PROFILE OF AMBLYOPIA AT SABATIA EYE HOSPITAL

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DECLARATION

I declare that this is my original work and it has never been published or presented for a degree in any other university

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LIST OF ABBREVIATIONS

Δ	-	Prism diopters
AAPOS	-	American Association for Pediatric Ophthalmology and Strabismus
ATS	-	Amblyopia Treatment Studies
BCSVA	-	Best corrected spectacle visual acuity
BE	-	Both Eyes
BPEDS	-	Baltimore Pediatric Eye Disease Study
CC	-	With Correction / Spectacles
CPCM	-	Cycles per centimeter of surface
D	-	Diopters
KNH/UON	-	Kenyatta National Hospital / University of Nairobi
LE	-	Left Eye
LogMAR	-	Logarithm of the Minimum Angle of Resolution
MEPEDS	-	Multi-ethnic Pediatric Eye Disease Study
OCO	-	Ophthalmic Clinical Officers
PEDIG	-	Pediatric Eye Disease Investigator Group
RE	-	Right Eye
REDCap	-	(Research Electronic Data Capture)
SC	-	With Correction / Spectacle Corrected
SE	-	Spherical Equivalent
VA	-	Visual Acuity

ABSTRACT

BACKGROUND

Amblyopia is a visual development disorder whose onset is in childhood. It becomes resistant to treatment after the critical period of 7 – 8 years when the visual system is estimated to have matured. Therefore early diagnosis is vital to the prevention of visual impairment caused by amblyopia.

STUDY OBJECTIVE

This study aims to determine the proportion of children who have amblyopia among those presenting at the Sabatia Eye Hospital in 2014, as well as the profile of amblyopia in these children.

METHODOLOGY

Study Design: Quantitative, hospital-based, retrospective case series study.

Study Population: All children aged below 16 years who fit the case definitions of amblyopia and were seen at Sabatia Eye Hospital between 1st January and 31st December 2014.

Data Collection and Management: The 2014 outpatient records to recruit the study population as per the flow chart and study case definitions. Data was analyzed using SPSS 20.0. Frequencies and percentages were used to analyze categorical variables while continuous variables were analyzed using mean, median, mode, and range. P-value <0.05 was considered statistically significant. The analyzed data was presented in the forms of tables and graphs.

Results: A total of 268 patients (451 eyes) were recruited in the study from the 4,269 files assessed, giving a proportion of 6.3%. Most patients [183 (68.28%)] had bilateral amblyopia while 85 (31.72%) had unilateral amblyopia. Refractive amblyopia (56.54%) was the most common type. It had a late diagnosis with two thirds of children presenting after the age of 8 years, and was predominantly due to ametropia which is bilateral by definition. Moderate amblyopia (58.47%) was more common than deep amblyopia (41.53%) and was predominantly due to refractive errors.

Conclusion: Pre-school vision screening programmes are recommended for early diagnosis and timely treatment of refractive errors since they do not have obviously visible signs.

1. INTRODUCTION

1.1 Background

Amblyopia is an important cause of visual impairment in adult and children. It is a visual development disorder whose onset is in childhood, and it becomes more resistant to treatment with increasing age. Additionally, visual acuity in an amblyopic eye is at risk of deterioration if the amblyopia is left untreated[1]. Delay in treatment or lack of treatment results in a lifetime of irreversible visual impairment in one or both eyes. Early diagnosis is therefore vital in the prevention of blindness and visual impairment caused by amblyopia. Blind-person years, defined as one year of blindness for an individual, is high when blindness develops in childhood rather than in adulthood.

1.2 Amblyopia Definition

Amblyopia is defined as a reduction in the best spectacle corrected visual acuity that cannot be attributed to any structural abnormality of the eye or the posterior visual pathways[2].

1.3 Pathophysiology of Amblyopia

Vision normally develops when the brain is stimulated by a clear retinal image from each eye. If for some reason one eye has an abnormal visual experience, then the brain (due to plasticity and immaturity of its' neurologic structures during the sensitive period of visual development) will learn to ignore images from this eye and use the clear image from the other dominant eye. Vision in the eye with the abnormal visual experience will therefore fail to develop. The result is unilateral or bilateral amblyopia.

The abnormal visual experience occurs in two ways. First, there may a discrepancy in the image clarity or direction from the two eyes, therefore preventing binocular fusion. Due to two conflicting images, the higher visual centers eventually learn to exclude the input from one eye (usually the eye with poorer vision), and this persists during monocular viewing. Secondly, the visual axis may be obstructed. Normal development and maturation of the visual system requires

that a sharply focused image is formed and delivered to the higher visual centers. An obstruction in the visual axis prevents this from happening, hence the development of amblyopia.

The first few months of life are the most vulnerable to amblyopia, and this vulnerability to induction of amblyopia decreases with increasing age. There is a critical period, estimated to be up to 7 - 8 years, when the decrease in visual acuity in amblyopia is reversible using various treatments options because the visual system is still developing [3, 4, 5].

At the end of the critical period, it is estimated that the visual system has developed to full maturity, and the decrease in visual acuity is irreversible. This is demonstrated in a study by Holmes et al which showed that the response to amblyopia treatment was less in children aged 7 to 13 years when compared to children less than 7 years[6].

This critical period is earlier for stimulus deprivation amblyopia when compared to anisometropic amblyopia (up to the teen years when good binocular function is present[4]) and strabismic amblyopia (about 7 – 8 years)[2].

1.4 Types of Amblyopia

Amblyopia is classified into 3 main types – Strabismic, Refractive and Stimulus deprivation amblyopia.

Strabismic amblyopia is the most common type of amblyopia and it develops in children who have a squint. It is usually unilateral and occurs in the deviated eye. In children with freely alternating or intermittent strabismus, the risk of amblyopia is low. It is more common in esotropia than in exotropia, because in exotropia there is fusion at near fixation. Therefore, the type of strabismus that typically results in amblyopia is the constant, non-alternating esotropia.

Refractive amblyopia develops as a result of blurring of images due to refractive error in one or both eyes. There are 3 types of refractive amblyopia - Anisometropic, Ametropic (Isometropic) and Meridional (Astigmatic) amblyopia.

Anisometropic amblyopia, which is the second most common type of amblyopia, is due to unequal refractive status of the two eyes. A refractive error difference as small as 1D between the two eyes can be amblyogenic[3,2]. This type of amblyopia can be relatively asymptomatic and many cases are detected during screening and visual acuity testing. Amblyopia occurs less

commonly in children who have anisometropic myopia because they are able to use the myopic eye for near vision. However, high unilateral myopia (≥ 6D) has been found to result in severe amblyopic vision loss[2]. Mild hyperopia or astigmatic anisometropia (1-2D) can also result in a mild amblyopia[2].

Ametropic (isometropic) amblyopia is induced in children with high hypermetropia (>5D) or high myopia (>6D), due to blurred retinal images in both eyes[2]. It occurs when the large uncorrected refractive error is almost equal in both eyes and is therefore usually bilateral. High myopia is less likely to cause amblyopia than high hypermetropia because near vision enables normal visual development[7]. Additionally, a patient with high hypermetropia is less likely to develop bilateral amblyopia if accommodative esotropia is present.
Meridional (astigmatic) amblyopia occurs as a result of uncorrected astigmatism resulting in blurred images in only one meridian. It can be unilateral or bilateral.

Stimulus deprivation amblyopia is the third and least common type of amblyopia which occurs as a result of occlusion of the visual axis. The occlusion may be caused by congenital or early acquired cataract (most common cause of stimulus deprivation[2]), corneal opacities, vitreous haemorrhage, congenital ptosis, hyphema or occlusion amblyopia. Stimulus deprivation amblyopia is usually unilateral, causes deeper amblyopia, and is the most difficult type to treat. The depth of amblyopic vision loss (refer to appendix 12.3 - Depth of Amblyopia) in cases of unilateral stimulus deprivation is usually higher when compared to similar cases with bilateral stimulus deprivation[2]. Amblyopia occurs in a shorter period of time in stimulus deprivation (within 1 week for every year of life in children below the age of 6 years[3]) when compared to strabismus or anisometropia. Additionally, the critical period when treatment is no longer effective, occurs earlier in stimulus deprivation amblyopia when compared to strabismic and anisometropic amblyopia.

1.5 Diagnosis of Amblyopia

Amblyopia is diagnosed when reduced Best Corrected Spectacle Visual Acuity (BCSVA) is found in a child with an amblyogenic causative factor such as strabismus, cataract or refractive error. If there are no amblyogenic factors on examination then the visual acuity should be

reassessed using different testing methods (accurate visual acuity in children is usually difficult to obtain) or subtle ocular pathology (macula disease or optic nerve hypoplasia) is considered.

Visual acuity is an important factor in the screening, diagnosis and management of amblyopia. Visual acuity of 20/20 (6/6, LogMAR [Logarithm of the Minimum Angle of Resolution] 0.0) or better is considered normal for adults. However, in children <5 years, a visual acuity reading worse than this is considered normal despite the absence of any ocular disease because the visual system has not matured. Visual acuity at birth is around 3/60 and improves as the child grows older[8]. The Multi-Ethnic Paediatric Eye Disease Study (MEPEDS) on visual acuity norms in pre-school children established that visual acuity thresholds which excluded <5% of normal children were as follows: ≤ 20/63 for 30-35 months; ≤20/50 for 36-47 months; either ≤20/40 or ≤20/32 for 48-59 months; and ≤20/32 for 60-72 months[9]. During the MEPEDS study, 66% of 2 year old children could not complete the visual acuity testing protocol. Children under 30 months old were not included in the analysis of visual acuity norms possibly due to the difficulties in obtaining accurate visual acuity readings in this age group.

Due to this variation of visual acuity in children based on age, the screening and diagnosis of amblyopia generally uses cut-offs of 20/40 (6/12, LogMAR 0.3)[10, 11] to 20/50 (6/15, LogMAR 0.4)[12, 13] or worse, rather than 20/20 (6/6, LogMAR 0.0).

The MEPEDS study also found that the mean absolute interocular difference (IOD) in LogMAR visual acuity was 0.05 for children aged 30 – 35 months and 0.06 in children aged 36 -72 months[9]. A ≥2 line interocular difference (IOD) in best corrected spectacle visual acuity is widely used in the diagnosis of amblyopia.

Accurate assessment of visual acuity in children under 2 -3 years old is a recognized challenge in many other studies. The Baltimore Paediatric Eye Disease Study (BPEDS) on the prevalence of amblyopia did not include children <30 months of age from the report on amblyopia rates, as was the case in the MEPEDS study[13]. In a study by Birch et al on the clinical profile of amblyopia in children under 3 years of age, diagnosis of amblyopia was based on fixation preference. The diagnosis was made if there was poor or fair fixation by one eye or failure to maintain fixation for >2 seconds when the fellow eye is uncovered[14]. Fixation preference is accepted as a method of diagnosing amblyopia in preverbal and nonverbal children[2, 14] despite its imperfections[15].

1.6 Treatment of Amblyopia

Amblyopia treatment improves the visual acuity in the amblyopic eye and therefore preserves binocular function, widens career choices and provides a spare eye in case of injury or disease that affects vision in the good eye[16].

Cycloplegic refraction is done for all amblyopic children and the appropriate spectacles prescribed to correct any significant refractive errors. After refractive correction, the child is monitored until there is a plateau in the visual acuity improvement (about 16 – 22 weeks), before additional treatment is initiated[16, 17]. This 'refractive adaptation' is a form of amblyopia treatment that may improve or resolve anisometropic or ametropic amblyopia[2, 17].

Various methods are then used to reduce use of the good eye and therefore force the child to use the eye with poorer vision. The first method used to limit use of the good eye is occlusion. This is done using patches, spectacle mounted occluders or opaque contact lenses. In general, older children with deeper amblyopia are treated with longer sessions (hours per day) and for a longer period (total number of weeks of patching). The amount of patching required has been examined in studies by the Paediatric Eye Disease Investigator Group (PEDIG) through their Amblyopia Treatment Studies (ATS). The Amblyopia Treatment Study 2B (ATS02B) on children aged 3 – <7 years with moderate amblyopia, showed that 2 hours of daily patching produced similar magnitude of improvement in visual acuity as 6 hours of daily patching[11]. The Amblyopia Treatment Study 2A (ATS02A) on children aged 3 – <7 years with severe amblyopia, showed that 6 hours of daily patching was as effective as full-time daily patching[18]. Therefore 2 hours of daily patching is used in the treatment of moderate amblyopia, while 6 hours of daily patching is used for severe amblyopia. The main disadvantage of patching is the risk of non-compliance and allergic skin reactions.

Review is done 3 monthly following the initiation of amblyopia treatment. Younger children who have deeper amblyopia and higher doses of patching require more frequent reviews. Once visual acuity has been stable for 2 consecutive 3 monthly visits, then the dose of patching is tapered off and eventually stopped[16].

If the visual acuity fails to improve within 6 months of initiating treatment, then refraction should be repeated and the fundus re-examined for subtle ocular pathology such as optic nerve hypoplasia or macula pathology. If visual acuity continues to deteriorate as treatment is ongoing despite a good refraction and normal eye examination, then neuroimaging should be done urgently[16].

The second method of limiting use of the good eye is by penalization whereby the image produced in the good eye is degraded to the point that it becomes worse than that in the poor eye. The most common penalization method is pharmacologic penalization using a cycloplegic agent (such as atropine or homatropine) to blur the retinal image in the better eye. Other penalization methods include fogging, diffusing filters, translucent tape on spectacles and a bangerter foil on spectacles. Atropine is as effective as patching in moderate amblyopia, but initially takes longer to work[19]. The advantage of atropine over patching is that it is more cosmetically acceptable and the risk of non-compliance is low. The disadvantage of atropine is the risk of iatrogenic amblyopia in the good eye and the risk of systemic side effects. The Amblyopia Treatment Study 4 (ATS04) showed that weekend atropine is as effective as daily atropine in treatment of amblyopia[20]. Weekend atropine reduces the total amount of atropine administered to the child and hence reduces the chances of systemic side effects.

The Amblyopia Treatment Study 1 (ATS01) compared the outcome of occlusion and pharmacologic therapy for the treatment of moderate amblyopia. It found that the outcome - at 2 and 10 years after treatment - was the same in the two groups[19].

1.7 Response to Treatment.

Response to treatment varies based on age of the patient[2, 6, 21], depth of amblyopia[2, 6, 21], type of amblyopia[2,22], choice of therapeutic approach[2, 21], and compliance with treatment[2,1,22].

A study by Holmes et al on the effect of age to treatment response in amblyopic children aged 3 – 13 years found that children aged 7 - <13 years had less response to treatment than children aged 1 - <7 years with moderate and severe amblyopia. Additionally, children aged 3 - < 5 years with severe amblyopia had greater response to treatment than those aged 5 - <7 years with severe amblyopia[6]. This effect of age to treatment response may be explained by the fact that plasticity of the visual system is reduced as it matures.

The Amblyopia Treatment Study 3 (ATS03) evaluated the treatment of amblyopia in children aged 7 to 17 years. It was found that responders to treatment were more in the group of children treated with patching and atropine when compared to those treated with optical correction alone. Additionally, in the 13-17 year old age group, there were more responders in the children treated with patching than in those treated with optical correction. This demonstrates the fact that the choice of therapeutic approach affects the outcome of treatment[21].

The Amblyopia Treatment Study 2A (ATS02A) on patching regimens for severe amblyopia found that deeper amblyopia had better outcome than milder amblyopia[18].

1.8 Recurrence of Amblyopia

Recurrence is said to have occurred if the reduction in visual acuity from cessation of treatment is of 2 or more LogMAR levels. This should be confirmed on a second consecutive examination. Recurrence within one year of completion of treatment (both full and partial treatment) occurs in 24% - 25% of patients treated for amblyopia[2, 23, 24].

Recurrence has been found to be more common when treatment is stopped abruptly without weaning to 2 hours per day in patients who were on moderately intense patching (6 – 8 hours per day)[23].

Other factors associated with a higher risk of recurrence include a better visual acuity at the time of cessation of treatment, a greater number of lines improved during the previous treatment and a prior history of recurrence[24]. From these findings it is clear that those patients who have greater central plasticity respond very well to treatment but once the treatment is stopped abruptly the greater central plasticity results in a regression in visual acuity.

Interestingly, age has not been found to be a risk factor for recurrence[24, 25].

1.9 Long term impact of Amblyopia.

Amblyopes have poorer age-appropriate fine motor skills especially on tasks that need speed and accuracy, compared to their age mates who are not amblyopic[26]. This results in more errors and longer execution times when performing tasks, and is worse with deeper levels of amblyopia[27]. The impact may be felt later in life in their education, occupation and recreational activities.

A study by Tommila et al, found that there was a high incidence of loss of vision in the healthy eye of amblyopic patients during the 20 year period of their study. Trauma was the cause of

blindness in 61% of these cases while ocular disease caused 39% of blindness. Most of the trauma cases (43%) were workplace accidents[28]. Other studies have found that amblyopes had almost three times risk of 5 year incident visual impairment in the better seeing eye[29] and nearly double the lifetime risk of bilateral visual impairment compared to the normal population[30].

Amblyopia has an impact on education as it has been found that fewer people with amblyopia complete their university degree[29].

Certain occupations have various levels of visual standards that need to be met. These occupations included the navy, army, driver (large goods, bus post office, train, cab and fork lift truck), pilot (private and commercial), flight navigator, flight engineer, police, prison officer, air traffic control officer, merchant seaman, life boat crew and fire brigade[31]. Amblyopes are disqualified from entry into these wide range of occupations, depending on the depth of their amblyopia. The choice of occupation in adult life for amblyopic children is therefore limited by their visual impairment.

A study by Packwood et al on the psychosocial effects of amblyopia, found that a substantial number of patients felt that amblyopia interfered with school, work and their lifestyle[32]. They also had greater amounts of interpersonal sensitivity, depression, anxiety, somatization and obsessive-compulsive behavior compared to the control subjects.

1.10 Screening for Amblyopia

While some causes of amblyopia like ptosis, are obvious and easily detected by parents, others like refractive errors may remain unnoticed for a prolonged period and may be picked up during screening. Screening may be done in the practitioners' office or it may be a community-based vision screening programme.

In the UK, screening of school age children has been done since 1908 in school eye clinics[33]. A study by Ingram in 1973 showed that 43% of children found to have a squint and amblyopia through these school-based screening programs were over the age of 7 years[34] – the critical period when amblyopia treatment becomes less effective. It was therefore recommended that

screening should be done before school age or in the first few months of school in order to pick up amblyopia and amblyogenic factors early.

The United Kingdom National Screening Committee (UK NSC) currently recommends that screening for visual impairment should be carried out in children between 4 and 5 years by an orthoptic-led service to pick up strabismus, amblyopia and refractive error[35]. It has been found that visual acuity results before the age of 4 years are too unreliable for a satisfactory screening programme. Additionally, the earlier amblyopia treatment is started, the more successful the outcome will be. Bearing these two factors in mind, testing between the ages of 4 – 5 years is viewed as the gold standard[36].

United States of America has also established the need for vision screening in children. The American Association for Pediatric Ophthalmology and Strabismus (AAPOS) recommends that acuity-based screening is the gold standard for detection of visual impairment when screening pre-school and older children[37]. Additionally, AAPOS has published Vision Screening Recommendations which specify specific screening tests for various age groups (from newborns to children over 5 years) and when to refer[38]. These 2014 guidelines were designed for use by primary care providers and school nurses.

The United States Preventive Services Task Force (USPSTF) recommended that vision screening should be done for all children at least once between the ages of 3 and 5 years, to detect amblyopia or its risk factors[39].

Various forms of pre-school vision screening programmes or recommendations are in place in other countries such as Israel[40], Sweden[41, 42], Denmark[43], Iran[44], South Korea[45], Japan[46], Netherlands[47] and Canada[48].

Williamson et al found that visual acuity was the best test for screening for amblyopia with the highest percentage of true positives. However when visual acuity is used alone as a screening tool, it is possible to miss ocular pathology which has not yet caused amblyopia but has the potential to do so[33].

Screening methods used in pre-school vision screening therefore depend on the objectives. If the main aim of screening is primary prevention of amblyopia, then methods that screen for potential

amblyogenic factors are sufficient, for example checking the red reflex of infants at birth. If the objective of the screening is secondary prevention of amblyopia, then visual acuity measurement is sufficient. However, if the objective is to identify both amblyogenic and non-amblyogenic ocular pathology, then visual acuity and eye examination are carried out.

Various studies have been done that compare the prevalence of amblyopia among populations that have been screened and those that have not been screened. One example is a study by Morad et al in Israel which found that children who were not screened had a 53% higher chance of developing amblyopia when compared to those who had been screened[40]. Köhler et al in Sweden found that the risk of finding amblyopia was 10 times greater when an unscreened child was examined than when a screened child was examined[41]. Polling et al in Poland found that the prevalence of amblyopia was three times higher in the unscreened population compared to screened populations[49]. Vinding et al, in Denmark found that 2.9% of unscreened older population had amblyopia which was higher than the residual amblyopia prevalence of 1% in the screened population[43]. A study published in 2000 by Eibschitz-Tsimhoni et al in Israel, compared two cohorts – one of the cohorts had been screened for amblyopia and amblyogenic risk factors in infancy while the second cohort were not screened in infancy. Prevalence of amblyopia was found to be 1% in the screened group and 2.6% in the unscreened group[50]. These examples demonstrate that amblyopia screening is effective as the prevalence of amblyopia in screened population is consistently found to be lower than that in the unscreened population.

An amblyopia study carried out in Bulgaria, which does not have a national vision screening programme, found cases of amblyopia diagnosed after the age of 8 years. Introduction of a national vision screening program was therefore recommended[51].

2. LITERATURE REVIEW

Many amblyopia studies are population or school based. Hospital based studies have been done in Ethiopia[52, 53], Pakistan[54], India[55, 56], Nepal[57], Australia[58] and United Kingdom[59]. Given the relatively low population prevalence of amblyopia, hospital based studies are suitable for assessing the clinical profile of the disease as a large number of patients can be assessed.

On review of these various studies, it's generally found that countries which have established pre-school screening programmes and / or good health and referral systems tend to have a lower age at presentation than countries in which the opposite is true. For example, the Woodruff et al study in United Kingdom found the mean age at presentation was 3.3 years, 4.4 years and 5.6 years for strabismic and mixed (strabismic and anisometropic) and anisometropic amblyopia respectively[59]. These ages are well below the critical ages of 7 – 8 years when visual maturity is expected to be complete and therefore treatment outcome is expected to be good. Similarly, Chua et al, in Australia, found that the mean age at presentation with amblyopia was 32.9 months (≈2.7 years) [58]. Amblyopia was being identified quite early in these patients despite the absence of a formal screening program, possibly due to good health systems in the country.

In contrast, Sharma et al at Himalayan hospital in India found an average age at presentation of 8.56 ± 3.80 years, which is relatively late for amblyopia treatment. Additionally, 48.15% of these patients were in the 10 – 14 year group[56]. India is not known to have formal amblyopia screening programs. A similar study by Menon et al at the All India Institute of Medical Sciences in India found and average age at presentation 7.97 ± 6.18 years. And interesting find in this study is that 11.85% of the patients were above the age of 20 years with a range of 20 to 62 years. Amblyopia in these adult patients was discovered when they came due to another eye complaint or after they were considered unfit for a certain service[55]. Similarly, Sapkota et al, in Nepal (which does not have a formal screening programme) found that the mean age of children with a diagnosis of amblyopia was 7.74 ± 2.97 years.

Closer to home, a study by Woldeyes et al, in Ethiopia found that the average age at presentation of amblyopia was 6.9 ± 3.0 years[52]. This can be also be explained by the fact that Ethiopia is not known to have a formal amblyopia screening program.

The cause of amblyopia has been found to influence the age at first presentation. Generally, strabismic amblyopia tends to present much earlier than other types probably because it physically manifests itself to caregivers and teachers. In contrast, refractive amblyopia (Anisometropic, Ametropic / Isometropic and Meridional / Astigmatic Amblyopia) presents much later due to the lack of physical manifestation as well as inability of the child to recognize and communicate the reduction of vision.

This trend is demonstrated in the study by Woodruff et al in United Kingdom, where the mean age at presentation was 3.3 years, 4.4 years and 5.6 years for strabismic and mixed (strabismic and anisometropic) and anisometropic amblyopia respectively. Additionally, this study shows that even in countries that tend to have early diagnosis of amblyopia, strabismic amblyopia is still diagnosed earlier than anisometropic amblyopia.

Sethi et al in Pakistan found that 57% of patients presented at 4 – 9 years, while 43% were between 10 – 14 years old. This was attributable to strabismus being the most common cause of amblyopia in these patients and therefore there was early detection and referral[54].

Sharma et al in India found that the average age at presentation for strabismic amblyopia was 5.64 ± 2.84 years. Combined amblyopia was diagnosed at 8.87 ± 3.80 years while sensory deprivation amblyopia at 9.25 ± 3.15 years. Anisometropic amblyopia, as expected, was diagnosed quite late at 10.11 ± 3.38 years[56].

There were similar findings in the study by Menon et al, in India where strabismic amblyopia was diagnosed earliest diagnosis at 7.67 ± 5.5 years, followed by ametropic amblyopia at 8.22 ± 5.93 years, then sensory deprivation amblyopia at 8.33 ± 6.63 years, combined amblyopia at 8.62 ± 6.23 year, meridional amblyopia at 9.42 ± 7.39 years, and finally anisometropic amblyopia at 10.03 ± 6.92 years.

The same general trend is seen in the study by Woldeyes et al in Ethiopia where the average age at presentation was 6.2 ± 3.2 years for combined amblyopia, 6.8 ± 2.9 years for strabismic amblyopia, 7.4± 3.96 years for anisometropic amblyopia and 7.5 ± 3.1 years for sensory deprivation amblyopia[52].

The above studies also show that among the refractive amblyopias, anisometropic amblyopia tends to present later than ametropic amblyopia. This may be because the unequal refraction between the two eyes in anisometropic amblyopia causes the child to effectively use the good eye and therefore there's failure by the child and other caregivers to realize the vision reduction in the other eye. In contrast, in ametropic amblyopia, both eyes have reduced vision due to a significant refractive error. Chances of early diagnosis are therefore higher with larger refractive errors but not for smaller refractive errors.

Various studies show the most common causes of amblyopia to be strabismic and anisometropic while the least common are sensory deprivation and meridional amblyopia. This is demonstrated in the study by Woodruff et al where strabismic amblyopia was found to be the most common type (55%), followed by combined anisometropia and strabismus (27%) and finally anisometropic amblyopia (17%)[59]. Chua et al, in Australia, found that strabismic amblyopia was the most common type at 55%. Combined strabismic and anisometropic was the second most common at 17%, followed by stimulus deprivation amblyopia at 13% and anisometropic amblyopia at 11%.

Menon et al in India, found that strabismic amblyopia was also the most common type (37.38%) followed by anisometropic amblyopia at 22.1%, combined amblyopia at 18.44% and ametropic amblyopia at 12.88%. The least common types of amblyopia were sensory deprivation at 7.63% and meridional amblyopia at 5.56%[55].

In the study by Sethi et al at Khyber Teaching Hospital, Pakistan, strabismic amblyopia was the most common type (55%), followed by anisometropic amblyopia (21%), while stimulus deprivation amblyopia was the least common type (2%). Severe amblyopia in this study was more if there was a combined mechanism of amblyopia[54].

Woldeyes et al in Ethiopia found a similar trend where strabismic amblyopia was the most common cause at 39.3%. Combined amblyopia accounted for 27.3% of cases, ametropic amblyopia accounted for 13.7% of cases and sensory deprivation accounted for 13.1% of cases. Anisometropia caused 6.0% of cases of amblyopia while 0.01% was due to meridional amblyopia[52].

Some studies have however shown anisometropic amblyopia to be more common than strabismic amblyopia. This includes the study by Sharma et al, in India where 33.33% of cases were due to anisometropic amblyopia while 27.78% were due to strabismic amblyopia and 25.93% were due to combined amblyopia. Sensory deprivation amblyopia accounted for 11.11% of patients while meridional amblyopia was the least common type at 1.85%[56]. Sapkota et al in Nepal found anisometropic amblyopia to be the most common at 53% followed by ametropic amblyopia at 29%. Strabismus accounted for only 14% of amblyopia cases.

Among the patients with strabismus, esodeviations usually cause amblyopia more often than exodeviations. This is believed to be due to the fact that those patients with exodeviation are able to fuse for near vision therefore promoting the development of vision. This finding has been consistent in various studies. Woldeyes et al found that 78.9% of strabismic amblyopia patients had esodeviations, Sethi et al found that 75% were esodeviations, Sharma et al found 57.58% esodeviations and Menon et al found 56.47% were esodeviations.

The type of amblyopia has been found to have an influence on the depth of amblyopia (Depth of amblyopia is defined in Appendix 12.3). The depth of amblyopia was assessed in the study by Sharma et al, at the Himalayan hospital, India. This study found that 66.67% of patients with anisometropic amblyopia had visual acuity that ranged from 6/18 to 6/36 (classified as moderate to severe amblyopia as per Appendix 12.3), while 50% of patients with sensory deprivation amblyopia had vision <3/60 (categorized as severe amblyopia as per Appendix 12.3)[54]. This showed that most of the patients with anisometropic amblyopia had milder amblyopia while those with sensory deprivation amblyopia tend to have deeper amblyopia.

Woodruff et al in United Kingdom found that the mean visual acuity prior to starting treatment was 6/20.3 for patients diagnosed with strabismic amblyopia, 6/16.6 for pure anisometropic amblyopia and 6/25.8 for mixed amblyopia[59]. Also three groups therefore had moderate amblyopia and none had severe amblyopia. The most likely explanation for this is that the screening programmes identify amblyopia early, before it has had the time to become severe.

Sethi et al, found that combined amblyopia gave deeper amblyopia than other pure types of amblyopia. This may be attributable to the additive effect of the two (or more) types of amblyopia giving a more profound cortical suppression and hence a deeper amblyopia.

Woldeyes et al and Sharma et al found that sensory deprivation caused deeper amblyopia (poorer visual acuity) than other types of amblyopia like anisometropia. This point still holds in their studies despite that fact that they used a different method to classify the depth of amblyopia[52].

The proportion of children with amblyopia among those visiting an outpatient eye or paediatric ophthalmology department is an indicator of the magnitude of the disease. Woldeyes et al, in Ethiopia found that 9.1% of patients visiting this pediatric ophthalmology clinic in the capital city, had amblyopia[52]. A different study by Mehari et al - in an outpatient eye department Ethiopia but in a rural eye hospital - found that in 3.1% of patients with visual impairment, the cause was amblyopia[53]. Additionally, among the children who had bilateral visual impairment, amblyopia was the cause in 14.3% of the cases. Sapkota et al at the Nepal Eye Hospital found an amblyopia prevalence of 0.7%. These studies are however not comparable due to the differences in the methodology and hence the large variation in proportions. In the Woldeyes et al study, children <15 years seen over a 6 month period were included in the study. Additionally the study was done in a paediatric ophthalmology clinic which explains the relatively high proportion (compared to those studies in a general ophthalmology clinic). The Mehari et al study in a rural eye hospital included children <16 years but excluded repeated cases, those who presented for medical check-up and those who had no ocular disease. Moreover, this study was conducted in an outpatient eye department (not paediatric) resulting in a larger denominator and hence a lower proportion. The Saptoka et al study included children only up to the age of 13 years (unlike the previous two which used a cut-off of 15 or 16 years). Furthermore, the setting of a tertiary eye care center (and hence the likelihood of a wide variety of cases being referred to it) may contribute to the lower proportion.

Besides the Ethiopian study, there is lack of other hospital-based amblyopia studies in Africa and Kenya. Various studies in Kenya have however shown that amblyopia is one of the causes of visual impairment and blindness in Kenya. A study done on children attending schools for the blind and resource centers in Eastern Africa, Malawi, Tanzania and Uganda showed that amblyopia was the most common cause of poor visual acuity in children who had undergone cataract surgery[60]. Njambi et al found that 13.4% of visual impairment in children attending occupational therapy clinic at Kenyatta National Hospital was due to strabismic amblyopia[61]. Onsomu et al found that amblyopia was present in 56% of children aged 3 to 5 years who had

strabismus and attend city council day nursery schools in Nairobi Province, Kenya[62]. In addition, Kalua et al found that 40% of children with strabismus in Kenyatta National Hospital have amblyopia[63]. However, there is lack of amblyopia-specific studies in Kenya.

3. JUSTIFICATION

Amblyopia is a treatable cause of low vision and blindness which has a long term impact on the quality of life and choice of occupation in adulthood[31]. Early detection and treatment is the key to prevention of low vision caused by amblyopia. The earlier treatment is started, the more successful the outcome of treatment[6].

Various forms of pre-school vision screening programmes are established in countries such as United Kingdom[35], United States of America[38,39], Israel[40], Sweden[41, 42], Denmark[43], Iran[44], South Korea[45], Japan[46] and Netherlands[47]. One of the aims of these various programmes is early detection (and subsequent treatment) of amblyopia. However, for many countries in Africa, including Kenya, there is lack of a formal or mandatory policy for pre-school vision screening.

Various studies done in Kenya have found that amblyopia is a cause of visual impairment in children[61, 62, 63]. However, there is lack of amblyopia-specific studies that show the average age and clinical profile of amblyopic children in eye clinics in Kenya, without any formal screening program in place. The study will find out whether amblyopia is being diagnosed and treated early enough in this busy ophthalmology outpatient clinic. The results may justify the need for specific pre-school screening programs in future. Since amblyopia has an estimated population prevalence of between 1 – 4%, the hospital setting easily gives larger numbers and varieties of amblyopia cases than a population-based study[10, 7, 16].

This study will serve as a baseline of the prevalence and clinical profile of amblyopia in busy eye hospital in Kenya. This is useful information when planning strategies for appropriate therapeutic measures for the hospital which can be applied to other similar hospitals.

The hospital serves patients who come from a large number of counties in the Western Kenya region. Determining how far these patients with amblyopia have travelled will provide a useful guide as to the regional gaps in the provision of paediatric eye care. Resources, training and screening programs can in future be directed to these regions in order to enable earlier identification of possible amblyopia patients.

4. OBJECTIVES

4.1 Broad Objective(s)

To determine the proportion of children with amblyopia among those presenting at the Sabatia Eye Hospital, as well as the profile of amblyopia in these children.

4.2 Specific Objectives

1. To determine the proportion of patients with amblyopia among the children who presented at Sabatia Eye Hospital between 1st January 2014 and 31st December 2014.
2. To determine the different types of amblyopia (and their characteristics) in these children.
3. To determine the depth of amblyopia (as defined in Appendix 12.3) in these children.
4. To assess the catchment area of these children.

5. METHODOLOGY

5.1 Study Design

Quantitative, hospital-based, retrospective case series study.

5.2 Study area / Centre description.

The Sabatia Eye Hospital, a tertiary/ referral eye hospital is the study center. The hospital is located in a rural setting along the Eldoret- Kapsabet- Chavakali road in Vihiga County, western Kenya. The nearest urban town is Kakamega, a farming town twenty-five kilometers from the hospital. Sabatia's catchment area consists of western Kenya, the northern Rift Valley and the lake basin region, where the main economic activities are farming and fishing. The hospital serves a catchment area of 15 million people from 17 different counties.

Over 3,000 children are seen in the outpatient clinic each year; many are referred from surrounding centers. The children undergo vision screening at the low vision clinic before undergoing a clinical examination. The hospital has daily clinics for adults and children, which are run by Ophthalmic Clinical Officers (OCO). The OCOs appropriately refer children who need to be reviewed by the pediatric ophthalmologists. There are currently two Pediatric ophthalmologists who provide the pediatric ophthalmology services including surgeries. Services offered include management of refractive errors, strabismus, pediatric cataract, ocular allergy, management of amblyopia, among others.

There is a low vision clinic that supports the pediatric eye services. Vision screening for young children, refraction, issuing of glasses and low vision devices, school placement and follow up are carried out by this department. Refractions are done by the resident optometrist or the pediatric ophthalmologists using 1% cyclopentolate eye drops. Spectacles are dispensed from the optical shop. The clinic is thus able to offer a comprehensive pediatric eye service to the paediatric population.

Figure 1: Map showing the location of Sabatia Eye Hospital[64]

5.3 Study population

All children aged below 16 years who fit the case definitions of amblyopia and were seen at Sabatia Eye Hospital between 1st January 2014 and 31st December 2014.

5.4 Inclusion criteria

- All children below 16 years, who fit the definition of a case of amblyopia.

5.5 Exclusion criteria

- Files with missing records.

5.6 Definition of cases

5.6.1 Unilateral Amblyopia.

a) Quantitative visual acuity measurement

- ≥2 line interocular difference (IOD) in Best corrected spectacle visual acuity (BCSVA)[12, 13] or Best corrected spectacle visual acuity (BCSVA) of Snellen ≤6/12 (20/40) (LogMAR 0.3)[10] and
- Amblyogenic risk factor - Strabismus, Refractive error, Stimulus deprivation[12, 13] and
- No other structural abnormality of the eye or the posterior visual pathways

b) Qualitative visual acuity measurement

- Strong fixation preference for one eye and inability to hold fixation with the non-preferred eye[2, 12] plus
- Unilateral amblyogenic factor
- No other structural abnormality of the eye or the posterior visual pathways

5.6.2 Bilateral Amblyopia[12, 13]

a) Bilateral subnormal Best Corrected Spectacle Visual Acuity (BCSVA)

- Worse than 20/50 (6/15) (LogMAR 0.4) in 30 to 47 month old children, or
- Worse than 20/40 (6/12) (LogMAR 0.3) in ≥ 48 month old children

b) And either of:

- Evidence (past or present) of bilateral visual axis obstruction
- Bilateral ametropia
    - ≥ 4.00D spherical equivalent hyperopia
    - ≥ 6.00D spherical equivalent myopia
    - ≥ 2.50D astigmatism

c) No other structural abnormality of the eye or the posterior visual pathways

5.6.3 Strabismic amblyopia

The following must be present:

- Amblyopia (Unilateral or bilateral as per case definitions above)
- Heterotropia at distance or near fixation or a history of strabismus surgery[12, 13]
- Absence of combined amblyopia[11, 18]

5.6.4 Anisometropic amblyopia

The following must be present:

- Amblyopia (Unilateral or bilateral as per case definitions above)
- Anisometropia[12,13]
    - ≥ 1.00 D anisohyperopia or
    - ≥ 3.00 D anisomyopia or
    - ≥ 1.50 D anisoastigmatism.

- Absence of combined amblyopia[18]

5.6.5 Ametropic amblyopia:

The following must be present:

- Amblyopia (Unilateral or bilateral as per case definitions above)
- Bilateral high ametropia[12,13]
    - ≥ 4.00 D hyperopia or
    - ≥ 6.00 D myopia or
    - ≥ 2.50 D astigmatism.
- Absence of combined amblyopia.

5.6.6 Meridional amblyopia:

The following must be present:

- Amblyopia (Unilateral or bilateral as per case definitions above)
- Potential visually significant refractive error in both eyes:
    - Regular astigmatism >1.00 D of astigmatism in any meridian[9] or
    - Irregular astigmatism in both eyes[52]
- Absence of combined amblyopia.

5.6.7 Sensory deprivation amblyopia:

The following must be present:

- Amblyopia (Unilateral or bilateral as per case definitions above)
- Past or present visual axis obstruction by:
    - Cataract
    - Corneal opacities
    - Vitreous haemorrhage
    - Congenital ptosis
    - Hyphema
    - Occlusion amblyopia
    - Any other media opacity[12, 13]
- Absence of combined amblyopia[55]

5.6.8 Combined mechanism amblyopia[52, 55, 18]:

A combination of the various types of amblyopia:

- Combined Strabismic and Refractive amblyopia
- Combined Strabismic and Sensory deprivation amblyopia
- Combined Sensory deprivation and Refractive amblyopia
- Combined Strabismic, Refractive and Sensory deprivation amblyopia

5.7 Sampling Procedures

5.7.1 Study Team

The study team will comprise of two research assistants (one records officer and one ophthalmic clinical officer) and one principal investigator.

5.7.2 Training procedures for Research Assistants

The two research assistants will be adequately trained to avoid bias. The training will be on how to identify the files of patients <16 years seen in 2014 using the outpatient records, and how to exclude the files of patients who had vision that does not fit the case definitions of amblyopia. Additionally, they will be provided with a copy of "Data collection procedures for research assistants" (Appendix 12.6) for quick reference of how to do this. If they have any doubts regarding a particular file, they will refer to the principal investigator.

5.7.3 Recruitment Procedures

All children under 16 years seen at Sabatia Eye Hospital between 1st January 2014 and 31st December 2014 will be included in the study. There is an outpatient record book at the hospital which contains daily records of all the patients who were seen as well as their file number, age and diagnosis. However, the diagnosis indicated is usually that of the amblyogenic factor (strabismus, refractive error, cataract or ptosis among others) rather than "amblyopia". Amblyopia patients will therefore be identified by a process of exclusion; the first few steps of this exclusion will be done by the research assistants. The role of the research assistants in this study is to identify the files of children <16 years seen in 2014 and to exclude those whose vision

does not fit the case definition of amblyopia. The principal investigator will then peruse the remaining files to identify the cases of amblyopia.

The first research assistants (a records officer) will peruse through the outpatient records of Sabatia Eye Hospital to identify all children <16 years seen between 1st January 2014 and 31st December 2014. The date of visit, age, hospital number and visual acuity will be entered in a table ("List of children <16 years during the study period" – Appendix 12.2). This list will not have the patients' names but will have the hospital number in order to avoid duplication (to ensure that patients who visited the hospital more than once during the study period are counted only once). This is important because the total number of children <16 years obtained from this table will be the denominator used to calculate the proportion of children with amblyopia at the hospital during the study period. The research assistant will retrieve each of these files and hand them over to the second research assistant.

The second research assistant (ophthalmic clinical officer) will go through each file and exclude the following files:

a) Presenting visual acuity equal to or better than 6/9 (20/32) (LogMAR 0.22) in the worse eye. This will exclude the children under 16 years whose vision at first presentation is better than the threshold for amblyopia. The "Visual Acuity Conversion Table" (Appendix 12.4) will be used for reference.
b) Files without any quantitative visual assessment (for example, Snellen fractions, LogMAR, Decimal notation, CPCM among others) or qualitative record (for example, fixation preference, perception of light, picking objects) of visual acuity.

The second research assistant will record the presenting visual acuity in the "List of children <16 years during the study period" table (Appendix 12.2) and indicate whether the patient has been included or excluded from the study.

The following methods are used to assess visual acuity in children at Sabatia Eye Hospital:

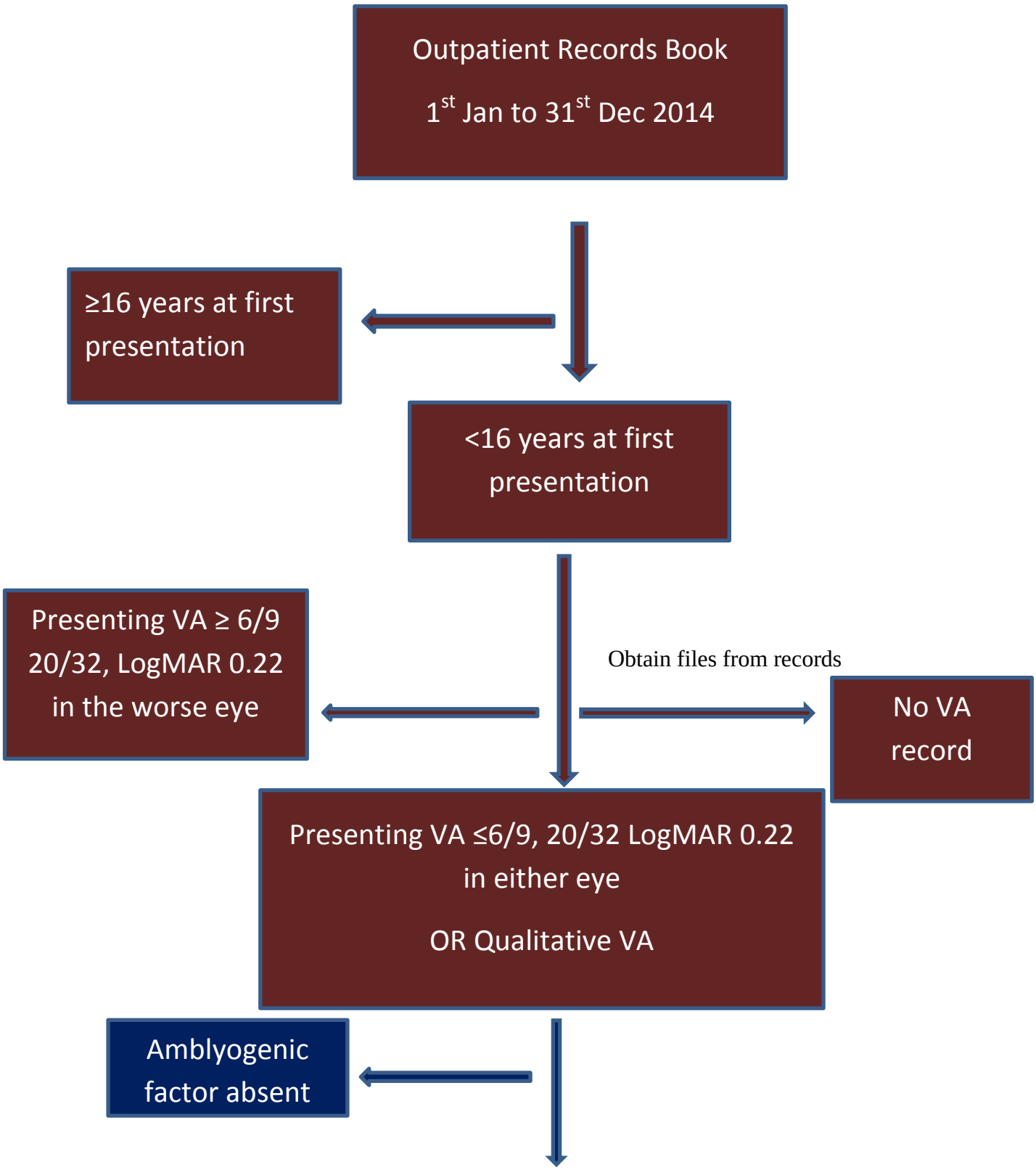
a) Snellen chart
b) Lea Gratings: 0.00 CPCM to 8.0 CPCM (Cycles per centimeter of surface)

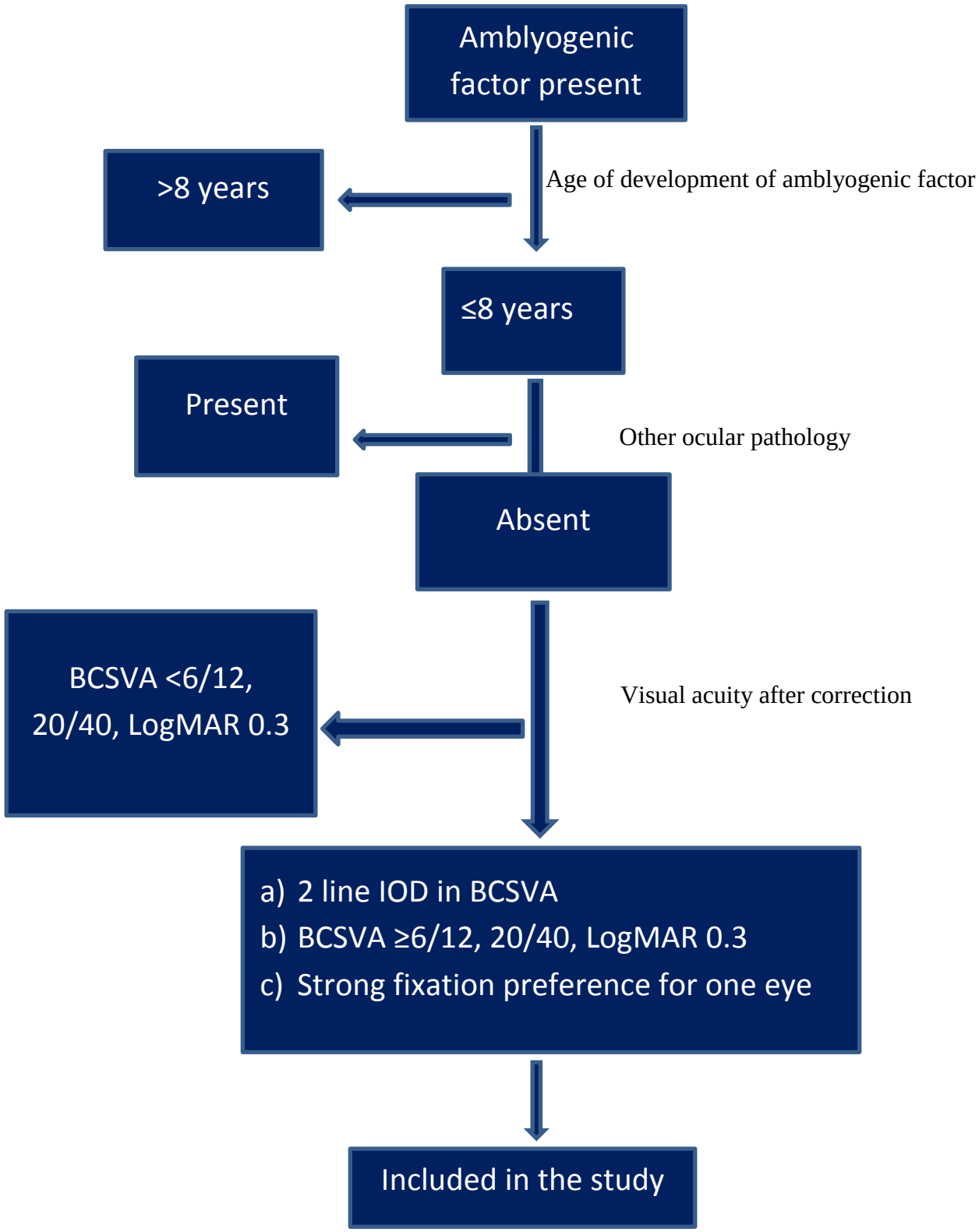
c) Lea Symbol: Single symbol book for visual acuity, performed at a distance of 3m. Visual acuity is given as Snellen fractions (in meters and feet), LogMAR and Decimal notation.
d) Cardiff Acuity Tests: Performed at either 50cm or 1m, depending on the patients' co-operation. Visual Acuity is given in different formats – Snellen fractions (in meters and feet) and LogMAR.
e) LVRC (Low Vision Resource Centre) Flip Cards: Performed at 4m. The types include Tumbling E, SLOAN letters and Numbers. Visual Acuity formats used include LogMAR, Feet and Letter size M.
f) Hundreds and thousands: If they pick at 30cm, this is equivalent to 6/24 (20/80 or LogMAR 0.6)
g) Picking objects 1mm size.
h) Picking objects 2cm size.
i) Picking objects 4cm size.
j) Toy
k) Torch: For perception of light.

If the visual acuity is recorded using a method that is not a Snellen fraction or LogMAR, the research assistant will retain the patient in the study for further evaluation by the principal investigator.

The principal investigator will peruse each of these remaining files to identify if there is an amblyogenic factor (strabismus, refractive error or visual axis obstruction) that occurred before the age of 8 years. If the amblyogenic factor was absent or it developed after the age of 8 years, then the patient will be excluded from the study. The presence of other ocular pathology that may account for the decrease in visual acuity will also exclude the patient from the study.

Flow Chart of the Recruitment procedure





Key:

To be performed by the research assistants

To be performed by the principal investigator

5.8 Data Collection.

5.8.1 Data Collection Procedures

The study data collection form (Appendix 12.1) will be created on REDCap (Research Electronic Data Capture). REDCap is a password-secured web application which is used to capture data for research studies. The study data collection form will be filled out from the patients' file for each case of amblyopia. Each data collection form will have a form number and will not contain the name and hospital number of the patient. A separate document will be used to link the patient hospital number and questionnaire number, in case there is need to refer back to the file.

Since analysis will be done using LogMAR, appropriate conversion of all visual acuities to LogMAR will be done using the "Visual Acuity Conversion Table". (Appendix 12.4). Qualitative visual acuity measurements will be indicated for separate analysis from the quantitative visual acuity measurements. The "Depth of Amblyopia" (Appendix 12.3) and the "Revised W.H.O. categorization of blindness and visual impairment" (Appendix 12.5) will be used to categorize the amblyopia and blindness respectively for each patient.

5.8.2 Data Collection Instruments

- Data collection form on REDCap (Research Electronic Data Capture).
- Computer and internet connection.
- Visual acuity conversion table.
- Depth of amblyopia table
- Revised W.H.O. categorization of blindness and visual impairment table
- Flash disk for storing and backing up data.
- Folder.

5.8.3 Quality assurance procedures.

Data will be directly entered into the data entry form on REDCap (Research Electronic Data Capture). This will reduce the number of errors as the data will be entered once.

Each data entry form will be reviewed for completeness at the end of each day. Any missing information will be identified and corrected using the patients' file.

5.8.4 Ethical Considerations and Confidentiality

Approval for the study will be sought from the Kenyatta National Hospital - University Of Nairobi (KNH/UON) Ethics and Research Committee before the research is carried out. Permission to carry out the study and collect data has been obtained from Sabatia Eye Hospital. (Appendix 12.7)

Due to the retrospective nature of the study, the principal investigator will not have direct contact with the patients. In a similar study by Sapkota et al in Nepal, written informed consent was waived due to the retrospective nature of the study[57]. Information obtained from the patients' file will remain confidential. The patients' hospital identification number will be coded on a separate document (List of children <16 years during the study period in Appendix 12.2) from the study data collection form that contains the patients' data. This means that the study data collection form will not contain the patients' name, patients' hospital identification number or the clinicians' name. The data collection form will be stored in a password-protected application. Data collected will be accessed by the principal investigator, research assistants, supervisors and statistician only. The "List of children <16 years during the study period" (in Appendix 12.2) will be safely kept and will be destroyed by burning once the data analysis is complete. All data in software form will be deleted, on completion of the study. The recycle bin on the computer will be emptied.

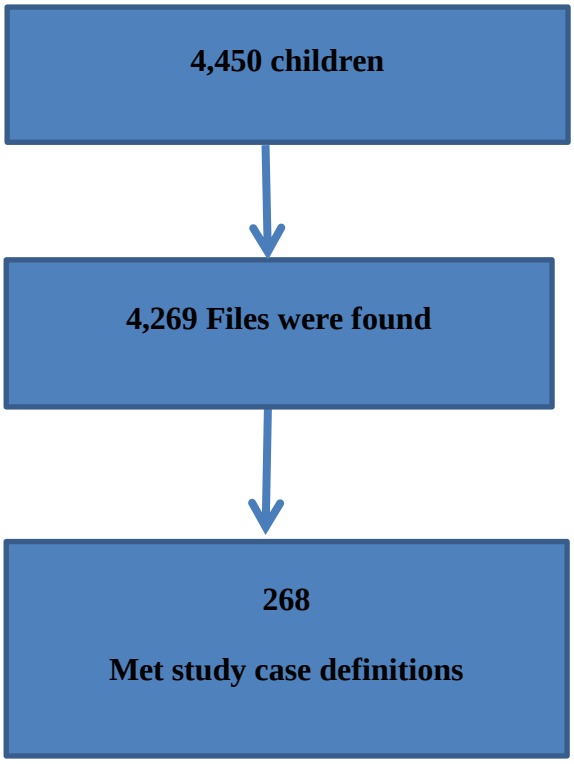
5.8.5 Data management and statistical analysis plans

Data from the data collection form on REDCap will be exported the Statistical Program for Social Sciences (SPSS) version 20 for data analysis, with the assistance of a statistician. Data will be saved on the hard drive of the computer at the end of each day and a backup copy will be saved on a flash disk. The output variables are as follows: Proportion of children with amblyopia in 2014, Age at first presentation, Residence, Type of amblyopia and Depth of amblyopia. Frequencies and percentages will be used to analyze categorical variables while continuous variables will be analyzed using mean, percentile, range and standard deviation, as appropriate. A p value of less than 0.05 will be considered statistically significant.

The analyzed data will be presented in the forms of tables and graphs.

6. RESULTS

Figure 2: Flow Chart of Data Collection



A total of 268 children met the case definitions and were enrolled in the study, with 136 (50.75%) being male while 132 (49.25%) were female. The difference between the two groups was not statistically significant (p-value 0.8).

Bilateral amblyopia [183 (68.28%)] was more common than unilateral amblyopia [85 (31.72%)]. This difference was statistically significant with a p-value of 0.0. Due to the bilateral cases, the total number of eyes in the study was 451.

6.1 Proportion of Patients with Amblyopia

Since 4,269 patients' files were assessed and 268 patients enrolled in the study, the resulting amblyopia proportion was 6.3%.

6.2 Types of Amblyopia (and their characteristics)

Table 1: Types and Subtypes of Amblyopia

n = 451

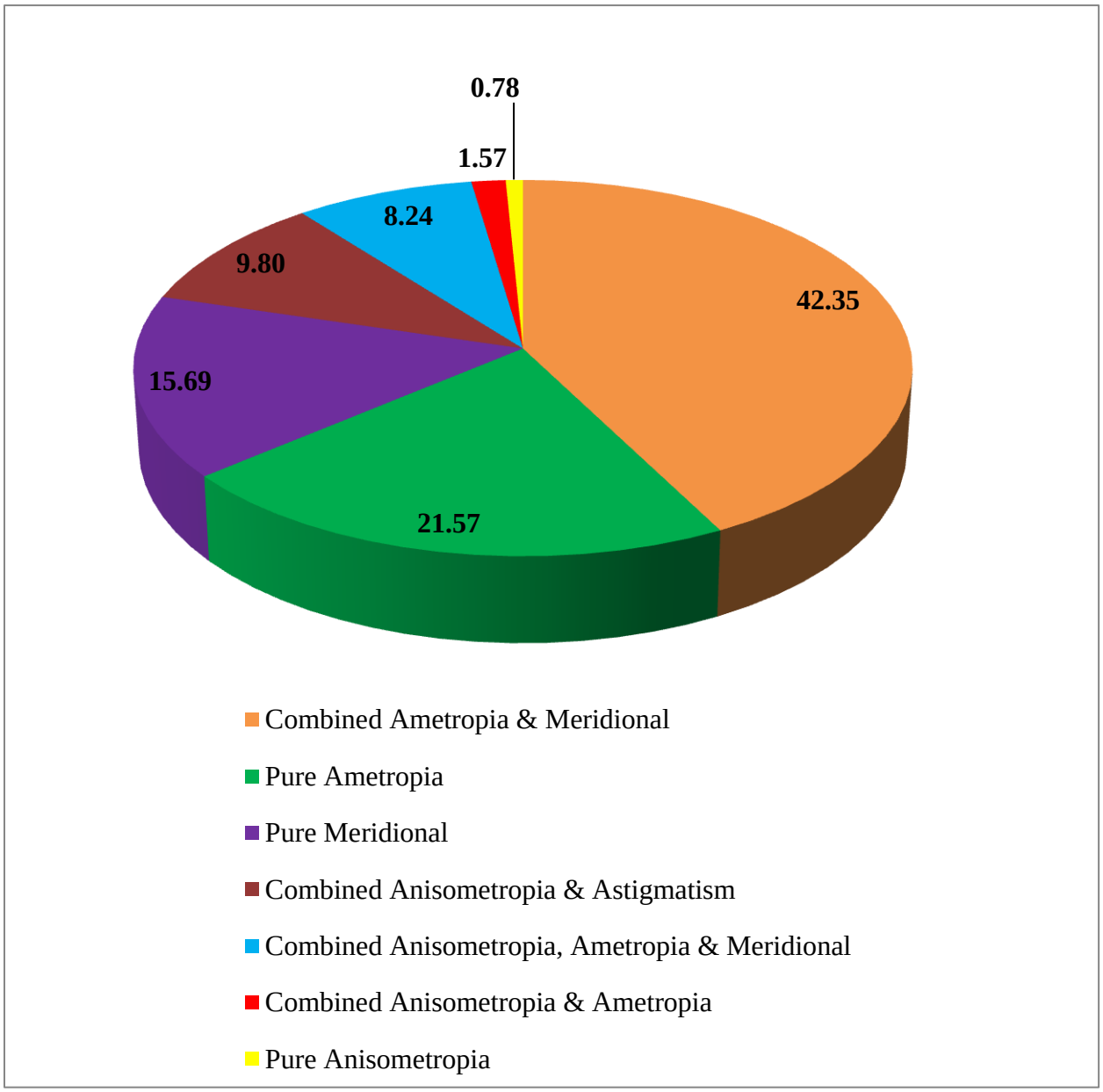
	AMBLYOPIA TYPE	Number		Percentage
1	**Refractive Amblyopia**	**255**		**56.54**
	a) Combined Ametropia & Meridional		108	23.95
	b) Pure Ametropia		55	12.20
	c) Pure Meridional		40	8.87
	d) Combined Anisometropia & Meridional		25	5.54
	e) Combined Anisometropia, Ametropia & Meridional		21	4.66
	f) Combined Anisometropia & Ametropia		4	0.89
	g) Pure Anisometropia		2	0.44
2	**Combined Amblyopia**	**142**		**31.49**
	a) Combined Sensory Deprivation & Refractive		109	24.17
	b) Combined Strabismic, Refractive & Sensory Deprivation		16	3.55
	c) Combined Strabismic & Refractive		11	2.44
	d) Combined Strabismic & Sensory Deprivation		6	1.33
3	**Pure Sensory Deprivation Amblyopia**	**42**		**9.31**
4	**Pure Strabismic Amblyopia**	**12**		**2.66**
	TOTAL	**451**		**100.00**

There were 4 main types of amblyopia with Refractive Amblyopia (56.54%) being the most common and Pure Strabismic Amblyopia (2.66%) being the least common type.

Refractive amblyopia was further classified into 7 subtypes while combined amblyopia was further classified into 4 subtypes.

Figure 3: Pie chart showing subtypes of Refractive Amblyopia (percentage)

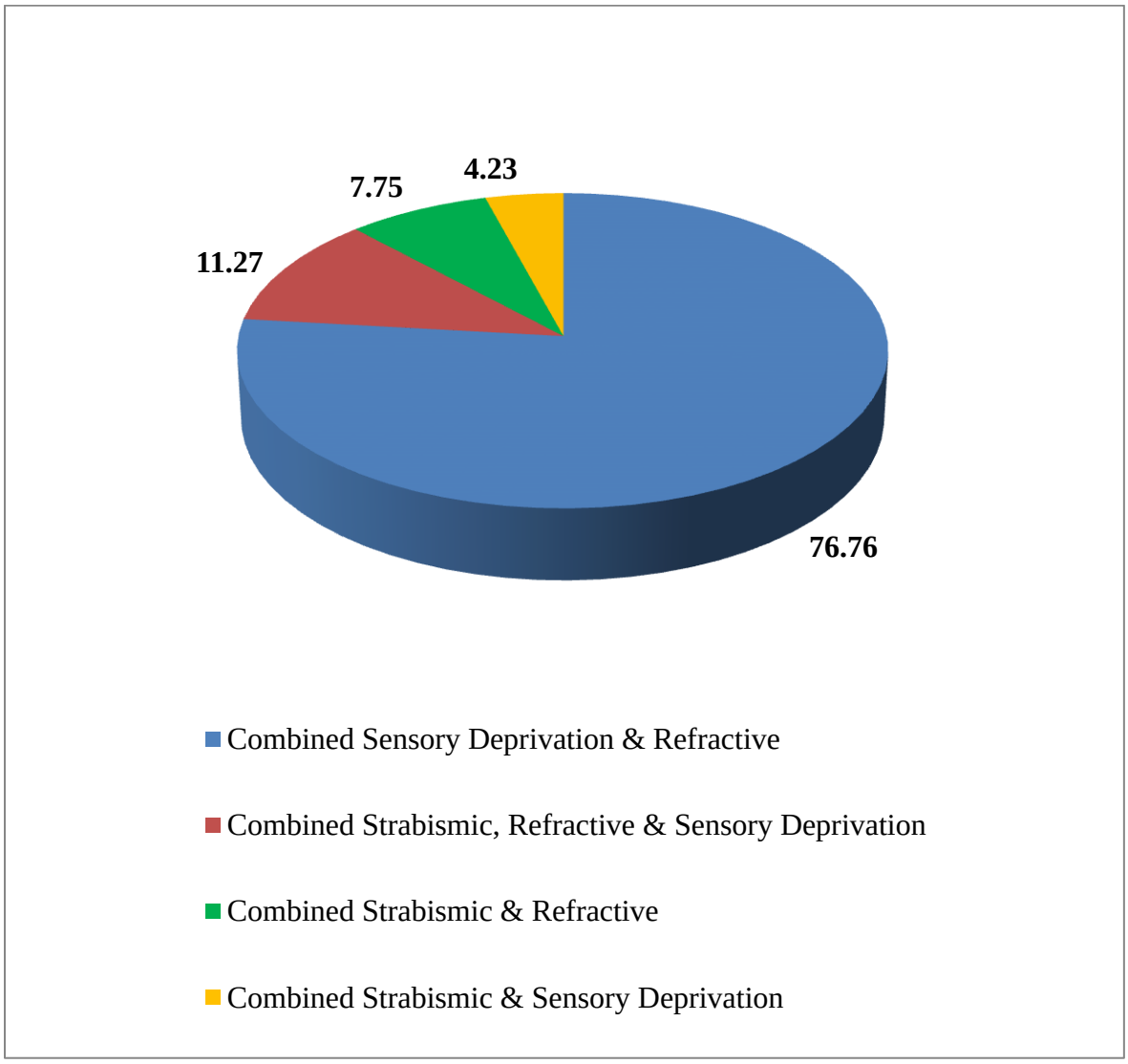
n=255



Combined Ametropic & Meridional Amblyopia (42.35%) was the most common sub-type of refractive amblyopia followed by Pure Ametropia (21.57%). Pure anisometropic amblyopia (0.78%) was the least common sub-type.

Figure 4: Pie Chart showing subtypes of Combined Amblyopia (percentage)

n = 142



Combined Sensory Deprivation & Refractive Amblyopia was found to be the dominant (76.76%) subtype of combined amblyopia.

Table 2: Amblyopia types and subtype based on sex.

n = 451

	AMBLYOPIA TYPE	MALE	FEMALE	p-value
1	**Refractive Amblyopia**	**132**	**123**	0.57
	a) Combined Ametropia & Meridional	59	49	0.34
	b) Pure Ametropia	33	22	0.14
	c) Pure Meridional	15	25	0.11
	d) Combined Anisometropia, Ametropia & Meridional	15	6	0.05
	e) Combined Anisometropia & Meridional	8	17	0.07
	f) Pure Anisometropia	1	1	1
	g) Combined Anisometropia & Ametropia	1	3	0.32
2	**Combined Amblyopia**	**73**	**69**	0.73
	a) Combined Sensory Deprivation & Refractive	59	50	0.39
	b) Combined Strabismic, Refractive & Sensory Deprivation	7	9	0.62
	c) Combined Strabismic & Refractive	5	6	0.76
	d) Combined Strabismic & Sensory Deprivation	2	4	0.41
3	**Pure Sensory Deprivation Amblyopia**	**29**	**13**	0.01
4	**Pure Strabismic Amblyopia**	**3**	**9**	0.08
	TOTAL	**237**	**214**	0.73

The difference seen in sex of patients with the various types and subtypes of amblyopia was statistically significant only in Pure Sensory Deprivation amblyopia.

Males (15) were more than females (6) in Combined Anisometropia, Ametropia & Meridional Amblyopia with borderline statistical significance.

Table 3: Amblyopia type and subtype based on laterality

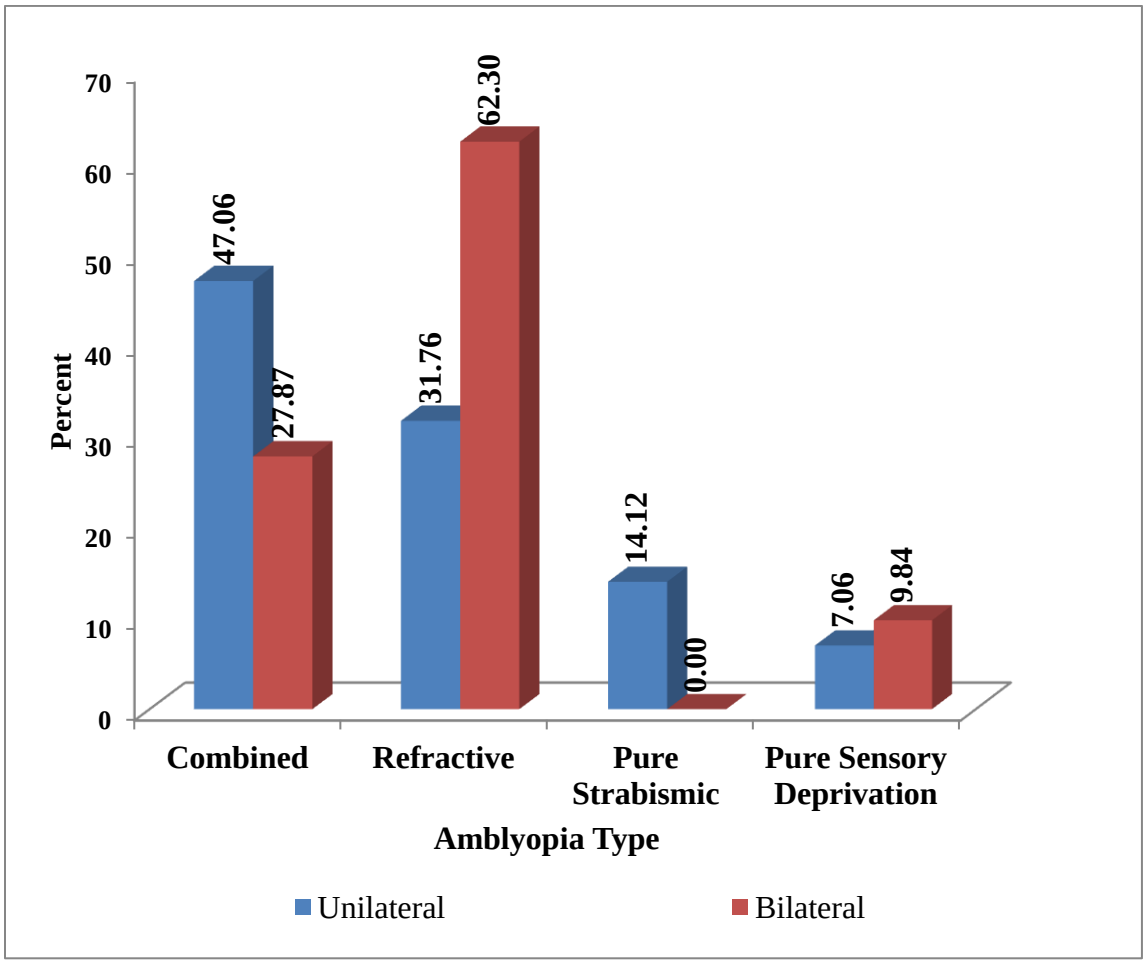
n = 451

	AMBLYOPIA TYPE	Unilateral	Bilateral	p-value
1	**Combined Amblyopia**	**40**	**102**	0.00
	a) Combined Sensory Deprivation & Refractive	24	85	0.00
	b) Combined Strabismic, Refractive & Sensory Deprivation	7	9	0.62
	c) Combined Strabismic & Sensory Deprivation	5	1	0.1
	d) Combined Strabismic & Refractive	4	7	0.37
2	**Refractive Amblyopia**	**27**	**228**	0.00
	a) Combined Anisometropia & Meridional	19	6	0.01
	b) Pure Meridional	6	34	0.00
	c) Pure Anisometropia	2	0	__
	d) Combined Ametropia & Meridional	0	108	__
	e) Pure Ametropia	0	55	__
	f) Combined Anisometropia, Ametropia & Meridional	0	21	__
	g) Combined Anisometropia & Ametropia	0	4	__
3	**Pure Strabismic Amblyopia**	**12**	**0**	__
4	**Pure Sensory Deprivation Amblyopia**	**6**	**36**	0.00
	TOTAL	**85**	**366**	**0.00**

The difference between bilateral and unilateral cases was found to be statistically significant with p-value of 0.00.

Combined Ametropia & Meridional was the largest (29.51%) cause of bilateral amblyopia.

Figure 5: Bar Chart showing the contribution of each amblyopia type to unilateral and bilateral amblyopia



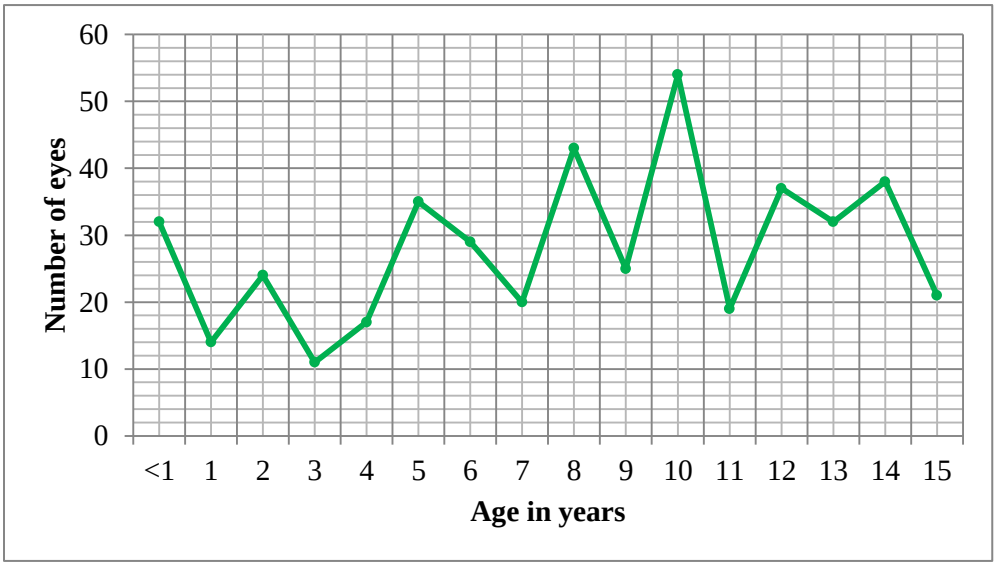
The two largest contributors to bilateral amblyopia were refractive (62.30%) and combined (27.87%) amblyopia.

Table 4: Frequency Distribution Table showing age at first presentation for all amblyopia types

n=451

Age (yrs)	Number of eyes	Relative frequency (%)	Cumulative %
<1	32	7.10	7.10
1	14	3.10	10.20
2	24	5.32	15.52
3	11	2.44	17.96
4	17	3.77	21.73
5	35	7.76	29.49
6	29	6.43	35.92
7	20	4.43	40.35
8	43	9.53	49.89
9	25	5.54	55.43
10	54	11.97	67.41
11	19	4.21	71.62
12	37	8.20	79.82
13	32	7.10	86.92
14	38	8.43	95.34
15	21	4.66	100.00
TOTAL	451		

Figure 6: Frequency Distribution Polygon for age at first presentation for all amblyopia types.



Half of the patients with all types of amblyopia first presented after the critical age of 8 years. The most common age at first presentation was 10 years (11.97%).

Table 5: Frequency Distribution Table showing age at first presentation for Refractive Amblyopia

n = 255

Age (yrs)	Number of eyes	Relative Frequency (%)	Cumulative (%)
<1	0	0	0
1	2	0.78	0.78
2	1	0.39	1.18
3	2	0.78	1.96
4	5	1.96	3.92
5	22	8.63	12.55
6	15	5.88	18.43
7	12	4.71	23.14
8	23	9.02	32.16
9	13	5.10	37.25
10	42	16.47	53.73
11	16	6.27	60.00
12	29	11.37	71.37
13	25	9.80	81.18
14	31	12.16	93.33
15	17	6.67	100.00
TOTAL	**255**		

Two thirds of the children found to have refractive amblyopia first presented after the age of 8 years. Ten years was the most common (16.47%) age at first presentation.

Table 6: Frequency Distribution Table showing at age first presentation for Pure Sensory Deprivation Amblyopia

n = 42

Age (yrs)	Number of eyes	Relative Frequency (%)	Cumulative (%)
<1	4	9.52	9.52
1	4	9.52	19.05
2	4	9.52	28.57
3	0	0.00	28.57
4	2	4.76	33.33
5	6	14.29	47.62
6	1	2.38	50.00
7	2	4.76	54.76
8	3	7.14	61.90
9	2	4.76	66.67
10	3	7.14	73.81
11	2	4.76	78.57
12	3	7.14	85.71
13	3	7.14	92.86
14	2	4.76	97.62
15	1	2.38	100.00
TOTAL	**42**		

Most (61.9%) of the children with Pure Sensory Deprivation amblyopia had presented to hospital by the critical age of 8 years.

Five years was the most common (14.29%) age at first presentation.

Table 7: Frequency Distribution Table showing age at first presentation for Pure Strabismic Amblyopia

n = 12

Age (yrs)	Number of eyes	Relative Frequency (%)	Cumulative (%)
<1	3	25.00	25.00
1	1	8.33	33.33
2	1	8.33	41.67
3	2	16.67	58.33
4	2	16.67	75.00
5	0	0.00	75.00
6	0	0.00	75.00
7	0	0.00	75.00
8	0	0.00	75.00
9	0	0.00	75.00
10	1	8.33	83.33
11	0	0.00	83.33
12	2	16.67	100.00
13	0	0.00	100.00
14	0	0.00	100.00
15	0	0.00	100.00
TOTAL	**12**		

Seventy five percent of patients with pure strabismic amblyopia presented before the age of 8 years. The most common age at first presentations was <1 year (25%).

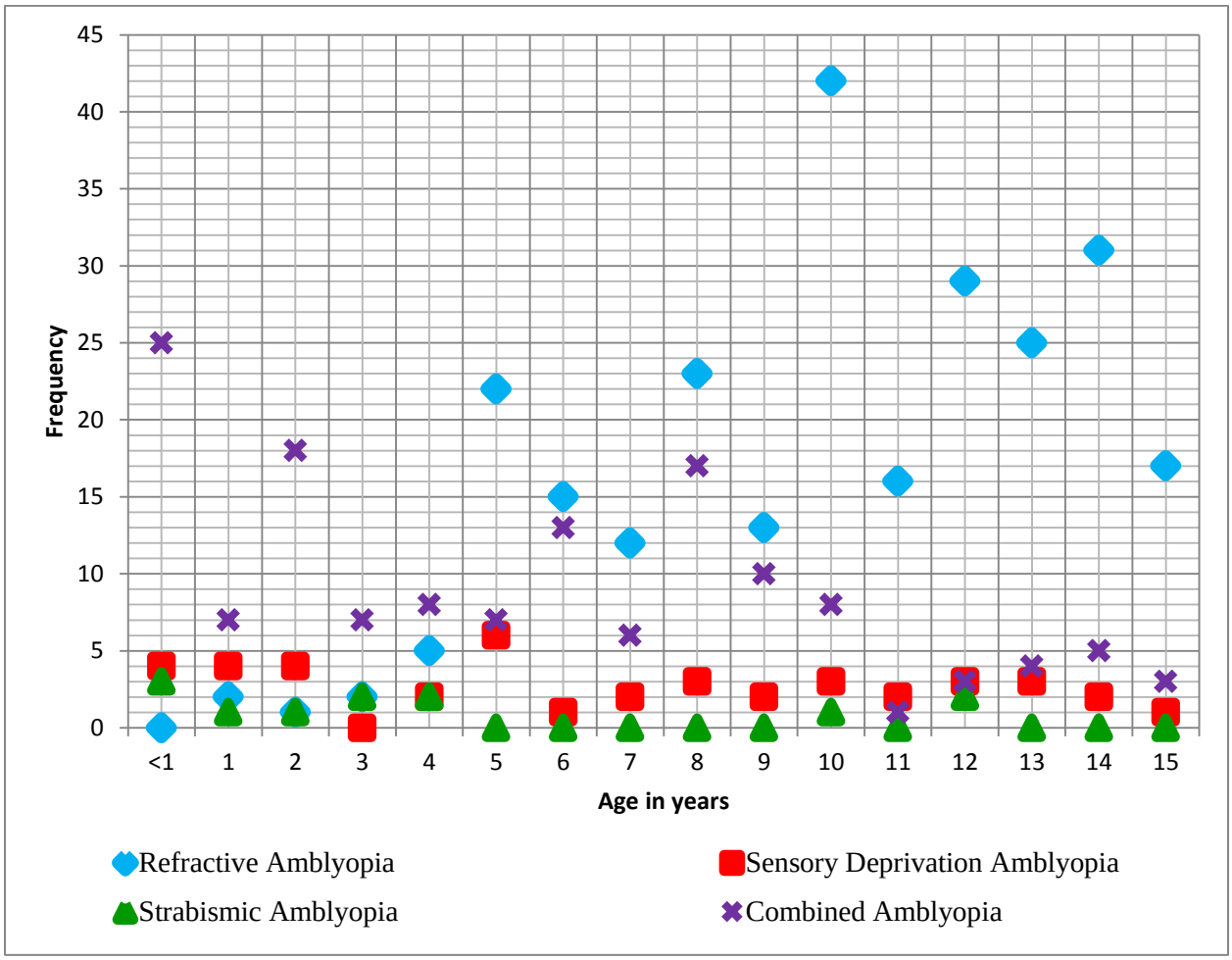
Table 8: Frequency Distribution Table showing age at first presentation for Combined Amblyopia

n = 142

Age (yrs)	Number of eyes	Relative Frequency (%)	Cumulative (%)
<1	25	17.61	17.61
1	7	4.93	22.54
2	18	12.68	35.21
3	7	4.93	40.14
4	8	5.63	45.77
5	7	4.93	50.70
6	13	9.15	59.86
7	6	4.23	64.08
8	17	11.97	76.06
9	10	7.04	83.10
10	8	5.63	88.73
11	1	0.70	89.44
12	3	2.11	91.55
13	4	2.82	94.37
14	5	3.52	97.89
15	3	2.11	100.00
TOTAL	**142**		

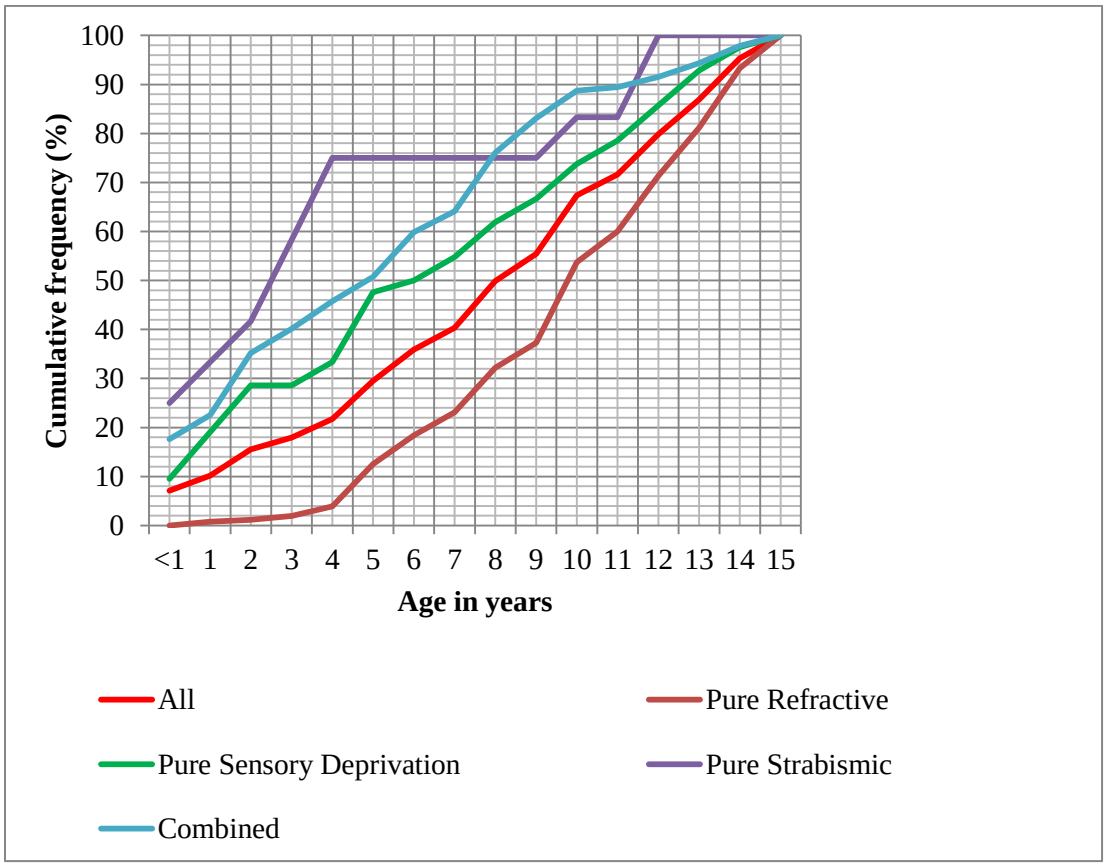
Most (76.06%) of the children found to have combined amblyopia had presented by the age of 8 years. The most common (17.61%) age at first presentation was before their first birthday.

Figure 7: Age at first presentation for the four amblyopia types.



Refractive amblyopia was the most common type of amblyopia and most of these patients first presented late. In contrast, most of the patients with combined amblyopia presented at an early age, and their numbers decrease with increasing age.

Figure 8: Cumulative Frequency Polygon of age at first presentation for the four amblyopia types.



By the age of 8 years, 49.89% of all amblyopia patients, 32.16% of refractive amblyopia patients, 61.90% of pure sensory deprivation patients, 75% of pure strabismic amblyopia patients and 76.06% of combined amblyopia had presented to the hospital.

Table 9: Measures of location for age at first presentation.

n = 451

	AMBLYOPIA TYPE	MEAN	MEDIAN	MODE
1	**Refractive Amblyopia**	**10.09**	**10**	**10**
	a) Combined Anisometropia, Ametropia & Meridional	10.91	12	10
	b) Combined Ametropia & Meridional	10.57	11	14
	c) Combined Anisometropia & Meridional	10.24	11	14
	d) Pure Ametropia	9.66	10	10
	e) Pure Meridional	9.15	10	10
	f) Pure Anisometropia	8.50	8.5	N/A$^{\delta}$
	g) Combined Anisometropia & Ametropia	8.25	8	8
2	**Sensory Deprivation Amblyopia**	**6.77**	**6.5**	**5**
3	**Combined Amblyopia**	**5.52**	**5**	**<1**
	a) Combined Strabismic & Sensory Deprivation	6.40	7	N/A$^{\Phi}$
	b) Combined Strabismic, Refractive & Sensory Deprivation	6.23	5.5	2
	c) Combined Strabismic & Refractive	6.03	7	8
	d) Combined Sensory Deprivation & Refractive	5.31	5	<1
4	**Strabismic Amblyopia**	**4.40**	**3**	**4**
	TOTAL	**8.19**	**9**	**10**

$^{\delta}$ Two eyes had pure anisometropia, each with different ages.

$^{\Phi}$ Six eyes had combined strabismic and sensory deprivation, each with different ages.

The overall median age at first presentation was 9 years. It was highest in refractive amblyopia at 10 years and lowest for strabismic amblyopia at 3 years.

It is notable that the most common age (mode) at first presentation for children with combined amblyopia was <1 year.

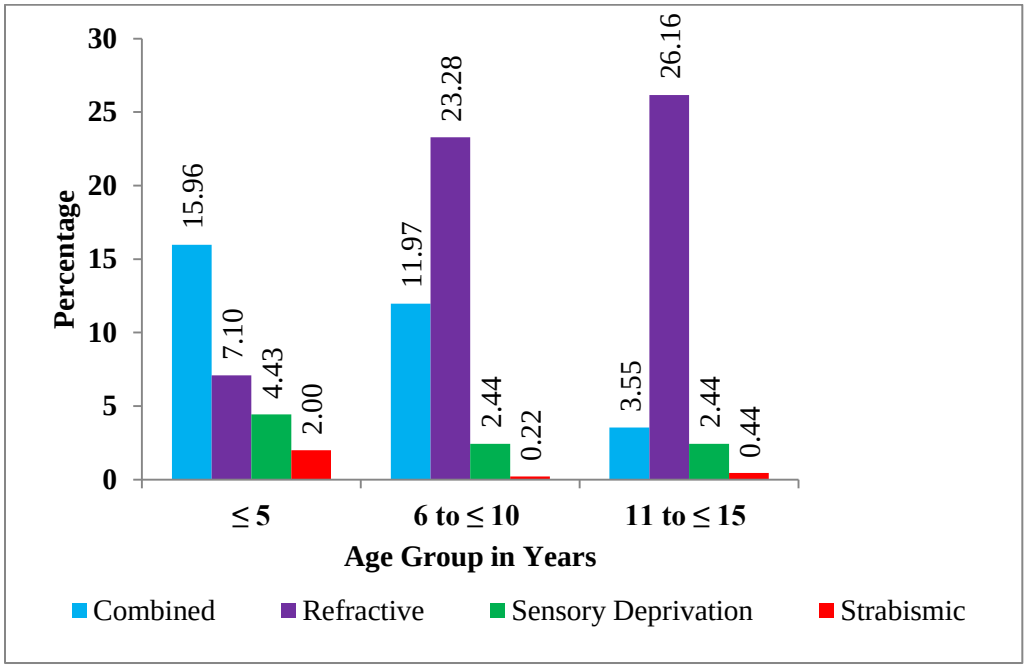
Table 10: Table showing age grouping of the four types of amblyopia

n = 451

	≤ 5 years		6 to ≤ 10 years		11 to ≤ 15 years		Total	
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Combined	72	15.96	54	11.97	16	3.55	142	31.49
Refractive	32	7.10	105	23.28	118	26.16	255	56.54
Sensory Deprivation	20	4.43	11	2.44	11	2.44	42	9.31
Strabismic	9	2.00	1	0.22	2	0.44	12	2.66
All	**133**	**29.49**	**171**	**37.92**	**147**	**32.59**	**451**	**100.00**

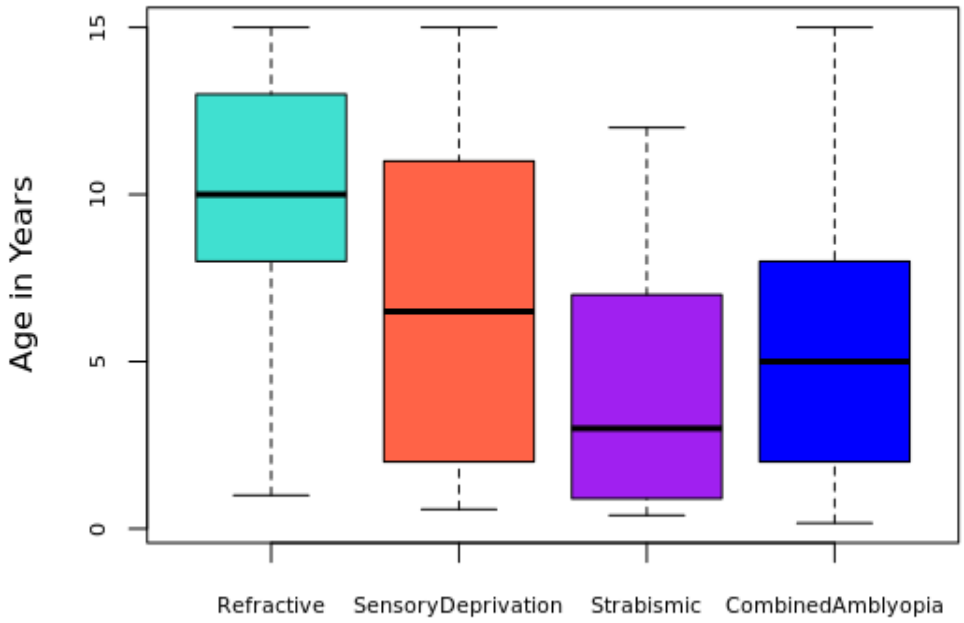
Figure 9: Clustered Bar Chart showing the distribution of the amblyopia types in different age groups.

n = 451



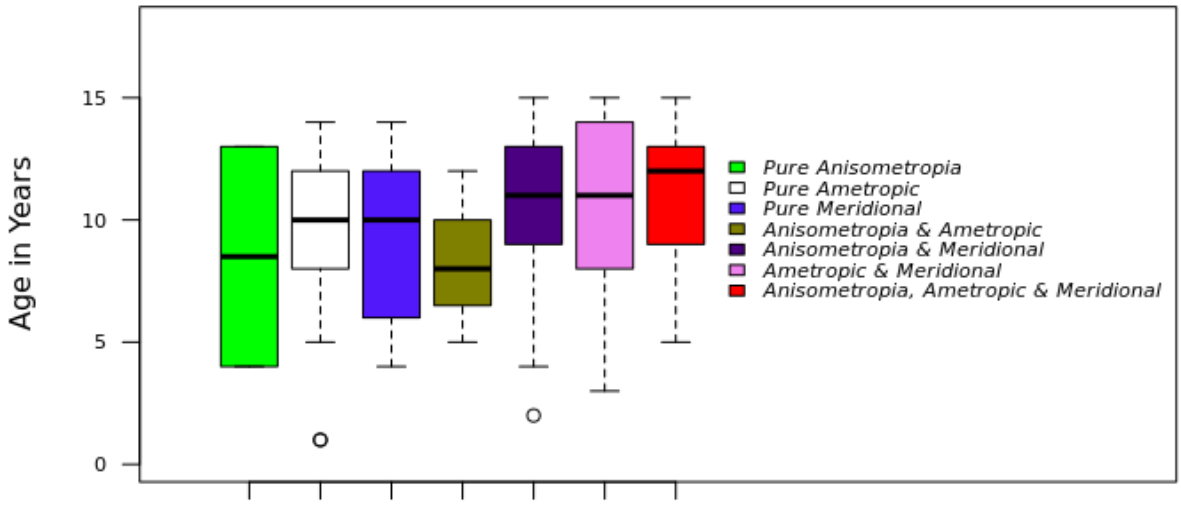
Most of the amblyopic eyes were in the 6 to ≤ 10 years age group (37.92%). The ≤5 years age group had the highest proportion of eyes for pure strabismic (2.00%), pure sensory deprivation (4.43%) and combined (15.96%) amblyopia, while the 11 to ≤15 years age group had the highest proportion for refractive (56.54%) amblyopia eyes.

Figure 10: Box and Whisker Plot showing age at first presentation for the four amblyopia types



A median age above 8 years was found in refractive amblyopia (10 years) but not in pure sensory deprivation (6.5 years), combined amblyopia (5 years) and pure strabismic (3 years).
The interquartile range was widest for pure sensory deprivation amblyopia (2 to 10.75 years) and narrowest for refractive amblyopia (8 to 13 years).

Figure 11: Box and Whisker Plot showing age at first presentation for the Refractive Amblyopia subtypes.

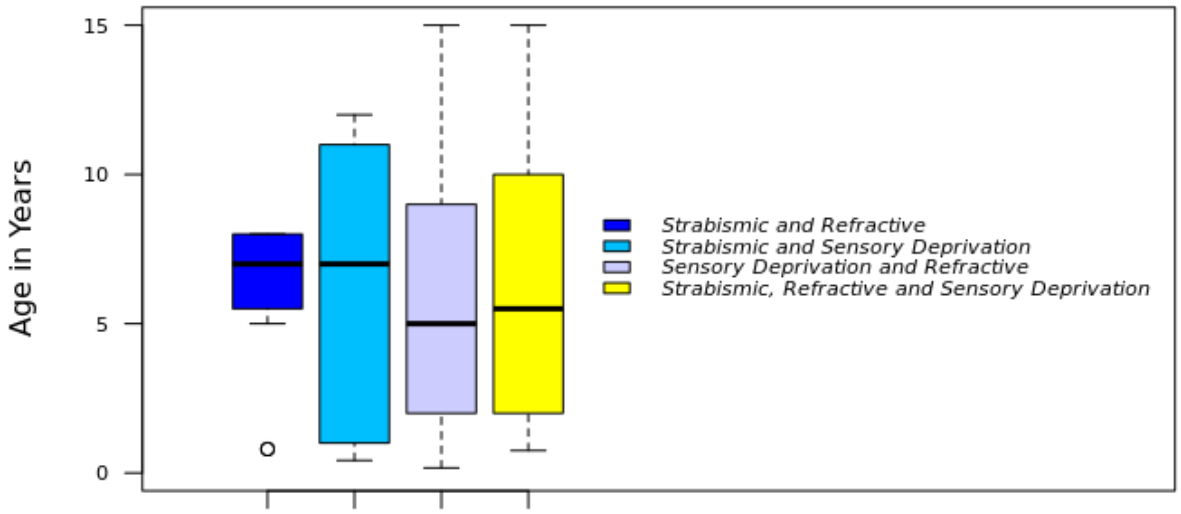


The median age was lowest for 'combined anisometropia & ametropia amblyopia' (8 years) and highest for 'combined anisometropia, ametropia & meridional amblyopia' (12 years).

The interquartile range was widest for 'pure anisometropia' (4 to 13 years) and narrowest for 'combined anisometropia & ametropia' (7.25 to 9 years).

The oldest patients were found in the 'ametropic & meridional subtype'.

Figure 12: Box and Whisker Plot showing age at first presentation for the Combined Amblyopia subtypes



The median age was highest for 'combined strabismic & refractive amblyopia' (7 years) as well as 'combined strabismic & sensory deprivation amblyopia' (7 years), and lowest for 'combined sensory deprivation and refractive' (5 years). It is notable that for all the combined amblyopia subtypes, the median age at first presentation was below 8 years.

Table 11: Refractive status of eyes with amblyopia

n = 451

Refractive Status	**n**	**%**
Myopic Astigmatism	243	53.88
Hypermetropic Astigmatism	72	15.96
Myopia	51	11.31
Hypermetropia	48	10.64
No Record	25	5.54
Astigmatism	9	2.00
Emmetropia	3	0.67
TOTAL	**451**	**100.00**

Myopic astigmatism was the most common refractive status (53.88%) in eyes with amblyopia followed by hypermetropic astigmatism (15.96%). Emmetropia was the least common refractive status (0.67%).

Table 12: Relationship between refractive status and types of amblyopia

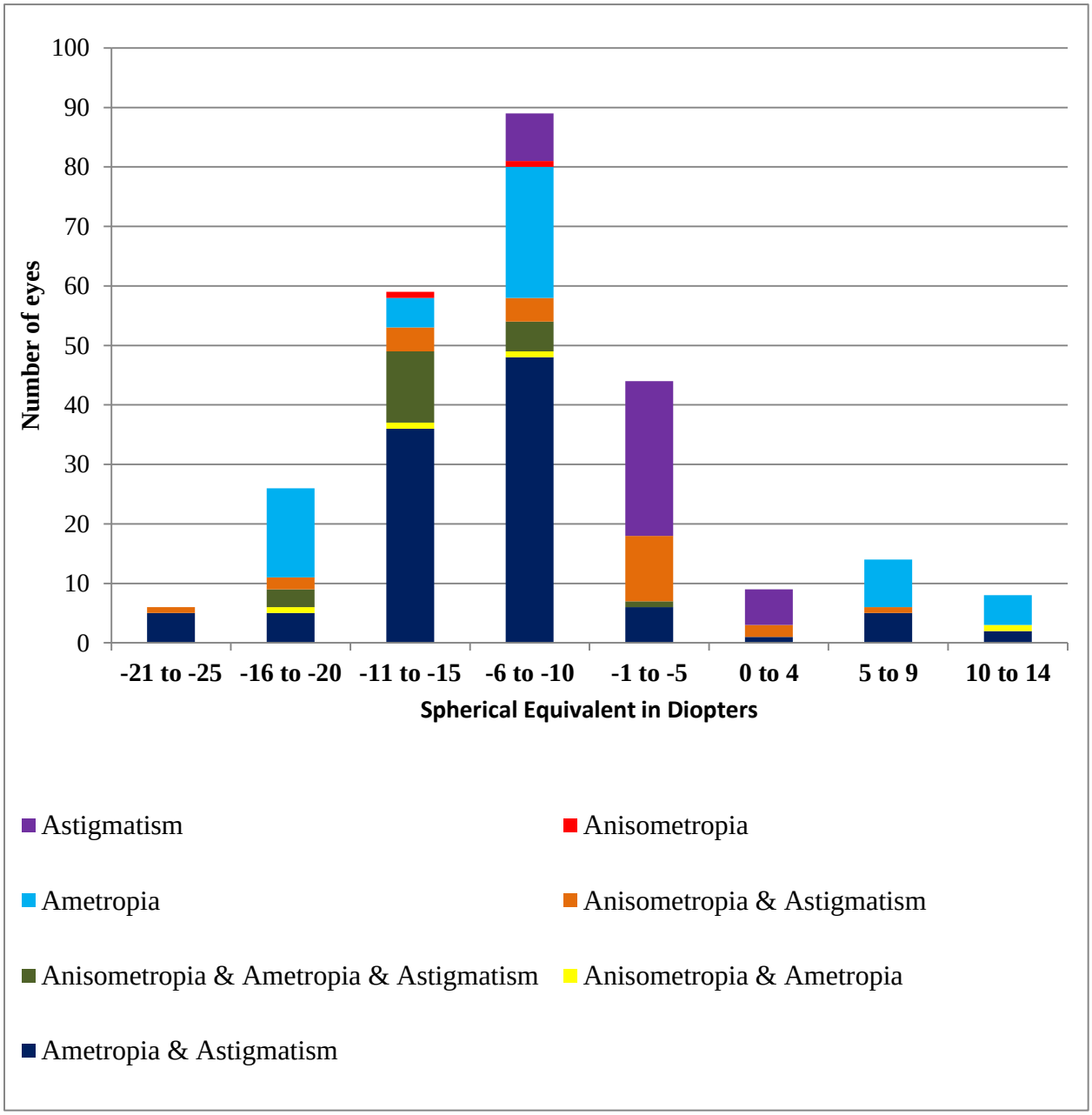
n = 451

	AMBLYOPIA TYPE	Myopic Astigmatism	Hypermetropic Astigmatism	Myopia	Hypermetropia	Not recorded	Astigmatism	Emmetropia	Total	P - value
1	**Refractive Amblyopia**	**174**	**22**	**42**	**12**	**0**	**5**	**0**	**255**	**0.00**
	Combined Ametropia & Meridional	97	10	0	0	0	1	0	108	0.00
	Pure Meridional	34	4	0	0	0	2	0	40	0.00
	Combined Anisometropia, Ametropia & Meridional	21	0	0	0	0	0	0	21	_
	Combined Anisometropia & Meridional	17	6	0	0	0	2	0	25	0.00
	Pure Ametropia	3	2	39	11	0	0	0	55	0.00
	Combined Anisometropia & Ametropia	1	0	2	1	0	0	0	4	0.78
	Pure Anisometropia	1	0	1	0	0	0	0	2	1.00
2	**Combined Amblyopia**	**59**	**43**	**6**	**27**	**4**	**2**	**1**	**142**	0.00
	Combined Sensory Deprivation & Refractive	47	33	4	23	0	2	0	109	0.00
	Combined Strabismic, Refractive & Sensory Deprivation	11	4	0	1	0	0	0	16	0.01
	Combined Strabismic & Refractive	1	6	2	2	0	0	0	11	0.15
	Combined Strabismic & Sensory Deprivation	0	0	0	1	4	0	1	6	1.00
3	**Pure Sensory Deprivation Amblyopia**	**10**	**4**	**2**	**4**	**20**	**2**	**0**	**42**	0.04
4	**Pure Strabismic Amblyopia**	**0**	**3**	**1**	**5**	**1**	**0**	**2**	**12**	0.36
	TOTAL	**243**	**72**	**51**	**48**	**25**	**9**	**3**	**451**	**0.00**

Myopic astigmatism was the most common refractive status for refractive (68.24%), pure sensory deprivation (23.81%) and combined (41.55%) amblyopia and this was statistically significant. Hypermetropia (41.67%) was the most common refractive status in strabismic amblyopia, but this was found to not be statistically significant.

Emmetropia (0.67%) was the least common refractive status among all 451 amblyopic eyes.

Figure 13: Stacked column chart showing the range of Spherical Equivalents for eyes with refractive amblyopia.



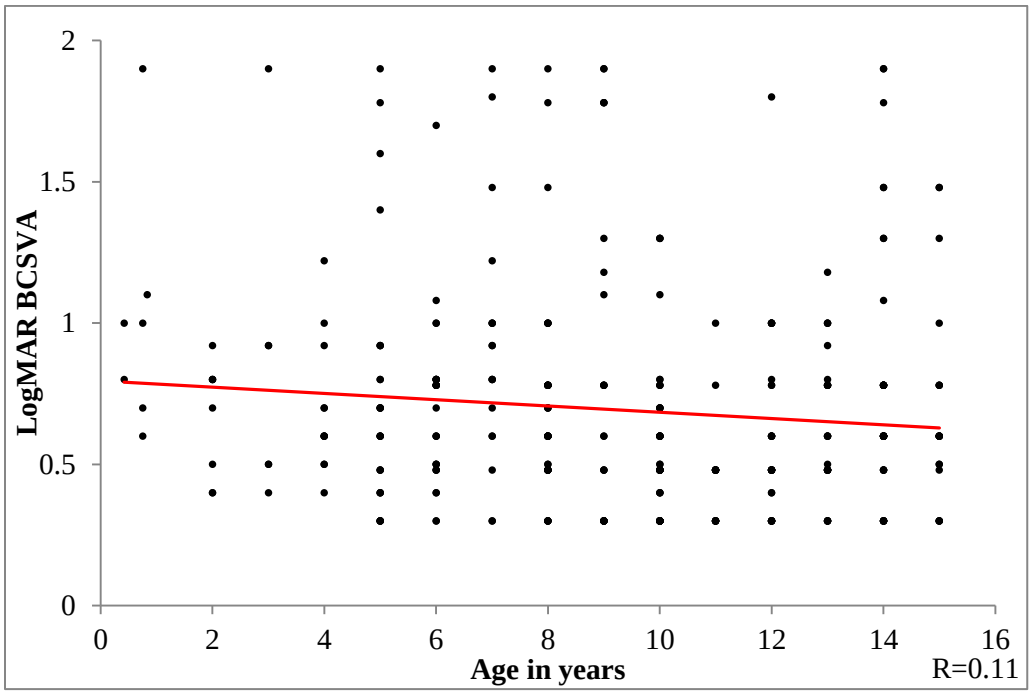
The range of spherical equivalent for eyes with refractive amblyopia was -23.38 to +13.00 with an interquartile range of -12.88 to -4.69.

Table 13: Measures of location of spherical equivalent based on amblyopia type and subtype

	AMBLYOPIA TYPE	MEAN	MEDIAN	MODE
1	**Pure Strabismic Amblyopia**	**+0.60**	**+0.75**	**+1.00**
2	**Combined Amblyopia**	**+0.19**	**-1.25**	**-1.38**
	a) Combined Strabismic & Sensory Deprivation	+1.00	+1.00	N/A
	b) Combined Sensory Deprivation & Refractive	+0.42	-1.38	-1.38
	c) Combined Strabismic & Refractive	-0.16	+2.00	+2.00
	d) Combined Strabismic, Refractive & Sensory Deprivation	-1.26	-2.31	-4.75
3	**Pure Sensory Deprivation Amblyopia**	**-0.17**	**-0.38**	**-0.38**
4	**Refractive Amblyopia**	**-8.05**	**-8.50**	**-9.00**
	a) Pure Meridional	-4.06	-3.56	-5.00
	b) Combined Anisometropia & Ametropia	-6.81	-11.13	N/A
	c) Combined Anisometropia & Meridional	-6.86	-5.00	-1.00
	d) Pure Ametropia	-6.94	-9.00	-9.00
	e) Combined Ametropia & Meridional	-9.55	-9.81	-11.00
	f) Pure Anisometropia	-10.13	-10.13	N/A
	g) Combined Anisometropia, Ametropia & Meridional	-12.32	-12.5	-15.50
	TOTAL	**-4.75**	**-5.00**	**-9.00**

The refractive amblyopia eyes were generally high myopes while pure sensory deprivation eyes were low myopes. Eyes with pure strabismus were hypermetropic while those with combined amblyopia had a mixture of myopia and hyperopia.

Figure 14: Scatter plot showing the correlation between LogMAR Best Corrected Spectacle Visual Acuity (BCSVA) and age at first presentation for all amblyopia cases.



Pearson's Correlation Coefficient: -0.11

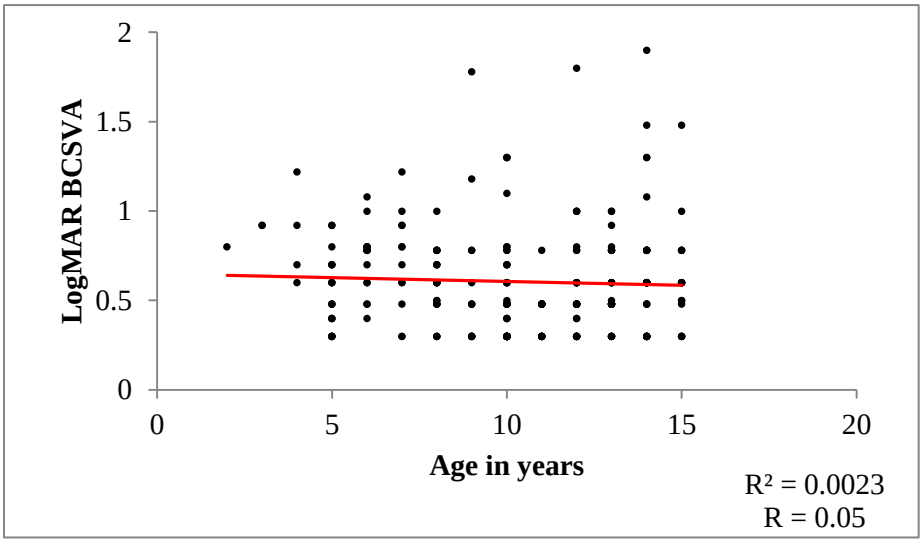
There was no evidence of a linear correlation between the age at first presentation and the BCSVA.

The Coefficient of Determination (R^2) was 0.018.

Adjusted R^2: 0.211 (Adjusted for laterality, type and refractive status)

The p-value was 0.18.

Figure 15: Scatter plot showing the correlation between LogMAR BCSVA and age at first presentation for Refractive Amblyopia

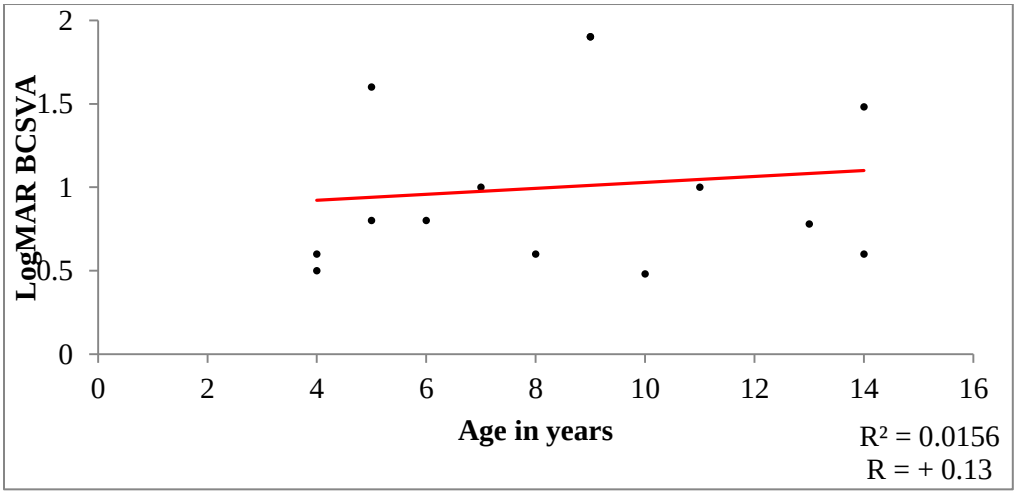


Pearson's Correlation Coefficient: -0.05

Coefficient of Determination (R^2): 0.00

There was no evidence of linear correlation between age and LogMAR BCSVA for patients with refractive amblyopia.

Figure 16: Scatter plot showing the correlation between LogMAR BCSVA and age at first presentation for Pure Sensory Deprivation Amblyopia

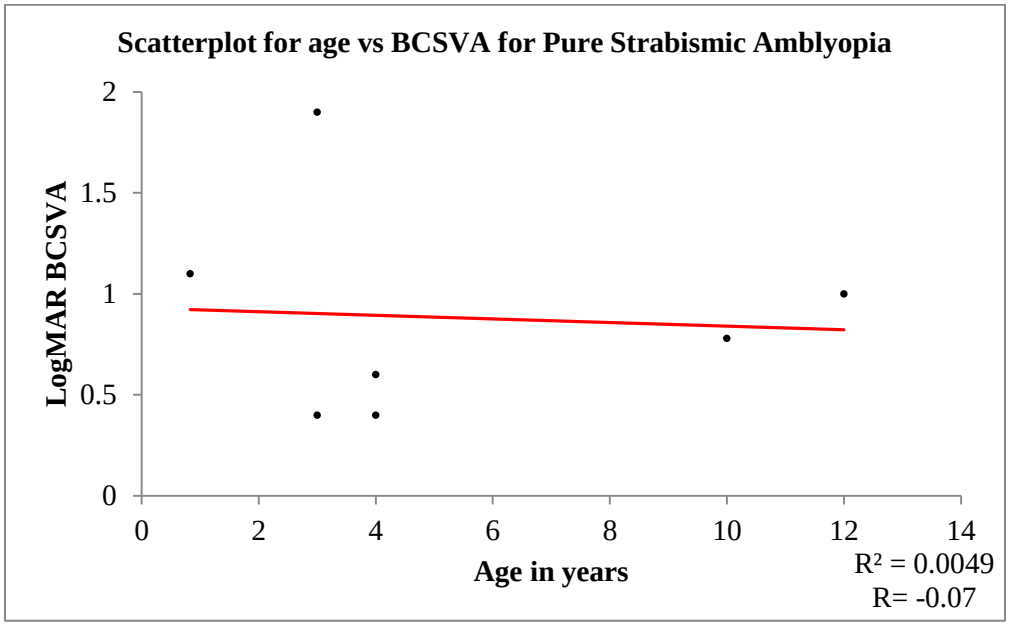


Pearson's Correlation Coefficient: +0.13

Coefficient of Determination (R2): 0.02

There was no evidence of linear correlation between age and LogMAR BCSVA for patients with pure sensory deprivation amblyopia.

Figure 17: Scatter plot showing the correlation between LogMAR BCSVA and age at first presentation for Pure Strabismic Amblyopia

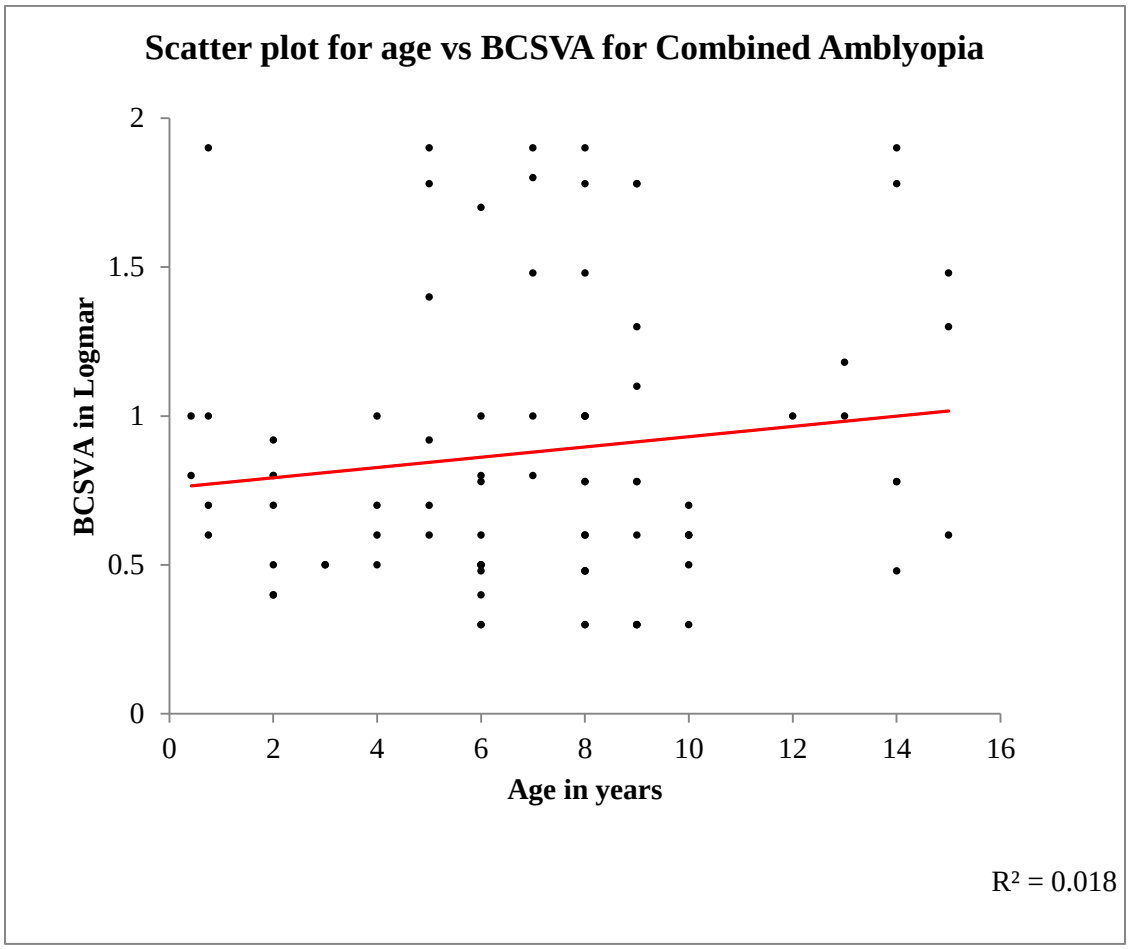


Pearson's Correlation Coefficient: -0.07

Coefficient of Determination (R^2): 0.01

There was no evidence of linear correlation between age and LogMAR BCSVA for patients with pure strabismic amblyopia.

Figure 18: Scatter plot showing the correlation between LogMAR BCSVA and age at first presentation for Combined Amblyopia



Pearson's Correlation Coefficient: +0.13

Coefficient of Determination (R^2): 0.018

There was no evidence of linear correlation between age and LogMAR BCSVA for patients with combined amblyopia.

Table 14: Causes of Sensory Deprivation.

Sensory deprivation was an amblyogenic factor in 173 eyes (108 patients).

	Cataract	Corneal opacity	Other	Congenital Ptosis	Hyphema	Occlusion Amblyopia	Haemorrhage	Total
Combined Sensory Deprivation & Refractive Amblyopia	97	13	3*	0	0	0	0	113
Sensory Deprivation Amblyopia	39	3	0	0	0	0	0	42
Combined Strabismic, Refractive & Sensory Deprivation Amblyopia	15	0	1^{Φ}	1^{δ}	0	0	0	17
Combined Strabismic & Sensory Deprivation Amblyopia	6	0	0	0	0	0	0	6
TOTAL	**157**	**16**	**4**	**1**	**0**	**0**	**0**	**178**

*Three cases that presented with Posterior Capsule Opacity and had a history of cataract surgery done elsewhere.

$^{\delta}$ A case of bilateral high hypermetropia and left eye esotropia with a history of left eye Frontalis Sling Surgery done elsewhere.

$^{\Phi}$ Congenital pupillary membrane.

Cataract was the most common (88.20%) cause of sensory deprivation.

Table 15: Type of tropia in the eye with Strabismic Amblyopia.

n = 45

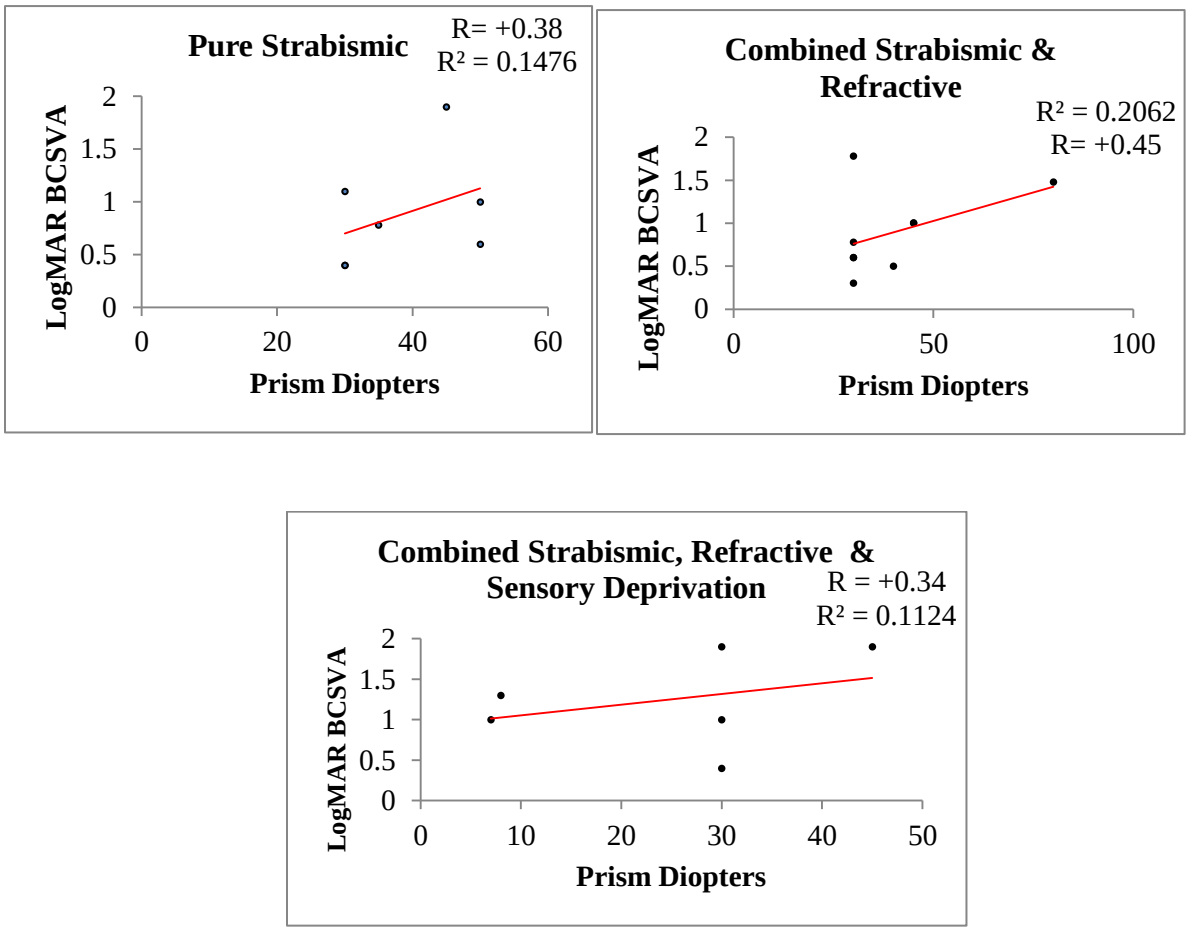
		Esotropia	Exotropia	Hypertropia	TOTAL	P-value
1	Pure Strabismic Amblyopia	12	0	0	**12 (27%)**	-
4	Combined Strabismic, Refractive & Sensory Deprivation Amblyopia	9	7	0	**16 (36%)**	0.78
2	Combined Strabismic & Refractive Amblyopia	6	4	1	**11 (24%)**	0.18
3	Combined Strabismic & Sensory Deprivation Amblyopia	3	3	0	**6 (13%)**	1
	TOTAL	**30 (67%)**	**14 (31%)**	**1 (2%)**	**45**	**0.00**

Strabismus was an amblyogenic factor in 45 out of the 451 eyes enrolled in the study. Esotropia (67%) was found to be the most common form of strabismus, followed by exotropia (31%) and hypertropia (2%). This difference in the strabismus types was statistically significant with a p-value of 0.00.

Most (73%) of the eyes with strabismus were in the combined amblyopia category (Combined strabismic & refractive 24%; Combined strabismic & sensory deprivation 13%; Combined strabismic, refractive & sensory deprivation 36%), as opposed to the pure strabismic amblyopia (27%) category.

All eyes with pure strabismic amblyopia had esotropia while those in the combined type had esotropia, exotropia and hypertropia. However, these differences were not statistically significant.

Figure 19: Scatter plots showing the correlation between Prism Diopters and LogMAR BCSVA for the various subtypes that involved strabismus as an amblyogenic factor.



Pearson's Correlation Coefficient was +0.38 for pure strabismus, +0.45 for combined strabismic & refractive amblyopia and +0.34 for combined strabismic, refractive & sensory deprivation amblyopia. The Coefficient of Determination (R^2) was 0.15, 0.21 and 0.11.

In these three categories, there was evidence of a weak positive linear correlation between the prism diopters and the LogMAR BCSVA - that is, as the value of prism diopters increases, the LogMAR BCSVA also increases.

6.3 Depth of Amblyopia

Table 16: Depth of Amblyopia in eyes with quantitative amblyopia

n = 354*

	VISUAL ACUITY ASSESSMENT	QUANTITATIVE VISUAL ACUITY							
		Moderate Amblyopia (<0.7)			Severe Amblyopia (≥0.7)			Total (100 %)	P-Value
	AMBLYOPIA TYPE	n		%	n		%		
1	**Refractive Amblyopia**	**164**		**65.86**	**85**		**34.14**	**249**	**0.00**
	a) Combined Ametropia & Meridional		66	61.11		42	38.89	108	0.29
	b) Pure Ametropia		38	71.7		15	28.3	53	0.01
	c) Pure Meridional		32	88.89		4	11.11	36	0.00
	d) Combined Anisometropia & Meridional		15	60		10	40	25	0.01
	e) Combined Anisometropia, Ametropia & Meridional		12	57.14		9	42.86	21	0.00
	f) Combined Anisometropia & Ametropia		1	25		3	75	4	0.32
	g) Pure Anisometropia		0	0		2	100	2	-
2	**Combined Amblyopia**	**35**		**41.67**	**49**		**58.33**	**84**	**0.42**
	a) Combined Sensory Deprivation & Refractive Amblyopia		30	44.78		37	55.22	67	1.00

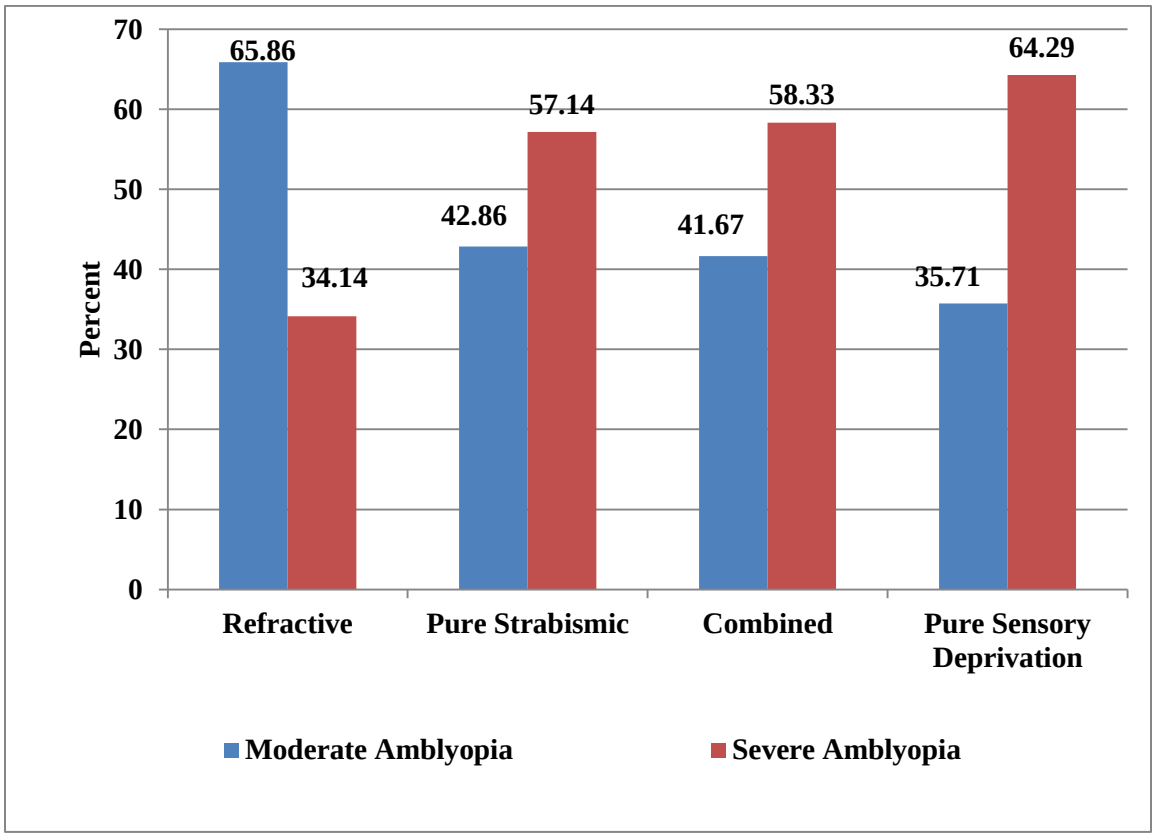
	b) Combined Strabismic & Refractive Amblyopia		4	44.44		5	55.56	9	0.10
	c) Combined Strabismic, Refractive & Sensory Deprivation Amblyopia		1	12.5		7	87.5	8	0.66
	d) Combined Strabismic & Sensory Deprivation Amblyopia		0	0		0	0	0	-
3	**Pure Sensory Deprivation Amblyopia**	**5**		**35.71**	**9**		**64.29**	**14**	**0.04**
4	**Pure Strabismic Amblyopia**	**3**		**42.86**	**4**		**57.14**	**7**	**0.01**
	TOTAL	**207**		**58.47**	**147**		**41.53**	**354**	**0.13**

*354 of the 451 eyes had quantitative amblyopia. The remaining 97 (21.51%) had a qualitative amblyopia assessment.

Amblyopia was mostly moderate in refractive amblyopia (65.86%) and severe in pure sensory deprivation amblyopia (64.29%) and pure strabismic amblyopia (57.14%). These differences were found to be statistically significant.

The difference between moderate (41.67%) and severe (58.33%) for combined amblyopia was not statistically significant.

Figure 20: Clustered Bar Chart showing the percentage of moderate and severe amblyopia for the four amblyopia types

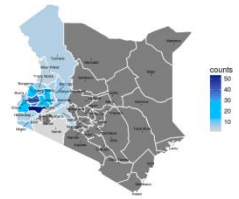


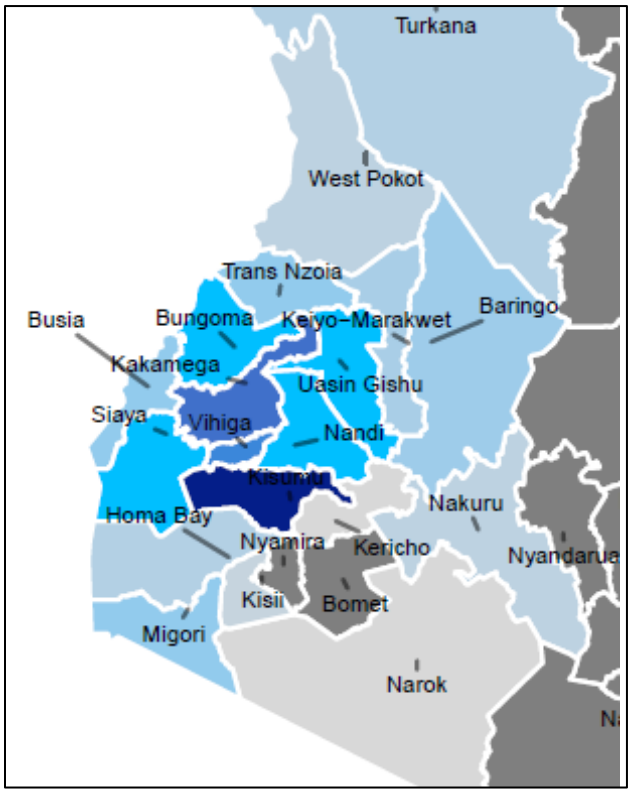
Most (64.29%) eyes with pure sensory deprivation had severe amblyopia. The reverse is true for refractive amblyopia; 65.86% had moderate amblyopia.

6.4 Catchment Area

Table 17: Catchment area for all children with amblyopia.

n=268





All the patients came from the Western and North-Western parts of Kenya. Most of the patients came from Kisumu county (19.78%) followed by Kakamega county (13.81%) and Vihiga county (12.69%).

COUNTY	n	%
Kisumu	53	19.78
Kakamega	37	13.81
Vihiga	34	12.69
Uasin Gishu	25	9.33
Nandi	22	8.21
Bungoma	22	8.21
Siaya	15	5.60
Trans Nzoia	8	2.99
Busia	8	2.99
Migori	8	2.99
Baringo	7	2.61
Elgeyo-Marakwet	6	2.24
Turkana	5	1.87
Homa Bay	5	1.87
West Pokot	4	1.49
Nakuru	4	1.49
Kisii	3	1.12
Narok	1	0.37
Kericho	1	0.37
TOTAL	**268**	**100.00**

Table 18: Catchment area for the various amblyopia subtypes.

n = 451

	Refractive	Combined	Pure Sensory Deprivation	Pure Strabismic
	n (%)	**n (%)**	**n (%)**	**n (%)**
Baringo	0 (0.00)	8 (5.63)	3 (7.14)	0 (0.00)
Bungoma	12 (4.70)	7 (4.93)	**8 (19.05)**	**4 (33.33)**
Busia	12 (4.70)	3 (2.11)	0 (0.00)	0 (0.00)
Elgeyo-Marakwet	5 (1.96)	2 (1.41)	2 (4.76)	1 (8.33)
Homa Bay	4 (1.57)	3 (2.11)	0 (0.00)	0 (0.00)
Kakamega	42 (16.47)	19 (13.38)	5 (11.90)	0 (0.00)
Kericho	1 (0.39)	0 (0.00)	0 (0.00)	0 (0.00)
Kisii	2 (0.78)	3 (2.11)	0 (0.00)	0 (0.00)
Kisumu	**53 (20.78)**	**27 (19.01)**	5 (11.90)	**4 (33.33)**
Migori	3 (1.18)	8 (5.63)	1 (2.38)	1 (8.33)
Nakuru	3 (1.18)	4 (2.82)	0 (0.00)	0 (0.00)
Nandi	18 (7.06)	19 (13.38)	1 (2.38)	1 (8.33)
Narok	0 (0.00)	0 (0.00)	2 (4.76)	0 (0.00)
Siaya	15 (5.88)	6 (4.23)	2 (4.76)	0 (0.00)
Trans Nzoia	6 (2.35)	5 (3.52)	3 (7.14)	0 (0.00)
Turkana	2 (0.78)	5 (3.52)	1 (2.38)	0 (0.00)
Uasin Gishu	28 (10.98)	12 (8.45)	5 (11.90)	0 (0.00)
Vihiga	47 (18.43)	10 (7.04)	2 (4.76)	0 (0.00)
West Pokot	2 (0.78)	1 (0.70)	2 (4.76)	1 (8.33)
TOTAL	**255 (100.00)**	**142 (100.00)**	**42 (100.00)**	**12 (100.00)**

Most of refractive amblyopia (20.78%) and combined amblyopia (19.01%) came from Kisumu County (20.78%). Most of pure sensory deprivation amblyopia cases came from Bungoma County (19.05%). Most of strabismic amblyopia cases came from Bungoma (33.33%) and Kisumu (33.33%) counties.

7. DISCUSSION

There were 7,041 visits to the outpatient clinic by children aged <16 years between 1st January to 31st December 2014. After excluding the re-visits, it was found that 4,450 children were seen during this period. 181 files were not found and were therefore excluded. On review of the 4,269 files which were found, 268 patients met the case definitions and were enrolled in the study.

Proportion

This study found that 6.3% of the children <16 years who attended Sabatia Eye Hospital outpatient eye department in 2014 had amblyopia. This proportion was found to be 0.7% of the general paediatric population at Nepal Eye Hospital, 9.1% at Menilik II Hospital paediatric ophthalmology clinic in the capital city of Ethiopia and 14.3% at Grarbet Eye Hospital outpatient eye department in rural Ethiopia.

Prevalence of amblyopia in the general North American population is in the range of 2 – 4%[2]. However, there are no local prevalence figures the Kenyan population. The study was carried out in a hospital setting and therefore suffers from a selection bias as the children present to hospital are self-selecting. There are probably some children who have amblyopia but have never visited hospital for various reasons that may range from finances, distance, accessibility, neglect and ignorance. With the absence of school screening programmes, this hospital-based proportion is not applicable to the general population. Worldwide, there were few hospital-based studies for comparison as most amblyopia studies have been school-based or population-based.

The hospital setting where the patients present may have an influence on the proportions obtained in various studies, that is, whether they presented to a general hospital or to an eye hospital; the general outpatient eye department[53,54,57,58] or to a specialized paediatric ophthalmology[52,56] or orthoptic clinic[55,58,59]. These factors have an influence on both the numerator and denominator of the proportions and may account for the wide variations seen. Urban versus rural setting may also account for differences in proportions probably due to easier or better access to eye services[67,68,69]. An example of this is a study on refractive errors by Murthy et al[67] on school-aged children in an urban India which found an amblyopia prevalence

of 4.4%, while a similar study by Dandona et al[68] in rural India found an amblyopia prevalence of 12%.

The proportion of 6.3% gives us an indication of the burden of the disease in this rural hospital and this can help in planning purposes. This proportion seems relatively low, but is actually significant when you consider that these are children who still have many years ahead of them. Consequently the Disability-adjusted Life Year (DALY) and Quality-adjusted Life Year (QALY) will be affected significantly in the children with unilateral amblyopia. Blind-person years will be increased for the children with untreated bilateral severe amblyopia.

Demographics

The number of male 136 (50.75%) and female 132 (49.25%) patients was almost equal. This finding is similar to that of Woldeyes et al[52] in Ethiopia where 49.7% were male while 50.3% were female.

Bilateral amblyopia [183 (68.28%)] was more common in the 268 patients compared to unilateral amblyopia [85 (31.72%)], with a p-value of 0.00. This difference can be explained by the finding that 94 patients (35.07%) in this study had ametropia which by definition is bilateral. Additionally, 60 patients (22.3%) had bilateral sensory deprivation due to bilateral cataract. This finding differs from Woldeyes et al[52] where 88% of cases were unilateral while 12% were bilateral and the most common cause of amblyopia was strabismus. Ganekal et al[69] in India did a population-based screening of school children and found that 18 children (41%) had bilateral amblyopia while 44 (59%) had unilateral amblyopia. Ametropia (50%) was the most common cause of amblyopia in his study. Similarly, Sapkota et al[57] found 29% bilateral amblyopia which was attributed to ametropia.

Types and subtypes of amblyopia

This study found that a number of eyes met the case definitions of two or more types and subtypes of amblyopia. The "combined" types and subtypes account for these multiple amblyogenic factors since it could not be clearly determined which factor played the lead role in the development of amblyopia.

Comparison of the types of amblyopia among different studies was challenging due to the variation in classification of case definitions among the different studies. An example is the study by Menon et al[55], where 37.38% of eyes had strabismic amblyopia, while 22.1% had anisometropic amblyopia, 18.44% had combined, 12.88% had ametropic, 5.56% had meridional amblyopia and 7.63% had sensory deprivation amblyopia. Strabismic amblyopia (37.38%) was reported to be the most common subtype, but if this study's classification was to be used, then refractive amblyopia (22.1% anisometropia; 12.88% ametropia; 5.56% meridional amblyopia) would be the most common subtype at 40.54%. Sapkota et al[57] classified anisometropic and ametropic amblyopia as refractive, but did not include meridional.

There are differences noted in the specific case definitions for types and subtypes of amblyopia in the various studies. The Menon et al[55] and Sharma et al[56] case definition for 'strabismic amblyopia' included patients with strabismus along with refractive errors of >1D spherical equivalent in one or both eyes or eyes with regular astigmatism ≥1.5D in any meridian. Such patients in this study were categorized under 'combined strabismic and refractive amblyopia' while Repka et al[10] called it 'combined mechanism amblyopia'. In contrast, this study's case definition for 'pure strabismic amblyopia' excluded any refractive errors. Repka et al[10] case definition ensured that cases with refractive errors were excluded from the 'strabismic amblyopia' type, while the Woldeyes et al[52] case definition excluded anisometropia.

Patients who met the case definition for both anisometropic amblyopia and meridional amblyopia in the Menon et al[55] study were categorized under 'anisometropic amblyopia'. However, in this study they were categorized as 'combined anisometropia and meridional amblyopia'. Additionally, Menon et al[55] defined 'combined amblyopia' as a squint and anisometropia or meridional combination, while Woldeyes et al[52] defined it as heterotropia plus anisometropia. However, this does not account for the four possible variations of 'combined amblyopia' i.e. combined strabismic & refractive, combined strabismic & sensory deprivation, combined sensory deprivation & refractive and combined strabismic, refractive & sensory deprivation.

Variations in the various cut-offs for refractive status in case definitions further added to the difficulty in comparison of studies. In the "ametropic amblyopia" case definition, Menon et al[55] and Chua et al[58] used a cut-off of >1D spherical equivalent while Woldeyes et al[52] used >1.5D spherical equivalent. This study used cut-offs of ≥ 4.00D spherical equivalent hyperopia, ≥ 6.00D spherical equivalent myopia and ≥2.50D astigmatism. These cut-offs that were used in the Multi-Ethnic Pediatric Eye Disease Study Group (MEPEDS)[12] and Baltimore Pediatric Eye Disease Study (BPEDS)[13] are cognizant of the normal variations in refractive status of younger children and that high (not low) bilateral refractive errors are amblyogenic.

The difference in diopters between the two eyes in anisometropic amblyopia case definitions also showed variations between the studies. Woodruff et al[22] used ≥1D sphere or cylinder, while Menon et al[55] and Sharma et al[56] used ≥1D spherical equivalent or ≥1.5D difference in astigmatism. Woldeyes et al[52] used ≥1.5D spherical equivalent or ≥1.5D difference in astigmatism, while Mehari et al[53] in rural Ethiopia used 2D. In this study, the cut-offs were ≥1.00D for anisohyperopia, ≥3.00D for anisomyopia and ≥1.5D for anisoastigmatism, in line with MEPEDS and BPEDS. Woodruff[22] found 17% pure anisometropia, Woldeyes et al[52] found 6% anisometropia, Menon et al[55] found 22.1% anisometropia, Sharma et al[56] found 33.33% anisometropia, while this study found 0.44% for pure anisometropia. In the PEDIG study by Repka et al[10], 'anisometropic amblyopia' was synonymous with 'refractive amblyopia' and the cut-off was ≥0.50 D spherical equivalent or ≥1.50D astigmatism in any meridian. Generally lower diopter cut-off may have slightly higher proportions, making comparison difficult.

The Woldeyes et al[52] and Menon et al[55] case definition for meridional amblyopia was irregular astigmatism in both eyes or ≥1.5D regular astigmatism in any meridian. MEPEDS[9] and this study used ≥1.00D.

The lower limit of visual acuity in amblyopia case definitions has been a source of variation for quantitative amblyopia. Sapkota et al[57] used ≤ 6/9.5 (20/30) (0.22) as the cut-off. Woldeyes et al[52] and Menon et al[55] and Sharma et al[56] used <6/12 (20/40) (0.3) while The Paediatric Eye Disease Study Group (PEDIG)[10] and this study used ≤6/12 (20/40) (0.3).

The various hospital based studies had variations in the age of patients included in the study. Sethi et al [54] at Khyber Teaching Hospital used 4 – 14 years, while Woldeyes et al[52] at Menilik II Hospital used <15 years and Mehari[53] at Grarbet Eye Hospital used ≤15 years. Sapkota[57] in Nepal Eye Hospital used ≤13 years. Menon et al[55] at Dr Rajendnra Prasad Centre for Ophthalmic Services and Chua[58] at The Children's hospital in Australia had no age restriction. These age variations make comparison difficult.

One of the reasons for the wide variations in the results from these studies is the selection bias due to the variations in case definitions. There is a need to standardize the various case definitions for amblyopia.

Despite this, it has been widely reported in various books[2] and studies[52, 54, 58, 59] that strabismus is the most common cause of amblyopia. However, this study findings contradict this. The hospital setting for this study is probably a source of bias, as it is likely that there are children with squint who have never been to hospital for reasons that vary from finances, poor accessibility and ignorance. There is also a possibility of cultural beliefs regarding squint that may cause parents to accept the condition and seek coping mechanisms rather than treatment in hospital. As the region is in a rural setting, it is also likely that traditional medicine has a role to play in the low strabismus proportions in this hospital. It is also possible that the prevalence of strabismus in the regional population is low. A population-based study on prevalence as well as knowledge, attitude and practice regarding strabismus would make all this clear. Under-diagnosis especially of microstrabismus is also a possible reason for the low proportions of strabismus.

It is not uncommon for an amblyopia study to find high proportions of refractive amblyopia compared to strabismic amblyopia. The prevalence and etiology study by Ganekal et al[69] had results that are quite similar to this study in that a large proportion of eyes had refractive error and few had strabismus – ametropia 50%; anisometropia 40.9%; strabismus 6.8%. Anisometropic amblyopia was the most common type in studies by Sharma et al[56] (33.33%) and Høeg et al[70] (45.5%). Chia et al[71] in Singapore found refractive (85%) to be the most common amblyopia type followed by strabismus (15%). The most frequent refractive errors were anisometropia (42%) and isometropia / ametropia (29%). Sapkota et al[57] at Nepal Eye Hospital

found refractive amblyopia to be the most common (anisometropia 53%; ametropia 29%) type and was a significant cause of amblyopia compared to strabismic amblyopia (14%).
Menon et al[55] in India reported strabismic amblyopia as the most common subtype (37.38%) but if anisometropic amblyopia (22.1%), ametropic amblyopia (12.88%) and meridional amblyopia (5.56%) were all combined then refractive amblyopia (40.54%) would in fact be the most common cause of amblyopia.

The high proportion of refractive amblyopia in this study is suggestive of a high population prevalence of refractive errors which are diagnosed late. A screening programme would therefore be useful.

Laterality

One hundred and eighty three patients (68.28%) had bilateral amblyopia while 85 (31.72%) had unilateral. This is unlike most other studies[55,56,57] which have found unilateral amblyopia to be more common. This can generally be attributed to the high proportion of refractive amblyopia cases and specifically to the ametropia cases which by definition, are bilateral.

This finding is explained by the fact that 73.73% of the 255 eyes with refractive amblyopia had ametropia (pure ametropia 21.57%; combined anisometropia & ametropia 1.57%; combined ametropia & meridional 42.35%; combined anisometropia, ametropia & meridional 8.24%), which by definition is bilateral.
Additionally, 60 (22.39%) of the 268 patients in the study had bilateral sensory deprivation due to cataract.

Age at first presentation.

As discussed earlier, the critical period when amblyopia is reversible with treatment is estimated to be up to 7 – 8 years[3,4,5]. In this study, 50.11% of all amblyopia patients presented after the age of 8 years. 67.84% of children with refractive amblyopia presented after the age of 8 years which would make their treatment less effective. However, this proportion was lower for sensory deprivation (38.1%), strabismic (25%) and combined (23.94%) amblyopia. This finding could be explained by the presence of an obviously visible manifestation of disease in the case of sensory

deprivation, strabismic and combined amblyopia. Pure refractive amblyopia does not have any visible manifestation therefore it may take a while for parents, guardians and teachers to pick it up as the child is unlikely to complain of poor vision, especially in the case of anisometropia. Additionally, refractive amblyopia tends to be moderate rather than severe and therefore may easily be missed.

The interquartile range for refractive amblyopia was found to be 8 to 13 years, which is the school going age. It is therefore likely that the poor visual acuity was picked up when the child started going to school and noted to have difficulty seeing the blackboard. A screening programme would identify these children much earlier (before they start school) so that they are able to get timely treatment. In contrast, the interquartile range for sensory deprivation (2 to 10.75 years), strabismic (0.96 to 5.5 years) and combined amblyopia (2 to 8 years) included the pre-school years.

The most common age (mode) at first presentation for refractive amblyopia was 10 years. However, for combined amblyopia, the mode was less than one year. The multiple amblyogenic factors in combined amblyopia would probably cause a more severe amblyopia and when combined with a visible manifestation (like squint or cataract), would cause the parent or guardian to be aware much earlier that there is a problem with the childs' eye.
Woldeyes et al[52] in Ethiopia found an overall median age of 7.0 years which is close to this study of 9 years.

The overall mean age at first diagnosis is 8.19 years in this study. This is comparable to Menon et al[55] in India where it was 7.97 ± 6.18 years, and Sapkota et al[57] in Nepal where it was found to be 7.74 ±2.97 years.
In sharp contrast, Chua et al[58] in Australia found an overall mean presenting age of 32.9 months (≈2.7 years) while Woodruff et al[59] in United Kingdom found a mean age of 4.0 years. These are counties with relatively good health and referral systems resulting in earlier diagnosis. Additionally, United Kingdom is known to have established pre-school vision screening programmes.

The average age at first presentation for combined amblyopia (5.52 year) in this study is similar to the 6.2±3.2 years found by Woldeyes et al[52] in Ethiopia. However, the figures for strabismus were markedly different with a mean age of 6.8±2.9 years and a median age of 7 years. This study found that the strabismus patients were much younger (Mean age 4.4 years).

Most of the amblyopic eyes were in the 6 to ≤ 10 years age group (37.92%). The ≤5 years age group had the highest proportion of eyes for pure strabismic (2.00%), pure sensory deprivation (4.43%) and combined (15.96%) amblyopia, while the 11 to ≤15 years age group had the highest proportion for refractive (56.54%) amblyopia eyes.
This is similar to findings by Chua et al[58] where stimulus deprivation was identified earliest while refractive amblyopia was identified latest in age (p=0.02)

Refractive Status

This study found that the most common refractive status was myopic astigmatism (53.88%), followed by hypermetropic astigmatism (10.64%), myopia (11.31%), hypermetropia (10.64%), astigmatism (2.00%) and emmetropia (0.67%). This is explained by the fact that 42.35% of eyes with refractive amblyopia (the most common amblyopia type) had 'combined ametropia & meridional' as the amblyopia sub-type.

Myopic astigmatism was the most common refractive status for refractive (68.24%), pure sensory deprivation (23.81%) and combined (41.55%) amblyopia and this was statistically significant.
The most common type of refractive error for eyes with pure strabismic amblyopia was hypermetropia (41.67%). Similar findings were also found by Woldeyes et al[52] (63.9%) and Sapkota et al[57] (47.6%)
Emmetropia (0.67%) was the least common refractive status among all 451 amblyopic eyes. All eyes with emmetropia had strabismus as an amblyogenic factor.

It is notable that studies such as Sethi et al[54] which had strabismus as the most common amblyogenic factor, also had hypermetropia (60%)as the most common refractive status.

This is unlike Sapkota et al[57] where astigmatism (59.3%) was the most common refractive status followed by simple hyperopia (33.4%) and simple myopia (7.3%).

Sharma et al[56] also found that hypermetropia (93.33%) was the most common refractive status in strabismus. This study however accounted for hypermetropia and myopia, but not for astigmatism, hypermetropic astigmatism, myopic astigmatism and emmetropia. Although it is not clearly stated, it is likely that spherical equivalent was used to classify the refractive status.

Woldeyes et al[52] found hypermetropia to be the most common refractive error in combined (84%) and ametropic (60%) and anisometropic (72.7%) while emmetropia was the most common in sensory deprivation (83.3%). While these figures differ significantly from this, it is notable that the Woldeyes[52] study had 3 categories of refractive error – hyperopia, myopia and emmetropia.

Depth of Amblyopia

This study found moderate amblyopia (<0.7 LogMAR BCSVA) to be more common (58.47%) than severe amblyopia (≥0.7 LogMAR BCSVA). This can be explained by the fact that the most common amblyogenic factor found was refractive which is known to cause a milder amblyopia than strabismic or sensory deprivation[2].

A breakdown of type versus depth of amblyopia found that most refractive amblyopia (65.86%) was moderate while most pure sensory deprivation amblyopia (64.29%) and pure strabismic amblyopia (57.14%) were severe. These differences were statistically significant. Menon et al[55] had similar findings in that the BCSVA in the amblyopic eye showed a significant association with the diagnosed subtype of amblyopia. ($p<0.001$). Additionally, our study findings for severe amblyopia (41.53%) are similar to those Sapkota et al[57] (40%).

However, the difference between moderate (41.67%) and severe (58.33%) amblyopia for combined amblyopia was not statistically significant. Combined amblyopia is therefore just as likely to cause deep amblyopia as it is likely to cause moderate amblyopia. This is probably due

to the wide variability that can be obtained with different combinations of the amblyogenic factors.

Depth of amblyopia could not be established in 97 eyes (21.51%) because they had a qualitative assessment of amblyopia. This is similar to Woodruff et al[59], where 20% had qualitative assessment of amblyopia. In the Woldeyes et al[52] study, 8.3% of patients had a qualitative amblyopia assessment.

Age versus Best corrected spectacle visual acuity (BCSVA)

Age of the patient[2,6,21] and depth of amblyopia have independently been found to have an influence on the outcome of treatment. However, we found that there was no evidence of a linear correlation between the age at first presentation and the BCSVA for all amblyopia as well as the four types of amblyopia. Pearson's Correlation Coefficient was -0.11.

The strength of linear relationship (using the absolute value) is graded as follows: Strong correlation >0.80; Moderate correlation 0.50 to 0.80; Weak correlation 0.3 to <0.50; No correlation <0.3. The Coefficient of Determination (R^2) was 0.018 while the Adjusted R^2: 0.211 (Adjusted for laterality, type and refractive status). The p-value was 0.18.

R^2 gives us the strength of relationship between the two variables. It measures how well the regression line represents the data so that the further the line is away from the points, the less it is able to explain it. Values approaching zero suggest that the variables are widely spread around the regression line while values approaching 1 suggest a strong correlation. In this case, R2 of 0.211 means that only 2.1% of the data can be explained by a linear relationship between age and BCSVA suggesting that there is no linear correlation between the two variables.

These findings are in keeping with a similar study by Menon et al[55] where there was no correlation between BCSVA and age at first presentation. (Correlation coefficient of 0.074). Another study by Sapkota et al[57] found that the depth of amblyopia was not associated with the age ($p>0.05$).

The most likely explanation for this is the presence of other unmeasured confounding factors. Duration of the amblyogenic factor is one such confounding factor. For the younger child, the assumption is that the visual system has more plasticity & immaturity and therefore capable of developing deep amblyopia even with short durations of the amblyogenic factor. The older child with a long history of an amblyogenic factor may also get deep amblyopia.

Strabismus

Strabismus was an amblyogenic factor in 45 out of the 451 eyes in the study. Most (73%) of the eyes with strabismic were in the combined amblyopia category (Combined strabismic & refractive 24%; Combined strabismic & sensory deprivation 13%; Combined strabismic, refractive & sensory deprivation 36%), as opposed to the pure strabismic amblyopia (27%) category.

There was evidence of a weak positive linear correlation (+0.38, +0.45 and +0.34 in pure strabismus, combined strabismic & refractive, and combined strabismic, refractive & sensory deprivation respectively) between the prism diopters and the LogMAR BCSVA. This means that as the value of prism diopters increases, the LogMAR BCSVA also increases.

Esotropia (67%) was found to be the most common form of strabismus, followed by exotropia (31%) and hypertropia (2%). This difference in the strabismus types was statistically significant with a p-value of 0.00.

This is in keeping with a study by Menon et al[55] where esodeviation was the most common deviation seen (56.47%), followed by exodeviation (36.23%) and finally vertical deviation (7.29%). Similarly, Sethi et al[54] found 75% esotropes and 25% exotropes.

All eyes with pure strabismic amblyopia had esotropia while those in the combined type had esotropia, exotropia and hypertropia. However, these differences were not statistically significant.

Catchment Area.

The children came from the Western and North Western parts of Kenya with the highest proportion coming from Kisumu County followed by Kakamega and Vihiga counties. These are therefore the areas that could be initially targeted when initiating a pre-school vision screening programme. Additionally, most of the counties listed are largely rural and therefore there may be a challenge in accessibility to specialized paediatric eye care.

8. STUDY LIMITATIONS

1) Retrospective case series study design
    a) This design depends on the availability of files. In this study, some files could not be traced and were therefore excluded leading to a selection bias.
    b) This study design depends on accuracy of records in the files.
    c) Incomplete medical records are a limitation in this study design.
2) Qualitative visual acuity measurement could potentially miss out on moderate amblyopia.

9. CONCLUSIONS

1) The burden of amblyopia at Sabatia Eye Hospital is estimated to be 6.3%.
2) Refractive amblyopia was the most common type. It had a late diagnosis and was predominantly due to ametropia which is bilateral.
3) Moderate amblyopia is more common than deep amblyopia and is predominantly due to refractive errors.
4) The hospital serves the Western and North Western parts of Kenya.

10. RECOMMENDATIONS.

1) There is need to standardize amblyopia case definitions for the purposes of comparison with various studies.
2) Pre-school vision screening programmes are recommended for early diagnosis and timely treatment of refractive errors since they do not have obviously visible signs.
3) Improved record-keeping both at outpatient records department and in the patients' files.
4) A prospective study on amblyopia.

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12. APPENDICES

12.1 Study Data Collection Form

A) BIODATA

Questionnaire Number: ……

Date of Birth:

Age at First Presentation:

GENDER: 1 = Male
2 = Female

Residence:

B) VISUAL ACUITY AND REFRACTION

	RIGHT EYE	LEFT EYE
VA at first presentation		
	LogMAR	LogMAR
Cycloplegic refraction		
Refractive status	1 = Emmetropia 2 = Myopia 3 = Hypermetropia 4 = Astigmatism	1 = Emmetropia 2 = Myopia 3 = Hypermetropia 4 = Astigmatism
BCSVA		
	LogMAR	LogMAR
Interocular difference in BCSVA		

C) AMBLYOGENIC FACTOR

ii) Strabismus:

	RIGHT EYE	LEFT EYE
Heterotropia at distance or near fixation	1 = Yes 2 = No ☐	1 = Yes 2 = No ☐
Prism Diopters		
Type of Tropia	1 = Esotropia 2 = Exotropia 3 = Hypertropia ☐ 4 = Hypotropia 5 = Other……. 6 = None	1 = Esotropia 2 = Exotropia 3 = Hypertropia ☐ 4 = Hypotropia 5 = Other……. 6 = None
Alternating Tropia with preference	1 = Yes 2 = No ☐	1 = Yes 2 = No ☐
Variability	1 = Constant 2 = Intermittent 3 = Cross-fixation ☐	1 = Constant 2 = Intermittent 3 = Cross-fixation ☐
History of strabismus surgery	1 = Yes 2 = No ☐	1 = Yes 2 = No ☐

5) Refractive Error

Anisometropic Amblyopia

	YES	NO
≥ 1.00 D anisohyperopia	□	□
≥ 3.00 D anisomyopia	□	□
≥ 1.50 D anisoastigmatism	□	□

Ametropic amblyopia (Bilateral high ametropia):

	RIGHT EYE	LEFT EYE
1 = ≥ 4.00 D hyperopia		
2 = ≥ 6.00 D myopia		
3 = ≥ 2.50 D astigmatism		

Meridional amblyopia:

	RIGHT EYE	LEFT EYE
1 = Regular astigmatism >1.00 D of astigmatism in any meridian		
2 = Irregular astigmatism		

6) Sensory deprivation amblyopia:

	RIGHT EYE	LEFT EYE
1 = Cataract		
2 = Corneal opacities		
3 = Vitreous haemorrhage		
4 = Congenital ptosis		
5 = Hyphema		
6 = Occlusion amblyopia		
7 = Absent		
6 = Other (Specify)		

D) AMBLYOPIA TYPE

	RIGHT EYE	LEFT EYE
1 = Unilateral Amblyopia		
2 = Bilateral Amblyopia		
3 = Strabismic Amblyopia		
4 = Anisometropia Amblyopia		
5 = Ametropic / Isometropic Amblyopia		
6 = Meridional / Astigmatic Amblyopia		
7 = Sensory Deprivation Amblyopia		
8 = Combined Strabismic and Refractive amblyopia		
9 = Combined Strabismic and Sensory deprivation amblyopia		
10 = Combined Sensory deprivation and Refractive amblyopia		
11 = Combined Strabismic, Refractive and Sensory deprivation amblyopia		

12.2 List of Children <16 Years during the Study Period

Visit Date	Age	File Number	VA RE	VA LE	Included (Y/N)	Data Collection Form

12.3 Depth of Amblyopia

	Moderate Amblyopia[19]	Severe Amblyopia[8]
20ft Snellen fraction	20/40 to < 20/100	≥ 20/100 to 20/400
6m Snellen fraction	6/12 to < 6/30	≥ 6/30 to 6/126
3m Snellen fraction	3/6 to < 3/15	≥ 3/15 to 3/63
LogMAR	0.3 to < 0.7	≥ 0.7 to 1.3

12.4 Visual Acuity Conversion Table[7, 65]

	True Snellen Fractions (numerator = test distance)					US equivalent	LogMAR
	6m	**5m**	**4m**	**3m**	**1m**	**20ft**	
	6/600	5/500	4/400	3/300	1/100	20/2000	2
	6/480	5/400	4/320	3/240	1/80	20/1600	1.92
Near-blindness	6/380	5/320	4/250	3/190	1/63	20/1250	1.8
	6/300	5/250	4/200	3/150	1/50	20/1000	1.7

	6/240	5/200	4/160	3/120	1/40	20/800	1.6
	6/190	5/160	4/125	3/95	1/32	20/630	1.52
Profound low vision	6/150	5/125	4/100	3/75	1/25	20/500	1.4
	6/126	5/100	4/80	3/63	1/20	20/400	1.3
	6/95	5/80	4/63	3/47	1/16	20/320	1.22
	6/75	5/63	4/50	3/37	1/12.5	20/250	1.1
Severe low vision	6/60	5/50	4/40	3/30	1/10	20/200	1.0
	6/48	5/40	4/32	3/24	1/8	20/160	0.92
	6/38	5/32	4/25	3/19	1/6.3	20/125	0.8
	6/30	5/25	4/20	3/15	1/5	20/100	0.7
Moderate low vision	6/24	5/20	4/16	3/12	1/4	20/80	0.6
	6/19	5/16	4/12.5	3/9	1/3.2	20/63	0.5
	6/15	5/12.5	4/10	3/7	1/2.5	20/50	0.4
	6/12	5/10	4/8	3/6	1/2	20/40	0.3
Mild	6/9.5	5/8	4/6.3	3/5	1/1.6	20/32	0.22
	6/7.5	5/6.3	4/5	3/4	1/1.25	20/25	0.1
	6/6.0	5/5	4/4	3/3	1/1	20/20	0.0
	6/4.8	5/4	4/3	3/2.4	1/0.8	20/16	-0.1
	6/3.8	5/3.2	4/2.5	3/1.9	1/0.63	20/12.5	-0.2
	6/3.0			3/1.5		20/10	-0.3
Normal vision	6/2.4			3/1.2		20/8	-0.4

For clinical naming it is acceptable to round 32 to 30, 63 to 60, 1250 to 1200, 0.92 to 0.9, etc.

12.5 Revised World Health Organization (W.H.O) Categorization of Blindness and Visual Impairment[66]

Presenting distance visual acuity			
Category		**Worse than**	**Equal to or better than**
0	Mild or No Visual Impairment		6/18 (0.3) 20/70
1	Moderate Visual Impairment	6/18 (0.3) 20/70	6/60 (0.1) 20/200
2	Severe Visual Impairment	6/60 (0.1) 20/200	3/60 (0.05) 20/400
3	Blindness	3/60 (0.05) 20/400	1/60 (0.02) 20/1200 (Counting Fingers at 1m)
4	Blindness	1/60 (0.02) 20/1200 (Counting Fingers at 1m)	Light perception
5	Blindness	No light perception	
9		Undetermined or unspecified	

12.6 Data Collection Procedures for Research Assistants.

- Obtain outpatient records for patient seen between 1st January 2014 and 31st December 2014 at Sabatia Eye Hospital.
- Exclude patient who are 16 years and above at the time of presentation. Include patient who are below 16 years of age.
- Fill out the "List of children <16 years during the study period"
    - Record the visit date, name, age, hospital number
- Use the hospital number to obtain each patient's file.
- Peruse each file to find the presenting visual acuity.
    - If the presenting visual acuity in the worse eye is equal to or better than 6/9.5, 20/32 or LogMAR 0.22, the patient will be excluded from the study. Indicate this visual acuity in the "Visual Acuity" column of the "List of children <16 years during the study period" document. Fill in "N" in the "Included" column to indicate that the patient will not be included in the study.
    - If the presenting visual acuity in the worse eye is worse than 6/9.5, 20/32 or LogMAR 0.22 or worse, then the patient will remain in the study. Indicate this visual acuity in the "Visual Acuity" column of the "List of children <16 years during the study period" document. Fill in "Y" in the "Included" column to indicate that the patient is still included in the study.
    - If there is no record of visual acuity, indicate "None" in the "Visual Acuity" column of the "List of children <16 years during the study period" document. Fill in "N" in the "Included" column to indicate that the patient has been excluded from the study.
    - If the visual acuity has been recorded in a format other than the Snellen fraction or LogMAR the patient will remain in the study. Examples of such formats include picks hundreds and thousands at 30cm, picks objects 1mm size, picks objects 2cm size, picks objects 4cm size, picks a toy, fixates and follows objects, perceives light and no perception of light.

12.7 Approval from Sabatia Eye Hospital

Friends Church - Sabatia Eye Hospital

P.O.Box 214
Wodanga 50311
Vihiga District, Kenya
Chavakali-Kapsabet-Eldoret Rd.
www.sabatiaeyehospital.org

Fax: 020 2393883
Zain: 0733 731013
Safaricom: 0723 721316
Landline: 020 2393883
email: sabeyehosp@gmail.com

3rd August 2015

Dr. Maria Wanyonyi
UON Department of Ophthalmology,
NAIROBI.

Dear Madam,

RE: PROFILE OF AMBLYOPIA AT SABATIA EYE HOSPITAL

Thank you for choosing Sabatia Eye Hospital to conduct study on the above subject.

We would like to inform you that the request has been approved. You will carry out the study under the supervision of Dr. Sarah Sitati.

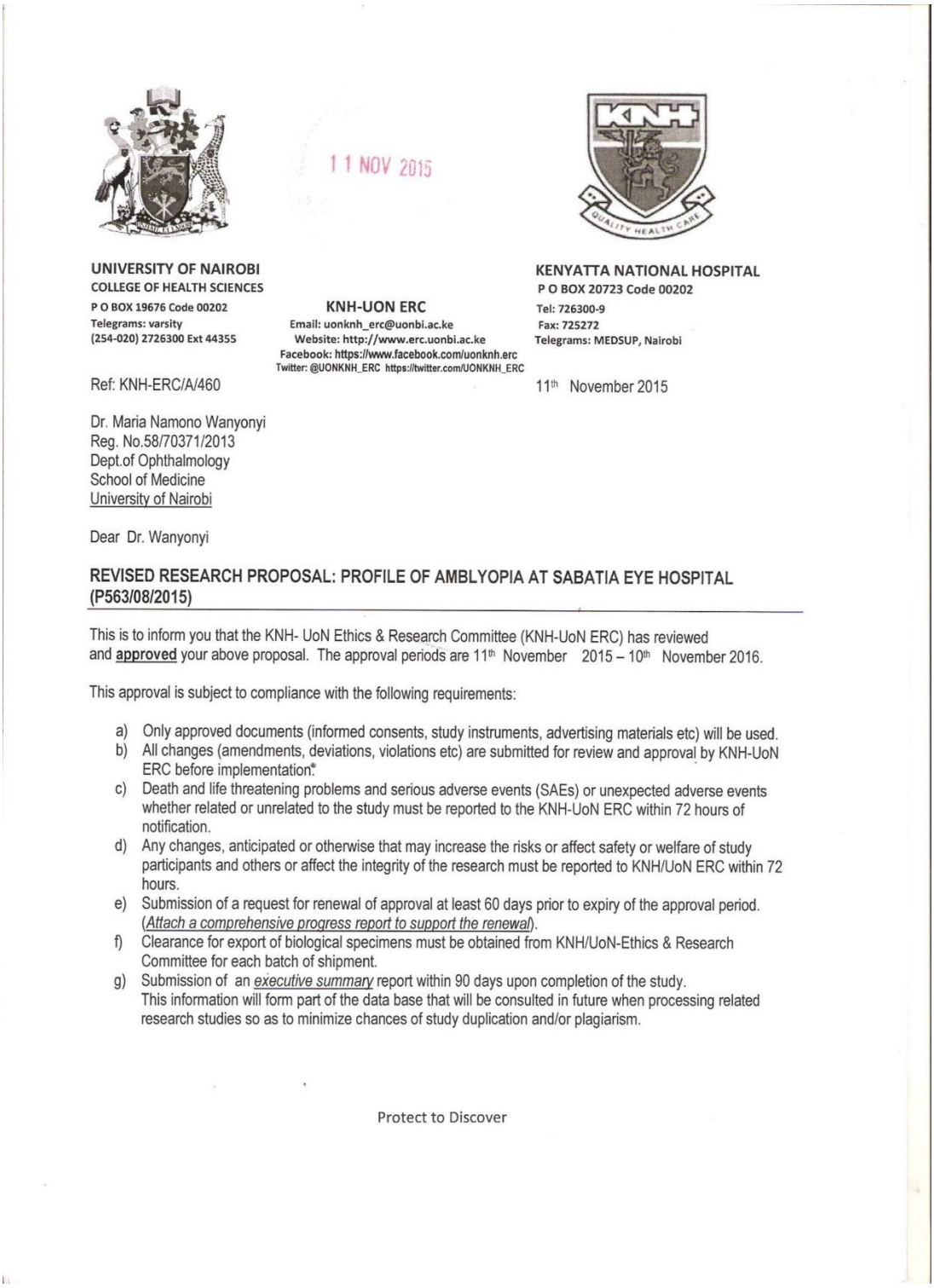
At the end of the study you are required to furnish the hospital with a copy of the research findings.

Yours faithfully,

for Dr. Ernest Ollando.
MEDICAL DIRECTOR/CONSULTANT OPHTHALMOLOGIST

OUR MOTTO: "WE TREAT, HE HEALS"

12.8 Ethical Approval Certificate



11 NOV 2015

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH-UON ERC
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Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/460

11th November 2015

Dr. Maria Namono Wanyonyi
Reg. No.58/70371/2013
Dept.of Ophthalmology
School of Medicine
University of Nairobi

Dear Dr. Wanyonyi

REVISED RESEARCH PROPOSAL: PROFILE OF AMBLYOPIA AT SABATIA EYE HOSPITAL (P563/08/2015)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and **approved** your above proposal. The approval periods are 11th November 2015 – 10th November 2016.

This approval is subject to compliance with the following requirements:

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

Protect to Discover

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

Yours sincerely,

PROF. M.L . CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept.of Opthalmology, UoN
Supervisors: Dr.Lucy Njambi, Dr. Millicent Muthoni Kariuki

12.9 Budget

Mmed Thesis Budget

TITLE: PROFILE OF AMBLYOPIA AT SABATIA EYE HOSPITAL

Principal Investigator: Dr. Maria Wanyonyi

Sabatia Eye Hospital

Item	Quantity	Unit Cost	Total Cost
Proposal/Ethical approval			
Proposal writing & printing (55 pages)	1 copy	Ksh. 10 per page	550
Photocopy Proposal (55 pages)	5 copies	3 per copy	825
Binding Proposal	6 copies	100	600
KNH-ERC fee	1	2000	2,000
		Subtotal	**3,975**
Data Collection			
REDCap registration / hosting			10,000
REDCap data tool			10,000
Printing Data Collection Procedures	1 page (2 copies)	10 per copy	20
Visual Acuity Conversion Table	2 pages (3 copies)	10 per copy	50
Printing “List of children <16 years”	1 page	10 per copy	10
Photocopy “List of children <16 years”	140 pages	3 per copy	420
Flash Disk		1500	1,500
Box file	1	300 each	300
		Subtotal	**22,300**

Transport			**8,000**
Internet (Proposal development and data collection)			**10,000**
Accommodation / Food			**12,000**
Contracted services			
Statistician	1		50,000
Research Assistants	2	20,000	40,000
		Subtotal	**90,000**
Printing costs and binding of Final book			
Finished book printing(80 pages approximately)	1 copy- 60 pages	Ksh. 10 per page	600
	10 copies- coloured 15 pages approximately	Ksh. 30 per page	4,500
Photocopy	9 copies – 60 pages	Ksh. 3 per copy	1,620
Binding (Hard cover)	10 copies	500	5,000
		Subtotal	**11,720**
TOTAL			**157,995**

12.10 Timeline

ACTIVITIES	MAR '15	APR '15	MAY '15	JUN '15	JUL '15	AUG '15	SEP '15	OCT '15	NOV '15	DEC '15	JAN '16	FEB '16
Proposal Development												
Research & Ethical Committee Approval												
Data Collection												
Data Analysis												
Report writing and dissemination of findings.												