Queensland Health

Queensland Community Pharmacy Scope of Practice Pilot

Acute Otitis Media – Clinical Practice Guideline

Guideline Overview

Pilot and professional obligations

- Initial patient eligibility and suitability for management within the scope of the pilot
- Patient informed consent
  - Pilot participation
  - Financial
  - Pharmacist communication with other health practitioners
- Professional standards
- Privacy
- Documentation and record keeping
- Interprofessional communication

Refer when

Refer to a medical practitioner if:

- The patient has 'red flag' warning signs
- A clear diagnosis of AOM cannot be made and when the TM cannot be visualised
- The patient is < 2 years of age

Gather information and assess patient's needs

- Patient history
- Ear examination
  - Otoscopy
  - Pneumatic otoscopy
- Complications requiring referral

Management and treatment plan

- Supportive management
- Pharmacotherapy
- Analgesia

Treat (if clinically appropriate) and concurrently refer

- The patient has otic discharge/otorrhea present
- Children presenting with signs and symptoms of a complication, or at a high risk of complications from AOM (table 1)
- The patient's symptoms do not improve and/or worsen after 48 hours of appropriate analgesia and supportive management
- Symptoms are recurrent (3 or more episodes in 6 months or 4 or more episodes in 12 months)
- The patient has persistent otitis media with effusion (glue ear)

Children who are prescribed antibiotic therapy must be concurrently referred to a medical practitioner for review

Confirm management is appropriate

- Contraindications and precautions
- Drug interactions
- Pregnancy and lactation

Communicate agreed treatment plan

- How to use
- Patient resources/ information
- Adverse effects
- General and preventive advice
- Communication with other health practitioners

Clinical review

- Response to treatment
- Adverse effects
- Communication with other health practitioners

‘Red flag’ warning signs at patient presentation that necessitate:

a. Urgent referral to a medical practitioner including emergency care (without concurrent antibiotic therapy):

- Recent trauma to the ear or head (this may be associated with hearing loss or balance issues)
- Severe symptoms or rapidly worsening symptoms including intense pain, headache or facial paralysis/palsy, red, swollen and tender behind the ear (possible acute mastoiditis)
- Tympanic membrane (TM) ‘red flag’ signs:
  - Crust/scab or granulation in attic region (discharge/odour may be present)
  - Severely retracted (sucked in) TM or retraction pocket in attic area of eardrum
  - Dull white mass behind TM
  - Perforation in attic region, near the edge of the TM or medium to large in size (refer to Figure 1).
- Signs or symptoms of sepsis including fever or hypothermia, significant concern from parent/carer, respiratory distress, vomiting, tachycardia, rash, hypotension and/or cold extremities or other significant systemic symptoms including weakness, irritability, difficulty sleeping and/or loss of appetite.

b. Antibiotic therapy may be provided concurrently to medical practitioner referral:

- Otic discharge/otorrhea present
- Children with symptoms that worsen or do not improve after 48 hours of regular analgesia and supportive management
- Symptoms are recurrent (3 or more episodes in 6 months or 4 or more episodes in 12 months)
- The patient has persistent otitis media with effusion (glue ear)
- Children with signs and symptoms of a complication, or at high risk of complications:
  - **all children** who are immunocompromised, have a cochlear implant, craniofacial abnormalities (including cleft palate), developmental delay or Down syndrome, severe visual impairment, current hearing loss
  - **Aboriginal and Torres Strait Islander children** who reside in a remote community, first experience of otitis media at <6 months, family history of chronic suppurative otitis media (CSOM), current (or history of) perforation [1].

Key points

- Acute otitis media (AOM) is predominantly a childhood infection, however, it may also occur in adults [2]. The peak age prevalence is 6-18 months [3].
- AOM is commonly viral but may also be bacterial, or a combination of both [4].
- In the majority of paediatric cases, AOM is self-limiting and spontaneously resolves without the requirement for antibiotics [3, 4]. The mainstay of treatment for AOM is conservative management with regular and adequate analgesia and aural hygiene. Antibiotics can be safely withheld in most cases and are often inappropriately prescribed [4].
- Pain alone is not sufficient to diagnose AOM; pneumatic otoscopy is required to diagnose and exclude other ear conditions with similar presentations[4].
- Ear conditions are often very painful, particularly for young children, and it is important to approach with care [1]. If the patient will not allow for otoscopic examination due to pain, advice should be provided on appropriate analgesia and the patient referred to a medical practitioner.

When applying the information contained within this clinical practice guideline, pharmacists are advised to exercise professional discretion and judgement. The clinical practice guideline does not override the responsibility of the pharmacist to make decisions appropriate to the circumstances of the individual, in consultation with the patient and/or their carer.

Refer when

- The patient has 'red flag' warning signs
- A clear diagnosis of AOM cannot be made and when the TM cannot be visualised
- The patient is < 2 years of age

Treat (if clinically appropriate) and concurrently refer:

- The patient has otic discharge/otorrhea present
- Children presenting with signs and symptoms of a complication, or at a high risk of complications from AOM (refer to Table 1)
- The patient's symptoms do not improve and/or worsen after 48 hours of appropriate analgesia and supportive management
- Symptoms are recurrent (3 or more episodes in 6 months or 4 or more episodes in 12 months)
- The patient has persistent otitis media with effusion (glue ear).

Children who are prescribed antibiotic therapy must be concurrently referred to a medical practitioner for review.

Gather information and assess patient's needs

In both children and adults, the diagnosis of AOM is based on clinical history and ear examination using a pneumatic otoscope [1, 2, 4, 5].

- Children with AOM may present with ear pain and signs of systemic illness including fever, vomiting, diarrhoea, irritability, poor feeding and ear discharge within the preceding 6 weeks [1]. Tugging, holding or rubbing the ear may indicate ear pain in younger children [4].
- In children, a diagnosis of AOM requires the rapid onset (within 48 hours) of:
    - pain
    - signs of acute inflammation of the TM:
        - TM is bulging and opaque
        - TM may be red from inflammation or white from pus in the middle ear
    - signs of middle ear effusion
        - otorrhoea can be indicative of TM perforation and middle ear effusion if AOE has been excluded [1, 3, 4, 6]
        - otitis media with effusion is characterised by middle ear effusion without other signs and symptoms of AOM, where this is present longer than 3 months is suggestive of persistent otitis media with effusion (glue ear) [4]
        - otorrhea that has been present for $\geq$ 2 weeks and a perforation is suggestive of chronic suppurative otitis media (CSOM) [1].
- **A red TM or pain alone is not diagnostic of AOM** [4].
- In adults, unilateral symptoms are most common and include mild to severe ear pain and decreased hearing.
    - An upper respiratory tract infection (URTI) or allergic rhinitis will often precede the onset of AOM [2].
    - Other symptoms in adults include dizziness/vertigo (infrequent), systemic symptoms (particularly fever), partial or complete opacification of the TM, or erythema [2].
- In adults, the key signs of AOM are bulging and reduced mobility of the TM [2].

Patient history

Sufficient information should be obtained from the patient to assess the safety and appropriateness of any recommendations and medicines.

The patient history should consider:

- age
- whether the patient identifies as Aboriginal and Torres Strait Islander
- nature, severity and frequency of symptoms including pain, itch, discharge, hearing loss, a feeling of fullness and dizziness/vertigo
- onset and duration of symptoms including preceding illnesses

- recent history of URTI
- other presenting symptoms including temperature > 38°C or < 35.5°C, rash, increased respiratory rate/distress, dehydration and/or reduced urine output, runny nose, sore throat or cough
- family history of ear conditions and hearing loss
- previous history of AOE, OM or other ear conditions:
    - hearing loss and recent hearing tests
    - patient age at first episode of ear conditions
    - under the care of an ENT specialist or audiologist
    - ear surgery, current or previous tympanostomy tubes (grommets)
- precipitating and relieving factors
- underlying medical conditions, e.g., immunocompromised (including diabetes), cochlear implant, craniofacial abnormalities, persistent hearing loss, that mean the patient is at high risk of experiencing AOM complications (refer to Table 1)
- delayed speech or language development (referral is required if this is evident and has not been assessed by a medical practitioner)
- social history including arrangements to support management at home, ability to access further care and to undertake appropriate self-care
- current medications (including prescribed medicines, vitamins, herbs, other supplements and over-the-counter medicines)
- frequency and method of ear cleaning
- medication and other strategies tried to treat current symptoms
- drug allergies/adverse drug effects
- immunisation status as per the Australian Immunisation Handbook.

Assessment

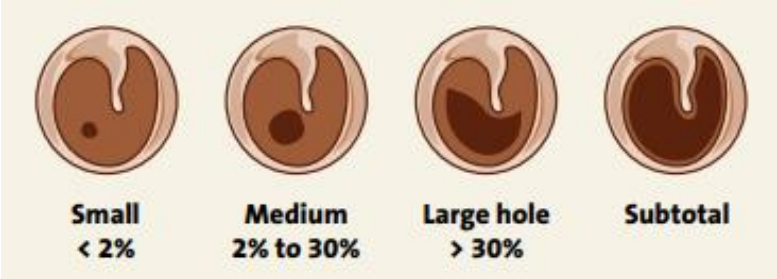
- Conduct assessment of vital signs
- Examine for tender or enlarged cervical lymph nodes
- Conduct visual examination and palpation of mastoid area.

Ear examination using otoscopy

- Physical examination including otoscopy of both ears is required to differentiate between AOE, AOM and other ear conditions [2, 4, 5].
- Ear examination should be conducted in accordance with the Queensland Health and Royal Flying Doctors Primary Clinical Care Manual (p519-521). An ear differential diagnosis flowchart is also included on p521-522 [1].
- Before performing the ear examination, the ear canal must be gently cleaned to remove any discharge with a tissue rolled up to a point (dry mopping) to visualise ear drum [1, 7]. The Remote Primary Health Care Manual – Clinical Procedure Manual (p258) [7] and the Queensland Health and Royal Flying Doctors Primary Clinical Care Manual (p530) contain a step by step guide for dry mopping [1].

- The TM must be visualised to confirm a diagnosis of AOM, although this can be difficult in the presence of extensive otorrhoea [4].
    - If the TM cannot be visualised in paediatric patients when they first present and antibiotics are not indicated, they should be advised on appropriate analgesia and either asked to return within 48 to 72 hours for reassessment, or to seek medical practitioner care if their condition deteriorates [4].
    - If the TM cannot be visualised in adult patients, they should be referred to a medical practitioner.
    - Perforation of the TM in children is not uncommon and may result in ear discharge and relief of pain [1].
        - In AOM with perforation, the pharmacist should document the size and position of the perforation to allow ongoing assessment of progression of the condition and to guide use of therapies [8].
        - All medium to large perforations and perforations in the attic region of the TM (refer to Figure 1) must be referred to a medical practitioner.
- If pain levels allow, pneumatic otoscopy may be conducted to check for TM movement:
    - If the TM moves freely back and forward, perforation and fluid in the middle ear (AOM) can generally be excluded.
    - Reduced mobility of an intact TM is a good indication of the presence of middle ear fluid [8].
- Check for other symptoms if required (nose, throat, cough) [1].

Figure 1. Guide for size of perforation of tympanic membrane [8]



- TM “red flag” signs that may suggest a serious complication and require immediate referral to a medical practitioner include:
    - severe retraction of the TM
    - perforation or retraction in the attic region or near the edge of the TM
    - crust, granulation or discharge in the attic region
    - a dull white mass behind TM or chalky patches [1].

Complications of AOM

Aboriginal and Torres Strait Islander children are generally at higher risk of complications arising from AOM. Complications in adults and non-First Nations children are less common [1, 6].

Children at high risk of complications are outlined in Table 1.

Table 1. Children at high risk of complications from AOM [1]

Table 1. Children at high risk of complications from AOM [1]	
Aboriginal and Torres Strait Islander children if: • residing in a remote community • < 2 years old • first episode of OM experience < 6 months of age • family history of CSOM • history (or current) perforation	**All children if:** • immunocompromised • cochlear implant • craniofacial abnormalities including cleft palate • developmental delay, delayed speech, Down syndrome • severe visual impairment • current hearing loss

All children at high risk of complications must be referred to a medical practitioner for management. Antibiotic therapy may be provided concurrently to medical practitioner referral where clinically appropriate.

In rare cases, AOM infection may spread from the middle ear (intracranial spread) causing mastoiditis, petrositis or labyrinthitis [6].

Intracranial spread can cause meningitis or other intracranial complications that are slow to resolve, particularly in immunocompromised patients.

- Signs of intracranial complications include severe headache, confusion, focal neurologic signs, facial paralysis/palsy and dizziness/vertigo [6].

Management and treatment plan

Pharmacist management of patients with AOM involves[1]:

- **supportive management:**
  - Aural hygiene and care at home in accordance with The Royal Children's Hospital Melbourne Fact sheet: Ear infections and glue ear and the Australian Medicines Handbook: drugs for ear infections [9, 10].
  - If discharge is present, advice and education regarding keeping ears dry and the use of dry mopping with tissue spears. The Queensland Health and Royal Flying Doctors Primary Clinical Care Manual (p530) contain a step by step guide for dry mopping [1].

- **pharmacotherapy:**
  - Analgesia in accordance with the Therapeutic Guidelines: Pharmacological management of acute pain.
  - Oral antibiotic therapy[3] in accordance with the Therapeutic Guidelines: Otitis media [4, 8, 10].
- Consider immunisation where the patient has not received all routine vaccines in accordance with the Australian Immunisation Handbook.

NB1: There is limited evidence to guide the management of AOM in adult patients. The Therapeutic Guidelines state that management of AOM is similar to children; adequate and regular analgesia is the primary treatment [4]. As with paediatric patients, a shared decision-making approach is required to manage patient expectations of antibiotic treatment [4].

NB2: Paracetamol, Ibuprofen and Naproxen (in preparations containing 250mg or less) can be sold as Schedule 2 medicines.

NB3: Antibiotic therapy in paediatric patients should only be commenced in accordance with the Therapeutic Guidelines and the Otitis Media Guidelines for Aboriginal and Torres Strait Islander People for children with discharge/otorrhoea (from a small perforation), children with symptoms that have not improved or worsened after 48 hours and Aboriginal and Torres Strait Islander children [1, 4, 8]. Children who are prescribed antibiotic therapy must be concurrently referred to a medical practitioner for review.

Confirm management is appropriate

Pharmacists must consult the Therapeutic Guidelines, Australian Medicines Handbook and other relevant references including the Otitis Media Guidelines for Aboriginal and Torres Strait Islander People (if applicable) to confirm that the treatment recommendation is appropriate, including for:

- contraindications and precautions
- drug interactions
- pregnancy and lactation.

Communicate agreed management plan

Comprehensive advice and counselling (including supporting written information when required) as per the Australian Medicines Handbook and other relevant references should be provided to the patient regarding:

- individual product and medicine use (e.g., dosing)
- how to manage adverse effects
- when to seek further care and/or treatment (including recognising patient deterioration)
- when to return to the pharmacist for clinical review.

It is the pharmacist's responsibility to ensure the suitability and accuracy of any resources and information provided to patients (and parents/caregivers if applicable) and to ensure compliance with all copyright conditions.

The agreed management plan should be shared with members of the patient's multidisciplinary healthcare team, with the patient's consent.

Patient resources/ information

- The Royal Children's Hospital Melbourne Fact sheet: Ear infections and glue ear [9].

General advice

AOM symptoms should start to improve within 48 to 72 hours after onset, regardless of whether antibiotic treatment is required, but full resolution of symptoms may take 8 days or longer for effusion [4].

- Middle ear effusion that persists for several weeks after AOM is common and is not a sign of treatment failure [10]
- An acute perforation and discharge should resolve within 10-14 days [1].

Patients commenced on antibiotics who have been concurrently referred to a medical practitioner should be advised (or their parents/caregivers if applicable) to seek further urgent care where:

- the response has been inadequate after 48-72 hours of commencing antibiotic treatment
- the patient's condition deteriorates, including if they develop systemic signs and symptoms or if their symptoms worsen
- otorrhea continues for ≥ 2 weeks [4].

For all patients, it is important to avoid local trauma to ear canal, including not using cotton ear buds and dry mopping with a tissue spear instead [1]. The Remote Primary Health Care Manual – Clinical Procedure Manual (p258) [7] and the Queensland Health and Royal Flying Doctors Primary Clinical Care Manual (p530) contain a step by step guide for dry mopping [1].

Pharmacists should also provide advice on the importance of preventing ear infections in children to avoid associated hearing loss, poor language and social skills [8]. Preventative advice that can be provided by pharmacists includes:

- ensuring vaccinations against *S. pneumoniae*, *H. influenzae* type B, and influenza are up to date
- minimising exposure to smoke e.g., cigarettes and woodfires
- encourage personal hygiene e.g., frequent hand and face washing and drying, nose blowing techniques [4, 8, 10, 11].

Decongestants, antihistamines and corticosteroids are not effective and should not be recommended for adult or paediatric patients [3, 10].

Antibiotics have limited benefits for most paediatric patients and are not indicated for most children presenting with mild infection [4].

- The use of antibiotics in paediatric patients almost doubles the incidence of diarrhoea, vomiting and rash [10]
- Pharmacists should address misconceptions regarding antibiotic effectiveness and discuss the relative harms and benefits of treatment [3].

Clinical review

Clinical review should occur in line with recommendations in the Therapeutic Guidelines, the Queensland Health and Royal Flying Doctors Primary Clinical Care Manual, and other relevant guidelines.

- Patients with an intact TM are recommended to be reviewed at 3 months to check for persistent fluid behind the TM; if fluid is still present or the patient experiences a recurrence of AOM during this time, they must be referred to a medical practitioner [1].
- Patients with small acute perforations are recommended to be reviewed between **4-6 weeks** to assess healing. If the perforation is still evident, the patient must be referred to a medical practitioner [1].

The decision regarding the timing and necessity of a clinical review should be determined on an individual basis, considering the patient's (or parents/caregivers) ability and available support to manage the condition effectively. The pharmacist should discuss the importance of clinical review with the patient and/or their caregiver, including the timing of review, and where review by a medical practitioner is indicated.

For children under the age of 5, the improvement of the condition and the presence of complications (e.g., parent/carer concerns related to the child's speech and language) should be closely monitored [12].

For patients who have already been referred to a medical practitioner following initial assessment and/or management by the pharmacist, further clinical review by the pharmacist is generally not required.

Pharmacist resources

- Therapeutic Guidelines: Antibiotic
  - Otitis media
- Therapeutic Guidelines: Pain and analgesia
  - Pharmacological management of acute pain
- Australian Medicines Handbook
  - Otitis Media
  - Drug for ear infections
  - NSAIDs
- Australian Immunisation Handbook:
  - Pneumococcal disease
  - Influenza (flu)
  - Haemophilus influenzae type b (Hib)
- MSD Manual (Professional version) - Otitis media
- Remote Primary Health Care Manual:
  - Clinical Procedure Manual
  - CARPA Standard Treatment Manual
- Three minute tool kit (UK) - Spotting the Sick Child
- Queensland Health and Royal Flying Doctors Service (Queensland branch) Primary Clinical Care Manual 11th edition 2022
- The Royal Children's Hospital - Clinical Practice Guidelines – acute otitis media
- 2020 Otitis Media Guidelines for Aboriginal and Torres Strait Islander Children
- McGovern Medical School - Ear disease photo book

References

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