Modelling costs and outcomes of newborn hearing screening – The economic part of a German health technology assessment project

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ABSTRACT

Objectives: The prevalence of newborn hearing disorders is 1-3 per 1000. Crucial for later outcome are correct diagnosis and effective treatment in the first year of life. With BERA and TEOAE low-risk techniques for early detection are available. Universal screening is recommended but not realised in most European health care systems.

Objective of the study was to examine the scientific evidence of newborn hearing screening, thus to compare cost-effectiveness of different programmes, differentiated by type of strategy (risk screening, universal screening, no screening).

Methods: In an interdisciplinary health technology assessment project all relevant studies on newborn hearing screening were identified and data on medical outcome, costs and cost-effectiveness extracted. A Markov model was designed to calculate cost-effectiveness ratios.

Results: Economic data were extracted from 20 relevant publications. In the model total costs for screening of 100.000 newborns with a time horizon of ten years were calculated: 2.0 Mio .€ for universal screening (U), 1.0 Mio. € for risk screening (R) and 0.6 Mio. € for no screening (N). The costs per child detected: 13,395 € (U) respectively 6,715 € (R) and 4,125 € (N).

Conclusions: A remarkable small number of economic publications mainly of low methodological quality was found. In our own model we found reasonable cost-effectiveness ratios also for universal screening. Considering the outcome advantages of higher numbers of cases detected a universal newborn hearing screening is recommended.

INTRODUCTION

According to calculation of the WHO world-wide approximately 350 Mio. People have hearing disorders. The overall prevalence of congenital hearing disorders is 1-3 in 1000 newborns, the prevalence in risk groups is estimated at about 10 times higher. Risk factors are e.g. early child birth, infection in early pregnancy or family history of hearing disorders.
The neurological development of hearing abilities requires an acustic stimulation in the first two years of life. Deficits due to absent acustic stimulation during the first years of life are nearly impossible to improve by later rehabilitation [Walger 2000]. Diagnosis and treatment as early as possible are necessary therefore for a successful and effective treatment of congenital peripheral hearing disorders.
If congenital hearing disorders are detected and treated in time, most of the children are enabled to pass through a normal development of speech and no special education is necessary [Kiese-Himmel and Ohlwein 1999; Markides1986; Walger 2000]. For the detection of hearing disorders with TEOAE (transient evoked oto-acustic emmissions) and BERA (brainstem evoked response audiometry) tests with a acceptable sensitivity and specificity are available. TEOAE is easier to perform, less time consuming and cheaper, but shows more false positive results. BERA requires more time, sometimes needs sedation of children, but is seen as gold standard for diagnosis of hearing disorders. Although for screening purposes a shorter version of BERA is discussed, most of the programmes are performed using TEOAE.
Usual treatment of congenital hearing disorders consists of supply with hearing aid. If treatment with hearing aids do not improve hearing, cochlea implants should be considered.

The mean age of diagnosis of congenital hearing disorders in Germany, like in most other western countries, is 2-4 years of age, depending on the amount of hearing loss. Treatment is started in average 9 months later [Hartmann and Klinke 1998]. There is a marked discrepancy between these findings and the recommendation of international consensus groups.
Recommendations of the European consensus development conference on neonatal hearing screening [European consensus conference 1998] are: diagnosis in first 6 months of life and treatment in first 12 months of life. To achieve an early diagnosis and treatment an universal screening for hearing disorders is recommended. But a regular screening of newborns is not implemented in Germany and most other health care systems. In Germany newborn hearing screening is only done by individual hospital or physicians' own initiative and the tests are only reimbursed by sickness funds if there is a suspected hearing disorder.

The objectives of this interdisciplinary economic health technology assessment project were to compare the costs, effects and cost-effectiveness-ratios of three different strategies:

1. Universal screening of all hospital born newborns
2. Risk screening of all hospital born newborns with risk factors
3. Present situation in Germany without regular screening

Cost-effectiveness ratios to be calculated were:

1. Costs per screened child
2. Costs per case detected (Case defined as hearing loss >25dB on better ear)
3. Costs per case detected in time (In time defined as in the first 6 months of life)

The different tests or test combinations of BERA and TEOAE are available. The at present most common strategy is a so-called two-step TEOAE-strategy with a single TEOAE test in the first days of life and a second similar test a few days later, if in the first test no TEOAEs were detected. If the first or second test is negative, the children are classified as test negative, if the first and the second test is positive the tested newborns are classified as test positive.

METHODS

According to the methodological recommendation for health technology assessment projects in Germany [Leidl et al. 1999], cost and cost-outcome calculations based on published literature data combined with actual item costs were performed. To estimate long-time outcomes an additional Markov model was designed.

COST CALCULATIONS

As possibly relevant cost components were defined:

Direct medical costs:

- Costs for implementation of screening programme
- Cost for screening tests
- Costs for organisation of screening programme
- Costs for tracking
- Costs for further diagnostic of (true and false) screening positives
- Treatment for detected cases of hearing disorder
    - Regular controls
    - Treatment with hearing aid (supply, controls, batteries etc.)
    - Treatment with cochlear implants (Pre-op, device, operation, rehabilitation)

Direct non-medical costs:

- Transportation costs for diagnostic and treatment
- Caregiving time for brothers and sisters
- Additional education costs for special institutions for children with hearing disorders

Indirect costs:

- Work time loss for parents
- Work time loss for grown up persons with hearing disorders
- Income loss due to hearing disorders
- Productivity loss due to premature mortality

A predefined, externally reviewed literature search for publications on newborn hearing screening of all relevant electronic databases was performed. If costs or cost calculations were

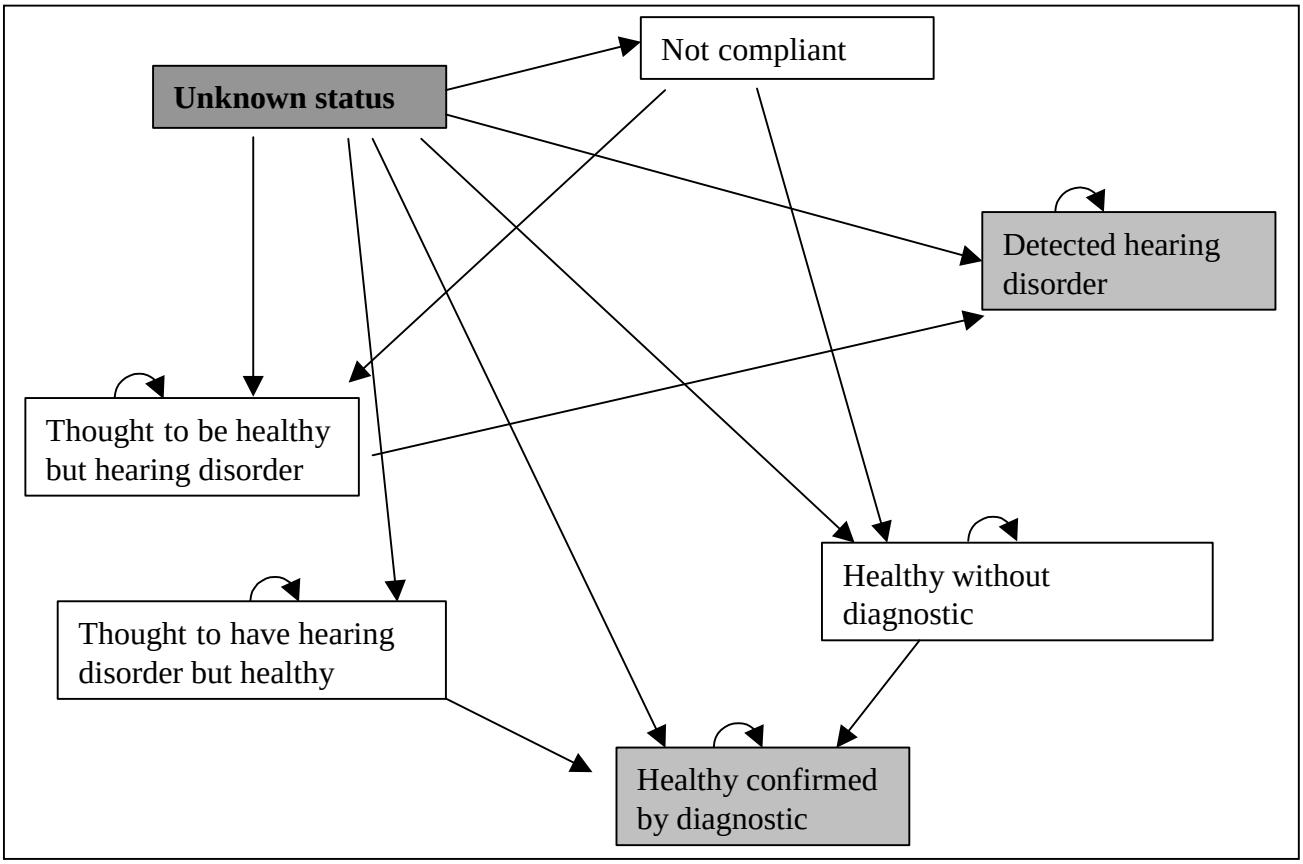
mentioned in title, abstract or MESH-words, publications were included for the economic evaluation and full text versions scanned. “Gray literature” like conference booklets, relevant internet homepages or publications not listed in literature databases was scanned by hand. A detailed description of the literature search strategy can be obtained from the authors on request.

Detected publications were scored according to a established standardised questionnaire [Leidl et al. 1999] and included respectively excluded for further evaluation. Data from included studies were standardised to EUR of 1999 using the OECD PPPs and the German health sector specific inflation rates. Relevant economic parameter were modified and aggregated if adequate.

MARKOV MODEL

For design and calculation of the Markov model the software DATA Treeage was used. The literature search was extended to publications dealing with direct or indirect costs of hearing disorders, costs and cost-effectiveness and long-time outcomes of children supplied with hearing aids and/or cochlear implants. As the most widespread and relevant strategy a two-step TEOAE test strategy as described above was chosen.

Graph 1: Structure of Markov model



For the cost calculations costs of TEOAE-tests, detection of children with risk factors, and costs for further diagnostic were included. Because of the lack of outcome or cost data costs for medical treatment and education of children as well as indirect costs could not be included.
"Universal screening" (U), "risk screening"(R), and "no screening"(N) as above described were defined as alternative strategies.

Predicted outcomes were defined as:

1. Number of true positively detected cases of congenital hearing disorder at 6 months
2. Number of "detected child months" at 6, 12 and 120 months
3. Costs per 100,000 screens

The outcome "Number of detected child months" (2.) is described as the amount of months in the defined time frame of 6, 12 or 120 months in which a hearing disorder is known. For example in a time horizon of 6 months a child with hearing disorder detected at birth is equivalent to 6 detected child months. Detection with 4 months is equivalent to two detected child months. This outcome measure was chosen in addition to the classical outcome "Number of cases detected" (1.) to underline the importance of early detection.

As cost-effectiveness outcomes were calculated:

1. Costs per case of hearing disorder additionally detected
2. Costs per detected child month

A societal perspective, a discount rate of 5%, a cycle length of 1 month and a overall time horizon of 10 years were chosen for the base case. Sensitivity analyses were performed on all relevant parameter. All assumptions made and parameters used are shown in table 1.

Table 1: Relevant parameter and assumptions of Markov model. References on request from authors

Parameter	Baseline (Range) %
Prevalence of congenital hearing disorder	0,15 (0,09-0,3)
Prevalence of ≥ 1 risk factor	20 (10-30)
Prevalence of hearing disorders	
In children with risk factor	0,38
In children without risk factor	0,09
Prevalence of risk factor in children with hearing disorder	50 (46-56)
Screening S-TEOAE/S-ABR	
Sensitivity	96 (96-100)
Specificity	89 (77-96)
Further diagnostic:	
Sensitivity	98
Specificity	98
Participation in screening	90 (85-95)
Follow-up after screening	80 (75-85)
Probability of (false) suspect of hearing disorder in healthy	0,1 (0-0,5)
Discount rate	3 per year (0-5)
Probability of „natural“ detection of hearing disorder	Empirical function of detection according to unpublished data, mean detection at 18 months

RESULTS

Overall 39 economic publications on newborn hearing screening were found. Because of a lack of transparent cost data 19 publications were excluded. For further calculations 20 publications remained: 16 journal articles, 3 health technology assessment reports [ANAES 1999; Davis et al. 1997; MSAC 1999] and 1 conference abstract. A series of three publications [Turner 1991; Turner 1992a; Turner 1992b] reporting the results of the same project was combined to one. Because the HTA-reports did not present primary studies, overall 15 different studies on newborn hearing screening with economic components were included.

Besides the intervention costs for the screening test itself most of the studies limited the calculation to the costs for tracking and further diagnostic of hearing disorders. One study included the costs for implementation of the screening programme. The costs for further medical treatment of detected cases and special education were included only by one study. No study considered other direct non-medical cost or indirect costs. Also no studies with utility measures or health related quality of life were found (see also table 2).

After adjustment to € of 1999 the studies showed a 4 to 5 time range of costs for screening tests, tracking and further diagnostic. The highest single item costs with more than 500,000 € were calculated for long-time treatment and special education of children with hearing disorders. In contrast to this importance these costs were included only by one study.

With 7-36€ respectively 3-13€ the costs per screened child and the costs per case detected showed the same range of results. There was no systematic difference or trend towards a definite test-method (see also Table 2).

Table 2: Costs and cost-effectiveness according to published studies, adjusted to € of year 2000

Study	Test strategies	Cost per newborn (€ 2000)	Costs per case detected (€ 2000)	Long-time cost-effectiveness ratio
Friedland et al. 1996	BERA	26.90-100.56 according to setting	13411-49434 according to setting	-
Heinemann & Bohnert 2000	BERA TEOAE	7.05-22.07 according to test method	-	-
Kemper & Downs 2000	BERA TEOAE	Risk group: 1.59 Universal: 9.93	Risk group: 3097 Universal: 11564	-
Kezirian et al. 2001	BERA	13.05-25.45 according to test method	5170-9575 according to test method	-
Markowitz 1990	BERA	54.82-90.91 according to test method	3083-4712 according to test method	-
Mason & Herr-mann 1998	BERA	28.59	19768	-
Maxon et al. 1996	TEOAE	32.30	5428	-
Mehl & Thomp-son 1998	BERA TEOAE	27.84	total: 10692 bilateral: 13699	Savings: 4.2 Mio by 54000 newborns/a over 12 years
Messner et al. 2001	BERA	27.71	-	-
Stevens et al. 1998	BERA TEOAE	17.73-36.07 according to test method	-	-
Turner 1991/1992	BERA	47.53-187.38 according to test method and setting	6517-96404 according to test method and setting	-
Verkerk & Boshuizen 1998	subjective testing	24.61-27.85 according to test method	34852-59902 according to test method	-
Vohr et al. 2001	BERA	16.33-25.23 according to test method	8149-11666 according to test method	-
Watkin 1996	TEOAE	17.83	8913	-
Weirather et al. 1997	TEOAE	8.68	-	-

MARKOV MODEL

Graph 1 shows the structure of the Markov model. All children begin in the starting state "status unknown" and end up in one of the absorbing states "detected hearing disorder" or "healthy, confirmed by diagnostic". With a certain probability children are screened. This probability is 1,0 in strategy U (universal screening), according to the prevalence of at least one risk factor 0,2 in strategy R (risk screening) and 0,0 in strategy N (no screening). A successful tracking is assumed and further diagnostic is performed in all screening positive children. The children with hearing disorders, who were not screened (in strategies R and N), are detected with a "natural" detection rate, based on an empirical function taken from the register of hearing disorders of the area of Munich.

For the calculation presented here the at present most widespread screening strategy of a two-step TEOAE-test was chosen. According to the specific sensitivity and specificity of a two-step TEOAE-screening some children are screening positive but healthy, some are screening negative with undetected hearing disorder. A small drop out either at screening or at follow up after positive screening test also is included in the model calculation.

With the assumed prevalence of 0.15 % in a cohort of 100,000 newborns 150 cases of congenital hearing disorder are present. At 6 months of life with a universal screening strategy 108 cases (72%) are detected, with a risk screening 64 (43 %), without regular screening 20 (13 %). Out of possible 900 detected child months with an universal screening 630 months, with a risk screening 354 months and without screening 78 detected child months were achieved.

The costs for screening 100,000 newborns using TEOAE are calculated with about 2.0 Mio. € for a universal screening, 1.0 Mio. € for screening of risk groups. The costs for a strategy without regular screening were 0.6 Mio. €. This leads to costs per newborn of 20 € (U), 10 € (R) respectively 6€ (N). The costs per case of congenital hearing disorder detected were calculated with 13,395 € (U), 6,715€ (R) and 4,125 € (N) (see also table 3).

Table 3: Results of the Markov model, base case, discount rate 5% (undiscounted)

Outcome-Parameter	**Universal Screening U**	**Risk Screening R**	**No Screening N**
Detected child months at 6 months	630 (634)	354 (356)	78 (79)
Detected child months at 12 months	1298 (1361)	801 (813)	304 (309)
Detected child months at 120 months	13926 (16205)	12063 (14178)	10201 (12153)
Cases detected at 6 months (per 100,000)	108	64	20
Cases detected at 120 months (per 100,000)	150	150	150
Incremental Analysis: Add. detected child months	U vs. R: 44 U vs. N: 88	R vs. N: 44	-
Total costs (per 100,000; over 120 months)	2,009,281 € (2,019,902 €)	1,007,297 € (1,084,795 €)	618,677 € (713,057 €)
Costs per child (over 20 months)	20,09 € (20,20 €)	10,07 € (10,85€)	6,18 € (7,12 €)
Costs per case detected	13,395 € (13,466 €)	6,715 € (7,232 €)	4,125 € (4,754 €)
Costs per detected child months	144 € (125 €)	84 € (77 €)	61 € (59 €)

Sensitivity analyses of all relevant parameters and assumptions were performed. Similar for all strategies the strongest influence on outcomes was seen if prevalence was varied. The variation of discount rate had little influence; the model was insensitive to test parameters (sensitivity and specificity) and loss to follow up. The costs were strongly influenced by variation of test costs, test parameters especially the number of false test positives, and the probability to be detected without screening. Prevalence and discount rate did not affect the results.

DISCUSSION

As part of a German interdisciplinary health technology assessment project the economic consequences of newborn hearing screening were investigated. In a detailed literature search over all nearly 700 publications dealing with hearing screening were found. Despite this relatively large number only 15 studies with own economic calculations were detected. Only one single study included costs of treatment and education and chose a time horizon of more than 1 year, which is considered as state of the art methodological standard. In general most of the economic publications showed a relatively poor methodological quality according to international recommendation for economic evaluation studies of health care programmes [Gold et al. 1996; CCOHTA 1996; Drummond et al. 1997]. The cost calculations were not transparent, sources for resource uses and valuation as well as the perspective of the calculation often remained unclear.

Possibly also due to the different methodological approaches the costs per screening test and the costs per case detected showed – although adjusted and standardised to one currency and one year – a wide range (four- to fivefold) without a clear tendency for a definite test method.

The results of the published studies are insufficient to answer the policy question for the economic consequences in a sense of costs and cost-effectiveness of different strategies for detection of congenital hearing disorders. There is a lack of convincing studies presenting results on a high level of evidence according to recommendations of evidence based medicine and the need for further research must be underlined.

To estimate the costs and outcomes of newborn hearing screening a Markov model was designed. Markov models in medical decision analysis are seen as explicit and quantifying approach for decisions between alternatives under uncertainty. The decision is made according to the trade off between medical risks, benefits and costs. As all models also Markov models are not able to reflect all aspects of clinical reality, but the most relevant structures and parameters are demonstrated and offered for discussion.

The model presented here considers the aspects that, on one hand side, all cases of congenital hearing disorders are detected sooner or later, but on other hand side they should be diagnosed as early as possible. Therefore in addition to the classical outcome of screening studies “number of cases detected by screening” we included the date of detection in the outcome measure “detected child months”.

On the outcome side expressed in the number of cases detected and the number of detected child months the model shows clear advantages for newborn hearing screening compared to

no regular screening. At the crucial date of 6 months without screening only 9% of the cases are detected, with a screening of children with one or more risk factors the detection rate is 40%, with an universal screening about 70%. A universal screening strategy shows a higher rate of cases detected in time and a percentage of 40% detected with a risk screening seems not sufficient considering the importance of early diagnosis and treatment. Combining the mentioned advantages in medical outcome with still acceptable and reasonable costs a universal hearing screening is recommended.

We chose a two-step TEOAE-strategy for the model calculation presented here, but the model could easily been adjusted for other test strategies. The advantage of a TEOAE-screening is the absence of risks and side effects for the screened children. There is no sedation or anaesthesia necessary and the few minutes time required is relatively short. The test itself is easy to perform and is not necessarily to be done by specially trained physicians. A one-step TEOAE-strategy shows a higher rate of false positives, why usually a two-step strategy is preferred.

The cost-effectiveness ratios are not directly comparable to those of other health care technologies. But with costs per case detected of 14,000€ an universal screening strategy seems to be reasonable if the lifelong benefits are taken into account. If it is assumed in a conservative calculation that half of the children benefit from earlier detection and their quality of life improves by 10% over 50 years, 2.5 QALYs are gained. The costs per QALY would be less than 10,000€.

Because of the lack of literature data on health care resource use and the percentage of children, who are able to visit a regular school after treatment with hearing aid or cochlea implant – the existing studies to cochlea implantation used a different population only of children with severe hearing disorders – the cost calculations are incomplete. Any savings connected to a better outcome because of an earlier detection and treatment were not included. If these savings as well as indirect costs e.g. estimated as the avoided loss of income due to hearing disorders, would be included in the calculation, there might well be a overcompensation of screening costs. Further studies will have to answer these questions. Nevertheless the present data on medical and economic outcomes suggest a recommendation of a universal hearing screening with TEOAE or other test strategies, as long as there are no side effects or risks of screening.

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10/00 Claudia Werker: „Market Performance and Competition: A Product Life Cycle Model“

11/00 Joachim Schwerin: „The Dynamics of Sectoral Change: Innovation and Growth in Clyde Shipbuilding, c. 1850-1900“

12/00 Lucas Bretschger/Sjak Smulders: „Explaining Environmental Kuznets Curves: How Pollution Induces Policy and New Technologies“

13/00 Franz Hessel: „Wertigkeit der Augeninnendruckmessung mittels Non-contract Tonometrie durch Augenoptiker in Deutschland. Eine Kosten-Wirksamkeits-Analyse“

14/00 Lucas Bretschger: „Internationaler Handel im Ostseeraum - sozioökonomische Hintergründe“

15/00 Hans Pechtl: „Die Kongruenzhypothese in der Geschäftsstättenwahl“

01/01 Joachim Prinz: „Why Do Wages Slope Upwards? Testing Three Labor Market Theories“

02/01 Armin Rohde/Ole Janssen: „Osteuropäische Currency Board-Länder und die optimale Integrationsstrategie in die Europäische Währungsunion am Beispiel Estlands“

03/01 Lucas Bretschger: „Wachstumstheoretische Perspektiven der Wirtschaftsintegration: Neuere Ansätze“

04/01 Stefan Greß, Kieke Okma, Franz Hessel: „Managed Competition in Health Care in The Netherlands and Germany – Theoretical Foundation, Empirical Findings and Policy Conclusions"

05/01 Lucas Bretschger: „Taking Two Steps to Climb onto the Stage: Capital Taxes as Link between Trade and Growth“

06/01 Udo Schneider: „Ökonomische Analyse der Arzt-Patient-Beziehung: Theoretische Modellierung und empirische Ergebnisse“

07/01 Paul Marschall: „Lernen und Lebensstilwandel in Transformationsökonomien“

08/01 Thomas Steger: „Stylised Facts of Economic Growth in Developing Countries“

09/01 Hans Pechtl: „Akzeptanz und Nutzung des B-Commerce im B2C. Eine empirische Analyse“

10/01 Hannes Egli: “Are Cross-Country Studies of the Environmental Kuznets Curve Misleading? New Evidence from Time Series Data for Germany”

01/02 Stefan Greß, Kieke G.H. Okma, Jürgen Wasem: “Private Health Insurance in Social Health Insurances Countries – Market Outcomes and Policy Implications”

02/02 Ole Janssen, Armin Rohde: „Monetäre Ursachen der Arbeitslosigkeit in Currency Board-Systemen?“

03/02 Alexander Dilger: „Never Change a Winning Team – An Analysis of Hazard Rates in the NBA”

04/02 Thomas Steger: “Transitional Dynamics in R&D-based Models of Endogenous Growth”

05/02 Franz Hessel, Eva Grill, Petra Schnell-Inderst, Jürgen Wasem: “Modelling costs and outcomes of newborn hearing screening ”