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
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%
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, ?efficiency</td>
<td>• Efficient, accurate, economical</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Newborn to 6 mo</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>Red reflex 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&lt;sup&gt;a&lt;/sup&gt; when available</td>
<td>—</td>
<td>—</td>
<td>b</td>
<td>x</td>
<td>c</td>
</tr>
<tr>
<td>Visual acuity fixate and follow response</td>
<td>x&lt;sup&gt;f&lt;/sup&gt;</td>
<td>x</td>
<td>x</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Visual acuity age-appropriate optotype&lt;sup&gt;d&lt;/sup&gt; assessment</td>
<td>—</td>
<td>—</td>
<td>x&lt;sup&gt;e&lt;/sup&gt;</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

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<sup>b</sup> 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. A future AAO policy statement will likely reconcile what appears to be a discrepancy.

<sup>c</sup> Instrument-based screening at any age is suggested if unable to test visual acuity monocularly with age-appropriate optotypes.
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?

知名企业进行更多的研究来测试现有的视力筛查方法
  - 仪器基线的视力筛查方法
    - 正在获得流行
    - 研究正在兴起
    - 成本

开发新方法吗？
Birth To Three Study
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 questionnaire

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

**Study Personnel:** Gayathri Srinivasan OD, Bruce Moore OD, Jane Squires PhD, Kathy Majzoub RN, MBA, Paulette Tattersall DipPharm, M.Sc, Stacy Lyons 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 ___________________________

## 6-12 months of age:

<table>
<thead>
<tr>
<th>1. Does your child recognize family members before hearing their voice?</th>
<th><strong>OFTEN</strong></th>
<th><strong>SOMETIMES</strong></th>
<th><strong>NOT YET</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Does your child look at his/her toys or his/her hands?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Does your child follow your movement across the room? For example, do his/her eyes follow you as you walk across the room?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Does your child pick up cereal or small objects with her thumb and forefinger?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. When your child looks at you, does it ever feel like he/she sees right through you?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## 7-12 months of age:

<table>
<thead>
<tr>
<th>7. Does anyone in the family have crossed-eyes or one eye that turns in a different direction?</th>
<th><strong>YES</strong></th>
<th><strong>NO</strong></th>
<th><strong>UNSURE</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Was anyone in the family told to wear glasses at age 4 or younger?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. When your baby was born, did he/she have to stay in the hospital for more than 5 days?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. During pregnancy, did the mother smoke more than 5 packs of cigarettes per month?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Was your child at least 8 weeks premature or born with low birth weight (3.5 lbs or less)?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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>3.5</td>
<td>0</td>
<td>0.995</td>
</tr>
<tr>
<td>4</td>
<td>0.0513</td>
<td>0.995</td>
</tr>
<tr>
<td>4.5</td>
<td>0.0513</td>
<td>0.989</td>
</tr>
<tr>
<td>5</td>
<td>0.128</td>
<td>0.973</td>
</tr>
<tr>
<td>5.5</td>
<td>0.154</td>
<td>0.967</td>
</tr>
<tr>
<td>6</td>
<td>0.256</td>
<td>0.946</td>
</tr>
<tr>
<td>6.5</td>
<td>0.308</td>
<td>0.886</td>
</tr>
<tr>
<td>7</td>
<td>0.436</td>
<td>0.832</td>
</tr>
<tr>
<td>7.5</td>
<td>0.487</td>
<td>0.739</td>
</tr>
<tr>
<td>8</td>
<td>0.692</td>
<td>0.658</td>
</tr>
<tr>
<td>8.5</td>
<td>0.718</td>
<td>0.533</td>
</tr>
<tr>
<td>9</td>
<td>0.872</td>
<td>0.37</td>
</tr>
<tr>
<td>9.5</td>
<td>0.974</td>
<td>0.163</td>
</tr>
<tr>
<td>10</td>
<td>0.974</td>
<td>0.0598</td>
</tr>
</tbody>
</table>

Two reasonable questionnaire cut off scores with moderate sensitivity and specificity.
Area under the curve 0.703
Survey Performance (Continued)

- 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

<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>3.81 (1.82-8.00)</td>
<td>0.000</td>
</tr>
<tr>
<td>Survey Score &lt;8</td>
<td>4.32 (2.05-9.10)</td>
<td>0.000</td>
</tr>
<tr>
<td>Age*</td>
<td>1.01 (0.97-1.06)</td>
<td>0.606</td>
</tr>
<tr>
<td>Age**</td>
<td>1.01 (0.97-1.05)</td>
<td>0.660</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>
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 (44.9-78.5)</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