Centre of Research Excellence in EAR AND HEARING HEALTH of Aboriginal and Torres Strait Islander Children

Hearing for Learning

Otitis media and hearing loss among Aboriginal and Torres Strait Islander children:

a research summary

Australian Parliament's Standing Committee on Health, Aged Care and Sport public hearing in reference to the Inquiry into the Hearing Health and Wellbeing of Australia.

8:00 am June 7th 2017

via teleconference with

Professor Amanda Leach and Professor Peter Morris

(attending the International Symposium on Recent Advances on Otitis Media in the Gold Coast).

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Current status

Research data from remote communities

1. Our most recent population survey of healthy children across multiple NT communities in 2013[1] found that

    a. only 7% of one year old children had bilateral normal ears
    b. half (51%) the children had glue ear
    c. 41% had bulging or perforated ear drums.
    d. OM was rarely associated with pain (reported by parent)

2. The proportion of young children with bilateral normal ears has been below 10% since 2001[1-3].

3. The proportion of young children with runny ears (chronic suppurative OM), the most disabling form of OM, has declined since 2001, from 24% to around 14%[1, 2], which still exceeds WHO criterion of 4% CSOM for a public health emergency[4].

4. A birth cohort study (unpublished) of almost 400 infants recruited at one month of age and seen at 1, 2, 4, 6, 12, 18 and 36 months of age shows

    a. 40% of one month old infants have OM
    b. 95% of one year old infants have bilateral OM
    c. Only one baby had normal ears at every visit to age 7 months
    d. Runny ears were seen in 5% infants at 4 months of age and 27% at 36 months of age
    e. Colonization of the nasopharynx by multiple OM bacteria was 50% at one month of age

5. Social determinants underpin slow progress in OM improvements (crowding, smoke exposure, poor hygiene)[3].

Current Gaps and Implications for Practice

Monitoring prevalence and response to program change:

OM prevalence and incidence are greatly under-estimated by Primary Health Care (PHC) data because

1. OM is normalized (even runny ears)
2. OM is asymptomatic (painless)[1]
3. OM management is difficult (long term)
4. OM is an uncommon reason for families to access to PHC (compared to burden)
5. Hearing loss or speech delay is almost never a presenting concern of parents

6. Diagnostic skills are poor (otoscopy)
7. OM is difficult to diagnose in very young children
8. OM is different in Aboriginal and Torres Strait Islander children (rarely see normal)
9. Recommended equipment for diagnosis (video otoscopy or tympanometry) is not available, not working, or not understood

10. Health Care Providers are unclear about benefits and harms of antibiotics in high-risk children
11. PHC responsibility for ear health shifted to audiology and ENT services
12. Referral pathways to Audiologist or ENT are inefficient and unable to service true burden

Recommendations:

1. Raised awareness and profile of OM – Nationally
2. Policy and Practice – commitment and support of evidence based PHC practice, nationally
3. Address social determinants & risk factors – a Whole of Government coalition
4. Clinical training in PHC – digital apps and evidence-based Guidelines
5. Resources – video otoscopy and tympanometry in PHC supported by comprehensive on-line image database to help verify diagnosis.
6. Evaluation research
7. Qualitative research
8. Intervention research

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Framing the Problem

https://www.youtube.com/watch?v=WzRqPfPDLcg 'Catching Dragonflies' documentary trailer gives some insights into the lived experience of otitis media for Indigenous children. This includes an interview with Ear Nose and Throat surgeon Professor Kelvin Kong, Australia's first Indigenous surgeon and Chief Investigator of the Centre of Research Excellence in Ear and Hearing Health of Aboriginal and Torres Strait Islander children.

Aboriginal children have the highest rates of otitis media, a middle ear infection that causes hearing loss, than any other people in the world.

The main forms of the disease include acute otitis media (AOM), also known as a 'bulging eardrum'; otitis media with effusion (OME), commonly known as 'glue ear'; and chronic suppurative otitis media (CSOM), known as 'runny ear', which describes the pus discharged when a bulging eardrum bursts.

All forms are associated with hearing loss, particularly CSOM or 'runny ears'.

In 1996 – the most recent year comparative global data available – the World Health Organization reported that the prevalence of chronic suppurative otitis media (CSOM, or "runny ears") was highest in the Inuit (Eskimo) and Australian Aboriginal populations: at around 12% to 46%[5].

This was followed by Native Americans at 4% to 8%; South Pacific Islanders, Africans, Koreans and Indians at around 2% to 6%; and was lowest in United States and United Kingdom, at less than 1%.

The World Health Organization states that a 4% prevalence of runny ears or chronic suppurative otitis media as a massive public health problem requiring urgent attention.

Tragically, population surveys in remote Northern Territory communities in 2013 found almost all, 90%, Aboriginal children in remote areas have some form of otitis media: 50% have glue ear, 30% have bulging ear drums, and around **15% have runny ears**[1].

These infections are invariably bilateral and persist throughout the early childhood years.

For Aboriginal children we have documented that the severe pain classically associated with bulging ear drums is rarely experienced by Aboriginal infants and young children in remote areas. We do not know the reason for this, but it does mean that parents and health care providers do not see the warning signs, infections go untreated and readily become chronic.

Impact of hearing loss on life trajectory

Aboriginal and Torres Strait Islander children are at a significantly higher risk of otitis media and hearing loss compared to non-Indigenous children. One national study found Aboriginal and Torres Strait Islander children were five times more likely to be diagnosed with severe otitis media than their non-Indigenous counterparts. During the eight-year period, Aboriginal and Torres Strait Islander children saw their GP for discharge in their ear 40 times more than non-Indigenous children[6].

The longer the infection is left untreated, the further risk it poses to hearing. All forms of OM cause hearing loss which can delay normal development of speech, language and communication. Children with persistent hearing loss often also have communication and behavioural problems, avoid social interactions, poor school attendance, low levels of literacy and numeracy; poor employment opportunities, increased poverty, youth justice issues and increased incarceration rates. Auditory processing disorders established during a childhood of sound deprivation can be life-long, even if hearing is restored.

In fact, hearing is the most prevalent barrier to educational attainment for Aboriginal and Torres Strait Islander children in the Northern Territory. In the NT in 2007 to 2011, 53% of Aboriginal and Torres Strait Islander children receiving audiology services had some kind of hearing loss and 33% had a hearing impairment.

The relationship between childhood OM and hearing loss, with lifelong frustration and shame due to communication and comprehension problems, is only just being realized. Shockingly, a very high proportion of incarcerated Aboriginal and Torres Strait Islander youth and adults have some hearing loss (90%), of whom 35% have significant hearing loss of > 35dB, due to damage caused during years of otitis media[7]. This hearing impairment may have influenced their trajectory or compromised their communications with the justice system.

Prevention

Pathology: Otitis media is middle ear inflammation caused by bacteria and viruses that initially colonise the nasopharynx (back of the nasal passages) and access the middle ear space via the Eustachian tube. The host immune response causes fluid accumulation and prevents the tympanic membrane from vibrating and conducting sound to the brain (hence conductive hearing loss). Respiratory viral infections can increase bacterial load and thereby exacerbate OM, but viruses are a relatively rare primary cause of OM in Aboriginal and Torres Strait Islander children. In most non-Aboriginal children, viral otitis media tends to occur in 'winter peaks' and resolves naturally. The predominant bacterial otopathogens are *Streptococcus pneumoniae* (pneumococcus, Spn), non-typeable *Haemophilus influenzae* (NTHi) and *Moraxella catarrhalis* (Mcat). Young children under 5 years of age are the major carriers of these bacteria. Bacterial transmission occurs via human-human contact, spread of nasal secretions via cough, sneezing, kissing and hand contamination.

Risk factors and potential strategies for preventing episodes of otitis media.

Randomized controlled trials have shown that pneumococcal conjugate vaccines can prevent infections caused by several (up to 13) strains of pneumococcus. However, there are no vaccines licensed for NTHi or Mcat (although one vaccine has included NTHi-proteinD with some efficacy). Furthermore, there are over 90 pneumococcal strains can cause OM. Developing an effective OM-vaccine is an enormous challenge, not yet fully achieved.

Most other prevention strategies are informed by observational studies of risk factors for OM, rather than randomized controlled trials designed to determine the benefits or harms of these strategies.

Overcrowded housing, specifically where there are more than 2 children in the household, has been identified as a significant risk factor for serious OM.

Exposure to campfire and tobacco smoke is also a risk factor for early otitis media in infants. Smoking rates are still very high in Aboriginal and Torres Strait Islander people, including pregnant women.

Breastfeeding during the first six months of life can prevent many episodes of OM. Exclusive breastfeeding in this period is associated with around a 43% reduction of acute otitis media in the first two years of life. Exclusive breastfeeding is almost universal in remote communities, but has become less popular over time, particularly in urban settings.

Pacifier use and child care attendance are risk factors in some populations, but are currently rare in remote community settings.

Poor maternal education is associated with increased risk of OM, and a family history of OM is predictive.

Improved hygiene practices reduce the incidence of diarrhoeal and respiratory infections in some populations and in child care settings, but the impact on OM has not been reported. We found that 4% children in day care centres in Darwin have hand contamination with otopathogens, compared to 40% in children living in remote communities. Strategies for reducing hand contamination and cross infection have not been funded or evaluated in remote communities.

State of crisis in otitis media among Aboriginal and Torres Strait Islander people

Research has shown that for Aboriginal and Torres Strait Islander children in remote areas, the prevalence of OM is extremely high and severe; first episode of otitis media occurs within weeks of birth[8]. Infants become infected with multiple pathogens simultaneously. These come from multiple contacts with siblings and other young children. The infant immature immune system fails to eradicate each pathogen before the next is acquired. This sets up a vicious circle, resulting in recurrent and persistent disease which does not resolve for months or years[9].

Our most recent standardized population surveillance across many remote communities in the NT and in WA shows that almost 90% of toddlers have some form of OM (generally bilateral), and 14% to 20% have "runny ears" (chronic suppurative otitis media, CSOM)[1]. The WHO has a criterion for CSOM prevalence of 4% as a public health emergency requiring immediate action. Australia is the only western country with documented CSOM rates above 6%[4].

Otitis media prevalence is also high in Aboriginal and Torres Strait Islander children living in urban and rural communities; around 40% children up to 8 years of age have OM (2% have perforations), age-inappropriate speech, and language delays[10].

Research overview (see APPENDIX ONE)

Our research program has focused on understanding the natural history and pathology of OM in remote communities; age of onset, aetiology, risk factors, incidence and prevalence, natural cure rate[8]. This work informed subsequent clinical trials and biological studies to find what works best in prevention of early

onset OM and prevention of disease progression[11]. Our recent and current research determines what vaccine schedules, treatment regimens or surgical procedures are most effective for AOM and CSOM, such as whether two vaccines should be used to prevent early onset[12], whether single dose azithromycin can be used to treat AOM[13], does a combination or oral and topical treatments resolve CSOM, which surgical procedures such as tympanostomy tubes or adenoidectomy are effective in resolving OME and restoring hearing.

To date, our research has found that otitis media is harder to treat in Aboriginal and Torres Strait Islander people compared to international settings. Prevention and treatment strategies are not as effective in this population compared to results from clinical trials in the international literature, generally in affluent settings. Our microbiological studies indicate that this poor efficacy is partially due to early age of onset, diversity and multiplicity of OM-pathogens, and the density of bacterial infections[14]. This means longer courses and higher doses of antibiotics are required. Because primary infections are beginning as early as one month of age – before the standard vaccines at 2, 4 and 6 months of age are given, vaccines may be more effective if given earlier. We have designed innovative trials of combination antibiotic regimens and early combination vaccine schedules to address these issues[12, 15].

All trails have contributed to systematic reviews and meta-analyses[16, 17] the 2010 Guideline [18].

Social determinants such as inadequate crowded and dysfunctional housing, poor education and lack of employment also contribute to these very high rates of untreated acute and chronic infections. OM and hearing loss are problems of low priority within communities, which are unrecognized to the point where a discharging, or pussy, ear is seen as normal and language delay or failing to talk by 4 years of age is not a concern. Parents rarely seek help for any of these conditions (unpublished data).

Health services in remote areas and also in urban settings are overwhelmed by management of chronic disease. Scheduled comprehensive child health checks[19] are literally ignored in the PHC setting, placing unrealistic and unnecessary load on Audiology and ENT services. Ear examinations in small babies and children are difficult. Primary Health Care services provide clinical care on a daily basis need continuous medical education, support and appropriate equipment (video otoscopes and tympanometers) to develop skills in OM diagnosis. New technologies such as the OM-app we are developing with scant funds from the CRE_ICHEAR have the potential to improve clinician skills and confidence and improve management of all forms of OM accordingly. Such strategies must be evaluated.

It is critical that ear health services are available in Primary Health Care settings, for families to access regularly for diagnosis and follow-up – without being placed on impossibly long waiting lists for 6-monthly audiology services.

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Centre of Research Excellence in Ear and Hearing Health
of Aboriginal and Torres Strait Islander children
(CRE in Indigenous Children's Healthy EARs, CRE_ICHEAR)

Overview of the CRE (www.earandhearinghealth.org.au)

The National Health and Medical Research Council (NHMRC) funds a range of research schemes including the Centres of Research Excellence. The Centres of Research Excellence (CRE) scheme provides support for teams of researchers to pursue collaborative research and develop capacity in clinical, population health and health services research. Each year 6 CREs in clinical research are funded at a level of $2,500,000 over 5 years. These CREs focus on value-adding to a substantial established core program of work (core portfolio) being undertaken by researchers with strong track records. The five key CRE domains are New Knowledge, Research Transfer, Capacity Building, Collaboration, and Track Record.

Prior funding arrangements (core portfolio):

The CRE_ICHEAR is funded from 2014 to end 2019. Menzies research in otitis media and hearing loss commenced in 1992. The first NHMRC-funded randomised controlled trial (RCT) commenced in 1998. We have had continuous success in project grants and researcher funding from the NHMRC and Industry, with some smaller projects funded by Channel 7, Financial Markets for Children (14 RCTs and over 30 other grants). Menzies researchers have established collaborations with CRE partner organisations; for example the Telethon Kids Institute (the Kalgoorlie OM longitudinal study[20]), the University of Sydney (metaanalyses and national epidemiology[6, 21]), University of Melbourne (the SURE-I-HEAR RCT of surgical interventions), and the Western Sydney University (the WATCH antibiotic RCT[22]) in 2014.

Current Strategy: mission and objectives

The CRE ICHEAR is a national research collaboration dedicated to improving ear and hearing health of Indigenous children, through high quality innovative research, Indigenous leadership, and more effective and sustainable research translation. In particular, the CRE collaboration encompasses expertise in health promotion research, evaluation of Government initiatives such as housing, vaccine trials for otitis media (OM) prevention, antibiotic trials for treatment of acute otitis media (AOM) and chronic suppurative otitis media (CSOM), surgical trials for hearing restoration, clinical trials of novel therapeutics, and data linkage with education outcomes, expanded analyses and mathematical modelling of combined data over a 20 year period. Studies of the microbiology of otitis media, early infection, strain virulence, diversity and antimicrobial resistance are being studied. Novel approaches to therapeutics and surgical techniques. The impact of vaccines on the microbiome – pathogens and non-pathogens, and of antimicrobial prescribing and bacterial resistance is also being studied (APPENDIX TWO).

Our mission is to 'close the gap' in educational and social disadvantage associated with the high prevalence of otitis media (OM) and conductive hearing loss in Australian Aboriginal and Torres Strait Islander children.

Overall objectives are

1. To establish a National Strategic Plan for Otitis Media and Hearing Loss Prevention Research through a coordinated collaborative systematic review (the Review) of research programs in high-risk populations that identifies research strengths, gaps and priorities.
2. To use CRE-funded extensions to our core research program to generate New Knowledge that will address these gaps and priorities directly. This new knowledge will inform policy and practice in the prevention and treatment of OM and in reducing the associated hearing loss in Aboriginal and Torres Strait Islander children across Australia.
3. To build a multidisciplinary Aboriginal and Torres Strait Islander-led network of high calibre researchers to lead research that addresses the priorities of Aboriginal and Torres Strait Islander child health across Australia.
4. To improve quality, consistency and translation of all the work done by relevant Australian research groups. We will facilitate collaboration through regular face-to-face meetings of the Governance Group (GG) and the Leadership Group (LG). The GG and LG will have strong leadership from Aboriginal and Torres Strait Islander representatives.

Structure: teams and people

Technical: This NHMRC Centre of Research Excellence in Ear and Hearing Health of Aboriginal and Torres Strait Islander children has ten senior chief investigators and 10 associate investigators representing Australia's geographic diversity and expertise in multidisciplinary research.

Governance: The CRE_ICHEAR is managed on a day-to-day basis by the Leadership Group of 6 persons (3 of whom are Aboriginal and Torres Strait Islander) assisted by a research program manager (0.8FTE) based at Menzies. High level strategic advice is provided by the Governance Group with agreed terms of reference. The Governance Group also includes significant representation of Aboriginal and Torres Strait Islander leaders, and consists of experts in paediatrics, audiology, ear nose and throat surgery, infectious diseases, microbiology and immunology, and clinical trials. All members have experience in Aboriginal and Torres Strait Islander health research. All members are also members of professional societies with influence on policy and practice in Australia.

Administration: Menzies is the administering institution with experienced and dedicated senior research administrative support, Finance, HR, Chief Operations and Business management at institutional and Division levels.

CREs proven model in reducing rates of otitis media

The CRE model will follow the principles of conducting the highest quality research to address key gaps in knowledge about what works and why. We aim to directly inform policy and practice through up-to-date evidence based Guidelines of the highest quality including translation and evaluation. The CRE_ICHEAR is funding a 2017 upGRADE (https://gradepro.org/) of our 2010 Guideline[18]. From this we are developing and multi-platform OM-app to enhance clinical training. From here we aim to raise community awareness by adapting these novel technologies into language and stories, to support participation of Aboriginal and Torres Strait Islander people in improving ear and hearing health.

Overall reduction in OM prevalence

Since the first otitis media research by Menzies in the early 1990s, we have shown that the prevalence of severe otitis media (chronic suppurative otitis media, or "runny ears") has fallen from 24% in 2001 to around 13% in 2013.

What has driven this reduction?

Vaccines: Our standardized and structured methodology used in surveys of otitis media across the Northern Territory since 2001 shows that the reduced prevalence of severe OM is mainly attributed to introduction of pneumococcal conjugate vaccines.

Monitoring change: We are confident of this finding because our standardized and structured surveillance methodology reduces the bias that is associated with alternative methods of measuring prevalence, such as audits of administrative data. The latter method is subject to changes over time in health seeking behavior, health service priorities, clinician skills and other factors that may influence OM prevalence (trends in breastfeeding or smoke exposure). Overall, over 8000 children have participated in Menzies Ear Health Research Program. We have established a database (BIGDATA) to combine all research data from those 8000 children. We aim to use our combined research data to determine the most efficient way to continue to effectively, efficiently and accurately monitor changes in OM prevalence and severity over time. A monitoring strategy based in sentinel surveillance could be used by Government to measure the impacts of large scale program change, such as vaccination, clinical training and so on.

Evidence based clinical guidelines: Other important factors affecting the reduction in rates of otitis media are likely due to medical education. Our group published "Recommendations for Clinical Care Guidelines on the Management of Otitis Media in Aboriginal & Torres Strait Islander Populations", first published 2001 and updated in 2010 with funding from the Commonwealth Government (the OATSIH Eye and Ear measure). The 2010 OM Guideline was disseminated nationally to all Aboriginal Community Controlled Health Services and was accompanied by clinical training and equipment supply. A public campaign was launched "Care for Kids Ears" targeting health professionals, teachers and families.

Strategic importance of the 2010 OM Guideline upGRADE

The recommendations from the 2010 OM Guideline have been adapted across Australia by each State and Territory. The recommendations underpin and provide the evidence base for local clinical guidelines and ear health manuals and frameworks (CARPA manual in rural regions, WA manual, Deadly Ears strategic plan in Qld, Ear Health Frameworks in SA and WA).

Seven years later, in 2017, the CRE_ICHEAR is funding a major revision and update of the 2010 OM Guideline, in line with international trends to ensure comprehensive, transparent and unbiased recommendations using digital platforms to provide information accurately, rapidly and in real-time. We strongly recommend that the dissemination and impact evaluation of the 2017 OM Guideline and OM-app be measured and funded in well designed trials.

Influencing Policy

Following the November 2016 Parliamentary Roundtable on Ear Health (#EarHealthForLife) hosted by the RACS, Ear Health was included on the AHMAC agenda and subsequent Communique from COAG Health Council. The Commonwealth Government has committed to a national approach to reducing the burden of ear and hearing health in Close the Gap targets for education and employment. The Government is also clear that investment will be made in evidence-based strategies.

The 2017 OM Guideline recommendations will be central to that evidence-base.

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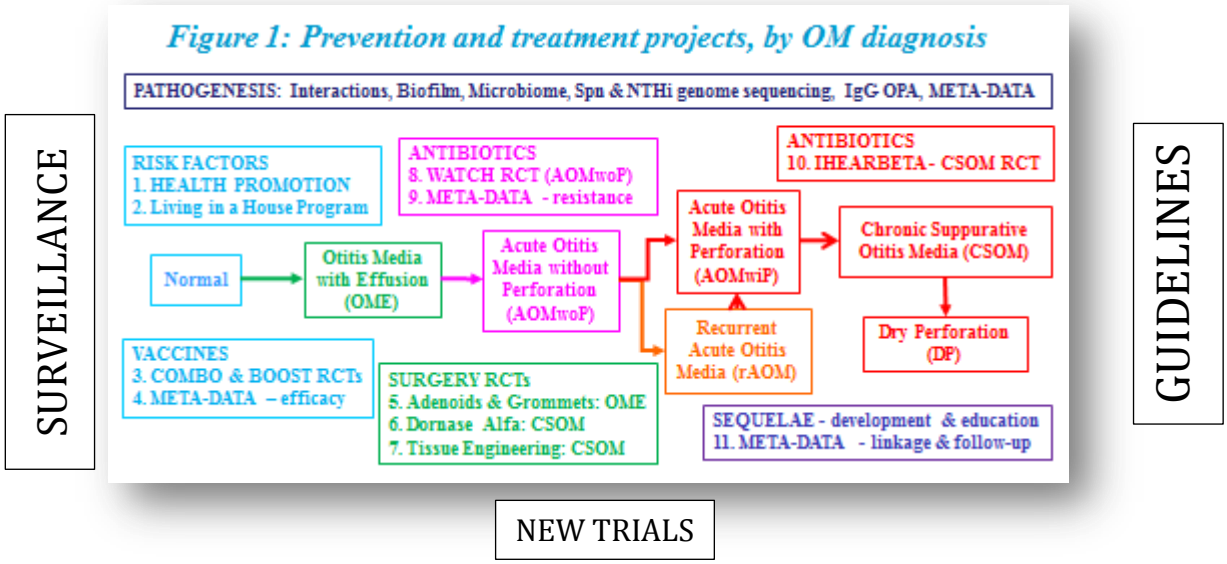
What we are doing and vision for the future? – current core portfolio and CRE-extension projects and recommendations for future

Figure 1 summarizes the research activity of the Centre of Research Excellence in otitis media and hearing loss of Aboriginal and Torres Strait Islander children. The central flow diagram depicts the clinical transitions between otitis media diagnoses, from normal to chronic suppurative otitis media.

Items 1 to 11 in the boxes refer to the current portfolio of funded research on which the CRE_ICHEAR will build further individual extension studies (**APPENDIX TWO**). The box position and colour relate to the OM condition most directly addressed by each study. Across the top is the pathogenesis box, summarizing the laboratory research that underpins each clinical study.



The CRE is based on a strong core portfolio of research conducted by the Chief Investigators over many years. This core portfolio has been funded by NHMRC, Industry and other Institutional research funds. The CRE provides additional resources to extend the core portfolio work, providing researchers with opportunities to obtain pilot data for larger grant submissions, to complete a study, test feasibility of technologies, or to pursue new ideas or student projects not covered by core portfolio funds.

The NHMRC CRE program provides $500,000 per year for 5 years ($2.5m). The CRE_ICHEAR funds are distributed among the CRE Chief Investigators, representing five participating institutions in NSW, WA and NT. The CRE appoints a Research Program Manager (0.8FTE). All other funds are for Projects and Capacity Building, Scholarships and other training, plus research meetings and conferences such as the bi-annual Australian Otitis Media (OMOZ) meeting and the International Symposium on Otitis Media.

Our recommendations and plans for a national approach to otitis media research

It is our intention to develop a national strategic and collaborative approach to otitis media research that continues to deliver high quality evidence that will influence policy and practice, use innovative approaches to understanding pathogenesis, and determine the efficacy of interventions such as novel

combinations and schedules of vaccines and antibiotics needed in high risk Aboriginal and Torres Strait Islander children (expanded in project sections below). As suggested in the diagram above, research outcomes will be incorporated in to Systematic Reviews and meta-analyses, Guideline updates and an iterative process of research transfer and dissemination across the health service delivery and consumer sectors.

The work of the CRE over 5 years is expected to generate greater research capacity across Australia, to build a network of Aboriginal and Torres Strait Islander researchers to inform, lead and to undertake these and more clinical trials to improve efficacy of prevention strategies and treatment regimens for otitis media and hearing loss in high-risk children.

Future aspirations

Clinical trials

Clinical trials must take place across the country to ensure evidence is appropriate to high, medium and low-risk groups. This includes urban, rural and remote communities, multi-site hospitals or multi-site Aboriginal Medical Services. We urgently need to expand our capacity in clinical trials and laboratory research, through wider collaboration, commitment and capacity building. This will deliver outcomes from the trials in a timelier manner. For instance our two current vaccine trials commenced in remote communities in 2011 and 2013 and will not complete until mid-2018 and 2019. In participating communities the populations are small, however the consent rate for these trials has been almost 70% and retention of participants and completion of all study procedures is close to 95% - extraordinary success! Earlier study completion would be achieved with a larger number of participating communities. However, due to funding constraints we could not afford the staff and resources to travel to additional communities. This needs to change. Research needs to be scaled up to deliver outcomes far more rapidly. Communities need to be better informed about research and about how their contribution to research improves the quality of health care for their people - locally and nationally.

Health literacy

Much more is needed to inform and engage Aboriginal and Torres Strait Islander families in understanding the impact of OM and hearing loss on their children's social and educational prospects. The qualitative research will assist in developing messages that are relevant and motivating for families and the health care sector. Research is needed to design and evaluate implementation of such programs. These types of research methodology are also constrained and need to be scaled up. Important qualitative work on Aboriginal and Torres Strait Islander perspectives of OM is being undertaken to determine ear and hearing health literacy of Aboriginal and Torres Strait Islander families. The first Aboriginal and Torres Strait Islander Masters student is working in a small suburban population near Perth, other Aboriginal and Torres Strait Islander researchers are working in three Aboriginal Medical Services in NSW, and another (a CRE-funded PhD student) will soon commence in three remote NT communities. These small studies are important and ground breaking, but are unlikely to represent the clinical spectrum, or the cultural and socio-economic diversity of Australia's Aboriginal and Torres Strait Islander communities. A failure to do so could lead to inappropriate generalizations about how research information might be incorporated into education programs or campaigns, such as has been reported from the "Care for Kids Ears" campaign.

Trials that address barriers to health care provider education and diagnostic training, and trials of family support programs, trials of speech therapy, hearing aids for younger children, and school acoustics and

sound field systems are also needed to ensure investment is directed at interventions that deliver effective outcomes.

More cross-portfolio research is needed to inform the service sectors of health, education, employment and justice about the implications of otitis media and hearing loss throughout life course. A national strategy is being drafted to inform and guide Commonwealth Government investment to ensure resources are appropriately allocated to both prevent and treat OM, hearing loss and their consequences for individuals, families and the community potential to lead full and productive lives.

Our work has clearly shown the complexity of otitis media and the complexity of interventions intended to prevent or treat otitis media. The overarching impact of social determinants such as crowding, dysfunctional housing, poor health literacy and a vicious cycle of poor health and poverty undermine the value of managing otitis media in individual children. A population approach is needed if the vicious cycle is to be broken. Family and community awareness must be addressed.

Targets

Key targets will be to eradicate CSOM (runny ears) in remote communities, to prevent early onset and recurrent acute infections in first 6 months of life, to reduce the high rates of otitis media with effusion (OME, glue ear), particularly persistent and bilateral OME and associated hearing loss, to determine how to improve and maintain clinical skills of health practitioners through evaluation of technological advances in medical education and to match this with monitoring best practice management. Finally we aim to establish a national approach to strategic monitoring of OM prevalence, through improved medical records, sentinel surveillance and mathematical modelling of current BIGDATA.

APPENDIX ONE

Research outcome statements from the Menzies Ear Health Research Program:

1. OM commences within weeks of birth, and persists throughout childhood due to multiple bacterial infections
2. Antibiotics prevent progression of OM and reduce rates of tympanic membrane perforation
3. Antibiotics compared to placebo do not increase rates of bacterial resistance (~40% in both groups)
4. Topical antibiotic drops have a modest impact on CSOM (~30%)
5. Single dose azithromycin has similar efficacy to 7 days amoxicillin for acute OM (~50%)
6. Hygiene interventions in kindergartens reduce transmission of OM-pathogens
7. Pneumococcal conjugate vaccine reduced rates of vaccine-serotype OM
8. Pneumococcal conjugate vaccine delayed onset of tympanic membrane perforation
9. Bacterial density predicts more severe OM
10. Surveillance of OM among young children across over 30 remote communities in the Northern Territory before and during successive changes in pneumococcal conjugate vaccine formulations
    a. Prevalence of any form of OM has been 90% from 2001 to 2013 (i.e. 10% have normal ears)
    b. Prevalence of suppurative OM (infections needing antibiotics) declined from 50% to 40%
    c. Prevalence of tympanic membrane perforation has declined from 24% to 13%
    d. Prevalence of 'glue ear' (OME) has increased from 30% to 40%
    e. Most children have both ears affected (88%)
    f. Non-typeable Haemophilus influenzae (NTHi) is the dominant pathogen in OM.
    g. One vaccine has potential to protect from NTHi-OM.
    h. The strongest risk factor is household crowding (3 or more children)
11. Maternal pneumococcal vaccination does not reduce infant OM.
12. Viral infections can increase density of bacteria and progress AOM, but are relatively rare.
13. Mobile phone messages do not increase health care seeking for children who have CSOM.
14. Swimming does not resolve ear discharge in children with CSOM

Current RCTs are addressing the following clinical questions

1. Should Aboriginal infants receive both formulations of pneumococcal conjugate vaccines to increase protection from both NTHi and 13 strains of pneumococcus?
2. Should Aboriginal infants receive first dose of pneumococcal conjugate vaccine at 1 month of age?
3. Which vaccine formulation should be given to Aboriginal infants as a booster dose?
4. Should booster dose be given earlier, at 12 months of age?
5. What is the relationship between different immune responses to pneumococcal conjugate vaccine?
6. Should children with CSOM receive both topical antiseptics and oral antibiotics, in addition to topical antibiotics?
7. What is the relationship between clinical diagnosis and hearing threshold in 12 month old infants?
8. What is the relationship between ear disease, hearing loss and developmental milestones?
9. What is the impact of persistent otitis media on developmental milestones at 3 years and how might these affect school readiness?
10. Should urban Aboriginal children with acute otitis media receive antibiotics, or watchful waiting?
11. Should urban Aboriginal children with otitis media with effusion use 'otovent', or no 'otovent'?

Current research grant requests

1. Should Aboriginal children with CSOM and already vaccinated with 13-valent pneumococcal conjugate vaccine also receive pneumococcal-*Haemophilus influenzae* protein D vaccine?

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APPENDIX TWO

CRE_ICHEAR extension project grants : Phase I (2015to 2017)

In 2015 and 2016, the CRE_ICHEAR invited two rounds of research extension applications from CRE partners; 16 extension projects were approved. The following is a list of funded project titles, more detail is available at www.earandhearinghealth.org.au. Phase II activity (to end 2019) is to be developed in late 2017 by the Leadership Group.

Evidence Based Best Practice

#1. Updating evidence Guidelines for OM and designing better ways to translate best practice to health care providers (2017 Guideline and the OM-app).

#2. Collaborations to identify and publish best evidence from new randomised controlled trials of treatments for CSOM ("runny ears") – antiseptics or antibiotics?

#3. Building Aboriginal and Torres Strait Islander capacity in clinical trials and qualitative research.

Monitoring OM prevalence and impact of OM and HL on life course

#4. How common is OM among healthy urban Aboriginal and Torres Strait Islander children in NSW

#5. BIG ANALYSES of BIG DATA - meta-analyses and mathematical models to learn more from combined studies.

Prevention strategies

#6. Remote Aboriginal and Torres Strait Islander family perspectives of OM prevention strategies – a PhD proposal.

#7. How can cross-infection be reduced among Aboriginal and Torres Strait Islander families with a young baby – enhanced opportunities to wash hands and faces – a pilot study.

#8. Aboriginal perspectives of OM in urban Perth – impact on the child, family and services.

#9. Early language development in Aboriginal infants living in Perth.

Research Transfer

#10. Research transfer – an innovative approach to raise awareness of ear and hearing health – the HealthLAB 'gets an ear'.

Laboratory research

#11. What makes some bacteria target the middle ear? Using DNA sequencing to find OM-virulence and antimicrobial resistance genes.

#12. Exploring treatment outcomes in children with "runny ears" – using molecular microbiology to compare treatment failure with success – why some treatments are not working.

#13. Do some strains of important bacterial pathogens escape vaccines by turning off the vaccine-target protein?

#14. Novel therapeutics delivered to the middle ear during surgery to improve clinical outcomes – inclusion of Aboriginal and Torres Strait Islander samples.

#15. How bacterial communities establish and change in the noses of young babies with and without middle ear infection.

Collaboration and networking

#16. Bringing Australian researchers and health care providers together to share knowledge, identify gaps and prioritize research questions – the OMOZ conference.

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