

PAEDIATRIC HOSPITAL LEVEL ESSENTIAL MEDICINES LIST
CHAPTER 2: ALIMENTARY TRACT
NEMLC 8 DECEMBER 2022 – REPORT

MEDICINE AMENDMENTS

SECTION	MEDICINE	ADDED/DELETED/NOT ADDED
2.1.3 Necrotising Peridontitis	Amoxicillin/clavulanic acid	Dose and frequency amended
2.2.4 Diarrhoea, acute <i>Hypokalaemia</i>	Potassium	Caution and guidance provided
2.2.4 Diarrhoea, acute <i>Very young infants</i>	Ampicillin	Retained
	Gentamicin	Retained
2.2.5 Persistent Diarrhoea	Co-trimoxazole	Dose and Frequency aligned
2.2.7 Dysentery	Cefotaxime	Removed
	Ceftriaxone	Dose aligned
2.2.9 Peptic Ulcer Disease	Amoxicillin	Dose retained
	Metronidazole	Dose retained
2.3.4 Hepatitis, Viral, Acute	Hepatitis B Vaccine	Removed for prophylaxis
	Hepatitis B Vaccine	Removed for neonatal transmission
	Hepatitis B immunoglobulin	Removed for neonatal transmission
2.3.9 Liver Failure, acute	Cefotaxime	Dose aligned
2.4.1 Malnutrition, severe acute	Neonatal maintenance solution	Removed
	Amoxicillin	Dose and frequency amended

2.2.3 Necrotising Peridontitis

Amoxicillin/clavulanic acid: Dose and frequency amended.

As with other areas of the Paediatric STGs and EML, the amoxicillin/clavulanic acid dose has been amended to a 12 hourly, 90 mg/kg/day dose.

The text was amended as follows:

- Amoxicillin/clavulanic acid, oral, ~~45~~ 25-mg/kg/dose of the amoxicillin component ~~12~~ 8-hourly for 5 days.

2.2.4 Diarrhoea, acute

Hypokalaemia

Potassium: caution and guidance provided

A safety box was added to outline precautions to take with administering IVI potassium.

Additionally, a statement was included to recommended oral potassium in stable patients with severe hypokalaemia. The use of oral/enteral potassium has been shown to have similar efficacy to IV potassium replacement in cardiac ICUs.^{1,2}

The following caution box was added:

If potassium is 2.5 mmol/L to 3.5 mmol/L:

- Potassium chloride, oral, 25–50 mg/kg/dose 8 hourly.

If potassium is < 2.5 mmol/L:

- Potassium IVI replacement:

- » IV potassium only to be used where appropriate monitoring is available which must include continuous ECG and bedside serum potassium/blood gas analysis.
- » Ensure slow administration, over 4 hours.

- The maximum concentration of potassium in a litre of fluid is 40mmol and should not exceed 0.5 to 1 mmol/kg/hour. For sodium chloride 0.9%/dextrose 5%, the maximum volume of 15% potassium chloride in 1L is 20ml. (1ml 15% potassium chloride has 2 mmol potassium)
- Mix well before administration.
- Run at normal rehydration rate (as above).

Note: In stable patients with severe hypokalaemia, correction with oral potassium supplementation can be considered.

Very young infants

Ampicillin: retained

Gentamicin: retained

An external comment was received indicating that the antimicrobial dosing recommendations for very young infants seems too broad to cover the various categories of very young infants <2 months as it potentially includes low birth weight babies. The Committee however noted that dosing for neonates and premature babies is covered in the Neonatal chapter.

2.2.5 Persistent diarrhoea

Co-trimoxazole: Dose and frequency aligned.

An external commenter noted that the co-trimoxazole dosing for *Cystoisospora belli* was different in two area of this section. The dose was aligned to: co-trimoxazole, oral, 5 mg/kg/dose of trimethoprim component 12 hourly for 10 days, in line with the latest CDC recommendations.³

¹ Siddiqui NR, Mercant Q, Hasan BS, Rizvi A, Amanullah M, Rehmat A, ul Haq A. Comparison of enteral versus intravenous potassium supplementation in hypokalaemia in paediatric patients in intensive care post cardiac surgery: open-label randomised equivalence trial. *BMJ Open*. 2017, 7: e011179.

² Moffett BS, McDade E, Rossano JW, Dickerson HA, Nelson DP. Enteral potassium supplementation in pediatrics cardiac intensive care unit: evaluation of a practice change. *Pediatr Crit Care Med*. 2011, 12 (5): 552-554.

³ Centers for Disease Control and Prevention.

https://www.cdc.gov/parasites/cystoisospora/health_professionals/index.html

2.2.7 Dysentery

Cefotaxime: removed

Ceftriaxone: dose aligned

An external commenter queried the Cefotaxime dose. The paediatric Committee on review noted that two options was not necessary. Ceftriaxone is the more affordable option, with a simpler regimen. Cefotaxime was thus removed.

Ceftriaxone dose aligned to 100 mg/kg daily as done in other areas and chapters.

Where oral medication cannot be used:

- ~~Cefotaxime, IV, 75 mg/kg/dose 8 hourly for 5 days.~~

OR

- Ceftriaxone, IV, 50 ~~100~~ mg/kg as a single daily dose for 5 days.

2.2.9 Peptic Ulcer Disease

Amoxicillin: dose retained

Metronidazole: dose retained

An external commenter proposed the addition of weight band dosing. The Committee however recommended retaining the mg/kg dosing.

2.3.4 Hepatitis, viral acute

Hepatitis B Vaccine: Removed for prophylaxis

Hepatitis B Vaccine: Removed for neonatal transmission

Hepatitis B immunoglobulin: Removed for neonatal transmission

An external comment was received noting that acute viral hepatitis is seldom due to Hepatitis B. It was noted that Hepatitis B vaccine is administered at 6, 10, 14 weeks and 18 months as part of the routine immunisation schedule, and If the child is up to date with the recommended immunisations for age, an additional dose as “prophylaxis” in a child with acute viral hepatitis isn’t appropriate.

The Paediatric Committee agreed with the commenter, and recommended the removal of the Hepatitis B vaccine for prophylaxis. Additionally the neonatal transmission recommendations were removed as noted as not appropriate in this section. This guidance is covered in the PHC STGs and EML 2020, perinatal transmission of Hepatitis B section.

The section was updated as follows:

GENERAL AND SUPPORTIVE MEASURES

- » Isolate patient if Hepatitis A for 7–10 after the onset of jaundice.
- » Inform patient of infectivity risk if hepatitis B, or C.
- » Bed rest does not alter the course of the disease.
- » Hepatitis B is vaccine preventable, see Primary Health Care STGs and EML, Chapter 13: Immunisation.–

MEDICINE TREATMENT

- » If Hepatitis B treatment is being considered, discuss with specialist
- » See section below for chronic hepatitis B

Prophylaxis

- ~~Hepatitis B vaccine, IM, 0.5 mL:~~
 - ~~If < 1 year: Outer side of the right thigh.~~
 - ~~If > 1 year: Upper arm.~~

~~Use opposite side to that for the DPT/Td injection.~~

~~Give at 6, 10 and 14 weeks as part of the routine expanded programme on immunisation.~~

Neonatal transmission:

~~Babies born to mothers with acute hepatitis B infection at the time of delivery or to mothers who are HBsAg-positive or HBeAg-positive:~~

- ~~Hepatitis B immunoglobulin, IM, 0.5 mL within 12 hours of delivery.~~

PLUS

- ~~Hepatitis B vaccine, IM, first dose within 12 hours of delivery.~~
 - ~~Continue hepatitis B immunisation according to the recommended immunisation schedule.~~

REFERRAL

- » Acute hepatitis with bleeding tendency and altered level of consciousness – isolation recommended.
- » Prolonged jaundice or raised transaminases.
- » Chronic hepatitis with/without cirrhosis

2.3.9 Liver Failure, acute

Cefotaxime: dose aligned

An external commenter queried the dosing recommendations of Cefotaxime. This was updated with the South African Medicines Formulary.⁴

The text was updated as follows:

- Cefotaxime, IV, 75 50 mg/kg/dose, 8 6 hourly.

⁴ Division of Clinical Pharmacology, UCT. South African Medicines Formulary. Health and Medical Publishing Group of SAMA.

2.4.1 Malnutrition, severe acute

Stabilisation/Rehabilitation phase

Dietician referral added for both stabilization and rehabilitation phase and occupational therapy referral added for rehabilitation phase.

Symptomatic or persistent hypoglycaemia

Neonatal maintenance solution: Removed

Both neonatal maintenance solution and dextrose 10% were listed as management for persistent hypoglycaemia. The Committee recommended removal of neonatal maintenance solution, retaining only dextrose 10% IV.

Antibiotics

Amoxicillin: dose and frequency amended

Amoxicillin dose standardized to a 45 mg/kg/dose 12 hourly dose, as done in other areas of the STGs

Follow up/discharge

A referral to the National Department of Health Integrated Management Children with Acute Malnutrition in South Africa – Operational Guidelines, was added.

A note to advice care-giver on nutrient and energy-dense food options with proposed food items was added.

The following was added:

- » See the National Department of Health Integrated Management of Children with Acute Malnutrition in South Africa – Operational Guidelines.
- » Advice care-giver on nutrient and energy-dense food options – see table 1 below:

Table 1: Sample meal combinations

Starch	Protein	Fat	Other
• Bread	• Peanut butter (counted as fat and protein)	• Margarine	• Syrup/jam
• Pap/Potato	• Peanut butter (counted as fat and protein) • Milk (FC milk/milk powder) • Eggs • Sardines/Pilchard • Liver • Chicken • Beef • Mutton • Pork		• Sugar
• Rice/Samp	• Beans		
• Vegetables	• Peanut butter		• Sugar

PAEDIATRIC HOSPITAL LEVEL ESSENTIAL MEDICINES LIST
CHAPTER 2: ALIMENTARY TRACT
NEMLC 25 AUGUST 2022 – REPORT

MEDICINE AMENDMENTS

SECTION	MEDICINE	ADDED/DELETED/NOT ADDED
2.2.1 Cholera	Azithromycin	Added
2.2.4 Diarrhoea, acute Shock	Sodium Chloride 0.9%	Dose and administration time amended.
2.2.4 Diarrhoea, acute Child failing oral/NGT treatment	½ darrows/dextrose 5%	Removed
	Sodium chloride 0.9% /dextrose 5%	Added
2.2.4 Diarrhoea, acute Flow chart for correction of dehydration	Flow chart	Updated
2.2.4 Diarrhoea, acute Hypokalaemia	Potassium IVI	Dosing outlined
2.2.4 Diarrhoea, acute Hypernatraemia	½ darrows/dextrose 5%	Removed
	Sodium chloride 0.9%/Dextrose 5% added	Added
2.2.4 Diarrhoea, acute Mineral and micronutrient supplementation	Zinc	Dose decreased

2.2.1 Cholera

Azithromycin: Added

In line with the latest National Institute for Communicable Diseases (NICD) Cholera alert for healthcare workers, Azithromycin was added as a treatment alternative. ⁵

2.2.4 Diarrhoea, acute

Acute shock

Sodium Chloride 0.9%: Dose amended and administration time added.

The text was updated as follows:

- Sodium chloride 0.9%, IV, ~~20~~10 mL/kg given as a bolus over 20 minutes.

Although there is no specific evidence for this amendment, the recommendation is considered best practice and in line with recommendations by Paediatric Advanced Life Support (PALS) and Advanced Paediatric Life Support (APLS). Additionally this is in line with recommendations for the management of septic. This will allow for consistency in treatment across all types of shock.

⁵ National Institute for Communicable Diseases: Cholera Alert for Healthcare Workers 2019. https://www.nicd.ac.za/wp-content/uploads/2019/04/CHOLERA-ALERTforHCW_4-April-2019.pdf

Failing to oral/NGT treatment

½ darrows/dextrose 5%: Removed

Sodium chloride 0.9%/dextrose 5%: Added

The use of an isotonic solution in combination with 5% dextrose is in line with clinical guidelines, included in the National Institute for Health and Clinical Excellence (NICE) guideline.⁶

The text was reordered to emphases continuing with oral rehydration. The text was amended as follows:

2b) If the above treatment (oral/NGT treatment) fails, and patient was in shock or has already failed at primary health care level then:

IV fluid *

- ~~• ½ Darrows/Dextrose 5%, IV, 10 mL/kg/hour administered for 4 hours, then re-assess.~~

~~* (This rate is in line with current safety evidence but the need for regular reassessment 4-hourly remains.)~~

PLUS

Oral rehydration solution

- Oral rehydration solution (ORS), oral, 80 mL/kg over 4 hours using frequent small sips (i.e. 5 mL/kg every 15 minutes for 4 hours) or NGT rehydration 20 mL/kg/hour over 4 hours.

PLUS

Oral feeds at normal feed volumes and times if:

- the level of consciousness is normal,
- the child is not in severe distress,
- not shocked and,
- has no surgical abdomen.

PLUS

IV fluid *

- Sodium Chloride 0.9%/Dextrose 5%, IV, 10 mL/kg/hour administered for 4 hours, then re-assess.
 - Alternative isotonic fluids can be used, e.g. sodium chloride 0.9% or modified ringers lactate.

* (This rate is in line with current safety evidence but the need for regular reassessment 4-hourly remains.)

Figure 1: Summary flow chart for correction of dehydration in diarrhoeal disease

Flow chart updated to be in line with text changes.

Hypokalaemia

The dosing concentration of potassium IVI was specified for clarity as follows:

- Potassium IVI replacement:

- The maximum concentration of potassium in a litre of fluid is 40mmol and should not exceed 0.5 to 1 mmol/kg/hour. For sodium chloride 0.9%/dextrose 5%, the maximum volume of 15% potassium chloride in 1L is 20ml. (1ml 15% KCl has 2 mmol potassium)

- ~~If Potassium < 2.5 mmol/L:~~

- ~~½ Darrows /dextrose 5%, 200 mL plus potassium chloride 15%, 2 mL, into the fluid bag:~~

- ~~1 mL potassium chloride 15% = 2 mmol potassium. If 2 mL is added in the above solution it gives a combined K⁺ of 37 mmol/L — do not exceed this amount.~~

- Mix well before administration.

- Run at normal rehydration rate (as above).

⁶ National Collaborating Centre for Women's and Children's Health (UK). Diagnosis, Assessment and Management in Children Younger than 5 Years. *NICE Clinical Guidelines, No. 84*. London: RCOG Press; 2009.

Hypernatraemia (>150 mmol/L)

½ darrows/dextrose 5%: Removed

Sodium chloride 0.9%/Dextrose 5%: Added

Mineral and micronutrient supplementation:

Zinc dose: lowered

A multicenter randomized trial found that using lower doses of zinc had noninferior efficacy for the treatment of diarrhea in children and were associated with less vomiting than the standard 20 mg/day dose.⁷

- The percentage of children with diarrhoea for more than 5 days was 6.5% in the 20 mg group, 7.7% in the 10-mg group, and 7.2% in the 5 mg group. The difference between the 20 mg and 10 mg groups was 1.2 percentage points (upper boundary of the 98.75% confidence interval [CI], 3.3), and that between the 20 mg and 5 mg groups was 0.7 percentage points (upper boundary of the 98.75% CI, 2.8), both of which were below the set noninferiority margin of 4 percentage points.
- Vomiting within 30 minutes after administration occurred in 19.3%, 15.6%, and 13.7% of the patients in the 20 mg, 10 mg, and 5 mg groups, respectively; the risk was significantly lower in the 10 mg group than in the 20 mg group (relative risk, 0.81; 97.5% CI, 0.67 to 0.96) and in the 5 mg group than in the 20 mg group (relative risk, 0.71; 97.5% CI, 0.59 to 0.86).

The text was amended as follows:

- Zinc (elemental), oral, 10 mg/day for 14 days:
 - ~~If < 10 kg:~~ 10 mg/day.
 - ~~If > 10 kg:~~ 20 mg/day.

⁷ Dhingra U, et.al. Lower-dose zinc for childhood diarrhea – a randomized, multicenter trial. New England Journal of Medicine. 2020, 383: 1231-1241.