Department of Paediatrics
Paediatric Infectious Disease Service
Mater Dei Hospital
Tal-Qroqq, Msida
MSD 2090
Mater Dei Hospital

ANTIBIOTIC GUIDELINES

NPICU

Written by:	Dr David Pace	Department of Paediatrics
Checked and approved by:	Prof Simon Attard-Montalto	
	Dr Raymond Parascandalo	
	Dr Paul Soler	
	Dr Michael Borg	Infection Control Unit
	Dr Christopher Barbara	Pathology Department
	Antibiotic Team	Mater Dei Hospital
	Ms Ann-Marie Cassar Flores (author of Reconstitution and Administration section)	Pharmacy Department
Effect date	25th February, 2013	

INITIAL ANTIBIOTIC REGIMES FOR NEONATES WITH SEPSIS

<table>
<tr><th>Sepsis syndrome</th><th colspan="2">Antibiotics</th></tr>
<tr><td>Early onset sepsis
(<72 hours old)</td><td>Benzylpenicillin + gentamicin</td><td rowspan="3">Add Cefotaxime if suspicion of meningitis or if there is no response to initial antibiotic regimen</td></tr>
<tr><td>Late onset sepsis (in neonates >72 hours old admitted from home or obstetric wards)</td><td>Amoxicillin + gentamicin
(switch amoxicillin to flucoxacillin if clinical evidence of Staph. infection)</td></tr>
<tr><td rowspan="2">Late onset sepsis for term neonates and preterm infants >72 hours old already on NPICU</td><td>Amoxicillin + gentamicin
If neonate has central line: change amoxicillin to teicoplanin</td></tr>
<tr><td colspan="2">Switch to meropenem + gentamicin if G-ve rods seen in CSF or isolated from blood cultures pending availability of antibiotic susceptibility or if there is no response to initial antibiotic regimen (keep teicoplanin if has central line)</td></tr>
<tr><td>Late onset sepsis in infants with indwelling ventricular device or central line</td><td>Teicoplanin + gentamicin</td><td>Add meropenem if suspicion of meningitis</td></tr>
<tr><td>Necrotising Enterocolitis</td><td colspan="2">Amoxicillin (Teicoplanin if have central line) + gentamicin + metronidazole</td></tr>
<tr><td>Neonates born to mothers with suspected chorioamnionitis</td><td>Amoxicillin + gentamicin</td><td>Add Cefotaxime if suspicion of meningitis</td></tr>
</table>

ANTIBIOTIC DOSING, RECONSTITUTION AND ADMINISTRATION GUIDELINES

Antibiotic	Age	Dose	Frequency	Intravenous Administration	Special circumstances
Amoxicillin	<7 days	50mg/kg	12 hourly	Infusion over 30 minutes	Use 100mg/kg in meningitis in <28 days of age
	7-28 days	50mg/kg	8 hourly		
	>28 days	50mg/kg	4-6 hourly		No dose change for meningitis if >28 days old
Benzylpenicillin	<7 days	50mg/kg	12 hourly	Infusion over 30 minutes	Use 75mg/kg 8 hourly in meningitis
	≥7-28 days	50mg/kg	8 hourly		
Cefotaxime	<7 days	50mg/kg	12 hourly	Slow injection over 3-5 minutes	Give 6 hourly in severe infections and meningitis ONLY if **> 21 days old**
	7-21 days	50mg/kg	8 hourly		
	21-28 days	50mg/kg	6-8 hourly		
	>28 days	50mg/kg	8 hourly		

ANTIBIOTIC DOSING, RECONSTITUTION AND ADMINISTRATION GUIDELINES

Antibiotic	Age	Dose	Frequency	Intravenous Administration	Special circumstances
Flucloxacillin	<7 days	25mg/kg	12 hourly	Slow injection over 3-4 minutes	Give double dose in severe infection
	7-21 days	25mg/kg	8 hourly		
	21 – 28 days	25 mg/kg	6 hourly		
	>28 days	12.5 – 25mg/kg	6 hourly		
Gentamicin	**SEE SEPARATE PROTOCOL: PID002 ver 1**				
Meropenem	<7 days	40mg/kg	12 hourly	Infusion over 15-30 minutes	Use **40 mg/kg in meningitis** in infants > 28 days old
	7 – 28 days	40mg/kg	8 hourly		
	>28 days	20mg/kg	8 hourly		

ANTIBIOTIC DOSING, RECONSTITUTION AND ADMINISTRATION GUIDELINES

Antibiotic	Age	Dose	Frequency	Intravenous Administration	Special circumstances
Metronidazole	Birth – 2 months	7.5mg/kg	12 hourly	Infusion over 20 – 30 minutes	
	≥2 months	7.5mg/kg	8 hourly		
Teicoplanin	<28 days	**Loading dose: 16mg/kg;** then 24 hours later 8mg/kg	Once daily	Infusion over 30 minutes	
	≥28 days	**Loading doses: 10mg/kg for 3 doses;** then 24 hours later 6mg/kg	Loading doses: 12 hourly; Subsequent doses once daily		In severe infections or neutropenia: 10 mg/kg every 12 hours for 3 doses then 10 mg/kg once daily

ANTIBIOTIC DOSING, RECONSTITUTION AND ADMINISTRATION GUIDELINES

General Points:

1. **ALL** drugs have a potential of **displacement volume**; if part vial is required, displacement volume must be taken into consideration for ALL drugs.
2. Information provided for each drug is specific to the mentioned **brand**. In the event that brands change, the Patient Information Leaflet / Summary of Product Characteristics for that particular brand should be consulted.
3. Be aware of the **sodium-content of medications** when using Sodium chloride 0.9% infusion fluid as the diluent of choice in patients with renal failure, heart failure and those on a restricted sodium intake.

Name of Antibiotic	Reconstitution Instructions ADMINSTER DOSE PRESCRIBED ON TREATMENT CHART	Route of Administration	Comments
Amoxicillin 250 mg powder (Bowmed), 500 mg (Bowmed)	i. Dissolve 250 mg in 5 mL water for injection OR dissolve 500 mg in 10 mL water for injection ii. May be further diluted with 5% glucose or 0.9% sodium chloride for administration by infusion	Intravenous infusion over 30 minutes	
Benzylpenicillin 600 mg powder (Crystapen; Genus Pharmaceuticals)	i. Dissolve 600mg in 10 mL 0.9% sodium chloride or water for injection. ii. Dilute as necessary using 0.9% sodium chloride or 5% glucose.	Intravenous infusion over 30 minutes	For patients with renal failure, heart failure and who are fluid- restricted, benzylpenicillin sodium BP should **not** be reconstituted in sodium-containing liquids such as sodium chloride Injection because of sodium overload and/or heart failure.
Cefotaxime 1g powder (Wockhart)	i. Reconstitute 1g with 4mL water for injection or 0.9% sodium chloride	Intravenous injection over 3 - 5 minutes	
Flucloxacillin 250 mg powder (Wockhart)	i. Dissolve 250 mg in 5 mL water for injection. ii. May be further diluted in 0.9% sodium chloride or 5% glucose	Intravenous injection over 3 - 4 minutes	

ANTIBIOTIC DOSING, RECONSTITUTION AND ADMINISTRATION GUIDELINES

Name of Antibiotic	Reconstitution Instructions ADMINSTER DOSE PRESCRIBED ON TREATMENT CHART	Route of Administration	Comments
Gentamicin 80 mg/2 mL solution (Hospira)	i. Dilute 1ml (40mg) in up to 20ml of 5% glucose or 0.9% sodium chloride	Intravenous infusion over 30 minutes	
Meropenem 500 mg powder (Sandoz)	i. Reconstitute 500 mg with 10 mL 0.9 % sodium chloride or 5 % glucose. ii. Dilute further up to 50 mL using the same diluent. iii. Calculate the volume required as prescribed	Intravenous infusion over 15–30 minutes	
Metronidazole 500 mg/100 mL (Braun)	No dilution is required.	Intravenous infusion over 20-30 minutes	
Teicoplanin 200 mg powder (Sanofi)	i. Add entire contents of the water ampoule slowly to the vial. ii. Roll gently until the powder is completely dissolved (avoid formation of foam) iii. Dilute up to 50 mL using 0.9% sodium chloride or 5% dextrose iv. Calculate the volume required as prescribed	Intravenous infusion over 30 minutes	If the solution does become foamy then allow to stand for about 15 minutes for the foam to subside. Concentration of reconstituted solution is 200 mg in 3 mL.

References:

B. BRAUN MELSUNGEN AG, 2006. Summary of Product Characteristics Metronidazole B. Braun 5mg/ml Solution for Infusion. *Medicines Authority*. [online]. Available from: http://www.medicinesauthority.gov.mt/products/SPC_MA223%2000501_Metronidazole%20B.Braun%20500mg_Solution%20for%20infusion_Metronidazole%205mg%20per%20ml_B.%20Braun%20Melsungen%20AG_Germany_PoM_J01XD01_30.10.06.pdf [Accessed 18 February 2013].

BOWMED LIMITED, 2009. Amoxicillin 250 mg, 500 mg or 1 g, Powder for Solution for injection or Infusion (package insert). Herts: Bowmed Limited.

GENUS PHARMACEUTICALS, 1999. Summary of Product Characteristics Crystapen Injection. *Electronic Medicines Compendium*. [online]. Last updated 2008 Available from: http://www.medicines.org.uk/EMC/medicine/2962/SPC/Crystapen+Injection [Accessed 18 February 2013].

HOSPIRA UK LTD, 2010. Summary of Product Characteristics Gentamicin 40 mg/ml Injection. *Electronic Medicines Compendium*. [online]. Last updated 2011Available from: http://www.medicines.org.uk/EMC/medicine/21665/SPC/Gentamicin+40+mg+ml+Injection/ [Accessed 18 February 2013].

PAEDIATRIC FORMULARY COMMITTEE, 2012-2013. *British National Formulary for Children*. London: BMJ Group, Pharmaceutical Press, and RCPCH Publications.

SANDOZ, 2010. Summary of Product Characteristics Meropenem 500 mg, powder for solution for injection. *Medicines Authority*. [online]. Available from: http://www.medicinesauthority.gov.mt/products/SPC_MA685%2001601_Meropenem%20500mg_Powder%20for%20Solution%20for%20Injection%20and%20Infusion_Meropenem%20Trihydrate%200.57078grams_Sandoz%20Pharmaceuticals%20DD_Slovenia_PoM_J01DH02_09.09.10.pdf [Accessed 18 February 2013].

SANOFI, 2006. Summary of Product Characteristics Targocid® 200 mg. *Medicines Authority*. [online]. Last updated 2012 Available from: http://www.medicinesauthority.gov.mt/products/SPC_MA082%2003401_Targocid%20200mg_Powder%20and%20solvent%20for%20solution%20for%20injection_Teicoplanin%20200mg_Sanofi-Aventis%20Malta%20Ltd._Malta_PoM_J01XA02_21.12.06.pdf [Accessed 18 February 2013].

WOCKHARDT UK LTD, 2002. Summary of Product Characteristics Cefotaxime Powder for solution for injection or infusion (Wockhardt UK Ltd). *Electronic Medicines Compendium*. [online]. Last updated 2008 Available from: http://www.medicines.org.uk/EMC/medicine/7339/SPC/Cefotaxime+Powder+for+solution+for+injection+or+infusion++(Wockhardt+UK+Ltd) [Accessed 18 February 2013].

WOCKHARDT UK LTD, 2003. Summary of Product Characteristics Flucloxacillin 250mg Powder for Solution for Injection or Infusion. *Electronic Medicines Compendium*. [online]. Last updated 2013. Available from: http://www.medicines.org.uk/EMC/medicine/13034/SPC/Flucloxacillin+250mg+Powder+for+Solution+for+Injection+or+Infusion/ [Accessed 18 February 2013].