Efficacy Of A Novel Vision Screening Tool For Detection Of Vision Disorders: Birth To Three Study
Gayathri Srinivasan OD, MS, FAAO
Assistant Professor of Optometry
New England College of Optometry, Boston, MA

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
Development of age appropriate visual functions
- 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

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?
- Yes

What can we do to detect them early?

<table>
<thead>
<tr>
<th>Comprehensive eye exams</th>
<th>Vision Screenings</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Performed by eye doctors</td>
<td>• Performed by lay personnel (NP, Pediatricians, Early educators)</td>
</tr>
<tr>
<td>• Limited access to providers*</td>
<td>• Relatively easy access</td>
</tr>
<tr>
<td>• Time consuming, inefficiency</td>
<td>• Efficient, accurate, economical</td>
</tr>
</tbody>
</table>

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 (EPSDT)
  - 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: Infants, Children, and Young Adults

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Newborn to 6 mos</th>
<th>6-12 mo</th>
<th>1-3 y</th>
<th>4-5 y</th>
<th>6 y and older</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ocular history</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>External inspection of lids and eyes</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Refraction testing</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Pupil examination</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Ocular motility assessment</td>
<td>—</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Instrument-based screening</td>
<td>—</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>when available</td>
<td></td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Visual acuity tests and follow-up</td>
<td>x</td>
<td>x</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Visual acuity age-appropriate optotype assessment</td>
<td>—</td>
<td>—</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

* The American Academy of Pediatrics (AAP) has recommended instrument-based screening at age 3 years. However, the role of instrument-based testing in this age group, and the method of applying interventions is controversial. This statement will likely revise what appears to be a consensus.

** Adapt this statement to reflect revision of prior guidelines.

Notes: This schedule is intended for children who are not part of the feeding tube program.

* AAP recommendations are either not feasible or efficient or economical

o 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

24-36 months:
- Pointing to objects/features in pictures
- Recognizing and naming familiar pictures

24-36 months:
- Color matching

8-12 months
2 months:
- Social Smile

Visual developmental questionnaire

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

<table>
<thead>
<tr>
<th>cutoff</th>
<th>sensitivity</th>
<th>specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>0.8</td>
<td>0.905</td>
</tr>
<tr>
<td>4</td>
<td>0.903</td>
<td>0.905</td>
</tr>
<tr>
<td>5</td>
<td>0.903</td>
<td>0.900</td>
</tr>
<tr>
<td>6</td>
<td>0.914</td>
<td>0.907</td>
</tr>
<tr>
<td>7</td>
<td>0.916</td>
<td>0.904</td>
</tr>
<tr>
<td>8</td>
<td>0.946</td>
<td>0.870</td>
</tr>
<tr>
<td>9</td>
<td>0.946</td>
<td>0.853</td>
</tr>
<tr>
<td>10</td>
<td>0.967</td>
<td>0.850</td>
</tr>
</tbody>
</table>

Two reasonable questionnaire cut off scores with moderate sensitivity and specificity.

Survey Performance (continued)

Area under the curve 0.703

Survey Performance (Continued)

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>OR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survey Score &lt;7</td>
<td>5.8 (1.82-18.00)</td>
<td>0.000</td>
</tr>
<tr>
<td>Survey Score &lt;8</td>
<td>6.32 (2.05-19.10)</td>
<td>0.000</td>
</tr>
<tr>
<td>Age*</td>
<td>1.01 (0.57-1.60)</td>
<td>0.886</td>
</tr>
<tr>
<td>Age**</td>
<td>1.01 (0.57-1.60)</td>
<td>0.886</td>
</tr>
<tr>
<td>Sex*</td>
<td>0.47 (0.21-1.05)</td>
<td>0.065</td>
</tr>
<tr>
<td>Sex**</td>
<td>0.45 (0.20-1.01)</td>
<td>0.053</td>
</tr>
</tbody>
</table>

- 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

<table>
<thead>
<tr>
<th>Spot Screener Results</th>
<th>ARF</th>
<th>ARF +</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
<th>PPV (95% CI)</th>
<th>NPV (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pass</td>
<td>159</td>
<td>13</td>
<td>62.9 (44.9-73.5)</td>
<td>89.8 (84.4-93.9)</td>
<td>55.0 (38.5-70.7)</td>
<td>92.4 (87.4-95.9)</td>
</tr>
<tr>
<td>Fail</td>
<td>18</td>
<td>22</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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