

Health Technology Assessment of “Portable Automated ABR” Neonatal Hearing Screening Device

Summary of findings

- Clinical efficacy, cost-effectiveness and operational challenges were assessed in the implementation of ‘Portable Automated ABR’ neonatal hearing screening devices in health-care facilities of Odisha.
- “Portable Automated ABR”, designed based on the principle of BERA, developed by the School of International Bio design (SIB), Dept. of Biotechnology (DBT) Govt. of India.
- It was found to be cost-effective as compared to OAE and can be used as a part of Universal Health Coverage (UHC) of hearing screening among infants in out-reach areas.

Background

Hearing impairment is one of the leading contributors to years lived with a disability, with over 5 percent of the world’s population (360 million people) currently living with a disabling Hearing Loss (HL). Congenital hearing impairment in infants and children has been linked with lifelong deficits in speech and language acquisition, poor academic performance, individual and social maladjustments, and emotional difficulties. Excessive emphasis is placed on the importance of early detection, reliable diagnosis, and timely intervention, as it can help in developing better skills among the hearing impaired infants equivalent to their peers.

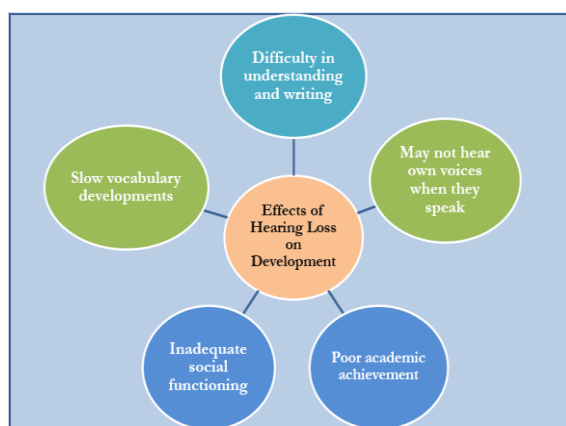


Figure 1: Effects of hearing impairment on child development

Studies indicated a prevalence of 5-6 per 1000 live births in India [1], of neonatal hearing loss (HL), with highly considerable repercussion on lifelong disability and Quality of Life (QoL). However, this figure only indicates a tip of the iceberg as the majority of hearing impairment cases remain undetected [2, 3].

Policy Recommendations

- For Universalizing the hearing screening services, provisions of screening services should be available at nearest facilities such as sub-divisional hospital, CHCs, and if possible at PHCs to reduce both indirect as well as intangible cost.
- Portable Automated ABR can be recommended in out-reach areas replacing BOA in RSBK at SDHs, CHCs and PHCs for greater coverage of UNHS.
- It is suggested to conduct a small scale implementation using existing infrastructure to identify, if any, operational challenges of the implementation as well as facilities available for cochlear implant for assessing budgetary implications before a large scale implementation.

As per RBSK program, an Otoacoustic Emission (OAE) is used at the facility level, while Behavioural Observation Audiometry (BOA) is adopted at the community level for hearing screening. For further confirmation, it is followed by Brainstem Evoked Audiometry Response (BERA) at referral facilities (4). Community-based screening is being carried out using a brief questionnaire and behavioural testing by a trained health worker during visit of mobile health team (MHT) under RBSK. Any infant who did not pass the screening is to be followed up at the district hospital for OAE and automated Auditory Brainstem Response audiometry (AABR) testing.

Major concern associated with the present hearing screening program under Rashtriya Bal Swasthya Karyakram (RBSK) was that it is provided through the District Early Intervention Centres (DEICs) which are available at the DHH level or higher level of medical care. In India, where non-institutional deliveries are still among the prevalent practices, the vast majority of the infants are left out from the early detection and intervention for the hearing impairment. Deliveries at CHC, PHCs and community level are also among the few missed cases of hearing screening and goes without any intervention or treatment. Other issues in the implementation of the program were identified as a lack of human resources, inadequate infrastructure, equipment-related shortcomings, and low priority for deafness prevention. These indicated the need for a portable technology which can detect the hearing impairment through first level of screening with better or similar diagnostic accuracy at various levels of care and at the same time it should be user-friendly too.

The “Portable Automated ABR” is a non-invasive, safe and simple technology been designed based on the principle of BERA. The device has been developed by the School of International Bio design (SIB) start-up Portable Automated ABR Innovation Labs India Pvt. Ltd by Dept. of Biotechnology (DBT) Govt. of India. The present Health Technology Assessment (HTA) was aimed to determine the cost-effectiveness of this technology by comparing Portable ABR against OAE as well as BERA, and examine the potential ethical implication prior to its introduction into the universal screening program.



Figure 2: Portable Automated ABR Neonatal Hearing Screening Device

Methods

OAE hearing screening test, which is commonly used under RBSK program, was compared with ‘Portable Automated ABR’. HTA was classified into three broad areas: diagnostic validation of ‘Portable Automated ABR’, economic evaluation and assessment of Quality of Life (QoL) of ‘Portable Automated ABR’, and ethical and social implication of ‘Portable Automated ABR’ implementation.

Results

‘Portable Automated ABR’ was found to be cost-effective. The sensitivity results revealed that the ‘Portable Automated ABR’ device had higher sensitivity in comparison to OAE. The number of false positive cases were far less in ‘Portable Automated ABR’ as compared to the OAE method, resulting into lower costs (direct, indirect and intangible), and less stress and anxiety on the families of new-borns. Study revealed that per unit cost for screening a new-born using ‘Portable Automated ABR’ was lower than that of OAE device.

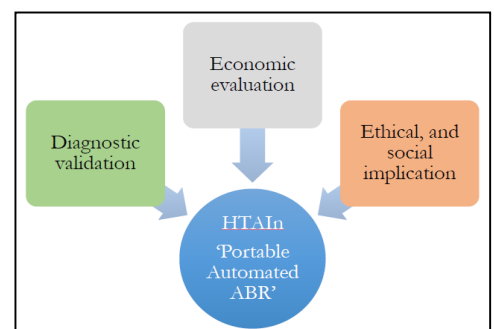


Figure 3: Overview of Health

The Portable Automated ABR device was found to be less costly and more effective. Cost-Effective Analyses (CEA) indicates that implementing Portable Automated ABR in the UNHS program will help in reducing the cost for the health system in long run but also to significantly reduce the societal cost.

	PHCs		CHCs		SDHs	
	Portable Automated ABR	OAE	Portable Automated ABR	OAE	Portable Automated ABR	OAE
Cost per facility	7,31,025	6,60,500	7,42,750	6,71,000	7,42,750	6,71,000
Total facilities in India	25650	25650	5624	5624	1108	1108
Amount in Crore (INR)	1876	1695	418	377	82	74

Table I: Expected overall budget implication for implementation of Portable Automated ABR at Primary Health Centres/ Community Health Centres (CHCs)/Sub-Divisional

Key Findings

- The Portable Automated ABR device has portability and doesn't requires any soundproof room.
- The test duration per baby was recorded between 10-15 minutes and it does not require considerable reliance on high manpower such as audiologist and is user-friendly in the nature. Hearing screening can be performed by any healthcare staffs, (preferably a staff nurse) with basic skill based training (3–5 days).
- Per-unit cost for screening a new-born using 'Portable Automated ABR' was lower than that of OAE device.
- Portable Automated ABR can detect **6240 cases** and OAE, **9360 cases** per annum
 - per unit cost of ABR and OAE are **INR 97** and **INR 67** respectively.
- The UNHS by Portable Automated ABR will cost lesser if we focus on the budgetary provisions as compared to OAE as it results into
 - **ICERs -7,17,889** for system implementation.
- Considering the annual birth rate, the prevalence rate of hearing loss, and the high diagnostic accuracy of device,
 - Portable Automated ABR imposes lower costs than the OAE device in long run.
 - In absence of skilled manpower can be easily taught to other staffs.

References

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