Outcome Report

Health Technology Assessment of Telemedicine-enabled Otoscope for Prevention of Ear Diseases

User Department

Ministry of Health and Family Welfare, New Delhi

HTAIn Regional Resource Hub

Research Team

Principal Investigator

Dr. Sanghamitra Pati, Scientist-G & Director

ICMR-Regional Medical Research Centre, Bhubaneswar

Co-Investigators

Dr. Debdutta Bhattacharya, Scientist-D

Dr. Krushna Chandra Sahoo, Public Health Specialist

Dr. Girish Chandra Dash, Research Officer (Health Economics)

Mr. Rakesh Kumar Sahoo, Project Assistant

ICMR-Regional Medical Research Centre, Bhubaneswar

Ms. Jyotsna Naik, Scientist-C,

Department of Health Research, Ministry of Health & Family Welfare, New Delhi

Acknowledgements

First and foremost, we are thankful to the Department of Health Research, Ministry of Health and Family Welfare, Govt. of India for designating ICMR-Regional Medical Research Centre Bhubaneswar, Regional Resource Hub for HTAIn and assigning us to take the HTA on "Health Technology Assessment of Telemedicine-enabled Otoscope for Prevention of Ear Diseases". We would like to thank all the Technical Appraisal Committee members of HTAIn for their valuable feedback and approval of this study.

We would like to extend our sincere gratitude to Dr. Balram Bhargava, Secretary, Department of Health Research, Ministry of Health & Family Welfare, Government of India and Director General, Indian Council of Medical Research for his continuous inspiration. We would also like to extend our sincere gratitude to Smt. Anu Nagar Joint Secretaries of DHR, for always providing us with their positive feedback and constant encouragement during this study. We are also thankful to Deputy Secretaries and Under Secretaries and Dr. Kavitha Rajsekar, Scientist E. Without their timely and continuous support, it was impossible to complete the project on time. We would like to express our gratitude to Dr. Sudha Chandrasekar and Dr. Shankar Prinja TAC committee for their advice during the study. We are thankful to the Department of Health and Family Welfare, Govt. of Odisha for providing permission to conduct this study.

We would also like to acknowledge all the support we got from our stakeholders like NHM, RBSK for sharing their data and their experiences that helped us achieve this task. We thank Dr. Shubhankar Dubey and Dr. Azhar Uddin for their support in the systematic review. We also thank other staff including administrative and accountings of RMRC, Bhubaneswar for their continuous support.

Finally, yet very importantly, we are thankful to all the staff of DHR for all their assistance, cooperation and extra efforts for sharing our burden and helping us in completing the study smoothly and timely. Our sincere gratitude to all others unnamed here who have helped in various ways for this HTA study.

Dr. Sanghamitra Pati
Principal Investigator

Table of Contents

List of Tables

List of Figures

List of Abbreviations

C-DAC: Centre for Development of Advanced Computing

CHWs: Community Health Workers

DHH: District Hospital

HWCs: Health and Wellness Centres

HTAIn: Health Technology Assessment in India

IDI: In-depth Interview

PICO: Intervention, Comparator, and Outcome

LMICs: Low- and middle-income countries

NPPCD: National Program for Prevention and Control of Deafness

OPD: Outpatient department

PHCs: Primary Health Centres

PTA: Pure-tone Audiometer

TAC: Technical Appraisal Committee

TEO: Telemedicine-enabled otoscope

UT: Union Territory

UHC: Universal Health Coverage

WHO: World Health Organization

YLD: Years Lives with Disability

Executive Summary

Background

The World Health Organization (WHO) estimates that untreated hearing loss costs the global economy $980 billion per year. This includes healthcare costs (excluding hearing aids), educational support costs, lost productivity, and societal costs. Low- and middle-income countries (LMICs) bear roughly 57% of these costs. Untreated ear infections can lead to hearing loss, social isolation, loneliness, psychosocial distress, anxiety, and depression. The primary barriers to treatment are a lack of awareness and limited care in primary health care (PHCs) for ear care.

Adult-onset hearing loss was estimated to have a prevalence of 7.6 percent in India. In India, barriers to early detection and intervention for hearing impairment include a lack of infrastructure, a shortage of expertise, a lack of awareness of hearing screening programmes among primary care providers, and a lack of advanced technology in primary health care settings. Additionally, late-onset hearing impairment is frequently missed because 20% of the population stated that the financial burden of treatment was a barrier to seeking treatment and 41% of screened respondents indicated that they did not have enough time to get an ear check-up. As a result, regular or routine hearing examinations were grossly neglected, necessitating door-to-door services utilizing digital health technology.

Telemedicine services are critical in areas where the doctor-patient ratio is significantly lower than the WHO recommended ratio (1:1000). In India, there is one doctor for every 1445 population. Medical services, particularly doctors, are scarce in rural and remote areas, where health care services are challenging. Telemedicine was conceptualized by the Ministry of Health and Family Welfare in 2018 to aid in implementing the Ayushman Bharat scheme. Teleconsultations in India were developed by the National Telemedicine Service, or eSanjeevani, of the Union health ministry. On April 13, 2020, the eSanjeevani out-patient-department was launched to enable patients to receive health care by a specialist at the nearest PHCs.

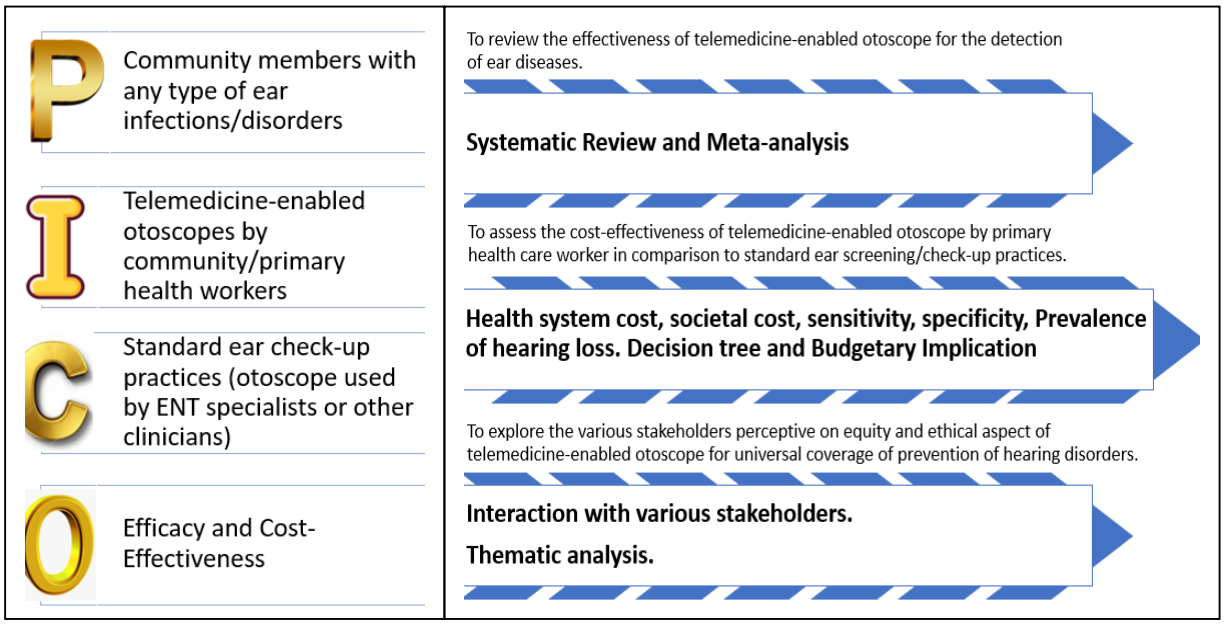
Rationale and objective

Hearing loss prevention is essential throughout the life span, from prenatal and perinatal stages to middle age and beyond. It is critical to developing effective prevention strategies for hearing loss at various stages of life. As a result, community-based hearing screening using digital technology is critical for reducing the burden of hearing loss. As a result, we assessed the cost-effectiveness and operational feasibility of implementing a telemedicine-enabled otoscope (TEO) ear disease prevention.

Methods

This Health Technology Assessment in India (HTAIn) study is classified into three broad areas: efficacy, economic evaluation and ethical and social implication of implementation.

Figure 1. Population, Intervention, Comparator, and Outcome (PICO) and study design



This was approved by the Technical Appraisal Committee of Health Technology Assessment, Department of Health Research, Ministry of Health and Family Welfare, Government of India. The ethical clearance was obtained from the Institutional Ethical Committee of RMRC Bhubaneswar. Permission was taken from the concerned local authorities, and consent was obtained from the participants.

Findings

The pooled sensitivity and specificity of an otoscope are 89 percent (CI 0.81–0.96) and 87 percent (CI 0.74–0.98), respectively. The telemedicine-enabled otoscope has a sensitivity of 82 percent (CI 0.73–0.90) and a specificity of 95 percent (CI 0.91–0.98). The pooled sensitivity and specificity of physicians employing telemedicine-enabled otoscopes is 84 percent (CI 0.75–0.92) and 91 percent (CI 0.85–0.96), respectively. Community Health Workers (CHWs) employing telemedicine-enabled otoscopes have a pooled sensitivity of 80% (CI 0.64–0.94) and a pooled specificity of 97 percent (CI 0.94–1.00).

Many patients stated that they were unable to travel to district hospitals due to a lack of time, distance, the need for travel money, and the assistance of a companion. PHCs and CHCs lack ENT specialists and advanced diagnostic equipment. In the future, the Health and Wellness Centres support the use of telemedicine-enabled otoscopes (TEO). The ENT doctor suggested using a mobile phone or tablet to remotely monitor and diagnose.

Figure 2. Proposed model for hearing screening/check-up – traditional ear check-up, telemedicine enabled otoscope at primary health centre and community.

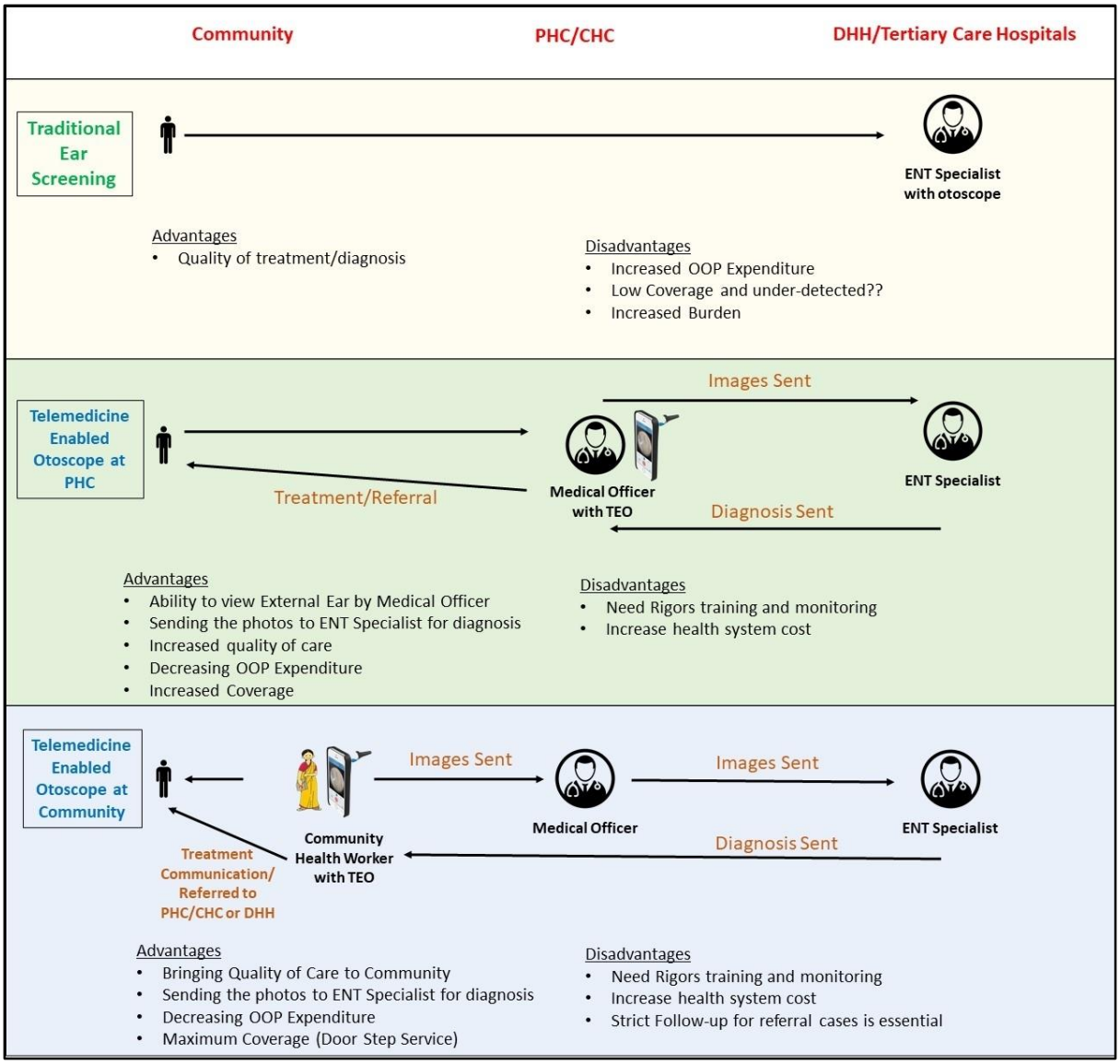


Table 1. Implementation cost

Variables	**Telemedicine-enabled Otoscope by Medical Officer at each Primary health centres**	**Telemedicine-enabled Otoscope by Community Health Workers at Community level**	**Screening with Traditional Otoscope by ENT specialist at tertiary health care facilities**
Annual Heath System cost per facility	**₹1.46 Lakhs**	**₹6.49 Lakhs**	**₹14.5 Lakhs**
Expected no of cases per year	7280	31200	13780
Unit cost per patient (Health System)	**₹ 20.07**	**₹ 20.82**	**₹ 105.45**
Societal Cost	₹ 202.74	₹ 103.24	₹ 344.15
Total Cost	**₹ 222.81**	**₹ 124.06**	**₹ 449.60**

Table 2. Budget Implication

Average number of facilities and annual implementation cost	Telemedicine-enabled Otoscope by Medical Officer at each Primary health centres	Telemedicine-enabled Otoscope by Community Health Workers at Community level	Screening with Traditional Otoscope by ENT specialist at tertiary health care facilities
At district level (facilities)	71	71	2
At district level (Cost)	6.9 Crore	12.5 Crore	29 Lakhs
At state level (facilities)	1360	1360	62
At state level – Odisha (Cost)	132.5 Crore	239.7 Crore	9.0 Crore
At national level (facilities)	29899	29899	2258
At national level – India (Cost)	2913.5 Crore	5271.2 Crore	328.1 Crore

Conclusions and Implication

The annual health system cost per facility for ear screening with a traditional otoscope by an ENT specialist at tertiary health care facilities will be 14.5 lakhs INR with a per-patient cost of 105.45 INR without societal cost; nevertheless, coverage will be less than primary health care or CHWs model. Similarly, the annual health system cost per facility for ear screening with TEO by a Medical Officer at each Primary Health Centre will be 1.46 lakhs INR with a patient cost of 20.07 INR. Without societal cost, the yearly health system cost per facility for ear screening with TEO by CHWs at the community level will be 6.46 lakhs INR or 20.82 INR per patient. Primary health care and CHW models with TEO both have a high level of coverage. Although the annual cost of implementing ear screening with a typical otoscope by ENT specialists at tertiary health care facilities will be 328.1 Crore INR at the national level, coverage will be extremely low. At the national level, the yearly cost of implementing ear screening with TEO by Medical Officers in Primary Health Centers will be 436.87 crore INR, while the CHW model with TEO will cost 1942.42 crore INR, but will provide universal coverage. The ICER value of TEO by Medical Officers in Primary Health Centers and TEO by CHWs at the community level are found to be Rs 19.19/Qaly gained and 1.44/Qaly gained respectively. To address the dearth of expert ear care workers in India and other resource-poor settings, primary care strengthening through telemedicine has been advocated as one way to close the gap in human resources for health. It has the potential to significantly improve access to ear and hearing services, including screening, community awareness, and basic treatment.

Chapter 1

Backgrounds of the Project

1.1. Hearing Impairment: Global Epidemiology and Economic Burden

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 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, handicaps, 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 World Health Organisation (WHO) 2017 report on "global costs of unaddressed hearing loss and cost-effeteness 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 missing. 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 Years Lives with Disability (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 Low-and-Middle Income Countries (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.

Health system perceptive: It results into loss of productivity, unemployment and premature retirement (causing $105 billion cost annually).

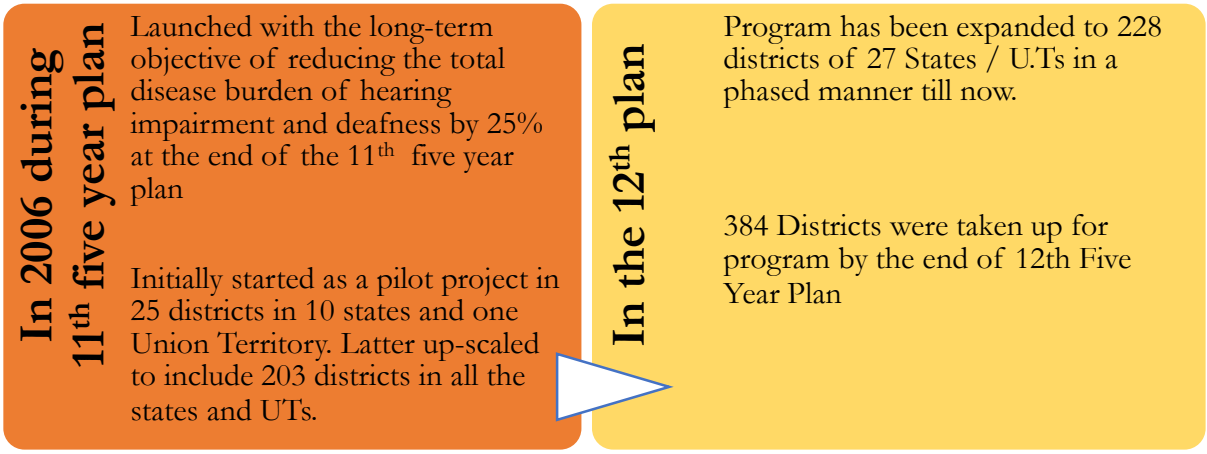
Societal perspective: It results into social isolation, communication difficulties and stigma (causing $573 billion cost annually). Evidences suggest that early identification and management of hearing losses can prevent long term consequences for health system as well as for society.

1.2. Hearing Impairment: Indian Scenario

In India, almost 6.3 percent of the total population – around 63 million people have some type of significant hearing loss. Almost five out of every 1000 children suffer from severe to profound hearing problems (Varshney 2016). The estimated prevalence of adult-onset deafness in India was found to be 7.6 percent and childhood-onset of deafness was 2 percent (Galhotra and Sahu, 2019; Garg et al. 2009). The National Survey on the estimation of out-of-school children, 2014 has revealed that a total of 220425 children between the ages group of 6 – 13 have reported with hearing disability; out of which, 42556 were school children (19.31%) (SRI 2014). Hearing impairment is severe though most neglected health condition in India, which needs to be tackled properly.

1.3. Deafness Program and Hearing Screening in Public health System in India

The Government of India (GoI) initiated the National Program for Prevention and Control of Deafness (NPPCD) in 2006. The program was a 100% centrally sponsored scheme during the 11th five-year plan.



The NPPCD was launched with the long-term objective of reducing the total disease burden of hearing impairment and deafness by 25% at the end of the 11th five-year plan. It was initially started as a pilot project and was implemented in 25 districts in 10 states and one Union Territory (UT). It was up-scaled to include 203 districts in all the states and UTs during the year 2007–2012. The program aims to cover three levels of prevention and care: Primary, secondary, and tertiary ear care by the provision of an appropriate response at these levels. It aims at preventing avoidable hearing loss on account of disease or injury, identifying early and treating major ear problems, and medically rehabilitating persons with deafness of all age groups. In the 12th plan, it is proposed to expand the program to an additional 200 districts in a phased manner probably covering all the states and UTs by March 2017.

Primary care	Awareness for prevention and early detection of deafness and minimum intervention for treatment at the block level hospitals
Secondary care	Detection of deafness and treatment of curable causes including microsurgery and rehabilitation as far as practicable at the subdivision and district-level hospitals
Tertiary care	Specialized treatment modality: modern specialized treatment modalities available at the city hospitals (Medical College Hospitals, Advanced Corporate Hospitals) for the hearing handicapped providing microsurgical facilities, availability of cochlear implantation surgery and selection and distribution of highly efficacious modern hearing aids

National Program for Prevention and Control of Deafness (NPPCD)	Rashtriya Bal Swasthya Karyakram (RBSK)
• **Early identification, diagnosis and treatment** of ear problems responsible **for hearing loss and deafness.** • **Availability of** various **services** like **prevention**, early **identification**, **treatment**, referral, **rehabilitation** for hearing impairment and deafness as the PHCs/CHCs / DHs largely cater to their need. • **Awareness creation** among the health workers through the PHCs and district medical officers	• **Children from 0 to 18 years for 4 Ds** including hearing impairment. • For new born **facility-based newborn screening** at public health facilities & community based newborn screening through **HBNC**. • For **children 6 weeks to 6 years** AWC based **screening by MHTs** • For children **6 years to 18 years** Govt. and Govt. aided **school based screening** by MHTs.

Mostly the screening at community level through Behavioural Observation Audiometry, lack of advance screening technology for community-based hearing screening.

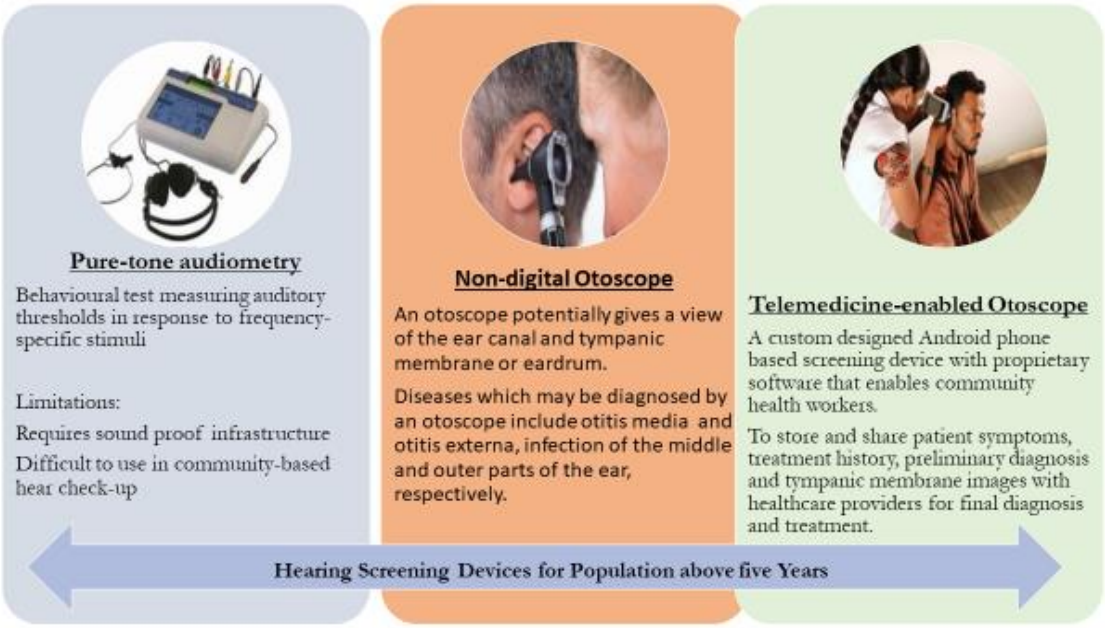
1.4. Ear Check-up Devices

A pure-tone audiometer (PTA) is used among children four years and older. It is a behavioral test measuring auditory thresholds in response to frequency-specific stimuli through earphones, which is able to produce sounds at different frequencies and intensities into the child's ears. Each ear should be tested at 500, 1000, 2000, and 4000 Hz. Results greater than 20 dB at any frequencies indicate a possible hearing loss. In this age group, the child is simply asked to respond in some way when the tone is heard in the earphone.

- Advantages: ear-specific results; assesses the auditory perception of child
- Limitations: depends on the level of understanding and cooperation of the child, and it also requires soundproof infrastructure, hence, it is difficult to use in community settings.
- Average time: 15- to 30-minutes for a test

An otoscope potentially gives a view of the ear canal and tympanic membrane or eardrum. Locating the tympanic membrane, identifying normal anatomy and characterizing pathology are all skills that have historically been taught with verbal descriptions and/or static images due to the inability of the teacher and learner to perform the physical exam concurrently. A digital otoscopy using a hand-held smartphone and performed by an attending/resident team may facilitate increased learner comfort with the procedure and increased the ability to identify pathologic states. The digital otoscope consists

of a smartphone with an otoscope attached directly to the camera lens. The device projects an image of the tympanic membrane onto the smartphone screen.



1.5. Challenges in Deafness Management in India

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 has 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. Nearly 41% of screened respondents mentioned that they did not have enough time to get an ear check-up. Therefore, community-based hearing screening is significant in order to reduce the burden of hearing loss.

In India, barriers to early detection and intervention for hearing impairment include a lack of infrastructure, a shortage of expertise, a lack of awareness of hearing screening programmes among primary care providers, and a lack of advanced technology in primary health care settings. Additionally, late-onset hearing impairment is frequently missed because 20% of the population stated that the financial burden of treatment was a barrier to seeking treatment and 41% of screened

respondents indicated that they did not have enough time to get an ear check-up. As a result, regular or routine hearing examinations were grossly neglected, necessitating door-to-door services utilizing digital health technology.

1.6. Community-Based Hearing Screening in India

Medtronic started the “Shruti” program during the year 2013 in India. The focus is to understand and address ear-related problems in low-income populations like urban settlements and rural areas by leveraging medical technology, telecommunication, and frugal innovation. The program operationalized through trained community health workers (CHW) equipped with an ear screening kit, and with an ENT surgeon as the central point of care.

The programme trains and equips community health workers with an ear screening kit called ENTRaview (telemedicine-enabled otoscope – an android phone-based screening device with proprietary software) in order to gather patient details, symptoms and other information, including an image of the ear canal and tympanic membrane – with a built-in algorithm for field triaging of ear diseases. It has an internet connectivity feature that enables backup and central storage of data. It is equipped with rechargeable batteries; it is portable for easy use in the field. The instruments are used throughout the entire process from screening to treatment and rehabilitation. Patients with ear problems are given counseling regarding further treatment at in-network hospitals, including medical management, minor procedures, surgical intervention, and rehabilitation. The complete patient case recorded via this application is transmitted to a server where an ENT surgeon can access the case and recommend the next course of action. Patients with a positive provisional diagnosis are routed to the point of care for receiving low-cost treatment, including advanced diagnosis, medicines, audiometric tests and surgical interventions. In 2016, “Shruti” was operating in five states of India with trained community health workers through partnerships with ear-care institutions for screening and post-treatment surveys.

1.7. Scope of the Digital Health Platform in India

Telemedicine services are critical in India, where the doctor-patient ratio is significantly lower than the World Health Organization's recommended ratio (WHO). There is one doctor for every 1445 Indians in India (the WHO recommended ratio is 1:1000). In rural and distant sections of the country, medical services, especially doctors, are minimal. In these circumstances, it is critical to have a system that provides consulting services to rural and backward/hilly residents that may prevent them from visiting hospitals. Additionally, it has also been beneficial in controlling the spread of Covid while allowing for non-Covid needed treatment to be provided.

The Ministry of Health and Family Welfare conceptualised telemedicine use to aid in implementing the Ayushman Bharat health insurance scheme in 2018. Teleconsultations in India have been designed by the Union health ministry's National Telemedicine Service or eSanjeevani. Patients, physicians, and specialists around the country have embraced the National Telemedicine Service's virtual platform. The health ministry's unique digital health project has overcome the constraints of geography, distance, and time to establish itself as an alternative stream of healthcare service delivery.

The eSanjeevani platform built by the Centre for Development of Advanced Computing (C-DAC) in Mohali was customised and launched as eSanjeevaniAB-HWC in 2019 as a doctor-to-doctor telemedicine platform. eSanjeevaniOPD was launched on April 13, 2020, to facilitate the provision of health care to patients in the comfort of their own homes. In many states, eSanjeevaniOPD enables the delivery of health services 24 hours a day, seven days a week. The eSanjeevaniOPD services are accessible via a web browser or an Android application, which may be used with an iOS application. It entails a structured and secure online consultation between a doctor and a patient (eSanjeevani OPD). The state governments select the panel of physicians for the service. With the advent of this service, residents of the most remote places will receive health consultations as well. Patient registration and token creation via queue management are the primary features of eSanjeevani OPD. Consultation through audio-video with a physician – e-Prescription and SMS/Email notifications. Free service provided by state physicians - fully programmable concerning the number of daily slots, the number of doctors/clinics, waiting room slots, and the consultation duration limit. This data is collected when patients register on the App and stored on a C-DAC server. The app assigns the user a patient ID that is associated with the server data. Any registered user can read your profile and edit, delete, or add information to it. Uploaded personal data is encrypted before being sent to the cloud.

Figure 1.1. eSanjeevani OPD appointment process

Chapter 2

Rationale, Overall Aim and Brief Methodology

2.1. Rationale of the Project

Untreated hearing conditions have various negative consequences, including social isolation, loneliness, psychosocial distress, anxiety, and depression. Hearing aid fitting is a cost-effective intervention as compared with rehabilitation and can increase the quality of life of people with hearing loss. 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. All these factors highlight the need for a community-based hearing screening to reduce the burden of hearing loss; which will reduce long waiting times for ENT specialists and improve primary care.

Additionally, a paucity of audiologists and inadequate infrastructure, particularly in rural and remote areas, has prevented the establishment of large-scale hearing screening programs. In existing programs, considerable challenges exist with respect to follow-up for diagnostic testing, long-distance traveling for patients to access services and potential wage losses during that time. Hence, the tele-hearing screening and diagnostic follow-up improved the follow-up in comparison to in-person follow-up by a community-based hearing screening program (O'Donovan et al. 2019). The community health workers will be trained to conduct accurate screenings in rural communities. Furthermore, ENT care is also included in comprehensive primary health care at Health and Wellness Centres (HWCs) under the Ayushman Bharat scheme of Govt. of India. The telemedicine-enabled otoscope may be included under NPPCD as well as the Ayushman Bharat scheme for early detection and prevention of hearing disability among school children and other community members. It could also use by the mobile health team under RBSK in order to early detection and prevention of ear diseases in remote areas.

2.2. Overall aim

To assess the cost-effectiveness and operational feasibility of implementation of a telemedicine-enabled otoscope for the prevention of ear diseases among community members.

Specific objectives

- To review the effectiveness of telemedicine-enabled otoscope for the detection of ear diseases.

- To assess the cost-effectiveness of telemedicine-enabled otoscope by a primary health care worker in comparison to standard ear screening/check-up practices.
- To explore the various stakeholders' perspectives on the equity and ethical aspect of a telemedicine-enabled otoscope for universal coverage of prevention of hearing disorders.

2.3. Population, Intervention, Comparator, and Outcomes (PICO)

This Health Technology Assessment in India (HTAIn) study is classified into three broad areas: efficacy, economic evaluation and ethical and social implication of implementation.

- **P-**Community members with any type of ear infections/disorders
- **I-** Telemedicine-enabled otoscopes by community/primary health workers
- **C-** Standard ear check-up practices (otoscope used by ENT specialists or other clinicians)
- **O-** Efficacy, Cost-Effectiveness, and QALYs gain

Table 2.1: Detail Methods

Specific Objectives	Settings and Participants	Analysis
Effectiveness of telemedicine-enabled otoscope for the detection of ear diseases.	• Systematic Review and Meta-analysis	
Cost-effectiveness of telemedicine-enabled otoscope by a primary health care worker in comparison to standard ear screening/check-up practices.	• Health system cost, societal cost, sensitivity, specificity, PPV, NPV, Prevalence of hearing loss, Quality of Life	• Decision tree • Budget Impact Analysis
Stakeholders' perceptive equity and ethical aspect of a telemedicine-enabled otoscope for universal coverage of prevention of hearing disorders.	• Interaction with stakeholders	• Thematic analysis

2.4. Ethical Considerations

This study was approved by the Technical Appraisal Committee (TAC) of Health Technology Assessment in India, Department of Health Research (DHR), Ministry of Health and Family Welfare, Government of India. The ethical clearance was obtained from the Institutional Ethical Committee of RMRC Bhubaneswar and State Ethical Review Committee, Department of Health and Family Welfare, Govt. of Odisha. Permission was obtained from the concerned local authorities. All the study stakeholders provided their consent before the interaction.

Chapter 3

Systematic Review and Meta-analysis of Sensitivity and Specificity of Otoscope and Telemedicine-enabled Otoscope

3.1. Introduction

According to WHO (2018), the burden of hearing loss is 6.3 percent in India (Davey et al. 2018). The unaddressed hearing problem will cost the global economy approximately 980 billion US dollars every year. In most LMICs, ENT specialists and modern technologies are only available at tertiary healthcare facilities. As a result, the ear infection is neglected at the grassroots level, resulting in delays in care and problems. Early detection and screening for ear pathology are critical. In everyday practice, the physician used pneumatic otoscopes to examine the ear. It is not possible for an individual living at a distance to obtain specialist care with a traditional otoscope. Relying on conventional healing methods in the face of available technologies is not a sensible practice in the contemporary environment. However, the telemedicine-enabled otoscope (TEO) will directly connect the beneficiary and ENT specialists, saving money and travel time. It will aid in early detection and healing and contribute to the achievement of the universal health coverage (UHC) goals. This review aims to assess and compare the effectiveness of the TEO to the traditional otoscope.

3.2. Methods

A systematic review of Telemedicine-enabled Otoscope for detection of ear diseases" registered in PROSPERO with registration no CRD42020175123/ 28th April 2020. We conducted a comprehensive search of the PubMed, Cochrane, and Embase databases for publications that fulfilled the Population, Intervention, Comparator, and Outcome (PICO) criteria.

- Population: Diagnostic validation studies in the context of hearing loss
- Intervention: Telemedicine enabled Otoscope (TEO)
- Comparator: Conventional or traditional otoscope
- Outcome: Sensitivity, specificity, positive predictive value and negative predictive value

We didn't include reviews, commentaries, guidelines, or any other work directly related to the research question. Two reviewers looked at the title and abstract. We carried out the screening process independently and resolved disagreements. We extracted data on populations, telemedicine type, study design, study setting, sample size, mean age, sensitivity, specificity, positive predictive value, and negative predictive value. We used the JBI Checklist for Diagnostic Test Accuracy studies to

critically analyse the publications included in this evaluation. We used random-effects models in MS Excel 2016 and MetaXL software Version 5.3 to conduct a meta-analysis of a telemedicine-enabled otoscope's pooled sensitivity and specificity. The heterogeneity of the studies was determined using I2 statistics. We considered heterogeneity if I2 was greater than 30%.

3.3. Findings

Total 1278 records identified – 859 duplicate records removed and 360 excluded after the title and abstract screening. Fifty-nine studies were considered for full-text review, and finally, we included 12 studies. We presented the detailed PRISMA Flow diagram in figure 3.1. The quality assessment of the included studies is presented in figure 3.2.

Figure 3.1: PRISMA Flow diagram of studies identified from the systematic review

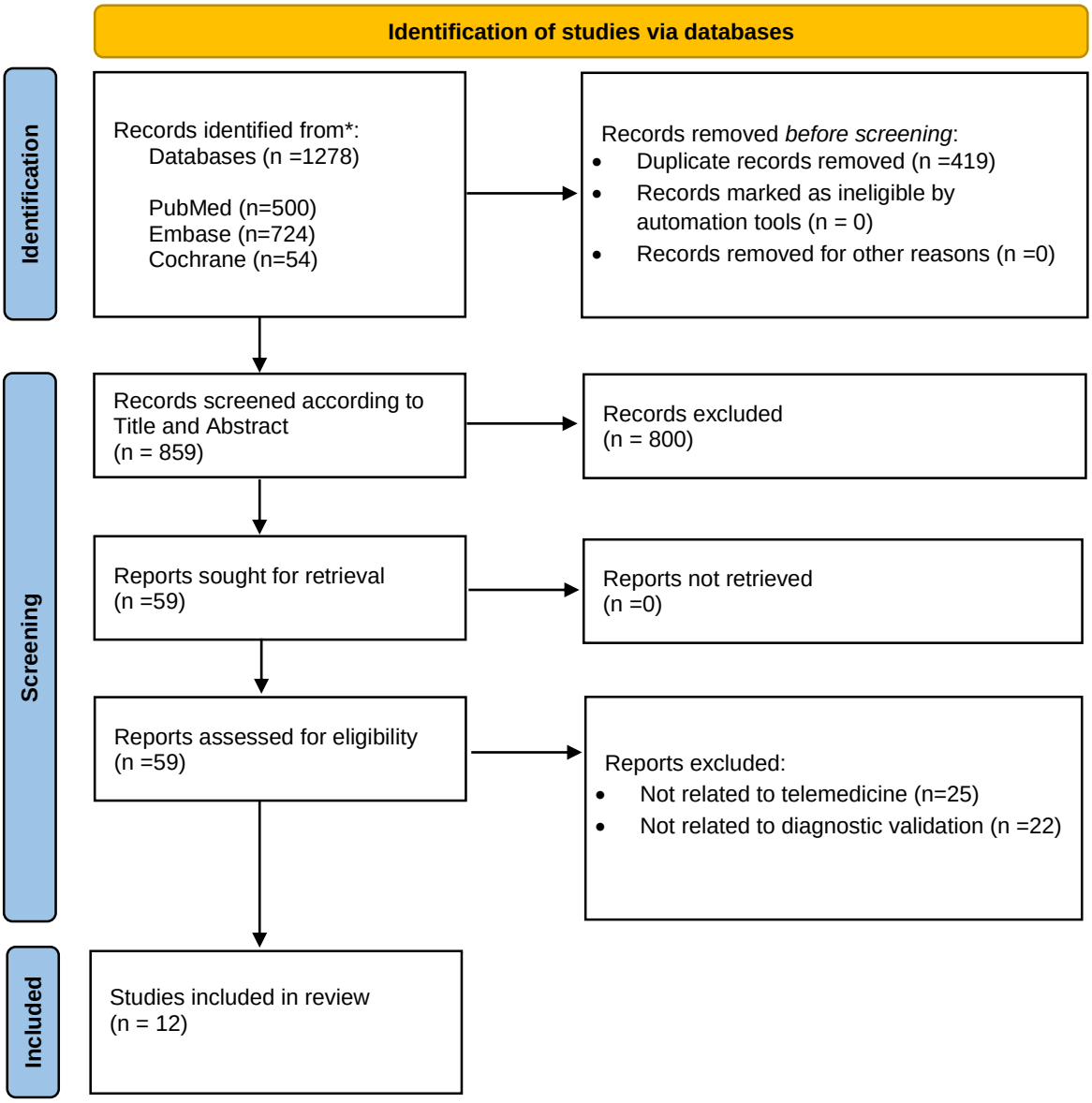


Figure 3.2: Quality assessment of the included studies

	Quality Appraisal using JBI Critical Appraisal Checklist for Diagnostic Test Accuracy Studies	Mandavia et al.	Schuster-Bruce et al. 2020	Samantha et al. 2018	Biagio et al. 2013	Richards et al. 2015	Shah et al. 2018	Lundberg et al. 2017	Gupta et al. 2019	Lundberg et al. 2014	Bhavna et al. 2018	Moshtaghi et al. 2017	Eikelboom et al. 2004
PATIENT SELECTION	1. Was a consecutive or random sample of patients enrolled?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	2. Was a case-control design avoided?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	3. Did the study avoid inappropriate exclusions?	Y	Y	Y	Y	Y	Y	Y	Y	Y	U	U	U
INDEX TEST	4. Were the index test results interpreted without knowledge of the results of the reference standard?	Y	Y	Y	Y	Y	Y	Y	U	Y	U	Y	U
	5. If a threshold was used, was it pre-specified?	NA	NA	Y	NA	NA	NA	NA	Y	NA	NA	NA	NA
	6. Is the reference standard likely to correctly classify the target condition?	Y	Y	U	Y	Y	Y	Y	Y	Y	Y	Y	Y
	7. Were the reference standard results interpreted without knowledge of the results of the index test?	Y	U	U	Y	Y	Y	Y	Y	Y	U	Y	U
	8. Was there an appropriate interval between the index test and reference standard?	Y	Y	Y	U	Y	U	Y	Y	Y	U	U	Y
	9. Did all patients receive the same reference standard?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	10. Were all patients included in the analysis?	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

where, Y=Yes N=No U= Unclear NA= Not Applicable

Figure 3.3: Pooled sensitivity of Otoscope

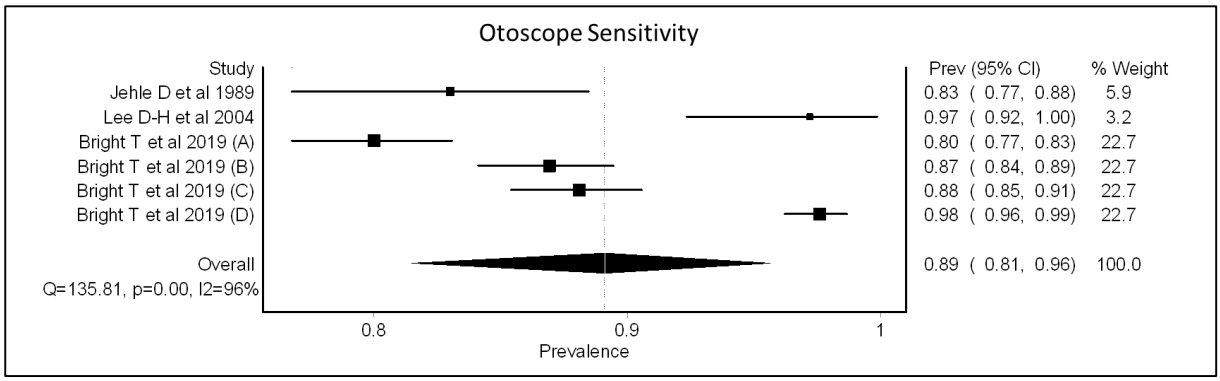


Figure 3.4: Pooled specificity of Otoscope

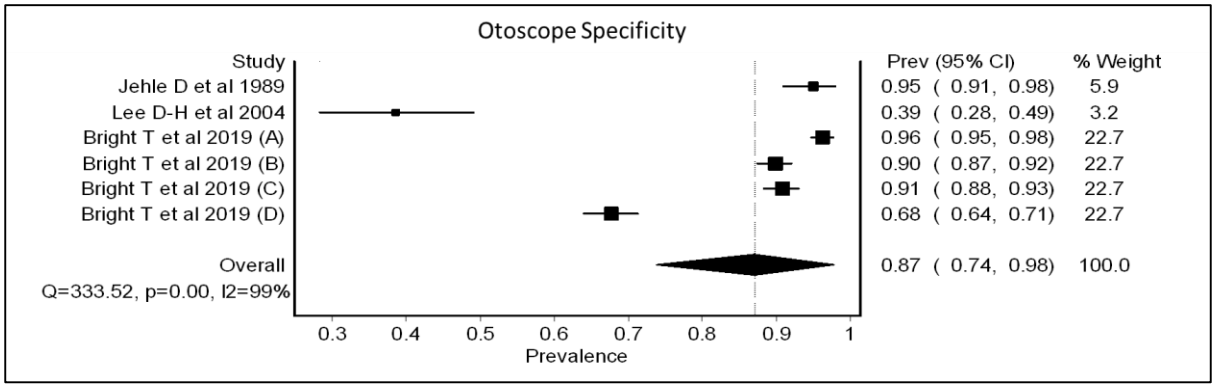


Figure 3.5: Pooled sensitivity of Telemedicine Enabled Otoscope (Overall)

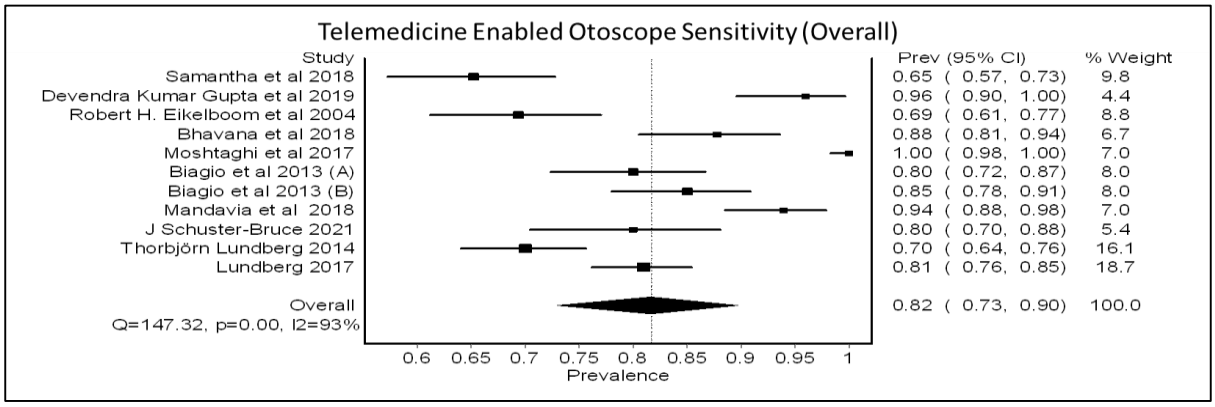
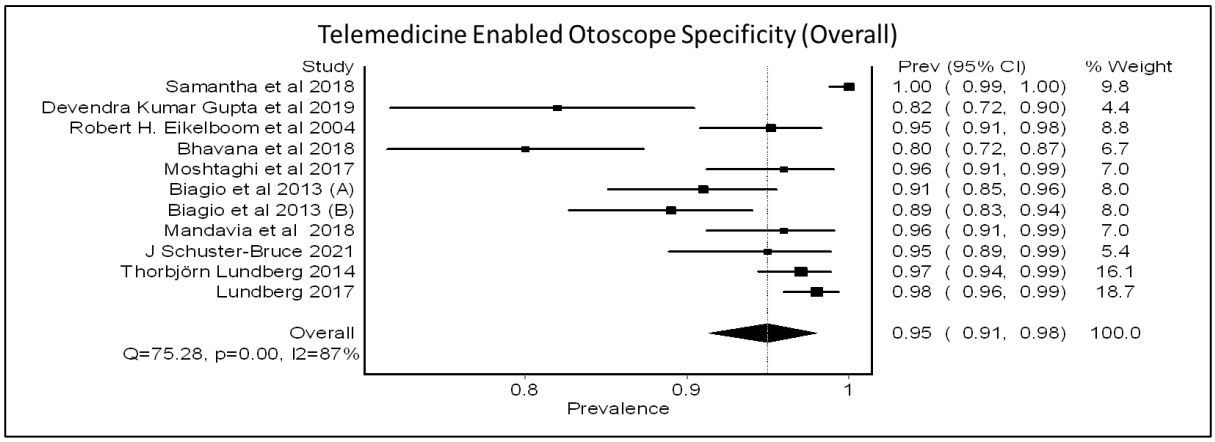


Figure 3.6: Pooled specificity of Telemedicine Enabled Otoscope (Overall)



According to our findings, the pooled sensitivity of an otoscope is 89% (CI 0.81 – 0.96) (figure 3.3), and the specificity is 87% (CI 0.74 – 0.98) (figure 3.4). Similarly, 11 studies demonstrated the sensitivity and specificity of telemedicine-enabled otoscopes. The overall pooled sensitivity of telemedicine-enabled otoscope is 82% (CI 0.73 – 0.90) (figure 3.5). The overall pooled specificity is 95% (CI 0.91 – 0.98) (figure 3.6).

Figure 3.7: Pooled sensitivity of Telemedicine Enabled Otoscope (by Physicians)

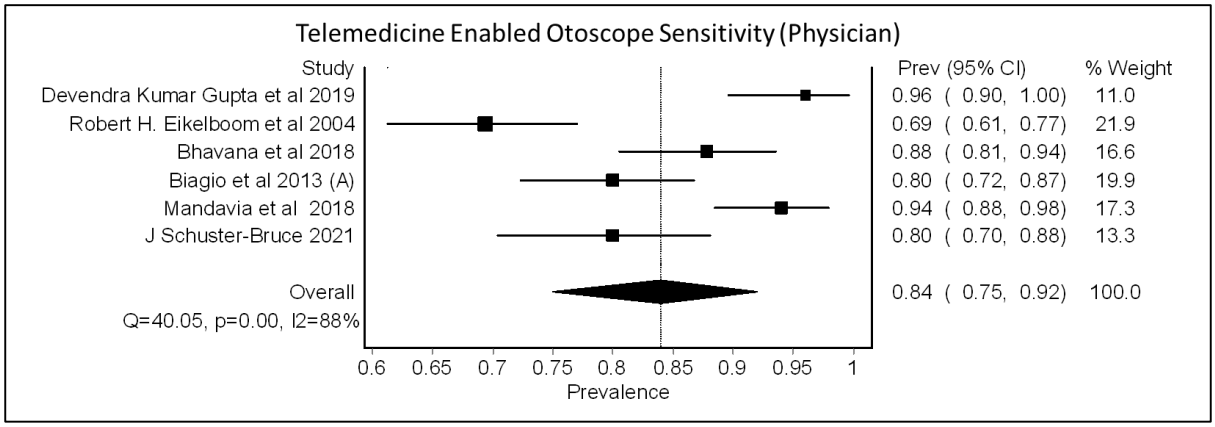
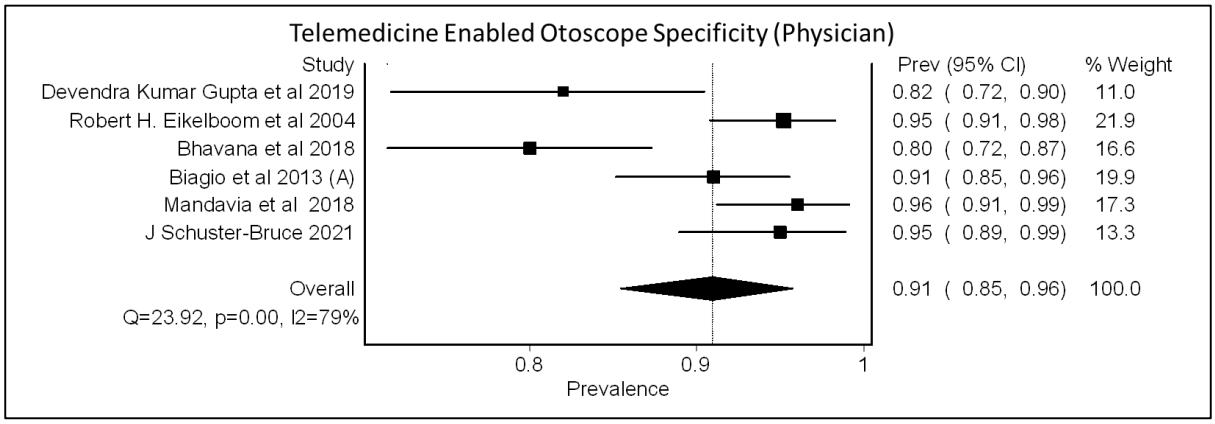


Figure 3.8: Pooled specificity of Telemedicine Enabled Otoscope (by Physicians)



We found six studies that demonstrated the sensitivity and specificity of telemedicine-enabled otoscopes by physicians. The pooled sensitivity of physicians using telemedicine-enabled otoscopes is 84% (CI 0.75 – 0.92) (figure 3.7). The pooled specificity of physicians using telemedicine-enabled otoscopes is 91% (CI 0.85 – 0.96) (figure 3.8).

Figure 3.9: Pooled sensitivity of Telemedicine Enabled Otoscope (by Community Health Workers)

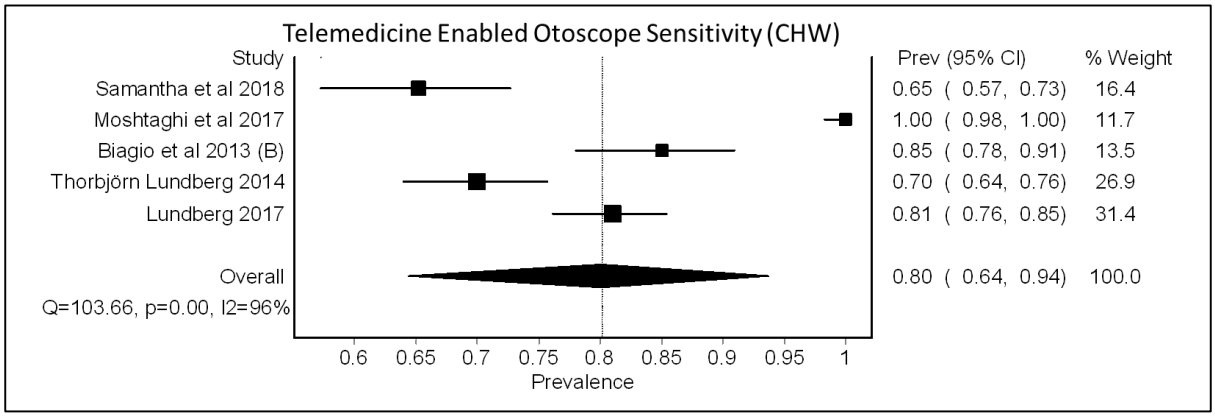
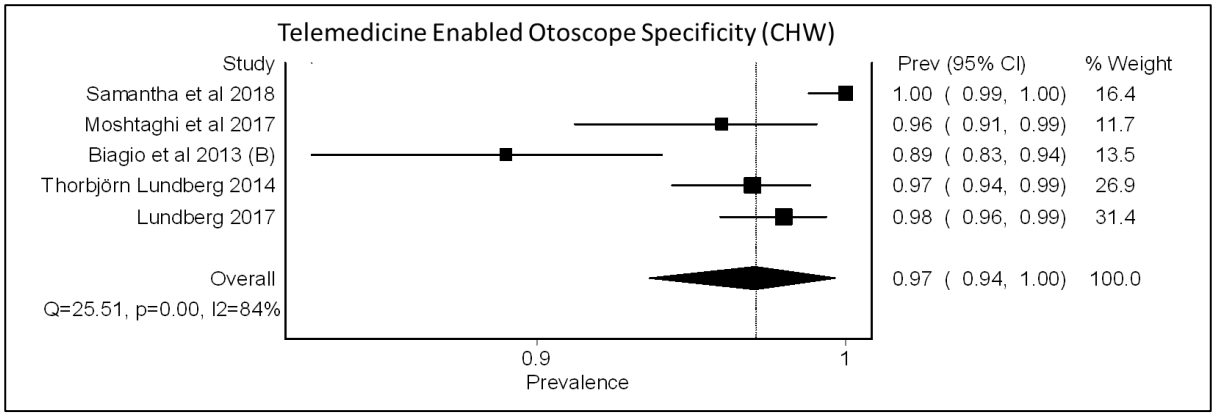


Figure 3.10: Pooled specificity of Telemedicine Enabled Otoscope (by Community Health Workers)



We found five studies that showed the sensitivity and specificity of telemedicine-enabled otoscopes by community health workers (CHWs). The pooled sensitivity of CHWs using telemedicine-enabled otoscopes is 80% (CI 0.64 – 0.94) (figure 3.9). The pooled specificity of CHWs using telemedicine-enabled otoscopes is 97% (CI 0.94 – 1.00) (figure 3.10).

Agreement between the traditional otoscope and Telemedicine enabled otoscope.

Average agreement from the six studies having kappa value was calculated to be 0.72. The agreement was moderate among the traditional otoscope and TEO. There was strong agreement (k=0.82) among physicians. The agreement was week among parents/guardians in the study performed by shah el al. The study by Shah et al also found the agreement could be affected due to presence of wax which the parents/guardians were not able to easily remove.

Table 3.1 Agreement between the traditional otoscope and Telemedicine enabled otoscope.

Sl No	Authors & Year of Publication	Country	Study Setting	Investigator	Total Participants	Kappa Value
1.	John R. Richards etal 2015 (A)	USA	Hospital Based	Resident Physician	51	0.74
2.	John R. Richards etal 2015 (B)	USA	Hospital Based	Attending Physician	51	0.86
3.	Mandavia et al 2018	Nepal	Hospital Based	Physician	52	0.95
4.	Bhavana et al 2018	India	Hospital Based	Medical Students	50	0.67
5.	Shah 2018 (A)	USA	Hospital Based	Parents/Guardians	40	0.42
6.	Shah 2018 (B)	USA	Hospital Based	Physician	40	0.74

Photo Capturing and Quality

The study by Eikelboom et al in 2004 found that not just the images but comprehensive clinical history data are equally important in to make correct diagnoses and provide management advice. Bhavana et al found the efficacy of visualization of external canal and tympanic membrane are 97% and 96.7% respectively. Moshtaghi et al in a study found that practitioner removed cerumen when necessary prior to obtaining the image; this may prove to be challenging for patients who do not have the capability to do this at home or for primary care physicians who may not have the necessary equipment to perform cerumen debridement prior to obtaining an SEO image. The study also found that patients and family members may not recognize the TM and instead image the ear canal, reducing the efficacy of the device. Biagio et al found that a greater number of video-otoscopic images taken by the facilitator were judged to be unacceptable in quality (23.4%) compared with the images taken by the otolaryngologist (15.0%). The study suggested to take multiple photographs to avoid reexamination of patients. Lundberg et al reported an improvement in image quality over time as a function of experience of the investigators.

3.4. Conclusions

The review revealed that the pooled sensitivity of an otoscope is 89%, and the specificity is 87%. The overall pooled sensitivity of telemedicine-enabled otoscope is 82%, and specificity is 95%. The pooled sensitivity of physicians using telemedicine-enabled otoscopes is 84%, and specificity is 91%. The pooled sensitivity of CHWs using telemedicine-enabled otoscopes is 80%, and specificity is 97%.

Table 3.2: Pooled Sensitivity and Specificity of Traditional and Telemedicine Enabled Otoscope

Device	Sensitivity % (95% CI)	Specificity % (95% CI)
Traditional Otoscope (Overall)	89% (81– 96%)	87% (74-98%)
Telemedicine Enabled Otoscope (Overall)	82% (73-90%)	95 (91-98%)
Telemedicine Enabled Otoscope (Physician)	84% (75-92%)	91% (85-96%)
Telemedicine Enabled Otoscope (Community Health Workers)	80% (64-94%)	97% (94-100%)

Chapter 4

Current care-seeking pathways for ear disorders and stakeholders' perceptive on telemedicine-enabled otoscope for universal coverage of prevention of hearing disorders

4.1. Introduction

The stakeholder viewpoint is an important part of the entire policy analysis process. Stakeholders may be involved in the definition of a problem by providing a context for a problem that may not have arisen through literature. A study has shown that trained non-medical workers can be used for basic assessment and treatment in remote areas (Mandavia et al. 2018). Another study found that residents and attending physicians agreed that the telemedicine-otoscope was easy to use and made more accurate diagnosis possible (Richards et al. 2015). In a study, 10% of the images were out of focus or too dark to make a valid decision (Elliott et al. 2010). The use of telemedicine-enabled otoscopes under the Shruti program is currently operating across seven cities in India – Delhi, Gurgaon, Faridabad, Hyderabad, Aurangabad, Jaipur and Chennai through community health workers.

4.2. Methods

We discussed existing ear disease prevention strategies with service providers, programme managers, and patients and how the telemedicine-enabled otoscope helps fill in existing gaps. We collected data on patient load (average monthy load from August 2020 to August 2021) , ear disease diagnosis, and ear check-up technology from various health care facilities at four district hospitals (DHH) – two in coastal districts and two in tribal population-dominant districts. Each district's headquarter hospitals, one community health centre (CHC), one urban health and wellness centre (UPHC), and two rural health and wellness centres (PHCs) were selected with care. Clinical data and technology used for ear examinations were gathered using a predesigned checklist.

Additionally, at DHH, we conducted In-depth Interviews (IDIs) with ENT specialists, hospital administrators, and administrators of telemedicine sites. We conducted IDIs among Medical Officers

and Pharmacists in CHCs and PHCs. Additionally, we interviewed twelve patients with reported ear problems – five at PHCs, three at CHCs, and four at DHHs. Four of them lived in cities, while the remaining eight resided in rural areas. Male and female patients were enrolled in equal numbers in this study. The average age of the patients was 37 years, with a range of 24 to 65 years.

4.3. Results

Risk population, current diagnosis and treatment practices for an ear disorder

4.1: Clinical information and technology used at Primary Health Centres (PHCs)

	Urban Health & Wellness Centre (UPHCs)					Rural Health & Wellness Centre (PHCs)							
Clinical information	**Average**	**UPHC 1**	**UPHC 2**	**UPHC 3**	**UPHC 4**	**PHC 1**	**PHC 2**	**PHC 3**	**PHC 4**	**PHC 5**	**PHC 6**	**PHC 7**	**PHC 8**
Patients attending OPD daily, Average (Range)	85 (35 - 150)	150	65	150	90	150	80	75	35	35	65	35	100
Patients visiting with ear problems, Average (Range)	7 (2 - 20)	20	3	20	5	9	4	5	2	5	3	3	5
Treated for minor infection, Average (Range)	70%	16	2	16	4	6	3	3	1	3	2	2	3
Referred to higher centre	30%	4	1	4	1	3	1	2	1	2	1	1	2
Technology or device used													
Have otoscope at the facility	0%	No	No	No	No	No	No	No	No	No	No	No	No
Used otoscope	0%	No	No	No	No	No	No	Yes	No	No	No	No	No
Aware about telemedicine otoscope	0%	No		No	No	No	No	No	No	No		No	No
Familiar with using the smartphone application	100%	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Willing to involve in telemedicine ear check-up	100%	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Telemedicine decreases work load	100%	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes
Patients would get better services	100%	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Supporting staff for telemedicine	Nurse	Nurse	Nurse	Nurse	Nurse	Nurse	Nurse	Nurse	Nurse	Nurse	Nurse	Nurse	Nurse

In Table 4.1, detailed clinical information and technology used at Primary Health Centres (PHCs) are provided. The average number of patients attending OPD daily was 85; 12% reported ear problems. Around 70% were treated at those facilities who had minor ear infections. None of the facilities providers uses otoscope. Similarly, about 200 individuals visit CHCs each working day, with approximately 20 to 30 patients with ear problems. They rarely examine ears with an otoscope. They are treating minor ear infections with eardrops and medicines. Around 5% of significant cases are referred to higher hospitals. In Table 4.2, the detailed clinical information and technology used at CHCs are described.

Table 4.2: **Clinical information and technology used at Community Health Centres**

Clinical information	**Average**	**CHC 1**	**CHC 2**	**CHC 3**	**CHC 4**
Patients attending OPD daily, Average (Range)	174 (120 - 200)	200	120	200	175
Patients visiting with ear problems, Average (Range)	14 (6 - 30)	30	6	9	10
Patients diagnosed with ear diseases (%)	90%	90%	90%	90%	90%
Treated at your facility (%)	78%	70%	80%	80%	80%
Referred to higher centre (%)	20%	20%	20%	20%	20%
Technology or device used					
Have otoscope at the facility	0%	No	No	No	No
Used otoscope	0%	No	No	No	No
Aware about telemedicine otoscope	0%	No	No	No	No
Familiar with using smartphone application	100%	Yes	Yes	Yes	Yes
Willing to involve in telemedicine ear check-up	100%	Yes	Yes	Yes	Yes
Telemedicine decreases work load	100%	Yes	Yes	Yes	Yes
Patients would get better services	100%	Yes	Yes	Yes	Yes
Supporting staff for telemedicine	Nurse	Nurse	Radiographer	Nurse	Nurse

Table 4.3 summarises the clinical data and technology utilised in tertiary health care facilities – district hospitals. Daily average attendance at ENT out patient department (OPD) was 95, with approximately 50 patients reporting ear problems. Over 95% of patients are treated at the DHH, with the remainder being referred to medical college hospitals by ENT specialists. Each of them possessed an otoscope, which they used for ear examinations. Half of them were aware of the otoscope equipped with telemedicine. They all lauded the initiative to bring telemedicine-related ear care to primary health centres in order to increase coverage and quality of care. All participants are willing to participate in future telehealth interventions for ear care. They suggested that they require a tablet or that they operate the platform via personal mobile device rather than a computer in the facilities. They can also

monitor, review, and diagnose remotely if they use a telehealth facility via a mobile phone or tablet – even after duty hours if the situation is urgent or during their leisure time.

Table 4.3: Clinical information and technology used at tertiary health care facilities – district hospitals

Clinical information	Total	DHH 1	DHH 2	DHH 3	DHH 4
Patients attending OPD daily, Average (Range)	95 (60 to 160)	80	80	160	60
Patients visiting with ear problems, Average (Range)	50 (26 to 92)	38	42	92	26
Patients diagnosed with ear diseases (%)	95%	95%	95%	95%	95%
Treated at your facility (%)	90%	90%	95%	90%	90%
Referred to another higher centre (%)	5-10%	10%	5%	10%	10%
Technology or device used					
Have otoscope at the facility	100%	Yes	Yes	Yes	Yes
Used otoscope	100%	Yes	Yes	Yes	Yes
Aware about telemedicine otoscope	50%	No	No	Yes	Yes
Familiar with using smartphone application	100%	Yes	Yes	Yes	Yes
Willing to involve in telemedicine ear check-up	100%	Yes	Yes	Yes	Yes
Telemedicine decreases work load	100%	Yes	Yes	Yes	Yes
Patients would get better services	100%	Yes	Yes	Yes	Yes
Supporting staff acquiring the images		Nurse	Audiologist	Nurse	Nurse

Patients' perceptive on ear check-up and treatment

Almost all patients reported that when they experienced ear problems such as earache, discharge, persistent itching, or hearing loss, they visited nearby private providers or primary health care facilities. According to them, they seek treatment at PHCs for common problems. However, the doctor frequently referred patients to district hospitals. Several patients stated that it was not always possible to seek care from district hospitals on time. The various reasons cited for delaying the visit to DHH included a lack of time, long-distance, the need to arrange for travel money, and the support of an accompanying person. Some patients stated that they preferred not to visit PHCs or CHCs for their or their relatives' ear-related problems and recommended community members to visit DHH because of PHCs and CHCs lack ENT specialists and advanced diagnostic facilities.

> *"I'm experiencing severe ear pain. To begin, I visited our nearby PHC. I visited twice, but my pain did not subside, so I arranged money and travelled to DHH to consult an ENT. If any treatment is available at PHC, it will save our money and time." (Rural female 38 years)*

> *"Many people in my village have experienced ear problems. Three people in my family have ear pain. They were able to treat themselves in 2-3 days without the assistance and support*

of a doctor. There is no ear doctor at PHC or CHC, and DHH is a long-distance away". (Rural male 50 years)

A woman from an urban slum brought her six-year-old child to cure ear pain and accompanied her neighbour. She is not stable financially and hence prefers to walk to the PHC. She saw a physician who recommended ear drops and other pain medicine. The elderly were required ear examination at PHC because ear problems were more prevalent in them, and it was inconvenient for them to attend DHH and wait in a long line.

"Ear problems are more prevalent in older age. We always require an accompanying while travelling district hospital. We will be happier if we receive proper ear-related check-ups and treatment at PHC. If PHC facilities improve, we will no longer need to travel long distances and wait longer at district hospitals at this age." (Rural male 65 years)

Healthcare providers experience and suggestions on digital health

The purpose of this study was to ascertain the physician's perspective on initiating a novel treatment approach via telemedicine for patients who present with ear-related disorders. Many providers appreciated the telemedicine-enabled otoscope effort. They responded that telemedicine would be an excellent initiative for giving convenient and high-quality healthcare to everyone at nearby facilities. They suggested that the photos be taken by their radiographer or staff nurse. Training is critical, as this would be a novel instrument to operate. For proper screening, a minimum of two days of training is required.

Two computers are connected to the internet at the facility, one in the programme management unit and another in the establishment department. One data entry operator is allocated to the programme management unit and is responsible for hospital data under the supervision of an official. Almost all PHCs (Health and Wellness Centers) have a computer system and internet access, and telemedicine is currently available via the e-sanjeevani platform. According to the providers, e-sanjeevani is presently employed in medicine, paediatrics, and gynaecology.

When we informed them about the launch of telemedicine otoscope, they remarked on how beneficial it would be to the public. However, many providers expressed concern about vacant positions at HWCs, which frequently complicate the management of the facilities' high patient load. There is one doctor assigned to a PHC who manages approximately 100 patients every day on their own. Due to the limited workforce in a PHC, additional people are required to manage the new

technologies. From the patient's perspective, they would be pleased and satisfied. The establishment of this service at CHCs would be more beneficial, given there are currently no ENT experts on staff.

District-level managers views on e-Sanjeevani and telehealth facilities

Telemedicine we started in the year 2011 and e-Sanjeevani during 2020. The e-Sanjeevani is open three days a week – Monday, Wednesday, and Friday from 11 a.m. to 1 p.m. Monday are reserved for the medicine department, Wednesday is reserved for paediatrics, and Friday is reserved for gynaecology. Typically, the medicine department's doctor arrives after completing his OPD rounds, sometimes as early as 11 or 11:30 a.m., and continues to see patients for two hours continuously. The patient can either wait at PHC for direct online consultation or inform the doctor there, who will document all issues and communicate them to the DHH doctor later. They can also share the prescription and accompanying photographs. Certain individuals are not adept at this; they are sending messages to my WhatsApp about what I show the doctor. In the future, ENT specialists, like other specialists, may be included in this e-Sanjeevani programme.

4.4. Conclusions

Several patients said they couldn't always get to district hospitals on time. Lack of time, distance, need for travel money, and assistance from an accompanying person were all listed as reasons for postponing the visit to DHH. Because PHCs and CHCs lack ENT experts and advanced diagnostic facilities, some patients preferred DHH for their ear problems. The Health and Wellness Centres support the use of TEO in the future. TEO will also use existing infrastructure such as computers, internet, printers, and servers from the e-Sanjeevani platform at Health and Wellness Centres. All providers are open to future remote ear care initiatives. The ENT doctor suggested using a tablet or personal mobile device to control the platform rather than a computer in the facility. They can also monitor, review, and diagnose remotely using a mobile phone or tablet, even after duty hours if necessary or in their own time.

Chapter 5

Cost of Telemedicine-enabled Otoscope and Standard Ear Check-up

Costing of TEO consisted of Human resources, Device Costs, Consumables and Non-Consumables and Training cost. Data will be collected from both primary and secondary sources. Secondary data will be collected through various databases, programmatic data, and literature reviews.

5.1. Health System Cost: Human Resources

Table 5.1: Human Resources for Telemedicine enabled otoscope and Traditional Otoscope

Human Resources cost per Annum (INR)	Monthly Salary (as per 7th pay commission)	Percentage of Time Spent on Screening and Reporting*		Units	Annual Cost at single unit of healthcare		
		TEO	Traditional Otoscope		TEO by MO at PHC (INR)	TEO by CHWs at Community level per PHC (INR)	Screening with Traditional Otoscope by ENT specialist at DHH (INR)
ENT specialist	120000	20%	50%	2	576000	576000	1440000
Medical officer	65637	20%		1	157529	157529	0
ANM/ Nurse	25000	10%		1	30000	0	0
Data Entry operator	18000	30%		1	64800	64800	0
ASHA/ CHWs	3500	25%		30	0	315000	0
				Total	828329	1113329	1440000

*primary data collected via stakeholder interviewsTable 5.1 indicates the human resource cost for implementation of Telemedicine enabled otoscope by Medical Officer at each PHC, TEO by Community Health workers at community level per PHC and existing screening with traditional

otoscopes by ENT specialists at each DHH/SDH. The cost of each human resource was calculated according to the percentage of time spend for screening/reporting. An average of 30 ASHAs/CHWs were considered per PHC who would perform the ear screening at the community level.

5.2. Health System Cost: Devices

Table 5.2: Device Cost

Device detail	**Otoscope DHH**	**TEO at PHC**
	Cost in (INR)	**Cost in (INR)**
Unit cost (INR)	25000	61753
Lifespan (in Years)	5	3
Units	2	1
Discount factor	0.03	0.03
Annual Maintenance Rate	0.05	0.1
Annualization Factor	0.2184	0.3535
Estimated Uniform Annual Cost (EUAC) (INR)	10917.72857	21831.56053
Annual Maintenance Cost (INR)	2500	6175.3
Present worth of Maintenance (INR)	2156.52	5651.27
Total Annual Cost (INR)	13074.25	27482.83
Electricity per annum (INR)	2500	2500

Note: Device cost was obtained from the procurement cost of the central government institute in the year 2020-21; Other costs were obtained for the year 2020-21 by record review and interaction with stakeholders

Table 5.2 indicates the Device Costs of Traditional Otoscope and Telemedicine Enabled Otoscope. The Lifespan of Telemedicine was considered as 3 years as per the average lifespan of a smartphone. Two units of Traditional Otoscope is required for the two essential ENT specialists at a DHH. The Total Annual Cost for each unit of the Traditional Otoscope and TEO was Rs 13074.25 and Rs 27482.83 respectively.

5.3. Health System Cost: Consumables and Non-Consumables

Table 5.3: Consumables and Non-Consumables

Variables	Computer (10% use)	Internet (20% use)	Printer (20% use)	Consumables (paper, printer ink)	Tablet at DHH
Unit cost (INR)	20000	1000	3000	1500	25000
Lifespan (in Years)	5	Single use	5	Single use	3
Units	1	12	1	1	2
Discount Factor	0.03	0	0.03	0	0.03
Annual Maintenance Rate	0.05	0	0.05	0	0.05
Annualization Factor	0.2184	1.0000	0.2184	1.0000	0.3535
Estimated Uniform Annual Cost (EUAC) (INR)	4367.091428	12000	655.0637142	15000	17676.51817
Annual Maintenance Cost (INR)	1000	0	150	0	2500
Present worth of Maintenance (INR)	862.61	0.00	129.39	0	2287.85
Total Annual Cost (INR)	5229.70	12000.00	784.46	15000.00	19964.37
Percentage of Use	0.1	0.2	0.2	1	1
Total Cost (INR)	522.97	2400	156.89	15000	19964.37

Note: Costs were obtained for the year 2020-21 by record review and interaction with stakeholders

Table 5.3 indicates the Consumables and non-consumables required for the implementation of Telemedicine enabled otoscope at PHC and at community level. Percentage of use of few equipment was considered as the infrastructures are already established in the health care setting.

5.4. Health System Cost: Training

Table 5.4.1: Training Cost for implementation of TEO at PHC level Per Batch of 30 Participants for 2 Days ENT/Medical Officers/Nurse

Activities	Unit	Days	Per Unit Cost	Total Cost
Travel of Participants	30	2	200	12000
Venue Cost	2	2	3000	12000
Food Cost	30	2	200	12000
Materials Cost	32	1	50	1600
Banner Cost	2	1	500	1000
Travel Trainer	2	1	2000	4000
Food Allowance for Trainers	2	2	450	1800
Honorarium for Trainers	2	1	2000	4000
Accommodation	2	1	2250	4500
			Total	**52900**

Table 5.4.1 indicates the training cost for a batch of 30 participants of ENT/ Medical Officers/ Nurse for 2 days.

Table 5.4.2: Training Cost for implementation of TEO at PHC level Per Batch of 30 Participants for 2 Days ASHA/ANM/HW(M)

Activities	Unit	Days	Per Unit Cost	Total Cost
Travel of Participants	30	2	100	6000
Food Cost	30	2	100	6000
Materials Cost	32	1	50	1600
Banner Cost	2	1	500	1000
Travel Trainer	2	1	200	400
Food Allowance for Trainers	2	2	450	1800
Honorarium for Trainers	2	1	100	200
			Total	**17000**

In Table 5.4.2 provides detailed the training cost for a batch of 30 participants of ASHA/ANM/HW(M) for 2 days.

Table 5.4.3: Training Cost for TEO at PHC and Community Level Screening

Variables	TEO at CHC	TEO at Community
Training Cost for at PHC: 1 MO 1 Nurse and 1 ENT Specialist for 2 Days	5290	5290
Training Cost Per Batch of 30 Participants for 2 Days ASHA/ANM HW(M)	0	17000
Total	5290	22290

*30 ASHA per PHC, 1 MO, 1 ENT, 1 Nurse

In Table 5.4.3 the training cost for each program for the implementation of TEO by MO at PHC and TEO by CHWs at each community level per PHC is provided.

5.5. Annual Health System Cost

Table 5.5: Annual Screenings

Variables	TEO at PHC	TEO at Community	Screening with Otoscope by ENT specialist
The devices' lifespan	3 years	3 years	5 Years
Salvage value	0 INR	0 INR	0 INR
Average duration for taking photo, history and upload in the portal	10 minutes	10 minutes	0
Average duration for diagnosis of a single photo and send diagnosis report by ENT/Medical Officer/ANM/Nurse	5 minutes	5 minutes	8 minutes
Total time for screening a single patient	15 minutes	15 minutes	8 minutes
Average duration of device function in one day	7 hours (7*60=420 minutes)	7 hours (7*60=420 minutes)	7 hours (7*60=420minutes)
Average number of person screening per day	28	120	53
Average number of working days in a year	260 days		
Average number of person screening per year	**7280**	**31200**	**13780**

Note: Lifespan of Electronic devices(TEO) were assumed to be 3 years and manual Otoscope assumed to be 5 years.

5.6. Societal Cost

Table 5.6.1: Transport Cost per visit

Average transport cost per visit	
Medical college hospital	440.65
District or Sub-divisional Hospital	300.08
Primary Health Centre	99.5

Note: Primary data collected from previous study on "Health Technology Assessment of "Portable Automated ABR" Neonatal Hearing Screening Device"

In Table 5.6 the transport cost at various levels of health care facilities is presented.

Table 5.6.2: Societal cost

Variables	TEO by MO at each PHC	TEO by CHWs at each Community level	Screening with Traditional Otoscope by ENT specialist at DHH/SDH
No of Screening per Year	**7280**	**31200**	**13780**
1st Time Visit	724360	0	4135102
Referred to DHH (30%)	655374.72	2808748.8	0
Referred to Tertiary Care (10%)	96237.96	412448.4	607216
Total	1475972.68	3221197.2	4742318
Cost Per Unit	**202.74**	**103.24**	**344.15**

5.7. Annual Coverage

Table 5.7.1 District Level

Variables	TEO by MO at PHC	TEO by CHWs at Community level per PHC	Screening with Traditional Otoscope by ENT specialist at DHH
Annual No of Screening per Year per facility	**7280**	**31200**	**13780**
No of DHH/ SDH at District Level	0	0	2
No of PHCs at District Level	71	71	0
Estimated Annual No of Screening	**5,16,880**	**22,15,200**	**27,560**

Table 5.7.2 State Level

Variables	TEO by MO at PHC	TEO by CHWs at Community level per PHC	Screening with Traditional Otoscope by ENT specialist at DHH
Annual No of Screening per Year per facility	**7280**	**31200**	**13780**
No of DHH/ SDH at State Level	0	0	62
No of PHCs at State Level	1360	1360	0
Estimated Annual No of Screening	**99,00,800 (99.00 Lakhs)**	**4,24,32,000 (4.24 Crore)**	**8,54,360 (8.54 Lakhs)**

Table 5.7.3 National Level

Variables	TEO by MO at PHC	TEO by CHWs at Community level per PHC	Screening with Traditional Otoscope by ENT specialist at DHH
Annual No of Screening per Year per facility	**7280**	**31200**	**13780**
No of DHH/ SDH at National Level	0	0	2258
No of PHCs at National Level	29899	29899	0
Estimated Annual No of Screening	**21,76,64,720 (21.76 Crore)**	**93,28,48,800 (93.28 Crore)**	**3,11,15,240 (3.11 Crore)**

5.8. Conclusions

Human resource costs for TEO at PHC, TEO at Community and ENT specialist at DHH are Rs 8,28,329, Rs 11,13,329 and Rs 14,40,000 respectively. Societal Cost is minimum at the community level (Rs 103.24) followed by PHC (Rs 202.74) and DHH (Rs 344.15). The Average number of screenings is highest at the community level (31200) followed by DHH (13780) and PHC (7280). In the State level and National level, the maximum number of screening was at the Community level followed by PHC and DHH.

Chapter 6

Decision Tree Model for various ear check-up

Figure 6.1: Decision Tree Model

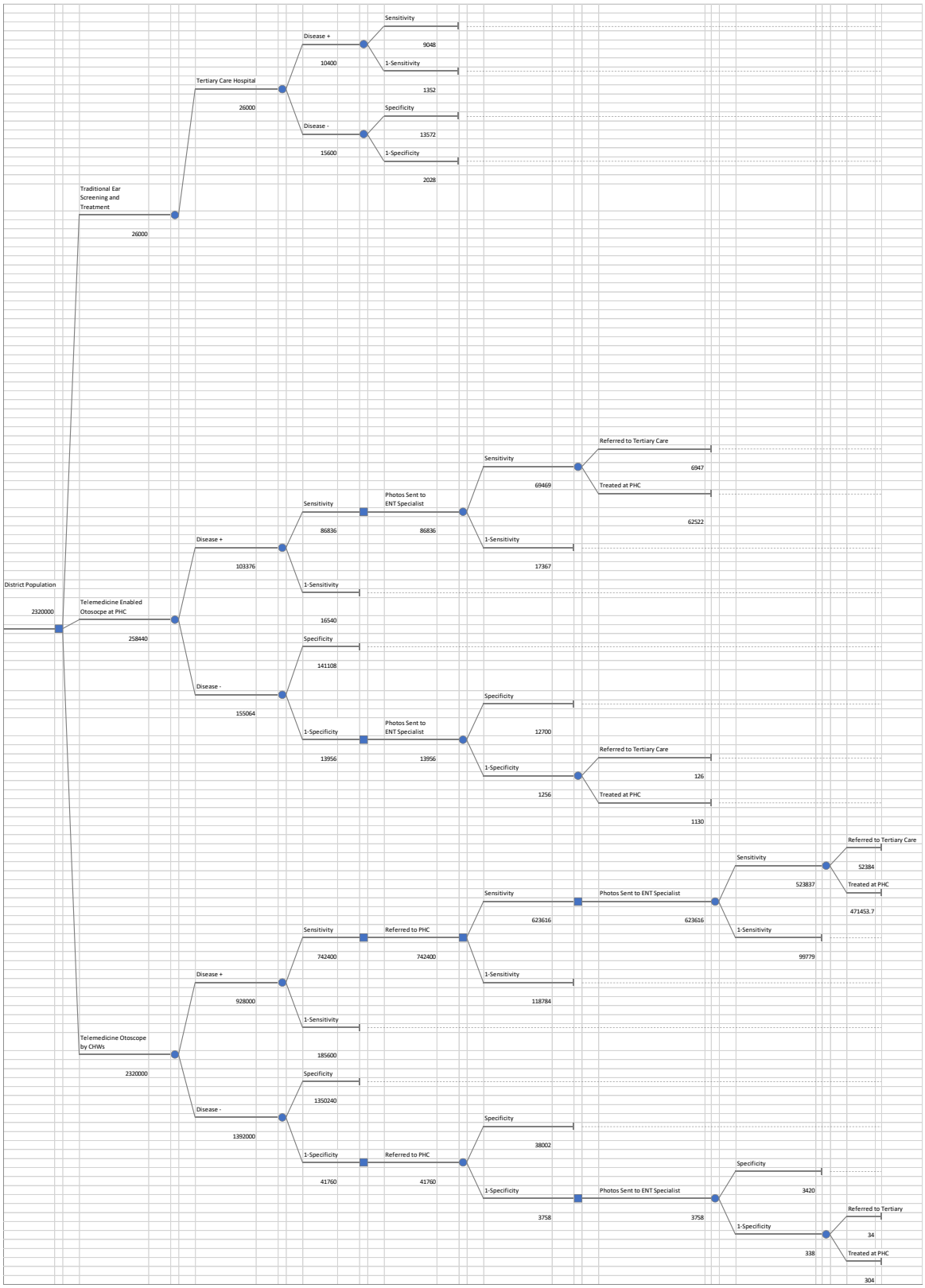


Figure no 6.1 shows the three types of models through which an individual is going to be screened and treated at the respective health care facilities. The stimulation has been done according to the population of Balasore district i.e., 23,20,000 (2011 Census) which was one of our study areas.

Figure 6.1.A Traditional ear screening practice and treatment

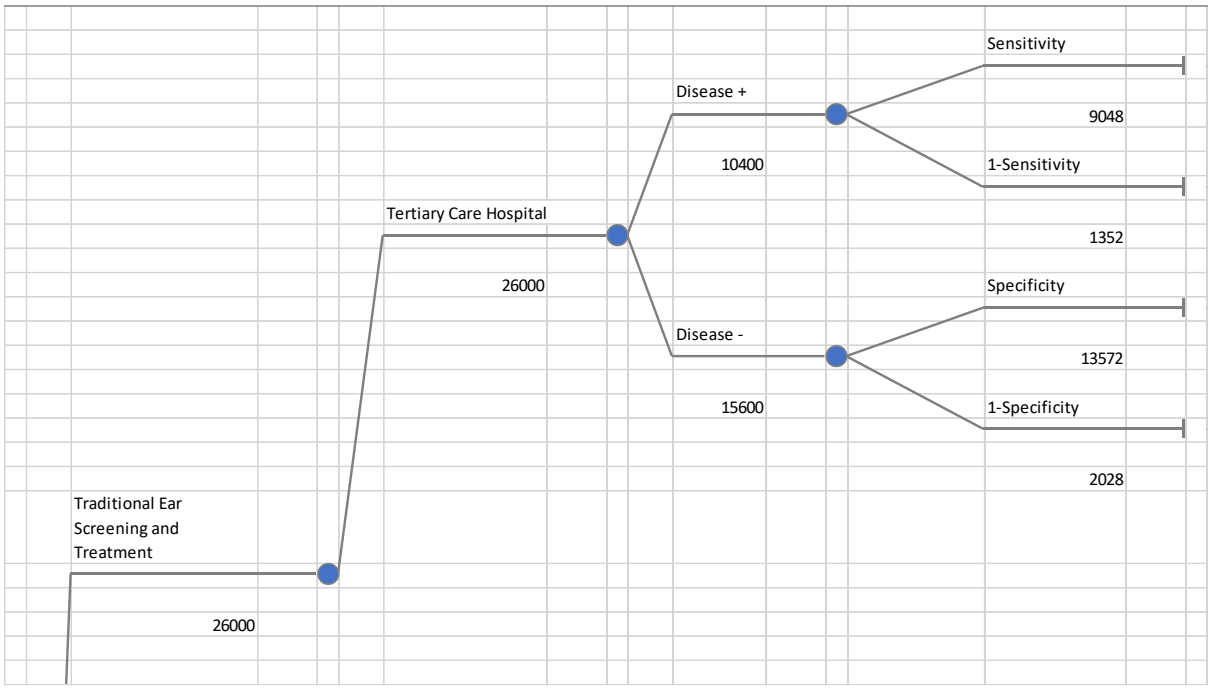


Figure 6.1.A shows the traditional ear screening practices followed in the ear screening and treatment passage followed at tertiary care hospital and PHCs. Annually, out of the total population of Balasore district, 26,000 patient visit to Tertiary Care. [Ref Table 6.2] Analysis at the tertiary care hospital was calculated using Sensitivity (89%) and Specificity (87%) of Screening with general otoscope. [Ref Fig 3.3, 3.4] At PHC level, otoscope is present under desirable according to IPHS (Indian Public Health Standards) 2012 guidelines. Ground data obtained during the field visits showed that none of the PHCs were having otoscopes and none of the medical officers were using it. Following which analysis was done using Sensitivity (50%) and Specificity (50%) as no data was available. Out of the total beneficiaries, 22620 patients were diagnosed correctly and treated at tertiary care hospitals and PHC respectively.

Figure 6.1.B Telemedicine enabled otoscope at PHC

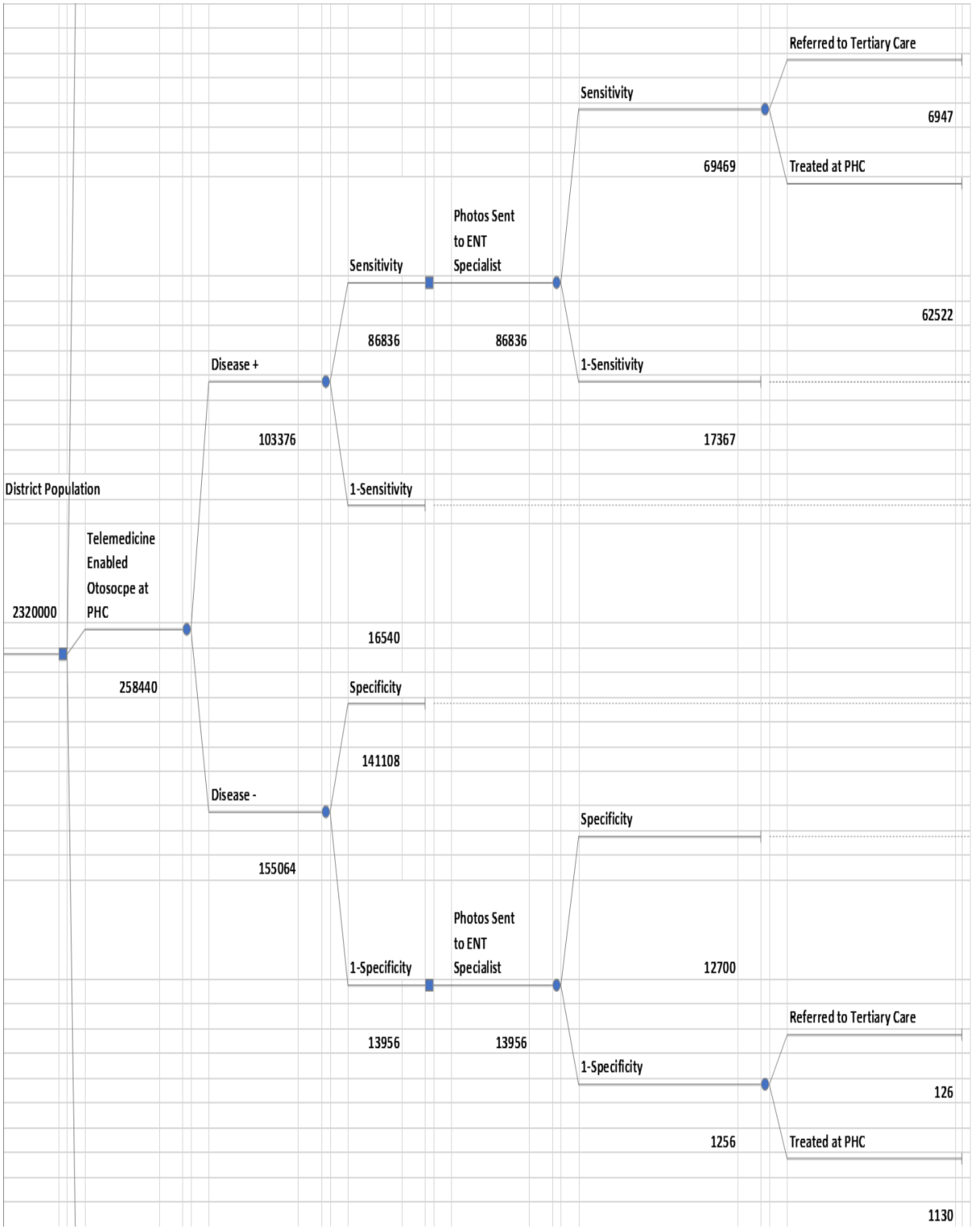


Figure 6.1.B shows the decision tree model of telemedicine enabled otoscope at PHC for screening of ear diseases. Analysis at the PHC level was performed using Sensitivity (84%) and Specificity (91%) of the physician using a digital otoscope. [Ref Fig 3.7,3.8] Annually, out of the total beneficiaries 7,073 and 62,522 patients were diagnosed correctly at PHC and treated at tertiary care hospitals and PHC respectively.

Figure 6.1.C Telemedicine Enabled Otoscope by Community Health Workers (CHWs)

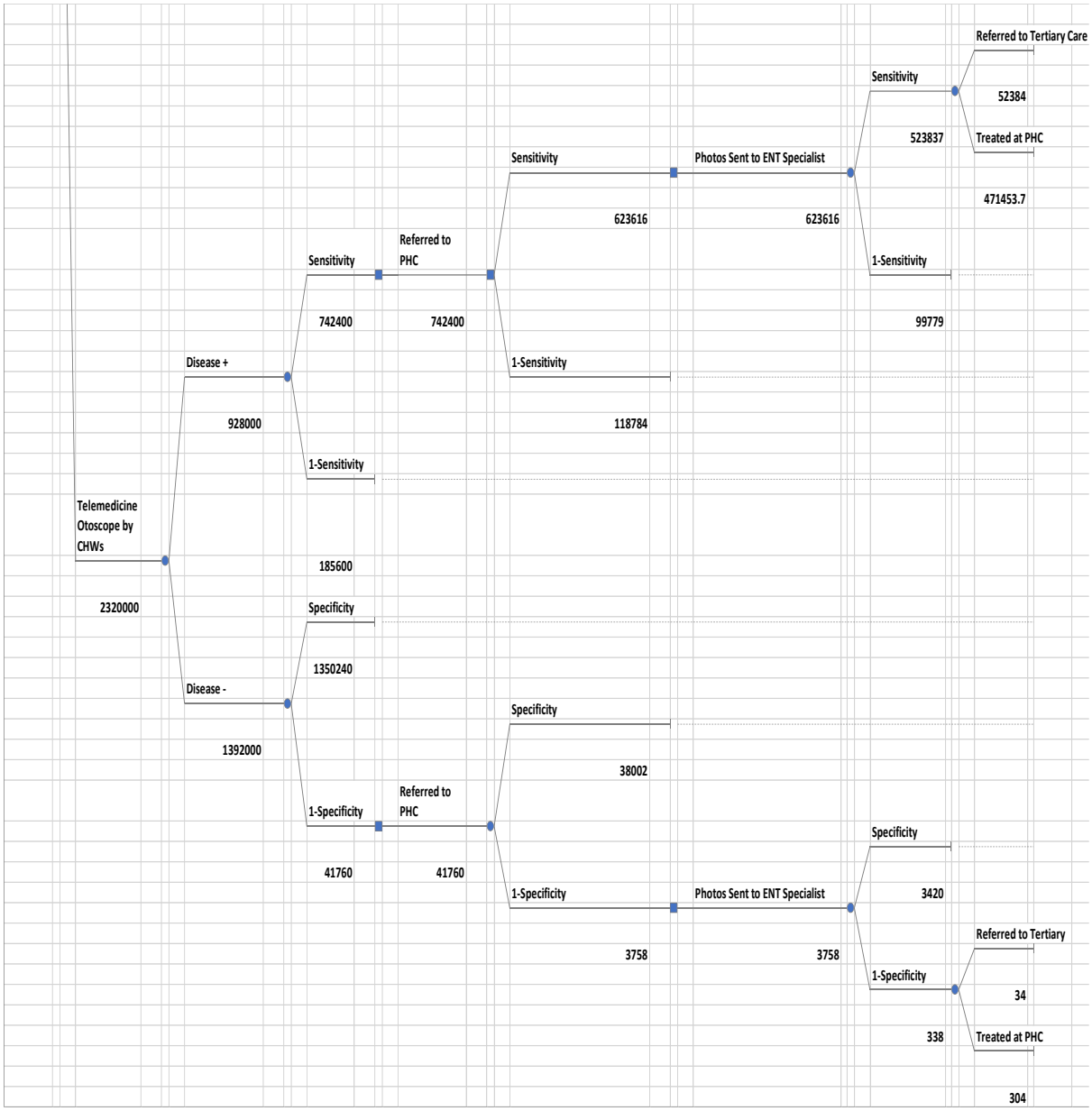


Figure 6.1.C shows the decision tree model of telemedicine enabled otoscope by CHWs at the community level for screening of ear diseases. Analysis at the community level was performed using Sensitivity (80%) and Specificity (97%) of CHWs using a digital otoscope. [Ref Fig 3.9,3.10] Analysis at PHC level was performed using Sensitivity (84%) and Specificity (91%) of physicians using a digital otoscope. [Ref Fig 3.7,3.8] Annually, out of the total beneficiaries 52,384 and 4,71,453 patients were diagnosed correctly at the community level and treated at tertiary care hospitals and PHC respectively.

Table 6.1 Information regarding data used in the decision tree model

Data	Source
Reference Population	Balasore District Population from Census 2011
No of Patients Visiting PHC/CHC	Primary Data collected via record review and interviews (Chapter 4)
Sensitivity and Specificity of Devices	Systematic Review (Chapter 3)
Reference to Tertiary Care	Primary Data collected via record review and interviews (Chapter 4)

Table 6.2 Expected Annual Screening from a Cohort

Variables	TEO by MO at PHC	TEO by CHWs at each Community level	Screening with Traditional Otoscope by ENT specialist at DHH/SDH
Population	2320000	2320000	2320000
Average of Cases Visit Per Day	14	NA	50
No of Facility in District	71	NA	2
No of Days	260	NA	260
Annual Cases	258440	2320000	26000
Percentage of Cohort Visiting Facility	11.14%	100%	1.12%

Table 6.2 shows the expected number of annual screening from a cohort of one district (ref Balasore district). TEO by MO at PHC level shall be providing services to around 11.14% of the cohort

Table 6.3: Total and per-unit cost for implementation of Telemedicine enabled otoscope and Traditional Otoscope

Variables	TEO by MO at each PHC	TEO by CHWs at each Community level	Screening with Traditional Otoscope by ENT specialist at DHH/SDH
Human Resource	₹ 8,28,329.00	₹ 11,13,329.00	₹ 14,40,000.00
Device Cost	₹ 27,482.83	₹ 2,74,828.35	₹ 13,074.25
Consumables and Non-Consumables	₹ 1,10,844.23	₹ 3,50,044.23	0
Training Cost	₹ 5,290.00	₹ 22,290.00	0
Electricity	₹ 2,500.00	₹ 2,500.00	0
Total Cost per facility (Annual Heath System)	**₹ 9,74,446.00**	**₹ 17,62,991.00**	**₹ 14,53,074.00**
	(9.7 Lakhs)	**(17.6 Lakhs)**	**(14.5 Lakhs)**
Expected no of cases per year	7280	31200	13780
Unit Cost per patient (Health System)	**₹ 134.00**	**₹ 57.00**	**₹ 105.00**
Societal Cost	₹ 202.74	₹ 103.24	₹ 344.15
Total Societal Cost	**₹ 336.60**	**₹ 159.75**	**₹ 449.59**
Average number of facilities at district level	**71**	**71**	**2**
Average annual implementation cost at district level (Balasore)	₹ 6,91,85,666.00	₹ 12,51,72,361.00	₹ 29,06,148.00
	(6.9 Crore)	(12.5 Crore)	(29 Lakhs)
Average number of facilities at state level	1360	1360	62
Average annual implementation cost at state level (Odisha)	₹ 1,32,52,46,560.00	₹ 2,39,76,67,760.00	₹ 9,00,90,588.00
	(132.5 Crore)	(239.7 Crore)	(9.0 Crore)
Average number of facilities at national level	29899	29899	2258
Average annual implementation cost at national level (India)	₹ 29,13,49,60,954.00	₹ 52,71,16,67,909.00	₹ 3,28,10,41,092.00
	(2913.5 Crore)	(5271.2 Crore)	(328.1 Crore)

Table 6.3 indicates the Total annual cost, the unit cost per patient and total societal cost for implementation of TEO by MO at each PHC.

Quality of Life Years (QALY) and Incremental Cost Effectiveness Ratio (ICER)

Table 6.4 Utility Values used for calculation of QALYs

Variables	Base Value	Ref
Normal Hearing in children*	0.95	RMRC Study, SOHUM
Normal Hearing in Adults*	0.90	Ref Clemens et al 2014, Nguyen et al 2015
Hearing Loss	0.67	Bamford J et al 2007, Barton GR et al,
Normal Hearing[a]	0.91	Assumption
Ear Problems[b]	0.81	Assumption

*May have other health problems; [a]Average of Normal Hearing in Children and Normal Hearing in Adults according to population of India; [b]Average of hearing loss and normal hearing in children

Table 6.5 QALYs calculated per district population

Variables	TEO by MO at PHC	TEO by CHWs at Community level	Traditional Otoscope by ENT specialist at DHH
QALYs (per district)	**44,08,661**	**8,55,84,094**	**9,63,898**

Table 6.6 ICER Calculation for TEO by MO at PHC and TEO by CHWs at Community level

Variables	TEO by MO at PHC	TEO by CHWs at Community level
ICER (per district)	**Rs 19.19/QALY gained**	**Rs 1.44/QALY gained**

6.1. Conclusions

Unit Cost for implementation is lowest at PHC Level than community level. Total Societal Cost is lowest for Community-level intervention (Rs 124.06) followed by PHC (Rs 222.81) and DHH (Rs 449.60). If the budget impact analysis is done with the existing manpower, then the cost of implementation would be considerably low. ASHA could be given some kind of incentive per case if required. The annual Cost of implementation was lower at the PHC level (1.46 Lakhs) than at the community level per PHC (6.49 Lakhs).

Chapter 7

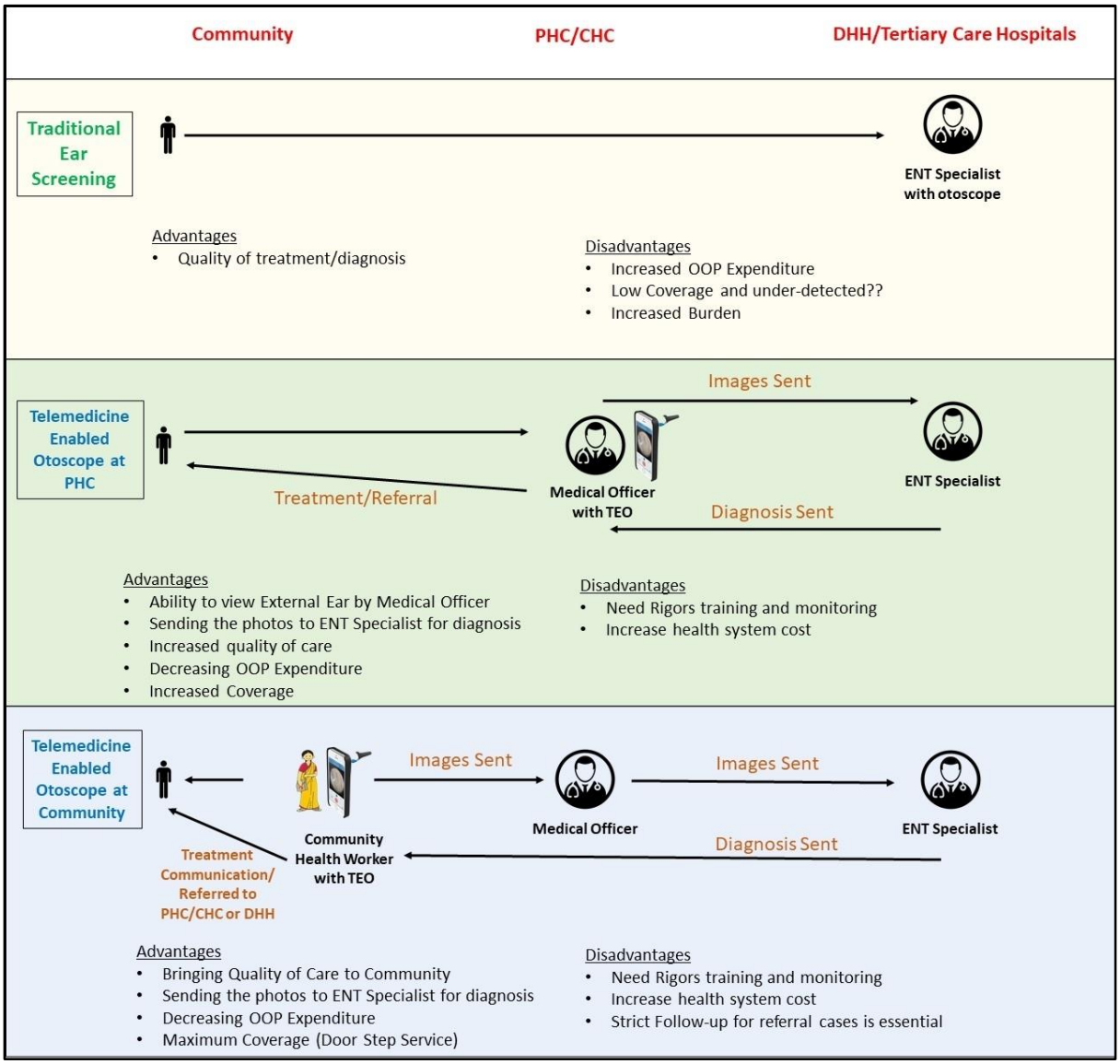
Conclusions and Policy Implications

The global burden of hearing loss is unequally distributed, with around 80% of those affected living in LMICs. Hearing disorders that are left untreated have a variety of severe repercussions, including social isolation, loneliness, psychosocial distress, anxiety, and depression. Hearing aid fitting is a more cost-effective solution than therapy and can significantly improve the quality of life for individuals with hearing loss. The delay in ear care is frequently observed, particularly in rural and remote locations, due to a lack of early screening and treatment at primary health care settings, a significant health system concern in LMICs pursuing universal health coverage.

Adults typically seek treatment five to 10 years after developing hearing issues. Lack of awareness towards ear issues is the primary barrier to treatment. These issues underscore the importance of community-based hearing screening to improve hearing care, thus reducing long wait times for ENT specialists and improving primary care. Additionally, a scarcity of audiologists and insufficient infrastructure, particularly in rural and remote locations, have made large-scale hearing screening programmes impossible to create. Existing programmes have significant challenges concerning diagnostic testing follow-up, long-distance travel for patients to obtain services, and potential salary loss during that time. Thus, when compared to in-person follow-up by a community-based hearing screening programme, tele-hearing screening and diagnostic follow-up enhanced follow-up.

To address the shortage of specialist ear care practitioners in resource-limited areas, CHWs and primary health care clinicians have been advocated as one option for addressing the human resource gap. They have the potential to play a critical role in increasing access to ear and hearing services, including screening, community awareness, and primary treatment. They have shown the ability to close the ear and hearing care gap for disease detection and treatment. This method has the potential to boost both local and national health systems and have positive consequences for individuals and society more broadly. However, much of the previous research has not examined their involvement in preventative efforts, the most effective techniques for training and supporting primary health care practitioners or CHWs, or the sustainability and cost-effectiveness of such models. Although there are significant implementation issues, ENT care is covered as part of comprehensive primary health care at Health and Wellness Centres (HWCs) in India under the Ayushman Bharat scheme.

Figure 7.1. Proposed model for hearing screening/check-up – traditional ear check-up, telemedicine enabled otoscope at primary health centre and community.



The provision of affordable diagnostic and treatment technologies and community engagement is crucial. Telemedicine-enabled otoscopes could be implemented into the NPPCD and Ayushman Bharat schemes to detect and prevent hearing impairments in community members. Telemedicine has a long history in otolaryngology. Otolaryngology, on the other hand, is a sophisticated anatomical structure. Due to a lack of specialized medical competence, many patients are unable to describe their clinical signs and symptoms. As a result, otolaryngologists are frequently required to make diagnoses online or provide treatment advice based on scant information, resulting in a preliminary diagnosis. Using this gadget in conjunction with a customized application, clinicians can quickly examine the external auditory canal and tympanic membrane. Studies have demonstrated the benefits of portable devices as a quick diagnostic aid and as a teaching adjunct for pre-clinical medical students. Numerous applications are possible with this technology. The device's ease of use encourages adoption at all

levels of healthcare, thus improving the quality of diagnosis and treatment accessible. Remote otological assessment by video-otoscopy has demonstrated promise as a safe and effective tool for detecting the presence of ear disease in a variety of healthcare settings. The study revealed that TEO at primary care centres is optimal for initial implementation as a medical officer supervises it. Remote usage of these instruments enables more successful telehealth appointments or situations that previously required an in-person visit. Such solutions can help otolaryngologists, and general practitioners increase their use of telemedicine during an emergency.

The annual health system cost per facility for ear screening with a traditional otoscope by an ENT specialist at tertiary health care facilities will be 14.5 lakhs INR with a per-patient cost of 105.45 INR without societal cost; nevertheless, coverage will be less than primary health care or CHWs model. Similarly, the annual health system cost per facility for ear screening with TEO by a Medical Officer at each Primary Health Centre will be 1.46 lakhs INR with a patient cost of 20.07 INR. Without societal cost, the yearly health system cost per facility for ear screening with TEO by CHWs at the community level will be 6.46 lakhs INR or 20.82 INR per patient. Primary health care and CHW models with TEO both have a high level of coverage. Although the annual cost of implementing ear screening with a typical otoscope by ENT specialists at tertiary health care facilities will be 328.1 Crore INR at the national level, coverage will be extremely low. At the national level, the yearly cost of implementing ear screening with TEO by Medical Officers in Primary Health Centers will be 436.87 crore INR, while the CHW model with TEO will cost 1942.42 crore INR, but will provide universal coverage. To address the dearth of expert ear care workers in India and in other resource-poor settings, primary care strengthening through telemedicine has been advocated as one way to close the gap in human resources for health. It has the potential to significantly improve access to ear and hearing services, including screening, community awareness, and basic treatment. The ICER value of TEO by Medical Officers in Primary Health Centers and TEO by CHWs at the community level are found to be Rs 19.19/Qaly gained and 1.44/Qaly gained respectively.

The availability of hearing screening with TEO is an outstanding achievement. However, primary health care practitioners must be trained in the execution of TEO. Proper training on how to utilize TEO should be provided to physicians and other individuals capturing photographs. However, electricity and internet connectivity in rural and urban areas are critical for successful implementation of TEO. Several studies have demonstrated that the quality of the photos captured impedes accurately diagnosing the condition. Although many studies did not provide data about the tools used to train primary health care clinicians and CHWs, the WHO introductory ear care training manuals were the

most frequently recommended training materials. Digital or mobile technologies offer the potential to improve the delivery of training and continuous expert support, as they have in other areas of primary health care provider education.

References

Abegunde DO, Mathers CD, Adam T, Ortegon M, Strong K. The burden and costs of chronic diseases in low-income and middle-income countries. Lancet 2007; 370:1929–38. 2 World Health Organization. Fact sheet. Deafness and hearing impairment.

Bamford J, Fortnum H, Bristow K, Smith J, Vamvakas G, Davies L, et al. Current practice, accuracy, effectiveness and cost-effectiveness of the school entry hearing screen. London; 2007.

Barton GR, Bankart J, Davis AC, Summerfield Q a. Comparing utility scores before and after hearingaid provision : results according to the EQ-5D, HUI3 and SF-6D. Appl Health Econ Health Policy. 2004; 3: 103–5. Available: http://www.ncbi.nlm.nih.gov/pubmed/15702947. PMID: 15702947

Barton GR, Stacey PC, Fortnum HM, Summerfield a Q. Hearing-impaired children in the United Kingdom, IV: cost-effectiveness of pediatric cochlear implantation. Ear Hear. 2006; 27: 575–88. doi: 10.1097/01.aud.0000233967.11072.24 PMID: 16957506

Bhavana K, Ahmad M, Sharma P. Smartphone otoscopy sans attachment: a paradigm shift in diagnosing ear pathologies. OTO open. 2018 Jul;2(3):2473974X18786496.

Biagio L, Swanepoel DW, Adeyemo A, Hall III JW, Vinck B. Asynchronous video-otoscopy with a telehealth facilitator. Telemedicine and e-Health. 2013 Apr 1;19(4):252-8.

Biagio, L. (2015). *Telehealth for primary health care ear disorders: a study in video-otoscopy* (Doctoral dissertation, University of Pretoria).

Clemens S, Begum N, Harper C, Whitty J a, Scuffham P a. A comparison of EQ-5D-3L population norms in Queensland, Australia, estimated using utility value sets from Australia, the UK and USA. Qual Life Res. 2014; doi: 10.1007/s11136-014-0676-x

Directorate General of Health Services. National programme for prevention and control of deafness, Project proposal. New Delhi: Ministry of Health and Family Welfare; 2006.

Eikelboom RH, Mbao MN, Coates HL, Atlas MD, Gallop MA. Validation of tele-otology to diagnose ear disease in children. International journal of pediatric otorhinolaryngology. 2005 Jun 1;69(6):739-44.

Galhotra A, Sahu P. Challenges and solutions in implementing hearing screening program in India. Indian journal of community medicine: official publication of Indian Association of Preventive & Social Medicine. 2019 Oct;44(4):299.

Garg, S., Chadha, S., Malhotra, S., & Agarwal, A. K. (2009). Deafness: Burden, prevention and control in India. *Natl Med J India*, *22*(2), 79-81.

Garg, S., Kohli, C., Mangla, V., Chadha, S., Singh, M. M., & Dahiya, N. (2018). An Epidemiological Study on Burden of Hearing Loss and Its Associated Factors in Delhi, India. *Annals of Otology, Rhinology & Laryngology*, *127*(9), 614-619.

Govender Samantha M., Mars Maurice. Assessing the efficacy of asynchronous telehealth-based hearing screening and diagnostic services using automated audiometry in a rural South African school. S. Afr. J. Commun. Disord. [Internet]. 2018 [cited 2022 Mar 10] ; 65(1): 1-9. Available from: http://www.scielo.org.za/scielo.php?script=sci_arttext&pid=S2225-47652018000100013&lng=en. http://dx.doi.org/10.4102/sajcd.v65i1.582

Gupta DK, Pati S, Singh S, Roy R, Chugh R, Goyal S, Bansal S, Sangwan K. Efficacy of android based mobile device as a screening tool for hearing loss in quiet and noisy environments. J Evol Med Dent Sci. 2019 Aug 12;8(32):2577-81.

Gupta, D. K., Pati, S., Singh, S., Roy, R., Chugh, R., Goyal, S., ... & Sangwan, K. (2019). Efficacy of Android Based Mobile Device as a Screening Tool for Hearing Loss in Quiet and Noisy Environments. *Journal of Evolution of Medical and Dental Sciences*, *8*(32), 2567-2572.

Gupta, N., Chawla, N., Gupta, D., Dhawan, N., & Janaki, V. R. (2017). Community triage of otology patients using a store-and-forward telemedicine device: A feasibility study. *ENT: Ear, Nose & Throat Journal*, *96*(7).

Krumm, M., & ferrari, D. (2008). Contemporary telehealth and telemedicine applications in audiology. *Audiology Today*, *20*(5), 36-41.

Lundberg T, Biagio L, Laurent C, Sandström H, Swanepoel DW. Remote evaluation of video-otoscopy recordings in an unselected pediatric population with an otitis media scale. International journal of pediatric otorhinolaryngology. 2014 Sep 1;78(9):1489-95.

Lundberg T, De Jager LB, Swanepoel DW, Laurent C. Diagnostic accuracy of a general practitioner with video-otoscopy collected by a health care facilitator compared to traditional otoscopy. International journal of pediatric otorhinolaryngology. 2017 Aug 1;99:49-53.

Mandavia R, Lapa T, Smith M, Bhutta MF. A cross-sectional evaluation of the validity of a smartphone otoscopy device in screening for ear disease in Nepal. Clinical Otolaryngology. 2018 Feb;43(1):31-8.

Moshtaghi O, Sahyouni R, Haidar YM, Huang M, Moshtaghi A, Ghavami Y, Lin HW, Djalilian HR. Smartphone-enabled otoscopy in neurotology/otology. Otolaryngology–Head and Neck Surgery. 2017 Mar;156(3):554-8.

National Sample Survey Organization. Disabled persons in India, NSS 58th round (July–December 2002) Report no. 485 (58/ 26/1). New Delhi: National Sample Survey Organization, Ministry of Statistics and Programme Implementation, Government of India, 2003.

Nguyen K-H, Smith AC, Armfield NR, Bensink M, Scuffham PA (2015) Cost-Effectiveness Analysis of a Mobile Ear Screening and Surveillance Service versus an Outreach Screening, Surveillance and Surgical Service for Indigenous Children in Australia. PLoS ONE 10(9): e0138369. doi:10.1371/journal.pone.0138369

O'Donovan J, Verkerk M, Winters N, Chadha S, Bhutta MF. The role of community health workers in addressing the global burden of ear disease and hearing loss: a systematic scoping review of the literature. BMJ global health. 2019 Mar 1;4(2):e001141.

Ramkumar, V., John, K. R., Selvakumar, K., Vanaja, C. S., Nagarajan, R., & Hall, J. W. (2018). Cost and outcome of a community-based paediatric hearing screening programme in rural India with application of tele-audiology for follow-up diagnostic hearing assessment. *International journal of audiology*, *57*(6), 407-414.

Richards JR, Gaylor KA, Pilgrim AJ. Comparison of traditional otoscope to iPhone otoscope in the pediatric ED. The American journal of emergency medicine. 2015 Aug 1;33(8):1089-92.

Roland, L., Fischer, C., Tran, K., Rachakonda, T., Kallogjeri, D., & Lieu, J. E. (2016). Quality of life in children with hearing impairment: systematic review and meta-analysis. *Otolaryngology–Head and Neck Surgery*, *155*(2), 208-219.

Schuster-Bruce J, Ali A, Van M, Rogel-Salazar J, Ofo E, Shamil E. 36 A Randomised Trial to Compare How Undergraduates Diagnose Common Ear Pathology Using A Smartphone Otoscope and Standard Otoscope in A Simulated Setting. British Journal of Surgery. 2021 May;108(Supplement_2):znab134-110.

Shah MU, Sohal M, Valdez TA, Grindle CR. iPhone otoscopes: currently available, but reliable for tele-otoscopy in the hands of parents?. International journal of pediatric otorhinolaryngology. 2018 Mar 1;106:59-63.

Smith, A. C., Armfield, N. R., Wu, W. I., Brown, C. A., & Perry, C. (2012). A mobile telemedicine-enabled ear screening service for Indigenous children in Queensland: activity and outcomes in the first three years. *Journal of telemedicine and telecare*, *18*(8), 485-489.

Suen, J. J., Bhatnagar, K., Emmett, S. D., Marrone, N., Robler, S. K., Swanepoel, D. W., ... & Niemang, C. L. (2019). Hearing care across the life course provided in the community. *Bull World Health Organ*, *97*(10), 681-90.

Tucci, D. L., Merson, M. H., & Wilson, B. S. (2010). A summary of the literature on global hearing impairment: current status and priorities for action. *Otology & Neurotology*, *31*(1), 31-41.

Varshney, S. (2016). Deafness in India. *Indian journal of otology*, *22*(2), 73.

Winters, N., O'Donovan, J., Verkerk, M., Chadha, S., & Bhutta, M. F. (2019). The role of community health workers in addressing the global burden of ear disease and hearing loss: a systematic scoping review of the literature. *BMJ Global Health*, (2).

World Health Organization. (2017). *Global costs of unaddressed hearing loss and cost-effectiveness of interventions: a WHO report, 2017*. World Health Organization.

Yousuf Hussein, S., Swanepoel, D. W., Mahomed, F., & Biagio de Jager, L. (2018). Community-based hearing screening for young children using an mHealth service-delivery model. *Global health action*, *11*(1), 1467077.