CLINICAL GUIDELINE FOR GENTAMICIN PRESCRIBING AND THERAPEUTIC DRUG MONITORING.

1. Aim/Purpose of this Guideline

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

2. The Guidance

2.1. Gentamicin has bactericidal activity against aerobic Gram-negative organisms.

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 except for the treatment of bacterial endocarditis.

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

- nephrotoxicity
- ototoxicty

2.5. 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.

2.6. 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.

2.7. 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). Hence 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.

2.8. Remember, eGFR over estimates the true GFR in AKI patients. In evolving AKI please see paragraph 2.7.

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

2.10. This guideline **excludes** the following patients:

- pregnant or breast feeding
- < 16 years of age
- with ascites
- with bacterial endocarditis
- with cystic fibrosis
- CAPD peritonitis

2.11. Gentamicin dosing table

Height		Age <65 years and eGFR >60mls/min Dose 5mg/kg		Age >65 years or eGRF<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

2.12. Instructions for using the gentamicin dosing table

2.13. Determine whether your patient is under or over 65 years of age and whether their eGFR is above or below 60mls/min.

2.14. Next, determine height in feet and inches or centimetres and then the gender of your patient.

2.15. Select an appropriate dose based on these parameters from the dosing table above. For example, if your patient is male, 30 years of age with eGFR>60 and 5'10" tall you will need to prescribe a 360mg dose of gentamicin.

2.16. Height is used to estimate the patient's ideal body weight (see appendix 4) and as such if your patient has a low BMI (below 18.5) you will need to dose on patient's actual body weight as height would overestimate the weight.

2.17. The recommended doses can be made up from the three available gentamicin bags strengths (80mg, 240mg and 360mg bags).

2.18. 160mg = 80mg/80mls + 80mg/80mls bag,

2.19. 240mg = 240mg/80mls bag,

2.20. 320mg = 240mg + 80mg/80mls bag,

2.21. 360mg = 360mg/120ml bag,

2.22. 440mg = 360mg/120ml bag + 80mg/80mls bag.

3. Monitoring

3.1. Target trough levels are <1mg/L and should therefore be taken 0 to 6 hours prior to next anticipated dose (i.e. 18-24 hours after the previous dose).

3.2. 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.

3.3. Patients under 65 years of age with an eGFR >60mls/min should be given the second dose of gentamicin at the scheduled time regardless of whether the level has been reported. If necessary high trough levels can be acted upon prior to the third dose. At the doses recommended in these guidelines it is likely these patients will have cleared the gentamicin (trough<1mg/L) and therefore delaying doses has the potential for greater harm through missed doses.

3.4. For patients undergoing renal replacement, those over 65 years of age or with an eGFR of less than 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.

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

3.6. Specimens for aminoglycoside assays should:

- not be taken from either intravenous lines or cannulae.
- be sent in a clearly labelled vacutainer (gold top tube).
- be 5 ml of clotted blood. (adequate also for all routine chemistry)

- sent to clinical chemistry
- available 24/7

3.7. The following details are essential:

- time specimen taken
- dose and frequency of gentamicin therapy

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

3.9. 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.

4. Timings of doses and administration.

4.1. The first dose of gentamicin must be given as soon as possible and therefore at any time of day. Moving subsequent dose timings towards midday will facilitate appropriate timings of gentamicin trough levels.

4.2. 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.

4.3. Gentamicin should be administered as an intravenous infusion over a minimum of 20 minutes. If the dose requires the infusion of two gentamicin bags then these are to be infused simultaneously. A Baxter Secondary Medication Set (REF MMC5913D) will need to be attached to the main giving set to allow both bags to be infused simultaneously.

4.4. For fluid restricted patients gentamicin ampoules are available from pharmacy and may be given undiluted as a slow intravenous bolus over not less than 3 minutes.

5. Responding to high gentamicin trough levels

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

5.2. If the level is not a true trough, evidenced by the timings, then retake the level at the correct time. Do not stop gentamicin based on a trough >1mg/L if taken at the incorrect time.

5.3. If the level is a true trough and genuinely high then you will need to reduce the dose of gentamicin.

5.4. A proportion of the pre filled gentamicin bag can be removed prior to the infusion to give the desired reduced dose.

5.5. Use the summary table below to guide your decision making on dose adjustment.

Age <65 years and eGFR >60mls/min			**Age >65 years or eGRF<60mls/min or AKI**	
<1mg/l	>1mg/l &<2mg/l	>2mg/l	>1mg/L	<1mg/L
Continue therapy	Reduce dose but give at the next scheduled time. Re-check levels prior to next dose. This level should be <1mg/l	WITHOLD Dose will need reducing, speak to senior colleague, pharmacy or microbiology	WITHOLD dose, repeat trough levels until cleared. (NB half-life is 2-3 hours in normal kidney function extended in renal impairment) Reduce dose and repeat	Repeat dose

5.6.Contact Numbers

5.7. Microbiology

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

5.8. Clinical Chemistry (analytical enquiries only)

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

5.9. Pharmacy

- Antibiotic Pharmacist Bleep 3129
- Ward Pharmacist – contact via bleep (available via pharmacy)
- Pharmacy (8.40am – 5.00pm Monday – Friday) ☎ 01872 252588
- Pharmacy (8.30am – 12.30pm Saturday) ☎ 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

5.10. Remember sensible antibiotic prescribing saves lives, saves money, 6inimizes adverse effects and reduces problems with resistant organisms.

6. Monitoring compliance and effectiveness

Element to be monitored	Prescribing and therapeutic drug monitoring
Lead	Neil Powell

Tool	Audit
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

7. Equality and Diversity

7.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Diversity & Human Rights Policy' or the Equality and Diversity website.

7.2. Equality Impact Assessment

7.3. The Initial Equality Impact Assessment Screening Form is at Appendix 3.

Appendix 1. Guideline Mobile Summary

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

Appendix 2. Governance Information

Document Title	Gentamicin prescribing and therapeutic drug monitoring guideline						
Date Issued/Approved:	02/09/2014						
Date Valid From:	02/09/2014						
Date Valid To:	02/09/2017						
Directorate / Department responsible (author/owner):	Neil Powell Antibiotic Pharmacist						
Contact details:	01872 252590						
Brief summary of contents	Safe effective prescribing and monitoring of gentamicin						
Suggested Keywords:	Gentamicin, TDM, prescribing						
Target Audience	RCHT	PCH	CFT	KCCG			
	✓						
Executive Director responsible for Policy:	Medical Director						
Date revised:	02/09/14						
This document replaces (exact title of previous version):	Gentamicin prescribing and therapeutic drug monitoring guideline v2						
Approval route (names of committees)/consultation:	Antimicrobial Stewardship Management Committee, Medicines Practice Committee						
Divisional Manager confirming approval processes	Not required						
Name and Post Title of additional signatories	Renal Physician, Stephen Dickinson (16.9.14) CSSC Governance Lead, Janet Gardner						
Signature of Executive Director giving approval	{Original Copy Signed}						
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only				
Document Library Folder/Sub Folder	Clinical / Pharmacy						
Links to key external standards							
Related Documents:							
Training Need Identified?	Yes – FI teaching done.						

Version Control Table

Date	Version No	Summary of Changes	Changes Made by *(Name and Job Title)*
2/9/14	3	• 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

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This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Controlled Document

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Appendix 3. Initial Equality Impact Assessment Form

Name of Name of the strategy / policy /proposal / service function to be assessed (hereafter referred to as *policy*) (Provide brief description): CLINICAL GUIDELINE FOR GENTAMICIN PRESCRIBING AND THERAPEUTIC DRUG MONITORING	
Directorate and service area: Pharmacy	Is this a new or existing Policy? Existing
Name of individual completing assessment: Neil Powell	Telephone: 01872 252590
1. Policy Aim* Who is the strategy / policy / proposal / service function aimed at?	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 the outcome?	Compliance with the guideline will be measure six monthly
5. Who is intended to benefit from the policy?	Patients under the care of the Royal Cornwall Hospital Trust
6a) Is consultation required with the workforce, equality groups, local interest groups etc. around this policy? b) If yes, have these *groups been consulted? C). Please list any groups who have been consulted about this procedure.	No

7. The Impact Please complete the following table.			
Are there concerns that the policy **could** have differential impact on:			
Equality Strands:	Yes	No	Rationale for Assessment / Existing Evidence
Age		**no**	

Sex (male, female, trans-gender / gender reassignment)		**no**	
Race / Ethnic communities /groups		**no**	
Disability - learning disability, physical disability, sensory impairment and mental health problems		**no**	
Religion / other beliefs		**no**	
Marriage and civil partnership		**no**	
Pregnancy and maternity		**no**	
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian		**no**	

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:

- You have ticked "Yes" in any column above and
- No consultation or evidence of there being consultation- this excludes any *policies* which have been identified as not requiring consultation**. or**
- Major service redesign or development

8. Please indicate if a full equality analysis is recommended.		**No**

9. If you are not recommending a Full Impact assessment please explain why.
All of the columns are "no".

Signature of policy developer / lead manager / director	Date of completion and submission 2/9/14

Names and signatures of members carrying out the Screening Assessment	1. 2.	

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust's web site.

Signed _____

Date _____

Appendix 4.

Ideal body weight chart

MALE PATIENTS			FEMALE PATIENTS		
Height feet and inches	Centi-metres	Ideal body weight (kg)	Height feet and inches	Centi-metres	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			