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Screening Amblyopic Risk Factors in a Pediatric Population Using an Automated Vision Screener

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Screening Amblyopic Risk Factors in a Pediatric Population Using an Automated Vision Screener by

REBECCA DAWN SLOMINSKI

EVIDENCE-BASED PRACTICE PROJECT REPORT

Submitted to the College of Nursing and Health Professions of Valparaiso University, Valparaiso, Indiana in partial fulfillment of the requirements for the degree of

DOCTOR OF NURSING PRACTICE

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DEDICATION

I WOULD LIKE TO DEDICATE THIS TO MY PARENTS AND GRANDPARENTS WHO WERE NOT AROUND TO SEE ME ACHIEVE MY DNP DEGREE AND MY PROJECT WORK. I KNOW THEY ARE WATCHING FROM ABOVE AND ARE SMILING DOWN ON ME. I WOULD LIKE TO DEDICATE THIS TO MY CHILDREN IN HOPES BY WATCHING AND HELPING ME THROUGH THIS PROCESS I HAVE SHOWN THEM YOU ARE NEVER TOO OLD TO FOLLOW YOUR DREAMS. ALSO, NO MATTER WHAT OBSTACLES OR HOW DIFFICULT A GOAL YOU MUST CONTINUE TO PUSH THROUGH IN ORDER TO SUCCEED. I WOULD LIKE TO DEDICATE THIS TO MY HUSBAND, FAMILY, AND FRIENDS WHO ENCOURAGED AND SUPPORTED ME ALL THE WAY TO THE END. I SHARE IN THIS ACCOMPLISHMENT AND JOY WITH ALL OF YOU. THANK YOU ALL SO VERY MUCH!
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• Special thanks to my family and friends for their support through this process. Thank you to my place of employment for being so flexible and understanding. Last but not least my heavenly father who taught me the lesson of patience and endurance through this advanced educational degree and gave me the wisdom, knowledge, and understanding to persevere

• (Trust in the Lord with all your heart and do not lean on your own understanding. In all your ways acknowledge Him and He will make your paths straight Proverbs 3:5-6; Biblehub.com; The New American Standard Bible).
# TABLE OF CONTENTS

**Chapter Page**

DEDICATION .......................................................................................................................... iv

ACKNOWLEDGMENTS ........................................................................................................ v

TABLE OF CONTENTS ........................................................................................................ vi

LIST OF TABLES ................................................................................................................ vii

LIST OF FIGURES ............................................................................................................. ix

ABSTRACT .......................................................................................................................... x

CHAPTERS

  CHAPTER 1 – Introduction ............................................................................................... 1

  CHAPTER 2 – Theoretical Framework and Review of Literature ............................ 9

  CHAPTER 3 – Implementation of Practice Change ............................................. 51

  CHAPTER 4 – Findings ................................................................................................. 58

  CHAPTER 5 – Discussion .............................................................................................. 66

REFERENCES ..................................................................................................................... 78

AUTOBIOGRAPHICAL STATEMENT ............................................................................. 83

ACRONYM LIST .............................................................................................................. 84

APPENDICES

  APPENDIX A – Attendance Roster Flowsheet .................................................... 85

  APPENDIX B -- PlusOptix™ Quick Reference Guide ......................................... 86

  APPENDIX C – Post-Implementation Flow Sheet .............................................. 89

  APPENDIX D – De-Identify Post -Implementation Flow Sheet ............................ 90

  APPENDIX E – Pre-Implementation Flow Sheet .................................................. 91
APPENDIX F – De-Identify Pre-Implementation Flow Sheet…………………………92
LIST OF TABLES

Table Page

Table 2.1 Literature Search Results ................................................................. 21

Table 2.2 Levels of Evidence............................................................................. 37
# LIST OF FIGURES

**Figure**

- Figure 4.1 Age Groups .................................................................60
- Figure 4.2 Gender .................................................................61
- Figure 4.3 Race .................................................................61
- Figure 4.4 Type of Initial Exam Results .............................................64
ABSTRACT

Amblyopia is the most common visual disorder in children and is potentially curable if detected early and treated properly in the first few years of life. Amblyopia is the leading cause of monocular vision loss in children (Bradfield, 2013). It is a developmental neuroplasticity which derives from birth causing structural and functional changes in the eye and brain. With this structural and functional disruption, visual blur occurs due to refractive amblyopia, strabismic amblyopia, cataracts (form-deprivation amblyopia), or a combination of any of these (Solebo, Cumberland, & Rahi, 2015). Refractive errors related to amblyopia can also occur. The purpose of this evidence-based practice project was to determine if screening a pediatric population ages 9 months, 24 months, 36 months, and 48 months using an automated visual screener would affect the number of refractive errors detected. The Stetler Model’s stepwise process for gathering sound evidence was used to guide this evidence-based practice project at a busy Midwest pediatric clinic. Anyone that failed the screening was referred to ophthalmology for further testing. Post-intervention group data were collected on patients from the designated age groups receiving visual screening during a well-child check-up by two designated providers over a three-month period. Pre-intervention group data were collected from electronic health records for patients in the same designated age group receiving a well-child check-up by the same two providers as post-intervention data over a three-month period. Data were analyzed using Pearson’s Chi-Square Goodness of Fit test in an effort to show the sensitivity and specificity of the automated visual screener to screen for amblyopic risk factors. Of the total sample size (N = 322), there were 161 in the pre-implementation group and 161 in the post-implementation group. Results supported the PlusOptix™ S12 vision screener in identifying more refractive errors than traditional visual exams performed during routine well child check-ups ($\chi^2 = 20.184^a$, $p < 0.001$, 99% CI).
Amblyopia is the most common visual disorder in children and is potentially curable if detected early and treated properly in the first few years of life. Amblyopia is the leading cause of monocular vision loss in children (Bradfield, 2013). According to Bradfield (2013), Amblyopia “is defined as reduced best-corrected visual acuity caused by abnormal visual development” (p. 348). It is a developmental neuroplasticity which derives from birth and causes structural and functional changes in the eye and brain. With this structural and functional disruption, visual blur occurs due to refractive amblyopia, strabismic amblyopia, cataracts (form-deprivation amblyopia), or a combination of any of these (Solebo, Cumberland, & Rahi, 2015). Refractive errors related to amblyopia include myopia (nearsightedness), hyperopia (farsightedness), and astigmatism (abnormal curvature of the cornea). Another serious cause of visual blur and of great importance to detect as early as possible is retinoblastoma. “Retinoblastoma is the most common intraocular tumor of childhood and seventh most common pediatric malignancy” (Hered, 2011, p. 77).

The US Preventive Services Task Force (USPSTF) statement recommends vision screening at least once between the ages 3 and 5 (2011). The USPSTF also states that detection and treatment of amblyopia and amblyopic risk factors in children between ages 3 to 5 years of age leads to great improvement of visual acuity (Mu, et al. 2016; USPSTF 2011). According to the USPSTF there has not been sufficient evidence to assess the benefits or harms of vision screening earlier than age 3. However, the American Academy of Pediatrics (AAP) (2003), and American Association of Pediatric Ophthalmology and Strabismus (AAPOS) (2003), recommend early childhood screenings starting in newborns and performed with every well child visit thereafter.
Vision screenings in the very young can be difficult to perform due to unwillingness to cooperate and lack of verbal skills. Automated visual screeners (AVS) have been shown to be effective in the very young population as well as those individuals with autism, attention deficit hyperactivity disorder (ADHD), and other behavioral issues.

AVS were available commercially about two decades ago. Since then AVS have improved and continue to become popular in pediatric clinics, family practice clinics, as well as schools for vision screenings. Studies continue to demonstrate the validity of AVS and are approved by the AAP in use of preschool age children. AVS are quick and easy to use within a pediatric clinic and can easily be incorporated into a well-child check without adding much time (Donahue et al., 2013; Peterseim et al., 2015).

When screening and treating for visual disorders at this early age, especially refractive disorders, partial to full blindness can be prevented and barriers to literacy, social-emotional development, self-esteem, and higher academics can be eliminated (AAP, AAPOS, 2003; Halegoua, 2015; Yan et al., 2015).

**Statement of the Problem**

This evidence-based practice project was to address vision screening among a preschool population in a pediatric clinic to detect and mitigate long term effects of amblyopic risk factors. Sources revealed early detection, especially in the preschool years, of vision abnormalities can result in full recovery of vision and decrease developmental abnormalities of binocular vision. Early detection may also decrease costs due to decreased medical visits and treatments. The AAP, AAPOS, American Academy of Ophthalmology (AAO) and American Association of Certified Orthoptists (AACO) (2003), report children should have a full visual assessment at the newborn stage and at all subsequent well child examinations following. The AAP, AAPOS, AAO and AACO (2003) reported in a policy statement, that early detection of visual abnormalities is vital to help prevent blindness, identify serious disease (including neurologic disorders) and prevent school performance problems in the future.
In children, visual impairment can delay learning causing children to be inadequately prepared to start preschool or kindergarten. It can also reduce quality of life and function due to blurring of vision. If visual problems are not detected prior to preschool, visual pathways do not develop properly and irreversible vision loss occurs. Physiological changes within the eye not only affects learning but can also have long term effects on an individual’s socialization ability and self-esteem as early childhood is an important time of social and functional development (AAP, AACO, AAPOS, AAO, 2003; Bradfield, 2013; Forcina et al., 2017; Koning et al., 2013).

Preschool is the age group in greatest need of screening for refractive errors (Bradfield, 2013; Forcina et al., 2017; Koning, et al., 2013). However, this age group can be the most difficult to screen due to inability to read visual acuity charts, identify picture charts, and lack of cooperation while being thoroughly examined for refractive disorders. AVS such as the PlusOptix™ series photoscreeners can quickly scan patients’ eyes and measure binocular refractive abnormalities, pupil size, ocular alignment and interpupillary distance without using pupil dilatation or cycloplegia (Terveen, Moser, & Spencer, 2015).

AVS have been shown in many studies to provide practical, fast, and easy vision screenings. They are easy to use, portable, and provide quick and accurate detection of visual issues, which can be addressed by the primary care provider (PCP) or referred to pediatric ophthalmology for further evaluation and treatment. Studies have shown PlusOptix™ photoscreeners to have sensitivity as high as 94.79% and specificity up to 99% depending on which amblyopic risk factors are being identified (Arnold & Armitage, 2014; Chang et al., 2015; Singman et al., 2013; Yan et al., 2015). Sensitivity is the ability of the AVS to correctly identify children with amblyopia or refractive vision disorders and specificity is the ability of the AVS to correctly identify children without vision abnormalities (Koning et. at., 2013). Arnold and Armitage (2014) reported the PlusOptix™ series as having sensitivity of 83% and Specificity of 88%. Yan et al. (2015) reported the PlusOptix’s™ sensitivity of 80.6% and specificity of 76.3% for amblyopia.
The PlusOptix™ photoscreener is designed to screen for amblyopia risk factors, refractive error, anisocoria (unequal pupil size), myopia, hyperopia, astigmatism, retinal abnormalities, and strabismus (eyes are unparalleled) in children starting at age six months (Chang et al., 2015; PlusOptix, 2017). Vision screening can be performed in any child, including those with developmental delays and attention disorders, as the only required compliance is a short fixation on the camera. Fixation on the camera is provoked by a “warble” sound, which grabs the attention of the child. The PlusOptix™ has been shown in studies to be accurate. It screens both eyes simultaneously, accommodating the short attention of the child. It measures pupil sizes and corneal reflexes automatically, compares refraction of both eyes simultaneously, checks corneal irregularities, checks farsightedness and nearsightedness, and checks symmetry of eye alignment all within a few seconds. The PlusOptix™ stores data allowing the provider to review information in chronological order or it can be downloaded to the patient’s electronic health record (EHR) and then becomes a permanent part of the patient’s chart. A print out can be made from the vision screener as well and given to parents to take with them (Bradfield, 2013; Peterseim et al., 2015; Terveen, Moser, & Spencer, 2015; PlusOptix, 2017; Yan et al., 2015; Yilmaz et al. 2015).

**Data from the Literature Supporting Need for the Project**

The USPSTF (2011) reported “1 to 5 percent of U.S. preschool aged children have some sort of visual impairment”. The USPSTF also reported on a population based study in Los Angeles county California of over 6,000 children; amblyopia was present in 2.6 percent of Hispanic/Latino children and 1.5 percent black children (USPSTF, 2011). The USPSTF did not list the age group of these 6,000 children or specific ethnicity. A Cochrane database systematic review reported the prevalence of amblyopia between 2 and 5 percent in preschool aged children (Powell & Hatt, 2009).

USPSTF reported finding adequate evidence to report early detection and treatment of amblyopia and amblyopic risk factors between ages 3 and 5 leads to “improved vision
outcomes” (USPSTF, 2011, p. 222). USPSTF also concluded “with moderate certainty that vision screening for children three to five years of age has a moderate net benefit” (USPSTF, 2011, 222).

Bradfield (2013) reported on a meta-analysis of four randomised clinical trials which evaluated the treatment effect on children based on age of amblyopia treatment. The meta-analysis concluded children treated prior to seven years old, between ages 3 and 7, were more responsive to treatment compared to those treated after age seven.

A Cochrane database systematic review done by Powell and Hatt (2009) reports no evidence of randomised controlled trials looking at the impact of early vision screening, detection, and treatment of amblyopia. Another aspect of Powell and Hatt’s review was to report evidence of disabilities in those living with uncorrected amblyopia. The evidence cited was observational studies from children screened. Powell and Hatt concluded there was not enough evidence from good quality trials at the time to show optimal protocols for vision screening

Studies are starting to surface looking at the effectiveness of AVS at detecting visual abnormalities in the preschool age. Studies report the effectiveness of screeners by determining their sensitivity, specificity, (defined previously) and positive predictive value. Positive predictive value (PPV) is the true positive measure of a diagnostic test, which describes the test function (Gordis, 2014). PPV helps answer the question of what proportion of individuals that test positive actually are positive for a disorder or disease (Gordis, 2014). Singman, Matta, Fairward, and Silbert (2013), reported the PlusOptix™ photoscreener having a sensitivity of 88%, specificity of 87% and a predictive value of 94% in an age group of < 1 year of age to 15 years. Mu et al. (2016) reported the PlusOptix™ photoscreener as having great promise with sensitivity of 94.79% and specificity of 85% for detection of amblyopia risk factors in a population of 4 to 7-year old. Arnold and Armitage (2014) reported in their comparative analysis of four different photoscreeners, the PulseOptix™ screener had 80%-83% sensitivity, and a
specificity of 85% to 88% with a positive predictive value of 87% in a population of 1 to 12-year old.

The American Academy of Pediatrics issued a news report in December 2015 condoning instrument-based screening as a valid method of screening in very young children (AAP, 2016). The AAP also reported AVS can detect visual impairments most commonly found in young children, such as amblyopia, high refractive error, and strabismus (AAP, 2015).

Data from the Clinical Agency Supporting Need for the Project

The facility where the doctor of nursing practice (DNP) project took place was in a large Midwest community which opened its doors in 1977 to provide clinical and research programs focusing on childhood disorders such as deafness, and visual impairment. The hospital now offers a broad range of clinical services including: general pediatric care; inpatient hospital; surgery center; ear, nose and throat service; orthopaedic; internal medicine; pediatric gastroenterology; allergy and asthma; pediatric pulmonology; behavioral health; audiological and ophthalmologic care. The hospital and clinics have kept to their original mission of providing healing and hope to children and their families with physical and mental illnesses. The hospital strives to assemble nationally known personnel in research and clinical treatment to provide state of the art continuum of care (https://www.boystownhospital.org/AboutUs/aboutUs/Pages/Mission.aspx).

In keeping with the mission, the pediatric clinics aim was to implement earlier visual screenings in their six general pediatric clinics with the PlusOptix™. By implementing AVS in each of the six general pediatric clinics, providers were able to obtain more accurate visual screenings with early detection of visual abnormalities. Providers could then refer patients to specialists on site as needed for continuity of care.

The pediatric clinics abide by state law in providing comprehensive vision screenings using the Snellen eye chart and physician eye exam at pre-kindergarten and seventh grade physicals (Nebraska State Legislature 79, 2013). Visual screenings using the Snellen chart
were not typically done at other well-child check-ups (WCC) due to patient load, time constraints, and unwillingness of preschool age children. Provider visual exams were being done at WCC. However, visual checks with the naked eye cannot pick up all the many different visual abnormalities without the use of cycloplegia retinoscopy (pupil dilatation). By implementing use of PlusOptix™ visual screeners, providers were able to perform regular visual screenings starting at age 9 months, 24 months, 36 months, and 48 months which have been shown in literature to be of importance for visual screenings.

**Purpose of the Evidence-Based Practice Project**

Sources show early detection, prior to starting preschool or kindergarten, of visual abnormalities is of vital importance for early and maximal treatment. This evidence-based practice (EBP) project was implemented within a general pediatric clinic which serves a wide range of socioeconomic and ethnic populations in a large Midwest community. The purpose was to implement automated visual screenings at well-child visits for ages 9 months, 24 months, 36 months, and 48 months to check for amblyopia risk factors and visual abnormalities. Screening for these age groups prior to the PlusOptix™ were done by the providers visual exam of the eye. No Snellen Chart testing was done on a regular basis for these age groups.

**Compelling Clinical Question/PICOT Question**

Would screening pediatric patients within this general pediatric clinic result in early findings of amblyopia and amblyopia risk factors? This led to the PICOT question: In a pediatric population aged 9 months, 24 months, 36 months, and 48 months (P), how does early vision screening using automated photo vision screeners (I) compared to traditional vision screening techniques (C) affect the number of refractive errors detected (O) within three months (T)?

**Significance of the EBP Project**

The ultimate goal of this EBP was to compare vision screening results from traditional provider screening methods to screening results from an AVS, the PlusOptix. This would compare referral rates between the two groups. Failed screening results from the pre- and post-
implementation groups would be compared to follow-up ophthalmology results to check for sensitivity and specificity of screening methods provided during WCC. By implementing and gathering data on AVS outcomes within these pediatric clinics, the clinics could show sensitivity and specificity of the PlusOptix, the necessity of having this type of screening tool in each clinic, and continued need for early vision screenings prior to kindergarten. Collection and aggregation of data on screenings and referrals benefits individual patients within the clinics as well as the broader population served in the community by advancing the understanding of early vision screenings, visual disorders, and treatment.
CHAPTER 2
THEORETICAL FRAMEWORK, EBP MODEL, AND REVIEW OF LITERATURE

In this chapter, an overview of the theoretical framework and EBP model chosen to guide the DNP project are provided, along with their application, strengths, and limitations. Sources of relevant evidence are revealed with the hierarchy levels and appraisal information. Synthesis of critically appraised literature, best practice model recommendation, and how the best practice model answered the clinical question are discussed.

Theoretical Framework

Overview of Theoretical Framework

Health Promotion Model (HPM) by Nola J. Pender was used as the theoretical framework to help guide the EBP project. Pender’s HPM was originally published in 1982, it was revised in 2001 into the Pender Health Promotion Model by Pender, Murdaugh, and Parsons (George, 2011). The HPM complements other health protection models to enhance health and well-being. It offers a process to help motivate individuals to participate in positive behaviors to enhance their health. Pender’s HPM stresses the importance of self-direction, self-regulation, and perceptions of self-efficacy (George, 2011). The HPM operates from four main assumptions: Individuals seek to regulate their own behavior; individuals interact with the environment, transforming themselves and the environment; health providers make up part of an individuals’ interpersonal environment, which will influence the individual throughout the lifespan; and self-initiated rearrangement of the person-environment is necessary for behavior patterns to change.

There are eight theoretical propositions or behaviors within the HPM believed to be major motivators in individual health-promotion and include: perceived benefits of action, perceived barriers to action, perceived self-efficacy, activity-related affect, interpersonal influences, situational influences, commitment to a plan of action, and immediate competing demands and preferences (Friedman, Bowden, & Jones, 2003; George, 2011). Perceived
benefits of action come from an individuals’ personal experience either from being directly involved or observation of a family member or friend. Perceived barriers to action are just that “perceived” but can have a major impact on decision making. Perceived self-efficacy is related to one’s own judgement about self, individual skills, and whether an individual can accomplish the desired behavior. Activity-related affect is the result that a particular behavior or action had on an individual. The activity-related affect considers the affect before, during, and after the action. The more positive the subjective feeling has on an individual the greater the feelings of efficacy. These greater feelings of efficacy can lead to positive affect. Interpersonal influences are the individual’s own thoughts or beliefs, which may or may not accurately describe a behavior or situation, and can be influenced by family, friends, or other outside sources. Situational influences affect a behavior in different situations based on a person’s perceptions of options available or demanding characteristics of the environment such as: hand washing requirements in a work place or dress code requirements. Situational behaviors require the individual to participate in a way they may not normally. Commitment to a plan of action identifies a strategy for reinforcing or carrying out a behavior which then leads to implementation of the behavior. Immediate competing demands and preferences refer to alternative behaviors where the individual has little control such as work or family commitments, whereas competing preferences are alternative behaviors where the individual has high control such as choosing to eat ice cream.

The HPM postulates that specific behaviors and cognitions are directly related to individual health promotion behaviors (Friedman, Bowden, & Jones, 2003; George, 2011). An individual’s prior behavior as well as inherited and acquired characteristics have great impact on the individual’s beliefs, affect, and how the individual views health promoting behaviors. An individual is more likely to engage in behaviors where valued beliefs are enhanced. When an individual has positive perceptions, believes there are minimal barriers to the action, has positive feelings about the health behavior, has positive family and peer support, has positive
role models and available environmental resources the individual tends to commit to a plan of action. This in turn promotes positive health behavior. The intent of the health promotion plan is that the individual will realize positive benefits to their health and well-being. The benefits realized would not just be for the present but benefits which will lead to overall health to last them a lifetime and be passed down to generations to come (Friedman, Bowden, & Jones, 2003; George, 2011).

**Application of Theoretical Framework to EBP Project**

Pender’s HPM focuses on individual characteristics, experiences, behavior-specific cognitions, and one’s affect and behavioral outcomes. The HPM was appropriate for this EBP project as the clinic location for the project prides itself on health promotion and disease prevention. Pediatric providers highly recommend routine yearly health maintenance checks until patients reach 19 years of age or 23 years of age (when they are finished with college). Well-child checks are gently reinforced by requiring patients to be listed as a new patient if they have not been seen within the clinic setting by their PCP for two years or longer. Appropriate appointment times can then be set to allow enough time for a thorough exam to make sure the individual is healthy and their chart is accurately updated. By requiring individuals to maintain yearly well-checks, providers are able to catch health issues before they become a major problem and possibly preventing health problems. Yearly well-checks also allow providers to stay abreast of chronic health conditions so when there is an acute illness, proper care can be taken to insure a quick and uncomplicated recovery. The goal of requiring regular exams is to model and promote positive health behaviors which will influence individuals to commit to for a lifetime.

New implementation of AVS was one-way the providers could continue to promote health and disease prevention within their general pediatric clinics. By using the latest technology of AVS, providers were able to screen at earlier ages for visual errors as well as provide a more in-depth screening at well-child checks (WCC). Many studies have shown early
detection, prior to starting preschool or kindergarten, of visual abnormalities is of vital importance for early and maximal treatment. Visual abnormalities reduce quality of life and function due to blurring of vision. If visual problems are not detected prior to preschool, visual pathways do not develop properly and irreversible vision loss occurs (AAP, AACO, AAPOS, AAO, 2003; AAP, 2016; Bradfield, 2013; Donahue et al., 2013; Terveen, Moser, & Spencer, 2015). The USPSTF reported “1 to 5 percent of U.S. preschool aged children have some sort of visual impairment” (USPSTF, 2011, p. 2) and Mu et al. (2016), estimate 1.6% to 3.6% of children in industrialized nations have a preventable visual impairment. Koning et al. (2013) found in a 7-year cohort of 4624 children with an overall prevalence of amblyopia to be 3.6%.

Pender’s HPM suggests if a family perceives a threat and there are opportunities for decreasing that threat, such as health screenings, the family will be more likely to act on it (Friedman, Bowden, & Jones, 2003). By using AVS within the clinic setting during routine WCC, providers could perform in depth vision screenings to detect problems, a screening the patient might not have received otherwise. This Midwest hospital and clinics serve a wide socioeconomic and ethnic population with the majority of them having little to no insurance. Therefore, many of the patient population does not seek out preventive eye care from an optometrist or ophthalmologist. The HPM was used to help modify patient behaviors by looking at modifying factors (demographic variables, sociopsychological variables, structural variables) to show perceived threats and provide cues to action.

The six major motivators were taken into consideration when using the HPM as a guide for educating parents and patients for the need of early vision screening. Education was provided prior to performing AVS screenings from evidence found in the literature which shows benefits of action (early vision screening). When providing information, parents and patients will be able to actively own the behavior of early vision screening. Perceived barriers to action, such as little or no insurance, were addressed by assuring families most insurance companies cover vision screenings using AVS. Clients were not charged for the screening using the PlusOptix™
if insurance did not cover it or cover all the cost. Early vision screenings can reduce treatment length and overall cost, further addressing perceived barriers to screening. This further influences the six behavioral motivators affecting optimal well-being, personal fulfillment, and productive living.

**Strengths and Limitations of Theoretical Framework for EBP Project**

Health promotion and disease prevention should be the primary focus in the health care setting and needs to be easy to understand in order to change or reinforce positive health behaviors. The HPM allows for ease of applicability by its simplistic stepwise approach. Its’ holistic focus based in nursing gives it strength by promoting independent practice which provides health promoting interventions and education to individuals. The HPM can be used by other disciplines even though it was proposed as a framework for nursing. The HPM was intended for any individual in any situation other than the illness state. By using the eight theoretical propositions or variables the model allows for a complete picture of the patient and progression toward improving health behaviors. However, the many variables within the HPM also can be a limitation making it difficult to test all of the relationship statements. Without being able to test all the theoretical propositions or variables at once, one is not able to see how the variables influence each other or the outcomes of health promotion. Not only is testing all the variables difficult to do, it may also be difficult for providers to implement all eight variables within a reasonable time-frame. George (2011) points out another limitation within the HPM. The spiritual growth component is not considered under personal factors of the HPM. Spiritual growth is a component often listed and helps in guiding an individual when using other theoretical models.

**Evidence-based Practice Model**

**Overview of EBP Model**

The term “evidence-based practice” (EBP) derives from the definition of “evidence-based medicine” (EBM) and is defined as: “Evidence based nursing practice is the conscientious,
explicit, and judicious use of theory-derived, research-based information in making decisions about care delivery to individuals or groups of patients and in consideration of individual needs and preferences” (Ingersoll, 2000, p. 152).

The Stetler Model (SM) provides a stepwise process for gathering sound evidence that can guide safe and effective care or evidence-based practice. The SM uses a prescriptive approach emphasizing critical thinking as a key role. The SM relies on five steps which include: preparation, validation, comparative evaluation/decision making, translation/application, and evaluation (Stetler, 2001).

Preparation entails identifying a need, identifying the environment it involves, organizing, and initiating evidence research. The SM advises nurses or providers to be very clear during the preparation phase by emphasizing clarity of purpose along with potential significance of internal or external factors (organizational goals, imposed deadlines or politics involved with making a change, etc.). Clarity includes specifics regarding who the stakeholders are, what types of research or information will be needed to show the need for change, and how the outcomes will be defined (Ciliska et al., 2011; Stetler, 2001; Young, 2012).

Validation requires combing through a body of evidence to select evidence which best identifies the need for change. In this second phase of the Stetler model, APN’s and nurses decide if there is enough credible evidence to support the wanted or needed change to continue moving forward with the process. The process is done by utilization focused critique and synopsis (Ciliska et al., 2011; Stetler, 2001; Young, 2012).

Comparative evaluation/decision making involves applying a set of criteria to evidence collected in the validation phase to further decide what evidence best identifies or supports the practice change. Comparative evaluation/decision making is where organization of collected evidence and critical appraisal of evidence collected takes place. Evidence is either labeled not to use, to use, or to consider use (still being considered until additional information or internal evidence is gathered) based on strength of the evidence once the critical appraisal is done.
Final decisions are then made as to whether enough research exists to support the practice change (Ciliska et al., 2011; Stetler, 2001; Young 2012).

Translation/application requires converting the evidence findings into practice by disseminating the evidence to those involved and needed in the application process. Then a plan is put into action. Translating or applying the plan is not always an easy process depending on the type of change to be made and who is involved. Getting everyone on board is often difficult. Providers need to carefully consider how information will be distributed to all involved parties. Young (2012), purports “change is the heart of this phase” (p. 390).

Evaluation then involves assessing the new plan of practice to ensure goals were met, monitor for any adverse occurrences, if any changes need to be made, and how to continue providing the new plan of practice (Ciliska et al., 2011; Young, 2012). In the evaluation process and decisions are made if the new process or clinical practice change can be extended into other clinic areas. The evaluation process is also a continuous process of internal data collection, feedback from the users of the clinical practice change in order to obtain continual improvements.

**Application of EBP Model to EBP Project**

Previous screening practices at the project site included detailed vision screenings using the Snellen chart at ages 4 and 5 years prior to beginning kindergarten. Even then, screenings did not include comprehensive refractive error screenings that typically involve pupil dilatation known as cycloplegic screening. As mentioned previously in this paper, early visual screenings for refractive errors is crucial within the early years of life. The project site providers see patients across a wide range of socioeconomic and ethnic backgrounds, many with little to no insurance coverage. That being said, many will not see an optometrist or ophthalmologist for preventive visual screenings. It was hoped that the AVS would provide needed refractive error screenings to the project site pediatric population.
Using the (SM), evidence was collected and aimed to show the use of AVS are effective at screening for refractive visual errors as early as age nine months, as recommended by the AAP and USPSTF (The American Academy of Pediatrics [AAP], 2015; AAP, 2016; Forcina et al., 2017; Koning et al., 2013). The American Academy of Pediatrics issued a news report in December 2015 stating instrument-based screening is a valid method of screening in the very young children (AAP, 2015; AAP, 2016). The AAP and USPSTF also reported endorsing AVS as they can detect amblyopia and ocular conditions known to cause amblyopia such as high refractive errors and strabismus. (AAP, 2015; AAP, 2016). After carefully weighing available research, the project manager believed there was significant evidence to proceed with the EBP project.

Careful condensing, organizing, and labeling of evidence gathered during the evidence phase was done by applying the Critical Appraisal Skills Programme (CASP) tool. After careful consideration, CASP was decided upon for its reliability, completeness, and its ease of use. CASP includes a set of eight appraisal tools to evaluate systematic reviews, randomised controlled trials, cohort studies, case control studies, economic evaluations, diagnostic studies, qualitative studies and clinical prediction rule (http://www.casp-uk.net/casp-tools-checklists). Melnyk and Fineout-Overholt's (2011) Rapid critical appraisal checklist was used to carefully evaluate the clinical guidelines found while collecting evidence. Enough sound evidence was collected to move onto the fourth phase of the SM.

Evidence was communicated to all providers and staff who were involved in carrying out the change in practice through copies of research information collected, power points and videos provided from PlusOptix™. PlusOptix™ screeners were put in the budget plan in hopes the clinics would purchase some of the screeners to be tried out within the general pediatric clinics. Based on evidence provided and one of the clinics provider having previous experience with using this type of visual screener, budget was approved for purchase of six screeners. One screener was placed in each of the six general pediatric clinics. Education was provided to each
provider and clinic staff member who were involved in using the screeners. Education included information on the devices themselves, as well as policy and procedure for using the PlusOptix™ within the clinic setting.

Phase five of the Stetler model evaluated expected outcomes stemming from the original PICOT question: In a pediatric population aged 9 months, 24 months, 36 months, and 48 months, how does early vision screening using automated vision screeners compared to traditional vision screening techniques affect the number of refractive errors detected within three months?

**Strengths and Limitations of EBP Model for EBP Project**

The Stetler Model has a great use within individual practice, emphasizing critical thinking and decision making. Its five phase step approach aids in the critical thinking and decision-making process with ease of use. It allows for synthesis of internal and external evidence in routine practice which fits well within the general pediatric clinic settings. The systematic approach aids in critiquing and translation of research findings into clinical practice. By using the systematic approach of the SM, evidence is substantiated to support the needed clinical change within the project setting.

The SM is not set up for ease of use as an overall organizational change process but more for an individual clinic practice change agent. Ciliska et al. (2011) reports overall organizational change is not as easy application for the SM due to its practitioner focus for clinical change. The SM guides practitioners in a five-phase approach and how the practitioner can implement research findings to direct patient care.

**Literature Search**

**Sources Examined for Relevant Evidence**

An extensive literature search for relevant and best evidence was conducted using multiple databases including Cumulative Index of Nursing and Allied Health Literature (CINAHL), ProQuest Nursing and Allied Health, Johanna Briggs Institute EBP Database, The
Cochrane Library, Medline with full text, and National Guideline Clearinghouse. A hand search was also conducted from relevant articles’ references and reviewed for applicability to the EBP project.

Key words from the PICOT question were used for search terms. A combination of search terms were tested during this evidence search yielding no results. After combining key words, implementing Boolean phrases, playing with date limiters, employing the use of quotations and asterisks a “best search” was reached. The final set of keywords/terms settled on and yielding the best results in all six databases were: PlusOptix™, Amblyopia, refractive error, vision screen, and photoscreen (see Table 2.1).

The “best search” yielded 429 relevant sources. Forty-nine were chosen by the project leader after reading through the summaries for literature review. From the 49, seven were kept by the project leader based on relevance to the EBP project, evidence level, and inclusion criteria. Inclusion criteria were the years between 2007 and 2017 and English language for literature review.

CINAHL yielded 70 sources with four kept for best evidence. ProQuest Nursing and Allied Health yielded 146 sources using the key terms. The three sources kept from ProQuest overlapped with Medline and CINAHL. Johanna Briggs Institute yielded eight sources with no sources kept for best evidence. The Cochrane Library yielded 33 total sources using keywords, with two sources kept for best evidence. Medline with full text using the final set of search terms yielded the most sources at 172 for best evidence. Seven sources were kept from Medline. Three of the sources overlapped with CINAHL and three sources overlapped with ProQuest. No articles were kept through the hand search process for best evidence.

Articles included in final results pertained to pediatric population ages birth to 5 years, male and female, need for early vision screening, automated vision screener comparisons to each other and to traditional cycloplegia retinoscopy, and early screening methods. Final results included after searching databases listed, key words/terms, inclusion criteria and hand
searching; ten sources were kept for best evidence including 2 guideline summaries. Ten sources (including text books) and three guideline summaries were kept for use as background knowledge in this EBP project.
Table 2.1

**Literature Search Results**

<table>
<thead>
<tr>
<th>Database</th>
<th>Keyword(s)</th>
<th>Limiters</th>
<th>Date Limiters</th>
<th>Results</th>
<th>Relevance/Kept</th>
</tr>
</thead>
<tbody>
<tr>
<td>CINAHL</td>
<td>PlusOptix OR Amblyopia OR &quot;refractive error**&quot; AND “vision screen**” OR photoscreen*</td>
<td>English language</td>
<td>2007-2017</td>
<td>70</td>
<td>4 (3 overlap with Medline; 1 overlaps with ProQuest)</td>
</tr>
<tr>
<td>ProQuest Nursing and Allied Health</td>
<td>PlusOptix OR Amblyopia OR &quot;refractive error**&quot; AND “vision screen**” OR photoscreen*</td>
<td>English language</td>
<td>2007-2017</td>
<td>146</td>
<td>3 (2 overlap with Medline; 1 overlaps with CINAHL)</td>
</tr>
<tr>
<td>Johanna Briggs Institute</td>
<td>PlusOptix OR Amblyopia OR &quot;refractive error**&quot; AND “vision screen**” OR photoscreen*</td>
<td>English language</td>
<td>2007-2017</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Cochrane</td>
<td>PlusOptix OR Amblyopia OR &quot;refractive error**&quot; AND “vision screen**” OR photoscreen*</td>
<td>English language</td>
<td>2007-2017</td>
<td>33</td>
<td>2 (1 from Cochrane review; 1 from trials)</td>
</tr>
<tr>
<td>Medline with Full text</td>
<td>PlusOptix OR Amblyopia OR &quot;refractive error**&quot; AND “vision screen**” OR photoscreen*</td>
<td>English Language, Word in major subject heading (MJ)</td>
<td>2007-2017</td>
<td>172</td>
<td>7 (3 overlap from CINAHL; 3 overlaps with ProQuest)</td>
</tr>
</tbody>
</table>
Levels of Evidence

Critical appraisal of evidence is necessary to obtain evidence that is valid, reliable, and applicable to support the clinical change. In order to critically appraise evidence, sources must be ranked on a hierarchy scale. Sources of evidence for this EBP project were evaluated and categorized using the “Hierarchy of Evidence for Intervention/Treatment Questions” also known as “Pyramid of Evidence” (Melnyk & Fineout-Overholt, 2011; Russel, 2012) (see Table 2.2). A total of seven sources were kept and ranked using the Pyramid of Evidence. Hierarchy of evidence is a rating scale used to grade evidence pertaining to the topic at hand in order to guide the investigator to the most reliable information. There are seven essential levels to the pyramid of evidence, Melnyk and Fineout-Overholt mentions (2011). The highest of the rankings start at the top of the pyramid as Level I and moves down towards Level VII. Level I include systematic reviews and meta-analysis of all relevant randomised controlled trial. These are considered the best evidence for guiding practice. Level II is evidence obtained from well-designed randomised controlled trials. Level III evidence is obtained from well-designed non-randomised controlled trials. Level IV is evidence from case-control and cohort studies. Level V includes systematic reviews or descriptive and qualitative studies. Level VI are sources of evidence from single descriptive or qualitative studies. Level VII consists of evidence from authoritative opinions and/or reports from expert committees such as guidelines from USPSTF or AAP (Melnyk & Fineout-Overholt, 2011; Russel, 2012). By placing the available research or information gathered into a hierarchy pyramid, as Melnyk and Fineout-Overholt recommends, it allows for clarity in evaluation of the evidence as it pertains to the PICOT question being asked.

The CASP tool was used to test the strength of the evidence for validity, importance of results of the evidence, and if the results of the evidence are useful (http://www.casp-uk.net/checklists). CASP provides a set of eight questionnaires to be used when reading research to help grade each level of evidence for strength, results, and usefulness. Once the evidence has been found valid, clinical significance of the results needs to be determined.
looking at confidence intervals, \( p \) values, and sensitivity analysis. Evidence is then given an appraisal rating based on quality of the study performed. CASP does not provide this rating scale with its questionnaires for each type of study. It is up to the clinician to apply a rating scale. Appraisal rankings in this EBP project were labeled: high, medium, and low. If clinical significance is found, then determination needs to be made how the evidence applies to the individual clinical practice change. Critical appraisal of evidence helps provide transparency to the evidence found and helps examine sources for bias.

There are four main types of biases: selection, detection, attrition, and performance. Selection bias is controlled by randomization, concealment of population, treatments, and results. Detection bias is controlled by researchers and all participants involved, including data collectors and population participants being masked to outcomes, and grouping of participants. Attrition bias looks at how participants lost to fall out are accounted for. Performance bias is controlled by masking of participants and researchers to group allocation (Powell & Hatt, 2009).

**Appraisal of Relevant Evidence**

**Level I Evidence**

A systematic review by Powell and Hatt (2009) was retrieved from the Cochrane Database of Systematic Reviews. The purpose of the review was to look at randomised controlled trials and cluster-randomised trials to evaluate vision screening and its results on amblyopia compared to non-screened pediatric population. Powell and Hatt (2009) assessed study summaries independently then obtained relevant full text articles. However, they discovered there were no studies on screened versus unscreened children to review. The studies were all observational.

One-thousand forty-nine sources were obtained, three sources were kept for the systematic review. Powell and Hatt (2009) found that despite the large amount of literature available regarding pediatric vision screenings, they were not able to find research trials designed to compare prevalence of amblyopia in screened versus non-screened children. They
concluded there is no optimal protocol for carrying out screening and there is a clear need for more reliable research on the effectiveness of vision screening programs. Powell and Hatt suggested the impact of screening for amblyopia is to detect other vision abnormalities such as refractive errors. Recommendations were made for more evidence regarding living with uncorrected amblyopia. Appraisal quality given to this systematic review is high as the review clearly addressed the focused questions, best studies were used, three databases were used to find sources relevant to focused question, and rigor was used to assess quality of studies found. Overall results were clear; however, specific statistics were not indicated with confidence intervals, odds ratio, or other statistical data.

The Oregon Evidence-based Practice Center (EPC) conducted a systematic review of randomised trials and controlled observational studies searching from 1950 to July 2009 (Oregon Evidence-based Practice Center [EPC], 2011). The EPC looked to answer eight key questions:

- Is vision screening in children ages 1-5 years associated with improved health outcomes?
- Does effectiveness of vision screening in children ages 1-5 years vary in different age groups?
- What is the accuracy and reliability of risk factor assessment for identifying children ages 1-5 years at increased risk for vision impairment?
- What is the accuracy of screening tests for vision impairment in children ages 1-5 years?
- Does accuracy of screening tests for vision impairment vary in different age groups in children ages 1-5 years?
- What are the harms of vision screening in children ages 1-5 years?
- What is the effectiveness of treatment for vision impairment in children ages 1-5 years?
What are the harms of treatment in children ages 1-5 years at increased risk for vision impairment or vision disorder? (Oregon Evidence-based Practice Center [EPC], 2011).

To answer question one, the EPC could not find randomised trials evaluating outcomes of vision screenings in children ages 1-5 years compared to children without having vision screenings. However, the EPC did find a large randomised trial, felt to be of fair quality, nested within a population-based cohort study. The randomised trial showed decreased likelihood of amblyopia at age 7.5 years after having repeated orthoptists screenings between ages 8 months to 37 months. No randomised trials were found comparing outcomes of preschool vision screening in different age groups to answer question 1a. No difference between vision screenings were reported in one of the cohort studies looking at vision screenings at ages 2 and 4 years compared to screenings prior to age 2 years. The EPC found no studies evaluating the accuracy or reliability to identify children at higher risk based on demographic or clinical features, answering question 2.

Question three by the EPC revealed thirty-one studies looking at the accuracy of various preschool vision screening tests compared to standard cycloplegic refraction screening. None of the studies were recorded as being “good-quality”. Overall conclusion by the EPC was all screening tests showed accuracy estimates suggesting usefulness for identifying children ages 1-5 years at higher risk for amblyopic risk factors.

Question four was difficult for the EPC to answer as evidence related to comparing accuracy of screening tests for vision impairment in different age groups from ages 1 year to 5 years was limited. Four of the studies reviewed found no difference among the various age groups. Four studies found lower testability using certain screening methods in ages 1 year to 3 years compared to children ages 4 years to 5 years. Studies were limited on the harms of vision screening in children ages 1 to 5 years. A large cohort reported a fifty percent reduction in odds of being bullied at age 7.5 years of age in children who did receive vision screening compared
to those children who did not receive vision screening. No study looked at harms to unnecessary treatment or use of corrective lenses for amblyopia on long-term vision or functional outcomes.

Question five was addressed with one good quality trial showing patching of one eye plus eyeglasses and eyeglasses alone were more effective than no treatment at all. Two other studies reviewed showed small average improvement in visual acuity in children with amblyopia after a five to twelve-week follow-up. No studies were found that looked at effects of treatment compared with no treatment on school performance.

Five studies reviewed showed some increased risk for temporary vision loss in the non-amblyopic eye when the amblyopic eye was treated, helping to answer question 6 of the EPC’s review questions. No risk was found in three trials for increased risk for visual acuity loss between patching and using atropine regimens for treatment.

After attempting to answer all six questions posed by the EPC, the overall conclusion by the EPC was that preschool vision screenings are effective for diagnosis and treating visual disturbances, mainly refractive errors, compared to no early screenings in preventing long term problems. Appraisal score given to this systematic review is high. The EPC clearly addressed all six of the focused questions, a large assortment of study trials were included. Detailed information was given as to the rigor of studies included with overall results of each study reviewed listed in the report. All important outcomes were considered including population setting. The EPC did report all study trials reviewed were studies done within community settings or ophthalmology setting and this could be a limiting factor.

**Level II Evidence**

Arnold and Armitage (2014) performed a random controlled trial on 108 children ages 1 year to 12 years in an Alaska Pediatric eye practice. The purpose was to compare four different visual photoscreeners, the GoCheckKids™ (www.gochekkids.com), PlusOptix S09™ (https://PlusOptix.com), SPOT™ (www.welchallyn.com), and iScreen
GoCheckKids™ is software that can be uploaded to Apple products such as; iPhone® and iPod touch®. Images of eyes are taken then uploaded to the GoCheckKids™ website for interpretation. PlusOptix S09™ is an infrared photoscreener which has the individual fixate on a light emitting from camera. Images are taken of eyes/pupils then interpreted by PlusOptix™ software for refractive error, ocular alignment, and pupil size. SPOT™ is a hand-held photoscreener which takes images of the eyes/pupils and makes estimation of pupil size, interpupillary distance, ocular alignment, and refractive error. The SPOT™ has a WIFI remote printer so readings can be printed. iScreen™ is also a hand-held photoscreener which has a keyboard, monitor, and port for data import or export. iScreen™ operates with a red laser beam that is aimed at the eyebrows, it then captures an image of the pupils. Images can be sent to an iScreen™ interpretation database immediately or stored and uploaded some later time once multiple screenings have been completed (Arnold & Armitage, 2014).

Each participate was screened with each of the four screeners in random order by orthoptist and pediatric ophthalmologist with results masked to the participant and the screeners until all screenings were completed (Arnold & Armitage, 2014). Validation statistics were completed using a 2X3 table to show sensitivity and specificity of each photoscreener used. Sensitivity of all four photoscreeners averaged 80%. Specificity of all four photoscreeners averaged 88%. Arnold and Armitage reported all four screeners had advantages and disadvantages. The PlusOptix™ was not cordless and required connection to a computer with a monitor by a cable; therefore, it was less portable than other screeners. It also had more difficulty yielding results for children with high refractive errors. However, the PlusOptix™ was able to report refractive error, ocular alignment, pupil size, and interpupillary distance as well as having good validation and calibration calculations due to revisions of prior models. iScreen’s™ central interpretation location leading to a longer wait time for results and refractive error was not estimated. iScreen™ was reported as being easy and quick to use with “excellent ABCD
statistics and ir-sensitivity” (Arnold & Armitage, 2014, pg. 51) the terms chosen by Arnold and Armitage to indicate inconclusive in the denominator of analysis (ABCD) and inconclusive referrals (ir-sensitivity).

The SPOT™ took a little longer with a visual fixation time of 2 seconds or greater. However, the SPOT™ was reported as having “extensive eye examination” (Arnold & Armitage, 2014) consisting of pupil size, interpupillary distance, refractive error, and an estimate of ocular alignment. GoCheckKids™ required steadiness by the screener in order to produce proper image quality.

GoCheckKids™ had no stimulus light on the phone for the individual to fixate to assure proper image. Screening with the GoCheckKids™ looks at ocular alignment and red reflex dimensions. Images need to be uploaded for interpretation and are not readily available for viewing. GoCheckKids™ was applauded for its simplicity for interfacing with the iPhone®.

Conclusion of all four photoscreeners was that all are good for accuracy of vision screening and valuable in identifying treatable vision disorders early enough for therapy to be successful.

The appraisal score given to this random controlled trial was medium. The interpreter of the visual images was not completely blinded to patient identities. Researchers were not as accustomed to the GoCheckKids™ screening tool compared to the PlusOptix™, iScreen™, and SPOT™, as it was a newly acquired tool for them. Arnold and Armitage (2014) also reported the individuals screened were attending a pediatric eye clinic. Therefore, the population studied may not have been a good representation of the population typically seen in a general pediatric clinic within the community. Statistical outcomes were given but there were no in-depth discussions regarding statistical analysis used. Good information and sensitivities and specificities were provided regarding each photoscreener.

**Level III Evidence**

Mu et al. (2016) performed a non-randomised control trial to compare visual screening with SPOT™ photoscreener to traditional cycloplegia retinoscopy. Children ($N = 155$), ages 4-7
years, attending a specialty eye clinic at Tianjin University hospital in Helsinki for eye check-ups were screened. The children were screened first with a complete ophthalmologic examination, then photo screening using the SPOT™ screener, followed by cycloplegia and retinoscopy. Optometrists were masked from results using the SPOT™ screener as well as the individual being screened. Measurements were unobtainable from 13 of the original 168 children due to fear, and others previously diagnosed with hyperopia, esotropia, congenital ptosis, congenital nystagmus, and congenital cataracts. Successful screening was done on 155 children, 71 girls and 84 boys. Twenty-six children had amblyopia, 115 had amblyopic risk factors, 65 had hyperopia, 28 had myopia, 59 had astigmatism, 32 had anisometropia, and 37 had strabismus. Wilcoxon signed rank test showed the difference between SPOT™ photoscreener and cycloplegic retinoscopy was not statistically significant at \( p < 0.01 \) indicating a weak correlation. The Bland-Altman plot test showed moderate agreement between the SPOT™ photoscreener and cycloplegic retinoscopy. The SPOT™ showed high sensitivity of 94.79% and specificity of 85% in detecting amblyopia risk factors based on the AAPOS 2013 guideline. Mu et al. concluded the SPOT™ showed moderate agreement with the results of cycloplegia retinoscopy and detecting amblyopic risk factors was satisfactory but could be further improved with optimizing screening criteria.

Critical appraisal score was high. The aim of the research was made clear. Ethical and bias issues were addressed and clearly laid out in this source. Statistical analysis was discussed in detail to show how sensitivity and specificity was reached. One limitation was the population screened had a high prevalence of amblyopia risk factors compared to community population or school based samples from other studies.

Singman et al. (2013) conducted a retrospective medical records review on an autistic pediatric population, ages <1 year to 15 years with the average age being 6 years, in an ophthalmology practice. Children \( (n = 4) \) were identified as having autism in the retrospective medical records review. The children were seen between January 1, 2001 and April 12, 2012.
Twenty-five of the forty-eight children had undilated PlusOptix™ photo screenings done with their clinical exam during the times listed and were chosen to be analyzed. The chosen population was tested two times with the PlusOptix™. The goal of the review was to compare reliability of the PlusOptix™ to traditional pediatric vision screenings in a pediatric population with autism. The PlusOptix™ does not use a flash, which can sometimes upset individuals with autism. It does use a chirp sound that can be turned off if the child has difficulty with noises. The PlusOptix™ was shown to be easy to use with rapidly available vision screening results. Results of double testing with the PlusOptix™ revealed 17 (68%) children had amblyopia risk factors with both testing’s. The PlusOptix™ was found to have a sensitivity of 88%, specificity of 87%, positive predictive value of 94%, and negative predictive value of 78%. Singman et al. concluded that it was difficult to get reliable screening results in children with autism. When using the PlusOptix™ providers/clinicians can obtain a quick, reliable vision screening result in individuals with autism and other disorders where attention span and focus is a hurdle.

Low level critical appraisal ranking was given to Singman et al. (2013). The aim of the research was clearly stated and qualitative methodology was appropriate to address the aims of the research. Data were gathered in a way to address the research issue. However, biases, limitations, and ethical issues were not discussed. There was no in-depth discussion on findings and how it related to other studies in the literature.

Yan et al. (2015) performed a controlled trial without randomization to assess the accuracy of PlusOptix A09™ photoscreener in detecting amblyopia risk factors in children. One-hundred-seventy-eight children ages 2 years to 14 years attending an ophthalmology clinic at Provincial Hospital in Shandon Helsinki were chosen for the controlled trial. Comprehensive ophthalmic exams were done in the following order: PlusOptix A09™ screening; orthoptic exam with prism alternative and cover test; anterior segment assessment using slit lamp; fundus exam; and then a cycloplegic retinoscopy exam. Each child was tested two times with the PlusOptix™. The Optometrists performing cycloplegic retinoscopy were masked to the
measurements obtained from the PlusOptix™. Data analysis to compare refractive measurements between PlusOptix™ and cycloplegic retinoscopy were calculated. Descriptive data were presented as mean, standard deviation, and frequency. Paired t-test and curve estimation regression analysis were performed to assess differences and quantitative relationships. The Bland-Altman plot test was used to measure agreements between the PlusOptix™ and retinoscopy. ROC curve was used for cut-off points. Pearson’s correlation coefficient was used to confirm consistency of the two measurements from the PlusOptix™.

Results showed 86 (48.3%) children diagnosed with amblyopia (Yan et al., 2015). Sixty-three (35.4%) children were diagnosed with strabismus. The PlusOptix A09™ showed sensitivity for detecting refractive amblyopia risk factors of 80.6%. Specificity of the PlusOptix A09™ for detecting amblyopia risk factors was 76.3%. After applying ROC curve, the overall sensitivity of the PlusOptix A09™ in detecting refractive amblyopia was 94.9% and specificity for detecting refractive amblyopia was 63.2%. Spherical equivalent showed significant difference between the PlusOptix A09™ screening results and the cycloplegic retinoscopy screening results with \( p = 0.00 \). Paired t-test showed \( p = 0.14 \) for mean cylinder power value (Jackson cross cylinder at axis 0°) and \( p = 0.26 \) (Jackson cross cylinder at axis 45°). The Bland-Altman plots showed agreement between the PlusOptix A09™ and cycloplegic retinoscopy for spherical equivalent and Jackson cross cylinder power values at 45° and 0°. Consistency measurements from PlusOptix A09™ and cycloplegic retinoscopy confirmed with Pearson’s correlation coefficient, \( r = 0.95, \ p = 0.00 \).

Conclusion by Yan et al. (2015) showed the PlusOptix A09™ is useful in large scale screenings for refractive errors but may not be suitable for large scale strabismus screenings. It does not need connection to a computer using cords which made it easily portable as well as providing faster data acquisition. It was also user and patient friendly. The critical appraisal score given to the Yan et al. study was high. Yan et al. clearly stated the aims of the research with appropriate methodologies applied. Recruitment strategy was clearly stated with any
exclusions to the study listed. The researchers clearly reported data collection and testing/screenings performed. There could be potential bias in this study related to the population chosen as it was individuals already attending an eye clinic for a check-up. This population may not reflect a typical cohort in a general pediatric clinic setting being seen for routine well child exams. Ethical issues were taken into consideration. Yan et. al discussed how findings were important in clinical practice and where research was still needed.

**Level IV Evidence**

Six physicians on behalf of the American Association for Pediatric Ophthalmology and Strabismus organizations (AAPOS) performed a prospective population-based study review on a pediatric population ages 12 month to greater than 72 months (Donahue et al., 2013). The review was done to help develop and update guidelines to improve reporting of results and comparison technologies for detecting amblyopia. Updated guidelines would help propose and determine levels for detecting amblyopia risk factors to separate those children who are at most risk with those children who are not (Donahue et al. 2013). Donahue et al. reported several prospective population based studies to show childhood amblyopia prevalence was approximately 2%, same as previous reports. However, prevalence of amblyopia risk factors was greater than previously thought at approximately 15%-20%. These numbers showed that not all children with amblyopia risk factors develop amblyopia and this finding was confirmed by a longitudinal follow-up study.

Findings from the reviewed studies led Donahue et al. (2013), to search for information to update referral guidelines to decrease “over-referrals.” Donahue et al. recommended vision screenings should take place at several intervals during the early developmental years instead of one particular time in early childhood. Findings also revealed refractive risk factor targets with automated preschool vision screenings. Donahue et al. concluded as technology continues to advance, reassessment of means for detecting amblyopia and amblyopia risk factors will need to take place to maintain sound screening tools.
Critical appraisal for these guidelines ranked as high. Donahue et al. (2013) had a valid development strategy which was explicit, sensible, and used an impartial process to identify and select evidence. The guidelines did not make explicit recommendations but rather recommendations that are applicable to general practice vision screenings. It was not noted if the guidelines had been subjected to peer review and each guideline was not tagged by strength of evidence in which it was linked with scientific evidence. Recommendations for use in the national arena of providers were clinically relevant outcomes that can be measured through standard care.

The U.S. Preventive Services Task Force (USPSTF) is one organization that helps set guidelines for clinical practice. In 2011, the USPSTF updated vision screening guidelines in children ages 1 year to 5 years. The USPSTF acknowledged 2 to 4 percent of pre-school aged children had amblyopia recognizing a possible cause for this as an alteration in the visual neural pathway in the developing brain. If amblyopia is left untreated it can lead to permanent vision loss. Based on review of the information, the USPSTF agreed vision screening tools, including AVS, have reasonable accuracy to detect visual disorders. The USPSTF also found adequate evidence that early detection and treatment of amblyopia improves visual outcomes with moderate certainty in ages 3 years to 5 years. The USPSTF discussed limited evidence on the harms of vision screenings.

Final conclusions by the USPSTF (2011) for visual screening guidelines included: adequate evidence of early treatment of amblyopia in children younger than 3 years leads to improved outcomes. There was inadequate evidence for recommendations of intervals for vision screening. Screening and treatment later in preschool years appeared to be effective but may take longer to resolve thus increasing financial burden on families.

Critical appraisal score given to the USPSTF (2011) summary guidelines was a high. The updated USPSTF guideline used a valid development strategy which was explicit and sensible. The USPSTF used an impartial process to identify and select evidence. The
guidelines did not make explicit recommendations but recommendations that are applicable to
general practice of vision screenings. It was not noted if the guidelines had been subjected to
peer review and each guideline was not tagged by strength of evidence in which it was linked
with scientific evidence. The updated guidelines by the USPSTF provides for use in the national
arena of providers which were/are clinically relevant listing outcomes that can be measured
through standard care.

**Level VI Evidence**

In a cross-sectional study, Chang et al. (2015) looked at 137 preschoolers attending six
different preschools in O‘ahu Hawai‘i. Ages screened ranged from 8 months to 5 years 2
months. Race characteristics of the preschoolers included: 48 full/part Hawaiian or Pacific
Islander, 56 of mixed races, 21 Asian, and 12 Caucasian. The purpose of the study was to look
at ease of use of hand-held portable vision screeners in the preschool setting. Chang et al.
found 108 (79%) of the preschoolers passed the screening. Four were referred for astigmatism,
four referred for hyperopia, one referred for gaze asymmetry, and two referred for
anisometropia. Cycloplegic eye examination was not done to compare vision screening results.
However, Chang et al. concluded the hand-held screening device has the potential to facilitate
early vision screening in preschools in Hawaii. The AVS was quick and easy to use and also
well tolerated by pre-school children.

Critical appraisal score for Chang et al. (2015) cross-sectional study is low. The research
design was appropriate for the aims of the research along with the recruitment strategy.
However, fall out reasons were not listed or discussed. The study consisted of a small
population size and the varied environments where screenings were done were not consistent.
The lighting in each location was different and not taken into account when first setting up
screening stations. Too much or too little light affects the screening results by the hand-held
vision screener, therefore lighting is important. No in depth statistical analysis were discussed or
sensitivity and specificity calculated due to poor referral follow-up for cycloplegic retinoscopy to
compare results to the hand-held screener. The cross-sectional study by Chang et al. did offer good information on ease of use by lay persons and tolerability of preschoolers.

The Lions Club of western South Dakota performed vision screenings on children ages six months to 12 years with the mean age being 79 months. Screenings took place in five different school and community center locations (Terveen, Moser, & Spencer, 2015). A total of 4,722 children were screened with 2,373 being female and 2,349 being male. Terveen, Moser, and Spencer set up a quantitative descriptive design to look at data collection on the SPOT™ photoscreener in the South Dakota pediatric population. Data were stratified by age group with four different age groups: 12months - 30months; 31months - 48months; 49months – 72months; and 73months – 144months. Data were collected on sex and percentage of children referred for hyperopia, myopia, astigmatism, anisocoria, anisometropia, and ocular misalignment. Sex was compared using chi-square test.

Results from Terveen, Moser, and Spencer’s (2015) descriptive trial showed 563 failed the vision screening with the SPOT. No significant difference was noted in referrals based on sex ($p = 0.598$). Children 73 months – 144 months had the highest referral rate at 12.2%. Children twelve months to thirty months had the lowest referral rate at 7.9%. Reasons for referral included: 371 (7.9%) astigmatism; 24 (0.5%) for ocular misalignment; 101 (2.1%) anisometropia; 135 (2.9%) myopia; 36 (.8%) for hyperopia; 16 (0.3%) anisocoria. There was an overall referral rate of 11.9% using the SPOT™. Terveen, Moser, and Spencer also found a cost benefit of early amblyopia screening. If left untreated, amblyopia can diminish a 30-year, income in South Dakota, by $281,510.00. The 30-year loss was generalized to be approximately a $23 million yearly loss in earning power for the western South Dakota area workforce.

Conclusion of Terveen, Moser, and Spencer (2015) was early detection and treatment result in quicker outcomes as effectiveness of treatment has been shown to decrease as children get older. Also, early detection with early treatment has been shown to decrease length
and cost of treatment. Medium ranking was given to this source for critical appraisal. The aim of the research was clearly stated. The qualitative methodology was appropriate for this study and appropriate to address the aims of the research. Statistical analysis was performed to show abnormal screening results and percent of individuals referred with the reason for referral. However, no statistical analysis was performed to show sensitivities and specificities of the SPOT™ photoscreener. Bias considerations were also not discussed in regard to the role of the researchers but researchers did discuss poor follow-up accounting for inability to calculate and compare date to cycloplegic retinoscopy.
Table 2.2

Levels of Evidence

<table>
<thead>
<tr>
<th>Author(s), Level of Evidence</th>
<th>Population Setting</th>
<th>Design, Intervention(s)</th>
<th>Outcomes</th>
<th>Appraisal Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arnold, R. W., &amp; Armitage, D. (2014) Level II</td>
<td>108 Children ages 1 to 12 years in Alaska Pediatric Eye Practice</td>
<td>Random Controlled Trial</td>
<td>Pediatric Eye exams performed using four different photoscreeners (GoCheckKids™, PlusOptix S09™, SPOT™, iScreen 3000®)</td>
<td>Each photoscreener had sensitivity and Specificity as well as positive predictive values &gt;80% except the iScreen® screener</td>
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<td>Interpreter of visual images was not completely blinded to patient identities</td>
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<td>Statistical outcomes were given. Validation statistics using a 2X3 table to show sensitivity and specificity of each photoscreener used. No in-depth statistical analysis</td>
</tr>
<tr>
<td>Author(s), Level of Evidence</td>
<td>Population Setting</td>
<td>Design, Intervention(s)</td>
<td>Outcomes</td>
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<tr>
<td>Chang et al., 2015 Level VI</td>
<td>137 Preschool age at six different preschools in O’ahu Hawai‘i. Age range 8 months to 5 years 2 months</td>
<td>Cross-sectional study design</td>
<td>108 preschoolers (79%) passed the screening 4 referred for astigmatism 4 referred for hyperopia 1 referred for gaze asymmetry 2 referred for anisometropia Sensitivity and specificity data were not obtained due to lack of follow-up for referrals Photo screener was quick and easy to use and well tolerated by pre-school children</td>
<td>Low Research design was appropriate for the aims of the research Recruitment strategy was appropriate for aims of research design Fall out was not listed Small population size Environments for screenings varied; lighting was not taken into consideration when setting up screening stations No in depth statistical analysis discussed with sensitivities, specificities, CI, OR Poor follow-up to compare and calculate results from cycloplegic retinoscopy Did offer good information on results in general and tolerability for screeners and screeners</td>
</tr>
<tr>
<td>Author(s), Level of Evidence</td>
<td>Population Setting</td>
<td>Design, Interventions</td>
<td>Outcomes</td>
<td>Appraisal Score</td>
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<tr>
<td>Donahue, S. P., Arthur, B., Neely, D. E., Arnold, R. W., Silbert, D., &amp; Ruben, J. B. (2013, February) Level IV</td>
<td>Pediatric preschool population (12 months to &gt;72 months)</td>
<td>Prospective population-based study review</td>
<td>Prevalence of amblyopic risk factors higher than previously thought at 15% to 20%</td>
<td>High</td>
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<td>Six physicians on behalf of American Association for Pediatric Ophthalmology and Strabismus developed new guidelines to improve reporting of results and comparison of technologies of detecting amblyopia. To propose levels for detecting amblyopia risk factors to separate those children who are at most risk with those children who are not</td>
<td>Vision screenings should take place at several intervals during early development years instead of 1 particular time in early childhood</td>
<td>Valid development strategy was explicit &amp; sensible; used impartial process to identify and select evidence; was used for review to improve guidelines</td>
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<td>Recommendation/Guidelines updated: Detection of amblyopia risk factors in toddlers (12-30 months) Detection of amblyopia risk factors early in preschool children (31-48 months) Detection of amblyopia risk factors in late preschool and kindergarten children 49-72 months Detection of amblyopia risk factors in school-aged children (&gt;72 months) Detection of amblyopia and decreased visual acuity using traditional (Optotype-based) screening Detection of amblyopia and decreased visual acuity using instruments other than photoscreeners and autorefractors</td>
<td>Guidelines did not make specific, explicit recommendations but recommendations applicable to general practices performing vision screenings Was not noted if guidelines were subject to peer review Each guideline was tagged by strength of evidence which it was linked with scientific evidence Recommendations provided for use in national arena of providers; recommendations were clinically relevant, listing outcomes that can be measured through standard of care</td>
</tr>
<tr>
<td>Author(s), Level of Evidence</td>
<td>Population Setting</td>
<td>Design, Intervention(s), Comparisons</td>
<td>Outcomes and Effect Measures</td>
<td>Appraisal Score</td>
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<tr>
<td>Mu, Y., Bi, H., Ekure, E., Ding, G., Wei, N., Hua, N., ... Li, X. (2016, February 16) Level III</td>
<td>Pediatric population ages 4 to 7 years at Tianjin University Hospital eye clinic in Helsinki</td>
<td>Non-randomised control trial Compare visual screening with Spot photoscreener to traditional cycloplegia retinoscopy</td>
<td>155 were screened, 71 were girls, 84 were boys; 26 (16.8%) had amblyopia risk factors. 115 (74.2%) had amblyopic risk factors; 65 had hyperopia, 28 had myopia, 59 had astigmatism, 32 has anisometropia, and 37 had strabismus</td>
<td>High</td>
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<td>155 children attending eye hospital for screening or a check-up were screened</td>
<td>Wilcoxon signed-rank test showed difference was not statistically significant at a p value of &lt;0.01</td>
<td>Linear, quadratic, cubic models were constructed to assess correlation between the two screenings</td>
<td>Aim of research was clear</td>
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<td>Bland-Altman showed moderate agreement between the SPOT photoscreener and cycloplegic retinoscopy</td>
<td>Spot showed high sensitivity (94.79%) and specificity (85%) in detecting amblyopia risk factors based on AAPOS 2013 guidelines</td>
<td>Ethical and bias issues were addressed</td>
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<td>Statistical analysis was discussed in detail</td>
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<td>Limitation noted: population screened had a high prevalence of amblyopia risk factors compared to community population or school based samples as screening took place at ophthalmology clinic</td>
</tr>
<tr>
<td>Author(s), Level of Evidence</td>
<td>Population Setting</td>
<td>Design and Intervention(s)</td>
<td>Outcomes</td>
<td>Appraisal Score</td>
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<tr>
<td>Oregon Evidence-based Practice Center (2011)</td>
<td>Children ages 1-5</td>
<td>Systematic review</td>
<td>Reviewers found: No randomised control trials compared preschool visual screenings to no preschool screenings. One study found repeated screening, from ages 8 months to 37 months, most likely reduced amblyopia by age 7.5 years. One study found a one-time vision screening at age 37 months had no significance difference at risk for amblyopia by age 7.5 years compared to no screening. No screening test had both high sensitivity and high specificity. 3 studies showed preschool age children with amblyopia or unilateral refractive error receiving treatment resulted in small improvement at 5 weeks post treatment or after 1-year post treatment but improvement was noted. Conclusion: more evidence needed to compare early screening and treatment to later screening and treatment of visual problems such as amblyopia or refractive error.</td>
<td>High</td>
</tr>
<tr>
<td>Level I</td>
<td></td>
<td>Looking at randomised trials and controlled observational studies that evaluated screening for impaired visual acuity in preschool aged children. Looking at randomised trials and controlled observational studies that reported outcomes associated with treatments. Two independent investigators assessed study quality.</td>
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<tr>
<td>Author(s), Level of Evidence</td>
<td>Population Setting</td>
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<tr>
<td>Level I</td>
<td></td>
<td>Randomised controlled trials, cluster-randomised trials</td>
<td>3 articles were kept</td>
<td>Clearly addressed focused questions</td>
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<td></td>
<td></td>
<td>To review and evaluate vision screening and its results on amblyopia compared to non-screened pediatric population</td>
<td>None were randomised controlled trials</td>
<td>Best studies were used</td>
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<td></td>
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<td>Information obtained is from observational studies</td>
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<td>Multiple databases were used to find sources</td>
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<td>Prevalence of amblyopia was measured; Preschool group had slightly better outcomes reported in treatment compared to school age children treated</td>
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<td>Rigor used to assess quality of studies found</td>
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<td></td>
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<td>No screening protocol clarified</td>
<td></td>
<td>Overall: results were clear</td>
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<td>Determined more evidence needed</td>
<td></td>
<td>Specific statistical analysis (CI, OR) were indicated</td>
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<tr>
<td>Author(s), Level of Evidence</td>
<td>Population Setting</td>
<td>Design, Intervention</td>
<td>Outcomes and Effect Measures</td>
<td>Appraisal Score</td>
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<tr>
<td>Singman, E., Matta, N., Fairward, A., &amp; Silbert, D. (2013)</td>
<td>Autistic pediatric population, ages &lt;1yr to 15 yr., with average age of 6 years</td>
<td>Retrospective medical records review</td>
<td>17 (68%) were found to have amblyopia risk factors</td>
<td>Low</td>
</tr>
<tr>
<td>Level III</td>
<td>48 children were identified with autism for this study, 25 were final number screened</td>
<td>Children were tested 2 times</td>
<td>2nd testing found the same 17 with amblyopia risk factors</td>
<td>Aim of the research was clearly stated</td>
</tr>
<tr>
<td></td>
<td>Goal was to compare reliability of PlusOptix photoscreener to traditional pediatric vision screen in a pediatric population with autism</td>
<td>Goal was to compare reliability of PlusOptix photoscreener to traditional pediatric vision screen in a pediatric population with autism</td>
<td>PlusOptix photoscreener was found to have sensitivity of 88%, specificity of 87%, positive predictive value of 94% and negative predictive value of 78%</td>
<td>Qualitative methodology was appropriated to address aims of the research</td>
</tr>
<tr>
<td></td>
<td>Conclusion by Singman et al = is difficult to get reliable screening results in children with autism; the PlusOptix vision screener provides a quick and reliable way of screening</td>
<td>Conclusion by Singman et al = is difficult to get reliable screening results in children with autism; the PlusOptix vision screener provides a quick and reliable way of screening</td>
<td></td>
<td>Data were gathered in a way to address the research question</td>
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<td>Biases, limitations, and ethical issues were not discussed</td>
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<td></td>
<td>No statistical analysis information was detailed with sensitivities, specificities, false (+), false (-), PPV or NPV, CI, OR</td>
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<td>No in-depth discussion on how findings relate to other studies in literature</td>
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<tr>
<td>Author(s), Level of Evidence</td>
<td>Population Setting</td>
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<tr>
<td>Terveen, D. C., Moser, J. M., &amp; Spencer, T. S. (2015)</td>
<td>Children ages 6 months to 12 years (mean age was 79 months) were screened by trained Lions Club volunteers using Spot photoscreener</td>
<td>Quantitative descriptive design</td>
<td>563 failed the screening</td>
<td>Medium</td>
</tr>
<tr>
<td>Level VI</td>
<td>Data stratified by age group; 4 different age groups: 12-30mo, 31-48mo, 49-72mo, 73-144mo; Data stratified for sex and percentage of children referred for hyperopia, myopia, astigmatism, anisocoria, anisometropia, and ocular misalignment</td>
<td>Indications using Spot photoscreener indicated no follow-up or referral for complete eye exam</td>
<td>No significance difference in referrals based on sex (p=0.598)</td>
<td>Aim of the research was clearly stated</td>
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<td>Final group of 4722 children screened, 2373 were female, 2349 were male</td>
<td></td>
<td>Children 73-144 months had highest referral rate (12.2%); 12-30 months had lowest referral rate (7.9%)</td>
<td>Qualitative methodology was appropriate for this study and appropriate to address the aims of the research.</td>
</tr>
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<td></td>
<td>Took place in five different community locations by Lions Clubs in western South Dakota</td>
<td></td>
<td>Reasons for referral: 371 (7.9%) astigmatism, 24 (0.5%) ocular misalignment, 101 (2.1%) anisometropia, 135 (2.9%) myopia, 36 (0.8%) hyperopia, 16 (0.3%) anisocoria</td>
<td>Statistical analysis was performed to show abnormal screening results and percent of individuals referred with reason for referral</td>
</tr>
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<td>11.9% overall referral rate using Spot screener</td>
<td>No statistical analysis was discussed to show sensitivities and specificities of the SPOT photoscreener</td>
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<td>Cost benefit of amblyopia was found to be favorable, showing untreated amblyopia can diminish a 30-year income by $281,510.00;</td>
<td>Bias considerations were not discussed in regard to the role of the researchers; did discuss poor follow-up accounting for inability to calculate and compare date to cycloplegic retinoscopy</td>
</tr>
<tr>
<td>Author(s), Level of Evidence</td>
<td>Population Setting</td>
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<tr>
<td>U.S Preventive Services Task Force. (2011)</td>
<td>Pediatric population, 1 to 5 years of age</td>
<td>Summary recommendations for vision screening in children</td>
<td>Recommends vision screening all children ages three to five years of age with Grade B evidence</td>
<td>High</td>
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<td>Found adequate evidence of benefits of early detection and treatment of amblyopia improves visual outcomes with moderate certainty in ages 3 years to 5 years</td>
<td>Used valid development strategy which was explicit and sensible; Used impartial process to identify and select evidence</td>
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<td></td>
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<td>Limited evidence on harms of vision screenings</td>
<td>Guidelines did not make specific, explicit recommendations; recommendations were applicable to general practices of vision screenings</td>
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<td>Adequate evidence of early treatment of amblyopia in children younger than 3 years leads to improved outcomes</td>
<td>Was not noted if the guidelines were subjected to peer review</td>
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<td>Did not find adequate evidence for recommendations of intervals for vision screening</td>
<td>Each guideline was not tagged by strength of evidence in which it was linked with scientific evidence</td>
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<td>Found screening and treatment later in preschool years appears to be effective but may take longer to treat increasing financial burden</td>
<td>Updated guidelines provide for use in the national arena of providers which were clinically relevant; outcomes listed can be measured through standard care</td>
</tr>
<tr>
<td>Author(s), Level of Evidence</td>
<td>Population Setting</td>
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<td>Yan, X., Jiao, W., Li, Z., Xu, W., Li, F., &amp; Wang, L. (2015, June 1)</td>
<td>Children ages 2 to 14 years attending an ophthalmology clinic at Provincial Hospital in Shandong Helsinki</td>
<td>Controlled trial without randomization To assess the accuracy of PlusOptix A09 photoscreener in detecting amblyopia risk factors in children Comprehensive ophthalmic exam in order: PlusOptix A09, orthoptic exam with prism alternative and cover test, anterior segment assessment using slit lamp, fundus exam with cycloplegic retinoscopy</td>
<td>86 (48.3%) children diagnosed with amblyopia 63 (35.4%) children diagnosed with strabismus With mean deviation of 27.1 ± 18.5 PD Sensitivity for detecting refractive amblyopia risk factors was 80.6% Specificity for detecting refractive amblyopia risk factors was 76.3% After applying ROC curve, overall sensitivity of PlusOptix A09 in detecting refractive amblyopia was 94.9% and specificity for detecting refractive amblyopia was 63.2% Spherical equivalent showed significant difference between PlusOptix and cycloplegic retinoscopy with ( p = 0.00 ) Paired t-test showed ( p = 0.14 ) for mean cylinder power value (Jackson cross cylinder at axis 0°) and ( p = 0.26 ) (Jackson cross cylinder at axis 45°) Bland-Altman plots showed agreement between the PlusOptix A09 and cycloplegic retinoscopy for spherical equivalent</td>
<td>High Aims of research clearly stated with appropriate methodologies applied Recruitment was clearly stated with reasons for exclusions Data collection was clearly reported Potential bias: population was already attending eye clinic. May not be easily applied to general pediatric clinic population Ethical issues were considered</td>
</tr>
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</table>
Consistency measurements from PlusOptix A09 and cycloplegic retinoscopy confirmed with Pearson’s correlation coefficient ($r = 0.95, p = 0.00$)

Conclusion = PlusOptix A09 is useful in large scale screenings of refractive errors but may not be suitable for large scale strabismus screening
Construction of Evidence-based Practice

Synthesis of Critically Appraised Literature

Amblyopia is the most common visual disorder in children and is potentially curable if detected early and treated properly in the first few years of life. Amblyopia is the leading cause of monocular vision loss in children (Bradfield, 2013). Other visual abnormalities include refractive errors such as myopia, hyperopia, and astigmatism causing blurring of vision. Retinoblastoma is another vision concern requiring early screening to detect and mitigate before it causes long term effects (Hered, 2011). In children, visual impairment can delay learning causing children to be inadequately prepared to start preschool or kindergarten. Delayed detection of visual problems can lead to neural visual pathways not developing properly therefore causing irreversible vision loss (AAP, AACH, AAPOS, AAO, 2003; Bradfield, 2013; Chang et al. 2015; Forcina et al., 2017; Hered, 2011; USPSTF, 2011).

It has been shown in the literature that early detection and treatment of amblyopia and amblyopic risk factors between the ages 3 years and 5 years lead to improved visual outcomes and has moderate net benefit (USPSTF, 2011). Sources reveal early detection, especially in preschool years, of vision abnormalities can result in full recovery of vision and decrease developmental abnormalities of binocular vision (AAP, AACH, AAPOS, AAO, 2003; Bradfield, 2013; Forcina et al., 2017).

Data within the literature demonstrated automated visual screening instruments, also known as photo screeners, have become more accurate at detecting visual abnormalities specifically amblyopia, amblyopia risk factors, refractive errors, and strabismus in the pediatric population, ages six months to five years (Arnold & Armitage, 2014; Mu et al., 2016; Powell & Hatt, 2009; Singman et al., 2013; Yan et al., 2015). AVS provide practical, fast, and easy vision screenings. Most AVS screen both eyes simultaneously, accommodating a short attention span of a young, non-verbal child or a child with autism or learning disabilities (Bradfield, 2013; Peterseim et al., 2015; Terveen, Moser, & Spencer, 2015; Yilmaz et al., 2015).
PlusOptix™ photoscreeners have been shown in the literature to have a high sensitivity for detecting amblyopia and amblyopic risk factors and specificity for detecting those individuals without amblyopia and amblyopic risk factors (Mu et al., 2016; Singman et al., 2013). Singman, Matta, Fairward and Silbert (2103) reported the PlusOptix SPOT™ photoscreener to have a sensitivity of 88% and a specificity of 87% for detecting individuals with and without amblyopic risk factors. Mu et al. (2016) reported the PlusOptix™ photoscreener having a sensitivity of 94.79% and specificity of 85% for detecting amblyopic risk factors.

Overall results from literature show that automated photoscreeners, including the PlusOptix™ series, are easy to use, time-saving, have good compliance with children, and are accurate in detecting visual abnormalities in the young pediatric clients.

**Best Practice Model Recommendation**

Based on the evidence, children ages six months to five years need early vision screening for early detection of amblyopia, amblyopia risk factors, strabismus, and retinoblastoma to prevent long term vision loss. Using the evidence found in the literature, the project manager used Nola Pender’s HPM and the Stetler evidence practice model to guide the new clinical practice change. The EBP project incorporated automated visual screeners, the PlusOptix™ in particular, into well child exams within pediatric clinics located in a large Midwest city.

Vision screenings took place using the PlusOptix™ at ages 9 months, 24 months, 36 months, and 48 months. Boxes were created by IT in the EHR under the visual screening tab for nurses to document “pass” and “refer” from the PlusOptix™ results. A copy of the results from the PlusOptix™ were printed and placed in the patient’s EHR. The printout contained specific abnormalities found from the screening. Any failed vision exams were referred to onsite ophthalmology or ophthalmology of the parents’ choice. The project leader followed-up with patients, via EHR, who were referred to ophthalmology to compare traditional eye screening results to the printed results of the PlusOptix™. The EBP project leader also compared
PlusOptix™ results on a set number of patients over three months using the PlusOptix™ in the clinic setting to three months of vision screening referrals prior to implementation of the PlusOptix™. This comparison helped provide evidence on the accuracy of the PlusOptix™ within the clinic setting by comparing referral rates of the pre-implementation group to the post-implementation group and showing sensitivity.

**How the Best Practice Model Will Answer the Clinical Question**

The best practice recommendation answered the clinical question: In a pediatric population aged 9 months, 24 months, 36 months, and 48 months, how does early vision screening using automated photo vision screeners compared to traditional vision screening techniques affect the number of refractive errors detected within three months. The hope was by performing vision screenings with the PlusOptix™ in the stated population then comparing the results to the results of vision screenings performed by traditional screening methods, prior to the use of the PlusOptix™, the clinical question would be answered.
CHAPTER 3

IMPLEMENTATION OF PRACTICE CHANGE

Participants and Setting

A total number of 322 preschoolers were recruited in the sample with 161 in each the pre- and post-implementation groups. It was estimated 100 pediatric patients would be screened in the post-implementation group based on the number of WCC from the previous year in the same three months. Pre-implementation vision information was obtained from EHR once post-implementation data was collected and the number was known with the assistance of IT personal at the clinic site. The pre-implementation group was identified based on age groups, WCC, and same providers as the post-implementation group. One-hundred-sixty-one WCC were performed in the post-implementation group using the EBP project parameters, therefore that became the size of each sample group.

The setting for this EBP project was a general pediatric clinic in a large Midwest city. The pediatric clinic is part of a large not-for-profit organization that sees clients of various ethnic and socioeconomic backgrounds. There are six different pediatric clinics with many pediatric providers. However, only one clinic and two providers WCC information was used to collect data regarding vision screening results and referrals. Participants were pediatric clients in the clinic for a well-child check at ages 9 months, 24 months, 36 months, and 48 months.

Data collected post-implementation was to show the specificity and sensitivity of the PlusOptix™ comparing vision screening results to the pre-implementation group. The project was to compare data of vision screenings using the PlusOptix™ over a 3-month period to vision screening results using traditional visual screening methods performed by pediatric providers from three months prior to implementation of the PlusOptix™ in order to compare referral rates. Data collected post-implementation of the PlusOptix™ also compared screening results from failed PlusOptix™ screenings to ophthalmology screenings after being referred by the pediatric provider to look at sensitivity.
Outcomes

Data collection took place over a three-month period. Data collected post-implementation of the PlusOptix™ was compared to data collected from screening results 3 months prior to implementation of the PlusOptix™. Data were also collected from ophthalmology referral results post-implementation and compared to the child’s PlusOptix™ results. It was believed the data collected would show ability of the PlusOptix™ photoscreener to detect visual abnormalities, specifically amblyopia, and amblyopic risk factors accurately at the early ages of 9 months, 24 months, 36 months, and 48 months. Data analysis on these two groups was to show accuracy, specificity, and sensitivity.

Intervention

Vision screenings took place in the above-mentioned Midwest pediatric clinic using the PlusOptix™ at ages 9 months, 24 months, 36 months, and 48 months. Data collected was not only to show specificity and sensitivity of the PlusOptix™ but also to show accuracy in the age groups 9 months, 24 months, 36 months, and 48 months. The previous traditional visual screenings at WCC included the Snellen chart starting at age 4 years by some pediatric providers and at kindergarten age by other pediatric providers. Vision problems are difficult to screen for in this age group using traditional eye charts due to the child’s preverbal development, the inability to recognize objects and letters, and the inability to cooperate due to age and attention span. Previously, Snellen chart screenings were also done at sports physical check-ups or if there were a concern by a parent, teacher, or other contact person of the child. At all WCC, a visual exam by the provider was performed without the use of cycloplegia retinoscopy as cycloplegia is typically done in an ophthalmology clinic. Screening with PlusOptix™ offers the advantage of being able to fully screen the 9 months, 24 months, 36 months, and 48 month age groups, thereby increasing the available data starting at an earlier age. Limitations of traditional vision screenings methods of Snellen chart and pediatric provider
visual exams during WCC had prevented children in these age groups from being fully screened for refractive errors at this clinic.

Boxes was created by IT in the electronic health record (EHR) under the visual screening tab for nurses to document “pass” or “refer.” Nurses were to check the appropriate box once screening was completed using the PlusOptix. This documentation screen was also used to generate billing for the screenings. If documentation does not occur in this screen, a patient or their insurance is not billed. If the child was unable to be screened the nurse had the option to long hand document in the vision screening tab that information and why they were not screened. The nurse was to use the word “NULL” on the project flow sheets if a child was not screened or was unable to be screened and give the reason such as small eyes, uncooperative, or already seeing ophthalmology. A copy of the results from the PlusOptix™ was printed and placed in the patient’s EHR. The printout contained specific abnormalities found from the PlusOptix™ screening. Any failed vision exams were referred to onsite ophthalmology or an ophthalmology of the parents’ choice. Data were collected over three months post-implementation of the PlusOptix™ using flow sheets in the clinic and by EHR. Data were also collected for three months pre-implementation for comparison. The project leader followed-up with patients, via EHR, who were referred to ophthalmology to compare ophthalmology eye screening results to the child’s PlusOptix™ “refer” printed results kept in the child’s EHR. The comparison was to show sensitivity and specificity of the PlusOptix™.

Planning

Approval to implement the PlusOptix™ was granted by the medical board, which governs policies and procedures for the pediatric clinics, after best practice evidence information was provided. Initial request for the PlusOptix™ was presented along with information received from current literature to pediatric providers working within the pediatric clinics. Information from the literature was disseminated to providers and a capital request form was filled out and submitted by nursing administration. After receiving feedback from providers
and nursing administration, evidence was presented to the medical board where approval was granted for the use of the PlusOptix™ vision screener within the pediatric clinics. Approval was also obtained by Valparaiso University and the project facility’s Internal Review Boards.

Staff education was conducted by selecting superusers from each clinic. Superusers were chosen based on those who volunteered to be trained as such. The project manager, nursing administration, and superusers received formal education on the PlusOptix™ photoscreener via Skype® from a PlusOptix™ Inc consultant. There was also a PowerPoint® that was part of the training by the PlusOptix™ representative as well as online videos walking the viewer through the process of using the PlusOptix screener™. The videos included use, meaning of test results, maintenance, and troubleshooting of the PlusOptix™. Individual staff members within the individual clinics were trained with the use of the online videos provided by PlusOptix™. The staff members watched the videos and reviewed the PowerPoint® during a staff meeting and those who were not able to attend the staff meeting set up a time with the project manager or supervisor to watch the training videos and demonstrate competency. Competency was checked off using an attendance roster flow sheet (see Appendix A) as each staff member accurately demonstrated back proper use, cleaning, and storage of PlusOptix™. Staff members were also required to demonstrate proper use of the photoscreener on a superuser or the project manager and on one patient. A “cheat sheet” (Quick reference guide) provided by PlusOptix Inc™ (see Appendix B) was given to each staff member with use and meaning of vision screening results. A copy of the “cheat sheet” was also kept with the PlusOptix™ for easy access while using the photoscreener.

Data

Measures

One group in which data were collected was the portion of patients where refractive errors were detected by the PlusOptix™ (post-implementation). Post-implementation data of failed screenings was compared to visual screening results from ophthalmology after referral.
was made. The project manager was able to access and follow-up on ophthalmology results via EHR if the child was seen by ophthalmology within the same organization. If a child was not seen for referral within the same organization, referral results were unknown. Another group was the portion of patients screened, pre-implementation of the PlusOptix™ by pediatrician’s visual exam and Snellen Chart. Pre-implementation group data were chosen randomly with the help from IT. A chi-square goodness of fit test was performed to check which group would find more refractive errors. A chi-square test was also performed to test for any significance of results based on gender or race. An independent-samples t-test was performed to test for differences between both groups based on age. Both sets of data were normally distributed and measured using the same criteria of pass or refer, and number of failed screenings found between the PlusOptix™ post-implementation and the traditional screening pre-implementation.

Data collected was statistically analyzed after input into the most current SPSS system, a computer program for statistical analysis.

Collection

Data collection post-implementation was tracked by flowsheets in the pediatric clinic. One flowsheet contained four columns; one for the medical record number, one for DOB, one for PlusOptix™ results (pass, refer), and one for an assigned identification number (IDN), (see Appendix C). Another flow sheet contained four different columns to de-identify data; one column for IDN, one for the PlusOptix™ results, one for the Ophthalmology results if referred, and one for DOB (see Appendix D). The same flow sheets were created for pre-implementation data (see Appendices E & F). PlusOptix™ screenings and screening results were also kept in each child’s EHR. Screening results scanned into the patient’s chart from the PlusOptix™ contained detailed results such as eye/pupil measurements, alignment and refractive errors. Nursing staff recorded patient’s medical record number, date of birth, pass, refer, or NULL on the flow sheets of children within the specified age group having visual screenings with the
PlusOptix™. If “NULL” was listed in the results column a notation was made as to why no results were obtained such as uncooperative or eyes too small.

The project manager assigned an IDN once the flowsheet had been filled or at the end of data collection whichever came first. Nursing staff also recorded results in the correct location of each child’s EHR. A printed copy of the PlusOptix™ results from the remote PlusOptix™ printer was scanned into the EHR and became a permanent part of the EHR. Once results were documented within the patient chart, the project manager used the flowsheet to locate the results. Vision screening results were obtained from the same number of charts, within the same age groups, on children receiving screenings during WCC, 3 months prior to implementation of the PlusOptix™. Charts were chosen randomly with assistance from IT. Some post-implementation data were obtained solely from the EHR with the assistance of IT as implementation of the PlusOptix™ was implemented by providers prior to full IRB approval for data collection by the project site. IRB approval was given for this process as well. Pre-and post-implementation data were compared to determine referral rates of detecting refractive amblyopic risk factors between the two groups. PlusOptix™ failed results were compared to ophthalmology results to help show sensitivity and specificity.

Management and Analysis

Management of the flowsheets was taken into great consideration as to not compromise the identity of each child screened. The initial flowsheet was securely located in a locked cupboard with the PlusOptix™ at the nurse’s station at the end of each clinic day. The second flowsheet, that the project manager used, was kept in a locked file cabinet in the supervisor’s office when the project manager was not on site. The only patient identifiers on the flow sheets were DOB and medical record number.

Once all data were obtained the project manager reviewed all data collected by comparing data on the flowsheets to data within each individual’s chart. The project manager also reviewed appointment schedules for the three months post-implementation to make sure
no WCC visual screenings were missed on the data collection flow sheets. Data were then organized using an SPSS code book so data could be entered into the most current version of SPSS for analysis.

A chi-square test was performed to compare the two groups and show referral rates. It also looked at statistical differences based on gender and race. An independent-samples t-test was performed using data collected in order to show if there was a statistical difference based on age between the two groups.

Any follow up/referrals seen outside the clinics network were inaccessible for review and comparisons.

**Protection of Human Subjects**

Institutional Review Board (IRB) approval was obtained from Valparaiso University and the project facility’s IRB prior to implementing this EBP project. There were no patient identifiers transcribed on any written material or stored in any databases, spreadsheets, or word documents. No protected health information (PHI) was put into the PlusOptix™, which is possible with this screener so patient data can be directly uploaded into the patient’s chart. By not imputing PHI into the PlusOptix™ patient information is protected in the event the vision screener became missing or stolen. Flowsheets with patient medical record number and DOB were kept in a locked cupboard at the nurse’s station and in the supervisor’s office at the end of each clinic day so it is easily accessible to the nursing staff and the project manager but secure to protect information. The project leader was able to locate patient’s vision screening results within the EHR by using medical record number information and DOB from the flowsheet. The project leader was also able to track referrals to ophthalmology through the EHR and follow-up screenings if done within the same facility so no release of information was needed by parents or guardians. Follow-up results for anyone seeing ophthalmology outside of the clinics network were inaccessible for comparison.
CHAPTER 4

FINDINGS

The PICOT question for this project was: In a pediatric population aged 9 months, 24 months, 36 months, and 48 months, how does early vision screening using an automated photo vision screener, compared to traditional vision screening techniques affect the number of refractive errors detected within three months? The purpose of this EBP was to implement an automated visual screener at all well-child visits for the ages listed within the PICOT question to check for amblyopia risk factors and refractive abnormalities. Pre-implementation screenings for these age groups were performed by the provider using ophthalmoscope without cycloplegic retinoscopy (pupil dilatation). Snellen chart was used only for those receiving a kindergarten well check. No Snellen chart screenings were used on the age groups listed above unless there was a concern by a parent, legal guardian, or school program. Screening for these age groups post-implementation was performed using the PlusOptix S12™ automated visual screener.

This chapter provides data on the participants’ characteristics using descriptive statistics, independent t-test, as well as the Chi-Square Goodness of Fit test for the outcome measure.

Participants

Size and Characteristics

This EBP practice project was implemented in a Midwest pediatric clinic during well-child check-ups for ages 9 months, 24 months, 36 months, and 48 months. It included all children in these age groups from different genders and races. No one was excluded. Data were captured on those that were unable to be screened due to lack of cooperation, already seeing ophthalmology, or some other reason not documented and recorded as “NULL” on the data collection flow sheet.

A total of 322 children were recruited in the sample size with 161 children in each the pre- and post-implementation groups. Three were lost to attrition in the pre-implementation
group (final $n = 158$) and 14 in the post-implementation group (final $n = 147$). Attrition from these groups was due to unwillingness to cooperate with the screening (0% pre-implementation group; .01% post-implementation group), they were already being followed by ophthalmology (2% pre-implementation group; 2% post-implementation group), or unknown reasons (0% pre-implementation group; 6% post-implementation group) as it was not documented by the nurse why the visual exam was not performed. Those individuals not screened were documented as “Null” in the dataset for input into SPSS and documented as “attrition” on final charts and figures.

No release of information was needed for this EBP project as only chart data were used, including any referral follow-up information. Parents were not contacted and reminded to follow-up with ophthalmology if they had not done so by the end of data collection. Nor were parents contacted to see if they had followed-up with ophthalmology at another facility at the end of data collection. All pre-implementation referral follow-ups were completed and accounted for. Only two of the children screened pre-implementation were referred and did follow-up with ophthalmology. Refractive errors were confirmed on follow-up. Out of the $(n = 147)$ post-implementation group, 16 children were referred to ophthalmology for follow-up. Of the 16 referred to ophthalmology, seven follow-ups were accounted for and refractive errors confirmed.

Of the recruited sample size ($N = 322$), pre- and post-implementation, 24.8% were 9 months, 30.4% were 24 months, 24.5% 36 months, and 20.2% were 48 months. The majority of those screened were 24 months of age (see Figure 4.1). Gender and race were also captured for patients in both the pre- and post-implementation groups for comparison in outcomes (see Figures 4.2; 4.3).

Age, gender, and race were compared between the two groups. In order to find if there were differences in results between the pre- and post-implementation group based on age an independent $t$-test was performed. The independent $t$-test found no significant difference ($t(2) = .086, p > .05$) in visual abnormalities among age groups pre- and post-implementation. The
mean for age of the pre-implementation group ($M = 2.29$, $SD = 1.05$) was not significantly
different from the mean of the post-implementation group ($M = 2.50$, $SD = 1.07$). A chi-square
test of independence was used to compare the frequency of visual abnormalities among
genders and races. Gender was found to have no significance in the outcome of visual
abnormalities ($\chi^2 = .262, p > .05$). Race was also found to have no significance in frequency
of visual abnormalities ($\chi^2 = 3.622, p = > .05$) between the two groups.

Figure 4.1. Ages Groups

![Age Groups](image)

*Figure 4.1. Age group comparisons between pre- and post-implementation samples.*
**Figure 4.2. Gender**

![Gender comparison between pre- and post-implementation samples.](image)

**Figure 4.3. Race**

![Race comparison between Pre and Post-Implementation Samples.](image)
Changes in Outcomes

Statistical Testing

It was anticipated that each refractive error found with the PlusOptix™ would also be found with an ophthalmology exam. It was also anticipated that the PlusOptix™ photo screener would find more refractive errors than traditional pediatric eye exams, without dilatation, during well-child check-ups within the pediatric clinic. Descriptive frequencies were calculated to compare the rate of refractive errors found with the PlusOptix™ compared with follow-up ophthalmology exams. The Chi-Square Goodness of Fit was used to test if the PlusOptix™ photo screener would find more refractive errors than traditional pediatric eye exams. The chi-square test was chosen for its ability to compare observed frequencies to expected frequencies. This test helps the observer decide if there is a real treatment effect or if observations are just by chance (Polit & Beck, 2012). The chi-square test was also used to compare frequency of visual abnormalities among different genders and races. An independent t-test was used to compare the frequency of visual abnormalities among age groups. The independent t-test was chosen as it tests the mean of two independent groups to determine if the population means are significantly different. It tells the observer if there is a difference and if that difference is true or a random effect (Polit & Beck, 2012). All statistical analyses were performed using IBM® SPSS® Statistics, version 22.

Significance

The PlusOptix S12™ was implemented in a pediatric clinic in the Midwest. The data collected post-implementation, using the PlusOptix,™ were collected over three months and compared to visual screening data from three months pre-implementation. Data from the PlusOptix™ were also compared to visual screenings performed at ophthalmology follow-up screenings to show sensitivity. Specificity could not be calculated as not every child being screened during their well-child check-up could be sent to ophthalmology to test for absence of disease. This was due to time and funding constraints. Using Chi-Square ($\chi^2$) test, a statistical
significance was found of the PlusOptix™ to identify more refractive errors than the traditional vision screening performed by the PCP during a well-child check-up ($\chi^2 = 20.430$, $p < 0.001$).

Of the children ($n = 158$) screened pre-implementation, two were referred to ophthalmology. Both children were confirmed to have some sort of refractive error. Of the children ($n = 147$) screened post-implementation, 16 children were referred to ophthalmology but only seven followed-up with ophthalmology (see Figure 4.). All of the seven were confirmed to have some sort of refractive error, therefore showing the PlusOptix™ as having 100% sensitivity at identifying visual abnormalities in this sample. Each child in the pre and post-implementation groups passing his/her visual screening was not sent to Ophthalmology to confirm normal vision results. Therefore, specificity was not obtainable as specificity is the ability of the test to correctly identify no disease.
Figure 4.4. Type of Initial Exam Results

![Exam Results Chart]

Figure 4.4. Type of Initial exam results pre-implementation (pediatrician) and post-implementation (PlusOptix™) showing higher referral rate referral with the PlusOptix™.
CHAPTER 5
DISCUSSION

This EBP project examined the clinical research question: Will an automated visual screener detect more refractive errors than traditional visual exams performed by pediatric providers during routine well child checks. The goal was to implement the PlusOptix S12c™ automated visual photo screeners into the pediatric clinics of a Midwest organization. Automated visual screeners were supported by the literature to be sensitive for detecting amblyopic refractive errors. Visual screenings were performed using the PlusOptix S12c™ in four different age groups \( n = 161 \) during routine well child check-ups. Any “refer” results were referred to ophthalmology. The pre-implementation group \( n = 161 \), the same number as the post-implementation group) charts/EHR were randomly chosen from three months prior to implementation of the PlusOptix™ based on age, well-child check-up, and provider. Both groups \( N = 322 \) were compared to help show sensitivity and specificity of the PlusOptix™ This chapter will examine the findings, applicability of the theoretical framework, EBP framework, strengths and weaknesses of the EBP project, and implications for the future.

Explanation of Findings

The PICOT question asked: “In a pediatric population aged 9 months, 24 months, 36 months, and 48 months, how does early vision screening using an automated photo vision screener, compared to traditional vision screening techniques affect the number of refractive errors detected within three months?”

A total of 322 children were recruited in the sample size with 161 children in each the pre- and post-implementation groups. Three were lost to attrition in the pre-implementation group (final \( n = 158 \)) and 14 in the post-implementation group (final \( n = 147 \)). All pre-implementation referral follow-ups were completed and accounted for. Only two of the children screened pre-implementation were referred and did follow-up with ophthalmology. A refractive error or errors were confirmed on follow-up. Out of the \( n = 147 \) post-implementation group, 16
children were referred to ophthalmology for follow-up. Of the 16 referred to ophthalmology, seven follow-ups were accounted for and refractive errors confirmed.

A chi-square test was used to analyze data to see if the PlusOptix™ would identify more refractive errors than traditional visual exams performed by the PCP without pupil dilatation. The chi-square test was also used to look at gender and race in each the pre- and post-implementation groups to see if there was a significant difference among these characteristics. A t-test was performed to compare frequencies of visual abnormalities among the different age groups. Sensitivity was also looked at for the PlusOptix™ to compare findings from this EBP project to the findings within the literature.

Statistical analysis using the chi-square test showed statistical significance of the PlusOptix™ to identify more refractive errors than the traditional PCP visual exam without the use of pupil dilatation ($\chi^2 = 20.430^a, p < 0.001$). The chi-square test showed no statistical significance in the outcome of visual abnormalities by gender ($\chi^2 = .262,^a p = > .05$) or race ($\chi^2 = 3.622,^a p = > .05$). The independent t-test also showed no significant difference in visual abnormalities detected among age groups pre- ($M = 2.29, SD = 1.05$) or post-implementation ($M = 2.50, SD = 1.07$).

All children failing ($n = 16$) vision screenings post-implementation ($n = 147$) using the PlusOptix™ automated visual screener and that followed-up ($n = 7$) with ophthalmology were confirmed to have visual refractive abnormalities. After statistical analysis was performed, the referral and follow-up rate post-implementation showed the PlusOptix™ to have a sensitivity of 100% and referral rate of 11%. In the pre-implementation group ($n = 156$), 2 children were referred to ophthalmology and both followed-up. Both children were confirmed to have a visual refractive error or errors. After statistical analysis was performed the referral and follow-up rate for the pre-implementation group, PCP exams were shown to have a referral rate of 1.3%.
Therefore, showing the PlusOptix™ to have a higher referral rate than provider referrals from traditional visual exams and a high sensitivity for identifying refractive errors.

Statistical analysis from this EBP project coincides with information found within the literature. Arnold and Armitage (2014) showed the PlusOptix™ as well as other AVS to have a sensitivity and specificity greater than 80% at detecting refractive errors. Mu et al. (2016) found the AVS used in their research to have a sensitivity of 94.79% and specificity of 85%. Singman et al. (2013) reported the PlusOptix™ to have a sensitivity of 88%, specificity of 87%, and was a quick, reliable way of screening the pediatric population especially those with autism. Terveen et al. (2015) showed an 11.9% referral rate using an AVS and no significance difference in referrals based on gender. Yan et al. (2015) also showed the PlusOptix™ to have sensitivity of 94.9%.

**Evaluation of Applicability of Theoretical and EBP Frameworks**

**Theoretical Framework**

The Health Promotion Model (HPM) by Nola J. Pender (Friedman, Bowden, & Jones, 2003; George, 2011) was used as the theoretical framework to help guide this EBP project. The HPM complements other health protection models to enhance health and well-being. It offers a process to help motivate individuals to participate in positive behaviors to enhance their health. Pender’s HPM stresses the importance of self-direction, self-regulation, and perceptions of self-efficacy (Friedman, Bowden, & Jones, 2003; George, 2011). The HPM allows for ease of applicability by its simplistic stepwise approach.

Pender’s HPM focuses on individual characteristics, experiences, behavior-specific cognitions, and one’s affect and behavioral outcomes. The HPM was appropriate for this EBP project because the EBP project site prides itself on health promotion and disease prevention. Pediatric providers highly recommend routine yearly well-child check-ups. Nursing staff help remind parents of this when in clinic or when a parent or patient calls the clinic to speak with a nurse. The goal of requiring regular well-child check-ups is to model and promote positive health
behaviors. This modeling can lead to overall good health maintenance which can last a lifetime and be passed on to family members. The HPM has a holistic focus based in nursing which gives it strength by promoting independent practice to provide health promoting interventions and education to individuals.

Implementation of the AVS was one way the providers and nurses could continue to promote health and disease prevention. Pender’s HPM suggests if a family perceives a threat and there are opportunities for decreasing that threat such as health screenings or vision screenings, the family will be more likely to act on it. In this project, children were being seen for well-child check-ups and many of them continued to promote health by going to the ophthalmology clinic based on individual screening results.

**EBP Framework**

The Stetler Model (SM) provides a stepwise process for gathering sound evidence that can guide safe and effective care or evidence-based practice. The SM uses a prescriptive approach, emphasizing critical thinking as a key role. The SM relies on five steps which include: preparation, validation, comparative evaluation/decision making, translation/application, and evaluation (Stetler, 2001).

Preparedness entails identifying a need, the environment it involves, organizing, and initiating evidence research (Ciliska et al., 2011; Stetler, 2001; Young, 2012). It was identified within the EBP facility there was a need to offer more in depth visual screenings while children were in for well-child check-ups. This would offer an opportunity to promote health and help instill the importance of routine visual exams. Eye problems tend to go un-noticed until there are developmental delays or struggles in school (Bradfield 2013; Forcina et al., 2017; Koning et al., 2013; USPSTF, 2011).

The validation process requires combing through a body of evidence to select evidence which best identifies the need for change. For this EBP project, five databases were searched for best evidence using search terms identified to reveal the best sources. Four-hundred-twenty-
nine sources were revealed, with some sources overlapping in the different databases. After reviewing abstracts and relevance, 10 sources were kept for final best practice evidence.

Moving into the next phase is comparative evaluation/decision making. This phase involves applying a set of criteria to evidence collected in the validation phase to further decide which evidence best identifies or supports the practice change. Evidence for this EBP project was appraised and leveled using Melnyk and Fineout-Overholt’s Hierarchy of Evidence and the Critical Appraisal Skills Programme© (CASP).

Translation/application then occurs requiring conversion of evidence findings into practice by dissemination, leading to the final phase of evaluation. The translation/application process for this EBP began with an initial request for implementation being presented to pediatric providers, the facility administration, and the facility medical board along with evidence from the literature showing sensitivity and specificity of automated visual screeners. A capital request form was submitted to the budget committee to request funding for the PlusOptix™ screeners. Approval was granted by the facility medical board to implement the screeners. Budget was approved to purchase the screeners. Approval was also obtained from the EBP facility IRB and Valparaiso University IRB to implement the project.

Once approvals were received, formal education was given by the PlusOptix Inc™ representative to the project manager, nursing administration and super users. Education on use and maintenance of the PlusOptix™ screener via Skype®, PowerPoint®, and online videos was included. The clinic nursing staff members watched videos from the PlusOptix Inc™ website and performed practice screenings before competency was verified.

A documentation box was created in the electronic health record by a facility IT representative within the visual screening assessment screen to mark “pass” or “refer” based on the child’s screening results from the PlusOptix™. If a child received a “refer”, he/she was referred to ophthalmology onsite for further visual exam to confirm if there was a true refractive error identified.
Flowsheets were created by the project manager to collect screening results for pre- and post-implementation and to de-identify personal health information (PHI). Nursing staff documented screening results from the PlusOptix™ along with the medical record number and date of birth on the flowsheets. The project manager used the flowsheets to review the chart, screening results, and any follow-up ophthalmology results that were obtained. A flowsheet was also created to document the same information from the pre-implementation group.

Data were collected over three months using the PlusOptix™ screener in the designated age groups, during well-child check-ups, provided by two of the providers within the Midwest facility. One-hundred-sixty-one children were identified in the post-implementation group over the 3 months. Once the post-implementation group number of children was determined to be \( n = 161 \), the same number of patient charts were randomly pulled from EHR by IT, using the same parameters for age, well-child check-up, and provider as post-implementation. The initial number of well-child check-ups was unknown. It was anticipated there would be at least 100 in the sample size. One-hundred-sixty-one check-ups were done during the three months, therefore, that became the recruitment number for each the pre- and post-implementation samples.

No release of information was obtained as only chart data were collected. Children were referred to onsite ophthalmology so the project manager could follow ophthalmology results through the EHR. No parents were contacted to remind them to follow-up with ophthalmology or contacted to see if they had followed up with ophthalmology at an outside facility.

Evaluation, the final phase of the SM, involves assessing the new plan of practice to ensure goals were met, monitor for any adverse occurrences, identify any changes that need to be made, and how to continue. The evaluation process is a continuous process. The project manager was easily available on site or via cell phone to help monitor nursing staff to make sure screenings were being performed appropriately. Lighting and distance parameters had to be maintained during screenings to assure an accurate screening result by the PlusOptix™. The
project manager was also available for any trouble shooting, questions with the flowsheets, and reviewing EHR weekly to make sure screenings were getting documented appropriately.

**Strengths and Limitations of the EBP Project**

**Strengths**

Involvement of the providers and administration from the beginning of this EBP project implementation process was advantageous. Administration was onboard due to evidence from the literature showing high sensitivity and specificity of AVS. Other facilities within the community were starting to use AVS and the EBP project facility makes it a priority to stay abreast of new technologies and what is being used within the local community to help stay competitive. The EBP facility also prides itself on research which lent a hand to implementation of this project and support. Providers within the facility were also very interested in the results that were being obtained from the PlusOptix™ and how it compared to screening methods prior to its use.

Nursing staff at the EBP project facility was very helpful in the implementation process of the AVS within the clinic setting. The staff was in frequent communication with the project manager about how the AVS use in clinic was going.

There were many that helped make this EBP project a success. The IT specialist which assisted in gathering EHR information was a great help and resource for this EBP project. He was able to capture EHR that fit the parameters of the project so the project manager could gather pre-implementation data. He also helped retrieve EHR for the post-implementation group so the project could start on time at the beginning of October. Facility IRB was not approved to collect data on the EBP project until the beginning of November. The facility IRB and Valparaiso IRB gave approval to collect data from the EHR dating back to the beginning of October when the AVS were first being used.

Assistance was received from the director of research at the EBP project site and with a statistician consult on the use of SPSS and data results.
Parents bringing their children in for a well-child check-up in the specified age groups for screenings were very receptive and even intrigued by the use of an AVS. Parents were informed and educated on the use of the PlusOptix™ and different refractive errors it could detect.

Visual screenings were faster and easier for nursing staff to perform using the PlusOptix. Children were very cooperative with the visual screenings due to a picture on the machine, the “warble” sound it makes, the quickness of the screening, and that the child was not confined during the screening.

The PlusOptix Inc™ representative for the area where the EBP facility was located was very helpful and readily available via email. She provided the initial education on the PlusOptix™, its use, trouble shooting, results interpretation, and maintenance. She was available to the project manager to educate on how to perform calculations using the results from the PlusOptix™ in order to see why the child was being referred to ophthalmology.

**Limitations**

Limitations to this EBP project included incomplete documentation by nursing staff for several children which resulted in no screening results. The screening technique/routine was new for the nursing staff and documentation within the EHR changed from the previous processes. Having a float nurse from another clinic or prn staff that was not aware of the data collection system also contributed to no screening results. All regular nursing staff at the EBP facility were aware of the data collection and were trained in the use of the flowsheets and which provider patient population was being used. However, prn staff and staff from the other five facilities were not aware of the data collection process. If the project manager was not onsite the day prn staff or staff from another clinic worked, they were not always made of aware of the data collection process on the flow sheets. In the future, prn staff and any float staff could be given a folder with the data collection information to help decrease missed screening documentation on flow sheets.
Not all children completed follow-up with ophthalmology to further support sensitivity of the PlusOptix™ or contribute to specificity results. No release of information was obtained from those being screened and only chart data were collected. Therefore, parents were not contacted and reminded to follow-up with ophthalmology or to check if they had followed-up with ophthalmology at an outside facility. When performing a project like this in the future, the project manager would recommend release of information be obtained when implementing the project. Then parents could be contacted to encourage follow-up appointments with ophthalmology referrals leading to more data to further confirm sensitivity of the PlusOptix.

Specificity was not obtainable for this EBP project as not all children who completed the visual screening were sent to ophthalmology to confirm the absence of disease. This situation was due to time and funding limitations. However, there were data within the literature to show high specificity of AVS. A time-frame of three months was implemented for this EBP project and there was no funding to cover ophthalmology screenings without a referring diagnosis.

**Implications for the Future**

**Practice**

The USPSTF reports 1% to 5% of U.S preschool aged children have some sort of visual impairment (USPSTF 2011), and the AAP, AAPOS, AAO, and AACO (2003) recommend visual screenings starting in newborns then with every well-child check-up visit thereafter. It is important for advanced practice registered nurses (APRN), as well as all providers, to stay abreast of new research regarding health promotion and illness prevention such as visual screenings. By implementing the most up to date recommendations, APRN’s are able to offer the best care and information to help mitigate chronic diseases.

It is important for APRN’s and nurses to develop a strategy to communicate with parents regarding the importance of health maintenance, such as regular visual screenings and follow-up with ophthalmology for any abnormal findings. This will help aid in health promotion.
Automated visual screeners, such as the PlusOptix™ have greater sensitivity and referral rates than visual screenings performed by providers alone during a well-child check-up. Therefore, AVS should be considered for implementation in pre-school age children screenings performed by nursing staff during well-child check-ups and in many different settings.

**Theory**

The Health Promotion Model (HPM) postulates that specific behaviors and cognitions are directly related to individual health promotion behaviors (Friedman, Bowden, & Jones, 2003). An individual’s prior behavior as well as inherited and acquired characteristics have great impact on the individual’s prior behavior. The inherited and acquired characteristics have a great impact on the individual’s beliefs, affect, and how the individual views health promoting behaviors. The pre-school age group is not yet able to have their own views about health promoting behaviors, but by teaching parents these behaviors they can be passed down to their children. Therefore, it is important to create positive affects in the individual’s beliefs and health promotion behaviors to pass down to future generations.

The HPM allows for ease of applicability by its simplistic stepwise approach and was intended for any individual in any situation other than the illness state. These features of the HPM make it very adaptable in the health promotion, disease prevention setting, and a good model for APN’s and nurses to follow when implementing new screening techniques such as AVS. If a family perceives a threat and there are opportunities for decreasing that threat, such as vision screenings, the family will be more likely to act on it. When providing information, parents will be able to actively own the behavior of early vision screening.

**Research**

Further research and education is needed to continue to show sensitivity and specificity of AVS and then be disseminated to primary providers. Research with funding is needed so all those within the recruited population can be screened both with an AVS and then with ophthalmology to show those confirmed to have disease (sensitivity) and those without disease.
(specificity). More research is needed in a variety of settings using AVS to better show their ability to be effective at detecting refractive errors, especially in the very young preschool ages.

**Education**

Continued education is needed for APN’s, nurses, and all healthcare providers on the importance of early vision screening as recommended by the USPSTF and other organizations. In order to get this education out there, continued research with its results and projects such as this EBP project need to be published and disseminated to all providers and facilities who provide visual screenings. AVS are reliable, easy to use, highly sensitive pieces of equipment that should be available in many different settings. Dissemination of information can include research conferences, nursing conferences, advanced practice conferences, and manuscript publishing of findings. Also, organizations such as the Lion’s Club, who advocate for good vision programs and help with vision screenings in many communities, are a good resource to help in purchasing AVS. AVS are expensive but there are many organizations that are willing to help with various health promotion activities, such as screenings, to help gather funding for new screening equipment. It is important for APRN’s and nurses to continue to educate the communities in which they serve about the importance of wellness and health promotion. By attending yearly well exams, chronic disease can be diminished and better outcomes accomplished. APRN’s and nurses also need to continue their own education by staying abreast of new research being done and printed in the literature and also by attending conferences with up-to-date information. Being informed better prepares APN’s and nurses to promote health and wellness to their community.

**Conclusion**

In conclusion, the goal of this EBP project was to implement an AVS, the PlusOptix™, in a Midwest pediatric clinic for visual screenings as AVS were shown in the literature to have high sensitivity and specificity to detect refractive errors. Findings from this EBP project demonstrated that AVS can statistically improve the detection rate of refractive errors in 9-
month, 24-month, 36-month, and 48-month-old children. Data showed a referral rate of 1.3% in the pre-implementation group. A referral rate of 11.3% was revealed in the post-implementation group with a sensitivity of 100%. Findings from this EBP project were similar to that reported in the literature and answered the PICOT question: will an automated visual screener detect more refractive errors than traditional visual exams performed by pediatric providers during routine well-child checks. The Plusoptix™ found more refractive errors than traditional visual exams in this pediatric population. Thus, primary care providers should consider implementing AVS into their routine well-child check-ups for young children who are pre-verbal and those populations with behavioral or developmental disabilities, as they are a great asset to detect and mitigate visual abnormalities.
REFERENCES


Boys Town National Research Hospital. (n.d.). https://www.boystownhospital.org/AboutUs/aboutUs/Pages/Mission.aspx


Critical Appraisal Skills Programme (2017). CASP (Systematic Review, Randomized Controlled Trial, Quantitative, Controlled Trial) Checklist. [online] Available at: https://casp-uk.net/casp-tools-checklists Accessed: June 2017


Nebraska State Legislature 79, § 214 (2013).


Mrs. Slominski is a Nebraska native where she graduated from Southeast Community College in 1994 with a diploma in practical nursing. She continued her education at Bryan School of Nursing by earning her registered nurse diploma in 1995 and a Bachelor of Science in Nursing from Nebraska Wesleyan University in 1998. She has worked in various nursing settings including: intensive care, cardiac intensive care, home health, school nursing and pediatrics. Mrs. Slominski returned to Valparaiso University to pursue her DNP as a family nurse practitioner. Mrs. Slominski currently works at Boys Town National Research Hospital in Omaha, Nebraska, as a pediatric staff RN. She is a member of the American Association of Nurse Practitioners (AANP) and Midwest Nursing Research Society (MNRS). Mrs. Slominski is interested in pursuing a post-graduate certificate in psychiatry and behavioral health after completing her DNP. Mrs. Slominski became interested in psychiatry and behavioral health after her family members with psychiatry issues went un-diagnosed/misdiagnosed for years. During her time at Boys Town, Mrs. Slominski experienced first-hand the shortage and need for mental health and behavioral health providers in pediatrics. Mrs. Slominski would like to eventually serve in a humanitarian role with her husband by volunteering for mission trips overseas using her nursing and advanced practice nursing skills. Mrs. Slominski’s evidence based practice project involved the use of an automated visual screener to screen preschoolers ages 9 months, 24 months, 36 months, and 48 months during well child visits. The aim of the project was to show the accuracy and sensitivity of the PlusOptix™ vision screener in detecting amblyopic risk factors and refractive errors within the pediatric clinic where she works.
ACRONYM LIST

AACO: American Association of Certified Orthoptists
AAO: American Academy of Ophthalmology
AAP: American Academy of Pediatrics
AAPOS: American Association of Pediatric Ophthalmology and Strabismus
ADHD: Attention Deficit Hyperactivity Disorder
AVS: Automated Visual Screener(s)
CASP: Critical Appraisal Skills Programme
CINAHL: Cumulative Index of Nursing and Allied Health Literature
DNP: Doctorate of Nursing Practice
EBP: Evidence Based Practice
EHR: Electronic Health Record
EPC: Oregon Evidence-based Practice Center
HPM: Health Promotion Model
IDN: Identification Number
PCP: Primary Care Provider(s)
PHI: Protected Health Information
PPV: Positive Predictive Value
SM: Stetler Model
USPSTF: US Preventive Services Task Force
WCC: Well Child Check(s)
## Boys Town National Research Hospital
### ATTENDANCE ROSTER

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**SCREENING AMBLYOPIC FACTORS 84**

**APPENDIX A**
Quick reference guide - Vision Screener plusoptiX S12C

Thank you for choosing plusoptiX S12C. An award winning, 4th generation vision screening device. This quick reference guide will support you in performing your first vision screening in 8 easy steps:

**Step 1**
Ensure that the batteries are inserted with the proper orientation. Follow the guide in the battery compartment. Then close the lid. Press On/Off button to switch device on.

**Step 2**
Choose date and time format by touching the appropriate buttons on screen. Then set date and time using the arrow buttons. Confirm with green checkmark button to proceed to start screen. Select age group of patient by touching appropriate button on screen.

**Step 3**
The patient needs to fixate on camera lens. Level camera to patient’s eyes and press shutter to see camera picture on screen.
Step 4
Tilt camera so that screen is inclined by 45 degrees. Avoid sunlight and distractions. Adjust room light to obtain proper pupil size of 4 to 8mm.

Step 5
Identify right measurement distance by observing camera picture on screen. Start at 4 feet. Camera picture is blurred. Move closer until picture is in clear focus. A warble sound is being played and measurement starts automatically.

Distance too far: Pupils crowded in white squares
Right distance: Pupils circled in green
Distance too close: Pupils almost do not fit onto screen

Step 6
A ping sound is played at the end of a measurement. Camera picture freezes and a green “pass” or red “refer” screening result is shown on screen. Use orange arrow buttons to toggle in between result screens.

Step 7
A “pass” vision screening result indicates that all readings are below the referral thresholds, i.e. are in normal range.

In some cases an error message will be displayed on screen. In this case vision screening result is inconclusive. Review user manual for hints on how to avoid an aborted measurement and retry. If error message reads “measurement incomplete” in two consecutive attempts, vision screening result is deemed to be “refer”.

A “refer” vision screening result indicates that one or more readings are at or above referral thresholds. These patients need to be sent to an eye care professional for a comprehensive eye exam. Pass Picture out
Step 8

In settings you will find five validated sets of referral thresholds to choose from. They range from very sensitive (and less specific) to very specific (and less sensitive). Pay attention to the description provided on screen and access on screen help to review referral thresholds in detail.

Please note:
Children with glasses are already under the care of an eye care professional and therefore need not be screened. If your program requires screening of children with glasses then the child should be screened wearing the glasses and the glasses should be tilted up at the temples to reduce glare.

Plusoptix devices are specifically designed for the purpose of detecting the most common vision disorders in toddlers and preschool children. The screening of adults is only valid to identify the possibility of refractive error (need for glasses). Adults should receive comprehensive eye examinations to detect early stages of age related eye diseases. The methods used for children’s screening are not able to detect adult eye/vision diseases.

These steps as well as all other features of your device are explained in detail in the user manual. The user manual describes error messages and fixes in detail, too. In case you don’t have a copy of the user manual, you can download it here: www.plusoptix.com/images/plusoptix/doku/usermanualS12USA.pdf

Once the device is switched on, you have access to additional information by touching the blue “i” icon located at the bottom right corner of each screen. This button opens an on screen help page.
**APPENDIX C**

Post-Implementation Data Flow Sheet

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APPENDIX D

De-identified Post-Implementation Flow Sheet

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APPENDIX E

Pre-Implementation Data Flow Sheet

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