



PAEDIATRIC

Tobramycin/Gentamicin Therapeutic Drug Monitoring

(Affix patient identification label here)

URN:

Family Name:

Given Names:

Address:

Date of Birth:

Sex: M F I

PURPOSE

The purpose of this worksheet is to provide specific drug dosing and therapeutic drug monitoring information to assist with safe prescribing of Tobramycin and Gentamicin in our paediatric patient population. This worksheet is intended to be used by medical, nursing and pharmacy staff.

All patients receiving Tobramycin/ Gentamicin should have appropriate drug levels ordered at the time of prescribing. All patients (except Cystic fibrosis patients) requiring more than 48 hours of Tobramycin/Gentamicin, need Infectious Diseases (ID) input and approval to receive ongoing therapy.

INSTRUCTIONS

Dosing: **Non-Cystic Fibrosis patients**

Commence dose of intravenous (IV) Tobramycin/Gentamicin at **age appropriate mg/kg dose**.

In obese patients, use ideal body weight for dose calculation.

Premature neonates (younger than 35 weeks post menstrual age): Please refer to Neonatal dosing recommendations on the CHQ AMS website – link: <https://www.childrens.health.qld.gov.au/chq/health-professionals/antimicrobial-stewardship/guidelines/neonatal-dosing>

Term Neonates week 1 to 4 of life: 5mg/kg/day

Infants over 1 month of age and Children younger than 10 years old: 7.5mg/kg/day (max 320mg initial dose)

Children >10 years old and adolescents: 6mg/kg/day (max 560mg initial dose)

Septic/critically ill children >10 years old: 7mg/kg/day (max 640mg initial dose)

Dosing: **Cystic Fibrosis patients**

Commence **IV Tobramycin** at:

- **1 month to 12 years of age:** 10mg/kg once daily (maximum 640mg initial dose) OR previously optimised mg/kg dose¹ adjusted for current weight (if less than 3 months has elapsed between admissions)
- **Adolescents more than 12 years of age:** 7.5mg/kg once daily (Maximum 640mg initial dose)
- **Caution:** Teenage patients dose requirements can decrease with increasing age (reduced renal clearance and volume of distribution with increasing age) – seek specialist advice on dosing.

Timing of dose: Doses are ideally charted for **administration at 8am DAILY** to allow 2 and 6 hour post dose levels to be collected in business hours (exception endocarditis; consult with Ward Pharmacist).

Reconstitution and administration: It is recommended that the aminoglycoside dose be made up to 30mL with Sodium Chloride 0.9% and given over 30 minutes via a syringe driver (60mL/hr) (unless patient is fluid restricted or a neonate – smaller volume may be required). It is important to record whether the line was primed with drug. Infusing faster or slower will change the peak serum tobramycin level (C_{max}). It is essential for nursing and medical staff to accurately record times for administration and blood sampling. Small deviations can alter the calculated area under the curve (AUC) and therefore accuracy of dose recommendations.

If administration duration/time variations occur, please note details and reason on this form.

THERAPEUTIC DRUG MONITORING

Cystic Fibrosis/Non CF Bronchiectasis:

Perform AUC therapeutic drug monitoring (a pair of blood samples taken 2-3 hours and 6-8 hours post dose - timed from start of infusion), after DOSE ONE and then as recommended by the clinical pharmacist in consultation with respiratory team. Recheck 2 hour and 6 hour post dose levels (to recalculate AUC) as well as renal function to ensure clearance has not changed, after each dose adjustment and after 7 days. Weekly urine dipstick for proteinuria is also required. Consider audiology in patients who are likely to receive prolonged/ repeated courses of aminoglycosides or who might be at risk of ototoxicity.

FOR ALL OTHER INDICATIONS

Uncomplicated infections (for example Urinary tract infections):

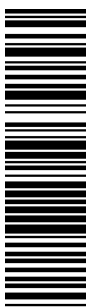
Perform a pre-dose (true trough) level before dose TWO or THREE if treatment is likely to continue for 72 hours or longer. Aim for trough level less than 1mg/L. (Caution: Trough level monitoring only indicates renal clearance of the aminoglycoside, not therapeutic efficacy).

Complicated infections (for example febrile neutropenia, sepsis/ septic shock, bacteraemias):

Perform AUC therapeutic drug monitoring after DOSE ONE or TWO if course is to continue for 5 or more days. Recheck 2 hour and 6 hour post dose levels (to recalculate AUC) as well as renal function to ensure clearance has not changed, after each dose adjustment and after 7 days.

Your Clinical Pharmacist is available for advice on all dose adjustments.

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Safety check before each dose:

- Check Tobramycin/ Gentamicin levels before next dose is given, and whenever '2 and 6 hour post dose levels' indicated on medication form.
- If management plan not recorded, discuss results with Doctor (or Pharmacist) to ensure prescribed dose can be given.
- If Tobramycin/ Gentamicin results are not available prior to next dose (and no management plan documented), notify Doctor immediately and discuss whether to withhold pending results, or administer with or without taking a trough level prior. Document decision on this form (*Record management plan* section).

Nursing and Medical staff to complete

Date of blood tests: _____ Weight: _____ kg Height: _____ cm

Line primed with drug: Yes No Mode of administration: Burette Syringe driver

Indication for therapy: Cystic Fibrosis Bronchiectasis Other (specify): _____

Aminoglycoside: Tobramycin Gentamicin Dose (mg): _____

Actual infusion start time² (hh:mm): _____ Actual administration finish time² (hh:mm): _____

Actual time blood taken (2-3 hours post start of infusion) T1 (hh:mm): _____

Actual time blood taken (6-8 hours post start of infusion) T2 (hh:mm): _____

Accurate recording of times for administration and blood sampling is essential as small deviations can alter the interpretation of trough level results and accuracy of dose recommendations.

If administration duration/time variations occur, please note details and reason on this form.

To reduce risk of contamination when collecting Tobramycin/Gentamicin blood samples from Central venous access devices (CVAD), flush CVAD with Sodium chloride 0.9% 5-10mL, then draw back and discard 5-10mL blood from CVAD, before taking sample.

PHARMACY USE ONLY

THERAPEUTIC DRUG MONITORING TARGETS

• Cystic Fibrosis – Tobramycin:

Pseudomonas eradication: AUC 90-110, Cmax 25-35mg/L, C24 <0.5mg/L

Pseudomonas negative or chronic pseudomonas colonisation: AUC 80-100, Cmax 25-35mg/L, C24 <0.5mg/L

• Other indications (including Bronchiectasis) – Tobramycin/Gentamicin:

Empiric target: AUC 70-90, Cmax >20mg/L, C24 <0.5mg/L

Directed therapy: Minimum inhibitory concentration (MIC) for micro-organism cultured may inform the Cmax targets to ensure therapeutic efficacy. Seek ID specialist or AMS Pharmacist advice.

Dose recommendations are based on attainment of the targets. Consider patient's clinical condition, microbiology results and concomitant drug therapy.

When dose change is indicated

- **The calculation from the AUC calculator is only a guide.** Dose changes should be in the order of **1-2mg/kg** at a time.
- Consider ease of administration when finalising total dose (e.g. round for easy and accurate measurement).
- **Repeat the 2 hour and 6 hour blood test** after next dose (maximum 3 paired tests per week OR per Consultant decision).

When decision is to remain on current dose

- For critically ill OR renally impaired patients retest 2 hour and 6 hour levels in approximately 2 to 3 days time.
- For non-critically ill patients (with stable renal function), recheck patient clearance with a 2 hour and 6 hour post dose Aminoglycoside level in 7 days time and compare to baseline result.

²**Note:** A 10 minute discrepancy can result in a clinically significant dose error.

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AUC Calculator available: http://qheps.health.qld.gov.au/rch/docs/pharmacy/AUC_cal.xls

Concentration at T1 (mg/L):

Concentration at T2 (mg/L):

AUSLAB/AUSCARE times correlate with ward recorded times: Yes No

Calculated AUC (mg/L*hr):

Predicted C_{max} (mg/L):

Predicted C₂₄ (mg/L):

Record Management Plan – Date: / /

*For example: AUC in range, C_{max} and C₂₄ good – remain current dose, retest 6 hour level in 7 days.
Discussed with Dr X Paed reg OR AUC & C_{max} targets not obtained, require dose increase to X mg and retest 2 & 6hr level.
Discussed with Dr X PICU reg.*

Further reading: Young et al (2013), Optimization of anti-pseudomonal antibiotics for cystic fibrosis pulmonary exacerbations: V. Aminoglycosides. *Pediatr. Pulmonol.*, 48: 1047–1061.

★ **Print and attach a copy of the AUC calculation to this form for scanning and filing into ieMR** ★

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