

# Infant Hearing Screening in Maternal and Child Health Centres Using Automated Otoacoustic Emission Screening Machines: A One-year Pilot Project

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## Abstract

The Maternal and Child Health Centres (MCHCs) of the Department of Health have been using the Distraction Test (DT) as the main tool for infant hearing screening. Recognising the limitations of the test, a one-year pilot project was conducted to investigate the feasibility of implementing Automated Otoacoustic Emission (AOAE) screening in MCHCs and to compare the performance of the two screening tools. We report here our experience of using the AOAE test and its performance in a group of 3,949 babies at 4 pilot MCHCs. Comparison is made with the performance of DT in another group of over 45,000 babies. The AOAE test, with a test-repeat rate of 9.2%, a screen-refer rate of 3.8% and a yield of 0.76 per 1,000 babies screened, was shown to be a superior test to the DT. We conclude that AOAE screening is a promising tool for universal infant hearing screening in Hong Kong.

## Key words

Child health; Distraction test; Feasibility study; Infant hearing screening; Otoacoustic emissions

## Introduction

Bilateral permanent childhood hearing impairment (PCHI) is an important health problem because of its adverse effect on a child's language and communication skills, social and emotional development and educational achievement.<sup>1</sup> The prevalence of PCHI of moderate or greater degrees is about 1.2 per 1,000 live births,<sup>2</sup> which is higher than that of congenital hypothyroidism, a condition routinely screened in newborn babies.<sup>3</sup> The majority of PCHI is present at birth.<sup>2</sup> It is believed that the first six months of life is the critical period for language skill acquisition.<sup>4</sup> Initial evidence, which shows that identification and habilitation prior to the age of 6 months improve language and communication,<sup>5</sup> however, remains to be further substantiated by good quality studies.<sup>1</sup>

In the Maternal and Child Health Centres (MCHCs), hearing screening has been an integral component of the Comprehensive Observation Scheme (COS) since its implementation in 1978. The Distraction Test (DT) is the main tool for infant hearing screening.

### **Limitations of DT as a Hearing Screening Tool**

A number of limitations in the use of DT as a screening tool have been identified. Firstly, as a behavioural test, the distraction test cannot be reliably performed until the child reaches the age of around six months. Secondly, the DT has high demands on test environment as well as skills of testers. Stringent requirement of the test environment, such as sound treatment of test room, appropriate lighting, adequate space, etc, must be met and elaborate skills training (and re-training) of testers is needed. Thirdly, the effectiveness of DT as an infant hearing screening tool has been questioned in several study reports, for example, it has been reported to perform no better than the vigilance programme.<sup>6-8</sup> Although performance of our DT screening in terms of uptake, refer rate and yield (unpublished data) is comparable to those reported in UK studies,<sup>2</sup> the yield of babies with bilateral moderate or greater hearing loss per 1,000 babies screened is far less than the expected prevalence of the condition of about 1.2 per 1,000 (Table 1).

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Received February 7, 2003

**Table 1** Performance of hearing screening by Distraction Test in Hong Kong MCHCs and the UK

	DT screening in MCHCs <sup>i</sup>	DT screening in the UK <sup>2</sup>
Uptake	81.7%	80-95%
Repeat test rate	17.5%	-
Screen refer rate	4.6%	5-10%
Yield	0.09/1,000 babies screened <sup>ii</sup> 0.20/1,000 babies screened <sup>iii</sup>	~0.25/1,000 live births
Age of hearing loss identification	9-12 months	12-20 months

<sup>i</sup> unpublished data; <sup>ii</sup> refers to bilateral *sensori-neural* hearing loss of  $\geq$  moderate grade; <sup>iii</sup> includes *all* bilateral hearing loss of  $\geq$  moderate grade

### **The Availability of More Effective Means of Screening**

With the advent of easy-to-use electro-physiological screening methods like otoacoustic emission (OAE) and auditory brainstem response, hearing status of very young, or even newborn babies, can be predicted accurately. These neonatal hearing screening tests have higher sensitivity and specificity than infant DT.<sup>9</sup>

OAEs are sounds generated by outer hair cells housed in the cochlea and can be measured in the external ear canal. Detection of OAEs can be hampered by obstructions in the external ear canal and middle ear. Detectable OAEs, therefore, reflect normal function of the auditory pathway as far as the level of the outer hair cells of the cochlea. This technology can be used to detect sensory hearing loss but not retro-cochlea neural dysfunctions.<sup>10</sup>

The technology of OAE has been found to be an effective tool in universal newborn hearing screening.<sup>11</sup> Since the 1990s, using OAE as newborn hearing screening has become popular in Europe and USA, mainly in birthing hospitals. To date, more than half of the states in the USA have legislation mandating universal hearing screening as a public health programme.<sup>12</sup> In the UK, even though the infant DT has been used for hearing screening since the 1940s, the Department of Health has recently decided to pilot the implementation of universal newborn hearing screening.<sup>13,14</sup>

### **Pilot Project of AOA Screening in MCHCs**

Because of the limitations of DT and the availability of objective, accurate and easy-to-use automated OAE (AOAE) screening machines, a pilot project was conducted in four MCHCs from August 2000 to July 2001, to test the feasibility of implementing AOA screening in the MCHC settings and to compare the performance of AOA and DT screening. The target

condition to be screened for was bilateral *sensori-neural* hearing impairment of moderate to profound grade (i.e. greater than 40 dB hearing loss).

## **Method**

### **The 4 Selected MCHCs**

Among the 50 MCHCs, four were selected to pilot the AOA screening programme. They were chosen because of their high attendance of more than 1,000 newborn babies annually and the availability of a separate room for performing the test. This screening programme was introduced as an additional service.

### **The Instrument**

The instrument used was the 950-AuDX K portable OAE machine with a default screening protocol. It produced Distortion Product OAE ( $2F_1 - F_2$ ) at  $F_2$  frequencies of 2K, 3K, 4K and 5K Hz. After testing, the result of "Pass"/"Refer" would be displayed according to its pre-programmed pass/fail criteria, which was based on a large scale study in which hearing impairment was defined as a behavioural, pure tone audiometric threshold of 25 dB HL or greater at a particular frequency.<sup>15</sup> No interpretation of test results by the tester was required.

At the beginning of the project (August 2000-January 2001), two AOA machines were shared among four MCHCs. Since February 2001, two more AOA machines were acquired and each MCHC had its own AOA machine. This saved time for transporting the machines and allowed delivering the test in a more flexible way.

### **The AOA Tester**

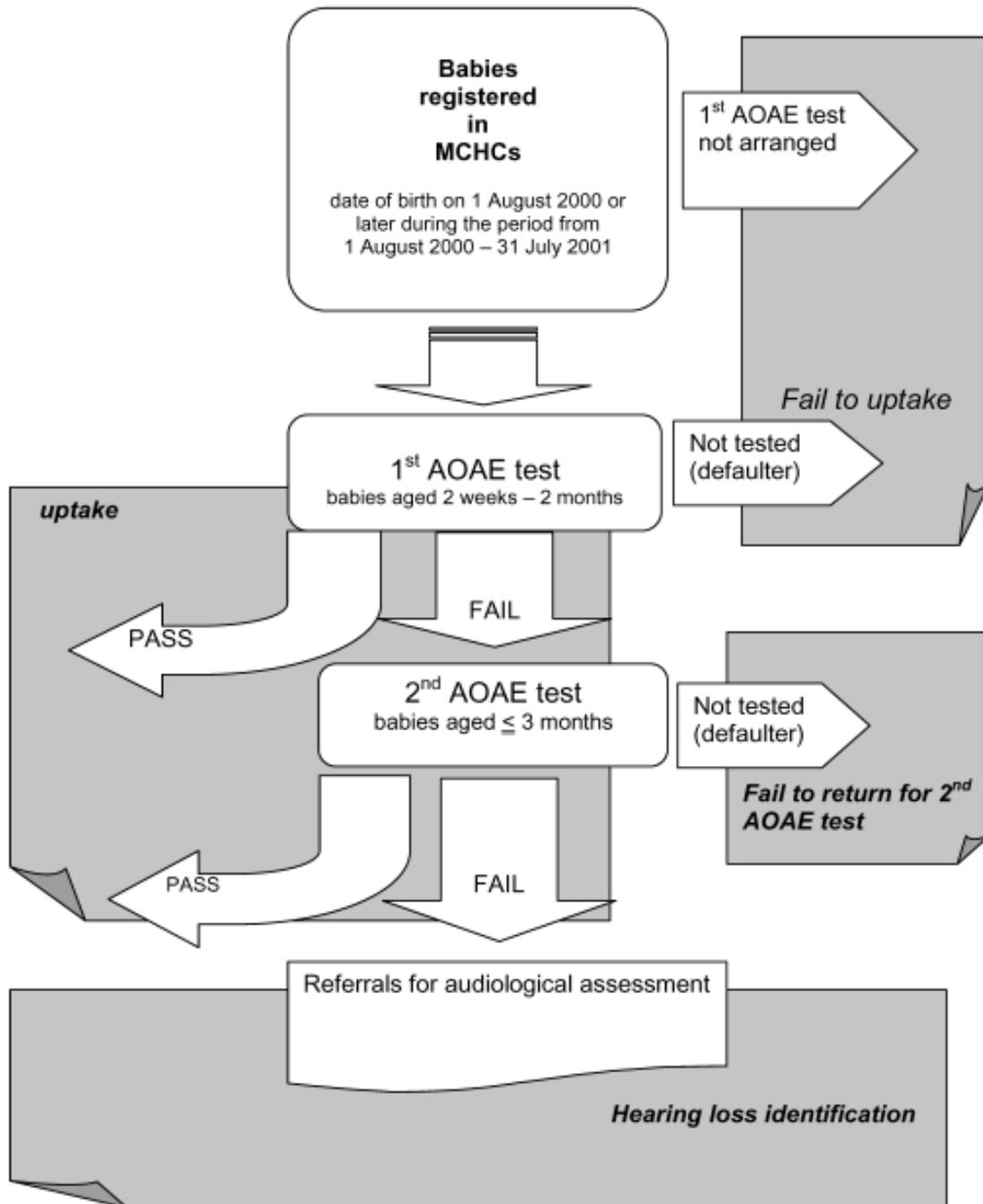
Nine enrolled nurses were trained to be AOA testers.

The training was conducted by audiologists and consisted of a 7-hour lecture on the principles of AOAE testing and machine operation as well as a 4-hour supervised practical session. In addition to AOAE testing, these nine nurses were performing usual duties at these MCHCs.

**The Protocol**

Figure 1 outlines the protocol for the AOAE screening project.

We invited all babies born on or after 1 August 2000 who were registered at the MCHCs during the period from



**Figure 1** Protocol of AOAE screening in Maternal and Child Health Centres.

1 August 2000 to 31 July 2001 to enroll in the programme, regardless of hearing risk status. Babies without external ear canals were excluded for the obvious reason that AOAE testing could not be performed. We did not recommend the programme to babies who had passed hearing screening at their birthing hospitals or those who had audiological follow-up arranged.

Two strategies were built in the protocol to minimise false-positive results. First, we recommended no AOAE testing before the age of 2 weeks. This was to avoid performing the test in very young babies who tended to have unresolved fluid in the middle ears or debris in their ear canals, resulting in undetectable OAE.<sup>11</sup> Second, we adopted a two-stage screening protocol that only babies who had failed both the 1st and the 2nd AOAE tests would be referred.<sup>16</sup> The 2nd AOAE test was performed at least 2 weeks after the 1st AOAE test.

This protocol also excluded older babies, for example, the 1st AOAE test was not offered to babies older than 2 months and the 2nd AOAE test was not performed in babies older than 3 months of age. This was essentially a practical consideration since older babies could not be settled easily during testing and longer time would be required for completing the test.<sup>11,17</sup>

### The Procedures

When a baby first registered at any of the 4 selected MCHCs, the AOAE screening programme would be introduced to the family during the initial interview. If a baby was considered eligible and consent from the parents was obtained, the family would be given an appointment together with an information leaflet, outlining the programme as well as giving advices on preparing the baby for testing.

The test was performed in a non-sound treated room, which was usually a consultation room in the MCHC. No otoscopic examination or cleaning of ear canal was required.

Each AOAE test consisted of testing both ears. A "passed" AOAE test result would mean that the baby had passed the test in both ears while a "failed" AOAE test result might mean that the baby had failed the test in one or both ears or that he/she had failed to complete the test. If a baby had failed the 1st AOAE test, a 2nd test would be arranged. A baby would only be referred for diagnostic evaluation if both tests had been failed. Babies who passed either the 1st or the 2nd AOAE test (after failing the 1st AOAE test) would be discharged from the programme. Parents were advised to continue observing the child for normal hearing behaviours and arrange for routine hearing screening test (i.e. DT) between six and nine months of age.

### Statistical Analysis

Statistics of the AOAE screening programme were essentially descriptive. Key performance indicators of the AOAE and DT screening programmes viz. repeat rate, refer rate and yield were compared, using the Chi-squared test.

## Results

### Performance of AOAE Screening

#### Programme Uptake and Completion-rate

During the study period, 5,449 babies (with date of birth on or after 1 August 2000) were registered at the four selected MCHCs. Of these, 3,949 babies (72.5%) enrolled in the programme and received an AOAE test. There were two main groups of babies who failed to enroll in the programme. The first group were babies who were not scheduled for the AOAE test at registration (n=832). The second group consisted of babies who defaulted the appointment (n=668). The reasons for babies not participating in the programme are summarised in Table 2.

Of the 365 babies who failed the 1st AOAE test, 328

**Table 2** Uptake of AOAE screening in Maternal and Child Health Centres

	Count	%
<b>Babies registered</b>	<b>5,449</b>	<b>100.0</b>
(1) Babies received 1st AOAE test	3,949	72.5
(2) Babies not scheduled for 1st AOAE test	832	15.3
▪ <i>Babies had audiological assessment received / arranged by birthing hospitals, including universal / targeted newborn hearing screening.</i>	77 (1.4)	
▪ <i>MCHCs failed to provide the test because of a fully booked testing schedule.</i>	129 (2.4)	
▪ <i>MCHCs did not offer the test because babies were registered &gt; the age of 2 months.</i>	540 (9.9)	
▪ <i>Babies could not attend the test because of leaving Hong Kong / being transferred to another MCHC.</i>	65 (1.2)	
▪ <i>Families declined the screen at registration.</i>	21 (0.4)	
(3) Babies scheduled for but defaulted the 1st AOAE test	668	12.2

babies (89.9%) returned for the 2nd AOAE test. Thus over 99% of the 3,949 babies who enrolled in the programme had completed the screening.

#### *Timing of Screening Tests*

The median ages of babies taking the 1st and the 2nd AOAE test were 30 days and 54 days respectively. By the age of 2 months, 96.2% babies enrolled had received the 1st AOAE test. As for the 328 babies who returned for the 2nd AOAE test, 91.8% had completed the 2nd AOAE test by the age of 3 months.

#### *Repeat and Refer Rates*

Of the 3,949 babies who enrolled in the programme, 3,584 (90.8%) passed the 1st AOAE test. Three hundred and twenty-eight babies then went on to receive a repeat test and 178 of them passed (54.3%).

One hundred and fifty babies failed the screening and required referrals for diagnostic audiological evaluation. The screen-refer rate was 3.8%.

#### *Programme Yield*

While 150 babies were referred out after completing the screening, 128 babies (85.3%) did turn up for diagnostic evaluation. After the initial audiological assessment, 81 babies (63% of those evaluated) were confirmed to be normal while 47 babies had some form of abnormal audiological findings which required follow-up assessment.

Of these 47 babies, 16 were confirmed to be suffering from sensori-neural hearing loss where 7 were affected bilaterally and 9 unilaterally. Four babies were found to have bilateral hearing loss of moderate to profound grade, where 3 were confirmed to be of sensori-neural

in nature, giving a yield of 0.76 per 1,000 babies screened (3/3,949).

#### *Timeliness of Referral and Diagnosis*

As for the timing of referral and diagnosis, the majority (91.8%) of referrals were made before the age of 3 months and the median age of referral was 54 days. By the age of 6 months, 93.7% of referred babies had completed the diagnostic audiological assessment and the median age of confirming the hearing status was 85 days.

#### **Performance of AOAE and DT Hearing Screening Programmes Compared**

The performance of AOAE screening and DT screening in MCHCs is outlined in Table 3. The series of babies who underwent DT screening were the cohort of babies born in 2000 who attended COS in MCHCs between June 2000 and September 2001 (unpublished data). Procedures of DT are briefly outlined in the Appendix. The performance of AOAE screening was better than that of DT in repeat rate ( $p<0.001$ ), refer rate ( $p=0.008$ ) and yield ( $p=0.001$ ).

Regarding resources, the median time (excluding time for settling the baby, explaining to parents, etc) for completing an AOAE test was 6 minutes while that for a DT was about 3 minutes. The latter test required two nurses (a tester and a sound presenter).

## **Discussion**

The aim of this pilot project was to explore the feasibility of implementing AOAE screening in MCHCs and to compare the performance of AOAE and DT as hearing

**Table 3** Performance of AOAE & DT screening in MCHCs

	<b>AOAE screening</b>	<b>DT screening</b> <sup>i</sup>	<b>P value</b> <sup>ii</sup>
Repeat test rate	9.2%	17.5%	<0.001
Screen refer rate	3.8%	4.6%	0.008
Yield			
■ Target condition <sup>iii</sup>	0.76 / 1,000 babies screened	0.09 / 1,000 babies screened	0.001
■ All bilateral HL of ≥Moderate grade	1.0 / 1,000 babies screened	0.2 / 1,000 babies screened	0.003
Median testing time <sup>iv</sup>	6 minutes <sup>v</sup>	3 minutes <sup>vi</sup>	
Median age at referral	54 days <sup>vii</sup>		
Age of hearing loss identification	85 days <sup>viii</sup>	>180 days (9-12 months) <sup>ix</sup>	

<sup>i</sup> Unpublished data; <sup>ii</sup> The chi-squared test was used; <sup>iii</sup> Target condition=Bilateral sensori-neural hearing loss of ≥moderate grade; <sup>iv</sup> Testing time=Actual time spent on performing the test to obtain results on both ears, excluding time spent on explanation, settling the baby and recording of results; <sup>v</sup> Time measured just before insertion of ear-probe until removal of ear-probe. Data collected from a sub-sample of N=246 babies; <sup>vi</sup> Time measured when sound presenter entered the room until she left the room. Data collected from a sub-sample of N=240 babies; <sup>vii</sup> Data collected from a sub-sample of N=150 babies; <sup>viii</sup> This is the median value. Data collected from a sub-sample of N=127 babies; <sup>ix</sup> This is only an estimation.

screening tools. The Year 2000 Position Statement of the Joint Committee on Infant Hearing<sup>18</sup> had recommended certain benchmarks for an effective universal newborn hearing screening, including an uptake of 95% or greater, return-for-follow-up of 75% or higher and screen-refer of less than 4%. Although these benchmarks are intended mainly for universal hospital-based hearing screening programme where the settings are different from those in MCHCs, we consider these recommendations useful as references.

### **Performance of AOAE Screening Programme**

#### *Programme Uptake and Completion-rate*

For a universal newborn hearing screening programme to effectively detect PCHI, which is an uncommon condition in the general newborn population, a high programme uptake, say up to 95%, is required.<sup>18</sup> A programme uptake of 72.5% from our one-year experience was undesirable. Babies not covered by the programme fell largely into two groups. The first group were those who did not register at the MCHCs until after the age of 2 months and were therefore excluded from entry into the programme by the protocol. According to routine statistics of the Family Health Service in the past five years, over 90% of all newborn babies had registered with the MCHC,<sup>19-23</sup> a much higher coverage rate should therefore be attainable. We consider it necessary to inform all parents about the programme well beforehand so that they would bring their babies to the MCHCs at an appropriate age. The second group were families that failed to keep the appointment for the test. Timely reminder, for example by telephone, would be required to reduce the number of defaulters. It was interesting to note that very few families declined to enrol in the screening programme in the first place.

Besides, failing to offer the test because of a fully-booked schedule was another reason for some of the babies not being covered by the programme. This happened mainly during the initial period of the project when two AOAE machines were shared amongst four MCHCs. Similar problem had scarcely occurred since each MCHC had its own machine, which enabled test schedules to be arranged flexibly to cope with the fluctuating numbers of new registrants.

The return-for-2nd AOAE test rate of 89.9% and screen-completion rate of 99.1% are remarkably high. These suggested that once the babies had undergone test for the first time, they tended to return for a second test if indicated.

Even though a low rate of return-for-follow-up has frequently been reported in other newborn hearing screening programmes, this did not seem to be a problem here.<sup>3,24,25</sup> This could have been an advantage of the community-based over the hospital-based programme.<sup>17</sup>

#### *Repeat and Refer Rates*

Less than 10% of babies tested required a repeat test. Similar results could be found in other screening programmes.<sup>17,26</sup> A repeat test for babies who have failed the initial test helped to reduce the refer rate to 3.8%, which meets the recommended benchmark of 4% or less.<sup>18</sup> The two-stage protocol is thus important to minimise false-positive results and reduce the number of referrals.

#### *Follow-up for Audiological Assessment*

Nearly 15% of babies referred from the programme had defaulted their audiological assessment appointment. Many of these babies would receive a DT at 6 to 9 months at their MCHCs. However, it would be important to ensure that all babies referred do receive audiological assessment especially when DT is to be phased out, a likely situation with full implementation of the AOAE screening programme.

#### *Programme Yield*

In a general neonatal population, between 10% and 16% are reported to have risk indicators for hearing impairment.<sup>1</sup> The range in the prevalence of hearing risk indicators reflects the different neonatal intensive care unit (NICU) admission criteria.<sup>27</sup> MCHCs provide child health service mainly to the well-child population while babies with high risk indicators such as the NICU graduates or those with cranio-facial anomalies are usually taken care of by paediatricians or other specialists. Among the 3,949 babies who enrolled in the AOAE screening programme, only 2.2% had hearing risk indicators<sup>28</sup> identified. It is notable that all three babies with confirmed bilateral, sensori-neural hearing loss of moderate to profound grade had no hearing risk indicators. The yield of universal newborn hearing screening in low-risk population had been estimated to be 0.36-0.49 per 1,000 babies screened.<sup>1</sup> Our yield of 0.76 per 1,000 babies screened is of a similar order.

It is remarkable that while a newborn baby has a one-in-a-thousand chance (or lower as in the case of a baby without risk indicators) of having bilateral, sensori-neural hearing loss of moderate to profound grade, babies referred from this programme had a one-in-fifty (2.0%) chance of having

the condition (3/150). This figure is comparable to the estimated positive predictive value of 2.2% at a two-stage newborn screening in a well-baby nursery.<sup>1</sup>

#### *Limitations of AOAE Screening*

When applied to the newborn, the AOAE technique has two major limitations. Firstly, it assesses the hearing pathway as far as the cochlea and any retro-cochlear pathology will be missed. However, retro-cochlear pathologies are expected to be rare in the low-risk babies. Moreover, the prevalence, natural history and optimal mode of management of auditory neuropathies are unknown<sup>29</sup> and therefore the benefit of early detection is uncertain. We therefore consider the AOAE technique adequate for routine use in the MCHC population. Secondly, the test results depend on the status of the external and middle ears.<sup>30</sup> By avoiding the early neonatal period when test results are frequently affected by the presence of debris in the external ear canal and fluid in the middle ear, and by using a two-stage AOAE/AOAE protocol, we were able to keep the repeat and referral rates at reasonable levels.

#### *Practical Issues*

In the MCHC setting, the test rooms were not sound-treated. Despite the sealing effect of an appropriate-sized earpiece, it was found that the tests were often affected by ambient noises such as those arising from a crowded waiting hall or the public announcement system. As a result, longer testing time might be required.

The age and state (of being quiet or restless) of the baby at testing and baby-handling skills of testers might also affect test results.<sup>31,32</sup> The testers reported that the optimal age for testing was around 21 days and they found that older babies tended to be easily aroused and have more movements. With a total of 4,277 tests performed, only 1.2% (n=50) of tests failed to be completed. This probably reflected the amount of effort taken to prepare babies for the test and the competence of the testers in handling babies.

#### **Comparing the Performance of AOAE and DT Hearing Screening Programmes**

It is apparent that AOAE screening performed more favourably than the DT in areas such as repeat rate, refer rate and yield. The yield of identifying the target condition of bilateral sensori-neural hearing loss of at least moderate grade by AOAE was many folds that by DT (0.76 vs 0.09 per 1,000 babies screened). However, it must be emphasised that although both series of babies were of low risk status

for hearing loss, they were not randomly selected groups. Studies have shown that the incremental yield from infant DT would be negligible when neonatal hearing screening has been in place.<sup>33,34</sup>

Manpower resources required by AOAE test and DT, in terms of testing time, are comparable. The median time for completing an AOAE test was doubled that for a DT. However, the latter required two nurses to perform the test. In contrast to the DT, which requires intensive training and re-training of testers to maintain quality of performance, AOAE results can be obtained without any interpretation. Findings of this project confirm that training of enrolled nurses to perform AOAE tests is feasible and only brief training of the testers is required.

One of the frequently cited advantages of AOAE over DT in hearing screening is the possibility of earlier identification and management of the condition. From our experience, the majority of referrals from the AOAE programme were made before the age of 3 months and the majority of audiological evaluations were completed before the age of 6 months. This was a definite improvement over the DT screening programme.

## **Conclusion**

AOAE test is an objective, valid and easy-to-use hearing screening tool. It can be performed by enrolled nurses after brief training. This pilot project showed that hearing screening by AOAE yielded better results than DT in terms of lower repeat and refer rates as well as a higher yield of the target condition. Moreover, the pilot AOAE programme met recommended benchmarks on refer rate and return-for-follow-up for universal hearing screening. Rolling out the AOAE screening to all MCHCs will benefit the majority of babies in Hong Kong.

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## Appendix

The Distraction Test is performed in babies aged 6 to 9 months, by a pair of trained nurses, a tester and a sound presenter. The child is sat on the parent's lap, facing the tester who tries to hold the child's attention by showing him interesting objects. Four frequency-specific sounds (Manchester High Frequency Rattle: 7000-8000 Hz; voice of 's-ss': 3000-4000 Hz; C-chime bar: 500 Hz & voice of 'o-oo': about 250 Hz) of intensity 45 or 50 dB(A), depending on the noise level of the room, are presented from behind to the baby's each ear in turn, as the tester covers or hides the interesting objects. A definite head turn in the direction of the sound source is recorded as a pass. The baby is said to have passed the distraction test if he shows positive responses to all the test stimuli in both ears.