

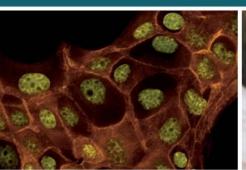


Automatic Cortical Audiometer (HEARLab module 3)

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NSW Health Innovation Symposium – 11 October 2013

creating sound value™









HEARing CRC



Mission

The HEARing Cooperative Research Centre (CRC) is focused on the twin challenges of:

- more effective prevention
- improved remediation of hearing loss

Aims

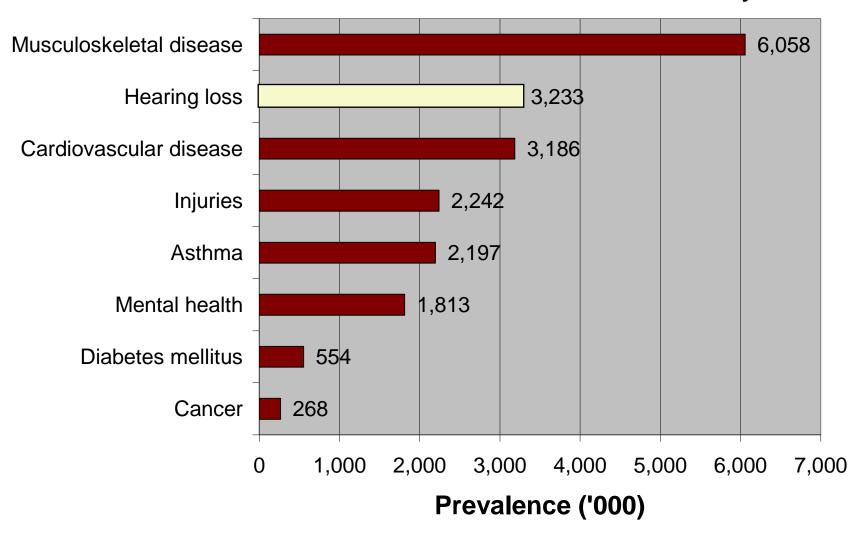
Through research and its use, the HEARing CRC aims to reduce the economic impact of hearing loss by

- maximising lifelong hearing retention
- reducing loss of productivity resulting from hearing loss
- increasing uptake and use of hearing technology
- providing postgraduate and professional education and training to support uptake and use of prevention and remediation initiatives.

The Health Challenge



Prevalence re National Health Priority Areas



Economic Impact of Hearing Loss

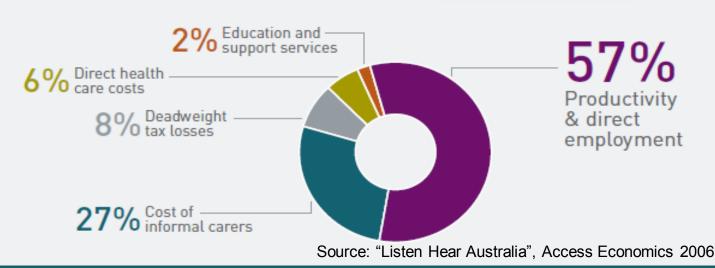


Impact of hearing loss on Australia

\$11.75bn p.a. financial cost +\$11.30bn p.a. disability & lost well- being cost

\$23.05bn p.a.

Contributors to financial impact



HEAR

LISTEN HEAR!

The Hearing Healthcare Chain



Common feature is requirement for assessment tests/tools

Outcomes



Clinical / surgical follow up testing

Intervention



 Assessment tools to verify benefits being obtained

Clinical Process



Fitting hardware/software tools to appropriately fit / program device(s)

Technology



 Assessment tools to ensure proper selection of device(s) to meet needs of client

Client



 Test Battery (screening & diagnostic) used to detect and identify degree/type of hearing loss

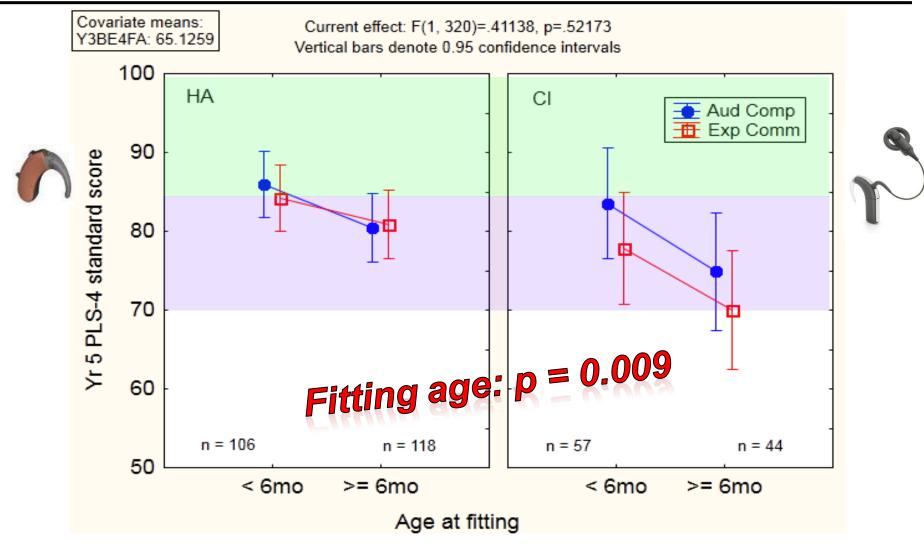
The Health Challenge



The Problem	HEARworks Solution / challenge
Audiological tests traditionally based on using specific equipment	Implement audiological test suite as software modules for standard PC
Limitation on ability of healthcare agencies to purchase new equipment	Single PC-based portable hardware with multiple (and expandable) functionality through software
Inability to acquire upgrades to tests without additional costs	Software modules enable easy and low cost upgrade of test procedures
Patients (infants) cannot cooperate with testing, current tests often require sedation	Use of electrophysiology tests does not require patient cooperation or patient to be asleep
Most tests/equipment require a skilled professional to interpret outcomes	Automated response analysis built in to enable use by non-specialist
Commercial interests focused on individual devices for specific tests	Identify manufacturer willing to accept entire concept

Practical Steps ~ identify key user needs





At 5 years of age, earlier fitting of devices to hearing impaired children is associated with better performance (n= 325)

Practical Steps ~ identify key user needs



Meetings with end-users to identify what they need to manage

hearing loss in infants?



Universal newborn screening



Evaluation methodology enabling objective confirmation of diagnosis

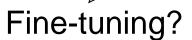


Evaluation method enabling fitting of appropriate device



Verification method for fitting

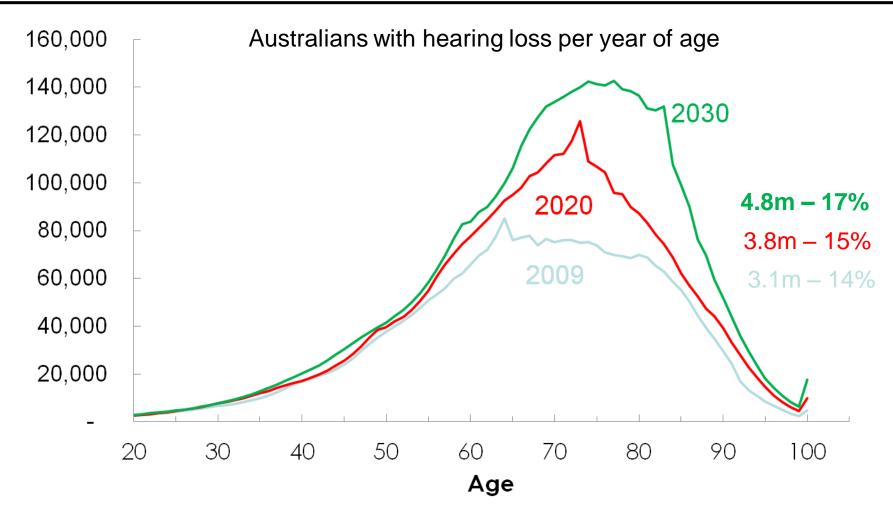
& outcomes



Cochlear implant?

Practical Steps ~ identify key user needs





- Increasing number of elderly patients with cognitive decline who may not be able to cooperate with audiological assessment or device fitting

Project Overview:



Rationale

There is a need for process of measuring hearing thresholds in infants fitted with hearing aids and/or cochlear implants with adequate frequency specificity without sedation

Broad Aim of Project

Develop a Cortical Audiometer that tests hearing function through detection of electrical responses from the brain in response to speech sounds implemented in software that can be configured and run on standard PC

End user

Clinicians to measure aided hearing of infants and adults who are unable or unwilling to be measured with behavioural audiometry

HEARLab™ ~ the enabling platform

















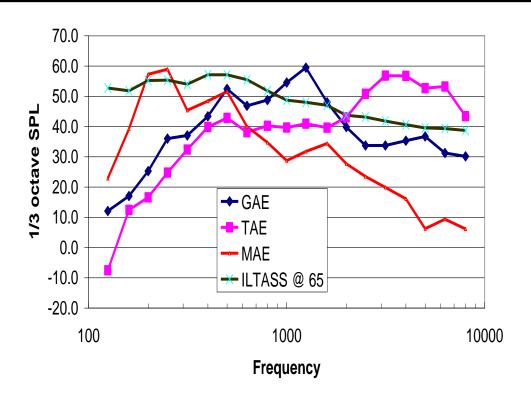




- Technology transfer process enabled identification of a manufacturer with an international distribution network and respected market position whose commercial interests aligned with platform/software strategy
- Key issue was commercial licence to initial platform and first test module coupled with options on future modules expanding functionality

HEARLab™ ~ the enabling platform





 Speech stimulus sampled from running speech, cover relevant range in both intensity and frequency:

$$/m/(0.25 - 0.5 \text{ kHz}), /g/(0.8 - 1.6 \text{ kHz}), /t/(2 - 8 \text{kHz}),$$

- 3 intensity levels
 - Soft speech (55dB), conversational speech (65dB), loud speech (75dB)
- Aided and unaided speech

Why Cortical Auditory Evoked Potential?



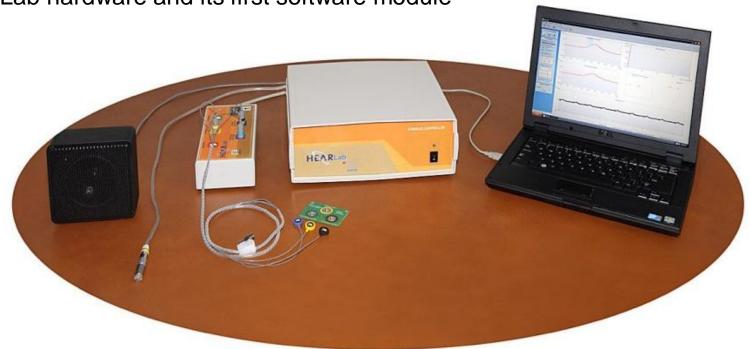
- CAEPs can be reliably generated in response to sound stimuli, for adults and for infants/children
 - -CAEP testing is feasible using speech stimuli in HEARLab
 - can be used for fitting of hearing aids & BAHA, and for fitting CIs
 - can be used without sedation by non-experts in standard clinical setting



Project Outcomes



The HEARLab hardware and its first software module



- Module 1 Aided Cortical Assessment (ACA™) used to fit hearing aids in infants and in elderly/aged patients with cognitive decline
- FDA & EU regulatory approvals
- current sales/use in Australia, USA, Europe and Asia
- patent granted on electrode system
- Module 2 Auditory Brainstem Response (ABR) test near complete



Next Steps: Module 3



Rationale

There is a need for automating the entire process of measuring hearing thresholds in infants with adequate frequency specificity without sedation and in an awake state

Broad Aim of Project

Develop an Automatic Cortical Audiometer that automatically detects response, calculates the next test level and calculates hearing threshold, that can be used for remote assessment

End user

Clinicians to measure aided hearing of infants and adults who are unable or unwilling to be measured with behavioural audiometry

Medical Devices Fund Recipient

Key Learnings



Identify intended impact and end-users

- ✓ As in the CRC objective "through .. commercialization of research findings" help to "increase the effectiveness with which hearing loss is treated"
- ✓ Provided a new tool for clinicians to assess audibility of speech to infant who are fitted with hearing aids based on Universal Newborn Screening

Identify path to market as early as possible

✓ Involvement of Frye Electronics enabled clear objectives in terms of engineering and software development requirements, and captured future market for new modules developed

Involve partners / end-users in development

✓ Involvement of end-users enables us to clearly identify the needs that we were addressing and ensure the most rapid market take up of the commercial device and software

Acknowledging Partners





Core Members











Support Members















































