

**ASSESSMENT OF ASTHMA CONTROL AND ASSOCIATED RISK FACTORS AT JIMMA UNIVERSITY MEDICAL CENTER, JIMMA, SOUTH WEST ETHIOPIA.**



**BY, - DAGNE FEYE (MD)**

**A THESIS TO BE SUBMITTED TO JIMMA UNIVERSITY, INSTITUTE OF HEALTH, MEDICAL FACULTY, DEPARTMENT OF INTERNAL MEDICINE; IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR SPECIALIZATION IN INTERNAL MEDICINE.**

**JANUARY, 2021**

**JIMMA, ETHIOPIA**

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**BY, - DAGNE FAYE (MD, INTERNAL MEDICINE RESIDENT)**

**ADVISORS- 1) SAMUEL YOO (PROFESSOR, PULMONOLOGIST)**

**2) GOBEZIE TEFERA (ASSISTANT PROFESOR, INTERNIST)**

**3) MELAT WODAJE (MPHE)**

**JANUARY, 2021**

**JIMMA, ETHIOPIA**

## DECLARATION

I, the under signed declare that this is my original work and has not been presented for seeking a degree in any university and that all resources or the materials used for the thesis have been dully acknowledged.

Name of investigator: - Dagne Faye (MD), Signature \_\_\_\_\_, Date\_\_\_\_\_

Advisors: 1. Professor Samuel Yoo (pulmonologist). Signature \_\_\_\_\_, Date\_\_\_\_\_

2. Melat Wodaje (MPHE), Signature\_\_\_\_\_, Date\_\_\_\_\_

3. Dr. Gobeze Tefera (Assist. Prof, Internist), Signature \_\_\_\_\_, Date\_\_\_\_\_

## Abstract

**Background:** -Asthma control is below the goal set by national guidelines in different parts of the world. Identifying the level of asthma control and risk factor for poor asthma control may greatly improve the quality of life and potentially lessens the financial burden of the disease. The level of asthma control and risk factors for uncontrolled asthma are rarely known in Ethiopia.

**Objective:** - To assess the level of asthma control and identify risk factors associated with uncontrolled asthma among adult patients attending chest clinic of JUMC.

**Methods:** - A facility-based cross-sectional study design was conducted on 119 asthmatic patients attending the chest follow-up clinic of JUMC from September 01 to November 30, 2020. Asthma control was assessed using the ACT questionnaire. Data were entered into the computer by EpiData manager version 4.6 and exported to STATA version 16.0 for analysis. The potential factors associated with the outcome variable were tested using Chi-square test and P-value of  $< 0.05$  was used to declare statistical significance. The variables which were significant in a bivariate analysis at a cut point of P-value of  $< 0.05$  were analyzed by multivariate logistic regression analysis.

**Result:** Of one hundred and nineteen (119) included in the study 77 (64.7%) of asthmatic clients have uncontrolled asthma. A multivariate analysis showed that having co-morbidities like gastroesophageal reflux disease and allergic rhinitis (AOR= .056 95% C.I 0. 010-0.324,  $p = 0.001$ ), frequent asthma exacerbation (AOR = 0.022, 95% C.I 0.002- 0.195,  $P = 0.001$ ) and low level of adherence to treatment (AOR=0.010- 95% C.I 0.001-0.090,  $p = 0.001$ ) were found to be significant factors associated with uncontrolled asthma.

**Conclusion:** Large proportions of asthmatic clients have uncontrolled level of asthma. Commodities like GERD and allergic rhinitis, level of adherence to treatment and frequent asthma exacerbation were associated with uncontrolled level of asthma. Further large-scale study should be conducted to identify determinants of the uncontrolled level of asthma.

**Keywords-**JUMC, Asthma, control, associated factors

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## **List of Acronyms**

ACQ- Asthma Control Questionnaire

ACT- Asthma Control Test

AIRMAG- Asthma Insights and Reality in the Maghreb

AOR- Adjusted Odds Ratio

BMI- Body Mass Index

ECRHS II - European countries in the frame of the European Community Respiratory Health Survey II

FEV1/ FVC - Forced Expiratory Volume of One Second/ Forced Vital Capacity

GERD- Gastro-Esophageal Reflux Disease

ICS - Inhalational Corticosteroid

ISSAC - International Study of Asthma and Allergies in Childhood

JUMC - Jimma University Medical Center

LABA- Long-Acting Beta Agonist

MDI- Meter Dosed Inhaler

MMAS-8 - Morisky medication adherence scale-8

NAEPP- National Asthma Education and Prevention Program

OCS- Oral Corticosteroid

PEF- Peak Expiratory Flow

PFT- Pulmonary Function Test

REALISE- Recognize Asthma and Link to Symptoms and Experience

SABA- Short-Acting Beta Agonist

SSA- Sub-Saharan Africa

TASH- Tikur Anbessa Specialized Hospital

# CHAPTER- ONE

## INTRODUCTION

### 1.1. Background

Asthma is a common, chronic respiratory disease characterized by variable symptoms of wheeze, shortness of breath, chest tightness and/or cough, and by variable expiratory airflow limitation. It is estimated that 300 million people of all ages and diverse ethnicities suffer from asthma(1), and about 1 in every 250 is estimated to die from asthma worldwide(2, 3). It is a major health concern in developed countries as well as in low-income countries. The number of disability-adjusted life years lost due to asthma worldwide has been estimated at 15 million per year currently. The results of the International Study of Asthma and Allergies in Childhood (ISSAC) show that the prevalence of asthma in Africa ranges from 4.4% to 21.5% (4).

Currently, the level of asthma control is determined by the Global Initiative for Asthma (GINA) criteria, Asthma patients are classified as having controlled, partially controlled, or uncontrolled asthma based on symptoms, limitations in activities of daily living, nocturnal awakenings, use of rescue medication and pulmonary function(5).

In the presence of the availability of new drugs options and new combinations of existing drug therapies, suboptimal asthma control rate is still high. A population-based survey conducted in 11 European countries in the frame of the European Community Respiratory Health Survey II (ECRHS II), demonstrated that 32% of patients had controlled asthma. Recently, a survey conducted in five European countries indicated that 50.4% of asthmatic patients were not well controlled and this percentage increased to 56.6% in a more recent survey conducted in the same countries(6). Several clinical studies suggest that asthma of many subjects is still uncontrolled and that asthma morbidity remains high while the disease seems to be far from optimal control although effective and safe treatments, such as inhaled corticosteroids (ICS) and long-acting beta-adrenergic agonists (LABA) are widely available. It has been recommended that effective and safe treatment must be graded based on a periodic assessment of asthma control which represents the major goal of therapy. It has

been shown, in a randomized controlled study, that combining ICS with LABA was more effective than ICS alone in achieving the control of asthma (7).

The number of asthmatic patients in Ethiopia has been assessed at 2 million people (2.3% of the population) (8). Identifying risk factors for uncontrolled asthma may greatly modify those adverse effects and potentially lessen the financial burden of the disease. The level of asthma control and risk factors for uncontrolled asthma is rarely known in Ethiopia. Only three Studies were done in Ethiopia and the result showed uncontrolled asthma was ranging from 43.8 to 76.1% (9-11).

Various risk factors associated with poor disease control have been described, including age, education, asthma severity, drug adherence, allergic rhinitis, and patients' knowledge of the disease. Improved awareness of these factors could lead to improved management of asthma. Studies also reported obesity is associated with subsequent poor asthma control(12)

## 1.2. STATEMENT OF THE PROBLEM

Many studies done in Europe and North America have shown that asthma controls are below expectations and the result showed a control rate of 24–45% (13)

A recent report by Chapman et al. in approximately 10,500 patients presenting in general practices in Canada; low control was associated with more hospitalizations, emergency and unscheduled visits. Uncontrolled asthma was associated with increased risk of daily activity limitations in 66% (13). In the United States, most asthma costs can be attributed to uncontrolled asthma symptoms, with 80% of the direct costs distributed among approximately 20% of patients with difficult-to-control asthma. The estimated annual cost for patients with difficult-to-control asthma in the US was more than \$2,500 per patient(14).

In Africa, studies focused on asthma control are lower in numbers as compared to other parts of the world (15). The AIRMAG study which involved 3 countries of North Africa reported 71.3% of uncontrolled asthma, whereas, in another study in Ethiopia, the proportion was 71.4%(9). Failure of asthma control increases the morbidity of the disease, affects the quality of life of patients, and significantly increases the use of health care services (4, 16).

Many factors, such as disease severity, smoking status, occupational and environmental factors can also influence level of asthma control. Other factors associated with the level of asthma control are many including access to guidelines, co- morbidities and cultural aspects, while treatment-related aspects as a whole, including poor adherence, inadequate therapy, poor inhalation technique, poor tolerability play a major role(15). Treatment-related factors representing 60.0 % and 42.6 % of all reasons for poor control respectively (17).

Uncontrolled asthma (75.8% in Ethiopia at Black Lion Hospital, in 2016) is one of the leading causes of poor quality of life, unproductively, school loss, and high-cost burden to individuals and the country as the whole(10). Currently, management guidelines (GINA-2019) for asthma also changed and Short acting beta agonist (SABA) only treatment is no longer recommended (18). Therefore, the study is aimed to determine the level of asthma control and associated factors both of which are essential elements for improving the management of this disease.

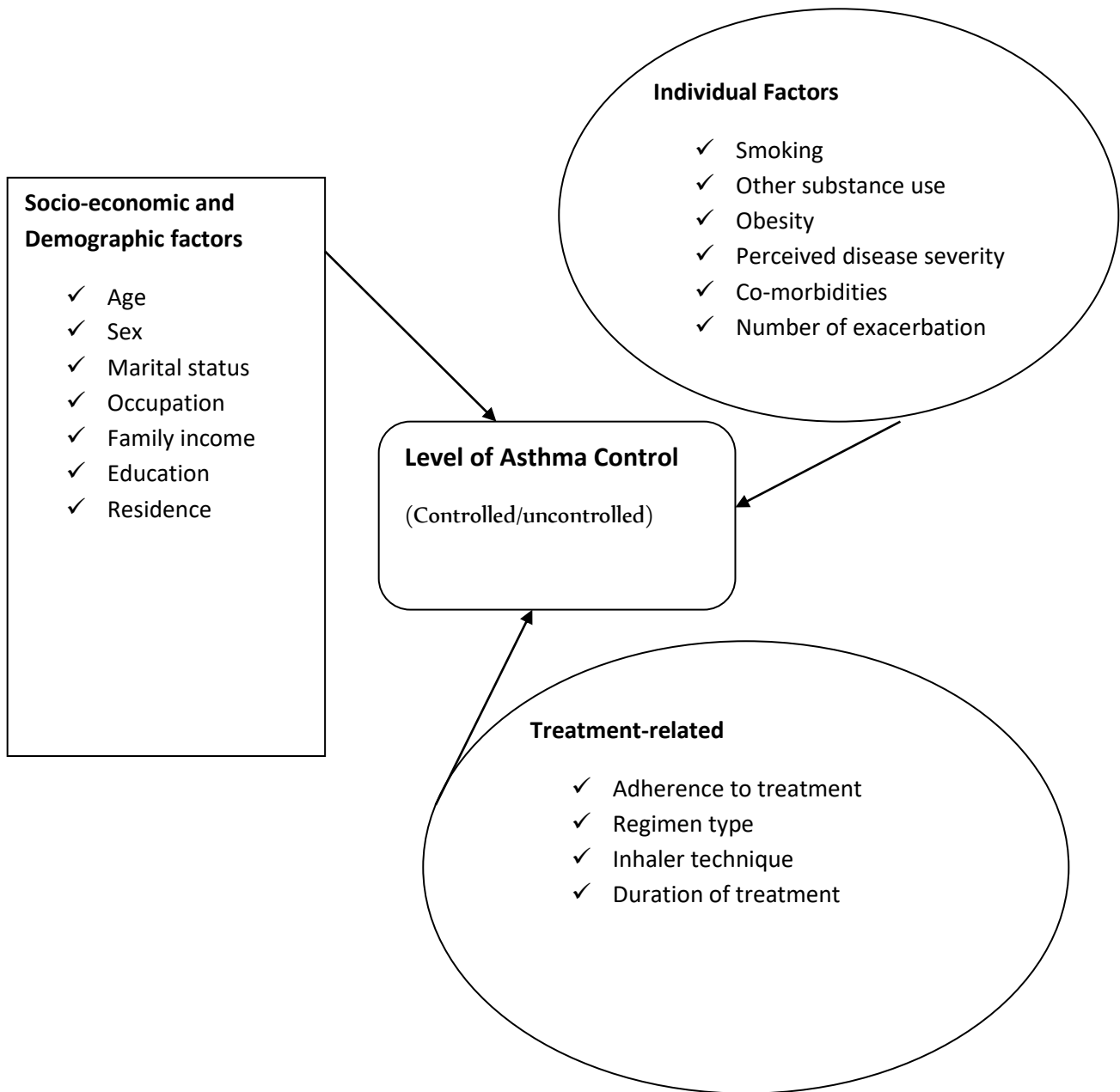
### **1.3. Significance of the study**

Bronchial asthma is one of the chronic airway diseases affecting a large proportion of the population worldwide including Ethiopia. Only one study was conducted in Jimma, and uncontrolled asthma was found to be high and few associated factors were identified (9). It is a major public health problem that negatively impacts patients, their families, and the community by inducing work and school loss, poor quality of life, frequent emergency visits, hospitalizations and death. Furthermore, a large proportion of direct and indirect asthma costs have been attributed to severe and uncontrolled asthma. Knowing the level of asthma control is helpful for the clinician caring for asthma patients to modify treatment regimens. Also identifying risk factors for poor asthma control may greatly modify these adverse effects and potentially lessen the financial burden of the disease. This study will provide a pattern of asthma control to guide clinicians caring asthmatic to improve the management of patients. Also, it will be important for the patient to reduce the unnecessary costs for the medication and improves the quality of life. Furthermore, it will help as baseline information for further studies and as a source of information for health planners and stakeholders.

### **1.4. Research Questions**

1. What is the level of Asthma control?
2. What are risk factors for *uncontrolled* asthma?

Figure 1. Conceptual Framework of Study (4,11,12, 25-40)



## CHAPTER- TWO

### 2. LITERATURE REVIEW

#### 2.1 Level of Asthma Control

Surveys assessing the current level of asthma control in asthmatic children and adults in different regions of the world have indicated that asthma control was suboptimal. Asthma control in clinical practice is suboptimal despite available therapies over the last decade. European studies have shown little apparent improvement in the levels of symptom control. Report data from the Recognize Asthma and Link to Symptoms and Experience (REALISE) survey, conducted in 11 European countries among 8,000 individuals (2014) who use social media-the largest. Overall, 20.1% of respondents had controlled asthma according to the GINA criteria, 34.8% had partially controlled asthma, and 45.1% had uncontrolled asthma. Over half of the respondents had awoken at night or had symptoms that interfered with daily activities. Overall, 44.0% of respondents reported having used oral steroids for asthma in the previous 12 months, 23.9% reported having visited an emergency department and 11.7% reported having been hospitalized overnight (19).

A nationwide cross-sectional observational study was conducted in China between November 2012 and June 2013 and asthma was controlled in 44.9% of the participants and remains uncontrolled in 55.1% of them (20).

A prospective, multicenter, Cross-sectional study was done in Europe and the result was 43.5 % of the patient showed controlled asthma, 18.0 % had partly controlled asthma, and 38.5 % uncontrolled asthma(17). Other cross-sectional, self-reported, European National Health and Wellness Surveys conducted in France, Germany, Italy, Spain, and the UK (2010), the proportion of treated asthma patients assessed as having not well-controlled asthma was 53.5%. A significant part of asthmatics remain uncontrolled across five European countries (2016), consequence in a significant impact on health resources and patients' health status (21-24).

A Survey done in Atlanta in 2015 showed 50% of adults with current asthma had uncontrolled asthma (25).

An observational cross-sectional study in Italy and Spain in 2017, showed subjects with uncontrolled asthma (ACT < 20) were about 50% of the whole study population. A participant with symptoms worsening the level of uncontrolled asthma was high which was 77.8%; even in patients asking for the renewal of drug prescription 28.6% of participants showed uncontrolled asthma. The difference between the two groups was statistically significant ( $p < 0.0001$ ) (26). Another multi-center, cross-sectional, 6-month observational, non-interventional study carried out in 16 Pulmonary Units in Italy was conducted in 2013 and showed only 9.1% of patients had asthma controlled, while partly controlled and uncontrolled asthma accounted for 39.6% and 51.3% respectively (27).

Cross-sectional web-based survey, carried in Australia in 2015 indicated that asthma was well controlled for 54.4% of participants, not well controlled for 22.7%, and very poorly controlled for 23.0% (28). Another Cross-Sectional Study in Cameroon which was done in 2016 showed 42% of patients of the study population had inadequately controlled asthma. ((4, 29).

Multicenter Observational Study of Asthma in Rabat (MOSAR) done in 2018 in Morocco showed that from 7440 patients screened by 28 physicians, 396 were included in the study. 53% of the participants suffered Controlled, 18% had partly controlled and 29% had uncontrolled asthma symptoms (30)

A study was done in Kenya in 2010, which involved 124 asthma patients showed 69.3% had uncontrolled asthma, 22.6% had partly controlled asthma. (31). Another study in Kenya revealed that 82.9% of patients had poor control (32).

In Ethiopia, a cross-sectional study conducted in the chest clinic at Tikur Anbessa Specialized Hospital (TASH) in Addis Ababa, between July and December 2015, only 24.2% subjects had well-controlled asthma; 22.5% were partially controlled and 53.3% were uncontrolled (10). A retrospective cross-sectional study was conducted in Hadiya Zone, Southern Ethiopia, between January 2014 and January 2016, from 174 studied asthmatic patients, 56.2% were having poorly controlled asthma while the rest were controlled asthma -43.8% (11).

## **2.2. Risk factors for uncontrolled asthma**

A cross-sectional observational study was conducted in China between November 2012 and June 2013 and showed that uncontrolled asthma was found in participants with poor asthma treatment



adherence (66.2%) or no adherence (77.3%), with rhinitis had a higher frequency of uncontrolled asthma than those without rhinitis (57.5% versus 53.6%,  $p = 0.016$ ) (20, 33).

A recent study conducted in 2019 on Spanish asthmatic patients followed-up in Primary Care identified factors of poor control of the disease as forgetting the medication, living in a rural environment, the presence of a stressing event, poor therapeutic- compliance, the underlying severity of asthma, and the need for oral corticosteroids as baseline treatment(34). Co-morbidities include anxiety, exposure to some agents in the workplace, being the older, active smoker, female gender, obesity, lower socioeconomic level, previous hospital admissions, higher frequency of exacerbations in the previous year and need for treatment with asthma medications(35-37).

A Survey done in Atlanta in 2015 showed uncontrolled asthma was significantly associated with being 45 years or older, having an annual household income of <\$25, 000, being "other" race, having less than a 4-year college degree, being a current or former smoker, reporting cost as barriers and being obese. Besides, being on long-term control medications was significantly associated with having very-poorly-controlled asthma (33%) than not being on long-term control medication (17.8%)(25). An observational cross-sectional study in Italy and Spain in 2017 revealed that when participants asked about the perception of their level of asthma control, patients with uncontrolled asthma reported being well or fully controlled in 20% of cases, and partially controlled in 48% of cases (26).

Another multi-center, cross-sectional, 6-month observational study carried out in 16 Pulmonary Units in Italy was conducted in 2013 and identified female sex, obesity low FEV1, exacerbations as the strongest independent factors associated with the uncontrolled disease(27).

A cross-sectional study was done with 216 asthmatics aged 18 and over consecutively recruited from tertiary clinics and the community in Kinshasa, Democratic Republic of Congo between June 2017 and February 2018, and abnormal FEV1 -65%, sensitization to two allergens (cat dander and dust mites) 18%, sleep disorders 37%, and heartburn 60%. Male, low educational level, sensitization to both cat dander and dust mites, sleep disorders (AOR 1.96; 95% CIs 1.04–3.71), and heartburn (AOR 2.02; 95% CIs 1.04–3.92) were significantly associated with uncontrolled asthma(38).

A study was done in Kenya in 2010, which involved 124 asthma patients showed that uncontrolled asthma was strongly associated with the incorrect use of an inhaler device, the use of oral

corticosteroids, abnormal PFT, the presence of comorbidity, lack of adherence to inhaled corticosteroids (31).

Uncontrolled asthma was more common in obese women, compared to those of the non-obese group, with the conclusion that obesity is an important risk factor for uncontrolled asthma (12, 39, 40).

In Ethiopia, a cross-sectional study conducted in the chest clinic at Tikur Anbessa Specialized Hospital (TASH) in Addis Ababa, between July and December 2015, excess salbutamol (SABA) use (> 200 doses/ month), longer duration of asthma (> 30 years), incorrect inhaler technique, asthma exacerbation in the last 12 months, and use of biomass fuel for cooking were found to be associated with uncontrolled asthma(10). A retrospective cross-sectional study was conducted in Hadiya Zone, Southern Ethiopia, between January 2014 and January 2016, from 174 studied asthmatic patients, there is a strong association between asthma exacerbation and social drug use (tobacco) (p-value=<0.05) among the asthmatic patient(11).

In summary, asthma control has been evaluated in several regions including Europe, the USA, and Asia-Pacific with poor levels of control reported by both physicians and patients in recent large-scale and prospective studies. Sub-optimal asthma control ranges from approximately 78% in Europe, 50% in the USA-Atlanta, 46% in Australia to over 60% in most Asian countries. Nonetheless, there are still gaps in our current knowledge of asthma control in Ethiopia (only three small centers that didn't include a new treatment approach of asthma (GINA-2019). Available data are from the AIRMAG study reported asthma control in 264 patients from Algeria, Tunisia, and Morocco (16), and an ACT-based assessment was reported for 1000 asthmatic patients in Saudi Arabia is suboptimal. In Ethiopia, including Jimma asthma control is also sub-optimal ranging from 43.8 to 76.1% Factors cited as impacting the level of asthma control are many and varied and include access to guidelines, environmental and patient-related influences such as exposure to allergens, seasonal changes, active smoking, disease-related features, comorbidities, while treatment-related aspects as a whole, including poor adherence, inadequate therapy, poor inhalation technique, poor tolerability play a major role all of which vary inherently by region.

## **CHAPTER THREE: OBJECTIVE**

### **3.1. General Objective**

- ✓ To assess the level of asthma control and identify associated factors with uncontrolled asthma in asthmatic patients at JUMC outpatient chest clinic.

### **3.2. Specific Objective**

1. To assess the level of asthma control among asthmatic patients in JUMC chest clinic
2. To identify risk factors associated with uncontrolled asthma among asthmatic patients in JUMC chest clinic

## **CHAPTER FOUR: METHODS AND MATERIALS**

### **4.1 Study area and period**

The study was conducted in JUMC Chest Clinic, Jimma University, and Jimma Zone from September to October 2020. Jimma zone comprises Jimma town and its nearby woredas. It is located in the South West of Ethiopia, Oromia regional state, with an estimated population of 2,486,155. The town is located 346 KM from the capital, Addis Ababa(41).

JUMC which is one of teaching and referral hospitals for the southwest population in the country. JU runs both undergraduates and postgraduate programs in several disciplines. The hospital gives health service at the inpatient and outpatient level as a referral Hospital for 15 million populations in the South West of the country. It has general medical wards and sub-specialty units with a total of 120 beds. It has a chest clinic. The total numbers of people enrolled in the chest clinic were 200 at the time of study periods.

At the outpatient level, chronic asthma care and service are delivered for these patients at a chest clinic by trained nurses, residents, and specialists on once-weekly bases.

Data collection was conducted from September to November 2020.

### **4.2 Study design**

Cross-sectional study design was employed

### **4.3. Source and Study Population**

#### ***4.3.1 Source population***

All Asthmatic patients on follow up at JUMC chest clinic during the study period.

#### ***4.3.2 Study population***

All Asthmatic patients on follow up at JUMC chest clinic who fulfill inclusion criteria.

## 4.4. Eligibility Criteria

### 4.4.1. Inclusion Criteria

- All adult patients with age  $\geq 18$  year with physician-diagnosed asthma (both clinical and spirometric criteria) and who give consent for participation during the study.
- Those who used asthma medications for at least the previous 3 months

### 4.4.2. Exclusion Criteria

- Active lung infections
- Bronchiectasis
- Pregnancy or incomplete data

## 4.5. The sample size Determination and Sampling Technique

### 4.5.1. Sample Size Determination

The required sample size is computed using single population proportion formula,

$$n = \frac{(Z_{\alpha/2})^2 p(1-p)}{d^2} = \frac{(1.96)^2 * 0.5 * (1-0.5)}{(0.05)^2} = 384$$

Assumptions,

n = Calculated sample size

P = Proportion = 50%

$Z_{\alpha/2}$  = Critical value at 95% level of confidence (Z = 1.96)

d = Margin of error (5%)

According to information obtained from the hospital, on average around 25 asthmatic patients visit weekly at the chest clinic. During the two months (excluding Saturday and Sunday) of the study period, the total numbers of asthmatic patients visiting at chest clinic are estimated to be about 200. Because of sampling is from a finite population of size, the corrected sample size (n') will be calculated by applying finite population correction formula:

$$n' = \frac{n}{\left(1 + \frac{n}{N}\right)} = 132, \text{ where } n = 384, N = 200$$

Considering the 5% non-response rate, the final sample size is **139** asthmatics.

#### ***4.5.2. Sampling technique***

A systematic random sampling technique was used and the number of asthmatic patients visited the chest clinic of the hospital during study period was 200. Consecutive sampling of clients coming to the clinic on their appointment dates was conducted. Every asthmatic patient that came to the chest clinic and fulfilled inclusion criteria was recruited.

### **4.6. Study Variables**

#### ***4.6.1. Dependent Variables:-***

- Level of asthma control

#### ***4.6.2. Independent Variables:-***

- Socio-demographic information(Age, Sex, Place of residence, Occupation, Income, Smoking, chat, alcohol, Education)
- Co morbidities like Allergic rhinitis, Gastro esophageal reflux
- Anthropometry-Body mass index (BMI)
- Regimen type
- Active or passive smokers
- Treatment adherence
- Duration of asthma

## **4.7. Data collection procedure and measurement tools**

### **4.7.1. Data collection**

A structured questionnaire was used to obtain sociodemographic and clinical information, including personal history of allergic disease, concomitant disease (e.g. rhinitis), smoking history asthma symptoms, and asthma duration since diagnosis, asthma-related treatments and tests, and asthma treatment adherence was collected from participants' medical charts during their visits. BMI was measured and classified as normal ( $18.5 \leq \text{BMI} < 24.9$ ), lean ( $\text{BMI} < 18.5$ ), overweight ( $25 \leq \text{BMI} < 29.9$ ), and obesity ( $\text{BMI} \geq 30$ ) based on Criteria Of Weight(42). Asthma treatment adherence was assessed by two nurses who had been trained for the this study using the eight-item Morisky medication adherence scale (MMAS-8) The 8-item MMAS is valid for assessing medication adherence in patients with asthma(43). This scale produces scores ranging from 0 to 8, Patients who scored 8 points, <8 to >6 points and  $\leq 6$  points on the scale are considered to have high, medium, and low adherence respectively. The inhalation technique was scored when inhaling placebo medication and using the short version, validated inhaler-specific checklist of the National Asthma Council Australia. The checklist measures the adequacy of the most essential preparation and breathing maneuvers necessary for optimal drug delivery. Incorrect inhalation technique is defined as one or more negative scores on Preparation or breathing maneuvers. The level of asthma control was assessed based on the asthma control test (ACT) questionnaire. Based on ACT score, the level of asthma control is classified into two groups. These are controlled asthma if ACT Score is  $\geq 20$  and uncontrolled if it is  $< 20$ . A cutoff point  $\leq 19$  will be used for under control of asthma(44) (Annex II).

### **4.7.2. Spirometry**

Pulmonary function test was determined that generates FEV1 and FEV/FVC. A portable minidigital spirometer (CareFusion UK 232 Ltd Quayside, Chatham Maritime, Kerit, ME4 4QY, UK ) was used with calibration according to the manufacturer's recommendations to assess therapeutic intervention(45). Low FEV1 or FEV/FVCC is associated with frequent asthma exacerbation and poor asthma control(18). Spirometric acceptability and reproducibility was determined using the published criteria of the European Respiratory Society and the American Thoracic Society which is described in detail in annex II. The test was repeated at least three times to make sure that the results are consistent. It was repeated more times when there was a lot of variation between the test results (greater than 5% variability among the results). The highest value from three closes (with < 5% variability) test readings used as our final result.

### **4.7.3. Data quality assurance**

All data were collected using a uniform data collection form. To ensure data quality, a pre-test was conducted on 5% of the sample, training was given to data collectors and supervisors on the data collection process. The collected data was checked for completeness and consistency on the day of collection. The principal investigator led the overall activities during the data collection period. Questionnaires were prepared in English and back-translated into Afan Oromo/Amharic and translated back into English to check its consistency. The Afan Oromo /Amharic versions were used for data collection after pretesting on 5% of the actual sample size at Shanan Gibe Hospital before the data collection. Amendments were made accordingly after pre-testing.

### **4.7.4. Data Processing and Analysis**

Data were entered, coded, and cleaned in EpiData manager version 4.6 software applications by data analyzer. Then it was exported to STATA Version 16.0 for analysis. Summary findings were presented by tables. Descriptive statistics was used to determine the demographic characteristics and patterns of asthma control. The potential predictor variables were tested using Chi-square test and a p-value < 0.05 was used as a



cut-off point for the presence of statistical significance. The variables which were significant in a bivariate analysis at a cut point of P-value of  $< 0.05$  were analyzed by multivariate logistic regression analysis.

#### **4.7.5. Ethical consideration**

Ethical clearance was obtained from the Ethical Review Committee of Jimma University. Permission was obtained from the hospital. Patient confidentiality was ensured during the study period. There were no risky procedures that applied to patients. Any identifier to an individual patient, such as social security number, identification number, and full name, was not collected.

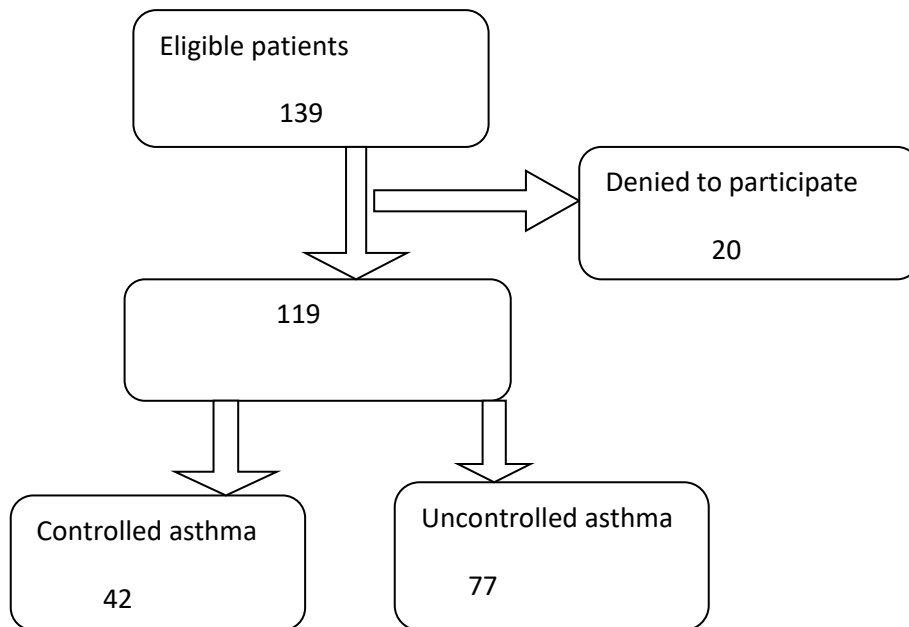
#### **4.7.6. Dissemination and Communication of the Result**

The findings of the study will be disseminated to all relevant stakeholders like Jimma University, Clinicians, researchers, and others through presentation Seminars and publications. Copies of the research will be given to Jimma University, Faculty of public health postgraduate program, and the Department of Internal Medicine. Publications in peer-reviewed, national or international journals will also be considered.

## CHAPTER FIVE- RESULT

### 5.1. Socio-demographic characteristics of the study participants

Out of one hundred and thirty nine participants, 119 were given consent and interviewed giving a response rate of 85.6%. The mean age of the participants was 44.7[95% CI, (41.9 - 47.5)] years. Out of the total asthmatic patients interviewed (119), 44.5 % of them were less than 40 years old, followed by 39.5% of them in the range of 40-65 years and 19.4% of them were in the age group of 65 years and above. The majority (58.8%) of the study participants were female in gender. Major educational status of respondents was primary school which accounts 37.8% followed by secondary school which is 26.1% and 20.2% of them never attended formal education. None of them were smokers or other substance users (table 1).



**Figure 1, Enrolment of study participants**

**Table 1: Socio-demographic characteristics of asthmatic clients in Jimma University medical center, outpatient chest clinic**

<b>Variables</b>	<b>Categories</b>	<b>Frequency (n=119)</b>	<b>Percentage</b>
<b>Age group (in years)</b>	<=40	53	44.5
	40-65	47	39.5
	>=65	19	15.9
<b>Sex</b>	Male	49	41.2
	Female	70	58.8
<b>Education</b>	Never attended school	24	20.2
	Primary school	45	37.8
	Secondary school	31	26.1
	College and above	19	15.9
<b>Residence</b>	Urban	76	64.4
	Rural	42	35.6
	Employee(GO, NGO, private)	39	32.8
<b>Occupation</b>	Merchant	14	11.8
	Farmer	32	26.9
	Housewife	29	24.4
	other occupations	5	4.2
<b>Monthly Income (in ETB)</b>	<500	23	19.3
	500-3000	66	55.5
	3001-5000	23	19.3
<b>Smoker</b>	>=5001	7	5.9
<b>Other substance use</b>	Never	119	100
	Never	119	100

## **5.2.Clinical characteristics of the study participants**

Asthma control was assessed by the ACT score for all 119 individuals; 77 subjects (64.7%) scored less than or equal to 19 that corresponds to uncontrolled asthma and the rest scored 20 and more that corresponds to controlled asthma. Body mass index was determined and 2.65% of participants were found to be obese. Spirometry test was done successfully in 111 (93.3%) participants but 8 participants

couldn't generate reliable result due to their fatigability. Approximately 44.1% of clients showed FEV1 value <60% of predicted value and in 40.5%, FEV1 $\geq$  80% of predicted value. All of them (111) have FEV1/FVC ratio < 70%. As shown in table 2 , majority (73.11%) of participants have unscheduled visit, and 61.34% of the participants have low level of adherence, while 75.4% of asthmatic patients have good inhaler techniques.

**Table 2. Clinical characteristics of the study participants**

<b>Variable</b>	<b>Variable category</b>	<b>Frequency(n=119)</b>	<b>Percent</b>
BMI	Underweight (<18.5 kg/m <sup>2</sup> )	6	5.31
	Normal weight(18.5- 25 kg/m <sup>2</sup> )	91	80.53
	Overweight (25 - 30 kg/m <sup>2</sup> )	13	11.50
	Obese ( $\geq$ 30 kg/m <sup>2</sup> )	3	2.65
FEV1	$\geq$ 80% of predicted value	45	40.54
	60-80%	17	15.32
	< 60%	49	44.14
FEV1/FVC	<70%	111	100
Co-morbidities relevant to the respiratory tract (n=30)	Gastro-esophageal reflux (symptom of heart burn)	17	56.67
	Chronic rhino-sinusitis	17	56.67
Unscheduled visit(due to worsening of symptoms)	Yes	32	26.89
	No	87	73.11
Frequent asthma	Yes	35	29.41
Exacerbation ( $\geq$ 2/year)	No	84	70.59
History of admission	Yes	26	21.85
	No	93	78.15
Adherence	Good (MMAS-8 Score $\geq$ 7)	46	38.66
	Poor (<7)	73	61.34
Inhaler technique	Good techniques (10/10)	86	75.44
	Poor techniques (<10/10)	28	24.56

### **5.3. Factors associated with uncontrolled asthma among asthmatic patients**

The chi square test revealed that adherence to treatment, monthly income; commodities, FEV1, and perceived severity of asthma were significantly associated with uncontrolled level of asthma.

Monthly income was statically a significant ( $X^2= 11.995$ , P-Value = 0.007) factor associated with uncontrolled level of asthma. About 17.7% of participants with monthly income less than 500 birr were categorized to uncontrolled asthma. Only 8.4% of participants with monthly income between 3001-5000 birr have uncontrolled asthma.

Clinical factors like co morbidities mainly gastro-esophageal reflux disease (GERD) and allergic rhinitis ( $X^2= 14.563$ , P-value=0.001) were associated with uncontrolled asthma. Approximately 24 % of asthmatic patients who have co morbidities have uncontrolled asthma.

FEV1 is also associated with level of asthma control ( $X^2=17.491$ , P-Value=0.003). Approximately 64 % of participants with FEV1 less than 60% of predicted value have uncontrolled asthma as compared to those who have score more than or equal to 80% of predicted value (FEV1) accounted 17.1% of uncontrolled asthma.

Frequent asthma exacerbation ( $\geq 2$ /past one year) has significant associations with uncontrolled asthma ( $X^2=22.844$ , P-Value=0.002). Patients with history of frequent asthma exacerbations have their asthma uncontrolled in 28.6 %. Low adherence MMAS $<7$  ( $X^2=36.018$ , P-Value=0.002) and incorrect inhaler techniques ( $X^2=17.087$ , P-Value=0.002) were also found to be significant factors for uncontrolled level of asthma (table 3).

**Table 3: Chi-square test of asthma control status and associated factors among asthmatic clients in Jimma University medical center, outpatient chest clinic.**

Variables	Categories	Asthma status		Pearson Chi2	P-value
		Controlled Freq. (%)	Uncontrolled Freq. (%)		
<b>Age</b>	<45 years	26 (21.8)	40 (33.6)	1.091	0.296
	≥45 years	16 (13.5)	37 (31.1)		
<b>Gender</b>	Male	17 (14.3)	32 (26.2)	0.013	0.909
	Female	25 (21.0)	20 (38.5)		
<b>Residence</b>	Urban	29 (24.6)	47 (39.8)	1.096	0.295
	Rural	12 (10.2)	30 (25.4)		
<b>Educational status</b>	No formal education	7 (5.9)	17 (14.3)	6.269	0.099
	Elementary school	12 (10.1)	33 (27.7)		
	High school	12 (10.1)	19 (15.9)		
	College/University	11 (9.3)	8 (6.7)		
<b>Adherence</b>	Good	41 (35.3)	32 (26.9)	36.018	<b>0.002</b>
	Poor	1 (0.8)	45 (37.8)		
<b>Monthly income (in birr)</b>	<500	2(1.7)	21(17.7)	11.995	<b>0.007</b>
	501-3000	25(21.0)	41(34.5)		
	3001-5000	13(10.9)	10(8.4)		
	≥5001	2(1.7)	5(4.2)		
<b>Comorbidities</b>	Yes	2 (1.2)	28 (24.1)	14.563	<b>0.001</b>
	No	39 (33.3)	47 (40.5)		
<b>FEV1</b>	<60%	8 (7.2)	41 (63.9)	17.491	<b>0.003</b>
	60-80%	6 (5.41)	11 (9.9)		
	>80%	26 (23.4)	19 (17.1)		
<b>Frequent asthma exacerbations</b>	Yes	1 (0.8)	34 (28.6)	22.844	<b>0.002</b>
	No	41 (34.5)	43 (36.1)		
<b>Inhaler technique</b>	Correct	40 (33.6)	46 (38.7)	17.087	<b>0.002</b>
	Incorrect	2 (1.7)	31 (26.05)		
<b>Treatment type</b>	SABA and ICS	15 (12.8)	41(35.1)	2.6181	0.270
	SABA only	23 (19.7)	33 (28.2)		
	Others	2 (1.7)	3 (4.3)		

In multivariate logistic regression analysis, (table 4), frequent exacerbation of asthma ( $\geq 2$ /year) (Adjusted Odds Ratio (AOR) = 0.022, 95% C.I 0.002- 0.195, P = 0.001), lower adherence to treatment (AOR=0.010- 95% C.I 0.001-0.090, p = 0.001) and co-morbidities (AOR= .056 95% C.I 0. 010-0.324,p = 0.001) were factors associated with uncontrolled asthma.

**Table 4: Multivariate logistic regression model for factors associated with uncontrolled asthma among asthmatic clients in JUMC, outpatient chest clinic.**

Variables	Category	p-value	AOR	[95% C.I]	
<b>Educational status</b>	No formal education		1		
	Elementary school	.596	.460	.026	8.099
	High school	.238	.266	.030	2.396
	College/University	.052	.098	.009	1.023
<b>Adherence</b>	Good		1		
	Low	<b>.0001</b>	.010	.001	.090
<b>Frequent asthma exacerbation</b>	Yes	<b>.001</b>	.022	.002	.195
	No		1		
<b>Co -morbidities</b>	Yes	<b>.001</b>	.056	.010	.324
	No		1		
<b>FEV1</b>	>80%	.140	3.640	.655	20.242
	60-80%	.150	5.090	.556	46.592
	<60%		1		

*Adjusted for sex, age, Educational status, Residence, monthly income, frequent asthma exacerbation, Co-morbidities, FEV1, and adherence; 1 reference category*

## Discussion

The main finding of this study is that asthma control in the chest clinic of JUSH is generally poor. Using the ACT test score based algorithm, 64.7% of the respondents were classified as having uncontrolled asthma. Our study showed that the rate of uncontrolled asthma is fewer than that was done in Jimma (77.1%) so far [9].

The results of our study (uncontrolled asthma) are higher than that of the worldwide control of asthma in North America and Europe which fall between 24% and 45% but it is comparable with that of Asia and Middle East [19,22-28]. In a recent study from Cameroon, 42% of the study population had inadequately controlled asthma [29]. Similar studies from Nigeria, Morocco and Ethiopia have reported uncontrolled disease in 69.3, 42.3, and 77.8% of asthmatics, respectively [10, 31-33]. When we combine the number of asthmatics with partially controlled and uncontrolled disease, our results are within the range of the findings of these studies when the ACT score based algorithm was used in all studies mentioned above.

This finding is lower than that of a recent pan-European cross-sectional survey done in 2014, with results of 79.9% of adult asthmatics had not well-controlled asthma on a validated symptom instrument (ACT score <20) [20]. These difference might be due to the larger numbers of sample size in these studies as compared to our result (64.7%). A previous study done in Jimma also demonstrated that uncontrolled asthma is higher (76.1%) than the present study [9]. These gaps might be attributable to the small sample size of our study.

We identified several factors associated with uncontrolled asthma. The chi square test of association revealed that adherence, monthly income, commodities (GERD and allergic rhinitis), FEV1, and perceived severity of asthma were found to statistically significant association with uncontrolled level of asthma.

However, multivariate logistic regression analyses showed that only adherence to treatment; co-morbidities like GERD and allergic rhinitis and frequent exacerbation of asthma (greater or equal to 2 in the past one year) were associated with uncontrolled asthma.

Our study identified clinical factors like co- morbidities which include GERD and allergic rhinitis (AOR= 0.056, 95% C.I 0. 010-0.324, p = 0.001) were risk factors for uncontrolled asthma.



A study conducted in China showed that participants with rhinitis had a higher frequency of uncontrolled asthma than those without rhinitis (57.5% versus 53.6%,  $p = 0.016$ ) (21, 34). This value is higher than results observed in our result which might be due large sample size. Approximately 24% of our study participants who have co morbidities have uncontrolled asthma demonstrating similarities with study carried in Kenya and Democratic Republic of the Congo [20,31, 33, 38]. When compared with the study done 9 years back in Jimma, co- morbidities were also included but not found to be statistically significant risk factors.

Another study done in tertiary clinics and the community in Kinshasa, Democratic Republic of the Congo revealed that 60% of GERD (heart burns) participants have uncontrolled asthma and was found to be significant associated factor for lower asthma control (39).

Participants with frequent asthma exacerbation were found to have less well controlled asthma (AOR = 0.022, 95% C.I 0.002- 0.195,  $P = 0.001$ ), only 0.8% of patients with frequent asthma exacerbation have controlled asthma compared with 28.6% who have uncontrolled asthma. This result was similar with the study done in the China, Kenya, Italy and Ethiopia (TASH and Hadiya zone) [10, 20, 27, 31].

Finally, low adherence to treatment with MMAS-8 Score  $<7$  (AOR=0.010, 95% C.I 0.001-0.090,  $p = 0.001$ ) was risk factor for uncontrolled level of asthma. This result is similar with the study conducted in 2019 on Spanish asthmatic patients followed-up in Primary Care as well as in China and identified poor therapeutic- compliance as factor for poor asthma control. This factor was not identified in previous study done in Jimma because it was not included in their study design.

Age, gender, level of education, types of asthma therapy, occupation, place of residence and duration of asthma were not related to asthma control in our study. It is not consistent with the studies done in Italy, Atlanta and Spanish and Ethiopia [26, 28, 37]. We consider the difference might be due to the small sample size in our study. Further large-scale study may be needed to clarify this issue.

## **Conclusion**

Asthma control is still poor in Jimma but it is better than the previous study. This study identified that the presence of commodities, low level of adherence to treatments and frequent asthma exacerbation history in the past 12 months were associated with uncontrolled level of asthma.

## **Recommendation**

Physicians caring for asthmatic patient should focus on counseling of them on adherence to treatment, identifying and treating co morbidities to improve asthma control. The Ministry of health should take in to account Individual and treatment related factors. Further large- scale study should be conducted to identify determinants of the uncontrolled level of asthma.

## **Limitations**

One of the limitations of this study was that the small sample size of 119 participants for whom asthma control was measured by the validated ACT measurement and 111 individuals on whom appropriate spirometry was done, gives a multi co linearity which reduced statistical power among subgroup multinomial analyses and difficult to do logistic regression analysis. Therefore, studies on larger samples are needed to monitor trends of asthma control and identify further independent factors for control.

A second limitation was difficulty in assessing inhalational technique by checklist as it is more subjective and needs follow up of participants to be objective over a period of time.

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## ANNEXES

### ANNEX I- Measurement Tools and Procedure

#### I. Spirometry

Spirometry is standard test doctors use to measure how well your lungs are functioning. It works by measuring airflow into and out of the lungs. It is used to diagnose asthma and monitor response to treatment. In this study, the spirometric measurement value is only used to assess response to treatment

#### How to prepare for a spirometry test

Participants (asthmatics) shouldn't use bronchodilators and smoke one hour before a spirometry test. She/he should also need to avoid alcohol that day as well. Eating too large of a meal could also impact the patient's ability to breathe.

The patient should not wear clothing that's so tight that it could restrict his/her breathing. The doctor may also have instructions about whether he/she should avoid using inhaled breathing medications or other medications before the test.

#### Infection precaution during Covid-19

- The exam room at the doctor's office should be well ventilated
- Data collector should wear a facemask preferably N-95 and face shield before the procedure
- Hand sanitizers should be available in the procedure room and used after each procedure.
- A participant with suspicious for Covid-19 shouldn't be a candidate for spirometry

#### Spirometry procedure

1. Check the spirometer calibration
2. Explain about the test to the participant
3. Prepare the subject
4. Ask about smoking, recent illness, medication use, etc.
5. Measure weight and height without shoes
6. The patient will be seated in a chair in an exam room at the doctor's office. A doctor or a nurse places a clip-on Patient's nose to keep both nostrils closed. They also place a cup-like breathing mask around the client's mouth.
7. The doctor or nurse next instructs you to take a deep breath in, hold your breath for a few seconds, and then exhale as hard as you can into the breathing mask.

8. Repeat this test at least three times to make sure that your results are consistent. It may be repeated more times if there is a lot of variation between your test results. They'll take the highest value from three close test readings and use it as your final result.
9. A trained nurse enters correct values for age, height, and gender as these values are used to generate the appropriate predicted values for the individual patient.
10. If the participant is coughing, sneezing or experienced an exacerbation of shortness of breath, the procedure will be interrupted and he/she advised to get rest will be resuscitated if get critical

### Acceptability and Reproducibility of Test

- A clear start to the test with a maximum effort and smooth, continuous exhalation maintained for at least 6 seconds, without coughing or Valsalva's maneuver.
- An obvious end to the test (no change in volume for at least 2 seconds)
- The subject should perform a minimum of three and a maximum of eight FVC maneuvers until at least two acceptable curves are obtained
- The reproducibility of the two largest curves should be within 5% or 0.1 L, whichever is greater, i.e. the variability between two consecutive measurement results shouldn't be greater than 5%.
- If the variability is greater than 5%, the result will be rejected
- The recorded FVC should be the maximum value from the acceptable curves

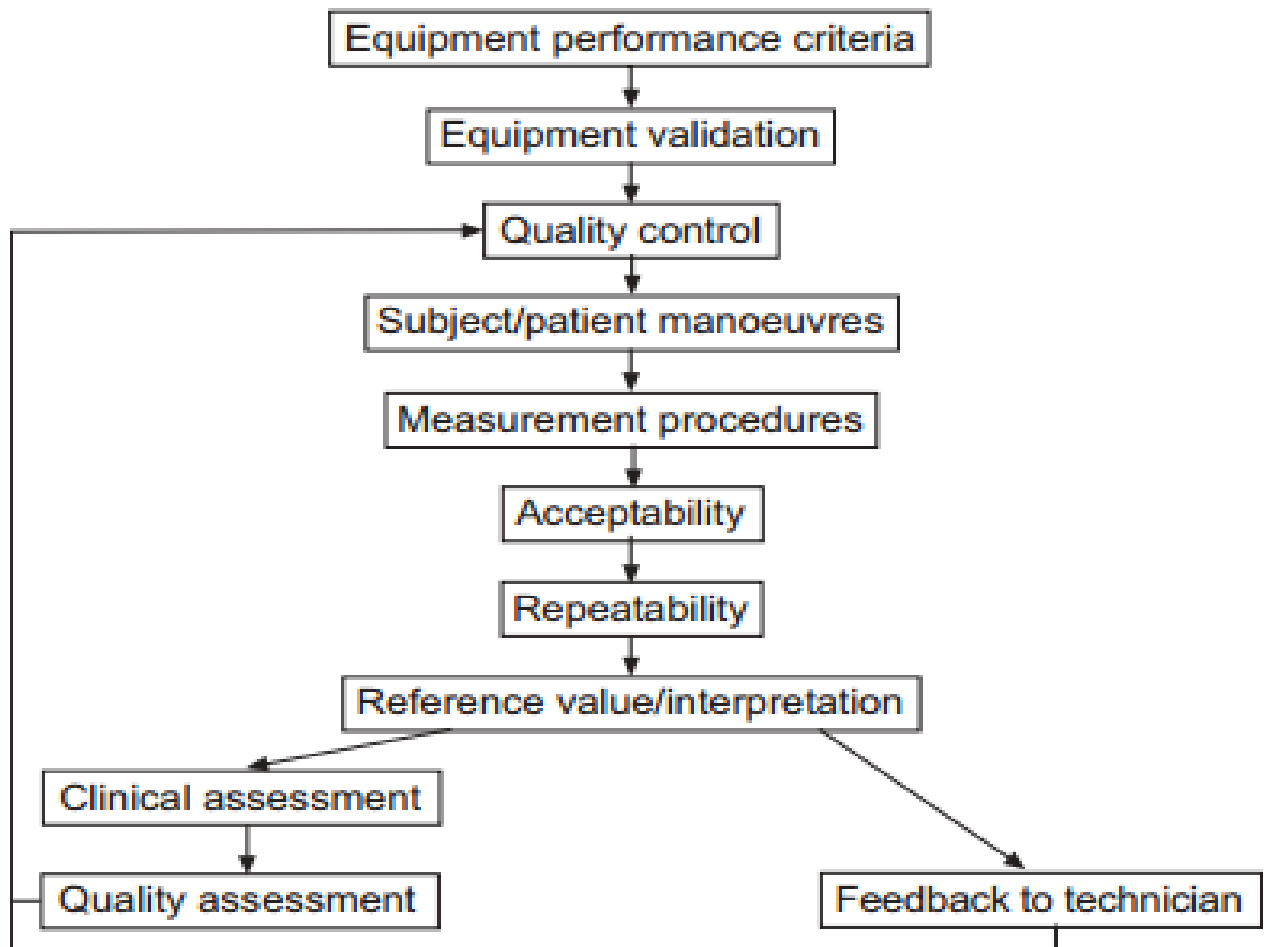
### Spirometry normal values

#### FEV1 measurement

A lower FEV1 value shows you might have a breathing obstruction.

**Table-5 Norman and abnormal values of the pulmonary function test**

Percentage of predicted FEV1 value	Interpretation
80% or greater	Normal
60%–79%	moderately abnormal
Less than 60%	severely abnormal
FEV/FVC $\leq$ 70%	Airway Obstruction



**Spirometry standardization criteria**

From the [American Thoracic Society](#) Guidelines.



**Table 6. Eight-item Morisky Medication Adherence Scale (MMAS-8)**

Below is a list of statements. Participant indicates the extent to which he/she agree or disagree with them by circling the number of the appropriate box. The total score is range 0-8 and the level of adherence is graded as high, medium, and low if the score is 8, 6/7, and <6 respectively.

Questions	Answers		score
1. Do you sometimes forget to take your medication?	Yes=0	No=1	
2. Over the past 2weeks, were there any days when you didn't take your medication?	Yes=0	No=1	
3. Have you ever stopped taking your medication without telling your doctor because you felt worse when you took it?	Yes=0	No=1	
4. When you travel or leave, home, do you sometimes forget to bring your medications?	Yes=0	No=1	
5. Did you take all your medications yesterday?	Yes=0	No=1	
6. When you feel like your symptoms are under control, do you sometimes stop taking your medication?	Yes=0	No=1	
7. Taking medication every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	Yes=0	No=1	
8. How often do you have difficulty remembering to take all your medication	None=1	Sometime/all-=0	
Total score			

**Table 7.MDI Inhaler technique check List**

MDI Inhaler technique check List	yes	No
1. Remove inhaler cap		
2. Hold inhaler upright and shake well		
3. Breathe out gently, away from the inhaler		
4. Put mouthpiece between teeth without biting and close lips to form a good seal		
5. Breathe in slowly through the mouth and, at the same time, press down firmly on canister		
6. Keep breathing in slowly and deeply and hold breath for about 5 seconds or as long as comfortable		
7. While holding breath, remove inhaler from mouth		
8. Breathe out gently, away from the inhaler		
9. If an extra dose is needed, repeat steps 2 to 8		
10. Replace cap		

**Table 8. Asthma Control Test (ACT) Score Assessments Tools**

ACT Test Questions		Circle one answer	Score
Q1	During the past 4 weeks, how often did your asthma prevent you from getting as much done at work, school, or home?	<ul style="list-style-type: none"> <li><input type="radio"/> All of the time= 1</li> <li><input type="radio"/> Most of the time =2,</li> <li><input type="radio"/> Some of the time =3</li> <li><input type="radio"/> A little of the time =4</li> <li><input type="radio"/> None of the time =5</li> </ul>	
Q2	During the past 4 weeks, how often have you had shortness of breath?	<ul style="list-style-type: none"> <li><input type="radio"/> More than once a day=1</li> <li><input type="radio"/> Once a day=2</li> <li><input type="radio"/> 3-6 times a week =3</li> <li><input type="radio"/> 1-2 times a week =4</li> <li><input type="radio"/> Not at all =5</li> </ul>	
Q3	During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, chest tightness, shortness of breath) wake you up at night or earlier than usual in the morning?	<ul style="list-style-type: none"> <li><input type="radio"/> 4 or more times a week=1</li> <li><input type="radio"/> 2-3 nights a week= 2,</li> <li><input type="radio"/> Once a week =3</li> <li><input type="radio"/> Once or twice= 4</li> <li><input type="radio"/> Not at all =5</li> </ul>	
Q4	During the past 4 weeks, how often have you used your reliever inhaler (usually blue)?	<ul style="list-style-type: none"> <li><input type="radio"/> 3 or more times a day=1</li> <li><input type="radio"/> 1-2 times a day=2</li> <li><input type="radio"/> 2-3 times a week=3</li> <li><input type="radio"/> Once a week or less =4</li> <li><input type="radio"/> Not at all=5</li> </ul>	
Q5	How would you rate your asthma control during the past 4 weeks?	<ul style="list-style-type: none"> <li><input type="radio"/> Not controlled=1</li> <li><input type="radio"/> Poorly controlled =2</li> <li><input type="radio"/> Somewhat controlled =3</li> <li><input type="radio"/> Well controlled= 4,</li> <li><input type="radio"/> Completely controlled =5</li> </ul>	
		Total Score	

Based on ACT score, the level of asthma control is classified as follows:-

Controlled if ACT Score is  $\geq 20$ , uncontrolled if it is  $< 20$ .

## **Annex III: Information Sheet and Consent Form (English)**

### **A. Information Sheet (English version)**

#### ***Title of the research project***

Assessment of level of asthma control and its associated risk factors at chest clinic of Jimma University medical center, Jimma, southwest of Ethiopia

#### **Name of the organization:-**

Jimma University, Department of Internal Medicine

#### **Purpose of the study**

The purpose of this study is to assess the level of asthma control and its associated risk factors at chest clinic of Jimma University medical center, Jimma, southwest of Ethiopia. So this study will provide the level of asthma control and its future management plan for asthmatics and caring physicians.

#### **Confidentiality**

Any information that will be obtained about you will be kept confidential. This is assured by avoiding the use of any identifier about you and information will be recorded with the code number. Your information will be used only for this study purpose

#### **Voluntary participation**

Participation in this study is the voluntary basis of participants while having the right to refuse participation at any time. I would like to inform you that ethical clearance was obtained and it will be approved by Jimma University Research Ethical Review Committee. In the end, you may ask questions now and in the future, if you do not understand something that is being done. Here are the addresses of principal investigator and advisors who you can contact:

Name of the investigator: - Dagne Feye, Cell number:- 0923104512

Name of advisors: - Professor Samuel Yoo-----0985176033

-Dr. Gobeze Tefera-----0917014525

- Melat Wodaje (MPHE)...--0945973625

**B. Consent Form (English version)**

Participant identification number \_\_\_\_\_

Full name of participant \_\_\_\_\_

I have read or information sheet has been read to me fully in my own language the information on it. I understood that the research project has got ethical approval from the Research Ethical Review Committee of the College of Public Health and Medical Sciences, Jimma University. And also, I understood well the information about the purpose and benefits of the study, the confidentiality of the information, and other information's regarding the study. Therefore, I am volunteering to participate in the study and give information.

I \_\_\_\_\_ have given my consent freely for the participation on the study on the assessment of the level of asthma control and its associated risk factors at chest clinic of Jimma University medical center, Jimma, southwest of Ethiopia,2020

Participant signature \_\_\_\_\_, Date \_\_\_\_\_

Data collector name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Witnesses**

1. Name: \_\_\_\_\_ signature: \_\_\_\_\_ Date: \_\_\_\_\_

2. Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## C. Consent Form in Afaan Oromoo

Odeeffannoo qoratamaaf kennamu

Ani maqaan koo Dr.Daanyee Fayyee yoon ta’u karoorra barreeffama eebbaa irratti hirmaataa akka naaf taataniif kabajaan isin gaafadha. Gaggeessi qorannoo kanaa bifa gaaffiif deebiitiin,meeshaa qorannoo sombaa kan dhukkuba Asmaaf oolu fi kaardii yaalumsa keessanii irraa odeeffannoo fudhachuun ta’a. Yaadni qorannoo kanarraa argamu hojii fuuldura adeemsifamuuf bu’aaguddaa kan kennu qoratamaa irrattiimmoo dhiibbaa kan hingeessifnedha. Qorannoo kana keessaas yeroo barbaaddanitti ba’uu kan dandeessan yoo ta’u kun immoo tajaajila isin argattanirratti dhiibbaa hin qaqqabsiisu.

Qorannaa irratti hirmaachuuf yoo walii galtan bakka armaan gadii irratti mallattoon mirkaneessaa.

Galatoomaa

Mallattoo hirmaataa.....

Maqaa qorataa.....

Guyyaa.....

Yoo qo’annaa irratti qooda fudhachuu hinbarbaadne galateeffadhaa dhiisaa.

## ሀ. የጥናቱ ማብራሪያ ቅፅ (አማርኛ ግልጻጭ)

### የጥናቱ ርዕስ

Assessment of level of asthma control and its associated risk factors at chest clinic of Jimma University medical center, Jimma, southwest of Ethiopia, 2020.

### የጥናቱ አላማ

የዚህ ጥናት አላማ የአስም ህመም ደረጃ ና ተያያዥ ምክንያቶችን ሲሆን በ ጅም ዩንቨርሲቲ ህክምና ማእከል በ አዋቂ ተመላላሽ ክፍል ውስጥ ለህክምና ክትትል የሚመጡ የ አስም ታማሚዎች ላይ ማጥናት ነው።

ስለዚህ ይህ ጥናት በእነዚህ ጉዳዮች ላይ መረጃን ይሰጣል።

### ቅደም ተከተል

የእርሶ ፈቃደኝነት ከሰጡ በኋላ ስፕይሮመትሪ ለመውሰድ የሚከተውን ቅደም ተከተል እናደርጋለን።

- በቅድሚያ ወንበር ላይ ቀና ብለው ይቀመጣሉ
- ትንፋሽ ወደ ውስጥ በደንብ ይስባሉ
- የትንፋሽ መለኸያ ጫፍ አፍ ውስጥ ያስገባሉ
- የትንፋሽ ወደ ውጭ ሳይቆረጥ አስኪደክሞት በደንብ ያስወጣሉ
- ለተወሰነ ደቂቃ አረፍት ካረጉ በሁዋላ ይህንኑ ለ ሶስት ጊዜ ይደግማሉ

በጥናቱ ሳቢያ ሊከሰቱ የሚችሉ ጉዳዮች

ስፕይሮመትሪ በምንወስድበት ጊዜ ደረጃውን የጠበቀ ቀደም ተከተል ስለምንከተል በዚህ ጥናት ሳቢያ በእርሶ ላይ ምንም አይነት ጉዳት አይከሰትም። ምናልባትም የምትተነፍሱ ግዘ ማሳልና ትንፋሽ ማጠር ሊከሰት ይችላል።

**የጥናቱ ጥቅሞች**

በጥናቱ ተሳታፊ ከሆነ የ አስም ህመም ደረጃን ና የምያዛቡ ምክንያቶች ለማወቅ፣ በተጨማሪም ለሚያክመው ሃኪም ትክክለኛ መድሀኒት ለማዘዝ ያግዛል።

**ሚስጥር ስለመጠበቅ**

ከርሶ የሚውሰዱ መረጃዎች ሚስጥራዊነታቸው የተጠበቀ ይሆናሉ። ከርሶ የተወሰደ መረጃ ለዚህ ጥናት ዓላማ ብቻ ይወላል።

**ተሳትፎ**

በዚህ ጥናት ላይ ለመሳተፉ የእርሶ ሙሉ ፈቃደኝነት ላይ የተመሰርተ ይሆናል። በመሆኑም በጥናቱ ላይ አልሳተፍም የማለት መብቱ የተጠበቀ ነው። ይህ ጥናት ከጅም ዩኒቨርሲቲ የጥናቶች ስነ ምግባር አጣሪ ኮሚቴ ታይቶ የፀደቀ መሆኑን ላሳውቆት እወዳለሁ። በመጨረሻም ስለ ጥናቱ ያልገባዎት እና ምን እንደሚደረግ መረጃ ከፈለጉ በሚቀጥሉትን ጥናቱን የሚያካሄደውንና የጥናቱ አማካሪዎች አድራሻ ላይ ማግኘት ይችላሉ።

**ጥናቱን የሚያካሄደው ስም** :ዶ/ር ዳኚ ፈዴ ስልክ: 0923104512

**የአማካሪዎች ስም**:- ፕሮፌሰር ሳሙኤል ዩ :- 0985176033

- መላት ወዳጆ :- 0945973625

- ዶ/ር ጎበዝ ተፈራ :- 0917014525

**ጅም ዩኒቨርሲቲ**



## D. Consent Form in Amharic

የፍቃደኝነት መጠየቂያ ቅፅ (አማርኛ ግልባጭ)

የተሳታፊው ሙሉ ስም፤ \_\_\_\_\_

ስለጥናቱ አስፈላጊ የሆኑ ሙሉ መረጃዎች በምችለው ቋንቋ አንብቤ ወይም ተነብልኝ ጥናቱ ከጅም ዩኒቨርሲቲ የጥናቶች ስነ-ምግባር አጣሪ ኮሚቴ ታይቶ የፀደቀ መሆኑን ተረድቻለሁ። በተጨማሪም ስለ ጥናቱ አላማውንና ጥቅም፣ ቅድመ ተከተል፣ በጥናቱ ሳቢያ ሊከሰቱ የሚችሉ ጉዳዮች፣ ሚስጥር አጠባበቅ እና ሌሎችም ጥናቱን በሚመለከቱ ጉዳዮች ገለጻ ተደርጎልኝ በሚገባ ተረድቻለሁ። ስለዚህ በጥናቱ ለማሳተፍና ለመስጠት እንዲሁም የተጠየኩትን መረጃ ለመስጠት ፍቃደኛ ነኝ።

እኔ አቶ/ወ/ሮ/ወሪት፤ \_\_\_\_\_ በጥናቱ ላይ ለመሳተፍ በፍቃደኝነት ላይ የተመሰረተ የተሳትፎ ስምምነት የሰጠሁ መሆኑ በፍርማዬ ለማረጋገጥ እወዳለው ።

ፊርማ፤ \_\_\_\_\_, ቀን፤ \_\_\_\_\_

ዳታ ሰብሳቢ ስም፤ \_\_\_\_\_

ፊርማ፤ \_\_\_\_\_

ማንኛውም ጊዜ መረጃ መስጠት ካልፈለጉ ማቋረጥ ይችላሉ።

**መጠይቅ (አማርኛ ግልጻዎ)**

**ጅም ዩኒቨርሲቲ ጤና ኢኒስቲቲዩት**

**የ ውስጥ ደወ ሕክምና ት/ክፍል**

የመጠየቅ ልዩ መለያ ቁጥር \_\_\_\_\_

ክፍል አንድ፣ ስለ ተሳታፊ የሚጠየቁ መጠይቆች

ተቁ	ጥያቄ	መልስ
1	እድሜ	/_____/ በወራት፣ /_____/ በአመት
2	ጾታ	/_____/ ወንድ፣/_____/ ሴት
3	የመኖሪያ አድራሻ	/_____/ ከተማ፣ /_____/ ገጠር
4	የትምህርት ደረጃ	/_____/ ኮሌጅ/ዩኒቨርሲቲ ያጠናቀቀች፣ /_____/ 2ተኛ ደረጃ፣ /_____/1ተኛ ደረጃ ያጠናቀቀች፣ /_____/ መፃፍና ማንበብ፣/_____/ ያልተማረች
5	ስራ	/-----/መንግስት ስራተኛ/-----አርሶ አደር /---የበት አመበት/--- ሰላ-----
6	አማካይ ወርሃዊ ገቢ በብር	/_____/
7	በቤት ውስጥ ለምግብ ማዘጋጃ የሚወልድ ዋናው የሀይል ምንጭ	/_____/ የማገዶ እንጨት፣/_____/ ከሰል፣ /_____/የእንስሳትፍግ፣/_____/ኬሮሲን፣/_____/ኤሌክትሪክ
8	በቤት ውስጥ ሲጋራ የሚጠቅሙ ሰው አለ?	/_____/አዎን ፣/_____/አይደለም
9	አሁን ሲጋራ ያጨሳሉ	/-----/አዎ/-----/አይደለም/
10	አድንዛኝ አስ ይጠቅማሉ	/-----/አዎ/-----/አይደለም/

**ክፍል ሁለት፡- ስለ ተሳታፊዉ ጤንነትና ሁኔታ መጠይቅ**

10	የአስም መለኪያ ጥያቄዎች	መልስ	ውጤት
I.	በባለፈዉ ወር ዉስጥ ምን ያህል ጊዘ ቀን ላይ ትንፋሽ ማጠር አጋጥሞታል	<ul style="list-style-type: none"> <li>• ምንም</li> <li>• &lt;2 ቀን/ሳምንት</li> <li>• &gt;2 ቀን/ሳምንት</li> <li>• በየቀኑ</li> <li>• ቀኑን ሙሉ</li> </ul>	
II.	በባለፈዉ ወር ዉስጥ ምን ያህል የ አስም ምልክቶች ከ አንቅልፍ ቀስቅሶታል ?	<ul style="list-style-type: none"> <li>• ምንም</li> <li>• 1-2/ወር</li> <li>• 3-4/ወር</li> <li>• &gt;1/ሳምንት</li> <li>• 7 ጊዘ/ሳምንት</li> </ul>	
III.	በባለፈዉ ወር ዉስጥ ምን ያህል የአስም ማስታገሻ መድሃኒት ተጠቅመዋል	<ul style="list-style-type: none"> <li>• ምንም</li> <li>• &lt;=1 ቀን/ሳምንት</li> <li>• 2-3x ቀን/ሳምንት</li> <li>• ብዙ ጊዘ/ቀን</li> <li>• በየቀኑ</li> </ul>	
IV.	በባለፈዉ ወር ዉስጥ ምን ያህል ቀናት በ አስም ምክንያት ከ ስራ/ትምህርት ቀርተዋል?	<ul style="list-style-type: none"> <li>• ምንም</li> <li>• ሁል ጊዘ</li> <li>• ብዙ ግዘ</li> <li>• አንዳንድ</li> <li>• ጥቂት ጊዘ</li> </ul>	
V.	በባለፈዉ ወር ዉስጥ ያለዊን የ አስም መቆጣጠር ደረጃ አንደት ያዩታል	<ul style="list-style-type: none"> <li>• መቆጣጠር አልተቻለም</li> <li>• ደካማ ቁጥጥር</li> <li>• በ መጠኑ ተቆጣጥረነዋል</li> <li>• መቆጣጠር ተችሉዋል</li> <li>• ሙሉ በ ሙሉ ተቆጣጥረነዋል</li> </ul>	ድምር =
11	ተደራራቢ ህመም አዎ/አይ	አዎ ካሉ, ከሚከተሉት ያክብቡ a. የ አፍንጫ አለርጂ b. ቃር c. ጭንቀት d. ደብርት	
12	አስሙ ተባብሶ ያውቃል?	አዎ ( ምን ያህል)----- አይ-----	
13	ያለ ቀጠሮ ታይተው ያቃሉ	አዎ ( ምን ያህል)----- አይ-----	
14	ላለፈው አንድ አመት ውስጥ ሆስፒታል ተኝተው ያቃሉ	አዎ ( ምን ያህል)----- አይ-----	
15	ቢምአይ(	a. < 18      c. 18-25      d. 25-30 e. > 30	

16	ስፓይሮመትሪ (FEV1)	a. $\geq 80\%$ b. 60-80%    c. $< 60\%$
17	አሁን የምትጠቀመው መድሃኒት ምንድነው?	a. SABA    b. ICS,    c. ICS-LABA    d. LABA e. OCS    f. ለሎች -----
18	አስም ከያዘት ስንት ጊዜ ሆንዋል?	----- (በ አመት) / ወይም በ ወር -----
19	የ አስም መከላከያ መድሃኒት አጠቃቀም አስተምረዎታል	አዎ                      አይ
20	መድሃኒት በትክክል መውሰዱን መገምገሚያ (MMAS-8 Score) ፣አዎ =1                      አይ=0	
I	አንዳንድ ጊዜ መድሃኒት መውሰድ ይረሳሉ?	አዎ                      አይ
II	ባለፈው 2 ሳምንት , መድሃኒት ያልወሰዱበት ከን አለ?	አዎ                      አይ
III	ያለ ሃኪምት ምክር መድሃኒት አቁጥርጠው ያቃሉ	አዎ                      አይ
IV	ከበት በሚሰዱበት ጊዜ መድሃኒቶን ረስተው ያቃሉ?	አዎ                      አይ
V	ትላንትና ሁሉንም መድሃኒቶን ወስደዋል?	አዎ                      አይ
VI	የ ህመም መሳል ሲኖርዎት መድሃኒቶን ያቋርጣሉ	አዎ                      አይ
VII	መድሃኒት በየቀኑ መውሰድ ምቹት አንደለለው አና የአርሶ ህክምና አቅድ ላይ ጉዳት አንደሚሰጥዎት ያቃሉ?	አዎ                      አይ
VIII	ምን ያህል ጊዜ መድሃኒት መውሰድ ይረሳሉ?	a. በፍሱም/ጥቂት ጊዜ    b. አንድ ጊዜ ቢቻ    c. አንዳንድ ጊዜ d. ብዙ ጊዜ    e. ሁሉ ድምር ውጤት =
21	መድሃኒት በትክክል አንድይወስዱ የሚያደርግ ነገር ምንድነው?	a. የመድሃኒቱ የ ጎንዮሽ ጉዳት    b. አውቀት ማነስ c. አለመመቻት    d. ለላ-----

## ANNEX IV – Questionnaire

### **Jimma University, Institute Of Health Science, Medical Faculty, Department Of Internal Medicine**

Questionnaire for the data collection on the Assessment of asthma control and its associated risk factors with uncontrolled asthma at chest clinic of Jimma University medical center, Jimma, southwest of Ethiopia, 2020

#### **Part I. Socio-demographic characteristics**

No	Questions	Response
1	Age	/_____/ in years
2	Sex	/___/ Male, /_____/ Female
3	Place of residence?	/___/ Urban, / ___/ Rural
4	Educational status	/_ / College or University complete, /___/ High school , /___/ Elementary school, Read and write, / Illiterate
5	occupation	/_____/ Employee (GO, NGO, private), /___/Merchant, /_____/ Farmer, /_____/ Housewife, and Others (specify)_____
6	Family income per month in birr	/_____/
7	What is your main source cooking fuel energy?	/___/ Firewood, /___/ Charcoal, /___/ Animal dung, /___/ Kerosene, /___/ Electricity
8	Is/are smokers in house?	/___/ Yes , /_____/ No
9	Currently, are you a smoker?	/___/ Yes , /_____/ No
10	Do you use substance?	/___/ Yes , (specify)----- /_____/ No

## Part II Clinical related characteristics of study participants

10	Asthma control Assessment questions	Circle one answer	ACT Score
I	During the past 4 weeks, how often have you had shortness of breath at day time?	1. Throughout the day 2. Daily 3. >2 days/week 4. <2 days/week 5. None	
II	During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, chest tightness, shortness of breath) wake you up at night or earlier than usual in the morning?	1. 7 times/week 2. >1/week 3. 3-4/month 4. 1-2/month 5. None	
III	In the past 4 weeks, how often have you used a reliever inhaler?	1. Several times/day 2. Daily 3. 2-3 days/week 4. <=1day/week 5. None	
IV	In the past 4 weeks, how often did your asthma prevent you from getting as much done at work, school, or home?	1. All of time 2. Most of time 3. Some of time 4. A little None 5. None	
V	How would you rate your asthma control during the past 4weeks?	1. Not controlled 2. Poorly controlled 3. partially Controlled 4. well-controlled 5. completely controlled	
			Total =
11	Comorbidities Yes/no	If yes, circle the following a. Chronic rhino sinusitis b. GERD c. Anxiety d. depression	
12	Was your asthma get Exacerbated? If yes how often?	Yes ( how often)----- No -----	
13	Did you have an Unscheduled visit?	Yes ( how often) ----- No -----	
14	Have you been Hospitalized in the past 12months?	Yes( how often)----- No -----	
15	BMI	a. < 18 c. 18-25 d. 25-30 e. > 30	
16	FEV1	a. ≥ 80% b. 60-80% c. < 60%	
17	What is your Current asthma medication?	a. SABA b. ICS, c. ICS-LABA d. LABA	

		e. OCS      f. others specify-----
<b>18</b>	What is the Duration of your asthma?	------(in year) /or months -----
<b>19</b>	Have you ever educated on how to use the inhaler technique?	Yes                  No
<b>20</b>	<b>Adherence assessment (MMAS-8 Score)</b>	
<b>I</b>	Do you sometimes forget to take your medication?	Yes                  No
<b>II</b>	Over the past 2weeks, were there any days when you didn't take your medication?	Yes                  No
<b>III</b>	Have you ever stopped taking your medication without telling your doctor because you felt worse when you took it?	Yes                  No
<b>IV</b>	When you travel or leave, home, do you sometimes forget to bring your medications?	Yes                  No
<b>V</b>	Did you take all your medications yesterday?	Yes                  No
<b>VI</b>	When you feel like your symptoms are under control, do you sometimes stop taking your medication?	Yes                  No
<b>VII</b>	Taking medication every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	Yes                  No
<b>VIII</b>	How often do you have difficulty remembering to take all your medication?	a. Never/rarely b. once in a while c. sometimes d. usually e. all the time

21. MDI Inhaler technique check List	yes	No
1. Remove inhaler cap		
2. Hold inhaler upright and shake well		
3. Breathe out gently, away from the inhaler		
4. Put mouthpiece between teeth without biting and close lips to form a good seal		
5. Breathe in slowly through the mouth and, at the same time, press down firmly on canister		
6. Keep breathing in slowly and deeply and hold breath for about 5 seconds or as long as comfortable		
7. While holding breath, remove inhaler from mouth		
8. Breathe out gently, away from the inhaler		
9. If an extra dose is needed, repeat steps 2 to 8		
10. Replace cap		