IDENTIFICATION OF THE RISK FACTORS AND MANAGEMENT OF ASTHMA AMONG CHILDREN IN NAIVASHA, KENYA

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A dissertation submitted in partial fulfilment of the requirements for the award of the degree of Master of Pharmacy in Clinical Pharmacy, School of Pharmacy, University of Nairobi.

August 2014

DECLARATION

I hereby declare that this research dissertation is my original work and has not been presented to any other academic institution for evaluation for research and examination to the best of my knowledge.

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DEDICATION

This dissertation is dedicated to my mother, a strong and gentle soul who was an inspiration and taught me to trust in God and believe in hard work.

I also dedicate this work to my dad for the support and encouragement to believe in myself.

Last but not least, this dissertation is above all in debt to God the Almighty for the gift of life and the strength to face each day.

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ABBREVIATIONS AND ACRONYMS

ACQ Asthma Control Questionnaire

COPD Chronic Obstructive Pulmonary Disease

DLTLD Division of Leprosy, Tuberculosis & Lung Diseases

EIB Exercise induced Bronchospasm

EPR Expert Panel Report

ERC Ethics and Research Committee

FEV_1 Forced Expiratory Volume in one second

FVC Forced Vital capacity

GINA Global Initiative for Asthma

ICS Inhaled corticosteroids

ISAAC International Study of Asthma and Allergies in Childhood

KAPTLD Kenya Association for the Prevention of Tuberculosis and Lung Disease

LABA Long Acting ß-agonist

NHLBI National Lung Heart & Blood institute

PEF Peak Expiratory Flow

PI Principal Investigator

PMDI Pressurized Metered Dose Inhaler

PRIME-K Partnership for Innovative Medical Education in Kenya (PRIME-K)

SABA Short Acting ß-agonist

UON University of Nairobi

USA United States of America

WHO World Health Organization

OPERATIONAL DEFINITION OF TERMS

Adherence: Is the extent to which a person's behaviour while taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider

Co-morbidities: Is a concomitant though unrelated disease of pathological process

Non adherence: Refers to minimal or no adherence (in this context) to prescribed medication

Asthma control patients should experience none to minimal attacks (including at night), have no limitations on their activities (including exercise), have no (or minimal) requirement for rescue medications, have near normal lung function and experience only very infrequent exacerbations

Current clinical control: is the frequency and intensity of symptoms and functional limitations that a patient experiences or has recently experienced as a consequence of asthma and includes measures of day and night symptoms, use of reliever therapy, activity limitations, and lung function. The period for which current clinical control should be assessed is proposed to be the previous 2 to 4 weeks for adults and at least 4 weeks for children. The number of asthma exacerbations requiring oral systemic corticosteroids (for more than 3 days) in the previous year should also be considered in evaluating overall asthma control.

Exacerbations (commonly referred asthma attacks or acute asthma) are episodes of progressive increase in shortness of breath, cough, wheezing, chest tightness, or a combination of these symptoms.

Hypertrophy: Increase in individual muscle cell size.

Hyperplasia: Increase in cell number.

Caregiver: Either the biological mother, father, stepmother or guardians who have stayed with the child for over 3 months.

Exposure: defined as either child or caregiver working in a flower farm, living or attending school 500m within a flower farm.

'**Near' Flower Farm** Residing within a 500m radius of a flower farm.

Dissemination plan; - The dissemination plan (which is a part of the overall project plan) explains how the project will share outcomes with stakeholders, relevant institutions and organisations, and how it will contribute to the overall dissemination strategy for the programme.

Pesticide; - A substance used for destroying insects or other organisms harmful to cultivated plants and animals.

ABSTRACT

Background: In Kenya, asthma affects 10% of the population. Major factors contributing to asthma morbidity and mortality are environmental exposures to risk factors, under diagnosis and under treatment. Most asthma exacerbations can be prevented if management is comprehensive. Poorly managed asthma leads to emergency treatment and hospitalization, which are much more costly for patients than effectively managed treatment.

Study objective: The study's objective was to evaluate the risk factors and management of asthma among children aged 5-12 years in Naivasha District.

Study Design: The study was a hospital-based cross-sectional study.

Study Population: The study population was composed of 150 Children aged 5-12years diagnosed with asthma in Naivasha District.

Methodology: Purposeful sampling of children diagnosed with asthma**,** aged 5-12yrs old attending Naivasha District Hospital, Karagita Dispensary and Finlay Hospitals was done to enroll 150 children into the study. Questionnaires were administered to caregivers of children diagnosed with asthma. In addition, the prescriptions were examined to check for clinician's drug prescribing patterns. Data was analyzed using stata version 12 and the results summarized in tables. Inferential and descriptive statistics was derived by using P values and confidence intervals.

Results: Factors that were found to be significantly associated with asthma control were; duration of stay in or near a flower farm, presence of a smoker in the family and presence of household pet. Conditional logistic regression models were fitted to estimate odds ratio and 95% confidence intervals (CI). Uncontrolled asthma was associated with presence of a smoker in the household(OR= 0.46; 95% CI, 0.095-22.629), presence of household pets(OR= 4.36; 95% CI, 1.182-16.057) and duration of stay near a pesticide treated farm(OR=0.72; 95% CI, 0.0538-0.975).There was no significant relationship between the child's asthma control and age of child, sex of child, distance of school from flower, guardian's level of education, guardian's income, and guardian's occupation as a flower farm worker, child's age of diagnosis and use of indoor pesticides. In addition, asthma management was not in line with the national guidelines resulting in suboptimal therapy.

Conclusion: In conclusion, environmental pollutants are risk factors to asthma control. The factors that had a strong association to asthma control were environmental tobacco smoke (p=0.008), duration of stay near a pesticide treated flower farm (p=0.022) and presence of

household pets (P=0.009). Under utilization of the national asthma guidelines also contributed to poor asthma treatment outcomes.

Recommendations: This study was a cross sectional. We therefore recommend that a case control study be carried out using these study findings as a baseline to determine the strength of association between the risk factors and asthma control. .

CHAPTER ONE: INTRODUCTION

1.1 Background:

An estimated 300 million individuals are affected by asthma globally. WHO estimates that 15 million Disability Adjusted Life Years (DALYs) are lost and over 180 000 asthma related deaths are reported worldwide. It is estimated that 80% of asthma deaths occur in low and middle income countries [(1)]. It is projected that by 2025 an additional 100 million persons will have asthma [(2)]. WHO estimates that asthma accounts for about 1 in every 250 deaths in the world.

Asthma prevalence data in Africa are limited to the ISAAC studies in selected countries. The prevalence was as follows: Ethiopia 9.1%, Nigeria 13.0%, and South Africa 20.3%, Algeria 8.7%, Morocco 10.4%, and Tunisia 11.9% [(3, 4)]. About 10% of the Kenyan population has asthma [(5, 6)].The prevalence of asthma in Nairobi was found to be 17.1% while the prevalence in Eldoret was 10.4%. This could be due to the effects of increased urbanization and industrialization.

Asthma is a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role. The chronic inflammation causes an associated increase in airway hyper-responsiveness that leads to recurrent episodes of wheezing, breathlessness, chest tightness and coughing, particularly at night or in the early morning. These episodes are usually as a result of widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment [(7)]. The symptoms include wheezing, chest tightness, breathlessness and sputum production.

The risk factors of this disease include genetic predisposition, infectious-respiratory infection, allergens environment, exercise, drugs and preservatives and occupational stimuli [(8, 9)].

The Pathophysiology of asthma is characterized by bronchial hyper responsiveness in response to physical, chemical and pharmacologic stimuli. Histological changes in the lining of the airways manifests as hypertrophy and hyperplasia of the airway smooth muscle, increased airway wall thickness with an exudate inflammatory reaction, epithelial desquamation and edema and mucus gland hypertrophy and hyper secretion. Some of the cells involved in airway inflammation include mast cells, eosinophils, airway epithelial cells,

macrophages and activated T-Lymphocytes. These cell types can contribute mediators and cytokines to initiate and amplify both acute inflammation and the long-term pathologic changes. The mediators released produce an intense, immediate inflammatory reaction involving bronchoconstriction, vascular congestion, edema formation, increased mucus production, and impaired mucociliary transport [7, 10].

The pathophysiologic hallmark of asthma is a reduction in airway diameter brought about by contraction of smooth muscle, vascular congestion, edema of the bronchial wall, and thick, tenacious secretions. The net result is an increase in airway resistance, a decrease in forced expiratory volumes and flow rates, hyperinflation of the lungs and thorax, increased work of breathing, alterations in respiratory muscle function, changes in elastic recoil, abnormal distribution of both ventilation and pulmonary blood flow with mismatched ratios, and altered arterial blood gas concentrations. Virtually all aspects of pulmonary function are compromised during an acute attack [10].

Diagnosis involves taking the patient's clinical history, obtaining lung function test (FVC, FEV1 and PEF) and measurement of airway hyperresponsiveness using small doses of an inhaled bronchoconstrictor. Diagnosis of asthma in children < 5years may be difficult since lung function testing is difficult in young children. The diagnosis therefore relies on clinical suspicion, physical examination and a trial treatment [7]. Management involves patient education and Pharmacotherapy.

Naivasha town is the home of Kenya's largest horticultural flower farms, contributing 80% of the Kenya's horticultural production. These flower farms are concentrated in the Lake Naivasha basin. Chemicals are extensively used in these farms to control pests and diseases. Most of the pesticides used in these farms are classified as WHO class I and II, which are termed extremely hazardous and highly hazardous respectively. These pesticides are highly persistent and accumulate in the environment and therefore present potential hazards to public [11].

1.2 Problem Statement

WHO estimates that asthma accounts for about 1 in every 250 deaths in the world, many of which are preventable. The deaths are mostly attributed to long term sub optimal therapy and delay in obtaining help in acute attacks [2]. Studies have shown that damage of the airway

epithelium as a result of deleterious effects of uncontrolled asthma, predisposes children to respiratory tract infections such as pneumonia [11, 13].

About 4 million people in Kenya have asthma. From the Kenyan ISAAC studies, the prevalence of asthma in children ranges from 1-18%. The prevalence is high in the urban areas than the rural areas, due to increased urbanization and industrialization. In Kenya it is estimated that more than 1.3 million children are forced to stay out of school due to poor diagnosis and management of asthma, this was declared by KAPTLD during the 'Help Me Breath' campaign launched in 2013 [14].

There is increasing evidence that environmental factors such as pollutants contribute to development and exacerbation of asthma. Naivasha flower farms introduce persistent pesticides into the environment, which are believed to promote development of asthma or exacerbate already existing asthma [15]. These pesticide treatments can result in deposition of pesticides beyond the application site resulting in human exposure. Household proximity to treated farms may increase children's exposure if pesticides drift onto residential property or other areas in which children are active [16]. However, this relationship has not been studied extensively in Kenya.

The Kenya national asthma guidelines were developed to provide clinicians with a 'road map' to guide the care of individual patients with asthma in Kenya. The asthma guidelines were developed to increase the awareness of asthma among health workers and to improve asthma management. Studies have shown that under utilization of these guidelines by clinicians have resulted in poor asthma treatment outcomes [17].

1.3. Purpose of Study

The purpose of this study was to check the possible risk factors of asthma and whether chronic pesticide exposure from the Flower farms in Naivasha has an effect on asthma control in exposed children in response to treatment. This study also sought to find out if management of asthma is in line with the national guidelines, the knowledge of care giver about asthma, accessibility to prescribed medication and adherence to relevant prescribed treatment. This will help to inform policy on management of asthma where pesticide exposure to pesticide and other environmental agents is suspected. It is also expected to

assess and promote Kenya national asthma management guideline utilization in relation to levels of asthma control.

1.4. Research Questions

1. Is there a difference in asthma control between children who reside in and around the flower farms and those who do not?
2. Which drugs are used to treat asthma in Naivasha Sub County?
3. What is the level of knowledge of the care givers on asthma management?

1.5. Objectives

1.5.1. Main objective

It was to evaluate the risk factors and management of asthma among children in Naivasha Sub County.

1.5.2. Specific objectives

1. To compare the level of asthma control between children residing in and around the flower farms and those who do not.
2. To identify the prescription pattern in the management of childhood asthma in Naivasha Sub County.
3. To evaluate the level of knowledge among caregivers on the management of childhood asthma.

1.6. Significance and anticipated output

The rapid increase in the prevalence of asthma observed in many countries is due to urbanization and industrialization. Pesticides exposure originates from a variety of sources, including residues in food and water; applications to public spaces such as home, garden, and lawn use; and occupational exposures. Given the widespread use of pesticides and the fact that they adversely affect human health, there is need for increased surveillance of pesticides poisoning and exposure monitoring. There is a fair amount of evidence that specific components of both outdoor and indoor air pollution cause exacerbation of existing asthma.

Pesticides have been considered as a possible etiologic factor in the etiology of asthma. [18]Findings from this study if integrated into regulatory & public policy processes may minimize the health impacts of pesticides. The beneficiaries of these findings will include the health policy formulators, the hospitals involved, the patients and the local community.

1.7. Limitation

Caregiver's report may have grossly exaggerate the extent of their children's adherence and allergen exposure possibly out of the desire to give a socially acceptable response. This may give rise to information bias.

1.8.Conceptual/TheoreticalFramework

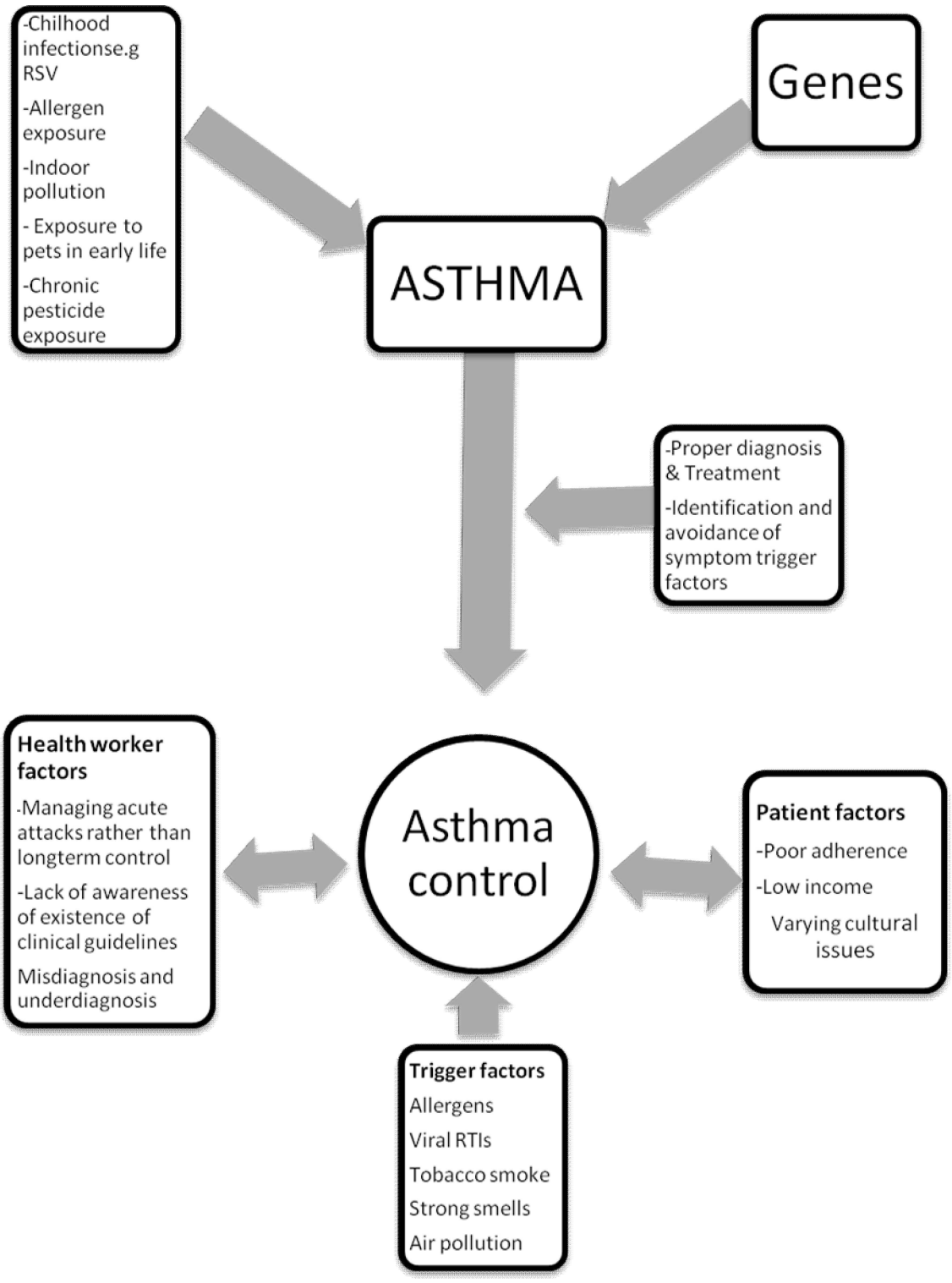

Figure 1

There are asthma risk factors that increase the risk of developing asthma and there are those that exacerbate already existing asthma. Those that predispose an individual to develop Asthma include; genes, atopy, allergen exposure, indoor pollution, occupational exposure etc. While the trigger factors for asthma include; allergens, tobacco smoke, strong smells, air pollution, emotional reactions etc. Poor Asthma management, exposure to trigger factors and patient factors like poor adherence interfere with asthma control. Asthma control in this case is the dependent variable. The independent variables such as chronic pesticide exposure, patient education, caregivers' knowledge on asthma management, adherence, exposure to risk factors (pollutants, stress, pollens, dust) will determine the extent of asthma control. (Figure 1)

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

2.2 Risk factors of asthma in children in Naivasha District.

There are two categories of risk factors: those that increase the risk of developing asthma and those that increase the risk of an asthmatic attack or exacerbation in persons who have developed asthma [5].Studies have indicated that both genetic and non genetic factors contribute to asthma [19].

A cohort study carried out in London revealed that the prevalence of asthma in first degree relatives of asthmatic children was significantly higher than relatives of control children. These findings pointed out that asthma is hereditary [20].

A study carried out in Kenya showed a strong association between asthma and home environment factors such as dust mites, cockroaches, insecticides, dampness, smoking and pets [8].

A cross sectional study performed on children in Lebanese public schools indicated an association between exposure to pesticides and chronic respiratory symptoms that included chronic wheeze and chronic phlegm [21].

A 6 year prospective study on pre-school children with a family history of atopy showed a strong association between exposure to moulds in damp environments and development of asthma by age 7 [22].

A study carried out in England, showed an association between environmental tobacco exposure and asthma exacerbation in children 8 months to 13 years. Study findings revealed high levels of cotinine in the urine of children who frequently experienced asthma exacerbations [23]. This was similarly supported by another study carried out in London that concluded that odds of wheezing were significantly increased in infants exposed to maternal smoking during pregnancy [24].

A study was carried out by university of Manchester study to explore the modifiable risk factors of asthma exacerbations in children aged 3-17 years. The study findings strongly

linked virus infections and allergen exposure like pets and dust to acute asthma exacerbation and resultant hospitalization [25].

Asthma occurs predominantly in boys in childhood with a male to female ratio of 2:1 until puberty, when the male to female ratio becomes 1:1.A study carried out in Al majmaah Health province sought to explore the socioclinic profile of children with asthma. The findings revealed that male children represented 69% of the sample. This was similarly supported by an ISSAC study on asthma prevalence carried out in Brazil that showed predominance of asthma in males [26, 27].

A case control study carried out in southern California demonstrated an association between environmental exposures and childhood asthma. Children exposed to herbicides and pesticides in the 1st year of life were significantly at a higher risk of asthma compared to the non exposed [9].

Avoidance of asthma triggers or allergens in the prenatal phase and in early life reduces the chance of developing asthma. This was illustrated in a case control study in Canada on infants genetically predisposed to asthma [28].

A Study carried out in preschool children indicated that Rhinovirus (RV) illness at infancy stage is a significant risk factor for the development of wheezing in children. In another study, RV was associated with wheezing in children [29, 30].

Prior childhood pneumonia due to Respiratory Syncytial Virus (RSV), mycoplasma pneumonia and Chlamydia species was found in more than 50% of a study sample of children aged 7-9 years who later had asthma [32].

A prospective study of children aged 2–15 years hospitalized for severe asthma. The findings revealed that *M. pneumoniae* may play a role in the onset of asthma in predisposed children and could be a trigger for recurrent wheezing. Similarly, studies have shown that damage to the airway epithelium as result of asthma predisposes children to respiratory tract infections [31, 33].

2.3 Prescription patterns in management of childhood asthma.

The key goals of asthma management as outline by GINA guidelines include: Control chronic and nocturnal symptoms, maintain normal activity; including exercise, prevent acute episodes of asthma, minimize emergency department visits & hospitalization, ensure minimal need for reliever medications, maintain near normal pulmonary function, avoid adverse effects of asthma medication and prevent asthma mortality [5, 34].

According to the 'Kenya national asthma guidelines', drugs used to treat asthma are classified into 2 groups: Relievers (bronchodilators) and controllers (anti-inflammatory drugs).The relievers are used on an 'as-needed' basis to promptly reverse broncho-constriction and relieve symptoms. However, controllers which have anti-inflammatory effects are used on a daily basis to keep asthma under control as classified in table 1. These drugs are used on a long term basis by majority of asthma patients. The ideal route of administration of most of these medicines is inhalation since the drug is directly delivered in the airways, allowing for the use of small doses (micrograms), ensuring high local concentrations and reduced adverse effects[5].

Inhaled corticosteroids (ICS) form the 'backbone' of asthma control. All patients except those with mild and intermittent symptoms should be on inhaled corticosteroids [35].

Use and adherence to ICS promotes asthma control. This was evident in a study that monitored inhaled corticosteroid (ICS) usage in asthmatic children. From the findings, optimal Asthma control was linked to adherence to ICS [36]. In another study, budesonide treatment was associated with significant reduction in hospital admissions as a result of severe asthma and improved lung function [36].

In a study was carried in New Zealand to compare regular versus on-demand inhaled bronchodilator therapy, regular inhalation of beta sympathomimetic agent was associated with deterioration of asthma control [37].

Another study was carried out to compare the effectiveness of a β2 agonist; terbutaline and ICS; budesonide in managing newly diagnosed asthma. The findings revealed that budesonide was more superior to terbutaline [38].

Asthma management guidelines provide recommendations for the optimal control of asthma. Adherence to asthma guidelines can improve compliance and patient care which in overall results in improved patient outcomes as highlighted in table 1 [39,40].

A cohort study carried out in Connecticut demonstrated that increased provider adherence to asthma guidelines resulted in a decrease in overall hospitalization rates, asthma emergency department visits and outpatient visits [41].

Studies have also revealed that adherence to guideline recommendation to use ICS was associated with a decrease in the relative risk of asthma related hospitalization in developing countries [42].

Oral salbutamol is commonly used in Kenya as it is cheap and widely available. It has however been associated with frequent and severe side effects such as palpitations and tremors [5].

Table 1: GINA Asthma Management Plan [1, 5].

Development of a close partnership between the patient and the health care provider
Assessment of asthma severity, institution of appropriate treatment based on asthma severity and monitoring of response to treatment
Identification and avoidance of triggers of asthma symptoms.
Management of asthma exacerbations
Provide regular follow-up care

2.4 Effect of pesticides on the level of asthma control

Proximity to pesticide treated farms expose children to these chemicals through drift of the pesticides from the farms, contaminated breast milk from farm worker mothers, playing in the fields, pesticide tracking into the residents by farm working parents or other household members and incidental ingestion through their hand to mouth behaviour among others. This may continually exacerbate asthma and result in poor asthma control [43].

Epidemiological studies carried out in the US indicate that children of farmworkers are at elevated risk for pesticide related diseases including asthma.One particular study showed that children living with parents who work agricultural pesticides or who live in proximity to treated farms had higher exposure than other children living in the same community [44].

Another study in Washington study brought a strong association between take-home exposure pathway and pesticide contamination in the homes of farm workers, this in return exposed their children high levels of pesticides [45].

Children are more susceptible to the adverse effects of pesticides and may sustain higher exposures than adults in the same environment. Children living in agricultural areas may therefore be exposed to higher pesticide levels [23, 28].

Pesticides have been known to cause inhibition of cholinesterase and thus can arouse manifestations of bronchospasm through increased cholinergic activity. At high concentrations and doses, some pesticides may act as irritants to the airway. These two mechanisms present an increased susceptibility to asthma. A study by Hoppin and colleagues indicated that wheezing was more likely to be reported with exposure to pesticides in non asthmatics farm workers as compared to asthmatics. There was an association between pesticide exposure and asthma development [23, 24].

2.5 Knowledge among caregivers on the management of childhood asthma

Patient education is essential to prevent unnecessary concerns about asthma and asthma medicines; this improves adherence and subsequently outcome. Comprehensive patient education equips the patient and the caregiver with knowledge on curative and preventive measures. According to WHO, comprehensive patient education and increased dialogue between patient and with clinician can prevent approximately 25,000 childhood deaths due to asthma each year. Patients also need to learn how to manage their asthma: how and when to take their medicines and when to seek help from health care facilities [1].

A study was carried out in London to educate caregivers of asthmatic children on environmental control measures. One year later, there was a significant reduction in asthma exacerbation in children in the intervention group [46].

A systematic review and meta analysis of 32 studies on effect of educational interventions on asthma outcomes showed an improvement in patient outcomes quality of life and asthma control [48].

A study on group education program on asthma targeting children 9-13 years and caregivers was carried out in Uruguay, Spain and Cuba which revealed a strong association between asthma control and knowledge of child and caregiver on asthma [47,49].

A good relationship between the patient and the clinician promotes effective communication, which in turn enhances adherence to prescribed treatment. A clinician making direct eye contact, showing genuine interest in what the patient says, explaining treatment thoroughly, acknowledging treatment adherence and problem solving, and expressing willingness to modify the treatment plan in accordance with the patient's concerns are ways to also promote adherence as outlined in table 2.This gives the patient a sense of control within the relationship and with the treatment plan [34].

TABLE 2: Strategies to improve adherence [5]

Educate	Provide sufficient information about disease and its treatment; involve all members of the treatment team in educating patients
Communicate:	Discuss treatment in detail, listen to the patient, provide written instructions, build trust
Negotiate	Establish treatment goals together with the patient adapt and simplify the dosing regimen to the patient's characteristics.
Streamline	Eliminate barriers that prevent patient's contact with the care giver, increase frequency and availability of appointments.
Individualize	Be resourceful with more difficult patients, increase telephone contacts, design individualized education and action plans, involve other family members, refer dysfunctional patients for psychological help

CHAPTER THREE: METHODOLOGY

3.1 Introduction

This section describes the study design, sampling techniques, data collection and analysis. The inclusion and exclusion criteria as well as the ethical considerations are clearly outlined.

3.2 Study Design

A cross section study design was employed. The study aimed to collect data from respondents on possible risk factors of asthma, levels of asthma control in relation to pesticide exposure and knowledge on asthma management. This involved collection of primary data through interviews of the consenting participants in the study after approval from the KNH/UON ERC and permission from the concerned hospital administrators. This approach involved single point contact between the researcher or the assistants and the study subjects.

3.3 Study Area

The study was carried out in Naivasha District located in Nakuru County in the Central part of Rift Valley. It is located, about 100km Northwest of Nairobi. Naivasha District has a total of 50 health facilities, 11 of which are GOK owned while remaining are Faith based and privately owned. Naivasha District was picked because it is home to some of the biggest flower farms in Kenya and pesticides are therefore extensively used. These flower farms use pesticides which pollute the environment and may promote development of asthma or exacerbate asthma.

This study was carried out in Naivasha District Hospital, and 2 other health facilities in Naivasha district. The proposed health facilities include: Karagita Dispensary and Finlay medical centre. These facilities were located within the vicinity of flower farms .Multiple health facilities were include in this study in order to cover a wide area and therefore collect data that will give more comprehensive information on the study of interest.

3.4 Target Population

Diagnosis of asthma is difficult in children under 5 years since lung function testing is difficult. Therefore, children aged 5 - 12 years with an asthma diagnosis were therefore sampled. The Care givers of children aged 5-12years with an asthma diagnosis were

interviewed. The caregivers in this case were either the biological mother, father, stepmother or guardians who had stayed with the child for over 3 months.

3.4.1 Inclusion criteria

- Consenting care givers of children aged 5-12 years old with a diagnosis of asthma.
- Children who assented to participating in the study.

3.4.2 Exclusion criteria

These included;

- Asthmatic children below 5 years old or above 12 years old, since diagnosis of asthma in children under 5 years is difficult
- Children with URTI & LRTI, since the clinical manifestations may resemble asthma.
- Children of non- consenting care givers.

3.5 SAMPLE SIZE DETERMINATION

According to the national guidelines the overall prevalence of asthma in Kenya is 10 %[5].

By use of Fischer's formula [63], sample size will be calculated

$$n = \frac{z^2 \text{ x } P(1-P)}{d^2}$$

Where:

n is the sample size

Z is 1.96 which is the normal deviate corresponding to a confidence interval of 95%

P is 0.1 which is the prevalence of asthma in Kenya

d is 5% degree of precision/accuracy.

$$n = \frac{1.96^2 \text{ x } 0.1(1-0.1)}{0.05^2}$$

n = 138.30

To improve validity and take care of any loss of data, the sample size was increased to 150 children.

3.6 Sampling Method

The patients were selected through purposeful sampling. Asthmatic children aged 5-12 years who met the inclusion criteria were selected and their caregivers interviewed. However, consent from the caregivers was a requirement. Older children who demonstrated some understanding of the research were given the opportunity to assent; they however were not required to sign a consent form. The caregivers in this case were the biological mother, father, stepmother or guardian for over three months. In addition, the children's prescriptions were analyzed to assess the prescription patterns. Any child or guardian who declined to assent or consent respectively were thanked their decision upheld.

3.7 Data Collection

Data was collected by the Principal Investigator (PI) and research assistants using a structured questionnaire. The questionnaire collected information on demographics, family history of asthma, household environment (pets, wood smoke, and tobacco smoke), status of pesticide exposure, level of asthma control, adherence to medication and knowledge on asthma by care givers. A seven item validated Asthma Control Questionnaire (ACQ) as used to determine asthma control [5, 49]. A validated Asthma knowledge questionnaire was administered to caregiver test knowledge on symptoms, triggers and interventions [50].The researcher also checked the prescriptions for clinician prescribing patterns and also enquired from the caregiver about the drugs the child uses for the treatment of their asthma. The dose and frequency of using the drugs was assessed. Validity and reliability was enhanced by engaging multiple methods such as observations, interviews and recording.

3.7.1 Validity

Internal validity was ensured by pre-testing the questionnaire before beginning the actual data collection to ensure that the questions were well understood, training of research assistants before data collection, proper selection of the study participants based on the inclusion criteria.

External validity was ensured by use of appropriate sample size representative of the prevalence of asthma in the country.

3.7.2 Reliability

Pre-testing of the questionnaires was carried out to pre-identify potential problems with the research, to ensure that the questions are well understood and to determine the response of the participants to the questionnaire. The pre-testing was done on ten respondents before going to the field for data collection, and the necessary adjustments to the questionnaire were made.

3.8 Ethical Considerations:

Ethical approval was sought from the UoN/KNH Ethics Committee. Subsequently permission to carry out study in Naivasha was sought from the administrators of the respective hospitals. Informed consent was obtained from all the study participants. The data collected was treated with confidence and no names were written on the questionnaire in order to guarantee the confidentiality of the participants. Coding of the questionnaire was done.

Participants were required to understand and sign a consent form summarizing the discussion prior to admission to the study (**Appendix 3**). A copy of the signed informed consent statement was to participants while a second copy was retained by the investigator.

3.8.1 Participant recruitment

This was done through on-site screening at the outpatient paediatric clinic and enrolment done by health care workers and the investigators at paediatric clinic at the respective hospitals. The informed consent was administered to the participants by the research investigators.

3.8.2 Compensation

Participants were not compensated on account of their participation in the study

3.9 Data Management

3.9.1 Data processing and analysis

Filled questionnaires were accessible only to the investigator and were kept safely and later analyzed. The collected data, it was cleaned and then entered into an excel sheet and thereafter analyzed using STATA version 12. Descriptive statistics were used to summarize the socio-demographic details of the study respondents. The categorical predictor variables such as gender, exposure to pesticides, allergens, pets etc were summarized using frequencies and percentages whereas the continuous predictor variables such as age were summarized using the mean and standard deviation for data that normally distributed or using the median and interquartile range for data that was skewed.

3.9.2 Qualitative study

Content analysis of the qualitative data was carried out. The interview transcripts were read through and data classified into categories. Once all the data was sorted into categories, it was examined to determine the emerging themes that may arise. Continuous data was categorized and the chi square test was used to determine the association between categorical predictor and outcome variables. A p-value less than 0.05 was considered to be statistically significant.

3.9.3 Data quality control

Before commencement of data collection, the research assistants will be trained on how to ethically conduct the interviews and fill questionnaire. The questionnaire will be pretested to ensure feasibility.

3.9.4 Retention of Research Data and Primary Materials

The paper records were converted to an electronic format and were retained until the research process was over. The primary materials will be kept under lock and key until the dissertation was handed over to the examiners.

CHAPTER FOUR: RESULTS

4.1. Introduction

This chapter gives an account of the results according to the study objectives. They include; socio-demographic characteristics of children and their guardians, risk factors of asthma, status of pesticide exposure and the level of asthma control as well as caregiver's knowledge of asthma. It also compares the association between the level of asthma control and various predictor variables. A total of 150 structured questionnaires were administered in tandem with the calculated sample size. There were no rejected or incompletely filled questionnaires. The analysis was tested at a level of significance of 0.05.

4.2 Socio demographic characteristics

4.2.1 Socio demographic characteristics of Asthmatic children

The mean age of the children was 8.7 years with a standard deviation of 2.0 years. Of the 150 children, males represented 56.7% (n=85) (Table 3)

Table 3: The socio-demographic characteristics of the Asthmatic children

Factor	Categories	Frequency	Percent (%)
Sex	Male	85	56.67
	Female	65	43.33
School attendance	Yes	146	97.33
	No	4	2.67
Distance between school and flower farm	<500m	75	50.00
	>500m	75	50.00
Previous school attendance near a flower farm?	Yes	14	9.33
	No	58	38.67
	N/A	78	52.00

Half of the children (n=75) attended schools that were near the flower farms while the other half attended schools that were far from the flower farms. Of the children who reported not attending school near the flower farms, 14(9.33%) had previous attended a school near a flower farm, while the remaining children had never attended a school near a flower farm.

4.2.2 Socio demographic characteristics of guardians

Majority of the children were accompanied by their mother while 18% of the guardians were fathers. Majority of the parents were flower farm workers, with 83% being fathers and 92% being mothers. Fifty three percent of the flower farm workers had worked for more than 5 years. This represents potential risk of chronic exposure. The other parents occupations included businessmen (8.7%), motorcycle riders (7.3%) and housewives (13.3%).Among the guardians that were not flower farm workers, 74.7% had previously worked in a flower farm indicating a previous exposure.

Majority of the guardians had some considerable level of formal education ranging from primary education (34.7%) to secondary education (53.3%), with the least number of guardians having attained tertiary education .Only two guardians had no formal education. (Appendix 7)

4.3 Risk factors for Asthma

Majority (61.33%) of the children, were first diagnosed with asthma at age between 6 and 12 years. Only 22.67% of these children had a family history of asthma. Passive smoking within the house was present among 21.33% of the children and their asthma symptoms worsened on exposure to tobacco smoke. 74.67% of the guardians worked in a flower farm and approximately a similar percentage brought home farm equipment and clothes. This was regarded as a form of take-home pesticide exposure risk to the children. Worth noting is that 70% of the asthmatic children's households had proximity to a flower farm. Families that lived near the flower farms were aware of pesticide use by the flower farms and they reported that they noted that 64% of the children's asthma worsened during the pesticide spraying period. Residential exposure such as pets, indoors pesticides, indoor pollution (smoke) and indoor pets were differently distributed among the households as outlined in Appendix 8.

4.4 Prescription patterns

During the interview, guardians were required to produce a prescription of the drugs to assess the prescription patterns in relation to asthma drugs. The findings are summarized in Table 4.

Table 4: Prescription patterns

Drug	Prescribed	Frequency	Percentage (%)
Oral salbutamol	Yes	97	64.67
	No	53	35.33
Inhaled salbutamol	Yes	12	8.00
	No	138	92.00
Oral steroid	Yes	10	6.67
	No	140	93.33
Oral Theophylline	Yes	5	3.33
	No	145	96.67

Majority of the children (64.7%) were prescribed oral salbutamol. Contrary to the national guidelines, only 8% of the children were prescribed inhaled salbutamol. Only 6.67% of the children were prescribed steroids as a controller drug as stipulated in the National Asthma guidelines [(5)] Theophyllines (Franol) which are contraindicated in children were prescribed and used by 3.33% of the children.

On analysis of the appropriateness of the drug dosages, Table 5 gives an outline of drugs prescribed and their dosages. The prescriptions were reviewed to determine appropriateness of the dose and frequency. Oral salbutamol was more likely to be given as a higher dose. Inhaled salbutamol, and corticosteroids (Oral and inhaled) were appropriately dosed.

Table 5: Appropriateness of dose of prescribed drugs

Drug	Dose	Frequency	Percentage (%)
Oral salbutamol	Under dose	14	9.33
	Normal dose	23	15.33
	High dose	60	40.00
	N/A	52	34.67
Inhaled salbutamol	Under dose	2	1.33
	Normal dose	62	41.33
	High dose	3	2.00
	N/A	83	55.33
Inhaled steroid	Normal dose	12	8.00
	High dose	1	0.67
	N/A	137	91.33
Oral steroid	Under dose	5	3.33
	Normal dose	5	3.33
	N/A	140	93.33
Theophylline	N/A	145	96.67
	Contra indicated	5	3.33

The prescriptions were reviewed to determine appropriateness of the dose and frequency. Forty percent of oral salbutamol was more given as a higher dose than recommended. Inhaled salbutamol, and corticosteroids (Oral and inhaled) were appropriately dosed in most cases. To assess adherence to prescribed drugs, parents were asked if their children had ever missed and

the reason for missing. Only 6.67 % of the parents reported non adherence and the reasons given were medication stock outs (2%), forgetfulness (2%) and feeling that the child was well (2.67%).This is shown in Table 6.

Table 6: Adherence to prescribed medicines

Factor	**Categories**	**Frequency**	**Percentage (%)**
Ever skipped controller drug	Yes	10	6.67
	No	10	6.67
	N/A	130	86.67
Reasons for missing drug	Drug stock out	3	2
	Forgot	3	2
	Child was well	4	2.67
	N/A	140	93.33

4.5. Caregiver knowledge on asthma

A validated questionnaire on Asthma was administered to caregivers to test knowledge on symptoms, triggers and interventions. The maximum possible score was 10 points. The mean caregiver knowledge score was 8.97 with a standard deviation of 1.5 and a range of 5-10.The knowledge was categorized as high if it was 6 points or more and low if it was 5 points or below. Majority (98%) of the guardians had high knowledge on asthma while only 2% had low knowledge scores as shown in table 7. A larger proportion of their children (74%) had uncontrolled asthma.

Table 7: Caregiver knowledge on asthma

Categories	Frequency	Percentage (%)
High knowledge	147	98
Low knowledge	3	2
Total	150	100

4.6. Level of asthma control

Majority (76%) of the children, had poorly controlled asthma while 24% had well controlled asthma as outlined in Table 8

Table 8: Level of asthma control

Categories	Frequency	Percentage (%)
Asthma not controlled	114	76
Asthma controlled	36	24
Total	150	100

Participants were asked if there was a family member who smoked at home. Chi square analysis revealed that there was a statistically significant association between the level of asthma control and the presence of a smoker in the house (χ^2= 7.0264, p=0.008). Presence of a smoker in the house is associated with frequent asthma attacks hence poorly controlled asthma (Table 9).

Table 9 Association between the level of asthma control and the presence of a smoker in the house

Category	Smoker present	No smoker Present	Total	χ^2= 7.0264 p=0.008
Asthma not controlled	30(20%)	84(56%)	114 (76%)	
Asthma controlled	2(1.3%)	34(22.7%)	36 (24%)	
Total	32 (21.3%)	118(78.7%)	150(100%)	

Most of the guardians resided near a flower farm for more than 5 years (Table 10).There was a statistically significant association between the level of asthma control and the duration of staying in a flower farm (χ^2=13.197, p=0.022).Parents who stayed in farms for long were more likely to have children with poorly controlled asthma than those whose parents had stayed in farms for shorter periods.

Table 10: Asthma control and duration of guardian's stay near flower farm

Category	6 months	1 year	2 years	5 years	>5 years	N/A	Total
Asthma not controlled	2 (1.33%)	4 (2.67%)	16 (10.67%)	20 (13.33%)	41 (27.33%)	31 (20.67%)	114 (76%)
Asthma controlled	3 (2%)	5 (3.33%)	8 (5.33%)	3 (2%)	12 (8%)	5 (3.33%)	36 (24%)
Total	5 (3.33%)	9 (6%)	24 (16%)	23 (15.33%)	53 (35.33%)	36 (24%)	150 (100%)

Participants were asked if they kept pets in the houses. Majority reported that they did not have pets. Chi square analysis revealed that there was a statistically significant association between the level of asthma control and the presence of pets in a household as outline in table 11.

Table 11: Asthma control and the presence of household pets

Category	Pets	No pet	Total	
Asthma not controlled	34 (22.7%)	80(53.3%)	114(76%)	$\chi^2 = 6.801$
Asthma controlled	3(2%)	33(22%)	36(24%)	P=0.009
Total	37(24.7%)	113(75.3%)	150(100%)	

On regression analysis**,** the three predictor variables that were found to be statistically significant included: the presence of a smoker in the household, presence of pets in the household and duration of stay near flower farm.

Conditional logistic regression models were fitted to estimate odds ratio and 95% confidence intervals. This analysis was carried out to determine the effect of the significant predictor variables, taken together, on the outcome variable which is the level of asthma control. The null hypothesis to be tested in the logistic regression model was that; 'there was no effect of the predictor variables, taken together, on the outcome variable'. The outcome of the logistic regression model is outlined in table 12.

Table 12: Associations between asthma control and presence of smoker in household, presence of household pets and duration of stay near a pesticide treated farm.

Predictor Variable	Odds Ratio	95% CI Lower	95% CI Upper	Coefficient	p value
Presence of a Smoker	0.463	0.094	22.629	0.77	0.698
Attacks on exposure to smoke	4.040	0.409	39.896	1.40	0.232
Presence of pets	4.358	1.182	16.057	1.47	0.027
Duration of stay in farm	0.723	0.538	0.975	-0.32	0.032

The p value obtained (p=0.0013) was less than 0.05, the null hypothesis was therefore rejected. In conclusion, the predictor variables when taken together have an effect on the level

of asthma control. The logistic regression model for the four variables taken together is represented using the equation below:

Log odds of asthma control = 1.47 pets + 1.40 presence of smoke attacks – 0.77 smoker in the household – 0.32 duration of stay in the farm – 6.27

4.7 Summary of results

Factors that were found to be significantly associated with asthma control were; duration of stay in or near a flower farm, presence of a smoker in the family and presence of household pet. From these results there is a 4.36 times increase in the odds of asthma being uncontrolled when there are pets present in the household and a 0.72 times increase in the odds of asthma being uncontrolled when the subjects had stayed in the farms for longer periods. When logistic regression is carried out the effect of the other 2 variables disappears. This suggests that when the three variables are taken together, the presence of pets in the household and long duration of stay in the farm are the stronger predictors for asthma control. There was no significant relationship between the child's asthma control and age of child, sex of child, distance of school from flower, guardian's level of education, guardian's income, and guardian's occupation as a flower farm worker, child's age of diagnosis and use of indoor pesticides.

CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1. Introduction

This chapter discusses findings of the study in relationship to other studies. The conclusions and recommendations are also outlined.

5.2 Discussion

Exposure to tobacco smoke, chronic residential proximity to a pesticide treated flower farm and house hold pets were associated with increased asthma exacerbations. The major source of exposure was smoking by parents and other household members. Ninety three percent of children who had smokers in their households had uncontrolled asthma. These results are consistent with an accumulating body of evidence that have indicated that environmental tobacco smoke resulted in diminished pulmonary function and frequent asthma exacerbations [23, 51, 53]. A particular study gave further insight into this association by using urine cotinine levels to measure actual exposure to smoke [23]. This is further supported by a study that found that educational interventions that emphasized reduction in environmental tobacco smoke exposure resulted in a significant reduction in acute exacerbations of asthma and related hospitalizations [52].

Children living with parents in proximity to pesticide treated farmland for prolonged periods of time have poor asthma control asthma compared to those whose parents had stayed near flower farms for shorter periods. This is due to cumulative exposure to pesticides through various pathways including pesticide drift from the nearby flower farms, diet, drinking water and children's hand to mouth behaviour as they play near the flower farms. Research has shown that exposure to pesticides aggravates the airways of asthmatics since they have hyper sensitized lungs. Pesticides can cause respiratory muscle weaknesses, bronchoconstriction, enhanced bronchial secretions, wheezing and general respiratory distress. Children are particularly vulnerable and reactions can occur even at very low concentrations [21, 54, 55]. It has been suggested that children's hand to mouth behaviour, low ratio of skin surface to body mass, reduced ability to detoxify toxic substances and increased sensitivity of cholinergic receptors to pesticides make them more vulnerable to the toxic effects of pesticides especially during their early lives. Additionally since their respiratory system is immature, it is more

vulnerable to the deleterious effects of pesticides [21, 56].This finding is confirmed by studies that have revealed high concentrations of organophosphate metabolites in urine samples of children who lived within 400m of pesticide treated orchard farms. This study also revealed that pesticides residues were found in house dust of those households near pesticide treated orchards. These pesticides reach homes within the vicinity of pesticide treated farmlands through pesticide drift and can travel as far as a distance of 400m [16]. In another study, exposure to pesticides was associated with chronic respiratory symptoms and disease among Lebanese children. In this study, any exposure to pesticides, including residential, paraoccupational and domestic was associated with respiratory disease and chronic respiratory symptoms like chronic wheeze and chronic phlegm [21]. Of note is that this study added the element of time to distance from pesticide treated flower farms. Most families had stayed near flower farms for more than 5 years and a chi square analysis revealed that there was a statistically significant association between the level of asthma control and the duration of staying in a flower farm .We hypothesized that the cumulative effect of small amounts of pesticides exposure over time is responsible for the uncontrolled asthma. Subsequent and prolonged exposure to a stimulus can cause an extreme reaction in a hyper-reactive airway. Studies have shown that pesticides alter the nerve function controlling the smooth muscle lining of the airway, causing the airway to contract and restrain airflow thus leading to an asthma attack. Pesticides can also trigger asthma attacks by directly damaging the cell the line the lungs [56, 57, 58].

Another risk factor assessed in this study was household pets. It was found that there was a statistically significant association between the level of asthma control and presence of household pets. Pets interfere with asthma control because their dander, saliva and urine can cause an allergic reaction. In addition the hair or fur can collect dust, mold and other allergens that can in turn trigger an asthmatic attack. Animal hair is often spread throughout the home via floor and ceiling fan, wind and forced air breathing [59].

Studies have given contradicting findings with regards to pets and asthma. One study revealed that children with no family history of asthma had a reduced risk of wheezing on exposure to a cat, while those with a family history of asthma had an increased risk of wheezing at or after the age of 3 years. The study found no association between wheezing and

exposure to dog or dog allergen. Other studies have found no association between asthma and pet exposure while others found pet ownership protective of asthma [9].

Prescriptions verified that, salbutamol was prescribed in majority of the prescriptions. Oral salbutamol was more prescribed compared to inhaled salbutamol. The preferred route of administration of bronchodilators (Reliever drugs) is the inhaled route. The inhaled route is preferable because it allows small doses to be used and delivers the drug directly to airways thus achieving high concentrations and limiting systemic adverse effects like palpitations and tremors [5]. Oral salbutamol was widely used because it is affordable and widely available than inhaled salbutamol. The national asthma guidelines stipulate that reliever drugs should be used on an 'as-need' basis to quickly reverse broncho-constriction and relieve symptoms. Controller medications should be taken on a daily basis to keep asthma under control through their anti-inflammatory effects. From our findings 3.33% of the children were put on Franol (Theophylline + Ephedrine).This particular combination is contraindicated in children below 12 years. Moreover, according to the national guidelines, theophylline is not the preferred bronchodilator because of its narrow therapeutic window. It is only reserved for patients who fail repeated doses if inhaled β_2 agonists. However, slow release formulations of theophylline should only be added in patients who are not adequately controlled on low dose inhaled corticosteroids [5].Only 6.67% of the children were on corticosteroids as a controller medication. Majority of the clinicians preferred oral corticosteroids to inhaled corticosteroids. According to the national and international guidelines the use of anti-inflammatory medicines is the backbone of asthma treatment, of which inhaled corticosteroids are the most effective ([5, 34, 35].An accumulating body of evidence indicates that use and adherence to inhaled corticosteroids promote asthma control. A study that monitored the usage of inhaled corticosteroids in asthmatic children found that optimal asthma control was linked to adherence to inhaled corticosteroids [36].Another study revealed that budesonide treatment was associated with significant reduction in hospital admission as a result of severe asthma since it improved lung function.

From assessment of the prescriptions choice of drugs and dosages were not in line with the national guidelines. Studies have shown that under utilization of these guidelines by clinicians have resulted in poor asthma treatment outcomes [17]. Oral salbutamol was more

likely to be given as high dose and asthma management guidelines provide recommendations for optimal control of asthma. Adherence to asthma guidelines can improve compliance and patient care resulting in improved patient outcome [39, 40].A cohort study carried out in Connecticut showed that increased provider adherence to asthma guidelines resulted in a decrease in overall hospitalization rates, asthma emergency department visits and frequent outpatient visits [41]. Other studies have also revealed that adherence to guideline recommendations to use inhaled corticosteroids was associated with a decrease in the relative risk of asthma related hospitalization in developing countries [42].

5.3 Conclusion

The study brought out a number of risk factors that interfere with asthma control in Naivasha district. Our results suggest that environmental exposure and lifestyle factors play a crucial role in the etiology of childhood asthma. The factors that had a strong association to asthma control were environmental tobacco smoke, duration of stay near a pesticide treated flower farm and presence of household pets. Children living in proximity to pesticide treated Naivasha flower farms for a long duration of time (more than 5 years) have higher exposures than do other children in the same community. From the study findings, these high exposures to pesticide were associated significantly with poor asthma control.

5.4 Recommendation

5.4.1 Recommendation for practice and policy

- Regular in-service trainings and updates on asthma management should be given to health workers by the ministry of health to streamline their knowledge on asthma.
- Targeted dissemination of the national asthma guidelines should be done to ensure wide access and utilization of the guidelines by all levels of care.
- Asthma education programmes should be offered at the community level by community health workers under community strategy to promote behaviour change.
- Health talks on asthma and its risk factors with emphasis on pesticide exposure should be carried out in the hospitals to create awareness.

- Involvement of community partners composed of farmworkers, healthcare providers, flower farm administrators, representatives of community groups, county health and agricultural departments, in planning, coordinating, and conducting interventions to reduce pesticide exposures to young children residing around the flower farm regions.

5.4.2 Recommendations for research

Further research should be done;-

- To find out whether low level chronic exposure to pesticides is associated with other adverse health effects in children.
- To find out if exposures to pesticides and the flower farm environment in the1st year of life may increase the risk for early-onset persistent asthma.
- To determine whether exposure to pesticides in utero or during the postnatal period is associated with poor neurodevelopment stunted growth and increased prevalence of respiratory symptoms and disease.

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APPENDICES

Appendix 1: Funding Information

This study is part of a wider Partnership for Innovative Medical Education in Kenya- Medical Education (PRIME K) Maternal Newborn and Child Health Linked Research topic; ‘‘**Identification of the risk factors and management of Asthma among children in Naivasha**’’ and was carried out in three health facilities in Naivasha Sub county, Kenya.

PRIME-K is made up of a partnership involving the Universities of Nairobi in Kenya and the Universities of Washington and Maryland Baltimore in the United States of America (USA)

The PRIME-K program aims to provide opportunities for multidisciplinary teams of post graduate students to carry put research that will enhance the clinical and research capacity at the University of Nairobi and thus improve health care delivery in Kenya.

Appendix 2: Ethical Approval Letter

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/143 Link:www.uonbi.ac.ke/activities/KNHUoN 15th May 2014

Dr. Wamalwa M.N. Cecilia
Dept.of Pharmaceutics and Pharmacy Practice
School of Pharmacy
University of Nairobi

Dear Dr. Wamalwa

RESEARCH PROPOSAL: ASSESSMENT OF THE EFFECT OF PESTICIDE EXPOSURE ON MANAGEMENT AND CONTROL OF ASTHMA IN CHILDREN AT NAIVASHA DISTRICT (P61/02/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 15th May 2014 to 14th May 2015.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **www.uonbi.ac.ke/activities/KNHUoN.**

Protect to Discover

Appendix 2: Ethical approval letter (continued)

Yours sincerely

PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Chairperson, KNH/UoN-ERC
The Assistant Director, Health Information, KNH
The Dean, School of Pharmacy, UoN
The Chairman, Dept. of Pharmaceutics and Pharmacy Practice, UoN

Appendix 3: Informed Consent Form

Title of the study:

Evaluation of the Risk factors and management of asthma among children in Naivasha District

Introduction

You are invited to participate in a research conducted by Dr Cecilia Wamalwa, a student at the University of Nairobi, School of Pharmacy. This research is part of the Master of Pharmacy degree. Your participation in this study is voluntary. Please feel free to ask any questions or to seek clarification if you do not understand. If you decide to participate, you will be asked to sign this form and you will be given a copy of the form to keep.

Purpose or objectives of the study

The purpose of this study is to evaluate the risk factors and management of asthma among children in children at Naivasha District**.**The study is for research purposes only and the information collected will be used to help design interventions that will improve asthma management.

Study Procedures

If you decide to participate in the study, you will be interviewed by use of a questionnaire.

By participating in the study, you will provide information that will help us understand the management of asthma in relation to risk factors. This information will help us take necessary actions to improve the Asthma quality of care.

Participant selection

The participants in this study are the care providers who are directly involved in care of asthmatic children aged 5-12 years old. You have been purposively selected to participate in this study because you have an asthmatic child within the mentioned age bracket.

Benefits of participating in the study

All participants regardless of whether they are well informed on asthma or correctly answer the questions will be educated on asthma, the risk factors and management concept. They will also be taken through the various asthma drugs prescribed and frequency of administration, specifically bringing out the difference between the relievers and controller medication.

Results will be published for the benefit of other health practitioners involved in the management of asthma.

Potential risks/ inconvenience of participating in the study

The study will involve interviewing you.There is no direct risk is anticipated in this study except for discomfort in answering questions that may be deemed personal

Voluntarism

Your participation in this study is voluntary. You may choose not to participate in the study. You may withdraw consent at any time and decide not to continue participating in the study.

Confidentiality

No names or personal information will be collected at any stage during the study. A coded number will be assigned to the questionnaire as opposed to the name. Interviews will be conducted in private. Any information that will be collected during the study will be kept confidential and not shared with a 3rd party unless your consent is sought first. The data collected from the study will be stored under lock and key and presented as a thesis towards the Master of Pharmacy degree.

Information on researchers

If you require any additional information regarding the researcher, please contact:

Dr Cecilia Wamalwa

Telephone number: 0727 901816

Email address: cclyaw@gmail.com or c_wamalwa@yahoo.com

or

Dr. P N Karimi,

Lead Supervisor,

School of Pharmacy

University of Nairobi

Telephone 0722436019

Email address ndirang@gmail.com

Information on the UoN/KNH Ethics and Research Committee

If you would like to contact of the University of Nairobi/Kenyatta National Hospital Ethics and Research Committee regarding any aspects of this study, the contact details are:

University of Nairobi/Kenyatta National Hospital Ethics and Research Committee

Telephone 2726300 Ext 44355

The study proposal has been reviewed and approved by the University of Nairobi/Kenyatta National Hospital Ethics and Research Committee.

Signature of Research Participant

I have read the above information. I have been given the opportunity to ask questions and the questions have been answered satisfactorily. I agree to participate in the study.

Name of participant:_____

Signature of participant: _____

Date:_____

Signature of Investigator

I have explained the research to the participant and answered his/her questions to the best of my ability. I confirm that consent has been given freely.

Name of Investigator: _____

Signature of Investigator: _____

Date: _____

Name of Investigator: _____

Signature of Investigator: _____

Date: _____

Appendix 4: Child assent form (7-12 years)

I am Dr. Cecilia Wamalwa from the University of Nairobi. I am doing a study to identify the risk factors and management of asthma among children in Naivasha, Kenya. We are asking you to take part in the research study because your parent recommended you for this study.

For this research, we will ask you some questions about to about your asthma and the treatment. We will keep all your answers private, and will not show them to parent(s)/guardian, friends or teacher. Only people working on the study will see them.

We don't think that any big problems will happen to you as part of this study, but you might feel some slight pain when blood will be withdrawn from your hand.

Benefits: No direct benefit to you is anticipated other than the knowledge obtained that may be used to reduce pesticide exposure and as a result improve on asthma control hence this will lead to reduced health burden, mortality and school absenteeism among children in the study area. You can feel good about helping us to make things better for other kids who might have problems at their home and school.

You should know that:

- You do not have to be in this study if you do not want to. You won't get into any trouble with (parent/guardian, your doctor, the school or me) if you say no.
- You may stop being in the study at any time. (If there is a question you don't want to answer, just leave it blank.)
- Your parent(s)/guardian(s) were asked if it is OK for you to be in this study. Even if they say it's OK, it is still your choice whether or not to take part.
- You can ask any questions you have, now or later. If you think of a question later, you or your parents can contact the following researchers or institution;

Information on researchers

If you require any additional information regarding the researcher, please contact:

Institution: Department of Pharmaceutics and Pharmacy Practice, School of Pharmacy, University of Nairobi, P.O BOX 30197-00400, Nairobi.

Investigator: Dr.Wamalwa Cecilia, P.O. Box 30801-00100, NAIROBI, Email address; c_wamalwa@yahoo.com or cclyaw@gmail.com , Mobile no. 0727901816.

Supervisors:

1. Dr. Peter N. Karimi, M. Pharm, MSc, MBA; Department of Pharmaceutics and Pharmacy practice, University of Nairobi; Mobile no. 0722436019
2. Dr. DR. George Wandolo, MB.ChB, MSc (Chemical Pathology); Department of Human Pathology (clinical Chemistry Unit), University of Nairobi; Mobile no. 0721563947
3. Dr. Kefa Bosire Ogonyo, M.Pharm (Pharmaceutical Analysis) Department of Pharmacology and Pharmacognosy, University of Nairobi Mobile no. 0713542111

Information on the UoN/KNH Ethics and Research Committee

If you would like to contact of the University of Nairobi/Kenyatta National Hospital Ethics and Research Committee regarding any aspects of this study, the contact details are:
University of Nairobi/Kenyatta National Hospital Ethics and Research Committee
Telephone 2726300 Ext. 44102

Study approval

The study proposal has been reviewed and approved by the University of Nairobi/Kenyatta National Hospital Ethics and Research Committee.

Name of Parent(s) or Legal Guardian(s)

……

……

Researcher explaining study

Signature …… Printed Name ……. Date ……

Appendix 5: Patient Questionnaire

A. Biodata

Study no.: _____ Date: _____

Data collector's Initials:_____ Prescription code number:_____

Child's Sociodemographic Characteristics

1) Date of Birth: _____ Age (years): _____
2) Gender: Male ☐ Female ☐
3) Does child go to school? ☐ Yes ☐ No Specify grade: _____
4) Is the school located near a flower farm? ☐ Yes ☐ No
5) It yes: specify the distance ☐ ≤ 500m ☐ > 500m
6) If no, has child ever attended school near flower farm? ☐ Yes ☐ No

Guardian's Sociodemographic Characteristics

1) Type of Guardian: ☐ Father ☐ Mother ☐ Other, specify: _____
2) If guardian is not birth parent, specify period he/she has managed the child's asthma:

☐ < 3 months ☐ 3 – 6 months ☐ 6-12 months

3) Guardian's Occupation:

☐ Father:_____ ☐ Mother: _____ ☐ Other, Specify: _____

4) Have any of the parents/ guardian ever worked in a flower farm?

☐ Yes ☐ No

5) If yes, specify duration: _____

☐< 3 months ☐ 6months ☐ 1 year☐ 2years ☐ 5year ☐ > 5years

6) Monthly income range in Ksh: _____

☐ <5000 ☐ 5000-10000 ☐ >10,000

7) Highest educational level of parent/guardian:

□ No formal Education □ Primary □ Secondary □Tertiary: □ Degree □ Diploma □ certificate

B) Risk Factors of Asthma

1) At what age was child's asthma diagnosed?

□ Birth □ 3months– 1year □ 2 - 5years years □ 6 - 12years

2) Is there a family history of asthma: □ Yes □ No

3) If yes, specify the relationship with the members with asthma: (limit upto grandparents.)

_____

4) Is a there a family history of allergies □ Yes □ No

5) If yes, specify the type of allergy.....

6) Is there as smoker in the household? □ Yes □ No

7) If yes above, does the child ever experience asthmatic attacks when exposed to the smoke?

□ Yes □ No

8) Does any household member work in the flower farm?

□ Father □ Mother **(go to question 9)** □ Sibbling □ Other specify: _____

9) Did mother work on the flower farm while pregnant or breastfeeding asthmatic child?

□ Yes □ No

10) Does the above mentioned household farm employee come home with any of these (Tick appropriately)

□ Work clothes □ Farm equipment □ Farm Chemicals □ Other, specify_____

11) Mention area of residence (Location): _____

12) Is it near flower farm? □ Yes **(go to question 13)** □ No **(go to question 14)**

13) State approximate distance: _____

□ ≤500m (Exposure to Pesticides) □ > 500m (Unexposed to Pesticides)

14) Have you ever lived near or on flower farm? □ Yes □ No

15) **If yes above**, specify length of time you lived near or on flower farm? _____

16) How is the child's asthma since you moved away from the flower farms?

□ No asthma attacks □ Less frequent attacks □ No difference □ Other specify:_____

17) Are you aware of that the flower farms use pesticides?

□ Yes □ No

18) **If yes above**, are you aware of the period pesticides are sprayed in the farms?

□ Yes □ No □ Don't know

19) **If yes above**, during this pesticide spraying period, how is your child's asthma?

□ More asthma attacks □ Less frequent attacks □ No difference □ Other specify:_____

20) What source of energy do you use for cooking at home?

□ Charcoal □ Firewood □ Gas □ Electricity □ other, specify_____

21) What is your source of lighting? _____

□ Kerosene lamp □ Electricity □ Candles □ Other, specify: _____

22) Do you have household pets? □ Yes □ No

23) **If yes,** specify: _____

24) Do you use indoor pesticides? □ Yes □ No

25) **If yes,** Specify: _____

C) Levels of Asthma Control

Childhood Asthma Control Test (ACQ) [5,49]

Instructions on how to fill Asthma Control Test

Step 1: Let child answer the first four questions (1-4).If child needs help reading or understanding the question, the caregiver may help, but let the child choose the answer. The remaining questions (5-7) should be answered by caregiver without letting the child's answers influence their answers. (Stress that there are no right or wrong answers)

Step 2: Write number of answer in the score box provided

Step 3: Add up the scores in each box to calculate the total score

Ask the child to answer these questions				
1) How does your asthma make you feel today?				Score
0= I feel very ill today	1= I feel ill today	2= I feel well today	3= I feel very well today	
2) How much does your asthma bother you when you run, exercise, play sports or perform chores?				
0= It bothers me alot, i can't do what i want to do	1= It bothers me and I don't like it	2= It bothers me a bit but its okay me	3=It doesn't bother me	
3) Do you cough because of your asthma?				
0= Yes, always	1= Yes, most of the time	3= Yes, some of the time	4 = No, Never	

4) Do you wake up during the night because of asthma?				
0= Yes, always	1= Yes, most of the time	2 = Yes, some of the time	3= No, never	
Ask the caregiver				
5) During the past 4 weeks, how many days did your child have any daytime symptoms?				

5= Not at all	4= 1-3 days	3= 4-10 days	2=11-18 days	1=19-24 days	0=everyday	

6) During the past 4 weeks, how many days did your child wheeze during the day because of asthma?						
5= Not at all	4= 1-3 days	3= 4-10 days	2= 11-18	1= 19-24	0= everyday	

7) During the past weeks, how many days did you child wake up during the night because of asthma?						
5= Not at all	4=1-3 days	3=4-10 days	2=11-18 days	1=19-24 days	0= Everyday	
Total Score (Question 1-7)						

Interpretation of Childhood ACQ

Score 20 or more: Child's asthma may be under control

Score 19 or less: Child's asthma may not be as well controlled

D) Caregiver Knowledge on Asthma

In this section, respond as true or false

1. Wheezing is not a symptom of asthma ___

2. Smoking in the home can make a child's asthma worse ____
3. Attacks can happen when you breathe things like paint, fumes, gasoline, smoke or pollution___
4. Keeping an asthma attack from happening is something only a doctor can do ___
5. An asthma attack involves coughing chest tightness and wheezing ____
6. If asthma symptoms such as chest tightness and wheezing do not occur for several months, a child has outgrown his/her asthma ____
7. With appropriate treatment, most children with asthma should lead a normal life with no restrictions on activities ____
8. Anger, crying or laughing can start an asthma attack ___
9. Exercising in the cold weather can start an asthma attack ____
10. Pets like dogs and cats are good for a child with asthma ____

E) Prescribed asthma drugs

1. How many different types of medicines are you currently using to control asthma in your child? (Guardian should show the prescription or drugs dispensed)

2. List the drugs out in the table provided below

□ Yes □ No □ Not sure

Drug	**Dose**	**Frequency of administration**	**Remarks (Dose appropriate or not)**

F) Adherence information

1. List out the asthma drugs prescribed or dispensed and ask the caregiver to give you the information from recall.

(This information should be sought from the caregiver to understand usual practice)

Drug	**Dose**	**Frequency of administration**	**Remarks(Appropriateness of dose and frequency)**

2. Is a controller drug (Corticosteroid-inhaled or oral) prescribed?

□ Yes □ No

3. When was the last time the child missed the controller medication?

□ Specify _____

□ Never skip medications

2) If missed medication. Why?

□ Drug stock out

□ Forgot

□ Unbearable side effects

□ Child was well

□ Other. Specify----------

G) Additional comments

Thank you very much

Appendix 6: Level of asthma control in patients ≥5 years of age

Characteristics	**Controlled(All of the following)**	**Partly controlled(Any measure present in any week)**	**Uncontrolled**
Daytime symptoms in the past 2-4 wk	≤2 d/wk but not more than once a day	>2 d/wk or more than once a day but ≤2 d/wk	3 or more of the features of partly controlled in any week
Limitations of activities in the past 2-4 wk	None	Some limitation	
Nocturnal symptoms/awakenings in the past 2-4 wk	None	≤2 nights/wk	
Need for short-acting inhaled $ß_2$-agonists in the past 2-4 wk	≤2 d/wk	>2 d/wk	
Exacerbations (requiring oral or systemic corticosteroids)	0-1/y	2/y	
Lung function is not a reliable test for children 5years and younger			

Appendix 7: Guardian Sociodemographic characteristics

Factor	Categories	Frequency	Percent
Guardian	Father	27	18
	Mother	121	80.67
	Aunt	1	0.67
	Father and mother	1	0.67
Father occupation	Flower farm worker	83	55.33
	Farmer	7	4.67
	Business man/lady	13	8.67
	Fisherman	4	2.67
	Motor cycle rider	11	7.33
	Salonist	1	0.67
	Waiter	1	0.67
	Mechanic	5	3.33
	Carpenter	4	2.67
	Tailor	1	0.67
	Barber	4	2.67
	Jobless	1	0.67
	Driver	4	2.67
	Police	1	0.67

	Watchman	2	1.33
Mother occupation	Flower farm worker	92	61.33
	Farmer	6	4.00
	Business man/lady	14	9.33
	Salonist	6	4.00
	Housewife	20	13.33
	Waiter	2	1.33
	Hotelier	1	0.67
	House help	1	0.67
	Tailor	4	2.67
	Cook	1	0.67
	Billing clerk	1	0.67
	Teacher	1	0.67
Parent ever worked in a flower farm	Yes	112	74.67
	No	38	25.33
Duration of working in flower farm	6 months	5	3.33
	1 year	9	6.00
	2 years	24	16.00
	5 years	23	15.33
	>5 years	53	35.33

	N/A	36	24.00
Monthly income	<5000 sh	7	4.67
	5000-10000 sh	110	73.33
	>10000 sh	33	22.00
Guardian education level	No formal education	2	1.33
	Primary	52	34.67
	Secondary	83	55.33
	Degree	1	0.67
	Diploma	5	3.33
	Certificate	7	4.67

Appendix 8: Risk factors of Asthma

Factor	Categories	Frequency	Percentage
Age at first diagnosis	3 months-1 year	9	6.00
	2-5 years	49	32.67
	6-12 years	92	61.33
Family history of asthma	Yes	34	22.67
	No	116	77.33
Family member with asthma	Father	9	6.00
	Mother	15	10.00
	Grandfather	6	4.00
	Grandmother	3	2.00
	N/A	117	78.00
Family history of allergies	Yes	46	30.67
	No	104	69.33
Allergen type	N/A	102	68
	Dust	13	8.67
	Strong smell	4	2.67
	Cold	10	6.67
	Smoke	3	2
	Dust and strong smell	7	4.67

	Cold & Dust	6	4
	Fur	3	2
	Pollen	1	0.67
	Fur & Dust	1	0.67
Smoker in household	Yes	32	21.33
	No	118	78.67
Experience asthma attack while exposed to smoke	Yes	26	17.33
	No	5	3.33
	N/A	119	79.33
Household member working on farm	Yes	112	74.67
	No	38	25.33
Residence near farm	Yes	106	70.67
	No	44	29.33
Previous home near a flower farm	Yes	30	20.00
	No	15	10.00
	N/A	105	70.00
Mother worked on flower farm while pregnant	Yes	43	28.67
	No	107	71.33
Items the farm employee carries home	Work clothes	90	60.00
	Farm equipment	5	3.33

	Farm chemicals	1	0.67
	N/A	38	25.33
	None	16	10.67
Frequency of asthma attacks after moving away from farm	No asthma attacks	4	2.67
	Less frequent attacks	24	16.00
	No difference	4	2.67
	N/A	118	78.67
Awareness of pesticide use	Yes	136	90.67
	No	14	9.33
Awareness of duration of pesticide use	Yes	111	74
	No	27	18
	N/A	12	8
Frequency of asthma attacks during spraying period	No asthma attacks	96	64.00
	Less frequent attacks	1	0.67
	No difference	14	9.33
	N/A	39	26.00
Cooking source	Charcoal	119	79.33
	Firewood	11	7.33
	Gas	18	12.00
	Stove	2	1.33

Lighting source	Kerosene lamp	22	14.67
	Electricity	127	84.67
	Candles	1	0.67
Keep pets	Yes	37	24.67
	No	113	75.33
Type of pet	Cats	31	20.67
	Dogs	6	4.00
	N/A	113	75.33
Indoor pesticide use	Yes	46	30.67
	No	104	69.33
Type of indoor pesticide	Pyrethroid	46	30.67
	N/A	104	69.33