SPECIAL ARTICLE

Universal Screening for Hearing Loss in Newborns: US Preventive Services Task Force Recommendation Statement

US Preventive Services Task Force

The authors have indicated they have no financial relationships relevant to this article to disclose.

ABSTRACT

DESCRIPTION. This is the 2008 update of the 2001 US Preventive Services Task Force recommendation on universal newborn hearing screening.

METHODS. The US Preventive Services Task Force weighed the benefits and harms of universal newborn hearing screening, incorporating new evidence addressing gaps identified in the 2001 US Preventive Services Task Force recommendation statement. Published literature on this topic was identified (by using Medline and Cochrane databases) and systematically reviewed.

RECOMMENDATION. Screen for hearing loss in all newborn infants (B recommendation). *Pediatrics* 2008;122:143–148

- The US Preventive Services Task Force (USPSTF) makes recommendations about preventive care services for patients without recognized signs or symptoms of the target condition.
- It bases its recommendations on a systematic review of the evidence of the benefits and harms and an assessment of the net benefit of the service.
- The USPSTF recognizes that clinical or policy decisions involve more considerations than this body of evidence alone. Clinicians and policy makers should understand the evidence but individualize decision-making to the specific patient or situation.

www.pediatrics.org/cgi/doi/10.1542/peds.2007-2210

doi:10.1542/peds.2007-2210

Key Words
hearing loss, newborn screening, preventive services

Abbreviations
USPSTF—US Preventive Services Task Force
PCHL—permanent congenital hearing loss
OAE—otoacoustic emission
ABR—auditory brainstem response
UNHS—universal newborn hearing screening
JCIH—Joint Committee on Infant Hearing

Accepted for publication Jan 10, 2008

Address correspondence to Ned Calonge, MD, MPH, Chair, US Preventive Services Task Force, c/o Program Director, USPSTF, Agency for Healthcare Research and Quality, 540 Gaither Rd, Rockville, MD 20850. E-mail: uspstf@ahrq.hhs.gov

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275); published in the public domain by the American Academy of Pediatrics

SUMMARY OF RECOMMENDATION AND EVIDENCE

The USPSTF recommends screening for hearing loss in all newborn infants (B recommendation). See figure for a summary of the recommendation and suggestions for clinical practice. Table 1 describes the USPSTF grades, and Table 2 describes the USPSTF classification of levels of certainty about net benefits.

RATIONALE

Importance

Children with hearing loss have increased difficulties with verbal and nonverbal communication skills, increased behavioral problems, decreased psychosocial well-being, and lower educational attainment compared with children with normal hearing.

Detection

Because half of the children with hearing loss have no identifiable risk factors, universal screening (instead of targeted screening) has been proposed to detect children with permanent congenital hearing loss (PCHL). There is good evidence that newborn hearing screening testing is highly accurate and leads to earlier identification and treatment of infants with hearing loss.

Benefits of Detection and Early Treatment

Good-quality evidence shows that early detection improves language outcomes.

Harms of Detection and Early Treatment

There is limited evidence about the harms of screening, with conflicting research findings regarding anxiety associated with false-positive test results. There is limited information about the harms of treatment. Complications of cochlear implant surgery include increased risk of meningitis; however, the overall risks of complications of screening and treatment are estimated to be small.

Universal Screening for Hearing Loss in Newborns: Clinical Summary of US Preventive Services Task Force Recommendation

Population	**All Newborns**
Recommendation	**Screen for hearing loss in all newborn infants** **Grade: B**

Risk assessment	The prevalence of hearing loss in newborn infants with specific risk indicators is 10 – 20 times higher than in the general population of newborns. Risk indicators associated with permanent bilateral congenital hearing loss include: ▪ NICU admission for ≥ 2 d ▪ family history of hereditary childhood sensorineural hearing loss ▪ craniofacial abnormalities ▪ certain congenital syndromes and infections Approximately 50% of newborns with permanent bilateral congenital hearing loss do not have any known risk indicators.
Screening tests	Screening programs should be conducted by using a 1-step or 2-step validated protocol. A frequently-used 2-step screening process involves otoacoustic emissions followed by auditory brain stem response in newborns who fail the first test. Infants with positive screening test results should receive appropriate audiologic evaluation and follow-up after discharge. Procedures for screening and follow-up should be in place for newborns delivered at home, birthing centers, or hospitals without hearing screening facilities.
Timing of screening	All infants should have hearing screening before 1 mo of age. Infants who do not pass the newborn screening should undergo audiologic and medical evaluation before 3 mo of age.
Treatment	Early intervention services for hearing-impaired infants should meet the individualized needs of the infant and family, including acquisition of communication competence, social skills, emotional well-being, and positive self-esteem. Early intervention comprises evaluation for amplification or sensory devices, surgical and medical evaluation, and communication assessment and therapy. Cochlear implants are usually considered for children with severe-to-profound hearing loss only after inadequate response to hearing aids.
Other relevant recommendations from the USPSTF	Additional USPSTF recommendations regarding screening tests for newborns can be accessed at www.ahrq.gov/clinic/cps3dix.htm#pediatric.

For the full recommendation statement and supporting documents (including a summary of the evidence) please go to www.preventiveservices.ahrq.gov.

FIGURE
Clinical summary of USPSTF recommendation.

USPSTF Assessment

The USPSTF concludes that there is moderate certainty that the net benefit of screening all newborn infants for hearing loss is moderate.

CLINICAL CONSIDERATIONS

Patient Population Under Consideration

The patient population considered here includes all newborn infants.

TABLE 1 **What the USPSTF Grades Mean and Suggestions for Practice**

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	Offer/provide this service only if there are other considerations in support of the offering/providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read "Clinical Considerations" in the USPSTF Recommendation Statement. If offered, patients should understand the uncertainty about the balance of benefits and harms.

TABLE 2 **USPSTF Levels of Certainty Regarding Net Benefit**

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. The conclusion, therefore, is unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: the number, size, or quality of individual studies; inconsistency of findings across individual studies; limited generalizability of findings to routine primary care practice; or lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and the change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: the limited number or size of studies; important flaws in study design or methods; inconsistency of findings across individual studies; gaps in the chain of evidence; findings not generalizable to routine primary care practice; or a lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level on the basis of the nature of the overall evidence available to assess the net benefit of a preventive service.

Assessment of Risk

Risk factors associated with a higher incidence of permanent bilateral congenital hearing loss include NICU admission for ≥2 days, several congenital syndromes, family history of hereditary childhood sensorineural hearing loss, craniofacial abnormalities, and certain congenital infections. However, ~50% of infants with permanent bilateral congenital hearing loss do not have any known risk factors.

Screening Tests

Screening programs should be conducted by using a 1- or 2-step validated protocol. A frequently used protocol requires a 2-step screening process, which includes otoacoustic emissions (OAEs) followed by auditory brainstem response (ABR) in those who failed the first test. Equipment should be well maintained, staff should be thoroughly trained, and quality-control programs should be in place to reduce avoidable false-positive test results. Programs should develop protocols to ensure that infants with positive screening-test results receive appropriate audiologic evaluation and follow-up after discharge. Newborns delivered at home, birthing centers, or hospitals without hearing screening facilities should have some mechanism for referral for newborn hearing screening, including tracking of follow-up.

Treatment

Early intervention services for hearing-impaired infants should be designed to meet the individualized needs of the infant and family, including acquisition of communication competence, social skills, emotional well-being, and positive self-esteem. Early intervention includes evaluation for amplification or sensory devices, surgical and medical evaluation, and communication assessment and therapy. In recent years, cochlear implants have become more available for appropriate candidates; this surgery is usually considered in those with severe-to-profound hearing loss only after inadequate response to hearing aids.

Screening Intervals

All infants should have hearing screening before 1 month of age. Those infants who do not pass the newborn screening should undergo audiologic and medical evaluation before 3 months of age for confirmatory testing. Because of the elevated risk of hearing loss in infants with risk indicators, an expert panel has made a 2000 recommendation that these children should undergo periodic monitoring for 3 years.[1]

OTHER CONSIDERATIONS

Implementation

Thirty-nine US states have enacted legislation related to universal newborn hearing screening (UNHS). These laws differ with respect to whether screening is mandated or encouraged, how results are reported, and how screening is funded.

Research Needs/Gaps

Additional studies detailing the correlation between childhood language scores and functional outcomes (eg, school attainment and social functioning) are needed.

DISCUSSION

Burden of Disease

The focus of UNHS programs is on congenital (as opposed to acquired or progressive) hearing loss that may not be detected in the newborn period. According to the 2000 statement from the Joint Committee on Infant Hearing (JCIH), hearing screening should identify infants at risk for specifically defined hearing loss that interferes with development. The targeted hearing loss for UNHS programs is permanent sensory or conductive hearing loss averaging 30 to 40 dB or more in the frequency region important for speech recognition (~500–4000 Hz).[1] PCHL occurs in 1 to 3 per 1000 live births. The prevalence for PCHL is higher than for other conditions screened for in the newborn period. Children with hearing loss may have difficulty learning grammar, word order, idiomatic expressions, and other forms of verbal communication.[2] Delayed language and speech, low educational attainment, increased behavior problems, de-

creased psychosocial well-being, and poor adaptive skills are all associated with hearing loss in children.[1–3]

Risk factors associated with a higher incidence of PCHL include NICU admission for >2 days; syndromes associated with hearing loss, such as Usher syndrome and Waardenburg syndrome; family history of hereditary childhood hearing loss; craniofacial abnormalities; and congenital infections such as cytomegalovirus, toxoplasmosis, bacterial meningitis, syphilis, herpes, and rubella.[1] However, ~50% of infants with PCHL do not have any known risk factors.[2,4,5] In studies that included data on ethnicity and socioeconomic status, there has been a higher incidence of PCHL among white American infants compared with infants in other, less well-represented minority groups regardless of the age at which the hearing loss was identified.[2]

Scope of Review

The USPSTF examined the evidence for (1) the efficacy of UNHS in improving the initiation of treatment by 6 months of age for average- and high-risk infants compared with targeted screening, (2) the efficacy of treatment on language and communication outcomes if started before 6 months of age for those infants not identified by targeted screening, and (3) the harms of universal screening. There has been no direct evidence comparing targeted and universal screening programs in average- and high-risk infants.

Accuracy of Screening Tests

There are 2 approaches to screening newborns for hearing loss: UNHS of all newborns and targeted screening of high-risk newborns.[2] All states that have hearing-screening programs use universal screening. Infants who do not pass the newborn screening tests are referred for confirmatory testing before a diagnosis of PCHL is made. Referral rates have been lower in programs staffed by dedicated technicians rather than volunteers and students.[2]

Both OAEs and ABR tests are noninvasive and evaluate easily recorded physiologic activities in newborns that correlate with the degree of peripheral hearing sensitivity.

A large, good-quality community-based cohort trial showed that the 2-step approach to UNHS (OAEs followed by ABR for those who failed the first test) yielded a screening sensitivity of 0.92 and a specificity of 0.98.[4]

Effectiveness of Early Detection and/or Treatment

A nonrandomized, controlled trial consisting of infants at high and average risk yielded good-quality evidence that newborns who underwent UNHS had earlier referral, diagnosis, and initiation of treatment compared with those who were not screened.[5] The number of cases of PCHL referred before the age of 6 months for infants in the UNHS population was 19 times higher compared with that of the nonscreened infants. More children with true PCHL were referred to audiology services before 6 months of age if they were born during periods with UNHS, compared with children born during periods without screening. The odds ratio for early confirmation of hearing impairment before 10 months of age was 5.0 times greater for screened infants compared with nonscreened infants. The odds of initiating early management of hearing loss before 10 months of age was 8.0 times higher for screened infants compared with nonscreened infants.

For all infants involved in the aforementioned trial, an 8-year follow-up study was performed that followed infants with abnormal screening-test results at birth or later.[4] The proportion of infants with true hearing impairment who were referred before 6 months of age was 74% during periods with UNHS and 31% during periods without UNHS. After adjustment for the severity of hearing impairment, UNHS was even more strongly correlated with referral before 6 months of age. One additional case of PCHL was referred before 6 months of age for every 1969 infants in the UNHS population.

A community-based retrospective cohort trial yielded good-quality evidence that those children with bilateral permanent hearing impairment who had early diagnostic confirmation before 9 months of age and those who had UNHS (compared with those who had no screening) had moderately higher receptive language scores at 8 years of age.[6]

One fair-quality retrospective cohort study examined children from 7 to 8 years of age who were fitted with hearing aids for congenital hearing impairment by the age of 4.5 years. The study found that age at diagnosis did contribute significantly to variance on receptive vocabulary but did not for other language, speech, or reading measures.[7] There is fair-quality evidence, based on a retrospective cohort study, that an earlier age at the time of enrollment into an early child hearing intervention program results in better outcomes for receptive and expressive language compared with those treated at a later age, after controlling for degree of hearing loss and degree of outcome impairment at program entry.[8] A fair-quality retrospective cohort study that analyzed children enrolled for at least 6 months in a diagnostic early intervention program showed that children enrolled before 11 months of age had stronger vocabulary and reasoning skills than children enrolled at later ages, after adjustment for family involvement, degree of hearing loss, and nonverbal IQ.[9]

Potential Harms of Screening and Treatment

Limited evidence is available about the harms of screening. A fair-quality retrospective cohort study showed no differences in anxiety and attitude toward infant scores for mothers of infants who passed and did not pass screening tests.[10] There is fair evidence, based on a prospective cohort study, that there is no significant difference in the level of concern of mothers whose infants failed the first and second hearing-screening tests.[2] One poor-quality case-control study examined infants who were at risk for hearing impairment, who failed a distraction stress test, or who were controls for the other 2 groups. Parent-reported concerns about language development, general development, and perceived vulnerability to ill health did not differ among the groups, and

most negative emotions resolved after the child's definitive hearing test.[2]

Evidence regarding the harms of treatment is also limited. The have been few immediate complications of surgery reported in case series and case reports of cochlear implant surgery in infants; however, an increased risk of meningitis that may persist for several years after implantation has been reported. Note that these case series reflect the use of a no-longer-manufactured cochlear implant. Furthermore, children with congenital cochlear abnormalities may have a predisposition to meningitis regardless of the use of cochlear implants. The overall complications of screening and treatment are estimated to be small.

Estimate of Magnitude of Net Benefit

There is good evidence that newborn hearing-screening testing is highly accurate and leads to earlier identification and treatment of infants with hearing loss. With regard to the yield of screening 10 000 newborns for hearing loss by using universal versus targeted screening, universal screening would yield 7 more cases diagnosed by 3 months of age (1 with risk factors and 6 without known risk factors). The number needed to screen to diagnose 1 case is 878 and 178 for UNHS and targeted screening programs, respectively. The number needed to screen to diagnose 1 additional case by 3 months of age is 1333 for UNHS.[2]

RECOMMENDATIONS OF OTHER GROUPS

The JCIH endorses early detection and intervention for infants with hearing loss through integrated, interdisciplinary state and national systems of UNHS, evaluation, and family-centered intervention. The JCIH 2000 position statement (and recently released 2007 statement) provides guidelines that include UNHS soon after birth, before hospital discharge, or before 1 month of age; diagnosis of hearing loss through audiologic and medical evaluation before 3 months of age; and intervention through interdisciplinary programs for infants with confirmed hearing loss before 6 months.[1,11] The American Academy of Pediatrics Task Force on Newborn and Infant Hearing, the National Institute on Deafness and Other Communication Disorders, and the Centers for Disease Control and Prevention Early Hearing Detection and Intervention Program support the JCIH recommendations.[12–14] The American Academy of Audiology Task Force on the Early Identification of Hearing Loss agrees that the use of support personnel in newborn hearing-screening programs is an appropriate and often necessary strategy for achieving universal detection of congenital hearing loss.[15] The supervising audiologist should be experienced in both the development and maintenance of a UNHS program, including an understanding of technology options.

MEMBERS OF THE USPSTF

Members of the USPSTF at the time this recommendation was finalized were Ned Calonge, MD, MPH, USPSTF Chair (Colorado Department of Public Health and Environment, Denver, CO); Diana B. Petitti, MD, MPH, USPSTF Vice-chair (Keck School of Medicine, University of Southern California, Sierra Madre, CA); Thomas G. DeWitt, MD (Children's Hospital Medical Center, Cincinnati, OH); Leon Gordis, MD, MPH, DrPH (Johns Hopkins Bloomberg School of Public Health, Baltimore, MD); Kimberly D. Gregory, MD, MPH (Cedars-Sinai Medical Center, Los Angeles, CA); Russell Harris, MD, MPH (University of North Carolina School of Medicine, Chapel Hill, NC); George Isham, MD, MS (HealthPartners, Minneapolis, MN); Michael L. LeFevre, MD, MSPH (University of Missouri School of Medicine, Columbia, MO); Carol Loveland-Cherry, PhD, RN (University of Michigan School of Nursing, Ann Arbor, MI); Lucy N. Marion, PhD, RN (Medical College of Georgia, Augusta, GA); Virginia A. Moyer, MD, MPH (University of Texas Health Science Center, Houston, TX); Judith K. Ockene, PhD (University of Massachusetts Medical School, Worcester, MA); George F. Sawaya, MD (University of California, San Francisco, CA); Albert L. Siu, MD, MSPH (Mount Sinai Medical Center, New York, NY); Steven M. Teutsch, MD, MPH (Merck & Company, Inc, West Point, PA); and Barbara P. Yawn, MD, MSPH, MSc (Olmsted Medical Center, Rochester, MN). For a list of current task force members, go to www.ahrq.gov/clinic/uspstfab.htm.

REFERENCES

1. Joint Committee on Infant Hearing; American Academy of Audiology; American Academy of Pediatrics; American Speech-Language-Hearing Association; Directors of Speech and Hearing Programs in State Health and Welfare Agencies. Year 2000 position statement: principles and guidelines for early hearing detection and intervention programs. *Pediatrics.* 2000;106(4):798–817
2. Nelson HD, Bougatsos C, Nygren P. Universal Newborn Hearing Screening: Systematic Review to Update the 2001 U.S. Preventive Services Task Force Recommendation. *Pediatrics.* 2008;122(1):e266–e276
3. Helfand M, Thompson DC, Davis RL, McPhillips H, Homer CJ, Lieu TL. Newborn hearing screening. Rockville, MD: Agency for Healthcare Research and Quality; 2001. Systematic evidence review No. 5; AHRQ publication 02-S001. Available at: www.ahrq.gov/clinic/serfiles.htm. Accessed July 17, 2007
4. Kennedy C, McCann D, Campbell MJ, Kimm L, Thornton R. Universal newborn screening for permanent childhood hearing impairment: an 8-year follow-up of a controlled trial. *Lancet.* 2005;366(9486):660–662
5. Wessex Universal Neonatal Hearing Screening Trial Group. Controlled trial of universal neonatal screening for early identification of permanent childhood hearing impairment. *Lancet.* 1998;352(9145):1957–1964
6. Kennedy CR, McCann DC, Campbell MJ, et al. Language ability after early detection of permanent childhood hearing impairment. *N Engl J Med.* 2006;354(20):2131–2141
7. Wake M, Hughes EK, Poulakis Z, Collins C, Rickards FW. Outcomes of children with mild-profound congenital hearing loss at 7 to 8 years: a population study. *Ear Hear.* 2004;25(1):1–8
8. Moeller MP. Early intervention and language development in children who are deaf and hard of hearing. *Pediatrics.* 2000;106(3). Available at: www.pediatrics.org/cgi/content/full/106/3/e43

9. Calderon R, Naidu S. Further support of the benefits of early identification and intervention with children with hearing loss. *Volta Rev.* 2000;100(4):53–84
10. Kennedy CR. Controlled trial of universal neonatal screening for early identification of permanent childhood hearing impairment: coverage, positive predictive value, effect on mothers and incremental yield. Wessex Universal Neonatal Screening Trial Group. *Acta Paediatr Suppl.* 1999:88(432):73–75
11. American Academy of Pediatrics, Joint Committee on Infant Hearing. Year 2007 position statement: principles and guidelines for early hearing detection and intervention programs. *Pediatrics.* 2007;120(4):898–921
12. American Academy of Pediatrics, Task Force on Newborn and Infant Hearing. Newborn and infant hearing loss: detection and intervention. *Pediatrics.* 1999;103(2):527–530
13. Centers for Disease Control and Prevention. Infants tested for hearing loss: United States [published correction appears in *MMWR Morb Mortal Wkly Rep*. 2003;42(49):1210]. *MMWR Morb Mortal Wkly Rep*. 2003;52(41):981–984
14. National Institutes of Health. Early identification of hearing impairment in infants and young children. *NIH Consens Statement.* 1993;11(1):1–24
15. American Academy of Audiology. Considerations for the use of support personnel for newborn hearing screening. Available at: www.audiology.org/publications/documents/positions/Infant+ID/usp4nhs.htm. Accessed April 23, 2008