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Otitis media guidelines for Australian Aboriginal and Torres Strait Islander children: summary of recommendations

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In remote communities across the Northern Territory of Australia, only one in ten Aboriginal children younger than 3 years has healthy ears; five have otitis media (OM) with effusion (OME), or “glue ear”; and four have suppurative OM — acute OM (AOM) with or without perforation or chronic suppurative OM (CSOM).¹⁻³ Remote communities rely on fly in-fly out specialist services and a high turnover of resident primary health care professionals.⁴ Aboriginal and Torres Strait Islander children in rural and urban areas across Australia are also at increased risk of chronic OM, although the true prevalence of OM and associated conductive hearing loss is not known. All forms of OM cause conductive hearing loss, which is associated with language delay, speech problems, high vulnerability on entering school, social isolation, poor school attendance, and low education and employment opportunities.⁵⁻⁸

This 2020 update of the 2010 *Recommendations for clinical care guidelines on the management of OM in Aboriginal and Torres Strait Islander populations*⁹ followed the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. The 2020 OM guidelines provide recommendations for prevention, diagnosis and management of all forms of OM, including episodic OME, persistent OME, AOM without perforation, AOM with perforation, dry perforation, and CSOM, plus tympanostomy tube otorrhoea (TTO).

The overall objective of the 2020 OM guidelines is to prevent OM and improve detection and management of OM and associated hearing loss in Aboriginal and Torres Strait Islander children across Australia.

Methods

The Technical Advisory Group included representatives and members of the Royal Australasian College of Surgeons, the Royal Australian College of General Practitioners, and the Royal Australasian College of Physicians (adult and paediatric divisions), as well as trainees of these colleges, Aboriginal health practitioners, audiologists, scientists, researchers and consumers.

The methods for search strategies, grading recommendations, determination of quality and confidence, and generation of summary of findings tables¹⁰ used Cochrane Reviews, RevMan 5 (Cochrane Collaboration) and GRADEpro software as described in detail elsewhere (<https://grade.pro.org/>).

Abstract

Introduction: The 2001 *Recommendations for clinical care guidelines on the management of otitis media in Aboriginal and Torres Strait Islander populations* were revised in 2010. This 2020 update by the Centre of Research Excellence in Ear and Hearing Health of Aboriginal and Torres Strait Islander Children used for the first time the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.

Main recommendations: We performed systematic reviews of evidence across prevention, diagnosis, prognosis and management. We report ten algorithms to guide diagnosis and clinical management of all forms of otitis media. The guidelines include 14 prevention and 37 treatment strategies addressing 191 questions.

Changes in management as a result of the guidelines:

- A GRADE approach is used.
- Targeted recommendations for both high and low risk children.
- New tympanostomy tube otorrhoea section.
- New Priority 5 for health services: annual and catch-up ear health checks for at-risk children.
- Antibiotics are strongly recommended for persistent otitis media with effusion in high risk children.
- Azithromycin is strongly recommended for acute otitis media where adherence is difficult or there is no access to refrigeration.
- Concurrent audiology and surgical referrals are recommended where delays are likely.
- Surgical referral is recommended for chronic suppurative otitis media at the time of diagnosis.
- The use of autoinflation devices is recommended for some children with persistent otitis media with effusion.
- Definitions for mild (21–30 dB) and moderate (> 30 dB) hearing impairment have been updated.
- New “OMapp” enables free fast access to the guidelines, plus images, animations, and multiple Aboriginal and Torres Strait Islander language audio translations to aid communication with families.

The primary objectives were:

- to review all the available evidence to March 2017, using the GRADE approach;¹¹
- to include pathways for children at low or high risk (Box 1) of treatment failure; and
- to transform the 2020 guidelines into a user-friendly multiplatform application (app), “OMapp”, with multiple audiovisual features targeting multiple stakeholders (scientists, doctors, specialists, health workers, nurses, researchers, policy makers, children and parents).

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1 Algorithms for diagnosis and management of different types of otitis media for low and high* risk children

Algorithm	Description	Resources
1	Diagnosis. Could this child have a middle ear infection (otitis media)?	http://www.otitismediaguidelines.com/resources/Algorithms/Algorithm_1_Diagnosis.pdf
2	Management. Episodic bilateral otitis media with effusion	http://www.otitismediaguidelines.com/resources/Algorithms/Algorithm_2_Management_Episodic_OME.pdf
3	Management. Persistent bilateral otitis media with effusion	http://www.otitismediaguidelines.com/resources/Algorithms/Algorithm_3_Management_Persistent_OME.pdf
4	Management. Acute otitis media without perforation	http://www.otitismediaguidelines.com/resources/Algorithms/Algorithm_4_Management_AOMwoP.pdf
5	Management. Recurrent acute otitis media	http://www.otitismediaguidelines.com/resources/Algorithms/Algorithm_5_Management_rAOM.pdf
6	Management. Acute otitis media with perforation	http://www.otitismediaguidelines.com/resources/Algorithms/Algorithm_6_Management_AOMwiP.pdf
7	Management. Chronic suppurative otitis media	http://www.otitismediaguidelines.com/resources/Algorithms/Algorithm_7_Management_CSOM.pdf
8	Management. Dry perforation	http://www.otitismediaguidelines.com/resources/Algorithms/Algorithm_8_Management_Dry_Perforation.pdf
9	Management. Tympanostomy tube otorrhoea	http://www.otitismediaguidelines.com/resources/Algorithms/Algorithm_9_Management_TTO.pdf
10	Management. Could this child have an important hearing loss due to otitis media?	http://www.otitismediaguidelines.com/resources/Algorithms/Algorithm_10_Management_Hearing_Loss.pdf

* High risk of treatment failure includes one or more of the following risk factors: living in a remote community, younger than 2 years of age, first episode of otitis media before 6 months of age, a family history of chronic suppurative otitis media, a current or previous tympanic membrane perforation, craniofacial abnormalities, cleft palate, Down syndrome, immunodeficiency, cochlear implants, developmental delay, hearing loss, or severe visual impairment. ♦

The Commonwealth of Australia granted the Menzies School of Health Research licence to update the 2010 *Recommendations for clinical care guidelines on the management of otitis media in Aboriginal and Torres Islander populations*.

We generated 51 summary of findings tables¹⁰ (14 prevention and 37 treatment strategies) based on 191 PICOT (population, intervention, comparison, outcome, time) questions. We made 102 recommendations: 27 strong, 20 weak, and 55 by consensus. Recommendations were graded according to the quality and confidence of the evidence. Overall, the quality of evidence was usually low and the confidence or strength of the recommendations was usually weak. Randomised controlled trials were often ranked down, and few observational studies were ranked up. Effect sizes were rarely above 2 or below 0.5. Many studies had non-significant outcomes for which an effect size could not be determined. Few studies reported adverse events, but when reported, they were rare. Adverse events, confidence, effect size and intervention complexity determined the overall benefit statements (large, moderate or small benefit).

Recommendations

The full OM guidelines are available at <https://otitismediaguidelines.com>, where the OMapp can also be downloaded.

Primary prevention strategies

Early accurate detection and appropriate treatment of OM can prevent associated hearing loss, language delay, developmental problems and educational disadvantage. There are several OM preventive strategies, including breastfeeding for at least 6 months,¹² frequent handwashing for children attending day care centres,¹³ and avoiding smoke exposure.¹⁴ All are strongly recommended for their broad health benefits; however, most

were observational studies with very low quality of evidence. Vitamin D¹⁵ and probiotic supplementation (*Lactobacillus rhamnosis* GG),^{16–20} xylitol,²¹ and limited use of pacifier are weakly recommended (quality of evidence: low to moderate). Pneumococcal conjugate²² and influenza²³ vaccination are strongly recommended for the prevention of invasive pneumococcal disease and influenza, as the available evidence is very strong. However, the effect size for preventing OM is very small. Keeping the child away from sick children and those with a runny nose, especially at day care centres, is a consensus recommendation.¹³ There is no role for zinc in OM prevention.²⁴

Diagnosis and management of otitis media

Ten algorithms are provided, including one diagnostic and seven management algorithms. There is one algorithm for each type of OM, an additional new algorithm for the management of TTO, and an algorithm for the management of hearing impairment.

Algorithm 1: diagnosis of otitis media. We recommend otoscopy with tympanometry or pneumatic otoscopy to diagnose middle ear disease. Algorithm 1 presents a clear guide to diagnosis based on the answer to simple stepwise questions related to visualisation and mobility of the child's eardrum (Box 1).

Algorithms 2–8: management of all forms of otitis media. The management of OM ranges from watchful waiting to long term and high dose antibiotic therapy (Box 1).

- Where antibiotics are indicated, amoxicillin (50 mg/kg/day for 7 days) is recommended.²⁵
- For persistent OME or for OME in high risk children, amoxicillin (25 mg/kg/dose two times per day for 2–4 weeks) is recommended. Autoinflation devices may assist some children.

- When AOM persists for 7 days, we recommend increasing the dose to 90 mg/kg/day for a further 7 days and possibly continued for a total of 4 weeks at 50 mg/kg/day.²⁵ For unresolved AOM we recommend amoxicillin–clavulanate at 90 mg/kg/day for 7 days.²⁶ The same total daily dose can also be given in three divided doses if higher antibiotic levels are required.
- Where compliance is poor and refrigeration not available, we recommend a single-dose azithromycin.²⁷⁻³⁰
- For children with known penicillin allergy, we recommend co-trimoxazole.
- For high risk children with recurrent AOM or children at risk of developing AOM with perforation or CSOM, we recommend long term (3–6 months) prophylactic antibiotics (amoxicillin 25–50 mg/kg/day).
- For children with CSOM, topical quinolone antibiotics (ciprofloxacin, five drops twice a day) after cleaning are strongly recommended, but oral antibiotics alone are not routinely recommended. However, if topical antibiotics fail, then adjunct oral trimethoprim–sulfamethoxazole (8 mg/kg/day, calculated using the trimethoprim component, in two divided doses) can be recommended.
- Regular check-up by a health professional is recommended for all children, at least once per year (Priority 5).
- Oral analgesics (eg, paracetamol, 15 mg/kg/dose every 4–6 hours if needed) reduce ear pain.³¹
- Under direct medical supervision, topical analgesia (lignocaine aqueous 2%) may provide short term pain relief.

Algorithm 9: management of tympanostomy tube otorrhoea. Refer to the treating ear nose and throat (ENT) specialist if the child has continuous TTO for 4 weeks despite treatment, or if there is intermittent or recurrent TTO for 3 months or any complication.

Regular cleaning and use of topical ciprofloxacin drops are strongly recommended for the management of children with uncomplicated TTO. Topical steroid formulations are not recommended (Box 1).³² Weekly follow-up reviews for 4 consecutive weeks are recommended.

Fever (> 37.5°C), external ear cellulitis or bleeding indicate complicated TTO; systemic antibiotics that provide gram-negative cover (seek advice of an infectious diseases specialist) are recommended for fever and outer ear cellulitis, and topical ciprofloxacin and hydrocortisone are recommended for bleeding associated with TTO.³³

Algorithm 10: criteria for prioritisation of hearing and ENT assessments. According to the current classification of the World Health Organization, individuals with an average hearing level greater than 25 dB are considered to have some degree of hearing impairment. The Technical Advisory Group made a consensus recommendation for a level greater than 20 dB based on the burden of OM among Aboriginal and Torres Strait Islander children and the risk that lower levels of hearing loss may be associated with impacts on listening and communication skills development in this population.

Hearing assessment is recommended for OME (unilateral or bilateral) that persists for more than 3 months, recurrent AOM with or without perforation, CSOM, dry perforation for more than 3 months, and any speech, language, developmental delay or behavioural problems and any family concerns.

Children with episodic OME or AOM without perforation do not routinely require hearing assessment. Any child referred to an ENT specialist should be concurrently referred for a hearing assessment, to minimise consecutive waiting times.

Key messages for primary health care providers are summarised in (Box 2).

Antimicrobial management

Aboriginal and Torres Strait Islander children are the primary target population for the OM guideline recommendations although much of the data come from studies in other populations. In some areas (generally rural and remote communities, and in some urban settings), the clinical course of OM is characterised by an early age of onset, asymptomatic presentation, high prevalence and long duration of severe disease.^{34,35} Bacterial aetiology is common in high risk children, although viruses also play a role. Therefore, antimicrobial treatment is strongly recommended for high risk children. Recommendations may be different for other children and in other international guidelines, particularly regarding antimicrobial treatment.^{34,35}

Surgical management

For children at low risk of CSOM, tympanostomy tube (grommet) insertion is strongly recommended, if the child has persistent OME or OME and hearing loss greater than 30 dB and/or speech and language delay.³⁶⁻³⁸ Any child at high risk of

2 Key messages for primary health care providers

- Let families know that hearing is important for learning culture and language, for learning English and for getting a job. Aboriginal and Torres Strait Islander children are at greatly increased risk of persistent and severe otitis media (OM) and poor hearing that can affect their whole lives.
- Let families know that severe OM can be prevented with improved and less crowded living conditions, more hand and face washing, breastfeeding, avoiding smoke exposure, and getting all vaccinations on time.
- Let families know the importance of attending the local health clinic as soon as possible whenever a baby or child develops ear pain or ear discharge.
- Let families know that they can ask for their child's ears to be checked, even when the child is well. Health care providers should use either pneumatic video-otoscopy or both video-otoscopy and tympanometry whenever possible.
- Antibiotics (amoxicillin) are recommended for all children with acute otitis media with perforation and for children with acute otitis media without perforation if they are at high risk of chronic suppurative otitis media (CSOM). Antibiotics and regular review should be continued until the bulging and/or discharge have resolved. If discharge persists and the perforation size is bigger than a pinhole, topical antibiotic drops need to be added.
- CSOM should be diagnosed in children who have persistent ear discharge for at least 2 weeks. Effective treatment of CSOM requires a long term approach with regular dry mopping or syringing of ear discharge followed by the application of topical antibiotics.
- All children with persistent bilateral OM (all types) for > 3 months should have their hearing assessed, so that appropriate management and referrals can be planned.
- Let families of children with disabling hearing loss (> 30 dB) know the benefits of improved communication strategies, surgical procedures, and hearing aids.
- Let families know that all babies and young children learn to talk by hearing people. Babies and children with OM may have problems with hearing and learning. Families can help by encouraging a lot of talking, storytelling, reading books and following their child's conversational focus.
- Aim to provide patients or families with the knowledge to manage their own health needs. Use communication techniques, language translation and resources that facilitate true understanding.

CSOM should be referred for tympanostomy tube insertion if the child has bilateral persistent OME and/or speech and language delay, and if surgery is consistent with parental preferences.

Adenoidectomy alone is usually not recommended, although it is weakly recommended in children aged over 4 years with persistent bilateral OME despite previous tympanostomy tube insertions or if the child is at high risk of CSOM.³⁹ Adenoidectomy as an adjunct to tympanostomy tube insertion is strongly recommended in children with persistent OME.

Tympanostomy tube insertion is a weak recommendation for children with recurrent AOM who are at high risk of CSOM, have hearing loss and/or speech and language difficulties and have failed to improve with long term prophylactic antibiotics.⁴⁰⁻⁴⁵

Amplification

A consultation to determine a child's hearing, communication and amplification needs is recommended for children with CSOM, persistent OME or dry perforation with persistent bilateral hearing loss averaging more than 30 dB in the better ear, or if ENT consultation is delayed more than 6 months or not available, or specialist medical treatment has been unsuccessful.

Audiological assessment and management

This section of the guidelines addresses five areas: preventing hearing loss and its impacts on listening and communication skills, identifying hearing loss early, referral and specialist input, supporting listening and communication skill development in young children, and communicating with patients and co-workers who have hearing loss. This section provides information for health professionals and families regarding screening and surveillance, hearing assessment and rehabilitation options, and strategies for enhancing language acquisition at home, in early education centres and schools and for communicating with people with hearing loss.

OMapp

The OM guidelines app, OMapp, has been designed to be used in the clinic, is compatible with multiple digital platforms and is accessible free via the App Store and Google Play. The app has four sections:

- Clinical (diagnosis and management): algorithms for all types of OM.
- Communicate: audio recordings in multiple Aboriginal languages to assist the caregivers' understanding of messages and instructions regarding their child's ear health and hearing needs.
- Education: includes pneumatic otoscopy videos and a quiz and cartoons to explain hearing loss simulation, how the ear works, how ear infections can be prevented, and understanding referral pathways.
- Guidelines: evidence summaries for all prevention and treatment strategies, recommendations and their strength, quality and confidence, effect size, overall benefit, "what happens" PICOT statements, and links to GRADEpro summary of findings tables.¹⁰

Implications for policy and practice

Evidence-based guideline implementation and uptake is strongly influenced by features that facilitate their use. Our 2020 OM guidelines have a strong focus on decision making by health care providers. It is anticipated that the OMapp will be used by all stakeholders who are involved with the prevention, diagnosis and management of OM in Aboriginal and Torres Strait Islander children.

- Recommendations for low or high risk criteria can be applied to all Australian children.
- Otoscopy and tympanometry, or pneumatic otoscopy, are recommended for the diagnosis of OM.
- The diagnostic algorithms use a stepwise decision process supported by images, with links to medical and audiological management strategies for low and high risk children.
- The Communicate section provides audio recordings in Aboriginal and Torres Strait Islander languages to assist health care providers to communicate their recommendations.
- An Education section includes video images and a quiz for health care providers, and animation cartoons for families.
- The Guideline section is also a rich source of global evidence for research prioritisation and translation into policy and practice.

For health care providers to implement the OM guideline recommendations, awareness and training programs will be required, as current medical education does not equip professionals with the knowledge and skills to follow these recommendations. Current high turnover of health professional staff in remote areas demands effective and efficient orientation and training to meet the health care needs of the community. For example, the guidelines recommend either otoscopy with tympanometry, or pneumatic otoscopy as the gold standard techniques for OM diagnosis, but this will require capacity building, and/or new equipment in some services. Advances in technology such as optical eardrum scanning and smartphone devices should be evaluated, as they have the potential to increase confidence and, therefore, uptake and investment in state-of-the-art technologies and training.

Families can benefit from the culturally appropriate resources within the OMapp, such as the Communicate and Education sections. Awareness of these resources will need to be promoted.

The 2010 guidelines referred to children as high risk if they lived in populations with a CSOM prevalence greater than 4%. Prevalence data are scarce or out of date for jurisdictions outside the Northern Territory. The 2020 guidelines now refer to the low or high risk child or episode (risk of treatment failure), increasing the relevance of the OM guidelines to all Aboriginal and Torres Strait Islander children, including the majority living in metropolitan settings.

Implications for research

The GRADE approach provided a framework for assessing the quality and confidence of evidence available for best practice. The very low to moderate quality of most OM research and the relatively small effect size of most interventions have led to many

weak or consensus recommendations. Ongoing updates will assist identification of areas for high priority research. Much of the evidence for best practice is not followed in under-resourced primary health care. Many thousands of children in the Northern Territory and across Australia are on waiting lists for hearing tests and ENT consultations or surgeries. More research around models of best practice in primary health care, referral pathways and waiting list management is needed. Clinical trial networks should be encouraged to undertake trials to address these gaps and inefficiencies. However, these problems are not just research questions. Gaps in best practice are consequent on workforce and resourcing, which require government action.

Our multidisciplinary team included librarians, statisticians, epidemiologists, scientists, GPs, paediatricians, ENT surgeons, Aboriginal Health Practitioners, specialist medical trainees, audiologists and consumers. Technical expertise in multiple scripts for the OMapp, animations, interpreter services and artistic work have all contributed to the 2020 OM guidelines and OMapp.

Limitations to health care professional confidence in the 2020 OM guidelines include ease of use. Ongoing evidence updates, added features and improvements in OMapp functionality will be needed. Expertise is required in efficient and effective ways of gathering evidence, knowledge of the GRADE system for rating quality of studies, statistical expertise for meta-analyses and

generating summary of findings tables,¹⁰ and content expertise to prioritise research questions and to grade recommendations.

Conclusion

The 2020 OM guidelines and the new OMapp⁴⁶ improve access to the most up-to-date critically appraised evidence on best practice in OM and hearing loss prevention and management for Aboriginal and Torres Strait Islander children across all Australian settings.

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