are prescribed when clinically indicated, and at correct dosages for the right duration and at the lowest cost both to the patient and their community [5].

In practical terms, inappropriate use of medicines is exemplified in some of the following aspects[6]:

i. Failure to prescribe in accordance with guidelines
ii. Prescribing with under or over-dosing
iii. Prescribing of expensive drugs when cheaper drugs would be adequate
iv. Excessive use of injectable drugs when oral formulations are appropriate
v. Use of too many drugs per patient (polypharmacy)

Inappropriate use of drugs has far-reaching consequences including, but not limited to, emergence of antimicrobial resistance and adverse drug interaction. Recent reports indicate that tuberculosis, malaria, meningitis and other major diseases have developed resistance, to various degrees, to drugs that once effectively treated them[7]. Additionally, inappropriate drug-use has direct and indirect cost to the health system and individuals. It is estimated that 50% of national and up to 80% of personal health expenses go toward buying medicines[8].

In recognition of the problems associated with inappropriate use of drugs, WHO recommends that member countries should carry out periodic surveys on the use of drugs for effective containment of the spread of antimicrobial resistance. To monitor, standardise and afford comparability of results, WHO in collaboration with the International Network for the Rational Use of Drug (INRUD) developed core indicators for assessing drug use.

This study utilised these drug-use core indicators to describe patterns of drug use and complementary indices to assess antibiotic prescribing practices in Zambia.

1.2 Statement of the Problem

Efforts to improve appropriate or rational drug prescribing should first establish the current practices as baseline and ascertain the principal issues that drive inappropriate prescribing in order to develop interventions. With the third world spending a major part of their health budget on drugs and the ever spreading emergence of resistance to antibiotics, there is need for measuring the current use of drugs in general and antibiotics in particular at Primary Health Care (PHC) facilities. Currently, there is a paucity of information on the patterns of drug use in general and factors affecting appropriate antibiotic prescribing in Zambia. Previous studies have revealed inappropriate use of antimalarials among health workers in PHC facilities. It would, thus, be reasonable to expect that there is misuse of other types of drugs meant for the other commonly encountered infectious diseases. Since the majority of Zambians depend on PHC facilities, non-adherence to prescribing guidelines at these health facilities would result in wastage of essential drugs as well as potentially contribute to occurrence of drug adverse effects and drug resistance.

Information gathered from this study would inform efforts for quality assurance and quality improvement in addition to contributing in curricula review in health training institutions. Information generated should ultimately influence prescribing practices.

This research thus sought to answer the question ‘What are the current prescribing practices as measured by the WHO/INRUD drug- use indicators; and the effect of programmatic activities such as in-service training, supervision and availability of guidelines on appropriate antibiotic prescribing among primary health cares providers in Zambia?’.

1.3 Literature review

Drugs or medicines play a central role in health service delivery. To achieve the intended purposes drugs need to be used appropriately. Appropriate prescribing of drugs is linked to correct clinical processes beginning with history taking, physical examination, and diagnostics procedures, availability of the recommended drugs or medicines and provision of drug information to both the health workers and patients.

Various methods, which have endeavoured to capture all these processes to differing extents, have been used to measure drug prescribing. Efforts to standardise the methods for assessing drug use started with the establishment, as early as 1969, of the European Drug Utilisation Research Group which established drug-use research standards. In 1996 WHO accepted these standards, which were the precursors of the current drug-use indicators, to enhance drug-use research and standardise measurement of drug-use especially in the developing countries. This culminated in the WHO/INRUD drug-use core indicators.

1.3.1 WHO/INRUD drug-use or prescribing indicators

Prescribing or drug-use indicators measure outpatient treatment of the most common illnesses encountered at the PHC facilities or hospital outpatient departments. Results from studies assessing the use of drugs have often shown discrepancies and made comparability across countries, or within countries with repeated measurements, difficult. WHO/INRUD has developed drug-use core indicators to enable member countries standardise monitoring of drug use and also afford comparability between different health jurisdictions. These indicators are focussed on patient care, health worker performance and the environment in which the health worker operates. They are designed to be measured with ease and results applicable to the health facility[9].

Their main weakness is that they are not analytical and do not attempt to explain the observed parameters. However, descriptive results from the core indicators can be enhanced by measuring complementary parameters such as use of antibiotics and identifying factors influencing the observed prescribing patterns. Despite their apparent weakness, the indicators are capable of generating information that can be used to[10]:

i. examine changes in medicines utilisation

ii. set a reference point for comparison with similar countries or regions

iii. take inventory of health workers' adherence to prescribing guidelines

iv. evaluate the accessibility, quality and cost-effectiveness of health care

1.3.2 Appropriate or rational drug prescribing

Appropriate prescribing encompasses a sequence of sound decision making steps drawing on the knowledge of the disease process, consequences of the prescribed drug(s) on the process, interaction with concomitant drugs or diseases and further incorporates questions whether the prescribed drug(s) grant the greatest benefit to the patient and community at large. There is no consensus in the definition of what constitutes appropriate prescribing. Buetow et al has suggested that for purposes of health care setup, “appropriate” should be defined as “the outcome of a process of decision-making that maximizes net individual health gains within society's available resources’[11].

Attempts at objective measurement have seen the development of various methods of measuring appropriate use of drugs. However, the most widely accepted and used is The Medication Appropriateness Index (TMAI). The TMAI depends on 10 questions. The first three of which carries the highest weights are:

- Is there a clinical or medical indication for the drug?
- Is the drug effective for the clinical condition?
- Is the dosage correct?

Aronson argues that, the second question is the most critical because if the drug is ineffective then the prescription is inappropriate[12]. Buetow’s definition and Aronson’s arguments have a meeting point in what has come to be known as the Essential Drugs List (EDL). This is the WHO concept of increasing the availability of essential drugs to all who need them. WHO proposed that EDL should be made of drugs that match the health needs of the majority of the people: the drugs must be effective for the condition, and affordable to the concerned society. To ensure the drugs on the EDL are prescribed appropriately in terms of dosing and duration of treatment, countries are expected to develop a national formulary or treatment guidelines to assist the prescribers. Many countries have since adopted the EDL and developed treatment guidelines aligned to the drugs on each country’s list[13]. In this case, if health workers prescribe according to treatment guidelines, there is minimal chance of prescribing ineffective drugs.

1.3.3 Health worker assessment of patients

Studies in Asia and Africa (including Zambia) have demonstrated that health workers' history taking and physical examination is often poorly done; with inadequate duration of consultation time, and extensive inappropriate prescription of drugs[14,15,16,17].

1.3.4 Prescription habits

Several surveys on drug-use in developing countries have shown that antimicrobials are the most commonly prescribed drugs followed by analgesics. According to the 2004 World Medicine Situation report, data from 35 countries in the developing world revealed a mean number of 2.4 drugs prescribed per consultation, 44.8% of consultations ending in at least one antibiotic prescribed, 22.8% consultations with injections prescribed while 60.3% of drugs were from the essential drug[10]. In the majority of cases, however, these medications were not necessary. Trostle found that while antibiotics were prescribed in up to 60% of clinical encounters, fewer than 20% of these were appropriate[17]. A review of studies looking at drug prescribing habits by physicians and other health professional personnel in 12 developing countries underscored an inappropriate usage of antibiotics for the majority of patients during clinical consultations[18]. In one study in China, 63% of antimicrobials selected to treat proven bacterial infections were found to be inappropriate[19]. Desta et al. demonstrated that an antimicrobial agent was prescribed in over 70% of clinical encounters in Ethiopian PHC facilities with little clinical justification[20].

1.3.5 Polypharmacy

Polypharmacy, or prescribing multiple drugs per patient, lacks a uniform definition although the WHO/INRUD recommends an average of two or less drugs per prescription[21]. It is measured by calculating the average number of drugs per encounter or prescription. Studies conducted in the developing countries in Asia and Africa show that polypharmacy is a common practice among health workers, with averages per prescription ranging from 2.3 to 3.5 drugs[7]. Nsimba[14] found an average of 2.3 drugs per patient, while Indian studies showed averages of 3.2[21,22]. Most of the prescriptions in these studies included at least one antimicrobial agent.

1.3.6 Determinants of prescribing practices

Studies have revealed health-worker as well as patient related factors as influencing the prescribing habits of health workers.

Factors directly related to the health worker include inadequate knowledge about the differential diagnosis, the kinds of conditions treatable with antibiotics and appropriate therapies for bacterial infections. Others include worry that a displeased patient will consult other health workers especially when patients pay the health worker for the service; and fear of unfavourable clinical results if treatment was withheld[23]. Boonstra et al. found that factors associated with adherence to guidelines included: patients' age, specified diagnosis, type of health facility and nurses' years of practice[24]. In India, Bharathiraja et al. also demonstrated that Physicians with a paediatric postgraduate qualification and physicians with more than 20 years of experience are less likely to prescribe antibiotics, as are physicians who update their knowledge through academic means like Continuing Medical Education, seminars, journals etc. Physicians with only outpatient practices were more likely to prescribe antibiotics[25].

Patient-related factors have been identified as one of the many drivers of inappropriate antimicrobial use and could therefore contribute to the increasing prevalence of antimicrobial resistance. Most patients expect an antimicrobial for suspected infection thus influencing the prescribing practices of health providers. For example, Hamm et al.[26] and Macfarlane et al.[27] demonstrated that, in both developed and the developing countries, a prescriber's perception of patients' expectations and demands may indirectly influence the prescriber's prescribing practices.

1.4 Overview of Primary Health Care facilities in Zambia

Most of health services in Zambia are delivered through publicly owned health facilities. Patients are not required to pay for the drugs that are prescribed and dispensed in these facilities, although they may have to buy from private pharmacies if the prescribed drug is unavailable at the facility.

The majority of prescribers at PHC facilities are Clinical Officers and nurses especially in rural and the peri-urban areas. In most facilities, there is only one health worker who performs clinical consultations and dispenses drugs from the same room. At a few health facilities, health care providers without pre-service clinical training perform clinical consultations and treatment. These individuals are initially employed as auxiliary staff but may perform clinical duties when there are shortages of personnel with formal medical training. They are informally trained before they could perform such duties.

At most PHC facilities under-5s accounted for the majority of outpatient attendances. The 2005 health statistics bulletin indicated that there are approximately 5 to 6 times more under-5s visiting health centres compared to older patients; 1.88 compared to 0.30 per capita in 2004 for first attendances for routine health care[28]. The report also indicates that the incidence of malaria, non-pneumonia respiratory infection, diarrhoea, trauma, pneumonia (the top five diseases) was 383, 153, 75, 46 and 44 per 1000 respectively.

All health facilities have a systematic way of service delivery: specialised clinics like maternal and child health, tuberculosis treatment, provision of antiretroviral drugs and treatment of sexually transmitted diseases being separate from the routine health services. During the primary study patients attending these specialised services delivery points were not included. Patients attending the routine clinics are often first attendees for a current ailment. Very sick patients are admitted for observation at the health centre if facilities exist or are referred to the next level of care.

Primary health care is delivered through facilities called health centres which are classified by the Ministry of Health (MOH) as either rural or urban health centres. The ratio of the two types of health facilities is almost 1:1. Some PHC facilities are based at the district hospital and provide the same services as other peripherally situated health facilities. These are termed as Hospital Affiliated Health Centres (HAHCs). The HAHCs, however, have the advantage of access to the hospital laboratory, dispensary and likely to have Clinical Officers as opposed to the other types which are likely to be manned by nurses and other types of health workers.

Several programmatic activities from the MOH aimed at improving management of the common illness seen at the primary care level and promoting rational drug-use have been implemented in the recent past. These activities include in-service training of health workers in the Integrated Management of Childhood Illness (IMCI), management of malaria and HIV/AIDS/TB treatment and the provision of treatment guidelines like Standard Treatment Guidelines (STG) and Integrated Treatment Guidelines (ITG).

Data for this study was collected from the routine clinics and thus representative of the diseases prevalent in the communities where the health facilities are situated.

1.5 Definition of terms

Clinical Officer is a clinician with three-years pre-service medical training in management of the common health problems encountered at PHC primary health care level.

Nurse include Registered Nurse (RN) and Enrolled Nurse (EN) with three and two year diploma in nursing studies respectively

Environmental Health Technologist (EHT) holds a three-year diploma in environmental health. May assume clinical duties when there is a shortage of trained health workers

"Other" cadre includes**:**

i. *Community Health workers (CHW)* with six weeks training in diagnosis and treatment of common illnesses at the community level
ii. *Classified Daily Employees (CDE)* who have no clinical training and were initially employed for duties other than clinical work. In the absence of trained medical personnel, these categories of health workers may perform clinical duties including diagnosis and prescribing.

"Older patients" includes all patients aged 5 years and above

"Under-5s" includes children aged up to 59 months

Integrated Management of Childhood Illnesses (IMCI) is a syndromic approach to childhood illnesses aimed at preventing and treating the most common causes of under-5 morbidity and mortality.

"Routine Primary Health Care clinic" is the clinic providing health care for outpatients for sick children and adults, excluding children attending well-child clinics, immunisation clinics, maternal health and all patients with chronic diseases like tuberculosis, hypertension, and HIV/AIDS and Sexually transmitted diseases which are provided in special clinics.

1.6 Objectives

1.6.1 General objective

To investigate drug use and appropriateness of antibiotic prescriptions for patients seen at PHC facilities in Zambia

1.6.2 Specific objectives

i. To describe the morbidity patterns at routine PHC facilities in Zambia

ii. To describe the patterns of prescribing practices among health workers at PHC facilities using WHO/INRUD drug-use core indicators

iii. To determine the appropriateness of antibiotic prescribing for patients seen at PHC facilities

iv. To investigate determinants of appropriate antibiotic prescribing: correctness of indication and dosage

METHODS

2.1 Study design, Sampling and Study population

This was an analytical cross sectional study utilising secondary data analysis of a cross sectional cluster survey of all government and mission administered clinics in four districts of Zambia carried out in February to March 2004. The four districts were purposely selected and all health facilities included in the primary data collection. At each facility all consultations occurring at the routine outpatient clinics were included in the primary study. For the current study, all the electronic records representing prescriptions were included and prescriptions generated by a single health worker were considered as a cluster. The study population for this study was health workers' prescriptions at the primary health facilities.

To afford comparisons among health worker group, the required minimum sample size was 96 prescriptions per health worker group to achieve a level of confidence of 95% and margin of error ±10% assuming that the prevalence of most of the estimates of interest was around 50%. Because there was clustering of observations within the health worker, the sampling was not considered as random. To account for the clustering effect, a '*Design Effect'* factor of 1.5 was used. A design effect is simply a measure of how much of the observed variability between subjects is due to the intra-cluster correlation[29]. This meant that the total minimum sample size required was 144 prescriptions per health worker group. Because a larger sample sizes give more precise estimates, all the prescription records on the dataset were included in the analysis.

2.2 Description of the source of data and method of data collection

Data for this study was collected at PHC facilities in four districts of Zambia. The objective of the primary study was to measure health workers adherence to malaria treatment guidelines.

The four districts were purposively chosen to reflect different malaria ecologies in Zambia: from hyperendemic to hypoendemic areas. Two of the districts were rural, one mixed and one mainly urban. Consequently, 76% of the health centres were rural according to the classification of health centres by the Zambian MOH.

The primary survey included observation of patient-health worker consultations to study the process of consultation, exit interviews with patients, health worker interviews and health facility assessment. While observing the consultation, the survey team members recorded all symptoms reported by the patient or elicited by the health worker together with all physical examinations done. Patient-held records were checked to obtain information on laboratory tests ordered and the results, diagnosis indicated and drugs prescribed (route, dose, and duration). All health workers observed during consultation were interviewed to obtain basic demographic data, pre-service and in-service training; and also frequency of supervision. Health facilities were assessed to provide information on availability of antimalarial drugs, equipment, treatment or diagnostic wall charts, treatment guidelines and other job aids.

A total of 1535 under-5s and 819 older patients were observed during consultation; while 2225 were interviewed at exit. A total of 150 health facilities were included and 130 health workers who carried out consultations with the patients were interviewed to obtain their demographic and in-service training data.

2.3 Data extraction

In the current study, patients' presenting symptoms, weight, age, temperature, diagnosis and treatments given; health workers' and facility characteristics were extracted and linked as one table using Microsoft Access (see questionnaire in appendix B). This allowed for analysis of commonly encountered diseases, individual prescriptions as well as potential factors affecting antibiotic prescribing.

2.4 Measurements

2.4.1 Explanatory variables

Explanatory variables for assessment of potential predictors associated with prescription practices as revealed from other studies and relevant for this study included:

i. Age of the patient: categorized as under-5s and older patients

ii. Type of health worker (i.e. pre-service training): Clinical Officers, Registered Nurse, Enrolled Nurse, Environmental Health Technologist and "Other"

iii. Experience of health worker: measured as number of years worked after graduating from medical college. For health workers without formal medical training, how long they were working at the health facility was used as a proxy measure. This was categorized as less than 5 years, between 5 and 10 years; and more than 10 years.

iv. Clinical in-service training: the different types of clinical trainings reported were categorized in broad subject matter. All trainings with a focus on management of malaria were grouped as "any malaria training"; IMCI training was treated as a separate category as it is specifically for the management of childhood illness while HIV/AIDS/TB management training was also considered separately. The last category was, however, not included in the analysis for potential predictors of appropriate antibiotic prescribing since these patients were excluded from the primary data collection round. All trainings that included management of the commonly encountered diseases at PHC level were combined into one category "any clinical training", to measure the proportion of health worker who were trained in either one or any combination of the following: malaria, IMCI, Integrated or competence training (ICT).

v. Supervision: was measured as the number of times in the six months prior to the primary survey that a health worker was supervised accompanied by observation whilst performing clinical duties and having feedback on their performance.

vi. Possession or access to clinical guidelines: Access to clinical guidelines or availability of copy of the essential drugs list or formulary was measured as either availability of a booklet copy at the facility or personal possession of the guidelines. The main MOH official clinical guidelines in circulation were the Malaria Treatment Guidelines, Integrated Treatment Guidelines (ITG), IMCI and Zambia National Formulary (ZNF).

vii. Presence of clinical wall charts displayed in the consultation room: only diagnostic or dosage charts were included in the analysis.

viii. Duration of consultation: was calculated as the ending time less the starting time of a consultation. Any interruption for any reason was discounted.

ix. Type of health facility: Three levels of health facility type were created according to the MOH classification of facilities at the time of the primary study: hospital affiliated health centre, rural and urban health centres

2.4.2 Outcome variables

The outcome variables included a description of diseases commonly encountered at PHC facilities in Zambia, the constellation of WHO core drug-use indicators for defining the pattern of drug prescribing and the “appropriateness” of antibiotic prescriptions.

a. <u>Disease profile</u>

This was measured as proportions of each disease as diagnosed by the health workers. Where the health worker did not explicitly state the disease, signs and symptoms were used as proxy for the disease. Disease conditions rather than systems affected, in accordance with classification of diseases in ITG and IMCI guidelines.

b. <u>WHO/INRUD core drug-use indicators</u>

The WHO recommended core drug-use indicators were used in describing the general prescribing patterns among health workers[7]. The core indicators are descriptive and focus on:

i. Prescribing indicators: Average number of drugs per encounter, percentage of encounters with antibiotic prescribed, percentage of encounters with an injection prescribed, percentage of drugs prescribed by generic name, percentage of drugs prescribed from the essential drug list or formulary.

ii. Patient care indicators: Duration of consultation was measured as time spent in consultation between a patient and health worker. This included the dispensing time because at the majority of health facilities drugs were dispensed within the consultation room.

Prescribed antibiotics were classified following the 15^{th} list of WHO list of essential drugs[30] as shown in Table A2. Antibiotic eye ointment and skin creams and antidiarrhoeal preparations containing antibiotics were all counted as antibiotics. The ZNF was used as reference in order to assess whether a medicine was prescribed by its generic name.

Calculation of indicators was based on the following formulae:

a) Average number of drugs per consultation or encounter

$$= (\text{total number of individual drugs prescribed} \div \text{number of consultations})$$

b) Percentage of drugs prescribed by generic name

$$= (\text{total drugs prescribed by generic names} \div \text{total drugs prescribed}) \times 100$$

c) Percentage of consultations with antibiotics prescribed

= (prescriptions with least one antibiotic prescribed $\div$ total prescriptions) x 100

d) Percentage of consultations with injection prescribed

= (prescriptions with at least one injection prescribed $\div$ total prescriptions) x 100

e) Percentage of drugs prescribed from the Essential Drug List (EDL)

= (total drugs prescribed included in the EDL $\div$ total drugs prescribed) x 100

f) Average consultation time

= (sum of all consultation times $\div$ total no. of consultations)

c. <u>Appropriateness of antibiotic prescriptions</u>

To assess the appropriateness of the prescribed antibiotics and correctness of dosage, only systemic antibiotics were included in the analysis. The investigator checked each electronic record for the health worker's diagnosis and drugs prescribed. Where an antibiotic was prescribed, the diagnosis indicated was used to measure the appropriateness of the decision to prescribe the antibiotic. The health workers' decision to prescribe the antibiotic was judged as either 'Appropriate' for the indicated diagnosis if in accordance with the treatment guidelines (ITG, STG or IMCI guidelines for under-5s) or 'Inappropriate' if not. If the prescribed systemic antibiotic was found to be "appropriate", a further assessment for correctness of the dosage for that antibiotic was performed. Correctness of dosage was classified as either "Correct dose" or "Incorrect dose". "Incorrect dosage" included over-dose, under-dose or inadequate duration of treatment. To classify the correctness of dosage, patients' weight and/or age, and age only was used for the under-5s and older patients respectively.

Where the health worker did not explicitly indicate the diagnosis but prescribed antibiotics, the presenting symptom(s) were used as a proxy for the likely diagnosis that the health worker could have considered in deciding the treatment. Cough, shortness of breath and/or chest pains with elevated temperature (≥38.5) were considered in this investigation as enough suspicion of Lower Respiratory Tract Infection (LRTI) and thus appropriate to prescribe antibiotic. Cases with cough as the main complaints, sneezing and/or runny nose without shortness of breath or chest pain and temperature less than 38.5^{o}C were considered as Upper Respiratory Tract Infection (URTI) and thus inappropriate to give an antibiotic. Cases with history of only fever or fever with non-specific symptoms like malaise, joint pains, headache, chills without respiratory symptoms were considered as probable malaria and thus not appropriate to prescribe antibiotic.

For reliability and validation purposes, a randomly selected (using systematic sampling) subset of 100 classified prescription records involving a systemic antibiotic were also classified for appropriateness of indication and dosage by an independent blinded senior medical officer at University Teaching Hospital (Lusaka, Zambia). The Kappa statistic of at least 0.61 was considered as substantial inter-observer reliability[31].

2.5 Data management and analysis

Data cleaning and coding for relevant variables was done in Microsoft Access. A table linking each health worker to the health facility they operated in and to patients he/she saw in consultation and to the exit interview was created using unique identity codes. This allowed for the analysis of individual health workers' diagnosis(es) made and prescriptions; and factors relating to their exposure to training, guidelines, supervision and other factors that may influence prescription behaviour.

The unit of analysis was the individual prescription, reported at health worker level for most analyses. Some analyses were reported at the level of age groups to reflect differences in treatment guidelines between under-5s and older patients. Because individual health workers tend to prescribe in a consistent way, this study anticipated high correlation within prescriptions generated by each health worker. Therefore to account for clustering and obtain adjusted estimates, STATA was set to *svy mode*, selecting the primary sampling unit as the health worker.

The procedure of analysis was as follows:

1. Univariate analysis was done to describe the distribution of patients' and health worker characteristics, diagnosing and prescribing patterns. Descriptive statistics: proportions, means (median and range for non-normally distributed continuous data) and 95% confidence intervals were reported.

   If the normality of distribution and equal variance assumptions were satisfied for numerical data, analysis of variance (ANOVA) was used to test for statistical differences in means among the health worker cadres. The Bartlett's test for equality of variances was used to check for homoscedasticity. Pair-wise or multiple comparisons to identify differences between health worker groups was done using the Bonferroni method[32]. For categorical data Pearson Chi-square tests were used to compare differences among health worker groups. All statistical tests were two-sided and a *P*-value < 0.05 was considered as statistically significant. The term 'marginal statistical significance' was used to indicate associations with a *P*-value between 0.05 and 0.10

2. Bivariate analysis: To identify predictors of appropriateness of prescribing antibiotics and correctness of dosage for prescribed systemic antibiotics, logistic regression modeling was used. This allowed for estimating the correct unadjusted odds ratio (OR), *P*-value, and 95% CI for the association of the each outcome with the exposure factors.

   The following explanatory factors were assessed:

   i. Age of the patient

ii. Type of health worker (i.e. pre-service training)

iii. Experience of health worker

iv. Clinical in-service training

v. Health worker supervision

vi. Possession of or access to clinical guidelines

vii. Presence of clinical wall charts displayed in the consultation room

viii. Duration of consultation

ix. Type of health facility

Further, statistical interactions between in-service training and health worker pre-service training, supervision and in-service training, in-service training and availability of treatment wall charts, availability of guidelines and in-service training and availability of clinical wall charts and treatment guidelines were investigated.

3. Multivariate analysis: To adjust for potential confounders, factors with a *P*-value of 0.15 from the bivariate analysis were placed into multivariate logistic regression models. A stepwise addition of the factors that did not initially meet the entrance criteria for the multivariate analysis (i.e. 'non-significant' $P > 0.15$) was then done. Each time a new factor was added, the ORs of the factors already in the model were checked. If the addition of a new factor changed the OR of any already included variable by more than 10%, the additional variable was retained in the final multivariate model.

2.6 Ethical considerations

This study was submitted to the University of Witwatersrand for ethical clearance. The University of Zambia Research Ethics Committee reviewed and gave ethical clearance for the primary data collection. Permission to use the primary data set for secondary analysis was obtained from the Zambia National malaria Control Centre, Ministry of Health.

RESULTS

This chapter gives a brief description of the sample characteristics, disease profile and the drugs prescribed in order to comprehend the prescription patterns. This is followed by presentation of the selected WHO drug- use core indicators and factors affecting antibiotic prescribing.

3.1 Sample description

A summary description of the sample is shown in Table 3.1. A total of 2206 records representing clinical consultations and treatment prescriptions were included in the analysis. The prescriptions were generated by 130 health workers working at 105 health facilities. There was only one medical doctor who contributed three prescriptions. These prescriptions were excluded from the analysis.

Female patients were in the majority accounting for 54% and over 65% of consultations involved under-5s. Close to half of the health workers were Enrolled Nurses and just over 80% of all the health workers had worked for at least five years since graduation. Two out of five health care workers reported undergoing a clinical training on management of malaria while 25% had training in IMCI. Overall 72 (55%) reported having undergone “any clinical training” in the 10 years prior to 2004 when the primary data collection round was conducted. Close to 90% reported at least one supervisory visit in six months prior to the primary survey. Rural health centres accounted for 78% of the health facilities.

Malaria treatment and ITG guidelines were available to about 60% of the health workers, though less than 10% had access to the ZNF. Only 16% were working in health facilities that displayed any kind of clinical wall charts in the consultation rooms: diagnostic or treatment flow charts or drug dosage charts.

Table 3.1: Description of patient, health worker and health facility characteristics

Patient N=2206	n (%)
Age	
Under-5	1432 (65.3)
5yrs and above	760 (34.7)
Gender	
Male	1011 (46.1)
Female	1181 (53.9)
Health workers N=130	
Cadre	
Enrolled Nurse	58 (44.6)
Clinical Officer	39 (30.0)
Registered Nurse	12 (9.2)
EHT	11 (8.5)
Other	10 (7.7)
Age - median(range)	40.5 (20-70)
Years of Experience	
<5 years	24 (18.5)
5 to 10 years	30 (23.1)
>10 years	76 (58.4)
In-service training in last 10 years N=130	
Any malaria training	57 (43.8)
IMCI	32 (24.6)
HIV/AIDS/TB management	19 (14.6)
‡any clinical training	72 (55.4)
†Supervision in last 6 months N=115	
0 visits	13 (11.3)
1-3 visit	84 (73.0)
≥4 visits	18 (15.7)
§Possessions/Access to clinical guidelines	
ITG	75 (57.7)
IMCI	21 (16.2)
Malaria treatment guidelines	80 (61.5)
Zambia National formulary	10 (7.7)
Health Facilities N=105	
Health facility type	
Hospital affiliated HC	6 (5.7)
Rural health centre	82 (78.1)
Urban health centre	17 (16.2)
Availability of clinical/dosage wall charts	
Yes	17 (16.2)
No	88 (83.8)

‡ includes any malaria and IMCI. Also note that some health workers reported > 1 clinical training
†15 missing values
§ n>130 and %> 100 because some health workers reported possessing more than one type of guidelines

As reflected in Figure 3.1, the majority of consultations, and thus prescriptions, were performed by Enrolled Nurses and Clinical Officers. Health worker cadres without any pre-service clinical training were involved in only 7% of consultations.

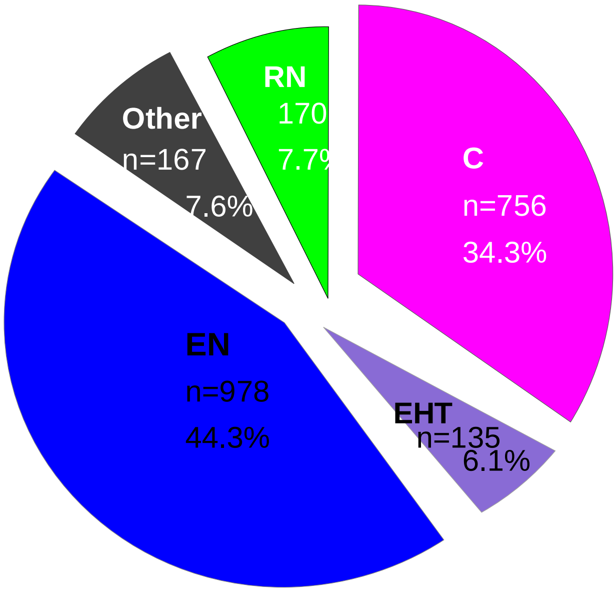

Figure 3.1: Distribution of consultations by health worker cadre

3.2 Morbidity patterns

3.2.1 Disease profile

A summary of diagnoses for the 2206 records is presented in Table 3.2 below. Malaria, respiratory tract infections, diarrhoeal diseases, anaemia and skin infections were the five commonest causes of morbidity among attendees in the study centres. While malaria was diagnosed in 64% of all encounters the second commonest, respiratory infections, was diagnosed in only 19% of encounters. Overall, infectious diseases accounted for 1591 (72%) of all morbidity. Localised infections of the eye, ear or throat were diagnosed in less than 5%. Diagnosis was not explicitly stated in 306 (14%) of consultations. Infrequent diseases, categorized as “others”, were mainly non-infectious in nature such as hypertension, musculoskeletal diseases, asthma, headache etc.

Table 3.2: Proportion of diagnoses for all patients

Diagnosis	N=2006	
	n	(%)*
Malaria	1421	(64.3)
Respiratory tract infections		
Pneumonia	147	(6.6)
URTI	277	(12.5)
Diarrhoea disease		
Non-bloody	149	(6.7)
Bloody(dysentery)	8	(0.4)
Anaemia	124	(5.6)
Skin infections	103	(4.7)
Conjunctivitis	92	(4.2)
Pharyngitis/otitis media	60	(2.7)
Malnutrition	40	(1.8)
Others	73	(3.3)
No diagnosis indicated	306	(13.9)

*proportions not adding up to 100% because some patients had more than one diagnosis

3.2.2 Diagnostic practices

Diagnostic practices was analysed as number of diagnoses made per encounter and presented as proportions. The results are shown in Table 3.3.

Overall health workers were able to indicate only one diagnosis in 58% of consultations. There seemed to be no significant differences regardless of the health care worker cadre as the confidence intervals were overlapping. “Other” cadres did not indicate diagnosis in close to 50% and had the least proportion with more than one diagnosis indicated. A statistically significant difference was observed between the “Other” and the trained health workers cadres in consultations where diagnosis was not explicitly indicated (x^2 = 11.04, p=0.001). Compared to other trained health workers, registered nurses performed poorly in that they did not indicate diagnosis in close to a quarter of their consultations.

Table 3.3: Proportions of number of diagnoses made per encounter stratified by cadre

Health worker Cadre	Number of diagnoses per encounter					
	0		**1**		**2-4**	
	n	% (95%CI)	n	% (95%CI)	n	% (95%CI)
CO (N=756)	93	12.3(6.9-21.1)	424	56.2(49.8-62.3)	239	31.5(25.2-38.8)
RN (N=170)	39	22.9(11.1-41.5)	99	58.3(43.5-71.6)	32	18.8(10.7-30.9)
EN (N=978)	78	8.0(4.1-14.9)	595	60.8(54.0-67.4)	305	31.2(25.6-37.4)
EHT(N=135)	16	11.8(5.4-23.9)	78	57.8(44.7-69.9)	41	30.4(18.1-46.2)
Other (N=167)	80	47.9(20.3-76.8)	76	45.5(20.4-73.2)	11	6.6(1.9-19.9)
Total =2206	306	13.9(10.1-18.8)	1272	57.7(53.7-61.6)	628	28.4(25.0-32.2)

3.3 Pattern of drug prescribing

This section presents an overview of drugs that were prescribed, routes of administration, and disease for which the drugs were prescribed.

3.3.1 Profile of prescribed drugs

Antimalarials, antipyretics, antibiotics, haematinics and oral rehydration salts solution were the top five prescribed drugs (Table 3.4). Three in four consultations were prescribed an antipyretic, mostly paracetamol. A total of 869 (40%) of encounters resulted in prescription of at least one antibiotic through various routes of administration. Of these, penicillins accounted for 44% of the prescribed antibiotics. These ranged from narrow spectrum ones like Penicillin V to the broad spectrum Amoxicillin and penicillinase resistant Cloxacillin. Cotrimoxazole and Tetracylines were prescribed in 37% and 20% of consultations respectively. Tetracycline was mostly in the form of eye ointment and usually in combination with other types of antibiotics. Blood boosting products (haematinics) mostly consisting of ferrous sulphate and folic acid were prescribed in 14% of all consultations. Oral rehydration salt solution (ORS) was prescribed in 12% of encounters. Only 68% of patients diagnosed with diarrhoea were prescribed ORS.

Table 3.4: Profile of the prescribed drugs

Type of drug	N=2206 n (%)
Antimalarials	1526 (69.2)
Antibiotics	869 (39.4)
Pencillins	*380 (44.5)*
Cotrimoxazole	*320 (37.4)*
Tetracyclines	*174 (20.4)*
Othe antibiotic$^{\psi}$	*44 (5.2)*
Analgesics/antipyretics	1700 (77.1)
Paracetamol	*1363 (80.2)*
NSAIDS $^{\Pi}$	*341 (20.1)*
Hematinics	312 (14.1)
ORS	260 (11.8)
Antihistamines	156 (7.1)
Multivitamins	126 (5.7)
Antihelminths	98 (4.4)
Antacids	60 (2.7)
Metronidazole	50 (2.3)
Steroids	32 (1.4)
Anti-emetics	26 (1.2)
Antitussive	44 (2.0)

$^{\Psi}$chloramphenicol, aminoglygosides,ciprofloxacin,erythromycin,nitrofuraantoin,cephalosporin and nalidixic acid
$^{\Pi}$ 4 patiets received both NSAID and paracetamol

3.4 WHO/INRUD rational drug-use indicators

This section summarizes the results of the selected WHO drug-use core indicators. The results for each health worker cadre are shown in Table 3.6.

3.4.1 Duration of consultation

Consultation time was calculated by subtracting the starting time from ending time of a consultation less any interrupting interval if any. For the 2187 consultations for which the duration of consultation was completed (19 patients had missing data), the majority (57%) were seen in five to 10 minutes, a third spent less than five minutes while just about 10% spent more than 10 minutes in consultation with a health worker. The consultation time was skewed as shown in Figure 3.2. The median time was five minutes (range 1-47 minutes, 75th percentile 7 minutes) and mean time was five minutes 48 seconds.

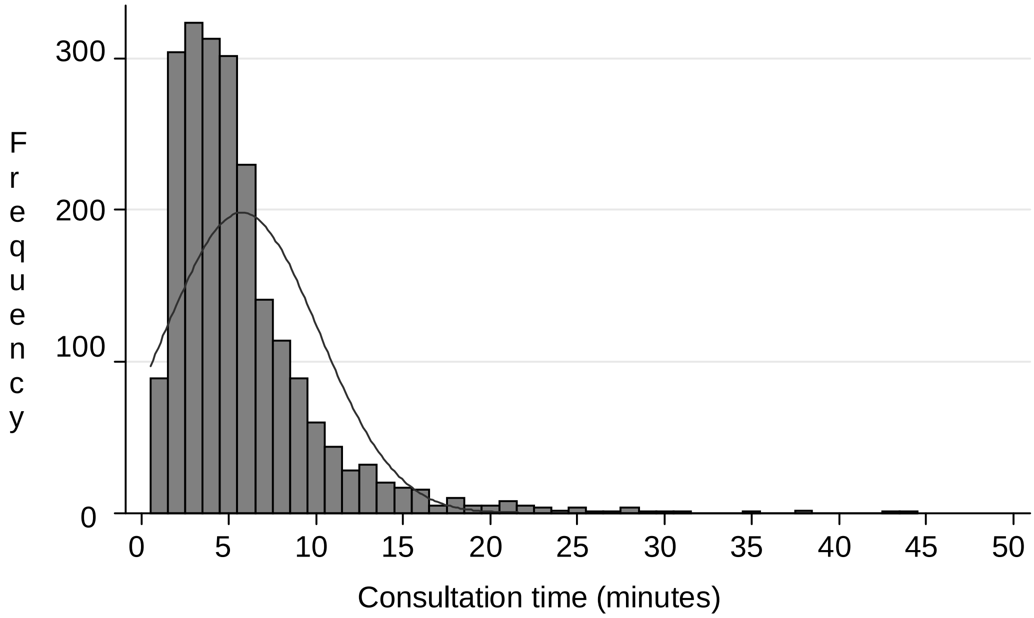

Figure 3.2: Distribution of duration of consultation time. Note the skewed distribution

3.4.2 Proportion of drugs prescribed by generic name and from EDL

Of the total 5543 individual drugs prescribed, 2465 (43%) were prescribed by generic names. The highest proportion of such prescriptions was made by EHTs at 51% while the lowest proportion was observed with Registered Nurses (31%). The Registered Nurses group showed a statistically significant difference from the rest of the cadres ($p<0.0001$).

Almost all (97%) the prescribed drugs were selected from the EDL. There was no significant statistical difference among the health worker categories.

3.4.3 Average number of drugs per consultation

A total of 5543 individual drugs were prescribed in 2206 encounters. Overall, the average number of drugs per encounter was 2.5 (95% CI 2.4-2.6). Registered Nurses averaged the lowest with 2.3 drugs per consultation while Clinical Officers averaged the highest at 2.6 drugs per consultation. Global analysis of variance showed that there was a statistically significant difference in the average number of prescribed by the various health worker cadre

(F statistic= 5.28, $p<0.001$). A pair-wise comparison of health worker cadre using Bonferroni procedure, showed that Registered Nurses group mean number of drugs prescribed per encounter differed significantly from the other groups (CO $p<0.001$, Enrolled Nurses p=0.02 and “Other” p=0.02), except for the EHT group (p-value = 0.13).

3.4.4 Proportion of encounters with at least one antibiotic prescribed

Analyzing for antibiotic prescription showed that 919 individual antibiotics were prescribed for 856 patients. Some patients had received more than one antibiotic: as a systemic preparation in combination with either a topical application or another systemic preparation. None of the patients received triple antibiotics. Overall, at least one antibiotic was prescribed in close to two out of every five encounters. The proportions of encounters with at least one antibiotic prescribed ranged from 30%, observed with Registered Nurses, to 40% seen with Clinical Officer and Enrolled Nurses. There was no significant statistical differences in proportions prescribed antibiotics among the health worker groups (x^2=7.68, p=0.59).

3.4.5 Proportion of encounters with at least one injection prescribed

Injections were prescribed in 93 (4.2%) encounters: as a combination of quinine and an antibiotic or either of the two types of drugs alone. There was no significant statistical difference in proportions of injection prescribing among the health worker (x^2=6.93, p=0.24).

Almost 90% of the injections involved an antibiotic. Among prescribed antibiotic injections, penicillins accounted for 89.3%. The rest of antibiotic injections consisted of gentamycin, chloramphenicol and cephalosporins. The penicillins were prescribed mostly for pneumonia, tonsillitis and skin infections. Skin infections which included abscesses, impetigo, scabies and septic sores or wounds accounted for over fifth of the total injections. Table 3.5 summarises the diagnoses for which the injections were prescribed.

Table 3.5: Indications for prescribed injections

Diagnosis	Number of encounters with injections prescribed N=93	
	n	**(%)**
Malaria	41	(44.1)
Pneumonia	13	(14.0)
Skin infection	21	(22.6)
Tonsillitis, Otitis media	10	(10.6)
Meningitis	3	(3.2)
No diagnosis indicated	5	(5.5)

3.4.6 Proportion of encounters without drug prescription

Only 34 (1.5%) of encounters did not result in drug prescription. Of the 34 consultations, nine cases were referred to higher level of health system, 16 had no diagnosis indicated and the remainder was diagnosed to have had URTI, suspected early pregnancy and malaria.

3.4.7 Availability of National formulary or Essential Drug List

Availability of ZNF or List of essential drugs was generally low with only 1 in 10 health workers having access. Availability ranged from 0 to 27%.

Table 3.6: Selected WHO/INRUD rational drug-use core indicators

Indicators	Health worker cadre					
	CO N=756 (95%CI)	RN N=170 (95%CI)	EN N=978 (95%CI)	EHT N=135 (95%CI)	Other N=167 (95%CI)	Total N=2206 (95%CI)
Drug use						
Average number of drugs per encounter	2.6 (2.4-2.7)	2.3 (2.0-2.5)	2.5 (2.4-2.6)	2.5 (2.2-2.8)	2.5 (2.3-2.8)	2.5 (2.4-2.6)
% of drugs prescribed by generic name	47.1 (44.9-49.4)	31.4 (26.8-36.3)	40.3 (38.4-42.3)	51.3 (45.9-56.8)	38.7 (34.1-43.5)	42.7 (41.4-44.0)
% of drugs prescribed from EDL	97.6 (96.9-98.3)	89.1 (85.5-92.0)	96.6 (95.8-97.3)	99.1 (97.4-99.8)	97.9 (96.0-99.0)	96.7 (96.2-97.2)
Injection use						
% of encounters with ≥1 injections prescribed	5.4 (3.8-7.0)	1.8 (-0.1-3.7)	3.9 (2.3-5.1)	5.9 (-0.2-12.1)	3.0 (0.9-5.1)	4.3 (3.4-5.2)
Antibiotic use						
% of encounters with ≥1 antibiotics prescribed	40.9 (34.1-47.6)	30.6 (19.0-42.1)	40.6 (35.7-45.4)	38.5(26.6-50.4)	35.9(22.8-49.0)	38.8 (35.1-42.6)
Antibiotics as % of drugs prescribed	16.8 (15.2-18.5)	12.5 (9.3-16.2)	17.1 (15.6-18.7)	16.8(13.0-21.2)	16.0(12.6-19.8)	16.6 (15.6-17.6)
Other indicators						
Consultation time (%)[a]						
<5min	42.5 (30.5-54-5)	45.3 (33.0-57.6)	24.5 (15.8-33.1)	15.7 (6.2-25.1)	38.9 (20.0-57.9)	32.8 (26.4-39.1)
5-10min	50.7 (40.4-61.0)	51.2 (40.6-61.8)	60.2 (51.7-68.8)	81.3 (71.8-90.9)	53.8 (39.2-68.6)	57.1 (51.5-62.7)
>10min	6.7 (2.9-10.5)	3.5 (0.6-6.4)	15.3 (7.7-22.9)	2.9 (-0.7-6.7)	7.2 (0.8-13.4)	10.1 (6.3-13.9)
Availability of essential drug list or formulary	26.7 (23.6-30.0)	0	3.0 (2.0-4.2)	11.9 (6.9-18.5)	0	11.2 (9.9-12.6)

[a] 20 missing values

3.5 Determinants of appropriate antibiotic prescribing

Overall, 758 consultations ended in at least one systemic antibiotic being prescribed. These were classified for appropriateness of indication and dosage. The Kappa statistic for validation of the classification of "appropriateness of indication" and "correctness of dosage" was 0.68 and 0.77 respectively. .

Of the 758 consultations with at least one systemic antibiotic prescribed, 237 (31.3%) prescriptions were of "appropriate" indication, though only 200 (26.4%) prescriptions were both of appropriate indication and correct dosage. This means if the indication was appropriate, the dosage of the antibiotics was correct in 84.4%.

Appropriateness of the prescribed systemic antibiotics was analysed at health worker cadre level and results presented in Figure 3.3. Health workers with pre-service clinical training were able to prescribe systemic antibiotics for the correct clinical indication and dosage from 23% (10 / 44) for EHT to 32% (16 / 50) for Registered Nurses. In contrast the "Other" health workers cadre, without pre-service medical training, prescribed systemic antibiotics for the correct disease indication and dosage in only 7.4% (4 / 54) of encounters in which they prescribed a systemic antibiotic. To further investigate, the health cadres with pre-service medical training were collapsed into one category and compared to the "Other"; there was a statistically significant difference (Fisher's exact p=0.001) in proportions of appropriate systemic antibiotic prescribed in terms of both clinical indication and dosage.

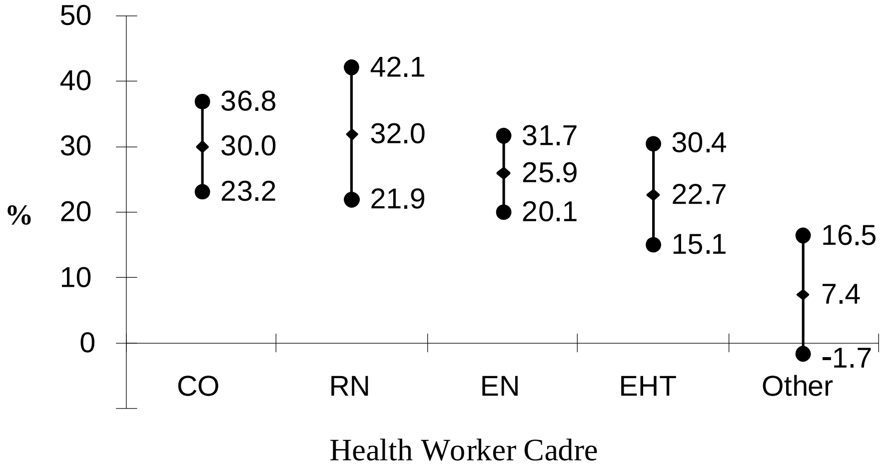

Figure 3.3: Proportion (with 95% Confidence limits) of appropriate antibiotic prescriptions (indication and dosage) by health worker cadre

Results of the analysis by age group are shown in Figure 3.4 below. Only 754 records were analysed because of missing age in four records. A slightly higher proportion of patients aged less than 5 were prescribed antibiotics only when clinically indicated compared to older patients ; 32.2% versus 29.1% (p-value = 0.03). However, when dosage is considered a higher proportion of older patient received the antibiotic when clinically indicated and at correct dosage; 27.2% compared 25.5% for those aged less than 5 years(p-value = 0.01).

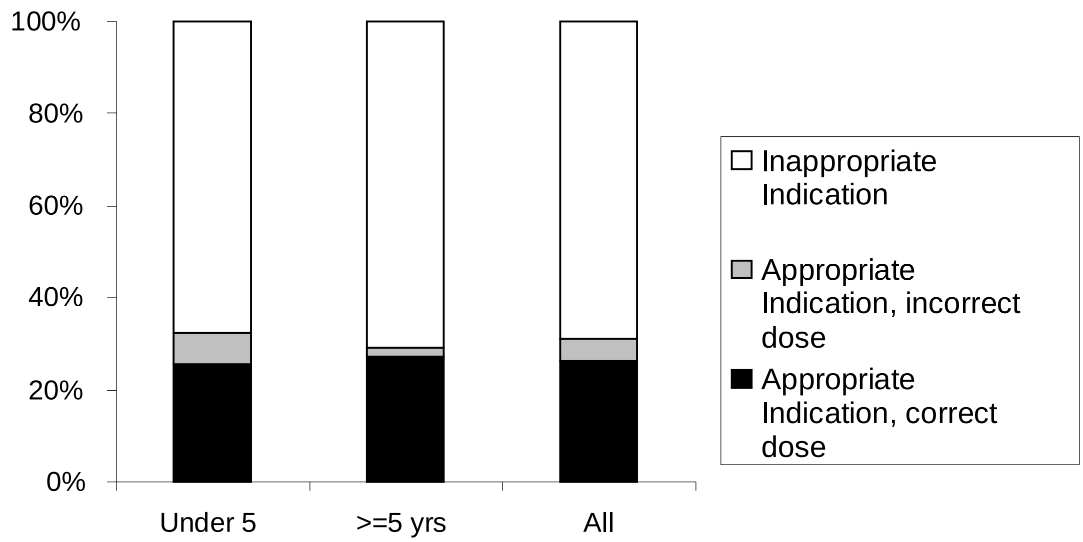

Figure 3.4: Proportion of appropriate antibiotic prescription (correct indication and dosage) by age group

3.5.1 Determinants of appropriateness of prescribing an antibiotic

Logistic regression was used to investigate factors and interaction terms that might influence appropriateness of antibiotics prescribing, that is whether it was justified to prescribe an antibiotic for the diagnosis(es) indicated for the patient in whom a systemic antibiotic was prescribed. Table 3.7 shows the ORs, CI and *P*-values of each of the factors for both bivariate and multivariate analysis. Patient's age, possession of clinical guidelines, and/or presence of clinical guidelines in consultation rooms were independently associated with correct indication for the prescribed systemic antibiotics in bivariate analysis. In multivariate analysis, patients' age and the interaction term between presence of clinical wall charts and treatment guidelines retained statistical significance. Under-5s were 1.7 times (p=0.02) as likely to receive antibiotics for appropriate clinical indication as were older patients controlling for availability of guidelines or clinical wall charts. The presence of either wall charts or treatment guidelines or both increased the likelihood of appropriately prescribing antibiotics two folds (p=0.01).

Supervision showed a trend consistency, though not attaining statistical significance, in that higher frequency of supervisory visits resulted in higher likelihood of prescribing antibiotics only when clinically indicated. Also noteworthy is that, in bivariate analysis Clinical Officers were 2.5 times as likely as the "Other" health cadre to prescribe antibiotics appropriately in bivariate analysis (although p value >0.05).

Table 3.7: Determinant of appropriateness of indication for prescribed antibiotics; bivariate and multivariate odds ratios (ORs), CI and p-values

	Bivariate			Multivariate		
Factor	OR	CI	p-value	OR	CI	p-value
Patient's age						
Under 5yrs	1			1		
≥ 5 yrs	0.7	0.5-0.9	0.02	0.6	0.5-0.9	0.02
Health worker cadre						
Clinical Officer	1					
Registered nurse	1.1	0.5-2.0	0.85			
Enrolled nurse	1.0	0.6-1.5	0.96			
EHT	0.9	0.6-1.2	0.49			
Other	0.4	0.1-1.4	0.15			
Years of experience						
Less than 5 yrs		1				
5 to 10 years	1.4	0.8-2.5	0.22			
>10 years	1.2	0.8-1.9	0.22			
Clinical In-service training						
No	1					
Yes	1.2	0.9-1.8	0.20			
Number Supervision visits						
0 visits		1				
1-3 visit	1.4	0.8-2.5	0.28			
≥ 4 visits	1.7	0.9-3.4	0.11			
Possession of guidelines						
No	1					
Yes	1.7	1.0-2.7	0.04			
Clinical wall charts						
No	1					
Yes	1.6	1.0-2.5	0.03			
Type of health facility						
HAHC	1					
Rural	1.0	0.5-2.1	0.98			
Urban	1.1	0.5-2.3	0.84			
Consultation time						
< 5 minutes	1					
5 – 10 minutes	1.0	0.7-1.4	0.95			
>10	1.2	0.7-2.1	0.45			
Wall chart & guideline interaction term				2.0	1.2-3.1	0.01

A further analysis to define for which conditions the antibiotics were prescribed was conducted. This was done for the commonest causes of attendance at primary health facilities:

malaria, respiratory tract infections and diarrhoea diseases. The analysis included only oral and injectable antibiotics excluding supportive therapies such as analgesics and antipyretics. The pattern of prescribing of antimalarial drugs and antibiotics for these diseases is summarised in Table 3.8. Among those patient diagnosed to have malaria only, close to fifth were prescribed an antibiotic in addition to an antimalarial drug. The same combination was prescribed to over half of those diagnosed to have malaria and URTI co-morbidity. Over half of the patients diagnosed to have only URTI were also prescribed an antibiotic. Those with a sole diagnosis of diarrhoea, 20% were prescribed an antibiotic.

Table 3.8: Antibiotic prescription for patients with malaria, pneumonia, URTI and diarrhoea

Treatment / Diagnoses	Antimalaria only n (%)	Antibiotic only n (%)	Antimalaria/ Antibiotic n (%)	None n (%)
Malaria N=1119	825 (73.7)	36 (3.3)	214 (19.1)	44 (3.9)
Pneumonia N=43	0	31 (72.1)	4 (9.3)	8 (18.6)
URTI N=148	7 (4.7)	79 (53.4)	7 (4.7)	55 (37.2)
Diarrhoea N=65	5(7.7)	14(21.5)	4(6.2)	42(64.4)
Malaria/Pneumonia N=97	2 (2.1)	5 (5.2)	87 (89.7)	3 (3.0)
Malaria/URTI N=129	60 (46.5)	5 (3.9)	62 (48.1)	2 (1.5)
Malaria/Diarrhoea N=84	60 (71.4)	1 (1.2)	18 (21.4)	5 (6.0)

3.5.2 Determinants of correctness of dosage for prescribed systemic antibiotic

Table 3.9 shows the results of bivariate and multivariate analysis of potential determinants of prescribing at correct dosage for the appropriately indicated antibiotics. Analysis was restricted to those encounters with prescribed systemic antibiotics. Patients' age and health worker cadre were significantly associated with correctness of antibiotic dosage in bivariate analysis. Only one level of health worker cadre ("Other") was significantly associated with the outcome. Patients' age and health worker cadre both retained statistical significance in multivariate analysis. Older patients were 3.3 times (p=0.03) more likely to receive an appropriately indicated antibiotic at the correct dosage than were under-5s controlling for the type of health worker cadre.

Clinical officers, as reference group, were 5 times more likely to prescribe antibiotics at correct dosage (p =0.002) than "Other" health worker cadre controlling for the patients' age. There was no statistically significant difference between clinical officer and each of the other trained health worker groups. None of the interaction terms considered to be logically important attained statistical significance.

Table 3.9: Determinants of correctness of dosage for appropriately indicated antibiotics; bivariate and multivariate odds ratios (ORs), CI and p-values

	Bivariate			Multivariate		
Factor	OR	CI	p-value	OR	CI	p-value
Patient's age						
Under 5yrs	1			1		
≥ 5 yrs	3.5	1.3-9.9	0.02	3.3	1.1-9.4	0.03
Health worker cadre						
Clinical Officer	1			1		
Registered nurse	1.4	1.0-10.0	0.72	1.2	0.2-7.2	0.83
Enrolled nurse	1.2	0.5-2.8	0.75	1.2	0.4-3.0	0.74
EHT	0.9	0.2-3.7	0.86	1.0	0.2-4.1	0.96
Other	0.1	0.04-0.4	0.001	0.2	0.05-0.5	0.002
Years of experience						
Less than 5 yrs	1					
5 to 10 years	2.0	0.6-6.5	0.24			
>10 years	1.9	0.7-5.2	0.18			
Clinical In-service training						
No	1					
Yes	1.2	0.5-2.9	0.58			
Number Supervision visits						
0 visits	1					
1-3 visit	2.2	0.7-7.5	0.17			
≥ 4 visits	1.2	0.3-4.3	0.77			
Possession of guidelines						
No	1					
Yes	1.8	0.5-6.3	0.36			
Clinical wall charts						
No	1					
Yes	0.8	0.3-2.2	0.70			
Type of health facility						
HAHC	1					
Rural	0.2	0.05-1.0	0.05			
Urban	0.4	0.06-3.2	0.41			
Consultation time						
< 5 minutes	1					
5 – 10 minutes	1.5	0.6-3.9	0.38			
>10 minutes	0.9	0.3-2.9	0.92			

DISCUSSION

This study showed that infectious diseases are the major causes of morbidity in patients seen at the outpatient departments. The study also highlighted that antibiotics played a significant role in PHC service provision prescribed in close to 40% of all encounters.

4.1 Diagnosis and general prescribing patterns

The disease profile described in this study corresponds well with the national health statistics; malaria, respiratory tract infections and diarrhoea accounting for most morbidity reported from the PHC centres through the Health Management Information Systems (HMIS). Prescribing of drugs closely matched the prevalent diseases. In this study, antimalarial drugs, antibiotics and antipyretics were the most prescribed drugs; though notable was the disproportionately low proportion of encounters with ORS being prescribed.

Correct use of drugs is closely linked with the processes of diagnosis, which begins with history taking and examination with or without laboratory work up. Additionally, the concerned health worker should be able to perform a differential diagnosis and have sufficient knowledge of pathophysiology of a disease and its recommended treatment. In this study, health workers without pre-service clinical training did not explicitly state the diagnosis in one in two patients despite prescribing drugs. The same group had the least proportion of patients with more than one diagnoses. This could mean that this group has little knowledge of the pathophysiology of conditions encountered or have no capacity to make a differential diagnosis. This finding calls for urgent training, if not replacement by trained health professionals, of this group of cadres on the need for indicating diagnoses as a medico-legal requirement and also for monitoring purposes. In addition, future studies should look at the correctness of the diagnoses made by this group of health worker by incorporating exit re-examinations of the patient by trained medical professionals.

Health workers with formal pre-service training in clinical medicine labelled 30% of the patients with multiple diagnoses. Much as co-morbidity is a likely occurrence in practice, this proportion is too high. The tendency to diagnose more than one diagnosis might reflect a lack of understanding of disease processes or failure to carry out a differential diagnosis. For instance URTI, which is mostly due to viral infections, is likely to present with non-specific symptoms similar to those of malaria while diarrhoea and cough may be part of clinical spectrum of malaria especially in children. Labelling a patient with URTI as having malaria or vice-versa leads to treating every symptom with a drug and hence polypharmacy.

The diagnosis of malaria in addition to either pneumonia or URTI occurred in close to 16% of consultations. This was accompanied by prescription of antimalarial with antibiotics. Pneumonia is a specific disease and easily recognized clinically. In the absence of microscopy, as was the case in most of the health facilities in this study, diagnosis of malaria depended on presence of fever. Since URTI or pneumonia may present with fever, in addition to respiratory symptoms, the validity of pneumonia/malaria or URTI/malaria combination and indeed the practice to treat both is questionable.

This finding might suggest that health workers are misapplying the recommendations of treating every acute fever as malaria in endemic areas. If the symptoms and signs of pneumonia are present, rational prescribing will require only an antibiotic and cut down on other unnecessary drugs. This is even more critical with the introduction of more expensive drugs to treat simple malaria. Making parasitological diagnosis as a pre-requisite for prescribing antimalarials would eliminate unnecessary antimalarial prescriptions. This should be coupled with training in clinical skills for the diagnosis of pneumonia and URTI. However, more studies to look at the prevalence of co-morbidity are required for correct interpretation of these findings.

One in five of those with co-existing malaria and diarrhoea or only diarrhoea were prescribed an antibiotic or antibiotic with antimalaria. Antibiotics are rarely indicated in non-bloody diarrhoea[33] and URTI[34] and the treatment guidelines recommend use of antibiotics only when there is dysentery. Studies in developing countries have isolated rota virus from 20-70% of faecal samples from children with acute diarrhoea. In India, Maiya et al[35] isolated rota virus from over a quarter of diarrhoeal stools in infants and young children while more sensitive methods have detected rota virus from 71% of children with acute diarrhoea[36]. These findings suggest that antimicrobials are unnecessary in the majority of acute diarrhoeal diseases in infants and young children except when there is dysenteric stool. The mainstay treatment for most episodes of diarrhoea is ORS. Unfortunately, few patients diagnosed to have diarrhoea where prescribed ORS which is supposed to be the mainstay of treatment.

Most respiratory tract infections are of viral aetiology and do not require antibiotics for their management. In this study, over half of patients with sole diagnosis of URTI were prescribed an antibiotic. The overuse of antibiotics for URTI in this study is similar to findings elsewhere. In China, Hui et al demonstrated tendency of health workers to prescribe unnecessary antibiotics for respiratory infections[19]. Similarly in Botswana, Boonstra[37] found that antibiotics were prescribed inappropriately in 79% of cases with acute respiratory infection and in all cases of diarrhoeal diseases while a study in Tanzania[38] revealed that inappropriate use of antibiotics in outpatients was as high as 80% and 93% for diarrhoea and acute respiratory infections respectively.

The overprescribing of antibiotics is worrying as it is known to contribute to the emergence of antimicrobial resistance[39,40] and increase the level drug adverse effects[41] ; and may also contribute to cost of health care delivery[42].

Most of the diseases, malaria, pneumonia and URTIs, found in the surveyed population present with fever as clinical feature. Therefore it was acceptable that 77% of the patients were prescribed an antipyretic with most of it being paracetamol. Findings from Ethiopia, which has a similar disease profile as Zambia, revealed similar results; antipyretics were the second commonest prescribed after antimicrobials[43]. However, caution is required in the use of these drugs as they contribute to the cost of running the health services. Additionally, paracetamol has the potential for causing liver damage.

The study shows that health workers tended to use narrow-spectrum antibiotics as opposed to broad-spectrum ones such as cephalosporins, aminoglycosides and chloramphenicol. This is commendable because it helps in preserving broad-spectrum antibiotics for serious infections and for treating bacterial infections that are resistant to the common antibiotics.

4.2 Quantitative WHO/INRUD core indicators

This study shows that health workers' performance on most of the WHO/INRUD core drug-use indicators is similar to what has been found in studies elsewhere. However, the findings have to be interpreted in the light of their various limitations. Most important limitations include: the inability of the indicators to measure appropriateness of the observed prescribing patterns and difficulties in comparing findings across different settings with different disease profiles. Therefore there are no defined standards against which these indicators can be compared [7]. Consequently, the results in this study though comparable to what has been found in other countries may not necessarily mean acceptable health workers' performance but merely provide a baseline for future studies on drug-use core indicators. To improve on the utility of the core indicators, it is recommended that complimentary indicators such as assessing the appropriateness of prescribed drugs or adherence to treatment guidelines for the diagnosed illness. This has been attempted in this study, but for antibiotics only.

Despite the aforementioned imitations, the indicators provide an objective method for comparing drug use in the same area especially with repeated surveys or allow health managers to monitor changes in the use of drugs in a local jurisdiction. The latter would alert health managers to changes in disease frequency; for instance when the prescribing of a certain antibiotic meant for a specific disease suddenly increases.

4.2.1 Consultation time

The average consultation time of 5.8 minutes was similar to what has been observed in other studies. Studies elsewhere have shown that this ranges from 0.9 minutes in Bangladesh to 9.2 in Brazil[20,22,44,45].

It is difficult to judge whether the duration of consultation was adequate for a health worker to carry out a well considered differential diagnosis and thus targeted treatment. The time prescribers spend with each patient limits what diagnostic processes and the quality of diagnosis and therefore treatment. A study conducted in the same health facilities and involving the same health workers revealed that health workers did not perform the majority of the tasks required in the assessment of a child presenting with fever[15]. It can be postulated that the consultation time was inadequate.

4.2.2 Average number of drugs per consultation

This indicator measures the degree of polypharmacy. For this study, the average number of drugs prescribed was 2.5 per consultation and is well within what has been observed elsewhere: 2.2 in Brazil[45], 2.9 in India[21], and 4.8 in Ghana[46]. The cadre of health worker did not seem to matter in terms of performance. However, in this study it is worth noting that the Registered Nurses group prescribed the lowest average number of drugs per encounter, the lowest proportion of injections and the lowest proportion of antibiotic.

The Interpretation and utility of this indicator parameter requires caution given the advent of HIV/AIDS and infectious co-morbidity in clinical practice. Polypharmacy may need redefining to reflect changes in disease profile in HIV prevalent countries like Zambia.

4.2.3 Proportion of encounters with antibiotic prescribed

Studies in other parts of the developing world in similar settings reveal proportions ranging from 25% in Equador, 48% in Nigeria to 63% in Sudan[18]. The findings from this study seem to suggest that Zambian health workers have a similar prescribing tendency as in other developing countries. The WHO/INRUD does not recommend what the acceptable proportion of antibiotics should be, but rather interpret the result in the context of prevalent infectious diseases in the population. This is an essential parameter for health system managers when the proportion is way above the expected range (determined using the local burden of infectious diseases) or when there is a remarkable increase above the usual consumption[7]. On such occasions, understanding the causes of such changes is imperative. Findings from this study thus can form the baseline for future studies and monitoring and evaluation of health worker adherence to guidelines regarding use of antibiotics.

Notable in this study is the finding that Registered Nurses differed considerably in their prescribing habits among other trained health workers: they prescribed the least number of drugs per encounter, least proportion of antibiotics and used injections conservatively. A qualitative study with this group of health workers may provide clues to improve other health workers drugs use habits.

4.2.4 Proportion of encounters with injection prescribed.

In this study, the proportion of consultations resulting in prescription of an injection, of 4.3% was comparable to other studies. There was no difference in the proportion of injection prescription among health worker cadre. Findings from other studies have ranged from 0.2% in India[21], 8.3% in Brazil[45], 37% in Nigeria to 48% in Uganda[7,18,].

Although injections were minimally used in this study, it is of concern that skin infection ranging from abscesses, infected rash to scabies accounted for over 20% of reasons for injections being prescribed. Injections are not without attendant risks; including transmission of HIV and Hepatitis B. Treatment guidelines thus encourage health workers to use topical antiseptics like gentian violet and topical antibiotics for most skin infections. Mechanical means such as washing with water and plenty of soap are also recommended. Oral antibiotics are recommended only in cases of extensive septic skin lesions accompanied by systemic symptoms and injectable antibiotics are often recommended for severe infection like cellulites. Incision and drainage, rather than antibiotics is all that is needed for those with abscess[47]. Nevertheless, the health workers should be commended for the low use of injections generally.

4.2.5 Proportion of Generic drugs and EDLs.

The proportion of drugs prescribed by the generic name was very low. This finding contrasts findings from most other studies. For instance, studies in India and Tanzania found prescribing by generic names in 75% and 87% of encounters respectively[14,18]. A Brazilian study, however, found results similar to the current study: 30%[45]. The contrasting results may be explained by differences in classification. Because the WHO tool for assessment allows for the consideration of common non-generic names of drugs like Aspirin (for acetylsalicylate) to be classified as generic, investigators differ in the approach to this question. For this study, only international non-proprietary names as listed in the ZNF were accepted as generic hence the low proportion observed.

The proportion of drugs prescribed from the EDL was high reflecting keenness of health worker to use drugs recommended for the effective treatment of the various local diseases. The finding is in agreement with results from other studies. This measurement is important when patients have to buy drugs that are prescribed in brand names, as they tend to be more expensive than the generic ones. However, in the facilities included in the study, patients obtained most, if not all, prescribed drugs free of charge. Thus the use of non-generic names does not have any negative consequences in this context. It is interesting that the use of formulary drugs is so high in spite of the limited availability of the EDL or formulary. However, there is need to increase the availability of these important documents to health workers if rational drug-use is to be achieved, particularly with respect to dosages

4.3 Determinants of appropriate antibiotic prescribing

This study has demonstrated that patients' age, cadre of the health worker and presence of treatment guidelines and/or clinical wall charts were associated with appropriate antibiotic prescribing. Compared to under-5s, older patients were more likely to be prescribed antibiotics when they were not needed (p=0.02), presence of clinical guidelines/wall charts improved antibiotic prescribing two fold (p=0.01), while the “other’ health worker cadre was more prone to commit errors of indication and dosages.

The finding that age is an important factor in the appropriateness of the decision to prescribe an antibiotic conforms to what has been revealed by other studies. In Sudan, Eltayeb and Awad found that antibiotic prescriptions were appropriate in less than half of patients who were prescribed an antibiotic at primary health facilities; most of the errors were observed in young children[48]. Similarly, older patients with respiratory tract infections in the Netherlands were prone to receive an antibiotic when not recommended[49,50].

The “Other” health worker cadres without pre-service clinical training were more prone to prescribe antibiotics inappropriately and at incorrect dosages ($p<0.01$) compared to trained health workers. They got both indication and dosage correct in only 7% of the total antibiotic prescription they issued. Having such an important role, it is worrisome that health workers were prescribing antibiotics when not indicated; and if indicated incorrect dosages were given to some patients. Although it is difficult to find similar studies involving non-clinically trained health worker prescribing antibiotics, evidence from elsewhere shows that type of health worker cadre has an effect on appropriate antibiotic prescribing. Nyquist et al demonstrated that specialised health care providers like paediatricians, when compared to general physicians, were less likely to prescribe inappropriately to children with common colds[51]. Knowledge of a disease is an important determinant of correct antibiotic prescribing. It is plausible that this health worker cadre lacked the necessary knowledge to make correct decision regarding which conditions to prescribe an antibiotic.

Notably, health workers without any pre-service clinical medicine training were more prone to err in dosages. Although there was no statistical evidence, these same cadres were also 2.5 less likely to prescribe antibiotics only when clinically indicated. The failure to achieve statistical significance could have been due to the small numbers consulting these health workers in the sample.

However, the majority of patients consulted health personnel with prior medical training and thus the major undesirable effects of this practice are likely due to the trained cadres. The undesirable effects include risks of patients developing allergic reactions to drugs, drug interactions and chronic resistant infections or mortality. At community level, there is a chance of introducing antimicrobial resistance in the community. This ultimately would lead to increased indirect and direct costs of medical services[52]. Management of frequent childhood bacterial infections such as acute otitis media poses a challenge with the emergence of antimicrobial resistance[53].

Among the various programmatic support activities, only the presence of treatment guidelines and/or clinical wall charts was associated with improved use of antibiotics by a factor of two (p=0.01). There was no association between appropriate prescribing of antibiotics and other exploratory factors such as supervision, clinical in-service training, years of experience and type of health facility. Several studies have also shown that programmatic activities such as pre-service and in-service training, provision of treatment guidelines and supervision seldom lead to improvement in health worker performance [16,54,55,56]. However, Zurovac et al found results to the contrary in a study conducted in Kenya: presence of wall charts, supervision and in-service training all influenced appropriate treatment of children with malaria to varying extents[57]. Nevertheless, the current study shows that clinical wall charts and treatment guidelines are independent predictors of appropriate antibiotic prescribing. Presence of treatment guidelines and/or clinical wall charts improved performance in terms of appropriateness of indication though the same had no effect on the correctness of dosage.

Some predictors could have lacked association in multivariate analysis because they could not be measured accurately. For example, in the primary study and original data collection round, in- service training was measured over a ten-year period preceding the primary survey. This was too long a period to accurately measure the effect of the training; the effect may have diminished over time to the time the study was conducted. For this study, all non-malaria trainings were analysed as “any type” of clinical training to accommodate all trainings that incorporated treatment of the common health problems seen at PHC level. Because health workers were not equally trained in terms of number and type, the effect of in-service training on the antibiotics use could be masked. Although supervision did not attain statistical significance as a predictor of performance, increased supervision seemed to improve the appropriate use of antibiotics.

There are a variety of reasons why clinicians would prescribe unnecessary antibiotics, as has been observed in this study. Butler et al.[58] demonstrated that prescribers added an antibiotic to maintain patient satisfaction and worry that the patient may deteriorate if an antibiotic is withheld in case there was a disease that was missed. It could also be due to the lack of understanding that antibiotics have no role to play in certain diseases: non-bloody diarrhoea in children is commonly due to viral infections and URTI in both age groups is commonly viral in origin. Appreciating that viruses account for the majority of acute, self-limiting diarrhoeal episodes in children will reduce the usage of antibiotics in these cases[59]. The majority of episodes of URTI are mostly due to viral infection and require no antibiotic treatment[33,60]. The Zambian treatment guidelines[61] do not recommend antibiotics in patients with acute respiratory tract infections (coryza, cough, acute bronchitis) without features of pneumonia. Despite the preceding picture of inappropriate antibiotic use, it is worrying that 25% of children diagnosed with pneumonia did not receive antibiotics as per guidelines. The health workers could have been aware of prior of antibiotics thus omitting the antibiotics. This data was not captured in the primary study. Future studies should ensure that prior drug use is captured.

According to the treatment guidelines, antibiotic dosages in children less than five are based on the weight of the child contrary to older patients where broad age bands are used. The finding that children less than five years were more likely to receive antibiotics at wrong dosages might suggest that health workers do not have ready access to the weight of the patients or are not prepared to consult the treatment guidelines constantly.

4.4 Bias and Limitations

The source of bias was mainly from the fact that retrospective data was used; a major weakness for this kind of study design. The primary data was collected during the peak malaria season and thus may have introduced bias as heath workers may tend to diagnose and prescribe for malaria more than they would at other times of the year given that Zambia is endemic for malaria with high seasonality in transmission. Direct observation of health-worker patient consultation could introduce the “Hawthorne” effect on the clinical performance and better prescription during the study. The results may thus not be reflective of the usual situation[62].

There was a potential for misclassification of diagnosis for the 90 consultations where health workers did not explicitly state the diagnosis despite having prescribed at least one systemic antibiotic. Another source of misclassification was the measure of appropriateness of indication for the prescribed antibiotic since the kappa statistic was only 0.68. There is a high potential for misclassification of diagnoses and a chance for high rate of inappropriate prescribing of antibiotics. Thus, the appropriateness of indication cannot be considered as "definitely correct". For instance if a health worker indicates "diarrhoea" instead of "bloody diarrhoea" and goes on to prescribe an antibiotic correct for bloody diarrhoea according to guidelines, this study classified such practice as inappropriate. Furthermore, some health workers may classify diseases such as tonsillitis and pharyngitis simply as URTI, while others may explicitly indicate tonsillitis or pharyngitis as diagnosis and proceed to prescribe an antibiotic. In the former case prescribing an antibiotic was considered as "inappropriate" while "appropriate" for the latter case. However, to avoid bias, the health workers' stated diagnosis was used as the primary reason for the decision to prescribe an antibiotic.

Interpretation of the results should take into account the various limitations of the study. The major limitation included that this study did not look at the correctness of treatment for the total prescriptions and thus is not meant to assess the overall health worker performance in the treatment of diseases other than those in which antibiotics were used.

The following WHO core indicators for drug use were not included in this study due to insufficient data from the primary study:

- duration of dispensing time
- patient knowledge about all the drugs prescribed
- percentage of drugs adequately labelled and availability of essential drugs
- availability of essential drugs

The primary survey did not include establishing of "gold standard diagnosis" by re-examination of the patients at exit, therefore, the correctness of antibiotic prescription was only judged on the basis of the health workers' diagnosis. This could have introduce bias if the health workers tended to prescribe correctly for their indicated diagnosis thus limiting the determination of the quality of drug choices. This study, however, was not aimed at assessing the quality of the diagnosis and suffices to check whether the health workers prescribed antibiotics only when indicated.

CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

This study has managed to highlight the following:

i. Most of the WHO drug-use core indicators are comparable to what has been found in other developing countries. Worthy of note is the low use of injection, high proportion of drugs prescribed from the EDL, and an average of only 2.5 drugs per prescription.

ii. Tendencies by health workers to make multiple diagnoses

iii. Where systemic antibiotics were prescribed, only about 31% were of appropriate indication. It is commendable, however, that when the indication was appropriate health workers prescribed the antibiotic at correct dosage 80% of the times.

iv. Health workers without prior formal clinical training generally performed poorer than those with training: they did not indicate diagnosis in close to 50% of consultations despite prescribing drugs and were less likely to prescribe antibiotics appropriately in terms of both decision to use antibiotics and correctness of dosage.

v. Under-5s were more likely to be prescribed antibiotics at wrong dosages while older patients were more likely to be prescribed unnecessary antibiotics

vi. Availability of clinical wall charts and treatment guidelines positively contributed to better antibiotic prescribing

vii. Supervision may have marginal effect on better antibiotic prescribing habits

5.2 Recommendations

The study design of the primary survey managed to capture more prescriptions from rural based health centres (78%) than urban areas. Therefore caution is required in the interpretation and generalisation of the findings. Despite this limitation, the study has highlighted problems in the utilisation of drugs in general. The following are the recommendations needed to address the highlighted issues taking advantage of the predictors found to have effect on the outcomes of interest:

a) Continuous medical education targeted at the different cadres in rational drug-use and refresher courses in diagnosing the most common diseases encountered at PHC levels.

b) Urgent attention needs to be directed at the “Other” health worker category. This cadre needs training in clinical assessment as well prescribing skills.

c) Increase availability and utilisation of guidelines and treatment charts. There is need to align and standardise trainings and all guidelines available to health workers.

d) Further research, probably including a qualitative component, is needed to delineate the reasons for the overuse of antibiotics. Additionally, the observation that children diagnosed to have pneumonia were not prescribed antibiotics requires further inquiry as to why this was so. Future research thus requires a detailed analysis of the correctness of diagnosis and collection of data regarding prior use of antibiotics.

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APPENDIX

Appendix A. Drug-use core indicators and Antimicrobial classification

Table A1. Core drug-use indicators
Prescribing indicators 1. *Average number of drugs per encounter* *2. Percentage of drugs prescribed by generic name* *3. Percentage of encounters with an antibiotic prescribed* *4. Percentage of encounters with an injection prescribed* *5. Percentage of drugs prescribed from essential drug list or formulary* Patient care indicators *1. Average consultation time* *2. Average dispensing time* *3. Percentage of drugs actually dispensed* *4. Percentage of drugs actually labelled* *5. Patient knowledge of correct dosage* Facility indicators *1. Availability of copy of essential drug list or formulary* *2. Availability of key drugs*

Table A2. Antimicrobial classification for prescribing indicators

Count as antibiotic	**Code in WHO list**	**Class**
	6.1.3	**Antifilarial**
	6.1.4	**Antischistosomiasis**
Yes	**6.2.1**	**Penicillins**
Yes	**6.2.2**	**Other antibacterials**
	6.2.3	**Antileprosy**
	6.2.4	**Antituberculous drugs**
	6.3	**Antifungal**
	6.4.1	**Antiamoebic**
	6.4.2	**Antileshimaniasis drugs**
	6.4.3	**Antimalaria drugs**
	6.4.4	**Antitrypanosomal drugs**
Yes	**13.2**	**Anti-infective dermatological drugs**
Yes	**21.1**	**Anti-infective ophthalmological agents**

Source: World Health Organisation. Model List of Essential Medicines 15th list, March 2007. Geneva, World Health Organisation, 2007.

Appendix B: Questionnaires

Appendix B1 Health worker prescription practices: Patient characteristics

ID Number..[__]-[__]-[__|__]-[__]-[__|__]

Date .... [__|__] [__|__] [__|__]

Name of District.....................................[____]

Name of HF ....[____]

Health worker study ....[__]-[__|__]-[__]

Consultation starting time…………………………………………..[__|__]hours [__|__]min

Consultation interrupted at ....[__|__]hours [__|__]min

Consultation continued at ………..[__|__]hours [__|__]min

Consultation ending time…………………………………………. [__|__] hours [__|__]min

Patient characteristics

Patient's **age** (years-months)...[__|__]-[__|__]

Patient's **sex** (M/F).. [__]

Patient's **weight** (kg)...[______]

Patient's **temperature** (kg) ....[______]

Patients'/Caregivers' main complaints

- fever.. [__]
- chills .... [__]
- shivering.. [__]
- headache.. [__]
- joint pain .... [__]
- general body weakness .... [__]
- neck pain .... [__]
- nausea.. [__]
- cough .... [__]

difficult breathing.. [___]
chest pain .... [___]
running nose .... [___]
throat problem .... [___]
vomiting.. [___]
diarrhoea .... [___]
constipation.. [___]
malaria... [___]
pain on micturation .... [___]
ear problem .... [___]
stomach ache.. [___]

skin problem .... [___]
other (specify)... [_______________________________][___]
other (specify)... [_______________________________][___]

Diagnosis & Treatment

a. Which diagnoses were **written on the card**? (Check the patient's card)

b. Treatment prescribed (including **name** of drug, **dose** and route of **administration**)

Appendix B2 Health worker and facility characteristics

1. Background

a. What is the health worker's **cadre**?

Doctor .... [__]
Clinical officer .... [__]
Nurse... [__]
Others (specify).................................. [_________________________________][__]

b. **Age** (years) ....[__|__]

c. **Sex** (M/F)... [__]

d. **How long** have you worked at this facility? (years-months)........................ [__|__]-[__|__]

2. Training

a. What year did you graduate **from clinical medicine or nursing or medical school? ....[__|__|__|__]**

b. Which clinical in-service trainings **did you attend in the last ten years?**

c. Which clinical guidelines **do you have(personal possession or facility's? [List below]**

3. Supervision

a. Do you have **supervision** on your job performance? (Y/N) .... [__]

b. Is the supervision done by someone **resident** (R) or someone **outside** (O) the facility? (R/O) .... [__]

c. How many times during the last 6 months have **you met with a supervisor** about your clinical performance? (times) ....[__|__]

d. For how many of those did he or she **observe** you doing consultations?(times)..................[__]

4. Health facility assessment

a. Are there exposed **clinical wall charts in the consultation room?**(Y/N)....................... [__]

If Yes, which charts? (write the names of all charts)

APPENDIX C: Research ethics clearance letter

Appendix C1: University of Witwatersrand Research Ethics Committee clearance certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Ndhlovu

CLEARANCE CERTIFICATE	PROTOCOL NUMBER M071040
PROJECT	Determinants of Health Workers' Prescription Patterns for Patients at Primary Health Care Facilities in Zambia
INVESTIGATORS	Dr M Ndhlovu
DEPARTMENT	School of Public Health
DATE CONSIDERED	07.10.26
DECISION OF THE COMMITTEE*	APPROVED UNCONDITIONALLY

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 07.10.30 CHAIRPERSON ....
(Professors PE Cleaton-Jones, A Dhai, M Vorster, C Feldman, A Woodiwiss)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Prof M Price

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10005, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

15.11.07

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix C2: University of Zambia Research Ethics Committee clearance certificate

THE UNIVERSITY OF ZAMBIA

RESEARCH ETHICS COMMITTEE

Telephone: 256067
Telegrams: UNZA, LUSAKA
Telex: UNZALU ZA 44370
Fax: + 260-1-250753
E-mail: unzarec@zamtel.zm
Assurance No. FWA00000338
IRB00001131 of IOR G0000774

Dean's Office
P.O. Box 50110
Lusaka, Zambia

Ref: 002-10-03
5 January, 2004

Dr Micky Ndhlovu, BSc HB, MB ChB (Unza)
National Malaria Control Centre
P.O. Box 32509
LUSAKA

Dear Dr Ndhlovu,

RE: SUBMITTED RESEARCH PROPOSAL

The following research proposal was presented to the Research Ethics Committee meeting on 5 November, 2003 where changes were recommended. We would like to acknowledge receipt of the corrected version. The research proposal has now been approved. Congratulations!!

Title of proposal: **'Evaluation of outpatient malaria case management in four areas of different malaria ecologies in Zambia'**

Conditions:

- This approval is based strictly on your submitted proposal. Should there be need for you to modify or change the study design or methodology, you will need to seek clearance from the Research Ethics Committee.
- If you have need for further clarification please consult this office. Please note that it is mandatory that you submit a detailed progress report of your study to this committee every six months and a final copy of your report at the end of the study.

Yours sincerely,

Prof. J. T. Karashani, MB, ChB, PhD
CHAIRMAN
RESEARCH ETHICS COMMITTEE
Date of approval: 5 January, 2004 Date of Expiry: 4 January, 2005
Please note that when your approval expires you may need to request for renewal. The request should be accompanied by a progress report (Progress Report Forms can be obtained from the Secretariat).