Neonatal otoacoustic emission screening and the identification of deafness

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Abstract

Using transient evoked otoacoustic emissions (TEOAEs), a two stage screen with the testing of failures by auditory brainstem response (ABR), has been implemented in Whipps Cross Hospital in East London. From January 1992 to 1995, 11,606 infants received an initial TEOAE test. Once initial difficulties were resolved, coverage of district residents remained stable at 91.5%. Long term follow up of the cohort is being undertaken. Of those receiving an initial test, 13% failed in both ears. Only 1.75% of the cohort failed both stages of the TEOAE screen bilaterally. These infants were tested by ABR. The yield of infants with a bilateral permanent hearing loss of moderate or worse degree was 2/1000. The overall cost of implementing the programme was not prohibitive and the cost per hearing impaired child detected was little more than the widely accepted notional cost of identifying such children through targeted at risk screens. The screen was clearly sensitive. The priority for such universal TEOAE programmes, however, is to increase specificity without losing this sensitivity. (Arch Dis Child 1996; 74: F16-F25)

Keywords: transient evoked otoacoustic emissions, screen, hearing loss, costing.

The identification of congenital hearing impairment early in infancy is accepted as an important and appropriate aim of health service provision. To this end screening the hearing of all neonates has been recommended in the USA by the National Institutes of Health.¹ Transient evoked otoacoustic emission screening (TEOAE) in the maternity unit, with testing of failures by auditory brain stem response (ABR), was recommended by the consensus panel.

ABR is an established and sensitive test of auditory function,² but the standard procedure is time consuming and requires a high level of audiological skill. Thus the initial screen recommended by the NIH was the recording of TEOAEs. These acoustic responses associated with the normal hearing process had originally been described at the Institute of Laryngology and Otology, London, by Kemp,³ and his further development, by 1987, of simple, quick, and non-invasive clinical recording techniques made universal screening a possibility.⁴

Reservations about the practicability, cost, and effectiveness of such universal TEOAE

screens were quickly expressed in the USA.5 Although there are obvious advantages in screening within the maternity unit, Haggard⁶ had already pointed out the logistical difficulties, cautioning that the main obstacle to credible screening is the swamping of available assessment facilities with false positive results. Just over half of neonates are discharged from maternity units in England and Wales within 48 hours (Department of Health, personal communication). Unfortunately, low pass rates with TEOAE screening are achieved within this period.⁷⁻⁹ Thus it may not be practicable to implement the programme recommended by the NIH in the United Kingdom. Although in most of the districts in this country a universal screen using the distraction test in the latter half of infancy is already in place, and many districts also selectively screen neonates, the results are variable and thus universal neonatal hearing screening has already reached the agenda.¹⁰¹¹ Most parents of deaf children would have welcomed neonatal identification, a recent study shows.¹²

This report details the introduction of a universal neonatal TEOAE screen in the East London district of Waltham Forest. A universal infant distraction test has been in place within the district since the 1970s, with a selective at risk neonatal screen being introduced in 1986. However, only 43% of the deaf children in a cohort from the district were identified by the selective screen.¹³ Although the infant distraction test was considered sensitive, the mean age of identification for those with congenital deafness remained at over 1 year.¹⁴

To further reduce this, a universal TEOAE screen of infants within the first 3 months of life was introduced in January 1992. The implementation of the screen followed a pilot study undertaken the previous year. The screen aimed at identifying infants with a congenital or early onset bilateral permanent hearing impairment of moderate or worse degree. It was acknowledged that mild degrees of hearing impairment as well as unilateral congenital deafness and middle ear disease may result in disability. However, it was considered that those targeted by the screen would probably most benefit from the earlier provision of multidisciplinary habilitation. The selective neonatal screen was replaced by this universal screen. The infant distraction test undertaken by the health visitors, and other surveillance methods established over many years in the district, were left in place.

Evaluation of the screen processes, outcome, and cost has been ongoing since 1992. The results of this three year evaluation to 1995 are presented here.

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Table 1 TEOAE result scoring criteria

Response present if all criteria met (pass)

- (a) Response present at higher intensity than noise derived from subtraction of both averaged waveforms
 (b) Overall correlation of both averaged waveforms >50%
 (c) Overall correlation of both averaged waveforms of 2 of the
- (c) Correlation of both averaged waveforms at 3 of the bandwidths from 1.6 kHz, 2.4 kHz, 3.2 kHz, and 4.0 kHz >50% with one >75%

(d) Bandwidth signal to noise ratio ≥ 5 dB in all 3 selected bandwidths with signal to noise ratio ≥ 10 dB in at least two

Borderline response in all criteria met

(a) Response present at higher intensity than noise derived from subtraction of both averaged waveforms
(b) Correlation of both averaged waveforms and/or bandwidth

signal to noise ratio does not meet pass criteria (c) Bandwidth signal to noise ratio ≥10 dB in two of the bandwidths

No response (fail)

(a) Even if a response is present if the bandwidth signal to noise ratio does not meet the criteria for a 'borderline' – no response scored

Methods

Waltham Forest is an East London borough with a population of 220 000. It ranks 20th lowest out of all local authorities in England and Wales in terms of social and economic deprivation. Paediatric and maternity services and the special care of neonates are provided by Whipps Cross Hospital. Around 3500 babies are born each year to residents of the district. Around 85% are born in Whipps Cross and the remainder in neighbouring or central London maternity units. A very small number of births are by home delivery. Additionally, around one quarter of babies delivered in Whipps Cross are to residents of neighbouring districts. All required inclusion in the hearing screening programme.

TEOAE TEST

The recording of TEOAEs was done by the commercially available Otodynamics ILO88. This system has been described in detail elsewhere,^{15 16} and typical results illustrated.^{17 18} The ILO88 was used in default mode with the derived non-linear cochlear emission collected. The emission recording was made 2.5 milliseconds after stimulation, and initially a time gate up to 20 ms was used. With the availability by 1993 of the ILO88 'QuickScreen', the sweep time was reduced to 12.5 ms. Click stimuli of 80 μ s rectangular pulses with peak stimuli kept near to 80 dBSPL were presented through a Knowles magnetic transducer inserted into the external auditory meatus. The emission was recorded through a transducer placed within the same probe in the ear.

The ILO88 system collects two independent averaged emission waveforms for each test and these are then used for cross comparison and frequency analysis. The cross power spectrum of the two waveforms is calculated and displayed for frequencies from 0-5 kHz. The frequency spectrum of the difference between the waveforms measures noise contained in the waveform. The response signal to noise ratio for specific frequency bandwidths is calculated and also graphically displayed from 0-5 kHz. The two emissions collected at the end of the test are also cross correlated both as the complete waveform and at specific frequencies. The intensity of the reproducible components of the waveforms is also computed as the emission intensity in dBSPL units. The analysis is updated throughout the test, as is information about noise, stimulus, probe fit and test progress. This allows for repositioning of the probe or termination of the test as required by the tester.

The procedures and criteria for evaluating test results were standardised for all the testers. Although the analysis software was updated with improvements made by Otodynamics, the criteria were equivalent throughout the three years.

The ear tested first was that which was most accessible. The ear canal was not cleared of debris, but if a weak initial stimulus was obtained the probe was cleaned and refitted. The TEOAEs were scored by the screener as response present, no response, borderline response and not possible to test. The response criteria are shown in table 1. Those ears with no response, a borderline response, or not possible to test were considered screen fails. The screeners were allowed to terminate the test if a clear response was present, but only after at least 60 data samples had been collected. If there was no response the test was terminated after 260 data samples had been averaged.

The TEOAE recordings were made by neonatal hearing screeners newly employed as basic grade or senior assistant technical officers. Training in the use of the ILO88 was given over a period of several weeks by the audiologists. The screeners were also taught to interpret the test results and discuss them with the parents. The results were entered on a database and also detailed in the parent held child health record books. Samples of the TEOAE recordings and the screeners' decisions were evaluated weekly, with a hierarchical system of checking by the senior screener and audiologists.

ABR TEST

The ABR test was undertaken by an experienced audiologist. Standard silver chloride electrodes were attached to the forehead and the ipsilateral and contralateral mastoid, with Blue Tak and Netelast.¹³ Using a Medelec Sapphire machine, an alternatively inverted click stimulus was presented at a rate of 30 pps through a standard TDH39 headphone held at the baby's ear. The analysis time was 10 ms and the filter bandwidth was 200–2000 Hz. The threshold was obtained for each ear by obtaining two repeatable waveforms acquired after a minimum of 1000 clicks.

SCREEN

A summary of the screen is illustrated in fig 1. The initial test was by TEOAE recording, undertaken in a small non-soundproofed room dedicated for hearing screening within the maternity unit. The baby was kept in the cot without additional sound attenuating measures. Before the test, each mother was given an explanatory leaflet. The initial test was undertaken whenever possible before discharge, but

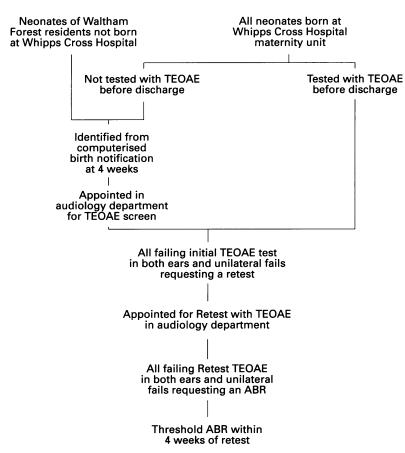


Figure 1 Flow diagram of neonatal screen.

as near to the time of discharge as possible. Those admitted to the special care baby unit were tested once they had moved to the low dependency part of the unit.

Those failing the initial test in both ears were sent an appointment for a retest within the audiology department of the hospital. The parents of those passing in one ear were given the choice of returning for a retest. Attempts were made to trace and test retest defaulters when the initial test had been failed bilaterally, but there was no coercion for unilateral failures. Those missed on the maternity unit, and those district residents born elsewhere, were given appointments for an initial test to be undertaken within the audiology department of the hospital. Their details were obtained 4 weeks after birth from an interactive computer system detailing district births. The time lag allowed for all neonates to have been entered on the system. Babies moving into the district after 4 weeks of age were referred into the programme at the time of their entry on to the district computer system, with screen entry being offered up to 3 months of age.

The initial test and retest were by TEOAE recording, with retest failures being referred for an ABR. If there were clear risk factors for deafness, parental concern, or delayed screen entry, failure at the initial TEOAE recording was followed by an ABR without a TEOAE retest. All babies referred for ABR were followed up by the audiology department. Screen passes entered the community health service hearing screening programme with hearing surveillance, parental questionnaires, and an infant distraction test at 7–9 months.

EVALUATION OF THE SCREEN

The combination of the initial TEOAE test, the TEOAE retest, and the ABR examination were considered to constitute the screen. Although the ABR examination was undertaken to threshold by an experienced audiologist, full audiological assessments were not carried out until the infants were referred into the diagnostic and rehabilitative clinics following the ABR. The ABR examination was thus included as a component of the screen in the evaluations undertaken.

Coverage of the screen was measured as the number of infants tested as a percentage of those babies recorded on the district's child health interactive computer system as having been born to residents of the district or born in Whipps Cross Hospital. Those becoming district residents up to 3 months from the date of birth were included. Those requiring and receiving each component test of the screen were enumerated. Defaulters of the retest and ABR were considered not to have been screened for calculation of coverage. Because the aim of the screen was the identification of bilateral hearing impairment, the retesting of unilateral TEOAE fails depended on parental decision. Thus only those failing the test bilaterally and not attending for the subsequent test were considered to have reduced the coverage. The crude test failure rates of the initial TEOAE and retest were also calculated. The yield was calculated from the ABR threshold in dBnHL obtained from the better ear. However, this may be misleading as such infants often have a hearing loss attributable to middle ear effusions. Such infants were not the target of the screen, and thus the yield of infants with a bilateral permanent hearing impairment of moderate or worse degree in the better ear was also enumerated. The infants were considered to have this impairment if the diagnostic audiological assessment confirmed average hearing thresholds in the better ear to be worse than 40 dBHL (or equivalent in other dB scales).

The cost of each test undertaken was computed from the cost of equipment and staff with equipment amortised over five years. Costs of disposables for the TEOAE tests and ABRs were included as was the cost of stationery. The cost for each test included the cost of clerical support and the cost of retesting the initial TEOAE failures and of undertaking the ABR examinations. The costs of audiological assessments undertaken on those referred into the diagnostic and rehabilitative clinics following the ABR were excluded. Overheads such as lighting, heating, and room costs were also excluded.

Results

RECIPIENTS OF THE INITIAL TEOAE TEST During the three year period of the evaluation, 14 353 babies were enrolled for the screen. Of these, 9850 (69%) were district residents born at Whipps Cross Hospital. Another 2832 (20%) were born at the hospital, but were not residents of Waltham Forest. Additionally, 1618 (11%) Waltham Forest residents were born outside the district or by home delivery, and a small number (53) were included although they were neither born in the district nor resident. Investigation of this small number demonstrated that they were incorrectly identified as residents, or were staying with relatives. Out of district neonates referred for diagnostic audiology were excluded.

In total 11 606 babies received an initial test. Of the infants tested, 810 (7%) had been admitted to the Whipps Cross or another special care baby unit. The proportion of those enrolled who received an initial TEOAE test is illustrated longitudinally for the three years of the evaluation in fig 2. Over the entire period only 81% of those eligible for entry into the screen received an initial TEOAE test. This was attributable to a rise in the proportion tested over the initial nine months. Two substantial improvements occurred. The first was at three months when the number of hearing screeners was increased. The second was at nine months, and involved several factors. The number of babies tested before discharge from the maternity unit was increased. This entailed more than doubling the proportion tested within the maternity unit during the first day of life. During the first nine months of 1992, only 18% of those receiving an initial screen were tested within the first 24 hours of life. However, this rose to 37.5% over the remaining period. The increase in those receiving the initial test was also assisted by the computerised identification of babies discharged before they were tested, and those not born at Whipps Cross. These improvements were implemented by the end of September 1992. Thereafter the proportion of those enrolled who received the initial TEOAE test rose to 94% and remained stable for the remaining period.

TEST CONDITIONS

The testing conditions are detailed in table 2. Samples of just over 1000 sequential tests undertaken on the maternity unit in 1993 and 1994 were analysed. The samples represented

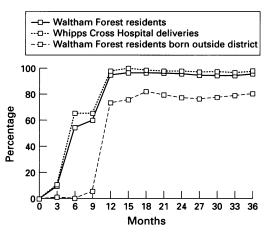


Figure 2 Proportion receiving initial TEOAE test, aggregated quantity.

 Table 2
 Testing conditions of initial TEOAE test

 undertaken in the maternity unit at Whipps Cross Hospital

		1993	3		1994	1
Version of ILO88		3.92			3.94	
Sweep time (ms)		12.5			12.5	
Sample size		1025	5		1010)
Stimulus (dB peak)						
Mean (SD)		86 (*	4)		85 (5	5)
5% 50% 95%	80	85 `		77	85 `	
Stimulus stability (%)						
Mean (SD)		77 (25)		74 (2	27)
5% 50% 95%	15	86		9	83 `	
Noise reject level (dB)						
Mean (SD)		46 (2)		48 (2	2)
5% 50% 95%	43	45 Ì		44	47 Ì	
No responses averaged						
Mean (SD)		143	(69)		154	(70)
5% 50% 95%	58	124	256	59		256
No responses rejected						
Mean (SD)		584	(588)		540	(548)
5% 50% 95%	75	378	1721	65	357	1618
Noise level (dB)						
Mean (SD)		35 (2	3)		37 (3	3)
5% 50% 95%	31	35	40	32	36	42
Test time (mins)						
Mean (SD)		3.0 ((2.6)		2.9 (2.3)
5% 50% 95%	0.7			0.8		

test conditions when the initial screen was being undertaken by different testers working to the same criteria and within the same testing environment.

AGE AT INITIAL TEOAE TEST

Of the 12682 Whipps Cross Hospital deliveries, 8750 (69%) were discharged home within 48 hours. This early discharge governed the age at which the initial test was possible. The age of the infants at the initial test is detailed in table 3. Of the babies tested, 10 649 were born at Whipps Cross, with an additional 957 infants being born elsewhere. For the total of 11 606 infants tested, the mean initial test age was 1.9 weeks. Inevitably the infants born elsewhere were tested after discharge from their maternity unit. Of the births at Whipps Cross, only 9133 (86%) could be tested before they were discharged home. The mean test age of these infants was 61 hours. Those missed on the maternity unit were called back later to the audiology department, along with those born elsewhere. The mean age of all the infants called back to the audiology department for their first test was 7.4 weeks.

Of those 9133 tested before discharge, 635 were cared for in the special care baby unit. Their mean test age was 2.7 weeks. The difference in the distribution of test age for all the infants, and for those requiring special care, is illustrated in fig 3. The exclusion of

Table 3	Age of	`infants at	initial test
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	No tested	Mean age	Age range
Infants admitted to SCBU			
Tested before discharge	635	2·7 w	2·9 h-19·8 w
Tested after discharge	175	7∙9 w	1·9 w–22·7 w
Total	810	3∙8 w	2·9 h–22·7 w
Infants not admitted to SCB	U		
Tested before discharge	8498	32·7 w	1·0 h –2·2 w
Tested after discharge	2298	7·4 w	1.0 w -20.3 w
Total	10796	1·7 w	1·0 h-20·3 w
All infants tested			
Tested prior to discharge	9133	61·4 h	1.0 h-19.8 w
Tested after discharge	2473	7.4 w	1.0 w-22.7 w
Total	11606	1.9 w	1.0 h-22.7 w

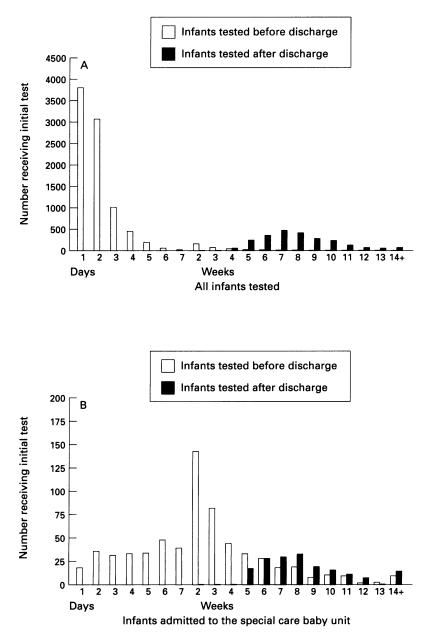


Figure 3 Distribution of initial test age.

those requiring special care reduced the mean age for those tested on the maternity unit before discharge to 32.7 hours.

RESULTS OF THE INITIAL TEOAE TEST

The number failing the test in both ears is detailed in fig 4 for the different sources of enrolment to the screen. The combined data are shown in fig 5. Of the cohort tested, 1527 (13%) failed the initial test in both ears. Of these 3054 ears, 2336 (10% of those initially tested) had no TEOAE response according to the scoring criteria used. An additional 261 ears (1%) were not adequately tested because the baby would not settle, and 457 (2%) were borderline responses. In addition, 2398 (21%) of the cohort tested failed in one ear. Of the bilateral failures, 134 (1.15% of those initially tested) were referred immediately for ABR. The other 1393 (12% of those initially tested) were referred for a TEOAE retest. Of the unilateral failures, 887 parents elected for a retest (7.5% of those initially tested).

Of the 1393 referred because of bilateral failure at the initial test, 1202 (86%) received a TEOAE retest. The mean age at the retest was 7.7 weeks (range 0.5 to 40 weeks). Of those retested, 999 passed in one or both ears. However, 203 (1.75% of those initially tested) failed the TEOAE screen on two occasions in both ears. Of these 406 ears, 300 demonstrated no TEOAE response, and of the remaining 106, 44 could not be adequately tested, and 62 were borderline.

Those with borderline responses or an inadequate test required an ABR along with those where there was clearly no response. Thus 337 infants (2.9%) of the initial cohort tested) required a diagnostic ABR because they had failed the TEOAE in both ears. Of the 887 unilateral failures who were retested by TEOAE recording, 108 (0.9%) of the initial cohort tested) failed the test again in one ear. In total 91 infants underwent ABR testing because they had failed the TEOAE unilaterally.

ABR EXAMINATION

Of the 337 infants referred for ABR examination because of bilateral TEOAE failure, 290 (86%) were tested. An additional 91 infants were tested because of failure in one ear. ABR was thus undertaken on 381 infants. The mean age of the ABR was 12.8 weeks, with a range from 1 to 33 weeks. Two of the ABR examinations were only completed in one ear. The ABR thresholds measured from the better and worse ears are detailed in fig 6.

COVERAGE OF THE SCREEN

The coverage of the screen for the different sources of enrolment and for the overall cohort was computed from the data presented in fig 4. The number receiving the initial TEOAE test was reduced by the number of bilateral failures not completing the retest and ABR components of the screen. The computed data for coverage are presented in table 4.

YIELD OBTAINED FROM THE SCREEN

The yield in terms of ABR threshold is detailed in table 5. The aim of the screen was to identify those with a moderate or worse degree of bilateral permanent hearing impairment. Most of those with a 40 dBnHL or worse ABR threshold had middle ear effusions without an underlying permanent hearing impairment. After diagnostic audiological assessment 23 were found to have a permanent hearing impairment targeted by the screen and requiring long term audiological rehabilitation. This was a yield of 2 per 1000 neonates who had received the initial test.

COST

The cost of the screen is detailed in table 6. The screen required a testing room on the maternity unit. Within this facility around 3500 tests were

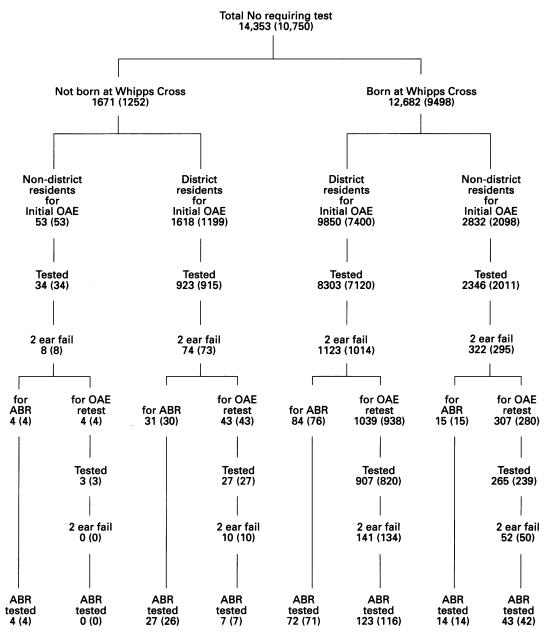


Figure 4 Results of screen from 1 January 1992 to 31 December 1994; numbers after 1 October in parentheses.

undertaken annually by an assistant technical officer employed for a single session every day including weekends. An average of 10 neonates were tested per 3.5 hour session, with parental discussion and the required administration. Cover for holidays was essential.

An additional 2500 appointments were made in the audiology department for a senior assistant technical officer to test those missed on the maternity unit, those born elsewhere, and the initial TEOAE failures. The number of appointments included a 20% non-show rate. The rate of testing was also 10 babies per 3.5hour session. The senior officer was employed full time. She had additional duties, including data entry, administration, and the responsibility for screening those babies admitted to the special care baby unit. Holiday cover has been included in the costing, but weekend cover was not required. She was assisted in the administration by a 0.5 whole time equivalent clerk.

A senior audiological scientist was employed in the audiology department to undertake the ABR examinations. This required two sessions per week. The subsequent diagnostic audiological assessments have not been included in the cost analysis. Staff costs were calculated as being midway on the salary scale including additional costs of National Insurance, Superannuation, and London Weighting. Equipment costs have been amortised over five years, with the annual cost of disposables including TEOAE probes, ABR electrodes, and stationery, etc, included.

The annual cost of screening 4500 neonates and of testing the screen failures with ABR was \pounds 44,200, or \pounds 9.80 per baby tested. With a yield of 2/1000 with a bilateral loss of moderate or worse degree, the cost per hearing impaired child usefully detected was \pounds 4900.

Discussion

The early identification of congenital deafness has been the frustrated aim of preventive child health services for many years. Yet quality

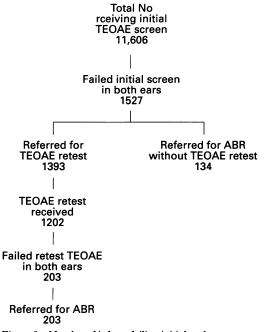


Figure 5 Number of infants failing initial and retest TEOAE in both ears.

standards have now been set, requiring the detection of 40% of bilateral congenital deafness within the first six months of life.¹⁹ Unfortunately, deafness presents subtly²⁰ and the only realistic way of meeting this target is by neonatal screening. Targeted neonatal screens may identify two thirds of the congenitally deaf,²¹ but the yield may be considerably lower.⁶ At risk neonatal screens would probably have to function with very high sensitivity to meet the quality standards.

The technology is now available for screening all neonates, and the temptation to implement such programmes is difficult to resist. This report details one of the first universal TEOAE screening programmes to be implemented in the United Kingdom. The process and outcome evaluation has been used to investigate some of the concerns expressed about practicability and cost.⁵⁶ Can high coverage be achieved at reasonable cost? Can a balance be struck between test sensitivity and specificity so that a worthwhile yield is achieved without inundating already stretched audiology departments with concerned parents and normally hearing neonates?

Experience with the distraction test has shown that the success or demise of a universal screen is intrinsically linked to the coverage.²² Poor coverage inevitably leads to a low yield, irrespective of the sensitivity of the test being used. The worth of the screen for a district depends on achieving high coverage. Surprisingly, it has not been possible to ascertain what coverage has been achieved from other reports of universal neonatal hearing screens applied in this country¹⁰ or in the USA.²³

The very attraction of implementation within the maternity unit is the presence of a captive population and the possibility of effectively testing a large proportion of those targeted for the screen. However, is this really practicable in a maternity unit where over two thirds of the babies are discharged within the first two days? District coverage also depends on the ability to undertake an initial test on those infants born elsewhere, and on retesting those failing the initial test. These different components of the screen were examined in Waltham Forest. Difficulties were encountered over the first few months following the introduction of the screen. However, thereafter the proportion of all those eligible for screening who received the first test rose to a stable level of 94%.

Over 96% of those born within the district maternity unit received an initial test, with 86% being tested before discharge home. This required the employment of weekend staff, and also holiday cover. The continuity of the screen during periods of absenteeism was facilitated by the deployment of two other assistant technical officers familiar with the programme but normally employed elsewhere within the district.

The proportion of those residents not born in the district maternity unit, who received an initial test, remained disappointingly low at 76%. Improvement may have been possible by TEOAE testing in community clinics. However, this would have considerably increased the programme cost, and because over 85% of district births occurred in the district hospital, the difficulties of enrolling those born elsewhere only marginally reduced the overall district coverage.

The proportion of those receiving a required TEOAE retest and ABR remained at 86%. This has been the coverage of other subsequent hearing screens within the district.¹⁴ Improving this required imaginative measures not yet achieved. Retest TEOAE failures should clearly result in an immediate ABR test but this has proved logistically difficult. However, despite these partly unresolved problems the reported screen methodology has achieved a stable district coverage of 91.5% since October 1992.

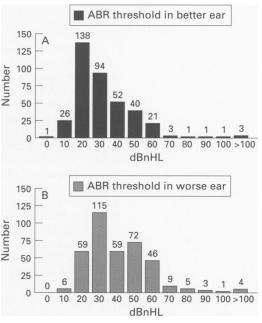


Figure 6 ABR thresholds in better and worse ears.

Table 4 Coverage of the screen for the different sources of enrolment

	Coverage		
	1/1/92 to 31/12/94	1/10/92 to 31/12/94	
Non-district residents not born at			
Whipps Cross	62.3%	62.3%	
District residents not born at			
Whipps Cross	55.6%	74.4%	
District residents born at Whipps Cross	82.6%	94.3%	
Non-district residents born at			
Whipps Cross	81.0%	93.5%	
All births at Whipps Cross	82.3%	94.1%	
All births of district residents	78.8%	91.5%	
All enrolled for screen	79.2%	91.8%	

Haggard's caution⁶ about universal screens swamping the available assessment facilities is well founded. The screen specificity was lower than has been reported elsewhere. The largest TEOAE screen has been the Rhode Island Hearing Assessment Project.²³ This was initiated some two years before the Whipps Cross programme and although the two stage procedure was essentially similar, the TEOAE scoring criteria were less stringent in the American programme. From the first cohort of 1850 Rhode Island births, the failure rate of the initial test was 27%. However, recategorisation of borderlines reduced this to 15%.

The age of initial testing was of necessity lower in the Whipps Cross programme. It has been established by other studies⁷⁻⁹ that testing within the first two days results in high failure rates. However, an acceptable level of coverage was only obtained by testing the well babies in the district maternity unit at a mean age of 33 hours. This inevitably affected the test specificity. The one and two ear failure rate of the initial test totalled 34%. Only 2% out of the 13% who failed in both ears, and 5% of the 21% failing unilaterally, were borderline responses. If these were considered to be screen passes, then the total initial failure rate would have fallen to 27%. This was considerably higher than the 15% reported from Rhode Island. The aim of the Whipps Cross programme, however, was the identification of bilateral losses. The policy of retesting all 13% who failed bilaterally, but only reappointing unilaterals as required, kept the programme manageable.

In part, the poor specificity seen in the current programme is attributable to the drive for increased testing before discharge. The advantages of having a captive population within the maternity unit were thus partly negated. However, the number of neonates discharged from the maternity unit within the first two days was some 20% higher than the national average. Such low specificity may

Table 5 Yield obtained from the TEOAE screen

ABR threshold in better ear	Number	Yield/1000 screened
≥40 dBnHL	122	10.5
≥50 dBnHL	70	6.0
≥60 dBnHL	30	2.6
≥70 dBnHL	9	0.8
≥80 dBnHL	6	0.2
≥90 dBnHL	5	0.4
≥100 dBnHL	4	0.3

therefore not be experienced by other districts.

The Whipps Cross programme could also have been made more specific by making the criteria less stringent and by the effective use of response filtering, and the same day retesting of babies failing the initial test. Such measures are being investigated, but increasing specificity must eventually result in reduced sensitivity. Because sensitivity measures require long term follow up of the entire cohort, such changes are being implemented with caution.

Measurement of the sensitivity of the test requires complete ascertainment of all those within the cohort with a permanent congenital hearing impairment. This will require at least five years of follow up of the cohort, and without a larger multicentre trial confidence limits of these measures will be wide. The effect on the age of detection of permanent hearing impairments within the district will also require long term follow up.

However, yield can be used as a short term surrogate for evaluating test sensitivity. The yield of infants identified with a bilateral permanent hearing loss of moderate or worse degree was 2/1000. There was a higher proportion of infants with a moderate loss, in keeping with the expected distribution of hearing threshold found in congenital deafness. Although specificities have been higher than that experienced within the present programme, this expected distribution has not been reported from behavioural universal neonatal screening using the Auditory Response Cradle.¹⁰

Following the ABR examination, 10.5/1000 were identified from the present cohort with a 40 dB or worse hearing loss in the better ear. Although this seems to be a high yield, most had middle ear effusions, and the value of identifying such temporary conductive losses at this age is currently unclear. Undoubtedly, this group also contains some with mild permanent losses. This will become clearer with the long term follow up of the cohort. The yield of those with a unilateral loss was also omitted from the present evaluation, as they were not targeted by the screen.

The yield shows that the screen was reasonably sensitively implemented. The prevalence within the district of congenital deafness of moderate or worse degree has averaged 3/1000 since 1973.¹⁴ The yield from the three year cohort receiving the neonatal screen is slightly lower. It is extremely unlikely that the programme sensitivity could have been 100% because of the inability to retest with ABR all those failing the TEOAE tests.

Table 6 Annual cost of TEOAE screening programme

Equipment amortised over 5 years 3 ILO88 systems 1 ABR Machine 1 Computer+software	£4560 £1900 £220
Annual cost of disposables Stationery, probes, electrodes, etc	£3100
Staff 0-2 WTE audiological scientist 0-8 WTE assistant technical officer 1-1 WTE senior assistant technical officer 0-5 WTE clerical assistant	£6200 £8424 £14 179 £5635
Total: cost/year	£ <u>44 218</u>

any programme evaluation. The total cost of the reported neonatal programme at just under $\pounds 45\,000$ a year was similar to the district's pricing of the infant distraction screen. The cost of each neonatal test was under f_{10} . Clearly this low cost reflected the professional grading of the hearing screeners. Because the TEOAE test is essentially repetitive and readily learnt over a few weeks, this component of the screen was implemented using assistant technical officers without previous audiological training. Although other universal screens have recommended the employment of nursery nurses,10 the performance of the former has been regularly monitored, and no significant problems have been encountered. However, the cost of the screen also included the employment of an audiologist to undertake threshold ABR examinations on the TEOAE failures. Such inclusion is at odds with the concept of a screen. The cost of the audiologist made up almost one quarter of the overall cost of the testers, and the use of automated ABR recording by the assistant technical officers is being investigated.

In 1990 the notional cost per deaf child identified by targeted neonatal screening was considered to be around £4000.6 When inflation is taken into account, the cost of identifying a deaf child by the reported universal screen was scarcely much more.

In Waltham Forest the infant distraction test has been retained until the sensitivity of the neonatal screen becomes clear. The incremental yield from this later screen is under evaluation. If this later screen can be withdrawn the saving will almost entirely offset the cost of the neonatal screen.

The screen detailed has been of undoubted worth to the district in terms of the yield of infants identified with a permanent hearing loss. Although such early identification does not necessarily allow for early and successful habilitation, the wider application of this universal screen nationwide requires consideration. Currently, large multicentre trials of TEOAE test sensitivity are being undertaken both in the USA and Europe. The current data have been included in the European cohort, and the district cohort is subject to long term follow up. The need to plan for the introduction of such a screen in other districts in the United Kingdom is not universally acknowledged. A selective neonatal screen of those with risk factors, sensitively applied, may identify most of those with congenital deafness. However, this was not the case in Waltham Forest, and similar districts should consider the opportunity afforded by the recently developed technology for the detection of otoacoustic emissions.

The logistics of implementing such a screen are challenging. Although the average test time for a TEOAE recording undertaken on a neonate on the maternity unit was three minutes, only between three and four babies could be tested each hour. Most of the time was taken up with transporting the baby to the test site, and discussions with the mother. With

a modal birth rate of 13 per day it was not feasible to achieve efficiently complete testing before discharge from the maternity unit. The number of new births per day ranged from four to 25. This inevitably resulted in days when complete coverage was not possible for the single screener employed to undertake initial tests for one 3.5 hour session each day. On almost 20% of days more than 16 babies were born. However, for 10% of days fewer than eight neonates required screening. Simply to increase the screening time to ensure a higher proportion tested before discharge would have been effective but not efficient. Instead the present methodology elected to recall a minority. The presence of a facility to test those missed on the maternity unit, and also those district babies born elsewhere was thus essential to achieve the coverage of over 90%. Districts with different birth rates require an individual logistical assessment, but the numbers born in Waltham Forest are not atypical, and similar problems can be anticipated elsewhere.

The maternity unit reported is atypical, however, in that almost 70% of the babies were discharged home within 48 hours. This resulted in a higher than expected failure rate from the initial TEOAE test. A two stage TEOAE test was therefore implemented. If initial testing can be delayed until after the first day or two of life the failure rate will be reduced.⁷⁻⁹ However, in the United Kingdom just over 50% of babies are discharged within the first two days, and thus in many maternity units similarly low specificity for the initial test will apply. A two stage test is effective in reducing the number of babies requiring an ABR examination.

Even with a two stage TEOAE screen, however, around 3% of the cohort required an ABR examination. Although it is anticipated that less stringent TEOAE scoring criteria can further improve test specificity, the local provision of a neonatal ABR service is considered an essential precursor to implementing a TEOAE screen.

Although the reported screen is now a valued and effective district service, it is still evolving some three years after initial implementation. It is not anticipated that the screen can have been absolutely sensitive to all degrees of congenital hearing impairment, and it is considered that methods of identifying progressive and acquired hearing losses later in childhood are still required.

In districts where an adequate yield of infants with congenital hearing loss cannot be achieved by selective at risk neonatal screens, it is feasible to implement a universal neonatal TEOAE screen. The cost is not prohibitive, and the number of infants identified by the Whipps Cross programme is testament to the sensitivity of the screen. The specificity of the screen was low because the pass/fail criteria were set to ensure a high level of test sensitivity. This was considered to be necessary with the implementation of a new programme. The achievement of high coverage also entailed the testing of most neonates within the maternity unit before they were 2 days old. This further reduced the test specificity. It is anticipated that this will be a problem common to many districts in the United Kingdom currently considering the implementation of such a universal neonatal screens. Even so the failure rate has not rendered the programme unacceptable. It is predicted that the criteria can be relaxed and this is currently under investigation. If the specificity can be improved without loss of sensitivity, then universal neonatal TEOAE screening becomes an attractive proposition, even in maternity units with high early discharge rates.

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