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A Model for home-based remote monitoring of asthmatic patients

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A Model for Home-Based Remote Monitoring of Asthmatic Patients

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Declaration

I declare that this work has not been previously submitted and approved for the award of a degree by this or any other University. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made in the thesis itself.

Julius Thomas Oduor

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Approval

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LIST OF ABBREVIATIONS/ACRONYMS

A&F	Audit and Feedback
CIN	Clinical Information Network
DDI	Metered-Dose Inhaler
HRIO	Health Record Information and Officers
EHR	Electronic Health Record
EPRP	External Peer Review Program
GSM	Global System for Mobile Communication
HRIO	Health Record Information Officer
ICT	Information Communication and Technology
IDE	Integrated Development Environment
ISAAC	International Study of Asthma and Allergies
IT	Information Technology
IOT	Internet of Things
KAPTLD	Kenya Association for the Prevention of Tuberculosis and Lung Disease
KEMRI	Kenya Medical Research Institute
KPA	Kenya Paediatric Association
KPI	Key Performance Indicators
LIC	Low Income Countries
MOH	Ministry of Health
OS	Operating System
REDCap	Research Electronic Data Capture
SAQs	Self-Administered Questionnaires
SMS	Short Message Service
WHO	World Health Organization

ABSTRACT

Asthma affects a large number of people in the world and it is the most common chronic illness of the lung among children. Monitoring and assessing the severity of a child's asthma at home has proven difficult and costly in many low resource settings, like Kenya. This is due to lack of easy to use and cost effective in-home monitoring tools for children suffering from asthma.

In this work, we present a wearable device that allows in-home remote monitoring of asthmatic child and instant determination of degree of asthma severity. Once the severity is known, the cases which are severe can be recalled to the clinic by the doctor for proper care and management. The device captures simultaneous measurements of heart rate and oxygen saturation using a pulse oximeter sensor. These readings are then analyzed using clinical algorithm for asthma management, and the resulting severity level sent to both the parent of the child and the assigned clinician.

The device was developed using Arduino Uno microcontroller, pulse oximeter sensor and Global System for Mobile Communication (GSM) module.

Keywords

Asthma, Arduino Uno microcontroller, GSM, SMS, Internet of things, pulse oximeter sensor.

CHAPTER ONE: INTRODUCTION

1.1 Background of the study

Asthma is the most common chronic illness of the lung, and it is characterized by respiratory symptoms such as shortness of breath, wheeze, chest tightness and cough, with children under-fives in particular, at the greatest risk (Asthma., 2016). Globally, it is estimated to affect over 300 million people (World Health Organization, 2013). Numerous reports indicate that the prevalence of asthma may be increasing in most parts of the world including low income countries (LIC) (Braman, 2006; Ng'ang'a et al., 1998). The International Study of Asthma and Allergies (ISAAC) reported that asthma prevalence among children was increasing in Africa and has contributed most to the burden of disease through its effects on quality of life (Bousquet et al., 2010).

In most health care settings around the world, particularly in developing countries, asthma still remains under-treated, poorly monitored and managed, (Bianchi et al., 2011; Clavenna et al., 2003); this may result in poor asthma control and lead to an increase in degree of severity, thus a deterioration in patient's health. On the other hand, inappropriate treatment is a cause of a substantial cases of hospital readmissions.

The public health focus of asthma relies on early case detection and placement of the affected individuals on appropriate and largely lifelong treatment with proper monitoring in order to control the disease. In most LIC such as Kenya, there are no public supported asthma-care programmes designed to optimize care for patients with asthma which greatly compounds the diagnosis, severity classifications and treatment problems. Under these circumstances, the development of standardized, well defined home-tailored interventions together with sound professional practice is crucial. This has seen concerned bodies and many countries developing clinical guidelines in order to improve treatment and management of asthmatic patients (Ministry Of Health, 2011; Ministry of Health (MOH) [Kenya], 2016).

In 2013, the Ministry of Health (MoH) in collaboration with the Kenya Medical Research Institute (KEMRI)-Wellcome Trust Research Programme, the Kenya Paediatric Association (KPA) and the SIRCLE saw the development and routine update of a basic paediatric protocol that constitutes clinical guidelines (algorithms) for under five years management (Ministry of Health (MOH) [Kenya], 2016). These guidelines focus on various illnesses, including classification of asthma severity, criteria for admission, treatment and inpatient management of the major causes of childhood mortality and related conditions.

Despite the laudable efforts that Kenya has made in drafting and developing asthma guidelines to better help diagnose, treat and properly manage asthmatic patients, previous studies have demonstrated poor clinician practices and adherence when diagnosing and administering treatment to these patients (Diette et al., 2001; Jin et al., 2000; Lagerlov et al., 2000; Scarfone, Zorc, & Capraro, 2001). A study by Oman, for instance, showed that majority of clinicians providing asthma management failed to demonstrate appropriate metered-dose inhaler (DDI) technique (Baddar et al., 2001). In addition, under-use of inhaled corticosteroids is resulting in inadequate asthma control, frequent unplanned visits to the emergency room or hospitalizations, and an unnecessary reduction in quality of life for those who live with asthma which, in low-income countries, places a disproportionate burden on the people with asthma and society at large (The Global Asthma Network, 2014).

Furthermore, very low budget allocation by the government that results into the shortage of public supported asthma-care programmes designed to improve care for patients with asthma (Ministry Of Health, 2011), plus the lack of remote-monitoring and evaluation devices at home for asthmatic patients hinder parents and caregivers from easily monitoring and assessing the state of asthma episodes at home which most often contributes to frequent hospital readmissions and attacks. When diagnosed and drugs administered, asthmatic patients are allowed to go home with no proper care or monitoring process. They are left on their own or in the hands of their families who often have no enough expertise to continuously monitor and assess them in order to prevent these attacks from happening (Ministry of Health (MOH) [Kenya], 2016; Scarfone et al., 2001).

With the recent popularity of smart health monitoring devices in medical sphere and m-health, real-time remote monitoring tools can help monitor asthmatic patient's health state, classify degree of asthma severity and alert clinicians on the health state of the patient

1.2 Statement of the Problem

In Kenya, asthma is the most common chronic disease among children and thus have an extensive effect on their education resulting into most of them missing school days.

Monitoring and assessing the severity of a child's asthma at home has proven difficult and costly in many low resource settings, like Kenya. Parents finds it difficult to determine the severity of a child's asthma state in-home, and they often face challenges in deciding whether the child requires administration of medicines, a visit to the clinician or emergency medical care. Thus, they are unable to prevent unexpected critical episodes, such as recurrent readmissions to emergency rooms, unnecessary acute attacks and sometimes loss of life.

They are always forced to visit hospitals in order to get to know their children asthma severity level. Furthermore, peak flow meter is the only suitable instrument used in hospitals and it is recommended for adults only. Children under 6years are thus unable to perform the asthma severity test.

Given the escalating number of asthma among children, the disease needs a proper management plan to prevent unexpected critical episodes such as frequent readmissions, unnecessary acute attacks and possible loss of life, rather than treating them at emergency rooms. With the recent advancement in e-health and m-health, it is evident that parents and clinicians are interested in real time solutions that make self-management and monitoring of chronic conditions such as asthma possible

1.3 Objectives

1.3.1 Broad Objective

To design and develop a model for monitoring status of asthma illness among children under five years of age at home.

1.3.2 Specific Objectives

i.) Investigate on the problems associated with the current home-based monitoring tools for asthmatic patients

ii.) To investigate problems associated with monitoring of asthma

iii.) To propose a model for home-based monitoring of asthmatic patients

iv.) To test the proposed model

1.4 Research Questions

i.) What are the problems that are associated with the current home-based asthma monitoring process?

ii.) What is the status of asthma management?

iii.) How can a home-based monitoring model be designed and developed that can monitor asthmatic patient at home?

iv.) How can the home-based monitoring prototype be tested to ensure that it meets asthmatic patient's needs?

1.5 Justification

The severity of asthma can be highly variable in any patient and the need for regular reviews is now recognized in the current guidelines. Routine clinical assessment and self-assessment are the primary methods of monitoring asthma and they are instrumental in establishing whether the goals of treatment are being met. Assessing the severity of asthma for a patient helps the clinician in selecting the correct level and frequency of treatment**.**

The research study thus provided a home based asthma monitoring module to determine asthma severity level for a patient, and alert the parent as well as caregiver and clinician on the status of the illness through SMS. This would provide the caregivers and clinicians with real time information for better informed clinical decisions regarding the most appropriate treatment and care for the asthmatic patients. All these stand to manage and save unnecessary deaths, frequent hospitalizations and ill-health as a result of poor monitoring of asthmatic patients. During the process, the burden of substantial social and economic losses among the asthmatic patients may be reduced.

1.6 Scope of Study

In order to design and develop the monitoring tool, children under the age of five years, being discharged daily with asthma in the 14 county referral hospitals in Kenya were the primary focus of the scope. They would be tracked at home through the use of home-based monitoring tool, which has the capability of determining severity level of patient's illness. National asthma guidelines based on basic paediatric protocol provided the clinical logics of interest up on which analytical algorithms were derived from.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter describes an exploration of theoretical and empirical literature in form of a review of asthma in Kenya, the current asthma classification, asthma management, existing devices that asthmatic patients use to monitor their health status at home and probable challenges they face. In addition to this, it outlined knowledge gap and proposed a novel approach to help develop the most effective home-based asthma monitoring models in resource constrained settings. The findings helped inform the design and development of a model to help track as well as remotely monitor asthmatic patients at home.

2.2 Asthma in Kenya

Asthma is a non-communicable disease characterized by recurrent attacks of breathlessness and wheezing, with varying severity in individuals, and may occur unexpectedly. In Kenya, a number of epidemiological studies that have shown that its prevalence is at 10% (Ministry Of Health, 2011), and it is on the rise. The illness appears to be more prevalent in densely populated regions such as urban areas compared to sparsely-populated rural areas. The major drivers of the burden of asthma in Kenya, as in other parts of the world, are largely unknown even though it is appreciated that complex and poorly understood genetic factors interact with environmental factors to lead to the manifestation of the disease.

Asthma patients face a number of challenges. Despite under-estimation of asthma severity levels, especially in children, poor prescription of drugs which could be either under prescribed or over prescribed, usually put their lives at risk(Bianchi et al., 2011). In addition to this, there are no public supported asthma-care programmes designed to optimize care which greatly compounds the diagnosis, severity classifications and treatment problems.

Asthma being a chronic disease, implies long term health consequences for the sick, greater health resource utilization and a heavy economic burden to the country as a whole. Although a large proportion of these diseases are preventable through adoption of appropriate healthy lifestyles, there are no proven ways to prevent the disease.

Asthma has important individual health consequences. Uncontrolled asthma results in recurrent or persistent symptoms that impair quality of life, reduce self-esteem, reduce social interaction, increase psychosocial trauma and occasionally lead to fatal outcomes. The economic costs of uncontrolled asthma may be enormous and include direct costs from health resource utilization (medical consultations, drug and hospitalization costs), indirect costs from work absenteeism or premature deaths and intangible costs of persistent illness.

Therefore, in order to prevent the patients from frequent readmissions, ill-health and save them from unnecessary loss of life, an individual patient should be diagnosed and severity level detected early enough, be placed on appropriate medication and lifelong treatment. It has been documented that patients suffering any disease who are managed according to set guidelines fair better than those managed otherwise (Barni et al., 2011; Sciarra, 2012; Vijayananthan & Nawawi, 2008).

2.3 Classification of Asthma

Poor classification of asthma severity by clinicians while attending to asthmatic patients have been demonstrated in a number of previous studies (Theodoropoulos, 2004), and this have detrimental effects to the health of an individual patient(Lin & Zhong, 2005). In order to administer an appropriate treatment to an asthmatic patient, the correct severity group for the patient needs to be established beforehand.

According to the Basic Paediatric Protocols for children under five years of age in Kenya, acute severe asthma has been classified by the Ministry of Health into severe, mild or moderate asthma (Ministry of Health (MOH) [Kenya], 2016). Severe asthma is characterized by the presence of central cyanosis, inability to talk, drink or breastfeed, Alertness Verbal response Pain responsiveness and Unresponsiveness (AVPU) of scale at either V, P or U, with measurements of oxygen saturation $< 90\%$ and pulse rate less than 200 bpm for children under three years and pulse rate greater than 180 bpm for those between four and five years. On the other hand, mild or moderate asthma comprises all asthmatic patients with presence of wheeze, plus any of the following: lower chest wall indrawing or fast breathing (RR ≥ 50 for aged 2-11 months and RR $\geq$ 40 for aged 12-59 months).

2.4 Management of Asthma

With the escalating number of asthma cases witnessed globally over the decades (Anandan, Nurmatov, van Schayck, & Sheikh, 2010), the disease need proper management plan. As a chronic illness with no cure, the nature of asthma requires proper diagnosis, appropriate severity classification, correct treatment and continuous monitoring by relevant clinicians (Asthma., 2016).

Patients on treatment for asthma should be reviewed regularly and their treatment adjusted as may be necessary. With appropriate treatment most patients with asthma can gain and maintain asthma control and thus lead normal productive lives. The clinician should assess the severity of asthma or the level of control for diagnosed asthma on treatment, initiate treatment at the appropriate treatment step based on the asthma severity or level of control and arrange for a home-based monitoring process to assess response to treatment and patient's progress. The main aim of day to day management of asthma helps prevent frequent readmissions, ill-health, unnecessary attacks and to bring back patients to productive lives. This has seen national and international concerned bodies developing clinical guidelines in order to control the management of asthmatic patients (Asthma., 2016; Ministry Of Health, 2011; World Health Organization, 2013).

Kenya is making efforts to improve the health of its population through strengthening of the primary health care system, and thus there has been efforts to manage asthma. In 2006, the Kenya Association for the Prevention of Tuberculosis and Lung Disease (KAPTLD) in partnership with the Ministry of Health and the pharmaceutical industry developed a 'consensus statement' on the management of asthma in Kenya. This was later renamed the 'Kenya national asthma guidelines' to reflect the purpose for which it has been developed. The primary purpose of this new document is to provide clinicians, researchers, policy makers, health programme developers and managers with a road map to guide the care of individual patients with asthma in Kenya(Ministry Of Health, 2011).

Further work in 2013 by the Ministry of Health (MoH) in collaboration with the Kenya Medical Research Institute (KEMRI)-Wellcome Trust Research Programme, the Kenya Paediatric Association (KPA) and the SIRCLE saw the development and routine update of a basic paediatric protocol as shown in *figure 1*, that constitutes clinical guidelines (algorithms) for under five years management(Ministry of Health (MOH) [Kenya], 2016). These guidelines focus on the classification of various illnesses' severity, among them asthma, criteria for admission, treatment and inpatient management of the major causes of childhood mortality.

The guidelines represent a major milestone in the development of asthma care services in Kenya. It is hoped that these guidelines will be widely disseminated and used by all cadres of health care providers in Kenya to promote asthma care practices that ensure the best possible outcomes for individuals who suffer this disease.

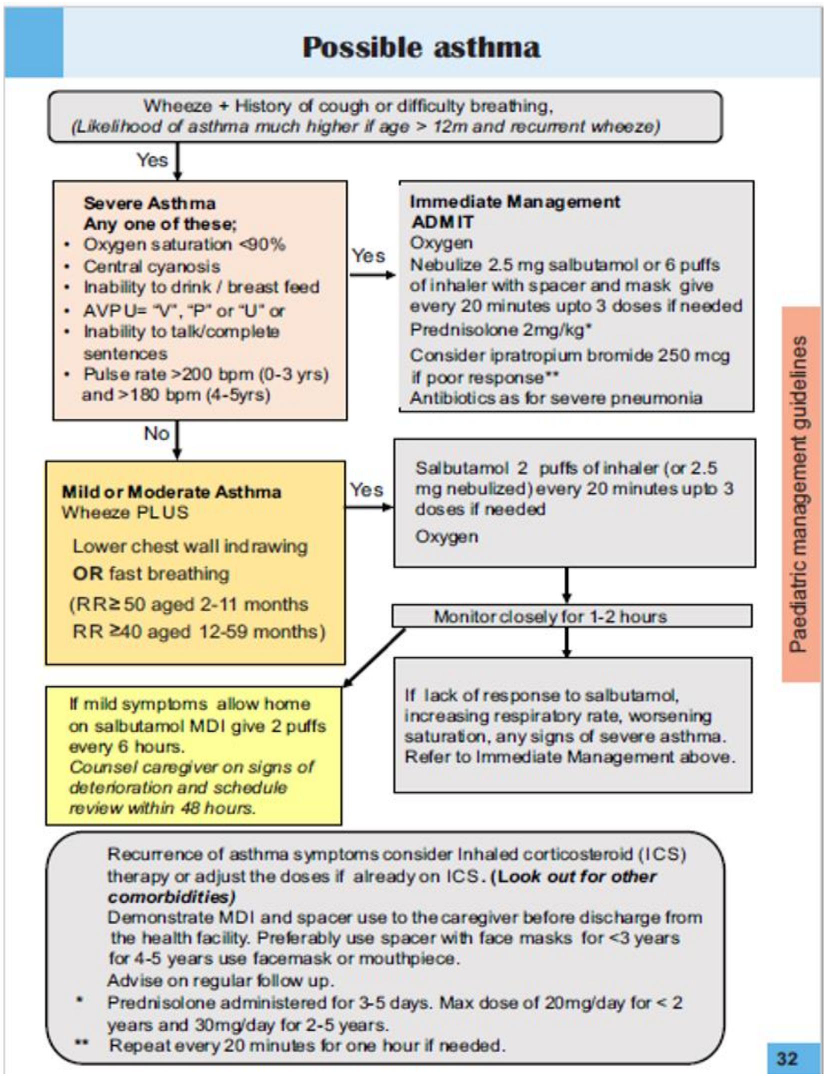

Figure 1: National Asthma Guidelines (Adopted from Basic Paediatric Protocol 2016)

2.5 Monitoring Asthma Management: Existing Technologies

There are a number of technologies that have been applied in health care to help monitor how asthma is managed both during hospital stay and at home. These tools include visualization tools that monitor asthma management during hospital stay, and home-based monitoring tools that monitor asthma management at home. The aim of these tools is to ensure that asthmatic patients are treated as per the national clinical guidelines, and that they are saved from any danger that may arise as a result of poor management.

2.5.1 Related Applications

There are a number of technologies that have been applied in health care to help monitor how asthma is managed both during hospital stay and at home. The aim of these tools is to ensure that asthmatic patients are treated as per the national clinical guidelines, and that they are saved from any danger that may arise as a result of poor management.

Persons suffering from chronic illnesses such as asthma should receive support to help them manage their illnesses as effectively as possible. IoT-based healthcare technologies have been applied in health sector in an attempt to address chronic illnesses (Riazul Islam, Daehan, Humaun Kabir, Hossain, & Kyung-Sup, 2015) Asthma is a growing problem among nations, and clinical guidelines have stressed the importance of at-home monitoring in the establishment and maintenance of asthma control, defined as the degree to which the manifestations of asthma are minimized by therapy.(Busse & Lemanske, 2007)

Examples include Identi-wheez, a portable and low cost device that aims to reduce the difficulties of asthma diagnosis, (Sakat, Ramchander, & Raskar, 2016) have been used as a device for in-home diagnosis of asthma. It is composed of a novel measurement hardware and diagnosis algorithm. The device acquires simultaneous measurements from multiple stethoscopes. The recordings are then sent to a specialist who uses assistive diagnosis algorithms that enable auscultation (listening to lung sounds with a stethoscope) at any location in the lungs volume by sound refocusing. The specialist is also presented with a sound “heat map” which shows the location of sound sources in the lungs.

In order to improve the condition of asthma patient, efforts have also been made to develop systems that monitor environmental conditions, such as air quality, and trigger warnings and alerts. Environment crowd sensing for asthma management has been developed for monitoring the environment, especially the air quality parameters relevant for asthma patients

(Vasilateanu, Radul, & Buga, 2015). Recent work from Vasilateanu had suggested a mobile application- AsthMate, to be used by asthma patients to monitor their health by doctors and by institutions. The device is able to detect high risk areas for asthma suffers based on quality of air measurements and incidence of the use of short—term relief medication. A work Towards Real-time Monitoring and Detection of asthma symptoms on resource-constraint mobile device,(Uwaoma & Mansingh, 2015) a smartphone application that could detect and quantitatively index early signs of asthma attack triggered by exercise. Here, the embedded microphone in the mobile phone records the user's breath sound while motion sensors- accelerometer, gyroscope and digital compass provide measurements on the level or intensity of activity and posture changes.

With the ever growing need to measure the degree of asthma severity among children, a study by (Zaharudin, Kazemi, & Malarvili, 2014) designed a capnography, a respiratory carbon dioxide (CO_2) measurement device for home monitoring of Asthma severity. It is based on MG-811 CO_2 sensor and Arduino microcontroller, and measures the concentration of CO_2 in breath out air. It uses infrared technology to determine the concentration of CO_2. Further studies by have explored the use of a smartphone-based system to automate detection of flow events from tracheal. Here, the breath sounds are analyzed to obtain flow measurements. Though significant advances have been made in this field, there continues to be a lack of an ideal solution that would facilitate in-home asthma diagnosis. Table 1 presents a comparison of existing solutions and demonstrates where home-based asthma severity monitoring tool finds its relevance.

Table 1: Relevance of asthma severity monitoring tool

Tool Functionalities	***Asthma symptoms monitoring***	***Asthmate***	***Indenti-Wheez***	***Asthma Severity Monitoring***
Designed as a child-friendly wearable device	**No**	**No**	**Yes**	**Yes**
Allows in-home measurements	Yes	Yes	**Yes**	**Yes**
Allows recordings for future references	Yes	Yes	**Yes**	**Yes**
Alerts clinicians via SMS in real-time	Yes	**No**	**No**	**Yes**
Allows asthma severity determination	**No**	**No**	**No**	**Yes**

2.5.2 Gaps in Existing Technologies

There exists a gap in an attempt to manage asthmatic patients from home. The existing tools such as peak flow meter or spirometer in figure 3 are difficult to use due to complications and contraindications. In addition, reliable results cannot be obtained as the patient instructions are complicated and the test causes chest pain. They are effort dependent, can give falsely high or low measurements, and require manual data entry in diary. Moreover, children below the age of 6 years old are generally unable to perform an adequate test, hence not appropriate for young children.

Figure 2: Typical Peak flow meter

Currently, once diagnosed and treatment administered, the asthmatic patients are discharged home and put under long-term drugs and inhalers. Rarely is their conditions monitored by clinicians at home during the treatment period, thus resulting into recurrent asthma attack, frequent hospital readmissions and poor health. Recent advances in medical sensors and smart health monitoring devices have greatly enabled remote health monitoring to support early diagnosis, detection of early signs of asthma attack and remote monitoring of asthmatic patients**.** However, the use of these tools as a home-based monitoring process to routinely assess patient's response to treatment and progress is yet to be exploited in the country. With the knowledge of patient's asthma severity levels at hand at intervals of time, the clinician is able to review regularly and adjust patient's treatment as may be necessary. With appropriate treatment, most patients with asthma can gain and maintain asthma control and thus lead normal productive lives.

This project aimed to improve on the home-based asthma diagnostic tool by (Sakat et al., 2016), and to develop further a simple to use remote monitoring tool based on pulse oximeter for asthmatic patients that will allow instant determination of severity level of asthma and alert the patient as well as the caregiver or clinicians about the patient status. This provides the caregivers and clinicians with real time information for better informed clinical decisions regarding the most appropriate treatment and care for the asthmatic child.

2.6 Description of the proposed device

2.6.1 Application Components

Asthmatic Patient

A patient under the age of five years who have been diagnosed with asthma at point of admission and have been discharged home under treatment. The patient is intended to use the application in order to determine the severity of asthma.

Pulse Oximeter sensor

This is a medical sensor that interconnects to the Arduino Uno microcontroller. When fitted on asthmatic patient's fingers, it captures both heart rate and oxygen concentration measurements and transfers the values to the microcontroller.

Arduino Uno Microcontroller

This is the central component of the application that controls all the processes of the application. The microcontroller converts the analog data from the pulse oximeter sensor to digital format, and then uploads the data into the cloud server using GSM module.

Cloud Server

A cloud-based database storage system that instantaneously stores all the asthmatic patient's data captured by the pulse oximeter sensor. The server ensures that the data captured is secured and accessible at any time for analysis.

Analytical Platform

This is the central point for data analysis. Data uploaded in to the server are instantly analyzed against algorithms based on clinical guidelines for asthma in order to determine the degree of asthma severity.

Mobile Phone

A tool that is used to convey SMS alerts from the analytical platform to relevant caregiver of the asthmatic patient.

Clinician/Caregiver

The main stakeholders involved in the application that provide care and asthma management to the asthmatic child.

2.6.2 Working principle of the proposed device

Basic Pediatric Protocols' clinical guidelines on asthma management for ages up to five years provided a gold standard analytical algorithm within which patient's measurements were matched against.

Arduino is used to control the whole process. With the pulse oximeter sensor fitted on the finger at intervals of time, the device is able to capture simultaneously the oxygen saturation and heart rate measurements of the asthmatic patient. The recordings are then analyzed instantly based on the analytical algorithm to determine whether the patient has severe, mild or moderate asthma. This is then automatically sent to both the same parent, relevant caregiver and the clinician via SMS using GSM module, thus providing them with real time information for better informed clinical decisions regarding the most appropriate treatment and care for the patient.

2.7 Components of the Architecture

Arduino Uno

The Arduino Uno is a microcontroller board based on the ATmega328. It has 14 digital input/output pins (of which 6 can be used as PWM outputs), 6 analog inputs, a 16 MHz ceramic resonator, a USB connection, a power jack, an ICSP header, and a reset button. It contains everything needed to support the microcontroller; simply connect it to a computer with a USB cable or power it with an AC-to-DC adapter or battery to get started.

Figure 3: Arduino Uno Microcontroller

After capturing data from pulse oximeter sensor, Arduino sends them to the database.

Pulse oximeter sensor

Pulse oximeter is a non-invasive device used to measure a patient's blood-oxygen saturation level and pulse rate.

Figure 4: Handheld pulse oximeter sensor (Adopted from https://www.protocentral.com/)

There exists several types of pulse oximeters, depending on area of application. While finger oximeters are used for spot checking by clinicians, patients, caregivers and consumers, they can also be used for personal health and wellness, homecare, hospital, and clinics. On the other hand, handheld fitted with sensors are suitable for spot checks or continuous monitoring; ideal for hospital, ambulatory or home.

GSM Module

GSM module is directly connected to Arduino**.** The microcontroller retrieves the exact measurement details from the pulse oximeter, then get analyzed and the results transmitted to GSM module for sending to the patient and clinician.

Figure 5: GSM Module

Mobile Phone

This monitoring device will send SMS alerts about the severity level of asthma to the same individual patient as well as relevant caregiver and the clinician.

Connecting Wires

Figure 6: Connecting wires

These are multiple set of wires that will be used to interconnect different components that make up the system.

2.8 Conceptual Framework

Figure 8 below gives a conceptual framework of the model for the system and its functionality. It consists of a home-based monitoring device for asthmatic patients after discharge from hospital.

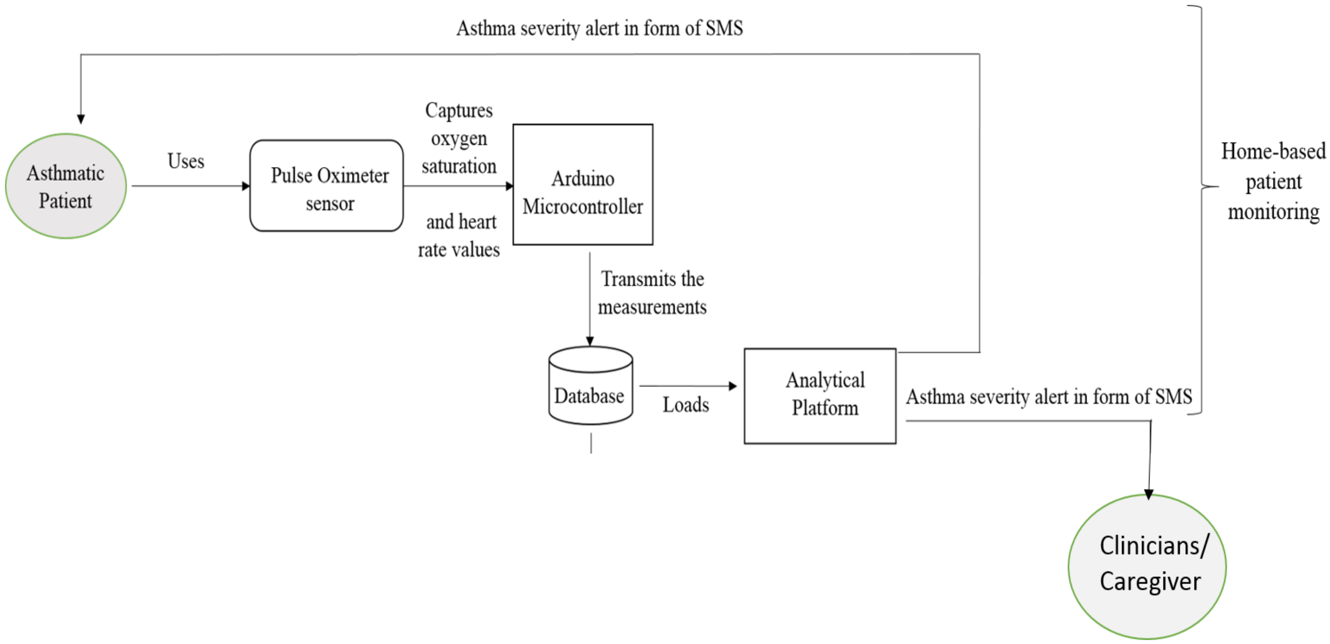

Figure 7: Conceptual Framework

Arduino microcontroller is used for controlling the whole process. With the pulse oximeter sensor fitted on the finger at intervals of time, the device is able to capture simultaneously the oxygen saturation and heart rate measurements of the asthmatic patient. The recordings are then sent to the server for storage before being analyzed instantly based on the analytical algorithm to determine whether the patient has severe, mild or moderate asthma. This is then automatically sent to both the parent and the clinician via SMS using GSM module. The real-time feedback is used by the clinician to inform clinical decisions regarding the patient's management.

Based on the feedback, the clinician is able to review regularly and adjust treatment according to the evolution of the severity state of the child. Furthermore, an urgent visit to the clinic in case the alert from the system indicates a severe health state can be recommended

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Introduction

This chapter describes the procedures that were undertaken in the collection of data with an aim of answering the research questions. It outlines the research methodology that was used, research design and setting, the target population and sample technique, data collection and data analysis.

Research is the process of discovering a new knowledge. The main aim of conducting this research was to gather information about asthmatic views on problems associated with monitoring of asthma at home and the current tools they use.

3.2 Research Design

Research design is a strategic plan used to incorporate different components of a research study into a coherent and reasonable way, in so doing, making sure the research problem is fully addressed. This constituted the selection of the population, sampling technique, methodology and plan for data collection and analysis.

A cross-sectional design was adopted for this study. In this type of research study, a sample of a population thereof was selected, and from these individuals, data were collected and analyzed to help answer research questions of interest. The study design thus helped gather information about asthmatic patient's possible use of the monitoring tool to determine degree of severity of asthma.

3.3 Research Site

The research study was conducted within 14 county referral hospitals in Kenya. Purposive sampling was used to select the hospitals within the Clinical Information Network (CIN) based on patients' diagnoses and the objective of the study.

3.4 Target population

The target population for the home-based monitoring device was asthmatic patients under the age of five within the 14 county hospitals in Kenya.

3.5 Sample Techniques and Sample Size Calculations

Approximately, 2180 children under the age of five years have asthma across the 14 county hospitals under the study. From this population, a probability sampling technique was used, where a sample is chosen at random from the whole population in order to get the correct number of respondents during the study. Using the formula below, and substituting appropriately for the values, the number of respondents was calculated.

$$n = \frac{NZ\,2 \times 0.25}{[d2 \times (N-1)] + (Z2 \times 0.25)}$$

Where:

n=sample size

N=Total asthmatic population (estimated)

d= Acceptable margin of error for mean of outcome (usually 0.1. or 0.05)

Z=Z statistic for a level of confidence

Thus, sample population, *n* was calculated as below"

$$n = \frac{2180 \times 1.96\text{^}2 \times 0.25}{[0.1\text{^}2 \times (2180-1)] + (1.96\text{^}2 \times 0.25)}$$

N = 87.86

The sample size was 87 and therefore questionnaires was administered to the same number.

For the purpose of testing the system usability, a sample of testing population was calculated from the total sample population as below.

$$n = \frac{87 \times 1.96\text{^}2 \times 0.25}{[0.1\text{^}2 \times (87-1)] + (1.96\text{^}2 \times 0.25)}$$

N= 15

The testing population sample size was 15 and therefore questionnaires was administered to the same number.

3.6 Data collection procedure

In order to collect data, quantitative research techniques was used. This involved the use of self-administered questionnaires (SAQs). The SAQ were administered to asthmatic patients' parents at point of discharge within the county hospitals. The questions were carefully drafted to ensure that the research objective was met.

3.6.1 Questionnaires

A research questionnaire was designed using the Research Electronic Data Capture (REDCap) tool (Harris et al., 2009). The research questionnaire was meant to be self-reporting with questions framed in an easily understandable for the interviewee, with an aim of answering the objectives in its wholeness, while at the same time ensuring that viability and reliability of the same was maintained.

A pilot will be run on patients who have no affiliations with KEMRI-Wellcome Trust Programme and are not aware of the CIN project.

3.6.2 Validation of Research Instrument

This mainly refers to how well a tool measures what it is purported to test. It's mainly focused on the accuracy of the test done. For this study therefore, the opinion of the expert about the tools to be developed was sought to ensure that the instruments meet the desired objectives and content validity. This entailed discussions and running a pilot of the instruments by the researcher.

3.6.3 Reliability of Research Instrument

The extent to which an assessment tool gives a consistent result on all tests carried out. It is important to consider the validity of the result, as a faulty tool can give a consistent but wrong result. Determining factors are mainly governed by the methodology, sample and context of the study.

3.7 Data Analysis Procedure

3.7.1 Analysing data from the questionnaires

Data analysis was conducted with an aim to assess research findings in order to redefine the research objectives that was to be achieved. Before beginning the analysis, level of measurements associated with the quantitative data collected was identified. Depending on the levels of measurement (nominal, ordinal, interval or ratio or scale) within which the data gathered fell in, a specific type of analysis was adopted. For instance, interval data (data that is continuous and has a logical order) where items will be measured on a Likert scale will adopt a different analysis approach as compared to nominal or ordinal data type.

Once the levels of measurement of the data was identified, suitable quantitative data analysis procedures was used. Since REDCap was used to collate quantitative data, data was exported to R, a statistical software and analysis on data tabulation (frequency distributions and percent distributions), graphical charts, data description and data disaggregation performed using the software.

3.8 Prototype development

3.8.1 Agile Software Development

Agile software development method was adopted for the study in order to develop the home-based monitoring device. This methodology is focused on developing solutions more quickly and efficiently. Agile methods highlight customer satisfaction by structuring the development process into iterations where each iteration produces sizeable amount of working code and prototypes of interest to intended users.

It provides incremental and iterative development by building a series of prototypes and continually modifying them to suit the needs of the user. *Figure 9* shows a stepwise approach that was followed to develop the entire system.

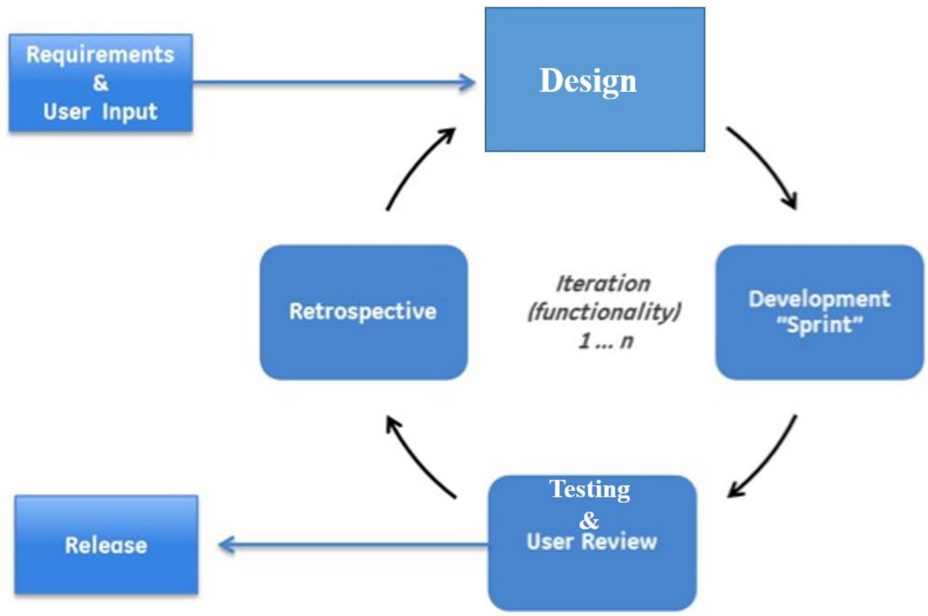

Figure 8: Prototype Development Process

3.8.2 Steps in Agile Development Process

User Requirements Gathering: A research was conducted to collect user requirement information with regards to the system to be developed. Data gathered from the asthmatic patients or their parents or caregivers best informed the development of a suitable and usable home-based monitoring device.

System Design: The architecture, components, modules, interfaces, and data for the system were defined.

System Development: This involved the actual programming and integration of various components of the system. The device was developed using Arduino IDE for node programming.

Solution Testing: Unit and usability testing was used to test the functionality of the system. The prototype was constantly reviewed and adjusted to meet the needs of asthmatic patients. This was done iteratively until the final product that meets users' requirements was achieved.

3.9 Ethical Considerations

Prior to conducting the data collection, permission was sought before using data of individuals after collection. An explanation about the purpose of the study was offered to all participants during questionnaire administration. Any personal information that was given by the respondents willingly or unwillingly was treated as confidential and stored privately so as not to infringe on the privacy rights of the participants. No participant was forced to participate in the study for the purposes of getting enough feedback. All Reference material used was duly referenced in this research. No personal identification information such as names was collected thus allowing for anonymity which in turn allows the respondent to fill in the questionnaire as honestly as possible.

CHAPTER FOUR: SYSTEM ANALYSIS, DESIGN AND ARCHITECTURE

4.1 Introduction

This chapter presents user requirements, research findings for the study and interpretation of the same. After having collected data in relation to the study objectives, the main themes were selectively assessed and analyzed in order to ensure that the system developed was accurately tailored to the user needs and answer the research questions that was set.

4.2 System Analysis

In order to develop the model, user requirements were gathered from the potential user of the system, who were the asthmatic children under the age of five years. This constituted conducting a series of interviews with their parents or guardians in order to collect information on what they would want the system to perform for them. The system requirements such as ease of use, user-friendliness and cost-effectiveness that were gathered informed the development of the model.

4.2.1 Socio-Demographic Profiles

Research respondents were sampled from 14 county referral hospitals in the country, which form the Clinical Information Network (CIN). Since the target population of study was asthmatic children of ages not more than five years, respondent to the study was defined. A parent (either mother or father), sister, brother or guardian who was found to be with the patient at time of discharge formed respondent during the research period. SAQs were administered to the respondents at point of discharge across the 14 health facilities in order to collect information about the asthmatic patients in question.

A total of 62 SAQs were responded to out of the targeted 87, giving a response rate of 71.26%. Majority of the respondents on behalf of the asthmatic children were their mothers (45.16%), followed by others (including either brothers, sisters, aunts etc.) (20.97%), fathers (17.74%) and lastly guardians (16.13%). According to the respondents, most children had a mean age of 3.3 years, forming 32.26% of the entire survey, with majority being male (61.29%). Moreover, most respondents (64.5%) had attained college or university level education. Further details of the target population's characteristics are listed in Table 2.

Table 2: Socio-Demographic Profiles

Variable	Level	Counts	Proportion (N=62)
Age			
	<1 years	1	1/62(1.61%)
	1 year	6	6/62(9.68%)
	2 years	8	8/62(12.90%)
	3 years	20	20/62(32.26%)
	4 years	14	14/62(22.58%)
	5 years	13	13/62(20.97%)
Gender			
	Male	38	38/62(61.29%)
	Female	24	24/62(38.71%)
School going			
	Schooling	37	37/62(59.68%)
	Not schooling	25	25/62(40.32%)

Approximately about more than half (59.68%) of the asthmatic children under the age of five years are school going (Figure 10).

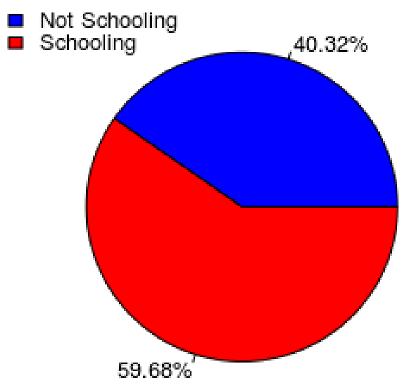

Figure 9: Patient Schooling status

4.2.2 Mobile phone Access and Health care Information Usage

The study also sought to establish the status of mobile-health awareness and usage. Respondents were asked whether they own or have access a mobile phone, and to what extent they use these mobile devices to discuss or seek information on health care. Further to this, their literacy level was assessed.

4.2.2.1 Mobile Phone Access

As presented in Figure 11, about 88.71% of the respondents either have access to or owned mobile phones.

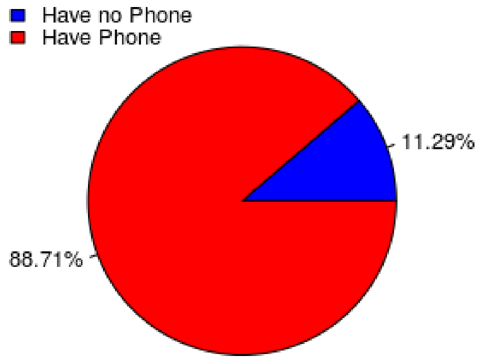

Figure 10: Mobile Phone Access

4.2.3 Mobile Health Care Use

Of the group that either own or have access to the mobile phones, an estimated 83.87% access health care information through phone usage.

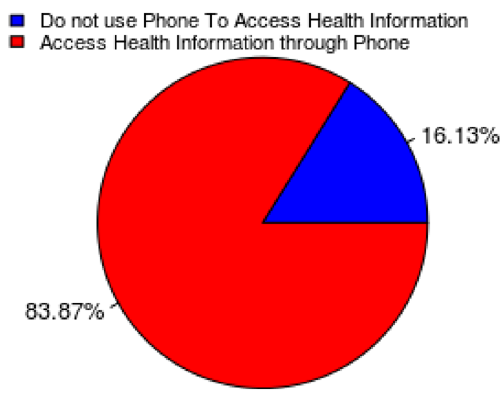

Figure 11: Mobile Health care usage

4.2.4 Relationship between Phone Ownership and Health care Information

Figure 13 presents the relationship between phone ownership and health care information access.

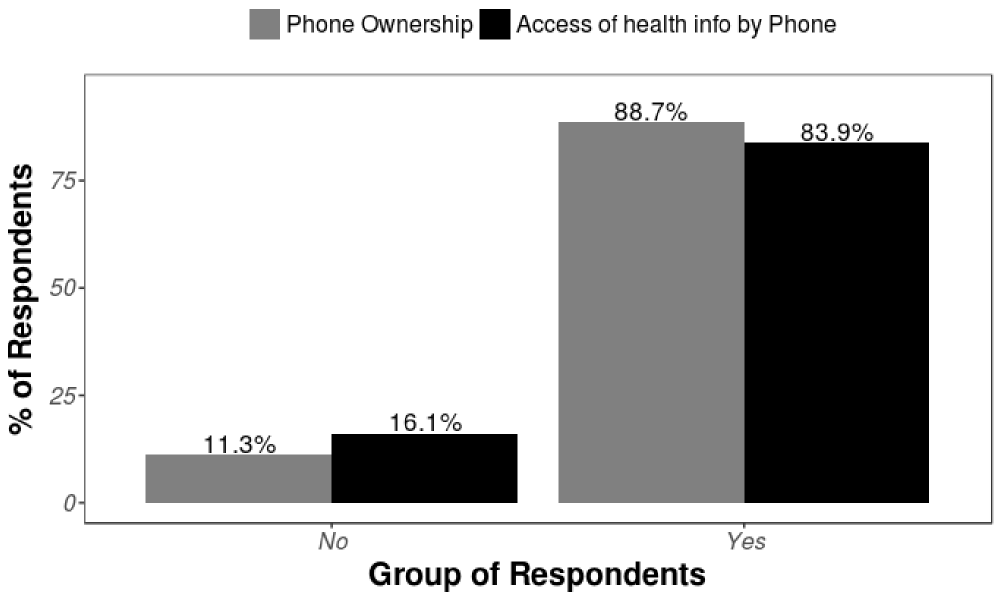

Figure 12: Relationship between phone ownership and health care information

Approximately 83.9% of respondents who owned mobile phones are able to access health care information through phone, especially by SMS.

4.2.5 Literacy Level

Of the total respondents, about 64.5% had attained college or university level, with 17.7% each having undergone primary and secondary education respectively.

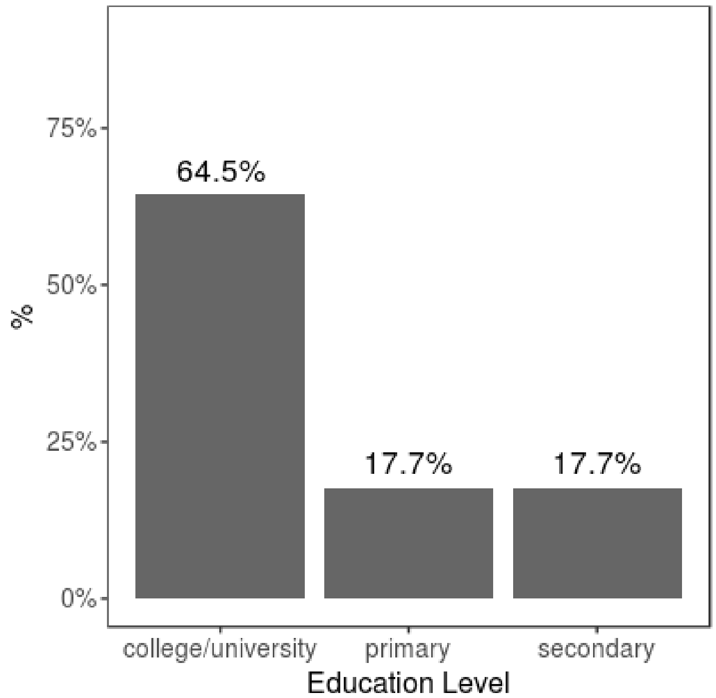

Figure 13: Education Level of Respondents

4.3 Asthma Management

The researcher sought to find out problems facing asthmatic patients and how asthma as a long-term illness is being managed within the hospitals and at home.

4.3.1 Frequency of attacks and hospital readmissions

Respondents were asked frequency of asthma attacks of their children and the number of times the same child get hospital readmissions due to asthma attack. Relationship between attack and frequency of readmissions was then assessed to inform proper management.

In Figure 15, according to the respondents, about two fifths of the asthmatic children experience at least an asthmatic attack (40.3%) and a hospital readmission (38.7%) in a month. However, only a marginal lower proportion (1.6%) rarely experience hospital readmission. A slightly larger percentage (45.2%) are readmitted weekly due to acute asthma attack.

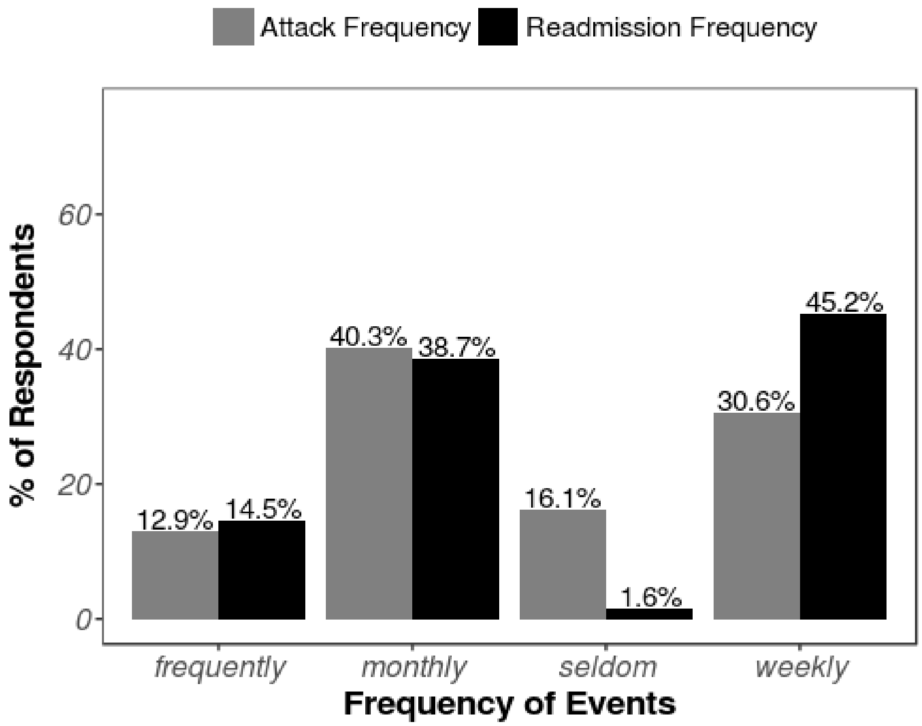

Figure 14: Relationship between frequency of attacks and hospital readmissions

4.3.2 Asthma Care Programmes

For well management of asthma, there is need for public asthma care programmes to tend to asthmatic patients. The respondents were asked whether they have enrolled their children to such programmes. Further information about whether they monitor the degree or level of asthma severity was sought and if so, the methods they use to monitor the same.

None of the respondents (0%) admitted to have enrolled their children to any public asthma care programmes, with a larger percentage (91.94%) furthermore stating that they don't monitor the degree of asthma severity in their children. Out of the smaller proportion that does monitor (8.06%), 75% stated that they frequently attend hospital to monitor degree of asthma severity. Asthma care programmes or home-based monitoring tools were never found to be used to monitor asthma severity among asthmatic patients.

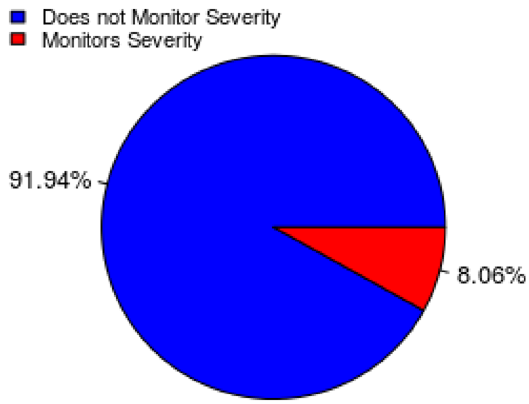

Figure 15: Asthma severity monitoring status among Asthmatic patients

4.4 Home-based Asthma monitoring device

To further understand respondents' requirements and views concerning the proposed tool in meeting their needs and helping manage asthma among their children, the researcher asked a number of questions relating to the device. Table 3 below gives a summary of the findings from the respondents.

Table 3: Home-based Asthma Monitoring device findings

	Proportion(N=62)
Proportion aware of any home-based asthma monitoring device used by asthmatic patients to monitor their status in Kenya	0/62(0%)
Proportion currently using asthma monitoring tools to determine asthma severity of asthmatic child	4/62(6.45%)
Proportion that would like to use a local based asthma monitoring device to determine asthma severity of their children	57/62(91.94%)
Proportion that would like to receive SMS alerts on the status of asthma of their children in real time	55/62(88.71%)
Proportion that would like clinicians and relevant caregiver to be informed in real time of the status of asthma of their children	54/62(87.1%)

Noticeable was that none of the respondents (0%) was aware of any home-based asthma monitoring tool used to monitor asthma in Kenya. The smaller proportion that admitted to monitoring asthma severity of their children (6.45%), are routinely forced to visit hospitals in order to determine or assess severity level of their children.

On the possibility of whether to adopt a local based asthma monitoring device to determine asthma severity at home, a larger percentage (91.94%) consented to this. Furthermore, almost the same number (88.71%) suggested that they had no problem receiving SMS alerts about the status of asthma of their children in real time. For confidentiality and privacy issues in this research, the respondents' permission were sought about whether they would be comfortable if clinician and relevant caregiver is informed in real time of the status of asthma severity of their children for better management, 87.1% of the respondents had no problem with this.

4.5 Benefits of Home-based Asthma Monitoring and Management

Having sought information from the respondents on the situation at hand about asthma management and their views about adopting home-based asthma monitoring tool, the researcher further sought their opinion on possible benefits that they could derive from using the device.

4.5.1 Use of home-based asthma Monitoring tool

The researcher aimed to find out from the respondents whether using home-based monitoring tool could reduce acute attacks and prevent frequent hospital readmissions. As visualized in figure 17, the total percent of those who agreed and strongly agreed formed the larger proportion (82.3%) than those who did not (17.7%).

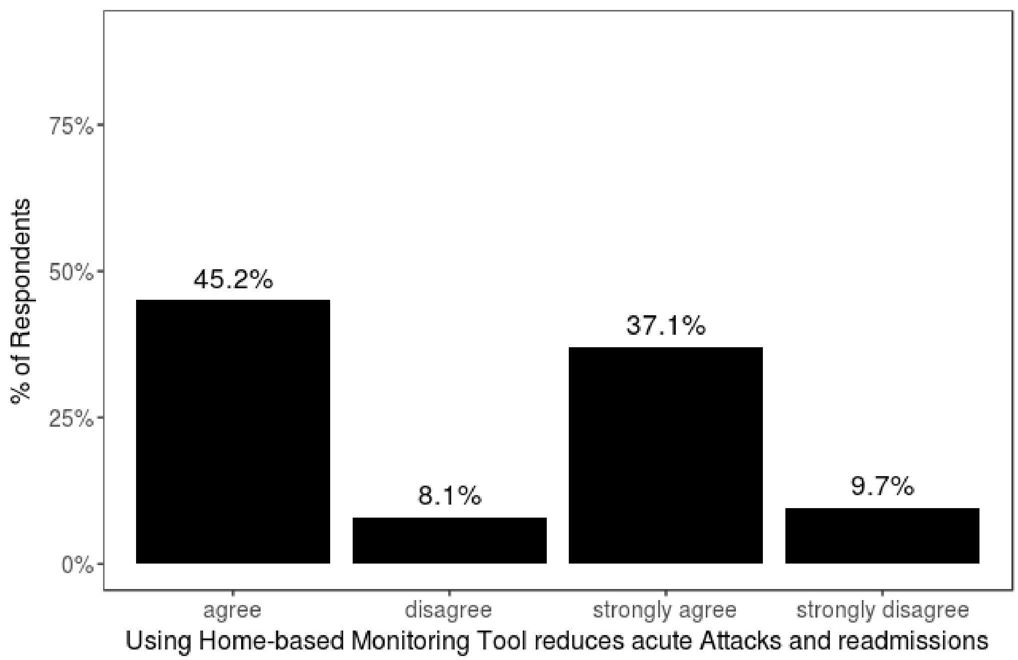

Figure 16: Asthma severity monitoring status among Asthmatic patients

4.5.2 Cost effectiveness of Home-based asthma Monitoring tool and phone Usage

To further find out whether the proposed tool would be easy to use and if it is very easy and economical to get health care alerts in terms of SMS on phones, a summary of the findings is presented in table 4.

Table 4: Cost effectiveness of Home-based Asthma Monitoring device and phone Usage

Indicators	***agree***	***Strongly agree***	***disagree***	***Strongly disagree***
Getting heath care alerts on phone in form of SMS is easy and economical	20.97%	70.97%	8.06%	0%
Home-based monitoring tool is easy to use	65.91%	20.45%	9.09%	4.55%

Most of the respondents (86.36%) agreed that the proposed tool would be easy to use, and that getting health care alerts on phone in form of SMS is easy and economical (91.94%).

4.5.3 Informing Parents and Clinicians about Child's asthma severity

There was a great consensus from the respondents on the opinion that informing clinicians as well as parents or guardians about asthmatic status of their children allow the illness to be controlled and properly managed. Approximately about 98.4% consented and did not see this as breach of confidentiality and privacy of health information.

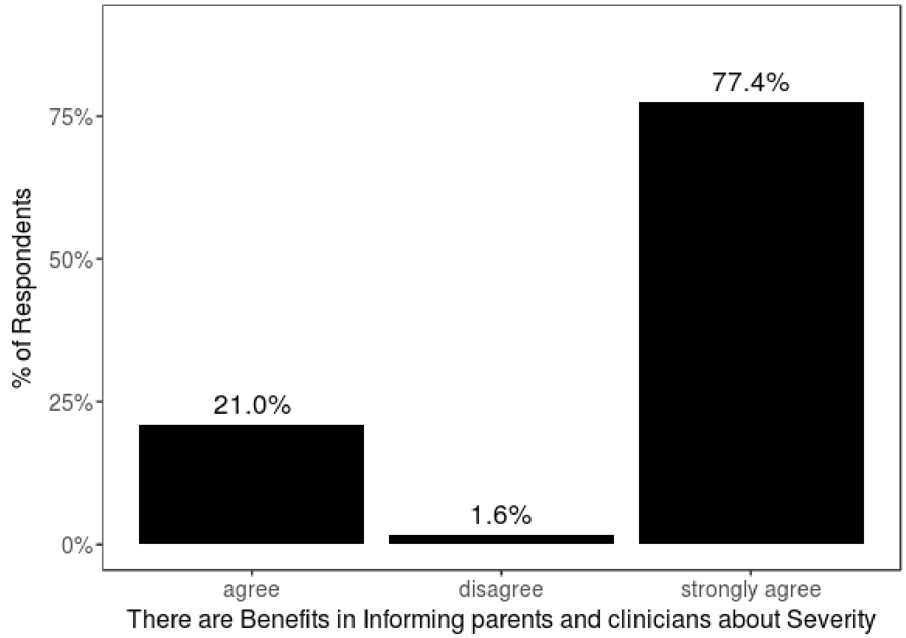

Figure 17: Asthma severity monitoring status among Asthmatic patients

4.6 Interpretation of Results

The findings of this research presented a number of themes that played a major role in informing the design and development of the proposed system. Since the main aim of the research was to gather user requirements in order to come up with the final product that meet users' needs, the following were essential to the development of the system:

i.) Frequent asthma attacks and hospital readmissions

Based on the findings of the data analysis, it is quite evident that frequent acute asthma attacks that results mostly into subsequent hospital readmissions is a major challenge that asthmatic patients grapple with, especially under five years of age. On assessing the respondents' views, the results present that most of these children suffering from asthma would survive at least a week before experiencing an attack, especially when not well managed. Proper monitoring of these children when at home is thus crucial in order to determine asthma severity level beforehand for better management. This will prevent frequent attacks as well as frequent hospitalizations thus reducing asthma burden.

ii.) School going asthmatic patients

From the findings, about more than half of the asthmatic children are school going. Once these patients are discharged home from hospitals, they are more than often left on the care of their parents or guardians who lack necessary expertise to attend to them. Moreover, their health status is never monitored neither at home nor in schools. From the respondents' preference, it is not an option that a local based asthma monitoring device could allow them monitor the degree of asthma severity of their children, thus alerting them in real time of their children condition, even when at school.

iii.) Mobile health usage and phone ownership

The figures presented on the ownership of phones by respondents gives a lot of confidence for the suitability of the project in line with one of the research objectives of alerting parents as well as relevant caregiver or clinicians on the degree of asthma severity through SMS. With the prior knowledge on phone usage to receive health information, the respondents will not face challenges in using their phones to receive alerts in form of SMS about their children conditions.

iv.) Lack of public asthma care programmes

It is quite clear from the findings that Kenya as a country lacks public asthma care programs to attend to the asthmatic patients. The study results showed that none of the respondents had enrolled their children to any of these programmes since none of them was aware of any. This then becomes very expensive and quite difficult to monitor and manage these patients. Adopting a home-based asthma monitoring tool instead would thus allow them to track and monitor their children for better management.

v.) Failure to monitor severity of asthmatic patients at home

According to the majority of the respondents, lack of easy to use, home-tailored asthma monitoring tool was the main reason why they had failed to monitor degree of severity of their children. Other reasons were attributed to lack of public asthma care programmes. With larger proportion consenting to the use of a local based monitoring device to determine asthma severity of their children, there was need to develop the device for the same.

vi.) Potential benefits of adopting home-based asthma monitoring device

Results showed that a larger proportion of the respondents supported potential benefits that the home-based asthma monitoring device was supposed to bring about. Most of the respondents believed that by using the device, frequent asthma attacks and hospital readmissions could be significantly reduced if not prevented. Furthermore, it is easy to use the device and quite economical and convenient when it comes to SMS as a way of communication. Additionally, informing clinicians, parents or relevant health care practitioners could help properly monitor and better manage the illness effectively and appropriately.

4.7 System Design And Architecture

4.7.1 System Architecture

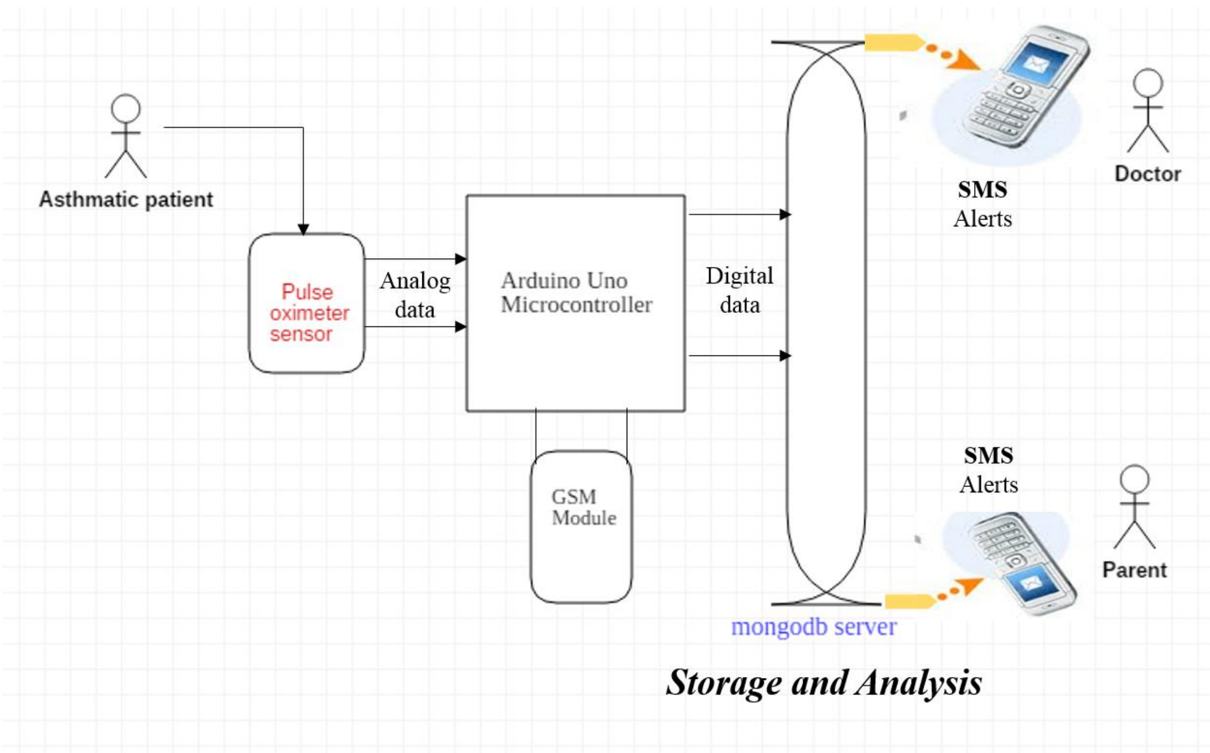

Figure 18: Home-based patient monitoring architecture

The home-based asthma monitoring architecture is comprised of pulse oximeter sensor, the SIM900 GSM module and Arduino Uno microcontroller which forms the hardware, and a data storage server at the backend.

The pulse oximeter sensor fitted to the finger of an asthmatic patient helps capture oxygen concentration and heart rate values. The Arduino Uno microcontroller converts the analog values captured by the pulse oximeter into digital format. The server side mongodb database stores the data which are transmitted by lightweight and secure MQTT protocol from arduino. The GSM module allows efficient communication between the Arduino Uno microcontroller and the server.

4.7.2 System Design

The study project also sought to explore the feasibility of monitoring and managing asthma among children under ages of five at home. The chapter therefore outlines the procedures that were undertaken in designing the system proposed. This includes detailed design of the home-based asthma monitoring system which comprised of the hardware and server side database backend.

4.7.3 Data Process Modelling

The home-based asthma monitoring device constituted a number of entities which was crucial for the successful operation of the device in determining and monitoring severity of asthma among asthmatic patients. Data Process modelling elaborates diagrammatically the logical model for the process of asthma monitoring.

The key entity is the asthmatic patient, while the parent or caregiver to the asthmatic child and the doctor were primary entities in the system. The main user (the asthmatic patient) is able to determine degree of asthma severity at any given time, while both the parent and the doctor receive the patient's asthma condition at any time. The primary entities are in charge of ensuring proper management of asthmatic child, while at home.

4.7.3.1 Data Flow Diagrams (DFD) Models

These are tools used to illustrate the flow of data and how it is processed by the system in terms of inputs and outputs.

Level 0 Representation of home-based Asthma Monitoring device

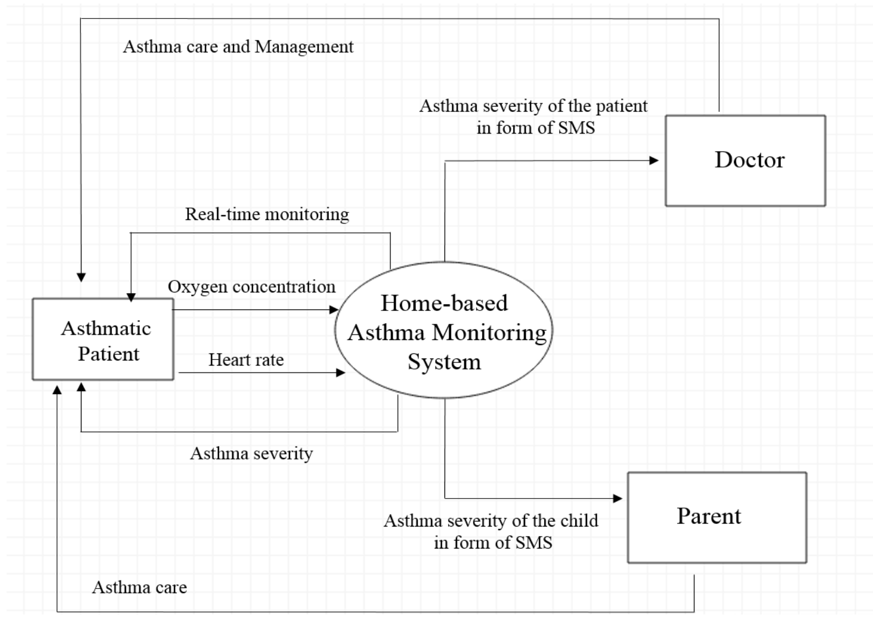

Figure 19: Level 0 Context Diagram

Level 1 Representation of home-based Asthma Monitoring device

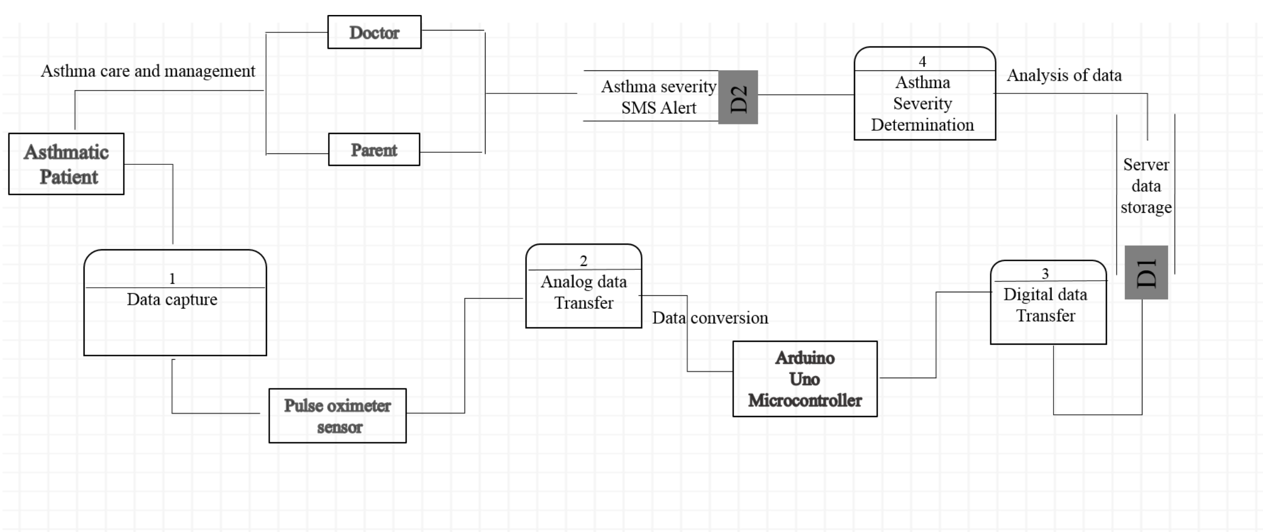

Figure 20: Level 1 Context Diagram

This level breaks down the processes in Level 0 to show all the sub-processes entailed in the system, together with the entities.

Detailed Process of Determination of Degree of Asthma Severity

Figure 22 below shows the details of process 4, 'Asthma severity Determination'. The process has been broken down further to show all the sub-processes needed for a successful execution of the process by the system as initiated by the asthmatic child.

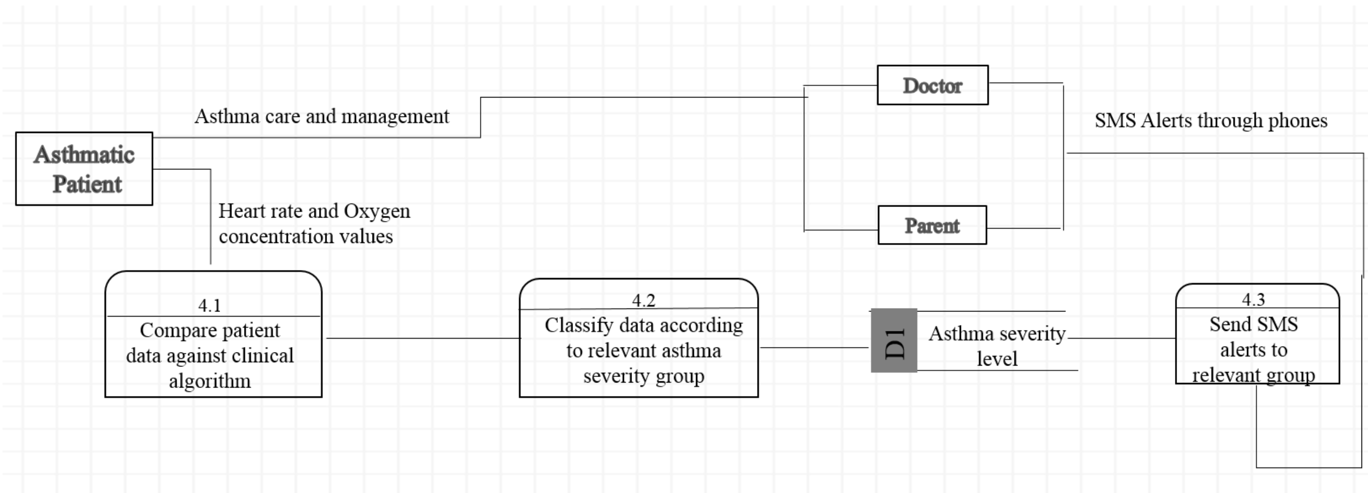

Figure 21: Detailed Process 4

4.7.3.2 Use Cases Modelling

The use-cases were used to model the functionality aspects of the home-based asthma monitoring system, in order to that design requirements of the system is achieved. The use-cases show the main actors and all other external influences and their interaction with the main functionalities of the system. The main actors are the asthmatic patient, the doctor or caregiver and the parent to the asthmatic patient.

Table 5 below outlines a series of the main events expected in the system.

Step 1: ***Data Capture***	Once the device is powered on and the pulse oximeter sensor fitted on to the patient's finger, the patient data is captured instantaneously.
Step 2: ***Analog data conversion***	The analog data is converted into digital data by the micro-controller.
Step 3: ***Digital data transfer***	The data from the pulse oximeter sensor is then transferred in to the server for storage
Step 4: ***Asthma severity determination***	The device checks against the predefined conditions based on asthma clinical algorithm and classifies the patient as either mild, moderate or severe.
Step 5: ***Asthma Severity notification***	The degree of asthma severity is sent to relevant clinician and the parent or caregiver to the asthmatic patient

Table 5: System Main Events Use Case

4.7.3.2.1 Use Case Diagram

Figure 23 shows a use case representation of the home-based asthma monitoring system. It gives detailed interaction between the various actors and the functionalities of the system.

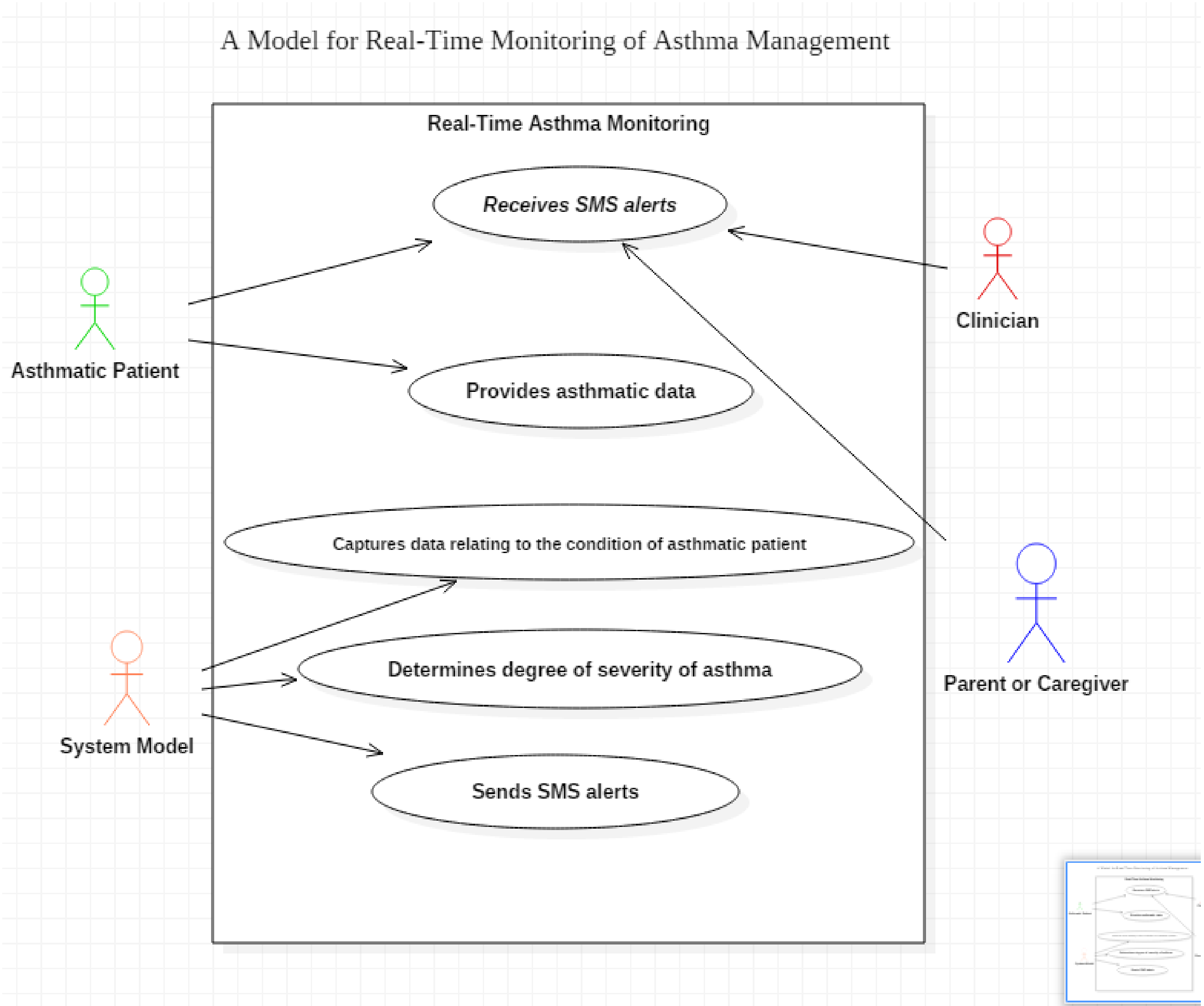

Figure 22: Use Case Diagram

4.7.3.2.2 Use Case Description

Table 6 presents the Use Case UC1: Provides asthmatic data. This module gives the actor the ability to provide data upon which determination of degree of severity of asthma will be based. The data from the patient is then fed into the system.

Table 6: Provides asthma data

Use Case Name:	*Provides asthmatic data*
Scenario:	Patient is asthmatic and want to use home-based monitoring tool
Event (Trigger):	Patient, relevant caregiver or the doctor want to know degree of severity of asthma
Brief Description:	Patient uses pulse oximeter sensor to provide data to the system
Actors:	Asthmatic patient
Stakeholders:	Asthmatic patient
Preconditions:	Patient must be asthmatic
Post conditions:	Patient data is captured by the system

Table 7 presents the Use Case UC2: Captures data relating to the condition of asthmatic patient. In order to capture asthmatic patient data and feed it into the system, this module is used.

Table 7: Captures data relating to the condition of asthmatic patient

Use Case Name:	*Captures data relating to the condition of asthmatic patient*
Scenario:	The device is worn by the asthmatic patient
Event (Trigger):	Patient data is needed in order to determine degree of severity of asthma
Brief Description:	The system uses pulse oximeter sensor to capture data
Actors:	Pulse oximeter sensor, asthmatic patient
Stakeholders:	Asthmatic patient
Preconditions:	The system is fitted with pulse oximeter sensor
Post conditions:	The analog data is converted to digital form by microcontroller

Table 8 presents the Use Case UC3: Determines degree of severity of asthma. This module ensures that the degree of severity of asthma is determined by checking the patient's captured data against the predefined conditions based on asthma clinical algorithm and classifies the patient as either mild, moderate or severe. The output is then shared to the doctor and the parent of the patient.

Table 8: Determines degree of severity of asthma

Use Case Name:	*Determines degree of severity of asthma*
Scenario:	Asthmatic patient data has been captured into the system and ready to be used to determine degree of severity of asthma
Event (Trigger):	The degree of severity of asthma is needed to be determined in order to regularly review the patient treatment and provide proper management
Brief Description:	The degree of severity of asthma is determined by checking the patient's captured data against the predefined conditions based on asthma clinical algorithm and classifies the patient as either mild, moderate or severe.
Actors:	Patient data (heart rate and oxygen saturation), clinical guidelines for asthma
Stakeholders:	Asthmatic patient, pulse oximeter sensor
Preconditions:	Patient data has been captured into the system
Post conditions:	The degree of severity of asthma is sent to the relevant caregiver

Table 9 presents the Use Case UC4: Sends SMS alerts. The SMS is used by the module to send alerts in form of texts to the doctor and the patient's parent.

Table 9: Sends SMS alerts

Use Case Name:	*Sends SMS alerts*
Scenario:	The degree of severity of asthma has been determined and notification ready to be sent to both the patient parent as well as the doctor
Event (Trigger):	The doctor, parent or caregiver wants to be informed about the degree of severity of asthma of the patient
Brief Description:	SMS is to be used to inform relevant caregiver of the degree of severity of asthma of the patient.
Actors:	Mobile phone

Stakeholders:	Doctor, parent
Preconditions:	The degree of severity of asthma is determined
Post conditions:	The doctor and the patient receives SMS alerts

Table 10 presents the Use Case UC5: Receives SMS alerts. The main actor in this case is the mobile phone, which is used to receive SMS alerts

Table 10: Receives SMS alerts

Use Case Name:	*Receives SMS alerts*
Scenario:	The doctor and patient's parent are to receive real-time monitoring information about the asthmatic patient.
Event (Trigger):	The degree of severity of asthma is needed to be determined in order to regularly review the patient treatment and provide proper management
Brief Description:	Phone is to be used to by the relevant caregivers t receive SMS alert about the asthmatic patient
Actors:	Mobile phone
Stakeholders:	Doctor, Parent
Preconditions:	SMS alert has been sent by the system to the relevant caregivers
Post conditions:	The relevant caregivers to use the alert to inform proper management of the asthmatic patient.

4.7.3.3 Entity Relationship Diagram

In *Figure 24*, an elaborate view of the relationships between all the entities of the home-based asthma monitoring system has been presented.

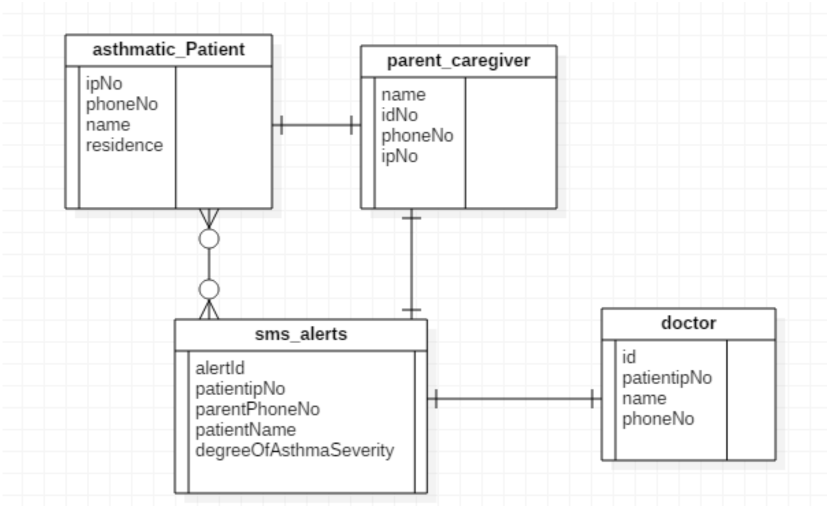

Figure 23: Entity Relationship Diagram

4.7.3.4 Sequence Diagram

Figure 25 is a sequence diagram that graphically depicts interactions between objects within the system. Once the pulse oximeter sensor has been activated through an AD/DC power or battery, it captures data from asthmatic child and sends it to the microcontroller, which then uses GSM module to transmit the data to server for storage. The data is then instantly analyzed and report in form of notification sent to relevant end users for appropriate decision making.

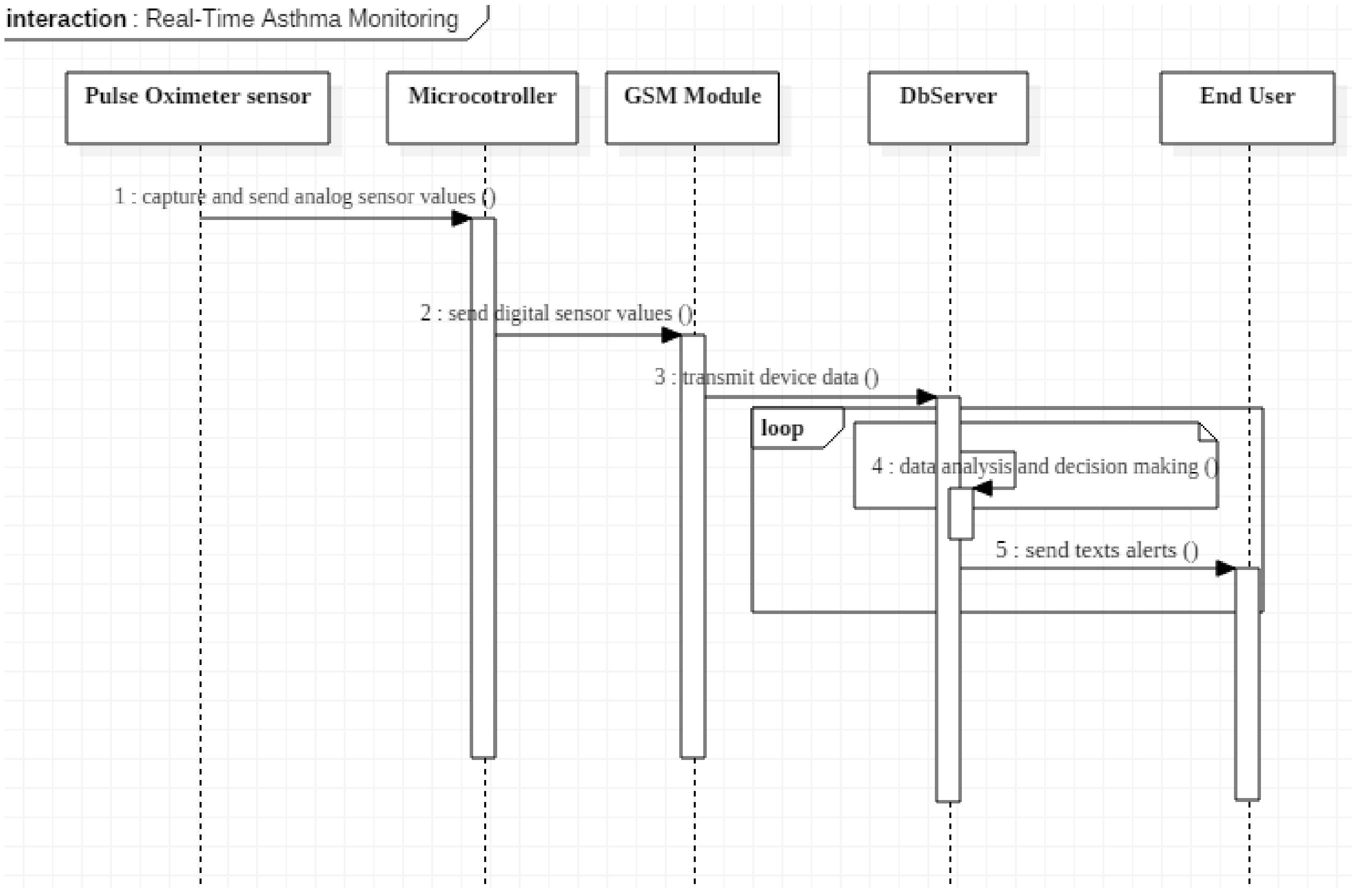

Figure 24: Sequence Diagram

4.7.3.5 Class Diagram

Figure 26 below is a class diagram that shows the blueprints of the home-based asthma monitoring system. Apart from modelling all the objects that make up the system, the class diagram also displays the interactions between these objects and their functionalities.

During system design, a class diagram helps bring out a better understanding of the requirements of the problem domain and in the identification of system's components.

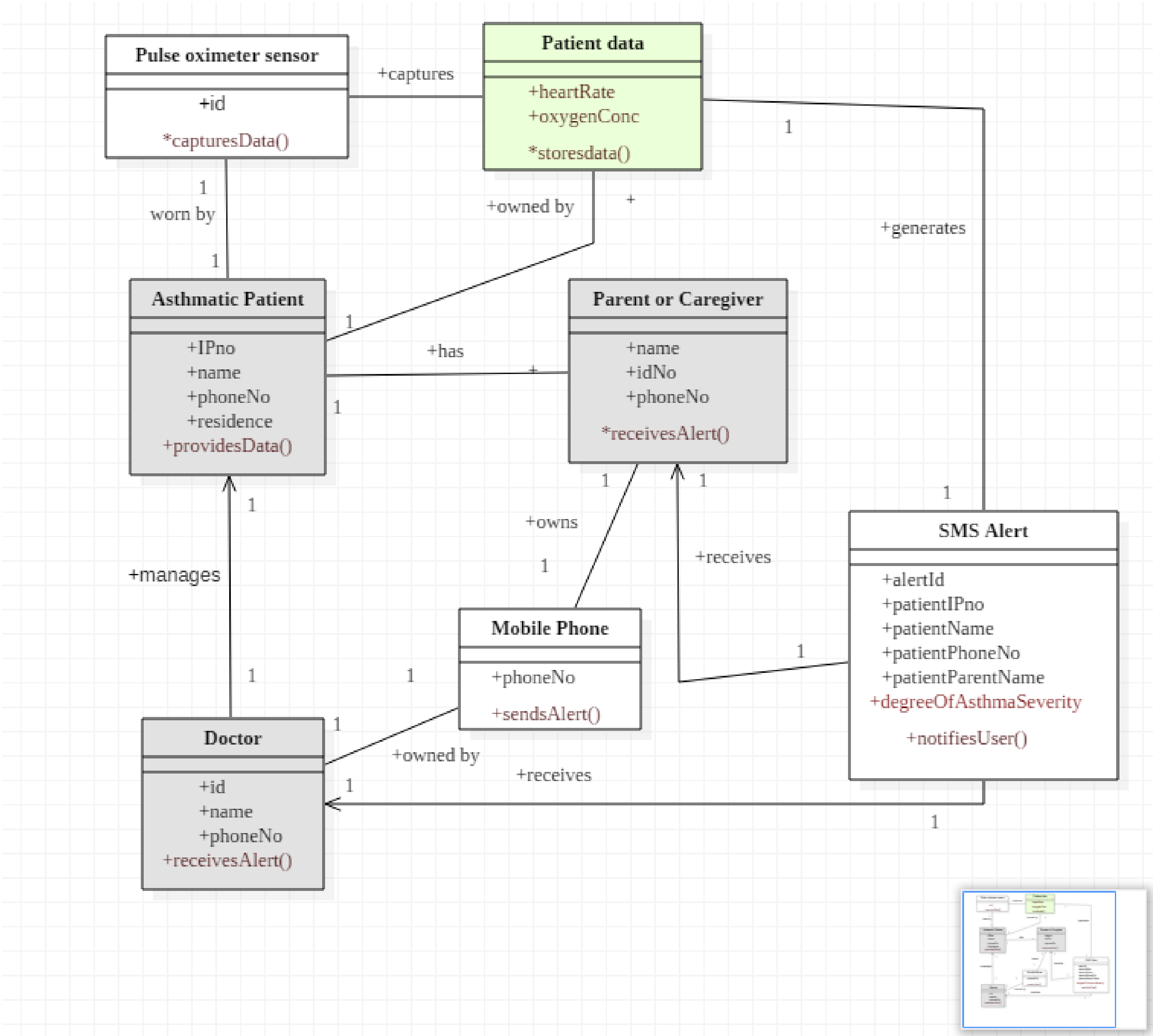

Figure 25: Class Diagram

4.7.3.6 Activity Diagram for determination of degree of severity of Asthma

The activity diagram in Figure 27 is a graphical representation of the conditional logic for the sequence of the system activities used to meet the needs of the system. The activity diagram represented is used to represent the parallel and alternative behavior and was further used to represent a use case process.

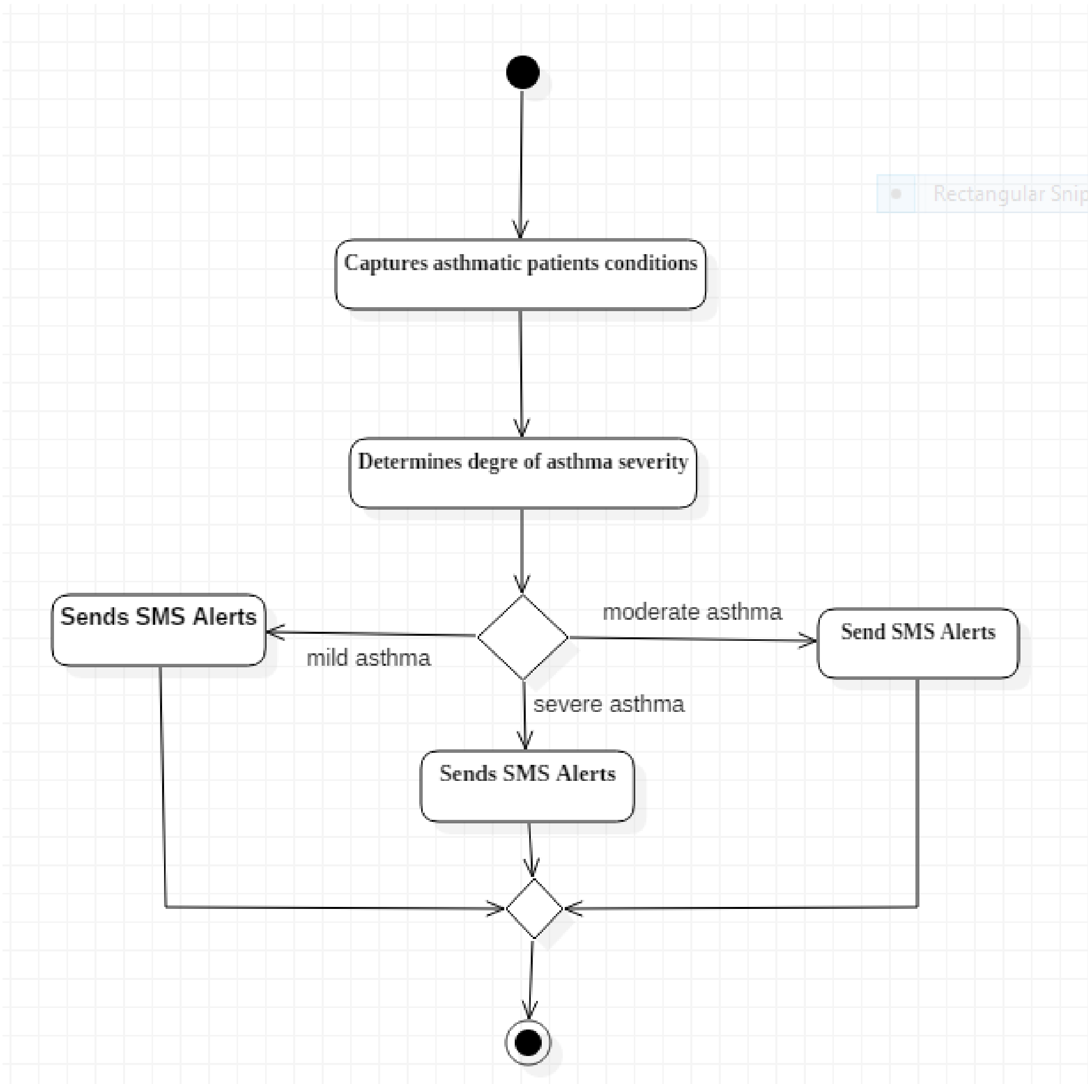

Figure 26: Activity Diagram for determination of degree of severity of Asthma

In the home-based asthma monitoring model, the activities that were required in achieving the objective of determining degree of severity of asthma constituted a set of activities, some including capturing asthmatic condition of the patient using pulse oximeter sensor fitted in to the system. Asthma clinical guidelines adopted from Basic Paediatric Protocol for asthma management was then used to derive an algorithm against which the patient data was matched on in order to determine degree of severity of asthma.

CHAPTER FIVE: IMPLEMENTATION AND TESTING

5.1 Introduction

This chapter covers how the system will be implemented and was tested. The testing was focused mainly on checking whether the system developed met user needs and requirements with respect to the objectives of the research.

5.2 Implementation

Asthmatic children with established diagnosis of asthma can use home-based asthma monitoring device to monitor their conditions in order to achieve and maintain control and if possible, prevent asthma exacerbations. Increased monitoring could be associated with improved patient awareness of degree of asthma severity, and possible risks that could signal onset of an asthma exacerbation. Better vigilance by patient, parents and relevant doctors can lead to better adherence to clinician-prescribed treatment plans and greater asthma control. Hence, when the degree of severity of asthmatic patient is appropriately monitored, frequent emergency visits and hospitalizations would be reduced, serious exacerbations prevented and control over asthma gained. The system developed, thus can be used for long-term monitoring to assess asthma severity and efficacy of treatments.

5.2.1 Implementing Home-based Asthma Monitoring Tool

Once the device in *Figure28* would have been redesigned in to a light-weight, easy to carry wearable, with low power consumption, it will be implemented at health care facilities level under homecare asthma programme. Every asthmatic patient who gets discharged home will be recruited into the programme. The implementation strategy is to provide them with the device at the point of discharge and assign them to relevant healthcare professional (doctor). The device will be used to track and monitor them while at home and send real-time notification at specified instances to the assigned doctors.

Figure 27: Implementing Home-based Asthma Monitoring Tool

In order to capture and send real-time feedback to relevant caregiver, the asthmatic patient will be required to use the device in the morning, at lunch hour and in the evening before they go to sleep. This aims to ensure that they get monitored at least three times a day.

5.2.2 Working Principle of Home-based monitoring device for children with asthma

Figure 29 shows finger probe connected to an asthmatic patient. Outlined below are the working principle of the device to be implemented.

i. A pulse oximeter sensor connected to Arduino is fitted on the finger of an asthmatic child using finger probe.

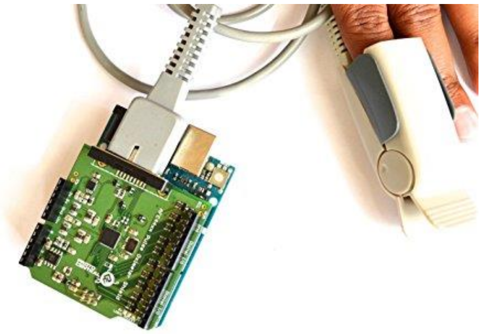

Figure 28: Pulse Oximeter

ii. At every instance, oxygen concentration and heart rate measurments are instanteneously transmitted to the arduino microcontroller. Through GSM module, the same data is concurrently uploaded to a cloud-based analytical server.

iii. A clinical algorithm based on asthma guidelines interprets and analyzes the data in order to determine the degree of severity of asthma.

iv. The degree of severity of asthma of a particular asthmatic patient is then automatically sent in real-time in form of a text alert to the family and relevant healthcare profession (doctor).

Figure 29: Sample of Asthma Degree of Severity Alert

5.3 System Testing

5.3.1 Functionality Testing

The functionality tests were mainly done by the developer, to ensure all bugs were fixed, and that the system met the main objectives of the study. The functionality testing was important in checking that the user requirements were met, and that the system executed perfectly. This was done iteratively during the entire process of system development. All these tests were done on Arduino programming platform.

5.3.2 Usability and User Experience

To explore the reception of the application in terms of usability and experience, the researcher sought to conduct a post-test survey on a number of users within purposively sampled hospitals as shown in appendix B. The testing involved 37.5% (3) male and 62.5% (5) female respondents as presented on *Figure 31*.

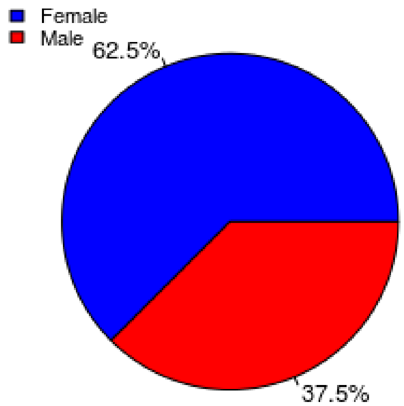

Figure 30: Gender Distribution

Table 11 gives summary of a number of user experience and usability responses among respondents perceived to be the intended system users.

Functionality, User Experience and Usability	**N= 8**		
	Yes	No	Neutral
The home-based monitoring device looks good	87.5%	0%	12.5%
The device is easier to use	100%	0%	0%
The device can be carried around with ease during monitoring process?	37.5%	62.5%	0%
The tool will help monitor and improve asthma management for the patient.	100%	0%	0%
I am willing to use the tool for my child’s benefit.	87.5%	12.5%	0%

Table 11: User Experience and Usability

a) *Ease of Use*

When asked on the ease of use of the home-based asthma monitoring device, all the respondents 100% (8) felt the device was easy to use.

b) *Device Portability*

In order to find out whether the users would feel free and easy to carry along the device comfortably, 62.5% of the respondents as presented in *Figure 32* below affirmed that the asthmatic children would face some difficulty and suggested a light-weight wearable device that they can easily move around with.

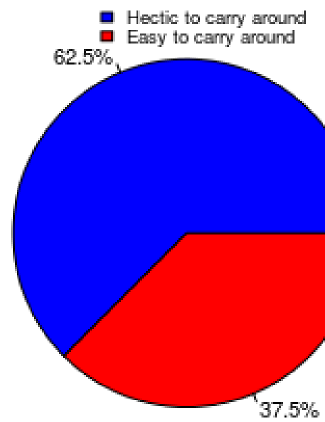

Figure 31: Device Portability

c) *Device Usefulness*

From the post-survey findings, approximately 100% of the respondents consented that the tool can help monitor and improve asthma management of their asthmatic children. Most of them added that since most of their children are school going, monitoring and management would be critical process at all times.

d) *Acceptance Testing*

The researcher sought to know how much the users would want the solution and there was 87.5% acceptance from the respondents. *Figure 33* gives an impression of what the users felt, this response could be pegged to the user experience and usability of the application.

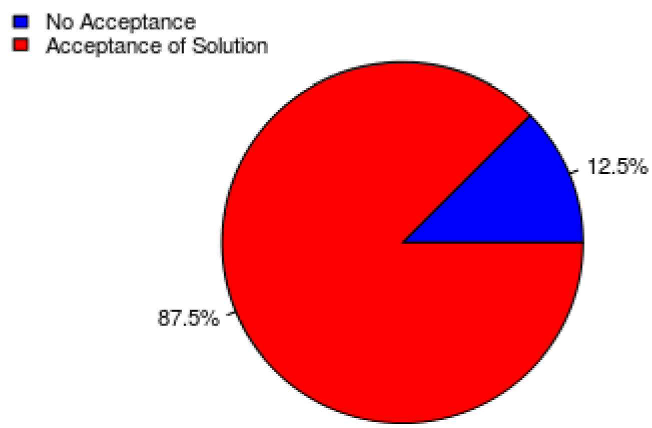

Figure 32: Acceptance Testing

5.4 Summary

Home-based asthma monitoring device's development was a user-centric process aimed at ensuring that all the user needs were well taken into consideration. For the success of the system, the developer was keen in ensuring that the final product would be an easy to use tool, one that would need minimal improvement during implementation. This process was key in enhancing user acceptance of the application during deployment.

Results gathered on the post-test analysis as indicated in *Table 6-1* gave a solid indication of the proposed solution meeting set objectives. The device was not only easy to use and highly acceptable to the users, but also good and tailored to the user needs. However, there is a substantial percentage of the respondents who suggested further improvement to the system. They advised the tool to be converted into a small, light-weight wearable device in order to ease patient's monitoring process. In order to handle false positives or negatives, the device takes a series of measurements, and based on this, it averages to produce a final output. Based on the patient data already accumulated over a while, it is also able to deduce conclusions.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Project Summary

The main aim of the research project was to design and develop a simple to use home-based tailored system for monitoring the degree of asthma illness among children under five years of age in Kenya. The research, throughout the whole process was iterative and involved the user all through the development lifetime so as to achieve the objectives set on the onset.

6.2 Contribution to Research

As technology advances, smart health monitoring devices and Internet of things (IOT) can play a critical role in chronic disease management. Home monitoring of chronic illnesses in health care can bring about positive impacts to the health of the patient. However, most LIC like Kenya have faced challenges in monitoring these diseases, especially asthma, where once an asthmatic child is discharged home, he or she is left under the care of their family who most often lack enough expertise required to appropriately offer better management. This always results into frequent hospitalizations, poor health and unnecessary acute attacks that can be prevented.

Recent advances in medical sensors and smart health monitoring devices have greatly enabled remote health monitoring to support early diagnosis, detection of early signs of asthma attack as triggered by exercise and identification of conducive environment for asthmatic patients**.** However, the use of these tools as a home-based monitoring process to routinely assess patient's response to treatment and progress is yet to be exploited in the country. With the knowledge of patient's asthma severity levels at hand at intervals of time, the clinician is able to review regularly and adjust patient's treatment as may be necessary. With appropriate treatment, most patients with asthma can gain and maintain asthma control and thus lead normal productive lives.

The home-based asthma monitoring tool, thus can greatly impact into home monitoring and proper management of asthma.

6.3 Conclusions

The main objectives of the research as set at the start of the study was thus achieved. The researcher explored on the current tools used to manage asthma, their potential benefit and possible gaps that still exist. This then informed on the development of home-based asthma monitoring device as a solution in order to fill in the gaps in asthma management in Kenya.

6.4 Recommendations

Despite the fact that the home-based asthma monitoring tool is easy to use and capable of monitoring in real-time the degree of severity of asthma among the patients, a number of users have suggested further improvement to the system. They advised that the tool should be converted into a small, light-weight wearable device in order to ease patient's monitoring process.

6.5 Future Research Work

The home-based asthma monitoring tool developed mainly exercises the use of a medical sensor to remotely capture patient data. The pulse oximeter sensor can only capture heart rate and oxygen saturation level, two of the key values used to determine severity level of asthma. It would be worthwhile incorporating the use of other conditions such as inability to drink, central cyanosis and indrawing in determining degree of asthma severity. In addition to this, the tool developed need to be redefined into small, light-weight wearable device that asthmatic patient can freely move around with for proper home monitoring and management of asthma.

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APPENDICES

7.1 Appendix A: Self-Administered Questionnaires

PROJECT: A tool for home-based remote monitoring of asthmatic patients

This is a project that aims to develop a monitoring tool that will be used to monitor remotely the severity level of asthmatic patients.

BRIEF INSTRUCTIONS FOR THIS QUESTIONNAIRE

a. The questionnaire has four sections. Please complete each section as necessary.

b. To answer each question, please fill in the space provided, by ticking [✓] in one of the boxes/spaces provided to indicate the answer that closely represents your answer for each question.

Part I: Bio data

	Questions							
1.	What is your relationship with the patient?	Father ☐	Mother ☐	Guardian ☐	Others ☐			
2.	State the gender	Male ☐	Female ☐					
3.	Select the age of the patient (Years)	<1 ☐	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	>5 ☐
4.	Is the child in school?	Yes ☐	No ☐					

Part II: ICT Capacity

Questions				
5.	Do you own or have access to a mobile phone?	Yes ☐	No ☐	
6.	What is your highest level of education?	Primary ☐	Secondary ☐	College/University ☐
7.	Do you use your mobile device to discuss or seek information on health care?	Yes ☐	No ☐	

Part III: Asthma Management

Questions					
		Frequently	***Weekly***	***Monthly***	***Seldom***
8.	How often does your child experience asthma attack?	☐	☐	☐	☐
9.	How often does your child get readmissions to hospital as a result of asthma?				
10.	Are there public health care asthma programmes that you have enrolled your child in?	Yes	No ☐		
11.	Do you monitor the degree or level of asthma severity in your child?	Yes ☐	No ☐		
12.	If yes, how do you monitor the degree of asthma in your child?	Hospital ☐	Asthma care programmes ☐	Home-based monitoring tool ☐	Others ☐

Part IV: Home based Asthma Monitoring device

Questions			
13.	Are you aware of any home-based asthma monitoring device used by asthmatic patients to monitor their status in Kenya?	Yes ☐	No ☐
14.	Do you currently use any of the asthma monitoring tools to determine asthma severity of your child?	Yes ☐	No ☐
15.	Would you like to use a local based monitoring device to determine asthma severity of your child?	Yes ☐	No ☐
16.	Would you like to receive SMS alerts on the status of asthma of your child in real time?	Yes ☐	No ☐
17.	Would you like clinicians and relevant caregiver to be informed in real time of the status of asthma of your child?	Yes ☐	No ☐

Part IV: Benefits of Home-based Asthma Monitoring and Management

Questions					
		Strongly Disagree	***Disagree***	***Agree***	***Strongly Agree***
18.	Using home-based monitoring tool to monitor degree of asthma severity in asthmatic patient reduces chances of acute attack and frequent hospital readmissions among the patients	☐	☐	☐	☐
19.	It is very easy and economical to get health care alerts in terms of SMS on phones	☐	☐	☐	☐
20.	Informing clinicians as well as parents or guardians about asthmatic status of their children allow the illness to be controlled and properly managed	☐	☐	☐	☐
21.	Home-based monitoring tools are easy to use	☐	☐	☐	☐

7.2 Appendix B: Post Test Questionnaire

Post Survey Questions: User Experience and Usability				
a.	The home-based monitoring device looks good?	Yes ☐	No ☐	Neutral ☐
b.	Select the gender of the patient	Male ☐	Female ☐	
c.	The device is easier to use?	Yes ☐	No ☐	Neutral ☐
d.	The device can be carried around with ease during monitoring process?	Yes ☐	No ☐	Neutral ☐
e.	The tool will help monitor and improve asthma management for the patient	Yes ☐	No ☐	Neutral ☐
f.	I am willing to use the tool for my child’s benefit.	Yes ☐	No ☐	Neutral ☐

7.3 Appendix D: Codes Used during System development

Arduino Configuration and Algorithm Codes

pulse_oximeter_monitoring_model | Interrupt

```
//##################################################
#include "SIM900.h"
#include <SoftwareSerial.h>
//#include "inetGSM.h"
#include "sms.h"
SMSGSM sms;

//Declarations
int numdata;
int value;
boolean started=false;
char smsbuffer[160];
char n[20];



// Sensor and pins variables
int pulsePin = 0;
int blinkPin = 13;

// Pulse rate variable
volatile int BPM;
float SPO2 = 0.0;

// Raw signal
volatile int Signal;

// Interval between beats
volatile int IBI = 600;
```

```
// Becomes true when the pulse is high
volatile boolean Pulse = false;

// Becomes true when Arduino finds a pulse
volatile boolean QS = false;
//----------------------------------------------------------------------------------------------------


void setup(){

  // Start Serial
  Serial.begin(115200);
  Serial.println(" ");
  Serial.println("           WELCOME TO THE HEART RATE AND OXYGEN SATURATION MONITORING MODEL");
  Serial.println(" ");
  delay(5000);

  // Sets up to read Pulse Sensor signal every 2mS
  interruptSetup();

  //
  Serial.println("OPENING THE GSM FOR COMMUNICATION,.....");

  if (gsm.begin(2400)){
    Serial.println("\nstatus=READY");
    started=true;
  }
  else Serial.println("\nstatus=IDLE");
}
```

```
volatile unsigned long lastBeatTime = 0;           // used to find IBI
volatile int P =512;                      // used to find peak in pulse wave, seeded
volatile int T = 512;                     // used to find trough in pulse wave, seeded
volatile int thresh = 512;                // used to find instant moment of heart beat, seeded
volatile int amp = 100;                   // used to hold amplitude of pulse waveform, seeded
volatile boolean firstBeat = true;        // used to seed rate array so we startup with reasonable BPM
volatile boolean secondBeat = false;      // used to seed rate array so we startup with reasonable BPM


void interruptSetup(){
  // Initializes Timer2 to throw an interrupt every 2mS.
  TCCR2A = 0x02;     // DISABLE PWM ON DIGITAL PINS 3 AND 11, AND GO INTO CTC MODE
  TCCR2B = 0x06;     // DON'T FORCE COMPARE, 256 PRESCALER
  OCR2A = 0X7C;      // SET THE TOP OF THE COUNT TO 124 FOR 500Hz SAMPLE RATE
  TIMSK2 = 0x02;     // ENABLE INTERRUPT ON MATCH BETWEEN TIMER2 AND OCR2A
  sei();             // MAKE SURE GLOBAL INTERRUPTS ARE ENABLED
}
//--------------------------------------------------------------------------------------------------------------

// THIS IS THE TIMER 2 INTERRUPT SERVICE ROUTINE.
// Timer 2 makes sure that we take a reading every 2 miliseconds
ISR(TIMER2_COMPA_vect){                         // triggered when Timer2 counts to 124
  cli();                                      // disable interrupts while we do this
  Signal = analogRead(pulsePin);              // read the Pulse Sensor
  sampleCounter += 2;                         // keep track of the time in mS with this variable
  int N = sampleCounter - lastBeatTime;       // monitor the time since the last beat to avoid noise

    //  find the peak and trough of the pulse wave
  if(Signal < thresh && N > (IBI/5)*3){       // avoid dichrotic noise by waiting 3/5 of last IBI
```


```
// Timer 2 makes sure that we take a reading every 2 miliseconds
ISR(TIMER2_COMPA_vect){                         // triggered when Timer2 counts to 124
  cli();                                      // disable interrupts while we do this
  Signal = analogRead(pulsePin);              // read the Pulse Sensor
  sampleCounter += 2;                         // keep track of the time in mS with this variable
  int N = sampleCounter - lastBeatTime;       // monitor the time since the last beat to avoid noise

    //  find the peak and trough of the pulse wave
  if(Signal < thresh && N > (IBI/5)*3){       // avoid dichrotic noise by waiting 3/5 of last IBI
```


```
    if (Signal < T){                        // T is the trough
      T = Signal;                         // keep track of lowest point in pulse wave
    }
  }

  if(Signal > thresh && Signal > P){          // thresh condition helps avoid noise
    P = Signal;                             // P is the peak
  }                                        // keep track of highest point in pulse wave

  //  NOW IT'S TIME TO LOOK FOR THE HEART BEAT
  // signal surges up in value every time there is a pulse
  if (N > 250){                                   // avoid high frequency noise
    if ( (Signal > thresh) && (Pulse == false) && (N > (IBI/5)*3) ){
      Pulse = true;                               // set the Pulse flag when we think there is a pulse
      digitalWrite(blinkPin,HIGH);                // turn on pin 13 LED
      IBI = sampleCounter - lastBeatTime;         // measure time between beats in mS
      lastBeatTime = sampleCounter;               // keep track of time for next pulse

      if(secondBeat){                        // if this is the second beat, if secondBeat == TRUE
        secondBeat = false;                  // clear secondBeat flag
        for(int i=0; i<=9; i++){             // seed the running total to get a realisitic BPM at startup
```

```
    if(firstBeat){                          // if it's the first time we found a beat, if firstBeat == TRUE
      firstBeat = false;                    // clear firstBeat flag
      secondBeat = true;                    // set the second beat flag
      sei();                                // enable interrupts again
      return;                               // IBI value is unreliable so discard it
    }


    // keep a running total of the last 10 IBI values
    word runningTotal = 0;                   // clear the runningTotal variable

    for(int i=0; i<=8; i++){                 // shift data in the rate array
      rate[i] = rate[i+1];                   // and drop the oldest IBI value
      runningTotal += rate[i];               // add up the 9 oldest IBI values
    }

    rate[9] = IBI;                           // add the latest IBI to the rate array
    runningTotal += rate[9];                 // add the latest IBI to runningTotal
    runningTotal /= 10;                      // average the last 10 IBI values
    BPM = 60000/runningTotal;                // how many beats can fit into a minute? that's BPM!
    QS = true;                               // set Quantified Self flag
    // QS FLAG IS NOT CLEARED INSIDE THIS ISR
  }
}
```

7.4 Appendix C: Participant information and consent sheet for hospital Staff and Asthmatic Patients (Family)

Institution	Investigators
Strathmore University, KEMRI-Wellcome Trust Research Programme	Mr Julius Thomas
Strathmore University	Dr. Joseph Orero
KEMRI-Wellcome Trust Research Programme	Prof. Mike English

Who is carrying out this study and what is this study about?

- This study is being carried out by Strathmore University in collaboration with KEMRI/Wellcome Trust Research Programme (KWTRP). KEMRI is a government organization that carries out medical research to find better ways of preventing and treating and managing illness in the future for everybody's benefit.

- Sometimes research involves only asking questions of patients, their parents, community members or health providers about what they know, feel or do.
- In this research, we want to learn more about how asthmatic patients are monitored at home. We want to gather information from asthmatic patients, their parents or guardians about the current monitoring devices they are using to monitor the severity level of asthma, and possibly what type of device they would want to use for the same. We would like to hold discussions with the administration and at least 1 clinician in a department to assess how they feel the device could be implemented in monitoring asthmatic patients in paediatric wards.

Why do you want to talk to me and what does it involve?

- *Explain selection*

Given your involvement in the potential use of the devic, we are interested in understanding your views and experiences in using home-based monitoring device to track your child's severity level. We feel that your experience as a person who has been involved with your child can contribute much to our understanding and knowledge of the device design, development and potential implementation.

- We would like to ask you a number of questions about your experience with such kind of device, what you would advise on the design of a local one that suits our set up and implementation of the same. If you do not want to answer any of the questions you may say so and the interviewer will move on to the next question. The discussion will take place at your work station or at a place where you feel comfortable within the hospital. No-one else but the interviewer will be present unless you would like someone else there.

- The discussion will be recorded to assist later in fully writing up the information. No-one will be identified by name in the recording.

Are there any risks or disadvantages to me of taking part?

The discussions should take approximately 15 minutes. There are no foreseeable risks in participating in this research.

Are there any advantages to me of taking part?

There are no individual benefits to taking part. In talking to us, you will contribute to knowledge of the design, development and implementation of home-based asthma monitoring tool that may help other asthmatic patients, especially children under the age of five in Kenya and elsewhere in the future, to properly monitor and manage their asthma conditions in order to maintain and live a productive life.

Who will have access to the information I give?

- All of our documents/ recordings are stored securely in locked cabinets and on password protected computers. The knowledge gained from this research will be shared in summary form, without revealing individuals' identities, with relevant stake holders such as the Ministry of Health and with international audiences through journal publications.

- In future, information collected or generated during this study may be used to support new research by other researchers in *Kenya and other countries* on implementation and further improvement of the tool to control the illness. In all cases, we will only share information with other researchers in ways that do not reveal individual participants' identities. For example, we will not disclose names of the participants. Any future research using information from this study must first be approved by a local or national expert committee to make sure that the interests of participants and their communities are protected.

Data sharing: In order to do this study, we will share anonymized individual and summary information we collect or generate with the Department of Information and Technology, Strathmore University, and KEMRI-Wellcome Trust, which is a collaborating institution in ways that do not reveal individual participants' identities.

Who has allowed this research to take place?

This research has been approved by Strathmore University (SGS) and KEMRI-Wellcome Trust arm: KEMRI CGMR-C Centre Scientific Committee- CSC and KEMRI Scientific & Ethics

Review Unit – SERU. They must agree that the research is important, relevant to Kenya and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.

What will happen if I refuse to participate?

All participation in research is voluntary. You are free to decide if you want to take part or not. If you do agree you can change your mind at any time without any consequences.

What if I have any questions?

You are free to ask me any question about this research. If you have any further questions about the study, you are free to contact the research team using the contacts below:

[*Researcher Name and Contact*] Mr._Julius Thomas Oduor_
Telephone: [0721 420195] or 0725922431

A model for Real-Time Monitoring of Asthma Management

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