Outcome Report



Cost-effectiveness of Hearing Aid Devices among Older Adults in India

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HTAIn Regional Resource Centre



User Department

Ministry of Health & Family Welfare, Govt. of India

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Table of Contents

Research Team	2
Acknowledgements	4
List of Abbreviations	5
List of figures	6
Figure 5 Compliance of hearing aid use	236
List of Tables	7
Executive Summary	8
Background	10
Statement of the Problems	10
Hearing Impairment among Geriatric Population	12
Global Priority for Hearing Impairment	12
Prevalence of Hearing Impairment among Older Adults in India	13
National Program for Prevention and Control of Deafness (NPPCD)	14
Rationale of the Study	15
Objectives	15
Methods	16
Study design	16
PICOT (Population, Intervention, Comparator, Outcomes and Time horizon)	16
Model Specification	16
Model assumptions and validation	17
Costs parameters	17
Quality-of-life assessment	17
Results	18
Consultation or medical cost	18
Cost of hearing aid (Device cost)	18
Quality-Adjusted Life Years (QALYs)	20
Decision Tree	22
Incremental Cost-Effectiveness Ratio (ICER)	22
Compliance of hearing aid use	23
Budget Impact Analysis	23
Policy Implication and Recommendation	24
Conclusions	26
Deferences	27

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Dr. Sanghamitra Pati Principal Investigator

List of Abbreviations

ADL: Activities of Daily Living

GBD: Global Burden of Diseases

HRQoL: Health-related Quality of Life

ICER: Incremental Cost Effectiveness Ratio

IADL: Instrumental Activities of Daily Living

LMICs: Low- and Middle-Income Countries

LASI: Longitudinal Aging Study in India

NPPCD: National Program for the Prevention and Control of Deafness

QALYs: Quality of Adjusted Life Years

NPPCD: National Program for the Prevention and Control of Deafness

UT: Union Territory

WHO: World Health Organisation

YLDs: Years Lives with Disability

List of figures

Figures		Page No
Figure 1	Consequences of hearing impairment	10
Figure 2	Trend of Older Adults in India	13
Figure 3	Detailed information on the lowest, moderate, and highest priced hearing aid with specifications	19
Figure 4	Decision Tree for Hearing Aid	22
Figure 5	Compliance of hearing aid use	23

List of Tables

Tables		Page No
Table 1	Hearing impairment categories (adopted from WHO, 2017)	11
Table 2	Prevalence of Hearing Impairment Among Older Adults in India (Longitudinal Aging Study in India (LASI, 2017-18)	14
Table 3	Direct medical cost for consultation among the hearing-impaired older adults using hearing aids (Intervention)	18
Table 4	Direct medical cost for consultation among the hearing-impaired older adults not using hearing aids (Comparison)	18
Table 5	Hearing aid fitting cost at range of price of device cost	20
Table 6	Utility score among older adults with hearing impairments who use hearing aids versus those who do not	21
Table 7	Parameters Definition and Value	21
Table 8	Budget Impact Analysis	23

Executive Summary

Background

With the aging population on the rise, hearing loss emerges as a significant social concern. Given the challenges in the biological restoration of hearing, hearing aid utilisation stands as the primary means of rehabilitation for the older population (60 years and above). In India, adult-onset deafness prevalence stands at an estimated 7.6 percent, yet it remains a severely overlooked health issue among older adults. The Indian government recognized this issue and initiated the National Program for the Prevention and Control of Deafness (NPPCD) in 2006. This program aims to prevent avoidable hearing loss and ensure early identification, diagnosis, and treatment. Hearing aids play a pivotal role in mitigating hearing disability among the older population, leading to noticeable improvements in their quality of life shortly after being fitted. However, sustained use of hearing aids is crucial for long-term cost-effectiveness. Under the NPPCD, individuals needing surgical intervention, hearing aid fitting, or rehabilitative therapy are referred to ENT specialists and audiologists at the district level. For those with sensorineural hearing loss requiring hearing aids, provision is made at the district level by the Ministry of Social Justice & Empowerment. Notably, the NPPCD lacks a dedicated budget allocation for hearing aid provision. Thus, this study evaluates the costeffectiveness and budget impact of hearing aid devices for hearing-impaired older adults in India.

Methods

We performed a cost-effectiveness study utilizing a Decision Tree model incorporating aggregate data, insights gleaned from literature reviews, and primary data concerning quality of life. The hearing impairment is defined as Mild (20 - 34 decibels), Moderate (35 - 64 decibels), and Severe (65 and above decibels) as per the WHO classification.

- **Population:** Older adults (aged 60 years and above) diagnosed with hearing impairment.
- **Intervention:** Utilization of the conventional procedure for fitting hearing aids.
- Comparison: Older adults with hearing impairment who do not use hearing aids.
- Outcomes: Costs per quality-adjusted life-year (QALY) gained.
- **Time horizon:** Evaluation over a 3-year period.

Findings

Among hearing-impaired older adults using hearing aids, the direct medical consultation cost was INR 4368, whereas for those not using hearing aids, it was INR 1583. The hearing fitting cost for **one ear is INR 12,368 and for both ears INR 20,368** including the direct medical cost for consultation. Among hearing-impaired older adults using hearing aids, the mean utility score stood at 0.832 (Standard Deviation: 0.211), translating to Quality-Adjusted Life Years (QALY) of 5.824. Conversely, among hearing-impaired older adults not using hearing aids, the mean utility score was notably lower at 0.601 (Standard Deviation: 0.352), resulting in QALY of 4.207.

Conclusion and Recommendations

The study findings underscore the economic considerations associated with hearing aid provision for older adults in India. Over a three-year period, the cost per individual for fitting a hearing aid, **priced at INR 8000 for Digital BTE**, amounts to INR 12,368 for a single ear

and INR 20,368 for both ears. Additionally, the Incremental Cost-Effectiveness Ratio (ICER) for hearing aid fitting is INR 6,670 per Quality-Adjusted Life Year (QALY) gained for one ear and INR 11,617 per QALY gained for both ears. The estimated total national cost for hearing aid provision over three years is approximately INR 1230.2 crore, translating to an annual expenditure of INR 410.0 crore for addressing the hearing needs of older adults in India.

Parameters	Population	Total (N)	Total
Number of Older Adults (60+) [Census 2011, predicted as on July 2022]	-	149000000	14.9 Crore
Prevalence of hearing impairment [Longitudinal Ageing Study in India, 2018]	10%	1,49,00,000	1.49 Crore
Need hearing aid among hearing- impaired older adults [Marbaniang et al. 2022]	4.7%	7,00,300	70.0 thousand
Prevalence of hearing impairment need hearing aid for one ear [LASI, 2018]	35.0%	2,45,105	24.5 thousand
Prevalence of hearing impairment need hearing aids for two ears [LASI, 2018]	65.0%	4,55,195	45.5 thousand
Cost per individual for single ear (for 3 years)		12368.00	
Cost per individual for both ears (for 3 years)		20368.00	
Total cost for single ear (for 3 years)		3,031,458,640.00	INR 303.1 Crore
Total cost for both ears (for 3 years)		9,271,411,760.00	INR 927.1 Crore
Total cost for hearing aid fitting (for 3 years)		12,30,28,70,400.00	INR 1230.2 Crore
Annual cost for fitting hearing aid		4,100,956,800.00	INR 410.0 Crore

To ensure comprehensive hearing healthcare, it is imperative to integrate hearing health into national and state-level **geriatrics health policies** and programs like NPPCD, incorporating regular screening, rehabilitation services, and caregiver support. **Ayushman Arogya Mandir's** policy on ear, nose, and throat (ENT) care underscores the importance of community-based services, with medical officers and audiologists receiving extensive training for successful implementation. Moreover, recognizing the impact of hearing impairment on communication and mental well-being, **Senior Citizen homes** must prioritize access to hearing aids within their healthcare services. Additionally, launching national awareness campaigns to destigmatize hearing loss and promote early intervention is critical, targeting both older adults and healthcare professionals to encourage regular screenings and timely treatment.

Background

Statement of the Problems

The phenomenon of population ageing has become increasingly pronounced in the twenty-first century, particularly in low- and middle-income countries (LMICs), owing to advances in healthcare and socio-economic development. In India, as per the 2011 census, individuals aged 60 years and above constitute 8.6% (approximately 103 million) of the total population (United Nations, World Population Prospects). Projections indicate a substantial increase to 19.5% (319 million) by 2050, primarily due to improved longevity (United Nations, World Population Prospects). This demographic shift poses significant economic, health, and social challenges, exacerbated by evolving family structures and limited social support systems. Consequently, policymakers face the imperative of implementing provisions to enhance the quality of life for the ageing population amidst these evolving dynamics.

Hearing impairment among the older population is a prevalent global health concern, affecting millions of individuals worldwide. According to the World Health Organization (WHO), approximately one-third of individuals aged 65 years and above experience disabling hearing loss, with this figure rising significantly among those aged 75 years and older. The prevalence of hearing impairment varies across regions, with higher rates observed in LMICs, where access to healthcare services and hearing interventions may be limited. Factors contributing to the increased prevalence of hearing loss in older age include cumulative exposure to noise over the lifespan, genetic predispositions, and age-related changes in the auditory system. As the global population continues to age, addressing the burden of hearing impairment among older adults remains a critical public health priority, necessitating comprehensive strategies for prevention, early detection, and management to enhance the quality of life for this vulnerable demographic.

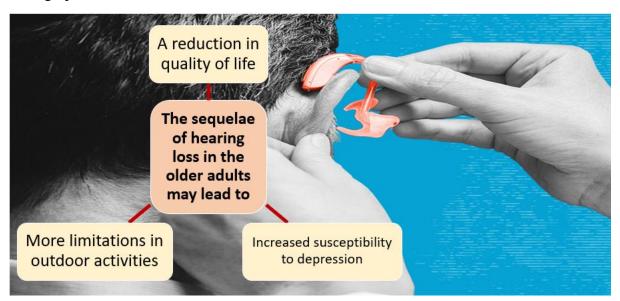


Figure 1. Consequences of hearing impairment

Hearing aids are 'needed' by 401.4 million persons worldwide. The vast majority (83 percent) do not use hearing aids, with higher rates in some locations, such as Africa (90 percent). Accounting for hearing aid coverage lowered morbidity by 14.6 percent (95 percent UI 13.1-16) - from 25 to 21.3 million Years Lives with Disability (YLDs) (Orji et al., 2020). It was

anticipated that if every single prevalent case in need used a hearing aid, the disease burden in this population would be decreased from untreated 25 million YLDs to 10.3 million YLDs, a 59 percent reduction. Some potential options to improve access to hearing aids include the development of innovative low-cost technology with successful service delivery models, governmental and regulatory changes to improve access, and combating stigma and lack of knowledge (Orji et al., 2020). The various stages of hearing impairment as per the WHO is provided in Table 1.

Despite the high prevalence of hearing impairment in human populations, hearing aid adoption remains low. A small percentage of adults with hearing loss seek therapy for their hearing difficulties and use hearing aids (Knudsen et al., 2010; Zhao et al., 2015). According to several studies, a high proportion of persons who could benefit from hearing aids do not have them. Furthermore, not all individuals who are given hearing aids use them, use them on a regular basis, or are satisfied with them. According to surveys undertaken in the United Kingdom, Australia, Finland, Denmark, and the United States, between 1% and 40% of hearing aids prescribed are never or rarely used. Four audiological determinants (hearing loss severity, hearing aid type, background noise acceptance, and insertion gain) and seven non-audiological determinants (self-perceived hearing problems, expectation, demographics, consultation, support from significant others, self-perceived benefit, and satisfaction) were identified as influencing hearing aid adoption and use (Ng et al., 2015). Furthermore, the difficulties in using hearing aids in LMICs are linked to socioeconomic variables. Many patients are not able to afford the cost of these devices. A prior study in India found that older persons who used hearing aids were satisfied. A recent study also found that older persons who use hearing aids are satisfied with the cost and services provided by the hearing aid. According to the findings of this recent study, the majority of older persons are concerned about the cosmetic appearance of their hearing aids (Sanju et al., 2018).

Table 1. Hearing impairment categories (adopted from WHO, 2017)

Hearing	Better ear hearing	Hearing in a quiet	Hearing in a noisy
impairment	level (decibels)	environment	environment
level			
Unilateral	< 20 in better ear	Does not have problems	May have real difficulty
	and $>=35$ in the	unless sound is near	following/ taking part in a
	worse ear	(poorer hearing ear)	conversation
Mild	20 - 34	Does not have problems	May have real difficulty
		hearing what is said	following/taking part in a
			conversation
Moderate	35 - 49	May have difficulty	Has difficulty hearing and
		hearing a normal voice	taking part in conversation
Moderately	50 - 64	Can hear loud speech	Has great difficulty in
Severe			hearing and take part in
			conversation
Severe	65 - 79	Can hear loud speech	Has very great difficulty
		directly in one's ear	hearing and taking part in
			conversation
Profound	80 - 94	Has great difficult	Cannot hear any speech
		hearing	

Hearing Impairment among Geriatric Population

A recent study conducted among adults aged 45 years and above in India found the prevalence of hearing impairment to be around 6.9% (Bharti et. al, 2022). People with hearing impairment demonstrated difficulty in mobility, activities of daily living (ADL)/instrumental activities of daily living (IADL), and socialization process (Bharti et. al, 2022). Hearing impairment may be perceived as a social stigma among older adults due to which they fail to seek help (Sprinzl, 2010). Older adults may avoid socialization and show paranoid tendencies. It may also result in anxiety and depression. Furthermore, this may also lead to non-compliance with drugs and other therapeutic interventions (Fook et al, 2000). Hearing impairment may also impair the normal communication process as the individuals cannot monitor their own speech.

Hearing impairment profoundly impacts the quality of life among the older population. As individuals age, they often experience gradual deterioration in hearing acuity, leading to difficulties in communication, social interaction, and emotional well-being. Hearing loss can hinder engagement in everyday activities, such as conversations with family and friends, participation in social gatherings, and enjoyment of leisure pursuits. Furthermore, it can contribute to feelings of isolation, loneliness, and depression, thereby affecting overall mental health. Beyond social and emotional implications, untreated hearing impairment is also linked to cognitive decline and a higher risk of developing conditions like dementia. Therefore, addressing hearing loss among older adults is crucial not only for preserving their physical health but also for promoting their overall quality of life and well-being. Access to affordable and effective hearing aids, along with supportive interventions, plays a vital role in mitigating the negative impact of hearing impairment and empowering older individuals to lead fulfilling lives.

Global Priority for Hearing Impairment

Hearing loss is considered as the major cause of disability globally with 10% of the global population with mild or greater hearing loss. Adult-onset hearing loss is ranked 13th among the leading cause of the global burden of diseases (GBD) and 9th in terms of years of healthy life lost as a result of the disability. With increased longevity, there has been reduced attention to disability, including deafness and hearing impairment. More than half of the global burden of hearing impairment is caused by preventable ear diseases specifically chronic otitis media. If secondary complications are not treated, ear disease may lead to sensorineural hearing loss.

Millions of people in the world are living with unaddressed hearing disabilities due to lack of awareness, unavailability of the required hearing care services and access to it. As per the WHO 2017 report on "global costs of unaddressed hearing loss and cost-effectiveness of interventions", information is available on the overall cost for healthcare sectors which ranges between \$67-107 billion, however separate estimates on the cost of providing hearing services and assistive devices are lacking. Hearing disabilities results in loss of productivity, unemployment, and premature retirement (causing \$105 billion costs annually) from the system perspective, and in terms of societal perspective, it results in social isolation, communication difficulties and stigma (causing \$573 billion costs annually) (WHO 2017).

Hearing loss is the second most common cause of YLD which is accountable for 4.7% of total YLD (WHO 2017). Though the impact of hearing loss is well established, still much information is not available for LMICs (WHO 2017). Evidence suggests that early identification and management of hearing losses can prevent long-term consequences for the

health system as well as for society. There is also a lack of crucial information and required country-specific data, especially for LMICs. Global cost for healthcare sectors ranges between \$67-107 billion for unaddressed hearing loss. From health system perceptive, it results into loss of productivity, unemployment and premature retirement (causing \$105 billion cost annually). From societal perspective, it results into social isolation, communication difficulties and stigma (causing \$573 billion cost annually). Evidences suggests that early identification and management of hearing losses can prevent long term consequences for health system as well as for society.

Prevalence of Hearing Impairment among Older Adults in India

Moreover, with an increase in the elderly population, hearing loss is a problem of considerable social relevance. As biological restoration of hearing is difficult, hearing aid use is the main rehabilitation instrument for these older population.

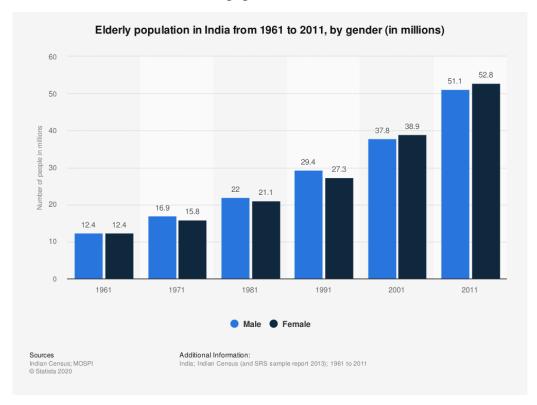


Figure 2. Trend of Older Adults in India

In India, almost 6.3 percent of the total population – around 63 million people have some type of significant hearing loss. The estimated prevalence of adult-onset deafness in India was found to be 7.6 percent (Galhotra and Sahu, 2019; Garg et al. 2009). Hearing impairment among older adults is severe though most neglected health condition in India, which needs to be tackled properly. The Longitudinal Aging Study in India (LASI, 2017-18), a nationally representative cohort, revealed a 10.06% prevalence of hearing impairment among older adults aged 60 years and above in India. Additionally, the study found that approximately 90% of individuals with hearing impairment were not undergoing any form of treatment (Table 2).

Table 2. Prevalence of Hearing Impairment among Older Adults in India (Longitudinal Aging Study in India (LASI, 2017-18)

Age (Years)	≥45	≥50	≥60
Sample size	65,562	52,380	31,464
Prevalence	4637 (7.09%)	4138 (7.92%)	3155 (10.06%)
Impairment in One Ear	40.74%	38.77%	34.77%
Impairment in Two ears	59.26%	61.23%	65.23%
Treatment Received	10.71%	9.99%	9%

Untreated ear infections have various negative consequences, including hearing loss, social isolation, loneliness, psychosocial distress, anxiety, and depression. Hearing aid fitting can increase the quality of life of people with hearing loss. It is a cost-effective intervention as compared with rehabilitation interventions required after the detection of hearing problems. However, adults generally delay seeking help usually five to ten years after the hearing problems. Lack of awareness and indifferent attitudes regarding ear problems are the key challenges preventing people from seeking treatment. Even in LMICs, only 20% population have reported that the financial burden of treatment was a hurdle in seeking treatment as compared to 24%, who reported that they did not think it was urgent and another 28% were not aware that in case of any hearing problem who they need to consult or discuss.

National Program for Prevention and Control of Deafness (NPPCD)

In 2006, the Indian government launched the National Program for the Prevention and Control of Deafness (NPPCD). During the eleventh five-year plan, the programme was completely centrally supported. The long-term goal of the NPPCD is to reduce the entire disease burden of hearing impairment and deafness by 25 percent by the end of the eleventh five-year plan. It was initially introduced in 25 districts in 10 states and one Union Territory as a trial initiative (UT). During 2007–2012, it was expanded to encompass 203 districts in all states and territories. The programme intends to cover three levels of preventive and care, including primary, secondary, and tertiary ear care, by providing an appropriate response at each level. It tries to prevent preventable hearing loss due to disease or accident, identify and treat significant ear issues early, and medically rehabilitate deaf individuals of all ages. In the 12th plan, it is envisaged to gradually expand the programme to an additional 200 districts, possibly encompassing all states and territories by March 2017.

The program's purpose is to prevent preventable hearing loss due to disease or injury; and to early identification, diagnosis, and treatment of ear issues that cause hearing loss and deafness. It also seeks to provide medical rehabilitation for deaf individuals of all ages. In addition, it intends to expand existing intersectoral links to ensure the continuation of the rehabilitation programme for deaf individuals, and to develop institutional capacity for ear care services by providing support for equipment, materials, and personnel training. In the twelfth plan hearing, the Ministry of social justice and empowerment will give AIDS medication (Department of disability). The two ministries have already inked an implementation agreement.

Rationale of the Study

The rationale for this study stems from the significant global burden of hearing impairment, affecting approximately 360 million individuals worldwide, with a predominant impact on those residing in LMICs where access to suitable ear and hearing care treatments is often limited. Hearing loss not only poses obstacles to individuals and their families but also leads to detrimental effects on communication, language learning, academic achievement, and employment opportunities. Moreover, untreated hearing loss contributes to feelings of loneliness, isolation, and cognitive impairment among older adults. Despite its profound consequences, there has been a relative lack of efforts to evaluate the economic costs of hearing loss, particularly in LMICs.

Prioritizing hearing impairment as a public health concern necessitates policymakers' investment in resources and effective planning for ear and hearing care promotion. The WHO emphasizes prevention, screening, and early intervention as crucial components of public health efforts to address hearing loss. However, to bolster the evidence base, there is a need for country-specific data on the cost of untreated hearing loss and the cost-effectiveness of interventions.

While hearing aids are recognized as a cost-effective intervention, ensuring their continuous use is essential for long-term effectiveness. Despite efforts like the NPPCD in India, which provides services such as **surgical intervention**, **hearing aid fitting**, **and rehabilitative therapy** at the district level, there remains a **gap in budget allocation** specifically for the provision of hearing aids, highlighting a crucial area for policy improvement and research attention.

According to WHO the interventions to address hearing loss included:

- Prevention: Evidence indicates that preventing hearing loss through early diagnosis
 and treatment of middle ear infection is very cost-effective. The allocation of health
 resources towards the prevention of noise-induced hearing loss is therefore a viable
 alternative.
- Screening programmes: In general, screening infants, school-aged children, and adults over the age of 50 for hearing loss is proven to be cost-effective. For maximum advantage, it is essential to limit false-positives and build a tracking system.
- Hearing aid devices: It has been demonstrated that hearing aids are cost-effective, particularly when used continuously and in conjunction with audiological rehabilitation. Hearing aid intervention is crucial for older adults due to the prevalence of hearing loss and its negative impact on communication, social interaction, and emotional well-being. Hearing aids improve hearing ability, facilitate better communication, and reduce feelings of isolation, loneliness, and depression. They also enhance cognitive function, leading to better engagement in cognitive activities and social participation, ultimately promoting mental and emotional health, social connectedness, and cognitive vitality.

Objectives

To evaluate the cost-effectiveness of hearing aid devices for hearing-impaired older adults in India.

Methods

Study design

We performed a cost-effectiveness study utilizing a decision tree model incorporating aggregate data, insights gleaned from literature reviews, retrospective data, and primary data concerning quality of life.

PICOT (Population, Intervention, Comparator, Outcomes and Time horizon)

Population: Older adults (aged 60 years and above) diagnosed with hearing impairment.

Intervention: Utilization of the conventional procedure for fitting hearing aids.

Comparison: Older adults with hearing impairment who do not use hearing aids.

Outcomes: Assessment of costs per quality-adjusted life-year (QALY) gained.

Time horizon: Evaluation over a 3-year period.

Model Specification

The hearing impairment is defined as Mild (20 - 34 decibels), Moderate (35 - 64 decibels), and Severe (65 and above decibels) as per the WHO classification (WHO, 2017). If hearing changes, there would be an opportunity to seek medical treatment. Then, some of these individuals would be fitted with monaural or binaural hearing.

A person with mild, moderate, or severe hearing loss who does not use a hearing-aid throughout the subsequent cycle would maintain that status (next year). To be prudent, the lifespan of hearing aids was set at 3 years. Every 3 years, the cost of hearing aids would be added to the bill of continuous hearing aid users. We believed that if their hearing status changed, all evaluations would be repeated and further fees would be incurred. From a social perspective, the cost-effectiveness of hearing-aid use will be calculated. In addition to direct expenditures, the analysis will consider indirect costs such as travel expenses and lost productivity.

This study determined the optimal decision regarding the adoption of hearing aid devices based on their cost and effectiveness in improving the quality of life for older adults with hearing impairment. This model employs a decision tree framework to analyze the cost-effectiveness of hearing aid devices. Decision trees are well-suited for evaluating complex decisions with multiple possible outcomes and uncertain variables, making them ideal for healthcare interventions such as the adoption of medical devices. The model focuses on older adults (aged 60 years and above) in India who experience hearing impairment. This population segment is of particular interest due to the prevalence of age-related hearing loss and the potential impact of hearing aid devices on their quality of life.

Cost variables encompass the initial purchase cost of hearing aid devices, along with maintenance and repair expenses, and the cost associated with professional fitting and follow-up appointments. Effectiveness variables focus on measuring improvements in hearing ability through standardized tests and the quantification of Quality-adjusted Life Years (QALYs) gained. Utility variables include pre and post-intervention Health-related Quality of Life (HRQoL) scores and assessments of patient satisfaction with hearing aid devices. Other variables considered are age, gender, socioeconomic status, comorbidities, and accessibility to healthcare services. Decision nodes within the model include the pivotal choice of whether to

adopt a hearing aid device, contingent upon factors such as cost, perceived benefits, and personal preferences. Subsequent decisions involve maintenance, repair, and follow-up appointments, as well as potential alternative interventions like cochlear implants if hearing aid devices prove ineffective. Outcomes are evaluated through metrics such as the cost-effectiveness ratio, comparing incremental costs and effectiveness to alternative interventions or no intervention, QALYs gained, and utility scores, which gauge the impact of hearing aid devices on overall health-related quality of life and patient satisfaction.

Model assumptions and validation

The effectiveness of hearing aid devices is grounded in empirical evidence gleaned from rigorous clinical trials and studies conducted within similar populations. Costs associated with these devices are meticulously estimated, taking into account prevailing market prices and healthcare service fees in India. The model operates under the assumption of a certain level of compliance and adherence to the prescribed use of hearing aid devices, crucial for accurate evaluation. To factor in the temporal dimension, future costs and benefits are appropriately discounted at a rate reflecting time preference. Sensitivity analysis forms a vital component of the model, serving to gauge its resilience to variations in key parameters such as device cost, effectiveness, and discount rate, while also exploring the impact of uncertainty in input variables on the model outcomes. Validation of the model is conducted through comparisons with real-world data and outcomes observed in clinical practice, ensuring its reliability and relevance. Additionally, the model's predictions are juxtaposed with those of alternative modelling approaches to ascertain consistency and enhance reliability in its findings.

Costs parameters

In this investigation, we considered costs from a societal perspective. Societal expenses consist of additional health care and non-health care expenditures (regardless of who pays for them), minus savings deriving from a potential increase in productivity due to the intervention. The costs connected with consultations (General Practitioner, ENT specialist or Audiologist, diagnostics (audiometry), hearing-aid fitting, the hearing-aid instrument, and hearing-aid use (batteries and repair) were included in the study. The direct non-health care costs including time and travel expenses, related to hearing-aid fitting.

Quality-of-life assessment

We interviewed 636 individuals having hearing problems, among 360 hearing-impaired older adults not using hearing aids and 276 hearing-impaired older adults using hearing aids. We utilised the EuroQol 5 Dimensions to assess the change in health-related quality of life (EQ-5D). This generic instrument comprises of five questions pertaining to the dimensions of overall health status (mobility, self-care, daily activities, pain and complaints, and feelings). The information collected from participants using the EQ-5D-5L is transformed into a health utility index, which provides a quantitative evaluation of the general state of health. Based on the responses to the five questions, the EQ-5D-5L score theoretically ranges from -1 (representing the highest possible health state) to -0.923 (indicating a condition worsening to the point of death). The utility values for every possible 3125 health states were obtained from a study conducted in India by Jyani et al. (2022). The mean utility score and standard deviation for each disease condition were calculated.

Results

The costing of hearing aid using older age group consisting consultation, device costs, transportation and maintenance costs. Data were collected from both primary and secondary sources. The secondary data have been collected through various databases and literature reviews. The primary data were collected from the older adults using structured questionnaires.

Consultation or medical cost

Table 3 shows the direct medical costs for consultation among hearing-impaired older adults who use hearing aids, while Table 4 shows the direct medical costs for consultation among hearing-impaired older adults who do not use hearing aids. The consultation and transportation costs were calculated over a three-year period, based on the average use of hearing aids.

Table 3. Direct medical cost for consultation among the hearing-impaired older adults using hearing aids (Intervention)

Costing	Average cost among the hearing-impaired older adults using hearing aids							
parameters			[source: pri	mary data],	(N=276)			
	1	Average Cos	st per perso	n	Frequency	Cost per		
	Severe	Moderate	Mild	Overall		person		
	(N=118)	(N=122)	(N=36)	(N=276)		(INR)		
Consultation	123.00	101.00	102.00	111.00	Once in 3 years	111.00		
Investigation	493.00	446.00	500.00	473.00	Three times per	4257.00		
(audiometry and								
post-visit cost)		year (473*3*3)						
Total						4368.00		

Table 4. Direct medical cost for consultation among the hearing-impaired older adults not using hearing aids (Comparison)

	Average cost among the hearing-impaired older adults not-using hearing aids [source: primary data], (N=360)								
Costing		Average Co	ost per pers	on	Frequency	Cost per			
parameters	Severe	Moderate	Mild	Overall		person			
	(N=76)	(N=131)	(N=153)	(N=360)		(INR)			
Consultation	192.00	100.00	100.00	131.00	Once in 3 years	131.00			
Investigation	766.00	415.00	118.00	363.00	Twice for first	1452.00			
					year; once for				
		subsequent years							
		(363*4)							
Total						1583.00			

Cost of hearing aid (Device cost)

We conducted a thorough search on the Government e-Marketplace (GeM) [https://gem.gov.in/aboutus] for information about the procurement of a hearing aid. Our search yielded a total of 293 available products, with prices ranging from 5,000 INR to 30,000 INR for single-ear unit. Figure 3 provides detailed information on the lowest, moderate, and highest-priced product for single ear, as well as their specifications. The cost includes device, maintenance, and battery prices.

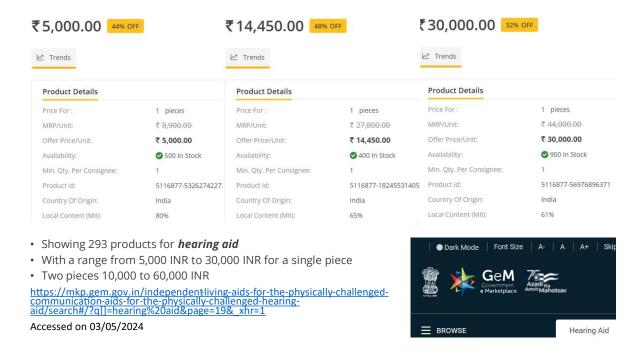


Figure 3. Detailed information on the lowest, moderate, and highest priced hearing aid with specifications

In addition to exploring the price of hearing aids, we conducted searches on both the Ministry of Social Justice and Empowerment's website and the Ministry of Health & Family Welfare's website. On the Ministry of Social Justice and Empowerment's website, we found information regarding the 'Aids and Assistive Devices for Persons with Disability under ADIP Scheme,' which detailed specifications for a BTE Digital Type Hearing Aid Type II. However, the specific price was not provided. Subsequently, our search on the Ministry of Health & Family Welfare's website yielded an office memorandum dated December 1st, 2020, outlining revised rates and guidelines for reimbursement of expenses on purchasing hearing aids under CS(MA) rules, 1944 and CGHS. The revised ceiling rates for various types of hearing aids for one ear were specified as INR 8000.00 for Digital BTE and INR 9000.00 for Digital ITC/CIC. These rates encompass all applicable taxes, including GST, and come with a three-year warranty. Additionally, the cost of BTE type hearing aids includes the expense of a hearing mould, while the cost of ITC/CIC type hearing aids covers the cost of a customized shell. With the consultation with the experts, we consider **Digital BTE (INR 8000) for our modelling**.





No. S.11011/37/2019-EHS
Government of India
Ministry of Health & Family Welfare
Department of Health & Family Welfare
[EHS Section]

Nirman Bhawan, New Delhi 1st December, 2020

OFFICE MEMORANDUM

Subject: Revision of rate & guidelines for reimbursement of expenses on purchase of Hearing Aids under CS(MA) Rules, 1944 and CGHS.

The undersigned is directed to refer to the Office Memorandum No. S.14025/10/2002/MS dated 26th May, 2015 on the above mentioned subject and to state that on the basis of recommendations of an Expert committee, it has been decided to revise the rates and guidelines for hearing aids reimbursement under CS(MA) Rules, 1944 and CGHS.

The revised ceiling rates fixed for various types of hearing aids (for one ear) are as under:-

Digital BTE

Rs.8,000/- [Eight thousand only]

Digital ITC/CIC

Rs.9,000/- [Nine thousand only]

The above revised cost of hearing aids shall include all taxes, including GST and shall carry three years' warranty. The cost of BTE type hearing aids shall also include the cost of hearing mould. The cost of ITC/CIC type hearing aids shall also include the cost of customized shell.

Table 5. Hearing aid fitting cost at range of price of device cost

	Device cost (in INR)
Device cost for one ear (A)	8000.00
Device cost for two ears (B)	16000.00
Direct medical cost for hearing aid fitting and post visit (C)	4368.00
Total cost for one ear (A+C)	12368.00
Total cost two ears (B+C)	20368.00

Quality-Adjusted Life Years (QALYs)

To calculate Quality-Adjusted Life Years (QALYs) from utility scores, we require two key pieces of information: the duration of time, which denotes the period over which a particular health state is experienced, and the utility score, representing the quality of life associated with that health state, typically measured on a scale from 0 to 1. In this scale, 0 signifies death and 1 denotes perfect health. The formula for computing QALYs is straightforward: QALYs =

Duration of time × Utility score= 7 years × mean utility score. Table 5 present the utility score among older adults with hearing impairments who use hearing aids versus those who do not.

Table 6. Utility score among older adults with hearing impairments who use hearing aids versus those who do not

Types of		ty score among the		Utility score among the hearing-			
hearing	ımpaıı	red older adults usi	ng hearing	impaired older adults not using			
problems		aids		ŀ	hearing aids (N=360)		
	(N=276)						
	N	Utility score	QALY	N	Utility score	QALY	
		Mean (SD)			Mean (SD)		
Severe	118	0.818 (0.170)	5.726	76	0.584 (0.351)	4.088	
Moderate	122	0.856 (0.173)	5.992	131	0.633 (0.351)	4.431	
Mild	36 0.780 (0.381) 5.46			153	0.583 (0.354)	4.081	
Overall	276	0.832 (0.211)	5.824	360	0.601 (0.352)	4.207	

^{*}SD: Standard Deviation, QALY; Quality Adjusted Life Years; Source: Primary Survey, 2023

For instance, let's consider the context of life expectancy in India. As of 2021, the life expectancy at birth, as per World Bank data, stands at 67 years. Thus, assuming a hypothetical health state persists from age 60 onward, the duration of time would be 7 years (67 - 60 = 7 years). This duration, when multiplied by the corresponding utility score, facilitates the calculation of QALYs, offering a quantitative measure of the quality-adjusted years of life experienced.

Table 7. Parameters definition and value

Parameter	Parameter Definition	Values	Sources
	Use hearing aid		
Cost	Cost of hearing aid fitting for single ear	12368.00	Device price*, and
Parameters	Cost of hearing aid fitting for both ears	20368.00	medical cost from
(in INR)			primary survey, 2023
QALY	With severe hearing problem	5.726	Primary survey, 2023
	With moderate hearing problem	5.992	
	With mild hearing problem	5.46	
	Overall	5.824	
	Not-use hearing aid		
Cost (in	Treating cost hearing problem	1583.00	Primary survey, 2023
INR)			
	With severe hearing problem	4.088	
QALY	With moderate hearing problem	4.431	
	With mild hearing problem	4.081	
	Overall	4.207	

^{* &}lt;a href="https://dgehs.delhi.gov.in/sites/default/files/DGHS/universal/omdgehs_9.pdf">https://dgehs.delhi.gov.in/sites/default/files/DGHS/universal/omdgehs_9.pdf

Decision Tree

A decision tree was constructed for comparing two treatments as shown in figure 4. It was assumed that those who had using hearing aids and those who had not using hearing aids. Table-7 summarised the cost and quality of life of each parameter. QALY for all outcome possibilities (severe, moderate and mild) are estimated.

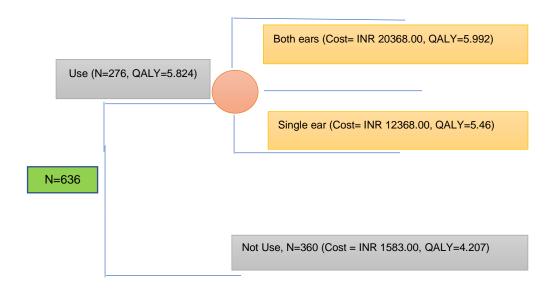


Figure 4. Decision Tree for Hearing Aid

Incremental Cost-Effectiveness Ratio (ICER)

The incremental cost-effectiveness ratio, was calculated as the incremental change in costs divided by the incremental change in health outcome. It represented the average incremental cost associated with 1 additional unit of the measure of effect (QALY).

```
ICER= Cost use HA - Cost not use HA / QALY use HA - QALY not use HA

= 12368- 1583/5.824 - 4.207

= 10785/1.617

=INR 6,670 per QALY gain (for one ear)

ICER= Cost use HA - Cost not use HA / QALY use HA - QALY not use HA

= 20368- 1583/5.824 - 4.207

= 18785/1.617

= INR 11,617 per QALY gain (for both ears)
```

The Incremental Cost-Effectiveness Ratio (ICER) represents the cost per Quality-Adjusted Life Year (QALY) gained. For the requirement of hearing aid fitting in one ear, the ICER stands at INR 6,670 per QALY gained. If there is a need for hearing aid fitting in both ears, the ICER increases to INR 11,617 per QALY gained.

Compliance of hearing aid use

Figure-5 represents the factor impacting the use or rejection of hearing aids, a systematic review and meta-analysis. It is clearing indicating that 38% of the population do not use their hearing aid devices. The causes for rejection are as follows such as lack of awareness of their condition, low or no perceived benefits from hearing aid use, inability to understand others, finding the device uncomfortable or difficult to use, social stigma and other social causes, lack of sufficient income, lack of social or family support and older age. About 38% do not use their hearing aid devices.

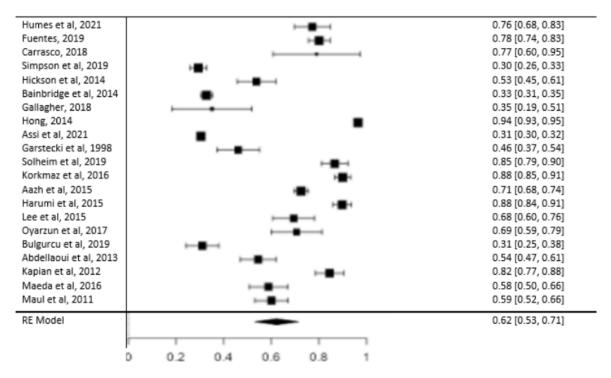


Figure-5: Factor Impacting the Use or Rejection of Hearing Aids: A Systematic Review and Meta Analysis

Budget Impact Analysis

The comprehensive budget impact analysis is delineated in Table 8. As of July 2022, the projected number of older adults (60+) in India stands at 14.9 crore, derived from the Census 2011 data. Based on findings from the Longitudinal Ageing Study in India (2018), the prevalence of hearing impairment among older adults is estimated at 10%, equating to approximately 1.49 crore individuals. Among these hearing-impaired older adults, research suggests that 4.7% require hearing aids, translating to roughly 70 thousand individuals [Marbaniang et al., 2022]. Among this group, 35% necessitate hearing aids for a single ear, while 65% require aids for both ears. The total cost for fitting hearing aids over a span of three years amounts to approximately INR 1230.2 crore, with an annual cost of INR 410.0 crore.

Table 8. Budget Impact Analysis

Parameters	Population	Total (N)	Total
Number of Older Adults (60+) [Census 2011, predicted as on July 2022]	-	149000000	14.9 Crore
Prevalence of hearing impairment [Longitudinal Ageing Study in India, 2018]	10%	1,49,00,000	1.49 Crore
Need hearing aid among hearing- impaired older adults [Marbaniang et al. 2022]	4.7%	7,00,300	70.0 thousand
Prevalence of hearing impairment need hearing aid for one ear [LASI, 2018]	35.0%	2,45,105	24.5 thousand
Prevalence of hearing impairment need hearing aids for two ears [LASI, 2018]	65.0%	4,55,195	45.5 thousand
Cost per individual for single ear (for 3 years)		12368.00	
Cost per individual for both ears (for 3 years)		20368.00	
Total cost for single ear (for 3 years)		3,031,458,640.00	INR 303.1 Crore
Total cost for both ears (for 3 years)		9,271,411,760.00	INR 927.1 Crore
Total cost for hearing aid fitting (for 3 years)		12,30,28,70,400.00	INR 1230.2 Crore
Annual cost for fitting hearing aid		4,100,956,800.00	INR 410.0 Crore

Policy Implication and Recommendation

The cost-effectiveness analysis of hearing aid devices among older adults in India suggests several key policy implications. Firstly, policymakers could explore options for subsidizing the cost of hearing aids or providing financial assistance to make them more accessible, particularly for those from lower socioeconomic backgrounds. Secondly, awareness campaigns targeting both older adults and healthcare professionals could be implemented to emphasize the importance of early detection and intervention for hearing loss. Thirdly, integrating hearing aid services into existing healthcare frameworks could enhance accessibility and availability. Additionally, incentivizing healthcare providers to prioritize hearing health and investing in research and development for improved technology are essential. Regulatory policies ensuring the quality and safety of hearing aid devices are also crucial. Overall, a collaborative approach involving policymakers, healthcare professionals, industry stakeholders, and advocacy groups is vital to address the cost-effectiveness of hearing aid devices and improve the hearing health of older adults in India.

To ensure comprehensive hearing healthcare for older adults in India, it is imperative to integrate hearing health as a priority area within national and state-level elderly health policies

and programs such as NPPCD. This entails incorporating provisions for regular screening, access to rehabilitation services, and support for caregivers of older adults with hearing loss. By implementing these policy recommendations, India can significantly enhance the provision of hearing aids among older adults, thereby improving their quality of life and reducing the burden of hearing loss-related disability.

Furthermore, it is essential to establish mechanisms for monitoring and evaluating the implementation of hearing healthcare policies and programs. This includes conducting regular assessments of access, quality of care, and outcomes for older adults, ensuring accountability, and facilitating adjustments based on feedback and emerging evidence.

Additionally, there is a crucial need to implement policies aimed at enhancing the accessibility and affordability of hearing aids across various socioeconomic strata. This could involve initiatives such as subsidization programs, tax incentives for manufacturers, or collaboration with NGOs and the private sector to provide low-cost options.

Moreover, specialized training for healthcare professionals, including audiologists, ENT specialists, and primary care physicians, is essential to improve their ability to diagnose and manage hearing loss effectively. Emphasizing proper assessment, fitting, and follow-up care for hearing aid users is paramount.

Integrating hearing healthcare services, including screening, diagnosis, and treatment, with existing primary healthcare systems is vital to ensure that older adults have access to comprehensive hearing care as part of routine health services, particularly in rural and underserved areas.

Promoting the use of tele-audiology and telemedicine services can help overcome barriers of distance and mobility, especially in remote areas, enabling older adults to access hearing healthcare professionals for assessment, consultation, and follow-up care without the need for travel.

Establishing and enforcing quality standards for hearing aids and related services is crucial to ensure that older adults receive devices that meet their needs and are safe to use. This may involve certification processes for manufacturers, guidelines for fitting and adjustment, and monitoring of service providers.

Additionally, launching nationwide awareness and education campaigns to destigmatize hearing loss and emphasize the importance of early intervention is essential. These campaigns should target both older adults and healthcare professionals, encouraging regular screenings and prompt treatment. Moreover, facilitating the establishment of community-based support groups and peer networks for older adults with hearing loss and their families can provide valuable emotional support, share information and resources, and advocate for the needs of people with hearing impairment at the local level.

Policy Perspective on Ear, Nose, and Throat (ENT) Care at Ayushman Arogya Mandir – Health and Wellness Centers (Part of Comprehensive Primary Health Care) 2020. The advocacy for appropriate ENT services, encompassing otological and audiological care, emphasizes the importance of delivering these services as close to the community as possible. This includes facilitating access to hearing aids and other auditory devices, as well as providing essential support services to aid users, such as guidance on daily care routines like battery replacement

and best practices for handling the aids. To ensure effective implementation, medical officers and audiologists at the medical college level, along with the Heads of Departments, will undergo a comprehensive one-day training session to familiarize themselves with the program's objectives and the role of medical colleges within it.

Similarly, ENT doctors and audiologists at district hospitals will receive specialized training tailored to their roles and responsibilities within the program. Regular refresher training sessions will also be conducted to enhance and update their skills and knowledge base. Consequently, the provision of hearing aids among older adults may be facilitated at Ayushman Arogya Mandir, in consultation with the ENT specialists or audiologists from the respective district hospitals or medical colleges. This collaborative approach ensures that individuals receive timely and appropriate ENT care within their communities, promoting overall health and well-being.

The provision of hearing aids in Senior Citizen homes across India is essential to ensuring the well-being and quality of life of elderly residents. Recognizing the prevalence of hearing impairment among older adults and its impact on communication, social interaction, and mental health, it is imperative for Senior Citizen homes to prioritize access to hearing aids as part of their healthcare services. This policy should encompass comprehensive assessments of residents' hearing needs, facilitated by trained healthcare professionals, followed by the provision of appropriate hearing aids tailored to individual requirements. Additionally, ongoing support and maintenance services should be integral components of this policy to ensure the effective use and longevity of hearing aids among elderly residents. By addressing the auditory needs of older adults in Senior Citizen homes, this policy contributes to fostering a supportive and inclusive environment that enhances the overall quality of life for seniors in India.

Conclusions

The study findings underscore the economic considerations associated with hearing aid provision for older adults in India. Over a three-year period, the cost per individual for fitting a hearing aid, priced at INR 8000 for Digital BTE, amounts to INR 12,368 for a single ear and INR 20,368 for both ears. Additionally, the Incremental Cost-Effectiveness Ratio (ICER) for hearing aid fitting is INR 6,670 per Quality-Adjusted Life Year (QALY) gained for one ear and INR 11,617 per QALY gained for both ears. The estimated total national cost for hearing aid provision over three years is approximately INR 1230.2 crore, translating to an annual expenditure of INR 410.0 crore for addressing the hearing needs of older adults in India.

To ensure comprehensive hearing healthcare, it is imperative to integrate hearing health into national and state-level elderly health policies and programs like the National Programme for Prevention and Control of Deafness (NPPCD), incorporating regular screening, rehabilitation services, and caregiver support. Ayushman Arogya Mandir's policy on ear, nose, and throat (ENT) care underscores the importance of community-based services, with medical officers and audiologists receiving extensive training for successful implementation. Moreover, recognizing the impact of hearing impairment on communication and mental well-being, Senior Citizen homes must prioritize access to hearing aids within their healthcare services. Additionally, launching national awareness campaigns to destignatize hearing loss and promote early intervention is critical, targeting both older adults and healthcare professionals to encourage regular screenings and timely treatment.

References

- Bharati B, Sahu KS, Pati S. The burden of vision, hearing, and dual sensory impairment in older adults in India, and its impact on different aspects of life-findings from LASI wave 1. Aging and Health Research. 2022 Mar 1;2(1):100062.
- Chundu S, Allen PM, Han W, Ratinaud P, Krishna R, Manchaiah V. Social representation of hearing AIDS among people with hearing loss: an exploratory study. International Journal of Audiology. 2021 Dec 1;60(12):964-78.
- Fook L, Morgan R. Hearing impairment in older people: a review. Postgraduate medical journal. 2000 Sep 1;76(899):537-41.
- Jyani G, Sharma A, Prinja S, Kar SS, Trivedi M, Patro BK, Goyal A, Purba FD, Finch AP, Rajsekar K, Raman S. Development of an EQ-5D value set for India using an extended design (DEVINE) study: the Indian 5-level version EQ-5D value set. Value in Health. 2022 Jul 1;25(7):1218-26.
- Marbaniang SP, Patel R, Kumar P, Chauhan S, Srivastava S. Hearing and vision difficulty and sequential treatment among older adults in India. Scientific Reports. 2022 Nov 9;12(1):19056.
- Ng JH, Loke AY. Determinants of hearing-aid adoption and use among the elderly: A systematic review. International Journal of Audiology. 2015 May 4;54(5):291-300.
- Orji A, Kamenov K, Dirac M, Davis A, Chadha S, Vos T. Global and regional needs, unmet needs and access to hearing aids. International journal of audiology. 2020 Mar 3;59(3):166-72.
- Sanju HK, Yadav AK, Choudhary M. Self-reported satisfaction with digital hearing aids among older adults in Indian context. Indian Journal of Anatomy and Surgery of Head, Neck and Brain. 2018 Mar.
- Sprinzl GM, Riechelmann H. Current trends in treating hearing loss in elderly people: a review of the technology and treatment options—a mini-review. Gerontology. 2010;56(3):351-8.
- United Nations. World Population Prospects—Population Division. Available online: https://population.un.org/wpp/ (accessed on 17 August 2022).
- Vestergaard Knudsen L, Öberg M, Nielsen C, Naylor G, Kramer SE. Factors influencing help seeking, hearing aid uptake, hearing aid use and satisfaction with hearing aids: A review of the literature. Trends in amplification. 2010 Sep;14(3):127-54.
- Zhao F, Manchaiah V, St. Claire L, Danermark B, Jones L, Brandreth M, Krishna R, Goodwin R. Exploring the influence of culture on hearing help-seeking and hearing-aid uptake. International journal of audiology. 2015 Jul 3;54(7):435-43.