Universal Hearing Screening in Newborns

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Objectives

• Describe epidemiology, causes and consequences of congenital hearing loss
• Major considerations in implementing a screening program:
  – logistic
  – networking
  – costs
  – legislative
• Hardware and software technology for neonatal hearing screening
• Published and local experience from universal hearing screening programs

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Universal hearing screening

Background

• Hearing loss in neonates is common, and potentially treatable
• Speech and language development
  – critical stages: ~ first 6 months of age
• Average age at identification of severe hearing loss in U.S.:
  – 2.5 years (1988) --> 1.2 years of age (1998)
  – Only ~50% of babies identifiable by “high risk registry” screening
• Evolution of technology
  – Permits neonatal screening, diagnosis, therapy

Congenital hearing loss & other screenable defects: expected yearly numbers in the U.S.

Prevalence of hearing loss in newborns and infants: 1.5-6.0/1000 live births

Based on: Colorado Dept of Health, 1996 data
Speech development is progressively impaired by delayed age at diagnosis of hearing loss

Marion Downs National Center for Infant Hearing, 1997

Early Identification and Treatment

- The only means of minimizing the consequences of neonatal hearing loss
Criteria for justification of universal screening

AAP, Pediatrics 103:527, 1999

★ Available test: easy-to-use, highly sensitive and specific (minimizes further assessment)

✔ Condition to be screened for is not detectable by clinical exam

✔ Therapeutic interventions available for the condition

✔ Screening, detection, and treatment -> improved outcome

✔ Screening program documented to be cost-effective

Rhode Island Hearing Assessment Program
Costs, 1990 $U.S.

Cost/infant identified

- Permanent hearing loss • $ 4609
- PKU • $40960
- Hypothyroidism • $40960
- Sickle cell anemia • $40960

Cost/infant screened

Permanent hearing loss $26
Other conditions (each) $3
New York State Bill A04152

AN ACT to amend the public health law, in relation to requiring hospitals to establish programs for hearing screening of newborn infants prior to discharge

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. The public health law is amended by adding a new section 2500-g to read as follows:

S 2500-G. NEWBORN HEARING SCREENING. THE COMMISSIONER SHALL, WITHIN THE AMOUNTS APPROPRIATED THEREFOR, AND IN CONSULTATION WITH HEALTH CARE PROVIDERS OR THEIR REPRESENTATIVES, ESTABLISH A PROGRAM TO SCREEN NEWBORN INFANTS FOR HEARING PROBLEMS. THIS PROGRAM SHALL INCORPORATE CONSENSUS MEDICAL GUIDELINES AND PROTOCOLS, REFLECTING THE MOST COST-EFFECTIVE METHODS FOR DETECTING HEARING PROBLEMS AS EARLY AS POSSIBLE IN AN INFANT’S LIFE. THE PROGRAM SHALL PROVIDE FOR FOLLOW-UP SCREENING INCLUDING REFERRALS FOR SCREENING OR CARE. SUCH PROGRAM SHALL ALSO PROVIDE FOR THE REIMBURSEMENT OF HEALTH CARE PROVIDERS PERFORMING SUCH SERVICES UNDER THE PROGRAM. IT SHALL BE THE DUTY OF THE ADMINISTRATIVE OFFICER, OR OTHER DESIGNATED PERSON, AT EACH INSTITUTION CARING FOR NEWBORN INFANTS, TO EITHER ADMINISTER SUCH A PROGRAM OR PROVIDE A REFERRAL FOR THE PATIENT TO OBTAIN THE SERVICE FOLLOWING DISCHARGE.

S 2. This act shall take effect April 1, 2000, and any rules and regulations necessary for the timely implementation of this act on its effective date shall be promulgated on or before such date.

New York State regulations

• As of January 2001, implementation of the regulations stemming from the preceding law awaits a 45-day period of public commentary and review
Essential elements for effective universal newborn hearing screening program (UNHSP)  
AAP, Pediatrics 103:527, 1999

Initial screening
Tracking and follow-up
Identification
Intervention
Program evaluation

Initial screening phase
Major considerations

• Parent education, information
• Physician education, communication
• Screening staff training, coordination
• Documentation, changes to hospital paperwork
  – Must also document refusals, “misses”, referrals

These are just screens; results do not diagnose a hearing condition!!!
Methods for screening neonatal hearing

• Otoacoustic emissions (OAE)
  – Transient-evoked OAE (TEOAE)
  – Distortion-product OAE (DPOAE)

• Auditory (brainstem) evoked responses (ABR, BAER)
  – AABR (automated, for screening)
  – DABR (semi-automated, for diagnostics)

These tests are automated, when used for screening purposes

Otoacoustic emissions

• OAE originate from the outer hair cells’ motion
• Measure the presence of the “active process” within the normal cochlea
• Require NO patient participation
• TEOAE and DPOAE methods
Otoacoustic emissions

- Otoacoustic emissions are present if:
  - normal cochlea
  - normal middle ear
  - open ear canal

- Otoacoustic emissions are absent if:
  - hearing loss
  - ear infection/fluid
  - ear canal is blocked
ABR
Algo response detection Algorithm

ALGO Earphone Coupler Design

• Disposable
• Scaled to size for infant ears
• adhesive over foam provides constant placement, regardless of infant movement
• closed foam, secure placement attenuate background noise (>14 dB at 2 kHz)
• Somewhat expensive
Newborn hearing screening methods (PPV 1-19%)

• OAEs
  • Cochlear function
  • Simple to learn, fast
  • Noise, debris (ME + canal) & operator-sensitive
  • Cheaper materials
    – TEOAE
      • 80 dB pSPL
      • SNR ≥ 3 dB @ 2, 3, 4 kHz
    – DPOAE
      • 65/50 or 75/75 dB SPL
• AABR
  • Cochlear + neural function
  • 30 dB nHL
  • Somewhat longer test time
  • More expensive materials
  • Lower referral rates (FP 2-6%)

NIH consensus panel, March 1993

• ...all infants should be screened for hearing impairment...
• with a test that measures otoacoustic emissions (OAEs)...
• accomplished most efficiently by screening prior to discharge...
NIH consensus panel, March 1993
Proposed protocol

- Stage I (inpatient screening):
  - OAE
  - If fails, repeat OAE or, do AABR
- Stage II (outpatient screening):
  - AABR for OAE failures
- Diagnosis:
  - DABR (after 44 weeks PCA)

Recent regional neonatal hearing screening program results

<table>
<thead>
<tr>
<th>Place</th>
<th>Sites</th>
<th>Screen Ref</th>
<th>n</th>
<th>Miss</th>
<th>Refer stage 1a/b</th>
<th>Refer (range)</th>
<th>Follow-up</th>
<th>Incidence bHL/1000</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dallas</td>
<td>9</td>
<td>TEOAE +/- AABR</td>
<td>54,228</td>
<td>3%</td>
<td>3%</td>
<td>0.6% - 21%</td>
<td>68%</td>
<td>3.14</td>
<td>Finitzo et al., Pediatrics 102:1452, 1998</td>
</tr>
<tr>
<td>Colorado (50%)</td>
<td>26</td>
<td>AABR &gt; TEOAE</td>
<td>41,796</td>
<td>12%</td>
<td>6%</td>
<td>?</td>
<td>48%</td>
<td>2.0</td>
<td>Mehl et al., Pediatrics 101(1): e4, 1998</td>
</tr>
<tr>
<td>Hawaii (KP)</td>
<td>1</td>
<td>AABR</td>
<td>10,372</td>
<td>4%</td>
<td>4%</td>
<td>96%</td>
<td>1.4</td>
<td>Mason et al., Pediatrics 101:221, 1998</td>
<td></td>
</tr>
<tr>
<td>East London</td>
<td>9</td>
<td>TEOAE</td>
<td>14,353</td>
<td>19%</td>
<td>3% (bilat)</td>
<td>86%</td>
<td>1.5</td>
<td>Watkin, Arch Dis Child 75:158, 1996</td>
<td></td>
</tr>
<tr>
<td>RI</td>
<td>8</td>
<td>TEOAE</td>
<td>52,695</td>
<td>0.6%</td>
<td>10%</td>
<td>8% - 12%</td>
<td>68%</td>
<td>2.1</td>
<td>Vohr et al., Ped Res 43:233A, 1998</td>
</tr>
</tbody>
</table>

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NYS Newborn Hearing Consortium
Ear & Hearing, 21:85-ff, April 2000

- 7 centers, 1995-1998
- Varied protocols & results
- \( n = 72,720 \) (<1998)
  - Stage 1 miss: 3.3 %
- Stage 1 fail: 4.3 %
  - range (FTN): 2% - 21%
- Refer for follow-up: 7.6 %
  - Returned: 51 %
- Stage 2 fail: 19 %
  - for DABR: 0.9 %
- Prevalence ( /1000)
  - bilat. SNHL: 1.2
  - unilateral: 0.7
  - combined: 2.0
    - NICU 7.6
    - FTN 0.8
- Age (mean) at:
  - Dx/EI refer: 3 months
  - Aid fitting: 7.5 months
- ~Cost/infant screened:
  - Year1: $ 31.74
  - Year2: $ 27.50

Essential elements for effective universal newborn hearing screening program (UNHSP)
AAP, Pediatrics 103:527, 1999

☆Initial screening
◎Tracking and follow-up
◎Identification
◎Intervention
◎Program evaluation

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Tracking (to diagnosis, treatment) & program management

• How many babies?
• Automated reports to:
  – Staff, Program Director, State -> CDC
• Data storage, automated letter generation, program databases (EI, pediatricians, audiologists), scheduling
• Software options:
  – Locally developed, and/or
  – Bundled with screening hardware, and/or
  – Purchased separately

Essential elements for effective universal newborn hearing screening program (UNHSP)

AAP, Pediatrics 103:527, 1999

☆ Initial screening
☑ Tracking and follow-up

☑ Identification

☑ DABR (referral to audiologist)

☑ Intervention (medical, social)

☑ IFSP (Individual Family Service Plan)

☑ County EI (Early Intervention) referral

☑ Program evaluation

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• Interim IFSP (Individual Family Service Plan)
• EI should include:
  – MD with expertise in childhood oto disorders
  – Audiologist with expertise in audiological assessment and fitting all types of amp devices
  – Speech and language pathologist with expertise in assessment and intervention of comm. skills
  – other professionals appropriate for needs of child and family

• Special instruction that includes:
  – the design and implementation of learning environments
  – activities that promote child development, language acquisition, and communication skills
  – curriculum planning which integrates and coordinates multidisciplinary personnel and resources so that intended outcomes of IFSP are achieved
  – ongoing monitoring of child’s hearing status, amplification needs and devel. of comm. skills
Essential elements for effective universal newborn hearing screening program (UNHSP)  

AAP, Pediatrics 103:527, 1999

- Initial screening
- Tracking and follow-up
- Identification
- Intervention

Program evaluation
- Local
- State
- National

Program evaluation

- Periodic internal reports (at least monthly, initially)
  - Performance feedback to staff (e.g., screening time, percent referral)
  - Report on percent missed, returns for follow-up
  - Report on diagnostics (ultimate results)
- State
  - Reports on program performance, to State DOH
- National
  - States (DOH) report to CDC
AAP-recommended UNHSP features
AAP, Pediatrics 103:527, 1999

Include:
• Physician medical director
• Regionalized referral system for diagnostics and therapy
• Screening $\geq 95\%$ = “universal”
• Use OAE, ABR, or both, preferably pre-discharge
• Complete all screening by 1 month of age
• Screening false positives $\leq 3\%$
• DABR referrals $\leq 4\%$
• Follow-up must be accomplished in $\geq 95\%$
• Reimbursement is essential

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UNIVERSAL HEARING SCREENING PROGRAM
INSTITUTIONAL ISSUES

• Preexisting programs
• Possible conflicts with some philosophies of newborn care (rooming in)
• Space allocation
• Time allocation
• If multidepartmental, someone must “own” it
• Communication across Departments and institutions
• Coordination of inpatient and outpatient activities
• Financial management
UNIVERSAL HEARING SCREENING PROGRAM

COMMUNITY ISSUES

• Pediatricians, audiologists
• EI referral
• Support from organizations of families of deaf children

UNIVERSAL HEARING SCREENING PROGRAM

STAFF ISSUES

• Turnover / longevity, experience, aptitudes
  – AMC initial range of screener referral rates: 0% - 29%;
    mean test times: 4 - 40 minutes
• Nursing screeners (flexibility; conflicting tasks)
• Temporary technicians, outside subcontractors, volunteers
• Qualifications: minimal (no diagnoses made)
• Program supervision critically important
• Leadership (how many Departments?)
• Accountability
• Performance tracking & feedback
UNIVERSAL HEARING SCREENING PROGRAM
SOFTWARE CONSIDERATIONS
• Limited customization available, presently
• Lack of interfacing with other hospital systems
• User data entry errors
• ALGO Databook NHS
  – Interfaces w/ ALGO AABR
  – ASCII transfers to State database
  – Can’t generate letters, or calculate referral rates
• OZ
• Hi*Track
  – Interfaces w/ OAE devices; ABR entries
  – Local database, letters, appointments and QA reports
  – Transfers to State database

HEARING SCREENING - HARDWARE ISSUES
Portability, database computer interfacing, accessories (printer), probes
• AABR
  – ALGO Portable (R -> L ear) List $10,900
    • Portable does not include DataBook Tracking software
  – ALGO 2e Color (R + L ear) List $17,500
    • + ear couplers $9.75 / baby (OAE probe tips $1.00 / baby)
• DPOAE
  – Bio-logic: AuDx (hand-held) $4,700
  – Otodynamics: ILO292 DP Echoport (portable)
• TEOAE
  – Otodynamics: Echocheck (hand-held) $4,500 + $300
  – Otodynamics: Echoport, ILO-88 (portable) $10,500; $6,500
  – Madsen: Echoscreen (hand-held)
• OAE + AABR: SonaMed Clarity $25,000
SUMMARY: CRITICAL ELEMENTS OF UNIVERSAL SCREENING PROGRAM

- Unified program staff and fully coordinated protocols (regardless of number of departments involved)
- Small, stable staff
- Staff easily supervised
- Reliable data tracking system coordinated with existing systems
- User friendly, customizable data tracking system

Universal Hearing Screening in Newborns

National Resources

- NCHAM (http://www.infanthearing.org)
  - Tel. 435-797-3584, Susan Friedman, Ph.D.
  - Provides information, software, training, technical support, equipment loans to hospitals to implement Universal Hearing Screening
  - Web-based program cost estimator (Excel)
- natus (http://www.natus.com)
  - Rich Filar 412-825-3788 x375
- Instrumentation Associates
  - Chris Jewell, Sherman Lord 800-345-4790
Albany Medical Center resources

• Program logistics:
  – Joaquim M.B. Pinheiro, M.D.
    • 518-262-5421
• Screening (inpatient/outpatient):
  – Hearing Center (Lisa Artino, Julie Kerwood)
    • 518-262-4535
• Diagnostics:
  – Anthony T. Cacace, Ph.D.
  – Karen Tan, M.D. (ENT)
    • 518-262-5897