Clinical Practice Guideline on the Diagnosis and Management of Acute Otitis Media

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Introduction

Acute otitis media is a common paediatric condition encountered by general paediatricians in private practice. This is also the most common infection for which antibiotics are prescribed for children.

The clinical management of acute otitis media is one of the topics proposed by the working group for the development of clinical management guidelines as it satisfied the selection criteria for guideline development by the College which includes: (1) Common conditions especially in the ambulatory settings; (2) Performance gap between the evidence based/best practice and the current practice; (3) Availability of good quality/high level of evidence for a evidence-based guideline.

For this guideline, the working group would like to try a new approach towards introducing clinical guidelines to local paediatricians. Instead of developing the guideline by going through a labour intensive and vigorous process of literature review by our local guideline development panel, which was the method adopted in the development of clinical management guideline on febrile convulsion, acute gastroenteritis and

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acute bronchiolitis, we would like to bring the College members and fellow's attention to two recently published clinical guidelines on otitis media. One is from the Scottish Intercollegiate Guideline Network (SIGN)¹ and the other from the American Academy of Pediatrics (AAP) and the American Academy of Family physicians.² Both guidelines are developed based on critical review of the current best evidence, but in the context of different health care systems.

The following review is a summary of the key recommendations from the two guidelines. Similarities and differences between these guidelines are highlighted. Two local experts, Dr. YC Tsao, a senior paediatrician and Dr. Hui Yau, an ENT surgeon, were invited to write commentaries on these 2 clinical guidelines with particular emphasis on the relevance of the recommendations to the local settings based on the local epidemiology and their perspective as a paediatrician and an otolaryngologist.

Readers are strongly encouraged to refer to the full version of the original guidelines for more detailed discussion on the evidence. It is noteworthy to point out that the grading systems of the 2 guidelines are different, which makes the direct comparisons of the strength of evidence difficult.

American Academy of Pediatrics & American Academy of Family Physicians. Clinical Practice Guideline: Diagnosis and Management of Acute Otitis Media (Pediatrics; May 2004; 113,5; Health module p. 1451)²

This evidence-based clinical practice guideline provides recommendation to primary care paediatricians for the management of children from 2 months through 12 years of age with uncomplicated acute otitis media (AOM).

The guideline aims to provide a framework for clinical decision-making, but is not intended to replace clinical judgement or establish a protocol for all children with this condition, and may not provide the only appropriate approach to the management of this problem.

The Guideline includes:-

- Definition of AOM
- Addresses pain management
- Initial observation versus antibacterial treatment
- Appropriate choices of antibacterial agents
- Preventive measures

Key Recommendations

Recommendation 1 - Diagnosis

A diagnosis of AOM requires:

- Recent, usually abrupt, onset of signs and symptoms of middle-ear inflammation and middle-ear effusion
- The presence of middle ear effusion, which is indicated by any of the following:
 - Bulging of the tympanic membrane
 - Limited or absent mobility of the tympanic membrane
 - Air-fluid level behind the tympanic membrane
 - Otorrhea
- Signs and symptoms of middle-ear inflammation as indicated by either
 - Distinct erythema of the tympanic membrane or
 - Distinct otalgia (discomfort clearly referable to the ear(s) that result in interference with or precludes normal activity or sleep

Recommendation 2 - Pain Management

- The management of AOM should include an assessment of pain. If pain is present, the clinician should recommend treatment to reduce pain
- Acetaminophen and ibuprofen (mainstay and effective); others include home remedies, topical agents, narcotic analgesia, and tympanostomy are of, limited effectiveness or entail potential risks

Recommendation 3A - Antibiotic Treatment

 Observation without use of antibacterial agents in a child with uncomplicated AOM is an option for selected children based on diagnostic certainty, age, illness severity, and assurance of follow-up.

Criteria for Initial Antibacterial-Agent Treatment or Observation in Children with AOM

Age	Certain diagnosis	Uncertain diagnosis
<6 mo	Antibacterial therapy	Antibacterial therapy
6 mo to 2 y	Antibacterial therapy	Antibacterial therapy if severe illness; observation option if nonsevere illness
≥2 y	Antibacterial therapy if severe illness; observation option if nonsevere illness	

Recommendation 3B

- If a decision is made to treat with an antibacterial agent, the clinician should prescribe amoxicillin for most children.
- When amoxicillin is used, the dose should be 80 to 90 mg/kg per day.
- The optimal duration of treatment is uncertain. Based on several more recent studies, the results favour standard 10 days therapy for children less than 2 years and for those with severe disease. For children 6 years of age and older with mild to moderate, a 5- to 7-day course is appropriate.

Recommendation 4

- If the patient fails to respond to the initial management option within 48 to 72 hours, the clinician must reassess the patient to confirm AOM and exclude other causes of illness.
- If AOM is confirmed in the patient initially managed with observation, the clinician should begin antibacterial therapy.
- If the patient was initially managed with an antibacterial agent, the clinician should change the antibacterial agent.

Recommended Antibacterial Agents for Patients Who Are Being Treated Initially with Antibacterial Agents or Have Failed 48 to 72 Hours of Observation

Temperature ≥ 39°C and/or severe otalgia	At diagnosis for patients being treated initially with antibacterial agents of failed observation		
	Recommended	Alternative for penicillin allergy	
No	Amoxicillin, 80-90 mg/kg per day	Non-type I: cefdinir, cefuroxime, cefpodoxime, type I: azithromycin, clarithromycin	
Yes	Amoxicillin- clavulanate, 90 mg/kg per day of amoxicillin, with 6.4 mg/kg per day of clavulanate	Ceftriaxone, 1 or 3 days	

Recommended Antibacterial Agents for Patients who Have Failed 48 to 72 hours of Initial Management with Antibacterial Agents

Temperature ≥ 39°C and/or severe otalgia	Clinically defined treatment failure at 48-72 hours after initial management with antibacterial agents		
	Recommended	Alternative for penicillin allergy	
No	Amoxicillin- clavulanate, 90 mg/kg per day of amoxicillin component, with 6.4 mg/kg per day of clavulanate	Non-type I: ceftriaxone, 3 days; type I: clindamycin	
Yes	Ceftriaxone, 3 days	Tympanocentesis, clindamycin	

Recommendation 5 - Prevention of Recurrence

Clinicians should encourage the prevention of AOM through reduction of risk factors

- Factors not amenable to change are genetic predisposition, premature birth, male gender, Native American, family history of recurrent otitis media, presence of siblings in the household, and low socioeconomic status
- Factors amenable for change include
 - Altering child care center attendance patterns
 - Breastfeeding for at least the first 6 months
 - Avoiding supine bottle feeding
 - Reducing or eliminating pacifier use in the second
 6 months of life
 - Eliminating exposure to passive tobacco smoke
- Immunoprophylaxis with killed and live-attenuated intranasal influenza vaccines has demonstrated more than 30% efficacy in prevention of AOM during the respiratory illness season

Recommendation 6

 No recommendation for complementary and alternative medicine (CAM) for treatment of AOM are made based on limited and controversial data

Scottish Intercollegiate Guidelines Network February 2003. Diagnosis and Management of Childhood Otitis Media in Primary Care – A National Clinical Guideline (SIGN 66)¹

Definitions of Acute Otitis Media (AOM)

- Inflammation of the middle ear of rapid onset presenting most often with local symptoms (the two most common being earache and rubbing or tugging of the affected ear) and systemic signs (fever, irritability and poor sleep for example)
- There may be a preceding history of upper respiratory symptoms including cough and rhinorrhea

Definitions of Otitis Media with Effusion (OME)

- Inflammation of the middle ear, accompanied by the accumulation of fluid in the middle ear cleft without the symptoms and signs of acute inflammation
- OME is often asymptomatic, and earache is relatively uncommon

Diagnostic Features of AOM and OME

	AOM	OME
Earache fever irritability	Present	Usually absent
Middle ear effusion	Present	Present
Opaque drum	Present	May be absent
Bulging drum	May be present	Ususally absent
Impaired drum mobility	Present	Present
Hearing loss	Present	Usually present

Treatment for AOM

• Antibiotics for AOM

- Children diagnosed with acute otitis media should not routinely be prescribed antibiotics as the initial treatment [Grade B Recommendation]
- If an antibiotic is to be prescribed, the conventional five day course is recommended at dosage levels indicated in the British National Formulary [Grade B Recommendation]

• Decongestants, antihistamines and mucolytics

- Children with AOM should not be prescribed decongestants or antihistamines [Grade A Recommendation]

• Analgesics

 Parents should give paracetamol for analgesia but should be advised of the potential danger of overuse [Grade D Recommendation]

• Oils

 Insertion of oils should not be prescribed for reducing pain in children with AOM [Grade B Recommendation]

• Homeopathy

 There is insufficient evidence available to recommend homeopathy in the management of AOM (or OME)

Referral for AOM Patients

• Children with frequent episodes (more than four in six months) of AOM, or complications, should be referred to an otolaryngologist [Grade D Recommendation]

Treatment for OME

• Antibiotics for OME

- Children with otitis media with effusion should not be treated with antibiotics [Grade D Recommendation]

• Decongestants, antihistamines and mucolytics

- Decongestants, antihistamines or mucolytics should not be used in the management of OME [Grade B Recommendation]

• Steroids

- The use of either topical or systemic steroid therapy is not recommended in the management of children with OME [Grade B Recommendation]

• Autoinflation

- Autoinflation may be of benefit in the management of some children with OME [Grade D Recommendation]

Referral for OME Patients

- Children under three years with persistent bilateral otitis media with effusion and hearing loss of ≤25dB, but no speech and language, development or behavioural problems, can be safely managed with watchful waiting.
 - If watchful waiting is being considered, the child should undergo audiometry to exclude a more serious degree of hearing loss. [Grade A Recommendation]
- Children with persistent bilateral otitis media with effusion who are over three years of age or who have speech and language, developmental or behavioural problems should be referred to an otolaryngologist. [Grade B Recommendation]

Patient Issues

- Information for parents, teachers and carers
 - Parents of children with otitis media with effusion should be advised to refrain from smoking. [Grade B Recommendation]
 - Parents should be advised that breastfeeding may reduce the risk of their child developing otitis media with effusion. [Grade C Recommendation]
 - Grommet insertion is not a contraindication to swimming. [Grade C Recommendation]

Comparison of Two Otitis Media Guidelines – Similarities and Differences³

There is strong agreement between the 2 guidelines on:

- Diagnostic features of AOM, with the SIGN guideline highlighting the importance of distinguishing AOM from OME, with different clinical features and management emphasis
- The recommended option of delayed antibiotic treatment
- The antibiotics to be used
- The use of analgesic
- Some of the risk factors

There are differences in the recommended duration of antibiotic treatment and the approach on initial management option.

American Academy of Pediatrics

- For younger children and for children with severe disease, a standard 10 day course is recommended
- For children 6 years of age or older with mild to moderate disease, a 5-7 day course is appropriate
- If the patient fails to respond to the initial management option within 48-72 hours, the clinician must reassess the patient to confirm acute otitis media and exclude other causes, and start antibiotic treatment for confirmed acute OM

Scottish Intercollegiate Guideline Network

- The optimum duration of treatment for infants and very young children, and for children with severe acute otitis media, has yet to be established
- If an antibiotic is to be prescribed, the conventional five day course is recommended
- Antibiotic to be collected at parents' discretion after
 72 hours if the child has not improved is an alternative approach which can be applied in general practice

The SIGN guideline put more emphasis to alert clinicians to watch out for hearing impairment in children with recurrent otitis media or otitis media with effusion.

Commentaries from Local Experts Paediatrician in Private Practice – Dr. YC Tsao

The Guidelines

Otitis media is a common childhood condition. Both the Scottish Intercollegiate Guideline Network (SIGN) in February, 2003 and the American Academy of Pediatrics and the American Academy of Family Physicians (AAP & AAFP) in May, 2004 have published guidelines on the diagnosis and management of acute otitis media for primary care clinicians.

Both of these guidelines were based on evidence gathered from published data. There is a strong agreement in all the conclusions reached but they differ in the tone of the recommendations.

Before we accept these guidelines for our practice, there are several limiting factors we must recognise. Firstly, they only refer to uncomplicated cases of otitis media. They exclude patients with anatomical abnormalities such as cleft palate, genetic conditions such as Down syndrome, immunodeficiencies and the presence of cochlear implants. Also excluded are children with clinical recurrences of acute otitis media within 30 days or acute otitis media with underlying chronic otitis media with effusion.

The SIGN guideline distinguishes acute otitis media and otitis media with effusion because of different management strategies although recognising that acute otitis media may leave a middle ear effusion for a variable period of time following resolution of acute symptoms and that the two forms of otitis media should be considered part of a disease continuum.

Both guidelines agree that pain is probably the most significant symptom of acute otitis media and that it can be relieved with paracetamol or ibuprofen.

On the diagnosis of acute otitis media, both agree that the sensitivity may be increased by using pneumatic otoscopic examination especially for detecting fluid in the middle ear. The external auditory canal should be cleared of cerumen and a well illuminated otoscope should be used. Examination can be supplemented by tympanometry and acoustic reflectometry. The presence of fluid can also be demonstrated by tympanocentesis or the presence of fluid in the external auditory canal as a result of perforation.

SIGN guideline recognised that most primary care clinicians will use only direct otoscopy.

Both guidelines mention that a certain number of patients probably do not need antibiotic treatment and can be watched for 48-72 hours.

The AAP and AAFP recommend the "observation option" only for children over 2 years of age, or those between 6 months to 2 years if the diagnosis is uncertain and the illness not severe. For those given the "observation option", it is important for the parent / care giver to be able to communicate with the clinician readily.

SIGN guideline recommends delayed antibiotic treatment for children 6 months to 10 years. The antibiotic is to be collected at the parent's discretion after 72 hours if the condition of the child has not improved. Only 24% of the parents used the antibiotic.

The use of antibiotic at the initial visit only serves to shorten the symptoms by only 1 day in 5-14% of children. This should be compared with the avoidance of common side effects in 5-10% of children, infrequent serious side effects and the emergence of antibiotic resistance.

Both guidelines recommend using amoxicillin or amoxicillin with clavulanic acid as the common pathogens involved are Strept. pneumoniae, H. influenzae and M. catarrhalis.

SIGN guideline recommends the standard five day course for uncomplicated ear infection in children. The AAP & AAFP guideline recommends 10 day course for young children and children with severe disease and 5-7 day course for children 6 years of age or older.

Decongestants, antihistaminics and mucolytic agents have not been shown to be useful in the treatment of otitis media, neither are topical or systemic steroid therapy.

Children with frequent episodes of acute otitis media (>3 in 6 months or >4 in 12 months), long standing effusion (children >3 years of age), chronic perforation and complications like mastoiditis or facial nerve paresis should be referred to the otolaryngologist.

Children who have otitis media with effusion should be followed up at 2-3 months intervals. Some may resolve by themselves. No difference has been shown in terms of language development, speech, sound production cognition and behaviour between early and delayed grommet insertion. There is some benefit from ventilation tube insertion for expressive language and verbal comprehension, but the timing of surgery is not critical.

How to Translate These Guidelines Into Our Local Practice?

Acute otitis media is diagnosed by the acute onset of earache, irritability and tugging of the ear, signs of inflammation of the eardrum (change in color, opacification) and fluid in the middle ear (bulging eardrum or perforation of the tympanic membrane discharging pus). Although mobility of the tympanic membrane can be better assessed by pneumatic otoscopy, most of our local primary care clinicians do not use such method of examination.

When the acute otitis media is not severe and uncomplicated, there is a case for withholding antibiotic for 48-72 hours, giving only paracetamol or ibuprofen for pain relief and to reduce the fever.

For children less than 6 months of age or for older children with severe illness, antibiotic treatment should be started immediately.

There is no evidence to show that the use of antihistamines, nasal decongestants or mucolytic agents affect the outcome of acute otitis media. They should only be used for other indications.

Children with frequent episodes of acute otitis media (>3 in 6 months or > 4 in 12 months), chronic perforation or those who develop complications like mastoiditis and facial paresis should be referred to the otolaryngolist.

Otitis media with effusion may persist after an attack or repeated attacks of acute otitis media, or it may be asymptomatic and discovered incidentally. Antibiotic treatment has not been shown to be of benefit. Children under 3 with mild to moderate hearing loss (≤25 dB) may be watched. Those over 3 with speech and language developmental delay should be referred.

Perspectives from a Paediatric Otolaryngologist – Dr. Hui Yau

Whereas acute otitis media (AOM) and its related pathologies such as otitis media with effusion (OME) are extremely common conditions in children, it is

important to realise that the pattern of disease has changed in Hong Kong and other developed countries over the last century.

In the early years of the 20th century and before antibiotics are generally available, AOM usually present clinically as a challenge in *sepsis management*. Left untreated, the infection took one of several routes. It may perforate the ear drum and drain itself. It may present as mastoiditis, and as the bone is thin in children, the pus in the mastoid may track towards the skin forming a subperiosteal abscess, or towards the temporal lobe resulting in an intracranial abscess. Therefore, surgery was often necessary to treat AOM in its advanced form and are usually performed as emergencies. The role of surgery was then prominent. Often the parents were satisfied when the life of the child was saved. The middle ear was sometimes left in a chronic discharging state.

With the improvement in socioeconomic condition, easy access to medical care and the availability of effective antibiotics, nowadays most AOM are readily quenched at an early stage. Life threatening sepsis that requires emergency surgery is uncommon. On the other hand, OME becomes more prevalent as a sequelae of AOM. OME altered the sound conduction mechanism by hindering vibration of the tympanic membrane and the ear ossicles, resulting in conductive hearing loss. The current challenge in the management of otitis media is the management of hearing loss and its associated problems. Audiology therefore plays an important role, not only in the diagnosis of the condition, but to accurately assess the magnitude of hearing loss so that treatment can be planned. Parents are no longer concerned about the risk to life, they complain about learning difficulties and learning / behavioural problems.

Comments on the Guideline

Diagnosis

 It cannot be overstated that a well illuminated otoscope is essential. An under-powered otoscope will make the tympanic membrane look dull which resembles the appearance of OME. It is also important to remember that crying alone may result in a transient hyperemic tympanic membrane that mimics AOM.

- Pneumo-otoscopy is easy to learn and perform, and gives useful clinical clue to the status of the middle ear.
- Audiology tests (pure tone audiometry and tympanometry) are useful adjuncts to diagnosis but they should not be interpreted on their own, especially if the tests are not performed by an audiologist in the proper setting.

Assessment of the Patient

- After a diagnosis of AOM or OME is made, it is important to assess the hearing and its impact on speech development. Pure tone audiometry is the recommended test. If audiology facilities are not available, a thorough history taking usually gives useful information.
- It is also important to realise that serous otitis media affects hearing to a different extent in different patients. An entirely fluid filled middle ear may result in an air bone gap of about 30 dB, or the hearing may be close to normal.
- If the air bone gap is greater than 30 dB, additional pathology may be present.

Treatment

- A wait-and-see policy is mentioned in both guidelines, generally recommended for the older child and when the symptoms are not severe. Critical to the safe adoption of this policy is close monitoring by an experienced clinician.
- In addition, if a wait-and-see policy is adopted, and hearing loss is significant, remember to send a note to the school teacher for preferential seating in class. Other means of facilitating communication are listed in the SIGN guideline (6.1). These advice are very useful.

Conclusion

My own objective in the management of AOM / OME is, through proper selection of treatment modality, to provide the child with educationally sufficient hearing for learning and speech development, and to prevent any long term otologic complication that the child may have to live with for the rest of his life. Nowadays in Hong Kong, this objective is easy to achieve in most

paediatric patients, but in some, a collective effort by family physicians, paediatricians, paediatric otolaryngologists and audiologists is necessary.

Treatment should not be entirely focused on infection and its eradication. Hearing loss and its related problems are important components of the illness and adequate emphasise should be put on the latter aspects of the disease.

Whereas the guidelines are useful, informative and evidence-based, treatment must be individualised as stated in its introduction (SIGN 1.3). Factors like the frequency of recurrences, severity of hearing loss, impact on speech development, behavioral issues, severity of tympanic membrane retraction, etc., are all factors that we have to consider. More aggressive therapy like grommet insertion should be considered when these unfavourable factors are present or persistent.

Normal hearing and speech ability add enormously to the competitive edge of any individual.

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References

- Diagnosis and management of childhood otitis media in primary care. Scottish Intercollegiate Guidelines Network. 2003 Feb.
- American Academy of Pediatrics and American Academy of Family Physicians. Diagnosis and Management of Acute Otitis Media. Pediatrics 2004;113:1451-65.
- J Harry Baumer. Comparison of two otitis media guidelines. Arch Dis Child Educ Pract Ed 2004;89:ep76-ep78.

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