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Original Article

The Effectiveness and Cost Analysis of a Pilot Newborn Hearing Screening Program at a Hospital in a Low- to Middle-Income Country

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BACKGROUND: When a universal newborn hearing screening program is not feasible, particularly in the early stages of its establishment when it requires a great deal of effort and resources, a smaller scale in screening, such as a specific geographical subset or targeted group, is suggested rather than doing nothing. This study aims to pilot a newborn hearing screening program at a hospital in a low- to middle-income country and determine its effectiveness and costs in the context of a lack of qualified audiologists.

METHODS: All high-risk births at Hatyai Hospital were recruited for newborn hearing screening between January and December 2021. Newborns who failed 2 stages of transient evoked otoacoustic emissions screening were referred for diagnostic assessment and subsequent interventions. The program's effectiveness was assessed based on the standards of the American Academy of Pediatrics. All costs related to screening, diagnostic, and intervention stages were also evaluated.

RESULTS: Out of 883 newborns, 792 newborns were screened, resulting in a 95.1% screening coverage. The referral rate regarding the diagnostic stage was 3.9%. Also, 28.3% and 12.9% lost-to-follow-up rates were observed in the secondscreening and diagnostic assessment stages, respectively. Ten children were confirmed as having permanent hearing loss, with a prevalence of 1.3%. The total cost was US$13 611, and the cost (for the screening stage) per case screened was US$4.

CONCLUSION: The program was considered effective with 2 out of 3 benchmarks achieved.

KEYWORDS: Cost analysis, effectiveness, newborn hearing screening, Thailand

INTRODUCTION

It has been shown that 0.3-15 per 1000 newborns across the world develop congenital hearing loss,[1] and 7-49 per 1000 newborns with a risk of hearing loss suffer from this disability.[2] As hearing loss can adversely affect speech and language development, the Joint Committee on Infant Hearing (JCIH) in 2019 recommended universal newborn hearing screening (UNHS) for early detection and timely intervention.[3] Although it is clearly demonstrated that UNHS with earlier intervention in hearing-impaired children could lead to positive long-term outcomes including language, reading, and academic performance compared to later intervention,[4,5] only 33% of newborns were screened for hearing loss under the available national hearing programs throughout the world.[1] In a high-income country (HIC), such as the United States, screening coverage could reach about 98% of all live births in 2020.[6] On the other hand, less than 1% of newborns in at least 64 low- to middle-income countries (LMICs), including Indonesia, India, Tajikistan, Nigeria, Ghana, and Malawi, were screened for hearing loss, which accounts for almost 40% of the world's newborn population.[1] Considerable number of newborns are not screened for hearing loss because a successful nationwide UNHS program is still challenging in many countries, particularly LMICs, and is influenced by various factors, including variation in the healthcare system and the cultural and national contexts in each country.[7]

Generally, there are a number of barriers to successful UNHS implementation, such as a lack of legislative support, poor hearing care accessibility, and limited financial and human resources.[7] However, the main obstacle to a successful national UNHS program in

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Thailand is a lack of qualified audiologists. It was shown in 2022 that there are only 203 audiologists in the healthcare system of Thailand,[8] whereas the 2021 Thai population was estimated at 66 171, 439 with 544 570 live births.[9] Moreover, around 60% of all audiologists were located solely in the capital city of Thailand, Bangkok.[8] This poor distribution across the country worsens the situation of scarce skilled personnel in other areas apart from Thailand's capital city.

In the lower southern region of Thailand, there are 7 provinces, including Trang, Phattalung, Satun, Songkhla, Pattani, Yala, and Narathiwat. These provinces are categorized as the 12th health service region under the Thai healthcare system. Hatyai Hospital is the public regional tertiary care hospital and the main referral center for all provincial hospitals across the twelfth health service region. To promote newborn hearing screening in 2021, the Thai government launched a policy for hearing screening in high-risk newborns for free under the universal health scheme. However, successful UNHS implementation is not necessarily limited due to financial support issues. In the 12th health service region, there are severe human resource shortages with only a few qualified audiologists available to conduct diagnostic tests and aural rehabilitation for hearing-impaired children, in the context of a clinical population comprising 5 000 255 people with 58 126 live births reported in 2021.[9] The shortage of qualified audiologists raises concerns about the suitability and effectiveness of UNHS implementation and potentially enormous costs in the 12th health service region. It is shown that ineffective screening procedures could lead to 80% of screenings being rendered useless in some settings.[7] Nonetheless, when a UNHS program is not feasible, particularly in the early stages of its establishment when it requires a great deal of effort and resources, a smaller scale in screening, such as a specific geographical subset or targeted group, is suggested rather than doing nothing.[7] Thus, our study was conducted to pilot targeted newborn hearing screening at Hatyai Hospital and to determine its effectiveness and costs considering the lack of qualified audiologists. This assessment was an initial critical step as per evidence-based local guidance to scale up a successful nationwide UNHS program.

METHODS

Ethical Clearance

Ethical approval was obtained from the Research Ethics Committee Hatyai Hospital, study code HYH EC 116-64-01, before the study began. Written informed consent was also obtained from all parents of subjects before they were enrolled in the study.

Study Design

A longitudinal descriptive study.

Subjects

All newborns at risk of hearing loss, from January 1 to December 31, 2021, at Hatyai Hospital, were recruited in the study. The risk factors were based on JCIH, 2019, which includes family history of childhood hearing loss, NICU stay of more than 5 days, hyperbilirubinemia with exchange transfusion, aminoglycoside administration of more than 5 days, history of asphyxia, history of extracorporeal membrane oxygenation (ECMO), in utero infections, craniofacial anomalies, syndromes associated with hearing loss, culture-positive infections associated with hearing loss, head trauma, chemotherapy, and caregiver concern.[3]

Location and Setting

Hatyai Hospital, with a capacity of 700 beds and an annual birth rate of about 5000 newborns, was selected for targeted newborn hearing screening for the following reasons. Two audiologists are available in the hospital, and 1 of them is qualified for diagnostic assessment and interventions for hearing-impaired children. In addition, since Hatyai Hospital is the main referral center for all provincial hospitals across the 12th health service region, Hatyai Hospital is the main tertiary care center responsible for all referred newborns.

Technology and Personnel

Transient otoacoustic emission (TEOAE) technology, Sentiero, PATH MEDICAL GmbH, Germany, was used for the screening procedure. The protocol is a nonlinear click stimulus with 85 dB peSPL. The pass criterion is a signal-to-noise ratio of at least 6 dB in 3 out of 5 frequencies (1, 1.5, 2, 3, 4 kHz), at least 60% reproducibility, stimulus stability above 80%, and artifact lower than 20%.

One audiologist in Hatyai Hospital, who was not qualified for diagnostic assessment and interventions in hearing-impaired children, was responsible for the screening procedure for high-risk newborns. The assignment was to obtain written consent forms, inform the parents of the importance of newborn hearing screening and subsequent follow-ups if required, perform the screening test, complete the case record forms, and make an appointment date if required.

One qualified audiologist in Hatyai Hospital was responsible for diagnostic assessment, including auditory brainstem response (ABR)/auditory steady-state response (ASSR) and subsequent intervention, in particular the fitting of hearing aids. Degree of hearing loss based on ABR/ASSR findings: mild 26-40 decibel estimated hearing level (dBeHL), moderate 41-55 dBeHL, moderately severe 56-70 dBeHL, severe 71-90 dBeHL, and profound >90 dBeHL.

All hearing-impaired infants who received early interventions, including hearing aid fitting and myringotomy with grommet insertions, had continued follow-up visits with a qualified audiologist and an otologist at the ear, nose, and throat (ENT) clinic.

Procedure

Two stages of TEOAE technology were used for the screening. Every high-risk newborn was screened at an age over 24 hours

MAIN POINTS

- In the 12th health service region of Thailand, there are several human resource shortages with only a few qualified audiologists available to conduct diagnostic tests and aural rehabilitation. As a result, this raises concerns over the suitability to implement a universal newborn hearing screening program.
- When a universal newborn hearing screening program is not feasible, particularly in the early stage, targeted newborn hearing screening is suggested, rather than doing nothing.
- The results from this study based on the targeted newborn hearing screening program can serve as evidence-based guidance for the government and other settings where their cultural and national contexts shoud be always considered in order to optimize newborn hearing screening protocols.

at a well-baby nursery (WBN) or the NICU by an audiologist. Any newborn who did not pass the screening in either ear was scheduled for another TEOAE test within 1 month of age at the NICU or the ENT outpatient clinic. The second-stage screening was also conducted by an audiologist. Any newborn who did not pass the second-stage test in either ear was scheduled for diagnostic assessment within 3 months of age. All hearing-impaired newborns were enrolled for interventions, including hearing aid fitting by 6 months of age and myringotomy with grommet insertions if indicated. All newborns were informed about the date of follow-ups if required by the screener with both verbal and written reminders. Parents who did not return for any of the appointments were contacted by phone.

Cost analysis was conducted for all screening, diagnostic, and intervention stages in US dollars for a whole year of the program. Equipment costs were calculated based on the manufacturer's price, amortized over 5 years (screening TEOAE machine) and 10 years (tympanometer, diagnostic TEOAE, ABR/ASSR, and real ear measurement machines) at a discount rate of 3%.[10] Wages of personnel were calculated based on their salaries and durations spent on screening, diagnostic, or intervention procedures. Hearing aid devices with maintenance costs were calculated based on the manufacturer's price. Surgical intervention, namely myringotomy with grommet insertions, was derived from hospital charges listings.

Primary Outcome Measures

The effectiveness of the program was determined with benchmarks from the American Academy of Pediatrics (AAP).[11]

1. Screening coverage ≥ 95%.
2. A referral rate ≤ 4%.
3. A follow-up rate ≥ 95%.

Data Management

The subjects were recorded as numbers with neither their first name nor surname written in the case record forms. Demographic data, risk factors associated with hearing loss, and screening/diagnostic/intervention results were recorded in the case record forms. All data were transferred to a spreadsheet (Microsoft, Redmond, US) for basic statistical analysis.

RESULTS

Program Performance

Out of 833 live births with risks of hearing loss, 792 newborns were successfully screened before 1 month of age, resulting in a screening coverage of 95.1% (Figure 1). Among 41 newborns not screened (4.9%), 32 newborns died from severe health conditions within 1 month of age, which prevented them from being successfully screened, and 9 newborns missed the screening because they were admitted to other wards outside routine WBN due to patient overload. Consequently, the screener did not recognize nor track these newborns. In terms of the referral rate, out of the total of 792 newborns screened, 31 newborns were referred for diagnostic assessment before 3 months of age, showing a referral rate of 3.9% (31/792). Although 127 newborns appointed for the second-stage screening, 36 newborns were lost to follow-up (28.3%, 36/127). In addition, among 31 newborns appointed for diagnostic assessment,

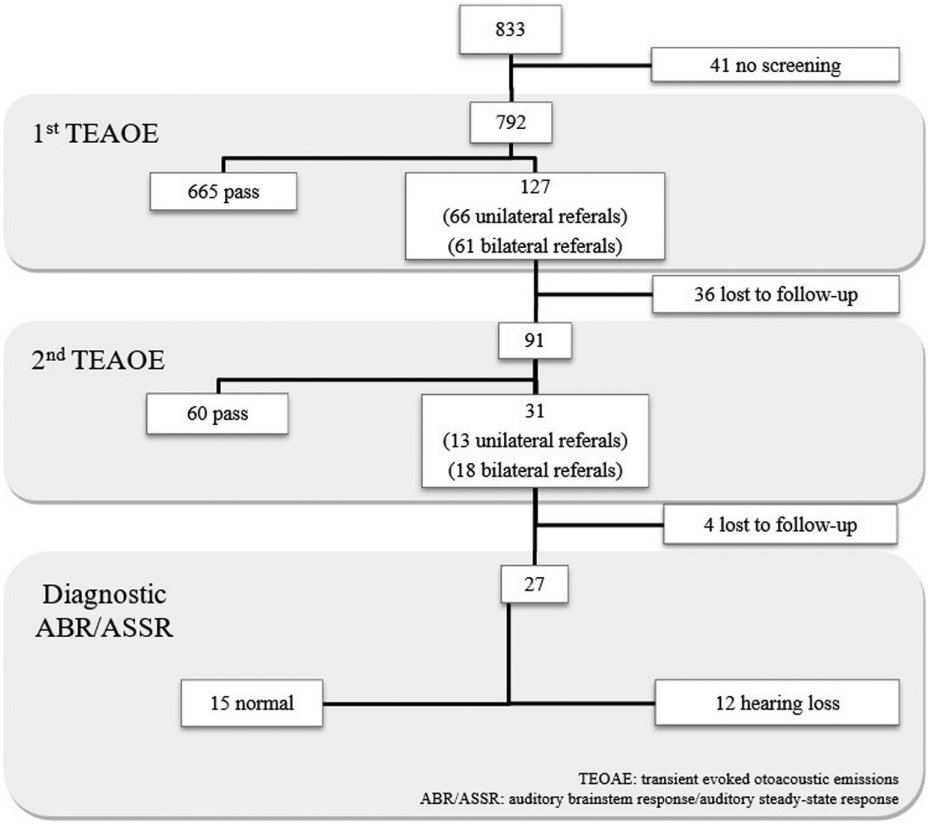

Figure 1. A flowchart of the screening procedure.

4 newborns were lost to follow-up (12.9%, 4/31). Three main reasons for being lost to follow-up, as explained by their parents, were travel inconvenience, work responsibilities, and avoidance visiting the hospital due to the coronavirus 2019 (COVID-19) situation.

Twelve hearing-impaired newborns were finally identified (Table 1). Five newborns had bilateral loss, and 7 had unilateral hearing loss. Four newborns developed OME, and 3 of them required myringotomy with grommet insertions at an age over 6 months. Ten newborns developed permanent hearing loss with a sensorineural component, yielding a prevalence of 1.3% (10/792).

Risk factors identified among newborns are shown in Figure 2. Also, basic costs used in the screening are detailed in Table 2.

Table 1. Characteristics of 12 Subjects with Confirmed Hearing Loss

Case	Type of HL (Right)	Type of HL (Left)	Other Disability	Intervention
1	Moderate CHL	Normal	Cleft palate	Myringotomy with grommet insertions
2	Mild CHL	Moderate mixed HL	Cleft palate	Myringotomy with grommet insertions
3	Mild CHL	Profound SNHL	Cleft palate	Myringotomy with grommet insertions
4	Mild CHL	Mild CHL	No	Watchful waiting
5	Mild SNHL	Normal	Cleft palate	Observation
6	Mild SNHL	Mild SNHL	No	Observation
7	Mild SNHL	Mild SNHL	No	Observation
8	Severe SNHL	Normal	No	Observation
9	Normal	Profound	No	Observation
10	Normal	Profound	No	Observation
11	Severe SNHL	Severe SNHL	No	Hearing aids
12	Profound SNHL	Profound SNHL	Cerebral palsy renal anomaly	Death

CHL, conductive hearing loss; HL, hearing loss; SNHL, sensorineural hearing loss.

DISCUSSION

Program Effectiveness

Regarding our program's effectiveness, 2 out of 3 AAP benchmarks[11] were achieved. Firstly, an AAP screening coverage rate of not lower than 95% was met, as 95.1% of live births were screened before 1 month of age. Nonetheless, 9 newborns (1.1%) missed the screening as they were admitted to other wards outside the WBN. This was unrecognized by the screener because those newborns were immediately transferred to other wards instead of the routine WBN or NICU due to patient overload; as a result, those newborns were finally discharged without hearing screening. Although this issue was related to communication between wards, to avoid missing screenings, all capable wards for newborn care in our hospital must be informed about routine hearing screening for every high-risk newborn, prior to discharge.

Secondly, a 3.9% referral rate was observed in the study, lower than the 4% rate the AAP[11] considers necessary. As a low referral rate can result in lower time and cost expenditures for a hearing screening program, especially in our setting where qualified personnel are very limited, the referral rate is a vital indicator in our program, ensuring that diagnostic assessment is effective and beneficial for all referred newborns. We believe that the main reason our referral rate is not too high is because an audiologist was assigned to the screening procedure rather than other trained health care providers. Although it is unnecessary to assign an audiologist for a screening procedure, we did this for 2 reasons. It is common to observe high-risk newborns with other severe health conditions, such as heart or lung diseases, and life support equipment including ventilators, pulse oximeters, and vital sign monitors. Thus, internal and external noise from newborns and any life support equipment, respectively, could limit success in a screening procedure with inexpert screeners. In addition, it is imperative for any newborn hearing screening program, particularly during its early implementation, where great effort and resources are required, to operate with the necessary amount of qualified personnel. We believe that, due to the limited number of qualified audiologists in the diagnostic stage of the program, it is even more important that screening is effective, ensuring an optimal referral rate rather than risk compromising the process due to screeners with insufficient expertise. Ineffective screening procedures could result in an overload in the diagnostic stage, leading to ineffective

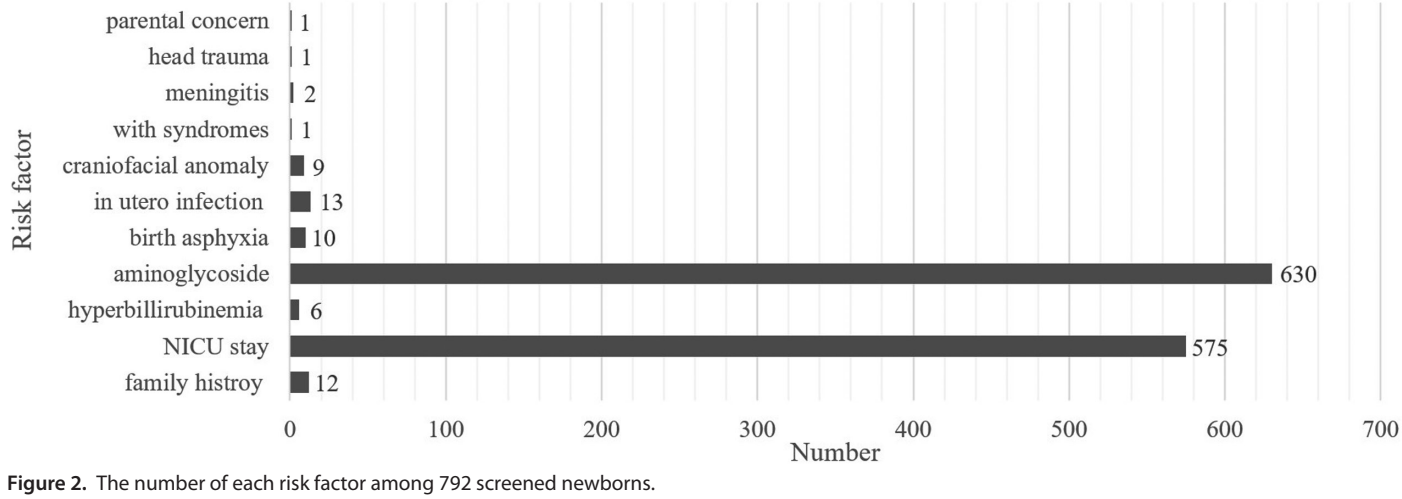

Figure 2. The number of each risk factor among 792 screened newborns.

Table 2. Basic Costs for the Newborn Hearing Screening and Intervention Program

Cost Item	US Dollar	Description/Assumption
Screening stage		
Screening TEOAE machine	2004	A TEOAE machine costs $10 938/unit. The cost was calculated based on the manufacturer's price per device, amortized over 5 years at a discount rate of 3%.[11]
Supplies	75	Reusable ear tips cost $75 for 1 pack of 30 pieces. One pack was used.
Wage	1287	Assumes 1 screener spent on average 15 min/newborn, at a wage of $6.5/h. 792 newborns were screened.
Diagnostic stage		
ABR/ASSR machine	3998	An ABR/ASSR device costs $41 875/unit. The cost was calculated based on the manufacturer's price per device, amortized over 10 years at a discount rate of 3%.[11]
Diagnostic TEOAE machine	1200	A diagnostic OAE machine costs $14 063/unit. The cost was calculated based on the manufacturer's price per device, amortized over 10 years at a discount rate of 3%.[11]
Tympanometer	666	A tympanometer machine costs $7813/unit. The cost was calculated based on the manufacturer's price per device, amortized over 10 years at a discount rate of 3%.[11]
Supplies	135	Disposable electrodes for ABR/ASSR testing cost $1.9/infant. The reusable ear tips for OAE and tympanometry cost $3.1/infant. 27 infants were tested.
Wage	351	Assumes 1 audiologist spent on average 2 h/infant, at a wage of $6.5/h. 27 infants were tested.
Intervention stage		
REM machine	2666	A REM machine costs $31 250/unit. The cost was calculated based on the manufacturer's price per device, amortized over 10 years at a discount rate of 3%.[11]
Hearing aids	782	The hearing aid used in the study costs $391/unit. One infant was fit bilaterally.
Myringotomy with grommet insertions	291	Myringotomy costs $97/procedure, and 3 infants underwent the surgery.
Wage	156	Assumes 1 speech-language therapist spent on average 1 h/infant for a total of 24 sessions (in 6 months), at a wage of $6.5/h. One infant had aural rehabilitation.
Total program expenditure	13 611	Total expenditure includes screening, diagnostic, and intervention costs.
Cost (for the screening stage) per case screened	4	Out of 833 live births, 792 newborns were screened.
Cost (for all stages) per case screened	17	Out of 833 live births, 792 newborns were screened.
Cost (for all stages) per case detected	1361	Only permanent hearing loss was determined. Out of 12 newborns confirmed for hearing loss, 10 newborns developed permanent hearing loss with a sensorineural component.
Exchange rate	1.00 US dollar = 32.00 Thai Baht (July 2, 2021)	

ABR/ASSR, auditory brainstem response and auditory steady-state responses; OAE, otoacoustic emissions; REM, real ear measurement; TEOAE, transient evoked otoacoustic emissions.

diagnostic assessment, as shown in some settings where 80% of poor screening arose from ineffective screening procedures.[7] Thus, for any settings with an early establishment of newborn hearing screening, especially in LMICs where a shortage of qualified audiologists for diagnostic assessment is commonly encountered,[12] we highlight the requirement for highly skilled and experienced screeners for high-risk newborns to ensure that an effective diagnostic assessment can be achieved.

Thirdly, lost-to-follow-up rates of 12.9-28.3% were found in the study, far exceeding the under 5% rate of AAP bechmarks.[11] The reasons for these high rates given by the parents included travel inconvenience, work responsibilities, and avoidance visiting the hospital during the COVID-19 situation. This potentially implies a pattern of not recognizing hearing loss as an important illness among those parents. Although the importance of newborn hearing screening was emphasized to the parents by the screener, this seems to have been ineffective. In fact, it is reported, in a systematic review, that the 3 most common factors leading to loss to follow-up were lack of knowledge among parents, distance, and work constraints.[13] Nevertheless, a high lost-to-follow-up rate is still a challenge in both LMICs and HICs, where nearly 50% of 27 countries that reported trustworthy findings showed a lost-to-follow-up rate over 30%.[1] Furthermore, among 53 studies reviewed, a wide range of 0.31-68% lost-to-follow-up rates was evident, and the most common strategy used to reduce this rate was a database management system,[13] which requires a considerable financial investment to develop a tracking system capable of monitoring all misses and referrals in screening programs. Another possible option for any setting with a limited financial resources, similar to ours, is to coincide follow-up appointments with immunization schedules to improve the follow-up rate at the second-stage screening.[14]

In terms of prevalence, our study found the prevalence of permanent hearing loss to be 1.3%, lower than in a previous report from Thailand[15] and others from HICs[16,17] at 6.7% and 2.3-4.6%, respectively. Two reasons related to loss of follow-up and the screening technology used, namely TEOAE, could explain our lower prevalence. First, high loss-to-follow-up rates (12.9-28.3%) were observed in our study. We do not know how many newborns lost to follow-up develop hearing loss. Second, since another technology, namely automated ABR, was not used in our program, auditory neuropathy could be missed

at the screening stage with TEOAE technology.[18] The prevalence of auditory neuropathy, which is commonly found in newborns at the NICU, could range from 0.2% to 24.1%.[18,19] It is worthwhile noting that we did not use automated ABR for the screening test in the program due to its higher cost compared to TEOAE. In consideration with financial limitations at our hospital for such a pilot hearing screening program, only TEOAE technology was available for the screening test at that time. Although many risk factors were also identified in our study population, an NICU stay and aminoglycoside administration were the main common risk factors found in all newborns screened, accounting for 72.6% (575/792) and 79.5% (630/792), respectively. Whereas the NICU stay seems unavoidable for newborns who needed intensive care, using aminoglycoside or other antibiotics associated with ototoxicity could raise concerns and warrant a discussion between the pediatric and ENT departments at our hospital regarding their benefits and harms. This, at least, can minimize the risk of hearing loss to newborns as much as possible.

Cost Analysis

The cost per case screened for the program was US$4 (Table 2), which is cheaper than routine newborn screening costs for phenylketonuria or hypothyroidism in Thailand. Also, it should be noted that congenital hearing loss in high-risk newborns is far more prevalent than phenylketonuria (0.0004%) and hypothyroidism (0.06%).[20] Furthermore, according to our empirical evidence in southern Thailand,[21] targeted newborn hearing screening (TNHS) had a chance of 93% to be cost-effective. Therefore, we believed that our program could be effectively implemented with reasonable costs. However, it is shown that TNHS only detected 50% of all children with congenital hearing loss.[7] That is, a half of all hearing-impaired children cannot be detected and are unlikely to receive early interventions with TNHS.

Upscaling a Newborn Hearing Screening Program

It is possible to upscale our program to screen all live births at Hatyai Hospital with 3 considerations. First, screeners should be any healthcare providers, for example, a nurse, nurse assistant, or health worker who can be trained by audiologists. These screeners, rather than audiologists, will be the main personnel responsible for screening all live births under supervision. Second, regarding the annual birth rate of around 5000 in the hospital and our current program performance at a referral rate of 3.9%, nearly 195 newborns/year (or around 16 newborns/month) will need comprehensive diagnostic assessment. This figure is feasible for a qualified audiologist to perform effective ABR/ASSR assessment with around one newborn/working day (16/20). Finally, automated ABR technology, despite its higher cost compared to TEOAE, should be acquired to screen high-risk newborns because this technology is not only able to identify more newborns with hearing loss, especially auditory neuropathy, but also has the ability to achieve a lower referral rate relative to TEOAE technology.[22] A low referral rate will be key to avoiding overload in the diagnostic stage of the program, particularly in areas where qualified audiologists are severely limited as seen in our setting.

Although our program was considered effective in subset groups, namely high-risk newborns, there are a number of challenges to upscaling the program for effective UNHS across the 12th health service region of Thailand. Firstly, inadequate numbers of qualified audiologists are currently encountered. As a tertiary care center, Hatyai Hospital needs more qualified audiologists to conduct competent diagnostic assessments and timely interventions for hearing-impaired children referred from provincial hospitals. Considering that there are 58 126 live births in the region and the current program performance is at a referral rate of 3.9%, 2267 newborns/year (or 189 newborns/month) are referred to our hospital for comprehensive diagnostic assessment. It is almost impossible for 1 qualified audiologist to perform effective ABR/ASSR assessments for around 10 newborns per working day (189/20). Therefore, more qualified audiologists are required at Hatyai Hospital or provincial hospitals must be developed to serve as additional referral centers, especially for the comprehensive diagnostic assessment by qualified audiologists in this region. Secondly, it should be noted that the 3 southernmost provinces, Pattani, Yala, and Narathiwat, in the 12th health service region, have been facing insurgency-related violence for decades. The culture of these southernmost provinces is deeply influenced by their bordering country, and such conflict is also linked to social, economic, and political tensions in southern Thailand. Also, it is reported that the maternal mortality ratio, often used as an indicator of the health of overall populations, in southern Thailand, was higher than in other regions due to unequal access to public health service and culture differences.[23] Public awareness campaigns regarding the importance of early detection and timely interventions in hearing-impaired children will be particularly helpful in this region. Additionally, a community-based service using telemedicine showed a success in newborn hearing screening[24] and can be another option, particularly in a setting where the unavailability of audiologists and limited infrastructure were encountered, similar to the situation in Thailand's three southernmost provinces. Therefore, all the issues mentioned above should be addressed and carefully tackled with a robust plan towards achieving effective UNHS in this region. Otherwise, if UNHS is implemented but referrals have poor access to or limited diagnostic assessment, any funding will be wasted.

Therefore, our results can serve as evidence-based guidance for the government and other settings where their cultural and national contexts should always be considered in order to optimize newborn hearing screening protocols. This is in addition to ensuring that financial resources, which are usually limited, are prioritized for health conditions on a needs basis and provide maximum benefit to hearing-impaired children.

Limitations

Two limitations in the study were observed. Firstly, the actual prevalence of hearing-impaired children in our high-risk newborns might be underestimated. This is because automated ABR was not used in the program; consequently, auditory neuropathy will be missed.[18] Also, considerable loss to follow-up was evident in the study; as a result, there may be some hearing-impaired newborns in this loss. Secondly, the referral rate of the program is likely to be lower if automated ABR is used because screening with TEOAE is more susceptible to ear canal debris, leading to a higher referral rate.[22]

CONCLUSION

TNHS at Hatyai Hospital was considered effective with 2 out of 3 benchmarks achieved, and all costs spent for the program were US$13 611 with the cost (for the screening stage) per case screened at US$4.

Ethics Committee Approval: This study was approved by the Ethics Committee of Hatyai Hospital (Approval No: HYH EC 116-64-01, Date: 9 December 2021).

Informed Consent: Written informed consent was obtained from the parents who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – P.L., P.P.; Design – P.L., P.P.; Supervision – P.P.; Resources – P.L.; Materials – P.L.; Data Collection and/or Processing – P.L.; Analysis and/or Interpretation – P.P.; Literature Search – P.L., P.P.; Writing – P.L., P.P.; Critical Review – P.P.

Declaration of Interests: The authors have no conflicts of interest to declare.

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