Otology

Acute otitis media in children (NECPG)

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Abbreviations

AAP	*American academy of pediatricians*
AAFP	*American academy of family practitioners*
AOM	*Acute otitis media*
CPG	*Clinical Practice Guideline*
GRADE	*Grading of Recommendations Assessment, Development and evaluation*
MEE	*Middle ear effusion*
MRI	*Magnetic Resonance Imaging*
OME	*Otitis media with effusion*
RCT	*Randomized controlled trial*
TM	*Tympanic membrane*

Executive Summary

*The **scope** of the guideline is the diagnosis and management of AOM and recurrent AOM in children 6 months and older without any other underlying conditions.*

The diagnosis of AOM should be made in children who present with moderate to severe bulging of the TM or new onset of otorrhoea not due to acute otitis externa or mild bulging of the TM and recent (less than 48 hours) onset of ear pain or intense erythema of the TM (Strong recommendation)

AOM management should include pain evaluation and management. (Strong recommendation)

Antibiotics should be prescribed for bilateral or unilateral AOM in children aged at least 6 months with severe signs or symptoms and for non-severe bilateral AOM in children (6-23 months). (Strong recommendation)

Unilateral non-severe AOM in children (6-23 months) and non-severe (unilateral or bilateral) AOM in children over 24 months may be managed either with antibiotics or with close follow up and withholding antibiotics unless the child worsens or does not improve within 48-72 hours of symptom onset. (Conditional recommendation)

Amoxicillin-clavulanic acid is the antibiotic of choice. (Conditional recommendation)

Clinicians should re-evaluate a child whose symptoms have worsened or not responded to the initial antibiotic treatment within 48-72 hours and change treatment if indicated. (Conditional recommendation)

Antibiotics have no preventive role in AOM. (Conditional recommendation)

Tympanostomy tubes could be offered for recurrent attacks of AOM. (Conditional recommendation)

Adenoidectomy offers little benefit in case of recurrent AOM. (Conditional recommendation)

Pneumococcal and annual Influenza vaccines are recommended to prevent AOM. (Strong recommendation)

Introduction, purpose, scope and audience

Introduction and definitions

Acute otitis media (AOM) is defined as the presence of inflammation in the middle ear cleft with an effusion. The onset of symptoms and signs is rapid. It should be differentiated from otitis media with effusion (OME) [1]

Otitis media with effusion OME; inflammation of the middle ear with fluid collected in the middle ear and absence of signs and symptoms of acute infection. [2]

Middle ear effusion MEE; liquid in the middle ear without reference to etiology, pathogenesis, pathology, or duration [2]

Persistent otitis; Persistence or worsening of symptoms after the initial management [3]

Recurrent otitis media; three or more documented and separate episodes of AOM within 6 months or four or more episodes within 12 months with at least one episode in the past 6 months. [4]

Uncomplicated AOM; AOM without otorrhoea [5]

Non-severe AOM; AOM with the presence of mild otalgia and a temperature below 39°C [6]

Severe AOM; AOM with the presence of moderate to severe otalgia or fever equal to or higher than 39°C [6]

Tympanometry; measuring acoustic immittance (transfer of acoustic energy) of the ear as a function of ear canal air pressure [7]

Initial antibiotic therapy; treatment of AOM with antibiotics that are prescribed at the time of diagnosis with the intent of starting antibiotic therapy as soon as possible after the encounter [8]

Initial observation; initial management of AOM limited to symptomatic relief, with commencement of antibiotic therapy only if the child's condition worsens at any time or does not show clinical improvement within 48 to 72 hours of diagnosis. [9]

Purpose

The main goal of this guideline is to establish uniformity in the assessment and management of children with acute otitis media.

To reach a proper diagnosis of AOM and exclude other causes of pain and hearing loss in children. Direct to proper management, and advise when to prescribe the proper antibiotic if and when needed, to improve the quality of life of our patients.

The primary outcome of interest was the total antibiotic prescription incidence for AOM. Secondary outcomes included the type of antibiotic prescribed and the prescription of analgesics.

***Scope**:*
The scope of the guideline is the diagnosis and management of AOM and recurrent AOM in children 6 months and older without any underlying conditions. The guideline also aims at recommending the different ways of preventing recurrence of AOM.

***Target audience**:*
ENT, Pediatricians and family physicians, to be used for management and/or appropriate referral of children with acute otitis media.

Methods

Methods of development
Stakeholder Involvement: Individuals who were involved in the development process. Including the above-mentioned Otology Chief Manager, Otology Executive Manager, Assembly Board, Grading Board and Reviewing Board.

Information about target population experiences were not applicable for this topic.

Search method
Electronic database searched:
Pubmed, Medline, Egyptian Knowledge Bank, Medscape, WebMD, Google Scholar
***Keywords**:*
Acute Otitis Media, Guidelines, Children

The adaptation cycle passed over: set-up phase, adaptation phase (Search and screen, assessment: currency, content, quality & /decision/selection) and finalization phase that included revision and external reviewing.
Time period searched: from January 2004 to December 2020.

Results
Five national otorhinolaryngologists reviewed the guidelines available. Guidelines from the American Academy of Pediatrics (AAP) and American Academy of Family Physicians gained the highest scores as regards currency, contents and quality.
It was graded GRADE by twenty two experts and reviewed by six expert reviewers to improve quality, gather feedback on draft recommendations.
The external review was done through a rating scale as well as open-ended questions.

***Setting**: Primary, secondary and tertiary care centers & hospitals, and related specialties.*

Interpretation of strong and conditional recommendations for an intervention [10]

Audience	Strong recommendation	Conditional recommendation
Patients	Most individuals in this situation would want the recommended course of action; only a small proportion would not. Formal decision aides are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Most individuals in this situation would want the suggested course of action, but many would not
Clinicians	Most individuals should receive the intervention. Adherence to the recommendation could be used as a quality criterion or performance indicator.	Different choices will be appropriate for individual patients, who will require assistance in arriving at a management decision consistent with his or her values and preferences. Decision aides may be useful in helping individuals make decisions consistent with their values and preferences.
Policymakers	The recommendation can be adopted as policy in most situations.	Policy-making will require substantial debate and involvement of various stakeholders.

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to Decision frameworks (GRADE Working Group 2013)

Grade	Definition
High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low	Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very Low	We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

Recommendations

The following statements and flowchart were adapted from the Guidelines from the American Academy of Pediatrics (AAP) and American Academy of Family Physicians which received the highest scores as regards the currency, contents, and quality.

Recommendations statements

Accepted statements	
Modified statements	
Added statements	

Clinical questions	Action recommendation	Evidence Quality	Strength of Recommendation	Study Type	Reference
Diagnosis and Examination	Clinicians should diagnose AOM in children who present with moderate to severe bulging of the tympanic membrane (TM) or new onset of otorrhoea not due to acute otitis externa.	High	Strong Recommendation	Systematic Review	11,12,13
	Clinicians should diagnose AOM in children who present with mild bulging of the TM and recent (less than 48 hours) onset of ear pain (holding, tugging, and rubbing of the ear in a nonverbal child) or intense erythema of the TM.	Moderate	Strong Recommendation	Systematic Review	11,12,13
	Clinicians should not diagnose AOM in children who do not have middle ear effusion (MEE) (based on pneumatic otoscopy and/or tympanometry).	Moderate	Conditional recommendation	Systematic Review	11,12,13
Management of pain	The management of AOM should include an assessment of pain. If pain is present, the clinician should recommend treatment to reduce pain.	High	Strong Recommendation	Randomized Control Trial	14
Antibiotic administration in severe cases.	The clinician should prescribe antibiotic therapy for AOM (bilateral or unilateral) in children 6 months and older with severe signs or symptoms (moderate or severe otalgia or otalgia for at least 48 hours or temperature 39°C or higher)	Moderate	Strong Recommendation	Systematic Review	15
Antibiotic administration in non-severe bilateral AOM in young	The clinician should prescribe antibiotic therapy for bilateral AOM in children 6 months through 23 months of age without severe signs or symptoms (mild otalgia for less than 48 hours and temperature less than 39°C).	Moderate	Conditional Recommendation	Systematic Review	16
Non-severe unilateral AOM in young children	The clinician should either prescribe antibiotic therapy or offer observation with close follow-up based on joint decision making with the	Moderate	Conditional Recommendation	Placebo-Controlled Trial	17

	parents/caregiver for unilateral AOM in children 6 months to 23 months of age without severe signs or symptoms (mild otalgia for less than 48 hours and temperature less than 39°C). When observation is used, a mechanism must be in place to ensure follow-up and begin antibiotic therapy if the child worsens or fails to improve within 48 to 72 hours of onset of symptoms.				
Non-severe AOM in older children	The clinician should either prescribe antibiotic therapy or offer observation with close follow-up based on joint decision-making with the parents/caregiver for AOM (bilateral or unilateral) in children 24 months or older without severe signs or symptoms (mild otalgia for less than 48 hours and temperature less than 39°C). When observation is used, a mechanism must be in place to ensure follow-up and begin antibiotic therapy if the child worsens or fails to improve within 48 to 72 hours of onset of symptoms.	Moderate	Conditional recommendation	Systematic Review	18
Choice of antibiotics	Clinicians should prescribe amoxicillin clavulanate as first line choice for AOM when a decision to treat with antibiotics has been made due to high resistance to amoxicillin. Clinicians should prescribe Clarithromycin in cases of penicillin allergy or intolerance.	Moderate Moderate	Conditional Recommendation Conditional recommendation	Randomized Controlled Trial Systematic Review	19 20
Follow-up of patients	Clinicians should reassess the patient if the caregiver reports that the child's symptoms have worsened or failed to respond to the initial antibiotic treatment within 48 to 72 hours and determine whether a change in therapy is needed	Moderate	Conditional Recommendation	Meta-analysis	21,22
The use of prophylactic	Clinicians should not prescribe prophylactic	Moderate	Conditional	Cohort study	23

antibiotics	antibiotics to reduce the frequency of episodes of AOM in children with recurrent AOM.		Recommendation		
Role of tympanostomy tubes	Clinicians may offer tympanostomy tubes for Role of recurrent AOM (3 episodes in 6 months or tympanostomy tubes 4 episodes in 1 year with 1 episode in the preceding 6 months).	Moderate	Conditional Recommendation	Randomized Controlled Trial	24
Role of adenoidectomy	The additive benefit of adenoidectomy to tympanostomy tubes in recurrent AOM and otitis media with effusion is controversial and age-dependent	Moderate	Conditional recommendation	Systematic Review	25
Role of pneumococcal vaccine	Clinicians should recommend pneumococcal conjugate vaccine to all children according to the schedule and regulations set by the Ministry of Health and Population.	Moderate	Strong Recommendation	Systematic Review	26
Role of influenza vaccine	Clinicians should recommend annual Influenza vaccination to all children according to the regulations set by the Ministry of Health and Population.	Moderate	Conditional Recommendation	Randomized Controlled Trial	27
Role of immunoglobulins in otitis prone children	Immunoglobulin administration is recommended for patients with low serum IgG2 levels, whose recurrent AOM cannot be controlled by other available treatment modalities.	Low	Conditional Recommendation	Observational Study	28
Role of breast- feeding	Clinicians should encourage exclusive breastfeeding for at least 6 months.	Moderate	Conditional Recommendation	Cohort Study	29
Role of active and passive tobacco	Clinicians should encourage avoidance of tobacco smoke exposure.	Low	Conditional Recommendation	Case Controlled Study	30

Research needs

There is a need to conduct randomized controlled trials (RCTs) to better determine the efficacy and choice of antibiotics.

There is a need to conduct RCTs to determine the efficacy of adenoidectomy and its added benefit.

Monitoring and evaluating the impact of the guideline

Monitoring/ Auditing Criteria:

- *Management of pain with analgesics*
- *Administration of amoxicillin-clavulanate as the first choice antibiotic treatment when a decision to treat with antibiotics has been made*

Updating of the guideline

Updating Procedure:

Any recommendation of this guideline will be updated when new evidence that could potentially impact the current evidence base for this recommendation is identified. If no new reports or information are identified for a particular recommendation, the recommendation will be revalidated. The focus will be on recommendations supported by very-low- or low certainty evidence and where new recommendations or a change in the published recommendations may be needed.

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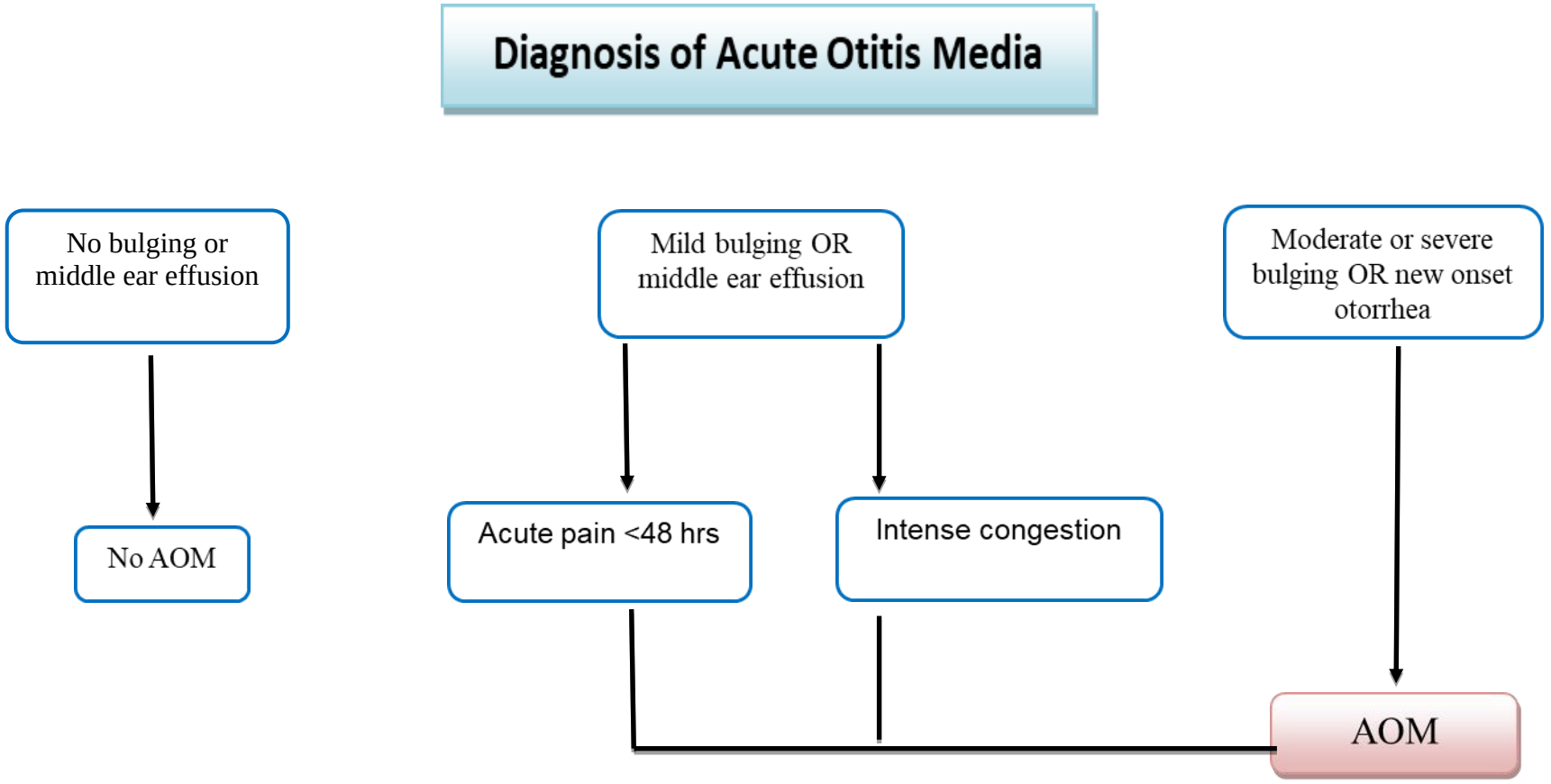
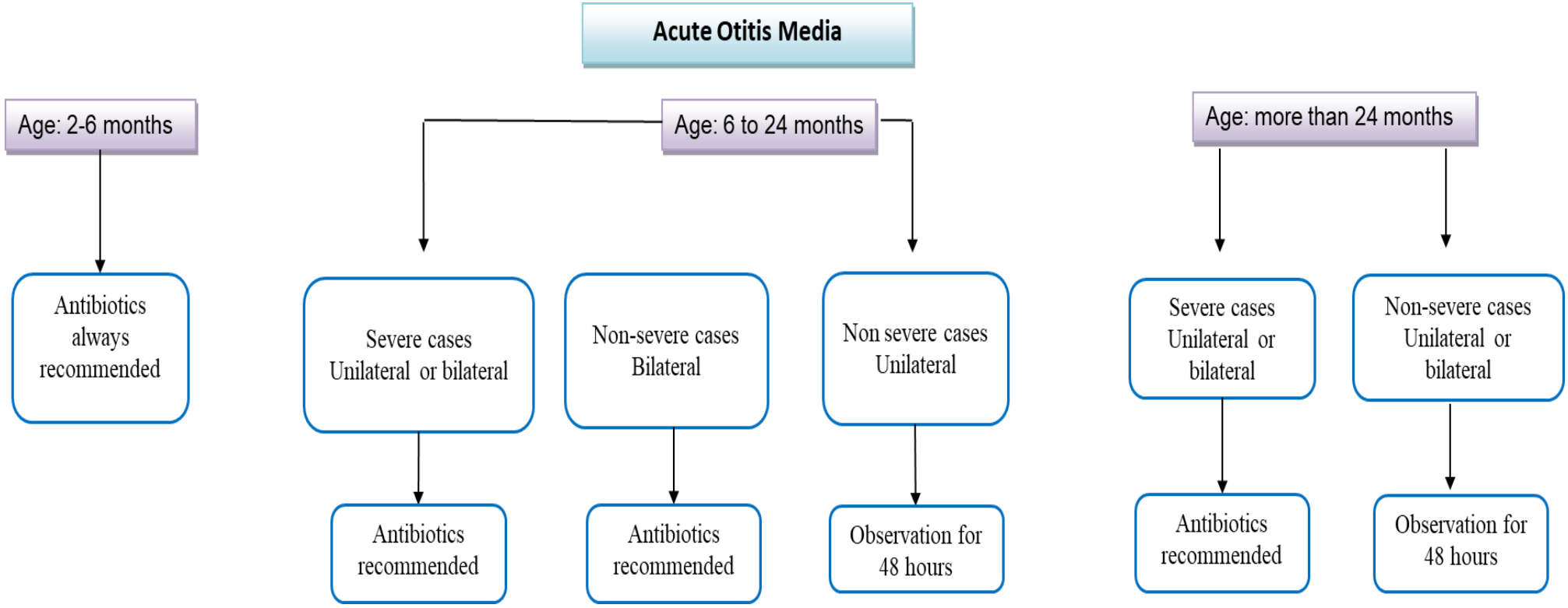
Annexes

Editorial Independence:

- *This guideline was developed without any external funding.*
- *All the guideline development group members have declared that they do not have any competing interests.*

Annex 1: Guideline Flowchart




Acute Otitis Media
Age: 2-6 months
Antibiotics always recommended
Age: 6 to 24 months
Severe cases Unilateral or bilateral
Antibiotics recommended
Non-severe cases Bilateral
Antibiotics recommended
Non severe cases Unilateral
Observation for 48 hours
Age: more than 24 months
Severe cases Unilateral or bilateral
Antibiotics recommended
Non-severe cases Unilateral or bilateral
Observation for 48 hours

Acute Otitis Media

Recommended antimicrobial therapy

Severity of disease	Initial management		If treatment fails after 48 hours of observation		If treatment fails after 48 hours of initial antimicrobial agent	
	Recommended antibiotic	Alternative	Recommended antibiotic	Alternative	Recommended antibiotic	Alternative
Non-severe	Amoxicillin-Clavulanate	Clarithromycin	Amoxicillin-Clavulanate	Clarithromycin	Cefdinir	Clindamycin/ Ceftriaxone (3days)
Severe	Cedinir	Ceftriaxone (3days)	Cefdinir	Ceftriaxone (3days)	Ceftriaxone (3days)	Tympanocentesis + clindamycin

Offer regular doses of Paracetamol or Ibuprofen to manage pain with the right dose for age/weight.
Evidence suggests that decongestants and antihistamines do not provide help

Consider immediate antibiotics:
Patients with AOM and otorrhea.
Children with bilateral AOM.
Patients with only hearing ear.

Evidence on antibiotics:
Antibiotics make little difference to the number of children whose symptoms improve.
Antibiotics do not change the number of children with recurrent infections or perforated tympanic membranes.
There is no evidence that antibiotics prevent complications.

Evidence on antibiotics:
Pneumococcus is the most important pathogen.
It is increasingly resistant to sulphonamides, macrolides and to some cephalosporins.

Duration of treatment:
Children under 2 years require a minimum of 10 days to prevent recurrence.
For older children with a good response, 5 days should be enough.
Failure of adequate response after 48-72 hours should prompt to switch antibiotic.

Annex 2: Tables of appraisal of selected guidelines: Currency (table 1), Content (table 2) and Quality (table 3) of the selected guidelines.

Name	Responsible organization	Date of publication	Expected review date
The American Academy of Pediatrics (AAP), The American Academy of Family Physicians (AAFP)	Subcommittee on Management of Acute Otitis Media Diagnosis and Management of Acute Otitis Media	2004 updated 2013	unknown
National Institute for Health and Core Excellence, UK (NICE)	Acute Otitis Media	July 2018	July 2023
Institut National d'Excellence en Santé et Services Sociaux, Québec, Canada	Otite moyenne aigue chez l'enfant de 3 mois et plus	Mar 2016	unknown
Royal Children Hospital Melbourne, Australia.	Royal Children Hospital Melbourne, Australia.	April 2018	unknown
Japanese Otological Society (JOS)	Clinical Practice Guidelines for the Diagnosis and Management of Acute Otitis Media (AOM) in Children in Japan	2011 Updated 2013 Updated 2018	unknown
Danish guidelines on management of otitis media in preschool children	Danish Health and Medicines Authority The Danish Society of Otorhinolaryngology, Head and Neck Surgery	2016	unknown

Table 1

	The American Academy of Pediatrics (AAP), The American Academy of Family Physicians (AAFP)	National Institute for Health and Core Excellence, UK (NICE)	Institut National d'Excellence en Santé et Services Sociaux, Québec, Canada	Royal Children Hospital Melbourne, Australia.	Japanese Otological Society (JOS)	Danish Health and Medicines Authority, The Danish Society of Otorhinolaryngology, Head and Neck Surgery
Credibility	9	9	9	9	9	9
Observability	8	8	6	6	6	7
Relevance	8	8	8	8	8	8
Relative advantage	8	8	6	7	7	7
Easy to install	9	9	7	7	6	7
Compatibility	8	8	8	7	7	8
Testability	8	8	7	7	7	7
Total Score	58	58	51	51	50	53

Table 2

	The American Academy of Pediatrics (AAP), The American Academy of Family Physicians (AAFP)	National Institute for Health and Core Excellence, UK (NICE)	Institut National d'Excellence en Santé et Services Sociaux, Québec, Canada	Royal Children Hospital Melbourne, Australia.	Japanese Otological Society (JOS)	Danish Health and Medicines Authority, The Danish Society of Otorhinolaryngology, Head and Neck Surgery
Transparency	A	A	C	C	A	A
Conflict of interests	A	A	unknown	unknown	A	A
Development group	A	A	C	B	A	A
Systematic review	A	B	C	C	B	B
Grading of evidence	A	A	B	C	A	A
Recommendations	A	B	C	C	A	A
External review	A	B	C	C	B	B
Updating	C	A	B	A	A	A

Table 3

Annex 3: The risks and benefits of added and/or modified statements

Statement	Risk	Benefit
Clinicians should prescribe amoxicillin clavulanate as first line choice for AOM when a decision to treat with antibiotics has been made due to high resistance to amoxicillin. Clinicians should prescribe Clarithromycin in cases of penicillin allergy or intolerance.	Augmented penicillin should be usually reserved to specific infections.	Due to antibiotic abuse, we strongly believe that amoxicillin has become ineffective in the community
The additive benefit of adenoidectomy to tympanostomy tubes in recurrent AOM and otitis media with effusion is controversial and age-dependent	Subjecting children to unwanted surgery	The adenoid pad can sometimes be responsible for Eustachian tube obstruction, or act as a cause of recurrent upper airway infection
Clinicians should recommend pneumococcal conjugate vaccine to all children according to the schedule and regulations set by the Ministry of Health and Population.	No risk	We added that the vaccination should be done according to regulations set by the ministry of health
Clinicians should recommend annual Influenza vaccination to all children according to the regulations set by the Ministry of Health and Population.	No risk	We added that the vaccination should be done according to regulations set by the ministry of health
Immunoglobulin administration is recommended for patients with low serum IgG2 levels, whose recurrent AOM cannot be controlled by other available treatment modalities	No risk	We strongly believe that because of overcrowding and malnutrition, IgG2 can add benefit in boosting immunity