Journal of Biology and Medical Sciences
ISSN 2409-5117 An International Peer-reviewed Journal
Vol.3, 2015
www.iiste.org

Investigation of Over the Counter Diagnosis and Drug Dispensation in Chemists A Case Study in Thika District, Kenya (An Observational Study)

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Abstract
Over-the-counter (OTC) drugs are medicines that may be obtained directly by a consumer without a prescription from a healthcare professional, as compared to drugs sold to consumers possessing a valid prescription. In many countries, Kenya included, these drugs are often located on the shelves of stores like any other packaged product. Some drugs may be legally classified as OTC but may only be dispensed by a pharmacist after an assessment of the patient's needs and/or the provision of patient education. OTC drugs are capable of being misused, abused especially where inappropriate drugs and incorrect dosages are given which may lead to short and long-term negative effects. The major concern surrounds the correct diagnosis and the appropriateness of the dispensed drugs and information provided to the consumers. This study focused on the OTC drugs in chemists. It was important to know why people opt for OTC drugs instead of the prescribed drugs. To meet this objective, an observational study was carried out in Thika District of Kenya to determine why patients prefer the OTC drugs to prescribed drugs. The results showed that the cost of prescription, source of diagnosis information, source of prescription information, amount of income of the respondent and previous experience on the same similar symptoms were determinants of buying OTC drugs. Education levels, age, place of residence, occupation and hospital type near the respondent were the covariates. The results of this study have enabled the researcher to come up with recommendations to the Ministries of Medical Services and that of Public Health on the best policies to use in dispensing OTC drugs.

CHAPTER ONE
1.0 INTRODUCTION

The chemists in Thika are frequented by drug buyers. Majority of the buyers buy the medicine without a medical doctors' prescription. The aim of this study was to seek to establish why they buy the drugs without the doctors' prescription. A qualified drug seller in a chemist is a person trained to dispense medicine following a medical doctors' prescription and is not trained in diagnosis of an illness. The fact is that the chemist attendants sell the drugs without a prescription and at times they offer consultation regarding some illnesses. However, concerns surround the appropriateness of drugs and information that medicine sellers provide. Often the type or dose of medicine was inappropriate for the complainant (Abiola et al; 1983). In a baseline survey in Kenya, only 4% of children given store-bought chloroquine received an appropriate dose and only 2% received this recommended three-day period. (Marsh et al; 1999). Aspirin was widely used although it is not recommended for children, with 22% receiving potentially toxic doses. (Geissler et al; 2000), moreover, drugs may be as substandard quality because of poor manufacture and storage (Van der Geest; 1987). In some encounters with their customers, medicine sellers simply sell what the customer requests. Few sellers are presented with a prescription from a trained health professional, nor do they request one prior to making a sale, (Adome; 2004). In Kenya, many customers who ask for such advice from drug shop staff are often given instant diagnoses and drug recommendations, operating as storefront clinics (Ongore & Nyabola; 1996). However, medicine sellers rarely ask customers questions about the illness and vary widely in the amount, accuracy, and quality of information given on how to take the medicines. (Nshakira et al; 2002). Instructions are often unclear, and misinformation is often provided. (Wolf-Gould et al; 1991). Like any business, medicine sellers maintain their existence in response to consumer demand, in this case for accessible convenient, reliable, and affordable drug supplies.

1.1 Definition of Terms

Population - refers to the totality of items under investigation. Its size is denoted by N.
Sample - is a subset of the population that can be used to estimate the properties of entire population. It size is denoted by n.
Study variable - is the variable of interest being investigated, measured or observed.
Thika District – this refers to the administrative area comprising of Thika municipality, Kakuzi division, Gatanga Division, Kamwangi division, Gatundu and Ruiru division.
OTC – these initials stands for over the counter. These refers are medicines that may be obtained directly by a consumer without a prescription from a medical doctor.
Stratums – this refers to a subset of the population with similar characteristics
Anova – analysis of variance

Ancova – analysis of covariance
Chi-Square – this is a tool of inferential statistics or significance testing. It is a test of the Significance of Association shown in Contingency Tables (Cross tabulations).
Hospital type – this refers to administration of a hospital either government or private

1.1 Problem statement and justification

Why people buy drugs in chemists and drug stores without medical doctors' recommendations or prescription.
The main concern of this study was the drug dispensation to the patients without diagnosis by a medical professional, yet:

- The symptoms of some diseases like malaria are headache, fever, joint pains, vomiting among others. The same symptoms are also similar to that of typhoid and meningitis. The drug sellers are not able to tell accurately the disease that a customer is suffering from and at times they give the wrong drug.
- The customers self diagnosis based on their past experiences or that of the others. That is the case of customers inquiring from their friends the drugs that they are supposed to take and they just buy the drugs as per their friends' advice.
- The danger of over the counter drug consultation is that the drug sellers do not base their prescription on any medical Doctors' diagnosis.
- Frequent self misdiagnosis.

It has repeatedly been shown that a large proportion of the public does not consider advice or information-giving to be a primary function of the pharmacist, at least not when given spontaneously (Salter et al; 2007). The reason for patients not being positive about such a role for the pharmacists could be a lack of faith in pharmacists' competence in this field (Anderson et al; 2004), fear of asking stupid questions (Schommer;1997), having the impression that they already have all information necessary, perceiving that pharmacists have limited access to patients records (Kettis Lindblad et al; 2006) and lastly they can't ask for an over the counter prescription due to privacy issues.

1.2 Research Questions

i. How does cost of consultation and laboratory tests influence the choice of OTC drugs to the prescribed drugs in Thika District?
ii. Does the time taken to seek doctors' consultation affect peoples' preference of drugs?
iii. Does the distance that a patient covers to access a medical facility influence his choice between the OTC drugs and prescribed drugs?
iv. Does the customer awareness on the dangers of OTC influence their decision to buy OTC drugs?

1.3 Hypotheses

i. The cost of accessing health care does not determine the choice of OTC drugs to prescribed drugs.
ii. Time spent in accessing health care does not influence the choice of OTC drugs to prescribed drugs.
iii. Access of health care does not determine the choice of drugs.
iv. Customers awareness on the risk factors of drugs does not influence their choice of drugs

1.4 Objectives

1.4.1 Main objective

This study aimed at determining factors that make people prefer the OTC drugs to the prescribed drugs.

1.4.2 Specific objectives

i. To determine the effect of cost on the preference of OTC drugs to the prescribed medicine in Thika District.
ii. To determine whether the time a patient takes to get a doctors' prescription affects the choice of drugs taken.
iii. To determine the effect of accessibility of medical health care to the preference of OTC drugs.
iv. To determine the level of customer awareness on the dangers of taking drugs without a doctor's prescription.

1.5 Significance

The study was important in finding the negative effects of over the counter drug dispensation and wished to come up with recommendations to the ministry of public health and sanitation. The study has helped come up with the reasons why people opt for the over the counter prescription.

CHAPTER TWO

2.0 LITERATURE REVIEW

Prescription of drugs means an order to take certain medications. Prescription may also include clinical assessments, laboratory tests, and imaging studies relevant to optimizing the safety or efficacy of medical treatment. The prescription should be given by a medical professional or qualified prescriber who should take responsibility for the clinical care of the patient and in particular for monitoring efficacy and safety.
Drugs need to be dispensed in formal establishments like chemists, or a health facility like a hospital. A study

has shown that in some settings, the drug seller market is extremely informal, including market traders with bowls of exposed tablets and capsules among which customers pick and choose, and hawkers wandering the streets (van der Geest; 1998). This study failed to tell why the buyers of drugs buy these drugs from these informal establishments.

Studies have been done on the knowledge of drug sellers. One study done about medicine sellers has shown that *medicine* sellers' knowledge of drugs and doses is often poor (Massele et al ;1993). In the treatment of malaria it was established that often the type or dose of medicine is inappropriate for the complaint (Abiola, et al ; 1983). Post intervention, for example, 60% of shop treated fevers still did not receive an adequate dose of a recommended antimalaria drug in Kilifi, Kenya, (Marsh *et.al; 2004)*. Similarly in another study about 50% of private practitioners failed to give the correct antimalaria dose in Luwero, Uganda (Tawfik, et al ; 2006). Some studies, however, have taken a different approach by looking at the relationship between selling drugs and making profit. The drug sellers in Kenya both in formal and informal facilities are concerned about money. A study has shown that limited competition was associated with high retail mark-ups in rural Kenya. (Indalo; 1997). Other studies however have shown that in most encounters with their customers, medicine sellers simply sell what the customer requests. Few sellers are not presented with a prescription from a trained health professional, nor do they request one prior to making a sale. (Fassin; 1988). It has been established in another study that chemists are not always staffed by appropriate personnel, (Goel et al ;1996). A different study has shown that instructions are often unclear, and misinformation is often provided. (Wolf-Gould et al ;1991). Many drug sellers don't offer any information regarding drugs, however; some sellers give a considerable amount of advice on drugs and doses. (Brieger et al ;2004). In some cases studies have shown some dealers sell sub-optimal drug doses. (Adome, et al ;1996).

It has been shown that a large proportion of the public does not consider advice- or information-giving to be a primary function of the pharmacist, at least not when given spontaneously (Salter et al ;2007) The reason for patients not being positive about such a role for the pharmacists could be a lack of faith in pharmacists' competence in this field (Anderson et al; 2004), fear of asking stupid questions (Schommer ;1997), having the impression that they already have all information necessary and perceiving that pharmacists have limited access to patient records (Kettis et al ; 2006), and some patients can't make inquiries from a chemist due to privacy issues (McAuley et al; 2009).

Although studies have shown that some medicine sellers don't have enough knowledge on the drugs they sell, (Goodman ; 2004). The study does not tell why patients buy drugs without the doctor's prescription.

CHAPTER THREE
3.0 MATERIALS AND METHODS
3.1 Introduction
In this chapter, the methods that will be used to collect and analyze data are discussed. The major sections include the study site, demographic and population profile, research design, sampling methods, methods of data collection, ethical considerations, data processing and analysis methods.

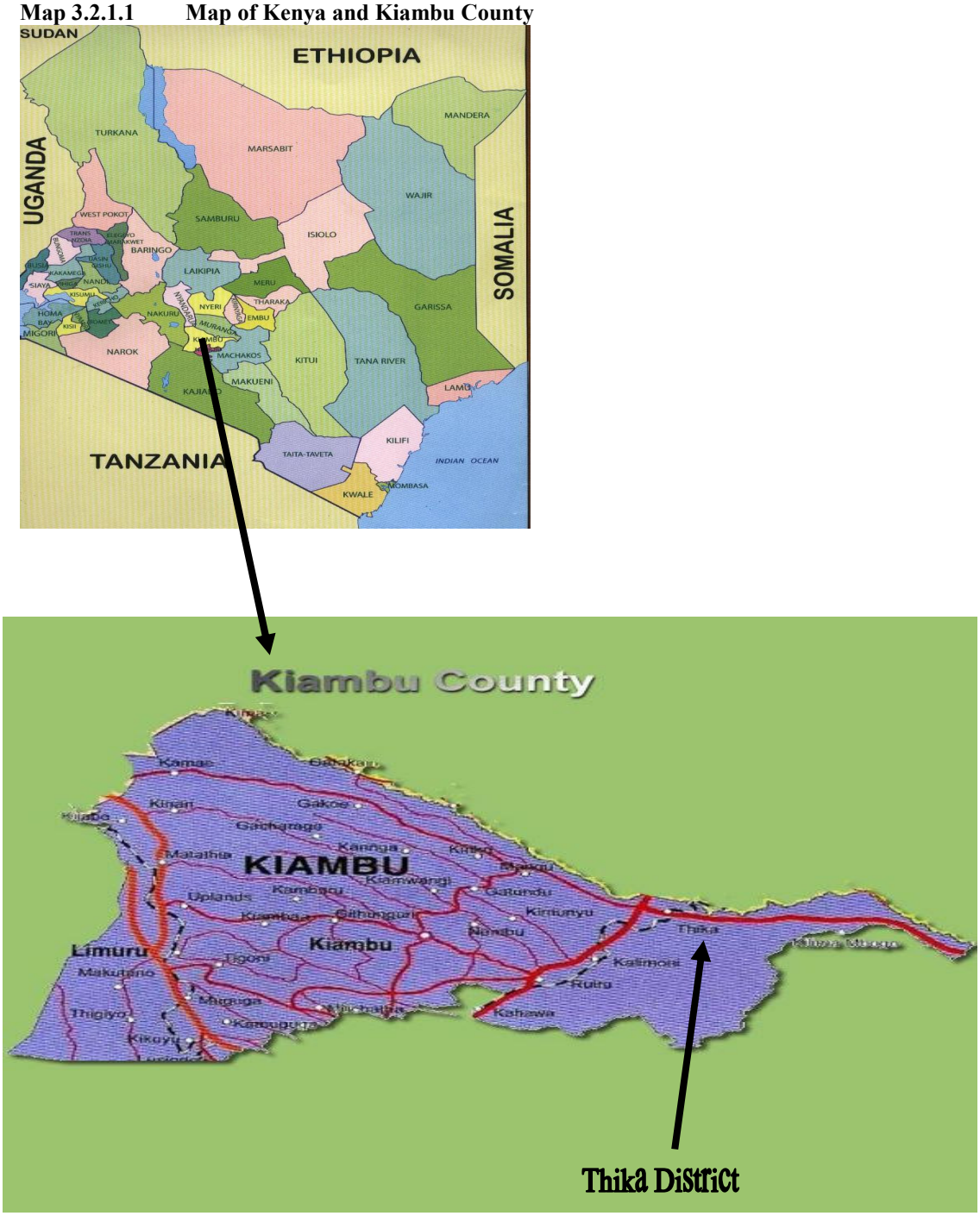
3.2.0 Study site
Thika District is one of the seven districts in Kiambu County in Central Province of Kenya. The district covers an area of 1,960.2 sq Km². It borders Nairobi City to the south, Kiambu District to the west, Maragua district to the north and Machakos District to the east. The district lies between latitudes 3°53′ and 1° 45′ south of Equator and longitudes 36° 35′ and 37° 25′ east. The district is divided into 6 divisions namely Ruiru, Gatundu South, Thika Municipality, Kakuzi, Gatanga, and Kamwangi (Gatundu North), 20 locations and 89 Sub-locations. (DDP, 2005, Thika). http://ncpd-ke.org/strategicplans/Thika.pdf

3.2.1 Demographic and Population Profile of Thika District
The district is quite densely populated but with diverse distribution varying from one division to the other. Gatundu, Thika Municipality and Gatanga Divisions are the most densely populated with Gatundu having the highest population. The lower parts of Ruiru and Kakuzi Divisions have the least density population. High population density in most parts of the district has put pressure on land leading to fragmentation into smaller uneconomical units. Agriculture dominates the economy of the district and provides livelihood to 75% of the County's population. The major economic activities include tea and coffee, horticulture, dairy farming and poultry farming. In addition to Thika district being a rich agricultural district, it is one of the leading industrial districts of the country. Other economic activities include employment of skilled and unskilled workers, trading in wholesale, retail, hawking, micro enterprises, touting, non-motorized transport business, taxi buses, minibuses transport, industrial business, by products factory and subsistence farming. However there are isolated pockets of poverty in the district and mainly found in urban slums in Thika municipality, Ruiru Town and Juja. (http://www.geohive.com/cntry/kenya.aspx). The table below summarizes the population per division. (KDHS; 2008/2009).

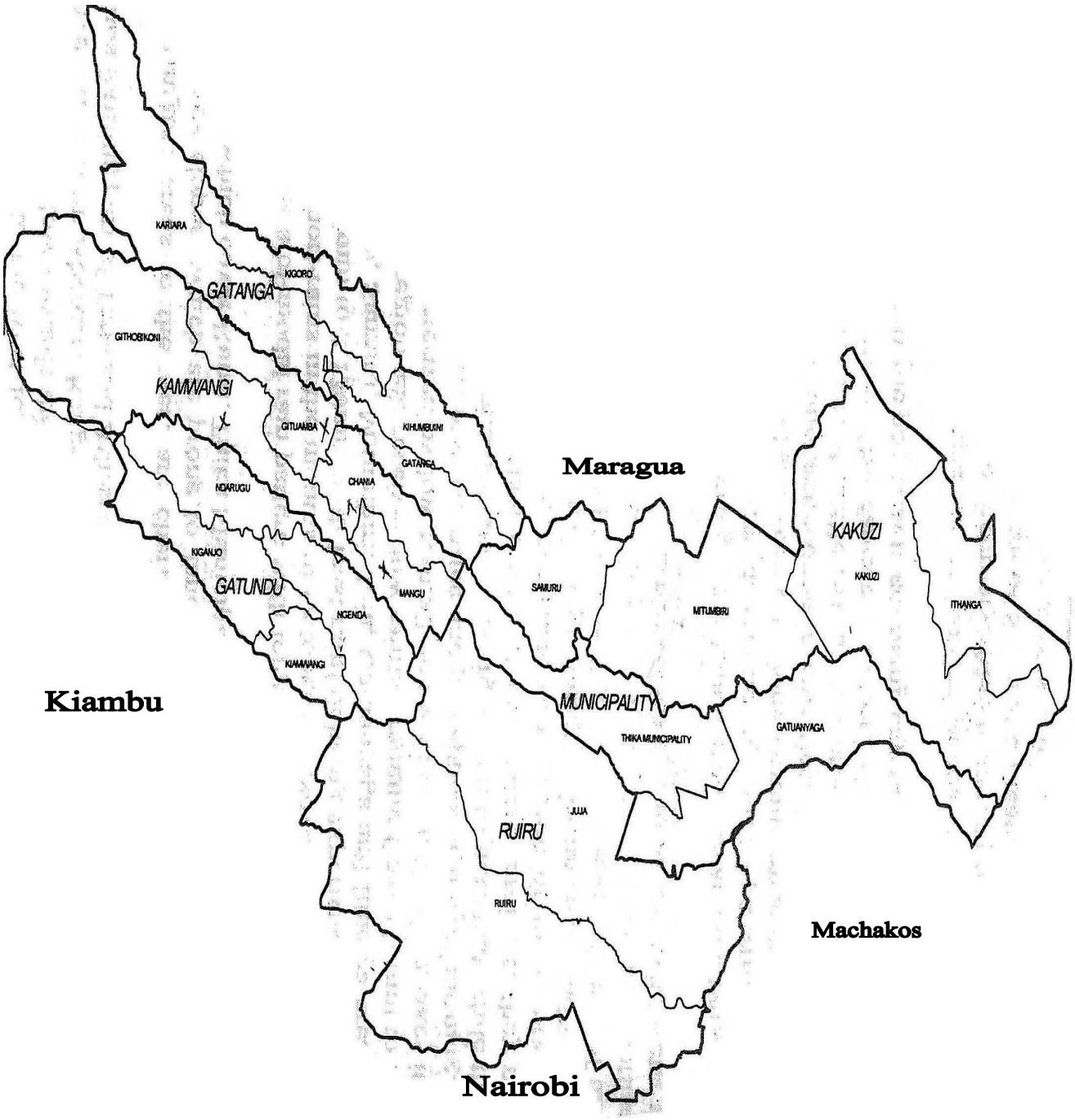
Table 3.2.1.1 population distribution in the district

	DIVISION	POPULATION
1	THIKA MUNICIPALITY	111,174
2	KAKUZI	73,368
3	GATANGA	113,067
4	KAMWANGI (GATUNDU NORTH)	99,291
5	GATUNDU SOUTH	118,533
6	RUIRU	159,435
	TOTAL	**674868**

Map 3.2.1.1 Map of Kenya and Kiambu County



Map 3.2.1.2 Map of Thika District.



3.2.3 Health status

In the year 2010, Thika had over 105 health facilities spread across the District. The doctor/population ratio is about 1:21,940 showing over-utilization of doctors. The average distance to a health facility is less 5 Km. The most prevalent diseases are Malaria, HIV/AIDs and Broncho-pneumonia while the childhood diseases include anaemia, Marasmus, eye infection, pneumonia, malaria, Kwashiorkor etc. HIV/AIDs in Thika is a major health problem with the prevalence averaging 34%. (DDP Thika; 2005. http://ncpd-ke.org/strategicplans/Thika.pdf)

3.2 Research Design

The study will be a cross sectional descriptive survey. It will be used to collect both quantitative and qualitative data to establish factors that contribute to people buying drugs from chemists and drug stores without a prescription. In-depth interviews will be conducted with patients found buying drugs at the chemists without a medical doctor's prescription.

3.3 Sampling Methods

The study sample for patients was selected purposefully to enable the researcher interview only patients found buying drugs at chemists and drug stores without a medical doctor's prescription.

3.4 Study population

Study participants will mainly be recruited at community pharmacies in Thika District. They will all be adults (over 18 years old), and used medicines regularly to treat a variety of medical conditions. The recruiter will use subjective judgment to exclude individuals with poor understanding of English and Kiswahili, and those suspected of suffering from cognitive impairment. Age, gender and type of drugs will be monitored to get a wide variation of respondents.

3.7 Sample Size Determination

3.7.1 Pilot study

In the pilot study we took a sample of 225 and only 165 respondents were found to be buying drugs from chemists in Thika district without a prescription. In order to determine the proportion of respondents who buy OTC drugs, we divided 165 by 255 to get P =0.733

3.7.2 Sample size

The sample size (n) will be determined as with (Kothari; 2003) method of sample size estimate from a finite population

$$n = \frac{z^2\ p.\ q.\ N}{(N-1)e^2+z^2\ p.\ q} = \frac{1.96^2 \times 0.733 \times 0.267 \times 380277}{380276 \times 0.05^2 + 1.96^2 \times 0.267 \times 0.733} = 300$$

Where

N= is the total population above 19 years in the district =380277).

n= is the sample size =300

z= value of the standard variate =1.96 at 95% CI

e= is the acceptable error = 0.05

p= proportionate target population with the particular characteristic (p=.733)

q=1-p = 0.267

A sample size of 300 participants will be taken.

To collect the data from the 300 respondents, the population in the study area was divided into 6 stratums as per the administrative boundaries. Proportional allocation was employed to distribute the 300 respondents in to 6 stratums (6 administrative divisions).

Stratum	**Nn**
1. Thika municipality	111,174
2. Kakuzi	73,368
3. Gatanga	113,067
4. Kamwangi (Gatundu north)	99,291
5. Gatundu south	118,533
6. Ruiru	159,435
Total	**674868**

Proportional allocation

$$\text{Strata 1} \quad \frac{(111{,}174 \times 300)}{674868} = 49$$

$$\text{Strata 2} \quad \frac{(73{,}368 \times 300)}{674868} = 32$$

$$\text{Strata 3} \quad \frac{(113{,}067 \times 300)}{674868} = 50$$

Strata 4 $\frac{(99{,}291 \times 300)}{674868} = 44$

Strata 5 $\frac{(118{,}533 \times 300)}{674868} = 53$

Strata 6 $\frac{(159{,}435 \times 300)}{674868} = 71$

3.5 Data analysis – Statistical Tests

The study generated both quantitative and qualitative data and this data was collected and analyzed in several different ways. Data collected included structured and unstructured interviews and data from the administration of a questionnaire. Data was analyzed using the constant comparison method for qualitative research, and descriptive statistics for questionnaire data. The study hypotheses were tested using Pearson product-moment correlation coefficient to help predict relationships between independent and dependent variables. It enabled the researcher to determine the strength of the association between the two variables. The study was aimed at determining the effect of independent variables on the independent variables. The confounding factors were analysed using ANCOVA. The study findings were discussed and presented in form of tables, and percentages using SPSS package.

Interpretation of data was performed using the perspective of usefulness, which was the potential for results being applicable and useful for developing community pharmacy practice.

The data on choice was tested by performing single group ANOVA on the average factor scores within each dimension.

3.6 Ethical considerations

The researcher strived for a relationship with the study respondents that were characterized by openness, veracity and privacy. The study purpose and general outline was described and briefly explained to the study subjects. It was made clear that the researchers were acting independently of the pharmacy. Furthermore, the freedom of participation was stressed. Study subjects were informed that their participation was voluntary and that they could withdraw at any time without having to explain anything. Their treatment at the pharmacy was to be unaffected by their decisions to refuse participating in part of or the whole study. Study subjects were given time to think about their participation, and their consent was required.

CHAPTER FOUR

4.0 RESULTS AND DISCUSSION

All the chi square tests done were able to determine that cost of prescription was significant in determining whether a patient buys drugs without a prescription. Thus the cost of accessing health care does determine the choice of OTC drugs to prescribed drugs. Source of diagnosis information, source of prescription information, amount of income of the respondent, previous experience on the same similar symptoms and gender were also significant in determining whether a respondent would buy drugs from a chemist without a doctors' prescription. Age, place of residence, occupation, hospital type near the respondent, nearness to a chemist / hospital, time taken to reach hospital, Awareness of dangers were all not significant in determining whether a patient will buy drugs without a medical doctors prescription.

When occupations, place of residence, level of education, hospital type near respondent were entered as covariates, the overall model changed. Time taken to reach hospital, awareness of dangers and nearness to a chemist/hospital which were initially not significant became significant. These suggest that the apparent relationship between income and possessing a medical doctor's prescription is merely an artifact of the underlying relationship between education levels and having a doctor's prescription. Since income tends to rise as education rises, apparent relationships between income and other variables may actually be the result of differences in levels of education.

Awareness of the dangers of buying drugs without a prescription is significant when levels of education are entered as a covariate. Since levels of awareness of dangers decreases as levels of education decreases, then processing a doctor's prescription is influenced by awareness of dangers as a result of levels of education.

More private hospitals are nearer to the respondents than government hospitals. When hospital type is entered as a covariate, then nearness to hospital which was initially not significant became significant. This shows that processing a doctor's prescription is influenced by nearness to hospital as a result of the hospital type near the respondent.

Time to reach hospital was not significant in determining if a respondent had a doctors' prescription but when place of residence was entered as a covariate, then time taken to reach hospital became significant in determining if a respondent would have a doctors' prescription. This also suggests that the relationship between time taken to reach hospital and possessing a doctor's prescription is merely an artifact of the underlying

relationship between nearness to hospital, place of residence to having a doctor's prescription.

CHAPTER FIVE

5.0 CONCLUSION AND RECOMMENDATION

5.1 Conclusion

This research project has contributed to the understanding of the diverse representations that are held by patients who buy drugs at community pharmacies without a doctors' prescription. It also provided some insights on how drug dispensation might be evaluated from the patient perspective.

Patients who ever got sick and were treated, they tend to associate their previous similar symptoms with the current symptoms and thus they find no need of getting a medical doctors' prescription in order to buy drugs. This is well shown by table Tables 4.0.30 and 4.0.31.

The cost of accessing health care does determine the choice of OTC drugs. This meant that 199 out of 208 respondents preferred to buy drugs without a doctor's prescription in order to avoid extra expenses like consultation fee, laboratory fee, registration (card fee) among others.

More private hospitals and clinics are located near the people than the government hospitals. These private hospitals/ clinics are expensive which makes people fear the cost of getting prescription from the doctor.

We also found that there is no relationship between awareness of the dangers of buying drugs over the counter without a medical doctor's prescription. This indicates that People are not aware of the dangers of buying drugs over the counter without a medical doctor's prescription.

Possessing a doctor's prescription while purchasing OTC drugs is not determined by the time a patient takes to get services from a medical doctor in a hospital. According to table 4.0.24, 77 respondents out of 114 bought OTC drugs without a prescription despite living in places where they could have taken less than 30 minutes to hospital/ clinic. Equally 74 respondents out of 108 lived in places where they could have taken less than 1 hr yet they decided to buy OTC drugs without a medical doctor's prescription.

Chemists are located nearer to the people than the hospitals and clinics across the district and thus more people live close to the chemists as compared to the hospitals. This makes the people to prefer to buy OTC drugs without necessary going to get the doctors' prescription.

Income of the respondent influences the decision of buying drugs with a medical doctors' prescription or to buy the OTC drugs without a prescription. Higher income earners tend to seek a doctors consultation as compared to low income earners who buy OTC drugs without a medical doctors' prescription.

Ages of the respondents influences the decision to buy OTC drugs without a medical doctor's prescription though experience. Thus effect of one's education level and place of residence is confounded in the previous table 4.1.1 as they influence time taken to hospital and ones experience on various disease and their diagnosis.

More men than women buy OTC drugs without a medical doctors' prescription. Men don't like admitting getting sick since they take it as an element of defeat. Moreover men look down upon female doctors in hospital and more or less they don't like the questions asked in hospital and so they may opt to buy drugs without visiting a hospital for a prescription. Thus the gender of the respondents determined if one had a prescription or not when buying OTC drugs.

The source of information regarding where the respondents were suffering from determined if they had a prescription when buying the OTC drugs or not. More people preferred to get their diagnosis from the chemist than in the hospitals.

Prescription is the instruction on the medicine a patient should take for a certain illness. The source of this information was highly significant in determining in the respondent had a medical doctors prescription when buying the OTC drugs.

5.2 Recommendation

- The ministry of health and ministry of public health should increase the number of health facilities such as clinics and dispensaries to all areas in the district. This will reduce the time taken when accessing the medical care in the district.
- More awareness should be made to sensitize people on the dangers of buying OTC drugs without a medical doctors' prescription.
- The government should come up with measures to ensure that the drug sellers are qualified enough to dispense the OTC drugs.
- The expenses involved in getting a medical doctors prescription such as registration fee, consultation fee among others should be abolished by the government though the ministry of health and public health to make it more affordable.

5.3 Areas for further research

Shops across the country sell pain killers, fever tablets, anti malaria tablets among others. Many of the sellers are business minded as opposed to offering medical care. This drugs can easily be abused through wrong

diagnosis, wrong prescription as well as creating resistance to the diseases they are meant to treatment. A research should be made to recommend how these drugs can be dispensed.

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