



Efficacy Of A Novel Vision Screening Tool For Detection Of Vision Disorders: Birth To Three Study

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Disclosures

- Joanne Angle Investigator Award from Prevent Blindness 2016



Overview

- Visual development
- Early Detection
- Vision screening practices in US
- Birth to Three Study
 - Visual developmental assessment
 - Relevance to you
 - Pilot study
 - Results
- Future Directions



Visual Development – Birth to Three Years

- Development of age appropriate visual functions
 - Ex: Social smile established at 2 months
- Normal visual input is critical for child's development
- Equally important to have normal visual input for visual development to occur
- Visual impairment impacts
 - Motor developmental milestones
 - Overall development
 - Cognitive ability



Causes of Visual Impairment

- Amblyopia (Lazy Eye)
 - Developmental disorder that results in decreased vision in one or both eyes in the absence of eye disease
 - Prevalence 2-3% in the US in children under 6 years of age
 - Preventable and can be successfully treated if identified early
 - If not treated
 - Irreversible
 - Long term visual and functional consequences for the child



Causes of Visual Impairment

- Amblyogenic risk factors
 - Significant (equal) refractive errors (farsightedness, nearsightedness, astigmatism) i.e Isoametropia
 - Significant (unequal) refractive errors i.e Anisometropia
 - Eye misalignment i.e Strabismus
 - Childhood cataracts or other media opacities
 - Prevalence 8-10% in US
- Eye Diseases – Rare
 - Prevalence 0.1%



Detection Of Vision Problems

Is early detection of vision problems beneficial?

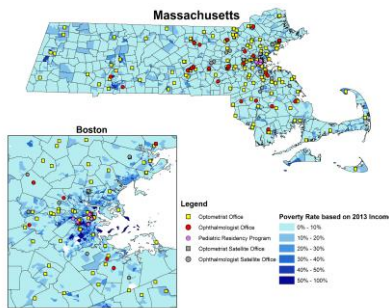
- o Yes

What can we do to detect them early?

Comprehensive eye exams	Vision Screenings
<ul style="list-style-type: none"> Performed by eye doctors Limited access to providers* Time consuming, ?efficiency 	<ul style="list-style-type: none"> Performed by lay personnel (NP, Pediatricians, Early educators) Relatively easy access Efficient, accurate, economical



Access to Pediatric Eyecare in MA



Children Who Should Bypass Vision Screening and Go Directly to Eye Exam

- Parents who believe their child has a vision problem
- Readily observable ocular abnormalities
- First-degree relatives with strabismus or amblyopia
- Systemic conditions with associated ocular abnormalities
- Neurodevelopmental disorders
- Prematurity and/or low birth weight
- Motor abnormalities such as Cerebral Palsy
- Down Syndrome
- Cognitive impairment
- Hearing impairments
- Speech/language delays
- Autism spectrum disorders



Vision Screenings in the US

- ↳ Mandated by Federal Programs
 - Early and Periodic Screening, Diagnosis, and Treatment Program
 - Administration for Children and Families- Head Start/Early Head Start
 - Maternal and Child Health Bureau

- ↳ Recommendations by professional organizations
 - American Academy of Ophthalmology (AAO)
 - American Academy of Optometry (AAO)
 - American Academy of Pediatric Ophthalmology and Strabismus (AAPOS)
 - American Academy of Pediatrics (AAP)

- ↳ United States Preventive Services Task Force (USPSTF)



Traditional vision screening

- ↳ Visual acuity (Distance/Near)
- ↳ Depth Perception (Stereopsis)
- ↳ External inspection of the eyes
- ↳ Test of eye movements
- ↳ Red reflex testing

- ↳ These tests are extremely difficult to perform in children below three years of age, even with training!



Vision screening in children from birth to three years

- ↳ Where do these children "collect"?
 - Pediatrician's offices
 - Early Education and Care centers (EECs)

- ↳ Early Head Start programs
 - Vision screening to be performed or results obtained within 45 days of enrollment (within 30 days if a Migrant program)
 - No recommendation for procedure to use

- ↳ American Academy of Pediatrics guidelines (AAP)
 - Pediatricians



AAP recommendations

TABLE 1 Periodicity Schedule for Visual System Assessment in Infants, Children, and Young Adults

Assessment	Newborn to 6 mo	8-12 mo	1-3 y	4-5 y	6 y and older
Ocular history	x	x	x	x	x
External inspection of lids and eyes	x	x	x	x	x
Red reflex testing	x	x	x	x	x
Pupil examination	x	x	x	x	x
Ocular motility assessment	—	x	x	x	x
Instrument-based screening ^a	—	—	x	x	x
when available					
Visual acuity fixate and follow response	x ^f	x	x	—	—
Visual acuity age-appropriate optotype ^g assessment	—	—	x ^g	x	x

^b The American Academy of Ophthalmology (AAO) has recommended instrument-based screening at age 6 mo. However, the rate of false-positive results is high for this age group, and the likelihood of ophthalmic intervention is low.¹⁸ A future AAO policy statement will likely reconcile what appears to be a discrepancy.

^a Instrument-based screening at any age is suggested if unable to test visual acuity monocularly with age-appropriate optotypes.

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Birth to three — Bottom Line

- Vision screening tools should be studied for accuracy and feasibility
 - Research is limited
- Current recommendations are either not feasible or efficient or economical
 - Patient cooperation and time consumption are the most common barriers for vision screening in this age group
- Bottom line - We do not know what tools to use in this young population



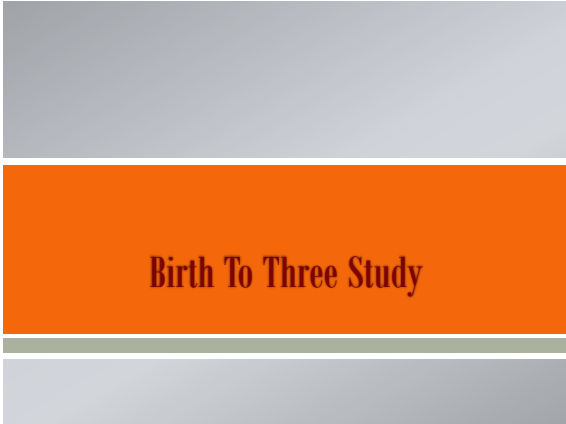
What do we do then?

- Conduct more studies to test current methods of vision screening
 - Instrument based vision screening
 - Gaining popularity
 - Research is emerging
 - Cost



- Develop new methods?





Birth to Three Project

- National Center for Children’s Vision and Eye Health
 - Established by Prevent Blindness in 2009 and supported, in part, by the Maternal and Child Health Bureau
 - Represented by Ophthalmology, Optometry, Pediatrics, Family Advocates, and Public Health
 - Supports infrastructure to “promote and ensure comprehensive multi-tiered continuum of eye health and vision care for young children”
 - MA selected as a pilot state
 - CVMA – 75 member state-based coalition
 - Feasibility of visual developmental questionnaire



Visual developmental questionnaire

- Developmental assessment in pediatric practice
 - PEDS/ASQ
- Impact on motor, social and emotional development
- Understanding visual milestones
 - Eg: 2 month infant should make eye contact with caregivers
 - Early toddler should start taking interest in playing with toys
- Scandinavian experience
- Vision in current developmental tools
- Two components
 - Visual developmental assessment
 - Risk assessment



Visual developmental milestones

Red **Green**
Orange **Blue**

Pincer Grasp
24-26 months

2 months: Social Smile

NATIONAL CENTER
for Eye Development Research
A PREVENT RESEARCH

Visual developmental questionnaire

VISUAL DEVELOPMENT AND RISK ASSESSMENT SURVEY QUESTIONNAIRE
Healthy Eyes Healthy Futures Massachusetts
The New England College of Optometry

Study Personnel: Gayatri Srinivasan OD, Bruce Moore OD, Jane Squires PhD, Kathy Majumdar RN, MBA, Paulette Tattersall DipPharm, MSc, Stacy Lynn OD, Kass Braden MD.

Child's name _____ Date of Birth ____/____/____ Early education center location _____

These questions are about your child's vision development. Please read them carefully and answer the questions by placing a checkmark in the column that is most appropriate. Be sure to try each activity with your baby before answering the question. Make sure your baby is fed and well rested. Please return this questionnaire by _____.

6-23 months of age:		OFTEN	SOMETIMES	NOT YET
1. Does your child recognize family members before hearing their voice?				
2. Does your child look at his/her toys or his/her hands?				
3. Does your child follow your movement across the room? For example, do his/her eyes follow you as you walk across the room?				
4. When your child looks at you or a toy does one of his/her eyes appear turned in or out while the other eye is not?				
5. Does your child pick up small objects with her thumb and fingers?				
6. When your child looks at you, does it ever feel like he/she sees right through you?				

		YES	NO	UNSURE
7. Does anyone in the family have crossed eyes or one eye that turns in a different direction?				
8. Was anyone in the family told to wear glasses at age 4 or younger?				
9. Was your baby ever born, did he/she have to stay in the hospital for more than 5 days?				
10. During pregnancy, did the mother smoke more than 5 packs of cigarettes per month?				
11. Was your child at least 8 weeks premature or born with low birth weight (3.5 lbs or less)?				

Why is this relevant to you?

- ➦ Address gaps in vision screening recommendations
- ➦ Potential for the new tool to be administered in a cost-effective, feasible way with minimal training



Goals of this study

- ☞ Compare the efficacy of
 - Newly developed tool
 - Visual developmental questionnaire
 - Currently available tool
 - Instrument based screening
- ☞ To
 - Gold standard eye exam by masked eye doctors



Methods

- ☞ Venue
 - Early Education & EI sites in Boston and Springfield
- ☞ Protocol
 - Age appropriate questionnaire completed by parent
 - Eye exam conducted on the On-Sight mobile van



Results

- ☞ Sample
 - 249 recruited (Target 250)
 - Males - 141
 - Females - 108
 - Average age 23.14 mo (3-36 months)
 - 26 questionnaires were excluded from analysis
 - 21 filled out incorrect surveys
 - 3 incomplete
 - 2 missing



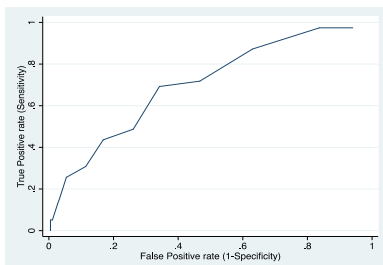
Performance Metrics For The Survey

cutoff	sensitivity	specificity
3.5	0	0.995
4	0.0513	0.995
4.5	0.0513	0.989
5	0.128	0.973
5.5	0.154	0.967
6	0.256	0.946
6.5	0.308	0.886
7	0.436	0.832
7.5	0.487	0.739
8	0.692	0.658
8.5	0.718	0.533
9	0.872	0.37
9.5	0.974	0.163
10	0.974	0.0598

Two reasonable questionnaire cut off scores with moderate sensitivity and specificity



Survey Performance (continued)



Area under the curve 0.703



Survey Performance (Continued)

Risk factor	OR (95% CI)	P Value
Survey Score <7	3.81 (1.82-8.00)	0.000
Survey Score <8	4.32 (2.05-9.10)	0.000
Age*	1.01 (0.97-1.06)	0.606
Age**	1.01 (0.97-1.05)	0.660
Sex*	0.47 (0.21-1.05)	0.065
Sex**	0.45 (0.20-1.01)	0.053

Odds of failing the eye exam increases 3x for score of <7 and 4x for score of <8
Age and Sex were not significant risk factors



Welch-Allyn Spot



Spot Vision Screener - Results

Spot Screener Results	ARF -	ARF +	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
Pass	159	13	62.9 (44.9-78.5)	89.8 (84.4-93.9)	55.0 (38.5-70.7)	92.4 (87.4-95.9)
Fail	18	22				

Testability:

- Missing spot data in 14
- 6 truly untestable (defined as unable to measure after three failed attempts)
- 8 untestable because Spot screener manufacturing criteria is only for >6 months



Summary of Results

Questionnaire:

- ∞ Identified two reasonable pass/fail scores with moderate sensitivity and specificity
- ∞ Good area under the curve (0.703)
- ∞ Odds ratio analysis identified strength of the predictor variables (score, age, gender) to the odds of having vision problems

Spot vision screener:

- ∞ High specificity and moderate sensitivity
- ∞ Testability rate high



Limitations:

- ∞ Limited sample size
 - Age wise analysis was not feasible
 - Not enough children in 0-6 mo group

Future directions:

- ∞ Large scale study
- ∞ Refine current version
- ∞ Grant opportunities



Conclusion of today's presentation

- Normal visual development is critical for overall development
- Early detection of vision disorders ensures successful treatment
- Current vision screening practices for children below three years of age are unclear
- There is a need for evidence based support for validation of current tools and novel tools
- New visual developmental assessment tool shows promise in detection of vision disorders
- Large scale studies are needed to confirm preliminary results



Questions for the presenters?



Thanks