Worcestershire Acute Hospitals NHS Trust

Guideline for the Safe Use of Gentamicin in Neonates

This is the most current document and should be used until a revised version is in place

Owner/Lead:	Dr Weckemann	
Approval Date:	14th February 2024	14th August 2024
Approved by:	Neonatal Guidelines Review Meeting	Medicines Safety Committee
Review Date: This is the most current document and should be used until a revised version is in place	14th February 2027	

Key Amendments

Date	Amendments	Approved by
20th May	Guideline updated to make dosing times as well as when to take levels clearer.	Paediatric QIM
February 2024	Document approved for 3 years	Neonatal Guidelines Review Meeting

Introduction

This guideline was developed to reduce the risk of incidents involved with the administration of gentamicin at the incorrect time, prescribing errors and issues relating to blood level monitoring as identified nationally by the NPSA. It has subsequently been amended following publication of NICE Guidance 149 'Antibiotics for early-onset neonatal infection'.

The guideline covers all neonates receiving gentamicin as in-patients. A neonate, for this guideline, is defined as all babies up to 4 weeks corrected gestational age.

This guideline is for use by the following staff groups:

All doctors, nurses and midwives caring for neonates

BACKGROUND

Patient safety incidents

A review of neonatal medication incidents reported to the Reporting and Learning System (RLS) between April 2008 and April 2009 identified 507 patient safety incidents relating to the use of intravenous gentamicin – 15 per cent of all reported neonatal medication incidents.

Analysis of these incidents highlighted that in 36 per cent of cases (182 incidents) the reason for the incident related to administration of the medicine at the incorrect time. In 24 per cent (124 incidents) of cases there had been a prescribing error, and in 17 per cent (86 incidents) there were issues relating to gentamicin blood level monitoring.

Ninety-six per cent (483) of incidents reported to the RLS resulted in no harm or low harm, and four per cent (23 incidents) were reported as causing moderate harm. However, it should be noted that the incidence of long-term hearing or renal damage as a result of

gentamicin toxicity may not be apparent until sometime after discharge from the neonatal unit, and therefore may not be captured in incident reports.
As a result of these safety incidents, the NPSA has produced a Patient Safety Alert to help reduce the risk of using gentamicin in neonates which includes actions for NHS organisation. This guideline has been produced to ensure these actions are enforced and therefore covers all in-patient babies on gentamicin currently admitted to the Neonatal Unit, Delivery Suite, Transitional Care unit and Post Natal ward.

National Institute for Health and Clinical Excellence (NICE) clinical guideline 195 'Antibiotics for early-onset neonatal infection' April 2021

This guideline offers best practice advice on the care of babies at risk of early-onset neonatal infection. The recommendations include a suggested dose regimen of gentamicin, duration of treatment and therapeutic monitoring guidance. Although many of the recommendations are based on low quality clinical evidence, they have been produced pragmatically, with the wide expertise of the Guideline Development Group, following research into current practice on neonatal units. Efficacy, safety, and practicality (time to receive reports on blood cultures) were key considerations.

Following the publication of NICE guideline 195 this Trust guideline has incorporated the advice on dose regimen and pharmacokinetic monitoring

DETAILS OF GUIDELINE

Prescribing

Gentamicin should be prescribed for suspected infection at a starting dose of 5mg/kg on the designated Gentamicin Chart (see Appendix 1). The main drug chart should include a prompt in the regular medications section 'See Gentamicin Chart'

If a second dose is to be given it should usually be given 36 hours after the first dose in most neonates but see below for exception *, and extreme care must be taken to ensure that all non-administration boxes in highlighted rows are blocked out as below. The interval may be shortened, based on clinical judgement, for example if:

- the baby appears very ill
- the blood culture shows a Gram-negative infection

***Neonates with CGA of 32/40 or more should usually be given the second and subsequent doses at 24 hourly intervals once they reach the age of 7 days and above.**

Subsequent doses and intervals should be decided taking into account the blood gentamicin concentrations (see 'monitoring' section below).

Doses should be rounded to the nearest 0.1mg, for ease of administration

The time of prescribing should always be made using the 24 hour clock. Please prescribe subsequent doses for the agreed drug times on NNU/TCU (6.00h and 18.00h or 12.00h and 24.00h).

Duration of treatment: in babies prescribed gentamicin because of risk factors for infection or clinical indicators of possible infection, review and **stop treatment at 36 hours after initial dose if**:

- the blood culture is negative, and
- the initial suspicion of infection was not strong, and
- the baby's clinical condition is reassuring with no clinical indicators of possible infection, and
- the levels and trends of C-reactive protein, if measured, are reassuring

Administration

Intravenous gentamicin should be administered to neonates using the Gentamicin Chart (Appendix 1) which includes the following four elements:

- Ensure that the prescription is completed as described above

- Interruptions during the preparation and administration of gentamicin should be minimised by staff preparing administration of Gentamicin in designated IV medication areas (Neonatal Unit ITU Room 4, Postnatal Ward Medication Room)

- A double-checking prompt has been incorporated into the Gentamicin prescription chart and should be used preparation and administration (Appendix 1).

- The prescribed dose of gentamicin should be given within one hour of the prescribed time.

The incorporated care bundle is a number of clinical interventions that a particular patient group should receive collectively and consistently during one clinical episode of care. The aim of the care bundle is to achieve 100% compliance with all of its 4 elements for each patient receiving gentamicin.

Gentamicin is already in solution and can be given as an intravenous bolus dose over 3-5 minutes. If preferred, gentamicin can be further diluted with an appropriate volume of sodium chloride 0.9% to aid administration, and/or given as an infusion over 30 minutes.

Gentamicin is incompatible with a number of other antibiotics and medications, and lines used to administer gentamicin should be flushed well with sodium chloride 0.9%.

Monitoring

Blood levels should be collected in clear topped bottles at a volume of at least 0.3ml. Specimens should be clearly labelled and sent to the Biochemistry Department with a gentamicin assay requested on ICE.
If a second dose of gentamicin is to be given, measure the trough blood concentration immediately before giving the second dose. Consider the trough concentration before giving a third dose of gentamicin as it should have been reported by microbiology within this timescale. If, however, the trough concentration is not available, do not withhold the next

dose of gentamicin unless there is clear evidence of renal dysfunction (for example, an elevated serum urea or creatinine clearance, or urine output of less than 0.5ml/kg/hour). After giving the third dose, every effort should then be made to discover the blood concentration result from microbiology as soon as it is available.

The aim is to achieve a trough concentrations of less than 2mg/l before the second dose. If the course of gentamicin lasts more than two doses, a trough concentration of less than 1mg/litre is advised for subsequent trough levels.

Repeat the measurement of trough concentrations immediately before every third dose of gentamicin (ie before the 5th, 8th 11th dose etc.), or more frequently if necessary (for example if there has been concern about previous trough concentrations or renal function).
Consider measuring peak blood gentamicin concentrations in selected babies such as those with:

- oedema
- macrosomia (birth weight more than 4.5kg)
- an unsatisfactory response to treatment
- proven Gram-negative infection.

Peak concentrations are measured one hour after starting the gentamicin infusion and the usual range is 5 -10 mg/litre. If a baby has a Gram-negative or staphylococcal infection, consider increasing the dose of gentamicin if the peak concentration is less than 8mg/litre.

It is usual practice for the ward to be contacted in the event of a gentamicin level outside the target. If this does not happen, any deviation should be discussed with the Microbiology Department via extension 30212 (WRH) during office hours, or the on-call Consultant Microbiologist should be contacted via the hospital switchboard at all other times. An individual doctor should not change the dose of gentamicin without seeking advice.

REFERENCES

1. National Institute for Health and Clinical Excellence *Antibiotics for early-onset neonatal infection NICE Clinical Guideline 195, 20* April 2021, Available at: http://www.nice.org.uk/CG195

2. National Patient Safety Agency. *Safer use of intravenous gentamicin for neonates. (Gentamicin Alert.)* (Version 1, 03 Feb 2010) http://www.nrls.npsa.nhs.uk/resources/?entryid45=66271 [Accessed January 2024]
3. British National Formulary for Children (BNFc). 2021-2022 London: British Medical Association and Royal Pharmaceutical Society of Great Britain
4. Medusa Injectable Medicines for Paediatrics Guide online resource
5. Neonatal Formulary: Drug Use in Pregnancy and First Year of Life. 8th ed. Oxford: Oxford University Press 2020
6. Neonatal Guidelines (2020- 2022), Staffordshire, Shropshire & Black Country Neonatal Operational Delivery Network AND Southern West Midlands Neonatal Operational Delivery Network.

MONITORING TOOL

STANDARDS	%	CLINICAL EXCEPTIONS
Compliance to the care bundle as defined by the NPSA	100	Nil
All prescriptions of gentamicin will be prescribed and monitored according to this guideline	100	Microbiological advice

How will monitoring be carried out? Clinical Audit as part of the Directorate Audit Forward Plan

Who will monitor compliance? Paediatric Clinical Governance Committee

Contribution List

Key individuals involved in developing the document

Name	Designation
Louise Williams	Lead Pharmacist for Paediatrics and Neonatal WRH
Linda McDonald	Advanced Neonatal Nurse Practitioner WRH
Dr V Weckemann	Consultant Paediatrician
Dr Hugh Morton	Consultant Microbiologist

Circulated to the following individuals for comments

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Circulated to the chair of the following committee's / groups for comments

Name	Committee / group
Alison Smith	Medicines Safety Committee

Worcestershire Acute Hospitals NHS Trust

Appendix 1

Affix Patient Label here or record:

Name: _____

NHS No:

Hosp No:

D.O.B: / / Male Female

WARD: CONS:

INTRAVENOUS GENTAMICIN PRESCRIPTION SHEET

NHS Worcestershire Acute Hospitals NHS Trust

DOSING INSTRUCTIONS: If this is the first time you are prescribing on this chart, please ensure you fill in your details on the front page.

Corrected gestational age	Dose	Frequency
< 7 days – all gestations	5mg/kg	36 Hourly
> 7 days BUT < 32 weeks	5mg/kg	36 Hourly
> 7 days AND > 32 weeks	5mg/kg	24 Hourly

Administration: Give as a slow bolus over 3 – 5 minutes

Monitoring: Take trough level pre 2nd dose (give dose if renal function is satisfactory}, then take level every 3rd dose unless more frequent monitoring is indicated (e.g. in renal impairment}

Target Range: **First level <2mg/L Subsequent levels: <1mg/L**
REFER TO FORMULARY ON HOW TO MANAGE LEVELS OUTSIDE OF THESE RANGES

Current weight:	kg	Days of age:	days	Corrected gestational age at start of treatment:	weeks	Creatinine:	micromole/L

GENTAMICIN PRESCRIPTION DETAILS						GENTAMICIN DOUBLE CHECKING PROMPT Sign each check to confirm that they have been undertaken correctly								THERAPUTIC DRUG MONITORING (TDM)					Given/ Checked by		Pharmacy
Date	Time to be given	Frequency	Dose	Route	Prescriber signature	Is the frequency and prescribed dose correct for the baby's gestational age?		Check the time when the dose was last given and its frequency. Is the dose due?		Is a level due (check 'TDM' section to the right)? Take a level before administering the dose if required		If pre-dose level was taken, check target range. If not has the frequency been changed? If level unavailable, speak to on-duty registrar.		Pre-dose level required	Time level taken	Initial once level taken	Result of level (mg/L)	Action on level	Initials	Time	
						Check	Double Check	Check	Double Check	Check	Double Check	Check	Double Check								

Supporting Document 1 – Equality Impact Assessment form

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust	x	Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	**Dr Weckemann**

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
Date assessment completed			

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title:** Guideline for the Safe Use of Gentamicin in Neonates			
What is the aim, purpose and/or intended outcomes of this Activity?				
Who will be affected by the development &	❑	Service User	x	Staff
	x	Patient	❑	Communities
	❑	Carers	❑	Other _____

implementation of this activity?	❑	Visitors	❑		
Is this:	❑ Review of an existing activity ❑ New activity ❑ Planning to withdraw or reduce a service, activity or presence?				
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.					
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)					
Summary of relevant findings					

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	**Potential positive impact**	**Potential neutral impact**	**Potential negative impact**	**Please explain your reasons for any potential positive, neutral or negative impact identified**
Age				
Disability				
Gender Reassignment				
Marriage & Civil Partnerships				
Pregnancy & Maternity				
Race including Traveling Communities				
Religion & Belief				
Sex				

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Sexual Orientation				
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)				
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)				

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
		.		
How will you monitor these actions?				
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)				

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation
1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.
1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	
Date signed	
Comments:	
Signature of person the Leader Person for this activity	
Date signed	
Comments:	

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	
2.	Does the implementation of this document require additional revenue	
3.	Does the implementation of this document require additional manpower	
4.	Does the implementation of this document release any manpower costs through a change in practice	
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval