DEVELOPMENT, DIAGNOSTIC ACCURACY AND FEASIBILITY OF A SCREENING TOOL FOR EARLY DETECTION OF BLINDING EYE DISEASES AMONG INFANTS IN IBADAN, NIGERIA

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CERTIFICATION

We certify that this work is original and the research project was carried out under our supervision by **Bolutife Ayokunnu OLUSANYA** in the Department of Epidemiology and Medical Statistics, Faculty of Public Health, College of Medicine, University of Ibadan. We also certify that the work has neither been presented for any purpose to any other Institution or examination body nor has it been submitted elsewhere for other purpose.

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DEDICATION

This thesis is dedicated to the Almighty God, my teachers, my parents and my family.

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ABSTRACT

Approximately seventy per 100,000 children are blind worldwide. Early detection and prompt treatment play vital roles in prevention of blindness from cataract and other eye diseases in children. However, there are no established screening programmes for blinding eye diseases among infants in Nigeria. This has contributed to delayed presentation to hospital among children with blinding eye diseases. Therefore, this study was conducted to develop and validate a simple screening tool for the early detection of blinding eye diseases among infants as well as assess the perceptions of health care workers regarding the feasibility of using the tool.

This cross-sectional study was conducted in 3 phases. The first phase was the development and validation of a screening checklist. This entailed a literature review, expert opinion, stakeholders' input, content validation and pretesting of the checklist. The second phase was a diagnostic accuracy study which compared the newly developed checklist to a gold standard, which was eye examination by an ophthalmologist. This phase was carried out on 1214 infants receiving immunisation in eight primary health care centres located in four urban Local Government Areas in Ibadan metropolis. Each infant was first screened by a primary health worker (immunisation staff) using the checklist and subsequently examined by the ophthalmologist. The sensitivity, specificity, positive and negative predictive values as well as reliability indices of the checklist were determined. The third phase was a questionnaire survey to assess the perceptions of all the participating immunisation staff (38 in number) about the feasibility of using the checklist. Data were analysed using descriptive statistics. Level of significance was set at $_{\alpha}0.05$.

A checklist with two sections and 11 items was developed. The first section consisted of six questions that the health workers asked the infants' mothers or caregivers; while the second section contained five questions that were answered by the health workers after a quick examination of the children's eyes. The mean age of the infants was 5.2±3.8 months and 52.5% were males. The screening checklist had a sensitivity of 70.0% for detection of blinding eye disease. In addition, it had a specificity of 94.8% for detection of blinding eye disease. The inter-observer agreement was 96.6% (Kappa = 0.71); while test-retest reliability showed an intra-class correlation coefficient of 0.90. All the immunisation staff were females, with a mean age of 43.1±7.6 years. They all reported that the checklist was useful in screening for eye diseases among infants. Majority (81.6%) reported that the checklist was very easy to use. About one-third (34.2%) experienced challenges, such as poor cooperation from mother or child, while using the checklist.

A screening tool with good sensitivity, high specificity and high reliability was developed for the early detection of blinding eye diseases in infants. Primary health care workers found the checklist to be easy to administer and useful for screening. Adoption of this checklist as a screening tool at the primary health care level could be instrumental in the establishment of screening programmes and early detection of blinding eye diseases among children.

Keywords: Childhood blindness, Eye disease screening checklist, Primary eye care, Sensitivity and Specificity

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CHAPTER ONE

INTRODUCTION

1.1 Background

At the global level, the prevalence of childhood blindness is estimated to be about 0.7 per 1000 children with about half a million children becoming blind every year (Gilbert and Awan, 2003). In addition, children are estimated to account for 4% of the total population of blind individuals worldwide (Kong, Fry, Al-Samarraie, Gilbert, and Steinkuller, 2012). Specifically, the number of children with bilateral blindness is estimated to be 1.14 million globally (Rahi and Gilbert, 2017; Gilbert, Bowman, and Malik, 2018), with over 75% of these children living in developing countries (Kong *et al*., 2012).

Despite the relatively low prevalence of blindness in children, it is still of public health significance because of the concept of "blind person years". (Kong *et al.*, 2012) Blind children who survive childhood have a life of blindness awaiting them, therefore, childhood blindness is responsible for a huge number of "blind person years", that is, the number of years that a blind person remains alive after becoming blind (Murthy, John, Gupta, Vashist, and Rao, 2008). In fact, the sum of "blind person years" caused by childhood blindness is second only to that caused by cataract in adults (Gogate and Gilbert, 2007).

Moreover, blindness from childhood has significant impact on the child, the family and the society. A blind child potentially has a lifetime of 'darkness' ahead of him or her (Murthy *et al.*, 2008). Apart from the fact that childhood blindness delays the psychomotor and social development of the affected infant, it also has a negative effect on the child's educational and occupational prospects (Pring and Tadic, 2010; Singh, 2015; Vervloed, van den Broek, and van Eijden, 2020). Besides, the care of blind children can be burdensome as well as expensive to the family (Kong *et al.*,

2012). Beyond the affected child and the family, the community also indirectly bears the burden of childhood blindness with regards to lost productivity and significant health care costs.

Blindness in childhood is an important public health problem, particularly in developing countries. With the present level of technological advancement, however, no child should remain blind. Indeed, the major proportion of the blindness that occurs in children is either preventable or treatable (Courtright, Hutchinson, and Lewallen, 2011). Notwithstanding, in sub-Saharan Africa, a large number of children are blind due to childhood cataract, especially as the disease is becoming a major cause of blindness in childhood within the region (Courtright, 2012).

Unfortunately, a significant proportion of these children remain blind despite treatment (Randrianotahina and Nkumbe, 2014). A major reason for the poor outcome of treatment is the delay that occurs before the child presents to hospital for treatment (You *et al.*, 2011). When children who have cataract are treated late, the outcome is often poor because the visual developmental processes have been irreversibly disrupted by the time the treatment is given. On the other hand, if the treatment is administered in a timely fashion, the normal visual development is restored, the child regains vision and the treatment is effective. A previous study from Southeast Nigeria reported that delay in presentation is one of the challenges in the management of childhood cataract in Nigeria (Ezegwui, Aghaji, Uche, and Onwasigwe, 2011).

Early detection and prompt referral for surgical treatment is, therefore, very crucial in the successful management of children who are born with cataract or develop the condition during childhood (Kim, Kim, Kim, and Yu, 2012; DeSantis, 2014; Lenhart *et al.*, 2015; Khokhar, Pillay, and Agarwal, 2018). Several studies have shown that early surgery for congenital cataract is associated with better surgical outcomes (Forbes and Guo, 2006; Gouws, Hussin, and Markham, 2006; Birch, Cheng, Stager, Weakley, and Stager, 2009; Kim *et al.*, 2012; Khanna, Foster, Krishnaiah, Mehta, and Gogate, 2013). Surgery can only be performed early if the visual problem is detected early, and the child is brought to hospital immediately, following appropriate referral. Other causes of eye disease in infancy including congenital glaucoma, corneal opacity, congenital ptosis and strabismus also require early detection and prompt treatment.

Understandably, early detection, appropriate counselling and prompt referral are dependent upon adequate knowledge and skills of the health care provider to whom the child initially presents. It is important to note, however, that the role of the parents in noticing that there is a problem with the child's eye and then seeking help immediately is even more vital than the role of health workers. Studies have shown that the health seeking behaviour of parents is a significant factor in the delayed presentation of children with cataract (Bronsard, Geneau, Shirima, Courtright, and Mwende, 2008; Leite and Zin, 2011). The negative impact of delayed parental detection of the problem can be mitigated by screening for eye diseases in infants and children during well-child clinic visits such as immunisation visits. In addition, key informants within the community have been shown to play a pivotal role in the detection and referral of children with eye diseases (Mackey, Murthy, Muhit, Islam, and Foster, 2012; Duke *et al.*, 2013).

While early detection and treatment of congenital eye diseases is the standard practice in developed countries, late treatment is commonplace in developing countries such as Nigeria (Bodunde and Ajibode, 2006; Lawan, 2008; Ezegwui *et al.*, 2011). One major factor that ensures early detection and treatment in developed countries is neonatal screening for congenital abnormalities and vision screening of infants and young children by primary care health providers during well-child clinic visits (Solebo and Rahi, 2014; Lenhart *et al.*, 2015). Screening has been shown to improve the promptness of surgical intervention and is well established in many developed countries (Magnusson *et al.*, 2003; You *et al.*, 2011). Unfortunately, the same cannot be said about developing countries in Africa including Nigeria.

The screening programmes in developed countries are performed at the primary care level usually by primary care providers or nurses. These primary care staff are able to counsel parents and caregivers properly and then refer them appropriately and promptly. The programmes also incorporate good referral systems which, ensure that children who require further examination by the specialist receive urgent attention and care.

Screening for eye disease at birth and during the neonatal period has been recommended in the literature (Lennerstrand, Jakobsson, and Kvarnstrom, 1995; Weinstock, Weinstock, and Kraft, 1998; Cagini, Tosi, Stracci, Rinaldi, and Verrotti,

2016; Mansoor, Mansoor, and Ahmed, 2016). Certain professional bodies such as the American Academy of Ophthalmology, American Academy of Paediatrics, American Association for Paediatric Ophthalmology and Strabismus as well as the Canadian Society for Paediatrics have all published recommended guidelines for vision screening in neonates, infants and young children (Committee on Practice Ambulatory Medicine Section on Ophthalmology, American Association of Certified Orthoptists, American Association for Pediatric Ophthalmology and Strabismus, and American Academy of Ophthalmology, 2003a; Committee on Practice Ambulatory Medicine Section on Ophthalmology, American Association of Certified Orthoptists, American Association for Pediatric Ophthalmology Strabismus, and American Academy of Ophthalmology, 2003b; Canadian Paediatric Society, 2009; Donahue *et al*., 2016a). These guidelines specifically recommend that the new born babies and infants should be screened using the red reflex test (Bruckner test) with the aid of an ophthalmoscope.

The ophthalmoscope is a hand-held optical instrument that can be used to examine the back of the eye and it is a medical device that is expected to be available at the primary health care level (World Health Organization, 2015). The red reflex test when performed by primary care providers using the ophthalmoscope has been shown to be effective in ensuring the early detection of eye diseases in new born babies and infants (Litmanovitz and Dolfin, 2010). It is routinely practised in many developed countries which have well established vision screening programs and it is probably a major factor contributing to the prompt treatment of congenital cataracts in those countries.

To the best of the author's knowledge, red reflex testing is not routinely performed on neonates in Nigeria and it appears that there are no well-structured programs in place to ensure the detection of eye disease at birth. This lack of screening programs might have contributed to the late presentation of congenital cataracts and other congenital eye diseases in our setting. Therefore, early screening for eye diseases in neonates is advocated.

1.2 Problem statement

Late detection and delayed presentation are important problems among Nigerian children with cataract (Ezegwui *et al.*, 2011; Umar, Abubakar, Achi, Alhassan, and

Hassan, 2015; Abuh, Brennan, Congdon, and Jin, 2018; Musa *et al.*, 2018; Olusanya, Ugalahi, Adeyemo, and Baiyeroju, 2020b). Similarly, reports from other African countries have documented that significant proportions of patients with childhood cataract present late for treatment as a result of delayed diagnosis (Mwende *et al.*, 2005; Bronsard *et al.*, 2008; Randrianotahina and Nkumbe, 2014). A study from a tertiary hospital in Kaduna, Northern Nigeria conducted between 2008 and 2009 reported that only 22.6% of congenital cataracts were detected at birth and 37.1% were diagnosed after the child's first birthday (Umar *et al.*, 2015). Another report from University College Hospital Ibadan in southwest Nigeria conducted between 2011 and 2015 stated that only 28.4% of children with congenital cataract presented to hospital within the first 3 months of life (Olusanya *et al.*, 2020b).

In a country like Nigeria, where, to the best of the author's knowledge, there are no established screening programs for eye disease in infants, the lack of functioning ophthalmoscopes in primary care settings further compounds the problem and leads to delayed diagnosis and treatment of congenital cataracts and other eye diseases. Delayed treatment is associated with poor treatment outcomes with a large proportion of treated children remaining blind despite intervention (Randrianotahina and Nkumbe, 2014). Studies on visual outcome after cataract surgery in different African countries, including Nigeria, have reported that between 11.5% and 88.9% of children who had undergone cataract surgery had a postoperative visual outcome worse than 3/60 in their better eye, that is, they were still blind after treatment (Olusanya, Baiyeroju, and Fajola, 2006; Ezegwui *et al.*, 2011; Randrianotahina and Nkumbe, 2014; Umar *et al.*, 2015; Aghaji, Okoye, and Bowman, 2018). Such poor outcomes can be attributed to delayed presentation and treatment of the children.

Moreover, it appears that a significant proportion of the primary care workers who should be involved in the screening may not be aware of the necessity of such programs and do not know how to perform vision screening or use an ophthalmoscope for red reflex testing (Mafwiri, Kisenge, and Gilbert, 2014). There is dearth of literature on the knowledge and skills of primary health care staff with respect to the need for early detection and treatment of eye diseases in children, particularly, congenital cataract. Besides, there are no previous studies on screening methods for

eye disease among infants in Nigeria reported in the literature as far as the author searched.

Furthermore, to the best of the author's knowledge, there is no tool that has been developed for vision screening of neonates and infants in low-resource settings where ophthalmoscopes are not readily available at the primary health care level. Consequently, there is an urgent need to develop a screening tool that can be used by primary health care workers to detect eye diseases in this category of children without the need for an ophthalmoscope.

1.3 Justification for the study

In view of the economic challenges facing the country and the low budgetary allocation to health in Nigeria, it is unlikely that screening equipment such as ophthalmoscopes will be readily available in primary health care facilities within the foreseeable future. It is therefore desirable to have a simple screening tool that can be used by primary care providers without the need for such equipment as the ophthalmoscope. The availability of such a screening tool may be instrumental in the development and establishment of vision screening programs at the primary health care level and ultimately enable early detection and treatment of congenital cataracts and other ophthalmic problems in infants leading to better treatment outcomes. Successful establishment of screening programs should enable recommendations to be made towards policies that will ensure that most infants with eye disease especially cataract are treated early, have good vision and live productive lives.

In addition, parents of these children and their healthcare providers are potential beneficiaries of this research. The benefit to the parents will be a direct extension of the benefit to the child in addition to better value for money spent on the child's care as well as less anxiety about the child's future. For the health care providers, especially the ophthalmologists who care for the children, the satisfaction of achieving a successful treatment outcome and preventing a lifetime of blindness should be a significant benefit. Moreover, the establishment of neonatal screening policies, laws and programmes that ensure early detection of childhood cataracts will be of public health benefit to the society at large.

1.4 Aim and objectives of the study

1.4.1 Study aim

The aim of this study is to develop and validate a simple screening tool that does not require the use of an ophthalmoscope for the early detection of blinding eye diseases among infants with a view towards recommending it as a screening tool for blinding eye diseases in childhood.

1.4.2 Specific objectives

The specific objectives of the study are:

1. To develop a simple screening tool that can be used by primary health care workers to detect eye diseases in infants without the use of ophthalmoscopes.
2. To determine the diagnostic accuracy (sensitivity, specificity and predictive values) of the screening tool when compared with the gold standard for detection of eye diseases in infants, namely, eye examination by an ophthalmologist
3. To determine the reliability of the screening tool
4. To assess the perceptions of immunisation clinic staff on the feasibility of using the tool based on their experience of using it during the study

1.5. Delimitation of the study

The early detection of common causes of childhood blindness is the focus of this research. The specific blinding eye diseases that would be considered are childhood cataract, corneal opacity, childhood glaucoma, blepharoptosis, strabismus, and retinoblastoma. The geographical scope of the study is Ibadan, particularly, the following Local Government areas: Ibadan Northeast, Ibadan North, Ibadan Southeast, and Ibadan Southwest.

CHAPTER TWO

LITERATURE REVIEW

2.1 EPIDEMIOLOGY AND BURDEN OF CHILDHOOD BLINDNESS

2.1.1 Definition of childhood blindness

Childhood blindness is classically defined as a condition of severe visual impairment characterized by a visual acuity that is less than 3/60 in the better eye of a person who is less than 16 years of age (Gilbert, 2001). This definition of childhood blindness apparently stems from the World Health Organization (W.H.O.) definition of blindness as a visual acuity of less than 3/60 in combination with the United Nations Children's Fund (UNICEF) definition of a child as an individual aged less than 16 years (Gilbert and Foster, 2001b).

In lay terms, however, the W.H.O. describes childhood blindness as "a group of diseases and conditions occurring in childhood or early adolescence, which, if left untreated, result in blindness or severe visual impairment that are likely to be untreatable later in life" (World Health Organization, 2018a). This definition highlights one of the reasons why childhood blindness has often been considered separately from adult blindness; which is that, childhood blindness is usually caused by diseases or conditions that are amenable to cost-effective interventions which can avert irreversible blindness when administered promptly.

2.1.2 Prevalence and magnitude of childhood blindness

Childhood blindness is relatively uncommon. At the global level, the prevalence of childhood blindness is about 0.7 per 1000 children with about 1.14 million blind children worldwide (Rahi and Gilbert, 2017; Gilbert et al., 2018). Children are estimated to account for about 4% of the total population of blind individuals all over the world (Gogate and Gilbert, 2007; Kong *et al.*, 2012). The vast majority of these children are thought to be living in developing countries (Gilbert, 2007; Kong *et al.*, 2012). In addition, more than half of the cases of childhood blindness in low-resource countries is avoidable, that is, blindness from causes that can either be prevented or treated (Aghaji, Okoye, and Bowman, 2015; Muhit *et al.*, 2018; Kilangalanga *et al.*, 2020).

The prevalence of childhood blindness in sub-Saharan Africa has been reported to range between 0.9 and 1.5 per 1000 children (Courtright *et al.*, 2011; Kong *et al.*, 2012; du Toit, Courtright, and Lewallen, 2017; Rahi and Gilbert, 2017; Kilangalanga *et al.*, 2020). As at 2010, an estimated 420,000 blind children were living in sub-Saharan Africa (Chandna and Gilbert, 2010). With regards to Nigeria, only a handful of population-based studies have reported on the prevalence of childhood blindness in the country. Muhammad, Maishanu, Jabo, and Rabiu (2010) reported a prevalence of 0.2 per 1000 children in Sokoto, north-western Nigeria. Duke *et al.* (2013) estimated the prevalence in Cross River State to be 0.09-0.22 per 1,000 children, while Aghaji *et al.* (2017) found a prevalence of 0.12 per 1000 children in Nsukka Local Government Area (LGA), one of the 17 LGAs in Enugu State, south-eastern Nigeria. It is important to point out, however, that these studies were conducted using the key informant method to identify the blind children. This may be influenced by selection bias and the accuracy of the prevalence estimates is heavily dependent on the accuracy of the census figures which the authors used for their calculations. Nevertheless, approximately 75,000 Nigerian children are estimated to be blind (Adio and Komolafe, 2013).

With regards to the incidence of childhood blindness, limited data is available and very few studies have reported on the incidence of childhood blindness (Rahi and Gilbert, 2017; World Health Organisation, 2019). A W.H.O. report in 2002 stated that every minute a child becomes blind (World Health Organisation, 2002). This was

based on an estimate that about half a million children become blind every year (World Health Organization, 1997). More recently, however, Rahi, Cable, and British Childhood Visual Impairment Study (2003) reported a cumulative incidence of 5.9 per 10000 by the age of 16 years for childhood blindness in the United Kingdom. While another study from Kuwait documented an incidence of 7.35 per 100,000 person years among individuals aged less than 20 years old (Al-Merjan, Pandova, Al-Ghanim, Al-Wayel, and Al-Mutairi, 2005).

2.1.3 The burden of the childhood blindness

The prevalence of blindness in children is only about one-tenth of the prevalence of blindness in adults (Kilangalanga *et al.*, 2020). Despite this fact, preventing childhood blindness is a public health priority (Yorston, 1999). This is mainly because of the concept of "blind person years" (Gogate and Gilbert, 2007; Kong *et al.*, 2012). This concept describes the number of years that a blind individual has to live with the disability of blindness (Murthy *et al.*, 2008). The estimated number of "blind person years" caused blindness from childhood is 70 million years (Shamanna and Muralikrishnan, 2004). This represents a huge number of Disability Adjusted Life Years (DALYs) and adult cataract is the only condition that is responsible for a greater number than this (Gogate and Gilbert, 2007; Kong *et al.*, 2012). Accordingly, it has been suggested that restoring sight to a blind child corresponds to the restoration of sight in 10 adults (Gilbert and Foster, 2001a; Gudlavalleti, 2017).

Furthermore, a direct correlation between childhood blindness and childhood mortality has been described (Maida, Mathers, and Alley, 2008; Chandna and Gilbert, 2010). Blind children have been reported to have a higher likelihood of dying during childhood compared with sighted children (Kilangalanga *et al.*, 2020). It has been estimated that about 6 out of every 10 blind children in developing countries die within one year of the onset of blindness (Courtright *et al.*, 2011; Kong *et al.*, 2012) (World Health Organization, 2000). This further underscores the reason why the prevalence of childhood blindness greatly underestimates the burden (Gilbert and Awan, 2003).

Actually, the under-five mortality rates of many countries have been used as an indirect means for estimating the prevalence of childhood blindness in developing

countries (Gogate, Kalua, and Courtright, 2009). This correlation exists because some of the conditions associated with blindness in children, such as measles, vitamin deficiency and congenital rubella syndrome, are also causes of child mortality (Gilbert and Foster, 2001b; Kemmanu *et al.*, 2018a). Thus, the prevention and treatment of blindness in children has a direct positive impact on child survival (Gilbert and Foster, 2001b). This buttresses the significance of childhood blindness as a public health problem despite its relative rarity.

Moreover, the disability due to childhood blindness has significant impact on the child, the family and the society. A blind child potentially has a lifetime of 'darkness' ahead of him or her (Murthy *et al.*, 2008). Childhood blindness does not only retard the psychomotor and social development of the affected infant, it also has a negative effect the child's educational and occupational prospects (Pring and Tadic, 2010; Singh, 2015; Vervloed *et al.*, 2020). Besides, the care of blind children can be burdensome as well as expensive to the family (Kong *et al.*, 2012). Furthermore, having to raise such a child whose blindness could have been prevented can be considered a tragedy (Yorston, 1999).

Beyond the affected child and the family, the community also indirectly bears the burden of childhood blindness in terms of lost productivity and significant health care costs (Li *et al.*, 2019). The estimated global financial cost of childhood blindness with regards to the of loss of earning capacity (per capita GNP), is greater than the cost of adult blindness and has been projected to be between US$ 6 billion and $27 billion (Rahi, 2007). As a matter of fact, childhood blindness is thought to be responsible for over one third of the total economic cost of blindness (Maida *et al.*, 2008). It is therefore pertinent that prevention and treatment of blindness from childhood should receive priority attention especially when such blindness is avoidable (preventable or curable).

The burden of childhood blindness informed the inclusion of the control of childhood blindness as one of the major priorities of "VISION 2020: The right to sight" (Gilbert and Awan, 2003). This global initiative for the elimination of avoidable blindness was jointly launched in 1999 by The World Health Organization (W.H.O.) and the International Agency for the Prevention of Blindness (IAPB) (Gilbert and Foster, 2001a). The major objective of the initiative is to reduce the global burden of

avoidable blindness by half by the year 2020 and to reduce the prevalence of childhood blindness from 0.75 per 1000 children to 0.4 per 1000 by 2020. It remains to be seen whether the later objective has been achieved.

2.1.4 Historical trends in the literature on epidemiology of childhood blindness

The discussion in the literature on childhood blindness has a relatively short history. Childhood blindness only became an important concept in the early 1990s following a ground breaking meeting on the Prevention of childhood blindness held at the instance of the World Health Organization in May 1990 (Gilbert, Foster, Negrel, and Thylefors, 1993). Initially, the discussion mainly revolved around the epidemiology of childhood blindness with most of the attention being paid to the prevalence and causes of childhood blindness as well as its prevention.

Among the pioneers in the early literature on childhood blindness were Foster and Gilbert (Foster and Gilbert, 1992; Gilbert *et al.*, 1993) whose articles brought the importance of studying childhood blindness to the fore. Their innovation in designing a form for recording causes of childhood blindness was instrumental in harmonizing the methods of collecting data on childhood blindness. This led to a significant increase in the literature on childhood blindness.

Subsequently, as a result of information that was generated on its magnitude and burden, childhood blindness was included as one of the priority areas for the control of blindness in the global initiative "VISION 2020: The Right to Sight" (Gilbert and Awan, 2003). This aspect of the history of the research on childhood blindness is typified by another paper by Gilbert and Foster (2001b) in which they discussed the strategies needed to control childhood blindness within the setting of VISION 2020.

More recently, attention has shifted to the changing patterns in the epidemiology of childhood blindness. This shift in the literature is exemplified by publications by Gogate *et al.* (2009) and Kong *et al.* (2012). These articles addressed the global and regional changes in the prevalence and causes of childhood blindness that presumably have occurred as a result of preventive measures that were instituted in the late 1990s.

2.2 AETIOLOGY OF CHILDHOOD BLINDNESS

A variety of eye diseases that occur in children can result in childhood blindness. Such diseases are generally referred to as blinding eye diseases (Gilbert et al., 2018). Examples of blinding eye diseases include childhood cataract, childhood glaucoma, corneal opacity, blepharoptosis, strabismus, and retinopathy of prematurity (Courtright *et al.*, 2011). Other causes of childhood blindness include high uncorrected refractive errors, uveitis, cerebral visual impairment, congenital hydrocephalus as well as other congenital abnormalities such as aniridia, microphthalmia, colobomas, retinal dystrophies, and optic nerve hypoplasia (Rahi and Gilbert, 2017). In addition, neoplasms such as retinoblastoma, rhabdomyosarcoma, and brain tumours can lead to childhood blindness.

Globally, the commonest causes of childhood blindness are cataract, corneal opacity, retinopathy of prematurity and glaucoma (Courtright *et al.*, 2011; Solebo and Rahi, 2014). At the regional level, however, there is a marked variation in the causes of childhood blindness (Rahi and Gilbert, 2017; World Health Organization, 2018a; Kilangalanga *et al.*, 2020). This variation is thought to be mainly related to differences in the level of socioeconomic development in different countries (World Health Organization, 2018a). It is also a reflection of the balance between the various determinants of the occurrence of eye diseases in children such as the quality of primary health care and preventive services (Solebo and Rahi, 2014; Rahi and Gilbert, 2017). These factors also influence the regional differences in the prevalence of childhood blindness.

In addition to the regional variation in the aetiology of childhood blindness, a temporal variation has been observed in the epidemiology of childhood blindness globally (Gogate *et al.*, 2009; Kong *et al.*, 2012). Over the past decade, changes in regional patterns of the prevalence and causes of childhood blindness have been described (Kong *et al.*, 2012). Previous studies reported the commonest cause to be corneal opacity as a consequence of vitamin A deficiency and measles infection (Foster and Gilbert, 1992; Gogate *et al.*, 2009). More recent studies, however, have shown that the prevalence of corneal opacity has reduced significantly because of effective vitamin A supplementation and measles vaccination programmes (Gilbert and Muhit, 2008; Gogate *et al.*, 2009; Courtright *et al.*, 2011). As a result of the

changing epidemiology, childhood cataract is now becoming more important as a cause of childhood blindness (Gilbert and Muhit, 2008; Courtright, 2012).

Thus, in low-income countries, mainly in the sub-Saharan region, the major causes are: 1) corneal opacities secondary to measles, vitamin A deficiency, and use of harmful traditional eye medications; 2) congenital cataract often due to congenital rubella; and 3) other congenital conditions such as congenital glaucoma (Courtright *et al.*, 2011; World Health Organization, 2018a). Retinopathy of prematurity and cataract are the leading causes in mid-income countries while optic nerve diseases and hereditary retinal dystrophies are the common causes in the high-income countries (Solebo, Teoh, and Rahi, 2017; World Health Organization, 2018a).

Besides, the common causes of childhood blindness in Nigeria have been reported by a few population-based studies. The major causes in Sokoto state, northwest Nigeria were corneal scarring (55%) and childhood cataract (15%) (Muhammad *et al.*, 2010). Cataract (28%) was the commonest cause in Cross River state, followed by corneal scars (16%) and glaucoma (8%) (Duke *et al.*, 2013). This was similar to the report from Enugu state where cataract (40%) and corneal scar (13%) were the commonest causes of blindness in childhood (Aghaji *et al.*, 2017).

2.3 RISK FACTORS AND CLINICAL FEATURES OF SOME BLINDING EYE DISEASES OF CHILDHOOD

The early detection of common causes of childhood blindness is the focus of this research. Accordingly, the risk factors as well as clinical features (symptoms and signs) of some of these diseases, as described in the literature, are discussed in this section. The blinding eye diseases that would be discussed are childhood cataract, corneal opacity, childhood glaucoma, blepharoptosis, strabismus, and retinoblastoma. Although retinoblastoma is not as common as the other diseases, it has been included because it is the commonest cause of cancer of the eye in children and, in addition to childhood blindness, it can lead to death of an affected child particularly when it is diagnosed late.

2.3.1 Childhood cataract

Childhood cataract may be defined as the presence of an opacity in the lens of a child's eye that interferes with vision (Shrestha, 2012; Sheeladevi, Lawrenson, Fielder, and Suttle, 2016). It is becoming the major cause of childhood blindness in sub-Saharan Africa and other developing countries (Courtright *et al.*, 2011; Courtright, 2012; Bronsard *et al.*, 2018). The literature on childhood cataract as a cause of childhood blindness increased only in the last few years. This is because childhood cataract became more prominent following the observed changes in the epidemiology of childhood blindness (Gogate *et al.*, 2009). Some of the publications which have focused on the control of childhood cataract include Gilbert and Muhit (2012) and Courtright (2012). These papers are good examples of the discussion of the increasing need to focus more attention on the control of blindness from childhood cataract through the provision of affordable and accessible high quality surgical services.

Notwithstanding, the available data on the epidemiology of childhood cataract is considered to be limited (Sheeladevi *et al.*, 2016; He and Li, 2017). This paucity appears to be partly responsible for the variation in global prevalence estimates. Sheeladevi *et al.* (2016) in their systematic review reported that the overall prevalence of cataract in childhood ranged from 0.32 – 22.9 per 10,000 children across the globe. While another review reported that the global prevalence was between 0.01- 0.15 per 100 children (He and Li, 2017). Another reason for the wide range is the regional variation in the prevalence of childhood cataract; the prevalence being higher in developing countries of Africa and Asia in comparison to the developed economies of Europe and America (Khokhar *et al.*, 2017). Furthermore, the burden of visual impairment and blindness due to childhood cataract in low income countries is ten times the burden in developed countries (He and Li, 2017). Meanwhile, the global incidence of childhood cataract is reported to range between 1.8 – 3.6 per 10,000 per annum (Sheeladevi *et al.*, 2016).

The common causes of childhood cataract include familial (inherited) cataracts, intrauterine infections such as Rubella, eye trauma, as well as chromosomal and genetic abnormalities (Johar, Savalia, Vasavada, and Gupta, 2004; Khokhar *et al.*, 2017; Lambert, 2017). Childhood cataract may also be associated with some

syndromes such as Down syndrome and Marfan syndrome (Zetterstrom, Lundvall, and Kugelberg, 2005; Adio and Nwachukwu, 2016). There is a global variation in the causes and risk factors for childhood cataracts. The most common identifiable cause in Europe and North America is heritable cataract, usually autosomal dominant (Chan, Biswas, Ashworth, and Lloyd, 2012; Wu, Long, Lin, and Liu, 2016; Lambert, 2017). While in Asia and Africa, cataracts caused by trauma and those associated with presumed congenital Rubella syndrome represent a significant proportion of the identified causes of childhood cataract (Courtright, 2012; Borrell, Dabideen, Mekonen , and Øverland, 2013; Babber, Saraswat, Ojha, Tandon, and Sharma, 2016). Rubella cataract and traumatic cataract have also been found to be common in Nigeria (Duke, Oparah, Adio, Eyo, and Odey, 2015; Musa *et al.*, 2018).

Childhood cataracts can be classified according to the age of the child at onset of the disease. Congenital cataracts are present at birth or become obvious within the first one year of life; while developmental cataracts manifest after the age of 1-2 years (Courtright, 2012). In addition, childhood cataracts can affect only one eye (unilateral cataract) or both eyes (bilateral cataracts). Another classification system for childhood cataracts is based on the structure, location and density of the lens opacity, that is, the morphology of the cataract. The morphological types include total, nuclear, posterior, lamellar, membranous and sutural cataracts among others (Amaya, Taylor, Russell-Eggitt, Nischal, and Lengyel, 2003; Zetterstrom *et al.*, 2005).

The common symptoms for childhood cataract include white spot(s) in the eye(s), poor vision, and shaky unsteady eyes (Lambert, 2017). Poor vision in infants and young children may be suspected when they fail to make eye contact with the mother and other individuals or fail to return smiles, as well as when they bump into objects or fall over items easily (Adio and Nwachukwu, 2016). For older children, poor performance at school may suggest poor vision. Clinical signs of childhood cataract that can be detected on examination include leukocoria (white pupil), nystagmus, and strabismus (Lambert, 2017). In addition, features of associated ocular or systemic disease may be found during examination (Zetterstrom *et al.*, 2005; Adio and Nwachukwu, 2016).

2.3.2 Corneal opacity

A corneal opacity is the presence of a white scarred area in the cornea of the eye which results in a loss of its transparency (Ashaye and Oluleye, 2004). The transparent nature of the normal cornea is vital for clear vision. When there is an opaque area in the cornea, the vision of the affected eye is impaired depending on the density and the size of the opacity (World Health Organization, 2018b).

Corneal opacity was previously the leading cause of childhood blindness but the changes in the epidemiology of childhood blindness have brought about a decline in the frequency of corneal opacity in children (Gogate *et al.*, 2009; Courtright *et al.*, 2011). Across the globe, there are regional variations in the epidemiology of corneal opacity as a cause of childhood blindness. The proportion of childhood blindness caused by corneal opacity is much higher in sub-Saharan Africa and southeast Asia compared to Europe and south America (Kong *et al.*, 2012). Furthermore, within each of these regions, the proportion varies within and between countries according to the level of development; with less developed and rural areas having higher proportions of childhood blindness that is attributed to corneal opacity (Gupta *et al.*, 2015; Hashemi, Pakzad, Yekta, and Khabazkhoob, 2018).The common causes and risk factors of corneal opacity in children include measles keratopathy with associated vitamin A deficiency, microbial keratitis (corneal infections), trauma and the use of harmful traditional eye medications (Panjiyar, Gautam, Rai, and Puri, 2016; Solebo *et al.*, 2017; Tuft, 2017). In sub-Saharan Africa, corneal infections, the use of traditional remedies and vitamin A deficiency are the major risk factors for corneal opacity in children (Solebo *et al.*, 2017); while in southeast Asia, the major causes are trauma and corneal infections (Wang, Zhang, Li, Wang, and Liu, 2014; Gupta *et al.*, 2015). In Europe and North America, however, genetic and congenital corneal diseases are the major causes (Tuft, 2017).

The symptoms of corneal opacity include white spot in the eye(s) and poor vision, while the main clinical sign is an opacity in the cornea (Tuft, 2017). Other signs that may be present include irregularities both in the depth of the anterior chamber of the eye and in the shape of the pupil (Tuft, 2017).

2.3.3 Childhood glaucoma

Glaucoma has been defined as a group of heterogeneous eye diseases in which there is progressive optic neuropathy characterized by pallor and cupping of the optic nerve head, as well as visual field loss in which elevated intraocular pressure is a risk factor (Foster, Buhrmann, Quigley, and Johnson, 2002; World Health Organization, 2018c). Childhood glaucoma refers to eye diseases characterized by ocular damage due to elevated intraocular pressure (Thau *et al.*, 2018). There are different forms of glaucoma in children (Kipp, 2003; Papadopoulos and Khaw, 2017). The commonest form is primary congenital glaucoma (Ho and Walton, 2004; Papadopoulos, Cable, Rahi, Khaw, and Investigators, 2007). Other types are primary juvenile/ developmental glaucoma, secondary glaucoma such as glaucoma following trauma, uveitis or cataract surgery and glaucoma associated with eye disease such as congenital anomalies or intraocular tumours (Kipp, 2003; Papadopoulos *et al.*, 2007; Thau *et al.*, 2018). The primary forms of childhood glaucoma are idiopathic in origin and the main risk factors include parental consanguinity, positive family history and genetic mutations (Papadopoulos and Khaw, 2017). While, the causes and risk factors for secondary childhood glaucoma are ocular trauma, uveitis, cataract surgery, as well as congenital eye diseases such as Aniridia, Axenfeld-Rieger's syndrome and Peter's anomaly (Kipp, 2003; Papadopoulos and Khaw, 2017).

The main symptoms of congenital glaucoma have been described as a classical triad of watering of the eye(s), photophobia and blepharospasm (Papadopoulos and Khaw, 2017). Photophobia is sensitivity of the eyes to light which causes the individual to avoid bright lights. Blepharospasm means spasm of the eye lids with associated difficulty in opening the eyes. A child who presents with this triad of symptoms is very likely to have congenital glaucoma. Other common symptoms of childhood glaucoma are poor vision, white spots in the eye(s) and large eyeballs (Papadopoulos and Khaw, 2017). Clinical signs of childhood glaucoma include buphthalmos (bull's eye), corneal haziness, elevated intraocular pressure as well as optic disc pallor and cupping (Kipp, 2003; Papadopoulos and Khaw, 2017)..

2.3.4 Blepharoptosis

Blepharoptosis, simply referred to as ptosis, is defined as drooping of the upper eyelid (Pavone *et al.*, 2018). It is can affect one eye (unilateral) or both eyes (bilateral) (Weaver, 2018). The drooping upper lid may impair vision by causing obstruction of the visual axis of the eye or by distorting the curvature of the cornea with resulting astigmatism (Marenco *et al.*, 2017). The severity as well as the laterality of ptosis determines the impact of the condition on the vision of the affected child (Pavone *et al.*, 2018; Weaver, 2018).

There are 2 main types of ptosis namely congenital ptosis and acquired ptosis (Pavone *et al.*, 2018). Congenital ptosis, which is the more common type, is usually present from birth or develops within the first year of life (Marenco *et al.*, 2017). Risk factors for congenital ptosis include genetic mutations and a positive family history (SooHoo, Davies, Allard, and Durairaj, 2014). Congenital ptosis may be caused by birth trauma and could occur in association with conditions such as Bleharophimosis syndrome, Duane syndrome and Marcus Gunn syndrome (SooHoo *et al.*, 2014; Marenco *et al.*, 2017). Acquired ptosis occurs any time after the first birthday and may occur following trauma, upper lid infections, paralysis of the elevators of the upper lid and brain tumours (Pavone *et al.*, 2018; Weaver, 2018).

The main symptom of ptosis is drooping of the upper eyelid(s) (Kersten and Collin, 2017). Another symptom is elevation of the chin, especially in patients with bilateral ptosis. Clinical signs of ptosis include reduced palpebral aperture (the distance between the upper and lower lids), furrowing of the forehead, and abnormal head posture (Kersten and Collin, 2017)..

2.3.5 Strabismus

Strabismus is defined as a misalignment of the visual axes of the eyes which is a consequence of abnormal deviation of one or both eyes (Kanski, 2003). In normal circumstances, the two eyes look towards the same object of regard. When there is a misalignment of the visual axes, the two eyes look towards different directions or objects, and this is associated with the presence of an angle of deviation between the visual axes of the eyes.

Strabismus may be classified into primary and secondary types depending on the cause (von Noorden and Campos, 2002). Primary strabismus is idiopathic and occurs without any apparent cause or organic pathology affecting the eyes (Wright, Spiegel, and Thompson, 2006). Risk factors for primary strabismus include a positive family history, prematurity, cerebral palsy and seizure disorders. (Pennefather and Tin, 2000; Kristjansdottir, Sjostrom, and Uvebrant, 2002; Holmstrom, Rydberg, and Larsson, 2006; Donahue, 2007). Secondary strabismus has an identifiable cause which can either be an eye disease with associated visual impairment or neuromuscular disease (von Noorden and Campos, 2002). Causes of secondary strabismus include high refractive errors, amblyopia, cranial nerve palsy, intraocular tumours, and visual impairment from any cause (von Noorden and Campos, 2002; Ticho, 2003; Wright *et al.*, 2006).

Symptoms of strabismus include deviation of one or both eyes, double vision, poor vision and abnormal head position (von Noorden and Campos, 2002; Wright *et al.*, 2006). Clinical signs of strabismus include convergent or divergent deviation, limitation or restriction of eye movements, diplopia, abnormal head posture and visual impairment (Wright *et al.*, 2006; Azonobi, Olatunji, and Addo, 2009; Bodunde, Onabolu, and Fakolujo, 2014).

2.3.6 Retinoblastoma

Retinoblastoma is an abnormal proliferation of the precursor cells of the photoreceptor cells of the retina (Mehta *et al.*, 2012). It is an intraocular malignancy and is the commonest intraocular tumour in children (Ortiz and Dunkel, 2016; AlAli, Kletke, Gallie, and Lam, 2018). It is relatively uncommon and accounts for about 3% of all childhood cancers (Rodriguez-Galindo, Orbach, and VanderVeen, 2015; Rao and Honavar, 2017). Risk factors for retinoblastoma include genetic mutation, positive family history and older paternal age (Mehta *et al.*, 2012; Mills, Hudgins, Balise, Abramson, and Kleinerman, 2012; Cassoux *et al.*, 2017). Apart from being a cause of blindness in affected children, the disease can lead to death in the absence of treatment (Rao and Honavar, 2017).

Retinoblastoma usually presents in early childhood and one of the earliest symptoms is a “cat’s eye reflex” (Gallie and Soliman, 2017). This is an abnormal reflection of

light that is seen from the affected eye especially in the dark. It is very similar to the reflection seen from the eyes of cats at night. Other symptoms of retinoblastoma include squint (abnormal deviation of the eye), white spot in the eye and poor vision (Mehta *et al.*, 2012; Ortiz and Dunkel, 2016; Rao and Honavar, 2017; AlAli *et al.*, 2018). Advanced retinoblastoma may present with protrusion of the eye and multiple masses on the scalp (Mehta *et al.*, 2012; Gallie and Soliman, 2017). The clinical signs of the early stages of the disease include leukocoria, strabismus, and detection of retinal mass(es) on fundoscopy (Ortiz and Dunkel, 2016; AlAli *et al.*, 2018). In late stages, there may be extraocular spread of the tumour with associated proptosis, orbital masses as well as features of intracranial extension (Mehta *et al.*, 2012; Gallie and Soliman, 2017).

2.4 DETECTION OF CHILDHOOD EYE DISEASES

Identification of eye disease or visual impairment in infants and young children is challenging (Nirmalan *et al.*, 2004a). One reason for this is that infants and toddlers are unlikely to complain about visual symptoms or inability to see well. Especially, since they may be unaware that their visual experience is abnormal. In fact, it has been reported that even older children with visual impairment perceive their vision to be equivalent to that of their colleagues with normal vision (Nirmalan *et al.*, 2004a)

Another reason for the difficulty with detection of eye disease in children is the inability of parents to notice when there is a problem with their child's vision (Kemmanu *et al.*, 2018b). Several studies have demonstrated the fact that parents and care givers may be unaware or have misconceptions about causes, signs and treatment of childhood eye diseases (Nirmalan *et al.*, 2004b; Muhit, Shahjahan, Hassan, Wazed, and Ahmed, 2011; Balasubramaniam, Kumar, Kumaran, and Ramani, 2013; Senthilkumar, Balasubramaniam, Kumaran, and Ramani, 2013; Donaldson, Subramanian, and Conway, 2018; Sukati, Moodley, and Mashige, 2018). Furthermore, parents are not likely to seek routine eye examinations for their children. Amiebenomo *et al.* (2016) reported that majority of parents in Benin city sought eye care for their children only after he or she had a complaint.

Therefore, in a situation where the child does not complain and the parents are unaware, the presence of eye disease or visual impairment may go unnoticed. This

usually leads to delayed detection of the eye problem and late presentation of the child to the health care provider. It is in view of the possibility that a young child with visual impairment may not be detected early that efforts to identify such children should not depend on the decision and action of the parents or care giver only. Health care providers need to actively seek to identify children with features suggestive of visual impairment or eye diseases. The following sections discuss the importance of early detection, the factors associated with delayed detection as well the techniques and methods used for early detection of childhood eye diseases.

2.5 IMPORTANCE OF EARLY DETECTION AND TREATMENT OF CHILDHOOD EYE DISEASES

The sense of vision in humans is not fully developed at birth (Mills, 1999; Bremond-Gignac *et al.*, 2011). In fact, it takes about 7-8 years for the process of visual development to reach completion (Day, 1997; Wright *et al.*, 2006). Normally, visual development is an intricate process that requires appropriate stimulation of the visual system in order to achieve the best visual potential in an individual. Appropriate visual stimulation involves three basic components namely: (i) the formation of clear retinal images in each eye (ii) the proper alignment of the visual axes of both eyes and (iii) comparably equal image clarity between the two eyes (von Noorden and Campos, 2002; Wright *et al.*, 2006).

Therefore, whenever there is abnormal visual stimulation due to disruption of any of these components during early childhood, the process of visual development does not follow the normal course and optimal visual maturation is not achieved (Mills, 1999). Abnormal visual stimulation occurs when indistinct images are perceived by one or both eyes, and/or when there is misalignment of the visual axes of the eyes (Bremond-Gignac *et al.*, 2011). Thus, eye diseases such as cataract, corneal opacity, glaucoma, ptosis, and strabismus can all result in abnormal visual stimulation and subsequently, abnormal visual development. And this implies that a child who suffers any of such diseases is subject to a "double jeopardy" phenomenon. In other words, the eye disease not only causes poor vision directly, it also indirectly diminishes the best visual potential by disrupting the process of visual maturation.

Apart from the failure to achieve maturity of visual function, other consequences of abnormal visual development include structural abnormalities in the visual centres of the brain, lack of binocular vision and amblyopia (von Noorden and Campos, 2002; Wright *et al.*, 2006). Some fallouts of these consequences include poor visual acuity, poor depth perception and low contrast sensitivity (Mills, 1999; Levi, Knill, and Bavelier, 2015). These result in a worse degree of visual impairment than that which is directly due to the eye disease that caused the abnormal visual stimulation in the first place. Thus, the severity of visual loss in a child is actually worse than in an adult with the same disease of similar severity because the adult had attained visual maturity before the onset of the disease.

The implication for the child with such eye disease is that, treatment of the eye disease alone is not sufficient to restore normal vision. In addition to the treatment of the eye disease, consideration has to be given to the institution of measures that will foster the reinstatement of normal visual development (Wright *et al.*, 2006). These measures, however, can only be effective if initiated during the early period of visual development when the abnormal processes can still be "normalised". This means that the treatment of the eye disease must also be administered during that period. Moreover, when treatment of the eye disease is delayed beyond the period of visual development, the consequences of the abnormal visual stimulation become irreversible leading to permanent visual impairment irrespective of the quality of treatment (Mills, 1999; Bremond-Gignac *et al.*, 2011; Park, 2019).

Although visual development continues until the age of 7-8 years, it is most active and vulnerable during the first 3 months of life. Therefore, this period is referred to as the critical period of visual development (Daw, 1998). Thereafter, the developmental processes progress less rapidly and are less modifiable (Mills, 1999). It is because of the critical period that congenital eye diseases can cause severe and permanent visual impairment when they are not detected early and treatment is delayed beyond the first few months of life. In addition, diseases with onset during the latter half of the 1st year of life up till the 8th year, must be identified on time and treated promptly.

Furthermore, the visual impairment in childhood has a negative impact on mental and educational development of the affected child (Dale and Salt, 2007). Children learn mostly by copying others and about 80% of learning is based on the sense of vision

(Zaba, 2011). This further indicates the urgency that is required in the treatment of childhood eye diseases that cause blindness. Early treatment of such diseases does not only improve the child's vision; it also enhances the mental development and educational prospects of the affected child (Gogate, Gilbert, and Zin, 2011). Therefore, the need for early detection and prompt intervention in childhood eye diseases cannot be overemphasised.

2.6 DELAYED DETECTION OF CHILDHOOD EYE DISEASES IN DEVELOPING COUNTRIES

Based on the foregoing, it is quite clear that early detection and prompt treatment of childhood eye diseases is vital for achieving the best visual outcome in affected children. In developed countries, most children with eye diseases that can cause blindness are identified early and treatment is usually administered promptly (Rahi, Cumberland, Peckham, and British Childhood Visual Impairment Interest, 2010). Unfortunately, the same cannot be said about developing countries, particularly those in Sub Saharan Africa, where delayed detection of eye diseases and blindness in childhood is common. This delay, undoubtedly, leads to late presentation of such children to hospital for treatment. Several studies on the late presentation of children with eye diseases, especially, cataracts have been published from developing countries (Mwende *et al.*, 2005; Bronsard *et al.*, 2008; Gogate *et al.*, 2010; Courtright *et al.*, 2011; Ezegwui *et al.*, 2011; Leite and Zin, 2011; You *et al.*, 2011; Randrianotahina and Nkumbe, 2014; Schulze Schwering, Finger, Barrows, Nyrenda, and Kalua, 2014; Sheeladevi *et al.*, 2018).

One of the reasons for the delayed detection of childhood eye diseases is the lack of screening programs in developing countries (You *et al.*, 2011; Sheeladevi *et al.*, 2018). This is contrary to what obtains in the developed countries where well-coordinated screening programmes facilitate the early detection of blinding eye diseases in neonates and infants (Rahi *et al.*, 2010). Another reason is the parental awareness and attitude to eye problems of children, as has been mentioned earlier. In addition, poor knowledge and skills of primary health care provider may contribute to the delay in detecting blinding eye diseases in children (Kishiki, Hogeweg, Dieleman, Lewallen, and Courtright, 2012). Thus, even when a parent seeks eye care on account

of a suspicion that there is a problem with a child's eye, wrong advice from the health care provider can lead to delay in diagnosis and treatment (Courtright *et al.*, 2011).

The major concern with delayed detection as well as late presentation and treatment of children with eye disease is the associated poor outcome. The poor outcome of treatment is due to the disruption of visual development caused by the eye disease and the subsequent amblyopia (Sheeladevi *et al.*, 2018). Amblyopia may be simply defined as inability of an eye to see optimally in the absence of any organic pathology or despite complete treatment of eye disease (American Academy of Ophthalmology, 2008). It is usually associated with any eye disease that causes abnormal visual stimulation during early childhood. The earlier the onset of the disease, the worse the amblyopia (Gogate *et al.*, 2011). When diagnosed early, amblyopia can also be treated effectively with resultant improvement in vision to normal or near-normal levels (Park, 2019). However, when it is diagnosed after the period of visual development, the visual impairment due to amblyopia is permanent (Bremond-Gignac *et al.*, 2011). For this reason, early detection and treatment of blinding eye diseases, especially during the first year of life, is very crucial in the prevention of permanent visual impairment from amblyopia.

2.7 INTERVENTIONS FOR EARLY DETECTION OF CHILDHOOD EYE DISEASES

In view of the importance of early detection of childhood eye diseases, a number of measures or interventions have been developed or recommended by some professional societies and non-governmental organisations including the World Health Organisation. Examples of these interventions include the following:

2.7.1 Eye examination at birth and during well baby visits

Routine examination of the eye of new-borns soon after birth or in the early neonatal period has been broadly recommended by several professional bodies in developed countries. These societies include the American Academy of Paediatrics, the American Academy of Ophthalmology, the American Association for Paediatric Ophthalmology and Strabismus, American Academy of Family Physicians, American Optometric Association and the Canadian Paediatric Society (Committee on Practice

Ambulatory Medicine Section on Ophthalmology *et al.*, 2003a; Committee on Practice Ambulatory Medicine Section on Ophthalmology *et al.*, 2003b; Canadian Paediatric Society, 2009; Donahue *et al.*, 2016a; Donahue *et al.*, 2016b; Earley and Fashner, 2019). These examinations are often performed by a physician or nurse soon after delivery or during infant welfare clinic visits.

Specifically, in the United States of America (U.S.A.), new born babies routinely undergo a comprehensive new-born examination within the first 48 to 72 hours of life; the assessment, which includes examination of the eyes, is usually performed by a paediatrician (Lowe and Woolridge, 2007; Lewis, 2014). In addition, infants undergo periodic examinations by either a family physician or a paediatrician during well-child visits that usually take place at the ages of one, two, four, six, nine and twelve months (Bell, Rodes, and Collier Kellar, 2013; Committee On Practice and Ambulatory Medicine and Bright Futures Periodicity Schedule Workgroup, 2017; Moreno, 2018; Turner, 2018). Furthermore, the American Optometric Association offers free comprehensive eye examinations to all infants aged between 6 and 12 months through the InfantSEE program (Miller, 2007).

Furthermore, the United Kingdom (UK) Government through the UK National Screening Committee has laid out guidelines for examination of the eyes of new-borns and infants (Carr and Foster, 2014; Public Health England, 2019). Thus, in the United Kingdom, all babies go through a New-born Infant Physical Examination (NIPE) within 72 hours of birth and this incorporates an eye examination to detect congenital abnormalities (Mansoor *et al.*, 2016). This examination is usually performed by paediatrician or a midwife; and a follow-up examination is conducted when the child is 6 to 8 weeks old by a general practitioner (Green and Oddie, 2008; Parish, Tailor, and Gandhi, 2018). Moreover, many European countries including Sweden, Denmark, Italy, Netherlands and Norway have established programs in which neonates and infants undergo routine comprehensive assessments with eye examination performed by paediatricians or general practitioners (Haargaard, Nystrom, Rosensvard, Tornqvist, and Magnusson, 2015; Perilli, Lanci, Romanzo, Sabatini, and Fusilli, 2015; Sloot *et al.*, 2015).

Unfortunately, the same cannot be said about many of the countries in Asia and Africa, with specific regards to full term normal neonates. Reports from India and

China suggest that most full-term babies do not undergo routine eye examination in the neonatal period or during infancy (Li and Lin, 2013; Vinekar *et al.*, 2015; Ma *et al.*, 2018). In the same vein, most African countries, Nigeria inclusive, do not have routine eye screening examinations for neonates and infants (Atowa, Wajuihian, and Hansraj, 2019; Jac-Okereke, Jac-Okereke, Ezegwui, and Okoye, 2020).

In the Nigerian health system, there are some opportunities for such eye examinations to be carried out on neonates and infants such as during examination of new-borns immediately after birth and at post-natal clinic visits as well as during immunisation visits. Indeed, the National Eye Health policy recommends that frontline primary health care workers should be adequately trained to recognise and refer childhood eye diseases within the total provision of child healthcare package, that is, neonatal examination, immunisation and growth monitoring (Federal Ministry of Health Nigeria, 2019). However, there is the no evidence to that eye examinations are done routinely or that children detected to have eye disease are referred promptly and appropriately.

On the other hand, there are relatively well-established programmes that provide screening for Retinopathy of Prematurity (ROP) among premature babies born in Asia (Mora, Waite, Gilbert, Breidenstein, and Sloper, 2018; Adams, 2020). Such programmes, which are generally limited to premature and low birth weight babies, usually lead to the early detection of other ophthalmic conditions in such babies (Jayadev *et al.*, 2015). Over the last few years, similar programmes have been set up and are expanding across African countries, including Nigeria, such that a good proportion of premature African babies have the opportunity to undergo ROP screening examinations (Ademola-Popoola and Oluleye, 2017; Wang, Duke, Chan, and Campbell, 2019; Olusanya *et al.*, 2020a).

2.7.2 Preschool vision screening

Preschool vision screening of children between the ages of 3 and 5 years is also recommended by various professional societies including those mentioned above (Earley and Fashner, 2019). In addition, the government of the United States of America through the U.S. Preventive Services Task Force (USPSTF) has a well

outlined policy for examination of the eyes of children of preschool age (Jonas *et al.*, 2017; U. S. Preventive Services Task Force *et al.*, 2017).

Preschool vision screening facilitates the early detection of poor vision and eye diseases that may lead to visual impairment such as refractive errors, amblyopia, and media opacities in children before they start school. Evidence exists that visual impairment may have a negative impact on learning and educational development of an affected child (Atkinson *et al.*, 2002; Roch-Levecq, Brody, Thomas, and Brown, 2008; VIP-HIP Study Group *et al.*, 2016).Therefore, it is pertinent to ensure that any vision disorder or eye disease is detected before school entry. Indeed, there are reports about the usefulness of these programs in early detection of amblyopia and the impact of early treatment on education and learning (Azizoglu *et al.*, 2017; Joint Clinical Practice Guideline Expert Committee of the Canadian Association of Optometrists and the Canadian Ophthalmological Society *et al.*, 2019; Thorisdottir, Faxen, Blohme, Sheikh, and Malmsjo, 2019; O'Colmain, Neo, Gilmour, and MacEwen, 2020).

Such preschool vision screening programs are well established in developed countries. However, none of these screening programs exist in sub-Saharan African countries (Atowa et al., 2019). A few studies have been reported from Asia and Latin America but none from Africa (Latorre-Arteaga *et al.*, 2014; Jeong and Kim, 2015; Chew *et al.*, 2018; de Venecia, Bradfield, Trane, Bareiro, and Scalamogna, 2018; Paul and Sathyan, 2018).

2.7.3 Primary eye care services (in sub-Saharan Africa)

Primary health care workers should play an important role in the early detection of eye diseases in children (Olowoyeye, Musa, and Aribaba, 2019). This is because they are often the first port of call for mothers and children in their search for health care. Unfortunately, this role does not appear to have been well established in many African countries as a result of the poor knowledge and skills which health workers possess regarding primary eye care (Byamukama and Courtright, 2010; Kishiki *et al.*, 2012; Kalua *et al.*, 2014; AbdulRahman, Rabiu, and Alhassan, 2015). This is contrary to the expectation that these health workers should actually be knowledgeable and skilled in primary eye care, since they are taught about eye diseases during their basic training programmes. In Nigeria, for example, the curriculum and the standing orders of

community health officers (CHOs) and community health extension workers (CHEWs) contain modules on eye care including the identification and prompt referral of children with cataract (Shodehinde, Kila, Akinrolabu *et al*, 1995; Community Health Practitioners Registration Board of Nigeria, 2006a; Community Health Practitioners Registration Board of Nigeria, 2006b). Various reasons have been suggested for this mismatch between the basic training and the practice of primary eye care by primary health workers. They include lack of supervision and retraining; lack of equipment for basic examination such as visual acuity charts, pen torches and ophthalmoscopes; lack of medications; and poor referral systems (Courtright, Seneadza, Mathenge, Eliah, and Lewallen, 2010; AbdulRahman *et al.*, 2015; Aghaji, Gilbert, Ihebuzor, and Faal, 2018; Olowoyeye *et al.*, 2019).

As far back as the year 2002, the World Health Organisation in conjunction with the Lions Sight First project for the prevention of blindness in children recommended 10 Key activities, which if implemented by primary health workers would promote Healthy eyes in children (World Health Organization, 2002). The activities are listed in Table 2.1. Some of the activities promote the general health of children and are not specific to eye health while some activities, such as detection and prompt referral of children with white pupil and eye injuries, are directly related to eye health. In addition, the nature and spectrum of the activities strongly suggest that strengthening primary health care plays a vital role in the prevention of childhood blindness. Sadly, there is little evidence that this recommendation by the World Health Organisation has been adopted by most African countries (Mafwiri *et al.*, 2014). This has had a negative impact on the implementation of the policy of early detection of eye disease in children at primary health care level.

Mafwiri *et al.* (2014). conducted some studies on the implementation of these activities and their integration into primary health care in Tanzania. They found that prior to training, primary health workers were only performing some activities but after training, all 10 activities were being performed by the primary health workers. This demonstrates the fact that training and retraining of primary health workers and integration of primary health care activities may go long way in ensuring the children with eye diseases are detected early.

Furthermore, studies on the prevalence and causes of childhood blindness have used a case finding approach for the detection of eye diseases in children (du Toit *et al.*, 2017). Volunteer health workers are trained on some of the features of eye diseases and blindness in children. These workers, who have been termed "Key informants", then go into communities which they are familiar with, to identify children who may be blind or visually impaired. All the identified children are subsequently brought for examination by an ophthalmologist on a particular day to confirm the presence of eye disease or blindness. However, this method of detecting eye disease in children is not sustainable and may not achieve the aim of early identification and prompt referral.

Table 2.1 Ten key activities to promote healthy eyes in children

1. Give vitamin A supplements to children routinely
2. Give vitamin A supplements to mothers after delivery
3. Promote breast feeding and good nutrition
4 Give vitamin A supplements to children with measles or malnutrition
5. Immunize children against measles
6. Clean the eyes of babies at delivery and apply antibiotic eye drops
7. Keep children's faces clean
8. Refer children with poor vision or white pupils to an eye worker
9. Avoid the use of traditional eye medicines
10. Refer children with history of injury to an eye worker

Source: (World Health Organization, 2002)

2.8 PRINCIPLES OF SCREENING FOR DISEASES

Wald (1994) defined screening as "the systematic application of a test or inquiry to identify those individuals at sufficient risk of a specific disorder to benefit from further investigation or direct preventive action, among persons who have not sought medical attention on account of symptoms of that disorder". Essentially, the underlying principle of screening for any disease is that early detection is deemed to be beneficial at the individual level as well as to the community, from a public health perspective.

2.8.1 Criteria for screening

The most popular set of screening criteria is the Wilson and Jungner criteria, first published by the World Health Organisation in 1968. These criteria, which are listed

below, are a set of requirements that should be met before screening may be considered appropriate for a disease.

1. The disease condition should be an important health problem.
2. There should be an accepted treatment for patients with recognized disease.
3. Facilities for diagnosis and treatment should be available.
4. There should be a recognizable latent or early symptomatic stage.
5. There should be a suitable test or examination.
6. The test should be acceptable to the population.
7. The natural history of the condition, including development from latent to declared disease, should be adequately understood.
8. There should be an agreed policy on whom to treat as patients.
9. The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole.
10. Case-finding should be a continuing process and not a 'once and for all' project.

Although, these criteria have been modified and improved upon by different authors and health agencies, they still form the traditional criteria for justification of screening for diseases. Blindness and visual impairment in childhood fulfil these criteria to a large extent and therefore screening for causes and risk factors of visual impairment and blindness among infants and young children is justified.

2.8.2 Screening tools in health care

Screening has been used for the early detection of various types of diseases including cancer, genetic conditions, infections, vascular conditions and psychological disorders. There are various forms of tests or tools used for screening. These tools include blood tests, urinalysis, radiological investigations such as X-rays and ultrasonography, endoscopy as well as clinical and pathological examinations. These

tests may be based on the measurement of a specific chemical or substance in body fluids or the detection of a particular characteristic or feature during examination or investigation (Maxim, Niebo, and Utell, 2014).

Checklists have also been used as screening tools in health care. Checklists are cognitive tools that are used in various fields of endeavour to aid memory and decision making (Winters *et al.*, 2009; Kramer and Drews, 2017). In the field of health care, they have been particularly useful in the reduction of medical errors and optimisation of patient safety as well as in performance evaluation of health care providers (Hales and Pronovost, 2006; Rosen and Pronovost, 2014). With respect to screening, however, the role of checklists appears to be less prominent. Even so, their use has been well studied with regards to screening for autism and other developmental disabilities (Petrocchi, Levante, and Lecciso, 2020). Examples of checklists that have been in employed in screening for different diseases include the Modified-Checklist for Autism in Toddlers (M-CHAT), the Baby Paediatric Symptom Checklist (BPSC), the Preschool Paediatric Symptom Checklist (PPSC), the Temporomandibular disorders (TMD) checklist, the Posttraumatic stress disorder (PTSD) Checklist, and the Hypomania Checklist.

2.9 TECHNIQUES OF SCREENING FOR EYE DISEASE IN INFANTS AND YOUNG CHILDREN

Examination of young children is not easy because of poor cooperation. Objective vision assessment is also difficult and often requires special equipment or instruments. Subjective assessments may also be prone to misinterpretation. Therefore, some techniques have been identified to be useful in screening for eye disease or visual impairment among infants and young children. These techniques include the Red reflex (Bruckner) test, photo-screening instruments, and use of checklists. These techniques generally involve brief examination of the child, require minimal cooperation of the children and can provide enough information to determine the presence or absence of eye disease.

2.9.1 Red reflex test (Bruckner test)

The red reflex test is a very important screening technique for eye disease in infants and young children (Loh and Chiang, 2018). It is performed with the aid of a direct ophthalmoscope. A direct ophthalmoscope is a special equipment used to examine the posterior aspect of the eye. It is routinely used by ophthalmologists and general physicians to examine the vitreous, retina and optic nerve of the eye. When the light from the instrument is shown on the eye, a reflection of light is perceived by the examiner as he/she looks through the instrument. This reflection has an orange or red colour (that is, a red reflex) and the quality of the reflection gives an indication of the transparency of cornea, the lens and other internal structures of the eye. In addition, the reflexes from both eyes can be viewed simultaneously and compared (Bruckner test) for differences between the two eyes.

This test is very valuable for the detection of media opacities such as cataract, corneal opacity. It can also detect strabismus, ptosis, congenital glaucoma and retinoblastoma. In addition, high degrees of refractive errors can also be detected using the red reflex test.

It is the recommended test for screening among neonates and infants especially because it does not depend on the child's cooperation (Loh and Chiang, 2018). And is widely practised in the developed countries. In those settings, the test is usually performed by primary care providers. Various studies have been conducted on the sensitivity and specificity of the test in detecting eye diseases in infants and young children. The reported sensitivity of the Red reflex test ranged between 13.9% and 85%, while the specificity ranged between 38.5% and 98.7% (Eventov-Friedman, Leiba, Flidel-Rimon, Juster-Reicher, and Shinwell, 2010; Saiju, Yun, Yoon, Shrestha, and Shrestha, 2012; Mussavi, Asadollahi, Janbaz, Mansoori, and Abbasi, 2014; Sun *et al.*, 2016).

Challenges with the use of the Red reflex test, in developing countries, include the fact that the direct ophthalmoscope is a relatively expensive instrument, and the test requires some degree of expertise for performing it and interpreting the various results. Consequently, direct ophthalmoscopes are not readily available in many health

care facilities especially primary and secondary centres. Moreover, the health workers in these facilities lack the knowledge and skill required to perform the test.

2.9.2 Photo-screening

Photo screening is the use of instruments to screen for refractive errors, amblyopia and other eye diseases among preschool children usually between the ages of 3 and 5 years. Children at this age may not be able to cooperate for objective visual assessment that require matching of optotypes such as the Lea and HOTV charts. Examples of the instruments that been developed for photo-screening include iScreen, SPOT, PlusOPtiX, MTI, and remote autorefractors (Retinomax, Suresight). They are more or less based on the red reflex test, in that they project a light into the child's eye, evaluate the red reflex and interpret the findings. Their limitation is cost and availability. In addition, they are not very useful in neonates and infants.

2.9.3 Checklists

A number of checklists have been used for the screening of young children for eye disease (Table 2.2.). These have been developed by various non-governmental organisations and government agencies in developed countries to aid parents, teachers and other lay individuals in the identification of children that require referral for comprehensive eye examination by an optometrist or ophthalmologist. A total of 11 vision checklists were identified and retrieved during a web search using the terms "vision OR eye" AND "screening" AND "checklist OR tool" AND "infant OR child". However, a search of medical literature databases including PubMed, Google Scholar, Embase, Medline, and CINAHL, using the same search terms, did not reveal any reports of studies on any of the identified vision screening checklists. Therefore, there are no literature describing the development nor validation of these checklists, as far as the author searched.

Majority (seven) of the 11 checklists are from organisations in the United States of America (U.S.A.), two are from Canadian organisations, while there is one each from the United Kingdom and Australia. Not one of the checklists is from Africa, Asia or any other developing country. The number of items in the checklists ranges from 10 to 46 items; while the number of sections ranges from 1 to 7 sections. Only one of the

checklists has a clearly defined scoring system while the interpretation of the screening result and the recommended action were not described for three checklists.

Six of the 11 vision checklists are designed mainly for parental use and they include the *Red Flags Vision Checklist* (Child Development Programs, 2007); the *Vision checklist for young children* (Mayfair Eye Care, 2018) and the *Parent checklist* (Children's Eye Foundation, 2019). Others are *Children's Vision Checklist* from the Family Vision Development Centre (2019) based in Illinois, U.S.A; *the Vision and Learning Checklist* (VisionHelp Group, 2015) and the *Vision Checklist* designed by Dr. Lynn Hellerstein (2010) a developmental optometrist in the U.S.A. These parental checklists essentially contain lists of items or questions that can point to the presence of features of eye disease or poor vision in children. They range from questions about the appearance of the child's eyes to the visual behaviour of the child. However, most of the questions are applicable to toddlers and preschool children and not infants. In addition, some of the concepts/questions are specific to the culture of the countries that the checklists are designed for and may, therefore, not be applicable in our own setting.

Other checklists which are designed for use by teachers in schools include the *Teacher's Classroom Vision Checklist* (Australasian College of Behavioural Optometrists, 2015); the *Educator's Checklist* (Optometric Extension Program Foundation, 1985); the *Teacher's checklist of observable clues to classroom vision problems* (VisionCare Optometry, 2012); the *Vision Screening Checklist* of the Arizona State Schools for the Deaf and the Blind (2007); and the *ABC Checklist for Vision Observation and History* (Texas School for the Blind and Visually Impaired, 2016). The "ABC" in the last checklist is an acronym for "Appearance, Behaviour and Complaints". Indeed, all these teacher checklists include questions or items related to the appearance of the eyes, the visual behaviour the child and complaints about vision problems by the child. Thus, they are similar to the parent checklists except that they enquire about the presence of visual complaints and are, therefore, designed for use in school aged children and not infants. Also, the questions are largely culture-specific.

One major drawback of these checklists is that the process of their development and validation was not documented and their collective or individual sensitivity and specificity in the detection of blinding eye disease in children have not been evaluated.

A possible reason for this is that, in those countries where they have been put to use, they simply serve as adjuncts to the main techniques for early detection of eye diseases in children which are: (i) the red reflex performed by physicians or nurses during routine neonatal and well child examinations; (ii) photo-screening tests and devices.

Other drawbacks of these checklists include the fact that they were developed primarily for use at home or in school by lay people to screen toddlers and older children for eye diseases. Thus, they are not designed for use in health facilities by health professionals and may not be appropriate for use in infants. In addition, they may not be culturally applicable to the Nigerian setting. Moreover, the use of these checklists is generally limited to developed countries such as the United States of America, Canada, United Kingdom, Australia and European countries. And to the knowledge of the author, there are no similar checklists that have been designed for use in developing countries, especially Sub-Saharan countries such as Nigeria.

Table 2.2. Vision screening checklists in use in developed countries

S/N	Name of checklist	Organisation & Country (Citation)	Person required to complete checklist	Number of sections/ domains	Number of items	Scoring system	Interpretation/ Decision making/ Recommended action	Development of checklist	Validation of checklist
1	Red Flags Vision Checklist	Child Development Programs (2007) Canada	Parent	1 section Not classified into domains	17	None	Stated	Not described	Not reported
2	Vision checklist for young children	Mayfair Eye Care (2018) Canada	Parent/ Teacher	2 domains (Appearance & Behaviour)	13	None	Not stated	Not described	Not reported
3	Parent checklist	Children's Eye Foundation (2019) U.S.A.	Parent	4 sections Not classified into domains	32	None	Stated	Not described	Not reported
4	Children's Vision Checklist	Family Vision Development Centre (2019) U.S.A.	Parent	3 sections Not classified into domains	23	None	Stated	Not described	Not reported
5	Vision and Learning Checklist	VisionHelp Group (2015) U.S.A.	Parent	1 section Not classified into domains	10	Yes	Not stated	Not described	Not reported
6	Vision Screening Checklist	Hellerstein & Brenner Vision center (2010) U.S.A.	Parent	3 sections Not classified into domains	19	None	Stated	Not described	Not reported
7	Teacher's Classroom Vision	Australasian College of	Teacher	5 sections 3 domains	42	None	Stated	Not described	Not reported

	Checklist	Behavioural Optometrists (2015) Australia		(Appearance, Behaviour & Complaints)					
8	Educator's Checklist	Optometric Extension Program Foundation (1985) U.S.A.	Teacher/ School nurse/ Psychologist	7 sections 3 domains (Appearance, Behaviour & Complaints)	46	None	Not stated	Not described	Not reported
9	Teacher's checklist of observable clues to classroom vision problems	VisionCare Optometry (2012) U.K.	Teacher	3 domains (Appearance, Behaviour & Complaints)	43	None	Stated	Not described	Not reported
10	Vision Screening Checklist	Arizona State Schools for the Deaf and the Blind (2007) U.S.A.	Teacher/ Early childhood care staff	3 domains (Appearance, Behaviour & Complaints)	26	None	Stated	Not described	Not reported
11	ABC Checklist for Vision Observation and History	Texas School for the Blind and Visually Impaired (2016) U.S.A.	Teacher	3 domains (Appearance, Behaviour & Complaints)	23	None	Stated	Not described	Not reported

2.10 DEVELOPMENT, VALIDATION AND FEASIBILITY OF CHECKLISTS USED FOR SCREENING

2.10.1 Development of screening checklists

The processes of development of the various checklists that have been previously used in screening for childhood eye diseases were not described by the institutions and organisations who developed such checklists. Furthermore, it has also been observed that there is no universal or standardised procedure for the development of checklists used in healthcare generally (Hales, Terblanche, Fowler, and Sibbald, 2008; Burian, Clebone, Dismukes, and Ruskin, 2018). As such, there are differences in the processes and steps used to develop many of the checklists currently utilised in screening for medical conditions.

The process of development of a checklist affects its quality and utilisation. (Schmutz, Eppich, Hoffmann, Heimberg, and Manser, 2014). A poorly conceived or designed checklist is less likely to be properly implemented; while a checklist developed through a systematic process has a higher chance of being used for the purpose for which it was created. Thus, paying attention to the process is important in ensuring that an effective checklist is developed.

A few authors have suggested stepwise processes for developing medical checklists (Winters *et al.*, 2009; Schmutz *et al.*, 2014; Burian *et al.*, 2018). Broadly, these steps include: conception/identifying the purpose of the checklist; determining the checklist design; selection of checklist items; and pilot testing of the checklist. It is important to note that these steps were described mainly for the development of checklists designed for performance evaluation and patient safety. Nevertheless, developers of a number screening checklists have used different combination of these steps in the process of developing their checklists.

The conception of a medical checklist requires identifying the specific disease condition, patient population, clinical procedure, training scenario or outcome for which it is being created (Winters *et al.*, 2009). The design of the checklist usually depends on various factors including the type of clinical setting (e.g. emergency ward, theatre, out-patient clinic); the expected level of competence of the users (e.g. novice,

intermediate, expert); and the method of completing the checklist (e.g. "Do and confirm" or "Read and do") (Burian *et al.*, 2018). In designing screening checklists, it is also important to consider incorporating and utilising a flow of items that would facilitate both memory and decision making.

Selection of checklist items is essentially the process of deciding which questions would be included in the checklist. This step usually involves a review of existing literature in addition to drawing on the clinical experience of physicians and/or patients as well as obtaining a consensus opinion of experts in the relevant field. In addition, this step is necessary for ascertaining the content validity of the checklist (DeVon *et al.*, 2007; Kimberlin and Winterstein, 2008). Examples of screening checklists that have used a combination of literature review and expert opinion in selecting checklist items include: the Fibromyalgia Rapid Screening Tool (FiRST) (Perrot, Bouhassira, Fermanian, and Cercle d'Etude de la Douleur en, 2010); the Baby Paediatric Symptom Checklist (BPSC) (Sheldrick *et al.*, 2013); and the Preschool Paediatric Symptom Checklist (PPSC) (Sheldrick *et al.*, 2012). FibroDetect, on the other hand, is a screening checklist for fibromyalgia that was developed based on information obtained from face-to-face interviews with patients and focus group discussions with clinicians in addition to literature review (Baron *et al.*, 2014).

Pilot testing entails the testing of a beta-version of the checklist by potential users with subsequent revision based on the findings of the test (Winters *et al.*, 2009). This can be achieved by conducting the tests using real-life scenarios in the clinical units where the checklist will be used or in a simulated setting. During this step, some types of checklists, especially those for performance evaluation or screening, should also undergo psychometric analyses and validation. According to findings from a review by Burian *et al.* (2018), this important step was either not performed or was not reported by a significant proportion of publications that described the process of development of various medical checklists.

2.10.2 Validation of screening checklists

The process of validating a screening checklist is usually accomplished during the pilot-testing phase of its development. The validation often involves the comparison of the diagnostic accuracy of the checklist with that of a well-established gold

standard for detecting the disease, risk factor or condition in question. This step provides evidence of the ability of the checklist to detect the disease in a population of screened individuals. It represents a form of criterion-related validity, specifically, concurrent validity (Bolarinwa, 2015); and is measured in terms of the sensitivity and specificity of the screening checklist.

Sensitivity is the proportion of individuals that are truly positive within the group which a screening test classifies as positive; while specificity is the proportion that are truly negative among those classified as negative by the screening test (Camp, 2006). In other words, sensitivity is a measure of the ability of a screening test to correctly identify individuals with the disease or risk factor; and specificity measures the ability of a test to correctly identify those who do not have the disease or risk factor (Trevethan, 2017). A number of studies on validation of screening checklists for different diseases or conditions have reported the sensitivity and specificity of such checklists. Examples include: the Modified Checklist for Autism in Toddlers (MCHAT) (Coelho-Medeiros *et al.*, 2019; Sangare *et al.*, 2019), the Hypomania Checklist-32 (HCL-32) (Meyer, Castelao, Gholamrezaee, Angst, and Preisig, 2017; Kim, Lee, Kim, and Kim, 2018), the Intensive Care Delirium Screening Checklist (ICDSC) (George *et al.*, 2011), and the Basic Foot Screening Checklist (Bower and Hobbs, 2009).

Reliability is another aspect of checklist validation that can be assessed during the pilot study. Reliability refers to the ability of a screening checklist to produce consistent results upon repeated testing of the same individual (DeVon *et al.*, 2007; Kimberlin and Winterstein, 2008). The various aspects of the reliability of a checklist include: test-retest reliability, interrater reliability and internal consistency. Test-retest reliability, also known as stability, measures the correlation between the results of the screening checklist when administered on two different occasions. It is relevant for characteristics or attributes that are not expected to change significantly with passage of time (DeVon *et al.*, 2007). Interrater reliability or inter-observer agreement is a measure of the correlation or agreement of results obtained by different raters or observers when using the checklist on the same individual. While the internal consistency of a checklist refers to the extent to which different sets of items within the checklist are measuring the same concept or construct. The Cronbach alpha

coefficient is the most commonly reported measure of internal consistency (Kimberlin and Winterstein, 2008). Table 2.3. contains a description of the development and validation of some checklists that have been used in screening for various childhood diseases other than eye diseases.

2.10.3 Feasibility of screening checklists

Feasibility generally refers to the degree to which an objective or a goal can be achieved or a program put into practice. In public health research, feasibility studies are usually conducted to determine the prospects of implementing an intervention or project. According to Bowen *et al.* (2009) the concept of feasibility in health research encompasses several components including: acceptability, demand, implementation, practicality and adaptation. Therefore, the essence of assessing the feasibility of a screening tool should include an evaluation of its acceptability and ease of use in order to envisage its uptake in real-life situations. Such assessment may be performed along with the pilot study conducted for validation of the screening checklist.

While there is a dearth of literature on the feasibility of available vision screening checklists, a good number of reports have been published with respect to the different components of the feasibility of screening checklists for other diseases. For example, Ewers *et al.* (2020) studied the feasibility of the Intensive Care Delirium Screening Checklist (ICDSC) by exploring Intensive Care Unit staff perceptions of the usability of the checklist. In addition, Keetarut *et al.* (2017) conducted a feasibility study on patients with inflammatory bowel disease to determine the ease of use and acceptability of the patient-administered malnutrition universal screening tool (MUST).

Table 2.3. Description of some screening checklists that have been developed and validated for other childhood diseases

S/N	Name of checklist	Disease/ condition screened for	Number of sections/ domains	Number of items	Scoring system	Interpretation of score	Development (Item selection)	Reference standard(s) used for Validation	Psychometric properties reported
1	Baby Paediatric Symptom Checklist (Sheldrick *et al.*, 2013)	Social/emotional problems	3	12	Yes	Described	Literature review, Expert Opinion, Factor analysis	Ages & Stages Questionnaire: Social/Emotional (ASQ:SE)	ICC >0.70; Cronbach α = 0.70; r = 0.51 (p <0.01)
2	Preschool Paediatric Symptom Checklist (Sheldrick *et al.*, 2012)	Social/emotional problems	4	18	Yes	Described	Literature review, Expert Opinion, Factor analysis	Child Behavior Checklist (CBCL)	ICC = 0.75; Cronbach α = 0.88; Sensitivity = 0.88; Specificity = 0.89
3	Modified Checklist for Autism in Toddlers (M-CHAT) (Robins, Fein, Barton, and Green, 2001)	Autism spectrum disorders (ASD)	4	23	Yes	Described	Literature review, Authors' clinical experience, Discriminant function analysis	Complete developmental evaluation	Cronbach α = 0.85; Sensitivity = 0.87; Specificity = 0.99
4	Quantitative-Checklist for Autism in Toddlers (Q-CHAT) (Allison *et al.*, 2008)	Autism spectrum conditions (ASC)	1	25	Yes	Described	Literature review, revision of a previous checklist	Clinical diagnosis of ASC	ICC = 0.82;

5	Simple behavioral–developmental checklist (Eom, Dezort, Fisher, Zelko, and Berg, 2015)	Developmental delay and behavioral disorders in Epilepsy	1	7	Yes	Described	Derived from unstandardized parent questionnaire, Expert opinion, Item response rate and sensitivity analysis	Ages & Stages Questionnaires, Third Edition (ASQ-3)	Sensitivity = 0.83; Specificity = 0.88
6	Child Evaluation Checklist (CHECK) (Rosenblum, Zandani, Deutsch-Castel, and Meyer, 2019)	Neurodevelopmental disorders	2	40	Yes	Described	Literature review, review of previous screening questionnaires, Interviews with parents of patients	Behavior Rating Inventory of Executive Function-Preschool Version (BRIEF-P)	Cronbach α = 0.90 to 0.92; $r = -0.23$ to -0.62 ($p < .001$)
7	Developmental Behaviour Checklist-Early Screen (DBC-ES) (Gray, Tonge, Sweeney, and Einfeld, 2008)	Autism among children with developmental delay	1	17	Yes	Described	Selection of items from the Developmental Behaviour Checklist (Primary carer version, DBC-P) using Confirmatory factor analysis	Clinical evaluation for Autism	ICC = 0.772; Cronbach α = 0.87; Sensitivity = 0.83; Specificity = 0.48
8	Checklist for Early Signs of	Autism spectrum disorders (ASD)	1	25	Yes	Described	Literature review, review	Developmental assessment for	Sensitivity = 0.80; Specificity = 0.94

	Developmental Disorders (CESDD) (Dereu *et al*., 2010)						of previous checklists, Authors' experience, Stakeholders' opinion	ASD	
9	The Preschool Feelings Checklist (PFC) (Luby, Heffelfinger, Koenig-McNaught, Brown, and Spitznagel, 2004)	Depression in young children	1	20	Yes	Described	Details not reported	Diagnostic Interview Schedule for Children Version modified for young children and the Child Behavior Checklist (CBCL)	Cronbach α = 0.76; Sensitivity = 0.92; Specificity = 0.84
10	Checklist of the Movement Assessment Battery for Children (M-ABC) (Schoemaker, Smits-Engelsman, and Jongmans, 2003)	Developmental co-ordination disorder	4	48	Yes	Described	Details not available	Movement Assessment Battery for Children Test (M-ABC) test	Cronbach α = 0.96; Sensitivity = 0.79; Specificity = 0.65

2.11 CONCEPTUAL FRAMEWORK FOR THE STUDY

Bronsard *et al.* (2008) in their study on the reasons for delayed presentation among children with cataract observed that the factors which explain the delay involve "complex interactions of sociocultural barriers at the family and community level as well as socio-organizational barriers within the health care system". The proposed conceptual framework (Figure 2.1) for this study is derived from their report.

The major focus of this study is the early detection of blinding eye diseases in children by developing a simple tool that primary health workers can use to screen infants. In developed countries, screening plays a very important role in the early detection of childhood eye diseases. However, in developing countries, where there are no routine screening programmes, delayed detection and late presentation of children with eye diseases for treatment is a common occurrence.

In addition to lack of screening programmes, there are other health system factors that are considered important in the context of delayed detection and late presentation of children with eye disease. These include lack of equipment as well as poor knowledge and skills among health workers which lead to incorrect diagnosis, wrong advice to parents, and inappropriate or delayed referrals. Family and community factors such as awareness, attitude, beliefs and care-seeking behaviour also interact with these health system factors to influence the detection and presentation of children with eye diseases.

The poor outcome of the treatment received following late presentation for care also has the potential to have a negative impact on the beliefs and attitudes of members of the community thereby increasing the likelihood of late presentation of other children. On the other hand, the establishment of routine screening programmes with resultant early detection, presentation and good treatment outcome can generate increased awareness and positive attitudes towards childhood eye diseases within the community. In addition, the screening activities by health workers would be expected to lead to an improvement in their knowledge and skills which would also result in positive feedback towards the awareness and attitudes at the family and community levels. Overall, developing a simple screening tool for use by primary health care

workers for the detection eye diseases in children may have significant implications for the reduction of avoidable childhood blindness.

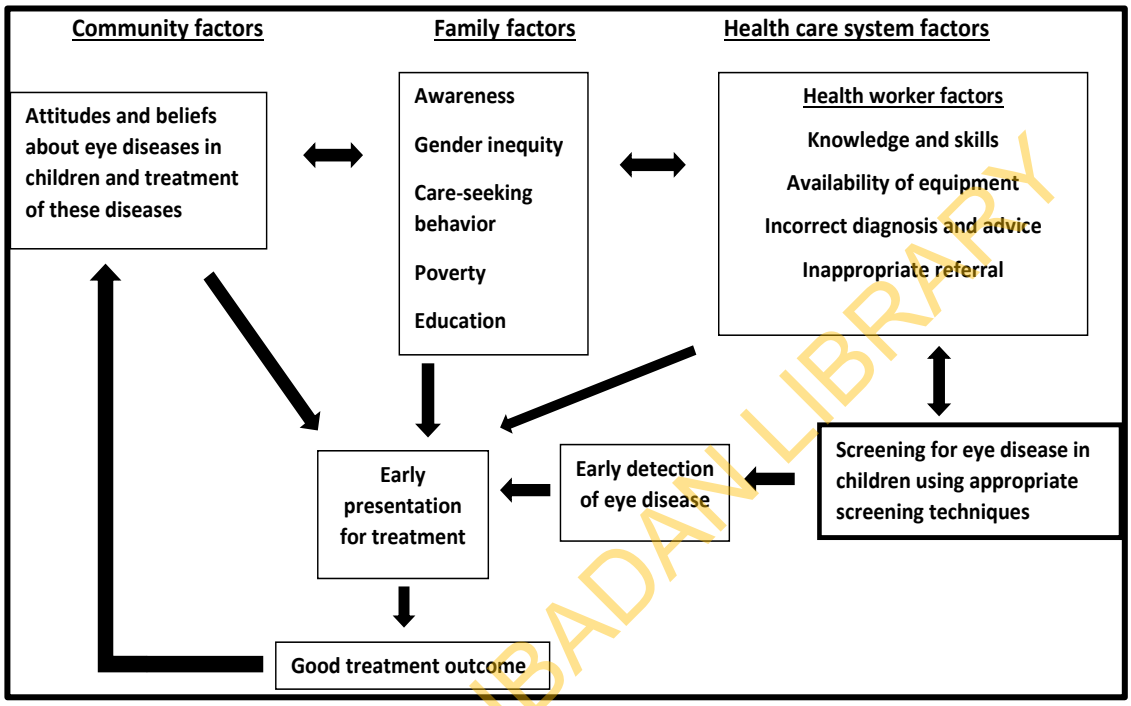

Figure 2.1. A conceptual framework showing the benefit of screening in early detection of eye diseases

CHAPTER THREE

METHODS

3.1 Study setting

This study was conducted in Oyo State which is located in the South-West region of Nigeria. Oyo State is divided administratively into 33 Local Government Areas (LGAs) and had a projected population of 7,840,864 people in 2016 (National Bureau of Statistics, 2017).

Specifically, the study was carried out in Ibadan, the capital city of Oyo State. Ibadan metropolitan area consists of 11 LGAs, five of which are urban and six are semi-urban. The urban LGAs are Ibadan North, Ibadan Northeast, Ibadan Northwest, Ibadan Southeast, and Ibadan Southwest LGAs. While the semi-urban ones are Akinyele, Egbeda, Ido, Lagelu, Ona Ara, and Oluyole LGAs. Ibadan Metropolis had a projected population of 3,596,500 people in 2016 according to the National census figures, with Ibadan Northeast and Ibadan North LGAs being the most populous (City Population, 2020).

Orthodox health services in Oyo State are predominantly provided by the three tiers of government (Federal, State and Local) as well as private health facilities. There are four teaching hospitals, 43 secondary health facilities including 28 state general hospitals and one children's hospital. In addition, there are 11 comprehensive health centres and 558 primary health care centres in Oyo State (Oyo state government, 2020). There are also several mission hospitals and numerous private hospitals, clinics and maternity homes.

Most hospitals are located in urban centres. The University College Hospital (UCH) located in Ibadan, is the largest of the hospitals, and is a referral centre for the other facilities. It is a training centre for specialists in several medical specialties in Internal Medicine, Surgery, Paediatrics, and Ophthalmology. The Paediatric ophthalmology unit of the Ophthalmology Department has been designated a Child Eye Health Tertiary Facility (CEHTF) by the World Health Organisation. The State hospital, located at Ring road, Ibadan has an eye clinic which is manned by a Consultant Ophthalmologist and operates as a secondary eye care centre. In addition, the Eleta Eye institute which is owned by the Catholic Archdiocese of Ibadan is a secondary eye care centre in Ibadan.

The study was conducted in selected public immunisation clinics in four of the urban local government areas, namely Ibadan Northeast, Ibadan North, Ibadan Southeast, and Ibadan Southwest LGAs. These LGAs were selected because of their size as well as their proximity to the tertiary health centre (UCH) which would enable easy access for children who were identified to have eye diseases and were referred for specialist care.

Only public facilities were selected for this study because their immunisation services are largely free making them relatively more accessible to the general population when compared to private facilities. Apart from administration of vaccines, other activities that take place at these immunisation clinics include health promotion talks and growth monitoring of infants and young children.

3.2 Study design

A cross-sectional study design conducted in three phases was used. The first phase involved the development and validation of the screening tool; the second phase entailed a diagnostic accuracy study in which the screening tool was compared to a gold standard; while the third phase was a survey to assess the perceptions of immunisation clinic staff on the use of the checklist based on their experience of using it during the second phase.

3.2.1 Phase 1: Development and validation of the screening tool

In developing the checklist, a series of steps were followed, as described below. These steps are based on a harmonisation of three different sets of steps described by previous authors for the development of medical checklists (Winters *et al.*, 2009; Schmutz *et al.*, 2014; Burian *et al.*, 2018). The reason for the harmonisation was that those descriptions were not specifically for developing screening checklists but were either for developing checklists for assessing clinical performance of trainees (Schmutz *et al.*, 2014) or general medical checklists such as those designed for improving patient safety and reducing medical errors (Winters *et al.*, 2009; Burian *et al.*, 2018). Furthermore, previous descriptions of the development of screening checklists were not comprehensive and did not include all the necessary steps for the development of medical checklists. Accordingly, the steps described below are comparable to the steps described by Odole *et al.* (2013) for the process of development of health outcome measuring instruments. The main difference is based on the fact that the process they described was specifically for developing an instrument for the assessment of a therapeutic intervention, while the focus of the present study is the development of a screening tool for blinding eye disease.

The steps followed were:

1. Justification for the development of the screening tool.

   The first step in the development of a screening tool is to justify the need for a new instrument or tool. It is certainly unnecessary to develop a new instrument if one already exists that can serve the same specific purpose as the proposed instrument.

   Currently, the recommended screening program for the early diagnosis of eye disease at birth and during infancy involves the Bruckner test (Red reflex test) which requires the use of an ophthalmoscope.

   In resource-limited settings, such as Nigeria, ophthalmoscopes are not available at the primary health care level where screening should be conducted. And even if ophthalmoscopes are provided, maintaining them in good working condition is likely to be a challenge. Therefore, in order to establish screening programs for eye diseases in infancy, a screening tool that does not require the use of an ophthalmoscope is highly desirable.

2. Defining the purpose and the conceptual basis of the screening tool

   The screening tool is to serve as a checklist which primary health care workers especially immunisation clinic staff can use to detect the presence of eye disease in children. The purpose of the checklist is to function as a simple and handy guide for primary health care workers who may not have received any specific training in primary eye care.

   The conceptual basis of the tool is that early detection of eye disease in children is necessary for early presentation and treatment which is required for optimal visual outcome and prevention of amblyopia following intervention. Such early detection is hampered by lack of screening programs as well as lack of equipment (ophthalmoscopes) at the primary health care centres.

3. Devising the items on the screening tool

   The items were devised in three steps:

   a. Literature review to identify the clinical features of infantile eye diseases which health workers who are not ophthalmic personnel should be able to detect without the use of an ophthalmoscope. The eye diseases which the literature review focussed on were congenital cataract, congenital glaucoma, corneal opacity, strabismus, congenital ptosis, and retinoblastoma. These are the common causes of eye disease in infancy and childhood that require early detection to prevent blindness or death (in the case of retinoblastoma).

   b. Expert opinion: Items were also included based on the clinical experience of experts (general ophthalmologists) who are familiar with the clinical features of these diseases in Nigerian children. A total of 10 general ophthalmologists were selected from across the country, each of them having at least 10 years post-qualification experience. The first draft was sent to them individually by email. Their input was solicited and feedback received via the same mode of communication. In addition, during face-to-face meetings, the opinion of seasoned experts on the process of development of health measuring instruments was sought with regards to the appropriateness of the items.

   c. Stakeholder input: Meetings were organised with immunisation staff to explain the purpose and conceptual basis of the screening tool to them. They were requested to make suggestions for the modification of the

items identified in first two steps above, with a view to making the items meaningful and relevant to them. Three meetings were held in different primary health care centres in Ibadan North Local Government Area.

4. Content validation

To ascertain content validity, the list of items identified was reviewed by a panel of paediatric ophthalmologists, different from the initial group of general ophthalmologists. A total of five paediatric ophthalmologists were selected from across the country with a minimum of 2 years' experience in the practice of paediatric ophthalmology and strabismus. Detailed explanation on the purpose and conceptual basis of the screening tool was provided to them and they were asked to assess the content coverage and relevance of the items. They were asked to rate the relevance of each item using a 5 point scale as follows (Streiner and Norman, 1989):

5. Essential: Item is essential and must be included in the screening tool
4. Important: Item is important and should be included in the screening tool
3. Acceptable: Item is acceptable and may be included in the screening tool
2. Marginally relevant: Item is only marginally relevant and does not need to be included in the screening tool.
1. Not relevant: Item is irrelevant and should not be included in the screening tool

The expert panel were also asked to indicate items that had not been included which they thought were essential or important in screening for eye diseases among infants by immunisation clinic staff.

Based on the feedback from the panel of experts, a consensus was arrived at and those items deemed to be irrelevant were deleted from the list while items recommended for inclusion were added to the list. The consensus meeting was held via a telephone conference call with the panel of experts.

5. Items selection

Following content validation, a draft of the screening checklist was pretested among 30 infants by immunisation staff at the Sango Primary health care

centre of Ibadan North local government Area. These 30 infants were not involved in the second phase of the study.

The aim of the pre-test was to identify and rephrase or remove ambiguous and incomprehensible items as well as double-barrelled items (items asking more than one question). Such items were identified by debriefing the health workers after the pre-test and reviewing the responses to all items on the checklist. Subsequently, only items that were unambiguous, comprehensible and single-barrelled were selected and included in the checklist.

3.2.2 Phase 2: Diagnostic accuracy testing of the screening tool (validation)

This phase of the study involved comparison of the newly developed screening tool with the gold standard for detection of eye diseases in infants, in this case eye examination by an ophthalmologist.

3.2.2.1 Study population

The participants for the diagnostic accuracy study were children aged 12 months and below who presented to the selected clinics for immunisation during the period of the study.

Inclusion criteria

1. Children aged 0-12 months who were brought for immunisation in selected immunisation clinics during the study period.
2. Willingness of mother / caregiver to participate in the study.

Exclusion criteria

1. Children who were ill and were unable to receive immunisation or undergo ocular examination, for example, children who had fever, vomiting and diarrhoea or other early childhood illnesses.

3.2.2.2 Sample size determination

In determining the minimum number of infants that were to be screened for validation of the screening tool, the sample size was calculated using the formula below (Buderer, 1996):

Minimum sample size (n) based on expected sensitivity = $\frac{Z_{\alpha}^2 \times S_N (1-S_N)}{D^2 \times P}$

OR

Minimum sample size (n) based on expected specificity = $\frac{Z_{\alpha}^2 \times S_P (1-S_P)}{D^2 \times (1-P)}$

Where:

S_N = expected sensitivity. This was set at 82.5% for this study, based on a previous study that reported a sensitivity of 82.5% for the red reflex test (Bruckner test) (Saiju *et al.*, 2012).

S_P = expected specificity. This was set at 98.7% for this study, based on a previous study that reported a specificity of 98.7% for the red reflex test (Bruckner test) (Saiju *et al.*, 2012).

Z_{α} = standard normal deviate corresponding to 95% confidence interval = 1.96

D = absolute precision desired for sensitivity or specificity, 10% for this study

P = prevalence of condition/disease being screened for. A prevalence of 5.7% for eye diseases in early childhood was used as a proxy for this study (Cumberland, Pathai, Rahi, and Millennium Cohort Study Child Health, 2010). Although, the study was carried out in the United Kingdom, the prevalence was used to calculate the sample size for this study because there were no similar studies on the prevalence of eye diseases infants and young children in Africa or other developing countries, as far as the author searched.

This gave a minimum of 983 infants to be screened in order to achieve a precision of 10% for 82.5% sensitivity and a minimum of 6 infants to achieve a precision of 10% for 98.7% specificity.

The calculated sample size for sensitivity was much larger than for specificity. Therefore, a minimum sample of 983 infants was required for screening using the tool.

However, to account for the possibility that some of the recruited infants may not complete all the 3 stages of the study, a non-completion rate of 20% was estimated; and the sample size was adjusted using the following formula:

$$\text{Target sample size} = \frac{\text{Minimum sample size}}{100\% - \text{Non-completion rate}} = \frac{983}{0.8} = 1229 \text{ infants}$$

The number of infants screened in each of the 4 LGAs was determined using the proportional allocation procedure based upon the average number of children immunised in each of the clinics annually as obtained from their records at the Local government headquarters.

3.2.2.3 Sampling strategy

The selection of immunisation clinics in each of the local government areas was based on the records of the monthly average of the number of infants who receive immunisation in the clinics. The top 2 clinics in each LGA with the highest monthly average were selected. This was to ensure that a larger number of children would be screened within a short time. Thus, a total of 8 immunisation clinics were involved in the study. All eligible immunisation clinic staff in each selected immunisation clinic were recruited into the study.

All consecutive eligible children presenting for immunisation in each of the eight selected immunisation clinics were recruited and screened by the immunisation staff until the number of infants apportioned to be screened in each clinic was achieved. In addition, participating immunisation staff in each clinic were allocated an equal proportion of infants to screen based on the number of staff and the number of infants apportioned to the clinic. The immunisation clinics that were selected in each LGA as well as the number of infants allocated to each LGA are shown in Table 3.1.

Table 3.1 Selected immunisation clinics and allocated number of infants per local government area

Local government area (LGA)	Selected immunisation clinics	Number of infants (n) [LGA level]	Number of infants (n) [Clinic level]
Ibadan North	Agbowo PHC*	340	177
	Idi Ogungun PHC		163
Ibadan Northeast	Iwo road PHC	310	190
	Oke Adu PHC		120
Ibadan Southwest	Awodife PHC	298	141
	Foko PHC		157
Ibadan Southeast	Agbongbon PHC	281	159
	Oranyan PHC		122
Total		1229	1229

*PHC – Primary healthcare centre

3.2.2.4 Pre- study activities

1. Ethical approval was sought and obtained from the University of Ibadan/University College Hospital Ethical Review Board.
2. Approval was sought and obtained from the Oyo State Ministry of Health and the consent of the Director of Primary health care was sought.
3. The Medical officer for health as well as the Primary Health care coordinator in all the selected local governments were informed and their cooperation sought.
4. Advocacy meetings were held with the Officers in charge of each of the selected immunisation clinics to inform them about the project and to seek their approval and cooperation.

5. During the pre-study visits to the immunisation clinics, meetings were held with the immunisation clinic staff to train them on the use of the screening tool and to recruit them into the study. Specifically, they were given copies of the checklist and were taught on how to administer it and record their findings. They were also educated on the scoring system and its interpretation.
6. Training of research assistants on administration of questionnaire.

3.2.2.5 Study team

1. Ophthalmologist (PhD student)
2. 3 research assistants

3.2.2.6 Study materials

1. Data collection instruments
    a. Infant medical history questionnaire (Appendix A)
    b. Immunisation staff questionnaire (Appendix B)
    c. Screening checklist (screening tool developed in Phase 1 of the study) (Appendix C)
    d. Eye examination proforma (Appendix D)
2. Pen torches
3. Direct Ophthalmoscope
4. Binocular indirect ophthalmoscope
5. Dilating eye drops (Tropicamide 1% and Phenylephrine 5% eye drops)

3.2.2.7 Data collection procedure

The data for this Phase of the study was collected in three stages as follows:

1. Firstly, the demographic information and clinical history such as antenatal, birth, neonatal, past medical and developmental history of participating infants were collected using a structured questionnaire (Appendix A). This was translated to Yoruba by a linguist for easy communication with the mothers/ caregivers who did not understand English. The Yoruba version was back translated into English by another linguist to check for consistency of translations. The questionnaire was administered by trained research assistants

to each child's mother/caregiver while waiting for immunisation. In addition, a self-administered structured questionnaire (Appendix B) was used to obtain the demographic and other individual characteristics of the immunisation staff.

2. Secondly, immunisation staff administered the screening tool (Appendix C) on each infant during vaccination in order to detect the presence of eye disease. The result of the screening was recorded on the screening tool sheet. The staff were instructed to use a light source, specifically, a pen torch light while examining the infants. Picture cards containing images of the eye diseases being screened for were provided to assist the staff in the administration of the tool.

   The immunisation staff were blinded to the information that was collected by the research assistants using the questionnaire. They were also blinded to the subsequent examination findings by the ophthalmologist.

   Every tenth baby screened by an immunisation clinic staff, was also screened by another randomly selected immunisation staff in the clinic during the same immunisation visit (Figure 3.1). This was to test the inter-observer variation of the screening tool. The second immunisation staff was blinded to the result of the screening by the first immunisation staff.
3. Finally, each infant was examined by an ophthalmologist for the presence of eye disease. The ophthalmologist was blinded to the result of the preceding screening by the immunisation staff. The findings of the examination by the ophthalmologist were recorded in a proforma (Appendix D).

Each infant was assigned a unique serial number that was recorded on each of the 3 data collection instruments for each child, namely, the questionnaires, screening tool sheets and proforma. Similarly, each immunisation staff was assigned a unique identification number that was recorded on their questionnaires and the screening tool sheets that they administered on the infants.

3.2.2.8 Examination procedure

The procedure for examination of the infants by the ophthalmologist was as follows:

- Assessment of visual acuity using Fix and Follow method
- Examination of ocular adnexae (facial symmetry, eye lids and eye lashes) using a pen torch

- Examination of anterior segment (conjunctiva, cornea, iris, lens) of the eye using a pen torch
- Red reflex test and dilated fundus examination using an indirect ophthalmoscope. Dilation of the pupils was achieved with the instillation of Tropicamide and Phenylephrine eye drops into both eyes.

Children who were found to have eye disease during examination by the ophthalmologist were referred to the Paediatric ophthalmology unit of UCH Ibadan using a referral form (Appendix E).

3.2.2.9 Study flow chart for infants

The sequence of movement of the infants through the study is presented in Figure 3.1.

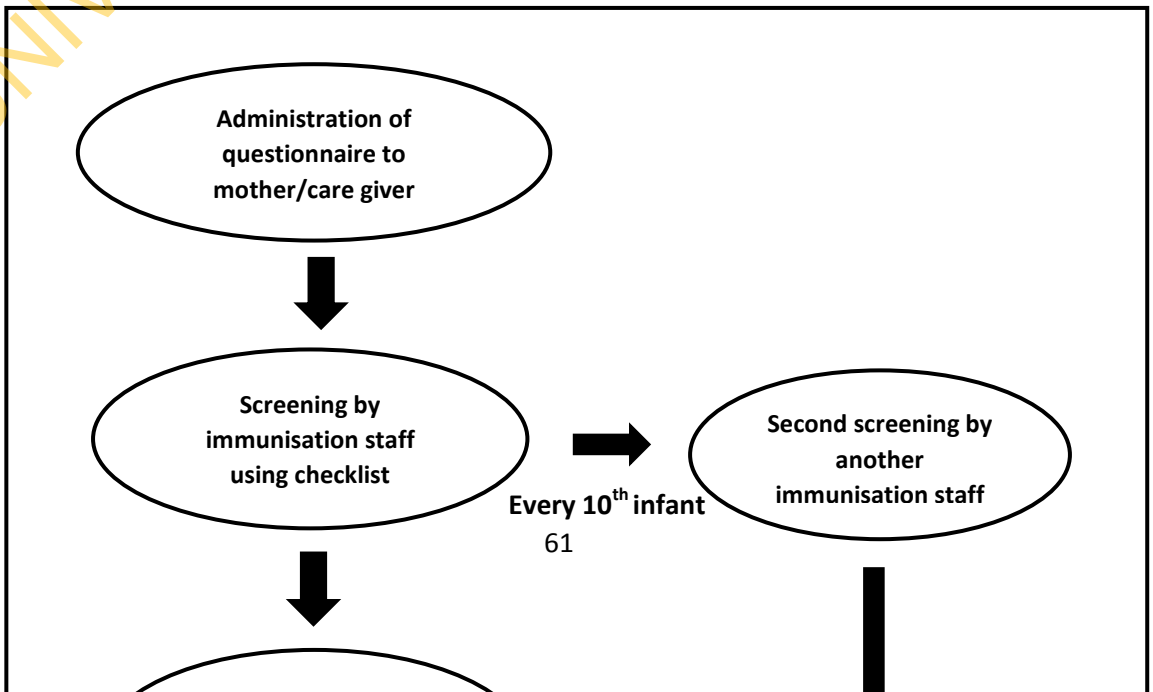

Figure 3.1. Study flow chart for infants

3.2.2.10 Case definitions

The study's operational definitions for the common eye diseases that occur and can be detected during eye examination of infants are as follows:

1. Cataract – opacity of the crystalline lens of the eye
2. Congenital glaucoma – enlarged eye ball with corneal haziness and photophobia with or without optic disc pallor and cupping
3. Corneal opacity - clouding or opacification of the cornea that obscures the view of the anterior chamber and iris/pupil
4. Ptosis – downward drooping of the upper eye lid

5. Nasolacrimal duct obstruction – persistent tearing or mucoid discharge from one or both eyes starting about 4-6 weeks after birth without associated redness, corneal opacity or photophobia
6. Conjunctivitis – redness of the eyes with associated watering and discharge in the presence of a clear cornea
7. Strabismus – obvious misalignment of the eyes
8. Optic atrophy – pallor of the optic disc (optic nerve head) without cupping
9. Cerebral visual impairment – visual impairment associated with a history suggestive of perinatal brain injury from hypoxia or infection, in the absence of any ocular pathology
10. Delayed visual maturation – poor fixation and following of visual targets in the absence of any ocular pathology or history suggestive of perinatal brain injury

3.2.3 Phase 3: Survey of immunisation clinic staff perception on feasibility of the checklist

After the completion of the second phase of the study in each immunisation clinic, a survey was conducted among the staff who participated in the screening of infants using the checklist. The aim of the survey was to evaluate their perceptions on the feasibility of using the checklist based on their experience of using it during the study.

3.2.3.1 Study population

The participants for phase 3 were members of staff who administer vaccines to infants at the immunisation clinics in the 4 local government areas (LGAs) selected for the study.

Inclusion criteria

1. Clinic staff directly involved with the administration of vaccines to infants at the immunisation clinics, especially nurses, community health extension workers and community health officers.
2. Willingness to participate in the study

Exclusion criteria

1. Staff who were on leave during the period of the study

3.2.3.2 Sample size

The total population of eligible immunisation clinic staff in the selected immunisation clinics were recruited and trained on the use of the screening checklist during the pre-study visits. All those who participated in the use of the checklist in phase 2 were also invited to participate in phase 3 of the study.

3.2.3.3 Study instrument and data collection.

Data was collected with the use of a questionnaire (Appendix F). This was a self-administered structured questionnaire that was used to obtain information about the perceptions of the immunisation staff regarding the ease of use as well as the usefulness of the checklist.

3.3 Data management and analysis

All completed questionnaires, screening tool sheets and proformas were collected and safely kept in a confidential place under lock and key. They were reviewed daily and checked for errors and any implausible entries were removed. Data collected was entered into a spread sheet and analysed using IBM SPSS software version 22. Quantitative variables were summarised using means and standard deviations and categorical variables were summarised using frequencies and proportions.

The characteristics of immunisation staff who participated in Phase 2 of the study were compared with the characteristics of staff who were recruited but did not participate in the study, in order to detect any bias in participation of the staff. Quantitative variables were compare using T-test, while categorical variables were compared using Chi square test. The Fisher's exact test was used when the expected values in any of the cells of a contingency table was less than 5.

Statistical validation of the screening tool was performed by determining its sensitivity, specificity, positive and negative predictive values as well as positive and negative likelihood ratios. These values were calculated with the use of contingency

(2x2) tables in which the outcome the screening was cross-tabulated with the outcome of the red reflex test or the ophthalmologist's examination (see Table 3.2).

Internal consistency reliability of the tool was tested using Cronbach's alpha, while test-retest reliability was assessed using intra-class correlation coefficient (ICC). Spearman correlation test was used to compare the scores of the 1st and 2nd screenings among the infants who were screened by a second immunisation staff. Also, the level of inter-observer agreement between clinic staff beyond the agreement due to chance was evaluated using Kappa statistic. The level of significance for all tests was set at α=0.05

Table 3.2 Example of contingency table for calculating sensitivity, specificity, predictive values and likelihood ratios

		Gold standard		
		YES	NO	TOTAL
Screening test	YES	a	b	a+b
	NO	c	d	c+d
	TOTAL	a+c	b+d	a+b+c+d

Where:

a= number of **diseased** individuals who test **positive** with screening test (**true positives**)

b= number of **disease-free** individuals who test **positive** with screening test (**false positives)**

c= number of **diseased** individuals who test **negative** with screening test (**false negatives**)

d= number of **disease-free** individuals who test **negative** with screening test (**true negatives**)

The formulae for calculating the various values are as follows:

Sensitivity = $a \div (a + c)$

Specificity = $d \div (b + d)$

Positive predictive value = $a \div (a + b)$

Negative predictive value = $d \div (c + d)$

Positive likelihood ratio = $(a \div (a + c)) \div (b \div (b + d))$

Negative likelihood ratio = $(c \div (a + c)) \div (d \div (b + d))$

3.4 Ethical considerations

Ethical approval was sought and obtained from the University of Ibadan/University College Hospital Ethical Review Board (Appendix G) and the study adhered to the tenets of the Helsinki Declaration.

- *Confidentiality*: The information collected from the participants was kept confidential and completed questionnaires and proformas were stored in a locked file cabinet. Collected information was entered and stored in password protected computer. Only the principal investigator, study team members and supervisors had access to the computer and the file cabinet. Individuals who were not involved in the study were not given access to any part of the data.
- *Beneficence to participants*: The immunisation staff received training that enhanced their capacity to detect eye diseases in infants. The infants underwent detailed ophthalmic examination. Infants with minor eye problems

were treated as necessary while those requiring specialist attention were referred to the Paediatric ophthalmology clinic, UCH, Ibadan.

- *Non-Maleficence to Participants*: The study procedure of asking questions from mothers (caregivers) and examining the infants did not cause any harm or injury to them.
- *Voluntariness*: Participation in the study was entirely voluntary. Written informed consent (Appendix H) was obtained from all participants (immunisation staff and mothers/ caregivers of infants) before recruitment into the study. Also, the participants were made to understand that they were free to withdraw from the study at any point in time without losing any benefits of being part of the study.

CHAPTER FOUR

RESULTS

The study was conducted in three phases. The first phase was the development and validation of the screening checklist, the second phase was the diagnostic accuracy study, while the third phase was a survey to assess the perceptions of immunisation clinic staff on the use of the checklist based on their experience of using it during the second phase. The results of the first phase are presented first, followed by the results of the second and third phases of the study.

4.1 Phase 1: Checklist Development and Validation

4.1.1 Initial drafts of screening checklist

Based on a review of relevant literature, an initial draft version of the screening checklist containing 8 items was developed (Figure 4.1). This first draft was sent individually to ten experienced general ophthalmologists, who had been practicing ophthalmology for at least 10 years, for their expert opinion. Based on their input, ten new items were included in the checklist, one of the items in the initial draft was modified while the other 7 items were retained. Thus, the second draft of the checklist contained 18 items (Figure 4.2).

4.1.2 Stakeholder input

Subsequently, meetings were held with immunisation clinic staff in three different Primary Health Care centres in Ibadan North Local Government Area of Oyo State to show them the second draft of the checklist and to obtain their input. During these meetings the health workers were educated on the purpose and conceptual basis of the screening checklist as well as the need for screening for eye disease among infants and young children. Some of the health workers expressed concern about the likelihood that the use of the checklist would be an addition to their workload in view of short-staffing at the health centres. They, therefore, strongly recommended that the checklist be as brief and simple as possible. Their recommendation was well considered in further development of the checklist.

INITIAL DRAFT OF SCREENING CHECKLIST

Section A: Ask the mother / caregiver the following questions

1. Do you think there is any problem with your child's vision/ eyes? Yes = 2; No = 0
2. Does your child look at peoples' faces directly? Yes = 0; No = 2

Section B: Look at the child's eyes

3. Does the child fixate on your face continuously as you move your head from side to side? Yes = 0; No = 2
4. Is there a white spot in the black portion of the eye? Yes = 4; No = 0
5. Does one eye look bigger or smaller than the other eye? Yes = 4; No = 0
6. Are both eyes looking towards the same direction? Yes = 0; No = 4
7. Are the eyes persistently shaking or unsteady? Yes = 4; No = 0
8. Is there any other abnormality apart from those stated above? Yes = 4; No = 0

Scoring

Add the scores for all the 8 items

Total Score = ...

Decision making

For a child with a score of 0, the eyes are likely to be normal. Reassure mother but repeat screening once again within 3 months, preferably at the next immunisation visit.

For a child with a score of 2, there is a need to repeat the screening within 4 weeks.

For a child with a total score of 4 and above, please refer to an ophthalmologist immediately.

Figure 4.1. First draft of screening checklist for eye diseases among infants

SECOND DRAFT OF SCREENING CHECKLIST – Modified after input from general ophthalmologists

Section A: Ask the mother / caregiver the following questions

1. Do you think there is any problem with your child's vision/ eyes?	Yes = 2;	No = 0
2. Does your child look at peoples' faces directly?	Yes = 0;	No = 2
3. Do you notice if the eye(s) of your child shines like that of a cat in the dark/ at night?	Yes = 0;	No = 4
4. Do you notice if the eye(s) of the child is always bringing out tears?	Yes = 0;	No = 4
5. Does the child always try to avoid looking at bright light?	Yes = 0;	No = 4
6. Does your child bump into objects when crawling/walking/running?	Yes = 0;	No = 4
7. Is there anybody with eye problem in the family?	Yes = 0;	No = 2
8. Is there anybody who does not see well in the family?	Yes = 0;	No = 2
9. Is there persistent redness of the eyes (more than 2 weeks duration)?	Yes = 0;	No = 4

Section B: Look at the child's eyes

10. Is the child able to follow a light shone unto his/her face?	Yes = 0;	No = 2
11. Does the child look steadily on your face continuously as you move your head from side to side?	Yes = 0;	No = 2
12. Is the child reaching out for objects?	Yes = 0;	No = 2
13. Is there any limitation of opening or closing the eyelids?	Yes = 0;	No = 4
14. Is there a white spot in the black portion of the eye?	Yes = 4;	No = 0
15. Does one eye look bigger or smaller than the other eye?	Yes = 4;	No = 0
16. Are both eyes looking towards the same direction?	Yes = 0;	No = 4
17. Are the eyes persistently shaking or unsteady?	Yes = 4;	No = 0
18. Is there any other abnormality apart from those stated above e.g. Redness, Discharge, Tearing e.t.c?	Yes = 4;	No = 0

Scoring

Add the scores for all the 18 items

Total Score = ...

Decision making

For a child with a score of 0, the eyes are likely to be normal. Reassure mother but repeat screening once again within 3 months, preferably at the next immunisation visit.

For a child with a score of 2, there is a need to repeat the screening within 4 weeks.

For a child with a total score of 4 and above, please refer to an ophthalmologist immediately.

Figure 4.2. Second draft of screening checklist for eye diseases among infants

4.1.3 Content validation

The expert panel of five paediatric ophthalmologists reviewed the second draft of the checklist to assess content coverage and relevance of the items. Based on their responses using the 5-point scale, each of the items was assigned a relevance value. The relevance value was the sum of the responses of the five experts regarding the relevance of each item. Thus, the 18 items were ranked in decreasing order of relevance (Table 4.1). A meeting was then convened via telephone conference call during which a consensus was reached regarding the items as follows:

a. Items that were removed: 7, 8, 11, 13 and 18.

b. Items that were modified: 2, 4, 6, 9, 10, 12, 15 and 17 (Items 2 and 6 were merged into one item. Items 10 and 12 were also merged).

c. Items that were retained (without modification): 1, 3, 5, 14, and 16.

d. No new items were added.

In addition, the panel deliberated on the nature of the scoring system and the allocation of scores to each of the items. The possible response to each item was either "YES" or "NO" and a score was allocated to each response depending on whether it indicated the presence or absence of eye disease. A score of "0" was assigned when the response was suggestive of normal eyes, that is, the absence of eye disease. While, responses which suggested the presence of eye disease were assigned either a "full score" or "half score". A full score was assigned when the response indicated a feature whose presence, in isolation, is strongly suggestive of eye disease. A half score was assigned when the response indicated a feature that, when present in isolation, is not strongly suggestive of eye disease. This means that the presence of another feature is necessary before a feature assigned half score becomes strongly suggestive of eye disease. Thus, the panel allocated a full score to items 2, 3, 4, 5, 6, 10, 12, 14, 15, 16 & 17 and half score to items 1 & 9. A full score was set at "10", while half score was set at "5".

At the end of the meeting, the third draft of the checklist had 11 items (Figure 4.3).

Table 4.1. Ranking of the 18 items on second draft of checklist based on relevance scores as assigned by expert panel

Item Number	Relevance value	Rank
1	28	1
2	19	15
3	28	2
4	26	5
5	23	11
6	26	6
7	16	17
8	15	18
9	21	14
10	24	9
11	22	13
12	24	10
13	18	16
14	28	3
15	25	7
16	27	4
17	24	8
18	23	12

THIRD DRAFT OF SCREENING CHECKLIST- modified after expert panel meeting

Section A: Ask the mother / caregiver the following questions (Questions for mother)

1. Do you think there is any problem with your child's vision/ eyes?	Yes = 5;	No = 0
2. Ask mother only one option (a, b or c) based on child's age		
a. Less than 6 months:-Does your child look at your face when breastfeeding?	Yes = 0;	No = 10
b. Between 6 and 10 months:- Does your child reach out for objects?	Yes = 0;	No = 10
c. Above 10 months:- Does your child bump into objects when crawling/ walking/running?	Yes = 10;	No = 0
3. Do you notice if the eye(s) of your child shines like that of a cat in the dark/ at night?	Yes = 10;	No = 0
4. Do you notice if the eye(s) of your child is always bringing out tears even when he/she is not crying?	Yes = 10;	No = 0
5. Does your child always try to avoid looking at bright light?	Yes = 10;	No = 0
6. Are your child's eyes always red?	Yes = 5;	No = 0

Section B: Look at the child's eyes and observe the following (To be performed by health worker)

7. Observe only one option (a, b or c) based on child's age		
a. Less than 3 months:- Is the child able to notice a light (blinking or closing the eyes when a light is shone unto his/ her eyes)?	Yes = 0;	No = 10
b. Between 3 and 6 months:- Is the child able to follow a light shone unto his/her face?	Yes = 0;	No = 10
c. Above 6 months:- Is the child able to reach out for objects?	Yes = 0;	No = 10
8. Is there a white spot in the black portion of the eye?	Yes = 10;	No = 0
9. Does one eye look bigger or smaller than the other eye or do both eyes appear bigger than those of children of similar age?	Yes = 10;	No = 0
10. Are both eyes looking towards the same direction?	Yes = 0;	No = 10
11. Are the eyes always (continuously) shaking or unsteady?	Yes = 10;	No = 0

Score

Add the scores for all the 11 items **Total Score** = ...

Interpretation of score

A. If score = 0	The child's eyes are likely to be normal. Reassure mother but a repeat screening at another visit within 3 months is recommended.
B. If score = 5	The child's eyes may be abnormal. Repeat the screening within 4 weeks.
C. If score = 10 or more	The child's eyes are abnormal. Refer the child to an ophthalmologist immediately.

Figure 4.3. Third draft of screening checklist for eye diseases among infants

4.1.4 Results of Pretesting of the third draft of the checklist

None of the items were identified to be ambiguous, incomprehensible or double-barrelled during the pre-test. Therefore, all the 11 items in the third draft were selected for the final version of the checklist without any modifications.

4.1.5 Description of the final version of checklist

The final version of the screening checklist is a 2-part, 11 item checklist (Appendix C). The first part consists of 6 questions which the health worker would enquire of the infant's mother or caregiver; while the second part is made up of 5 questions that would be answered by the health worker after a quick examination of the child's eyes. Each item requires a single response of either "Yes" or "No".

The response to each of the items was allocated a score. The score is to guide decision making by the health worker with regards to the presence of eye disease and the need for prompt referral to an ophthalmologist. The sum of the scores of the responses to all 11 questions is the total score for the child being screened. The minimum total score is 0 while the maximum total score is 100. The total score is classified into 3 categories (A, B or C) and the category determines what action should be taken by the health worker based on the result of the screening. Category A refers to a total score of 0 which indicates that the child's eyes are likely to be normal and the mother should be reassured that referral is not required. Category B refers to a total score of 5 and suggests that screening should be repeated within 4 weeks. While, Category C refers to a total score of 10 and above which points to the presence of eye disease and the need for referral to an ophthalmologist.

4.2 Phase 2: Diagnostic Accuracy Study

4.2.1 Immunisation clinic staff characteristics

A total of 55 immunisation staff were recruited and trained during the pre-study visits. Thirty-eight (69.1%) of them were involved in screening the infants using the checklist. The remaining 17 immunisation staff did not participate in screening because they were either absent or off duty on the days that the study team visited

their centres for screening. The distribution of the staff across the eight primary health centres (PHCs) and the 4 local government areas is shown in Table 4.2.

There were no significant differences between the 38 staff who participated and the 17 who did not participate with respect to their age, number of years since qualification and years of experience in administration of immunisation to infants (Table 4.3). Similarly, there was no statistically significant association between participation in the screening of infants and any of the following variables: gender, local government area/ primary health care centre, previous training in eye care and previous experience with detection of eye problems in infants (Table 4.4). However, a higher proportion (44.8%) of community health extension workers did not participate in the screening compared to 15.4% of the other cadres of immunisation clinic staff - Nurses and community health officers (Odds ratio = 0.22; 95% Confidence Interval = 0.06 – 0.82; p=0.018) [Table 4.4].

Table 4.2. Frequency distribution of the immunisation staff who participated in the screening of infants across the PHCs and the local government areas

Local government area (LGA)	Primary health care centre (PHC)	Number of staff recruited (n)	Number of staff who participated (n)	Percent (%)	
				At PHC level	At LGA level
Ibadan North	Agbowo	7	4	10.5	23.6
	Idi Ogungun	7	5	13.1	
Ibadan Northeast	Iwo road	5	3	7.9	23.8
	Oke Adu	7	6	15.9	
Ibadan Southwest	Awodife	6	6	15.9	26.4
	Foko	7	4	10.5	
Ibadan Southeast	Agbongbon	7	5	13.1	26.2
	Oranyan	9	5	13.1	
Total		55	38	100	100

Table 4.3. Comparison of mean age and years of experience of immunisation staff who participated in Phase 2 of the study with those who did not participate

Variables	Immunisation staff participation		t-test	P-value
	Yes	No		
Mean age (years)	43.1(±7.6)	43.1(±9.6)	-0.027	0.979
Mean number of years since qualification	16.8(±9.5)	17.3(±10.8)	-0.184	0.855
Mean number of years of experience in administration of immunisation to infants	15.8(±8.0)	15.5(±9.3)	0.141	0.889

Table 4.4. Comparison of characteristics of immunization staff who participated in Phase 2 of the study with those who did not participate (N=55)

Variable		Staff Participation YES n (%)	Staff Participation NO n (%)	χ^2	p value
Local Government area‡	IBN	9 (64.3%)	5 (35.7%)	1.046	0.790
	IBNE	9 (75.0%)	3 (25.0%)		
	IBSE	10 (62.5%)	6 (37.5%)		
	IBSW	10 (76.9%)	3 (23.1%)		
Gender	Male	0 (0.0%)	2 (100%)		0.092^
	Female	38 (71.7%)	15 (28.3%)		
Qualification#	CHEW	16 (55.2%)	13 (44.8%)	5.565	0.018*
	Others	22 (84.6%)	4 (15.4%)		
Received training on eye care	YES	25 (65.8%)	13 (34.2%)	0.627	0.428
	NO	13 (76.5%)	4 (23.5%)		
Had noticed eye problems in infants	YES	19 (65.5%)	10 (34.5%)	0.367	0.545
	NO	19 (73.1%)	7 (26.9%)		

‡IBN- Ibadan North; IBNE – Ibadan Northeast; IBSE- Ibadan Southeast; IBSW - Ibadan Southwest

^ Fisher's Exact test

#CHEW – Community Health extension worker; Others- Nurse, Community Health Officer

* p value < 0.05 (significant)

4.2.1.1 Demographic characteristics of immunisation staff who participated in Phase 2 of the study

The mean age of the immunisation staff was 43.1 (± 7.6) years with a range of 23 to 56 years. Twenty-five (65.8%) respondents were aged above 40 years. All of them (100.0%) were females and all (100.0%) respondents were married.

4.2.1.2 Professional qualification and eye care training of immunisation staff who participated in Phase 2 of the study

Sixteen (42.1%) of the immunisation staff were community health extension workers (CHEWs), 12 (31.6%) were registered nurses while seven (18.4%) were community health officers. The mean number of years since their qualification was 16.8 (±9.5) years with a range of 1 to 33 years. While the mean number of years of their experience in administration of immunisation to infants was 15.8 (±8.0) years with a range of 2 to 30 years.

Twenty-five (65.8%) reported that they had received some training on eye care during the course of their training, but only 12 (48.0%) of these 25 respondents were trained on how to detect eye diseases in infants and young children.

4.2.1.3 Experience of immunisation staff on detection of eye diseases in children

Regarding their experience on detection of eye diseases in children, 34 (89.5%) respondents stated that it is possible to detect eye disease in children who are brought for immunisation. One (2.6%) respondent thought that it is not possible while three (7.9%) were not sure whether it is possible. Furthermore, 19 (50.0%) of the immunisation staff reported that they had actually noticed eye problems in children who had been brought for immunisation in the past. Among these 19 respondents, the number of times that they had observed such eye problems in the past 5 years ranged from once to 20 times with a median of 3 times. Table 4.5 summarises the frequency distribution of the eye problems that had been noticed by the immunisation staff at the most recent occasion of noticing such problems in a child that was brought for immunisation.

Table 4.5. Frequency distribution of eye problems noticed by immunisation staff at the most recent occasion

Eye problem	Frequency (n)	Percent (%)
Eye discharge/ Conjunctivitis/ Red eye	13	68.4
Poor vision	2	10.5
"Cataract"	1	5.3
Staff not sure of the nature of eye problem	3	15.8
Total	19	100

With regards to the action taken by the immunisation staff at the most recent occasion of noticing an eye problem, 11 (57.9%) respondents had referred the child to a secondary eye care facility such as Ring Road State hospital eye clinic, and Eleta Eye clinic or to the University College Hospital Eye clinic, a tertiary eye care facility, all in Ibadan. Five (26.3%) respondents treated the child with topical or systemic medications while two (10.5%) respondents simply advised the mother/ caregiver to clean the eyes with cotton wool and clean water.

Only five (13.2%) of the 38 immunisation staff had heard about the Red reflex test as a tool for screening for eye diseases in children. None of these five respondents had performed the Red reflex test before and none of them could state the name of the equipment that is used to perform the test, that is, the Ophthalmoscope.

None of the eight primary health centres (PHCs) had a Pen torch nor Ophthalmoscope. Only two (25.0%) of the PHCs had Visual acuity charts.

4.2.2 Infants characteristics

A total of 1253 infants were screened at the eight PHCs across the four selected local government areas. Thirty-nine (3.1%) of these infants did not complete all the stages of Phase 2 of the study and were found to have incomplete questionnaires and/or screening checklists. They were excluded from further analysis. Thus, the study completion rate was 96.9%.

The frequency distribution of the remaining 1214 infants who were included in the analysis from the various PHCs and the local government areas is presented in Table 4.6.

4.2.2.1 Demographic characteristics of infants who completed all stages of Phase 2

The mean age of the infants was 5.2 (± 3.8) months with a range of 1 week to 12 months. Six hundred and twenty-three (51.3%) were aged below 6 months. There were 637 males (52.5%) giving a male to female ratio of 1.1:1. The age and sex distribution of the infants is shown in Figure 4.4.

Table 4.6. Frequency distribution of the infants who completed all stages of

Local government area (LGA)	Primary health care centre (PHC)	Number of infants (n)	Percent (%) [PHC level]	Percent (%) [LGA level]
Ibadan North	Agbowo	175	14.5	28.7
	Idi Ogungun	172	14.2	
Ibadan Northeast	Iwo road	182	15.0	25.5
	Oke Adu	128	10.5	
Ibadan Southwest	Awodife	147	12.1	23.6
	Foko	140	11.5	
Ibadan Southeast	Agbongbon	140	11.5	22.2
	Oranyan	130	10.7	
Total		1214	100	100

Phase 2 across the PHCs and the local government areas

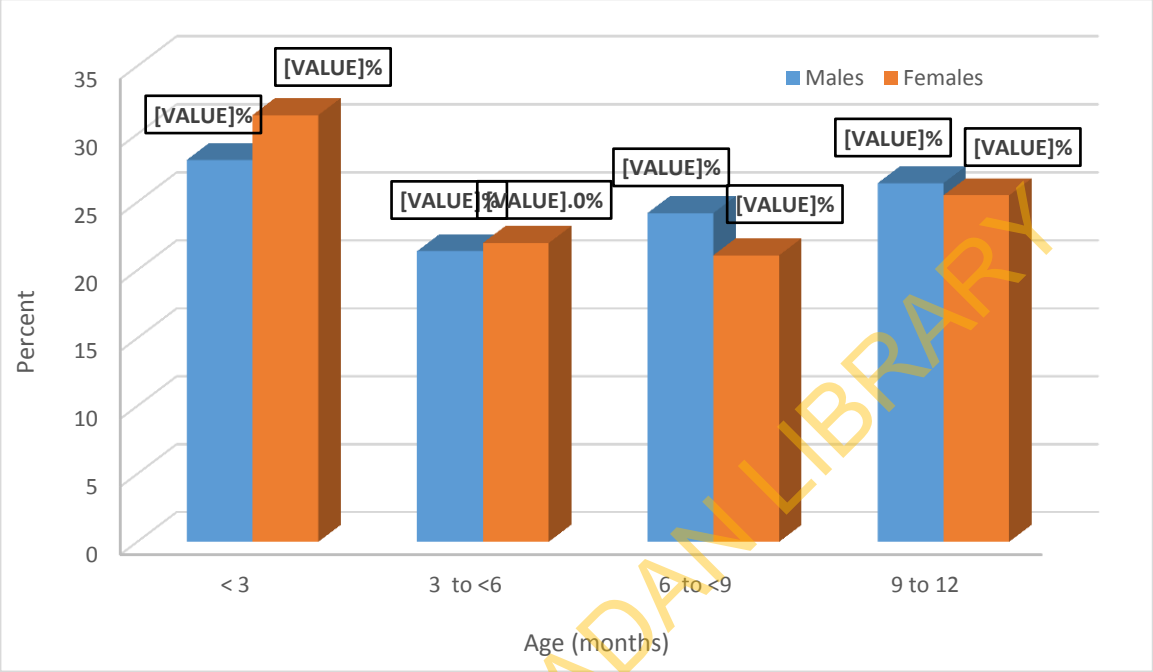

Figure 4.4. Age and sex distribution of infants who participated in the screening

There was no significant difference in the age distribution of the males compared with the females (χ^2 = 2.47; p = 0.481). Similarly, there was no significant difference in the mean age of males (5.3 ± 3.3 months) compared with that of females (5.1 ± 3.3 months) [t= 1.05; p = 0.296].

The person who brought the child for immunisation and responded to the questionnaire was the mother for 1198 (98.7%) of the infants. Sixteen infants were brought for immunisation by care givers which included grandmother (13 infants), aunt (2 infants), and mother's friend (1 infant). The mean age of the mothers was 28.9 (± 5.6) years, with a range of 15 to 47 years. While 1,031 (84.9%) mothers had at least secondary level education.

4.2.2.2 Relevant clinical history of infants (obtained from mothers / caregivers with the use of questionnaires)

A total of 1114 (91.8%) of the mothers/ caregivers stated that they had no past or present complaints about their child's eye. Only 100 (8.2%) of the respondents reported that they had complaints about their child's eye. The specific complaints reported included eye discharge in 55 (4.5%) children, redness of the eye(s) in 8 and itching/rubbing of the eyes in 7 infants. The frequency distribution of the complaints is shown in Table 4.7.

A total of 828 (68.2%) respondents stated that they had never observed any of the abnormal features that were specifically enquired about with respect to their child's eye; while 386 (31.8%) reported that they had noticed at least one of the abnormal features in their child's eye. The abnormal features that were reported and their frequency distribution is presented in Table 4.8.

Table 4.7. Frequency distribution of complaints reported by mothers /care givers regarding infants' eyes (N=1214)

Complaint	Frequency (n)*	Percent (%)
Eye discharge	55	4.53
Eye redness	8	0.66
Eye itching/ rubbing	7	0.58
Watering of the eyes	5	0.41
Yellowish discoloration	5	0.41
White spot in the eye(s)	3	0.25
Eyelid swelling	2	0.16
Difficulty opening the eye(s)	1	0.08
Crossed eyes	1	0.08
Not specified	18	1.48

* Some infants had more than one complaint reported by the respondent

Table 4.8. Frequency distribution of abnormal features that respondents had noticed in the infants' eyes (N=1214)

Abnormal feature	Frequency (n)*	Percent (%)
Persistent eye discharge	353	29.08
Redness of the eye(s)	52	4.28
Persistently watery eye(s)	30	2.47
White spot in the eye(s)	18	1.48
Eye(s) not opening well	8	0.66
Crossed eyes	4	0.33
Persistently shaking eyes	4	0.33
Eye ball(s) bigger than normal	1	0.08
Eye ball(s) smaller than normal	1	0.08

* Some infants had more than one abnormal feature noticed by the respondent

4.2.2.3 Outcome of screening by the immunisation staff using the newly developed checklist

Each of the 1214 infants was screened at least once by one of the immunisation staff. Based on their checklist scores, infants were classified into 3 categories in accordance with the recommended decision and action plan as follows:

- Category A – Infants with a score of 0 and were considered normal.
- Category B – Infants with a score of 5 and for whom a repeat screening in 4 weeks was recommended.
- Category C – Infants with a score of 10 and above and who required immediate referral to an ophthalmologist.

A total of 1101 (90.7%) infants were in Category A, 37 (3.0%) infants were in Category B, while 76 (6.3%) where in Category C. The frequency distribution of the checklist scores is shown in Table 4.9.

4.2.2.4 Eye examination findings of the ophthalmologist

A. Visual acuity

Among the children, 1200 (98.85%) had good fixation in both eyes, two (0.16%) had good fixation in only one eye, seven (0.58%) had poor fixation in both eyes while five (0.41%) children had no fixation in both eyes.

B. External eye examination

A total of 2,378 eyes (97.9%) were normal on external eye examination. Twenty-three eyes (0.9%) were found to have strabismus. Twenty-two eyes (0.9%) had watering of the eyes, while six eyes (0.2%) had eye lid discharge. Two eyes (0.1%) had ptosis of the upper eye lid. Two eyes (0.1%) had microphthalmos, while one eye (0.04%) had buphthalmos.

Table 4.9. Frequency distribution of checklist scores obtained by immunisation staff during screening of 1214 infants

Check list score	Frequency (n)	Percent (%)	Category
0	1101	90.7	A
5	37	3.0	B
10	51	4.2	C
15	11	0.9	C
20	12	1.0	C
35	2	0.2	C
Total	1214	100	

C. Anterior segment examination

A total of 2,399 eyes (98.8%) had normal findings on anterior segment examination. The abnormal findings included brownish discoloration of the conjunctiva in 10 (0.4%) eyes, injection of the conjunctiva in nine (0.4%) eyes, cataract in 5 (0.2%) eyes, corneal opacity in 2 (0.1%) eyes and jaundice in 2 (0.1%) eyes. One eye (0.08%) had an afferent pupillary defect.

D. Posterior segment examination

There was no view of the posterior segment in five eyes (0.2%) due to media opacity (cataracts), while three eyes (0.1%) were found to have pale optic discs. The remaining 2,420 eyes (99.7%) had normal posterior segment findings.

E. Red reflex test

A total of 1,199 (98.8%) children had normal red reflex test in both eyes. While, 15 (1.2%) infants had abnormal red reflexes in one or both eyes.

F. Summary of examination findings

To sum up, 84 (3.5%) eyes of 47 (3.9%) infants had at least one abnormal finding on eye examination. Thirty-seven (3.0%) infants had abnormalities in both eyes; six (0.5%) children had an abnormality in the right eye alone, while only the left eye was involved in four (0.3%) infants.

4.2.2.5 Eye diseases diagnosed upon eye examination by ophthalmologist

A total of 46 (3.8%) infants were diagnosed to have eye diseases. Thus, the prevalence of eye disease among the infants screened was 3.8%. The most common disease was Nasolacrimal duct obstruction found in 11 (0.9%) of the infants. The distribution of the eye diseases is presented in Table 4.10. Twenty (1.6%) infants had a blinding eye disease, defined as eye disease that can cause visual impairment in children (see Table 4.10).

Table 4.10. Frequency distribution of eye diseases diagnosed by ophthalmologist among 1214 infants

Eye Disease	Frequency (n)	Percent (%)
Nasolacrimal duct obstruction	11	0.90
Conjunctivitis^	10	0.82
Strabismus*	8	0.66
Cerebral visual impairment*	5	0.41
Delayed visual maturation	5	0.41
Cataracts*	3	0.25
Congenital glaucoma*	1	0.08
Corneal opacity*	1	0.08
Ptosis*	1	0.08
Optic atrophy*	1	0.08

Note: ^Conjunctivitis- includes allergic (7), bacterial (2) and phlyctenular (1) types of conjunctivitis; *Blinding eye diseases

4.2.3 Diagnostic accuracy of the newly developed checklist

For the purpose of assessing the diagnostic accuracy of the checklist, two scenarios were regarded as being positive test results of screening using the checklist. The first scenario was classification of an infant into Category C (infants with a score of 10 and above) while the second scenario was classification of an infant into either Category B or Category C (infants with a score of 5 and above). For the first scenario, a negative result was the classification of an infant into either Category A or Category B. While, for the second scenario, a negative result was classification of an infant into category A only.

A total of 113 (9.3%) infants were classified into Category B and Category C based on a checklist score of ≥ 5 upon screening, and 76 (6.3%) were classified into Category C based on a score of ≥ 10. These proportions were used to determine diagnostic accuracy of the screening checklist as follows:

4.2.3.1 Checklist versus Red reflex test performed by ophthalmologist

The ability of the checklist to correctly classify the infants into categories was compared to detection of abnormal red reflex by the ophthalmologist. The sensitivity of the checklist to classify an infant into Category C (score of ≥ 10) in the presence of an abnormal red reflex was 73.3%, with a specificity of 94.6% (Table 4.11). The sensitivity of the checklist to classify an infant into Category B or Category C (score of ≥ 5) in the presence of an abnormal red reflex was 73.3%, with a specificity of 91.4% (Table 4.12).

Table 4.11. Diagnostic accuracy of the newly developed checklist using Category C classification* in the presence of abnormal Red reflex test

		Abnormal Red Reflex test		
		YES	NO	TOTAL
Category C	YES	11	65	76
	NO	4	1134	1138
	TOTAL	15	1199	1214

Sensitivity= 73.3% 95% Confidence Interval (C.I.) = 44.9% - 92.2%

Specificity= 94.6 % 95% Confidence Interval (C.I.) = 93.1% - 95.8%

* Checklist score ≥ 10

Table 4.12. Diagnostic accuracy of the newly developed checklist using Category B or C classification* in the presence of abnormal Red reflex test

		Abnormal Red Reflex test		
		YES	NO	TOTAL
Category B or C	YES	11	102	113
	NO	4	1097	1101
	TOTAL	15	1199	1214

Sensitivity= 73.3% 95% C.I. = 44.9% - 92.2%

Specificity= 91.4% 95% C.I. = 89.8% - 93.0%

* Checklist score ≥ 5

4.2.3.2 Checklist versus Presence of Eye disease on eye examination by ophthalmologist

The ability of the checklist to correctly classify the infants into categories was compared to diagnosis of eye disease by the ophthalmologist. The sensitivity of the checklist to classify an infant into Category C (score of ≥ 10) in the presence of an eye disease was 63.0%, with a specificity of 96.0% (Table 4.13). The Positive and Negative Predictive Values were 38.2% and 98.5% respectively, while the Positive and Negative Likelihood Ratios were 15.7 and 0.4 respectively (Table 4.13).

The sensitivity of the checklist to classify an infant into Category B or Category C (score of ≥ 5) in the presence of an eye disease was 76.1%, with a specificity of 93.3% (Table 4.14). The Positive and Negative Predictive Values were 31.0% and 99.0% respectively, while the Positive and Negative Likelihood Ratios were 11.4 and 0.3 respectively (Table 4.14).

Table 4.13. Diagnostic accuracy of the newly developed checklist using Category C classification* in the presence of eye disease

		Eye disease present		
		YES	NO	TOTAL
Category C	YES	29	47	76
	NO	17	1121	1138
	TOTAL	46	1168	1214

Sensitivity= 63.0% 95% C.I. = 47.6% - 76.8%

Specificity= 96.0 % 95% C.I. = 94.7% - 97.0%

Positive Predictive Value= 38.2% 95% C.I. = 30.2% - 46.9%

Negative Predictive Value= 98.5 % 95% C.I. = 97.8% - 99.0%

Positive Likelihood Ratio= 15.7 95% C.I. = 11.0 - 22.4

Negative Likelihood Ratio= 0.4 95% C.I. = 0.3 - 0.6

* Checklist score ≥ 10

Table 4.14. Diagnostic accuracy of the newly developed checklist using Category B or C classification* in the presence of eye disease

		Eye disease present		
		YES	NO	TOTAL
Category B or C	YES	35	78	113
	NO	11	1090	1101
	TOTAL	46	1168	1214

Sensitivity= 76.1%	95% C.I. = 61.2% - 87.4%
Specificity= 93.3%	95% C.I. = 91.7% - 94.7%
Positive Predictive Value= 31.0%	95% C.I. = 25.5% - 37.0%
Negative Predictive Value= 99.0%	95% C.I. = 98.3% - 99.4%
Positive Likelihood Ratio= 11.4	95% C.I. = 8.7 - 14.9
Negative Likelihood Ratio= 0.3	95% C.I. = 0.2 - 0.4

* Checklist score ≥ 5

4.2.3.3 Checklist versus Blinding eye disease diagnosed on eye examination by ophthalmologist

The ability of the checklist to correctly classify the infants into categories was compared to diagnosis of blinding eye disease by the ophthalmologist. The sensitivity of the checklist to classify an infant into Category C (score of ≥ 10) in the presence of a blinding eye disease was 70.0%, with a specificity of 94.8% (Table 4.15). The Positive and Negative Predictive Values were 18.4% and 99.5% respectively, while the Positive and Negative Likelihood Ratios were 13.5 and 0.3 respectively (Table 4.15).

The sensitivity of the checklist to classify an infant into Category B or Category C (score of ≥ 5) in the presence of a blinding eye disease was 75.0%, with a specificity of 91.8% (Table 4.16). The Positive and Negative Predictive Values were 13.3% and 99.6% respectively, while the Positive and Negative Likelihood Ratios were 9.1 and 0.3 respectively (Table 4.16).

Table 4.15. Diagnostic accuracy of the newly developed checklist using Category C classification* in the presence of blinding eye disease

		Blinding eye disease present		
		YES	NO	TOTAL
Category C	YES	14	62	76
	NO	6	1132	1138
	TOTAL	20	1194	1214

Sensitivity= 70.0%	95% C.I. = 45.7% - 88.1%
Specificity= 94.8%	95% C.I. = 93.4% - 96.0%
Positive Predictive Value= 18.4%	95% C.I. = 13.4% -24.7%
Negative Predictive Value= 99.5%	95% C.I. = 99.0% - 99.7%
Positive Likelihood Ratio= 13.5	95% C.I. = 9.3 - 19.6
Negative Likelihood Ratio= 0.3	95% C.I. = 0.2 - 0.6

* Checklist score ≥ 10

Table 4.16. Diagnostic accuracy of the newly developed checklist using Category B or C classification* in the presence of blinding eye disease

		Blinding eye disease present		
		YES	NO	TOTAL
Category B or C	YES	15	98	113
	NO	5	1096	1101
	TOTAL	20	1194	1214

Sensitivity= 75.0%	95% C.I. = 50.9% - 91.3%
Specificity= 91.8%	95% C.I. = 90.1% - 93.3%
Positive Predictive Value= 13.3%	95% C.I. = 10.0% - 17.4%
Negative Predictive Value= 99.6%	95% C.I. = 99.0% - 99.8%
Positive Likelihood Ratio= 9.1	95% C.I. = 6.7 -12.5
Negative Likelihood Ratio= 0.3	95% C.I. = 0.1 - 0.6

* Checklist score ≥ 5

4.2.4 Reliability indices of the newly developed checklist

Eighty-eight (7.2%) of the infants underwent a second screening performed by a second immunisation staff using the checklist. The second immunisation staff was unaware of the outcome of the screening by the first immunisation staff. The frequency distribution of the checklist scores obtained among these 88 infants during the 1st and 2nd screening is shown in Table 4.17.

4.2.4.1 Correlation between 1st and 2nd screening scores

The second immunisation staff obtained the same score as that obtained by the first staff in 83 (94.4%) of the 88 infants. Three (3.4%) infants had a higher first score; while 2 (2.3%) had a higher second score. There was a significant positive correlation between the 1st checklist score and the 2nd checklist score ($r = 0.77$, $p < 0.001$).

4.2.4.2 Agreement between 1st and 2nd screening classification

Comparing the proportions of infants classified into Category C (checklist score ≥ 10), the overall agreement was 96.6% (Kappa = 0.71; $p<0.001$) between the first and second screenings (Table 4.18). The proportion of positive agreement was 72.2%, while the proportion of negative agreement was 98.2%.

With regards to the proportions of infants classified into either Category B or C (checklist score ≥ 5), the overall agreement was 96.6% (Kappa = 0.75; $p<0.001$) between the first and second screenings (Table 4.19). The proportion of positive agreement was 76.9%, while the proportion of negative agreement was 98.2%.

Table 4.17. Frequency distribution of checklist scores obtained by immunisation staff during 1st and 2nd screening of 88 infants

Check list score	Check list category	First screening Number (%)	Second screening Number (%)
0	A	81 (92.0)	82 (93.2)
5	B	0 (0.0)	2 (2.3)
10	C	5 (5.7)	2 (2.3)
15	C	2 (2.3)	1 (1.1)
25	C	0 (0.0)	1 (1.1)
Total		88 (100)	88 (100)

Table 4.18. Number of infants classified into Category C* based on 1st screening versus 2nd screening

		2nd score ≥ 10		
		YES	NO	TOTAL
1st score ≥ 10	YES	4	3	7
	NO	0	81	81
	TOTAL	4	84	88

Overall agreement = 96.6% Kappa = 0.71; p<0.001

Positive agreement = 72.2% Negative agreement = 98.2%

* Checklist score ≥ 10

Table 4.19. Number of infants classified into Category B or C* based on 1st screening versus 2nd screening

		2nd score ≥ 5		
		YES	NO	TOTAL
1st score ≥ 5	YES	5	2	7
	NO	1	80	81
	TOTAL	6	82	88

Overall agreement = 96.6% Kappa = 0.75; p<0.001

Positive agreement = 76.9% Negative agreement = 98.2%

* Checklist score ≥ 5

4.2.4.3 Internal consistency reliability of screening checklist

The internal consistency of the checklist as determined using the Cronbach's alpha coefficient was low ($\alpha = 0.356$).

4.2.4.4 Test-retest reliability of screening checklist

The test – retest reliability of the screening checklist was determined based on the checklist scores of the 88 infants who underwent a second screening. The scores obtained during the first screening performed by an immunisation staff were compared with the scores obtained during the second screening performed by a different immunisation staff.

The intra-class coefficient (ICC) was 0.90 (95% C.I. = 0.85 - 0.94), $p < 0.001$. There was a significant positive correlation between the scores obtained during the screening by the first compared with second immunisation staff.

4.3 Phase 3: Survey of Immunisation Clinic Staff Perception of Checklist

4.3.1 Perception of immunisation clinic staff about usefulness and ease of use of the screening checklist

All the 38 (100%) respondents who participated in the screening found the checklist useful in screening for eye diseases among infants. Thirty-five (92.1%) respondents found it "very useful", one (2.6%) found it "moderately useful", while two (5.3%) found it "a bit useful".

Furthermore, all 38 respondents found it easy to use the checklist to screen children for eye disease. Thirty-one (81.6%) respondents reported that they found it "very easy" to use, five (13.1%) said they found it "moderately easy" to use, while two (5.3%) found it "a bit easy" to use.

4.3.2 Reported average duration of time spent per child

The median of the average period of time the immunisation staff reported that they spent using the checklist per infant was 5 minutes with a range of 28 minutes. Twenty

(52.6%) of the respondents reported that they spent an average time of 5 minutes per child (Figure 4.5).

4.3.3 Challenges experienced by immunisation staff while using the checklist during the study

Thirteen (34.2%) respondents reported that they experienced some challenges with the use of the checklist during the study (Table 4.20). The commonest challenge reported was "Inadequate number of staff" (23.7%). None of the respondents reported any difficulty with understanding how to use to the checklist or difficulty with interpreting the scores on the checklist.

4.3.4 Knowledge and skills acquired while using the checklist during the study

Thirty-two (84.2%) respondents stated that they acquired new knowledge and/or skill(s) during the course of the study. Table 4.21 shows a summary of the new knowledge and skills acquired by the immunisation staff.

4.3.5 Confidence of immunisation staff regarding their ability to detect eye diseases in children

Thirty-seven (97.4%) of the respondents felt confident that they can detect eye diseases in children using the screening checklist. Among those who felt confident, 25 (67.6%) respondents felt "much confidence", nine (24.3%) felt "moderate confidence", while three (8.1%) felt "a little confidence".

4.3.6 Suggestions and recommendations for modifying or improving the checklist

Only one (2.6%) of the respondents had a suggestion or recommendation for modification or improvement of the screening checklist. Her suggestion was that a small pocket book containing information on eye diseases in children could be made available for further guidance of immunisation staff on the use of the checklist.

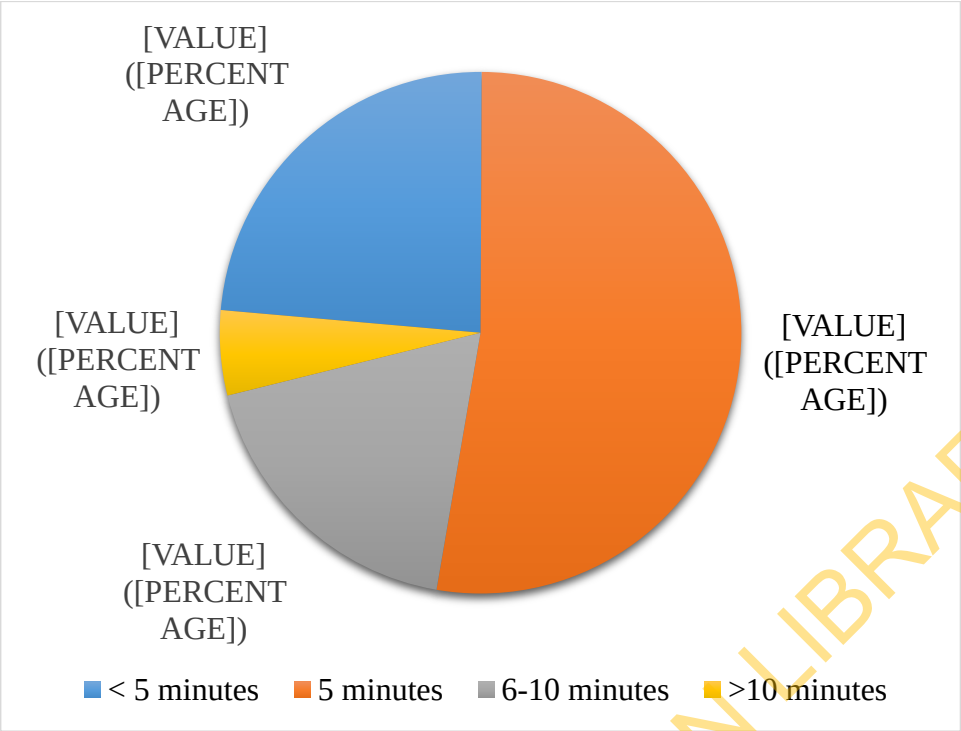

Figure 4.5. Distribution of the reported average duration of time spent by immunisation staff while screening an infant using the checklist

Table 4.20. Challenges experienced by immunisation staff while using the checklist during the study (N=38)

Challenge	Frequency (n)*	Percent (%)
Inadequate number of staff (short staffing)	9	23.7
Poor cooperation from some children / Difficulty with examination of some children	7	18.4
Poor cooperation from some mothers / Difficulty with obtaining answers from some mothers	5	13.1
Use of checklist was time consuming	1	2.6
Language barrier	1	2.6
No challenge experienced	25	65.8

* Some immunisation staff reported more than one challenge

Table 4.21. Knowledge and skills acquired by immunisation staff while using the checklist during the study (N=38)

Knowledge/skill	Frequency (n)*	Percent (%)
Ability to detect abnormal features in children's eyes	16	42.1
Knowledge on importance of screening for eye disease in babies	14	36.8
Use of pen torch	8	21.1
Knowledge about cat's eye reflex	4	10.5
Checking for inequality in the size of the eyes	2	5.3
Checking for squint	1	2.6
Checking for nystagmus	1	2.6
Checking for cataract	1	2.6

* Some immunisation staff reported acquisition of more than one type of knowledge/skill

CHAPTER FIVE

DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Discussion

The main objective of this study is to develop a simple screening tool for the early detection of blinding eye diseases in infants at primary health care level. The implication of describing the tool as being simple is to underscore the fact that the screening tool does not require any special equipment for its use. Indeed, the checklist that has been developed can be used on its own without any equipment. It specifically does not require the use of an ophthalmoscope for screening. The simplicity of the tool also highlights the fact that the tool is not difficult or complex to use. In addition, it is neither elaborate nor sophisticated. Therefore, the tool is suitable for use by primary health care workers to detect eye diseases that can lead to blindness in infants. The availability and use of this newly developed screening checklist could be instrumental in the establishment of screening programs for childhood eye disease at the primary health care level.

In addition to being simple and suitable for use by primary health workers, the newly developed checklist also has advantages over other checklists that have been used for screening for eye disease among children and overcomes many of their limitations. Such advantages include its usefulness for screening of infants in addition to toddlers and preschool children as well as the fact that it is culturally applicable to our setting. The other checklists are generally not appropriate for use in infants but are designed for screening older children in foreign countries which are culturally different from Nigeria. Moreover, the process of development and the diagnostic accuracy of the checklist is being described in this thesis while the development and validation of the

foreign checklists have not been described by the individuals or organisations who developed them.

5.1.1 Development of the screening tool

The steps taken in the process of developing the checklist involved literature review, expert opinion, stake holder input and content validation. These steps are essentially a harmonisation of three different sets of steps described by previous authors regarding the development of medical checklists (Winters *et al.*, 2009; Schmutz *et al.*, 2014; Burian *et al.*, 2018). In addition, the steps are similar, with slight differences, to the steps for the process of development of health outcome measuring instruments as described by (Odole *et al.*, 2013). The modification was because the process they described was specifically for developing an instrument for the assessment of a therapeutic intervention, while the focus of the present study is the development of an instrument for screening for disease.

A review of the literature and available knowledge about the current state of the practice of child eye care in Nigeria provided evidence for the justification for the development of the tool. Specifically, the need for a simple screening tool is manifest for the following reasons: the lack of well-established screening programmes for eye diseases in children; the lack of ophthalmoscopes at primary health care level; and the propensity for children with blinding eye disease to present late to hospital. The literature review also revealed that there is no simple screening checklist that had previously been developed for early detection of childhood eye diseases in low-resource settings such as Nigeria. In addition, the literature review was instrumental in devising the items (questions) that were included in the first draft of the checklist. Symptoms and signs of childhood eye diseases which primary health workers should be able to elicit and detect such as poor vision, red/watery eyes, leukocoria, squint, and nystagmus were identified during the review of literature.

Literature review has also been an important step in the development of checklists for screening for other health conditions in children. In describing the process that they utilised in developing 2 different checklists for the early detection of emotional and behavioural problems in children, Sheldrick *et al.* (2012; 2013) emphasised the role of extensive review of the literature in identification of candidate items for inclusion and

the creation of the initial lists of items for both checklists, that is, the Baby Paediatric Symptom Checklist and the Preschool Paediatric Symptom Checklist. Other authors have similarly described literature review as an important step in the development of screening checklists (Baron *et al.*, 2014; Salaffi *et al.*, 2020).

The opinion of ten general ophthalmologists was sought in devising the questions for the checklist. Each of these specialists had at least 10 years' experience of practising ophthalmology and this availed them with the requisite knowledge about the clinical presentation of the childhood eye diseases of interest, particularly the features which should easily be detected or elicited by primary health workers who have no experience in eye care. Physician's clinical experience has also been found to be useful in the selection of items for screening checklists for other diseases. Sheldrick *et al.* (2012; 2013) reported that some of the items in their initial lists were included on the basis of the authors' clinical experience. Baron *et al.* (2014) also drew on the clinical experience of physicians and patients in the selection of items for a fibromyalgia screening checklist by conducting focus group discussions with clinicians, and face-to-face interviews with patients. In addition, the input of stakeholders, that is, the primary health care workers, was vital in ensuring that the questions were not complicated but were appropriate for their low level of experience in eye care.

The review of the initial drafts of the checklist by a 5-man expert panel of paediatric ophthalmologists was to ascertain the content validity of the tool. The panel members are specialists who had undergone further training in the diagnosis and treatment of childhood eye disease and are expected to possess a higher level of expertise than general ophthalmologists. Thus, they were able to rate the relevance of items that had been initially included following literature review and opinion of the general ophthalmologists. The relevance scale that the panel members used to rate the questions was designed for developing health measurement scales and has been found to be useful for the same purpose (Streiner and Norman, 1989). As a result of the review and input of the expert panel, it can be safely concluded that the checklist has a strong content validity (DeVon *et al.*, 2007; Kimberlin and Winterstein, 2008; Alphonso *et al.*, 2017).

5.1.2 Sensitivity, specificity and reliability of the screening tool.

The validity of the newly developed checklist as a screening tool for blinding eye diseases in children was determined by evaluating its diagnostic accuracy (sensitivity, specificity and predictive values) and its reliability. The checklist has fairly good sensitivity and moderately high specificity for detecting any eye disease and blinding eye disease among infants. Unfortunately, there are no similar previous studies available for comparison. Notwithstanding, the checklist compares favourably with the Red reflex test. Previous studies have reported that the sensitivity of the Red reflex test ranged between 13.9% and 85%, while its specificity ranged between 38.5% and 98.7% (Eventov-Friedman *et al.*, 2010; Saiju *et al.*, 2012; Mussavi *et al.*, 2014; Sun *et al.*, 2016). It is worthy of note that these previous studies were conducted among young children screened at secondary or tertiary levels of care and not primary health care as is the case for this study.

In view of the high false positive rate and the low positive predictive value of the checklist, there is a significant risk of "over-referral" of normal infants. This is associated with the attendant issues of parental anxiety and increasing the patient load at the tertiary level. The low prevalence of eye diseases in this study should, however, be borne in mind as a contributing factor to the low positive predictive value. Moreover, the relatively high positive likelihood ratio is supportive of use of the checklist despite low prevalence of eye diseases at primary health care level.

Changing the cut-off for referral to the ophthalmologist (that is, Category C compared to Category B or C) increases the sensitivity of the checklist but the associated decrease in specificity and positive predictive value suggest that only Category C infants should be recommended for immediate referral. Therefore, Category B infants should undergo a repeat screening, as originally suggested during development of the checklist.

The checklist exhibits a high reliability with respect to reproducibility and inter-observer variation. There was a significant positive correlation with regards to the checklist scores obtained by the two different immunisation staff among the infants that were screened twice. Similarly, the overall agreement with respect to classifying

the infants was very high. This shows that the checklist has reproducible results and the inter-observer variation is low.

On the other hand, the checklist demonstrates a low internal consistency reliability as shown by the low value of the Cronbach's alpha coefficient. This may be as a result of the fact that the various questions on the checklist address specific features of different childhood eye diseases and not just one eye disease. This, however, appears to be unavoidable given the fact that the screening tool has been designed to detect several different eye diseases. This could be seen as a trade-off between having several checklists (each for one eye disease) and one checklist that can detect several eye diseases.

5.1.3 Feasibility of using the checklist to detect childhood blinding eye diseases

In assessing the feasibility of using the newly developed checklist for detecting childhood blinding eye diseases at primary health care level it is very important to consider the perceptions of primary health care workers on the checklist as well as their acceptance of it. Such information is also vital while making any plans for upscaling the use of the checklist. This is because the success of screening programs for childhood eye disease at the primary health care level is very dependent on its acceptance by the health workers.

In this study, the health workers, based on their responses, were favourably disposed to the checklist. Most of them reported that they found the checklist "very useful" and "very easy" to administer. This perception of usefulness and ease of use is necessary to enhance the acceptability of the checklist by the workers. In addition, majority of them reported that they acquired new knowledge or skills while using the checklist. Acquisition of new knowledge and skills should be a motivation for primary health care workers to use the checklist.

These findings are in accordance with a report by Poterio *et al.* (2000) that the conduct of vision screening during immunisation activities is simple and rapid. In their study, Brazilian children were screened for poor vision and eye diseases by paramedics during a vaccination campaign, and they observed that such screening provided an opportunity for children with vision disorders to be identified while they were

receiving preventive health care services. Furthermore, the opportunity of providing a screening program in addition to another health care service (immunisation), which caregivers have brought their children for, is beneficial and cost-saving for both the beneficiaries and the health care providers. This is an example of integration of health care services that can help to strengthen primary health care delivery systems.

5.1.4 Limitations of the study

One of the limitations of the study is that the checklist may not be able to detect some eye diseases in infants and children such as retinopathy of prematurity and refractive errors. Another limitation is the low prevalence of eye diseases in the study which affected the positive predictive value of the checklist.

Furthermore, there is a possibility of selection bias in the population studied. This stems from the fact that not all children routinely attend immunisation clinics. Therefore, the findings of this study may not be completely generalizable to all infants.

The possibility of "Hawthorne-like" effect with respect to the participation of the immunisation clinic staff should also be considered as a limitation to this study. The health workers may not use the checklist the same way in their normal activities as they did during the study.

Finally, this study did not investigate the actual uptake of referrals by the mothers or caregivers of infants who were referred. It is possible that they may still present late to hospital after early detection using the checklist or they may not present at all to the hospital. Thereby, negating the ultimate goal of reducing late presentation.

5.2 CONCLUSION

This study has developed a simple screening tool for the early detection of eye diseases in infants and young children. The newly developed tool is in the form of a checklist that can be used in screening for blinding eye diseases in children without any additional special equipment such as ophthalmoscopes. The main advantages of the checklist include its simplicity, its appropriateness for use in infants and the fact that it is culturally applicable to the Nigerian setting.

In addition, based on the input of the expert panel, the screening checklist has strong content validity. It also demonstrated fairly good criterion validity and high reliability. The checklist was reported to be useful for screening and easy to administer by immunisation clinic staff. These properties of the checklist in addition to its simplicity are suggestive of the fact that using it for screening at primary health care level is a suitable strategy in the prevention of avoidable childhood blindness in Nigeria and other developing countries.

5.3 RECOMMENDATIONS

Taking into account the findings of this study, the adoption of the checklist as a screening tool at the primary health care level is recommended. Such implementation could be instrumental in the establishment of eye disease screening programs among children which would go a long way in reducing the burden of childhood blindness among Nigerian children. Firstly, dissemination of information about the checklist to State primary health care board as well as association of primary health care workers in Oyo state is recommended. In addition, knowledge translation strategies and activities are necessary to guarantee the benefit of this research project towards reducing the burden of childhood blindness at the local, national and international levels.

The opportunities for integration of the use of this checklist during examination of new-born babies, post-natal clinics and immunisation visits should be explored. Moreover, there is an urgent need for the development of a national policy on childhood eye disease screening programs in Nigeria. This would pave the way for the establishment of routine eye screening for infants and children and facilitate the early detection and treatment of children with blinding eye disease.

5.4 CONTRIBUTION TO KNOWLEDGE

The major contribution to knowledge of this study is the development of a simple screening tool for early detection of blinding diseases among infants by primary health care workers. Prior to this study, there had been a lack of an appropriate tool for screening and detection of eye diseases among infants in low-resource settings at the primary health care level. The development of this checklist has provided a solution to

this problem and it is expected that its adoption would ultimately contribute to a reduction in the prevalence and burden of childhood blindness in developing countries. Furthermore, this study has demonstrated that the newly developed screening tool is valid, reliable and its use by primary health care staff is feasible.

5.5 SUGGESTIONS FOR FURTHER RESEARCH

Additional studies may be conducted on the validation of the checklist in other primary health care settings different from immunisation clinics. It is also necessary to conduct similar studies in other parts of the country that have socio-cultural settings that are from that of Ibadan, the location of the present study. Such studies could also investigate the effect of further refining or modification of the checklist items with a view towards increasing its sensitivity and positive predictive value. In addition, further studies could be conducted on the evaluation of its use on a larger scale as well as to determine its cost-effectiveness.

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APPENDICES

APPENDIX A. QUESTIONNAIRE FOR INFANTS' MEDICAL HISTORY

Study Number: _____

Study title: Developing a screening tool for eye diseases in infants attending immunisation clinics in Ibadan, Nigeria.

Dear mother/ caregiver,

This study is aimed at improving the early detection of eye disease among infants during immunisation visits in Ibadan. Be assured of utmost confidentiality, your answers shall not be linked to you. We will not write your name or phone number or any other thing that can identify you on this form. Listen to the questions carefully and provide sincere and honest answers.

Date: _____

Local Government Area: _____

Immunisation clinic: _____

Please circle or tick the appropriate answer

Section A: Socio-demographic data

1. Age of child in months: _____ (If <1 month, state age in weeks)
2. Gender: Gender: (a) Male (b) female
3. Informant: (a) Mother (b) Caregiver (Specify relationship): _____
4. Mother's age: (last birthday)_____ years
5. Father's age: (last birthday)_____ years
6. Mother's level of education: (a) No formal education (b) Primary education (c) Secondary education (d) Tertiary education (e) Post graduate education
7. Father's level of education: (a) No formal education (b) Primary education (c) Secondary education (d) Tertiary education (e) Post graduate education
8. Mother's occupation: _____
9. Father's occupation: _____
10. Where was the child delivered?
    (a) Government hospital (b) Private hospital & maternity
    (c) Mission home (d) Traditional birth attendant's facility
    (e) At home (f) Others (please specify): _____
11. Which immunisation is to be received today:_____

Section B: Ocular history

12. Do you have any complaint about your child's eye? (a) Yes (b) No
13. If Yes to Q.12, Specify _____
14. Which of the following features have you ever noticed in your child's eyes? (Tick Yes or No for each item):

	Feature	**Yes**	**No**

a.	White spot in the eye(s)		
b.	Big eye ball(s) (Eye ball that is bigger than what you normally see in children)		
c.	Small eye ball (s) (Eye ball that is smaller than what you normally see in children)		
d.	Persistent watering of the eye(s)		
e.	Eye(s) not opening well		
f.	Redness of the eye(s)		
g.	Persistently Discharging eye(s)		
h.	Crossed eyes (The two eyes are looking in different directions)		
i.	Persistently shaking eyes		

15. If your child has or had any of the features in Q.14, have you sought eye care? (a) Yes (b) No
16. If Yes to Q.15, where did you go? (Specify) _____
17. Has your child sustained any injury to the eye(s) in the past? (a) Yes (b) No
18. Has your child received any treatment for an eye problem in the past? (a) Yes (b) No

Section C: Other medical history

19. History of prematurity in child (a) Yes (b) No
20. History of maternal fever or rash during pregnancy (a) Yes (b) No
21. History of illness in child since birth (a) Yes (b) No
22. If Yes to Q.21, specify _____
23. History of delayed milestones in the child (a) Yes (b) No

24. Family history of eye disease in childhood (a) Yes (b) No

25. If Yes to Q.24, specify _____

IWE IBEERE LATI WADI ILERA AWON OMODE

Onka Leseese: _____

Iya Owon/Alagbato Owon,

Afojusun iwadi yi ni sise agbelaruge titetese awari aisan oju laarin awon omode ni akoko wiwa si ile alabere ajesara ni Ibadan.

Efokanbale wipe aabo to daju wa, a koni fi idahun yin dayin mo, ao ni ko oruko tabi nomba ero ibanisoro yin tabi awon nkan miran tole fi yin han lori iwe yi, e farabale gbo awon ibeere dada kie si fesi ninu otito.

Ojo: _____

Agbegbe Ijoba Ibile: _____

E jowo yi odo tabi kie fami si idahun toye

Ipele A: Ibeere lori ara eni

1. Ojo ori omo ni osu: _____ (Ti koba to osu kan, daruko ojo ori ni ose)
2. Eniyan wo ni: (a) Ako (b) Abo
3. Olufesi: (a) Iya (b) Alagbato (Se afihan enitiise)
4. Ojo ori iya (ojo ibi kehin) _____ odun
5. Ojo ori baba (ojo ibi kehin) _____ odun

6. Iwe ti iya ka: (a) Ko kawe rara (b) Alakobere
   (d) Ile eko grama (e) Ile eko giga (e) Ile eko giga agba
7. Iwe ti baba ka: (a) Ko kawe rara (b) Alakobere
   (d) Ile eko grama (e) Ile eko giga (e) Ile eko giga agba
8. Ise iya: _____
9. Ise baba: _____
10. Ibo labi omo naa si?
    (a) Ile iwosan ijoba (b) Ile iwosan adani
    (d) Ile agbebi (e) Agbebi nipa ti ibile
    (e) Ni ile (f) Nibomiran (jowo daruko):

_____

11. Abere ajesara wo lofe gba loni:

_____

Ipele B: Itan lori ayewo oju

12. Se o ri ariwisi si oju omo re? (a) Beeni (b) Beeko

13. To baje Beeni lo si Ibere Kejila, safihan

_____

14. Ewo ninu eyi letikofiri ni oju omo yin?

(Fami si beeni tabi beeko fun okookan eyi):

	Ibeere lokanjokan	**Beeni**	**Beeko**
a.	Kele funfun ni inu oju		
b.	Eyinju totobi (Eyin oju totobi jojo ju eyiti a nri loju omode lo)		
d.	Eyin oju to kere (eyin oju to kere ju eyi ti a nri loju omode lo)		
e.	Oju to nsomi nigbogbo igba		
e.	Oju tiko la daradara		
f.	Oju pipon		

g.	Oju ti nsepin ni gbogbo igba		
gb.	Oju meji to nwo ona otooto		
h.	Oju ti ko duro soju kan		

15. Ti omo yin bani okan ninu awon ibere kerinla, se e tiwa itoju oju

(a) Beeni (b) Beeko

16. Topba je beeni, lo si ibere kedogun, ibo ni e lo (safihan)

_____

17. Latehinwa, se omo yin ni egbo oju ri? (a) Beeni (b) Beeko

18. Latehinwa, se omo yin gba itoju fun aisan oju ri? (a) Beeni (b) Beeko

Ipele D: Awon itan ilera miran

19. Itan kogbokogbo nipa omo (a) Beeni (b) Beeko

20. Itan iba inu oyun tabi kokoro ara (a) Beeni (b) Beeko

21. Itan ailera lati igba tia bi omo (a) Beeni (b) Beeko

22. Toba je beeni lo si ibere ketalelogun, safihan _____

23. Itan lori aisedeede kan laye omo naa (a) Beeni (b) Beeko

24. Itan idile lori aisan oju lati ewe (a) Beeni (b) Beeko

25. Toba je beeni lo si ibere kerinlelogun, safihan _____

APPENDIX B. QUESTIONNAIRE FOR IMMUNISATION CLINIC STAFF

Study Number: _____

Study title: Developing a screening tool for eye diseases in infants attending immunisation clinics in Ibadan, Nigeria.

Dear participant,

This study is aimed at improving the early detection of eye disease among infants during immunisation visits in Ibadan. Be assured of utmost confidentiality, your answers shall not be linked to you. Please do not write your name or phone number or any other thing that can identify you on this form. Read the questions carefully and provide sincere and honest answers.

Date: _____

Local Government Area: _____

Immunisation clinic: _____

Please circle or tick the appropriate answer

Section A: Bio data, Qualification and Training

1. Age in years (last birthday): _____
2. Gender: (a) Male (b) female

3. Marital status: (a) Single (b) Married (c) Separated (d) Divorced
4. What is your qualification?
   (a) Registered nurse (b) Midwifery (c) Community Health extension worker (CHEW) (e) Other (Please specify):_____
5. What year did you acquire this qualification? _____
6. For how long have you been administering immunisation to children? _____
7. Did you have any course(s) on eye care during your training? (a) Yes (b) No
8. Did you receive training on how to detect eye diseases in infants and young children? (a) Yes (b) No
9. Have you had any refresher course on eye care since you graduated? (a) Yes (b) No
10. Do you think it is possible to detect eye diseases in children when they are brought for immunisation? (a) Yes (b) No (c) Not sure
11. Have you previously noticed that a child who was receiving a vaccine had an eye problem? (a) Yes (b) No
12. If Yes, about how many times in the past 5 years did you notice eye problems in children that were brought for immunisation? ……
13. At the most recent occasion (i.e., the last time you noticed) what eye problem did you think the child had? ……..
14. At the most recent occasion (i.e., the last time you noticed) what action did you take? ……

APPENDIX C. FINAL VERSION OF THE SCREENING CHECKLIST USED FOR THE STUDY

Infant Serial Number: _____ Immunisation staff Serial Number:_____

Date: _____ LGA: _____ Primary Health Centre: _____

CHILDHOOD BLINDING EYE DISEASE SCREENING CHECKLIST

Section A: Ask the mother / caregiver the following questions (Questions for mother)

1.	Do you think there is any problem with your child's vision/ eyes?	Yes = 5;	No = 0
2.	Ask mother only one option (a, b or c) based on child's age		
a.	Less than 6 months:-Does your child look at your face when breastfeeding?	Yes = 0;	No = 10
b.	Between 6 and 10 months:- Does your child reach out for objects?	Yes = 0;	No = 10
c.	Above 10 months:- Does your child bump into objects when crawling/ walking/running?	Yes = 10;	No = 0
3.	Do you notice if the eye(s) of your child shines like that of a cat in the dark/ at night?	Yes = 10;	No = 0
4.	Do you notice if the eye(s) of your child is always bringing out tears even when he/she is not crying?	Yes = 10;	No = 0
5.	Does your child always try to avoid looking at bright light?	Yes = 10;	No = 0
6.	Are your child's eyes always red?	Yes = 5;	No = 0

Section B: Look at the child's eyes and observe the following (To be performed by health worker)

7.	Observe only one option (a, b or c) based on child's age		
a.	Less than 3 months:- Is the child able to notice a light (blinking or closing the eyes when a light is shone unto his/ her eyes)?	Yes = 0;	No = 10
b.	Between 3 and 6 months:- Is the child able to follow a light shone unto his/her face?	Yes = 0;	No = 10
c.	Above 6 months:- Is the child able to reach out for objects?	Yes = 0;	No = 10
8.	Is there a white spot in the black portion of the eye?	Yes = 10;	No = 0
9.	Does one eye look bigger or smaller than the other eye or do both eyes appear bigger than those of children of similar age?	Yes = 10;	No = 0
10.	Are both eyes looking towards the same direction?	Yes = 0;	No = 10
11.	Are the eyes always (continuously) shaking or unsteady?	Yes = 10;	No = 0

Score

Add the scores for all the 11 items **Total Score** = ...

Interpretation of score

A. If score = 0	The child's eyes are likely to be normal. Reassure mother but a repeat screening at another visit within 3 months is recommended.
B. If score = 5	The child's eyes may be abnormal. Repeat the screening within 4 weeks.
C. If score = 10 or more	The child's eyes are abnormal. Refer the child to an ophthalmologist immediately.

APPENDIX D. PROFORMA FOR OPHTHALMIC EXAMINATION OF INFANTS

Study Number: _____

Study title: Developing a screening tool for eye diseases in infants attending immunisation clinics in Ibadan, Nigeria.

This proforma is to be completed by the examining ophthalmologist

OCULAR EXAMINATION (**Please fill in the correct option into the box for each eye)**

		RIGHT EYE	LEFT EYE
1.	Visual acuity	☐	☐
	a) Good fixation (Central, steady, and maintained)		
	b) Poor fixation (Eccentric or Unsteady or Unmaintained)		
	c) No fixation		
2.	Eyelids	☐	☐
	a) Normal		
	b) Ptosis		
	c) Tearing		
	d) Discharge		
	e) Other abnormality (Please describe) ……..	……	
3.	General eye examination	☐	☐
	a) Eye appears normal		
	b) Nystagmus		
	c) Buphthalmos		
	d) Microphthalmos		
	e) Leukocoria		
	f) Strabismus		

		RIGHT EYE	LEFT EYE
4.	Conjunctiva	☐	☐
	a) Normal		
	b) Injected		
	c) Other abnormality (Please describe) ……		
5.	Cornea	☐	☐
	a) Normal		
	b) Opacity		
	c) Other abnormality (Please describe) …..……		
6.	Anterior chamber	☐	☐
	a) Normal depth		
	b) Shallow		
	c) Deep		
	d) Other abnormality (Please describe) ……		
7.	Pupil	☐	☐
	a) Normal (Round and reactive to light)		
	b) Abnormal		
	c) If abnormal (Please describe) ……..		
8.	Lens	☐	☐
	a) Normal		
	b) Cataract		
	c) Other abnormality (Please describe) ……		
9.	Red reflex test	☐	☐
	a) Normal		
	b) Abnormal		

	RIGHT EYE	LEFT EYE
10. Fundus	☐	☐
a) Normal fundus		
b) Abnormal fundus		
c) If abnormal (Please describe) ……..		
11. Conclusion	☐	☐
a) Normal examination findings		
b) Abnormal examination findings (Please specify)…….		

12. Other comments

……

……

……

APPENDIX E. REFERRAL FORM

Study title: Developing a screening tool for eye diseases in infants attending immunisation clinics in Ibadan, Nigeria.

REFERRAL FORM

Consultant Paediatric Ophthalmologist

Eye clinic

UCH, Ibadan.

Dear sir/ma,

Patient name……

Age …….. Sex ……

Please urgently see and evaluate the above-named child who was found to have features suggestive of …….. during eye screening at an immunisation clinic.

Thank you.

……

Dr B.A. Olusanya

APPENDIX F. POST-STUDY QUESTIONNAIRE FOR IMMUNISATION CLINIC STAFF

Study Number: _____

Study title: Developing a screening tool for blinding eye diseases in infants attending immunisation clinics in Ibadan, Nigeria.

Dear participant,

This questionnaire is aimed at evaluating your experience with use of the checklist for screening for eye diseases in children during the study period. Be assured of utmost confidentiality, your answers shall not be linked to you. Please do not write your name or phone number or any other thing that can identify you on this form. Read the questions carefully and provide sincere and honest answers.

Date: _____

Local Government Area: _____

Primary Health Care centre: _____

Please circle or tick the appropriate answer

1. Did you find the checklist for screening eye diseases in children useful?
   a. Yes b. No c. Not sure

2. If yes to question 1, how useful was the checklist for screening for eye diseases in children?
   a. A bit useful b. Moderately useful c. Very Useful

3. Did you find it easy to use the checklist to screen for eye disease in children?
   a. Yes b. No c. Not sure

4. If yes to question 3, how easy was it to use the checklist to screen for eye diseases in children?

a. A bit easy b. Moderately easy c. Very easy

5. What was the average period of time that you spent using the checklist on one child? _____ minutes

6. Did you experience any challenge or difficulty while using the checklist during the study?
   a. Yes b. No
7. If Yes to Question 6, which challenge(s) did you have?
   (You may select more than one option, if applicable)
   a. Difficulty with understanding how to use the checklist (If yes, mention the section or question that you had difficulty with……..)
   b. Difficulty with interpretation of the scores on the checklist
   c. Difficulty with obtaining answers from some mothers/caregivers
   d. Difficulty with examining some of the children
   e. Poor cooperation from some mothers/caregivers
   f. Poor cooperation from some children
   g. Use of the checklist was time-consuming
   h. Inadequate number of staff
   i. Others (Please specify):…… …..
8. Did you learn any new skill(s) while using the checklist during the study?
   a. Yes b. No

9. If yes to question 8, mention one skill you learned while using the checklist during the study.

   ……
   ……

10. Do you feel confident that you can detect eye diseases in children by using the checklist after the study period?

a. Yes b. No c. Not sure

11. If yes to question 10, how confident are you?

a. A little confidence b. Moderate confidence c. Much confidence

12. Do you have any suggestion(s) for modifying or improving the checklist?

a. Yes b. No

13. If Yes to question 12, please mention the suggestion(s) that you have for modifying or improving the checklist.

……

……..

……

……..

Thank you for your cooperation and participation in the study

APPENDIX G. ETHICAL APPROVAL

INSTITUTE FOR ADVANCED MEDICAL RESEARCH AND TRAINING (IAMRAT)
College of Medicine, University of Ibadan, Ibadan, Nigeria.

Director: **Prof. Catherine O. Falade,** MBBS (Ib), M.Sc., FMCP, FWACP
Tel: 0803 326 4593, 0802 360 9151
e-mail: cfalade@comui.edu.ng lillyfunke@yahoo.com

UI/UCH EC Registration Number: **NHREC/05/01/2008a**

NOTICE OF FULL APPROVAL AFTER FULL COMMITTEE REVIEW

Re: Development and Validation of a Screening Tool for Early detection of Eye Diseases among Infants attending Immunization Clinics in Ibadan, Nigeria

UI/UCH Ethics Committee assigned number: UI/EC/17/0116

Name of Principal Investigator: **Dr. B. A. Olusanya**
Address of Principal Investigator: Department of Ophthalmology
College of Medicine,
University of Ibadan, Ibadan

Date of receipt of valid application: 05/04/2017

Date of meeting when final determination on ethical approval was made: **N/A**

This is to inform you that the research described in the submitted protocol, the consent forms, and other participant information materials have been reviewed and *given full approval by the UI/UCH Ethics Committee.*

This approval dates from **08/05/2017 to 07/05/2018.** If there is delay in starting the research, please inform the UI/UCH Ethics Committee so that the dates of approval can be adjusted accordingly. Note that no participant accrual or activity related to this research may be conducted outside of these dates. *All informed consent forms used in this study must carry the* UI/UCH EC *assigned number and duration of* UI/UCH EC *approval of the study.* It is expected that you submit your annual report as well as an annual request for the project renewal to the UI/UCH EC at least four weeks before the expiration of this approval in order to avoid disruption of your research.

The National Code for Health Research Ethics requires you to comply with all institutional guidelines, rules and regulations and with the tenets of the Code including ensuring that all adverse events are reported promptly to the UI/UCH EC. *No changes are permitted in the research without prior approval by the* UI/UCH EC *except in circumstances outlined in the Code. The* UI/UCH EC *reserves the right to conduct compliance visit to your research site without previous notification.*

UI/UCH EC APPROVED COLLEGE OF MEDICINE, U.I.

Professor Catherine O. Falade
Director, IAMRAT
Chairperson, UI/UCH Ethics Committee
E-mail: uiuchec@gmail.com

APPENDIX H. CONSENT FORMS

A. Informed consent form - Immunisation staff

Study title: Developing a screening tool for eye diseases in infants attending immunisation clinics in Ibadan, Nigeria.

INFORMED CONSENT TO PARTICIPATE IN THE STUDY

Study number: _____

IRB Research approval number:

This approval will elapse on:

My name is Dr. Bolutife OLUSANYA, a PhD candidate of the Department of Epidemiology & Medical Statistics, University of Ibadan. I also work as a paediatric ophthalmologist in the Department of Ophthalmology, University College Hospital, Ibadan.

I am conducting a study on early detection of eye disease among infants during immunisation visits. The aim of the study is to determine whether a newly developed screening checklist can improve the ability of immunisation clinic staff to detect eye diseases in infants. It is believed that the information generated by this study will be useful for developing and implementing interventions that will ensure early detection, early presentation and prompt treatment of eye diseases in children.

As an immunisation clinic staff working in Ibadan, Oyo state, you are being invited to partake in this study. Your participation will involve filling a short questionnaire and the use of a checklist to screen infants during their immunisation clinic visits. It is expected that the screening process for each child will take about 5 minutes. You will be requested to screen between 15 and 20 babies over a period of 3 - 4 months.

After you have screened an infant, a consultant ophthalmologist will also examine the child to confirm the presence of absence or eye disease. The ophthalmologist will not be allowed to have any information on the result of your screening, to avoid bias. This

examination by the specialist is to ascertain to what extent the screening tool can correctly guide immunisation staff in the detection of eye disease in children.

There are no risks involved in your participation in this study. No harmful or invasive procedures are involved in the study; therefore, no physical harm is envisaged.

The benefits that you may derive from participation in this study include improvement in your knowledge and ability to detect eye diseases in children.

Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. Also, you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Confidentiality of the information you provide will be ensured throughout the study. All information collected in this study will be given code numbers and no name will be recorded. This cannot be linked to you in anyway and your name or any identifier will not be used in any publication or reports from this study. As part of my responsibility to conduct this research properly, officials from Research Ethics Committee may have access to these records.

If you agree to participate in this study, kindly sign the attached form. Thank you.

Statement of person obtaining informed consent:

I have fully explained the aim and study procedure for this research to _____ and have provided adequate information, including the risks and benefits, to allow an informed decision to be made.

DATE:_____SIGNATURE: _____

NAME: _____

Statement of person giving consent:

I have carefully read and thoroughly understand the explanation of the research. I have also had a satisfactory discussion with the investigator. I have full understanding that my participation is voluntary. I have adequate knowledge about the aim, procedures, risks and benefits of the research to allow me decide that I want to take part in it. And I understand that I may freely withdraw from the study at any time.

DATE:_____SIGNATURE: _____

NAME: _____

WITNESS' SIGNATURE (if applicable): _____

WITNESS' NAME (if applicable): _____

Additional information:

In addition, if you have any questions about your involvement in this research, you can contact the researcher, Dr Bolutife OLUSANYA, Department of Ophthalmology, University College Hospital, Ibadan. (Phone No. +2348034051563; Email: bolutifeo@yahoo.com).

This research has been approved by the Ethics Committee of the University of Ibadan and the Chairman of this Committee can be contacted at Biode Building, Room 210, 2nd Floor, Institute for Advanced Medical Research and Training, College of Medicine, University of Ibadan, E-mail: uiuchirc@yahoo.com and uiuchec@gmail.com

B. Informed consent form – Infants' mothers/ caregivers

<u>Study title</u>: Developing a screening tool for eye diseases in infants attending immunisation clinics in Ibadan, Nigeria.

INFORMED CONSENT TO PARTICIPATE IN THE STUDY

Study number: _____

IRB Research approval number:

This approval will elapse on:

My name is Dr. Bolutife OLUSANYA, a PhD candidate of the Department of Epidemiology & Medical Statistics, University of Ibadan. I also work as a paediatric ophthalmologist in the Department of Ophthalmology, University College Hospital, Ibadan.

I am conducting a study on early detection of eye disease among infants during immunisation visits. The aim of the study is to determine whether a newly developed screening checklist can improve the ability of immunisation clinic staff to detect eye diseases in infants. It is believed that the information generated by this study will be useful for developing and implementing interventions that will ensure early detection, early presentation and prompt treatment of eye diseases in children.

As a mother or caregiver who has brought your child for immunisation you are being invited to partake in this study. Your participation will involve answering some questions about your child's medical history. Thereafter, the immunisation staff will use a checklist to check if your child has eye disease. It is expected that this screening process will take about 5 minutes.

After your child has been screened by the immunisation staff, a consultant ophthalmologist will also examine the child to confirm the presence or absence of eye disease. This examination by the specialist should take about 5 minutes and its purpose is to ascertain to what extent the screening tool can correctly guide immunisation staff in the detection of eye disease in children.

There are no risks involved in your participation in this study. No harmful or invasive examination procedures are involved in the study, therefore no physical harm is envisaged.

The benefits that you may derive from participation in this study include reassurance that your child does not have any eye problem. However, if we detect any eye problem in your child, a referral for further evaluation and treatment at the Eye clinic, University College Hospital, Ibadan will be given to you. We promise to attend to your child immediately you present there.

Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. Also, you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Your confidentiality will be ensured throughout the study. All information collected in this study will be given code numbers and no name will be recorded. This cannot be linked to you in anyway and your name or any identifier will not be used in any publication or reports from this study. As part of my responsibility to conduct this research properly, officials from Research Ethics Committee may have access to these records.

If you agree to participate in this study, kindly sign the attached form. Thank you.

Statement of person obtaining informed consent:

I have fully explained the aim and study procedure for this research to _____ and have provided adequate information, including the risks and benefits, to allow an informed decision to be made.

DATE:_____SIGNATURE: _____

NAME: _____

Statement of person giving consent:

I have carefully read and thoroughly understand the explanation of the research. I have also had a satisfactory discussion with the investigator. I have full understanding that my participation is voluntary. I have adequate knowledge about the aim, procedures, risks and benefits of the research to allow me decide that I want to take part in it. And I understand that I may freely withdraw from the study at any time.

DATE:_____SIGNATURE: _____

NAME: _____

WITNESS' SIGNATURE (if applicable): _____

WITNESS' NAME (if applicable): _____

Additional information:

In addition, if you have any questions about your involvement in this research, you can contact the researcher, Dr Bolutife OLUSANYA, Department of Ophthalmology, University College Hospital, Ibadan. (Phone No. +2348034051563; Email: bolutifeo@yahoo.com).

This research has been approved by the Ethics Committee of the University of Ibadan and the Chairman of this Committee can be contacted at Biode Building, Room 210, 2nd Floor, Institute for Advanced Medical Research and Training, College of Medicine, University of Ibadan, E-mail: uiuchirc@yahoo.com and uiuchec@gmail.com

B. Iwe Erongba – Iya Omo/alagbato

<u>Akole Iwadi:</u> Sise agbedide irinse ti yoo tojo fun ti tete se awari awon aisan oju laarin awon omode to nwa si ile alabere ajesara ni ilu Ibadan

AFIHAN ERONGBA LATI LOWO NINU IWADI NAA

Iye Onka:_____

Onya Iyonda iwadi IRB:

Iyonda yi yoo wa sopin ni:

Dokita Bolutife OLUSANYA ni orunko mi, akeko ipele agba (PhD) ni eka to nwadi lori itankale ati kikapa awon orisirisi arun ati ririsi igbelewon eto ilera ti ile eko giga Unifasiti Ibadan. Mo si tun nsise gegebi dokita oloju ti awon omode ni eka itoju oju ti ile iwosan Oritamefa Ibadan.

Mo nse iwadi lori titete se awari aisan oju laarin awon omode lakoko tiwon wa gba abere ajesara. Afojusun lori iwadi yi ni boya awon osise nile abere ajesara le ja fafa si lati se awari aisan oju loju awon omode nipase agbejade iwe fifowosi tuntun kan. Igbagbo wa nipe awon oro ti a ba gba sile ni akoko iwadi yi yoo je lilo fun igbelaruge ati agbekale awon eto fun aridaju titete se awari, titete se afihan ati sise itoju awon aisan oju awon omode deede.

A npe yin gegebi iya tabi alagbato to mu omo rewa gba abere ajesara lati kopa ninu iwadi yi. Ikopa yin yoo mu yin dahun awon ibeere kan nipa ilera omo yin.

Lehinnaa, ni osise alabere ajesara yoo ye akosile wo boya omo yin ni. A nireti wipe gbogbo eto ayewo yi yoo gba to bii iseju marun.

Lehin ti osise alabere ajesara bati ye omo yin wo tan Dokita agba oloju yoo tun ye omo naa wo lati fidi re mule boya omo naa ni aisan oju tabi koni. Ayewo ti akose-mose seyi yoo tun gba bii iseju marun miran, eredi re si nipe bi ohun elo ayewo se le se deede to lati se atona osise alabere ajesara nipa sise awari aisan oju lara omode. Kosi ewu kankan fun yin bie ba kopa ninu iwadi yii.

Igbese ayewo kankan ko lewu ninu iwadi yii nitori kosi ohunkohun to le payin lara.

Awon anfaani to seese kie rigba teba kopa ninu iwadi yii ni ninu idaniloju wipe aisan kankan kosi loju omo yin ewe, ti a baganni aisan kan loju omo yin, ao kowe lati ma aba agbeyewo ati itoju oju naa lo ni ile itoju oju ti ile iwosan nla Oritamefa ibi le yin lowo. A seleri lati tete dayin lohun ni kete tie bati de ibe.

Tie bafe ni e le kopa, kosi si idajo tabi adanu kankan tie ba ko. Bakanna e le da ikopa duro nigbakugba laisi adanu tabi yiya kankan. A mu dayin loju pe gbogbo oro yin lakoko iwadi yi lao pamo, ao kan se ami onka le won lori ni ao si ni ko oruko kankan sile. Koni seese fun enikeni lati fi eyi dayin mo, beeni a koni te oruko yin tabi idanimo yin kankan jade tabi ninu abo iwadi yi.

Gegebi abala kan ojuse mi lati seto iwadi yi dada, o seese ki awon osise alamojuto eto iwadi ni awon akosile yi.

Jowo buwo lu iwe yi ti o bat i gba lati kopa ninu iwadi yi. E se pupo

Oro eni to ngba ohun sile:

Mo ti salaye kikun nipa iwadi yi fun_____ mo si ti bawon soro ti o to titi fimo awon ewu ati anfani, eyi tole muwon pinnu.

OJO: _____ BUWO LUWE: _____

ORUKO: _____

Oro eniti a ngba ohun re sile:

Mo ti ka apejuwe iwadi yi o si ti yemi. Mo si ti ba oluwadi so eyi totemi lorun. O yemi wipe bimo bafe ni mole kopa, mo ti mo pupo nipa eredi, liana, ewu ati anfani iwadi yi to nse afihan wipe mofe lati kopa nibe ati yonda lati se ayewo aisan oju fun omo mi.

O yemi wipe mole da ikopa mi ninu iwadi yi duro nigbakugba.

OJO: _____BUWOLUWE: _____

ORUKO: _____

BIBUWO LUWE ELERI (to baye): _____

ORUKO ELERI (to bawa): _____

Afikun oro:

Ni afikun, tie bani ibeere nipa ikopa yi lori iwadi yi, e lekan si. Oluwadi agba, Dokita Bolutife OLUSANYA eka to ntoju oju ni ile iwosan nla Oritamefa, Ibadan. (Nomba Ero ibanisoro +2348034051563; Ero ayelujara: bolutifeo@yahoo.som)

Iwadi yi ti gba ase lati odo awon igbimo to nri si oro iwadi ni ile-eko giga Unifasiti Ibadan, a sile kan si Alaga igbimo ti Ile Biode, yara igba-le-mewa ni aja keji, Ero ayelujara: uiuchirc@yahoo.com ati uiuchec@gmail.com

Plate 1. Training of primary health workers on screening for childhood eye diseases using the screening checklist

Plate 2. Research assistant administering the study questionnaire on an infant's mother

Plate 3. An immunisation staff asking questions from an infant's mother while using the screening checklist

Plate 4. An immunisation staff examining an infant while using the screening checklist

Plate 5. Examination of an infant's eyes by the ophthalmologist

Plate 6. Red reflex test being performed on an infant's eyes by the ophthalmologist