Original articles

Long term follow up of newborns tested with the auditory response cradle

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SUMMARY The auditory response cradle is being used in a mass hearing screening project. Babies are assessed in the first week after birth by the fully automatic, microprocessor controlled cradle. The test, lasting from two to 10 minutes, compares physiological auditory responses to natural behaviour measured in control trials. More than 5000 babies have been tested and full follow up information at the age of 7 to 9 months is available from over two thirds of these. Less detailed information is available for 71% and 64% of those babies who have been followed up at 18 months and three years of age respectively.

A total of 439 of 5553 neonates tested failed the first screening test. Eighty eight (1.6%) failed a second screening test while still in the maternity unit but 61 of these were subsequently shown to be normal, giving a false positive rate of 1.1%. The babies who failed the screening tests included 9 with sensorineural hearing loss, three with secretory otitis media, and three with abnormal auditory brain stem response tests. One child who passed the initial screening tests was found to have a moderately severe hearing loss at the age of 18 months.

The importance of the early detection of hearing impairment has been stressed by all those dealing with the deaf.¹ ² An intact auditory pathway is essential for the acquisition of speech and language and as the critical time for the development of these skills is during the first two years of life, early diagnosis is highly desirable.³ The earlier the hearing loss is identified the sooner appropriate management can be instituted that will allow the child to achieve his full potential.⁴

In an attempt to achieve early diagnosis a 'high risk' register has been widely used but only approximately 50% of hearing impaired babies are on such a list.⁵ ⁶ More centres have recently begun to use auditory evoked potentials, in particular brainstem responses, for the differential diagnosis of hearing impairment.⁷ These procedures, however, are time consuming, require expensive equipment, and need skilled personnel for interpretation,⁸ all of which tend to negate their use for mass screening.

Traditional techniques for the assessment of hearing in children aged up to 2 years have centred around the observation of behavioural responses to sound. Below the age of 6 to 7 months this is exceptionally difficult. Although child development patterns are well documented, observer bias, lack of testing standardisation, and inexperience affect the reliability of response detection and classification. In neonates the situation is little better as there is need to distinguish spontaneous activity from specific responses to sound; strict conformity with arbitrary criteria has resulted in high false positive and negative rates.⁹ ¹⁰

The auditory response cradle was developed to classify neonatal responses to sound accurately. These responses were measured and subjected to statistical analysis in extensive research trials¹² ¹³ and the automatic, microprocessor controlled auditory response cradle was designed from the results obtained. The auditory response cradle consists of a trolley mounted unit comprising a pressure sensitive mattress and head rest (Figure). These incorporate non-contacting sensors for head turn, startle or head jerk,¹⁴ ¹⁵ body activity, and respiration.¹³ ¹⁵ A 2600 Hz high pass noise of 85 dB SPL is used as the test stimulus and is presented via close coupled ear probes fitted with tips similar to those used for acoustic impedance testing. High pass noise is used because of the prevalence of high frequency impairment among the congenitally deaf. The sound
stimulus is presented to the infant on a number of occasions and the resulting motor and respiratory responses are detected and stored in the memory of the microprocessor; equal numbers of interspersed, no sound control trials, carried out in an identical fashion, enable calculation of the probability that the responses to sound are specific reactions and not spontaneous events. When this probability exceeds 97% (calculated using binomial probability distribution), the baby is considered to have normal responses and is ‘passed.’ If the sound level at the probe tip falls below 82 dB SPL or abnormal respiratory patterns are detected, however, fault lights are illuminated on the control console and the test is automatically inhibited, allowing user intervention. The auditory response cradle test is fully automatic and once initiated continues until the baby ‘passes’ or ‘fails’. ‘Failure’ is used in this paper to identify those babies who do not achieve the 97% confidence level. On the auditory response cradle this is indicated by a ‘refer’ light illuminating on the control console.) Once the baby is settled, the test is completed in two to 10 minutes.

Neonates failing the auditory response cradle screen are retested on a separate occasion during their hospital stay as it is necessary to eliminate those who fail the first screen because of unresponsiveness which may be unrelated to deafness (for example deep sleep, jaundice, or traumatic delivery). Babies in special care units are tested on their discharge from the unit.

The study presented in this paper is an evaluation by long term follow up of the effectiveness of the auditory response cradle as a device for screening hearing in neonates.

Method

Subjects. A total of 5553 newborn infants (weight 2-27 to 5 kg) have been tested in the auditory response cradle to date. Some 4861 of the 5553 babies have been followed up at the age of 7 to 9 months by a clinic hearing screen, 2853 have been followed up at 18 months by questionnaire, and 1026 have been followed up by a further questionnaire at the age of 3 years. Babies are tested in the auditory response cradle at any time during their hospital stay, although it has been found that waiting until at least two days after birth and using the period one hour after a feed to one hour before the next feed ensures a more settled baby. The mother is approached on the ward to obtain informed consent and the nursery nurse, who carries out the test, completes a questionnaire which helps to determine whether or not the baby is ‘at risk’ for deafness using the following criteria:

1. A history of hereditary childhood hearing impairment.
2. Rubella or other non-bacterial intrauterine fetal infections (for example cytomegalovirus or herpes infection).
3. Congenital malformations of the ear, nose, or throat.
4. Birthweight less than 1.5 kg.
5. Hyperbilirubinaemia (342 μmol/l: 20 mg/100 ml, or more) or exchange transfusion.
(6) Five minute Apgar score of less than 5. While still on the ward the baby is made comfortable, a polythene band containing the respiration transducer is positioned around the abdomen over the clothes, and the baby is swaddled to reduce the arousal state.

Test procedure. The auditory response cradle is housed in a room at the quiet end of the antenatal ward. The room is darkened with blinds and fitted with a sound attenuating door but it is not otherwise sound treated. Once in the test room the child is placed in the trolley mounted unit, the ear probe is positioned gently in the external meatus, and the test is initiated. The sound stimulus is generally presented only to the right ear of the babies not at risk for deafness. In the case of infants who are either at risk (as determined from the questionnaire) or have been in the special care baby unit, the stimulus is presented to both the right and left ears individually.

Immediate follow up. Two auditory response cradle failures place the baby into a follow up programme comprising a full paediatric examination, tympanometry and acoustic reflex measurements, and auditory brainstem response testing. For the evoked response test, monaural broadband click stimuli are presented to the infant at a rate of 30 second through an electromagnetically shielded headphone. Approximately 2000 sweeps are averaged at each stimulus intensity, ranging from 80 dB re adult hearing level (nHL) down to electric response threshold decreasing in 10 dB steps. The responses are filtered (bandpass 0-3 to 4.5 kHz) and recorded on both X-Y plotter and floppy discs for permanent storage. The child is subsequently ‘cleared’ if wave V is observed to have a normal latency down to 30 dB HL for each ear. As maturation noticeably alters response latency and influences waveform morphology in preterm infants auditory brainstem response testing is not carried out until the baby reaches a conceptual age of at least 42 weeks. Conceptual age is defined here as the sum of the infant’s gestational age at birth plus his or her postnatal age at time of test. At this early stage of life, sedation is unnecessary and testing is begun after the baby has been fed and is in a state of natural sleep. Babies who cannot attend this follow up for a couple of months (due to family holidays or families moving house) are sedated with a mixture of trimethazine (3 mg/kg) and chloral hydrate (30 mg/kg).

Auditory brainstem testing and all hearing assessments performed on children recalled throughout the three year follow up programme are carried out in an anechoic chamber.

Follow up at age 7 to 9 months. Records from all infants tested with the auditory response cradle, with the exception of those whose deafness has been confirmed, are sent to the district health authority who subsequently return the results of their developmental 7 to 9 month clinic hearing screening programme. An unconditioned sound lateralisation technique (distraction testing) is used for correlation with the neonatal screen. Babies that fail are referred to their local audiology centre and all test results are sent to the auditory response cradle evaluation programme. If the child does not attend the clinic screen on two consecutive occasions a follow up questionnaire, enclosing a prepaid reply envelope, is sent to the mother with questions about the child’s babble, awareness of sounds, and history of ear infections. Any suspicion of hearing loss arising from the returned form results in recall for tympanometry and acoustic reflex measurements and distraction testing.

Follow up at age 18 months. The subsequent follow up at 18 months takes the form of a questionnaire (enclosing a prepaid reply envelope) which is sent to the mother of every baby originally tested in the auditory response cradle except those already confirmed as being deaf. The following questions are included in this questionnaire:

1. Do you have any reason to be concerned that your child may have a hearing loss? If so, please explain why.
2. Does your child turn to find sounds?
3. Does your child have a vocabulary of five to 6 words?
4. Does your child appear to have good balance?

The child is recalled for hearing assessment if the mother replies ‘Yes’ to question (1) or ‘No’ to two or more of the remaining questions. At this assessment impedance testing is routinely employed and distraction testing is carried out using conventional stimuli, namely cup and spoon, sibilant ‘ss’, high frequency rattle, and voicing at low frequencies. The child is said to have hearing within normal limits if a response is obtained to all stimuli at a minimal level of 30 dB HL for each ear. Information at specific frequencies is obtained with a Linco AU2 warble tone generator and a Peters AP22 free field audiometer. Visual reinforcement audiometry employing pure tones is carried out where entirely satisfactory responses to the distraction test are not given. The visual reinforcement auditory system consists of two illuminating stationary toys each placed at an angle of 45 degrees to the child. Testing is controlled from the anteroom and the child’s responses are monitored by a high contrast 8 inch video monitor.
Follow up at age 3 years. The final follow up when the child is 3 years old again takes the form of a questionnaire which includes the following questions:

1. Do you have any reason to be concerned that your child may have a hearing loss? If so, please explain why.
2. Does your child speak in sentences easily understood by friends and relatives?
3. Does your child have good balance?
4. Has your child had a hearing test other than at birth or the one given at 7 to 9 months by the child health clinic? If so, please explain the reason for the test and the result.

The child is recalled for hearing assessment if the replies are ‘Yes’ to question (1), ‘No’ to questions (2) or (3), or if the answer to question (4) or any additional comments on the returned questionnaire are at all suggestive of hearing loss. The battery of tests carried out at this recall include pure tone headphone audiometry using an Oscilla TS3–7 audiometer and a speech discrimination test (McCormick Toy test) in the anechoic chamber, along with tympanometry, acoustic reflex measurements, and otoscopy. The child is said to have hearing within normal limits if:

(a) The threshold for air conduction is less than 20 dB HL at 0.5 to 4 kHz, and less than 30 dB HL at 8 kHz in each ear.

(b) The audiogram is supported by the speech discrimination test with 100% discrimination being obtained at a minimal level of 40 dB HL.

The results of all hearing assessments carried out at each stage of the auditory response cradle follow up programme are sent to the consultant paediatrician and district health authority.

Results

The results of the screening trials are shown in Tables 1 to 4. Table 1 provides the basic pass/refer statistics. Of the original 5553 neonates tested 439 (7.9%) failed the first screen but this figure was reduced to 88 (1.6%) after the second test. Sixty one of the 88 babies referred for follow up by auditory brainstem response and impedance testing were subsequently cleared, giving a false positive rate of 1.1%.

Table 1—first time failures. Nine newborns who failed the first auditory response cradle test were discharged from hospital before they could be tested again. One child returned three weeks later and was found to have serous otitis media, which was treated medically. He was subsequently tested elsewhere with electrocochleography and no action potential was observed. The child is now 3 years old and wears two Phillips 8146 hearing aids (volume setting 5). Unaided, localising responses were obtained to a drum and xylophone at 100 to 110 dB HL and aided, the following responses were obtained bilaterally—55 dB HL at 250 Hz and 500 Hz; 65 dB HL at 1 kHz; no response at 2 kHz and 4 kHz.

The second child did not return for the repeat auditory response cradle test and information was next obtained via the three year questionnaire which described him as having poor speech development. He lived too far away to attend a recall, but results from his local audiology clinic showed him to have a profound high frequency hearing loss. Of the remaining 7 infants who did not attend for retest, 6 were cleared at the 7 to 9 month child health clinic screen, and the child who did not attend this clinic screen was subsequently cleared by both the 18 month and three year questionnaires.

Table 1—second time failures. (a) Sensorineural losses

The second test failures included five babies with bilateral and two with unilateral sensorineural losses. The average auditory brainstem response threshold for those with bilateral sensorineural losses was equal to or greater than 80 dB HL. All five children have now been issued with hearing aids. The child with a severe unilateral loss had normal brainstem responses for the left ear down to a stimulus level of 40 dB HL, but no responses could be detected on the right for a stimulus level up to 80 dB HL. The child moved out of the area just before he was due to attend the age 7 to 9 months hearing...
screen and we are currently awaiting the detailed results of the distraction test carried out by his local child health clinic, which has confirmed a loss in the right ear. The child with a moderate unilateral hearing loss had abnormal auditory brainstem response on the left and no detectable response on the right up to a stimulus level of 80 dB HL. He subsequently passed the 7 to 9 months clinic hearing screen but was nevertheless recalled for further assessment because of the distraction test/auditory brainstem response disparity. Normal middle ear function was obtained on impedance testing but on distraction testing he was found to have a threshold of 30 dB HL for all frequencies on the left ear and a moderate hearing loss on the right ear (60 dB HL at 500 Hz, 1 kHz, 2 kHz; greater than 90 dB HL at 4 kHz).

(b) Middle ear pathologies
There were three newborns in whom brainstem evoked response testing showed a hearing loss which was found by tympanometry and acoustic reflex testing to be due to secretory otitis media.

(c) Brainstem latency and rate abnormalities
Three brainstem latency and rate abnormalities have been detected. One infant who was resuscitated after apnoea and asystole showed poor auditory brainstem response bilaterally. The child now suffers from severe spastic quadriplegia and as he is still in hospital care at the age of 18 months, no further hearing assessment has been possible. The second child was born 6 weeks preterm, severely jaundiced, and had been in intensive care for a week as a result of episodes of apnoea. When tested in the auditory response cradle his left ear was normal but abnormal responses were obtained on the right. No brainstem responses could be detected for the right ear up to a stimulus level of 80 dB HL and impedance testing showed middle ear dysfunction. Further tests are currently being carried out to determine whether this is a conductive, sensorineural, or mixed loss. The third infant was 11 weeks preterm (weight 1·2 kg) and was tested in the response cradle at 5 months of age (weight 3·6 kg) after a stormy neonatal period. No auditory brainstem response could be detected for either ear. Results of the local child health clinic assessment are awaited.

(d) Other abnormalities
One of the babies who failed the auditory response cradle test was microcephalic. There was no indication of any high risk factors and on auditory brainstem response test normal latencies were obtained for wave V for both ears down to a stimulus level of 40 dB HL. The child’s electroencephalographic trace, however, which is continuously monitored throughout evoked response audiometry, seemed abnormal and a full paediatric assessment diagnosed him as microcephalic. Another infant who failed the auditory response cradle test was found to have abnormal brainstem responses for both ears at 8 weeks of age. On distraction testing at 8 months, poorly localised 45 to 50 dB HL responses were obtained and impedance testing showed bilateral secretory otitis media. As it was unclear whether the poor localisation was due to developmental immaturity or a sensorineural loss with conductive overlay, the child is awaiting definitive diagnosis.

(e) Lost to follow up
Only one baby who failed the test was lost to follow up during the neonatal period. This family is difficult to trace due to mobility relating to the father’s occupation.

(f) Awaiting results
Eleven infants are currently awaiting follow up.

Table 2—follow up at age 7 to 9 months. After the auditory response cradle screen, follow up is carried out at 7 to 9 months of age by the child health clinic. As shown in Table 2, 4861 infants tested at birth have now reached this age. One of the 3970 babies that attended and passed this screen had previously failed the cradle test and auditory brainstem response follow up. He was recalled for further

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Results of child health clinic follow up at 7 to 9 months of age</th>
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</thead>
<tbody>
<tr>
<td>Number of subjects</td>
<td>4861</td>
</tr>
<tr>
<td>Passed†</td>
<td>3970 (81·7%)</td>
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<tr>
<td>Failed</td>
<td>7 (0·1%)</td>
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<tr>
<td>Gross loss to follow up</td>
<td>884 (18·4%)</td>
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<tr>
<td>No information available</td>
<td>285 (6·0%)</td>
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<tr>
<td>Mother refused test</td>
<td>14 (0·3%)</td>
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<tr>
<td>Non-attendance</td>
<td>256 (5·3%)</td>
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<td>Moved with no forwarding address</td>
<td>188 (3·9%)</td>
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<tr>
<td>Moved out of follow up area</td>
<td>123 (2·5%)</td>
</tr>
<tr>
<td>Died</td>
<td>14 (0·3%)</td>
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<tr>
<td>Adopted</td>
<td>4 (0·1%)</td>
</tr>
<tr>
<td>Less replies to letter</td>
<td>333 (6·9%)</td>
</tr>
<tr>
<td>Net loss to follow up</td>
<td>551 (11·3%)</td>
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</table>

*†Same children in Table 1.
assessments and was found to have a response threshold at 30 dB HL for all frequencies on the left and a moderate sensorineural loss on the right (60 dB HL at 500 Hz, 1 kHz, 2 kHz; greater than 90 dB HL at 4 kHz).

Seven babies failed the clinic hearing screen; one had previously failed the auditory response cradle test and had subsequently been proved deaf and 6 infants had passed the response cradle test. One of these 6 was tested by electrocochleography at 14 months of age and was found to have a severe bilateral sensorineural loss. This is believed to be evidence of a hereditary progressive loss as an elder sibling has been exhibiting a similar loss for 7 years. The remaining five babies passed when tested again; three of them had secretory otitis media. (Many more than three children actually failed the 7 to 9 month screen due to secretory otitis media but were recorded by the child health clinic as having passed if the middle ear dysfunction had resolved when they were tested again).

Despite exhaustive follow up, 884 babies (18-4%) have been lost at this stage of the programme. Reasons for failing follow up are listed in Table 2. The largest group is the 'no information available' group which includes babies for which no test results have been received. The district health authority presumed that they had not attended clinic or had moved. No further follow up was carried out by the clinic as these children were by then well over 18 months old. The number of losses from this group is reduced by subtracting the number of 18 month or 3 year questionnaires that have been returned with satisfactory replies. The losses due to 'moved out of follow up area' are reduced in the same manner by subtracting from the number of 18 month or 3 year questionnaires returned with satisfactory replies. Another large group of losses is that of 'non attendance' and represents the children who did not attend the clinic screen on two consecutive occasions. This number is also reduced by the follow up questionnaire.

7. Follow up at 18 months of age. A total of 2853 questionnaires have been sent out to children who have reached 18 months of age and 2045 (72%) have been returned (Table 3). Nineteen of the 26 babies recalled were cleared and 7 were found to have middle ear dysfunction (secretory otitis media) and were referred through the consultant paediatrician and senior clinical medical officer for appropriate treatment.

Thus far no false negatives (that is babies who passed the auditory response cradle test but actually have a hearing impairment) have been found through the 18 month questionnaire.

### Table 3 Results of 18 month follow up programme via questionnaire

<p>| | |</p>
<table>
<thead>
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<th></th>
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<tbody>
<tr>
<td>Number of questionnaires sent</td>
<td>2853</td>
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<tr>
<td>Number returned</td>
<td>2045 (72%)</td>
</tr>
<tr>
<td>Number giving satisfactory replies to hearing, balance and vocabulary questions</td>
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</tr>
<tr>
<td>Number recalled</td>
<td>26</td>
</tr>
<tr>
<td>Number cleared</td>
<td>26</td>
</tr>
<tr>
<td>Serous otitis media</td>
<td>19</td>
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</tbody>
</table>

### Table 4 Results of 3 year follow up programme via questionnaire

<p>| | |</p>
<table>
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<th></th>
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</thead>
<tbody>
<tr>
<td>Number of questionnaires sent</td>
<td>1026</td>
</tr>
<tr>
<td>Number returned</td>
<td>654 (64%)</td>
</tr>
<tr>
<td>Number giving satisfactory replies to hearing, balance and vocabulary questions</td>
<td>629</td>
</tr>
<tr>
<td>Number recalled</td>
<td>25</td>
</tr>
<tr>
<td>cleared</td>
<td>25</td>
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<tr>
<td>Serous otitis media</td>
<td>16</td>
</tr>
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<td>High frequency S/N loss</td>
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</tr>
</tbody>
</table>

*Same baby in Table 1.

### Table 4—Follow up at 3 years of age. The last stage of the follow up programme occurs when the baby reaches the age of 3 years and the final questionnaire is sent to the mother. To date 1026 questionnaires have been sent of which 654 (64%) have been returned (Table 4). As a result of the 25 questionnaires returned with unsatisfactory replies, 24 children have been recalled; 16 of these children have been cleared and 8 were found to have middle ear dysfunction (secretory otitis media). The remaining child was shown by his local audiology clinic to have no high frequency hearing on pure tone headphone audiometry. This child had failed the auditory response cradle test once in the neonatal period (see Table 1) and had not returned for a retest. As he lived outside the district health authority area no results from a 7 to 9 month hearing screen had been obtainable and the mother had not replied to the 18 month questionnaire. He was eventually picked up via the 3 year questionnaire because of poor speech development.

### Discussion

Because of the low incidence of congenital hearing loss very large numbers of subjects are required to validate fully any screening device. The figure recommended by the Department of Health is that of 6000 children to be followed to the age of 3 years.
Thus far nearly 5000 infants have been followed to age 9 months, 3000 to age 18 months, and 1000 to 3 years and the indications to date are most promising. The false positive rate of 1-1% is acceptably low for a screening device and compares favourably with that reported by Shepard in a 'modified mass screening programme'.

The cradle was designed to detect moderate and severe non-recruiting hearing losses and as shown in Table 1, 12 infants have been confirmed as having a hearing impairment. The detection of unilateral sensorineural loss was not one of the aims of the research programme as this condition does not affect the acquisition of speech and language appreciably. As the sound stimulus was presented to one ear only in most infants tested, it follows that only approximately 50% of unilateral losses will be detected; in practice two neonates with a unilateral loss have been found.

The finding of three neonates with serous otitis media has important implications. In the trials with the prototype apparatus it was found that neonates have a very sharply defined behavioural threshold to acoustic stimuli. This varied with the type of stimulus used and was measured to be 72 dB for broad band noise. In each case the reduction of the intrameatal sound pressure level by 5 dB below this threshold caused the response rate to fall to that of the 'no sound' control trials. This behavioural reaction can be likened to a simple muscle reflex, for example the stapedius reflex. Because of this it was originally hypothesised that if the test sound level was set at 15 dB above the measured threshold, infants with losses in excess of this would have their response rate reduced to the control value and would fail the auditory response cradle test. It was consequently expected that both moderate and severe losses could be detected by the screen. The presence of the three babies with middle ear dysfunction in the fail group seems to support the hypothesis, as hearing losses from this condition of greater than 40 dB are unlikely and cannot be greater than 60 dB on a pure transmission basis.

As previously described, babies confirmed deaf within the first few months of age did not attend their local child health clinic at age 7 to 9 months as they were referred to specialist audiology units. For this reason only one baby is shown in Table 2 as having previously failed the auditory response cradle test.

Follow up losses in screening programmes are inevitable. During the neonatal period only one of the 89 infants recalled for testing (Table 1) was lost to follow up. At this stage of the programme, losses were kept to a minimum by providing transport for any mother and child otherwise unable to attend.

After the neonatal period the loss to follow up increased considerably—18-3% at 7 to 9 months; 28% at 18 months; 36% at 3 years. The gross loss of 18-3% was reduced to a net loss of 11-3% by means of questionnaires as described previously. This is a more satisfactory figure and represents a follow up loss mainly due to families who have moved and left no forwarding address. At the 18 month and 3 year follow up, the attendance rate of children recalled was 100% as transport was provided whenever necessary. The follow up losses at these two stages of the programme were almost entirely due to families having moved. The increasingly greater loss to follow up with time in this evaluation study reinforces the need to screen when the largest proportion of the population is available—in the newborn nursery. A programme is currently being carried out to trace all children via their family doctor, the community health service, and the local housing department.

The auditory response cradle validation study will be complete when every neonate originally tested with the cradle has been followed up to the age of 3 years. The infants who failed the cradle test but were subsequently cleared are being kept under careful review and will all be recalled for pure tone headphone audiometry, impedance testing, and a speech discrimination test. It is anticipated that these goals will have been achieved by 1986. A number of other centres are now equipped with the auditory response cradle and further validation will be forthcoming.

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References
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