SCHOOL OF PUBLIC HEALTH
COLLEGE OF HEALTH SCIENCES
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REFRACTIVE AND OCULAR SURFACE ABNORMALITIES IN CHILDREN AND YOUNG ADULTS WITH DIABETES MELLITUS AT KORLE-BU TEACHING HOSPITAL

BY

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THIS DISSERTATION IS SUBMITTED TO THE UNIVERSITY OF GHANA, LEGON IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF MASTER OF PUBLIC HEALTH DEGREE

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DECLARATION

I Kwame Okyere Osei, hereby declare that apart from references of peoples' work that have been duly acknowledged, this dissertation is the result of my own original research under supervision. And that this work, either in whole or in part has not been submitted to any other institution for the award of a similar or another degree.

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DATE...21/04/2021

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(SUPERVISOR)

DEDICATION

This study is dedicated to all children and young adults suffering from diabetes mellitus related eye complications in Ghana.

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My sincere appreciation goes to the Almighty God for His goodness and mercies that has taken me through this journey. And He is more than able.

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LIST OF ABBREVIATIONS

SSA – Sub Saharan Africa

DM – Diabetes Mellitus

WHO – World Health Organization

VI – Visual Impairment

T1DM – Type 1 Diabetes Mellitus

T2DM – Type 2 Diabetes Mellitus

DR – Diabetic Retinopathy

IGFBP3 – Insulin-like Growth Factor Binding Protein 3

OPD – Out Patient Department

VA – Visual Acuity

CD – Compact Disk

IRB – Institutional Review Board

KBTH – Korle Bu Teaching Hospital

BMI – Body Mass Index

SD – Standard Deviation

SHS – Senior High School

NV – Near Vision

SVI – Severe Visual Impairment

MVI – Mild Visual Impairment

MODVI – Moderate visual Impairment

JHS – Junior High School

ABSTRACT

Background:

Refractive and ocular surface abnormalities as a result of diabetes mellitus is one of the leading causes of visual impairment and blindness in young patients globally, and this poses major public health concern in developing countries of which Ghana is not exempted. Diabetes in children and young adults is becoming a health problem in developing countries. There is a gap in literature so far as information on refractive and ocular surface abnormalities are concern in children and young adults with diabetes in Sub Saharan Africa (SSA).

General Aim:

To determine the prevalence of refractive errors, irregular corneal curvature and other ocular surface abnormalities in Ghanaian children and young adults who visit Korle Bu Teaching Hospital with diabetes.

Results:

A total of sixty-one (61) children and young adults participated in this study. Females were 64%. Mean age was 16.0 years (SD =3.1 years). Mean age at diagnosis was 10.3 years (SD = 4.0 years). Mean duration of diabetes was 5.7 years (SD =3.9 years). Majority (98%) had type 1 diabetes, while 2% had type 2 diabetes. Fifty-nine percent (59%) had normal vision, 39% had mild to moderate vision and 2% had severe visual impairment. Astigmatism was the highest (60.7%) type of refractive error observed in the study. Allergic conjunctivitis (32.8%) was the most common ocular surface abnormality. This is followed by dry eye syndrome with 18%, 4.9% for cataracts, and 9.8% with cornea infection. There was no association between duration of diabetes and type of ocular surface abnormality (p-value > 0.05).

Conclusion

Astigmatism and allergic conjunctivitis were the most common types of refractive error and ocular surface abnormality respectively. Duration of diabetes was not associated with the type of ocular surface abnormality.

Key words: Refractive errors, diabetes, ocular surface, abnormalities, children.

CHAPTER ONE

1.0 INTRODUCTION

Good vision is very important for one to achieve full developmental milestones especially when it comes to children. Since early childhood academic achievement rely heavily on how well the eye coordinates with the brain to process visual stimulus. Corrected vision as well as ocular surface free from abnormalities and discomfort in children and young adults' guarantees success in schools and working environments. One of the conditions which affect the functions of anterior surface of the eye is diabetes mellitus (Urban et al., 2013). Prevention of these refractive and ocular surface abnormalities, its early detection and immediate treatment are therefore crucial, especially if the problem concerns children and young adults since this group of population is considered to be the future of every nation (Urban et al., 2013).

Persons with diabetes are more likely to be visually impaired and may have ocular surface abnormalities, including retinal complications, which is one the leading cause of blindness (Zhu et al., 2017). Diabetes mellitus causes blindness through its effects on some structures such as cornea, lens and retina.

Diabetes mellitus (DM) is defined as "a chronic disease that occurs when the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces" (Alberti & Zimmet, 1998), and is a major global public health problem (Shih et al., 2017). It is one of the most common systemic diseases in the world with increasing prevalence (Markoulli et al., 2018). The American Diabetes Association estimated that 25.8 million children and adults, approximately 8.3% of the population in the United States of America have the condition (Charnogursky et al., 2014).

It is known that clinical characteristics of type 1 and 2 diabetes in people from sub-Saharan Africa can differ somewhat from typical European populations (Hall et al., 2011b).

Young patients with diabetes also suffer from cardiovascular diseases such as cerebrovascular disease, coronary heart disease and eye complications (Amoah et al., 2002). It is widely known that the effects of DM on the anterior structures of the eye are less frequently reported than its effects on the retina (Huntjens et al., 2012). And this has clinically led to retina complications as a result of diabetes being relatively understood by most eye health providers (Markoulli et al., 2018). On the other hand, ocular surface abnormalities associated with DM which include the conjunctiva, cornea, lacrimal glands, iris, anterior chamber, lens, as well as refractive statuses are usually not well recognized although some significant section of patients report to experience changes or abnormalities in these ocular structures (Vieira-Potter et al., 2016). Of which usually also leads to visual problems.

It has been suggested that diabetes induced changes occurring in the aqueous humour, cornea, and crystalline lens could play a key role in refractive fluctuations (Kato et al., 2001; Larsson et al., 1995; Lee et al., 2006; Wiemer et al., 2008). Some studies have examine the effects on refractive error of changing blood glucose levels after insulin treatment has been instigated for the first time in newly diagnosed diabetic patients (Giusti, 2003; Okamoto et al., 2000; Sonmez et al., 2005). However, such work may not reflect the response of the eye to the more typical glucose fluctuations that are experienced by long-term diabetic patients on day-to-day basis. Limited clinic based data in Ghana suggest that the prevalence of childhood and young adults with diabetes is on the increase, similar to the trend of ethnic minority population in western countries (Hall et al., 2011a). Eye or ocular abnormalities as a result of diabetes mellitus is one of the leading causes of blindness in young patients globally, and this poses major public health concern in developing

countries of which Ghana is not exempted (Vieira-Potter et al., 2016). It is in the light of these that this study aim to investigate the prevalence of refractive and ocular surface abnormalities associated with diabetes in children and young adults that visit Korle-Bu Teaching Hospital. And this data will be essential to the guidance of public health policies designed to reduce the burden of these abnormalities in children and young adults with diabetes in Ghana.

1.1 PROBLEM STATEMENT

Globally, ocular surface abnormalities such as loss of cornea integrity, dry eyes, and tear film abnormalities have been reported to be common with patients with diabetes mellitus (Sacchetti & Lambiase, 2014). Diabetes and the complexities of its management has become a global challenge for all ages. A study conducted on refractive surgery of diabetic patients in United States of America reported poorer visual outcomes in a group with diabetes (Spadea & Paroli, 2012). The same study also found out an ocular complication rate of 47% in patients with diabetes compared to 6.9% in those without diabetes (Spadea & Paroli, 2012).

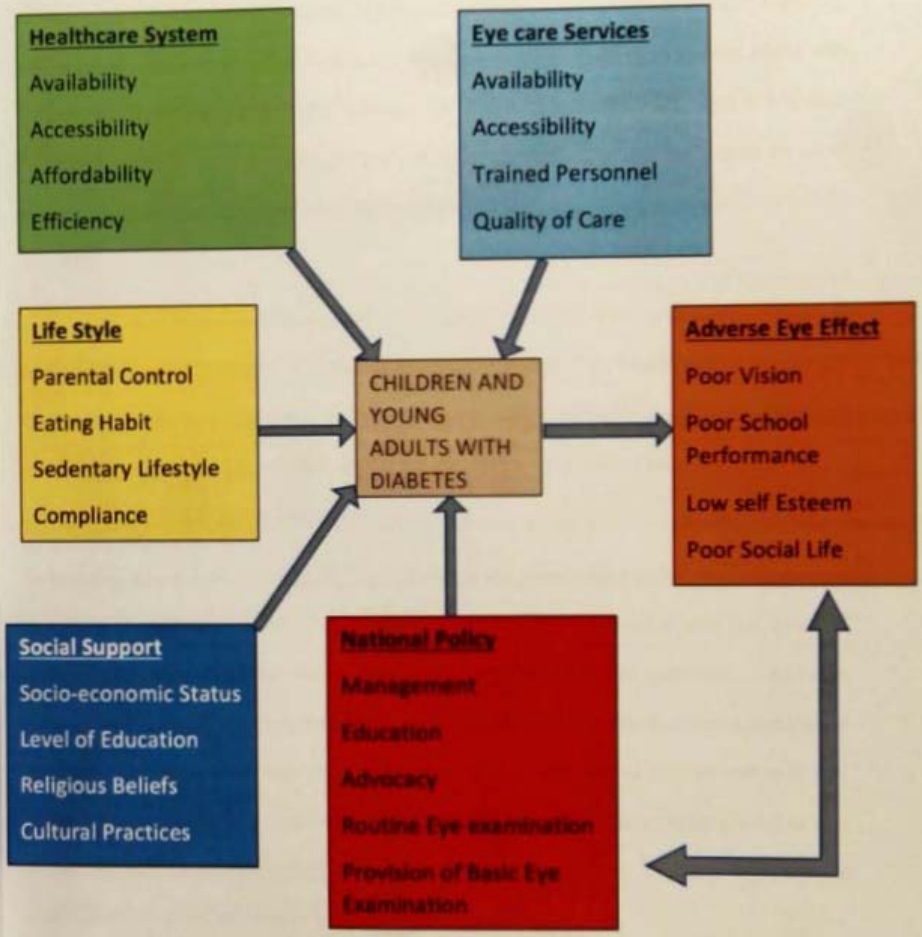
It has been observed from literature that very little is usually reported about refractive errors and ocular surface abnormalities in diabetic patients compared to retina complications (diabetic retinopathy) from other studies (Huntjens et al., 2012; Markoulli et al., 2018).

In addition, it is widely accepted that there is a rapid epidemiological shift with younger obese and overweight patients suffering from type 2 diabetes in Western countries (Eppens et al., 2006). And it is possible that this shift may soon or have already manifesting in Sub-Saharan Africa. As this is expected to also increase refractive and ocular surface abnormalities in children and young adults with diabetes. And it is imperative for this gap to be filled so far as information on refractive and ocular surface abnormalities are concern in children and young adults in Sub Saharan Africa (SSA). The little available data focused on adults, and this makes it important for a study which

will concentrate on children and young adult patients. Currently, there is no national policy for the management of diabetes related eye abnormalities for Ghanaian children and young adults.

Coupled with the above makes it necessary for this research to help find out the prevalence of these abnormalities in children and young adults with diabetes who visit Korle Bu teaching hospital in Accra. And the result from this study can help policy makers formulate early periodic eye screening programs for younger populations with diabetes in Ghana to prevent future complications.

1.2 CONCEPTUAL FRAMEWORK



1.3 NARRATIVE OF CONCEPTUAL FRAMEWORK

This framework focuses to explain eye and ocular effects of diabetes in children and young adults. Diabetes can result in several systemic complications such as kidney failure, renal dysfunction, cardiovascular conditions, and as well as eye complications. For children and young adults with diabetes, ocular abnormalities usually becomes one of the issues to deal with, since at this stage they will require good vision for school and academic activities. If proper health systems are in place, the effect of poor vision in children and young adults living with diabetes mellitus can be prevented.

Holistically, for effective management of systemic diabetes, there must be availability, accessibility, and affordability of effective health care system. The health system should also function to educate on eating habits, sedentary lifestyle or the need for regular exercises as well as compliance with medications. Couple with the above can help to reduce most of the complications diabetes present including eye abnormalities.

To help deal with eye and vision problems in children and young adults with diabetes, there must be availability and accessibility of eye care services. In addition to well trained eye care staff capable of delivering quality of care in well-resourced facilities should be established. If the above conditions are not met, eye complications as a result of diabetes in children and young adults can lead to poor vision in their early stage of life. Poor school performance coupled with low self-esteem can also result. At the regional and national level, there should be a policy to have all eyes of children and young adults with diabetes be screened periodically for early detection and management of all refractive and ocular surface abnormalities.

1.4 SIGNIFICANCE OF THE STUDY

Prevention of childhood blindness have gained global public health attention, as it forms one of the priority areas in Vision 2020-The Right to Sight program of the World Health Organization (WHO). Data from this study can help inform stakeholders in planning and implementation of effective policies for diabetic eye screening. Such policy will lead to the early detection of diabetic eye complications in children and young adults for improved care. In addition, early screening programs of such nature is also important to prevent vision loss later in life for children and young adults with diabetes mellitus. The outcome of this study may support the training and mentorship for upcoming optometrist, ophthalmologist and biomedical scientists and thereby help to build capacity towards clinical care and research in children and young adults living with diabetes mellitus in Ghana.

1.5 RESEARCH QUESTIONS

1. What is the prevalence of refractive and irregular cornea abnormalities in children and young adults with diabetes?

2. What level of visual acuity do children and young adults with diabetes have?

3. What common ocular surface abnormalities can be found in juvenile diabetic patients?

4. Is there an association between duration of diabetes and the presence of ocular surface abnormalities among children and young adults presenting at Korle-Bu Teaching Hospital?

1.6 OBJECTIVES OF THE STUDY

1.6.1 General Objectives

To determine the prevalence of refractive status and ocular surface abnormalities in Ghanaian children and young adults who visit Korle Bu teaching hospital with diabetes mellitus.

1.6.2 Specific Objectives

1. To determine the level of visual impairment (VI) among 70% of children and young adults with diabetes that visit diabetic clinics in Korle-Bu teaching hospital during the data collection stage.
2. To determine the presence of any degree of corneal curvature abnormalities in 60% of diabetic children and young adults available in Korle-Bu teaching hospital at the data collection stage.
3. To determine the presence of any possible ocular infection or inflammation from lid to the lens in 70% of children and young adults with diabetes that visit Korle-Bu teaching hospital during data collection
4. To determine the association between duration of diabetes and the presence of any ocular surface abnormalities in 60% of children and young adults with diabetes in Korle-Bu teaching hospital during data collection stage.

CHAPTER TWO

LITERATURE REVIEW

2.0 Introduction

Diabetes mellitus is a group of metabolic diseases caused by high sugar levels in the blood due to a defect in insulin secretion ("Diagnosis and classification of diabetes mellitus," 2005) which is more common in the older population. However, children can be born with or develop this disease at an early age. It presents with a lot of complications in the entire body system as well as the ocular system. Complications of diabetes mellitus in the eye includes diabetic retinopathy, refractive error, allergic conjunctivitis, macular degeneration, cataract, glaucoma, dry eyes and just to mention a few (Nathan, 1993). A significant number of studies have been conducted to understand the pathophysiology of the diseases, its complications and how to manage it. Below is a discussion on what has been published about diabetes in children.

2.1 Refractive Errors in Children and Young Adults

Refractive error is one of the major course of blindness and visual impairment in the world. Even though refractive errors can be corrected, most people living with the condition have no idea what is wrong with their vision or don't even know what to do about it. The various types of refractive errors include myopia, hyperopia and astigmatism, and all can also be found in children. Due to communication barriers and certain degree of naïve from the part of children, most significant refractive errors are missed before they get to certain age. In children, adequate retinal stimulation is essential for normal visual development. Refractive errors usually produces blur retinal images which prevents the development of normal visual system. This could easily result in amblyopia (lazy eye) if the error is not corrected before the child reaches the age of 10 years. It is therefore essential to screen all children for refractive errors and correct them as soon as possible before

getting to teenage and possibly to adulthood. A study conducted in Florida reported a prevalence of 15.8% of refractive error in children (Maul et al., 2000). The study also confirmed that refractive error caused 56.3% of the eyes with reduced vision. This indicates how serious uncorrected refractive error in children can be. For a diabetic child, the risk of developing refractive error is even higher compared to a non-diabetic child.

2.2 Epidemiology of Diabetes

Worldwide, diabetes Mellitus is thought to affect 415 million people and its prevalence continues to rise, with estimates that diabetes will affect more than 640 million people by the year 2040 (Cho et al., 2018).

Diabetes Mellitus is classified as type 1 (T1DM), which results from pancreatic beta cell failure such that insufficient insulin is produced to effectively clear blood glucose. Type 2 diabetes (T2DM), which is defined by a state of insulin resistance whereby target cells fail to effectively respond to the hormone. And gestational DM, occurs when pregnant women develop insulin resistance during pregnancy. In 2013, an estimated 382 million people were diagnosed with diabetes with T2DM accounting for 90% of the cases (Nathan, 2015). The cause of T1DM is uncertain and it is not preventable, while T2DM is almost always preventable through behavioral approaches such as diet, exercise, and weight control (Nathan, 2015)

When diabetes is not properly managed, long term complications of a group of diseases can be severe which may include heart disease, stroke, and kidney failure. Importantly, diabetes also profoundly impacts the ocular tissues with damage to the eye organ occurring even at the early stages of the disease (Usuelli & La Rocca, 2015). Most of the profound alterations that occur in the ocular structures are usually seen in the cornea and retina.

When diabetes mellitus (DM) becomes chronic, corneal impairments are almost inevitable. Once the eye has been exposed to hyperglycemia for long-term, the basement membrane accumulate enough toxic end products which will lead to cell death, opacity, and eventually an irreversible visual impairment (Herse, 1988).

2.3 Diabetes in Children

Type1 Diabetes Mellitus is one of the most common chronic diseases among children, and the disease can affect either anterior and posterior eye or ocular structures (Dhillon et al., 2016; Tekin et al., 2017). Diabetic retinopathy (DR), which is the most common microvascular complication of type 1 DM, is still one of the leading causes of blindness even in developed countries (Ciulla et al., 2003). Although paediatric subjects with type 1 DM would appear to be at low risk for this type of eye complication, Hautala and associates reported a high prevalence of DR (94%) and proliferative DR (35%) after an 18-year follow-up period in patients who had type 1 DM since childhood (Hautala et al., 2014).

In the last 30 years diabetes in children and adolescents is becoming a health problem in developing countries as shown by the growing number of reports (Adeleke et al., 2010; Afoke et al., 1992; Elamin et al., 1997; Majaliwa et al., 2007; Swai et al., 1993). In published studies, prevalence of type 1 diabetes has varied from low: 0.33 per 1000 in a Nigerian hospital and 0.95 per 1000 in Sudanese school children, 1.5 per 100, 000 per year in Tanzania, too high in Sudanese population, 10.1 per 100,000 per year (Afoke et al., 1992; Elamin et al., 1997; Swai et al., 1990). Retrospective studies have reported that 0.31% of hospital admissions were in children with type 1 diabetes, whilst the other had significant numbers of adolescent patients attending with type 1 diabetes (Adeleke et al., 2010). This large difference could be attributable to methodological discrepancies between studies, although true ethnic dissimilarities cannot be excluded. It is important to note that

most of these reports were hospital based, and are old, and may have underestimated the true prevalence of diabetes in children and adolescents.

Clinical studies from South Africa, Tanzania, Ethiopia and Ghana reviewed by Hall et al, (2011) suggested that the characteristics of type 1 and 2 diabetes in people from sub-Saharan Africa can differ somewhat from typical European populations (Lester, 1984; Olsen et al., 2004; Swai et al., 1990). As expected, insulinopenia is a prominent feature (Swai et al., 1990).

However, there has been a rapid epidemiological shift in the western countries, with younger obese and overweight patients suffering from type 2 diabetes (Eppens et al., 2006). And it is possible that this shift may also manifest in Sub-Saharan Africa (SSA). It has been suggested that the age of onset of type 1 diabetes is later in African communities (22-29 years) including Tanzania (15-19 years), South Africa (21-30 years), and Ethiopia (20-25 years) compared to European populations (Mbanya et al., 2010). Although there is some data on the prevalence of adult types 1 and 2 diabetes, there is no data on the prevalence of type 1 or 2 diabetes in younger persons less than 20 years in Ghana.

2.4 Diabetes and Refractive Errors

It is hypothesized that glucose enters the crystalline lens via the aqueous humour by a process of facilitated diffusion. Some experimental studies suggest that, in diabetes, hyperglycemia leads to an excessive uptake of glucose into the lens cells and fibres, which activates alternative routes for glucose handling such as the aldose reductase pathway. This instigates intracellular accumulation of sorbitol (Huntjens et al., 2012) followed by lenticular swelling (Huntjens et al., 2012), which causes a myopic shift. During hyperglycemia, the increased flux of glucose through the polyol pathway accounts for as much as one- third of the total glucose turnover (Huntjens et al., 2012). Aldose reductase- induced osmotic stress seems to be the cause of diabetic cataract (Huntjens et

al., 2012). Conversely, a decrease in glucose concentration in the aqueous humour is predicted to change the osmotic pressure between the aqueous humour, lens and vitreous humour with a decrease in the refractive index of the lens, leading to a hyperopic refractive shift.

Most studies have examined the effects on refractive error of changing blood glucose levels after insulin treatment has been instigated for the first time in newly-diagnosed diabetic patients (Giusti, 2003; Okamoto et al., 2000; Saito et al., 1993; Sonmez et al., 2005). Several studies involve small selected subsets of patients who have recently complained of visual blur, rather than typical, unselected, diabetic individuals (Riordan Eva et al., 1982; Wiemer et al., 2008). However, such work may not reflect the response of the eye to the more typical glucose fluctuations that are experienced by long-term diabetic patients on a day-to-day basis (*Alan Rubin - Google Scholar Citations*, n.d.). Rubin and friends investigated the diurnal variation in refractive errors in one diabetic patient versus one non-diabetic subject using an auto-refractor, but found no clinically significant differences between the subjects (Rubin et al., 2004). A study also found a stable refraction and visual acuity in fifty-three diabetic patients at different occasions within a month (Agardh et al., 2011).

2.5 Ocular Surface Abnormalities in Children and Young Adults

Ocular surface abnormalities are disorders that affects the eyelids, conjunctiva, cornea and lacrimal glands. Even though the prevalence is on the rise it is one of the most undiagnosed and undertreated ocular condition (Khanna, 2017). In children, allergic conjunctivitis is one of the common ocular surface disease. Allergic conjunctivitis is a spectrum of disorders comprising of seasonal allergic conjunctivitis, perennial allergic conjunctivitis, atopic keratoconjuctivitis, vernal keratoconjunctivitis and giant papillary conjunctivitis (Khanna, 2017).

Dry eye syndrome is another common ocular surface disease seen in children. It is characterized by feeling of dryness of the eyes due to tear instability on the ocular surface. This condition is worsened by the presence of conditions like diabetes mellitus, sjorgren's syndrome and hypertension which is more prevalent in women than in men (Schaumberg et al., 2003). Other forms of ocular surface abnormalities includes eyelid disorders due to lack of personal hygiene. Blepharitis is a common condition seen in children due to poor personal hygiene. It could be caused by staphylococcus or could be seborrheic. Staphylococcal blepharitis is more seen in children because they are more likely to touch the eyes with dirty hands. It causes severe itching and feeling of dryness which could affect other structures of the eye close to the eyelids like the cornea in which case, it becomes blepharo-keratoconjuctivitis. Other ocular surface abnormalities like pterygium are more seen in adults and young adults and is hardly seen in children.

2.6 Abnormalities of Diabetes in the Cornea and Ocular Surface

It is known that diabetes is associated with impaired wound healing. This is evident in the corneal epithelium. Diabetic eyes are at increased risk of dry eye, superficial punctate keratitis, recurrent corneal erosion syndrome and persistent epithelial defects (Shih et al., 2017). As the corneal epithelium is the first layer of the eye, it is constantly subjected to wear and tear and it needs to be constantly regenerated. Any process that affects wound healing or the speed of epithelial regeneration will have physiological impact and increases morbidity including ocular pain and redness (Shih et al., 2017). Recently a human study conducted in a hospital showed for the first time that tear levels of type 1 and 2 diabetic individuals had significantly higher insulin-like growth factor binding protein (IGFBP3) compared with age-matched normal adults.

Clinically observed diabetic cornea alterations include increased corneal thickness, epithelial defects, epithelial fragility and recurrent erosions, ulcers, edema, superficial punctate keratitis,

delayed and incomplete wound repair, endothelial changes, and neuropathy exemplified by reduced corneal sensitivity (G Bikbova, 2012). Similar to diabetic retina, diabetic corneas are also affected by dyslipidemia with increased content of sphingosines and ceramides (Ljubimov, 2017).

In the epithelium, diabetic problems are often summarily referred to as diabetic keratopathy emphasizing the major impact on corneal epithelium. Signs of diabetic keratopathy include epithelial fragility, defects and recurrent erosions, non-healing ulcers, corneal edema due to altered epithelial barrier function, superficial punctate keratitis, abnormally slow and often incomplete wound healing, lower cell density especially in the basal layer, and increased susceptibility to injury (Ljubimov, 2017). The data on the prevalence of diabetic keratopathy depending on the type of diabetes remain inconsistent and need to be revisited (Priyadarsini et al., 2017). It has been long suggested that diabetic keratopathy is a sign of peripheral neuropathy (Priyadarsini et al., 2017). This idea was substantiated by later findings of frequent association between corneal epithelial changes and manifestations of diabetic neuropathy (Bikbova et al., 2018).

chart to test visual acuity and slitlamps. The eye center has a pharmacy, an 18 bed ward
atients as well as a diagnostic wing with lasers and Humphrey visual field equipment.

artment also serves as a training center for undergraduate and postgraduate training in
mology and has contributed significantly towards the realization of the vision 2020 theme
years serving both foreigners and Ghanaians. It records an average daily Out Patient
ient (OPD) attendance of 140 old cases and about 40 new cases respectively.

ational Diabetes Management and Research Centre

ter is one of the well-resourced clinics that manages diabetic patients from the southern
hana. The center has 4 full time specialist physicians and 3 trained ophthalmic nurses. It
patient clinics for diabetic patients for all ages from Monday to Friday. There are 5
ng rooms, and 12 bed ward for emergency and patients in need of admission. The center
s almost 30 patients comprising new and old cases with diabetes every day.

ic also trains medical students and post graduates residents in endocrinology and internal
e.

ediatric Endocrine Clinic

diatric endocrine clinic in Korle-Bu teaching hospital is the first of its kind in the country.
ic offers specialize services to children and adolescents with diabetes and endocrine
s referred from most southern part of Ghana. And has the capacity of healthcare team that
lized in taking care of children with endocrine disorders and diabetes. The healthcare team
best of care as well as educating families of children with diabetes. The unit is also a
site for undergraduate medical and dental students, post-graduates residents of Ghana and
frican College and nursing students, and a fertile ground for research due to the availability

of clinical data. As a result, have collaborative research with other departments of the hospital, ministry of health and university of Ghana.

The unit OPD is the first point of call to all patients with eight nurses and five specialist physicians. It has an emergency room which is also a ward where very ill children requiring admissions are stabilized before being admitted to the other wards. The clinic has three medical wards, one babies unit for infants under 6 months and one surgical ward. And it has all the basic equipment and tools needed for effective health care delivery.

3.2 Target Population

All children and young adults age between 4 – 30 years diagnosed with diabetes mellitus and reported to Korle-Bu Teaching Hospital (the out -patients clinics of the Departments of Child Health, Medicine, Eye Centre and the National Diabetes Management and Research Centre) and who satisfied the inclusion criteria was recruited after written informed consent given by their parents, caretakers or themselves, and assent given by the children aged between 8 – 17.

3.3 Inclusion Criteria

All patients with diabetes mellitus, aged 4 – 30 years, and/or whose parents or guardians consented for inclusion, and assent given by those between ages 8 to 17 years was included for the study.

3.4 Exclusion Criteria

Children and young adults with diabetes who were sick on admissions, had severe respiratory disorders, cardiovascular or neurological derangement, and or patients not medically fit for ocular examination procedures was excluded.

3.5 Sample Size Calculation

The sample size for the study was determined using Cochran (1977) sample size formulae.

The denoted Cochran formulae entails:

$n=Z^2 (p)(q)/d^2$

Where n= minimum sample size required for the study

Z= desired confidence level at 95% (standard value of 1.96)

P=expected proportion in the population (the proportion of children and young adults with diabetes mellitus at Korle-Bu teaching hospital estimated to be recruited for this study was set at 50%)

d= precision (was set at 10% in this study, and expressed as 0.1)

q=1-p

Calculation

$n=Z^2 (p)(q)/d^2$

$n= (1.96)^2(0.5)(0.5)/(0.1)^2$

$n=96.04 \approx 96$

Therefore the minimum sample size required for this study is approximately 96 participants.

3.6 Sampling Procedure

The procedure for this study was to collect and analyze data to answer the research questions. Purposive sampling technique was used to select specific departments in Korle-Bu for the study. And systematic random sampling was employed to select final study participants during the data collection stage. After obtaining informed consent from the study subjects as well as their guardians, predesigned questionnaires was administered to collect all clinical and systemic data

(including patient demography, past medical history, laboratory investigations, for example blood glucose and glycated hemoglobin at diagnosis and during follow-up, type of DM that is either type 1 or 2). This was done after obtaining the list of patients with appointments on the day. And patients were consecutively called and examined one after the other based on time reported to the clinic. When a participant refused to take part in the study after he/she was consecutively invited, the next person on the list was called to continue with the process.

An average of 10 participants were recruited daily with strict observation of anti COVID-19 protocols. This was because, based on available evidence that corona virus is transmitted between people through close contact and droplets. The virus has also been reported to be transmitted through the mucous membranes of the eye and enters the tears through droplets, which pass through the nasolacrimal ducts and into the respiratory tract (Liang and Wu, 2020; Qing et al., 2020). Hence the measures below were considered during examinations of study participants.

3.6.1 Waiting and Screening Arrangement for COVID 19:

1. Wearing of face mask by the investigator and study participants including parents and guardians were observed strictly.
2. Temperatures of each participant and their accompanying parents/guardians was taken with a non-contact thermometer gun before entry into the clinic.
3. Study participants including their accompanying parents/guardians after hand washing was asked to sit at the patient waiting area for their turn. At least 2 meters apart social distancing was observed by participants and guardians at the waiting area.
4. Pens and tools for consenting were sanitized with alcohol based hand sanitizer.

5. Parents and guardians accompanying participants after informed consent were asked to wait outside of the examination room (waiting area) observing social distance protocol of two meters apart.

3.6.2 Clinical Examination Protocols for COVID 19:

1. Researcher wore N95 face mask, gloves, gown and a plastic shield over the eyes.
2. At the consulting room, study participants were given an alcohol based sanitizer to sanitize their hands before the start of examination.
3. There was a special plastic breadth shield on the slit-lamp machine to protect principal investigator and participants from any possible contamination from droplets.
4. Participants were requested to refrain from speaking during slit lamp and refraction procedures until completion. Participants were later allowed to talk and also answered questions at a safe physical distance from each other.
5. There was disinfection of instruments including slit lamps, retinoscopes, autorefra-keratometers, controls, accompanying breath shields and tonometer tip, keyboards, desks, door handles and chairs after examination of each patient.

3.7 Ocular Examinations

All study subjects were made to undergo an eye examinations, and ocular findings of visual acuity (VA), refractive errors (including keratometric readings), and ocular surface assessment of (lid, conjunctiva, cornea, tear film, anterior chamber and lens) was recorded. Visual acuity for children below 6 years was carried out using revised Sheridan Gardiner test cards at a distance of 3 meters. HOVT test chart was used to assess the vision of children between ages 6 and 7 years at a test distance of 3 meters. Snellen acuity chart was used for children of 8 years and above including young adults at a distance of 6 meters. Objective refractions were performed with United States

made WelchAllyn hand held Retinoscope and Righton Retinomax K-plus 3, hand held Auto Ref/Keratometre made in Tokyo, Japan. Subjective refraction findings were confirmed using an Indian made Trial Lens Set at a distance 3 and 6 meters depending on participants' age. Keratometric readings was taken using Righton Retinomax K-plus 3 hand held Auto Ref/Keratometre made in Tokyo, Japan. Dilating eye drops used for cycloplegic refractions included 1% Cyclopentolate hydrochloride ophthalmic solution made from Alcon group, 1% Tropicamide Ophthalmic solution from Alcon, 2.5% Phenylephrine Hydrochloride ophthalmic solution from Alcon, and 1% Amethocaine ophthalmic solution eye drop made from Alcon group of companies.

Ocular surface examination was performed with SL 3G slitlamp stereoscopic converging biomicroscope which uses halogen bulbs made from Topcon medical systems, Japan. Together with 20 D (diopter) Volk lens of Germany made for detailed anterior eye segment assessment.

3.8 Pre-Testing

The questionnaire was pre-tested among children and young adults with diabetes mellitus at Greater Accra Regional hospital. The purpose of pre-testing was to get to know if the questions are clear enough to be understood by the study participants. Pre-testing also helped in identifying lapses in the questions, and assisted the researcher to determine the duration of time required to administer the questions. All forms of anomalies in the questionnaire detected was corrected before actual data collection started.

3.9 Data Handling

Data coding, quality assurance, security and confidentiality of participant information

The study was done keeping the Declaration of Helsinki for human subjects in medical research. For this study, data security, quality assurance and confidentiality of participants' information were held paramount. Consequently, the principal investigator ensured that adequate, accurate and relevant data was collected and not excessive for the purposes of the study to uphold quality assurance. The principal investigator will ensure appropriate archiving of data generated during the study and at the end of the study. Identities of study participants were concealed by codes. The researcher assigned codes to each questionnaire or participants' information. Information of study participants was treated confidential, in such a manner that names of participants did not appear on any write-up. All non-electronic research data has been stored in locked filling cabinets (including CD and flash drive) and will ensure this is accessible only to authorized persons. All unwanted documentation or paper which contains confidential data was disposed appropriately. However, at the end of the study, all documentation or data connected with the study will be kept for five years in a secured cabinet. The principal investigator, the Institutional Review Board (IRB) of the Korle Bu Teaching Hospital and University of Ghana School of Public Health will be the authorized persons who will have access to the stored data.

3.10 Data Processing and Analysis

Data was cleaned before analysis, and analysis was done using stata/IC version 15.0. Continuous numerical data has been presented as Mean and Standard deviation (SD) and categorical data as percentages (%). Data has also been presented as frequency tables and pie or bar charts as appropriate. Chi-square test has been used to compare proportions and test for independence of conditions among the categories of patients. T-test and ANOVA was used to compare means of

age groups where appropriate. The level of visual impairment was measured and classified as normal, mild, moderate and severe visual impairment. The presence of any degree of corneal curvature abnormalities, and any possible infection or inflammation from lid to lens have also been documented. The association between duration of diabetes (duration of diabetes have been categorized as; 0-5 years, 6-10 years and more than 10 years) and the presence of ocular surface abnormalities among the children and young adults presenting at the Korle-Bu Teaching Hospital were analyzed using Chi-square test of association. Significance was set at α=0.05.

3.11 Ethical Consideration

Ethical approval was sought from the Institutional Review Board (IRB) of Korle Bu Teaching Hospital (KBTH). Permission was also gotten from Departmental Management Teams of the three study sites/departments, and patient information was treated very confidential. This was done by ensuring names of patients did not appear on questionnaire or any write-up. Information obtained from study participants would be kept in a file which will not have the participant's name but a code number assigned.

There was very minimum risk to participants in this study. Some of the eye drops which was instilled during examination procedures caused temporal vision loss for 4 to 6 hours after which vision was restored fully. However, no experimental procedures were involved. Participants had the right to voluntarily participate or refused to participate in the study and did not offend the investigator in any way.

3.12 Limitation

The Covid-19 pandemic posed a major limitation to the study during the data collection stage. In the sense that, persons with underlying conditions such as diabetes are said to be at risk of developing severe illness when they contract the virus. As a result, most of the diabetic patients

were not willing to come to the hospital for regular reviews even after some of the COVID-19 pandemic restrictions have been eased. This situation reduced the number of children and young patients with diabetes who reported monthly to Korle-Bu teaching hospital for regular medical check-ups.

Another limitation had to do with the fact that, children were among the population advised by the ministry of health and Ghana health service to always stay at home as a result of the COVID-19 pandemic. In view of this, some of the parents of children with diabetes were reluctant to come to the hospital even when personal telephone calls were made to bring their children.

The two above afore mentioned situations contributed to not getting the number of patients for the estimated sample size.

Despite these limitations, the study will still be able to contribute to the body of knowledge regarding refractive and ocular surface abnormalities among children and young adults suffering from diabetes.

3.13 Funding

The study participants were provided with an amount of money for transportation to and from the hospital with the support of ophthalmology unit at the university of Ghana medical school. Again participants who were prescribed spectacles and could not afford were provided the financial support to help them acquire.

CHAPTER FOUR

RESULTS

4.0 Introduction

This study examined the refractive, cornea curvature irregularities and ocular surface abnormalities to find out the prevalence of these conditions among children and young adults with diabetes mellitus that visit Korle-Bu teaching hospital for regular monthly medical reviews. A well-structured questionnaire was used to collect demographic data about their medical condition and also had their eyes examined. The data obtained was analyzed using stata/IC version 15.0 statistical software. Following are the results from the study.

4.1 Demographic and clinical characteristics of study participants

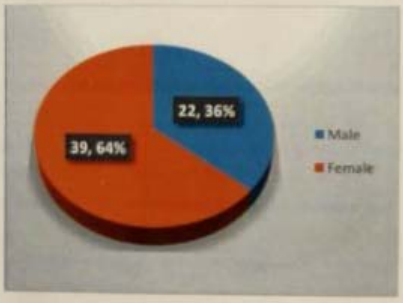


Figure 4.1: Sex distribution of children and young adults with diabetes

The figure above shows the sex distribution of the participants. A total of sixty-one (61) children and young adults participated in this study. And out of the total study participants, 36% were males and 64% females as seen in figure 4.1.

Figure 4.2: Age group characteristics of participants

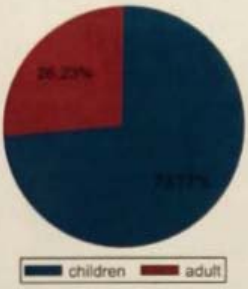
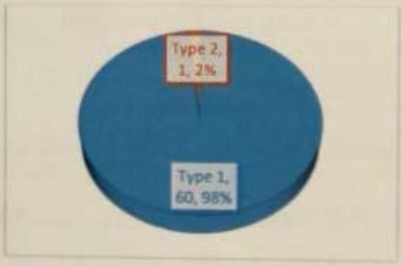
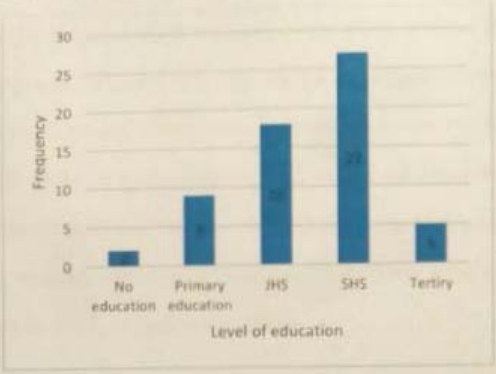


Figure 4.3: Distribution of Types of Diabetes among Participants



In figure 4.2 and 4.3 above, it was revealed that there were more children with diabetes (73.77%) compared to young adults (26.23%) among the study participants. With majority of the participants having type 1 diabetes of 98%, while 2% had type 2 diabetes.

Figure 4.4: Distribution of educational level of children and young adults with diabetes



Results from the study showed that 44.26% of the participants have senior high school education (SHS), and 3.27% with no level of education. It was also revealed that participants with junior high school education (JHS) was (29.51%). While those with primary and tertiary educations were found to be 14.75% and 8.20% respectively.

Table 4.1: Demographic characteristics of children and young adults with diabetes

Variable	Mean	standard deviation	median	min	max
Age	16.0	5.1	15.0	7	29.0
Age at diagnosis	10.3	4.0	10.0	4.0	20.0
Duration of diabetes	5.7	3.9	5.0	1.0	19.0
Body mass index	23.4	5.2	22.8	14.0	34.2
Tear break up time	11.4	2.6	12.0	5.0	16.0

In figure 4.1 above, the results show the mean age of participants was 16 years, with SD +/-5.1, median 15.0 years, minimum of 7 years and maximum years of 29. Mean age of being diagnosed of diabetes was 10.3 years, SD +/-4.0, median of 10 years, minimum of 4.0 years, and maximum of 20.0. Mean duration of diabetes among participants was found to be 5.7, SD of +/- 3.9, median of 5.0, minimum 1.0 and maximum of 19.0. Results also noted that mean body mass index (BMI) among participants was 23.4, with SD +/- 5.2, median 22.8, minimum 14.0 and maximum 34.2. Again in table 4.1, mean tear break up time (TBUT) was found to be 11.4, SD +/- 2.6, median of 12.0, minimum 5.0, and maximum of 16.0.

Table 4.2: Clinical characteristics of children and young adults with diabetes

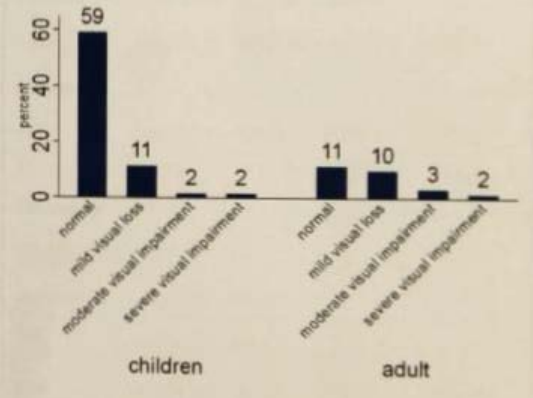
Variable	Number	Percentage (%)
Type of treatment		
Insulin	61	100.0
Oral hypoglyceamia	-	-
Combination	-	-
Comorbidities	7	11.5
Family history of diabetes	18	29.5
History of spectacle use	17	27.9
History of eye trauma	7	11.5
History of eye surgery	4	6.6
BMI category		
Underweight	12	19.7
Normal	36	59.0
Over weight	7	11.5
Obesity	6	9.8

BMI = Body mass index

Table 4.2 the shows clinical characteristics of study participants. And it was indicated that all study participants were using insulin as a primary source of treatment. Again the results shows that only 11.5% of the participants have other comorbidities such as hypertension, sickle cell anaemia or asthma in addition to their diabetes. The table also revealed 29.5% of the participants have family history of diabetes. In terms of participants' previous history of wearing spectacles, 27.9% responded affirmatively whiles comparing previous history of eye trauma to eye surgery, it was found that 11.5% have history of eye trauma and 6.6% having history of eye surgery.

4.2 Levels of Visual Impairment among Children and Young Adults with Diabetes

Figure 4.5: Shows level of Visual impairment among participants



Regarding visual impairment, results showed that 59% of the children with diabetes had normal vision (NV), while 11% of young adults achieved similar level of vision. But only 2% of both children and young adults each recorded severe visual impairment (SVI) with a P-value of 0.06

and Chi square of 8.15. The figure also revealed that in the children's age group 11% have mild visual loss, while 10% have mild visual loss in the young adult group. With respect to moderate visual impairment it was noted to be 2% in children and 3% among young adults.

Table 4.3: Shows demographic characteristics and level of visual impairment among children and young adults with diabetes.

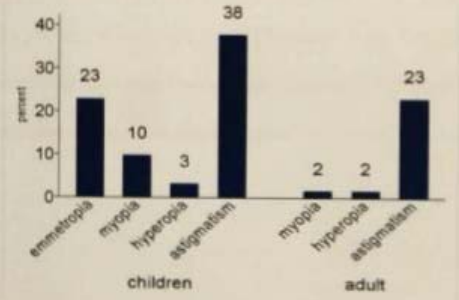
Demographic profile (%)	Classification of VI				P-value	Total
	NV n(%)	MVI n(%)	MODVI n(%)	SVI n(%)		
Sex					**0.291**	
Male	15(24.6)	4(6.6)	1(1.6)	2(3.3)		22(36.1)
Female	28(45.9)	9(14.8)	2(3.3)	-		39(63.9)
Total	43(70.5)	13(21.3)	3(4.9)	2(3.3)		61(100.0)
Age group					**0.063**	
4-17	34(55.7)	6(9.8)	1(1.6)	1(1.6)		42(68.9)
18-30	9(14.8)	7(11.5)	2(3.3)	1(1.6)		19(31.1)
Education					**0.573**	
No education	2(3.3)	-	-	-		2(3.3)
Primary	8(13.1)	1(1.6)	-	-		9(14.8)
JHS	13(21.3)	4(6.6)	-	1(1.6)		18(29.5)
SHS	18(29.5)	5(8.2)	3(4.9)	1(1.6)		27(44.3)
Tertiary	2(3.3)	3(4.9)	-	-		5(8.2)

VI = Visual impairment, NV= Normal Vision, MVI = Mild Visual Impairment, MODVI = Moderate Visual Impairment, SVI = Severe Visual Impairment.

Table 4.3 shows that 24.6% of males have normal vision (NV), while about 45.9% of females also recorded normal vision. Again it was also noted that 3.3% of males had severe visual impairment (SVI), but surprisingly no female had vision of severe impairment giving (P-value of 0.29) which is statistically not significant. The table revealed that there was no statistical significance between children and young adults with respects to their levels of visual acuities (P-value = 0.063). Participants' educational level also showed no significant association with levels of their visual acuities (P-value of 0.573).

4.3 Type of Refractive Errors and Cornea Irregularities among Children and Young Adults

Figure 4.6 Characteristics of Type of Refractive Error among Participants



Results about the type of refractive errors among participants in figure 4.6 revealed astigmatism to be the most common type of refractive error among the participants (60.7%), whereas hyperopia was the lowest (4.9%). Specifically, the figure above shows 38% of children, and 23% of adults have astigmatism as well as 3% of children and 25% of adults having hyperopia. Again it was noted that, among the children age group 10 % have myopia whereas only 3% have hyperopia. Meanwhile among the adults, 2% of the participants have myopia and hyperopia separately.

Table 4.4: Demographic characteristics and corneal curvature abnormalities in diabetic children and young adults

Demographic characteristics	Abnormal	Normal	P-value	Total
Age			0.165	
4-17	6(9.8)	36(59.0)		42(68.9)
18-30	6(9.8)	13(21.3)		19(31.1)
Sex			0.553	
Male	4(6.6)	18(29.5)		22(36.1)
Female	8(13.1)	31(50.8)		39(63.9)

In table 4.4, both children and young adults have high normal cornea curvatures of 59.0% and 21.3% respectively and given (P-value = 0.16; Chi square = 4.36). Male and female participants also recorded normal cornea curvatures of 29.5% and 50.8% respectively (P-value = 0.55), with no level of statistical significance.

4.4 Ocular Surface Abnormalities among Children and Young Adults

Table 4.5: Characteristics of ocular surface abnormalities among participants

Ocular infections	Number N (%)
Dry eyes	11(18.0)
Lid abnormalities	4(6.6)
Allergic conjunctivitis	20(32.8)
Cornea	6(9.8)
Cataract	3(4.9)

The ocular surface abnormalities table above shows conjunctivitis as the most prevalent ocular surface abnormality among the participants with a percentage of 32.8%. This is followed by dry eye syndrome with 18%, 4.9% for cataracts, and 9.8% with cornea infection.

Table 4.6: Demographic characteristics and ocular infection in diabetic children and young adults

Demographic characteristics	Dry eyes	Lid	AC	Cornea	Cataract	Total
n(%) n(%) n(%)	n(%)	n(%)	n(%)			
Age						
4-17	4(6.6)	1(1.6)	12(19.7)	4(6.6)	2(3.3)	23(37.8)
18-30	7(11.4)	3(4.9)	8(13.1)	2(3.3)	1(1.6)	21(34.3)
Total	11(18.0)	4(6.5)	20(32.8)	6(9.9)	3(4.9)	44(72.1)
Sex						
Male	5(8.2)	1(1.6)	10(16.4)	2(3.3)	1(1.6)	19(31.1)
Female	6(9.8)	3(4.9)	10(16.4)	4(6.6)	2(3.3)	25(41.0)
Total	11(18.0)	4(6.5)	20(32.8)	6(9.9)	3(4.9)	44(72.1)

AC = Allergic conjunctivitis.

Noting from table 4.6 with age group perspective in children and young adults, those of ages (4-17) have 19.7% of allergic conjunctivitis, 6.6% dry eyes and 3.3% with cataract. Among the adults (18-30), there is an indication that 13.1% have allergic conjunctivitis, 11.4% with dry eyes and 1.6% with cataract. Also indicated is both female and males recorded similar percentages of 16.4% for allergic conjunctivitis but different percentages for dry eyes. With dry eyes, the females recorded 9.8% and males recorded 8.2%. Males recorded 1.6 for cataract while females had 3.3%.

4.5 Association between duration of diabetes and Presence of any Ocular Surface Abnormality

Table 4.7: Association between duration of diabetes and the presence of ocular surface abnormalities among the children and young adults with diabetes

Demographic characteristics	Dry eyes	Lid	AC	Cornea	Cataract	Total
n(%) n(%) n(%)	n(%)	n(%)	n(%)			
Duration of diabetes						
1-5	4(6.6)	1(1.6)	11(18.0)	4(6.6)	3(4.9)	23(37.7)
>5	7(11.4)	3(4.9)	9(14.8)	2(3.3)	-	21(34.4)
Total	11(18.0)	4(6.6)	20(32.8)	6(9.8)	3(4.9)	44(72.1)
P-values	0.179	0.303	0.503	0.488	0.254	

AC = Allergic conjunctivitis.

The table above indicates that there is no statistical significance between longer duration of having diabetes and the presence of any ocular surface abnormalities among study participants. Since all anterior segment variables examined gave P-values greater than 0.05 (thus $p>0.05$).

CHAPTER FIVE

DISCUSSION

5.0 Introduction

This study sought to examine the prevalence of refractive and ocular surface abnormalities among children and young adults with diabetes mellitus at Korle-Bu teaching hospital to get understanding and also add unto knowledge about the characteristics of these abnormalities. Participants answered questions from structured questionnaire and also had their eyes examined following signed informed consent. Results revealed certain patterns of refractive error and ocular surface abnormalities among the participants. And therefore this chapter summarizes how their age, sex, type of diabetes and duration of having diabetes affected the occurrence of these abnormalities among study participants.

5.1 Sociodemographic Characteristics of Participants

From the results, more females (64%) than males (36%) participated in the study. And many of the participants fell under the age bracket of children (4-17 years) thus 73.77% compared to 26.23% of young adults' age group (18-30). Results also showed that 98% of the study participants had type 1 diabetes, and all of them are insulin dependent. This collaborate with a study conducted by Dhilon et al (2016) in a tertiary diabetic clinic in the United Kingdom, which indicated Type1 diabetes as one of the most common chronic diseases among children, and showed longer duration of having diabetes to be the risk factor for developing diabetic related eye complications. It was surprising to note from the results that 59.0% of children and young adults with diabetes that visit Korle-Bu teaching hospital had normal Body Mass Index (BMI) of 18.5 – 24.9.

As stated in the results, most of the participants for the study had at least Senior High School (SHS) education of 44.26%, with only 8.2% of the young adult group owning a tertiary education. This can be attributed to the fact that most of the participants were children compared to the young adults. Meanwhile 29.51% had Junior high school (JHS) education, 14.75% were at the primary school level, and 3.28% having no level of education.

It was interesting to note from study findings that only 11.5% of participants had other comorbidities like hypertension, asthma or sickle cell anaemia in addition to diabetes. Compared to the description of family history of diabetes among participants which was 29.5%. On the other hand, 27.9% were noted to have had previous history of using prescription spectacles and ready to be prescribed a new pair of glasses.

Participants' previous history of eye trauma and injuries were found to be 11.5% and 6.6% respectively among participants which were all not statistically significant.

5.2 Levels of Visual Impairment Found among Participants

The first specific objective of this study was to determine the level of visual impairment among children and young adults with diabetes mellitus visiting clinics at Korle-Bu teaching hospital. This was because, the selected departments from Korle-Bu teaching hospital is said to offer some of the first class management approaches to diabetic patients not only in Ghana but also to other neighbouring countries. The study confirmed that most of the children and young adults have normal vision (NV) of 59% and 11% respectively, but was not statistically significant. However only 2% of each of the children and young adult groups had acuities of the severe visual impairment levels ($p>0.05$). Chi square value from this study indicates levels of visual impairment among participants is independent of the age grouping (Chi 2 = 8.15). As this was consistent with

a study conducted by Agardh et al (2011) and reported stable visual acuities in fifty-three diabetic patients in United States who visited the clinic four different times in one month.

5.3 Characteristics of Refractive Error and Cornea Curvature

Refractive errors and cornea curvature irregularities were among the key variables in diabetic children and young adults that this study sought to investigate. It was interesting to find from study results that astigmatism happened to be the most common type of refractive error among the study participants of 60.7%. And again astigmatism continued to be the most prevalent type of refractive error among both children and the young adult age groups of 38% and 23% respectively. Comparing these findings with the study done by Agardh and friends (2011), which found refraction to be completely stable among 43 out of 53 patients and went further to conclude that refraction and visual acuity test results were highly reproducible and stable in patients with reasonably well controlled diabetes. Again, Rubin and friends investigated the diurnal variation in refractive errors in one diabetic patient versus one non-diabetic subject using an auto-refractor in United States, but found no clinically significant differences between the subjects (*Alan Rubin - Google Scholar Citations*, n.d.)

It was also revealed that most children and young adults had normal cornea curvatures of 59.0% and 21.3% respectively ($p>0.05$), and Chi square revealing no association between cornea abnormality and age groups (Chi 2= 4.36)

5.4 Ocular Surface abnormalities among Children and Young Adults with Diabetes

Allergic conjunctivitis had a higher prevalence among children and young adults as reported in a couple of studies. Results of this study showed 32.8% of the participants were diagnosed with allergic conjunctivitis followed by dry eyes with a prevalence of 18%. A study conducted in Taiwan in 2016 found a higher risk of developing allergic conjunctivitis in children with type 1

diabetes mellitus than children without diabetes. This observation was attributed to higher T cell counts that was found in children with diabetes (Chen et al., 2017). Some studies argue that development of allergic conjunctivitis is highly influenced by socio-economic status and environmental factors. However, other recent studies also found contradicting results where prevalence of allergic conjunctivitis was significantly higher in children with diabetes irrespective of their socio-economic status or the nature of their environment (Stene & Joner, 2004). It is evident that more research need to be done to determine whether allergic conjunctivitis in diabetic children is actually due to environmental factors and socio-economic status or it's due to the presence of diabetic mellitus. Nevertheless, my study supports the theory that, the presence of diabetic mellitus increases the risk of developing allergic conjunctivitis.

Tear stability on the cornea is facilitated by adequate amount of lipid production from the Meibomian glands. Poor glycemic control is able to disrupt the adequate metabolism of lipids in the body resulting in higher incidence of dry eyes. A study was done in Israel in 2005 which concluded that poor glycemic control correlates with the use of artificial tears in diabetic patients (Kaiserman et al., 2005). This was in line with this study as a significant number (18%) of the participants had dry eyes.

Cataract was the least prevalent ocular complication in this study which was as expected based on the younger age groups of the study population. Most cataract cases are age related and would always have a lower prevalence in a younger age group.

5.5 Duration of Diabetic Mellitus and the Presence of Ocular Surface Abnormalities

The correlation between duration of diabetic retinopathy and ocular complications have been reported to be positive in most publications. However, in this study children with less than 5 years duration of having type 1 diabetes mellitus had higher prevalence of ocular surface abnormalities

compared to those with more than 5 years duration of the disease. This contradicts the findings of most related published works. As this could be due to low sample size of the study and the fact that the association between ocular surface disease and duration of diabetic mellitus was not statistically significant ($p>0.05$).

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

The association between diabetes and ocular surface abnormalities has been documented in various studies. Children with diabetic mellitus are at higher risk of developing ocular surface diseases compared to non-diabetic children.

All the objectives of this study was successfully achieved. Most of the diabetic children had normal vision but 2% of the study participants had severe visual impairment. Also there was 11% and 10% of mild visual impairment observed in the children and young adult age groups respectively. Although these results were not statistically significant, they represent a certain degree of clinical significance.

Astigmatism was the highest type of refractive error observed in the study followed by myopia, with hyperopia being the lowest type of refractive error. This was justified by the highest prevalence of irregular cornea curvature which resulted in higher prevalence of astigmatism.

The highest prevalent ocular surface abnormality was allergic conjunctivitis, followed by dry eyes, with cataract having the least prevalence. These results were as expected based on young ages of the target population.

There was no statistically significant association between duration of diabetes and type of ocular surface abnormality even though other studies have found otherwise. This could be attributed to low sample size of this study.

CHAPTER SIX

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6.2 RECOMMENDATIONS

The following recommendations are being suggested to help prevent complications resulting from refractive and ocular surface abnormalities among children and young adults with diabetes:

Clinical level

- It is important for physicians and/or pediatricians to refer children with diabetes mellitus to eye departments for early refractive assessment to prevent the risk of developing lazy eyes (amblyopia) among the said populations.
- Further clinical test needs to be done to determine whether ocular surface abnormalities in diabetic mellitus children are due to the environmental factors or the disease itself.

Government and Policy level

- The need for policies towards early eye screening programs for children and young adults with diabetes to prevent the occurrence of any possible future visual complications.
- Recommend policy implementation framework towards drawing national guidelines for diabetic eye abnormalities management, since currently there is no such policy in Ghana

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APPENDICES

Appendix A: Informed Consent Form for Young Adult Participants

Personal details of study participants:

Title:	Surname:	First Name:	Middle Name:

Place of birth	Date of birth	Gender
		Male [ ] Female [ ]

Phone number(s)	e-mail address

Home address	Postal address if any

Nationality: Ghanaian [ ] Foreigner [ ]. If foreigner, State Country:

Occupation:

Person to notify in case of emergency	
Name:	Telephone:

Principal investigator's information:

Project title: Refractive and Ocular surface abnormalities in children with diabetes in Korle-Bu Teaching Hospital
Principal Investigator (PI): Dr. Kwame Okyere Osei
Addresses: Optometry Unit, Lions International Eye Centre, Korle Bu Teaching Hospital, Accra. P. O. Box DT 2622, Adenta, Accra.

General information about the research:

Refractive errors and ocular surface abnormalities associated with diabetes is becoming a public health concern. As children and young adults requires clear and comfortable vision for well sustain developmental, school and work activities. Ocular abnormalities that comes with diabetes needs to be addressed in children and young adults to prevent future visual complications. The primary goal of this study is to determine the prevalence of refractive and ocular surface abnormalities in children and young adults at Korle Bu Teaching hospital.

Procedures of the study:

All study participants will undergo an eye assessment, and ocular findings of visual acuity (VA), refractive errors (including keratometric readings), anterior segments (lid, conjunctiva, cornea, pupils, anterior chamber and lens) findings will be recorded. Predesigned questionnaires will be administered to collect all clinical data: systemic (including patient demography, past medical history, laboratory investigations, for example blood glucose and glycated hemoglobin at diagnosis

and during follow-up, type of DM that is either type 1 or 2). A second structured questionnaire will be designed to find out from parents or caregivers how children from 4 to 17 years with diabetes comply with daily intake of anti-diabetic medications coupled with other forms of dietary and lifestyle management.

Possible Risks and Discomforts:

This study may result in very minimal risk or danger to participants. Some of the eye drops which may be instilled during examination procedures may sting for few seconds. In addition as an adverse effect some eye drops can cause temporal vision loss especially at near for 4 to 6 hours after which vision will be restored fully. No experimental procedures are involved. Participants name will not be documented.

Possible Benefits:

There is no direct financial benefit to participants. However, information from this study represents important baseline measures essential for national eye care policies, and for assessing trends in improvement in these measures with interventions over time.

Confidentiality:

Information obtained from study participants would be treated as confidential and kept in a file which will not have the participant's name on it but a code number assigned, which will not be disclosed to anyone.

Compensation:

There is no financial compensation or any form of reward for participating in this study.

Voluntary Participation and Right to Leave the Research:

Study participants have the right to voluntarily participate or refuse to participate in this study which will not offend the investigators in any way. Thus, participating in this research is voluntary and participant can withdraw without any penalty.

Contacts for Additional Information:

The proposal has been reviewed and approved by the Institutional Review Board (IRB) at the Korle-Bu Teaching Hospital which has the mandate to protect participants from harm. In case of any research-related injury or pertinent questions about the rights of study participants, participants may contact the IRB Office between the hours of 8am-5pm through the landline below. Study participants may also contact the investigator with the address and telephone numbers below for further information about the study.

Contact Information:

The Chairman,

Institutional Review Board,

Korle-Bu Teaching Hospital, Accra.

0302666766

Email addresses: rdo@kbth.gov.gh

Dr Kwame Okyere Osei

Optometry Unit, Lions International Eye Centre, Korle-Bu Teaching Hospital, Accra.

Tel.: 0501212669

Volunteer Agreement:

I.....Parent/Guardian of..... have been invited to let my child/ward take part in the above-stated research (Refractive and Ocular Surface Abnormalities in Children and Young Adults at Korle-Bu Teaching Hospital). I have had the opportunity of understanding the benefits, risks and procedures for the research title.

I have also been given an opportunity to have any questions about the research answered to my satisfaction. I agree voluntarily with the participation of my child/ward.

....

Name and signature of participants' parent/guardian Date

If participants' parent/guardian cannot read the form themselves, a witness must sign here:

I was present while the benefits, risks and procedures were read to the volunteer. All questions were answered and the volunteer has agreed with the participation of the child/ward in the research.

....

Name and signature of witness Date

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above individual.

....

Name signature of person who obtained consent

Appendix B: Child Assent Form

Introduction

My name is Dr Kwame Okyere Osei and I am from the Eye Centre at the Korle Bu Teaching Hospital. I am conducting a research study entitled "Refractive and Ocular Surface Abnormalities in Children and Young Adults with diabetes mellitus at Korle Bu Teaching Hospital, Ghana". I am asking you to take part in this research study because I am trying to learn more about the demographics, clinical features and progression of Refractive Errors and Ocular Surface Abnormalities in children and young adults with diabetes that present at Korle Bu Teaching Hospital. This will take about three months to complete.

General Information

If you agree to be in this study, you will be asked to complete a set of questionnaire to assess your demographic (age, sex, history of symptoms) and clinical (ophthalmic, and other medical) history.

You will also be interviewed to solicit information about their eyes and general body symptoms. An eye examination with a slit lamp biomicroscope, and refraction using a retinoscope or handheld automatic refractometer will be performed. Information from your medical records will be entered in a questionnaire and kept confidential.

Possible risks

There may be some minimum risks in participating in this study. For example some of the eye drops which may be instilled during examination procedures may sting for few seconds. In addition, some eye drops can cause blurriness of vision for 4 to 6 hours after which vision will be restored fully. No experimental procedures are involved. And there will not be any documentation of participants' name.

Possible Benefits:

The results from the study will also provide a scientific basis for early diagnosis and management of children and young adults having refractive and/ or any ocular surface abnormality associated with diabetes. This would lead to an improved care to prevent future visual complications. The outcome of this study may also contribute to the body of knowledge relating to early detection and management of diabetic related eye abnormalities in children and young adults in Ghana.

Voluntary Participation and Right to Leave the Research

You can stop participating at any time if you feel uncomfortable. No one will be angry with you if you do not want to participate.

Confidentiality

Your information will be kept confidential. No one will be able to know how you responded to the questions and your information will be anonymous.

Contacts for Additional Information

You may ask me any questions about this study. You can call me at any time [Tel: 050 1212669] or talk to me the next time you see me.

Please talk about this study with your parents before you decide whether or not to participate. I will also ask permission from your parents before you are enrolled into the study. Even if your parents say "yes" you can still decide not to participate.

Your rights as a Participant

This research has been reviewed and approved by the Institutional Review Board of Korle Bu Teaching Hospital for Medical Research (KBTH-IRB). If you have any questions about your rights as a research participant you can contact the IRB Office between the hours of 8am-5pm through the landline 0302666766 or email addresses: rdo@kbth.gov.gh

VOLUNTARY AGREEMENT

By making a mark or thumb printing below, it means that you understand and know the issues concerning this research study. If you do not want to participate in this study, please do not sign this assent form. You and your parents will be given a copy of this form after you have signed it. This assent form which describes the benefits, risks and procedures for the research titled "refractive and ocular surface abnormalities in children and young adults with diabetes presenting at the Korle Bu Teaching Hospital, Ghana" has been read and or explained to me. I have been given an opportunity to have any questions about the research answered to my satisfaction. I agree to participate.

Child's Name: ..... Researcher's Name: .....

Child's Mark/Thumbprint: .....

Researcher's Signature: .....

Date: ..... Date: .....

Appendix C: Parental Consent Form

Introduction

My name is Dr Kwame Okyere Osei and I am from the Eye Centre at the Korle Bu Teaching Hospital. I am conducting a research study entitled "Refractive and Ocular Surface Abnormalities in Children and Young Adults with diabetes mellitus at Korle Bu Teaching Hospital, Ghana". I am asking you to allow your child/ward to take part in this research study because I am trying to learn more about the demographics, clinical features and progression of Refractive Errors and Ocular Surface Abnormalities in children and young adults with diabetes that present at Korle Bu Teaching Hospital. This will take about three months to complete.

General Information

If you agree with your child/ward taking part in this study, your child/ward will be asked to complete a set of questionnaire to assess his/her demographic (age, sex, history of symptoms) and clinical (ophthalmic, and other medical) history.

Your child/ward will also be interviewed to solicit information about his/her eyes and general body symptoms. An eye examination with a slit lamp biomicroscope, and refraction using a retinoscope or handheld automatic refractometer will be performed. Information from your child/ward's medical records will be entered in a questionnaire and kept confidential.

Possible risks

There may be some minimum risks as your child/ward participates in this study. For example some of the eye drops which may be instilled during examination procedures may sting for few seconds. In addition, some eye drops can cause blurriness of vision for 4 to 6 hours after which your

child/ward's vision will be restored fully. No experimental procedures are involved. And there will not be any documentation of participants' name.

Possible Benefits:

The results from the study will also provide a scientific basis for early diagnosis and management of children and young adults having refractive and/ or any ocular surface abnormality associated with diabetes. This would lead to an improved care to prevent future visual complications. The outcome of this study may also contribute to the body of knowledge relating to early detection and management of diabetic related eye abnormalities in children and young adults in Ghana.

Voluntary Participation and Right to Leave the Research

Your child/ward can stop participating at any time if he/she feels uncomfortable. No one will be angry with you or your child/ward if you do not want your child/ward to participate.

Confidentiality

Your child/ward's information will be kept confidential. No one will be able to know how your child/ward responded to the questions and your child/ward's information will be anonymous.

Contacts for Additional Information

You may ask me any questions about this study. You can call me at any time [Tel: 050 1212669] or talk to me the next time you see me.

Please talk about this study with your child/ward before they decide whether or not to participate. Although I am asking permission from you before your child/ward enrolls into the study, he/she is at liberty to still decide not to participate.

The rights of your child/ward as a participant in the study

This research has been reviewed and approved by the Institutional Review Board of Korle Bu Teaching Hospital for Medical Research (KBTH-IRB). If you have any questions about the rights of your child/ward as a research participant you can contact the IRB Office between the hours of 8am-5pm through the landline 0302666766 or email addresses: rdo@kbth.gov.gh

VOLUNTARY AGREEMENT

By making a mark or thumb printing below, it means that you understand and know the issues concerning this research study. If you do not want to participate in this study, please do not sign this consent form. You will be given a copy of this form after you have signed it.

This consent form which describes the benefits, risks and procedures for the research titled "refractive and ocular surface abnormalities in children and young adults with diabetes presenting at the Korle Bu Teaching Hospital, Ghana" has been read and or explained to me. I have been given an opportunity to have any questions about the research answered to my satisfaction. I agree with my child/ward participating in this study.

Parent's Name: ..... Researcher's Name: .....

Parent's Mark/Thumbprint: .....

Researcher's Signature: ..... Date: .....

Appendix D: Diabetic Study Questionnaire

A. Demographic Data

1. Identification number.....

2. Folder number..... 3. Age ..... Sex male☐ female☐

4. Ethnicity..... 5. Educational level... .....

6. Date of diagnosis.....7. Age at diagnosis.....

8. Weight (kg).....9.Height (m).....10. BMI.....

11. Address:

.....

12. Referred from (more than one applicable)

a. Paediatrician ☐

b. Physician ☐

c. Peripheral hospital ☐

d. Other (please specify) ☐

A. History

1. Presenting ocular complaint

i.....

.....

.....

ii. None.....

SYSTEMIC EVALUATION

Type of Diabetes Mellitus

a. Type I..... b. Type II.....

3. Duration of DM.....

4. Maximum F.B.S..... Minimum F.B.S.....

5.HbA1c

a. First..... b. Current.....

6.Type of treatment (insulin =1, oral hypoglycaemics =2, combination=3)

a. 1 b. 2 c.3

7.Presence of other co-morbid conditions

a. Hypertension
b. Asthma
c.
d. Hyperlipidaemias
e. Other (please specify).....

8. Immunization History (tick appropriately)

a. Complete
b. Incomplete for age
c. Not done

9. Family History of Diabetic Mellitus? (circle appropriately)

a. Father (positive/negative)
b. Mother (positive/negative)
c. Other (please specify): .....

10. Number of siblings and Diabetic mellitus status

a. How many siblings.....
b. Is anyone diabetic? Y/N
c. If yes, how many.....

Ocular Examination:

1. History of wearing spectacles Yes: ..... No: .....

Current prescription if YES: RE ..... LE .....

2. History of any eye injury/trauma Yes: ..... No: .....

3. Any history of previous eye surgery Yes: ..... No: .....

Type of surgery if Yes: .....

1.Visual Acuity

Visual acuity	RE	LE
>6/18		
6/18->6/60		
6/60->3/60		
<3/60		
FFL		

2. Refraction

	RE	LE
Refraction		
Keratometry		
Intra-Ocular Pressure		

3. Ocular Surface Manifestations

	RIGHT EYE		LEFT EYE	
LID	Yes	No	Yes	No
Chalazion				
Hordeolum				
Edema				
Blepaharitis				
Meibomian gland dysfunction				
CONJUNCTIVA	Yes	No	Yes	No
Conjunctivitis				

Papillae				
Growth				
Papillae				
VKC				
CORNEA				
Cornea growth				
Ulcers				
Scars				
Edema/Cloudy				
Trantra/B'tot spots				
Dry eyes				
KP's				
Others (Please Specify)				

4.Anterior Segment Manifestations (please tick)

	RIGHT EYE		LEFT EYE	
	Yes	No	Yes	No
IRIS				
Iritis				
Iris Atrophy				
Rubeosis Iridis				
Uveitis				
ANTERIOR CHAMBER				
Cells				
Flares				

LENS				
Type of cataract				
• cortical				
• nuclear				
• Posterior subcapsular				
• Other (please specify)				

5. Neurological examination

Extraocular motility: Right eye

Left eye

Hirschberg:

Anisocoria: Yes ☐ No ☐

RAPD: Yes No

Appendix E: Ethical Clearance from Korle-Bu Institutional Review Board

In case of reply the number
And the date of this
Letter should be quoted

My Ref. No.
Your Ref. No.

KORLE BU TEACHING HOSPITAL
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Website: www.kbth.gov.gh

28th July, 2020

DR. KWAME OKYERE OSEI
EYE CLINIC
KORLE BU

INSTITUTIONAL APPROVAL: KORLE BU TEACHING HOSPITAL-SCIENTIFIC AND TECHNICAL COMMITTEE/INSTITUTIONAL REVIEW BOARD (KBTH-STC/IRB/00073/2020

Following approval of your study entitled: "Refractive and Ocular Surface Abnormalities in Children and Young Adults with Diabetes Mellitus at Korle-Bu Teaching Hospital" by the Korle Bu Teaching Hospital-Scientific and Technical Committee/Institutional Review Board.

I am pleased to inform you that institutional approval has been granted for the conduct of your study in Korle Bu Teaching Hospital.

Please contact the Head of Department to discuss the commencement date of the study.

Please note that, this institutional approval is rendered invalid if the terms of the Institutional Reviewed Board/Scientific and Technical Committee approval are violated.

Sincere regards,

Dr. Ali Samba
Director of Medical Affairs
For: Chief Executive Officer

Cc. The Chief Executive
Korle Bu

MEDICAL DIRECTORATE
KORLE BU TEACHING HOSPITAL

28th July, 2020

LETTER OF INTRODUCTION – DR. KWAME OKYERE OSEI
"REFRACTIVE AND OCULAR SURFACE ABNORMALITIES IN CHILDREN AND YOUNG ADULTS WITH DIABETES MELLITUS AT KORLE-BU TEACHING HOSPITAL"

I have the pleasure to introduce to you the above-named Investigator from Eye Centre, Korle Bu. Dr. Kwame Okyere Osei sought and has been granted approval to conduct a study entitled: "Refractive and Ocular Surface Abnormalities in Children and Young Adults with Diabetes Mellitus at Korle-Bu Teaching Hospital".

He is to contact you to discuss the commencement date of the study.

Please verify his identity with a Government issued National ID card and accord him the needed assistance.

Attached is the Scientific and Technical Committee and Institutional Review Board approval, which specifies the terms.

Sincere regards,

Dr. Ali Samba
Director of Medical Affairs
For: Chief Executive

DISTRIBUTION

1. The Head, Eye Centre, Korle Bu
2. The Head, National Diabetes Mgt & Research Centre, Korle Bu
3. The Head, Child Health, Korle Bu
4. The Head, Dept. of Medicine, Korle Bu

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And the date of this
Letter should be quoted
My Ref. No. KBTH/IRB/00620
Your Ref. No.

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27th July, 2020

DR. KWAME OKYERE OSEI
EYE CLINIC
KORLE BU

REFRACTIVE AND OCULAR SURFACE ABNORMALITIES IN CHILDREN AND YOUNG ADULTS WITH DIABETES MELLITUS AT KORLE-BU TEACHING HOSPITAL

KBTH-IRB /00073/2020

Investigator: Dr. Kwame Okyere Osei

The Korle Bu Teaching Hospital Institutional Review Board (KBTH IRB) reviewed and granted approval to the study entitled: "Refractive and Ocular Surface Abnormalities in Children and Young Adults with Diabetes Mellitus at Korle-Bu Teaching Hospital".

Please note that the Board requires you to submit a final review report on completion of this study to the KBTH-IRB.

Kindly, note that, any modification/amendment to the approved study protocol without approval from KBTH-IRB renders this certificate invalid.

Please report all serious adverse events related to this study to KBTH-IRB within seven days verbally and fourteen days in writing.

This IRB approval is valid till 30th June, 2021. You are to submit annual report for continuing review.

Sincere regards,

DR. DANIEL ANKRAH
VICE CHAIR (KBTH-IRB)
FOR: CHAIR (KBTH-IRB

Cc: The Chief Executive Officer, KBTH

The Director of Medical Affairs, KBTH