

**2020 Otitis Media Guidelines for Australian Aboriginal and Torres Strait Islander Children:  
Applying the GRADE approach and a transition to an OMapp**

Amanda J Leach<sup>1,2\*</sup>, Peter S Morris<sup>1,2,3</sup>, Sam Brophy-Williams<sup>1,2</sup>, Sumon Kumar Das<sup>1,2</sup>, Hasantha Gunasekera<sup>4,5</sup>, Samantha Harkus<sup>6</sup>, Katherine Jarosz<sup>1,2</sup>, Kelvin Kong<sup>7</sup>, Jarod Pak<sup>1,2</sup>, Paul Torzillo<sup>5,8</sup>.

**Affiliation:**

<sup>1</sup>Menzies School of Health Research

<sup>2</sup>Charles Darwin University

<sup>3</sup>Northern Territory Department of Health

<sup>4</sup>The Children's Hospital at Westmead

<sup>5</sup>University of Sydney

<sup>6</sup>Hearing Australia

<sup>7</sup>John Hunter Children's Hospital

<sup>8</sup>Nganampa Health Council

**Corresponding author\***

Amanda Jane Leach

Child Health Division, Menzies School of Health Research, Darwin

Charles Darwin University, Casuarina

NT, Australia

Email: [amanda.leach@menzies.edu.au](mailto:amanda.leach@menzies.edu.au)

Web: [www.menzies.edu.au](http://www.menzies.edu.au)

## Abstract

**Background:** Otitis Media (OM) management guidelines for Australian Aboriginal and Torres Strait Islander populations were first published in 2001 and updated in 2010. Addressing chronic OM and disadvantage associated with hearing loss are a national priority. Our objective was to use rigorous strategies to update the evidence for best practice in prevention, diagnosis and management of all forms of otitis media and conductive hearing loss in Aboriginal and Torres Strait Islander children, also delivered in a user-friendly freely downloadable OMapp.

**Methods:** A Technical Advisory Group of appropriate experts led the revision. We used the Grading, Recommendations, Assessment, Development, and Evaluation (GRADE) approach. Search strategies included all publications to March 2017. We included all interventions for prevention and treatment, and all outcomes including adverse events, and all data relevant to low- and high-risk children.

**Results:** Twenty relevant Cochrane reviews and eight meta-analyses contributed data for import to GRADEpro and assessment of quality and strength of recommendations. A total of 56 relevant questions and 191 Population Intervention Comparator Outcome and Time (PICOT) statements generated 51 Summary of Findings (SoF) tables and 102 recommendations. Ten algorithms for diagnosis and management of OM and hearing loss, including referral pathways were revised. Transition to a multi-platform OMapp enables inclusion of images (still and videos), and audio recordings in Aboriginal and Torres Strait Islander languages (Pitjantjatjara, Eastern and Central Arrernte, Murrinh Patha, Tiwi, Yolgnu Matha) to improve communication.

**Conclusion:** The 2020 OM Guidelines and OMapp provide evidence for best practice in ear and hearing health care for Aboriginal and Torres Strait Islander children at low- or high-risk of poor outcomes of otitis media.

**Keywords:** Guideline, otitis media, GRADE approach, methods, Aboriginal and Torres Strait Islander, conductive hearing loss, acute otitis media, otitis media with effusion, chronic suppurative otitis media, tympanostomy tube otorrhea

## Introduction

### Background and rationale:

Almost all children experience at least one episode of otitis media (OM or middle ear infection) within the first few years of life.(1) The global burden of OM and preventable hearing loss among children under 5 years of age and in the poorest countries is substantial.(2) In Australia, OM is still considered a major public health issue for all Aboriginal and Torres Strait Islander children, particularly children living in remote communities.(3) Recent research has identified that in the remote Northern Territory communities surveyed only 10% of Aboriginal children younger than 3 years of age had bilateral healthy ears.(4) Chronic OM and associated hearing difficulties negatively impact on wellbeing,(5) school attendance(6) and performance,(7) and may be associated with future unemployment and negative interactions with youth justice system.(8)

In 2010, the Recommendations for Clinical Care Guidelines on the Management of Otitis Media in Aboriginal and Torres Islander populations (the 2010 OM Guidelines) was published as a collaboration between the Australian Government Department of Health and Ageing and Menzies School of Health Research.(9) The aim was to develop a series of acceptable recommendations for prevention, diagnosis and treatment for the various forms of OM and associated hearing loss. The 2010 OM Guidelines informed strategic policy and practice recommendations in states and territories, including the Northern Territory, Western Australia, South Australia, Queensland, and New South Wales. In 2013, a survey of the awareness and use of the 2010 OM Guidelines in General Practice was undertaken.(10) Findings indicated low awareness and use of the Guidelines. Recommendations included the need for frequent training to address high staff turnover in primary health care services, particularly in remote settings(11) and a secondary level of expertise at the regional (more sustainable) level. Otitis media and associated hearing loss among Aboriginal and Torres Strait Islander and Torres Strait Islander children have since become a national priority.(12, 13)

In 2016, the National Health and Medical Research Council-funded Centre of Research Excellence in Ear and Hearing Health of Aboriginal and Torres

Strait Islander Children (GNT1078557) formed a Technical Advisory Group (TAG) to lead the update of the 2010 OM Guidelines. The TAG recommended that the revision follow the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. The GRADE is a transparent system for rating the quality of a body of evidence and subsequently grading recommendations.(14, 15) It was first developed in 2000 to provide a common international grading system for the development of recommendations in systematic reviews and guidelines. In addition to critically appraising evidence quality,(16) the decision on the strength of a recommendation by GRADE also takes into account other factors such as benefits and harms, the estimated effect size, the values and preferences of the patient population, cost, and health equity.(17) It has become the most widely used clinical recommendation grading system globally.(18) Utilizing the GRADE approach, all the evidence published in the 2010 OM Guidelines was re-examined and included with all new evidence derived from a process of explicit searching of the medical literature to March 2017. The main aim of the revision, and also of the transition to an OMapp, was to ensure access to evidence-based information on OM in Aboriginal and Torres Strait Islander children across Australia, to promote best practice management of ear disease and conductive hearing loss among Aboriginal and Torres Strait Islander children. This paper describes the methodology used to update the 2010 OM Guidelines and transition to a freely downloadable multi-platform digital app with audio-visual education and language translation capability for health care providers and their Aboriginal or Torres Strait Islander clients.

### Objectives

Our goal is to reduce the high prevalence of otitis media and associated hearing loss, and the social and educational disadvantage of Australian Aboriginal and Torres Strait Islander children. Although excellent guidelines exist,(9) they were out-of-date and under-utilised. Our objectives were firstly to apply the Grading, Recommendations, Assessment, Development, and Evaluation (GRADE) approach of evidence synthesis and quality assessment for prevention, diagnosis and management of all forms of otitis media (see Box 2) and conductive hearing loss in Aboriginal and

Torres Strait Islander children, and secondly to deliver this in a user-friendly, free, and fully downloadable OMapp for use across Australia.

### **Research questions**

The update was focussed on three main strategies (i) Prevention of OM and associated hearing loss, (ii) Clinical management of different types of OM and associated hearing loss, and (iii) Audiological management of hearing loss. A total of 56 research questions were developed and data extracted (Table 1). For meta-analyses with multiple outcomes (e.g. multiple time-points), consensus decisions were made to prioritise ~67 research questions for final reporting. Hearing outcomes were prioritised if reported, followed by the primary outcome then secondary outcomes reported. Short-, medium-, and long-term effects were included. Adverse events were included if reported, including if none were found.

### **Literature Search, data extraction and analysis**

A Technical Advisory Group of appropriate experts in otitis media in Aboriginal and Torres Strait Islander children led the revision (see author and co-author contributions). The literature search replicated the search strategy utilised in the 2010 Guidelines, extending it to 28<sup>th</sup> March 2017 in MEDLINE (accessed via PubMed) electronic database. The project timeframe is summarised in Table 2.

The search was performed in five Phases (Table 3). A broad search strategy was used, aiming for sensitivity rather than specificity, and designed to minimise the chance of missing novel research in this area (Table 3). For the first time the OM Guidelines include tympanostomy tube otorrhoea (TTO).

1. For each type of OM, all potential interventions and outcomes were included in the search and relevant articles were hand-searched to ensure all relevant articles were captured
2. Question drafted – e.g.,: “should antibiotics be used for treatment of OME?”
3. Publication type was prioritised as follows:
  - a. meta-analyses (if Cochrane, latest version used)
  - b. systematic reviews

- c. randomised controlled trials (RCTs),
- d. clinical trials or any other observational studies.

4. We included reviews not conducted by Cochrane in the meta-analysis. If not amenable to pooled analysis but considered informative to the question, data are presented separately.
5. If meta-analyses were not found within the last 5 years, reference lists of any systematic reviews were hand-searched for studies published prior to the search period, those studies were retrieved and assessed.
6. If no systematic reviews were available, studies from 5 years prior to the final search were used.

After removal of duplicates the search identified a total of 3864 articles, including 20 Cochrane systematic reviews and eight other meta-analyses (Figure 1).

### **Criteria for strength of recommendations**

Based on the GRADE criteria for critical synthesis of the studies, strength of recommendations (Strong or Weak) were allocated and agreed by the TAG. Where GRADE was unable to be used due to a paucity of evidence, consensus recommendations (replacing Good Practice Point, 2010 edition) were made. Where applicable, recommendations specific to either low- or high-risk children were included. The confidence of each recommendation is reflected by the Quality of evidence. Quality is categorised as “Very Low, Low, Moderate, or High” using the GRADE assessment criteria for design,(19) risk of bias,(19) inconsistency,(20) indirectness,(21) imprecision,(22) and upgrade or downgrade criteria.(16) In addition, the TAG designed the “What happens” statement in PICOT (Population, Intervention, Comparison, Outcome, Time) format for inclusion in the Summary of Findings tables.(see Figure 2)(14) These “What Happens” statements use the confidence qualifiers of ‘possibly’ for Very Low and Low quality and ‘probably’ for Moderate or High quality. The effect size is provided for statistically significant differences, including number needed to treat or harm where possible.

A total of 51 Summary of Findings (SoF) tables were created from GRADEpro. These SoF tables addressed a total of 56 research questions (Table 2) and 191 PICOT statements. The outcomes for each of the SoF, are listed in order of priority; hearing loss if reported, then primary and secondary outcomes, and adverse events. For each outcome, explanations for quality scoring were listed (see Figure 2). Finally, a total of 102 recommendations were made; 27 were strong recommendations, 20 were weak recommendations and 55 were consensus recommendations (Table 4).

For each type of OM, the TAG broadly includes accurate diagnosis, education, treatment or pain relief, surgical management, specialist referral (Ear Nose and Throat, and Audiology), subsequent review or follow-up.

### ***OMapp development***

The OMapp was developed using Xcode (from the appstore), Nodejs (version 8.11.3), NPM (version 6.2.0), Ionic (version 3.20.0), Cordova (version 8.0.0), Android Studio, Gradle, Google Backup and Sync, visual studio code, and Source tree etc. Data for the website and the mobile app were drawn from the same data source. All data were populated via the app web-browser using the interface called directus. Data were first published in the test web-version as a draft for TAG revision and Beta testing. Finally, after iterative reviews, all data were published in the OMapp. The contents appear under the following four main windows:

- (i) Clinical (Diagnosis and Management): The user is stepped through each of ten Algorithms (also presented as 2D decision flow diagrams with zoom capacity).
- (ii) Communication: This window provides audio translations in multiple Aboriginal languages (Pitandjatjara, Eastern and Central Arrernte, Murrinh Patha, Tiwi, Yolgnu Matha, and clear English), of information for parents or patients about their diagnosis, impact of possible hearing impairment, and proposed management and follow-up, including medical, audiological and surgical advice.
- (iii) Educational resources for professionals, families and children: Pneumatic otoscopy videos and explanations, and a quiz are

included to aid diagnosis and treatment. Cartoons for children and their parents simulate hearing loss, and others explain prevention strategies (Breathe Blow Cough and Wash), and ear and hearing health service referral pathways including hearing tests and surgical procedures.

- (iv) Guidelines: There are three major windows. (i) About: this section includes details of guideline development and TAG member affiliations, a summary of the GRADE approach, an overview on OM, priority clients for primary health care services in resource-poor settings. (ii) Guidelines and Evidence: this summarises evidence for all strategies and recommendations for prevention and treatment of all types of OM following the GRADE approach which are finally linked with respective Summary of Findings tables, and (iii) Appendices: privacy policy, legal disclaimer, definitions, and references (including hyperlinks).

### ***Target user and evaluation of OM Guidelines and OMapp***

The OMapp is a multi-platform app available free of charge on App Store and Google Play with downloadable content for offline use.(22) A Web version of the OMapp is available(23) and a summary of key clinical recommendations has been published.(24) The OM Guidelines and OMapp were designed for health care professionals (Aboriginal Health Practitioners, nurses, doctors, specialists and researchers) who provide care for Aboriginal and Torres Strait Islander children across Australia. Frequency of downloads will be periodically evaluated by analysis of data from the App Store or Google Play. Online surveys will assess the 2020 OM Guidelines or OMapp useability and day-to-day satisfaction. This will help to identify sectors or regions for focussed promotion. A living evidence approach to updating the OMapp is planned.

### **CONCLUSIONS**

Our goal is to improve ear and hearing health of Aboriginal and Torres Strait Islander children across Australia. Appropriate management of otitis media relies on accurate diagnosis with either pneumatic otoscopy or tympanometry combined with otoscopy. For each diagnosis an algorithm to

support evidence-based decision making and comprehensive referral pathways from primary health care to specialist referral is available for both low- and high-risk children and episodes. Increased confidence in following these recommendations relies on quality of evidence.

## DECLARATIONS

- Ethics approval and consent to participate – not applicable
- Consent for publication

The Menzies School of Health Research was granted a copyright license from the Australian Government Department of Health to use the 2010 “Recommendations for Clinical Care Guidelines on the Management of Otitis Media in Aboriginal and Torres Strait Islander Populations” for creating and producing and copying, reproducing, printing, communicating and distributing an App and App content.

- Availability of data and materials – not applicable
- Competing interests

All authors declared that they do not have any conflict of interest. The TAG does not accept any contractual, tortious or other liability with respect of their contents or any consequences arising from the review. While all advice and recommendations are made in good faith, the TAG does not accept legal liability or responsibility for such advice or recommendations.

- Funding

The OM Guideline update and OMapp development were funded by the NHMRC Centre of Research Excellence in Ear and Hearing Health of Aboriginal and Torres Strait Children (GNT1078557) and GlaxoSmithKline outreach project (Grant - 2016-093 – 4235983).

- Authors' contributions (all authors and co-authors are members of the Technical Advisory Group (TAG) who participated in face-to-face and teleconference meetings since conception in 2015.

All TAG members reviewed drafts and read the final submitted version). AL (Senior Research Fellow), conceived the study, obtained funding,

supervised evidence reviews, drafted the manuscript, wrote and read the final submitted version. PM (Paediatrics), conceived the study, obtained funding. SB-W (Paediatrics registrar) conducted systematic reviews, meta-analyses and GRADEpro. SKD (Senior Research Officer) prepared data for the OMapp, drafted the manuscript, assisted TAG. HG (Paediatrics), obtained funding. SH (Hearing Australia), wrote the Audiology section. KJ (Paediatrics registrar) conducted systematic reviews, meta-analyses and GRADEpro, drafted Summary of Findings tables. KK (ENT surgeon), obtained funding. JP (medical student) script writer and OMapp developer. PT (Chair of TAG, Medical Director, Nganampa Health Council).

*The following co-authors are acknowledged alphabetical*

Chris Brennan-Jones<sup>9,10</sup>, Harvey Coates<sup>10</sup>, Kathy Currie<sup>3</sup>, David Isaacs<sup>11</sup>, Deborah Lehmann<sup>9</sup>, Sandra Nelson<sup>3</sup>, Stephen O'Leary<sup>12</sup>, Hemi Patel<sup>3</sup>, Chris Perry<sup>13</sup>, Jennifer Reath<sup>14</sup>, Peter Richmond<sup>9,10</sup>, Jessica Sommer<sup>1,2</sup>

Affiliations: <sup>1</sup>Menzies School of Health Research, <sup>2</sup>Charles Darwin University, <sup>3</sup>Northern Territory Department of Health, <sup>9</sup>Telethon Kids Institute, <sup>10</sup>University of Western Australia, <sup>11</sup>Department of Infectious Diseases, The Children's Hospital at Westmead, <sup>12</sup>University of Melbourne, <sup>13</sup>Children's Health Queensland Hospital and Health Service, <sup>14</sup>Western Sydney University

Co-author contributions

CB-J (Audiology). HC (ENT surgeon). KC (Audiology). DI (Paediatrics). DL (Research Fellow). SN (Aboriginal Health Practitioner). SOL (ENT surgeon). HP (ENT surgeon). CP (ENT surgeon). JR (General Practice). PR (Paediatrics). JS (Registrar).

- Dedication

The 2020 OM guidelines are dedicated to the memory of Judith Boswell who passed away 4th April 2017. She was co-author of the 2001 inaugural national Otitis Media Guideline and the 2010 update. Despite her ill-health, she joined the TAG for this 2020 OM Guidelines.

- Acknowledgements

We would also like to acknowledge others who significantly supported and contributed to the OM

Guideline update and OMapp development: (i) Noma Bengler Chidanpee for the artwork, (ii) Legal advisory group for advice and management of copyright license between Commonwealth of Australia and Menzies School of Health Research, (iii) Aboriginal and Torres Strait Islander children, families and communities across Australia who have participated in original studies that inform this OM Guideline, (iv) Children whose tympanic membrane images and videos are included, (v) Hearing Australia, AWABAKAL, Healthy Ear project outreach, and Oliver Abbott for the education animations, (vi) Data System Management at Menzies School of Health Research for IT support of the OMapp, and (vii) the Aboriginal Interpreter Service (NT).

- **Competing interests**

All authors declared that they do not have any conflict of interest.

- **Legal Disclaimer**

The 2020 OM Guidelines have been prepared following consultation with experts in the field of ear and hearing health and are based on information available at the time of their preparation. Practitioners should have regard to any information on these matters which may become available subsequent to the preparation of these 2020 OM Guidelines.

The TAG and the Menzies School of Health Research does not accept any contractual, tortious or other liability whatsoever in respect of their contents or any consequences arising from their use. While all advice and recommendations are made in good faith, the TAG and the Menzies School of Health Research does not accept legal liability or responsibility for such advice or recommendations.

## References

1. Teele D, Klein J, Rosner B, tGBOMSG. Epidemiology of otitis media during the first seven years of life in children in Greater Boston: a prospective cohort study. *J Clin Infect Dis*. 1989;160(1):83-94.
2. Monasta L, Ronfani L, Marchetti F, Montico M, Vecchi Brumatti L, Bavcar A, et al. Burden of disease caused by otitis media: systematic review and global estimates. *PLoS One*. 2012;7(4):e36226.
3. Morris PS, Leach AJ, Silberberg P, Mellon G, Wilson C, Hamilton E, et al. Otitis media in young Aboriginal children from remote communities in Northern and Central Australia: a cross-sectional survey. *BMC Pediatr*. 2005;5:27-37.
4. Leach AJ, Wigger C, Beissbarth J, Woltring D, Andrews R, Chatfield MD, et al. General health, otitis media, nasopharyngeal carriage and middle ear microbiology in Northern Territory Aboriginal children vaccinated during consecutive periods of 10-valent or 13-valent pneumococcal conjugate vaccines. *Int J Pediatr Otorhinolaryngol*. 2016;86:224-32.
5. He VY, Guthridge S, Su J-Y, Howard D, Stothers K, Leach A. The link between hearing impairment and child maltreatment among Aboriginal children in the Northern Territory of Australia: is there an opportunity for a public health approach in child protection? *BMC Public Health*. 2020;20(1).
6. Su JY, He VY, Guthridge S, Howard D, Leach A, Silburn S. The impact of hearing impairment on Aboriginal children's school attendance in remote Northern Territory: a data linkage study. *Australian and New Zealand journal of public health*. 2019;43(6):544-50.
7. Su JY, Guthridge S, He VY, Howard D, Leach AJ. The impact of hearing impairment on early academic achievement in Aboriginal children living in remote Australia: a data linkage study. *BMC Public Health*. 2020;20(1):1521.
8. He VY, Su JY, Guthridge S, Malvaso C, Howard D, Williams T, et al. Hearing and justice: The link between hearing impairment in early childhood and youth offending in Aboriginal children living in remote communities of the Northern Territory, Australia. *Health Justice*. 2019;7(1):16-28.
9. Morris P, Leach A, Shah P, Nelson S, Anand A, Daby J, et al. Recommendations for Clinical Care Guidelines on the Management of Otitis Media in Aboriginal & Torres Strait Islander Populations (April 2010). Publications Approval Number D0419 ed2010.
10. McDonald E. Evaluation of implementation of best practice models of care based on the updated recommendations for clinical care guidelines on the management of otitis media in Aboriginal and Torres Strait Islander Populations. *Australian Indigenous Health Bulletin*. 2013;14(1).
11. Russell DJ, Zhao Y, Guthridge S, Ramjan M, Jones MP, Humphreys JS, et al. Patterns of resident health workforce turnover and retention in remote communities of the Northern Territory of Australia, 2013-2015. *Human resources for health*. 2017;15(1):52.
12. PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA. Still waiting to be heard...Report on the Inquiry into the Hearing Health and Wellbeing of Australia. In: House of Representatives Standing Committee on Health Aged Care and Sport, editor. 2017.
13. Siggins Miller. Examine Australian Government Indigenous Ear and Hearing Health Initiatives. 2017(SON2647271-24).
14. Guyatt G, Oxman AD, Akl EA, Kunz R, Vist G, Brozek J, et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. *J Clin Epidemiol*. 2011;64(4):383-94.

15. Schünemann HB, J; Guyatt, G; Oxman, A GRADE handbook for grading the quality of evidence and the strength of recommendations using the GRADE approach. Updated October 2013. 2013.
16. Guyatt GH, Oxman AD, Sultan S, Glasziou P, Akl EA, Alonso-Coello P, et al. GRADE guidelines: 9. Rating up the quality of evidence. *J Clin Epidemiol.* 2011;64(12):1311-6.
17. Zhang Y, Coello PA, Guyatt GH, Yepes-Nunez JJ, Akl EA, Hazlewood G, et al. GRADE guidelines: 20. Assessing the certainty of evidence in the importance of outcomes or values and preferences-inconsistency, imprecision, and other domains. *J Clin Epidemiol.* 2019;111:83-93.
18. Neumann I, Brignardello-Petersen R, Wiercioch W, Carrasco-Labra A, Cuello C, Akl E, et al. The GRADE evidence-to-decision framework: a report of its testing and application in 15 international guideline panels. *Implementation science : IS.* 2016;11:93.
19. Guyatt GH, Oxman AD, Vist G, Kunz R, Brozek J, Alonso-Coello P, et al. GRADE guidelines: 4. Rating the quality of evidence--study limitations (risk of bias). *J Clin Epidemiol.* 2011;64(4):407-15.
20. Guyatt GH, Oxman AD, Kunz R, Woodcock J, Brozek J, Helfand M, et al. GRADE guidelines: 7. Rating the quality of evidence--inconsistency. *J Clin Epidemiol.* 2011;64(12):1294-302.
21. Guyatt GH, Oxman AD, Kunz R, Woodcock J, Brozek J, Helfand M, et al. GRADE guidelines: 8. Rating the quality of evidence--indirectness. *J Clin Epidemiol.* 2011;64(12):1303-10.
22. Guyatt GH, Oxman AD, Kunz R, Brozek J, Alonso-Coello P, Rind D, et al. GRADE guidelines 6. Rating the quality of evidence--imprecision. *J Clin Epidemiol.* 2011;64(12):1283-93.
23. Menzies School of Health Research. Otitis Media Guidelines for Aboriginal and Torres Strait Islander children. 2020. Available from: <https://otitismediaguidelines.com/#/start-main>  
<https://apps.apple.com/au/app/otitis-media-guidelines/id1498170123>.  
<https://play.google.com/store/apps/details?id=com.otitismediaguidelines.guidelines>  
[http://www.otitismediaguidelines.com/resources/SoF/SoF\\_Tables\\_1-51.pdf](http://www.otitismediaguidelines.com/resources/SoF/SoF_Tables_1-51.pdf)
24. Leach AJ, Morris P, Coates HLC, al. e. Otitis media guidelines for Australian Aboriginal and Torres Strait Islander children: summary of recommendations. *Med J Aust.* 2021;[in press].

### Box 1. List of abbreviations

2010 OM Guidelines	Recommendations for Clinical Care Guidelines on the Management of Otitis Media in Aboriginal and Torres Islander populations
2020 OM Guidelines	Otitis Media Guidelines for Aboriginal and Torres Strait Islander children
AOM	Acute Otitis Media
AOMwiP	Acute Otitis Media with Perforation
AOMwoP	Acute Otitis Media without Perforation
CRE	Centre of Research Excellence
CSOM	Chronic Suppurative Otitis Media
DP	Dry perforation
GRADE	Grading, Recommendations, Assessment, Development, and Evaluation
OM	Otitis Media
OMapp	Application for OMG
OME	Otitis Media with Effusion
PICOT	Population Intervention Comparator Outcome and Time
RCT	Randomised Controlled Trial
SoF	Summary of Findings
TAG	Technical Advisory Group
TTO	Tympanostomy Tube Otorrhoea
WHO	World Health Organization

**Box 2:** Definitions and abbreviations for all types of otitis media

- **Otitis Media with Effusion (OME):** Presence of fluid behind the tympanic membrane without any acute symptoms. Other terms have also been used to describe OME (including ‘glue ear’, ‘serous otitis media’ and ‘secretory otitis media’) A type B tympanogram or reduced mobility of the tympanic membrane on pneumatic otoscopy are the most reliable indicators of middle ear fluid.
- **Episodic OME:** Episodic OME would be OM as defined above of duration less than 3 months.
- **Persistent (Chronic) Otitis Media with Effusion (pOME):** Presence of fluid in the middle ear for more than 3 months without any symptoms or signs of inflammation.
- **Acute Otitis Media without perforation (AOMwoP):** Presence of fluid behind the tympanic membrane plus bulging tympanic membrane with or without one of the following, red tympanic membrane, fever, ear pain or irritability. A bulging tympanic membrane, and ear pain are the most reliable indicators of AOMwoP.
- **Acute Otitis Media with Perforation (AOMwiP):** Discharge of pus through a perforation (hole) in the tympanic membrane within the last 2 weeks. The perforation is usually very small (a pinhole; <2% of the pars tensa) when the tympanic membrane first ruptures. The perforation can heal and re-perforate after the initial onset of AOMwiP. The size of the perforation should be recorded, as this directs management, and duration of discharge is often difficult to establish.
- **Recurrent Acute Otitis Media (rAOM):** 3 or more episodes of AOM (AOMwoP or AOMwiP) in a 6-month period, or occurrence of 4 or more episodes in the last 12 months.
- **Chronic Suppurative Otitis Media (CSOM):** Persistent ear discharge through a perforation (hole) in the tympanic membrane lasting 2 weeks or longer and tympanic membrane perforation large enough to allow penetration of topical antibiotics into the middle ear space (generally  $\geq 2\%$  of the pars tensa). The size of the perforation should be determined and recorded, as this directs management, and duration of discharge is often difficult to establish.
- **Tympanostomy Tube Otorrhoea (TTO):** Middle ear discharge through tympanostomy tubes (“tympanostomy tubes”) in situ. TTO may be further classified as: Early post-operative – occurring within 4 weeks of TT insertion, delayed- occurring after 4 weeks of TT insertion, chronic- persisting 3 months or longer or recurrent- 3 or more discrete episodes.
- **Dry Perforation (DP):** Presence of a perforation (hole) in the tympanic membrane without any signs of discharge or fluid behind the tympanic membrane. Also referred to as inactive CSOM.

**Table 1:** Otitis Media Guidelines research questions.

<b>Prevention. Among Aboriginal and Torres Strait Islander children ...</b>	
1.	Should breastfeeding vs. other feeding be used for prevention of OM?
2.	Should household tobacco smoke exposure vs. no household tobacco smoke exposure be used for prevention of AOM ?
3.	Should hygiene promotion programs vs. no intervention be used for prevention of AOM ?
4.	Should multivalent pneumococcal conjugate vaccines vs. placebo / other vaccine / no treatment be used for prevention of AOM ?
5.	Should seasonal influenza vaccine vs. placebo / no treatment be used for prevention of AOM in children?
6.	Should parental counselling to restrict pacifier/dummy use vs. unrestricted pacifier/dummy use be used for prevention of AOM?
7.	Should probiotics vs. placebo be used for prevention of AOM ?
8.	Should vitamin D supplementation vs. placebo be used for prevention of AOM?
9.	Should xylitol (administered as syrup, gum or lozenge) vs. placebo be used for prevention of AOM ?
10.	Should zinc supplementation vs. placebo be used for prevention of AOM?
<b>Among Aboriginal and Torres Strait Islander children with otitis media with effusion (OME) ...</b>	
11.	Should antibiotics vs. placebo / no treatment / unproven therapy be used for children with OME?
12.	Should topical/intranasal steroids vs. placebo be used for OME?
13.	Should oral steroids vs. placebo be used for OME?
14.	Should tympanostomy tubes vs. no surgical intervention be used for OME?
15.	Should adenoidectomy +/- tympanostomy tubes vs. tympanostomy tubes alone or no surgery be used for OME?
16.	Should antihistamines and/or decongestants vs. placebo be used for OME?
17.	Should autoinflation devices vs. watchful waiting be used for OME?
<b>Among Aboriginal and Torres Strait Islander children with acute otitis media (AOM) ...</b>	
18.	Should topical analgesia as an adjunct to simple oral analgesia vs. Placebo ear drops be used for pain relief in AOM?
19.	Should topical anaesthetic vs. naturopathic therapy be used for as adjunct to simple oral analgesics for AOM?
20.	Should paracetamol vs. NSAIDs or combined be used for pain relief in AOM?
21.	Should immediate antibiotics vs. watchful waiting be used for AOM ?
22.	Should antibiotics vs. placebo be used for AOM?
23.	Should short course (<48hrs) vs. longer course (7-10 days) antibiotics be used for children with AOM?
24.	Should short course (3-5 days) vs. longer course (7-10 days) antibiotics be used for children with AOM?
25.	Should short course (3-5 days) vs. longer course (7-10 days) be used for children <2 years with AOM?
26.	Should short course (3-5 days) vs. longer course (7-10 days) be used for children =>2 years AOM?
27.	Should short course (3-5 days) vs. longer course (7-10 days) be used for children with AOM - Sensitivity analysis: same antibiotic in treatment arms?
28.	Should short course (3-5days) vs. longer course (7-10 days) be used for children with AOM - Sensitivity analysis Amoxicillin both arms?
29.	Should short course (3-5 days) vs. longer course (7-10 days) be used for children with AOM - GI side effects?
30.	Should twice daily vs. three daily doses of amoxicillin (+/- clavulanate) be used for AOM?
31.	Should short course (3-5 days) vs. longer course (7-10 days) antibiotics be used for AOM?
32.	Should azithromycin vs. amoxicillin with or without clavulanate be used for AOM?
33.	Should prophylactic antibiotics vs. placebo / no treatment be used for prevention of recurrent AOM?
34.	Should adenoidectomy vs. no adenoidectomy be used for recurrent AOM in children who are undergoing tympanostomy tube placement?

35.	Should adenoidectomy +/- tympanostomy tubes vs. no surgery / tympanostomy tubes alone be used for recurrent AOM?
36.	Should adenoidectomy +/- tympanostomy tubes vs. no surgery / tympanostomy tubes alone be used for recurrent AOM?
37.	Should tympanostomy tubes vs. no surgery be used for recurrent AOM?
<b>Among Aboriginal and Torres Strait Islander children with chronic suppurative otitis media (CSOM)...</b>	
38.	Should topical antibiotics vs. ear toilet alone be used for CSOM?
39.	Should topical quinolone antibiotic vs. topical antiseptic be used for CSOM?
40.	Should topical quinolone vs. topical non-quinolone antibiotic be used for CSOM?
41.	Should topical quinolone with steroids vs. topical quinolone without steroids be used for CSOM?
42.	Should systemic antibiotic vs. topical antibiotic be used for CSOM?
43.	Should oral trimethoprim/sulfamethoxazole vs. placebo be used for adjunct treatment (with topical quinolones) for CSOM?
44.	Should swimming in a chlorinated pool vs. no swimming be used for treatment CSOM?
<b>Among Aboriginal and Torres Strait Islander children with tympanostomy tube otorrhoea (TTO) ...</b>	
45.	Should antibiotic eardrops (with or without a corticosteroid) vs. no treatment be used for children with TTO?
46.	Should antibiotic eardrops (with or without a corticosteroid) vs. saline rinsing of the ear canal be used for children with TTO?
47.	Should antibiotic(s) + corticosteroid eardrops vs. antibiotic eardrops be used for children with TTO?
48.	Should antibiotic eardrops (with or without a corticosteroid) vs. oral antibiotics be used for children with TTO?
49.	Should oral antibiotics vs. saline rinsing of the ear canal be used for children with TTO?
50.	Should oral antibiotics vs. placebo or no treatment be used for children with TTO?
51.	Should oral corticosteroids vs. placebo be used for children with TTO?
52.	Should ear plugs vs. no ear plugs when swimming or bathing be used for prevention of TTO?
53.	Should no swimming or head submersion during bathing vs. unrestricted swimming or head submersion during bathing be used for prevention of TTO?
54.	Should antiseptic irrigation of middle ear at time of surgery vs. no treatment be used for the prevention of postoperative TTO?
55.	Should saline irrigation of middle ear at time of surgery vs. topical antibiotics be used for the prevention of post-operative TTO?
56.	Should single dose ciprofloxacin vs. prolonged application ciprofloxacin be used for the prevention of post-operative TTO?

**Table 2:** Time frame for Otitis Media Guidelines update and App development

	<b>Task carried out for OM Guidelines update and OMapp development</b>	Time and date
1	Identify the scope of Guidelines update, development of concept, exploring and receiving grant from NHMRC	2016
2	Appointment of Technical Advisory Group (TAG) Chair by the CRE Leadership Group.	2016
3	Identify and prioritise clinical questions for all types of OM following PICOT format	2016
4	Systematic review, data extraction and synthesis	2016 to 28 <sup>th</sup> March 2017
5	GRADE recommendations	2018
6	Draft Guidelines update	2019
7	Otitis Media mobile app development	2018 to 2019
8	Write narrative clinical context, Language translations	2019
9	Populate data into the app	2018 to 2020
10	Revise and update	2019
11	Disseminate	2020

**Table 3: Literature search phases**

<p><b>Phase 1. Evidence-based guidelines, evidence summaries and systematic reviews</b></p> <p><b>1.</b> For systematic reviews and meta-analyses: ("otitis"[MeSH Terms] OR otitis[Text Word] OR "hearing loss"[MeSH Terms] OR deafness[Text Word] OR "hearing loss"[Text Word]) AND (meta-analysis[PTYP] OR meta-analysis[Text Word] OR meta analysis[Text Word] OR (review[PTYP] AND systematic[Text Word]) OR overview[Text Word])</p> <p>In MEDLINE (accessed via PubMed and all search limited data search limited to 1<sup>st</sup> January 2010 to 27<sup>th</sup> March 2017, English language and Humans subject.)</p> <p><b>2.</b> For clinical practice guidelines: ("otitis"[MeSH Terms] OR otitis[Text Word] OR ("hearing loss"[MeSH Terms] OR ("hearing"[All Fields] AND "loss"[All Fields]) OR "hearing loss"[All Fields]) OR deafness[Text Word] OR hearing loss[Text Word]) AND practice guideline[PTYP]</p>
<p><b>Phase 2. All papers</b></p> <p><b>1.</b> For all papers: (otitis[Text Word] OR "otitis"[MeSH Terms]) AND media[Text Word]</p> <p><b>2.</b> For trials of interventions/treatment: (otitis [MeSH Terms] OR otitis [Text Word] OR hearing loss [MeSH Terms] OR deafness [Text Word] OR hearing loss [Text Word]) AND (clinical trial [PTYP] OR random* [Text Word])</p> <p><b>3.</b> For diagnostic tests: (otitis [MeSH Terms] OR otitis [Text Word]) AND (sensitivity and specificity [MeSH Terms] OR sensitivity [Text Word] OR specificity [Text Word] OR (predictive [Text Word] AND value* [Text Word]))</p> <p><b>4.</b> For prognostic information (otitis [MeSH Terms] OR otitis [Text Word]) AND (cohort studies [MeSH Terms] OR prognos* [Text Word] OR risk [Text Word] OR case control* [Text Word])</p>
<p><b>Phase 3. More specific searches to cover papers which may have been missed above</b></p> <p><b>1.</b> For chronic OM specifically: "Chronic": ((otitis[Text Word] OR "otitis"[MeSH Terms]) AND media[Text Word]) AND chronic[Text Word] AND ((Guideline[ptyp] OR Clinical Trial[ptyp] OR Randomized Controlled Trial[ptyp] OR Journal Article[ptyp])</p> <p><b>2.</b> For hearing impairment: Hearing Impairment: ((otitis[Text Word] OR "otitis"[MeSH Terms]) AND media[Text Word]) AND hearing impairment[Text Word] AND ((Guideline[ptyp] OR Clinical Trial[ptyp] OR Randomized Controlled Trial[ptyp] OR Journal Article[ptyp])</p> <p><b>3.</b> For dry perforation (given the term "otitis" may not appear in these papers) perforat* AND (ear OR tympan*) AND (dry OR chronic).</p> <p><b>4.</b> For tympanostomy tube otorrhoea (tympanostomy OR grommet*) AND (otorrhoea OR otorrhea)</p> <p><b>5.</b> For diagnostic guidance tympanometry AND (child* OR paediatric OR pediatric OR infant OR young) AND (otitis OR infection OR effusion) otoscopy AND (child* OR paediatric OR pediatric OR infant OR young) AND (otitis OR infection OR effusion)</p>
<p><b>Phase 4. Searches of other databases</b> (using "otitis OR hearing loss", limited by date and language where possible)</p> <ul style="list-style-type: none"> <li>• Aboriginal and Torres Strait Islander Health Information Database (healthinfonet)</li> <li>• Scottish Intercollegiate Guidelines Network</li> <li>• National Guideline Clearinghouse</li> <li>• Agency for Healthcare Research and Quality</li> <li>• Canadian Medical Association Clinical Practice Guidelines</li> <li>• Centres for Disease Control and Prevention</li> <li>• UK Health Technology Assessment</li> </ul>

- Cochrane library
- BMJ Clinical Evidence

**Phase 5. Using PubMed Clinical Queries function**

To ensure comprehensive results, PubMed's "Clinical Queries" functions were utilized, which is a set of pre-defined algorithms, coupling the [otitis media] term with, in turn, broad filters for Therapy, Etiology, Prognosis, Diagnosis and Clinical Prediction Guides, with each search again limited by date as above, and limited to English language papers, excluding animal studies.

- (Therapy/Broad[filter]) AND ("otitis media")
- Etiology/Broad[filter] AND "otitis media"[All Fields]
- Diagnosis/Broad[filter] AND "otitis media"[All Fields]
- Prognosis/Broad[filter] AND "otitis media"[All Fields]
- Clinical Prediction Guides/Broad[filter] AND "otitis media"[All Fields]

**Figure 1:** Selection framing of literature for systematic reviews and meta-analyses

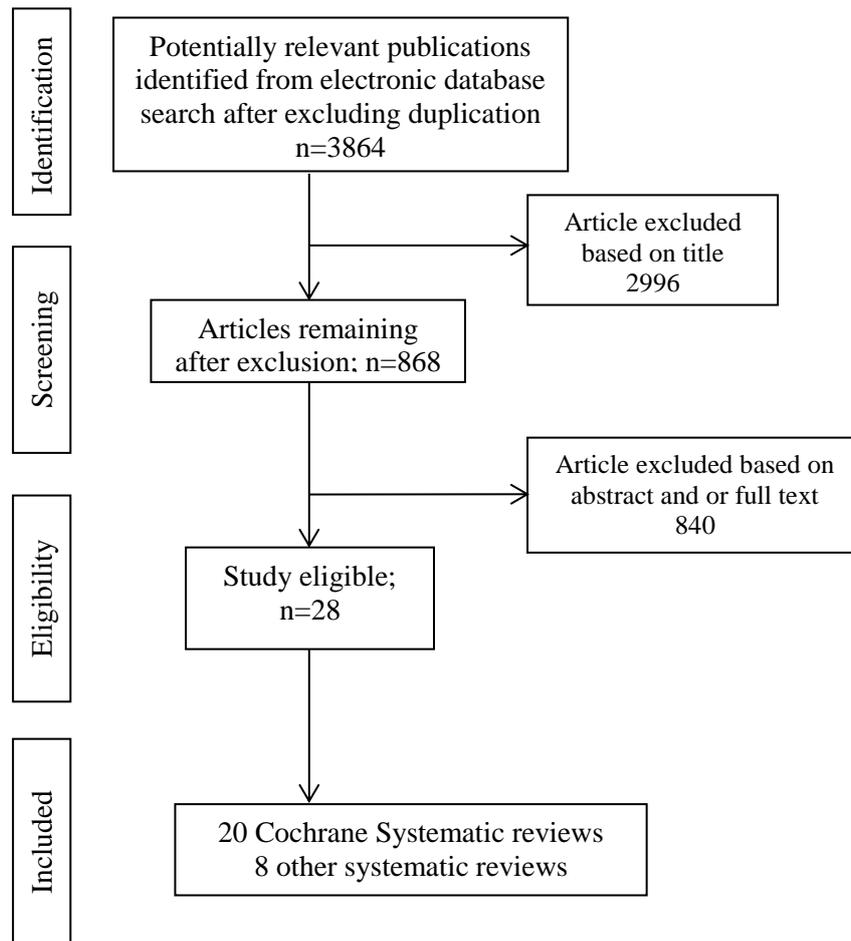


Figure 2: Example of GRADEpro Summary of Findings

Summary of findings:						
12 Antibiotics compared to placebo / no treatment / unproven therapy for children with otitis media with effusion						
Patient or population: Children aged 0 to 15 years who have otitis media with effusion.						
Setting: Primary health care						
Intervention: Antibiotics (Studies used: amoxicillin (20-50 mg/kg/day in single or 3 divided doses for 14 days to 6 months), trimethoprim-sulfamethoxazole (8 mg and 40 mg/kg/day in 2-3 divided doses for 2-4 weeks) and amoxicillin/clavulanic acid (40 mg/kg/day in 3 divided doses (maximum 750 mg/day) for 2 weeks to 3 months).						
Comparison: Placebo / No treatment / Unproven therapy.						
Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Quality	What happens
		Without antibiotics	With antibiotics	Difference		
Hearing outcomes assessed with: pure tone average and speech reception threshold follow up: range 2 to 4 weeks № of participants: 784 (2 RCTs) <sup>1,a,b</sup>	Mandel 1987 reported no statistically significant differences in mean speech recognition threshold between antibiotic and placebo groups at 4 weeks. Mandel 1991 reported a statistically significant difference in the mean speech recognition threshold between antibiotic and placebo groups at 2 weeks (left and right ears). At 4 weeks a statistically significant result was only found in the right ears.				⊕○○○ VERY LOW <sup>c,d,e</sup>	In children with OME treated with antibiotics compared to placebo / no treatment / unproven treatment there is possibly no improvement in hearing outcomes at 2-4 weeks.  NNT Not Applicable
Complete resolution of OME assessed with: tympanometry +/- pneumatic otoscopy follow up: range 2 to 3 months № of participants: 484 (6 RCTs) <sup>1,f</sup>	RR 2.00 (1.58 to 2.53)	24.7%	49.3% (39.0 to 62.4)	24.7% more (14.3 more to 37.7 more)	⊕⊕○○ LOW <sup>g,h</sup>	In children with OME treated with antibiotics compared to placebo / no treatment / unproven treatment there is possibly more resolution of OME at 2-3 months follow-up.  NNT ~ 5
Complete resolution of OME (long term) assessed with: tympanometry +/- pneumatic otoscopy follow up: median 6 months № of participants: 606 (5 RCTs) <sup>1,i</sup>	RR 1.75 (1.41 to 2.18)	25.5%	44.5% (35.9 to 55.5)	19.1% more (10.4 more to 30 more)	⊕⊕○○ LOW <sup>g,i</sup>	In children with OME treated with antibiotics compared to placebo / no treatment / unproven treatment there is possibly more resolution of OME at 6 months follow-up.  NNT ~ 6
Adverse effects (diarrhoea, vomiting or skin rash) follow up: range 2 to 8 weeks № of participants: 742 (5 RCTs) <sup>1,k</sup>	RR 2.15 (1.29 to 3.60)	4.5%	9.7% (5.8 to 16.2)	5.2% more (1.3 more to 11.7 more)	⊕⊕○○ LOW <sup>g,k,m</sup>	In children with OME treated with antibiotics compared to placebo / no treatment / unproven treatment there are possibly more adverse events at 2-8 weeks follow-up.  NNH ~ 20

In original tables, these numeric superscripts refer to studies, and alphabetical superscripts refer to explanatory notes on quality.

Table 4: Number and strength of recommendations for OM or hearing loss interventions

OM Type	Strong	Weak	Consensus
Prevention	6	4	4
Persistent OME	4	6	5
AOM without perforation	8	2	8
AOM with perforation	0	0	6
Recurrent AOM	1	4	3
CSOM	4	1	7
Dry Perforation	0	0	4
TTO	4	3	6
Audiology	0	0	12
<b>Total (102)</b>	<b>27</b>	<b>20</b>	<b>55</b>