Impact of a Protocol Change on Antibiotic Prescription for Acute Otitis Media in Children: A Retrospective Study in a Belgian Paediatric Emergency Department

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Keywords

Antibiotic Treatment ; Public Health ; Otitis Media

Abstract

Introduction

Acute otitis media (AOM) is a major driver of antibiotic use in children, though most cases are self-limiting. In October 2023, a revised protocol was introduced to align with national antibiotic stewardship guidelines. This study evaluated the impact of the protocol change on antibiotic prescribing and identified factors associated with prescription decisions.

Methods

We conducted a retrospective cohort study of children aged 3 months to 16 years diagnosed with AOM during two six-month periods: before (PRE) and after (POST) protocol implementation. Patients with comorbidities, prior antibiotic use, or incomplete records were excluded. Logistic regression was used to assess the effect of the protocol and clinical variables on systemic and local antibiotic use.

Results

Of 1,868 visits, 1,669 were included (905 PRE, 764 POST). Systemic antibiotic prescriptions decreased significantly from 59.0% to 46.6% ($p < 0.001$). POST-period presentation was associated with lower odds of systemic antibiotic use (OR = 0.59; 95% CI: 0.43–0.81). Factors increasing systemic antibiotic use included younger age and clinical red flags. Five-day treatment courses rose from 16.2% to 45.2%, while delayed prescriptions increased modestly. Overall local antibiotic use remained stable. Older children were more likely to receive local treatment.

Conclusion

The revised protocol significantly reduced systemic antibiotic use and encouraged shorter, more targeted treatments. Further education is needed to limit unnecessary local antibiotic use.

Introduction

Acute otitis media (AOM) is one of the most common paediatric infections and a leading reason for antibiotic prescription in children (1,2). Though typically self-limiting, AOM accounts for a high proportion of unnecessary antibiotic use, contributing to antimicrobial resistance and avoidable side effects (3,4). International guidelines, including those from the Belgian Antibiotic Policy Coordination Committee (BAPCOC) and the World Health Organisation (WHO), have increasingly emphasized watchful waiting and restricted indications for antibiotic therapy in uncomplicated AOM cases (5,6).

Recommendations for immediate antibiotic therapy in children with acute otitis media (AOM) vary across national guidelines. The American Academy of Pediatrics (AAP; USA) recommends antibiotics for all children under 6 months, those with severe symptoms (fever ≥39°C or significant otalgia), otorrhea or bilateral AOM in children under 2 years. The Haute Autorité de Santé (HAS; France) advises antibiotics for all children under 2 years or in case of severe symptoms or otorrhea regardless of age. The National Institute for Health and Care Excellence (NICE, UK) and the Nederlands Huisartsen Genootschap (NHG, The Netherlands) recommend antibiotics for systemically unwell children, and favours observation for those with otorrhea or bilateral AOM in children under 2 years. All guidelines agree on treating severe cases immediately, but differ in age thresholds and how bilateral involvement and otorrhea influence management. A more conservative, watchful-waiting strategy is emphasized in UK and Dutch guidelines compared to the US and French guidelines (7-10).

At the Queen Fabiola Children's University Hospital (HUDERF), the local protocol for AOM management (Appendix 1 and 2) was revised in October 2023 to reflect stricter prescribing criteria and encourage shorter antibiotic courses. Following the BAPCOC guidelines, indications for antibiotic therapy have been limited to patients younger than 6 months, those with comorbidities, or

those presenting with « red flags » (Appendix 3) (5). The duration of treatment has also been reduced to 5 days for all children, and the sole indication for topical antibiotics is in children with tympanostomy tubes and otorrhea. This study aimed to evaluate the impact of protocol change on prescribing behaviour and to identify clinical factors associated with systemic and local antibiotic prescriptions in children presenting with AOM.

The protocol has been revised by the infectious diseases team in collaboration with the ear-nose-throat (ENT) team. The revised protocol was disseminated to all relevant clinicians, including paediatricians, ENT specialists, and residents in paediatrics, emergency medicine, and surgery. Communication took place through multiple channels: the protocol was circulated by email, presented during a departmental "grand tour" meeting, and uploaded to our hospital's online protocol database (ENNOV ®). In addition, a printed version was integrated into the emergency department's (ED) protocol map, which is updated with each new protocol release and systematically reviewed every three months to ensure accuracy and accessibility.

Materials and Methods

Study design and setting:

This was retrospective, non-interventional, monocentric cohort study based on the review of electronic medical records from the paediatric emergency department (ED) of HUDERF (Brussels). Two 6-month periods were analysed: pre-intervention group (PRE; 01/11/2022 to 30/05/2023) and post-intervention group (POST; 01/11/2023 to 30/05/2024).

Our paediatric ED is staffed by a fixed team of paediatric emergency physicians, paediatricians, and general practitioners/family medicine physicians. The resident pool includes emergency medicine residents (general track), paediatric residents, and family medicine residents. Night shifts are covered by residents in emergency medicine, paediatrics, and surgery, under supervision of the attending staff.

In this study, a diagnosis of acute otitis media (AOM) was reserved for children meeting internationally accepted criteria, ensuring that only true AOM cases were included. AOM was defined as the presence of middle ear effusion with signs of acute inflammation, such as a bulging, opaque, or erythematous tympanic membrane, often with visible purulent fluid. Cases presenting with isolated tympanic membrane redness, without effusion or other otoscopic signs of acute infection, were not classified as AOM (7).

Inclusion and exclusion criteria:

Patients aged 3 months to 16 years with a final diagnosis of AOM were included. Exclusions applied to patients with comorbidities (immunodeficiency, craniofacial anomalies, Down syndrome), prior antibiotic use, concurrent infections (e.g., pneumonia, tonsillitis), hospitalization, or incomplete clinical records. Patients below the age of 3 months (90 days) were excluded because they are not included in our local treatment protocol for AOM and are treated according to our fever below the age of 3 months protocol.

Data collection:

For each included patient, demographic data, clinical signs, and prescribing details were extracted. Variables included age, fever duration and intensity, presence of red flags, purulence, bilateral involvement, prescriber type, and antibiotic details (agent, route, duration, delayed vs immediate). Given the retrospective nature of the study, not all clinical variables were documented for every patient (for example, fever characteristics were occasionally missing from the medical record). Patients with missing data were not excluded from the overall cohort but were omitted from specific subanalyses involving the unavailable parameter.

TABLE 1: Demographic and clinical characteristics for both groups.

Factor	n	PRE	n	POST	p
Age (years)	905	2,8 (1,4-4,8)	764	3 (1,4-5,0)	NS
Sex (male %)	905	55,6	764	53,7	NS
Tympanostomy tube (%)	905	1,9	764	2,8	NS
Any fever (%)	891	67	756	61,8	NS
Highest reported fever (°C)	538	39,3 (39,0-40,0)	432	39,3 (38,9-40,0)	NS
Fever duration (h)	556	48 (24-96)	449	48 (24-96)	NS
Otalgia (%)	905	53,4	753	59,5	NS
Unilateral pain (%)	905	43,3	753	46,2	NS
Bilateral pain	905	10,1	747	13,4	0,035
Otorrhea (%)	905	26,4	763	27,2	NS
Red flags (%)	905	3,5	764	3,1	NS
Bilateral AOM (%)	905	32,5	764	32,3	NS
Purulent AOM	905	76,2	764	72,9	NS

TABLE 2: Logistic regression table for factors associated with the probability of systemic antibiotic use. Nagelkerke R^2: 0.23 indicating that 23% of antibiotics prescription rate is due to these variables.

Factor	OR	95% CI	p
POST period	0.59	0.43-0.81	0.0008
Younger age	0.85 per year	0.79-0.91	< 0.0001
Longer fever duration	1.005 per hour	1.00-1.01	0.0016
Highest reported fever	1.35 per °C	1.07-1.69	0.0103
Bilateral AOM	2.33	1.68-3.23	< 0.0001
Red flags	5.05	1.51-16.91	0.0087
Purulent AOM	3.21	2.28-4.54	< 0.0001

Manuscript preparation:

Translation from French to English of the preliminary version of the article was generated with the support of ChatGPT (OpenAI, June 2025 version, https://chat.openai.com), based strictly on the content of the original dissertation. All statistical interpretation and written content were critically reviewed, corrected, and approved by the authors to ensure accuracy and fidelity to the source material.

Statistical analysis:

Univariate comparisons between PRE and POST groups were conducted using chi-square, t-tests, or Mann-Whitney U-tests as appropriate. Multivariable logistic regression was used to identify factors associated with systemic and local antibiotic prescriptions. Statistical analysis was performed using JASP (v0.19.3) and MedCalc (v23.1.3).

Ethics:

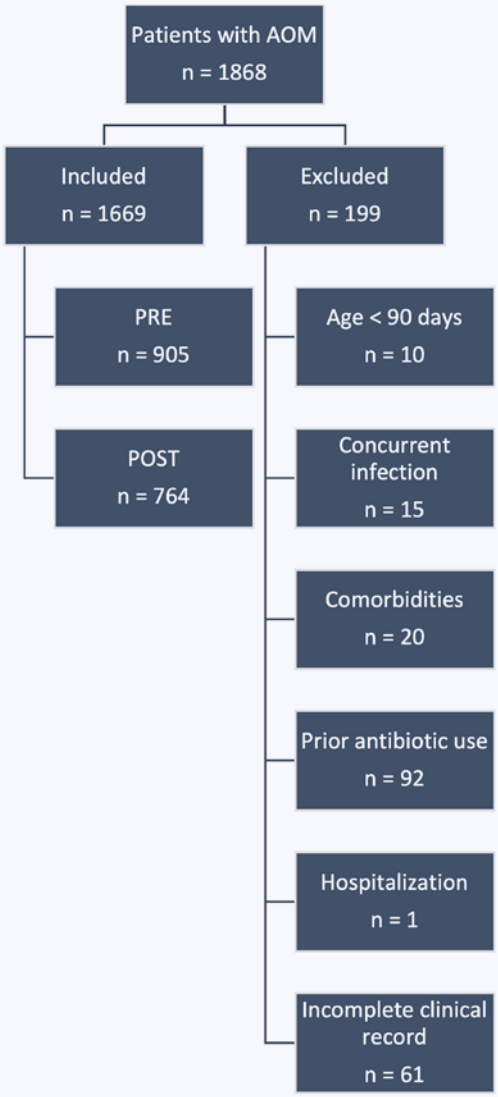
The study was approved by the HUDERF ethics committee (CEH 40/24).

Results

Population:

A total of 1,669 AOM cases were included (905 PRE, 764 POST) (Figure 1). In the pre-intervention period, 23 children were younger than 6 months, 312 were between 6 and 24 months, and 570 were older than 24 months. In the post-intervention period, these numbers were 14, 272, and 478 respectively, difference between age distribution is not significant. The distribution of prescriber type differed significantly between the two periods ($x^2 = 63.9$, $p < 0.0001$), mainly due to a difference between the number of patients treated by emergency medicine residents (175 vs. 71), while general practitioners were more frequently involved in the post-intervention period (152 vs. 81). The proportions of patients seen by the staff physicians (101 vs. 85) and paediatric residents (548 vs. 456) remained stable across both periods. Demographic and clinical characteristics were comparable between groups (Table 1).

FIGURE 1: Study flow diagram illustrating patient inclusion and exclusion criteria.



Systemic antibiotic prescriptions:

Systemic antibiotic use decreased significantly in the POST period (59.0% vs 46.6%, $p < 0.001$). Most prescriptions were for amoxicillin (95.9%). The proportion of delayed prescriptions increased from 0.88% to 3.4% ($p < 0.001$). The proportion of 5-day treatments increased significantly post-intervention (from 16.2% to 45.2%, $p < 0.0001$).

Subgroup analysis according to cut-of-ages in the BAPCOC guidelines, showed a decrease in systemic antibiotic prescription rate in all age categories. In infants under 6 months of age, systemic antibiotics were prescribed in 100% of cases during the PRE period and 76.2% in the POST period. Although this reflects a numerical decrease, no statistical comparison could be performed due to the absence of untreated cases in the PRE period. Differences for the age groups 6 to 24 months (79,9% vs. 69,8%, $p = 0.0054$) and above 24 months (43,5% vs. 32,2%, $p = 0.0002$), and pairwise comparison between all age groups for every

FIGURE 2: Subgroup analysis according to cut-of-ages. Differences for the age groups 6 to 24 months and above 24 months, and pairwise comparison between all age groups for every period were statistically significant.

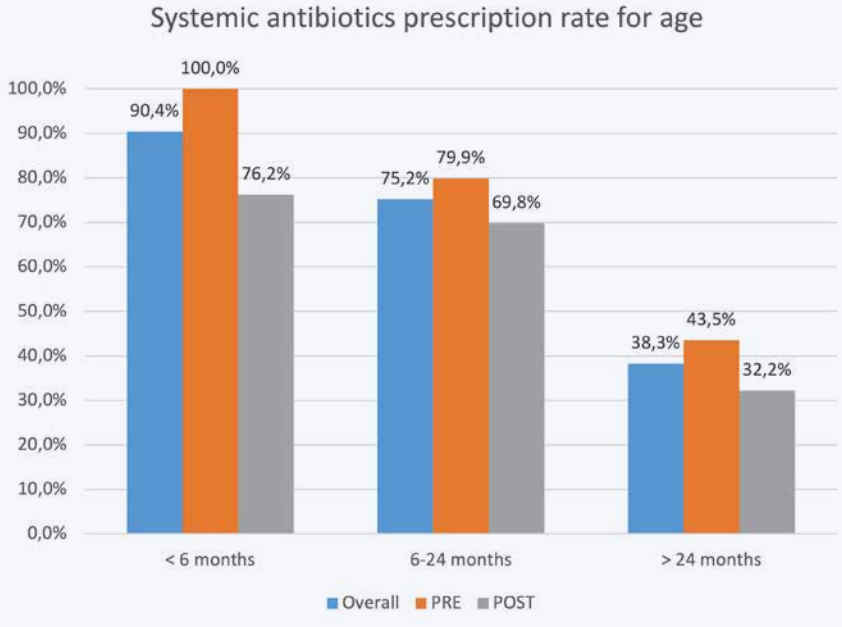


FIGURE 3: Pairwise comparison for treatment duration between both periods.

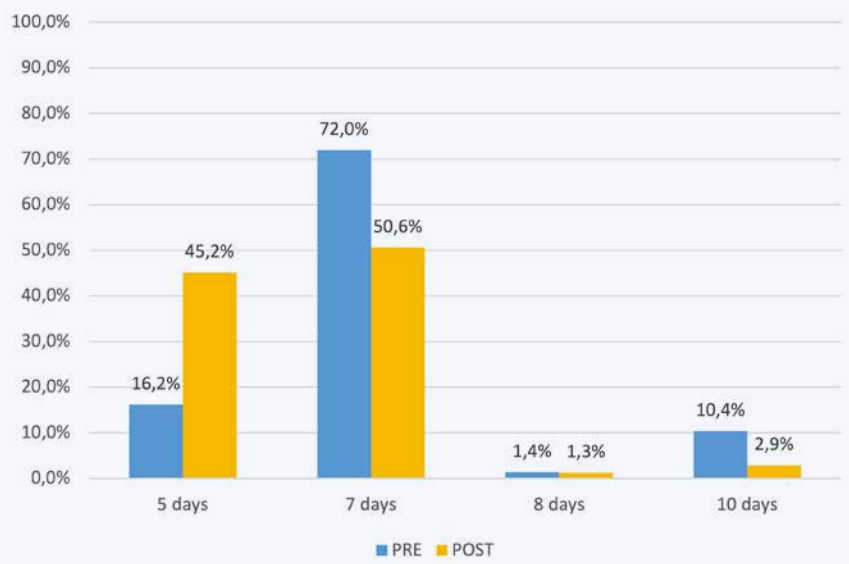


TABLE 3: Logistic regression table for factors associated with the probability of local antibiotic use. Nagelkerke R^2: 0.10 indicating that 10% of antibiotics prescription rate is due to these variables. There is no significant difference between the two periods.

Factor	OR	95% CI	p
POST period	1.24	0.92-1.66	NS
Older age	1.14 per year	0.79-0.91	0.0001
Shorter fever duration	0.99 per hour	0.99-1.00	< 0.0001
Bilateral AOM	0.64	0.47-0.87	0.0047
Purulent AOM	0.54	0.39-0.74	0.0002

period (p = 0.001) were statistically significant (Figure 2).

Treatment duration:

The proportion of children prescribed, for whom a 5-day course of antibiotics was prescribed, more than tripled following the protocol revision, increasing from 16.2% in the PRE period to 45.2% POST period (p < 0.0001). Conversely, the use of 7-day treatment courses significantly declined, from 72.0% to 50.6% (p < 0.0001) (Figure 3).

Factors associated with systemic antibiotic use, as identified with logistic regression, are described in table 2 (Table 2; Figure 4).

Local antibiotic prescriptions:

Overall local antibiotic prescription rates rose modestly (35.0% to 40.7%, p = 0.017), with a significant shift from ciprofloxacin and combination drops toward chloramphenicol/dexamethasone.

Factors associated with local antibiotic use, as identified with logistic regression, are described in table 3 (Table 3; Figure 5);

There was no significant difference in the use of local antibiotics between both periods (POST period: OR 1.24 (95% CI 0.92-1.66, NS)).

Prescriber behaviour:

General practitioners (GPs and GP trainees) at our ED prescribed fewer systemic antibiotics than (resident) paediatricians and emergency physicians (46.4% vs 53.8%, p = 0.034). Specialist prescribing significantly decreased after the protocol update (58.7% to 47.2%, p < 0.0001), while no significant change was observed in GP prescribing.

Discussion

This study confirms that a structured protocol change at HUDERF reduced systemic antibiotic prescriptions in children with AOM. We were encouraged to observe a significant reduction in systemic antibiotic prescriptions following the implementation of the revised protocol, indicating a positive shift toward more judicious use.

Although clinical severity indicators (younger age, high/long fever, bilateral/purulent AOM, red flags) seemed to drive systemic antibiotic use, overall prescription rates remain high, particularly in age groups where a more conservative approach is often justified. Notably, 69.8% of otherwise healthy children aged 6 to 24 months and 32.2% of children over 2 years still received antibiotics. These figures suggest that, despite progress, there is still room for improvement, especially in reinforcing the appropriateness of watchful waiting in non-severe, uncomplicated cases (11,12).

The revised protocol led to a clear improvement in prescribing practices regarding treatment duration, with a significant increase in the proportion of children receiving the recommended 5-day course. This suggests an ongoing process in adherence to updated guidelines and awareness of the benefits of shorter antibiotic therapy. However, 7-day courses, which are no longer in line with the protocol for children over 2 years without complications, remained the most frequently prescribed duration in the post-intervention period. This persistence may reflect prescriber habit, clinical caution, or a lag in fully adopting the new recommendations. Continued educational efforts and targeted feedback may be needed to further align prescribing behaviour with evidence-based standards.

There was a shift towards local antibiotic use, multivariate analysis suggests this shift reflects substitution for systemic therapy in milder cases (older age, less severe presentation). However, given that local treatment is generally not recommended except in otorrhea with tympanostomy tubes, this highlights a potential area for further clinician education (13).

GPs in our ED consistently prescribed fewer antibiotics, aligning with outpatient care literature (14). Interestingly, the improvement post-intervention was mainly observed among (resident) paediatricians and emergency physicians, suggesting effective internal dissemination and adherence to the new protocol.

Strengths and limitations

This study has several strengths. It is based on a relatively large cohort of paediatric patients, with strict inclusion and exclusion criteria and a clearly defined clinical endpoint. The before-and-after design allowed a pragmatic assessment of the impact of a targeted intervention (a revised prescribing protocol) in a real-world emergency department setting. Detailed clinical data,

including fever characteristics and otoscopic findings, enabled robust multivariable analysis of factors influencing prescribing behaviour.

However, the study also has limitations. Its retrospective and monocentric nature restricts generalizability beyond our institution. Prescribing decisions were not always explicitly documented, which may introduce residual confounding. The reliance on clinician diagnosis, without systematic confirmation by otoscopy by an ENT or tympanometry, may affect diagnostic consistency. Finally, some subgroup analyses (e.g., infants < 6 months) involved small sample sizes, limiting statistical power or preventing formal testing.

Conclusion

The implementation of a revised local protocol for AOM at HUDERF significantly reduced systemic antibiotic prescriptions and encouraged shorter treatment durations and delayed prescribing. Clinical severity remained the main driver of prescribing decisions. The persistent use of local antibiotics, even when not strictly indicated, suggests a need for further education targeting both clinicians and caregivers.

Future research should explore long-term sustainability of these trends and the impact on clinical outcomes, parental satisfaction, and resistance patterns.

The authors have no conflicts of interest to declare with regard to the topic discussed in this manuscript.

FIGURE 4: Factors associated with systemic antibiotic prescription, logarithmic scale.

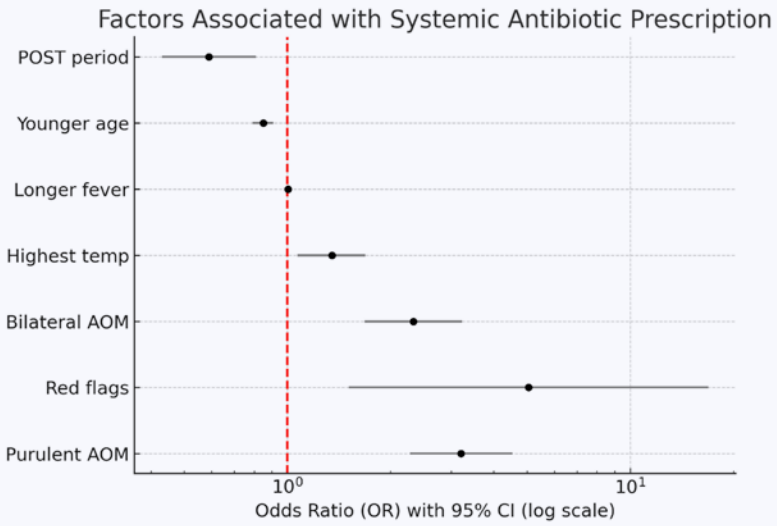
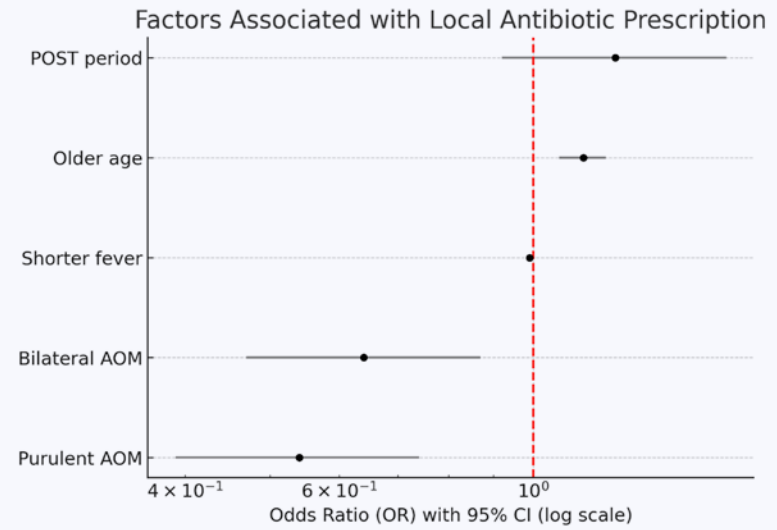


FIGURE 5: Factors associated with local antibiotic prescription, logarithmic scale.



REFERENCES

1. Huang GJ, Lin BR, Li PS, Tang N, Fan ZJ, Lu BQ. The global burden of otitis media in 204 countries and territories from 1992 to 2021: a systematic analysis for the Global Burden of Disease study 2021. Front Public Health. 2025 Jan 21;12:1519623.
2. Paul CR, Frohna JG. Acute Otitis Media. Pediatrics In Review. 2025 Mar 1;46(3):139-47.
3. El Feghaly RE, Nedved A, Katz SE, Frost HM. New insights into the treatment of acute otitis media. Expert Rev Anti Infect Ther. 2023 May;21(5):523-34.
4. Venekamp RP, Sanders SL, Glasziou PP, Rovers MM. Antibiotics for acute otitis media in children. Cochrane Database Syst Rev. 2023 Nov 15;11:CD000219.
5. BAPCOC. Guide belge des traitements anti-infectieux en pratique ambulatoire: Mise à jour 2024. 2024 [Internet] [cited 2025 June 3]:{10-11 pp.]. Available from: https://organesdeconcertation.sante.belgique.be/fr/documents/guide-belge-de-traitement-anti-infectieux-en-pratique-ambulatoire-mise-jour-2024.
6. World Health Organization. Effectiveness of shortened course (≤ 3 days) of antibiotics for treatment of acute otitis media in children [Internet]. [cited 2025 Jun 3]. Available from : https://www.who.int/publications/i/item/9789241598446 .
7. American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media. The diagnosis and management of acute otitis media. Pediatrics. 2013 Mar;131(3):e964-99.
8. Haute Autorité de Santé [Internet]. [cited 2025 Jun 3]. Choix et durées d'antibiothérapies : Otite moyenne aiguë purulente de l'enfant. Available from: https://www.has-sante.fr/jcms/c_2722749/fr/choix-et-durees-d-antibiotherapies-otite-moyenne-aigue-purulente-de-l-enfant
9. National Institute for Health and Care Excellence (NICE). Otitis media (acute): antimicrobial prescribing. NICE Guideline NG91 [Internet]. 2018 [cited 2025 Jun 3]. Available from : https://www.nice.org.uk/guidance/ng91/chapter/recommendations
10. Otitis media acuta bij kinderen | NHG-Richtlijnen [Internet]. [cited 2025 Jun 3]. Available from: https://richtlijnen.nhg.org/standaarden/otitis-media-acuta-bij-kinderen
11. Uijen JH, Bindels PJ, Schellevis FG, van der Wouden JC. ENT problems in Dutch children: Trends in incidence rates, antibiotic prescribing and referrals 2002-2008. Scand J Prim Health Care.2011 Jun;29(2):75-9.
12. Suaya JA, Gessner BD, Fung S, Vuocolo S, Scaife J, Swerdlow DL, et al. Acute otitis media, antimicrobial prescriptions, and medical expenses among children in the United States during 2011-2016. Vaccine. 2018 Nov 26;36(49):7479-86.
13. van Dongen TMA, van der Heijden GJMG, Venekamp RP, Rovers MM, Schilder AGM. A trial of treatment for acute otorrhea in children with tympanostomy tubes. N Engl J Med. 2014 Feb 20;370(8):723-33.
14. Blachford A. Influence of Clinical Setting on Antibiotic Prescribing Practices for Acute Otitis Media in Children at an Urban Academic Medical Center [Internet]. Journal of Urgent Care Medicine. 2024 [cited 2025 Jun 3]. Available from: https://www.jucm.com/influence-of-clinical-setting-on-antibiotic-prescribing-practices-for-acute-otitis-media-in-children-at-an-urban-academic-medical-center/

APPENDIX 1:
Initial protocol (October 2022)

Indications for Immediate Antibiotic Treatment

Immediate antibiotic therapy is recommended for the following categories of children:

- Children under 6 months of age
- Bilateral AOM in children under 2 years of age
- Severe AOM, defined as AOM with:
  - Moderate to severe otalgia
  - Otalgia lasting ≥ 48 hours
  - Temperature ≥ 39°C
- AOM that remains symptomatic (e.g., fever, otalgia) in the presence of purulent otorrhea
- In cases of prolonged purulent otorrhea (> 4 days) or infection with uncommon pathogens, antibiotic treatment is also recommended at a later stage
- Presence of underlying conditions associated with an increased risk of severe AOM (e.g., immunodeficiency, craniofacial anomalies, etc.)
- Recurrent AOM, defined as ≥ 3 episodes within a 6-month period

First-Line Treatment

In children presenting with a new episode of AOM (either a first episode or one occurring more than 3 weeks after the previous episode), without purulent conjunctivitis and without a history of recurrent AOM, amoxicillin 90 mg/kg/day divided into 3 doses, is the antibiotic of choice.

Duration of Antibiotic Therapy

A 10-day antibiotic course is recommended for:

- Children under 2 years of age
- Symptomatic AOM with purulent otorrhea
- Cases of recurrent AOM

A 5-7 day course may be prescribed for:

- Children over 2 years of age, without tympanic membrane perforation and without a history of recurrent AOM

APPENDIX 2:
Current protocol (October 2023)

Immediate oral antibiotic therapy is recommended in the following cases:

- Children under 6 months of age
- Presence of comorbidities such as (but not limited to):
  - Immunodeficiency
  - Craniofacial anomalies
  - Down syndrome

In all other cases:

50-80% of all cases of AOM cases resolve spontaneaously within 3 days, 90% within 7 days.

- If no otorrhea is present, and/or the child is 2 years and older: No antibiotics
- If otorrhea is present and/or the child is 6-24 months old, consider management based on the overall clinical situation and choose between:No antibiotics
- Delayed oral antibiotic prescription
- Immediate oral antibiotic prescription
- Prefer local antibiotic treatment (eardrops) in children with tympanostomy tubes

Antibiotic Regimens

- First-line therapy amoxicillin 80-100 mg/kg/day, divided into 3 doses, for 5 days
- Second-line therapy amoxicillin 40-50 mg/kg/day plus amoxicillin-clavulanate 40-50 mg/kg/day, in 3 divided doses, for 5 days, recommended in case of:
  - Recurrence within 3 weeks
  - Failure of initial treatment
  - Associated purulent conjunctivitis

APPENDIX 3:
Red flags

- Age < 90 days
- Severe pain not relieved by analgesics
- Severe/persistent headaches
- Retro auricular edema/erythema
- Focal neurological signs
- Meningeal signs
- Facial nerve paralysis
- Visual disturbances
- Difficult to arouse
- Excessive crying, irritability
- Loss of interest in play
- Nasal flaring, grunting, increased respiratory effort
- Dry mucous membranes
- Pallor/cyanosis of the skin and mucosa
- Drinking < 50% of unusual intake
- Significantly decreased urine output