Rapid evidence summary - Does ear health screening improve outcomes in young children?

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http://www.healthinfonet.ecu.edu.au/ear_summary

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Rapid evidence summary - Does ear health screening improve outcomes in young children?

Question
Among children older than one month of age, does screening for otitis media and/or conductive hearing loss (compared with no screening) improve health or developmental or educational outcomes? This Rapid Evidence Summary will concern itself specifically with this question in relation to management of otitis media in Australian Indigenous children.

Answer
We identified 1 Cochrane systematic review and 3 large randomised controlled trials. None of the trials directly compared screening versus no screening. The evidence was limited to comparisons of screening plus early surgery versus screening plus watchful waiting in unselected children. We found no evidence that screening plus early surgery for otitis media and/or conductive hearing loss improves health or developmental or educational outcomes for children at risk of otitis media with effusion in the first four years of life.
Definitions

Otitis media

Otitis media refers to all forms of inflammation and infection of the middle ear.[1] It includes otitis media with effusion, acute otitis media, and chronic suppurative otitis media.

Conductive hearing loss

Conductive hearing loss related to otitis media varies in its severity depending on factors such as the severity and type of otitis media experienced. The severity of the hearing loss is also likely to fluctuate as the condition changes over time. A child with bilateral otitis media with effusion is likely to have a hearing loss of approximately 25 decibels (dB).[1] Chronic suppurative otitis media causes the most severe hearing loss and is usually associated with a hearing loss of approximately 35 decibels, though more severe cases can cause a hearing loss of up to 60 decibels.[1] The practical implications of the varying degrees of conductive hearing loss can be summarised as follows:

Table 1. The practical implications of the varying degrees of conductive hearing loss

<table>
<thead>
<tr>
<th>Average threshold (dB)</th>
<th>Description</th>
<th>Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td>-10 - 15</td>
<td>Normal hearing</td>
<td>None</td>
</tr>
<tr>
<td>16 - 25</td>
<td>Slight loss</td>
<td>May have difficulty hearing a whisper</td>
</tr>
<tr>
<td>26 - 40</td>
<td>Mild loss</td>
<td>Difficulty hearing a whisper</td>
</tr>
<tr>
<td>41 - 55</td>
<td>Moderate loss</td>
<td>May have difficulty hearing a conversation</td>
</tr>
<tr>
<td>56 - 70</td>
<td>Moderately severe loss</td>
<td>Difficulty hearing a conversation. Normal talking will not be understood</td>
</tr>
<tr>
<td>71 - 90</td>
<td>Severe loss</td>
<td>Normal talking will not be understood</td>
</tr>
<tr>
<td>91+</td>
<td>Profound loss</td>
<td>Normal talking will not be understood</td>
</tr>
</tbody>
</table>

Screening and surveillance

There is significant confusion around the distinction between screening and surveillance. This is not surprising as there is also some inconsistency in the literature about the definition of each.[2] This issue will only be briefly addressed here but for a more comprehensive discussion please refer to references [2] and [3].

The practice of screening can perhaps best be understood by looking at this definition of a screening test:

‘Any measurement aimed at identifying individuals who could potentially benefit from intervention. This includes symptoms, signs, lab tests, or risk scores for the detection of existing or future disease’.[4]

In brief, screening identifies those who appear to be well but in fact probably have a condition from those who probably don’t have a condition. Screening tests are not generally diagnostic and the results should determine whether a diagnostic test is warranted. A common theme in the literature that “follow up of those who undergo a screening test is as important as the test itself”.[2]

For the purpose of this paper, ear health and hearing screening (i.e. screening for otitis media and/or conductive hearing loss) is defined as:

Audiometric testing or audiological testing
plus
Otoscopy and tympanometry and/or otoscopy including pneumatic otoscopy and/or otoscopy including pneumatic otoscopy and tympanometry.

According to Stone et al (1990, as cited in Oberklaid et al, 2002) Child health surveillance, refers to:

“...the systematic and ongoing collection, analysis, and interpretation of indices of child health, growth, and development in order to identify, investigate and, where appropriate, correct deviations from predetermined norms”.[5]

In surveillance the defining difference is that it is “routine” and the follow up with intervention when required is inherent. In other words it is part of routine care.

According to the WHO, “Screening” is often thought of (and in practice often is) a cross sectional, short term operation...while surveillance conveys rather a long term vigil over the health of an individuals or of a population.”[3]

Burden of disease

The overall incidence of otitis media in Indigenous Australian children is extremely high however the prevalence and severity of otitis media varies greatly between communities. One recent study concluded that Australian Indigenous children seen in the primary healthcare setting are five times more likely to be diagnosed with severe otitis media than non-Indigenous children.[6]
The National Health Survey (2001) reported that 11% of Indigenous children aged 0 - 14 and 13% of Indigenous Australians aged 15 - 24 years had ear health and/or hearing problems compared with 5% of non-Indigenous people in both age-groups.[7] In the Western Australian Aboriginal Child Health Survey undertaken in 2001 and 2002 it was reported that 20% of Indigenous people aged 0-11 years, and 14% aged 12-17 years had recurring ear infections.[8] Data from remote communities shows an even more serious public health problem. In a 2002 survey 709 children from 29 communities throughout the Northern Territory aged between 6 and 30 months (over 90% of this age group in the communities) were examined by the Menzies School of Health Research. An overall average of 25% of young Aboriginal children had perforated ear drums, 31% had middle ear fluid in both ears and only 7% of children had normal ears. Five communities had perforation rates greater than 40%.[9]

Rationale for screening or not screening

The rationale for screening for otitis media and/or conductive hearing loss includes the following:

• a. Onset of otitis media commences within weeks of birth in Australian Indigenous infants in remote communities.[10]

• b. Early onset otitis media usually initially presents as otitis media with effusion which is often asymptomatic and therefore difficult to diagnose.

• c. Otitis media is associated with hearing loss and therefore screening may provide an opportunity for identification and thus intervention for children most at risk of developmental and educational sequelae.

• d. Screening programs provide a platform from which to raise awareness about ear health and hearing and can provide community and family education.

• e. Anecdotally, screening is popular at the community level.

Rationale for not screening for otitis media and/or conductive hearing loss includes the following:

• a. Universal screening programs require considerable resources including human resources and workforce training and accreditation and other financial resources.

• b. Resources spent on screening programs (opportunity costs) could be better spent on other strategies to prevent and manage otitis media identified through surveillance in routine care.

Potential benefits and harms

The potential benefits of a screening program include referral for effective treatment of otitis media and associated hearing problems. Potential secondary benefits also include increased opportunities for community education resulting in increased awareness of prevention and management strategies and a better understanding of the importance of ear health and hearing at the community level.

There are also potential harms associated with a screening program (as there is with all screening programs). Arguably, the most significant potential harm associated with a screening program is that resources used for screening programs (which are very expensive due to their inclusive nature) could be used more effectively in addressing ear health and hearing problems using other means such as e.g. workforce development and support for the prevention and management of otitis media).

Current level of uncertainty

There is currently a great deal of uncertainty about the best way to improve outcomes for otitis media in young Indigenous children. Screening programs have existed until recently in Australia, as in the case of the New South Wales Otitis Media Strategy, and are anecdotally very popular at a community level. Interestingly, a recent review of this strategy found that the evidence to support its continuation was not adequately strong so that the mass screening program is being replaced with a new focus on maternal health.[11]

Objective

The objective of this Rapid Evidence Summary is to review the evidence on whether screening for otitis media and/or conductive hearing loss (compared with no screening) improves health or developmental or educational outcomes.

The search strategy

Only 2 databases have been searched for the purpose of this Rapid Evidence Summary - PubMed (Medline) and the Cochrane database. (Please refer to Appendix A for the complete search strategy.)

1. The PubMed database was searched on October 15th 2009 with the following search strategy:

media OR hearing loss OR “Hearing Disorders”[MeSH] OR hearing disorder OR deafness OR deaf) AND (systematic [sb] OR clinical trial [pt])

43 titles were identified from these as relevant and the abstracts of these papers were reviewed. In one instance the abstract was not available for review so the whole paper was reviewed. Four abstracts were relevant, Three of these described the same study. Therefore, 2 studies were identified that were relevant, as well as one other paper that may be relevant.

2. Cochrane Database was searched October 15th 2009 with the very similar search terms adapted for the Cochrane database. Nil additional studies were identified. (Please refer to Appendix A for the complete search strategy.)

The Evidence

One systematic review was identified containing three eligible trials and no additional eligible trials since the most recent update of the systematic review were identified. It didn't identify any trials comparing screening with no screening but did identify three studies that reported the effect of screening and treatment on those children identified with clinically significant otitis media with effusion in the first four years of life. In all three trials treatment consisted of insertion of ventilation tubes (i.e. grommets). Children with OME were randomised to either:

Treatment with grommets
OR
1. No treatment 2. Watchful waiting or 3. Late treatment with grommets

Summary of results

The systematic review identified is as follows:

Study ID No. 1


Five studies that described three separate trials (which were the same as those identified by the search strategy) were cited in the systematic review:

Study ID No. 2.


Study ID No. 3.


Study ID No. 4.


Study ID No. 5.


Study ID No. 6.

Table 2. Five studies that described three separate trials (which were the same as those identified by the search strategy) were cited in the systematic review

<table>
<thead>
<tr>
<th>Study ID/ Year</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Outcomes</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study ID No. 1 2003</td>
<td>Children in the first 4 years of life in the general population or with OME identified through screening, or the</td>
<td>1. Screening procedures. 2. Interventions for treating OME</td>
<td>Outcomes for children randomised to be screened for OME and outcomes for children who were not randomised to be screened for OME</td>
<td>Primary: Language and behavioural assessments. Expressive and receptive language test. Secondary: Hearing assessment and resolution of effusions assessed by tympanometry and/or clinical examination</td>
<td>No evidence of clinically important benefit in language development from screening and treating children with clinically important OME.</td>
</tr>
<tr>
<td>Study ID No. 2 1989</td>
<td>1249 children aged 24 months. 1050 completed screening, 152 referred, 144 seen, 84 eligible, consent of trial obtained for 51 children. 43 were followed up.</td>
<td>1. Tympanometry every 3 months. Otoscopy was done when the tympanogram was flat. 2. Ventilation tube insertion</td>
<td>No ventilation tube insertion.</td>
<td>Language development tests before allocation and 6 months afterwards. Followed up 2 years later.</td>
<td>No significant differences in language development over 6 months.</td>
</tr>
<tr>
<td>Study ID No. 3 2001</td>
<td>30,099 children age 9 months, 26,430 screened and followed up. 1081 visited ENT dept. 386 eligible for treatment, 187 enrolled, 158 followed up.</td>
<td>1. Routine hearing screening (Ewing test.) Otoscopy and tympanometry when child failed 3 successive hearing tests. 2. Ventilation tube insertion</td>
<td>No ventilation tube insertion i.e. watchful waiting.</td>
<td>Hearing tests at randomisation, 3, 6 and 12 months of follow up. Language development assessment at randomisation, 3, 6 and 12 months of follow up. Tympanometry and otoscopy every 3 months for 12 months.</td>
<td>No significant differences in language development between children who were screened and received ventilation tubes and those who were screened and underwent watchful waiting.</td>
</tr>
<tr>
<td>Study ID No. 4 2001</td>
<td>6330 infants aged 2 - 61 days. 588 eligible 429 randomised for early and late treatment of OME and 402 were followed up.</td>
<td>1. Tympanometry, pneumatic otoscopy every month (in most cases). Audiometric testing in all children with effusions for 8 weeks. 2. Ventilation tube insertions as soon as practical</td>
<td>Insertion of ventilation tubes 6 months later if bilateral effusion persisted and 9 months later if unilateral effusion persisted.</td>
<td>Developmental testing ASAP after their 3rd birthday and within 2 months (for full details refer to Systematic Review). Audiometric examinations before and after randomisation. Otoscopy on a month for 3 years.</td>
<td>No significant differences between the children who were screened and had early treatment with ventilation tubes and those who were screened and underwent late treatment with ventilation tubes.</td>
</tr>
<tr>
<td>Study ID No. 5 2003</td>
<td>6330 infants aged 2 - 61 days. 588 eligible 429 randomised for early and late treatment of OME and 402 were followed up.</td>
<td>1. Tympanometry, pneumatic otoscopy every month (in most cases). Audiometric testing in children with effusions for 8 weeks. 2. Ventilation tube insertions as soon as practical</td>
<td>Insertion of ventilation tubes 6 months later if bilateral effusion persisted and 9 months later if unilateral effusion persisted.</td>
<td>Developmental testing ASAP after their 4th birthday and within 2 months (for full details refer to Systematic Review). Audiometric testing in all children who were about to undergo developmental testing and in children whose parents suspected hearing loss.</td>
<td>No significant differences in the children who were screened and had early treatment with ventilation tubes and those who were screened and underwent late treatment with ventilation tubes.</td>
</tr>
<tr>
<td>Study ID No. 6 2004</td>
<td>6330 infants aged 2 - 61 days. 588 eligible 429 randomised for early and late treatment of OME.</td>
<td>1. Pneumatic otoscopy plus tympanometry (in most cases) at least monthly until 3 years of age. Audiometric testing before and after randomisation and at 6 years of age. 2. Ventilation tube insertion.</td>
<td>Insertion of ventilation tubes 6 months later if bilateral effusion persisted and 9 months later if unilateral effusion persisted. Is this right?</td>
<td>Developmental testing at 6 years of age. Audiometric testing plus pneumatic otoscopy and tympanometry at 6 years of age.</td>
<td>The early intervention group showed higher rates of tympanic membrane abnormality. Hearing impairment was slightly more common in the early intervention group.</td>
</tr>
</tbody>
</table>

Notes:
NB: OME = Otitis media with effusion
Quality of the studies

The authors of the systematic review concluded that the methodological quality of the three trials (five studies) was high, and that sufficient numbers of children were screened.[12] However, they also noted that the proportion of eligible children who received treatment was relatively low raising the possibility of selection bias.[12] Though different outcome measures were used, they were all clearly identified and the results were clearly presented.[12] Three trials reported that the participants were randomised either to treatment or control groups and each study described concealment of allocation.[12] Two of the three trials, which produced four of the included studies (Zeilhuis 1989; Paradise 2001; Paradise 2003; Johnston 2004) used blinding of outcome assessments. In the remaining trial (Rovers, 2001) the outcome assessment was not blinded. [12] Loss to follow up was adequately described in all trials.[12]

As well as these important characteristics being adequately reported, the quality of the studies included in the systematic review was assessed independently for the various types of potential bias using the scheme described in the Cochrane Handbook for Systematic Reviews of Interventions.[12] Data extraction and analysis was also adequately described in the trials.[12] Lastly, the systematic review clearly describes the heterogeneity of the studies in terms of the following:

- Age;
- Settings and subjects;
- Screening procedure;
- Interventions for randomisation;
- Duration of follow-up; and
- Measurement of outcomes. [12]

PubMed

Searched on October 15th 2009

Search Terms


AND

(systematic [sb] OR clinical trial [pt])

Combined:


This translates into:


Result = 969

43 titles were identified from these as relevant and the abstracts of these papers were reviewed. In one instance the abstract was not available for review so the whole paper was reviewed. Four abstracts were relevant, three of these described the same study. Therefore, two studies were identified that were relevant:


One other paper was identified that was relevant:


Table 3. Cochrane (from July 2008)

<table>
<thead>
<tr>
<th>#</th>
<th>Description</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>MeSH descriptor Otitis Media explode all trees</td>
<td>940</td>
</tr>
<tr>
<td>2</td>
<td>otitis media OR hearing loss OR hearing disorder OR deaf*</td>
<td>3480</td>
</tr>
<tr>
<td>3</td>
<td>MeSH descriptor Mass Screening explode all trees</td>
<td>3868</td>
</tr>
<tr>
<td>4</td>
<td>screen* OR examin* OR physical examin*</td>
<td>72494</td>
</tr>
<tr>
<td>5</td>
<td>MeSH descriptor Hearing Tests explode all trees</td>
<td>610</td>
</tr>
<tr>
<td>6</td>
<td>newborn* OR babies OR infant* OR child*</td>
<td>72510</td>
</tr>
<tr>
<td>7</td>
<td>otoscop* OR hearing test OR tympanometry</td>
<td>1378</td>
</tr>
<tr>
<td>8</td>
<td>MeSH descriptor Diagnostic Techniques, Otological explode all trees</td>
<td>729</td>
</tr>
<tr>
<td>9</td>
<td>MeSH descriptor Hearing Disorders explode all trees</td>
<td>992</td>
</tr>
<tr>
<td>10</td>
<td>MeSH descriptor Physical Examination explode all trees</td>
<td>21782</td>
</tr>
<tr>
<td>11</td>
<td>(#1 OR #2 OR #9)</td>
<td>3673</td>
</tr>
<tr>
<td>12</td>
<td>(#3 OR #4 OR #5 OR #7 OR #8 OR #10)</td>
<td>90667</td>
</tr>
<tr>
<td>13</td>
<td>(#6 AND #11 AND #12)</td>
<td>940</td>
</tr>
</tbody>
</table>

One systematic review was identified, that had already been identified in the PubMed search.

Discussion

We identified no evidence that screening for otitis media and/or conductive hearing loss improves health or developmental or educational outcomes for children with otitis media with effusion in the first four years of life.

The systematic review constituted the highest level of evidence available. As already described, it didn't identify any trials comparing screening with no screening but did identify three studies that reported the effect of screening and treatment on those children identified with clinically significant OME in the first four years of life.[12] The outcome measures of the trial included clinical findings, hearing assessments, and the main outcome measure was language development. In two of the three trials, the primary purpose of screening was identifying eligible children to partake in a treatment trial. It is therefore possible that these screening programs might have identified milder cases than may be identified through regular care i.e. surveillance.[12]

It is not possible to simply extrapolate the findings of the systematic review to the Australian Indigenous context. These trials were all conducted in mainstream populations in developed countries and they therefore are not completely transferable to developing country settings or highly marginalised populations within developed countries such as Indigenous Australians.[12] Lead time bias is a common problem in screening, i.e. those who may benefit the most from treatment as follow-up to screening may have soon been identified through routine surveillance and care.12

The literature stresses that screening is only beneficial if it leads to early detection which is then followed up by effective treatment which in turn leads to an improved clinical outcome).[2] [3] [12] In these studies, where both the identification technique and treatment methods are being assessed, the fact that no beneficial effect has been demonstrated tells us that either the screening or the treatment measure or both may be ineffective. [3]

The issue of effective treatment is also important in other ways. In the evidence identified, only surgical treatment was assessed and there is still a great deal of uncertainty about the effectiveness of insertion of ventilation tubes for otitis media. Approaches to treatment remain highly controversial and there is considerable variation in clinical practice, complicating matters even further. According to the World Health Organisation an essential prerequisite for screening programs should include an accepted treatment method.[3] as cited in [12] Non-surgical interventions, such as antibiotic therapy, were not assessed. This is of particular
importance in regards to the Australian Indigenous context where the recommended clinical management is antibiotics in the first instance.[12]

In addition, the National Health and Medical Research Council’s has put forth that "Strong evidence indicates that long term developmental effects of otitis media with effusion detected through screening are minimal" and that "Otitis media with effusion is a fluctuating condition, so that one off screening makes no sense. If screening were to occur it should be repeated many times for each child. However, treatment of children detected through repeated screening has been shown to provide no long term developmental or academic benefit;"[2] However, in regards to the Australian Indigenous context, they acknowledge that no research has been conducted to assess the benefit “for children with significant persistent conductive hearing impairment, as opposed to those with persistent otitis media with effusion regardless of hearing status.”[2]

**Conclusion/recommendations**

There is currently no high quality evidence to support the recommendation of screening for otitis media and/or conductive hearing loss in children at risk of otitis media with effusion in the first four years of life.

**Implications for policy and practice**

No evidence from randomised controlled trials either for or against screening as an intervention to improve outcomes of otitis media in children less than four years of age was identified in this Rapid Evidence Summary. The lack of good-quality evidence in this area remains a serious problem. However, there is substantial evidence from three trials that programs of screening plus early surgery for otitis media in developed countries (or low risk populations) are of little or no benefit. There appears to be no evidence of any benefit in high risk populations either, but further research needs to confirm this in both high and low risk populations.

It would appear that the benefits of any intervention for persistent otitis media with hearing loss are small at best. However, in the Indigenous context, where the problem is much larger, even small benefits may be significant.

It is the opinion of the authors that resources that might be used in screening for otitis media in Indigenous would be better used in workforce development and other strategies that improve the routine care i.e. surveillance (diagnosis and management) of otitis media in the community setting.

**Implications for research**

It is necessary to note that even though no benefit was identified for screening in the first four years of life absence of demonstrated benefit does not rule at that benefit exists.[12] Further in-depth research needs to be conducted with the aim of identifying children most likely to benefit from treatment.[12] It is possible that the identified trials had thresholds for treatment that were too low and that if eligibility for treatment was limited to children with more severe otitis media with effusion, beneficial effects may have been seen. However, there is an increased likelihood that such children will be symptomatic (as is the case with acute otitis media and chronic suppurative otitis media) and therefore more easily detected through routine surveillance and care. This view could also been seen to undermine the case for screening asymptomatic children in the general population.

**Appendix A - Search strategy**

Rapid Evidence Summary - Does ear health screening improve outcomes in young children?

**Question:**

Among Children older than one month of age, does screening for conductive hearing loss and/or otitis media (compared with no screening) improve health or developmental or educational outcomes?

Only 2 databases have been searched for the purpose of this Rapid Evidence Summary - PubMed and the Cochrane database. The search strategies were developed taking time into consideration and therefore this Rapid Evidence cannot be considered comprehensiveness in nature.
Rapid evidence summary - Does ear health screening improve outcomes in young children?

References

1. Menzies School of Health Research (2001) Recommendations for clinical care guidelines on the management of otitis media in Aboriginal and Torres Strait Islander populations. Canberra: Commonwealth Department of Health and Aged Care


The Australian Indigenous HealthInfoNet is an innovative Internet resource that contributes to ‘closing the gap’ in health between Indigenous and other Australians by informing practice and policy in Indigenous health.

Two concepts underpin the HealthInfoNet’s work. The first is evidence-informed decision-making, whereby practitioners and policy-makers have access to the best available research and other information. This concept is linked with that of translational research (TR), which involves making research and other information available in a form that has immediate, practical utility. Implementation of these two concepts involves synthesis, exchange and ethical application of knowledge through ongoing interaction with key stakeholders.

The HealthInfoNet’s work in TR at a population-health level, in which it is at the forefront internationally, addresses the knowledge needs of a wide range of potential users, including policy-makers, health service providers, program managers, clinicians, Indigenous health workers, and other health professionals. The HealthInfoNet also provides easy-to-read and summarised material for students and the general community.

The HealthInfoNet encourages and supports information-sharing among practitioners, policy-makers and others working to improve Indigenous health – its free on line yarning places enable people across the country to share information, knowledge and experience. The HealthInfoNet is funded mainly by the Australian Department of Health and Ageing. Its award-winning web resource (www.healthinfonet.ecu.edu.au) is free and available to everyone.