

**THE PREVALENCE AND ASSOCIATED FACTORS OF
ATOPIC DERMATITIS IN CHILDREN AGED
BETWEEN SIX MONTHS AND TWELVE YEARS
ATTENDING THE PEDIATRICS DERMATOLOGY
CLINIC AT KENYATTA NATIONAL HOSPITAL,
KENYA**

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**The Prevalence and Associated Factors of Atopic Dermatitis in
Children aged between Six Months and Twelve Years Attending the
Pediatrics Dermatology Clinic at Kenyatta National Hospital, Kenya**

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**A Thesis Submitted in Partial Fulfilment of the Requirements for
the Degree of Master of Medicine in Dermatology of the Jomo
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DECLARATION

This thesis is my original work and has not been presented for a degree in any other University

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This thesis has been submitted for examination with our approval as the University Supervisors.

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DEDICATION

I dedicate this work to my children, Hafsa, Sundus, Maryam, and, In Sha Allah, the ones to come. May you find peace and interest in learning.

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ACRONYMS AND ABBREVIATIONS

AAD	American Academy of Dermatology
AD	Atopic Dermatitis
AOR	Adjusted Odds Ratio
CI	Confidence Interval
EASI	Eczema Area and Severity Index
KNH	Kenyatta National Hospital
KNH-UON ERC	Kenyatta National Hospital, University of Nairobi Ethics Review Committee
OR	Odds Ratio
POEM	Patient-Oriented Eczema Measure
RR	Relative Risk
TCI	Topical Calcineurin Inhibitors
TCS	Topical Corticosteroid
WHO	World Health Organization

DEFINITION OF OPERATIONAL TERMS

- Atopic diseases** are a group of diseases linked by a shared underlying problem with the immune system. Characterized by an exaggerated IgE-mediated immune response to environmental allergens that are usually harmless. Childhood atopic disease includes atopic dermatitis, allergic rhinitis, conjunctivitis, asthma, and food allergy.
- The atopic march** The natural history of allergic diseases as they develop over the course of infancy and childhood. Often starts with atopic dermatitis in infancy, followed by food allergy and then potentially asthma and allergic rhinitis (hay fever) in older children and adults.
- Filaggrin** is a structural protein that is fundamental in the development and maintenance of the skin barrier. It helps to bind keratin filaments together, creating a tightly packed matrix that strengthens the skin barrier and prevents water loss.
- Lichenification** is a condition where the skin becomes thickened, hardened, and leathery due to chronic irritation or scratching, commonly seen in atopic dermatitis.
- The POEM (Patient-Oriented Eczema Measure) score** is a validated tool used to assess eczema severity from the patient's perspective. It is a self-administered questionnaire that helps measure the frequency of eczema symptoms, such as itchiness, disturbed sleep, and skin changes, over the past week. Scores typically range from 0 to 28, with higher scores indicating more severe eczema and being useful in the outpatient setting.

ABSTRACT

Background: Atopic dermatitis (AD), is chronic inflammatory skin disease characterized by acute flare-ups of intense pruritus and dry scaly lesions. The onset of AD is usually between 2 and 6 months of age, although it can begin at any age. AD affects up to 20% of children and 3% of adults; latest global data shows increases in its prevalence. In Africa, the prevalence of AD ranges from 4.7% to 23%. In Kenya, the prevalence and the associated factors among pediatrics is poorly defined as there is paucity of evidence around it. As such, the clinicians attending to these clients often rely on the theoretical and literature evidence sourced from other parts of the world. The study main objective is to determine the prevalence and associated factors of atopic dermatitis among pediatric patients aged between six months and twelve years seen at the dermatology clinic at Kenyatta National Hospital, Kenya. This was a cross-sectional study conducted at the Dermatology Pediatrics Clinic in the period between August and November 2024. The sample for the study was recruited consecutively until the sample size of 148 children was achieved. A structured questionnaire was used to collect data. The data collected include demographic, family and personal history of associated atopic conditions, atopic dermatitis diagnosis and severity of atopic dermatitis using POEM score. Ethical Approval was acquired from KNH-UON ERC. Data was analyzed using SPSS v.25 and the prevalence of atopic dermatitis was calculated as a proportion of the total sample size and expressed as percentage. Binary logistic regression was performed to investigate factors associated with AD. Significance was assessed at $p < 0.05$. The results showed that majority of the patients, $N=90(60.8\%)$ were female, $N=59(39.9\%)$ were aged more than 10 years, most patients had 1-5 siblings $N=62(41.9\%)$ and $N=112(75.7\%)$ had their mothers unemployed. The prevalence of atopic dermatitis was $N=38(25.7\%)$ with a CI of between 18.9% to 33.5%. After adjusting for cofounders, the adjusted odds ratio showed that factors associated with Atopic Dermatitis included age of 5 years and below (aOR = 12.11, 95% CI: 3.11, 56.37, $p < 0.001$), males (aOR = 2.83, 95% CI: 1.32, 6.03, $p = 0.015$), family history of allergic asthma (aOR = 8.33, 95% CI: 3.67–33.11, $p < 0.001$), family history of allergic rhinitis (aOR = 18.13, 95% CI: 7.67–70.11, $p < 0.001$), family history of allergic conjunctivitis (aOR = 6.11, 95% CI: 2.64–20.78, $p = 0.007$), family history of atopic dermatitis (aOR = 7.11, 95% CI: 1.36–23.63, $p = 0.019$), allergic asthma (aOR 11.18, 95% CI 3.14, 25.11 $P < 0.001$), allergic rhinitis (aOR 12.88, 95% CI 2.65, 51.02 $P < 0.001$) and allergic conjunctivitis (aOR 15.53, 95% CI 1.71, 52.75 $P < 0.001$). The severity of eczema among patients $N=38$ was assessed using the POEM score. The findings showed that 44.7% had minimal eczema, 34.2% had mild eczema, 13.1% had moderate eczema, and 7.4% had severe eczema. The study concluded that one in four children attending dermatology clinic were found to have atopic dermatitis. Younger children, males, and those with unemployed mothers had higher odds of developing AD. A family history of allergies and personal factors like allergic asthma, rhinitis, and conjunctivitis also increased the risk of AD. Thus, healthcare providers prioritize early screening for AD in children, especially those with a family history of allergies.

Keywords: *Atopic dermatitis, Eczema, pruritus, prevalence, associated factors*

CHAPTER ONE

INTRODUCTION

1.1 Background of the Study

Atopic dermatitis (AD), also called atopic eczema, is a common chronic inflammatory skin disease characterized by acute flare-ups of intense pruritus and dry scaly lesions (Hadi et al., 2021). Symptoms of AD include patches of skin that are red or brownish, dry, cracked, or scaly, and itchy skin, especially at night. In infants, eczema usually appears as vesicles on the cheeks, while older children and adults often experience vesicles on the knees or elbows (often in the folds of the joints), on the backs of the hands, or on the scalp. AD affects up to 20% of children and 3% of adults; the latest global data shows increases in its prevalence (Mandlik et al., 2021). A study by Sendrasoa et al (2020) reported a prevalence of 5.6% for atopic dermatitis among pediatrics aged 6 months to 14 years. In Africa, the prevalence of AD among pediatric patients ranges from 4.7% to 23% (Margolis et al., 2014).

The onset of AD is usually between 2 and 6 months of age, although it can begin at any age. It was previously thought that it resolved by adulthood in most cases, but evidence suggests that it is a chronic condition that may persist into adulthood. It is subdivided into infantile, childhood, and adult subtypes (Hadi et al., 2021).

The etiology of atopic dermatitis (AD) is multifactorial with interaction between genetics, immune, and environmental factors. The strongest known genetic risk factor for developing AD is the presence of a loss-of-function mutation in filaggrin and therefore a primary defect in the epithelial barrier leading to secondary immunologic dysregulation and resulting in inflammation (Nutten et al. 2015) The increased global prevalence of AD cannot be attributed to genetics alone suggesting that evolving environmental exposures may trigger and/or flare disease in predisposed individuals. There is a complex interplay between different environmental factors, including prenatal exposures, individual use of personal care products, irritants and pruritogens, pathogens, climate factors, including temperature, humidity, ultraviolet radiation,

outdoor and indoor air pollutants, tobacco smoke exposure, water hardness, diet, breastfeeding, probiotics, and prebiotics, on AD (Nutten et al. 2015).

AD usually starts in early childhood and may represent the initial step of the so-called ‘atopic march’, which represents the natural history of atopic manifestations (Abdo et al., 2020). It is characterized by a typical sequence of atopic diseases (asthma and allergic rhinoconjunctivitis) in childhood preceding the development of other allergic disorders later in life (Hadi et al., 2021). Roughly 50% of all those with AD develop other allergic symptoms within their first year of life, and probably as many as 85% of the patients experience an onset below 5 years of age. Patients usually outgrow the disease in late childhood, as around 70% of the patients with a disease onset during childhood have a spontaneous remission before adolescence (Hadi et al., 2021).

AD poses a significant burden on health-care resources and patients’ quality of life (mainly because of sleep deprivation due to itchiness, employment loss, time to care, and financial costs). The environmental factors may vary from one region to another or from one household to another. This speaks of the need to understand the main probable environmental risk factors locally for effective preventive care.

1.2 Statement of the Problem

Atopic dermatitis is a chronic, inflammatory condition that affects millions of children and adults globally. Although prevalence has plateaued in some high-income regions, it is rapidly increasing in low - and middle-income countries like Kenya. Atopic Dermatitis also poses a significant burden on health-care resources and patients’ and caregivers quality of life

In Kenya, there is a lack of local data on Atopic dermatitis (children), leading to under-diagnosis and inadequate resource allocation to these populations affected most. This study was conducted to determine the prevalence and associated factors of AD in the Kenyan children

1.3 Objectives of the Study

1.3.1 Broad Objective

To determine the prevalence of atopic Dermatitis and its associated factors among children aged between 6 months and 12 years attending the pediatrics dermatology clinic at the Kenyatta National Hospital from August to November 2024.

1.3.2 Specific Objectives

1. To determine the prevalence of atopic dermatitis among pediatric patients attending KNH Dermatology clinic
2. To determine the sociodemographic factors associated with atopic dermatitis among pediatric patients attending KNH Dermatology clinic
3. To determine the associated atopic conditions (in self and family) among pediatric patients attending KNH Dermatology clinic
4. To determine the severity of Atopic Dermatitis using the POEM score among pediatric patients attending KNH Dermatology clinic

1.4 Research Questions

1.4.1 Broad Research Question

What is the prevalence and factors associated with atopic dermatitis among pediatric Patients aged between 6months and 12 years attending dermatology clinic at Kenyatta National Hospital from August to November 2024?

1.4.2 Specific Research Questions

1. What is the prevalence of atopic dermatitis in the pediatric population at the Kenyatta National Hospital Dermatology clinic?
2. What are the sociodemographic factors associated with atopic dermatitis in the pediatrics population at Kenyatta National Hospital Dermatology clinic?
3. What are the atopic conditions associated with atopic dermatitis in the pediatrics population at Kenyatta National Hospital Dermatology clinic?

4. What is the severity of atopic dermatitis among the population under study according to POEM score?

1.5 Study Justification

Atopic dermatitis affects both the young and the old, recent global estimate suggest that AD is on the rise in Africa. A majority of the studies around atopic dermatitis are concentrated in the developed world or the Asian countries. However, there is significant evidence paucity in Africa, and Kenya. Findings from other countries may not be extrapolated or generalized to mean they are similar in African setting, due to differences in factors such as genetic and environmental exposures. Therefore, there is need to collect data on the prevalence and factors associated with AD in Kenya to inform public health policy. The current study sought to collect accurate data on the main factors associated with AD using descriptive cross-sectional study at Kenyatta National hospital. An understanding of these complex factors is crucial to developing targeted preventive strategies, health promotion materials, and instituting appropriate interventions in the disease management in millions. It also serves as a baseline for future researches in the similar study areas.

CHAPTER TWO

LITERATURE REVIEW

2.1 Etiology of Atopic Dermatitis

Atopic dermatitis is a chronic skin condition that is characterized by chronic inflammation. The condition is triggered by environmental factors and is associated with cutaneous hyperactivity (Mandlik&Mandlik, 2020). The condition is characterised by recurrent eczema with associated dry skin and intense itch. A combination of factors is attributed to the occurrence of the disease, ranging from a dysfunction of the skin barrier mechanism and augmented by skin inflammation, leading to the development, progression, and chronicity of the disease (Nakahara et al., 2021). According to Abdo et al. (2020), the skin is an integral part of the body and the largest organ that constitute 15% of the body weight. The skin plays an important role in providing the body with a barrier against external physical, chemical, biological, and other environmental threats. Also, it is involved in thermoregulation and prevents the body from losing excess water, among other vital functions. The skin is comprised of three layers, that is, the epidermis, dermis, and subcutaneous tissue. The skin is continuous with the mucous membrane that lines the body's internal surfaces.

The dysfunction of the skin's barrier mechanism leads to enhanced skin irritability to non-specific stimuli and epicutaneous sensitization (Nakahara et al., 2021). Eichenfield et al. (2022) opine that the disease manifests in early childhood, often before the manifestation of other atopic diseases such as allergic rhinitis, asthma, or food allergies. The onset of atopic dermatitis usually manifests in children between 3 and 6 months of age. It is estimated that about 60% of the children with atopic dermatitis present with symptoms within the first 12 months of life. Hadi et al. (2021) cautioned that even though atopic dermatitis presents in children, the condition may also affect individuals in adulthood. Co-morbidities such as bronchial asthma and allergic rhinitis occur in patients with atopic dermatitis, especially in infancy or early childhood.

The pathophysiology of atopic dermatitis is multifactorial. However, there are two suggested hypotheses for the development of the disease, that is, the imbalance of the adaptive immune system and a defective skin barrier (Mandlik et al., 2021). In the first immunological hypothesis, it is argued that there is an imbalance of T cells, especially the T helper cells type 1, 2, 17, and 22, including the regulatory T cells, as a result of a genetic predisposition (Thomsen, 2014). In the situation of acute eczema in atopic dermatitis, there is predominance of T helper 2 differentiations of naïve CD4⁺ T helper cells, causing an increased production of interleukins 4, 5, and 13. There is a subsequent increase in the level of IgE, leading to inhibition of differentiation of T helper 1 cells (Thomsen, 2014).

Immunological factors such as T helper cells 1, 17, and interleukin 4, 13, 31 are the primary inflammatory mediators identified in the Pathophysiology of atopic dermatitis (Hadi et al., 2021; Eichenfield et al., 2022). Also, T helper 2, 22 pathways, and those of T helper 1 are found in acute disease and are intensified in chronic disease. The activation of these pathways and upregulation of these inflammatory mediators make the body unable to recognize pathogens, making the skin more susceptible to re-infections. The skin epidermis forms the outer layer of the skin and the first line of defence. The epidermis consists of five layers: the stratum basale, the stratum spinosum, the stratum granulosum, the stratum lucidum, and the stratum corneum (the outermost part of the epidermis). In the second hypothesis, the skin barrier disruption leads to high production of thymic stromal lymphopoietin from keratinocytes in the epidermis. Also, interleukin 25 & 33 are produced, resulting in type 2 immune deviation with resultant inflammation. Subsequently, there down regulation of filaggrin, a structural protein responsible for homeostasis in the stratum corneum of the epidermis, exacerbating the barrier dysfunction. The pathophysiology of chronic itch in atopic dermatitis is a result of cross-talk between the keratinocytes, the immune system, and the non-histaminergic sensory nerves (Nakaraha et al., 2021).

The skin barrier dysfunction is genetically determined, which occurs due to alterations of the epidermis and or lipid composition resulting in inflammation (Nuttan, 2015). The damaged epidermis easily allows allergen entry and their resultant interaction with local antigen-presenting cells and immune effector cells, causing atopic disease due to

systemic IGE sensitization. Disease flares and chronicity are triggered by allergic sensitization, which in this case is a secondary phenomenon. The presence of genetic variations of filaggrin and other genes manifested with early onset and severe forms of atopic dermatitis increases an individual's risk of other allergic diseases such as asthma. The colonization and infection of the skin in atopic dermatitis by bacteria such as *Staphylococcus aureus* cause further skin barrier damage from their exogenous proteases. Environmental interactions in patients with atopic dermatitis, such as washing with soap, often lead to further skin barrier impairment.

2.2 Prevalence of Atopic Dermatitis in Paediatrics

Globally, atopic dermatitis is estimated to affect 15 – 20% of children and 1 – 3% of adults. The manifestations of allergic symptoms in atopic dermatitis occur in about 50% of children within the first year of life and in 85% of children before the age of 5 years. The incidence of atopic dermatitis is estimated to have increased in the last few decades by 2 – 3 fold in industrialized countries (Nutten, 2015). Hadi et al. (2021) indicate that only an estimated 25% of children with atopic dermatitis will continue to be affected by the disease in adulthood. It is thus postulated that about 75% of atopic dermatitis of childhood onset will cease to manifest the disease symptoms by adulthood.

Atopic dermatitis is estimated by the World Health Organization (WHO) to affect an estimated 230 million individuals globally (Yavena & Derlenski, 2021). Atopic dermatitis is considered the fourth leading cause of non-fatal disability and affects 15 – 20% and 1 – 10% of children and adults, respectively.

A study by Radtke et al. (2017) and Augustin et al. (2015) estimated 10.25% and 3.76% prevalence in atopic dermatitis in children and adult respectively, in Germany. The prevalence of atopic dermatitis in the United States was estimated to be 10.2%, 7.2%, and 7.3% in 2013, 2015, and 2019, respectively, in adults above 18 years (Silverberg et al., 2015; Silverberg et al., 2013; Fuxench et al., 2019). In children aged 5, 9, and 15 years, McKenzie et al. (2019) reported prevalence was 15%, 15.1%, and 14.5%, respectively, with an estimated average prevalence of 14.8% in children 5 – 15 years. In children 0 – 5 years, the prevalence was reported at 24%, evidencing the high

prevalence in this age group as opposed to older children, adolescents, and adults (Al-Naqeeb et al., 2019).

A study by Catro et al. (2010) among 3600 children aged 6 – 7 years found a prevalence rate of 9.6% in Brazil over 1 year. Goh et al. (2018) found a 13.4% prevalence among children aged 1 – 6 years in a study among 384 children in Malaysia. In China, Guo et al. (2016) studied 13,998 children in 2014 and found a 12.94% prevalence of atopic dermatitis in children aged 1 – 7 years.

A prevalence of 12.3% in children aged 17 years and below in the United Kingdom following an evaluation of over 8 million citizens in 1994 and 2013 was reported by Abuabara et al. (2019). This evaluation showed a lifetime prevalence of atopic dermatitis among persons aged 0 – 99 years to be 9.9%, with the highest prevalence among children. Henriksen et al. (2015) found a lifetime prevalence of atopic dermatitis of 13% from an evaluation of 972,836 children at age 5 years who were born from 1997 to 2011. In Sendrossoa et al. (2020) study, the prevalence of atopic dermatitis was reported to be 5.6% among children aged between 6 months and 14 years.

In Africa, the available studies showed an average prevalence of 3.85% (Hadi et al., 2021). Hogewoning et al. (2010) indicated that studies carried out in Ghana, Gabon, and Rwanda among 4,839 school-going children aged 4 – 20 years showed a prevalence of 1.6%, 4.0%, and 0.8%, respectively. A study sample of 1,617 children aged 5 – 6 years in Tunisia by Amouri et al. (2011) showed a prevalence of 0.65% of atopic dermatitis. Mukesi et al. (2017) found the highest prevalence of atopic dermatitis in a study in 2014 at 43.3%. Herrant et al. (2015) found a 12.2% in Senegal among 321 children below the age of 15 years.

2.3 Common Atopic Dermatitis Presentations

According to Kapur, Watson, and Carr (2018), atopic dermatitis is known to be a chronic condition presenting with itchiness and inflammation of the skin, especially in children. The clinical manifestations vary with age groups. Children below 2 years develop edematous papules and plaques that may have vesicles or crusts on the

forehead, cheeks, and chin on the face and the neck, the extensor surface of extremities, scalp, and trunk. The diaper area is generally spared but may be susceptible to other causes of diaper dermatitis, such as candida or seborrheic dermatitis. Children 2 years to puberty, classically have less exudative patches and plaques mainly in the flexural surface of extremities, neck, wrist, and ankles. On the other hand, adults exhibit chronic lichenified lesions in the flexure surface of extremities, the hands, and feet in atopic dermatitis.

Individual lesions may also be further classified into acute (edematous, erythematous papules or plaques and /or vesicles/crusting), subacute (erythema, scaling with variable crusting), or chronic (thick plaques with lichenification and scales) stages.

Skin infections, especially from *Staphylococcus aureus*, affect about 90% of people with atopic dermatitis, and this presents as honey coloured crusts on the lesions.

2.4 Diagnostic Criteria of Atopic Dermatitis by Kapur et al. (2018)

There is no confirmatory lab test for atopic dermatitis, and therefore, diagnosis is based on diagnostic criteria by Kapur, Watson, and Carr (2018), which indicates that the clinical manifestations of atopic dermatitis form the basis for diagnosis of the disease, as there is no specific diagnostic test. This is a modified UK Party's diagnostic criteria.

Atopic dermatitis diagnosis is made where there is the presence of itchy skin in addition to three minor criteria, as shown in **Table 2.1** below.

Table 2.1: Diagnostic Criteria of Atopic Dermatitis

Major criteria	Presence of an itchy skin condition
Minor criteria	Old children and adults <ul style="list-style-type: none">i. History of skin itchiness in skin creasesii. Personal history of asthma or allergic rhinitisiii. Personal history of general dry skin in the last year.iv. Visible flexural dermatitis.v. Age of onset of symptoms at age of below 2 years Children less than 4 years of age <ul style="list-style-type: none">i. History of skin itchiness of the cheeks.ii. History of atopic disease in a first-degree relative.iii. Eczema of the cheeks, forehead, and outer limbs.

Source: (Kapur, Watson & Carr, 2018)

2.5 Risk Factors for Atopic Dermatitis among Pediatrics

2.5.1 Exposures in Utero

Hartwig et al. (2014) assessed the relationship between prenatal adverse life events and the development of atopic diseases. The longitudinal study was carried out among 1587 children and mothers from the Western Australian Pregnancy Cohort Study, with assessment of children using clinical examination at 6 years and 14 years of age. Maternal stress was determined using a 10-point stressful life events point questionnaire. The study findings revealed a significant risk of asthma higher at age of 14 than at 6 years of age (1 life event AOR 2.24 vs 1.10, 2 life events AOR 1.96 vs 1.34, and 3 or more life events AOR 1.81 vs 0.99) for maternal events until 18 weeks gestation and similar relationship for events 18 – 34 weeks gestation age (1 life event AOR 1.31 vs 2.24, 2 life events AOR 1.83 vs 1.96, and 3 or more life events AOR 1.65 vs 1.81). The study found significant risk of developing allergic rhinitis at 6 years than at 14 years (1 life event OR 1.10 vs 1.09, 2 life events OR 0.92 vs 0.96, 3 or more life events OR 1.62 vs 0.96) maternal life events until 18 weeks' gestation and inverse findings for maternal life event 18 – 34 weeks (1 life event AOR – 1.05 vs 1.16, 2 life events AOR 1.10 vs 1.49, and 3 or more life events OR 1.24 vs 2.38). Similar findings were shown on the occurrence of eczema with higher odds at the age of 6 years than at 14 years. There were higher odds for the development of asthma among children

whose mother had no history of asthma than the contrary for maternal life events 18 – 24 gestation (1 life event AOR 3.52 vs 1.14, 2 life events AOR 3.07 vs 0.77, 3 or more life events AOR 1.92 vs 0.98).

2.5.2 Early Life Exposure to Dirt and Pathogens

The exposure to indoor allergens and lifestyle factors in a child's early life was hypothesized by Kapszewicz et al. (2022) to be associated with the occurrence of atopic disease. The study was carried out using the data from Poland and a follow-up of a final 103 children up to 10 years of age. The final participants' sample was the children whose parents had not moved from the same house since the birth of the children. The children were clinically assessed, and mothers were administered a questionnaire based on the International Study of Asthma and Allergies in Childhood. Clinical evaluation and diagnosis by a physician were used to confirm the presence of asthma, allergic rhinitis, and atopic dermatitis. The presence of allergic sensitization from allergens such as house dust mite, dog, cockroach, mouse, and alternaria was confirmed using the skin prick test. The child's exposure to environmental tobacco smoke and the presence of humid and/ or fungal areas in the house were also assessed by interview. The study findings showed that a high concentration of allergens in house dust had a significant association with the development of asthma at 10 years, with a geometric mean of 15.09, but found no association with the development of atopic dermatitis or allergic rhinitis. Also, the development of atopic dermatitis was linked to frequent house cleaning (OR = 0.61).

2.5.3 Other Exposures

A case control study carried out by Angelova-Fischer et al. (2014) to assess the effect of cumulative dermal exposure with alkaline agents on twenty volunteers with atopic dermatitis free of inflammatory lesions for at least 4 weeks before the study, and using only emollients for treatment, vs 20 healthy individuals participated in the study. Irritants were exposed to the participants for 4 consecutive days on the mid-back. The study found a significant effect on skin barrier function with higher transepidermal water loss among participants with atopic dermatitis than healthy individuals. In

contrast, the study did not find a significant difference in natural moisturising factor reduction in both groups.

There is a significant relationship between atopic dermatitis and climate and environmental pollutants, as was determined by Kathuria and Sliverberg (2016) in a study involving 91,642 children aged 0 – 17 years. Pollutants and climatic conditions such as outdoor air temperature, ultraviolet index, and precipitation levels had a significant association with the prevalence and severity of eczema. The study revealed that moderate to severe eczema was associated with higher levels of nitrate, zinc, lead, particulate matter, copper, and organic carbon.

A sample of 5,595 children was recruited in a study in the US to assess the relationship between the severity and persistence of atopic dermatitis and the long-term weather patterns. The environmental conditions assessed in the study included daily sun exposure, temperature, and daily humidity. High temperatures were found to be associated with poorly managed disease, with every 5°F increase in temperature (OR 0.85) leading to a 15% increase in severity of disease. Similarly, increased sun exposure was linked to poor disease control, with a 5% increase in sun exposure causing a 11% increase in poorly controlled eczema (OR 0.89). Lastly, increased humidity was significantly associated with poorly controlled atopic dermatitis, with a 10% increase in humidity causing a 10% increase in poor control (OR 0.90).

Individual-level exposures to drugs and environmental factors showed their association with atopic eczema symptoms in the International Study of Asthma and Allergies in Childhood (i.e, ISAAC) Phase Three, involving a final 353,958 children aged 6 – 14 years from 53 countries. In children aged 6 – 7 years, paracetamol (AOR 1.28) and antibiotic (AOR 1.41) use in the 1st year had the highest odds of influencing worsening of disease symptoms in the last 12 months. Other factors associated with the severity of atopic dermatitis included farm animals in utero (AOR 1.11), dogs, cats, and other farm animals in the first year (AOR 1.10, 1.05, 1.16), and current fire cooking (AOR 1.12). Moreover, current heavy traffic (AOR 1.11), paternal smoking (AOR 1.04), and maternal smoking (AOR 1.06) were associated with the severity of atopic dermatitis symptoms (Rutter et al., 2019).

2.6 Management of Atopic Dermatitis

The four components of treatment include trigger avoidance, daily skin care, anti-inflammatory therapy, and other complementary modalities. The main objective for the treatment of atopic dermatitis is the restoration of the skin barrier using interventions aimed at hydrating the skin, limiting itchiness, and reducing inflammation. A multifaceted approach is required in the successful management of atopic dermatitis, where the patient and the caretaker are provided with health education on the management and control of symptoms (Kapur, Watson, & Car, 2018).

The following key recommendations in practice, as described by Frazier and Bhardwaj (2020), were derived for systemic reviews and meta-analyses, consensus guidelines, randomised control trials, and various other studies. First, the primary therapy for atopic dermatitis flare-ups and maintenance should be emollients. Second, patients are advised to have a once-a-day bathing with lukewarm water for a time not exceeding 5 – 10 minutes. Third, in atopic dermatitis flare-ups, topical corticosteroids are the first line of treatment as opposed to oral or injected corticosteroids. Fourth, in moderate to severe atopic dermatitis, topical calcineurin may be used in combination with topical corticosteroids. Fifth, the second-line treatment for moderate to severe atopic dermatitis is ultraviolet B phototherapy. Lastly, oral antibiotics prophylaxis has no evidence-based benefit in the management of atopic dermatitis and should only be used in the management of secondary bacterial infections.

The following are additional recommendations by the American Academy of Dermatology, as referenced by Frazier and Bhardwaj (2020). First, pricking the skin for blood tests, such as routine evaluation of eczema using the radioallergosorbent test, should be avoided. Secondly, the use of oral antibiotics should be avoided without clinical evidence of infection. Lastly, the use of oral or injected corticosteroids should not be used in long-term treatment of atopic dermatitis. **Table 2.2** below summarizes the management of atopic dermatitis in various severity stages described by Fishbein et al. (2019).

Table 2.2: Management Approaches for Atopic Dermatitis

	Non-lesional	Mild	moderate	severe
Maintenance therapy	<p>BASIC MANAGEMENT Skin care Moisture, liberal and frequent [petroleum-based; choice per patient preference] Warm baths or showers using non-soap cleansers, usually once daily and followed by moisturizer [even on clear areas] Trigger avoidance Proven allergens, common irritants [e.g., soaps, wool, temperature extremes] Consider co-morbidities</p>	<p>BASIC MANAGEMENT Moisturizer, liberal and frequent [choice per patient preference] Warm baths or showers, non-soap cleansers, usually once daily and followed by moisturizer [even on clear areas] Antiseptic avoidance Antibiotics, if needed</p>	<p>BASIC MANAGEMENT +TOPICAL ANTI-INFLAMMATORY MEDS Apply on areas of previous or potential symptoms Maintenance TCS Low potency 1-2times daily including the face Medium potency 1-2times daily (except the face) OR maintenance TC (pimecrolimus,tacrolimus) 1-2times daily or 2-3times weekly OR crisaborole 2% 2times daily</p>	<p>BASIC MANAGEMENT+ REFERRAL TO AD specialist) Phototherapy Dupilumab Systemic immunosuppressants Cyclosporine A Methotrexate MMF Azathioprine Corticosteroids Consider acute treatment for some patients to help gain control: Wet-wrap therapy Short-term hospitalizatio</p>
Acute treatment	<p>Apply TCS to inflamed skin Low-medium potency TCS 2times daily for 3-7days beyond clearance (Consider TCI,Crisaborole)</p>	<p>Apply TCS to inflamed skin Low-medium potency TCS 2times daily for 3-7days beyond clearance(Consider TCI,Crisaborole)</p>	<p>Apply TCS to inflamed skin Medium-high potency TCS 2times daily for 3-7days beyond clearance (Consider TCI, Crisaborole) If not resolve in 7days consider (nonadherence, infection, misdiagnosis, contact allergy to meds, REFERRAL</p>	<p>SAME AS MODERATE</p>

Source: (Fishbein et al., 2019)

2.7 Associated Conditions with Atopic Dermatitis in Paediatrics

Yavena and Derlenski (2021) asserted that atopic dermatitis is linked to the occurrence of asthma. The global prevalence of asthma is estimated to be 300 million individuals globally, with an estimated 100 million additional cases by the year 2025. Notably, about 70 – 90% and 50% of all asthma in children and adults, respectively are atopic asthma. Other common conditions associated with atopic dermatitis are food allergy and allergic rhinitis in the presence or absence of elevated IgE levels. According to Acharya, Bajgain, and Yoo (2019), allergic rhinitis presents with watery rhinorrhoea, itchy nose, sneezing, and nasal congestion. In occasional circumstances, allergic rhinitis presents with itchy conjunctiva, throat, and ears.

Atopic march is considered the transition from one atopic disease to another with overlapping pathogenetic mechanisms. The atopic march occurs in an almost specific age range. The foundation of other atopic diseases is based on the pathology of atopic disease, which is characterised by disruption of the skin barrier, inflammation, and bacterial dysbiosis, leading to sensitization, which is a prerequisite for the development of these diseases. However, in some situations, asthma or allergic rhinitis can occur before atopic dermatitis. Food allergy often manifests before asthma or allergic rhinitis and can occur before atopic dermatitis, and in these circumstances may be the first sign of atopic march (Yavena&Derlenski, 2021).

Family history is an important risk factor for atopic diseases, including atopic dermatitis, allergic rhinitis, and atopic asthma. The strong positive association between family history and risk of atopy is persistent across studies in both adults and children. In a study by Bohme et al. (2003) found out 27.1% of children whose parents were atopic had developed atopic dermatitis compared to those with single or double parental atopic history at 37.9% and 50% respectively.

2.8 Factors Associated with Atopic Dermatitis

Few studies have looked at factors associated with atopic dermatitis, especially in children. Understanding these factors is important for the health care personal, the caregiver, and children themselves to provide care to the affected pediatric population.

Factors such as sex, age, age of onset, breastfeeding, weaning, personal and family history of atopy, urbanization, and several other factors may be directly or indirectly associated with atopic dermatitis, especially in the younger population.

A retrospective and descriptive study carried out in the University Hospital Joseph Raseta Befelatanana in Antananarivo Madagascar from 2010 to 2016 by Sendrasoa et al. found out that; of the children under study, (52.9%) were < 2 years and 47.1% were > 2 years, the mean age of AD patients was 4 years, the mean age of onset was 3 years, the age of onset before the age of 5 years was at 69%, there was also a female preponderance (sex-ratio: 0.73), children born in dry season had the highest risk of AD (12.39% of cases) and they found out No association between breast-feeding and urbanization with AD.

A study in Mekelle, Ethiopia by Kelbore et al. (2015) found that among the total respondents, 237 (50.4 %) were males and 233 (49.6 %) were females. They also found out that those who had maternal asthma (AOR: 11.5), maternal hay fever history (AOR: 23.5) and atopic dermatitis history (AOR: 6.0), Paternal asthma (AOR: 14.4), Paternal hay fever history (AOR: 13.8) and personal asthma (AOR: 10.5), and hay fever history (AOR: 12.9), age at 3 months to 1 year (OR: 6.8) and weaning at 4 to 6 months of age (AOR: 3.9) were all a significant predictors of atopic dermatitis

2.9 Severity of Atopic Dermatitis in Children

The assessment severity of atopic dermatitis helps to evaluate the disease process, response to treatment, and quality of life of both patients and caregivers.

A cross-sectional study in Singapore by Xu et al. (2019) found that the caregivers' mental and physical health was directly affected by their children's health –related quality of life. Poor quality of life in children with atopic dermatitis could lead to poor mental and physical functioning among caregivers.

In a 15 years (2004-2019) cross-sectional study carried out by Wan et al. (2021) *The Association of Atopic Dermatitis severity with learning disability in children in the United States of America* using POEM scores in children with physician-confirmed

atopic dermatitis, confirmed that those with mild, moderate, or severe disease were significantly more likely to report a learning disability diagnosis by a health care practitioner compared with those with clear or almost clear skin. Worsening severity was associated with higher rates of learning disability in a dose-dependent manner.

There is no universally accepted pediatric AD severity measure for use in clinical practice or research. Clinical research studies have used different scoring methods, such as the Patient-Oriented Eczema Measure (POEM), the SCORing of Atopic Dermatitis index, the Eczema Area and Severity Index (EASI), and others. This study will use the Patient-Oriented Eczema Measure as it is very convenient to use in outpatient clinics.

2.10 Conceptual Framework

The study's main focus revolves around understanding how frequent atopic dermatitis is among the pediatric population visiting the dermatology clinic at KNH, the associated factors, and the severity of the condition. The relationship around these factors is best captured in the conceptual framework schematic presented in **Figure 2.1** below. The independent factors, which are believed to have an interplay that leads to the development of atopic dermatitis, are categorized into different groups such as sociodemographic factors, the family related history, and personal medical factors. The primary outcome (dependent) variable is the atopic dermatitis diagnosis.

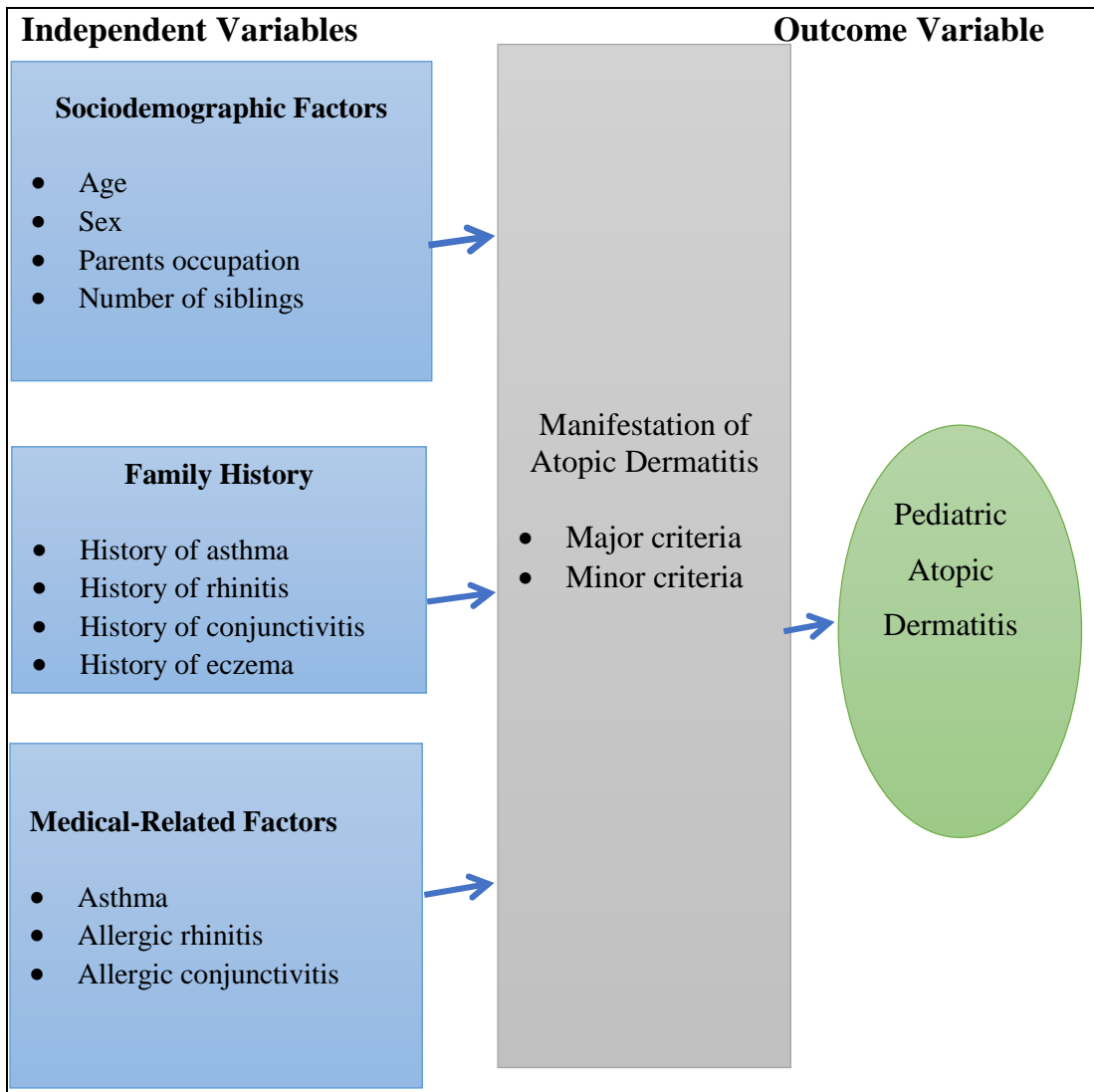


Figure 2.1: Schematic Illustration of Conceptual Framework

CHAPTER THREE

METHODOLOGY

3.1 Study Design

This was a facility-based descriptive cross-sectional study. The design was appropriate for this research, given that it is one of its kind in the facility, and seeks to have a foundation based on the associated factors and the prevalence of atopic dermatitis. Moreover, cross-sectional studies are regarded as the best designs for evaluating the prevalence of a condition.

3.2 Study Site and Setting

The study was carried out in the dermatology pediatrics clinic at the Kenyatta National Hospital (KNH), Nairobi, Kenya. The facility, KNH, is the largest referral facility, not only in the country, but also in the Eastern and Central African region, with a bed capacity of around 1800. Although the facility serves a wide range of referral cases nationally and regionally, it also serves as a primary health facility for the surrounding communities. In addition, KNH serves as a teaching hospital for the Jomo Kenyatta University of Agriculture and Technology faculty of medicine, University of Nairobi, Kenya Medical Training College, among other medical Institutions.

It is located on the west side of the country's capital city (Upper Hill), Nairobi. The dermatology clinic is one of the many outpatient clinics in the facility, and 235 patients attend monthly, where 32% are pediatric patients, according to the KNH Statistics Department. Ideally, every dermatological case seen in the facility has to go through the dermatology clinic. The Pediatrics Dermatology Clinic is located in clinic No.23 and runs on Wednesdays every week except on public holidays. Therefore, this was the most appropriate setting for accessing cases of atopic dermatitis seen at KNH.

3.3 Study Population

The study population comprised of pediatrics aged between six months and twelve years, seeking dermatological care from the KNH Pediatrics Dermatology Clinic.

3.4 Eligibility Criteria

3.4.1 Inclusion Criteria

Those to be recruited in the study had to meet the following inclusion criteria;

1. Children aged between 6 months and 12 years attending the pediatric dermatology clinic at KNH
2. Parents/guardians willing to give consent and an Assent form for older adults for the study

3.4.2 Exclusion Criteria

Despite meeting the above inclusion criteria, the child was eliminated in cases where these exclusion criteria applied.

1. Any child with a severe skin condition that requires emergency stabilization before enrollment
2. Previous enrollment in the study

3.5 Study Sample and Sampling

3.5.1 Sampling Technique

The participants were enrolled in the study through a consecutive sampling technique where every eligible child caregiver was approached, consented, and enrolled until the sample size was met. The sampling technique was appropriate for this study, given the rarity of atopic dermatitis, and hence every available case was critical for a descriptive profile.

3.5.2 Sample Size Calculation

The actual size of the sample to be recruited was estimated using Cochran's (1977) formula for calculating an adequate sample in cross-sectional studies. The calculations were based on the findings reported by a study in Ethiopia, which found that the prevalence of AD was 9.6%

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

Where;

- n = is the desired sample,
- z = standard normal variate (1.96 for 95% confidence interval),
- P = estimated proportion of population with the targeted outcome, which 9.6%
- D = the absolute error, in this case, 5%

Substituting the values,

$$n = \frac{1.96^2 \times 0.096(1 - 0.096)}{0.05^2}$$

$$n = 134$$

The sample is then adjusted upward by 10% to account for attrition and incomplete data that may be filtered during analysis. The overall sample is, therefore, N = 148 pediatric patients attending the dermatology clinic.

3.5.3 Participants' Enrolment Procedure

The potential participants were identified after the diagnosis had been made by the dermatologist(s), using the Kapur et al.2018 criteria in the clinic. The parent/guardian was approached by the principal investigator or the research assistants, introduced to the study topic, objectives, and expectations. Where the children are big enough to speak for themselves, they were also briefed about the study in the presence of their parents. The consenting process was initiated to ensure that the parent and the child understands about the study before agreeing to be part of the study. If the parents and the child are illiterate, they were asked to appoint an independent literate witness who would act in their best interest during the consenting process. After the consent and assent forms were signed, the parent and the child were ushered into a pre-prepared room that meets privacy standards in readiness for completing the questionnaire that was read to them by the principal investigator or the research assistant.

3.6 Data Collection

The data collection section enumerates the main variables that were of interest in this study, the tool used in data collection, and the data collection procedure.

3.6.1 Data Variables

The main variables, which form crucial data to be sourced from the participants, is categories into sections, as presented in *Table 3.1*

Table 3.1: Data Variables

Objectives	Dependent variable	Independent Variables	Source of Data
To determine the Sociodemographic factors associated	Atopic Dermatitis	Age Sex Number of siblings Parents occupation	Patient's file, the participant's parent/guardian
Personal Atopy	Atopic Dermatitis	History of Asthma History of allergic rhinitis History of allergic conjunctivitis	Child or parent/caregiver
Family history of atopy	Atopic Dermatitis	Family history of asthma Family history of atopic dermatitis Family history of allergic rhinitis Family history of allergic conjunctivitis	Child or parent/caregiver
Severity of Atopic Dermatitis	Atopic Dermatitis	Patient-oriented eczema measure score	Child or parent/caregiver

3.6.2 Study Tool

The data were gathered through a structured questionnaire, which was administered to the participants. The questionnaire was formulated with insights from the literature and previous studies to ensure it was valid and reliable. The questionnaire included details on all the targeted variables, including the baseline characteristics, the associated factors, and the severity of AD. The questionnaire underwent review from supervisors and a qualified biostatistician, and a pilot study was conducted to enhance

its feasibility. The severity of the disease was determined using the Patient-Oriented Eczema Measure score.

3.6.2.1 Patient- Oriented Eczema Measure (POEM) Score

The Patient-Oriented Eczema Measure (POEM) is a validated, patient-derived assessment measure for monitoring atopic eczema severity. It concentrates on the disease symptoms as experienced by the patient and is a widely accepted system.

POEM scores consist of seven questions of equal weight evaluating itch, skin dryness, bleeding, weeping, crack formation, exfoliation, and sleep disturbance, which are completed by the patients or their parents/caregivers concerning their disease experience during the past one week. The responses are given in a scale of 0 to 4: Zero score, which is the minimum score, is indicated by no day, 1-2 day experience indicates one score, 3-4 days experience indicates two scores, 5-6 days score 3, and an everyday scores four, which is the maximum score, which indicates very severe eczema. A total minimum of 0 score with a maximum score of 28 can be achieved from the questionnaire. When it comes to interpretation, POEM classifies eczema severity into 5 categories with the following bandings, as shown below.

Table 3.2: Patient- Oriented Eczema Measure (POEM) Score

Number of scores	AD severity
0-2	Clear or almost clear
3-7	Mild eczema
8-16	Moderate eczema
17-24	Severe eczema
25-28	Very severe eczema

3.6.3 Data Collection Procedure

The data collection commenced after the approval of the proposal by the Dermatology Department-KNH, the KNH-UON Ethics Review Committee, and permission from the KNH research department. First, the research assistants underwent training to ensure they fully comprehend the protocol, the applicable standards, operation procedures, the consenting process, and the data to be collected. The research

assistants were medical students. Such a background allowed them to interact with the participants and is able to comprehend the medical language from the patient's notes.

After the training, the study tool was pretested with ten cases from a different facility, Mbagathi Hospital, to ensure that the tool is feasible, valid, and reliable. Any areas of amendments were done before the actual data collection began. The principal investigator was tasked with the mandate to ascertain data quality, completeness, and correctness daily to ease addressing any data queries promptly. The completed questionnaires were locked in a cabinet, only accessible to the study team. The consent forms were stored in a different folder from the questionnaire to enhance confidentiality. The data was then entered into an Excel spreadsheet for cleaning and coding before it was exported to the SPSS software for analysis.

3.7 Data Management

3.7.1 Data Analysis and Reporting

The data collected was analyzed using SPSS version 25, with specific tests run based on the specific objective requirements. Descriptive analysis was done using mean and standard deviation for continuous data and frequencies and proportions for categorical data. The prevalence of atopic dermatitis was calculated as a proportion of the total sample size and expressed as a percentage. Factors associated with AD were determined using logistic regression analysis. The odds ratio was used to investigate the strength of the association. The level of significance was assessed at 0.05.

3.7.2 Data Quality Control and Assurance

The strength of evidence presented in any study is, by a significant proportion, dependent on the quality of the data. In this study, the data quality was enforced by a raft of measures. First, the data collection was done by qualified health care providers who were trained. Secondly, the study tool was pre-tested before deployment to ensure the targeted data was obtainable, and the data collected would be adequate to respond to the study objectives. Thirdly, the data collected was appraised for completeness,

correctness, and clarity before proceeding to ensure there are minimal data errors at the analysis level.

3.8 Ethical Considerations

Undertaking this research, which qualifies as human research, we followed and conformed to research ethics and regulations. The commencement was only done after the study had been approved by the KNH-UON ERC following a successful proposal defense at the department level. Those recruited as participants were required to have both informed written consent and Assent, which were obtained without any form of coercion, intimidation, or blackmail. There was no risk or harm to any of the study participants. There were no monetary or other types of compensation for participating in this study

3.9 Results Dissemination

The results obtained were disseminated at different levels to ensure the targeted audiences are able to benefit from the findings for practice, policy, or scholarly implications. The report was made available at the JKUAT library, it was added to the JKUAT research repository, a manuscript was published in a reputable international journal (East African Journal of Health and Science Article DOI: <https://doi.org/10.37284/eajhs.8.1.2866>), and the findings were shared with the study setting. Kenyatta National Hospital was also given a report on the study findings.

CHAPTER FOUR

RESULTS

The present study sought to determine the prevalence of atopic Dermatitis and its associated factors among children aged between 6 months and 12 years attending the pediatric dermatology clinic at the Kenyatta National Hospital. A total of 148 children were enrolled in the study and included in the analysis.

4.1 Demographic Characteristics of Participants

The demographic characteristics of the 148 pediatric patients attending the dermatology clinic revealed that 59 (39.9%) were aged more than 10 years, while 51 (34.5%) were aged 6-10 years. A higher proportion were female, 90 (60.8%). Most patients had 1-5 siblings, 62(41.9%). A larger percentage lived in extended family settings, 81(54.7%), as shown in Table 4.1.

Table 4.1: Demographic Characteristics of All Study Participants (N =148)

	Frequency	Percent
Age		
≤5 years	38	25.7
6 - 10 years	51	34.5
More than 10 years	59	39.9
Gender		
Male	58	39.2
Female	90	60.8
Number of siblings		
No siblings	39	26.4
1 - 5 siblings	62	41.9
More than 5 siblings	47	31.8
House setting		
Nuclear	67	45.3
Extended	81	54.7
Mother occupation		
Employed	36	24.3
Unemployed	112	75.7
Father occupation		
Employed	78	52.7
Unemployed	70	47.3

4.1.1 The Associated Atopic Conditions (in Self and Family)

The two most common atopic conditions, both in family history and in personal diagnoses, are allergic rhinitis and allergic asthma. In family history, allergic rhinitis was reported by 25(65.8%). When investigating personal related factors, 17(11.5%) of the patients had allergic asthma while 16(10.8%) had allergic rhinitis as shown in Table 4.2

Table 4.2: The Associated Atopic Conditions (in Self and Family)

	Frequency	Percent
Family history		
Allergic asthma	14	9.5
Allergic rhinitis	25	16.9
Allergic conjunctivitis	11	7.4
Atopic dermatitis	13	8.8
Personal-related factors		
Allergic Asthma	17	11.5
Allergic rhinitis	16	10.8
Allergic conjunctivitis	14	9.5

4.2 The Prevalence of Atopic Dermatitis

The prevalence of atopic dermatitis was 38(25.7%) with a confidence interval of between 18.9% to 33.5%, as shown in Figure 4.2.

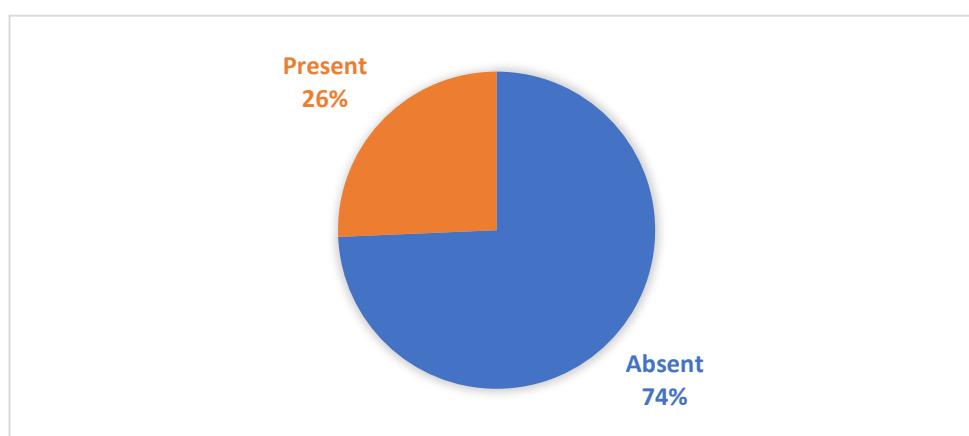


Figure 4.1: The Prevalence of Atopic Dermatitis

4.3 Factors Associated with Atopic Dermatitis

Binary logistic regression was conducted to investigate factors associated with atopic dermatitis, as shown in Table 4.3. The findings showed that children aged 5 years or younger had a significantly higher chances of having atopic dermatitis (OR = 16.99, 95% CI: 5.12, 56.37, $p < 0.001$). In addition, children aged 6-10 years also had a significantly higher odds ratio of having atopic dermatitis compared to those aged more than 10 years (OR = 4.70, 95% CI: 1.42, 15.53, $p = 0.011$). Males had a significantly higher odds ratio of having atopic dermatitis compared to females (OR = 2.83, 95% CI: 1.32, 6.03, $p = 0.007$). Children with unemployed mothers had a significantly higher odd of having atopic dermatitis compared to those who were employed (OR = 2.39, 95% CI: 1.12, 5.10, $p < 0.001$).

Table 4.3: Factors Associated with Atopic Dermatitis

	Atopic dermatitis present		OR (95%CI)	P value
	Absent n(%)	Present n(%)		
Age				
≤5 years	17(44.7)	21(55.3)	16.99(5.12, 56.37)	<0.001
6 - 10 years	38(74.5)	13(25.5)	4.70(1.42, 15.53)	0.011
More than 10 years	55(93.2)	4(6.8)	Ref	
Sex				
Male	36(62.1)	22(37.9)	2.83(1.32, 6.03)	0.007
Female	74(82.2)	16(17.8)	Ref	
Number of siblings				
No siblings	28(71.8)	11(28.2)	Ref	
1 - 5 siblings	43(69.4)	19(30.6)	1.12 (0.47, 2.72)	0.794
More than 5 siblings	39(83.0)	8(17.0)	0.52 (0.19, 1.47)	0.261
Housing unit				
Nuclear	50(74.6)	17(25.4)	Ref	
Extended	60(74.1)	21(25.9)	1.03 (0.49, 2.16)	0.939
Mother occupation				
Employed	30(82.1)	6(17.9)	Ref	
Unemployed	80(71.4)	32(28.1)	2.39 (1.12, 5.10)	<0.001
Father occupation				
Employed	62(79.5)	16(20.5)	Ref	
Unemployed	48(68.6)	22(31.4)	1.78(0.84, 5.10)	0.131

4.3.1 Personal and Family Atopic Conditions Related to AD Diagnosis

The odds of having Atopic Dermatitis are much higher in individuals with a family history of allergic asthma (OR = 9.46, 95% CI: 2.76–32.45, $p < 0.001$), allergic rhinitis

(OR = 23.33, 95% CI: 7.67–70.11, $p < 0.001$), allergic conjunctivitis (OR = 5.98, 95% CI: 1.64–21.78, $p = 0.007$), and atopic dermatitis itself (OR = 8.22, 95% CI: 2.36–28.63, $p = 0.001$). Additionally, personal factors also show strong associations with AD. Individuals with allergic asthma are 13.78 times more likely to have AD (OR = 13.78, 95% CI: 4.14–45.86, $p < 0.001$), allergic rhinitis have 12.23 times higher odds (OR = 12.23, 95% CI: 3.65–41.02, $p < 0.001$), and allergic conjunctivitis significantly increases the odds (OR = 14.53, 95% CI: 3.79–55.75, $p < 0.001$) as shown in Table 4.4.

Table 4.4: Personal and Family Atopic Conditions Related to AD Diagnosis

	Atopic dermatitis present		OR(95%CI)	P value
	Absent n(%)	Present n(%)		
Family history of allergic asthma				
No	106(79.1)	28(20.9)		
Yes	4(28.6)	10(71.4)	9.46(2.76, 32.45)	<0.001
Family history of allergic rhinitis				
No	105(85.4)	18(14.6)		
Yes	5(20.0)	20(80.0)	23.33(7.67, 70.11)	<0.001
Family history of allergic conjunctivitis				
No	106(77.4)	31(22.6)		
Yes	4(36.4)	7(63.6)	5.98(1.64, 21.78)	0.007
Family history of atopic dermatitis				
No	106(78.5)	29(21.5)		
Yes	4(30.8)	9(69.2)	8.22(2.36, 28.63)	0.001
Personal factors				
Allergic Asthma				
No	106(80.9)	25(19.1)		
Yes	4(23.5)	13(76.5)	13.78(4.14, 45.86)	<0.001
Allergic rhinitis				
No	106(80.3)	26(19.7)		
Yes	4(25.0)	12(75.0)	12.23(3.65, 41.02)	<0.001
Allergic conjunctivitis				
No	107(79.9)	27(20.1)		
Yes	3(21.4)	11(78.6)	14.53(3.79, 55.75)	<0.001

4.3.2 Multivariable Logistic Regression

The factors that were found to have a statistically significant association were then incorporated in a multivariable logistic analysis, adjusting for cofounders. These results are presented in Table 4.5 below. The data indicated that Children 5 years and

below had a significantly higher likelihood (aOR =12.11,95%CI 3.11,56.37 P=<0.001) of having atopic dermatitis compared to those of other age groups. Males are more likely to develop atopic dermatitis than females (aOR 2.83, 95%CI 1.32,6.03 P=0.015). Those with a family history of allergic asthma are at a higher risk (aOR 8.33, 95% CI 2.44,25.15 P=<0.001) of developing Atopic Dermatitis. A family history of allergic rhinitis and allergic conjunctivitis is strongly associated with atopic dermatitis (aOR 18.13,95% CI3.67,33.11 P=<0.001, and aOR 6.11,95% CI2.64,20.78 P=0.007 respectively). A family history of atopic dermatitis also increases the risk (aOR 7.11,95% CI1.36,23.63 P=0.019). Those with allergic asthma have an increased risk of developing atopic dermatitis (aOR 11.18 95% CI3.14,25.11 P=<0.001). Similarly, allergic rhinitis (aOR 12.88, 95% CI 2.65, 51.02 P=<0.001) and allergic conjunctivitis (aOR 15.53,95% CI 1.71,52.75 P=<0.001) are strong risk factors as shown in Table 4.5

Table 4.5: Multi-Variable Regression Analysis of Independent Factors Associated with Atopic Dermatitis

	aOR (95%CI)	P value
Age		
≤5 years	12.11(3.11, 56.37)	<0.001
6 - 10 years	5.10(1.87, 13.13)	0.011
More than 10 years	Ref	
Sex		
Male	2.83(1.32, 6.03)	0.015
Female	Ref	
Family history of allergic asthma		
No		
Yes	8.33(2.44, 25.15)	<0.001
Family history of allergic rhinitis		
No		
Yes	18.13(3.67, 33.11)	<0.001
Family history of allergic conjunctivitis		
No		
Yes	6.11(2.64, 20.78)	0.007
Family history of atopic dermatitis		
No		
Yes	7.11(1.36, 23.63)	0.019
Personal factors		
Allergic Asthma		
No		
Yes	11.18(3.14, 25.11)	<0.001
Allergic rhinitis		
No		
Yes	12.88(2.65, 51.02)	<0.001
Allergic conjunctivitis		
No		
Yes	15.53(1.71, 52.75)	<0.001

4.4 The Disease Severity Using the POEM score

The most common symptom was "skin feeling dry or rough due to eczema," with 16(42.1%) of children reporting this condition every day. The findings also showed that 18(47.4%) reported no flaking as shown in Table 4.5

Table 4.6: The Disease Severity Using the POEM Score (N =38)

Statements	No days n(%)	1 - 2 days n(%)	3 - 4 days n(%)	5 - 6 days n(%)	Everyday n(%)
Over the last week, on how many days has your child's skin been itchy because of their eczema	11(28.9)	10(26.3)	5(13.2)	2(5.3)	10(26.3)
Over the last week, on how many nights has your child's sleep been disturbed because of their eczema?	15(39.5)	3(7.9)	2(5.3)	6(15.8)	12(31.6)
Over the last week, on how many days has your child's skin been bleeding because of their eczema?	14(36.8)	5(13.2)	7(18.4)	9(23.7)	3(7.9)
Over the last week, on how many days has your child's skin been weeping or oozing clear fluid because of their eczema?	17(44.7)	9(23.7)	5(13.2)	2(5.3)	5(13.2)
Over the last week, on how many days has your child's skin been cracked because of their eczema?	13(34.2)	13(34.2)	3(7.9)	0	9(23.7)
Over the last week, on how many days has your child's skin been flaking off because of their eczema?	18(47.4)	13(34.2)	0	4(10.5)	3(7.9)
Over the last week, on how many days has your child's skin felt dry or rough because of their eczema?	3(7.9)	1(2.6)	8(21.1)	10(26.3)	16(42.1)

4.4.1 Overall Severity of Atopic Dermatitis

The overall severity of eczema among the patients was assessed and scored using the POEM score, where the findings showed that 17(44.7%) of the patients had minimal eczema, 13(34.2%) had mild eczema, 5(13.1%) had moderate eczema, while 3(7.4%) of the AD patients had severe eczema, as shown in Figure 4.2.

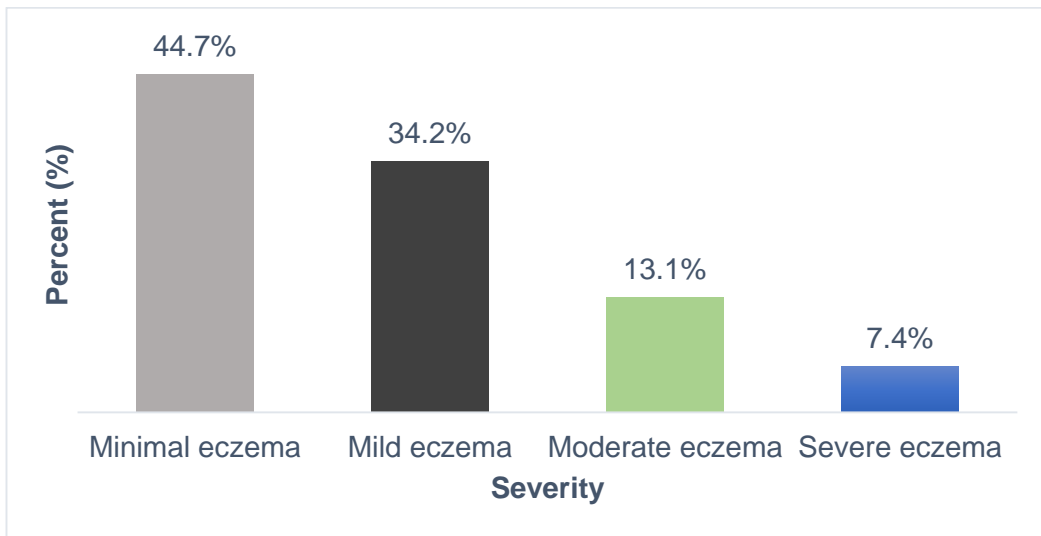


Figure 4.2: Overall Severity of Atopic Dermatitis

CHAPTER FIVE

DISCUSSION

AD poses a significant public health concern, mainly among children, although in the local context, it remains largely unexplored, which presents the need to understand its prevalence, severity, and associated factors. This chapter discusses the findings from the present study in relation to past literature in order to contextualize our present findings.

5.1 Characteristics of the Pediatric Patients Attending Dermatology Clinic

The current study showed that more than half of the patients were aged less than 10 years. These findings align with those from a study in Ethiopia, which revealed that more than two-thirds of those recruited into their study were aged less than 10 years (Kelbore et al., 2015). Similarly, findings from a study in Malaysia also found that most of the patients were aged less than 10 years (Sendrasoa et al., 2020). Many skin conditions, such as atopic dermatitis, eczema, and childhood rashes, are more common in early childhood. Pediatric dermatological conditions often emerge in the first decade of life, resulting in a higher proportion of young patients seeking dermatological care. Children are also more susceptible to various dermatologic issues like rashes, insect bites, and allergic reactions that may require medical intervention.

Our findings also showed that almost two-thirds of the patients were female. These findings are consistent with previous studies, which also found that most of the pediatric patients presenting at a dermatology clinic are female (Böhme et al., 2003; Kelbore et al., 2015; Sendrasoa et al., 2020). This could be explained by the assertion that certain skin conditions, such as eczema and rosacea, are more prevalent in females during early childhood and adolescence. The pattern may be partly explained by genetic predisposition, as well as environmental triggers that may affect females differently.

5.2 Prevalence of Atopic Dermatitis

Our current study established that one in four pediatric patients presenting at the dermatology clinic has atopic dermatitis. These findings are consistent with those from Al-Naqeeb et al., who found that in children 0 – 5 years the prevalence was reported at 24%, evidencing the high prevalence in this age group as opposed to older children, adolescents, and adults (Al-Naqeeb et al., 2019). Another study in Switzerland also revealed that the average age was 6.8 years, and infants and school children represented 60% of the study population. Half of the patients (51%) were external referrals, almost one-third (29%) presented spontaneously, and the remaining 20% were sent from other hospital departments. With a frequency of 25.9%, atopic dermatitis was the most frequent diagnosis, followed by pigmented nevi (9.1%) and warts (5.0%) (Wenk & Itin, 2003). Environmental factors such as air pollution, allergens, and climate change are significant contributors to the rise in allergic conditions like atopic dermatitis. Kenya, particularly in urban areas, has seen increased exposure to air pollutants, dust, and allergens. The urbanization of Kenya has led to overcrowded living conditions, increased exposure to dust mites, and other environmental triggers that are known to worsen the condition. Most of the patients in our study were residing in an urban setting, which could affirm this explanation.

However, the findings from the present study highlight a higher burden of AD compared to other studies. A study in Ethiopia established that the burden of AD was 9.6% (Kelbore et al., 2015). Another study in Northeast Croatia among school-going children aged between 12 and 14 years revealed that the estimated lifetime (ever) prevalence rate of atopic dermatitis symptoms was 7.55% and the estimated 12-month prevalence rate was 5.75% (Munivrana Skvorc et al., 2014).

Catro et al. (2010) conducted a study in Brazil involving 3,600 children aged 6-7 years and found a prevalence rate of 9.6% over a 1-year period. This rate indicates a moderate prevalence of atopic dermatitis in this age group in Brazil. The relatively high prevalence may reflect a combination of genetic and environmental factors, including urbanization, changes in lifestyle, and dietary habits, which have been linked to the rising incidence of allergic diseases such as AD in various parts of the world. Goh et al. (2018) studied 384 children aged 1-6 years in Malaysia and found a

prevalence of 13.4%. This higher prevalence compared to the Brazilian study could be due to different environmental, cultural, and healthcare factors specific to Malaysia. The higher burden of atopic dermatitis found in the present study could be attributed to a combination of genetic predisposition, environmental factors, healthcare access, and lifestyle differences, as compared to the studies conducted in Ethiopia, Northeast Croatia, Brazil, and Malaysia. The findings highlight the complexity of AD and underscore the need for context-specific research to understand the factors contributing to its prevalence and develop effective prevention and management strategies.

5.3 Factors Associated with Atopic Dermatitis

Our findings showed that the burden of AD was significantly higher in those aged less or equal to five years or younger. These findings align with those from a multicentre study in the United States examining the epidemiology and burden of AD; a significant portion of cases were found in younger children. The study highlighted that early childhood is a critical period for the onset of AD, with a higher incidence and burden observed in children under 5 years old (Sanclemente et al., 2021). Another study in Turkey reported that AD was most prevalent in infants and preschool children. Among 672 pediatric dermatology patients, a significant number were diagnosed with AD during the first five years of life, underscoring the higher burden of the disease in this age group (Tamer et al., 2008). This study supports the notion that early childhood is a pivotal time for both the manifestation and burden of AD. These findings emphasize the assertion that AD typically begins in the first year of life, and the severity of symptoms can peak during early childhood, making it a significant burden during this period. The immune system's developmental phase during this time may contribute to the higher prevalence and more severe manifestations of AD.

Despite the majority of female patients attending the dermatology clinic, our study established that the risk of AD was significantly higher in male pediatric patients. These findings align with those from a study in South Africa, which established that there was a significantly higher rate in male patients compared to women (Katibi et al., 2016). Another study in Sweden found that AD is more common in boys during early childhood (Bylund et al., 2020), which aligns with our study's findings. The higher prevalence in males is often observed in the first few years of life, but by

adolescence, the gender difference tends to level out or even reverse, with females becoming more affected. This study suggests that males are at a higher risk of developing AD at younger ages, particularly in the infantile and preschool years.

Our findings also showed that the odds of AD were higher among children whose mothers were unemployed. Unemployment is often associated with lower socioeconomic status, which can limit access to quality healthcare, preventive measures, and early interventions for conditions like AD. Children in lower-income households may have limited access to specialized dermatological care, leading to higher rates of undiagnosed or poorly managed AD.

The current study shows that individuals with a family history of allergic asthma, allergic rhinitis, allergic conjunctivitis, and atopic dermatitis themselves have significantly higher odds of developing AD. The odds ratios (OR) for these conditions are substantial, with allergic asthma having an OR of 9.46, allergic rhinitis 23.33, allergic conjunctivitis 5.98, and atopic dermatitis itself 8.22. These findings are consistent with the understanding that AD, along with other allergic conditions, often runs in families due to shared genetic predispositions. The higher the family history of these conditions, the more likely individuals are to develop AD, which can be attributed to common genetic factors influencing the immune system, skin barrier function, and inflammatory pathways. These findings are consistent with those from the United States, which revealed that children with a family history of allergic conditions like asthma, rhinitis, and eczema were significantly more likely to develop AD, supporting our finding that family history plays a critical role in the onset of AD (Sancllemente et al., 2021). These findings also align with those from a study in Croatia, which revealed that the factors found to be associated with the symptoms of atopic dermatitis ever were positive family atopy and positive family atopy (Munivrana Skvorc et al., 2014). The findings from a study in Ethiopia also established that family history of asthma and AD were associated with increased likelihood of AD among children (Kelbore et al., 2015).

The personal history of allergic asthma, allergic rhinitis, and allergic conjunctivitis also strongly correlates with higher odds of having AD. These personal associations reflect the concept of the "atopic march," where individuals with one allergic condition

(such as asthma) are more likely to develop other atopic diseases like AD, often starting in early childhood (Kelbore et al., 2015). This is due to similar immunologic mechanisms, particularly the involvement of the Th2 immune response, which is central to both AD and other allergic diseases. The immune system's heightened sensitivity to environmental allergens, such as pollen, dust mites, and pet dander, triggers inflammatory pathways that affect different parts of the body, leading to conditions like asthma, rhinitis, conjunctivitis, and AD. Yavena and Derlenski (2021) highlighted that atopic dermatitis (AD) is closely linked to asthma. According to Acharya, Bajgain, and Yoo (2019), allergic rhinitis typically causes symptoms like a runny nose, itchy nose, sneezing, and nasal congestion. In some cases, it can also cause itchiness in the eyes, throat, and ears.

5.4 Severity of Atopic Dermatitis

The distribution of eczema severity in this study highlights a predominance of minimal and mild cases, with a smaller percentage of patients experiencing moderate or severe eczema. These findings are comparable to those from a prospective cohort study in China, which examined early-onset AD in children and tracked the persistence of eczema up to the age of 12. The study found that the majority of cases were mild, but persistent AD cases had more moderate or severe forms of eczema, which aligns with the findings of higher severity in long-term AD cases (Zhang et al., 2021). This pattern suggests that a majority of AD patients in this cohort have relatively mild forms of the disease, which can typically be managed with basic skincare practices and topical treatments. However, the presence of moderate and severe cases, while less common, indicates the need for a more intensive, multifaceted approach for those with more severe symptoms.

Furthermore, the findings also suggest that there is a significant proportion of patients with manageable symptoms, which may help in designing educational programs aimed at promoting proper skin care, trigger avoidance, and early intervention. For those with more severe forms of AD, specialized care, including advanced therapies and psychological support, may be needed to address both the physical and emotional challenges of the disease.

5.5 Study Strengths and Limitations

The study was carried out in Kenyatta National Hospital, which is the largest referral and teaching hospital in the country, and was able to incorporate participants from different parts of the country and different socioeconomic classes. Also, this study is the first of its kind in the facility and in Kenya; thus, it offers a great foundation for evidence generation and reference.

Despite the notable strengths, the study was carried out in one Centre and may not give a general picture of atopic dermatitis in the whole country, as it was carried out in a public hospital, but this may differ in the private sector. However, this limitation did not affect the quality of the study findings, given that they are anticipated as per the study design.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

Our study revealed that atopic dermatitis (AD) is a significant concern in the pediatric population, accounting for 1 in 4, with a notable proportion of children presenting with mild to moderate forms of eczema. The severity of AD in these patients was assessed using the POEM score, with findings showing that 44.7% of patients had minimal eczema, 34.2% had mild eczema, 13.1% had moderate eczema, and 7.4% had severe eczema.

Interestingly, despite a higher number of female patients attending the dermatology clinic, our study showed that male children were at a significantly higher risk of developing AD. In addition, AD was also significantly higher among children aged five years and below. Family history of allergic conditions, such as allergic asthma, rhinitis, conjunctivitis, and atopic dermatitis, plays a significant role in increasing the likelihood of developing AD. The odds ratios for these conditions were substantial, emphasizing the genetic component and shared immunological pathways that contribute to the development of AD in children. The personal history of allergic asthma, allergic rhinitis, and allergic conjunctivitis also strongly correlates with higher odds of having AD.

6.2 Recommendations

The study offers the following recommendations in reference to findings related to Pediatric Atopic Dermatitis at the Kenyatta National Hospital, Kenya.

1. Implement early screening programs in pediatric dermatology clinics
2. Public health campaigns should emphasize the importance of recognizing the signs of atopic dermatitis early, especially for children at high risk due to family history and personal allergic conditions

3. Educational programs should be developed to help families understand the role of family history in AD and the importance of early skin care routines, allergen avoidance, and moisturization for at-risk children.
4. Future scholars interested in Atopic Dermatitis in children should investigate the effectiveness of early intervention programs for children at high risk of AD, particularly those with personal and family history of allergic diseases.

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APPENDICES

Appendix I: Parental/Guardian/ Care Giver Consent Form (English)

Participant Information and Consent Form for Enrollment in the Study

Title of the study: The Prevalence of atopic dermatitis and its Associated Factors w in Children between 6month and twelve years attending the Pediatrics Dermatology Clinic at Kenyatta National Hospital, Kenya (A Cross-Sectional Study)

Principal investigator/ and institutional affiliation: Dr. Zahara Haji Hassan, Registrar dermatology, College of Health Sciences, Jomo Kenyatta University of Agriculture and Technology.

This informed consent form has two parts:

- Information sheet (to share information about the study with you)
- Certificate of consent (for a signature if you choose to participate)

Part I: Information Sheet

Introduction

I am Dr. Zahara Haji Hassan, a medical doctor studying at the Jomo Kenyatta University of Agriculture and Technology, Department of Dermatology. I am conducting a survey on the '*The Prevalence of atopic dermatitis and its Associated Factors with in Children between six months and twelve years Attending the pediatrics Dermatology Clinic at Kenyatta National Hospital, Kenya.*' I am going to give you information about this study and invite you to participate in the study. Before you decide, you are free to ask for clarifications. This consent form may contain words that you do not understand. Please ask me to stop as we go through the information, and I will take time to explain. If you have questions later, please feel free to ask.

What is the study about?

The researcher and research assistant will enroll children aged 6 months through 12 years who are attending the dermatological clinic at KNH and evaluate their prevalence, symptoms, and factors related to atopic dermatitis. Since most of those targeted are children, you as the parent/guardian/care giver will be requested to consent on their behalf.

What will happen if you decide to be in this research study?

If you agree to participate in this study, the researcher and research assistant will determine if you are eligible for the study by exploring your diagnosis. You will be asked some questions on behalf for the child, but the child can as well respond if they are able to, about their atopic dermatitis condition. We will also use the child's health record for data that might not be recalled, but recorded in the health records. Your role will therefore be acting on behalf of the child, since they are a minor and not eligible to bidding consent.

Are there any risks, harms discomforts associated with this study?

There will be no physical harm or discomfort. We will protect your privacy using a code number to identify you in a password-protected computer database and keep all our paper records in a locked file cabinet.

The researcher and research assistants are professionals with special training in data collection in this type of study. In case of any concern during the survey, contact the study staff immediately at the number provided at the end of this document.

Are there any benefits in this study?

There will be no monetary or other compensation for participating in this study. This information is a contribution to science and will assist in developing guidelines that will help children facing the same problem of atopic dermatitis.

Will being in this study cost you anything?

No, being in this study will not cost you anything.

What If you have questions in the future?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your rights as a research participant, you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No.0202726300 Ext—44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay back your charges to these numbers if the call is for study-related communication.

Part II: Certificate of Consent

I _____ being the parent/guardian/carer of _____ I have been explained about the study “*The Prevalence of atopic dermatitis and its s Associated Factors in Children between six months and twelve years attending the Pediatrics Dermatology Clinic at Kenyatta National Hospital, Kenya.*” I have been invited to given consent voluntarily and without coercion to allow the child participate in the study. I have read the preceding information, or it has been read to me to my understanding. I have had the opportunity to ask questions about it and any questions I have been asked have been answered satisfactorily. I, therefore, consent willingly to allow the child be involved in this study.

Print Name of Parent/Guardian/Care giver _____

Signature of Parent _____ Thumbprint of

Date _____ (Day/Month/Year)

If not able to read and write,

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness _____

Signature of witness _____ Date _____

Day/month/year

Part III: Assent Form

Minor Assent Form (7-12 years)

Project Title: The Prevalence and Associated Factors of Atopic Dermatitis in Children between Six months and Twelve Years Attending the KNH Pediatrics Dermatology Clinic

Investigator: Dr Zahara Haji Hassan

My name is Dr Zahara Haji Hassan am a research and we are doing a research study about *the number of children with an itchy skin condition called topic dermatitis and how bad it can be.*

Permission has been granted to undertake this study by the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (KNH-UoN ERC Protocol **Ref. No. KNH-ERC/A/272.**

This research study is a way to learn more about children with skin problem. At least 148 children will be participating in this research study with you.

If you decide that you want to be part of this study, you will be asked to few questions concerning your personal information, how bad your disease has been last week but no one will examine your body nor any form of injections will be given.

There is no direct benefit when you participate in this study but this will help us know the number of children with eczema during this study period.

When we are finished with this study we will write a report about what we learned.

This report will not include your name or that you were in the study.

You do not have to be in this study if you do not want to be. If you decide to stop after we begin, that's okay too.

Your parents know about the study too.

If you decide you want to be in this study, please sign your name.

I, _____, want to be in this research study.

_____ (Signature/Thumb stamp)

Date.....

Statement by the researcher/person taking consent/Assent

I have accurately read out the information sheet to the potential participant, and to the best of my ability, making sure that the participant understood. I confirm that the participant was allowed to ask questions about the study, and all the questions asked have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the permission has been given freely and voluntarily.

Print Name of person taking the consent/Assent_____

Signature of person taking the consent_____

Date _____

Role in the study:

For more information, contact me, Dr Zahara Haji Hassan on 0721244752 or the Supervisor Dr Jacqueline Kavete on 0721580182

Appendix II: Fomu ya Idhini ya Mzazi/Mlezi

MAELEZO NA FOMU YA RIDHAA YA MSHIRIKI KWA KUJIANDIKISHA KATIKA MASOMO

Kichwa cha utafiti

Kuenea kwa ugonjwa wa Ngozi ya Atopiki na Sababu yanayohusishwa katika Watoto walio kati ya miezi sita na miaka kumi na miwili wanaohudhuria Kliniki ya Madaktari wa Ngozi ya Watoto katika Hospitali ya Kitaifa ya Kenyatta, Kenya

Mpelelezi mkuu/ na uhusiano wa kitaasisi:

Dk. Zahara Haji Hassan, Daktari wa Ngozi, Chuo cha Sayansi ya Afya, Chuo Kikuu cha Kilimo na Teknolojia cha Jomo Kenyatta.

Fomu hii ya idhini ina sehemu mbili:

- Karatasi ya taarifa (kushiriki nawe taarifa kuhusu utafiti)
- Cheti cha idhini (kwa sahihi ikiwa utachagua kushiriki)

Sehemu ya I: Karatasi ya Taarifa

Utangulizi

Mimi ni Dkt. Zahara Haji Hassan, daktari anayesoma katika Chuo Kikuu cha Kilimo na Teknolojia cha Jomo Kenyatta, Idara ya Madaktari wa Ngozi. Ninafanya uchunguzi kuhusu Kuenea kwa ugonjwa wa ngozi ya Atopiki na Sababu yanayohusishwa katika Watoto walio na umri kati ya miezi sita na miaka kumi na miwili wanaohudhuria Kliniki ya Madaktari wa Ngozi ya Watoto katika Hospitali ya Kitaifa ya Kenyatta, Kenya. Nitakupa taarifa kuhusu utafiti huu na kukualika kushiriki katika utafiti. Kabla ya kuamua, uko huru kuuliza ufafanuzi. Fomu hii ya idhini inaweza kuwa na maneno ambayo huelewi. Tafadhali naomba nisimame tunapopitia taarifa, na nitachukua muda kueleza. Ikiwa una maswali baadaye, tafadhali jisikie huru kuuliza.

Utafiti unahusu nini?

Mtafiti na msaidizi wa utafiti wataandikisha watoto wenye umri wa miezi 6 hadi miaka 12 wanaohudhuria kliniki ya ngozi katika KNH na kutathmini kiwango chao cha maambukizi, dalili na mambo yanayohusiana na ugonjwa wa Ngozi ya Atopiki. Kwa kuwa wengi wa walengwa ni watoto, wewe kama mzazi/mlezi utaombwa uidhinisha kwa niaba yao.

Je, nini kitatokea ukiamua kuwa katika utafiti huu?

Ukikubali kushiriki katika utafiti huu, mtafiti na msaidizi wa utafiti wataamua kama unastahiki utafiti kwa kuchunguza uchunguzi wako. Utaulizwa maswali kwa niaba ya mtoto, lakini mtoto anaweza pia kujibu ikiwa anaweza, kuhusu hali yao ya ugonjwa wa atopiki. Pia tutatumia rekodi ya afya ya mtoto kwa data ambayo huenda isikumbukwe, lakini iliyorekodiwa katika rekodi za afya. Kwa hivyo jukumu lako litakuwa likifanya kazi kwa niaba ya mtoto, kwa kuwa ni mtoto mdogo na hastahili kupata kibali cha zabuni.

Je, kuna hatari zozote, hudhuru usumbufu unaohusishwa na utafiti huu?

Hakutakuwa na madhara ya kimwili au usumbufu. Tatalinda faragha yako kwa kutumia nambari ya msimbo ili kukutambua katika hifadhidata ya kompyuta iliyolindwa na nenosiri na kuweka rekodi zetu zote za karatasi kwenye kabati ya faili iliyofungwa.

Mtafiti na wasaidizi wa utafiti ni wataalamu walio na mafunzo maalum ya ukusanyaji wa data katika aina hii ya utafiti. Iwapo kuna wasiwasi wowote wakati wa utafiti, wasiliana na wafanyakazi wa utafiti mara moja kwa nambari iliyotolewa mwishoni mwa waraka huu.

Je, kuna manufaa yoyote katika utafiti huu?

Hakutakuwa na pesa au fidia nyingine kwa kushiriki katika utafiti huu. Taarifa hizi ni mchango kwa sayansi na zitasaidia katika kuandaa miongozo ambayo itasaidia watoto wanaokabiliwa na tatizo sawa la ugonjwa wa ngozi ya atopiki.

Je, kuwa katika utafiti huu kutagharimu chochote?

Hapana, kuwa katika utafiti huu hakutakugharimu chochote.

Je, ikiwa una maswali katika siku zijazo?

Ikiwa una maswali zaidi au wasiwasi kuhusu kushiriki katika utafiti huu, tafadhali piga simu au tuma ujumbe mfupi wa maandishi kwa wafanyikazi wa utafiti kupitia nambari iliyotolewa chini ya ukurasa huu.

Kwa maelezo zaidi kuhusu haki zako kama mshiriki wa utafiti, unaweza kuwasiliana na Katibu/Mwenyekiti, Hospitali ya Kitaifa ya Kenyatta-Kamati ya Maadili na Utafiti ya Chuo Kikuu cha Nairobi Nambari ya Simu Na.0202726300 Ext—44102 barua pepe uonknh_erc@uonbi.ac.ke.

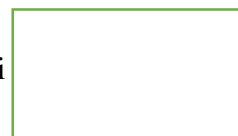
Wafanyikazi wa utafiti watalipia ada zako kwa nambari hizi ikiwa simu ni ya mawasiliano yanayohusiana na masomo.

Sehemu ya II: Cheti cha Idhini

Mimi _____ kama mzazi/mlezi/mlezi wa _____ Nimefafanuliwa kuhusu utafiti "Kuenea kwa Ugonjwa wa ngozi ya Atopiki na Sababu yanayohusishwa na Ugonjwa huo katika Watoto walio kati ya umri wa miezi sita hadi miaka kumi na miwili wanaohudhuria Kliniki ya Madaktari wa Ngozi ya Watoto katika Hospitali ya Kitaifa ya Kenyatta, Kenya." Nimealikwa kutoa idhini kwa hiari na bila shuruti kumruhusu mtoto kushiriki katika utafiti huu. Nimesoma habari iliyotangulia, au imesomwa kwangu kwa kuelewa kwangu. Nimepata fursa ya kuuliza maswali kuhusu hilo na maswali yoyote niliyoulizwa yamejibiwa vya kuridhisha. Kwa hivyo, ninakubali kwa hiari kuruhusu mtoto kushirikishwa katika utafiti huu.

Chapisha Jina la Mzazi/Mlezi/Mlezi _____

Sahihi ya Mzazi _____ Alama ya Kindole ya Mzazi



Tarehe _____ (Siku/Mwezi/Mwaka)

Kama hujui kusoma na kuandika,

Nimeshuhudia usomaji sahihi wa fomu ya idhini kwa mshiriki anayetarajiwa, na mtu huyo amepata fursa ya kuuliza maswali. Ninathibitisha kuwa mtu huyo ametoa kibali kwa uhuru.

Chapisha jina la shahidi _____

Saini ya shahidi _____

Tarehe _____ Siku/mwezi/mwaka

Sehemu III: Fomu Ndogo ya Uidhinishaji (miaka 7-12)

Kichwa cha Mradi: Kuenea na Sababu Zilizohusishwa za Ugonjwa wa Ngozi ya Atopiki kwa Watoto Kati ya Miezi Sita na Miaka Kumi na Miwili Kuhudhuria Kliniki ya Madaktari wa Ngozi ya KNH.

Mpelelezi: Dk Zahara Haji Hassan

Naitwa Dr Zahara Haji Hassan ni mtafiti na tunafanya utafiti kuhusu idadi ya watoto wenye ugonjwa wa ngozi unaoitwa topic dermatitis na jinsi inavyoweza kuwa mbaya.

Ruhusa imetolewa kufanya utafiti huu na Hospitali ya Kitaifa ya Kenyatta-Kamati ya Maadili na Utafiti ya Chuo Kikuu cha Nairobi (KNH-UoN ERC Protocol Ref. No.KNH-ERC/A/272).

Utafiti huu ni njia ya kujifunza zaidi kuhusu watoto wenye tatizo la ngozi. Angalau watoto 148 watashiriki nawe katika utafiti huu.

Ukiamua kuwa ungependa kuwa sehemu ya utafiti huu, utaulizwa maswali machache kuhusu taarifa zako za kibinafsi, jinsi ugonjwa wako ulivyokuwa mbaya wiki iliyopita lakini hakuna mtu atakayechunguza mwili wako wala aina yoyote ya sindano itakayotolewa.

Hakuna manufaa ya moja kwa moja unaposhiriki katika utafiti huu lakini hii itatusaidia kujua idadi ya watoto walio na ukurutu katika kipindi hiki cha utafiti.

Tukimaliza na somo hili tutaandika ripoti kuhusu tulichojifunza. Ripoti hii haitajumuisha jina lako au kwamba ulikuwa kwenye utafiti.

Si lazima uwe katika utafiti huu ikiwa hutaki kuwa. Ukiamua kuacha baada ya sisi kuanza, hiyo ni sawa pia.

Wazazi wako wanajua kuhusu utafiti pia.

Ukiamua ungependa kuwa katika utafiti huu, tafadhali saina jina lako.

Mimi, _____, nataka kuwa katika utafiti huu.

_____ (Sahihi/Muhuri wa kidole gumba)

Tarehe.....

Taarifa ya mtafiti/mtu anayekubali

Nimesoma karatasi ya habari kwa usahihi kwa mshiriki anayetarajiwa, na kwa uwezo wangu wote, kuhakikisha kuwa mshiriki anaelewa. Ninathibitisha kuwa mshiriki aliruhusiwa kuuliza maswali kuhusu utafiti, na maswali yote yaliyoulizwa yamejibiwa kwa usahihi na kwa uwezo wangu wote. Ninathibitisha kuwa mtu huyo hajashurutishwa kutoa idhini, na ruhusa imetolewa kwa uhuru na kwa hiari.

Chapisha Jina la mtu anayepokea kibali _____

Sahihi ya mtu anayekubali idhini _____

Tarehe _____

Appendix III: Questionnaire Tool

In facilitating the successful undertaking of this study as a participant, you are requested to respond to the prompts/questions listed below with utmost sincerity. The questionnaire is short one and your details are anonymized. At no single point will you be required to provide your personal data in this questionnaire, but you might have been asked to do so in the consent form.

Questionnaire Identity Number

Section A: Sociodemographic information

1. Age in full years and months _____ years, _____ month
2. Sex Male Female
3. Household setting Nuclear Extended
4. Number of siblings Alone less than 5 more than 5
5. Mother's occupation Employed Unemployed
6. Father's occupation Employed Unemployed

Section B: Associated Atopic Conditions

7. Is there family history (first degree) of any of these conditions?
 - a. Allergic Asthma Yes No
 - b. Allergic rhinitis Yes No
 - c. Allergic conjunctivitis Yes No
 - d. Atopic dermatitis Yes No
8. Which of these conditions have you ever been diagnosed with?
 - a. Allergic Asthma Yes No
 - b. Allergic rhinitis Yes No
 - c. Allergic conjunctivitis Yes No

Section C: Atopic Dermatitis Diagnosis

Diagnostic Criteria of Atopic Dermatitis using Kapur et al (20218) Criteria

Diagnosis is made where there is presence of itchy skin in addition to three minor criteria

Major criteria	Presence of an itchy skin condition
Minor criteria	Old children and adults
	vi. History of skin itchiness in skin creases
	vii. Personal history of asthma or allergic rhinitis
	viii. Personal history of general dry skin in the last year.
	ix. Visible flexural dermatitis.
	x. Age of onset of symptoms at age of below 2 years
	Children less than 4 years of age
	iv. History of skin itchiness of the cheeks.
	v. History of atopic disease in a first degree relative.
	vi. Eczema of the cheeks, forehead, and outer limbs.

Atopic Dermatitis present (.....) Absent (.....)

Section D: severity of AD Pediatric Patients using POEM score

Please circle one response for each of the seven questions below about your child's eczema. If your child is old enough to understand the questions, then please fill in the questionnaire together. Please leave blank any questions you feel unable to answer.

- Over the last week, on how many days has your child's skin been itchy because of their eczema?
No days 1-2 days 3-4 days 5-6 days Every day
- Over the last week, on how many nights has your child's sleep been disturbed because of their eczema?
No days 1-2 days 3-4 days 5-6 days Every day
- Over the last week, on how many days has your child's skin been bleeding because of their eczema?
No days 1-2 days 3-4 days 5-6 days Every day
- Over the last week, on how many days has your child's skin been weeping or oozing clear fluid because of their eczema?
No days 1-2 days 3-4 days 5-6 days Every day
- Over the last week, on how many days has your child's skin been cracked because of their eczema?

No days 1-2 days 3-4 days 5-6 days Every day
6. Over the last week, on how many days has your child's skin been flaking off because of their eczema?

No days 1-2 days 3-4 days 5-6 days Every day
7. Over the last week, on how many days has your child's skin felt dry or rough because of their eczema?

No days 1-2 days 3-4 days 5-6 days Every day

TOTAL SCORE.....

Thank you for your participation

THE END

Appendix IV: Study Timelines

Time Activity	2024						2025	
	February	March	April	May- July	August- November	December 2024-feb 2025	march	April- June
Topic search and approval								
Concept paper preparation								
Proposal development and approval at department level								
ERC review and approval								
Data collection								
Data analysis and results presentation								
Final report writing								
Manuscript preparation and dissemination								

Appendix V: Study Budget

Study phase	activity	Units	Unit costs	Total (Ksh)
Overall	Stationary i.e., pens.	60	10	600
	Internet.	2000/month	6	12,000
Proposal development.	Photocopying.	70	5	350
	Printing charges.	70	10	700
	Binding charges.	70	3	210
	ERC+NACOSTI	1	1	3000
Data collection.	Printing questionnaires, consent forms, and enrolment log	200 questionnaires 200 consents 10 enrolment logs	10	6000
	Research assistance levy.	2 persons	@10,000kshs monthly.	40,000
Data analysis.	Statistician's fees.			40,000
Dissertation write- up.	Printing dissertation.	70 x 2	10	1400
	Communications.	2000/month	2 months	6,000
Miscellaneous				30,000
Total				Ksh. 163,000