Senate Community Affairs Committee Inquiry into Hearing Health in Australia

Prepared February 2010

Disclosure

This submission has been prepared by Pfizer Australia – a wholly owned subsidiary of Pfizer Inc., based in New York. Wyeth is now a part of Pfizer Inc. The merger of local Wyeth and Pfizer entities is pending in Australia and is subject to completion of various local legal and regulatory obligations.

Wyeth markets Prevenar® (7-valent pneumococcal conjugate vaccine) in Australia. In addition, the Therapeutic Goods Administration is currently reviewing the 13-valent pneumococcal conjugate vaccine (13vPnC) for licensure in Australia.

Our interest

We welcome the opportunity to consult as one of the many stakeholder groups striving to secure good hearing health for the Australian population.

Our role in the hearing health paradigm is to limit the loss of hearing due to avoidable causes, namely through the provision of vaccines to minimise the likelihood of auditory complications associated with pneumococcal disease. Within the Hearing health inquiry's broad terms of reference our focus is on a) the causes of hearing impairment in Australia and e) specific issues affecting Indigenous communities.

Our foundation for preparing this submission is to support the ongoing commitment shown since 2005 by the Government when it took decisive action to help protect Australian infants and young children against pneumococcal disease by adding the pneumococcal conjugate vaccine to the National Immunisation Schedule (NIP). We recognise this is only one part of the hearing health paradigm but an important part from which significant health benefits have and will continue to be delivered.

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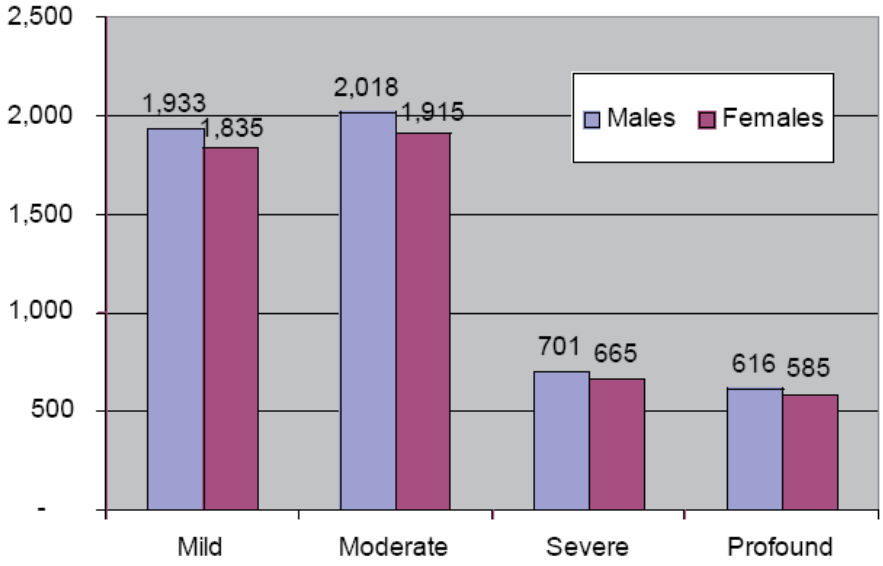
Hearing healthy in Australia

a) The extent, causes and costs of hearing impairment of hearing impairment in Australia

The personal significance of the impact of hearing loss to any Australian is unquestionable. The impact of hearing loss to the Australian economy has been estimated to be more than $12 billion annually.[1] Hearing loss may result from many causes which can be broadly categorised in three types: conductive hearing loss, sensorineural hearing loss and mixed hearing loss.

There are directly relevant reports from two Australian studies based on information from the national service for children with hearing loss (defined as those children who use any form of hearing device). These data suggest a prevalence of pre-lingual (0-4 years) hearing loss of 1.2/1,000 live births and of child acquired loss (4-14 years) as 3.2/1,000 live births.[7, 8]



Source: Based on Australian Hearing (2005) data.

Figure 1: Prevalence of hearing loss, by severity and gender, in children ≤14 years, 2005[1, 7]

Causes of hearing loss in Australia

Conductive hearing loss, acquired or congenital, is caused by blockage or damage in the outer and/or middle ear, due to:

- physical blockages of the ear canal
- outer ear infection (sometimes the result of swimming)
- 'glue ear' (otitis media (OM) with effusion or middle ear infection)
- perforated eardrum, from infection or trauma
- otosclerosis
- partial or complete closure of the ear canal.

Glue ear, either idiopathic or due to infections, is not associated with pain and fever and may result in acute otitis media (AOM); or the reverse can happen where AOM can lead to glue ear.

Sensorineural hearing loss, acquired or congenital, is caused by damage to, or malfunction of, the cochlea (sensory part) or the hearing nerve (neural part), due to:

- the ageing process
- excessive noise exposure
- diseases such as meningitis and Meniere's disease
- viruses, such as mumps and measles
- drugs which can damage the hearing system
- head injuries.

Streptococcus pneumoniae is a bacterial pathogen responsible for a proportion of two significant causes of hearing loss – meningitis and acute otitis media (AOM). Meningitis is one form of invasive pneumococcal disease (IPD) where the bacteria disseminate across the blood-brain barrier. AOM is one form of non-invasive pneumococcal disease where the bacteria infect the middle ear.

Deafness is the most common of all forms of permanent damage following meningitis, affecting as many as 10% of all children who recover with 6% of all hearing impairment in children due to bacterial meningitis.[2]

AOM is a common problem in early childhood; two-thirds of children have at least one episode by age 3, and 90% have at least one episode by school entry.[3] Peak age prevalence is 6-18 months. Unlike glue ear, AOM is accompanied by short-lived pain and fever. AOM can turn into glue ear. Causes of AOM are:

- viral (25%)
- *Streptococcus pneumoniae* (35%)
- non-typable strains of *Haemophilus influenzae* (25%)
- *Moraxella catarrhalis* (15%).

AOM also contributes a significant proportion of GP visits for children. Data from GP-patient encounters collected as part of the Bettering the Evaluation And Care of Health (BEACH) project for the period of April 2000 to March 2005 estimated the annual number of clinical otitis media GP visits for children <5 years to be approx 632,000.[4]

The risk for AOM in indigenous children is higher than in the general population. In 2001, a community-based survey examined 709 (78%) of 914 eligible children, aged 6 months to 2.5 years, from 29 aboriginal communities in Australia identified 24% as having perforated tympanic membranes (15% had chronic suppurative otitis media (OM), 2% dry perforation, and 7% AOM with perforation). An additional 26% had AOM without perforation.[5] Episodes of severe OM were most often associated with infection with one or more types of *S. pneumoniae* or *H. influenzae*, and frequently both organisms.

One of the outcomes of severe or complicated OM is hospitalisation for surgical intervention to open a hole in the tympanic membrane (eardrum) in a procedure known as myringotomy and to insert ventilation tubes, commonly known as grommets. In Australia, for 2001/02 there were approximately 17,950 myringotomy procedures in children under 5 years.[6]

Mixed hearing loss results when there is a problem in both the conductive pathway (in the outer or middle ear) and in the nerve pathway (the inner ear). An example of a mixed hearing loss is a conductive loss due to a middle-ear infection combined with a sensorineural loss due to damage associated with ageing.

Prevention of hearing loss in Australia

In 2001, Prevenar® (7-valent pneumococcal conjugate vaccine) was licensed by the Therapeutic Goods Administration (TGA) for use in Australia for the "*Active immunisation against disease caused by Streptococcus pneumoniae serotypes 4, 6B, 9V, 14, 18C, 19F and 23F (including sepsis, meningitis, pneumonia, bacteraemia and acute otitis media) in infants and children from 6 weeks up to 9 years of age*."[9]

Prevenar® was included into the National Immunisation Program (NIP) for Indigenous Australians and the medically at-risk individuals in 2001; it became universally included for all Australian infants from January 2005. Infants are vaccinated at 2, 4 and 6 months of age.

Since 2005 in Australia there has been a dramatic decrease in the incidence of serious pneumococcal disease. [10] For IPD, between 2002-2006, there has been a 90% reduction in cases of IPD caused by the vaccine serotypes in children less than two years of age.[11]

Furthermore, a recent Australian study of the direct impact pre and post vaccination on the rate of myringotomy with ventilation tube insertion (MVTI) procedures in children less than 3 years of age showed significant reductions in all age groups; 23%, 16% and 6% in children aged <1, 1, and 2 years respectively.[12]

In a retrospective evaluation of a large US insurance database, for children under 2 years ambulatory visits for AOM were reduced by 42.7% and antibiotic prescriptions for AOM were reduced by 41.9% compared with resource utilisation in a setting without vaccination (2004 vs. 1997-99).[13] Similarly, reductions in healthcare utilisation have also been seen in Quebec, Canada with a 13.2% reduction for physician claims for OM for children <5 years and in Ligura, Italy with a 36.4% reduction in the incidence of AOM hospitalisations for the birth cohort in the time period post the availability of pneumococcal vaccination. [11, 14] While direct cause-and-effect cannot be inferred from observational analyses of this type, these consistent temporally-related findings do strongly suggest vaccination plays an important role in reducing the AOM burden in children.

Vaccines are now and will continue to be an important preventative health strategy in Australia against pneumococcal disease, including meningitis and acute otitis media. Pneumococcal vaccines with broader serotype coverage will play an important role in the future.

The TGA is currently reviewing the 13-valent pneumococcal conjugate vaccine (13vPnC) for licensure in Australia. 13vPnC includes coverage of seven of the serotypes (4, 6B, 9V, 14, 18C, 19F and 23F) already included in Prevenar® and six additional serotypes (1, 3, 5, 6A, 7F and 19A) which are associated with the greatest remaining burden of invasive disease.

13vPnC will provide the broadest serotype coverage of any pneumococcal conjugate vaccine and leading to further reductions in the serious public health risk and economic burden associated with pneumococcal disease.

There are many forms of preventable hearing loss and impairment due to infectious disease. Vaccination provides a vital opportunity to minimise one area of preventable hearing loss.

e) specific issues affecting Indigenous communities

Although the epidemiology of hearing loss due to preventable causes is difficult to quantify, particularly in the Indigenous population, avoidable hearing loss remains an issue.[15] Limited information on the extent of hearing loss in Australia has serious implications in regard to identifying and implementing strategies to eliminate preventable sources of hearing loss.

Of great concern was the reported prevalence of OM in 10 to 45% of children in Indigenous communities. The United Nations specifies that a prevalence exceeding 4% is a significant public health problem. Rates of hearing loss were between 10-41%. This highlights the need for greater research around hearing health within the context of overall healthcare and implementation of strategies to minimise or eliminate sources of preventable hearing loss particularly in Indigenous communities.

Key areas to benefit hearing health in Australia are:

1) **Continued development of high quality epidemiological studies on preventable causes of hearing loss, e.g. infectious diseases.**
2) **Continued refinement of the excellent surveillance programmes to track the effectiveness of hearing health preservation programmes, particularly in remote and Indigenous communities.**

References

1. Access Economics. February, 2006. Listen hear! The Economic Impact and Cost of hearing loss in Australia. http://www.accesseconomics.com.au/publicationsreports/search.php?searchfor=hearing&from=0
2. Tarlow MJ 1997 Macrolides in the management of streptococcal laryngitis/tonsillitis. Pediatr Infect Dis J. 1997 Apr;16(4):444-8.
3. Royal Children's Hospital Melbourne, Clinical Practice Guidelines, Acute Otitis Media http://www.rch.org.au/clinicalguide/cpg.cfm?doc_id=5235
4. BEACH data used with permission (Data on file)
5. Morris PS, Leach AJ, Silberberg P, et al. Otitis media in young Aboriginal children from remote communities in Northern and Central Australia: a cross-sectional survey. BMC Pediatr 2005;5:27.
6. Australian Institute of Health and Welfare Procedures Data Cubes Accessed 20 May 2009. http://www.aihw.gov.au/hospitals/datacubes/datacube_proc.cfm
7. Australian Hearing (2005) Demographic details and aetiology of persons under the age of 17 years with a hearing impairment who have been fitted with a hearing aid. {From Access Economics, 2006. [1]]
8. Upfold LJ, Ispey J (1982) "Childhood deafness in Australia – Incidence and maternal rubella, 1949-1980" Medical Journal of Australia 2:323-326.
9. Prevenar Product Information.
10. Roche P, Krause V, Cook H, et al. Invasive pneumococcal disease in Australia, 2006. Commun Dis Intell 2008;32:18–30.
11. Durando P, Crovari P, Ansaldi F et al. Universal childhood immunisation against Streptococcus pneumoniae: The five-year experience of Liguria Region, Italy. Vaccine. 2009;27: 3459–62
12. Jardine A, Menzies RI, Deeks SL et al., The Impact of Pneumococcal Conjugate Vaccine on Rates of Myringotomy With Ventilation Tube Insertion in Australia. Pediatr Infect Dis J 2009;28: 1–5.
13. Zhou F, Shefer A, Kong Y, Nuorti JP. Trends in acute otitis media-related health care utilization by privately insured young children in the United States, 1997-2004. Pediatrics. 2008;121(2):253-260.
14. De Wals, Carbon M, Sevin E et al. Reduced Physician Claims for Otitis Media After Implementation of Pneumococcal Conjugate Vaccine Program in the Province of Quebec, Canada. Pediatr Infect Dis J 2009;28: e271–e274
15. Access Economics, 2005. The cost burden of otitis media in Australia. http://www.accesseconomics.com.au/publicationsreports/search.php?searchfor=otitis&from=0