The impact of childhood atopic dermatitis on caregiver quality of life at Rahima Moosa Mother and Child Hospital.

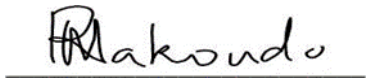
Rulani Makondo

A research report (in the format of a “submissible” paper) submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree Master of Science in Medicine (Dermatology).

Johannesburg, 2023

Declaration

I, Rulani Makondo, declare that this research report (in the format of a "submissible" paper) is my own, unaided work. It is being submitted for the Degree of Master of Medicine in Dermatology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



Signature of candidate

8th day of December 2023 in Johannesburg

Contribution of the candidate to the paper

Declaration: Student's contribution to article(s) and agreement of co-author(s)

I, Rulani Makondo, student number 1175756, declare that this Research Report is my own work and that I contributed significantly towards research findings presented in the paper intended for publication below.

Signature of Student:  Date: 08/12/2023

Name of Primary Supervisor 1: Nombuyiselo Mvulane

Signature of Primary Supervisor 1:  Date: 08/12//2023

Name of Primary Supervisor 2: Lindinkululeko Nkehli

Signature of Primary Supervisor 2:  Date: 08/12/2023

Agreement by co-authors: By signing this declaration, the co-authors listed below agree to the use of the article(s) by the student as part of her Research Report. In cases where the student is not the 1st author of a published article, the primary supervisor must explain (under comments) why the student is entitled to use the paper for his/her degree purposes.

Article Title: The impact of childhood atopic dermatitis on caregiver quality of life at Rahima Moosa Mother and Child Hospital.

Author	Name	Signature	Date
1st	Rulani Makondo		08/12/2023
2nd	Nombuyiselo Mvulane		08/12/2023
3rd	Lindinkululeko Nkehli		08/12//2023

Comments……

Dedication

This research report is dedicated to my loving and supportive family.

Acknowledgements

I would like to express my sincere gratitude to my supervisors Dr N Mvulane and Dr L Nkehli for the time, guidance and dedication to this research. I am also most grateful to the study participants without whom this study would not have been possible.

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Rulani Makondo [1] | Nombuyiselo Mvulane [1] | Lindinkululeko Nkehli [1]

1. Department of Internal Medicine, Division of Dermatology, Faculty of Health Sciences, The University of the Witwatersrand, Johannesburg, South Africa

7 York Road, Parktown, Johannesburg, South Africa, 2193

ruliemak@gmail.com/ 1175756@students.wits.ac.za

Tel: +27 11 488 3644

The authors declare that there is no conflict of interest.

Abstract

Background. Atopic dermatitis (AD) is the most common childhood skin disorder with a rising prevalence in developing countries, likewise South Africa. It is characterized by recurring pruritic cutaneous lesions, the control of which necessitates specific skin care measures and avoidance of triggers. The resultant impact on the quality of life (QOL) of the affected child is well established. Moreover, it places an added burden on caregivers as they have to allocate time and resources in activities aimed at achieving disease control to make the affected child comfortable.
Objectives. The primary objective of this study was to determine the psychosocial impact of childhood AD on caregiver QOL at Rahima Moosa Mother and Child Hospital (RMMCH) and to describe the association with disease severity and sociodemographic factors.
Methods. This was a cross-sectional study conducted at RMMCH, Coronationville, Johannesburg, South Africa from February to June 2022. Children aged 3 months to 16 years fulfilling the Hanifin and Rajka clinical diagnostic criteria for AD diagnosis presenting to the outpatient dermatology clinic with their primary caregiver were recruited into the study. Caregiver QOL was measured using the Dermatitis Family Impact (DFI) questionnaire which assesses the family impact of atopic dermatitis through a series of 10 lifestyle questions that are scored from 0 to 3. The overall DFI score ranges from 0 (no impact on family life) to 30 (maximum impact on family life). The score was further defined as follows; 0-5 = normal QOL; 6-10 = minor caregiver impact; 11-20 = moderate impact and greater than 20 = high impact. Disease severity was classified as per the scoring atopic dermatitis (SCORAD) index into either mild (score of at least 25), moderate (25-50) or severe (above 50) based on lesion extent, intensity and subjective patient symptoms. Patient demographics (age, gender, race, comorbidities, disease duration and treatment duration) and caregiver sociodemographic characteristics (relationship to the patient, gender, age, marital status, family set-up, other dependents, educational level, source of income and medical history) were recorded on the data collection sheet. Statistical tests were concluded at 5% level of significance.
Results. A total of 180 AD patient-caregiver pairs were recruited into the study. The median patient age (interquartile range (IQR)) was 60 months (36, 84) while the caregiver mean age (standard deviation (SD)) was 36 years (9). The mean QOL (SD) was 9.8 (7.3). Based on our suggested classification, 64 (35.6%) had a normal quality of life, 49 (27.2%) suffered a mild impact, 47 (26.1%) had moderate impact and 20 (11.1%) recorded the highest impact on their QOL. Most (72%) of the participants had mild disease while 20% had moderate and 8% had severe disease. There was positive association between the disease severity score and QOL score at 5% level of significance ($p<0.001$). The QOL perspectives reported by most as worst affected were emotional distress, expenditure, sleep disturbance, food preparation and housework interruption respectively. Patient age, disease duration and treatment duration inversely correlated with QOL scores. Except for marital status, the QOL impact score was independent of caregiver sociodemographic factors.
Conclusion. The study showed that childhood AD impacts negatively on caregiver QOL at a tertiary hospital in South Africa. The magnitude of which correlates with disease severity. The effect was independent of all caregiver sociodemographic factors except marital status. Patient treatment outcomes are dependent on the caregiver. Therefore, patient monitoring should incorporate caregiver QOL assessments.
Key words. Atopic dermatitis, quality of life, Dermatitis family impact questionnaire, scoring atopic dermatitis

Background

Atopic dermatitis (AD) is the most common childhood skin disorder worldwide [1]. Prevalence studies done in developing countries show a rising trend [1,2,3]. In South Africa, few epidemiologic studies have been done, Todd reported one year rates between 1-13.3% across the various paediatric age groups [4]. The disorder follows a chronic relapsing course characterized by itchy skin lesions that appear on different parts of the body [3]. Onset is often early in childhood, with the majority of cases presenting during the first year of life [5]. Disease activity often resolves by late adolescence, however in approximately 40% of the cases, it persists into adulthood [6].

It is well established that AD has a negative impact on the psychosocial wellbeing of the affected child [7]. In addition, paediatric chronic disorders affect the lifestyle of the caregiver who is responsible for providing care [8]. The impact of childhood AD on caregiver quality of life (QOL) has been shown to be comparable to disorders considered to be pathologically more severe such as insulin dependent diabetes mellitus [9]. Various facets that contribute to QOL are modified by having to care for a child with AD including the psychosocial, interpersonal and financial perspectives. Additional time and resources have to be committed to activities aimed at making the affected child as comfortable as possible. This is at the expense of income generating, recreational and self-care activities. The effect is decreased productivity in these areas with resultant loss of income and psychosocial wellbeing [10]. The magnitude of impact varies from mild to profound and is influenced by various factors. Chief amongst these factors is disease severity which has been shown to correlate with worsening QOL scores [11]. Poor caregiver QOL in turn is associated with worse treatment outcomes for affected children [12]. Several tools exist to assess the health related QOL in the setting of chronic disorders like AD. These range from tools that can be used for different disorders to disease specific tools. The Dermatitis Family Impact Questionnaire (DFI) is a validated standardized tool designed to specifically assess the impact of childhood AD on the QOL of the other family members [6].

Studies in Europe and Asia have demonstrated the impact of childhood AD on caregiver lifestyles [6,10,13]. In South Africa however, the magnitude of this impact is less well understood, with only one study on the subject known to the authors [12]. Any possible associations that may exist between this impact and sociodemographic factors in our setting have also never been explored. The objectives of this study were to determine the impact of childhood AD on caregiver QOL and to understand the relationship with disease severity and sociodemographic factors at a South African tertiary hospital. This knowledge will advocate for the development of context specific childhood AD care packages which incorporate caregiver QOL in assessments to guide treatment interventions. Such holistic care will contribute to the attainment of ideal patient and family outcomes particularly crucial in the face of rising AD prevalence rates in South Africa.

Methods

The study was conducted at Rahima Moosa Mother and Child Hospital (RMMCH), a public tertiary teaching hospital located in Coronationville, Johannesburg, South Africa. A cross-sectional study design was utilized. Participants were recruited from the outpatient paediatric

dermatology clinic which is conducted once a week. Eligible pairs comprised of children aged between 3 months and 16 years fulfilling a diagnosis of AD as per the Hanifin and Rajika criteria [14] presenting with the primary caregiver who was not responsible for the care of another dependent child with a chronic disorder other than AD. Consent and assent were obtained after the patient-caregiver pairs were counselled on the details of the study. A total of 180 successive consenting AD patient- caregiver pairs were recruited between February 2022 to June 2022. All data for each participant pair was collected on the same day at the clinic by the researcher. Caregiver QOL was assessed using the validated DFI questionnaire [15] administered by the researcher in either English or two of the local languages (isiZulu and seSotho) depending on participant preference. The isiZulu and seSotho questionnaires were back translated to english prior to use by independent translators to improve accuracy. The questionnaire comprised of 10 questions which assessed the changes to various areas of caregiver lifestyle over the past week as a result of caring for a child with AD. Each question was scored from 0 to 3 where; 0= Not at all; 1= A little; 2= A lot; 3= Very much. The overall DFI score was obtained by summing the individual scores of all the questions. The minimum DFI score was 0 (= no impact on life of the family) and the maximum was 30 (= maximum effect on the life of the family). Despite the absence of validated score banding descriptors for the DFI questionnaire [6], a suggested classification utilized in several other studies was used as follows; 0-5 = normal; 6-10 = minor family impact; 11-20 = moderate impact and greater than 20 = high family impact [16-18]. Disease severity was assessed using the scoring atopic dermatitis (SCORAD) index [19], which is a clinical tool that utilizes a formula to generate scores that are categorized to classify AD as either mild (score of at least 25), moderate (25-50) or severe (above 50) based on lesion extent, intensity and subjective patient symptoms. Patient demographics (age, gender, race, comorbidities, disease duration and treatment duration) and caregiver sociodemographic characteristics (relationship to the patient, gender, age, marital status, family set-up, other dependents, educational level, source of income and medical history) were recorded on the data collection sheet.

Ethics

Institutional and department approval to conduct the study was obtained from the relevant authorities at RMMCH. Ethical clearance was obtained from the Human Research Ethics (Medical) Committee at The University of the Witwatersrand (Ethics Reference: M2111139).

Statistical methods

Proportions were used to summarize qualitative data. The mean and standard deviation or median and interquartile ranges were used to summarize quantitative data, respectively where appropriate. The linear regression was used to determine association between demographic variables and the quality of life score. Statistical tests were concluded at 5% level of significance. All data analysis was carried out in STATA software package.

Results

Sociodemographic characteristics

A total of 180 patient-caregiver pairs were recruited into the study. The median patient age was 60 months; with 154(86%) being black and 106(60%) female. All the respondents were primary caregivers with a mean age of 36 years; 174(97%) were female with 165(92%) being mothers of the study participants. Seventy-two (40%) of the caregivers were single while 51(28%); 46(26%) and 11(6%) were married, cohabitating or had other forms of marital status respectively. About 133(74%) of the caregivers had at least another dependent aged below 16 years, 5(3%) of which had a known diagnosis of AD as well. Regarding employment status; 48(27%) were formally employed, while 44(24%), 28(16%), 50(28%) and 10(5%) were self-employed, housewives, unemployed or had other forms of employment, respectively. The most common caregiver comorbidity was HIV infection affecting 8% of the respondents; only 5% also had AD and another 5% had hypertension. Additional participant sociodemographic characteristics are presented in Table 1.

Table 1: Participant sociodemographic characteristics

Variable	Response (n (%))
Patient	
Age in months, median (IQR)	60 (36 – 84)
Age at diagnosis in months, median (IQR)	6 (3 – 18)
Disease duration in months, median (IQR)	45 (24 – 69)
Treatment duration in months, median (IQR)	44 (23 – 63)
Caregiver	
Age in years, mean (SD)	36 (9)
Comorbidities	
No	137 (76)
Yes	43 (24)
Family set-up	
Grandparent	6 (3)
Nuclear	99 (55)
Single	75 (42)
Caregiver level of education	
Primary	11 (6)
Secondary	100 (56)
Tertiary	69 (38)

Caregiver quality of life

The QOL (standard deviation (SD)) score was 9.8 (7.3). On further classification; 64 (35.6%) had normal QOL, 49 (27.2%) had mild impact on their QOL, 47 (26.1%) had moderate impact and 20 (11.1%) had the highest impact. The QOL domains that reported the most impact as measured by the highest numbers of "very much" and 'a lot" responses were emotional distress with 106 caregivers reporting it had more than a "little effect" on their lifestyles followed by expenditure (n=96), sleep disturbance (n=72) and food preparation (n= 56). Fewer caregivers reported an impact on shopping and relationships with 140 (78%) and 139 (77%) reporting taking care of a child with AD had "no effect" on these parameters respectively. Caregiver responses to the DFI questionnaire are provided on Fig 1.

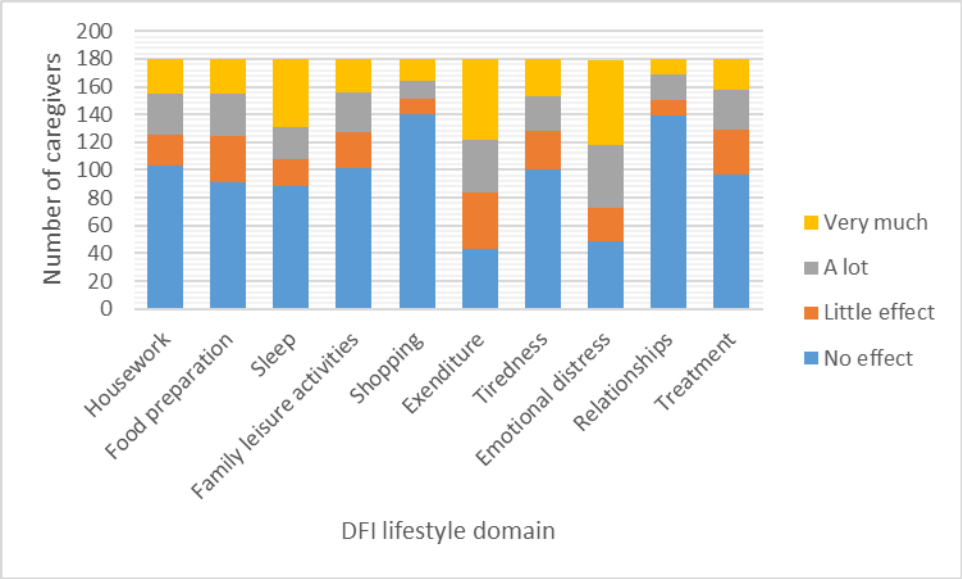

Fig 1: Responses from the Dermatitis Family Impact questionnaire (N=180)

Disease Severity

AD severity was classified as mild in 72% (n=128) of the patient participants, moderate in 20% (n=36) and severe in 8% (n=15).

Association between quality of life and disease severity

There was a statistically significant association between the QOL and the disease severity score ($p < 0.001$), participants with moderate and severe disease scores had QOL scores of 11 and 14.94 higher than for those with mild disease. The caregivers of children with higher disease severity scores therefore had worse QOL. The mean (SD) QOL score was 6.4(4.4) for mild disease severity, 17.4 (5.5) for moderate and 21.3 (5.2) for severe disease. Additional information is available in Fig 2.

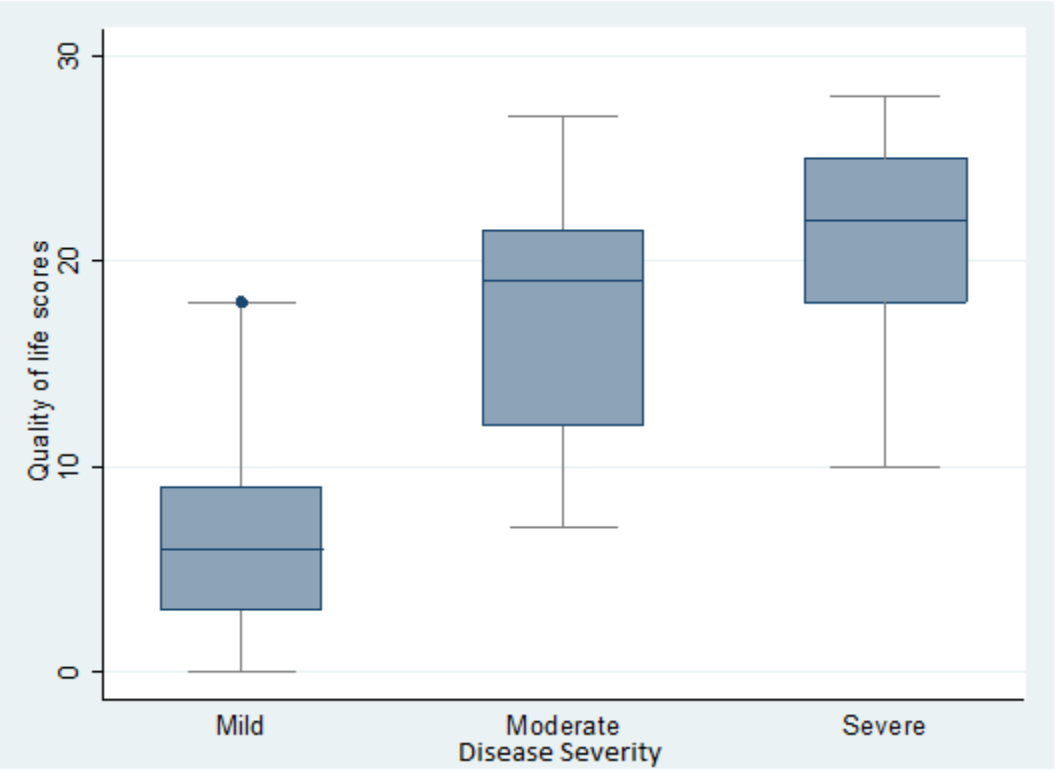

Fig 2: Disease severity and quality of life

Association between quality of life and participant sociodemographic characteristics

There was a statistically significant association between the patient's age and quality of life (p = 0.010), for a month increase in the age of the patient, the quality of life score decreases by an average of 0.04. Participants with disease duration greater than one year had average QOL scores 4.5 times less than those below a year. There was also an association between treatment duration and QOL, with those who had been on treatment for more than a year having scores 3.85 times less than those with less than a year. Therefore, increasing patient age, disease and treatment duration was associated with better caregiver QOL outcomes. Caregiver sociodemographic characteristics were not associated with QOL scores except marital status (p = 0.021), for which unmarried participants had worse QOL outcomes, with their average QOL scores 3.43 times higher than those of their married counterparts. Additional information is available in table 2.

Table 2. Association between quality of life and other study variables

Variable	*B* (95% CI)	p-value
Age in months	-0.04 (-0.07; -0.01)	0.010
Gender		
Female	Ref	-
Male	1.67 (-0.52; 3.85)	0.134
Race		
African	Ref	-
Other	-1.95 (-4.99; 1.09)	0.208
Age at diagnosis	-0.02 (-0.07; 0.03)	0.386

Disease duration in months	-0.03 (-0.06; 0.01)	0.072
Disease duration in years		
<1 year	Ref	-
>=1 year	-4.25 (-7.53; -0.96)	0.012
Treatment duration in months	-0.02 (-0.05; 0.01)	0.176
Treatment duration in years		
<1 year	Ref	-
>=1 year	-3.85 (-7.11; -0.59)	0.021
Caregiver gender		
Female	Ref	-
Male	2.3 (-3.7; 8.2)	0.458
Caregiver age	-0.09 (-0.21; 0.04)	0.171
Caregiver marital status		
Married	Ref	-
Single	1.19 (-1.42; 3.81)	0.368
Unmarried	3.43 (0.54; 6.34)	0.021
Other	0.57 (-4.18; 5.13)	0.813
Relationship to patient		
Mother	Ref	-
Other	-1.33 (-5.23; 2.55)	0.499
Other dependents		
None	Ref	-
Yes	1.29 (-1.15; 3.73)	0.300
Other family member comorbidities		
No	Ref	-
Yes	4.09 (-2.42; 10.60)	0.217
Family setup		
Single	Ref	-
Nuclear	-0.23 (-2.43; 1.96)	0.833
Grandparent	-5.47 (-11.55; 0.62)	0.078
Caregiver level of education		
Primary	Ref	-
Secondary	1.19 (-3.40; 5.78)	0.609
Tertiary	0.89 (-3.80; 5.58)	0.708
Parental Income		
Child grant	Ref	-
Parental income	-1.05 (-3.74; 1.63)	0.439

Discussion

Our study established that childhood AD impacts the QOL of caregivers at a tertiary hospital in South Africa. Using our suggested DFI score band descriptors, 64.4% of caregivers suffered a negative impact on their QOL due to the disorder. Mild impact was recorded in 27.2%, moderate in 26.1% and the highest on 11.1%. The impact was higher with worsening disease severity as evidenced by QOL scores that were 3 to 3.5 times higher in the moderate to severe disease

groups versus the mild. The mean DFI values also suggested mild impact for mild disease severity, moderate impact for moderate disease and the highest impact for severe disease. Our findings are consistent with those seen in regional and international studies which have also demonstrated declining QOL in families of children with AD correlating with worsening disease severity [10,12,16,18]. Consequently, the observed overall mean DFI scores and magnitude of impact in these studies was influenced by disease severity in the study population. Our sample comprised mostly of participants with mild disease hence the observed higher prevalence of mild impact. The observed association between the impact on caregiver QOL and disease severity in our study is an expected result ensuing from the increased burden on caregivers to heighten measures to make the child more comfortable with worsening disease.

All the QOL perspectives measured in the study were affected. Emotional distress, expenditure, sleep disturbance, food preparation and housework interruption respectively attained the highest numbers for most effect. Similarly, a study done in Saudi Arabia found these same perspectives excluding housework interruption to have the highest level of disturbance [16].

The question on emotional distress in the DFI questionnaire was developed to represent various psychological features such as depression, frustration, feelings of guilt, resentment and helplessness [15]. A combination of various factors could be responsible for the levels of emotional distress reported in our study. Caregivers worry over the long term impact of AD on the physical and social development of the child with concern over lifelong negative sequelae. Anxiety may also exist on the natural progression of the disorder; with a fear it may be lifelong without remission. Use of treatment modalities over extended periods of time also creates concerns surrounding development of side effects. Caregivers feel responsible to make their child feel more comfortable yet disease flares can be unpredictable leaving them helpless and with emotions of guilt [13]. Caregivers in particular mothers of children with chronic disorders likewise AD have been shown to have higher rates of anxiety and depression with one study showing this impact to be independent of disease specifics such as severity [20]. 92% of caregivers in our study were mothers to the participants.

Childhood AD was reported to increase family expenditure by all caregivers in our study. This increase was related to funds being directed to treatment and activities targeting disease control. High income earners in South Africa have been shown to opt for private health institutions [21]. Our participants are likely lower income earners that utilize public hospitals and lack financial cushions to lessen the burden of added expenditure presented by AD further compounding the impact [21]. Although generally considered to be a mild skin disorder, the financial burden of AD has been shown to parallel seemingly more severe diseases like psoriasis and emphysema [10]. The chronicity and recurring nature of the disorder necessitates funds to be diverted towards hospital visits, frequent cleaning to eliminate house dust mite, purchase of prescribed medications, emollients, dressings and linens for extended periods of time [10]. In addition, higher rates of absenteeism and poor work performance have been demonstrated in caregivers of children with AD further contributing to loss of family income [13,22,23]. More than half of the caregiver respondents in our study held some form of employment which could likewise be affected.

Of the 10 QOL perspectives assessed in the study, food preparation was the 4th most affected. The causative role of diet in AD has been shown to be largely restricted to a small proportion of patients with severe disease. Evidence of such allergy is often also demonstrable on patient

symptom enquiry [5]. Benefit in avoidance of certain foods is only drawn in these select patients with true hypersensitivity. Despite this, a general misconception exists, placing AD as primarily a food allergy [24]. This belief possibly explains the magnitude of impact of AD on food preparation demonstrated in our study as caregivers' endeavor to provide exclusive diets free of foods considered to be major allergen culprits such as dairy and eggs. Provision of these diets on unselected patients has been shown to be of no benefit in AD symptom control [23]. Alternative diets considered to be hypoallergenic on the other hand may not be readily available and thus costlier to affected families. Moreover, they are also sometimes less palatable as well as deficient in vital nutrients resulting in poor feeding and malnutrition [25]. Our findings highlight the importance of improving caregiver knowledge on scientific proven AD management methods. Caregiver counselling on the individualized role of diet in AD can clarify misconceptions surrounding food preparation and avert unnecessary costly diets.

Regarding housework, daily activities such as washing and cleaning were reported to be significantly affected by almost a third of caregivers. In the South African context women who are often also the mothers in the family setup are usually responsible for housework [26]. Caregivers in our study were mainly female and mothers. During disease flares, activities to make the child more comfortable such as changing linens, distracting from scratching, attending to the child at night, applying emollients and prescription medications increase the housework burden and take time away from the usual household activities [10,13].

Questions on perspectives surrounding family leisure activities and shopping on the DFI were not tailored to the South African context. The activities inquired on such as swimming were not common practice in our study population and this may have affected the findings. Development of tools tailored to our population is key to producing reliable context specific results. Ambiguity also existed in differentiating between "very much" and "a lot" responses on the DFI questionnaire more so after translation to the local languages.

Despite our sample being drawn from a tertiary hospital were the assumption would be a population with severe disease, 72% of the patient participants had mild disease [27]. The sample mean treatment duration was 44 months. The prolonged treatment duration might correlate with improved disease control due to pharmacotherapy and improved caregiver knowledge on management of AD resulting in the higher proportion of mild cases observed in the study [28].

Except for marital status, QOL impact did not correlate with the caregiver sociodemographic factors studied such as age, educational status, comorbidities, gender and employment status. Single caregivers had higher QOL scores, possibly highlighting the burden of taking care of a child with AD without other forms of psychological, physical and financial support in the home. Extended family either in the form of a partner, spouse or other relative can provide a cushion to the primary caregiver therefore lessening the QOL impacts that come with taking care of a child with AD. Patient age, disease duration and treatment duration inversely correlated with QOL scores. This finding likely reflects a combination of both effective pharmacotherapy as well as improved caregiver knowledge on AD and its management.

Caregiver psychosocial and financial wellbeing is a key component of achieving good treatment outcomes in children with AD. Poor caregiver quality of life negatively impacts the care provided to the affected dependent child. Our study showed that childhood AD disease severity correlates well with caregiver QOL scores, therefore incorporating these to monitor treatment response will complement pharmacotherapy and allow early interventions to preserve caregiver

wellbeing. Context specific QOL tools that can easily be administered by clinicians during patient reviews should be developed. The findings of these assessments should complement patient clinical assessments to guide treatment. An information package on AD should be made available to all caregivers, promoting beneficial skin care practices and demystifying misconceptions as well as non-beneficial interventions. Caregivers should be provided with support structures, for example in the form of support groups within their reach to link them with people in similar situations to exchange ideas on psychosocial and financial coping mechanisms. Future research on context specific forms of social support systems for these caregivers will guide the development of appropriate structures. A referral system to the psychology and social services department should be developed for caregivers whose lifestyles have been severely affected to allow for appropriate interventions to restore wellbeing.

The study was done at a tertiary care facility located in an urban setting. In addition, the sample comprised mostly of participants with mild disease. The results might therefore not be representative of non-urban populations as well as patients with moderate to severe disease. The administrative setting of the study at a busy outpatient clinic limited the caregiver variables that we could investigate. Future studies addressing this limitation could provide additional information for policy development.

Conclusions

Paediatric AD negatively impacts the QOL of caregivers at a tertiary hospital in South Africa. This effect correlates with disease severity and is independent of most caregiver sociodemographic factors except marital status.

The control of childhood AD relies strongly on the caregiver who has to provide support and institute the recommended skin care practices. A burdened caregiver is unlikely to be in a position to provide this care. To improve patient treatment outcomes and maintain family wellbeing, it is crucial to include caregiver QOL assessments during patient treatment reviews. The development of context specific easy to administer QOL tools that can be used in a clinic setting is pertinent to guiding treatment and referring caregivers in need to appropriate psychosocial support structures within the community and healthcare setting. Information on the pathophysiology of AD should be continually reinforced to patients and their caregivers to promote beneficial skin care practices, alleviate fears and misconceptions regarding the disorder. Improved understanding will contribute not only to disease control but psychosocial wellbeing as well.

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Appendix A. Approved research protocol (with expanded literature review) and appendices

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

11 September 2023
Person No: 1175756
TAA

Dr R Makondo
Helen Joseph Hospital Doctors Quarters, Unit 38, 1 Pert
Auckland Park, 2092
Sandown
Helen Joseph Hospital Doctors Quarters, Unit 38, 1 Pert
2092
South Africa

Dear Dr Rulani Makondo

Master of Medicine in Dermatology: Change of title of research

I am pleased to inform you that the following change in the title of your Research Report for the degree of **Master of Medicine in Dermatology** has been approved:

From:	**The impact of childhood atopic dermatitis on caregiver quality of life at Rahima Moosa mother and child hospital (RMMACH)**
To:	**The impact of childhood atopic dermatitis on caregiver quality of life at Rahima Moosa Mother and Child Hospital**

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

06 January 2023
Person No: 1175756
PAG

Dr R Makondo
Helen Joseph Hospital Doctors Quarters, Unit 38, 1 Pert
Auckland Park, 2092
Sandown
Helen Joseph Hospital Doctors Quarters, Unit 38, 1 Pert
2092
South Africa

Dear Dr Rulani Makondo

Master of Medicine in Dermatology: Approval of Title

We have pleasure in advising that your proposal entitled *The impact of childhood atopic dermatitis on caregiver quality of life at Rahima Moosa mother and child hospital (RMMACH)* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

CANDIDATE'S SURNAME: [Please print] **MAKONDO**	FIRST RULANI NAME/S:	STUDENT NUMBER: **1175756**
CURRENT QUALIFICATIONS: **MBChB; MPH**		
TEL: **n/a**	CELL: **0603909667**	E-MAIL: **ruliemak@gmail.com** FAX:**n/a**
DEGREE FOR WHICH PROTOCOL IS BEING SUBMITTED: **MMed in Dermatology**		
PART-TIME OR FULL-TIME: **FULL-TIME**		
FIRST REGISTERED FOR THIS DEGREE:	TERM : **1**	YEAR: **2020**
DEPARTMENT: **MEDICINE (DERMATOLOGY)**		
TITLE OF PROPOSED RESEARCH: **THE IMPACT OF CHILDHOOD ATOPIC DERMATITIS ON CAREGIVER QUALITY OF LIFE AT RAHIMA MOOSA MOTHER AND CHILD HOSPITAL (RMMACH).**		
CANDIDATE'S SIGNATURE: RMakondo		DATE:**27/07/2021**
SUPERVISOR 1 (NAME & SURNAME): **NOMBUYISELO MVULANE**		% Supervision **50**
SUPERVISOR'S QUALIFICATIONS: **MBChB; MSc EPIDEMIOLOGY; FC DERM (SA)**		
SUPERVISOR'S DEPARTMENT: **DERMATOLOGY**		
SUPERVISOR'S ADDRESS / TEL / E-MAIL: **CMJAH, JUBILEE RD, PARKTOWN, JHB/ 082560270/ nombuyiselomvulane@gmail.com**		
SUPERVISOR 2 (NAME & SURNAME): **LINDINKULULEKO NKEHLI**		% Supervision **50**
SUPERVISOR'S QUALIFICATIONS: **MBChB, MMEd DERMATOLOGY (Wits), FC Derm (SA)**		
SUPERVISOR'S ADDRESS / TEL / E-MAIL: **CHBAH, 26 CHRIS HANI ROAD, DIEPKLOOF, JHB/ 0837852882/ jabszako@yahoo.co.uk**		
SUPERVISOR 3 (NAME & SURNAME):		% Supervision
SUPERVISOR'S QUALIFICATIONS		
SUPERVISOR'S ADDRESS / TEL / E-MAIL:		

***SYNOPSIS OF RESEARCH**:(Brief summary of proposed research project; between 200-300 words only; with subheadings: an introduction and justification for study, aim/s, proposed methodology and expected outcome/s)*
[Use reverse side of this page if more space is required]

Introduction

Atopic Dermatitis (AD) is the most common childhood skin disorder worldwide with increasing prevalence in developing countries like South Africa. AD falls within the category of chronic disorders which though inherently not life threatening on their own pathological basis, can still significantly impact the quality of life (QOL). The negative lifestyle impacts of AD on affected children are well established. Pediatric patients are dependent on a caregiver whose lifestyle is invariably affected by any chronic conditions affecting the child as they are responsible for their care. Studies done in other countries have shown the negative impact of pediatric AD on caregiver QOL. Few studies exist in our setting on the subject.

Justification

The purpose of this study is to assess the impact of pediatric AD on QOL as well as the factors related to it. The findings will inform practitioners to extend pediatric AD management to caregiver QOL changes. Such holistic care will preserve family wellbeing and improve patient related outcomes.

Aims

To determine the impact of pediatric AD on caregiver QOL

Methodology

The study will be done at RMMACH between January 2022 and December 2022. A minimum sample size of 177 will be drawn from patients attending the pediatric dermatology outpatient clinic. A prospective cross-sectional study design will be utilized. Convenience sampling will be used to recruit eligible participants after consent and assent is obtained. The researcher will collect the demographic data, administer the questionnaire and conduct the relevant physical examinations which are also form part of routine patient care.

Expected outcomes

- Information on the impact of pediatric AD on QOL
- Information on the factors related to the impact of pediatric AD on caregiver QOL in a South African setting

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WITS ETHICS NOT REQUIRED: Yes No WITS ETHICS PENDING: Yes No WITS ETHICS APPROVED: Yes No (circle appropriate symbol)* ***Please note the final human ethics clearance certificate or animal ethics certificate must be available prior to starting research**		IF SUPPLY ETHICS CLEARANCE CERTIFICATE AS ATTACHMENT AND INCLUDE ETHICS NUMBER HERE:
As supervisor/s, I/we confirm that I have read the protocol which has en submitted for assessment. be		
SIGNATURE OF SUPERVISOR/S:		.....
SIGNATURE PG OFFICE STAFF	REGISTERED YES..... NO.....	STAMP

THE IMPACT OF CHILDHOOD ATOPIC DERMATITIS ON CAREGIVER QUALITY OF LIFE AT RAHIMA MOOSA MOTHER AND CHILD HOSPITAL.

Student details

Student name	Rulani Makondo
Student number	1175756
Email address	ruliemak@gmail.com
Department	Internal Medicine, Division of Dermatology
Course	Master of Medicine in Dermatology

Supervisors

1. Dr Mvulane Nombuyiselo, MBChB, MSc Epidemiology (Biostatistics and Epidemiology), F C Derm (SA). Consultant, Department of Dermatology, CMJAH
2. Dr Nkehli Lindinkululeko, MBChB, MMed (Dermatology), F C Derm (SA). Acting Head of Unit, Department of Dermatology, CHBAH

1. INTRODUCTION

1.1 Background

Atopic dermatitis (AD) is the most common childhood skin disorder, with an estimated worldwide prevalence that lies between 5 - 20% [1]. Prevalence rates seem to vary with age and geographic location [2]. The prevalence in developed countries is reported to have plateaued between 10-20% [3]. Data on the epidemiology of atopic dermatitis in Africa is limited, however, studies report a rising prevalence [2,3]. According to Todd the few prevalence studies that have been done in South Africa show paediatric prevalence rates that lie between 1 - 13.3% [4].

AD is a complex skin disorder whose pathogenesis is still not fully understood. Studies indicate that its origins are multifactorial and result from an interplay of: genetics; impaired skin barrier function; infection; environmental factors; and immunological dysregulation [5]. Its onset is often early in life, with approximately 60% of cases starting within the first year of life [6]. Disease activity often resolves around puberty in the majority of the cases, however, for some it persists into adulthood [7]. It tends to be associated with other atopic disorders such as allergic rhino-conjunctivitis, food allergy, and bronchial asthma; often as the forerunner with the sequential progression to the other disorders coined the atopic march [8].

AD is characterized by a chronic relapsing course of skin lesions that are intensely itchy, particularly at night. The appearance of the lesions varies depending on the chronicity of the disease. Acute lesions are characterized by erythematous oedematous plaques with different degrees of vesiculation; subacute lesions are often oozing and crusted; while chronic lesions are typically lichenified, which describes the leathery thickening and exaggerated markings of the affected skin [3]. In addition, skin lesions often also present with secondary changes which follow scratching such as excoriations, erosions and superimposed infection [5]. The topography of the lesions on the body varies with age: the scalp, face, neck, and extensor extremities are commonly affected in infancy; early childhood is characterized by lesions on the inner flexural surfaces of the extremities, similar to late childhood and adolescence, which additionally shows involvement of the hands and feet [6].

To date, there is no specific test for the diagnosis of AD. The diagnosis is instead based on a constellation of findings from the patient's history and clinical examination, assisted by laboratory findings. Several criteria have been developed based on these findings to assist in making the diagnosis of AD. The 1980 Hanifin and Rajka criteria is the earliest and most widely used. According to this criteria, a diagnosis of AD is met when three out of four major or three out of twenty-three minor criteria are present as represented in Appendix 1 [9].

The management of atopic dermatitis is multifaceted and follows stepwise therapies guided by: the severity of the condition; the location of the lesions; and the age of the patient [9]. Education on the disorder, its chronicity, and avoidance of triggers is also provided. The liberal use of emollients or moisturizers is also emphasized. Pharmacotherapy consists of topical corticosteroids

and calcineurin inhibitors. More severe disease warrants the use of systemic immunosuppressive agents or the newer biologic agents. Adjuvant therapies for itch are also routinely prescribed, while treatment for superimposed viral and bacterial infections is provided as indicated [6].

1.3 Literature Review

Quality of Life

Quality of life (QOL) is a complex broad concept that defines an individuals' perception of their physical, psychological, financial, and social well-being in the environment in which they exist. Health related QOL assesses the direct and indirect impacts of disease by examining several facets which include the social, psychological, financial and emotional well-being [12].

Impact of paediatric AD on the lifestyle of caregivers

AD falls within the category of chronic disorders which, though inherently not life threatening on their own pathological basis, result in a significant impact on QOL [11]. Su et al found the impact of moderate to severe atopic dermatitis on family QOL to be comparable to that for insulin dependent diabetes mellitus despite the latter being considered to be a more severe disease [12]. Paediatric AD negatively impacts not only the lifestyle of the affected child, but additionally that of the caregiver who is responsible for providing care [13, 14, 15, 16]. Figure 1 summarizes the various components of patient and caregiver QOL affected by pediatric AD.

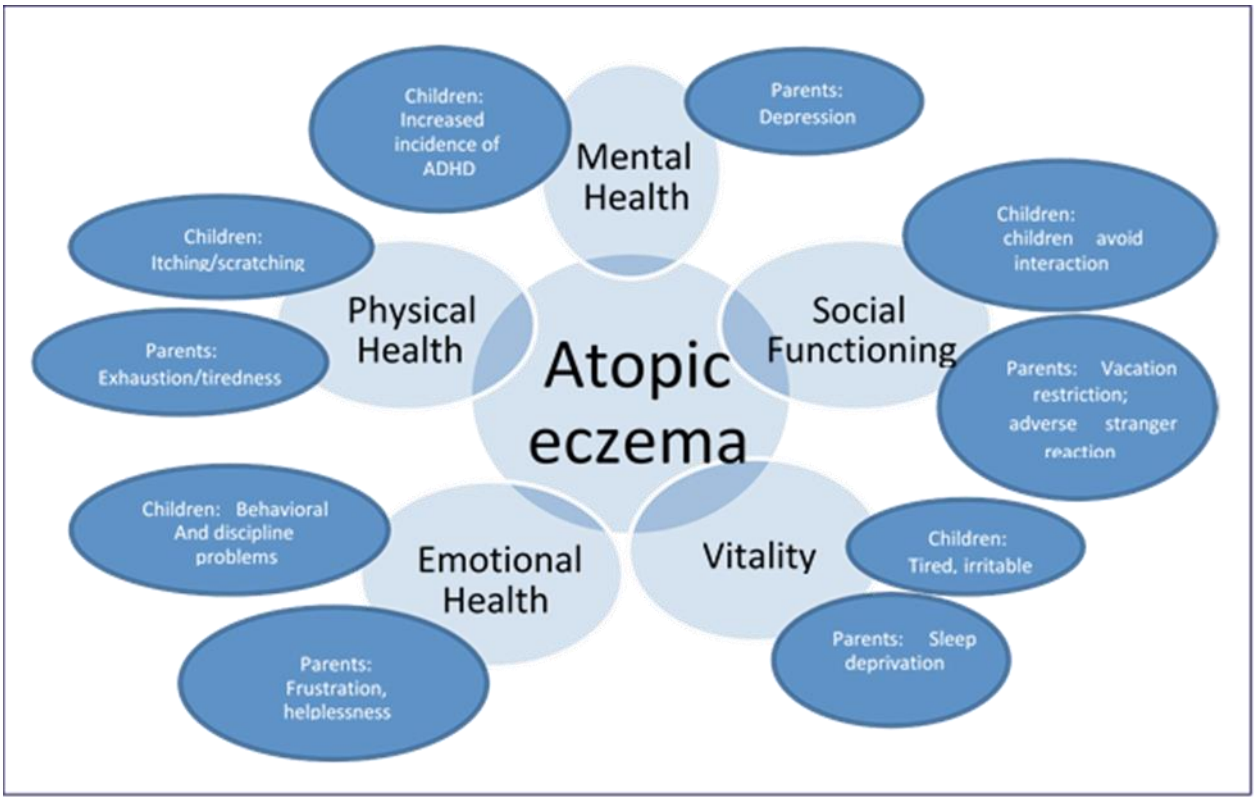

Figure 1: The influence of atopic dermatitis on quality of life aspects [1,18]

Up to 60% of children with AD are reported to have some form of sleep disturbance which includes: frequent waking episodes; inadequate sleep and difficulty falling asleep mainly due to the associated itch [7]. This translates to sleep disturbances in the caregivers, with approximately 60% having to wake up at least twice per night to tend to the affected child [14]. During exacerbations up to an additional mean of 18 hours per week can be spent by caregivers in activities related to AD such as: distracting from scratching; treatment applications; frequent bathing; special cleaning to eliminate house dust mite; the frequent changing of bed linens and on hospital visits [14,15]. The result is an interruption in participation in other daily activities; social and work related. There is fatigue, decreased work productivity, absenteeism and increased unemployment rates [7,15].

Caregivers also experience an array of psychological problems, ranging from: anger; frustration; mood instabilities; depression; feelings of helplessness and inadequacies as parents or caregivers [17]. Anxiety may also develop around use of prescribed medications, especially topical corticosteroids [18]. Family relationship dynamics are also affected [15]. Mothers in particular have been shown to bear the greatest burden of having a child with atopic dermatitis, as they are often the most involved in caring for the affected child [15]. The psychological impact is compounded by restrictions on family ownership of pets, and engagement in recreational activities such as swimming which have the potential to trigger AD episodes [15].

Moreover, the need for funds to be directed towards transportation to the hospital, consultation fees, emollients, prescribed medications, modified diets, special material clothing, linens, and frequent cleaning impacts on the family budget [14]. The financial impact of atopic eczema has been shown to be comparable to that of other chronic disorders such as psoriasis and emphysema [18]. Table 1, based on the findings from various studies, provides a summary of various caregiver lifestyle adverse outcomes that may occur as a consequence of caring for a child with AD.

Table 1: Impact of Atopic Dermatitis on Caregiver Quality of Life [7, 14, 15, 17, 19]

Key Area	**Lifestyle adverse outcome**
Psychological and Personal	• Stress • Mood instabilities • Depression • Sleep deprivation
Social	• Restrictions on owning pets • Restrictions on family recreational activities to avoidtriggers such as swimming • Reduced time for recreational or social activities
Interpersonal	• Family interpersonal relationship dynamics affected
Financial	• Financial strain with funds diverted to hospital consultations, medication, specialized diets, linen andcleaning

Professional	• Poor work performance and productivity • Poor coping skills • Increased work absenteeism • Increased job loss and unemployment rates

Assessment of caregiver QOL

The impact of disease on health related QOL is measured by instruments that assess the effect of the disease and its treatment on various lifestyle facets [19]. Various instruments have been validated to measure the impact of chronic disorders on QOL over the years [1]. Several of these can be applied to assess the effect of AD on the caregiver QOL. These range from generic instruments that can be applied for a wide array of chronic disorders, and are useful in comparing the lifestyle impacts of different conditions, to dermatology and atopic dermatitis specific measures (Table 2) [7]. Dermatology specific tools include the Dermatology Life Quality Index (DLQI) and the Family Dermatology Life Quality Index (FDLQI), these assesses the impact of different dermatological disorders, not just atopic dermatitis, on QOL. Of the AD specific tools, the Infants Dermatitis Quality of Life Index (IDQLI) is targeted at children aged below 4 years while the Dermatitis Family Impact (DFI) index (Appendix 7) specifically assesses the impact of childhood atopic dermatitis on the QOL of the other family members making it ideal for this study [7].

Table 2: Quality of Life Instruments for Atopic Dermatitis [7]

Instrument	QOL Target	Specificity	Description
Dermatitis Family Impact (DFI) Questionnaire	Family QOL instrument	AD specific	10 items, score range 0-30
Family Dermatology LifeQuality Index (FDLQI)	Family QOL instrument	Dermatology specific	10 items, score range 0-30
Infants' Dermatitis Quality of Life Index (IDQOL)	Children less than4 years old	AD specific	10 items, score range 0-30
Children's Dermatology Life Quality Index (CDLQI)	Children 4-16years	Dermatology specific	10 items, score range 0-30
Dermatology Life Quality Index (DLQI)	Adults	Dermatology specific	10 items, score range 0-30
Quality of Life Index for atopic Dermatitis (CoLIAD)	Adults	AD specific	25 items, score range 0-25

The DFI assessment involves the use a 10 item questionnaire that is completed by a family member aged 16 years and above. It assesses the personal, psychosocial and financial impact of living with a child with atopic dermatitis. Caregivers respond to 10 questions centered on how caring for a child with AD has affected various areas of their life in the past week. Each question is scored from zero to three, which represents an incremental impact on the lifestyle component being assessed as follows: 0= Not at all; 1= A little; 2= A lot; 3= Very much. The scores for each question are collated to obtain a final DFI score which lies between 0 to 30, 0 representing the minimum score corresponding to no impact on QOL and 30 being the maximum impact. No validated score banding descriptors have been developed as yet [7].

Factors related to the impact of paediatric AD on caregiver QOL

The impact of AD on caregiver QOL lies on a continuum from mild to profound [11]. Several patient and caregiver factors interact to influence the magnitude of the impact. The patient factors include age, disease duration, and severity. A younger age has been associated with fewer effects, while longer disease duration and higher severity scores are associated with greater effects. Poor caregiver mental and physical wellbeing also results in worse QOL outcomes [21]. Studies have also demonstrated a relationship between disease severity and the impact of caregiver QOL [13, 22]. An investigation of the impact of AD on caregiver QOL must therefore include an assessment of disease severity.

Assessment of the severity of AD

The severity of AD is assessed by using various severity grading tools. There is no single gold standard tool that exists for assessing AD severity, instead, several have been developed to date (Table 3). In general, the tools are based on the assessment of one or more of the following factors: disease extent; lesion intensity; and the degree of associated subjective symptoms such as itch and sleep deprivation. These parameters are weighted and the final calculated collated scores are used to classify AD severity as either mild, moderate, or severe [24]. Of the available scoring systems, the EASI (Eczema Area Scoring Index); SCORAD (Scoring Atopic Dermatitis); and POEM (Patient Orientated Eczema Measure) are amongst the most commonly used [25].

Table 3: Atopic dermatitis severity tools [26]

Evaluation Tool	Brief Description of assessment	Validation Performed	Inclusion of Patient Reported Symptoms
EASI	Assesses disease extent on a 7-point scale in 4 defined body regions, based on severity of 4 clinical signs on a 4-point scale, to a maximum score of 72	Yes	No
SCORAD	Assesses disease extent, severity of 6 clinical signs on a 4-point scale, and patient-reported pruritus and sleep loss to a maximum score of 103	Yes	Yes
PGA	Assesses overall disease severity at a given time point on a 6- point severity scale	No	No
BSA	Assesses disease extent as a percentage of total body surface area	No	No
ADSI	The sum of5 items rated on a 4- point scale (0- 3): erythema, excoriation, exudation, lichenification, and pruritus	No	No
SASSAD	Six clinical signs are scored from 0-3 at each of 6 sites on the body	Yes	No
POEM	Assesses severity and duration of 7 symptoms experienced over the preceding week on a 5- point scale	Yes	Yes
Pruritus NRS	0-10 scale of patient reported itch	Yes	No

In the year 2008, The Harmonizing outcome measures for eczema (HOME) initiative comprising of AD relevant professionals and patients was founded in an effort to bring order to AD outcome measures scoring. The mandate of the initiative is to define up to date, feasible and reliable

outcome measures to be used in AD related clinical and research settings to allow for standardization and comparison of results. The initiative recognizes the EASI and SCORAD as validated tools ideal for clinical signs assessment and the POEM for patient reported symptoms [26].

The EASI demonstrates internal and intra-observer consistency and is recommended by the HOME initiative for the assessment of the clinical signs of AD [24]. It however does not account for patient reported symptoms and its use should therefore be in conjunction with another subjective symptom assessment tool [26]. The SCORAD on the other hand is a composite tool that incorporates both the objective and subjective symptoms and correlates well with specific objective tools such as the EASI and subjective tools such as the Dermatitis Quality Life Impact making it ideal for use in this study [26]. It however, demonstrates inter-observer variation particularly on assessments of edema, papulation, erythema and excoriations. In smaller studies, this can be controlled by use of a single observer [27].

The SCORAD index was developed and published by the European Task Force in 1993. During patient evaluation the percentage of body area affected is estimated and recorded while the intensity is assessed by evaluation of one representative skin lesion for six key signs (erythema, oedema or papulation, excoriations, lichenification, oozing or crusting, and dryness). Each key sign is graded on a severity scale from 0-3. The subjective symptoms of itch and sleep disturbance are graded on a patient or caregiver reported scale from zero to ten. A formula incorporating all the assessed parameters is applied to generate the final score to grade AD severity as mild (<25), moderate (25-50), or severe (>50) [28].

In conclusion; it is well established that paediatric AD has an impact on the quality of life of the affected child. Studies in Europe and Asia highlight the impact on the caregiver QOL as well [7, 14, 15]. However, the impact of this condition on caregiver QOL in our setting is not well understood. Caregiver well-being is often overlooked with focus on the patient only. An increasing prevalence of paediatric AD has been observed in developing countries, likewise in South Africa [1,3]. Studying the impact of childhood AD on caregivers in our context will inform the clinician on aspects of caregiver well-being to pay attention to, so as to improve outcomes of treatment in children and preserve family wellbeing. Hence this research report to describe the impact of paediatric AD on caregiver QOL at RMMCH.

2. STUDY OBJECTIVES

2.1 Primary

- To determine the impact of paediatric AD on caregiver QOL at RMMCH

2.2 Secondary

- To determine the severity of paediatric AD at RMMCH
- To determine the relationship between severity of paediatric AD and caregiver QOL

3. METHODS

3.1 **Study design**: A quantitative, cross-sectional study design will be utilized.

3.2 **Study Setting**: The study will be conducted at RMMCH, a public teaching hospital affiliated with the University of Witwatersrand, located in Coronationville, Johannesburg, South Africa. The hospital specializes in maternity, neonatal and paediatric services. The paediatric dermatology clinic is conducted once every week in the outpatient department [26]. On average 30-50 patients attend each clinic. Patients are drawn from the surrounding catchment area as referrals from the local district and provincial hospitals.

3.3 **Study population and Sample**: The sample will be drawn from patient-caregiver pairs attending the RMMCH paediatric dermatology clinic between the 3rd of January 2021 and 31st of December 2022.

Inclusion criteria

Patient

- Must fulfill the Hanifin and Rajka criteria for AD diagnosis
- Between the ages of 3 months to 16 years

Caregiver

- Must be the primary caregiver *

Exclusion criteria

Patient

- Not fulfilling the Hanifin and Rajka criteria for AD diagnosis
- Below 3 months of age
- Above 16 years of age

Caregiver

- Presence of other children with chronic co-morbidities in the family necessitating care thus influencing study outcomes
- Not the primary caregiver

*Primary caregiver- parent or an adult aged 16 years and above who assumes the main role of supervising and taking care of the child.

3.4 **Sample size**: A total of 177 children will be recruited into the study as calculated by the Dobson formula.

3.5 **Sampling Procedures**: Convenience sampling will be used to recruit participants. Patient file numbers for the selected patients will be kept for cross-referencing to avoid multiple recruitments of the same individuals. Successive consenting participants will replace those who are eligible but refuse to participate.

3.6 **Data Collection**: All data for each patient will be collected on the same day. Consent (Appendix 3) and assent (Appendix 4) will be obtained after the patient and caregivers are counselled on the details of the study. The study information document will be handed over to all

participants (Appendix 2). The researcher will collect patient and caregiver sociodemographic data on the Data Collection Sheet (Appendix 5). Patient information will include age, gender, race, disease duration and treatment duration. Caregiver information will include their relationship to the patient, gender, age, marital status, other dependents, source of income and medical history. The researcher will also administer the Dermatitis Family Impact questionnaire to assess QOL (Appendix 7- English version; Appendix 8- isiZulu translation; Appendix 9- SeSotho translation). Each question will be scored from 0 to 3 where; 0= Not at all; 1= A little; 2= A lot; 3= Very much. The overall DFI score will be obtained by summing the individual scores of all the questions. The minimum DFI score is 0 (= no impact on life of the family) and the maximum is 30 (= maximum effect on the life if the family). Disease severity will be assessed according to the Scoring of the Atopic Dermatitis (SCORAD) Index. The child will be examined by the researcher and the final score will be used to classify AD severity as either, mild (<25), moderate (25-50), or severe (>50) (Appendix 3).

4. DATA ANALYSIS

All data will be recorded onto a Microsoft excel worksheet prior to analysis. The data will be analyzed using Statistical Product and Services Solution (SPSS). Graphs and summary tables will be used to highlight trends or associations between variables.

Inferential analysis will be used to quantify the strength and association of the relationship between the variables. A regression model will be used to assess the effect AD on caregiver QOL. Associations between the DFI score and categorical child and caregiver variables will be analysed using the Kruskal-Wallis test. The Pearson correlation coefficient will be used to investigate the association between AD severity and the DFI score.

5. ETHICS

Participation in the study will be voluntary. Eligible participants will be provided with a study information document (Appendix 2) describing the research, its nature, purpose, and objectives before providing informed assent for minors (Appendix 4) and consent for caregivers (Appendix 3). To maintain the patient's confidentiality, the dataset will be stored in a password protected device. Unique identification will be used to identify the patients. The researcher will safeguard any harm befalling the participants as a consequence of participation in the research. Should answering any of the questions trigger emotional distress, participants will be referred to the hospitals' Psychology department for appropriate counselling. Permission to conduct the study will be sought from the following relevant authorities; Department of Dermatology Head of Department (HOD), RMMCH Department of Paediatrics HOD; RMMCH Chief Executive Officer and the Human Research Ethics Committee (Medical) of the University of the Witwatersrand.

6. TIMELINE OF ACTIVITIES

Date / Task	05/21	09/21	10/21	11/21	12/21	01/22-12/22	01/23-03/23	04/23-06/23	07/23-08/23
Literature review									
Preparing protocol									
Protocol assessment									
Ethics application									
Collecting data									
Data analysis									
Writing up-thesis									
Writing up paper									

7. FUNDING

The study will be self-funded. The total cost will be R 1500

Item	**Cost**
Printing	R700
Binding	R800
Total	R1500

8. LIMITATIONS

- It is difficult to assess erythema in black patients which may affect the SCORAD score.
- Questions answered by caregivers on behalf of affected children may result in information bias.
- Responses on the impact of AD on lifestyle will also be based on the subjective experience of one caregiver and may be exaggerated or underreported.
- Newly diagnosed patient to caregiver pairs may be unaware of the chronicity of the disorder and its implications on their lifestyle, affecting their view on the presumed impact of the disease on their QOL.
- Convenience sampling might introduce selection bias thus reducing the generalizability of results. Selection bias might also be introduced if the study participation refusal rate is high.
- Local language translations of the Dermatitis Family Impact tool that will be used to assess QOL is not validated

9. REFERENCES

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Appendix One:

i. Plagiarism Declaration

ii. Statement of Principles for Postgraduate Supervision

iii. Recommendation for appointment of supervisor(s) of research report

Appendix Two:

i. Hanifin and Rajka criteria for diagnosis of Atopic Dermatitis

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Appendix Three: Hospital Permission Letters

i. CEO- Rahima Moosa Mother and Child Hospital

Appendix One:

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iii. Recommendation for appointment of supervisor(s) of research report

DEPARTMENT OF INTERNAL MEDICINE

School of Clinical Medicine, Faculty of Health Sciences,
7 York Road, Johannesburg 2193, South Africa
Tel: +27 11 717-2774 · Fax: +27 11 717 2775

Plagiarism declaration for written work

I, Rulani Makondo; Student number 1175756 as a postgraduate student registered for a MMed at the University of the Witwatersrand declare the following:

- I am aware that plagiarism is the use of someone else's work without their permission and or without acknowledging the original source.
- I am aware plagiarism is wrong.
- I confirm that this written work is my own work except where I have stated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or if I have failed to acknowledge the ideas or writing of others.

Signature Makondo

Date 29 September 2023

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG | FACULTY OF HEALTH SCIENCES

STATEMENT OF PRINCIPLES FOR POSTGRADUATE SUPERVISION

IN A CONTEXT OF ACADEMIC FREEDOM AND WITHIN A FRAMEWORK OF INDIVIDUAL AUTONOMY AND THE PURSUIT OF KNOWLEDGE THIS STATEMENT IS WRITTEN IN THE BELIEF THAT THERE IS A RECIPROCAL RELATIONSHIP AND MUTUAL ACCOUNTABILITY BETWEEN SUPERVISOR AND STUDENT.

THE SUPERVISOR AND THE STUDENT:

1. Will establish agreed roles and clear processes to be maintained by both parties. In the case of join supervision everybody's role needs to be clarified.
2. Will meet regularly and as frequent as is reasonable to ensure steady progress towards the completion of the proposal, research report, or dissertation or thesis. This time varies but the normal minimum requirement for face-to-face contact spread across each year of registration is: 10 contact hours for an Honours project, 15 contact hours for a Masters by a research report and 24 contact hours for a Masters by dissertation and a PhD.
3. Will keep appointments, be punctual and respond timeously to messages.
4. Will keep one another informed of any planned vacations or absences as well as changes in his/her personal circumstances that might impact on the work schedule. Unplanned absences or delays should be discussed as soon as possible and arrangements should be made, to catch up lost time.
5. Will ensure that research on animal or human subjects is concluded according to the procedures and the requirements of the relevant University Ethics committee.
6. Will together complete progress reports on the research project, as requested by each Faculty Graduate Studies Committee.

THE SUPERVISOR

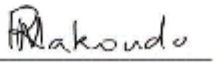
1. Undertakes to provide guidance for the student's research project in relation to the design and scope of the project, the relevant literature and information sources, research methods of data analysis.
2. Has a responsibility to be accessible to the students.
3. Will be prepared for the meeting with student. This includes being up to date on the latest work in his/her area of expertise.
4. Will expect written work as jointly agreed, and will return that work with constructive criticism within a timeframe (a suggestion of 2-4 weeks) jointly agreed at the outset of the research.
5. Will provide advice that can help the student to improve his/her writing. This may include referrals for language training and academic writing. The supervisor will provide guidance on technical aspects of writing such as referencing as well as on the discipline specific requirements. Detailed correction of drafts and instruction in aspects of language and style are not the responsibility of the supervisor.

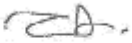
6. Will support the student in the production of a research report, dissertation or thesis. Provision should be allowed for adequate, mutually respectful, discussion around recommendations made.
7. Will assist with the construction of a written time schedule, which outlines the expected completion dates of successive stages of the work.
8. Will ensure the student has the opportunity to present work at postgraduate/staff seminars/national/international conferences as appropriate.
9. Will assist with the publication of research articles appropriate.
10. Will discuss the ownership of research conducted by the student in accordance with the University guidelines and rules on intellectual property, co-authorship and copyright.
11. Will ensure that the research is conducted in accordance with the University's policy on plagiarism.
12. Will ensure that the student is made aware in writing of the inadequacy of progress and/or of any work where the standard is below par. Acceptability will be according to criteria previously supplied to the student.
13. Has a duty to refuse to allow the submission of sub-standard work for examination, regardless of the circumstances. If the student chooses to submit without the consent of the supervisor, then this should be clearly recorded and the appropriate procedures followed.

THE STUDENT

1. Undertakes to work independently under the guidance of the supervisor. This includes reading widely to ensure that the literature pertinent to his/her chosen topic has been identified and consulted.
2. Is obliged to make appointments to see the supervisor and will arrange meeting times well in advance.
3. Will think carefully about how to get maximum benefit from these contact sessions by planning what s/he wants in these sessions.
4. Should submit written work for discussion with the supervisor well in advance of a scheduled meeting. The kind and frequency of written work should be agreed with the supervisor at the outset of the research.
5. Written work that is submitted should be relatively free from basic spelling mistakes, incorrect punctuation and grammatical errors. Responsibility for the accuracy of language, the overall structure and coherence of the final research report, dissertation or thesis rests with the student.
6. Undertakes to heed the advice given by the supervisor and to engage in discussion around suggestions made. Ultimately the student has to take responsibility for the quality and presentation of the work.
7. Should strive, within reasonable bounds, to maintain a focus on his/her research area and to work within the agreed time schedule.
8. Will prepare material for presentations at seminars and conferences.
9. Undertakes to submit papers for publication.
10. Agrees to honour agreements about ownership of the research and in accordance with the University's guidelines and rules in relation to co-authorship, copyright and intellectual property.
11. Will ensure that the work contains no instances of plagiarism and that all citations are properly referenced and that the list of references is accurate, complete and consistent.
12. Agrees to work in accordance with the criteria of acceptability as supplied by the supervisor.
13. Undertakes not to place the supervisor under undue pressure to submit work for examination until the supervisor is satisfied that it has reached an acceptable level of quality. We confirm that we have read and understood this statement and agree to be guided by its principles for as long as we continue to work together.

Please note: The University and Faculty endorse the Singapore Statement on research integrity. The principles of the Singapore Statement include honesty, accountability, professionalism and stewardship. Our responsibilities as researchers (i.e. both as students and supervisors) are as pledged in the Singapore Declaration: the assurance of appropriate "data integrity, data sharing, record keeping, authorship, publication, peer review, conflict of interest, reporting misconduct and irresponsible research, communicating with the public, complying with regulations, education, and social responsibilities (World Conference on Research Integrity, 2010)". These principles and responsibilities are important in training our postgraduate students and in promoting global research integrity. Ref: Resnik, DB and Shamoo AE (2011). The Singapore Statement on Research Integrity.Account Res. 18:71-75.

Name of student: Rulani Makondo Student's signature: 

Name of Supervisor 1: Nombuyiselo Mvulane Supervisor's signature: 

Name of Supervisor 2: Lindinkululeko Nkehli Supervisor's signature: 

The broad area of study is: The impact of childhood atopic dermatitis on caregiver quality of life at Rahima Moosa Mother and Child Hospital.

Provisional submission date is: 22/09/2023 Degree: Master of Medicine in Dermatology

School: Internal Medicine, Division of Dermatology Faculty: Health Sciences

Date: 22/01/2023
Specific agreement pertaining to: ownership and joint publication, funding, may be attached and signed.

GRIEVANCE PROCEDURES: It should be acknowledged that during the course of the research that both students and supervisors can feel aggrieved. In this event, these should be dealt with as swiftly as possible by the parties involved and, if necessary, the Postgraduate Coordinators and Committees. There is, in addition, a University Grievance Policy to help guide deliberations.

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

RECOMMENDATION FOR APPOINTMENT OF SUPERVISOR(S) OF RESEARCH REPORT, DISSERTATION OR THESIS

Motivation / Reason for Appointment:

Recommendation of Division / Department / School:

Student Surname and Full name(s)	MAKONDO RUTANI
Student number	1175756
Degree	MMed
Div / Dept / School	Internal Medicine
Title	The impact of childhood atopic dermatitis on caregiver quality of life at Rahima Moosa Mother and Child hospital (RMMACH).

[Supervisor 1]
Name &Surname: **Dr Nombuyiselo Mvulane**

Supervision %: 50%

Supervisor Qualifications: MBChB, MSC EPIDERMIOLOGY, FC DERM(SA)

Supervisor Department: DEPARMTENT OF INTERNAL MEDICINE, DIVISION OF DERMATOLOGY

Supervisor Telephone: 0825600270 E-mail: nombuyiselomvulane@gmail.com

Name &Surname: **Dr Lindinkululeko Nkehli**

Supervision %: 50%

Supervisor Qualifications: MBChB, MMed DERMATOLOGY, FC DERM(SA)

Supervisor Department: DEPARMTENT OF INTERNAL MEDICINE, DIVISION OF DERMATOLOGY

Supervisor Telephone: 0837852882 E-mail: jabszako@yahoo.co.uk

Student Signature: RMakondo

Supervisor 1 Signature:

Supervisor 2 Signature: 

RECOMMENDATION BY HEAD OF DIVISION / DEPARTMENT / SCHOOL:

PROF ISMAIL KALLA		11 July 2023
(Full name(s) and Surname)	(Sign)	(Date)

APPROVAL BY CHAIR OF ASSESSOR GROUP:
(On behalf of the FGSC)

(Full name(s) and Surname)	(Sign)	(Date)

PLEASE NOTE: RECOMMENDATION FOR APPOINTMENT OF SUPERVISOR(S) FOR CIRCULATION TO THE FGSC FOR APPROVAL

Appendix Two:

i. Hanifin and Rajka criteria for diagnosis of Atopic Dermatitis

ii. Study Information Document

iii. Participant Consent Sheet

iv. Assent form for minors

v. Data Collection sheet

vi. Scoring for Atopic Dermatitis Index

vi. Dermatitis Family Impact Questionnaire

vii. Dermatitis family Impact Questionnaire: isiZulu Translation

viii. Dermatitis Family Impact Questionnaire: SeSotho/ South Sotho Translation

Hanifin and Rajka criteria for diagnosis of Atopic Dermatitis [9]

1. Must have three or more major features described below	2. Must have three or more of the following minor features:
(1) Pruritus (2) Typical morphology and distribution Flexural lichenification in adults Facial and extensor eruptions in infants and children (3) Chronic or chronically relapsing dermatitis (4) Personal or family history of atopy (asthma, allergic rhinitis, atopic dermatitis)	(1) Xerosis (2) Ichthyosis/palmar hyperlinearity, keratosis pilaris (3) Immediate (type I) skin test reaction (4) Elevated serum IgE (5) Early age of onset (6) Tendency toward cutaneous infections (especially *staph*. *aureus* and *herpes simplex*), impaired cellmediated immunity (7) Tendency toward non-specific hand or foot dermatitis (8) Nipple eczema (9) Cheilitis (10) Recurrent conjunctivitis (11) Dennie-Morgan infraorbital fold (12) Keratoconus (13) Anterior subcapsular cataracts (14) Orbital darkening (15) Facial pallor, facial erythema (16) Pityriasis alba (17) Anterior neck folds (18) Itch when sweating (19) Intolereance to wool ad lipid solvents (20) Periofollicular accentuation (21) Food intolerance (22) Course influenced by environmental and emotional factors (23) White dermographism, delayed blanch

Study Information Document

Title of Study: THE IMPACT OF CHILDHOOD ATOPIC DERMATITIS ON CAREGIVER QUALITY OF LIFE AT RAHIMA MOOSA MOTHER AND CHILD HOSPITAL (RMMCH).

Dear Sir/Madam

Introduction

I, Dr Rulani Makondo will be doing research on eczema in children. Research is a process used in seeking new knowledge. In this study we want to learn how taking care of a child with eczema affects the lifestyle of the parent/caregiver. The requirements from you as a participant will be to answer general questions on the changes in your lifestyle as a result of having to take care of a child with eczema.

We are inviting you to participate in the study and also asking for your permission to include your child in the research study.

The study will be conducted at the RMMCH dermatology clinic on your child's routine follow-up visit. During the consultation, I will then also ask you general questions about your life and the adjustments you had to make in your lifestyle in the past week to cater for the needs of your child with eczema. The additional process will extend your usual consultation time by approximately 10-15 minutes.

There are no risks involved during participation in the study. However, should responding to the questions provoke any form of emotional distress, you will be referred to the hospital's psychology department for appropriate counselling and care.There will also not be any direct benefit to you in participating in the study, however the benefit will be tofuture eczema patients and their caregivers/parents.

Participation in the study is voluntary and refusal or withdrawal from the study will not affect thetreatment you are about to receive.

The researchers undertake to protect your identity and the nature of your contribution. To ensure your anonymity, the study will not contain information that may personally identify you such as your name. All file cabinets with study documents will be kept locked; those stored as computer files will be password protected. If we write a report or article about this research project, your identity will be protected.

You may contact the researcher if you have any queries relating to the study.
Researcher: Dr Rulani Makondo
Tel 060 3909667, Email: ruliemak@gmail.com, Dermatology Clinic (RMMCH)

If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Dr Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Thank you for reading this Study Information Sheet.
October 2021

Participant Consent Sheet

Project title: THE IMPACT OF CHILDHOOD ATOPIC DERMATITIS ON CAREGIVER QUALITY OF LIFE AT RAHIMA MOOSA MOTHER AND CHILD HOSPITAL (RMMCH).

1. I have been given a Participant Information Sheet which explains the nature and processes involved in this study, which is attached hereto;
2. I was given time to read it, or had it read to me, in the language I best understand;
3. I was given time to ask any questions I wanted to and found any answers given to me to be reasonable and satisfactory;
4. I believe I fully understand why the study is being conducted and what the intended outcomes will be;
5. I understand that there will be no immediate benefit to me, should I agree to participate, nor will I receive any payment; conversely, participation will not cost me anything but my time;
6. I understand that, even if I initially consent to take part in the study, I may subsequently withdraw at any time and would not be required to give any reasons; if that happened, any data collected about me for the purposes of the study would immediately be destroyed, unless I give consent for it to be retained
7. I have been given a range of contact details, listed below. If I require further information or become concerned about any aspect of this study, I am free to speak to any of these contacts.

Contact details:

Rulani Makondo, Principal Investigator, telephone no. 060 390 9667, or by e-mail at ruliemak@gmail.com,

Nombuyiselo Mvulane, Supervisor, on telephone no. 082 560 5270, or by e-mail at nombuyiselomvulane@gmail.com

Nkehli Lindinkululeko, Supervisor, on telephone no. 083 785 2882, or by email at jabszako@yahoo.co.uk,

Professor CB Penny, Chairperson of the Human Research Ethics Committee (Medical) at the University of Witwatersrand, on telephone no. 011 717 2301, or by e-mail at Clement.Penny@wits.ac.za.
Ms. Z Ndlovu or Mr Rhulani Mkansi, Committee Secretariat, telephone nos.: 011 717 2700 or 1234, or by e-mail at: Zanele.Ndlovu@wits.ac.za or Rhulani.Mkansi@wits.ac.za

A: Consent Given

I_____hereby give consent for me and my child to participate in the study.

Name of Child: _____
Date: _____
Place: _____
Signature or mark _____

Witnessed by:
Name of Witness: _____
Signature: _____
Date: _____

B: Consent not given

I_____do not consent to study participation.

Assent form for minors

Title of study: THE IMPACT OF CHILDHOOD ATOPIC DERMATITIS ON CAREGIVER QUALITY OF LIFE AT RAHIMA MOOSA MOTHER AND CHILD HOSPITAL (RMMCH).
Researcher's Name: Rulani Makondo

What is RESEARCH?

Research is something we do find **NEW KNOWLEDGE** about the way things (and people) work. We use research projects or studies to help us find out more about children and teenagers and the things that affect their lives, their schools, their families and their health. We do this to try and make the world a better place!

What is this research project all about?

This research is going to give us information on how having atopic dermatitis is affecting the lives of the people taking care of you.

Why have I been invited to take part in this research project?

You are being invited to participate in the study because you have a skin condition called atopic dermatitis which this study is on.

Who is doing the research?

My name is Dr Rulani Makondo. I am a studying to become a skin specialist with the University of Witwatersrand in Johannesburg.

What will happen to me in this study?

In this study we are going to examine your skin for any lesions as we always do at each clinic visit.

Can anything bad happen to me?

Participation in the study will not result in any harm to you.

Can anything good happen to me?

There will be no direct benefit to you for participating in the study. However, the information gained will be of use to future atopic dermatitis patients and their caregivers.

Will anyone know I am in the study?

Your participation in the study will be kept secret. If we write a report about the research project, your identity will also not be disclosed.

Who can I talk to about the study?

This research is being conducted by Rulani Makondo, a Master's in Medicine (Dermatology) student with the University of Witwatersrand. If you have any questions about the research study itself, please contact:

Rulani Makondo
Cell Number +27 603909667
Email: ruliemak@gmail.com

Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

1. HREC Chair/ Administrator: Prof P Cleaton Jones, Tel 011 717 2301, email peter.cleaton-jones1@wits.ac.za,
2. Ms Z Ndlovu (Administrative Officer) 011 717 2700/1234/1252, email zanele.ndlovu@wits.ac.za

What if I do not want to do this?

Participation in the study is voluntary. Refusing to participate will not affect the treatment or any other services you are about to receive. Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.

Do you understand this research study and are you willing to take part in it?

YES NO

Has the researcher answered all your questions?

YES NO

Do you understand that you can STOP being in the study at any time?

YES NO

_____ _____

Signature of Child Date

Data collection sheet

Unique identification number:

SECTION A: SOCIODEMOGRAPHIC CHARACTERISTICS

Patient demographics

1. Age:
2. Gender:
3. Race:
4. Comorbidities:
5. Date at diagnosis:
6. Age at diagnosis:
7. Disease duration
8. Date at commencement on treatment:
9. Treatment duration:

Caregiver and family demographics

10. Gender of Parent/caregiver:
11. Age of Parent/caregiver:
12. Marital status of Caregiver:

Single	Married	Separated	Divorced	Widowed	Unmarried, living with partner

13. Relationship to patient:

Mother	Father	Grandparent	Other

14. Type of caregiver

Primary	Secondary	Other

15. Number of other dependents less than 16 years:
16. Caregiver comorbidities:

17. Other family member comorbidities:
18. Family setup:

Nuclear	Single parent	Extended	Grandparent	Other

19. Parent/caregiver highest level of education:

Highest education level	None	Primary	Secondary	Tertiary

20. Parent/caregiver employment status :

Employment status	Formally employed	Self employed	Pensioner	Housewife	Unemployed	Student	Other

21. Source of income:

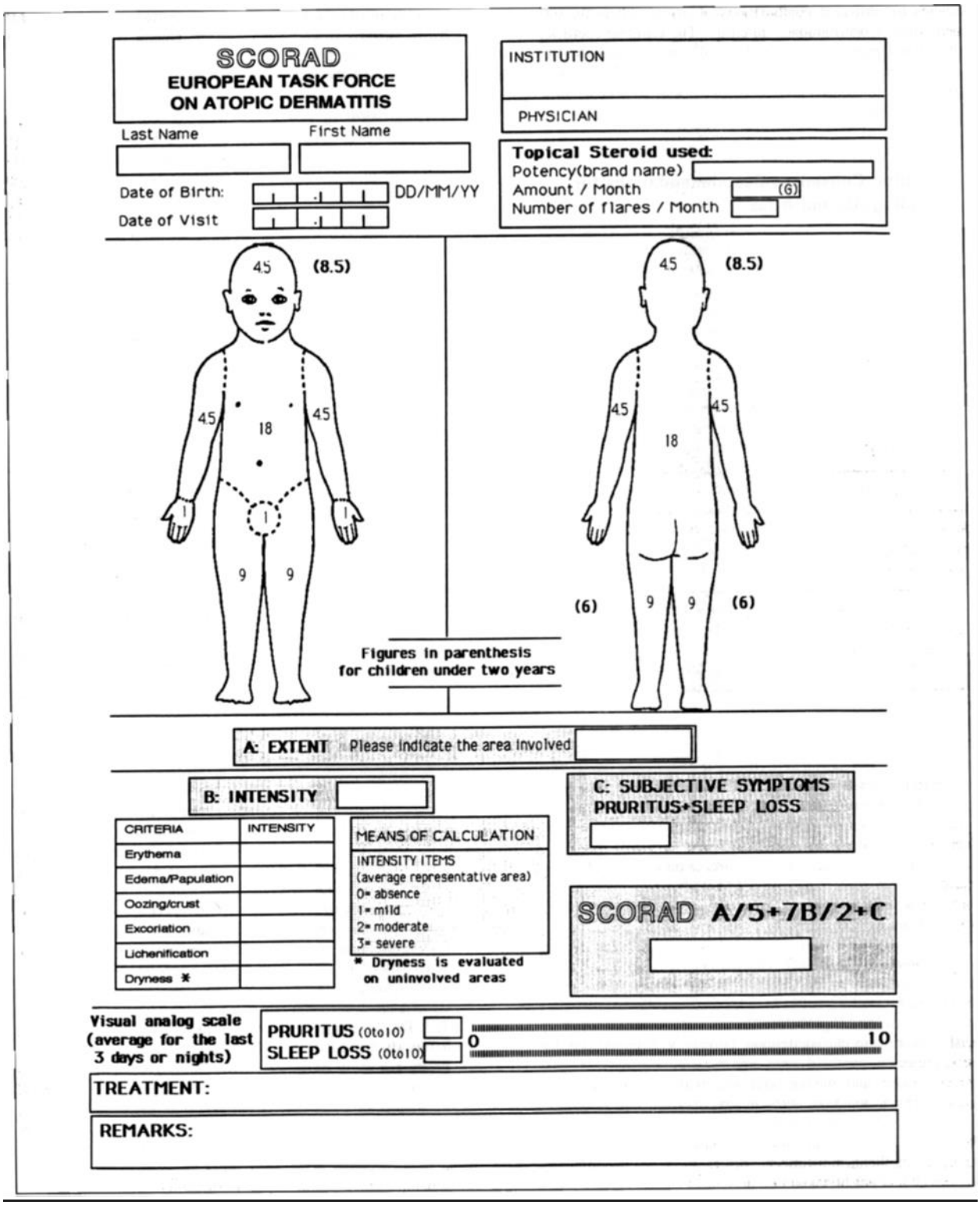
SECTION B: CLINICAL INFORMATION- Disease severity

Atopic dermatitis grading using the SCORAD score	Mild	Moderate	Severe

SECTION C: QOL

23. Parent/caregiver quality of life score:

Scoring for Atopic Dermatitis (SCORAD) Index [27]



Dermatitis Family Impact Questionnaire [28]

Unique identification number: **Score**

1.	Over the last week, how much effect has your child having eczema had on **housework**, e.g. washing, cleaning.	Very much ❒ A lot ❒ A little ❒ Not at all ❒
2.	Over the last week, how much effect has your child having eczema had on **food preparation** and **feeding**.	Very much ❒ A lot ❒ A little ❒ Not at all ❒
3.	Over the last week, how much effect has your child having eczema had on the **sleep of others in family**.	Very much ❒ A lot ❒ A little ❒ Not at all ❒
4.	Over the last week, how much effect has your child having eczema had on **family leisure activities**, eg swimming.	Very much ❒ A lot ❒ A little ❒ Not at all ❒
5.	Over the last week, how much effect has your child having eczema had on **time spent on shopping for the family.**	Very much ❒ A lot ❒ A little ❒ Not at all ❒
6.	Over the last week, how much effect has your child having eczema had on your **expenditure**, eg costs related to treatment, clothes, etc.	Very much ❒ A lot ❒ A little ❒ Not at all ❒
7.	Over the last week, how much effect has your child having eczema had on causing **tiredness** or **exhaustion** in your child's parents/carers.	Very much ❒ A lot ❒ A little ❒ Not at all ❒
8.	Over the last week, how much effect has your child having eczema had on causing **emotional distress** such as depression, frustration or guilt in your child's parents/carers.	Very much ❒ A lot ❒ A little ❒ Not at all ❒
9.	Over the last week, how much effect has your child having eczema had on **relationships** between the **main carer and partner** or between the **main carer and other children** in the family.	Very much ❒ A lot ❒ A little ❒ Not at all ❒
10.	Over the last week, how much effect has **helping with your child's treatment** had on the main carer's life.	Very much ❒ A lot ❒ A little ❒ Not at all ❒

Dermatitis Family Impact Questionnaire: isiZulu Translation

Umama/Ubaba/Umnakekeli **Usuku:** **Umphumela**

Inhloso yalolu uhlu lwemibuzo yikulinganisa ukuthi inkinga yesikhumba yengane yakho ithinte kangakanani wena nomdeni wakho NGEVIKI eledluleyo. Sicela impedulo eyodwa kumbuzo munye ngamunye.

1. Kuleliviki elilodwa eledlule, ukuba nengane ene eczema kuwuphazamise kanjani umsebenzi wakho wasendlini njengokuwasha, ukuklina nokunye?	Kakhulu Kakhudlwana Kancane Akuzange	□ □ □ □
2. Kuleliviki elilodwa eledlule, ukuba nengane ene eczema kuwuphazamise kanjani umsebenzi wokupheka nokulungisa ukudla?	Kakhulu Kakhudlwana Kancane Akuzange	□ □ □ □
3. Kuleliviki elilodwa eledlule, ukuba nengane ene eczema kubuphazamise kanjani ubuthongo nokulala komndeni wakho?	Kakhulu Kakhudlwana Kancane Akuzange	□ □ □ □
4. Kuleliviki elilodwa eledlule, ukuba nengane ene eczema kukuphazamise kanjani ukuzivoca nokuzijabulisa njengokubhukuda komndeni wakho?	Kakhulu Kakhudlwana Kancane Akuzange	□ □ □ □
5. Kuleliviki elilodwa eledlule, ukuba nengane ene eczema kusiphazamise kanjani isikhathi sokuya ezitolo ukuyothenga izidingo zomndeni wakho?	Kakhulu Kakhudlwana Kancane Akuzange	□ □ □ □
6. Kuleliviki elilodwa eledlule, ukuba nengane ene eczema kube nomthelela ongakanani ekusebenziseni imali yemithi noba yezinye izidingo njengezimpahla zokugqoka emndenini wakho?	Kakhulu Kakhudlwana Kancane Akuzange	□ □ □ □
7. Kuleliviki elilodwa eledlule, ukuba nengane ene eczema kube nomthelela ongakanani ekukhathaleni kwababo abanakekela ingane okungabazali noma izihlobo?	Kakhulu Kakhudlwana Kancane Akuzange	□ □ □ □
8. Kuleliviki elilodwa eledlule, ukuba nengane ene eczema kube nomthelela ongakanani ekuphukeni komoya kulabo abanakekela ingane, abazali noma izihlobo?	Kakhulu Kakhudlwana Kancane Akuzange	□ □ □ □

9. Kuleliviki elilodwa eledlule, ukuba nengane ene eczema kubuphazamise kangakanani ubudlelwano phakathi kwabazali, nalabo abanakekela ingane noma phakathi kwezingane emndenini?

Kakhulu □
Kakhudlwana □
Kancane □
Akuzange □

10. Kuleliviki elilodwa eledlule ukusiza ngokuqikilela ukuthi ingane iyayisebenzisa imithi yayo kuyiphazamise kangakanani impilo yalowo oyinakekelayo

Kakhulu □
Kakhudlwana □
Kancane □
Akuzange □

Dermatitis Family Impact: SeSotho/ South Sotho Translation

Mme / Ntate / Mohlokomedi **Letsatsi:** **Laduma** ☐

Morero oa lenane lena la lipotso ke ho lekanya hore na bothata ba letlalo la ngoana oa hau bo u amme hakae uena le ba lelapa la HAO BEKENG E FETILENG. Ka kopo fana ka karabo e le 'ngoe bakeng sa potso ka' ngoe.

1.	Bekeng e fetileng, ho eba ha ngoana hao le eczema ho ile hoa eba le tshosometso e kakang mosebetsing oa ntlo mohlomong ho dintho tse kang ho hlatsoa, ho hloekisa?	Haholo ☐ Tse ngatha ☐ Hanyane ☐ Ho hang ☐
2.	Bekeng e fetileng, ho eba le eczema hoa ngoana hao ho ile hoa eba le phello e kakang ho etseng hoa dijo le ho mo fepa?	Haholo ☐ Tse ngatha ☐ Hanyane ☐ Ho hang ☐
3.	Bekeng e fetileng, ho eba hoa ngoana hao le eczema ho ile hoa eba le phello e kakang borokong ba ba bang ka lapeng?	Haholo ☐ Tse ngatha ☐ Hanyane ☐ Ho hang ☐
4.	Bekeng e fetileng, ho eba le eczema hoa ngoana hao ho ile hoa eba le phello e kakang mesebetsing ea boikhathollo ea lelapa mohlala ho sesa?	Haholo ☐ Tse ngatha ☐ Hanyane ☐ Ho hang ☐
5.	Bekeng e fetileng, ho eba hoa ngwana hao le eczema ho ile hoa eba le phello e kakang ho nako ea ho e a dishopong ho ilo rekwa dintho tsa katlung?	Haholo ☐ Tse ngatha ☐ Hanyane ☐ Ho hang ☐
6.	Bekeng e fetileng, ho eba hoa ngoana hao le eczema ho ebile le phello e kae tjheleteng ea hao mohlomong eo o e sebedisang ho mo rekela mereane le diaparo?	Haholo ☐ Tse ngatha ☐ Hanyane ☐ Ho hang ☐
7.	Bekeng e fetileng, ho eba hoa ngoana hao le eczema ho bakile mokgathala o mokakang batswading ba ngoana hao kapa bahlokomeding ba ngoana hao?	Haholo ☐ Tse ngatha ☐ Hanyane ☐ Ho hang ☐
8.	Bekeng e fetileng, ho eba hoa ngoana hao le eczema ho ile hoa eba le phello e kakang ho bakeng hoa maikutlo a seng monate, ho fellwa ke matla, ho itshola?	Haholo ☐ Tse ngatha ☐ Hanyane ☐ Ho hang ☐

9.	Bekeng e fetileng, ho eba hoa ngoana hao le eczema ho ebile le phello e kakang mahareng a motswadi ea mohlokometseng haholo le molekane oa motswadi eno kapa mahareng a motswadi ea hlokomelang ngoana haholo le bana ba bang ka lapeng?	Haholo Tse ngatha Hanyane Ho hang	□ □ □ □
10.	Bekeng e fetileng, ho hlokomela hoa ngoana hao ho ebile le phello e kakang ho bophelong ba motswadi ea mo hlokomelang?	Haholo Tse ngatha Hanyane Ho hang	□ □ □ □

Appendix Three: Hospital Permission Letters

i. CEO- Rahima Moosa Mother and Child Hospital

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Rahima Moosa Mother and Child Hospital
Enquiries: Adjunct Professor Ashraf Coovadia
Tel: 011 470 9284/9100
Email: Karen.Marshall@wits.ac.za

TITLE OF RESEARCH PROJECT:
"THE IMPACT OF CHILDHOOD ATOPIC DERMATITIS ON CAREGIVER QUALITY OF LIFE AT RAHIMA MOOSA MOTHER AND CHILD HOSPITAL"

NAME OF SUPERVISOR:
Dr Mvulane Nombuyiselo

NAME OF RESEARCHER:
Dr Rulani Makondo
Department of Internal Medicine
Division of Dermatology
University of the Witwatersrand

NHRD REF NO: GP_202108_025

Dear Dr Makondo,

Permission is granted for you to conduct the research as indicated in the title above.

The terms under which this permission is granted is contained in the Researcher Declaration form that you have signed. Failure to comply with these conditions will result in the withdrawal of such permission.

It is crucial for you to inform the Research Coordinator, Karen Marshall of the actual start and end dates of your study. This could be done by e-mail.

Should the study commence more than 12 months after receipt of this approval letter you will have to go through the process of applying again.

You are strongly advised to keep a signed copy of the declaration form to ensure that the terms of this agreement are always complied with.

Yours sincerely,

DR NP MKABAYI
CHIEF EXECUTIVE OFFICER
Rahima Moosa Mother and Child Hospital
15.11.2021

Appendix B. Ethics clearance certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Rulani Makondo

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M2111139

NAME: (Principal Investigator)	Dr Rulani Makondo
DEPARTMENT:	Internal Medicine Dermatology Rahima Moosa Mother and Child Academic Hospital
PROJECT TITLE:	The impact of childhood atopic dermatitis on caregiver quality of life at Rahima Moosa Mother and Child Hospital (RMMACH)
DATE CONSIDERED:	26/11/2021
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr N. Mvulane and Dr L. Nkehli
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	20/01/2022

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **November** and will therefore be due in the month of **November** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Makondo — Principal Investigator Signature

25/01/2022 — Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix C. Turn-it-in report

Rulani Turnitin.docx

ORIGINALITY REPORT

10%	6%	9%	2%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	www.ncbi.nlm.nih.gov Internet Source	1%
2	MA Ben-Gashir. "Are quality of family life and disease severity related in childhood atopic dermatitis?", Journal of the European Academy of Dermatology and Venereology, 9/2002 Publication	1%
3	Submitted to Intercollege Student Paper	1%
4	"APhA 2019 abstracts of contributed papers", Journal of the American Pharmacists Association, 2019 Publication	1%
5	www.clinicaltrials.gov Internet Source	1%
6	Joëlle Y Friedman, Shelby D Reed, Kevin P Weinfurt, Kristijan H Kahler, Emmanuel B Walter, Kevin A Schulman. "Parents' reported preference scores for childhood atopic	1%

	dermatitis disease states", BMC Pediatrics, 2004 Publication	
7	www.bristol.ac.uk Internet Source	1 %
8	Hae Ji Jang, Seonyeong Hwang, Youngmee Ahn, Dae Hyun Lim, Min Sohn, Jeong Hee Kim. "Family quality of life among families of children with atopic dermatitis", Asia Pacific Allergy, 2016 Publication	1 %
9	M. Swanepoel, T. Haw. "A pilot study evaluating depression in mothers with children diagnosed with Down syndrome in state health care", Journal of Intellectual Disability Research, 2018 Publication	1 %
10	Sebastien Barbarot, Jonathan I. Silverberg, Abhijit Gadkari, Eric L. Simpson et al. "The Family Impact of Atopic Dermatitis in the Pediatric Population: Results from an International Cross-sectional Study", The Journal of Pediatrics, 2022 Publication	<1 %
11	www.researchgate.net Internet Source	<1 %

12	Matt Maughan, Thomas Voigt, Allen Parrish, Germán Bollero, William Rooney, D. K. Lee. "Forage and Energy Sorghum Responses to Nitrogen Fertilization in Central and Southern Illinois", Agronomy Journal, 2012 Publication	<1 %
13	"ECTMIH2021 Supplement", Tropical Medicine & International Health, 2021 Publication	<1 %
14	Submitted to Aston University Student Paper	<1 %
15	www.phasa.org.za Internet Source	<1 %
16	Suvipaporn Siripornpitak, Apichaya Sriprachyakul, Saruntorn Wongmetta, Piya Samankatiwat, Pirapat Mokarapong, Suthep Wanitkun. "Follow-up aortic dilatation in patients with repaired tetralogy of Fallot using cardiovascular magnetic resonance", European Journal of Radiology Open, 2021 Publication	<1 %
17	isad.org Internet Source	<1 %
18	Submitted to University of Witwatersrand Student Paper	<1 %

19	Seda Şirin Köse, Zülfikar Akelma, Serap Özmen. "Severity of disease and the quality of life indexes in infants with atopic dermatitis", Allergologia et Immunopathologia, 2022 Publication	<1 %
20	scholars.lib.ntu.edu.tw Internet Source	<1 %
21	Renate Strehlau, Megan Burke, Tamryn Aswegen, Louise Kuhn, Joanne Potterton. "Neurodevelopment in early treated HIV - infected infants participating in a developmental stimulation program compared with controls", Child: Care, Health and Development, 2020 Publication	<1 %
22	worldwidescience.org Internet Source	<1 %

Exclude quotes	On	Exclude matches	< 8 words
Exclude bibliography	On		

Appendix D. “South African Medical Journal” Author guidelines

Author Guidelines

Author Guidelines

The *SAMJ* has launched a new submission and tracking system. Authors will be required to register a profile on the in order to submit a manuscript.

To submit a manuscript, please proceed to: https://samajournals.co.za/index.php/samj

To access and submit an article already in production, please see the guidelines here.

Author Guidelines

Please watch the Author Tutorial for guidance on how to submit.

Please take the time to familiarise yourself with the policies and processes below. If you still have any questions, please do not hesitate to ask our editorial staff (tel.: +27 (0)21 532 1281, email: publishing@samedical.org).

SAMJ policies

- Types of articles considered by the SAMJ
- Article Processing Charges
- Authorship
- Conflict of interest
- Research ethics committee approval
- Clinical trials
- Protection of patient's rights to privacy
- Copyright notice
- Privacy statement
- Ethnic classification
- CPD

Manuscript preparation

- Preparing an article for anonymous review
- General article format/layout
- Preparation notes by article type
- Illustrations
- Tables
- References

From submission to acceptance

- Submission and peer-review
- Production process
- Changing contact details or authorship

Publication

- Online versus print
- Errata and retractions
- Indexing

SAMJ Policies

Type of articles considered by the SAMJ

The *SAMJ* will no longer limit the articles accepted to those that have 'general medical content', but is intending to capture the spectrum of medical and health sciences, grouped by relevance to the country's burdens of disease. This content will include research in the social sciences and economics that is relevant to the medical issues around our burden of disease. Please see 'A new vision for the *SAMJ* – and a call for papers' for a full discussion of the new directions for the *SAMJ*.

We accept the following types of articles:

Research
Reviews
Clinical trials
Editorials
In Practice (Previously Forum incl. Case Reports)
Correspondence
Obituaries
Book reviews
Ad hoc supplements e.g. guidelines, conference/congress abstracts, Festschrifts*

The following articles are by invitation only:

Guest editorial
Continuing Medical Education (CME)

*Contact claudian@hmpg.co.za for information on submitting ad hoc/commissioned supplements, including guidelines, conference/congress abstracts, Festschrifts, etc.

Publication Fees

All articles published in the *South African Medical Journa*l are open access and freely available online upon publication. This is made possible by applying a business model to offset the costs of peer review management, copyediting, design and production, by charging a publication fee of R7 440 (VAT incl.) for each research and In Practice article published. The publication fee is standard and does not vary based on length, colour, figures, or other elements.

The publication fee is payable when your manuscript is editorially accepted and before production commences for publication. The submitting author will be notified that payment is due and given details on the available methods of payment. Prompt payment is advised; the article will not enter into production until payment is received.

Authorship

Named authors must consent to publication. Authorship should be based on: (*i*) substantial contribution to conceptualisation, design, analysis and interpretation of data; (*ii*) drafting or critical revision of important scientific content; or (*iii*) approval of the version to be published.

These conditions must all be met (uniform requirements for manuscripts submitted to biomedical journals; refer to www.icmje.org)

If authors' names are added or deleted after submission of an article, or the order of the names is changed, all authors must agree to this in writing.

Please note that co-authors will be requested to verify their contribution upon submission. Non-verification may lead to delays in the processing of submissions.

Author contributions should be listed/described in the manuscript.

Conflicts of interest

Conflicts of interest can derive from any kind of relationship or association that may influence authors' or reviewers' opinions about the subject matter of a paper. The existence of a conflict – whether actual, perceived or potential – does not preclude publication of an article. However, we aim to ensure that, in such cases, readers have all the information they need to enable them to make an informed assessment about a publication's message and conclusions. We require that both authors and reviewers declare all sources of support for their research, any personal or financial relationships (including honoraria, speaking fees, gifts received, etc) with relevant individuals or organisations connected to the topic of the paper, and any association with a product or subject that may constitute a real, perceived or potential conflict of interest. If you are unsure whether a specific relationship constitutes a conflict, please contact the editorial team for advice. If a conflict remains undisclosed and is later brought to the attention of the editorial team, it will be considered a serious issue prompting an investigation with the possibility of retraction.

Research ethics committee approval

Authors must provide evidence of Research Ethics Committee approval of the research where relevant. Ensure the correct, full ethics committee name and reference number is included in the manuscript.

If the study was carried out using data from provincial healthcare facilities, or required active data collection through facility visits or staff interviews, approval should be sought from the relevant provincial authorities. For South African authors, please refer to the guidelines for submission to the National Health Research Database. Research involving human subjects must be conducted according to the principles outlined in the Declaration of Helsinki. Please refer to the National Department of Health's guideline on Ethics in Health research: principles, processes and structuresto ensure that the appropriate requirements for conducting research have been met, and that the HPCSA's General Ethical Guidelines for Health Researchers have been adhered to.

Clinical trials

As per the recommendations published by the International Committee of Medical Journal Editors (ICMJE), clinical trial research is any research that assigns individuals to an intervention, with or without a concurrent comparison/control group to study the cause-and-effect relationship between the intervention and health outcomes. All clinical trials should be registered with the appropriate national clinical trial registry (or any international primary register, if relevant), and the trial registration number should be cited at the end of the abstract. All clinical trial reports must also contain a data sharing statement as per the recommendations of the ICMJE. Statements are to indicate:

- whether individual deidentified participant data will be shared;
- what data in particular will be shared; whether additional, related documents will be available;

- when the data will become available and for how long; by what access criteria data will be shared.

Please see the ICJME announcement for further details and illustrative examples of data sharing statements: ICMJE Data Sharing Statements for Clinical Trials

Since 1st December 2005, all clinical trials conducted in South Africa have been required to be registered in the South African National Clinical Trials Register. The SAMJ therefore requires that clinical trials be registered in the relevant public trials registry at or before the time of first patient enrollment as a condition for publication. The trial registry name and registration number must be included in the manuscript.

Please refer to the general guidelines for all papers at the top of this article for additional requirements with respect to ethics approval, funding, author contributions, etc. The format of original research articles should be followed for reporting of clinical trial results.

Patient Consent

Information that would enable identification of individual patients should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) has given informed written consent for publication and distribution. We further recommend that the published article is disseminated not only to the involved researchers but also to the patients/participants from whom the data was drawn. Refer to Protection of Research Participants. The signed consent form should be submitted with the manuscript to enable verification by the editorial team.

Other individuals

Any individual who is identifiable in an image must provide written agreement that the image may be used in that context in the *SAMJ.*

Copyright notice

Material submitted for publication in the *SAMJ* is accepted provided it has not been published or submitted for publication elsewhere. Please inform the editorial team if the main findings of your paper have been presented at a conference and published in abstract form, to avoid copyright infringement. All research already published as 'Conference proceedings' needs to be substantially re-written, with a new title, a new abstract and new and important results to back up any study before it will be considered for a new publication. The *SAMJ* does not hold itself responsible for statements made by the authors.

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Privacy statement

The *SAMJ* is committed to protecting the privacy of its website and submission system users. The names, personal particulars and email addresses entered in the website or submission system will not be made available to third parties without the user's permission or due process. By registering to use the website or submission system, users consent to receive communication from the *SAMJ* or its publisher SAMA on matters relating to the journal or associated publications. Queries with regard to privacy may be directed to publishing@hmpg.co.za.

Ethnic/race classification

Use of racial or ethnicity classifications in research is fraught with problems. If you choose to use a research design that involves classification of participants based on race or ethnicity, or discuss issues with reference to such classifications, please ensure that you include a detailed rationale for doing so, ensure that the categories you describe are carefully defined, and that socioeconomic, cultural and lifestyle variables that may underlie perceived racial disparities are appropriately controlled for. Please also clearly specify whether race or ethnicity is classified as reported by the patient (self-identifying) or as perceived by the investigators. Please note that is not appropriate to use self-reported or investigator-assigned racial or ethnic categories for genetic studies.

Continuing Professional Development (CPD)

SAMJ is an HPCSA-accredited service provider of CPD materials. Principal authors can earn up to 15 CPD continuing education units (CEUs) for publishing an article; co-authors are eligible to earn up to 5 CEUs; and reviewers of articles can earn 3 CEUs. Each month, *SAMJ* also publishes a CPD-accredited questionnaire relating to the academic content of the journal. Successful completion of the questionnaire with a pass rate of 70% will earn the reader 3 CEUs. Administration of our CPD programme is managed by Medical Practice Consulting. To complete questionnaires and obtain certificates, please visit MRP Consulting

Manuscript preparation

Preparing an article for anonymous review

To ensure a fair and unbiased review process, all submissions are to include an anonymised version of the manuscript. The exceptions to this are Correspondence, Book reviews and Obituary submissions.

Submitting a manuscript that needs additional blinding can slow down your review process, so please be sure to follow these simple guidelines as much as possible:

- An anonymous version should not contain any author, affiliation or particular institutional details that will enable identification.
- Please remove title page, acknowledgements, contact details, funding grants to a named person, and any running headers of author names.
- Mask self-citations by referring to your own work in third person.

General article format/layout

Accepted manuscripts that are not in the correct format specified in these guidelines will be returned to the author(s) for correction, which will delay publication.

General:

- Manuscripts must be written in UK English.
- The manuscript must be in Microsoft Word format. Text must be single-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes).
- Please make your article concise, even if it is below the word limit.
- Qualifications, ***full*** affiliation (department, school/faculty, institution, city, country) and contact details of ALL authors must be provided in the manuscript and in the online submission process.
- Abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.
- Include sections on Acknowledgements, Conflict of Interest, Author Contributions and Funding sources. If none is applicable, please state 'none'.
- Scientific measurements must be expressed in SI units except: blood pressure (mmHg) and haemoglobin (g/dL).
- Litres is denoted with an uppercase L e.g. 'mL' for millilitres).
- Units should be preceded by a space (except for % and ºC), e.g. '40 kg' and '20 cm' but '50%' and '19ºC'.
- Please be sure to insert proper symbols e.g. µ not u for micro, a not a for alpha, b not B for beta, etc.
- Numbers should be written as grouped per thousand-units, i.e. 4 000, 22 160.
- Quotes should be placed in single quotation marks: i.e. The respondent stated: '...'
- Round brackets (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.
- If you wish material to be in a box, simply indicate this in the text. You may use the table format –this is the *only* exception. Please DO NOT use fill, format lines and so on.

SAMJ is a generalist medical journal, therefore for articles covering genetics, it is the responsibility of authors to apply the following:

- Please ensure that all genes are in italics, and proteins/enzymes/hormones are not.

- Ensure that all genes are presented in the correct case e.g. TP53 not Tp53.

**NB: Copyeditors cannot be expected to pick up and correct errors wrt the above, although they will raise queries where concerned.

- Define all genes, proteins and related shorthand terms at first mention, e.g. '188del11' can be glossed as 'an 11 bp deletion at nucleotide 188.'

- Use the latest approved gene or protein symbol as appropriate:

- Human Gene Mapping Workshop (HGMW): genetic notations and symbols
- HUGO Gene Nomenclature Committee: approved gene symbols and nomenclature
- OMIM: Online Mendelian Inheritance in Man (MIM) nomenclature and instructions
- Bennet et al. Standardized human pedigree nomenclature: Update and assessment of the recommendations of the National Society of Genetic Counselors. J Genet Counsel 2008;17:424-433: standard human pedigree nomenclature.

Preparation notes by article type

- Research
- Editorials
- CME
- In Practice and Case reports
- Reviews

- Clinical trials
- Correspondence
- Obituaries
- Book reviews
- Guidelines

Research

Guideline word limit: 4 000 words

Research articles describe the background, methods, results and conclusions of an original research study. The article should contain the following sections: introduction, methods, results, discussion and conclusion, and should include a structured abstract (see below). The introduction should be concise – no more than three paragraphs – on the background to the research question, and must include references to other relevant published studies that clearly lay out the rationale for conducting the study. Some common reasons for conducting a study are: to fill a gap in the literature, a logical extension of previous work, or to answer an important clinical question. If other papers related to the same study have been published previously, please make sure to refer to them specifically. Describe the study methods in as much detail as possible so that others would be able to replicate the study should they need to. Results should describe the study sample as well as the findings from the study itself, but all interpretation of findings must be kept in the discussion section, which should consider primary outcomes first before any secondary or tertiary findings or post-hoc analyses. The conclusion should briefly summarise the main message of the paper and provide recommendations for further study.

Select figures and tables for your paper carefully and sparingly. Use only those figures that provided added value to the paper, over and above what is written in the text.

Do not replicate data in tables and in text .

Structured abstract

- This should be 250-400 words, with the following recommended headings:
    - **Background:** why the study is being done and how it relates to other published work.
    - **Objectives:** what the study intends to find out
    - **Methods:** must include study design, number of participants, description of the intervention, primary and secondary outcomes, any specific analyses that were done on the data.
    - **Results:** first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.
    - **Conclusion:** must be supported by the data, include recommendations for further study/actions.
- Please ensure that the structured abstract is complete, accurate and clear and has been approved by all authors.
- Do not include any references in the abstracts.

Here is an example of a good abstract.

Main article

All articles are to include the following main sections: Introduction/Background, Methods, Results, Discussion, Conclusions.

The following are additional heading or section options that may appear within these:

- Objectives (within Introduction/Background): a clear statement of the main aim of the study and the major hypothesis tested or research question posed
- Design (within Methods): including factors such as prospective, randomisation, blinding, placebo control, case control, crossover, criterion standards for diagnostic tests, etc.
- Setting (within Methods): level of care, e.g. primary, secondary, number of participating centres.
- Participants (instead of patients or subjects; within Methods): numbers entering and completing the study, sex, age and any other biological, behavioural, social or cultural factors (e.g. smoking status, socioeconomic group, educational attainment, co-existing disease indicators, etc)that may have an impact on the study results. Clearly define how participants were enrolled, and describe selection and exclusion criteria.
- Interventions (within Methods): what, how, when and for how long. Typically for randomised controlled trials, crossover trials, and before and after studies.
- Main outcome measures (within Methods): those as planned in the protocol, and those ultimately measured. Explain differences, if any.

Results

- Start with description of the population and sample. Include key characteristics of comparison groups.
- Main results with (for quantitative studies) 95% confidence intervals and, where appropriate, the exact level of statistical significance and the number need to treat/harm. Whenever possible, state absolute rather than relative risks.
- Do not replicate data in tables and in text.
- If presenting mean and standard deviations, specify this clearly. Our house style is to present this as follows:
- E.g.: The mean (SD) birth weight was 2 500 (1 210) g. Do not use the ± symbol for mean (SD).
- Leave interpretation to the Discussion section. The Results section should just report the findings as per the Methods section.

Discussion

Please ensure that the discussion is concise and follows this overall structure – sub-headings are not needed:

- Statement of principal findings
- Strengths and weaknesses of the study
- Contribution to the body of knowledge
- Strengths and weaknesses in relation to other studies
- The meaning of the study – e.g. what this study means to clinicians and policymakers
- Unanswered questions and recommendations for future research

Conclusions

This may be the only section readers look at, therefore write it carefully. Include primary conclusions and their implications, suggesting areas for further research if appropriate. Do not go beyond the data in the article.

Editorials

Guideline word limit: 1 000 words

These opinion or comment articles are usually commissioned but we are happy to consider and peer review unsolicited editorials. Editorials should be accessible and interesting to readers without specialist knowledge of the subject under discussion and should have an element of topicality (why is a comment on this issue relevant now?) There should be a clear message to the piece, supported by evidence.

Please make clear the type of evidence that supports each key statement, e.g.:

- expert opinion
- personal clinical experience
- observational studies
- trials
- systematic reviews.

CME (by invite only)

CME is intended to provide readers with practical, up-to-date information on medical and related matters. It is aimed at those who are not specialists in the field.

From January 2016, all CME articles will be printed in full in the *SAMJ*. Please try to adhere strictly to the guidelines on word count as we have a page limit for the print issue of the *SAMJ*. We reserve the right to place some tables and reference lists online if this is necessary for space.

In practice, this means that each CME topic usually covers two issues of the print issue of the *SAMJ*.

The guest editor, in consultation with the editor, is responsible for convening a team of authors, deciding on the subjects to be covered and for reviewing the manuscripts submitted. The suggestion is for 4 - 5 articles, although there is some room for flexibility contingent on discussions with the editor.

For queries about these guidelines please feel free to contact the CME editor, Dr Bridget Farham, by email (ugqirha@iafrica.com) or telephone (+27 (0)82 452 2860)

Review process

The guest editor reviews the articles and returns them to the CME editor for review and final approval.

Guest editorials

Guideline word limit: 1 000 words

- Include the guest editor's personal details (qualifications, positions, affiliation, e-mail address, and a short personal profile (50words)).

- If possible, include a photograph of the author(s) at high enough resolution for print. It is preferable to provide two guest editorials, one for each issue, so that the content of the articles in each issue is covered.

Articles

Guideline word limit: 2 000 - 3 000 words

- Each article requires an abstract of ±200 words.
- The editor reserves the right to shorten articles but will send a substantially shortened article back for author approval.

Personal details

Please supply: Your qualifications, position and affiliations and MP number (used for CPD points); Address, telephone number and fax number, and your e-mail address; and a short personal profile (50words)and a few words about your current fields of interest.

In Practice

Guideline word limit: 2 000 - 3 000words

This section includes articles that would previously have been accepted into the Forum section, and case reports.

In practice articles are those that draw attention to specific issues of clinical, economic or political interest regarding medicine and healthcare in southern Africa. They are assigned to a topic:

Case report
Clinical practice
Clinical alert
Issues in medicine
Issues in public health
Healthcare delivery
Medicine and the environment
Medicine and the law
Cochrane corner

An In Practice article should follow the following format – sub-headings are not necessary, but may be used for clarity:

- Author affiliations and qualifications: to be the same as for Research. Provide all authors' names and initials, qualifications and full affiliations, and corresponding author.
- Short abstract: does not need to be structured, but should capture the essential features of the article
- Introduction: the reason for the article and the issue being addressed
- Recent research, discussion, local policy around the issue – include your own research where appropriate
- All statements should be referenced and, if opinion only, this should be stated

- Discussion: how this article adds to the discussion around a particular topic
- If a clinical practice or policy point is at issue, this needs to be emphasised, using a box with highlights if appropriate.

Essentially In practice is an opportunity for a more discursive approach to topics of clinical, economic or political importance in southern African health systems. It is not an opportunity to put forward unsubstantiated opinions!

Case reports

The *SAMJ* has recently started to accept case reports. The cases must come from Africa, preferably southern Africa unless the condition is common to all African countries, and must be either a completely new description of a clinical condition or result (use Google!) or a case that highlights important practice or management issues.

Please use the following format for case reports:

- Title of case: do not include the words 'a case report' in the title
- Summary/abstract: up to 150 words summarising the case presentation and outcome
- Background: why is this case important and why did you write it up?
- Case presentation: presenting features, medical, social, family history as appropriate
- Case management: should be according to best practice, and if not, please explain why
- Investigations, if relevant: save space by simply saying 'normal' if, for example, renal function was completely normal, rather than listing normal results, highlight the abnormal – or indeed the normal if this is clinically significant
- Differential diagnosis, if relevant
- Treatment, if relevant
- Outcome and follow-up
- Discussion – a VERY BRIEF review of similar published cases
- Teaching points: 3 - 5 bullet points
- References: as per the *SAMJ* house style
- Tables and figures: keep to a minimum. Use clinical images where relevant – we need hi-res versions for print, and identifiable persons must have a consent form
- Patient consent: please include a statement about patient consent to a written case report. This should be uploaded as a supplementary file.

Clinical trials

Guideline word limit: 4000 words

As per the recommendations published by the International Committee of Medical Journal Editors (ICMJE), clinical trial research is any research that assigns individuals to an intervention, with or without a concurrent comparison/control group to study the cause-and-effect relationship between the intervention and health outcomes. All clinical trials should be registered with the appropriate national clinical trial registry (or any international primary register, if relevant), and the trial registration number should be cited at the end of the abstract. Since 1st December 2005, all clinical trials conducted in South Africa have been required to be registered in the South African National Clinical Trials Register.
The *SAMJ* therefore requires that clinical trials be registered in the relevant public trials registry at or before the time of first patient enrollment as a condition for publication. The trial registry name and registration number must be included in the manuscript.

Please refer to the general guidelines for all papers at the top of this article for additional requirements with respect to ethics approval, funding, author contributions, etc. The format of original research articles should be followed for reporting of clinical trial results.

Review articles

Guideline word limit: 4 000 words

These are welcome, but should be either commissioned or discussed with the Editor before submission. A review article should provide a clear, up-to-date account of the topic and be aimed at non-specialist hospital doctors and general practitioners.

Please ensure that your article includes:

- Abstract: unstructured, of about 100-150 words, explaining the review and why it is important
- Methods: Outline the sources and selection methods, including search strategy and keywords used for identifying references from online bibliographic databases. Discuss the quality of evidence.
- When writing: clarify the evidence you used for key statements and the strength of the evidence. Do not present statements or opinions without such evidence, or if you have to, say that there is little or no evidence and that this is opinion. Avoid specialist jargon and abbreviations, and provide advice specific to southern Africa.
- Personal details: Please supply your qualifications, position and affiliations and MP number (used for CPD points); address, telephone number and fax number, and your e-mail address; and a short personal profile (50 words) and a few words about your current fields of interest.

Correspondence (Letters to the Editor)

Guideline word limit: 500 words

Letters to the editor should relate either to a paper or article published by the SAMJ or to a topical issue of particular relevance to the journal's readership

- May include only one illustration or table
- Must include a correspondence address.

Book reviews

Guideline word limit: 400 words

Should be about 400 words and must be accompanied by the publication details of the book. Provide a hi-res image of the cover if possible (with permission from the copyright holder).

Obituaries

Guideline word limit: 400 words

Should be offered within the first year of the practitioner's death, and may be accompanied by a photograph.

Guidelines

Guidelines should always be discussed with the Editor prior to submission.

Because of the intensive review process required to ensure Guidelines are independent, evidence-based and free from commercial bias, they are usually published as a supplement to the *SAMJ*, the costs of which must be covered by sponsorship, advertising or payment by the guideline authors/association. We will provide a quote based on the expected length of the guideline and whether it is to appear online only, or in print, which must be accepted by the body putting the guidelines together before submitting the work to the SAMJ.

The Editor reserves the right to determine the scheduling of supplements. Understandably, a delay in publication must be anticipated dependent upon editorial workflow.

All guidelines should include a clear, transparent statement about all sources of funding and an explicit, clear statement of conflicts of interest of any of the participants in the guidelines about industry funding for lectures, research, conference participation etc.

All guidelines should be structured according to Agree II.

Please access this website before putting the guidelines together, download the Agree 11 instrument and use this to put the guidelines together.

All submitted guidelines will be sent to the local Agree II appraisal committee for review and must be endorsed by an appropriate body prior to consideration and all conflicts of interest expressed.

A structured abstract not exceeding 400 words (recommended sub-headings: *Background, Recommendations, Conclusion*) is required. Sections and sub-sections must be numbered consecutively (e.g. 1. Introduction; 1.1 Definitions; 2.etc.) and summarised in a Table of Contents.

Illustrations/photos/scans

- If illustrations submitted have been published elsewhere, the author(s) should provide consent to republication obtained from the copyright holder.
- Figures must be numbered in Arabic numerals and referred to in the text e.g. '(Fig. 1)'.
- Each figure must have a caption/legend: Fig. 1. Description (any abbreviations in full).
- All images must be of high enough resolution/quality for print.
- All illustrations (graphs, diagrams, charts, etc.) must be in PDF or jpeg form.
- Ensure all graph axes are labelled appropriately, with a heading/description and units (as necessary) indicated. Do not include decimal places if not necessary e.g. 0; 1.0; 2.0; 3.0; 4.0 etc.
- Scans/photos showing a specific feature e.g. *Intermediate magnification micrograph of a low malignant potential (LMP) mucinous ovarian tumour. (H&E stain).* –include an arrow to show the tumour.
- Each image must be attached individually as a 'supplementary file' upon submission (not solely embedded in the accompanying manuscript) and named Fig. 1, Fig. 2, etc.

Tables

- Tables should be constructed carefully and simply for intelligible data representation. Unnecessarily complicated tables are strongly discouraged.
- Large tables will generally not be accepted for publication in their entirety. Please consider shortening and using the text to highlight specific important sections, or offer a large table as an addendum to the publication, but available in full on request from the author

- Embed/include each table in the manuscript Word file - do not provide separately as supplementary files.
- Number each table in Arabic numerals (Table 1, Table 2, etc.) and refer to consecutively in the text.
- Tables must be cell-based (i.e. not constructed with text boxes or tabs) and editable.
- Ensure each table has a concise title and column headings, and include units where necessary.
- Footnotes must be indicated with consecutive use of the following symbols: * † ‡ § ¶ || then ** †† ‡‡ etc.

Do not: Use [Enter] within a row to make 'new rows':

Rather:

Each row of data must have its own proper row:

Do not: use separate columns for *n* and %:

Rather:

Combine into one column, *n* (%):

Do not: have overlapping categories, e.g.:

Rather:

Use <> symbols or numbers that don't overlap:

References

NB: *Only complete, correctly formatted reference lists in Vancouver style will be accepted. Reference lists must be generated manually and not with the use of reference manager software. Endnotes must* ***not*** *be used.*

- Authors must verify references from original sources.
- Citations should be inserted in the text as superscript numbers between square brackets, e.g. These regulations are endorsed by the World Health Organization,[2] and others.[3,4-6]
- All references should be listed at the end of the article in numerical order of appearance in the Vancouver style (not alphabetical order).
- Approved abbreviations of journal titles must be used; see the List of Journals in Index Medicus.
- Names and initials of all authors should be given; if there are more than six authors, the first three names should be given followed by et al.
- Volume and issue numbers should be given.
- First and last page, in full, should be given e.g.: 1215-1217 **not** 1215-17.
- Wherever possible, references must be accompanied by a digital object identifier (DOI) link). Authors are encouraged to use the DOI lookup service offered by CrossRef:
    - On the Crossref homepage, paste the article title into the 'Metadata search' box.
    - Look for the correct, matching article in the list of results.
    - Click Actions > Cite
    - Alongside 'url =' copy the URL between { }.
    - Provide as follows, e.g.: https://doi.org/10.7196/07294.937.98x

Some examples:

- *Journal references:* Price NC, Jacobs NN, Roberts DA, et al. Importance of asking about glaucoma. Stat Med 1998;289(1):350-355. http://dx.doi.org/10.1000/hgjr.182
- *Book references:* Jeffcoate N. Principles of Gynaecology. 4th ed. London: Butterworth, 1975:96-101.
- *Chapter/section in a book:* Weinstein L, Swartz MN. Pathogenic Properties of Invading Microorganisms. In: Sodeman WA, Sodeman WA, eds. Pathologic Physiology: Mechanisms of Disease. Philadelphia: WB Saunders, 1974:457-472.
- *Internet references:* World Health Organization. The World Health Report 2002 - Reducing Risks, Promoting Healthy Life. Geneva: WHO, 2002. http://www.who.int/whr/2002 (accessed 16 January 2010).
- Legal references

    - Government Gazettes:

    National Department of Health, South Africa. National Policy for Health Act, 1990 (Act No. 116 of 1990). Free primary health care services. Government Gazette No. 17507:1514. 1996.

    In this example, 17507 is the Gazette Number. This is followed by :1514 - this is the notice number in this Gazette.

    - Provincial Gazettes:

    Gauteng Province, South Africa; Department of Agriculture, Conservation, Environment and Land Affairs. Publication of the Gauteng health care waste management draft regulations. Gauteng Provincial Gazette No. 373:3003, 2003.

    - Acts:

    South Africa. National Health Act No. 61 of 2003.

    - Regulations to an Act:

    South Africa. National Health Act of 2003. Regulations: Rendering of clinical forensic medicine services. Government Gazette No. 35099, 2012. (Published under Government Notice R176).

    - Bills:

    South Africa. Traditional Health Practitioners Bill, No. B66B-2003, 2006.

    - Green/white papers:

    South Africa. Department of Health Green Paper: National Health Insurance in South Africa. 2011.

    - Case law:

    Rex v Jopp and Another 1949 (4) SA 11 (N)

    Rex v Jopp and Another: Name of the parties concerned

    1949: Date of decision (or when the case was heard)

    (4): Volume number

    SA: SA Law Reports

    11: Page or section number

    (N): In this case Natal - where the case was heard. Similarly, (C) woud indicate Cape, (G) Gauteng, and so on.

    NOTE: no . after the v

- *Other references (e.g. reports) should follow the same format:* Author(s). Title. Publisher place: Publisher name, year; pages.
- Cited manuscripts that have been accepted but not yet published can be included as references followed by '(in press)'.

- Unpublished observations and personal communications in the text must **not** appear in the reference list. The full name of the source person must be provided for personal communications e.g. '...(Prof. Michael Jones, personal communication)'.

From submission to acceptance

Submission and peer-review

To submit an article:

- Please ensure that you have prepared your manuscript in line with the SAMJ requirements.
- The following are required for your submission to be complete:

  o Anonymous manuscript (unless otherwise stated)

  o Manuscript

  o Any supplementary files: figures, datasets, patient consent form, permissions for published images, etc.

- Once the submission has been successfully processed, it will undergo a technical check by the Editorial Office before it will be assigned to an editor who will handle the review process. If the author guidelines have not been appropriately followed, the manuscript may be sent back to the author for correcting.

Peer-review process

Production process

Please note that there is a 6-month waiting time for publication, once an article has been sent to the production team.

The following process will follow:

1. An accepted manuscript is passed to a Managing Editor to assign to a copyeditor (CE).
2. The CE copyedits in Word, working on house style, format, spelling/grammar/punctuation, sense and consistency, and preparation for typesetting.
3. If the CE has an author queries, he/she will contact the corresponding author and send them the copyedited Word doc, asking them to solve the queries by means of track changes or comment boxes.
4. The authors are typically asked to respond within 1-3 days. Any comments/changes must be clearly indicated e.g. by means of track changes. Do not work in the original manuscript - work in the copyedited file sent to you and make your changes clear.
5. The CE will finalise the article and then it will be typeset.
6. Once typeset, the CE will send a PDF of the file to the authors to complete their final check, while simultaneously sending to the 2nd-eye proofreader.
7. The authors are typically asked to complete their final check and sign-off within 1-2 days. No major additional changes can be accommodated at this point.
8. The CE implements the authors' and proofreader's mark-ups, finalises the file, and prepares it for the upcoming issue.

Changing contact details or authorship

Please notify the Editorial Department of any contact detail changes, including email, to facilitate communication.

Publication

Online v. print

The *SAMJ* is an online journal. The online version of the journal is the one that has the widest circulation, is indexed by bibliographic databases including PubMed and SciELO, and is accessible in academic libraries. A printed edition , containing material selected by the Editor is also published each month and distributed to the membership of the South African Medical Association.

Online

- The full text of all accepted articles is published in full online, open access.
- Citation information of each article is based on its online publication.
- You may want to make use of the advantages of online publication e.g. specify web links to other sources, images, data or even a short video.

Print

- Not all articles will be selected for print.
- An article may be selected for print in a different month from that in which it was published online.
- Research articles will appear *in abstract form only*, if selected for a print edition.

Errata and retractions

Errata

Should you become aware of an error or inaccuracy in yours or someone else's contribution after it has been published, please inform us as soon as possible via an email to publishing@samedical.org, including the following details:

- Journal, volume and issue in which published
- Article title and authors
- Description of error and details of where it appears in the published article
- Full detail of proposed correction and rationale

We will investigate the issue and provide feedback. If appropriate, we will correct the web version immediately, and will publish an erratum in the next issue. The correction will be indexed, as PubMed has a function for linking errata back to the original article. All investigations will be conducted in accordance with guidelines provided by the Committee on Publication Ethics (COPE).

Retractions

Retraction of an article is the prerogative of either the original authors or the editorial team of SAMA. Should you wish to withdraw your article before publication, we need a signed statement from all the authors.

Should you wish to retract your published article, all authors have to agree in writing before publication of the retraction.

Send an email to publishing@hmpg.co.za, including the following details:

- Journal, volume and issue to which article was submitted/in which article was published
- Article title and authors
- Description of reason for withdrawal/retraction.

We will make a decision on a case-by-case basis upon review by the editorial committee in line with international best practices. Comprehensive feedback will be communicated with the authors with regard to the process. In case where there is any suspected fraud or professional misconduct, we will follow due process as recommended by the Committee on Publication Ethics (COPE), and in liaison with any relevant institutions.

When a retraction is published, it will be linked to the original article.

Indexing

The *SAMJ* has an impact factor of 1.5.

Published articles are covered by the following major indexing services. As such articles published in the *SAMJ* are immediately available to all users of these databases, guaranteed a global and African audience:

- Index Medicus (Medline/PubMed)
- ExcerptaMedica (EMBASE)
- Biological Abstracts (BIOSIS)
- Science Citation Index (SciSearch)
- Current Contents/Clinical Medicine
- Scopus
- AIM
- AJOL
- Crossref
- Sabinet
- Scielo

Sponsored supplements

Contact claudian@samedical.org for information on submitting ad hoc/commissioned supplements, including guidelines, conference/congress abstracts, Festschrifts, etc.

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