Royal Cornwall Hospitals
NHS Trust

Gentamicin Prescription and Therapeutic Drug Monitoring Clinical Guideline

V7.0

June 2024

1. Aim/Purpose of this Guideline

1.1. To provide guidance to RCHT staff on the prescription and therapeutic drug monitoring for ONCE daily gentamicin therapy.

1.2. This version supersedes any previous versions of this document.

Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

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2. The Guidance

2.1. Gentamicin has broad spectrum bactericidal activity against aerobic Gram-negative organisms. With good penetration into the urinary and gastrointestinal tracts.

2.2. For indications refer to the Trust Antimicrobial Guidelines on the Trust intranet or the Microguide app on mobile devices.

2.3. Gentamicin should be used as a single once daily dose regime including treatment of bacterial endocarditis.

2.4. Gentamicin is contra-indicated in patients with myasthenia gravis and should not be used in this patient group.

2.5. Gentamicin has a potentially toxic side effect profile. Side effects include:

- Nephrotoxicity.
- Ototoxicity.

2.6. Gentamicin should be used with caution in any patients with an impaired renal function. Due to a reduced rate of drug clearance and the potential for accumulation, this group of patients are particularly susceptible to the adverse effects of gentamicin therapy.

2.7. Ototoxicity can be attributable to gentamicin therapy and can be independent of drug concentration. If ototoxicity is suspected (new: hearing loss, tinnitus, vertigo, poor balance, hearing loss or oscillating vision). Stop treatment and refer to microbiologist or antimicrobial pharmacist for advice on alternative therapy. If gentamicin continues for >7 days, refer for a formal Audiology assessment

2.8. When prescribing gentamicin be aware of the other risk factors for AKI e.g., contrast dyes, NSAIDS, ACE inhibitors, concomitant vancomycin, sepsis, and hypotension as these patients are at risk of AKI.

2.9. These guidelines do not cover all scenarios e.g. If a patient's creatinine deteriorates during their illness (e.g. after the first dose or other doses of gentamicin)- it will be difficult to determine whether this is related to the systemic illness, or gentamicin toxicity, and it will also be difficult to determine whether the patient will benefit more from further gentamicin (to treat infection) or would benefit more from protecting renal function (and hence using an alternative antibiotic from that point onwards). Thus, clinical decision making with advice from senior medical colleagues (including microbiology consultants if necessary) is recommended. The severity of the acute kidney injury will need to be taken into account.

2.10. Remember, eGFR overestimates the true GFR in AKI patients. In evolving AKI please see paragraph 2.9.

2.11. Renal function should be determined using eGFR in non AKI patients.

2.12. This guideline excludes the following patients:

- Pregnant or breast feeding.
- <16 years of age.
- With ascites.
- With cystic fibrosis (higher doses usually indicated).
- Extensive Burns (>20% body surface area).
- CAPD peritonitis.
- End stage renal disease.

2.13. Please seek alternative guidance or discuss with a clinical microbiologist in these cases.

2.14. To minimise the risk of toxicity, duration of treatment should normally be limited to 72 hours. All gentamicin prescriptions that continue beyond 5 days of treatment must be discussed with microbiology or an infection specialist.

2.15. Gentamicin dosing table

Height		Age ≤65 years and eGFR >60mls/min Dose 5mg/kg		Age >65 years or eGFR ≤60mls/min Dose 3mg/kg	
Feet and inches	**Centi-metres**	**Male**	**Female**	**Male**	**Female**
5'	**152.40**	240mg	240mg	160mg	160mg
5'1"	**154.94**	240mg	240mg	160mg	160mg
5'2"	**157.48**	240mg	240mg	160mg	160mg
5'3"	**160.02**	320mg	240mg	160mg	160mg
5'4"	**162.56**	320mg	320mg	160mg	160mg
5'5"	**165.10**	320mg	320mg	240mg	160mg
5'6"	**167.64**	320mg	320mg	240mg	160mg
5'7"	**170.18**	320mg	320mg	240mg	240mg
5'8"	**172.72**	360mg	320mg	240mg	240mg
5'9"	**175.26**	360mg	320mg	240mg	240mg
5'10"	**177.80**	360mg	360mg	240mg	240mg
5'11"	**180.34**	360mg	360mg	240mg	240mg
6'	**182.88**	360mg	360mg	240mg	240mg
6'1"	**185.42**	440mg	360mg	240mg	240mg
6'2"	**187.96**	440mg	440mg	240mg	240mg
6'3"	**190.50**	440mg	440mg	240mg	240mg
6'4"	**193.04**	440mg	440mg	240mg	240mg
6'5"	**195.58**	440mg	440mg	240mg	240mg
6'6"	**198.12**	440mg	440mg	320mg	240mg
6'7"	**200.66**	440mg	440mg	320mg	240mg

2.16. Instructions for using the gentamicin dosing table

2.16.1. Dosing of gentamicin is determined based on 4 factors:

- Height (a surrogate of ideal body weight)*.
- Sex.

- Renal function.
- Age.

*Height records can often be found under the MUST assessment section in a patients Nervecentre profile, including previous admissions if there is difficulty obtaining this from the patient directly.

2.16.2. In patients with a BMI <18.5, dose based on the **actual body weight not** height as this will inaccurately represent the tissue distribution of gentamicin.

2.16.3. Select the appropriate dose based on these parameters from the dosing table above (2.12).

2.16.4. When gentamicin is indicated as adjunctive therapy in **infective endocarditis** use 3mg/kg**.** This should be informed by microbiology findings and advice.

2.17. Monitoring

2.17.1. Serum trough levels for monitoring should be **TAKEN AT Least 18 HOURS AFTER THE PREVIOUS DOSE which should be between 0 and 6 hours before the due dose**

2.17.2. In patients with normal renal function the elimination half-life is between 2 to 3 hours. It usually takes 5 half-lives to eliminate a drug from the body. Therefore, at 18 hours post gentamicin dose, trough levels would be expected to be less than 1mg/L.

2.17.3. Ensure trough levels are taken 18-24 hours after the dose was **ADMINISTERED** by checking the specific time Gentamicin was actually given on the drug chart and **not the due time.**

2.17.4. Patients ≤ 65 years of age and an eGFR >60mls/min should be given the second dose of gentamicin at the scheduled time regardless of:

- Whether the level has been reported - high trough levels should be then acted upon prior to the third dose.
- If the trough level has not yet been taken by the due administration a trough level prior to the 3rd dose **must** be taken.

At the doses recommended in these guidelines it is likely these patients will have cleared the gentamicin (trough<1mg/L) and therefore risks in delaying doses has the potential for greater harm through missed antibiotic cover.

2.17.5. For patients undergoing renal replacement, > 65 years of age or with an eGFR ≤60ml/min, trough levels should be taken 0-6 hours prior to the next dose. Subsequent doses should be withheld until the trough level has been reported and is <1mg/L.

2.17.6. If the trough level has been taken late (more than 24 hours after the administration) measured serum gentamicin levels may not appropriately represent clearance and dose adjustments may still be required. A further trough level prior to the next planned administration should be considered for purposes of dose adjustment.

2.17.7. eGFR is only a useful approximation for renal function in patients with stable renal impairment where there is no marked fluctuation in creatinine.

2.17.8. Specimens for aminoglycoside assays should:

- Not be taken from intravenous cannulae.
- Be sent in a clearly labelled gold top tube (adequate also for all routine chemistry).
- Be sent to clinical chemistry.
- Be available 24/7.

2.17.9. The following details are essential:

- Time specimen taken.
- Dose and frequency of gentamicin therapy.

2.17.10. Continue to monitor urea, electrolytes, and creatinine on a regular basis.

2.17.11. It is recommended that magnesium levels should be checked if gentamicin therapy is continued for longer than 7 days. Hypomagnesaemia can be associated with long-term gentamicin therapy.

2.17.12. Frequency of monitoring is prior to the second dose and then twice weekly thereafter if kidney function is stable and initial gentamicin level is <1.

2.17.13. If kidney function is declining then more frequent monitoring/alternative therapy may be required, discuss with microbiology.

2.18. Timings of doses and administration.

2.18.1. The first dose should be given as soon as clinically indicated.

2.18.2. To facilitate future gentamicin trough level taking (if indicated) the second dose may be given 20 to 36 hours after the first dose provided the first gentamicin trough level is within the recommended range.

2.18.3. For fluid restricted patients gentamicin may be given undiluted as a slow intravenous bolus over not less than 3 minutes.

2.19. Responding to high gentamicin trough levels

2.19.1. Ensure the measured level was a true trough level.

- Check the time on the gentamicin level laboratory report. Ensure the timing of the trough was more than 18 hours post the gentamicin dose was **administered** (do not rely on the time prescribed).

2.19.2. If the level is not a true trough, then retake the level at the correct time. **Do not stop gentamicin based on a trough >1mg/L if taken at the incorrect time, i.e., <18 hours after the previous dose.**

2.19.3. If the level is a true trough reduce the dose of gentamicin on the next administration round. Repeat trough level 18-24 hours after the adjusted dose.

2.19.4. Use the summary table below to guide your decision on gentamicin therapy after a trough level.

Age ≤ 65 years AND eGFR >60mls/min		
≤ 1mg/l	1mg/l - 2mg/l	>2mg/l
Continue therapy	REDUCE dose ↓ Administer at the scheduled time ↓ Re-check levels prior to next dose	SUSPEND DOSE ↓ Dose will need reducing Seek microbiology / pharmacy advice

Age >65 years or eGFR ≤ 60mls/min or AKI	
≤ 1mg/L	>1mg/L
Continue therapy	SUSPEND DOSE ↓ Repeat trough level every 4-12 hours until ≤ 1mg/L ↓ Reduce dose and administer ↓ Re-check levels prior to next dose

2.19.5. Use the summary table below to guide your decision on any gentamicin dose reductions required.

Current Dose (mg)	Reduce dose to (mg):
160	**120**
240	**160**
320	**240**
360	**280**
440	**360**

2.20. Contact Numbers

2.20.1. Microbiology

- Office hours (9am – 5pm) 01872 254900.
- Out of Hours – on call microbiologist contact via switchboard.

2.20.2. Clinical Chemistry (analytical enquiries only)

- Office hours (9am – 5 pm) 01872 252540.
- Out of Hours – on call BMS contact via switchboard.

2.20.3. Pharmacy

- Antibiotic Pharmacist Bleep 3938 or 3248.
- Ward Pharmacist – contact via bleep (available via pharmacy).
- Pharmacy (8.40am – 5.00pm Monday – Friday) 01872 252588.
- Pharmacy (8.30am – 17.00pm Saturday and Sunday) 01872 252588.
- Medicines Information (8.40am-5.00pm Monday-Friday) 01872 252587.
- Out of Hours – on call pharmacist contact via switchboard.
- West Cornwall Pharmacy (8.30am-5.00pm Monday-Friday) 01736 874183.

2.20.4. Remember sensible antibiotic prescribing saves lives, saves money, minimizes adverse effects, and reduces problems with resistant organisms.

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Prescribing and therapeutic drug monitoring
Lead	Neil Powell Antibiotic Pharmacist
Tool	Adherence to guidelines will be monitored as part of the ongoing audit process within the department on a Word or Excel template specific to the topic.
Frequency	Yearly
Reporting arrangements	Report to Medicines Practice Committee via the Antibiotic Stewardship Management Committee
Acting on recommendations and Lead(s)	Antimicrobial Stewardship Management Committee
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within one month. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Gentamicin Prescription and Therapeutic Drug Monitoring Clinical Guideline V7.0
This document replaces (exact title of previous version):	Gentamicin prescription and therapeutic drug monitoring guideline V6.1
Date Issued/Approved:	24 May 2024
Date Valid From:	June 2024
Date Valid To:	June 2026
Directorate / Department responsible (author/owner):	Neil Powell, Antibiotic Pharmacist
Contact details:	01872 252590
Brief summary of contents:	Safe and effective prescribing and monitoring of gentamicin
Suggested Keywords:	Gentamicin, TDM, prescribing
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Antimicrobial Stewardship Management Committee. Medicines Practice Committee.
Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming consultation and ratification:	Kevin Wright
Links to key external standards:	None
Related Documents:	Gentamicin Dosing And Therapeutic Drug Monitoring Guideline. Appendix 1. Mobile Summary
Training Need Identified?	No

Information Category	Detailed Information
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
13/01/2010	V1.0	Initial Version	Neil Pollard, Pharmacy
12/12/13	V2.0	None	Neil Powell, Antibiotic Pharmacist
2/9/14	V3.0	• Gentamicin dosing table by ideal body weight. • Altering subsequent gentamicin dosing timings to ensure timely administration. • Caution gentamicin prescribing in the presence of AKI risk factors. Advise with prescribing gentamicin in AKI	Neil Powell, Antibiotic Pharmacist
08/11/17	V4.0	• Minor guidance on how to make up doses from pre-made bags • Appendix added with link to summary guidance (Appendix 1)	Neil Powell, Antibiotic Pharmacist
9/11/20	V5.0	• Minor typos corrected. • Bleep numbers updated. • Names of documents amended for consistency – intranet/document name to match. • Extensive Burns added to exclusion criteria. • Myasthenia gravis added as a contra- indication.	Verity Cross

Date	Version Number	Summary of Changes	Changes Made by
14/06/21	V6.0	• Disambiguation of guidance dosing and monitoring ranges. • Editorial for easier reading and emphasis on key points. • Changes to wording sections 2.14.1, 2.16.1, 2.16.2. • Inclusion of scope to include infective endocarditis patients and separate dosing regimen. • Inclusion of summary flow diagram for monitoring. • Included dose reduction table 2.16.4. • Changed advice on repeating high levels. • Advisory on toxicity and further initial actions, examination, and investigations. • Advisory on serum trough levels taken too late.	Edward Lau, Foundation Doctor). Andree Evans, Consultant Microbiologist)
26/11/21	V6.1	Frequency of monitoring added	Liam Wade, Antimicrobial Pharmacist
16/05/2024	V7.0	Inclusion of maximum 5 days of treatment, unless as per Infectious Disease specialist management plan.	Dan Hearsey, Antimicrobial Pharmacist

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance, please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Gentamicin Prescription and Therapeutic Drug Monitoring Clinical Guideline V7.0
Directorate and service area:	Pharmacy, Clinical Support
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Neil Powell, Antibiotic Pharmacist
Contact details:	01872 252590

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	Ensure gentamicin is prescribed and monitored safely at the Trust.
2. Policy Objectives	Safe effective prescribing of gentamicin.
3. Policy Intended Outcomes	Effective and safe gentamicin prescribing.
4. How will you measure each outcome?	Compliance with the guideline will be measured six monthly.
5. Who is intended to benefit from the policy?	Patients under the care of the Royal Cornwall Hospital Trust.
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No

Information Category	Detailed Information
	• Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Antimicrobial Stewardship Management Committee. Medicines Practice Committee.
6c. What was the outcome of the consultation?	Agreed.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	
Marriage and civil partnership	No	
Pregnancy and maternity	No	

Protected Characteristic	(Yes or No)	Rationale
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Neil Powell, Antibiotic Pharmacist.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Guideline Mobile Summary

Summary guidance published separately – available via Document Library (search for "Gentamicin" or click here).

Appendix 4. Ideal body weight chart

MALE PATIENTS			FEMALE PATIENTS		
Height feet and inches	**Centimeters**	**Ideal body weight (kg)**	**Height feet and inches**	**Centimeters**	**Ideal body weight (kg)**
			5’	152.40	45.5
			5’1”	154.94	47.8
5’	152.40	50	5’2”	157.48	50.1
5’1”	154.94	52.3	5’3”	160.02	52.4
5’2”	157.48	54.6	5’4	162.56	54.7
5’3”	160.02	56.9	5’5	165.10	57
5’4”	162.56	59.2	5’6	167.64	59.3
5’5”	165.10	61.5	5’7	170.18	61.6
5’6”	167.64	63.8	5’8	172.72	63.9
5’7”	170.18	66.1	5’9	175.26	66.2
5’8”	172.72	68.4	5’10	177.80	68.5
5’9”	175.26	70.7	5’11	180.34	70.8
5’10”	177.80	73	6’	182.88	73.1
5’11”	180.34	75.3	6’1	185.42	75.4
6’	182.88	77.6	6’2”	187.96	77.7
6’1”	185.42	79.9	6’3”	190.50	80
6’2”	187.96	82.2	6’4”	193.04	82.3
6’3”	190.50	84.5	6’5”	195.58	84.6
6’4”	193.04	86.8	6’6”	198.12	86.9
6’5”	195.58	89.1	6’7”	200.66	89.2
6’6”	198.12	91.4			
6’7”	200.66	93.7			