Vision Screening in Preschoolers (VSP) Study

A thesis presented to the graduate faculty of The New England College of Optometry in partial fulfillment of the requirements for the degree of Master of Science

May 1, 2009

Rajvinder K. Pabla

Vision Screening in Preschooler (VSP) Study

R. Pabla

This manuscript has been read and accepted by the Thesis Examination Committee in satisfaction of the thesis requirements for the degree of Master of Vision Science.

5/28/09
Date

Bruce Moore
Graduate Studies Faculty Advisor

D. Luisa Mayer, Ph.D.

Thesis Examination Committee

5/28/09
Date

Nancy J. Coletta
Director of Graduate Studies

The New England College of Optometry

Executive Summary

VISION SCREENING IN PRESCHOOLERS (VSP) STUDY

Rajvinder K. Pabla

The New England College of Optometry

Introduction:

There is urgent need to empower communities with sustainable, economic, and efficient eye care. Screenings are an effective means to identifying children who need further eye care. Using lay screeners to perform vision screenings improves accessibility to screenings for preschoolers, thereby increasing the detection of potentially visually impairing conditions like amblyopia.

Purpose:

The Vision Screening in Preschoolers (VSP) Study consisted of three phases. The purpose of Phase I was to evaluate and modify the VERAS cards to improve the user-friendliness and ergonomics of the test. Phase II aimed at training 12 lay screeners in El Salvador to use the M-VERAS cards developed in Phase I on preschoolers. Phase II also attempted to determine the testability of the M-VERAS cards in a small sample of El Salvadoran preschoolers. The primary purpose of Phase III was to determine the testability of the M-VERAS acuity cards and the Lea Light Box (LLB) acuity chart in preschoolers when screened by lay screeners. Secondarily, in Phase III, the sensitivities and specificities of the two tests were assessed by comparing the screening results to gold standard examinations (GSE).

Methods:

In Phase I, suggestions on how to improve the design, layout, and user-friendliness of the cards, were obtained from a focus group composed of Head Start volunteers in Boston. A questionnaire examined the volunteers' perceptions of the cards and screening process. The suggestions were analyzed and were incorporated into the modification of the current screening tools, creating the M-VERAS cards.

In Phase II, 12 lay screeners in El Salvador attended a half-day training session to learn to screen with the M-VERAS cards. Fifteen preschoolers between 3-6 years of age were screened by one of the 12 lay screeners in a preschool center in El Salvador. All 15 then underwent GSE in El Salvador.

Phase III involved training two lay screeners in Boston to perform screenings using the M-VERAS cards and the Lea Light Box (LLB) chart. Screenings took place across 9 Head Start centers in Boston. A randomized study design was utilized, whereby half the children were screened first with the M-VERAS cards and secondly with the LLB chart by the same screener, and vice versa. Fifty-two randomly selected children (23.8% of the passes) who passed both screening tests underwent GSE. Another 38 children who underwent GSE had failed the screening with either or both of the screening tests.

Results:

Through the feedback from the focus group, the M-VERAS cards were successfully developed. Lay screeners were successfully trained in Phase II and III to perform vision screenings. In Phase II, testability was found to be 93.3% with the M-VERAS cards. One child who failed the screening was found to have a congenital cataract by GSE. In Phase III,

277 children (3.94±0.61 years) were screened. The failure rate on screenings was 19.5%. The testability of the M-VERAS cards and the LLB chart was 100% for both. The sensitivities of the M-VERAS cards and LLB chart were 45.4% (CI 29.5, 61.2%) and 58.3% (CI 42.6, 74.0%) respectively. The specificities were 92.2% (CI 85.0, 99.5%) for the M-VERAS cards and 97.8% (CI 93.8, 100%) for the LLB chart. Statistically, the differences in the sensitivities and specificities between the two tests were not significant (p=0.3863 and p= 0.0736 respectively). All values were corrected for verification bias.

Conclusions:

Undoubtedly, access to high quality vision screenings for the preschool-age group is desperately needed. The M-VERAS cards and the LLB acuity chart are two easy-to-use and effective screening tools with a high rate of testability, at least in the population of preschoolers examined in this study. Due to small sample size, many limitations exist in this study and are discussed at length in the text. The sensitivities and specificities obtained for these two tools are comparable to values obtained in similar studies. As such, these two tools should be considered in the screening of preschoolers in the United States and globally.

Acknowledgements

I am deeply thankful for the Akal Purakh's immeasurable Kirpa, without which this project could never have begun, and could never have been completed.

I would like to thank my family for their infinite sacrifices, support, encouragement and love. I am whole-heartedly grateful to my loving husband whose support and love has helped me fulfill my dreams.

A special thanks is due to my mentor and friend Dr Bruce Moore, who has provided endless insight, support, encouragement, and guidance in the research and writing involved in this paper.

Many thanks to all who have contributed to this project—the Head Start personnel, the NECO library staff, especially Claire, Good-Lite Inc, my friends, and countless others.

TABLE OF CONTENTS

PHASE II

PHASE III

Figures

Tables

General Introduction

Importance of the Detection of Vision Disorders in the Preschool Years

Vision disorders are the fourth leading cause of disability in children in the United States (Ciner, Dobson, Schmidt, Allen, & Cyert et al, 1999), affecting nearly 8-10% of children under five years of age (Ferebee, U.S Preventative Services Task Force [USPSTF], 2004). The prevalence is believed to be greater in medically underserved areas (Ramsey & Bradford, 2006). Common visual impairments include significant refractive error, amblyopia and strabismus (Optometric Clinical Practice Guideline, 2002; Ciner et al, 1999; Ciner, Schmidt, Orel-Bixler, Dobson, Maguire, et al, 1998). Vision problems that are left untreated can lead to amblyopia and learning difficulties (Prevent Blindness America; Woodruff, 1972), affecting school performance, and later, adult self image (USPSTF, 2004). Fortunately, most common ocular conditions are treatable, and if detected early enough, permanent reduction of visual acuity can be prevented (Ciner, et al, 1999). Studies have shown that amblyopic patients have a greater chance of becoming blind in the fellow eye compared to the non-amblyopic control subjects (Jugnoo, Logan, Timms, Russell-Eggitt, & Taylor, 2002; Tomilla & Tarkkanen, 1981). It is arguable that the loss of vision in one eye alone may not be a great burden. However, the loss of functional vision in both eyes unquestionably is a major concern and as such, amblyopia could likely be the biggest public health issue concerning the vision of preschool populations (Moore, 2006). Due to the asymptomatic nature of many childhood vision disorders, these conditions often go undetected and untreated. Thus, early screening programs are necessary in order to improve

the early detection and treatment of these vision disorders. While astigmatism and refractive error are correctable with lenses, amblyopia and strabismus may involve more complex forms of treatment.

Importance of Amblyopia

Amblyopia

Amblyopia is a leading cause of monocular vision loss. Amblyopia is defined as reduced visual acuity in the absence of a detectable organic lesion of the eye and associated structures, and in the absence of simple uncorrected refractive error (USPSTF, 2004). There are three major amblyogenic risk factors or specific categories of amblyopia: strabismus, high refractive error and anisometropia, and visual form deprivation (Steinman, Steinman, & Garzia, 2000). About 2-5% of children are at risk for developing amblyopia (Joish, Malone & Miller, 2003; Donahue, Johnson, & Leonard-Martin, 2000; Thompson, Woodruff, Hiscox, Strong, & Minshull, 1991).

Strabismic Amblyopia

According to the definition used by Steinman et al (2000), strabismic amblyopia is amblyopia that is associated with the occurrence of strabismus. Amblyopia results when one eye is constantly esotropic or constantly exotropic. The deviating eye is unable to obtain a clear image and as such, suppression of that eye can result if left untreated. A critical period exists for which the condition can be treated and vision can be salvaged in the deviated eye. In the case of a unilateral constant strabismus, if the affected eye is not treated by about age 3-5 years, there can be irrecoverable visual acuity loss. This emphasizes the need for early detection of such conditions through sensitive and specific regimens.

Refractive and Anisometropic Amblyopia

Anisometropic amblyopia results when there is a difference between the refractive errors of the two eyes (Steinman, et al, 2000). A difference in refractive error is an amblyogenic factor because one eye will have a clearer image than the other as a result of consensual accommodative responses. The other eye will have a degraded image and as such, that eye and the visual cortex associated with vision from that eye does not have the opportunity to develop sharp resolution ability. This is especially important in hyperopia. Highly hyperopic children are also at risk for accommodative esotropia, a strabismus that develops as a by-product of the high refractive error.

Deprivation Amblyopia

Deprivation amblyopia is amblyopia that results due to an obstruction of the optical pathway or an abnormality in the retina or optic nerve that prevents the formation of a clear image on the retina (Steinman, et al, 2000). Such an obstruction may be due to untreated ptosis, corneal opacification, congenital or traumatic cataract, or an abnormality of the retina or optic nerve (e.g. optic nerve hypoplasia or atrophy, or a macular scar). It is the least common of the three types of amblyopias discussed. However, it has the most severe consequences for visual acuity loss.

Definitions Used in Screening Programs

Screening is defined as the presumptive identification of unrecognized disease or defect by the application of tests, examination or other procedures which can be rapidly applied to sort out apparently well persons who probably have a disease from those who

probably do not (van Belle, Fisher, Heagerty, & Lumley, 2004; MacPherson, Brauntein & La Roche, 1991).

Testability as used in the Vision Screening in Preschoolers (VSP) Study refers to the percentage of children who were actually able to do the screening tests. Literature reports for rates of testability vary greatly, depending on the screening tools used, screening personnel, and myriad other factors. The criteria for testability used in the VSP Study is discussed below in the Methods section (see Pass and Fail Criteria).

Two particular values of concern when calculating the efficacy of a screening program are sensitivity and specificity (Schmidt, 1992). Sensitivity refers to the ability of a screening tool to correctly identify the presence of a disease (true positive) while specificity looks at the ability of a screening tool to correctly identify the absence of disease (true negative). False positive tests refer to failing a screening test when the subject does not have the disease. A false negative test refers to passing the screening test when the subject has the disease (van Belle et al, 2004; Lin-Fu, 1971).

Characteristics of a Good Screening Program

In order to be efficacious, a good screening tool needs to possess the following qualities. The test needs to be accurate. In other words, it needs to have high specificity and sensitivity. Further, it needs to be precise, low-cost, and easy to administer. The test should also have clearly defined pass and fail criteria (Moore, 2006). The screening program itself should be aimed at detecting conditions with a high enough prevalence to warrant the cost associated with screening. The program also needs to be directed at detecting disease with significant morbidity for which treatment is available and effective in order to reduce

morbidity or to prevent disease. The screening program should also be targeted to the population most at risk for developing the condition being screened. More importantly, there needs to be some benefit for early detection for the condition being screened. Lastly, the availability of follow-up care is also an important consideration (Moore, 2006; MacPherson, et al, 1991).

Rationale for Vision Screenings

It is well-known that the majority of early learning is done through visual media. As such, visual impairments can seriously impede learning, leaving children with vision problems at greater risk for poor academic performance, poor self-esteem, and other psychosocial issues (Optometric Clinical Practice Guideline: Learning Related Vision Problems, 2000). To ensure all children receive the opportunity to develop to their maximum educational and social potential, it is necessary to ensure they have good vision. Ideally, it is believed that all children should receive comprehensive vision examinations before entering school. Yet this poses a question of whether it is possible for every child to undergo expensive eye examinations by eye care professionals who are unevenly distributed across the country and the globe. Very often, the cost of seeing an eye care professional makes it difficult for families to pay for eye care services for their children. Further, the Head Start, Medicaid, and CHIP: Partners for Healthy Children report outlines several other barriers to health care including language and cultural barriers, time away from work, and transportation issues. Ramsey and Bradford (2006) site an extreme example from Kentucky where children who do not show proof of having had a comprehensive eye exam could be denied entry into the school system. Implementation of such a law has been suspended due to opposition from

various groups who feel such requirements impose unnecessary financial burden on families. Clearly, full eye examinations for all children before the start of school are not feasible for many reasons.

Vision screenings are an effective and economic way to identify children in need of further examination by an eye care professional (Ramsey & Bradford, 2006; Joish, et al, 2003; Konig & Barry, 2002; Donahue, et al, 2000; Ciner, et al, 1999; Robinson, Bobier, Martin, & Bryant, 1999). Screenings are a quick, efficient and relatively accurate way to assess which children will benefit most from seeing an eye care specialist. Furthermore, according to national Head Start policy, all children are, in fact, required to receive a vision screening promptly after entering the Head Start system. The World Health Organization (WHO) also recommends vision screenings. However, what constitutes a satisfactory vision screening is not well defined. How vision screenings should be performed is partly what the VSP Study attempted to establish.

Benefits of Vision Screenings

Frequently, it is stated that 80% of all learning typically comes from the process of vision. As described earlier, 8-10% of preschool children have significant vision-related problems (USPSTF, 2004). Thus, for a significant percentage of preschool children, vision problems may be an impediment to learning. Furthermore, children with significant vision problems may often have behavioral and attentional deficits compounding their difficulty with the learning process. Therefore, vision problems play a very important role in a child's education. Early detection and mitigation of these vision problems may have dramatic affects on a child's ability to learn.

According to Moore (2006), the current system of vision screenings performed on preschoolers is fundamentally broken. Relatively few children (14%) receive eye examinations prior to entering school (Ciner et al, 1998). A larger number (21%) receive vision screenings but many of those screenings have been shown to be scientifically invalid, ineffective and inaccurate at detecting vision problems (Moore, 2006). In Scandinavia, this problem has largely been solved. Based upon their national health care system, a highly efficient and effective system of screening, treatment, and follow-up was established for detecting preschool vision disorders. By doing so, the prevalence of amblyopia in Scandinavia has dropped from the typical 3% prevalence in the developed world to 0.2%. This translates into a 90% reduction of the single largest cause of childhood vision impairment (Moore, 2006). It is obvious that the United States is not the same as Scandinavia in terms of population demographics or health care systems. The American population, and especially the Head Start population, is heterogeneous. We must develop screening tools that meet the needs of the diverse American population.

In children, according to various studies, the prevalence of ocular morbidity is largely due to refractive error and amblyopia. In a study of children 5-15 years of age in New Delhi, for example, it was found that 81.7% of visual impairment could be attributed to uncorrected refractive error (Murthy, Gupta, Ellwein, Munoz, Pokharel, et al, 2002). This group of investigators found amblyopia to be the second leading cause of visual impairment in their study population. Hornby, Gothwal, Gilber, Dandona and Foster (2000) investigated the cause of blindness in children (aged 0 to 15 years) enrolled in special education programs for the blind in India. These investigators found that 1 in 7 of these children were able to achieve

normal print visual acuities with proper optical correction. Evidently, visual impairment due to refractive error and amblyopia are common and are treatable. As such, it is only sensible to invest in developing an effective and sustainable screening program that may ultimately aid in the detection of these and other conditions, thereby improving the quality of life for children across the globe (Dandona & Dandona, 2001a).

While there is solid evidence to support superior visual outcome with earlier detection of vision disorders in children, there is also an undeniable economic benefit for the detection of childhood visual impairment. According to Shamanna, Dandona, and Rao (1998), the economic burden of blindness in the Indian population alone in 1997 was estimated at $US 4.4 million. Childhood blindness accounted for 28.7% of lifetime loss from blindness out of the cumulative loss of $US 77.4 million (World Health Organization, 2005). An Australian study demonstrated that the years of life lost due to disability from visual disorders is 2.7% of the national total in 2004. These figures run similar to those for diabetes and coronary heart disease in this country (WHO, 2005). Using the model of blind-person years, it has been reported that pediatric blindness globally accounts for 75 million blind-person years (Mandal, 2001). Conservative estimates that consider only the personal productivity loss of individuals with visual impairment, place the annual global economic impact of untreated blindness and low vision at $US 42 billion in the year 2000. This figure was projected to rise to $US 110 billion per year by the year 2020 if no intervention occurred (WHO, 2005). Undoubtedly, there are economic benefits to vision screening programs since early detection and treatment of these disorders may offset the high costs of later treatment and costs associated with visual impairment and blindness.

Rationale for Using Lay Screeners

Eye care professionals in many places around the United States and globally are poorly distributed and as such, doctors may not be readily accessible to conduct vision screenings promptly and regularly. On an international level, reports by the United Nations Educational, Scientific and Cultural Organization (UNESCO) have illustrated a large proportion of the world's population still remains outside of urban areas. As indicated above, most medical professionals are highly concentrated in urban centers. This means there is even a greater disparity for access to reasonable eye care for most of the world's population (Rius, Guisasola, Stobart, Grasas, & Rius, 2004). A necessary solution to this poor availability of eye care professionals is to train teachers and community workers to perform basic vision screenings.

Several studies in the United States (The Vision in Preschoolers [VIP] Study, 2005; Chui, Fraser, Hoar & La Roche, 2004; Donahue, et al., 2000) have shown that lay screeners are capable of achieving high rates of testability, sensitivity, and specificity once undergoing appropriate training and when screening using the right tools. According to the VIP Study (2005), lay screeners were able to administer the single Lea optotype visual acuity tests with equal sensitivity compared to nurse screeners administering the test. Furthermore, when lay screeners conducted the screenings at five-feet (after adjusting optotype size to maintain validity), sensitivity improved dramatically.

Limburg, Kansara, and d'Souza (1999) calculated that in India, an average population of 200 000 per ophthalmic assistant would mean 48 000 children need to be screened by each assistant—an impossible task. Limburg et al (1999) estimated that using teachers as primary

screeners reduced the workload by a factor of 20 for ophthalmic assistants and ophthalmologists who screen. Another group (Nirmalan, Vijaylakshmi, Sheeladevi, Kothari, Sundaresan, et al, 2003) found that lay screeners could be effectively trained to identify children with ocular abnormalities after a two-week training period. As such, it is not unreasonable to assume that screening systems can be effectively implemented in the developing world such that lay screeners with minimal training are able to effectively screen preschool children in their communities, thereby identifying children with potential visual problems earlier. Ideally, this would translate to earlier treatment and improved visual prognosis.

Crowded Lea Symbols as Stimuli for Visual Acuity Screening

Various different optotypes for use in children have been developed in the past. The crowded Lea optotypes were used in the VIP Study (2005). Several reports have indicated that Lea optotypes are very effective in screening children (VIP Study, 2005; Kvarnstrom & Jacobson, 2005; Shallo-Hoffman, Coulter, Oliver, Hardigan, & Blavo, 2004; Hered, Murphy, & Clancy, 1999). Shallo-Hoffman et al (2004) reported that a higher proportion of three-year-olds were testable with Lea symbols as compared with the HOTV optotypes. Both tests can be conducted without requiring the child to name the Lea or HOTV optotypes. The child instead matches the optotype that the screener presents at distance to one of the four optotypes on the lap card in front of the child. However, the Lea optotypes appear more useful for testing the multilingual and multiethnic preschool population compared to a test using letters like the HOTV set. Developmentally, children also become familiar with shapes sooner than they become familiar with letters, thereby making the Lea optotypes more salient

for screening preschool children. Several studies have determined that the Lea optotypes are effective in the detection of amblyopia and amblyogenic factors (Ruttum & Dahlgreen, 2006; Becker, Hubsch, Graf, & Kaufman, 2000). The Lea symbols are believed to be excellent optotypes since the optotypes are believed to blur equally, thereby reducing the chance of guessing the correct shape (Hyvarinen, Nasanen, & Laurinen, 1980). Becker et al (2000) further suggest that there is little difference between Lea symbol acuity and Landolt C acuity (the international standard) and these two tests may provide more accurate estimates of acuity since these symbols are more difficult to discern compared to letters.

The Spatial Crowding Phenomenon

Spatial crowding is a well-known effect defined as the reduction of visibility of a target when presented with neighboring distractors (Levi, 2008). While the visual acuity of all individuals is reduced to some degree by contour interaction and crowding, amblyopes are particularly susceptible to the effects of crowding (Levi, 2008).

While a full chart of optotypes is most effective for the detection of amblyopia, young children typically respond poorly to the full chart presentation, making testability particularly poor (Flom, Weymouth, & Kahneman, 1963). To improve testability, a line of optotypes or even single optotypes are often used instead of the full chart presentation. In order to maintain the crowding effect for the detection of amblyopia, a contour interaction bar is placed at a distance of half the optotype width around the optotypes in the linear or single optotype presentations. As such, we created a test appropriate for testing most preschool children using single optotypes surrounded by contour interaction bars, a design more likely

to screen for amblyopia, rather than using single optotypes without contours (Levi, 2008; Atkinson, Ankar, Evans, Hall, & Pimm-Smith, 1988; Flom, et al, 1963).

The spatial crowding phenomenon may also negatively impact reading. The reading task involves identifying a sequence of letters in close proximity to each other (Levi, 2008). It is therefore reasonable to assume that amblyopia can contribute to poorer reading abilities partly because the child will have greater difficulty determining letter-order, thereby leading to incorrect identification of the word. As such, amblyopia may have deleterious effects on a child's ability to learn and on academic performance (Levi, 2008). This further highlights the need to screen children to detect vision disorders early.

Importance of Developing a Rational Approach to Accessible Vision Screenings

Millions of children worldwide suffer from some form of visual impairment. Studies vary with the prevalence of decreased vision (less than 20/40 in either eye) ranging from 15.8% in China to 1.4 % in South Africa (Naidoo, Raghunandan, Masbige, Govender, Holden, et al, 2003; Dandona, Dandona, Srinivas, Sahare, Narsaiah, et al, 2002; Murthy, Gupta, Ellwein, Munoz, & Pokharel, 2002; Maul, Barroso, Munoz, Sperduto, & Ellwein, 2000; Negrel, Maul, Pokharel, Zhao, Willwein, et al, 2000; Pokharel, Negrel, Munoz, & Ellwein, 2000, Zhao, Pan, Sui, Munoz, & Sperduto, 2000). With a poor distribution of eye care professionals, the few available practitioners in the developing world tend to focus on the private sector or the management of disease and trauma (Naidoo, et al, 2003). As a result of this, little emphasis, if any, is placed on screenings for young children despite the fact that screenings are undeniably a simple, low-cost, effective initial step to identifying children who may benefit from further optometric or ophthalmologic intervention.

Studies have shown that poor vision is generally correlated to poorer scores on quality of life indices (Broman, Munoz, Rodriquez, Sanchez, Quigley, et al, 2002). Rius, et al's (2004) report further emphasizes the need for the detection of vision problems in children to prevent barriers to learning, and improving the child's quality of life, thereby creating future health cost savings. With such a negative impact on human life, a simple solution such as vision screening can ameliorate many of these problems, if programs are successfully implemented and sustained.

It is unambiguous that there are increased rates of visual impairment in poorer countries as compared to the developed world. Even within one country such as the United States, lower socioeconomic groups tend to be more vulnerable to eye-related illness. Particularly, the most at-risk seem to be low income earners, females, individuals with little or no education, and ethnic minorities (Dandona & Dandona, 2001b). These findings have huge implications on global health initiatives and even public health projects within the United States.

In an effort to improve the quality of life for children globally, and to maximize educational potential (Negrel, et al 2000), a low-cost vision screening program at the community level is desperately needed. Unquestionably, there is a great need to empower communities with respect to healthcare. Through appropriate training and the usage of the low-cost M-VERAS acuity cards and LLB acuity charts, basic vision care services can be provided in every community in the nation and globally. By making vision screenings more accessible to children in underserved communities, a greater number of children with vision disorders will be identified more promptly and at an earlier age before the development of

amblyopia. Early intervention of childhood vision problems will serve to reduce costs for later treatment and more importantly, early detection will help improve the child's ability to learn and gain maximal benefit from their environments.

General Purpose

The VSP Study consisted of three separate phases. The specific purpose of each component of this study is listed below.

Phase I: The primary purpose of this study was to modify the current VERAS cards into a more user-friendly, and ergonomically sound screening tool to be used by lay screeners for screening preschool-aged children.

Phase II: The primary purpose of this pilot study was to train lay screeners in El Salvador on the use of the M-VERAS cards and to determine the testability of these cards on El Salvadoran preschool children when screened by lay screeners.

Phase III: The purpose of this study was to determine the testability of the M-VERAS cards and the LLB chart on preschoolers in Head Start centers in the Boston area when the screenings were performed by lay screeners. Secondarily, data from this study provided information on trends related to the sensitivities and specificities of each test.

Overall, the VSP Study aimed to establish a sustainable, grassroots approach to vision screening with the expectation that preschoolers in underserved communities within the United States and in developing nations would be able to receive quality vision screening services as an early identification mechanism for those at risk for visual impairment.

Based on estimates from the VIP Studies, we hypothesized that about 20% of the children screened would be expected to fail the screenings. We anticipated that the rate of testability may be higher in the LLB chart compared to the M-VERAS cards since children

may be more likely to participate in a test that appears similar to a computer or television screen. However, the sensitivity and specificity of the two tests were expected to be similar since the optotypes used in both tests were the same.

Long-Term Goals

The long-term goals of this study include:

1. Developing and implementing cost-effective, sustainable, highly testable, sensitive and specific vision screening systems for preschool children by lay screeners with minimal training
2. Training local persons in methods of screening preschool children using the M-VERAS acuity cards and the LLB acuity chart
3. Educating and empowering local community members on the importance of vision screenings

General Materials and Methods

Setting

Phase I: The focus group to determine the modifications needed for the VERAS cards was held at one of the Head Start centers in the Boston area. The volunteers were recruited through the help of an onsite Head Start nurse. The session was open to both men and women of any ethnicity.

Phase II: The training session took place in a school in rural El Salvador with 12 lay screeners present. The screenings were conducted by one of the 12 lay screeners at a preschool site different from where the training took place. Gold standard examinations (GSE) took place at the screening site, immediately after the screenings. The tests involved in the GSE in Phase II are described in detail in the Methods section of Phase II.

Phase III: The two lay screeners involved in this phase of the study were trained at the New England College of Optometry (NECO). All screenings took place across 9 Head Start Centers in the Boston area. The children were screened by lay screeners at each of the Head Start sites. GSEs were conducted by licensed eye care professionals next to 6 Head Start sites in the Vision in Preschoolers (VIP) examination van. The VIP van is a 38-foot long vehicle outfitted with 2 exam rooms with full equipment for standardized comprehensive eye examinations on young children. The GSE in Phase III is described at length in the Methods section of Phase III and in Appendix X.

Overview of the Study Population

In Phase I, as mentioned in the section above, the focus session was open to anyone within the Head Start network (parents, staff, volunteers, and teachers) who wished to participate. Likewise, in Phase II, any lay screener who wished to attend the training session was welcome. The children in Phase II were selected since the preschool center they were located at was accessible to the VSP Study group within the geographic and time restraints of this phase of the study. The children were all between 3 and 6 years of age. In Phase III, the lay screeners were selected by the ABCD Head Start Health Administrators but were trained by the VSP Study group at NECO. The children in Phase III were 3-5 years of age and were screened in 9 randomly selected Head Start centers. Each classroom of children at each of the sites had an equally likely chance of being selected for the screenings.

Children reported to have special needs (e.g. children eligible for an early intervention program) were not included in the study since they may have performed differently on vision tests compared to other, typical Head Start children. For the children selected to participate in this study, parental consent was obtained.

Test Materials for Screenings

Modified-VERAS (M-VERAS) Acuity Cards

The original VERAS cards were 12 cards in a flipchart format. The first four cards of the flipchart contained 20/80 (1.6M) equivalent optotypes to be used for binocular testing. The next eight cards were 20/40 (0.8M) optotypes with cards 5-8 for testing the right eye and cards 9-12 for testing the left eye. One optotype was presented per card. The cards were white plastic cards with black optotypes surrounded by contour interaction bars with 50% of

optotype width space between the border of the optotype and the bar. The optotype size for the presented optotype was written on the back of the previous card such that the screener could see the size of the optotype, but not which optotype was being presented to the child. The original VERAS cards did not indicate which eye should be screened with which cards.

The original VERAS cards were then modified to a more ergonomic and user-friendly format, while maintaining all other properties of the original VERAS cards' design (ie same crowding principles, white cards, optotypes and optotype sizes, and same binocular to monocular presentation of the optotypes). Suggestions for changes in the format of the presentation of the cards came from a focus group held with Head Start volunteers in Boston in April 2007 (Phase I of the VSP Study). The Modified-VERAS (M-VERAS) acuity cards used in Phase II and III of the VSP Study were organized in a book format instead of as a flipchart. The single optotypes were printed on the right-sided pages of the book. On the same page, the eye to be tested was indicated and instructions to cover the other eye were also printed. The optotype sizes were not printed onto the cards in the M-VERAS booklet. Unlike the original VERAS cards, the correct optotypes in the M-VERAS cards were listed on the back cover of the booklet to help the screener determine the accuracy of the child's responses without having to turn the book around. The optotypes on the back cover were grouped under three headings: both eyes, right eye and left eye with the respective page number next to each optotype. A 5-foot string was attached to the cards for ease in measuring and maintaining the correct test distance. Figure 1 shows the four Lea optotypes as they appear on the M-VERAS book's lap card.

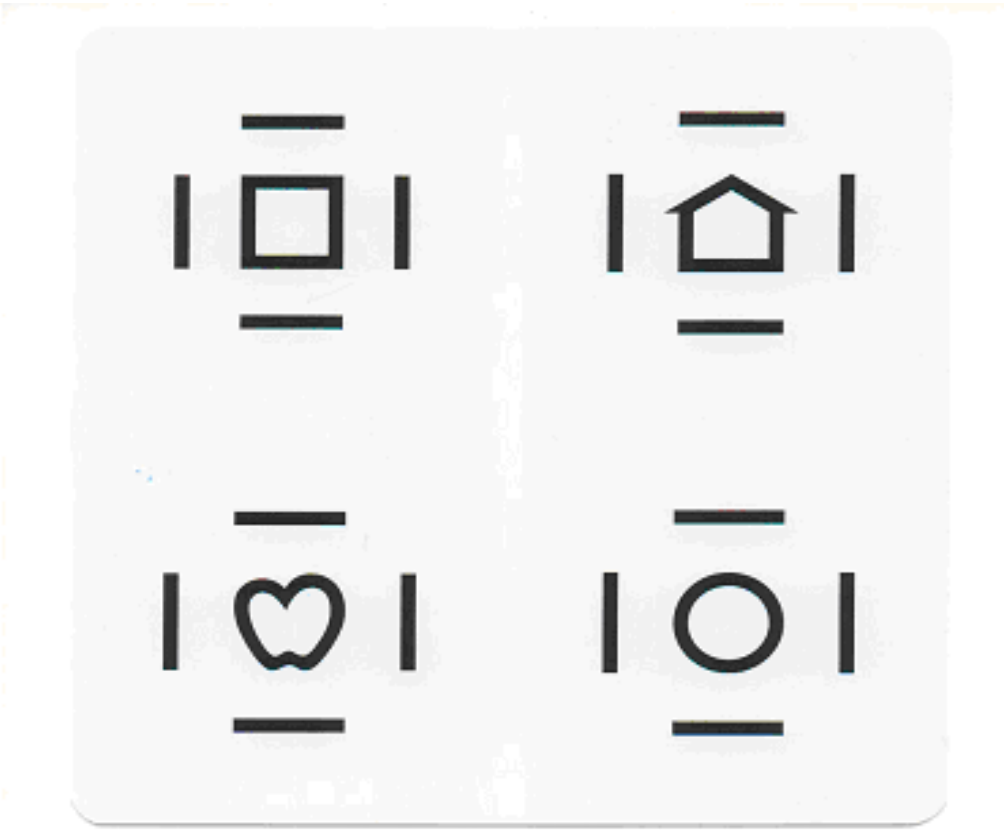


Figure 1: The Lea Optotypes as They Appear on the M-VERAS Lap Card. The optotypes appear one per page on the M-VERAS cards.

Lea Light Box (LLB) Acuity Chart

The LLB acuity chart was used in Phase III of the study. LLB charts were supplied by Good-Lite, Inc. (Steamwood, Illinois). The LLB chart had a 5-foot string attached to the side for ease in measuring the test distance from the child to the stimuli. On the LLB chart, Lea optotypes were surrounded by a solid contour interaction bar, with 50% of symbol width between symbols and the bars. The chart was placed in the front of a box and illuminated from behind with LEDs. The luminance of the chart surface was 95 cd/m^2. A remote control device allowed the screener to illuminate one line of optotypes at a time. To maintain the

child's attention, the remote control device could also be used to create a red bar beneath the optotype of interest without breaking the contour interaction bar. The first line contained four 20/100 (2M) optotypes which were viewed by the child binocularly. The next line contained two sets of 20/40 (0.8M) optotypes (four optotypes per set), one for each eye. The last line on the LLB chart contained 20/32 optotypes which were not used in this study. The chart used in the LLB test is shown in Figure 2 below.

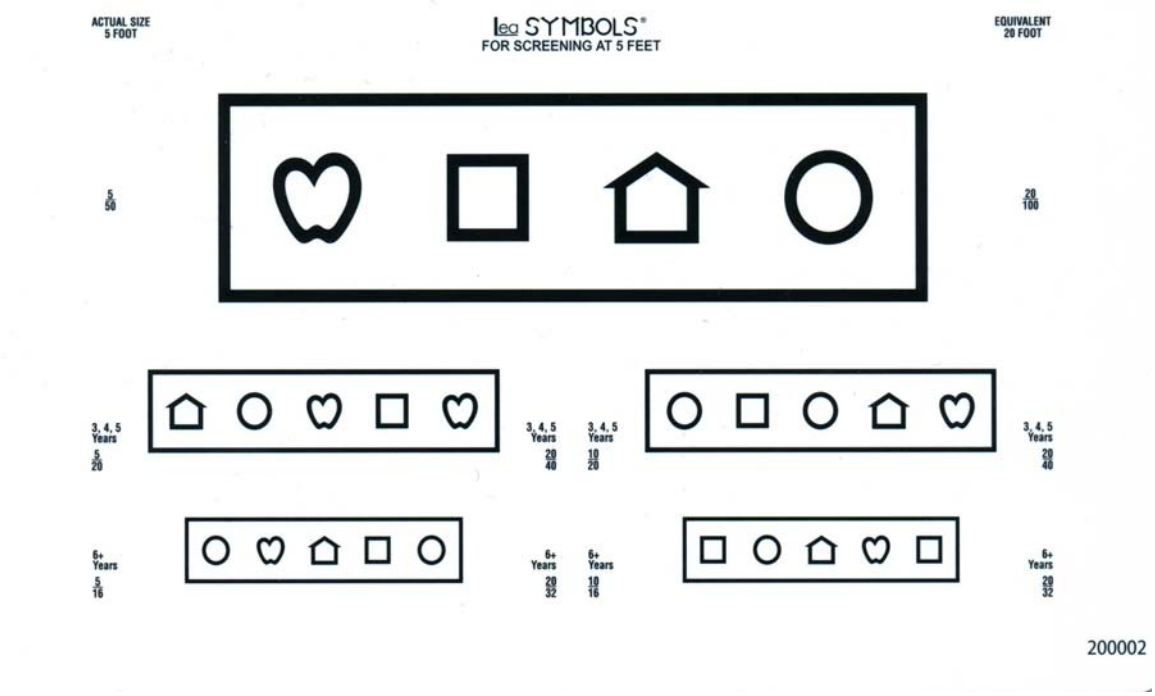


Figure 2: Optotype Chart Used in the Lea Light Box.

Although the M-VERAS cards and the LLB chart both use Lea optotypes, a number of key differences existed between the two tools. In the M-VERAS cards, the optotypes were presented as single optotypes surrounded by a broken contour interaction bar. In contrast, the optotypes on the LLB chart were presented in a linear fashion and were surrounded by a solid contour interaction bar. The optotypes in the M-VERAS cards were also presented on cards,

whereas in the LLB, they were presented on an illuminated chart. The optotypes for binocular testing in the M-VERAS cards were 20/80 optotypes but in the LLB chart, the binocular testing line contained 20/100 optotypes. There were four 20/40 optotypes per eye on the M-VERAS cards, but there were five 20/40 optotypes per eye on the LLB chart.

Pass and Fail Criteria

In both Phase II and III of the study, children were required to be able to see the 20/40 optotypes with each eye in order to pass the screening tests. For the M-VERAS cards, at least 3 out of 4 of the 20/40 optotypes had to be identified correctly for both eyes in order to pass. Similarly, for the LLB chart, at least 4 out of 5 of the 20/40 optotypes had to be identified correctly for both eyes in order to pass. Since Phase III used both the M-VERAS cards and the LLB chart, the children were required to pass both screening tests to count as "pass" on screenings. For both tests, two or more missed optotypes for either eye constituted failure and required the child to undergo GSE. Failure on either or both screening tests necessitated GSE.

If the child did not correctly identify two of the 20/80 optotypes in the M-VERAS cards or two of the 20/100 optotypes on the LLB chart, or if the child was not cooperative during screening, then a failure was assigned due to untestability (inability to perform the screening tests) and that child was identified to undergo a GSE. Children were also considered untestable if they gave inappropriate responses to the screening tests despite the best efforts of the screeners. For the purposes of the VSP Study, it was anticipated that at least 82% of the children screened would be testable by the two screening tools. This hypothesized value reflected the rates of testability achieved in other similar, well-designed

screening studies (eg Kvarnstrom & Jaccobson, 2005; VIP Study, 2005; Shallo-Hoffman, et al, 2004; Hered, et al, 1996) conducted on three-year old children using screening tools with Lea optotypes.

During the GSE in Phase II and III, any strabismus or ocular health condition constituted failure. As in the VIP Study (2005), in our study, refractive error that was considered clinically useful to detect as a risk for decreased vision or risk of the development of amblyopia was categorized as hyperopia >3.25 D, myopia >2.00 D, astigmatism >1.50 D and anisometropia >1.00 D. The cutoffs for bilateral amblyogenic refractive error were considered to be hyperopia >5.00 D, myopia > 8.00 D, and astigmatism >2.50 D. Our criteria for amblyogenic anisometropia were ≥2.00D for myopia, ≥1.00D for hyperopia, and ≥ 1.50D for astigmatism, which were consistent with the criteria used by Shallo-Hoffman, et al (2004).

PHASE I: Development and modification of the VERAS acuity cards.

Table of Contents

Purpose

The need for screening tools that are usable by lay screeners for the detection of common visual conditions affecting young children is a well recognized problem in the pediatric and public health communities. Several issues exist with the current form of the crowded single Lea optotype flipchart. In particular, the ergonomics and the user-friendliness of this test do not lend themselves well to be used by lay screeners with minimal training. Phase I of the VSP study aimed to correct the issues with this test and attempted to transform this screening tool into a tool that could be used effectively and efficiently by lay screeners, while maintaining test validity.

Methods

A focus group was held at the Dimock Head Start in Jamaica Plain, a Boston neighborhood in April 2007. The participants were recruited through the cooperation of one of the Head Start onsite nurse practitioners. Prior to holding the focus group, participants were provided with an information sheet about the background of the VSP Study, the importance of easy-to-use screening tools in Head Start centers, and the significance of detecting vision disorders in preschoolers. A copy of this information page has been included in Appendix 1. Participation in the focus group was entirely voluntary and informed consent was obtained. The informed consent form the participants signed is attached as Appendix II.

Participants were introduced to the purpose of the study and their contribution to the improvement of the VERAS cards. They were informed of the potential impact on improving the detection of childhood vision problems early in life and the likely benefits their input would have for children and their communities, here in the United States and abroad.

Then, participants were given a demonstration on how to use the VERAS cards. Participants were free to ask questions as they felt necessary. Written instructions were also provided to the participants for use as reference. This set of instructions is included in Appendix III. Following the demonstration, participants were given the opportunity to screen each other with the VERAS cards and were instructed to consider ways to improve their screening experience as they practiced using the cards with each other.

After a fifteen minute period of practice time, the participants were given a questionnaire (see Appendix IV). The questionnaire was designed to identify the participants'

demographic information, probe the participants' perceptions of the VERAS cards and their experience with the screening process. In a series of open-ended questions, participants were asked to write down their suggestions on how to improve the usability and ergonomics of the cards.

Further feedback through dynamic discussions between the participants of the focus group and the investigators was also actively obtained. Participants were offered a stipend of $50 for their time.

The feedback obtained from the focus group was used to modify the cards. Good-Lite, Inc. made the modifications and provided the VSP Study group with prototypes and the final products of the Modified-VERAS (M-VERAS) cards.

Results

The four participants were all females of Central American ancestry. All were either teachers or caseworkers at the Head Start site. The participants had an average age of 28.5 years and had at least completed high school.

The questionnaire indicated that the original VERAS cards were moderate to difficult to manipulate during the screening. Participants also had difficultly verifying the "child's" response without having to turn the screening test toward them. Screeners were also confused with which eye to screen with which cards.

The recommendations that emerged from this focus group are listed below.

1. Have the cards placed in a book format instead of as a flipchart.
2. Have the symbols on both sides of the cards or listed on the back for quick verification of the child's responses.
3. For each card, provide a label that tells the screener which eye should be covered and which eye should be tested.

A prototype of the modifications based on the suggestions made by the focus group participants was established and produced by Good-Lite, Inc. The modified-VERAS (M-VERAS) cards were then provided to the VSP Study group for use in Phase II and III of the study.

Discussion

Based on the feedback from this focus group, a more user-friendly and ergonomic screening tool was developed for lay screeners to accurately and efficiently screen preschool children. The book format was a sensible modification since most teachers and nurses would be comfortable showing children books.

The intention was to develop an easy-to-use screening tool for lay screeners to screen for vision disorders in preschool children in areas with little access to routine vision screenings. This would equip communities with the necessary tools to accurately screen children for common childhood vision disorders that have some potential for treatment if detected early enough.

A major shortcoming of this phase of the study was that the modifications were based on the input of only one focus group of females of a common ethnic background. It would have been ideal to have input from several different focus groups of various ethnicities, and both males and females. Further, it would have been ideal to undergo a number of different modifications with input from various focus groups over time as each iteration of the VERAS cards was developed. However, due to a lack of time, and the inherent difficulty in recruiting subjects from the Head Start parent, teacher, and volunteer pool, only one modification with one focus group was feasible at the time.

Future studies may involve investigating the change in screeners' perceptions of the screening tools before and after the modifications. It would also be worthwhile to examine

whether the time taken to perform the screening differed between the two versions of the VERAS cards.

The M-VERAS cards are currently being used in El Salvador to screen children across the country as part of the larger UNESCO VERAS project. Preliminary data suggests that the M-VERAS cards were found to be user-friendly and efficacious. In El Salvador, the M-VERAS cards are now being used to screen children in the Department of La Libertad, with much success. In the Department of Chaletenango, the screening is now in its third year, which suggests the program is sustainable, and running on its own (Janet Leasher, personal communication, April 2009).

PHASE II: Training lay persons to perform vision screenings on preschool-aged children using the Modified-VERAS acuity cards in rural El Salvador: A pilot study and review.

Table of Contents

Introduction

Scope of the Problem

An unfortunate reality in the developing world is that millions of children worldwide are believed to be blind and even more are believed to be visually impaired (WHO, 2005). According to the WHO, the developing world has a prevalence of childhood blindness five times greater than that of the developed world. The WHO estimates that 4% of the world's blind are less than fifteen years of age. However, the available data is likely an underestimation of the true magnitude of blindness and visual impairment due to a number of reasons. These reasons include the fact that blind registration data from the developing world is often incomplete, population based surveys in Africa and Asia usually fail to account for children in blind schools, certain childhood blindness conditions are associated with very high mortality rates, and children with multiple handicaps including visual disability are often not registered as blind until they are much older (WHO, 2005). Children with vision loss face a lifetime of poor vision or blindness. In the developing world, conditions of blindness are tightly linked to under-five mortality. In fact, nearly 60% of children die within a year of becoming blind (WHO, 2005). A number of studies (Resnikoff, Pascolini, Etya'ale, Kocur, Pararajasegaram, et al, 2004; Dandona & Dandona, 2001a; Holden, et al, 2000) also suggest that the current estimates of visual impairment may still be significantly lower than the true prevalence. This is due to the fact that the current definition of blindness does not include blindness due to refractive error. As such, presenting distance acuities need to be considered when determining the global estimates of visual impairment. According to one

estimate, the true global burden of visual impairment may be 259 million people—61% higher than current estimates by the WHO (Dandona & Dandona, 2006). Recently, however, renewed interest in this issue has emerged. Minto (2008) discusses emerging priority initiatives in the developing world aimed at training refractionists and optometrists in an effort to reduce unnecessary visual impairment due to uncorrected refractive error. Further, Tahhan, Frick, Naduvilath, Kierath, Ho, et al (2009) argue that the alarmingly high rate of uncorrected refractive error in parts of Sri Lanka highlights the acute need for further development and support for community based eye care services in these areas.

According to the WHO's report called Vision 2020: the Right to Sight (2005), about 75% of the world's blindness is avoidable. Alarmingly, close to 90% of the visually impaired live in the developing world with the poorest at greatest risk (Resnikoff, et al, 2004). With such a devastating effect on human life, visual impairment needs to be addressed. Sadly, few or no mechanisms are in place for the early detection and treatment of childhood vision disorders, despite the fact that many vision-related problems in children are treatable with excellent visually prognosis if detected early enough. This is particularly a problem since most vision problems in children are asymptomatic. Rius et al's (2004) report called Report on Visual Health Central America suggests there is a poor distribution of medical workers in the developing world, but the distribution of eye care providers is even poorer, with the majority of them centered near urban areas. This unequivocally means a large proportion of the human population that needs eye care has little or no access to quality eye care.

One proposed mechanism to identify children in need of further ocular evaluation is by way of vision screenings. However, screening tools that are cost-effective, usable by

nonprofessionals, and yield high rates of testability, sensitivity and specificity are desperately needed, especially in rural and poorer communities where eye care professionals may not be readily accessible.

Current State of Knowledge of Preschool Vision Screenings in the Developing World

Although many studies (Dandona & Dandona, 2006; Maul, et al, 2000; Pokharel, et al, 2000) have examined the prevalence of childhood refractive error in various parts of the world, there are few studies that investigate screening preschool-aged children in the developing world, despite the fact that the WHO in their report called Elimination of Avoidable Visual Disability Due to Refractive Errors (2000) has acknowledged the need to screen young children. There are even fewer studies from the developing world that explore preschool vision screenings done by lay screeners, even though this question has been examined more closely in countries like the United States.

One potential screening tool is the Tumbling E's test. Mbulaiteye, Reeves, Karabalinde, Ruberantwari, Mulwanyi, et al (2002) studied the use of Tumbling Es in an adult population where lay screeners screened adults for vision loss. The results of the screenings by lay screeners were compared to the results of visual acuities obtained by ophthalmic technicians and sensitivities and specificities for the E optotypes were reported to be 93% and 99% respectively. In one study involving children, an extensive school based screening initiative took place in India where children between the ages of 10 and 15 years were screened by their teachers using tumbling E optotypes (Limburg, et al, 1999). While the E optotypes may be effective for use in adults and in older children, this method of screening

has been heavily criticized for use in the preschool population since this age group has difficulty with directionality, resulting in very poor testability.

Lim, Yu, Park, Ahn, Kim, et al (2004) report another model for accessible screening of children in Singapore whereby parents were given home screening tools using picture symbols and a questionnaire to screen their preschoolers as an initial screening. Lim et al (2004) found a 98.1% testability rate for home testing. The 20.2% of children that failed were then screened again by trained nurses in public health centers. The 28.9% of preschoolers who failed this second screening were then referred to a local ophthalmologist. Of the children examined by an ophthalmologist, the positive predictive value was found to be 0.77. The investigators suggest that a home testing set may be an adequate method for initial screenings. Despite the relatively good success rate of Lim, et al's (2004) home screening program, there are numerous factors that need to be evaluated. Screenings in a home environment are unlikely to be standardized and may often lead to higher than expected false positives. Parental bias is also difficult to control in these settings.

In Kothari's (2007) study of 96 children, the Bruckner test was administered as a screening test and interpreted by a pediatric ophthalmologist. A sensitivity of 91% and specificity of 72.8% was achieved when the results of the screenings were compared to cycloplegic autorefraction. Despite a positive predictive value of 85.5%, this test remains difficult to justify in the use of wide-scale screenings. Firstly, this technique admittedly requires a highly skilled professional to administer and interpret the test in order to achieve adequate sensitivity and specificity, despite the high rate of testability. It is also difficult to quantify the crescent sizes and is therefore open to inter- and intra-observer variation.

Further, in children with high refractive error, there tends to be an absence of crescent formation, therefore making the test difficult to interpret. According to Kothari (2007), there is also likelihood that variations in fundus pigmentation can affect the sensitivity of the Bruckner test. Finally, the high cost of an ophthalmoscope is a likely deterrent to use this test as a field screening device.

Recently, an initiative by the United Nations has been started that involves training lay screeners to use the VERAS cards to screen children in participating Latin American countries. Preliminary data shows that the training of lay screeners has been successful (Moore, Leasher, Rius, Colome, & Villabos, 2008).

Purpose

The purpose of this phase of the study was to train lay El Salvadoran screeners on the proper protocols for the M-VERAS cards and then to determine the efficacy of the screening process by having lay screeners use the M-VERAS cards to screen El Salvadoran preschoolers.

Objectives

The objectives of this study included running a small pilot training session and pilot screening project in rural El Salvador to better gauge the feasibility of the M-VERAS cards as a vision screening tool in this preschool population.

The long-term application of this study is to train rural health promoters in El Salvador and other developing countries in Central America and beyond to effectively screen for potentially treatable vision disorders that are common in children. With an effective screening tool, and the appropriate training, rural screeners should have the ability to screen children that may otherwise not have access to any eye care services. Through this process, it is anticipated that those children who most need vision care will be readily identified early on.

Materials and Methods

Training of the Lay Screeners

The M-VERAS cards as developed in Phase I were used in Phase II of the VSP Study.

Twelve health promoters from various rural communities were invited to take part in a half-day training session in Chalchuapa, El Salvador in August, 2007. Health promoters are not medical professionals. They serve their communities by monitoring height and weight of children, providing nutritional tips to pregnant women, and participating in programs like ours to improve the basic health services in their communities.

The training session with these rural health promoters was held in collaboration with Dra Natalia Colome, a faculty member, from the Universidad Nacional San Salvador and four optometry students from the Universidad Nacional. One of the students had been involved in the larger UNESCO VERAS training project of lay screeners. This group was involved in translating for the VSP Study group. They also participated in the hands-on training of the lay screeners by providing feedback to the screeners on their technique.

The health promoters were provided background information on the development and history of the VERAS cards. Lay screeners were explained the significance of their efforts and the impact of these efforts on El Salvadoran children and children internationally.

Through translation and the help of the El Salvadoran collaborators mentioned above, the health promoters were briefed on the improvements to the M-VERAS cards over the previous few months. Significant emphasis was placed on the necessity of good lighting

during screening, covering the untested eye completely, maintaining test distance, and conducting the test in a location where children would not be distracted or would not receive hints from other children or parents.

Following this information session, the screeners received a demonstration of the screening process and then had the opportunity to practice the screening techniques on each other. Four groups of three screeners were formed. One person acted as the child, one as the screener and the other as the recorder. A copy of the data sheet is included in Appendix V. Each group was critiqued and given guidance by a member of the VSP Study group or the group from the Universidad Nacional. See Figure 3.

Figure 3. Lay Screeners Using the M-VERAS Cards.

There were no children present during the training session and as such, the lay screeners did not have an opportunity to practice the procedures on children while being observed by the VSP Study group.

Lay screeners were required to demonstrate that they could perform the screening accurately at least once on one of their colleagues and were able to record the data correctly. No written test for comprehension was administered to the screeners.

Consent

Government and health ministries in El Salvador viewed this pilot study as a public health initiative. The health and governmental authorities of El Salvador decided consent was not required for the VSP Study group to have the children screened and examined in this study. This is due to the reality that this study would likely be the only source of eye care the preschoolers would receive, and thus was considered to be a source of clinical care, and not a study, in the view of the Ministry of Health authorities queried. Further, no functional system exists for obtaining informed consent in the rural areas where the study took place. Finally, the Ministry of Health authorities viewed this project as helping the development of a sustainable eye care program for preschoolers, and thus a public health program, and not a research study.

Screenings and Gold Standard Examinations

A preschool in rural El Salvador identified as Nucleo Monte Oscura was chosen as a test site for the screenings. Fifteen children with a mean age of 5.1 years (range 3-6 years)

were screened with the M-VERAS cards. The screenings were conducted by one of the 12 health promoters.

Following the screening, all fifteen children were retested via GSE. The GSE consisted of the following: 1) Threshold monocular visual acuities measured with Lea optotypes presented in a full chart format at a 5-foot testing distance; 2) Assessment of extraocular motilities; 3) Bruckner test to check for strabismus, media opacities, and significant anisometropia; 4) Cover-uncover test performed at a 10 foot distance and at near (40 cm); 5) Pupillary asymmetries, responsiveness to light, and afferent pupillary defects using the swinging flashlight test; 6) Dry Retinoscopy; 7) Anterior segment assessment using a 20D lens and transilluminator or an ophthalmoscope; 8) Anterior segment angles assessment using the shadow technique; 9) Intraocular pressures assessment using digital palpation; 10) Posterior segment assessment using an ophthalmoscope. A cycloplegic refraction and dilated fundus examination were not performed on the children.

Any necessary advanced treatments were referred to the nearest eye clinic in the city of Santa Ana.

Results

During the half-day training session, the 12 lay screeners were able to successfully demonstrate that they could perform the screening test and record the results accurately. Since all the screeners attended the same training session and had close supervision during the training and practice sessions, we can assume that all the screeners received equal quality training. Although we did not have an opportunity to observe each screener screening actual children, there is no reason to believe that all these screeners would not be able to successfully screen children.

During the screening, a total of 15 children were screened with the M-VERAS cards. The testability rate was 93.3% since only one child was unable to do the screening test. One other child was testable but had failed the screening criterion, bringing the fail rate to 13.3% in our sample. Upon gold standard examination, the untestable child was found to have insignificant refractive error and unremarkable ocular health. The one child who was testable but had failed the screening was found to have a congenital cataract in one eye. The child was subsequently referred for a surgical consult with an ophthalmologist at a nearby ophthalmologic base in Santa Ana.

Discussion

The lay screeners were successfully trained to perform screenings on preschool children using the M-VERAS cards. Overall, the M-VERAS cards were easy to understand by lay screeners and involved minimal interpretation from the screeners themselves. There were a number of shortcomings of the training session. It would have been most ideal if we could have observed all the screeners screen children for their first day. This would have allowed further reinforcement of the screening methods and assurance that screeners adhered correctly to the study protocols. However, due to time restraints, this was not possible. Perhaps in a future training session, some form of written evaluation could also be administered in order to ensure understanding of the screening process by the lay screeners.

During the screening session, children related well to the Lea optotypes and even those who were too shy or hesitant to verbalize a response could effectively be screened since the children had the option of matching the presented optotype to the optotype on their lap card.

Despite a small sample size of 15, we were successfully able to identify the one child with a visually significant condition which would have otherwise gone undetected because of its monocular status. One of the limitations of the screening portion of this pilot study was the small sample size. Although we obtained a high rate of testability in this sample, it is difficult to extrapolate these results to the rest of the preschool population in El Salvador or in other nations. Despite the limitations of this pilot study, we have at least gained sufficient information based on this trial to conclude that the training protocol and screening regimen

used are feasible in this preschool population in rural El Salvador. Finally, despite the presence of capable colleagues from the Universidad Nacional, information is undoubtedly lost in translation. Future studies should investigate the use of the M-VERAS cards in a larger preschool population over a larger geographic distribution. This way, the results could be generalized to the global preschool-aged population. Further, differences in testability could be assessed in different populations. Validation of the results of the screenings should ideally be done with full cycloplegic examinations.

The M-VERAS cards were an effective tool for detecting vision disorders in our sample. Further, this is a low-cost screening tool. As such, it is relatively more affordable for small, rural communities to invest in a set of screening cards, rather than investing thousands of dollars in high-cost autorefractors.

With respect to the screening process, one study (Xichang Pediatric Refractive Error Study Group, 2008) found that teachers were most biased in their screening measurements when children presented with spectacles. These investigators recommended that all screenings be done without correction to maximize sensitivity by eliminating the phenomenon whereby teachers seemed to overestimate the vision of children tested with their eyeglasses. Finally, the use of lay screeners is highly cost-effective since using eye care professionals for initial screening is a poor use of resources (Murthy, 2000).

Sustainable, low-cost, effective visual screening methodologies are needed in much of the developing and the developed world. Sustainability can only happen if there is engagement and involvement at the level of the community. Nirmalan, et al (2003) proposed that eye care delivery requires a better understanding of attitudes and perceptions of

caretakers toward pediatric eye care, local cultures and traditions, and barriers to utilization of existing services. As such, training lay screeners to screen children in their own communities is important. Firstly, these screeners have regular access to school-aged children more so than outside personnel. Further, the lay screeners are more likely to be motivated to improve the quality of life of their own communities and therefore are more likely to perform the screenings. With a community member performing the screenings, it is also less likely that there will be communication and cultural barriers present during the screening process, thereby making the screenings more acceptable to parents and the children.

While there are irrefutable philanthropic motivations to developing screening programs for children, there is also an undeniable economic benefit to such a program. With one third of the total economic cost of blindness attributable to childhood vision loss (WHO, 2005), establishing an effective, low-cost screening system is paramount so that children with visual problems are detected early, thereby translating into a lifetime of health cost savings (Rius, et al, 2004).

Finally, while setting up a community-based screening program is necessary, Limburg, et al (1999) caution against implementing a screening program in the absence of a refracting professional, reasonable access to spectacles, and availability of appropriate follow-up services. In these instances, a vision screening program may lead to frustration and disappointment (WHO, 2000). However, screenings need to be interpreted only as an initial step to identifying those most at risk for visual impairment. Those identified, should subsequently be referred to the limited professional personnel for follow-up care.

PHASE III: Determination of the efficacy of the Modified-VERAS cards and the Lea Light Box acuity chart as screening tools used by lay screeners on preschool children.

Table of Contents

Introduction

Vision screenings need to be implemented for conditions that have a significant enough prevalence to warrant the costs associated with screenings. Such conditions should be easily detected with simple screening tools and should ideally lead to better visual prognosis with earlier detection (van Belle, et al, 2004; Lin-Fu, 1971). Vision screenings are a necessary, low-cost measure to help reduce the incidence and prevalence of disorders such as amblyopia.

Current State of Knowledge Regarding Preschool Vision Screenings in the United States

Although vision screening guidelines for preschoolers exist in more than half the states, it is only voluntary or recommended in many. The states that do require vision screenings for preschoolers have a wide range of screening tools, many outdated, not scientifically validated, or with poor specifications on who should perform the screenings or how they should be done (Ciner et al, 1999). These investigators further report that the language used in the laws mandating screenings is often vague and ambiguous about whether all preschoolers are entitled to the screenings. Ciner et al (1999) argue that despite recommendations and laws governing vision screenings for preschoolers, many of these children do not receive any form of vision screening until they enter kindergarten at age 4 or 5 years. Moore (2006) also reports that on a national level, few children are screened before entering school and even fewer receive comprehensive eye examinations. Ciner et al (1998)

estimate that only 14% of children below age 6 years receive eye examinations, while 21% are screened prior to entering kindergarten.

Numerous optotypes have been previously used in the pediatric population. Optotypes such as the Allen figures, albeit easy to use, have been heavily criticized for their cultural bias, lack of standardization and under-identification of amblyopes (De Young-Smith & Baker, 1986). While studies have found excellent comparability of E-optotypes with Snellen letters, this test too has been criticized for use in preschoolers since this age group typically has difficulty with directionality (Schmidt, 1991; De Young-Smith & Baker, 1986).

Undoubtedly, there is a need for vision screenings for preschoolers. A sound, scientifically valid, sensitive, specific, testable and cost-effective mechanism is desperately needed.

Purpose

The purpose of Phase III of the VSP Study was to assess the success in testing preschool children using the M-VERAS cards and the LLB chart when lay screeners administer the testing. Secondarily, the sensitivity and specificity of each of the tests as well as the test-retest reliability were investigated.

Materials and Methods

Training of the Lay Screeners

In September 2007, two lay screeners were identified and trained on the screening protocols for the M-VERAS cards and the LLB chart. Details of the two screening tools are provided in the General Materials and Methods section of this paper.

The two lay screeners were not the same volunteers who participated in Phase I of the study. The screeners were parents of Head Start children. They were of Asian ancestry with at least a high school education.

Screeners attended a half-day training session at the New England College of Optometry (NECO). The training was provided by the VSP study group. The screeners were provided background information about the screening process and their role in identifying children with visual problems. The screeners were trained to perform the screening procedures under strict study protocols. Detailed step-by-step outlines of the screening procedures for the M-VERAS cards and the LLB chart (see Appendices VI and VII respectively) were also provided for reference. Screeners received a demonstration of the screening methods and received ongoing support while they practiced the techniques amongst each other. The screeners were also trained on how to record the data correctly. Data sheets for both screening tools are included in Appendix VIII.

Screeners were required to demonstrate that they could perform the screening tests using the VSP study group members as subjects. No children were present during the training process. As such, we were unable to observe the screeners screening children. No written

examination following the training was administered to the lay screeners. The lay screeners were then equipped with a LLB acuity chart, an M-VERAS acuity card package, occluder glasses, recording sheets, and pens.

Informed Consent

Informed consent was obtained from the parents or guardians of the children who were to be screened and then examined via GSE. A copy of the parental consent form is included in Appendix IX. All study procedures adhered strictly to the Helsinki declaration and was approved by the institutional review board at NECO for each year of the study. A number of parents provided consent for screening, but not for GSE.

Screenings

Over a 1.5 year period, 277 preschoolers were screened by the lay screeners in nine Head Start centers in the Greater Boston Area. The children in these nine Head Start centers were ethnically diverse.

According to the study protocols, each screener screened each child twice—once with the M-VERAS acuity cards and once with the LLB acuity chart. Half the children were first screened with the M-VERAS cards followed by the LLB acuity chart. The other half were screened with the tests in the reverse order.

The screening data forms were collected from the lay screeners and returned to the VSP study group to score for pass and fail.

Any child who failed one or both screening tests was automatically enrolled for GSE. Untestable children were required to undergo GSE as well. Again, untestable children were

defined as those children who were unable to do the screening due to poor cooperation. An equal number of randomly selected children (23.8%) who passed both screening tests were also selected for GSE to provide insight to the sensitivities and specificities of the screening tools. Pass and fail criteria are discussed in the General Materials and Methods section of this paper.

Gold Standard Examination

Gold Standard Examinations (GSE) took place between November 2007 and December 2008. The GSEs were conducted by licensed optometrists in accordance to the study guidelines. The details of the GSE procedures are described at length in the Manual of Procedures (MOP) in Appendix X. Students of the New England College of Optometry were also present to assist the gold standard examiners. The gold standard examiners were blind to the results of the screenings. The GSEs were conducted in a 38-foot van fully equipped to do eye exams in two lanes. The van was parked outside the Head Start center. The children were escorted between the van and their classroom by Head Start staff. A total of 106 children were identified as requiring GSE. However, only 90 children received GSEs—52 children who had passed both screening tests and 38 children who had failed one or both screening tools. As mentioned early, obtaining consent for several of the children to undergo GSE was not possible. Some children were also absent on the day of the GSE or refused to be examined (see Results section below for exact numbers).

The GSE consisted of the following tests:

1. Visual acuity was tested to threshold with the MassVAT acuity cards. The MassVAT acuity cards are Lea-optotype based cards with five optotypes on each line surrounded by a solid contour interaction bar.
2. Entrance testing was performed and included lensometry, cover test at distance (10 feet) and near (40 cm), testing of the extraocular motilities, and assessment of pupillary function.
3. The anterior segment was examined and angles were grossly assessed using a transilluminator. Tactile intraocular pressures were obtained.
4. Cycloplegic retinoscopy and dilated fundus examinations were performed.

A prescription for the appropriate eyeglass correction was provided, if needed. The child's parent or guardian was responsible for filling the prescription. Appropriate referrals for follow-up treatment or further treatment were also made at the time of the examination. Upon completion of the examination, a parent report sheet (see Appendix XI) with an attached prescription (if appropriate) was sent to the child's home to inform the parents of the GSE findings.

A flow chart below (Table 1) demonstrates the sequence of the GSE. Refer to the MOP in Appendix X for the step-by-step protocol for each of the tests used in the GSE. The study participants were required to strictly adhere to the protocols in this MOP. All procedures performed in the GSE have been adopted from the VIP studies and from the Clinical Procedures for Ocular Examination 3rd Edition.

Table 1: Flow Chart for the Gold Standard Examinations

Visual Acuity (VA) Measurement and External Observations
VA was measured to threshold using the MassVAT acuity cards. The gold standard examiners grossly assessed the children's external features (facial and ocular)

↓

Entrance Tests
Lensometry
Cover Test at Distance (10 feet) and Near (40cm)
Extraocular Motilities
Assessment of Pupillary Function

↓

Assessment of the Anterior Segment
Assessment of adnexa, conjunctiva, cornea, anterior chamber. iris, pupil, and lens (examination done via direct ophthalmoscope or with a hand-held slit lamp). Gross assessment of angles and tactile IOPs were obtained.

↓

Refraction
Cycloplegic Retinoscopy (A combination drop containing 0.5% cyclopentolate, 2.5% phenylephrine, and 0.25% tropicamide was administered to each eye. After thirty to forty minutes, cycloplegic retinoscopy was performed.)

↓

Assessment of the Posterior Segment
Assessment of the posterior segment was conducted using a direct ophthalmoscope or a binocular indirect ophthalmoscope.

In the VSP Study, screening services and GSEs were administered to the children in the study at no cost to parents and guardians. The cost of follow-up examinations and eye glasses for most children are covered by the generous benefits provided by near universal healthcare coverage in Massachusetts. Assistance in obtaining access to treatment for those not covered was provided by Head Start and NECO.

Statistical Analysis

The mean ages and testability were determined using descriptive statistics. The following table provides insight into the terms used in the results and discussion sections of this paper.

Table 2: A Description of the Basic Statistical Terms Used in the Calculation of Sensitivity and Specificity.

		Gold Standard Examination	
		Pass	Fail
Screening	Pass	True Negative	False Negative
	Fail	False Positive	True Positive

Crude sensitivity is calculated by the following formula:
True Positive/ (True Positive + False Negative)

Crude specificity is calculated by the following formula:
True Negative/ (False Positive + True Negative)

Since there was an over-representation of children who failed the screenings in the GSE group, the sensitivity would likely be overestimated using the crude definition. Likewise, since only a portion (23.8%) of the children who passed the screening tests was examined by GSE, the specificity would likely be underestimated using the crude values. As

such, the verification bias must be corrected to arrive at a truer estimate of the sensitivity and specificity of each of the tools. See Zhou (1998) for further information on verification bias.

The McNemar test for paired subjects was used to determine which of the two tools had better sensitivity and which had better specificity.

Results

The two lay screeners were successfully trained to perform screenings with the M-VERAS cards and the LLB chart during their half-day training session.

Two hundred seventy-seven (277) preschool children with a mean age of 3.9 +/- 0.6 years were screened in nine different Head Start centers in the Boston area over a 1.5 year period. Two lay screeners conducted the tests: screener 1 with 132 children and screener 2 with 145 children. The M-VERAS cards were used as the first screening test with 161 children and the LLB chart was used first in 116 children. Data collection was ceased before more classrooms could be screened with the LLB chart first, thereby leaving more children who were screened first with the M-VERAS cards.

All children tested completed the screenings for both tests (100% testability). Fifty-four children failed screening on one or both tests, which resulted in a failure rate of 19.5%. Of these 54 children, 14 had failed by the M-VERAS cards only, 13 failed by the LLB chart only, and 27 failed on both of the tests. Out of these 54 children, 25 children were first screened with the LLB, and 29 were first screened with the M-VERAS cards.

A total of 106 children were identified as requiring GSEs. Parental consent could not be obtained for 9 children who failed the screening. These 9 children were not replaced due to lack of time. On the scheduled examination dates, a total of 5 children identified as failure by screenings were absent and 2 refused to be examined. Only one child who passed by screening tests was absent on the GSE date. Thus, 90 GSEs took place in six different Head Start centers in the Greater Boston Area. Thirty-eight of the children who received GSEs

failed one or both of the screening tests and 52 had passed both screenings. The age range of the children examined by GSE was 3.00 to 5.25 years with a mean age of 3.94± 0.59. The results of the screenings compared to the results of the GSEs are summarized in Table 3 below.

Table 3. Comparison of the Results of the Screenings with the Gold Standard Examinations. All values reflect the total number of children in each category. Failure by screening could have been for one or both screening tests. Percentages are proportions by column.

		Gold Standard Examination		
		Pass	Fail	Total
screening	Pass	45 (86.5) (True Negative)	7 (18.4%) (False Negative)	52 (57.8%)
	Fail	7 (13.5%) (False Positive)	31 (81.6%) (True Positive)	38 (42.2%)
	Total	52 (100%)	38 (100%)	90 (100%)

Considering all results, 38 failures were identified on GSE. Thirty-one were correctly identified from the screening process and 7 were incorrectly identified as passing on screening and thus were false negatives. Two of these false negatives had extraocular motility problems which did not have any impact on their visual acuity or binocularity in primary gaze. Accordingly, based on visual acuity criteria, the screening tests had identified these children correctly as passes. However, because of their ocular motility problems detected on GSE, they were considered as failures.

The most common diagnosis for failing the GSE was astigmatism >1.50 D. A summary of the diagnoses for those who failed the GSEs is included below in Table 4. A total of 16 eyeglass prescriptions were provided.

Table 4. Summary Data of the Diagnoses Constituting Failure on Gold Standard Examinations. The values in columns 2 and 3 are the number of children identified to have failed under each criterion on GSE. Row percentages are shown in parentheses in the last column. Since a child may have failed for more than one reason, the sums of the columns are greater than the failures for the column.

Failure Criteria	True Fails	False Negative	Totals (%)
>1.50D of Astigmatism	24	2	26 (68.42)
>3.25D of Hyperopia	7	3	10 (26.32)
>2.0D of Myopia	2	0	2 (5.26)
>1.0D of Anisometropia	7	2	9 (23.68)
Any Strabismus	2	0	2 (5.26)
Any Non-Strabismic Binocular Problem	1	1	2 (5.26)
Any Ocular Health Issue	0	0	0 (0.00)

For the following discussion on sensitivity and specificity of the M-VERAS cards and the LLB chart, refer to the next two tables (Table 5 and 6).

Table 5: Comparison of the Results of the Screenings with the M-VERAS Cards to the GSE. All values represent the number of children in each category. Percentages are proportions by column.

Screening with the M-VERAS Cards	Gold Standard Examination		
	Pass	Fail	Total
Pass	45 (86.5%)	15 (39.5%)	60 (66.7%)
Fail	7 (13.5%)	23 (60.5%)	30 (33.3%)
Total	52 (100%)	38 (100%)	90 (100%)

Table 6: Comparison of the Results of the Screenings with the LLB Chart to the GSE. All values represent the number of children in each category. Percentages are proportions by column.

Screening with the LLB Chart	Gold Standard Examination		
	Pass	Fail	Total
Pass	50 (96.2%)	11 (28.9%)	61 (67.8%)
Fail	2 (3.8%)	27 (71.1)	29 (32.2%)
Total	52 (100%)	38 (100%)	90 (100%)

In reference to Tables 5 and 6, if we use the crude sensitivity value as described in the Methods section above, the sensitivity would be 60.5% (23/38) for the M-VERAS cards and 71.1% (27/38) for the LLB chart. Likewise, the crude specificity would be 86.5% (45/52) of the M-VERAS cards and 96.2% (50/52) for the LLB chart. However, as described earlier, sensitivity and specificity needed to be adjusted to account for verification bias. Once verification bias was corrected for, the sensitivity of the M-VERAS cards dropped to 45.4% (95% CI: 29.5, 61.2%) and 58.3% (95% CI: 42.6, 74.0%) for the LLB. The specificities of the M-VERAS cards and LLB chart increased to 92.2% (95% CI: 85.0, 99.5%) and 97.8% (95% CI: 93.8, 100.0%) respectively.

Finally, we assessed which of the two tests was more sensitive and which was more specific. The McNemar test for paired subjects was used to determine which of the two tests had better sensitivity and specificity. The difference in the two tests with respect to sensitivity was not statistically significant ($p = 0.3865$). Although the difference in specificities of the two tests did not reach statistical significance ($p = 0.0736$), there was

certainly a trend toward greater specificity in the LLB chart compared to the M-VERAS cards.

Discussion

In Phase III of the VSP Study, the M-VERAS cards and the LLB chart obtained 100% testability. The testability in our study was modestly higher than other similar screening studies on preschoolers using Lea optotypes. Table 7 below shows a comparison of the testability obtained in four similar studies to the VSP Study.

Table 7. Comparison of Testability Values in Studies on Screening Preschool Children with Lea Optotype Tests. This table continues onto the next page.

Study and Sample Size	Age of Children	Screeners Used	Format of Screening Tool	Passing Visual Acuity Criteria	Testability
Vision in Preschoolers (2005) Study (n=1452)	3-5 years	Nurses and Lay Screeners	Linear Crowded Optotypes	10/25 in 3 year olds	99.4%
				10/20 in 4 year olds	
			Single Crowded Optotypes	5/12.5 in 3 year olds	
				5/10 in 4 year olds	
Kvarnstrom & Jakobsson (2005) (n=478)	3-4 years	Not identified	Full Chart	20/32	84.8% in 3 year olds
					92.8% in 4 year olds
Shallo-Hoffman, et al (2004) (n=268)	2-6 years	Not identified	Linear Display * Details of crowding not provided	20/40 in 3 year olds	86.0% in 3 year olds
				20/30 in 4 year olds	93% in 4 year olds

Hered, et al (1997) (n=777)	3-5 years	Not identified	Linear Display * Details of crowding not provided	20/40 in 3 and 4 year olds	92% in 3 year olds
					97% in 4 year olds
				20/32 in 5 year olds	98% in 5 year olds

The VSP Study also had a moderately higher rate of testability compared to another screening study by Schmidt (1991) using Allen symbols and the Landolt Broken Wheel Test in preschoolers. In this study, testability was found to be 85.3% (monocularly and binocularly) with the Allen symbols and 70.6% with monocular testing and 79.4% with binocular testing using the Landolt Broken Wheel Test.

High rates of testability using Lea optotypes may be the result of a number of factors. Lea optotypes may be more engaging and children may be more willing to participate in the screening task. This may be due to the fact that developmentally, children respond sooner to shapes than to letters. Because Lea-optotype-based tests use matching, children who were too shy to respond verbally could also be tested. With respect to testability, for the younger preschool children, Lea optotypes provide superior testability than other methods of testing including the HOTV cards (Kvarnstrom & Jakobsson, 2005; Shallo-Hoffmann, et al, 2004; Becker, et al, 2000; Hered, et al, 1997). In the VSP Study, the greater rate of testability compared to other studies using Lea optotypes may be partly attributable to our lay screeners. It is possible that our lay screeners may have been coaxing the children to respond and were more reluctant to identify children as untestable due to their own cultural biases.

Although all children in our study were testable, in future studies, it is recommended that all untestable children be considered as failures and should subsequently undergo GSE. This is supported by the VIP Study (2007) that found that the percentage of children with ocular problems was at least two times higher for untestable children compared to those children who passed the screening tests.

In our study, astigmatism was found to be the most common diagnosis for failing the GSE, followed by hyperopia and anisometropia. Because our sample size was much smaller than the multi-centered VIP studies, unlike that study, we could not stratify failures on GSE into levels of severity of amblyogenic risk factors or urgency to treat. Children who were considered to have clinically significant refractive error or who were either amblyopic or at elevated risk for amblyopia were provided an eyeglass prescription.

Donahue, et al (2000) reported on the use of a photoscreener by lay screeners for the detection of amblyopia and amblyogenic risk factors in preschool children. Their results showed that a high percentage of children with strabismus were detected but only 41% of children with astigmatism (>1.50D) were detected. Astigmatism (>1.50D) in our study was the most common diagnosis for failing the GSE and as such, the photoscreener may be a questionable screening tool for our study population.

In the VSP Study, the linear Lea optotypes had a sensitivity of 58.3% which was closer to the sensitivity of the single crowded Lea optotypes reported for both lay screeners and nurse screeners in the VIP Study (2005) (see Table 8). The M-VERAS cards, with the single crowded optotypes were found to have modestly higher sensitivity in the VSP Study

compared with the sensitivity obtained by lay screeners using linear Lea optotypes in the VIP Study (2005).

Table 8: Sensitivities Obtained in the Vision in Preschoolers (2005) Study with the Linear and Single Crowded Lea Optotypes Using Nurse and Lay Screeners.

	Nurse Screeners	**Lay Screeners**
Linear Crowded Lea Optotypes	49%	37%
Single Crowded Lea Optotypes	61%	61%

The results of the VSP Study found that the sensitivity of the LLB chart was slightly higher than the M-VERAS cards. Yet when comparing the two tests with the McNemar test for paired subjects, the difference between the sensitivities and specificities of the two tests did not reach statistical significance. However, the modestly greater sensitivity of the LLB chart in our study may be due to a number of reasons. Firstly, the LLB chart presented the Lea optotypes in a linear fashion surrounded by a solid contour interaction box. It is possible that this presentation may contribute to greater detection of vision disorders although this is contrary to the VIP Study (2005) findings where both nurses and lay screeners had greater sensitivity when testing with single crowded optotypes compared to the crowded linear presentation of the optotypes. Another possibility for the slightly greater sensitivity with the LLB chart may be the format of test presentation. Perhaps because of the similarity of the LLB chart to a television or modern electric device, this presentation could have represented a more salient stimulus, whereby children were more likely to stay engaged in the task and answer more accurately. This is similar to the findings of the VIP Study (2003) where the investigators found a greater response rate and sensitivity to the HOTV symbols that were

presented in an electric box format similar to the LLB chart. It is unlikely that the order of screening tools used in our study could have contributed to any differences in sensitivity and specificity between the two tests. This is because the study was designed such that half the children would be screened with the M-VERAS cards first, and half would receive the LLB chart first.

In Shallo-Hoffman et al's (2004) study, the screening process consisted of visual acuity screening with Lea and HOTV optotypes, as well as stereopsis testing with the Random Dot E test. The investigators performed GSEs on any child who failed either of the visual acuity tests or the stereopsis test. Their results indicated 100% sensitivity and 79% specificity of the screening process in general. In other words, they did not evaluate the sensitivity and specificity of each of their screening tools individually. Further, in their statistical analysis, they did not correct for the overrepresentation of failures in their GSEs. Therefore, the sensitivity of their screening process was likely overestimated and the specificity was likely underestimated. The sensitivity and specificity in our study is therefore not comparable to the values obtained by these investigators. Further still, the individuals who performed the screenings were not identified. As such, it is possible that the training level or background of the screeners may have influenced the sensitivity and specificity of the screening process used in that study.

The sample in our study was much smaller compared to the larger, multi-centered studies like the VIP studies. Unfortunately, in our study, a number of children who failed the screenings did not have parental permission to proceed to GSE. Further, 7 children identified by screening as failures and selected for GSEs were absent or refused to be tested on the day

of the GSEs, thereby leaving a slightly larger number of pass children to be examined by GSE. In other studies, such as the VIP study (2005), the screening environments were highly controlled and relatively distraction free. In our study, the screenings took place in the children's Head Start centers where the environment and background noise level was difficult to control. This may have contributed to a decrease in the sensitivity of the testing in our study. It is also possible that since our sample size was based on Head Start preschoolers, these children may not be representative of children across the United States or globally. Future projects like the VSP Study should aim to spend greater emphasis on the training of the lay screener and if possible, the investigators should observe the lay screeners for their first day and then subsequently at random for quality assurance.

General Discussion

Despite the fact that enormous volumes of data exist on vision screening in preschoolers in the industrialized nations, there is a paucity of data on lay screeners performing these tests in well designed, scientifically validated studies. One study (VIP, 2005) that investigated screenings in the hands of lay screeners found that lay screeners are capable of achieving results similar to those of nurse screeners. The results of the VSP Study suggest that the sensitivity and specificity achieved were similar to that achieved by the lay screeners used in the VIP Study (2005).

Further investigations on the use of lay screeners in the screening process are needed. High quality training modules that are standardized need to be developed and methods for periodic re-training of the screeners should be studied. In the current study, the VSP Study group decided which child would be considered as pass or fail in the screening process. Future studies should investigate the feasibility of having another higher trained, non-eye care professional take part in the pass/fail decision-making process. Given the poor and uneven distribution of eye care professionals around the country (and globally), it seems sensible, if not necessary, to train lay screeners to perform accurate screening tests (Moore, 2006).

Certainly, there are many economic considerations for policymakers involved in public health. Several investigators have shown that in fact, there are economic benefits to vision screenings. Chui, et al (2004) argue that earlier detection of amblyopia and strabismus allows earlier intervention and therefore more cost-effective treatment. Konig and Barry

(2002) conducted an analysis on cost-effectiveness of vision screenings using various pass/fail criteria and using a variety of different screening regimens varying from simple visual acuity screening, to complex ocular motor tests, to the use of expensive autorefractors. According to their analysis, it was determined that testing uncorrected monocular visual acuity was the most cost-effective method compared to all other methods of testing, including the use of autorefractors. It is particularly noteworthy that Konig and Barry's (2002) findings lend further support for the VSP Study that involves simple monocular visual acuity testing. Joish et al (2002) showed that cost-effectiveness and societal benefit with regards to financial burden was greatest for children screened between 3 to 4 years of age as compared to older children. Once again, this provides compelling support for the necessity of regular vision screenings for the early detection of vision disorders.

Previously, uncertainty existed with five-foot testing distances. However, the VIP Study (2005) found that a five-foot testing distance with the single crowded Lea optotypes increased sensitivity of the test when administered by lay screeners. Further, the five-foot testing distance is more likely to keep children engaged and less distracted. As such, we felt a five-foot testing distance would be most appropriate in the VSP study.

It is likely, however, that the rare low myope could have been missed using the five-foot testing distance. However, low degrees of myopia are extremely rare in preschool-aged children (Zhao et al, 2000). Fortunately, children with low myopia are not likely to become amblyopic since they have a point in space that is clear and so, they are not constantly looking through blur. Further, with annual screenings in place, children with progressive myopia would be identified in subsequent years of screening.

Undeniably, vision screenings in preschoolers are essential (Moore, 2006; Ciner et al, 1998). The findings of this study suggest that the M-VERAS and LLB tests may be useful screening tools in the preschool population, here in the United States and on an international scale. However, there are a number of limitations to the VSP study. Firstly, the sample sizes were small in all three phases of the study. In Phase I, multiple modifications of the VERAS cards would have been ideal. The change in the screeners' perceptions of each of the iterations of the VERAS cards could also be studied. It would have been worthwhile to investigate the differences in screening times between the original VERAS cards and the modified version. Although phase II was a pilot study, it would have been ideal to conduct the study across multiple preschool centers in El Salvador. The difference in the time it takes to screen preschoolers with the M-VERAS cards and the LLB chart should also be investigated. It would also be worthwhile to study the perceptions of the screeners to determine which screening tool (M-VERAS cards vs LLB chart) they preferred to use. Larger scale studies will need to be conducted in communities with different demographics than the preschoolers in the Boston area Head Start centers. Such studies will need to be conducted in different communities across the globe in order to establish the efficacy of these tools on a global scale.

General Conclusions

It is unequivocal that vision screenings are crucial to the early detection of vision disorders. There is abundant research to support the idea that earlier treatment leads to better visual prognosis. For far too long, various groups have debated the need for vision screenings, the personnel who will perform the screenings, and the tools needed to make this process efficacious, cost-effective, sustainable, and efficient. Ideally, screening tools need to be user-friendly, low-cost and effective with high testability, sensitivity and specificity. Further, the VSP study shows that the use of lay screeners is feasible and should be considered in order to provide basic vision screening services at a community level to all children nationally, and internationally. With adequate training and with the appropriate screening tools, motivated lay screeners are in an excellent position to provide basic vision screening services to preschoolers in their own communities. This study has established excellent testability of the M-VERAS cards and the LLB chart in preschool children as young as 3 years with relatively good sensitivity and specificity in the hands of lay screeners. These tools should be considered for vision screenings in preschoolers, here in North America, as well as in the developing world.

References

Atkinson, J, Anker, S, Evans, C, Hall, R, & Pimm-Smith, E. (1988). Visual acuity testing of young children with Cambridge Crowding Cards at 3 and 6m. *Acta Ophthalmologica, 66:* 505-508.

Becker, R, Hubsch, S, Graf, MH, & Kaufmann, H. (2000). Preliminary report: Examination of young children with Lea symbols. *Strabismus,* 8(3): 209-213.

Broman, AT, Munoz, B, Rodriquez, J, Sanchez, R, Quigley, HA, et al. (2002). The impact of visual impairment and eye disease on vision-related quality of life in a Mexican-American population: proyecto VER. *Investigative Ophthalmology & Visual Science,* 43(11): 3393-3398.

Carlson, N & Kurtz, D. (2004). Clinical Procedures for Ocular Examination. 3rd Ed. New York: The McGraw-Hill Company.

Chui L, Fraser T, Hoar K, & LaRoche GR (2004). Negative predictive value of a vision screening program aimed at children aged 3 to 4 years old. *Journal of AAPOS, 8(6): 566-570.*

Ciner E, Dobson V, Schmidt P, Allen, D, Cyert, L, et al. (1999). A survey of vision screening policy of preschool children in the United States. *Survey of Ophthalmology*, *43*: 445-457.

Ciner, EB, Schmidt, PP, Orel-Bixler, D, Dobson, C, Maguire, M, et al. (1998). Vision screening of preschool children: evaluating the past, looking toward the future. *Optometry and Vision Science, 75(8): 571-584.*

Dandona R. & Dandona, L. (2001a). Refractive error blindness. *Bulletin of the World Health Organization,* 79(3): 237-243.

Dandona, R. & Dandona, L. (2001b). Socioeconomic status and blindness. *British Journal of Ophthalmology,* 85: 1485-1488.

Dandona, R, Dandona, L, Srinivas, M, Sahare, P, Narsaiah, S, et al. (2002). Refractive error in children in a rural population in India. *Investigative Ophthalmology & Visual Science,* 43(3); 615-622.

Dandona L, & Dandona R. (2006). What is the global burden of visual impairment? *BMC Medicine,* 4:6

De Young-Smith, MA & Baker, JD. (1986). A comparative study of visual acuity tests. *American Orthoptic Journal,* 36: 160-164.

Donahue SP, Johnson TM, & Leonard-Martin TC. (2000). Screening for amblyogenic factors using a volunteer lay network and the MTI photoscreener: initial results from 15,000 preschool children in a statewide effort. *Ophthalmology, 107*:1637-1644

Ferebee A. The Center for Health and Health Care Schools. Childhood vision: Public challenges and opportunities – A brief policy. Available at http://www.healthinschools.org/sh/visionpolicy.asp. Accessed May 2007.

Flom, M, Weymouth, FW, & Kahnman, D. (1963). Visual resolution and contour interaction. *Journal of the Optical Society of America, 53(9):* 1026-1032.

Head Start Administration Bureau for Children, Youth, and Families. U.S. Department of Health and Human Services Administration for Children and Families: Head Start, Medicaid, and CHIP: A guide for Head Start Programs. Available at http://www.headstartinfo.org/pdf/chip.pdf. Accessed April, 2007.

Hered, RW, Murphy, S & Clancy, M. (1997). Comparison of the HOTV and Lea symbols charts for preschool vision screening. *Journal of Pediatric Ophthalmology & Strabismus, 34(1):* 24-28.

Holden, BA, Sulaiman, S, & Knox, K. (2000). The challenge of providing spectacles in the developing world. *Community Eye Health*, 13(33): 9-10.

Hornby, SJ, Adolph, S, Gothwal, VK, Gilbert, CE, Dandona, L, et al. (2000). Evaluation of children in six blind schools of Andhra Pradesh. *Indian Journal of Ophthalmology*, 48:195-200.

Hyvarinen, L., Nasanen, R, & Laurinen, P. (1980). New visual acuity test for preschool children. *Acta Ophthalmologica*, 58: 507-511

Joish, VN, Malone, DC, & Miller, JM. (2003). A cost-benefit analysis of vision screening methods for preschoolers and school-age children. *Journal of AAPOS*, 7:283-290.

Jugnoo, R, Logan, S, Timms, C, Russell-Eggitt, I, & Taylor, D. (2002). Risks, causes, and outcomes of visual impairment after loss of vision in the non-amblyopic eye: a population-based study. The Lancet.

Konig HH, & Barry JC. (2002). Economic evaluation of different methods of screening for amblyopia in kindergarten. *Pediatrics*, 109:e59.

Kothari, MT. (2007). Can the Bruckner test be used as a rapid screening test to detect significant refractive errors in children? *Indian Journal of Ophthalmology*, 55: 213-215.

Kvarnstrom, G. & Jaccobson, P. (2005). Is vision screening in 3-year olds feasible? *Acta Ophthalmologica, 83:* 76-80.

Levi, DM. (2008). Crowding—an essential bottleneck for object recognition: A mini-review. *Vision Research,* 48: 635-654.

Lim, HT, Yu, YS, Park, SH, Ahn, H, Kim, S, et al. (2004). The Seoul metropolitan preschool vision screening programme: results from South Korea. *British Journal of Ophthalmology,* 88: 929-933.

Limburg, H, Kansara, HT, & d'Souza, S. (1999). Results of school eye screening of 5.4 million children in India – a five year follow-up study. *Acta Ophthalmology Scandinavia,* 77: 310-314.

Lin-Fu, JS. (1971). Vision Screening of Children. US Department of health, Education and Welfare.

Macpherson, H, Braunstein, J, & Roche, GR. (1991). Utilizing basic screening principles in the design and evaluation of vision screening programs. *American Orthoptic Journal,* 41: 110-121.

Mandal, AK. (2001). Training ophthalmologists for children's eye care centres. *Community Eye Health,* 14(40): 62-64.

Maul, E, Barroso, S, Munoz, S, Sperduto, R, & Ellwein, L. (2000). Refractive error study in children: results from La Florida, Chile. *American Journal of Ophthalmology,* 129: 445-454.

Mbulaiteye, SM, Reeves, BC, Karabalinde, A, Ruberantwari, A, Mulwanyi, F, et al. (2002). Evaluation of E-optotypes as a screening test and the prevalence and causes of visual loss in a rural population in SW Uganda. *Ophthalmic Epidemiology,* 9(4): 251-262.

Minto, H. (2008). Optometry in developing countries. *Optometry and Vision Science,* 85(2): E74-E77.

Moore, B. (2006). The Massachusetts preschool vision screening program. *Optometry, 77(8):* 371-377.

Moore, BD, Leasher, J, Rius, A, Colome, N, & Villalbos, A. (2008). Project VERAS-Piloting cooperation toward development in vision care in Central America. *Investigative Ophthalmology & Visual Science,* 49: E-Abstract 3135.

Murthy, GV. (2000). Vision testing for refractive errors in schools. *Community Eye Health,* 13(33): 3-5.

Murthy, GV, Gupta, SK, Ellwein, LB, Munoz, SR, Pokharel, GP, et al. (2002). Refractive error in children in an urban population in New Delhi. *Investigative Ophthalmology & Visual Science,* 43(2): 623-631.

Naidoo, KS, Raghunandan, A, Masbige, KP, Govender, P, Holden, BA, et al. (2003). Refractive error and visual impairment in African chidren in South Africa. *Investigative Ophthalmology & Visual Science,* 44(9): 3764-3770.

Negrel, AD, Maul, E, Pokharel, GP, Zhao, J, & Wlllwein, LB. (2000). Refractive error study in children: sampling and measurement methods for a multi-country survey. *American Journal of Ophthalmology,* 120: 421-426.

Nirmalan, PK, Vijayalakshmi, P, Sheeladevi, S, Kothari, M, Sundaresan, K, et al. (2003). The Kariapatti pediatric eye evaluation project: baseline ophthalmic data of children aged 15 years or younger in southern India. *American Journal of Ophthalmology,* 136(4): 703-709.

Optometric Clinical Practice Guideline. (2000). Learning Related Vision Problems. American Optometric Association.

Optometric Clinical Practice Guideline. (2002). Pediatric Eye and Vision Examination. American Optometric Association.

Pokharel, GP., Negrel, AD, Nunoz, SR, & Ellwein, LB. (2000). Refractive error study in children: results from Mechi Zone, Nepal. *American Journal of Ophthalmology,* 129: 436-444.

Prevent Blindness America. Children's vision screening. Available at http://www.preventblindness.org/vision_screening/childrens_vision_screening.html. Accessed May 2007.

Ramsey, JE. & Bradford, GE. (2006). Legislative issues facing pediatric ophthalmology in 2006. *Current Opinion in Ophthalmology,* 17: 441-446.

Resnikoff, S, Pascolini, D, Etya'ale, D, Kocur, I, Pararajasegaram, R, et al. (2004). Global data on visual impairment in the year 2002. *Bulletin of the World Health Organization,* 82(11): 844- 851.

Rius A, Guisasola L, Stobart, L, Grasas, R, & Rius Q. *Report on Visual Health in Central America 2004.* UNESCO Chair in Visual Health and Development. April 2005 ISBN 84-689-1987-x.

Robinson B, Bobier WR, Martin E, & Bryant L. (1999). Measurement of the validity of a preschool vision screening program. *American Journal of Public Health, 89*:193-198.

Ruttum, MS & Dahlgren, M. (2006). Comparison of the HOTV and Lea symbols visual acuity tests in patients with amblyopia. *Journal of Pediatric Ophthalmology & Strabismus,* 43:157-160.

Schmidt, P. (1991). Comparisons of testability of preliterate visual acuity tests in preschool children. *Binocular Vision Quarterly,* 6(1): 37-42.

Schmidt, P. (1992). Allen figure and broken wheel visual acuity measurement in preschool children. *Journal of the American Optometric Association,* 63: 124-130.

Shallo-Hoffman, J, Coulter, R, Oliver, P, Hardigan, P, & Blavo, C. (2004). A study of preschool vision screening tests' testability, validity and duration: do group differences matter? *Strabismus, 12:* 65-73.

Shamanna, BR, Dandona, L, & Rao, GN. (1998). Economic burden of blindness in India. *Indian Journal of Ophthalmology,* 46(3): 169-172.

Steinman, SB, Steinman, BA, & Garzia, RP. (2000). Foundations of Binocular Vision. Chapter 9. New York: The McGraw-Hill Company.

Tahhan, N, Frick, TR, Naduvilath, T, Kierath, J, Ho, SM, et al. (2009). Uncorrected refractive error in the northern and eastern provinces of Sri Lanka. *Clinical Experimental Optometry,* 92(2): 119-125.

The Vision in Preschoolers (VIP) Study Group. (2003). Threshold visual acuity testing of preschool children using the crowded HOTV and Lea symbols acuity tests. *Journal of AAPOS, 7(6):* 396-399.

The Vision in Preschoolers (VIP) Study Group (2005). Preschool vision screening tests administered by nurse screeners compared with lay screeners in the Vision in Preschoolers Study. *Investigative Ophthalmology, 46:*2639-2648.

The Vision in Preschoolers (VIP) Study Group (2007). Children unable to perform screening tests in Vision in Preschoolers Study: proportion with ocular conditions and impact on measures of test accuracy. *Investigative Ophthalmology & Visual Science,* 48(1): 83-87.

Thompson, JR, Woodruff, G, Hiscox, F, Strong, N, & Minshull, C. (1991). The incidence and prevalence of amblyopia detected in childhood. *Public Health, 105:* 455-462.

Tommila V, & Tarkkanen A. (1981). Incidence of loss of vision in the healthy eye in amblyopia. *British Journal of Ophthalmology, 65*:575-577.

U.S. Preventive Services Task Force. Screening for visual impairment in children younger than ages 5 years: Recommendation statement, May 2004.

van Belle, Fisher, LD, Heagerty, PJ, & Lumley, T. (2004). Biostatistics: A Methodology for the Health Sciences. 2nd Ed. New Jersey: John Wiley & Sons, Inc.

World Health Organization (2000). Elimination of avoidable visual disability due to refractive errors—report of an informal planning meeting.

World Health Organization. (2005). State of the world's sight vision 2020: the right to sight 1999-2005. International Agency for the Prevention of Blindness: 1-110.

Woodruff, ME. (1972). Observations on the visual acuity of children during the first five years of live. *American Journal of Optometry and Archives of American Academy of Optometry, 49:* 205-215.

Xichang Pediatric Refractive Error Study (X-PRES) Group. (2008). Strategies to improve the accuracy of vision measurement by teachers in rural Chinese secondary school children. *Archives of Ophthalmology,* 126(10): 1434-1440.

Zhao, J, Pan, X, Sui, R, Munoz, SR, Sperduto, RD, et al. (2000). Refractive error study in children: results from Shunyi District, China. *American Journal of Ophthalmology*, 129: 427-435.

Zhau, XH. (1998). Correction for verification bias in studies of a diagnostic test's accuracy. *Statistical Methods in Medical Research,* 7: 337-353.

Appendix I: Recruitment Information for Participants of the Focus Group

Dear Head Start Parents, Volunteers, and Teachers,

Background:
Vision disorders can prevent children from developing their maximal social and academic potential. Most problems that lead to permanent reduction in visual acuity can be detected using simple screening techniques. Vision screening of all children in Head Start programs is a requirement by local and federal laws. The New England College of Optometry and the Boston area Head Start Centers work closely to ensure all Head Start children receive quality vision screenings.

Purpose:
Researchers at the New England College of Optometry are interested in engaging your community in the screening process. The purpose of this study is to improve the quality of the VERAS visual acuity screening instruments used in the preschool population. In order to do this, researchers intend to form a partnership with members of the Head Start communities so that communities can acquire the skills and know-how to perform high quality vision screenings.

Procedure:
During the trial session, participants will be trained on the procedures for screening children using the VERAS Crowded Single Lea Symbols Visual Acuity Test. Participants will then be asked to provide feedback on how to improve the ergonomics and usability of the VERAS cards. The feedback that participants provide will be used to develop a second generation of VERAS cards. Feedback may also be used to develop training materials for lay screeners.

Risks:
Participants will be at no risk during their role in this trial session.

Potential Benefits:
The potential benefits include the satisfaction of taking part in scientific research and contributing to the understanding and improvement of vision screening tools used in preschool children across the United States.

Confidentiality:
The information participants provide will remain entirely anonymous. However, the researchers may record participants' feedback by way of script or by way of a recording device. The privacy of all participants is assured.

Voluntary Participation or Withdrawal:
Being part of this project is voluntary. You may withdraw from the study at any time.

Compensation:
Participants will receive a $50 stipend for taking part in the trial session and for providing their feedback on the VERAS acuity cards.

Appendix II: Informed Consent Form for the Focus Group Participants

New England College of Optometry
Boston, Massachusetts
VSP Study

This form is to assert that I, _____, have been informed about my role in the trial focus session of the Vision Screening in Preschoolers (VSP) Study. I have been informed of any risks and benefits that I may be exposed to during this study by Dr Moore, O.D. and his research team.

I am aware that should I have any further questions about my participation in this study, I may contact Dr Moore at the New England College of Optometry 424 Beacon Street Boston, MA 02215 or via telephone at 617-236-6309, by cell at 617-921-5875 or via email at mooreb@neco.edu. If I feel my questions have not been satisfactorily answered, I can contact Dr Paul White, Chairman of the New England College of Optometry Institutional Review Board, at any time by calling 617-236-6247.

I acknowledge that I am participating in this study voluntarily and I am aware that I may withdraw my consent to participate at any time during the study. I have also been given a copy of this form.

_____ _____

Date **Signature of Participant**

_____ _____

Date **Witness to Signatures**

The participant has been fully informed about the purpose and nature of all procedures and the information collected. I have answered and will answer all the participants' questions to the best of my ability and knowledge. The participant will be informed of any changes in the procedures and the risks and benefits if any should occur during or after the course of the study.

_____ _____

Date **Doctor's or Designee's Signature**

This informed consent was approved by the New England College of Optometry Institutional Review Board.

_____ _____

Date **Signature of Chairman**

Appendix III: UNESCO Screening Protocol for the Original VERAS Cards

UNESCO Lea Symbols Distance Visual Acuity Test

What Are You Testing?

Visual acuity testing tests how well the child sees small objects far away. The test is performed from a distance of 5 feet (1.5 meters).

What You Need to Do the Test:

1. The VERAS Crowded Single Lea Symbols Visual Acuity Cards

Each card contains a symbol (an apple, house, circle, or square) surrounded by broken black crowding bars (lines around each symbol). The cards flip to expose one symbol to the next. A string measuring 1.5 meters must be attached to the acuity cards.

The test has 12 cards in total.
Cards 1-4 are used for training the child with both eyes open.
Cards 5-8 are used to test the right eye.
Cards 9-12 are used to test the left eye.

2. A lap card that has all of the 4 symbols on it.

3. Single, large symbols (one each of the apple, house, circle, and square) with crowding bars for pre-testing.

4. Two pairs of occluder glasses—one for testing the right eye and one for testing the left eye.

5. If the child will not wear the occluder glasses, use junior size eye patches (e.g. Opticlude patches) to occlude vision in the eye that is not being tested. [NOTE: The eye may be occluded with the palm of the hand only if all other methods fail.]

6. Chairs for the child and the screener

7. A data form and a pen.

Getting Ready:

1. Prepare a quiet place that has <u>good lighting</u> to test the children.

2. Have the child hold the attached string in the plane of their eye. Ensure that the

string is held taut and straight between the screener and child.

3. Make sure the child's name, birth date, test location, and date are on the data form. Write legibly.

4. Place the lap card in the child's lap/hand.

5. Arrange the four single, large symbols so that the symbols will face the child once the cards are exposed.

How You Do the Test:

1. If the child is wearing glasses, **do not** remove them prior to testing.
2. Make sure the child's eyes are lined up with the VERAS acuity cards.
3. Show the child the Lea lap card either by giving it to him/her to hold or by showing him/her where the lap card is displayed. The symbols should be right side up as the child is looking at them.
4. Pre-train the child binocularly (using both eyes) to practice identification of the symbols and find out whether the child is able to perform the test. Present the Lea flash cards and ask the child to correctly identify the shape presented.
5. Move to the 1.5 meter distance such that the string is extended maximally, before presenting the first four acuity cards one at a time. The child should identify the shape presented with both eyes open. Ask the child to name or point to the matching symbol on the lap card. If the child uses the lap card to identify the symbols, tell him/her to "touch" the symbol. Continue this procedure until all 4 symbols have been exposed. If the child cannot do the task by matching or naming, mark the child as "**Unable**" on the data form. If the child is able to do the task by matching or naming the symbols, mark the child as "**Able**."
6. Note: Other names for the symbols are acceptable as long as the child uses them **consistently**. For example, the child may call the apple a heart or the circle an "O" or the rectangle a window. However, if the child ever starts using a new name or there is ever any question about which symbol the child is referring to, the child should be asked to point to the symbol on the lap card.
7. Place the occluder glasses on the child so that the left eye is covered.
8. If you have difficulty getting the child to wear the occluder glasses, let the child admire himself/herself with the glasses on using a mirror.
9. If the child is unable or refuses to wear the occluder glasses, attempt to cover the child's left eye with a patch. To use the patch, point to the left eye and tell the child to close that eye. Then cover the left eye with the eye patch.

10. If the child refuses to wear the occluder glasses, or the patch, it is preferable to have a helper cover the child's eye with the palm of his/her hand. The examiner must monitor the child carefully to make sure he/she is not peeking and that the palm is not pressing against the child's eye. Covering the eye with **fingers** is not allowed because peeking is too easy with only fingers in front of the eye. If the child refuses to allow a helper to cover their eye, the child can cover his/her own eye with the palm of his/her hand.

11. Check the position of the child for testing. The child's eyes will need to be at the same height as the cards when held by the tester. It is important for the child to be able to look straight ahead at the cards and not be off to the side or lower or higher than the cards.

12. With the child's left eye covered, expose the next acuity card and ask the child to identify the symbol. The child may name the symbol or match the exposed symbol to the Lea lap card. If the child identifies the symbol correctly, flip to the next card and repeat the procedure until card 8 is exposed.

13. Mark on the data sheet how many symbols the child correctly identified out of the four using his right eye.

14. Occlude the child's right eye and repeat steps 12 and 13 using the child's left eye.

15. The child should be asked to match the symbols with the lap card if he/she responds with a symbol that is not one of the 4 on the chart.

16. If the examiner notices that a child gives a response while not paying attention to the VA task, that response should be ignored. The examiner should re-focus the child's attention on the task and continue testing.

17. Provide positive comments about the child's performance, regardless of whether the child identifies the symbol correctly or incorrectly.

What You Tell the Child

1. Urge the child to keep naming or matching the symbols even if the child must guess.

2. Remind the child to stay in the same position and look straight ahead at the cards

3. Encourage the child by saying "Good job!" even if the child names or matches the symbols incorrectly.

What You Write Down:

1. Mark "**Able**" or "**Unable**" for the Lea pretest.

   Pretest:
   Unable ( ) (STOP!)
   Able ( )

2. If the child identifies all four symbols correctly, write 4/4 beside the appropriate eye. If the child missed one symbol, record ¾ for that eye.

   a. If two of the symbols were identified incorrectly, the child fails the vision screening. The child must see an eye doctor.
   b. If the child missed one symbol or identified all the symbols correctly, the child has passed the vision screening. This child does not need to be screened again until the following year.

3. If the test is interrupted or incomplete after the child completes the pretest, write the capital letter "I" over the first symbol not presented to the child due to the interruption. If the interruption was on the right eye and the left eye was not tested, place an "I" in the space for the left eye.

Remember!

1. Make sure the child's name, birth date, test location, and date are on the data form.

2. Maintain the 1.5 meter distance during the test

3. Make sure the child does not peek around the occluder glasses, eye patch, or palm of his or her hand.

4. Keep urging the child to name or match each symbol

5. Do not tell the child he/she gave the wrong answer. Say "Good job!" no matter what the child answers. Do not allow a helper to tell the child the correct answer either.

Appendix IV: Focus Group Participant Questionnaire

Questionnaire-Vision Screening in Preschoolers (VSP) Study Phase I

Please indicate the following information about yourself:

1. Gender
   a. Female b. Male

2. Age _____

3. Ethnicity (Country of birth)_____

4. Native language
   a. English b. Spanish c. Other (please specify) _____

5. What is the highest level of education you have achieved?
   a. Did not complete high school
   b. Completed high school
   c. Attended, but did not complete college
   d. Completed college

6. Please specify which of the following titles is most appropriate for you in your role within the Head Start system:
   a. Nurse or health aide
   b. Teacher
   c. Parent
   d. Extended family member
   e. Case manager
   f. Other (please specify)_____

7. How easy was the training session to understand?
   a. Difficult
   b. Somewhat difficult
   c. Moderate
   d. Easy
   e. Very easy

8. How easy were the VERAS screening cards to use?
   a. Difficult
   b. Somewhat difficult
   c. Moderate
   d. Easy
   e. Very easy

9. What part of today's session did you find to be most difficult? Circle all that apply.
    a. The training session
    b. Understanding the instructions for how to screen
    c. Setting up the screening
    d. Explaining the instructions to the "child"
    e. Using the VERAS acuity cards
    f. Recording the results of the screening
    g. Deciding whether the child passed or failed the test
    h. Other (please specify): _____

10. Which part of today's session do you feel needs the most improvement?
    a. The training session
    b. Understanding the instructions for how to screen
    c. Setting up the screening
    d. Explaining the instructions to the "child"
    e. Using the VERAS acuity cards
    f. Recording the results of the screening
    g. Deciding whether the child passed or failed the test
    h. Other (please specify): _____

11. Would you feel confident screening a classroom of children by yourself after today's training session?
    a. Yes, I am ready to screen children
    b. Yes, but only after reviewing the procedures again
    c. Not sure
    d. No, I would like more practice time
    e. No, I would need more training

12. Please list some ways to improve the ease of use of the VERAS acuity cards.

    _____
    _____
    _____
    _____
    _____
    _____
    _____
    _____

13. Were you able to maintain the correct testing distance (5 feet) at all times?
    a. Yes
    b. No

14. Were you unsure which eye should be covered during the test?
    a. Yes
    b. No

    If yes, then please explain:
    _____
    _____
    _____
    _____

15. Did you have trouble deciding which card should be used to test each eye?
    a. Yes
    b. No

    If yes, then please explain:
    _____
    _____
    _____
    _____

16. Were you able to easily decide whether the "child" could see the symbol on the card?
    a. Yes, I could decide immediately
    b. Sometimes I was not sure
    c. Sometimes the child took too long to respond
    d. No, it was difficult to decide

17. Were you easily able to watch whether the child kept his/her eyes covered at all times?
    a. Yes, I was able to watch the child
    b. Sometimes I found myself unable to watch the child
    c. No, I was not able to watch the child

18. Did you feel you were able to easily give the screening instructions to the child?
    a. Yes, all the time
    b. Yes, but not every time
    c. Sometimes
    d. No, not always (please explain below)
    e. No, never (please explain below)

    _____
    _____
    _____
    _____
    _____
    _____

19. Would it help to have the symbols displayed as:
    a. Pages in a book
    b. A chart with all the symbols on one page
    c. Leave the symbols displayed as they are in the flip chart format
    d. Other (please explain)

_____
_____
_____
_____
_____
_____
_____

20. Which is the best way to display the answers to you?
    a. Have the answers printed on the back of each card
    b. The answers on the recording sheets are fine
    c. Other (please explain):

_____
_____
_____
_____
_____
_____
_____

21. Did you encourage the child to guess the symbol on the card?
    a. Yes, I always encouraged the child to guess
    b. Sometimes. I may have forgotten a few times
    c. No, I forgot to encourage the child to guess.

22. How many minutes did you spend in answering all the survey questions?

_____

Thank you for participating in the VSP Study. Your input is valuable!

The VSP Study Group
The New England College of Optometry

Appendix V: Spanish Data Sheet

Datos de Agudeza Visual

Nombre del niño:_____

Fecha de Nacimiento:_____

Escuela:_____
Maestro:_____

Ponga un √ en el símbolo si la respuesta es correcta.

Ponga una X en el símbolo si la respuesta no es correcta.

Resultado:

☐ **El niño ha sido incapaz de hacer el examen**
☐ **Pasó el examen**
☐ **Falló el examen**

Fecha:_____

Examinador:_____

Pagina #	Símbolo Correcto
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	

Appendix VI:
Screening Protocol for the M-VERAS Lea Symbols Distance Visual Acuity Cards

What Are You Testing?

Visual acuity testing tests how well the child sees small objects far away. The test is performed from a distance of 5 feet (1.5 meters).

What You Need to Do the Test:

1. The M-VERAS Crowded Single Lea Symbols Visual Acuity Cards

Each card contains a symbol (an apple, house, circle, or square) surrounded by broken black crowding bars (lines around each symbol). The cards flip to expose one symbol to the next. A string measuring 1.5 meters must be attached to the acuity cards.

The test has 12 cards in total.
Cards 1-4 are used for training the child with both eyes open.
Cards 5-8 are used to test the right eye.
Cards 9-12 are used to test the left eye.

2. A lap card that has all of the 4 symbols on it.

3. Single, large symbols (one each of the apple, house, circle, and square) with crowding bars for pre-testing.

4. Two pairs of occluder glasses—one for testing the right eye and one for testing the left eye.

5. NOTE: The eye may be occluded with the palm of the hand only if all other methods fail.

6. Chairs for the child and the screener

7. A data form and a pen.

Getting Ready:

1. Prepare a quiet place that has <u>good lighting</u> to test the children.

2. Have the child hold the attached string in the plane of their eye. Ensure that the string is held taut and straight between the screener and child.

3. Make sure the child's name, birth date, test location, and date are on the data

form. Write legibly.

4. Place the lap card in the child's lap/hand.

5. Arrange the four single, large symbols so that the symbols will face the child once the cards are exposed.

How You Do the Test:

1. If the child is wearing glasses, **do not** remove them prior to testing.
2. Make sure the child's eyes are lined up with the M-VERAS acuity cards.
3. Show the child the lap card either by giving it to him/her to hold or by showing him/her where the lap card is displayed. The symbols should be right side up as the child is looking at them.
4. Pre-train the child binocularly (using both eyes) to practice identification of the symbols and find out whether the child is able to perform the test. Present the Lea flash cards and ask the child to correctly identify the shape presented.
5. Move to the 1.5 meter distance such that the string is extended maximally, before presenting the first four acuity cards one at a time. The child should identify the shape presented with both eyes open. Ask the child to name or point to the matching symbol on the lap card. If the child uses the lap card to identify the symbols, tell him/her to "touch" the symbol. Continue this procedure until all 4 symbols have been exposed. If the child cannot do the task by matching or naming, mark the child as "**Unable**" on the data form. If the child is able to do the task by matching or naming the symbols, mark the child as "**Able**."
6. Note: Other names for the symbols are acceptable as long as the child uses them **consistently**. For example, the child may call the apple a heart or the circle an "O" or the rectangle a window. However, if the child ever starts using a new name or there is ever any question about which symbol the child is referring to, the child should be asked to point to the symbol on the lap card.
7. Place the occluder glasses on the child so that the left eye is covered.
8. If you have difficulty getting the child to wear the occluder glasses, let the child admire himself/herself with the glasses on using a hand-held mirror.
9. If the child is unable or refuses to wear the occluder glasses, it is preferable to have a helper cover the child's eye with the palm of his/her hand. The examiner must monitor the child carefully to make sure he/she is not peeking and that the palm is not pressing against the child's eye. Covering the eye with **fingers** is not allowed because peeking is too easy with only fingers in front of the eye. If the child refuses to allow a helper to cover their eye, the child can cover his/her own eye with the palm of his/her hand.

10. Check the position of the child for testing. The child's eyes will need to be at the same height as the cards when held by the tester. It is important for the child to be able to look straight ahead at the cards and not be off to the side or lower or higher than the cards.

11. With the child's left eye covered, expose the next acuity card and ask the child to identify the symbol. The child may name the symbol or match the exposed symbol to the Lea lap card. If the child identifies the symbol correctly, flip to the next card and repeat the procedure until card 8 is exposed.

12. Mark on the data sheet how many symbols the child correctly identified out of the four using his right eye.

13. Occlude the child's right eye and repeat steps 11 and 12 using the child's left eye.

14. The child should be asked to match the symbols with the lap card if he/she responds with a symbol that is not one of the 4 on the chart.

15. If the examiner notices that a child gives a response while not paying attention to the VA task, that response should be ignored. The examiner should re-focus the child's attention on the task and continue testing.

16. Provide positive comments about the child's performance, regardless of whether the child identifies the symbol correctly or incorrectly.

What You Tell the Child

1. Urge the child to keep naming or matching the symbols even if the child must guess.

2. Remind the child to stay in the same position and look straight ahead at the cards

3. Encourage the child by saying "Good job!" even if the child names or matches the symbols incorrectly.

What You Write Down:

1. Mark "**Able**" or "**Unable**" for the Lea pretest.

Pretest:

Unable ( ) (STOP!)
Able ( )

2. For each symbol identified correctly, place a check mark over the symbol. If a child responds incorrectly, place an X on top of the misidentified symbol.

a. If two of the first four symbols were identified incorrectly, the child fails

the vision screening. The child must see an eye doctor.

b. If two of the symbols from cards 5-8 are identified incorrectly, the child fails the vision screening. The child must see an eye doctor.
c. If two of the symbols form cards 9-12 are identified incorrectly, the child fails the vision screening. The child must see an eye doctor.
d. If the child missed one symbol or identified all the symbols correctly, the child has passed the vision screening. This child does not need to be screened again until the following year.

Remember!

1. Make sure the child's name, birth date, test location, and date are on the data form.

2. Maintain the 1.5 meter distance at all times during the test

3. Make sure the child does not peek around the occluder glasses, or palm of his or her hand.

4. Keep urging the child to name or match each symbol

5. Do not tell the child he/she gave the wrong answer. Say "Good job!" no matter what the child answers. Do not allow a helper to tell the child the correct answer either.

Appendix VII:
Screening Protocol for the Lea Light Box Distance Visual Acuity Chart

What Are You Testing?

Visual acuity testing tests how well the child sees small objects far away. The test is performed from a distance of 5 feet (1.5 meters).

What You Need to Do the Test:

1. The Lea Light Box (LLB) Acuity Chart

Each line is made up of several symbols (an apple, house, circle, or square) surrounded by solid black crowding bars (lines around each line of symbols). Each line of symbols can be illuminated individually. A red bar appears below the symbol the child must identify. A string measuring 1.5 meters must be attached to the LLB.

The LLB chart has 3 rows of symbols.

Line 1 contains a line of four large symbols. This line is used to train the child with both eyes open.
Line 2 contains two groups of five symbols. The left set of symbols is meant to test the left eye and the right set of symbols is meant to test the right eye.
Line 3 is meant to screen older children (6 and older) and are not needed in this study.

2. Laser pointer. This laser pointer illuminates the line of interest while testing. It can also be used to create a red bar beneath the symbol of interest.

3. A lap card that has each of the 4 symbols on it.

4. Single, large symbols (one each of the apple, house, circle, and square) with crowding bars for pre-testing.

5. Two pairs of occluder glasses—one for testing the right eye and one for testing the left eye.

6. NOTE: The eye may be occluded with the palm of the hand only if all other methods fail.

7. Chairs for the child and the screener

8. A data form and a pen.

Getting Ready:

1. Prepare a quiet place that has good lighting to test the children.
2. Place the LLB acuity chart on a flat surface so the exposed symbols will be at the child's eye level while the child is seated.
3. Extend the 1.5m string fully and place a chair at the 1.5m location such that the string ends halfway over the chair seat. Make sure the string is held taut and parallel to the ground when marking off this distance. Make sure the screening chair is directly in front of the LLB acuity chart.
4. Make sure the child's name, birth date, test location, and date are on the data form. Write legibly.
5. Place the lap card in the child's lap/hand.
6. Arrange the four single, large symbols so that the symbols will face the child once the cards are exposed.

How You Do the Test:

1. If the child is wearing glasses, **do not** remove them prior to testing.
2. Make sure the child's eyes are at the same level as the LLB chart.
3. Show the child the lap card by giving it to him/her to hold. The symbols should be right side up as the child is looking at them.
4. Pre-train the child binocularly (using both eyes) to practice identification of the symbols and find out whether the child is able to perform the test. Present the Lea flash cards and ask the child to correctly identify the shape presented.
5. Turn the LLB chart on using the switch located at the back of the box.
6. Direct the child's attention to the LLB acuity chart. Make sure the LLB chart is 1.5 m away from the child's eyes.
7. Isolate the top line of letters on the LLB chart.
8. The child should identify the shapes on the top line with both eyes open. Ask the child to name or point to the matching symbol on the lap card. If the child uses the lap card to identify the symbols, tell him/her to "touch" the symbol. Continue this procedure until all 4 symbols have been identified. If the child cannot do the task by matching or naming, mark the child as "**Unable**" on the data form. If the child is able to do the task by matching or naming the symbols, mark the child as "**Able**."
9. Note: Other names for the symbols are acceptable as long as the child uses them

consistently. For example, the child may call the apple a heart or the circle an "O" or the rectangle a window. However, if the child ever starts using a new name or there is ever any question about which symbol the child is referring to, the child should be asked to point to the symbol on the lap card.

10. Place the occluder glasses on the child so that the left eye is covered and the right eye is exposed. This will test the vision in the right eye.

11. If you have difficulty getting the child to wear the occluder glasses, let the child admire himself/herself with the glasses on using a hand-held mirror.

12. If the child is unable or refuses to wear the occluder glasses, it is preferable to have a helper cover the child's eye with the palm of his/her hand. The examiner must monitor the child carefully to make sure he/she is not peeking and that the palm is not pressing against the child's eye. Covering the eye with **fingers** is not allowed because peeking is too easy with only fingers in front of the eye. If the child refuses to allow a helper to cover their eye, the child can cover his/her own eye with the palm of his/her hand.

13. Check the position of the child for testing. The child's eyes will need to be at the same height as the LLB chart during testing. It is important for the child to be able to look straight ahead at the LLB chart and not be off to the side or lower or higher than the LLB chart.

14. With the child's left eye covered, expose the symbols on the second line on the right side of the box and ask the child to identify the symbols. The child may name the symbol or match the exposed symbol to the Lea lap card.

15. Mark on the data sheet how many symbols the child correctly identified out of the four using his right eye.

16. Occlude the child's right eye and repeat steps 14 and 15 using the child's left eye.

17. The child should be asked to match the symbols with the lap card if he/she responds with a symbol that is not one of the 4 on the chart.

18. If the examiner notices that a child gives a response while not paying attention to the VA task, that response should be ignored. The examiner should re-focus the child's attention on the task and continue testing.

19. Provide positive comments about the child's performance, regardless of whether the child identifies the symbol correctly or incorrectly.

What You Tell the Child

1. Urge the child to keep naming or matching the symbols even if the child must guess.

2. Remind the child to stay in the same position and look straight ahead at the symbols on the LLB chart.

3. Encourage the child by saying "Good job!" even if the child names or matches the symbols incorrectly.

What You Write Down:

1. Mark "**Able**" or "**Unable**" for the Lea pretest.

   Pretest:

   Unable ( ) (STOP!)
   Able ( )

2. For each symbol identified correctly, place a check mark over the symbol. If a child responds incorrectly, place an X on top of the misidentified symbol.

   a. If two of the first four symbols were identified incorrectly, the child fails the vision screening. The child must see an eye doctor.
   b. If two of the symbols from the group on the right on line 2 are misidentified, the child fails the vision screening. The child must see an eye doctor.
   c. If two of the symbols from the group on the left on line 2 are misidentified, the child fails the vision screening. The child must see an eye doctor.
   d. If the child missed one symbol in each group or identified all the symbols correctly, the child has passed the vision screening. This child does not need to be screened again until the following year.

3. If the test is interrupted or incomplete after the child completes the pretest, write the capital letter "I" over the first symbol not presented to the child due to the interruption. If the interruption was on the right eye and the left eye was not tested, place an "I" in the space for the left eye.

Remember!

1. Make sure the child's name, birth date, test location, and date are on the data form.

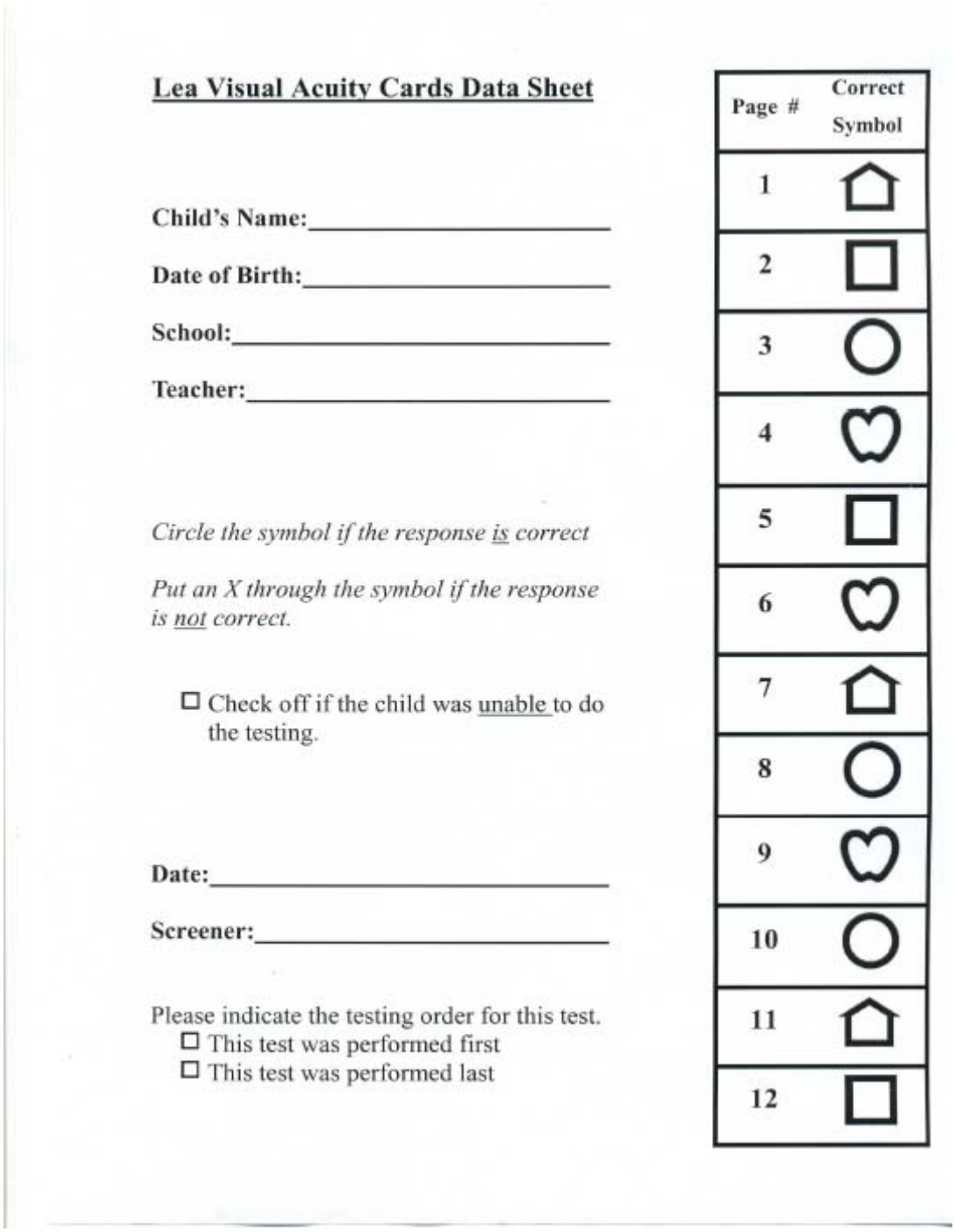
2. Maintain the 1.5 meter distance at all times during the test.

3. Make sure the child does not peek around the occluder glasses, or palm of his or her hand.

4. Keep urging the child to name or match each symbol.

5. Do not tell the child he/she gave the wrong answer. Say “Good job!” no matter what the child answers. Do not allow a helper to tell the child the correct answer either.

Appendix VIII: Data Sheets for the M-VERAS Cards and the LLB Chart



Lea Visual Acuity Cards Data Sheet

Child's Name:_____

Date of Birth:_____

School:_____

Teacher:_____

Circle the symbol if the response is correct

Put an X through the symbol if the response is not correct.

☐ Check off if the child was unable to do the testing.

Date:_____

Screener:_____

Please indicate the testing order for this test.
☐ This test was performed first
☐ This test was performed last

Page #	Correct Symbol
1	⌂
2	□
3	○
4	♡
5	□
6	♡
7	⌂
8	○
9	♡
10	○
11	⌂
12	□

Light Box Visual Acuity Data Sheet

Child's Name:_____

Date of Birth:_____

School:_____

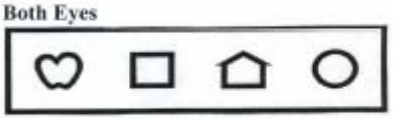
Teacher:_____

Circle the symbol if the response is correct

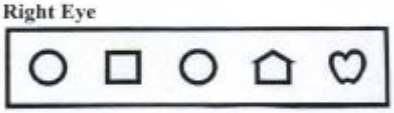
Put an X through the symbol if the response is not correct.

☐ Check off if the child was unable to do the testing.

Both Eyes



Right Eye



Left Eye

Date:_____

Screener:_____

Please indicate the testing order for this test.

☐ This test was performed first

☐ This test was performed last

Appendix IX: Informed Consent Form for Phase III

New England College of Optometry
Boston, Massachusetts
Informed Consent
VSP Study

Participant's Name: _____

BACKROUND:
Vision screening of all children enrolled in Head Start is required by local and federal regulations. In young children, visual acuity tests using the Lea Symbols (a house, circle, square, and apple) have been found to work better than letters, which are used for older children and adults. This study is being carried out to help find the best way to screen vision in preschool-aged children using the Lea Symbols either in the widely used series of plastic charts, or in a new way using a small box that has a built-in light, like a TV set or computer screen.

If you choose to have your child participate, he/she will be screened with both visual acuity tests, (this will take no more than 15 minutes) in a room at your child's Head Start. If he/she fails either test, the child will be given an eye exam on another day to determine if there is an important vision problem. Some children who pass both tests will also have an eye exam. You are welcome to attend that eye exam which will be carried out on The Vision In Preschoolers (VIP) Study 38-ft Vision Van parked at your child's Head Start Center. If you do not choose to participate in this project, your child will receive the vision screening usually carried out at the Head Start center by Head Start or other personnel.

This study is being conducted by the New England College of Optometry (NECO) and led by Bruce Moore, O.D., a professor of pediatrics at NECO. He and NECO have been involved for eight years in studies of preschoolers carried out in cooperation with ABCD Head Start in Boston and funded by the National Eye Institute and the National Institutes of Health. Most of these studies were part of The Vision In Preschoolers (VIP) Study.

PURPOSES:
A primary purpose of the previous VIP studies was to determine which vision screening tests can best identify preschool children in need of a fuller examination and vision care. The purpose of this present study is to find if we can further improve vision screening with the Lea Symbols by using a method that is more like a TV or computer, things children today are very familiar and comfortable with, and may work better than the older ways of doing vision screening.

PROCEDURE:
The first part of the project is a vision screening that will take place inside your child's Head Start Center, and will only take about 15 minutes to complete. Your child will be tested on

two types of visual acuity tests, one using plastic cards having pictures of a house, square, circle, or apple on it. Your child can either name the shape, or can match the picture to a card he/she holds on the lap. The other test uses the same symbols or shapes, but in a small box that is lit up and looks like a small TV or computer screen. We have found in previous studies that almost all 3-5 year old children with good vision can do these tests, even those that are shy or do not speak English or Spanish. Children that have eye problems are the ones that usually have difficulty doing the tests.

The second part of the project is a full eye examination. Those children who are not able to do both tests successfully will then be scheduled to have an eye exam on the VIP Vision Van a week or two later. Also, some children who pass the tests will also be asked to have an exam, so that we can scientifically determine if the tests work. We estimate that about 1 in 5 children will not pass the test (about a 20% failure rate), and we will randomly pick about the same number of children who pass the tests to also have an eye exam.

The eye exams will take place in a specially equipped 38-ft VIP Vision Van parked at your child's Head Start Center. Children will not be transported away from their Head Start Center. They will be closely supervised at all times and the children almost always have fun and an interesting experience on the van, much like going on a field trip.

This is what will happen on the Van parked at your child's Head Start Center:

- Your child will have a full eye examination which will include a test of your child's visual acuity, eye position, refractive error, and health of the eyes. Eye drops to dilate (enlarge) your child's pupils will be used to allow a thorough examination of the health of the eyes and to determine the refractive error. All of these tests are commonly included in regular eye exams of children. Note: these drops will not be used during the vision screening part of the project, but only for those children who receive a full eye examination.

- You are invited to attend the eye exam on the Van with your child, but you do not need to attend if you are not able or choose not to attend. Even if you choose not to go with your child to the eye examination, you will get a written report about your child's eyes and vision.

- If your child needs eyeglasses, we will give you a prescription for the eyeglasses to be filled wherever you choose. You will also get a report of the examination for your child's pediatrician or clinic. Head Start health personnel will also be given information about the examination. If your child needs follow-up care, we will work with you and the Head Start health personnel to make sure your child gets that care.

RISKS AND DISCOMFORTS:
The project does not include any serious health risks for your child but may involve the same minimum risks involved with any eye examination. All the tests done with your child are

routinely used in children's eye examinations. The risks and/or discomforts include:

- Eye drops will be used to temporarily reduce the accommodation (focusing of the eyes) so that the refraction and thorough examination of the health of the eyes can be done.

- Discomfort which lasts less than half a minute may occur when your child receives these eye drops.

- Because of the drops used, your child's eyes may be sensitive to light and the vision may be blurred for a few hours. Your child will be given non-prescription sunglasses to protect his/her eyes from light. Sunglasses are not needed if the child remains indoors.

- Eye drops are used in most children's eye examinations. Side effects from the drops happen rarely. Side effects which may occur include: irritation, tearing, or redness of the eyes; upset stomach, restlessness, sleepiness, weakness, disorientation and hallucinations. Side effects are most likely to occur while your child is still undergoing the eye examination. If side effects occur, treatment is rarely required and they go away in two to four hours. Simply having the child rest will alleviate these short-lasting symptoms.

- You may contact the The New England College of Optometry at **(617) 236-6309** or cell phone number **(617) 921-5875** or after-hours phone number **(617) 262-2020** to discuss any side effects that are of concern to you. In the unlikely event of more significant adverse effects, children will be referred to The Children's Hospital, The Massachusetts Eye and Ear Infirmary, Boston Medical Center, other facilities, or to their pediatrician for further care. Responsibility for any fees incurred in this follow-up care will be the responsibility of the parents. If the frequency or severity of adverse reactions from the use of eye drops or other causes warrants, the Institutional Review Board (Human Protection Committee) may alter the study protocols, suspend, or terminate the study. You will be made aware of any significant new findings that may influence your willingness for your child's participation.

POTENTIAL BENEFITS:
The benefit of the study to your child is that it would probably identify any eye problem and make it possible for the child to obtain prompt and appropriate treatment. In addition, the overall information from this research study will provide data on the purposes of the study described before.

CONFIDENTIALITY:
Your child's medical records will be kept as confidential as possible within the limitations of state and federal law.

If you decide to allow your child be a subject in this study, both demographic and technical information about your child will be collected. Demographic information may include, but

will not be limited to such things as name, date of birth, address, gender, ethnicity, etc. Technical information will include elements of your child's personal health history and results of all the tests and measurements related to the study. This information is collected in order to determine whether your child is eligible to be a subject in the study; that is, to meet the inclusion/exclusion criteria (the child is between 3 and 5 years of age and is enrolled in the ABCD Boston Head Start program) and, if so, to allow the study investigators to gather the data that is necessary to support the study's purpose. The results from all of the subjects in the study can then be analyzed to develop the study's conclusion.

All study-related information will remain confidential with the study investigators or administrative staff. However, any regulatory authority or the Institutional Review Board may inspect the investigator's records pertaining to your child as a subject. But they too should maintain confidentiality.

The results of the study may be used in health care education or in scientific publications. Neither your child's name nor any information that specifically could identify him/her will be used in any such presentation or publication.

PERSONAL HEALTH INFORMATION:
Your child's personal health information (PHI), as related to this study, is described in the "Confidentiality" section above. If you sign this informed consent form, it grants permission to use your child's PHI as specifically discussed. This permission does not have an expiration date, but you can cancel at any time by writing to the principal investigator(s) at the address below.

If you cancel your permission to use your child's PHI after the study has started but before your child's study participation would normally be concluded, your child will not be allowed to continue in the study and the investigators will stop collecting data. However, they retain the right to use the information they have already collected to evaluate the study's results.

PRIVACY PRACTICES AND YOUR RIGHTS:
Health care providers are required by law to keep private any health information that identifies people. Federal Privacy Regulations require that you authorize the release of any health information that may reveal your child's identity. The persons and entities that you are authorizing to use or inspect all of the health information generated or collected about your child during this study includes the study doctor(s), the study staff, the Institution, any study Sponsor (or the authorized agents of the sponsor), the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) agencies, and the Institutional Review Board. Because of the need to release information to these parties absolute confidentiality cannot be guaranteed. Once your child's personal health information is released it may be re-disclosed, at which point the health information may no longer be protected by federal privacy regulations.

You may ask the study investigator to see a copy of your child's PHI related to the study. You may also request the study investigator to correct any information that you feel is incorrect. However, you may have to wait until the end of the study to see your child's records so that the study can be organized and conducted scientifically.

You must be given notice of your investigator's privacy policies. The Confidentiality, Personal Health Information, and Privacy Practices and Your Rights sections of this form fulfill this requirement.

Unless you authorize the use and disclosure of your child's personal health information, your child cannot participate in this research study. If you refuse to give your authorization, your child's medical care will not be affected.

VOLUNTARY PARTICIPATION OR WITHDRAWAL:
Being part of this project is voluntary. Whether or not you chose to let your child take part in the project will have no bearing on his or her standing at Head Start or any care they or you may be receiving through The New England College of Optometry or your own practioner(s). You may take your child out of this project at any time. If your child's doctor says your child should not be in the project, you may take your child out. Taking your child out of this project will not affect your right to health care. The sponsor, Institutional Review Board, or the investigator may terminate your child's participation in the study (with or without your consent) if it is believed to be in your child's best interest or if your child fails to keep appointments or follow study instructions.

COMPENSATION:
If your child needs to receive follow-up care from another doctor because of health conditions which were found during the project, the cost of getting this follow-up care for your child will not be covered through the project, but may be covered by your health insurance. You and your child will not get paid money for being in this project.

Appendix X: Manual of Procedures for Gold Standard Examination

The following protocols for the gold standard examination procedures have been adopted from the VIP Study. Permission has been obtained in the reproduction and modification of these procedures. The gold standard examiners were expected to follow these protocols to maintain consistency across all the sites studied.

Visual Acuity Test

What Are You Testing?

Distance visual acuity testing assesses the ability to discriminate fine details of distance targets under monocular viewing conditions.

What You Need to Do the Test:

1. A set of MassVAT Lea acuity flip cards.
2. Single, large symbols with crowding bars for training the child.
3. A crowded Lea symbols lap card.

Getting Ready:

1. The overhead lights in the van should be on.
2. Using the measuring ribbon marking off the 10 foot testing distance as an aide, position the child in the exam chair.

How You Do the Test:

Binocular Training/Pretest:

1. Give the child the lap card with the Lea symbols on it and show the child one of the training cards at a distance approximately 2 feet from the child.

2. For each symbol, ask the child to point to the symbols on the lap card or to say a name for the symbol. Use the same names consistently during testing.

3. Repeat the procedure with all 4 symbols. If the response to a presentation is incorrect, ask the child a second time to identify the symbol after he/she has identified the other symbols. Allow a second attempt for each symbol incorrectly identified the first time. If the child cannot respond correctly to all 4 symbols, the child may be given a break and given another opportunity to identify the symbols as described above. If the child cannot respond correctly to all 4 symbols after a break or if there is no time in the schedule for a break, the child is scored "Unable" on the data form.

4. If the child spontaneously names all the letters correctly, the lap card may be abandoned and the child's verbal responses accepted.

Threshold Determination:

1. Prepare the child for monocular testing by placing the appropriate set of occluder glasses on such that the left eye is covered and so that the child cannot use the left

eye to see the letters. After testing the right eye, as described below, switch the occluder glasses to test the left eye.

2. If the child refuses to wear the occluder glasses, the child may occlude his/her eye with the palm of his/her hand. The examiner must monitor the child carefully to make sure he/she is not peeking and that the palm is not pressing against the child's eye. Covering the eye with fingers is not allowed because peeking is too easy with only fingers in front of the eye.

3. After every 2 or 3 responses, give positive comments to the child, regardless of whether the previous response was correct.

4. If the child will not give a response for a symbol, encourage the child to guess.

5. The child should be asked to use matching with the lap card if he/she responds with a symbol name that is not one of the 4 on the chart.

6. If the examiner notices that a child gives a response while not paying attention to the visual acuity task, that response should be ignored. The examiner should re-focus the child's attention on the task and continue testing.

7. Start with the largest line of symbols (20/80) and then flip to the smaller symbols until the child gets 4 out of 5 of the symbols on the line incorrect.

8. Throughout the testing, check to make sure that the child is looking at the acuity cards and is not squinting.

9. Record the visual acuity result by writing the denominator of the Snellen fraction displayed on the last card that the child responded correctly at least 3 out of 5 times.

10. Repeat the procedure by occluding the right eye with the appropriate glasses and testing the left eye.

What You Tell the Child:

Keep encouraging the child to respond appropriately and sit still in the chair. Tell the child that it is all right to guess if he/she is not sure about a symbol being presented.

What You Write Down:

1. If the child refuses to do the test or cannot do the test, mark "Unable."

2. Write down the denominator of the Snellen fraction for each eye.

3. If the child stops for any reason before completing the test, mark “Incomplete.”

Remember!

1. Make sure the occluder glasses or child’s palm completely covers the child's eye.

2. Give positive comments to the child, regardless of whether the previous response was correct.

3. Keep encouraging the child to guess

Lensometry

What Are You Testing?

Lensometry is a technique that measures the dioptric power of spectacle lenses.

What You Need to Do the Test:

1. A lensometer
2. The patient's spectacles

Getting Ready:

1. Adjust the focusing eyepiece of the lensometer so that it reads 0 D on the measuring drum with the target crisply in focus.

How You Do the Test:

1. Place the spectacles in the lensometer with the ocular surface away from the examiner.
2. Measure the right lens first. Then measure the left lens.
3. Center the spectacles within the carriage of the instrument so that the target is centrally aligned within the eyepiece reticule.
4. From an excess plus power direction, rotate the power drum of the lensometer so that the target comes to a sharp focus in the first meridian, simultaneously rotating the axis drum and making its target lines contiguous. This is the first meridian. Note the position of the power drum.
5. Continue rotating the power drum until the second meridian comes into sharp, contiguous focus. This is the second meridian. Note the position of the power and axis drums.
6. If both meridians come to a sharp focus simultaneously, the lens is spherical. If there are two distinctly different foci, the lens is spherocylindrical.
7. If there is an add, measure it. The multifocal add, if present, is recorded as a plus add.
8. The spherical or spherocylindrical power and axis is recorded in minus cylinder form.

Remember!

1. Focus the lensometer before each reading.
2. Carefully fine-tune the power and the axis drums.
3. If the lens is a multifocal lens, look carefully for the maximum plus power position of the lens.

Cover Test

What Are You Testing?

The purpose of performing a cover test is to determine the presence of primary position heterotropias (manifest strabismus) and heterophorias (latent strabismus), as these conditions are often associated with amblyopia in young children. The cover test provides a precise, objective measure of eye alignment and results in information on the presence, magnitude, direction, and frequency of the deviation.

What You Need to Do the Test:

1. A black plastic occluder.
2. A detailed picture for distance fixation.
3. A detailed target for near fixation.
4. Loose prisms or prism bars.

Getting Ready:

1. Have the targets provided for the near cover test ready for use.

How You Do the Test:

1. The examiner is seated facing the child and slightly to the child's side during distance testing, and directly in front of the child during near testing.
2. First perform the cover test (both the unilateral and alternating cover test procedures) in primary gaze using the distance target at 10 feet (3m).
3. Then, repeat testing at 40 cm.

Distance Cover Test:

Unilateral Cover (Cover-Uncover) Test:

1. Direct the child to look at **details** on the distance fixation target and ask the child to concentrate on the picture.
2. For testing of the right eye, place the occluder over the child's left eye while closely observing the child's right eye for movement after the left eye is covered. Allow 3-4 seconds before proceeding in case the child takes up fixation slowly and continue to observe the right eye only for movement.
3. For testing of the left eye, repeat the procedure but cover the child's right eye while closely observing the left eye for movement after the right eye is covered. Again, allow 3-4 seconds before proceeding.
4. Repeat the unilateral cover-uncover test a minimum of 3 times for each eye.

You may use more repetitions, if necessary, to determine the presence and frequency (i.e. constant or intermittent) of the deviation.

5. Make certain that the occluder completely covers the eye on each cover stroke.

6. If no movement of either the right or left eye is detected when performing the unilateral cover test, then the patient does not have a tropia. Proceed with the alternating cover test to detect the presence of a phoria.

7. If movement of the fellow eye is detected when testing either the right or left eye, the child is strabismics, record "**Tropia, total deviation**." Describe the tropia by completing the set of items listed below in steps 8-11.

8. Note the laterality:

a. Write *right* when the right eye deviates consistently.

b. Write *left* when the left eye deviates consistently.

c. Write *alternating* when fixation alternates.

9. Note the frequency: Constant or intermittent.

10. Note the direction:

a. If the deviating eye moves inward after the fellow eye is covered, an *exotropia* is present.

b. If the deviating eye moves outward after the fellow eye is covered, an *esotropia* is present.

c. If the deviating eye moves down after the fellow eye is covered, a *hypertropia* is present.

d. If the deviating eye moves up after the fellow eye is covered, a *hypotropia* is present.

11. Note the direction of the *larger* directional component of the strabismus: Eso, exo, hyper, hypo. Measure and record the magnitude of the larger component of the deviation using the "Measurement Procedure for Strabismus" (described next). All strabismic deviations must be neutralized with prisms, and not estimated.

Measurement Procedure for Strabismus:

12. Place either loose prisms or a prism bar before the deviating eye. The prism chosen for starting this procedure is based on the examiner's estimate of the amount of the larger deviation present. For example, if a child has an esotropia with a hypertropic component and the esotropia is larger, use a base-out prism and determine the prism value necessary to neutralize the esotropic component of the deviation.

13. Without allowing binocular fixation, alternately cover the right and left eyes while adding the appropriate base prism until the direction of the larger component of the strabismus in the deviating eye is neutralized (i.e. no movement is observed). Then add additional prism until the deviation reverses direction. For example; for esotropia, add base-out prism until a small exo movement is observed. The value in prism diopters used just before the direction reversal is recorded as the magnitude of the strabismus. Record this on the data form.
14. For your use in providing clinical care to the child, you may neutralize any other smaller deviation observed.

Alternating Cover Test Procedure for Phorias:

1. If there was no strabismus present on the distance unilateral cover test, the examiner should proceed with the distance alternating cover test to detect the presence and magnitude of a phoria.
2. The occluder is introduced and held in place in front of the left eye for at least 1-2 seconds and it is then moved quickly to the right eye and held in place for 1-2 seconds while **not allowing binocular fixation to occur**.
3. This cycle should be repeated at least 3 times as the examiner observes the eye that is being uncovered to detect a re-fixation movement.
4. If no movement is present on the alternating cover test, write "**No tropia or phoria**."
5. If a phoria is detected, write "**Phoria & no tropia**." Describe the phoria. Neutralize the phoria with loose prisms or a prism bar as described next in the "Measurement Procedure for Alternating Cover Test."
6. Note the direction:
    a. If the eye moves inward as the fellow eye is uncovered, an exophoria is present.
    b. If the eye moves outward as the fellow eye is uncovered, an esophoria is present.
    c. If the eye moves down as the fellow eye is uncovered, a hyperphoria is present in that eye.
    d. If the eye moves up as the fellow eye is uncovered, a hypophoria is present in that eye.

Measurement Procedure for Alternating Cover Test:

7. If a phoria is detected on the alternating cover test, place either loose prisms or a prism bar before one of the child's eyes. The base direction and amount of prism chosen is based on the examiner's estimate of the child's deviation.
8. Alternate covering the right and left eyes without allowing binocular fixation while increasing the prism power until the movement is neutralized (i.e. no movement is observed). Add additional prism until the direction of the deviation is first reversed.
9. The value in prism diopters obtained just before the direction is reversed is recorded as the magnitude of the phoria.

Near Cover Test:

1. Follow the distance unilateral and alternating cover test procedures as outlined above, but use a near viewing distance (40 cm) for the near cover test procedure.
2. Use the near targets provided at 40 cm instead of the distance target.
3. Establish the correct test distance (40 cm) at the beginning of the procedure. Re-check the viewing distance as needed if the child moves closer or further away during testing.
4. During the near cover test you may have the child "glue the target to the end of your nose" to maintain an accurate testing distance and to reinforce fixation. This will allow the examiner the use of both hands to hold the occluder and prism.
5. While testing, keep reminding the child to look at the fixation targets.
6. Engaging the child in describing the object will help maintain the child's attention and help to stabilize accommodation.
7. Other aspects of testing and measurement are the same to maintain near fixation as was described to maintain distance fixation.

What You Tell the Child:

1. When viewing the near fixation target, have the child describe the characteristics of the object or objects on the target. The important task is to make certain that the child maintains fixation on the near target. ("How many eyes does the clown have? What color is Big Bird?")

What You Write Down:

1. If a tropia is present, record the results as "**Tropia (total deviation)**" and

complete the boxed items for Laterality (right, left, or alternating); Frequency (constant or intermittent); the direction of the deviation (eso, exo, hyper, or hypo); and the magnitude of the total deviation. If the tropia is composed of both a horizontal and vertical component, record the characteristics of the larger component on the GSE form.

2. If no tropia is present but a phoria is detected, record the results as a "**Phoria & no tropia**." Indicate the direction (eso, exo, left hyper, or right hyper) and the magnitude of the deviation.
3. If no tropia is present and no phoria is present, record "**No tropia or phoria**."
4. Write "**Incomplete**" for laterality, frequency, direction, and/or magnitude if the test is aborted (e.g., due to the child's uncooperativeness) before an assessment could be made.

Remember!

1. Keep asking the child to describe the fixation target that you are using while you are doing the test. Direct the child's attention to the **details** on the targets.
2. Make sure the occluder completely covers the eye and stays over the eye for at least 3 seconds.
3. Prism neutralization of all strabismic deviations and phorias must be performed using the alternate cover test.
4. Have several different targets available and change them as needed to help maintain continued and accurate fixation.

Versions and Ductions

What Are You Testing?

Versions test binocular ocular motilities. Ductions test monocular motilities. Ductions are necessary only if abnormalities are detected while testing versions.

What You Need to Do the Test:

1. A transilluminator for the target.
2. If using a Heine instrument, use the tip for the transilluminator.

Getting Ready:

1. Seat the child (without eyeglasses) at arm's length from the examiner.

How You Do the Test:

Versions:

1. It is often helpful to stabilize the child's head with your left hand and move the target with your right hand.
2. Hold a transilluminator about 30 cm from the child in primary gaze.
3. Move the target to your right until the eyes are no longer able to follow. A slight end-point nystagmus (sometimes present) is normal.
4. Next, move the target up and down until the eyes cannot follow. Lift the eyelids on down gaze.
5. Return the target to the extreme right horizontal position and move the target to the opposite extreme left horizontal position.
6. Repeat the up and down positions on this side.
7. Return the target to the center and repeat the up and down positions.
8. Note any restrictions, relative overactions or underactions, A or V patterns, misalignment not in primary gaze, or other abnormalities.
9. If no abnormalities are observed, testing is completed.

Ductions:

1. The monocular procedure is necessary only if abnormalities are noted with the binocular procedure described above.
2. Have the child fixate on a transilluminator at 30 cm (without eyeglasses) as above. Occlude the left eye.
3. Move the light so the right eye is adducted about 23 degrees and move the

light straight up, keeping the light directed towards the eye.

4. Move the light down, keeping the light directed towards the eye.
5. Next, move the light so the eye is abducted 40 to 50 degrees. Move the target straight up, keeping the light directed towards the eye.
6. Move the light down, keeping the light directed towards the eye.
7. Maintaining the light in the horizontal plane, position the light in front of the eye being tested and move the light straight towards the nose.
8. Maintaining the light in the same horizontal plane, move the light directly towards the ear.
9. Note any restrictions.
10. Repeat monocular testing by occluding the right eye and asking the child to move the left eye.

What You Tell the Child:

1. Tell the child to fixate on the transilluminator as you move it.
2. It is often helpful to talk about the light in an effort to encourage the child to look at it. You can make comments about looking into the light to see what the child ate for breakfast, to see if a fairy lives inside the light, etc.

What You Write Down:

1. If you observe no binocular abnormalities, write "**Full and Smooth**."
2. If you observe binocular abnormalities, write what was observed: "**Restrictions**," "**Under/Overactions**," "**A/V Patterns**," "**Misalignment**," or "**Other**."
3. Write "**Unable**" if you are not able to test versions on the child (e.g., due to uncooperativeness).
4. If ductions were performed, write in your observations on the data form.
5. At the end of the data form, you may record other pertinent findings. For example, if you identify a syndrome such as Duane's retraction syndrome, you may note it there.

Remember!

1. Use the transilluminator, do not use a penlight.
2. Encourage the child to fixate on the transilluminator.
3. It may be helpful to stabilize the child's head with your left hand.

Assessment of Pupillary Function

What Are You Testing?

The direct and consensual pupillary responses will be assessed to determine the patency of the pupillary pathway.

What You Need to Do the Test:

1. A transilluminator or BIO as a bright light source
2. A distance fixation target: A TV and VCR placed at least 10 feet away from the child.
3. A millimeter ruler

Getting Ready:

1. Chairs for the child and the examiner are placed 2 feet apart
2. Seat the child (without eyeglasses) at arm's length from the examiner.
3. Have the transilluminator or BIO light ready for use
4. Turn on the VCR and TV and direct the child's attention to the video.
5. Dim the overhead illumination but ensure the pupils of the child's eyes are still visible

How You Do the Test:

1. Direct the light into the child's right eye and observe the direct pupillary response. Repeat at least two times.
2. Direct the light into the right pupil and now observe the consensual response of the left pupil. Repeat at least two times.
3. Repeat steps 1-2 for the left eye.
4. Perform the swinging flashlight test to assess for afferent pupillary defects.

What You Write Down:

1. If the two pupils are reactive to light, equal and round, and constrict equally on direct and consensual testing, then write "pupils equal, round, reactive, (-) afferent pupillary defect."
2. If the size of the pupils are unequal, use the millimeter ruler to measure the size of the two pupils in dim and bright light. If the difference between the pupils is the same in dim and bright light, write "physiologic anisocoria." If

the difference between the two pupils is not the same in dim and bright illumination, write “abnormal.”

Remember!

1. Maintain the child’s attention on the distance video target.

Anterior Segment Assessment Including Anterior Chamber Angle Assessment

What Are You Testing?

External inspection of the anterior segment assesses the structure and health status of the eye. The procedure includes an assessment of the anterior chamber to determine whether it looks adequately deep for dilation (prior to the instillation of cycloplegic/mydriatic drops).

What You Need to Do the Test:

1. A penlight.
2. A hand-held slit lamp.

Getting Ready:

1. Chairs for the child and the examiner are placed 2 feet apart.
2. Seat the child comfortably in the chair.
3. The examiner is seated facing the child.
4. Have the penlight and slit lamp ready for use.

How You Do the Test*:*

1. This procedure consists of observation of the child's eyes and face and is conducted using magnification and illumination of the slit lamp, as needed.
2. Specifically, observe the following:
   - Anterior chamber angle (this must be completed prior to drop instillation).
   - A penlight is used to illuminate the eye directly from the temporal side, parallel to the iris surface and the examiner looks for a shadow on the nasal iris, suggesting a very shallow anterior chamber. If there is no shadow, then the child may be dilated for the cycloplegic examination. It is recognized that complete assessment of the angle would include gonioscopy. The VSP Study investigators do not feel the procedure is feasible in young children and that the risk of angle closure glaucoma in children in this age range is extremely low.
   - Eyelashes.
   - Lid position and shape.
   - Eye positioning in orbit (enophthalmos or exophthalmos).
   - Completeness and frequency of blinking.
   - Epiphora or tearing.
   - Conjunctiva.
   - Cornea.

- Sclera.
- Iris and pupil.
- Lens.

What You Write Down:

1. Write down on the data form one of the following: "**Normal**," "**Abnormal**," or "**Unable**."
2. Note any anterior segment abnormalities that are clinically significant or conditions requiring further care or referral (i.e. ptosis, blepharitis, and conjunctivitis).
3. Indicate if you judge the anterior chamber to be too shallow to allow safe dilation of the child's eyes.

Remember!

1. Judge whether the anterior chamber appears adequately deep for dilation.

Cyclopegic/Mydriatic Drop Instillation

What Are You Testing?

Cycloplegic retinoscopy and binocular indirect ophthalmoscopy require prior instillation of cycloplegic/mydriatic drops. This procedure describes the technique of eye drop instillation.

What You Need to Do the Test:

1. A bottle of VSP combination drops.
2. A box of tissues.
3. An assistant, if available.

Getting Ready:

1. Wash your hands or use an antibacterial wipe prior to and after eye drop instillation.
2. Have the child lie down on the Freeman flip-top seat looking up towards the ceiling.

How You Do the Procedure*:*

1. If the anterior chamber is too shallow, do **not** administer drops. Indicate on the data form that no drops were given.
2. Grasp the child's top and bottom eyelids with your fingers and quickly instill one combination drop in each of the child's eyes. Wipe any excess drops or tears on the child's cheek with a tissue.
3. The hand holding the bottle should be braced on the child's forehead.
4. If available, have an assistant hold the child's head or hands.
5. Twenty to thirty seconds later, follow with a second combination drop in each eye, while pressing your finger on the child's lower punctum to minimize systemic absorption. Wipe any excess drops or tears on the child's cheek with a tissue.
6. Retinoscopy should occur in 30-40 minutes after the last drop.

What You Tell the Child:

1. Tell the child to look up at the ceiling.
2. Tell the child that you are going to place an eye drop in his/her eye.
3. Tell the child that he/she may briefly feel the first eye drop.
4. Prior to the instillation of the second drop, repeat the instruction to the child to keep looking up at the ceiling.

What You Write Down*:*

1. Indicate the drops that were administered to each eye.
2. Write down the time that the last drop was instilled.
3. Indicate on the data form if no drops were given.

Remember!

1. Block the punctum and wipe any excess tears or eye drops with the tissue.
2. Instill the eye drops quickly.

Cycloplegic Retinoscopy

What Are You Testing?

Cycloplegic retinoscopy measures the child's refractive error. It is the Gold Standard refraction technique. The retinoscopy spectacles ensure that the vertex distance is kept constant and that residual accommodation is relaxed.

What You Need to Do the Test:

1. A streak retinoscope.
2. A distance fixation target in the form of a VCR and tape.
3. Remote control for the VCR system.
4. A retinoscopy rack or trial lens set.
5. Retinoscopy spectacles corresponding to the examiner's working distance: +2.00 DS (50 cm), +1.75 DS (57 cm), or +1.50 DS (67 cm).
6. A box of tissues.

Getting Ready:

Place the examiner's chair to allow for a 50 to 67 cm working distance.

1. Set up the distance fixation target at least 10 feet from the child's chair.
2. Instill the eye drops a minimum of 30 minutes before performing cycloplegic retinoscopy.
3. Lower the VCR to the child's eye level.
4. Dim the lights by manually turning off the overhead lights.

How You Do the Test*:*

1. Position the child facing the distance fixation device at the end of the room.
2. The right eye is measured first.
3. The examiner is positioned facing the child so that his/her right eye is directly in front of the child's right eye.
4. Place the retinoscopy glasses (in the appropriate power for the working distance) on the child's face.
5. The examiner activates the distance fixation target with the remote control.
6. Use a retinoscopy lens rack or hand-held trial lenses to neutralize the refractive error.

7. The examiner may perform cycloplegic retinoscopy in his/her customary manner.
8. If the child has overt strabismus, care should be taken to perform retinoscopy on axis. Reposition the child and examiner as necessary to achieve distance fixation and to maintain the working distance.
9. The procedure is then repeated for the left eye.
10. Wipe off the temples and bridge of the glasses with a tissue after testing.

What You Tell the Child:

1. Tell the child to keep looking at the distance fixation target.
2. Tell the child that you are going to look in his/her eyes with a light.
3. Repeat the instruction to the child to keep looking at the distance fixation object.

What You Write Down*:*

1. The refractive error present over the retinoscopy spectacles is recorded in standard prescription notation (either plus or minus cylinder form) on the data sheet.
2. Record the power of the spherical and cylindrical lenses to the nearest 0.25 diopter. Lens powers must be recorded with two decimal places (.00, .25, .50, or .75).
3. You may use the optical cross on the data form as a scratch pad prior to recording the refractive error in standard prescription notation on the GSE form.

Remember!

1. The examiner must constantly remind the child to maintain fixation on the distance target so that retinoscopy occurs on axis and any residual accommodation, if present, is stable and relaxed.

Binocular Indirect Ophthalmoscopy

What Are You Testing?

Binocular Indirect Ophthalmoscopy (BIO) is a technique that provides a thorough view of the retina and vitreous through a dilated pupil in order to evaluate the health of the interior of the eye and to identify structural abnormalities that may be associated with reduced visual acuity thereby aiding in the diagnosis of amblyopia.

What You Need to Do the Test:

1. A binocular indirect ophthalmoscope.
2. A hand-held +20 D or +28 D condensing lens.
3. A penlight toy or sparkle ball to maintain interest and fixation by the child.

Getting Ready:

1. Chairs for the child and the examiner are placed 2 feet apart.
2. The child should have received the cycloplegic eye drops between 30 and 50 minutes prior to ophthalmoscopy.
3. Wash and dry your hands before performing the procedure on each child.

How You Do the Test:

1. The BIO is positioned on the examiner's head, and the headband, oculars, pupillary distance, and illumination system are adjusted.
2. The right eye is examined first.
3. The examiner is positioned facing the child, so that the examiner is directly in front of the child's right eye.
4. Hold the condensing lens in the left hand, between the thumb and index fingers.
5. **Posterior pole view:** Brace the dominant hand on the child's face while holding the condensing lens in front of the child's right eye, keeping the lens parallel to the child's face. It may be helpful to hold a penlight or fixation target near the examiner's right ear and encourage the child to look at the target with their left eye. This should allow the examiner to obtain a view of the disc and macula. Only hold the child's eyelids open if necessary.
6. **Mid-peripheral views:** Ask the child to look up and shine the BIO into the center of the condensing lens and pupil, adjusting the relationship between the BIO, condensing lens, and child's pupil to provide for a clear reflex filling the width of the lens.
7. Failure to obtain peripheral views does not require recording abnormal.

8. Scan the fundus through the condensing lens in all positions of gaze, directing the child to change fixation as instructed. Move the fixation target accordingly to help obtain peripheral views.
9. The procedure is then repeated for the left eye.

What You Tell the Child:

1. Tell the child that you are going to look into his/her eyes with a light.
2. Tell the child to keep looking in the proper direction of gaze (toward the fixation target) and to keep his/her eyes open wide.
3. Periodically repeat the instruction to keep looking in the proper direction of gaze toward the fixation target.

What You Write Down:

1. Indicate whether the structure is normal or abnormal for each anatomical site (macula, disc, media, and mid-peripheral retina). If a site cannot be viewed, write "**Incomplete**."
2. Abnormal should be written only if the findings indicate a condition or possible condition affecting eye health or vision. Such findings as nevi, large optic cups (but within the range of variation of healthy eyes) **should not be noted** as abnormal.
3. Specify abnormalities in the GSE form.

Remember!

1. Keep reminding the child to keep his/her eyes open and to maintain steady attention to the fixation target during the exam.
2. Keep the relationship between the BIO, condensing lens, and child stable and synchronized so that the image of the fundus within the condensing lens is optimal.

Appendix VI: Parent Education Form

New England College of Optometry
Vision Screening in Preschoolers (VSP) Study
617-266-2030

Date: _____

To the parents/guardian of _____

Your child just received a comprehensive eye exam to determine if he/she has a vision problem. Vision evaluations are important because vision problems are often not obvious. Also, children often do not know how they should see and generally have difficulty telling us how they are seeing.

☐ Your child completed all the tests in the eye exam and was not found to have a vision problem. You child should have another complete eye exam in 1 year.

☐ Your child was found to have the following vision problem(s):

- ☐ **Nearsightedness** (difficulty seeing far away objects)
- ☐ **Farsightedness** (the need to exert more effort in order to see clearly up close). Farsightedness can result in difficulty seeing up close, difficulty concentrating, blurred vision, eyestrain, and/or headaches with close work.
- ☐ **Astigmatism** (difficulty seeing at all distances without correction)
- ☐ **Anisometropia** (difference in the prescription between the two eyes)
- ☐ **Lazy Eye** (reduced vision that is unrelated to any eye health problem and is not immediately correctly with lenses. It can result from a failure to use both eyes together. Lazy eye will not go away on its own. Early treatment improves the chance for complete recovery.)
- ☐ **Eye Coordination Difficulty** (how the eyes work together as a team) Problems with eye alignment can cause double vision, blurred vision, eyestrain, and/or headaches.
- ☐ **Eye Health Problem:** _____

☐ Your child needs to wear glasses to correct his/her vision problem.

☐ Your child needs to have a follow-up eye exam.

COMMENTS:

_____

_____

Thank you for allowing your child to participate in our program. Please feel free to contact