ASSESSMENT OF ASTHMA CONTROL IN PEDIATRIC ASTHMATIC PATIENTS

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ASSESSMENT OF ASTHMA CONTROL IN PEDIATRIC ASTHMATIC PATIENTS

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DECLARATION

I, Dr. TUYISENGE Anne Marie, RMDC: 1473 , pediatric resident hereby declare that the work entitled "Assessment of asthma control level in Pediatric asthmatic patients"conducted at Teaching University Hospital of Kigali (CHUK) and Muhima District Hospital from 1st July 2015 to 30th January 2016 is my original work. I have not copied from any other students' work or from any other sources except where due to reference, acknowledgement was made explicitly in the text, nor has any part been written for me by another person.

I declare that this Dissertation contains my own work except where specifically acknowledged

Student Name and Number
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Signed on Date 15/4/2016

DEDICATION

To Almighty God who cares about us,

To my lovely husband SAMVURA Jean de Dieu

To our children MUGISHA Sam Henry and SHIMWA Sam Joshua, my joy is yours,

To my parents IYAKAREMYE Joseph and MUKANTAGWABIRA Christine, for the care and love you manifested to us,

To my two sisters and young brother for your encouragement,

This work is dedicated.

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Our respectful acknowledgement is addressed to all academic and administrative authorities of University of Rwanda (UR), College of Medicine and Health Sciences, Faculty of Medicine for high quality of education and training.

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Our deep gratitude is also addressed to my husband SAMVURA Jean de Dieu for his advices, support and technical help.

We express also our inmost gratitude to the staff working in the Pediatrics Department of Teaching University Hospital of Kigali (CHUK), we thank also all teachers for their effort done during our training.

Finally our thanks are addressed to our extended family, classmates, friends and everyone who contributed in the realization of this work; receive the expression of our deep gratitude.

ABSTRACT

Title of study: Assessment of asthma control in Pediatric asthmatic patient.

Background: Asthma is a commonest chronic disease which's increasing in prevalence. It affects patient quality of life even family economy and become a burden. The global burden of asthma can be reduced by efforts of individuals, health care providers, health care organizations and national governments to improve asthma control. GINA helps health providers to achieve to optimal asthma control by using guidelines according to the age. But developing countries are still facing barriers to achieve satisfactory asthma control.

Objectives: The main objective of this study was to evaluate asthma control level of asthmatic children presenting at in Pediatric department in CHUK and MUHIMA District Hospital.

Methods: This is a Cross section study which used an interview with questionnaires based on Global Initiative for Asthma **(**GINA) criteria on asthma control level categories for data collection. This data collection tool was used in order to make sure that information of asthmatic children from 3 years to 15 years old received at the Emergency department or Outpatient Department at CHUK and MUHIMA District Hospital for a period from 1st July 2015 to 30th January 2016 were included. By using logistic regression, factors associated with asthma control level and factors related were analysed and were arranged according to their strength.

Results: The study findings showed that 19% of asthmatic children presenting at selected hospitals were well controlled; 50% were partly controlled and 31 % were uncontrolled. We also observed that among those were followed at referral hospital, 89% were on drugs and 11 % no medications and 70% who were followed up in District hospital and Private clinic were on drugs and 30% were not on drugs.

In this study, findings showed also that gender, parent education level, time known as asthmatic, time spent on treatment and being followed by a same doctor are factors associated to the asthma control level.

Conclusion: Asthma control is still a challenging subject which can be improved by use of GINA guidelines. By using those guidelines, Asthma control can be achieved with a good follow up and education.

Key words: Asthmatic patient, Asthma control, outpatient follow up and factors related to asthma control.

LIST OF SYMBOLS AND ACRONYMES

CHUK: Centre Hospitalier Universitaire de Kigali

FEV_1: Force Expiratory Volume in one Minute

GINA: Global Initiative for Asthma

ICS: Inhaled Corticosteroid

IRB: Institutional Review Board

MDH: MUHIMA District Hospital

MS: Mutuel de Sante

NAEPP: National Asthma Education and Prevention Program

OPD : Outpatient Department

PEF: Peak Expiratory Flow

RMC: Rwanda Medical and Dental Council

RSSB: Rwanda Social Security Board

SABA: Short Acting Beta Agonist

UK: United Kingdom

USA: United States of America

WHO: World Health Organisation

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CHAPTER ONE: INTRODUCTION

1.1. BACKGROUND

Asthma is the commonest chronic pulmonary disease of childhood (Global Initiative for Asthma 2014) (Braman 2006). The prevalence of asthma is increasing in many countries, especially in children. In 2014, WHO estimated that 300 million individuals were affected by asthma in all ages and races. Asthma prevalence in East Africa is variable, with lower rates in Ethiopia 3.5% (Misganaw Dr. et al. 2014) and high rates in Kenya 12.6 % (Esamai et al. 2002). The mean prevalence of asthma in East Africa is 4.4% (Global Initiative for Asthma 2014) (Braman 2006).

The prevalence of asthma is higher in urban areas compared with rural areas. In Rwanda, there is no data on prevalence of asthmatic children; but there is a small unpublished study conducted to assess the prevalence and severity of asthma among urban schoolchildren which showed a prevalence 10.9% (Ntigurirwa Placide 2009). Uncontrolled asthma would lead to a poor quality of life due to emergency department visits, hospitalisations, school absence and impairment of daily activities. The burden of asthma in addition to patient morbidity and health care cost also falls on the family who should experience financial, social and work related difficulties due to the child‘s illness. WHO reports that some countries experience difficulties in accessing essential drugs (< 50% and Rwanda is among those countries). (Global Initiative for Asthma 2014) (Braman 2006)

The diagnosis of asthma in children under 5 years can be challenging, especially in those younger than 3 years. Infants and young children had smaller airways which can lead to wheezing with any episodic respiratory infection. There didn’t perform lung function tests which can help to diagnose asthma with certainty in young children. That was why the diagnosis of asthma in young children below 5 years was based largely on the clinical symptoms pattern and response to treatment. The management goal was to achieve and maintain control of asthma. The role of health professionals was to adjust patients current level of treatment to control symptoms for prolonged periods and to prevent exacerbation while maintain adequate safety and cost of treatment. The health professionals had to monitor asthma patients in routine follow up visits. The majority of medical visits for asthma was for urgent care. Efficacy of asthma

management required a proactive and preventive approach; the follow-up recommendation was 1 to 2 months according to the level of control. At each visit, they had to assess signs and symptoms, pulmonary function, quality of life, exacerbations, adherence with treatment, medications side effect and satisfactions of patient with care. Those aspects of the patient's asthma had an impact of asthma control level (Pedersen et al. 2011) (Gina 2008). (Bisgaard & Bønnelykke 2010)

The Global Initiative for asthma (GINA) guidelines help to recognize asthma control level and improve asthma management according to the asthma level of control by using clinical symptoms and lung function to define if the asthmatic patient was well controlled, partly controlled or uncontrolled. There were studies comparing GINA and Childhood Asthma Control Test c-ACT methods. Authors had concluded that GINA had consistency in providing long term evaluation of asthma control (Roy 2009). (Clark 2010)(Szefler 2010)

The consistency of asthma assessment was essential for effective treatment. There were some directions in the GINA guidelines that may be difficult to apply in developing countries which become a barrier to adequate treatment for asthma in low income settings(Global Initiative for Asthma 2014) (Braman 2006). The global burden of asthma could be reduced by efforts of individuals, health care providers, health care organizations and National governments to improve asthma control. Rwanda was among developing country with limited resources; they face the problems of an insufficient budget for the healthcare system, a limited number of qualified staff, and inadequate equipment. (Global Initiative for Asthma 2014) (Braman 2006) These factors were among other which other challenges to achieve optimal level of asthma control in children.(Yavuz et al. 2012) (Yang et al. 2007) (Rachelefsky 2009) (Schmier et al. 2007)

By considering the study done by Ntigurirwa in 2009 and found 10.9% of asthmatic children; it showed that we had a large number of asthmatic children, it was essential to assess the asthma control level keeping in mind that we were among countries with low income settings, accessibility to effective medications was a big challenge, cost of controller medications was often unaffordable, and behavioral issues complicated the care of chronic disease (Ntigurirwa Placide 2009). There are others contributors to morbidity and mortality from asthma, but especially the socioeconomic factors had a big impact on the life of the asthmatic child(Hoskins

et al. 2011a) (Sánchez-Borges et al. 2011) (Gandhi et al. 2013) (Zorc et al. 2009). (Ayuk et al. 2013)

The aim of our study was to evaluate the level of asthma control in asthmatic children presenting at CHUK and Muhima District Hospital. As there was no other study done before in this pediatric population, the process of defining asthma control level, help to identify where the gaps in healthcare were. Identifying the gaps would help us to make recommendations for improving patient quality of life related to asthma control.

1.2. OBJECTIVES OF THE STUDY

1.2.1. General objective

The main objective of this study was to evaluate the level of asthma control in asthmatic children presenting at CHUK and MUHIMA District Hospital

1.2.2. Specific objectives

Specific objectives in this study were:

- To categorize asthmatic children according to their asthma control level by using GINA guidelines.
- To identify follow-up pattern of pediatric asthmatic patients.
- To identify risks factors associated with asthma control level.

CHAPTER TWO: METHODOLOGY

2.1. DEFINITIONS OF TERMS

Asthma: is chronic inflammatory disorder of the airways which causes episodes of wheezing, difficulty breathing, and coughing particularly at night or in the early morning without viral infection (especially < 5yrs) and persists after age of 3 years.

Asthma control: means the extent to which the manifestation of asthma are reduced or removed, by adequate medical treatment.

Well controlled asthma: means the patient has no daytime symptoms (wheezing, cough, difficult of breathing), no nocturnal symptoms/awaking, no limitation of activities, no need for reliever/rescue inhaler with normal lung function (above 5 years).

Partly controlled asthma: means the patient has present daytime symptoms (wheezing, cough, difficult of breathing), any nocturnal symptoms/awaking, any limitation of activities, any need for reliever/rescue inhaler with lung function <80% (above 5 years).

Uncontrolled asthma: means the patient has present three or more features of partly controlled asthma.

2.2. STUDY DESCRIPTION

The study was seeking to assess the asthma control level of asthmatic children at CHUK and MUHIMA District Hospital (MDH). With the GINA guidelines patients were categorized according to clinical symptoms and signs plus lung function. Using the GINA checklist for check daytime symptoms, nocturnal symptoms/awakening, limitation of activities, need for reliever symptoms/rescue treatment, lung functions, number of exacerbations, a patient asthma was designated as either controlled, or partly controlled, or uncontrolled. We used a predesigned questionnaire to assess any enrolled patient for asthma control level according to GINA guidelines.

2.3. STUDY DESIGN AND PERIOD

This study was cross sectional descriptive and analytic design during the period from 1st July 2015 to 30th January 2016 (6 months).

2.3. STUDY SITE

The area of study was University Teaching Hospital of Kigali (CHUK), Pediatric Department, located in Kigali City at 11 km from Kigali National Airport, located to Nyarugenge District. It is National referral hospital which received many patients from the district hospital and for private clinics or patients coming directly from Home. It has clinical departments, and pediatric department is among of them. Pediatric Department has OPD where patients who are not admitted are met doctors and they can decide to be kept in hospital or to be followed out of hospital; Emergency department is a place where patients are received urgently for quick initiation of treatment and stabilization then after being received, transferred

in wards. We extended the study site to MUHIMA District Hospital, located also in Nyarugenge district which was an advanced district hospital with specialization to care mother and children. Those two sites are specialized in teaching especially medical and nurse students.

2.4. STUDY POPULATION

All asthmatic patients seen and treated in the Pediatric Department (Outpatient and Emergency Department) at selected hospitals during the period of the study.

2.4. SELECTION OF STUDY POPULATION

2.4.1. Inclusion criteria

- Asthmatic patient diagnosed at least 30 days prior to presentation.
- Aged between 3 to 15 years.
- Informed consent form signed by parents or guardian.

2.4.2. Exclusion criteria

- 1st time diagnosed asthma.

- Absence of any known chronic pulmonary or cardiac conditions.
- Refusal to be a part of study.
- Voluntary withdrawal from the study.

2.5. STUDY PROCEDURES

2.5.1. Procedures at enrollment

All known asthmatic children seen, during the study period, in Pediatric Outpatient Department or Pediatric Emergency Department at selected hospitals diagnosed at least 30 days prior to presentation after signing consent form was including in the study. We took children aged between 3 to 15 years old; this range was explained by the under 5 years may have wheezing without having asthma especially because of narrowed airway; especially those younger than 3 years.

Those children who wheeze before age 3 years resolve but some of them can persist until the age of 3 and those children with persisting wheezing may become asthmatic (Pedersen & Hurd 2011). They are other causes which can lead the child to have wheezing like infection (Lower respiratory tract infection, Rhino sinusitis, Bronchiolitis, Tuberculosis), Congenital (Broncho pulmonary dysplasia, congenital heart defect) and up to 15 years because is the upper limit of pediatric population received at CHUK in Pediatric Department and MUHIMA District Hospital.

For the patient who have presented their 1st exacerbation the follow up should be done within one week and then after he/she should be seen in 1 to 2 months and after every 3 months according to the clinical status those are the recommendations of GINA guidelines for setting up or down treatment. Asthmatic children who met the criteria to be included in the study, were been questioned in details to collect information on the frequency and severity of symptoms, impact on daily activities, medications used by the end who were above 5 years to perform lung function test by using questionnaires made ourselves based on criteria of asthma control level according to the GINA classifications which assess symptoms for the last 4 weeks prior the patient present to the clinic.

That was the reason to assess the asthma control at least after 30 days prior presentation. The follow up consisted to assess frequency of follow up, site of follow up, initial medication and current treatment, any adverse effect on treatment, environment factors and parents education

about asthma. GINA recommends asthmatic patient should be seen one to three months after the initial medical visit and every three months. Monitoring is still necessary even after to achieve control asthma is variable disease and management has to be adjusted periodically and when also medication is stopped every 3 to 6 months. During follow up, risks factors must be known by using skin prick test and educate how avoiding them, education how taking correctly medications, understand controllers and relievers. To know when taking action when asthma worsen.

2.5.2. Data management

Data was been collected using a questionnaire as a written in 2 different languages (Kinyarwanda and English) at the study sites; with a research team composed by two data collectors. The collected information was entered in a database and stored into a secured computer. All the data forms were kept in archives in Pediatrician office. The questionnaire was been emphasized about the criteria of GINA according to the different level of asthma control and according to the age. We also assessed the factors related to the asthma control level and asthma follow up aspects.

2.5.3. Analysis

Collected information for each participant were entered in a database using Epi data software, version 3.1 and data was been analyzed using Stata SE 13 software. The types of statistical tests that were used were P value, a P value < 0.05 was considered to represent a statistically significant difference between the results of the factors compared. Logistic regression was be used to determine the factors associated with asthma control level in the study. Stepwise method was be used to select from the total independent variable list, the ones which are highly associated with the outcome of interest.

*2.*6. ETHICAL CONSIDERATION

2.6.1. Confidentiality

Information regarding any patient participating in the study was only shared between the research group and the patient's parents; any health professional involved in the present project was reminded about ethical conduct governing the medical profession and instructed not to

disclose any information concerning study participants. All data abstracted included the study ID and it was kept on a list matched to the patient's medical ID number, however the list was been kept in the Pediatric Department in CHUK. At the end of the data abstraction this list was been destroyed.

2.6.2. Informed consent

Before recruiting any child or Adolescent, parents/guardian had been fully explained in languages they might understood about the present research; they were been given time to ask questions of their concerns and understand that participation was voluntary. They were been provided with an informed written consent form, translated in the maternal tongue and their child was been included if only a voluntary consent was obtained and the form signed by at least either of the parents or an authorized guardian.

2.6.3. Ethics comity approval

We started the data collections after ethical clearance was been granted by Institution Review Board CMHS-UR and after the study project was submitted to CHUK and MUHIMA District Hospital research committees for approval before the beginning of the study.

CHAPTER THREE: RESULTS

The study of which results are presented here was conducted at CHUK and Muhima District Hospital. A questionnaire was used to collect data. The data collection phase run from 1st July 2015 to 30th January 2016. The presentation of the research findings was structured according to the data collection tool. Data were entered using Epi data and analyzed by STATA 13.0. They were presented by means of tables, charts and percentages with their interpretations.

3.1. ASTHMA LEVEL OF CONTROL

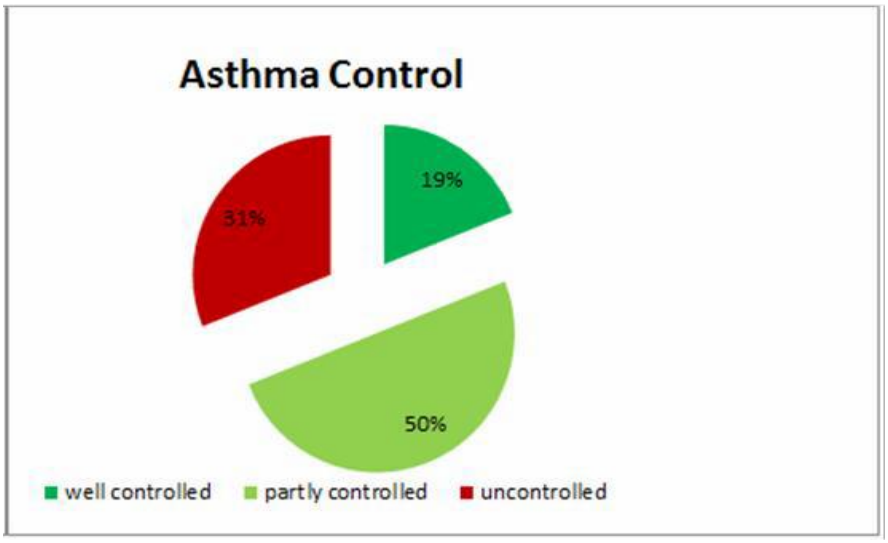


Figure 3. 1: Distribution asthma control level among patients (N= 58)

In this study about Assessment of asthma control in asthmatic children presenting to CHUK and Muhima District Hospital, we have found that 19% of asthamatic children were well controlled, 50% were partly controlled and 31% were uncontrolled. For futher analysis we had divided into two groups: Controlled asthma (well controlled + partly controlled) and uncontrolled a s t h m a due to the sample size to allow us to do deep analysis.

Table 3. 1: Distribution of Asthma control level among Demographic and other variables (N=58)

Items		**Asthma Controlled**			
		No		Yes	
		N	%	N	%
Age	3 to < 6 years	7	28%	18	72%
	6 to 15 years	11	33%	22	67%
Sex	Female	7	29%	17	71%
	Male	11	32%	23	68%
Insurance	Public	6	29%	15	71%
	Private	9	24%	28	76%
Child Education	None&Nursery	7	28%	18	72%
	Prim&Secondary	11	33%	22	67%
Parent Education	None&Primary	6	32%	13	68%
	Sec.&Higher	12	31%	27	69%
	Yes	11	30%	26	70%
Parent occupation	No	7	33%	14	67%

From the above table, we observed of control on age, health insurance and child education: 72% of the patients who are below 6 years old had asthma which was controlled against 67% of those who were 6 years old and above. For insurance, we observed that those who had private insurance had an asthma level which is more controlled as compared to those who attend the public insurance.

Regarding parent education and asthma control, 68% of those whose education level was at primary level or below had children with asthma level controlled and 69% for parents whose education level is secondary or above. Looking at the gender, we observed a percentage of females patients had asthma which was controlled in 71% and in 68% for males. In terms of

residency ,the population came mostly from in Kigali city was in total 57 (98%) only one came from South province.

3.2. ASTHMA FOLLOW UP IN OUT PATIENT DEPARTMENT (N=58)

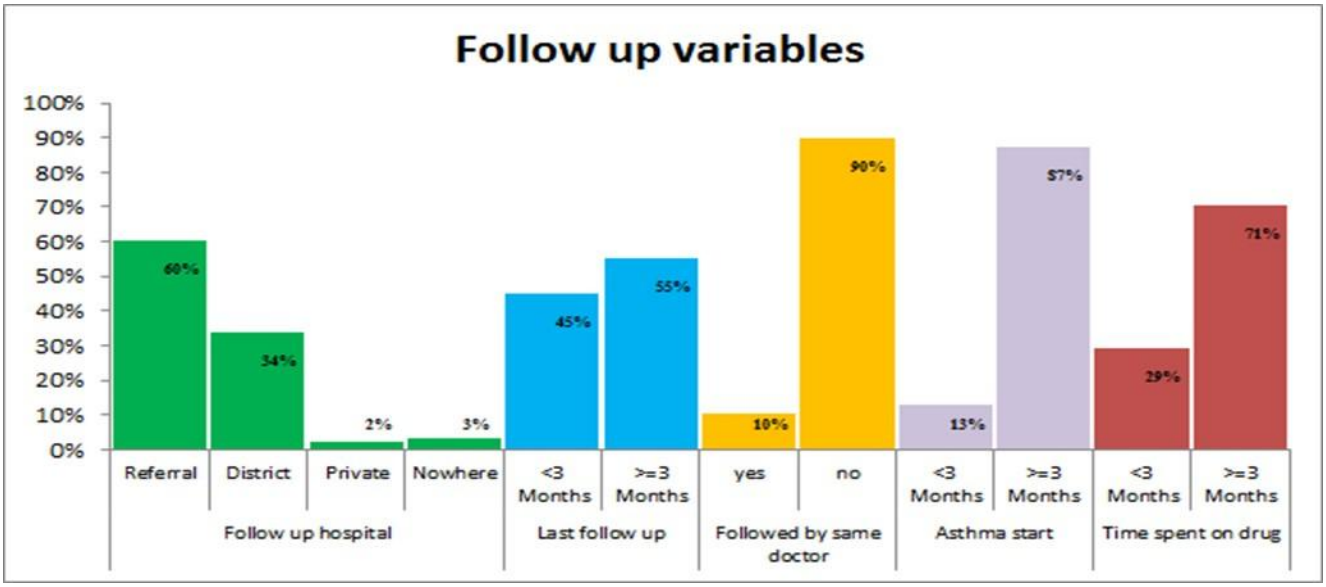


Figure 3. 2: Distribution of Follow up aspect among asthmatic patients.

Most of the asthmatic children seen during the period of study, were followed in Referral hospital especially at CHUK (60%) and other number were followed at District hospital (34%) and 2% in Private clinic and there is 3% who were not followed anywhere.

About the follow up 55% had medical visit in more than 3 months and 45% had a medical visit in 3 months. Asthmatic patient who were presented during the period of study most of them 82 % aware known for more than 6 months and 18% were known for less than 6 months and 71% spent time on asthma treatment more for than 3 months. Many of them were followed by different doctors 52 (90%) and 10% had one doctor following them.

Table 3. 2: Assessment of asthma medications (N=58)

Asthma drugs Start	Which current drug is on and How long are you on drug					
	Reliever		Controller		Both	
	within 3 months	more than 3 months	within 3 months	more than 3 months	within 3 months	more than 3 months
Within 3 months	0(0%)	0 (0%)	1(17%)	0(0%)	5(83%)	0(0%)
Above 3 months	0(0%)	16(39%)	0(0%)	9(22%)	0(0%)	16(39%)

During assessment of asthma drugs, among of recently known asthmatic, had less than 3 months, 17% were on controller drugs and 83% were on both drugs (Controller and Relievers) less than 3 months and those who were known Asthmatic more than 3 months, 16% were on relievers , 22% were on controllers and 39% were on both drugs (Relievers and Controllers) more than 3 months.They were 11 (19%) asthmatic children who were on any drugs.

Table 3. 3: Distribution of Follow among current drugs and site of follow up (N=58)

Follow up	Items	Reliever		Controller		Both		Nothing	
		N	%	N	%	N	%	N	%
Follow up hospital	Referral	11	31%	7	20%	13	37%	4	11%
	other	5	22%	3	13%	8	35%	7	30%
Last follow up	In 3 months	5	19%	7	27%	12	46%	2	8%
	More 3 months	11	34%	3	9%	9	28%	9	28%
Followed by same doctor	Yes	1	17%	4	67%	0	0%	1	17%
	No	15	29%	6	12%	21	40%	10	19%

For a follow up, we observed that 89% of those who were followed up in referral hospital are on drugs and 11 % no medications and 70% who were followed up in other hospital were on drugs and 30% were on no drugs.

Regarding time of last follow up 92% of those whose last follow up is below 3 months were on drug especially on both drugs 46% (Controller and Relievers) while 72% of those whose last follow up was above 3 months were on drugs especially on relievers 34%.

The percentage of those who are on drugs and followed by the same doctor was 83% and 81% for those who are followed up by different doctors. We observed that those are followed by a same doctor, the majority was on Controllers drugs 67% and those who are followed by different doctors the majority were on both dugs 40%.

During interview, 56 (97%) of the patients reported that they had atopy as compared to only 2 (3%) who mentioned that they were not affected by any allergy. About asthma education 2 out of 58 know about written asthma action plan.

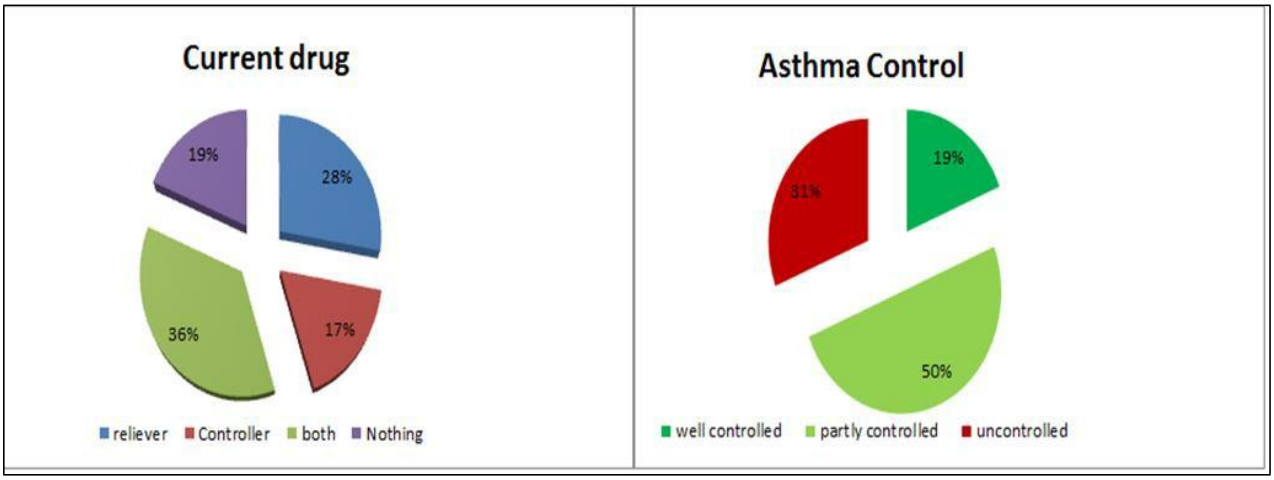


Figure 3. 3: Distribution of current drugs and asthma control level among patients (N=58)

The percentage of patients with well controlled was observed to be 19%, 50% with asthma level partially controlled and 31% with uncontrolled asthma level. For drugs, 28% were on reliever ,17% were on controller ,36% were on both drugs (Controller and Relievers) and 19 % weren't on any drugs.

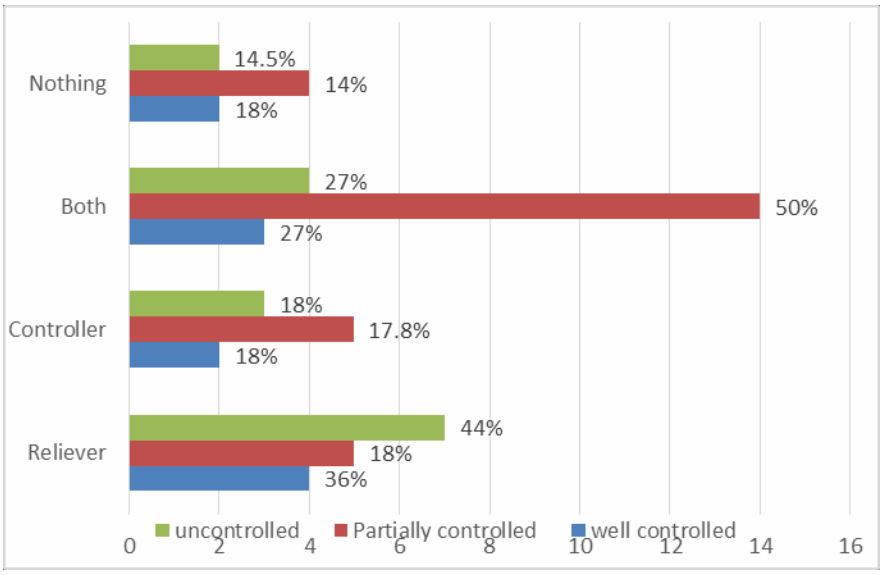


Figure 3. 4 Distribution of Asthma medication according to the asthma control level

In this study majority of asthmatic patients seen was partly controlled 50% and most of them were on Controllers and Relievers medications.

Table 3. 4: Asthma follow up site and asthma control (N=58)

Are you followed by the same doctor?	***Followed Place and Asthma control level***			
	Asthma uncontrolled		Asthma controlled	
	Referral	Other	Referral	Other
Yes	0(0%)	0(0%)	4(67%)	2(33%)
No	10(19%)	8(15%)	21(40%)	13(25%)

By reviewing, asthmatic children followed in referral hospital, the 60% who were from referral hospital, 71% have controlled asthma if they are followed by one doctor.

3.3. RISKS FACTORS ASSOCIATED WITH ASTHMA CONTROL LEVEL

Table 3. 5: Logistic regression: Asthma control level and associated factors (N=58)

		Odds Ratio	95% CI		P value
Age (3 to 6 years)	6 to 15 years	2.00	0.97	4.12	0.06
Sex (male)	Female	2.09	1.02	4.29	**0.04**
Insurance(Public)	Private	2.08	1.05	4.15	**0.03**
Child Education (None&Nursery)	Prim&Secondary	2.00	0.97	4.12	0.06
Parent Education (None&Primary)	Secondary & Higher	2.25	1.14	4.44	**0.02**
Parent Occupation (Yes)	No	2.00	0.81	4.96	0.13
Since when the child is known asthmatic (within 3 months)	More than 3 months	2.06	1.17	3.61	**0.01**
Follow up place (referral)	Other	1.88	0.79	4.42	0.15
Last Follow up (within 3 months)	More than 3 months	1.91	0.92	3.96	0.08
Followed up by same doctor (Yes)	No	1.89	1.07	3.34	**0.03**
Time spent on drug (within 3 months)	More than 3 months	2.15	1.12	4.16	**0.02**
Asthma Start (within 3months)	More than 3 months	2.15	1.12	4.16	**0.02**

Using logistic regression to look for those variable who were associated with asthma control level, we found that among all the considered variables: Gender, Health Insurance, Parent Education, time since the child is known to be asthmatic, followed by same doctor, time spent on

drug and time when asthma start were the ones which were significantly associated with the response (Asthma controlled Yes/No). We observed that:

Gender: the likelihood of females to have an asthma level which is controlled was two times higher as compared to the chance of male patients. Those with private insurance were likely to have an asthma level which was well controlled (odds=2.08) as compared to those with public insurance;

The education of the parent was found to be associated with the asthma control level where we saw that if those parents whose education level was secondary school or higher, the odds that their children had a controlled asthma are 2.25 time high as compared to the children whose parents did not attend school or only reached primary school level.

The longer the children knew that (s) he was as asthmatic higher the chance of having it controlled, this was shown by the odds of having asthma controlled which were 2 times high if a child was having asthma for more than 3 months as compared to a child who was recently diagnosed to be positive on asthma. We also realized that if a child is followed by the same doctor, his chance of having asthma controlled were 1.89 times higher as compared to the odds of those who reported that they were followed by more than one doctor. The odds of having asthma level controlled are doubled (2.15) if a child had spent more than 3 months on drugs or if asthma had started more than 3 months ago.

CHAPTER FOUR: DISCUSSION

4.1. CHARACTERISTICS OF ASTHMA CONTROL LEVEL

In this study about assessment of asthma control in asthmatic children, 19% were well controlled which is similar in a study done in Brazil, also a developing country where they have found 17.5% (de Magalhaes et al. 2012) of controlled asthmatic patients. In Africa, there's other study done in Maghreb's countries to assess asthma in pediatric population. They found results which some similarities with results found in this study. In Tunisia, 11% Controlled, 47% partly controlled and Uncontrolled 34%. In Algeria results showed some differences where 7.9% were controlled, partly controlled were 48.7% and uncontrolled 34% (El Ftouh et al. 2009). The developing countries have still a challenge to control asthma comparatively to the developed countries, study done in USA on assessment of asthma control, results showed 62.4% were well controlled, not well controlled were 21.9% and very poorly controlled were 15.7 %.(Scott et al. 2011) . The difference was explained by difference of setting and access of asthma medication.

4.2. SOCIO ECONOMIC ASPECT OF ASTHMA CONTROL

There was a difference regarding age, child education and health insurance with asthma control in this study:

Regarding the age; the majority was above six years 35% were uncontrolled compared to those are below 6 years ,finding was bit higher in Study done in Urban Brazilian 45.8 % (6-8 years old) but a bit higher (9-11years old) 54.3%(de Magalhaes et al. 2012). The reason explained as the children became less compliant as they approach adolescence with denial being asthmatic or severity of the disease, which was common reason for non-compliance on asthma treatment which was found in study done in UK (Hoskins et al. 2011b). And study done in UK showed under 9 year old were more compliant comparatively to those above nine years (Buston & Wood 2000).

Comparing level of education of the asthmatic child who were not in primary level represented 72% of controlled comparatively to those who are in primary level and above which the finding was similar in Chicago and Baltimore was respectively 62.4% and 57.2 % (Bloomberg et al. 2009).

In assessment of asthmatic children, children who presented private health insurance (RSSB + private insurance) were better controlled comparatively to public insurance(Mutuelle de Sante) which is same findings in US where the asthmatic children had Medicaid presented poor asthma controlled compare to those Commercial insurance. (Sarinho et al. 2007).

4.3. ASTHMATIC CHILDREN FOLLOW UP ASPECTS

In this study, we have assessed asthma patients seen in OPD and our findings findings showed that in 97% were followed only 3% had no clear follow up. The majority of asthmatic children 60% were followed at Referral hospital especially at CHUK. The majority of them 37% were on both drugs (reliever and controller). Comparing a study done in Tunisia where few asthmatic children were followed in University teaching hospital (14.3 %) a and other asthmatic patients are followed in Private clinic 59.3 % the reason in private clinic they met easily pediatricians and differently to our studies the majority of patients 59.8% are on other treatments and 42.4% are on short acting B agonist (El Ftouh et al. 2009). The common factors found in these two studies were the non-availability of clinical, they have not guidelines based on standard care like GINA which help medical doctors to bridge gap between current knowledge and practice. Clinical practice guidelines must be adopted to help health professionals and patients to achieve asthma control. The study showed the impact of guidelines for health care professional on their practice and health status as asthmatic patients (Dexheimer et al. 2014); (Global Initative for Asthma & Global Initiative for Asthma 2015).

4.4. FACTORS ASSOCIATED WITH ASTHMA CONTROL

We found that factors associated with asthma control were gender, parent education level, length of time since diagnosis and length of time taking asthma medication, plus follow up with same doctor.

Regarding the time spent on medications and known asthmatic patient had an impact on asthma control level 2.15 CI (1.12 - 4.16) P value = 0.02 which means being twice protective comparatively “the start” and “the time spent” and “known less than 3 months”, was also shown in Columbia district where they found the asthmatic children well controlled were those use long term medication (Subbarao et al. 2009). There is a stability of asthma control by long term use

medications on Asthmatic children above 6 months as it was shown by a study done by Bateman (Bateman et al. 2008).

Parent education level play role in asthma control level of asthmatic children, in this study we found parent whom present above primary level the asthma level was well controlled 2.25 C.I (1.14 - 4.44) P value = 0.02 comparatively to those whom education level don't go beyond primary level which is similar in the study done in Tropical America (Jónasson et al. 1999) found the parent who were in high level of education. The level of parent education play a role on asthma control children, because the capacity to understand on asthma and the attitude, help asthmatic children to achieve the asthma control (Zhao et al. 2013). The multiple logistic logistic regression help us to analyse any association with this simple size which could be stronger with large sample as we can see relationship in that population.

In this study male patients presented a relationship with asthma control: their asthma level which was uncontrolled was two time higher as compared to the chance of female patients 2.09 C.I (1.02 - 4.29) P value = 0.04, the same results was found in study where the male represented high number of uncontrolled asthma (Yawn et al. 2006) In Cameroon, asthma control was done among above 12 years found Female are well controlled comparatively to male (Almqvist et al. 2008). The male gender was shown to have an impact on asthma, the male presented higher levels of total Immunoglobulin E comparatively to girls and regarding sensitization and atopy, male gender is found to be a risk factor for any sensitization. Anatomically also, they present a difference comparatively to female, they are having smaller airways diameters relative to lungs volumes and there's an impact of hormones because after childhood, during puberty asthma is more prevalent in female to male (Trent et al. 2014).

There is an association between be followed by same doctor with asthma control, 1.89 times C.I (1.0- 3.34) P value = 0.03 the finding showed an association between which is similar to the study done in US (Zahran et al. 2014)(Cabana et al. 2006) showed the impact on asthma control to the patients are followed.

4.5. CHALLENGES AND LIMITATIONS

During interview, there were still misconceptions about asthma and atopy; there was still confusion about atopy manifestation. There was no skin prick test done which enhance limitation on knowledge about allergies and atopy. During asthma follow up, there was no lung function test performed no availability of test. The sample size population was a limitation we could not explore all factors associated with asthma control like allergic rhinitis and eczema.

CHAPTER FIVE: CONCLUSIONS AND RECOMMENDATIONS

The study about assessment of asthma control in asthmatic children presenting at selected hospitals found that majority was partly controlled asthmatic children. There's still a challenge in asthma control and follow up in clinic even with symptoms free. Many of them are still visiting clinic only when they present symptoms. This explains that much effort should be done during follow up especially on asthma education and use of drugs with reference on GINA guidelines

The reason why we recommend to make a national guideline based on GINA guidelines and its implementation at different level of Rwanda health care system; from Referral hospital to Health center level.

To Train health care providers to the guidelines. After that intervention, conduct a study on assessment at National level on asthma control level in asthmatic children.

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APPENDICES

APPENDIX I: TABLES SHOWING ASTHMA CONTROL

Level of Asthma control in children of 5 years and youngers

Characteristics	Controlled	Partly controlled	Uncontrolled
	All of the following	(Any measure present any week)	(Three or more features of partly controlled in any week)
Daytime symptoms (wheezing, cough, difficult of breathing)	**None** (Less than twice /week typically for short periods of on the other minutes and rapidly relieved by the use of a rapid acting bronchodilator)	**More than twice /week** (Less than twice /week typically for short periods of on the other minutes and rapidly relieved by the use of a rapid acting bronchodilator)	**More than twice/week** (Less than twice /week typically for short periods of on the other minutes and rapidly relieved by the use of a rapid acting bronchodilator)
Limitations of activities	**None** (child is fully active, plays and run without limitations or symptoms)	**Any** May cough, wheeze or difficulty of breathing during vigorous play or laughing)	**Any** May cough, wheeze or difficulty of breathing during vigorous play or laughing
Nocturnal symptoms /awakening	**None** (including no nocturnal cough during sleep)	**Any** Typically coughs during sleep or wakes cough or wheezing, and/or difficult of breathing	**Any** Typically coughs during sleep or wakes cough or wheezing, and/or difficult of breathing
Need for reliever or rescue	<2 day/week	>2days/week	>2 days/week

Level of Asthma control in children of 5-15 years

Characteristics	**Controlled** All of the following	**Partly controlled** (Any measure presented)	**Uncontrolled**
Daytime symptoms (wheezing, cough, difficult of breathing)	**None** (twice or less /week)	**More than twice /week** (more than twice /week	**Three or more features of partly controlled**
Limitations of activities	**None**	**Any**	
Nocturnal symptoms /awakening	**None**	**Any**	
Need for reliever or rescue	None (twice or less /week)	More than twice /week	
Lung function PEF or FEV1	Normal	80% predicted or personal best(If know)	

APPENDIX II: CONSENT AND ASSENT FORMS

II.1. Consent form for care taker of child-English Version

Study no……

I, ----------hereby, fully consent on behalf of my child to participate in this study on the **"Assessment of Asthma control in asthmatic children presenting at CHUK and Muhima district Hospital".**

I agree that my child can participate in this study and that any information obtained will be used for the development of the transition protocol.

I understand that I will incur no additional medical costs as a result of participation in this study. I have been fully informed about the purposes of the evaluations that will be done. I have had a chance to ask questions and they have been answered satisfactorily. I also understand that I may withdraw my child at any time with no adverse consequences whatsoever. I agree that on condition of anonymity, the information obtained from these assessments shall be used for educational and research purposes only. I am also aware that I can contact Dr Anne marieTuyisenge onTelephone +250 788571455andDr Angelique Charlie Karambizi+250788871553 DrLisineTuyisenge, on Telephone: +250 788411764 or CMHS/IRB members Dr Kato J. NJUNWA telephone 0788490522 or Dr Brenda KATEERA 0784 841
256in case of any further clarification or queries.

……..	……..	…../…./……
Name of the participant	Signature of participant	Date
……..	……..	…../…./……
Name of the researcher	Signature of the researcher	Date

II.2. Consent form for care taker of child -Kinyarwanda version

Ubushakashatsi no……

AMASEZERANO YO KWEMERA KUJYA MU BUSHAKASHATSI

UBUSHAKASHATSI: Assessment of asthma control in asthmatic children presenting at CHUK and Muhima District hospital.

Jyewe, ……...nemeye ko umwana wanjye ajya mu ubushakashatsi bwitwa**"Assessment of asthma control in asthmatic children presenting at CHUK".**Ubushakashatsi bwo kumenya uko Asima ihagaze mu bana bivuriza CHUK no ku bitaro bya **MUHIMA**. Nasobanuriwe ko kujya muri ubu bushakashatsi ari ubushake bwacu, ko nta gihembo ntegereje guhabwa, kandi ko nzagirirwa ibanga ku makuru yose nzatanga. Nasobanuriwe ko ibizava muri ubu bushakashatsi bizatangazwa.

Mfite uburenganzira bwo kuva muri ubu bushakashatsi igihe cyose nabishakira kandi ntibingire ingaruka mumivurirwe y`umwana wanjye. Ikindi kandi, nziko nshobora kuba nahamagara Dr. Anne marie TUYISENGE +250788571455 na Dr. Angelique Charlie Karambizina Dr. Lisine Tuyisenge: +250 788411764 **cyangwa abashinzwe ubushakashatsi mu ishuri ry' Ubuvuzi Dr. Kato J. NJUNWA 0788 490 522 or Dr Brenda KATEERA 0784 841 256** ndamutse ngize ikibazo.

…… …….. …….

Amazina n'umukono by'uwasobanuriwe Icyo apfana n'umurwayi Italiki

……. …….. …….

Amazina y'umushakashatsi Umukono w'umushakashatsi Italiki

II.3. Informed Assent form for a child aged 7 years and above-English Version

"Assessment of Asthma control in asthmatic children presenting at CHUK and Muhima District Hospital"

Study no……

I,----------hereby, fully assent to participate in this study on the" Assessment of Asthma control in asthmatic children presenting at CHUK and Muhima District Hospital"

I agree to participate in this study and that any information obtained will be used for the development of the transition protocol.

I understand that I will incur no additional medical costs as a result of participation in this study. I have been fully informed about the purposes of the evaluations that will be done. I have had a chance to ask questions and they have been answered satisfactorily. I also understand that I may withdraw at any time with no adverse consequences whatsoever. I agree that on condition of anonymity, the information obtained from these assessments shall be used for educational and research purposes only.

I am also aware that I can contact Dr. Anne Marie Tuyisenge on Telephone +250 788571455 and Dr. Angelique Charlie Karambizi 0788871553 Dr. Lisine Tuyisenge, on Telefone: +250 788411764 or CMHS/IRB members Dr. Kato J. NJUNWA telephone 0788 490 522 or Dr. Brenda KATEERA 0784 841 256 in case of any further clarification or queries.

……..	……..	…../…./……
Name of the participant	Signature of participant	Date
……..	……..	…../…./……
Name of the researcher	Signature of the researcher	Date

II.4. Informed assent form for child aged above 7 years -Kinyarwanda version

Ubushakashatsi no……

AMASEZERANO YO KWEMERA KUJYA MU BUSHAKASHATSI

UBUSHAKASHATSI: *Assessment of Asthma control in asthmatic children presenting at CHUK and Muhima district Hospital"*

Jyewe, …….. nemeye kujya mu ubushakashatsi bwitwa *" Assessment of Asthma control in asthmatic children presenting at at CHUK and Muhima district Hospital"*. Ubushakashatsi bwo gufasha kumenya uko Asima ihagaze mu bana bivuriza CHUK no ku bitaro bya **MUHIMA**. Nasobanuriwe ko kujya muri ubu bushakashatsi ari ubushake bwanjye, ko nta gihembo ntegereje guhabwa, kandi ko nzagirirwa ibanga ku makuru yose nzatanga. Nasobanuriwe ko ibizava muri ubu bushakashatsi bizatangazwa.

Mfite uburenganzira bwo kuva muri ubu bushakashatsi igihe cyose nabishakira kandi ntibingireho ingaruka mu mivurirwe yanjye. Ikindi kandi, nziko nshobora kuba nahamagara Dr. Anne Marie Tuyisenge +250 788752779 na Dr. Angelique Charlie Karambizi +250 788871553 Dr. LisineTuyisenge : +250 788411764 **cyangwa abashinzwe ubushakashatsi mu ishuri ry' Ubuvuzi Dr. Kato J. NJUNWA 0788 490 522 or Dr. Brenda KATEERA 0784 841 256** ndamutse ngize ikibazo.

…… ……..

Amazina n'umukono y` ukorerwaho ubushakashatsi Italiki

……. …….

Amazina n`umukono y'umushakashatsi Italiki

APPENDIX III: QUESTIONNAIRE

Age of the patient

3 -5

6-15

Sexe Male

Female

Residency

Nyarugenge

Gasabo

Kicukiro

Out of the town

Insurance

Public insurance (RAMA,MS)

Private insurance

None

Children level of education

None

Nursery

Primary

Secondary level

Parents level of education

None

Primary

Secondary

Higher level

Parent profession

Public

Private

None

Atopy

Parent asthma

Sibling asthma

Eczema

Inhalant allergen sensitization

Allergic rhinitis

Wheezing apart from colds

Food allergen sensitization

Unknown

Weight Z score

2-3 Z score

1 to -1 Z score

-2 to -3 Z score

<- 3 Z score

Height Z score

2-3 Z score

1 to -1 Z score

-2 to -3 Z score

<- 3 Z score

When the child is known asthmatic

Within 3 months

6 months

1 year

2years

3years

>3years

Where the child is followed

Referral

District

Private clinic

Nowhere

When the last follow up

Within 4 weeks

1 month

2 months

3 months

>3months

Are you followed by a same doctor?

Yes or No

Daytime symptoms in 4 weeks

None

Any

More than 3

Nightime symptoms in 4 weeks

None

Any

More than 3

Limitation activities in 4 weeks

None

Any

More than 3

Number of exacerbation in 4 weeks

None

Any

More than 3

Lung function (spirometry)

Normal

< 80%

Need for reliever rescue

None

More than twice /week

Which drug is on?

SABA (salbutamol spray)

ICS low dose

ICS medium dose

When do you start?

Within 4 weeks

1 month

2 month

3 month

>3months

Education

Asthma symptoms Yes No

Influencing factor Yes No

Reliever drug Yes No

Controller drug Yes No

Asthma action plan

Asthma symptoms Yes No

Medication to administer Yes No

Dosage Yes No

Method Yes No

When to obtain medical care Yes No

How to obtain medical care Yes No

Side effect of drugs Yes No

Environmental factor

Exposure to tobacco smoke Yes No

Drug allergen Yes No Food

allergen Yes No

House dust mites Yes No

Animals with fur (Cat, dog) yes No

Cockroaches Yes No

Outdoor pollens and mold (flowers, tree, humidity) Yes No

Indoor mold (humidity) Yes No

UNIVERSITY OF RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 08/10/2015
Ref: CMHS/IRB/**314**/2015

Dr TUYISENGE Anne Marie
School of Medicine and Pharmacy, CMH, UR

Dear Dr TUYISENGE Anne Marie

RE: ETHICAL CLEARANCE

Reference is made to your application for ethical clearance of the revised protocol of the study entitled **"Assessment of Asthma Control in Asthmatic Patient Presenting At University Teaching Hospital of Kigali."**

Having reviewed your application and been satisfied with your revised version incorporating the comments from the IRB, your study is hereby granted ethical clearance. The ethical clearance shall last for one year from the date it is issued and it is renewable on request upon submission of the progress report in accordance with the guidelines of the Institutional Review Board (IRB) of the College of medicine and Health Sciences. In addition, at the end, the IRB shall need to be given the final report of your study.

We wish you success in this important study.

Professor Kato J. NJUNWA
Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:
- Principal, College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate studies, UR

UNIVERSITY OF RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 12/01/2016

Dr TUYISENGE Anne Marie
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 013 /CMHS IRB/2016

Your Project title ***"Assessment of Asthma Control in Asthmatic Patient presenting at University Teaching Hospital of Kigali"*** has been evaluated by CMHS Institutional Review Board.

		Involved in the decision		
		Yes	No (Reason)	
Name of Members	**Institute**		**Absent**	**Withdrawn from the proceeding**
Prof Kato J. Njunwa	UR-CMHS	X		
Prof Jean Bosco Gahutu	UR-CMHS	X		
Dr Brenda Asiimwe-Kateera	UR-CMHS	X		
Prof Ntaganira Joseph	UR-CMHS		X	
Dr Tumusiime K. David	UR-CMHS	X	X	
Dr Kayonga N. Egide	UR-CMHS	X		
Mr Kanyoni Maurice	UR-CMHS	X		
Prof Munyanshongore Cyprien	UR-CMHS	X		
Mrs Ruzindana Landrine	Kicukiro district		X	
Dr Gishoma Darius	UR-CMHS	X		
Dr Donatilla Mukamana	UR-CMHS		X	
Prof Kyamanywa Patrick	UR-CMHS	X	X	
Prof Condo Umutesi Jeannine	UR-CMHS		X	
Dr Nyirazinyoye Laetitia	UR-CMHS		X	
Dr Nkeramihigo Emmanuel	UR-CMHS		X	
Sr Maliboli Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 31st December 2015, **Approval letter has been granted to your study.**

Please note that approval of the protocol and consent form is valid for **12 months**.
You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,

Date of Approval: The 12th January 2016
Expiration date: The 12th January 2017

Professor Kato J. NJUNWA
Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:
- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate studies, UR

REPUBLIC OF RWANDA

KIGALI CITY
NYARUGENGE DISTRICT
MUHIMA HOSPITAL
P.O BOX 2456 KIGALI
E-mail: muhimahospital1@gmail.com

ETHICS COMMITTEE/ COMMITTE D'ETHIQUE

December 30th, 2015 **Ref: MDH/EC/...../2015**

Review Approval Notice

Dear Dr Anne- Marie TUYISENGE

Your academic research project: **"Assessment of Asthma control in asthmatic children presenting at UTHK"**

During the meeting of the Ethics Committee of Muhima District Hospital that was held on 30/12/2015 to evaluate your demand of the above mentioned research project, we are pleased to inform you that the Muhima Hospital Ethic Committee has approved your protocol.

You are required to present your research results to Muhima Hospital Ethics Committee before the publication.

Yours sincerely,

MUHIMA HOSPITAL ETHIC COMMITTEE

Dr SABUSHIMIKE Doriane
Chair Person, Ethics Committee



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CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSDY TEACHING HOSPITAL

Ethics Committee / Comite d'ethique

July 20, 2015 Ref.:EC/CHUK/14212015

Review Approval Notice

Dear Dr Anne Marie TuyisCnge,

Your research project: "Assessment of asthma control in asthmatic children presenting al University teaching hospital of Kigali-CHUK."

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (Cl that was held on 20/07/2015 to evaluate your protocol of the above mentioned research pr we are pleased to inform you that the Ethics Committee/CHUK has approved your protocol.

You are required to present the results of your study to CHUK Ethics Committee t publication.

PS: Please note that the present approvai is valid for 12 months.

Yours sincerely,

ORSTEPHf:,\J RULi.:> ·
HEAD -DEPARTMENT OF CLINi_.,
RESEARCH
C lJK

Dr. Stephen Rulisa
The President, Ethics Committee,
Kigali University Teaching Hospital

<<*Univenity teaching hospital of Kigali Ethicl commltlee opuates according to sttu1dtml operallng procedures (Sops) are updated on an annual basis and in complilllu with GCP and Ethics guidelines IUid regullllions*>