PAEDIATRIC HOSPITAL LEVEL ESSENTIAL MEDICINES LIST
CHAPTER 17: EAR, NOSE AND THROAT
NEMLC 30 JANUARY 2020

A: PREVIOUS RECOMMENDATIONS

MEDICINE AMENDMENTS

SECTION	MEDICINE	ADDED/DELETED/NOT ADDED
General	Amoxicillin/Clavulanic acid, oral	Dose and frequency amended Ratio specified
17.7 Otitis Media, acute	Amoxicillin	Duration amended
	Amoxicillin/Clavulanic acid	Duration amended
17.9 Otitis Media, Chronic suppurative	Ofloxacin drops	Removed
	Ciprofloxacin drops	Added

B: AMENDMENTS FOLLOWING COMMENT

MEDICINE AMENDMENTS

SECTION	MEDICINE	ADDED/DELETED/NOT ADDED
General	Amoxicillin/Clavulanic acid, oral	Maximum doses
17.1 Abscess, retropharyngeal	Amoxicillin/Clavulanic acid, IV	Added
	Ceftriaxone	Removed
17.3.1 Acute Bacterial Tracheitis	Epinephrine nebulised	Not added
	Salbutamol nebulised	Not added
17.4 Epistaxis	Lidocaine spray	Directions amended
17.5 Acute Mastoiditis	Ceftriaxone	Dose amended
17.7 Otitis Media, Acute (AOM)	Amoxicillin	Duration amended
	Amoxicillin/Clavulanic Acid	Duration amended
17.9 Otits Media, Chronic, suppurative	Dexamethasone/ciprofloxacin drops	Not Added
17.11 Rhinitis, Allergic/Allergic reaction	Corticosteroid aqueous nasal solution	Added as a class
17.12 Sinusitis, Complicated	Ceftriaxone	Dose amended

General

Amoxicillin/clavulanic acid: Maximum doses added

Following external comment, it was recommended that maximum doses for amoxicillin and amoxicillin/clavulanic added be added.

The following maximum doses were added:[1]

- Amoxicillin /clavulanic acid 45 mg/kg/dose 12 hourly, maximum dose of amoxicillin component: 1.5 g 12 hourly.
- Amoxicillin 45 mg/kg/dose 12 hourly, maximum dose: 1.5 g 12 hourly.

Extrapolated from maximum dose of 1g 8 hourly

17.1 Abscess, retropharyngeal

Amoxicillin/clavulanic acid, IV: Added
Ceftriaxone: Removed

An external comment was received indicating that in this condition ceftriaxone and metronidazole are recommended, with a step-down to oral amoxicillin-clavulanic acid. It was proposed that it would simpler to use IV amoxicillin-clavulanic acid as the empiric regimen, as this would cover the likely spectrum of causative organisms (*Staphylococcus* aureus, *Streptococcus* species, and anaerobes*).*

The Committee agreed with this recommendation both in terms of organism coverage, simplifying empiric regimen, and simplifying IV to oral switch.

17.3.1. Acute Bacterial Tracheitis

Epinephrine nebulised: Not added
Salbutamol nebulised: Not added

An external comment queried whether nebulised epinephrine or salbutamol should be added for the management of acute bacterial tracheitis, no evidence was provided. The Paediatric Committee did not include nebulised epinephrine or nebulized salbutamol as no good evidence supporting this recommendation could be found.

17.4 Epistaxis

Lidocaine Spray: directions amended

The directions for the use of lidocaine spray were amended as the previous text alluded to application of the spray directly to the nostrils.

The text was amended as follows:

Apply topical anaesthesia ~~prior~~ to packing material:

- Lidocaine spray 2% solution.
  - Do not exceed 3 mg/kg dose applied topically.

[1] BMJ Group. The British National Formulary for children 2016-2017.

17.5 Acute Mastoiditis

Ceftriaxone: Dose amended

The ceftriaxone dose was simplified to common practice, and within the range used for management of meningitis.[2]

- ~~Ceftriaxone, IV, 80 mg/kg once daily.~~
- Ceftriaxone, IV, 100 mg/kg once daily.

17.7 Otitis Media, Acute (AOM)

Amoxicillin: Duration amended
Amoxicillin/clavulanic acid: Duration amended

At the NEMLC meeting in July 2019, the Paediatric Committee motivated to extend the duration of therapy for AOM from 5 days to 10 days based on a study by Hoberman et. al.[3], that found that the reduced duration antimicrobial treatment resulted in less favourable outcomes. Treatment failure was more likely in those treated for 5 days as compared to 10 days, 34% versus 16%; difference 17%, 95% CI 9 to 25.

NEMLC recommended that since antimicrobial resistance was a crisis in South Africa, strong rationale would be needed to move from 5 to 10 days of therapy. NEMLC recommended that 5 days be listed as the duration, and external comment be sought.

External comment received was generally mixed. Some clinician recommended that 10 days of amoxicillin-clavulanic acid (as used in Hoberman et. al.) be used. Others recommended that recommendations for those under 2 years (or those with recurrent infections) should be treated with antibiotic for 10 day (critical factors in language delays due to conductive hearing loss); while those greater than 2 years (and no history of recurrent infections) be treated for 5-7 days. All noted that accurate diagnosis was an important factor.

The Committee recommended that a duration of 10 days be used for both empiric therapy and those having a poor response. The evidence in the Hoberman study show that 10 days are superior to 5 days, and although there is concern about appropriate diagnosis, undertreating patients may lead to poor outcomes.

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[2] British National Formulary for Children, 2016-2017. BMJ Group and Pharmaceutical Press.
[3] Hoberman A, Paradise JL, Rockette HE, Kearney DH, Bhatnagar S, Shope TR, et. al. Shortened Antimicrobial Treatment for acute otitis media in young children. NEJM. 2016, 375: 2446 – 2456.

17.9 Otitis Media, Chronic, suppurative

Dexamethasone/ciprofloxacin drops: Not added

An external comment was received recommending the addition of ototopical dexamethasone and ciprofloxacin, as it has been shown to decrease granulation tissue, improve clinical cure and achieve greater rates of bacterial eradication when compared to ciprofloxacin alone.[4]

A study by Panchasara A et al[5], found that there was no difference in clinical or bacteriological improvement, when steroids were combined with topical antibiotic preparations for management of chronic suppurative otitis media. The Paediatric Committee thus agreed to retain the recommendation for fluoroquinolone drops on their own.

17.11 Rhinosinusitis, Acute Bacterial (ABRS)

Corticosteroid aqueous nasal solution: Added as a class

An external comment was received recommending that fluticasone be used rather than beclomethasone. The rational provide was that fluticasone is a newer class of intranasal corticosteroid with a better side effect profile and less systemic absorption compared to beclomethasone.[6, 7, 8]

The Committee recommended that the corticosteroid nasal solutions should be included as a therapeutic class, with the most affordable option listed as the example, as per Therapeutic Interchange Policy.

17.12 Sinusitis, Complicated

Ceftriaxone: Dose amended
See section 17.5 Acute Mastoiditis.

[4] Kutz JW, Roland PS, Lee KH.Ciprofloxacin 0.3% + dexamethasone 0.1% for the treatment for otitis media. Expert Opin Pharmacother. 2013; 14: 2399-2405

[5] Panchasara A, Singh A, Mandavia D, Jha S, Triphathi C. Efficacy and safety of ofloxacin and its combination with dexamethasone in chronic suppurative otitis media. A randomized, double blind, parallel group comparative study. Acta Otorhinolaryngologica italica. 2015; 35:39-44.

[6] Scadding GK, Lund VJ, Jacques LA, Richards DH. A placebo-controlled study of fluticasone propionate aqueous nasal spray and beclomethasone dipropionate in perennial rhinitis: efficacy in allergic and non-allergic perennial rhinitis. Clinical & Experimental Allergy. 1995 Aug;25(8):737-43.

[7] Boner A, Sette L, Martinati L, Sharma RK, Richards DH. The efficacy and tolerability of fluticasone propionate aqueous nasal spray in children with seasonal allergic rhinitis. Allergy. 1995 Jun;50(6):498-505.

[8] Derendorf H, Meltzer EO. Molecular and clinical pharmacology of intranasal corticosteroids: clinical and therapeutic implications. Allergy. 2008 Oct;63(10):1292-300.

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MEDICINE AMENDMENTS

SECTION	MEDICINE	ADDED/DELETED/NOT ADDED
General	Amoxicillin/Clavulanic acid, oral	Dose and frequency amended Ratio specified
17.7 Otitis Media, acute	Amoxicillin	Duration amended
	Amoxicillin/Clavulanic acid	Duration amended
17.9 Otitis Media, Chronic suppurative	Ofloxacin drops	Removed
	Ciprofloxacin drops	Added

General

Amoxicillin/clavulanic acid: Dose and frequency amended, ratio specified

The South African Medical Journal's updated recommendations for the management of upper respiratory tract infections in South Africa[9] recommend amoxicillin/clavulanic acid 12 hourly at a dose of 90 mg/kg/day amoxicillin and 6.4 mg/kg/day clavulanic acid (ratio 14:1), for children with acute otitis media and acute bacterial rhinosinositis. This dose is adequate to eradicate S. pneumoniae that are susceptible to or have high-level resistance to penicillin. [9]

Twelve hourly dosing of oral amoxicillin/clavulanic acid was incorporated into the ENT chapter, in the following indications: 17.1 Abscess, retropharyngeal, 17.3 Tosillitis, complicated (peritonsillar cellulitis, peritonsillar abscess), 17.5 Acute mastoiditis, 17.7 Otitis media, acute (AOM), 17.11 Rhinosinusitis, acute bacterial, 17.12 Sinusitis, complicated.

The recommendation was amended as follows:

- Amoxicillin/clavulanic acid, oral, 45 mg/kg/dose of amoxicillin component, 12 hourly (amoxicillin/clavulanic acid in a ratio of 14:1).~~Amoxicillin/clavulanic acid, oral, 30 mg/kg/dose of the amoxicillin component 8 hourly.~~

LOE: III

17.7 Otitis Media, Acute (AOM)

Amoxicillin: Duration amended from '5 – 10 days' to '5 days'.
Amoxicillin/clavulanic acid (oral): Duration amended from '5 – 10 days' to '5 days'.

A study by Hoberman et. al.[10] evaluating 5 days of amoxicillin-clavulanic acid therapy with 10 days in children 6-23 months with AOM, found that the reduced duration antimicrobial treatment resulted in less favourable

[9] Brink AJ, Cotton MF, Feldman C, Finlayson H, Friedman RL, Green R, et.al. Recommendations – Updated recommendations for the management of upper respiratory tract infections in South Africa. SAMJ. 2015, 105(5):345-352.
[10] Hoberman A, Paradise JL, Rockette HE, Kearney DH, Bhatnagar S, Shope TR, et. al. Shortened Antimicrobial Treatment for acute otitis media in young children. NEJM. 2016, 375: 2446 – 2456.

outcomes. Treatment failure was more likely in those treated for 5 days as compared to 10 days, 34% versus 16%; difference 17%, 95% CI 9 to 25.

The results by Hoberman et. al. are fairly compelling if you accept the combined end point, which included some less than clinically relevant endpoints (primary measure was the percentage of children who had clinical failure after treatment of index infection). It was however noted that based on this paper, there does seem to be a benefit to the longer duration. It was additionally noted that the study used amoxicillin-clavulanic acid as first line, instead of amoxicillin alone as in the STGs and EML current recommendation. The study also included correctly diagnosed AOM, which does not necessarily reflect practice.

NEMLC recommended that antimicrobial resistance was a crisis in South Africa, and thus moving to 10 days would need strong rationale. It was recommended that 5 days be listed as duration, and external comment be sought.

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17.9 Otitis Media, Chronic, suppurative

Ofloxacin drops: removed

Ciprofloxacin ear drops: added

The only registered fluoroqinolone ear drop is ciprofloxacin, this was added as the recommendation for fluoroqinolone ear drops.

17.10 Rhinitis, allergic/allergic rhinosinositis

The previous version of the chapter indicated cetirizine be used for periods of exacerbation, while nasal corticosteroids could be added in poorly controlled or severe cases. The Paediatric Committee noted that nasal corticosteroids were the backbone of therapy, with antihistamines only added for short courses as necessary. [11]

The text was updated as follows:

For patients whose symptoms affect their quality of life:

- Corticosteroid aqueous nasal solution, e.g.:
- Beclomethasone, 100 mcg, 1 spray into each nostril 12 hourly.

During periods of exacerbation of symptoms, a short course of non-sedating antihistamine can help: e.g.

- Cetirizine, oral, as a single dose at night if the predominant symptoms are sneezing, nasal itching and rhinorrhoea:
  - Children 3–12 years: 5 mg.
  - Children older than 12 years: 10 mg.

~~During periods of exacerbation of symptoms, a short course of antihistamine can help:~~

- ~~Cetirizine, oral, as a single dose at night if the predominant symptoms are sneezing, nasal itching and rhinorrhoea:~~
  - ~~Children 3–12 years: 5 mg.~~
  - ~~Children older than 12 years: 10 mg.~~

~~If poorly controlled/severe:~~

- ~~Corticosteroid aqueous nasal solution, e.g.:~~
- ~~Budesonide, 100 mcg, 1 spray into each nostril 12 hourly.~~

[11] Seidman MD, Gurgel RK, Lin SY, Schwartz SR, Baroody FM, Bonner JR. Clinical Practice Guideline: Allergic Rhinitis. Otolaryngology-head and neck surgery. 2015, 152(IS):S1-S43.