Health Screenings

- Can be a helpful, more affordable way of finding people with a disease (cost/benefit)
  - A screening tool is typically cheaper than a diagnostic (gold Standard) tool
  - ie: vision screening test (like the one for driver’s license exam) is cheaper than a complete eye exam
- Could give the individual a false sense of security

Why do vision screenings?

- Full eye exams may not be accessible (especially those with the least social and economic power, like children)
- Many eye problems are asymptomatic
- Screenings may raise the awareness of the need for eye care, but they are a double-edged sword in making people believe that if they had a vision screening, they don’t need an eye exam!

Screening Test vs Screening Program

- A screening test (instrument) is only as good as the people who deliver it, when used appropriately.
- A screening program includes:
  - Targeting the population
  - Marketing and implementing the program
  - Establishing effective instrument (s)
  - Ensuring access to care for referrals
  - Monitoring follow-up
  - Educating participants on advantages and disadvantages of screening program

Vision Screening Tests

- Visual Acuity charts
- Photoscreeners
- Autorefractors
- Side vision tests
- Tests of binocularity and depth perception
- Eye health assessment

What population/how frequently?

- Determine the area you will be working in
- Look up the population
  http://quickfacts.census.gov/qfd/states/01000.html
- Look up the health care need areas
  http://bhpr.hrsa.gov/shortage/
- Look up the prevalence of the disease or problems of interest if available
  http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5345a3.htm
  http://www.nei.nih.gov/eyedata/pbd_tables.asp
  - Or estimate them based on the composition of the population
Once you decide where...

— Targeting the population
— Marketing and implementing the program
— Establishing effective instrument(s)
— Ensuring access to care for referrals
— Monitoring follow-up
— Educating participants on advantages and disadvantages of screening program

Targeting the population

• Decide where the target population can be reached
  — i.e. Glaucoma screenings at churches and community centers
  — i.e. Amblyopia screenings at schools and daycare centers
• Determine the number of people you plan to reach
  — Based on the population and the prevalence

Work out the administrative details

• If national, contact the county health department, the local community centers, churches, schools, etc
• If international, contact the ministry of health of the country, a religious organization, VOSH.org, or a Lions or Rotary Club
• Contact drug reps
• Contact frame reps for discontinued frames
• Order pre-made bifocals, readers and sunglasses

Marketing and implementing the program

• Get promotional and educational materials in the language needed
  • http://www.nei.nih.gov/resources/
• Advertise locally!

Has the validity of the screening test been established?

• Search on PubMed for articles on validity of the tools to be used
• Determine
  — Age-appropriateness of tools
  — Costs and availability of tools
  — Comparison to a ‘Gold standard’
  i.e. Icare tonometer

• Has the validity of the screening test been established?
• What population/how frequently?
• Is the screening for a specific disease or a group of diseases?
• How will it be marketed?
• How will persons with positive results be referred or treated? Are they being educated on the condition suspected?
• Do you have a way to ‘check in’ on the screeners?
Monitoring follow-up

- Are you doing it all?
- Are you causing more stress?
- Do they have insurance?
- What about treatment?

Screening Terminology

- Prevalence
- Incidence
- Sensitivity
- Specificity
- False Positives
- False Negatives
- PPV
- NPV

Two-by-two table for screening

<table>
<thead>
<tr>
<th>Disease (+)</th>
<th>Screening test (+)</th>
<th>True positives</th>
<th>False negatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease (-)</td>
<td>False positives</td>
<td>True negatives</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Disease (+)</th>
<th>Screening test (+)</th>
<th>a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease (-)</td>
<td>c</td>
<td>d</td>
</tr>
</tbody>
</table>

Sensitivity

- Proportion of individuals who **have a disease** and test **positive** with the screening test
  - Sensitivity=$a/(a+b)$
  If the sensitivity of a screening test is not good, you may be missing people who have the disease

Specificity

- Proportion of individuals who **DO NOT have a disease** who test **negative** with the screening test
  - Specificity=$d/(c+d)$
  If the specificity of a screening test is not good, you may be wasting resources
Other Screening Terminology

- **False Positive rate (proportion)** = Proportion of individuals who DO NOT have a disease who test positive with the screening test
  
  False Positive proportion = 1 - Specificity

- **False Negative rate (proportion)** = Proportion of individuals who have a disease and test negative with the screening test
  
  False Negative proportion = 1 - sensitivity

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Vision In Preschoolers Study

- Comparing 11 preschool vision screening tests
- 2588 3-t-5 yo children in Headstart
- LEP=ODs and oMDs performed screenings and full exams (Gold Standard Exam=GSE) on all the children, however, they made sure that the LEP that screened a sample would be different from the one doing the GSE (masking)
- 4 targeted conditions:
  - Amblyopia
  - Strabismus
  - Significant refractive error
  - unexplained reduced visual acuity

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11 Screening Tests/instruments evaluated

- Non-cycloplegic retinoscopy (NCR)
- Retinomax (autoref)
- SureSight (autoref)
- PowerRefractor (auto)
- Lea (cards on flip-book)
- HOTV (Chart)
- Randot E (stereo)
- Stereo Smile (stereo)
- MTI (photoscreener)
- iScreen (photoscreen)
- Cover Test

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School-based screening
Full Exam

Ask these questions about the program...

- Has the validity of the screening test been established?
- What population/how frequently?
- Is the screening for a specific disease or a group of diseases?
- How will it be marketed?
- How will persons with positive results be referred or treated? Are they being educated on the condition suspected?
- Do you have a way to ‘check in’ on the screeners?

### TABLE 3

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Specificity</th>
<th>Sensitivity for Normal condition (%)</th>
<th>Sensitivity for Abnormal condition (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refraction</td>
<td>95%</td>
<td>87%</td>
<td>91%</td>
</tr>
<tr>
<td>Autorefract</td>
<td>95%</td>
<td>87%</td>
<td>91%</td>
</tr>
</tbody>
</table>

*The treatment of reverse differences is the patient's best primary meridian, the most negative meridian, and the magnitude of difference inside a 4-degree perception of measurements for all conditions.

MODEL: Induty cases, the VIP vision screening program may be programmed on the strength of a new school health. (Source: Parke, P.)

Example of Children’s Vision screening program in Alabama

- All children in public school in AL receive photoscreening by VisiScreen in kindergarten and 2nd grade
- Parents of children who fail receive a letter and are encouraged to seek a full eye exam
- Some children who pass the screening come in for a full exam and actually have an eye problem
- A large percentage of children who fail the vision screening are never taken for a full eye exam

### TABLE 4

<table>
<thead>
<tr>
<th>Antigen</th>
<th>Sensitivity</th>
<th>Screening test</th>
<th>Sensitivity</th>
<th>Screening test</th>
<th>Sensitivity</th>
<th>Screening test</th>
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</thead>
<tbody>
<tr>
<td>1 NCR</td>
<td>0.61 (0.50)</td>
<td>NCR</td>
<td>0.61 (0.50)</td>
<td>NCR</td>
<td>0.61 (0.50)</td>
<td>NCR</td>
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<td>0.61 (0.50)</td>
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<td>0.61 (0.50)</td>
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<tr>
<td>7 NCR</td>
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<td>NCR</td>
<td>0.61 (0.50)</td>
<td>NCR</td>
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</tr>
<tr>
<td>8 NCR</td>
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<td>NCR</td>
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</tr>
<tr>
<td>9 NCR</td>
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<td>NCR</td>
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<td>NCR</td>
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<tr>
<td>10 NCR</td>
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*The screening results with test sensitivity are listed alphabetically.

**Example:** Sensitivity of test 1 (VIP) for detecting the 4 VIP targeted disorders with specificity set at 0.94.

The current sensitivity comparisons were based on similar specificity for VIP VA, specificity for Random dot E, and 90% specificity for target condition.

The screening tests with the best sensitivity are listed alphabetically.

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Example:** Sensitivity of test 1 (VIP) for detecting the 4 VIP targeted disorders with specificity set at 0.94.
What about adult vision screenings

• Glaucoma Screenings
• Diabetic Retinopathy Screenings
• All-eye-problem screenings

Legal and Ethical Issues in Clinical Research

Marcela Frazier, OD, MPH, FAAO

Ethics in Research

• Ethics is based on morality (sense of right and wrong)
• Ethical analysis is the process of identifying and logically thinking through moral problems, it does not provide a universal right or wrong
• For research purposes it is important that something is not only morally, but also legally right

Ethical Analysis

• Identification of an ethical question
• Assessing why the question concerns morality
• Identifying and describing different moral perspectives on the question
• Listing potential solutions to the question
• Developing and defending the answer to the question

Legal issues in Research

• The legal system is based on justice and rights
• May have a more clear answer than ethical issues
• Informed Consent
• Inclusion of minorities, women, and minors
• Child Assent
• Right to withdraw at any point
• HIPAA

Institutional Review Board (IRB)

• All personnel involved in research must undergo IRB training and certification along with HIPAA training
• All research protocols must have IRB approval
• Yearly updates are necessary for IRB renewal
• IRB approval is necessary during data collection and analysis phases
• Any changes to the protocol must be approved by IRB as an addendum