**Canberra Health Services**

**Clinical Procedure**

**Intravenous Dosing and Monitoring of Aminoglycosides (gentamicin, tobramycin and amikacin) in Adults**

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| Purpose  |

To ensure the safe prescribing, administration and monitoring of intravenous aminoglycoside therapy for the treatment of systemic infection at Canberra Health Services (CHS).

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| Scope |

All approved Canberra Health Services (CHS) staff working within their scope of practice that prescribe, administer, monitor or advise on the use of intravenous aminoglycosides at Canberra Hospital and Health Services.

Approved health professionals working within their scope of practice should refer to the information in this document for the dosing, administration and monitoring of aminoglycoside therapy.

**Exclusions**

This procedure does not apply to:

* Routes of administration other than intravenous eg. inhaled, intra-peritoneal, topical or implantation
* Paediatrics – see [paediatric guidelines](http://www.cec.health.nsw.gov.au/__data/assets/pdf_file/0011/386291/Safe-Gentamicin-Prescribing-In-Paediatrics-Oct-2017.pdf)

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| Alerts  |

* Gentamicin and Tobramycin are “ORANGE” restricted antimicrobials: ID/AMS approval is required after 3 days of therapy
* Amikacin is a “RED” restricted antimicrobial: ID/AMS approval is required within the first 24 hours of prescription

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| Medication information  |

 **Mechanism of action**

Aminoglycosides inhibit bacterial protein synthesis by binding to a protein on the 30S subunit of bacterial ribosomes, resulting in cell membrane damage and cell death.

**Contraindications and Precautions**

Renal impairment is not an absolute contraindication to aminoglycosides. For patients with renal impairment, a single dose of aminoglycoside, with no subsequent doses, can be life-saving and is generally safe. If the patient may still require broad spectrum Gram-negative cover longer than 1 day, consultation with an Infectious Diseases Specialist or the Antimicrobial Stewardship Team is advisable.

**Absolute Contraindications:**

* Hypersensitivity to aminoglycosides
* Previous aminoglycoside-induced ototoxicity or nephrotoxicity

**Precautions:**

* Renal impairment
* Renal service should be consulted if patient’s Creatinine Clearance is less than 30mL/min for authorisation of further doses
* Pre-existing hearing impairment
* Neuromuscular disease
* Elderly
* Family history of aminoglycoside toxicity

**Presentation**

* Gentamicin sulphate 40mg/mL solution for injection
* Tobramycin sulphate 40mg/mL solution for injection
* Amikacin sulphate 250mg/mL solution for injection

**Interactions**

* Avoid concurrent administration with other nephrotoxic drugs
* Potent diuretics such as high dose frusemide may contribute to ototoxicity and may also cause alterations in serum and tissue concentrations
* Neuromuscular blocking activity of some drugs, such as anaesthetic agents or opioid analgesics may be enhanced

**Adverse Effects**

* Nephrotoxicity (usually reversible)
* Gradual worsening of renal function, increasing creatinine and proteinuria
* May present as acute tubular necrosis
* More common in patients with pre-existing renal impairment
* Associated with increased duration of therapy and large exposures
* See [paediatric guidelines](http://www.cec.health.nsw.gov.au/__data/assets/pdf_file/0011/386291/Safe-Gentamicin-Prescribing-In-Paediatrics-Oct-2017.pdf) for monitoring requirements
* Ototoxicity (irreversible in approximately half of cases)
* Nausea, vertigo
* Tinnitus
* High frequency hearing loss in up to 26% patients treated
* See [Section 2.4](#_Section_2.4._Clinical) for monitoring requirements
* Neuromuscular blockade
* May result in respiratory depression

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| Section 1: Prescribing the initial dose |

Empiric aminoglycoside dosing is dependent on the patient group and the clinical indication. Aside from the special patient considerations listed below, the majority of patients will be managed as per Section [1.1](#_Section_1.1:_Standard) and [1.2](#_Section_1.2:_Standard) (Standard dosing for gentamicin/tobramycin and amikacin).

**Intra-operative surgical prophylaxis**

Dosing for this indication is dependent on the surgical procedure and may vary from the doses recommended in this document. Refer to Therapeutic Guidelines: Antibiotic for more information.

**Special patient considerations: pregnancy, cystic fibrosis, mycobacterial infections and endocarditis**

These indications have unique dosing recommendations, please refer to [Section 1.3](#_Section_1.3_–) for guidance.

## Section 1.1: Standard gentamicin/tobramycin dosing

1. Determine the **total body weight** and age of the patient
2. Determine if the patient has severe sepsis
* For example: hypotension, high lactate or end organ dysfunction secondary to sepsis
1. Refer to the dose recommendations in Table 1
2. Calculate your dose to the mg then round the total dose UP to the nearest multiple of 40mg
3. Cap the dose to the maximum dose if the recommended dose is higher than the calculated dose
4. Dosing frequency is once daily – chart the initial dose on the ‘once only/stat’ section of the medication chart, and subsequent doses on the ‘variable dose’ section

Table 1: Gentamicin/tobramycin dosing table in patients without special considerations

|  |  |  |
| --- | --- | --- |
| **ADULT Once Daily IV gentamicin/tobramycin starting dose**  | **Standard Dosing**  | **Severe Sepsis**  |
|  | Age  | Dose  | Maximum Dose  | Dose  | Maximum Dose  |
| Females  | <75 yrs | 5-6 mg/kg | 400mg  | 7 mg/kg  | 480mg  |
|  | >75 yrs | 4 mg/kg  | 280mg  | 6 mg/kg  | 400mg  |
| Male  | <75 yrs | 5-6 mg/kg  | 480mg  | 7 mg/kg  | 560mg  |
|  | >75 yrs | 4 mg/kg  | 320mg  | 6 mg/kg  | 440mg  |

## Section 1.2: Standard amikacin dosing

1. Determine the **total body weight**, age of the patient
2. Determine if your patient has severe sepsis or not
* For example: hypotension, high lactate or end organ dysfunction secondary to sepsis
1. Refer to the dose recommendation in Table 2
2. Calculate your dose to the mg then round the total dose UP to the nearest multiple of 250mg
3. Cap the dose if the recommended dose is higher than the calculated dose
4. Dosing frequency is once daily – chart the initial dose on the ‘once only/stat’ section of the medication chart, and subsequent doses on the ‘variable dose’ section

Table 2: Amikacin dosing table in patients without special considerations

|  |  |  |
| --- | --- | --- |
| **ADULT Once Daily IV amikacin starting dose** | **Standard Dosing** | **Severe Sepsis** |
|  | Age | Dose  | Maximum Dose | Dose  | Maximum Dose |
| Females  | <75 yrs | 20-25 mg/kg | 1750mg | 30 mg/kg | 2000mg |
|  | >75 yrs | 15 mg/kg | 1250mg | 25 mg/kg | 1750mg |
| Male  | <75 yrs | 20-25 mg/kg | 2000mg | 30 mg/kg | 2250mg |
|  | >75 yrs | 15 mg/kg | 1250mg | 25 mg/kg | 1750mg |

## Section 1.3: Dosing in patients with special considerations

### Section 1.3.1: Cystic Fibrosis

Dosing requirements are higher in this population due to altered volume distribution and increased drug clearance. Aminoglycosides, particularly tobramycin, are commonly used for ‘tune-ups’ or infective exacerbations in patients colonised with *Pseudomonas*. Dosing weight should be calculated in this population using total body weight, as this is often lower than the ideal body weight.

Chart in the ‘Variable dose’ section of the medication chart:

Table 3: Starting doses in cystic fibrosis

|  |  |
| --- | --- |
| **Gentamicin/Tobramycin:**  | **Amikacin:** |
| 10 mg/kg x total body weight up to 660mg once daily OR Same dose used last admission if guided by previous Therapeutic Drug Monitoring. | 30-35 mg/kg x total body weight up to 2500mg once-daily ORSame dose used as last admission if guided by previous Therapeutic Drug Monitoring |

For mycobacterial infections, dose according to [Section 1.3.4](#_Section_1.3.4:_Mycobacterial) instead.

### Section 1.3.2: Aminoglycosides in Pregnancy

Use of aminoglycosides in pregnancy should be reserved for severe or life-threatening infections for which safer drugs are inappropriate. For more information consult the ward pharmacist, Medicines Information (ext. 43333), Antimicrobial Stewardship team (ext. 43378), or obstetrics.

Dosing weight should be calculated using **pre-pregnancy, total body weight.** Chart on the ‘variable dose’ section of the medication chart.

For standard indications, dose as per [Table 1](#_Section_1.1:_Gentamicin/tobramycin) for gentamicin/tobramycin, and [Table 2](#_Section_1.2:_Amikacin) for amikacin using the appropriate dosing weight.

For non-standard indications, refer to the relevant section for dosage and management, or consult the Infectious Diseases/Antimicrobial Stewardship teams.

### Section 1.3.3: Endocarditis

* Empiric therapy (organism unknown) – Prescribe once-daily dosing as per [Section 1.1](#_Section_1.1:_Gentamicin/tobramycin)
* Directed therapy – Prescribe synergistic therapy as below:

Gentamicin use in this setting is for synergy with penicillins and glycopeptides for gram positive organisms (see Therapeutic Guidelines for more information). Management should be guided by Infectious Diseases. The aim is to provide stable, detectable serum drug concentrations rather than concentration-dependent killing with high peaks and low troughs. Chart in the ‘regular medicines’ section of medication chart as per Table 4.

Table 4: Empiric gentamicin dosing for synergistic therapy

|  |  |
| --- | --- |
| Creatinine Clearance  | Gentamicin Dose (IBW) |
| CrCL ≥60 mL/min | 1 mg/kg 8-hourly |
| CrCL 30-60 ml/min | 1 mg/kg 12-hourly |
| CrCL if <30 ml/min | 1 mg/kg 24-hourly |

Refer to the [Appendix](#_Appendix) 1 for guidance on dose calculations using ideal body weight (IBW).

The use of once-daily dosing (i.e. 3 mg/kg 24-hourly) for synergistictherapy is not yet widely accepted as there is only limited evidence supporting its use for certain organisms. Use of this regimen should be on the advice of Infectious Diseases only.

### Section 1.3.4: Mycobacterial infections

Amikacin is used in combination with other antimicrobials for mycobacterial infections such as Multi-Drug resistant Tuberculosis and Non-Tuberculosis Mycobacterium, under the guidance of Infectious Diseases.

There is limited data on the optimal dose and regimen for this indication and the choice of regimen will depend on the assessment of the individual patient by Infectious Diseases or Respiratory (if infection is pulmonary in origin). The chosen regimen may differ from those listed below.

Commonly used starting doses for amikacin (using Ideal Body Weight – see [Appendix](#_Appendix) 1):

10-15 mg/kg daily 5-7 days a week\*
OR
25 mg/kg 2-3 times a week (if CrCL≥50 ml/min)\*\*

\*For dosage adjustment in renal impairment, see Table 5.

\*\*If CrCL < 50 ml/min, renally adjust from a starting dose of 10-15mg/kg daily as per Table 5.

Table 5: Dosage adjustment of daily amikacin in renal impairment for mycobacterial infection\*

|  |  |  |
| --- | --- | --- |
| Renal function (CrCL) | Percentage of dose | Dosing frequency |
| > 50 ml/min | 50-100% | 24-hourly |
| 10-50 ml/min | 50% | 48-hourly |
| <10 ml/min | 30% | 48-hourly |
| Dialysis/Renal Replacement therapy | Seek expert advice |

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| Section 2: Monitoring and prescribing of subsequent doses |

Ongoing dosing should be determined by Therapeutic Drug Monitoring (TDM). The aim of TDM is to ensure the dose is adequate and to avoid excessive drug exposure. Monitoring should ideally occur after the first dose in all patients.

**Alert:**

* For patients with severe sepsis or renal impairment, TDM after the first dose is mandatory
* In patients with CrCL<40ml/min, aminoglycosides should not be continued after the first dose unless on the advice of the renal unit
* Consult your pharmacist if the renal unit has approved ongoing aminoglycoside use in a patient undergoing haemodialysis or another form of renal replacement therapy
* For all other patients groups, TDM is mandatory if receiving more than 48 hours of therapy, but should ideally occur after the first dose
* Therapeutic drug monitoring is not required for single dose treatment only, such as surgical prophylaxis
* Second daily dosing is also not recommended, consult AMS if adequate exposure cannot be safely achieved with daily dosing

**Unique indications: Endocarditis and mycobacterial infections**

These patient groups have unique TDM requirements, refer to [Section 2.3](#_Section_2.3:_TDM).

**Amikacin therapy (not for unique indications) and patients with altered pharmacokinetics**

If your patient fits into the following categories, refer to [Section 2.2: Two sample TDM](#_Section_2.2:_Two-Sample).

1. Patients with altered pharmacokinetics:
* Patients admitted to the Intensive Care Unit
* Patients in shock
* Obese patients (BMI >30 kg/m2)
* eGFR < 30mL/min (if further doses authorised by the renal service)
* Patients with quadriplegia
* Patients with cystic fibrosis
* Patients with ascites
* Patients with burns
* Pregnant patients

**For all other patients:** refer to [Section 2.1: Single sample TDM](#_Section_2.1:_).

## Section 2.1: Single sample TDM

This method provides a computer generated recommendation for subsequent dosing by estimating the Area-Under the Curve (AUC) and C max using a single drug concentration.

One serum sample **6-8 hours** after the beginning of the antibiotic infusion is required to perform TDM:

**Ordering the sample:**

Document on the pathology form:

1. Gent-D or Tobra-D, depending on whether gentamicin or tobramycin is used
2. Date and time infusion was started (24 hour time)
3. The dose administered (mg)
4. Patient’s total body weight (kg)
5. Time the blood sample is due (24 hour time)



Dosing recommendations cannot be calculated by the pathology system if this information is not provided. This information can be provided to pathology retrospectively after a separate pathology form is submitted with the supplemental information if not provided with the initial request.

**Reviewing results:**

* Access the Gent-D or Tobra-D result via the Clinical Information System (CIS)
* Ensure that all of the input information that is displayed on the result is correct
* Adjust the dose based on the recommendations listed on the pathology result
* If a dose recommendation cannot be made by the pathology program, consult your pharmacist or AMS (ext. 43378)

**Frequency of subsequent TDM**

* If a dose change is recommended, repeat TDM after the new dose has been given
* If the pathology recommendation is to continue the same dose, repeat TDM every 2-3 days
* More frequent monitoring may be required if the patient is unstable, e.g. fluctuating renal function
* Serial decreasing dose requirements can be an early indication of deteriorating renal function, consider ceasing aminoglycoside therapy if an acute kidney injury is suspected

## Section 2.2: Two-Sample TDM

This method provides a computer generated recommendation for subsequent dosing by estimating the Area-Under the Curve (AUC) and C max using two drug concentrations.

**Two-Sample TDM Procedure:**
Serum drug concentrations should be taken:

* 1 hour after the beginning of the antibiotic infusion (infusion duration of 30 minutes)
**AND**
* 6-8 hours after the beginning of the antibiotic infusion
* The second sample can be taken as late as 10 hours post, as long as the result is above the limit of detection

**Alert:**

Pathology cannot provide automated AUC optimised dosage recommendations for the following groups: **Cystic Fibrosis, Amikacin.** For these patients, order TDM as above and contact your pharmacist for interpretation of concentrations and subsequent dosage recommendations.

If the patient does not have cystic fibrosis, and is not being prescribed Amikacin, the pathology system can provide a dose recommendation from a Gentamicin/Tobramycin-D request.

Document on the pathology form:

1. Gent-D or Tobra-D, depending on whether gentamicin or tobramycin is used
2. Date and time infusion was started (24 hour time)
3. The dose administered (mg)
4. Patient’s total body weight (kg)
5. Time the blood sample is due (24 hour time)

**Reviewing results and subsequent dosing and monitoring:**

Results can be reviewed on the CIS and subsequent dosing managed as per [single-sample TDM](#_Section_2.1:_). For patients with cystic fibrosis or prescribed amikacin, consult your pharmacist for subsequent dosing and monitoring.

## Section 2.3: TDM for unique indications

This section applies to patients with mycobacterial infections and endocarditis.

### Section 2.3.1: Mycobacterial infections

Patients treated with amikacin for mycobacterial infections often require a prolonged course and the dosing regimen differs from that of standard bacterial infections. The best monitoring strategy is not well established, however regular trough concentrations are usually recommended to exclude accumulation and toxicity risk. Sampling at other times, such as peak concentrations, may be conducted to help characterise the pharmacokinetic profile in patient, particularly if the patient is expected to have unpredictable pharmacokinetics (e.g. renal failure, cystic fibrosis). Consult the AMS/ID pharmacist for further advice.

**Trough (pre-dose) concentrations**

Perform after the first dose, then weekly for the first 2 weeks, and then monthly thereafter. More frequent monitoring may be required if there is a change in dose or if the renal function is not stable. The target trough concentration is <0.3mg/L (below limit of detection). Reduce the dose if the measured trough concentration exceeds this – seek advice from your pharmacist.

**Peak concentrations**

Peak concentrations are not considered routine practice. Concentrations between 25-45mg/L have been reported in the literature after a 15mg/kg dose, and concentrations between 65-80mg/L have been reported after a 25mg/kg dose. These ranges are not considered to be validated clinical targets. If required, peak concentrations are measured 30 minutes after the completion of the infusion.

See [Section 2.4](#_Section_2.3.3_Clinical) for additional information for clinical monitoring required for prolonged courses of aminoglycoside therapy.

### Section 2.3.2 Endocarditis – synergistic dosing

Trough (pre-dose) gentamicin concentrations should be performed at least twice a week for gentamicin synergistic regimens (8-hourly or 12-hourly). In patients with acute changes to their renal function it may be necessary to monitor trough concentrations daily. Aim for Trough concentrations 0.5-1mg/L to minimise toxicity. If trough concentrations are elevated it may be necessary to reduce the dose or dose frequency as per Table 6.

Table 6: Dose adjustments for synergistic gentamicin

|  |  |
| --- | --- |
| **Trough concentration**  | **Dose adjustment** |
| >1mg/L | Decrease dose or frequency |
| 0.5-1mg/L | Continue current dose |
| Undetectable  | Increase dose or frequency |

See [Section 2.4](#_Section_2.3.3_Clinical) for additional information for clinical monitoring required for prolonged courses of aminoglycoside therapy.

## Section 2.4. Clinical monitoring requirements

Additional clinical patient monitoring should occur in addition to Therapeutic Drug Monitoring. For more in depth information, refer to [Therapeutic Guidelines: Antibiotic](https://tgldcdp.tg.org.au/viewTopic?topicfile=aminoglycoside-use-principles&guidelineName=Antibiotic#toc_d1e1628).

**Monitoring for nephrotoxicity**:

* EUCs at baseline and then at least 2 to 3 times a week, increasing the frequency of monitoring if renal function is unstable
* Stop aminoglycoside therapy if there is a significant decrease in renal function (e.g. increase in serum creatinine by ≥30 micromol/L or ≥1.5 times the baseline)
* Monitor serial calculated dose requirements from pathology or pharmacy and consider the possibility of an acute kidney injury if dose requirements are consistently decreasing
* If further antibiotic therapy required seek expert advice

**Monitoring for vestibular and auditory toxicity**:

* All patients should be informed, if possible, of the potential for vestibular and auditory toxicity
* Instruct patients to report any balance or hearing problems and ask patients receiving aminoglycosides on each clinical review about whether they are experiencing gait ataxia, imbalance, blurred vision during head movement, sensation of bouncing vision, or hearing loss
* Spontaneous vertigo is not a feature of vestibular toxicity
* For prolonged courses of aminoglycoside therapy (>5 days) formal vestibular and audiometry testing should be performed, if available – contact ext. 45261 to speak with the audiologist on duty for further advice
* Perform baseline testing and then repeat periodically (e.g. weekly)
* If vestibular or auditory toxicity is noted, stop the aminoglycoside and seek expert advice if ongoing antibiotic therapy is required
* The audiology service is available on Monday and Tuesdays only

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| Section 3: Drug Administration |

The preferred method of administration for aminoglycosides is as an infusion over 30 minutes, as this is factored into the methods used to calculate AUC when monitoring drug concentrations. Administration as a slow bolus injection is appropriate in certain circumstances and will yield a higher peak concentration. If this is done, the pharmacist should be alerted if TDM is being performed as this may affect the interpretation of drug concentrations. A summary of guidance is provided in Table 7.

Table 7: Recommendations for administration of aminoglycosides

|  |  |  |
| --- | --- | --- |
| **Drug** | **Infusion** | **Bolus** |
| Gentamicin/Tobramycin | In 50mL sodium chloride 0.9% over 30 minutes | Slow injection over 3-5 minutes.  |
| Amikacin | In 100mL sodium chloride 0.9% over 30 minutes | Slow injection over 3-5 minutes: only recommended for doses under 500mg |

For more information, consult the latest edition of the [Australian Injectable Drugs Handbook](http://acthealthlibrary.idm.oclc.org/login?url=http://aidh.hcn.com.au) via the CHS Library website.

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| Related Legislation, Policies and Standards |

**Policies**

* Medication Handling Policy

**Procedures**

* Antimicrobial Stewardship Procedure

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| Search Terms |

Intravenous Dosing, Monitoring, Aminoglycosides, gentamicin, tobramycin, amikacin

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| Attachments |

**Appendix 1 – Dosing calculation using Ideal Body Weight (IBW)**

**Disclaimer**: *This document has been developed by Canberra Health Services specifically for its own use. Use of this document and any reliance on the information contained therein by any third party is at his or her own risk and Canberra Health Services assumes no responsibility whatsoever.*

*Policy Team ONLY to complete the following:*

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| --- | --- | --- | --- |
| *Date Amended* | *Section Amended* | *Divisional Approval* | *Final Approval*  |
| *21 February 2018* | *Complete review* | *Lisa Gilmore, ED CSS* | *CHHS Policy Committee* |
|  | *Template and document updated to reflect current organisational structure* | *Policy Team Leader* | *Co-chair CHS Policy Committee*  |
| *24 June 2021*  | *Review date extended until 1 December 2021*  | *Dr Nick Coatsworth*  | *Kath Macpherson**A/g Senior Director, Policy, Planning and Government Relations* |

*This document supersedes the following:*

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| --- | --- |
| *Document Number* | *Document Name* |
| *CHHS12/326* | *Once-Daily Aminoglycosides (ADULTS) Dosing and Monitoring Clinical Guidelines for gentamicin and tobramycin* |
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## Appendix 1 – Dosing calculation using Ideal Body Weight (IBW)

* Males:  50 kg + 0.9 kg/cm for each cm over 152 cm
* Females:  45.5 kg + 0.9 kg/cm for each cm over 152 cm
* If the patient is obese, calculate 40% of the difference between the IBW and the total body weight and add this to the IBW to give an adjusted dosing weight.

|  |  |
| --- | --- |
| Height (cm) | IBW (kg) |
| Male | Female |
| 150 | 50 | 46 |
| 155 | 53 | 48 |
| 160 | 57 | 53 |
| 165 | 62 | 57 |
| 170 | 66 | 62 |
| 175 | 71 | 66 |
| 180 | 75 | 71 |
| 185 | 80 | 75 |
| 190 | 84 | 80 |