SKELETAL AGE ASSESMENT IN BLACK AFRICAN CHILDREN IN KENYA: APPLICABILITY OF THE GREULICH AND PYLE METHOD

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DECLARATION

I declare that this is my original work and it has not been presented in any other University or institution for an award of a degree or any academic credit. No part of this work may be reproduced or transmitted in any form without prior permission from the author or University of Nairobi.

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DEDICATION

I would like to dedicate this work to my parents for always supporting my dreams and ambitions and my siblings for encouraging me each step of the way.

ACKNOWLEDGEMENT

I wish to sincerely thank my supervisors Dr. Ian Mathenge and Dr. Patricia Othieno for their invaluable input in the conception and development of this dissertation. I also wish to thank all my lecturers and the department of Diagnostic Imaging for all their contribution and support. I also wish to acknowledge Mr. Phillip Ayieko and Mr. Richard Gichuhi, biostatisticians, for their invaluable input.

TABLE OF CONTENTS.

ABBREVIATIONS

CA- Chronological Age

GE- General Electric Company

GP- Greulich and Pyle Atlas

KNH- Kenyatta National Hospital

SA- Skeletal Age

SPSS- Statistical Package for the Social Sciences

UON- University of Nairobi

OPERATIONAL DEFINITIONS

Chronological Age- The number of years the child has lived taken as the difference between the date of examination and their exact date of birth

Skeletal Age- The degree of maturation of the child's skeleton based on the number and structure seen on bones visible in their wrist radiograph

ABSTRACT

STUDY BACKGROUND

Skeletal age assessment is vital in diagnosis and follow up of pediatric growth and development disorders, as well as useful in medico-legal cases where age is unknown or unavailable.

The most popular method used worldwide for skeletal age assessment is the Greulich and Pyle method which was based on a study done in the 1940s on growth and development in Caucasian North American children.

BROAD OBJECTIVE

To determine the applicability of GP standards in assessment of skeletal age in black African children living in Kenya.

STUDY DESIGN AND SITE

A cross sectional study was carried out at Kenyatta National Hospital (KNH). The GE Digital radiography Revolution XRd machine installed at the radiology department in Kenyatta National Hospital, was used for the study.

PARTICIPANTS

The study included children and adolescents referred for hand and wrist radiographs at Kenyatta National Hospital.

SAMPLING METHOD AND SIZE

The study included a total of **110** participants.

The convenience sampling method was used to select the participants.

MATERIALS AND METHODS

Hand and wrist radiographs of children and adolescents referred for evaluation of trauma were used. Chronological age was calculated using the participants' date of birth.

Skeletal age was determined according to the Greulich and Pyle method by three independent investigators.

A data collection sheet was used to record the patients' demographic data, chronological age and skeletal age determined by each investigator.
A p value was derived from the correlation coefficient analysis was reported and significant correlation between the variables representing chronological and estimated age was determined by a cut off value of 0.05.

EXPECTED MAIN OUTCOME AND MEASURES

The mean differences between the chronological age and skeletal age from each investigator were analyzed. Inter-observer variability was also analyzed.
The data was analyzed using the statistical package for social scientists (SPSS) computer software package and the results presented in the form of tables, charts and graphs.
The data will be made available to UON and KNH.

CHAPTER ONE: INTRODUCTION

Background

Skeletal maturity is an important developmental indicator in children from birth up to early adulthood. Skeletal age can give an accurate assessment of growth and development, nutritional status and health of a child. Accurate skeletal age assessment is therefore invaluable in informing diagnostic and therapeutic decisions in pediatric patients.(1)

It can be used in diagnosing hereditary diseases and growth disorders accurately. Other uses include monitoring response to medical treatment. Estimation of skeletal age has recently become invaluable in cases where accurate birth records are not available. Age estimation in those who are unwilling or unable to provide their age has recently become a common medical request, especially due to open geographical borders with unrestricted movement of people. Birth documents maybe falsified or unavailable and thus an accurate age estimation becomes important to authorities.(1, 2)

Skeletal age assessment has a large medico-legal bearing in determining criminal liability where minors are involved, especially in developing countries where proper birth records may be unavailable.

There are several accepted methods used in assessment of skeletal age. The most commonly used methods are manual methods of Greulich and Pyle and Tanner Whitehouse methods. (3, 5) These involve direct visualization of hand and wrist radiographs to determine bone ossification. The disadvantage of these manual methods is great inter and intra-observer variability in application. (4)

The Tanner Whitehouse method for estimation of skeletal age has been in use for over three decades. The method was developed using radiographs of white children collected in the United Kingdom in 1950s and 1960s. Tanner Whitehouse method is a scoring method where a score is assigned to the maturity level of each bone, the total score is then converted to skeletal age.(3)

Recently more modern automated methods have been introduced, particularly in developed countries such as using ultrasound, computer assisted methods, BoneXpert Software(using artificial intelligence/machine learning) and using MRI.(2, 4)

The Greulich and Pyle method is most widely used since it is simple and faster than other methods. It is the method used in our hospital. This method is based on "The radiographic Atlas of Skeletal development of the hand and wrist" by Dr. William Walter Greulich and Dr. Sarah Idell Pyle. The last edition of the Atlas was published in 1959 and it is the most commonly used atlas for skeletal age assessment.(4)

Problem statement

The Greulich and Pyle Atlas was developed using data collected on human growth and development from the Brush study done among North American Caucasian Children of upper socio-economic class between 1931 and 1942. The Atlas consists of reference radiographs of the left wrist and hand from birth until 19years of age for males and 18 years of age for females. It relies on the fact that wrist and hand bone ossification centers appear in a sequential and fixed order. Skeletal age is estimated by comparing a subject's wrist and hand ossification centers with the closest reference image in the GP atlas for females and males separately.(5)

Applicability of the GP Atlas to different ethnicities around the world, socio-economic statuses and genetic groups has been subject to controversial discussion. Recent studies have shown that there may be differences in skeletal maturation in contemporary populations, attributed to genetic profile, socio-economic status and nutritional status.(4, 5)

Recent studies have suggested that secondary sexual characteristics in modern boys and girls begin earlier than they did several decades ago.(6, 7)

These factors have led to the need to evaluate the reliability of the existing Greulich and Pyle standard, especially in developing populations. This study seeks to investigate the accuracy level of the GP atlas in estimating skeletal age in Black African Children in Kenya.

CHAPTER TWO: LITERATURE REVIEW

Skeletal maturation

Skeletal maturation take place in phases which have been shown to be identical in different ethnic groups. Differences in time taken to pass through these different stages have been shown to exist among different age groups in different ethnicities. However it is thought it is the socio-economic status that determines rate of ossification, rather than ethnicity. Application of bone x-ray age methods to populations of low socio-economic status leads to under-estimation of age. Several factors such as nutrition, hormonal secretion and genetics influence skeletal development.(7)

A study done by Mackay assessing skeletal development among east African children showed that there is no difference in the order of appearance of the carpal ossification centers from that: commonly accepted for other races. The fact that skeletal maturation is more rapid in girls than in boys has been confirmed. The rate of skeletal maturation has been compared with findings of other writers on American children, and the African children investigated have been found to be from 11/2 to 2 years behind present American standards.(10)

Methods

Currently the most used methods of bone age assessment are Greulich and Pyle and Tanner Whitehouse methods. Greulich and Pyle methods is quicker and easier to use hence takes a few minutes to determine skeletal age from a single wrist radiograph.(4)

Computerized Skeletal age estimation systems that are more accurate have been recently developed. However they are still considered experimental.(11, 12)

A study done by Zafar et al in Pakistan to assess the reliability of GP atlas in Pakistani children in Karachi found that skeletal age was advanced in males in early childhood, delayed during middle and late childhood and advanced in adolescents. In females the skeletal age was higher than chronological age in all age groups.(13)

A similar study done in Lakarno area in Pakistan found that skeletal age in Pakistani children did not conform to the Greulich and Pyle standards. Mean differences of up to 13 months were found between skeletal age and chronological age.(4)

Among Indian children, assessment of skeletal age using GP atlas found that Indian boys showed delayed skeletal age by 0.7 years while the girls delayed by 0.33 years. Male and female children had delayed skeletal age in all age groups except 12-13 years whereby the girls had advanced age by 0.22years. More than 1 year difference between chronological age and skeletal age was found in males aged 7-12 years.(14)

Loder et all conducted a study to assess applicability of Greulich and Pyle skeletal age standards among Black and white children in Lake Erie area, North America. The study noted that skeletal age and chronological age were similar in white girls of all age groups. Black girls were skeletally advanced by 0.4-0.7 years in all age groups except 4-8years. White boys 4-8 years were skeletally delayed by 0.9years and during 9-13 years by 0.4 years, but were advanced during 13-18years by 0.5 years. Black boys in adolescent age group were skeletally advanced by 0.4 years.(15)

In Iranian children, mean skeletal age differences between 2-21.6 months was found in boys aged 7-14 years. Compared to chronological age, skeletal age was delayed by 6.6-11.9 months in girls aged 7-9 years and advanced by 2-12.2months in girls 10-14 years.(16)

In Turkish boys, GP atlas was not completely applicable. It was noted that in boys 7-13years, skeletal age was delayed by 0.61-0.32 years and was advanced by 0.13-0.89 years in boys aged 14-17 years.(17)

A similar study done in east Turkish children found low mean differences between skeletal age and chronological age of 0.2 and 0.13 years in girls and boys respectively which were found to be of low statistical significance.(18)

A study done in the united states to compare applicability of Greulich and Pyle atlas in skeletal age assessment among Asian, White, Black and Hispanic children noted that in Black girls skeletal age was advanced in all age groups except 4-8years.In late childhood and adolescence, skeletal age exceeded chronological age by about 10 months. In Hispanic adolescent girls skeletal age was more than chronological age by approximately 9 months. In Black adolescent boys, skeletal age was more than chronological age by 5 months with no discrepancies in other age groups. Preadolescent Asian boys showed significant skeletal age delay especially 4-8years where skeletal age lagged behind by almost 15months. In adolescent Asian boys, skeletal age exceeded chronological age by approximately 9 months. Adolescent Hispanic boys had and advanced

skeletal age by 11 months while pre-adolescent boys had a delayed skeletal age by approximately 4-8months.(19)

Among French children, it was noted that the mean difference between chronological age and skeletal age was -2.29months for males and -6.44months for females which showed overestimation of skeletal age for both genders. No statically difference between chronological age and skeletal age was found in both males and females.(20)

The GP atlas was found to be applicable to children of central European origin. The difference between chronological age and skeletal age was -1.5months. The differences were within the normal variation of skeletal maturation as reported by GP atlas.(21)

In South Indian population GP atlas underestimated skeletal age by 0.23 years for boys and overestimated skeletal age by 0.02years in girls and mild overall underestimation of 0/1 years was noted. However significant correlation was found between skeletal age and chronological age and thus the GP atlas was found reliable in assessing age in South Indian children aged 9-20years. (22)

A similar study done among Caucasian children of low-middle socio-economic status in Turkey found there was no statistically significant difference between chronological age and skeletal age. Skeletal age was advanced by 0.17-1.1year for all age groups in girls. Skeletal age was delayed at 11-14 age group by 0.01-0.5years but was not significant. Skeletal age was advanced in 15-17 age group by 0.8-0.9years and delayed in 18-19 years by 0.02-0.048years for boys.

In a Dutch Caucasian population, there was a significant strong correlation between skeletal age and chronological age in both girls and boys aged between 5-19years. On average, skeletal age was delayed by an insignificant amount (1.7 months in girls and 3.3 months in boys)(23)

A study done by Zhang et al among male and female Asian, African American, white and Hispanic children found that skeletal age was significantly overestimated in Asian and Hispanic children using the GP atlas. Skeletal age was advanced in Asian girls (10-13years) by 0.59years and 0.58years in Hispanic girls of the same age. In Asian boys (11-15years) significant overestimation of skeletal age by 0.97years was observed while in Hispanic boys of the same age skeletal age was overestimated by 0.83years. No significant differences between skeletal age and chronological age was observed in White and African American children.(6)

A similar study conducted among South African male adolescents found that the Greulich and Pyle atlas underestimated skeletal age by approximately 6 months compared to chronological age. Skeletal maturity as characterized by complete epiphyseal fusion occurred at about 2.1years later than the GP atlas estimate of 19 years. The difference between skeletal age and chronological age ranged from 2.4months to 8.4months in boys aged 13 and 18 years. In boys 19years, skeletal age was underestimated by 1 year.(24)

Mora et al conducted a study to determine skeletal age of healthy American children of European and African descent. It was noted that skeletal age was overestimated in African American pre-pubertal children by 0.09years. In children of European descent GP underestimated age by 0.17 years. Racial differences were observed in pre-pubertal children. European American post pubertal males had increased skeletal age compared to African American post pubertal males.(19)

Another study noted racial differences in skeletal age among Asian, African American, Caucasian and Hispanic children of different ages. It found that in Asian subjects the GP atlas showed decreased skeletal age in children 2-7 years (from 0.2 to 2.3 years) and showed increased skeletal age at age 8. In African American children the difference between skeletal age and chronological age was statistically significant. No significant differences in skeletal age and chronological age was found in Hispanic and Caucasian subjects.(25)

Among school going Pakistani children in Karachi, GP atlas was found to underestimate skeletal age by average 6.65 months in females and 15.7months in males(26)

The Greulich and Pyle atlas was found to be applicable to Iranian children aged 6-18years. It was noted that in male subject's skeletal age was 4.5months less than chronological age while in female subjects mean skeletal age was 0.5months less than chronological age. No statistically significant difference was found among the age subgroups in either males or females.(27)

Skeletal age assessment in children of a modern Scottish population found that differences between chronological age and skeletal age estimated by GP atlas ranged between an underage of 37months and an over age of 31 months for both females and males. On average the skeletal age was 1.95months less than chronological age in females and 1.63months less than chronological age in males.(28)

In children of Southern Turkish population aged 10-18years, mean differences between chronological age and skeletal age ranged from 0.01 to 1.11 years. The differences were statistically significant in the age group between 10-15 years for females ranging from -0.4 to -1.79 years. Skeletal age was significantly over estimated in 10-15 years in males and 10-18years in females.(29)

Skeletal age assessment using the GP atlas among Australian children found that overall skeletal age was 2.2 months less than chronological age. Skeletal age in males and females was under estimated by 1.5months and 3.7months less than chronological age respectively. No statistically significant differences were found.(30)

A study done on estimation of skeletal age in Italian children using the GP method found that overall skeletal age was 2.2 months less than chronological age. Skeletal age in males and females was underestimated by 1.5months and 3.7months less than chronological age respectively. No statistically significant differences were found.(31)

JUSTIFICATION

Skeletal age assessment has an important role in clinical and medico-legal cases. It can be used in diagnosis and treatment follow up of growth and development disorders. It is also of important in criminal and forensic cases involving minors and may have a critical role in ascertaining criminal liability. Accuracy of the skeletal age estimate is therefore of utmost importance. Only one African study has been found which was done in South Africa to assess the skeletal maturation of young male adolescents using the Greulich and Pyle Atlas. No study has been done to assess the applicability of the Greulich and Pyle Atlas in skeletal age assessment in Black African children.

HYPOTHESIS

Null hypothesis

The Greulich and Pyle method of skeletal age assessment is not accurate in estimating skeletal age in Black African children.

RESEARCH QUESTION

Is the Greulich and Pyle Atlas applicable to Black African children in estimation of skeletal age?

OBJECTIVES

Broad Objective

To determine the applicability of GP standards in assessment of skeletal age in black African children and adolescents living in Kenya.

Specific Objectives

To determine:

1. Correlation between chronological age and GP atlas skeletal age estimate in Black African children in Kenya
2. Inter observer variability of independent observers in skeletal age estimation using the GP atlas.

CHAPTER THREE: METHODOLOGY

Study design

This was a prospective cross-sectional study done at KNH radiology department

Study Area Description

Kenyatta National Hospital, Nairobi County, Kenya

Study population

The study included children and adolescents between 0-19 years who were sent to KNH radiology department for hand and wrist radiographs for evaluation of traumatic injury.

Inclusion criteria

1. African children 0-19years presenting to KNH radiology department during the duration of the study for hand and wrist radiographs for evaluation of traumatic injury
2. Patients whose date of birth is availed

Exclusion criteria

1. Children and adolescents presenting to KNH radiology department for hand and wrist radiographs but date of birth is not availed.
2. Children and adolescents with chronic illnesses or on long term medications that may affect skeletal maturation.
3. Decline to consent/assent
4. Images where hand and wrist is too damaged for an estimate to be made.

Sample size determination

To determine sample size in this correlation study, the sample size required to determine whether a correlation coefficient differs from zero Hulley *et al* 2013(32) will be used:

$$\text{Total sample size (N)} = \left[\frac{Z_\alpha + Z_\beta}{C}\right]^2 + 3$$

Where:

The standard normal deviate for α of 0.05 = Z_α = 1.96

The standard normal deviate for β of 0.2, representing 80% power = Z_β = 0.842

C = 0.5 * ln[(1+r)/(1-r)] = 0.255

The correlation coefficient between chronological age and GP atlas skeletal age = r (rho) = 0.25

Total sample size (N) $= \left[\frac{1.96+0.842}{0.255}\right] \wedge 2 + 3$

N = 108

Therefore, a total of 108 children were to be recruited and assessed using GP atlas

Sampling method

Convenience sampling was used to select the participants. The study was carried out over 1 year.

Study procedure

Radiographic images of the wrist and hand of children presenting to KNH radiology department for evaluation of trauma were used. The participants' age range was 0-19years. Left wrist and hand radiographs were used where available unless only the right hand was available or if the left hand was severely damaged.

Images to be included had to be clear, include distal radius and ulna, carpals, metacarpals and phalanges taken in the antero-posterior or postero-anterior views.

Chronological age was determined in months by subtracting date of birth from the date the image was taken. Skeletal age was determined according to the GP method where each selected radiograph was compared to the reference image which it most closely matched to generate the skeletal age estimate.

The selected radiographs were reviewed independently by two experienced consultant radiologists and one third year radiology resident in training. The investigators were blinded to the subjects' chronological age and were only given the gender.

The mean differences and standard deviations between the different readings were calculated in order to assess inter observer variations.

Data collection procedures

The data was collected after careful evaluation of the request form, and radiographic image.

The data was recorded on to a questionnaire (APPENDIX A) which was administered by the principal researcher and research assistants.

Materials

- KNH uses a (General electric Company) digital radiography Revolution XRd machine.
- Data collection tool/questionnaire.

STUDY PERSONNEL

- Radiographers working at the radiography unit in KNH.
- Biostastician to analyze the data.

Data Collection Tool

A structured data collection form (Appendix A) was completed by the principal researcher and research assistants who were the radiographers present at the time of examination. The data collection tool is provided in appendix c.

Data Handling

The questionnaires were sorted at Kenyatta National Hospital. The filled questionnaires were stored in the department of diagnostic imaging and radiation medicine under lock and key during data collection and entry and later moved for safekeeping at an offsite location.

Data was entered into a password protected Microsoft access database. Once entry was completed, the principal investigator compared contents of the database with the hard copy results to identify and correct any data entry errors.

Ethical Considerations

- Written informed consent was sought from the participants and/or their parents
- Ethical clearance was obtained to conduct this study from the KNH/UON Ethics and Scientific Review Committee.
- Institutional permission was sought from both KNH and University of Nairobi

- Confidentiality was maintained at all times during the study

Confidentiality of participants

The principal investigator ensured that there will be no identifiers that may link the research data to study participants. Each study participant was allocated a unique numeric identifier that was used in the data abstraction tool and database.

Confidentiality of data obtained

Access to the participant data will be restricted. No unauthorized persons will be allowed any access to participant records. All electronic databases will be password protected to control access.

Beneficence/Maleficence

The results of the study will be used to improve participant management .All participants will be protected from any health, physical, social or economic harm.

Data Management and Statistical Analysis Plans

Data management

All data abstraction tools and electronic databases (MS Excel) utilized in this study will be protected by procedures which are consistent with applicable laws, policies, regulations and standards in Kenya. Computers used to enter data will be password protected at the operating system level using software that is commercially available. Electronic databases will be password protected. Any hard copies will be kept under lock and key.

Data analysis

The Statistic Package for Social Science version 20.0 for Windows® was utilized for statistical analysis of data. Analysis of participants' demographic data was conducted using descriptive statistics. Demographic data was collected as categorical data and was analyzed using frequency distribution curves to determine the percentage of participants' with specific demographic traits. Data on the research was collected using a structured collection tool.

The following was analyzed:

- Chronological age in months

- Skeletal age in males according to the Greulich and Pyle atlas.
- Skeletal age in females according to the Greulich and Pyle atlas

Scatter plots of chronological age as independent variable and GP Atlas estimated age as independent (predictor) variable were used to explore the correlations between the two variables. A p value derived from the correlation coefficient analysis was reported and significant correlation between the variables representing chronological and estimated age were determined by a cut off value of 0.05. To determine interrater reliability, the radiographs were independently evaluated by three readers.

Data Dissemination

The results of this study will be bound in a Master's thesis book and disseminated to the department of Diagnostic imaging and Radiation medicine. A copy shall be provided to the KNH radiology department. This study will also be disseminated to a wider audience through publications in peer review journals, technical briefs and presentations in Kenyan and international meetings.

Study Limitations

- Lack of availability of participants exact date of birth

TIMELINE OF EVENTS

	NOVEMBER 2016-DECEMBER 2016	MARCH 2017	APRIL 2017	APRIL 2017 –OCTOBER 2017	SEPTEMBER 2017 – DECEMBER A 2017	NOVEMBER 2017– DECEMBER 2017
Proposal write up	X					
Submission to ERC& corrections		x				
Data collection			x	x		
Data entry and analysis					x	
Report writing and desertion submission						x

BUDGET

Item	**Unit cost (Ksh)**	**Number**	**Total cost**
Research assistants	1000.00	2	2000
Biostatistician fee	20000.00		20000
Supplies and equipment			
Printing paper	500	10	5000
Printing cartridges	10,000	2	20000
Folders	50	20	1000
USB flash drive	3000	1	3000
Miscellaneous including report writing, thesis preparation and publication			20000
Contingency			10000
Grand Total			**81000**

RESULTS

A total of 110 Hand-Wrist radiographs were evaluated. Of these 67 were male while 43 were female.

Minimum age was 9 months while maximum age was 18 years.

No statistically significant difference was found between readings by the 3 observers. (Maximum difference 6 months, Mean difference 2.6months, p =0.409)

Overall in girls, skeletal age was underestimated compared to chronological age with differences from 2 to 16 months (mean difference =12months) found between estimated skeletal age and chronological age

In boys, skeletal age was underestimated by 4 to 14 months (mean difference =11months) overall compared to chronological age.

Table 1: **Descriptive statistics for age estimation (age in months)**

Age Estimation	Mean	SD	Min	Max
Chronological Age	120.30	68.79	9	216
Investigator1	100.85	63.99	6	206
Investigator2	98.30	62.22	6	200
Investigator3	99.62	63.74	6	206
Mean Skeletal Age	99.59	63.64	6	203

Table 2: Comparison between readings from the three investigators

Description	Age in months
Investigator1	100.85
Investigator2	98.30
Investigator3	99.62
p-value	0.409

Table 3: Comparison between Chronological and Skeletal age in girls

Description	Age(months)
Mean Chronological Age	111.28
Mean Skeletal Age	99.59
Paired t test	0.7
p-value	0.007

Table 4: Comparison between Chronological and Skeletal age in boys

Description	Age(months)
Mean Chronological Age	120.28
Mean Skeletal Age	109.59
Paired t test	0.348
p-value	0.006

There was no statistically significant difference in estimation of skeletal age by the three observers. (P value= 0.409). Paired t test were performed and yielded p values of 0.005 and 0.009 in adolescent girls and boys respectively which was statistically significant.

DISCUSSION

The inter-observer agreement in skeletal age estimation was found to be good. There was no statistically significant difference in estimation of the skeletal age by the three observers. This was comparable with similar findings done in various other studies done in North America, Pakistan and India comparing skeletal age assessment in participants' of different ethnicities. (6, 13, 15)

There were significant differences between skeletal ages determined by the Greulich and Pyle method compared to the chronological age in black African children. Skeletal age was found to be underestimated in both boys and girls. These findings were comparable with the study conducted by Zhang et al on Racial differences in growth patterns of children assessed on basis of base age which showed significant cross racial differences in skeletal age.(6)

The findings are also comparable to a study done by Kundisai et al on applicability of GP age estimation in determining maturation in male Africans. Similar to this study, skeletal age determined by the Greulich and Pyle method was lower for a large population of the sample and it was determined that the Greulich and Pyle method was inapplicable to those above 17 years due to underestimation of skeletal age compared to chronological age. There was increasing tendency for age to be underestimated in black males with increase in chronological age as found in this study.(24)

Overall, skeletal age was underestimated by up to 16 months in girls and up to 14 months in boys. These results were similar to a study by Loder et al which investigated the applicability of GP skeletal age standards to contemporary black and white children. The study concluded that the method was applicable to white girls through all ages and white boys in early and late childhood but that the standards were not suitable to black girls of any age and adolescent black boys, and further studies were recommended.(15)

There was an increased number of subjects with mean differences between skeletal age and chronological age greater than 2SD which is comparable with the study done by Kundisai et al which found that skeletal development and maturation is underestimated in black children as compared to the Greulich and Pyle standards.(24)

Skeletal development has been shown to occur differently in children other than black Africans.

These findings are comparable to a study done by Zafar et al to assess applicability of Greulich and Pyle method in skeletal age estimation among Pakistani Children. It was found that in males, skeletal age was advanced in early childhood, underestimated in late childhood and overestimated

in adolescence. In females, the trend was similar except that skeletal age was overestimated in late childhood (13)

In this study it was found that in the early childhood age group, 5 children were found to have accelerated scaphoid development compared to the other carpal bones in the same Greulich and Pyle standard. This was a unique finding in this study that raises the question of different skeletal development rate and patterns in children of different ethnicities and background. Further studies are necessary to ascertain this variability.

Previous similar studies conducted in children of different populations and ethnicities in North America, specifically African Americans, Asians and Hispanics suggested that different factors may affect skeletal development including race/ethnicity, nutrition, socio-economic status and genetics. In these studies Greulich and Pyle method overestimated skeletal age compared to chronological age in adolescent male and female African Americans and Hispanics which could draw the conclusion that our subjects showed underestimation of skeletal age by the Greulich and Pyle method. These findings provide a strong argument for nature versus nurture as a factor that affects skeletal development. Further studies that include individuals of different biological origin would be of value in drawing such a comparison. (19) (25)

Genetic differences and ethnic background are some factors thought to influence skeletal growth. This raises the question of the applicability of the Greulich and Pyle standards across children of different races and populations.

The main limitation of this study was the small number of subjects from each group and the utilization of pre-existing radiographs. Furthermore, the sample consisted of subjects attending the Kenyatta National hospital which is a government hospital that caters mainly to patients of low or no income thus limiting comparison based on socio-economic status.

CONCLUSION

The results suggest that black African children may have different skeletal development compared to American children from who the Greulich and Pyle atlas was derived.

The Greulich and Pyle standards showed decreased accuracy in determining skeletal maturity, particularly in adolescence whereby our subjects showed underestimation of skeletal ages of up to 16 months in adolescent girls and up to 12 months in adolescent boys.

Biological origin and ethnic background may have a strong effect on skeletal growth and should be considered in age estimation.

Greulich and Pyle standards should be used with great caution when making clinical or forensic decisions that require accurate age estimation in black African children due to decreased accuracy in this population.

RECOMMENDATIONS

Further studies with larger groups of participants residing in Kenya with diverse ethnic and socio-economic characteristics are recommended to allow further comparison based on these characteristics. These studies should be made in comparison to the newer artificial intelligence algorithms that are being used in developed countries.

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APPENDIX A: DATA COLLECTION TOOL

Participant number: _____

Gender: _____

Height_____Weight:_____BMI_____

Date of Birth_____

Date of Image_____

Parents/Guardians Employment Status: _____

Indication for radiograph: _____

Side of body_____

History of treatment for chronic illness/prolonged admission in hospital? YES NO

If YES, give details _____

Is the child currently taking any long term medications? YES NO

If YES, give details_____

CHRONOLOGICAL AGE	SKELETAL AGE		
	INVESTIGATOR 1	INVESTIGATOR 2	INVESTIGATOR 2

APPENDIX B (I): CONSENT FORM FOR PARENT/GUARDIAN

Study background: I am Dr. Caroline Kinoti from University of Nairobi department of diagnostic imaging. I am carrying out a study geared towards improving accuracy of radiographic skeletal age assessment in children and adolescents. This study has been approved by KNH-UON Ethics committee which regulates such studies. I am under supervision of Dr. I.M Mathenge, a consultant radiologist. Your child is undergoing a radiographic examination of the hand/wrist and I would like to recruit him/her for the study.

Study Objective: The main objective of this study is to assess the applicability of the standard Greulich and Pyle method of skeletal age assessment in Black African Children.

Voluntariness of Participation: Please note that your child's participation is voluntary and there will be no financial reward for participating.

Confidentiality: In this study, you will be asked some personal questions, but this will be kept confidential and your child's identity will not be revealed, as he/she will be identified by a code number and you/your child's name shall not appear anywhere.

Benefits/Risks: I will review the radiographic image and assess the skeletal age based on the bones seen on the image. I will not influence the diagnosis/treatment your child receives in any way. Hence this study will not have any direct positive/negative contribution to your child's current treatment. The study will only benefit future patients. There are no additional risks to your child from participating in the study.

Right to Withdrawal: Your consent or lack of it to participate, will not jeopardize your child's treatment whatsoever and you are free to withdraw from the study at any time.

CONSENT BY PARENT/GUARDIAN

TITLE OF STUDY: Skeletal Age Assessment in African children at Kenyatta National Hospital: Applicability of Greulich and Pyle method.

RESEARCHER: Dr. Caroline Kinoti, a postgraduate student in the Department Of Diagnostic Imaging and Radiation Medicine at the University of Nairobi.

I hereby confirm that the above named doctor has explained the study to me and I understand fully.

I understand that my child's participation is voluntary and that I have not been forced to participate.

I understand that I can refuse to participate without giving a reason and my child's medical care will not be affected.

I understand that I will not receive any compensation, monetary or otherwise for participating in the above study.

I understand that my child's personal information availed for purpose of this study will be kept confidential.

I hereby consent for my child to take part in the above study.

Participant number: _____ Signature: _____
Date: _____

I certify that the participant has understood and consented to participation in the study.
Dr. Caroline Kinoti
Signature _____
Date _____

CONTACTS

Researcher:

Dr. Caroline Kinoti

Department Of Diagnostic Imaging

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APPENDIX B (II) FOMU RIDHAA KWA MZAZI/MLEZI

TAARIFA ZA MSINGI

Mtafiti mkuu: Jina langu ni Daktari Caroline Kinoti. Mimi ni mwanafunzi katika chuo kikuu cha Nairobi nikisomea taaluma ya udaktari. Ningependa kushirikisha mtoto wako katika utafiti wangu unaochunguza umri mifupa tathmini kwa watoto waafrika katika hospitali kuu ya Kenyatta. Niko chini ya usimamizi wa Daktari I.M Mathenge, mshauri wa Radiology. Utafiti huu umeidhinishwa nakamati ya maadili ya KNH-UON.

Utaratibu wa utafiti: Watoto wote wanaohudumiwa katika idara ya eksirei ya hospitali Kuu ya Kenyatta na ambao wazazi watapeana idhini watashirikishwa katika utafiti huu. Dodoso litatumika kuuliza maswali kuhusu tarehe ya kuzaliwa, magonjwa na dawa ambazo mtoto anatumia. Nitaikagua eksirei na kutathmini umri kulingana na mifupa inayoonekana kwenye picha.

Madhumuni: Utafiti huu utaboresha usahihi wa umri mifupa tathmini kwa watoto waafrika.

Hiari ya kushiriki: Kushiriki kwa mtoto wako ni kwa hiari yako na hakuna malipo ya fedha kwa ajili ya kushiriki

Usiri: Mambo ya utafiti huu yatatunzwa kwa siri na kutumika katika utafiti tu. Utambulisho wako na mtoto wako hautawekwa bayana katika makaratasi yoyote. Makaratasi yote yatawekwa katika kabati lililofungwa na kifunguu kuwa na mtafiti mkuu.

Faida ya kushiriki: Hakuna malipo yoyote kwa kushiriki katika utafiti huu.. Majibu yatakayotokana na utafiti huu yatasaidia katika kuboresha usahihi wa umri mifupa tathmini kwa watoto waafrika.

Madhara: Hakuna madhara yoyote yatakayohusishwa kutokana na utafiti huu.

Haki ya kukataa: Kushiriki katika utafiti huu ni kwa hiari. Unaruhusiwa kutoka katika utafiti wakati wowote bila madhara yoyote.

Kama una swali lolote unaweza kuafikiana na mtafiti mkuu ukitumia nambari 0720705011 na idara ya maadili KNH-UON kwa nambari +254 202726300-9 Ext 44355

Tia sahihi ama weka alama iwapo umekubali kushiriki katika utafiti huu

Mzazi/Mlezi …… Mtafiti …… Tarehe ……

MAWASILIANO

Mtafiti Mkuu:

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Msimamizi:

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APPENDIX C (I): ASSENT FORM FOR OLDER CHILDREN BUT BELOW 18YEARS

Background Information: This informed assent form is for children aged between 9 to 18 years who are undergoing wrist radiograph examinations at KNH and who we are inviting to participate in the research on skeletal Age assessment in Black children at KNH based on the Greulich and Pyle atlas.

My name is Dr. Caroline Kinoti,I am a resident in Diagnostic Imaging Department, University of Nairobi. I am carrying out a research on Skeletal age assessment in Black african children at KNH. I will invite you to be part of this research study.

Study objective: The main objective of this study is to assess the applicability of the standard Greulich and Pyle method of skeletal age assessment in Black African Children.

Voluntariness of paticipation: You can choose whether you will want to participate in the study or not.. We have discussed this with your parent/guardian and they are aware that we are asking you for your permission to participate in the study. If you agree to take part in the study, your parents will also have to give permission. Should you not want to take part in the research, you will not be forced, even if your parents have agreed.

Confidentiality

In this study, you will be asked some personal questions, but this will be kept confidential and your identity will not be revealed, as you will be identified by a code number and your name shall not appear anywhere.

Benefits/Risks

I will review the radiographic image and assess the skeletal age based on the bones seen on the image. I will not influence the diagnosis/treatment you receive in any way. Hence this study will not have any direct positive/negative contribution to your current treatment. The study will only benefit future patients. There are no additional risks to you from participating in the study.

Right to Withdrawal

Your assent or lack of it to participate, will not jeopardize your treatment whatsoever and you are free to withdraw from the study at any time.

If there are any aspects that are not clear, please feel free to ask for clarification, I will be happy to assist.

CERTIFICATE OF ASSENT

I understand that the research is about assessment of skeletal age in Black african children at KNH. I understand that I will be asked personal questions and my radiograph reviewed by the researcher.I have read and understood this information (or had the information read to me). Any questions I had have been answered and I know that I can ask other questions if I have any.

I agree to take part in the study.

Only if child assents:

Print name of child _____

Signature of child: _____Date: _____

Name of Researcher/person taking the assent_____

Signature of Researcher /person taking the assent_____Date_____

Parent/Guardian has signed an informed consent ___Yes ___No _____(initialed by researcher/assistant)

CONTACTS

Researcher:
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Telephone number- +254 720705011
Email- kiendekinoti1@gmail.com

Supervisor

Dr. I.M Mathenge

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APPENDIX C(II): FOMU YA KUKUBALI KUSHIRIKI KWA WASHIRIKI CHINI YA MIAKA 18

TAARIFA ZA MSINGI

Hii fomu ni ya watoto wenye umri kati ya miaka 9 hadi 18 wanaofanyiwa eksirei katika idara ya eksirei ya KNH.Tunawaalika kushiriki katika utafiti unaochunguza usahihi wa umri mifupa tathmini kwa watoto waafrika katika hospitali kuu ya Kenyatta.Jina langu ni Dkt, Caroline Kinoti mwanafunzi katika idara ya Radiology, chuo Kikuu cha Nairobi.Mimi ninafanya utafiti unaochunguza usahihi wa umri mifupa tathmini kwa watoto waafrika katika hospitali kuu ya Kenyatta. Pendekezo hili limekubaliwa na kamati ya maadili ya KNH-UON ambayo ni kamati ya kuhakikisha kuwa wanaoshiriki katika utafiti wanalindwa kutokana na madhara.

Madhumuni: Utafiti huu utaboresha usahihi wa umri mifupa tathmini kwa watoto waafrika.

Hiari ya kushiriki: Kushiriki kwako ni kwa hiari yako na hakuna malipo ya fedha kwa ajili ya kushiriki. Iwapo hutakubali kushiriki katika utafiti, hakutakuwa na mabadiliko katika matibabu ambayo utapata katika kliniki. Tumejadiliana na mzazi/mlezi wako na anajua ya kwamba tunakuuliza ruhusa kukushirikisha katika utafiti huu. Ukikubali kushiriki katika utafiti huu, wazazi wako pia watahitajika kutoa ruhusa. Iwapo hautaki kushiriki hautalazimishwa hata kama wazazi wako wamekubali.

Usiri: Mambo ya utafiti huu yatatunzwa kwa siri na kutumika katika utafiti tu. Utambulisho wako hautawekwa bayana katika makaratasi yoyote. Makaratasi yote yatawekwa katika kabati lililofungwa na kifunguu kuwa na mtafiti mkuu.

Faida ya kushiriki: Hakuna malipo yoyote kwa kushiriki katika utafiti huu.. Majibu yatakayotokana na utafiti huu yatasaidia katika kuboresha usahihi wa umri mifupa tathmini kwa watoto waafrika.

Madhara: Hakuna madhara yoyote yatakayohusishwa kutokana na utafiti huu.

Haki ya kukataa: Kushiriki katika utafiti huu ni kwa hiari. Unaruhusiwa kutoka katika utafiti wakati wowote bila madhara yoyote.

Iwapo kuna swali lolote unaweza uliza sasa ama baadaye. Nambari yangu ya simu 0720705011.

CHETI CHA KUKUBALI KUSHIRIKI

Mtafiti amenifafanulia kuhusu utafiti na jinsi nitakavyoshiriki- kwa njia ya majadiliano ya kikundi au katika mahojiano. Nimesoma habari / nimesomewa habari. Nimeuliza na kujibiwa maswali yote niliyokuwa nayo. Ninafahamu kwamba nikiwa na maswali yoyote, niko huru kuuliza. Mimi kwa hiari yangu nakubali kutoa idhini ili niweze kushiriki katika utafiti huu.

Andika jina la mtoto _____

Saini ya mtoto: _____ Tarehe:_____

Kauli na mtafiti / mtu kuchukua ridhaa

Nimeshuhudia kusomwa kwa fomu kwa mtoto na amepewa nafasi yakuuliza maswali.

Ninadhibitisha kuwa ridhaa imepewa kwa hiari bila kushurutishwa.

Nakala ya fomu hii ya kupata kibali umetolewa kwa mshiriki.

Andika Jina la Mtafiti _____

Saini ya Mtafiti _____ Tarehe _____

MAWASILIANO

Mtafiti Mkuu:
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Msimamizi:

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APPENDIX D (I): CONSENT FORM FOR THOSE WHO ARE 18YEARS AND ABOVE

Study background: I am Dr. Caroline Kinoti from University of Nairobi department of diagnostic imaging. I am carrying out a study geared towards improving accuracy of radiographic skeletal age assessment in children and adolescents. This study has been approved by KNH-UON Ethics committee which regulates such studies. I am under supervision of Dr. I.M Mathenge, a consultant radiologist. You are undergoing a radiographic examination of the hand/wrist and I would like to recruit you for the study.

Study Objective: The main objective of this study is to assess the applicability of the standard Greulich and Pyle method of skeletal age assessment in Black African Children.

Voluntariness of Participation: Please note that your participation is voluntary and there will be no financial reward for participating.

Confidentiality: In this study, you will be asked some personal questions, but these will be kept confidential and your identity will not be revealed, as you will be identified by a code number and your name shall not appear anywhere.

Benefits/Risks: I will review the radiographic image and assess the skeletal age based on the bones seen on the image. I will not influence the diagnosis/treatment you receive in any way. Hence this study will not have any direct positive/negative contribution to your current treatment. The study will only benefit future patients. There are no additional risks to you from participating in the study.

Right to Withdrawal: Your consent or lack of it to participate, will not jeopardize your treatment whatsoever and you are free to withdraw from the study at any time.

CONSENT BY PARTICIPANT

I hereby confirm that the above named doctor has explained the study to me and I understand fully.

I understand that my participation is voluntary and that I have not been forced to participate.

I understand that I can refuse to participate without giving a reason and my medical care will not be affected.

I understand that I will not receive any compensation, monetary or otherwise for participating in the above study.

I understand that my personal information availed for purpose of this study will be kept confidential.

I hereby consent to take part in the above study.

Participant number: _____ Signature: _____

Date: _____

I certify that the participant has understood and consented to participation in the study.

Dr. Caroline Kinoti

Signature _____

Date _____

CONTACTS

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Supervisor

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APPENDIX D (II): FOMU RIDHAA KWA MSHIRIKI JUU YA MIAKA 18

TAARIFA ZA MSINGI

Mtafiti mkuu: Jina langu ni Daktari Caroline Kinoti. Mimi ni mwanafunzi katika chuo kikuu cha Nairobi nikisomea taaluma ya udaktari. Ningependa kushirikisha mtoto wako katika utafiti wangu unaochunguza umri mifupa tathmini kwa watoto waafrika katika hospitali kuu ya Kenyatta. Niko chini ya usimamizi wa Daktari I.M Mathenge, mshauri wa Radiology. Utafiti huu umeidhinishwa nakamati ya maadili ya KNH-UON.

Utaratibu wa utafiti: Watoto wote wanaohudumiwa katika idara ya eksirei ya hospitali Kuu ya Kenyatta na ambao wazazi watapeana idhini watashirikishwa katika utafiti huu. Dodoso litatumika kuuliza maswali kuhusu tarehe ya kuzaliwa, magonjwa na dawa ambazo mtoto anatumia. Nitaikagua eksirei na kutathmini umri kulingana na mifupa inayoonekana kwenye picha.

Madhumuni: Utafiti huu utaboresha usahihi wa umri mifupa tathmini kwa watoto waafrika.

Hiari ya kushiriki: Kushiriki kwako ni kwa hiari yako na hakuna malipo ya fedha kwa ajili ya kushiriki

Usiri: Mambo ya utafiti huu yatatunzwa kwa siri na kutumika katika utafiti tu. Utambulisho wako hautawekwa bayana katika makaratasi yoyote. Makaratasi yote yatawekwa katika kabati lililofungwa na kifunguu kuwa na mtafiti mkuu.

Faida ya kushiriki: Hakuna malipo yoyote kwa kushiriki katika utafiti huu.. Majibu yatakayotokana na utafiti huu yatasaidia katika kuboresha usahihi wa umri mifupa tathmini kwa watoto waafrika.

Madhara: Hakuna madhara yoyote yatakayohusishwa kutokana na utafiti huu.

Haki ya kukataa: Kushiriki katika utafiti huu ni kwa hiari. Unaruhusiwa kutoka katika utafiti wakati wowote bila madhara yoyote.

Kama una swali lolote unaweza kuafikiana na mtafiti mkuu ukitumia nambari 0720705011 na idara ya maadili KNH-UON kwa nambari +254 202726300-9 Ext 44355

Tia sahihi ama weka alama iwapo umekubali kushiriki katika utafiti huu

Mshiriki …… Mtafiti …… Tarehe ……

MAWASILIANO

Mtafiti Mkuu:

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Department Of Diagnostic Imaging

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Msimamizi:

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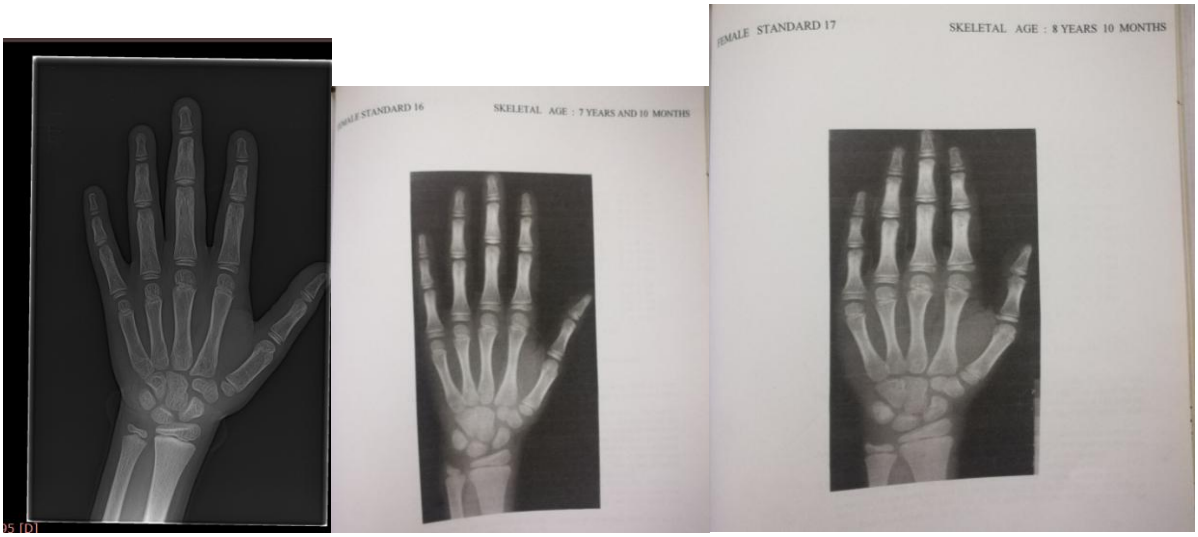
APPENDIX E : IMAGES

Chronological age : 13 yrs 1 month Skeletal age : 12 yrs 6 months



Chronological age : 8 yrs 4 months Skeletal age : 7 yrs 10months

APPENDIX F: KNH ETHICAL APPROVAL LETTER

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COLLEGE OF HEALTH SCIENCES
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KNH-UON ERC
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Ref: KNH-ERC/A/184

5th June, 2017

Dr. Caroline K. Kinoti
Reg. No. H58/74630/2014
Dept. of Diagnostic Imaging and Radiation Medicine
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Kinoti,

REVISED RESEARCH PROPOSAL – SKELETAL AGE ASSESSMENT IN BLACK AFRICAN CHILDREN IN KENYA: APPLICABILITY OF THE GREULICH AND PYLE METHOD (P194/04/2017)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above revised proposal. The approval period is from 5th June, 2017 – 4th June, 2018.

This approval is subject to compliance with the following requirements:

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

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

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Yours sincerely,

PROF A.N. GUANTAI
CHAIR, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept. of Diagnostic Imaging and Radiation Medicine, UoN
Supervisor: Dr. Ian Mathenge Muriithi

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