



## 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



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## 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



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## 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




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## 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




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## 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%




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




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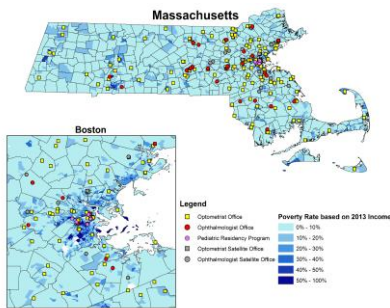
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## Access to Pediatric Eyecare in MA




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## 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




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## 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)




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## 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!




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## 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




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## 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




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## 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




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## 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




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## 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




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## 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




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### 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




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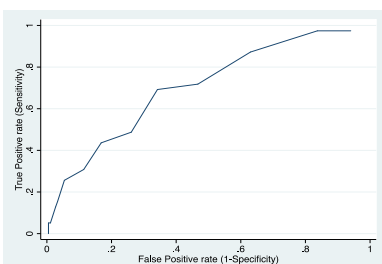
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### Survey Performance (continued)



Area under the curve 0.703




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### 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




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## Welch-Allyn Spot




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## 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




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## 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




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## 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




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## 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




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## Questions for the presenters?




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Thanks



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