NHS
Greater Glasgow and Clyde

CLINICAL GUIDELINE

Synergistic Gentamicin for Endocarditis in Adults

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Approval Group:	Antimicrobial Utilisation Committee

Important Note:

The Intranet version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

NHSGGC Guidelines: Synergistic Gentamicin for Infective Endocarditis in Adults

ALL patients with suspected or proven infective endocarditis (IE) should be discussed with microbiology or Infectious Diseases (ID) within 72 hours of starting antibiotic therapy AND re-discussed after 1 week if continuation of gentamicin is being considered at that point.

Synergistic gentamicin is recommended in the initial empirical treatment of endocarditis and for some particular endocarditis pathogens, in accordance with national guidelines. When treating a patient with IE remember to consider resistance, clinical response, toxicity and suitability for outpatient parenteral antibiotic therapy (OPAT).

This guideline does NOT apply to:

- Patients requiring full treatment dose (non-synergistic) gentamicin - **refer to the Gentamicin dosing guideline in the Therapeutics Handbook for managing these patients**

For the following patient groups discuss the suitability of gentamicin with microbiology or infectious diseases before starting it (do NOT delay initiating any other appropriate antibiotics pending this discussion about gentamicin)

- Patients treated in renal units or receiving haemodialysis or haemofiltration
- Major burns
- Ascites
- Cystic fibrosis

Contraindications (see the BNF/product literature for full details)

- hypersensitivity
- myasthenia gravis
- patients who have previously experienced vestibular or auditory toxicity whilst on aminoglycosides
- patients with known family history of aminoglycoside induced auditory toxicity or a maternal relative with deafness due to mitochondrial mutation m.1555A>G
- patients with a known mitochondrial mutation
- decompensated liver disease (jaundice, ascites, encephalopathy, variceal bleeding or hepatorenal syndrome)

Cautions (see the BNF/product literature for full details)

- CrCl <21 ml/min, ≥50% increase in serum creatinine or oliguria for >6 hours in the past 48 hours
    - If gentamicin is clinically indicated, give one dose as per guidance and check with microbiology, infectious diseases or pharmacy before giving a second dose
- Patients with pre-existing auditory, vestibular impairment
- Co-administration with neurotoxic or nephrotoxic agents, e.g. neuromuscular blockers, nonsteroidal anti-inflammatory drugs, ACE Inhibitors; potent diuretics (i.e. IV diuretics, PO furosemide >80mg/daily, PO bumetanide >2mg/day, combination diuretics in refractory oedema e.g. furosemide + metolazone), other aminoglycosides (see www.medicines.org.uk)
- Patients with known conditions characterised by muscular weakness

Mitochondrial DNA Mutation Genetic Testing
Consider the need for genetic testing especially in patients requiring recurrent or long-term treatment with aminoglycosides (e.g. enterococcal endocarditis, complex drug-resistant infections including tuberculosis or cystic fibrosis or recurrent neutropenic sepsis) but DO NOT delay urgent treatment in order to test. Results can take up to 28 days to come back

Estimating renal function for transgender patients

- Following ≥ 6 months of hormonal gender affirming therapy or at any time after completion of gender affirming surgery calculate CrCl (see calculators on Therapeutics Handbook App and on the NHS GGC StaffNet) and ideal body weight according to the patient's gender identity.
- If gender affirming therapy does not meet the criteria above use the patient's sex at birth, according to their electronic clinical records. The second last digit of a CHI number informs of a patient's assigned sex at birth - for those assigned male it is odd and for those assigned female it is even.

1. Initial Dosage Guidelines

These guidelines aim to produce a 1 hour post dose "peak" concentration of 3-5 mg/L, and an end of dosage interval "trough" concentration of <1 mg/L. **Doses should be administered by IV bolus injection over 3-5 minutes.**

Gentamicin: Synergistic Dosage Guidelines

	Patient Actual Body Weight				
Creatinine Clearance* (do NOT use eGFR)	**<45 kg**	**45-65 kg**	**66-85 kg**	**86-110 kg**	**>110 kg**
<25 ml/min	40 mg	60 mg	80 mg	100 mg	120 mg
	Take a sample after 24 hours. Do not give a further dose until the concentration is <1 mg/L Discuss with microbiology or ID if CrCl <21ml/min (see cautions)				
25-44 ml/min	40 mg 24 hourly	60 mg 24 hourly	80 mg 24 hourly	100 mg 24 hourly	120 mg 24 hourly
>44 ml/min	40 mg 12 hourly	60 mg 12 hourly	80 mg 12 hourly	100 mg 12 hourly	120 mg 12 hourly

***** *If creatinine is not known: give 1 mg/kg gentamicin (maximum 120 mg) and seek advice from pharmacy.*

***Do NOT use eGFR:** creatinine clearance must be calculated using the NHSGGC Creatinine Clearance Calculator on StaffNet or the NHSGGC medicines app.*

If the patient is already receiving full treatment dose gentamicin and is to switch to synergistic dosing

- If renal function is stable AND a gentamicin concentration taken in the past 48 hours is within the range expected for the current full treatment dose regimen then switch to synergistic dosing when the next dose of gentamicin is due.
- If renal function is not stable OR there are no gentamicin concentration results in the past 48 hours OR the concentration result suggests that an altered dose interval is required then confirm that the patient's gentamicin concentration is <1mg/L before switching to synergistic dosing.

2. Prescribing

On HEPMA prescribe as *GENTAMICIN SYNERGISTIC (ENDOCARDITIS)*. Enter the dose, dosage frequency and intended duration (if known) on HEPMA. Read the *HEPMA prescribing of Gentamicin IV and Vancomycin IV advice for adults* document on StaffNet.

Do NOT use the (maroon) standard 'Adult Parenteral Gentamicin (GGC): Prescribing, Administration & Monitoring Chart' to prescribe *synergistic* gentamicin. The 'Adult Parenteral Synergistic Gentamicin (GGC): Administration & Monitoring Chart' (see Appendix below) should be printed out and

used on the ward for accurate recording of administration and sample times; this is ESSENTIAL for the correct interpretation of gentamicin concentration results. This chart must **NOT** be used as a prescription chart; doses and dose times must be prescribed on HEPMA and amended on HEPMA if the dose regimen is altered.

3. Monitoring

- Take a blood sample for gentamicin analysis one hour after the first gentamicin bolus injection has been administered (a "peak" sample).
- Take a second blood sample for gentamicin analysis at the end of the first dosage interval (a "trough" sample, just before the next dose is due) then give the next dose. **Do NOT delay giving the second gentamicin dose while waiting for the trough concentration to be reported, unless there are concerns over deteriorating renal function.**
- Record the exact time of all gentamicin samples on the Synergistic Gentamicin Administration and Monitoring Chart (see Appendix below). Ensure all TrakCare sample request forms are printed at the time of sample collection (so that accurate sample times are recorded on TrakCare/Clinical Portal).
- See the table below for advice on interpreting gentamicin concentration results.
- Monitor the patient's creatinine daily and record this on the Synergistic Gentamicin Administration and Monitoring Chart (see Appendix below).
- If the prescribed dose amount/dose frequency is altered ensure this is updated and prescribed on HEPMA.

If the measured gentamicin concentration is expectedly HIGH or LOW

- Were dose and sample times recorded accurately?
- Was the correct and full dose administered?
- Was the sample taken from the line used to administer the drug?
- Was the sample taken at the correct time?
- Has renal function declined or improved?
- Does the patient have oedema, ascites or an extreme weight?

If in doubt, take another sample before re-dosing and/or seek advice from pharmacy.

Gentamicin result	Recommended action
Both the peak result is in range (3-5mg/L) AND the trough result is in range (<1mg/L)	Continue the present dosage regimen (dose amount and dose frequency). There is no need to repeat the peak sample, unless renal function changes or there are concerns over response to therapy. Repeat the trough sample every 2 days, provided renal function remains stable. Repeat the trough sample daily and discuss with pharmacy if renal function changes/is unstable. Target trough for ongoing monitoring <1mg/L.
The trough sample is ≥1 mg/L	**See above for checks to make before interpreting the result** **If a further dose has already been administered:** take another trough sample at the appropriate time and await the result before re-dosing. Seek advice from pharmacy and do NOT give a further dose until the gentamicin concentration is <1 mg/L. **If a further dose has not already been administered:** seek advice from pharmacy and do NOT give a further dose until the gentamicin concentration has been confirmed as <1 mg/L.
The peak result is out of range	**See above for checks to make before interpreting the result** Discuss with pharmacy.

4. Duration of Synergistic Gentamicin

Microbiology or ID should be consulted to advise on the duration of synergistic gentamicin at the following times:

- Within 72 hours of starting antibiotic therapy
- At 1 week of therapy, if continuation of gentamicin is being considered at that point
- If the patient is causing concern (e.g. failure to respond, evidence of toxicity; see below)
- If discharge/OPAT is being considered (N.B. there are alternatives to synergistic gentamicin if patients are being discharged via OPAT)

In general, synergistic gentamicin therapy should continue for up to 2 weeks, except in the case of enterococcal IE when it may be given for 2-6 weeks on microbiology/ID advice. The addition of synergistic gentamicin in staphylococcal **native valve** IE is no longer routinely recommended as it increases renal toxicity without evidence of additional benefit.

If a patient is switched from full treatment dose gentamicin to synergistic dosing (without a significant break in therapy) then the days of full dose gentamicin therapy WOULD count towards the intended synergistic course duration.

5. Toxicity

Gentamicin can cause nephrotoxicity and ototoxicity (cochlear and vestibular). The risk of gentamicin toxicity increases with increasing duration of therapy.

Nephrotoxicity

- Monitor creatinine daily. Seek advice from pharmacy if renal function is unstable (e.g. a change in creatinine of >15-20%)
- Be alert for and react to any signs of renal toxicity e.g. increasing creatinine, decreased urine output/oliguria
- Discuss the ongoing need for gentamicin with microbiology/ID if the patient has signs of worsening renal function

Ototoxicity

- Gentamicin-induced ototoxicity occurs independently of drug concentration
- Toxicity is usually associated with prolonged gentamicin use (usually >7 days, however it may occur sooner) and is secondary to accumulation of drug within the inner ear
- Ototoxicity is suggested by any of the following: new tinnitus, dizziness, poor balance, hearing loss, oscillating vision
- Patients prescribed gentamicin should be advised to report signs of ototoxicity (see below regarding the Patient Information Leaflet which should be issued to the patient). Patients should be asked regularly about any signs and symptoms of ototoxicity and this should be documented in the case notes
- If gentamicin continues for >7 days the patient should be referred to audiology for ongoing audiometry testing and the case re-discussed with microbiology or ID. Contact the local audiology department directly to confirm their referral method/requirements.
- If ototoxicity is suspected **STOP** gentamicin treatment and refer to microbiology/ID for advice on ongoing therapy

6. Gentamicin Patient Information Leaflet

All patients prescribed synergistic gentamicin should be given a copy of the NHSGGC Gentamicin Patient Information Leaflet 'Information for patients about intravenous gentamicin' (see Appendix below) at the earliest opportunity. This should be documented in the relevant section of the Synergistic Gentamicin Administration and Monitoring Chart (see Appendix below). If this is not possible the reasons for non-issue of the leaflet should be recorded on the chart.

Appendices

Adult Parenteral Synergistic Gentamicin (GGC): Administration & Monitoring Chart

&

NHSGGC Gentamicin Patient Information Leaflet: 'Information for patients about Intravenous Gentamicin'

Approved by Antimicrobial Utilisation Committee and Cardiology MCN August 2023, Review Date August 2026

ADULT PARENTERAL SYNERGISTIC GENTAMICIN (GGC): ADMINISTRATION & MONITORING CHART

Refer to the 'Synergistic Gentamicin for Endocarditis in Adults' guideline for more information. All patients with suspected or proven endocarditis should be discussed with an infection specialist.

NHS Greater Glasgow and Clyde

Patient name: .....

Date of birth: .....

CHI no.: .....

Affix patient label

The prescriber should issue the gentamicin **patient information leaflet** (PIL) to the patient/carer as soon as possible (unless this is considered to be inappropriate).

PIL issued to: patient ❑ Other: .....

Reason(s) for non-issue: .....

Date of issue: ..... Signature: .....

Signs of gentamicin toxicity

Renal: ↓urine output/oliguria or ↑creatinine

Oto/vestibular: NEW tinnitus, dizziness, poor balance, hearing loss, oscillating vision

Toxicity may occur irrespective of gentamicin concentration

STEP 1 Calculate the initial dose of synergistic gentamicin from the dosage table below:

	Patient Actual Body Weight				
Creatinine Clearance* (Do NOT use eGFR)	**<45 kg**	**45-65 kg**	**66-85 kg**	**86-110 kg**	**>110 kg**
<25 ml/min	40 mg	60 mg	80 mg	100 mg	120 mg
	Take a sample after 24 hours. Do not give a further dose until the concentration is <1 mg/L Discuss with microbiology or ID if CrCl <21ml/min (see cautions)				
25-44 ml/min	40 mg 24 hourly	60 mg 24 hourly	80 mg 24 hourly	100 mg 24 hourly	120 mg 24 hourly
>44 ml/min	40 mg 12 hourly	60 mg 12 hourly	80 mg 12 hourly	100 mg 12 hourly	120 mg 12 hourly

**If creatinine is not known: give 1 mg/kg gentamicin (maximum 120 mg) and seek advice from pharmacy.*

***DO NOT use eGFR:** creatinine clearance must be calculated using the NHSGGC Creatinine Clearance Calculator on StaffNet or the NHSGGC medicines app.*

STEP 2 Prescribe the initial dose of gentamicin on HEPMA, ensuring that the gentamicin dose, frequency and dosage time are clear

- This chart must NOT be used as a prescription chart; doses and dose times must be prescribed on HEPMA and amended on HEPMA if the dose regimen is altered.

STEP 3 Administration & gentamicin monitoring (record using the chart overleaf)

- Administer each synergistic gentamicin dose as an intravenous bolus injection over 3-5 minutes and record the exact time of ALL gentamicin doses overleaf on this monitoring chart. Ensure that HEPMA is also signed for each dose administered.
- Record the exact time of ALL gentamicin samples overleaf on this monitoring chart AND ensure that all TrakCare sample requests are printed at the time of sample collection.
- Take a 'peak' sample 1 hour after the first gentamicin bolus dose. The recommended target peak is 3-5 mg/L.
- Take a 'trough' sample just before the second gentamicin dose is due (i.e. at the end of the dosage interval) but **DO NOT** await the result before re-dosing unless there are concerns about deteriorating renal function. The recommended target trough is <1 mg/L.
- Thereafter repeat a gentamicin trough concentration at least every 2 days, or daily if renal function deteriorates or if measured concentrations are not within target range.
- Seek advice from pharmacy if you are unsure how to interpret the result or if the concentrations measured are not within the recommended ranges above.
- If the prescribed dose or dose frequency is altered ensure this is updated on HEPMA.

STEP 4 Assess daily: the ongoing need for gentamicin and for signs of toxicity

- Issue the NHSGGC 'Information about intravenous gentamicin' leaflet to the patient and record this in the relevant box above.
- Gentamicin can cause renal toxicity (see above). Monitor & record creatinine daily on the monitoring chart. Discuss with microbiology/ID if renal function is worsening.
- Gentamicin can cause ototoxicity (see above). Ask patients about signs of ototoxicity regularly and document this in the casenotes. Refer patients to audiology for assessment and re-discuss the case with microbiology/ID if gentamicin continues for >7 days. Stop therapy and discuss with microbiology/ID if ototoxicity is suspected.

Approved by Antimicrobial Utilisation Committee and Cardiology MCN August 2023, Review Date August 2026

Patient name: ……………………………………………….. **CHI no.:** ……………………………………………………………..

TOXICITY (see overleaf) Renal & **Oto-vestibular Function** should be reviewed daily	**Synergistic Gentamicin Administration Record**				**Synergistic Gentamicin Monitoring Record**				
	Complete each time gentamicin is administered (**in addition to HEPMA**)				To be completed by ALL staff taking blood for gentamicin concentration monitoring **Record ALL sample dates/times accurately below**				
	Date given	Gentamicin dose (mg) ***Bolus over 3-5 mins***	Time given (24 hour clock)	Given by	Date of sample	Time of sample (24 hour clock)	Blood sample taken by PRINT name and status	Result (mg/L)	Action/ Comment
Cr = **micromol /L**				Sig 1: Sig 2:					
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Information for patients about Intravenous Gentamicin

NHS Greater Glasgow and Clyde

Why have I been given this leaflet?

This leaflet gives you some important information on a medicine called gentamicin. This is to help you to:

- Be more involved in your treatment
- Understand why we take blood samples
- Be aware of the important potential side effects of gentamicin
- Understand the importance of letting the doctor, nurse or pharmacist know if you have any side effects
- Feel able to ask questions about your treatment

What is gentamicin and what is it used for?

Gentamicin is a powerful antibiotic that we use to treat certain types of serious bacterial infections. We have prescribed you gentamicin because it is the appropriate antibiotic for your infection.

When serious infection is suspected doctors aim to give gentamicin as soon as possible. Therefore if you are very unwell we sometimes start treatment before you or your family have had a chance to read this leaflet.

If you answer 'Yes' to any of these questions, please tell your doctor, nurse or pharmacist immediately:

- Do you have any hearing or balance problems, or have you (or your relatives) had hearing or balance problems as a side effect from previous antibiotic use?
- Do you (or your relatives) have a mitochondrial disease (mutations in the parts of your cells which help make energy)?
- Are you allergic to gentamicin or any other antibiotics?
- Are you pregnant or breast feeding?
- Do you have reduced kidney function?
- Do you have myasthenia gravis?
- Are you taking any other medicines: including 'water tablets' such as furosemide; over the counter medications; or herbal remedies?
- Have you taken gentamicin before?

How is gentamicin given?

The nurses in hospital will give you gentamicin as an injection into a vein or via a drip. We may change the dose and how often you take it during the course of treatment.

How will I be monitored?

We will measure the amount of gentamicin in your blood to make sure you are on the right dose by taking a blood test. This will also tell us how your kidneys are working. You may also need a hearing and balance test (see possible side effects).

How long will I take gentamicin?

Usually you will take gentamicin for up to 4 days. If you need gentamicin for more than 5 days, your doctor will arrange for you to have hearing and balance tests (see possible side effects).

What are the possible side effects?

Like all medicines, gentamicin may cause side effects. However, most are rare and not all patients will experience them. **It is extremely important that you tell your doctor, nurse or pharmacist if you experience any of these side effects at any time** as they could be serious or long-term.

- **Reduced kidney function**: you might not have any symptoms but may notice you are passing less urine
- **Allergic reactions**: including rash, itch, fever, shortness of breath, a tight chest or wheezing, chills or shivers, swelling or redness of the skin
- **Hearing or balance problems**, these may include:
  - **Hearing impairment**: you may experience a ringing in your ears (tinnitus) or hearing loss
  - **Disturbances in balance:** you may feel dizzy or have difficulty in keeping your balance
  - **Visual disturbances:** you may experience jerky or bouncing vision

If you have any questions while in hospital, please ask a member of staff. When you go home, you should contact your GP, Practice Nurse or Community Pharmacist for any further advice if required. If you are ill on a day or at a time when your GP surgery is closed, you can call NHS 24 on 111.