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.

Neonates week 1 of life (term): 5mg/kg/day
Neonates week 2 of life (term) and children <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:
• previously optimised mg/kg dose adjusted for current weight OR
• if extended time (>1 year) has elapsed between admissions 10mg/kg/day (maximum 640mg initial dose)
• Caution: Teenage patients dose requirements can decrease 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 (Cmax).

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.

AUC therapeutic drug monitoring requires a pair of blood samples ➤ 2-3 hours and 6-8 hours post dose:
• For Cystic Fibrosis/Non CF Bronchiectasis after DOSE ONE and then as recommended by the clinical pharmacist in consultation with respiratory team.
• For all other indications after DOSE ONE or TWO if course is to continue for 5 or more days

After 7 days, recheck 2 hour and 6 hour post dose levels (to recalculate AUC) as well as renal function to ensure clearance has not changed. Weekly urine dipstick for proteinuria is also required.

Consider audiology in patients who are likely to receive prolonged/repeated courses of aminoglycosides.

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

1 This can be accessed in business hours by calling the Ward Pharmacist, or from previous admission medication charts.
Tobramycin/Gentamicin Therapeutic Drug Monitoring

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

<table>
<thead>
<tr>
<th>Date of blood tests:</th>
<th>Weight: kg</th>
<th>Height: cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Line primed with drug: Yes ☐ No ☐</td>
<td>Mode of administration: ☐ Burette ☐ Syringe driver</td>
<td></td>
</tr>
</tbody>
</table>

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.

Pharmacy Use Only

THERAPEUTIC DRUG MONITORING TARGETS

- Cystic Fibrosis: Tobramycin ➤ AUC 90-110, Cmax 25-35mg/L, C24 <0.5mg/L
- Other indications (including Bronchiectasis): Tobramycin/Gentamicin ➤ AUC 70-90, Cmax >20mg/L, C24 <0.5mg/L

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 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.

²Note: A 10 minute discrepancy can result in a clinically significant dose error.
Tobramycin/Gentamicin Therapeutic Drug Monitoring

Pharmacy Use Only


<table>
<thead>
<tr>
<th>Concentration at T1 (mg/L):</th>
<th>Concentration at T2 (mg/L):</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Calculated AUC (mg/L*hr):</th>
<th>Predicted Cmax (mg/L):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Predicted C24 (mg/L):</th>
</tr>
</thead>
</table>

Record Management Plan – Date: / /

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


★ Print and attach a copy of the AUC calculation to this form for scanning and filing into iEMR ★
Tobramycin/Gentamicin
Therapeutic Drug Monitoring

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

<table>
<thead>
<tr>
<th>Date of blood tests:</th>
<th>Weight: kg</th>
<th>Height: cm</th>
</tr>
</thead>
</table>

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 time\(^2\) (hh:mm):

Actual administration finish time\(^2\) (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.

Pharmacy Use Only

THERAPEUTIC DRUG MONITORING TARGETS
- Cystic Fibrosis: Tobramycin ▶ AUC 90-110, \(C_{\text{max}}\) 25-35mg/L, C24 <0.5mg/L
- Other indications (including Bronchiectasis): Tobramycin/Gentamicin ▶ AUC 70-90, \(C_{\text{max}}\) >20mg/L, C24 <0.5mg/L

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 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.
Tobramycin/Gentamicin
Therapeutic Drug Monitoring

<table>
<thead>
<tr>
<th>Pharmacy Use Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration at T1 (mg/L):</td>
</tr>
<tr>
<td>AUSLAB/AUSCARE times correlate with ward recorded times:</td>
</tr>
<tr>
<td>Calculated AUC (mg/L*hr):</td>
</tr>
<tr>
<td>Predicted C24 (mg/L):</td>
</tr>
</tbody>
</table>

| Record Management Plan – Date: | / | / |

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


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